# Anodic oxidized implants inserted into fresh frozen bone grafts

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أثبتت الدراسات الحديثة نجاح الغرسات المؤكسدة والمؤينة، لكن لاتتوفر أية تقارير حول هذه الغرسات الموضوعة في الطعوم العظمية الذاتية. أجريت دراسة استرجاعية لمجموعة من الغرسات الموضوعة في طعوم ذاتية بهدف تقييمها. شملت الدراسة ٢٤ مريضاً (١٧ أنثى و ٧ ذكور بمتوسط عمر ٥٢ سنة) تم وضع ٩١ غرسة من الغرسات المؤكسدة والمؤينة. متوسط متابعة الحالة ٢٩ شهراً. تراوح قطر الغرسات ٣ إلى ٥ ملم وطولها ٨ إلى ١٦ ملم. استعملت الغرسات لتعويض سبعة قواطع وأربعة أنياب و ٣٩ ضاحك و ٤١ رحى. ومع فقدان غرستين، بلغت نسبة نجاح الغرسات ٩٧.٨ ٪. تم الربط بدلالة إحصائية بين مواقع التطعيم والغرس السني وقطر الغرسات مع الارتباط بين الدعامة والغرسة. يمكن الاستنتاج على أن الطعوم الذاتية تعتبر ملائمة لوضع الغرسات السنية، واثبتت الغرسات المؤكسدة والمؤينة نسبة نجاح عالية مقارنة بنتائج الدراسات السابقة لإجراءات المرحلتين والمواقع غير المطعمة. وبناء على ذلك تعتبر الغرسات المؤكسدة والمؤينة ملائمة للغرس في مواقع التطعيم الذاتي، مع توقع نسبة امتصاص عظم حفافي عالية في الفك السفلي المطعم في مناطق الضواحك والأرحاء وعند استعمال الغرسات ذات الأقطار الكبيرة.

***BACKGROUND:*** In the last decade, several investigators have reported that anodic oxidized surface implants (AOSIs) have achieved excellent results. However, there have been no reports regarding AOSIs inserted into homografts. ***OBJECTIVE:*** A retrospective study on a series of AOSIs inserted into homologue grafts is performed in order to evaluate their clinical outcome. ***PATIENTS and METHODS:*** In the period between December 2003 and December 2006, 24 patients (17 females and 7 males with a median age of 52 years) were operated on and 91 AOSIs inserted. The mean implant follow-up was 29 months. Implant diameter and length ranged from 3 to 5 mm and from 8 to 16 mm, respectively. Implants were inserted to replace 7 incisors, 4 cuspids, 39 premolars and 41 molars. ***RESULTS:*** Since only 2 out of 91 implants were lost (i.e. survival rate SVR = 97.8%). Graft site (i.e. maxilla); implant site (i.e. cuspids and incisors) and implant diameter (i.e. narrow and standard diameter) correlated with a statistically significant lower delta Implant Abutment Junction (IAJ) (i.e. reduced crestal bone loss) and thus, a better clinical outcome. ***CONCLUSION:*** Homologues bone is a reliable material for the insertion of fixtures. AOSIs had a high survival and success rate similar to those reported in previous studies of two-stage procedures in non-grafted bone. AOSIs inserted into homografts can be considered reliable devices, although a higher marginal bone loss has to be expected in grafted mandibles, in premolar and molar regions and when wide diameter implants are used.

## 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 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 anesthesia, and donor site morbidity.[1] On the other hand, biomaterials are good but expensive, and may extrude 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 increasingly used 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]

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Anodic oxidized surface implants (AOSIs, type Nobel Replace Straight-nT, surface TiUnite®, Nobel Biocare AB, Göteborg, Sweden) are one of the most frequently used fixtures in implant surgery.[5]

Several reports are available regarding the use of AOSIs in native bone[5-8] and in autografts:[9,10] all studies have demonstrated a high survival (SVR i.e. number of implants still in place at the end of the follow-up) and success rate (SCR i.e. good clinical, radiological and aesthetic outcome).

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

## PATIENTS AND METHODS

### 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, 24 patients (17 females and 7 males) with a median age of 52 years were treated with AOSIs. Informed written consent approved by the local Ethics Committee was obtained from patients to use their data for research purpose. The mean implant follow-up was 29 months.

