

Evaluation of Three Different Validation Procedures regarding the Accuracy of Template-Guided Implant Placement: An In Vitro Study

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ABSTRACT

Purpose: The study aims to evaluate the accuracy of the NobelGuide™ (Medicim/Nobel Biocare, Göteborg, Sweden) concept maximally reducing the influence of clinical and surgical parameters. Moreover, the study was to compare and validate two validation procedures versus a reference method.

Material and Methods: Overall, 60 implants were placed in 10 artificial edentulous mandibles according to the NobelGuide™ protocol. For merging the pre- and postoperative DICOM data sets, three different fusion methods (Triple Scan Technique, NobelGuide™ Validation software, and AMIRA® software [VSG – Visualization Sciences Group, Burlington, MA, USA] as reference) were applied. Discrepancies between the virtual and the actual implant positions were measured.

Results: The mean deviations measured with AMIRA® were 0.49 mm (implant shoulder), 0.69 mm (implant apex), and 1.98°mm (implant axis). The Triple Scan Technique as well as the NobelGuide™ Validation software revealed similar deviations compared with the reference method. A significant correlation between angular and apical deviations was seen ($r = 0.53$; $p < .001$). A greater implant diameter was associated with greater deviations ($p = .03$).

Conclusion: The Triple Scan Technique as a system-independent validation procedure as well as the NobelGuide™ Validation software are in accordance with the AMIRA® software. The NobelGuide™ system showed similar or less spatial and angular deviations compared with others.

KEY WORDS: computer-assisted, computerized tomography, flapless implant surgery, precision, stereo lithography, surgical guides

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INTRODUCTION

As a rule, precise and accurate preoperative prosthetic and surgical planning serves as a necessary prerequisite for later clinical success in dental implantology.¹ Implementation of complex prosthetic planning in a three-dimensional surgical field frequently represents a major surgical challenge.² Template-guided, computer-aided treatment concepts such as NobelGuide™ (Medicim/Nobel Biocare, Göteborg, Sweden) are to ensure precise surgical implementation of preoperative prosthetic planning. Moreover, navigated implant surgery provides for improved implant positioning at anatomically sensitive structures such as the maxillary sinus, the mandibular canal, and the mental foramen.³ Modern

template-guided systems make use of the advantage of the minimally invasive access. However, apart from the benefits of a more rapid procedure and reduced perioperative bleeding and decreased postoperative patient discomfort, there is also a residual risk of uncontrolled, blind implant placement.⁴ For the reasons outlined, *ex vivo* and *in vivo* studies have evaluated the implementation accuracy of computer-aided implantation systems.^{1,4-8} Appropriate validation procedures have been developed and used for evaluating the implementation accuracy of navigated implant systems. The validation procedures serve for the illustration and the quantification of deviations from the preoperatively planned to the postoperatively achieved implant positions. A review of Schneider and colleagues showed average deviations of 1.2 mm at the implant shoulder and of 2 mm at the implant apex with an average angular deviation of 5.7 degrees.⁹ These deviations represent the summation of any possible clinical and technical errors.¹⁰ Implementation errors in clinical and experimental use may be associated with various causes such as scanning, processing, surgery, and prosthetics.¹¹⁻¹³ Separate presentation and quantification of technical and application-related implementation errors within the process sequence appear to be difficult. As yet, none of the studies known to the authors has assessed the influence of validation procedures on the calculation of implementation accuracy.

For this reason, this experimental study was firstly aimed to evaluate the implementation accuracy of the NobelGuide™ concept avoiding clinical impact parameters, and secondly to validate two validation procedures versus a reference method.

MATERIALS AND METHODS

The study was conducted using 11 identical polyurethane dummy mandibles (Dentsply Friadent, Mannheim, Germany) for simulating a completely edentulous arch. One synthetic dummy mandible served as planning and reference model. The other 10 dummy mandibles were used as surgical models.

