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CLINICAL ADVATANGES OF GUIDED SURGERY

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Table of content:

List of abbreviations 3

General introduction 5

Research objective 11

Chapter I:

Literature review 15

Part 1:

Different techniques of static/dynamic guided surgery: modalities and indications. 15

Part 2:

Static guided surgery: accuracy and efficacy. 39

Chapter II:

An RCT comparing guided implant surgery (bone or mucosa supported) with mental navigation or the use of a pilot-drill template. 65

Chapter III:

Depth and lateral deviations in guided implant surgery. An RCT comparing guided surgery with mental navigation or the use of a pilot-drill template. 85

Chapter IV:

An RCT comparing patient-centered outcome variables of guided surgery (bone or mucosa supported) with conventional implant placement. 101

Chapter V:

Implant and patient-centered outcome of guided surgery, a 1-year follow-up. An RCT comparing guided surgery with conventional implant placement. 123

Chapter VI:

Accuracy and patient-centered outcome variables in guided implant surgery. An RCT comparing immediate with delayed loading. 141

Concluding discussion 161

Summary 169

Samenvatting 173

Reference List 177

Curriculum Vitae 181

Acknowledgements/Dankwoord 185

List of abbreviations

°	*Degrees*
2D	*two dimensional*
3D	*three dimensional*
BL	*Buco-lingual*
Bop	*Bleeding on probing*
CAD CAM	*Computer-Aided Design and Computer-Aided Manufacturing*
CBCT	*Cone Beam Computer Tomography*
Fac Bo	*Facilitate™/ bone*
Fac Mu	*Facilitate™/ mucosa*
HRQOL	*Health-related quality of life*
ICP	*Iterative Closest Point*
kV	*kilo Volt*
LJ	*lower Jaw*
mA	*milli Ampère*
Mat Bo	*Materialise Universal®/ bone*
Mat Mu	*Materialise Universal®/ mucosa*
Max.	*Maximum*
MD	*Mesio-distal*
Mental	*Mental navigation*
Min.	*Minimum*
Min.	*Minutes*
mm	*millimeter*
MSCT	*Multi- Slice Computer Tomography*
n	*number*
NWC-T	*Number of words chosen*
OHIP	*Oral Health Impact Profile*
PPD	*Pocket Probing Depth*
PRI-T	*Pain rating index*
RCT	*Randomized Clinical Trial*
SD	*Standard deviation*
Templ	*Pilot-drill template*
UJ	*Upper Jaw*
Vas	*Visual analogue scale*
y	*year*
α	*Angular deviation*
µm	*micrometer*

General introduction

Oral rehabilitation by aid of osseointegrated titanium implants is one of the most innovative concepts in dental treatment today. The original protocol for implant treatment was described by Brånemark and co-workers (1969). This first implant was a titanium turned threated screw with an external hex on the implant shoulder *(Figure 1)*. The surgical protocol consisted of a 2-stage surgical procedure, followed by a healing period, and then the abutment was connected to the implant (Adell et al. 1981). Osseointegration has been defined as the direct anchorage of an implant by the formation of bony tissue at the bone implant interface as observed by light microscopy (Brånemark et al. 1970) *(Figure 2)*. Experimental animal studies demonstrated that predicable and long-term integration could be established between a titanium surface and regenerated bone and marrow (Rahal et al. 1993). Today the concept of osseointegration has become a routine therapy for the rehabilitation of partially and fully edentulous patients (Jung et al. 2012, Pjetursson et al. 2012).

Conventional implant surgery consists of several steps to prepare the final osteotomy *(Figure 3)*. Several drills with increasing diameter are used to widen the osteotomy systematically. During each step the correct inclination and depth is checked by the surgeon. Therefore the placement of endosseous implants is a demanding procedure for the performing clinician. Two-dimensional or three dimensional radiographs are consulted pre-operatively to estimate the available bone-volume. During surgery this information has to be transferred to the clinical situation considering all aspects for future prosthetic treatment (esthetics and bio-mechanics) (Sethi et al. 1995). A thorough preoperative planning of the number of implants to be placed, their size, position and inclination could free the surgeon's mind, allowing concentrating on the patient and the tissues handling.

Fig. 1 *Titanium turned threated Brånemark implant with an external hex.*

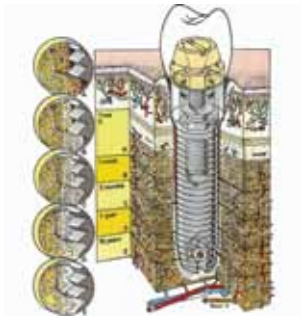

Fig. 2 *Physiologic evolution of the biology of the bone-implant interface over time. Copyright P-I Brånemark.*

Fig. 3 *Conventional implant placement: surgical protocol consists of several steps to widen the osteotomy. After implant placement the implant can heal underneath the soft tissue (A) or the abutments can be placed immediately, perforating the gingiva (B). (Courtesy to DENTSPLY implants, Mölndal, Sweden).*

Such preoperative planning is ideally performed on three dimensional images (Bou Serhal et al. 2002). The latter is possible via multi-slice (msCT) or cone beam computed tomography (cbCT) (Bornstein et al. 2014, Jacobs et al. 1999). The introduction of CBCT, offering imaging at low dose and relatively low costs, has increased the applicability and strengthened the justification of 3D based presurgical plannings (Guerrero et al. 2006, Loubele et al. 2008). Today specific software programs have been developed for the planning of implant surgery in the jaw bones (Vercruyssen et al. 2008). As such the surgeon can, after consulting the dentist who provides a template representing the planned prosthesis, properly position implants in a virtual reality. When the planned prosthesis is incorporated into these CT images, the planning can take into account both the jaw bone anatomy and the planned superstructure. This should improve biomechanics and esthetics (Sethi et al. 1995). Moreover it may optimize the mutual interaction between the surgical and the prosthetic team.

Different methods have been proposed for the transfer of the software planning to the surgical field: computer-guided (static) or computer -navigated (dynamic) surgery (Jung et al. 2009). For computer-guided surgery a static surgical guide is used, that transfers the virtual implant position from computerized tomographic data to the surgical site. These guides are produced by computer-aided design/computer-assisted manufacture (CAD/CAM) technology, such as stereolithography; or manually in a dental laboratory (using mechanical positioning devices or drilling machines). With computer-navigated surgery the position of the surgical instruments in the surgical area is constantly displayed on a screen with a 3D image of the patient. In this way, the system allows real-time transfer of the preoperative planning, and visual feedback on the screen.

It is important to mention that for the transfer of the planning to the operative field, a huge step forward was achieved in the mid-nineties, when a research team at the KU Leuven proposed the use of the double-scan procedure for integration of the prosthesis or radiological template, prepared by the dentist, within the craniofacial model (Verstreken et al. 1996, 1998, Jacobs et al. 1999). The precision was determined first on 2 cadavers and later in 8 consecutive human patients (van Steenberghe et al. 2002).

Between static surgical guiding systems for implant placement, significant variations in product handling can be observed (Van Assche et al. 2012). Some use for one patient different templates with sleeves with increasing diameter while others use removable sleeves in one single template with removable sleeve inserts or sleeve on drills *(Figure 4)*(Koop et al. 2012). Some systems designed special drills or drill stops to allow depth control, while others have indication lines on the drills. After the preparation of the implant osteotomy, some systems allow a guided placement of the implant while for other systems the template has to be removed before implant insertion.

The major concern for the transfer of the planning to the operative field is the accuracy, this is the deviation between the planned position of the implants and the postoperative result (Tahmaseb et al. 2014). Critical anatomical structures, such as the mandibular or mental nerve, must be avoided at any cost to prevent neurological complications (Jacobs et al. 2002, Bou Serhal et al. 2002). In order to avoid these anatomical structures it is important to know the deviation in depth and in mesio-distal direction. In cases of limited bone volume the buco-lingual deviation is crucial. Therefore it is important to have sufficient knowledge about the amount of deviation in all dimensions associated with static guided implant surgery (Verhamme et al. 2012, 2013).

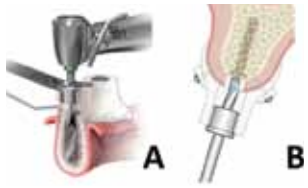

Fig. 4 *Example of a sleeve insert (A) or a sleeve on drill (B). (Courtesy to DENTSPLY implants, Mölndal, Sweden).*

In the approach to treat edentulous patients with guided surgery significant variation exist *(Figure 5).* In case of a flapless approach a punch-technique is applied or a small crestal incision is performed before positioning the guide directly on the mucosa. The drilling procedure is than performed with minimal exposure of the bone. In case of a bone supported guide, the guide is positioned on the jawbone after reflecting of a mucoperiosteal flap with a crestal incision *(Figure 6)*. This includes a rather extensive full-thickness flap to be able to position the guide in a stable and correct manner. This leaves the bone exposed during the entire process of drilling and implant placement.

Flapless implant placement is thought to reduce patient morbidity (Lindeboom & van Wijk 2010). Different methods to determine the postoperative discomfort and the quality of life have been described (Gracely & Dubner 1987, Slade & Spencer 1994). A recent systematic review (Hultin et al. 2012) reported on the clinical advantages of guided surgery. They found three studies comparing patient centered outcomes of guided flapless surgery with conventional open flap surgery (Arisan et al. 2010, Fortin et al. 2006, Nkenke et al. 2007). These studies demonstrated a statistically significant reduction in immediate postoperative pain, use of analgesics, swelling, edema, hematoma, hemorrhage and trismus for flapless surgery. One of these studies (Arisan et al. 2010) also compared guided flapless with guided non-flapless surgery and demonstrated consistently better outcome for the flapless approach.

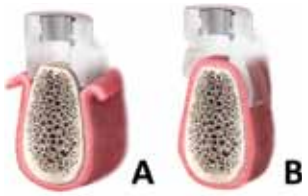

Fig. 5 *Cross-section of a bone-supported (A) and a mucosa-supported guide (B). (Courtesy to DENTSPLY implants, Mölndal, Sweden).*

Fig. 6 *Example of a bone-supported guide (A). An extensive full thickness flap has to be raised to place the guide directly on the bone (B).*

In conventional implant therapy the surgical protocol consist of a two stage or one stage surgical procedure (Figure 3). In a two stage procedure the implants are left to heal underneath the soft tissues and allowed to heal at least 3-4 months, before the abutments are installed. In a one stage procedure the abutments are immediately connected to the implants and the implants are left to heal with the abutments in connection with the oral cavity. After the healing process the prosthetic loading procedure is initiated, which also comprises different steps from impression taking, to final abutment selection, metal fit and finally placing the prosthesis in the mouth of the patient. 3D implant planning (Hultin et. al. 2012) and modifications in the implant surface (Wennerberg et al. 2010) have made it possible to speed up this procedure. Immediate loading involves the placement of a temporary or final prosthetic superstructure within 24 hours after implant placement. The pre-operatively planning of the "exact" position of the implants has made it possible to pre-operatively fabricate the prosthesis and to place it immediately after implant placement with some minor adjustments or within 24 hours after a final impression taking to correct for deviations between planning and operation.

General hypothesis and specific objectives of the thesis

- **General hypothesis:**

Computer guided implant placement offers clinical advantages compared to the use of conventional treatment protocols regarding: implant topographic accuracy, postoperative sequel, patient satisfaction, treatment time, technical and biological complications and implant outcome.

- **Specific objectives:**

Chapter I:

Part I: To review the present literature on the variation, advantages and indications of guided implant surgery.

Vercruyssen, M., Fortin, T., Widmann, G., Jacobs, R. & Quirynen, M. (2014) Different techniques of static/dynamic guided surgery: modalities and indications. Periodontology 2000. 66:214-27.

Vercruyssen, M., Jacobs, R., van Assche, N. & van Steenberghe,D. (2008) The use of CT scan based planning for oral rehabilitation by means of implants and its transfer to the surgical field: a critical review on accuracy. Journal of Oral Rehabilitation 35: 454–474.

Koop, R., Vercruyssen, M., Vermeulen, K. & Quirynen, M. (2012) Tolerance within the sleeve inserts of different surgical guides for guided implant surgery. Clinical Oral Implants Research 24: 630–4.

Part II: To review the present literature on the accuracy and eiificacy of guided implant surgery.

Vercruyssen, M., Hultin, M., van Assche, N., Svensson, K., Naert I. & Quirynen, M. (2014) Static guided surgery: accuracy and efficacy. Periondontology 2000. 66:228–46.

Van Assche, N., Vercruyssen, M., Coucke, W., Teughels, W., Jacobs, R. & Quirynen, M. (2012) Accuracy of computer-aided implant placement. Clinical Oral Implants Research 23: 112–123.

Chapter II:

To determine the accuracy of different CT-based surgical drill guides. To compare the difference in accuracy between mental navigation (meaning without the use of any guide), a pilot-drill template and a CT-based surgical drill guide. Furthermore to compare the accuracy of different CT-based surgical drill guides (mucosa versus bone supported).

Vercruyssen, M., Cox, C., Coucke, W., Naert, I., Jacobs, R., Quirynen, M. (2014) An RCT comparing guided implant surgery (bone or mucosa supported) with mental navigation or the use of a pilot-drill template. Journal of Clinical Periodontology 41: 717-23.

Chapter III:

To determine the accuracy of guided and non-guided surgery in all dimensions. To register the deviations in a vertical (depth) and horizontal (lateral) plane. The latter further subdivided in BL (bucco-lingual) and MD (mesio-distal) deviations.

Vercruyssen, M., Coucke, W., Naert, I., Jacobs, R., Quirynen, M. (2014) Depth and lateral deviations in guided implant surgery: an RCT comparing guided surgery with mental navigation 1 or the use of a pilot-drill template. Clinical Oral Implants Research. In press.

Chapter IV:

To assess the postoperative discomfort of the patients after non-guided or guided surgery and flapless or non-flapless surgery.

Vercruyssen, M., De Laat, A., Coucke, W., Quirynen, M. (2014) An RCT comparing patient-centred outcome variables of guided surgery (bone or mucosa supported) with conventional implant placement. Journal of Clinical Periodontology 41:724-32.

Chapter V:

To assess the radiographic and clinical implant outcome and patient-centered outcomes of guided implant surgery at 1-year follow-up. Furthermore to compare the outcome with conventional implant surgery.

Vercruyssen, M., van de Wiele, G., Teughels, W., Naert, I., Jacobs, R., Quirynen, M. Implant and patient-centered outcome of guided surgery, a 1-year follow-up. An RCT comparing guided surgery with conventional implant placement. Journal of Clinical Periodontology. In press.

Chapter VI:

To determine the accuracy of a novel CT-based surgical drill guide (ExpertEaseTM) and to assess the postoperative discomfort for the patient after immediate or delayed/conventional loading.

Vercruyssen, M., Cox, C., Naert, I., Jacobs, R., Teughels, W., Quirynen, M. Accuracy and patient-centered outcome variables in guided implant surgery. A RCT comparing immediate with delayed loading. Clinical Oral Implants Research. In press.

Oral implants were delivered free of charge by DENTSPLY Implants (Mölndal, Sweden), Stereolithographic guides were delivered free of charge by the Materialise Dental Company (DENTSPLY, Leuven, Belgium).

Literature review Part 1

Different techniques of static/dynamic guided surgery: *modalities and indications.*

Abstract

For computer-guided surgery a static surgical guide is used, that transfers the virtual implant position from computerized tomographic data to the surgical site. These guides are produced by computer-aided design/computer-assisted manufacture (CAD/CAM) technology, such as stereolithography; or manually in a dental laboratory (using mechanical positioning devices or drilling machines). With computer-navigated surgery the position of the surgical instruments in the surgical area is constantly displayed on a screen with a 3D image of the patient. In this way, the system allows real-time transfer of the preoperative planning, and visual feedback on the screen. A workflow of the different systems is presented in this review.

Introduction

The placement of endosseous implants implies many constraints: patient movement, limited surgery time related to the use of local anesthesia, a restricted visualization of the operation field, mental transfer of two-dimensional radiographs (used pre-operatively) to the three-dimensional surgical environment, including aspects such as esthetics, biomechanics and functional constraints of the prosthetic treatment. Thus, during a limited time span and with a restricted view, the surgeon must take numerous decisions while nurturing a conscious patient under aseptic conditions. Therefore a thorough preoperative planning frees the surgeon's mind, allowing concentrating on the patient and the tissues handling.

Preoperative planning is ideally performed on three dimensional images *(3).* The latter is possible via multislice (msCT) *(27)* or cone beam computed tomography (cbCT) *(20,35-37)*. When the planned prosthesis is incorporated into these CT images, the planning can take into account both the jaw bone anatomy and the planned superstructure.

For each CT brand specific software exists, to support such 3-D planning. For example scans with Siemens spiral CT can be reconstructed with the Dental CT software (Siemens, Erlangen, Germany), while CT data acquired via a General Electric's MSCT, typically are reconstructed via Dentascan software (GE, Medical systems, Milkwaukee, USA) *(26)*. Similar software is available for CBCT companies (eg: iCat Vision, ISI, Hatfield, Pensylvania, USA; Ondemand 3D, Cybermed, Seoul, South Korea; an overview is listed on www.sedentexCT.eu.).

Today specific software programs have been developed for implant surgery planning *(28)*. This implies that the abovementioned reformatting programs are no longer needed. The specific software transforms the original data set in a DICOM (Digital Imaging and Communication in Medicine) format. Examples of software programs are presented in *Table 1 (30)*. After secondary reformatting of the images these programs allow to "import"implants of different sizes into the jaw bone images. The position of the implants in this virtual environment is mostly done intuitively as during surgery, starting from the coronal part of the jaw bone and heading to a more apical location. This is performed on transsectional views, to visualize the cortex and the trabecular bone. At the same time the position of the placed implant is checked in the other planes and in the 3-D virtual model. Depending on the software these views can be displayed either in a split-screen fashion or are visualized fully 3-D with integrated transsectional views. The latter means that, without recalculation, the three planes of space are visualized at the same time within one and the same image. One can compare this 3-D condition with images from 3 cameras that are following the implant, and where the clinician can at any time turn on one, two or three cameras, depending on the needs.

The use of (CB)CT implies a high radiation dose which should be weighted towards the added clinical value provided by the images *(29)*. Moreover even with the most optimal preoperative planning software, the transfer to the surgical field still needs to achieve a clinically and medico-legally acceptable accuracy (55). Several options are available for such transfer: computer-guided (static) surgery or computer–navigated (dynamic) surgery *(30)*. For computer-guided surgery a static surgical guide is used, that transfers the virtual implant position from computerized tomographic data to the surgical site. These guides are produced by computer-aided design/computer-assisted manufacture (CAD/CAM) technology, such as stereolithography; or manually in a dental laboratory (using mechanical positioning devices or drilling machines) *(52, 59)*. With computer-navigated surgery the position of the surgical instruments in the surgical area is constantly displayed on a screen with a 3D image of the patient. In this way, the system allows real-time transfer of the preoperative planning, and visual feedback on the screen *(4, 48, 71)*.
A workflow of the different systems is presented in *figure 1*.

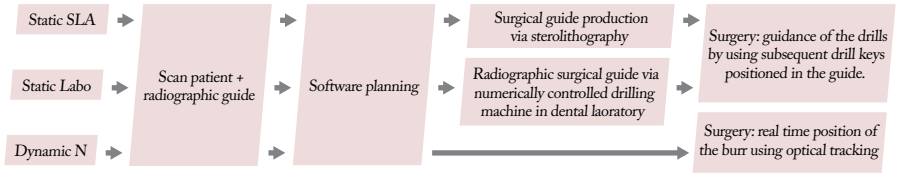

Fig. 1. *Workflow of the static and dynamic guided surgery systems.*
Legend: *SLA= sterolithography, Labo= laboratory, N= Navigation*

Application	*Website*	*Company*	*Virtual implant planning*	*Guide*	*Drill Guide production*
STATIC SYSTEMS (SURGICAL GUIDES)					
3D StendCad	www.implant3d.com	Media lab, Italy	yes	none	
Ay Tasarim	www.med.aytasarim.com	Ay Tasarim, Turkey	no	Surgical	SLA
Biodental Models	www.biomodel.com	BioMedical Modeling, USA	yes	Surgical	SLA
EasyGuide	www.keystonedental.com	Keystone Dental, USA	yes	Surgical	Labo
GALILEOS Implant	www.sicat.com	SICAT, Germany	yes	Surgical	Labo
Guide	www.bioparts.com.br	BioParts, Brazil	yes	Surgical	SLA
Implant 3D	www.med3d.de	Med30, Switzerland	yes	Surgical	Labo
ImplantViewer	www.annesolutions.com.br	Anne Solutions, Brazil	yes	none	
InVivo5	www.anatomage.com	Anatomage, USA	yes	Surgical	?
SICATImplant	www.sicat.com	SICAT, Germany	yes	Surgical	Labo
Nobelclinician	www.nobelbiocare. com	Nobelbiocare, Sweden	yes	Surgical	SLA
Scan2Guide	www.ident-surgical.com	I-Dent lmagmg, USA	yes	Surgical	SLA
Simplant	www.materialise.com	Materialise Dental, Belgium	yes	Surgical	SLA
Straumann® coDiag-nostiX	www.straumann.com	Straumann, Switserland	yes	Surgical	Labo
VIP	www.implantlogic.com	Implant Logic Systems, USA	yes	Surgical	Labo
DYNAMIC SYSTEMS (NAVIGATION)					
IGI	www.image-navigation.com	Image Navigation, USA	yes	none	Navigation
Ondemand3D Implant	www.cybermed.co.kr	Cybermed, Korea	yes	none	Navigation
Robodent	www.robodent.com	Robodent, Germany	yes	none	Navigation
Treon (medical)	www.medtronicnavigation.com	Medtronic Navigation, USA	yes	none	Navigation
VISIT		University of Vienna, Austria	yes	none	Navigation
Voxim	www.ivs-technology.de	IVS, Germany	yes	none	Navigation

Table 1 *Example of software programs for static and dynamic systems.*

Static surgical guides
• Stereolithography

As mentioned before, besides the bone volume, the ideal tooth position is visualized via a scan prosthesis, so that the implants can be positioned taking both the anatomic and prosthetic aspects into account. Since a standard resin prosthesis has a density, similar to that of the surrounding soft tissues, it is impossible to segment it easily from the CT images. Therefore a special scan prosthesis has to be prepared. This can be done in several ways. A first option is to prepare a copy of the prosthesis in radiopaque resin *(Fig. 2a)*. Now only one scan has to be made with the patient, wearing the prosthesis in the mouth.

A second method was developed in the mid-nineties by a research team at the University of Leuven. They proposed a double-scan procedure (patient with scan prosthesis in mouth, prosthesis alone) with afterwards an integration of the scan prosthesis or radiological template, planned by the dentist, within the craniofacial model *(61-63)*.

Therefore the scan prosthesis contains small gutta percha spheres (diameter ± 1 mm) *(Fig. 2b)*. The craniofacial images show the gutta percha markers with respect to the bone, without visualizing the prosthesis itself. The scan prosthesis is scanned alone, with alerted exposure parameters as such to allow the denture to be visualized *(Fig. 3)*.

Since the markers are visible in both sets of scans, they can be transformed and realigned to fuse the prosthesis within the maxillo-facial structures. Besides an adequate bone model, derived from scanning the patient with the denture in situ, the second scan allows optimal visualization of the prosthesis. Those two models can thus be presented separately, allowing planning on the bone *(Fig. 4a)* and/or prosthetic model. Moreover, by an accurate fusion, while maintaining an excellent image quality, the planning can be carried out and controlled towards the integrated model *(Fig. 4b)(27,58)*.

Fig. 2a Radiographic guide with radiopaque teeth.

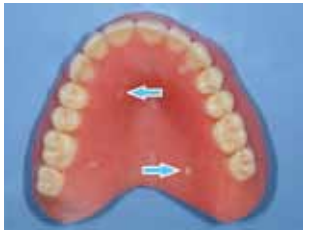

Fig. 2b *Radiographic guide with gutta-percha markers.*

Fig. 3 *Example of dual scan protocol.*

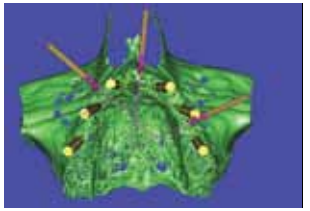

Fig. 4a *Example of 3D-model in planning software of the bone.*

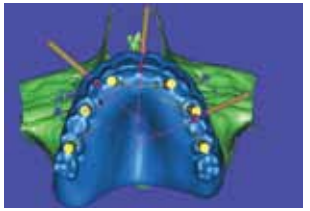

Fig. 4b *Example of integrated 3D-model of the bone and radiographic guide in the planning software.*

Regardless of the method used, correct positioning of the scan prosthesis is very important. Therefore an index is strongly recommended to position and stabilize the template in the mouth of the patient during the scanning process *(Fig. 5)*. An optimal fit of the scan prosthesis with the patient's soft tissue is crucial. One should determine whether air is visible between the scan prosthesis and the soft tissue. This is especially important for mucosa-supported guides, where the basis of the future surgical guide will be the same as the basis of the scan prosthesis.

The dicom images are imported in a software program, fusion of the scan prosthesis via the markers is accomplished and the ideal surgical site and implant dimensions are selected *(Figs 4a and 4b)*. Once the planning is completed and approved, the digital planning is send to the manufacture for production of the guide by means of stereolithography. Stereolithography is an additive manufacturing process using a vat of liquid UV-curable photopolymer resin, and an UV laser that selectively cures resin, layer by layer, into a mass representing the desired three-dimensional object. For each layer, the laser beam traces a part cross-section pattern on the surface of the liquid resin. Exposure to the UV laser light cures or solidifies the pattern traced on the resin and adheres it to the layer below. After a layer is finished (complete pattern has been traced), the object is lowered by one layer thickness and a new layer of liquid material is applied on top. The subsequent layer pattern is traced by the laser on this new surface and joined to the previous layer. This process is repeated until the object is completed. The supports are removed manually after the product is taken from the stereolithography machine (Fig. 6a). After this process the sleeves for the drill keys are positioned in the guide.

Fig. 5 Patient with radiographic guide and index in the mouth.

Fig. 6a Finished guide with the supports, which are removed manually (Courtesy of Materialise™, Leuven, Belgium).

When the guide is finished, it is send to the surgeon *(Fig. 6b)*. Depending on the system a list with an overview of the planned implants is included, as well as a case-specific manual. Before surgery, the surgical guide is fit in the mouth. After applying some compression the soft tissues underneath should become pale. The correct position of the guide is guaranteed by the use of an index. This index is used to stabilize the guide and to allow fixation *(Fig. 7)*.

The drilling procedure involves the use of drill keys inserted in the sleeves within the guide, which guide the consecutive drills with different diameters in the correct position and angulation. The drill key can for some systems be attached on the drills *(Fig. 8)* or can be designed as spoons *(Fig. 9)*. Different keys with increasing diameter are available to guide each separate drill. The drills can have a physical or a visual stop. Guidance of the implant is available depending on the system that is used. The tolerance of the drills in the key, of the key in the sleeve or of the implant driver in the sleeve might explain part of the inaccuracy inherent to guided surgery *(33,53)*.

The protocol can be resumed as followed:

1. Scan prosthesis with radiopaque teeth (one scan) or gutta-percha markers (dual scan).
2. (CB)CT scan of the patient with the radiopaque guide and radiological index in the mouth. Scan of the scan prosthesis without index (dual scan).
3. Implant planning in the software.
4. Production of the surgical guide by means of sterolithography.
5. Fit of the surgical guide in the mouth of the patient and preparation of the new surgical index.
6. Surgery. Fixation of the guide by means of screws. Drilling using subsequent drill keys.

***Fig. 6b** Fully developed surgical guide, with the internal sleeves.*

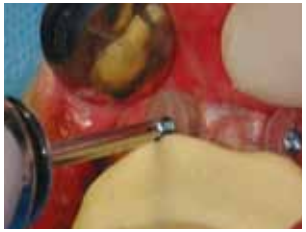

***Fig. 7** Fixation of the guide with screws, the guide is stabilized with the surgical index.*

***Fig. 8** Drill key on drill. The drill is placed with the drill key in the guide, than the drill moves through the key.*

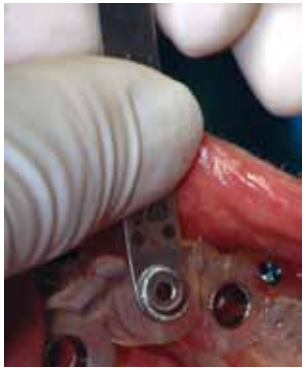

***Fig. 9** Drill key placed in the sleeve of the guide, here to guide the 2.0 diameter drill.*

Different implants companies have their own system, adapted at the specific properties of each implant system (e.g.: Astra™ – Facilitate®, Anthogyr™ – ANTHOGYR Guiding System®, Biomet 3i™ – Navigator®, Camlog™ – CAMLOG® Guide System, Dentsply Friadent™ – ExpertEase®, NobelBiocare™ – NobelGuide®, Straumann™ – Straumann Guided Surgery®, and Zimmer Dental™ – Zimmer Guided Surgery Instrumentation). Static guided surgery is difficult when inter-occlusal space is limited, therefore some guide systems have drill guides with lateral tube openings. They allow entry of the drills from the buccal or lingual side, thereby reducing the requested amount of inter-occlusal space. A guide can be tooth-supported, bone supported or mucosa supported. The choice is made on the number of remaining teeth for support of the guide, and on the need/wish for a flapless approach or not.

This technique was primarily aimed at improving diagnostic, surgical and prosthetic precision with relative success *(52, 60)*. However, since the trend in implant dentistry today has focused mainly on a rapid and simplified use, several systems are at present available where computer guided implant placement can be implemented in a complete sequence from flapless implant placement to immediate loading with a "prefabricated" *(Figs. 10 a-d)* fixed prosthesis *(18,54,56,57)*.