Homologues 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 mm in diameter and 8 mm in length; in addition, the patients had to agree to participate in a post-operative 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, anti-tumor chemotherapy, liver, blood and kidney diseases, immunosupressed patients, patients taking corticosteroids, pregnant women, 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, non-irradiated, only disinfected and frozen homologous bone.

### 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 the 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.[11,12]

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/year during forthcoming years.[13]

### Implants

A total of 91 AOSIs were inserted in 24 patients: 8 (8.8%) in the mandible and 83 (91.2%) in the maxilla. Implant diameter and length ranged from 3 to 5 mm and from 8 to 16 mm, respectively. Implants were inserted to replace 7 incisors, 4 cuspids, 39 premolars and 41 molars.

### 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 0.9. All patients were included in a strict hygiene recall.

### Statistical Analysis

Since only 2 out of 91 implants were lost (i.e. SVR = 97.8%) 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 control 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).[14] 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 up to 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 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».[15] Stepwise Cox analysis allowed detection of the variables most associated with implant survival and/or success.

## RESULTS

The investigated variables were graft site (mandible or maxilla), implant site (incisors, cuspids, premolars and molars), fixture length and diameter, and type of prosthetic restoration.

Delta IAJ changed as follows: mandible=3.3 mm (8 cases) and maxilla 1.7 mm (83 cases). Implants replaced 7 incisors, 4 cuspids, 39 premolars and 41 molars with a median delta IAJ of 1.4, 1.3, 1.6 and 2.1 mm, respectively. Ten fixtures are shorter than 13 mm, 62 are 13 mm long and 19 are longer than 13 mm and have a median delta IAJ of 1.4, 2.0 and 1.4 mm, respectively. Implant's diameter is less than 3.75, equal to 3.75 and larger than 3.75 mm in 41, 6 and 44 cases with a median delta IAJ of 1.6, 1.5 and 2.0 mm, respectively. There are 73 fixed prosthesis, 9 removable dentures and 9 unrestored implants with a median delta IAJ of 1.9, 1.4 and 1.3 mm, respectively.

Two implants were lost in the post-operative period (within 4 months).

Table 1 shows that graft site (i.e. maxilla); implant site (i.e. cuspids and incisors) and implant diameter (i.e. narrow and regular diameter) correlated with a statistically significant lower delta IAJ (i.e. reduced crestal bone loss) and thus, a better clinical outcome.

## DISCUSSION

The concept of osseointegration, i.e., the direct anchorage of endosseus implants made of commercially pure or titanium alloy to the bone

**Table 1.** 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 | 0.0074 | 0.0346 | 0.8300 | 0.9415 | 1.0780 |
| Gender | 0.0439 | 0.7053 | 0.9504 | 0.2622 | 4.1630 |
| Graft site | 1.6640 | 0.7779 | 0.0324 | 1.1497 | 24.2551 |
| Implant site | 1.1585 | 0.5413 | 0.0323 | 1.1025 | 9.2014 |
| Implant length | -0.4405 | 0.5137 | 0.3912 | 0.2352 | 1.7620 |
| Implant diameter | -0.7204 | 0.2942 | 0.0143 | 0.2734 | 0.8661 |
| Type of restoration | 0.2757 | 1.5204 | 0.8561 | 0.0669 | 25.9368 |

caused a breakthrough in oral rehabilitation.[16] The identification of factors for the long term survival rate (SVR i.e. total implants still in place at the end of the follow-up) and success rate (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 can be grouped as (1) surgery-, (2) host-, (3) implant-, and (4) occlusion-related factors.[17]

Surface is one of the implant-related factors. Variations in design and surface roughness have been found to be important for bone integration of implants.[18] A moderately rough surface implant TiUnite® (Nobel Biocare AB, Göteborg, Sweden) was introduced in 2000.[6] TiUnite® is a highly crystalline and phosphate enriched titanium oxide characterized by a microstructured surface with open pores in the low micrometer range.[19] The TiUnite® implant surface has repeatedly proven to give an enhanced bone response and greater amount of bone during healing compared to machined implant surfaces.[20-23] The enhanced bone response to TiUnite® results in faster and stronger osseointegration and thereby, better maintenance of the implant stability compared to machined titanium implants. When placed in soft bone and immediately loaded, the enhanced osseointegration of Nobel Biocare TiUnite® implants results in higher success rates. These claims are supported by extensive research.[8,24] Vanden Bogaerde *et al.*[5] demonstrated that the use of oxidized titanium implants for early functional loading in the maxilla and the posterior mandible resulted in a high implant SVR and a favorable marginal bone level during a follow-up of 18 months.

