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Flapless surgery and immediately loaded implants: A retrospective comparison between implantation with and without computer-assisted planned surgical stent

Matteo Danza, Francesco Carinci

SUMMARY

Objectives. Computer planned flapless surgery and immediate loading are the most recent topics in implantology. One new computer-planned implant system uses a three-dimensional parallelometer able to transfer the implant position from the virtual project to the master model. The aim of this study was to verify if the new medical device gives an advantage in term of implant failures and/or crestal bone remodeling.

Material and methods. A retrospective study was planned to analyze a series of 193 immediately loaded fixtures inserted by means of flapless surgery. From those sixty six implants were inserted with computer planning whereas 127 were inserted “free-hand”. Several variables related to patient, anatomy, implant, surgery and prosthesis were investigated. To detect the clinical outcome implant’ failure and peri-implant bone resorption were considered. Kaplan-Meier algorithm and Cox regression were then performed to detect those variables statistically associated with the clinical outcome.

Results. Implant length and diameter ranged from 10 to 16 mm and from 3.75 to 6.0 mm, respectively. Implants were inserted to replace 46 incisors, 30 cuspids, 75 premolars and 42 molars. The mean follow-up period was 15 months. Seven implants were lost (survival rate 96.4%) but no studied variable has a statistical impact on failures. On the contrary, implants inserted in sites with completed bone healing, wide diameter fixtures and implants inserted in totally edentulous jaw had a significantly lower crestal bone resorption. The other variables (age, gender, upper/lower jaws, tooth site, implant’ type and length, number of prosthetic units antagonist condition) did not have impact on crestal remodeling.

Conclusion. Computer-planned and cast model transferred implantology is a reliable technology that provides a slightly higher clinical outcome than “free hand” technique at least in healed sites, wider implants and totally edentulous jaws.

Key words: Bone, remodeling, resorption, ridge, alveolar, computer-guided, fixture, tomography.

INTRODUCTION

Two of the most notable trends in modern surgical specialities are minimally invasive surgery and the integration of computerized diagnostics and computer-guided surgery. In oral implantology these two trends are now mainstream in the form of the “flapless surgery” and “computer-guided implantology” [1, 2, 3].

Flapless surgery technique offers clinicians the possibility of placing implants in less time, with perceived less bleeding and with a reduced healing time [4]. The surgical approach requires penetration of the alveolar mucosa and bone without reflection of mucoperiosteal flap [4]. Avoiding the creation of a flap results in less postoperative patient discomfort and possible scar tissue formation. Leaving the periosteum intact on the buccal and lingual aspects of the ridge maintains a better blood supply to the site, reducing the likelihood of bone resorption [5]. Despite many benefits, however, flapless implant surgery

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has generally been perceived as a blind procedure because of the difficulty in evaluating alveolar bone contours and angulations and prone to errors leading to potentially serious complications. Therefore, this procedure has been limited to straight-forward cases in which the width of the bone crest is favorable and there is no considerable undercut [6, 7].

By using three dimensional (3D) radiographic techniques, such as computerized tomography (CT), anatomic limitations, bone morphology and the surgical site underneath the soft tissues can be evaluated precisely. Therefore, it is now possible to pre-surgically determine with a high degree of accuracy and with 3D views, the best position for implant placement and to plan the implant position and inclination, based on the final prosthetic outcome [8].

Despite patients are treated using minimally invasive procedures, the indication for CT-based diagnostics and treatment planning is limited to difficult clinical situations to minimize radiation exposure Therefore, the cost/benefit ratio must be taken into account and must be carefully discussed with the patient [8].

Recently, a system that combines computer planned data with a working cast model was reported [9]. The procedure allows the clinician to verify onto a master cast the correct implant positions. This cast is used to build an individual surgical stent that is intended to perfectly match the teeth and soft tissues as well as a provisional or definitive implant-supported prosthesis for partially or completely edentulous patients.

Since no report is still available on a series of implants inserted with this surgical procedure we performed a retrospective analysis on fixtures inserted with flapless surgical technique and immediately loaded. The aim of this study was to verify if computer planned implantology gives an advantage in term of implant failures and/or crestal bone remodeling. Sixty six implants were inserted with computer planning whereas 127 were inserted “free-hand”. The null hypothesis was that there is no difference between CT-guided and “free-hand” inserted implants considering number of lost implants and crestal bone resorption.

