

## Guided versus freehand single implant placement: A 3-year parallel randomized clinical trial

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### ABSTRACT

**Objectives:** The present parallel randomized clinical trial aimed to assess, after a 3-year follow-up period, whether the choice of surgical technique—either manual or guided—and of the operator - non-expert operator or skilled - can affect the stability of peri-implant marginal bone levels in implants placed 1 mm sub-crestal.

**Materials and methods:** Patients received platform-switched implants (Anyridge, MegaGen Implant Co., Gyeongbuk, South Korea) featuring a 5-degree internal conical connection and supporting single screw-retained fixed crowns. The implants were randomly assigned to be placed through a digitally static guided surgery procedure (Test group - GS) or a freehand surgical technique (Control Group - FH). A non-expert operator (fewer than 20 implants placed in his professional activity) was selected to perform procedures for the GS Group, while a skilled operator (with over 1000 implants placed in his professional activity) was chosen for the FH Group. Marginal bone level (MBL) was measured at prosthesis installation (t0) and at 1 (t1), 2 (t2) and 3 years (t3) of follow-up. Changes in MBL from t0 to t3 were analyzed through periapical radiographs. Moreover, MBL changes at all time points were correlated to different supra-crestal soft tissue heights (STH): less than 3 and  $\geq 3$  mm, respectively.

**Results:** 60 implants in 18 patients were examined, with 30 implants allocated to the GS group and 30 to the FH group. The difference in MBL change between the two groups was  $0.11 \pm 0.22$  mm, which was not statistically significant ( $p = 0.61$ ). At the time of prosthetic loading, the mean MBL for implants with STH less than 3 mm was 0.33 mm higher than implants with STH  $\geq 3$  mm, though this difference was not statistically significant ( $P = 0.065$ ).

**Conclusions:** Digitally static guided implant placement, performed by a non-expert operator, does not limit marginal bone remodeling, when compared to a freehand procedure performed by an experienced operator.

**Clinical significance:** After correct and careful planning, early marginal bone levels (MBL) around conical connection, platform-switched implants placed sub-crestally may be stable in time. Digital planning and surgery have the potential to assist non-expert clinicians in achieving implant placements with comparable outcomes to those performed by experts.

### 1. Introduction

Implant rehabilitations are meticulously tailored to address the

restorative needs of patients while accommodating the unique technical and functional demands of each clinical case, all within the constraints posed by anatomical considerations. The selection of an alveolar bone

**Abbreviations:** MBL, marginal bone level; GS, guided surgery group; FH, freehand group; STH, supra-crestal soft tissue height; CBCT, cone beam computed tomography; 3D, three-dimensional; IAC, implant-abutment connection; EP, emergence profile; EA, emergence angle; STL, Standard Triangulation Language; CAD, computer-aided design; mBI, modified sulcus bleeding index; mPI, modified plaque index; PPD, peri-implant probing depth.

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site of sufficient dimensions and quality, coupled with precise three-dimensional (3D) implant placement, stands as a pivotal factor not only in ensuring the survival and osseointegration of implants but also in achieving the desired biological, functional, and esthetic outcomes in prosthetic reconstructions [1-3]. Failure to do so can cause biological and esthetic issues, and force prosthetic compromises which may lead to mechanical and/or technical complications [2-4].

In recent years, static-guided implant surgery facilitated by surgical guides for implant site preparation and fixture placement has emerged as a promising approach in implantology [5-7].

Through correct three-dimensional (3D) surgical planning within dedicated software based on cone beam computed tomography (CBCT) observations, the ideal position, inclination, and depth of the fixture can be precisely determined [8]. Simultaneously, the incorporation of 3D patient models and diagnostic wax-ups into the planning software enables the preliminary definition of the ideal emergence of the future prosthetic restoration [9]. This information is then translated into physical reality with the realization of a 3D-printed surgical template for implant insertion. [5-7,10]. The advantages of this approach are multiple, including prosthetically-driven implant placement that prevents functional and esthetic compromises, safe surgery that averts any risk for anatomical structures, and the possibility to apply a minimally invasive or flapless procedure with reduced intraoperative discomfort and postoperative swelling and/or pain for the patient [5-7,10]. Furthermore, potentially, another important advantage of static guided surgery is that it may facilitate immediate loading of the positioned implants.

However, certain procedural aspects, such as the risk of reduced irrigation at the surgical stage, may result in damage to the receiving bone during guided surgery procedures [11]. Bone necrosis of the implant site due to lack of irrigation and overheating can cause greater peri-implant bone remodeling compared to conventional freehand implant placement [12]. Notably, a recent systematic literature review concluded that the impact of this risk in guided surgery remains inconclusive due to the lack of medium to long-term clinical data [13].

