Development of an auricular prosthesis positioning guide using additive manufacturing technologies

André Heydenrych

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Supervisor:	Dr Kobus van der Walt, D Tech Eng: Mech
Co-supervisor:	Prof. Cules van den Heever, MChD Prosthodontics

Bloemfontein

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Declaration of independent work

DECLARATION WITH REGARD TO INDEPENDENT WORK

I, André Heydenrych, identity number and student number , do hereby declare that this research project submitted to the Central University of Technology, Free State (CUT) for the MASTER OF ENGINEERING: MECHANICAL ENGINEERING degree, is my own independent work; and complies with the code of academic integrity, as well as other relevant policies, procedures, rules and regulations of the Central University of Technology, Free State; and has not been submitted previously to any institution by myself or any other person in fulfilment of the requirements for the attainment of any qualification.

SIGNATURE OF STUDENT  DATE June 2020

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Last but not least, to my wife and best friend, thank you for your support and love.

Abstract

Facial deformities associated with congenital disorders or loss of facial features due to trauma or disease can have a devastating effect on the social well-being of a patient. This study focuses on deformed or missing auricles (ears) and their replacement with silicone prostheses. These prostheses are retained by craniofacial implants which are implanted into the temporal bone area of the skull in the appropriate position of the auricle. Surgeons find it difficult to place the implants accurately in relation to the missing auricle. The patient lies on their side on the operating table during the procedure and is largely covered by drapes to create a sterile working area. This makes it difficult to reference the position of the prosthesis, since the face and opposite auricle are covered.

The aim of this study was to develop patient-specific devices using additive manufacturing technologies and associated software to indicate the positions of craniofacial implants which retain the auricular prostheses and to correctly orientate the prostheses relative to the positions of the implants. The geometry of the patient is determined using Computed-Tomography (CT) scanning and the opposite auricle is mirrored in the virtual environment through specialized software from Materialise. An iterative design process was followed to develop a positioning guide for placing the implants, with each design iteration improving on the previous one. In addition to the positioning guide, an orientation guide was developed that orientates the prosthesis accurately in relation to the implants. This is a new development in the field of maxillofacial prosthetics and has not been attempted before. The positioning/orientation guides are produced in nylon through the laser sinter additive manufacturing process. Craniofacial implants were developed and placed for patients in three case studies. The accuracy of placements was determined by CT scanning the area with the implants and overlaying the images onto the originally planned positions. Results showed relatively accurate positioning of the implants using the positioning guides, while reducing risk by not having to drill without reference points. The cost of the procedure is also reduced by shortening operating theatre time.

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List of abbreviations

3D	Three Dimensional
3DP	3D printing
AM	Additive Manufacturing
CAD	Computer Aided Design
CAM	Computer Aided Manufacturing
CRPM	Centre for Rapid Prototyping and Manufacturing
CNC	Computer Numerical Control
CT	Computed Tomography
CUT	Central University of Technology, Free State
DICOM	Digital Imaging and Communications in Medicine
DMLS	Direct Metal Laser Sintering
EOS	Electro Optical Systems
FDM	Fused Deposition Modelling
MRI	Magnetic Resonance Imaging
SL	Stereolithography
SLM	Selective Laser Melting
SLS	Selective Laser Sintering
STL	Standard Triangulation Language

Chapter 1: Overview of study

1.1 Foreword

It is generally accepted that people are judged on their outward appearance. First impressions are important in our everyday life and our facial features play a significant role in this regard. Two eyes, two ears, a nose and mouth are the norm and any deviation or defect is seen by society as different or abnormal. The psychological [1] and social impact of facial defects on patients play a very crucial role in their quality of life. Self-esteem suffers and this leads to depression. Craniofacial rehabilitation can have a tremendous impact on these patients' psychosocial health [2]. This study focuses specifically on replacing missing or deformed auricles (ears) with artificial silicone prostheses as well as how these prostheses are positioned and attached. A variety of factors contribute to the loss of an auricle, such as congenital disorders and trauma which include motor vehicle accidents, dog bites, burns as well as disease such as cancer, to mention a few. Besides the psychological impact of losing an auricle, it also impacts negatively on the physical hearing ability of the patient. The outer ear shell forms an integral part of the ear as it collects, amplifies and directs sound to the auditory canal.

1.2 Problem statement

Different techniques are used to retain silicone auricular prostheses. However, the bar clip retention method is generally accepted to be the "gold standard" for osseointegrated implant-retained auricular prosthesis. Generally, two to three implants are implanted into the temporal bone area of the skull behind the anthelix of the auricle. The prosthesis is then retained through friction or magnetic components. The existing techniques used to position craniofacial implants which retain the prostheses are lacking, and thus far, a standard method has yet to be developed. Many of the techniques rely solely on the surgeon's perception of where to position the prosthesis. If the opposite auricle is intact, this can be used

to estimate the position where the prosthesis should be placed. However, during implant surgery, the area surrounding the side of the patient's head is covered with drapes to create a sterile work area. This makes it very difficult to judge the positions of the implants since the facial features and opposite auricle are covered. If the patient's auditory canal is still intact, this is used as guide to position the implants, but this is often not the case. Asymmetry in a patient's facial features as a result of a genetic/congenital disorder causes further problems in determining where to position the implants to achieve an acceptable aesthetic outcome. Techniques that have been developed for auricular prostheses positioning focused only on positioning of the implants but did not assist with orientating the prosthesis in relation to the implants.

Possible solutions to problems experienced in positioning auricular prostheses can be found in utilizing dedicated additive manufacturing software and processes. Using software like Magics from Materialise, one can design a patient-specific positioning guide to assist the surgeon during implant placement. From the patient's Computed Tomography/Magnetic Resonance Imaging (CT/MRI) data, the thickness of the bone can be determined so as to place the implants at the ideal positions to minimize risk. Furthermore, orientation guides can be designed to ensure that auricular prostheses are placed in the most aesthetically pleasing positions in relation to the implants. Implementing positioning and orientation as part of the treatment plan for placing auricular prosthesis can potentially reduce patient-doctor interaction time and minimize risk as a result of surgical complications.

1.3 Aim

The aim of this study was to develop patient-specific devices through additive manufacturing technologies and associated software to indicate the positions of craniofacial implants that retain auricular prostheses and to orientate the prostheses relative to the positions of the implants.

1.3.1 Primary objectives

1. Perform an in-depth literature study on existing techniques to produce auricular prostheses and techniques to position bone-anchored implants to retain the prostheses.
2. Develop a patient-specific guide to accurately and safely position craniofacial implants using additive manufacturing technologies and associated software.
3. Develop an orientation guide to position prosthetic auricles in relation to implants using additive manufacturing technologies and associated software to ensure an aesthetically pleasing outcome.

1.3.2 Secondary objectives

1. Develop standard CAD components that can be used in the design of auricular positioning devices to shorten the design process as part of the proposed workflow.
2. Develop a standard workflow to speed up the design and delivery of additively manufactured auricular positioning devices.

1.4 Methodology and research design

An action research approach was taken in this study which can be described as a reflective process of progressive problem-solving to produce guidelines for best practice. The development of the auricular positioning device was explored through consecutive iterations of the device which were improved upon through feed-back from surgeons who used the device in each case. This process was started as early as 2013 when the Centre for Rapid Prototyping and Manufacturing (CRPM) became involved in the field of auricular prosthesis fabrication and positioning. The first three case studies performed in this field are described together with what was learnt from using the devices.

The following research approach was followed in the continued development of the auricular positioning device in the current study:

- Three more real-world case studies were performed in the development of the auricular positioning device in addition to what had already been done. After the use of each consecutive iteration of the device, the surgeons were asked to give feedback on the device in terms of problems experienced as well as any suggestions for improvements. A comprehensive log of these findings was kept and design improvements were incorporated into the next version.

- A log was also kept in terms of time and cost to produce the positioning devices. The time taken to position the implants in theatre was logged. A time comparison could then be drawn between positioning the implants with and without the positioning device. Time saved in using the device can be translated to operation theatre cost, which is calculated per minute, to determine if it is worthwhile to use the device from a cost point of view.

- To evaluate the effectiveness and accuracy of the positioning device, the actual placement positions of the implants were compared to the positions that were planned in the virtual environment. For this purpose, a CT scan was taken of the patient after implant placement and the CT data overlaid on the original planning data. This was done for the three case studies and gave a clear indication of how the intended and actual positions of the implants compared.

- A workflow for designing and manufacturing the positioning device, as well as for placing the implants using the device, was developed from the case studies performed. To speed up the design of the positioning device, standard CAD components that can be used in the design of the positioning device were designed. The layout of the composition of the dissertation is presented in Figure 1.1.

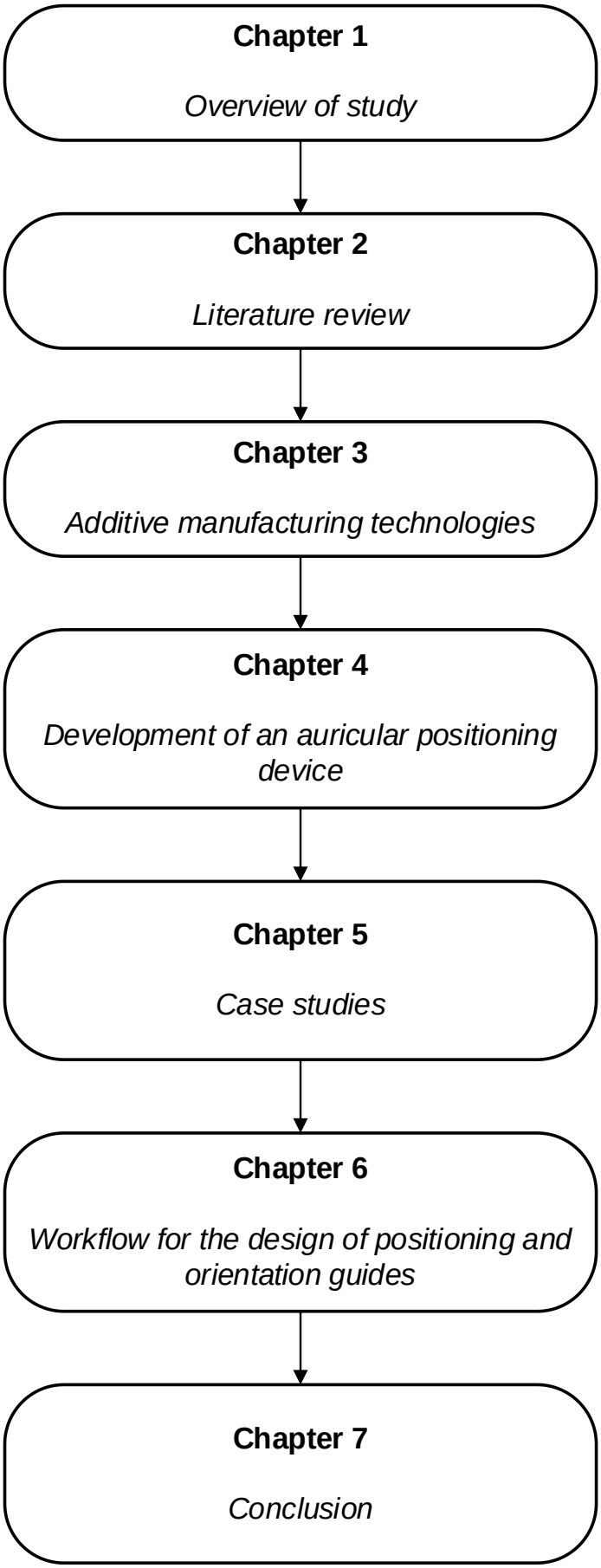


Figure 1.1 Flowchart of the composition of the dissertation.

1.5 Ethical considerations

Patient confidentiality was a priority when case studies were conducted and consent was obtained from patients and surgeons. No photographs where patients could be identified were used in the dissertation or will be placed in articles that may emanate from the research.

Chapter 2: Literature review

2.1 Introduction

Facial deformities have a significant influence on patients' self-image and how they are perceived by society. Various factors can contribute to the loss or deformation of these features such as trauma, disease or congenital disorders. According to a study performed by Bartel-Friedrich and Wulke, 50% of malformations of the auricle, nose and throat region affect the auricle and 58–61% of malformations of the outer and middle auricle are on the right side. In newborns, the incidence of ear malformations is ca. 1:3800 [3]. Japanese, native American and Hispanic populations have seen an increased incidence in recent years [4].

The loss of an auricle also has a physical impact on the hearing of a patient since it collects, amplifies and directs sound to the auditory canal. Figure 2.1 below shows the anatomical features of a normal auricle.

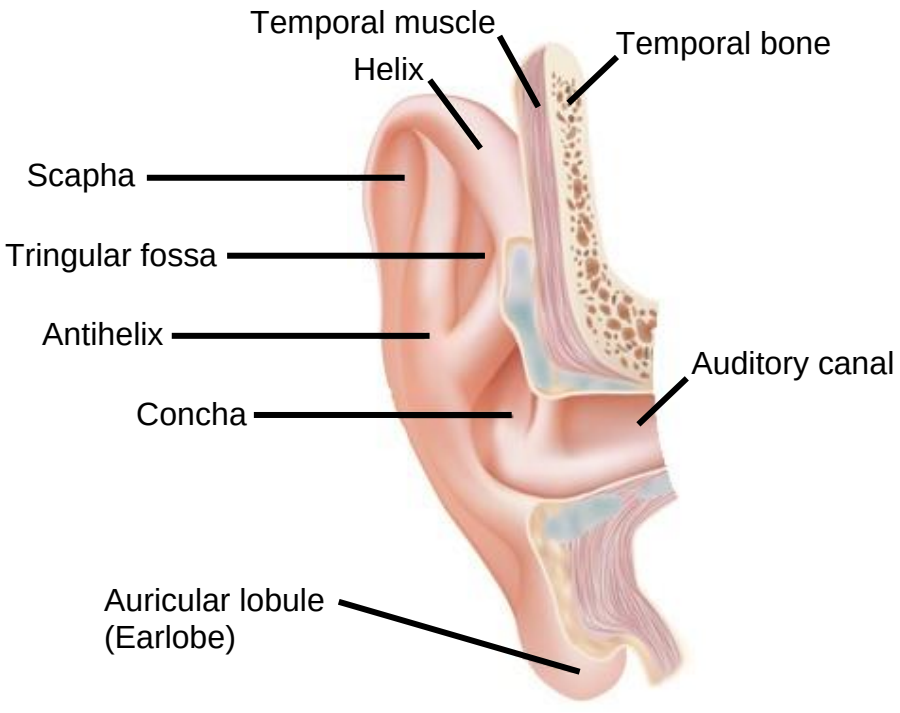


Figure 2.1 Anatomical diagram of right auricle [5].

Many congenital or acquired factors can attribute to the loss or absence of an auricle [6][7][8]. Congenital malformations (Figure 2.2) include otofacial, craniofacial, and otocervical dysostosis, while acquired causes may originate from motor vehicle accidents, burns, dog attacks, cancer, etc. [9][10][11].

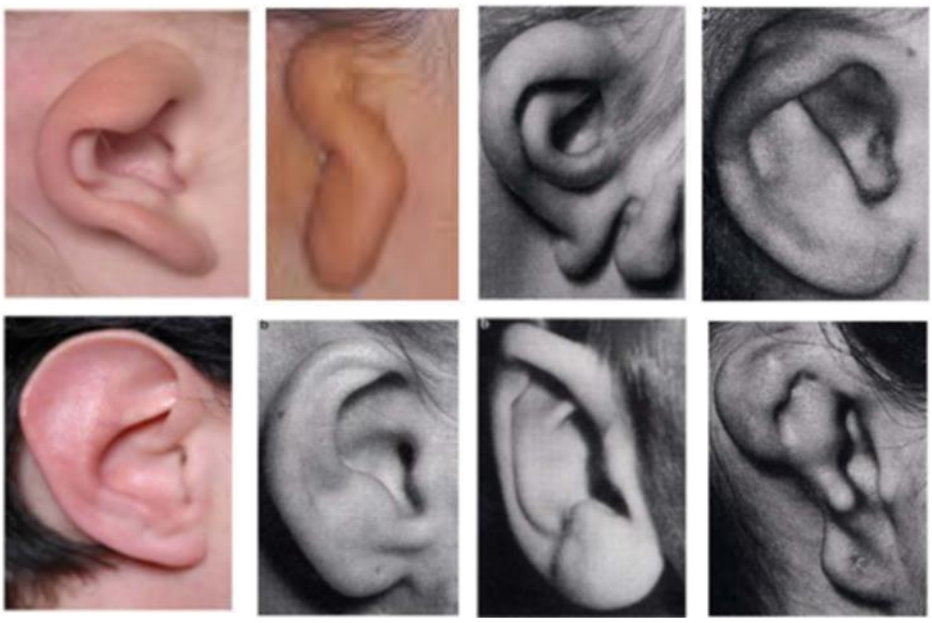


Figure 2.2 Typical congenital malformations [2].

2.2 External prosthesis

An artificial silicone external prosthesis is one of the treatment options available to patients who have lost an auricle. The manufacturing of such an external prosthesis is a labour-intensive process which requires great skill because of the complex geometry of the ear.

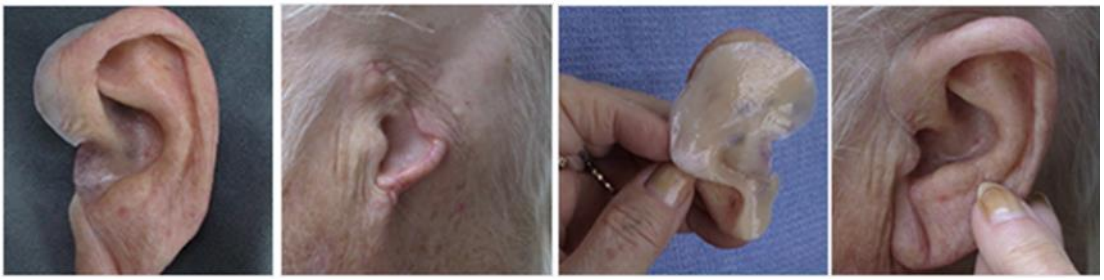
2.3 Retention of prosthesis

The type of retention method which is used to attach the prosthesis to the patient's skull has a big impact on the functionality of the prosthesis. Regardless of the method used for retention, the prosthesis must fit securely onto the patient and look as natural as possible. Considering that most prostheses need to be removed on a regular basis for cleaning behind the prosthesis, it is important that

the retention mechanism can handle the cyclic usage. Some of the more popular retention methods include adhesive-retained, anatomically retained, implant-retained, magnetically retained and slip-over methods [12], which will be described next.

2.3.1 Adhesive-retained auricular prosthesis

This method is the simplest to attach an auricular prosthesis (Figure 2.3a) as it requires no surgery (Figure 2.3b). Medical-grade adhesive is applied to the back of the prosthesis (Figure 2.3c), left to dry and carefully pressed into position (Figure 2.3d). One of the disadvantages of using adhesive as a retentive method is that some patients have allergic reactions to the adhesive [12]. This technique is also not well-suited to regions with high summer temperatures where sweating may cause problems with the adhesion of the prosthesis.

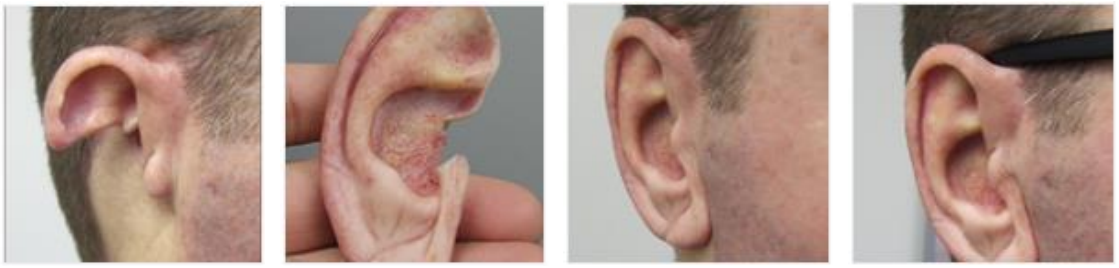


(a) (b) (c) (d)

Figure 2.3 (a–d) Adhesive-retained auricular prosthesis [12].

2.3.2 Anatomically retained auricular prosthesis

In the case of a partial auriculectomy (Figure 2.4a), the remaining ear structure is used to support the prosthesis (Figure 2.4b). The partial prosthesis is moulded to fit into the triangular fossa and concha cymba (Figure 2.4c). Adhesive is applied to the margins for a secure fit. For extra support, the prosthesis can also be mounted onto a hairband or spectacle frame, such as shown in Figure 2.4d [12].

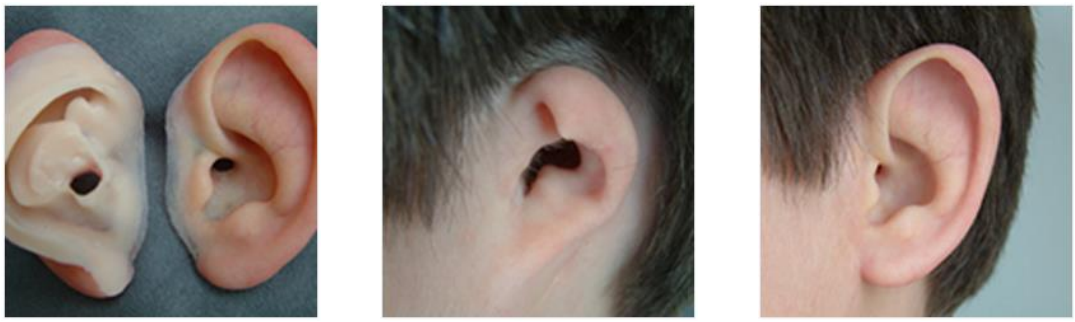


(a) (b) (c) (d)

Figure 2.4 (a–d) Anatomically-retained auricular prosthesis [12].

2.3.3 Slip-over auricular prosthesis

The slip-over auricular prosthesis functions exactly as the name implies: it fits over existing ear cartilage undercuts. This type of prosthesis (Figure 2.5a) is a good alternative for patients with surgically constructed ears who want more normally shaped ears. This method is also often preferable for patients who do not want to have remaining ear features (Figure 2.5b) removed, such as is required for an implant-retained prosthesis.



(a) (b) (c)

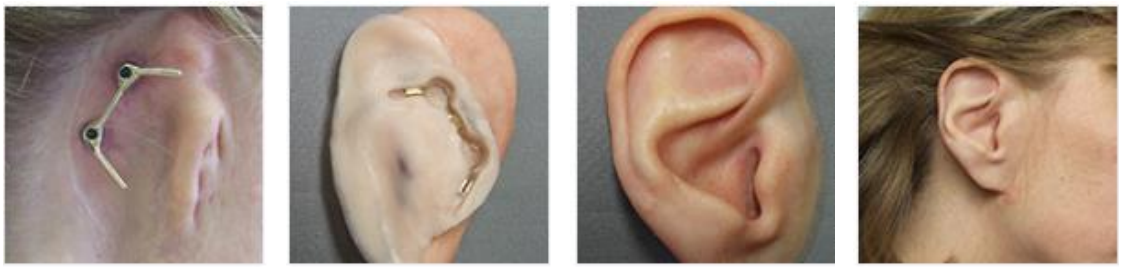
Figure 2.5 (a–c) Slip-over auricular prosthesis [12].

Generally, the slip-over prosthesis attains a good aesthetic appearance (Figure 2.5c) and allows patients the opportunity to evaluate this option before their natural ear tissue is surgically removed [12].

2.3.4 Implant-retained auricular prosthesis

2.3.4.1 Bar clip attachment

The bar clip retention method has become the gold standard for osseointegrated implant-retained silicone prostheses [12]. For this technique, two to three titanium implants are implanted directly into the skull of the patient. After three to six month's healing, abutments are mounted onto the implants (Figure 2.6a). A gold alloy bar is custom-made to fit onto the abutments and is screw-mounted into place (Figure 2.6a). A rigid frame is made in acrylic with clips to fit onto the metal bar. The silicone is then moulded over the frame with the clips protruding through the prosthesis on the inside (Figure 2.6b). The prosthesis (Figure 2.6c) can be easily clipped onto the metal bar and removed as required (Figure 2.6d). The bar that fits onto the abutments must be manufactured very accurately, since misalignment will induce tension on the implants when the bar is screwed onto the abutments. This will result in necrosis of the bone surrounding the implants.



