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CLINICAL OUTCOME OF NARROW DIAMETER IMPLANTS INSERTED INTO ALLOGRAFTS

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ABSTRACT

Objective: Narrow diameter implants (NDI) (i.e. diameter <3.75 mm) are a potential solution for specific clinical situations, such as reduced interradicular bone, thin alveolar crest and replacement of teeth with small cervical diameter. NDI have been available in clinical practice since the 1990s, but only few studies have analyzed their clinical outcome and no study have investigated NDI inserted in fresh-frozen bone (FFB) grafts. Thus, a retrospective study on a series of NDI placed in homologue FFB was designed to evaluate their clinical outcome. Material and Methods: In the period between December 2003 and December 2006, 36 patients (22 females and 14 males, mean age 53 years) with FFB grafts were selected and 94 different NDI were inserted. The mean follow-up was 25 months. To evaluate the effect of several host-, surgery-, and implant-related factors, marginal bone loss (MBL) was considered an indicator of success rate (SCR). The Kaplan Meier algorithm and Cox regression were used. Results: Only 5 out of 94 implants were lost (i.e. survival rate – SVR 95.7%) and no differences were detected among the studied variables. On the contrary, the Cox regression showed that the graft site (i.e. maxilla) reduced MBL. Conclusions: NDI inserted in FFB have a high SVR and SCR similar to those reported in previous studies on regular and NDI inserted in non-grafted jaws. Homologue FFB is a valuable material in the insertion of NDI.

Key words: Kaplan Meier algorithm. Cox regression analysis. Small diameter implants. Graft. Bone.

INTRODUCTION

Narrow diameter implants (NDI) (i.e. diameter <3.75 mm) are an example of an implant-related variable that has specific indications. In fact, the choice of implant diameter depends on the type of edentulism, the volume of the residual bone, the amount of space available for the prosthetic reconstruction, the emergence profile, and the type of occlusion. NDI are indicated in specific clinical situations, for example, where there is reduced interadicular bone or a thin alveolar crest, and for the replacement of teeth with a small cervical diameter. In general, it seems that guidelines developed for surgical placements and the prosthetic restoration of regular size implants (RDI) can be applied to NDI. Although NDI have been available since the 1990s, only few studies have analyzed the clinical outcome of such implants[5,7,9,19-21]. These reports show good medium and long-term results with two-stage surgical procedures[5,7,9,19-21]. However, among the reports of good clinical results in recent literature, there is no report on the clinical outcome of NDI inserted in homologous fresh-frozen bone (FFB) grafts.

Many forms of banked bone homograft are available to the surgeon. Among the grafts available are (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[10,11,16,18].

Regarding the use of FFB in Oral and Maxillofacial Surgery, only two articles are found in the literature: in 1992 Perrot[12] used FFB in combination with autologous bone from the iliac crest to restore atrophic jaws (8 patients) and alone in one case of ameloblastoma and one case of mixoma of the mandible (2 patients): his outcome was, after prosthetic restoration, a survival rate of 95.8% (one implant lost over 29). In 2002 Rochanawutanon[15] demonstrated that FFB can also be used after resection of large portions of the mandible. This author reported 4 cases with over 12 years of follow-up.

Since both NDI and FFB have an increasing number of clinical applications and no report is available, a retrospective study on a series of NDI placed in homologue

FFB was performed to identify which variables are significantly associated with the clinical outcome.

MATERIAL AND METHODS

Patients

In the period between December 2003 and December 2006, 81 patients (52 females and 29 males) with mean age of 52 years were grafted with FFB at the Civil Hospital, Castelfranco Veneto, Italy. Among them, 36 patients (22 females and 14 males, mean age 54 years) were treated with NDI. Informed written consent approved by the local Research Ethics Committee was obtained from patients regarding the specific procedure and the use their data for research purposes. The last check-up was performed in November 2007, with a mean follow-up time of 25 months.

Homologue FFBs were grafted in the 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 additional 6 months.

Subjects were screened according to the following inclusion criteria: controlled oral hygiene, absence of any oral lesions and attendance to a postoperative follow-up program.

Exclusion criteria were as follows: severe bruxism, smoking more than 20 cigarettes/day and excessive consumption of alcohol, localized radiation therapy in the oral cavity, antitumor chemotherapy, liver, blood and kidney diseases, immunosupression, use of corticosteroids, pregnancy, inflammatory and autoimmune diseases of the oral cavity, poor oral hygiene.