The design of the prosthetic reconstruction also contributes to the long-term success of implants. The quality of the implant-abutment connection (IAC) is a well-known key factor influencing marginal bone loss (MBL) [14]. Micro-gaps within the connection provide sites for dental plaque aggregation and maturation, potentially compromising peri-implant tissue health [14]. Moreover, micromovement due to an imperfect fitting [15] and abutment disconnection and reconnection [16] can further exacerbate this issue. Poorly designed superstructures with a suboptimal emergence profile (EP) can also favor plaque accumulation and impede oral hygiene measures, increasing the risk of developing peri-implant disease [17,18]. In addition, cemented implant restorations are 3.6 times more prone to peri-implantitis compared with screw-retained ones [19]. This is mainly attributed to the risk of leaving excess cement in the sub-mucosal region, especially if resin luting agents are utilized [19]. Hence, deep sub-mucosal margins should be avoided to ensure adequate visibility and access for cement removal [20]. Finally, bone-level implant designs, combined with convex restorations at an angle exceeding 30°, significantly increase the risk of peri-implantitis [18]. An interproximal emergence angle (EA) of  $\leq 30^\circ$  and a buccal EA between 30° and 45° are deemed more suitable to limit peri-implant bone resorption [21,22].

In light of these considerations, the present prospective randomized controlled trial aims to evaluate the Marginal Bone Level (MBL) changes around implants placed by an inexperienced operator using a surgically static-guided protocol in comparison to implants placed freehand by an experienced clinician. The null hypothesis is that the surgical technique does not influence the outcome. Additionally, the study aims to investigate the relationship between supra-crestal tissue height (STH) and marginal bone level changes.

## 2. Materials and methods

### 2.1. Patient selection and assessment

The present study is a parallel randomized controlled trial reported in accordance with CONSORT (CONsolidated Standards of Reporting Trials) guidelines. A single experienced operator conducted patient recruitment and treatment between January 2020 and May 2021 at the university dental clinic. The study protocol was designed in agreement with Helsinki Declaration recommendations for investigations on human subjects (as revised in Fortaleza 2013). Ethical approval was obtained from the relevant ethical committee (Prot. No. EC 1564/18), and the study protocol was retrospectively registered in a public registry of clinical trials ([www.clinicaltrials.gov](http://www.clinicaltrials.gov) — NCT06250621). All enrolled patients provided written informed consent after receiving comprehensive information regarding the objectives of the study and its protocol, including alternatives and associated risks.

Patients eligible for inclusion were those requiring implant fixed rehabilitation at one or more sites and meeting the following criteria:

1.  $\geq 18$  years of age;
2. Need for implant placement therapy in the posterior area (from the second premolar to the second molar) due to a failing tooth;
3. Presence of adjacent and opposing natural teeth;
4. Sufficient mesial-distal and interocclusal space for placement of the implant and definitive restoration;
5. Sufficient apical bone to achieve a minimum primary stability of 30Ncm.

The exclusion criteria were:

1. Diagnosis of periodontal disease;
2. Medical or general contraindications for the surgical procedure, such as systemic diseases, history of head and neck radiation therapy, current steroid treatment, neurological or psychiatric conditions affecting oral hygiene, immune-compromised status, severe clenching, or bruxism;
3. Heavy smoking ( $>10$  cigarettes/day);
4. Active infection at the implant site.

Implant site selection criteria included a minimum bone availability of 1 mm of residual buccal and lingual bone and a minimum bone height of 10.5 mm, allowing the placement of an implant with a length of at least 8.5 mm. The implant diameter was chosen to maintain at least 1.5 mm of bone between the fixture and adjacent tooth, with a horizontal space of 3 mm between two adjacent implants. More detailed inclusion and exclusion criteria are reported in Tables 1 and 2.

Sample size was calculated via Monte-Carlo simulation ( $B = 1000$ ) assuming a hierarchical model with implants nested within patients. Outcome was simulated from a Gaussian distribution with residual standard deviation of 0.35 mm. The main effect of interest was the differential MBL variation from baseline to one year in the two groups (time\*group interaction term), which was assumed to be at least 0.45 mm. The simulated model assumed a single random term (standard deviation intercept = 0.3). The number of implants within patient was simulated using a zero-truncated Poisson distribution (approximately 1 to 8 implants per patient range). A total of 60 implants allowed a power of at least 95% at a 5% significance level.

An independent investigator (AP), not involved in patient treatment, prepared a computer-generated randomization list using a balanced, randomly permuted block algorithm, assigning the implants to the different groups (Test and Control). Randomization codes were enclosed in numbered, identical, sealed, opaque envelopes. Treatment allocation was concealed to the operators in charge of enrolling and treating the patients of the present trial.

**Table 1**  
Inclusion criteria of the study.

Inclusion Criteria
Age between 18 and 70 years
Absence of mandibular and/or maxillary atrophy
Partial edentulism of at least one pair of elements
A minimum amount of residual bone of 5 mm in thickness and 10 mm in height
Presence of an antagonistic element with respect to the tooth to be rehabilitated

**Table 2**  
Exclusion criteria of the study.

Exclusion Criteria	
Systemic	Local
Systemic diseases and metabolic deficits	Untreated periodontitis
Leukocyte dysfunction/deficiency	Bruxism condition or clenching habit
Blood disorders	Habitual oral infections
Hemophilia	Mucosal disorders (erosive lichen planus)
Dicoumarolic drug therapy	Oral lesions (ulcers, malignant lesions)
Neoplasms resulting in chemotherapy and/or radiation therapy in the head and neck district	Inadequate oral hygiene
Chronic renal and liver diseases	Poor compliance
Bone metabolism disorders	
Ongoing pregnancy and/or lactation.	
Habitual smokers (greater than 10 cigarettes per day)	
Need for bone augmentation with autogenous bone for implant placement	

## 2.2. Surgical procedures

The pre-operative evaluation comprised panoramic and peri-apical radiographs as initial assessments of bone quantity before implant placement. Additionally, a cone beam CT scan was conducted as a secondary examination to ensure accurate and prosthetically guided implant placement. For each planned implant, an STL digital file was obtained to create a tooth-retained template for surgically guided placement. The R2Gate (Megagen implants, Daegu, South Korea) digital workflow was used to create the surgical template for guided implant placement.

