Long-Term Follow-Up on Soft and Hard Tissue Levels Following Guided Bone Regeneration Treatment in Combination with a Xenogeneic Filling Material: A 5-Year Prospective Clinical Study

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ABSTRACT

Purpose: In the present prospective study, bone augmentation by guided bone regeneration (GBR) in combination with bovine hydroxyapatite (BHA) as filling material was evaluated with regard to soft and hard tissue stability over time.

Materials and Methods: Implant survival, radiologic bone level (marginal bone level [MBL]), and clinical soft tissue parameters (marginal soft tissue level [MSTL]) were observed. Twenty patients received a total of 41 implants (Brånemark System, Nobel Biocare, Göteborg, Sweden) in conjunction with GBR treatment. The end point of the study was after 5 years following implant placement.

Results: The cumulative implant survival rate was 97.5% corresponding to one implant failure. The radiologic evaluation of the MBL demonstrated a crestal bone height above the level of the fixture head. The bone height decreased from −3.51 to −2.38 mm ($p < .001$). The MSTL was −1.52 mm at baseline and −1.15 mm at the 5-year follow-up ($p < .04$) demonstrating a stable submucosal crown margin throughout the study period.

Conclusion: GBR treatment in combination with a xenogeneic filling material (BHA) is a viable treatment option in order to maintain stable hard and soft tissue levels in conjunction with augmentative procedure related to oral implant treatment.

KEY WORDS: Bio-Oss®, biodegradable membranes, bone augmentation, bovine hydroxyapatite, e-PTFE, guided bone regeneration, implants, membranes

Dental rehabilitation with oral implants has become a common practice in the last decades with reliable long-term results.[1–3] However, because of secondary effects of tooth loss with subsequent ridge alterations, implant placement in particular in the maxilla might be suboptimal from an aesthetic point of view. Bone grafting procedures have been described in the literature with acceptable results.[4–7] The number of studies, evaluating these techniques long term, is still somewhat limited. The majority of these procedures are resource demanding, and the postoperative morbidity associated with this type of reconstructions should not be neglected.[8] Hence, clinical research has been oriented toward other alternatives.

Guided bone regeneration (GBR) treatment has been described as a suitable technique with regard to biology and aesthetics by the formation of new bone tissue.[9–25]

The quality of the regenerated bone by GBR technique is not an uncontroversial issue. Rasmussen and colleagues[26] demonstrated experimentally extensive

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DOI 10.1111/j.1708-8208.2009.00163.x

bone resorption of the regenerated bone after membrane removal.

Chiapasco and colleagues[27] also reported an increase in bone resorption following clinical loading of the implants. In contrast, other studies support the combination of GBR barrier technique and a suitable filling material in order to achieve a more predictable and lasting regenerative outcome.[28–30] The aim of this prospective study was to evaluate the GBR technique combined with a xenogeneic bone substitute material over a 5-year period with regard to the stability of hard and soft tissue levels over time.

MATERIALS AND METHODS

Twenty systemically healthy individuals (8 men and 12 women aged between 18 and 62 years; mean 39.9 years) who were referred to two implant centers for rehabilitation in the anterior region were included in the study. The patients demonstrated alveolar ridge defects (Figures 1 and 2) and the need for surgical correction of the bone deficit to improve implant support and the final aesthetic outcome of the implant – implant restoration.

The exclusion criteria were: (1) severe medical conditions, (2) active periodontal disease, (3) mucosal disease, (4) poor oral hygiene, and (5) noncompliant patients.

Surgical Procedure

Implant installation and simultaneous GBR treatment were performed in local anesthesia in all patients. Intravenous sedation was carried out in 13 patients (0.2 mg midazolam/kg b.w.) A buccal–crestal incision on the edentulous ridge was utilized (Figure 2). The incision was extended via the gingival sulcus of the neighboring teeth. Mesial and distal releasing incisions were performed, and full-thickness, buccal, and palatal flaps were elevated. By means of a surgical stent, the optimal position for the implants was determined. Following standard protocol (Adell and colleagues), the implants were placed at an ideal position although with supracrestal exposure of threads and fixture head protruding from the marginal bone level (MBL) caused by bone resorption. Care was taken to obtain an optimal primary stability. Finally, short healing abutments were placed (3 mm) in order to act as supporting and tenting devices for the membrane, and to optimize interproximal bone augmentation. A total of 41 Brånemark System® implants (Nobel Biocare, Göteborg, Sweden) were installed (Figures 3 and 4).

