CLINICAL ORAL IMPLANTS RESEARCH

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Computed tomography-based evaluation of template (NobelGuide™)-guided implant positions: a prospective radiological study

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Abstract

Objectives: This prospective study was intended to evaluate the overall deviation in a clinical treatment setting to provide for quantification of the potential impairment of treatment safety and reliability with computer-assisted, template-guided transgingival implantation.

Material and methods: The patient population enrolled (male/female = 10/8) presented with partially dentate and edentulous maxillae and mandibles. Overall, 86 implants were placed by two experienced dental surgeons strictly following the NobelGuide™ protocol for template-guided implantation. All patients had a postoperative computed tomography (CT) with identical settings to the preoperative examination. Using the triple scan technique, pre- and postoperative CT data were merged in the Procera planning software, a newly developed procedure – initially presented in 2007 allowing measurement of the deviations at implant shoulder and apex.

Results: The deviations measured were an average of 0.43 mm (bucco-lingual), 0.46 mm (mesio-distal) and 0.53 mm (depth) at the level of the implant shoulder and slightly higher at the implant apex with an average of 0.7 mm (bucco-lingual), 0.63 mm (mesio-distal) and 0.52 mm (depth). The maximum deviation of 2.02 mm was encountered in the corono-apical direction. Significantly lower deviations were seen for implants in the anterior region vs. the posterior tooth region ($P<0.01$, 0.31 vs. 0.5 mm), and deviations were also significantly lower in the mandible than in the maxilla ($P=0.04$, 0.36 vs. 0.45 mm) in the mesio-distal direction. Moreover, a significant correlation between deviation and mucosal thickness was seen and a learning effect was found over the time period of performance of the surgical procedures.

Conclusion: Template-guided implantation will ensure reliable transfer of preoperative computer-assisted planning into surgical practice. With regard to the required verification of treatment reliability of an implantation system with flapless access, all maximum deviations measured in this clinical study were within the safety margins recommended by the planning software.

As dental implants represent an established treatment option in dentistry, its use has widely increased even in difficult and complex cases with limited bone volume and quality (Ohtani et al. 2009). However, inaccurate implant positioning may not only involve aesthetic impairments of the implant–prosthetic restorations but also may result in complications associated with increased implant loss rates (Ruppin et al. 2008). Computer-assisted, template-guided implantology allows for precise and accurate preoperative implant positioning; furthermore, it allows for prosthetic planning, identification of anatomically sensitive structures (BouSerhal et al. 2002; Katsoulis et al. 2009) and will help in avoiding complications such as sinus perforation, fenestration, dehiscence and injury of the mandibular nerve (Verstreken et al. 1998).

The templates, prepared in CAD/CAM systems in most of the cases, are to ensure accurate intraoperative implementation of the planned implant positions. *In vivo* and *ex vivo* studies have shown adequate accuracy of this treatment concept with bone-supported templates (van Steenberghe et al. 2002, 2003).

With guided implant insertion additionally implemented in the new generation of implantation templates, an enhanced implementation precision can be expected vs. template systems exclusively using guided implant bed preparation.

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Thus, the risk of linear and angular deviations frequently encountered in clinical use in the posterior tooth region (Naitoh et al. 2000; Wagner et al. 2003; van Steenberghe et al. 2003; Hümmeke et al. 2004) should be reduced.

Moreover, the added fixability of state-of-the-art templates at the jaw to be operated on should provide for an increased implantation accuracy based on planning data. In an *ex vivo* study in mucosa- and tooth-supported templates, Van Assche et al. (2007) were able to demonstrate an increased implementation precision.

However, it has been suggested that use of purely or partially mucosa-supported templates may make accurate intraoperative repositioning of the template more difficult and thus may affect implementation precision. This might be due to alterations in the local mucosal environment involving an increased resilience. Therefore, maximum implantation precision is required for mucosa-borne templates allowing no direct control of the implants inserted (Vercruyssen et al. 2008). In particular, the use of flapless implant placement is to be critically evaluated in clinical studies (Van Assche et al. 2007; Dreiseidler et al. 2009) as template-guided minimally invasive implantology has already become a commonly used treatment concept.