On the day of surgery, an independent investigator opened the randomization envelope for each implant site and communicated the assigned treatment to the surgeon. Envelopes were opened only after flap reflection. All patients received the same implant system (Anyridge, MegaGen Implant Co., Gyeongbuk, South Korea), following a two-stage protocol. Implants were then placed using either a template for a static guided surgery approach (GS Group) or a standard freehand surgical approach without additional devices (FH Group). A non-expert operator (fewer than 20 implants placed in their professional activity) was selected to perform procedures for the GS Group, while a skilled operator (with over 1000 implants placed in their professional activity) was chosen for the FH Group.

The implants were placed 1 mm below the crestal level [22] as recommended by the manufacturer, maintaining an inter-implant distance of at least 3 mm and/or an interproximal space of 1.5 mm to 3 mm between an implant and the adjacent tooth [23–25]. Supra-crestal soft tissue (STH) measurements were obtained with a calibrated probe after flap elevation. Flaps were repositioned over the implants to allow a submerged healing.

Antibiotics were prescribed for 5 days (amoxicillin/clavulanate 1 g twice daily), alongside ibuprofen 600 mg when required. If requested by patients, removable prostheses or provisional fixed bridges were temporarily used during the healing period. Surgical re-entry was performed three months after the implant placement and trans-mucosal healing abutments were installed.

## 2.3. Prosthetic protocol

Two weeks after surgical stage two, an impression was taken to fabricate screw-retained temporary restorations. Scan Post 9 or 13 mm was used for digital impression (Medit Scanner i500, Seoul, South Korea); the restorations were inserted within a window of one to six weeks post-impression. After 8 to 12 weeks of peri-implant soft tissue conditioning, the definitive impression was obtained by following the same workflow of the provisional restorations and the prosthesis was finalized. All restorations consisted of screw-retained single crowns and were placed in the posterior jaw region, spanning from the second premolar to the second molar. In order to avoid any interference of the prosthetic design on peri-implant tissue stability [26–28], specific emergence profile shapes were incorporated into the crown design [29, 30]. These included a convex esthetic profile to support the gingival margin and establish the cervical morphology of the implant crown, a concave boundary profile apical to the esthetic profile and in direct contact with the peri-implant junctional epithelium tissue, and a straight profile immediately coronal to the implant platform and in direct contact with the peri-implant connective tissue. Additionally, emergence angles (EA) were carefully selected for all definitive restorations [26]. An interproximal EA  $\leq 30^\circ$  and a buccal EA between  $30^\circ$  and  $45^\circ$  were digitally planned using dedicated CAD software (Exocad, Darmstadt

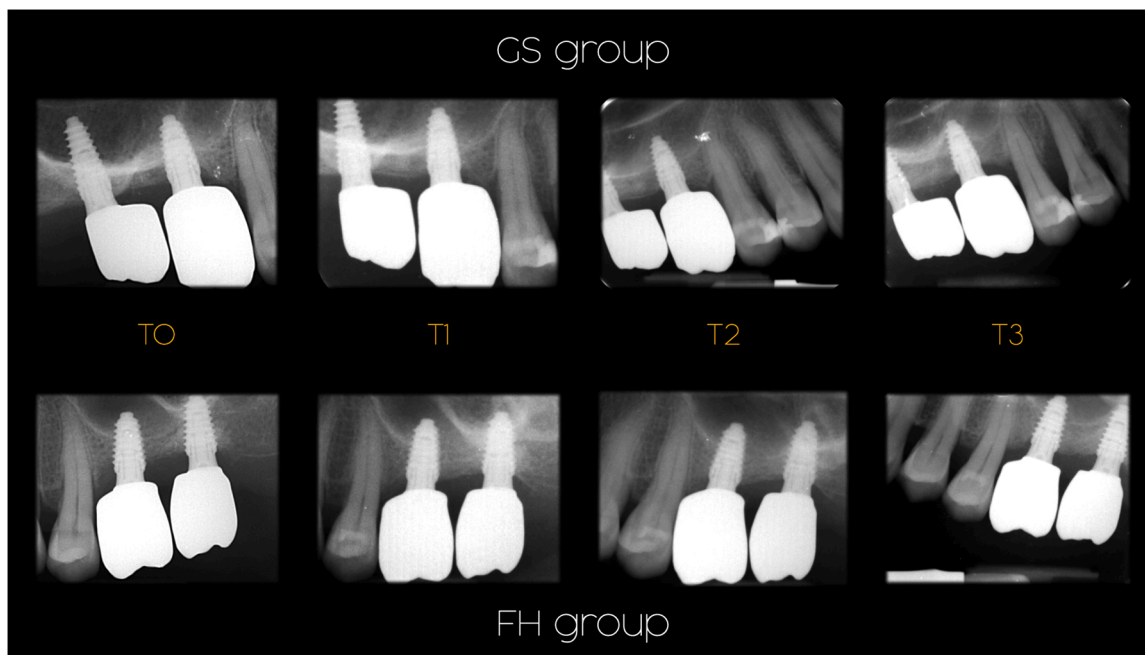
Germany) [26].

