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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.
Materials 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 cranio-maxillofacial implants using skin-supported surgical templates. Surprisingly, the use of bone-fixated pins worsened the accuracy.

1. Introduction

Reconstruction of cranio- and maxillofacial (CMF) defects is challenging due to complex anatomy and proximity of vital structures (Thimmappa and Girod, 2010; Bai et al., 2012; Parthasarathy, 2014). 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 (Tjellström et al., 1981; Dings et al., 2011; Visser et al., 2018; Vander Poorten et al., 2016).

Successful prosthetic-driven rehabilitation depends on accurate diagnosis, preoperative planning, and subsequent placement of endosseous implants (Asher et al., 1999; Dandekeri et al., 2013; Verhamme et al., 2015a; Cotert and Yilmaz, 2016).

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 (D'Haese et al., 2012a; Dandekeri et al., 2013). This 3D information allows accurate virtual planning using prosthetically oriented true-sized implants. As such, guided implant placement allows minimally invasive procedures, and reduces errors that are involved in standard implant surgery (Behneke et al., 2012; Dandekeri et al., 2013; Cassetta et al., 2014).

CMF osseointegrated implants may be placed in a conventional manner or by stereolithographically (SLA) generated surgical

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guides (Cotert and Yilmaz, 2016). Virtual planning software has enabled 3D computer-aided design and computer-aided 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 (Ciocca et al., 2009; Neugebauer et al., 2010; Vercruyssen et al., 2014b; Pettersson et al., 2014). Surgical guides can be skeletal, dental or mucosal supported (Van der Meer et al., 2012a; Van Assche et al., 2012; Van der Meer et al., 2012b). 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 (Ersoy et al., 2008; Vercruyssen et al., 2008; Arisan et al., 2010; Pettersson et al., 2010; Van Assche et al., 2012; Behneke et al., 2012; D'Haese et al., 2012a; Dreiseidler et al., 2012; Verhamme et al., 2013; Cassetta et al., 2014; Verhamme et al., 2015a). To our knowledge, only a few studies have reported on the accuracy of CMF implant placement with the aid of CAD/CAM-guided surgical templates (Ciocca et al., 2011; Van der Meer et al., 2012a; Van der Meer et al., 2012b). 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 would allow proper implant placement, implying that differences between virtually planned implants and the actual positions would be less than 1 mm. Furthermore, it was expected that the use of bone-fixated pins would improve the accuracy of the guided implant placement procedure.

2. 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 as in live 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 s. The field of view was 22 cm with a voxel size of 0.300 mm. Data were converted into Digital Imaging and Communications in Medicine (DICOM) format. 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 mm 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; ⌀3.75 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 (Figs. 1–3).

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 relied only 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'.

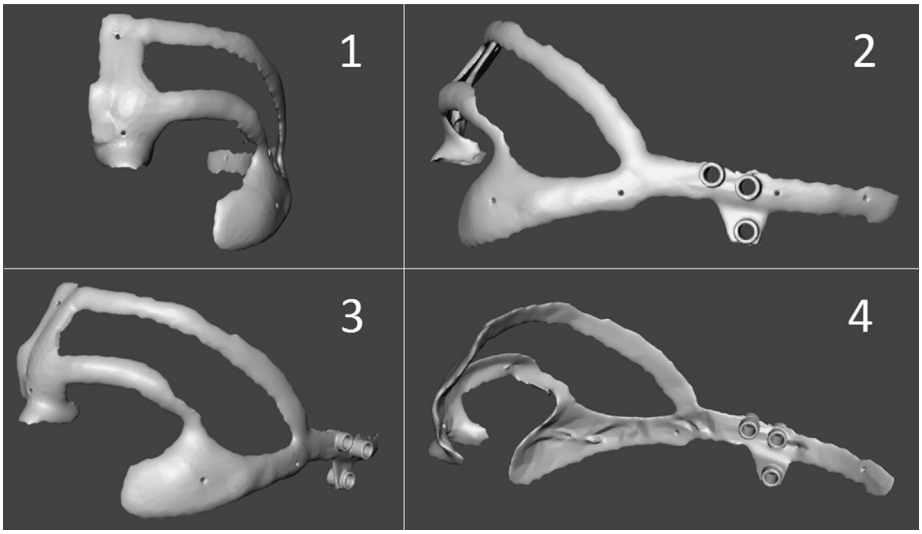

Fig. 1. Auricular template: frontal view (1), lateral view (2), three-quarter view (3), medial view (4).