Graft Material

The FFB - obtained from the Veneto Tissue Bank in Treviso (Italy) - is a mineralized, non-irradiated, only disinfected and frozen homologous bone (GRV prot. n. 3948, 15 Dec 2000).

Data Collection

Before surgery, orthopantomograph films and CT scans were examined. In each patient, periimplant crestal bone levels were evaluated by the calibrated examination of orthopantomograph films. Measurements were recorded before surgery, after surgery and at the end of the follow-up period (Figure 1 and 2). 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 immediately 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. All data where normalized to the known length of fixtures in order to have the exact evaluation of bone loss.

Periimplant probing was not performed because controversy still exists regarding the correlation between probing depth and implant success rates[13,14].

The implant success rate (SCR) was evaluated according to the following criteria: (1) absence of persisting pain or dysesthesia; (2) absence of periimplant infection with suppuration; (3) absence of mobility; and (4) absence of persisting periimplant bone resorption greater than 1.5 mm during the first year of loading and 0.2 mm/year during the follow-up years[1]. Criteria 1 to 3 derived from clinical charts.

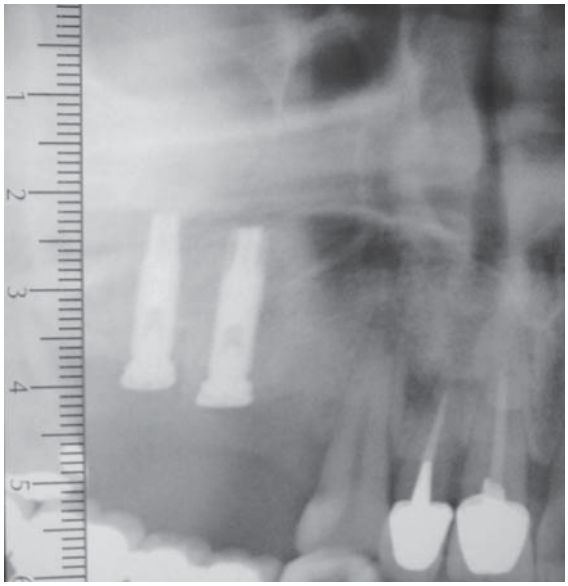

FIGURE 1- Two implants inserted in the upper right maxilla previously grafted with fresh-frozen bone (FFB): the implant-abutment junction (IAJ) is at the alveolar bone crest level. The known implant length was used as internal standard

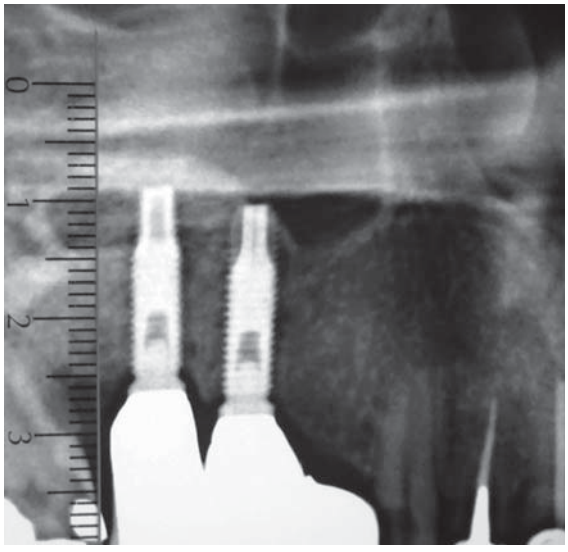

FIGURE 2- The same two implants after 24 months: there is a small bone resorption around the fixture neck

Implants

A total of 91 NDIs were inserted in 36 patients: 16 (17.6%) in the mandible and 75 (82.4%) in the maxilla. There were 23 (25.3%) Double etched (3i implants; Biomet Inc., Warsaw, IN, USA), 7 (7.7%) SLA_1 (Astra implants; Astra Tech Inc., Waltham, MA, USA), 1 (1.1%) Grit blasted and acid $etched_1$ (Frialit implants; Friadent, Dentsply Inc., Milford, DE, USA), 41 (45.1%) Anodic oxidized (Nobel Biocare implants, TiUnite, Nobel Biocare Inc., Yorba Linda, CA, USA), 9 (9.9%) $CaPo_4$ ceramic-blasted (RBM implants, Lifecore Biomedical Inc., Chaska, MN, USA), 8 (8.8%) SLA_2 (Sweden & Martina implants, Sweden & Martina Spa, Italy), 2 (2.2%) Grit blasted and acid $etched_2$ (ITI Implants, Straumann Inc., Andover, MA, USA). Patients received randomly various implant types. There were 4 experienced operators involved in implant placement.

