Correlation between accuracy in computer guided implantology and peri-implant tissue stability: a prospective clinical and radiological pilot study

Pier Paolo Poli
University of Milan
Mattia Manfredini (mattiamanfredinidr@gmail.com)
University of Milan
Carlo Maiorana
University of Milan
Mario Beretta
University of Milan

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Abstract

Purpose The present pilot study was designed to fill this gap in the literature, hypothesizing a possible correlation between lack of accuracy in implant placement and deterioration of peri-implant hard and soft tissue health.

Methods a total of 5 male and female patients were enrolled. Patients underwent computer-guided implant surgery and full arch immediate load between 2013 and 2014. After a follow-up of 5 years, all patients treated with the computer-guided implant placement technique and undergoing evaluation of the accuracy of computer-guided implant placement by postoperative CBCT were recalled for a clinical-radiographic evaluation of peri-implant health status. Accuracy of implant placement was then related to peri-implant hard and soft tissue health variables such as marginal bone resorption, amount of keratinized tissue, recession and plaque and bleeding.

Results: Mean linear deviation was 0.57 ± 0.23 mm at implant head and 0.69 ± 0.26 mm at implant apex, while mean angular deviation of the long axis was 2.88° ± 1.22°. A mean MBL of 1.16 ± 0.94 mm and 2.01 ± 1.76 mm was observed after 1 and 5 years of follow-up, respectively. At 5 years, mean PPD was 4.09 ± 1.44 mm, 66.6% of the evaluated implants showed BOP, KM was < 2 mm in 48.4% of cases, REC ≥ 1 mm was assessed in 45.4% of the included implants, plaque accumulation occurred in 66.6% of cases. A negative correlation was observed between bucco-palatal/lingual linear inaccuracy and MBL, PPD, BOP and KM.

Conclusions: with the limit of a pilot study, it can be observed that the accuracy of computer-guided implant surgery as described here, obtained satisfactory results. A reduction in accuracy leading to the placement of an implant in an excessively vestibular position may be the cause of peri-implant hard and soft tissue suffering in terms of marginal bone resorption, amount of keratinized mucosa and bleeding on probing.

Background:

Over the last few years, following the introduction of cone-beam computed tomography (CBCT) and the development of software for computer-guided implant positioning, a significant technological evolution in the fields of implantology and oral rehabilitation has begun. As a matter of fact, increasing evidence advocates the association of computer-guided implantology and flapless surgical approaches, thanks to the superimposition of patient's clinical features and radiological data. These techniques, after an accurate diagnostic process, allow simplifying the surgical phase while reducing the invasiveness of the operation to a minimum [1]. At the same time, computer-guided workflows yielded favorable results in terms of accuracy, with linear deviations of less than one millimeter and angular deviations of the implant axis of no more than 4-6 degrees [2, 3]. Thus, computer-guided implant insertion can be particularly useful in different challenging clinical situations. These include anatomical regions where correct prosthetically driven implant positioning may be hindered by the amount of available bone in atrophied ridges, or by noble structures located in close proximity to the ideal implant site. In addition, patient-related conditions where implants should be inserted with minimal elevation of mucoperiosteal flaps or with a flapless surgical approach can also benefit from computer-guided surgery [4-6].

Accuracy, as mentioned above, is a critical parameter to assess the reliability of computer-guided implantology. It is described as the deviation between the pre-operative implant position planned in the planning software and the position actually obtained in the intra-operative surgical phase[7]. At the same time, the health and stability of peri-implant hard and soft tissues is another key factor in the long-term prognosis of implant-supported rehabilitation [8, 9].

It is noteworthy that, to the best of the authors' knowledge, there is very little evidence currently available investigating and describing the clinical and radiological relation between implant health and accuracy in implant positioning. This aspect might be of interest in the clinical setting, in order to understand whether a reduction in the degree of accuracy in terms of linear and angular deviations could have repercussions on the clinical and radiographic variables related to peri-implant hard and soft tissue health years later. In view of the above, the aim of the present pilot study was to evaluate the possible correlations between the degree of accuracy achieved intrasurgically and the health conditions of peri-implant bone and mucosa, in terms of marginal bone resorption, amount of keratinized mucosa, peri-implant vestibular and/or lingual/palatal recessions, depth of peri-implant probing, and presence of plaque and bleeding at peri-implant probing. The null hypothesis was that there would be no statistically significant differences between the degree of accuracy obtained during the surgical procedure and the peri-implant health status determined by the variables listed previously in a sample of patients treated with computer-guided implantology surgery and immediate loading.

Materials And Methods:

Study design

A total of 5 patients were enrolled at the authors' Department according to specific inclusion criteria: 1) male or female patients aged 18 years or older; 2) total or partial edentulism with terminal dentition at the maxillary and/or mandibular arch; 3) any extraction of residual teeth performed $\geq$ 2 months prior to the planning phase; 4) any bone regeneration surgery performed at least 6 months prior to the planning phase; 5) presence, at the time of implant insertion, of an adequate amount of bone, in order to avoid simultaneous bone augmentation procedures; 6) presence of a quantity of keratinized mucosa $\geq$ 2 mm circumferentially around the future implant site. The following local exclusion criteria were adopted: 1) local mucosal inflammation and possible presence of periodontal disease; 2) presence of erosive mucosal disease; 3) presence of bone lesions; 4) history of local radiation therapy; 5) post-extraction sites not fully healed and/or less than two months after element avulsion; 6) regenerative bone surgery such as grafting or guided bone regeneration procedures performed less than 6 months ago; 7) keratinized gingiva < 2 mm; 8) parafunctional patients with bruxism habit; 9) patients with inadequate oral hygiene or otherwise unmotivated for home care. The following systemic exclusion criteria were identified: 1) chronic pathologies requiring the administration of antibiotic prophylaxis (rheumatic disease, bacterial endocarditis, congenital heart valve anomalies); 2) medical conditions that require the prolonged use of steroid drugs and bisphosphonates; 3) immunocompromised patients with a history of leukocyte deficiency; 4) patients with coagulation disorders; 5) patients with a history of neoplastic diseases that require or have required the use of radio or chemotherapy; 6) patients with a history of renal failure; 7) patients with a history of uncontrolled endocrinopathies; 8) patients with physical and/or mental handicaps that prevent proper and adequate oral hygiene; 9) patients subject to alcohol or drug abuse; 10) patients with HIV; 11) smoking patients (> 10 cigarettes/day); 12) presence of conditions or circumstances that could in any way interfere with the proper participation of the patient in the study.

Each patient underwent computer-guided implant surgery according to the 3DIEMME® digital workflow (3DIEMME srl, Cantù, Como, Italy) using the Camlog® guide system (Camlog Biotechnologies AG, Basel, Switzerland) between 2013 and 2014. Implants (Screw-line Camlog Guide, Promote Plus, Camlog Biotechnologies AG, Basel, Switzerland) were subsequently loaded using immediate-loading protocols with implant-supported screw-retained provisional prostheses relined intraoperatively. The final prosthesis was delivered after 6 months. All patients were included in a follow-up recall program consisting of annual dental visits and biannual professional oral hygiene sessions. In addition, each patient underwent follow-up orthopantomograph performed 12 months after prosthetic loading. After a follow-up of 5 years, all patients treated with computer-guided implant placement and immediate loading who underwent accuracy evaluation by means of postoperative CT scan were recalled for a clinical and radiographic evaluation of the peri-implant health status.

Pre-surgical protocol

Any patient eligible for the study underwent a pre-operative screening. Anamnestic data were collected, as well as information about any ongoing pharmacological therapy and, if necessary, specific hematochemical tests were requested. After inclusion, an informed consent containing the purpose and the methodology of the study was given, explained, and signed by the patient.

Preoperative intra-oral photographs were taken, and a pre-operative professional hygiene session and motivation to oral hygiene procedures was scheduled. Clinical and radiological evaluation were performed to exclude the need of simultaneous bone augmentation procedures (Fig. 1).

