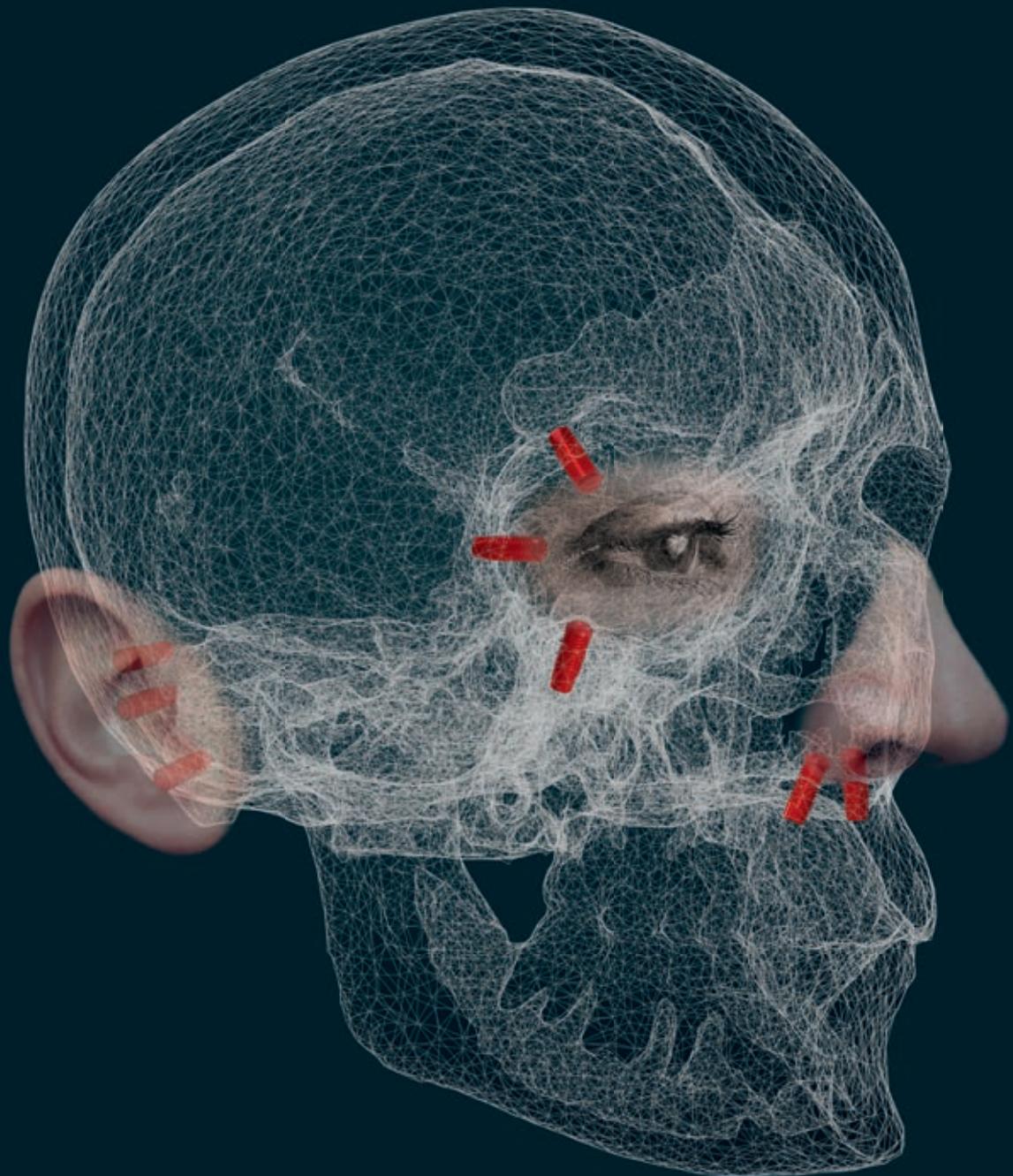


# Craniomaxillofacial implant surgery



Jeroen P.J. Dings



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**Jeroen P.J. Dings**

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# **Craniomaxillofacial Implant Surgery**

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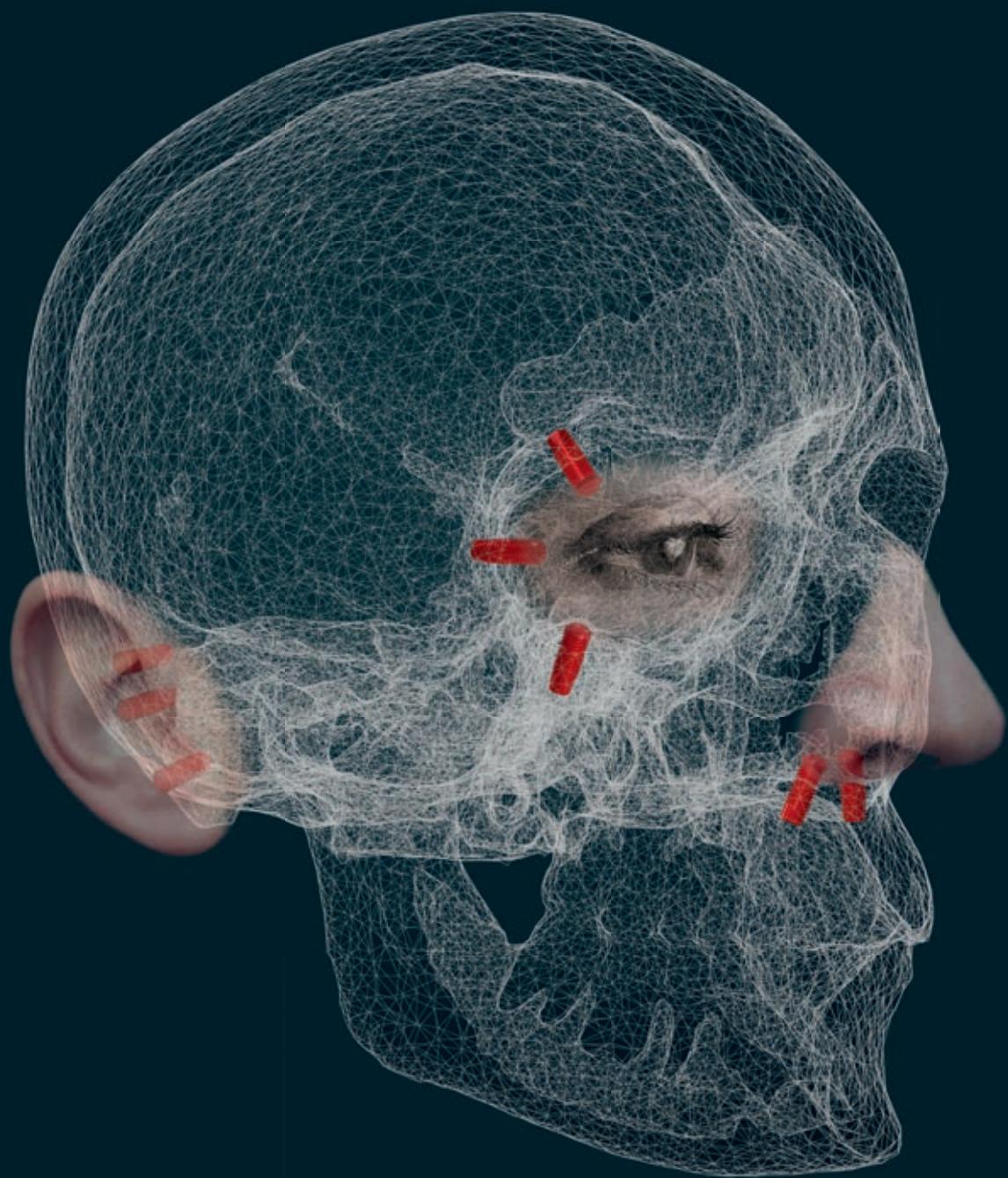
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*Voor mijn ouders*

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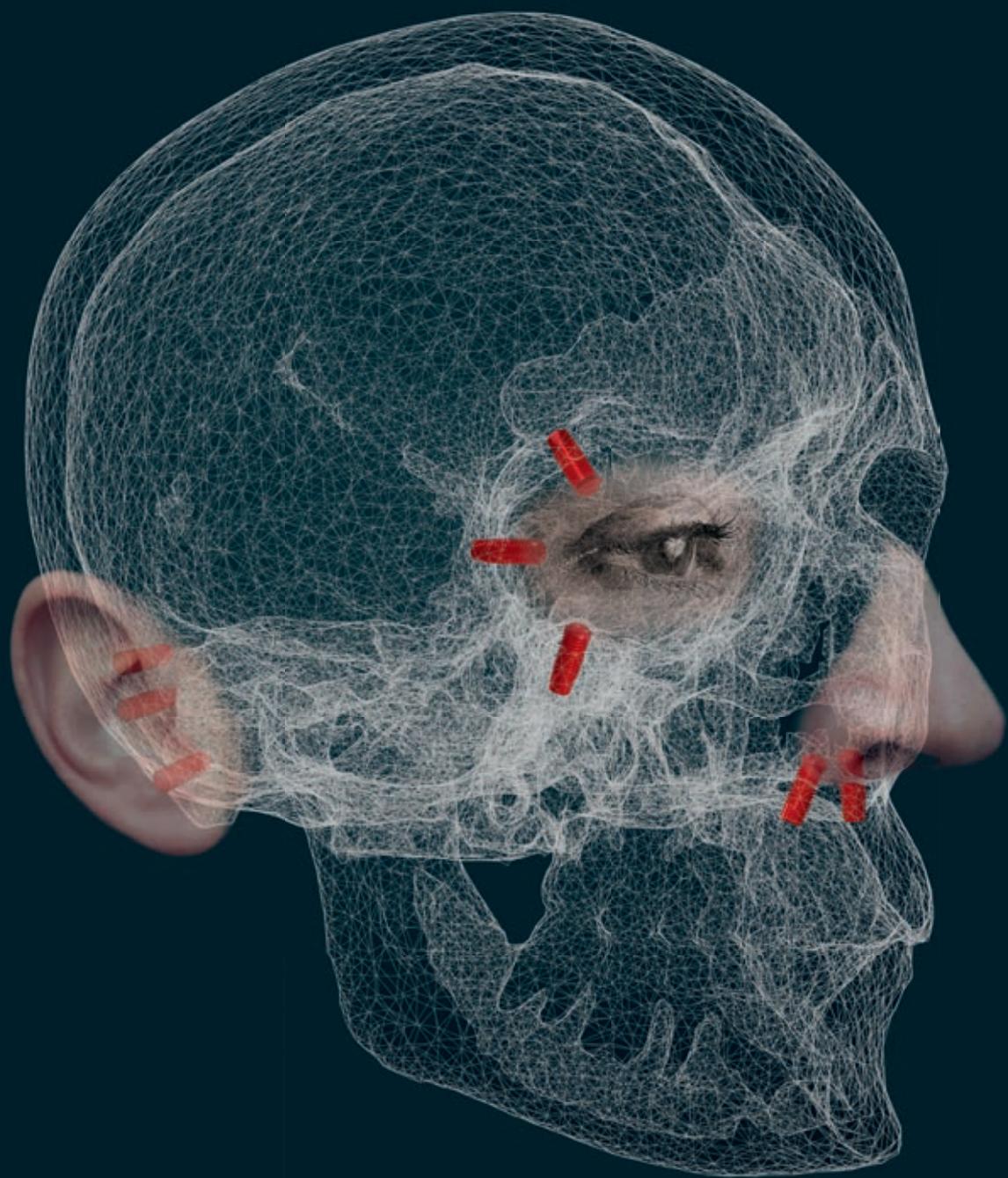
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# Part I

## Introduction



# Chapter 1

General introduction and  
outline of this thesis



## 1. GENERAL INTRODUCTION

Acquired- or congenital defects in the craniomaxillofacial (CMF) region result in multiple functional-, esthetic- and psycho-social difficulties and, therefore, are a major challenge in reconstructive surgery<sup>1,2</sup>.

As most CMF defects are unique in size and shape, the challenge is to find the optimal treatment for each individual patient. Addressing these defects can be accomplished by surgical reconstruction or prosthetic rehabilitation, or a combination of both methods<sup>3</sup>. As such, CMF prostheses, or epiphyses, are artificial substitutes for facial defects<sup>4</sup>.

It was not until the discovery of osseointegration by Brånemark that osseointegrated implants became a viable treatment option in CMF reconstruction, offering optimal retention and stability of CMF prostheses<sup>5,6</sup>. On the same basis, Tjellström *et al.* pioneered the use of percutaneous titanium fixtures for anchorage of a hearing aid in 1979<sup>7</sup>.

Ultimately, the choice of surgical-, prosthetic- or combined treatment depends upon the characteristics of the defect (size, location and etiology), motivation and condition of the patient, and interdisciplinary cooperation<sup>8,9</sup>.

## 2. RECONSTRUCTION OF CRANIMAXILLOFACIAL DEFECTS

### 2.1 Surgical reconstruction

Surgically reconstructive approaches using autogenous tissue can be used as a permanent and effective method<sup>10,11</sup>. Literature abundantly presents modern techniques in plastic facial surgery that provide a wide array of reconstructive possibilities<sup>12-14</sup>. However, complex nasal-, auricular- and orbital defects pose esthetic- and functional demands that are frequently beyond the capacity of local reconstructive efforts necessitating multiple surgical steps that increase the total treatment time and can lead to unpredictable aesthetic outcomes<sup>4,15,16</sup>. Surgical reconstruction is challenged by increased size of the defect, insufficient residual hard- or soft tissue, constraints related to radiation therapy, the need for direct visual inspection of the defect for tumor recurrence, esthetic importance, and the medical- or physical condition of the patient<sup>10,17,18</sup>.

## 2.2 Craniomaxillofacial (CMF) prosthetic rehabilitation

Craniomaxillofacial (CMF) prosthetic rehabilitation postures a valid alternative when surgical reconstruction is not feasible or desirable<sup>19,20</sup>.

Traditionally, retention of maxillofacial prostheses involves the use of medical-grade skin adhesives, anatomic undercuts, or connection to spectacles or intraoral prostheses<sup>21</sup>. The use of adhesives, however, has several disadvantages, including instability, discoloration of the prosthesis, dermatologic reactions, and poor performance during activity or perspiration<sup>22-24</sup>.

## 3. CRANIMAXILLOFACIAL (CMF) IMPLANTOLOGY

Since the success of intraoral endosseous implants, the introduction of the osseointegration concept in the late 1970s/early 1980s, has drastically improved prosthetic rehabilitation of CMF defects with regard to improved retention, aesthetic outcome, and ease of placement<sup>21,25</sup>. Endosseous implants are nowadays established as viable, secure treatments in prosthetic rehabilitation of CMF defects, allowing tumor cavities to be accessed for inspection of possible recurrences and improving patient acceptance, level of function and quality of life<sup>26,27</sup>. Disadvantages include the inapplicability for replacement of mobile parts of the face, necessity of prosthetic- and implant maintenance and the risk of implant dislodgment when loaded unfavorably<sup>4,21,28</sup>. CMF implants can be categorized as systems with solitary implants, such as the Bränemark System (Nobel Biocare AB, Gothenburg, Sweden), or the ITI System (Institut Straumann AG, Waldenburg, Switzerland.) and sub-periostal systems that are fixed with several bone screws, like the Epitec® system (Leibinger Stryker, Freiburg, Germany.) and the Epiplating Plate System® (Medicon, Tuttlingen, Germany.). The latter can be combined with a hearing device abutment<sup>4,24</sup>.

### 3.1 Virtual planning and surgical templates

Successful prosthetic driven rehabilitation depends upon accurate diagnosis, preoperative planning, and subsequent placement of endosseous implants<sup>29,30</sup>.

The development of multi-slice computed tomography (MSCT), multi-detector computed tomography (MDCT) and cone-beam computed tomography (CBCT) allows all three dimensional (3D-) visualization and objective measurement of bony dimensions prior to implant placement<sup>31</sup>.

Virtual preoperative planning is essential for evaluation of the available bone quantity and density to improve reliable treatment planning of CMF implants<sup>32,33</sup>. Besides evaluating the available bone dimensions and characteristics, planning is also critical in determining the spatial proximity of anatomical locations and avoiding vital structures<sup>34,35</sup>. Although osseointegration of CMF implants is predictable, its success rate is mainly determined by sufficient primary implant stability. It is crucial in virtual preoperative planning to respect a zone of at least 2 mm of peri-implant bone to ensure primary implant stability and a predictable restorative outcome<sup>36-38</sup>.

Translation of the virtual treatment plan to the surgery is essential for predictable clinical- and prosthetic outcomes<sup>39</sup>. Virtual planning software enables 3D-computer-aided designing (CAD) and also computer-aided manufacturing (CAM) of surgical templates<sup>31</sup>. The use of surgical templates facilitates correct intra-operative positioning of extra-oral implants in predetermined areas with sufficient bone volume, thereby shortening operation time<sup>39-41</sup>. The accuracy of surgical templates, that compare deviations between virtually planned and actually placed implants, has been widely documented in different study designs that show variable results and unfavorable outcomes in terms of magnitude of error<sup>42,43</sup>. However, few studies have reported on the accuracy of CMF implant placement in a conventional manner versus installation with the aid of digitally designed surgical templates<sup>29,40,41</sup>. Advances in manufacturing technology and material science has led to various clinical applications of surgical templates<sup>1</sup>. Surgical guides can be skeletal-, dental- or mucosal supported<sup>42</sup>. The use of soft tissue supported surgical templates offers the opportunity for flapless implant placement, thereby maintaining an intact periosteum and blood supply<sup>38,44</sup>. This is beneficial, especially with regard to maxillofacial defects of oncologic origin, which often have compromised healing ability due to scar tissue and irradiation<sup>2</sup>. Furthermore, minimally invasive surgery reduces the morbidity and surgery duration, while preserving the soft tissue architecture and hard tissue volume<sup>45-47</sup>. On the other hand, minimally invasive surgery also has disadvantages, such as limited surgical overview due to a lack of visibility of anatomical landmarks and vital structures. Furthermore, absence of tactile control may lead to an increased risk for mispositioning and malalignment of implants<sup>48,49</sup>.

The accuracy of guide systems is of significant concern, as computer-planned implant surgery involves a sequence of diagnostic- and therapeutic steps. The overall transfer accuracy of planned implant positions reflects the sum of errors from preoperative scan, digital processing of information through virtual planning software, and the implant installation procedure itself<sup>42,46,50,51</sup>. Suboptimal placement of implants may induce damage to vital anatomical structures (e.g. nerves, adjacent roots of teeth or even, intracranial tissues)<sup>52</sup>. The limits of the guided surgery systems are set by the maximum deviations between planning and postoperative position of CMF implants<sup>53</sup>. However, 3D-printing technologies continue to improve in accuracy, material selection and lower costs.

### **3.2 Survival rate and timing of placement of implants**

As reported in literature, failure rates for CMF implants reveal an overall risk of 5.5%<sup>2</sup>. However, earlier studies report a wide variety of survival rates for CMF implants. This wide variation can be explained by differences in treatment techniques, used implant types, duration of follow-up, patient factors and criteria for implant success<sup>2,6</sup>. Implant survival is reported to be site-specific, and among others, related to associated stress distribution, irradiation dose and fractionation<sup>5,54,55</sup>. However, no clear relationship between radiation treatment and implant survival is established in literature<sup>2,6,56</sup>. Furthermore, many aspects in relation to oncology therapy remain controversial, such as favorable time of placement and the role of hyperbaric oxygen in case radiation therapy is applied<sup>2</sup>.

Some studies suggest that pre- and postoperative HBO therapy may improve the eventual success rate of endosseous implants<sup>57,58</sup>. The studies indicate that there is some benefit in revitalizing the bone through improvement of the tissue oxygen level, thereby increasing collagen synthesis, neovascularization and activation of osteoblasts and osteoclasts in irradiated tissue<sup>59</sup>. However, results from recent meta-analyses comparing implant survival of dental implants placed in irradiated fields 'with and without' the use of HBO showed no statistically significant difference<sup>2,60</sup>. Careful indication and surgery are required for patients who were exposed to radiotherapy.

Another controversial issue in literature is the influence of timing of placement of CMF implants. A systematic review on the effects of pre- versus post-implantation irradiation therapy on dental implant failure could not establish a significant difference in survival rate<sup>61,62</sup>.

### 3.3 Retention methods and prosthetic materials

Successful prosthetic rehabilitation depends largely on the quality of retention and stability of the prosthesis. There are four ways to retain a prosthesis: anatomically, mechanically, surgically, or by adhesion<sup>3</sup>. The choice of retentive mechanisms depends on the number of implants, flexibility of the prosthesis, and also local anatomic aspects. Bar-clips, for example, are the most indicated system for retention of auricular prostheses. Magnets are mostly used for orbital- and nasal defects, because they can compensate for non-parallelism of the installed implants<sup>3,25</sup>. Moreover, magnets induce relatively low lateral forces and minimize the amount of stress delivered to the implants<sup>19</sup>. Current magnetic systems increase ease of use, are simple to clean, and have adequate retention<sup>63</sup>.

Generally, a prosthetic material must possess and maintain physical- and mechanical properties comparable to the tissue it replaces. Ideally, material properties include durability, biocompatibility, flexibility, reasonable tensile strength, softness, ease of cleaning, and lightness<sup>64</sup>. A variety of materials have been used including metal, glass, rubber, porcelain, plastic, or silicone. Established materials for CMF prostheses comprise methacrylate's and silicone elastomer products<sup>24</sup>. Although methacrylates are more durable, they are relatively hard in comparison to silicones. Today, silicone rubbers are the most widely used materials in CMF prosthetics with regard to ease of manipulation, their absorbance of pigmentation and ability to match the color and texture of surrounding structures, low viscosity, capacity to adapt to body temperature, high tensile strength, high elongation, and dimensional stability<sup>65,66</sup>. However, drawbacks are their restricted mechanical- and physical properties and tendency for discoloration requiring replacement as early as six months<sup>3</sup>. To date, none of the commercially available materials satisfy all the requirements of the ideal CMF prosthetic material. Further research into the development of new or alternative CMF prosthetic materials is essential, as clinical practice still faces problems with the serviceability of CMF prostheses<sup>3</sup>.

### 3.4 Quality of life and patient satisfaction

The face has a unique role in social- and emotional expression and communication<sup>67</sup>. Therefore, reconstruction of CMF defects may have important psychosocial implications in affected patients, because social interactions and emotional expression depend mainly upon the structural and functional integrity of the head- and neck region<sup>68</sup>. A successful prosthetic rehabilitation is one, in which patients do not experience the

prosthesis, as an extraneous object and that improves function and esthetics from both a psychological- and social point of view<sup>69</sup>.

Patient satisfaction and the assessment of quality of life (QOL) is becoming increasingly important in the quality of care. Treatment success and the level of reintegration is mainly determined by a subjective analysis of the patient<sup>70</sup>. In addition, satisfaction is directly related to appropriate retention delivered by CMF implants<sup>6</sup>. A limited number of studies have primarily focused on quality of care measuring satisfaction after CMF rehabilitation and also on the impact of treatment on the patient's subjective analysis and functional outcomes<sup>22,27,71</sup>. Generally, available literature indicates a good overall acceptance of CMF prostheses, showing high satisfaction with anatomic form, color, and wearing comfort<sup>72</sup>.

## 4. GENERAL AIMS OF THE THESIS

The overall aim of the research described in this thesis was to assess the clinical outcome of CMF implant surgery in perspective of new planning techniques and to compare these to autologous reconstructions, meaning surgical restoration using patient own tissues.

Part I: This part focuses on the evaluation of CMF implant placement using computer planning and skin-supported surgical templates.

### Aims

- To assess the reliability and accuracy of linear measurements on three-dimensional (3D-) cross-sectional images, both acquired with cone-beam computed tomography (CBCT) and multi-detector row CT (MDCT) with regard to guided CMF implant surgery (**Chapter 2**);
- To determine the accuracy of guided implant placement in the orbital-, nasal- and auricular region using computer-aided designed stereolithographic skin-supported surgical templates 'with and without' bone fixation pins (**Chapter 3**).

Part II: The issue of survival rate of CMF implants being placed during, or after, ablation of the tumor was elucidated in **Chapter 4**.

### Aims

- To register the survival rate of CMF implants being placed during, or after, ablation of the tumor.

Part III: The clinical outcome of CMF implant surgery was determined by evaluating patient satisfaction after prosthetic rehabilitation and by comparing this with patient satisfaction after autologous reconstructive treatments of comparable CMF defects.

### Aims

- To describe the long-term quality of life of patients, who have been treated with CMF prostheses with different retentive systems over a 14-year period unit (**Chapter 5**);
- To measure the subjective perception of medical professionals, laypersons and patients with auricular- or nasal defects with respect to esthetic outcome of autologous versus prosthetic reconstruction of auricular and nasal defects (**Chapter 6**).

## OUTLINE OF THE THESIS

Reconstruction of acquired or congenital defects in the craniomaxillofacial (CMF) region is a complex procedure that leads to miscellaneous results.

The main objectives of this thesis were to gain insight into the common errors in virtual planning and clinical placement of CMF implants, the impact of a CMF reconstruction on the quality of life and patient satisfaction, as well as professional and lay judgment on facial esthetics following reconstruction of CMF defects.

As the position of CMF implants is crucial to obtain the best clinical results and survival rate, the reliability and accuracy of image-guided planning, and consecutive placement of the CMF implants, were assessed in two cadaver studies (**Chapters 2 and 3**). A retrospective multicenter investigation focused on the survival rate of CMF implants and on the optimal timing of implant placement in relation to ablative surgery (**Chapter 4**). Lastly, two clinical studies using comprehensive questionnaires were performed. The first to investigate different aspects of satisfaction after CMF prosthetic rehabilitation (**Chapter 5**) and the second to determine the subjective perception of different observer panels towards various reconstructive treatment

options (**Chapter 6**). The main results of the studies conducted performed in this thesis are discussed in **Chapter 7**. Comments on the potential influences of the newly gained insights on reconstructive treatment planning, outcome, evaluation and technological advancements will be appraised in the second part of **Chapter 7**, called: ‘future perspectives’.

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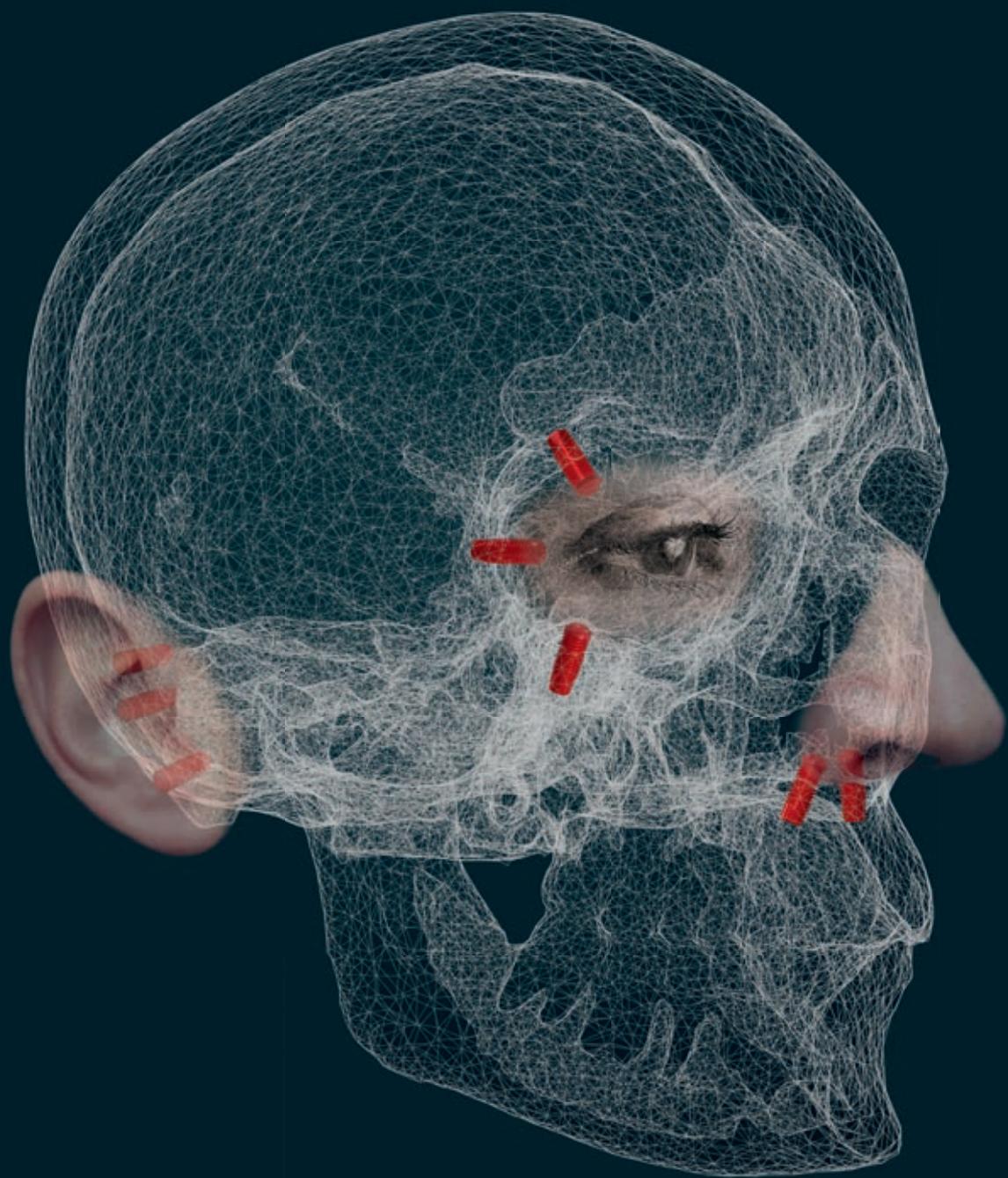
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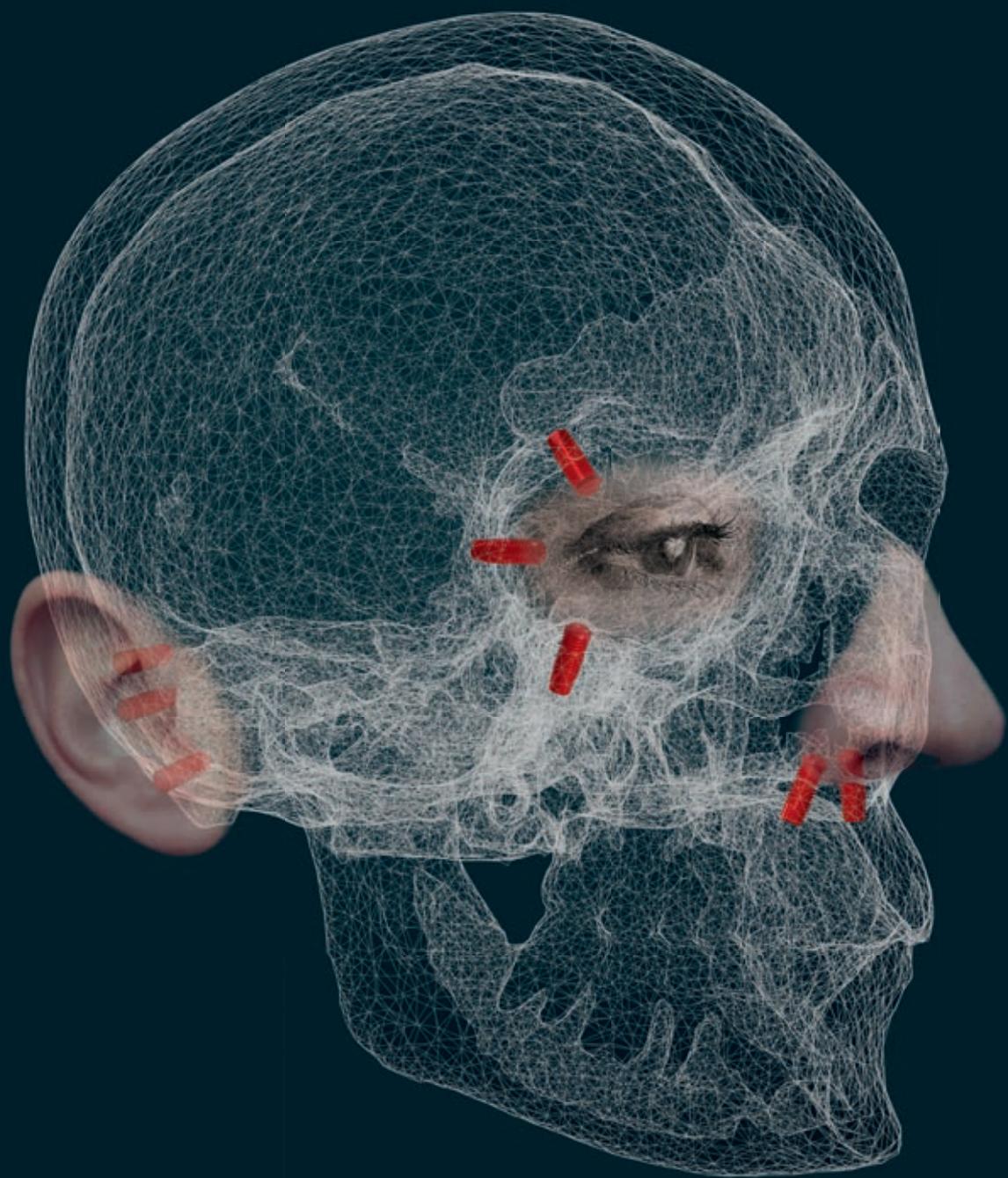
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# PART II

Evaluation of accuracy of  
craniomaxillofacial implant  
planning and placement



# Chapter 2

Reliability and accuracy of cone  
beam computed tomography  
versus conventional  
multidetector computed  
tomography for image-guided  
craniofacial implant planning:  
an in vitro study

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## ABSTRACT

**Purpose:** To assess the reliability and accuracy of linear measurements on three-dimensional (3D) cross-sectional images, both acquired with cone beam computed tomography (CBCT) and multi-detector row CT (MDCT). Bone thickness was evaluated with regard to imageguided planning of craniofacial implant surgery.

