Tommie Van de Velde
Fadi Glor
Hugo De Bruyn

A model study on flapless implant placement by clinicians with a different experience level in implant surgery

Authors' affiliations:
Tommie Van de Velde, Hugo De Bruyn, Department of Periodontology and Oral Implantology, University of Ghent, Ghent, Belgium
Fadi Glor, Materialise NV, Leuven, Belgium

Correspondence to:
Mr Van de Velde, Tommie
Department of Periodontology and Oral Implantology
University of Ghent, De Pintelaan 185
Ghent 9000
Belgium
Tel.: +32 9 240 5922
Fax: +32 9 240 3851
e-mail: Tommie.vandevelde@telenet.be

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Abstract:
Introduction: Some implant companies advocate that flapless surgery is easy to perform and beneficial for aesthetics and patients morbidity. However, studies objectively analyzing the position in the bone of implants installed with this approach are lacking. This *in vitro* model study was performed to analyse deviations in position and inclination of implants placed with flapless surgery compared with the ideally planned position and to examine whether the outcome is affected by experience level.
Methods: Identical radio-opaque resin models were developed with a silicon lining mimicking the soft tissues and six edentulous single tooth spaces. Eighteen clinicians (six periodontists, six general dentists and six students) drilled four implant sites each (Straumann AG, Basel, Switzerland) with a flapless approach. Corresponding CT-scan images of the models were available. A virtual implant program (Simplant, Materialise NV, Leuven, Belgium) was used to plan the ideal position and to compare this with the implant angulation and position of the test implants.
Results: There were no significant differences between the experience groups for all parameters except for global deviations between dentist and students, angle deviations between dentists and students and horizontal deviations between specialists and students.
In incisor sites, specialists and students deviated significantly more in global deviation and depth than dentists. In premolar and molar sites, there were no significant differences except for horizontal deviations between specialists and dentists in molar sites. As a consequence of the malpositioning, perforations were seen in 59.7% (43/72) of the implant occasions when the artificial mucosa was removed from the model.
Conclusion: The three-dimensional location of implants installed with flapless approach differs significantly from the ideal, although neighbouring teeth were present and maximal radiographical information was available. Within the limitations of this *in vitro* model study it seems necessary to point out that these deviations would in a clinical situation lead to complications such as loss of implant stability, aesthetical and phonetical consequences. The outcome is not influenced by the level of experience with implant surgery. This points out that more precise measurements of soft tissue *in situ* or additional use of guiding systems are recommendable.

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Oral implantology tends to evolve into a less time-consuming, a more aesthetic and a less invasive way to restore a lost dentition. In this context, some implant companies advocate that flapless implant surgery is easy to perform and beneficial for aesthetics and patient morbidity. A variety of tools are available to improve the outcome of flapless surgery. The use of radiographic images is necessary to evaluate the surgical site underneath the soft tissues. Computerized tomographic (CT) images provide an accurate image of the surgical field in three dimensions (3D) (Todd et al. 1993; Gher & Richardson 1995). When using radio-opaque material, it is possible to visualize both soft and hard tissue dimensions on the CT images in relation to the template. This presurgical CT image is often used for implant selection but not for precise implant positioning. With conventional surgery, the radiological information obtained on the CT image is not exactly transferred to the intra-operative situation. In most cases, the surgeon decides *in situ* on the chosen implant position once the flap is raised, the bone exposed and with the template as a direction indicator. As a consequence, in most cases an extended flap is needed to visualize the bone sufficiently in order to avoid perforations of critical anatomical structures. Minimizing the surgical flap can have advantages for soft tissue healing and patient comfort (Fortin et al. 2006). If one wants to conduct flapless surgical procedures, an exact transfer of the anatomical information obtained via the CT images to the intra-oral situation during surgery is necessary. Several authors have advocated the use of drill guides (Demey & Vrielinck 1999; van Steenberghe et al. 2003; Di Giacomo et al. 2005) or intra-operative navigation systems (Casap et al. 2005) to link the virtual preoperative treatment plan based on the CT images to the situation encountered during surgery.