All the restorations were inserted with a torque of 25 N/cm using a torque wrench. Following a two-week loading period, patients were recalled for evaluation, during which an intraoral periapical radiograph of the restored implant site was obtained, and peri-implant clinical parameters were assessed.

## 2.4. Radiographic and clinical evaluations

Peri-apical radiographs for Marginal bone level (MBL) measurements were captured using a standardized parallel technique with an X-ray apparatus supplied with a long cone and a Rinn Universal Collimator (Dentsply RINN, York, Pennsylvania). The exposure parameters were 65–90 kV, 7.5–10 mA, and 0.22–0.25 s. The radiographs were stored on a PC and analyzed using software (Image J, National Institute of Health, Bethesda, Rockville, MA, USA). Before measurement, each radiograph was calibrated using the implant diameter and length as reference measures to correct for any distortion. The Marginal Bone Level (MBL) was measured at each implant's mesial and distal aspects using the Image J software. Measurements were reported in millimeters. As the implants were sub-crestally positioned, measurements where the bone was below the implant-to-abutment level were classified as negative values, while measurements where the implant neck was above the bone crest were classified as positive values.

For each implant-supported prosthesis, radiographs taken at the time of prosthetic delivery and at follow-up visits were analyzed and compared to detect any changes in the peri-implant marginal bone level (Figs. 1 and 2). The analysis was conducted for each intraoral periapical radiograph using reference measurements: (i) implant neck diameter and (ii) implant length measured from the implant neck to the most apical point of each implant along an ideal line parallel to the implant axis. Mean MBL values between the mesial and distal aspects were



**Patient 1.** Intraoral X-rays: comparison between guided surgery method (above) and freehand technique (down) after final restoration (T0), at 1-year of follow up (T1), at 2-years of follow up (T2) and at 3-years of follow up (T3).



**Patient 2.** Intraoral X-rays: comparison between guided surgery method (above) and freehand technique (down) after final restoration (T0), at 1-year of follow up (T1), at 2-years of follow up (T2) and at 3-years of follow up (T3).

calculated. Intra-operator reliability was assessed for the emergence angle measurement.

Furthermore, peri-implant soft tissue parameters such as modified Sulcus Bleeding Index (mBI) and modified Plaque Index (mPI) [31,32] were evaluated with a calibrated plastic probe (TPS probe, Vivadent, Schaan, Liechtenstein). Both mBI and mPI scores ranged from 0 to 3, measured at four sites for each implant (mesial, distal, buccal and lingual). Mean values between the mesial and distal aspects were calculated for the mBI and mPI indexes. Mean marginal bone level change (MBL change) was assessed based on different timelines, surgical

techniques and supra-crestal soft tissue heights.

### 2.5. Statistical analysis

The data analysis considered each implant as the statistical unit. Data were described using mean and standard deviation for quantitative variables and counts and percentages for categorical variables. Given the hierarchical structure of the data (i.e., Implants nested within patients), data were modelled using Generalized Linear Mixed Models (GLMM) with a Gaussian family for PPD and MBL and a Poisson



distribution for BOP and PI, expressed as counts within patient. The results are reported as estimates (difference for Gaussian models, rates for Poisson models) and corresponding 95% confidence intervals. All tests assumed a 5% two-sided significance level. All analyses were performed using R (version 4.3.2, R Core Team).

### 3. Results

Eighteen patients (8 males and 10 females) aged from 22 to 84 (mean age:  $55.6 \pm 32.4$  years) were enrolled in the present study. They underwent treatment involving 60 implants and were consecutively monitored over 3 years following the insertion of definitive prostheses. Tables 3 and 4 detail the features of the implants according to the different sizes.

The mean emergence angle (EA) for restorations was  $22.6^\circ \pm 7^\circ$  and  $45.2^\circ \pm 4^\circ$  for interproximal and buccal aspects, respectively. MBL measurements revealed an apical bone remodeling of 0.27 mm, 0.45 mm, 0.47 mm, and 0.56 mm at t0 (prosthetic loading) and after 1, 2, and 3 years of follow-up, respectively (Table 5). Statistical comparisons of MBL at different time points showed no significant differences (P values ranging from 0.07 to 0.89). The mean MBL change after 3 years of follow-up was  $0.35 \text{ mm} \pm 0.47$  and  $0.23 \text{ mm} \pm 0.75$  in the GS and FH groups, respectively (Table 6). The MBL change difference between the two groups after 3 years of follow-up was  $0.11 \text{ mm} \pm 0.22$ , which was not statistically significant ( $p = 0.61$ ) (Table 7).