An overall six implant bed preparations according to the manufacturer's protocol (Nobel Biocare, Göteborg, Sweden) were performed on the planning model. The implant bed preparations were done for two implants, each of the types NobelReplace™ Tapered NP (narrow platform: 3.5×10 mm), NobelReplace™ Tapered RP (regular platform: 4.3×10 mm), and

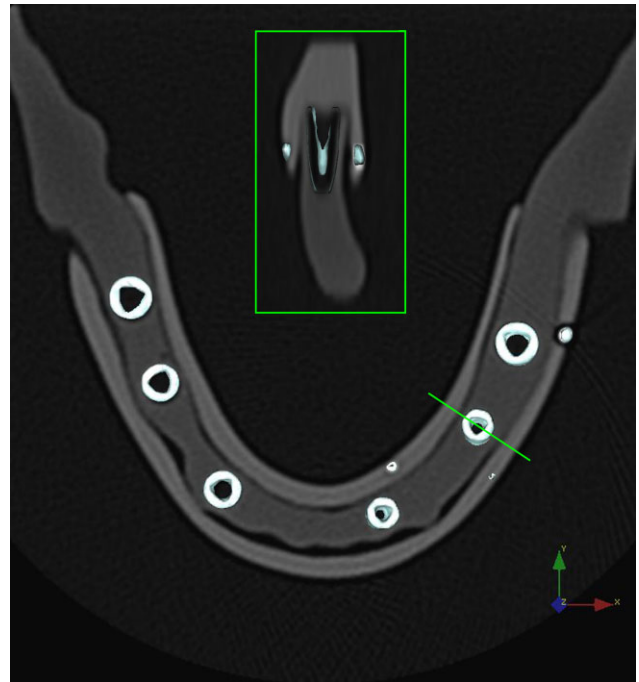


Figure 1 Merged DICOM data sets showing the preoperative artificial mandible with the postoperative segmented implant positions (Procera® software; Triple Scan Technique).

NobelReplace™ Tapered WP (wide platform: 5×10 mm) (Figure 1). According to the NobelGuide protocol and based on the planning model, a computed tomography (CT) template with appropriate fiducial markers as reference points was fabricated from gutta-percha (1×1.5 mm). Using the double scan technique,¹⁴ preoperative low-dose, high-resolution multislice CT scans (Tomoscan SR-6000, Philips Medical Systems, Eindhoven, The Netherlands) of the planning model and the template were performed. Both CT scans were performed according to the NobelGuide protocol with a slice thickness of 1 mm and a voxel size of 0.5 mm.

Planning Procedure

The DICOM data collected for the planning model and the CT template were converted and merged in the Procera® planning software (Version 2.2, Nobel Biocare) for imaging the synthetic bone and the template for three-dimensional preoperative implant positioning. The fiducial markers were used to relate the CT template to the planning model, which is essential for accurate planning. Based on the implant bed preparations of the planning model, the virtual positioning of the corresponding implants was performed. According to the

NobelGuide™, three additional anchor pins for the stabilization of the template were planned. The finalized planning data were electronically transferred to a certified manufacturing facility (Nobel Biocare) for the production of a stereolithographic surgical template with appropriate guide sleeves manufactured.

Surgical Procedure

Using the NobelGuide™ template, all 10 surgical procedures were performed by one experienced surgeon (C.V.). After verifying the precise seat of the surgical template, the fixation with the anchor pins was performed. Guided implant bed preparation and subsequent implant placement were carried out in strict compliance with NobelGuide™ guidelines under continual monitoring of the accurate seat of the surgical template.

Postsurgical Procedure

After experimental implant placement, all 10 dummy mandibles were again scanned with CT using the same image acquisition parameters and the same device as for the preoperative examination. For merging the pre- and postoperative DICOM data sets, three different fusion methods were used. The Triple Scan Technique⁴ and NobelGuide™ Validation software (Version 2.0.0.4, Medicim/Nobel Biocare) were applied to compare the surgical results with the planned implant positions and to further evaluate these two validation methods; the AMIRA® software (Version 5.4, VSG – Visualization Sciences Group, Burlington, MA, USA) was considered as reference.^{15–18} For the Triple Scan Technique and AMIRA®, the fiducial markers on the CT template of the preoperative and postoperative DICOM data were used for the fusion process (Figure 1). With the NobelGuide™ Validation software applying a three-dimensional voxel-based registration, the postoperative data were registered to the preoperative data by the calculation of mutual information between the corresponding voxels in the two data sets (Figure 2).¹⁹ Discrepancies between the virtual and the actual implant positions were measured as linear deviations at implant shoulder and implant apex as well as angular deviations between the longitudinal axes of the planned and placed implants (Figures 3 and 4). The metric and angular deviations obtained by the three validation methods were collected in a table and prepared for further statistical evaluation.



