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In-vitro evaluation of the tolerance of surgical instruments in templates for computer-assisted guided implantology produced by 3-D printing

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Abstract

Objective: The aim of this *in-vitro* study was to compare the tolerance of surgical instruments in surgical guides produced by 3-D printing, without metal sleeves to a surgical guide with conventional metal sleeves from two different manufacturers.

Materials and methods: Lateral movements of drill tips caused by tolerance between the sleeve and drill key and between the drill key and the drill were recorded after application of a standardized force to the surgical instruments. Four groups were tested: Control 1 (C1): metal sleeve from commercially available surgical system 1; Test 1 (T1): 3-D-printed sleeve for surgical system 1; Control 2 (C2): metal sleeve from commercially available surgical system 2. Test 2 (T2): 3-D-printed sleeve for surgical system 2.

Results: The mean total lateral movement was 0.75 mm (0.5–1.04 mm) in the C1 group and 0.91 mm (0.54–1.34 mm) in the C2 group. The mean amount of movement from tolerance between sleeve and drill-guiding key was 0.31 mm (range 0.22–0.41 mm) in C1 and 0.42 mm (range 0.29–0.56 mm) in C2. This lateral movement was in mean reduced by 0.24 mm (32%) in T1 and by 0.39 mm (43%) in T2 group. This reduction was statistically significant in both groups ($P < 0.001$).

Conclusion: The tolerance of surgical instruments and the lateral movements of the drills were significantly reduced by the use of 3-D printing with reduced sleeve diameter. This reduction could improve the overall accuracy in computer-assisted template-guided implant dentistry. The lateral movement of the drill can be further reduced by using a shorter drill and a higher drill key. This can be considered during implant planning and CAD/CAM of surgical guides.

Computer-assisted implant planning (CAIP) and template-guided implant placement is a novel technology applying digital technologies in dentistry. In the past, numerous systems for planning and template production have been developed and are commercially available. The introduction of cone-beam computer tomography (CBCT) and its increasing application in the dental field has widened the indication for 3-dimensional radiographic examination, also in connection with preoperative implant surgery planning (Nitsche et al. 2011).

Basically, there are two different workflows for surgical template production. With some systems, the radiographic template containing information on the prosthetic set-up is manually produced by a dental technician. After recording the CT-image and determination of the future implant position in the

planning software, the template is modified with the use of coordinate tools. An instrument guiding metal sleeve is attached in the corresponding position in the surgical guide. During implant bed preparation, this metal sleeve will serve as a guidance for drill-guiding drill keys that will be inserted into the sleeve. Also, the implant mount will be guided by this sleeve during implant insertion.

Other systems use the digital planning data for CAD/CAM production of a surgical guide by rapid prototyping. Usually, the same kind of metal sleeves is incorporated into the guide as in guides produced by a dental technician.

Numerous preclinical and clinical studies reporting on the accuracy of computer-assisted template-guided surgery have been published (Ozan et al. 2009) (Sarment et al.

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2003) (Di Giacomo et al. 2005) (Van Assche, et al. 2007). Systematic reviews on computer-assisted implant dentistry, including studies on accuracy, revealed mean deviations between the planned to the effectively reached implant position of approximately 1 mm at the implant shoulder and 1.5 mm at the apex of the implant (Schneider et al. 2009) (Jung et al. 2009). Possible sources of errors resulting in deviations of the final implant position can be found at various stages within the workflow. Up to date, little knowledge is present on the origin and exact amount of inaccuracies within the different steps of the workflow.

In a recent *in-vitro* study, a marked tolerance of the surgical instruments was reported (Van Assche & Quirynen 2010). In that study, lateral movements of the instrument tip of up to 2.7 mm were recorded if the drills were actively moved within their guides. It is possible that the deviations reported in accuracy studies partially result from unwanted movements of surgical components within their guiding sleeves. Therefore, a reduction in this tolerance could increase the overall accuracy of computer-assisted template-guided implant dentistry.

Recently, 3-D printing has become popular in industrial application. Due to its relatively low costs and its high precision, this technology has also been introduced for surgical guide production from biocompatible acrylate materials. These surgical guides can be designed and/or modified by the use of computer-aided design (CAD) software. This allows to eliminate the incorporation of metal guiding sleeves and possibly to decrease the tolerance between the printed sleeves and the drill-guiding keys.

The objective of this *in-vitro* study is to compare the tolerance of surgical instruments in surgical guides produced by 3-D printing, without metal sleeves to a surgical guide with conventional metal sleeves from two different manufacturers.