The following step consisted in the evaluation of articulated plaster models and fabrication of a preliminary prosthetic wax-up, corresponding to the exact replica of the final prosthesis accepted by the patient, integrated with aesthetic and functional principles. Then, a radiological stent was fabricated on the basis of the preliminary prosthetic wax-up, as a duplication of the final prosthesis. The radiological stent was equipped with an extraoral radiopaque marker for 3D position tracking, necessary during the subsequent superimposition of the scans. Each subject underwent CT scan of the edentulous jaw while wearing the radiopaque stent in order to integrate the anatomical data with the functional and aesthetic parameters. Subsequently, an optical scan of the prosthesis itself was performed, as required by the digital workflow. The aforesaid scans were imported and matched within the planning software and the ideal virtual 3D implant position was decided according to the anatomy of the jaw and the prosthetic design. This was possible thanks to the processing of the data in stereolithographic interface format (STL) acquired from the optical scan superimposed on the data obtained from the CT device in DICOM format, using the geometric marker present in both scans. This allowed the simultaneous display of the axial, 3D, panoramic and transverse images integrated with the prosthetic profile on the computer monitor. At this point, it was possible to transfer the virtual project into a 1:1 scale model (XLTEK RealPATIENT, Excel Tech Ltd., Oakville, ON, Canada) using a rapid prototyping technique. Finally, the model was used as a reference to fabricate a surgical stent using the principle of stereolithography (Fig. 2)..

Surgical protocol

All surgical procedures were performed by the same surgeon on an outpatient basis. The surgical guide was previously prepared by chemical decontamination with ethylene oxide. Antibiotic prophylaxis consisting of 2 g amoxicillin clavulanate (Augmentin, GlaxoSmithKline S.p.A., Verona, Italy) was administered 1 hour before surgery. After bacterial decontamination with a 0.2% chlorhexidine solution (Dentosan, Recordati S.p.A., Milan, Italy) and intramuscular injections of 4 mg/mL dexamethasone sodium phosphate (Soldesam, Laboratorio Farmacologico Milanese, Varese, Italy) to reduce postoperative edema, local anesthesia was induced with 2% carbocaine with epinephrine 1:100,000 (AstraZeneca S.p.A., Milan, Italy). The surgical stent was then fixed in an appropriate position using a silicone index, with guided insertion of surgical pins on the buccal side of the alveolar process according to the virtual plan in order to preserve the anatomical structures (Fig. 3). The surgical stent allowed the use of calibrated drills, without changing the metal cylinders contained in the stents. Thus, greater precision in implant bed preparation and placement was achieved, with a low risk of inappropriate insertion. A circular mucosal operculectomy was performed with a surgical mucotome to remove the gingival plug from the implant site, followed by serial osteotomies performed with disposable internally cooled drills, until the planned depth was reached. The implants (Screw-line Camlog Guide, Promote Plus, Camlog Biotechnologies, Basel, Switzerland) were then placed in the desired position according to the manufacturer's instructions (Fig. 4). [7] After removal of the pins and surgical template, 100 mg of oral nimesulide (Aulin, Helsinn Birex Pharmaceuticals Ltd., Dublin, Ireland) was administered for pain relief. A temporary screw-retained prosthesis relined intraoperatively was finally delivered to the patient. Postsurgical CT scan was conducted with the same apparatus and settings as the preoperative radiological exam. The pre- and post-operative CT scans were then overlapped using a specific algorithm, in order to compare the virtually planned and actual implant positions and determine the accuracy level. Three deviation parameters were recorded between each planned and placed fixture: linear deviation (mm) at the implant head and apex, and angular deviation (°) of the implant long axis (Fig. 5). All measurements were conducted using dedicated software (3Diagnosys data software) (Fig. 6). The final rehabilitation was delivered after 6 months (Fig. 7), and a follow-up orthopantomograph was performed (Fig. 8).

After a follow-up of 5 years, all patients treated with the computer-guided implant placement technique and undergoing evaluation of the accuracy of computer-guided implant placement by postoperative CBCT were recalled for a clinical-radiographic evaluation of peri-implant health status.

5-year follow-up examination

With respect to the radiographic examination, each patient was prescribed a follow-up orthopantomograph to assess peri-implant marginal bone levels. To this end, the orthopantomograph performed 12 months after prosthetic loading and the 5-year orthopantomograph were used as references to compare the variation of peri-implant marginal bone levels throughout the years and determine the peri-implant marginal bone resorption (pi-MBR). Ten orthopantomograms were therefore taken into consideration: nine were in digital format (JPEG), and one was originally available in analogue format. This radiograph was scanned and digitized by a scanner at a resolution of 1200 dpi. In all orthopantomographs, at each implant site, the distance in mm between the implant shoulder and the first visible most coronal bone-to-implant contact reflecting the pi-MBR was measured at 10-15x magnification at both mesial and distal aspects. The measurements were performed with a specific software (Image J; U.S. National Institutes of Health, Bethesda, MD, USA). To solve the problem of distortion, the measurements were calibrated on the basis of a known landmark, in this case the known length of the implant itself. In cases where the peri-implant marginal bone level was more coronal than the implant shoulder as a result of apico-coronal placement of the implant deeper than the bone crest, the value "0" was reported, regardless of the actual distance between the two references [10].

Considering the clinical examination, each patient was recalled for a follow-up visit 5 years after prosthetic loading. At this time, intra-oral photographs were taken, the definitive implant-supported prostheses were removed, and peri-implant health was evaluated with a millimetric plastic periodontal probe (12-UNC COLORVUE®; Hu-Friedy, Chicago, IL, USA). In detail, the following clinical parameters were assessed and registered: a) peri-implant probing depth (PPD), calculated in mm from the peri-implant mucosal margin to the bottom of the peri-implant sulcus, measured at 6 sites for each implant: buccal, mesio-buccal, disto-buccal, palatal/lingual, mesio-palatal/lingual, disto-palatal/lingual; b) peri-implant buccal and palatal/lingual mucosal recession (REC), intended as an apical shifting of the peri-implant mucosal margin from the restorative margin, recording the highest value in mm at the buccal and palatal/lingual level; c) presence and amount of peri-implant keratinized mucosa (KM), measured in mm at the narrowest distance between the mucosal margin and the mucogingival junction, at the buccal and lingual/palatal level; d) presence of plaque, recorded as a dichotomous variable (YES/NO) by visual inspection; e) peri-implant bleeding on probing (BOP), recorded as a dichotomous variable (YES/NO) by visual inspection 30 seconds after gentle probing of the peri-implant sulcus.

Statistical analysis

During the study, data were inserted into a spreadsheet (Excel; Microsoft Corp., Redmond, WA, USA). Using statistical analysis software (R Statistical Software, v4.0.2; R Core Team 2020), a descriptive analysis of all assessed variables was carried out and the data were presented as means ± standard deviations. The implant was chosen as the reference statistical unit. As the sample size ranged from 3 to 50, the Shapiro-Wilk test was used to check whether or not the data followed a normal distribution. Depending on the distribution of the data obtained, parametric or non-parametric statistical tests were adopted to evaluate the trend of the study variables. To assess whether there were statistically significant correlations between the previously recorded accuracy values and the clinical and radiographic data measured at 12 months and 5 years after prosthetic loading, generalized linear models were constructed using linear and angular deviations as predictors and pi-MBR, PPD, KM and REC as variables. For the dichotomous variables, the implants were dichotomized into two groups, namely with or without plaque and BOP respectively, and then the values of the variables were quantified in each of the two groups. To see an association between the presence of plaque/BOP and to detect an association between plaque/BOP and the predictors, any significant difference in the distribution of values was quantified by a p-value obtained from a Wilcoxon signed rank test. For all statistical analyses performed, a p-value of < 0.05 was considered statistically significant. Statistical analysis and graphical representation of the results were performed using the R language, version 4.0.2 (R Core Team 2020). The linear models were created using the lm function, the graphs were generated using the functions of the ggplot2 package (R Core Team 2020).

