Bone Assessment in Grafted and Ungrafted Sockets After Dental Implant Placement: A 10-year Follow-up Study

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Purpose: The purpose of this study was to compare success and outcomes among implants positioned either in grafted or ungrafted alveoli during 10 years of follow-up. Materials and Methods: This retrospective analysis was conducted on data of subjects who underwent tooth extraction and alveolar ridge preservation. Sites, one per patient, were ranked into three groups: postextraction ungrafted alveoli, and postextraction grafted alveoli with either synthetic magnesium-enriched hydroxyapatite or porcine bone. An absorbable collagen sheet was used to completely cover all the sockets. A secondary intention healing was sought for all procedures. Data regarding implant survival and marginal bone loss around implants were gathered until the 10-year follow up. Pairwise comparisons were performed with nonparametric tests, and statistical significance was set at .01. Results: Sixty-three subjects were included: 42 implants (19 and 23 in the magnesium-enriched hydroxyapatite and porcine bone groups, respectively) placed in grafted sites and 21 in nongrafted sites. The success rate of the grafted groups was 88.1% (CI: 78.3% to 97.9%) at the 10-year follow-up. On the other hand, in the ungrafted group, the overall success rate was 85.7% (CI: 70.8% to 100%). Peri-implant marginal bone loss at the 10-year follow-up for the magnesium-enriched hydroxyapatite group was 1.2 (0.7) mm, while for the porcine bone group, it was close to 0. The behavior of the ungrafted group appeared to be significantly different compared with both grafted groups; however, marginal bone levels ranging from 0.1 to 0.4 mm were observed from 3 to 10 years. Conclusion: A difference in terms of long-term success rates between grafted and ungrafted sites was not revealed. Bone loss was significantly higher in the magnesium-enriched hydroxyapatite grafted group compared with those in the other groups (without or with other bone substitute material). Int J Oral Maxillofac Implants 2020;35:576–584. doi: 10.11607/jomi.7969

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Several pathologic processes can locally contribute to damage the integrity of one or more walls of the postextractive alveolus, and the severity of the fresh socket damaged depends on the number and depth of the dehiscence defects.1,2

In clinical situations in which mechanical engagement of the implant in the bone walls is prevented by an alveolus with a dimension that is too large, especially in cases of the anterior area, with or without buccal bone damage following tooth extraction, an undesired esthetic situation may arise from advanced bone loss.3

Several surgical procedures are advocated to preserve alveolar bone or to augment alveolar bone volume following dental avulsion, that is, guided regeneration,4,5 allograft, autograft, and xenograft.6,7

Due to their excellent biocompatibility and bioactivity, the utilization of bioeceramics for bone grafting or as a constituent of dental devices is a common practice widely used throughout the dentistry sector.8,9

In fact, hydroxyapatite ceramics have been extensively employed as potential scaffold materials for bone regeneration because of their property to induce mesenchymal cells to change to osteoblasts.10–12

Likewise, inorganic animal bone particles are used as grafting material in alveolar crest preservation, which seems to be essential for maintenance of good volume.13–15

A different study reported two scaffolds as materials grafted in fresh extraction sockets.16 When synthetic
magnesium-enriched hydroxyapatite and porcine bone were compared, histologic examination after 4 months showed similar behaviors both in bone resorption and bone formation.17

Nevertheless, a significant difference in the amount of bone volume resorption is an important factor to really assess the effectiveness of the biomaterials; the process of tissue remodeling and maturation after implant placement is essential in the transition to secondary stability.

The purpose of this study was to compare success and outcomes among implants positioned either in grafted or ungrafted alveoli at the 10-year follow-up.

**MATERIALS AND METHODS**

**Patient Selection**

Subjects were selected for this retrospective analysis among consecutive patients treated by a single surgeon (U.C.) and a single prosthodontist (R.C.) at Tuscan Dental Institute between January 2008 and June 2009 and were followed up until 10 years after surgery for the period from 2009 to 2019 at the Complex Operating Unit of Maxillo-Facial Surgery of the University of Pisa.

This study followed the Declaration of Helsinki on medical protocol and ethics, and the regional Ethical Review Board of the University of Pisa approved the present retrospective data analysis.

**Inclusion Criteria**

The inclusion criteria were as follows:

- Patients underwent dental implant rehabilitation after alveolar ridge preservation.
- Presence of three bone walls of the alveolus with loss of the buccal plate.
- Patients in good general health (without chronic systemic diseases).
- Two-step procedure with delayed placement of implants from 8 to 10 weeks after tooth extraction.
- Presence of keratinized gingiva with a thickness greater than or equal to 3 mm.18
- Implant-supported single crown or fixed partial dentures.
- Ten years of follow-up period after loading the implant.