Figure 2 Three-dimensional voxel-based registration of the artificial mandibles showing the virtually planned implant positions (NobelGuide™ Validation software).

Statistical Methods

Several descriptive statistics and boxplots were created to show the data. In order to test several hypotheses, a

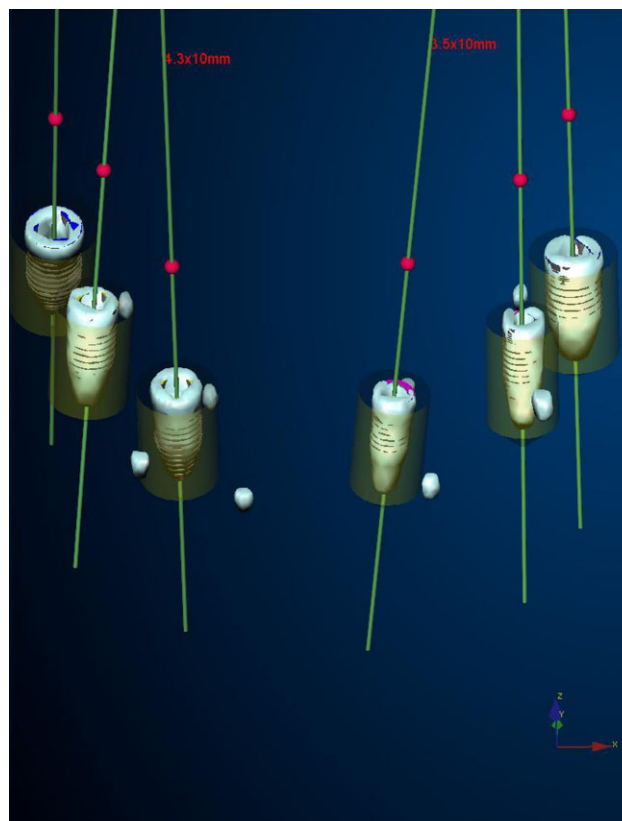


Figure 3 Discrepancies between the preoperative planned implants and the postoperative achieved segmented implants (Procera® software; Triple Scan Technique).

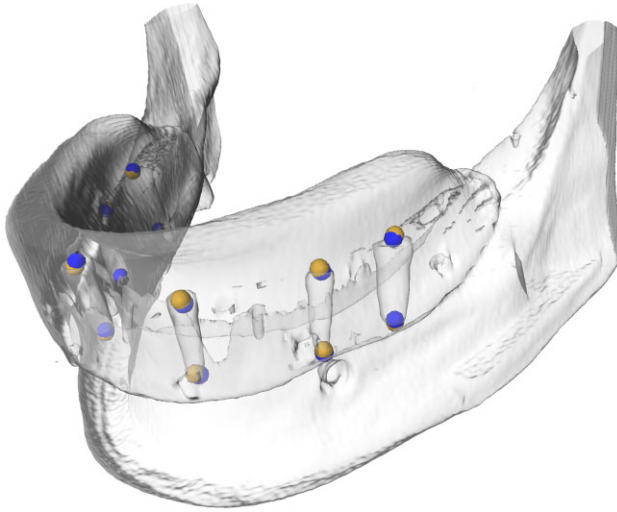


Figure 4 Merged artificial mandibles (AMIRA®) showing the spatial deviations at implant shoulder and implant apex (preoperative: blue; operative: yellow).

linear mixed model²⁰ including implant as a random effect and a fixed effect for implant diameter was computed. To correlate implant angle and implant apex, Pearson's r was applied. For an assessment of the reliability of different validation procedures, intraclass correlation (ICC) (3,1) was calculated.²¹ All p values were Bonferroni corrected; p values $< .05$ were considered significant. R 2.15.1 and ggplot2 were used for all calculations and graphics, respectively.^{22,23}

RESULTS

The stereolithographic surgical template provided a precise and stable seat on all dummy mandibles operated. All guided drillings with consecutive guided implant placements were performed according to the manufacturer's surgical protocol. For the measurement

