Osseotite implants inserted into fresh frozen bone grafts

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Abstract

Background In the last decade, several investigators have reported that double etched implants have achieved excellent results. However, no report regarding double etched implants inserted into fresh frozen bone is available.

Aims We planned to perform a retrospective study on double etched implants inserted into fresh frozen bone grafts.

Setting and design 28 patients (17 females and 11 males with a median age of 52 years) were operated on and 114 double etched implants inserted. Implant diameter and length ranged from 3.25 to 5.0 mm and from 10.0 to 15 mm, respectively.

Results Since only 4 out of 114 implants were lost (i.e. Survival Rate SVR = 96.5%) and no statistical differences were detected among the studied variables. The type of prosthetic restoration (i.e. fixed prostheses) correlated with a statistically significant lower delta Implant Abutment Junction (i.e. reduced crestal bone loss) and thus a better clinical outcome.

Conclusion Double etched implants inserted into fresh frozen bone had a high survival and success rate similar to those reported in previous studies of two-stage procedures in non-grafted bone, although a higher marginal bone loss has to be expected when removable prosthetic restorations are used.

Keywords Iliac crest · Allograft · Homograft · Double etched · Implant

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Introduction

Alveolar crest defects should ideally be corrected with autologous bone by augmentation. Although autografts are the standard procedure for bone grafting, it is sometimes not possible to harvest an adequate amount of bone from other donor sites on the same patient. Moreover, autologous bone grafts have the drawback of requiring secondary surgery for autograft retrieval, with increased operation time and anaesthesia, and donor site morbidity [1]. On the other hand, biomaterials are good but expensive, and may become infected at a later date [2]. So, the use of homograft bone provides a reasonable alternative to meet the need for graft material [1,2].

Bone homograft transplantation has been performed in humans for more than one hundred years and is being used increasingly by orthopedic surgeons [3].

Many forms of banked bone homograft are available to the surgeon: Fresh-frozen Bone (FFB), Freeze-dried Bone (FDB), and Demineralized Fresh Dried Bone (DFDB). Each one of these grafts carries risks and has unique limitations and handling properties. In order to use these materials appropriately, the surgeon must be familiar with the properties of each and must feel confident that the bone bank providing the graft is supplying a safe and sterile graft [4].

Double etched implants (i.e. DEIs, 3i implants, Implant-Innovation Inc.) are fixtures which are used worldwide. They are characterized by an osseotite surface which is etched using HCl and HSO resulting in a non-machined roughened implants [5].

Several reports are available regarding the used of DEIs in native bone: [5–11] all the studies have demonstrated high survival (SVR i.e. number of implants still in place

at the end of the follow-up) and success rates (SCR i.e. good clinical and radiological results).

Since FFB has ever increasing clinical applications and reports are available on DEIs inserted into FFB we therefore decided to perform a retrospective study.

Patients and methods

A) Patients

In the period between December 2003 and December 2006, 81 patients (52 females and 29 males) with a median age of 52 years were operated on at the Civil Hospital, Castelfranco Veneto, Italy. Among them, 28 patients (17 females and 11 males) with a median age of 52 years were treated with DEIs. Informed written consent approved by the local Ethics Committee was obtained from patients to use their data for research

Table 1 Distribution of series as regards graft site and delta IAJ

Graft site	N	Median
Mandible	32	1.6
Maxilla	82	1.9

Table 2 Distribution of series as regards implant site and delta IAJ

Implant site	N	Median
Incisors	14	1.9
Cuspids	5	1.9
Premolars	47	1.7
Molars	48	1.9

Table 3 Distribution of series as regards implant length and delta IAJ

Implant length	N	Median
Less than 13 mm	26	1.4
13 mm	65	2.1
More than 13	23	1.4

Table 4 Distribution of series as regards implant diameter and delta IAJ

Implant diameter	N	Median
Diameter < 3.75 mm	23	1.6
Diameter = 3.75 mm	56	1.9
Diameter > 3.75 mm	35	1.8

Table 5 Distribution of series as regards prosthetic restoration and delta IAJ

Prosthetic Type	N	Median
None	22	1.6
Fixed prosthesis	71	1.8
Removable dentures	21	2.0

purpose. The mean implant follow-up was 23 months.

Homologue FFB grafts were previously inserted into patient's jaws under general anesthesia. Usually the mean post-grafting period was 6 months before implant surgery and the final prosthetic restoration was delivered after an additional 6 months.