Although retrospective studies indicate that implant survival rates obtained with flapless surgery are predictable with an appropriate technique and patient selection (Rocci et al. 2003), the results seem to be highly influenced by the practitioner's learning curve (Campelo & Camara 2002). Little is known of the exact implant position when freehanded flapless surgery is performed because re-entry studies objectively analysing the position of the implant in the bone are lacking. The aesthetical and phonetical outcome is often not reported in clinical implant survival studies. This outcome is highly influenced by correct implant positioning and bone support especially on the buccal side. Several studies (Lundqvist et al. 1992a, 1992b; Molly 2005) reported a period of 3 months to 3 years after implant surgery for speech and articulation adaptation. These studies did not report whether implant positioning in the bone and in relation to the prosthetic suprastructure influenced the alterations in speech and articulation.

The aim of the present *in vitro* model study was to analyse deviations in the position and inclination of a flapless implant procedure without a drill guide compared with the ideally planned position and to examine whether the outcome is affected by the experience level.

Materials and methods

Model planning

A total of 12 models were constructed with different degrees of radio-opacity of teeth, bone and soft tissue. All models (mixture of Exaktoform (Bredent, Senden, Germany) with 10 wt% barium sulphate powder) were identical and had missing teeth at positions 16, 14, 12, 22, 24 and 26 (Frasaco GmbH, Tettnang, Germany) and a silicone lining (Omnidouble, Omnident GmbH, Rodgau Nieder-Roden, Germany) mimicking the soft tissues. All sites had a sufficient amount of bone (Fig. 1) to receive a Straumann implant (Straumann AG, Basel, Switzerland) but at premolar sites an artificial bone defect was created to make the implant location critical in width (Fig. 2).

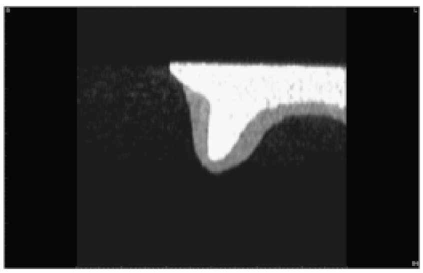

Fig. 1. Cross-sectional computerized tomographic - scan image of the model at molar area 14.

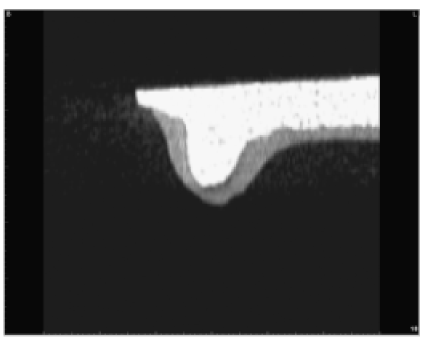

Fig. 2. Cross-sectional computerized tomographic - scan image of the model at premolar area 16.

The experimental model was scanned (Volume Zoom, Siemens, Erlangen, Germany). The CT data were imported in SimPlant™ PRO 9.2 (Materialise NV, Leuven, Belgium). Because of the different degrees of radio-opacity used in the model, the software was able to delineate the bone, the soft tissue and teeth easily (Figs. 3 and 4). Virtual implant location was performed on six tooth positions (Fig. 5). Within this software, it is possible to virtually install an implant in its most ideal position taking the bony morphology, the soft tissues and the prosthetic outcome into account. All implants were planned according to the criteria described by Buser et al. (2004). This treatment plan was considered as the 'golden standard'.

