Reconstruction of Severely Atrophic Jaws Using Homografts and Simultaneous Implant Placement: A Retrospective Study

Alessandro Viscioni, MD[1]
Leone Rigo, MD[1]
Maurizio Franco, MD[1]
Giorgio Brunelli, MD[2]
Anna Avantaggiato, MD[2]
Vincenzo Sollazzo, MD[3]
Francesco Carinci, MD[2]*

In the past decade, several investigators have reported that implants inserted in autografts in the same operation (ie, simultaneously inserted implants [SIIs]) have achieved excellent results. However, no report regarding SIIs placed in fresh frozen bone (FFB) is available. Thus, the authors planned a retrospective study on a series of SIIs placed in homologue FFB (but not immediately loaded) to evaluate their clinical outcome. In addition, a comparison with implants inserted in FFB in a second stage (ie, delayed inserted implants) was performed. Seventeen patients were grafted with FFB, and 48 implants were inserted in the same operation. Implant diameter and length ranged from 3.25 to 4.0 mm and from 10.0 to 15 mm, respectively. Data were compared with 302 implants inserted in FFB in a second operation during the same period in 64 patients. Analyzing SIIs, it was noted that only 3 implants were lost (ie, survival rate [SVR] = 93.7%), and no differences were detected among the studied variables by using lost implants as a predictor of clinical outcome. On the contrary, by using crestal bone resorption around the implant's neck and specific cutoff values, it was possible to demonstrate that prosthetic restoration (ie, removable overdentures) correlated with a statistically significant lower delta insertion abutment junction (ie, reduced crestal bone loss) and thus with a better clinical outcome. By comparing SIIs with implants inserted in a second stage in FFB, a better outcome for delayed implants was demonstrated. Implants inserted simultaneously with FFB grafts had a high survival and success rate. SIIs inserted in FFB can be considered reliable devices, although a higher marginal bone loss is to be expected when fixed prosthetic restorations are used. Implants inserted in a second surgical stage have a better SVR and success rate than SIIs.

Key Words: Kaplan-Meier algorithm, Cox regression, iliac crest, allograft, homograft, implant, atrophic jaw

[1] Department of Maxillofacial Surgery, Civil Hospital, Castelfranco Veneto, Italy.
[2] Maxillofacial Surgery, University of Ferrara, Ferrara, Italy.
[3] Orthopedic Clinic, University of Ferrara, Ferrara, Italy.
* *Corresponding author*, e-mail: crc@unife.it

INTRODUCTION

The treatment of choice for edentulousness, which cannot be adequately compensated for by a denture because it causes considerable oral dysfunction, is a bridge construction on osseointegrated titanium fixtures. In those cases, where the quantity or quality of the alveolar ridge does not provide enough bone tissue for implant anchorage, jaw bone restoration is required. In an attempt to evaluate the best material and method for bone reconstruction, clinical studies on various grafting procedures were performed.[1–7]

Several reports are available on autologous iliac bone grafted in the upper jaw with different surgical techniques.

Isaksson and Alberius[1] reported data from 8 patients using onlay iliac bone grafts to restore atrophic maxillary alveolar ridges associated with immediate implant insertion. The patients were observed for 32–64 months, and 83% of the fixtures were well integrated. Astrand et al[2] used the same technique in 17 patients who were observed during a 3-year period with an implant survival rate of 75%.

Other authors have focus on a 1-stage surgical procedure in the maxillary sinus area. Daelemans et al[3] had 8 failures over 121 implants placed in grafted sinuses with a mean follow-up of 40 months after loading. Peleg et al[4] collected data from 2132 implants in 731 patients with a cumulative survival rate of 97.9% (n = 2091 implants) at 9 years.

Le Fort I osteotomy was also used to insert inlay autologous iliac bone grafts (also known as Sailer or horseshoe surgical technique). Isaksson et al[5] studied 12 consecutive patients treated with 59 implants immediately inserted: 14 fixtures (21%) were removed. Li et al[6] analyzed 139 implants with an average follow-up of 33 months: 25 fixtures (18%) failed to osseointegrate. Yerit et al[7] reported 100 implants with 14 fixtures lost at 5 years.

On the contrary, no report, to the best of our knowledge, is available on 1-stage surgical procedure (ie, bone graft plus implant insertion) in the mandible.

Although good clinical outcomes have been reported, especially in recent years, there have been no studies on immediate implant insertion in homologue fresh frozen bone (FFB).

A homograft (or allograft) is a transplant in which transplanted cells, tissues, or organs are sourced from a genetically nonidentical member of the same species. In contrast, a transplant from another species is called a xenograft. An isograft is a transplanted organ or tissue from a genetically identical donor (ie, an identical twin). An autograft is a tissue transplanted from one site to another on the same patient.