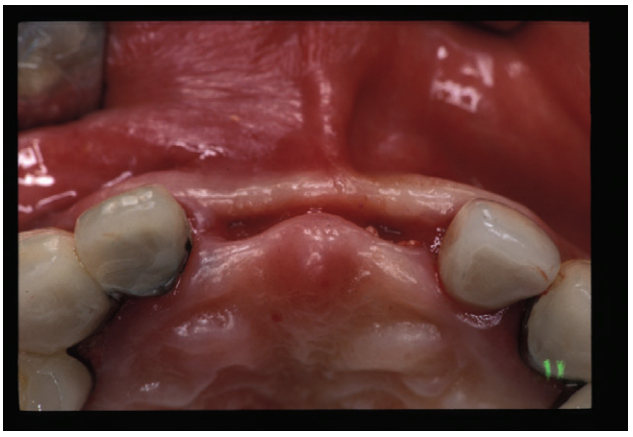

Figure 1 Axial view demonstrating a narrow alveolar ridge following extraction of tooth 11,21 because of endodontic failure.

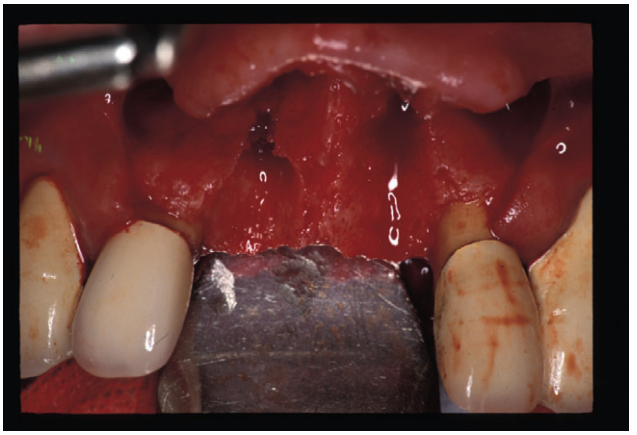

Figure 2 Edentulous space in the anterior region of the maxilla. Note the loss of the buccal bone plate.

The defect area in conjunction with the MBL and implants was filled with BioOss® (Geistlich Pharmaceutical, Wolhusen, Switzerland) in a mixture with approximately 20% autogenous bone chips collected from the implant preparation procedure.

In 12 patients, an e-PTFE membrane (W.L. Gore & Assoc., Inc., Flagstaff, AZ, USA) was trimmed and adjusted to cover the area, and was stabilized by means of titanium fixation tacs (Frios®, Friadent, GmbH, Mannheim, Germany). In the remaining eight patients, a resorbable membrane Bio-Gide® (Geistlich Pharmaceutical) was used (Figure 5). After careful periosteal releasing incisions in order to obtain absolute tension-free closure, the flaps were sutured in two layers with horizontal mattress (4-0 e-PTFE) sutures and 6-0

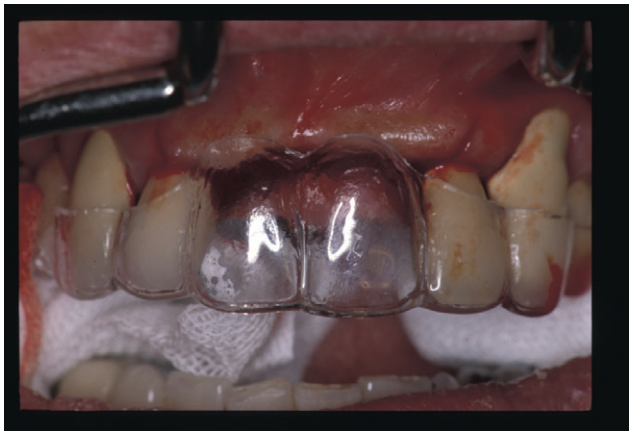

Figure 3 Upon placement of the surgical template, the ideal three-dimensional, prosthetic drive implant placement can be appreciated.