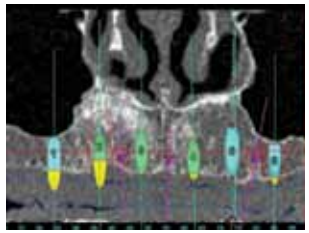

Fig. 10a *Clinical case. Software planning.*

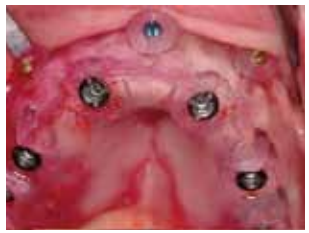

Fig. 10b *Flapless surgery (punch technique).*

Fig. 10c *Surgical guide with implant drivers in the sleeves.*

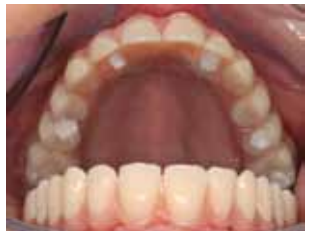

Fig. 10d *Immediate loading with temporary bridge in place.*

• Laboratory

The surgical guide can also be produced in the dental laboratory. With a mechanical system, the scan prosthesis is transformed into a surgical guide. Fortin and co-workers have published several studies using this technique *(15-19)*.

The restorative dentist makes a study prosthesis on a diagnostic casts, which represents the final restorative prosthesis *(Fig. 11a)*. After satisfactory testing in the patient's mouth, the prosthesis is duplicated in acrylic resin and then serves as a scanning template. To be clearly visible on the(CB)CT, the teeth are made of radiopaque resin. A prefabricated cube, so-called X-cube (Keystone Dental, Boston, Massachusetts, USA), made of acrylic resin is then attached to the scan prosthesis before CT examination so that when it is in the mouth the cube is outside, in front of the lip *(Fig. 11b)*. The X-cube will be used to transfer the planned implant positions onto scan prosthesis via a drilling machine. The X-cube includes two tubes of titanium in very precise positions, perpendicular and uncrossed. CT scans are acquired with the template in the patient's mouth and images are directly input to an imaging PC Computer. Planning of the implants occurs via a custom-designed Easyguide™ software (Keystone Dental). The position is visualized on a 3D view and on three planes: the axial slice and two reformatted views *(Fig. 11c)*.

Once the final positions of implants are defined they have to be transferred to the scan prosthesis. Therefore the scan prosthesis is firmly fixed to a drilling machine via the X-tube *(Fig. 11d)*. The titanium tubes in the X-cube are used by the system to establish a mathematical link between the CT images and the drilling machine so that the position of the planned implant are drilled on the guide with high precision at the desired diameter *(Fig. 11e)*.

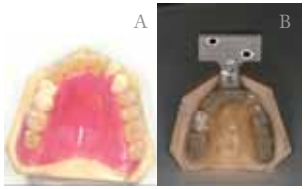

Fig. 11a *Study prosthesis is realized on diagnostic casts, which represents the final restorative prosthesis.*

Fig. 11b *Duplicate of the study prosthesis in acrylic resin. A prefabricated cube is attached to the scan prosthesis so that when the prosthesis is in the mouth the cube is outside and in front of the lip.*

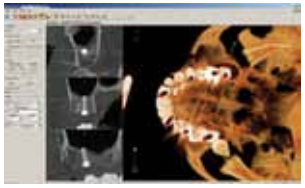

Fig. 11c *Planning software with implant planning on a 3D view and on three planes: axial planes, tangential and perpendicular.*

Fig. 11d *The scan prosthesis is firmly attached to a drilling machine by placing the resin cube on a dedicated device and by passing two metal shafts through the two titanium tubes.*

Fig. 11e *The scan prosthesis is drilled according to the planned implant position by a drilling machine.*

The accuracy was very high as reported in an in vitro study *(17)*. The X- cube is then separated from the template, which becomes a conventional surgical guide *(Fig. 11f)*. Metal tubes, used as drill sleeves, are inserted through the holes in the surgical guide previously realized by the drilling machine. Different guides with different diameters are prepared and have to be placed consecutively or can one can use drill keys. In partially edentulous patients, the guide is supported by residual teeth. In full maxillary edentulous patients the guide is supported by the mucosa especially the hard palate area *(Figs 11g and 11h)*.

The protocol can be summarized as followed:

1. Production of the scan prosthesis with radiopaque teeth + X-cube.
2. CT scan with scan prosthesis in the mouth of the patient.
3. Planning via the software.
4. Drilling the implant positions in the scan prosthesis with the numerically controlled drilling machine (fully automatic). The scan prosthesis becomes the surgical guide.
5. Surgery. The guide is then easily replaced in the mouth of the patient, in the same position as during CT-examination.

Fig. 11f *For the surgical procedure, the cube is removed. The scan prosthesis becomes the surgical guide.*

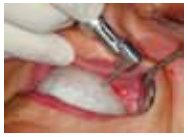

Fig. 11g *For completely edentulous patients, the guide is secured, under occlusal pressure, to the bone with fixation screws to avoid movement of the guide.*

Fig. 11h *Drilling sequence can be done through subsequent drill keys.*

Navigation (dynamic systems)

Surgical navigation systems are able to track a surgical tool relative to the patient, and to dynamically display the position of the surgical tool within the patient's presurgical computed tomography (CT) scan, updated in real time *(13,14,21,83)*. Thus, navigation systems allow for: localization of surgical targets and critical anatomical structures, orientation of a surgical tool within the patient's anatomy and to navigate a surgical tool along a predefined surgical plan.

• Tracking technology

Navigation systems for oral and craniomaxillofacial surgery are based on optical tracking technology *(13,83) (Fig. 12a)*. The technology can be compared to the guidance of cars by the global positioning system (GPS). Similar to the car with the GPS device that is tracked by a satellite and guided along the predefined route on the map, the surgical drill with LED's (light emitting diodes) or passive reflecting tracking elements is tracked by a stereoscopic optical camera and guided along the predefined implant plan on the CT data *(Fig. 12b)*. The accuracy of the optical tracking currently lies within a range of 0.1 – 0.4 mm (31). In order to track the position of the moveable head of the patient, a dynamic reference frame (DRF) is mounted to the patient *(65, 66, 69)*. The DRF can be invasively fixed to the bone or non-invasively mounted to a denture fixed template *(5, 6, 84, 85) (Fig. 12c)*.

• Image-to-patient registration

Before navigation is possible, the physical space coordinates of the patient have to be linked to the patient's image coordinates, a process called registration *(10)*. In the paired-point technique, the coordinates of corresponding anatomical or artificial (fiducial) points are determined and the geometrical transformation that best aligns these points is computed *(77, 80)*. The corresponding points are defined in the image data and indicated on the patient with a localizer probe of the navigation system. The most accurate method and gold standard are bone markers (e.g. mirco screws), which are invasively anchored to the patient's alveolar process or frontal bone *(64, 87)*

Fig. 12a *Navigation system for dynamic surgical guidance. Workstation, graphical user interface, and stereoscopic camera (Courtesy of IVS Solutions AG, Chemnitz, Germany).*

Fig. 12b *Surgical drill with tracking elements (Courtesy of RoboDent GmbH, Garching b. München, Germany).*

Fig. 12c *Dynamic reference frame (DRF) mounted to a denture supported template (Courtesy of RoboDent).*

Fig. 13a *Image-to-patient registration (mark er definition in the image data). Bone marker registration.*

(Fig. 13a). These markers are invasive, need additional surgery, may infect, and include patient discomfort and therefore should not stay in place for an extended period *(38)*.
Therefore non-invasive techniques have been explored *(13)*. Denture fixed radiographic scan templates may be provided with fiducial markers to serve as a registration template *(11-12)*. Alternatively, external registration frames (jaw surrounding frames with fiducials) may be mounted to a scan prosthesis or a vacuum mouthpiece *(1, 2, 78, 79, 72) (Fig. 13b)*.

Under ideal conditions, registration templates or external registration frames may provide similar registration accuracy to bone markers with mean target registration errors of 0.93 – 0.94 mm for all three methods *(82)*. However, registration templates require a repositioning procedure and thus may lose or misfit *(71, 75)*.
In edentulous patients, the resilience of the oral mucosa precludes stable and invariant positioning of registration templates or external registration frames *(75)*. The problem may be successfully solved by securing the template to the underlying bone, e.g. via a fixed reference system, provided by three mini-screws with adapter spheres *(25, 73, 81)*.

• Surgical navigation

After registration, the navigation system is ready for surgical use. The tracked surgical drill and DRF have to be continuously recorded by the stereoscopic camera (Fig. 14a). As visualized on the computer screen or head mounted devices, special guidance views help to find the planned implant location and to follow the implant path into the bone *(42) (Fig. 14b)*. The navigation software indicates the accuracy of the drill's position and angulations but the actual drilling still lies on the manual skills of the surgeon *(75) (Fig. 14c)*.

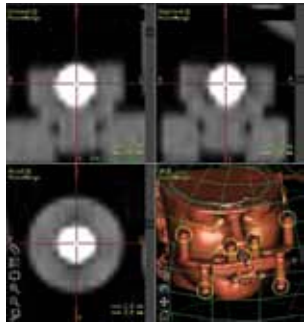

Fig. 13b *External registration frame.*

Fig. 14a *Dynamic guidance. Simulated implant surgery in dental dummy. For guidance, the surgeon has to look at the navigation screen.*

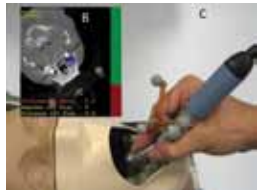

Fig. 14b *Guidance view indicating location, angulations and drilling depth.*

Fig. 14c *Hand moved dynamically tracked surgical drill.*

The protocol can be outlined as followed:

1. Scanning of patient + scan prosthesis/ registration template, external registration frame or bone markers.
2. Software planning of the implant position.
3. Image-to-patient registration via registration templates, external registration frames or bone markers.
4. Surgery: navigation of the drill along the predefined surgical plan.

Surgical navigation allows for a highly significant improvement in drilling accuracy when compared with unguided manual implantation *(4, 24, 34)*. When comparing computer-guided stereoltihographic surgical templates with two surgical navigation systems no statistically significant differences were found *(45)*. In a prospective randomized clinical comparison of two navigation systems, mean lateral errors of 0.7 – 0.8 mm (maximum, 1.6 – 2 mm) for the implant shoulder and 1.0 – 1.2 mm (maximum, 2.4 – 3.4 mm) for the implant apex were reported *(9)*. Successful clinical applications for oral implant surgery in partial and fully edentulous patients, flapless approaches, difficult anatomic situations, and after tumor surgery have been reported *(23, 51, 86)*.

In addition to oral implant surgery, dynamic guidance has proven to be a valuable tool in various surgical procedures such as zygoma implant surgery *(67, 68, 70)* removal of tumors and foreign bodies *(9, 22, 43, 49)*, orthognathic and reconstructive surgery *(33, 39-41, 44, 46)*, temporomandibular joint surgery *(13, 47)*, skull base surgery *(7, 8)*, and for education and training purposes *(76)*.

• Surgical template fabrication using navigation systems

Surgical navigation systems may also be used for fabrication of surgical templates *(78)*. Instead on the patient, the navigation procedure is performed on the patient's registered dental stone cast in the laboratory *(78, 79) (Fig. 15a)*. The DRF can be easily mounted to the base plate of the laboratory set-up *(Fig. 15b)*.
A scan prosthesis may not be necessary because the wax-up can be indicated with the navigation probe on the dental stone cast. Unlike dynamic guidance of the tracked drill, a stereotactic targeting device is used *(Fig. 15c)*. The stereotactic targeting device is a tracked adjustable mechanical arm with 6 degrees of freedom, which is aligned with the planned trajectory and allows for rigid drill guidance at best technical levels *(80, 74)*.

Fig. 15a *Stereotactic guidance for surgical template production. Dental stone cast.*

Fig. 15b *Dynamic reference frame (DRF).*

Fig. 15c *Stereotactic targeting device for navigated trajectory alignment.*

To produce a surgical guide, the dental stone cast is drilled using the stereotactic targeting device *(Fig. 16a)*. Thereafter, metal rods are inserted into the stereotactic drill holes and used to position surgical bur tubes. The bur tubes are fixed into a resin template in a single session in the dental laboratory. Alternatively, a surgical bur tube may be positioned on the dental stone casts by a metal rod advanced through the stereotactic targeting device and polymerized into prefabricated template using an ultraviolet (UV) light-curing resin *(79) (Fig. 16b)*. Preclinical results of the surgical templates on dental stone casts of patients showed mean lateral errors of 0.6 ± 0.4 mm (maximum, 1.4 mm) at the implant shoulder, 0.7 ± 0.4 mm (maximum 1.4 mm) at the implant apex, and angular errors of 1.7 ± 0.6 degrees (maximum 2.8 degrees) *(78)*. In fully edentulous patients, flapless surgery using similar surgical templates that are mounted via 3 fixed reference points (FRP) may provide similar accuracy as reported for tooth-supported surgical templates or surgical navigation *(73)*. In human cadavers, oral implants were placed with mean lateral errors of 0.7 ± 0.5 mm (maximum, 2.0 mm) at the implant shoulder, 0.9 ± 0.7 mm (maximum, 3.1 mm) at the implant apex, and angular errors of 2.8° ± 2.2° (maximum, 9.2°) *(81)*.
In contrast to dynamic guidance, the "static" guidance via surgical templates does not allow changes to be made to the surgical plan at the time of surgery. However, the templates' bur sleeves permit rigidly guided and highly controllable drillings, which may be an advantage in areas where irregular bone exists. Further, the intraoperative set-up of a navigation system, and the time constraints and potential inconvenience of intraoperative registration and tracking are not required.

Fig. 16a Surgical template production. Method 1: The dental stone cast of the patient is drilled via stereotactic targeting device to support metal rods and bur sleeves for surgical template fabrication.

Fig. 16b Method 2: The stereotactic targeting device is used to support a bur sleeve that is polymerized into a prefabricated surgical template.

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Literature review Part 2

Static guided surgery:
accuracy and efficacy.

Abstract

Today, different computer assisted implant placement procedures are available. They differ in software, template manufacturing, guiding device, stabilization and fixation. The literature seems to indicate that one has to accept a certain inaccuracy of ± 2.0 mm, which seems large at first sight, but is clearly less than for non-guided surgery. A reduction of the accuracy below 0.5 mm seems extremely difficult. A common dilemma identified in the studies included for this review has been the inconsistency of reporting clinical data and outcome variables. Another shortcoming is the low number of comparative clinical studies. In order to find the best guiding system or the most important parameters for optimal accuracy, more RCTs are necessary. Information on cost-effectiveness and patient-centered evaluations (i.e. questionnaires and interviews) must also be included.

Introduction

Preoperative three-dimensional planning has gained popularity, because of the introduction of the cone beam computer tomography. Different concepts have been proposed to transfer the virtual digital planning on the PC to the surgical field; computer-guided (static) surgery or computer –navigated (dynamic) surgery *(42)*. For the first, a static surgical guide is used, that transfers the virtual implant position from computerized tomographic data to the surgical site. These guides are produced by computer-aided design/computer-assisted manufacture (CAD/CAM) technology, such as stereolithography; or manually in a dental laboratory (using mechanical positioning devices or drilling machines) *(42,73,78,80)*. During computer-navigated surgery, the position of the surgical instruments in the surgical area is constantly displayed on a screen with a 3D image of the patient. In this way, the system allows real-time transfer of the preoperative planning, and visual feedback on the screen. *(16,67,82)* In the review of Jung and co-workers *(42)* a statistically significant higher mean precision was found in favor of dynamic systems compared with the static surgical guides. However this difference could be explained by the fact that there were more preclinical studies on accuracy for the dynamic systems and more clinical studies for the static systems. In contrast to dynamic guidance, the "static" guidance via surgical templates does not allow changes to be made to the surgical plan at the time of surgery. However, the templates' bur sleeves permit rigidly guided and highly controllable drillings, which may be an advantage in areas where irregular bone exists. Further, the intraoperative set-up of a navigation system, and the time constraints and potential inconvenience of intraoperative registration and tracking are not required. Intraoperative optical navigation devices are more frequently used in craniomaxillofacial surgery. Even if some clinical and accuracy studies are available, today dynamic systems have a very limited indication in implant dentistry and are not in widespread use due to the initial high costs. The computer-navigated surgery systems are not included in the current review.

Using 3D-planning software, the surgeon can, after consulting the dentist who provides a template representing the planned prosthesis, properly position implants in a virtual reality. When the planned prosthesis is incorporated into these CT images, the planning can take into account both the jaw bone anatomy and the planned superstructure. This should improve biomechanics and esthetics. Moreover it may optimize the mutual interaction between the "surgical" and the "prosthetic" teams. Precise preoperative planning has made it possible to implement immediate loading in a relative predictive manner, and in this way reduce the treatment time for the patient and increase the patient comfort. Furthermore, with the combination of flapless surgery it is presumed that the postoperative patient morbidity and discomfort may be reduced. As a result, implant placement may develop from difficult towards simple surgery, from stress towards relative comfort for both the patient and the surgeon.

The limits of the use of the static guided surgery are set by the maximum deviation observed between planning and postoperative outcome. Deviations may reflect the sum of all errors occurring from imaging to the transformation of data into a guide, to the improper positioning of the latter during surgery. Thus all errors, although seldom, can be cumulative. Much attention will be paid to the latter aspect. Indeed, when blind surgery is performed, as during a flapless approach, this is very relevant. Critical anatomical structures, such as the mandibular canal or mental foramen, must be avoided at any cost to prevent neurological complications. The preoperative radiological determination of the distances between anatomical landmarks can lack precision *(15)*. Especially in the case of blind surgery this constitutes a serious risk. Within the systems working with surgical guides, significant variations can be observed (e.g. for example the guidance of the drills in the surgical templates). Some use different templates with sleeves with increasing diameter for one patient. Others apply removable sleeves in one single template (with removable sleeve inserts or sleeve on drills). Some systems designed special drills or drill stops to allow depth control while others have indication lines on the drills. After the preparation of the implant osteotomy, some systems allow a guided placement of the implant, while for other systems the template has to be removed before implant insertion. These are only some examples to illustrate how difficult it is to interpret and compare individual studies. The systematic review from Jung and co-workers (2009) and Schneider and co-workers (2009), who besides the accuracy, also reviewed the clinical efficacy, concluded that differing levels and quantity of evidence were available for computer-assisted implant placement and that future research should be directed to increase the number of clinical studies with longer observation periods and to improve the systems in terms of accuracy and efficacy.

This review aims to give an overview of the accuracy of the procedure and as a second objective to give an overview of the efficacy of the static guided surgery. Data from two recent systematic reviews *(73, 37)* were implemented in this paper.

Accuracy

• Definition

The accuracy is defined by matching the position of the planned implant in the software with the actual position of the implant in the mouth of the patient.
The accuracy of the implant or the osteotomy site is mostly expressed by four parameters *(Fig. 1)*: 1) deviation at the entry point, 2) deviation at the apex, 3) deviation of the long-axis, 4) deviation in height/depth. The matching between planned and placed implant position can be based on a second (cone beam) CT (allowing a matching between preoperative planning and postoperative implant positions) or via "model matching" (by comparing pre-and postoperative models of the treated jaw) *(43)*. The mean deviations for model and CT matching are quite similar; respectively 0.5 mm (range 0.1-1.2) and 0.8 (range 0.1-2.7 mm) mm at the entry and 0.5 mm (range 0.1-1.3) and 1.1 mm (range 0.2-3.6) at the apex *(46,59)*.

• Results

Data from a recent systematic review *(73)* revealed an overall mean deviation at the entry point of 1.0 mm (SE 0.12 mm, 95% CI 0.8 – 1.2), ranging from 0 mm to 6.5 mm. The corresponding data at the apex were 1.2 mm (SE 0.1 mm, 95% CI 1.0 – 1.6), ranging from 0 mm to 6.9 mm. The overall mean angulation was 3.8° (SE 0.3°, 95% CI 3.2 – 4.4), ranging from 0.0° to 24.9°. The overall mean vertical deviation (based on 5 studies) was 0.5 mm (SE 0.1, 95% CI 0.2 – 0.7), with a maximum ranging from 2.3 mm to 4.2 mm. This review included 19 articles, which reported on accuracy. From the included studies, 2 were model based, 5 were on human cadaver and 12 were on patients. The range of included patients was 4-54, with a total of 279 patients. 10 different static image guided systems have been reported on accuracy *(Table 1)*. Thus large deviations can occur. One should realize that the total deviation is the cumulative result of deviations that can occur at each step *(80, 82)*. One might consider these deviations as very large, but an in vivo RCT with comparison between guided surgery and mental navigation (with or without any type of surgical template) is currently

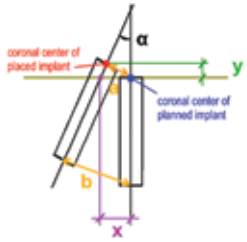

Fig. 1 *The accuracy is expressed by four parameters: a deviation at the entry point of the implant or cavity, b: deviation at the apex of the implant or cavity, α: deviation of the axis of the cavity or implant, y: deviation in height/depth.*

not available. Two in vitro studies on acrylic models *(65, 53)* compared deviations for mental navigation with deviations for guided surgery. A significant improvement was observed in favour of guided surgery for all deviations. When for example the angular deviations were compared they were respectively 4.5° and 8.0° *(65)*, 4.2° and 10.4° for guided and mental navigation *(53)*. An in vivo pilot study confirmed the higher accuracy with guided surgery *(79)*.

Possible sources of error

Radiographic technique:

The preoperative planning can be done via multislice computed tomography (CT) or cone beam computed tomography (CBCT) *(38,39,49,57)*, the latter offering imaging at low dose and relatively lower costs. Poeschl and co-workers *(60)* compared the accuracy of MSCT and CBCT for its use in image guided surgery in an in vitro model study. Acrylic mandibular models with four precise metal reference markers were scanned with MSCT and CBCT. First, the distances between the fixed reference markers were measured by a 3-axis drilling machine, then they were measured for MSCT and CBCT, applying different software systems. There was no statistically significant difference found between MSCT and CBCT. The difference of the overall mean values to the reference was 0.4 mm for MSCT and 0.5 mm for CBCT.
Arisan and co-workers *(5)* compared the accuracy of MSCT and CBCT in a clinical study. Similar deviation values were found for MSCT and CBCT, respectively 0.8 mm (SD 0.3) and 0.8 mm (SD 0.3) at the entry, 0.8 mm (SD 0.3) and 0.9 mm (SD 0.3) at the apex and 3.3° (SD 0.4) and 3.5° (SD 0.4) for angulation.

Patient's movement:

The image quality of the (CB)CT can impede the system's accuracy if motion or metal artifacts are present *(27)*. Metal artifacts can result from metal-dense tooth restorations and motion artifacts result from patient movement (due to lack of compliance or inappropriate fixation during the radiological investigation) *(Fig. 2)*. Pettersson and co-workers *(59)* observed, during the matching procedure, that in some cases the segmented implants from the follow-up CBCT were no longer cylindrical in shape. This could be explained by minor movements during scanning. Pettersson and co-workers *(59)* emphasized that such movements, in most cases, are not always visible on the 3D images. Furthermore, the automatic superimposing procedure of gutta-percha markers (visible on the patient CBCT data and the prosthesis CBCT data in case of dual scan) sometimes proceeded without any notification of errors. The "movement" factor has a significant influence on the final accuracy. However, this statistically significant difference may not prove to be clinically relevant.

Position of the scan prosthesis:

The correct positioning of the scan prosthesis, in particular in cases where the scan prosthesis is transferred into the surgical guide, is extremely important. Therefore an index is strongly recommended to position and stabilize the template in the mouth of the patient during the scanning process *(Fig. 3)*. Optimal fit of the scan prosthesis with the patient's soft tissue is crucial. This can be controlled using the software to determine whether air is visible between the scan prosthesis and the soft tissues *(Fig. 4a)*. If the scan prosthesis does not fit well, following shortcomings have to be foreseen: incorrect position of teeth in relation to the jaw bone, incorrect planning of the implant positions, bad fit of the surgical guide resulting in instability of the guide and incorrect position of the surgical guide resulting in inaccuracy. Furthermore it is also important that the scan prosthesis has sufficient thickness *(Fig. 4b)*.

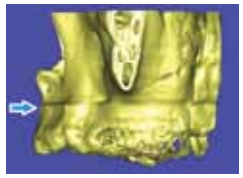

Fig. 2 *Example of movement of patient during scan. The blue arrow on the 3D- model of the jaw, shows a clear step, indicating that the patient has moved his head in a vertical manner.*

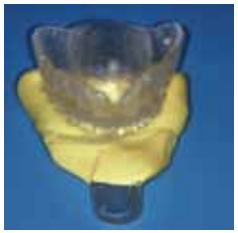

Fig. 3 *Scan prosthesis with gutta-percha markers and index to stabilize the guide during the scanning procedure.*

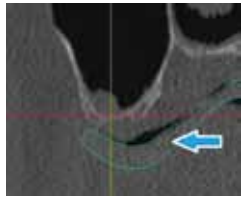

Fig. 4a *Crossectional image in the planning software, the blue arrow indicates the air between the radiographic guide and the mucosa.*

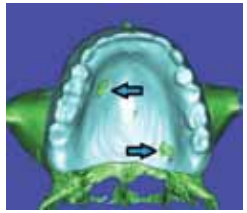

Fig. 4b *3D-model of the jaw and the scan prosthesis, the blue arrows indicate insufficient thickness of the prosthesis.*

Surgical guide production:

The production of the surgical guide can be subdivided in two main approaches: stereolithography and laboratory production (for the latter the scan prosthesis is transferred into a surgical guide) *(78)*. The overall deviation in the production process of a stereolithographic guide is less than 0.25 mm *(Fig. 5) (14, 64, 69)*. This deviation might occur during one of the three following steps: the (CB)CT scan for acquisition of anatomical data of the patient, the image segmentation using dedicated software packages combined with data processing, and finally the building of the model itself, using one of several available RPT technologies *(68)*. The guide production in the laboratory can be executed manually with the aid of a coordinate transfer apparatus or with the computer numerical control (CNC) milling machine *(11, 27, 28)*. The deviation of the latter is less than 0.5 mm *(27)*. This overall deviation is also the sum of three steps: image quality of the (CB)CT, the production of the scan prosthesis and the production accuracy of the device, which transfers the planned implant positions to the corresponding drill sleeve positions in the scan prosthesis.

Positioning and stabilization of the surgical template:

The positioning and stabilization of the surgical template can also influence the inaccuracy *(Fig. 6a)*. This is even more the case when several consecutive guides are used for drills with increasing diameter *(2,4)*. Arisan and co-workers *(4)* reported that their consecutive bone-supported guides frequently moved spontaneously away from the alveolar bone during drilling. This was especially seen in dense bone areas with a thin alveolar crest. But even when one guide was used and fixed by fixation pins they occasionally found that fixation screws were loosened and required tightening. Therefore one must check whether the guide remains stable in the correct position during the drilling process. *Figure 6b* shows an ideal distribution of fixation pins, with the distal pins behind the most posterior implant position. Furthermore it is recommended to tighten the most posterior pins before the anterior pins, because of the undercutting of the jaw in the front region, there is a risk of tilting the surgical guide when the anterior pins are tightened first. Another study *(20)*

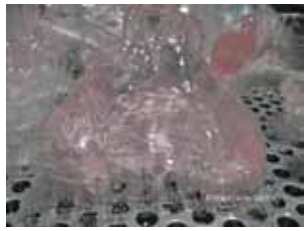

Fig 5 *Example of a stereolithographic guide (In courtesy of Materialise Dental®)*

Fig. 6a *Example of a surgical guide with the surgical index, which will stabilize the guide during fixation on the underlying bone.*

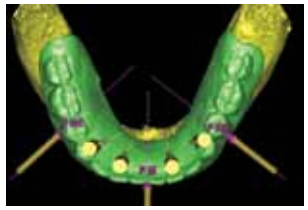

Fig. 6b *Implant planning in software. Three fixation screws are planned, well distributed, one at the midline and two posterior of the last implant position.*

reported on a method to enhance the stabilization of the guide by means of a combination of bone-tooth supported guides. Via laser scanning, detailed dentition information was obtained, which is more accurate than the dentition information retrieved from the three-dimensional skull model reconstructed from CT images. The laser-scanned dentition model was than superimposed on the CT-model, to serve as the basis for a more accurate 3-D model and resulting stereolithographic guide, which is both tooth and bone supported. One publication *(24)* evaluated the inter-implant deviation within a patient, to see whether the deviation is related to malpositioning of the surgical guide, or to individual malpositioning of the implants. They observed that the mean deviation was substantially different from the inter-implant deviation (1.3 versus 0.3 mm for apical inaccuracy). These results indicate that the inaccuracy is mainly determined by the mispositioning of the surgical guide. Future studies should look to both aspects.

Tolerance of the drills:

The tolerance of the drills within the drill guide and/or keys, as reported in two in vitro studies, *(74, 47)* underlines the importance of the position of the drill within the guide. The maximal deviation of the drill within the surgical guide can reach a maximum horizontal deviation of 1.3 mm at the implant shoulder and 2.4 mm at the apex for a 13 mm implant. A maximum deviation in angulation of 5.2° was observed *(47)*. The latter is specific for each guiding system. This can also explain a deviation of the implants to the right for right handed surgeons or to the mesial (especially for the more distal implants). Data on these phenomena are limited. Di Giacomo and co-workers *(26)* as well as Vasak and co-workers *(77)* found significant lower deviations for anterior implants compared to posterior ones. But there are of course other explanations for this deviation. Horwitz and co-workers *(36)* observed that attrition of sleeves and drills, after longer use, are a contributing factor.

Mucosal thickness:

The mucosal thickness (depending on the biotype or related to smoking), can influence the accuracy of mucosa supported templates *(23, 77)*. The mean deviation at entry for example was 1.04 mm in thick (smokers) versus 0.80 mm in thin mucosa (non-smokers) *(23)*. Another study *(77)* observed that an increase in the buccal mucosal thickness of 1 mm resulted in an increase of the bucco-lingual deviation of 0.41 mm.