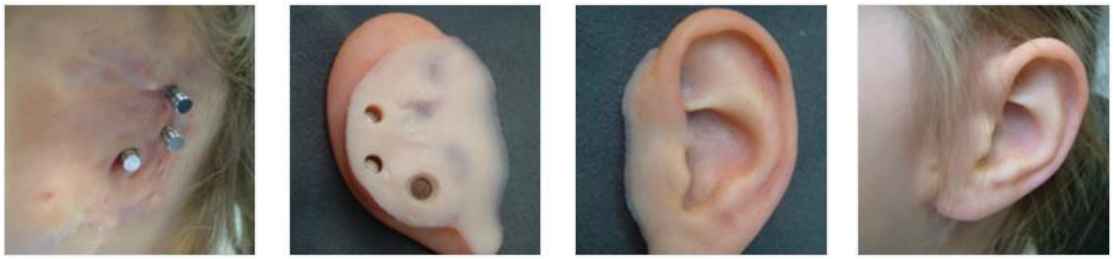
(a) (b) (c) (d)

Figure 2.6 (a–d) Implant-retained auricular prosthesis [12].

2.3.4.2 Magnetically retained auricular prosthesis

Another example of an implant-retained auricular prosthesis is the independent abutment/magnet method of attachment. It does not require the fabrication of a bar, but uses individual magnetic components (Figure 2.7a) that attach to the prosthesis (Figure 2.7b, Figure 2.7c) [12]. Two or three small titanium implants are placed and allowed to heal for three to six months whereafter abutments are

fitted [12]. The magnets in the prosthesis (Figure 2.7b) are recessed which ensures a snug fit on the patient (Figure 2.7d).



(a) (b) (c) (d)

Figure 2.7 (a–d) Magnetically retained auricular prosthesis [12].

This technique presents an advantage in that the retention mechanism does not wear out as with the bar and clip technique. Furthermore, there is no risk that tension being applied to the implants as a result of misaligned retention-device components.

2.4 Procedure for placing implants for auricular retention

The surgical procedure for conventional implant placement for bar and clip and magnetic-retention techniques can be summarized in the following steps [13]:

i. Selecting the implant site
ii. Making the incision
iii. Reducing the subcutaneous tissue
iv. Drilling with guide drill
v. Drilling with widening drill
vi. Placing the implants
vii. Closing

The procedure for placing implants is explained with reference to Figure 2.8 (a– p) [13].

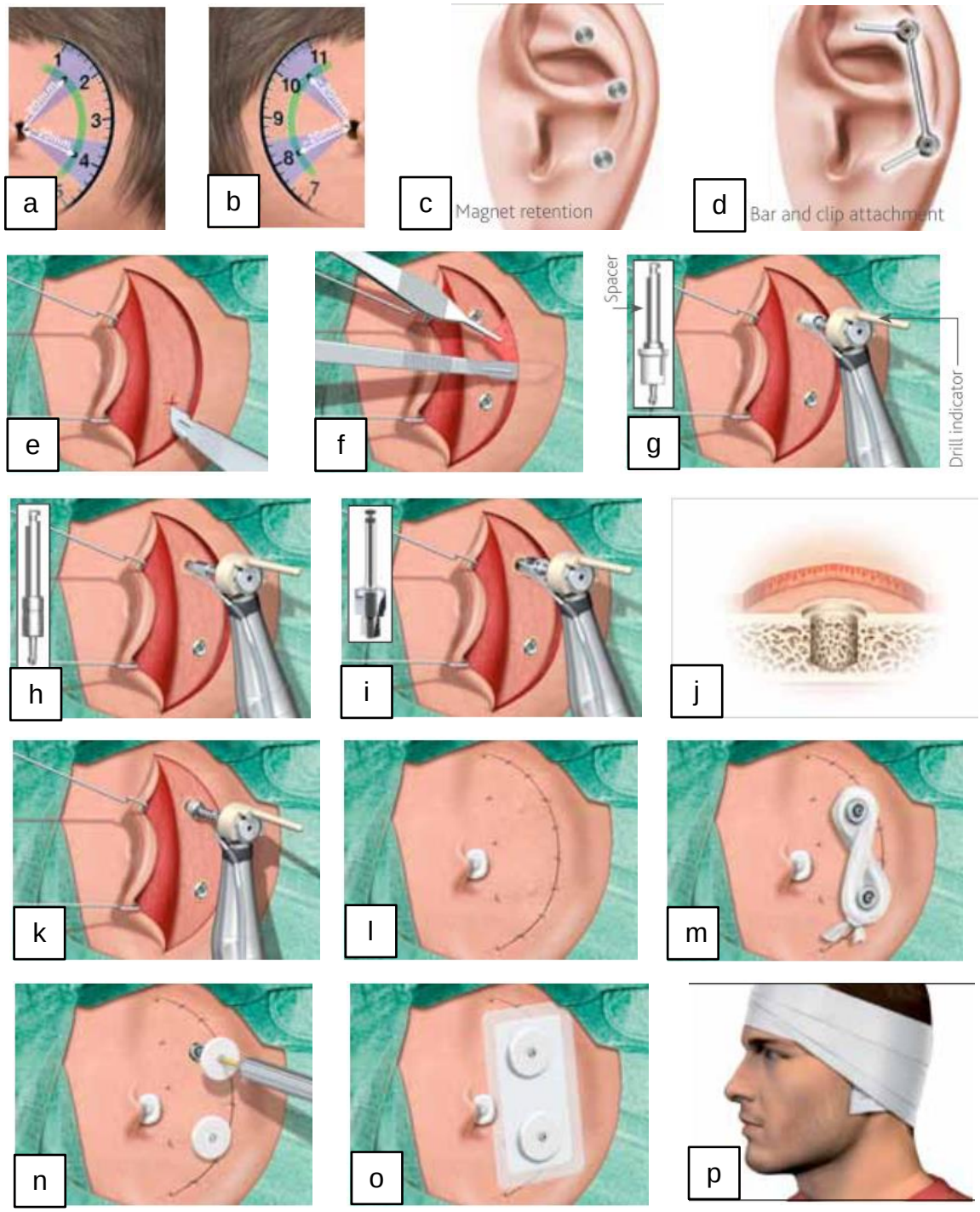


Figure 2.8 (a–p) Surgical procedure for implant placement [13].

i) Selecting the implant site

The anatomical landmarks are used to carefully mark the implant sites (Figure 2.8a and Figure 2.8b) with a thin needle and surgical ink. This is done with the patient in a sitting position to allow a better view of the patient's face. The ideal location to place implants is approximately 20 mm from the opening of the external ear canal. For the left side, the positions will be at 16:00 and 13:30 (Figure 2.8a) and for the right side, they will be at 08:00 and 10:30 (Figure 2.8b). Two implants (Figure 2.8d) are usually sufficient but three may be required for optimal retention. With magnetic retention, three implants (Figure 2.8c) are typically used.

The position of the implants should be located directly under the anti-helix to allow enough depth for the retention bar. When three implants are used, they should be positioned at 13:30, 15:00 and 16:30 for the left ear (Figure 2.8a) and 10:30, 09:00 and 07:30 for the right ear (Figure 2.8b). To facilitate cleaning around the abutments, they should be placed at least 10 mm from each other.

ii) Making the incision

An incision is made approximately 10 mm behind the implant site down to the periosteum. At each implant site, an incision (Figure 2.8e) is made in the periosteum and the skin flap is raised with the help of skin hooks.

iii) Reducing thetion of subcutaneous tissue

The subcutaneous tissue at the edges of the flap must be removed by making incisions with the blade parallel to the skin (Figure 2.8f). Soft tissue should be trimmed down to the periosteum to avoid regrowth of tissue. It is, however, essential that the periosteum stays intact to ensure blood supply necessary for healing. To avoid hair growth, which could lead to irritation around the abutments, it is essential to remove any hair from the flap.

iv) Drilling with guide drill

The drill should be set to the high-speed setting and positioned perpendicular to the bone surface. The use of coolant is essential during drilling as osteocyte will die after 1 minute at 42° C. A guide drill with 3 mm spacer (Figure 2.8g) is used

for the first stage. After a visual inspection has been performed and the surgeon is satisfied with the thickness of the bone available, the spacer can be removed to drill to a depth of 4 mm (Figure 2.8h).

v) Drilling with widening drill

Next, the holes need to be widened to the correct diameter. Again, the high-speed setting should be used in combination with a 3 or 4 mm widening drill (Figure 2.8i). The drill must be moved up and down during drilling to ensure that coolant reaches the tip of the drill. When the bone surface has been reached, the widening drill is used to create a countersink (Figure 2.8j).

vi) Placing the implants

The drill must be set to the requited torque setting and the torque limit adjusted to suit the quality of the bone. For successful osseointegration, it is critical that the surface of the implant be kept free of contamination. Slight pressure may be required during the initial insertion when placing the implant (Figure 2.8k).

vii) Closing

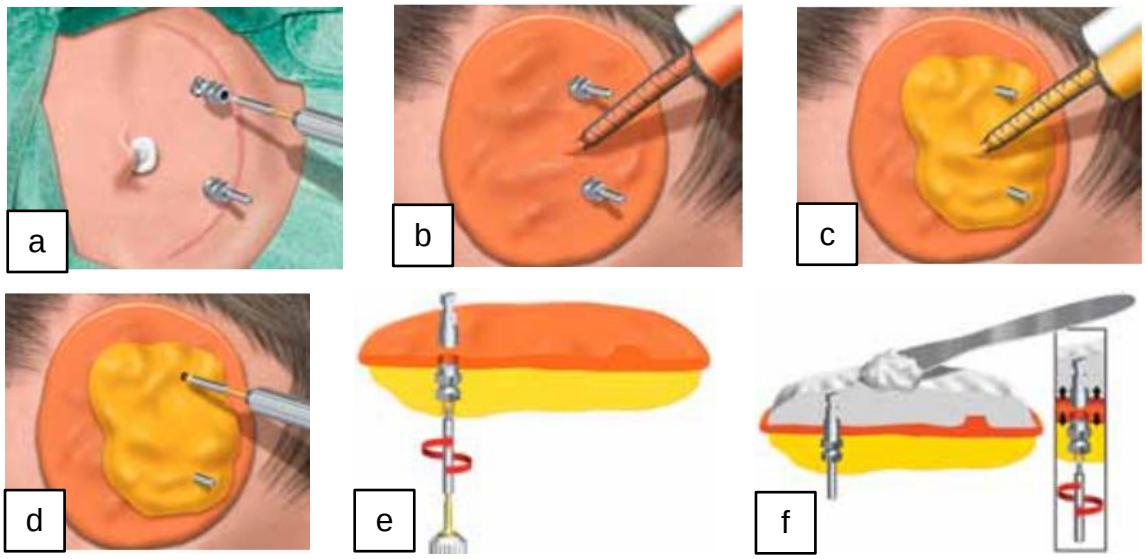
The edges around the flap should be sutured down to the periosteum after which the flap is laid back and sutured down (Figure 2.8l). Healing abutments are placed to facilitate proper healing and a separate dressing is placed around the abutments (Figure 2.8m). Next, healing caps are placed onto the abutments (Figure 2.8n). Lastly, a dressing can be placed over the healing cap, followed by a mastoid dressing (Figure 2.8o and Figure 2.8p).

2.5 Traditional technique for manufacturing implant-retained auricular prostheses.

The traditional method of making an auricular prosthesis can be summarized in the following steps [13]:

i. Take an impression of the implant site
ii. Prepare a working model
iii. Take an impression of the opposite ear
iv. Design a framework
v. Manufacture an acrylic plate
vi. Sculpt and fit the wax model
vii. Fabricate a plaster mould
viii. Prime the acrylic plate
ix. Mix silicone and pack the mould
x. Final patient fitting

The traditional method of manufacturing an auricular prosthesis is explained with reference to Figure 2.9(a–v).



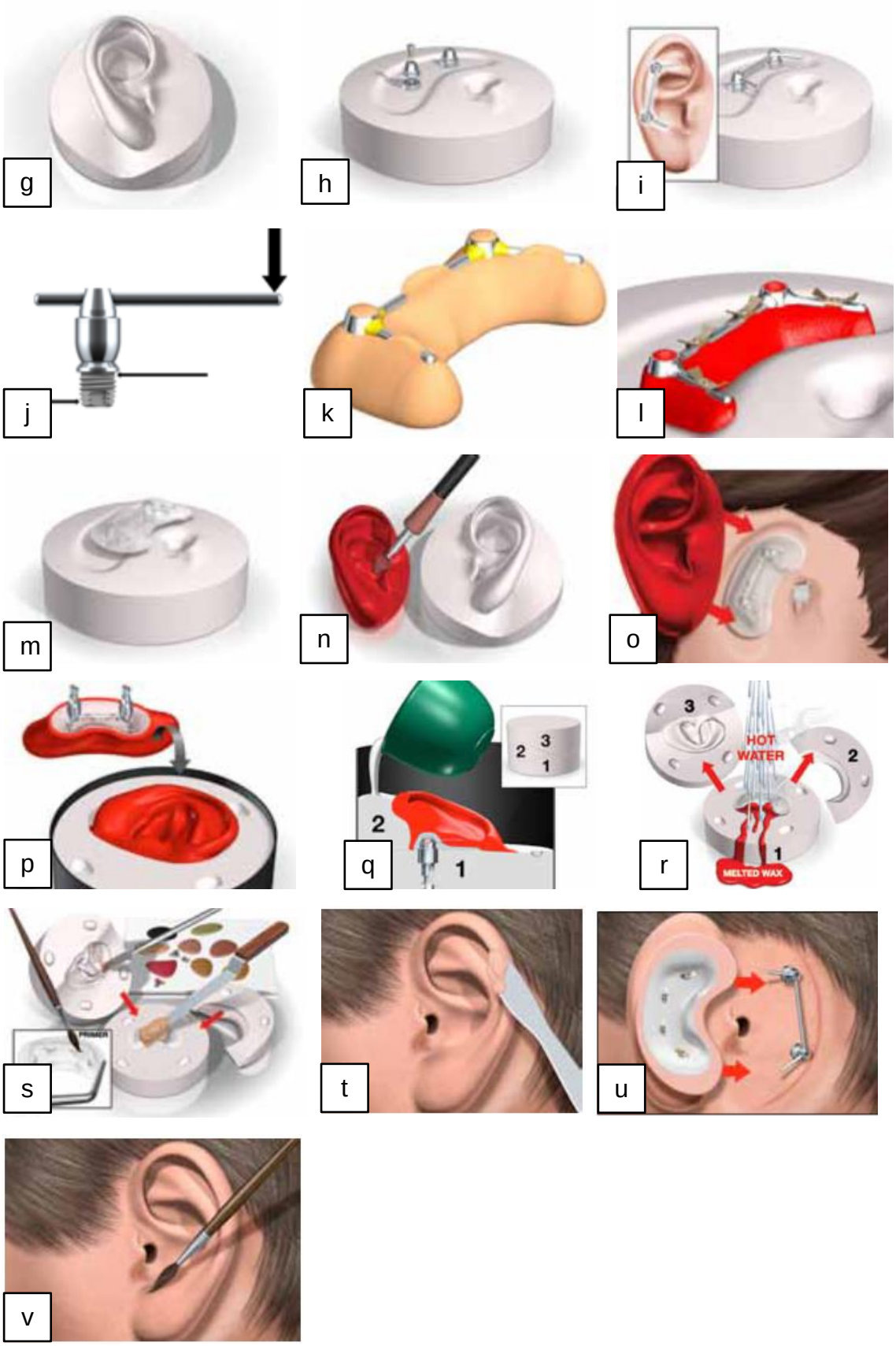


Figure 2.9 (a–v) Traditional method for manufacturing auricular prosthesis [13].

i) Take an impression of the implant site

The surgeon should ensure that the abutment screws, as described in Section 2.4 vi), are firmly anchored and the skin around the abutments is clean. The external ear canal should be closed off with gauze to prevent impression material from entering. Impression copings are attached to the abutments (Figure 2.9a) and a thin layer of flexible impression material is applied around the copings and over the area (Figure 2.9b and Figure 2.9c). Next, a second layer of impression material is applied that sets rigid to form a stable backing for the flexible material underneath.

ii) Prepare a working model

After the silicone impression material has set, the guide pins are removed (Figure 2.9d) and abutment replicas are attached to the impression copings using guide pins (Figure 2.9e). Next, the impression with copings and replicas are cast in dental stone plaster (Figure 2.9f). This will yield an exact working model of the patient's defect area which has the exact position, direction and height as the skin-penetrating abutments.

iii) Take an impression of the opposite ear

To facilitate the sculpting process of the prosthesis, an impression of the opposite ear can be taken to use as a reference (Figure 2.9g). The negative impression is filled with dental stone and left to harden to create a positive ear model.

iv) Design the framework

At this stage, gold cylinders are placed onto the abutment replicas of the working model (Figure 2.9h) and gold alloy bar is cut to stretch between and beyond the abutments whilst keeping the appropriate shape (Figure 2.9i). To minimize torque on the implants, the bar should not extend more than 8–10 mm beyond the abutments (Figure 2.9j).

Next, the bar is attached to the gold cylinders with wax and removed from the working model (Figure 2.9k). The bar and gold cylinders can then be soldered together and fitted on the patient to ensure an accurate fit. It is critical that the bar

does not apply any stress on the implants, since this may result in necrosis of the surrounding bone tissue, as mentioned under Section 2.3.4.1.

v) Manufacture the acrylic plate

The bar construction is placed onto the working model and retention clips are added. Wax is sculpted to fill the space between the bar and model (Figure 2.9l). Acrylic resin is poured over the bar and clip construction (Figure 2.9m) and the wax is removed after the acrylic has set. The finished plate is fitted on the patient to ensure an accurate fit.

vi) Sculpt and fit the wax model

Next, a wax model of the prosthesis (Figure 2.9n) is sculpted and positioned onto the acrylic plate on the patient (Figure 2.9o). It is critical to check the model's fit from all angles to ensure a proper fit.

vii) Fabricate the plaster mould

The abutment replicas are placed onto the gold cylinders of the bar construction, whereafter it is positioned into the clips of the acrylic plate (Figure 2.9p). In order to cast the prosthesis in silicone, a three-piece plaster mould needs to be produced which will allow for separation of the mould pieces after the silicone has set (Figure 2.9q). Here the complex shape of the ear with undercuts must be taken into consideration.. The fitting side of the wax ear and bar is embedded in plaster to create the first part of the mould. A separating agent is used to separate the plaster pieces after setting. Keyholes are made to ensure correct fit between the mould pieces. The second part of the mould is poured up to the helix. Once more, keyholes are made, and the third part of the mould is poured. After the mould has set, boiling water is used to melt out the wax model (Figure 2.9r).

viii) Prime the acrylic plate

To achieve a strong bond between the acrylic and silicone, it is critical that the acrylic plate is prepped before silicone is placed into the mould. This can be achieved by following the steps below:

1) Roughen the surface of the acrylic plate
2) Clean the roughened surface with acetone

3) Apply primer in two thin layers and allow to dry

Lastly, place the prepped acrylic plate onto the bar.

ix) Mix the silicone and pack the mould

A biocompatible silicone and colour pigments are mixed to match the skin tone of the patient (Figure 2.9s). A catalyst must be added to the silicone according to the manufacturer's specifications in order for it to cure.

The silicone is applied to the inside of the mould pieces, the assembled mould clamped with a G-clamp and the silicone cured in an oven for one hour at 70 ºC. The prosthesis is then carefully removed from the mould and trimmed if necessary (Figure 2.9t).

x) Final patient fitting

Finally, the silicone prosthesis is fitted on the patient to evaluate effective retention and approximate colour (Figure 2.9u). Lastly, with a thin brush, colouring is applied to the prosthesis to give a more natural look (Figure 2.9v).

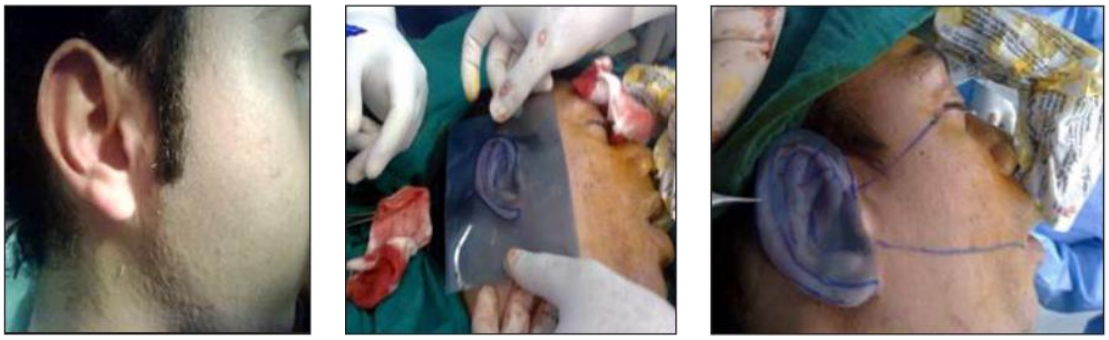
2.6 Existing techniques for positioning auricular prostheses

Surgeons have difficulty determining where to position the craniofacial implants for auricular retention while the patient is lying on their side on the operating table during surgery. Surgical drapes cover most of the patient, exposing only the area where the surgeon makes the incision. This leaves the surgeon with little to no reference point to work with.

The literature shows that different methods have been employed by surgeons to ensure that implants are placed correctly as this influences the final placement of the prosthesis and thus the aesthetic outcome. The different positioning devices/methods range from surgical templates to face bows and three-dimensional resin templates and will be described next.

2.6.1 Surgical templates

Through case studies, El Charkawi *et al*. [14] demonstrated a simplified technique to position craniofacial implants. This method, however, cannot be applied to patients with bilateral missing auricles as one intact auricle is required. The technique is also not suitable for patients with asymmetrical features as a result of congenital abnormalities. In this technique, the intact auricle (Figure 2.10a) with its external anatomy is precisely drawn onto a transparent radiographic film (Figure 2.10b). Reference marks are made on the film and measurements are taken from anatomical features, like the canthus of the eye and corner of the mouth (Figure 2.10c), to the reference marks. The film is then flipped over to produce a mirror image of the auricle. Using the distances and angulations from the intact side, the film is positioned on the surgical site and marked. This provides a drawing which indicates the area where implants should be placed.



(a) (b) (c)

Figure 2.10 (a) Normal side of patient. (b) Radiographic film on normal side. (c) Orientation of normal ear to canthus of the eye and corner of the mouth [14].

Some of the advantages that El Charkawi *et al.* mention in using this technique include time-saving in the planning phase, it eliminates patient exposure to radiation, and is cost effectiveness.

Dostalova *et al*. [15] used this same technique although they only applied it to the positioning of the final prosthesis (Figure 2.11). The fabrication and position of the prosthesis was based on the opposite auricle.

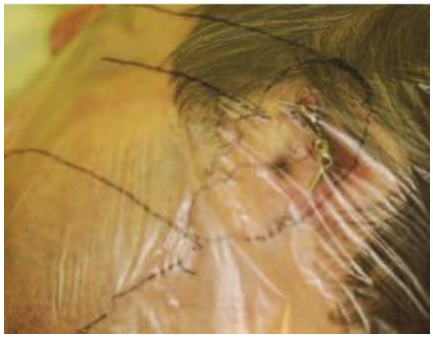
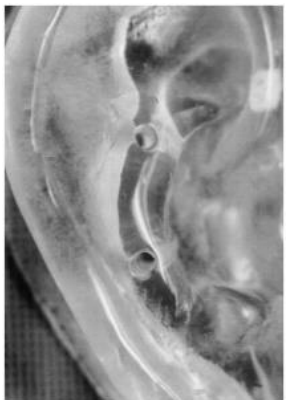
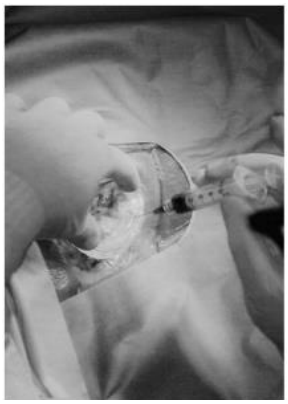


Figure 2.11 Reference marks from opposite auricle [15].

Asher *et al*. [16] implemented a method whereby they fabricated a three-dimensional surgical template in acrylic resin using the standard cast impression technique with some modifications. Before surgery, the surgical template (Figure 2.12a) is positioned using major landmarks such as the external auditory meatus, the ramus of the mandible and the contralateral auricle [16].



(a)



(b)

Figure 2.12 (a) Surgical template. (b) Methylene blue dye is injected through the template [16].

The periosteum is marked before reflecting the flap to expose the bone by passing a 38 mm 22-gauge needle through the holes in the template and skin and injecting a small amount of dye (Figure 2.12b) [16]. After the skin is reflected, the markings are used to drill the guide holes for implant placement [16]. A similar stent is described by Barreto *et al.* [17].

Wang [18] also used a technique similar to Asher *et al.* to produce a resin surgical template. A trough is cut into the resin guide (Figure 2.13) which serves as an ideal area for implant placement. This allows the surgeon to reposition an implant where the bone is found to be too thin.