MATERIALS AND METHODS

Study design/sample

To address the study aim, a retrospective cohort study was designed. The study population was composed of 60 patients (34 female and 26 male, median age 48 years) operated between June 2004 and June 2008. Informed written consent approved by the local Ethics Committee was obtained from patients to use their data for research purpose.

Subjects were screened according to the following inclusion criteria: controlled oral hygiene, sufficient residual bone volume to receive implants of 3.75 mm in diameter and 10 mm in length. In addition, the patients had to agree to participate in a post-operative check-up program.

The exclusion criteria were: insufficient bone volume to receive implants of 3.75 mm in diameter and 10 mm in length, bruxism, smoking more than 20 cigarettes/day and excessive consumption of alcohol (i.e. more than 2 glasses of wine per day), localized radiation therapy of the oral cavity, antitumor chemotherapy, liver, blood and kidney diseases, immunosupressed patients, patients taking corticosteroids, pregnant women, inflammatory and autoimmune diseases of the oral cavity (detected by clinical evaluation).

Computer planned implantology

The method is based on the transfer of geometric and mathematical values relative to implants three-dimensional position obtained by CT and elaborated with a computer program (Implant 3D Software Media-Lab co. La Spezia, Italy) to the custom model by means a three-dimensional parallelometer called Ray-Set apparatus (Biaggini Medical Devices, La Spezia, Italy). The Ray-Set apparatus transfers data from the virtual to the real dimension and it allows verifying the planned rehabilitation on the model [9].

All patients underwent the same surgical protocol. An antimicrobial prophylaxis was administered with 500 mg Amoxycillin twice daily for 5 days starting 1 hour before surgery. Local anesthesia was induced by infiltration with articaine/epinephrine and post-surgical analgesic treatment was performed with 100 mg Nimesulid twice daily for 3 days. Oral hygiene instructions were provided.

After placing the surgical guide, mucotomy was performed, bone drilled and implants (Alpha Bio LTD, Petah-Tikva, Israel) inserted as previously planned with CT-guided protocol. No surgical guide was used for “free-hand” inserted implants. The implant platform was positioned at the alveolar crest level, provisional restoration immediately delivered, and implant loaded. After 8 weeks the final restoration was usually delivered. The number of prosthetic units (i.e. implant/crown ratio) was 0.78. All patients were included in a strict hygiene recall (Fig. 1-7).

Variables

Several variables were investigated: demographic (age and gender), anatomic (maxilla and mandible, tooth site), implant (type, length and diameter), surgical (post-extractive) and prosthetic (number