Materials and methods

The present study was performed at the facilities of the center for dental medicine of the University of Zürich. It was designed as a controlled *in-vitro* study involving four study groups:

Control group 1

Metal sleeve, drill keys, and drills from the Astra Facilitate Guided Surgery System (Astra Tech Dental, Mölndal, Sweden) were

used in this group. The sleeve height was 4 mm, and the inner diameter was 4.7 mm. Drill-guiding keys were 1, 2, 3, and 4 mm in height, the diameter of the part that is inserted into the sleeve is 4.6 mm. Drills of 18, 22, and 25 mm in length and 3.2 mm in diameter were used (Figs 1 and 2).

Control group 2

Metal sleeve, drill keys, and drills from the Straumann Guided Surgery System (Institut Straumann AG, Basel, Switzerland) were used in this group. The sleeve height was 5 mm, and the inner diameter was 5 mm. Drill-guiding keys were 1 and 3 mm in height, the diameter of the part that is inserted into the sleeve is 4.85 mm. Drills of 16, 20, and 24 mm in length and 3.5 mm in diameter were used (Figs 1 and 3).

Test group 1

3-D-printed sleeves for the drill keys and drills from the Astra Facilitate Guided Surgery System (Astra Tech Dental) were used in this group. The inner diameter of the sleeve was computer designed with a diameter of 4.75 mm. The same instruments were applied as in control group 1. (Figs 1 and 2).



Fig. 1. Study set-up. A standard metal sleeve is incorporated into the left control site; no metal sleeve is present in the printed test site at the right. The same set-up was used for Test 1/Control 1 and Test 2/Control 2, with the respective sleeves corresponding to the surgical system.



Fig. 2. Surgical system used in control 1 and test 1 group: Drills of 18, 22 and 25 mm in length and drill guides of 1, 2, 3, and 4 mm in height were used.



Fig. 3. Surgical system used in control 2 and test 2 group: Drills of 16, 20, and 24 mm in length and drill guides of 1 and 3 mm in height were used.

Test group 2

3-D-printed sleeves for the drill keys and drills from the Straumann Guided Surgery System (Institut Straumann AG) were used in this group. The inner diameter of the sleeve was computer designed with a diameter of 5.02 mm. The same instruments were applied as in control group 2. (Figs 1 and 3).

A T-shaped 4-mm-thick device containing two holes simulating a surgical guide was designed using a CAD Software (Swissmeda medical applications, Zurich, Switzerland) and fabricated from acrylate material (exo-1,7,7-trimethylbicyclo[2.2.1] hept-2-yl acrylate) by 3-D printing (Objet Ltd., Rehovot, Israel) (Fig. 1). The diameter of the hole measured 6.4 mm (C1) or 6.3 mm (C2) at the control site to receive the standard metal sleeve provided by the manufacturer. At the test sites, the diameters of the holes have been designed to receive only the drill-guiding keys without additional metal sleeves. The respective diameters of the holes were 5.7 mm at test 1 (T1) and 5.05 mm at test (T2). The hole diameters at the test sites were evaluated during a pilot study to reduce instrument tolerance but still to ensure adequate handling of surgical drill keys and implant mounts for guided implant placement.

Subsequently, the original metal sleeve provided by the implant manufacturer was pressed and glued into the prefabricated canal at the control sites. Scaled paper was then firmly attached to the device serving as reference in the background for later measurements (Figs 1, 4 and 5).

The printed device containing the test and control sleeves was then firmly attached to a table. Surgical drill keys and drills from standard surgical kits were then inserted into the sleeves according the recommended surgical protocol. The drills were held by a surgical hand piece.

With these instruments in place, a standardized controlled force was applied on the

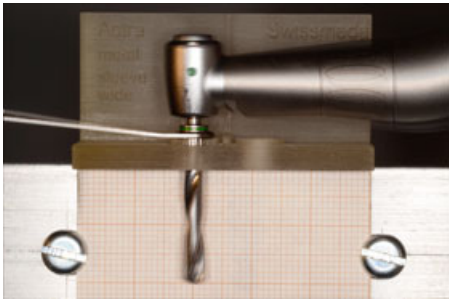


Fig. 4. Superimposed images showing lateral movement of drill, group C1. Drill diameter 3.2 mm, drill key height 1 mm, drill length 25 mm.