Subjects were screened according to the following inclusion criteria: controlled oral hygiene, the absence of any lesions in the oral cavity, sufficient residual bone volume (autologous plus FFB graft) to receive implants of at least 3.25 mm in diameter and 10.0 mm in length; in addition, the patients had to agree to participate in a postoperative check-up program.

Exclusion criteria were as follows: insufficient bone volume, a high degree of bruxism, smoking more than 20 cigarettes/day and excessive consumption of alcohol, localized radiation therapy of the oral cavity, antitumor chemotherapy, liver, blood and kidney diseases, immunosuppressed patients, patients taking corticosteroids, pregnant women,

inflammatory and autoimmune diseases of the oral cavity, poor oral hygiene.

B) Graft material

The FFB - obtained from the Veneto Tissue Bank in Treviso (Italy) - is a mineralized, non-irradiated, only disinfected and frozen homologous bone. The bone harvesting is obtained from the anterior and posterior iliac crest, in the first 12 hours after donor death. The bone is then disinfected, for at least 72 hours at -4°C, in a polychemotherapeutic solution of vancomycin, polymyxine, glazidine and lincomycin, following that the sample is irrigated with a sterile saline solution. The sample is then subdivided into cortico-medullary blocks, packed in double sterile casing and frozen at -80°C.

The requirements for homologous bone donors are more stringent with respect to those of organ donors. The presence of risk factors such as contagious disease, neoplasm, rheumatic and/or degenerative disease and sepsis necessarily disqualifies the donor. In order to detect infectious

agents, the following tests are performed on donor blood samples taken within 8 hours of death: anti-HIV-I/II Ab, anti-HCV Ab, HbsAg, anti-HBc Ab, anti-HBs Ab, anti-HTLV-I/II Ab, anti-Ag Treponemal Ab, anti-CMV IgG Ab, anti-CMV IgM Ab, anti-Toxoplasma IgG Ab, anti-Toxoplasma IgM Ab. A culture is also performed to detect aerobic and anaerobic bacteria, mycobacteria and mycological agents. As a further safety method, a serological follow-up is conducted using Polymerase Chain Reaction techniques to detect any viral RNA or DNA of HIV, HCV and HBV. This method reduces the 'diagnostic window period' to 7 days for HIV, HCV and HBV.

C) Data collection

Before surgery, radiographic examinations were done with the use of orthopantomograph and CT scans.

In each patient, peri-implant crestal bone levels were evaluated by calibrated examination of orthopantomograph x-rays. Measurements were recorded before surgery; 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 edge of the implant 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. The measurement was rounded off to the nearest 0.1 mm. A peak Scale Loupe with a magnifying factor of seven times and a scale graduated in 0.1 mm was used.

Peri-implant probing was not performed since controversy still exists regarding the correlation between probing depth and implant success rates [12,13].

The implant success rate (SCR) was evaluated according to the following criteria: (1) absence of persisting pain or dysesthesia; (2) absence of peri-implant infection with suppuration; (3) absence of mobility; and (4) 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 [14].

D) Implants

A total of 114 DEIs were inserted in 28 patients: 32 (28.1%) in the mandible and 82 (71.9%) in the maxilla. Implant diameter

Table 6 Failed implant

Implant diameter	Implant length	Graft site	Implant site	No of months post implant insertion	Prosthesis
3.25	13	Maxilla	26	4	None
3.25	13	Maxilla	16	4	None
3.25	10	Mandible	35	5	None
3.25	10	Mandible	36	3	None

Table 7 Output of the Cox regression reporting the variables associated statistically with delta IAJ by evaluating delta IAJ (i.e. SCR)

Variable	B	S.E.	Significance (P<0.05)	95% Confidence interval	
				Lower	Upper
Age	-0.312	0.0230	0.1744	0.9265	1.0139
Gender	-0.4492	0.3957	0.2562	0.2938	1.3858
Graft site	0.1535	0.5601	0.7840	0.3890	3.4949
Implant site	-0.3845	0.2242	0.0864	0.4387	1.0565
Implant length	0.3866	0.3201	0.2271	0.7860	2.7566
Implant diameter	0.4162	0.2708	0.1242	0.8919	2.5777
Type of restoration	-0.7740	0.3698	0.0364	0.2234	0.9520

and length ranged from 3.25 to 5.0 mm and from 10.0 to 15 mm, respectively. Implants were inserted to replace 14 incisors, 5 cuspids, 47 premolars and 48 molars.