**Materials and Methods:** Five dry human skulls were used. Cuts were made with a circular bone saw at the ideal implant positions in the nasal, orbital, and temporal regions prior to acquisition of CBCT and MDCT scans. After imaging examination, bone width was assessed by three independent observers using a caliper and defined as a reference. In the next step, cross-sectional images of the regions with the aforementioned cuts were reconstructed from 3D virtual models generated from the digital DICOM datasets with the use of 3D image-based planning software. Subsequently, linear measurements were performed. The systematic difference and interobserver and intraobserver variation of MDCT and CBCT linear measurements were compared with the physical measurements at different locations in the nasal, orbital, and temporal region, respectively. Also, the potential influence of different gray-level values was investigated. The quantitative accuracy of distance measurements was performed using a two-way analysis of variance (ANOVA) and variance component analyses. Only differences with  $P$  values  $<.05$  were considered significant.

**Results:** All radiologic measurements showed a significant overestimation of the bony dimensions, reaching more than the used voxel sizes of 0.3 mm for CBCT and 0.5 mm for MDCT. For CBCT, an average measurement bias of 0.39 to 0.53 mm and for MDCT of 0.57 to 0.59 mm was found. MDCT images showed less interobserver variation in linear measurements on cross-sectional images from 3D virtual models compared with CBCT images. Contrast settings statistically significantly influenced linear measurements of bone width for CBCT images ( $P < .0015$ ) and interobserver variation on MDCT imaging ( $P < .029$ ).

**Conclusion:** Both CBCT images (KaVo 3D eXam Imaging System) and MDCT images (Aquilion ONE, Toshiba) showed a highly consistent submillimeter overestimation of the anatomical truth in assessing bone thickness of nasal, orbital, and temporal regions of ex vivo specimens. When using CBCT and MDCT images for presurgical assessment, one should be aware of the overestimation of the cortical bone thickness.

## INTRODUCTION

Endosseous implants are established as a secure treatment in prosthetic rehabilitation of craniofacial defects.<sup>1</sup> Although osseointegration of craniofacial implants is predictable, its success rate is mainly determined by primary implant stability. Therefore, preoperative planning is essential for evaluation of the available bone quantity and density to improve reliable treatment planning of craniofacial implants.<sup>2-12</sup> Besides evaluating the available bone thickness, planning is also critical in determining the spatial proximity of anatomical locations and avoiding vital structures.<sup>5,13-15</sup>

Obviously, a prerequisite for implant planning is the high geometric accuracy of the image data.<sup>16</sup> Pre-surgical planning and image-guided surgical procedures, nowadays, are mainly based on three dimensional (3D) imaging acquired by medical multi-detector row computed tomography (MDCT) or cone beam computed tomography (CBCT).<sup>2,10,17,18</sup> MDCT and CBCT are both feasible as high-resolution diagnostic imaging modalities for oral and maxillofacial procedures and implant planning.<sup>15,18-20</sup>

MDCT is still held as a reference standard in terms of geometric accuracy in maxillofacial surgery today.<sup>2,10,15</sup> However, low-cost CBCT poses an alternative to traditional MDCT systems in providing images without superimposition and blurring. In addition, as compared to traditional MDCT, CBCT offers principal advantages, such as reduced radiation exposure, more rapid data acquisition and less disturbance from metallic artifacts, while still permitting reconstruction of the soft tissue profile. Therefore, CBCT is nowadays widely used for oral and maxillofacial procedures.<sup>4,5,8,10,14,15,20-31</sup> However, disadvantages of CBCT include susceptibility to movement artifacts, lower image contrast, higher noise, limited field of view and inability to quantitatively measure tissue density in comparison to MDCT.<sup>11,24,32</sup> These quantitative values expressing x-ray attenuation of a voxel relative to the attenuation of water are represented by Hounsfield units (HU) and are more accurate when voxel sizes are smaller and less material is averaged.<sup>4,29,32,33</sup>

A wide variety of engineering, medical and dental software packages are currently available.<sup>34</sup> Cross-sectional images in multiplanar reconstructions of CBCT and MDCT image data enables linear measurements to be performed on bone surface size and cortical thicknesses.<sup>3,18</sup> Literature comparing MDCT and CBCT shows moderate variability in image quality and high degree of dimensional accuracy of linear and

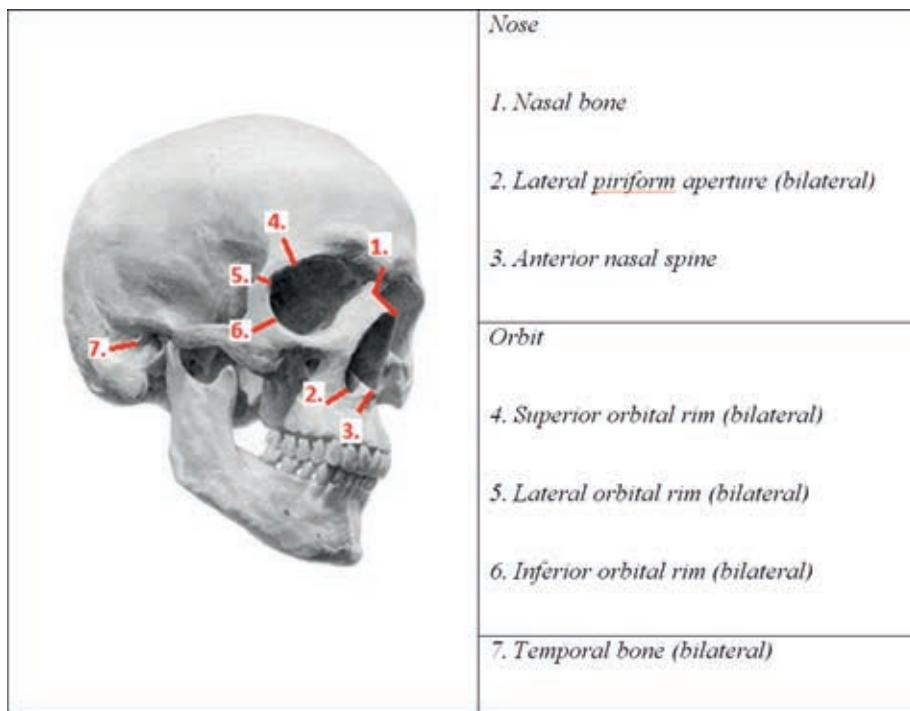
three-dimensional measurements compared to physical gold standards.<sup>15,16,18-20,22,26,35,36</sup> Some authors conclude that accuracy of linear measurements does not statistically differ from multiplanar images of the craniofacial complex obtained by MDCT or CBCT and both yield submillimeter accuracy.<sup>15,18,19,21,24,26,37-39</sup> Other studies show MDCT providing the most accurate images with least mean deviation in measurement errors, although these differences may not be of clinical significance for diagnostic purposes and pre-surgical planning.<sup>3,16,21,36,40</sup> In contrast, studies have also been published, which describe the opposite, namely that clinically and statistically significant differences in measurement errors were observed in favor of CBCT.<sup>6,41-43</sup> These different findings in literature can be explained by methodical differences, protocols for image acquisition, spatial resolution selection, and operator skill in interpretation of the composite image.<sup>12,18,28,30,44</sup>

To our knowledge, no literature exists on the accuracy of linear measurements for planning of craniofacial implants on cross-sectional image derived from MDCT and CBCT data. The purpose of this study was to evaluate the accuracy of these image-based linear measurements. Furthermore, the effect of different brightness and contrast settings was evaluated.

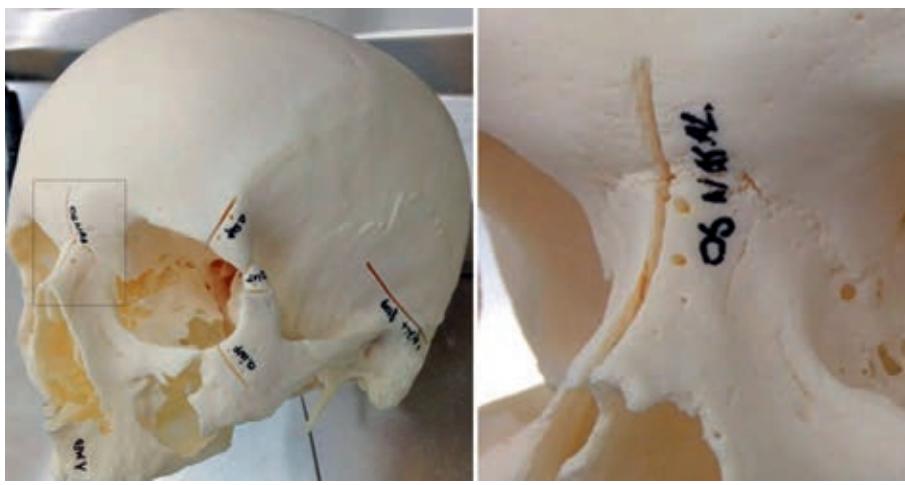
## MATERIALS AND METHODS

### *Specimen*

Five human dry skulls of similar size were obtained from the department of Anatomy of the Radboud University Medical Centre Nijmegen, the Netherlands. Seven anatomical sites were identified, of which 5 were bilateral (Figure 1). These sites represent potential locations of craniofacial implants<sup>45</sup>. Cuts were made at these anatomical locations with a surgical circular bone saw. Two millimetre aside of each cut two reference holes were prepared with a 1.0 mm drill (high-speed turbine) and a 0.8-mm-diameter tungsten carbide surgical bur (Zekry, Dentsply, York, Pennsylvania) parallel to the cut surface (Figure 2).



**Figure 1.** Seven anatomical locations are defined to measure the bone width



**Figure 2** (a) Cuts were made at these anatomical locations with a reciprocating bone saw. Then, 2 mm of each two reference holes cut were prepared with a 1-mm drill parallel to the cut surface (right). (b) Cut and prepared hole in detail.

### ***Image acquisition***

To prevent movement artefacts the cadaver skulls were stabilized in an upright position for the CBCT scan and in a supine position for the MDCT scan like in the real clinical situation. CBCT images were obtained using the KaVo 3D eXam Imaging System® (KaVo Dental GmbH, Biberach, Germany). 3D imaging data were acquired at 120 kV and pulses of 1.2 mA. The scan time was 40 seconds. The field of view was set to an 23 cm diameter and a 17 cm height with a voxel size of 0.3 mm. Data were converted into DICOM format (Digital Imaging and Communications in Medicine).

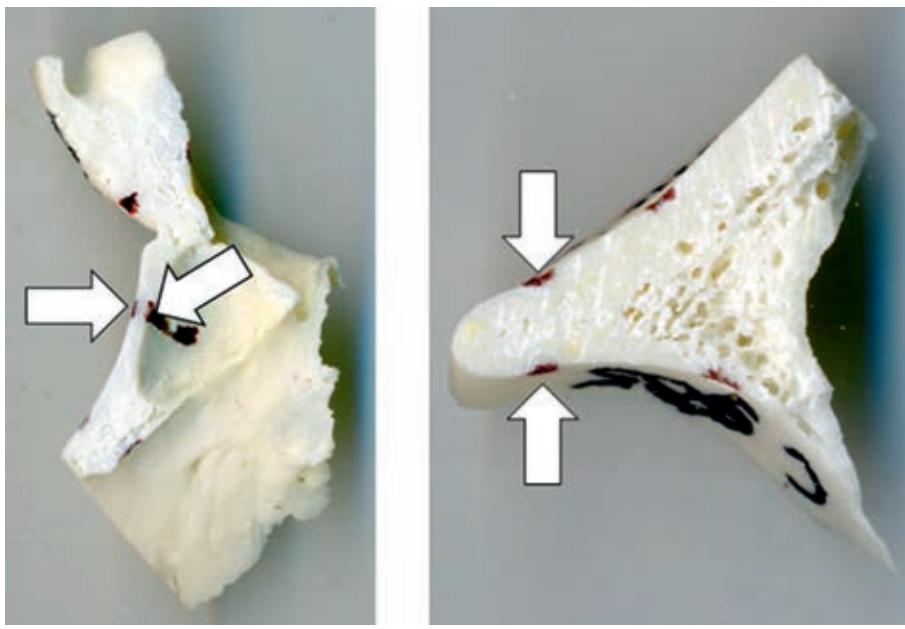
MDCT examination was carried out with a commercially available 320-detector row CT-system (Toshiba Aquilion ONE; Toshiba Medical Systems Corporation, Tochigi, Japan) with the following scan parameters kept identical for all specimens: tube voltage 120 kV, slice thickness 0.5 millimetre (increment, 0.3 mm) with a radiation exposure per slide of 61.8 mGy and a total exposure of 1619.1 mGy with a 26.2 cm diameter circular field of view.

### ***Physical measurements***

After volumetric image data acquisition the cuts in the skulls were sectioned into small skull blocks since most anatomical landmarks prevented direct access for caliper measurement. Indelible ink marker lines were drawn from the drill holes perpendicular to the cut surface indicating the points of physical measurement with a high precision digital caliper (Digimatic Caliper 0-150 mm, Mitutoyo, Kawasaki, Japan) (Figure 3). Three oral and maxillofacial surgeons independently conducted three measurements at each marked point on the cut surface at three different days with minimum intervals of seven days to determine the inter-observer and intra-observer variability. Each measurement was recorded with an accuracy of 0.01 mm. Means of these measurements were used as the physical reference standards.

### ***Radiological measurements***

The radiological data were rendered using commercially available software tools for DICOM data review (Maxilim, v2.3.0.3, Medicim Medical Image Computing, Mechelen, Belgium). All images were reconstructed using multiplanar reformatting. After localizing cuts and bony reference holes, cross-sectional planes were placed parallel to the cuts on the 3D surface rendered reconstructions using the planning software (Figure 4). A software module was developed to create perpendicular planes on these cross-sectional planes parallel to the cut surfaces. On this perpendicular plane the reference holes were localized. Digital markers

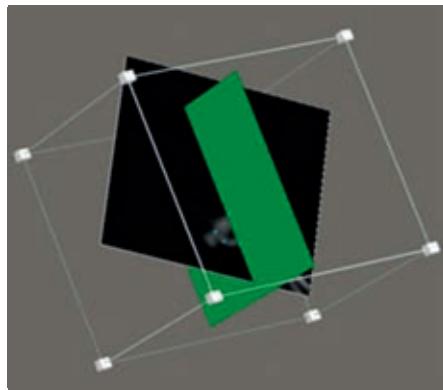
**a****b**

**Figure 3** Detail of (a) segment of the nasal bone and (b) segment of the orbital rim. Between the black marks (arrows), the bone width was measured.

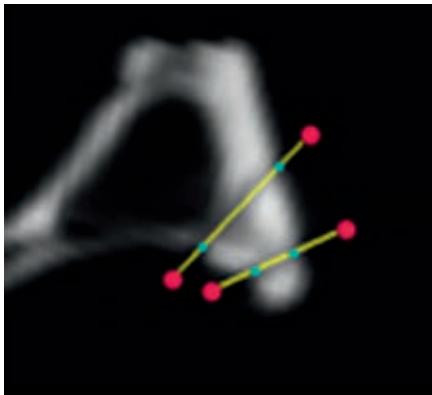
were placed on the radiographic plane parallel to the cut surface at the intersection with the latter perpendicular plane (Figure 5). These digital markers correspond to the ink marked points on the cut surface for physical measurement. Corresponding digital markers were connected by a straight line extending the outer bony dimensions (Figure 6). The digital markers were then removed enabling observers to perform individual measurements on a straight digital line (Figure 7). Linear measurements on the radiographic image of the outline of the outer cortical bone were carried out with a digital volumetric analysis tool and repeated three times by 3 independent surgeons with experience in examining MDCT and CBCT at least 1 week apart.



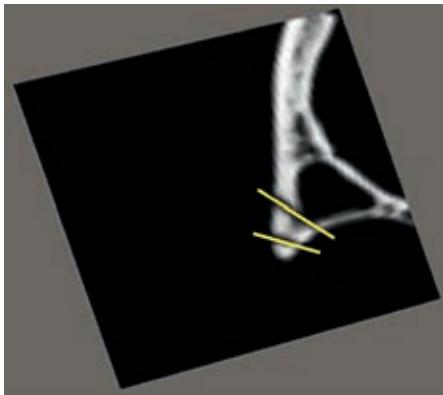
**Figure 4** Localization of reference holes.



**Figure 5** Digital plane perpendicular to cut surface and parallel to reference hole.



**Figure 6** Digital markers (blue) indicating outer bony dimensions connected by a straight yellow line parallel to bony reference holes.



**Figure 7** Cross-sectional image for linear measurements of the bone width.

All measurements were performed using the same non-glare 23-inch flat panel colour monitor screen with a resolution of 1920x1080, luminance 250 cd/m<sup>2</sup> with an color depth (DFC) at 16.7M and pixel pitch (mm) of 0.2652 (H) x 0.2652 (V). Brightness and contrast settings were fixed at two different standard bone settings of planning software programs: window level 276 and window width 1500 (Procera System; NobelGuide<sup>tm</sup>; Nobel Biocare, Göteborg, Sweden) and window level 600 and window width 3200 (Maxilim). Linear measurements were made at these two different settings.

### **Statistical analysis**

The mean of measurements of all observers obtained from CBCT and MDCT images were compared amongst themselves and to the mean of physical measurements as

reference standard. A 2-way analysis of variance (ANOVA) was used to compare the measurements from CBCT and MDCT images at two different contrast settings. The level of significance was 5%. The intraclass correlation coefficient (ICC) was calculated with a variance component analysis for the physical and radiological measurements to determine the intra- and inter-observer agreement. Comparisons of interobserver variability between methods were done using the likelihood ratio test comparing the model with equal variability with the model with different variabilities for the methods. The statistical analyses were performed using SAS system software, 9.4 release.

## RESULTS

The reference standard as mean of physical measurements had an average inter-observer error of 0.15 mm. The reliability (ICC) indicates a very good repeatability of the radiological and physical measurements (Table 1)<sup>46</sup>. The inter- and intraobserver reliability were similar for the CBCT and MDCT measurements and ranged between 0.98 and 0.99.

**Table 1.** Reliability (ICC), inter- and intra-observer measurement error for CBCT, MDCT measurements at different contrast settings and caliper measurements. P-value indicates significance between two different contrast settings for each imaging modality.

		Reliability (ICC)	Inter-observer measurement error (mm)	Intra-observer measurement error (mm)	Systematic difference with gold standard (observers pooled; 95% confidence interval)	
CBCT	CBCT 0.3 mm (Procer)	0.98	0.39	0.35	0.53 mm (0.36-0.71)	P < .0001
	CBCT 0.3 mm (Maxilim)	0.98	0.42	0.42	0.39 mm (0.19-0.59)	P = .0003
MDCT	MDCT 0.5 mm (Procer)	0.99	0.21	0.21	0.57 mm (0.45-0.70)	P < .0001
	MDCT 0.5 mm (Maxilim)	0.99	0.26	0.22	0.59 mm (0.45-0.73)	P < .0001
Caliper (gold standard)		0.99	0.28	0.26		

Overview of the absolute difference between CBCT and MDCT linear measurements versus the gold standard expressed in millimeters. The mean and 95% confidence interval are depicted.

Interobserver measurement error on MDCT images was statistically significant influenced by different brightness and contrast setting ( $P = .03$ ). After pooling of the CBCT and MDCT images a statistically significant difference in interobserver measurement error is found of 0.40 mm and 0.24 mm, respectively ( $P < .0001$ ).

All absolute differences of linear measurements obtained from CBCT and MDCT reconstructions and the reference standard show statistically significant overestimation (Table 1). However, systematic difference of linear measurements with the gold standard on CBCT images was statistically significant influenced by different brightness and contrast settings ( $P = .0015$ ). No such influence was found for linear measurements on MDCT images ( $P = .51$ ).

Data was also examined for absolute differences between the different imaging modalities, contrast settings and anatomical locations (Table 2). No statistically significant differences with the gold standard were found for in CBCT imaging at the anterior nasal spine for both contrast settings. Linear measurements on CBCT images at the supraorbital ridge only proved statistically significant different at one contrast setting. With regard to linear measurements on MDCT images, no statistically significant differences with the gold standard were found at the lateral orbital ridge and temporal bone region.

Differences in interobserver measurement error between pooled CBCT and pooled MDCT images proved statistically significant for the anterior nasal spine, piriform aperture and inferior orbital ridge with MDCT imaging showing less variation in linear measurements (Table 2).

## DISCUSSION

We assessed the reliability and accuracy of linear measurements on cross-sectional images linked to the 3D hard-tissue surface representations from CBCT and MDCT image data sets. High reliabilities in this study allowed further comparisons with the average of measurements for each imaging modality and different brightness and contrast settings (ranging from 0.98 to 0.99).

In contrast to the findings of Wikner<sup>18</sup>, our findings demonstrated statistically significant submillimeter overestimation for linear measurements on digital CBCT (0.39-0.53 mm) and MDCT images (0.57-0.59 mm) in comparison to physical measurements with a caliper. Inaccuracy of caliper measurements in this study was 0.15 mm although this uncertainty can be considered clinically insignificant. Literature shows not to overestimate spatial resolution in MDCT and CBCT volumes with a maximal accuracy in the range of half a millimeter.<sup>15</sup>

**Table 2.** Systematic difference of linear distance measurements with golden standard (GS) in relation to different anatomical locations.

Anatomical location	Scan type	Bias Observers-GS (95% confidence interval)	P value (GS)	Interobserver error of linear distance measurements	P value (interobserver)
Nose	Nasal bone	CBCT (Procera)	0.57 (0.35-0.79)	<.001	0.24
		CBCT (Maxilim)	0.30 (0.05-0.55)	0.020	0.24
		MDCT (Procera)	0.52 (0.26-0.77)	<.001	0.27
		MDCT (Maxilim)	0.37 (0.08-0.65)	0.014	0.21
	Anterior nasal spine	CBCT (Procera)	-0.11 (-0.59-0.38)	0.657	0.70
		CBCT (Maxilim)	-0.13 (-0.77-0.50)	0.669	0.56
		MDCT (Procera)	0.87 (0.68-1.06)	<.001	0.24
		MDCT (Maxilim)	0.97 (0.75-1.19)	<.001	0.19
	Piriform aperture	CBCT (Procera)	0.85 (0.52-1.18)	<.001	0.44
		CBCT (Maxilim)	0.81 (0.43-1.18)	<.001	0.43
		MDCT (Procera)	0.66 (0.45-0.87)	<.001	0.20
		MDCT (Maxilim)	0.87 (0.69-1.05)	<.001	0.25
Orbit	Supraorbital ridge	CBCT (Procera)	0.26 (0.05-0.48)	0.018	0.39
		CBCT (Maxilim)	-0.06 (-0.39-0.28)	0.732	0.29
		MDCT (Procera)	0.56 (0.37-0.74)	<.001	0.29
		MDCT (Maxilim)	0.59 (0.38-0.80)	<.001	0.23
	Lateral orbital ridge	CBCT (Procera)	0.74 (0.48-0.99)	<.001	0.31
		CBCT (Maxilim)	0.71 (0.39-1.02)	<.001	0.25
		MDCT (Procera)	0.25 (-0.05-0.55)	0.101	0.30
		MDCT (Maxilim)	0.37 (0.00-0.74)	0.050	0.23
	Inferior orbital ridge	CBCT (Procera)	1.10 (0.70-1.49)	<.001	0.30
		CBCT (Maxilim)	0.87 (0.50-1.23)	<.001	0.39
		MDCT (Procera)	0.65 (0.40-0.91)	<.001	0.18
		MDCT (Maxilim)	0.50 (0.22-0.79)	0.001	0.17
Temporal bone	Temporal bone	CBCT (Procera)	0.59 (0.19-1.00)	0.007	0.32
		CBCT (Maxilim)	0.54 (0.23-0.85)	0.002	0.42
		MDCT (Procera)	0.29 (-0.02-0.61)	0.063	0.34
		MDCT (Maxilim)	0.29 (-0.10-0.69)	0.132	0.22

Interobserver error of linear distance measurements. P-value (interobserver) indicate statistical significance of differences between (pooled) CBCT and (pooled) MDCT interobserver variation in linear measurements

Although our study made use of dried skulls like many other papers, the clinical truth is hampered by the absence of soft-tissue attenuation.<sup>3,4</sup> Linear measurements on objects without a simulated soft tissue component may be more accurate due to a more optimal high-contrast resolution and decreased scatter.<sup>10,14,26</sup> However, Ganguly *et al*<sup>14</sup> found no effect of soft tissues on the accuracy of measurements. In our study no metallic artifacts were present and, due to stabilization of the skulls, motion artifacts were ruled out. Image acquisition was completed in normal scanning position, although several studies have stressed that linear measurements on CBCT and MDCT images are not significantly influenced by the position and inclination of the object during scanning.<sup>2,10,18,22,30</sup> Also, tube current reduction in CBCT and scan mode is shown to have little influence on image quality.<sup>5</sup> In the study of Al-Ekrish *et al*<sup>41</sup> lower image contrast only affected low-contrast resolution. However, with regard to the goal of pre-surgical assessment of bone volume only high-contrast resolution is required.<sup>35,41</sup>

Most measurements in this study comprised only a few millimeters in bone width necessitating a high spatial resolution.<sup>35</sup> Spatial resolution, as the size of the acquisition voxel, depends on different reconstruction parameters (i.e. reconstruction algorithm), geometrical aspects and acquisition mode. The optimal exposure settings for obtaining clinically adequate image quality needs to be determined for each CBCT and MDCT device.<sup>5,31</sup>

A limitation of this study is that only one CBCT and MDCT scanner was used with only one image acquisition protocol and one imaging software package. Chen *et al*<sup>34</sup> showed different software packages offering reliable dimensional measurements but with underestimation compared to gold standard measurements. However, significant differences were observed in volume and cross-sectional measurements using different CBCT and MDCT scanners.<sup>20</sup>

Conform standard practice settings in our university clinic the spatial resolution in our study was 0.3 mm for the CBCT and 0.5 mm for the MDCT scan. In comparison to MDCT, CBCT voxels are very small (ranging from 0.076 to 0.4 mm) and generally isotropic. These characteristics make linear measurements possible in all planes.<sup>37,42,43</sup> Some publications state that voxel size has no significant influence on accuracy of diagnoses or image quality.<sup>12,13,35</sup> In contrast, Maret *et al*<sup>39</sup> and Shokri<sup>9</sup> *et al* indicated a slight tendency toward underestimation in volumetric measurements with increasing CBCT voxel size. Maret *et al*<sup>39</sup> elucidated a statistically significant underestimation using voxel sizes of 0.3 mm and beyond. However, a voxel is only a very crude predictor

of available spatial resolution negatively influenced by motion blur and scatter of tissue.<sup>11,39</sup>

In this study, no relationship was found between accuracy of linear measurements and different anatomical locations with varying bone widths. Representation of thin bone layers on digital images may be reduced if bony densities are lowered with surrounding air segmentation.<sup>3,20,21</sup> Appropriate segmentation is essential in determining the thresholding of bone pixel values and suppression of surrounding tissue values to enhance the structure of interest.<sup>28,44</sup> Segmentation accuracy is influenced by the disadvantages of CBCT as scattered radiation, truncated view artifact and artifacts caused by beam hardening.<sup>10</sup> ‘Partial averaging effect’ described by Gerlach *et al*<sup>3</sup> may also hamper correct volumetric depiction of bony contours in averaging different densities within a voxel.

Diagnostic accuracy of CBCT is found to exhibit differences in relation to the anatomical location.<sup>12,28</sup> Lascala *et al*<sup>47</sup> found statistically significant underestimation of real measurements recorded at the skull base but not in dento-maxillofacial structures. Halperin<sup>48</sup> *et al* indicated less diagnostic accuracy for the anterior areas compared to the posterior arches. No clear relationship between accuracy of measurements and anterior or posterior anatomical regions could be established in our study.

Lund *et al*<sup>22</sup> showed that small distortions can result from the different reformation processes. In our study one reconstruction protocol was used enabling appropriate comparison of the different imaging modalities. The orientation of a radiographic plane parallel to the cut surface ensuring reliable measurements may have influenced measurements due to the slice-thickness which was set on a reconstructed slice increment of 0.3 mm for respectively CBCT and MDCT imaging. If this plane was not optimally positioned, an error in measurement is introduced due to possible variation in bony dimensions and mathematical reconstruction of images. The influence of varying slice thicknesses was not examined separately in this study. Literature shows an overestimation of distance measurements on CBCT and MDCT images resulting from increased slice thickness with margins of cortical bone appearing thicker.<sup>2,9</sup>

All measurements were executed on the same LCD monitors with identical mouse sensitivity. Al-Ekrish *et al*<sup>49</sup> mentioned no differences in the reliability of linear measurements using different LCD monitors and different contrast resolution

capabilities. In this study, variation in brightness and contrast settings showed statistically significant less variation in interobserver error on cross-sectional images from CBCT image data ( $P=.03$ ) but statistically significant greater difference with regard to absolute errors compared to MDCT ( $P = .0015$ ). However, comparing outcomes with other studies is difficult due to various measurement methods, reconstruction protocols and different model generations of radiological devices.

## CONCLUSION

Within the limitations of the present study, linear measurements on cross-sectional images derived from CBCT and MDCT image data with different contrast settings yield statistically significant submillimeter overestimation of the anatomical truth. For most clinical purposes both MDCT and CBCT are reliable imaging modalities for pre-surgical planning of craniofacial implants, however, digital exaggeration of measurements should be taken into account.

Future standardized studies should consider including multiple MDCT and CBCT scanners, image acquisition protocols and software packages in investigating the accuracy and reliability of craniofacial implant site measurements.

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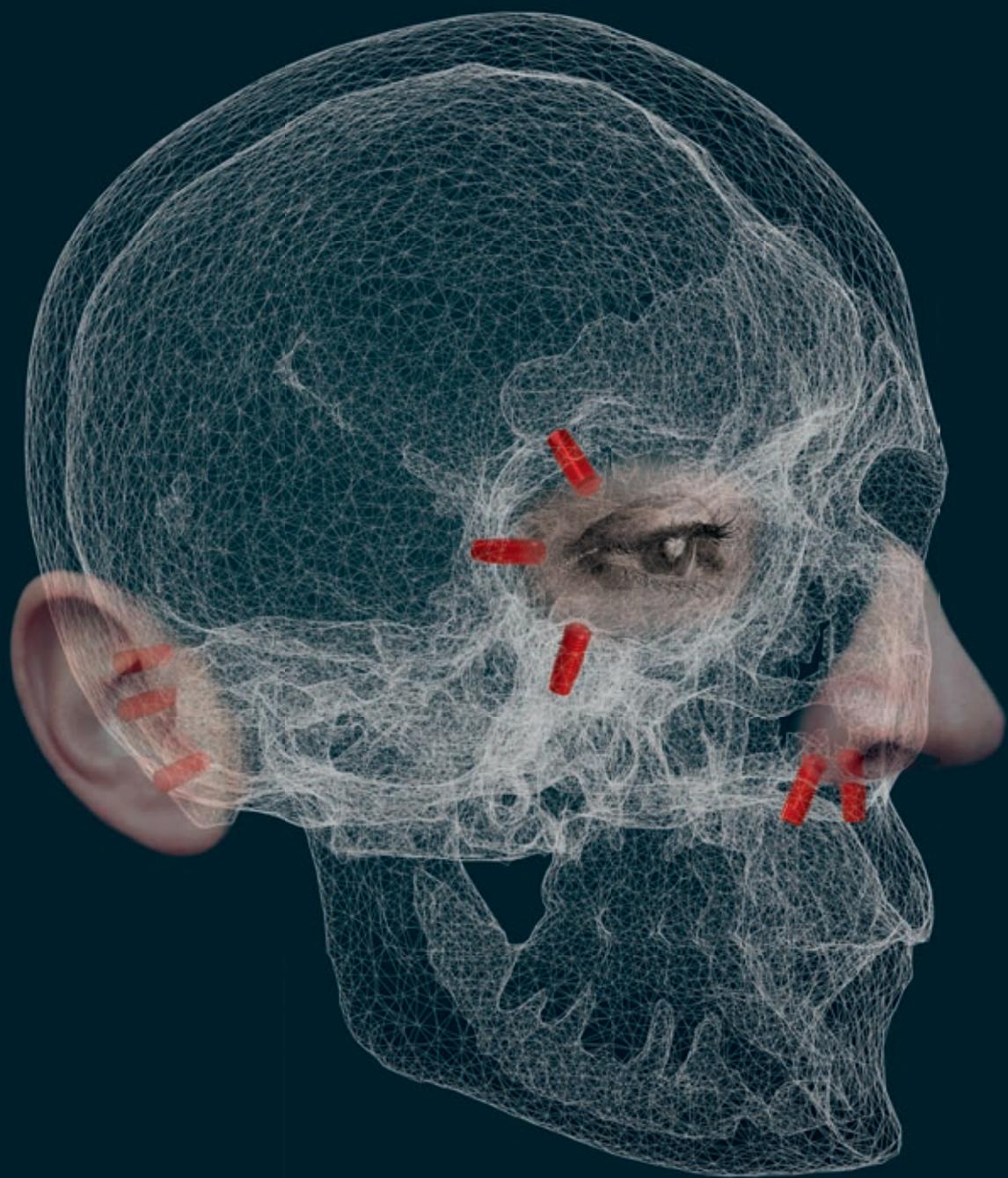
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# Chapter 3

Reliability and accuracy of  
skin-supported surgical  
templates for computer-  
planned craniofacial implant  
placement, a comparison  
between surgical templates:  
with and without bony fixation

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## ABSTRACT

### Introduction

The purpose is to determine the accuracy of guided implant placement in the orbital, nasal, and auricular region using computer-aided designed stereolithographic skin-supported surgical templates with and without bone fixation pins.