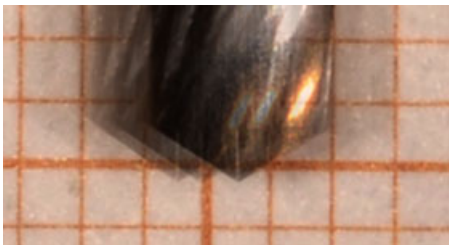


Fig. 5. Superimposed images showing lateral movement of drill, group C1, detail. Magnification $\times 25$.

drill key containing the drill to provoke the maximum lateral movement of the drill tip in the surgical components. Based on the calculation (length of the lever arm \times weight used to perform the movement), a standardized torque of 4.2 Ncm was applied for the lateral movement, both to the left and right. Standardized photographs were taken capturing the position of the bur tip in its mostly deflected position to either side.

The same torque was then applied on the hand piece to provoke movement of the drill within the drill key, without movement of the drill key within the sleeve which was stabilized. Again, a photograph was taken. This way, two measurements could be obtained: One measurement of the movement of the drill keys within the sleeves and another measurement of the movement of the drill within the drill key (Fig. 4).

In the same manner, a series of photographs was taken using different drill key and drill dimensions for all four groups (Tables 1 and 2).

The photographs were imported and superimposed using a software program (Photoshop Elements 6, Adobe). The superimposed semi-transparent images were then imported into another software for linear measurements (ImageJ, National Institute of Health, Bethesda, MD, USA). Calibration of the length measured within the software was performed using the scaled paper in the background of each photo-

graph. After applying $\times 25$ magnification, measurements of the lateral deviation at the tip of the surgical drill were performed in the software (Fig. 5). Movements resulting from tolerance between the drill key and the sleeve as well as the drill and the drill key were measured. The total movement was calculated by adding these two values. The relative amount of the movement within the components was calculated in relation to the total movement.

Descriptive statistics were applied to quantify the amount of lateral movements resulting from tolerance of the drill key in the sleeve and the drill in the drill key for all four groups. SPSS Version 20 (IBM, Armonk, NY, USA) was used for statistical analysis and Prism Version 6 (Graph Pad Software, La Jolla, CA, USA) to generate graphs. In addition, the proportion of the drill key movement within the sleeve was calculated for the whole lateral movement of the instruments in all groups. Nonparametric Wilcoxon signed-rank test for matched pairs was applied for evaluation of the reduction in instrument tolerance of the test with respect to the control group as measured by tolerance drill key-to-sleeve. Results of statistical analysis with P -values < 0.05 was considered statistically significant.

Results

The results of the measurements are summarized in Tables 1 and 2 and Figs 6–9. The lateral movements of the tip of the drills were dependent on the drill length and the drill key height. The longer the drill and the shorter the drill key, the more pronounced were the lateral movements.

In control group 1 ($n = 12$), the mean lateral movement of the tip of the drill caused by tolerance between drill key and sleeve amounted to 0.31 mm (median 0.32, range 0.22–0.41 mm). This means a relative tolerance of 42% of the total instrument tolerance (i.e., amount of movement of drill in drill key plus amount of movement of drill key in sleeve). The movement of the drill within the drill key was in mean 0.44 mm (median 0.45, range 0.28–0.63 mm). The mean total lateral movement resulted in 0.75 mm (median 0.76, range 0.5–1.04 mm).

In the test 1 group ($n = 12$), the mean tolerance between drill key and sleeve was 0.04 mm (median 0.05, range 0.01–0.08 mm). This is equivalent to 9% of the total instrument tolerance. The movement of the drill within the drill key was in mean 0.46 mm (median 0.49, range 0.27–0.65 mm). The

mean total instrument tolerance amounted to 0.51 mm (median 0.53, 0.34–0.69 mm). Compared with the control group 1, the total lateral tolerance in the test 1 group was significantly reduced by 0.24 mm or by 32% ($P < 0.001$) with 95% CI (0.20 and 0.28 mm) and minimum 0.16 mm and maximum 0.35 mm.

In the control group 2 ($n = 6$), the mean lateral movement of the tip of the drill caused by tolerance between drill key and sleeve amounted to 0.42 mm (median 0.41, range 0.29–0.56 mm). This means a relative tolerance of 47% of the total instrument tolerance. The movement of the drill within the drill key was in mean 0.49 mm (median 0.46, range 0.25–0.77 mm). The mean total lateral movement resulted in 0.91 mm (median 0.89, 0.54–1.34 mm).