Results:

The data presented in this pilot study have been prospectively collected from 34 rough-surfaced dental implants placed in 5 patients (4 males and 1 female) who underwent computer-guided flapless implant placement and immediate loading. Overall, 16 implants were placed in the mandible and 18 in the maxilla. The implant diameters used were 3.8 mm (27 implants) and 4.3 mm (7 implants), while the lengths used were 11 mm (17 implants), 13 mm (13 implants) and 9 mm (5 implants). Demographic data are reported in Table 1.

Table 1
Demographic data.

Patient ID	Surgical site	Age	Sex	Implant ID	Implant position	Implant diameter (mm)	Implant length (mm)
1	Mandible	55	M	1	31	3.8	11
		55	M	2	33	3.8	11
		55	M	3	42	3.8	11
		55	M	4	44	3.8	11
	Maxilla	55	M	5	14	4.3	11
		55	M	6	15	4.3	9
		55	M	7	23	4.3	13
		55	M	8	25	4.3	13
2	Mandible	72	M	9	32	3.8	11
		72	M	10	35	3.8	13
		72	M	11	43	4.3	11
		72	M	12	45	3.8	13
	Maxilla	72	M	13	15	4.3	11
		72	M	14	25	4.3	13
3	Mandible	70	M	15	32	3.8	13
		70	M	16	34	3.8	13
		70	M	17	42	3.8	13
		70	M	18	44	3.8	13
4	Maxilla	62	M	19	12	3.8	11
		62	M	20	14	3.8	11
		62	M	21	16	3.8	11
		62	M	22	22	3.8	11
		62	M	23	24	3.8	11
		62	M	24	26	3.8	11
5	Mandible	42	F	25	32	3.8	13
		42	F	26	35	3.8	13

	42	F	27	42	3.8	13
	42	F	28	45	3.8	13
Maxilla	42	F	29	12	3.8	9
	42	F	30	14	3.8	11
	42	F	31	16	3.8	11
	42	F	32	22	3.8	9
	42	F	33	24	3.8	9
	42	F	34	26	3.8	9

Out of 34 inserted implants, one failed to osseointegrate in the immediate post-operative period, and has been replaced with another fixture having the same diameter and length. This latter implant has not been considered in the correlation analysis as it has been placed with a free-hand approach.

Of the 34 inserted implants, linear deviations of the implant head and apex displacement vector including the mesio-distal, bucco-lingual/palatal, and corono-apical deviations, and the angular deviation of the long axis were calculated and reported in Table 2. A mean linear deviation of 0.57 ± 0.23 mm (Fig. 9) and 0.69 ± 0.26 mm (Fig. 10) was found for the implant head and apex respectively. The mean angular deviation of the long axis was 2.88° ± 1.22°.

Table 2
Accuracy data.

Patient ID	Implant ID	Linear deviation (mm)		Angular deviation (°)
		Head	Apex	
1	1	0.4	0.62	2.12
	2	0.3	1.2	4.94
	3	0.39	0.36	1.85
	4	0.61	0.65	2.33
	5	0.33	0.24	2.69
	6	0.66	0.1	1.11
	7	0.63	0.73	1.82
	8	0.37	0.73	3.22
2	9	0.3	0.37	2.17
	10	0.94	0.94	2.43
	11	0.58	0.67	1.85
	12	0.71	0.66	1.23
	13	0.49	0.65	4.18
	14	1.09	1.1	1.92
3	15	1	0.966	3.4
	16	0.572	0.946	1.79
	17	0.802	0.975	3.44
	18	0.913	0.759	2.46
4	19	0.375	0.849	3.24
	20	0.997	0.633	3.023
	21	0.328	0.9	5.306
	22	0.299	0.321	3.308
	23	0.656	0.674	4.087
	24	0.652	0.722	4.202
5	25	0.585	0.803	0.535
	26	0.844	1.218	2.74

	27	0.613	0.556	2.638
	28	0.75	1	2.282
	29	0.459	0.714	6.189
	30	0.41	0.282	3.166
	31	0.372	0.554	1.931
	32	0.246	0.48	3.035
	33	0.491	0.75	4.961
	34	0.391	0.396	2.492

Considering the 33 implants in function at the latest 5-year recall, a mean pi-MBR of 1.16 ± 0.94 mm was observed at 12 months, whereas a mean pi-MBR of 2.01 ± 1.76 mm was found after 5 years. A mean pi-MBR difference of 0.84 ± 1.99 mm has been noted between 12 months and 5 years, yielding a hypothetical mean annual bone loss of 0.21 ± 0.49 mm. With respect to the clinical variables, a mean PPD of 4.09 ± 1.44 ranging from 1 to 7 mm was measured considering the highest PPD value registered at each of the 33 implant sites among the 6 sites. A total of 22 (66.6%) implants showed BOP; 16 (48.4%) presented with KM < 2 mm; 15 (45.4%) had REC ≥ 1 mm, ranging from 1 to 4 mm; finally, plaque accumulation was noticed in 22 (66.6%) implants Table 3.

Table 3
Data recorded at the 5-year follow-up examination

Patient ID	Implant ID	pi-MBR (mm)	Highest PPD (mm)	BOP (+/-)	KM (mm)	REC (mm)	Plaque (+/-)
1	1	0.91	5	YES	1	0	YES
	2	1.005	5	YES	0	1	YES
	3	1.025	4	YES	1	1	YES
	4	1.27	5	NO	2	4	NO
	5	0.605	4	YES	1	1	YES
	6	1.43	4	YES	0.5	0	NO
	7	2.14	4	NO	1	0	YES
	8	2.62	7	YES	0	2	YES
2	9	0.36	2	NO	2	0	NO
	10	8.06	6	NO	2	0	NO
	11	2.795	3	NO	3	0	NO
	12	7.35	6	NO	1	1	YES
	13	4.465	5	NO	4	0	NO
	14	3.395	5	YES	4	0	NO
3	15	0.49	1	YES	2	0	YES
	16	1.19	3	NO	2	1	NO
	17	0	2	YES	4	0	NO
	18	0.375	2	YES	3	1	YES
4	19	1.89	5	NO	0	2	NO
	20	1.99	4	NO	1	2	NO
	21	Implant lost					
	22	3.455	6	YES	0	0	YES
	23	2.64	7	NO	0	0	YES
	24	2.095	6	YES	1	0	YES
5	25	0.965	3	YES	3	0	YES
	26	0.355	4	YES	1	2	YES

	27	1.35	3	YES	3	0	YES
	28	1.54	3	YES	3	3	YES
	29	1.44	3	YES	2	0	YES
	30	1.76	4	YES	3	0	YES
	31	2.325	4	YES	2	1	YES
	32	2.93	3	YES	1	0	YES
	33	0.95	3	YES	1	1	YES
	34	1.335	4	YES	2	1	YES

The results emerged from the statistical analysis showed a statistically significant correlation between pi-MBR and a bucco-palatal/lingual linear deviation of both the head and the apex ($p = 0.046$ and $p = 0.044$ respectively). Therefore, a tendency toward an increased pi-MBR was found when implants were inserted more buccally. Similarly, a statistically significant correlation between bucco-palatal/lingual inaccuracy and amount of KM was found for both the head ($p = 0.029$) and apex ($p = 0.009$), so that implants displaced more buccally were more likely to present with less keratinized tissue. In a similar fashion, bucco-palatal/lingual inaccuracy at the implant head and apex was also statistically significantly correlated with increased BOP ($p = 0.031$ and $p = 0.029$ respectively) and PPD ($p = 0.03$ and $p = 0.041$ respectively). The remaining linear and angular deviations were not correlated with the radiological and clinical variables in a statistically significant way ($p > 0.0$)

Discussion:

In the present pilot study, accuracy of implant positioning following flapless computer-guided surgery has been correlated to clinical and radiological variables that commonly define peri-implant tissue health. The aim was to test the null hypothesis that there would be no statistically significant differences between the level of accuracy obtained during the surgical procedure and the peri-implant health status. Results were heterogeneous, as the null hypothesis has been accepted in some cases, and rejected in others. In particular, the variables that proved to be statistically significantly correlated with inaccuracy were pi-MBR, KM, BOP, and PPD.