Learning curve:

The literature is not consistent on whether a learning curve is important, one clinical trial observed a learning curve *(77)*, while 2 other studies did not *(18,70)*.

Jaw position:

There is an inconsistency in the observations comparing the data of the maxilla with the mandible. Some publications reported no differences *(6, 11, 26, 29)*, while others observed less deviation for the mandible *(59,77)*.

Computer-assisted implant system:

Because of the heterogeneity in study designs included in the systematic review *(73)* a comparison between different static computer-assisted implant systems (Ay-Design®, Aytasarim®, EasyTaxis®, SinterStationHiQ®, SurgiGuide®, Safe SurgiGuide®, SICAT®, Med3D®, NobelGuide®, Facilitate®) became impossible. Each guiding system has its advantages and disadvantages. More randomized studies are needed, using the same study design including a large patient population, in order to calculate deviations for equivalent subgroups (same surgeon, same guiding device, same scanning, same matching procedure).

Efficacy

• Definition

To examine the efficacy of guided implant placement, following parameters can be defined. The efficacy can be determined by comparing the implant survival or success rate and the prosthesis survival rate of guided placement, with conventional implant treatment. Furthermore different clinical protocols such as flapless surgery can also contribute to the efficacy of guided surgery.

• Results

Implant survival or success rate:

Several studies presenting prospective observational data on clinical performance of guided implant placement were identified *(37)*. However, most of these studies have an observational period of less than 2 years *(see table 2)* and only one study *(63)* had a follow up period of up to 5 years. For these studies one can envisage comparable survival rates as for conventional implant treatment.
Also for smokers treated with guided surgery lower success rates have been observed *(3, 7, 8, 41)*. A cohort study *(63)* for example reported cumulative survival rates for the smokers of 81.2%, while the non-smokers achieved 98.9%. The latter was confirmed in a prospective clinical study of D'haese and co-workers *(22)*, where patients were treated with flapless guided surgery in the maxilla (69.2% implant survival in smokers versus 98.7% in non-smokers).

Prosthesis survival rates:

Prosthesis survival rates showed a wide range (62 to 100%) *(see table 3)* probably due to several factors (e.g. definition of prosthesis survival, immediate or delayed loading, evaluation of temporary or permanent prosthesis) and direct comparison with conventional technique can therefore become difficult. The computer guided implant concept in combination with immediate loading *(Figs. 7a-d)* is marketed as easy, safe and predictable. However, several complications or unexpected events were reported *(see table 2)*, e.g. fracture of the surgical guide *(Fig. 8)*, dehiscences *(31)* and soft tissue laceration *(26)*. Misfit of the temporary prosthesis was the most common prosthetic complication, due to inaccurate placement of the implants

Fig. 7a-d *Clinical case of a patient treated with flapless guided surgery and immediately restored with a temporary partial bridge.*

Fig. 8 *Example of a fracture of the surgical guide (In courtesy of Prof. Björn Klinge).*

(Fig. 9a). After placement of the temporary prosthesis the most common complication was prosthesis fracture *(Fig. 9b)*. It seems obvious that guided surgery, especially in combination with immediate loading, cannot be regarded as easier than conventional techniques.

Clinical protocol:

Flapless surgery gained interest since several articles have shown that raising a flap leads to bone resorption. *(30, 34, 83).* Via a flapless approach the periosteum and blood supply to the bone remains intact *(10, 17)* *(Figs. 10a and 10b)*. Three studies compared guided flapless surgery with conventional open flap surgery and reported on patient centered outcomes *(4, 32, 55)*. These studies demonstrated a statistically significant reduction in immediate postoperative pain, use of analgesics, swelling, edema, hematoma, hemorrhage and trismus for flapless surgery. One of these studies *(4)* also compared guided flapless with guided open flap surgery and demonstrated consistently better outcome for the flapless approach. These results are supported by the good scores for patient comfort and satisfaction reported by several observational studies on guided flapless surgery *(1, 54, 75)*. A prolonged oral surgical intervention may increase postoperative pain and discomfort for the patient *(66)*. One of the above mentioned controlled studies reported that the duration of the treatment with flapless guided surgery was less than half (24 min) compared to open flap guided surgery and/or conventional surgery *(4)*. This observation is supported by Komiyama and coworkers *(45)* who reported that the duration of the flapless guided surgical intervention including immediate reconstruction (Teeth-in-an-Hour concept, Nobel Biocare AB, Gothenburg, Sweden) took 30-45 minutes. Thus, the time factor may indeed be a part of the explanation why less pain and discomfort was reported by patients after flapless guided surgery. Even if the duration of the surgical intervention may be shorter with flapless guided surgery compared to conventional techniques it seems that much more time has to be invested in the preoperative planning. The flapless guided implant placement technique allows the surgeon to install the implants with a minimal surgical trauma to the bone and associated soft tissues. As such, these techniques may

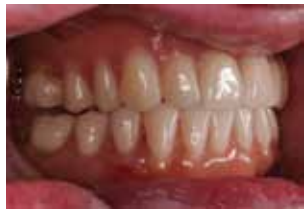

Fig. 9a *Misfit of the prefabricated prosthesis.*

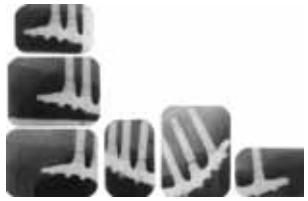

Fig. 9b *Radiographs showing the misfit of the prefabricated prosthesis.*

Fig. 10a *Clinical picture of flapless surgery in the upper jaw after removal of the guide.*

Fig. 10b *and after placement of the abutments.*

be particularly attractive to use in frail patient groups. However, again very limited information is available. Horwitz *(36)* described the use of flapless guided implant placement in an irradiated cancer patient and showed good results after 2 years. In the study by Barter *(9)*, 6 patients were treated with flapless guided surgery to avoid a secondary exposure of earlier grafted sites. The implant survival rate was 98% and all prostheses were still in use after four years.

• Cost effectiveness

The cost effectiveness of different guided surgery protocols is difficult to judge since no information regarding this parameter could be found in the scientific literature. An interesting clinical question is if these techniques can be used as an alternative to bone augmentation. Unfortunately, only one article addresses this question. Fortin and coworkers *(33)* used the guided technique in partially edentulous cases with severely resorbed maxilla's and reported a 98% implant survival rate after 4 years.

Conclusion

Today, different computer assisted implant placement procedures are available. They differ in software, template manufacturing, guiding device, stabilization and fixation. The literature seems to indicate that one has to accept a certain inaccuracy of ± 2.0 mm, which seems large at a first view, but is clearly less than for non guided surgery. A reduction of the accuracy below 0.5 mm seems extremely difficult. A common dilemma identified in the studies included for this review has been the inconsistency of reporting clinical data and outcome variables. Another shortcoming is the low number of comparative clinical studies. In order to find the best guiding system/most important parameters for optimal accuracy, more RCTs are necessary, including also information on cost-effectiveness, patient-centered evaluations (i.e. questionnaires and interviews) and longer follow-ups. Future research should consider the use of flapless guided implant placement in special subgroups of patients (e.g. severally resorbed jaws, radiotherapy, osteoporosis,.)

Study	Study-design	No. of impl	Site	Sup-port	Sys-tem	Tem-plate	Numb of tem-plates	Pins	Implant guided	Error entry (mm)		Error apex (mm)		Error angle (°)		Error depth (mm)	
										mean	SD	mean	SD	mean	SD	mean	SD
Arisan et al. (6)	In vivo	279	max + mand		Ayt, Safe S	SLA											
				B	Ayt	SLA	3	0	no	1,7	0,52	1,99	0,64	5	1,66		
				B	Safe S	SLA	3	0	no	1,56	0,25	1,86	0,4	4,73	1,28		
				M	Ayt	SLA	1	3	no	1,24	0,51	1,4	0,47	4,23	0,72		
				M	Safe S	SLA	1	3	yes	0,7	0,13	0,76	0,15	2,9	0,39		
				T	Ayt	SLA	1	0	no	1,31	0,59	1,62	0,54	3,5	1,38		
				T	Safe S	SLA	1	0	yes	0,81	0,33	1,01	0,4	3,39	0,84		
Behneke et al. (12)	In vivo	132	max + mand	T	Med 3D	L	1	0	some-times	0,28		0,42		1,94			
		87	max							0,32		0,53		2,02			
		45	mand							0,32		0,42		2,25			
		24								0,21		0,28		1,49			
Cassetta et al. (18)	In vivo	227	max + mand	T, M, B		SLA											
		116			Surg	SLA	3	0	no	1,47	0,68	1,83	1,03	5,09	3,7	0,98	0,71
		57			Safe S	SLA	1	yes	yes	1,49	0,63	1,9	0,83	3,93	2,34	0,85	0,63
		54			Safe S	SLA	1	0	yes	1,55	0,59	2,05	0,89	5,46	3,38	0,63	0,43
D'Haese et al. (24)	In vivo	77	max	M	Fac	SLA	1	>4	yes	0,91	0,44	1,13	0,52	2,6	1,61		
Di Gia-como et al. (25)	In vivo	21	max + mand	T, B	Surg	SLA	3	0	no	1,45	1,42	2,99	1,77	7,25	2,67		
Di Gia-como et al. (26)	In vivo	60	max + mand	M	Sin	SLA	1	2	no	1,35	0,65	1,79	1,01	6,53	4,31		
		22	max							1,51	0,62	1,86	1,07	8,54	4,2		
		38	mand							1,26	0,66	1,75	0,99	5,37	3,98		
Dreise-idler et al. (27)	In vitro	54	max + mand	T		L											
		24			Nob		1	0	yes	0,217	0,099	0,343	0,146	1,09	0,51	0,254	0,204
		30			SIC		1	0		0,15	0,12	0,4	0,12	1,18	0,55		
Ersoy et al. (29)	In vivo	94	max + mand		Ay-D	SLA	>1	NA	no	1,22	0,85	1,51	1	4,9	2,36		
		23		M						1,1	0,7	1,7	1	4,9	2,2		
		45		B						1,3	1	1,6	1,5	5,1	2,7		
		26		T						1,1	0,6	1,3	0,7	4,4	1,6		
		48	max							1,04	0,56	1,57	0,97	5,31	0,36		
		46	mand							1,42	1,05	1,44	1,03	4,44	0,31		
Ozan et al. (56)	In vivo	110	max + mand	T, M, B	Ay-D	SLA	>1	0	no	1,1	0,7	1,41	0,9	4,1	2,3		
		58	max							0,95	0,5	1,41	1	4,85	2,4		
		52	mand							1,28	0,9	1,4	0,9	3,32	1,9		
		30		T						0,87	0,4	0,95	0,6	2,91	1,3		
		50		B						1,28	0,9	1,57	0,9	4,63	2,6		
		30		M						1,06	0,6	1,6	1	4,51	2,1		

***Table 1** Part 1*

Study	Study-design	No. of impl	Site	Sup-port	Sys-tem	Tem-plate	Numb of tem-plates	Pins	Implant guided	Error entry (mm)		Error apex (mm)		Error angle (°)		Error depth (mm)	
										mean	SD	mean	SD	mean	SD	mean	SD
Petters-son et al. (58)	Ex vivo	145	max + mand	M	Nob	SLA	1	3 to 5	yes							0,39	0,59
		78	max							0,83	0,57	0,96	0,5	2,02	0,66		
		67	mand							1,05	0,47	1,24	0,58	2,46	0,67		
Petters son et al. (59)	In vivo	139	max + mand	M	Nob	SLA	1	yes	yes	0,8		1,09		2,26		-0,15	
		89	max							0,8		1,05		2,31		-0,06	
		50	mand							0,8		1,15		2,16		-0,29	
Ruppin et al.(62)	Ex vivo	~60	mand	B	Surg	SLA	3	0	no	1,5	0,8	NA		7,9	5		
Sarment et al. (65)	In vitro	50	mand	E	Surg	L	3		osteo-tomies	0,9	0,5	1	0,6	4,5	2		
Valente et al. (70)	In vivo	89	max + mand	T, M, B	Surg	SLA	3	NA	no	1,4	1,3	1,6	1,2	7,9	4,7	1	1
Van Assche et al.(71)	Ex vivo	12	max + mand	T	Nob	SLA	1	0 or 1	yes	1,1	0,7	1,2	0,7	1,8	0,8		
Van Assche et al. (72)	In vivo	19	max + mand	T	Nob	SLA	1	0 or 1	yes	0,6	0,3	0,9	0,4	2,2	1,1		
van Steen-berghe et al. (76)	Ex vivo	10	max	M	Nob	SLA	1	0	yes	0,8	0,3	0,9	0,3	1,8	1		
Vasak et al. (77)	In vivo	79	max + mand	T, M	Nob	SLA	1	yes	yes	0.46 BL, 0.43 MD	0.35 BL, 0.32 MD	0.7 BL, 0.59 MD	0.49 BL, 0.44 MD	3,53	1,77	0,52	0,42
				M						0.49 BL, 0.46 MD		0.64 BL, 0.62 MD		3,5		0,6	
				T						0.37 BL, 0.35 MD		0.88 BL, 0.49 MD		3,7		0,37	
			max							0.47 BL, 0.45 MD		0.70 BL, 0.59 MD		3,55		0,57	
			mand							0.41 BL, 0.36 MD		0.70 BL, 0.57 MD		3,68		0,34	
Wid-mann e t al.(81)	Ex vivo	51	max + mand	3 screws	Easy	L	1	3	yes	1,1	0,6	1,2	0,7	2,8	2,1		

Table 1 *First line of each study represents overall data, if data mentioned for subgroups, they are in lines below. Guide: SLA= stereolithography, L=laboratory, Support: T=tooth involved, M=mucosa, B=bone,E=epoxy, System= Guiding system, Pins= fixation pins, Ay-D= Ay-Design, Ayt= Aytasarim, Fac= Facilitate, Sim= Simplant, Surg = SurgiGuide, Safe S= Safe SurgiGuide, Nob=NobelGuide, Sin= SinterStationHiQ,SIC=SICAT,Easy= Easy Taxis Aiming Device.*

				Complications at guided implant placement			Complications after guided placement		
Study	Study design	Follow up period (months)	System	Reason	No. of prosthetic events	Reason	No. of prosthetic events	No. of prosthetic events	Reason
Abad-Gallegor et al (1)	RO	NR	Nobel Guide	Lack och primary stablility. Limited oral aperture.	NR	Lack of passive fit. Implant pain. Change to angulated abutment.	10	NR	Screw loosening. Fracture of prosthesis or teeth.
Arisan et al (4)	PC*	2-4	Aytasarim classic, Simplant-SAFE	Fracture of bone supported surgical guides.	NA		5	NA	
Barter et al (9)	PO	mean 49	coDiagnostiX and GonyX		NR		1	NR	
Berdougo et al (13)	RC*	12-48	EasyGuide and CAD Implant system		NR		10	NR	
Cassetta et al (19)	RO	NA	SimPlant Safe	Uncontrolled removal of gingiva. Alteration of external hexagon. Laceration. Template breakage. Limited implant stability.	NA		NA	NA	
Danza et al (21)	RC*	1-41 (mean 14)	Implant 3D and Ray-Set		NR		0	NR	
D´haese (22)	PO	12	Astra Facilitate	Misplacement due to misfabrication of surgical guide.	0		13	3	Esthetic reasons. Prosthesis fracture.
Di Gia-como er al (26)	PO	30	Implant Viewer 1.9 & Rhinoceros 4.0	Pulling of soft tissue. Insertion of wider implants than planned. Instability. Pain.	1	Midline deviation.	1	1	Prosthesis fracture.
Fortin et al (32)	RCT*	NA	CAD Implant system		NR		NR	NR	
Fortin et al (33)	PO	48	EasyGuide	Implant lost before loading.	NA		0	NR	
Gillot et al (35)	PO	12-51	Nobel Guide	Guide difficult to insert. Absence of primary stability.	1	Major occlusal adjustment required for one patient.	4	11	Fractures of resin. Prosthetic screw loosening.
Johansson et al (40)	PO	12	Nobel Guide	Misfit of occlusal index. Misfit of the surgical guide. Problems installing the implants.	15	Problems getting the prosthesis in the exact position. Major occlusal adjustments.	2	1	Prosthesis remade using standard abutments due to difficulties in maintaining adequate oral hygiene.
Katsoulis et al (43)	PC*	3	Nobel Guide		NA		NR	NR	
Komi-yama et al (45)	PO	6-44 (mean ≥15)	Nobel Guide	Fracture of surgical template.	8	Misfit of prosthesis. Major occlusal adjustments.	19	3	Prosthesis had to be removed due to implant loss.
Komi-yama et al (44)	PO	>12 (mean 19)	Nobel Guide		NA		NA	NA	
Linde-boom and van Wijk (48)	RCT	1	Nobel Guide		NA		NR	NR	

Table 2 *Part 1*

				Complications at guided implant placement			Complications after guided placement		
Study	Study design	Follow up period (months)	System	Reason	No. of prosthetic events	Reason	No. of prosthetic events	No. of prosthetic events	Reason
Malo et al (50)	PO	6-21 (mean 13)	Nobel Guide		NR		2	10	
Meloni et al (51)	RO	18	Nobel Guide	Fracture of surgical template.	2	Temporary prosthesis did not fit at time of placement.	2	2	Fracture of the temporary prosthesis.
Merli et al (52)	PO	8	Nobel Guide	Fracture of surgical guide. Lost implant because primary stability could not be achieved.	4	Prosthesis did not fit at time of placement.	2	5	Fracture of temporary prosthesis. Prosthetic screw loosening. Fracture of porcelain coating of permanent prosthesis.
Nikzad et al (54)	PO	12	Simplant, SurgiGuide		NA		2	2	Fixtures lost. No seating of prosthesis.
Nkenke et al (55)	PC*	12	NobelGuide		NR		0	NR	
Pomares (61)	RO	12	NobelGuide	Fracture of surgical template.	3	Misfit of temporary prosthesis.	4	8	Fracture of the temporary prosthesis.
Sanna et al (63)	PO	6 - 60 (mean 26)	NobelGuide		NR		9	NR	
van Steenberghe et al (75)	PO	12	NobelGuide		2	Prosthetic misfit. Midline deviation.	0	3	Occlusal material fracture. Prosthetic screw loosening.
Yong and Moy (84)	PO	mean 27	NobelGuide	Too deep placement of one implant which was removed (failure).	2	Incomplete seating of prosthesis due to bony interference.	7	12	Speech problem. Bilateral cheekbiting. Fracture of prosthesis. Heavy occlusal wear. Screw loosening.

Table 2 *PC = Prospective comparative; PO = Prospective observational; RC = Retrospective comparative; RO = Retrospective observational; RCT = Randomised control trial; * = Control group included conventional*

			Survival rate					
Study	Immediate / Delayed loading		Implants		Prosthesis			Other outcome
	With guided placement	Without guided placement	With guided placement	Without guided placement	With guided placement	Without guided placement	Follow up period (months)	
Barter et al (9)	NR	NR	98%	NA	100%	NA	mean 49	
Berdougo et al (13) *	NR	NR	96%	99%	NR	NR	12-48	
Danza et al (22) *	I / D	I / D	100%	96%	NR	NR	1-41 (mean 14)	
D'haese (22)	I / D	NA	89%	NA	62%†	NA	12	99% impl. surv. rate in nonsmokers and 74% in smokers. Smoking and immediate loading in combination in edent. maxillas increased impl. loss.
Di Giacomo er al (26)	I	NA	96%	NA	92%	NA	30	
Fortin et al (33)	D	NA	98%	NA	NR	NA	48	
Gillot et al (35)	I	NA	98%	NA	100%	NA	12-51	Removal and replacement of adjustable abutments used in the temporary prosthesis were unpleasant for the patients.
Johansson et al (40)	I	NA	99%	NA	96%	NA	12	Mean marginal bone loss of 1.3mm. 19% of the subjects had >2mm bone loss. Mucosal inflammation in 23% of probed sites.
Komiyama et al (45)	I	NA	89%	NA	84%	NA	6-44 (mean ≥15)	Bleeding on probing: 82% (16-100). Bone loss more common when pressure-like mucosal ulcers was detected under the prosthesis.
Malo et al (50)	I	NA	98%	NA	NR	NA	6-21 (mean 13)	21% of all measured sites at 6 months and 28% at 12 months had >2mm radiographic bone loss.
Meloni et al (51)	I	NA	98%	NA	87%‡	NA	18	Mean marginal bone loss of 1.6 mm after 18 months.
Nikzad et al (54)	D	NA	96%	NA	NR	NA	12	Mean pain score on VAS-scale at the follow-up was within the range for little or no pain.
Nkenke et al (55) *	I	I	100%	100%	100%	100%	12	Guided surgery generated less postoperative pain and swelling compared to open flap surgery.
Pomares (61)	I	NA	98%	NA	100%	NA	12	
Sanna et al (63)	I	NA	95%	NA	NR	NA	6-60 (mean 26)	Mean marginal bone loss of 2.6mm in smokers and 1.2 mm in non-smokers.
van Steenberghe et al (75)	I	NA	100%	NA	100%	NA	***12***	Mean marginal bone loss of 1.2 mm mesial and 1.1 mm distal.
Yong and Moy (84)	I	NA	91%	NA	NR	NA	mean 27	

Table 3 *I = Immediate loading; D = Delayed loading; NR = Not reported; NA = Not applicable.*

** = Control group included conventional surgery open flap; † = Survival rate reported on temporary prosthesis for the immediate loaded cases; ‡ = Survival rate reported on temporary prosthesis.*

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An RCT comparing guided implant surgery 2

with mental navigation or the use of a pilot-drill template.

(bone or mucosa supported)

Abstract

Aim: To assess in a randomized study the accuracy of guided surgery (mucosa and bone supported) compared to mental navigation or the use of a surgical template, in fully edentulous jaws.

Material and Methods: Sixty patients (72 jaws), requiring four to six implants (maxilla or mandible), were consecutively recruited and randomly assigned to one of the following treatment groups; guidance via Materialise Universal®/ mucosa, Materialise Universal®/ bone, Facilitate™/ mucosa, Facilitate™/ bone, or mental navigation or a pilot-drill template. The precision was assessed by matching the planning CT with a postoperative CBCT.

Results: A significant lower mean deviation at the entry point (1.4 mm, range: 0.3-3.7),) at the apex (1.6 mm, range: 0.2-3.7) and angular deviation (3.0˚, range: 0.2-16˚) was observed for the guiding systems when compared to mental navigation (2.7 mm, range: 0.3- 8.3; 2.9 mm, range: 0.5-7.4 and 9.9˚, range: 1.5-27.8) and to the surgical template group (3.0 mm, range: 0.6- 6.6; 3.4 mm, range: 0.3-7.5 and 8.4˚,range: 0.6-21.3˚). Differences between bone and mucosa support or type of guidance were negligible. Jaw and implant location (posterior-anterior, left-right) however, had a significant influence on the accuracy when guided.

Conclusion: Based on these findings, guided implant placement appears to offer clear accuracy benefits.

Introduction

For computer-guided surgery often a static surgical guide is used. Such guides are produced by computer-aided design/computer-assisted manufacture (CAD/CAM) technology such as stereolithography, or in a dental laboratory (using mechanical positioning devices or drilling machines)(van Assche et al. 2012, Vercruyssen et al. 2008, Vercruyssen et al. 2014b). Preoperative three-dimensional planning has recently gained popularity, especially after the introduction of cone beam computer tomography (Loubele et al. 2007, Loubele et al. 2006). Furthermore, with the combination of flapless surgery, it is presumed to reduce the postoperative patient morbidity and discomfort (Hultin et al. 2012).

The limitations of static guided surgery are set by the maximum deviation observed between planning and postoperative outcome. Deviations reflect the accumulation of all errors from imaging over the transformation of data into a guide, to the improper positioning of the latter during surgery. There is no consensus about the maximum deviation needed for an acceptable accuracy of image-based transfer to surgery. Critical anatomical structures, such as the mandibular and mental nerve, must of course be avoided at any cost to prevent neurological complications (Jacobs et al. 2002, Mraiwa et al. 2004, Bou Serhal et al. 2002). Especially in case of so-called " blind surgery" this constitutes a serious risk.

Within the systems working with surgical guides significant variations can be observed (van Assche et al. 2012, Vercruyssen et al. 2008). Some systems designed special drills or drill stops to allow depth control while others have indication lines on the drills (Koop et al. 2012). After the preparation of the implant osteotomy, some systems allow a guided placement of the implant while for other systems the template has to be removed before implant insertion.

Currently there are no randomized prospective clinical studies comparing the accuracy of different CT-based surgical drill guides to each other, and/or to mental navigation.
For the Materialise Universal® system publications on accuracy are lacking. The aim of the study is to determine the accuracy of the Materialise Universal® system (mucosa or bone supported) and of the Facilitate™system (mucosa or bone supported), and to compare both to mental navigation or to the use of a simple surgical stent. The accuracy is assessed by comparing pre- and postoperative (CB)CT (matching). The planned implant positions will be compared to the actual implant positions after insertion.

Material and methods

• Patients

Sixty consecutive patients (72 jaws, mean age=58, 29 males, 31 females, seven smokers) with sufficient bone volume to place four to six implants in the edentulous lower (n=33) or upper jaw (n=39), were consecutively recruited and randomly assigned to one the of the following treatment groups; Materialise Universal®/ mucosa (Mat Mu), Materialise Universal®/ bone (Mat Bo), Facilitate™/ mucosa (Fac Mu), Facilitate™/ bone (Fac Bo), mental navigation (Mental) and a pilot-drill template (Templ). For the allocation a computerised random number generator was used. Patients who entered the study twice, for treatment in the upper and lower jaw, were also assigned twice to an intervention group.
For the determination of the sample size, the following calculation was made. An expected standard deviation of 0.8 to 0.9 mm and an expected difference between treatments of a mean coronal deviation of 1mm resulted in a sample size of 11 (SD=0.8) to 13 (SD=0.9), needed to obtain a power of 80% with a confidence level of 95%. The final sample size was the average of the two calculated sample sizes, which resulted in 12 patients (jaws) for each treatment group. For inclusion in the study subjects had to fulfill all of the inclusion and exclusion criteria *(see Table 1)*. The study was approved by the ethical committee of the University Hospital of the Catholic University of Leuven *(B32220095376)*.

INCLUSION CRITERIA	
1	provision of informed consent
2	an age of at least 18 year
3	extraction socket healing for at least 6 months
EXCLUSION CRITERIA	
1	unlikely to be able to comply with study procedures
2	history of intravenous bisphosphonate treatment
3	medical history that makes implant insertion unfavorable
4	current pregnancy
5	present alcohol and/or drug abuse
6	major systemic diseases
7	untreated, uncontrolled caries and/or periodontal disease
8	history of local irradiation
9	need for bone grafting and/or sinus lift in the planned implant area

Table 1 *The inclusion and exclusion criteria.*

• Planning procedure

A scan prosthesis was prepared at the prosthetic department of the University Hospital of Leuven containing all information for future prosthetic restoration. If the existing denture fulfilled these conditions, this denture was transformed into a scan prosthesis, if not a new denture was fabricated starting from a new set-up of teeth. A minimum of eight small gutta markers were inserted in the prosthesis, using a warm gutta-percha injection technique (Obtura II®, Obtura Corporation, Fenton, MO, USA). These markers served as radio-opaque feducials to allow visualization of the scan prosthesis in the software, using the dual scanning technique (Verstreken et al. 1998).
To secure an optimal fit of the scan prosthesis during the scanning process, a bite index in centric relation was prepared in putty material (SheraExact®85, Shera GmbH & Co., Lemförde, Germany). A first MSCT scan (Somatom Definition Flash®, Siemens, Erlangen Germany, at 120 kV and 90 mAs, 0.6 mm slice thickness, voxel size 330 µm) was made of the patient with the scan prosthesis and bite index positioned in the mouth. A second scanning was performed of the prosthesis alone, with altered exposure parameters to visualize, besides the feducials, also the entire denture (Verstreken et al. 1996). Both sets of dicom images were imported in Simplant® software (Materialise Dental, Leuven, Belgium). The implants were planned in the most optimal position towards both the jawbone and the prosthetic demands. Patients were only enrolled when the planning indicated sufficient bone volume for successful implant placement without the need of a bone graft. At that moment the patient was randomly assigned to one of the intervention groups. For all patients with guided surgery, the planning was transferred to the manufacture (Materialise Dental) for the fabrication of a stereolithographic drill guide.
For the patients in the mental navigation group, scanning and planning was similar to the procedures in the aforementioned groups, but no guide was used. Only images from the software planning as a reference were allowed, together with some rough distance calculations. For the pilot-drill template group, the scan prosthesis was prepared in barium sulfate and the patient was scanned with a single scan. This scan prosthesis was then transformed into a surgical template by drilling holes (diameter 2mm) at the planned implant positions, based on the respective position towards the teeth.

• Surgical protocol

Surgery was performed under local anesthesia at the department of periodontology of the University Hospital of Leuven. In case of mucosa support, the stereolithographic guides were positioned on the mucosa using a bite index to secure a proper position. The bone supported guides were positioned on the jawbone after reflecting of a full thickness mucoperiosteal flap with a crestal incision.

All the stereolithographic guides were fixed to the underlying bone by three to four anchor pins, equally distributed in the jaw. The drilling procedure involved the use of drill keys inserted in the sleeves within the guide, which guide the consecutive drills with different diameters in the correct position and angulation. The drill keys are designed as spoons. Different keys with increasing diameter are available to guide each separate drill.
For the Materialise Universal® group there was no physical stop during drilling. The depth had to be checked at all times visually, and also the implant was placed without guidance. For the Facilitate™system, a physical stop on the drills was present and the implant insertion was guided by a fixture mount that closely fitted the sleeve.
During mental navigation implants were placed in a conventional way after reflecting a mucoperiosteal flap. During surgery the software planning was visualized and the surgeon attempted to place the implants conform this planning (mental navigation). For the Template group a surgical stent was used to indicate the implant position with the pilot drill, the stent was then removed and further drilling was performed in the conventional way.
Three hundred fourteen Astra Tech implants™ with diameter 3.5 or 4 mm, and lengths ranging from 8-15 mm were inserted. After 3 to 4 months of healing, the final prosthetic superstructure was prepared.