Patients were excluded if any of the following items were shown in the medical record:

- Heavy smoking habit (> 10 cigarettes a day)
- Presence of a tilted implant
- Report of having poor oral hygiene (Plaque Index [PI] > 1 and Sulcus Bleeding Index [SBI] > 1)19

The study was conducted according to the principles embodied in the Helsinki Declaration of 1975, revised in 2000, for biomedical research involving human subjects. The authors analyzed preexisting and nonidentifiable data of patients, who were all informed about the nature of data treatment and signed a written informed consent.

**Surgery**

At least 60 minutes before surgery, each patient received 1 g amoxicillin and then 1 g twice daily for 7 days. Local anesthesia was achieved by injecting a solution of optocaine 20 mg/mL with adrenaline 1:100,000. The tooth was extracted atraumatically by using an electromagnetic device (Magnetic Mallet, Osseotouch Total Control) without flap elevation with the maximum preservation of hard and soft tissue; then, a periodontal probe was employed for looking at the integrity (or not) of the socket bony walls.

**Grafted**

Alveoli were preserved either with a synthetic fully absorbable graft made of magnesium-enriched hydroxyapatite (Ca_{10-x}Mgx(PO_4)_6(OH)_2) available in granular form (SintLife, Finceramica) or corticocancellous porcine bone xenograft (OsteoBiol Gen-Os, Tecnoss).

After 3 minutes of hydration with sterile solution, each biomaterial was grafted in the extraction socket, and then, an absorbable collagen sheet was used to cover the employed biomaterial. A collagen sheet (Condress, Abiogen Pharma) was placed in order to completely cover the socket, and then secured with silk sutures15 (Fig 1).

**Ungrafted**

After tooth avulsion, the fresh extraction socket underwent the following treatment. Gentle curettage was performed to grasp possible soft tissue remnants close to the bone near the apex of extraction, but inflammatory tissue, which was located above the vertical bony walls of the postextractive socket, was not curetted; in fact, the intrasocket granulation tissue was only gently separated from roots and left in the socket.20 No flap was raised without a detachment of the peristomeum of the bone. The collagen sheet was secured by sutures to cover the buccal bone defect.21 Apposition of the free gingival edges of the postextraction alveolus was not needed due to the secondary intention healing. The sutures were not tight and were aimed at protecting the tissues in recovery conditions (Fig 2), but no primary closure was attained.22,23

Approximately 90 days after extraction, either titanium plasma spray internal hex (Frialit-CELLplus Frialit-CELLplus, Dentsply Friadent) or an implant with an external-connection machined neck of 0.8 mm, a rough
surface, and a body with a progressive thread design (Outlink, Sweden & Martina), were placed in each site. The osteotomy was kept apical to the graft, such that the implant apex was engaged in the native bone.

**Prosthetic Protocol**
Delayed dental implants were loaded after 3 months of submerged healing with provisional crowns. Impressions were made with the addition of silicone of two different consistencies (polyvinyl siloxane impression material, Flexitime Heavy + Flow, Heraeus/Kulzer) in an individual acrylic impression tray. A definitive ceramic-fused-to-metal restoration was cemented or screwed at 6 months after surgery. Occlusion was verified using an 8-μm foil (Shimstock).

**Radiographic Assessments**
Periapical digital radiographic images were acquired using the XCP-ORA device (the eXtention Cone Paralleling-One Ring and Arm positioning system, Dentsply International). A complementary metal-oxide semiconductor (CMOS) digital sensor (Schick CDR Elite, Schick Technologies) and imaging software (FONA Computed Dental Radiography DICOM 4.5, Schick Technologies) were used at baseline, and then at 3, 5, and 10 years after implant placement (Figs 1f, 1g, 2d, and 2g to 2i).

A paralleling device and an individualized bite block, made of polyvinyl siloxane (Flexitime, Heraeus/Kulzer), were used for the standardization of radiograph acquisition.
Free software (Osiris 4.19, University of Genève) allowed a blinded radiologist to measure the bone loss around implants over time at the mesial and distal aspects. Marginal bone level (MBL) was the distance between either the implant platform or the implant-abutment junction and the most coronal point of bone-to-implant contact. Bone loss (ΔMBL) was the change of bone level from baseline (first surgery) to subsequent time points (3, 5, and 10 years) as per equation 1:

\[
\text{MBL}_{\text{baseline}} \rightarrow \text{postoperative} = \text{BL}_{\text{postoperative}} - \text{BL}_{\text{baseline}}
\]

**Clinical Outcomes**

Information regarding the following clinical parameters was gathered from patients’ records: pain, occlusion, and prosthesis mobility. Dental implant failing criteria used in the present study were presence of implant mobility, radiolucent area close to the implant surface, suppurative mucosa, and associated pain, either spontaneous or due to the application of external strength. Survival rates were calculated.