In terms of pi-MBR, marginal bone levels measured after 12 months and 5 years from the prosthetic loading were analyzed on orthopantomographs. The data collected from 33 implants still in function at 5 years, showed a mean pi-MBR of 1.1 mm at 12 months and approximately 2 mm at 5 years. These values are in line with the 2017 World Workshop on the Classification of Periodontal and Peri-Implant Diseases and Conditions definitions of implant health [11] and Albrektsson's 1986 success criteria [12, 13]. When compared with the latter, the mean value of pi-MBR at 12 months after prosthetic loading observed in the present study is not only within the normal range, but is also slightly lower than the mean value reported by Albrektsson et al., which is 1.5 mm [12]. Interestingly, pi-MBR remained rather stable over time, being approximately 2 mm at 5 years, confirming a positive prognosis for the medium-term hard tissue health at implants placed with computer-guided flapless surgery. In this matter, the criteria of implant success described by Albrektsson in 1986 accepted an annual resorption of peri-implant marginal bone of 0.2 mm after the initial remodeling phase [12]. In the present study, the differences in pi-MBR obtained between 12 months and 5 years of function were also analyzed, yielding an overall bone loss of 0.84 mm during 4 years, transposed into a 0.21 annual pi-MBR. Although this value approximates that mentioned above, it remains only hypothetical, as radiological data were not collected on an annual basis. Therefore, any progression or acceleration of the pi-MBR throughout the years cannot be extrapolated from the present data. This constitutes a limitation of the present study. Nonetheless, the results observed herein are consistent with those reported in similar studies. In 2013, Marra and co-workers published a study evaluating pi-MBR after a 3-year follow-up period in 30 fully edentulous patients who had been treated with computer-guided flapless implant surgery [14]. A total of 312 implants were analyzed, and a mean pi-MBR of 1.9 ± 1.3 mm was reported at 3 years. A paper published in 2017 by Lopes et al. evaluated pi-MBR in edentulous patients treated with implant-supported fixed total rehabilitations with All-on-Four concept by means of computer-guided flapless implant surgery with a 5-year follow-up [15]. Overall, 111 patients were included in the study, and the average marginal bone loss calculated after 5 years was 1.27 mm for tilted implants and 1.34 mm for axial implants. Better results were obtained by Tallarico and co-workers who published a study comparing pi-MBR values after a 5-year follow-up from prosthetic loading in edentulous patients rehabilitated with implant-supported prostheses undergoing computer-guided flapless surgery [16]. The mean pi-MBR observed after 5 years was 0.87 mm ± 0.40. According to the results of the present study and those found in pertinent literature, it appears that marginal bone levels obtained after medium-term prosthetic loading following flapless computer-guided workflows are stable and predictable over time.

Apart from the pi-MBR values reported to give an overview on the stability of peri-implant hard tissue, data on the accuracy achieved with computer-guided implant surgery were also pivotal in the present study. Accuracy is intended as the matching of the implant position planned within the software with that actually obtained in the patient's mouth. The linear deviations of the implant head and apex measured in the bucco-lingual/palatal, mesio-distal, and corono-apical directions, together with the angular deviation of the implant long axis were considered. It is known that the level of accuracy strongly depends on the reliability and precision of the workflow and methodology used during the planning phase, from the diagnosis up to the surgical step. Every aspect must be carefully developed in order to reduce the margin of error in all the steps that characterize the planning phase and the operative phase. An adequate precision and accuracy of all these sequential steps is therefore of paramount importance considering that each error is cumulative and is transferred to the subsequent steps. A review published by Bover-Ramos and colleagues analyzed 34 articles providing 3033 implants placed with partially and fully guided surgery in vitro (8 studies), in cadaver (4 studies), and in vivo (22 studies) [17]. The data regarding the accuracy of implants placed in patients with fully guided surgical protocols showed an average implant head deviation of 1.00 mm ± 0.08 mm, an average apical deviation of 1.35 mm ± 0.12 mm and an angular deviation of 3.62° ± 0.29°. No statistically significant differences were also found between the accuracy of implants placed with fully guided surgery in vivo and on cadavers. Marlière and co-workers published a systematic review that included 7 studies realized between 2011 and 2016, in which they evaluated the accuracy of implants placed with computer-guided surgery in patients with total rehabilitations[18]. Angular deviation ranged from 1.85° to 8.4°, implant head deviation fell within a range of 0.71 mm – 2.17 mm, and apical deviation showed an interval of 0.77 mm – 2.86 mm. The systematic review with meta-analysis published by Schneider and colleagues included 8 studies related to implant placement with computer-guided flapless surgery, in which accuracy was also calculated [2]. Considering the in vivo studies only, the mean deviation at the implant head was 1.16 mm, the mean apical deviation was 1.96 mm, and the mean angular deviation was 5.73°. The values found in the present pilot study showed a mean linear deviation of the implant head of 0.57 mm, a mean linear deviation of the implant apex of 0.69 mm, and a mean angular deviation of the long axis of 2.88°. These values were lower when compared to those reported in the systematic reviews mentioned above, meaning that a high level of accuracy was achieved with the workflow described herein. Multiple reasons have been identified:

traditionally, intra-oral gutta-percha markers placed inside the radiographic stent were used to integrate the prosthetic plan with the patient's anatomy in virtual planning. However, in the presence of metal prosthetic restorations, the identification of the radiopaque marker given by the gutta-percha is challenging [7].

In the present study, an extra-oral radiopaque marker was used, consisting of a well-defined geometric device. A total of 30,000 points were scanned and superimposed during the matching procedure, with greater accuracy in overlapping DICOM data and radiographic stent than traditional protocols.

Additionally, in traditional protocols, two CT scans were usually performed, one of the patient and one of the radiological model. In the present study, the radiological template was scanned using an optical scanner, which provides STL data, which are more accurate than DICOM data because they are independent of the Hounsfield unit threshold based on the radiologist-defined gray-level segmentation.

This has allowed the surgeon to determine the exact thickness of the soft tissue, resulting in more accurate virtual planning.

An optimal level of precision was also achieved through fixation of the surgical template to the surgical site.

The surgical protocol performed involved the insertion of vestibular endosseous pins disposed in tripod formation, whose position and depth was guided by special sleeves, previously established not to interfere with the positions of the implants.

This way it was possible to avoid movements and deformations of the surgical template caused by the pressures promoted during the preparation of the implant sites.

Again, in order to achieve a higher level of accuracy in the present protocol, disposable drills were used.

In fact, by increasing the cutting capacity, the risk of possible deviations in the osteotomies, caused by excessive wear of the drills, is reduced. [7]

The high rate of accuracy found in the present study could explain the medium-term stability of the marginal bone profile evaluated at the 5-year follow-up. On the other hand, the linear deviation of the implant head and apex in the bucco-palatal/lingual direction was significantly correlated to higher values of pi-MBR. A similar trend was also noted for the peri-implant keratinized mucosa. In this case, implants placed more buccally compared to the virtual plan were more prone to develop a contraction of peri-implant hard and soft tissues. A translation of the displacement vector in the vestibular direction could have led to an excessive remodeling of the buccal cortical thickness, with a consequent reduction in the amount of peri-implant keratinized mucosa [19]. In this respect, Monje and colleagues analyzed the critical threshold value of the thickness of the buccal cortical wall to prevent pathological resorption [20]. In particular, an animal study was conducted in which 36 implants were inserted in sites presenting a residual buccal cortical plate < 1.5 mm, while 36 implants were placed in sites that maintained ≥ 1.5 mm of buccal bone. There were no implant failures, but it was interesting to note that implants placed too buccally, with a residual buccal bone < 1.5 mm, showed more recession of the buccal mucosa. Interestingly, a recent study published by Romandini and co-workers confirmed that an implant placed too buccally is associated with an almost three times higher risk of presenting peri-implantitis. This was related to the reduced thickness of the residual buccal bone, which is likely to resorb and provoke mucosal recession, with consequent exposure of the implant surface and increased risk of bacterial colonization [21]. These observations somehow corroborate those reported herein. Although mucosal recession was not mathematically associated to buccal inaccuracy, a contraction of the peri-implant keratinized mucosa was noted. It can be speculated that with a longer follow-up period, more soft tissue contraction may occur, leading to mucosal recession in accordance with the previous studies.