The variation of MBL in relation to the supra-crestal soft tissue height (STH) was investigated at each time point. For implants with  $\text{STH} < 3$  mm, mean MBL values of 0.18 mm, 0.46 mm, 0.47 mm, and 0.58 mm were measured at t0, t1, t2 and t3, respectively. Meanwhile, for implants with  $\text{STH} \geq 3$  mm, mean MBL values of 0.50 mm, 0.43 mm, 0.44 mm, and 0.51 mm were measured at the corresponding time points (Table 8). At the time of prosthetic loading, the mean MBL for implants with STH less than 3 mm was 0.33 mm higher than implants with  $\text{STH} \geq 3$  mm (Table 9) with a value P value of 0.065. MBL values related to STH over time and comparisons between the GS and FH groups are reported in Tables 10–12, respectively.

In the FH group, mean pocket probing depth (PPD) values of 3.7 mm, 3.9 mm, 4.1 mm and 4.3 mm were measured at t0, t1, t2 and t3 (Table 13). PPD differences between the two groups were not statistically significant at any time point (Table 14). Similar findings were observed for both mPI (Table 15) and mBI indexes (Table 16).

### 4. Discussion

In the recent literature, only two studies analyzed implant placement in static-guided surgery using the R2Gate system, which was employed in the current study. In the first study, Chandran et al. [7] assessed surgical, biological and prosthetic success with the R2Gate system. This innovative guided surgery system demonstrated clinical reliability, with 112 out of 124 initially planned implants (90.3%) successfully inserted through surgical templates in 52 patients. The clinicians reported that the templates used were of very high quality, fit, and stability. Notably, one year after the delivery of the final fixed prosthetic restorations, all implants were in function, resulting in an overall implant survival rate of 100%. In a second study conducted by Chandran et al. [33], the

**Table 3**

Frequency of implant length in GS Group (Guided surgery) and FH Group (free-hand).

	GS	FH	Total
Implant Length (mm)			
7	1 (3%)	1 (3%)	2 (3%)
8.5	5 (17%)	5 (17%)	10 (17%)
10	16 (53%)	16 (53%)	32 (53%)
11.5	8 (27%)	6 (20%)	14 (23%)
13	0 (0%)	2 (7%)	2 (3%)
Total	30	30	60

**Table 4**

Frequency of implant diameter GS Group (Guided surgery) and FH Group (free-hand).

	GS	FH	Total
Implant Diameter (mm)			
3.5	0 (0%)	6 (20%)	6 (10%)
4.0	29 (97%)	23 (77%)	52 (87%)
4.5	1 (3%)	1 (3%)	2 (3%)
Total	30	30	60

**Table 5**

Absolute values of MBL in relation to time (T0, T1, T2, T3) without comparison between GS and FH groups.

time	Media	conf.low	conf.high
T0	-0.27	-0.49	-0.05
T1	-0.45	-0.67	-0.23
T2	-0.47	-0.69	-0.25
T3	-0.56	-0.78	-0.35

**Table 6**

Variation of MBL in relation to time (T0, T1, T2, T3) without comparison between GS and FH groups.

contrast	Media	conf.low	conf.high	p.value
T1 - T0	-0.18	-0.39	0.02	0.0783
T2 - T0	-0.20	-0.40	0.01	0.0582
T2 - T1	-0.01	-0.22	0.19	0.8923
T3 - T0	-0.30	-0.50	-0.09	0.0051
T3 - T1	-0.11	-0.32	0.10	0.2908
T3 - T2	-0.10	-0.30	0.11	0.3569

**Table 7**

Absolute values of MBL in relation to time (T0, T1, T2, T3) and with comparison between GS and FH groups.

FH_GS	time	estimate	conf.low	conf.high
FH	T0	-0.34	-0.57	-0.10
	T1	-0.39	-0.63	-0.16
	T2	-0.48	-0.71	-0.24
	T3	-0.57	-0.81	-0.34
GS	T0	-0.11	-0.48	0.27
	T1	-0.42	-0.80	-0.05
	T2	-0.37	-0.74	0.01
	T3	-0.46	-0.84	-0.09

**Table 8**

Variation of MBL in relation to time (T0, T1, T2, T3) and with comparison between GS and FH groups.

time	contrast	estimate	conf.low	conf.high	p.value
T0	FH - GS	-0.23	-0.65	0.19	0.29
T1	FH - GS	0.03	-0.39	0.45	0.90
T2	FH - GS	-0.11	-0.53	0.31	0.60
T3	FH - GS	-0.11	-0.53	0.31	0.61

**Table 9**

Absolute values of MBL with STH values in relation to time (T0, T1, T2, T3).

STH	time	Media	conf.low	conf.high
<3	T0	-0.18	-0.42	0.06
	T1	-0.46	-0.70	-0.22
	T2	-0.47	-0.71	-0.23
	T3	-0.58	-0.82	-0.34
$\geq 3$	T0	-0.50	-0.84	-0.17
	T1	-0.43	-0.76	-0.10
	T2	-0.44	-0.78	-0.11
	T3	-0.51	-0.84	-0.18

**Table 10**  
Variation of MBL with STH values in relation to time (T0, T1, T2, T3).

time	contrast	Media	conf.low	conf.high	p.value
T0	<3 - ≥3	0.33	-0.02	0.67	0.065
T1	<3 - ≥3	-0.03	-0.38	0.32	0.870
T2	<3 - ≥3	-0.03	-0.37	0.32	0.879
T3	<3 - ≥3	-0.07	-0.41	0.28	0.710

**Table 11**  
Absolute values of MBL with STH values in relation to time (T0, T1, T2, T3) and with comparison between GS and FH groups.