Study participants

Eighteen clinicians with a different level of experience in oral implantology working at the University Dental School participated

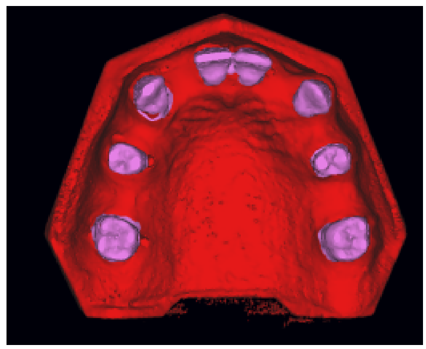

Fig. 3. Computer image of the model. Red represents soft tissue, purple represents the teeth.

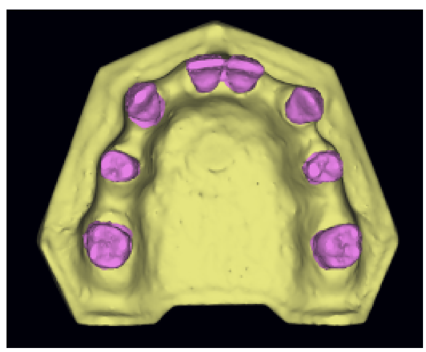

Fig. 4. Because the phantom contains different degrees of radio-opacity, the soft tissue can easily be separated from the bone (yellow) in the software.

