CLINICAL ORAL IMPLANTS RESEARCH

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

Key words: accuracy, clinical research, CT imaging, guided implant surgery, surgical techniques

Abstract

Aim: To assess the accuracy of guided surgery compared with 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 into BL (bucco-lingual) and MD (mesio-distal) deviations.

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

Between static surgical guiding systems for implant placement, significant variations in product handling can be observed (Vercruyssen et al. 2008, 2014c; Van Assche et al. 2012). 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). 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 (Vercruyssen et al. 2014b).

The limitations of static guided surgery are set by the maximum deviation observed

between planning and postoperative outcome. 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°). These deviations reflect the sum of all errors occurring from imaging over the transformation of data into a guide, to the improper positioning of the latter during surgery. 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 (BouSerhal et al. 2002; Jacobs

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Vercruyssen M, Coucke W, Naert I, Jacobs R, Teughels W, Quirynen M. Depth and lateral deviations in guided implant surgery: an RCT comparing guided surgery with mental navigation or the use of a pilot-drill template. *Clin. Oral Impl. Res.* **00**, 2014, 1–6 doi: 10.1111/clr.12460 et al. 2002; Mraiwa et al. 2004). To avoid these anatomical structures, it is important to know the deviation in depth and in mesiodistal 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 this study is to report on deviation in a vertical (depth) and horizontal (lateral) plane, the latter further subdivided into 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. 2012; Verhamme et al. 2013). For this study, the population used in a previous paper (Vercruyssen et al. 2014a) 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), FacilitateTM/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 Vercruyssen et al. (2014a). 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 dosereduced 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 toward both the jawbone and the future prosthetic reconstruction (Verstreken et al. 1996b, 1998). For all patients with guided surgery, the planning was transferred to the manufacturer (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 Sulfate 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. Afterward, 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 \geq three fixation pins. The drilling was conducted according to the manufacturer's instructions. In the Materialise Universal[®] group, drilling and implant placement was performed 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 was 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 and fourteen ASTRA TECH Implant System OsseoSpeed[™] implants (DENTSPLY Implants, Mölndal, Sweden) with diameter 3.5 or 4 mm and lengths ranging from 8 to 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 μ m) to check the final position of the implants. The postoperative positions were matched to the preoperative planning using the Mimics[®] software (Materialise Dental), 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). Data on standard deviation parameters (global coronal, global apical, and angular deviations) have already been published (see Vercruyssen et al. 2014a).

The enrollment, assignment of the patients, the implant planning, and the

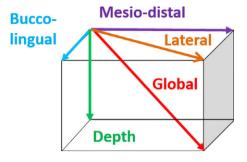


Fig. 1. Three dimensions of direction. Red: global coronal deviation, orange: lateral deviation, green: depth deviation, blue: bucco-lingual deviation, purple: mesio-distal deviation.

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 Vercruyssen et al. 2014a).

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 1 mm 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 FacilitateTM bone group were excluded from the analysis because of following reasons: one patient had a limited mouth opening, the two most distal implants could not be placed with the guide, and in another

| Table | 1 | | Numl | oer | of | pat | ients | and | imp | lants | ana | lyzed | per | grou | р |
|-------|---|--|------|-----|----|-----|-------|-----|-----|-------|-----|-------|-----|------|---|
|-------|---|--|------|-----|----|-----|-------|-----|-----|-------|-----|-------|-----|------|---|

| | 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 |
| Lateral (mm) | | | | | | |
| 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 |
| MD | | | | | | |
| 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 |
| 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 |
| | | | | | | |

n, number, SD, standard deviation, Min., Minimum, Max., Maximum.

Descriptive statistics of depth, lateral, bucco-lingual, and mesio-distal deviations for the different groups at the entry point of the implant (mm).

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 our previous paper (Vercruyssen et al. 2014a). In Table 1, the inaccuracy in vertical (depth) and in horizontal (lateral) direction is presented, the latter further subdivided into 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 group ($P \le 0.05$), 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 ($P \le 0.05$). 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

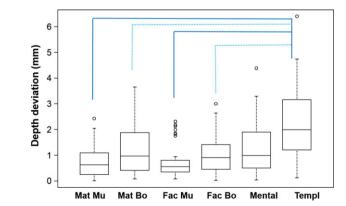


Fig. 2. Box plot of the depth deviation at the entry point. Significant differences between treatment groups are indicated with *P*-values: full line ≤ 0.001 , dotted line ≤ 0.05 .

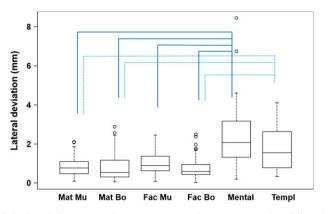


Fig. 3. Box plot of the lateral deviation at the entry point. P-values are presented as followed: full line ≤ 0.001 , dotted line ≤ 0.05 .

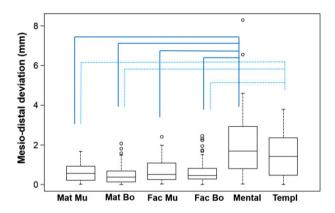


Fig. 4. Box plot of the mesio-distal deviation at the entry point. *P*-values are presented as followed: full line ≤ 0.001 , dotted line ≤ 0.05 .

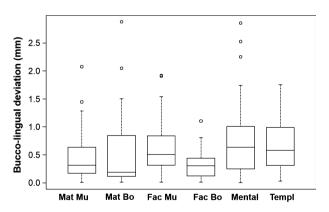


Fig. 5. Box plot of the bucco-lingual deviation at the entry point. No statistical differences were found.

was found in the non-guided groups (larger deviation in mesio-distal, than in bucco-lingual sense, $P \le 0.001$), 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 \pm 0.8 (range: 0.0–3.7). 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 FacilitateTM 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 with the Mat Mu group and for the Fac Bo versus Mat Bo group, which is consistent with the abovementioned 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 $0.9 \text{ mm} \pm 0.6$ (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 located 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 \pm 0.6 (range: 0.0 to 2.5), and 0.6 mm \pm 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 \pm 0.3 (range: 0.0 to 1.4) vs. 0.6 mm \pm 0.5 (range 0.0 to 2.9) for the upper jaw. In a clinical study of Verhamme et al. (2013), detailed measur-

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)

| | 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) | | | | | | |
| IJ | | | | | | |
| 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) | | | | | | |
| IJ | | | | | | |
| 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 |

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. SD, standard deviation, Min., Minimum, Max., Maximum, LJ, lower Jaw, UJ, Upper Jaw.

ments 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 mesiodistal and bucco-lingual direction for the

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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 $0.9 \text{ mm} \pm 0.8$ (range: 0.0 to 3.7) and 0.9 mm \pm 0.6 (range: 0.0 to 2.9) for the lateral deviation. In MD direction, this was 0.6 mm \pm 0.5 (range: 0.0 to 2.5) and 0.5 mm \pm 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.

Conflict of interest and source of funding statement

There is no conflict of interests. Oral implants were delivered free of charge by DENTSPLY Implants (Mölndal, Sweden), and Stereolithographic guides were delivered free of charge by the Materialise Dental Company (Leuven, Belgium).

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Supporting Information

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

Data S1. CONSORT 2010 checklist of information to include when reporting a randomised trial.