Fig. 1. Frontal view of the occlusion

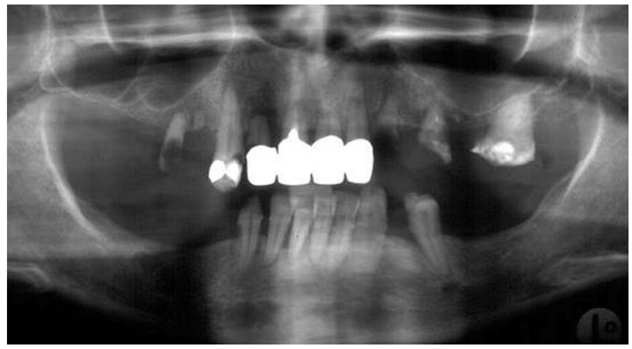

Fig. 2. Pre-surgical panoramic radiographs

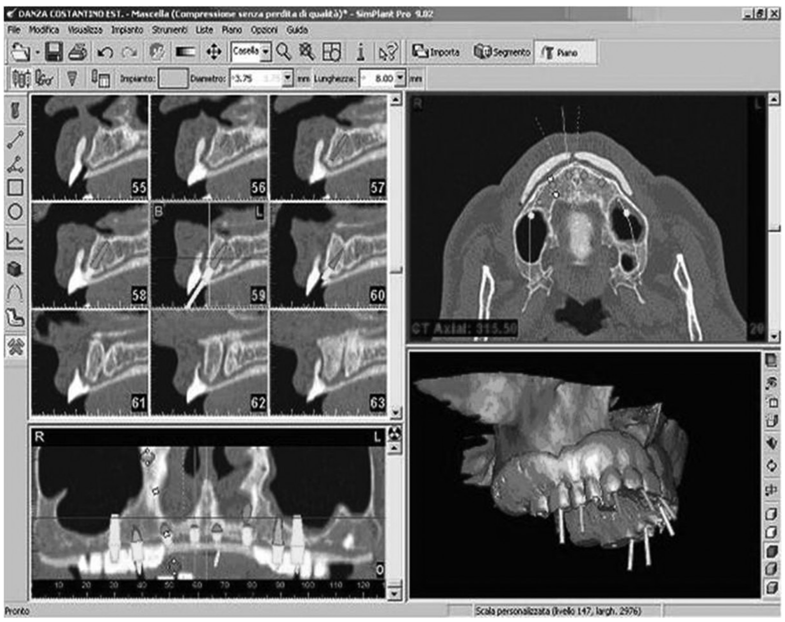

Fig. 3. Computer simulation of implant insertion

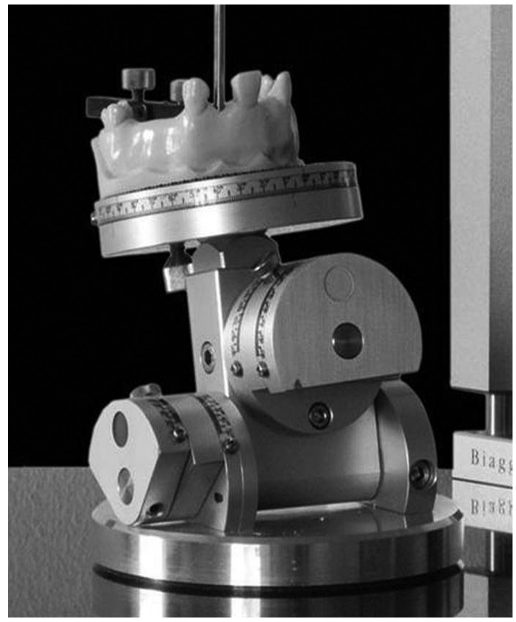

Fig. 4. Parallelometer able to transfer the implant position from the virtual project to the master model

Fig. 5. The surgical guide onto the mucosa

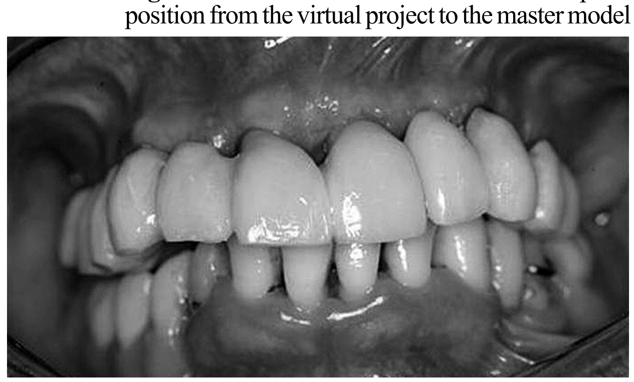

Fig. 6. The provisional restoration

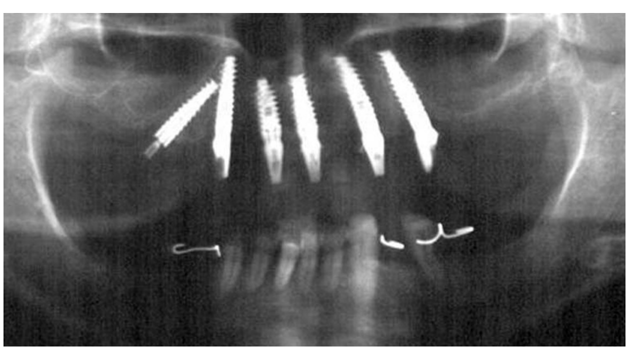

Fig. 7. Post-surgical panoramic radiographs

of prosthetic units, edentulness, and dentition in the antagonist arch) variables.