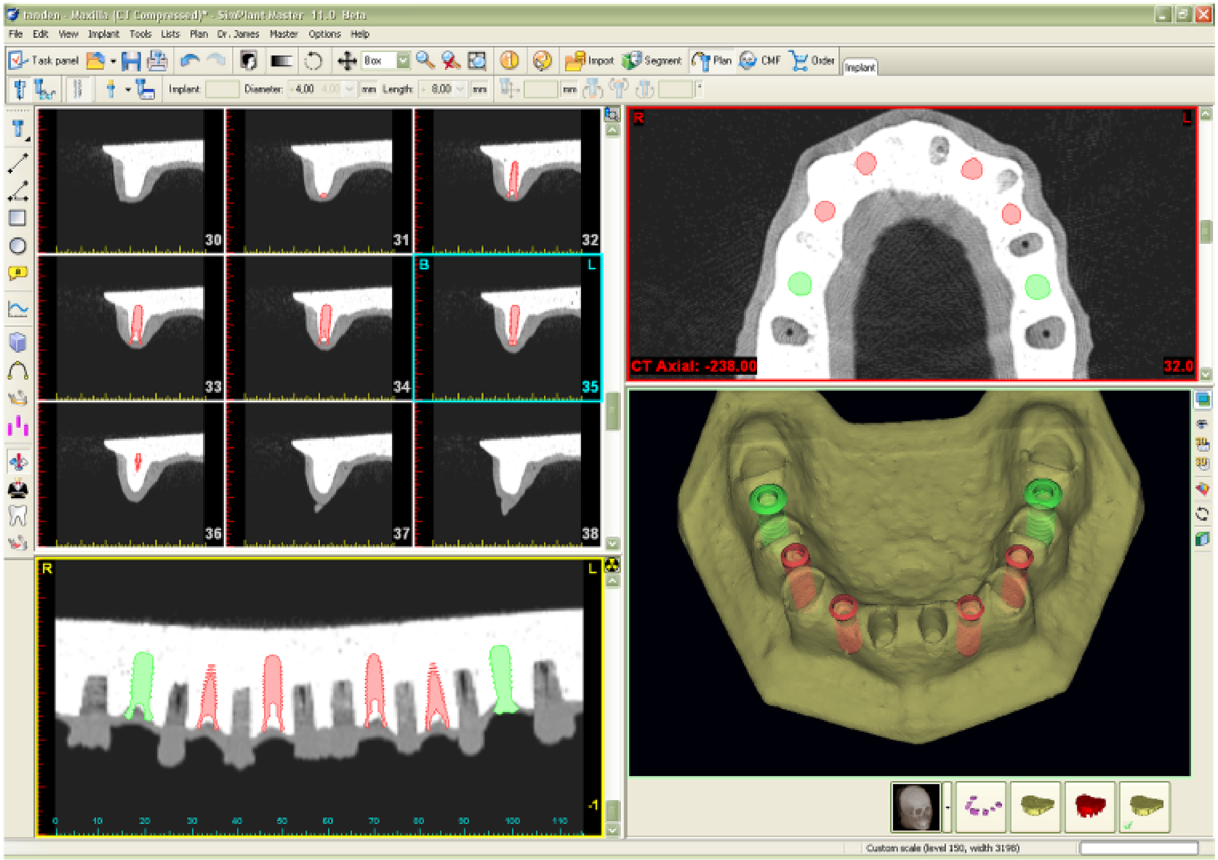

Fig. 5. The treatment plan was done on the CT scan data of the model imported in SimPlant® PRO 9.2 (Materialise NV, Leuven, Belgium)

in this study; six were trained periodontists performing implant surgery, six were general dentists and six were last-term dental students, all unexperienced in implant surgery. Before the test run, all participants were informed about the goals of the model study during a seminar. They received a brief review on the implant procedure and were instructed in flapless surgery and the specific sequence of drilling. All candidates were provided with a set of surgical drills (round burr Ø2.2 mm; pilot drill Ø2.2 mm; pilot drill Ø2.8 mm; twist drill Ø3.5 mm; twist drill Ø4.2 mm) provided by Straumann (Straumann AG), a periodontal probe, to investigate the thickness of the artificial soft tissue by means of bone sounding, a panoramic overview of the model, an axial section and a cross-sectional image of each edentulous zone obtained by the CT scan.

All 18 participants were asked to prepare four recipient sites with a flapless approach on four specific locations on one or two identical models. They were allowed to pretest the model and the drilling procedure. The models were placed on a flat surface and could be freely rotated in order to inspect and drill the sites. Each participant was given four predetermined locations and drilled at least one incisor and one premolar for a 4.1 mm Straumann implant and one molar for a wide 4.8 mm implant. In total, the 18 participants drilled 24 incisors, 24 premolars and 24 molars. It was decided not to install implants in the drill sites in order to avoid artefacts on the post-operative CT scan.

A CT scan was taken from every drilled model. The drill holes were segmented manually in Mimics 9.0 (Materialise NV) and reconstructed in 3D. Cylinders of the same size as the body of the implants were constructed in Magics 9.9 (Materialise NV) and virtually installed in the prepared drill holes. A detailed description of the registration algorithm is given in the Mimics manual (Mimics 9.0 Reference Guide). This registration algorithm allowed for the cylinders to be positioned at the place where the implant would have been if the implants had been inserted exactly in the drilled location. The drilled cast together with the registered cylinders was exported

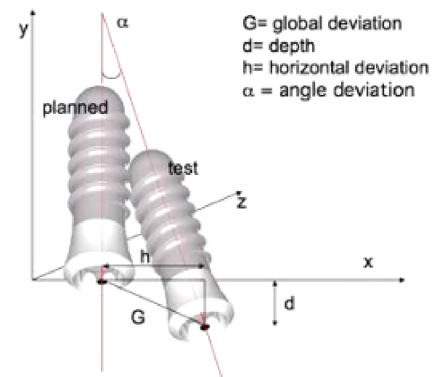

Fig. 6. Planned implant and test implant seen in the same coordinate system.

as an 'stl-file' and registered on the original CT scan containing the treatment plan.

As a result of this procedure, the coordinates of every drill hole were known in the coordinate system of the original CT scan. Because the treatment plan was carried out in that coordinate system, the coordinates of the planned implants and drill holes can be compared with each other. Figure 6 shows the planned implant and the test implant in the same coordinate system.