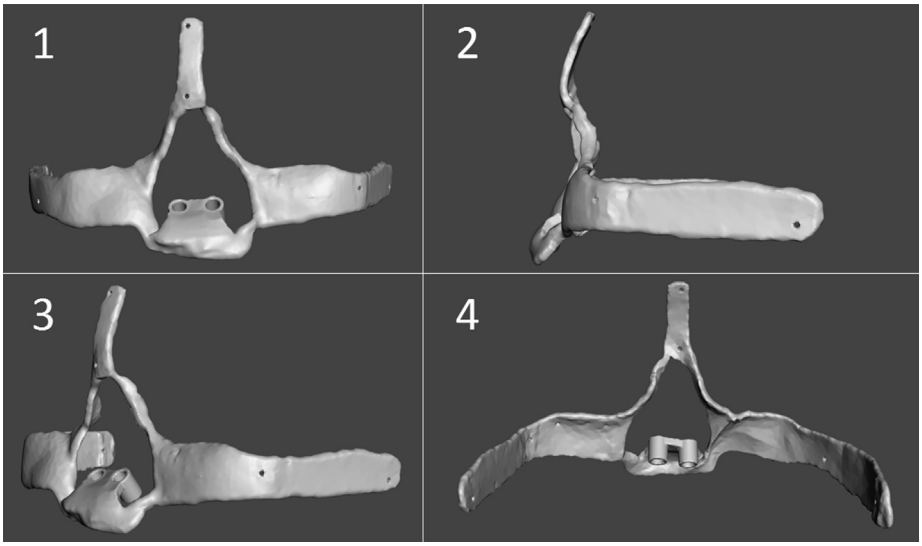

Fig. 2. Nasal template: frontal view (1), lateral view (2), three-quarter view (3), medial view (4).

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 stepwise 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).

3. Results

A total of 136 Branemark MK III TiU implants with regular platform (⌀ 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.

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-fixated 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.

4. Discussion

In this study, single-type personalized surgical templates were 3D-printed after the computer-based transfer of the 3D-planned