In view of the scientific evidence reported above, the values found in this study regarding the correlation between buccal implant displacement and higher pi-MBR together with a contraction of the keratinized mucosa are interesting. Implants inserted with less accuracy in the bucco/palatal-lingual direction and particularly in a position that is too buccal compared to the initial planning showed greater pi-MBR and less keratinized mucosa. This in turn may lead to an increased risk of developing peri-implant inflammation. Accordingly, the data collected herein supported the fact that inaccuracy of implant positioning in the bucco/palatal-lingual direction had a statistically significant effect on the presence of peri-implant bleeding on probing. In this respect, Perussolo and colleagues investigated the correlation between reduced peri-implant keratinized mucosa (< 2 mm), pi-MBR, plaque, bleeding, and patient discomfort in home oral hygiene procedures [22]. Implants with a reduced amount of keratinized mucosa (< 2 mm) were found to be associated with greater pi-MBR, a higher degree of soft tissue inflammation in terms of plaque and bleeding on probing, and finally, greater difficulty in daily home cleaning by the patient. These results are consistent with those obtained in the present work, as pi-MBR, keratinized mucosa and bleeding on probing were all interconnected and strictly correlated to buccal implant displacement. Although domiciliary compliance was not evaluated in this study, it is likely that buccally placed implants induced a contraction of the keratinized mucosa, leading to more brushing discomfort with consequent plaque accumulation, biofilm-related inflammation, and ultimately bone loss. This favorably complies with a study published by Souza and co-workers who concluded that implant sites with a band of < 2 mm of KM were shown to be more prone to brushing discomfort, plaque accumulation, and peri-implant soft tissue inflammation when compared to implant sites with ≥ 2 mm of KM[23].

All of this taken together may also explain the significant correlation between inaccuracy and PPD. Indeed, those implants inserted too buccally, that presented with a state of inflammation detected by bleeding on probing, also showed higher values of PPD compared to implants that were placed more accurately. It should be mentioned that, when defining the health of an implant, probing depth values might vary as they are dependent on the peri-implant soft tissue height [13]. Accordingly, a narrative review published by Coli and coworkers aiming at analyzing the correlation between probing depth and peri-implant health, concluded that there is no precise threshold value of PPD that can indicate the presence of disease [24]. In the present work, PPD ranged from 1 to 7 mm, emphasizing the fact that PPD might not be solely correlated to implant health or disease but can also be attributed to other variables not assessed herein. However, the fact that implants placed more buccally were also associated to higher PPD values as a potential consequence of higher inflammation and bone loss is worthy of note.

It should be stressed at this point that the findings reported in this study should not be overgeneralized due to the small sample enrolled. Indeed, although interesting observations emerged from the data, the lack of external validity remains a limitation of the present research. Therefore, further studies including a larger sample of patients will be needed to validate or deny the correlation between accuracy and the variables analyzed in the present study.

Conclusion:

In light of the results obtained in the present pilot study, it can be concluded that the accuracy of computer-guided implant placement has an effect in peri-implant hard and soft tissue health. In particular, implants placed more buccally compared to the virtual plan were significantly correlated with higher values of pi-MBR, BOP and PPD, and reduced KM. Thus, reduced accuracy in computer-guided implant placement may adversely affect marginal bone levels and peri-implant soft tissue health.

Declarations

Ethics approval and consent to participate

The present monocentric prospective pilot study was conducted in accordance with the fundamental principles of the 1975 Helsinki Declaration on clinical analysis involving human subjects as revised in 2008, and was additionally approved by the local ethics committee of the Fondazione IRCCS Cà Granda Ospedale Maggiore Policlinico (Milan area 2), in relation to digital workflows (#0002693-U). All patients involved in the present study signed an informed consent to participate.

Consent for publication

Written and signed consent to publish the images in this study were obtained from the patients.

Availability of data and materials

The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

Conflict of interest

The authors declare no competing interests.

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Author’s contribution

M.B. and P.P.P. conceptualization; P.P.P. and M.M. Formal Analysis; P.P.P. Investigation and Methodology; M.M. Writing original draft; M.B. and P.P.P. Writing – Review & Editing; C.M. Project Administration.

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Not Applicable.

Authors' information

[1] Implant Center for Edentulism and Jawbone Atrophies, Maxillofacial Surgery and Odontostomatology Unit, Fondazione IRCCS Cà Granda Ospedale Maggiore Policlinico, Milan, Italy

[2] Department of Biomedical, Surgical and Dental Sciences, University of Milan, Milan, Italy.

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Figures

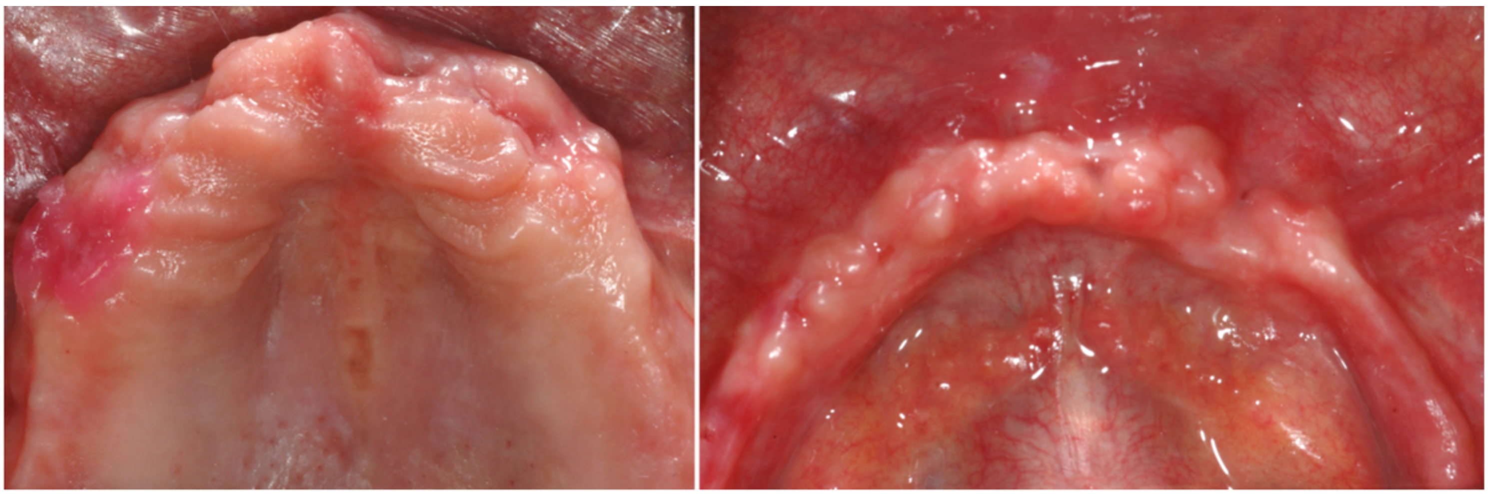

Figure 1

Preoperative occlusal view of the edentulous jaws.

Figure 2

Radiological stent with an extraoral radiopaque marker.