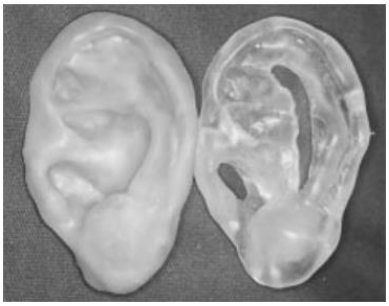


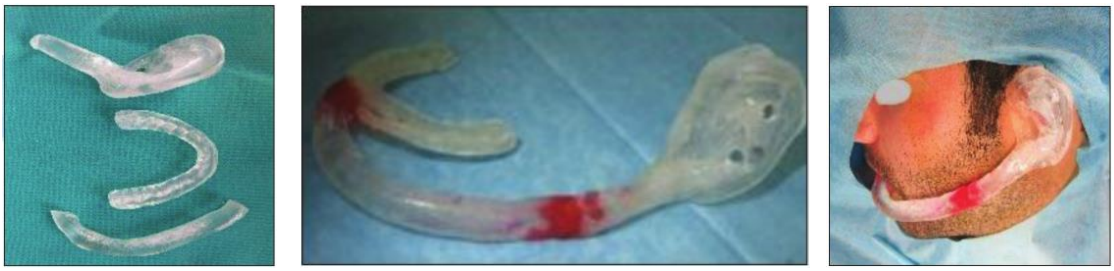
Figure 2.13 Acrylic resin guide duplicated from wax auricle [18].

Some of the advantages of this method include a shortened sculpting process and fewer mould pieces which are used to produce the surgical template. However, it is time-consuming and more costly to produce [18].

2.6.2 Three-dimensional resin stent

Rezaei and Nematollahi aimed to develop a surgical stent which is simple, cost-effective and stable during all phases of surgery [19]. Impressions of the maxillary arc, intact auricle and defected site are taken and used to fabricate a three-piece acrylic stent (Figure 2.14a). This acrylic stent consists of a maxillary acrylic resin splint, acrylic resin auricle and a resin bar which connects the two pieces together (b). Holes are drilled into the acrylic auricle to indicate ideal implant locations.

The three-piece stent is assembled by inserting the maxillary splint into the patient's mouth while an assistant holds the acrylic auricle in the pre-marked position. An autopolymerizing acrylic resin bonds the three pieces together [19] and the completed guide is then used to place the implants during surgery (Figure 2.14c) [19].



(a) (b) (c)

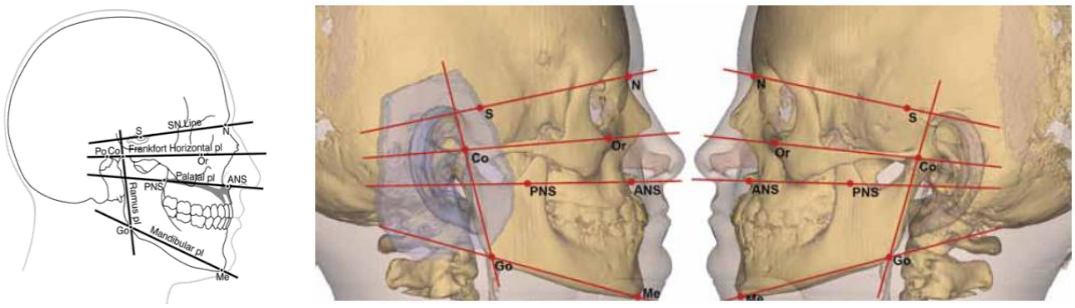
Figure 2.14 (a) Acrylic stent, consisting of three pieces. (b) Assembled guide. (c) Utilizing guide during implant surgery [19].

According to Rezaei and Nematollahi, this method proved to be safe as it did not require exposing the patient to radiation. It could also be useful for cases with bilateral missing auricles. Another benefit is that only two appointments are required with the patient to fabricate the positioning device and place the implants [19].

Bai *et al.* [20] also describe a positioning guide where the patient's teeth were used as reference points.

2.6.3 Digital design

A Computer-Aided Design/Computer-Aided Manufacturing (CAD/CAM) auricular positioning technique is presented by Kolodney *et al.* [21]. Computed Tomography (CT) data of the patient enables the surgeon to examine not only the soft tissue topography of the patient but also the bone thickness. Additional software from Materialise is used to generate a mirror image of the intact ear. Cephalometric lines (Figure 2.15), (Table 2.1) are taken into consideration while positioning the mirror copy of the ear into a symmetrical orientation.



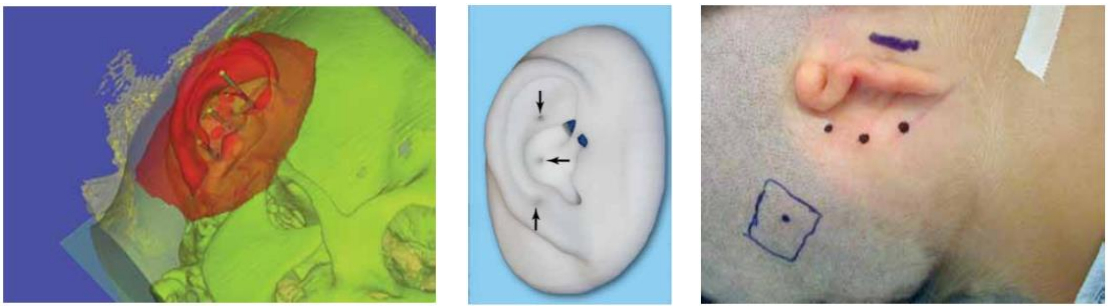
(a) (b)

Figure 2.15 (a) Cephalometric lines and planes. (b) Digital image of left mirrored auricle positioned to obtain cephalometric position of its counterpart on the right [21].

Table 2.1 Cephalometric lines and planes [21].

Plane or Line	Start Point	End Point
SN line	Center of sella turcica (S)	Anterior point of frontonasal suture (Nasion)
Frankfort Horizontal plane	Lowest point of orbit (Orbitale)	Superior point of external auditory meatus (Porion)
Palatal plane	Anterior nasal spine (ANS) of maxilla	Posterior nasal spine (PNS) of palatine bone
Mandibular plane	Gonion (Go), most outward and everted point on angle of mandible	Menton (Me), most inferior point on symphysis of mandible
Ramus plane	Gonion (Go)	Condylion (Co)

Once the availability and consistency of bone have been determined, the location of the digital implants is finalized (Figure 2.16a). A 3D model of the auricle (Figure 2.16b), with guide holes is then 3D printed and used to guide the surgeon when placing the implants. The same procedure is used to mark the periosteum (Figure 2.16c), as mentioned for the previous two techniques,



(a) (b) (c)

Figure 2.16 (a) Planned surgical implant placement. (b) Model of missing auricle. (c) Locations for implants marked with aid of surgical guide [21].

the only difference being that guide holes were designed into the surgical guide rather than being added afterwards. Furthermore, the surgical guide can also be used as a reference model to sculpt the auricle prosthesis [21]. However, Kolodney *et al*. concluded that despite the advantages of virtual imaging, it would not replace the need for direct positioning confirmation on the patient [21].

Plaza *et al.* [22] describe a similar method of virtual planning to that performed by Kolodney *et al.*, where implants are placed in a virtual environment (Figure 2.17) and surgical guides are designed to locate on the mastoid bone (Figure 2.18) of the patient.

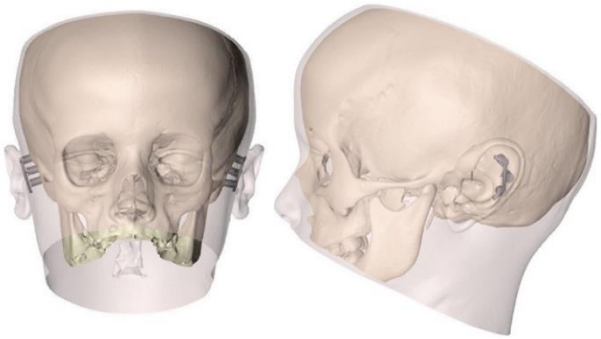


Figure 2.17 Virtual planning of implants [22].

The surgical guides are then used to place craniofacial implants, which are used to position the retention mechanism. In this case, a bar and clip mechanism was used.

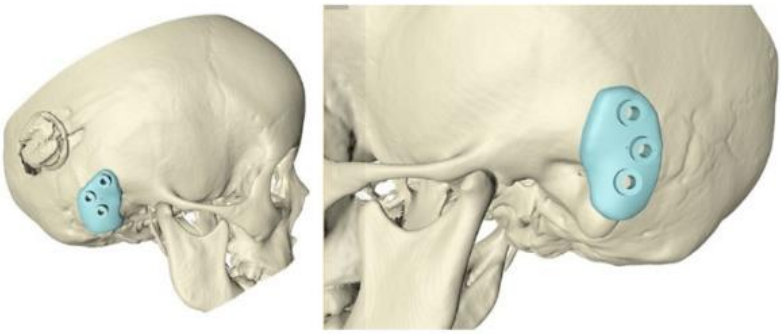
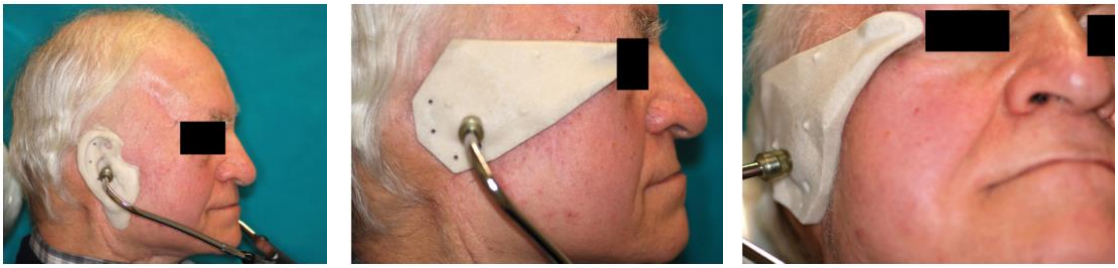


Figure 2.18 Surgical guides in position on mastoids [22].

Ciocca *et al*. [23] used a similar method to those described by Kolodney and Plaza *et al*. CAD/CAM technology and CT data was used to 3D print a mirror copy of the intact auricle and verify its location and position on the patient

(Figure 2.19a). Three ideal implant locations were identified and included in the design of the 3D-printed mirror copy [23]. Next, the mirrored copy of the auricle was converted into a diagnostic template which used the homolateral eye commissural rim as a reference point. The diagnostic template was also fitted on the patient to verify the position of the planned implants (Figure 2.19b and Figure 2.19 c).

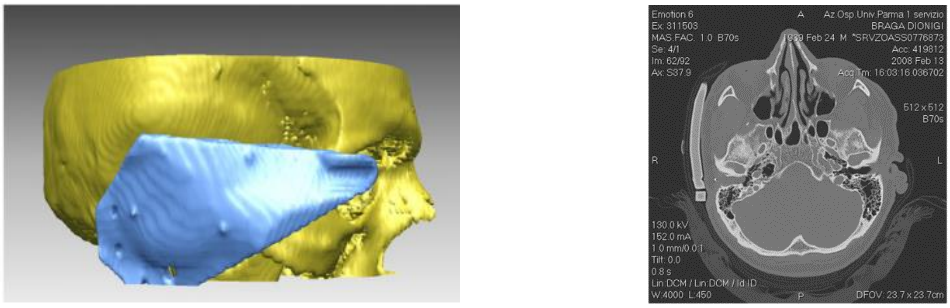


(a) (b) (c)

Figure 2.19 (a) Trial with 3D printed mirror copy. (b,c) Trial with diagnostic guide [23].

Next, the normal procedure was followed where a syringe needle filled with ink was passed through the holes in the surgical guide, through the skin and onto the temporal bone to mark the position where implants to retain the prosthesis were to be placed. The guide was removed and a C-shaped incision was made through the skin beyond the periphery of the three markings. The surgeon reflected the flap to expose the ink markings and place the implants accordingly.

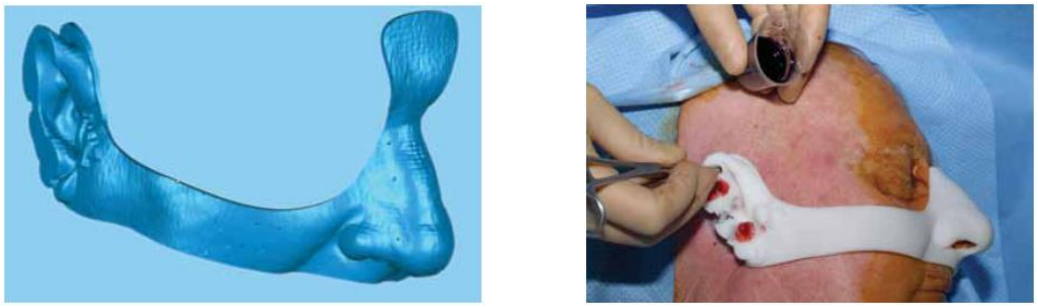
Ciocca *et al*. stated that the availability of bone is the main criterion that determines the ideal implant positions and this is taken into consideration in designing the guide [23]. He also mentioned that CAD/CAM technology allows for 3D visualisation in a virtual environment (Figure 2.20a) which is a significant improvement over X-ray film (Figure 2.20b) [23].



(a) (b)

Figure 2.20 (a) Virtual environment versus (b) X-ray film [23].

The method used by Reitemeier *et al*. [24] closely resembles than of Ciocca *et al*. except that they only took the topography of the soft tissue into consideration. CT data of the patient was used to create a 3D model. A mirror copy of the intact auricle was then made using the nose as a reference point. Next, the soft tissue in the virtual environment was trimmed to include the mirrored copy of the auricle, the nose and a piece of the glabella. The trimmed model was 3D printed using Fused Deposition Modelling technology (Figure 2.21a) [24].



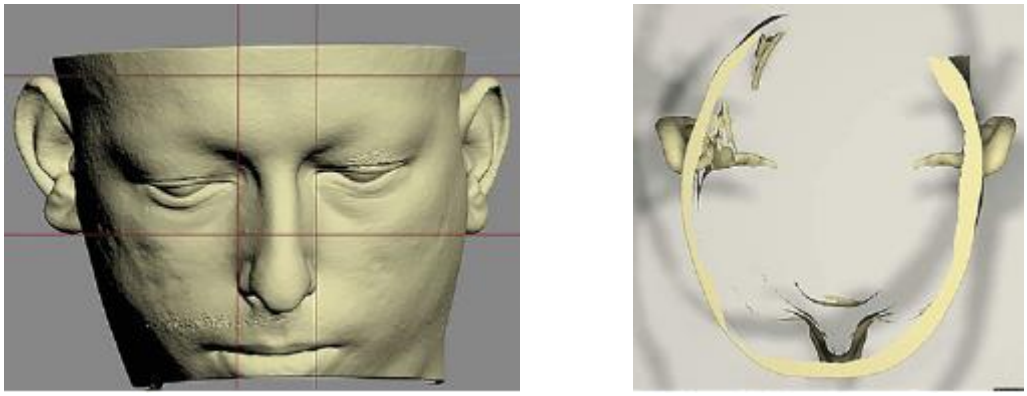
(a) (b)

Figure 2.21 (a) Virtual model of guide. (b) Marking of ideal implant placement [24].

After the optimal locations of the implants had been agreed upon by the surgeon and anaplastologist, holes were drilled through the template to represent these locations. Then the template was sterilized and used to mark the ideal locations for implant placement (Figure 2.21b). Next, the template was removed and the normal procedure for implant placement followed.

Turkyilmaz [25], Watson *et al.* [26], Liacouras *et al.* [27], Subburaj *et al.* [28], Wang *et al.* [29], Mohamed *et al.* [30], Çötert *et al.* [31] and Ferreira *et al.* [32]

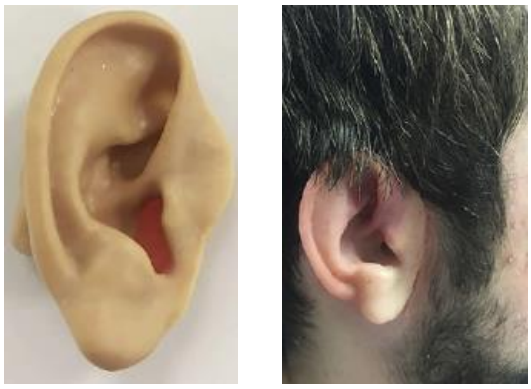
present case studies where digital planning was used in the manufacturing process of an auricular prosthesis. A prosthesis could be produced for patients with one intact auricle by scanning the auricle and using software to create a mirror copy, as described previously. Software design tools were used to position the mirror copy and blend the periphery to the existing soft tissue (Figure 2.22a and Figure 2.21b).



(a) (b)

Figure 2.22 Alignment of mirror copy of auricle from (a) frontal and (b) top view [25].

The digital prosthesis was 3D printed (Figure 2.23a) and duplicated in sculpting wax before the final silicone prosthesis (Figure 2.23b) was manufactured using the conventional process/method.



(a) (b)

Figure 2.23 (a) 3D-printed prosthesis model of auricle. (b) Final silicone prosthesis [25].

A similar method is followed by Mohammed *et al.* [30] to 3D print a model of the final prosthesis.

A study by Farook *et al.* [33], emphasizes the importance of digital libraries for facial prosthetics. With unilateral defects of auricles, it is easy to scan the patient using a variety of technologies and to use available software to create a mirror copy of the existing auricle to produce the final prosthesis. With bilateral defects, the geometry of a normal auricle is required. A digital scan library taken of facial features of people with different ages, gender and ethnicity will allow patients to choose the shape of their prosthesis. Another advantage of having a digital library is that after the prosthesis has reached the end of its lifetime through wear, it can be recreated using the “template” it was originally created from.

2.6.4 Prosthesis placement device

Piper *et al*. [34] describe the fabrication of a laser-level paralleling device (Figure 2.24) to translate anatomical landmarks from the side of the intact auricle to the defected side. The device is assembled with two lasers on opposing sides of an open-ended frame.

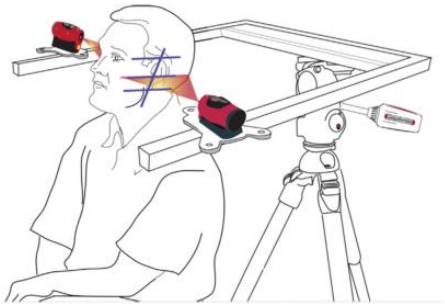
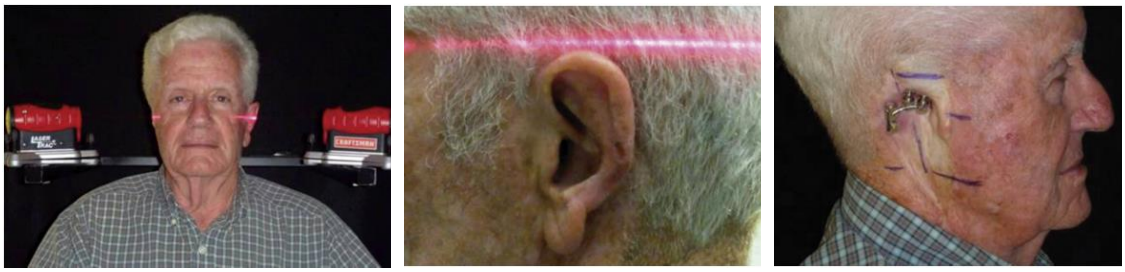


Figure 2.24 Schematic of laser-level paralleling apparatus [34].

The device is placed level with the floor and positioned directly behind the dental chair (Figure 2.25a). A piece of plain white paper is placed between the two lasers to check coincidence of the lines projected by the lasers. Alignment is made possible by means of the adjustable bases onto which the lasers are fixed. Next, the dental chair is elevated to the superior portion of the helix on the side of the intact ear (Figure 2.25b). This position, as indicated by the opposing laser line, is marked on the defected side and this process is repeated on the middle of the targus and inferior portion of the lobule (Figure 2.25c).

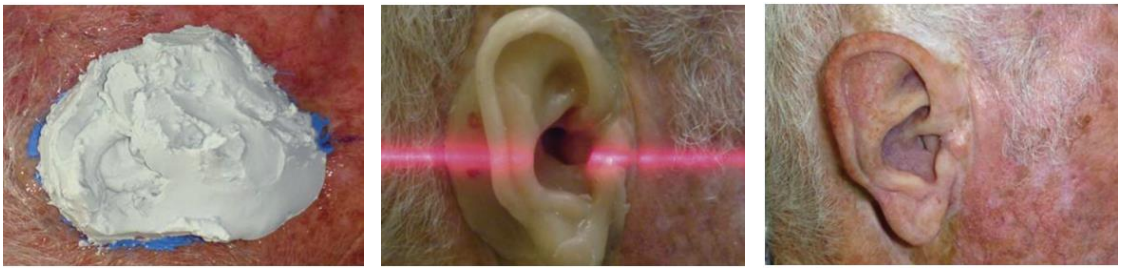


(a) (b) (c)

Figure 2.25 (a) Ear prosthesis position indicated by laser device. (b) Superior portion of helix. (c) Anatomic reference marks transferred to defect side [34].

Next, both lasers are rotated in a vertical position to record the vertical axis of the intact ear. The manufacturing of the auricular prosthesis follows the standard procedure of taking an impression of the existing auricle (Figure 2.26a) and sculpting a mirror image in wax.

Lastly, with the wax model fitted on the patient, the reference lines are verified using the laser-level paralleling device (Figure 2.26b). With the wax model completed, the silicone prosthesis can be finalized using traditional laboratory techniques (Figure 2.26c).



(a) (b) (c)

Figure 2.26 Moulage of existing ear. (b) Wax model is evaluated. (c) Silicone prosthesis [34].

In a paper by Gunay *et al*., the authors mention that tattoo markers were also used to assist in placing craniofacial implants [35].

2.7 Discussion on existing techniques to place auricular prostheses

The various methods used to place craniofacial implants and position external prosthesis thereafter are still lacking in some respects. Only the CAD/CAM techniques described take the bone thickness around the implant site into consideration. This information is obtained from CT data and then used to produce positioning guides which are used to mark the positions of the implants through the skin onto the underlying bone using a needle and dye. After resection of the skin flap, the surgeon drills into the skull according to the markings. In some cases, the dye marking is not clearly visible on the underlying bone, which makes this technique ineffective. In the case of bilateral absent auricles, most of the techniques cannot be performed as they require at least one intact auricle as reference point.

Most of the current methods rely solely on the judgement of the physician when positioning the external prostheses in relation to the implants. As it is critical to position the retention mechanism under the antihelix of the prosthetic auricle, where there is sufficient depth, and simultaneously position the auriculas in the best aesthetical location on the patient, it becomes more important to be accurate with placement.

Chapter 3: Additive manufacturing technologies

Possible solutions to problems experienced in positioning auricular prostheses, as described in Chapter 2, can be found in utilizing dedicated additive manufacturing software and processes. Software, such as Magics from Materialise, can be used to design a patient-specific positioning guide to assist the surgeon during implant placement. The patient's CT/MRI data can be used to determine the bone thickness available to place the implants at the ideal positions so as to minimize the risk of surgical complications. Furthermore, a orientation guide can be designed to ensure that external prostheses are placed in the most aesthetically pleasing positions in relation to the implants. Implementing positioning and orientation guides as part of the treatment plan for placing auricular prosthesis can potentially reduce patient-doctor interaction time and minimize risk of surgical complications.

3.1 Additive manufacturing

Additive manufacturing (AM) is a process that dates back to the late 1980s. It stands in contrast to the conventional subtractive manufacturing methods of machine milling and turning. Until recently, standard terminology for AM has been lacking. The ASTM F2792-12a standard [36] now offers standard terminology for AM which clearly defines abovementioned processes as follows:

"Additive manufacturing, a process of joining materials to make objects from 3D model data, usually layer upon layer, as opposed to subtractive manufacturing methodologies".

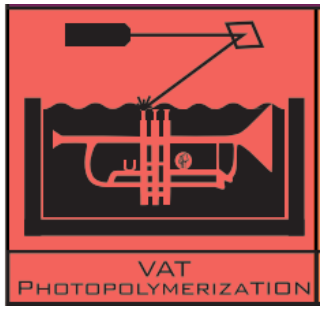
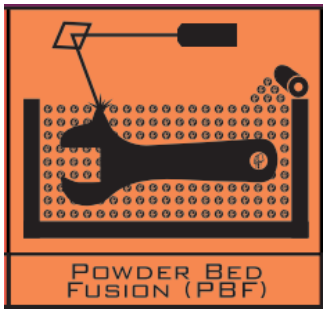
"Subtractive manufacturing, making objects by removing of material (for example, milling, drilling, grinding, carving, etc.) from a bulk solid to leave a desired shape, as opposed to additive manufacturing".