This prospective study was intended to evaluate the overall deviation in the clinical treatment setting to allow quantification of a potential impairment of treatment reliability of computer-assisted, template-guided transgingival implantation.

Material and methods

Patients

The study protocol was submitted to the Ethics Committee of the Medical University Vienna and approved (Study Number: EK320/2006) and the study was conducted at the Department of Oral Surgery, Bernhard Gottlieb Dental University Clinic. In the time from October 2006 to February 2008, 18 consecutive patients were enrolled in the study after having signed the informed consent.

The patient population enrolled (male/female = 10/8) included patients with partially dentate and edentulous mandibles and maxillae. Excluded were patients with the need of a bone augmentation procedure due to insufficient residual bone volume for implant placement. All patients were operated by one of two experienced surgeons using the template-guided implantation system NobelGuide™ (Nobel Biocare, Gothenburg, Sweden).

Presurgical procedure

After having designed a prosthetically idealized partial and total prosthesis, a CT template with appropriate fiducial markers was prepared according to protocol. Using the double scan technique (Verstreken et al. 1998), the preoperative low-dose, high-resolution multislice CT scans (Tomoscan SR-6000, Philips Medical Systems, Eindhoven, the Netherlands) of patient and template were performed. All CT scans were performed according to the NobelGuide™ protocol with a slice thickness of 1 mm and a voxel size of 0.5 mm.

Planning phase

The DICOM data collected for the patient and the CT template were loaded in the Procera™ planning software (Nobel Biocare) for imaging the jawbone with idealized tooth position for three-dimensional preoperative implant positioning. Implant positions were defined under adequate consideration of the anatomical and prosthetic environment and conditions. As soon as implant positioning had been defined, the planning data were communicated to a certified manufacturing facility (Nobel Biocare) for having a stereolithographic implantation template with appropriate guide sleeves manufactured.

Surgical procedure

All surgical procedures were performed by two experienced surgeons using the NobelGuide™ template. Depending on jaw situation and residual dentition, either a mucosa-supported or a tooth- and mucosa-supported template was used.

Following review of the precise seat of the template and bite registration with the opposing dentition or the antagonist prosthesis, block or infiltration anaesthesia was performed in the usual manner.

After renewed positioning and fixation of the template by the bite registration, bony fixation with anchor pins was performed. Guided implant bed preparation and the subsequent implant insertion were performed in strict compliance with NobelGuide™ guidelines under continual monitoring of the accurate seat of the template.

Postsurgical procedure

Following NobelGuide-guided implant insertion, a CT scan with the individually manufactured preoperative CT template was taken with the healing abutments not yet mounted (Triple Scan Technique – developed by Zechner and Vasak in 2007). As for the preoperative examination, the CT templates were encoded by a bite registration with the opposing dentition or the antagonist prosthesis and kept *in situ* during the examination. The postoperative CT was taken with the same settings as the preoperative examination.

Using the fusion method, newly developed and initially presented by Zechner (2007) and based on the triple scan technique in the Procera™ planning software (Nobel Biocare), the postoperative CT data could be superimposed with the preoperative CT data and the planning data for the virtual implant positions (Fig. 1), thus allowing for dimensioning the deviations between planned and postoperatively achieved implant positions. The fiducial markers on the CT template were used for fusion of pre- and postoperative CT data. The average superimposition precision was 0.14 mm with a maximum deviation of 0.21 mm between the average 5.7 corresponding marker points from an average of 6.8 possible fiducial markers. Mesio-distal and bucco-lingual deviation as well as depth deviation at the level of the implant shoulder and the implant apex were taken as measurement parameters. According to the three-dimensional space coordinates, the *x*-axis was defined as bucco-lingual deviation, the *y*-axis as mesio-distal deviation and the *z*-axis as depth deviation. In addition, the angular deviation between the implant longitudinal axes of the planned and the postoperative implants was measured using the

