Accuracy of computer-assisted template-based implant placement using CAD/CAM stereolithographic surgical templates with or without metallic sleeves: a randomized controlled trial

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Randomization

One computer-generated restricted randomization list was created. Only one of the investigators, not involved in the selection and treatment of the patients, was aware of the random sequence and could have access to the randomization lists stored in a password-protected portable computer. The random codes were enclosed in sequentially numbered, identical, opaque, sealed envelopes. Envelopes were opened sequentially after the prosthetic-driven plan was approved.

Statistical analysis

Patient data were collected in a Numbers spreadsheet (Version 3.6.1 for Mac OS X 10.11.4). A bio-statistician with expertise in dentistry analyzed the data using SPSS software for Mac OS X (version 22.0; SPSS Inc., Chicago, IL, USA) for statistical analysis. Descriptive analysis was performed for numeric parameters using mean±standard deviation and median with confidence interval (95% CI). Implant failure and template-related complications between the two groups were compared using Fisher's exact probability test. The mean differences of the overall deviation in the clinical outcomes compared to the virtual plan, were compared between groups using a mixed-model repeated-measures analysis of variance (ANOVA). In the sleeve-less group, accuracy of open versus closed holes were also evaluated. All statistical comparisons were conducted with a P value set at 0.05.

Results

Thirty-two patients were considered eligible for this trial. Two patient was not included due to them not wanting to participate in this study. No patient dropped out, and all patients were treated according to the allocated interventions.

Fifteen patients (8 female and 7 male with a mean age of 45.1 years) were randomised to the control group (template with metallic sleeves) and 15 (10 female and 5 male with a mean age of 55.2 years) to the test group (without metallic sleeves). A total of 37 implants were placed in the control group while 43 implants were placed in the test group. Of these, 12 implants were placed through open sleeves and 31 through closed sleeves.

No implants failed and no complications were experienced. All the implants were inserted according to the manufacturer's instructions, with an insertion torque ranged between 35 an 45 Ncm.

In the control group, the analysis of the final implant accuracy revealed a total mean error of 2.25±1.41° (range 0.3–5.0°; 95% CI 0.52 to 1.65°) in angle; 0.52±0.30 mm (range 0.1–1.1 mm; 95% CI 0.39 to 0.61 mm) in the horizontal plan (mesio-distal), and 0.58±0.44 mm (range 0.0–1.6 mm; 95% CI 0.44 to 0.76 mm) in the vertical plan (apico-coronal).

Overall, in the test group, the analysis of the final implant accuracy revealed a total mean error of 1.61±1.90° (range 0.1–6.8°; 95% CI 0.17 to 1.31°) in angle; 0.54±0.41 mm (range 0.05–1.7 mm; 95% CI 0.31 to 0.55 mm) in the horizontal plan (mesio-distal), and 0.37±0.27 mm (range 0.0–1.3 mm; 95% CI 0.23 to 0.39 mm) in the vertical plan (apico-coronal).

Sub group analysis relieved a mean error in angle of 2.89±2.36° (range 0.2–6.8°; 95% CI 1.41 to 4.09°) with open sleeves and 1.20±1.43° (range 0.1–5.9°; 95% CI 0.2 to 1.2°) with closed sleeves; the differences was statistically significant (P = 0.0357). In the horizontal plan (mesio-distal), the mean error was 0.73±0.49 mm (range 0.2–1.5 mm; 95% CI 0.37 to 0.93 mm) with open sleeves and 0.49±0.38 mm (range 0.05–1.7 mm; 95% CI 0.27 to 0.53 mm) with closed sleeves; the

difference was not statistically significant (P = 0.1553). In the vertical plan (apico-coronal), the mean error was 0.43±0.34 mm (range 0.0–1.0 mm; 95% CI 0.16 to 0.54°) with open sleeves and 0.33±0.25 mm (range 0.05–1.3 mm; 95% CI 0.21 to 0.39 mm) with closed sleeves; the difference was not statistically significant (P = 0.4048).

Comparing the mean value of the control group (closed metallic sleeves) with mean value of the closed sleeves of the test group. There was a statistically significant difference in angle (P = 0.0063) and in the vertical plan (P = 0.0126) with lower values in the test group. While, there was not statistically significant difference in the horizontal plan (P = 0.7546).

Conclusions: With the limitation of the present randomized controlled trial, intraoral digital impression may be a viable option for the rehabilitation of partial edentulous patients when computer-guided template-assisted implant placement is used. Furthermore, intraoral digital impression reduces the number of appointments, resulting in shorter treatment time. In both groups, the maximum tridimensional deviations (angular, horizontal, vertical) did not exceed the safe offset of the software.

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Figure 1. Virtual implant planning.

Figure 2. Post-operative STL file derived from the intraoral scan

Figure 3. Geometrical alignment of the files exported from the planning, and the post-operative STL file by automated image registration.

Figure 4. The horizontal (lateral), vertical (depth) and angular deviation between virtual and placed implants calculated along the long axis of each implants.

Figure 5. Maximum angular deviation calculated according to the implant diameter and length.

Tables

Table 1. Main patient and implant characteristics.			
	Conventional (n=29)	Digital (n=28)	P value
Age	45.4±13	43.7±15.7	0.795
Female patients	5	6	1
Implants placed in the maxilla	18	15	0.596
Immediately loaded i plants	13	11	0.790
Post-extractive implants	4	1	0.352
Sinus lift procedures	2	1	1
Complete restorations	3	1	0.611
Partial restorations	3	2	1
Single restorations	7	18	0.003

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