Table 1. **Mean deviation from the ideal, expressed in millimetres and standard deviations (SDs) of different variables for all implant sites divided by experience group (*n* = 72)**

	Specialists		Dentists		Students	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Global deviation	2.971	1.195	2.444*	0.803	3.068*	1.199
Angle deviation	7.33	3.773	9.76*	5.131	6.234*	3.125
Depth	2.881	1.272	2.276	0.89	2.87	1.301
Horizontal deviation	0.678*	0.354	0.826	0.466	0.971*	0.425

*A statistically significant difference between parameters.

Table 2. **Mean deviation from the ideal, expressed in millimetres and standard deviations (SDs) of different variables for implants on incisor sites divided by experience group (*n* = 24)**

	Specialists		Dentists		Students	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Global deviation	3.667*	0.664	2.654*,**	0.514	4.148**	1.27
Angle deviation	7.745	4.545	11.563**	6.344	5.97**	2.233
Depth	3.636*	0.695	2.537*,**	0.533	4.028**	1.279
Horizontal deviation	0.705	0.341	0.881	0.525	1.039	0.447

*,**Indicates a statistically significant difference between parameters.

Table 3. **Mean deviation from the ideal, expressed in millimetres and standard deviations (SDs) of different variables for implants on premolar regions divided by experience group (*n* = 24)**

	Specialists		Dentists		Students	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Global deviation	3.355	1.135	2.589	0.968	2.869	0.806
Angle deviation	7.269	2.746	9.113	5.485	6.818	3.677
Depth	3.212	1.785	2.526	0.968	2.619	1.021
Horizontal deviation	0.862	0.557	0.622	0.394	1.011	0.46

Table 4. **Mean deviation from the ideal, expressed in millimetres and standard deviations (SDs) of different variables for implants on molar regions divided by experience group (*n* = 24)**

	Specialists		Dentists		Students	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Global deviation	2.122	0.895	2.028	0.717	2.271	0.871
Angle deviation	6.938	3.584	8.883	3.188	5.665	3.336
Depth	1.995	1.019	1.659	0.847	2.071	0.938
Horizontal deviation	0.576*	0.271	1.064*	0.429	0.847	0.385

*A statistically significant difference between parameters.

The distance between the two centres of the implants (Fig. 6) mimics the global deviation. It can be decomposed in a part along the axis of the planned implant (the depth deviation) and a part perpendicular to it (the horizontal deviation). The angle deviation is the 3D angle made by the centrelines of the planned and test implant.

Statistical analysis was performed with SPSS for Windows (12.0). Descriptive statistics (mean standard deviation) for all parameters were based on all implants and separately for incisor, premolar and molar sites. Student *t*-tests were used to examine statistical differences between test groups. χ^2 tests were used to evaluate different perforations per implant site.

Results

The evaluated parameters for the specialists vs. general dentist and students are summarized in Table 1 for all implants, and Tables 2–4 for implants placed, respectively, in the incisor, premolar and molar regions.

When all implants were measured, there were no statistically significant differences between the experience groups (Table 1) for all parameters, except for global deviations between dentist and students ($P<0.05$), angle deviations between dentists and students ($P<0.01$) and horizontal deviations between specialists and students ($P<0.05$).

In incisor sites (Table 2), the specialists and students deviated significantly more in global deviation and depth than the dentists ($P<0.01$). Angle deviations of the students were significantly less than those of the dentists ($P<0.05$). There were no statistical differences in premolar implants (Table 3) for all groups.

Statistically significant differences were seen for horizontal deviation between specialists and dentists in molar implants (Table 4).

As a consequence of the malpositioning, perforations were seen in 59.7% (43/72) of the implant locations when the artificial mucosa was removed from the model (Fig. 7).

These were located in 13/24 sites of the specialist group, 14/24 of the general dentist group and 16/24 of the student group (Table 5). Perforations were seen in 13/24 for incisor regions, 19/24 for premolar regions and 11/24 for molar regions (Table 6).

There were no statistically significant differences between experience groups. Perforations were evenly distributed in incisor, premolar and molar sites (χ^2 test $P>0.05$) but palatal dehiscences were statistically more frequent (χ^2 test $P<0.01$).