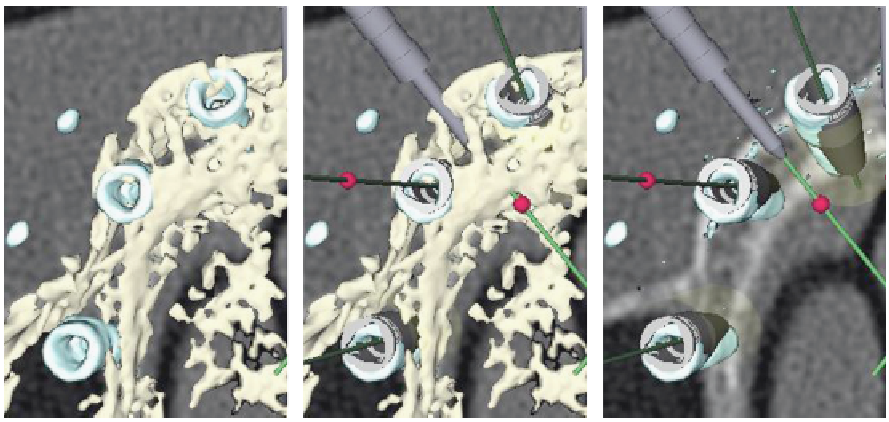

Fig. 1. Illustration of the fusioned preoperative (grey) and postoperative (blue) computed tomography scans (links) incorporating the preoperative planning data with (center) and without (right) imaging of the bone model.

appropriate measuring tool of the Procera planning software.

To ensure precise measurement of the deviations along the *x*-, *y*- and *z*-axis, the fused implants at the level of implant shoulder and implant apex were stored as screenshots in the form of jpeg files. Using Adobe Photoshop™ CS (version 8.0.1), the deviations along the *x*-, *y*- and *z*-axis were measured as pixel values after having determined the centre points at implant shoulder and implant apex and these values were then converted into mm using a reference level (implant diameter). The pixel and mm values obtained were collected in a table together with the angular deviations and prepared for further statistical evaluation.

For determining the potential impact of mucosal thickness on postoperative deviations, additional measurements of buccal and palatal mucosa thickness were taken.

Statistical methods

In a preliminary screening of the distributions of the 86 deviations for the seven outcome criteria, we found that distributions of all shoulder and apex values are right-skewed. The square root (rather than the log or another) transformation leads to approximate normal distributions, required for an analysis by ANOVA (analysis of variance).

For statistical analysis of the prognostic impact of maxilla vs. mandible (a), partially dentate vs. edentulous jaw (b) and implant position in anterior vs. posterior tooth region (c) on the magnitude of deviations along the axes and the angulation, a split-plot ANOVA was used with the patient considered as the random factor (block) and (a) and (b) specified as between-block factors and (c) as inner block factor.

The surgeon-specific learning effect was quantified by monotonic correlation according to Spearman, r_s, between deviation and consecutively assigned patient number.

The impact of buccal and palatal mucosal thickness on the average deviation per patient in the edentulous maxillae was again quantified by Spearman's r_s.

P-values smaller than 0.05 were considered as statistically significant, but were only of exploratory character. Therefore, we refrained from multiplicity adjustments. Statistical evaluation was performed using SAS (2008).

Results

The 18 patients enrolled showed an average age of 58 years (range 36–77 years). All patients underwent an uneventful one-stage implant surgery and were provided with healing abutments during conventional healing times of 2 months (lower jaw) and 3 months (upper jaw). An overall 86 implants (average 4.8 implants per jaw) were placed in the partially dentate ($n = 6$) and edentulous ($n = 12$) jaws (maxilla/mandible = 11/7). All implants were of the NobelReplace Tapered Groovy type with varying diameter (3.5–5 mm) and length (10–13 mm).

One implant was removed during the healing phase in the postoperative week 3 on account of a postoperative infection. Two patients enrolled in the study were withdrawn because of a displaced template during the postoperative CT and because of a mandibular osteosynthesis plate impairing exact fusion, respectively.