• Validation of the technique

Ten days after implant placement a CBCT scan (Scanora® 3D, Soredex, Tuusula, Finland) was taken (at 85 kV and 6 mA, voxel size 250 µm) to check the final position of the implants. The postoperative data were matched to the preoperative planning data using the Mimics® software (Materialise Dental, Leuven, Belgium) to determine deviations in the three dimensions *(Figure 1)*. This process is based on surface registration, which consists of a minimization of distances between both models (pre-op and post-op). In this case an iterative closest point (ICP) algorithm was used to match the jaws. The thereby established coordinate transformation operations were also applied to the 3D representations of the planned implants allowing for relative comparisons with respect to the postoperative implant positions. The intra-and inter-examiner variability of the procedure was calculated to verify its reproducibility.

The enrolment, assignment of the patients, the implant planning and the surgery were all performed by the same investigator (MV). The assessment of the accuracy was performed by another investigator (CC), who was blinded for the intervention. For calculation of the intra-examiner variability of the matching procedure, a number of cases was processed twice by the same investigator (CC), and for the inter-examiner variability the same set of cases were processed by two different investigators (MV, CC).

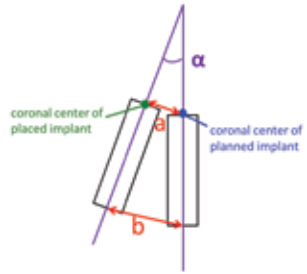

Fig. 1 *Figure representing the deviation in 3 dimensions.*

Statistical analysis

The primary outcome variable was the deviation at the entry point, at the apex of the implant and the angular deviation. The differences in deviation between techniques and influencing factors were analyzed with a linear mixed model taking treatment as a fixed factor and patient as a random factor. Residual dot plots and normal quantile plots were used to assess the assumptions of the model. Contrasts were built to test the specific hypotheses and a correction for simultaneous hypothesis testing was made according to Sidak (Šidák 1967), yielding a global significance level of 0.05. A post hoc power analysis, using the N-factor was also performed. The N-factor is the percentage of data extra points needed to achieve a clinically significant difference, considering that when expanding the data set, the variability of data would remain the same. To determine the intra- and inter-examiner variability the concordance correlation coefficient (-1: perfect negative association, 1: perfect positive association) was calculated for the deviation at the entry point and the angular deviation.

Results

All patients received their implant treatment between August 2009 and June 2012. No patients were lost before the second scan was taken. In each group 12 patients were enrolled. Three implants from the Facilitate™/ bone group were excluded from the analysis because of following reasons; one patient had a limited mouth opening and the two most distal implants could not be placed with the guide, in another patient a shorter implant was placed than which was foreseen in the planning. So a total of 311 implants were analyzed, 51 to 55 per group. Patient and implant demographics are shown in *Table 2*.

The deviation at the entry point, at the apex of the implant and the angular deviation were calculated for each group. These data are presented in *Table 3*. Box plots illustrating the differences between techniques are shown in *figures 2-4*. A significant difference in deviation at the entrance point, the apex and angular deviation was found for the Materialise Universal® group and the Facilitate™group

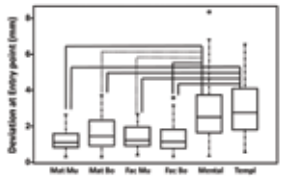

Fig. 2 *Box plot of the deviation at the entry point. P-values are presented as followed; full line ≤0.000x, dotted line ≤0.00x.*

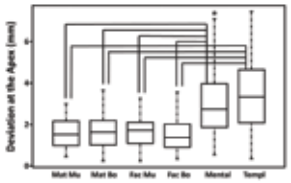

Fig. 3 *Box plot of the deviation at the apex. P-values ≤0.000x.*

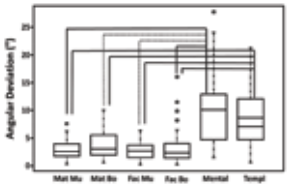

Fig. 4 *Box plot of the angular deviation. P-values are presented as followed; full line ≤0.000x, dotted line ≤0.00x.*

Treatment group	*Mat Mu*	*Mat Bo*	*Fac Mu*	*Fac Bo*	*Mental*	*Templ*
PARAMETER PATIENT LEVEL (N)						
Gender (Male/Female)	5/7	4/8	6/6	4/8	4/8	*8/4*
Age (Range)	38-78	31-72	46-74	43-65	39-72	*40-75*
Jaw (Lower/Upper)	6/6	3/9	5/7	6/6	9/3	*4/8*
Prosthetic rehabilitation (Fixed/Overdenture)	7/5	3/9	2/10	8/4	6/6	*4/8*
PARAMETER IMPLANT LEVEL (N)IMPLANT						
Total number of implants placed	55	53	52	52	51	*51*
Total number of implants lower/upper jaw	24/31	14/39	20/32	24/28	36/15	*16/35*
Implant diameter (3,5/4)	15/40	7/46	21/31	31/21	18/33	*47/4*
Implant length (8/9/11/13/15)	0/3/28/23/1	1/7/17/17/11	5/9/20/18	0/3/12/28/9	0/1/12/16/22	*2/10/17/18/4*

Table 2 *Patient and implant demographics. Abbreviations: Mat Mu = Materialise Universal®/ mucosa, Mat Bo = Materialise Universal®/ bone, Fac Mu = Facilitate™/ mucosa, Fac Bo = Facilitate™/ bone, Mental = Mental navigation, Templ = surgical template, (n) = number.*

		MatMu	*MatBo*	*FacMu*	*FacBo*	*Mental*	*Templ*
CORONAL (MM)	Mean	1.23	1.60	1.38	1.33	*2.77*	*2.97*
	SD.	0.60	0.92	0.64	0.82	*1.54*	*1.41*
	Min.	0.3	0.28	0.39	0.30	*0.33*	*0.55*
	Max.	2.65	3.73	2.68	3.58	*8.34*	*6.55*
APICAL (MM)	Mean	1.57	1.65	1.60	1.50	*2.91*	*3.40*
	SD.	0.71	0.82	0.70	0.72	*1.52*	*1.68*
	Min.	0.45	0.24	0.23	0.33	*0.53*	*0.34*
	Max.	2.99	3.66	3.27	3.56	*7.37*	*7.46*
ANGULAR (°)	Mean	2.86	3.79	2.71	3.20	*9.92*	*8.43*
	SD.	1.6	2.36	1.36	2.70	*6.01*	*5.10*
	Min.	0.27	0.53	0.20	0.19	*1.45*	*0.56*
	Max.	7.60	10.05	6.36	16.03	*27.76*	*21.28*

Table 3 *Descriptive statistics of the deviation of the different treatment groups. Abbreviations: Mat Mu = Materialise Universal®/ mucosa, Mat Bo = Materialise Universal®/ bone, Fac Mu = Facilitate™/ mucosa, Fac Bo = Facilitate™/ bone, Mental = Mental navigation, Templ = surgical template. SD = standard deviation, Min. = Minimum, Max. = Maximum.*

compared to the Mental navigation group and the Template group, both in favor of the guided surgery groups. However there were no statistical differences between bone and mucosa supported guidance or type of guidance. A post-hoc analysis yielded a N-factor of 291 for the difference between the two guided surgery groups. Thus, the difference between the two tested guided systems is statistically and clinically not relevant.

The following influencing factors were analyzed: jaw, implant position (posterior-anterior, left-right), bone quantity, bone quality, smoking habits, learning curve of the surgeon, implant length. From these the following factors had a significant influence on the deviation in the guided surgery groups: jaw (larger deviation in lower jaw) (p= 0.005), implant position in the upper jaw (larger deviation in posterior area and left side) (p= 0.02 and 0.01). In the non-guided surgery groups : jaw (larger deviation in lower jaw) (p= 0.02)and bone quality (larger deviation in poor quality bone)(p= 0.0006).

The intra- and inter-examiner variability was calculated for the deviation at the entry point and the angular deviation. The concordance correlation coefficient (range: -1.00 / +1.00) of the inter-examiner variability was 0.47 (entry point) and 0.72 (angular deviation), and 0.72 and 0.95 for the intra-examiner variability. If we express the inter-examiner variability in absolute values, it gives the following deviation for each investigator; at the entry point (mean 1.31 mm(SD 0.74) and 2.02 mm (SD 1.04)) and angular deviation (mean 3.48° (SD 2.27) and 3.86° (SD 2.55)).

Discussion

The data from the present study are comparable with other clinical studies on mucosa or bone-supported stereolithographic guides in fully edentulous jaws (D'Haese et al. 2012, Pettersson et al. 2010). If we compare the data from the test groups with the results of a recent systematic review (Van Assche et al. 2012), taken into account the data from the in vivo studies, results are also comparable (mean deviation at the entry (1.0 mm, range: 0.01 to 6.5); at the apex (1.4 mm, range: 0.0 to 6.9) and mean angular deviation (4.2°, range: 0.04° to 24.9°)).
In this review the type of support was also analyzed and a significant difference was found for bone versus mucosa-supported templates, however in this study we could not confirm these differences.

Since this is, upon the knowledge of the authors, the first RCT comparing different guiding systems, no comparable data are available. For the Materialise Universal® group there was no physical stop during drilling, this must be checked at all times visually and the implant was placed without guidance. For the Facilitate™group there was a physical stop on the drills and the implant insertion was guided by the fixture mount that closely fitted the sleeve. Based on these differences in product handling, one could assume that the Facilitate™group would be more precise, however in this study we could not confirm this hypothesis.

This study is the first to assess the reliability of the validation technique for determination of the precision. The intra-examiner variability scores showed great consistency within data processed by the same examiner. However the process is not fully computerized and manual adaptations are necessary, which is consistent with the lower scores for the inter-examiner variability. Vasak and co-authors (Vasak et al. 2013) evaluated three different validation procedures, comparing a system-independent validation procedure with two brand software systems and found similar deviations. One can conclude that the current validation procedures are reliable but one has to take into account that the procedure by itself if not being applied by one examiner, can also be a source for inaccuracy.
Several factors can contribute to higher deviations. In this study the preoperative planning was performed via multislice computed tomography (MSCT), because the initial protocol demanded the measurement of Hounsfiled Units (which is not possible with CBCT), and therefore a dose-reduced protocol was applied (Jacobs & Quirynen 2014). Nowadays this could also be performed with cone beam computed tomography (CBCT)(Loubele et al. 2009, Pauwels et al. 2012), the latter offering imaging at a relatively lower dose when compared to conventional medical CT and relatively

lower costs. Poeschl and co-workers (Poeschl et al. 2013) compared the accuracy of MSCT and CBCT for its use in image guided surgery in an in vitro model study and found no statically significant difference. Arisan and co-workers (Arisan et al. 2012) compared the accuracy of MSCT and CBCT in a clinical study and found similar deviation values. Based on this knowledge, we can conclude, If we would conduct this study today again, we would use a pre-operative as well as a postoperative CBCT to reduce the radiation exposure for the patients as much as possible.

In the present study special care was taken to exclude motion artifacts from patient movement (Dreiseidler et al. 2009, Petterson et al. 2010) and to obtain a correct positioning of the scan prosthesis. Therefore an index was used to position and stabilize the template in the mouth of the patient during the scanning process (Vercruyssen et al. 2014a). Optimal fit of the scan prosthesis with the patient's soft tissue was checked by controlling whether air was visible between scan prosthesis and soft tissues. If this was the case a new CT was taken, after obtaining oral consent of the patient, to continue with the study protocol.

The production of the surgical guide can be subdivided in two main approaches: stereolithography and laboratory production (for the latter the scan prosthesis is transferred into a surgical guide) (Vercruyssen et al. 2014a). The overall deviation in the production process of a stereolithographic guide is less than 0.25 mm (Santler et al. 1998a, Santler et al. 1998b).

The positioning and stabilization of the surgical template can also influence the inaccuracy. In this study a single guide was used, which was fixated with three to four pins, equally distributed to increase the stability of the guide. In a clinical study using consecutive guides for increasing diameter drills, it was observed that the consecutive bone-supported guides frequently shifted spontaneously away from the alveolar bone during drilling, because the guides were not fixated (Arisan et al. 2010a). This was especially seen in dense bone areas with a thin alveolar crest. One publication (D'Haese et al. 2012) evaluated the inter implant deviation within a patient, to see whether the deviation is related to malpositioning of either the surgical guide, or to individual implants. The authors suggested that the inaccuracy is mainly determined by the mispositioning of the surgical guide.

The tolerance of the drills within the drill guide and/or keys, as reported in two in vitro studies, (Koop et al. 2012, van Assche & Quirynen 2010) underlines the importance of the correct position of the drill within the guide. The maximal deviation of the drill within the surgical guide can reach a maximum horizontal deviation of 1.3 mm at the implant shoulder and 2.4 mm at the apex for a 13 mm implant. A maximum deviation in angulation of 5.2° is observed (Koop et al. 2012). The latter is specific for each guiding system. This could also explain the larger deviation of the implants in the upper jaw at the left side which was observed in the present study, because the surgeon was right-handed. Data on this phenomena are limited. But there are of course other explanations for this deviation. Horwitz and co-workers (Horwitz et al. 2009) observed that attrition of sleeves and drills, after longer use, are a contributing factor.

In the present study no influence of implant length on accuracy could be detected, in any of the treatment groups. However one study (D'Haese et al. 2012) found significant larger apical deviations for long implants compared to short ones. Di Giacomo and co-workers (Di Giacomo et al. 2012) as well as Vasak and co-workers (Vasak et al. 2011) found significant lower deviations for anterior implants compared to posterior ones. These results are consistent with the data from the present study, where in the upper jaw larger deviations were observed in the posterior region.

D'Haese & De Bruyn (2011) stated that differences in mucosal resilience between a smoking and a nonsmoking patient could lead to an alteration in the degrees of freedom when positioning a scanning prosthesis or

a surgical guide. In the present study no influence of smoking on accuracy was detected. Other clinical studies did find an effect of smoking (Cassetta et al. 2012, D'Haese & De Bruyn 2011). The literature is not consistent on whether a learning curve is important, one clinical trial observed a learning curve (Vasak et al. 2011), while 2 other studies, like the present study, did not (Valente et al. 2009, Cassetta et al. 2011).

In the present study a larger deviation was observed in the lower jaw. There is an inconsistency in the observations comparing the data for the maxilla with the mandible. Some publications reported no differences (Arisan et al. 2010b, Behneke et al. 2012, Di Giacomo et al. 2012, Ersoy et al. 2008),while others observed less deviation for the mandible (Vasak et al. 2011, Pettersson et al. 2010).

Conclusion

Inaccuracy of guided surgery (mean deviation at the entry point (1.4 mm, range: 0.3-3.7); at the apex (1.6 mm, r: 0.2-3.7); angular deviation (3.0°,range: 0.2-16°)) is clearly less than for non-guided surgery (2.8 mm, range: 0.3- 8.3; 3.1 mm, range: 0.3-7.5 and 9.1°, range: 0.6-27.8)). Based on these findings one can conclude that guided surgery has an added value, but at each step awareness for possible errors in deviation is crucial for treatment success.

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Depth and lateral deviations in guided implant surgery. 3

An RCT comparing guided surgery with mental navigation *or the use of a pilot-drill template.*

Abstract

Aim: To assess the accuracy of guided surgery compared to mental navigation or the use of a pilot-drill template in fully edentulous patients.

Material and Methods: Sixty consecutive patients (72 jaws), requiring four to six implants (maxilla or mandible), were randomly assigned to one of the following treatment modalities: Materialise Universal® mucosa, Materialise Universal® bone, Facilitate™mucosa, Facilitate™bone, mental navigation, or a pilot-drill template. Accuracy was assessed by matching the planning CT with a postoperative CBCT. Deviations were registered in a vertical (depth) and horizontal (lateral) plane. The latter further subdivided in BL (bucco-lingual) and MD (mesio-distal) deviations.

Results: The overall mean vertical deviation for the guided surgery groups was 0.9 mm ± 0.8 (range: 0.0 to 3.7) and 0.9 mm ± 0.6 (range: 0.0 to 2.9) in a horizontal direction. For the non-guided groups this was 1.7 mm ± 1.3 (range: 0.0 to 6.4) and 2.1 mm ± 1.4 (range 0.0 to 8.5), respectively ($p<0.05$). The overall mean deviation for the guided surgery groups in MD direction was 0.6 mm ± 0.5 (range: 0.0 to 2.5) and 0.5 mm ± 0.5 (range: 0.0 to 2.9) in BL direction. For the non-guided groups this was 1.8 mm ± 1.4 (range: 0.0 to 8.3) and 0.7 mm ± 0.6 (range 0.0 to 2.9), respectively. The deviation in MD direction was significantly higher in the non-guided groups ($p=0.0002$).

Conclusion: The most important inaccuracy with guided surgery is in vertical direction (depth). The inaccuracy in MD or BL direction is clearly less. For non-guided surgery the inaccuracy is significantly higher.

Introduction

Between static surgical guiding systems for implant placement, significant variations in product handling can be observed (Van Assche et al. 2012, Vercruyssen et al. 2008, Vercruyssen et al. 2014c). Some use different templates for one patient with sleeves with increasing diameter while others use removable sleeves in one single template with removable sleeve inserts or sleeve on drills (Koop et al. 2012, Vercruyssen et al. 2014b).

The accuracy of the entire procedure is defined as the deviation between the position of the implant post-operatively and of the implant in the planning. The comparison between both positions is the summation of all individual errors. In vivo data from a recent systematic review (Van Assche et al. 2012) revealed a mean deviation at the entry of 1.0 mm (range: 0.01-6.5); at the apex of 1.4 mm (range: 0.0-6.9) and a mean angular deviation of 4.2° (range: 0.04°- 24.9°). Apart from the presumed benefits of a more rapid procedure and decreased postoperative patient discomfort (Hultin et al. 2012), there remains a residual risk associated with blind implant placement. Critical anatomical structures, such as the mandibular or mental nerve, must be avoided at any cost to prevent neurological complications (Jacobs et al. 2002, Bou Serhal et al. 2002, Mraiwa et al. 2004). In order to avoid these anatomical structures it is important to know the deviation in depth and in mesio-distal direction. In cases of limited bone volume the buco-lingual deviation is crucial. Therefore it is important to have sufficient knowledge about the amount of deviation in all dimensions associated with static guided implant surgery.

The development of new software has made it possible to determine exactly these crucial deviations. The aim of the present study is to report on deviation in a vertical (depth) and horizontal (lateral) plane, the latter further subdivided in BL (bucco-lingual) and MD (mesio-distal) direction, for the following treatment groups:
the Materialise Universal® system (mucosa or bone supported) and the Facilitate™system (mucosa or bone supported) and to compare both to mental navigation or to the use of a pilot-drill template. The accuracy is assessed by comparing pre- and postoperative (CB) CT (matching). To our knowledge only few current papers on implant accuracy have reported on depth and lateral deviations and one research group so far has reported on inaccuracies in mesio-distal or bucco-lingual direction (Verhamme et al. 2011, 2013). For this study, the population used in a previous paper (Vercruyssen et al. 2014 a) was reexamined.

Material and methods

• Patients

Sixty consecutive patients (72 jaws, mean age=58, 29 males, 31 females, seven smokers) with sufficient bone volume to place four to six implants in the edentulous lower (n=33) or upper jaw (n=39), were randomly assigned to one the of the following treatment groups: Materialise Universal®/ mucosa (Mat Mu), Materialise Universal®/ bone (Mat Bo), Facilitate™/ mucosa (Fac Mu), Facilitate™/ bone (Fac Bo), mental navigation (Mental) and a pilot-drill template (Templ). In the mucosa-supported treatment groups, patients are treated with a flapless approach and in the bone-supported and non-guided groups a full thickness flap was elevated. For allocation a computerized random number generator was used. Patients who entered the study twice, for treatment in the upper and lower jaw, were also assigned twice to an intervention group. For inclusion in the study subjects had to fulfill all of the inclusion and exclusion criteria. For more details see Chapter II. The study was approved by the ethical committee of the KU Leuven University Hospital (B32220095376).

• Planning procedure

A scan prosthesis containing eight small gutta markers (Obtura II®, Obtura Corporation, Fenton, MO, USA) and a bite index in putty material (SheraExact®85, Shera GmbH & Co., Lemförde, Germany) were prepared at the prosthetic department of the KU Leuven University Hospital. A MSCT scan (Somatom Definition Flash®, Siemens, Erlangen Germany, at 120 kV and 90 mAs) was taken with the scan prosthesis and index positioned in the mouth. A second scan was made of the prosthesis alone, with altered exposure parameters to visualize, besides the feducials (gutta markers), also the entire denture (Verstreken et al. 1996a). A MSCT with a dose-reduced protocol was used because the initial protocol demanded the measurement of Hounsfield Units (which is not possible with CBCT) (Jacobs & Quirynen 2014). Both sets of dicom images were imported in Simplant® software (Materialise Dental, Leuven, Belgium). The implants were planned in the most optimal position towards both the jawbone and the future prosthetic reconstruction (Verstreken 1996b, Verstreken 1998). For all patients with guided surgery, the planning was transferred to the manufacture (Materialise Dental) for the creation of a stereolithographic drill guide. For the patients from the mental navigation group, the scanning and planning was similar, but no guide was used. For the pilot-drill template group the scan prosthesis was prepared in Barium Sulphate and the patient was scanned with a single scan. This scan prosthesis was then transformed into a surgical template by drilling holes at the planned implant positions.

• Surgical protocol

Surgery was performed under local anesthesia at the periodontal department of the KU Leuven University Hospital. In case of mucosal support (flapless approach) a punch-technique was applied or a small crestal incision was used to expose the bone. Afterwards the stereolithographic guide was positioned and fixed on the mucosa using a bite index to secure the correct position. In the bone supported treatment group, a mid-crestal incision and three vertical releasing incisions were used, two at the distal margins and one in the midline. Subsequently a full thickness flap was elevated buccally and lingually exposing the bone surface in an extensive way to prevent any interference with the guide. The guide was then positioned on the bone and fixed with ≥ three fixation pins. The drilling was conducted according to the manufacturer's instructions.
In the Materialise Universal® group drilling and implant placement was done without depth control and without guidance during implant placement. In the Facilitate™group drilling and implant placement is performed with depth control (physical stops) and specially designed tubes (with varying lengths) are fixed on top of the implants to guide the implants.
In the non-guided groups a mid-crestal incision with one or two vertical releasing incisions were applied.
In the mental group the drilling procedure was performed in the conventional way, but extra attention was paid to

place the implants conform
the planning in the software (mental navigation).
For the template group a surgical stent was used to indicate the implant position with the pilot drill, the stent was then removed and further drilling was conducted in a conventional way. Three hundred fourteen ASTRA TECH Implant System OsseoSpeed™implants (DENTSPLY Implants, Mölndal, Sweden) with diameter 3.5 or 4 mm, and lengths ranging from 8-15 mm were inserted.

• Validation of the technique

Ten days after implant placement a CBCT scan (Scanora® 3D, Soredex, Tuusula, Finland) was taken (at 85 kV and 6 mA, voxel size 250 µm) to check the final position of the implants. The postoperative positions were matched to the preoperative planning using the Mimics® software (Materialise Dental, Leuven, Belgium) and several inaccuracy parameters were defined. This process was based on surface registration via minimization of distances between both pre and post-operative jaw bone models. An iterative closest point (ICP) algorithm was used to match the jaws.

The global deviation is defined as the 3D distance between the coronal centers of the planned and placed implants. Depth deviation is the distance between coronal center of the longitudinal axis of the planned implant and a plane parallel through the coronal center of the placed implant. Moreover a reference plane was set in bucco-lingual direction by which both the mesio-distal and bucco-lingual deviation could be calculated *(Figure 1)*.

The enrolment, assignment of the patients, the implant planning and the surgery were all performed by one and the same research clinician (MV). The assessment of the accuracy was performed by another researcher, who was blinded for the intervention *(see Chapter II)*.

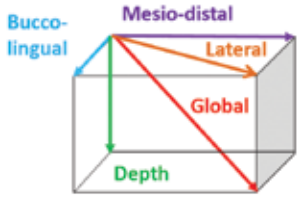

Fig. 1 *Three dimensions of direction. Red: global coronal deviation, orange: lateral deviation, green: depth deviation, blue: bucco-lingual deviation, purple: mesio-distal deviation.*

Statistical analysis

The outcome variables were analyzed with a linear mixed model taking treatment as a fixed factor and patient as a random factor. Residual dot plots and normal quantile plots were used to assess the assumptions of the model. Contrasts were built to test the specific hypotheses and a correction for simultaneous hypothesis testing was made according to Sidak (Šidák 1967). The level of significance was set at $\alpha = 0.05$. For the determination of the sample size, the following calculation was made. An expected standard deviation of 0.8 to 0.9 mm and an expected difference between treatments of a mean coronal deviation of 1mm resulted in a sample size of 11 (SD=0.8) to 13 (SD=0.9), needed to obtain a power of 80% with a significance level of 5%'As no prior data about the magnitude of the dependence were available, we assumed no dependence for the power analysis. Normality of data was assumed, and confirmed via normal quantile plots of residuals of the linear mixed model. The final sample size was the average of the two calculated sample sizes, which resulted in 12 patients (jaws) for each treatment group.

Results

All patients received their implant treatment between August 2009 and June 2012. No patients were lost to follow-up before the second scan was taken. In each group, 12 patients were enrolled. Three implants from the Facilitate™bone group were excluded from the analysis because of following reasons; one patient had a limited mouth opening and the two most distal implants could not be placed with the guide, in another patient a shorter implant was placed than foreseen in the planning. So a total of 311 implants were analyzed, 51 to 55 per group. Patient and implant demographics can be found in Chapter II. In *table 1* the inaccuracy in vertical (depth) and in horizontal (lateral) direction is presented, the latter further subdivided in mesio-distal and bucco-lingual direction. The box plots illustrating the differences between techniques are shown in *Figure 2-5*. In vertical direction (depth) significant differences were found between the guided surgery groups and the template

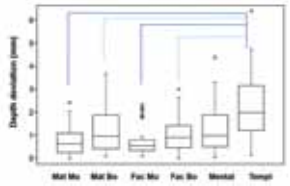

Fig. 2 *Box plot of the depth deviation at the entry point. Significant differences between treatment groups are indicated with p-values; full line ≤0.001, dotted line ≤0.05.*

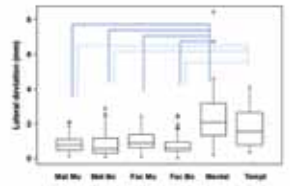

Fig. 3 *Box plot of the lateral deviation at the entry point. P-values are presented as followed; full line ≤0.001, dotted line ≤0.05.*

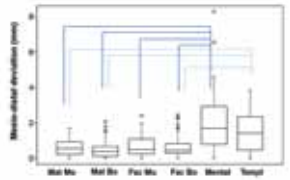

Fig. 4 *Box plot of the mesio-distal deviation at the entry point. P-values are presented as followed; full line ≤0.001, dotted line ≤0.05.*

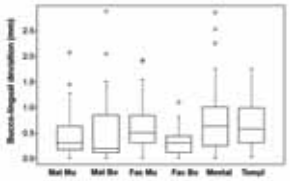

Fig. 5 *Box plot of the bucco-lingual deviation at the entry point. No statistically differences were found.*

group ($p \leq 0.05$), with the latter showing double the inaccuracy (2.2 mm versus a mean of 0.9 mm respectively). In horizontal direction significant differences were found for the global lateral and the mesio-distal deviations between the guided surgery and both the non-guided groups ($p \leq 0.05$). In the non-guided group the inaccuracy was around double the amount seen in the guided groups. In bucco-lingual direction no differences were found, although the non-guided groups again showed more inaccuracy. No statistical differences between bone and mucosa supported guidance or type of guidance (system) were noted. Furthermore a significant difference in direction of lateral deviation was found in the non-guided groups (larger deviation in mesio-distal, than in bucco-lingual sense, $p \leq 0.001$), but not in the guided groups. In *table 2* the maximum and minimum negative and positive values are presented of the deviation in depth, mesio-distal and bucco-lingual direction.

Discussion

In this study the overall mean depth deviation for the guided surgery groups was 0.9 mm ± 0.8 (range: 0.0 to 3.7). In vertical direction the depth ranged from -2.4 to 3.7. These data are comparable with data from a recent systematic review (range from -2.3 to 4.2 mm) (Van Assche et al. 2012). All the stereolithographic guides were fixed to the underlying bone by three to four anchor pins, equally distributed in the jaw. The drilling procedure involved the use of drill keys inserted in the sleeves within the guide, which guide the consecutive drills with different diameters in the correct position and angulation. For the Materialise Universal® group there was no physical stop during drilling. This depth had to be checked visually at all times, and the implant was placed without guidance. For the Facilitate™system there was a physical stop on the drills and the implant insertion was guided by a fixture mount that closely fitted the sleeve. Although statistically not significant, the box plot illustrates less deviation in depth for the Fac Mu group compared to the Mat Mu group and for the Fac Bo versus Mat Bo group, which is consistent with the above mentioned technical difference between systems.

In the non-guided groups implants were placed more coronal than planned. This could indicate that considering the bone volume in the planning software, implants were placed more apical, than one would do judging the bone volume in the clinical situation. So based on the software planning an underestimation of the available bone volume was made. When comparing the mucosa supported with the bone supported groups, implants in the mucosa supported groups were placed more apically (deeper) than planned. This could indicate a compression of the mucosal tissues, when fixing the guide.

In this study the overall mean lateral deviation for the guided surgery groups was 0.9 mm ± 0.6 (range: 0.0-2.9). The lateral deviation was not included in the systematic review by Van Assche et al. (2012). Cassetta et al. (2011) reported on lateral and depth deviations. In this study a heterogenic group was treated, partial and full edentulism, fixed and non-fixed surgical guides, mucosa, bone and teeth supported, which makes a comparison difficult. However, data for lateral deviation (mean 1.2 mm, range 0.1-2.6) are comparable with the present study. In the Mental group there is one out-layer with a large lateral deviation of 8.5 mm, mostly in mesio-distal direction (8.3 mm). In the planning software the implant was planned before the medial wall of the sinus and tilted to the distal to maximize the inter-implant distance. In free-handed surgery it was locates too mesially, with insufficient tilting.