In the test 2 group ($n = 6$), the mean tolerance between drill key and sleeve was 0.03 mm (median 0.03, range 0.02–0.04 mm). This is equivalent to 7% of the total instrument tolerance. The movement of the drill within the drill key was in mean 0.49 mm (median 0.46, range 0.25–0.77 mm). The mean total instrument tolerance amounted to 0.52 mm (median 0.50, 0.3–0.81 mm).

Compared with the control group 2, the total lateral tolerance in the test 2 group was again significantly reduced by 0.39 mm or by 43% ($P = 0.03$) with 95% CI (0.26 and 0.54 mm) and minimum 0.24 mm and maximum 0.53 mm.

Discussion

The present *in-vitro* study showed that the tolerance of surgical instruments and therefore the amount of lateral movement of drills can be significantly reduced by using a modified protocol for surgical guide production. This protocol includes CAD and the use of 3-D printing for surgical guide production without the use of any metal sleeves and with a more intimate contact between the guide and the drill-guiding drill key. The amount of lateral movement due to tolerance between the sleeve and the drill key was reduced by 32% in test 1 group and by 43% in test 2 group.

For geometric reasons, the amount of lateral movement at the tip of the drill also depends on the length of drills and drill keys. A longer guiding channel was found to be reducing the angular deviations of implants in an *in-vitro* investigation (Choi et al. 2004). Based on the lever principle, longer drills exhibit more lateral movement. Longer drill keys lead to a longer guidance of the drill

Table 1. Mean lateral tolerance in group T1 and C1 indicated in millimeters

	Metal sleeve (group C1)	% of total tolerance (%)	Printed sleeve (group T1)	% of total tolerance (%)
Drill key-sleeve				
Drill 18 mm				
Drill key 1 mm	0.27	36	0.02	4
Drill key 2 mm	0.26	38	0.04	9
Drill key 3 mm	0.24	43	0.01	3
Drill key 4 mm	0.22	44	0.03	8
Drill 22 mm				
Drill key 1 mm	0.37	41	0.03	5
Drill key 2 mm	0.33	43	0.06	11
Drill key 3 mm	0.30	43	0.05	11
Drill key 4 mm	0.29	45	0.06	13
Drill 25 mm				
Drill key 1 mm	0.41	39	0.06	9
Drill key 2 mm	0.36	41	0.07	10
Drill key 3 mm	0.35	43	0.04	8
Drill key 4 mm	0.34	43	0.08	13
Mean	0.31	42	0.04	9
Drill-drill key				
Drill 18 mm				
Drill key 1 mm	0.48	64	0.49	96
Drill key 2 mm	0.41	62	0.42	91
Drill key 3 mm	0.31	57	0.33	97
Drill key 4 mm	0.28	56	0.32	92
Drill 22 mm				
Drill key 1 mm	0.53	59	0.53	95
Drill key 2 mm	0.44	57	0.48	89
Drill key 3 mm	0.39	57	0.40	89
Drill key 4 mm	0.35	55	0.37	87
Drill 25 mm				
Drill key 1 mm	0.63	61	0.63	91
Drill key 2 mm	0.51	59	0.58	90
Drill key 3 mm	0.47	57	0.52	92
Drill key 4 mm	0.45	57	0.50	87
Mean	0.44	58	0.46	91
Total				
Drill 18 mm				
Drill key 1 mm	0.76	100	0.51	67
Drill key 2 mm	0.67	100	0.46	69
Drill key 3 mm	0.55	100	0.34	62
Drill key 4 mm	0.50	100	0.34	68
Drill 22 mm				
Drill key 1 mm	0.90	100	0.56	62
Drill key 2 mm	0.76	100	0.54	70
Drill key 3 mm	0.69	100	0.45	65
Drill key 4 mm	0.64	100	0.42	66
Drill 25 mm				
Drill key 1 mm	1.04	100	0.69	67
Drill key 2 mm	0.87	100	0.65	74
Drill key 3 mm	0.82	100	0.56	68
Drill key 4 mm	0.79	100	0.58	74
Mean	0.75	100	0.51	68

within the drill key, and therefore, the lateral movement of the drill is reduced. Also, the movement between the drill key and the sleeve seems to be reduced by increasing drill key height. However, this is related to the fact that the drill length is virtually reduced by the amount of the sleeve height. In summary, the amount of lateral movement could be reduced by the use of shorter drills and higher drill keys in all four groups. Other components possibly influencing the movement, the height of the guiding sleeve and its distance from the prospective implant shoulder were not evaluated in the present

study. Keeping in mind the geometric aspects, less movement will result if the sleeve is positioned more apically and closer to the future implant shoulder. However, the apical position of the sleeve is limited due to possible interference of the sleeve with the mucosa or the alveolar bone.