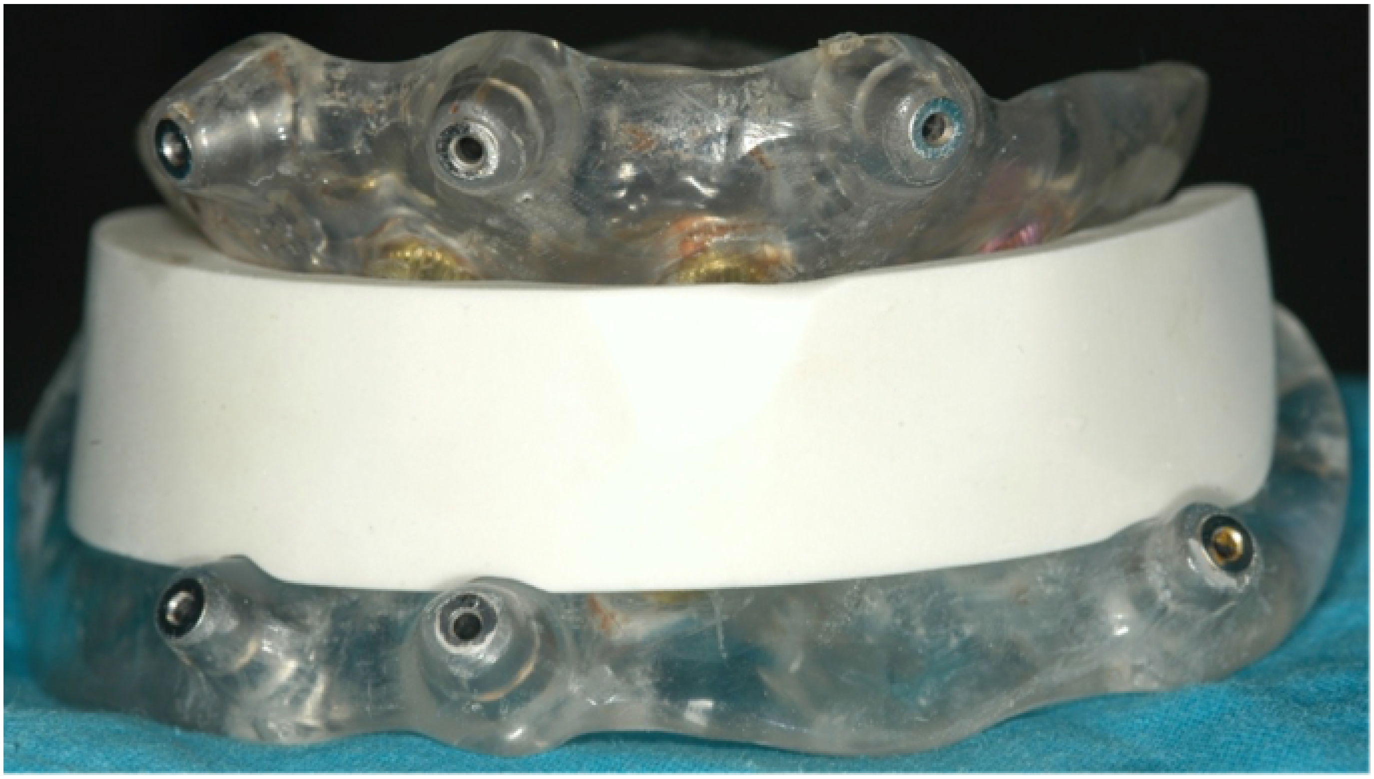

Figure 3

Surgical stent stabilization by silicone index.

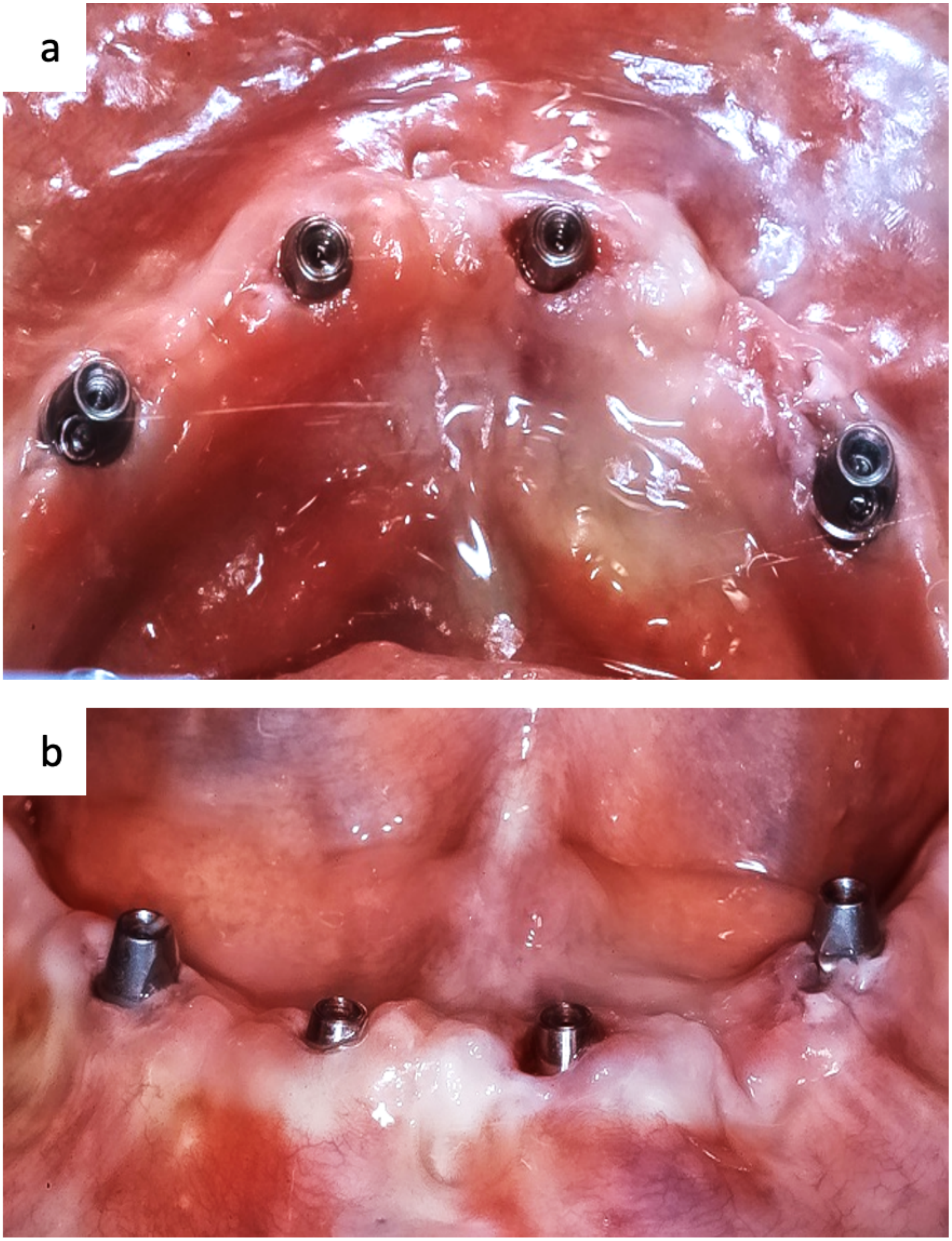

Figure 4

Implants placed in the desired position according to the manufacturer's instructions. a Lower implant inserion, occlusal view b Lower implant inserion, frotal view.