The overall mean deviation for the guided surgery groups of the present study in mesio-distal direction for the lower jaw was 0.6 mm ± 0.6 (range: 0.0 to 2.5), and 0.6 mm ± 0.5 (range: 0.0 to 2.3) for the upper jaw. In bucco-lingual direction the mean deviation for the lower jaw was 0.4 ± 0.3 (range: 0.0 to 1.4) versus 0.6 mm ± 0.5 (range 0.0 to 2.9) for the upper jaw. In a clinical study of Verhamme and co-workers (2013) detailed measurments in bucco-lingual and mesio-distal direction were also performed in fully edentulous patients requiring two to four implants in the upper jaw. They found a mean implant deviation bucco-lingually of 0.5 mm (max. 2.3) and mesio-distally of 0.6 (max. 2.2). These data are comparable with the data

of the present study. *Table 2* provides an indication of the sense (positive and negative values) of the deviation in mesio-distal and bucco-lingual direction for the upper and lower jaw. For the guided surgery groups, it ranged in the lower jaw from -2.5 to 2.4 mm in mesio-distal and from -1.4 to 1.3 mm in bucco-lingual direction, for the upper jaw it ranged from -2.3 to 0.8 mm and from -2.1 to 2.9 mm respectively. For the guided surgery groups there was no difference between the amount of deviation in bucco-lingual or mesio-distal sense, for the non-guided groups however there was significantly more deviation in mesio-distal than in bucco-lingual direction, and this was also significantly more than for the guided surgery groups. This could indicate that with guided surgery a more accurate "tooth position" could be achieved, which is considered important for future restorative rehabilitation.

Future research should further focus on determining the deviation in all dimensions, as such to allow clinical comparisons with other available static guided surgery systems. This is an important issue, considering that large variations in product handling between the different systems may occur.

Conclusion

The overall mean depth deviation for the guided surgery groups was 0.9 mm ± 0.8 (range: 0.0 to 3.7) and 0.9 mm ± 0.6 (range: 0.0 to 2.9) for the lateral deviation. In MD direction this was 0.6 mm ± 0.5 (range: 0.0 to 2.5) and 0.5 mm ± 0.5 (range: 0.0 to 2.9) in BL direction. The most important inaccuracy with guided surgery is in vertical direction (depth). Horizontal inaccuracies are clearly less. For non-guided surgery the inaccuracies are significantly higher in all directions.

		MatMu	MatBo	FacMu	FacBo	Mental	Templ
PATIENTS (N)		12	12	12	12	12	12
Implants (n)		55	53	52	49	51	51
Depth (mm)	Mean	0.74	1.18	0.74	1.00	1.25	2.20
	Median	0.63	0.97	0.55	0.91	0.96	1.99
	SD	0.57	0.94	0.65	0.69	0.95	1.44
	Min.	0.004	0.08	0.08	0.02	0.03	0.12
	Max.	2.42	3.65	2.32	3.00	4.38	6.40
	Mean	0.88	0.83	1.04	0.80	2.34	1.77
	Median	0.78	0.55	0.90	0.59	2.10	1.56
	SD	0.50	0.67	0.55	0.61	1.57	1.03
	Min.	0.09	0.08	0.08	0.03	0.20	0.35
	Max.	2.10	2.88	2.46	2.49	8.45	4.11
LATERAL (MM)	*Mean*	*0.61*	*0.54*	*0.69*	*0.68*	*2.06*	*1.49*
	Median	*0.57*	*0.38*	*0.51*	*0.46*	*1.69*	*1.42*
	SD	*0.48*	*0.5*	*0.56*	*0.62*	*1.64*	*1.12*
	Min.	*0.02*	*0.01*	*0.03*	*0.001*	*0.03*	*0.004*
	Max.	*1.69*	*2.07*	*2.41*	*2.45*	*8.29*	*3.79*
MD	*Mean*	*0.47*	*0.50*	*0.59*	*0.31*	*0.76*	*0.71*
	Median	*0.32*	*0.19*	*0.50*	*0.31*	*0.64*	*0.58*
	SD	*0.45*	*0.59*	*0.47*	*0.22*	*0.67*	*0.47*
	Min.	*0.01*	*0.01*	*0.01*	*0.01*	*0.004*	*0.03*
	Max.	*2.08*	*2.88*	*1.92*	*1.10*	*2.86*	*1.76*
	Max.	*1.69*	*2.07*	*2.41*	*2.45*	*8.29*	*3.79*
BL	*Mean*	*0.47*	*0.50*	*0.59*	*0.31*	*0.76*	*0.71*
	Median	*0.32*	*0.19*	*0.50*	*0.31*	*0.64*	*0.58*
	SD	*0.45*	*0.59*	*0.47*	*0.22*	*0.67*	*0.47*
	Min.	*0.01*	*0.01*	*0.01*	*0.01*	*0.004*	*0.03*
	Max.	*2.08*	*2.88*	*1.92*	*1.10*	*2.86*	*1.76*

Table 1 *Number of patients and implants analyzed per group. Descriptive statistics of depth, lateral, bucco-lingual and mesio-distal deviations for the different groups at the entry point of the implant (mm). Abbreviations: n= number,SD= standard deviation, Min. =Minimum, Max.= Maximum.*

		MatMu	MatBo	FacMu	FacBo	Mental	Sguide
DEPTH	Min.	-2.42	-0.66	-2.32	-1.89	*-4.38*	*-3.10*
	Max.	1.93	3.65	2.17	3.00	*3.30*	*6.40*
MD (mm)							
LJ	Mean	0.65	0.27	0.77	0.72	*1.72*	*1.27*
	SD.	0.52	0.21	0.70	0.65	*1.11*	*1.02*
	Min.	-1.69	-0.17	-1.58	-2.45	*-4.23*	*-3.22*
	Max.	1.37	0.76	2.42	0.35	*4.60*	*2.51*
UJ	Mean	0.57	0.64	0.65	0.65	*2.90*	*1.58*
	SD.	0.43	0.54	0.48	0.61	*2.33*	*1.16*
	Min.	-1.66	-2.07	-1.66	-2.32	*-8.29*	*-3.79*
	Max.	0.75	1.81	1.36	0.82	*4.58*	*3.29*
BL (mm)							
LJ	*Mean*	*0.40*	*0.12*	*0.52*	*0.28*	*0.70*	*0.71*
	SD.	*0.32*	*0.11*	*0.38*	*0.23*	*0.68*	*0.52*
	Min.	*-0.95*	*-0.30*	*-1.36*	*-0.50*	*-1.32*	*-1.55*
	Max.	*1.29*	*0.38*	*0.94*	*1.10*	*2.86*	*0.97*
UJ	*Mean*	*0.55*	*0.64*	*0.64*	*0.33*	*0.92*	*0.70*
	SD.	*0.57*	*0.64*	*0.52*	*0.21*	*0.65*	*0.46*
	Min.	*-2.08*	*-0.92*	*-1.92*	*-0.81*	*-0.40*	*-0.56*
	Max.	*0.99*	*2.88*	*1.11*	*0.67*	*2.25*	*1.76*

Table 2 *Descriptive statistics (maximum and minimum positive and negative values) of the depth, bucco-lingual and mesio-distal deviation presented in the upper and lower jaw (mean and SD of the absolute values are presented in italic), for the different groups at the entry point of the implant (mm). Depth: - placed deeper than planned/+ placed more occlusal than planned. Buco-lingual (BL): - placed more lingual than planned/+ placed more buccal than planned. Mesio-distal (MD): Maxilla: - placed more to the right than planned/+ placed more to the left than planned, Mandible: - placed more to the left than planned/ + placed more to the right than planned. Abbreviations: SD= standard deviation, Min. =Minimum, Max.= Maximum, LJ= lower Jaw, UJ= Upper Jaw.*

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An RCT comparing patient-centered outcome variables of guided surgery 4

with conventional implant placement.

(bone or mucosa supported)

Abstract

Aim: To assess in a randomized study the patient-centered outcome of two guided surgery systems (mucosa or bone supported) compared to conventional implant placement, in fully edentulous patients.

Material and Methods: Sixty patients (72 jaws) with edentulous maxillas and/ or mandibles, were consecutively recruited and randomly assigned to one of the treatment groups. Outcome measures were the Dutch version of the McGill Pain Questionnaire (MPQ-DLV), the Health-related quality of life instrument (HRQOL), visual analogue scales (VAS), the duration of the procedure, and the analgesic doses taken each day.

Results: Three hundred fourteen implants were placed successfully. No statistical differences could be shown between treatment groups on pain response (MPQ-DLV), treatment perception (VAS) or number or kind of pain killers. For the HRQOLI-instrument a significant difference was found between the Materialise Mucosa and Materialise Bone group at day 1 (p= 0.02) and day 2 (p= 0.01). For the duration of the surgery a statistical difference (p=0.005) was found between the Materialise mucosa and the Mental group, in favor of the first.

Conclusion: In this study little difference could be found in the patient outcome variables of the different treatment groups. However there was a tendency for patients treated with conventional flapped implant placement to experience the pain for a longer period of time.

Introduction

Implant dentistry is rapidly evolving with considerable emphasis on predictable treatment planning with maximum patient comfort and minimal patient morbidity (Lindeboom & van Wijk 2010, Vercruyssen et al. 2014b). Patient self-assessment indicated that implant placement is a mild to moderately painful and anxiety-provoking procedure (Hashem et al. 2006, Eli et al. 2003).

A recent systematic review (Hultin et al. 2012) reported on the clinical advantages of guided surgery. They found three studies comparing patient centered outcomes of guided flapless surgery with conventional open flap surgery (Arisan et al. 2010, Fortin et al. 2006, Nkenke et al. 2007). These studies demonstrated a statistically significant reduction in immediate postoperative pain, use of analgesics, swelling, edema, hematoma, hemorrhage and trismus for flapless surgery. One of these studies (Arisan et al. 2010) also compared guided flapless with guided non-flapless surgery and demonstrated consistently better outcome for the flapless approach. These results are sustained by the good scores for patient comfort and satisfaction reported by several observational studies on guided flapless surgery (Abad-Gallegos et al. 2011, Nikzad & Azari 2010, van Steenberghe et al. 2005).
A prolonged oral surgical intervention may increase postoperative pain and discomfort for the patient (Sato et al. 2009). One of these controlled studies investigated the time factor and found that the duration of the treatment with flapless guided surgery was less than half compared to open flap guided surgery and/or conventional surgery (Arisan et al. 2010).
A recent clinical study (Arisan et al. 2013) reported on another possible clinical advantage of a reduced surgical intervention time in flapless surgery. They investigated the effect of bacteremia with relation to conventional and computer-assisted flapless implant surgery and found that flapless implant placement reduces the incidence of surgery-related bacteremia. Thus, the time factor may be indeed an important factor in reducing the patient morbidity.

Different methods to determine the postoperative discomfort and the quality of life have been described: the Gracely scale (Gracely & Dubner 1987, Gracely & Kwilosz 1988), OHIP-49 (Slade & Spencer 1994), the Dental Anxiety Inventory (Stouthard et al. 1995), DIDL (Leao & Sheiham 1996), HRQOL-instrument (Shugars et al. 1996), OHIP-14 (Slade 1997) OIDP (Adulyanon et al. 1997),
The Minor Oral Surgery Outcome scale (Goodey et al. 2000), OHQoL-UK-16 items (McGrath & Bedi 2001), VAS (Eli et al. 2003), and the Impact of Event Scale-revised (IES-R)(Creamer et al. 2003).

The aim of the present study was to assess the patient-centered outcome of guided surgery and to compare these variables to non-guided surgery.

Material and methods

• Patients

Sixty consecutive patients (72 jaws, mean age=58, 29 males, 31 females, seven smokers) with sufficient bone volume to place four to six implants in the edentulous lower (n=33) or upper jaw (n=39), were consecutively recruited and randomly assigned to one the of the following treatment groups; Materialise Universal®/ mucosa (Mat Mu), Materialise Universal®/ bone (Mat Bo), Facilitate™/ mucosa (Fac Mu), Facilitate™/ bone (Fac Bo), mental navigation (Mental) and a pilot-drill template (Templ). In the mucosa-supported treatment groups, patients are treated with a flapless approach and in the bone-supported and control groups a full thickness flap was elevated. For inclusion in the study subjects had to fulfill all inclusion and exclusion criteria (see chapter II, Vercruyssen et al. 2014a).
The study was approved by the ethical committee of the KU Leuven University Hospital *(B32220095376)*.

• Preoperative procedure

A scan prosthesis was prepared containing all information for future prosthetic restoration at the prosthodontic department of the University Hospital KU Leuven. A MSCT scan (Somatom Definition Flash®, Siemens, Erlangen Germany, at 120 kV and 90 mAs) was performed of the patient with the scan prosthesis and index positioned in the mouth.
A MSCT was used because the initial protocol demanded the measurement of Hounsfiled Units (which is not possible with CBCT), and therefore a dose-reduced protocol was applied (Jacobs & Quirynen 2014). The implants were planned in the most optimal position towards both the jawbone and the prosthetic demands (Verstreken et al. 1996). For all patients with guided surgery, the planning was transferred to the manufacture (Materialise Dental) for fabrication of a stereolithographic drill guide. For the patients from the mental navigation group, the scanning and planning was similar, but no guide was used. For the pilot-drill template group the scanprosthesis was prepared in bariumsulphate and the patient was scanned with a single scan. This scan prosthesis was then transformed into a surgical template by drilling holes at the planned implant positions.

• Surgical protocol

Surgery was performed under local anesthesia at the periodontal department of the University Hospital KU Leuven. In case of mucosa support (flapless approach) a punch-technique is applied or a small crestal incision is performed to expose the bone in a minimal way. Afterwards the stereolithographic guide was positioned and fixated on the mucosa using a bite index to secure the correct position. In the bone supported treatment group a midcrestal incision and three vertical releasing incisions were performed. Two releasing incisions in the distal margins of the incision and one in the labial midline. Subsequently a full thickness flap was elevated buccaly and lingually exposing the bone surface in an extensive way to prevent any interference with the guide. The guide was than positioned on the bone and fixated with minimal three fixation pins. The drilling was performed using sequential drills with increasing diameter, and removable sleeves in the drill template according to the manufacturer's instructions.
In the Materialise Universal® group drilling and implant placement is performed without depth control (or guidance in the case of implant placement), this has to be checked at all times by the surgeon.
In the Facilitate™group drilling and implant placement is performed with depth control (physical stops) and specially designed tubes (with varying lengths) are fixed on top of the implants to guide the implants.
In the control groups a mid-crestal incision with one or two vertical releasing incisions were performed according to the visibility. In the mental group the drilling procedure was performed in the conventional way, but extra attention was paid to place the implants conform the planning in the software (mental navigation). For the template group a surgical stent was used to indicate the implant position with the pilot drill, the stent was then removed and further drilling was performed in the conventional way. Three hundred fourteen ASTRA TECH Implant System OsseoSpeed™implants (DENTSPLY Implants, Mölndal, Sweden) with diameter 3.5 or 4 mm, and lengths ranging from 8-15 mm were inserted. All patients received analgesics (Paracetamol 500mg, three times per day), antibiotics (Amoxycilline 500mg, three times per day) for

5 days, and 0.12 % chlorhexidine twice a day for 1 week. The duration of the procedure (in minutes) was filled out in the study forms after the surgery. Ten days after the implant procedure patients returned for an evaluation. The enrolment, assignment of the patients, the implant planning and the surgery were all performed by the same investigator (MV).

• Questionnaires

To assess postoperative pain, the Dutch version of the McGill Pain Questionnaire (MPQ-DLV) was used (Melzack 1975, Melzack 2005, Wilkie et al. 1990). The reliability and the validity of the MPQ-DLV has been confirmed in various publications (Vanderiet et al. 1987, van der Kloot et al. 1995, van Lankveld et al. 1992, Verkes et al. 1989). The questionnaire was handed out as a diary and patients were asked to fill in the questions every day, from day 1 until day 7. The MPQ-DLV consists of two parts. The first part of the questionnaire groups various pain descriptions according to their pain quality and ranks the descriptions of a certain quality according to their intensity. This gives two indices. The sum of the 'number of words chosen' gives the NWC-T (range 0-20). Furthermore the 'pain rating index' (PRI-T) was calculated (range 0-63), this is the sum of the intensity ranking of the chosen pain words (for example the pain adjective with lowest ranking 1, corresponds with the lowest pain intensity and a score 3-4 corresponds with the highest pain intensity). The second part consist of 100 mm VAS-scales to evaluate the amount of pain, ranging from 0 (no pain whatsoever) to 100 (worst pain imaginable) and the amount of swelling. The patients were asked to fill in the VAS-scales at the day of surgery every 4 hours and afterwards daily. Patients were asked to score their pain three times; the pain they felt at the moment of questioning, and the minimum and maximum amount of pain they felt during the past 4 or 24 hours. To assess the impact of the treatment on the quality of life, the Health-related quality of life (HRQOL) instrument was used (Shugars et al. 1996). The HRQOL consists of 15 questions concerning the quality of live. An example of one of the questions is: 'How many times during the past 24 hours you encountered difficulties to eat'. The frequency of each symptom is scored on a six-point scale, ranging from not applicable (score 0), not at all (score 1), rarely (score 2), sometimes (score 3), often (score 4) and very often (score 5). The scores are summed to yield a total HRQOL-Index (HRQOLI) score (range 0–75), with higher scores on the HRQOLI being indicative of more postoperative discomfort and inconvenience in daily life. These questions were also part of the diary, and to be filled in daily. The patients were also asked to document the number and the sort of analgesics taken each day. Furthermore patients were asked to fill in VAS-scales at the time of surgery and at the evaluation meeting after 10 days. They were asked to score the following questions; mean amount of pain during the past 24 hours, during surgery, if they would repeat the procedure in the future, if they found the duration of the procedure tolerable and if they would recommend the procedure to friends or family, ranging from 0 (maximal agreement) to 100 (maximal disagreement) (Nkenke et al. 2007).

Statistical analysis

The primary outcome variables were the NWC-T-index, the PRI-T-index, the HRQOL-instrument, the duration of the surgery, the VAS-scales and the amount of analgesic doses taken. Secondary outcome variables were the difference in patient-centered outcomes between the different treatment groups and the evolution of the patient-centered outcomes over time. The latter variables were analyzed with a linear mixed model taking treatment as a fixed factor and patient as a random factor. Residual dot plots and normal quantile plots were used to assess the assumptions of the model. Contrasts were built to test the specific hypotheses and a correction for simultaneous hypothesis testing was made according to Sidak, yielding a global significance level of 0.05 (Šidák 1967). For the allocation a computerised random number generator was used. Patients who entered the study twice, for treatment in the upper and lower jaw, were also assigned twice to an intervention group. In each group 12 patients were enrolled. Determination of the sample size was based on the accuracy assessment *(see chapter I)*. For the outcome variables from this study, a post hoc power analysis, using the N-factor was performed. The N-factor is the

percentage of data extra points needed to reach a level of significance (α= 0.05) for the currently found difference (considering that when expanding the data set, the variability of data would remain the same).

Results

All the patients received their implants between August 2009 and June 2012. No patients were lost to follow-up. In each group 12 patients were enrolled. Patient and implant demographics are shown in *Table 1*. No major adverse events were reported and no implants were lost before prosthetic rehabilitation. The descriptive statistics for the primary outcome variables are presented in *Table 2-6*. No difference between the treatment groups could be found for the NWC-T- index *(Table 2)*. Over time a significant reduction of the 'numbers of words chosen' could be found for the Mat Bo group after day 4 (p=0.002) compared with day 1, for the Mat Mu (p=0.001) and the Fac Mu (p= 0.008) group after day 5, for both the Mental (p=0.002) and the Templ group (p= 0.008) after day 7 and for the Fac Bo group no reduction was found. For the PRI-T-index the results were consistent with the above mentioned data, no difference could be found between treatment groups *(Table 2)*. Over time a significant decrease in the 'pain raiting index' could be found for the Mat Bo (p=0.003) and Fac Mu (p= 0.01) group after day 3 compared with day 1, for the Mat Mu (p=0.01) and the Mental group (p=0.03) after day 4 and for the Fac Bo and the Templ group no decrease could be detected.

For the HRQOL-instrument *(Table 3)* a significant difference was found between Mat Mu and Mat Bo at day 1 (p= 0.02) and day 2 (p= 0.01). Furthermore between the mucosa-supported versus bone-supported treatment groups (p=0.02), between the mucosa-supported versus the control groups (p= 0.0001), and between the control groups versus bone-supported treatment groups at day 1 (p=0.01). With lower post-operative discomfort for the first mentioned group. No difference was found between other individual treatment groups. Over time a significant reduction could be found for the Mat Bo and Fac Bo group after day 3 (p=0.0003), for the Fac Mu group after day 5 (p= 0.003),for the Mental (p=0.005) and Templ (p=0.004) group after day 6, while for the Mat Mu group no difference was found.

Regarding the duration of the surgery *(Table 3)* a statistical difference (p=0.005) was found between the Mat Mu group and the Mental group, with a significant shorter surgical time for the Mat Mu group. No difference could be detected between the other groups.

The VAS scores *(Table 4)* of the different treatment groups revealed also no difference between treatment groups. The evolution of the VAS-scores over time for the amount of swelling is shown in *figure 1*. For all the guided surgery groups a significant reduction in the amount of pain could be found after 6 days compared to 4 hours after surgery, while for the control groups no difference was found. Regarding the amount of swelling, a significant reduction was found for all treatment groups after 7 days. *Table 5* shows the amount of medication, taken by the patient. No difference in treatment groups was noted. Over time a significant reduction could be found for the Fac Bo (p= 0.03) and the Mental group (p= 0.04)after day 5; for the Mat Mu (p=0.001), the Mat Bo (0.01) and the Fac Mu group after day 6 (p= 0.003), while for the Templ group no difference was found. *Table 6* shows the VAS score filled in at the time of surgery and after 10 days. No difference between treatment groups or over time was revealed.

For the different outcome variables between the flapless guided surgery and the non-flapless guided surgery where no significant differences were found, a post-hoc analysis was performed, which yielded a N-factor at day 1 and day 2, of 108 and 99 for the NWC-T-index, of 275 and 66 for the PRI-T-index, of 16 and 23, 3 and 2 for the VAS-scales (pain and swelling momentarily) and 72 and 3 for the amount of analgesic doses taken. For most variables there is clinically and statistically no difference. For the amount of swelling there is a tendency for patients in the non-flapless guided surgery groups to experience more swelling.

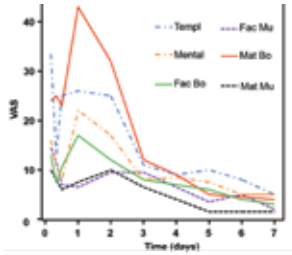

Fig. 1 *Graphic showing the evolution over time of the Vas-score of the mean amount of swelling experienced the past 24 hours.*

Discussion

In this study the postoperative discomfort for the patients in all the different treatment groups was low and that could be the explanation why little difference in postoperative outcome between the different treatment groups could be found, compared to the findings of a recent systematic review (Hultin et al. 2012).

However there are some potential shortcomings of the present study that should be discussed. In the present study all surgeries were performed by one surgeon. This could induce a surgeon-related bias because the surgeon has some "preferred" treatment process. A multi-center approach with different trained and calibrated surgeons would overcome this potential bias. Furthermore as part of the diary, the Health-related quality of life (HRQOL) instrument was used to assess the impact of the treatment on daily quality of life, but no starting conditions before surgery were recorded, inducing potential patient-related bias. In future studies, baseline records of patient condition/well-being, should be assessed before implant treatment as well to overcome this bias.

Other studies investigating the difference in postoperative discomfort between flapless surgery using an image-guided system, or a conventional open-flap procedure, indicated that with the flapless procedure, patients experienced pain less-intensely, and for shorter periods of time (Fortin et al. 2006). In the present study the McGill Pain Questionnaire (MPQ-DLV) was used for the assessment of pain. For the NWC-T index higher scores were noted after day six for the Mental, the Templ group and the Fac Bo group. Comparable PRI-T scores were noted for the Templ group and the Fac Bo group. This could indeed indicate that with guided surgery pain levels diminish more rapidly that when conventional implant placement is applied, however this seems not to be the case for bone-supported procedures.

The postoperative quality of life was measured using the HRQOLI-instrument. A significant difference was observed between Mat Mu and Mat Bo at day 1 and day 2, indicating more postoperative discomfort for the guided open flap procedure in the early days after surgery. The same was observed if we compared Mat Mu and Fac Mu verus Mat Bo and Fac Bo at day 1, at day 2 this difference was borderline significant ($p \leq 0,06$). However this was not confirmed by the data from the individuals groups of the Facilitate™system. Another study comparing flapless guided surgery with flap guided surgery could also find no difference between the two conditions (Lindeboom & van Wijk 2010). One should note however that in this particular study a flap was first raised and afterwards repositioned to place the guide on the mucosa and not on the bone, leaving the tissues unexposed during implant placement.

The duration of the surgery was reduced when a transmucosal approach (Mat Mu) was applied compared to conventional implant surgery. This observation was shared by Komiyama and coworkers (Komiyama et al. 2008) who reported that the duration of the flapless guided surgical intervention including immediate reconstruction took 30-45 minutes. However with a bone-supported guide there was little advantage in terms of operation time, because in these cases an extensive full-thickness flap had to be reflected to position the guide on the jawbone. This was also confirmed by Arisan and co-workers (Arisan et al. 2010), who found that the mean duration of the surgery with bone-supported guides was only 8 min shorter than conventional implant placement. In the present study some difference in product handling exist between the two guided implant systems. In the Facilitate™systems, extra steps have to be taken during implant placement, compared to the Materialise Universal® system. In the first mentioned system, guiding tubes are fixed in the implants, and subsequently the implants are placed with the fixture mounts. After placing the implants, these tubes have to be removed before the guided can be removed, often there is some friction when placing the implants, what made the removal of those tubes a time consuming step. This could be an explanation why no time reduction was observed in the Fac Mu group.

The amount of postoperative swelling in this trial was self-reported. In a study by Nkenke et al. (2007) the facial swelling was recorded at days 1 and 7 after surgery with an optical 3D sensor. They detected significant higher levels of swelling for the transmucosal implant placement compared with an open approach. In the present study it was noted that the amount of swelling for the non-guided groups was more prolonged than for the guided surgery approach.

Although a specific dosage of pain medication was prescribed, some patients took in a higher dose or a stronger pain medication. At day 7 most of the patients took no more painkillers. One patient in the MatMu and two patients in the MatBo group still used the prescribed amount of medication. In both the non-guided groups there were two patients who were still in need of stronger pain medications after 7 days. This would be consistent with the findings that the patients in the conventional treatment groups experienced pain for a longer period of time.

VAS-scales were completed by the patient at the time of surgery and at the evaluation meeting after 10 days. Answers to the questions were mostly positive for all treatment groups, resulting in low VAS-scores. Patients answered also very consistently, resulting in comparable scores immediately after surgery and after ten days.

Conclusion

In this study little difference could be found between the postoperative discomfort of guided surgery, flapless or non-flapless, in comparison to conventional implant placement. There was a tendency for patients treated with conventional flapped implant placement to experience the pain for a longer period of time compared to patients treated with the flapless guided approach. Although this study has some potential shortcomings, in general implant treatment seems to give little postoperative discomfort.