Primary and secondary estimates of clinical outcome were used. The primary predictor was the presence/absence of the implant at the end of the observation period. It was defined as survival rate (SVR) that was the total number of implants still in place at the end of the follow-up period.

The second predictor of outcome was the peri-implant bone resorption. It was defined as implant success rate (SCR) and it was evaluated according

Table 1. Failed implants

Implant diameter	Implant length	Implant site	Implant type	No. of months post implant insertion
3.75	16	13	SPI	1
5.0	16	21	SFB	1
4.2	10	25	SFB	1
4.2	13	34	SPI	14
3.75	16	11	SPI	0
6.0	11.5	25	SPI	41
4.2	11.5	46	SFB	7

Table 2. Output of Kaplan-Meyer analysis: no variable reach has a statistical significant value. Implant site is a comparison between incisors and canine vs. pre- and molars. In N.P.U. (i.e. number of prosthetic units, that is the i.e. implant/crown ratio) there were 2 groups N.P.U.=1 and N.P.U.<1. Partially or completely edentulous is referred to the operated jaw whereas type antagonist element is referred to the opposite jaw.

Variable	Log Rank	Degree of freedom	Significance
Maxilla/mandible	.10	1	.7537
Implant site	.02	1	.8748
Implant length	3.75	3	.289
Implant diameter	.68	3	.8769
Implant type	1.91	1	.1672
Post-extractive vs. late-implantation	2.23	1	.1352
N.P.U.	.77	1	.3817
Partially or completely edentulous	3.44	1	.0638
Type of antagonist element	.28	1	.5971
CT-planned	3.28	1	.0701

Table 3. Output of the Cox regression regarding variables analyzed by using the SVR. B is the natural log of the odds (i.e. risk); E = exponent 10-based.

Variable	B	Significance (P<0.05)	95% Confidence Interval	
			Lower	Upper
Age	-.1252	.6685	.4975	1.5649
Gender	-49.5407	.2749	7.332E-61	1.271E+17
Upper/lower jaw	-41.4964	.2807	1.721E-51	5.260E+14
Implant' site	33.7959	.3339	8.113E-16	2.790E+44
Implant type	14.9642	.3712	1.799E-08	5.531E+20
Implant length	3.3755	.4469	.0049	175195.51
Implant diameter	12.5434	.3778	2.198E-07	3.573E+17
Post-extractive vs. late-implantation	-31.0898	.3228	5.416E-41	1.828E+13
N.P.U.	65.8030	.2797	5.829E-24	2.456E+80
Partially or completely edentulous	-34.0696	.7685	4.668-114	5.476E+83
Type of antagonist element	1.5982	.8722	1.739E-08	1.405E+09
CT-planned	-45.7544	.6240	4.821-100	3.759E+59

to the absence of persisting peri-implant bone resorption greater than 1,5 mm during the first year of loading and 0.2 mm/ years during the following years [10].

Data collection methods and summary of operative methods

Before surgery, radiographic examinations were done with the use of panoramic radiographs and CT scans, peri-apical radiographs.

In each patient, peri-implant crestal bone levels were evaluated by the calibrated examination of peri-apical radiographs. Measurements were recorded after surgery and at the end of the follow-up period. The measurements were carried out mesially and distally to each implant, calculating the distance between the implant' platform and the most coronal point of contact between the bone and the implant. The bone level recorded just after the surgical insertion of the implant was the reference point for the following measurements. A second CT was not performed because of the quantity of X-rays delivered. The measurement was rounded off to the nearest 0.1 mm. A peri-apical radiograph was accomplished by means a customized Rinn holder device. This device was necessary to maintain the X-ray cone perpendicular to a film orientated parallel to the long axis of the implant. The peri-apical radiographs were taken using a long x-ray tube at 70 Kw of power, and performed with a computer system (Gendex, KaVo ITALIA srl, Genova, Italia) and saved in an uncompressed TIFF format for classification. Each file was processed with the Window XP Professional operating system using the Photoshop 7.0 (Adobe, San Jose, CA), on a 17" SXGA TFT LCD display with a NVIDIA GE Force FX GO 5600, 64 MB video card (Acer Aspire 1703 SM-2.6). Knowing the known dimensions of the implant, it was possible to establish the distance from the mesial and distal edges of the implant platform to the point of bone-implant contact.