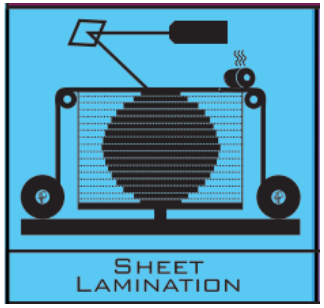
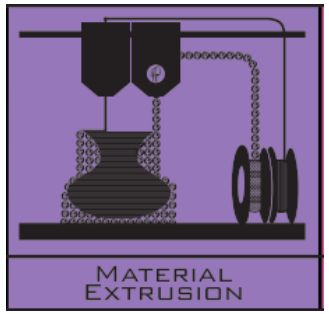
In the early days of AM, the process was mainly used to manufacture conceptual and functional prototypes. Today, however, AM also focuses on end-user parts/products [37]. There are a large number of technologies available that utilize the AM method. Some of the most popular include:

- Selective laser sintering (SLS)
- Stereolithography (SL)
- Fused deposition modeling (FDM)
- 3D printing (3DP)

Much work has been done to differentiate between the different technologies and processes. The table below (Table 3.1) shows a summary describing these processes [38].

Table 3.1 Families of Additive Manufacturing [38].

	Description:	Alternative names:	Strengths:	Typical materials:
	A vat of liquid photopolymer resin is cured through selective exposure to light (via a laser or projector) which then initiates polymerization and converts the exposed areas to a solid part.	SLA – Stereolithography Apparatus DLP – Digital Light Processing 3SP – Scan, Spin and Selective Photocure CLIP – Continuous Liquid Interface Production	• High level of accuracy and complexity • Smooth surface finish • Accommodates large build areas	UV-curable photopolymer resins (with various fillers)
	Powdered materials are selectively consolidated by melting them together using a heat source, such as a laser or electron beam. The unfused powder surrounding the consolidated part acts as support material for overhanging features.	SLS – Selective Laser Sintering DMLS – Direct Metal Laser Sintering SLM – Selective Laser Melting EBM – Electron Beam Melting SHS – Selective Heat Sintering MJF – Multi Jet Fusion	• High level of complexity • Powder acts as support material • Wide range of materials	Plastics, metal and ceramic powders, and sand
	Liquid bonding agents are selectively applied onto thin layers of powdered material to build up parts layer by layer. The binders include organic and inorganic materials. Metal or ceramic powdered parts are typically fired in a furnace after they are printed.	3DP – 3D Printing ExOne Voxeljet	• Allows for full-colour printing. • High productivity • Uses a wide range of materials	Powdered plastics, metal, ceramics, glass, and sand

	Description:	Alternative names:	Strengths:	Typical materials:
	Droplets of material are deposited layer by layer to make parts. Common varieties include jetting a photocurable resin and curing it with UV light, as well as jetting thermally molten materials that solidify in ambient temperatures.	Polyjet SCP – Smooth Curvatures Printing MJM – MultiJet Modeling Projet	• High level of accuracy • Allows for full-colour parts • Enables multiple materials in a single part	Photopolymers, Polymers, waxes
	Sheets of material are stacked and laminated together to form an object. The lamination method can be adhesives or chemical (paper/plastics), ultrasonic welding, or brazing (metals). Unneeded regions are cut out layer by layer and removed after the object is built	LOM – Laminated Object Manufacture SDL – Selective Deposition Lamination UAM – Ultrasonic Additive Manufacturing	• High volumetric build rates • Relatively low cost (non-metals) • Allows for combinations of metal foils, including embedding components.	Paper, plastic sheets, and metal foils/tapes
	Material is extruded through a nozzle or orifice in tracks or beads, which are then combined into multi-layer models. Common varieties include heated thermoplastic extrusion (similar to a hot glue gun) and syringe dispensing.	FFF – Fused Filament Fabrication FDM – Fused Deposition Modelling	• Inexpensive and economical • Allows for multiple colours • Can be used in an office environment • Parts have good structural properties	Thermoplastic filaments and pellets (FFF); liquids, and slurries (syringe types)

	Description:	Alternative names:	Strengths:	Typical materials:
	Powder or wire is fed into a melt pool which has been generated on the surface of the part where it adheres to the underlying part or layers by using an energy source, such as a laser or electron beam. This is essentially a form of automated build-up welding	LMD – Laser Metal Deposition LENS – Laser Engineered Net Shaping DMD – Direct Metal Deposition	• Not limited by direction or axis • Effective for repairs and adding features • Multiple materials in a single part • Highest single-point deposition rates	Metal wire and powder, with ceramics
	Laser metal deposition (a form of DED) is combined with CNC machining which allows additive manufacturing and "subtractive" machining to be performed in a single machine so that parts can utilize the strengths of both processes.	AMBIT – Created by Hybrid Manufacturing Technologies	• Smooth surface finish AND high productivity • Geometrical and material freedoms of DED • Automated in-process support removal, finishing, and inspection	Metal powder and wire, with ceramics

These AM technologies share certain similarities, although they differ in many other respects. Gibson *et al.* [39] describe a generic process for AM technologies. Figure 3.1 below, illustrates the process chain from Computer Aided Design (CAD) to final part [39][40].

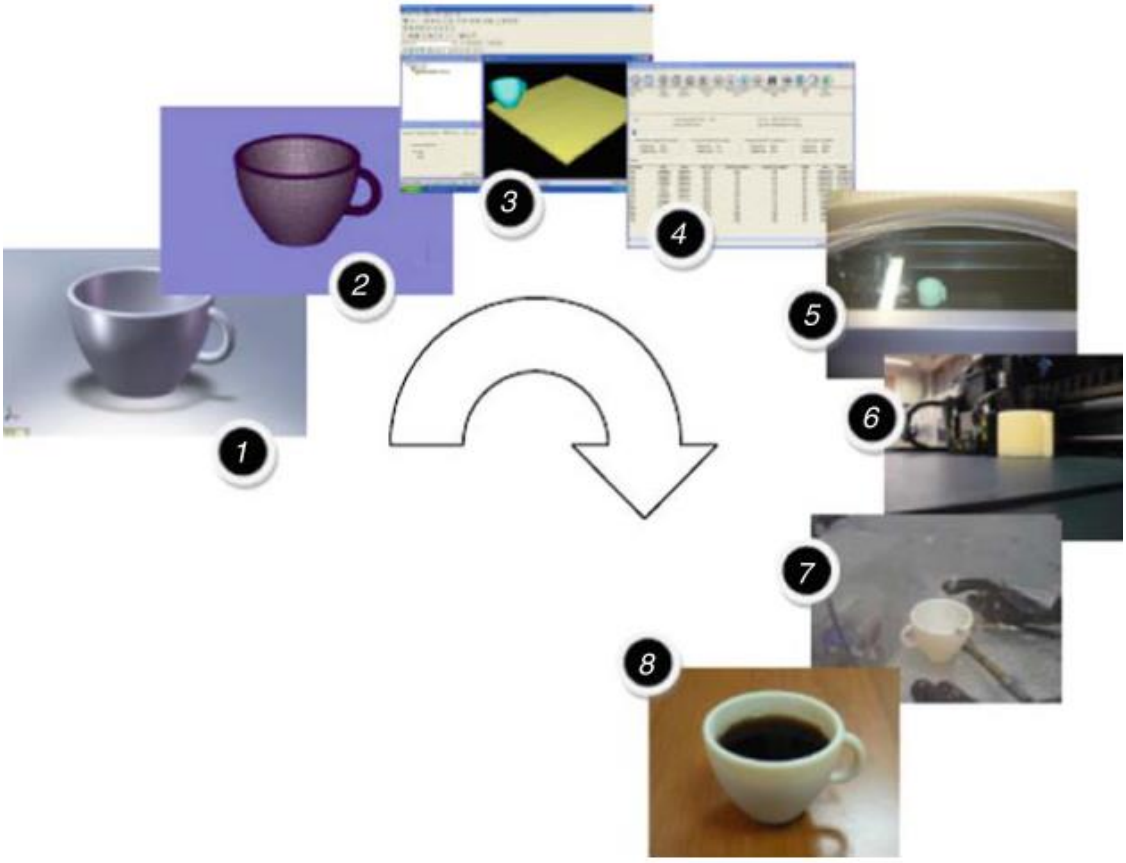


Figure 3.1 Generic process of CAD to AM part [39].

The following steps in sequence define the process of AM.

1) Conceptualization and CAD
2) Conversion to STL (STL is the standard file format for AM)
3) Manipulation, slicing and transfer of STL file to AM machine
4) Machine setup
5) Build
6) Part removal and cleanup
7) Post-processing of part
8) Application

The focus of this study will be on one process in particular, Selective Laser Sintering (SLS).

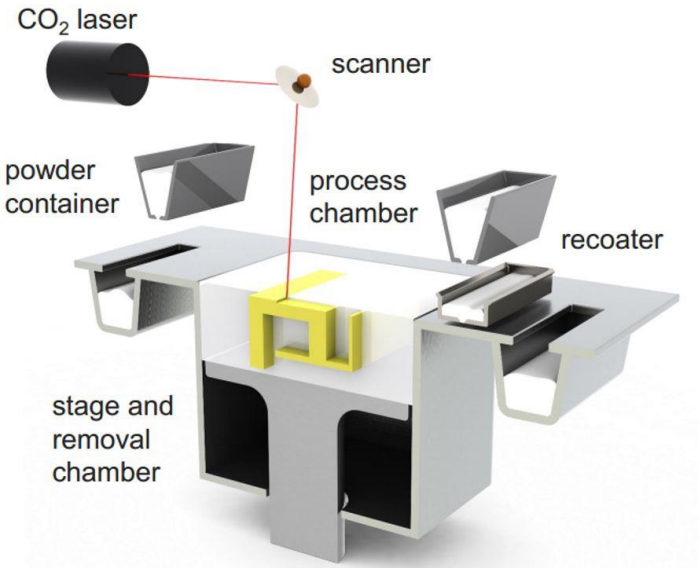


Figure 3.2 Diagram of Selective Laser Sintering (SLS) process [41].

SLS fuses thin layers of powder which have been deposited and spread out by a recoater (Figure 3.2) onto a building platform [42]. The process takes place inside an enclosed chamber filled with nitrogen gas to minimize oxidation and degradation of the powder. Infrared heaters above the process chamber are used to maintain a temperature just below the melting point of the powdered material. This reduces the amount of laser power required to fuse the material and prevents warping of parts due to non-uniform thermal expansion and contraction. The process starts with the preheating of a powder layer. Once this is achieved, a CO_2 laser beam is directed onto the powder with the help of galvanometers. The laser beam then thermally fuses the material of the cross-sectional area of the first slice. The surrounding powder remains loose and acts as support material for the layers to follow. No secondary support structures are required as is the case with other AM processes. After the first layer is completed, the building platform is lowered by one layer thickness and the recoater deposits a new layer of powder. The laser scans the cross-sectional area of the second slice. This cycle repeats until the 3D part is completed. With the SLS process, a cool-down period is required to allow the parts to cool down to a temperature where they can be handled. If parts are removed prematurely they may warp due to uneven thermal contraction.

SLS offers a few advantages compared to conventional manufacturing methods. These include optimized material usage, reduction in production steps and layer-

wise building, which enables geometrically complex parts to be produced. Disadvantages include machine and materials being expensive, a limited range of materials is available and special training on the machine is required.

3.2 Capturing patient data

One of the key design inputs to develop patient-specific devices is the scan data of the patient. There are different technologies available to obtain scan data but they do not yield the same information [43]. From a 3D scanner, only surface information can be obtained, while a CT/MRI scan yields internal data such as bone and soft tissue information [44]. Another big difference between the abovementioned is the size and cost of the equipment. A 3D scanner can be a small handheld device (Figure 3.3a) [45], whereas CT/MRI scanners (Figure 3.3b and Figure 3.3c) [46] are expensive and require a dedicated room because of their large size.

(a) (b) (c)

Figure 3.3 (a) 3D scanning [45]. (b) CT scanner vs (c) MRI [46].

CT scans are best suited for detecting cancers, diagnosing chest and lung issues and for viewing bone injuries. An MRI is more suited for viewing brain tumours, spinal cord injuries and examining soft tissue. The table below (Table 3.2) illustrates the differences between CT and MRI [47].

Table 3.2 Comparison of CT vs MRI [47].

	CT Scan	MRI
Acronym	Computed (Axial) Tomography	Magnetic Resonance Imaging
Principle used	Uses X-rays for imaging	Uses large external field, RF pulse and three different gradient fields
Effects on the body	CT can pose a small risk of irradiation.	No biological hazards
Cost	CT scans usually costs less than MRIs	MRI is usually more expensive than CT scans and X-rays
Time taken	Usually completed within five minutes. CT is less sensitive to patient movement than MRI.	Depending on what is to be looked for in the MRI scan, the scan may be quick (finished in 10–15 minutes) or may take a long time (two hours).
Bony structures	Good details of bony structures	Less detailed compared to X-rays
Soft tissues	CT scan images bone, soft tissue and blood vessels all at the same time	MRI scan yields much more soft tissue detail compared to a CT scan
Limitation	A large patient might not fit into the opening of CT scanner. CT scans are safe for patients with metal implants.	A large patient might exceed the table's weight limit. Any ferromagnetic object may cause trauma/burn.

For the purpose of this study, the focus will be on CT scanning which can be used as a starting point for the development of 3D CAD data that will be used to produce a physical model using 3D printing. From the CT scan, Digital Imaging and Communications in Medicine (DICOM) files are generated. Next, the DICOM

files are imported into segmentation software, such as MIMICS by Materialise, Belgium, for grey value images. By thresholding the DICOM images, it is possible to differentiate between soft tissue and bone. The data is then converted into STL (Standard Triangulation Language) files which can be processed by a 3D printer [48] [49].

Chapter 4: Development of an auricular positioning device

4.1 Preliminary work

The development of an auricular positioning device had already started in 2013 at the Centre for Rapid Prototyping and Manufacturing (CRPM) at Central University of Technology, Free State. A prosthodontic surgeon approached the centre and asked for assistance in developing a positioning device to accurately place craniofacial implants relative to where the final silicone prosthesis would locate. An iterative design process was followed in developing an auricular positioning device, with each new design improving on the previous, as illustrated in Figure 4.1.

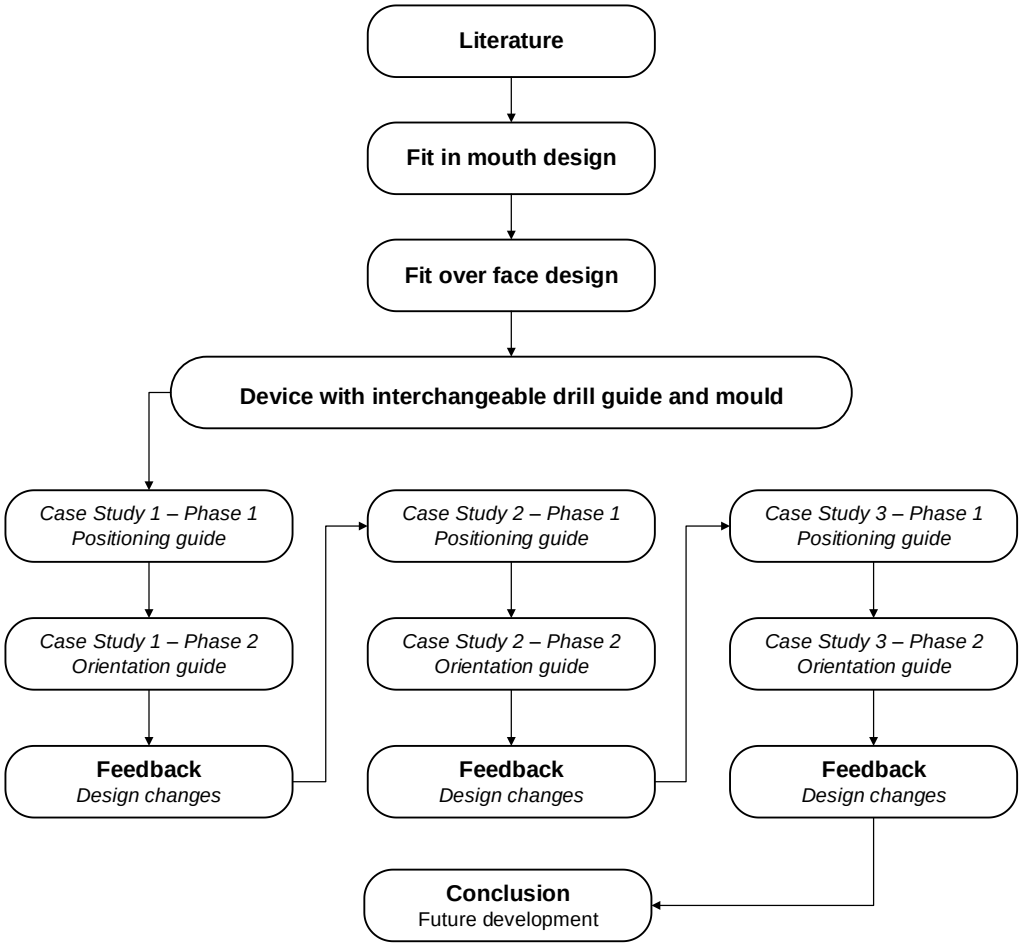


Figure 4.1 Iterative design process followed in study.

The initial three positioning devices, as develop at the CRPM, are described in Chapter 4 together with explantions on how the new positioning and orientation guides developed for this study, are used.

4.1.1 Fit in mouth device

A fit in the mouth device similar to that described by Rezaei and Nematollahi [19] (Section 2.4.2) was considered as a first attempt at an auricular positioning device. Instead of a manual means of producing the guide, as described by the authors, a CAD/CAM approach was taken. CT scans (Figure 4.2), were used to capture all the patient's data and saved as a DICOM file.

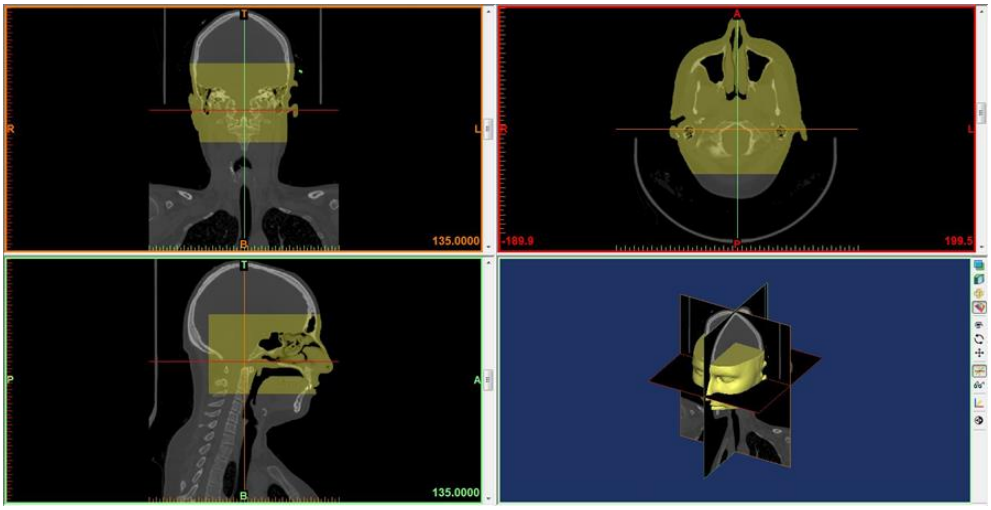


Figure 4.2 CT images of patient.

The data was then segmented using MIMICS software from Materialise to distinguish between soft tissue and bone data and converted to STL format. A mirror copy of the healthy auricle was positioned on the defect side (Figure 4.3), the ideal implant locations were identified, and the bone thickness examined through virtual slices of the skull image at each implant site. Small adjustments were made to the positions of the implants in the design to ensure that bone thickness was satisfactory for the implants.

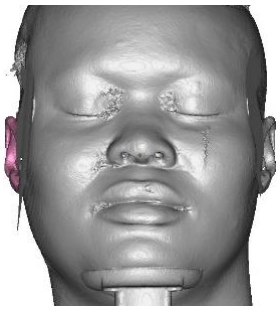
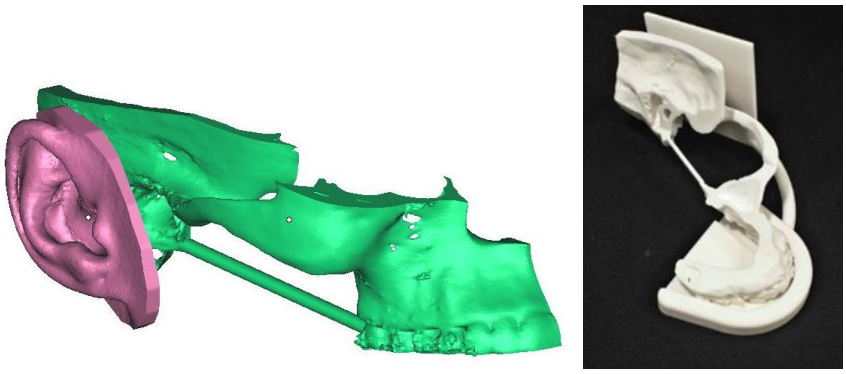


Figure 4.3 Mirror copy of healthy auricle.

Using the maxillary arch as reference point, a guide was designed to position the implants using software from SolidWorks® from Dassault Systèmes and Magics from Materialise. Next, the guide was 3D printed in nylon polyamide (PA2200) on an Electro Optical Systems (EOS) P 385 laser sintering machine.



(a) (b)

Figure 4.4 (a) CAD of fit in mouth positioning device and (b) 3D-printed device

To further assist the surgeon, copies of the defect auricle as well as the healthy and the mirror copy were 3D printed (Figure 4.5) and used as reference to sculpt the new auricle from wax.

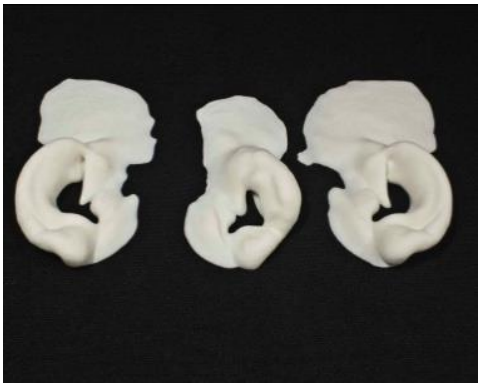


Figure 4.5 Additively manufactured copies of auricles.

This method did not perform very well as it was difficult to design the mouthpiece to fit perfectly onto the patient's teeth. The surgeons also found it difficult to insert the mouthpiece into the patient's mouth in the operating theatre. It should be kept in mind that the patient is under anaesthesia during placement of the implants and is therefore not able to bite down on the mouthpiece to accurately indicate the positions of the implants.

4.1.2 Fit over face device

The problems experienced with the previous design were reviewed and it was decided to use the facial features of the patient as reference points, similar to the method followed by Reitemeier *et al*. [24], as described in Section 2.6.3. Since significant movement of the cartilage and soft tissue of the nose is possible, it was decided to rather design a mask that fits over the face. There is less soft tissue across the bridge of the nose, the brow and the cheekbones and is a much more stable area as base for attaching a positioning guide. The design and manufacturing process followed was the same as for the previous positioning device. Figure 4.6 shows the design of the positioning device.

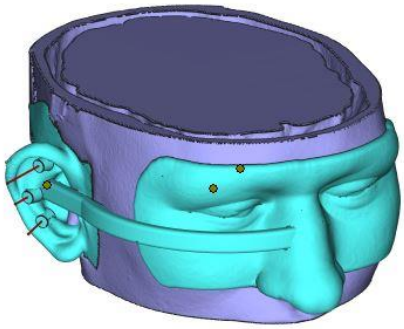
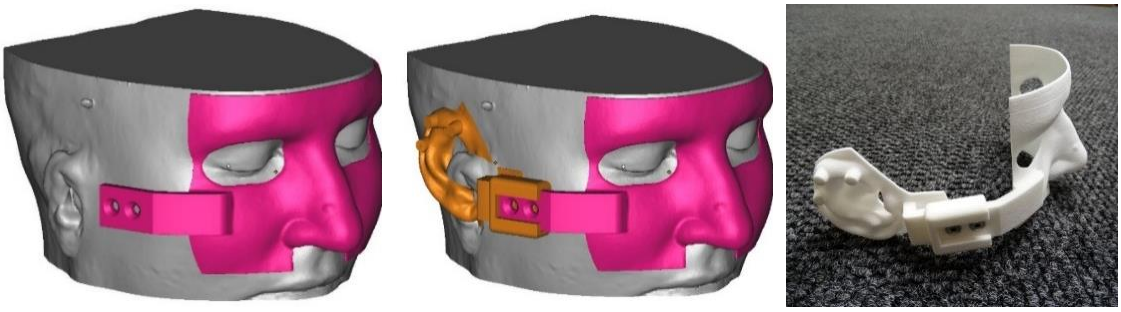


Figure 4.6 First mask design.