Treatment group	*Mat Mu*	*Mat Bo*	*Fac Mu*	*Fac Bo*	*Mental*	*Templ*
PARAMETER PATIENT LEVEL (N)						
Gender (Male/Female)	5/7	4/8	6/6	4/8	4/8	8/4
Age (Range)	38-78	31-72	46-74	43-65	39-72	40-75
Smokers	0	3	2	1	0	2
Jaw (Lower/Upper)	6/6	3/9	5/7	6/6	9/3	4/8
Prosthetic rehabilitation (Fixed/Over-denture)	7/5	3/9	2/10	8/4	6/6	4/8
Prosthetic rehabilitation (Fixed/Overdenture)	7/5	3/9	2/10	8/4	6/6	4/8
PARAMETER IMPLANT LEVEL (N)						
Total number of implants placed	55	53	52	52	51	*51*
Total number of implants lower/upper jaw	24/31	14/39	20/32	24/28	36/15	*16/35*
Number of implants placed one stage/two stage	51/4	35/18	48/4	47/5	41/10	*23/28*
Bone quality score (1/2/3/4)	8/25/22/0	6/17/30/0	4/36/12/0	8/36/8/0	12/33/1/5	*4/12/35/0*

Table 1 *Patient and implant demographics. Abbreviations: Mat Mu = Materialise Universal®/ mucosa, Mat Bo = Materialise Universal®/ bone, Fac Mu = FacilitateTM/ mucosa, Fac Bo = FacilitateTM/ bone, Mental = Mental navigation, Templ = surgical template, (n) = number.*

Treatment group	*Mat Mu*	*Mat Bo*	*Fac Mu*	*Fac Bo*	*Mental*	*Templ*
PAIN DESCRIPTION LIST (MPQ-DLV)						
NWC-T-INDEX						
Day 1	0; 2,5 (SD 4,6)	1; 4 (SD 3,8)	2; 4 (SD 3,7)	1; 3 (SD 5,1)	0; 6 (SD 4)	*1; 4 (SD 4,2)*
Day 2	0; 2 (SD 4,2)	1; 3 (SD 3,3)	0; 4 (SD 3,6)	2; 3 (SD 5,1)	0; 4 (SD 2,8	*0; 4 (SD 4,6)*
Day 3	0; 2 (SD 2.8)	0; 2 (SD 3.6)	0; 4 (SD 2.4)	1; 2 (SD 5.3)	0; 3 (SD 2.5)	*0; 3 (SD 4.9)*
Day 4	*0; 2 (SD 2,4)*	*0; 2 (SD 3,1)*	*0; 4 (SD 3,8)*	*0; 2 (SD 5,8)*	*0; 3 (SD 2,5)*	*0; 2 (SD 4,4)*
Day 5	*0; 1,5 (SD 1,7)*	*0; 1 (SD 3,9)*	*0; 3 (SD 2,2)*	*0; 2 (SD 6,5)*	*0; 3 (SD 2,5)*	*0; 2,5 (SD 3,6)*
Day 6	0; 0 (SD 2,6)	0; 1 (SD 3,5)	0; 1 (SD 2,3)	0; 2 (SD 6,5)	0; 3 (SD 2,8)	*0; 2,5 (SD 3,2)*
Day 7	*0; 0 (SD 1,5)*	*0; 1 (SD 3,1)*	*0; 1 (SD 2,5)*	*0; 2 (SD 4,4)*	*0; 2 (SD 3,3)*	*0; 2 (SD 3,2)*
PRI-T-INDEX						
Day 1	0; 3,5 (SD 7,4)	1; 5 (SD 9)	2; 5 (SD 8,3)	1; 3 (SD 10,1)	0; 7 (SD 7)	*1; 5 (SD 6,6)*
Day 2	0; 2 (SD 5,8)	1; 4 (SD 6,1)	0; 4 (SD 5,4)	2; 4 (SD 1,6)	0; 5 (SD 3,7)	*1; 4 (SD 8,4)*
Day 3	0; 2 (SD 3,3)	0; 2 (SD 5,8)	0; 4 (SD 2.9)	1; 3 (SD 7,8)	0; 4 (SD 3)	*0; 3 (SD 8,6)*
Day 4	0; 2 (SD 2,7)	0; 2 (SD 5,6)	0; 4 (SD 7,6)	0; 2 (SD 9)	0, 3,5 (SD 3,3)	*0; 3 (SD 7,5)*
Day 5	*0; 1,5 (SD 2,2)*	*0; 1 (SD 7)*	*0; 3 (SD 2,6)*	*0; 3 (SD 11,4)*	*0; 3 (SD 3,5)*	*0; 2,5 (SD 5,9)*
Day 6	*0; 0 (SD 3,8)*	*0; 1 (SD 6,1)*	*0; 1 (SD 2,7)*	*0; 2 (SD 11,7)*	*0; 3 (SD 3,5)*	*0; 2,5 (SD 5,5)*
Day 7	*0; 0 (SD 1,5)*	*0; 1 (SD 5,8)*	*0; 0 (SD 2,8)*	*0; 2 (SD 7,8)*	*0; 2,5 (SD 4,5)*	*0; 2 (SD 4,6)*

Table 2 *Descriptive statistics of the NWC-T and PRI-T-index. The NWC-T-index ranges from 0 to 20 and is indicative of the pain intensity based on the 'number of words chosen' to prescribe the pain. The PRI-T-index ranges from 0 to 63 and is the sum of the intensity ranking of the chosen pain words. Are presented: the mean, median and the standard deviation.*

Treatment group	*Mat Mu*	*Mat Bo*	*Fac Mu*	*Fac Bo*	*Mental*	*Templ*
HRQOL-INDEX						
Day 1	26.6 (SD 7,6)	43.4 (SD 10,8)	36.8 (SD 10,5)	41.8 (SD 10,7)	33.5 (SD 9,6)	*42.7 (SD 7,7)*
Day 2	23.4 (SD 5,1)	40.1 (SD 13)	29.2 (SD 10,8)	33.7 (SD 13,1)	31.7 (SD 10,1)	*38.7 (SD 8,4)*
Day 3	21.8 (SD 5,3)	32.2 (SD 12,9)	28.6 (SD 11,2)	30.8 (SD 12,2)	29.9 (SD 7,8)	*33.6 (SD 9)*
Day 4	*19.4 (SD 5,9)*	*29.4 (SD 14,8)*	*27.4 (SD 10,9)*	*24.8 (SD 11,6)*	*26.9 (SD 5,8)*	*33.4 (SD 9,4)*
Day 5	*19.9 (SD 5,9)*	*28.2 (SD 14,4)*	*25.4 (SD 11,1)*	*23.8 (SD 11,5)*	*26.8 (SD 7)*	*32.2 (SD 8,8)*
Day 6	20 (SD 5,2)	26 (SD 14)	25.8 (SD 11,1)	26.7 (SD 14,6)	25.9 (SD 6,1)	*30.7 (SD 12,2)*
Day 7	*19.8 (SD5,1)*	*26.6 (SD 10,9)*	*22 (SD 9,3)*	*21 (SD 11,6)*	*24.9 (SD 6,7)*	*21 (SD 2,2)*
DURATION SURGERY (MIN)						
	71.5 (SD 10,8)	95.5 (SD 22,6)	78 (SD 15,1)	87.5 (SD 22,5)	100 (SD 19,5)	*76.4 (SD 11,8)*

Table 3 *Descriptive statistics of the HRQOL-instrument and the duration of the surgery. The HRQOL-Index ranges from 0 to 75, with higher scores on the HRQOLI being indicative of more postoperative discomfort and inconvenience in daily life. The duration of the surgery is expressed in minutes (Min). Are presented: the mean and standard deviation.*

Treatment group	*Mat Mu*	*Mat Bo*	*Fac Mu*	*Fac Bo*	*Mental*	*Templ*
VAS (IN OFFICE)						
MEAN PAIN 24 HOURS						
After surgery	0.4 (SD 1)	0.2 (SD 0,9)	8.2 (SD 13,4)	1.9 (SD 2,5)	12.8 (SD 21,8)	1.8 (SD 3,7)
10 days	2.1 (SD 2,6)	1.8 (SD 3,2)	1.9 (SD 2,5)	3.9 (SD 4,7)	5.9 (SD 6,5)	4.5 (SD 3,8)
PAIN DURING SURGERY						
After surgery	10.5 (SD 13,2)	18.7 (SD 21,8)	21,8 (SD 25)	19,7 (SD 20,1)	21 (SD 25)	22,3 (SD 22,8)
10 days	21.6 (SD 32)	27,2 (SD 23,1)	18,7 (SD 25,6)	20,2 (SD 20,5)	19,8 (SD 20,5)	20,7 (SD 25,6)
REPEAT PROCEDURE						
After surgery	14.8 (SD 27)	14.2 (SD 27,8)	15.7 (SD 16,2)	11.5 (SD 20,4)	4.6 (SD 4,2)	17.2 (SD 28,1)
10 days	14 (SD 27,8)	14.2 (SD 27,7)	12.5 (SD 17,5)	7.6 (SD 9,6)	7 (SD 3,9)	19.8 (SD 24,9)
DURATION PROCEDURE						
After surgery	10.3 (SD 13,2)	20.4 (SD 31,3)	12.9 (SD 18,6)	11.5 (SD 13,2)	12 (SD 14,3)	14.1 (SD 12,2)
10 days	11.3 (SD 16,8)	21.1 (SD 29,9)	10.4 (SD 13,2)	10.5 (SD 11,7)	11.1 (SD 8,9)	16.5 (SD 18,7)
RECOMMEND PROCEDURE						
After surgery	2.9 (SD 2,8)	14.8 (SD 29,6)	13.5 (SD 16,1)	11.6 (SD 27,1)	4.9 (SD 3,9)	19.7 (SD 27,9)
10 days	6.5 (SD 8,7)	16.9 (SD 29,9)	13 (SD 17,4)	5.5 (SD 4,7)	7.2 (SD 4,1)	19.2 (SD 23,8)

Table 6 *Descriptive statistics of the Vas-scores filled in at the time of surgery and at the evaluation meeting after 10 days. Are presented: the mean and standard deviation.*

Treatment group	Mat Mu	Mat Bo	Fac Mu	Fac Bo	Mental	Templ
VAS (DIARY)						
AT THE MOMENT						
4 hours	14.5 (SD 7,8)	25.7 (SD 22,9)	29.6 (SD 25,3)	24.7 (SD 27,7)	27.5 (SD 31,6)	16.4 (SD 15,3)
8 hours	11.7 (SD 8,3)	27.1 (SD 26,1)	21.8 (SD 21,5)	15.2 (SD 12,4)	16.1 (SD 21,2)	14.5 (SD 12,9)
12 hours	12.5 (SD 13,1)	24.6 (SD 21,8)	19.2 (SD 15,6)	12.9 (SD 11,7)	10.9 (SD 10,2)	15.1 (SD 13,5)
Day 1	9.3 (SD 14,8)	17.7 (SD 21,7)	11.7 (SD 11,2)	13.6 (SD 16)	14.7 (SD 14,9)	10.2 (SD 11,7)
Day 2	8.7 (SD 10,5)	15.5 (SD 18,7)	14.8 (SD 13,7)	12.5 (SD 16,3)	15.8 (SD 19,9)	9.5 (SD 9,2)
Day 3	9.8 (SD 15,4)	8.8 (SD 8,2)	8.2 (SD 5,8)	9.5 (SD 7,6)	9.9 (SD 7,2)	10.2 (SD 10,4)
Day 4	9.2 (SD 13,2)	6.8 (SD 7,1)	10.8 (SD 16,7)	8.4 (SD 7,1)	9.4 (SD 6,6)	10 (SD 9,6)
Day 5	6.2 (SD 9,3)	4.1 (SD 5,5)	3.6 (SD 3,8)	8.8 (SD 9,9)	8.3 (SD 4,9)	8.6 (SD 6,5)
Day 6	6.9 (SD 9,6)	4.7 (SD 6,5)	4 (SD 4,5)	6.5 (SD 7,9)	10.8 (SD 11,9)	7.8 (SD 7,4)
Day 7	4 (SD 6,4)	2.8 (SD 3,2)	2.9 (SD 4,2)	5.1 (SD 4,9)	10.6 (SD 11,6)	6.8 (SD 5,8)
MINIMUM PAIN						
4 hours	16.2 (SD 11,6)	12.1 (SD 6,3)	24.2 (SD 22,4)	14.3 (SD 13,8)	25.7 (SD 31,8)	17.4 (SD 19,4)
8 hours	14.6 (SD 13,5)	17.6 (SD 14,8)	16.6 (SD 12,2)	13 (SD 10,6)	15.5 (SD 21,8)	17.5 (SD 16,8)
12 hours	11.1 (SD 8,7)	17.2 (SD 14,8)	15.9 (SD 12,1)	11 (SD 7,8)	11.3 (SD 11,8)	15.6 (SD 13,3)
Day 1	6.8 (SD 4,5)	11.4 (SD 12,1)	12.4 (SD 7,6)	8.4 (SD 4,3)	17.7 (SD 20,9)	11 (SD 13,9)
Day 2	9.1 (SD 9,5)	8.6 (SD 8,1)	13.2 (SD 13,3)	9 (SD 7,5)	14.8 (SD 21)	9.4 (SD 10,6)
Day 3	9.7 (SD 13,6)	6.2 (SD 5,1)	5.8 (SD 4,8)	7.5 (SD 5,3)	13.2 (SD 14,2)	8.3 (SD 8,6)
Day 4	8.5 (SD 11,2)	5.4 (SD 5)	8.8 (SD 13,9)	6.3 (SD 4,8)	7.6 (SD 4,3)	9.5 (SD 13,1)
Day 5	4.6 (SD 7,5)	3.6 (SD 4,7)	3.2 (SD 3,5)	5.7 (SD 3,6)	7.5 (SD 4,2)	6.9 (SD 7,2)
Day 6	4.7 (SD 7,3)	4.6 (SD 5,5)	3.9 (SD 4,7)	5.1 (SD 4)	10.6 (SD 11,7)	6.4 (SD 5,7)
Day 7	3.4 (SD 5,3)	2.7 (SD 2,9)	2 (SD 3,4)	3.6 (SD 2,1)	8.8 (SD 8,1)	5.2 (SD 5,7)
MAXIMUM PAIN						
4 hours	26,2 (SD 20,5)	38.3 (SD 31,2)	38.8 (SD 25,8)	33.6 (SD 26,5)	39 (SD 33,3)	28.5 (SD 17,1)
8 hours	24.6 (SD 21,5)	31 (SD 28,4)	26.8 (SD 24,1)	20.2 (SD 15,9)	20.9 (SD 24,8)	26.8 (SD 21,5)
12 hours	17.4 (SD 19,2)	29.9 (SD 28,3)	21.1 (SD 18,5)	16.2 (SD 13,9)	17.1 (SD 19,1)	18.1 (SD 12,2)
Day 1	14,2 (SD 19,4)	24.5 (SD 26)	26.6 (SD 17)	14.2 (SD 9,2)	21.8 (SD 24,4)	23.7 (SD 25,4)
Day 2	12,2 (SD13,6)	19.8 (SD 24,3)	19.7 (SD 14,3)	14.3 (SD 16,1)	20.8 (SD 21,3)	15.9 (SD 14,7)
Day 3	14,6 (SD 22,8)	15.1 (SD 20,3)	13 (SD 9,3)	12.2 (SD 10,3)	16.3 (SD 15,3)	14.1 (SD 15,4)
Day 4	13,5 (SD 22,1)	11.1 (SD 16,5)	14.1 (SD 19,2)	9.9 (SD 11,1)	11 (SD 8,2)	15.1 (SD 16,2)
Day 5	8,2 (SD 13,9)	6.6 (SD 7,4)	7.1 (SD 7,5)	8.6 (SD 7,8)	9.6 (SD 6,3)	14.2 (SD 13,8)
Day 6	9,4 (SD 14,5)	5.2 (SD 7)	4.6 (SD 4,4)	7.4 (SD 8,5)	11.1 (SD 9,6)	9.9 (SD 6,8)
Day 7	8 (SD 11,7)	4.3 (SD 4,6)	2.6 (SD 3,2)	4.9 (SD 5,7)	10.2 (SD 10,9)	7.9 (SD 7,2)
SWELLING						
4 hours	15.2 (SD 14,9)	32.1 (SD 25,2)	20.3 (SD 15,6)	24.4 (SD 23,9)	28.5 (SD 27)	31.1 (SD 21,9)
8 hours	15.9 (SD 18,1)	34.1 (SD 27,7)	15.4 (SD 13,2)	13.6 (SD 13,4)	23.5 (SD 28,7)	23.3 (SD 17)
12 hours	15.7 (SD 19,9)	33.1 (SD 28)	14.1 (SD 14,4)	18.9 (SD 23,4)	15.9 (SD 19)	25.1 (SD 20,5)
Day 1	15.1 (SD 20,4)	37.5 (SD 26,6)	13.8 (SD 13,4)	18.6 (SD 14,6)	29.2 (SD 23,8)	30.5 (SD 24,7)
Day 2	13.8 (SD 15,8)	36.2 (SD 30,4)	12.4 (SD 10,1)	17.7 (SD 15,7)	20.2 (SD 16,1)	28.9 (SD 21,2)
Day 3	10.8 (SD 11,9)	22.5 (SD 20,5)	9.5 (SD 8,8)	11.2 (SD 8,2)	10.8 (SD 7,4)	17.9 (SD 17,7)
Day 4	6.5 (SD 10,4)	13.9 (SD 12,5)	7.8 (SD 7,4)	7.5 (SD 6,1)	9.4 (SD 2,9)	13.1 (SD 12,5)
Day 5	4.6 (SD 7,7)	7.8 (SD 9,6)	4.8 (SD 6,1)	9.4 (SD 13,9)	8.3 (SD 3,9)	10.9 (SD 6,5)
Day 6	6 (SD 8,3)	5.3 (SD 6,3)	6.4 (SD 9,8)	7.6 (SD 12,2)	5.9 (SD 2,4)	7.9 (SD 7,1)
Day 7	4.3 (SD 6,8)	3.1 (SD 3,2)	3.4 (SD 4,1)	4.5 (SD 5,9)	4.9 (SD 1,6)	4.7 (SD 5)

Table 4 *Descriptive statistics of the Vas-scores filled in daily as part of the diary. Are presented: the mean and standard deviation.*

Treatment group	Mat Mu	Mat Bo	Fac Mu	Fac Bo	Mental	Templ
PAIN MEDICATION						
DAY 1						
no medication (%)	16.7	8.3	18.2	18.2	25	27.3
paracetamol 500 mg 3/d (%)	50	58.3	36.4	54.5	33.3	36.4
> paracetamol 500 mg 3/d (%)	25	33.3	27.3	18.2	25	18.2
stronger pain medication (%)	8.3	0	18.2	9.1	16.7	18.2
DAY 2						
no medication (%)	41.7	27.3	18.2	50	36.4	45.5
paracetamol 500 mg 3/d (%)	25	63.6	36.4	50	36.4	27.3
> paracetamol 500 mg 3/d (%)	25	9.1	18.2	0	9.1	9.1
stronger pain medication (%)	8.3	0	27.3	0	18.2	18.2
DAY 3						
no medication (%)	58.3	44.4	58.3	70	63.6	70
paracetamol 500 mg 3/d (%)	16.7	44.4	16.7	30	9.1	10
> paracetamol 500 mg 3/d (%)	16.7	11.1	8.3	0	9.1	0
stronger pain medication (%)	8.3	0	16.7	0	18.2	20
DAY 4						
no medication (%)	63.6	44.4	72.7	77.8	72.7	72.7
paracetamol 500 mg 3/d (%)	18.2	44.4	0	22.2	9.1	9.1
> paracetamol 500 mg 3/d (%)	9.1	11.1	9.1	0	0	0
stronger pain medication (%)	9.1	0	18.2	0	18.2	18.2
DAY 5						
no medication (%)	66.7	66.7	72.7	88.9	81.8	70
paracetamol 500 mg 3/d (%)	25	22.2	9.1	11.1	0	10
> paracetamol 500 mg 3/d (%)	0	11.1	0	0	0	0
stronger pain medication (%)	8.3	0	18.2	0	18.2	20
DAY 6						
no medication (%)	91.7	75	90	90	81.8	70
paracetamol 500 mg 3/d (%)	0	25	0	10	0	10
> paracetamol 500 mg 3/d (%)	8.3	0	0	0	0	0
stronger pain medication (%)	0	0	10	0	18.2	20
DAY 7						
no medication (%)	91.7	75	100	100	80	80
paracetamol 500 mg 3/d (%)	8.3	25	0	0	0	0
> paracetamol 500 mg 3/d (%)	0	0	0	0	0	0
stronger pain medication (%)	0	0	0	0	20	20

Table 5 *Descriptive statistics of the pain medication. Are presented: the percentage of patients.*

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Implant and patient-centered outcome of guided surgery 5

An RCT comparing guided surgery with conventional implant placement.

a 1-year follow-up.

Abstract

Aim: To assess in a randomized study the implant (clinical and radiological) and patient outcomes of guided implant placement at 1 year follow-up, compared to conventional implant treatment.

Material and Methods: A total of three hundred fourteen implants were placed in sixty patients, randomly assigned to one of the treatment groups. Radiographic and clinical parameters were recorded at the time of implant placement, prosthesis installment (baseline) and at 1-year follow-up. Patient satisfaction was measured with the oral health-related quality of life instrument (OHIP-49).

Results: No implants were lost. The mean marginal bone loss after the first year of loading was 0.04 mm (SD 0.34) for the guided surgery and 0.01 mm (SD 0.38) for the control groups. In the guided surgery groups the mean number of surfaces with BOP and plaque at 1-year follow-up was 1.41 (SD 1.25) and 1.10 (SD 1.22), for the control groups this was respectively 1.37 (SD 1.25) and 1.77 (SD 1.64). The mean pocket probing depth was 2.81 mm (SD 1.1) for the guided, and 2.50 mm (SD 0.94) for the control groups. For all treatment groups a significant improvement in quality of life was observed at 1 year follow-up ($p \leq 0.01$), no differences between groups were observed.

Conclusion: Within the limitations of this study no difference could be found at 1-year follow-up between the implant and patient outcome variables of guided or conventional implant treatment.

Introduction

Implant treatment became a routine procedure for partially and fully edentulous patients. Long-term implant success data are provided by different clinical studies (Jung et al. 2012, Pjetursson et al. 2012). Improved patient satisfaction following implant therapy has been documented as well (Pjetursson et al. 2005, Lang & Zitzmann 2012). Some ten years ago, guided implant placement, flapless or bone supported was introduced. However, only a few studies have compared the implant and patient-centered outcome of guided implant placement techniques with conventional non-guided protocols.

In a recent systematic review of Hultin and co-workers several clinical prospective studies on clinical performance of guided implant placement were analyzed (Hultin et al. 2012). Based on the available amount of data, the systematic review concluded that for guided implant placement comparable survival rates could be expected as for conventional implant treatment (Hultin et al. 2012). In the present randomized study two guided surgery systems were used. The first system (Materialise Universal®) can be used to place oral implants of different manufacturers, however drilling and implant placement is done without depth control and without guidance during implant placement. The second system (Facilitate™) is especially designed to place Astra Tech implants and drilling and implant placement is performed with depth control (physical stops).

The aim of the present paper is to report on the radiographic, clinical implant and patient-centered outcomes at 1-year follow-up.

Material and methods

• Patients

Sixty consecutive patients (72 jaws, mean age=58, 29 males, 31 females, seven smokers) with sufficient bone volume to place four to six implants in the edentulous lower (n=33) or upper jaw (n=39), were consecutively recruited and randomly assigned to one the of the following treatment groups; Materialise Universal®/ mucosa (Mat Mu), Materialise Universal®/ bone (Mat Bo), Facilitate™/ mucosa (Fac Mu), Facilitate™/ bone (Fac Bo), mental navigation (Mental) and a pilot-drill template (Templ). The mucosa-supported (Mu) treatment groups were treated with a flapless approach, in all the other groups a mucoperiosteal flap was reflected with a crestal incision. All study subjects fulfilled the inclusion and exclusion criteria (see Chaper II). The study was approved by the ethical committee of the KU Leuven University Hospital *(B32220095376)*.

• Implant treatment

All patients were scanned with a scan prosthesis and bite-index positioned in the mouth. Afterwards implant planning was performed for all treatment groups with 3D-software (Simplant®, Materialise Dental, Leuven, Belgium) *(for more details see Chapter II)*. Patients were treated under local anesthesia at the department of Periodontology of the KU Leuven University Hospital. For all patients with guided surgery (Mat Mu/Bo, Fac Mu/Bo), the planning was transferred to the manufacture (Materialise Dental) for fabrication of a stereolithographic drill guide. For the patients from the mental navigation group (Mental) no guide was used, only images from the software planning as a reference were allowed, together with some rough distance calculations. For the Template group (Templ) a surgical stent was used to indicate the implant position with the pilot drill, the stent was then removed and further drilling was performed in the conventional way. In case of mucosa support (Mat Mu, Fac Mu) the stereolithographic guide was positioned on the mucosa using a bite index to secure a proper position. The bone supported guides (Mat Bo, Fac Bo) were positioned directly on the jawbone. The drilling was performed using sequential drills with increasing diameter and removable sleeves in the drill template ***(for more details see Chapter II)***.
Three hundred fourteen ASTRA TECH Implant System OsseoSpeed™implants (DENTSPLY Implants, Mölndal, Sweden) with diameter 3.5 or 4 mm, and lengths ranging from 8-15 mm were inserted. After 3 to 4 months of healing, the final prosthetic superstructure was prepared.

• Radiographic examinations

Postoperative radiographic examinations were performed after insertion of the implants, after placement of the final prosthetic reconstruction (baseline) and 12 months later. Radiographs were taken with a phosphor plate (Digora®, Soredex, Tuusula, Finland) kept parallel and the X-ray beam (MINRAY®,60 kV, 7 mA, Soredex, Tuusula, Finland) perpendicular to the implant.
Each radiograph was calibrated individually using the whole implant length, the microthreated part and the first tree threads. Marginal bone loss was determined both at the mesial and distal site of each implant by measuring the distance between a reference point (lower border of the smooth implant collar or the upper moist point of the microthreated part) and the most coronal bone-to-implant contact using imageJ software. Since the whole implant length was not always visible on the radiograph, at least two landmarks were used to scale the amount of bone loss, the mean of their distortion was than utilized for calibration. All measurements were performed by an independent examiner (GvdW), who was not involved in the treatment process and who was blinded for the intervention.

• Clinical examinations

Patients were seen for control visits after implant placement (ten days and four months), after placement of the final prosthetic superstructure and after 1 year of loading. Pocket probing depth (PPD) was measured with a Merritt-B periodontal probe at four sites around each implant (mesial, distal, buccal and lingual units).
The pocket probing depth and bleeding on probing (BOP) were collected after placement of the prosthetic restoration and at 1-year follow-up. Plaque-scores (presence of plaque at the mesial, distal, buccal and lingual surface) were collected at 1- year follow-up. For BOP as well as the plaque index the score ranged from 0 to 4 per implant.

• Questionnaire

Patient satisfaction was measured by means of the OHIP -questionnaire (Slade & Spencer 1994).
The questionnaires were self-completed by the patients. There was a baseline questionnaire filled in before implant treatment and the same questionnaire was also filled in after 1 year of follow-up. These questionnaires were compared to assess the evolution in quality of life.
The patients filled in an additional questionnaire at 1 year to report their quality of life they had 1 year ago (situation before implant placement). This questionnaire was compared to the baseline questionnaire, to assess the reproducibility. The OHIP is a 49-question survey, concerning the quality of life, grouped as 6 subscales or domains: functional limitation, physical pain, psychological discomfort, physical disability, social disability, and other reasons for discomfort. The frequency of each symptom is scored on a six-point scale, ranging from not applicable (score 0), not at all (score 1), rarely (score 2), sometimes (score 3), often (score 4) and very often (score 5).
The scores are summed to yield a total OHIP score (range 0–245), with higher scores on the OHIP being indicative of more inconvenience in daily life.

Statistical analysis

Peri-implant bone-level changes and OHIP-scores were considered to be efficacy variables. Clinical data (pocket probing depth, bleeding on probing an plaque scores) were considered as descriptors. The primary outcome variable was the peri-implant bone level change and the secondary outcome variable was the patient-centered outcome (OHIP). Explanatory variables were the difference in marginal bone loss between the different treatment groups, the influencing factors on marginal bone loss (smoking, bone quality and quantity, history of periodontitis and bruxisme and the presence of plaque) and the evolution of the patient-centered outcomes over time. The latter variables were analyzed with a linear mixed model taking "the explanatory variables" as fixed factors and "patient" as a random factor. Residual dot plots and normal quantile plots were used to assess the assumptions of the model (residuals should be distributed with an equal variance and follow a normal distribution). Contrasts were built to test the specific hypotheses and a correction for simultaneous hypothesis testing was made according to Sidak (Šidák 1967). The level of significance was set at $\alpha = 0.05$. Determination of the sample size was based on the accuracy data *(see Chapter II)*. For the outcome variables from this study, a post hoc power analysis, using the N-factor was performed. The N-factor is the percentage of data extra points needed to reach a level of significance ($\alpha = 0.05$) for the currently found difference (considering that when expanding the data set, the variability of data would remain the same).
For the allocation a computerized random number generator was used. Patients who entered the study twice, for treatment in the upper and lower jaw, were also assigned twice to an intervention group. In each group 12 patients were enrolled.

Results

All patients received their implants between August 2009 and June 2012. In each group 12 patients were enrolled. One patient from the Mat Bo treatment group dropped out after year 1. So a total of 314 implants were analyzed at baseline and 310 implants at 1 year follow-up. Patient and implant features are shown in *table 1*. Three patients were diagnosed with peri-implantitis (Sanz et al. 2012) and two patients presented implants with acute abscess formation and suppuration, before loading of the implants. These patients were treated with resective surgery in combination with antibiotics (Mat Bo (1 patient), Fac Mu (3 patients), Fac Bo group (1 patient). Four out of the five patients were smokers and one them had also a history of bruxism. One patient had a periapical lesion on one of the implants, which was treated with a regenerative approach (Templ group).

• Clinical findings

At prosthesis installment the mean number of surfaces per implant with bleeding on probing was 1.32 (SD 1.28) for the guided surgery groups and 1.10 (SD 1.04) for the control groups. The mean pocket probing depth was 2.57 mm (SD 0.93) and 2.26 mm (SD 0.76) respectively. In the guided surgery groups the mean number of surfaces with bleeding on probing at 1-year follow-up was 1.41 (SD 1.25), the mean number of surfaces per implant with plaque was 1.1 (SD 1.22),and the mean pocket probing depth was 2.81 mm (SD 1.1).
For the control groups this was respectively 1.37 (SD 1.25), 1.77 (SD 1.64) and 2.50 mm (SD 0.94). *Table 2* shows the frequency distribution of the clinical conditions at prosthetic installment and at 1- year follow up.

• Radiographic findings

Table 3 shows the mean bone level, number of patients and implants at the various examination intervals.
At baseline (prosthesis installment) the bone-to-implant contact level was located on average 0.58 mm (SD 0.80) apical of the reference point on the implant for the guided surgery groups and on 0.55 mm (SD 0.75) for the control groups. The mean marginal bone loss during the first year of loading was 0.04 mm (SD 0.34) for the guided surgery and 0.01 mm (SD 0.38) for the control groups. *Figure 1* (implant level) and *figure 2* (subject level) present the cumulative percentage of implants/subjects that experienced varying amounts of bone-loss during the one year of observation. For the Mat Mu group 70% of the implants and subjects experienced no detectable bone loss. For the Fac Mu group this was 70 and 50 %, respectively. The number of implants that exhibited ≥1 mm peri-implant bone loss was 2 for the Mat Mu group (2 subjects) and 3 (2 subjects) for the Fac Mu group, no implants experienced ≥ 1.5 mm bone loss.
For the Mat Bo group 70 % of the implants and 58 % of the subjects experienced no detectable bone loss. For the Fac Bo group corresponding values were 60 % and 45 %. One implant in the Mat Bo group experienced more than 1 mm bone loss. No implants experienced ≥ 1.5 mm bone loss. For the Mental group 70 % of the implants and 50% of the subjects experienced no detectable bone loss. For the Templ group this was respectively 65 % and 60%. No implants of the Mental group exhibited ≥ 1 mm peri-implant bone loss. In the Templ group 3 implants experienced ≥ 1 mm (1 subject) bone loss, no implants exhibited ≥ 1.5 mm bone loss.