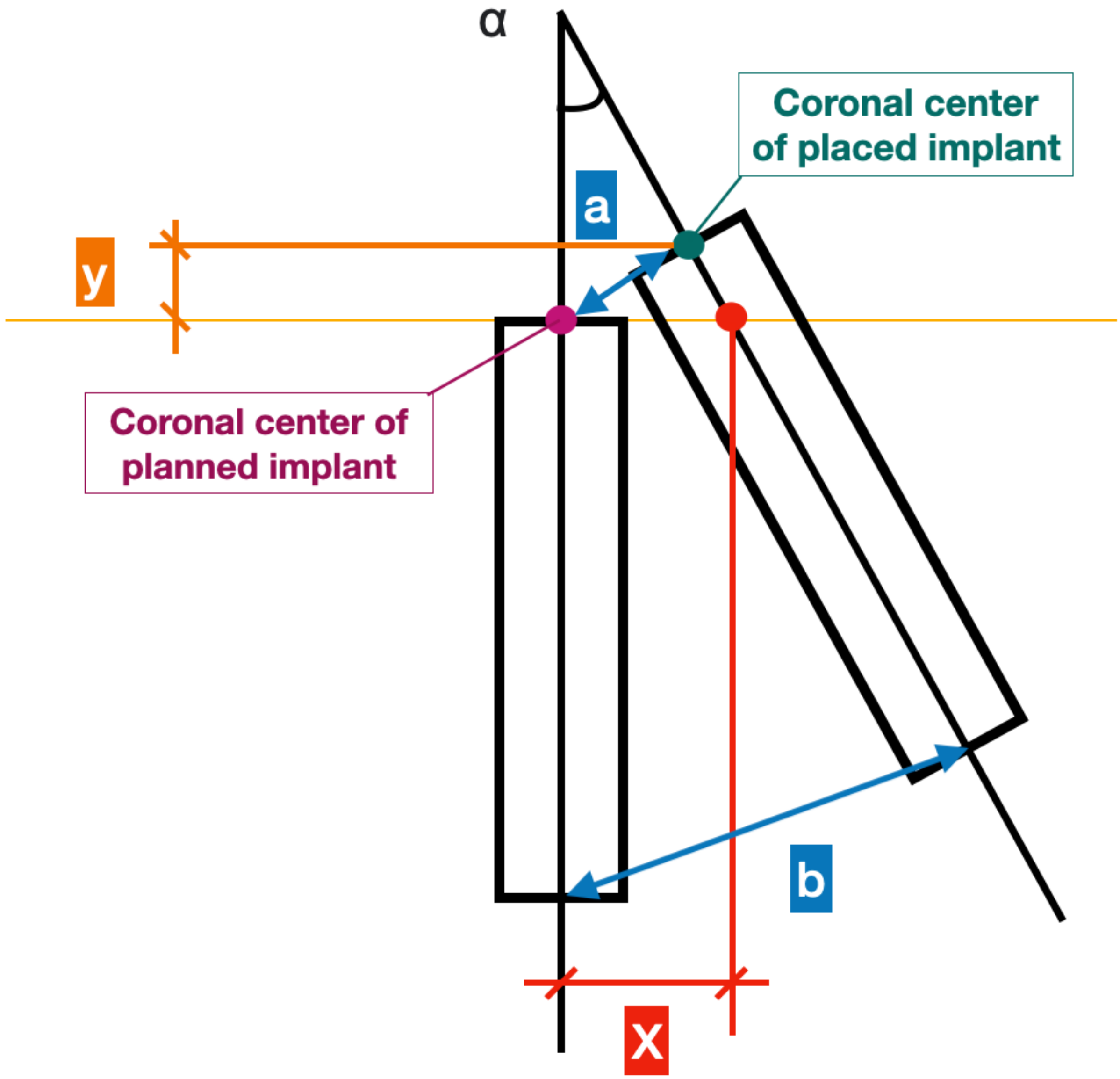

Figure 5

Graphic representation of the parameters describing accuracy expressed as: a) global deviation at the head of the implant; b): global deviation at the apex of the implant; x) horizontal/lateral deviation; y) height/depth deviation; α) angular deviation of the long axis of the implant.

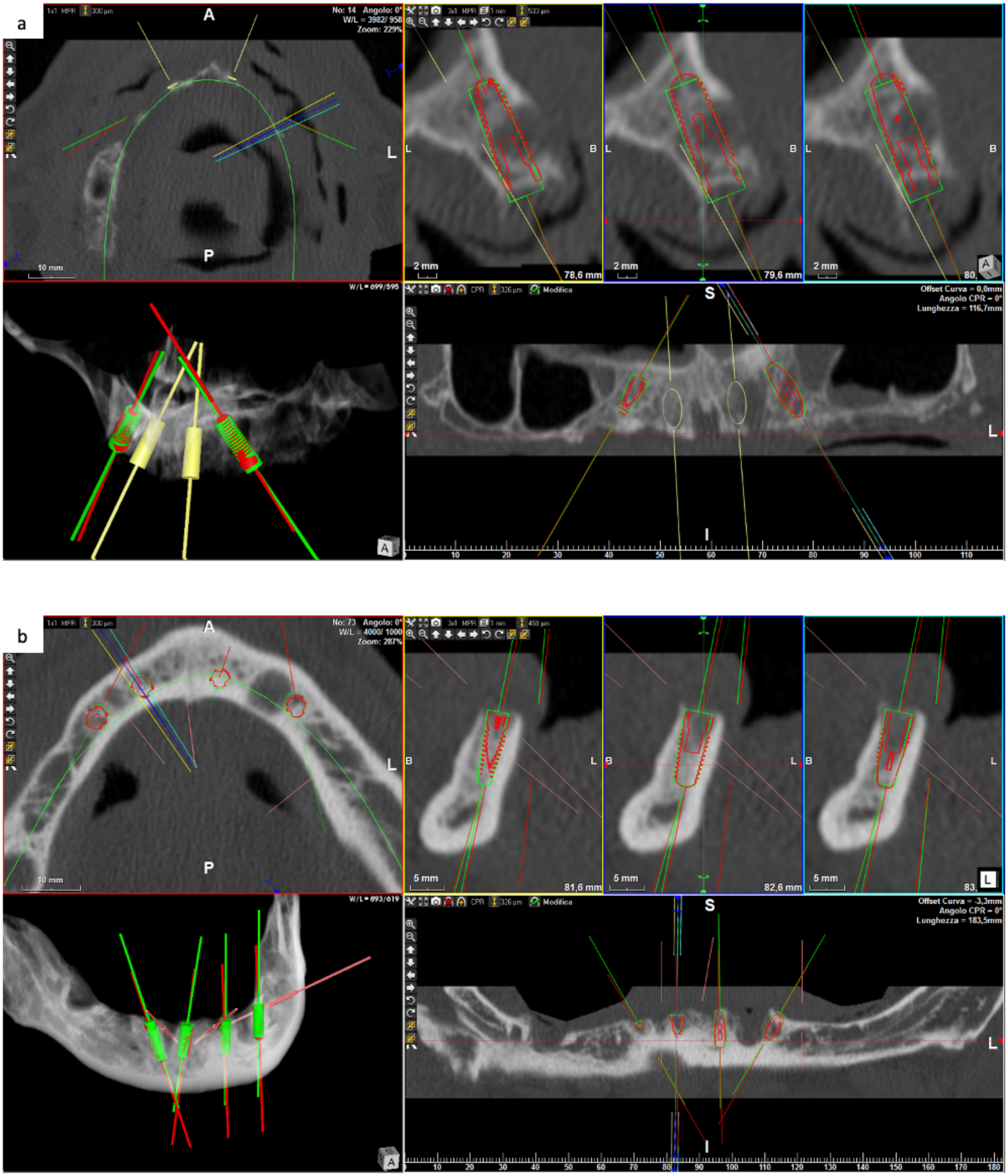

Figure 6

Accuracy analysis by Overlapping of the pre- and postoperative scans, planned implant positions in red, real implant positions in green. a Overlapping scan in upper jaw. b Overlapping scan in lower jaw.