The linear and angular deviations measured along the mesio-distal, bucco-lingual and corono-apical direction at implant shoulder and implant apex have been shown as box plots in Table 1 and in Figs 2–4. The maximum linear deviation with 2.02 mm was seen along the corono-apical direction in an edentulous maxilla. The maximum angular deviation with 8.1° was measured in the posterior tooth region in a patient with terminal tooth gap.

The effects of maxilla vs. mandible, partially dentate vs. edentulous jaws, and implant positions in the anterior vs. posterior tooth region have been described by means of untransformed deviations in Table 2. The split-plot analyses of variance show significantly smaller deviations for implants in the anterior tooth region than for those in the posterior region ($P < 0.01$) and significantly smaller deviations in the mandible vs. the maxilla ($P = 0.04$) in exclusively mesio-distal direction. No other significances could be observed.

Moreover, potential differences in application between the two surgeons and a potential learning effect over the time of performance of the surgical procedures were also statistically evaluated. With regard to the deviations measured, no statistically significant differences between the surgeons could be determined.

However, learning effects over the period of performance of the surgical procedures could be observed. For one surgeon, this learning effect related to the bucco-lingual deviation ($r_s = -0.59$), and for the other surgeon to a smaller deviation in depth at implant shoulder ($r_s = -0.38$) and implant apex ($r_s = -0.36$) over the period of performance of the surgical procedures.

The effect of buccal mucosal thickness on bucco-lingual deviation could be confirmed by means of Spearman's r_s ($r_s = 0.76$; $P = 0.028$). From a linear regression, we learnt (see Fig. 5) that an increase of mucosal thickness of 1 mm results in an average increase in deviation of 0.41 mm.

Discussion

Restorative-driven implant therapy requires accurate implant placement (Tarnow et al. 1992;

Table 1. **The means, standard deviations and maximum deviations of the linear deviations determined at the level of implant shoulder and implant apex and of the angular deviation**

	Deviations						
	x-shoulder	*y*-shoulder	*z*-shoulder	*x*-apex	*y*-apex	*z*-apex	Angle
Mean values	0.46	0.43	0.53	0.7	0.59	0.52	3.53
Standard deviation	0.35	0.32	0.38	0.49	0.44	0.42	1.77
Maximum deviation	1.42	1.5	1.85	1.84	1.89	2.02	8.1

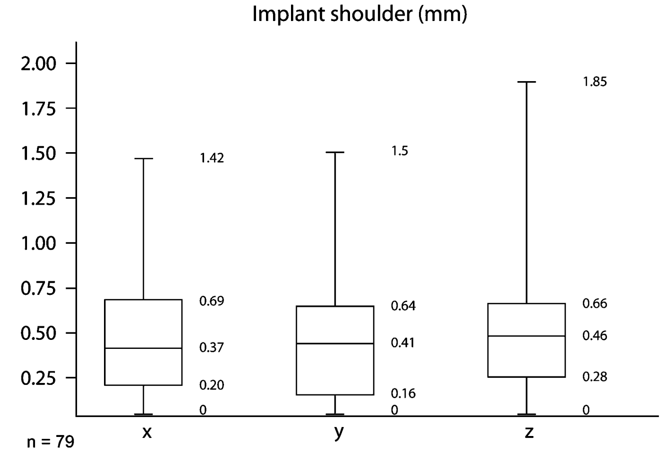

Fig. 2. Box plot of the deviations determined at the level of the implant shoulder along *x*, *y* and *z*-axis.

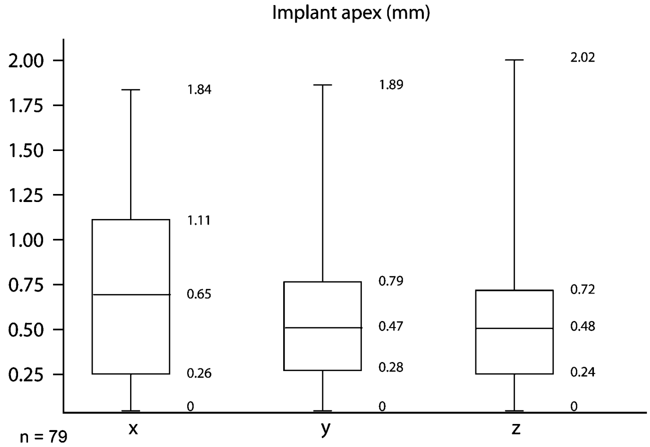

Fig. 3. Box plot of the deviations determined at the level of the implant apex along *x*, *y* and *z*–axis.