The difference between the implant-abutment junction and the bone crestal level was defined as the Implant Abutment Junction (IAJ) and calculated at the time of operation and during follow-up. The

Table 4. Distribution of series; the number of implants is out of parenthesis whereas the median delta IAJ is in parenthesis

Jaw	Implant site	Implant length	Implant diameter	Implant type	Post-extractive vs. late-implantation	N.P.U.	Partially or completely edentulous	Type of antagonist element	CT-planned
Mandible 61 (2.1)	Incisors and cuspids 73 (1.7)	10 mm 36 (2.0)	3.75 mm 40 (1.9)	SFB 141 (1.8)	Yes 109 (1.9)	N.P.U. <1 104 (1.8)	Total 52 (1.7)	Natural 94 (1.8)	Yes 62 (1.8)
Maxilla 125 (1.7)	Pre and molars 113 (1.9)	11.5 mm 24 (1.6)	4.2 mm 74 (1.8)	SPI 45 (1.8)	No 77 (1.8)	N.P.U.=1 82 (1.9)	Partial 134 (1.9)	Prosthetic 92 (1.8)	No 124 (1.8)
–	–	13 mm 75 (2.0)	5.0 mm 53 (1.8)	–	–	–	–	–	–
–	–	16 mm 51 (1.6)	6.0 mm 19 (1.8)	–	–	–	–	–	–

delta IAJ is the difference between the IAJ at the last check-up and the IAJ recorded just after the operation. Delta IAJ medians were stratified according to the variables of interest.

Peri-implant probing was not performed because controversy still exists regarding the correlation between probing depth and implant success rates [11, 12].

The mean follow-up was 15 months (min 1 – max 41).

One hundred and thirty (67.4%) implants were inserted into the maxillae and 63 (32.6%) into the mandible. There were 144 SFB (spiral flare bevel) and 49 SPI (spiral implant). Implant length and diameter ranged from 10 to 16 mm and from 3.75 to 6.0 mm, respectively. Implants were inserted to replace 46 incisors, 30 cuspids, 75 premolars and 42 molars. All patients underwent flapless surgery and immediate loading with fixed prosthetic restorations. One hundred and fifteen (59.6%) implants were placed in post extractive sockets; fifty two (26.9%) were inserted in totally edentulous jaw; the antagonist was a natural tooth in 99 cases and a prosthetic devices in the remaining 94.

Data analysis

Disease-specific survival curves were calculated according to the product-limit method (Kaplan-Meier algorithm) [13]. Log rank testing was used to compare survival/success curves, generated by stratifications for a variable of interest.

Cox regression analysis was then applied to determine the single contribution of covariates on the survival/success rate [14]. Stepwise Cox analysis allowed to detect the variables most associated with implant survival and/or success rates.

RESULTS

Seven implants were lost (Table 1). All were “free-hand” inserted. The overall SVR was 96.4%.

Table 5. Output of Kaplan-Meyer analysis: the type of prosthetic restoration has a statistical significant value

Implant diameter	Implant length	Implant type	No. of months post implant insertion
Upper/lower jaw	.92	1	.3374
Implant site	5.90	1	.0151
Implant length	4.99	3	.1727
Implant diameter	9.87	3	.0197
Implant type	.02	1	.8979
Post-extractive vs. late-implantation	9.21	1	.0024
N.P.U.	.06	1	.8138
Partially or completely edentulous	6.50	1	.0108
Type of antagonist element	3.12	1	.0771
CT-planned	.45	1	.5003

Table 6. Output of the Cox regression regarding variables analyzed by using the SVR. B is the natural log of the odds (i.e. risk); E = exponent 10-based.

Variable	B	Significance (P<0.05)	95% Confidence Interval	
			Lower	Upper
Age	.0205	.0231	1.0028	1.0390
Gender	.0722	.7749	.6554	1.7628
Implant site	.4904	.0569	.9857	2.7051
Implant diameter	-.3904	.0410	.4655	.9841
Post-extractive vs. late-implantation	.5099	.0480	1.0044	2.7603
Partially or completely edentulous	-.7303	.0276	.2515	.9228

Both univariate (Table 2) and multivariate (Table 3) analysis did not show any differences among the studied variables. Table 4 reports the median delta IAJ according to the studied variables. Kaplan Meier algorithm demonstrates that several variables are potentially associated to the crestal bone resorption (Table 5).