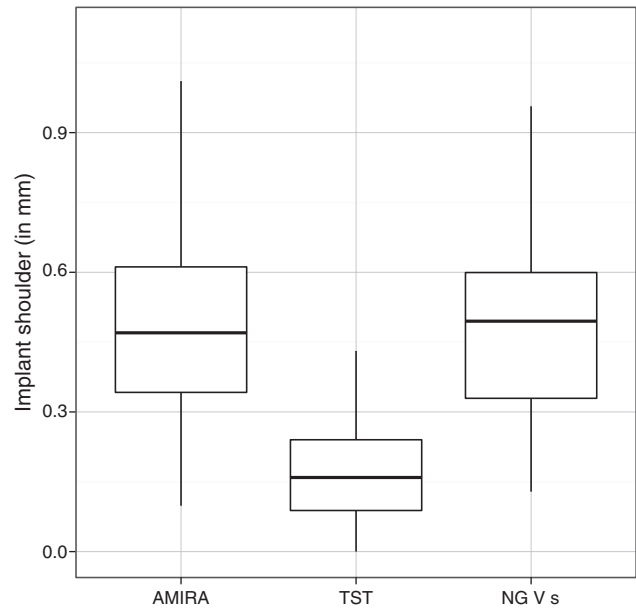


Figure 5 Box plot of the deviations determined by three different validation procedures at the level of the implant shoulder (TST – Triple Scan Technique; NG V s – NobelGuide™ Validation software).

of spatial and angular deviations, all three validation procedures showed reproducible results.

For the three validation methods, spatial deviations at implant shoulder and implant apex as well as angular deviations have been shown as values and box-plots in Table 1 and in Figures 5–7. For the AMIRA®, Triple Scan Technique, and the NobelGuide™ Validation software, the maximum spatial deviation with 1.99 mm, 1.32, and 1.05 mm, respectively, was seen at implant apex. The maximum angular deviations measured by the AMIRA®, Triple Scan Technique, and the NobelGuide™ Validation software were 4.51°, 3.7° and 3.93°, respectively.

TABLE 1 The Mean Values, Standard Deviations, Maximum and Minimum Deviations of the Spatial and Angular Deviations Determined by Three Different Validation Methods at Implant Shoulder, Implant Apex, and along the Longitudinal Axis of the Implants

	Deviations								
	AMIRA			Triple Scan Technique			NobelGuide Validation		
	Implant Shoulder	Implant Apex	Angle	Implant Shoulder	Implant Apex	Angle	Implant Shoulder	Implant Apex	Angle
Mean values	0.49	0.69	1.98	0.17	0.51	1.75	0.50	0.64	1.36
Standard deviation	0.20	0.34	1.00	0.10	0.20	0.88	0.24	0.26	0.80
Maximum deviation	1.01	1.99	4.51	0.43	1.05	3.70	1.11	1.32	3.93
Minimum deviation	0.10	0.16	0.12	0.00	0.05	0.20	0.13	0.18	0.00

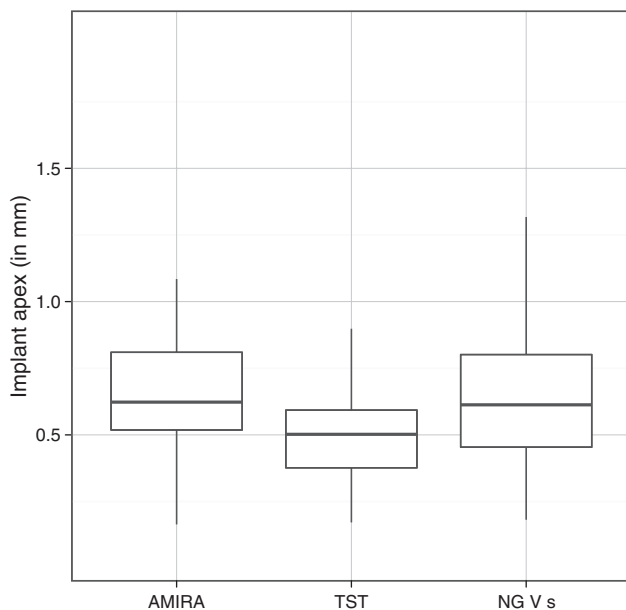


Figure 6 Box plot of the deviations determined by three different validation procedures at the level of the implant apex (TST – Triple Scan Technique; NG V s – NobelGuide™ Validation software).

Statistical analysis applying a linear mixed model to reveal effects for deviations at implant shoulder versus implant apex and for varying implant diameters was performed. It could be shown that a greater implant diameter is significantly related to greater deviations ($p = .03$). No other significances could be observed.