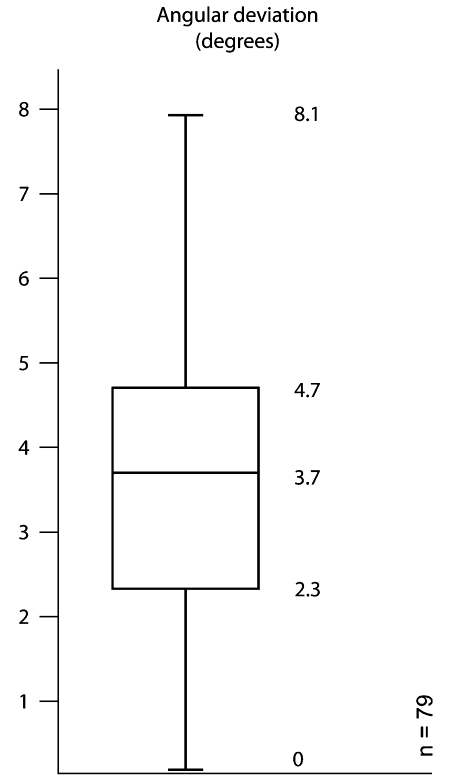

Fig. 4. Box plot of the angular deviations between virtually planned and postoperative implants.

Grunder et al. 2005). In such advanced cases, correct estimation of the bone conditions, determination of implant positions and precise drilling into the bone according to simulation are essential in ensuring the successful placement of a dental implant (Handelsman 2006; Wong et al. 2007). The concept of computer-assisted, template-guided implantation is to ensure an accurate implementation of preoperative planning and, consequently, safe implant insertion.

The deviations measured in the present clinical study were an average 0.43 mm (bucco-lingual), 0.46 mm (mesio-distal) and 0.53 mm (depth) at the level of the implant shoulder, and slightly higher with average values of 0.7 mm (bucco-lingual), 0.63 mm (mesio-distal) and 0.52 mm (depth) at the level of the implant apex. Dreiseidler et al. (2009) also observed significantly higher horizontal deviations at the implant apex vs. the implant shoulder. The maximum error was seen for the depth deviation at the implant apex with 2.02 mm. Statistically, this cannot be defined as an outlier, although about 50% of values are within the range of 0.24–0.72 mm.

In an *ex vivo* study of Van Assche et al. (2007) being the closest to an actual clinical setting, use of the same computer-assisted implantation system produced comparable or slightly higher deviations of an average 1.1 mm (range 0.3–2.3 mm) at the implant shoulder and of an average 2 mm (range 0.7–2.4 mm) at the implant apex.

In a clinical application study of Vrielinck et al. (2003) with bone-supported templates allowing guided implant bed preparation but no guided implant insertion, the average and maximum linear and angular deviations described were markedly higher than in the present study. The average linear deviation at the level of the implant shoulder was 1.51 mm with a maximum error of 4.7 mm and at the level of the implant apex 3.07 mm with a maximum error of 6.4 mm. Similarly, the average angular deviations with $>10^\circ$ were higher than the maximum deviation of 8.1° seen in the present study. Di Giacomo et al. (2005) recorded similar deviations for the clinical use of bone-supported templates of the same system. Van Steenberghe et al. (2003)

***Table 2.* The average deviations with regard to localization or dental status and their statistically significant differences**

	Deviations (mean values)						
	x-shoulder	*y*-shoulder	*z*-shoulder	*x*-apex	*y*-apex	*z*-apex	Angle
Maxilla	0.47	0.45*	0.57	0.7	0.59	0.57	3.55
Mandible	0.41	0.36*	0.38	0.7	0.57	0.34	3.68
Edentulous	0.49	0.46	0.6	0.64	0.62	0.6	3.5
Partially endentulous	0.37	0.35	0.31	0.88	0.49	0.3	3.7
Anterior region	0.57	0.31**	0.64	0.64	0.56	0.62	3.49
Posterior region	0.39	0.5**	0.46	0.74	0.6	0.46	3.63

Descriptive *P*-value (split-plot ANOVA) of *0.04 and **0.0047.