### Material and methods

Preoperatively, cone-beam CT (CBCT) and multiple detector computed tomography (MDCT) scans were acquired from 10 cadaver heads, followed by virtual planning of implants in the orbital margin, auricular region and nasal floor. Surgical skin-supported templates were digitally designed to allow flapless implant placement. Fixation pins were used for stabilization comprising half of all templates in predetermined bone areas. The accuracy of the surgical templates was validated by comparing the achieved implant location to its virtual planned implant position by calculating the linear and angular deviations.

### Results

Surgical templates with the use of bone fixation pins produced statistically significant greater implant deviations as compared to the non-fixated surgical templates.

### Conclusion

The results of this study indicate that significant deviation has to be taken into account when placing craniomaxillofacial implants using skin-supported surgical templates. Surprisingly, the use of bone-fixated pins worsened the accuracy.

## INTRODUCTION

Reconstruction of cranio- and maxillofacial (CMF) defects is challenging due to complex anatomy and proximity of vital structures<sup>1-3</sup>. Implant-supported prosthetic rehabilitation is nowadays regarded as a viable alternative to conventional reconstructive surgery. The introduction of endosseous implants marked a revolutionary step in the prosthetic rehabilitation of CMF defects with regard to improved retention, aesthetic outcome, and ease of placement<sup>4-7</sup>.

Successful prosthetic driven rehabilitation depends on accurate diagnosis, preoperative planning, and subsequent placement of endosseous implants<sup>8-11</sup>.

The development of multiple detector computed tomography (MDCT) and cone beam computed tomography (CBCT) provides graphic and detailed three-dimensional (3D) information regarding bone volume, bone quality, and anatomical restrictions<sup>9,12</sup>. This 3D information allows accurate virtual planning using prosthetically oriented true-sized implants. As such, guided implant placement offers minimal invasive procedures, and reduces errors that are involved in standard implant surgery<sup>9,13,14</sup>.

CMF osseointegrated implants may be placed in a conventional manner or by stereolithographic (SLA) generated surgical guides<sup>11</sup>. Virtual planning software has enabled 3D computer-aided designing and also manufacturing (CAD-CAM) of surgical templates to allow guided implant placement. These surgical templates (drill guides) facilitate intraoperative correct positioning of implants at a predetermined depth and angle<sup>15-18</sup>. Surgical guides can be skeletal-, dental or mucosal supported<sup>19-21</sup>. Determination of the accuracy of surgical templates, by comparing deviations between virtually planned and actually placed implants, has been widely documented in different study designs, unfortunately, with compromised comparability and unfavorable results in terms of magnitude of error<sup>12-14, 21-28</sup>.

To our knowledge only few studies have reported on the accuracy of CMF implant placement with the aid of CAD/CAM-guided surgical templates<sup>19,20,29</sup>. The objective of this *ex vivo* study was to determine the accuracy of CMF implants placed in the orbital, nasal, and auricular region using skin-supported surgical templates. In addition, the influence of bone-fixation pins was measured. The hypothesis was that surgical templates allow proper implant placement, implicating that differences between virtually planned implant and the actual positions would be less than 1 millimeter.

Furthermore, it was expected that the use of bone-fixated pins improved the accuracy of the guided implant placement procedure.

## MATERIAL AND METHODS

### 2.1. Procedures

Ten fresh frozen cadaver heads were collected by the Anatomy Department Radboud University Medical Centre Nijmegen and used in the present study.

The cadaver skulls were stabilized to prevent movement artefacts in an upright position for the CBCT scan and in a supine position for the MDCT scan like in real patients. CBCT images were obtained using the KaVo 3D eXam Imaging System (KaVo Dental GmbH, Biberach, Germany). 3D imaging data were acquired at 120 kV and pulses of 1.2 mA. The scan time was 40 seconds. The field of view was 22 cm with a voxel size of 0.300 mm. Data were converted into DICOM format (Digital Imaging and Communications in Medicine). MDCT examination was carried out with a commercially available 320-detector row CT-system (Toshiba Aquilion ONE; Toshiba Medical Systems Corporation, Tochigi, Japan) with the following scan parameters kept identical for all specimens: tube voltage 120 kV, slice thickness 0.5 millimetre with a radiation exposure per slide of 61.8 mGy and a total exposure of 1619.1 mGy with a field of view of 26.2 cm.

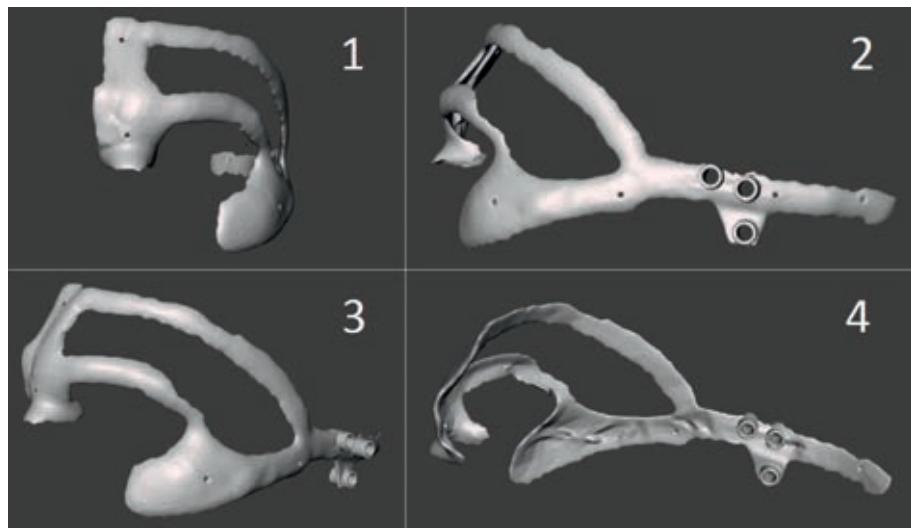
Subsequently, 3D-models of the entire cadaver heads were created from the DICOM files using Maxilim software (Medicim NV, Mechelen, Belgium). The 3D digital model of the skin surface was obtained by setting a suitable threshold value. Both models were achieved semi-automatically by threshold based segmentation, contour extraction, and surface reconstruction.

Branemark MK III TiU implants with regular platforms (RP; Ø3.75 mm; Nobel Biocare, Zürich, Switzerland) were virtually planned by an oral maxillofacial surgeon (JD) using the Procera System (NobelGuide; Nobel Biocare, Göteborg, Sweden) in optimal positions with respect to both the available bone volume and prosthetic demands. By including the exported 3D-computer models of the planned implants, a full surgical template was created with the aid of Autodesk 3ds Max Design software (version 2012; Autodesk Inc., San Rafael, CA, USA). Templates were exported as STL-files, transferred to the rapid prototyping system and 3D-printed from biocompatible resin with an

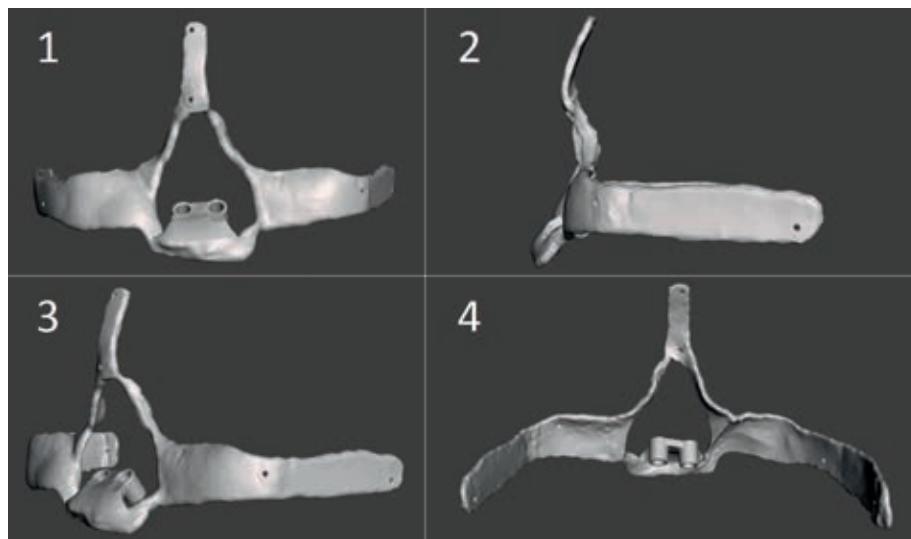
optimal fit between the inner surface of the template and skin surface of the concerned anatomical region. Cylindrical openings were designed in all surgical templates to allow installation of the stainless-steel guide sleeves, through which the bone bed was prepared. No relevant 3D-inaccuracies of the templates in comparison with the 3D-virtual models were determined, as measured with a high-accuracy non-contact 3D digitizer (Konica Minolta Vivid 910).

Auricular templates contained several extensions facilitating correct positioning of the template on the skin taking into account the supine position of the patient during implant surgery. Extensions of the template included an anterior arm extending over the zygomatic arch, orbital rim, and nasal bone to ensure support of regions that were covered by the least amount of mobile tissue. In order to reduce flexibility of the surgical template a connecting arm was designed from the nasal bone to the auricular region. To ensure visual control of an optimal fit of the surgical template the temporal region was not covered. Furthermore an distal extension was incorporated extending to the occipital region (fig. 1)

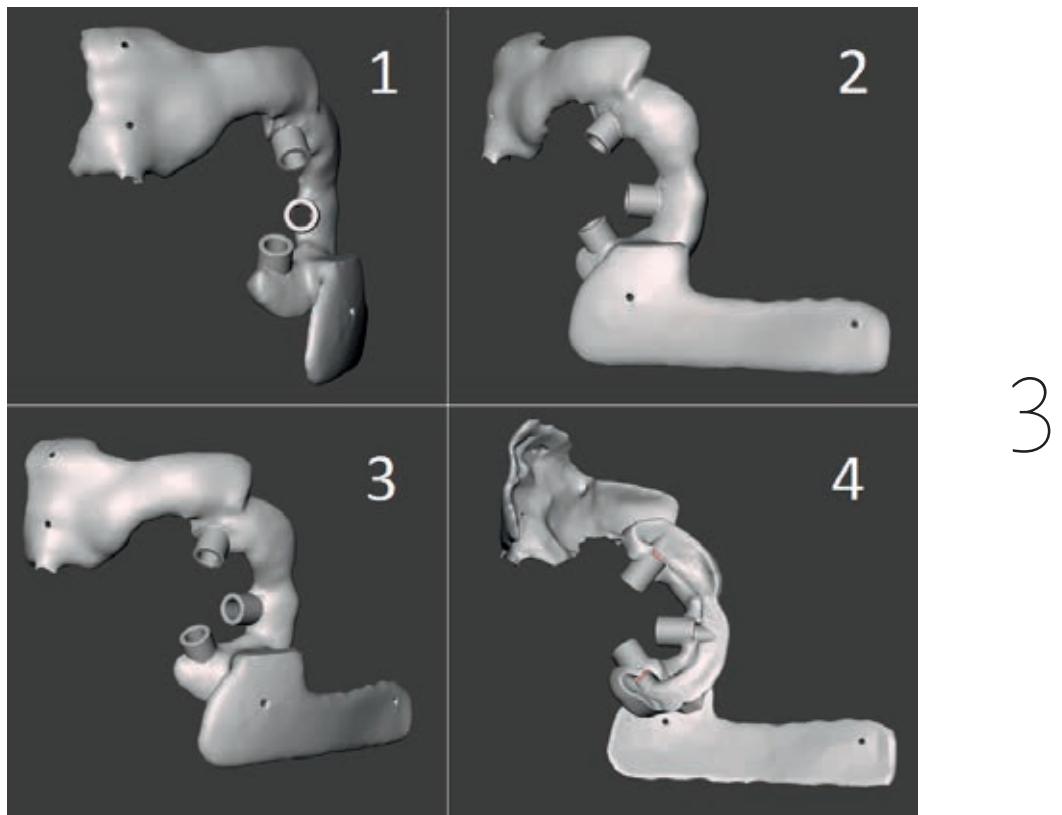
The surgical template for nasal implants was designed with bilateral extensions over the malar bone and zygomatic arch and one superior extension to the nasal bone (fig. 2). The surgical template for the orbital region encompassed the superior, lateral, and inferior lateral rim with extensions to the nasal bone, malar bone, and zygomatic arch (fig. 3). Temporary transcutaneous bone-fixation pins were incorporated in the planning and equally distributed with position on the malar, nasal, frontal, temporal and occipital bone (fig. 4-6).



**Figure 1.** Auricular template: frontal view (1), lateral view (2), three-quarter view (3), medial view (4).



**Figure 2.** Nasal template: frontal view (1), lateral view (2), three-quarter view (3), medial view (4).



**Figure 3.** Orbital template: frontal view (1), lateral view (2), three-quarter view (3), medial view (4).

Ears, eyes, and noses were removed prior to installation of implants. The (right-handed) surgeon who planned the virtual implants also performed the surgeries. During the implant placement procedure, positioning and fixation of the skin-supported surgical templates purely relied on visual guidance, provided by the soft tissue in contact with the outer linings of the template and digital pressure.

Drilling sequences for the cadaver surgeries simulated the actual clinical setting and were performed using the single-type surgical templates and according to the NobelGuide procedure (Nobel Biocare, Göteborg, Sweden). Standard components as adaptable stainless-steel guide sleeves, to allow proper guidance for the range of drills with increasing diameter, were used during implant installation. Also the implants themselves were template guided inserted and, subsequently, attached to the surgical template using a template abutment. (Guided Template Abutment Branemark System RP; Nobel Biocare AB).

For the evaluation of the surgical results in comparison with the pre-operative planned virtual positions all cadavers were rescanned after implant insertion. Postoperative CBCT and MDCT scans were acquired using the same settings as for the preoperative scans. These scans were superimposed to the preoperative scans that were used for the virtual implant planning using voxel-based registration. To obtain the postoperative tip and shoulder coordinates of the implants, the surgically installed implants were segmented from the postoperative scan for visualization purposes. 3D-image models of the virtually planned implants with equal length and diameter from the planning were aligned with these segmented implants followed by calculation of the 3D-deviations of the variables 'implant tip', 'implant shoulder', 'angulation' and 'depth'.

## **2.2. Statistical analysis**

Linear mixed models were used to analyse the influence of the implant variables on the deviations between planned and post-operative implant positions. In this model a random patient intercept was used, with the influence of implant characteristics as a fixed factor. Backwards step-wise regression was used for comparison between surgical templates with and without bone fixation pins. Differences were considered statistically significant with a P-value of  $<0.05$ . The statistical analysis was performed using SAS® version 9.4 (SAS Institute Inc., Cary, NC, USA).

# **RESULTS**

A total of 136 Branemark MK III TiU implants with regular platform ( $\varnothing 3.75$  mm) were placed in 10 cadaver heads (Table 1): 57 implants in the orbital region, 19 nasal implants and 60 auricular implants. Due to an impacted cuspid tooth one nasal implant could not be planned. Three orbital implants could not be planned due to bony defects in the orbital region. Bone fixation pins were used in 5 cadaver heads on 25 surgical templates. No statistically significant differences were shown between different lengths of implants and between implants placed at the left or right side of the cadaver head.

**Table 1.** Distribution of CMF implants per facial region

Anatomical location		Implant lengths		Surgical template	
		7 mm	10 mm	No fixation pins (no. of implants)	With fixation pins (no. of implants)
Orbit	Supraorbital ridge	N=5	N=14	9	10
	Lateral orbital ridge	N=7	N=13	10	10
	Inferior orbital ridge	N=3	N=15	8	10
Nose	Nasal floor (piriform aperture)	N=1	N=18	9	10
Temporal bone		N=33	N=27	30	30
Total		49	87	66	70

Overall, the use of fixation pins showed statistical significant larger mean deviations at the implant shoulder ( $P=.0248$ ), angle ( $P=.0179$ ), and depth ( $P=.0010$ ) in comparison to non-fixed surgical templates (Table 2). Mean implant deviations with regard to different anatomical locations are shown in Table 3. Mean implant deviations were shown to be highest for auricular implants with the exception of angular deviations. Surgical templates without fixation pins only showed a non-significant difference in angular deviation with regard to different anatomical regions. No statistically significant difference was found for depth of implants being placed with the bone-fixated surgical templates.

**Table 2.** Mean deviations (mm) with regard to the bone fixated and skin supported surgical template.

	Surgical templates		P-value
	Fixation pins [95% confidence interval]	No fixation pins [95% confidence interval]	
Implant tip (mm)	3.3 [2.6, 4.0]	2.5 [1.8, 3.2]	.0749
Implant shoulder (mm)	3.7 [3.0, 4.4]*	2.5 [1.8, 3.2]*	.0248
Angle (mm)	8.0 [6.9, 9.2]*	5.9 [4.7, 7.1]*	.0179
Depth (mm)	-0.8 [-1.2, -0.4]	0.2 [-0.2, 0.6]	.0010

\* Backward regression analysis shows anatomical location as statistically significant factor ( $P < .05$ ).

**Table 3.** Mean deviations in millimeters with regard to anatomical location for the implant tip, implants shoulder, angle and depth.

Anatomical region	Mean deviations		Shoulder (mm) [95% CI]		Angle (°) [95% CI]		Depth (mm) [95% CI]	
	Tip (mm) [95% CI]	Bony fixation	No bony fixation	Bony fixation	No bony fixation	Bony fixation	No bony fixation	Bony fixation
Supraorbital ridge	1.37 [0.35, 2.38]	2.23 [0.63, 3.83]	1.84 [0.75, 2.92]	2.20 [0.60, 3.81]	6.03 [3.1, 8.96]	9.39 [3.99, 9.08]	-0.38 [-1.25, 0.50]	-0.66 [-2.03, 0.71]
Lateral orbital ridge	1.43 [0.45, 2.41]	1.57 [-0.04, 3.17]	1.92 [0.86, 2.97]	2.05 [0.45, 3.65]	6.10 [3.31, 8.89]	7.36 [4.82, 9.90]	-0.66 [-1.50, 0.18]	-0.49 [-1.86, 0.88]
Inferior orbital ridge	1.88 [0.83, 2.94]	2.08 [0.48, 3.68]	2.22 [1.11, 3.33]	2.92 [1.32, 4.53]	4.34 [1.26, 7.42]	6.53 [3.99, 9.08]	-0.05 [-0.97, 0.86]	-1.15 [-2.52, 0.22]
Auricular region (superior implant)	3.38 [2.40, 4.36]	4.79 [3.03, 6.23]	3.15 [2.10, 4.21]	4.99 [3.39, 6.60]	6.15 [3.36, 8.94]	5.68 [3.14, 8.23]	0.70 [-0.14, 1.55]	-0.89 [-1.86, 0.38]
Auricular region (middle implant)	3.23 [2.25, 4.21]	6.16 [4.56, 7.76]	3.11 [2.05, 4.17]	6.00 [4.39, 7.60]	5.14 [2.35, 7.94]	7.51 [4.96, 10.05]	0.83 [-0.01, 1.67]	-0.68 [-2.05, 0.69]
Auricular region (inferior implant)	2.96 [1.99, 3.94]	4.63 [3.03, 6.23]	2.80 [1.75, 3.86]	4.65 [3.05, 6.26]	5.34 [2.55, 8.14]	7.41 [4.86, 9.95]	0.57 [-0.27, 1.41]	-1.49 [-2.86, -0.12]
Nasal floor (piriform aperture)	2.70 [1.69, 3.72]	1.77 [0.17, 3.37]	2.55 [1.47, 3.63]	2.88 [1.27, 4.48]	7.70 [4.78, 10.63]	12.18 [9.64, 14.72]	0.22 [-0.65, 1.10]	-0.36 [-1.73, 1.01]
Pvalue	.0013	.0002	0.0817	.0036	.7393	.0154	.0423	.9181

+ = the actual implant position was coronal to the planned vertical position

- = the actual implant position was apical to the planned vertical position

## DISCUSSION

In this study single-type personalized surgical templates were 3D-printed after the computer-based transfer of the 3D-planned implant position from both CBCT and MDCT imaging modalities. The Brånenmark system was the first implant system to be used extraorally<sup>30</sup>.

In contrast with studies focusing on transfer accuracy of computer-aided oral implantology the actual CMF implant positions in our study showed a considerable deviation as compared to their virtual planned position<sup>31</sup>. However, it is difficult to make direct comparisons between studies due to differences in study design (*in vitro* versus *in vivo* versus *ex vivo*), type of support, single versus multiple surgical templates, number of implants and inconsistency in reported observations<sup>13,21</sup>.

Few studies evaluated the influence of surgical templates on deviations of CMF implants. As such, Van der Meer *et al*<sup>19</sup> showed a high concordance between planned and actual implants in the nasal floor. However, accuracy of actual implant positions were only described for two nasal implants in one patient<sup>19</sup>. In their study, distance deviations for the implant shoulder were 0.496 and 1.924 mm, for the apex 0.702 and 0.9441 mm and deviation in angulation was 0.98 and 4.66 degrees. In contrast with our study design, surgical templates were fitted on the dentition in all three patients. Unfortunately, all cadaver heads in this study were fully edentulous since maxillary teeth cusps serve indeed as ideal fixed reference points.

Another study of Van der Meer *et al*<sup>20</sup> reported on the magnitude of error in transferring the planned position of auricular implants with the aid of a skin-supported surgical template. In comparison to this study, they described less pronounced differences between actual and virtual positions encompassing 1.56 mm (SD 0.56) for the implant shoulder, 1.40 mm (SD 0.53) for the apex and 0.97 degrees (SD 2.33) for the angulation. Other studies include several technical papers and notes with regard to the fabrication and use of surgical templates for CMF implant placement but without validation of accuracy<sup>11,32-34</sup>.

Deviations found in this study are presumably more clinically relevant in the orbital and nasal region with regard to maintaining a zone of at least 2 mm of peri-implant bone to ensure a predictable restorative outcome procedure<sup>28,35-39</sup>. However, possible influence

on the level of bone-implant contact was not separately determined. Furthermore, since maxillofacial prostheses frequently indicate the use of individualized framework using angled or customized implant abutments an improper position of an extra-oral implant can mostly be restored<sup>40,41</sup>.

Reported deviations can be explained by the resilience of the skin, since accuracy is mainly dependent on precise and stable positioning and inherent support of the surgical template<sup>42,43</sup>. Resiliency is likely to be negatively influenced by the reduced quality and altered thickness of the soft tissue of fresh frozen cadavers who were defrosted several times. In an effort to minimize positional discrepancies, bone-fixation pins were used in this study. Disadvantageously, placing of fixation pins can introduce an extra error by bringing the surgical template out of balance<sup>28</sup>. As Neugebauer *et al* pointed out, fixation is not necessarily carried out in the same position as during virtual planning<sup>16</sup>. Our results are consistent with the results of Verhamme *et al*<sup>10</sup> showing that bone-fixation pins do not offer more accurate transfer from planning to placement of maxillary implants. However, in our study statistically significant greater differences were found in deviation of the shoulder, angle, and depth with regard to implants being placed with the use of bone fixated surgical templates. Larger deviations of auricular implants in our study are hypothesized to be influenced by the eccentric location of the guide sleeves in the surgical templates for auricular implants. Manual pressure may cause tilting of the template and henceforth unfavorable rotation and translation during implant surgery. All auricular implants were planned on cross-sectional images derived from MDCT data. Widmann *et al* and Primo *et al* demonstrated no clinical relevant difference in accuracy for 3D-printed surgical templates using CBCT or MDCT imaging modalities<sup>44,45</sup>.

Unintentional deformation of surgical templates during printing or per-operative bending might have occurred since the templates and extending arms covered a large surface<sup>21</sup>. To minimize dimensional changes an overall thickness of 3.0 mm of surgical templates was planned<sup>31</sup>. Furthermore, possible dimensional printing errors were assessed through laser surface scanning in this study and showed no relevant dissimilarities.

Mean angular deviations in this study were also likely to be influenced with the position of the drill within the guide sleeves. Van Assche *et al*<sup>31</sup> described a maximum angular deviation of 4.71 degrees for a maximal inclination of the drill. Large deviations for nasal

implants in this study can possibly be explained by local anatomical characteristics. The narrow, cortical ridge of the lateral nasal floor may have led to deviation of the drill frustrating the optimal implant position<sup>21</sup>. When bony contours or anatomic situations are unfavorable for craniofacial implant placement subperiosteally anchored titanium plates are a viable alternative treatment option and reported to show good overall success rates<sup>46,47</sup>.

Verhamme *et al*<sup>10</sup> and Van Assche *et al*<sup>48</sup> showed that deviations at the implant tip are expected to be higher as compared to the implant shoulder with the latter being in a closer position to the surgical template. No such relation was shown in our study. Furthermore, no statistically significant differences were found between implants with different lengths<sup>10,48</sup>.

Recommendations for future research include the added value of the installation of osteosynthesis screws prior to pre-operative imaging<sup>49</sup>. These can be used as guide for the pre-operative implant planning, as also for the support for the surgical template during implant surgery. Navigation surgery using optical tracking systems avoids positional errors of surgical templates and may prove an alternative for transferring virtual planned positions to the surgical area<sup>21,50</sup>.

## CONCLUSION

The potential of guided flapless implant placement depends on the maximal deviations that will occur in clinical practice. The linear and angular deviations found in the current study, when comparing actual CMF implant positions versus the preoperatively planned implant positions, underline that the inaccuracies, introduced by digitally designed skin-supported surgical templates, are clinically unacceptable. Surprisingly, the use of bone-fixated pins even worsened this inaccuracy.

Considering the potential benefits and implications of achieving an acceptable level of accuracy, further clinical research and technical improvements are indicated for development of surgical templates with optimal fit and stability.

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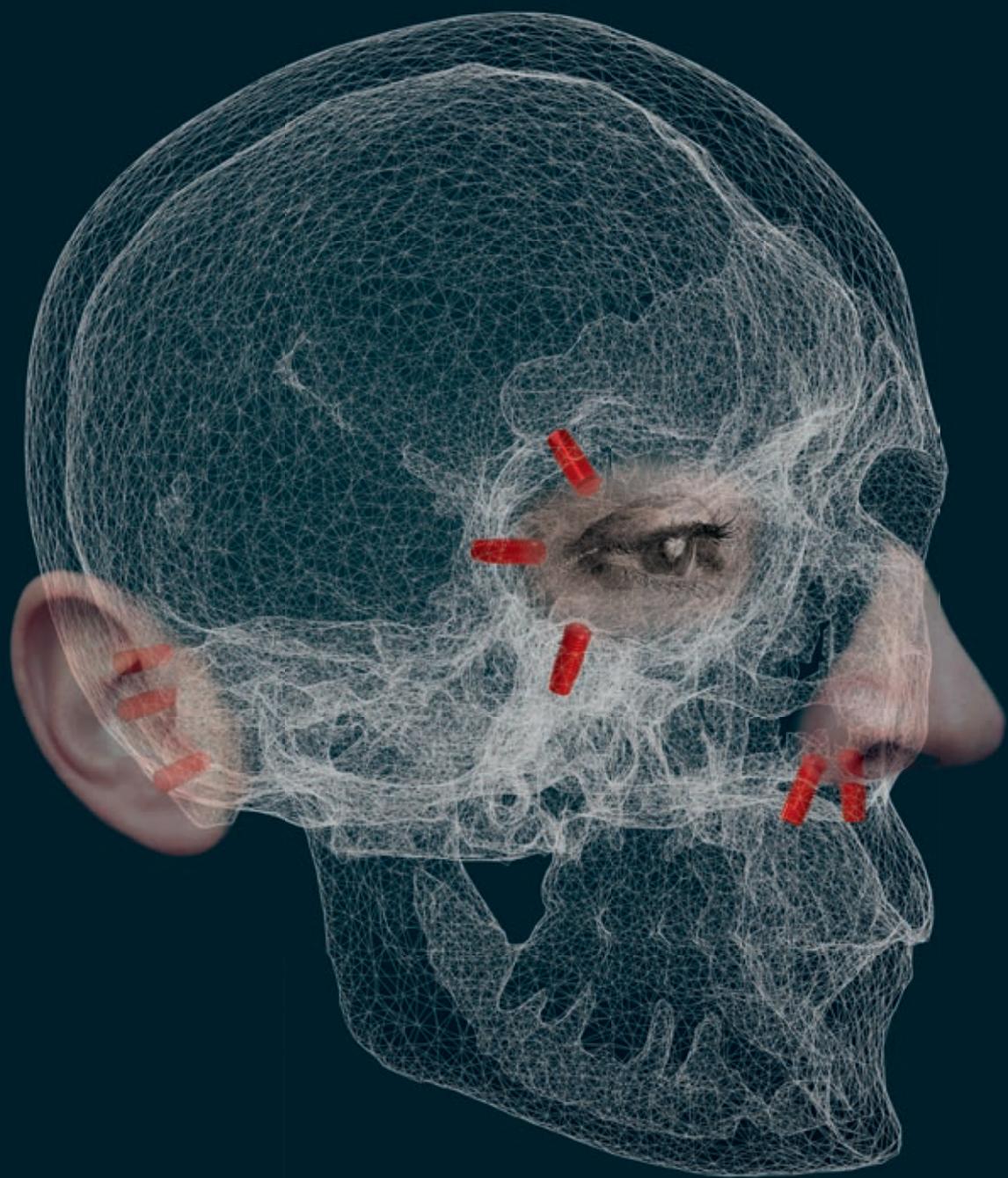
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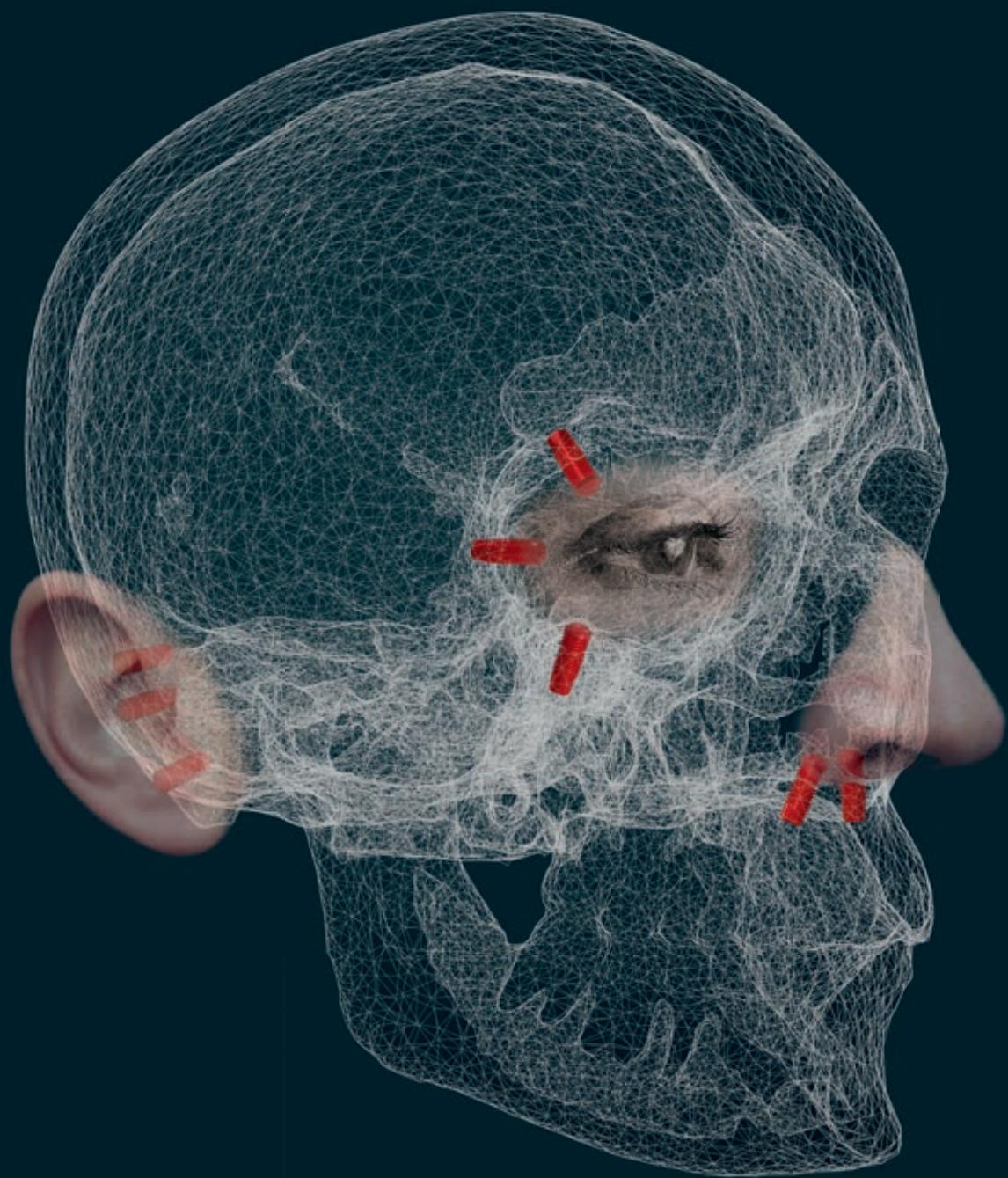
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# PART III

Timing of placement of  
craniomaxillofacial implants  
and survival rate



# Chapter 4

## Extra-oral implants – insertion per- or postablation?

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## ABSTRACT

Although the benefit of extra-oral implants in the reconstruction of maxillofacial oncological defects is undisputable, some relevant issues need to be clarified. The purpose of this retrospective study was to evaluate the relationship between implants placed during ablation (DA-implants) and after ablation (AA-implants) of the tumor with respect to implant survival. In total, 103 implants were assessed: 44 nasal implants (17 patients) and 59 orbital implants (18 patients). All patients received their implantretained maxillofacial epithesis between 1997 and 2010, with a mean follow-up of 35 months (range 8–156 months). The survival rate of DA-implants was 90.0% for the orbital region and 93.5% for the nasal region. The survival rate of the AA-implants for the orbital and the nasal region was 82.8% and 61.5%, respectively. This study shows a significant higher survival rate of extra-oral implants placed during ablative surgery compared to implants in a later stage ( $p = 0.044$ ), thereby stressing the importance of installing extra-oral implants during the ablative surgical session.