Monosof interrupted sutures for the mucosal incision. The patients received V-penicillin 2 g 1 hour prior to surgery and continued twice daily for 10 days postoperatively. Postoperative instructions included a soft diet for 2 weeks and appropriate oral hygiene with 0.2% chlorhexidine rinse twice daily for 14 days.

Sutures were removed 14 days postoperatively, and temporary dentures or bridges were allowed after careful adjustment in order to avoid any contact between the prosthesis and the soft tissues overlying the reconstructed areas. Healing was allowed for 7 months prior to abutment connection.

At abutment connection, e-PTFE membranes and tacs were removed. Temporary crowns were attached, and soft tissue healing was allowed for up to 6 months prior to finalization with porcelain crowns.

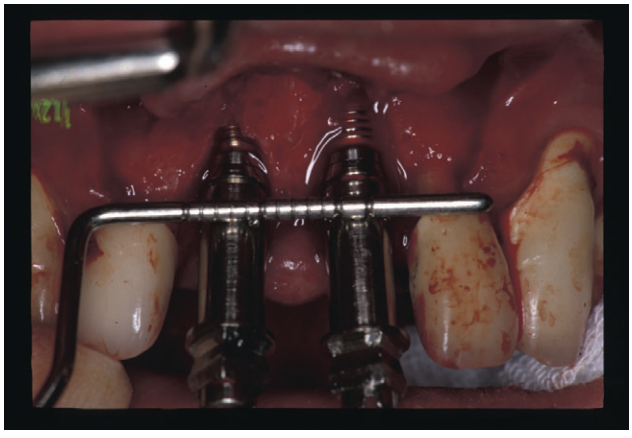

Figure 4 The implant was to be located about 2 mm apically to the border of the surgical template and the enamel/cemental junction of the neighboring teeth.

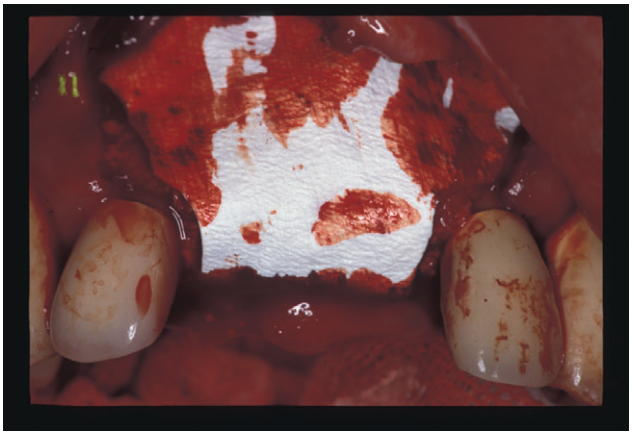

Figure 5 Considerable amount of bone-filling material was placed in order to recreate in slight excess the original contour of the alveolar ridge. To prevent soft tissue ingrowth and favor bone-forming cells, a bioabsorbable membrane was applied over the reconstructed area.

Parameters Evaluated and Follow-Up

The following parameters were evaluated: (1) implant survival, (2) MBL, and (3) marginal soft tissue level (MSTL) related to the crown margin (Zitzmann and colleagues).[28]

Implant Success and Survival Rates

The criteria for implant survival included the criteria proposed by Albrektsson and colleagues.[31]

Radiographic Assessments of Marginal Bone Remodeling After Implant Placement

Routine radiographic documentation of the treated patients was obtained with panoramic radiographs and intraoral radiographs taken preoperatively, immediately after reconstruction and implant placement, abutment connection, at the time of prosthetic reconstruction, and annually thereafter (Figure 6A).