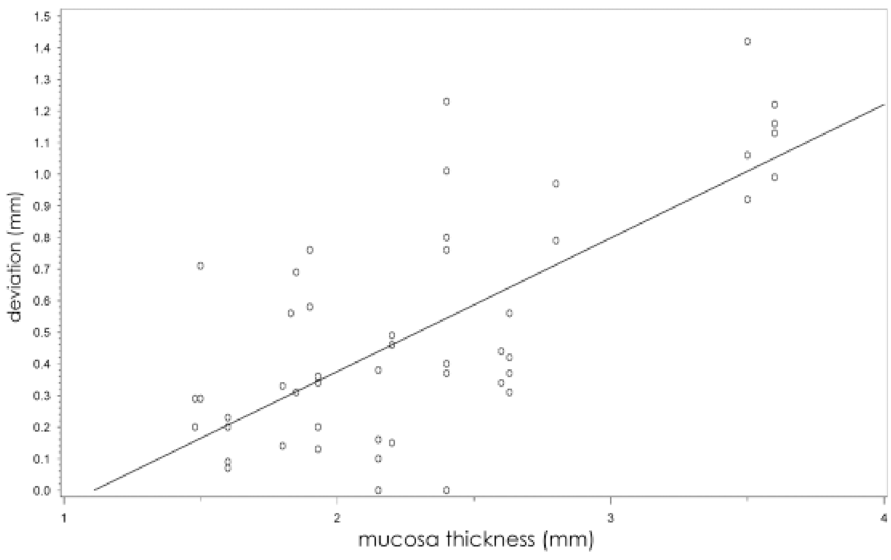

Fig. 5. Illustration of the effect of buccal mucosa thickness on average deviations quantified by a linear regression line ($b = 0.41$ mm).

suggested the template-unguided implant insertion as the potential reason for this increased inaccuracy.

A review article of Schneider et al. (2009) reviewed studies on implantation accuracy of computer-assisted template-guided implantation published between 2002 and 2009. Overall, eight studies were included in the review with four cadaver and one model study as well as three clinical studies. Evaluation of the study results showed average deviations of 1.1–1.5 mm with partly considerable maximum deviations failing to justify flapless implantation according to the authors. Moreover, no significant differences with regard to these deviations could be identified between bone-supported, tooth-supported and mucosa-supported templates.

However, upon separate evaluation of the individual studies, potential clinical parameter could be identified as reason for the deviations encountered. In a comparative study of Ozan et al. (2009) with stereolithographically designed templates, significantly lower deviation values were determined with tooth-supported vs. bone- and mucosa-supported templates with regard to the angular deviations and the deviations seen at the implant apex level. Ersoy et al. (2008) also found significantly lower deviations with purely tooth-supported templates than with mixed supported or purely mucosa-supported templates. Similarly, in their study Van Assche et al. (2007) reported significantly higher deviations with templates with mixed support (especially at terminal gaps) vs. purely tooth-supported templates with regard to mesio-distal deviations and indicated mucosal resilience as well as distortion of the template as reasons for this finding. This finding could also be confirmed in the present study as implants placed in the anterior region showed a significantly smaller mesio-distal deviation than those placed in the posterior tooth region. Moreover, a significant correlation between mucosal thickness at the implantation site and the degree of deviation could be identified. Similarly, an increased mucosal thickness may affect reproducibility of template position as well as the seat of the template regardless of anchoring elements, especially for purely mucosa-supported applications. Reduced accessibility and the longer burs and implant mounts especially used with limited mouth opening have been described as additional factors for increased deviations in the posterior tooth region (Becker & Kaiser 2000; Akça et al. 2002; Valente et al. 2009).