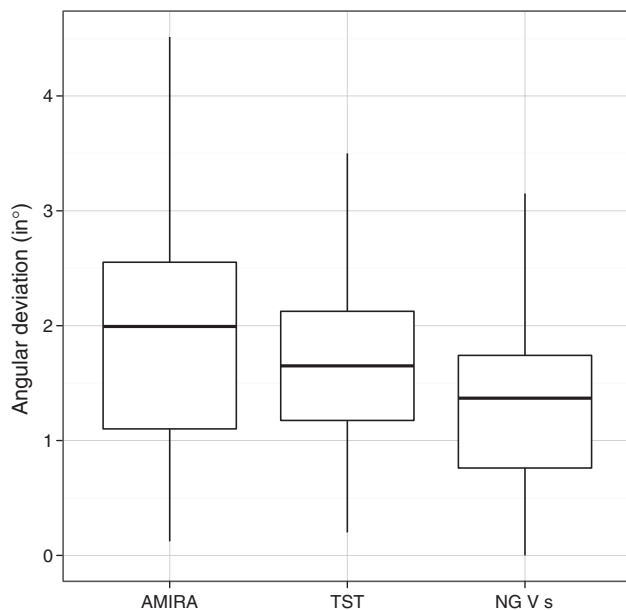


Figure 7 Box plot of the angular deviations determined by three different validation procedures between virtually planned and postoperatively achieved implant axes (TST – Triple Scan Technique; NG V s – NobelGuide™ Validation software).

TABLE 2 Intraclass Correlation (ICC) Coefficient for Spatial and Angular Deviations of the Tested Validation Procedures Showing No Correlation with the Reference Method (AMIRA®)

ICC Coefficient	Implant		Angular Deviation
	Shoulder	Apex	
Triple Scan technique	0.01	0.35	0.36
NG Validation software	0.24	0.32	0.17

The effect of angular deviation on the spatial deviation at implant apex could be confirmed by means of Pearson's r ($r = 0.53$; $p < .001$). From the linear regression, we learned that an increase of an angular deviation results in an average increase in deviation at the implant apex.

Moreover, potential differences in the application of the three validation procedures were statistically evaluated by ICC. The ICC compared the variations of deviation values independent of their height. For both validation procedures tested (Triple Scan Technique and NobelGuide™ Validation software), no correlation with the reference method (AMIRA®) could be observed (Table 2). However, spatial and angular deviations of the Triple Scan Technique and the NobelGuide™ Validation software were similar to the results of the reference method (Table 1).

DISCUSSION

The concept of computer-assisted, template-guided systems is to ensure a precise transfer of preoperative complex planning and, consequently, safe flapless implant placement. Ex vivo and in vivo studies showed certain discrepancies between the virtually planned and postoperative implant positions achieved.^{1,4-8} The accuracy of computer-aided implant dentistry depends on all cumulative and interactive errors involved, from the technical process chain to the surgical procedure.¹⁰ An independent evaluation and measurement of separate errors represent a particular challenge. Therefore, the aim of this study was to evaluate the accuracy of the NobelGuide™ concept without the influence of clinical and surgical parameters. Furthermore, the study was conducted to compare and validate two validation procedures with a reference method (AMIRA®).¹⁵⁻¹⁸

Two main findings were obtained from the results just presented. First, the evaluated concept for

template-guided implant placement showed similar or less spatial and angular deviations compared with others. And finally, the NobelGuide™ Validation software and the Triple Scan Technique as a system-independent validation technique⁴ showed a similar measurement accuracy as the reference method (AMIRA®).