The radiographic analysis was performed according to Zitzmann and colleagues.[28] In brief, the radiographs were made in occlusal contact with patient biting on radiograph holder. The parallel technique was applied in such a way that implant threads were clearly visible. When deviation from a proper parallel implant projection was observed, the radiographs were redone during the same visit. Measurements were made mesial and distal to each implant by means of a transparent ruler. Of the two values measured, the greater distance was used for analysis. The measurements were performed by one of the authors, which were calibrated prior to the

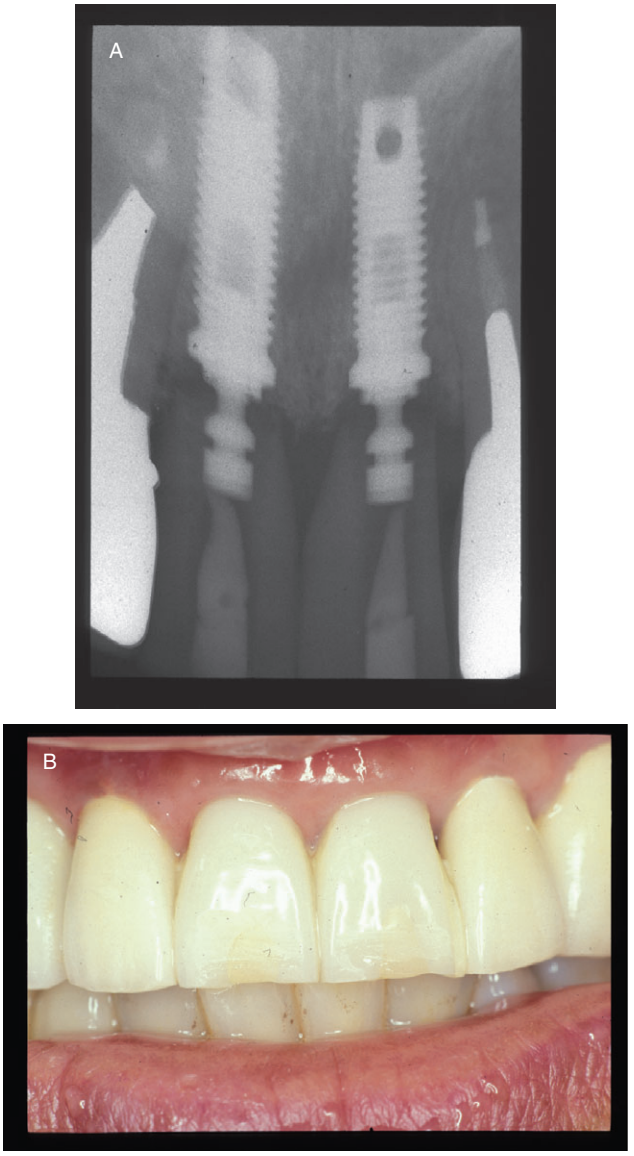

Figure 6 *A,* The intraoral radiograph taken after abutment connection and the placement of the provisional dentition. *B,* Insertion of the screw-retained implant provisional. The peri-implant tissue is checked for maturation and stabilization.

study. The distance from the most coronal level of the bone to the lower border of the hexagon head of the implants was measured. The measurements were recorded to the nearest 0.5 mm (Figure 7A).

Assessments of the Mucosal Tissue Levels After Implant Placement and Augmentative Procedures

The MSTL related to the crown margin. The distance was expressed in millimeters to the nearest 0.5 mm and presented as positive value when the abutment margin was located supramucosally or as a negative value with a submucosal position for this reference. All measurements were carried out using a periodontal probe (CP-12, Hu-Friedy, Chicago, IL, USA).

Statistical Analysis

t-Test for two sample groups was used for comparison of data. The probability level of $p < .05$ was considered as the level of statistical significance.