FH_GS	STH	time	Mean	conf.low	conf.high		
FH	<3	T0	-0.17	-0.46	0.12		
		T1	-0.33	-0.62	-0.04		
		T2	-0.41	-0.71	-0.12		
		T3	-0.52	-0.81	-0.23		
	≥3	T0	-0.68	-1.08	-0.29		
		T1	-0.51	-0.90	-0.11		
		T2	-0.58	-0.98	-0.19		
		T3	-0.65	-1.05	-0.26		
		GS	<3	T0	-0.14	-0.54	0.27
				T1	-0.53	-0.93	-0.12
				T2	-0.47	-0.88	-0.07
				T3	-0.58	-0.98	-0.17
≥3	T0		-0.06	-0.55	0.43		
	T1		-0.11	-0.61	0.38		
	T2		-0.05	-0.54	0.44		
	T3		-0.12	-0.61	0.37		

**Table 12**  
Variation of MBL with STH values in relation to time (T0, T1, T2, T3) and with comparison between GS and FH groups.

FH_GD	time	contrast	estimate	conf.low	conf.high	p.value
FH	T0	<3 - ≥3	0.51	0.07	0.96	0.024
	T1	<3 - ≥3	0.18	-0.27	0.62	0.430
	T2	<3 - ≥3	0.17	-0.28	0.61	0.456
	T3	<3 - ≥3	0.13	-0.32	0.58	0.566
GS	T0	<3 - ≥3	-0.08	-0.47	0.32	0.702
	T1	<3 - ≥3	-0.41	-0.81	-0.02	0.041
	T2	<3 - ≥3	-0.42	-0.82	-0.03	0.036
	T3	<3 - ≥3	-0.46	-0.86	-0.07	0.022

**Table 13**  
Absolute values of PPD in relation to time (T0, T1, T2, T3) and with comparison between GS and FH groups.

Tecnique	T0	T1	T2	T3
FH	3.763266	3.880916	4.145622	4.322092
GS	3.665771	3.743899	4.118901	4.337650

**Table 14**  
Variation of PPD in relation to time (T0, T1, T2, T3) and with comparison between GS and FH groups.

contrast	time	Estimate	p-value
FH - GS	T0	0.10 (-0.10; 0.29)	0.33
FH - GS	T1	0.14 (-0.06; 0.33)	0.17
FH - GS	T2	0.03 (-0.17; 0.22)	0.79
FH - GS	T3	-0.02 (-0.21; 0.18)	0.88

accuracy of immediate implant placement in post-extraction sockets using static guided surgery versus the freehand technique was evaluated. The authors concluded that guided implant surgery is significantly more accurate than freehand surgery for immediate implant placement in post-extraction sockets. Interestingly, the guided surgery protocol does not appear to be influenced by the site of the implants in the jaw.

**Table 15**  
Rate of BoP in relation to time (T0, T1, T2, T3) and with comparison between GS and FH groups.

Percentages (%)					
FH_GD	time	rate	conf.low	conf.high	
FH	T0	5.7	2.7	12.1	
	T1	18.7	12.2	28.8	
	T2	31.8	22.6	44.6	
	T3	40.7	30.0	55.4	
GS	T0	2.5	0.8	7.9	
	T1	23.3	15.2	35.7	
	T2	34.1	23.5	49.5	
	T3	47.5	34.0	66.3	

FH_GD	contrast	ratio	conf.low	conf.high	p.value
FH	T1 / T0	3.29	1.41	7.66	0.0059
	T2 / T0	5.57	2.49	12.46	<0.001
	T3 / T0	7.14	3.24	15.75	<0.001
GS	T1 / T0	9.33	2.84	30.70	<0.001
	T2 / T0	13.67	4.23	44.13	<0.001
	T3 / T0	19.00	5.95	60.67	<0.001

**Table 16**  
Rate of PI in relation to time (T0, T1, T2, T3) and with comparison between GS and FH groups.

Percentages (%)					
FH_GD	time	rate	conf.low	conf.high	
FH	T0	11.7	6.8	20.1	
	T1	31.7	22.4	44.8	
	T2	34.2	24.4	47.8	
	T3	47.5	35.4	63.7	
GS	T0	7.2	3.7	14.2	
	T1	35.3	24.9	50.0	
	T2	36.1	25.5	51.0	
	T3	53.7	39.7	72.7	

FH_GD	contrast	ratio	conf.low	conf.high	p.value
FH	T1 / T0	2.71	1.47	5.01	0.0014
	T2 / T0	2.93	1.60	5.37	<0.001
	T3 / T0	4.07	2.27	7.31	<0.001
GS	T1 / T0	4.89	2.39	10.01	<0.001
	T2 / T0	5.00	2.44	10.23	<0.001
	T3 / T0	7.44	3.71	14.93	<0.001

However, both surgery protocols exhibited fewer deviations from the planned position in the mandible than in the maxilla.