## INTRODUCTION

Maxillofacial defects may be the result of malformative or infective processes, trauma, or oncologic therapy. Most maxillofacial defects have an oncology-related origin, resulting in multiple functional, esthetical, and psychosocial difficulties<sup>1-3</sup>.

As replacement of an eye or nose by solely surgical means often results in a less cosmetic outcome compared with prosthetic rehabilitation, a prosthetic device is often chosen<sup>1,2,4-8</sup>. Understandably, mechanical retention of the prosthetic device is crucial. Conventionally, retention was achieved by using skin adhesives, obtaining hard and soft tissue undercuts, or attachment to glasses<sup>1,4,9-11</sup>. Since the success of intraoral endosseous implants, the osseointegration concept has also been introduced in maxillofacial defects, as it offers better predictability, prosthetic adaptability, and esthetics, resulting in higher convenience for patients<sup>12-14</sup>. Of utmost importance, in contrast with surgical reconstructions, prostheses allow cavities to be accessed for inspection of possible tumor recurrences<sup>9,15</sup>. Moreover, implant-supported extraoral prostheses, also called epitheses, have been shown to improve patient acceptance, level of function, and quality of life<sup>1,4,5,9,16-22</sup>. Disadvantages include the necessity of prosthetic and implant maintenance, periodic replacement of prostheses, and the risk of implant dislodgement when overloaded<sup>13</sup>.

Although the use of osseointegrated implants is an accepted treatment modality, many aspects in relation to oncologic therapy remain controversial, such as favorable time of placement and the role of hyperbaric oxygen (HBO) in case radiation therapy is applied<sup>23</sup>. In addition, implant survival is reported to be site specific and, amongst others, related to associated stress distribution at the bone-implant interface, irradiation dose, and fractionation<sup>8,13,16,18,24</sup>.

There are only a few studies determining the optimal timing of implant placement in relation to ablative surgery. The objective of the present study was to evaluate differences in survival time between extra-oral implants placed during ablation (DA-implants) of nose or orbit, compared to those placed in a later stage, the so-called after ablation (AA-) implants. The second objective is to determine differences in survival rate for implants placed before irradiation compared to implants, which are placed in already irradiated bone.

## Materials and methods

A retrospective study was conducted on 35 consecutive patients with osseointegrated implant-retained maxillofacial prostheses due to an oncologic disease. All patients were treated at the Departments of Oral and Maxillofacial Surgery and Special Dental Care of the Radboud University Nijmegen Medical Center (RUMC) and University Medical Center Utrecht (UMCU), the Netherlands between 1997 and 2010. Patient records were assessed for demographic data, tumor type and location and treatment (surgery, radiotherapy, and chemotherapy).

Medical and dental charts were reviewed to collect data on the number of implants placed, time of ablative surgery, radiation status, time and site of implant placement, and time of irradiation (Table 1).

**Table 1:** Craniofacial implant data regarding time of placement, radiation therapy and types of implants

		DA-implants (during ablation)	AA-implants (after ablation)
<b>Inserted before irradiation</b>	No. Implants	43	-
	RTX (SD)	60 (6.4)	-
	Time interval (months)	2 (range 1-3 months)	-
	No. of implants lost	4	-
	Follow-up (months)	33 (range 11-156 months)	-
	Succes rate	90.7%	-
	Types of implants	Astra (10) Branemark (29) Xive(4)	-
<b>Inserted after irradiation</b>	No. Implants	18	42
	RTX (SD)	57 (7.3)	58 (4.7)
	Time interval (months)	27 (range 20-36 months)	98 (12-300 months)
	No. of implants lost	1	10
	Follow-up (months)	30 (range 10-84 months)	39 (8-104 months)
	Succes rate	94.4%	76.2%
	Types of implants	Astra (3) Branemark (9) Xive (3) Unknown (3)	Astra (8) Branemark (13) Xive(14) IMZ (7)

Survival rates were based on osseointegration of the implant. If an osseointegrated implant needed to be removed or buried due to misplacement, it was still considered successful. The length of the observation period corresponded to the last relevant medical chart note or death of a patient. If HBO therapy was given, the consistency of

the protocol was controlled; 20 sessions before implant placement and 10 sessions, thereafter.

As the literature describes different survival rates with respect to implant location, patients were divided into two groups (orbital and nasal). This study comprised 18 orbital defects (59 implants) and 17 nasal defects (44 implants) among 19 men and 16 women with a mean age of 65.5 years (range 22–83 years) and 69.3 years (range 18–90 years), respectively (Table 2). Primary diseases are depicted in Table 2. The mean follow-up for orbital and nasal implants was 44 months (range 8–156 months) and 23 months (range 8–82 months), respectively.

**Table 2:** Overview of type of extraoral prostheses, time of placement, data on patients and no. of implants

Type of prostheses	Time of placement	No. of patients	Mean age in years	Gender ratio (male/female)	Primary disease (no. of patients)	No. of implants	Implant Failure	Success rate
Orbital	During ablation	9	73.4 (range 60–87)	4/5	- Basal cell carcinoma (2) - Squamous cell carcinoma (5) - Melanoma (5) - Osteosarcoma (1) - Other* (5)	30	3	90.0%
	After ablation	9	54.7 (range 18–82)	4/5		29	5	82.8%
Nasal	During ablation	11	71.4 (range 52–90)	7/4	- Basal cell carcinoma (4) - Squamous cell carcinoma (11) - Melanoma (2)	31	2	93.5%
	After ablation	6	66.7 (range 59–75)	4/2		13	5	61.5%
<b>Total</b>		<b>35</b>	<b>66.8</b>	<b>19/16</b>		<b>103</b>	<b>15</b>	<b>85.4%</b>

\* Adenocystic carcinoma (2), adenosquamous carcinoma, retinablastoma, rhabdomyosarcoma

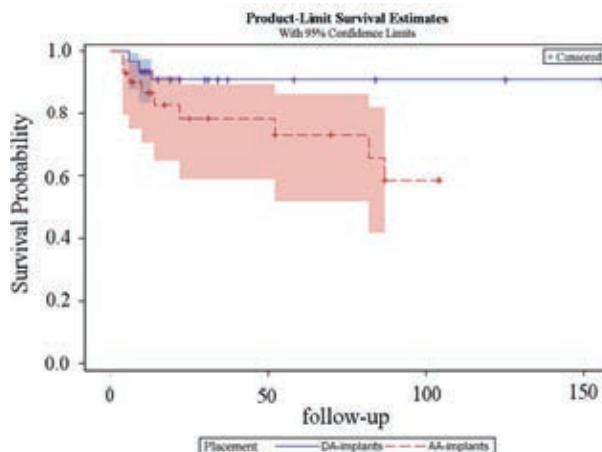
### Statistical analysis

Survival curves were estimated using the Kaplan–Meier product limit method. Between groups, the Kaplan–Meier curves were compared using the log-rank test. A p-value below 0.05 is considered statistically significant. Statistical analysis was performed using SAS 9.2 (SAS Institute Inc., Cary, NC, USA).

## RESULTS

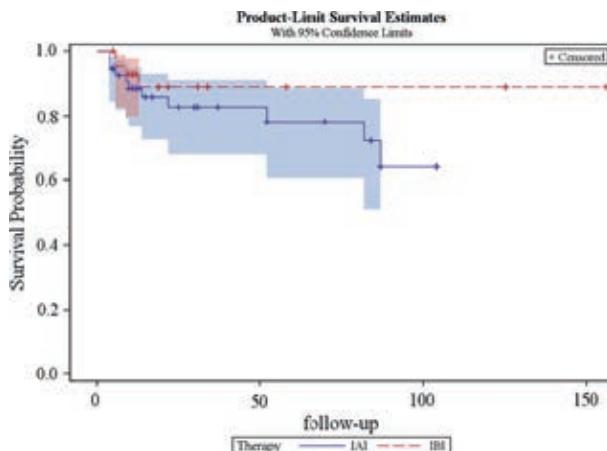
This study comprised 103 implants, of which 15 failed to integrate, three remained buried and two were removed due to cosmetic reasons. The mean survival time of the 85 functional implants was 32 months (range 8–156 months). The most common method of retention for both nasal and orbital epiphyses was bar splint and clip assemblies.

With respect to the time of implant placement in relation to the ablation, significantly ( $p = 0.044$ ) more implants were lost for the AA-implants (10 out of 42), compared to the DA-implants (five out of 61) (Table 1, Fig. 1).



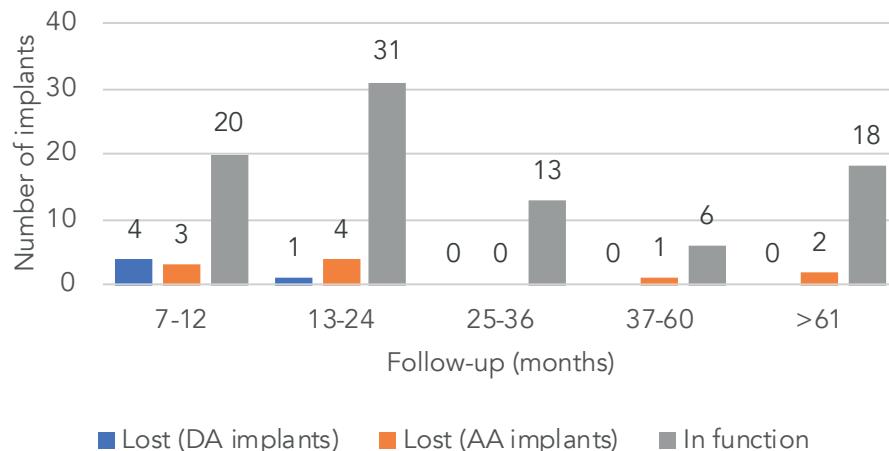
**Figure 1** Survival in extra-oral implants placed during (DA-implants) or after ablative surgery (AA-implants). (Difference between the two groups was evaluated by log-rank test and resulted statistically significant ( $p = 0.044$ )).

In total 60 implants were placed in already irradiated bone, of which 11 (18.3%) were lost. Of the 43 implants, installed in non-irradiated bone, and irradiated after the ablative surgery four (9.3%) implants failed. This difference was not significant ( $p = 0.225$ , Fig. 2).

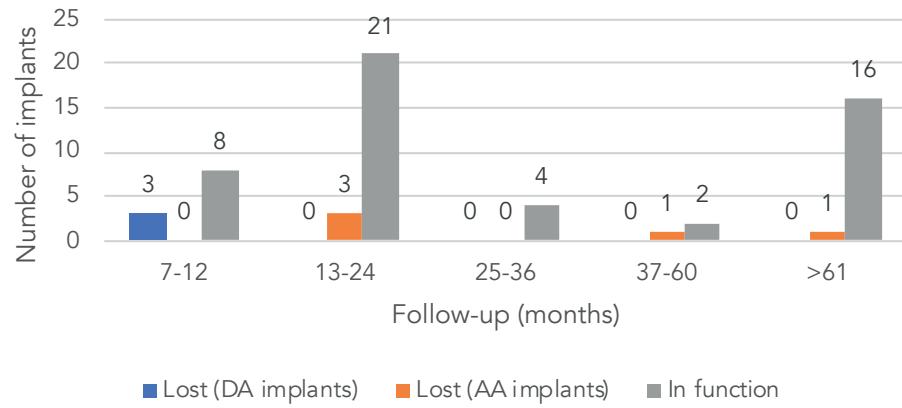


**Figure 2** Survival in extra-oral implants placed before (inserted before irradiation, IBI) or after irradiation therapy (inserted after irradiation, IAI). (Difference between the two groups was evaluated by log-rank test and resulted statistically nonsignificant ( $p = 0.225$ ).

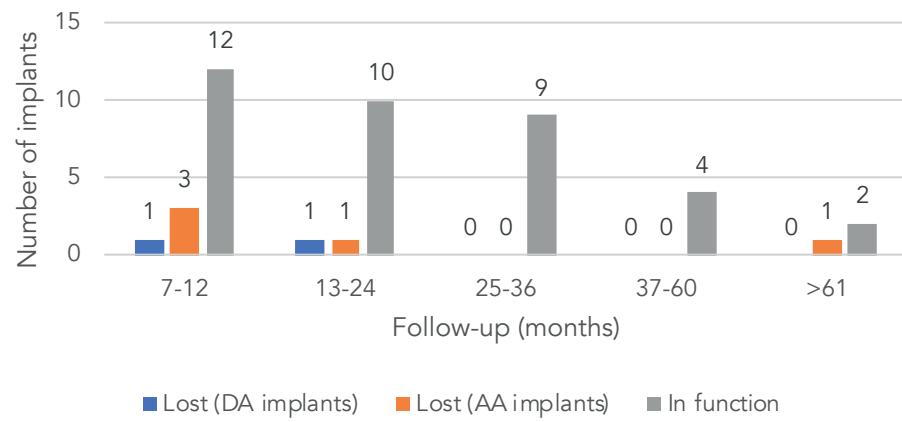
Three patients lost two implants, six patients lost one implant and one patient lost three implants. The follow-up periods of the orbital and nasal implants are depicted in Figs. 3–5. Loss of orbital and nasal implants occurred after 22.8 months (range 8–87 months) and 20.9 months (range 8–82 months) in function, respectively.



**Figure 3** Distribution of craniofacial implants according to the follow-up periods.



**Figure 4** Distribution of orbital implants according to the follow-up periods.



**Figure 5** Distribution of nasal implants according to the follow-up periods.

Two orbital implants were lost in the supraorbital rim, one in the lower rim and five at the lateral rim. Four implants were lost at the piriform site, one at the anterior nasal spine and two paranasal (horizontally positioned). Differences in implant loss between various anatomical implant locations were not significant ( $p = 0.408$ ).

Eleven patients (34 implants) received adjunctive HBO treatment, eight patients with 26 orbital implants and three patients with seven nasal implants. Conform to the protocol, HBO therapy was indicated for patients who received radiation therapy prior to their extra-oral implant surgery. It could not be shown that HBO significantly improved functional outcome of implants which were installed in already irradiated bone ( $p = 0.612$ ).

## DISCUSSION

This retrospective study focussed on the survival of endosseous implants in the orbital and nasal region in treated oncology patients in relation to the timing of placement.

The overall patient mortality following oncological orbital exenteration varies between 26% and 63% at 5 years<sup>25,26</sup>. Melanoma and adenocystic carcinoma are specifically reported to have a poor long-term survival<sup>26,27</sup>. However, prognosis is dependent on a large number of variables, such as surgical free margins, tumor location, origin, and extent, and histological cell type. As squamous cell carcinoma is mostly seen in the nasal cavity, the overall 5-year cumulative survival rate for different types of malignant tumors of this cavity has been shown to be approximately 50%<sup>28</sup>.

As reported in the literature reviews, survival rates for orbital and nasal implants vary between 33% and 100%<sup>8,16,29,30</sup>. This wide variation can be explained by the differences in treatment techniques, duration of follow-up, patient factors, and criteria for implant success<sup>1,10-12,18,23,31</sup>. The current study shows an 5 years overall implant survival rate of 90.1% for extraoral implants placed during ablative surgery and 65.8% for extraoral implants placed after ablative surgery. In our opinion loss of extra-oral implants is not caused by epithesioologic loading but primarily by factors related to osseointegration. However, because of the heterogenous data collected from two different departments over a longer period (1997–2010), comparison has to be taken carefully. Moreover, statistical analysis in this study is based on individual implants considering the observations as independent samples instead of taking multiple measurements in individual patients.

Extra-oral implants can be placed during ablative surgery or during a second surgical session. Literature shows no consensus regarding the time of implant insertion<sup>17,32-35</sup>. Maxillofacial prosthetic reconstruction poses a challenging positioning of implants with respect to bone quality and volume often being limited. Pre-operative surgical planning and preparation could enhance the success rate and produce a more predictive treatment and cosmetic outcome when gross alterations in the anatomical situation occur<sup>36</sup>. Other advantages of implant placement during ablative surgery are: avoidance of implant surgery in a area compromised by radiotherapy; more space for manipulation while placing implants; avoidance of additional surgery; opportunities for earlier prosthetic rehabilitation and cost difference in preventing extra operating

sessions<sup>34,36,37</sup>. However, optimal timing of inserting implants remains controversial with literature debating advantages in secondary placement including more accurate patient assessment or implant placement and less risk of interference with oncological therapy<sup>32,34,37</sup>. Disadvantages include placing implants in irradiated tissues with decreased vascularisation and regenerative ability. Collected data in this study significantly show favorable clinical outcomes for implants that are placed during ablative surgery ( $p = 0.044$ ).

Irradiation of the bone is the most well-known cause of implant failure<sup>8,34</sup>. Ablative oncology almost inevitably requires adjunctive radiotherapy and hence poses patients to known negative vascular and cellular side effects. As a result, the rate of remodeling of periimplant bone decreases, thereby compromising the bone–implant contact. This usually occurs during the early stage of the osseointegration process<sup>36,38–42</sup>. Subsequent failure of extra-oral implants seldom leads to osteoradionecrosis<sup>34,43</sup>. Some studies suggest recovery of bone perfusion 6–12 months after radiotherapy<sup>30,43</sup>. This study shows a slight favorable outcome for implants being placed in non-irradiated bone compared to implant inserted in irradiated bone with a mean time of 69 months (range 12–300 months) between irradiation and placement of implant (Table 1). Presumably, if initial healing is already commenced in a nonirradiated osseous environment, a higher bone–implant contact can be achieved. Due to the size of the cohorts and length of observation, our analysis could not lead to significant differences in survival of implants placed in irradiated versus non-irradiated bone. As this cohort is further enhanced with more patients, implants and longer follow-up, future data should employ to verify how irradiation influences (long-term) survival of extra-oral implants.

The relevance of HBO therapy as a requirement for successful maxillofacial implantation remains controversial<sup>16,44–47</sup>. Pre- and post-operative HBO therapy may improve the success rate of endosseous implants<sup>4,8,10,13,17,41,44</sup>. It is claimed to revitalize the bone through improvement of the tissue oxygen level, thereby increasing collagen synthesis, neovascularization, and activation of osteoblasts and osteoclasts in irradiated tissue<sup>16,41,44–48</sup>. The results of this study, however, could not ascertain an additive value for the already irradiated patients receiving HBO treatment.

Favorable locations for orbital prostheses are the lateral portion of the supraorbital rim and the lateral rim due to local increased thickness and bone quality<sup>6,12</sup>. In this study, no relationship between loss of implants and maxillofacial location could be established.

## CONCLUSION

Implants placed during ablative surgery lead to significantly higher survival rates compared to implants placed in a secondary procedure. We therefore recommend inserting implants immediately following ablative surgery.

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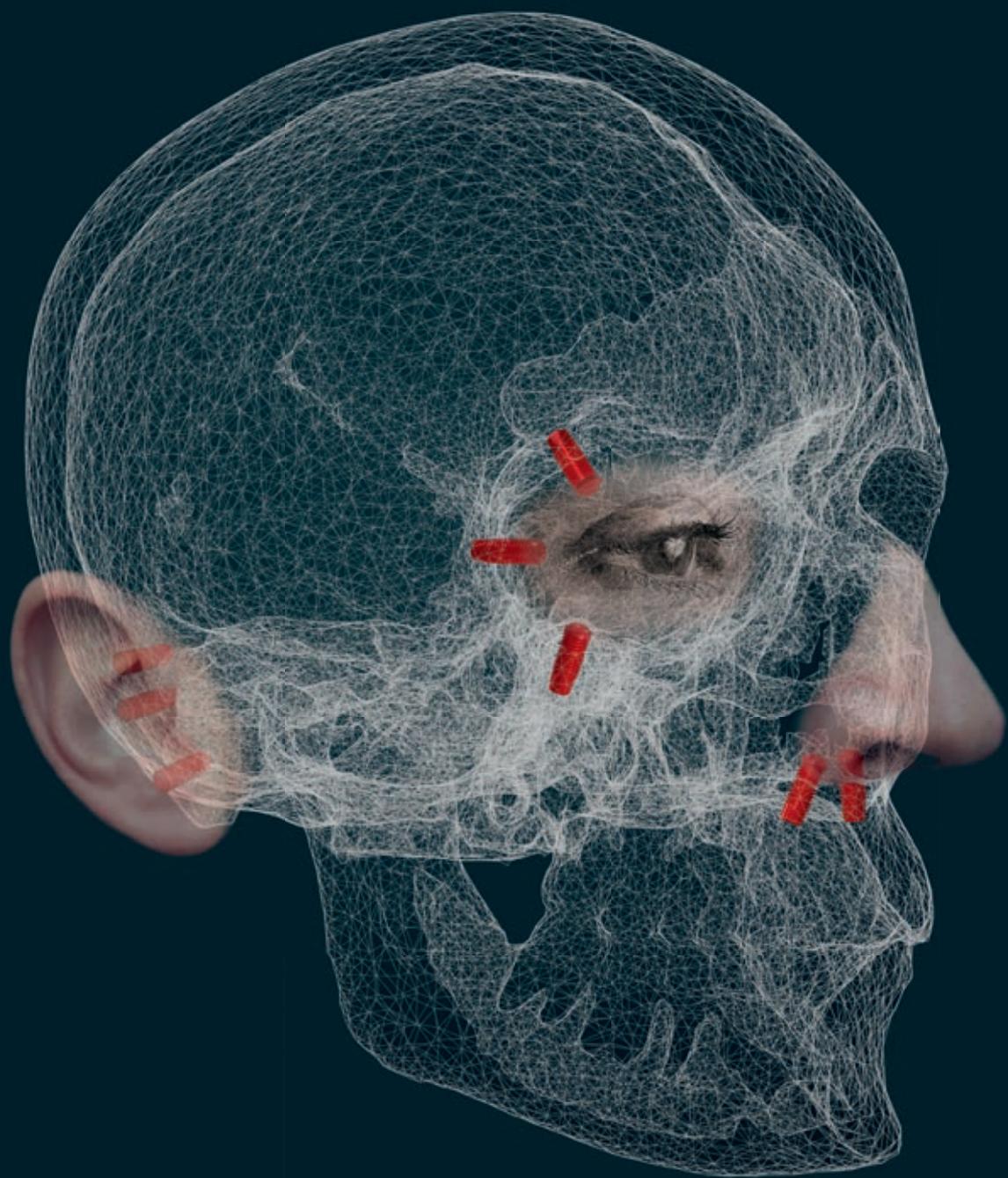
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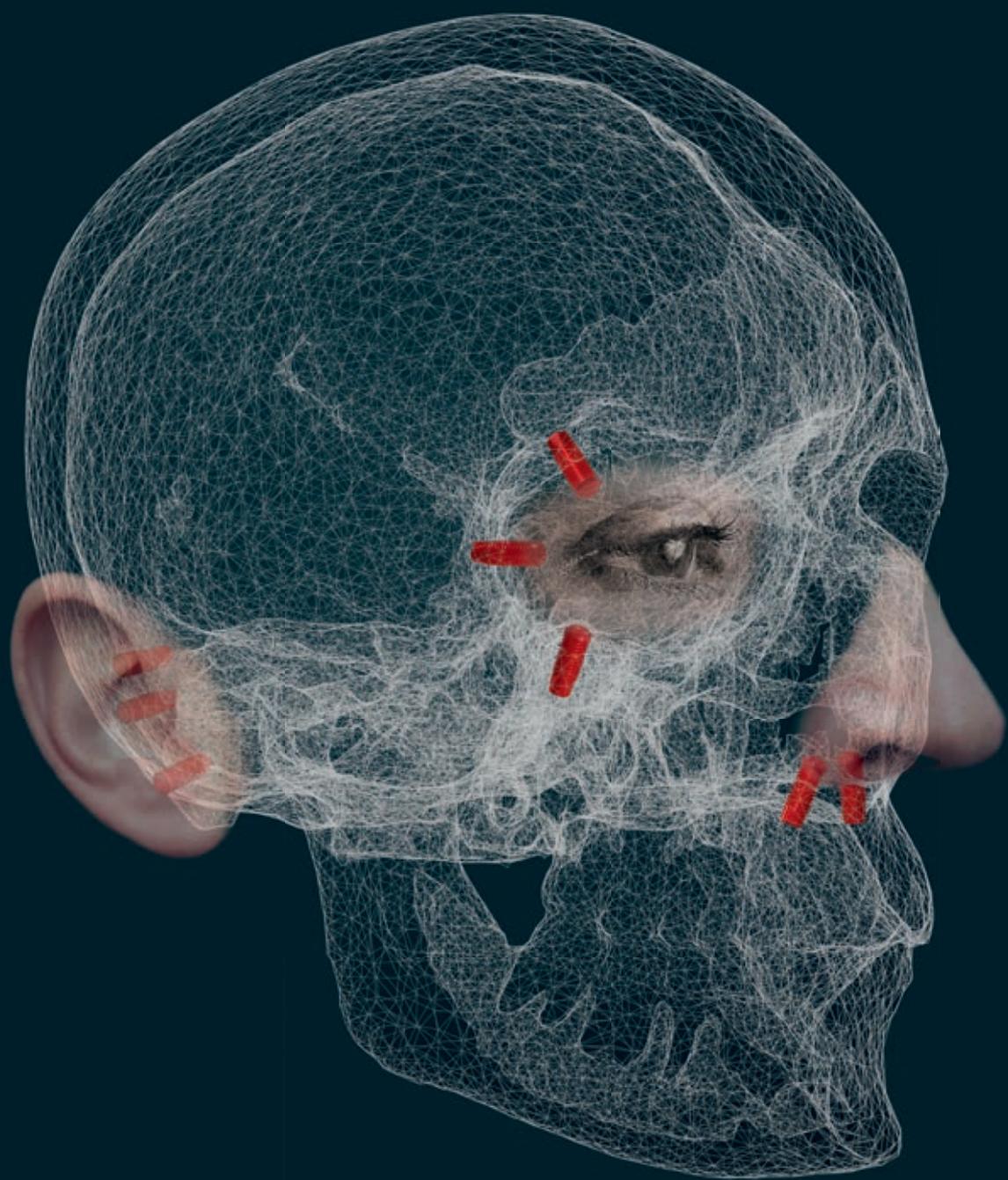
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# PART IV

Clinical outcome of  
craniomaxillofacial implant  
surgery



# Chapter 5

## Maxillofacial prosthetic rehabilitation: a survey on the quality of life

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## ABSTRACT

**Statement of problem.** Maxillofacial prostheses, especially those supported by endosseous implants, are regarded as a viable, secure treatment for the reconstruction of facial defects to restore quality of life.

**Purpose.** The purpose of this clinical study was to assess the long-term quality of life of patients treated with facial prostheses with different retentive systems over a 14-year period at a Dutch oral and maxillofacial surgery unit.

**Material and methods.** A total of 66 patients with facial prostheses were inventoried and categorized into anatomic location and type of retention. A 62-item questionnaire was designed to survey daily prosthetic use, care, quality, durability, longevity, and the reliability of retention. Furthermore, issues relating to general satisfaction, self-image, and socialization frequency were addressed.

**Results.** Completed validated questionnaires were returned by 52 patients. Of the prosthetic replacements, 23% (n=12) were orbital, 33% (n=17) nasal, and 44% (n=23) auricular prostheses. The survey showed that a prosthetic reconstruction led to high satisfaction scores with regard to wearing comfort, anatomic fit, color, and anatomic form. A significant difference was shown for implant-retained facial prostheses, which provided enhanced retention and increased ease of placement and removal (Fisher exact test  $P=.01$  and  $P=.04$ ). Patients with nasal prostheses were less satisfied with the junction of their prostheses to the surrounding soft tissue and more aware of others noticing their prosthetic rehabilitation. Patients with auricular defects were less embarrassed ( $P=.01$ ) by their prostheses. Although auricular prostheses were less frequently cleaned ( $P=.01$ ), no significant difference was found in minor soft tissue complications between different anatomic locations and the various retentive systems.

**Conclusions.** Implant-retained prostheses have advantages over adhesive-retained prostheses in terms of ease of handling. However, improvements in prosthetic material properties, including color stability and durability, are needed to increase the longevity of facial prostheses.

## INTRODUCTION

The face has a unique role in social and emotional expression and communication<sup>1,2</sup>. Maxillofacial defects, and their eventual reconstruction, may have important psychosocial implications in affected patients because social interactions and emotional expression depend mainly upon the structural and functional integrity of the head and neck region<sup>1,3-8</sup>. Maxillofacial prosthetic rehabilitation poses a valid alternative when surgical reconstruction is not feasible or desirable<sup>5,9-17</sup>. Traditionally, the retention of maxillofacial prostheses involved skin adhesives, anatomic undercuts, and connection to spectacles or intraoral prostheses<sup>14,18</sup>. The use of adhesives, however, has several disadvantages, including discoloration of the prosthesis, dermatologic reactions, and poor performance during activity or perspiration<sup>9,12,19</sup>. The introduction of craniofacial endosseous implants has improved the retention and stability of prostheses with low surgical risks and few postsurgical complications<sup>15,18,20,21</sup>. A successful prosthetic rehabilitation is one in which patients do not experience the prosthesis as an extraneous object and which improves function and esthetics from both a psychological and social point of view<sup>3,12,22</sup>. Another advantage of a prosthesis is the possibility of tumor surveillance compared with surgical reconstruction, which covers up the surgical defect<sup>17</sup>. Despite well-documented psychological benefits, maxillofacial prostheses are also subject to limitations, including material durability and color stability. These limitations necessitate frequent reprocessing of the prosthesis, which is time consuming for both patient and maxillofacial prosthodontist and costly for the patient<sup>15,18,23,24</sup>.