The face-mask-type auricular positioning device performed better in practice compared to the previous design. However, it was found to be too narrow and allowed for slight vertical play in the positions indicated for the craniofacial implants. Furthermore, technologists who produce auricular prostheses found it difficult to position the prosthesis accurately in relation to the implants to match the opposite auricle in terms of angle and rotation.

4.1.3 Device with interchangeable positioning and orientation guide

To address the shortcomings of the previous auricular positioning devices, a third concept was designed and produced. This design incorporated a face mask with interchangeable attachments (Figure 4.7a to Figure 4.7c). The first attachment was a marking guide with similar design to the one in the previous face mask.



(a) (b) (c)

Figure 4.7 (a) Mask with bracket only. (b) Mask with positioning guide attachment. (c) Additively manufactured positioning guide

To address the problem of orientating the prosthesis correctly according to the craniofacial implants and opposite auricle, an orientation mould attachment was also designed and produced (Figure 4.8a and& Figure 4.8b).

(a) (b)

Figure 4.8 (a) Mask with orientation attachment. (b) Additively manufactured orientation guide

This was achieved by mirroring the opposite auricle about the mid-plane of the face in the virtual environment using Magics from Materialise software to achieve the correct angle and rotation of the auricle. The image of the mirrored ear was

then subtracted from a solid block in the virtual environment using Magics software to create a negative image of the auricle. Once the tissue surrounding the implants had healed and the abutments with the magnets were placed, a further fitting of the positioning device was required. This time the marking guide was replaced by the negative mould of the auricle. To determine the correct orientation of the implants to the mould, the mould is filled with impression material and pressed over the implants with the impression abutments. When the impression material has cured, it is removed from the abutments and mould and processed using the normal plaster mould and silicone casting process to produce the prosthesis. This technique has not been previously attempted by any other researchers.

The reasoning behind the design of the face mask with interchangeable attachments was to save money by not having to produce two masks. However, the mask would be contaminated with blood from the implant placement surgery, which made reusing it unhygienic.

The surgeons found it difficult to successfully mark the positions of the implants by inserting a syringe needle through the holes in the positioning guide, piercing the skin and then injecting a small amount of dye. Considerable force had to be applied to the syringe needle to leave a mark in the bone. When the incision was made and the skin reflected forward, the markings on the temporal bone should have been clearly visible to indicate where to drill to place the implants. However, this was not the case and it was also found that it was no longer possible to reposition the positioning guide since the skin in the area was reflected forward and was in the way of the arm of the guide. Therefore, the arm should rather be repositioned above the position of the incision and marking should be done directly on the temporal bone with the skin already reflected.

The orientation guide also did not function as intended, with the rigid attachment between the mask and mould proving to be problematic. The technique, however, proved to be feasible and simplified the orientation of the prosthesis in relation to the implants considerably.

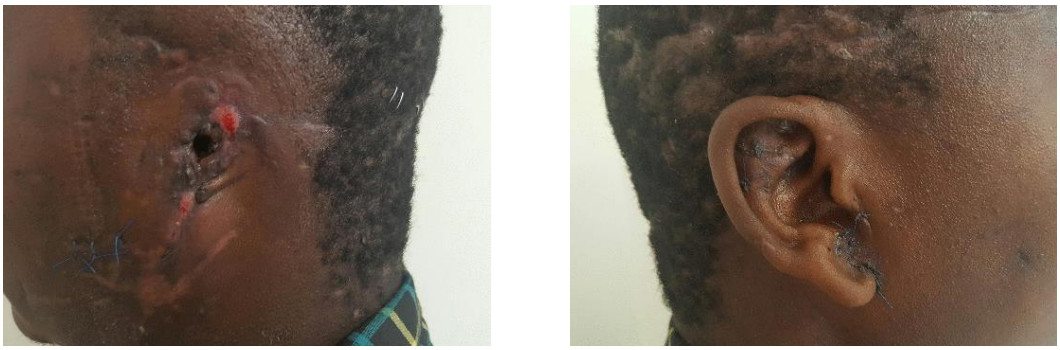
Chapter 5: Case studies

In the continued development of the aricular prosthesis positioning device, three additional design iterations were performed for the current study. These were in the form of actual case studies of patients requiring auricular prostheses. After each consecutive iteration of the device was used, the surgeon was asked to give feedback on the device in terms of problems experienced as well as any suggestions for improvements. A comprehensive log was kept of the surgeons' findings and design improvements were incorporated in the next version of the device.

5.1 Case study 1

5.1.1 Phase 1: Positioning guide

Case study 1 involved a 32-year-old male patient who presented with a missing left auricle as a result of a canine attack (Figure 5.1a). The right auricle was torn but could be repaired with stiches (Figure 5.1b).

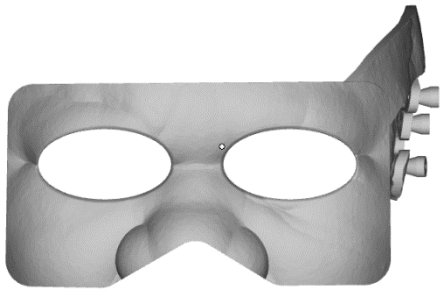


(a) (b)

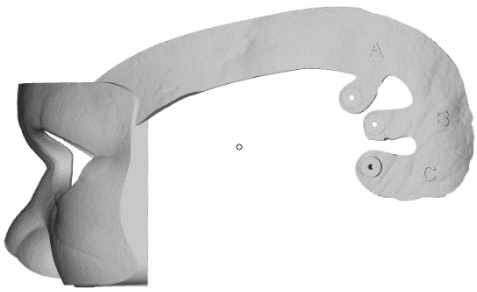
Figure 5.1 Case study 1 left (a) and right (b) auricle.

From CT scan data, an auricular prosthesis positioning device was designed to place three craniofacial implants in locations with sufficient bone thickness. To assist the surgeon during surgery, a set of screen captures of the bone thickness at each implant position was supplied. This helped the surgeon to select an

appropriate drill when placing the implants. The positioning guide was designed following a similar CAD/CAM technique as described for the third positioning guide performed by the CRPM (Section 4.1.3), and printed using laser sintering in nylon at the CRPM. The complete design process for the positioning guide is described in Chapter 6. The arm that connects the face mask to the marking guide was designed such that it extended above the left auricle position to allow the skin flap to be resected forward when the incision has been made to place the implants. This was an improvement on the third design (Section 4.1.3) that was done at the CRPM where the arm connecting the mask to the positioning guide prevented the skin flap from being resected forward. The holes for marking were also enlarged compared to the previous positioning guide to allow for marking directly onto the temporal bone with a drill instead of using a syringe needle with dye.



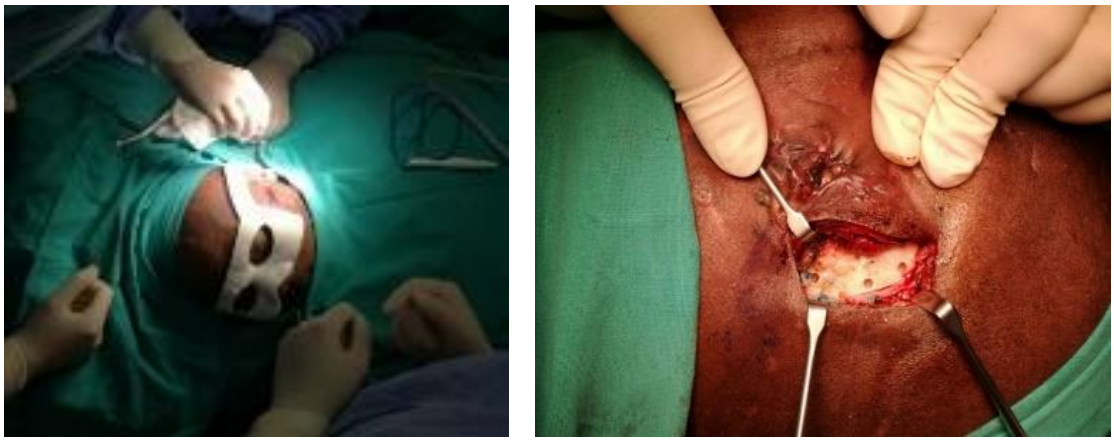
(a)



(b)

Figure 5.2 Case study 1 auricular prosthesis drill guide (a) front view and (b) side view

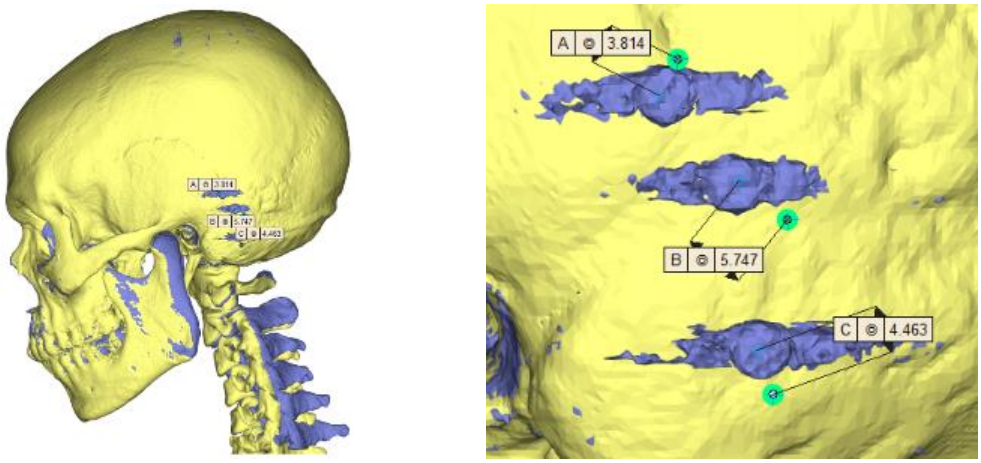
The craniofacial implant procedure was performed at Pelonomi Hospital in Bloemfontein by Dr Charles van Niekerk, while the prosthesis was produced by Prof Cules van den Heever at Central University of Technology, Free State (CUT).



(a) (b)

Figure 5.3 (a) Case study 1 patient with positioning guide in place and (b) implant locations drilled.

After a healing period, the patient was CT scanned once more to evaluate how accurately the implants had been placed using the positioning guide compared to the ideal positions that were originally planned. The new scan was converted to a 3D model and superimposed onto the original image (Figure 5.4a) which showed the planned implant positions. The planned positions are indicated in green in Figure 5.4b while the actual implant positions are shown in purple. From this, the accuracy can be compared and measured (Figure 5.4b).



(a) (b)

Figure 5.4 (a) Case study 1 superimposed 3D models of patient to (b) determine accuracy of guide.

The table below (Table 5.1) indicates the measurements taken at each implant position relative to the initial design position.

Table 5.1 Implant deviation from designed position.

Position	Deviation (mm)
Position A	3.814
Position B	5.747
Position C	4.463
Average	4.675

5.1.2 Surgeon's feedback on positioning guide design

This was the first time the surgeon used this type of guide to position implants.

1) Did you experience any problems in using the positioning guide during placement of implants?

   "I found the guide easy to use. Using a drill to mark the positions of the implants directly onto the bone was much easier than marking through the skin with a needle and dye. The pictures that indicate the bone thickness at each implant position are very helpful in evaluating the quality of the bone at each implant position. The problems I experienced were as follows: the three cylinders in the guide that is used for marking the implant positions did not protrude all the way to the bone which made marking a bit difficult. The holes in the cylinders were also too small. I would like to to use a bigger diameter drill to mark each implant position."

2) If you experienced problems with the guide, how do you propose it can be improved upon?

   "The skin in the temporal area is between 6 and 8 mm thick. Therefore, the three cylinders in the guide that are used for marking the implant

positions should extend up to the bone after the skin flap has been raised. Also, increase the marking holes to a diameter of 2 mm."

3) How long would it take to place implants using conventional methods to determine the implant positions for this specific case?

"It would have taken me about an hour to place the three implants for this patient without the guide."

4) Did the positioning guide reduce the theatre time for this case? If yes, how much time did it save?

"Yes, it took me about 20 minutes to place the implants with the new guide. I therefore saved about 40 minutes."

5.1.3 Phase 2: Orientation guide

After a period of three months to allow for osseointegration of the implants, the second stage of rehabilitation could commence. An auricular orientation guide with a slider mechanism was designed, which is an improvement over the rigid orientation guide described in Section 4.1.3, to translate the implant positions onto the prosthesis. The design for the orientation guide is fully described in Chapter 6.

(a) (b)

Figure 5.5 (a) Positioning guide for Case study 1 and (b) implant positions translated to prosthesis impression.

(a) (b)

Figure 5.6 (a) Final prosthesis of Case study 1 and (b) close-up image of prosthesis.

5.1.4 Prosthodontist's feedback on orientation guide

Prof Cules van den Heever found the new orientation guide with the slider mechanism a significant improvement over the orientation guide initially developed at the CRPM (see Section 4.1.3). The use of the orientation guide was found to substancially reduce time in producing an auricular prosthesis. The prosthesis mould was prepared beforehand by scanning and mirroring the opposite auricle using digital software, which saved time sculpting the prosthesis by hand. Only minor adjustments had to be made to the moulded wax mock-up of the prosthesis before casting in silicone. Prof van den Heever estimated that it would have taken him about 15 hours to produce the prosthesis using the traditional technique, while it took him 12 hours using the new technique.

5.2 Case study 2

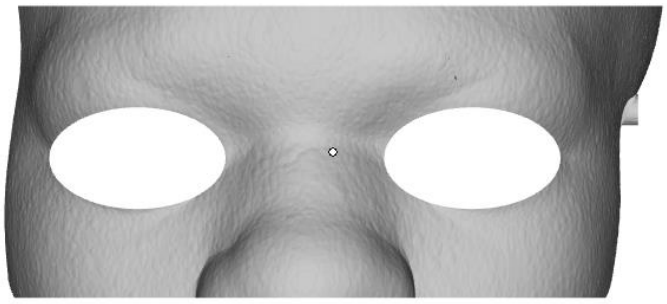
5.2.1 Phase 1: Positioning guide

Case study 2 involved a 14-year-old male patient who presented with an underdeveloped auricle on the right side (Figure 5.7a) but with a normal auricle on the left (Figure 5.7b).

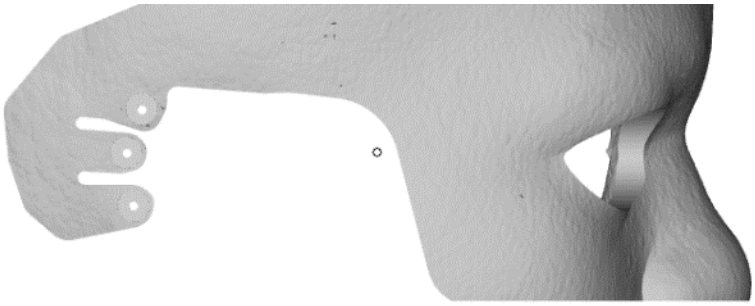
(a) (b)

Figure 5.7 Case study 2 right (a) and left (b) auricle.

An implant positioning device was designed, as shown in Figure 5.8a and Figure 5.8b, and 3D printed as shown in Figure 5.9a and Figure 5.9b. The part of the guide that indicates the marking positions was extended to rest against the temporal bone when the skin is resected, as suggested by the surgeon in Case study 1. The diameter of the holes in the marking guide was also increased to 2 mm as requested. The craniofacial implant procedure, as shown in Figure 5.10a and Figure 5.10b, was performed at Cure Day Clinics Bloemfontein by Dr Charles van Niekerk assisted by Prof Cules van den Heever, who also produced the auricular prosthesis.



(a)

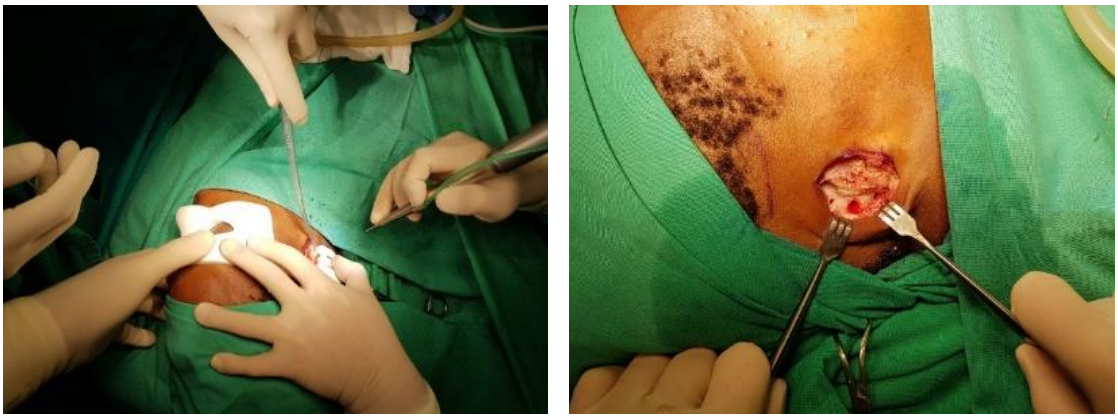


(b)

Figure 5.8 Auricular prosthesis positioning guide design for Case study 2 (a) front view (b) side view.

(a) (b)

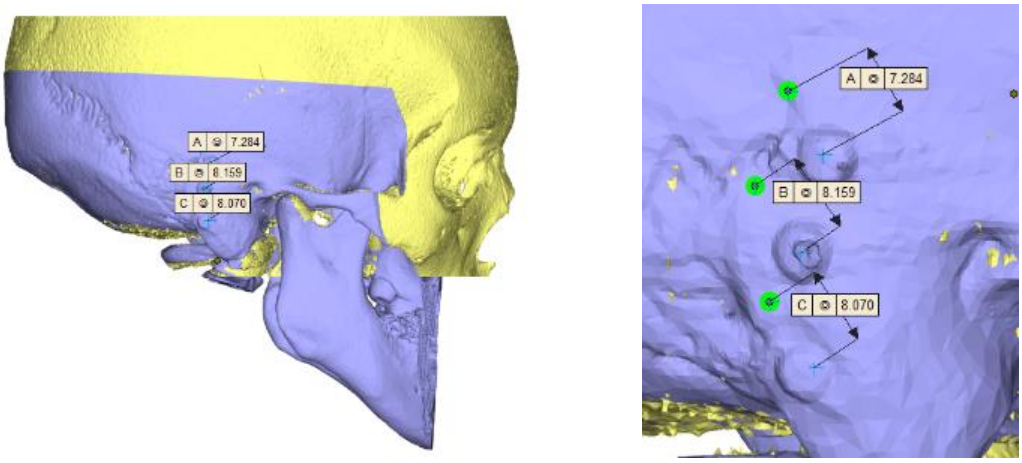
Figure 5.9 Printed auricular prosthesis positioning guide for Case study 2 (a) side view and (b) inside view.



(a) (b)

Figure 5.10 (a) Marking of implant positions, (b) Implant positions drilled to size.

As with the previous case study, a CT scan of the patient was taken to evaluate the accuracy of the positioning guide. The 3D model of the designed positions (Figure 5.11a - yellow) were superimposed onto the 3D model of the actual implants in their positions (Figure 5.11b - purple) to determine accuracy of placement.



(a) (b)

Figure 5.11 (a) Superimposed 3D models of patient to (b) determine accuracy of implant placement.

The table below (Table 5.2) indicates the measurements taken at each implant position relative to the initial design position.

Table 5.2 Implant deviation from designed position

Position	Deviation (mm)
Position A	7.284
Position B	8.159
Position C	8.070
Average	7.838

5.2.2 Surgeon's feedback on positioning guide design

1. Did you experience any problems in using the positioning guide during placement of implants?

   "The guide worked fine, extending the guide holes to touch the bone made marking easier. The arm which connects the face mask to the marking indicator was somewhat in the way of the skin flap when it was resected."

2. If you experienced problems with the guide, how do you propose it can be improved upon?

   "Moving the arm which connects the face mask to the marking indicator higher should prevent this part of the guide interfering with the skin flap during the operation. The face mask can also be made wider to help reduce play in indicating the positions of the implants."

3. How long would it take to place implants using conventional methods to determine the implant positions for this specific case?

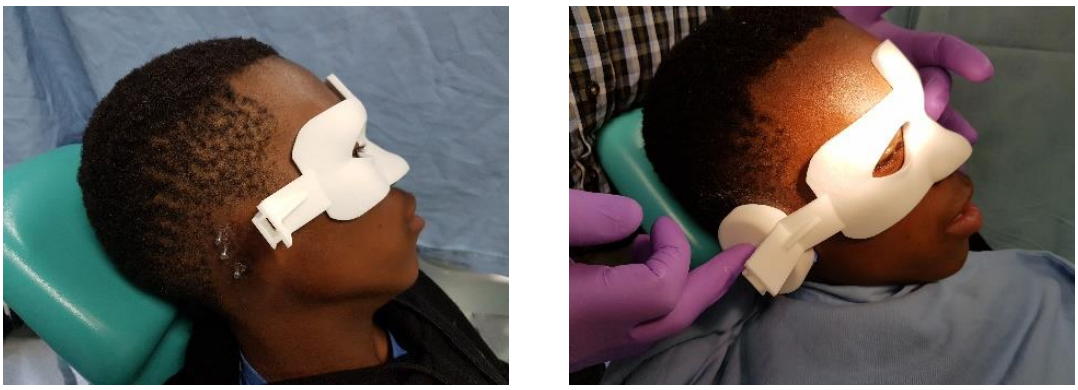
   "Similar to the previous case study, it would have taken me about an hour to place the three implants for this patient without the guide."

4. Did the positioning guide reduce the theatre time for this case? If yes, how much time did it save?

   “Yes, again similar to the previous case, using the guide saved about 40 minutes.”

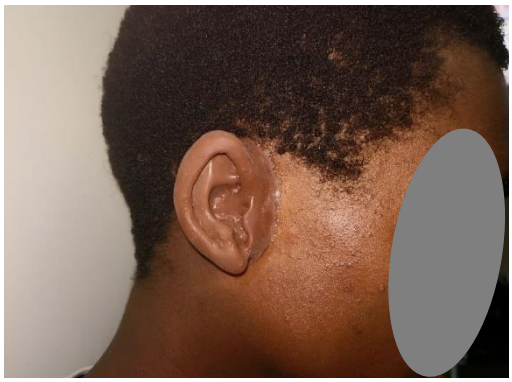
5.2.3 Phase 2: Orientation guide

The same as with the previous case study, an auricular positioning guide with a slider mechanism was designed and produced. Figure 5.12a shows the guide with the implants in position and Figure 5.12b the positioning guide with mould while taking an impression.



(a) (b)

Figure 5.12 Auricular prosthesis positioning guide for Case study 2 (a) and (b) taking an impression with the device.



(a)

Figure 5.13 Final prosthesis of Case study 2.

5.2.4 Prosthodontist's feedback on orientation guide

Prof van den Heever estimated that similar to the previous case study, it would have taken him about 18 hours to produce the prosthesis using the traditional technique, while it took him 12 hours using the new technique. The additional time it would have taken to produce this prosthesis conventionally compared to the previous case, is due to the patient not having an external auditory canal. This makes fitting the prosthesis much more difficult.

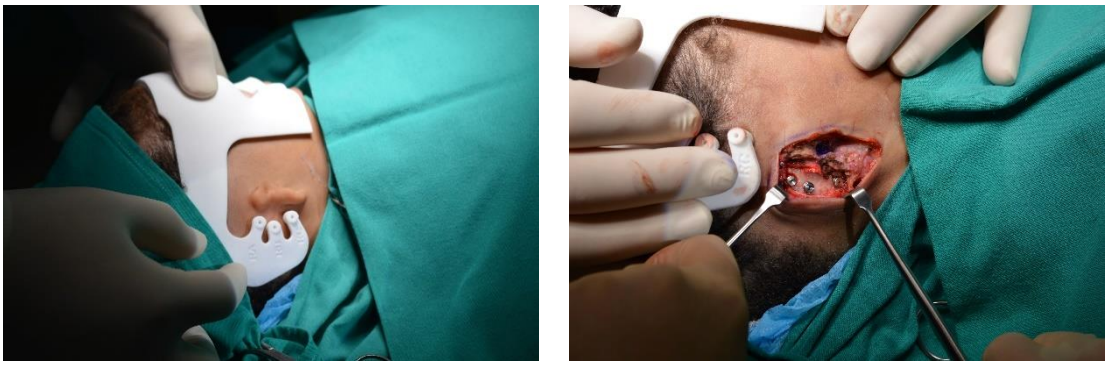
5.3 Case study 3

5.3.1 Phase 1: Positioning guide

The patient for Case study 3 was an eight-year-old boy who presented with bilateral underdeveloped auricles (Figure 5.14a and Figure 5.14b). A positioning device were designed and produced similar to the previous two case studies. Following the recommendations of the surgeon from Case study 2, the arm connecting the face mask to the marking guide was raised to give more clearance to resect the skin flap forward. The mask was also designed significantly wider to limit play in the indicated implant positions. Figure 5.15a and Figure 5.15b and Figure 5.16a and Figure 5.16b show the positioning guide in use and the surgical procedure for placing the implants respectively for the two sides. The implant procedure was performed at Kalahari Day Theatre and Cataract Centre, Upington by Dr Charles van Niekerk, while Prof Cules van den Heever produced the auricular prostheses.