Craniofacial skeletal defects should ideally be corrected with autologous bone or cartilage by replacement or augmentation. Although autografts are the standard procedure for bone grafting, it is sometimes not possible to harvest bone[8] and collect 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, anesthesia, and donor site morbidity. On the other hand, biomaterials are good but expensive and may extrude at a later date.[9] Thus, the use of homograft bone provides a reasonable alternative to meet the need for graft material.[8]

Bone homograft transplantation has been performed in humans for more than 100 years and is also being increasingly used by orthopedic surgeons[10] for ligament reconstruction, meniscal transplantation, and articular surface reconstruction.[11]

In Europe, organ centers play an intermediary role in the donation of tissue and organs to their allocation and transplantation. They take responsibility for donor medical/safety screening and organize pro-

curement. Tissue allocation is performed according to rules set by committees of renowned experts in the field.[12] Bone banking and the clinical use of banked tissue are the most common forms of preservation and transplantation in modern medicine.[13]

Many forms of banked bone homograft are available to the surgeon. Among the grafts available are FFB, freeze-dried bone, and demineralized fresh dried bone. Each of these grafts carries risks and has unique limitations and handling properties. 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.[14]

Regarding the use of FFB in oral and maxillofacial surgery, few articles are to be found in the literature: in 1992, Perrot[15] used it in combination with autologous bone from the iliac crest to restore atrophic jaws (8 patients) and alone in 1 case of ameloblastoma and 1 case of mixoma of the mandible (2 patients). His outcome was, after prosthetic restoration, a survival rate of 95.8% (1 implant lost out of 29). In 2002, Rochanawutanon[16] demonstrated that even after the resection of big portions of the mandible, FFB can be used: he reported 4 cases with a follow-up of more than 12 years. More recently, we reported the outcome of a series of patients treated with FFB.[17–19]

Since implants inserted in autografts in the same operation have a high success and survival rate and no studies are available on simultaneously inserted implants (SIIs) in FFB grafts, we decided to perform a study on 48 SIIs (but not immediately loaded) to evaluate their clinical outcome.

Materials and Methods

Patients

In the period between December 2003 and December 2006, 81 patients (52 women and 29 men) with a median age of 52 years were operated on at the Civil Hospital, Castelfranco Veneto, Italy. Among them, 17 patients (13 women and 4 men) with a median age of 55 years were treated with implants inserted in an FFB allograft during the same operation. Informed written consent approved by the local Ethics Committee was obtained from patients to use their data for research purposes. The last checkup was performed in November 2007, with a mean follow-up of 32 months.

In the remaining 64 patients, homologue FFB grafts were previously inserted into the patient's jaws under general anesthesia. Usually, the mean postgrafting 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, and 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 checkup program.

The exclusion criteria were as follows: insufficient bone volume; bruxism; smoking more than 20 cigarettes per day; excessive consumption of alcohol (2 glasses of wine per day); localized radiation therapy of the oral cavity; antitumor chemotherapy; liver, blood, and kidney diseases; immunosuppression; taking corticosteroids; pregnancy; inflammatory and autoimmune diseases of the oral cavity; and poor oral hygiene.

Graft material

The FFB, obtained from the Veneto Tissue Bank in Treviso, Italy, is a mineralized, nonirradiated, 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 corticomedullary blocks, packed in double sterile casing and frozen at $-80°C$.

The requirements for homologous bone donors are more stringent than 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. 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, and anti–Toxoplasma IgM Ab. A culture is also performed to detect aerobic and anaerobic bacteria, mycobacteria, and mycotical agents. As a further safety measure, 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.

Data collection

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

In each patient, peri-implant crestal bone levels were evaluated by the calibrated examination of ortopantomograph X rays. A periapical radiograph was impressed by means of a customized Rinn holder device. This device was necessary to maintain the X-ray cone perpendicular to a film pieced parallel to the long axis of the implant. The endoral X rays were taken using a long X-ray tube at 70 Kw of power and developed in acid in a darkroom according to standard procedures; they were scanned, transferred to a computer, and saved in an uncompressed TIFF format for classification.

Each file was processed with the Windows XP Professional operating system using Photoshop 7.0 (Adobe, San Jose, Calif) and shown on a 17-inch SXGA TFT LCD display with a NVIDIA GÈ Force FX GO 5600, 64-MB videocard (Acer Aspire 1703 SM-2.6). Each image was modified using the fit-on-screen function (maximized screen), and the necessary adjustments in contrast, brightness, and magnification were made. The measurements were taken at the highest level of resolution possible through the grid-and-ruler program options using various metric scales. Knowing the known dimensions of the implant and having located various points of reference on the profiles of the X-rayed fixtures (edge of the platform, bone crestal level, total length of the implant), it was possible to take linear measurements on the computer and thus execute a proportional metric calculation comparing the known dimensions of the implant's geometric design with those of the examined X-ray images. This made it possible to establish the distance from the mesial and distal edges of the implant platform to the point of bone-implant contact plus the visible crown (expressed in tenths of a millimeter) as an expression of marginal bone resorption. The proportional calculation of the measurements also made it possible to establish, where present, any distortion in the X-ray images for further screening, thereby reducing the margin of error of the analysis to a minimum.