The movements of the surgical instruments in this study were provoked in the full range allowed by the components. In clinical use, the instruments are usually held in a more passive, central position. Under simulated ideal conditions, a recent *in-vitro* study comparing the influence of different heights

of guides on accuracy of implant placement did not show significant differences between 4, 6, and 8 mm high guidance, if instruments were kept in central position within the surgical components (Park et al. 2009). In some situations, however, a passive guidance of the instruments may be difficult or impossible. This includes limited access and difficult insertion of the instruments due to impaired mouth opening. When drilling on oblique cortical surfaces, like on partially resorbed alveolar ridges or incompletely healed alveolae, instruments can also be deflected from their central position. Therefore, the investigational set-up is realistic and may be representative to many clinical situations. However, the impact on clinical outcomes using the presented altered manufacturing protocol for surgical guides still has to be investigated in a clinical study.

An important fact is that up to now, it remains unclear to what extent a deviation of the actually reached implant position from the planned position can be acceptable, as the impact of deviation depends on the anatomic situation, tooth, or gap size, prosthetic aim, etc.

One of the advantages of computer-assisted, template-guided implant dentistry is the instrument guidance during implant bed preparation and implant insertion. Therefore, its use has been suggested to be indicated in situations, where manual free-hand drilling is difficult, for example, in the anterior esthetic zone with incomplete alveolar healing or alveolar ridge resorption (Hammerle et al. 2009). The lower the tolerance of the surgical components would be, the better guidance would result. The tolerance between the rotating drills and the drill keys can hardly be reduced due to mechanical friction and debris. However, the tolerance within the sleeves bears the potential for reduction. A certain degree of tolerance, however, has to be maintained to ensure proper insertion of the drill keys and to allow rotation of the implant mounts. The amount of tolerance depends on the surgical system used.

With the use of CAD and 3-D printing, this tolerance can be easily modified according to the used surgical components. Among the various options in rapid prototyping, 3-D printing has several advantages. Compared with other technologies in rapid prototyping (e.g., stereolithography, milling, selective laser sintering, etc.), it is relatively low priced and therefore could be used even in smaller institutions such as dental laboratories or dental practices. With the printer used in the present investigation, a slice thickness

Table 2. Mean lateral tolerance in group T2 and C2 indicated in millimeters

	Metal sleeve (group C2)	% of total tolerance (%)	printed sleeve (group T2)	% of total tolerance (%)
Drill key–sleeve				
Drill 16 mm				
Drill key 1 mm	0.34	44	0.02	5
Drill key 3 mm	0.29	53	0.04	12
Drill 20 mm				
Drill key 1 mm	0.43	40	0.02	4
Drill key 3 mm	0.40	51	0.04	10
Drill 24 mm				
Drill key 1 mm	0.56	42	0.04	5
Drill key 3 mm	0.51	51	0.04	7
Mean	0.42	47	0.03	7
Drill–drill key				
Drill 16 mm				
Drill key 1 mm	0.42	56	0.41	95
Drill key 3 mm	0.25	47	0.26	88
Drill 20 mm				
Drill key 1 mm	0.64	60	0.59	96
Drill key 3 mm	0.38	49	0.40	90
Drill 24 mm				
Drill key 1 mm	0.77	58	0.76	95
Drill key 3 mm	0.49	49	0.51	93
Mean	0.49	53	0.49	93
Total				
Drill 16 mm				
Drill key 1 mm	0.76	100	0.43	57
Drill key 3 mm	0.54	100	0.30	55
Drill 20 mm				
Drill key 1 mm	1.06	100	0.61	57
Drill key 3 mm	0.78	100	0.44	56
Drill 24 mm				
Drill key 1 mm	1.34	100	0.81	60
Drill key 3 mm	1.00	100	0.55	55
Mean	0.91	100	0.52	57

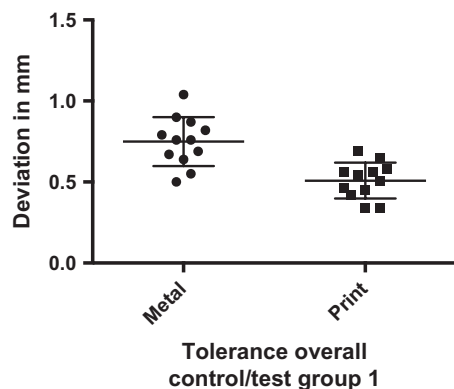


Fig. 6. Overall instrument tolerance (drill within drill key and drill key within sleeve) in millimeters, measured as lateral movement of the drill tip. The chart includes the movement for all lengths of drills and drill keys in each group. Control 1 group on the left and test 1 group on the right. The difference between groups is statistically significant ($P < 0.001$).