Between individual treatment groups no significant differences in bone loss could be observed. Furthermore there were no statistical differences between bone and mucosa supported guidance, or type of guidance. For the difference between flapless guided surgery and non-flapless guided surgery a post-hoc analysis was performed, which yielded a N-factor of 2 at the time of implant placement, of 12173 at the time of prosthetic placement and of 569 at 1 year follow-up.

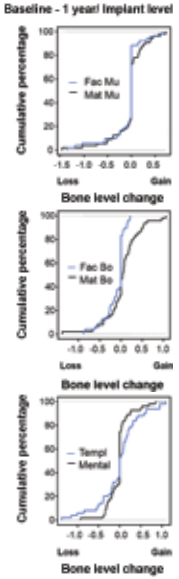

Fig. 1 *Empirical cumulative distribution of the implants according to mean peri-implant bone-level change between baseline and 1 year.*

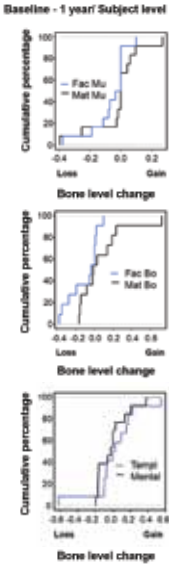

Fig. 2 *Empirical cumulative distribution of the subjects according to mean peri-implant bone-level change between baseline and 1 year.*

From the influencing factors on bone loss, smoking had a significant effect on the on the amount of bone loss between baseline and 1 year follow–up ($p = 0.03$). For the others factors no effect on bone loss was determined.

- **Patient satisfaction**

The data of the OHIP-questionnaires of the different treatment groups at the different time points are presented in *table 4*. For all treatment groups a significant improvement in quality of life was observed, between the questioning before implant installation (baseline) and at the 1 year follow-up visit ($p \leq 0.01$). No differences between individual treatment groups, bone and mucosa supported guidance or type of guidance were noted. The overall mean OHIP-score for all treatment groups improved from 105 before to 61 after implant therapy. At 1 year follow-up patients filled in the same questionnaire again to report on the quality of life one year ago (baseline situation, before implant placement). No significant difference was found for any treatment group between this questionnaire and the baseline questionnaire.

Discussion

In this study no implants were lost after 1 year follow-up. However this study had insufficient power to evaluate survival differences between individual treatment groups or between guided or conventional implant placement. In the systematic review of Hultin et al. (2012) the implant survival rate after one year ranged between 89-100% (study mean 97%). Most of these studies had an observational period of less than 2 years, and only one study (Sanna et al. 2007) had a follow up period up to 5 years. Three studies compared the outcome of guided surgery with conventional surgical protocols (Berdougo et al. 2010, Danza et al. 2009, Nkenke et al. 2007).These studies reported no differences in implant survival rates between the guided and non-guided protocol. For the cause of implant failure in guided surgery different explanations are given, one study (D'Haese et al. 2013) mentioned remnants of impression material causing abscess formation and another trial reported on heavy bruxism leading to non-integration (Malo et al. 2007).

Limited amount of studies have reported on marginal bone loss in guided surgery and no meta-analysis has been performed so far. In this study the bone-to-implant contact level at baseline was located on average 0.58 mm (SD 0.80) apical of the reference point on the implant and the mean marginal bone loss during the first year of loading was 0.04 mm (SD 0.34) for the guided surgery groups. D'haese and co-workers (2013) reported a mean bone loss in the upper jaw at 1 year follow-up of 0.47 mm (SD 0.94). Komiyama and co-authors (2012), reported a mean bone loss at 1 year of 1.37 mm (SD 1.64) in the upper and lower jaw. Comparable results (1.2 mm (SD 0.7)) were found by Marra and co-workers (2013). All these data (on immediate loading) should be compared to our observations of 0.61 mm (SD 0.86) mean bone loss after 1 year of loading.

In the present study the bone-to-implant contact level at baseline for the upper jaw was located on average 0.80 mm (SD 0.86) apical of the reference point on the implant for the guided surgery groups and on 0.87 mm (SD 0.88) for the control groups. For the lower jaw this was 0.17 mm (SD.49) and 0.28 mm (SD 0.47) respectively. During the first year of loading the mean marginal bone loss in the upper jaw was 0.05 (SD 0.41) mm for the guided surgery approach and 0.00 mm (SD 0.50) for the control groups. This could indicate more bone remodeling in the upper jaw, however after 1 year differences were negligible. For the lower jaw this was 0.02 mm (SD 0.16) and 0.02 (SD 0.24) respectively.

Two patients from the guided surgery group presented implants with acute abscess formation and suppuration, before loading of the implants. This could be indicative for suppurative osteomyelitis caused by heating of the bone during implant bed preparations. Guided surgery generates a higher bone temperature than classic drilling (dos Santos et al. 2014), because the sleeves limit direct irrigation from the active point of the drill (external irrigation). Furthermore dos Santos and co-authors reported that an increase in tissue temperature was directly proportional to the number of times the drills were used. In the present study only single use drills were applied,

but in combination with external irrigation. The main method to overcome bone overheating is irrigation (dos Santos et al.2014), internal irrigation and single-use drills should decrease the risk for possible osteomyelitis.

Although the number of smokers in this trial is small, a significant effect of smoking on bone loss was observed for all treatment groups. This is confirmed by D'haese and co-workers (2013), who found a mean bone loss at 1 year of 0.31 mm (SD 0.31) in non-smokers and 0.87 mm (SD 1.38) in smokers. These data are comparable with the data of Sanna and co-workers (2007), who found a mean marginal bone loss at 1 year of 0.8 mm (SD 1.1) in non-smokers and 1.1 mm in smokers (SD 1.4).

For all treatment groups a significant improvement in quality of life was observed between baseline and one year follow-up. These data are confirmed by other studies on guided surgery (Marra et al. 2013, Meloni et al. 2010) and non-guided surgical protocols (Pjetursson et al. 2005). In the OHIP-questionnaire 6 domains are scored. For each domain a significant improvement was noted for the guided surgery groups after 1 year of follow-up: functional limitation (23 versus 15), physical pain (23 versus 14), psychological discomfort (38 versus 21), physical disability (12 versus 8), social disability (10 versus 6), and other reasons for discomfort (10 versus 7). To assess the reproducibility, patients filled in the questionnaire once more at one year follow-up to report their quality of life at baseline conditions. The hypothesis was that patients would not remember or minimize the discomfort they experienced before implant installment. However no difference could be observed between both "baseline" questionnaires. This is confirmed by a study of Sutinen and co-workers (2007) who found no effect of a 1-month versus a 12-month reference period on responses to the OHIP-questionnaire.

Future research should focus on long-term follow-up to determine the implant-and patient based outcome. More comparative clinical trials with clear differences between the used methodologies (flapless, non-flapless, immediate loading) should be performed.

Conclusion

Within the limitations of this study no difference could be found at 1-year follow-up between the implant and patient outcome variables of guided or conventional implant treatment, guided surgery treatment seems to be a valid and predictable treatment option.

Treatment group	*Mat Mu*	*Mat Bo*	*Fac Mu*	*Fac Bo*	*Mental*	*Templ*
PARAMETER PATIENT LEVEL (N)						
Gender (Male/Female)	5/7	4/8	6/6	4/8	4/8	8/4
Age (Range)	38-78	31-72	46-74	43-65	39-72	40-75
Smokers	0	3	2	1	0	2
History of periodontitis (Yes/No)	9/3	9/3	10/2	11/1	8/4	6/6
Jaw (Lower/Upper)	6/6	3/9	5/7	6/6	9/3	4/8
Prosthetic rehabilitation (Fixed/Over-denture)	7/5	3/9	2/10	8/4	6/6	4/8
PARAMETER IMPLANT LEVEL (N)						
Total number of implants placed	55	53	52	52	51	*51*
Total number of implants at 1-year follow-up	55	49	52	52	51	*51*
Number of implants placed one stage/ two stage	51/4	35/18	48/4	47/5	41/10	*23/28*
Implant diameter (3,5/4)	15/40	7/46	21/31	31/21	18/33	47/4
Implant length (8/9/11/13/15)	0/3/28/23/1	1/7/17/17/11	5/9/20/18	0/3/12/28/9	0/1/12/16/22	2/10/17/18/4
Bone quality score (1/2/3/4)	8/25/22/0	6/17/30/0	4/36/12/0	8/36/8/0	12/33/1/5	4/12/35/0

Table 1 *Patient and implant features. Abbreviations: Mat Mu = Materialise Universal®/ mucosa, Mat Bo = Materialise Universal®/ bone, Fac Mu = FacilitateTM/ mucosa, Fac Bo = FacilitateTM/ bone, Mental = Mental navigation, Templ = surgical template, (n) = number.*

	Mat Mu	*Mat Bo*	*Fac Mu*	*Fac Bo*	*Mental*	*Templ*
PROSTHESIS INSTALLMENT (%)						
Bop > 0	76,4	58,5	76,9	58,5	67,3	66,7
Pockets ≤3	50,5	24,6	38,1	47,1	91,5	44
Pockets 4-5	49,5	74,6	61,9	52,9	8,5	56
Pockets ≥6	0	0,7	0	0	0	0
FOLLOW-UP 1 YEAR (%)						
Bop > 0	74,5	63,3	82,7	72,7	83,6	*58,8*
Plaque > 0	56,4	63,3	67,3	29,5	74,5	*64,7*
Pockets ≤3	55,3	27,9	29,8	30,8	55,2	*43,8*
Pockets 4-5	44,7	70,5	70,2	69,2	56,2	44,8
Pockets ≥6	0	1,6	0	0	0	0

Table 2 *Frequency distribution (%) of the clinical conditions at prosthetic installment and at 1- year follow up. Abbreviations: Bop= Bleeding on probing.*

	Mat Mu	*Mat Bo*	*Fac Mu*	*Fac Bo*	*Mental*	*Templ*
Implant placement	0.05 (SD 0,17)	0.35 (SD 0,53)	0.15 (SD 0,43)	0.15 (SD 0,46)	0.06 (SD 0,24)	0.03 (SD 0,11)
number of patients	12	12	12	12	12	12
number of implants	55	53	52	52	51	51
Prosthesis installment	0.41 (SD 0,60)	1.02 (SD 0,92)	0.48 (SD 0,89)	0.40 (SD 0,59)	0.29 (SD 0,46)	0.85 (SD 0,89)
number of patients	12	12	12	12	12	*12*
number of implants	55	53	52	52	51	*51*
Follow-up 1 year	0.44 (SD 0,62)	0.95 (SD 0,97)	0.55 (SD 1,03)	0.51 (SD 0,70)	0.30 (SD 0,42)	*0.85 (SD 1,07)*
number of patients	12	11	12	12	12	12
number of implants	55	49	52	52	51	51
Follow-up 1 year- baseline	0.03 (SD 0,34)	-0.04 (SD 0,40)	0.07 (SD 0,35)	0.11 (SD 0,24)	0.02 (0,27)	0.01 (SD 0,48)

Table 3 *Mean bone level, number of patients and number of implants at the various examination intervals and the marginal bone loss at 1-year follow-up. Between individual treatment groups no significant differences in bone loss could be observed*

		MatMu	*MatBo*	*FacMu*	*FacBo*	*Mental*	*Templ*
QUESTIONING BEFORE							
	Mean	96.67	102.92	108.75	116.38	106.55	99.17
	SD.	29.36	40	26.91	35.04	26.81	36.13
	Min.	59	47	62	64	79	60
	Max.	152	188	143	186	161	164
QUESTIONING AFTER							
Answer before	Mean	94.17	94.18	93.27	110.54	109.73	127.55
	SD.	26.05	40.31	26.21	51.58	33.45	32.26
	Min.	47	43	45	43	74	75
	Max.	129	175	129	206	169	177
Answer after	Mean	59.67 *	54.36 **	66.67 *	66.85 **	62.1 *	61.09 *
	SD.	18.33	22.33	12.67	29.67	21.7	24.35
	Min.	45	8	51	7	26	46
	Max.	109	89	87	123	109	128

Table 4 *Results of the OHIP-questionnaires of the different treatment groups at the different time points, before implant installation and at 1-year follow-up. For all treatment groups a significant improvement in quality of life was observed before and after implant therapy (**p ≤ 0.001, *p ≤ 0.01).*

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Accuracy and patient-centered outcome variables in guided implant surgery 6

A RCT comparing immediate with delayed loading.

Abstract

Aim: To assess the accuracy and patient-center outcome of a novel guided surgery system for placing implants in an edentulous maxilla.

Material and Methods: Fifteen consecutive patients with sufficient bone to place six implants in the maxilla were randomly assigned to the immediate loading (with delivery of the final prosthesis within 24 hours) or the delayed loading treatment group. Accuracy was assessed by matching the planning CT with a postoperative CBCT. Patient-centered outcome measures were the Dutch version of the McGill Pain Questionnaire (MPQ-DLV), the Health-related quality of life instrument (HRQOL), visual analogue scales (VAS), the duration of the procedure, and the analgesic doses taken each day.

Results: A mean deviation was found at the entry point of 0.9 mm (range: 0.1-4.45) and of 1.2mm (range: 0.2-4.9) at the apex, and an angular deviation of 2.7° (range: 0.0-6.6°) was observed. The mean vertical deviation was 0.5 mm (range: 0.0 to 3.2) and in a horizontal direction this was 0.7 mm (range: 0.1 to 3.1). The mean deviation in MD direction was 0.5 mm (range: 0.0 to 2.3), and in BL direction 0.5 mm ± 0.4 (range: 0.0 to 2.2). No statistical differences could be shown between treatment groups on pain response (MPQ-DLV), treatment perception (VAS), number or kind of pain killers, or for the HRQOLI-instrument.

Conclusion: The accuracy of a novel CT-based guide is comparable to the accuracy data of other systems. Within the limitations of this study, no difference could be found in patient outcome variables after immediate or delayed loading.

Introduction

For the treatment of edentulous patients with guided surgery significant variation in the approach exist (Vercruyssen et al. 2014d). Sometimes different templates with sleeves with increasing diameter for an individual surgical case are used, while in other cases removable sleeve inserts in one single template are used (van Assche at al. 2012). Furthermore different types of sleeve inserts are available. Handhold sleeve inserts are designed as a spoon and are stabilized by the surgeon's hand. Drill hold sleeve inserts or sleeve on drills are only attached to the drill (Koop et al. 2012). Some systems designed special drills or drill stops to allow depth control, while others have indication lines on the drills. After the preparation of the implant osteotomy, some systems allow a guided placement of the implant (with or without depth control) while for other systems the template has to be removed before implant insertion.

The accuracy of the entire guided procedure is defined as the deviation between the position of the placed implant and the planned implant and is a summation of all individual errors (Vercruyssen etal. 2008). In this study a novel guided surgery system (ExpertEase™) is investigated. This system uses sleeves on drills. One possible source for error is the amount of deviation during drilling due to the tolerance of the drill in the sleeve insert. In an in vitro study (Koop et al. 2012) we tested the tolerance within the sleeve inserts of different surgical guiding systems. In this study the sleeve on drills gave for all measurements larger deviations than hand hold sleeve inserts. However in this study a Plexiglas box was representing the bone and the drills were forced to the maximum in the left and the right direction. This is the first "clinical" study to determine the accuracy of this novel guiding system.

Guided implant surgery is considered to be a treatment with maximum patient comfort and minimal patient morbidity (Lindeboom & van Wijk 2010, Vercruyssen et al. 2014e). In a recent randomized clinical trial (Vercruyssen at al. 2014c) however little difference could be found in the patient outcome variables between bone versus mucosa-supported or guided versus non-guided surgery. In the latter study all patients were treated with a conventional loading protocol. In most clinical studies reporting on the outcome of guided surgery an immediate loading protocol is applied (Hultin et al. 2012). Besides the accuracy assessment the present randomized clinical trial also aimed to compare the patient-centered outcome variables of immediate and delayed/conventional loading.

Material and methods

• Patients

Fifteen patients with sufficient bone volume to place 6 implants in the edentulous upper jaw (mean age= 60 y., 12 males, 3 females, 2 smokers), were consecutively recruited and randomly assigned to the immediate loading (with delivery of the final prosthesis within 24 hours) or the delayed loading treatment group. For inclusion in the study subjects had to fulfill all of the inclusion and exclusion criteria *(Table 1)*. The study was approved by the ethical committee of the KU Leuven University Hospital *(B32220096198)*.

• Planning procedure

A scan prosthesis was prepared at the prosthetic department of the University Hospital KU Leuven containing all information for the prosthetic restoration. If the existing denture fulfilled these conditions, this denture was transformed into a scan prosthesis. To secure an optimal fit of the scan prosthesis during the scanning process, a bite index in centric relation was prepared in putty material (SheraExact®85, Shera GmbH & Co., Lemförde, Germany). A MSCT scan (Somatom Definition Flash®, Siemens, Erlangen Germany, at 120 kV and 90 mAs, 0.6 mm slice thickness, voxel size 330 µm) was made of the patient with the scan prosthesis and bite index positioned in the mouth. A MSCT was used because the initial protocol demanded the measurement of Hounsfield Units (which is not possible with CBCT), and therefore a dose-reduced protocol was applied (Jacobs & Quirynen 2014). A second scanning was performed of the prosthesis alone, with altered exposure parameters to also visualize the denture (Verstreken et al. 1996,1998). Both sets of dicom images were imported in Simplant® software (Materialise Dental, Leuven, Belgium). The implants were planned in the most optimal position towards both the jawbone and the prosthetic demands.

Patients were only enrolled when the planning indicated sufficient bone volume for successful implant placement without the need of a bone graft. At that moment the patient was randomly assigned to one of the intervention groups. For all patients the planning was transferred to the manufacture (Materialise Dental, Leuven, Belgium) for fabrication of a stereolithographic drill guide.

• Surgical protocol

Surgery was performed under local anesthesia at the department of periodontology of the University Hospital KU Leuven. The stereolithographic guides were positioned on the mucosa using a bite index to secure a proper position. All the stereolithographic guides were fixed to the underlying bone by three to four anchor pins, equally distributed in the jaw. The drilling procedure involved the use of sleeves on drills (Expertease™, Materialise Dental, Leuven, Belgium) which are inserted in the surgical guide and guide the consecutive drills (with different diameters) in the correct position and angulation *(Figure 1)*. The drills had a physical stop and the implant insertion was guided by a fixture mount that closely fitted the sleeve.

Ninety Ankylos implants™ (DENTSPLY Implants, Mölndal, Sweden) with diameter 3.5 or 4.5 mm, and lengths ranging from 9.5-14 mm were inserted. All patients received analgesics (Paracetamol 500mg, three times per day), antibiotics (Amoxycilline 500mg, three times per day) for 5 days, and 0.12 % chlorhexidine twice a day for 1 week. The duration of the procedure (in minutes) was registered. Ten days after the implant procedure all patients returned for a clinical evaluation.

Fig. 1 *Sleeve on drill. The drill is placed with the sleeve in the guide, than the drill moves through the sleeve.*

• Questionnaires

To assess postoperative pain the Dutch version of the McGill Pain Questionnaire (MPQ-DLV) was used (Melzack 1975, Melzack 2005). This questionnaire was handed out as a diary and patients were asked to fill in the questions every day, from day 1 until day 7.
The MPQ-DLV consists of two parts. The first part of the questionnaire groups various pain descriptions according to their pain quality and ranks the descriptions of a certain quality according to their intensity. This gives two indices. The sum of the 'number of words chosen' gives the NWC-T (range 0-20). Furthermore the 'pain rating index' (PRI-T) was calculated (range 0-63), this is the sum of the intensity ranking of the chosen pain words.
The second part consist of 100 mm VAS-scales to evaluate the amount of pain, ranging from 0 (no pain whatsoever) to 100 (worst pain imaginable) and the amount of swelling. The patients were asked to fill in the VAS-scales at the day of surgery every 4 hours and afterwards daily. Patients were asked to score their pain three times; the pain they felt at the moment of questioning, and the minimum and maximum amount of pain they felt during the past 4 or 24 hours.

To assess the impact of the treatment on the quality of life, the Health-related quality of life (HRQOL) instrument was used (Shugars et al. 1996). The HRQOL consists of 15 questions concerning the quality of live. The frequency of each symptom is scored on a six-point scale and the scores are summed to yield a total HRQOL-Index (HRQOLI) score (range 0–75), with higher scores on the HRQOLI being indicative of more postoperative discomfort and inconvenience in daily life. These questions were also part of the diary, and to be filled in daily.
The patients were also asked to document the number and the sort of analgesics taken each day. Furthermore patients were asked to fill in VAS-scales at the time of surgery and at the follow-up visit after 10 days, on the following questions; mean amount of pain during surgery, during the past 24 hours, if they would repeat the procedure in the future, if they found the duration of the procedure tolerable and if they would recommend the procedure to friends or family, ranging from 0 (maximal agreement) to 100 (maximal disagreement) (Nkenke et al. 2007).

• Prosthetic protocol

For patients with the immediate loading protocol, the final prosthesis was prepared pre-operatively at the department of prosthetic dentistry KU Leuven.
At the dental laboratory, implant replica's were fixed in a duplicate of the surgical drill guide by using the implant mounts in the drill sleeves and a working cast was poured. From this cast a soft-tissue cast was prepared and mounted in an articulator to allow the pre-manufacturing of the final CrCo-reinforced hybrid removable prosthesis. The silicone key-index was used to set the tooth arrangement according to the scan prosthesis. Directly after implant surgery, a final impression at implant level was performed. This allowed to fix the correct inter-implant positioning and to correct for deviations between planning and operation. At the day of implant surgery the patient left the department with healing abutments installed, without wearing his/her existing denture.
In the lab a second replica-cast was poured and the final SynCone abutment selection was performed. The day after the implant surgery the patient received the final prosthesis (a hybrid detachable prosthesis) *(Figure 2)*.
For the patients treated with the conventional loading protocol, cover screws were placed and patients were instructed not to wear their dentures during the first week after surgery. After 3 months of healing, abutments were installed and the final prosthetic superstructure was prepared.

***Fig. 2** A hybrid detachable prosthesis.*

• Accuracy of the technique

Immediately after implant placement a CBCT scan (Scanora® 3D, Soredex, Tuusula, Finland) was taken (at 85 kV and 6 mA, voxel size 250 µm) to check the final position of the implants. The postoperative data were matched to the preoperative planning data using the Mimics® software (Materialise Dental, Leuven, Belgium) to determine deviations in the three dimensions. This process is based on surface registration, which consists of a minimization of distances between both models (pre-op and post-op). In this case an iterative closest point (ICP) algorithm was used to match the jaws.
The global deviation is defined as the 3D distance between the coronal centers of the planned and placed implants. Moreover a reference plane was set in bucco-lingual direction by which both the mesio-distal and bucco-lingual deviation could be calculated (Vercruyssen at al. 2014a) *(Figure 3)*.
The enrolment, assignment of the patients, the implant planning and the surgery were all performed by the same investigator (MV). The assessment of the accuracy was performed by another investigator (CC).

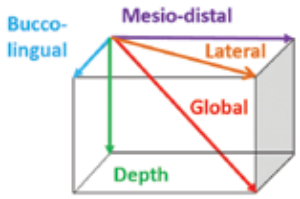

Fig.3 *Three dimensions of direction. Red: global coronal deviation, orange: lateral deviation, green: depth deviation, blue: bucco-lingual deviation, purple: mesio-distal deviation.*

Statistical analysis

The primary outcome variable was the deviation between the position of the planned and placed implant.
The secondary outcome variables were the NWC-T-index, the PRI-T-index, the HRQOL-instrument, the duration of the surgery, the VAS-scales and the amount of analgesic doses taken. The differences in patient-centered outcome variables between techniques were analyzed with a linear mixed model taking treatment as a fixed factor and patient as a random factor. Residual dot plots and normal quantile plots were used to assess the assumptions of the model. Contrasts were built to test the specific hypotheses and a correction for simultaneous hypothesis testing was made according to Sidak (Šidák 1967). The level of significance was set at $\alpha = 0.05$. For the secondary outcome variables from this study, a post hoc power analysis, using the N-factor was performed. The N-factor is the percentage of data extra points needed to reach a level of significance ($\alpha = 0.05$) for the currently found difference (considering that when expanding the data set, the variability of data would remain the same).
For the allocation a computerized random number generator was used.

• Results

All the patients received their implants between February 2010 and December 2013. In the immediate loading group 7 patients were enrolled versus 8 patients in the delayed loading group. Patient and implant demographics are shown in *Table 2*. This study was ended preliminary, because insufficient number of patients could be found meeting all the inclusion criteria (sufficient bone volume). All implants were analyzed for the accuracy measurements, one implant from the delayed treatment group was lost before prosthesis installment due to non-integration.

A mean deviation was found at the entry point of 0.9 mm (range: 0.1-4.45) and of 1.2mm (range: 0.2-4.9) at the apex, and an angular deviation of 2.7° (range: 0.0-6.6°) was observed. The mean vertical deviation was 0.5 mm (range: 0.0 to 3.2) and in a horizontal direction this was 0.7 mm (range: 0.1 to 3.1). The mean deviation in mesio-distal direction was 0.5 mm (range: 0.0 to 2.3), and in bucco-lingual direction 0.5 mm ± 0.4 (range: 0.0 to 2.2). In *Table 3* the minimum and maximum values of the vertical and horizontal deviations are presented.

The descriptive statistics for the secondary outcome variables are presented in *Tables 4-9*. The mean duration of the procedure was 82 minutes (range: 60-140). Over time a significant reduction of the NWC-T and PRI-T index could be found for the immediate loading group after day 7 ($p \leq 0.01$), no difference was found for the conventional group.

For the HRQOL-instrument *(Table 5)* over time a significant reduction could be found at day 4 for the immediate loading group ($p=0.009$), while for the conventional group no difference was found. The evolution of the VAS-scores over time for the amount of pain is shown in *Figure 4*. A significant reduction was found after day 6 for the conventional ($p= 0.04$) and after

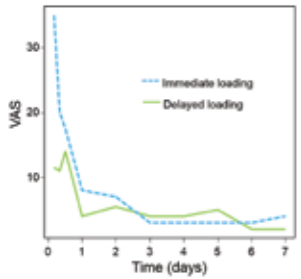

Fig. 4 *Graphic showing the evolution over time of the Vas-score of the mean amount of pain experienced at the moment.*

day 2 for the immediate loading group (p= 0.02). For the amount of swelling this was respectively after day 4 (p= 0.003) and day 3 (p= 0.001) *(Table 6)*. Over time a significant reduction could be found for the amount of medication taken by the patient *(Table 7)*, for the conventional loading group after day 6 (p=0.04) and for the immediate loading group after day 3 (p= 0.001). *Table 8* shows the VAS score at the time of surgery and after 10 days. No difference for both groups was revealed over time.

No statistical differences could be shown between treatment groups on pain response (MPQ-DLV), treatment perception (VAS), number or kind of pain killers, or for the HRQOLI-instrument. A post-hoc power analysis was performed and for most variables there was clinically and statistically no difference (N-factor >6). However there was a tendency for the conventional loading group to experience more postoperative discomfort (HRQOLI) for a longer period of time (N- factor <3).

Discussion

The accuracy data from the present study are comparable with other clinical studies on mucosa or bone-supported stereolithographic guides in fully edentulous jaws (Arisan et al. 2012, D'Haese et al. 2012, Pettersson et al. 2010). If we compare the data with the results of a recent systematic review (Tahmaseb et al. 2014), taken into account the data from the in vivo studies, results are comparable as well (mean deviation at the entry (1.12 mm, Max.: 4.5 mm); at the apex (1.39 mm, Max.: 7.1 mm) and mean angular deviation (3.89°, Max.: 21.16°)). Measurements in mesio-distal and bucco-lingual direction are also comparable to previous reports (Verhamme et al. 2013, Vercruyssen et al. 2014a).

The guided system tested in this study has some specific properties. The drill was guided with a sleeve, which was attached directly to the drill. A physic drill stop indicated the correct depth during the drilling procedure. For the implant placement an implant holder guided the implant in the correct position with a visual stop. In an in vitro study (Koop et al. 2012) we observed that the use of drill hold sleeve inserts gave for all measurements larger deviations than hand hold sleeve inserts. In a recent randomized clinical trial (Vercruyssen at al. 2014b) we compared two other guided surgery systems. For both systems hand-hold sleeve inserts were used. If we compare only the data for the mucosa-supported guides, comparable data could be found for the Materialise Universal® System (mean deviation at the entry (1.2 mm, range: 0.3-2.7 mm); at the apex of 1.6 mm (range: 0.5-3.0), and angular deviation (2.9° (range: 0.3-7.6°)), the Facilitate™system (mean deviation at the entry (1.4 mm, range: 0.4-2.7 mm): at the apex of 1.6 mm (range: 0.2-3.3), and angular deviation (2.7° (range: 0.2-6.4°)); and the Expertease™system (mean deviation at the entry (0.9 mm, range: 0.1-4.45 mm): at the apex of 1.2 mm (range: 0.2-4.9 mm), and angular deviation (2.7° (range: 0.0-6.6°)). So although in-vitro data showed larger deviations for the drill hold sleeve, these differences seem to be clinically no longer relevant.

Because of preliminary ending of this study, the power to evaluate the patient-centered differences between treatment groups is limited. Furthermore the postoperative discomfort for the patients in both treatment groups was low. Both groups were treated with a flapless protocol. And although it is generally accepted that flapless surgery gives less postoperative discomfort (Hultin et al. 2012), data from a recent randomized clinical trial (Vercruyssen at al. 2014c) revealed little difference in patient-centered outcome for mucosa or bone supported guided surgery.