Implant diameter and length ranged from 3.0 to 3.5 mm and from 10 to 16 mm, respectively. Implants were inserted to replace 18 incisors (19.8%), 10 canines (11.0%), 39 premolars (42.9%) and 24 molars (26.4%).

Surgical and Prosthetic Technique

All patients underwent the same surgical protocol. An antimicrobial prophylaxis was administered with 500 mg Amoxicillin twice a day for 5 days starting 1 h before surgery. Local anesthesia was induced by infiltration with articaine/epinephrine and postsurgical analgesic treatment was performed with 100 mg Nimesulid twice a day 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-week period. The number of prosthetic units (i.e. implant/crown ratio) was about 0.8. All patients were included in a strict hygiene recall program.

Statistical Analysis

Since only 5 out of 91 implants were lost (i.e. SVR = 95.7%) 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 differences between the implant abutment junction and the bone crestal level was defined as the implant abutment junction (IAJ) and calculated at the time of the operation and during the follow-up period. Delta IAJ is the difference between IAJ at the last control and IAJ recorded right after the operation. Delta IAJ medians were stratified according to the studied variables.

Disease-specific survival curves were calculated according to the product-limit method (Kaplan-Meier algorithm)[8]. Time zero was defined as the date of the implant's insertion. Implants which are still in place were included in the total number at risk of loss only up to the time of their last follow-up. Therefore, the survival rate only changed when implant loss occurred. The calculated survival

TABLE 1- Distribution of case series

Graft site	Implant site	Implant length	Implant diameter	Implant surface	Prosthetic type
Mandible	Incisors	Short (<13mm)	Diameter < 3.5 mm	Double etched	None
16 (1.6)	18 (2.1)	25 (1.8)	37 (1.7)	23 (1.6)	15 (1.8)
Maxilla	Canines	Standard (13mm)	Diameter = 3.5 mm	SLA	Fixed prosthesis
75 (2.0)	10 (2.4)	54 (2.1)	54 (2.1)	7 (5.3)	69 (2.0)
-	Premolars	Long (>13mm)	-	Grit blasted and acid etched	Removable dentures
	39 (1.8)	12 (1.5)		1 (7.0)	7 (1.7)
-	Molars	-	-	Anodic oxidized	
	24 (1.8)			41 (1.6)	-
-	-	-	-	$CaPo_4$ ceramic-blasted	-
				8 (1.1)	
-	-	-	-	Others	-
				2 (2.0)	

The number of cases is out of parenthesis and mean delta IAJ is given in parenthesis.

TABLE 2- Failed implants

Implant diameter	Implant length	Graft site	Implant site	Implant type	Months	Prosthesis
3.25	10	Mandible	35	Double Etched	3	None
3.25	10	Mandible	36	Double Etched	3	None
3.5	13	Maxilla	26	Double Etched	4	None
3.5	13	Maxilla	16	Double Etched	4	None
3.5	13	Maxilla	26	Anodic Oxidized	1	None

TABLE 3- Cox regression results showing the variables associated statistically with delta IAJ by evaluating delta implant abutment junction (DIAJ) (i.e. success rate -SCR)

Variable	B (beta coefficient)	S.E. (standard error)	Significance 95% (p<0.05)	Confidence Interval Lower	Upper
Age	0.0840	0.0401	0.0362	1.0054	1.1766
Gender	-2.2839	0.8249	0.0056	0.0202	0.5132
Graft site	2.4999	0.9739	0.0103	1.8059	82.1628
Implant site	0.2524	0.7114	0.3990	0.7160	2.3140
Implant length	-0.8594	0.5625	0.1266	0.1406	1.2752
Implant diameter	-0.9688	0.5843	0.0973	0.1207	1.1929
Implant type	0.3446	0.1731	0.0465	1.0054	1.9813
Type of restoration	-1.3697	0.8815	0.1202	0.452	1.4304

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 to occur. If the associated probability was less than 5% ($p<0.05$), 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»[6]. Stepwise Cox analysis allowed detecting the variables most associated to implant survival and/or success.

RESULTS

Table 1 reports the men delta IAJ according to the studied variables.