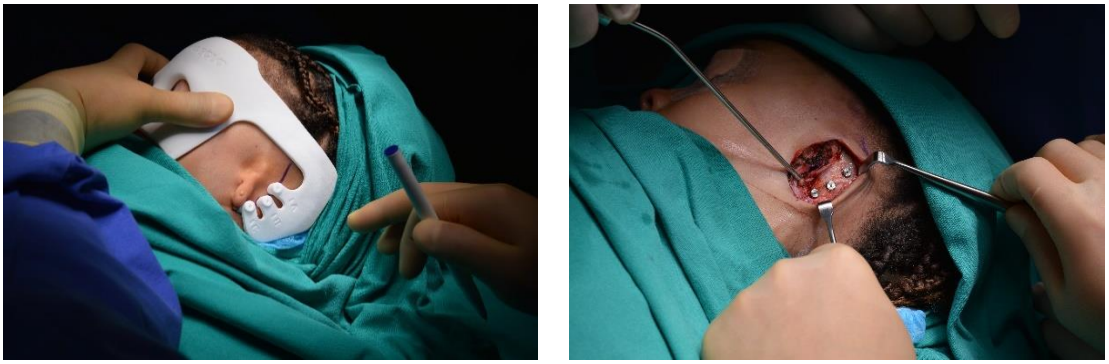
(a) (b)

Figure 5.14 Case study 3 underdeveloped (a) right and (b) left auricle.



(a) (b)

Figure 5.15 Case study 3 right side, (a) marking of implant positions and (b) implants placed.



(a) (b)

Figure 5.16 Case study 3 left side, (a) marking of implant positions and (b) implants placed.

The bone thickness at position LA (Figure 5.17) on the left side of the patient was determined to be 2.705 mm, but during surgery it was decided to move this implant location to where more bone was available. This was carried out in theatre using the 3D model of the patient which was generated from CT scan data. The new position of the implant was considered as the designed position.

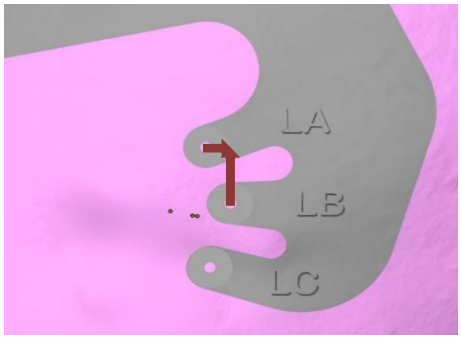
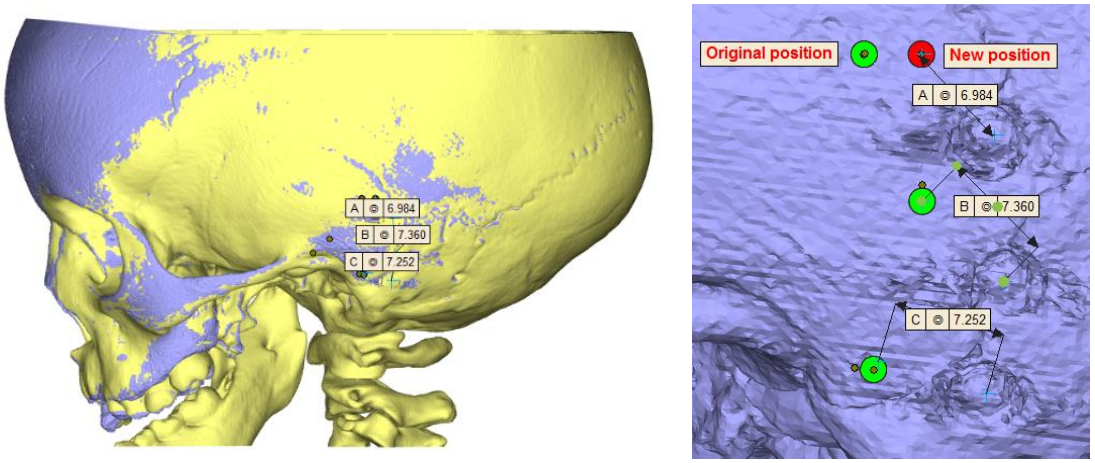


Figure 5.17 Case study 3 new location of implant position A for left auricle.

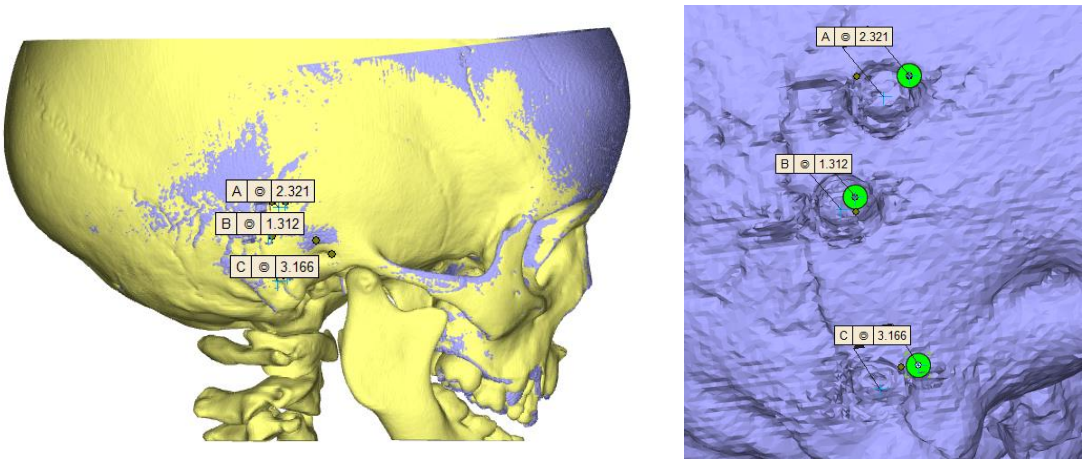
Figure 5.18a shows the superimposed 3D model of the designed positions onto the 3D model of the actual implants for the left side procedure, while the deviation is shown in Figure 5.18b.



(a) (b)

Figure 5.18 (a) Case study 3 superimposed 3D models of patient to (b) determine accuracy of implant placement.

Next, the right side was evaluated using the same method as shown in Figure 5.19a, while the deviations are shown in Figure 5.19b.



(a) (b)

Figure 5.19 (a) Case study 3 superimposed 3D models of patient to (b) determine accuracy of implant placement.

The table below (Table 5.3) indicates the measurements taken at each implant position relative to the initial design position.

Table 5.3 Implant deviations from designed positions.

Position	Deviation (mm) Right side	Deviation (mm) Left side
Position A	2.321	6.984
Position B	1.312	7.360
Position C	3.166	7.252
Average	2.266	7.199

5.3.2 Surgeon's feedback on positioning guide design

1) Did you experience any problems in using the positioning guide during placement of implants?

"Raising the arm connecting the face mask with the marking indicator allowed for more space to resect the skin flap forward during the implant placement procedure. The wider mask also helped to limit play in the indicated implant positions."

2) If you experienced problems with the guide, how do you propose it can be improved upon?

"I did not experience any problems with the third design positioning guide. If the guide can be designed so that it holds the resected skin flap in place during the procedure, it would be useful. This will make it unnessasary to use the skin hooks we are currently using to hold the flap out of the way and free up more space to work."

3) How long would it take to place implants using conventional methods to determine the implant positions for this specific case?

"Since implants had to be placed for bilateral prostheses, placing the implants takes significantly longer. I would estimate about one and a half hours."

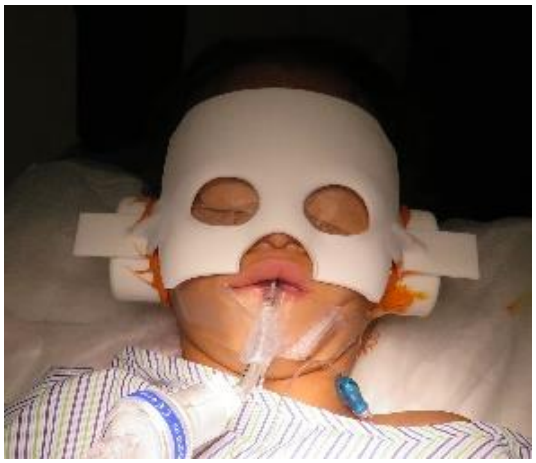
4) Did the positioning guide reduce the theatre time for this case? If yes, how much time did it save?

"Yes, placing the implants using the positioning guides took about 40 minutes, thus saving about 50 minutes.

5.3.3 Phase 2: Orientation guide

A bilateral auricular orientation guide with a slider mechanisms was designed and produced for this case study. Figure 5.20a shows the guide with the implants in position and Figure 5.20b the orientation guide with moulds while taking an impression.

(a)



(b)

Figure 5.20 (a) Printed bilateral auricular orientation guide for Case study 3 and (b) guide in use.

(a)

(b)

Figure 5.21 Final prosthesis of Case study 3 of the a) right auricle prosthesis and (b) left auricle prosthesis.

5.3.4 Prosthodontist's feedback on orientation guide

Prof van den Heever estimated that it would have taken him about 24 hours to produce the bilateral prostheses using the traditional technique, while it took him 16 hours using the new technique.

5.4 Discussion on accuracy of implant placement

Across all three case studies, the biggest deviation from the planned implant position was 8.159 mm and the smallest deviation 1.312 mm (Figure 5.22). The average deviation for all 3 case studies was 5.495 mm.

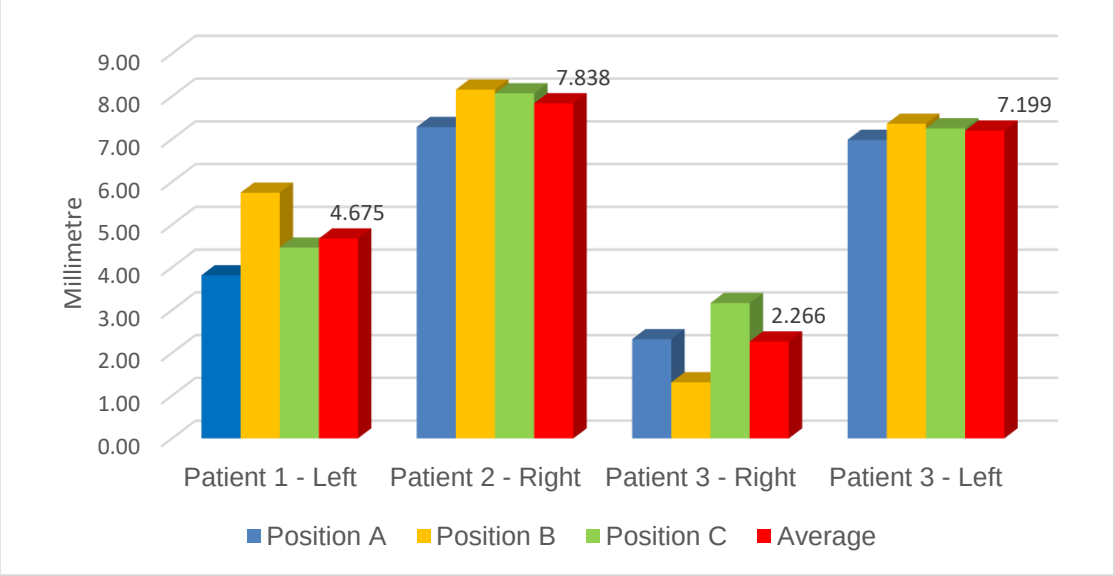


Figure 5.22 Deviation of planned and actual implant placements.

The factors which could have played a role in the accuracy of the devices are as follows:

1. The surgeon using the device (human error).
2. The quality of the CT scan.
3. The software used to convert the CT data to a 3D model.
4. The designer (human error).
5. The manufacturing process (SLS process).

Using the device incorrectly during surgery is likely the single largest cause of inaccuracy during implant placement. With limited access to the operating area, the surgeon must take care to ensure the mask is placed properly onto the patient's facial landmarks. Since the skin across the facial landmarks allows for movement, slight movement of the mask could occur depending on where pressure is applied to hold it in place. As a result, the indicated positions for

placing the implants will also have some deviation. It is important the surgeon is properly instructed how to use the mask before surgery.

The quality of the CT scan is critical to accurately design the positioning device. If the patient did not relax their facial muscles during the CT scan, this could alter the result of the fitment of the mask and in turn the placement of the implants. If the slice thickness is too large, the software will interpret the data between each slice, which will also lead to inaccuracies.

The software used to convert the CT data to a 3D model is validated and CE marked. This ensures that each operation performed by the software is accurate and repeatable and makes it less likely to be the cause of any inaccuracies in the final product. The designer, however, is more likely to have an influence on the outcome of the device. If incorrect values and tolerance were used, for example during the segmentation of the CT data or design, it could influence the fit of the mask on the patient's face which would alter the positions of each implant.

With the manufacturing process, the machine must be calibrated to ensure accurate components and with the SLS process having a heated chamber, the premature removal of parts from the machine could result in warpage, which would alter the accuracy of the positioning guide. Proper training on the machine and process is essential to ensure all 3D-printed parts are of the highest quality in terms of strength and accuracy. Since all devices were 3D printed at the CRPM, which is an ISO 13485 certified centre, the risk of human error in this regard is somewhat reduced. The extent to which each factor stated above may influence the accuracy of implant has not been quantified and will require further study.

5.5 Time and cost comparison

A time and cost comparison, as shown in Table 5.4, was performed to compare the time and cost it would take to produce an auricular prosthesis using conventional means and the positioning/orientation guides developed in this study. The cost of theatre time was based on The Mediclinic Southern Africa Private Tariff Schedule 2020 [50].

Table 5.4 Case study 1: Time and cost comparison between conventional and CAD/CAM technology to produce auricular prostheses.

Case study 1	Conventional			CAD/CAM Technology		
Description	**Time**	**Cost**	**Comment**	**Time**	**Cost**	**Comment**
CT scan for 3D model	0 hrs	R 0	No CT scan required.	30 min	R 3 500	CT scan of head required.
Device to mark implant positions	5 hrs	R 10 000	Two appointments are required: Firstly, to take an impression of the healthy side and create a mirrored wax up of the auricle. Secondly, to determine the position of the wax auricle on the patient. From this wax up, an acrylic guide template is made to use during surgery.	20 hrs	R 6 196	Positioning guide is designed. No appointment required. Design of device = 4 hours, 3D printing of device = ±16 hours, which includes cleaning of device. Standard cost from CRPM for positioning guide.
Marking implant positions	1 hr	R 15 000	The acrylic guide is used to mark through the soft tissue with a needle dipped in ink and tapped into the bone to leave a mark. Alternatively, a long drill can be used to drill through the soft tissue to leave a mark on the bone surface.	10 min	R 2 500	Positions are marked during surgery, using the positioning guide.
Theatre time to place implants	1.5 hrs	R 22 500	After positioning the acrylic guide and verifying its position, the implant positions are marked. Next, the skin is resected and the implants can be placed.	20 min	R 5 000	After the skin is resected, the positioning guide is placed on the patient and a 2 mm burr drill is used to mark the implant positions through the guide.
Device/method to position and manufacture prosthesis	2 hrs	R 4 000	The wax auricle, together with acrylic guide, is used to determine the relative position of the wax auricle to the abutments. This is verified on the patient. If implant placement was inaccurate, adjustments can be made.	18 hrs	R 7 574	Impression can be taken immediately after surgery. Design of orientation guide = 2 hours, 3D printing of device = ±16 hours, which includes cleaning of device. Standard cost from CRPM for orientation guide.
Labour to manufacture prosthesis	18 hrs	R 37 000	Two appoinments are required: Firstly, to take an impression of abutments fitted on implants. Conventional plaster mould technique is used to manufacture prosthesis. Additional material of ± R1 000 is required. Secondly, to finalise the position of prosthesis on the patient to achieve an aesthetically pleasing result.	12 hrs	R 24 000	Reduced time to manufacture prosthesis using orientation guide. No additional appointments required to finalize fit of prosthesis. Aesthetically pleasing result much easier to achieve.
Total	27.5 hrs	R 88 500		51 hrs	R 48 770	
Theatre time (R/min)	R	250.00				

Table 5.5 Case study 2: Time and cost comparison between conventional and CAD/CAM technology to produce auricular prostheses.

Case study 2	Conventional			CAD/CAM Technology		
Description	**Time**	**Cost**	**Comment**	**Time**	**Cost**	**Comment**
CT scan for 3D model	0 hrs	R 0	No CT scan required	30 min	R 3 500	CT scan of head required
Device to mark implant positions	5 hrs	R 10 000	Two appointments are required: Firstly, to take an impression of healthy side and create a mirrored wax up of the auricle. Secondly, to determine the position of the wax auricle on the patient. From this wax up, an acrylic guide template is made to use during surgery.	20 hrs	R 6 196	Positioning guide is designed. No appointment required. Design of device = 4 hours, 3D printing of device = ±16 hours, which includes cleaning of device. Standard cost from CRPM for positioning guide.
Marking implant positions	1 hr	R 15 000	The acrylic guide is used to mark through the soft tissue with a needle dipped in ink and tapped into the bone to leave a mark. Alternatively, a long drill can be used to drill through the soft tissue to leave a mark on the bone surface.	10 min	R 2 500	Positions are marked during surgery using the positioning guide.
Theatre time to place implants	1.5 hrs	R 22 500	After positioning the acrylic guide and verifying its position, the implant positions are marked. Next, the skin is resected and the implants can be placed.	20 min	R 5 000	After the skin is resected, the positioning guide is placed on the patient and a 2 mm burr drill is used to mark the implant positions through the guide.
Device/method to position and manufacture prosthesis	2 hrs	R 4 000	The wax auricle, together with acrylic guide, is used to determine the relative position of the wax auricle to the abutments. This is verified on the patient. If implant placement was inaccurate, adjustments can be made.	18 hrs	R 7 574	Impression can be taken immediately after surgery. Design of orientation guide = 2 hours, 3D printing of device = ±16 hours, which includes cleaning of device. Standard cost from CRPM for orientation guide.
Labour to manufacture prosthesis	18 hrs	R 37 000	Two appointments are required: Firstly, to take an impression of abutments fitted on implants. Conventional plaster mould technique is used to manufacture prosthesis. Additional material of ± R1 000 is required. Secondly, to finalise position of prosthesis on patient to achieve an aesthetically pleasing result.	12 hrs	R 24 000	Reduced time to manufacture prosthesis using orientation guide. No additional appointments required to finalize fit of prosthesis. Aesthetically pleasing result much easier to achieve.
Total	29 hrs	R 88 500		51 hrs	R 48 770	
Theatre time (R/min)	R	250.00				

Table 5.6 Case study 3: Time and cost comparison between conventional and CAD/CAM technology to produce auricular prostheses.

Case study 3	Conventional			CAD / CAM Technology		
Description	**Time**	**Cost**	**Comment**	**Time**	**Cost**	**Comment**
CT scan for 3D model	0 hrs	R 0	No CT scan required.	30 min	R 3 500	CT scan of head required.
Device to mark implant positions	10 hrs	R 20 000	Two appointments are required: Firstly, to take an impression of healthy side and to create a mirrored wax up of the auricle. Secondly, to determine the position the wax auricle on the patient. From this wax up, an acrylic guide template is made to use during surgery.	22 hrs	R 7 594	Positioning guide is designed. No appointment required. Design of device = 5 hours, 3D printing of device = ±17 hours, which includes cleaning of device. Standard cost from CRPM for postioning guide.
Marking implant positions	2 hrs	R 30 000	The acrylic guide is used to mark through the soft tissue with a needle dipped in ink and tapped into the bone to leave a mark. Alternatively, a long drill can be used to drill through the soft tissue to leave a mark on the bone surface.	20 min	R 500	Positions are marked during surgery, using the positioning guide.
Theatre time to place implants	2 hrs	R 30 000	After positioning the acrylic guide and verifying its position, the implant positions are marked. Next, the skin is resected and the implants can be placed.	40 min	R 12 500	After the skin is resected, the positioning guide is placed on the patient and a 2 mm burr drill is used to mark the implant positions through the guide.
Device/method to position and manufacture prosthesis	4 hrs	R 8 000	The wax auricle, together with acrylic guide, is used to determine the relative postion of the wax auricle to the abutments. This is verified on the patient. If implant placement was inaccurate, adjustments can be made.	20 hrs	R 9 281	Impression can be taken immediately after surgery. Design of orientation guide = 3 hours, 3D printing of device = ±17 hours, which includes cleaning of device. Standard cost from CRPM for orientation guide.
Labour to manufacture prosthesis	24 hrs	R 50 000	Two appointments are required: Firstly, to take an impression of abutments fitted on implants. Conventional plaster mould technique is used to manufacture prosthesis. Additional material of ± R2 000 is required. Secondly, to finalise position of prosthesis on patient to achieve an aesthetically pleasing result.	16 hrs	R 32 000	Reduced time to manufacture prosthesis using orientation guide. No additional appointments required to finalize fit of prosthesis. Aesthetically pleasing result much easier to achieve.
Total	42 hrs	R 138 000		59.5 hrs	R 67 375	
Theatre time (R/min)	R	250.00				

5.6 Discussion on time and cost

From Tables 5.4 to 5.6, it is evident that using CAD/CAM technology to position and orientate auricular prostheses saves time and reduces the costs involved. The number of appointments needed to finalise the prostheses is also reduced as most of the planning is done digitally. The conventional placement of implants for the case studies would generally not be very difficult as the patients all had somewhat symmetrical faces. Where the positioning guide plays a bigger role is with patients with congenital disorders such as Treacher Collins Syndrome. With assymetrical faces, it becomes more difficult to position implants using the conventional methods to retain the auricular prosthesis. Another consideration is the absence of the auditory canal, which is normally used as a reference in positioning implants, and finally the prosthesis. With the CAD/CAM method, the software used to position the implants allows the user to see the auditory canal, although it might not be visible externally for the surgeon to use as reference during the conventional planning phase.

One of the main benefits of using the CAD/CAM method outlined in this study is the orientation device used to obtain the relative position of the implants to the prosthesis. This method saves a considerable amount of time and produces an aesthetic result.

In Case study 1 and Case study 2, a cost reduction of 44.89% was achieved compared to the conventional method. In Case study 3, a cost reduction of 51.18% was achieved. Although the positioning and orientation guides are quite expensive, this technique does not require much of the surgeon's time during the process. The largest portion of time is taken in the design and 3D printing of the guides. Therefore, the reduction in time achieved using this CAD/CAM method more than justifies the expense of the two guides.

The cost of the positioning and orientation guides used in the case studies is derived from the design time, cost of 3D printing, software licensing and cleaning of the guides. The cost to produce an auricular prosthesis in the United States

ranges from $4 000–$8 000, which is more or less in line with the cost in South Africa, depending on the exchange rate at the time [51].

Chapter 6: Workflow for the design of positioning and orientation guides

This chapter describes the workflow that was developed for designing and using the positioning and orientation guides, as described in Chapter 5, for both unilateral and bilateral absent auricles.

6.1 Design Process: Positioning Guide for unilateral absent auricle

For the positioning guide, it is important to first assess the cause of the defect as this will play a key role in positioning the implants during the design phase. If the defect was caused by trauma, the healthy opposite auricle can usually be mirrored onto the defect side (Figure 6.1) and positioned in relation to landmarks such as the auditory canal (Figure 6.2) and healthy auricle. The mirror copy represents the position of the final prosthesis (Figure 6.3).

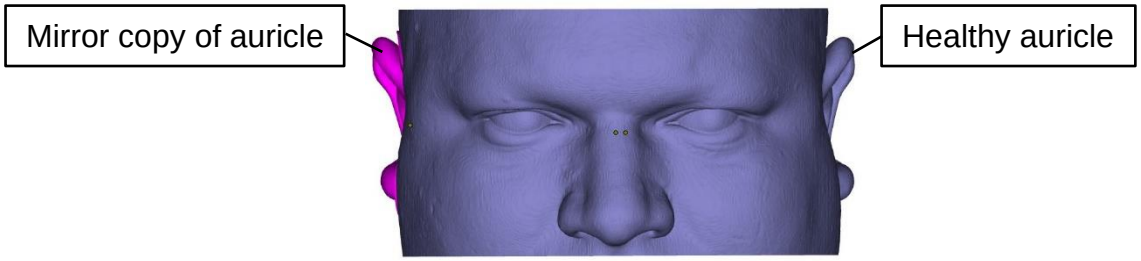


Figure 6.1 Mirror copy of healthy auricle.