**Statistical Analysis**

Dedicated software was used for all statistical analyses (Statistics Toolbox, MatLab 7.11, The MathWorks). Only one site per patient was enrolled in each group. Normal distributions of the groups and subgroups were not
confirmed. The three groups, magnesium-enriched hydroxyapatite, porcine bone, and ungrafted group, were independent; the unpaired two-sample Wilcoxon test was used for each pairwise comparison. For matched data, Wilcoxon signed rank test compared bone level and loss. In the text and tables, data are described as median (interquartile range) and rounded to the nearest decimal. A P value < .01 was the threshold for statistical significance.

RESULTS

Clinical Outcomes
Sixty-three subjects, 41 women and 22 men (mean age: 56.2 years; range: 38 to 68 years), were selected for the present analysis. Eighty-eight teeth were extracted, and delayed dental implants were positioned. One implant per patient was selected because this study used patients as the statistical unit. Sixty-three dental implants were selected for further analyses: 29 were internal-hex implants, and 34 were external-hex implants. Implants selected for each group were as follows: 42 implants (19 and 23 in magnesium-enriched hydroxyapatite and porcine bone group, respectively) placed in grafted sites and 21 in ungrafted sites.

Minor swelling of gingival mucosa was encountered in the first days after surgical procedures. No mucositis or flap dehiscence with suppuration was found. Suitable wound healing around provisional abutments was registered, with a fine adaptation to the provisional crown. In the first years, no pain or definitive prosthesis mobility was recorded.

Radiographic Evaluation
The results of MBL and ΔMBL for each group are shown in Fig 3 and Table 1, respectively.
Intragroup analysis suggested that negligible marginal bone loss, from 0 (0.1) mm to 0.6 (0.5) mm, was measured from 3 to 5 years in the magnesium-enriched hydroxyapatite group. Then, significant and progressive bone loss, with \( P < .0001 \), was registered. The loss at the 10-year follow-up was 1.2 (0.7) mm. Meanwhile, in the porcine group, radiographic bone levels appeared very stable over time, with no statistically significant differences. In approximately half of the cases, xenogeneic material particles were located at the most coronal aspect of the ridge, even at the last follow-up time point (Figs 1 and 3).

In the ungrafted group, a few days after implant placement, the bone level seemed to have a reliably measurable impact, with a value of –1.4 (0.5) mm. However, at 3 years after implant placement, a bone gain was observed with a \( \Delta \text{MBL} \) of +1.5 (0.9) and a slightly positive value of MBL, that is, +0.4 (0.60) mm; this was statistically significantly different compared with the baseline value (\( P = .0001 \)). From this point forward, the changes in MBL appeared altogether stable with just significance between the 5- and 10-year follow-ups (\( P = .0087 \)).

In the intergroup analysis, peri-implant MBL for both grafted groups showed a moderate decrease until the 3-year follow-up (MBL of –0.3 [0.2] mm to –0.1 [0.1] mm for magnesium-enriched hydroxyapatite and porcine bone group, respectively) without a statistically significant difference between grafted groups. At the 5-year follow-up, radiographic examination revealed a mean bone loss at the interproximal sites of the implant of 0.6 (0.5) mm for the magnesium-enriched hydroxyapatite group and 0 (0.1) mm for the porcine bone group (Table 1). This time point marked the first statistically significant difference between grafted groups (\( P < .0001 \)). The statistically significant difference remained at the 10-year follow-up (\( P < .0001 \)); in fact, for the magnesium-enriched hydroxyapatite group, a mean bone loss of 1.2 (0.7) mm was reported, while for the porcine bone group, a bone loss had not been registered.

The behavior of the ungrafted group appeared to be significantly different compared with the grafted groups at the baseline, at the 3-year follow-up, and from 5 to 10 years, compared with the porcine group alone (\( P < .0001 \)). This is due to the apparent loss in MBL at the baseline and the equal apparent gain registered for the \( \Delta \text{MBL} \) as early as the third year, which helps to balance the bone level very close to 0 (from 0.1 to 0.4 mm, as shown in Table 1).

### Success Rate

In both grafted groups after the 1-year follow-up, two implants were lost, and a survival rate of 95.2% (CI: 88.8% to 100%) was reported. No implant was lost in the ungrafted group.

At the 10-year follow-up, overall, three implants belonging to the magnesium-enriched hydroxyapatite group showed an MBL < 2 mm; this decreased the cumulative success rate to 82.6% (CI: 67.1% to 98.1%) at the 10-year follow-up.