Table 6 shows a better result for implant inserted in sites with completed bone healing, wide diameter implants (i.e. 4.2 mm or larger) and inserted in totally edentulous jaw.

DISCUSSION

Flapless implant surgery has been suggested as one possible treatment option for enhancement of implant aesthetics and easy to perform [15]. However, by performing this blind procedure, one should be aware of risking deviating implants for the difficulty in evaluating alveolar bone contours and angulations. Pre-surgical diagnostics with appropriate software programs provides all the information necessary regarding the implant site and anatomical landmarks. If adequate support of the guide is provided, precise and efficient surgeries can be performed [16]. The use of radiographic images is necessary to evaluate the surgical site underneath the soft tissue and CT images provide an accurate 3D picture of the surgical field [17-21]. In addition, several authors have advocated the use of drill guides [19, 22-24] to link the virtual preoperative treatment plan based on the CT images to the situation encountered during surgery.

Cone beam computed tomography (CBCT) greatly reduces the radiation of patient thus changing the way dental practitioners of viewing the oral and maxillofacial complex [25, 26]. CBCT uses radiation in a similar manner as does conventional diagnostic imaging and reformats the raw data into Digital Imaging and Communications in Medicine (DICOM) data. DICOM data are imported into viewing software that enables the manipulation of multiplanar reconstructed slices and three-dimensional volume renderings. DICOM data also may be used in third-party software to aid in dental implant placement, orthognatic surgery and orthodontic assessment.

Previously, an “in vitro” study of Kramer et al. [25] showed that the precision of navigated surgery was better than conventional surgery for repeated implant placements to restore a maxillary single tooth. The variation in inclination, depth and angle deviation was less when a tactile navigation system was used compared with conventional surgery.

Since computer planned implantology offers the possibility to obtain the best positioning of fixtures in the bone and the Ray Set (Biaggini Medical Devices) is a parallelometer which verify the virtual data with the cast model [9], a retrospective study on 193 fixtures was planned to estimate implant survival and changes in crestal bone resorption.

Seven implants were lost (i.e. survival rate SVR=96.4%) but no differences were detected among the variables investigated although all failed implants were “free-hand” inserted. On the contrary, by using the crestal bone resorption as indicator of clinical outcome, the Cox regression showed that implant inserted in sites with completed bone healing (i.e. not late implantation), wide diameter implants (i.e. 4.2 mm or larger) and inserted in totally edentulous jaw correlated with a statistically significant lower crestal bone loss and thus a better clinical outcome. These data can be explained with (i) a lower bone remodeling in the healed site [26], (ii) a higher loading distribution between implant and bone surface in wide diameter implants [27] and (iii) a more favorable oral health in total edentulism [28].

The fact that no difference in survival rate (i.e. fixtures still in place at the end of the follow-up) was detected can be attributed to the high overall clinical outcome to free-hand inserted implants, which is in agreement with the recent literature [26, 27]. Widmann et al. established that compared with the conventional technique, this sophisticated technology of computer-aided implant surgery requires substantially more financial investment and effort but seems superior on account of its potential to eliminate possible manual placement errors and to systematize reproducible treatment success [29].

A lower bone resorption was detected for healed sites and totally edentulous patients. Most extractions were performed in periodontally compromised teeth. Thus a moderate inflammatory process of alveolar sockets cannot be excluded. In a similar way, partially edentulous patients, especially those with a history of chronic periodontitis, may exhibit significantly greater long-term probing pocket depth, peri-implant marginal bone loss and incidence of peri-implantitis compared with periodontally healthy subjects. However, no conclusive data are available in the recent literature [28].

Finally, wide diameter implants have a lower bone resorption. It is generally accepted that this fact is related to the augmented implants-bone contact area that improves the ability of posterior implants to tolerate occlusal forces [30, 31].

CONCLUSION

Computer-planned and cast model transferred implantology is a reliable technology that provides a slightly higher clinical outcome than "free hand" technique at least in healed sites, wider implants and totally edentulous jaws.

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