Discussion

The results of this *in vitro* study suggest that flapless implant placement without the use of any surgical guidance is a non-accurate procedure. The variations in implant positioning deviated from the ideal implant position irrespective of surgical experience. Flapless implant placement is a popular topic in implant dentistry. This concept was introduced in the late 1970s (Ledermann 1977) but rarely investigated in the scientific literature. With the evolution in radiological imaging and introduction of new techniques, it became a more predictable procedure. One should be aware, however, of the possible complications related to a blind surgical procedure whereby implants are installed without raising a flap and without exposing the alveolar crest.

Fig. 7. Photograph of a model when the artificial mucosa is removed with a palatal dehiscence on a premolar region.

A study of Becker et al. (2005) describes the benefits of a flapless implant procedure as being reduced surgical time, minimal changes in crestal bone levels, probing depth and inflammation; perceived minimized bleeding; and lessened post-operative discomfort. Campelo & Camara (2002) evaluated retrospectively 770 implants placed with a flapless approach over a period of 10 years. The cumulative success rate for implants placed using a flapless one-stage surgical technique after a 10-year period varied from 74.1% for implants placed in 1990 to 100% at 2000. Considering this learning curve and the results of this *in vitro* study, one should be aware of risking to deviate implants by performing a blind procedure. The benefits related to flapless surgery could easily turn into an aesthetical disaster when perforating the implant bed by performing a free-handed flapless surgery. Even now, we cannot recommend freehanded flapless implant surgery as a treatment of first choice.

As a consequence of malpositioning, perforations were seen around 50% of the implants in this study. In a clinical setting, the absence of a bony support for gingival tissues can lead to aesthetical problems (Belser et al. 2004; Buser et al. 2004), phonetical problems or even loss of implant stability and may jeopardize the clinical outcome in the long run. This does not necessarily lead to higher failure rates but could have an impact on the patient's appreciation of the implant treatment.

We would like to point out that all implant sites were drilled and no implants were placed in the models. This was done for reasons of radiological analysis. It should be noted that perforations could even become worse when installing an implant in its prepared site because there is a 0.6 mm difference in diameter between the final drill and the intended implant. After evaluation of the perforations, implants were inserted into every site to evaluate this phenomenon. It was seen that perforations increased in size by pushing the borders of the resin outwards (Fig. 8). At sites where the implants were well surrounded by resin, this was not the case. This could mean that complications could be underestimated in this study. Because the elasticity of the model resin does not match the elasticity of human bone and the model bone was not protected by a firm periosteum, this should be evaluated in a clinical setting.

There were no significant differences in deviations (global, angle, depth and horizontal deviation) between specialists and general dentists when all implants were measured (Table 1). Students differed significantly from general dentists for global and angle deviation and from specialists for horizontal deviation. However, no conclusive tendencies were seen on measuring all implant locations. Statistical differences showed up especially in incisor sites. Specialists and students deviated significantly more in 'global deviation' and depth of implants compared with the general dentists (Table 2). One explanation could be that specialists and students tried to overcome aesthetical problems by placing the implants slightly deeper. There was also a tendency to shift the implant position to the palatal side. Twelve out of 13 perforations in incisors were palatal dehiscences; 35/43 perforations were located at the palatal side for all implant sites (Table 5). It is clear that those perforations were caused to avoid the buccal plate to minimize the risk for aesthetical complications. However, a palatal-located implant could compromise the desired emergence profile, increasing

Table 5. **Number of perforations divided by experience group**

	Specialists	General dentists	Students	Total
Palatal	11/24*	13/24*	11/24*	35/72*
buccal	2/24*	1/24*	5/24*	8/72*
total	13/24	14/24	16/24	43/72

*A statistically significant difference between palatal and buccal perforations.