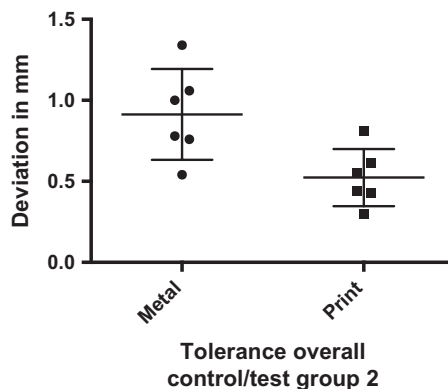


Fig. 7. Overall instrument tolerance (drill within drill key and drill key within sleeve) in millimeters, measured as lateral movement of the drill tip. The chart includes the movement for all lengths of drills and drill keys in each group. Control 2 group on the left and test 2 group on the right. The difference between groups is statistically significant ($P = 0.03$).

of 16 μm can be achieved resulting in a high printing resolution. A large variety of acrylic materials with different colors and mechanical properties can be used, and objects made from several materials can be printed, including biocompatible materials. This technology has the potential for widespread use for medi-

cal and nonmedical application. It has already been used for manufacturing of orthognathic splints (Metzger et al. 2008) and models for craniomaxillary anatomy reconstruction (Silva et al. 2008) (Ibrahim et al. 2009).

The conclusions based on the present study are limited due to its *in-vitro* design. It

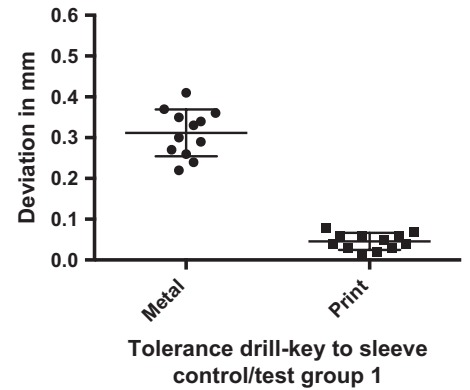


Fig. 8. Instrument tolerance resulting from movement of drill key within sleeve in the control 1 group (left) and test 1 group (right). ($P < 0.001$)

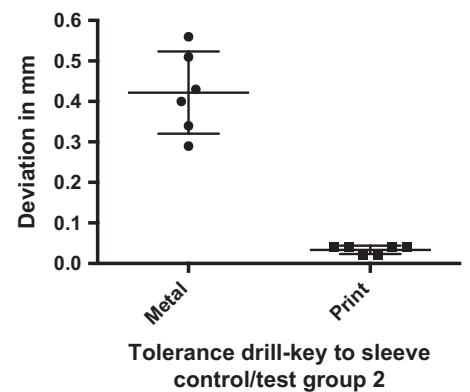


Fig. 9. Instrument tolerance resulting from movement of drill key within sleeve in the control 2 group (left) and test 2 group (right). ($P < 0.001$).

remains unknown whether the forces applied on the instruments in the present study are identical with forces occurring in clinical use. Also, only two surgical systems using a similar set-up of surgical instruments were tested. Systems using different surgical instrumentarium might exhibit different lateral tolerance values. Unfortunately, no drills of the same diameter were available from the manufacturers to exclude a possible influence of the drill diameter. Other factors possibly causing deviations like movements caused by improper occlusal or mucosal rest or deformation of the surgical guide were excluded on purpose in the present investigation. In the clinic, these and other factors can further contribute to deviations of the implant position from the initial plan and have to be investigated separately.

Conclusion

The tolerance of surgical instruments and the lateral movements of the drills were

significantly reduced by the use of 3-D printing with reduced sleeve diameter. This reduction could improve the overall accuracy in computer-assisted template-guided implant dentistry. The lateral movement of the drill can be further reduced by using a shorter drill and a higher drill key. This can be considered during implant planning and CAD of surgical guides. Passive fit of drilling instruments should be aimed for during surgery.

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Conflict of interest

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