In the ungrafted group, for most of the implants, there was a fine adaptation to the provisional restorations. However, three implants (placed in the posterior mandible) showed an MBL much smaller than 2 mm, with a cumulative success rate of 85.7% (CI: 70.8% to 100%).

### Confounding Factors

The position of the implant, ie, both anterior/posterior site and maxilla/mandible, was checked to test the influence of the variation in the marginal bone change among the three groups. Friedman tests did not reveal any significant influence on the changes, either between the maxilla and mandible or between the anterior and the posterior sites (Table 2).

### DISCUSSION

In this study, survival of dental implants placed in healed sockets filled with porcine bone and magnesium-enriched hydroxyapatite were similar to those of systematic reviews that reported 2-year cumulative survival rates for implants placed into ridge-preserved sites filled by use of a demineralized freeze-dried bone.24,25
That means that despite the absence of histologic evaluation of the augmentation site, a sufficient quality and quantity of bone to ensure successful osseointegration for implants was available.

Although different percentages of residual graft material may damage the osseointegration of the implants, a study showed remaining bovine bone particles embedded very close to the implants; this led to a normal bone-to-implant contact since the particles took place in the remodeling process.

However, little is known, at a long follow-up period, about the healing and osseointegration processes at the interface between titanium and grafting materials.

In this study, a statistically significant bone loss around dental implants was registered from the 3- to 10-year follow-up (P < .0001) for sites preserved with magnesium-enriched hydroxyapatite. At the 10-year follow-up, for the magnesium-enriched hydroxyapatite group, a median bone loss of 1.2 mm was reported. The porcine group showed more significant MBL maintenance (P < .0001) than the magnesium-enriched hydroxyapatite group. On the contrary, the results of the porcine bone appeared very stable, with negligible peri-implant marginal bone loss, even if, in some cases, the xenogeneic material was not completely metabolized within years, thus remaining in the bone tissue around implants and hampering bone level assessment. It was still possible to observe the granules of porcine bone in radiographs after 10 years.

In two different studies, implants placed in augmented sinuses with inorganic bovine bone were retrieved due to fracture from 4 to 5 years. They were removed, and histologic sections were examined. In both samples, many particles of inorganic bovine bone appeared to be easy to see even with low magnification, when peri-implant bone in the grafted area was investigated. Bone substitute particles appeared very close to the titanium surface even if a direct contact with the implant was very rare. Acute or chronic inflammatory cell infiltration or foreign body reactions were present neither around particles nor at bone-to-implant contact; moreover, a high percentage of bone-to-implant contact was reported at 4 years (72% ± 4%) and at 5 years (close to 50%). These results showed that slow resorption materials did not compromise dental implant osseointegration.
In the present study, the lack of significant differences for bone loss between grafted groups within the third year confirmed the findings of Norton and coworkers, who reported that, although there was a relatively high amount of grafted material around implants at the onset for secondary stability, clinical and radiographic observations indicated the achievement of suitable osseointegration.

The radiographic results of the ungrafted group were very similar to those reported in a previous study, where new bone formation around implants placed in augmented bone defects filled with reactive soft tissue was evaluated by means of cone beam computed tomography.

In the present study, patients presented buccal bone defects after tooth extraction. Granulation tissue was left in the defects, and no grafts were used.

The lack of bone opacity around implants just after their placement could indicate a partially demineralized bone due to an extraction socket that was not fully healed. However, after a 3-year follow-up, radiographic images revealed an apparent significant mesial-distal bone gain, which attested not a secondary gain, but just an increase in mineralization of the woven bone.

A steady state of the peri-implant tissues may be understood as a balance between the functional strengths and the reaction of supporting tissues; thus, positive bone remodeling is just a response to mechanic stimuli.

The bone-implant interface is characterized by a continuous remodeling in which the bone reacts to the functional strengths with significant improvement in the quality of bone structure.

Given the retrospective nature of the study, it should be noted that the presence of long-term data remains one of the most important criteria. On the other hand, the strengths of the present study were the detailed description of the phenomenon (bone level and loss) and the uniformity of surgical performances.

CONCLUSIONS

This clinical and radiographic study revealed a difference in terms of the long-term success rate when grafted and ungrafted sites were compared. Bone loss was higher in the magnesium-enriched hydroxyapatite grafted group than those in the other groups (both with xenogeneic porcine bone substitute and without biomaterial). Moreover, grafted groups reported more events of peri-implantitis and presence of grafted material in the coronal implant position.

On the other end, in the group without grafting material, absence of biomaterials allowed an extremely ample variability among patient outcomes, although long-term assessment of the bone loss around implants suggested significant preservation in bone height.

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