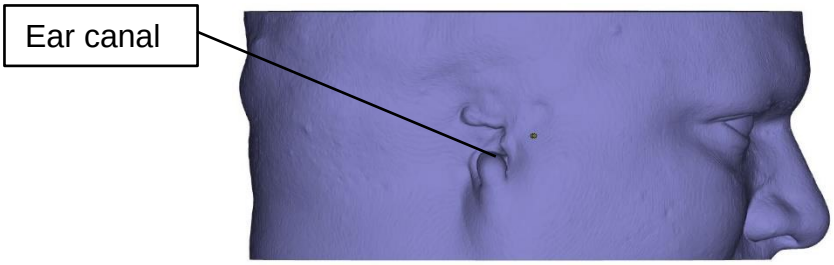


Figure 6.2 Using auditory canal as reference point to position prosthesis.

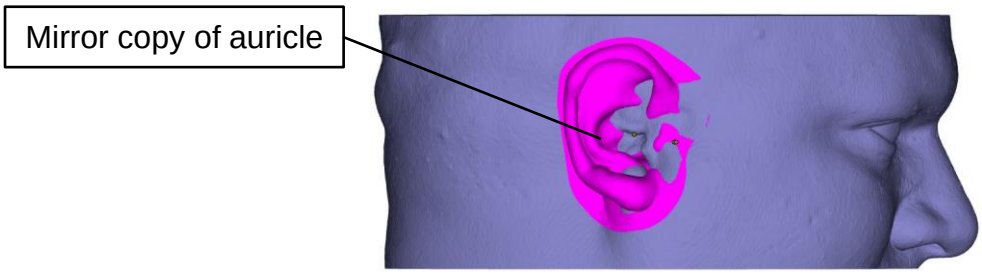


Figure 6.3 Mirror copy of health auricle.

Accurate positioning of the mirror copy of the healthy auricle is essential as this will determine the ideal implant locations relative to the prosthesis. The auditory ear canal can be used as a first reference point to position the mirror copy of the healthy auricle. Minor adjustments can then be made by using the healthy auricle to position the mirror copy. A front view with the Z-axis visible (Figure 6.4) allows easy adjustment in the vertical direction. From a top view, the mirror copy can be positioned in the anterior and posterior directions (Figure 6.5).

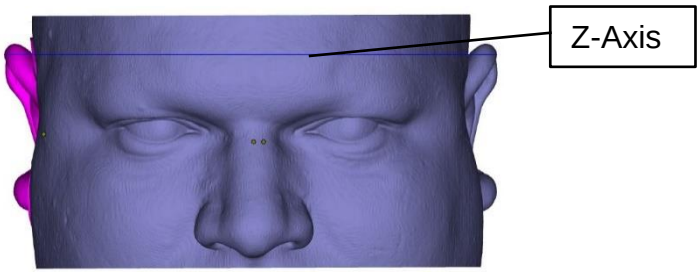


Figure 6.4 Front view of patient with Z-axis visible.

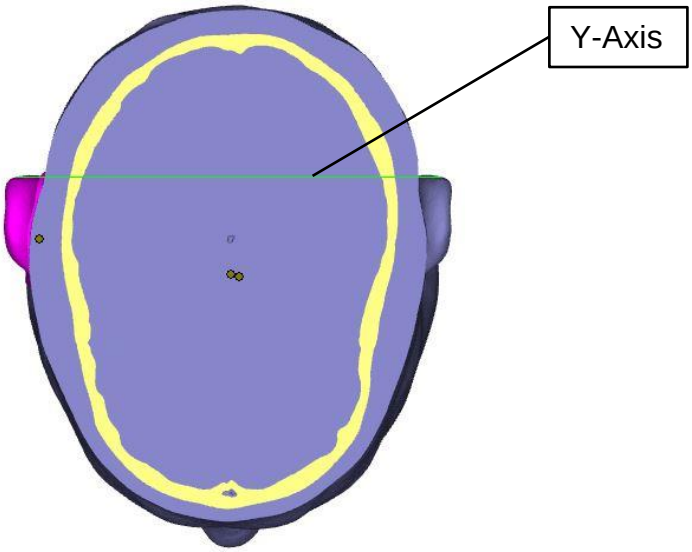


Figure 6.5 Top view of patient with Y-axis visible.

After the mirror copy has been placed in its final position, the ideal implant locations can be identified. The literature review shows that there are different views as to where implants for auricular prostheses should be placed [13][21]. Many prefer to place implants in a C-shape behind the antihelix as the prosthesis provides sufficient depth in this area to hide retentive units. Initial placements of the implants are made (Figure 6.6) followed by minor adjustments to ensure that sufficient bone is available at each implant site. To achieve this, the Z-axis is moved to each implant location where the bone thickness is measured and recorded. Where it is found that there is insufficient bone thickness available, the implant is moved (Figure 6.7 and Figure 6.8).

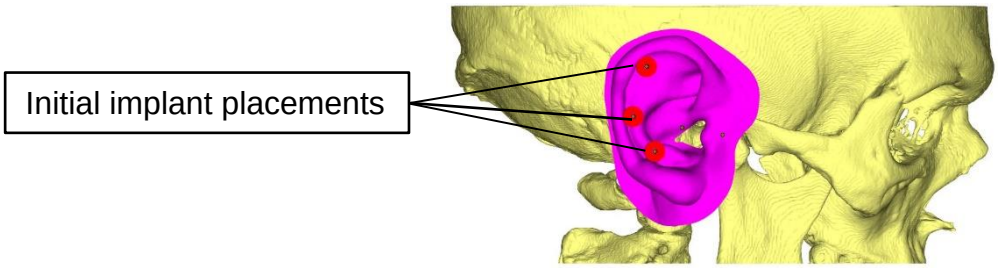


Figure 6.6 Initial placement of implants.

The thickness of the bone available at each implant position is recorded (Figure 6.8) and this information is used during surgery to determine the length of the drill to be used.

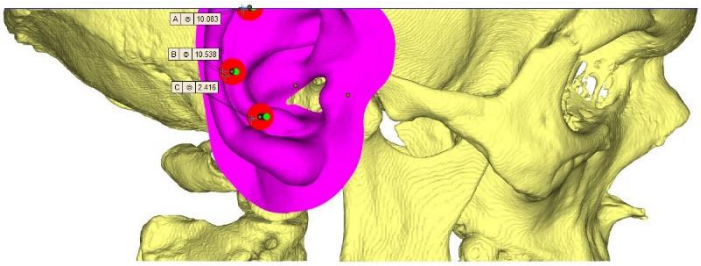


Figure 6.7 Bone thickness analysis at implant sites from right view.

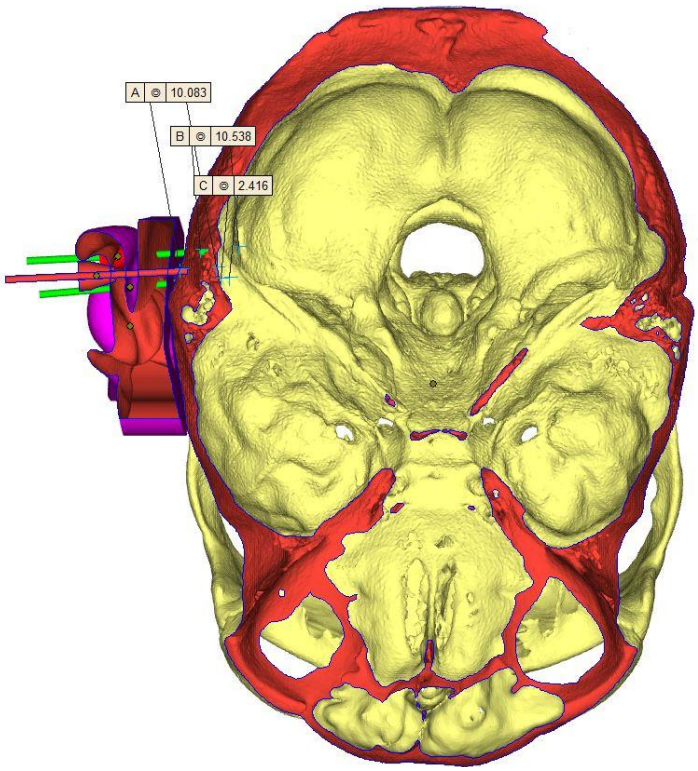


Figure 6.8 Bone thickness analysis at implant sites from top view.

Next, with the use of Magics software from Materialise, a mask is designed from the patient's facial features to use as a reference point to connect the mirror copy of the healthy auricle (Figure 6.9).

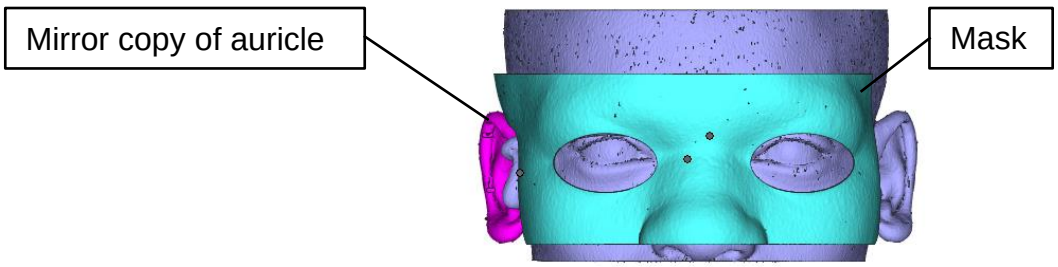


Figure 6.9 Front view of mask on patient.

The pins, which represent the drill path, are removed from the design to leave holes at each implant position. These holes will be used during surgery to mark each implant site (Figure 6.10).

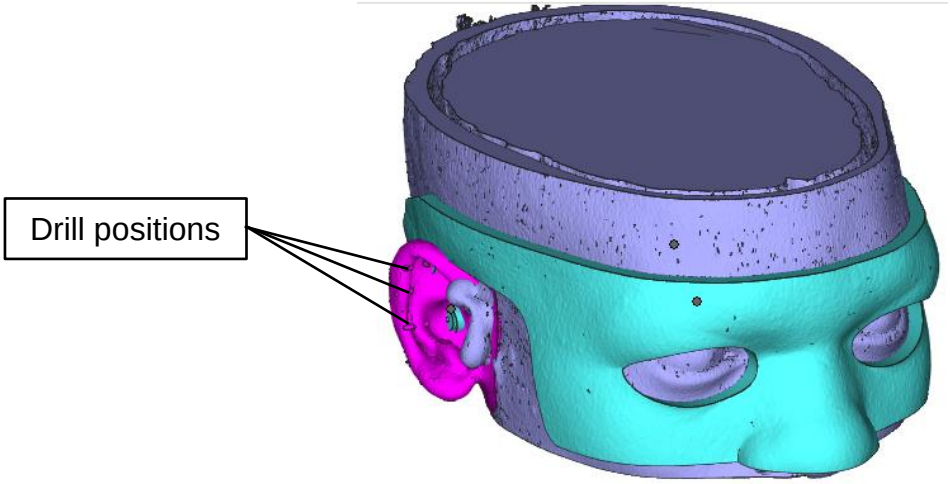


Figure 6.10 Completed unilateral drill guide.

If a genetic disorder is the reason why an auricular prosthesis is required, other factors need to be taken into account. Does the patient have functional hearing? Are the patient's facial features more or less symmetrical or asymmetrical? The combination of these factors can also play a role during the design process. The placement of implants on an asymmetrical patient with functional hearing must not try to bring symmetry to the appearance of the patient. The ear canal might not be in the correct position relative to the prosthesis, but alterations to the prosthesis can compensate for this. It is not always possible to achieve perfect symmetry with the healthy auricle.

6.1.1 Design process: Positioning guide for bilateral absent auricles

For patients with bilateral absent auricles (Figure 6.11 and Figure 6.12) and no functional hearing, the design process is simplified as the symmetry of the patient will lead the designer. If a patient has functional hearing, the design must focus on using the ear canals as reference points. After these considerations have been taken into account, the whole process follows the exact same procedure as mentioned above.

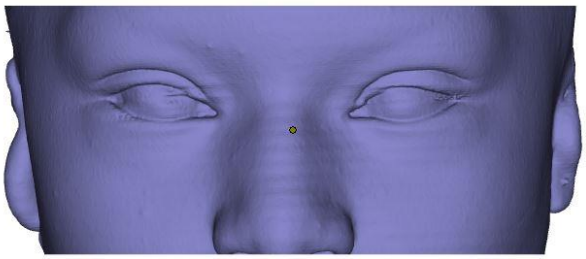


Figure 6.11 Patient with bilateral absent auricles.

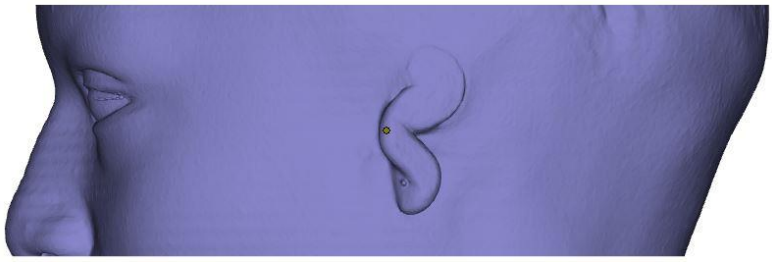


Figure 6.12 Left view of patient with bilateral absent auricles.

The only difference with bilateral prostheses is that a scan of a family member or friend's auricle (Figure 6.13) is required for use in the design.

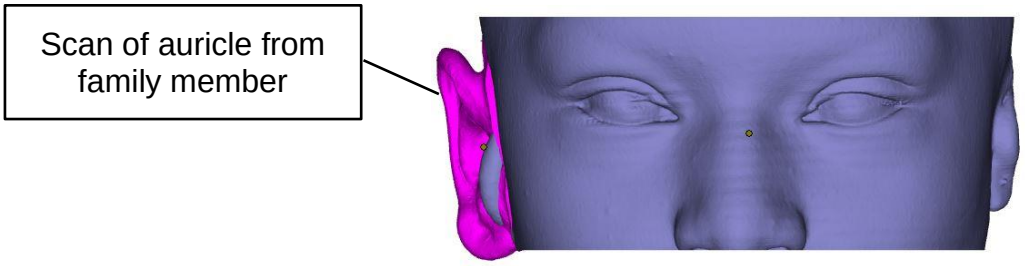


Figure 6.13 Scanned auricle in position on patient.

It is only necessary to scan one auricle since the scan can be used to make a mirror copy of whichever side is required (Figure 6.14).

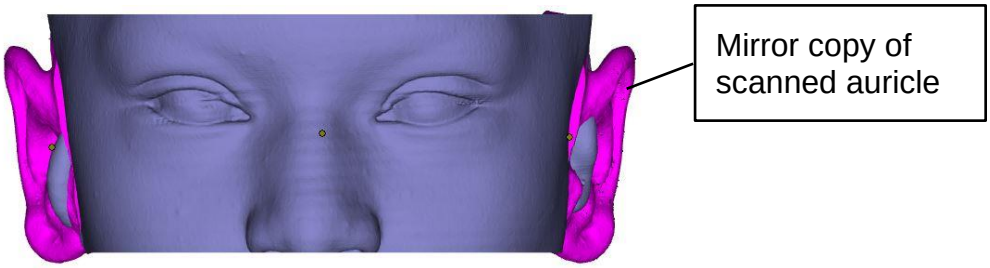


Figure 6.14 Mirror copy of auricle in position on patient.

After the auricles have been positioned in the virtual environment, the thickness of the patient's bone can be analyzed and drill paths created. Finally, a mask can be generated which connects to both auricles (Figure 6.15 and Figure 6.16).

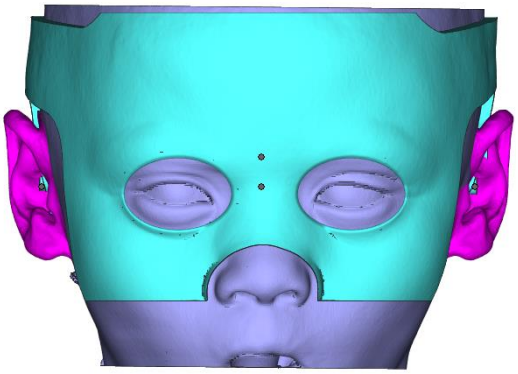


Figure 6.15 Front view of the mask on patient.

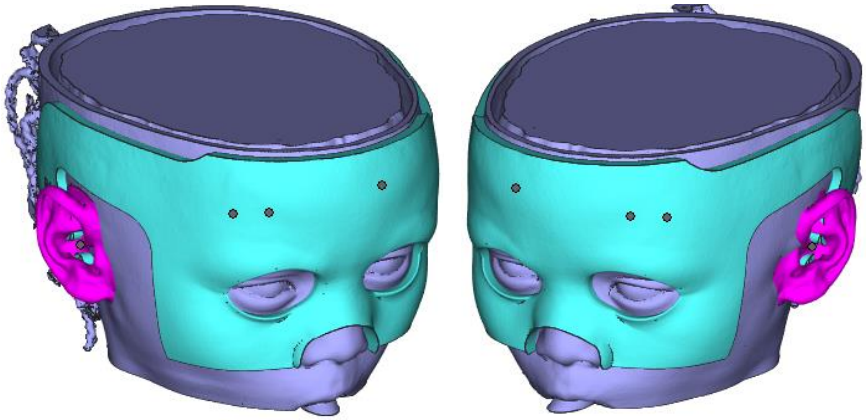


Figure 6.16 Complete bilateral drill guide

6.1.2 Manufacture of positioning guide

The positioning guide is manufactured using the SLS process as described in Section 3.1. Polyamide powder (PA2200) is used as build material, which is ideal since it is biocompatible [52] and can be sterilized through autoclaving.

6.1.3 Operation

During the surgical procedure, the mask is placed on the patient's face to determine where the incision will be made. After the incision is made, the skin is

resected using surgical instruments and the mask is placed in position. Using a round burr (Figure 6.17), the surgeon marks each implant location onto the bone through the holes provided in the positioning guide. Next, the guide is removed to reveal the markings made by the burr. A 2 mm pilot drill is used to drill a pilot hole on each marked position. For each implant size a dedicated drill with specific length and diameter is used to expand each hole to the required diameter. (Figure 6.17). Figure 6.17 represents the drill sequence for Southern Implants (Pty) Ltd. prosthetic retention and reconstruction implants. This will vary from supplier to supplier.

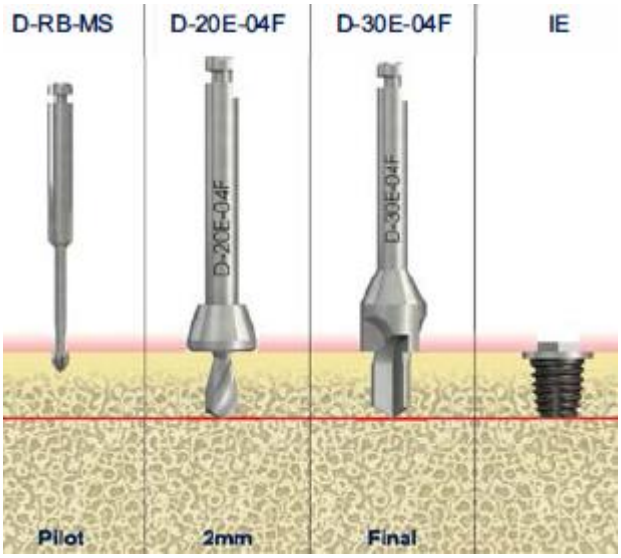


Figure 6.17 Drill sequence for implant placement [53].

After each implant location has been drilled, the implants are screwed in place and torqued to the required setting. This depends on the type of implant used and the quality of bone (Figure 6.18) [54]. Figure 6.18 shows the recommended torque settings for the Southern Implants (Pty) Ltd. product line.

Implant	Medium–soft bone	Hard bone
IE3, IE4	10–20 Ncm	30–50 Ncm
IE6	20–30 Ncm	60–70 Ncm
IET4	10–20 Ncm	40–50 Ncm

Figure 6.18 Torque settings for various implants corresponding to bone quality at implant site [54] .

Each implant is fitted with a healing abutment before the incision is closed up. This is to ensure that the implant will be accessible to fit retention units at a later stage.

6.1.4 Design Process: Orientation guide for unilateral and bilateral absent auricle(s).

The orientation guide consists of an impression tool and slider mechanism to determine the relative position of the final prosthesis to the implants. This process is the same for unilateral or bilateral absent auricles. The slider mechanism described here for an orientation guide is an improvement over the rigid mechanism described in Section 4.1.3.

To streamline the design process, the impression mould and slider mechanism are designed in Solid Works only once and then saved as standard components to be imported into the design software for each new case. Two oval components (purple) are used to create the eye openings in the mask while the impression moulds and slider mechanisms are indicated in green and orange, respectively (Figure 6.19). These components can be scaled to size for different patients and positioned as required.

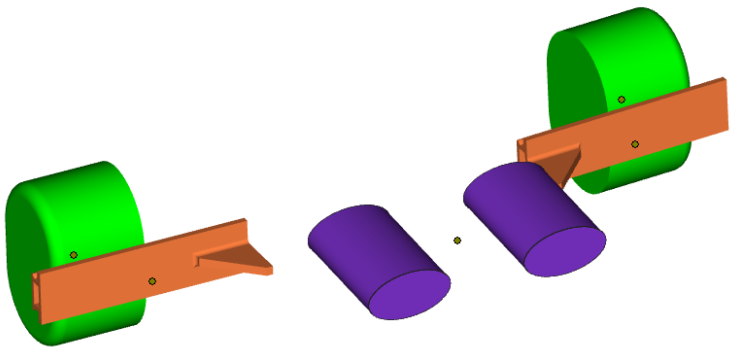


Figure 6.19 Impression tool and slider mechanism

The same mask designed for the positioning guide is used and adapted for the auricular orientation guide. The two impression moulds are placed in such a

manner that they envelop both auricles and make full contact with the patient's soft tissue surrounding the auricles. (Figure 6.20).

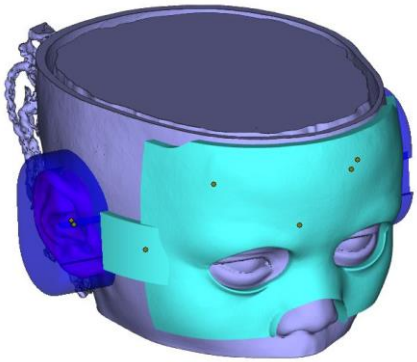


Figure 6.20 Transparent moulds placed on auricles of patient.

The two slider rails (Figure 6.21) are positioned on both sides of the impression moulds. They must be placed perpendicular (Figure 6.22) to the patient's head to ensure that the angle is correct when an impression is taken.

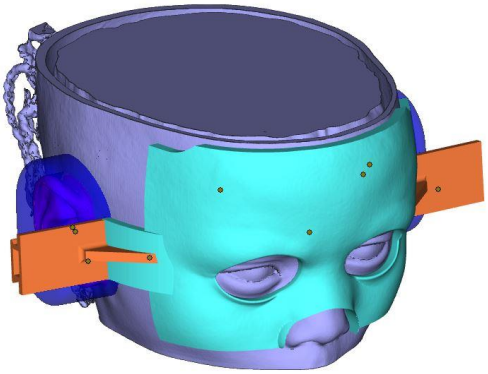


Figure 6.21 Slider rails positioned on impression moulds.

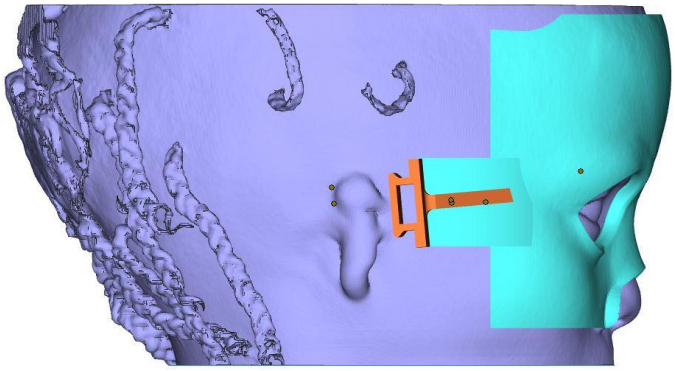


Figure 6.22 Rails placed perpendicular to patient's head.

Any remaining auricular soft tissue is often surgically removed from the implant site to simplify the surface. The same is done on the mould design in the virtual environment (Figure 6.23 and Figure 6.24).

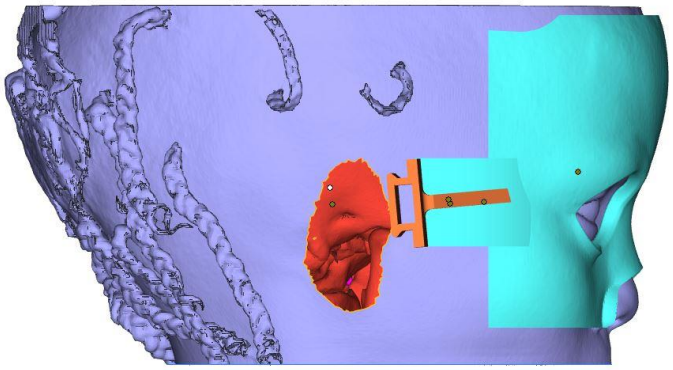


Figure 6.23 Removing defective auricle.