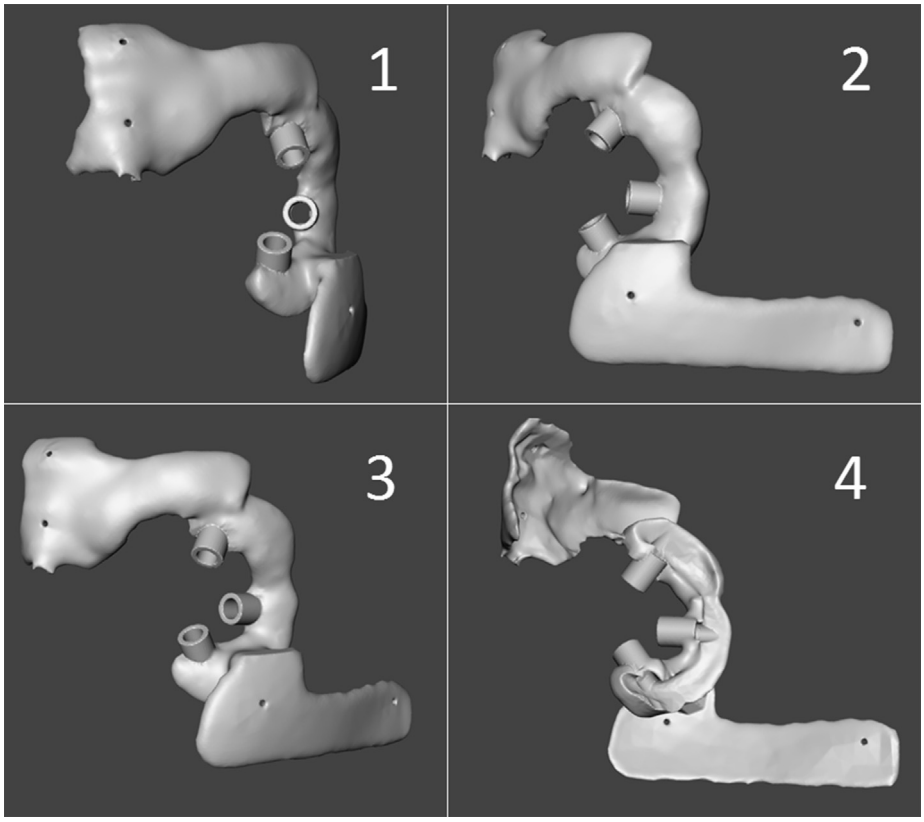

Fig. 3. Orbital template: frontal view (1), lateral view (2), three-quarter view (3), medial view (4).

implant position from both CBCT and MDCT imaging modalities. The Brånemark system was the first implant system to be used extraorally (Federspil, 2009).

In contrast to 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 positions (Van Assche et al., 2010). However, it is difficult to make direct comparisons among 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 of reported observations (Behneke et al., 2012; Van Assche et al., 2012).

Few studies have evaluated the influence of surgical templates on deviations of CMF implants. Van der Meer et al. (Van der Meer et al, 2012a) showed a high concordance between planned and actual implants in the nasal floor. However, accuracy of actual implant positions were described only for two nasal implants in one patient (Van der Meer et al, 2012a). In their study, distance deviations for

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

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, implant shoulder, angle and depth.

Anatomical region	Mean deviations							
	Tip (mm) [95% CI]		Shoulder (mm) [95% CI]		Angle (°) [95% CI]		Depth (mm) [95% CI]	
	No bony fixation	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 [3.11, 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 [−1.86-0.88)
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]
P value	.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.

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°. In contrast to 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 as ideal fixed reference points.

Another study of Van der Meer et al. (Van der Meer et al, 2012b) 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° (SD 2.33) for the angulation. Other study reports 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 (Cheng et al., 1998; Alfano et al., 2005; Kurtulmus et al., 2009; Cotert and Yilmaz, 2016).

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 (Van Steenberghe et al., 2003; Chrcanovic et al., 2010; D'Haese et al., 2012b; Turbush and Turkyilmaz, 2012; Van de Wiele et al., 2015; Verhamme et al., 2015b). 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 corrected (Nishimura et al.,1996; Nishimura et al., 1998).

Reported deviations can be explained by the resilience of the skin, since accuracy is dependent mainly on precise and stable positioning and on inherent support of the surgical template (Vrielinck et al., 2003; Soares et al., 2012). Resiliency is likely to be negatively influenced by the reduced quality and altered thickness of the soft tissue of fresh-frozen cadavers defrosted at 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 (Verhamme et al., 2015b). As Neugebauer et al. pointed out, fixation is not necessarily carried out in the same position as during virtual planning (Neugebauer et al., 2010). Our results are consistent with the results of Verhamme et al. showing that bone-fixation pins do not offer more accurate transfer from planning to placement of maxillary implants (Verhamme et al., 2015b). 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 (Primo et al., 2012; Widmann et al., 2016).

Unintentional deformation of surgical templates during printing or per-operative bending might have occurred, since the templates and extending arms covered a large surface (Van Assche et al., 2012). To minimize dimensional changes, an overall thickness of 3.0 mm of surgical templates was planned (Van Assche et al., 2010). 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. described a maximum angular deviation of 4.71° for a maximal inclination of the drill (Van Assche et al., 2010). 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 (Van Assche et al., 2012). When bony contours or anatomic situations are unfavorable for craniofacial implant placement, subperiosteally anchored titanium plates are a viable alternative treatment option and have been reported to show good overall success rates (Lünenbürger et al., 2016; Barreto et al., 2019).

Verhamme et al. (Verhamme et al., 2015a) and Van Assche and Quirynen (2010) 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 (Verhamme et al., 2015a; Van Assche and Quirynen, 2010).

Recommendations for future research include the added value of the installation of osteosynthesis screws prior to pre-operative imaging (Verhamme et al., 2017). These can be used as guides 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 provide an alternative for transferring virtual planned positions to the surgical area (Ruppin et al., 2008; Van Assche et al., 2012).

5. 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.

Conflicts of interest

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. None of the authors had competing interests.

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