Patient satisfaction and the assessment of quality of life (QOL) is becoming increasingly important in the quality of care<sup>3,25</sup>. Treatment success and the level of reintegration is mainly determined by a subjective analysis of the patient<sup>23,25</sup>. Studies primarily focused on the subjective analysis of patients with facial prostheses in perceived QOL and using validated questionnaires are sparse, and their relevance is often limited by small numbers<sup>3,10,14,22,23,26</sup>. However, these studies have shown improvement in QOL after maxillofacial prosthetic treatment and the need for site- and treatment-specific questionnaires<sup>14,15,27</sup>.

The purpose of this clinical study was to assess patients' opinions and satisfaction regarding facial prosthetic rehabilitation considering different parameters such as localization, chosen treatment modality, and specific type of retention. Furthermore,

the research elicited patient satisfaction as to differences with adhesive-retained prostheses to determine the best treatment option. The null hypothesis was that patient overall satisfaction with maxillofacial prostheses would be similar for all locations of facial defects. In addition, patients with adhesive-retained prostheses would report similar responses to those with implant-retained prostheses with regard to daily prosthetic use, retention, and socialization.

## MATERIAL AND METHODS

A total of 66 patients with a prosthesis of the ear, nose, or orbit were included. Patients had at least 12 months of experience wearing a facial prosthesis. No patients were excluded based on demographic data, defect etiology, or type of retention, except those deceased, lost to follow-up, or having combined prostheses or local recurrence of the malignant process. None of the authors were involved in fabricating the facial prostheses for the patients. All patients had been surgically and prosthetically treated between 1997 and 2013 at the Departments of Oral and Maxillofacial Surgery and Special Dental Care of the Radboud University Nijmegen Medical Center (RUMC), the Netherlands. The study protocol was approved by the medical ethical committee of the faculty. No separate analysis was performed to determine the number of specimens required in each separate test group, since this study aimed to maximize the group of respondents out of a limited number of patients with maxillofacial prostheses.

The cohort of patients was stratified according to the anatomic location of the defect and adhesive-retained versus implant-retained prostheses. The group with implant-retained prostheses was further divided into patients with magnetic or bar-clip retentive systems and those with or without previous experience of adhesive-retained prostheses. Patient data were confirmed with medical and dental charts (age, sex, prosthetic type, smoking, duration of time since cancer surgery, and prosthetic rehabilitation).

A comprehensive questionnaire to assess satisfaction with maxillofacial prosthetic rehabilitation was constructed in consultation with prosthodontists and psychologists and was reviewed by a statistician. The questionnaire contained 62 questions with multiple-choice answers or on a 5-point Likert rating scale. This scale varied from 'fully disagree' to 'fully agree.' Items evaluated as a score of 1 were considered negative, while

5 represented a positive appreciation. The questions were evaluated by lay people who identified no confusing or unclear questions and indicated no apparent need for reduction in items. Overall satisfaction was based on 12 questions on the 5-point Likert rating scale that inquired after the feel of the prosthetic material; junction of the prostheses to surrounding soft tissue, whether making facial expressions or not; similarity in color of skin, tendency to discoloration; shape of the prostheses; and obtained facial symmetry.

Daily prosthetic use was evaluated by 23 multiple choice questions inventorying how many hours and on which occasions the prosthesis was worn and identifying potential wear and durability by obtaining information on personal experiences, reasons for replacement, decrease in retention, and loss of superstructures or implants. User friendliness with regard to placing and removing of the prostheses was determined by 3 questions on the 5-point Likert rating scale and anchor terms. Twelve multiple choice questions focused on socialization by determining the level of functioning, self-esteem, body image, sexual role, and interference in social and job activities.

Patients could complement their responses with specific time spans and numbers, possible reasons for prosthetic replacement, and their general opinions and recommendations. Furthermore, 2 multiple choice and 2 open-ended questions asked patients who had previously worn adhesive-retained prostheses about differences between implant- and adhesive-retained prostheses with regard to quality of retention, ease of (daily) use, cleaning regimen, and varying time lengths till wear occurred.

All questionnaires were sent with an accompanying letter explaining the objectives and confidentiality of the study, asking patients to participate, and obtaining informed consent. A stamped, self-addressed envelope for return of the questionnaire was included.

Fisher exact tests were used to assess the difference in proportions between groups. Patient satisfaction scores for each question were statistically analyzed by 2-way analysis of variance (ANOVA) with type of defect and type of retention as factors (no interaction) ( $\alpha=.05$ ).

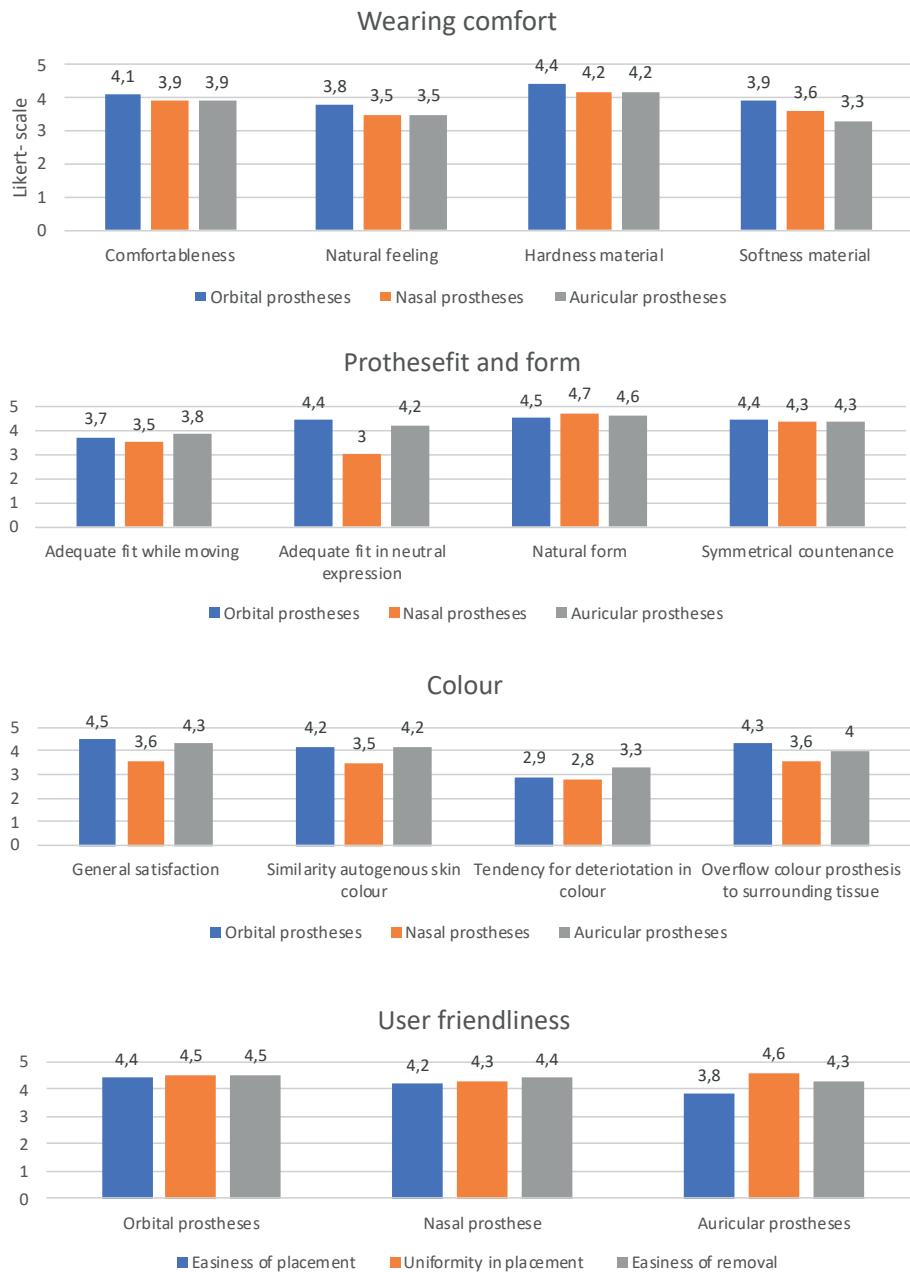
## RESULTS

A total of 66 patients with orbital, nasal, or auricular prostheses were mailed a questionnaire. Completed questionnaires were returned by 52 patients (79%). Their medical characteristics are given in Table 1.

**Table 1.** Distribution of population and prosthetic characteristics

	Orbital (12 patients)	Nasal (17 patients)	Auricular (23 patients)
Age in years: mean (range)	66.8 (39-82)	74.5 (59-93)	58.7 (21-88)
Sex	5 males / 7 females	10 males / 7 females	14 males / 9 females
Follow-up period in months: mean (range)	102 (21-291)	45 (17-109)	77 (24-197)
Retention type	3 bar-clips 7 magnet 2 adhesive	8 bar-clips 6 magnet 3 adhesive	12 bar-clips 2 magnet 9 adhesive
Defect etiology	12 oncology	17 oncology	1 trauma 8 congenital 7 oncology 7 unknown
Number of implant retained prostheses (range)	4.9 (2-16)	2.9 (1-10)	4.3 (1-10)
Years of functioning: mean (range)	2.2 (0.25-6)	1.4 (0.5-2)	2.6 (0-10)

Internal consistency of the questions against the 5-point Likert rating scale showed a Cronbach  $\alpha$  coefficient value of 0.82. None of the respondents mentioned having difficulties in understanding the questions. Fourteen patients (27%) wore adhesive-retained prostheses (9 auricular, 3 nasal, 2 orbital), and 38 patients wore implant-retained prostheses (73%), of whom 14 stated having previously worn adhesive-retained prostheses (7 nasal, 5 orbital, 2 auricular). No statistically significant differences based on age or sex were observed. With respect to 'wearing comfort,' no statistical differences in perception of materials with regard to anatomic location ( $P=.06$ ) and means of retention ( $P=.11$ ) were identified (Fig. 1).



**Figure 1.** Outcome Likert scales on wearing comfort, prosthesis fit and form, color, and user friendliness for different anatomic locations

Mean satisfaction scores were high on the anatomic form of the prosthesis and achieved symmetry of the face for all prostheses (Fig. 1). In comparison with the orbital and auricular region, nasal prostheses scored statistically significantly lower while holding the face in a neutral expression ( $P=.04$ ). Figure 1 shows the results on satisfaction with the characteristics of the color of the prostheses. Undesirable color change was noted at 11 months for orbital (range 1-36) and 10 months for nasal (6-16 months) and auricular prostheses (0-24 months). No statistically significant difference was found ( $P=.09$ ). No clear relation with smoking could be established.

Orbital, nasal, and auricular prostheses were worn for 18, 14, and 14 hours per day. Only 1 patient stated that he did not wear his adhesive-retained nasal prosthesis because of allergic reactions. Seventy-six percent of the respondents reported wearing their prostheses during the day. The remaining respondents also wore their prostheses while sleeping (36% of orbital prostheses, 7% of nasal prostheses, and 19% of auricular prostheses). One patient with a magnet-retained nasal prosthesis responded that he wore his prosthesis solely during social outings. None of the patients used devices to help place or remove their prostheses. However, 3 patients needed others to help apply the adhesives; one patient with an orbital prosthesis and 2 patients with an auricular prosthesis. With regard to anatomic location of the prosthesis, no statistically significant difference was found in 'ease of placement' ( $P=.59$ ) and 'ease of removal' ( $P=.92$ ). However, both activities proved more difficult with adhesive-retained prostheses ( $P=.01$  and  $P=.04$ ).

The longevity of maxillofacial prostheses was mainly determined by the fading of color (43.8% of auricular prostheses and 55.6% of nasal prostheses), independent of the type of attachment. The other main factor with nasal prostheses was the suboptimal junction (25%). With auricular prostheses, the wear of the silicone material (19%) and the suboptimal junction (22%) were prominent complaints. Magnets and adhesive attachments were equally divided with respect to the 'fading of color' of the silicone material, the suboptimal fit of the prosthesis, or the suboptimal junction of the silicone at the skin. Orbital prostheses with a bar-clip attachment ( $n=2$ ) only needed replacement because of color fading.

Seven patients reported the loss of an implant (2 orbital, 4 nasal, and 1 auricular prosthesis) with an equal distribution of type of attachment. Only 1 patient with a nasal prosthesis and 2 patients with an auricular prosthesis reported breakage of the bar-

clip system. Patients noted the loss of retentive force for bar-clip systems after a mean period of 14.4 months for nasal (n=5) and 10.5 months for auricular prostheses (n=6). None of the patients with orbital prostheses with bar-clip attachments reported loss of retention.

The results reveal that 46.1% of respondents reported minor soft tissue complications, such as slight redness of the peri-implant tissue. Seventy-three percent cleaned their prostheses and surrounding soft tissues daily. The remaining patients, of whom 73% wore auricular prostheses, cleaned their prosthesis only 2 or 3 times weekly. This difference was statistically significant ( $P=.01$ ). Prostheses and skin were mainly cleaned with soap and water. However, 6 patients used disinfectant alcohol or stain-removing powder. No relation with earlier deterioration in color or material properties could be established. In addition, 12 patients described protecting their prostheses from environmental influences by using sunblock hats (n=4), eyeglasses (n=3), or an eye patch (n=1) or by covering the auricular prostheses with hair (n=4).

Statistically significantly more patients with nasal prostheses felt noticed by others in their environment ( $P=.01$ ). Fewer patients with auricular prostheses felt embarrassed to show their defect in different social environments ( $P=.01$ ). However, questions concerning psychological and social aspects revealed no further statistically significant differences for anatomic location or type of attachment. For type of prosthesis, an equal distribution was found for patients who gained in self-confidence (44%) (Table 2).

Finally, patients were asked to score their prostheses using the traditional Dutch grading scale, which is based on a numeric scale from 0 to 10, where 10 represents the highest general satisfaction rate. In addition, patients were asked for suggestions on improvement (Table 3).

Responses to open-ended questions corresponded with earlier findings of the questionnaire, with patients suggesting improvement of color stability, longevity, and a more pleasant feeling of the prosthetic material. Two patients who previously wore adhesive-retained prostheses noted hygiene as an advantage over bar-clip systems. Two other patients regarded adhesive-retained prostheses as more user friendly (1 nasal, 1 auricular prosthesis).

**Table 2.** Influence of retentive mechanisms and anatomic location on psychological and social aspect

	Orbital prostheses (12 patients)						Nasal prostheses (7 patients)						Auricular prostheses (23 patients)						Orbital prostheses (12 patients)						Nasal prostheses (7 patients)											
	Bar-clip (3 pt.)			Magnet (7 pt.)			Adhesive (2 pt.)			Total (12 pt.)			Bar-clip (8 pt.)			Magnet (6 pt.)			Adhesive (3 pt.)			Total (17 pt.)			Bar-clip (12 pt.)			Magnet (2 pt.)			Adhesive (9 pt.)			Total (22 pt.)		
	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n						
I dont regard my prosthesis as part of myself (no. of patients)	-	1	-	1 (8)	3	-	1	1	4 (23)	-	1	1	2	1	2	3 (13)	2	6 (26)	13 (25)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)			
Negative influence on mood	1	1	1	3 (25)	2	1	1	1	4 (24)	3	1	2	2	2	2	2	6 (26)	13 (25)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)				
Negative influence on leisure	-	-	2	2 (17)	3	-	-	-	3 (18)	3	-	2	2	2	2	5 (22)	10 (19)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)	8 (15)					
Negative influence on school/work	-	-	-	0 (0)	-	-	-	1	1 (6)	-	-	1	1	1	1	1 (4)	2 (4)	1 (4)	1 (4)	1 (4)	1 (4)	1 (4)	1 (4)	1 (4)	1 (4)	1 (4)	1 (4)	1 (4)	1 (4)	1 (4)	1 (4)					
Negative influence on social activities	1	-	-	1 (8)	2	-	-	-	2 (12)	2	-	2	2	2	2	2	4 (17)	7 (14)	7 (14)	7 (14)	7 (14)	7 (14)	7 (14)	7 (14)	7 (14)	7 (14)	7 (14)	7 (14)	7 (14)	7 (14)	7 (14)	7 (14)				
Negative influence on sexual activity	-	-	-	0 (0)	1	-	-	1	1 (12)	-	-	-	-	-	-	0 (0)	2 (4)	2 (4)	2 (4)	2 (4)	2 (4)	2 (4)	2 (4)	2 (4)	2 (4)	2 (4)	2 (4)	2 (4)	2 (4)	2 (4)	2 (4)					
Others notice my prosthesis	2	4	1	7 (58)	7	4	1	1	12 (71)	2	-	-	4	4	4	4	6 (26)	25 (48)	25 (48)	25 (48)	25 (48)	25 (48)	25 (48)	25 (48)	25 (48)	25 (48)	25 (48)	25 (48)	25 (48)	25 (48)	25 (48)					
I am embarrassed by my prosthesis	-	-	-	0 (0)	1	-	1	-	1	2 (12)	-	1	1	1	1	1	1 (4)	3 (6)	3 (6)	3 (6)	3 (6)	3 (6)	3 (6)	3 (6)	3 (6)	3 (6)	3 (6)	3 (6)	3 (6)	3 (6)	3 (6)					
My self-esteem is improved by my prosthesis	2	3	1	6 (50)	3	2	1	1	6 (35)	8	-	-	3	3	3	3	11 (48)	23 (44)	23 (44)	23 (44)	23 (44)	23 (44)	23 (44)	23 (44)	23 (44)	23 (44)	23 (44)	23 (44)	23 (44)	23 (44)	23 (44)	23 (44)				

**Table 3.** Rating of general satisfaction of prostheses on different anatomical locations having different retentive mechanisms

Score (0-10)	Orbital prostheses			Nasal prostheses			Auricular prostheses		
	Bar-clip (n=3)	Magnet (n=7)	Adhesive (n=2)	Bar-clip (n=8)	Magnet (n=6)	Adhesive (n=3)	Bar-clip (n=12)	Magnet (n=2)	Adhesive (n=9)
Score implant-retained prostheses	9.7 (SD 0.6)	8.0 (SD 1.2)	7.0 (SD 1.4)	7.7 (SD 2.3)	7.8 (SD 1.2)	6.5 (SD 2.1)	8.9 (SD 0.8)	8.5 (SD 0.7)	8.3 (SD 1.4)
Score previous prostheses with adhesive attachment	n=1 0.0	n=4 3.0	n=0 - (SD 1.8)	n=4 - (SD 0.6)	n=3 5.5 (SD 0.6)	n=0 4.7 (SD 1.5)	n=2 - (SD 0.0)	n=1 8.0 (SD 0.0)	n=0 1.0 (SD 0.0)

## DISCUSSION

The data from this study led to the rejection of the null hypothesis that no differences would be found in overall satisfaction between the locations of facial defects and the types of retention for maxillofacial prostheses. Only the placement and removal of the prostheses were shown to be statistically significantly more difficult with adhesive-retained prostheses. No differences could be established between different retention systems and psychological or social aspects. In addressing all important details, the questionnaire was lengthy, containing more than 62 items. However, no remarks about the number of questions were received from any of the respondents.

Although the number of respondents was greater than in previous research and representative of the whole group, one limitation of the present study was the total number of patients included. Maxillofacial prostheses are sparse, and, as with most studies, our research was based on a heterogeneous and reduced cohort with different follow-up periods necessitating greater longitudinal comparison<sup>4</sup>. Difference in longevity may allow patients with longer survival to develop coping strategies.

The distribution by patient sex (56% male, 44% female) demonstrated similar proportions of the sexes as reported in previous studies<sup>23</sup>. In contrast with other studies, where women have been shown to be more susceptible to depressive symptoms, no statistical differences for age or sex were observed<sup>2</sup>. Although the influence of social support on the psychosocial functioning of the individual patient was not evaluated, available support can suppress depressive symptomatology<sup>2</sup>.

Atay *et al*<sup>3</sup> stressed that patients with nasal prostheses scored worse in all domains of QOL because the nose plays a key role in facial appearance and social interactions. In contrast, no such difference was shown in the present study, with only a few patients with auricular prostheses being embarrassed to show their defect in different social environments ( $P=.01$ ).

The longevity of maxillofacial prostheses in the present study varied from 0.5 to 10 years with a mean of 26, 17, and 31 months for orbital, nasal, and auricular prostheses. Whether this difference is caused by material properties or behavioral factors such as 'frequency of removing,' 'cleaning,' or 'maintaining of the prosthesis' is unclear. Karakoca *et al*<sup>15</sup> and Hooper *et al*<sup>22</sup> reported a mean life span of maxillofacial prostheses of 1 to 1.5

years. Visser *et al*<sup>19</sup> demonstrated a survival time of 1.5 to 2 years with some prostheses having a life span of more than 5 years.

Ideal prosthetic material properties include durability, biocompatibility, flexibility, ease of cleaning, and lightness<sup>11</sup>. The maxillofacial prostheses in this study were made of heat-polymerized and autopolymerizing silicone. Autopolymerizing silicone is the material of choice<sup>15,24</sup>. The majority of patients (86%) responded that they were comfortable wearing their prostheses; a few remarked on the hardness of the material (5%). Satisfaction is directly related to appropriate retention delivered by craniofacial implants. Several studies showed significant improvements with implant-retained facial prostheses in all domains of QOL in comparison with adhesive-retained groups<sup>5,10</sup>. In the current study, the distribution of prosthetic retention type was consistent with that of other studies<sup>17</sup>. In contrast with the findings of Nemli *et al*<sup>14</sup> and Goiato *et al*<sup>5</sup>, overall patient satisfaction scores were similar for the various retentive mechanisms. However, although not statistically significant, patients did tend to give higher scores for bar-clip systems. As in the studies of Chang *et al*<sup>10</sup> and Smolarz-Wojnowska *et al*<sup>8</sup>, the handling of implant-retained prostheses proved statistically significantly better than the adhesive-retained methods ('ease of placement' ( $P=.01$ ) and 'ease of removal' ( $P=.04$ )).

The choice of retentive mechanisms depends on the number of implants, flexibility of the prosthesis, and local anatomic aspects. Bar-clips are the most indicated system for retention of auricular prostheses<sup>13</sup>. Three patients with bar-clip-retained prostheses reported on mechanical failures of the acrylic resin substructure or the retentive structures. This is in accordance with previous studies where requirements for clip revision and repair are described as disadvantageous compared with the use of magnets<sup>12,15</sup>. Magnets are mostly used for orbital defects<sup>13</sup> and can compensate for nonparallelism of the installed implants. Moreover, magnets induce relatively low lateral forces and minimize the amount of stress delivered to the implants<sup>21</sup>. Current magnetic systems increase ease of use, are simple to clean, and have adequate retention<sup>12,13</sup>. In the present study, only one patient wearing an implant-retained orbital prosthesis with a magnet system reported troublesome dislodgment of his prosthesis at inopportune times, such as during exercise.

No statistically significant differences were shown in the prevalence of minor soft tissue complications with regard to different retentive mechanisms, although some

respondents reported the limiting aspect of bar-clips on local hygiene. This is in accordance with reports describing limited access for cleaning in the presence of bar-clip systems<sup>8,21</sup>. Nemli *et al*<sup>14</sup> reported a higher frequency of dermatologic problems for auricular prostheses as compared with nasal and orbital prostheses. No such difference was found in the present study, although auricular prostheses were statistically significantly cleaned less frequently ( $P=.01$ ) than other maxillofacial prostheses. Seven respondents reported the loss of 1 or more implants, 4 of whom had received radiation therapy. Bone irradiation is the best-known cause of implant failure, and implants in the temporal region tend to have the highest rate of success<sup>8,17,18,20</sup>.

Results in this study revealed negative influences of prostheses on mood (25.0%), leisure (19.2%), and social activities (13.5%). The extent to which this negative influence hampered social life was not specified. Negative influence on educational or working activities and diminished feelings of sexuality were only mentioned by 2 patients, 79 and 91 years old, indicating that the majority of (younger) patients were unaltered in their attitudes and habits. Respondents with nasal prostheses, more than others, felt their prostheses were noticeable ( $P=.01$ ). This was corroborated by Atay *et al*<sup>3</sup>, who showed the nasal region to be one of the most important features determining total facial appearance.

Larger and multicenter studies are needed to draw generalized conclusions on the impact of maxillofacial prosthetic rehabilitation on overall treatment satisfaction and patient quality of life. Future research should also focus on enhancing material durability and color stability to improve the service life of prostheses.

## CONCLUSIONS

Based on the findings of this survey, the following conclusions were drawn:

1. The overall acceptance of maxillofacial prostheses was good, showing high satisfaction with anatomic form, color, and wearing comfort.
2. Implant-retained prostheses provided more ease of placement and removal than traditional adhesive techniques.

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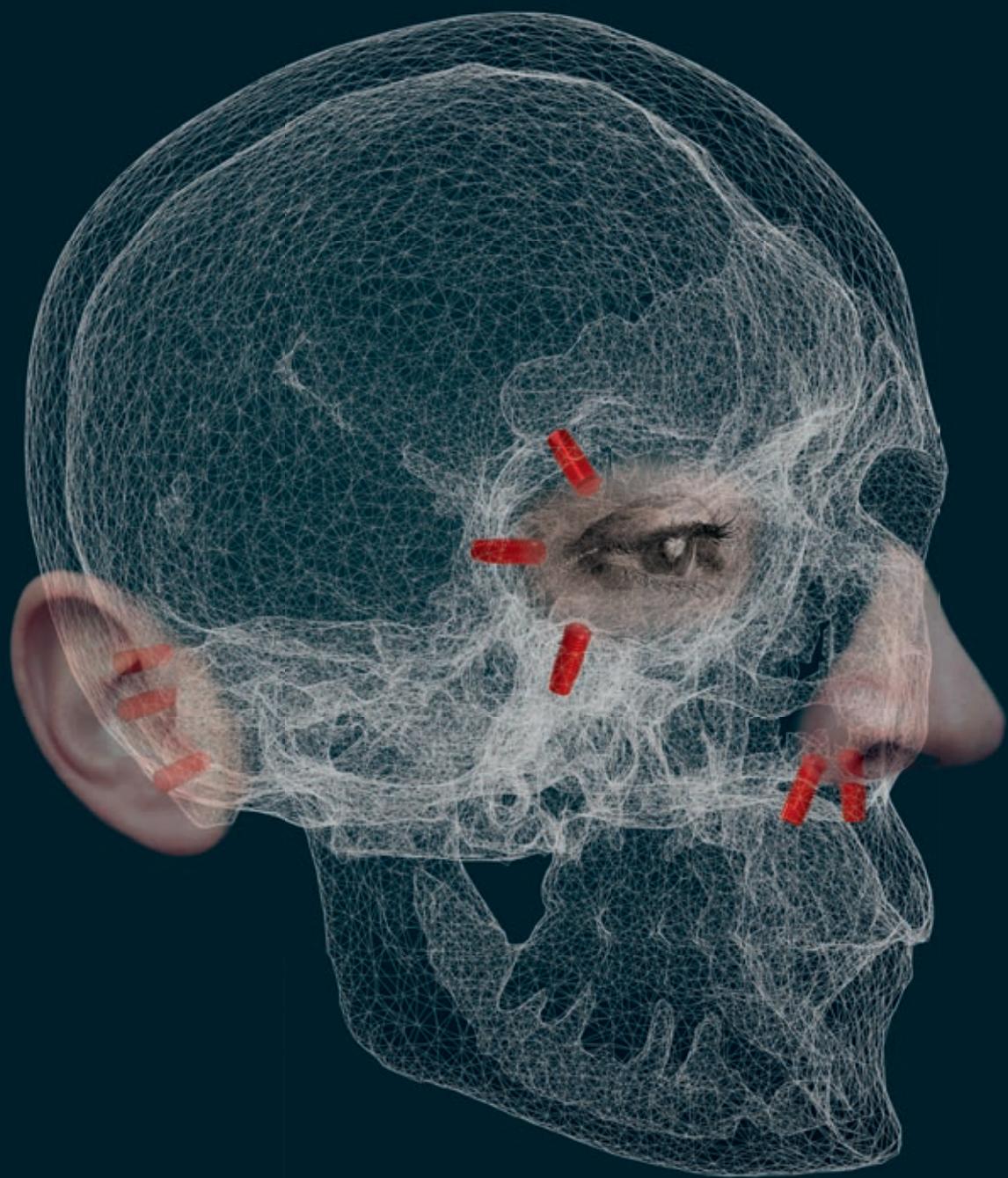
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## Appendix: Questionnaire



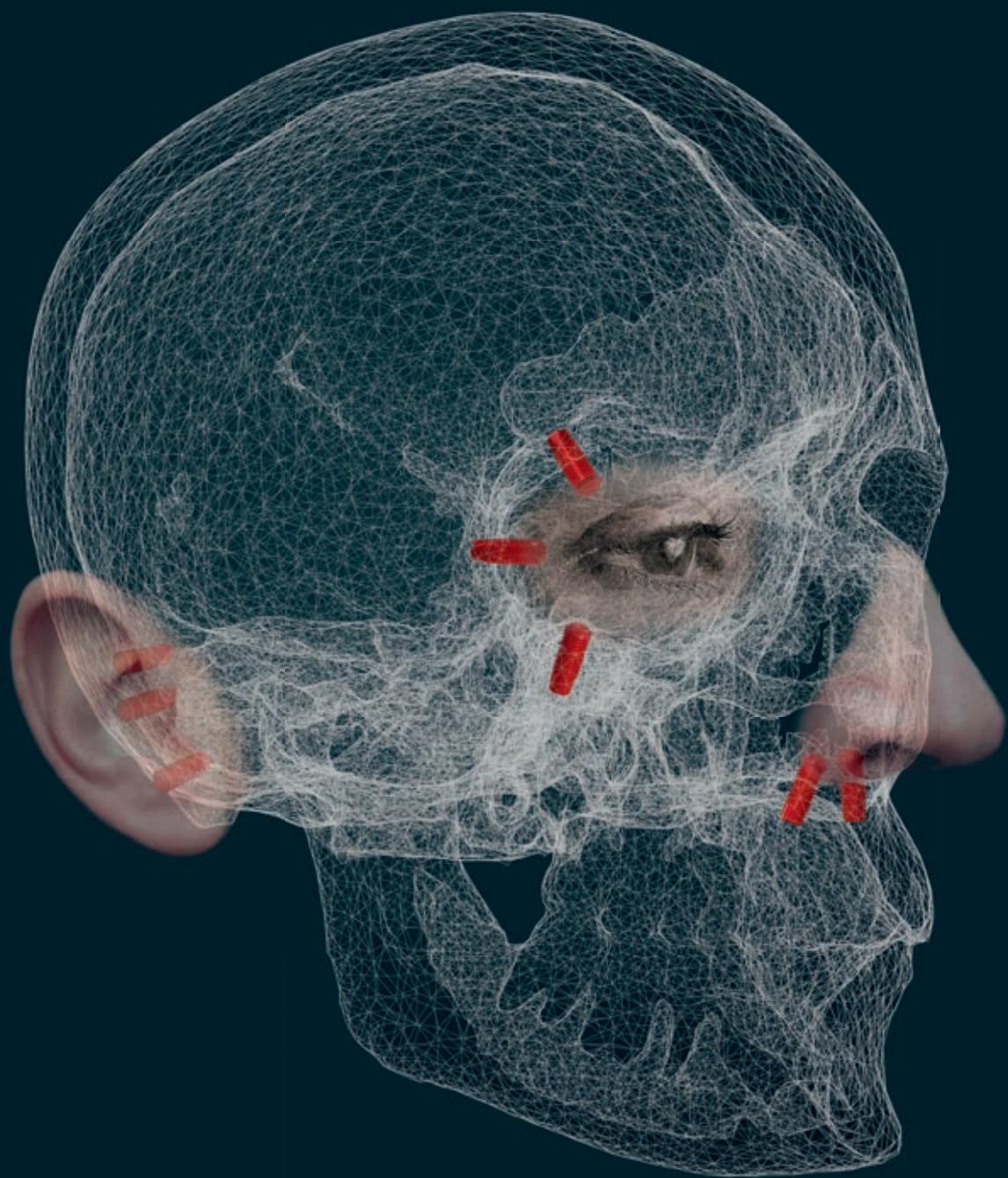
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# PART IV

Clinical outcome of  
craniomaxillofacial implant  
surgery



# Chapter 6

## Autologous versus prosthetic nasal and auricular reconstruction – patient, professional and layperson perceptions

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## ABSTRACT

The aim of this study was to retrospectively evaluate the perceptions of aesthetic outcome following the autologous and prosthetic reconstruction of nasal and auricular defects among patients, professionals (oral and maxillofacial surgeons and ear, nose and throat surgeons) and people unfamiliar with reconstructive surgery. The influence of anatomical subunits on the overall perception of nasal and auricular reconstructions was also determined. A total of 119 patients treated for nasal and auricular defects between 1997 and 2016, with a minimum follow-up period of six months, were selected, and photographs of 77 of these patients (65%) were presented in a digital survey and reviewed using a standardised questionnaire. No clinically relevant correlations were found between the age or gender of patients (as well as those of the respondents) and their scores. Prosthetic reconstructions of nasal and auricular defects were considered advantageous over autologous reconstructions in terms of the subjective aesthetic outcome in the view of the professionals, in particular oral and maxillofacial surgeons; however, the patients judged both techniques to be equally effective in terms of aesthetics. No anatomical subunits were found to have a significant impact on the overall match of a nasal or auricular reconstruction with the patient's face.