In the present study the diameter of the implant plays a statistically significant role in the clinical outcome with better results for narrower and regular diameters. However, in the literature, to the author's best knowledge, no topic focused on AOSIs by comparing different diameters but, it is generally accepted that wider implants have a better clinical outcome due to higher implant/bone contact surface.[25]

Bone quality, a host-related factor, is believed to be one of the strongest predictors of outcome.[26] In the present series, only 2 out of 91 implants were lost and thus, we have demonstrated that FFB is a reliable material for alveolar crest reconstruction prior to implant placement. Graft sites and implant sites have shown statistically significant results, with worse outcomes for mandibular grafts and molar regions. Friberg *et al.*[6] showed implant cumulative survival rates of 98.6% and 100% for the maxilla and mandible, respectively with the only 3 implants lost placed in low quality bone. Glauser *et al.*[7] had high SVR and SCR for implants inserted into posterior regions and into soft bone.

Among the occlusal-related factors, no statistically significant differences were detected. Previously Glauser *et al.*[7] studied 51 fixed prosthetic reconstructions and reported an implant SCR of 97.1%.

FFB is a reliable grating material for the insertion of AOSIs. AOSIs inserted into FFB had a high survival and success rate similar to those reported in previous studies on native bone and autografts. AOSIs inserted into FFB can be considered reliable devices, although a higher marginal bone loss has to be expected in grafted mandibles, in premolar and molar regions and when wide diameter implants are used.

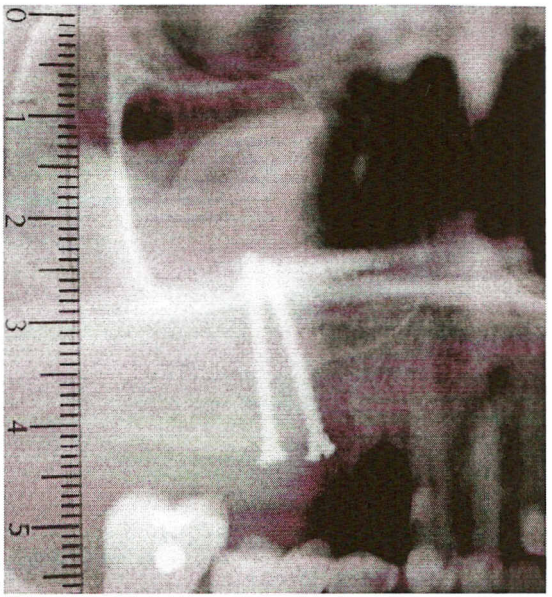

**Fig. 1.** Orthopantomograph showing the graft inserted in the uppers right maxilla and fixed with screws.

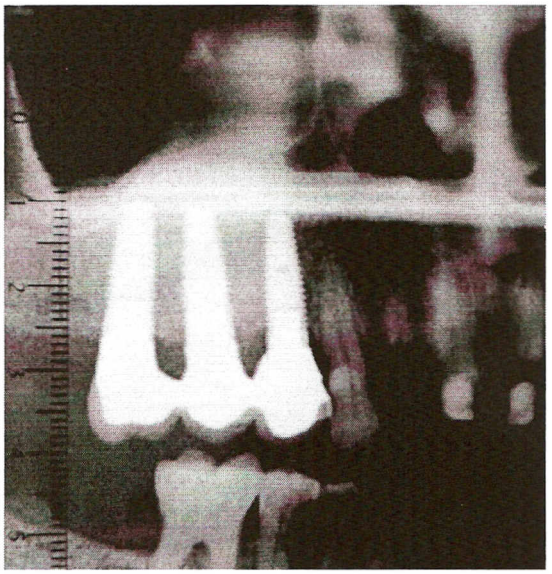

**Fig. 2.** Implants inserted in the upper right maxilla.

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