In addition, the present study evaluated the factor ''surgeon'' as potential reason for deviations. All patients underwent implantation by two experienced surgeons, strictly according to the protocol of the manufacturer. No statistically significant difference between the two surgeons could be identified regarding the deviations measured. However, a learning effect over the time period of performance of the surgical procedures could be observed regarding the bucco-lingual and depth deviations. In a study of Valente et al. (2009), a significant learning effect could also be registered with regard to angular and depth deviation. These observations show that navigated implantation may allow for the implementation of complex implant–prosthetic patient cases, but may only offer a simple guide without any gain in procedural reliability and security during the first implantations for the implantologically inexperienced dentist on account of the lacking approval process experience and the technological sensitivity of the system.

Apart from clinical factors, system-related causes for a deviation of postoperative implant position from the virtually planned position may either be due to the collection and evaluation of image data or the conversion and fusion of DICOM data in the planning software (Birkfellner et al. 2001) or may be associated with the manufacture of the implant template. Possible sources of errors in the preoperative CT scans may include an imprecisely located CT template or artefacts due to minimal movements of the patient during image data collection (Marmulla & Mühling 2006; Dreiseidler et al. 2009). With regard to the registration error, the present study found an average fusion inaccuracy of 0.14 mm with a maximum deviation of 0.21 mm. Reddy et al. (1994) quantified the potential error due to image acquisition and data processing as being <0.5 mm on average. Horwitz et al. (2009) reported a planning-phase-related inaccuracy of an average of 0.32–0.49 mm. The potential manufacturing inaccuracy of the stereolithographically manufactured implantation template is within a range of 0.1–0.2 mm (van Steenberghe et al. 2002). Another system-inherent cause of deviations may be the discrepancy between guide sleeve and bur or implant mount of about 0.15 mm with the present system. With respect to a different template (SurgiGuide™, Materialise Dental, Leuven, Belgium), Valente et al. (2009) quantified the gap between the internal diameter of the guide sleeve and the respective bur with 0.15–0.2 mm. However, a certain discrepancy between the guiding elements is required for mechanical reasons to ensure adequate implant bed preparation and implant insertion (Dreiseidler et al. 2009; Ohtani et al. 2009; Van Assche & Quirynen 2010).

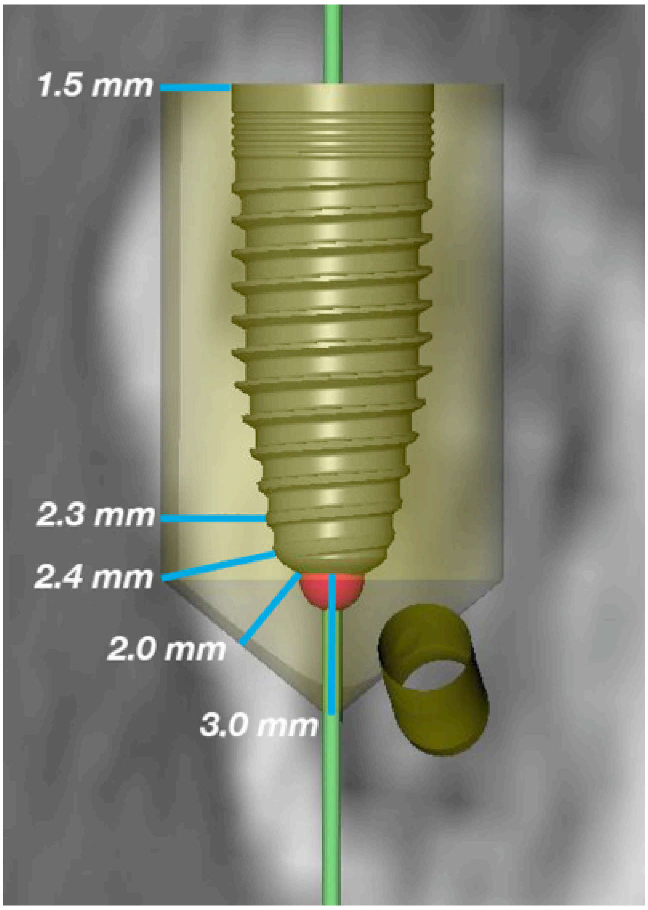

Fig. 6. Screenshot from the Procera planning software (Nobel Biocare) with illustration and quantification of the recommended peri-implant safety distance.