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 X rays were calibrated

using an internal standard that was the implant's length. 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.

Peri-implant probing was not performed because controversy still exists regarding the correlation between probing depth and implant success rates.[20,21]

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/y during the following years.[22]

Implants

A total of 48 SIIs were inserted in 17 patients: 22 (45.8%) in the mandible and 26 (54.2%) in the maxilla. Implant diameter and length ranged from 3.25 to 4.0 mm and from 10.0 to 15 mm, respectively. There were 18 double-etched (3i implants, Osseotite, Biomet Inc, Vicenza, Italy), 3 SLA_1 (Astra implants, Astratech Inc, Bologna, Italy), 2 anodic oxidized (Nobel Biocare implants, TiUnite, Nobelbiocare Inc, Milan, Italy), and 25 $CaPo_4$ ceramic-blasted surfaces (RBM implants, Lifecore, Biomedical Inc, Verona, Italy).

Implants were inserted to replace 18 incisors, 4 cuspids, 12 premolars, and 14 molars.

A total of 302 delayed implants inserted in FFB were placed during the same period in 64 patients.

Surgical and prosthetic technique

All patients underwent the same surgical protocol. Antimicrobial prophylaxis was administered with 2000 mg amoxicillin before surgery and 1000 mg twice daily for 7 days starting 1 hour before surgery.

The implants were inserted simultaneously with the bone grafts. The implant platform was positioned at the natural alveolar crest level or graft alveolar level in the case of onlay. Sutures were removed 10 days after surgery. Then, 24 weeks after implant insertion, the provisional prosthesis was provided, and the final restoration was usually delivered within an additional 8 weeks. The number of prosthetic units (ie, implant-crown ratio) was about 0.4. All patients were included in a strict hygiene recall.

Statistical analysis

Since 3 implants were lost (ie, survival rate [SVR] = 93.7%) 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 difference between the implant abutment junction and the bone crestal level was defined as the insertion 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 checkup 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).[23] Time zero was defined as the date of the insertion of the implant. Implants that were 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 changed only 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

TABLE 1		
Distribution of series with regard to graft site and delta insertion abutment junction (ie, bone resorption around implant neck)		
Graft Site	n	Median
Mandible	22	1.8
Maxilla	26	2.2

TABLE 4		
Distribution of series with regard to implant diameter and delta insertion abutment junction		
Implant Diameter	n	Median
Diameter <3.75 mm	3	1.0
Diameter = 3.75 mm	25	1.8
Diameter >3.75 mm	20	2.4

TABLE 2		
Distribution of series with regard to implant site and delta insertion abutment junction		
Implant Site	n	Median
Incisors	18	1.8
Cuspids	4	1.8
Premolars	12	1.9
Molars	14	2.6

TABLE 5		
Distribution of series with regard to implant type and delta insertion abutment junction		
Implant Type	n	Median
Double etched	18	2.1
SLA_1	3	2.3
Anodic oxidized	2	1.7
$CaPo_4$ ceramic-blasted	25	1.0

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 an event (ie, implant loss) is likely to occur. If the associated probability was less then 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."[24] Stepwise Cox analysis allowed us to detect the variables most associated with implant survival and/or success.

RESULTS

Tables 1 through 7 report the median delta IAJ according to the studied variables.

Three SIIs were lost in the postoperative period, and Table 8 reports their characteristics.

Table 9 shows that prosthetic restoration (ie, fixed prostheses) (Table 6) correlated with a statistically significant lower delta IAJ (ie, reduced crestal bone loss) and thus a worse clinical outcome.

No differences were detected among diameters (Table 4), lengths (Table 3), and implant type (Table 5). Also, graft site (Table 1), implant site (Table 2), and edentulism type (Table 7) did not show statistically significant differences.

Table 10 reports the median delta IAJ of the 2 groups of implants: inserted simultaneously with FFB (but not immediately loaded) and delayed inserted. Better results in terms of SVR (log-rank test, $df = 4.93$, significance = .0263) and SCR (log-rank test,

TABLE 3		
Distribution of series with regard to implant length and delta insertion abutment junction		
Implant Length	n	Median
Less than 13 mm	3	1.5
13 mm	20	2.3
More than 13	25	1.9

TABLE 6		
Distribution of series with regard to prosthetic restoration and delta insertion abutment junction		
Prosthetic Type	n	Median
None	4	2.5
Fixed prosthesis	7	2.6
Removable dentures	37	1.9

TABLE 7		
Distribution of series with regard to edentulism type and delta insertion abutment junction		
Edentulism Type	n	Median
Total	34	1.8
Partial	14	2.6

$df = 8.86$, significance $= .003$) were found for delayed-insert implants.