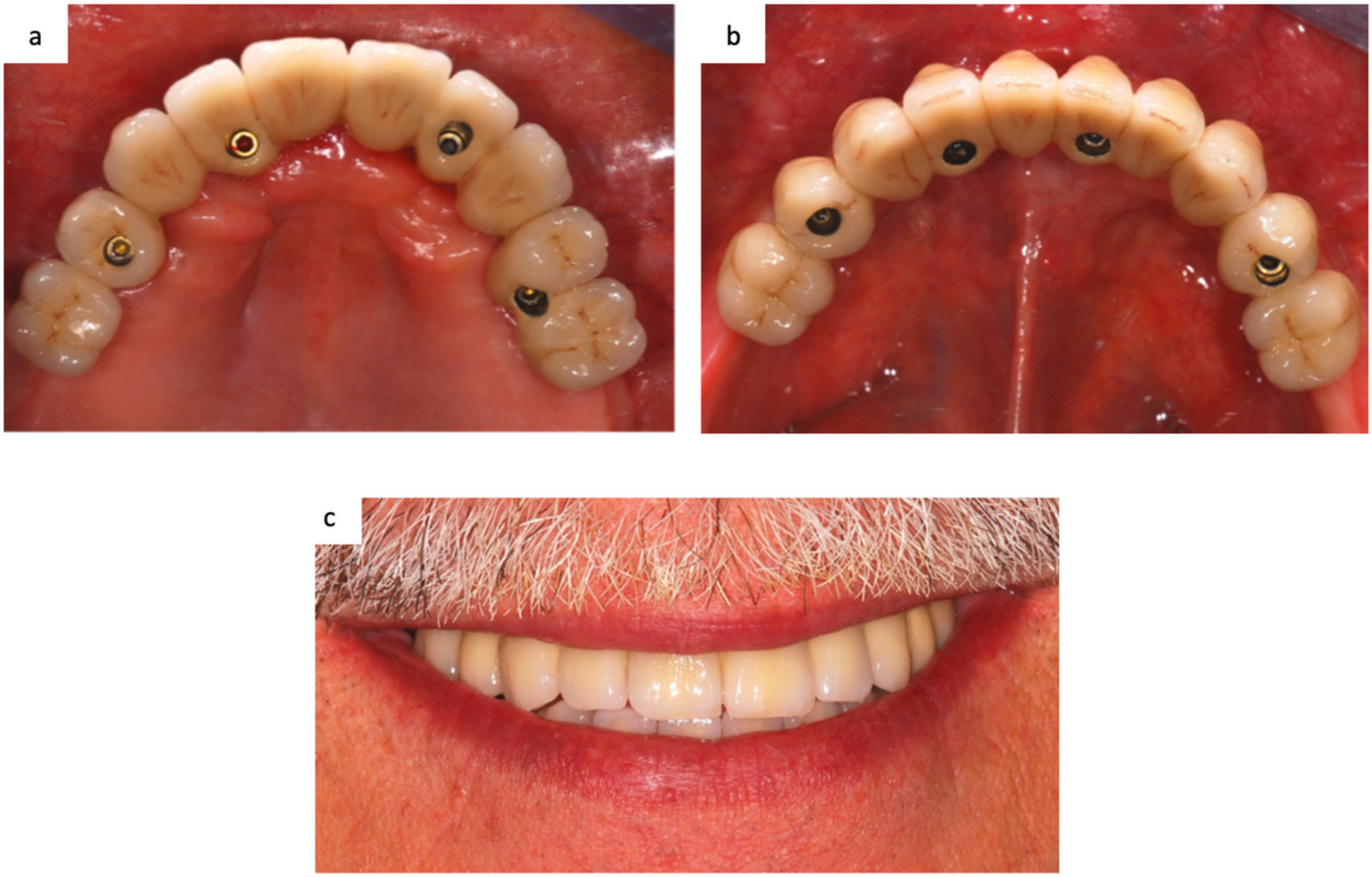

Figure 7

Final rehabilitation. a Upper restoration. b Lower restoration. c aesthetic result.

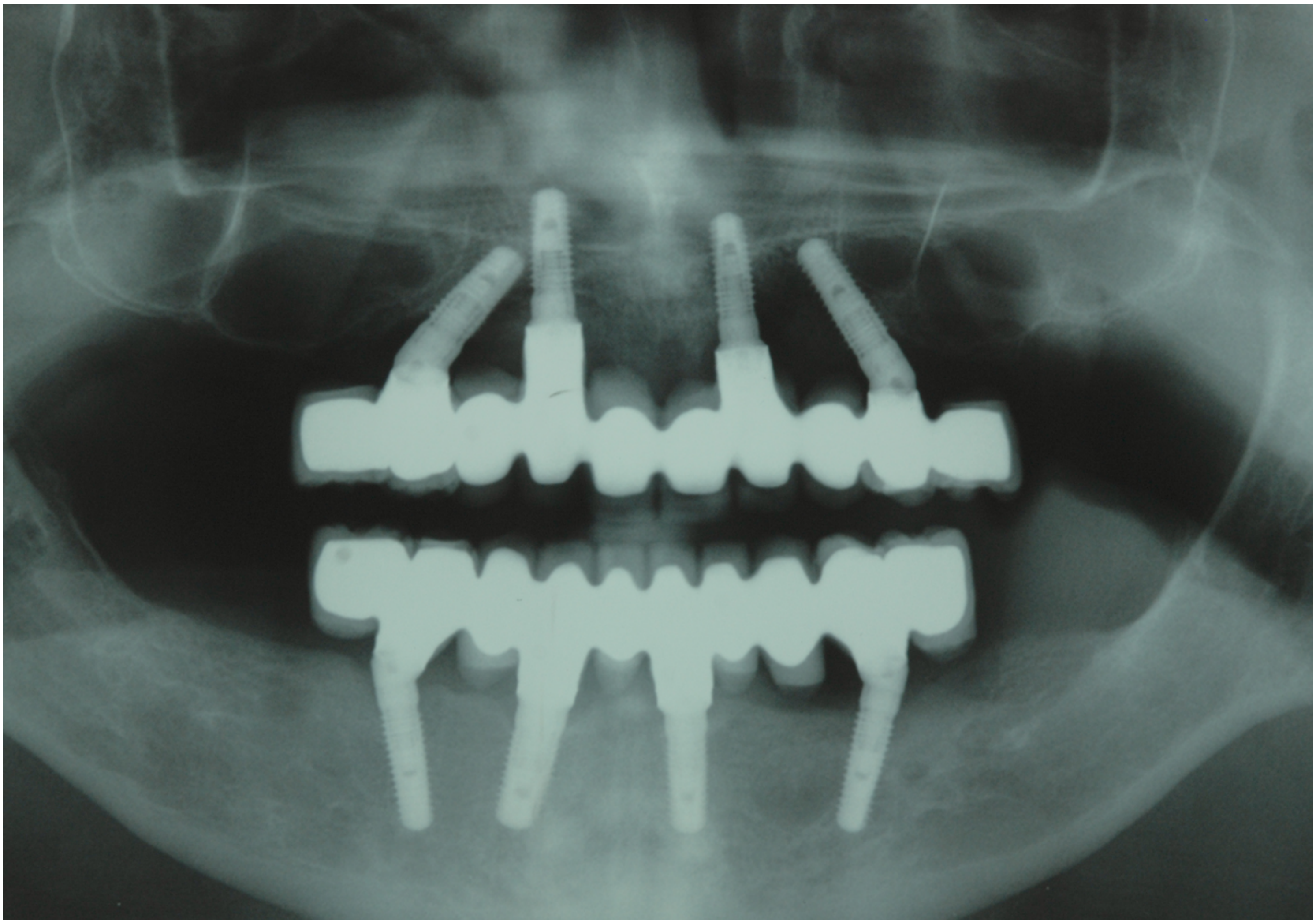

Figure 8

Follow-up orthopantomography.

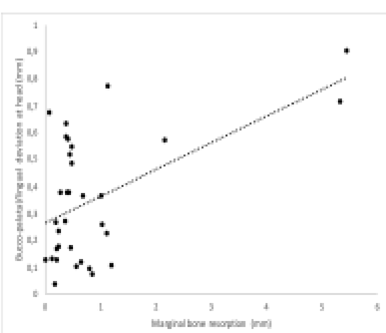

Figure 9

Graph describing the statistically significant correlation (p= 0.046) between implant head deviation in the vestibulo-lingual/palatal direction and marginal bone resorption

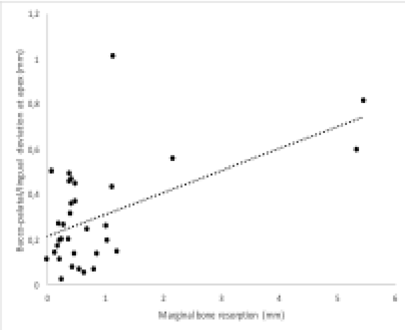

Figure 10

Graph describing the statistically significant correlation (p= 0.044) between implant apex deviation in the vestibulo-lingual/palatal direction and marginal bone resorption