Table 6. **Number of perforations divided by region and defect anatomy**

	Buccal dehiscence	Buccal fenestration	Palatal dehiscence	Palatal fenestration	Perforation
Incisors	0	1	12	0	13/24
Premolars	7	0	12	0	19/24
Molars	0	0	11	0	11/24

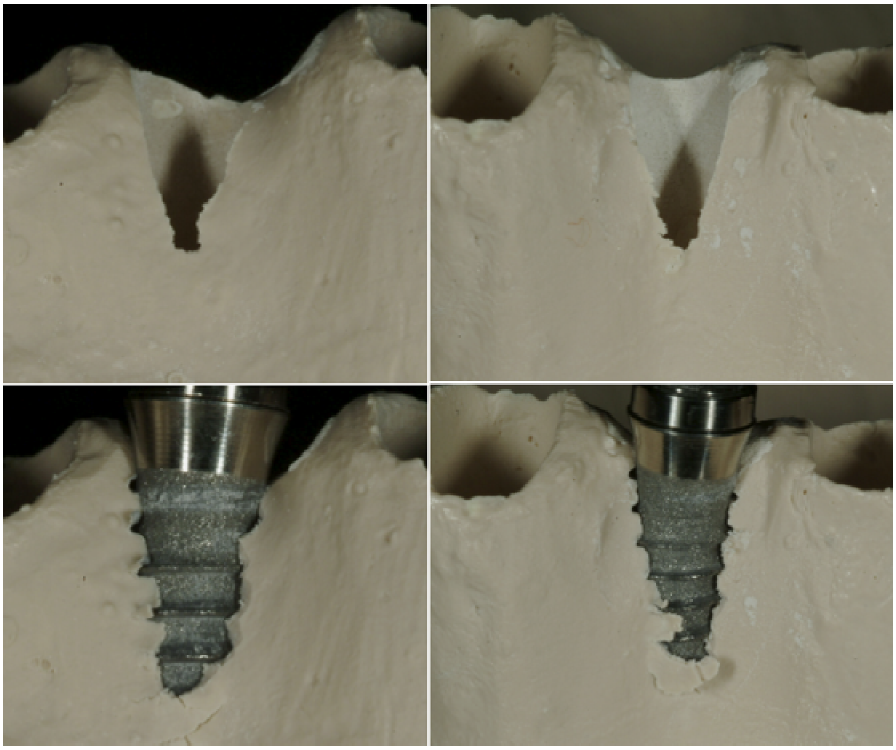

Fig. 8. Composed photograph of two sites with perforations. It is seen that when an implant is installed, the size of the perforations increases by pushing the borders of the resin outwards.

the risk for a ridge-lap restoration (toilet-seat design), a disharmonious scalloping of the gingival margins (Buser et al. 2004) or could lead to a phonetical problem.

An artificial defect was created at premolar sites in order to create an implant site with critical bucco-palatal dimensions. There were no statistically significant differences in deviations between experience groups (Table 2), but 79% of these sites showed perforations compared with 54% for incisors or 45% for molar regions. As a consequence of the limited amount of bone, premolar sites showed equal amounts of perforations both in palatal and buccal directions. The latter were not detected in incisors and molars. At molar sites, there were no statistically significant differences between experience groups, except for a smaller horizontal deviation of specialists compared with general dentists (Table 4). This is mainly because there was a safe sufficient width of the crest in the bucco-palatal direction. It seems from this finding that implant placement in molar sites is the easiest and most safe at least from a location and angulation point of view. Clinically, however, the bone condition and anatomical structures on molar areas are more likely to require an experienced surgeon.