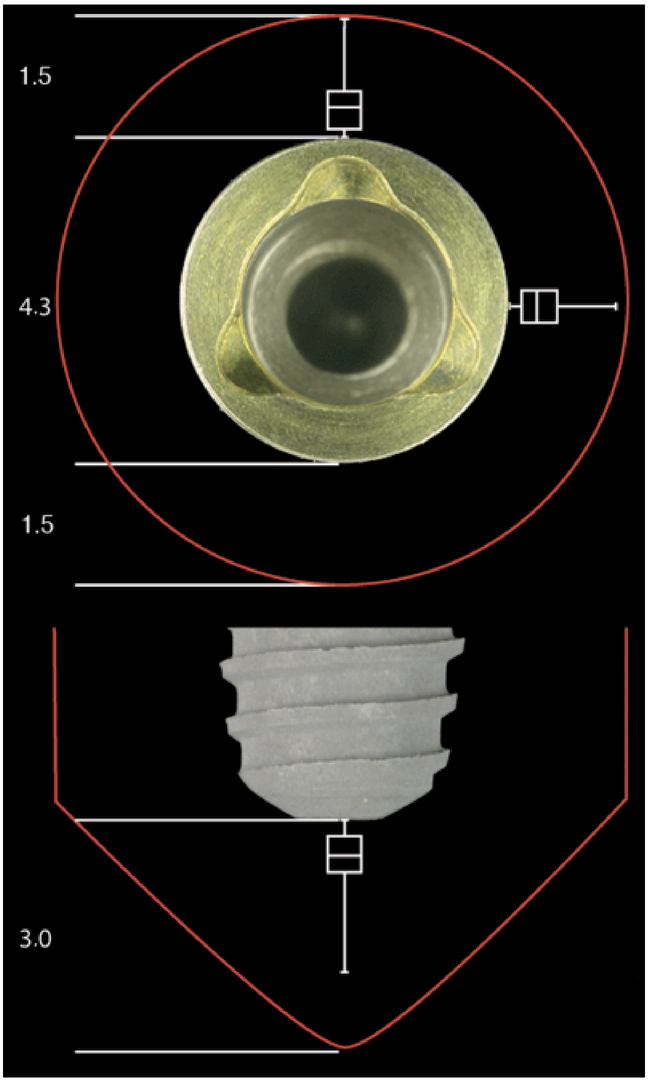

Fig. 7. Box plot illustrations of the deviations obtained along the *x*, *y* and *z*-axis with regard to the recommended safety distance.

For the verification of the safety distances of an implantation system, its use and validation in clinical practice in the context of *in vivo* studies is required (Van Assche et al. 2007; Vercruyssen et al. 2008; Dreiseidler et al. 2009). *In vitro* studies will serve for determining the implementation accuracy of a system without considering clinical aspects. The standard deviations of the linear and angular deviations measured will serve as statistical means for determining the variation of the system studied and will also be used for estimating the required safety distances. Actual conclusions regarding the treatment reliability and safety of an implantation system can only be provided by its use in clinical practice. However, the maximum deviations of a system should also be considered when determining the safety distances, especially with templates for flapless procedure (Vercruyssen et al. 2008).

Conclusion

Template-guided placement of dental implants provides for reliable transfer of preoperative computer-aided planning into surgical practice. The study results presented the accuracy of transferring the virtual planning by surgical templates, which could be additionally enhanced using anchoring elements and guided implant insertion. However, even with two experienced surgeons and with strict adherence to protocol-required procedures, spatial deviations between virtually planned and postoperatively obtained implants will be encountered. With regard to the requested verification of treatment safety of an implant system with flapless access, all maximum deviations measured in this clinical study were within the safety margin recommended in the planning software (Figs 6 and 7).

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Table S1. Supporting information in accordance with the CONSORT Statement 2001 checklist used in reporting randomized trials.

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