Five implants were lost in the postoperative period (within 4 months) and Table 2 describes their characteristics. Two 10-mm-long implants were lost because of graft failure 3 months after implant insertion. No additional complication was observed in the follow-up period.

The Kaplan Meier algorithm demonstrates that the graft site (Log rank=8.93 df=1 p=0.003) and implant type (Log rank test = 39.5 df = 6 p=0.001) were statistically different. Cox regression (Table 3) confirmed that the implant type and graft site (i.e. mandible - Table 1) correlated with a statistically significant lower delta IAJ (i.e. reduced crestal bone loss) and thus with a better clinical outcome. No significant differences were detected among unloaded implants, fixed or removable prosthetic restorations.

DISCUSSION

In implant dentistry, the use of RDI is generally recommended to ensure adequate bone to implant contact. Occasionally, the available space may be insufficient for the placement of RDI and, in these cases, NDI can be an acceptable solution[5,7,9,19-21]. NDI are used in areas where ridge dimension is narrow or space is limited. These conditions are frequently found in the maxilla, especially in situations where teeth are congenitally missing. Lack of sufficient space for an RDI is also common in the mandibular incisor, maxillary premolar and canine regions. Under these conditions, NDI have been successfully employed in non-grafted bone[5,7,9,19-21]. Although good outcomes have been reported for NDI[5,7,9,19-21], no reports are available on NDI inserted into FFB. In the present study, 91 NDI were inserted into FFB with only 5 failures during a mean period of observation of 25 months (SVR = 95.7%).

No statistically significant differences were detected

among the studied variables using SVR. Consequently, no or reduced MBL was considered an indicator of SCR to evaluate the effect of host-, surgery-, implant-, and occlusion-related factors.

In general, length, diameter and surface are considered to be relevant implant-related factors. Tarnow, et al.[17] proposed using 10 mm or longer implants in critical situations, such as in immediate loading. In the present series, implant length was not a critical point for SVR: among the lost fixtures there were three 13-mm- and two 10-mm- long implants (Table 2). The two 10-mm-long implants were lost because of graft failure that occurred 3 months after implant insertion. No statistically significant differences were found among implant diameters (i.e. diameter = 3.5 vs. diameter <3.5 mm) (Table 1). Conversely, a different SCR according to implant type was found with some differences among them. However, because there were 8 different implant types and some groups comprising a small number of fixtures, no conclusion can be reached. In addition, because in some groups there was more than one implant design, this last was not studied as an additional variable.

Generally, concerns may arise from the fact that reduced diameter means a reduction in the contact surface between the implant and the bone. One might also ask whether, in this case, osseointegration is sufficient to withstand occlusal forces, because it is generally accepted that decreasing the diameter implicates in increasing the risk for implant fracture due to reduced mechanical stability and increased risk of overload[5,7,9,19-21]. In the present study, no implant fracture was detected and neither difference was found in SRV and SCR among different prosthetic restoration types: The MBL is similar between removable dentures and fixed prosthetics, and both are almost equal to unloaded implants (Table 1).

Bone quality, a host-related factor, is believed to be one of the strongest predictors of implant outcome. It is well known that the mandible (especially the interforaminal region) has better bone quality than the maxilla, and this fact is probably the reason why several reports are available regarding implant immediate loading in the mandible[2-4]. Immediate implant loading is an example of a critical procedure in implantology. In this retrospective study, a better outcome for implants inserted in grafted mandible with respect to grafted maxilla was found (Table 1). The reason is unknown but it could be related to the well known difference in bone quality between the two jaws.

The mean time elapsed to follow up in this retrospective study was approximately 2 years. This period, although rather short, is the most relevant for implant osseointegration, and SVR failures occurred within the first 4 months. Longer follow-up periods are needed for a better evaluation of SCR, which corresponds to the crestal bone remodeling over time.

Concerns may arise from the fact that orthopantomograph and CT scans (for veneer) were used to detect both graft and implant measurements. Certainly the reproducibility of data is less precise than that obtained with the use of periapical radiographs. However, the mean value obtained with two measurements for each one of the 91 examined fixtures can provide quite a reliable datum to be used for any comparative analysis. At least, the present report is a baseline to referred additional studies.

CONCLUSION

In conclusion, FFB is a reliable graft material to support NDI, which has high SVR and SCR comparable to those of fixtures inserted in non grafted jaws. Within the limitation of the present study, it was shown that grafted site (i.e. better outcome for the mandible) presented significantly lower bone resorption as detected with radiological resources.

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