A recent in vitro study of Soares and colleagues on edentulous polyurethane mandibles covered with silicone representing the gingival tissue showed mean spatial deviations of 1.38 ± 0.42 mm and 1.39 ± 0.40 mm for implant shoulder and implant apex, respectively.²⁴ The mean angular deviation measured was $2.16 \pm 0.91^\circ$. For all validation procedures tested (AMIRA®, Triple Scan Technique and NobelGuide™ Validation software), the results of the present study showed less spatial deviations. In a similar experimental study design, Turbush and Turkyilmaz registered significantly higher deviations for mucosa-supported templates compared with tooth- or bone-supported templates as the artificial gingival tissue seems to allow a certain degree of template movement.²⁵ Nevertheless, mean linear deviations for the tooth-supported template (implant shoulder: 1.00 ± 0.33 mm; apex: 1.15 ± 0.42 mm) resulted in higher values compared with our results (shoulder: 0.49 ± 0.20 mm; apex: 0.69 ± 0.34 mm; AMIRA® as reference). However, in the study of Turbush and Turkyilmaz, all implants were planned and placed by a novice clinician, who had never placed implants before.²⁵ This difference on the clinician's level of experience could, to some extent, explain the varying deviations as a significant learning effect could be registered with regard to decrease in deviations.^{4,26} A meta-regression analysis of Van Assche and colleagues on in vitro studies revealed similar mean and maximum deviations compared with ours.²⁷

But what are the factors known so far causing deviations of postoperative implant positions from the virtually planned implant positions in an experimental study design? With respect to different kinds of templates, a system-inherent cause of deviations is the discrepancy between the guiding elements (0.15 – 0.20 mm)²⁶ required for mechanical reasons to ensure adequate implant bed preparation and implant insertion.^{28–30} A recent study of Koop and colleagues testing the impact of guiding tolerance revealed possible maximum coronal, apical, and angular deviations of 0.8 mm, 1.7 mm, and 4.5° , respectively, by maximum

drill inclination for a commonly used sleeve height of 5 mm.³¹ Linear and angular deviations were influenced by the height and the diameter of the sleeve, the type and the height of the sleeve insert, the distance of the sleeve to the bone, and the length of the osteotomy. As a consequence, the statistical analysis of the present study revealed a significant correlation between the angular deviation and the spatial deviation at the implant apex. These results are consistent with the observations of Verhamme and colleagues, who described discrepancies between the guiding elements for the examined NobelGuide™ concept of 0.22 to 0.23 mm.³² In addition, the present study observed significantly greater deviations for greater implant diameters as attrition of guiding sleeves and drills is a cumulative phenomenon.^{31,33}

Apart from surgical factors, technology-related deviations may be due to image data acquisition, processing and fusion of DICOM data, and the manufacturing process of the surgical template.^{13,34} The potential error due to scanning and three-dimensional volume rendering was quantified as 0.25 mm on average.³⁵ Furthermore, no significant differences between cone beam CT- and multislice CT-based three-dimensional images or models showing an appropriate accuracy for computer-aided dentistry were registered by recent studies.^{36–40} Nevertheless, Horwitz and colleagues reported a planning procedure-related inaccuracy of an average of 0.32 to 0.49 mm.³³ The potential manufacturing error of the stereolithographically manufactured surgical template was calculated to be within a range of 0.1 to 0.2 mm.⁴¹ An in vitro study on model-based manufactured templates revealed comparable results.⁴² Even unintentional incorrect settings of ISO values for the segmentation of the scan denture may cause dissimilarities at the stereolithographically manufactured template.⁴³ Therefore, the human error is somehow involved in almost all imaging, planning, and transfer errors, remaining an uncontrollable aspect even in guided implant dentistry.¹⁰

How big is the impact of various validation procedures on the measured deviations? At any rate, a substantial and scientifically comparable validation of different validation procedures requires an established reference method. The present comparative study evaluated the validity of two validation techniques (NobelGuide™ Validation software and Triple Scan Technique as a system-independent validation process) for the first time.

Statistical analysis showed no ICC for the tested validation procedures. However, a correlation of various validation procedures upon variations of deviation values independent of their height will be difficult to achieve as every method provokes its own separate minor inaccuracies.³² Therefore, comparable and reproducible deviation values for all three validation methods seem to be more clinically relevant.

The successful use of guiding templates requires comprehensive knowledge of and experience in using three-dimensional information for the virtual planning of implant position.⁴⁴ The clinician must account for the cumulative error that may be involved in all of the steps leading up to surgery.¹³ For further improvements of template-guided implantation systems, possible errors need to be diagnosed and avoided if possible. However, a reduction of accuracy below 0.5 mm seems to be extremely difficult.²⁷

CONCLUSION

The NobelGuide™ system showed similar or less spatial and angular deviations compared with others. The Triple Scan Technique as a system-independent validation procedure as well as the NobelGuide™ Validation software are in accordance with the AMIRA® software considered as reference.

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