## INTRODUCTION

Craniomaxillofacial (CMF) defects resulting from congenital malformation, cancer or trauma are generally considered severe impairments and can be functionally and emotionally devastating<sup>1</sup>. The recovery of a natural appearance and function through reconstructive surgery is important for patients to achieve social integration and enhance their quality of life<sup>2</sup>. The rehabilitation of CMF defects as complex as an absent nose or ear can be challenging for the surgeon however, as the final result is difficult to predict<sup>3-5</sup>.

In 1977, the first introduction of osseointegrated implants to regions outside the oral cavity marked an important step in the reconstruction of CMF defects<sup>6</sup>, making prosthetic reconstruction a viable and effective alternative to autologous reconstruction<sup>5,7</sup>. The drawbacks of prosthetic rehabilitation include the need for daily care, implant-related problems and the short lifespan of the prosthesis<sup>4,5,7</sup>.

Because most CMF defects are unique in size and shape, it can be challenging to find the optimal treatment plan for each individual patient. The choice of treatment modality depends on multiple factors, including the characteristics of the defect (size, location and aetiology), the motivation and physical condition of the patient, and the need for multidisciplinary medical care. Treatment success is predominantly measured by patient satisfaction with their postoperative facial appearance, social integration and overall quality of life<sup>8,9</sup>. However, few studies have reported on patient satisfaction with the aesthetics of nasal and auricular reconstructions<sup>10-15</sup>. Measuring the normalcy of appearance is difficult and different methods have been described for the evaluation of facial appearance<sup>1,16-18</sup>.

The current study evaluates subjective aesthetic outcome as perceived by patients, medical professionals and laymen after the autologous or prosthetic reconstruction of nasal and auricular defects. Additionally, we address the influence of anatomical subunits on the aesthetic value of nasal and auricular reconstructions.

## MATERIALS AND METHODS

### Patient group

All patients treated for nasal and auricular defects (either with surgery or prosthodontics) in a tertiary referral centre between 1997 and 2016 and who had a minimum follow-up period of six months were selected for inclusion in this study. All nasal and auricular defects were treated by medical specialists working at the Departments of Oral and Maxillofacial Surgery, Special Dental Care, Otorhinolaryngology or Plastic Surgery at the Radboud university medical center, Nijmegen, Netherlands. A total of 119 patients with autologous or prosthetic reconstructed nasal or auricular defects were identified, and standardised clinical photographs could be retrieved from the medical records of 65% of these patients (77 patients in total) (Table 1).

**Table 1** Patient demographics.

	Ear		Nose	
	Prosthetic (N=17)	Autologous (N=12)	Prosthetic (N=24)	Autologous (N=24)
<b>Sex</b>				
Male	9	10	13	13
Female	8	2	11	11
<b>Age*</b>				
Mean	42.2	21.4	72.0	58.8
Range	14–80	12–59	37–90	35–80

\*Age in years

### Questionnaire

Clinical photographs of the patients were presented in a digital survey, with a standardised questionnaire used to assess the subjective satisfaction with the aesthetic result. Using SurveyMonkey Inc. (*San Mateo, California, USA; www.surveymonkey.com*), two separate questionnaires were designed for patients with either nasal or auricular reconstructions. The questionnaires consisted of three parts: an assessment of the overall appearance of the reconstructed ear or nose, scored on a Visual Analogue Scale (VAS) from 0 (most negative) to 100 (most positive); general questions concerning the colour, facial position, and height and width of the reconstructed ear or nose; and finally an assessment of the aesthetic appreciation of the anatomical subunit. The second and third parts were scored on a five-point Likert scale (1 = 'very poor', 5 = 'excellent') to enable comparisons with previous research. An example of the full questionnaire is available in the appendix.

Control images were used for the anatomical subunit section of both questionnaires. For the auricular reconstruction questionnaire, a total of 20 non-affected, contralateral ears of patients with auricular reconstructions were used. For the nasal reconstruction questionnaire, standardised clinical photographs of 11 healthy, age- and gender-matched patients were used. Control and patient images were ordered randomly in both questionnaires.

## Respondents

Patients, professionals and laymen were selected to complete the questionnaires. In total, 10 laymen (people unfamiliar with reconstructive surgery), five patients who had previously undergone nasal or auricular reconstruction, and 10 medical professionals (five oral and maxillofacial (OMF) surgeons and five ear, nose and throat (ENT) surgeons) completed the questionnaires. The age and gender of all participants were noted (Table 2). Each participant received an e-mail with a link to the digital survey comprising the standardised questionnaires and instructions on how to complete the non-time-limited digital survey.

**Table 2** Respondent demographics.

	Layman (N=10)	Patient (N=5)	OMF (N=5)	ENT (N=5)
<b>Sex</b>				
Male	5	3	4	2
Female	5	2	1	3
<b>Age<sup>*</sup></b>				
Mean	54.9	69.2	48.0	42.8
Range	34–69	59–77	36–66	30–59

<sup>\*</sup>Age in years

## Statistical analysis

Mixed models were used to analyse the questionnaire responses. For the overall appearance and general questions, three fixed factors, type of observer (laymen, patient, OMF surgeon or ENT surgeon), type of organ (nose or ear), and type of reconstruction (prosthesis or reconstruction), were included in the model, which included all two- and three-way interactions and random effects between the photograph and the respondent. For the anatomical subunits part of the questionnaire, separate analyses were performed for the nose and ear data, since the questions differed between the two questionnaires. In these mixedmodel analyses, two fixed factors (type of observer and type of reconstruction) and a two-way interaction and random effects between the photograph and respondent were included.

Mixed models were used to determine the influence of appreciation of the different anatomical subunits on the overall view of the reconstructed nose or ear. A proportion of the autologous and prosthetic nasal reconstructions (94.7% and 23.1%, respectively) comprised partial reconstructions. The non-reconstructed anatomical subunits were not included in the questionnaires. Multiple imputation was used to handle missing data in the case of partial reconstruction, by selecting a random score for a control patient given by the same respondent. This procedure was repeated 10 times, resulting in 10 complete data sets. Multiple imputation was used instead of single imputation to reflect the uncertainty in the estimation of the distribution, resulting in unbiased estimates with correctly estimated standard errors and confidence intervals. The results of the analyses of each dataset were combined 19. A stepwise selection procedure was used to find a sparse but sufficiently accurate mixed model to describe the influence of separate anatomical subunits on the overall view of the reconstruction. A model with all anatomical subunits and all interactions between type of reconstruction and anatomical subunit was fitted, and the non-significant interactions ( $P > 0.05$ ) were individually removed from the model. Anatomical subunits that did not show a significant interaction with type of reconstruction were also removed from the model. The final model is described in more detail below.

Interquartile ranges (P25–P75) were used to calculate the influence of a nasal or auricular anatomical subunit on the score for the general appearance of a nasal or auricular reconstruction. The influence of the anatomical subunit on the overall appearance was assessed by calculating the difference in the mean (predicted) score of a subject with an anatomical subunit value equal to the third quartile minus the mean score of the anatomical subunit equal to the first quartile, taking into account the variation of that anatomical subunit (the larger the difference, the larger the influence). Comparisons returning a  $P$  value  $< 0.05$  were considered statistically significant. Differences of 10 units on the VAS scale and 0.5 units on the Likert scale were considered clinically meaningful. All analyses were performed using SAS® version 9.4 (SAS institute Inc., Cary, NC, USA).

## RESULTS

The mean values obtained for the questions on general appearance and characteristics were evaluated for each reconstruction group, according to the anatomical location. These data were analysed separately for each respondent group, as summarised in Tables 3 and 4. A mixed model analysis revealed the differences between these scores (Table 5).

**Table 3** Nasal reconstruction: mean VAS (0–100) and Likert (1–5) scores (95% confidence interval), calculated using a mixed model.

Nasal reconstruction	Layman		Patient		OMF surgeon		ENT surgeon	
	Prosthesis	Autologous reconstruction						
<b>Matches patient's face (0–100)</b>	53.64 (43.70–63.58)	54.62 (44.68–64.56)	71.33 (57.77–84.89)	71.38 (57.82–84.94)	59.59 (46.01–73.14)	45.71 (32.15–59.27)	60.15 (46.59–73.71)	64.43 (50.87–77.99)
<b>Colour (0–100)</b>	50.03 (40.90–59.16)	59.41 (50.29–68.54)	70.19 (58.18–82.20)	72.24 (60.23–84.25)	53.88 (41.88–65.89)	50.89 (38.88–62.90)	54.90 (42.89–66.91)	65.93 (53.03–77.04)
<b>Natural shape (0–100)</b>	53.07 (43.37–62.78)	46.75 (37.05–56.46)	69.55 (56.40–82.70)	62.58 (49.44–75.73)	58.00 (44.85–71.15)	42.84 (29.69–55.99)	61.12 (47.38–74.27)	60.75 (47.60–73.90)
<b>Position on the face (1–5)</b>	3.53 (3.16–3.90)	3.45 (3.08–3.81)	4.10 (3.60–4.60)	3.93 (3.44–4.42)	3.63 (3.13–4.13)	3.08 (2.59–3.57)	3.58 (3.08–4.08)	3.70 (3.21–4.19)
<b>Length (1–5)</b>	3.44 (3.06–3.82)	3.43 (3.06–3.81)	3.94 (3.43–4.45)	3.80 (3.29–4.31)	3.74 (3.23–4.25)	3.25 (2.74–3.76)	3.64 (3.13–4.15)	3.73 (3.22–4.23)
<b>Width (1–5)</b>	3.34 (2.97–3.72)	3.32 (2.95–3.69)	3.95 (3.44–4.46)	3.71 (3.20–4.21)	3.50 (2.99–4.01)	2.97 (2.46–3.47)	3.72 (3.21–4.23)	3.48 (2.98–3.99)

A higher VAS or Likert score corresponds with a higher appreciation of the concerning element.  
ENT, ear, nose and throat; OMF, oromaxillofacial.

**Table 4** Auricular reconstruction: mean VAS (0–100) and Likert (1–5) scores (95% confidence interval), calculated using a mixed model. A higher VAS or Likert score corresponds with a higher appreciation of the concerning element

Auricular reconstruction	Layman		Patient		OMF surgeon		ENT surgeon	
	Prosthesis	Autologous reconstruction						
<b>Matches patient's face (0–100)</b>	68.88 (58.57–79.18)	56.14 (45.32–66.96)	67.85 (53.96–81.73)	66.08 (51.74–80.43)	68.86 (54.97–82.75)	45.02 (30.67–59.36)	78.89 (65.01–92.78)	71.90 (57.55–86.25)
<b>Colour (0–100)</b>	71.18 (61.45–80.90)	69.87 (59.34–80.39)	81.02 (68.50–93.55)	77.42 (64.18–90.65)	72.32 (59.79–84.84)	58.75 (45.51–71.99)	77.12 (64.59–89.64)	80.00 (66.76–93.24)
<b>Natural shape (0–100)</b>	70.66 (60.55–80.78)	48.46 (37.76–59.15)	72.33 (58.81–85.84)	58.65 (44.62–72.68)	68.42 (54.91–81.94)	39.05 (25.02–53.08)	77.32 (63.80–90.83)	67.17 (53.14–81.20)
<b>Position on the face (1–5)</b>	3.80 (3.42–4.18)	3.53 (3.12–3.93)	3.64 (3.13–4.14)	3.78 (3.26–4.31)	3.82 (3.32–4.33)	3.05 (2.52–3.58)	4.07 (3.57–4.57)	3.82 (3.29–4.34)
<b>Length (1–5)</b>	3.91 (3.51–4.30)	3.56 (3.14–3.98)	3.78 (3.25–4.30)	3.60 (3.05–4.15)	3.99 (3.47–4.51)	3.03 (2.49–3.58)	4.13 (3.61–4.65)	3.87 (3.32–4.41)
<b>Width (1–5)</b>	3.76 (3.38–4.15)	3.58 (3.18–3.99)	3.61 (3.09–4.13)	3.55 (3.01–4.09)	3.89 (3.37–4.41)	3.15 (2.61–3.69)	4.14 (3.62–4.66)	4.15 (3.61–4.69)

**Table 5** Difference between the perceptions of prosthetic and autologous reconstructions for nasal and auricular defects (95% confidence interval), calculated using a mixed model.

	Layman			Patient			OMF surgeon			ENT surgeon				
	Ear	Nose	Ear	Nose	Ear	Nose	Ear	Nose	Ear	Nose	Ear	Nose		
<b>Matches patient's face (0–100)</b>	12.73 (4.49–20.97)	<0.01 (<0.01–0.98)	0.76 (−7.29–5.33)	1.76 (−7.35–10.88)	0.70 (−7.03–6.93)	−0.05 (−14.73–32.96)	0.99 (−14.73–32.96)	23.84 (6.89–20.85)	<0.01 (−2.12–16.11)	13.87 (6.89–20.85)	<0.01 (−2.12–16.11)	6.99 (−2.12–16.11)	0.13 (−11.26–2.70)	−4.28 (−11.26–0.23)
<b>Colour (0–100)</b>	1.31 (−8.62–11.24)	0.79 (−16.98–1.78)	0.02 (−7.06–14.27)	3.61 (−10.22–6.12)	0.50 (−10.22–6.12)	−2.05 (−2.90–24.23)	0.62 (−2.90–24.23)	13.57 (−5.17–11.16)	0.01 (−5.17–11.16)	2.99 (−5.17–11.16)	0.47 (−5.17–11.16)	−2.88 (−13.55–7.78)	0.59 (−18.30–7.78)	−10.13 (−18.30–0.02)
<b>Natural shape (0–100)</b>	22.21 (13.57–30.84)	<0.01 (<0.29–12.93)	0.06 (4.18–23.18)	13.68 (−0.31–14.24)	0.01 (−0.31–14.24)	6.97 (19.88–38.87)	0.06 (19.88–38.87)	29.37 (7.89–22.43)	<0.01 (7.89–22.43)	15.16 (7.89–22.43)	<0.01 (7.89–22.43)	10.15 (0.65–19.65)	0.04 (0.65–19.65)	0.37 (−6.90–7.65)
<b>Position on the face (1–5)</b>	0.27 (−0.06–0.61)	0.11 (−0.19–0.35)	0.08 (−0.22–0.29)	0.55 (−0.52–0.23)	−0.15 (−0.52–0.23)	0.44 (−0.14–0.47)	0.17 (−0.14–0.47)	0.27 (0.40–1.15)	<0.01 (0.40–1.15)	0.77 (0.40–1.15)	<0.01 (0.40–1.15)	0.55 (0.25–0.86)	0.25 (0.25–0.86)	−0.12 (−0.43–0.18)
<b>Length (1–5)</b>	0.35 (−0.01–0.70)	0.05 (−0.28–0.29)	0.01 (−0.22–0.29)	0.96 (−0.22–0.57)	0.18 (−0.18–0.46)	0.38 (−0.18–0.46)	0.14 (−0.18–0.46)	0.39 (0.56–1.35)	<0.01 (0.56–1.35)	0.95 (0.17–0.81)	<0.01 (0.17–0.81)	0.49 (0.17–0.81)	0.26 (0.17–0.81)	−0.09 (−0.40–0.23)
<b>Width (1–5)</b>	0.18 (−0.13–0.50)	0.26 (−0.23–0.28)	0.03 (−0.30–0.28)	0.83 (−0.30–0.42)	0.06 (−0.05–0.42)	0.73 (−0.05–0.53)	0.24 (−0.05–0.53)	0.10 (0.39–1.10)	<0.01 (0.25–0.82)	0.74 (0.25–0.82)	<0.01 (0.25–0.82)	0.53 (0.25–0.82)	0.01 (0.25–0.82)	0.24 (−0.05–0.52)

\* Difference was calculated by subtracting the score for the autologous reconstruction from the score of the prosthetic reconstruction, based on the mixed model analyses.

For the nasal reconstructions, the laymen and ENT surgeons expressed a preference for an autologous reconstruction only in the category of 'colour', while the patients observed no differences between the prosthetic or autologous nasal reconstruction in any of the domains. In contrast, the OMF surgeons showed a significant preference for prosthetic nasal reconstructions in all domains except for 'colour'.

Regarding the auricular reconstructions, the laymen showed a preference for the prosthetic solution in the domains 'matches the patient's face', 'natural shape' and 'length', while the patients preferred prosthetic ear reconstructions only for 'natural shape'. The OMF surgeons judged the prosthetic ear favourably in all domains. In contrast, ENT surgeons only favoured prosthetic reconstruction in the domain 'natural shape'. No other significant differences were seen (Table 5).

Appreciation scores for different anatomical subunits are shown in Tables 6 and 7. There were significant differences for both nasal and auricular reconstructions in favour of prosthetic rehabilitation for all anatomical subunits, with the exception of the nasion and nasal columella. OMF and ENT surgeons showed significant differences in the appreciation of the nasal dorsum reconstructed by prosthetic rather than autologous means; however, there were no significant differences in the appreciation scores from the laymen and patients. For the auricular reconstruction, only the ENT surgeon group did not report significantly higher appreciation scores of the triangular fossa reconstructed by prosthetic rather than autologous means.

No clinically relevant correlations were found between the age or gender of the different respondent groups and their scores. This was also true of the relationship between the age or gender of the patients featured in the questionnaire and the judgement of the various respondent groups. Furthermore, the mixed-model analyses revealed that no anatomical subunits had a clinically meaningful impact on the overall match of a nasal or auricular reconstruction with the patient's face.

Table 6 Satisfaction with the appearance of reconstructed nasal subunits (five-point Likert scale).

Anatomical subunits	Nasal reconstructions		Layman		Patient		OMF surgeon		ENT surgeon	
	Prosthesis	Autologous reconstruction	Control	Prosthesis	Autologous reconstruction	Control	Prosthesis	Autologous reconstruction	Control	Prosthesis
	<i>P</i> -value difference prosthesis versus autologous reconstruction		<i>P</i> -value difference prosthesis versus autologous reconstruction		<i>P</i> -value difference prosthesis versus autologous reconstruction		<i>P</i> -value difference prosthesis versus autologous reconstruction		<i>P</i> -value difference prosthesis versus autologous reconstruction	
Nasion	2.76 <i>P</i> =0.72	2.86	4.50	3.42	3.29	4.65	2.89	2.93	4.44	3.05
Nasal dorsum	2.92 <i>P</i> =0.07	2.55	4.32	3.69 <i>P</i> =0.13	3.36	4.58	3.18 <i>P</i> =0.03	2.71	4.09	3.47 <i>P</i> =0.01
Nasal tip	3.20 <i>P</i> =<0.01	2.60	4.32	4.03 <i>P</i> =<0.01	3.42	4.62	3.27 <i>P</i> =<0.01	2.76	4.33	3.52 <i>P</i> =<0.01
Right nasal ala	3.23 <i>P</i> =<0.01	2.64	4.41	3.91 <i>P</i> =<0.01	3.27	4.47	3.07 <i>P</i> =0.02	2.62	4.38	3.61 <i>P</i> =<0.01
Left nasal ala	3.18 <i>P</i> =0.01	2.75	4.39	3.87 <i>P</i> =<0.01	3.26	4.49	3.09 <i>P</i> =<0.01	2.26	4.38	3.53 <i>P</i> =<0.01
Nasal columnella	3.13 <i>P</i> =0.16	2.84	4.40	3.55 <i>P</i> =0.39	3.37	4.47	2.90 <i>P</i> =0.03	2.52	4.53	3.19 <i>P</i> =0.07
Nostrils	2.96 <i>P</i> =0.01	2.38	4.41	3.62 <i>P</i> =0.02	3.09	4.40	2.92 <i>P</i> =0.01	2.35	4.40	3.17 <i>P</i> =0.02

Mean score and *P*-value based on the mixed-model analyses (*P* < .05).

Table 7 Satisfaction with the appearance of reconstructed auricular subunits (five-point Likert scale).

Auricular reconstruction	Patient			OMF-surgeon			ENT-surgeon		
	Anatomical subunits	Prosthesis	Autologous reconstruction	Control	Prosthesis	Autologous reconstruction	Control	Prosthesis	Autologous reconstruction
	P-value difference prosthesis versus autologous reconstruction			P-value difference prosthesis versus autologous reconstruction			P-value difference prosthesis versus autologous reconstruction		
Helix	4.02	2.66	4.24	4.12	3.50	4.18	4.20	2.70	4.34
Antihelix	3.61	2.22	4.03	3.92	2.92	3.96	3.81	2.20	4.03
Scapha	3.63	2.14	4.07	3.86	2.83	3.95	3.84	2.03	3.95
Triangular fossa	3.51	2.21	4.21	3.93	2.73	4.09	3.71	2.13	4.09
Concha	3.51	1.55	4.28	3.72	2.10	4.09	3.60	1.57	4.25
Cymba	3.32	1.70	4.18	3.62	2.13	3.92	3.53	1.73	4.14
Tragus	3.15	1.46	4.16	3.40	2.12	4.02	3.52	1.55	4.15
Anti-tragus	3.19	1.51	3.98	3.64	2.05	3.64	3.68	1.73	4.04
Lobulus	3.42	2.31	4.08	3.78	3.17	3.81	3.78	2.22	4.14

Mean score and P-value based on the mixed-model analyses ( $P < .05$ ).

## DISCUSSION

The present study assessed the subjective appreciation of aesthetic outcomes following the prosthetic or autologous reconstruction of nasal and auricular defects among patients, medical professionals and laymen.

Although various instruments have been developed to evaluate patient satisfaction following facial plastic surgery, none have achieved widespread use, and the wide variety of questionnaires and methodological approaches in use makes the comparison of different studies difficult<sup>18,20</sup>. In this study, VAS was used to score the overall view of the ear and nose. In comparison with using a Likert scale to score patient satisfaction, VAS has been shown to be less vulnerable to bias from confounding factors and to better detect variation<sup>21</sup>. To facilitate the comparison of our results with those of previous research, we also used a five-point Likert scale to score the general questions and those relating to the anatomical subunits<sup>10-14</sup>. To the best of our knowledge, no previous study has evaluated the differences between panels in perceptions of the aesthetic outcome of prosthetic and autologous reconstruction for both nasal and auricular defects; however, some studies have reported on subjective satisfaction after these procedures<sup>10-15</sup>. Moolenburgh *et al.*<sup>10</sup> and Mureau *et al.*<sup>11</sup> found that medical professionals and laymen offered lower estimations of 'total nasal appearance' following autologous reconstruction than patient panels. These results (scored on a 5-point Likert scale) are in accordance with our own, which showed that patients scored total nasal appearance higher than the OMF surgeons and laymen, although we found no significant difference in the assessment of total nasal appearance by ENT surgeons and patients. A similar result was found in another study by Moolenburgh *et al.*<sup>12</sup>, who showed no difference in the assessment of autologous nasal reconstruction by laymen and professionals.

Moolenburgh *et al.*<sup>10</sup> also reported higher overall assessment scores for all anatomical subunits of the nose following autologous reconstruction than we reported here. Our patient satisfaction scores were also lower than those reported by Arden *et al.*<sup>13</sup> and Quatela *et al.*<sup>14</sup>, who evaluated patient and professional satisfaction with aesthetic outcomes following autologous nasal reconstruction; however, neither of these studies described the differences between both groups. Satisfaction with aesthetic outcome following auricular reconstruction by prosthesis was reported by Younis *et al.*<sup>15</sup>, who found that the majority of patients (85%) rated the aesthetic result as 'very good' (Likert

score: 4) or 'excellent' (Likert score: 5), although the overall patient satisfaction with the prosthesis was disappointing. The authors attributed this poor overall satisfaction to a high rate of skin complications. Although this was not assessed in our study, recent developments in implant and abutment design as well as surgical technique have resulted in a decrease in the rate of skin complications<sup>7</sup>.

Satisfaction with facial aesthetics after treatment has also been studied in cleft lip and palate patients. Similar to our findings, patients and professionals in these studies were found to be more satisfied with the treatment outcome than the laymen<sup>22-24</sup>. Gkantidis *et al.*<sup>22</sup> hypothesised that these differences could be attributed to the greater familiarity of medical specialists with the aesthetic consequences of treatment. Other studies report contradictory results however<sup>25,26</sup>; for example, Eliason *et al.*<sup>26</sup> found that professionals respond more negatively to the facial appearance of cleft lip and palate patients following treatment than the laymen. The authors suggest this difference could be due to professionals being more critical and focusing on isolated features, such as nasal alar asymmetries and lip scarring.

Two types of medical professionals were included in the present study, namely OMF and ENT surgeons. Both are involved in the reconstructive treatment of nasal and auricular defects. The OMF surgeons rated the prosthetic rehabilitations higher overall than did their ENT counterparts. The different experiences of individual OMF and ENT surgeons in reconstructive treatment modalities and associated technical difficulties may have influenced their perspectives on aesthetic outcome<sup>27,28</sup>.

Normal facial appearance is an important factor in decreasing the negative perceptions of patients following reconstructive surgery during social interactions, and is important for the psychological wellbeing of patients<sup>10,17,29,30</sup>. Smolarz *et al.*<sup>31</sup> suggested that satisfaction following reconstruction depends on the localisation of the defect. Auricular appearance and symmetry contribute to facial aesthetics and auricular defects, and abnormalities can be easily noticeable<sup>32</sup>. The nose arguably plays an even more essential role in facial aesthetics due to its central localisation, prominent and protruding aspect, and the fact that it cannot easily be concealed<sup>33,34</sup>. This means that reconstructions of the nose (and their camouflaged defects) are more conspicuous in facial appearance, and may therefore be rated lower than auricular reconstructions. Here, we found that satisfaction with auricular reconstructions was rated more highly than the nasal reconstructions, in particular when comparing auricular prostheses to nasal prostheses.

It is difficult to rate anatomical subunits without being influenced by surrounding structures; however, no anatomical subunits were found to have a clinically meaningful impact on the overall match of the prosthetic or autologous reconstruction with the patient's face in this study. Many factors unrelated to nasal or auricular defects and their reconstruction can also impact the perception of the aesthetic outcome, such as makeup or hairstyle<sup>16</sup>, but the possible influence of these features was not determined in the current study.

Other limitations of this study include variability in follow-up periods and the time at which the photographs were taken. The medical photographs were taken at different intervals following reconstructive surgery or prosthetic rehabilitation. Furthermore, these twodimensional images were used to score the three-dimensional anatomy of reconstructed facial defects. Lighting, head orientation, camera and background may affect the assessment of the nasal and auricular reconstructions<sup>35</sup>. Although the majority of the photographs were standardised, the lighting and background were not always identical, and may have affected the results of this study.

Furthermore, data regarding the characteristics of the prostheses (number and age) at time the photographs were taken could not be retrieved from the medical or dental charts; therefore, the possible influence of prosthesis wear or discoloration on the aesthetic outcome was not assessed. Another important factor is the experience of the reconstructive surgeons, as the literature shows there is a steep learning curve in the autologous reconstruction of nasal and auricular defects<sup>3</sup>. Higher levels of experience in reconstructive surgery may improve the aesthetic outcome of the autologous reconstructions performed by a surgeon over time, and thus influenced the outcome of this study<sup>36</sup>.

Psychological factors, such as self-esteem and coping mechanisms, may also determine satisfaction with nasal or auricular appearance<sup>29</sup>. The psychological and social functioning of the patients (and other) respondents are therefore likely to have influenced the results, although the extent of this influence was not determined. Additionally, patient and laymen educational levels may have varied in the current study. There is a high likelihood of bias from patients in reporting satisfaction to their surgeons<sup>37</sup>. Furthermore, the digital questionnaires were extensive, comprising over 1,250 questions and consequently taking a significant amount of time to complete. It is therefore possible that answers provided at the later stages of the questionnaire were

given less consideration.

In conclusion, despite the described limitations, both prosthetic and autologous reconstructions of nasal and auricular defects were shown to restore the facial appearance of the patient. Prosthetic reconstructions of nasal and auricular defects were considered advantageous (in terms of aesthetic outcome) in the view of professionals, particularly the OMF surgeons, while patients themselves judged prosthetic and autologous nasal and auricular reconstructions as being equal. Since no anatomical subunits were found to influence the aesthetic outcome of a reconstruction, the planning, modelling and manufacturing of nasal and auricular reconstructions should consider all features and anatomical subunits equally. The surgeon should consider the reconstruction as a whole, rather than focusing on specific anatomical subunits when performing nasal or auricular reconstructions. Numerous factors, such as the age of the patient, their health status and the location and size of the CMF defect, influence the decision on which is the most appropriate reconstructive treatment modality. OMF and ENT surgeons play a key role in providing patients with comprehensive information on the advantages and disadvantages of both techniques<sup>38</sup>. Patient-centred care and shared decision-making are of great importance, and increase the likelihood of patient satisfaction with the aesthetic outcome of their reconstructive treatment.

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## **APPENDIX: Questionnaire**

### **1. Overall appearance (VAS 0–100)**

1. Does the nose/ear fit the patient's face?
2. What do you think of the colour of the nose/ear?
3. Do you think the nose/ear has a natural shape?

### **2. General questions (Likert 1–5)**

1. What do you think of the position of the nose/ear on the face?
2. What do you think of the length of the nose/ear?
3. What do you think of the width of the nose/ear?

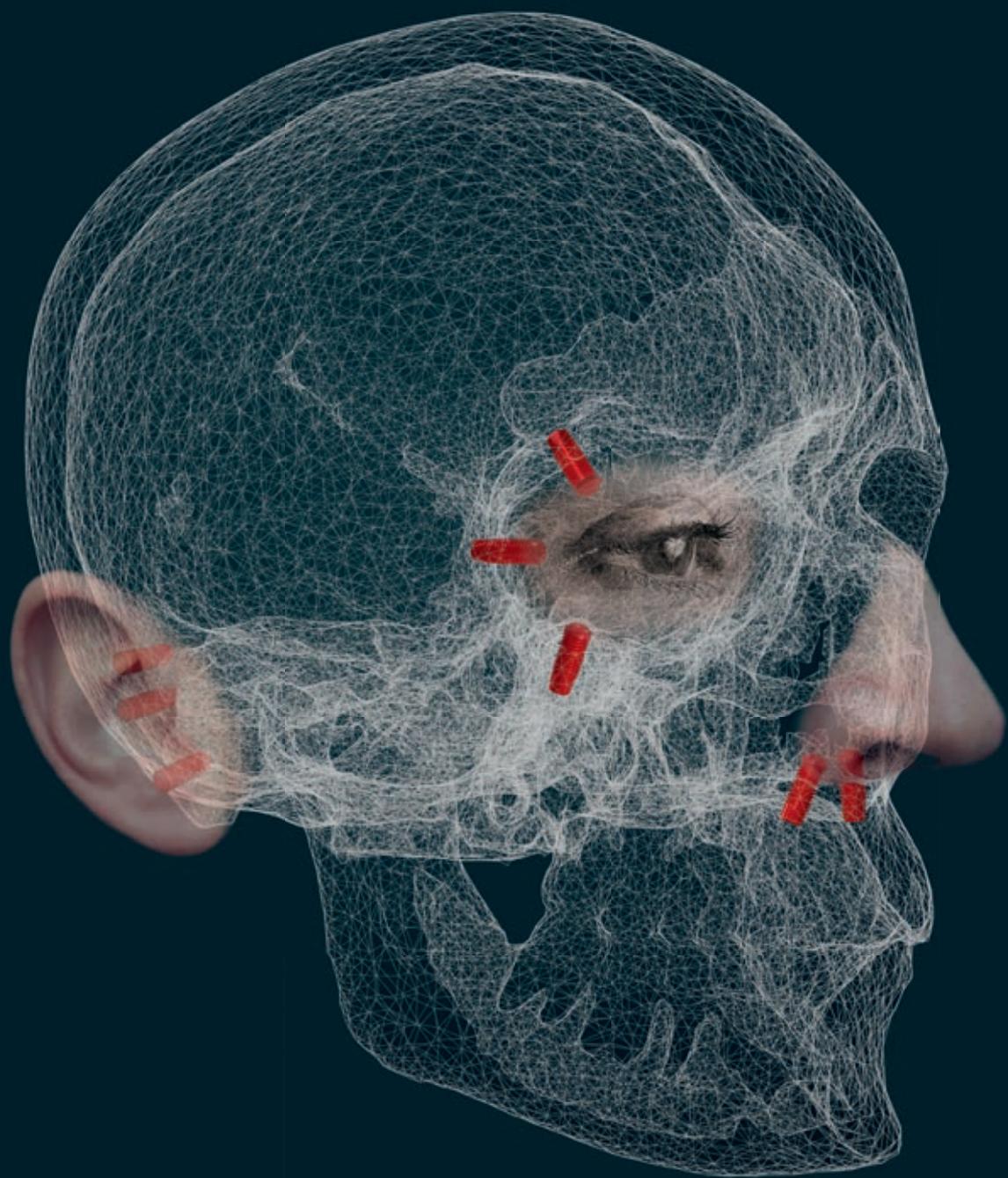
### **3. Anatomical subunits (Likert 1–5)**

#### ***a. Ear***

1. What do you think of the outer edge of the ear (helix)?
2. What do you think of the central fold of the ear (anti-helix)?
3. What do you think of the pit between the helix and anti-helix (scapha)?
4. What do you think of the pit between the foothills of the central fold (antihelix) in the ear (fossa triangularis)?
5. What do you think of the pit next to the ear canal (concha)?
6. What do you think of the narrow depression between the antihelix and root of the helix, above the concha (cymba)?
7. What do you think of the projection on the anterior side of the ear canal (tragus)?
8. What do you think of the projection on the inside of the ear above the earlobe (anti-tragus)?
9. What do you think of the earlobe (lobulus)?