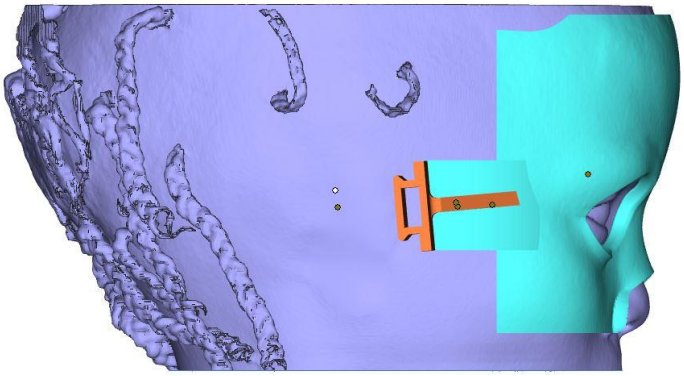


Figure 6.24 Simplified surface.

The complete orientation guide (Figure 6.25) can be used three months after implant surgery to determine the relative position of retention units to the final prosthesis.

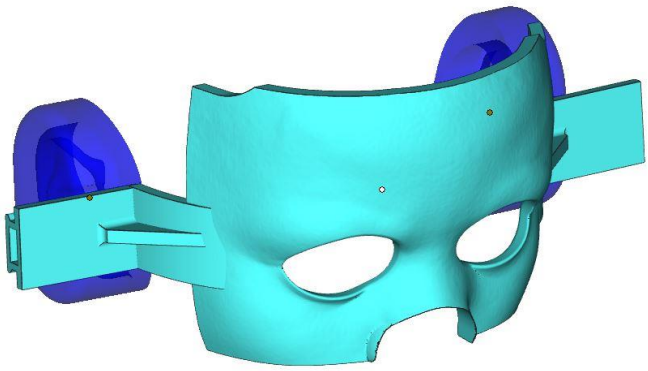
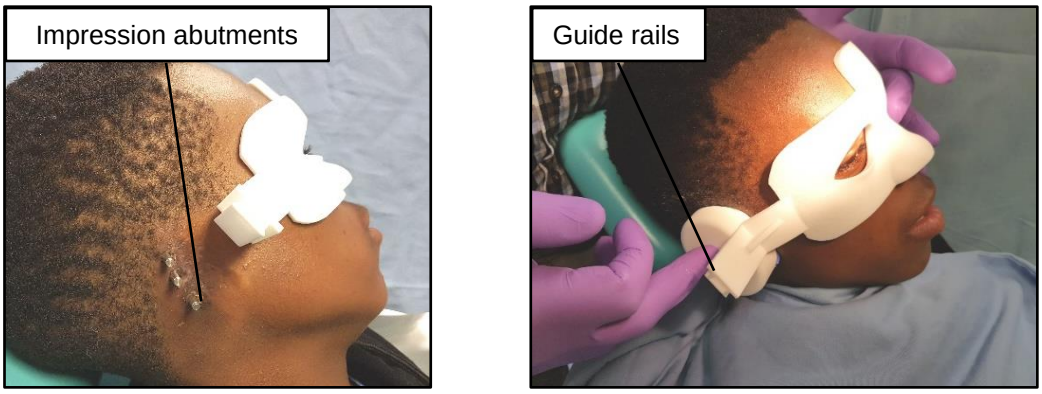


Figure 6.25 Complete impression mask

Additional time is allowed for any swelling to subside after the implants are exposed. This allows for a more accurate fit of the prosthesis.

6.2 Prosthesis manufacture using impression moulds

After the implants are exposed, impression abutments are screwed onto the implants (Figure 6.26a). The positioning mask is placed over the patient's face and the auricular moulds are slid over the guide rails (Figure 6.26b) to make sure that the impression abutments fit inside the moulds. The process for using the moulds is shown for bilateral absent auricles, but the same process is used for a unilateral absent auricle.



(a) (b)

Figure 6.26 (a) Impression abutments fitted and (b) guide rails of positioning mask.

Before taking the impressions, the area around the implants is coated with a separating medium, such as Vaseline (Figure 6.27), to prevent the impression material from sticking to the patient's hair.

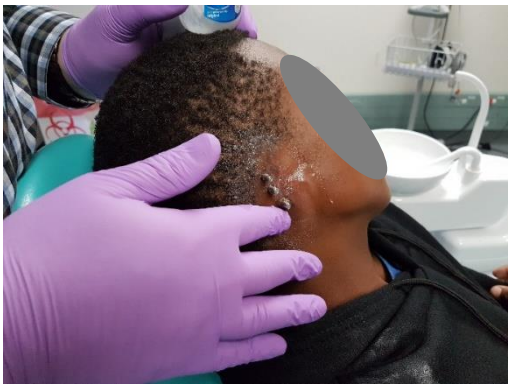


Figure 6.27 Area around implants coated with separating medium.

Next, a low viscosity two-part impression material is mixed and applied to the impression abutments to ensure that as much detail as possible is captured. High-viscosity two-part impression material is mixed, the auricular moulds are filled and slid over the guide rails on each side. While holding the positioning mask in place, the moulds are pressed onto the patient's skin and held in place for the impression material to cure (Figure 6.28).

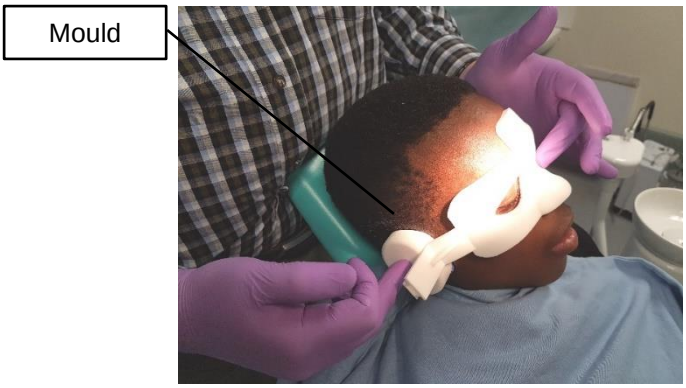


Figure 6.28 Mould with impression material held in place to cure.

After the impression material has cured, the moulds are removed from the guide rails (Figure 6.29) and the impression abutments from the implants for use in the following steps.

Figure 6.29 Moulds removed from guide rails.

The impression abutments are screwed onto another set of abutments which replicate the ones that are implanted. These combinations are then inserted back into the auricular impressions that have cured (Figure 6.30).

Figure 6.30 Impression with abutments.

Then a suitable flask size is selected which will encapsulate the entire assembly.

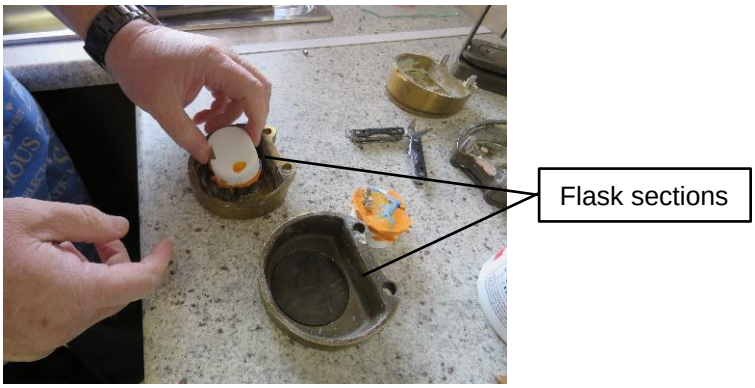


Figure 6.31 Selecting flask.

Next, plaster is mixed (Figure 6.32) and the bottom of the mould assembly is given a light coating.

Figure 6.32 Mixing gypsum.

The bottom section of each flask is filled with the plaster and the mould assemblies are lightly centred in the plaster (Figure 6.33).

Figure 6.33 Bottom section of flask with moulds secured in plaster.

After the plaster has hardened, the 3D printed moulds are removed. Next, the auricular impressions and hardened plaster is coated with Vaseline (Figure 6.34a) and the top section of the flask is placed on the bottom section (Figure 6.34b). The Vaseline acts as a release agent.

(a) (b)

Figure 6.34 (a) Bottom flask prepped with Vaseline. (b) Top section of flask placed on bottom flask.

Next, alginate is mixed and poured into the flask assembly and left to cure (Figure 6.35).

Figure 6.35 Alginate mixed and poured into flasks.

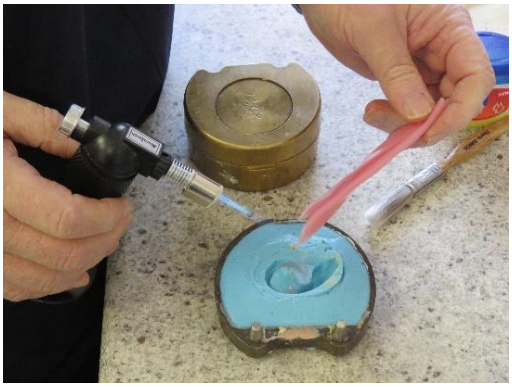
Since alginate is an elastic impression material, it is easy to remove the auricular impressions. The impression abutments are also unscrewed from the set of abutments which replicate the ones that are implanted. This leaves a bottom flask which represents the surface of the patient's skin where the implants are positioned and the top flask with a negative cavity of the auricula (Figure 6.36).

Figure 6.36 Bottom flask with implant positions and top flask with cavity.

Next, the bottom flasks are coated with Vaseline.

Figure 6.37 Bottom flask coated with Vaseline.

Dental wax is melted into the cavity of the alginate impression (Figure 6.38a). It is important that all undercuts and crevasses are filled with wax before the two flask halves are clamped together (Figure 6.38b).



(a)

(b)

Figure 6.38 (a) Top flask filled with molten wax. (b) Two flask sections clamped together.

After the wax has hardened, the flask is opened to reveal the two wax castings that will become the patterns for the final casting (Figure 6.39).

Figure 6.39 Bottom flask sections with wax patterns.

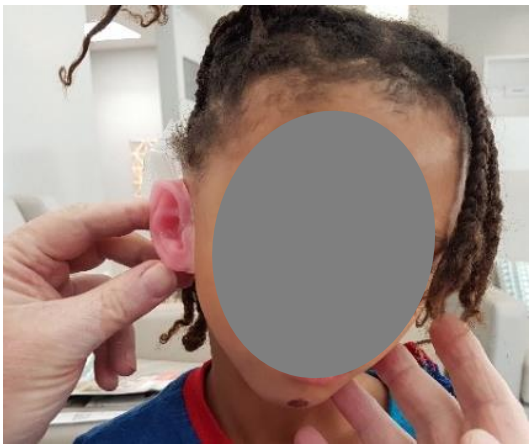
Since the process results in wax mouldings with rough edges that require smoothing, this is done using a gas flame and small metal instruments which are heated in the flame and used to sculpt the finer details into the wax pattern (Figure 6.40).

Figure 6.40 Smoothing the wax pattern with hot instrument.

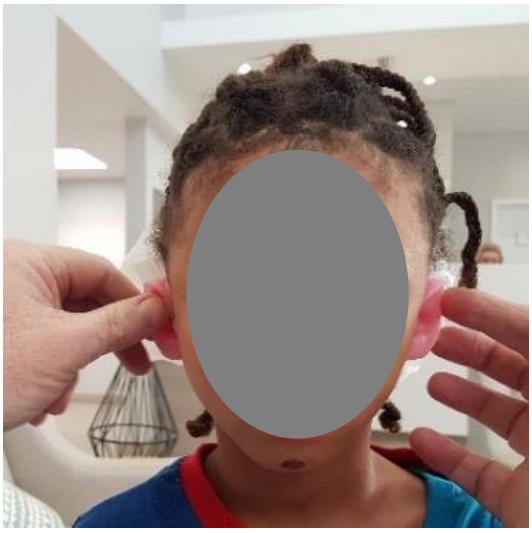
The image below shows the smoothed wax pattern of the right auricular (Figure 6.41).

Figure 6.41 Smoothed wax pattern.

The two wax patterns are then carefully removed from the bottom flask to do an initial fitment on the patient to ensure each implant location correlates with the positions on the wax patterns (Figure 6.42a). Symmetry is also verified (Figure 6.42b).



(a)



(b)

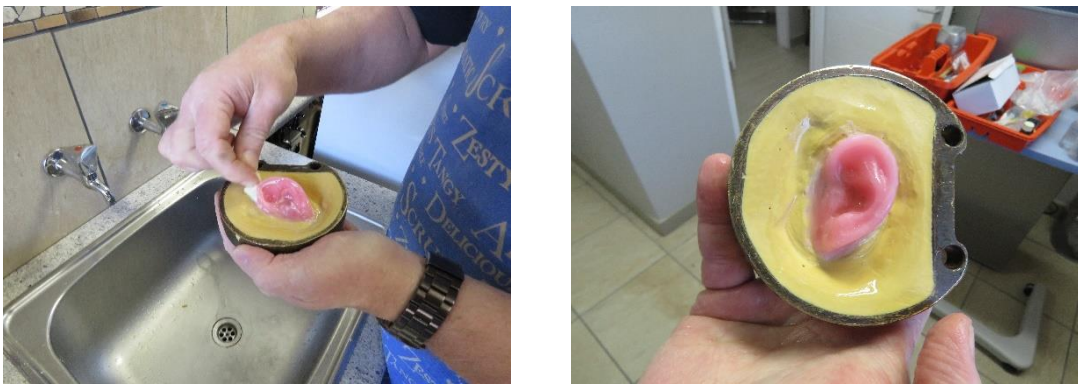
Figure 6.42 (a) Initial fitment to verify implant locations on prosthesis.(b) Verification of prosthesis height.

The periphery around the wax mock up is marked on the plaster impression in the bottom flask and the plaster on this periphery is carved away to ensure that the final prosthesis fits tightly against the patient's skin (Figure 6.43a). Where necessary, plaster is added with a fine brush (Figure 6.43b) and the edges smoothed and left to harden.

(a) (b)

Figure 6.43 (a) Periphery of wax pattern marked. (b) Adding plaster with fine brush.

Next, the wax patterns are placed back on the bottom flask and the periphery of each pattern is smoothed. Using soap and cotton, the wax pattern is polished to a light shine (Figure 6.44a). The bottom flask is coated with Vaseline for the next casting stage (Figure 6.44b).



(a) (b)

Figure 6.44 (a) Periphery of wax pattern is smoothed and polished. (b) Flask coated with Vaseline for next casting stage.

The top section of each flask is placed on the bottom section and plaster is mixed and carefully added around and behind the wax pattern (Figure 6.45a). The assembly is vibrated to release any air bubbles that might be trapped. The cavity is filled with gypsum before the top section lid is secured. The flasks are then left for a time to allow the gypsum to cure (Figure 6.45b).

(a) (b)

Figure 6.45 (a) Gypsum added around wax pattern. (b) Flask closed and left to cure.

After the gypsum has hardened, the flasks are opened (Figure 6.46a) and the wax patterns removed (Figure 6.46b). Any residual wax is melted out with boiling water (Figure 6.46c).

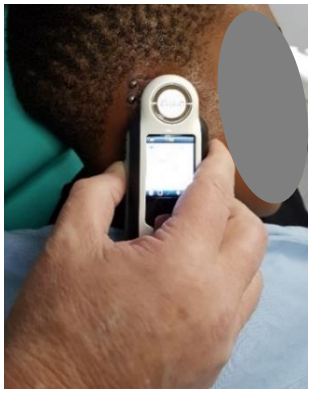
(a)

(b)

(c)

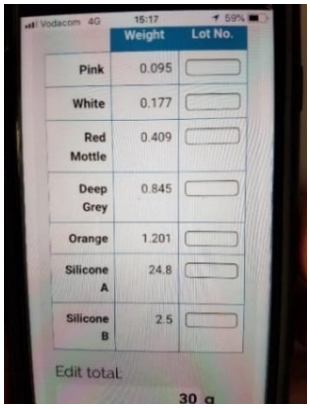
Figure 6.46 (a) Flasks with wax patterns. (b) Flasks with wax patterns removed. (c) Residual wax melted out with boiling water.

Next, colour matching is done to ensure the prosthesis matches the patient's skin tone. A spectrometer can be used for this purpose, such as the e-Skin system from Spectromatch. The e-Skin unit is pressed against the patient's skin close to where the prosthesis is to be fitted (Figure 6.47a) and the unit displays a matching colourant recipe from its database on the screen (Figure 6.47b). The colourant recipe corresponds to colour pigments which are available from Spectromatch (Figure 6.47c).



(a)

(b)



(c)

Figure 6.47 (a) Spectrometer reading being taken on patient. (b) Output code. (c) Matching colourant recipe.

The different colour pigments are weighed on a small jewellery scale to exact proportions and mixed with a two-part silicone. A dispensing gun is used to dispense the pigments (Figure 6.48).

Figure 6.48 Dispensing of pigments.

The pigments are mixed with the silicone and thinly spread out onto a clean glass pane (Figure 6.49a) to remove any air bubbles. The silicone is then brushed into the cavity of the plaster auricle mould, thus ensuring all the crevasses are filled (Figure 6.49b).

(a)

(b)

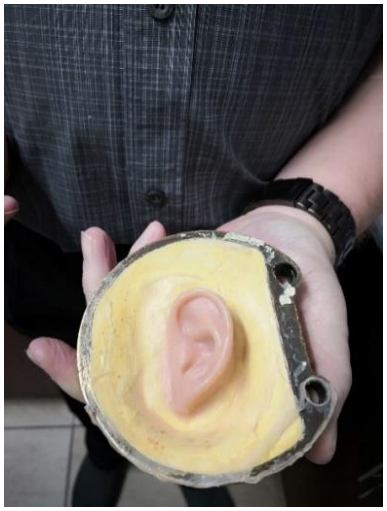
Figure 6.49 (a) Spreading silicone to remove air bubbles. (b) Filling all mould cavities with silicone.

After the flasks are filled with silicone, they are clamped tightly (Figure 6.50) and put in an oven at 80–100 °C for one hour and then left to cool inside the oven.

Figure 6.50 Flasks clamped tightly on top of each other.

Once the flasks have cooled down completely, they are opened (Figure 6.51a), the silicone prosthesis removed (Figure 6.51b) and trimmed.

(a)



(b)

Figure 6.51 (a) Flask opened (b) to reveal final silicone prosthesis.

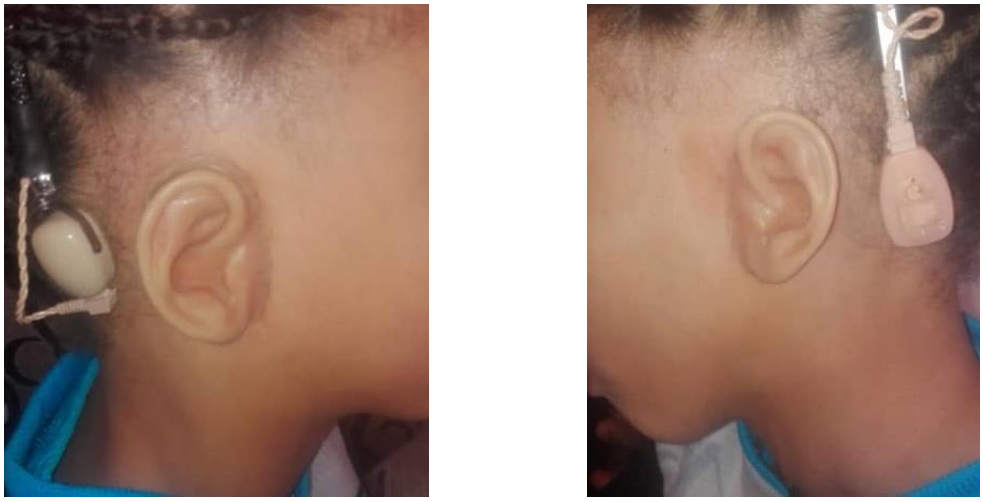
The final colour matching is done with the silicone prosthesis on the patient. Dye pigments are mixed (Figure 6.52a) and applied with cotton in a dabbing action on the prosthesis (Figure 6.52b).

(a)

(b)

Figure 6.52 (a) Mixing the dye pigments. (b) Staining the prosthesis to match patient's skin tone.

The final prosthesis is fitted onto the patient after all swelling has subsided (Figure 6.53a and Figure 6.53b).



(a) (b)

Figure 6.53 Final prosthesis of (a) right and (b) left auricle fitted on patient.

Chapter 7: Conclusion

The aim of this study was to develop patient-specific devices using AM technologies and associated software to position cranial implants for retaining auricular prostheses and orientate the prostheses correctly relative to the positions of the implants.

To achieve this aim, three primary and two secondary objectives were set. The first primary objective was to determine what other researchers have done in the field of auricular prosthetics through a literature review. The second and third primary objectives focussed on the development of patient-specific guides for positioning the craniofacial implants and orientating the prostheses in relation to the implants. The two secondary objectives support the primary objectives by proposing an investigation into techniques to reduce the time taken to produce the positioning/orientation guides. These objectives were to develop standard CAD components for use in the designs and to develop a standard workflow in the design process.

In order to meet Objective 1, a comprehensive literature review was undertaken and is presented in Chapter 2. The review focuses on the different retention methods that are used to retain auricular prosthesis. Furthermore, a detailed analysis of the implant placement process was performed to better determine the design parameters for the development of the positioning guides. Lastly, a broad review of the different methods and techniques which are employed to position craniofacial implants are presented. From this chapter, it was concluded that various improvements could be made to the positioning of auricular prosthesis using advanced technologies, such as AM and specialized software, that are available for this purpose.

Chapter 3 describes the different AM technologies and more specifically the SLS process which was mainly used in this study. AM has its own design rules which need to be considered when designing any device. The properties of the material used to produce the devices must be carefully considered. PA2200, the nylon

material used to produce the surgical guides, offers the benefits of being biocompatible and can be autoclaved.

Objectives 2 and 3 are addressed in Chapter 4 where the development of the preliminary three positioning guides produced at the CRPM are presented. This is followed by the further development of the positioning guides and the additional orientation guides in Chapter 5. Three case studies were performed to evaluate the effectiveness and accuracy of the positioning devices. A CT scan of each patient after implant placement was compared to the designed positions where it was clear that perfect placement could not be achieved. The surgeon who used the devices in the three case studies however agreed that although implant placement was not perfect, is was still good and similar results would be difficult to achieve without the use of the devices. A positioning device is not essential if the patient's auditory canal is present, since this can be used to guide placement of the implants. The real benefit of a positioning guide becomes clearer when there is no auditory canal or a congenital disorder is the cause of absent auricles. This leaves the surgeon with no reference point from which to start. Furthermore, the devices greatly reduce the risk of drilling blindly to place the implants. A cost and time comparison shows that the implants can be placed much faster using the positioning guides which also reduces cost by shortening operating theatre time. This translates to a cost reduction of more than 40% for both single and double auricular prosthesis procedures.

The second phase orientation guides were found to play an integral role in the positioning of the final prosthesis relative to the implants. This is particularly the case where the first phase placement of the implants was not one hundred percent accurate. Here, the orientation device can somewhat compensate to still achieve an aesthetically pleasing result. The negative moulds of the auricles provided with the guides also help to significantly reduce the time it takes to produce the prostheses.

Chapter 6 presents a workflow that was developed for using the auricular positioning/orientation guides in this study. This shows the entire process from designing the guides to producing the final prostheses. Standard components

were developed which were used in the design of the guides to significantly speed up the process. The two secondary objectives set for the study were thus met.

Considering the above, all the objectives for developing patient-specific devices to aid in the positioning of auricular prostheses were met. Therefore it can be concluded that the aim of the study was achieved.

7.1 Future Work

The drilling of holes in the temporal bone to place the implants is risky, since the holes can easily be drilled too deep; passing through the bone into the dura mater will result in uncontrolled bleeding, which may put the patient's life at risk. The positioning guides developed in this study were only used to mark the positions of the implants on the temporal bone. However, it should be possible to modify the guides by designing metal sleeves to fit into the guides so that only the the correct diameter drill bit can be inserted. This will improve the function of the guides so they are not only used as positioning guides but actual drill guides too. The guides can be designed to stop the drill bit at a pre-defined depth to prevent drilling too deep and causing damage. The thickness of the bone at each implant position can be determined from the patient's CT scan.

The SLS process and nylon material used to produce the positioning/ orientation guides in the study are expensive. An alternative may be to use Fused Deposition Modelling (FDM) and materials suitable for processing with the technology. Mechanical testing must be performed on the guides as well as clinical testing on the materials to ensure that they can be used for the intended application.

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