DISCUSSION

The identification of guidelines for the long-term SVR (ie, implant still in place at the end of the follow-up period) and SCR (ie, implant with low bone resorption around the fixture neck) 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.[25] The surgery-related factors comprise several variables, such as an excess of surgical trauma, including thermal injury, bone preparation, drill sharpness, and design.[26] Bone quality and quantity are the most important host-related factors,[27] while design, surface coating, diameter, and length are the most important implant-related factors.[28] Finally, quality and quantity of force and prosthetic design[29] are the variables of interest among the occlusion-related factors. All of these variables are a matter of scientific investigation since they may affect the clinical outcome.

In general, length (Table 4), diameter (Table 5), and type (Table 6) are considered to be relevant fixture-related factors. In the present study, none of these factors had a statistically significant impact on the clinical outcome. In their study, Peleg et al[4] compared a total of 2132 implants: 1374 microtextured screw type and 758 hydroxyapatite-coated cylinder type immediately placed into the grafted sinuses of 731 patients, finding high SVR and SCR in all cases.

Bone quality, a host-related factor, is believed to be one of the strongest predictors of 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 immediately loaded implants inserted into the mandible with a high SVR.[30] Our data show that FFB is an effective material to restore alveolar ridge volume for the insertion of implants in 1-stage surgical procedures as only 3 implants were lost and a low marginal bone level was resorbed. In addition, variables related to grafted jaws and implant sites were not statistically significant. Other authors had the same results for autologous bone: Ivanoff et al[31] reported in 1999 on 67 patients in a 3- to 5-year follow-up and concluded that no relationship exists between implant-failure and jaw type or implant site.

Among the occlusal-related factors, no differences were detected with regard to SVR. However, a better outcome was detected for removable dentures (Table 6). Edentulism type was not statistically significant for the SCR.

TABLE 8						
List of simultaneously inserted implants that were lost						
Implant Diameter	Implant Length	Graft Site	Implant Site	Implant Type	No. of Months After Implant Insertion	Prosthesis
3.75	13	Maxilla	26	$CaPo_4$ ceramic blasted	4	None
3.25	10	Mandible	35	Double etched	3	None
3.25	10	Mandible	36	Double etched	3	None

TABLE 9

Output of Cox regression reporting the variables associated statistically with delta insertion abutment junction (IAJ) by evaluating delta IAJ (ie, success rate)

Variable	B	SE	Significance ($P < .05$)	95% Confidence Interval	
				Lower	Upper
Age	0.1227	0.0866	.1562	0.9542	1.3396
Gender	1.2031	1.6121	.4555	0.1413	78.4644
Graft site	1.3452	2.5865	.6030	0.0241	610.7081
Implant site	0.7606	0.8504	.3711	0.4041	11.3302
Implant length	2.1883	1.5175	.1493	0.4556	174.6189
Implant diameter	1.1179	0.7144	.1176	0.7540	12.4061
Implant type	−0.5439	0.3876	.1606	0.2715	1.2409
Type of restoration	−3.1074	1.4537	.0326	0.0026	0.7725
Edentulism type	−2.2098	1.3934	.1128	0.0071	1.6843

To evaluate the clinical outcome of prosthetic treatment in edentulous patients in both grafted and nongrafted jaws, Smedberg et al[32] used a study group of 39 patients treated with intrasinus block bone grafts and implants in a 1-stage procedure and a control group of 37 patients treated with implants and no grafting, concluding that the prosthetic outcome was similar in both groups of patients, regardless of whether or not a bone-grafting procedure was used. In conclusion, implants inserted simultaneously with FFB grafts (but not immediately loaded) had a high survival and success rate similar to the rates reported in previous studies of implants inserted in 1 surgical step with autografts. Implants inserted simultaneously with FFB can be considered reliable devices, although a higher marginal bone loss is to be expected with fixed prosthetic restorations. However, a better outcome in terms of SCR and SVR was found for implants inserted in a second surgical step.

TABLE 10

Distribution of series with regards to insertion type, number of lost implants, and delta insertion abutment junction (in those implants still in place at the end of the follow-up period)

Insertion Type	n	No. of Lost Implants	Median
Immediate	48	3	2.0
Delayed	302	4	1.9

ABBREVIATIONS

FFB: fresh frozen bone

IAJ: insertion abutment junction

SCR: implant success rate

SII: simultaneously inserted implants

SVR: survival rate

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