#### ***b. Nose***

1. What do you think of the nose root (nasion)?
2. What do you think of the nose bridge (dorsum)?
3. What do you think of the nose tip?
4. What do you think of the right nose wing?
5. What do you think of the left nose wing?
6. What do you think of the skin below the nose between both nostrils (columella)?
7. What do you think of the nostrils?



# CHAPTER 7

General discussion



**Reliability and accuracy of cone-beam computed tomography versus conventional multidetector computed tomography for image-guided craniomaxillofacial (CMF) implant planning – an in vitro study (Chapter 2).**

Accurate estimation of the actual bony dimensions using an appropriate radiographic examination is fundamental for implant planning and subsequent placement to achieve good function and esthetics.

The two most common CT technologies used to date for CMF implant treatment planning are multi-detector row computed tomography (MDCT) and cone-beam computed tomography (CBCT). These images provide useful datasets towards generating both two-dimensional (2D-) planar projection and three-dimensional (3D-) surface or volume rendered images for use in implant treatment planning<sup>1,2</sup>.

The primary objective was to assess the reliability and accuracy of linear measurements of bone dimensions on multiplanar reconstructions from MDCT and CBCT data.

Results of this study, which used 10 cadaver heads, showed a consistent submillimeter overestimation of the anatomical truth in potential implant locations in the orbital-, nasal- and temporal region for both CBCT and MDCT images. Most studies in literature corroborate the sub-millimeter differences between CBCT and gold standard measurements<sup>2,3</sup>. However, contrary to our findings, most of these differences were not statistically significant. With regard to CMF locations, no clear trend can be established with studies both describing over- and underestimation between CBCT and gold standard measurements<sup>3</sup>.

To our knowledge, no similar cadaver studies exist addressing accuracy of linear measurements on potential locations for CMF implants and comparing these values to physical measurements using a digital caliper. Within the limitations of this study, linear measurements on CBCT images proved to be more accurate compared to MDCT images. This is in accordance with the results of the study by Al-Ekris and Ekram (2011), but in contrast with the study of Matta *et al.* (2016) who described MDCT to be slightly more accurate in comparison to CBCT scans<sup>1,4</sup>. There aside, several studies showed no significant difference at all in accuracy and submillimeter error range between CBCT imaging and MDCT<sup>5-7</sup>. However, variation in methodological approaches, CT devices and standard settings contribute to the difficulty in comparing results.

The high inter- and intra-observer reliability, ranging between 0.98 and 0.99 for both CBCT and MDCT measurements, was comparable with the available literature<sup>3</sup>. However, our study showed less inter-observer variation in linear measurements on cross-sectional MDCT images, as compared to CBCT images.

The accuracy of linear measurements in this study may be influenced by several factors. A possible drawback of this study is the use of dry skull models without providing a soft tissue equivalent attenuation. However, the majority of the 'in vitro' studies assessing the accuracy of potential sites of implant placement use dry skulls, mandibles or maxillae<sup>3</sup>. Three-dimensional volumetric depictions depend upon appropriate segmentation by means of thresholding. Voxels residing on tissue boundaries may contain different tissue types. Erroneous allocation of voxels to 'soft tissue' instead of 'bone' may occur and is known as the partial volume effect leading to subsequent measurement error<sup>8</sup>. This process is dependent on the software algorithm, the spatial- and contrast resolution of the scan, the thickness and degree of calcification, or cortication, of the bony structure. Although literature shows that accuracy outcomes are similar with- and without soft tissues, clinical extrapolation of the findings from our study is suboptimal, as experimental conditions differ from clinical<sup>9,10</sup>.

Furthermore, head orientation and position during image acquisition may influence measurement accuracy. Although cadaver heads used in this study were positioned and stabilized, as in a real clinical situation the eccentric anatomical locations may affect linear measurements. The role of the position of the head on linear measurement accuracy is still controversial. Several studies found no significant difference in measurement value with regard to different head positions or inclinations<sup>11,12</sup>. In contrast to these findings, Sabban *et al.* (2015) described a significant effect of the head position on measurement reliability in CBCT scans on intra-oral locations<sup>13</sup>. A systematic literature search by Wismeijer *et al.* (2018) revealed no adverse effect of the size of the field of view and partial rotations (180° vs. 360°) on linear measurements<sup>2</sup>.

Another potential drawback in our study is the use of standard settings of image acquisition parameters for both MDCT as CBCT scanners. The voxel size on MDCT and CBCT images were 0.3 mm and 0.5 mm respectively. As there are multiple image acquisition protocols available for each MDCT and CBCT scanner, different procedures could have been considered. However, a systematic review in this subject area by Fokas *et al.* denied a relation between different voxel sizes and measurement accuracy<sup>3</sup>.

Furthermore, also the clinical impact of possible influence of voxel sizes on measurement precision is questionable<sup>14,15</sup>. Brightness and contrast settings significantly influenced linear measurements of bone width for CBCT images ( $p < 0.0015$ ) and inter-observer variation on MDCT imaging ( $p < .029$ ). However, the difference only comprised 0.14 millimeter and 0.05 millimeter, respectively.

Another limitation of the present study was that only one imaging software package was used. However, Tolentino *et al.* and Wismeijer *et al.* (2018) showed that the different software protocols do not influence CBCT accuracy for linear measurements in multiplanar reconstructions<sup>2,15</sup>.

In conclusion, the results in Chapter 2 prove that CBCT and MDCT scans showed a submillimeter overestimation of the anatomical truth for preoperative evaluation of implant sites at the orbital, nasal and auricular region. This is in accordance with our clinical experience where during surgery, often less bone volume is available than presumed.

### **Reliability and accuracy of skin-supported surgical templates for computer-planned craniofacial implant placement, a comparison between surgical templates: with and without bony fixation (Chapter 3).**

This human cadaveric study was conducted to evaluate the accuracy of computer-aided designed stereolithographic skin-supported surgical templates with and without bone fixation pins in transferring the virtually planned implant positions to the clinical environment.

Computer-aided design and manufacturing (CAD/CAM) has been described in dental implant treatment extensively and has become an accepted standard of care for preoperative planning and prosthesis design<sup>2,16</sup>. Literature shows that accuracy is considerably improved with guided implantation when compared to conventional template or freehand implant placement<sup>17</sup>. Especially for difficult anatomical areas, such as the floor of the nose or orbital rim showing thin, low-density bone, strategic and accurate placement of CMF implants is crucial for an optimal clinical outcome<sup>16</sup>.

Skin-supported surgical templates were developed in this study with the aim of improving predictability and accuracy during surgical implant placement both in the auricular-, nasal- and orbital region. A disadvantage of these skin-supported templates

is the risk of malrotation caused by surgical debridement and the intrinsic elasticity of the supporting soft tissues<sup>18,19</sup>. Furthermore, no direct reference to the quality and quantity of the underlying bone is provided<sup>20</sup>.

A total of 136 CMF implants were template-guided installed in 10 cadaver heads, following the Nobel Guide® surgical protocol. Preoperatively, CBCT and MDCT scans were acquired to perform a virtual implant planning. Postoperatively, CBCT and MDCT scans were made for validation purposes. To prevent movement artefacts the cadaver skulls were stabilized in an upright position for the CBCT scan and in a supine position for the MDCT scan, as per a real clinical situation. The hypothesis was that surgical templates allow proper implant placement and the use of bone-fixated pins would improve precision. Accuracy was determined as a difference less than the clinically considered threshold of 1.0 millimeter between virtually planned implant and actual position [3]. This accuracy was analyzed by measuring the Euclidean distance between the planned and post-operative position of the implant at the tip and shoulder of the implants. The depth and the angular deviation of the central axis was also calculated. Results did not corroborate the hypothesis of this study. The linear and angular deviations found in the current study, when comparing actual CMF implant positions versus the preoperatively planned implant positions, were clinically unacceptable encompassing 1.8 to 4.4 millimeter at the implant shoulder and tip. The angular deviation ranged from 4.7 to 9.2 degrees. Surprisingly, the use of bone-fixated pins even worsened accuracy. This lack of added value of pins was also described in intra-oral implantology<sup>21</sup>.

Results of Chapter 3 indicate that accuracy of guided surgery is based on cumulative errors. Therefore, in case of CMF implants, guided surgery using surgical templates is insufficient for clinical application. It is difficult to judge if the main factor contributing to the final error was the fit of the surgical template or operation errors. The latter was not controlled in this study, since the analysis of deviation was made post-surgery. The influence of possible dimensional printing errors were assessed through laser surface scanning in this study and showed no relevant dissimilarities.

The success of a surgical template is mainly dependent on its fit, meaning its direct soft tissue contact. Therefore, the results of this study should be interpreted cautiously, as it is difficult to make direct comparisons between studies due to both study design (in vitro versus in vivo versus ex vivo studies, type of support, single versus multiple

surgical templates etc.) and the inconsistency in the reported observations<sup>19,22,23</sup>. Described deviations in this study can predominantly be explained by the resilience of the skin, since accuracy is mainly dependent on accurate and stable positioning, and inherent support of the surgical template<sup>24,25</sup>. Resiliency is likely to be negatively influenced by the reduced quality and altered thickness of the soft tissue of fresh frozen cadavers, who were defrosted several times. The initial state of preservation of the material and exact number of freeze-thaw cycles could not be determined. Despite the realistic appearance of fresh frozen cadavers, disadvantages include deterioration of tissue integrity and resiliency<sup>26,27</sup>. Klop *et al.* showed increased tissue friability with repeated freeze-thaw cycles<sup>28</sup>. Furthermore, implant surgery in this study took place at room temperature, while thawing temperature of cadaveric material at lower temperatures is preferred for preservation of physical properties<sup>28</sup>. Soft tissue thickness was not separately determined. To conclude, the thickness of the soft tissue and subsequent resiliency is likely to have impaired accuracy of the skin-supported surgical templates<sup>24,29</sup>.

Literature shows that guide support influences the clinical accuracy of computer-guided surgery with tooth-supported surgical templates that offer the highest accuracy<sup>2,19,30</sup>. Improvement may be found in the installation of osteosynthesis screws prior to the first radiographic scan before virtual planning. Surgical templates can be digitally designed to fit on these osteosynthesis screws to optimize its fit and reduce per-operative rotation and translation of the surgical template and subsequent inaccuracies during implant insertion<sup>31</sup>.

The results of this study are difficult to compare due to the heterogeneity in literature with regard to study design, methodologies and clinical variations. The linear and angular deviations are clinically unacceptable and further research and technical improvements are warranted to maintain a safety margin of 2 mm from critical anatomical structures.

#### **Retrospective multicenter investigation on the optimal timing of implant placement in relation to ablative surgery and survival rate for craniomaxillofacial (CMF) implants (Chapter 4).**

In this retrospective study, differences in survival time were evaluated between CMF implants placed during ablation (DA implants) compared to those placed in a later stage, the so-called after ablation (AA) implants. The survival rate for DA-implants with

a mean follow-up of 35-months (range 8-156 months) was 90.0% for the orbital region and 93.5% for the nasal region. The survival rate of the AA-implants for the orbital and the nasal region was 82.8% and 61.5%, respectively. In concordance with similar studies, implants that remained buried or were removed due to misplacement were considered as successful with regard to their osseointegration<sup>32,33</sup>.

A systematic review by Chrcanovic *et al.* on the survival rate of CMF implants revealed an overall risk of 5.5% on CMF implant failure. Similar to our results, the probability of implant failure for the nasal and orbital region was comparable<sup>33,34</sup>. Implants in the auricular region are shown to have the best prognosis due to the quality and volume of bone, surrounding immobile soft tissues, local hygiene and lower frequency of radiation therapy<sup>33,35,36</sup>. In contrast, the orbital- and nasal region exhibit limited volume of dense cortical bone and loose trabecular bone structure, respectively<sup>16</sup>. Orbital location is suggested to have an impact on implant survival with the lateral portion of the supraorbital rim and the lateral rim of the orbit being favorable with regard to implant survival<sup>34</sup>. A possible explanation for the higher loss in the infraorbital rim is the increased skin mobility leading to soft tissue reactions and subsequent infections, bone loss and implant failure<sup>37</sup>. However, in our study no relationship between orbital location and loss of implants was found. Toso *et al.* described a high rate of orbital implant failures shortly after placement attributed to non-osseointegration<sup>37</sup>. In contrast, Nishimura *et al.* indicated that longer follow-up periods may lead to an increase in failure rate due to impaired osseous remodeling capacity and peri-implant soft tissue complications<sup>38</sup>. In concordance with aforementioned systematic review by Chrcanovic *et al.* (2016), no clear relation was found in our study between the duration of the follow-up period and proportion of implant failures<sup>33</sup>. Overall patient mortality following oncological surgery in the head- and neck region may lead to overestimation of CMF implant survival. Furthermore, due to the heterogeneous data in literature and multitude of factors influencing implant survival, definitive conclusions have to be drawn carefully.

Surprisingly, no statistic significant difference in implant survival could be established in our study between implants installed in irradiated and non-irradiated bone ( $p = 0.225$ ). Although, an increased risk on impaired osseointegration due to radiation therapy with subsequent reduced vascularization is widely shown in literature<sup>18</sup>. Implant surgery in irradiated tissues increases the risk of implant failure and risk of complications<sup>33,34</sup>.

Results from our study showed statistically significant higher survival rates for implants placed during ablative surgery compared to implants placed in a secondary procedure. In avoiding additional surgery and allowing uncomplicated osseointegration prior to possible postoperative radiation therapy, we advocate to insert implants immediately following ablative surgery. Furthermore, prosthetic rehabilitation of the CMF defect can be achieved earlier. In contrast, secondary placement implants may be beneficial, with regard to more specific patient assessment and implant placement<sup>39</sup>. However, a systematic review on the effects of pre- versus post-implantation irradiation therapy on dental implant failure could not establish a significant difference in survival rate<sup>40</sup>.

No beneficial effect of HBO therapy on osseointegration could be retrieved from our results. The evidence in literature on the use of hyperbaric oxygen therapy to improve osseointegration in irradiated patients remains controversial. A meta-analysis by Chrcanovic *et al.* (2016) revealed no statistically significant difference on implant survival in irradiated fields, with or without adjunctive HBO therapy<sup>33</sup>.

Hygiene is of utmost importance in preventing soft tissue infection<sup>35</sup>. Impaired hygiene may result from monocular vision, prosthetic abutments and bar attachments, or difficult access with regard to the nasal region resulting in impaired implant hygiene<sup>33</sup>. Chronic inflammation of peri-implant soft tissue inflammation can cause implant failure. Due to the retrospective design of this study and incomplete records no information could be retrieved with regard to the specific role of implant hygiene.

Furthermore, no distinct relation could be retrieved from our results, or is known in literature, between survival rates of implants and variables as sex, age, type of implant and prosthetic type<sup>34,36</sup>. Only Toso *et al.* found a higher survival rate for orbital implants in female patients<sup>37</sup>. Furthermore, Toso *et al.* showed a statistically significant higher survival rate for Branemark titanium implants (Nobel Biocare AB, Gothenburg, Sweden.) in comparison with Straumann EO implants (Institut Straumann AG, Waldenburg, Switzerland.). This difference is attributed to the smooth-machined titanium surface of the Branemark implants<sup>37</sup>.

In conclusion, this study showed a higher survival rate of nasal- and orbital implants placed during ablative surgery compared to implants placed in a later stage. It is, therefore, advocated by the authors to insert the CMF implants during the ablative surgical session. However, considering that the reported rates are subject to numerous

variables in a heterogeneous cohort, the results of the present study should be interpreted with caution.

**Clinical studies by using comprehensive questionnaires to assess satisfaction with CMF prosthetic rehabilitation and to determine the subjective perception towards various reconstructive treatment options (Chapters 5 and 6).**

**Maxillofacial prosthetic rehabilitation – A survey on the quality of life (Chapter 5)**

This clinical study assessed the long-term quality of life of 66 patients treated with facial prostheses with different retentive mechanisms over a 14-year period at a Dutch oral and CMF surgery unit. To our knowledge, current validated questionnaires mainly address overall items measuring general Quality Of Life (QOL) and health condition<sup>41,42</sup>. Our study specifically focused on the subjective analysis of patients with facial prostheses in perceived QOL. Therefore, a new questionnaire was designed to obtain the patient's perception and treatment satisfaction with their facial prosthesis. The 62-item questionnaire addressed perceptions of comfort, fit and retention, usage, care, quality and durability of prosthetic materials and psychological aspects.

High overall satisfaction rates found in our study with regard to wearing comfort, anatomical fit, color, and anatomical form were comparable with previous studies evaluating QOL of patients with facial prostheses<sup>32,42</sup>. Important findings in the survey were in the area of social aspects; 1) statistically significant more patients with nasal prostheses felt noticed by others in their environment ( $p=0.01$ ) and 2) patients with nasal prostheses scored lower, while holding their face in a neutral expression ( $p=0.04$ ). This may be due to the fact that reconstructions of the nose are more conspicuous in facial appearance<sup>43,44</sup>.

Fewer patients with auricular prostheses felt embarrassed to show their defect in different social environments ( $p=0.01$ ). This is in accordance with the findings of Agarwal *et al.*, which describe a high level of comfort and stability on ear prostheses<sup>42</sup>. Most studies showed a higher confidence with implant-retained prostheses<sup>16,45</sup>. This was confirmed by the findings of our study, which describe a significant difference for implant-retained versus adhesive-retained facial prostheses with regard to retention and increased ease of placement and removal ( $p=0.01$  and  $p=0.04$ ).

As no physical examination was executed, the hygiene regimen, the possible need for aftercare or classification of peri-implant skin reactions were based on subjective assessment by the patients themselves. Therefore, no distinction could be made in the 46.1% of respondents with minor soft tissue complications according to the classification of Holgers with regard to peri-implant skin reactions<sup>46</sup>. Auricular prostheses were reported to be cleaned less frequently ( $p=0.01$ ), although no significant difference was found in minor soft tissue complications between different anatomic locations and the various retentive systems. Comparison with literature is difficult, as most studies lack information on the presence of skin complications, and do not make use of the aforementioned strict diagnostic criteria identified by Holgers *et al*, or hygiene maintenance.

In general, cleaning under bars is shown to be more difficult in comparison with magnets. However, to our knowledge, no relation is found in literature with regard to impact of hygiene on implant success<sup>32,33,36</sup>.

The choice for a retentive mechanism in these areas is principally governed by the location of the defect, design of the prosthesis indication and the practitioner's ability<sup>47</sup>. In our study, magnetic retention systems were predominantly used for orbital epitheses due to eased insertion of the prostheses, compensation of non-parallelism of the installed implants and low moment forces on the supporting abutments and implants. The same retention methods for orbital prostheses are predominantly described in literature<sup>37,47</sup>. Bar-clip retention is mostly used for retention of auricular prostheses<sup>47</sup>. For the nasal region, bar-clip, as well as magnet retention are reported. In general, bar-clips require more space within the future prosthesis, which is often lacking in the orbital- and nasal regions. Results from our study concerning psychological- and social aspects revealed no statistically significant differences for type of attachment.

Patients' experiences with implant-retained prosthesis and their previous adhesive-retained prosthesis were also determined in this study. All patients who had experience with adhesive-retained prostheses preferred bone anchorage with regard to enhanced and reliable retention, as also ease of handling ( $p=0.04$ ). An implant-retained prosthesis often is not experienced as an extraneous object due to its enhanced support and stability<sup>16,45,48,49</sup>. Furthermore, prosthetic durability is prolonged with regard to less discoloration and degradation of prostheses because no adhesives and solvents are used<sup>50</sup>.

Mean life-span for orbital-, nasal- and auricular prostheses in our study was 26-, 17- and 31-months, respectively. For facial prostheses, life-span reported in literature ranges from 1.5 to 2 year<sup>16,49</sup>. Discoloration was the predominant problem that limited the life-span of prostheses. Suboptimal junction was the second factor that restricted the longevity of prostheses.

Therefore, and with regard to the limited life-span of facial prostheses, continuous daily care of the implants in combination with a long-term commitment of the patient is required. Also, after implant installation and the subsequent placement of the CMF-prosthesis, the surgeon and maxillofacial-prosthodontist remain co-responsible for continuing patient care. Fortunately, fabrication of a new prosthesis is relatively simple and fast to accomplish using the existing patient specific mould.

A disadvantage of a newly introduced questionnaire is the difficulty of comparing our results with other studies<sup>42</sup>. Furthermore, the initial quality of life could not be retrieved, so additional benefits from prosthetic rehabilitation could not be determined. Literature shows that patients with facial deformities generally have overall poorer physical- and psychological health, as well as lower quality of life compared to controls<sup>41</sup>. Although patient self-confidence and satisfaction was shown to be improved wearing a facial prosthesis, no comparison with healthy controls was executed.

### **Autologous versus prosthetic nasal- and auricular reconstruction – patient, professional and layman's perception (Chapter 6).**

Restoration of craniomaxillofacial (CMF) defects occupies a high priority in the physical- and psychological rehabilitation of the patient. CMF defects may be reconstructed by plastic surgery or restored by implant-retained prosthetic constructs. Although numerous advantages have been described in literature with regard to microsurgery and reconstructive transplantation, autologous reconstruction of CMF defects remains challenging<sup>51,52</sup>, as surgical reconstruction may be hampered by the general health status of the patient, radiation therapy, risk of recurrence of illnesses, anatomical complexity or size of the defect<sup>33</sup>. Also, conventional surgery often comprises multiple procedures and the introduction of donor site morbidity<sup>34,42,52,53</sup>. Furthermore, in elderly patients, autologous tissue may be more brittle and less suitable for auricular reconstruction<sup>42</sup>.

Prosthetic rehabilitation has considerable advantages specifically in restoring large defects, such as the ability to evaluate recurrence of illnesses. In addition, little or no morbidity is involved, and aesthetical advantages are introduced, especially in complex anatomical sites, such as noses and ears<sup>18,36,47</sup>. However, implant-retained prosthetic reconstruction relies on sufficient bone stock at the implant site, an intact manual dexterity for handling of the prostheses and continued care by a CMF prosthodontist<sup>18</sup>.

Nowadays, quality of life and patient satisfaction are becoming increasingly important in clinical decision-making. Therefore, subjective outcomes of treatment are also becoming more imperative. Although surgical- and implant-retained reconstruction of nasal- and auricular defects are widely described, literature on comparison of different reconstructive methods for CMF defects is sparse<sup>54,55</sup>. Various instruments evaluating patient satisfaction have been developed within facial plastic surgery, but none of them has achieved widespread use.

The goal of the study presented in Chapter 6 was to compare the subjective evaluation of different observer panels on prosthetic rehabilitation and autologous reconstruction of CMF defects.

Orbital defects were not included in this study, as autogenous reconstruction of orbital defects is merely indicated for coverage of anatomical structures and does not meet the goal of esthetic rehabilitation<sup>32</sup>. Autologous repair and implant-retained prostheses are both good options for reconstruction of nasal- and auricular defects<sup>45,53</sup>. Traditionally, nasal- and auricular defects were reconstructed using autologous tissue in several laborious surgical stages. Reinisch *et al.* have introduced porous polyethylene as an alternative for the autologous costal graft for the reconstruction of the ear<sup>51-53</sup>.

The results of the study in Chapter 6 showed patients with reconstructed nasal- and auricular defects being perceived significantly less attractive in comparison to controls. This is in accordance to the findings of Moolenburgh *et al.* (2008), although their study only incorporated autologous reconstructions of nasal defects<sup>56</sup>.

In contrast to patients, laymen, ENT-surgeons and OMF surgeons expressed a preference for prosthetic reconstruction. An explanation could be that OMF-surgeons in the Netherlands both require a dental- and medical degree and, therefore, are more familiar with prosthetic rehabilitations. In contrast, our cohort of ENT-surgeons had more clinical experience with surgical correction of auricular- and nasal defects.

Prosthetic ear reconstruction was preferred by all observer panels over autologous reconstruction with regard to the overall anatomical shape. Results showed significant differences in appreciation of type of reconstruction in favor of prosthetic rehabilitation of both nasal- and auricular anatomical subunits. This is in accordance with the finding of Zuo *et al.* (2016), which describe superior aesthetic results in comparison to autogenous methods<sup>57</sup>. This finding indicates that the reconstructive surgeon should focus on the reconstruction as a unity, rather than specific anatomical substructures.

Comparison of our results with literature is difficult due to the wide variety of questionnaires and methodological approaches. Most of the pediatric patients with autologous reconstructed ears suffered from microtia. Literature describes autogenous reconstruction as the accepted standard approach in these cases<sup>58,59</sup>. Only in unfavorable cases with failed autogenous reconstruction, severe soft-tissue and/or skeletal hypoplasia with a low or unfavorable hairline, or in post-traumatic or post-ablative defects, osseointegrated auricular reconstruction is considered<sup>58</sup>. A drawback of prosthetic reconstruction is the need for ongoing maintenance and exclusion of possible subsequent autologous reconstruction when osseointegrated implants are placed. Therefore, the age of the patient should be taken into account. Ears continue to grow throughout life, although only moderate increase occurs after the first 8–10 years<sup>59</sup>. Completion of nasal growth takes place at the approximate age of 16 years old in men and 14 years old in women<sup>60</sup>. Restricted thickness of the parietal and temporal bone is no limiting factor for implant installation as short implants can be applied<sup>61</sup>.

In conclusion, although observer variability is present in the current study, prosthetic reconstructions of auricular and nasal defects tend to be advantageous in subjective aesthetic outcome. It is the task of the surgeon and multidisciplinary team to enable patients to make a well-informed decision. Surgical reconstructive options may be selected based upon surgeon-preference, as well as the available expertise of surgical and prosthetic colleagues in clinically equivalent situations.

## FUTURE PERSPECTIVES

With respect to CMF implants, over the past few decades, numerous enhancements in the area of design, materials and the manufacturing process have been made to improve the physical retention of facial prostheses.

The development of computer-aided (CAD) and computer-aided manufacturing (CAM) systems has upgraded the accuracy of implant treatment planning and subsequent placement. Furthermore, 3D-modeling and virtual-, as well as augmented reality have opened compelling perspectives for precise preoperative planning, the creation of physical replica models, the use of surgical guides and navigational surgery. Aside from the aforementioned advantages, 3D-software may also serve patients in education prior to reconstructive procedures<sup>62</sup>.

Due to exponential advancement in medical imaging techniques (such as multidetector computed tomography and cone-beam computed tomography), reduced size of scanners, better image resolution with a low radiation dose are to be expected against lower costs. Innovations in both imaging modalities and '3D-image based planning' software are likely to increase the accuracy in determination of true clinical bony dimensions. Future developments in reconstruction algorithms of software packages are also mandatory in improving the representations of the available bone volume. Both software as manufacturing of 3D-printed surgical guides used to be expensive. However, due to the increased popularity of 3D-printing technologies, improvement in accuracy, quality of materials, faster printing times and lower costs are to be expected<sup>63</sup>. Open-source software platforms may contribute to the development of new surgical protocols and the possibility of comparing different guide designs.

Virtual preoperative planning of possible implant locations, retention design and future prosthetic rehabilitation shortens the operation time, eliminates the need for a physical surgical guide, reduces the risk of damaging vital structures, and is likely to improve the restorative outcome<sup>20</sup>. Transfer of the virtual treatment planning can be achieved passively by the use of bone-, tooth- or soft tissue- supported templates. However, virtual planning with navigational technology is already widely described in literature to be efficient and effective, with regard to the complex geometric anatomy of the orbital-, nasal- and auricular regions<sup>64,65</sup>. As surgical guides demand extra drill length, normal drill lengths can be used during navigation, which is especially

convenient when operating in small spaces, such as in the orbital- and nasal cavities. Active guided implant placement involves navigational technology, which actively tracks the position of the surgical instruments and provides real-time information about the implant position to the surgeon. Virtual registration may be executed through invasive (usage of bony fixed markers or a neurosurgical head frame) and non-invasive registration methods (i.e. 3D-surface matching). Stereotactic navigational systems enhance clinical efficiency in eliminating the need of different laboratory steps in producing surgical templates<sup>18</sup>. Advances in virtual reality and 3D-image-based reconstruction will lead to faster data processing, reducing processing times. Accessibility of real time navigation systems using enhanced visualization has the potential to lead to more precise placements of CMF implants. However, controlled cadaver studies are needed to show the difference between the use of conventional surgical templates and stereotactic navigation since each navigational system and concomitant software has its own benefits and limitations.

Future studies should also focus on further improvements in the digital design and fabrication of CMF prostheses. The 3D-surface of a patient's face may be acquired and used to obtain an accurate representation in color. The major advantage of this method is the avoidance of conventional laboratory steps and ease in mirroring the unaffected facial region<sup>66</sup>. Although literature already reports on directly printed silicone CMF prostheses, these are still subject to refinement of manufacturing technology before they may become a valid treatment option and alternative to conventional approaches<sup>67</sup>.

In the long-run, future developments might include tissue engineering and 3D-bio-printing of patient specific organs allowing growth of natural tissue similar to the region of implantation. To date, biological scaffolds can be printed, but are still subject to clinical research with regard to ideal scaffold properties, growth factors, extracellular matrices and cells<sup>51</sup>. Although tissue engineering seems to be an attractive option, the issue of blood supply in the bio-printed constructs is, until now, an important challenge. Fortunately, with significant advances being reported, the future of this reconstructive method appears to be promising<sup>68</sup>.

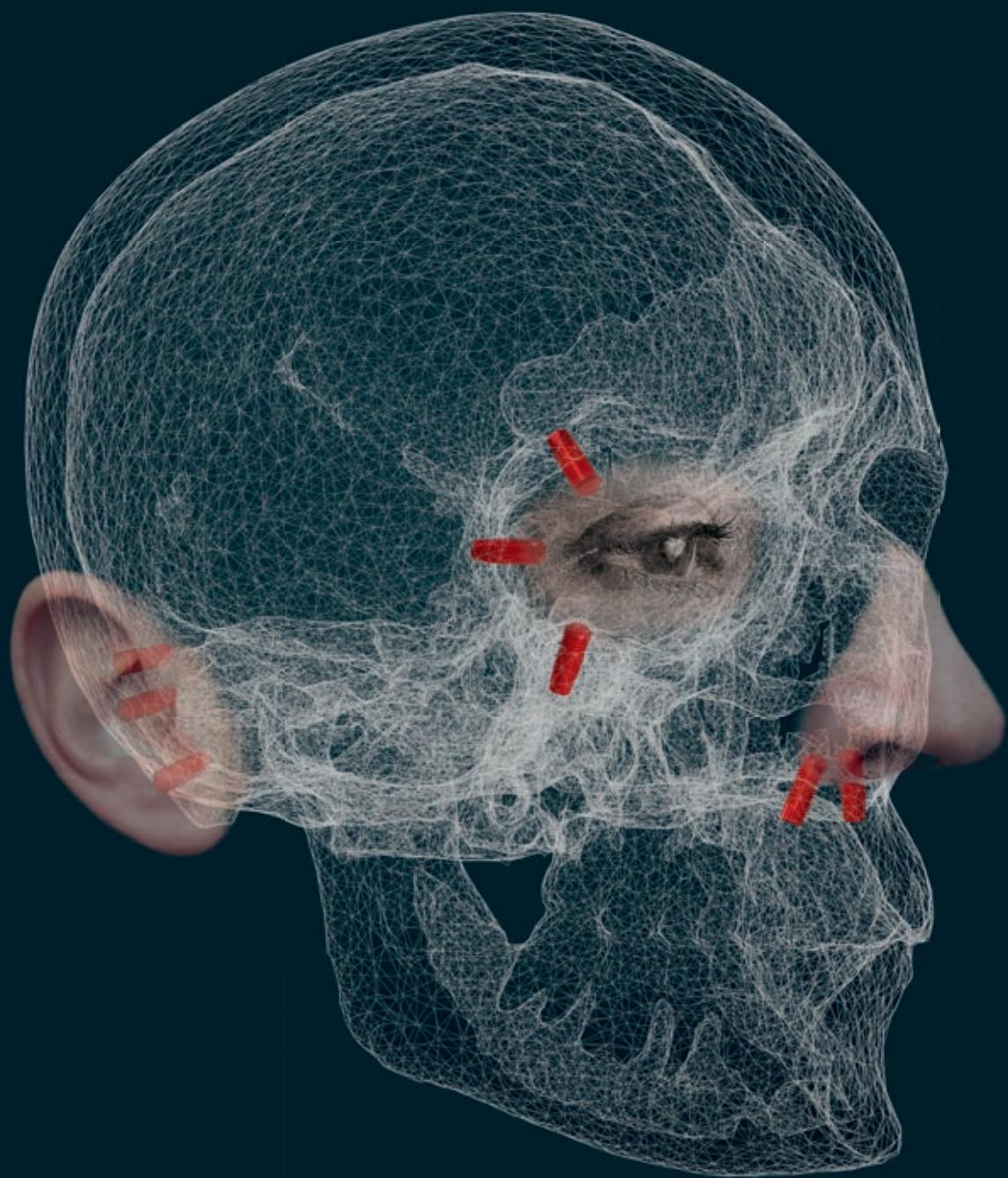
In conclusion, the 3D-revolution takes a central role in implantsurgery and will influence the way surgeons and maxillofacial prosthodontist will address the restoration of CMF defects.