E) Surgical and prosthetic technique

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 making a crestal incision a mucoperiosteal flap was elevated. Implants were inserted according to the procedures recommended. The implant platform was positioned at the alveolar crest level. Sutures were removed 14 days after surgery. After 24 weeks from implant insertion, the provisional prosthesis was provided and the final restoration was usually delivered within an additional 8 weeks. The number of prosthetic units (i.e. implant/crown ratio) was about 0.7. All patients were included in a strict hygiene recall.

F) Statistical analysis

Since only 4 out of 114 implants were lost (i.e. SVR = 96.5%) and no statistical differences were detected among the studied variables, no or reduced crestal bone resorption was considered an indicator of SCR to evaluate the effect of

several host-, implant-, and occlusion-related factors.

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 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.

Disease-specific survival curves were calculated according to the product-limit method (Kaplan-Meier algorithm) [15]. Time zero was defined as the date of the insertion of the implant. Implants which were still in place were included in the total number at risk of loss only upto the time of their last follow-up. Therefore, the survival rate only changed when implant loss occurred. The calculated survival rate was the maximum estimate of the true survival curve. Log rank testing was used to compare survival 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 rate. Cox regression analysis compares survival data while taking into account the statistical value of independent variables, such as age and sex, on whether or not an event (i.e. implant loss) is likely occur. If the associated probability was less than 5% ($p < .05$), the difference was considered statistically significant. In the process of doing the regression analysis, odds ratio and 95% confidence bounds were calculated. Confidence bounds did not have to include the value 1 [16]. Stepwise Cox

analysis allowed us to detect the variables most associated with implant survival and/or success.

Results

Tables 1 to 5 report the median delta IAJ according to the studied variables.

Four implants were lost in the postoperative period (within 4 months) and Table 6 describes their characteristics.

Table 7 shows that prosthetic restoration (i.e. fixed prostheses see Table 5) correlated with a statistically significant lower delta IAJ (i.e. reduced crestal bone loss) and thus a better clinical outcome.

Discussion

The identification of guidelines for the long term SVR (i.e. number of implants still in place at the end of the follow-up) and SCR (i.e. good clinical, radiological and aesthetic outcome) are the main goals of the recent literature. Several variables can influence the final result, but in general they are grouped as (1) surgery-, (2) host-, (3) implant-, and (4) occlusion-related factors [17]. The surgery-related factors comprise several variables such as an excess of surgical trauma like thermal injury [18], bone preparation, drill sharpness and design [19]. Bone quality and quantity are the most important host-related factors while design, surface coating, diameter and length [20] are the most relevant implant-related factors. Finally, quality and quantity of force and prosthetic design [21] are the variables of interest among the occlusion-

related factors. All these variables are a matter of scientific investigation since they may affect the clinical outcome.

In general, length (Table 3) and diameter (Table 4) are considered to be relevant fixture-related factors. In the present study no differences were detected among these variables: Lazzara et al. [7] in their study, comparing different diameters of DEIs, reported an SCR of 96.0% for 3.3 mm implants in the mandible and 95.5% in the maxilla, and 95% for 4.0 mm diameter implants in the mandible and 92.0% in the maxilla.

Bone quality, a host-related factor, is believed to be one of the strongest predictors of outcome [22]. In the present series, only 4 out of 114 implants were lost and thus, we have demonstrated that FFB is a reliable material for alveolar crest reconstruction prior to implant placement. In addition, no statistically significant differences were found among various graft-sites (Table 1) and implant-sites (Table 2). Similar results have been reported by others [8–5]. Testori et al. [8] detected a SCR of 99.4% and 98.4% in the posterior mandible and maxilla respectively, while Davarpanah et al. [5] observed a 5-years SRV of 97.2% in the maxilla and 95.8% in the mandible, noticing that the SVR was similar in the anterior (96.7%) and posterior (96.5%) segments.

As regards occlusion-related factors, a better clinical outcome was found for fixed prosthetic restorations (Table 5). This is not surprising as one of the critical points in immediate loading is to ensure a reduction of implant micromovement by splitting them with specific devices.

Conclusion

FFB is a reliable grafting material for the incision of DEIs. DEIs inserted into FFB had a high survival and success rate similar to those reported in previous studies of two stage procedures in non grafted bone.

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