Based on the existing literature, the R2Gate system may be helpful for implant planning and placement in static-guided surgery. This system offers several potential advantages. During implant planning, R2Gate provides a tool to assess bone density in future implant sites by standardizing CBCT scans, and color-coding them according to their densities. This assessment assist clinicians in evaluating bone density at future implant sites [34], in determining implant position and size, as well as the optimal drilling sequence, to achieve high primary implant stability [35].

The efficacy of guided surgery for implant placement has been demonstrated in various studies, showcasing superior accuracy compared to freehand techniques [36-40]. Cristache et al. [36] evaluated the accuracy of dental implant insertion using a guided surgery protocol, revealing high accuracy with a deviation of 0.79 mm (± 0.52) at the entry point and 1.17 mm (± 0.63) at the implant apex, along with an angular deviation of 2.34° (± 0.85), and a vertical deviation of 0.50 mm (± 0.38) at the entry point.

Similarly, Younes et al. [37] concluded that fully guided surgery stands out as the most effective approach for implant placement despite its higher economic cost compared to partially guided and freehand methods. Tan et al. [38] conducted a comparable study utilizing CBCT and surface scans to assess the accuracy of the final implant position in

relation to the planned implant position. They found that the implant angulation and the apex location were significantly closer to the planned positions with the guided surgery technique than with the freehand technique. Specifically, the difference in apical displacement from the planned position was 0.87 mm with guided surgery, whereas it was 1.48 mm with freehand surgery. Pessoa et al. [39] and Kivovics et al. [40] also identified statistically significant variations between 3D positioning in guided surgery versus the freehand method.

The primary outcome of the present study was to compare marginal bone resorption in implants placed sub-crestally using either a freehand technique or guided surgery. Generally accepted levels of crestal bone loss after loading are  $\leq 2$  mm in the first year and  $< 0.2$  mm per year in subsequent years. Our analysis revealed no statistically significant differences between the two methods at baseline and during the corresponding follow-up periods up to 3 years after prosthetic loading. Specifically, the difference in bone resorption between the two methods at  $T_0$  is 0.15 mm with a confidence interval (CI) of  $(-0.14; 0.44)$ . At  $T_1$ , the difference in bone resorption between the two methods was smaller than at  $T_0$ , measuring 0.07 mm (CI  $-0.23; 0.36$ ). Interestingly, at  $T_3$ , the difference in bone resorption between the two methods is negative, suggesting a slight increase in bone volume compared to  $T_1$ .

These results are in contrast with the data shown in a systematic review conducted by Mejia J et al. [41], which assessed marginal bone loss (MBL) around dental implants placed with static computer assistance in healed sites, including cases with a minimum follow-up time of 12 months. The mean MBL at 1-year follow-up was 1.06 mm (95% CI: 0.83 to 1.30 mm). Moreover, when they considered only studies with 3-year follow-up ( $n = 5$ ; 748 implants), the MBL was found to be 1.48 mm (95% CI: 0.81 to 2.15 mm).

While a significant body of positive evidence supports guided implant placement, it is important to acknowledge that the findings are not entirely consistent across studies. Studies examined by Yimarj P et al. [42] and Naeini E. et al. [43] did not find statistically significant differences in coronal and apical implant positions or angular deviations between static and dynamic computer-guided surgery.

In the present study, implants in the test group (GS) were placed by inexperienced operators, while an experienced operator placed those in the control group (FH). Our findings suggested that there is no significant difference in the outcomes in terms of peri-implant bone resorption when inexperienced operators receive adequate support through accurate surgical planning and clinical guidance, such as a surgical stent. Additionally, no significant differences were observed between the two implant groups in terms of any other peri-implant parameter. Specifically concerning probing depth, at baseline, probing depths were comparable in both groups: the freehand method group had a mean value of 3.76 mm, while the guided surgery method group had a value of 3.67 mm. Similar findings were observed at subsequent time points ( $T_1$ ,  $T_2$ , and  $T_3$ ), with a slight increase in probing depths at  $T_2$  and  $T_3$  to around 4 mm for both methods. These results are consistent with the current literature on peri-implant stability and health with regard to probing depth. Long-term clinical studies have demonstrated that healthy peri-implant mucosa often exhibits probing depths not necessarily smaller than 4 mm but frequently up to 6 mm [44].

The current evidence suggests that relying solely on probing depth values may not be sufficient to diagnose peri-implantitis accurately [45]. When bone loss is not correctly considered due to the absence of a baseline radiograph, probing depth becomes the sole determinant for diagnosis. This approach may contribute to the high reported prevalence of peri-implantitis in some studies. Huang and colleagues suggested that a baseline peri-implant probing depth should be established for comparison over time [46]. Additionally, a recent systematic review by Lee et al. concluded that monitoring progressively deepening probing depths may be more meaningful than using absolute probing pocket depth values of  $\geq 4$  or 5 mm [47].

Regarding bleeding on probing (BoP) and plaque indexes (PI), the implants in the present study exhibited low mBI and mPI both at

baseline and at the 3-year follow-up. These clinical findings suggest the overall health of peri-implant tissues in relation to the implant placement methods utilized in this study. This may also be attributed, in part, to the prosthetic emergence profiles chosen for crown manufacturing, which were integrated into the prosthetic workflow.