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# Chapter 8

Summary in English and Dutch



## SUMMARY

**Chapter 1** of this thesis provides a general introduction on different approaches to reconstruction of CMF defects. The evolution of endosseous implants in the last decennia results in an effective and safe anchorage tool for craniomaxillofacial (CMF) prostheses. The success of osseointegrated CMF implants in effectively anchoring CMF prostheses and, thereby, rehabilitating patients with extensive soft- and hard tissue defects has been widely confirmed in literature. Still, a number of technical and medical topics remain controversial. The general aim of the research described in this thesis was to assess the accuracy of preoperative planning, the subsequent placement, and the clinical outcomes of CMF implants, including the survival rate and patient-reported outcomes. In addition, prosthetic rehabilitation was compared with autologous reconstruction in restoring CMF defects.

Accurate estimation of the available bone dimensions is crucial for preoperative implant planning. Two imaging techniques are commonly used for pre-operative planning of CMF implants: multi-slice computed tomography (MSCT) or multi-detector computed tomography (MDCT) and, more recently, cone-beam computed tomography (CBCT). Unfortunately, literature is scarce on measurement accuracy of bony dimensions at craniofacial locations using CBCT and MDCT. Accuracy of implant treatment planning is dependent on performance differences among these imaging systems with regard to radiation dose, acquisition technique, reconstruction parameters, spatial resolution and perceived image quality. The aim of the study described in **Chapter 2** was to determine the accuracy of linear measurements on three-dimensional (3D-) cross-sectional images of different CMF regions obtained with CBCT and MDCT and the possible influence of brightness and contrast settings on the registered accuracy.

In total, five dry human cadaver skulls were used. For orientation, cuts were made with a circular bone saw at the ideal implant positions in the nasal-, orbital- and temporal regions prior to acquisition of X-Ray data. Subsequently, CBCT and MDCT images were ordered. Hereafter, clinical measurements with a digital caliper were executed by three independent observers. After the cross-sectional planes were located on the 3D-rendered reconstructions of the CBCT and MDCT images, linear measurements were carried out on the outer bony dimensions at the level of the bony reference holes. Two standard contrast settings of two different planning software programs were used when performing linear measurements on the radiographic images. Measurement

errors showed significant submillimeter overestimation of the bony dimensions with both the CBCT and MDCT imaging modalities. The different contrast settings resulted in an average measurement bias of 0.39 to 0.53 mm for CBCT and 0.57 to 0.59 mm for MDCT. This influence on measurement accuracy was only statistically significant for CBCT images ( $p<0.0015$ ) and for inter-observer variation on MDCT imaging ( $p<0.029$ ). Within the limitations of this study, it was demonstrated that linear measurements on cross-sectional images from 3D-virtual models for preoperative planning of CMF implants showed a consistent submillimeter overestimation.

In **Chapter 3**, an analysis of the accuracy of skin-supported surgical templates 'with and without' bone fixation is described. The study comprised 10 fresh frozen cadaver heads. After acquiring MDCT and CBCT scans, and subsequent virtual implant planning in the orbital, nasal and mastoid region, surgical templates were designed. In these templates, cylindrical openings were created to allow the application of guide sleeves and, thereby, enabling flapless implant placement. For each anatomical region surgical templates 'with and without' multiple fixations pins were produced. The accuracy of implant placement was determined three-dimensionally (3D-) by matching the virtually planned implant positions with the postoperative achieved implant positions. In total, 136 Bränemark MK III TiU® (Nobel Biocare, Kloten, Switzerland.) implants were installed; 57 in the orbital region, 19 nasal implants and 60 auricular implants. Overall, applying fixation pins showed statistical significant larger 'mean deviations' at the implant shoulder (range, 3.0 to 4.4 mm) ( $p=0.025$ ), angle (range, 6.9 to 9.2 degrees) ( $p=0.018$ ), and depth (range, -1.2 to -0.4 mm) ( $p=0.001$ ) in comparison to the use of non-fixed surgical templates ('mean deviations' at implant shoulder (range, 1.8 to 3.2 mm), angle (range, 4.7 to 7.1 mm) and depth (range, -0.2 to 0.6 mm), respectively). Mean implant deviations were shown to be highest for auricular implants with the exception of angular deviations. Surgical templates without fixation pins only showed a non-significant difference in angular deviation with regard to the various anatomical regions. No statistically significant difference was found for depth of implants being placed with the bone-fixed surgical templates. The reported unacceptable high deviations can presumably be explained by a suboptimal positioning of the skin-supported surgical template due to resilience of the skin. The larger 'mean implant deviation', associated with the use of surgical guides in combination with the fixation pins, are likely the result of suboptimal fixation of the template as a result of unfavorable movement during the fixation procedure. The eccentric location of the auricular region in the surgical template is supposed to have worsened this inaccuracy.

The linear- and angular deviations found in this study, when comparing actual CMF implant positions versus the preoperatively planned implant positions, indicate that the inaccuracies introduced by digitally designed skin-supported surgical templates are clinically unacceptable and further clinical research and technical improvement is warranted.

The second part of this thesis aimed to assess the survival rate of CMF implants. In **Chapter 4**, implant survival was related to 'timing of implant placement in relation to ablative surgery', 'radiation therapy' and 'adjunctive HBO treatment'. In this retrospective cohort study of 35 consecutive patients with a total of 44 nasal implants (17 patients) and 59 orbital implants (18 patients), the mean duration of follow-up was 35 months (8-156 months). It was concluded that orbital and nasal implants inserted during ablative surgery showed a significant higher survival rate ( $p=0.044$ ) than implants installed after ablative surgery. No significant difference in survival of implants placed in irradiated versus non-irradiated bone, possible benefit of preventive HBO therapy or relation with CMF location was found.

The third part of the thesis focused on the subjective assessment of patients and other observer groups with regard to the clinical outcome of prosthetic and autologous reconstruction of CMF defects. In **Chapter 5**, a retrospective clinical study is described, in which treatment outcome and quality of life was determined by using questionnaires regarding different aspects of CMF prostheses (durability, comfort, type of retentive system, prosthesis hygiene), overall satisfaction, self-image and impact on socialization. High Cronbach's alpha values (0.82) showed an adequate internal consistency. A total of 52 patients, comprising 12 orbital, 17 nasal, and 23 auricular prostheses, completed the questionnaires. High satisfaction scores were noted with regard to 'wearing comfort', 'fit' and 'aesthetics' of the prostheses. However, implant-retained prostheses were shown to be statistically significant more advantageous in comparison with adhesive-retained prostheses in terms of enhanced retention and ease of placement and removal ( $p=0.01$  and  $p=0.04$ , respectively). No significant differences were found in peri-implant tissue complications between the various anatomical locations and retentive systems although patients with auricular defects cleaned their prostheses significantly less frequently ( $p=0.01$ ). Patients with prosthetic rehabilitation of nasal defects were shown to be significantly more frequently dissatisfied with the junction of their prosthesis to the surrounding soft tissue and more aware of others noticing their prostheses. In contrast, patients with auricular defects were significantly less embarrassed ( $p=0.01$ ) by their prostheses.

Nasal- and auricular defects may be reconstructed using implant retained prostheses or by means of autologous reconstruction. The aim of the study in **Chapter 6** was to assess opinions of different observer panels on the aesthetic outcome of both reconstructive methods. Subjective assessments of the different types of reconstruction were conducted by patients, professionals (oral and maxillofacial (OMF) surgeons and ear, nose and throat (ENT) surgeons) as also laymen. Overall appreciation, aesthetic outcome of anatomical subunits and possible interaction between both, were scored. A total of 77 patients, treated between 1997 and 2016, were included. The cohort comprised 48 patients with nasal defects (24 autologous and 24 prosthetic reconstructions) and 29 with auricular defects (12 autologous and 17 prosthetic reconstructions). The control group included 31 non-affected patients (20 ears and 11 noses). Observer panels encompassed 10 laymen, 10 professionals (5 OMF surgeons, 5 ENT surgeons) and 5 patients with reconstructed auricular- or nasal defect.

Prosthetic reconstructions were frequently found to be associated with significantly higher scores. The only exception was the assessment of laymen and ENT surgeons with regard to the color of reconstructions of the nasal defects ( $p=0.02$  and  $p=0.02$ , respectively). Patient observers only showed a significant preference for prosthetic reconstruction with regard to the natural shape of the auricular reconstructions ( $p=0.01$ ). Laymen showed a preference for the prosthetic reconstructions in the domains 'matches the patient's face', 'natural shape' and 'length' ( $p=0.00$ ,  $p=0.00$ ,  $p=0.05$ ). The OMF-surgeons judged the prosthetic ear favorably in all domains. In contrast, ENT surgeons only significantly favored prosthetic reconstruction in the domain 'natural shape' ( $p=0.04$ ).

Nearly all anatomical subunits of prosthetically reconstructed auricular defects showed significantly higher appreciation scores. The only exception included ENT surgeons not significantly favoring prosthetic reconstructions of the triangular fossa.

With regard to nasal reconstructions, only prosthetic reconstruction of the nasal dorsum showed lower appreciation scores by laymen, OMF and ENT surgeons, although not at a significant level. No significant influence of anatomical subunits on overall appreciation of reconstruction type was found. Furthermore, no interaction with age or gender of observed patients or observers could be determined.

In **Chapter 7**, the major conclusions of this thesis are discussed. In addition, future perspectives and recommendations for further research are presented. In conclusion, endosseous implants represent a secure and reliable method in CMF reconstruction that offer a significant improvement in quality of life. However, accuracy in CMF implant surgery reflects the sum of errors from preoperative scan, 3D-planning and subsequent implant placement. Future improvements in these separate steps, as well as in prosthetic materials, are likely to result in a higher accuracy and efficiency both in diagnostics and implant surgery, as well as optimizing patient satisfaction.

## NEDERLANDSE SAMENVATTING

**Hoofdstuk 1** schetst een algemeen overzicht van de verschillende methoden om aangezichtsdefecten te reconstrueren. De introductie van in bot verankerde (geosseointegreerde) implantaten hebben in de laatste decennia geresulteerd in een effectieve en veilige retentiemethode voor faciale prothesen, ook wel epitheses genoemd. Het succes van deze geosseointegreerde implantaten bij het verankeren van epitheses, en daarmee het herstellen van uitgebreide aangezichtsdefecten, is uitgebreid beschreven in de wetenschappelijke literatuur. Desondanks bestaan tal aan technische en medische vraagstukken die nog nader onderzoek vergen. Doel van dit proefschrift was om de nauwkeurigheid te bepalen van de preoperatieve planning en de daaropvolgende plaatsing van implantaten in het aangezicht, ook wel extraorale implantaten genoemd. Aanvullend werd de uiteindelijke klinische uitkomst, waaronder de overlevingsduur en patiëntervaringen, gemeten. De resultaten van implantaat-gedragen epitheses werden vervolgens vergeleken met autologe reconstructie van aangezichtsdefecten. Hiermee worden chirurgische reconstructies bedoeld met patiëntieigen weefsel.

Precieze inschatting van botdiktes is cruciaal bij de preoperatieve planning van implantaten. Een tweetal beeldvormende modaliteiten worden veelal toegepast bij het preoperatief plannen van extraorale implantaten: multi-slice computed tomography (MSCT) of multi-detector computed tomography (MDCT) en cone-beam computed tomography (CBCT). Er is weinig wetenschappelijke literatuur vorhanden omrent de nauwkeurigheid van metingen van MDCT en CBCT scanners ter plaatse van crano-maxillo-faciale (CMF) locaties. Deze nauwkeurigheid wordt beïnvloed door de toegepaste stralingsdosis, methode van beeldacquisitie en beeldreconstructie, spatiële resolutie en waargenomen beeldkwaliteit.

In **Hoofdstuk 2** is een kadaverstudie beschreven waarin de nauwkeurigheid van lineaire metingen op dwarsdoorsneden van driedimensionale (3D) reconstructies van de CBCT- en MDCT- beelden ter plaatse van verschillende aangezicht locaties werd gemeten. Tevens werd de mogelijke invloed van de instelling van de mate van helderheid en contrast bepaald. Voor deze studie zijn 5 humane schedels gebruikt. Voorafgaand aan het vervaardigen van MDCT- en CBCT-scans werden gestandaardiseerde botsnedes aangebracht ter plaatse van gewenste implantaatposities in de neus, orbita en temporale regio. Parallel aan deze botsnedes werden aanvullend boorgaten

ter referentie aangebracht. Op de schedels werden met behulp van een digitale schuifmaat door drie afzonderlijke onderzoekers de afstand gemeten tussen de zaagsneden ter hoogte van deze boorgaten. Na het traceren van dezelfde locaties op de dwarsdoorsneden van de CBCT- en MDCT-scans werden dezelfde afstanden digitaal nagemeten. Deze afstandsmetingen werden uitgevoerd bij een tweetal standaard instellingen voor helderheid en contrast afkomstig van twee verschillende computerplanningsprogramma's. Zowel de afstandsmetingen op CBCT en MDCT beelden toonden een overschatting van de werkelijkheid. De vergroting bij twee verschillende instellingen voor helderheid en contrast varieerde tussen 0.39 tot 0.53 millimeter voor CBCT beelden en 0.57 tot 0.59 millimeter voor MDCT beelden. Afstandsmetingen waren enkel significant voor CBCT beelden ( $p<0.0015$ ) en voor de interobserver variatie bij MDCT beelden ( $p<0.029$ ). Binnen de beperkingen van dit onderzoek werd aangetoond dat afstanden gemeten op dwarsdoorsneden van 3D reconstructies ten behoeve van preoperatieve planning van extraorale implantaten een consistente overschatting rond de halve millimeter geven ten opzichte van de werkelijke botdimensies.

In **hoofdstuk 3** werd de nauwkeurigheid geëvalueerd van implantaatplaatsing met behulp van op huid afgesteunde boormallen; zowel *met* als *zonder* fixatiepinnen. Voor deze kadaverstudie werden 10 humane preparaten gebruikt. Na het vervaardigen van MDCT en CBCT scans werd een virtuele implantaatplanning uitgevoerd alsmede chirurgische boormallen ontworpen ten behoeve van orbitale, nasale en temporale implantaten. In deze boormallen werden boorcilinders gepland waardoor de implantaten 'flapless' konden worden geplaatst. Voor iedere anatomische regio (orbita, neus, temporaal) werden boormallen ontwikkeld met en zonder uitsparingen voor fixatiepinnen. De nauwkeurigheid van implantaatplaatsing werd 3D geëvalueerd door de postoperatieve scans te superponeren op de preoperatieve scans met de virtuele implantaatposities. In totaal werden 136 Bränemark MK III TiU® (Nobel Biocare, Kloten, Zwitserland) implantaten geplaatst; respectievelijk 57, 19 en 60 implantaten ter plaatse van de orbita, neus en temporale regio. Resultaten toonden significant grotere afwijkingen tussen de planning en uiteindelijke plaatsing van implantaten met behulp van boormallen met fixatiepinnen ter plaatse van de schouder ( $p=0.025$ ) en diepte ( $p=0.018$ ) alsmede een grotere hoekafwijking ( $p=0.001$ ). De gemiddelde afwijking tussen planning en uiteindelijke positionering waren het grootst bij temporale implantaten met uitzondering van de hoekafwijkingen. Bij de chirurgische boormallen zonder fixatiepinnen waren enkel de afwijkingen met betrekking tot hoekafwijking

niet significant bij zowel de orbitale, nasale als temporale regio. Bij de chirurgische boormallen met fixatiepinnen waren alleen de afwijkingen met betrekking tot de diepte niet significant. De aangetoonde afwijkingen bij de op huid afgesteunde mallen worden hoogstwaarschijnlijk verklaard door een suboptimale positionering ten gevolge van elasticiteit van de huid. De grotere afwijkingen bij implantaten die geplaatst zijn met behulp van boormallen met fixatiepinnen berusten waarschijnlijk op een nadelige beïnvloeding van de positie van de boormal ten gevolge van ongewenste verplaatsing tijdens het fixeren. De acentrische locatie van de temporale regio wordt verondersteld deze negatieve afwijking te versterken. De lineaire en hoekafwijkingen in deze studie zijn klinisch onacceptabel, zodat nader klinisch onderzoek en technische optimalisatie noodzakelijk zijn.

Het tweede deel van dit proefschrift beoogt indicatoren te identificeren die voorspellend zijn voor het falen van CMF implantaten. In **hoofdstuk 4** is een retrospectieve cohort studie beschreven waarbij de relatie werd onderzocht tussen de overlevingsduur van extraorale implantaten en het moment van plaatsing ten opzichte van de ablatieve chirurgie, bestralingstherapie en hyperbare zuurstoftherapie. Er werden 35 patiënten geïncludeerd met in totaal 44 nasale implantaten (17 patiënten) en 59 orbitale implantaten (18 patiënten). De gemiddelde follow-up-duur bedroeg 35 maanden (range 8-156). In deze retrospectieve studie werd aangetoond dat plaatsing van CMF implantaten ter plaatse van de orbitale en nasale regio tijdens ablatieve chirurgie een significant hogere overlevingsduur kent in vergelijking met extraorale implantaten die na ablatieve chirurgie worden geplaatst ( $p=0.044$ ). Er werden geen significante relatie gevonden met overlevingsduur en bestralingstherapie, toepassing hyperbare zuurstoftherapie of anatomische locatie.

Het derde deel van het proefschrift beschrijft de patiënttevredenheid na prothetische rehabilitatie en de subjectieve beoordeling van diverse panelgroepen ten aanzien van de esthetische uitkomst na prothetische of autologe reconstructie van aangezichtsdefecten.

In **hoofdstuk 5** wordt de kwaliteit van leven onderzocht van patiënten na prothetische rehabilitatie van aangezichtsdefecten. Er werden vragenlijsten opgesteld waarin geïnformeerd werd naar de algemene tevredenheid over de epithese alsmede specifieke tevredenheid aangaande prothesematerialen, retentie, hygiëne, kwaliteit van leven en invloed op sociaal functioneren. De hoge Cronbach's alpha waarde (0.82) toont aan

dat de vragenlijst een instrument met voldoende interne consistentie is. In totaal 52 patiënten retourneerden de vragenlijsten waarvan 12 patiënten met een orbitaprothese, 17 patiënten met een neusprothese en 23 patiënten met een oorprothese. Door alle patiëntengroepen werd zowel aan draagcomfort, pasvorm als esthetiek van de epithesen een hoge mate van tevredenheid toegekend. Implantaatgedragen epithesen werden significant beter beoordeeld met betrekking tot retentie ( $p=0.01$ ) en gebruiksgemak ( $p=0.04$ ) in vergelijking met conventioneel adhesief bevestigde epithesen. Er werden geen significante verschillen gevonden ten aanzien van peri-implantaire infecties in relatie tot de verschillende anatomische locaties of retentieve systemen alhoewel patiënten met auriculaire defecten hun epithese significant minder frequent reinigden ( $p=0.01$ ). Patiënten met nasale epithesen waren significant minder tevreden met de aansluiting van hun epithesen op de omringende weke delen en ervoeren vaker dat anderen de epithese in hun gelaat opmerkten ( $p=0.01$ ). Patiënten met auriculaire epithesen bleken significant minder schaamte te ervaren om zich in het openbaar te vertonen ( $p=0.01$ ).

Het doel van **hoofdstuk 6** was het vaststellen van de subjectieve beoordeling van patiënten, medisch specialisten (MKA-chirurgen en KNO-artsen) en leken aangaande het esthetisch resultaat na prothetische of autologe reconstructie van nasale of auriculaire defecten. Zowel de esthetische waardering over de gehele reconstructie als de anatomische subunits en eventuele interactie werd uitgevraagd. In de digitale enquêtes waren foto's van 77 patiënten opgenomen die tussen 1994 en 2016 een prothetisch of autologe reconstructie hadden ondergaan. Dit cohort bestond uit 48 patiënten met een nasale defect (24 autologe en 24 prothetische reconstructies) en 29 patiënten met een auriculair defect (12 autologe en 17 prothetische reconstructies). De controlegroep bestond uit 31 gezonde patiënten met onaangestaste oren ( $n=20$ ) en neuzen ( $n=11$ ). Gekozen werd voor 3 onafhankelijke panels: 10 leken, 10 medisch specialisten (5 MKA-chirurgen, 5 KNO-artsen) en 5 patiënten met een gereconstrueerd nasale of auriculair defect.

Resultaten tonen veelal een significant hogere mate van waardering voor prothetische reconstructies. Enige uitzondering hierop betreft de hogere waardering van leken en KNO-artsen ten aanzien van de kleur van de autologe reconstructies van nasale defecten (respectievelijk  $p=0.02$ ,  $p=0.02$ ). Het panel bestaande uit patiënten scoorde prothetische reconstructies alleen significant hoger ten aanzien van de natuurlijke vorm van auriculaire reconstructies ( $p=0.01$ ). Het panel bestaande uit leken

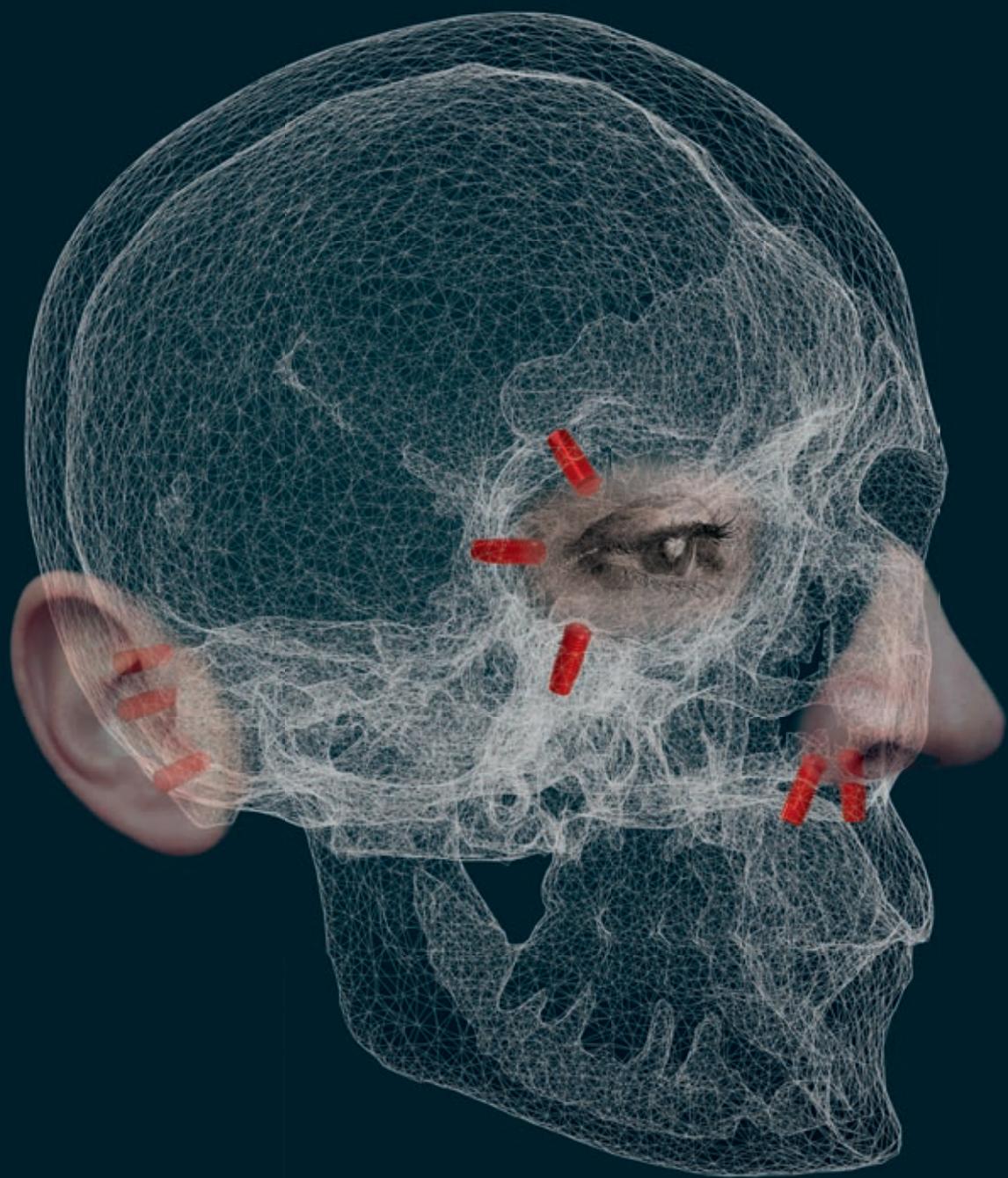
waardeerde prothetische reconstructies van auriculaire defecten significant hoger met betrekking tot algemeen passend zijn bij het verdere gelaat, natuurlijke vorm en lengte (respectievelijk  $p=0.00$ ,  $p=0.00$ ,  $p=0.05$ ). Het panel bestaande uit MKA-chirurgen beoordeelde prothetische reconstructies op alle criteria als significant beter ten opzichte van autologe reconstructies met uitzondering van kleur (niet significante voorkeur voor prothetische reconstructies). De KNO-artsen beoordeelden alleen de natuurlijke vorm van prothetische reconstructies van auriculaire defecten significant beter ( $p=0.04$ ).

Alle anatomische subunits van prothetische reconstructies bij auriculaire defecten ontvingen significant betere beoordelingen ten opzichte van autologe oor reconstructies. Uitzondering hierop betrof de niet significante voorkeur voor prothetische reconstructie van de triangulaire fossa door KNO-artsen. Behoudens de weke delen van de neusbrug, waarvan leken, MKA-chirurgen en KNO-artsen de autologe reconstructies enigszins (en niet significant) hoger beoordeelden werden alle nasale anatomische subunits bij prothetische reconstructies hoger gewaardeerd. Er kon geen significante invloed van anatomische subunits worden aangetoond in relatie tot de mate van algehele tevredenheid over de gehele reconstructie. Tevens kon geen relatie worden aangetoond tussen de esthetische waardering van het behandelresultaat en leeftijd of geslacht van panelleden dan wel beoordeelde patiënten.

In **Hoofdstuk 7** worden de belangrijkste uitkomsten bediscussieerd. Daarnaast worden aanbevelingen voor verder onderzoek gedaan en toekomstperspectieven geschatst. Concluderend kan worden gesteld dat gesoedointegreerde CMF implantaten een duidelijke klinische meerwaarde bieden wat betreft de retentie van epitheses, waardoor de kwaliteit van leven van betrokken patiënten verbetert. De nauwkeurigheid waarmee CMF implantaten gepland en geplaatst kunnen worden, wordt negatief beïnvloed tijdens de volgende procedures; het vervaardigen van de preoperatieve scans, de virtuele planning van implantaatposities, het ontwerpen en gebruik van boormallen en de uiteindelijke plaatsing.

Nieuwe technologische ontwikkelingen en optimalisatie van prothetische materialen zijn noodzakelijk om de voorspelbaarheid van epitheses en patiënttevredenheid naar een zo optimaal niveau te brengen.





# Part VI

## Appendices

## List of publications

Peer-reviewed full-text publications

### *In this thesis*

**Dings JPJ**, Verhamme L, Merkx MA, Xi T, Meijer GJ, Maal TJ. Reliability and accuracy of cone beam computed tomography versus conventional multidetector computed tomography for image-guided craniofacial implant planning: an in vitro study. *Int J Oral Maxillofac Implants* 2019; **34**: 665-672

**Dings JPJ**, Verhamme L, Maal TJ, Merkx MAW, Meijer GJ. Reliability and accuracy of skin-supported surgical templates for computer-planned craniofacial implant placement, a comparison between surgical templates: with and without bony fixation. *J Craniomaxillofac Surg* 2019; **47**: 977-983

**Dings JPJ**, Merkx MAW, de Clonie MacLennan-Naphausen MTP, van de Pol P, Maal TJ, Meijer GJ. Maxillofacial prosthetic rehabilitation: a survey on the quality of life. *J Prosthet Dent* 2018; **120**: 780-786

**Dings JPJ**, Maal Tj, Muradin MS, Ingels KJ, Klevering BJ, Koole Re, Merkx MA, Meijer GJ. Extra-oral implants: insertion per- or post-ablation? *Oral Oncol* 2011; **47**: 1074-8

**Dings JPJ**, Vijverberg MA, Hol MKS, Ulrich DJO, de Haan AFJ, Verhage-Damen GW, de Clonie MacLennan-Naphausen MTP, Kruyt IJ, Ghaeminia H, Bruekers-Schipper GB, Ingels KJAO, Dicker GJ, Meijer GJ, Merkx MAW. Autologous versus prosthetic nasal and auricular reconstruction – patient, professional and laymen perception. *Int J Oral Maxillofac Surg* 2020; online ahead of print, doi: 10.1016/j.ijom.2020.02.010.

### *Other*

Ghaeminia H, Gerlach NL, Hoppenreijts TJ, Kicken M, **Dings JPJ**, Borstlap WA, de Haan T, Bergé SJ, Meijer GJ, Maal TJ. Clinical relevance of cone beam computed tomography in mandibular third molar removal: a multicentre, randomised, controlled trial. *J Craniomaxillofac Surg* 2015; **43**: 2158-67

**Dings JPJ**, Mizbah K, Bergé SJ, Meijer GJ, Merkx MA, Borstlap WA. Secondary closure of small- to medium-size palatal defects after ablative surgery: reappraisal of reconstructive techniques. *J Oral Maxillofac Surg* 2014; **72**: 66-76

Mizbah K, **Dings JPJ**, Gonesh SJ, Merkx MA. A diagnosed follicular cyst turned out to be a squamous cell carcinoma. *Ned Tijdschr Tandheelk* 2013; **120**:18-20

Mizbah K, **Dings JPJ**, Kaanders JH, van den Hoogen FJ, Koole R, Meijer GJ, Merkx MA. Interforaminal implant placement in oral cancer patients: during ablative surgery or delayed? A 5-year retrospective study. *Int J Oral Maxillofac Surg* 2013; **42**: 651-5

**Dings JPJ**, van Damme PA. Face the facial furuncle. *Ned Tijdschr Tandheelk* 2008; **115**: 125-31

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*No one can whistle a symphony. It takes a whole orchestra to play it - H.E. Luccock*

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## Curriculum Vitae

Jeroen Paulus Johannes Dings was born on February 17, 1983, in Helmond, The Netherlands. After finishing secondary school with the distinction *cum laude*, he started studying Dentistry in 2001 at the Radboud University Nijmegen, in The Netherlands. During his study, he was Chairman of the Board of the dental student faculty association, TFVN, and a member of several committees. He completed an internship for several months in 2004 at the University of Pretoria, South Africa. In 2007, he obtained his Dental Medical Degree with the distinction *cum laude*. In 2006, he continued with a Master's Degree in Medicine, obtaining his Medical Degree with honors in 2011. During the years that he studied medicine, he worked as a Dentist and was trained in dento-alveolar surgery at the Department of OMF surgery at Medisch Spectrum Twente en ZGT, Almelo in The Netherlands.

Jeroen started his PhD research project at the Department of Oral & Maxillofacial (OMF) surgery at Radboud University Medical Centre Nijmegen (RUMC), the Netherlands in 2009. In April 2011, he began his residency in OMF surgery at the same department under the supervision of Prof. dr. S.J. Bergé. He has presented at several scientific conferences. His research has been recognized as award-winning by the Dutch Association of Oral and Maxillofacial surgery (NVMKA). Furthermore, he is a member of the Dutch association of oral implantology (NVOI).

After his registration as an OMF surgeon in 2015, he continued his career at the Elkerliek Hospital in Helmond and Deurne, The Netherlands. He has a specific interest in orthognathic surgery, implantology and traumatology. Jeroen is engaged to Ilone Meijnen, and together they have three children, Emma (2013), Floris (2014) and Sarah (2017).