Few studies report on the difference in patient-related outcome between conventional and immediate loading. In a study of Nkenke and co-authors (2006) it is mentioned that the patients who received an immediate restoration wore this superstructure when the postoperative data were acquired and patients who received implants that were allowed to heal in a submerged fashion wore the surgical template at the pre- and postoperative data acquisitions. However, it is not discussed if this difference in prosthetic rehabilitation

had an influence on the patient well-being. In this study, patients from the conventional/delayed group were not allowed to wear their prosthesis during the first week after surgery. This could be an explanation why there was a tendency for the conventional loading group to experience more postoperative discomfort (HRQOLI) for a longer period of time. For the other variables investigated in this study no difference could be found between the delayed and the immediate loading group. So within the limitations of this study, there seems to be little advantage with an immediate loading protocol versus a conventional loading in the first days after surgery.

Conclusion

The accuracy of a novel CT-based guide (ExpertEase™) is comparable to accuracy data of other systems. Within the limitations of this study no difference could be found in patient outcome variables after immediate or delayed/ conventional loading.

INCLUSION CRITERIA	
1	provision of informed consent
2	18 years or older
3	extraction sockets should have healed at least 4 months
4	sufficient bone volume to place 6 implants in the maxilla
5	no previous bone augmentation procedures
6	the mandible can be any kind of dentition as long as a well distributed contact relationship with the new prosthesis in the maxilla can be established.
7	accepting to comply with study procedures
EXCLUSION CRITERIA	
1	physical or psychological disorders prohibiting implant treatment
2	heavy smoking (>10 cigarettes/day)
3	present alcohol and/or drug abuse
4	physical handicap that may interfere with the ability to perform oral hygiene

Table 1 *The inclusion and exclusion criteria.*

Treatment group	*Immediate*	*Delayed*
PARAMETER PATIENT LEVEL (N)		
Total number of patients	7	8
Gender (Male/Female)	5/2	7/1
Age (Range)	45-71	49-70
Smokers	1	1
PARAMETER IMPLANT LEVEL (N)		
Total number of implants placed	42	48
Total number of implants analysed	42	48
Total number of implants lost before loading	0	1
Bone quality score (1/2/3/4)	0/18/24/0	0/16/30/2

Table 2 *Patient and implant features.*

	Depth (mm)	*MD (mm)*	*LB (mm)*
Min.	-3.18	-2.25	-2.17
Max.	1.79	1.33	1.65
Median	0.11	-0.12	-0.2

Table 3 *Descriptive statistics (median, maximum and minimum positive and negative values) of the depth, bucco-lingual and mesio-distal deviation at the entry point of the implant (mm). Depth: - placed deeper than planned/+ placed more occlusal than planned. Buco-lingual (BL): - placed more lingual than planned/+ placed more buccal than planned. Mesio-distal (MD): - placed more to the right than planned/+ placed more to the left than planned. Abbreviations: Min. =Minimum, Max.= Maximum.*

Treatment group	*Delayed*	*Immediate*
PAIN DESCRIPTION LIST (MPQ-DLV)		
NWC-T-INDEX		
Day 1	0; 2 (SD 2,5)	0; 3 (SD 1,9)
Day 2	0; 3 (SD 2,5)	0; 1 (SD 2,2)
Day 3	0; 2 (SD 2,4)	0; 1 (SD 1,5)
Day 4	0; 2 (SD 1,7)	0; 0 (SD 1,9)
Day 5	0; 1 (SD 1,6)	0; 0 (SD 1,9)
Day 6	0; 1 (SD 2,1)	0; 0 (SD 1,9)
Day 7	0; 0 (SD 1,8)	0; 0 (SD 1,1)
PRI-T-INDEX		
Day 1	0; 3 (SD 2,7)	1; 3 (SD 2,9)
Day 2	0; 4 (SD 2,9)	1; 2 (SD 2,6)
Day 3	0; 3 (SD 3,8)	0; 2 (SD 1,7)
Day 4	0; 3 (SD 2,7)	0; 0 (SD 3)
Day 5	0; 1 (SD 1,7)	0; 0 (SD 2,6)
Day 6	0; 1 (SD 3,1)	0; 0 (SD 2,3)
Day 7	0; 0 (SD 2,6)	0; 0 (SD 2,3)

Table 4 *Descriptive statistics of the NWC-T and PRI-T-index. The NWC-T-index ranges from 0 to 20 and is indicative of the pain intensity based on the 'number of words chosen' to prescribe the pain. The PRI-T-index ranges from 0 to 63 and is the sum of the intensity ranking of the chosen pain words. Are presented: the mean, median and the standard deviation.*

Treatment group	*Delayed*	*Immediate*
HRQOL-INDEX		
Day 1	27,9 (SD 10,5)	31,9 (SD 12,6)
Day 2	27,1 (SD 11,8)	25 (SD 9,6)
Day 3	27,4 (SD 13,5)	25,4 (SD 10,4)
Day 4	29,1 (SD 16,7)	20,7 (SD 5,1)
Day 5	23,6 (SD 8,2)	19,3 (SD 6,2)
Day 6	22,1 (SD 9,1)	19,1 (SD 4)
Day 7	20 (SD 8,2)	18,4 (SD 4,9)

Table 5 *Descriptive statistics of the HRQOL-instrument and the duration of the surgery. The HRQOL-Index ranges from 0 to 75, with higher scores on the HRQOLI being indicative of more postoperative discomfort and inconvenience in daily life. The duration of the surgery is expressed in minutes (Min). Are presented: the mean and standard deviation.*

Treatment group	*Mat Mu*	*Mat Bo*
VAS (DIARY)		
AT THE MOMENT		
4 hours	29 (SD 24,6)	46,6 (SD 16,4)
8 hours	20,5 (SD 14,3)	41,1 (SD 24,5)
12 hours	23,1 (SD 17,8)	29,5 (SD 18,2)
Day 1	11,8 (SD 10,7)	29,7 (SD 23,5)
Day 2	9,2 (SD 10,8)	11,1 (SD 6,7)
Day 3	10,4 (SD 13,8)	7,3 (SD 7,4)
Day 4	13,6 (SD 22,9)	11,3 (SD 17,5)
Day 5	12,2 (SD 26,7)	11,4 (SD 18,3)
Day 6	11,8 (SD 25,8)	11,1 (SD 19,1)
Day 7	10,2 (SD 20,2)	10 (SD 18,7)
MINIMUM PAIN		
4 hours	13,3 (SD 11)	17,9 (SD 6,8)
8 hours	14.6 (SD 13,5)	17.6 (SD 14,8)
12 hours	11.1 (SD 8,7)	17.2 (SD 14,8)
Day 1	6.8 (SD 4,5)	11.4 (SD 12,1)
Day 2	9.1 (SD 9,5)	8.6 (SD 8,1)
Day 3	9.7 (SD 13,6)	6.2 (SD 5,1)
Day 4	8.5 (SD 11,2)	5.4 (SD 5)
Day 5	4.6 (SD 7,5)	3.6 (SD 4,7)
Day 6	4.7 (SD 7,3)	4.6 (SD 5,5)
Day 7	3.4 (SD 5,3)	2.7 (SD 2,9)
MAXIMUM PAIN		
4 hours	29 (SD 24,6)	46,6 (SD 16,4)
8 hours	20,5 (SD 14,3)	41,1 (SD 24,5)
12 hours	23,1 (SD 17,8)	29,5 (SD 18,2)
Day 1	11,8 (SD 10,7)	29,7 (SD 23,5)
Day 2	9,2 (SD 10,8)	11,1 (SD 6,7)
Day 3	10,4 (SD 13,8)	7,3 (SD 7,4)
Day 4	13,6 (SD 22,9)	11,3 (SD 17,5)
Day 5	12,2 (SD 26,7)	11,4 (SD 18,3)
Day 6	11,8 (SD 25,8)	11,1 (SD 19,1)
Day 7	10,2 (SD 20,2)	10 (SD 18,7)
SWELLING		
4 hours	15.2 (SD 14,9)	32.1 (SD 25,2)
8 hours	15.9 (SD 18,1)	34.1 (SD 27,7)
12 hours	15.7 (SD 19,9)	33.1 (SD 28)
Day 1	15.1 (SD 20,4)	37.5 (SD 26,6)
Day 2	13.8 (SD 15,8)	36.2 (SD 30,4)
Day 3	10.8 (SD 11,9)	22.5 (SD 20,5)
Day 4	6.5 (SD 10,4)	13.9 (SD 12,5)
Day 5	4.6 (SD 7,7)	7.8 (SD 9,6)
Day 6	6 (SD 8,3)	5.3 (SD 6,3)
Day 7	4.3 (SD 6,8)	3.1 (SD 3,2)

Table 6 *Descriptive statistics of the Vas-scores filled in daily as part of the diary. Are presented: the mean and standard deviation.*

Treatment group	*Mat Mu*	*Mat Bo*
PAIN MEDICATION		
DAY 1		
no medication (%)	37.5	14.3
paracetamol 500 mg 3/d (%)	25	28.6
> paracetamol 500 mg 3/d (%)	12.5	28.6
stronger pain medication (%)	25	28.6
DAY 2		
no medication (%)	50	57.1
paracetamol 500 mg 3/d (%)	25	14.3
> paracetamol 500 mg 3/d (%)	0	14.3
stronger pain medication (%)	25	14.3
DAY 3		
no medication (%)	62.5	85.7
paracetamol 500 mg 3/d (%)	12.5	14.3
> paracetamol 500 mg 3/d (%)	0	0
stronger pain medication (%)	25	0
DAY 4		
no medication (%)	75	85.7
paracetamol 500 mg 3/d (%)	0	14.3
> paracetamol 500 mg 3/d (%)	0	0
stronger pain medication (%)	25	0
DAY 5		
no medication (%)	87.5	100
paracetamol 500 mg 3/d (%)	0	0
> paracetamol 500 mg 3/d (%)	0	0
stronger pain medication (%)	12,5	0
DAY 6		
no medication (%)	87.5	85.7
paracetamol 500 mg 3/d (%)	12.5	0
> paracetamol 500 mg 3/d (%)	0	14.3
stronger pain medication (%)	0	0
DAY 7		
no medication (%)	83.3	85.7
paracetamol 500 mg 3/d (%)	16.7	0
> paracetamol 500 mg 3/d (%)	0	14.3
stronger pain medication (%)	0	0

Table 7 *Descriptive statistics of the pain medication. Are presented: the percentage of patients.*

Treatment group	*Delayed*	*Immediate*
VAS (IN OFFICE)		
MEAN PAIN 24 HOURS		
After surgery	1 (SD 1,4)	5,9 (SD 12,1)
10 days	1,8 (SD 2,7)	7,4 (SD 8,3)
PAIN DURING SURGERY		
After surgery	9,9 (SD 11,2)	18.7 (SD 27)
10 days	13,5 (SD 18,9)	27 (SD 30,9)
REPEAT PROCEDURE		
After surgery	9,6 (SD 15,8)	23,1 (SD 31,1)
10 days	10 (SD 14,4)	23,9 (SD 29,7)
DURATION PROCEDURE		
After surgery	9,0 (SD 16,6)	13,9 (SD 21,2)
10 days	15,2 (SD 22,3)	13,1 (SD 17)
RECOMMEND PROCEDURE		
After surgery	9,9 (SD 16)	20,4 (SD 26,9)
10 days	9,5 (SD 14)	21,3 (SD 30,2)

Table 8 *Descriptive statistics of the Vas-scores filled in at the time of surgery and at the evaluation meeting after 10 days. Are presented: the mean and standard deviation.*

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Concluding discussion

• Accuracy (Chapter II, III, VI)

Today, different computer assisted implant placement procedures are available. They differ in software, template manufacturing, guiding device, stabilization and fixation. The major concern for the transfer of the planning to the operative field is the accuracy, defined as the deviation between the position of the placed implant and the planned implant. The accuracy is calculated by matching the position of the planned implant in the software with the actual position of the implant in the mouth of the patient. The matching is mostly based on a second (cone beam) CT, this process is based on surface registration, which consists of a minimization of distances between both models (pre-op and post-op) *(Figure 1)*.
In chapter II, the reliability of this validation technique was assessed. The intra-examiner variability scores showed great consistency within data processed by the same examiner. However the scores for the inter-examiner variability were lower. We can conclude that the current validation procedures are reliable (Vasak et al. 2013) but one has to take into account that the procedure by itself if not being applied by one examiner, can also be a source for inaccuracy.

The accuracy of the implant or the osteotomy site is mostly expressed by four parameters *(Figure 2)*: 1) deviation at the entry point, 2) deviation at the apex, 3) deviation of the long-axis, 4) deviation in height/depth. In this thesis *(Chapter III, VI)* additional measurements were performed to determine the clinical relevant deviations in bucco-lingual and mesio-distal direction *(Figure 3)*
(Verhamme et al. 2013, 2014). An important issue is that up to now, it remains unclear how much deviation of the actually reached implant position from the planned position can be acceptable, as the impact of the deviation depends on the anatomic situation (bone volume, presence of neurological structures), inter-implant/tooth distance, future prosthetic rehabilitation etc. (Schneider et al. 2014). The literature seems to indicate that one has to accept a certain inaccuracy of ± 2.0 mm, which seems large at a first view, but is clearly less than for non-guided surgery

Fig. 1 *Image of the software matching the pre- and postoperative jaw model. (In courtesy of Materialise Dental®).*

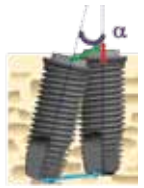

Fig. 2 *The accuracy is generally expressed by four parameters: green: deviation at the entry point of the implant or cavity, blue: deviation at the apex of the implant or cavity, purple: deviation of the axis of the cavity or implant, red: deviation in height/depth.*

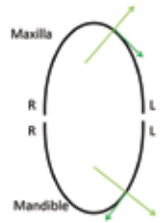

Fig. 3 *Assessment of the deviation in bucco-lingual and mesio-distal direction. Buco-lingual (BL): - placed more lingual than planned/+ placed more buccal than planned. Mesio-distal (MD): Maxilla: - placed more to the right than planned/+ placed more to the left than planned, Mandible: - placed more to the left than planned/ + placed more to the right than planned.*

(van Assche et al. 2012). This is confirmed by the data presented in this thesis. The overall accuracy data of the guided surgery systems (Materialise Universal®, Facilitate™ system, ExpertEase™) and the non-guided treatment groups (mental navigation and a pilot-drill template) are presented in *Table1*. The most important inaccuracy with guided surgery is in vertical direction (depth). Horizontal inaccuracies are clearly less. These findings were confirmed by Farley and colleagues (2013), who assessed the accuracy of guided and conventional surgical guides in a split-mouth design. For non-guided surgery the inaccuracies are significantly higher in all directions. Deviations of the different guided implant systems are comparable. Differences between bone and mucosa support or type of guidance were negligible. Jaw and implant location (posterior-anterior, left-right) however, had a significant influence on the accuracy when guided.

• Postoperative outcome (Chapter IV, VI)

In chapter IV and VI the postoperative outcome of the patients is assessed. Postoperative discomfort and pain is generally assessed by questionnaires. Questions dealing with pain and day to-day life is language-sensitive and it proved difficult to find questionnaires in Dutch, which have been assessed for their reliability and validity. Furthermore, in the literature there is a lack of standardized methods to determine the patient-centered outcome variables. In *Chapter IV and VI* little differences could be found in the patient outcome variables between different treatment groups. However in chapter IV there was a tendency for patients treated with conventional flapped implant placement to experience the pain (MPQ-DLV), for a longer period of time. And in chapter VI there was a tendency for the conventional loading group to experience more postoperative discomfort (HRQOLI) for a longer period of time. In this thesis the postoperative discomfort for the patients in all the different treatment groups *(Chapter IV and VI)* was low and that could be the explanation why little difference in postoperative outcome between the different treatment groups could be found. A recent systematic review concluded that guided flapless surgery was likely

		MatMu	*MatBo*	*FacMu*	*FacBo*	*ExpMu*	*Mental*	*Templ*
Coronal (mm)	Mean	1.23	1.60	1.38	1.33	0.92	2.77	2.97
	SD.	0.60	0.92	0.64	0.82	0.63	1.54	1.41
	Min.	0.3	0.28	0.39	0.30	0.11	0.33	0.55
	Max.	2.65	3.73	2.68	3.58	4.45	8.34	6.55
Apical (mm)	Mean	1.57	1.65	1.60	1.50	1.21	2.91	3.40
	SD.	0.71	0.82	0.70	0.72	0.70	1.52	1.68
	Min.	0.45	0.24	0.23	0.33	0.22	0.53	0.34
	Max.	2.99	3.66	3.27	3.56	4.94	7.37	7.46
Angular (°)	Mean	2.86	3.79	2.71	3.20	2.68	9.92	8.43
	SD.	1.6	2.36	1.36	2.70	1.55	6.01	5.10
	Min.	0.27	0.53	0.20	0.19	0.04	1.45	0.56
	Max.	7.60	10.05	6.36	16.03	6.62	27.76	21.28
Depth (mm)	Mean	0.74	1.18	0.74	1.00	0.54	1.25	2.20
	SD	0.57	0.94	0.65	0.69	0.57	0.95	1.44
	Min.	0.004	0.08	0.08	0.02	0.01	0.03	0.12
	Max.	2.42	3.65	2.32	3.00	3.18	4.38	6.40
Lateral (mm)	Mean	0.88	0.83	1.04	0.80	0.67	2.34	1.77
	SD	0.50	0.67	0.55	0.61	0.44	1.57	1.03
	Min.	0.09	0.08	0.08	0.03	0.09	0.20	0.35
	Max.	2.10	2.88	2.46	2.49	3.12	8.45	4.11
MD	Mean	0.61	0.54	0.69	0.68	0.47	2.06	1.49
	SD	0.48	0.5	0.56	0.62	0.33	1.64	1.12
	Min.	0.02	0.01	0.03	0.001	0.02	0.03	0.004
	Max.	1.69	2.07	2.41	2.45	2.25	8.29	3.79
LB	Mean	0.47	0.50	0.59	0.31	0.40	0.76	0.71
	SD	0.45	0.59	0.47	0.22	0.39	0.67	0.47
	Min.	0.01	0.01	0.01	0.01	0.00	0.004	0.03
	Max.	2.08	2.88	1.92	1.10	2.17	2.86	1.76

Table 1 *Descriptive statistics of the deviation of the different treatment groups. Abbreviations: Mat Mu = Materialise Universal®/ mucosa, Mat Bo = Materialise Universal®/ bone, Fac Mu = FacilitateTM/ mucosa, Fac Bo = FacilitateTM/ bone, Exp Mu= ExpertEaseTM mucosa, Mental = Mental navigation, Templ = surgical template. SD = standard deviation, Min. = Minimum, Max. = Maximum.*

to decrease pain and discomfort in the immediate postoperative period (Hultin et al. 2012). Other studies investigating the difference in postoperative discomfort between guided flapless surgery or a conventional open-flap procedure, indicated that with the flapless procedure, patients experienced pain less-intensely, and for shorter periods of time (Arisan et al. 2010, Fortin et al. 2006, Nkenke et al. 2007). Few studies have reported on the difference in patient-related outcome between conventional and immediate loading.

• Implant and patient-centered outcome after 1-year (Chapter V)

In chapter V the radiographic, clinical implant and patient-centered outcomes at 1-year follow-up are reported. No implants were lost after 1 year follow-up. However this study had insufficient power to evaluate survival differences between individual treatment groups or between guided or conventional implant placement. Limited amount of studies have reported on marginal bone loss in guided surgery and no meta-analysis has been performed so far. In this study the bone-to-implant contact level at baseline was located on average 0.58 mm (SD 0.80) apical of the reference point on the implant and the mean marginal bone loss during the first year of loading was 0.04 mm (SD 0.34) for the guided surgery groups. Two patients from the guided surgery group presented implants with acute abscess formation and suppuration, before loading of the implants. This could be indicative for suppurative osteomyelitis caused by heating of the bone during implant bed preparations. Clinicians should be aware that the risk for this phenomena is increased when using drills with external irrigation (dos Santos et al. 2014). We can confirm that with the ExpertEase™system (with internal irrigation) used in chapter VI, we didn't have any patients presenting these symptoms.

For all treatment groups a significant improvement in quality of life was observed between baseline and one year follow-up. For all treatment groups a significant improvement in quality of life was observed, between the questioning before implant installation (baseline) and at the 1 year follow-up visit ($p \leq 0.01$). No differences between individual treatment groups, bone and mucosa supported guidance or type of guidance were noted. To assess the reproducibility, patients filled in the questionnaire once more at one year follow-up to report their quality of life at baseline conditions. The hypothesis was that patients would not remember or minimize the discomfort they experienced before implant installment. However no difference could be observed between both "baseline" questionnaires.

• Future research

Future research should further focus on determining the deviation in all dimensions, as such to allow clinical comparisons with other available static guided surgery systems. This is an important issue, considering that large variations in product handling between the different systems may occur. To postulate recommendations to increase the accuracy, it is important to be aware, that deviations reflect the sum of all errors occurring from imaging to the transformation of data into a guide, to the improper positioning of the latter during surgery. For the first step it is important to take a correct scan of an immobilized patient with an optimal fitted scan prosthesis. During the surgical procedure much attention has to be paid to properly place and fixate the surgical guide. For the latter we strongly recommend to use fixation pins and if possible to use one surgical guide in combination with sleeves with increasing internal diameter.

During the drilling process, one has to be aware that a certain tolerance of the drills exists and that one has to check that the correct direction is followed during the entire drilling sequence. To reduce these systematic deviations, different solutions have been investigated. Increasing the drill key height, the guiding sleeve height and decreasing the distance between the sleeve and the prospective shoulder have improved the accuracy in in-vitro research (Koop et al. 2013). However clinically this has to be further investigated, longer sleeve inserts could require a larger mouth opening and the apical position of the sleeve is limited due to possible interference of the sleeve with the mucosa or the alveolar bone. Reducing the tolerance between drills and the drill keys by reducing the diameter of the drill keys is difficult due to mechanical friction and debris. Schneider and co-workers (2014) have investigated the tolerance between the drill key and the guiding sleeve. The accuracy was improved by reducing the sleeve diameter by the use of 3-D printing, however a certain degree of tolerance had to be maintained to ensure correct insertion of the drill keys and the implant fixture mounts. Reducing the number of steps needed will further improve the accuracy.

Considering patient-related outcome one has to consider that subject-related outcome is determined by inter-individual aspects such as the anatomy of the jaw, location of implant position, accessibility, medical history and compliance of the patient. Future research should focus on standardizing the methods to determine the patient-centered outcome variables and so facilitating the comparison between both the used methodology as the inter-individual aspects. Furthermore research should focus on long-term follow-up to determine the implant-and patient based outcome. More comparative clinical trials with clear differences between the used methodologies (flapless, non-flapless, immediate loading) should be performed.

Summary

A thorough preoperative planning of the number of implants to be placed, their size, position and inclination could free the surgeon's mind, allowing concentrating on the patient and the tissues handling. Such preoperative planning is ideally performed on three dimensional images. Today specific software programs have been developed for implant surgery planning and different methods have been proposed for the transfer of the software planning to the surgical field: computer-guided (static) or computer -navigated (dynamic) surgery. For computer-guided surgery a static surgical guide is used, that transfers the virtual implant position from computerized tomographic data to the surgical site. The guides used in this thesis are produced by means of stereolithography, a computer-aided design/computer-assisted manufacture (CAD/CAM) technology. Stereolithography is an additive manufacturing process using a vat of liquid UV-curable photopolymer resin, and an UV laser that selectively cures resin, layer by layer, into a mass representing the desired three-dimensional object, in this case a surgical guide.

The major concern for the transfer of the planning to the operative field is the accuracy, defined as the deviation between the position of the placed implant and the planned implant. The accuracy is calculated by matching the position of the planned implant in the software with the actual position of the implant in the mouth of the patient. In *chapter II and III* the accuracy of guided surgery is assessed and compared to mental navigation or the use of a surgical template, in fully edentulous jaws. Moreover, the accuracy of different guiding systems was determined, the Materialise Universal® system (mucosa or bone supported) and the Facilitate™system (mucosa or bone supported). Our results illustrated that guided implant placement appears to offer clear accuracy benefits compared to non-guided surgery. However no differences between bone and mucosa supported guidance or type of guidance were found. In chapter VI the accuracy of a novel guided surgery system (ExpertEase™) was assessed and comparable accuracy data were found.

In the approach to treat edentulous patients with guided surgery significant variation exist. In case of a flapless approach a punch-technique is applied or a small crestal incision is performed before positioning the guide directly on the mucosa. The drilling procedure is than performed with minimal exposure of the bone. In case of a bone supported guide, the guide is positioned on the jawbone after reflecting of a mucoperiosteal flap with a crestal incision. Flapless implant placement is thought to reduce patient morbidity. In *chapter IV and VI* the postoperative outcome of the patients was assessed. Our results indicated that in general implant treatment seemed to give little postoperative discomfort, for most treatment groups a significant reduction in postoperative discomfort was noticed during the first week after surgery. However differences between bone versus mucosa supported, guided versus non-guided surgery or immediate versus delayed/conventional loading were negligible.

In *chapter V* the radiographic, clinical implant and patient-centered outcomes at 1-year follow-up were reported. No implants were lost after 1 year follow-up. Between individual treatment groups no significant differences in bone loss could be observed. Furthermore there were no statistical differences between bone and mucosa supported guidance, or type of guidance. For all treatment groups a significant improvement in quality of life was observed, between the questioning before implant installation (baseline) and at the 1 year follow-up visit. No differences between individual treatment groups, bone and mucosa supported guidance or type of guidance were noted. From these results we can conclude that at 1-year follow-up the radiological and clinical performance of implants placed with guided surgery or in the conventional way seem to be similar.

Samenvatting

Een doorgedreven pre-operatieve planning waarbij het aantal, de positie en de inclinatie van de implantaten vastgelegd wordt, zorgt ervoor dat de chirurg zich tijdens de ingreep kan concentreren op de omgang met de patiënt en het correct uitvoeren van de planning. Zo een peroperatieve planning kan best uitgevoerd worden op basis van een drie-dimensionele radiografie (CT of CBCT). Momenteel bestaan er meerdere softwareprogramma's om implantaten te plannen in het kaaksbeen van de patiënt en verschillende methodes om de softwareplanning over te brengen naar de mond van de patiënt. De overdracht van de planningsgegevens vanuit de software naar de patiënt, vindt plaats via een richtplaat of via navigatie. Richtplaten kunnen op verschillende manieren vervaardigd worden. Op basis van de planningssoftware kan de richtplaat volledig computergestuurd worden vervaardigd (stereolitografie) of via een tussenstap in het labo. De richtplaten in deze thesis werden allemaal vervaardigd via stereolitografie. Stereolitografie is een proces waarbij een laser selectief laag per laag bepaalde delen van een vat met vloeibare polymeten gaat verharden, om uiteindelijke het gewenste 3D-object te bekomen.

Het belangrijkste aandachtspunt bij de overdracht van de planning naar de mond van de patiënt is de nauwkeurigheid of accuraatheid. Om de accuraatheid van een systeem na te gaan zal men doorgaans na het plaatsen van de implantaten een nieuwe CT of CBCT vervaardigen zodat men de implantaatplanning kan vergelijken met de effectieve positie van de implantaten. In *hoofdstuk II en III* werd de accuraatheid van geleide implantaat chirurgie bepaald en vergeleken met mentale navigatie of een eenvoudige chirurgische richtplaat bij patiënten, volledig edentaat in de boven- en/of onderkaak. Verder werd ook de accuraatheid van verschillende systemen met elkaar vergeleken, namelijk het Materialise Universal® systeem (mucosa- of botafgesteund) en het Facilitate™systeem (mucosa of botafgesteund). Uit onze resultaten bleek dat geleide implantaat plaatsing duidelijk nauwkeuriger was dan niet-geleide implantaat plaatsing. We konden echter geen verschil vinden tussen botafgesteunde of mucosa-afgesteunde richtplaten of het soort systeem dat gebuikt werd. In *hoofdstuk VI* werd de nauwkeurigheid van een nieuw geleid implantaatsysteem(ExpertEase™) nagekeken en vergelijkbare resultaten met andere systemen werden gevonden.

Bij het behandelen van edentate patiënten met geleide implantaat plaatsing zijn verschillende behandelopties mogelijk. Men kan de richtplaat rechtsreeks plaatsen op het tandvlees van de patiënt, waarbij men enkel een kleine cirkel tandvlees wegneemt of een kleine incisie maakt. Het boor-proces gebeurt dan met een minimale blootlegging van het bot, dit noemt men de" flapless" methode. Een tweede optie bestaat eruit, de richtplaat op het bot te plaatsen, hiervoor moet men dan wel eerst het tandvlees wegklappen.
In de literatuur is gebleken dat bij deze "flapless" methode de nalast voor de patiënt na de implantaatingreep was afgenomen. In hoofstuk IV and VI werd de postoperatieve uitkomst van de behandeling voor de patiënt onderzocht. Onze resultaten toonden aan dat een implantaat behandeling in het algemeen weinig nalast geeft, verder werd een sterke reductie van de nalast waargenomen in de eerste week na de ingreep. We konden echter geen verschil vinden tussen bot- of mucosa-afgesteunde richtplaten, geleide of niet-geleide implantaatplaatsing en onmiddellijke of conventionele belasting.

In *hoofdstuk V* werden de radiologische en de klinische resultaten van de implantaatbehandeling na 1 jaar gerapporteerd. Na 1 jaar waren er geen implantaten verloren gegaan. Tussen de verschillende systemen of tussen geleide en niet-geleide implantaat plaatsing kon geen verschil worden waargenomen in de hoeveelheid botverlies. Voor alle patiënten werd een significante verbetering in de levenskwaliteit waargenomen tussen de situatie bij de start voor de implantaatbehandeling en na 1 jaar van het dragen van de implantaat-afgesteunde prothese in de mond. Ook wat betreft de levenskwaliteit konden wij geen verschil vinden tussen de verschillende behandel strategieën. Uit deze data blijkt dat de radiologische en klinische resultaten van geleide implantaat plaatsing en conventionele plaatsing na 1 jaar weinig verschil toonden en dat beide behandelopties dus even goed presteerden.

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• Publications

Vercruyssen M, Naert I, Coucke W, Jacobs R Teughels W, Quirynen M.
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