In the present study, we also explored supra-crestal soft tissue height (STH) and its correlation with peri-implant bone stability, regardless of the surgery performed for implant placement. Soft tissue thickness and height are crucial in maintaining the stability of crestal bone around implants: Research has shown that when the vertical thickness of soft tissues is 2 mm or less, crestal bone resorption of approximately 1.5 mm occurs during the establishment of a biological seal between the soft tissues and the implant/abutment/restoration surfaces [48-50]. Vertical soft tissue thickness is a prerequisite for the stability of the biological width around implants. This biological seal is the primary barrier safeguarding the osseointegrated implant against the contaminated intraoral environment [49].

In a recent study, Spinato et al. [48] evaluated the relationship between marginal bone loss (MBL) stability and supra-crestal soft tissue height (STH). Patients were categorized based on the vertical mucosal thickness measured after vestibular flap reflection, and implants were placed accordingly: (group 1) 2 mm below the crestal level in the presence of thin mucosa ( $< 2.5$  mm); (group 2) 1 mm below the crestal level in the presence of medium mucosa (2.5–3.5 mm); (group 3) at the equi-crestal level in the presence of thick mucosa ( $> 3.5$  mm). In the presence of thick peri-implant mucosa (height  $> 3.5$  mm), minimal marginal bone resorption was observed at 3 months (mean 0.19 mm), stabilizing at 5 months (mean 0.22 mm). In cases with peri-implant mucosa between 2.5 and 3.5 mm, marginal bone resorption was slightly higher than with thick mucosa but followed a similar trend over time (0.26 mm at  $T_1$  and 0.32 mm at  $T_2$ ). Conversely, thin peri-implant mucosa ( $< 2.5$  mm) demonstrated significantly higher marginal bone resorption was recorded at different time points (0.41 mm and 0.66 mm at  $T_1$  and  $T_2$ , respectively).

In another study, Vervaeke et al. [49] examined the influence of soft tissue thickness on peri-implant bone remodeling. They compared two groups: in the control group, the implants were placed at the same level as the surrounding crest; in the test group, implants were positioned slightly below the crest to accommodate soft tissue thickness, ensuring at least 3 mm of space vertically to establish the biological width [50]. For instance, if STH at a site measured 2 mm, the implant was positioned at least 1 mm below the crest. The authors concluded that adjusting the implant's vertical position to anticipate the establishment of biological width was highly effective in preventing bone loss and exposure of the implant surface.

Similarly, in the present study, differences in MBL between  $STH < 3$  and  $STH \geq 3$  mm values were measured at 1-year and 3-year follow-ups. Such a cutoff was chosen because all the implants were placed 1 mm sub-crestally, as per manufacturer recommendations. Therefore, in the  $STH \geq 3$  mm group, adequate vertical space for a stable maturation of peri-implant biological width was expected to be sufficient. Conversely, some peri-implant early bone remodeling was anticipated at implant sites with  $STH < 3$  mm. We ensured no bias from prosthetic components by using fixed geometries for interproximal and buccal emergence profile shapes and dimensions, as outlined in the inclusion criteria. At baseline ( $t_0$ ), we observed a mean difference of 0.33 mm in bone remodeling between implants with STH less than 3 mm compared to those with STH greater than or equal to 3 mm, with a P value of 0.06. This outcome should be considered a trend rather than a definitive statement, as no statistical significance was found between the two groups. A larger sample size with such parameter taken as the primary outcome may help to confirm the data reported in the present study. Given the relatively small sample size of our trial, we recommend designing future clinical studies with larger sample sizes and focusing on soft tissue thickness as a primary outcome.

Finally, regarding the study protocol design, the authors carefully

considered the inclusion of two different types of operators: experts and beginners. This decision stemmed from the recognition that assessing the clinical utility of digitally provided templates required comparing the experiences of practitioners with varying skill levels. For expert practitioners, the placement of single implants is routine and does not significantly benefit from digital templates. Therefore, comparing their performance with and without templates would not yield meaningful insights. Conversely, it is of great interest to explore how digital templates could enhance the practice of less experienced clinicians. However, it is ethically untenable to subject patients to treatment by beginners without adequate support. While acknowledging the ethical constraints, the study underscores the importance of evaluating the efficacy of digital templates in improving outcomes for less experienced practitioners. Furthermore, the authors acknowledge the limitation of the sample size in terms of the number of patients and implants. Future research should consider recruiting a larger and more diverse sample of patients and implants to assess the validity of the present findings.

## 5. Conclusions

Digitally static-guided implant placement, performed by a non-expert operator, does not inherently prevent marginal bone remodeling, when compared to a manual procedure performed by an experienced operator. Despite this observation, digital planning and surgery have the potential to assist non-expert clinicians in achieving implant placements with comparable outcomes to those performed by experts.

## CRedit authorship contribution statement

**Diego Lops:** Writing – original draft, Data curation, Conceptualization. **Antonino Palazzolo:** Data curation. **Stefano Calza:** Formal analysis, Data curation. **Luca Proietto:** Data curation. **Annamaria Sordillo:** Writing – review & editing. **Magda Mensi:** Data curation. **Eugenio Romeo:** Supervision, Conceptualization.

## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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