It is our belief that the benefits of flapless implant surgery do count in specific cases, but care should be taken not to risk malpositioning by free-handed blind surgery. With todays technology, it is now possible to visualize the configuration of the bony volume without opening the mucosal tissues. CT images provide an accurate image of the surgical field in 3D (Todd et al. 1993; Gher & Richardson 1995; Andersen et al. 2002). When using designed scanning templates, it is possible to visualize both soft and hard tissues on the CT images. These data can be converted to use with software for 3D modelling and simulation of implant surgery (Tardieu et al. 2003). Computer-simulated implant positioning may provide benefits in predictable implant placement. Implant location and inclination can be planned according to restorative goals and anatomic limitations. Computer-designed surgical guides or navigation systems accurately transfer the planning to the surgical field (Fortin et al. 2000, 2003; Vrielinck et al. 2003; Di Giacomo et al. 2005; van Steenberghe et al. 2005).

An *in vitro* study of Kramer et al. (2005) showed that the precision of navigated surgery was better than free-handed surgery for repeated implant placements to restore a maxillary single tooth. The variation in inclination, depth and angle deviation was less when a tactile navigation system was used compared with free-handed surgery.

Conclusion

The 3D location of implants installed with flapless approach differs significantly from the ideal. Although neighbouring teeth were present and maximal radiographical information was available, practitioners with a different level in oral implantology failed to install implants within acceptable deviations to the ideal plan. As a consequence of malpositioning, a shocking 59.7% of perforations were noted. Within the limitations of this *in vitro* model study, it seems necessary to point out that these deviations would, in a clinical situation, lead to complications such as loss of implant stability, aesthetical and phonetical consequences. The evaluated parameters were not influenced by the level of experience in implant surgery. This indicates that more precise measurements of soft tissue *in situ* or additional use of guiding systems are recommended.

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要旨
序論：幾つかのインプラント・メーカーはフラップレスの術式は容易であり、審美性と患者の合併症の面でも有利であると主張しているが、本術式によって埋入したインプラントの骨内の位置を客観的に分析した研究はない。本研究はインビトロのモデルを用いて、理想的な位置との比較において、フラップレス手術によって埋入したインプラントの位置と傾斜角度のずれを分析し、術者の経験レベルが手術結果に影響を及ぼすかどうかを調べた。

方法：同一のＸ線不透過レジン製モデルにシリコンの裏装を施し、軟組織と６箇所の単独歯欠損空隙を模擬的に再現した。術者１８名（歯周療法専門医６名、一般歯科医６名と歯学部学生６名）が、各々フラップレスの術式でインプラント床を４箇所形成した（ストローマン社、ｽｲｽ､ﾊﾞｰｾﾞﾙ)。それに呼応するモデルのＣＴスキャン像を撮影した。バーチャル・インプラント・プログラム（シンプラント、Materialise 社、ﾘｭｰﾍﾞﾝ､ﾍﾞﾙｷﾞｰ）を用いて、理想的な埋入位置を計画し、これと試験インプラントの位置と傾斜角度を比較した。

結果：歯科医師と歯学部学生の間の全体的偏差、歯科医師と学生間の角度の偏差および専門医と学生間の水平的偏差以外に、全てのパラメータについて有経験の術者群の間に有意差はなかった。また切歯部位では専門医と学生は、全体的偏差と深さに関しては、一般歯科医より有意に大きな偏差を示した。小臼歯と大臼歯部位では、大臼歯部位での専門医と学生の間の水平的偏差以外に、有意差は認められなかった。位置偏差の結果として、人工粘膜をモデルから除去した際、インプラント部位の 59.7%（43/72）に穿孔が認められた。

結論：隣在歯があり、最大限の情報がＸ線像から得られたにもかかわらず、フラップレスの術式で埋入したインプラントの３次元的位置は、理想的な位置からは有意に異なっていた。インビトロ・モデルを用いた本研究の制約内において、これらの偏差は臨床的状況においてインプラントの安定性の喪失や非審美的な結果、発音上の問題などの合併症をもたらすと思われる。インプラント手術の経験の度合いは、結果に影響を及ぼさなかった。このことから、局所の軟組織のさらに精密な測定あるいは支援システムの追加的使用が推奨される。

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