RESULTS

In general, the patients healed uneventfully, although one membrane exposure was noted. This patient was

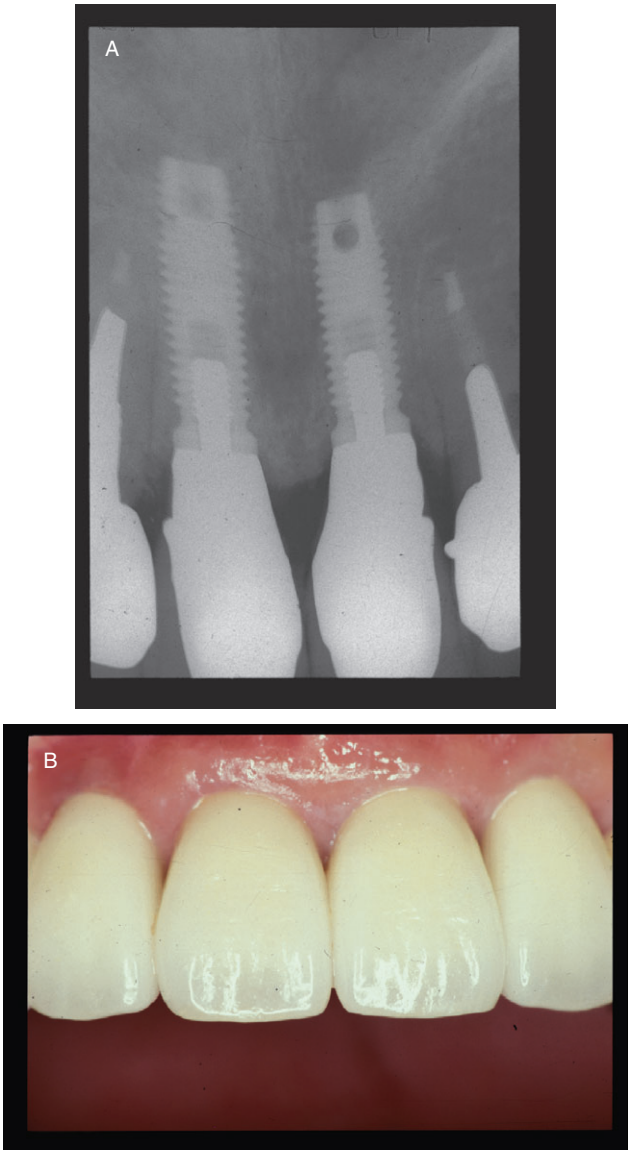

Figure 7 *A,* Final restorations seated in place. *B,* Intraoral radiographs at cementation of the final restorations. Note the remaining height of the newly formed interproximal bone tissue.

instructed to rinse the area with 0.1% chlorhexidine gel twice daily until the area was covered by new epithelium. One implant in one patient was considered mobile at the time of abutment connection. No further implant losses were recorded during the duration of the study, corresponding to a cumulative implant survival rate (CSR) of 97.5%. The observation period ranged from 53 to 72 months (mean 59.8).

The radiographic evaluation demonstrated a reduction in height of the MBL from a mean of −3.51 mm (SD 0.55) to −2.38 mm (SD 0.48) ($p < .0001$) over the 5-year observation period. The mean MSTL values were −1.52 mm at baseline (SD 0.47) and −1.15 mm (SD 0.53) at the 5-year follow-up (Figure 8). The reduction in MSTL was statistically significant ($p < .004$). (Table 1).

DISCUSSION

With increase awareness of the use of oral implants, there is mounting demand for treatment of more complex cases. A lot of focus has been put into the development of the aesthetic outcome of implant treatment. The results from the present study showed that vertical and horizontal defects in edentulous areas could successfully be corrected by GBR technique, and the results also maintained over time with only limited remodeling. The CSR of 97.5% corresponded well with other studies on implant survival in augmented bone.[29,30] Some previous investigators have questioned the necessity of GBR treatment of exposed implant surfaces.[32] From an implant survival point of view, there is probably little difference. Nevertheless, the introduction of more rough surfaces may be a concern because of colonization with bacteria on those surfaces and a subsequent risk for peri-implant infections (Quirynen and colleagues).[33] Furthermore, exposed threads underneath the peri-implant mucosa will hamper the final aesthetic result. Of clear interest are also the recent findings describing the physiological ridge alterations that occur following tooth loss. Because most of the buccal bone wall, in particular, in the aesthetic zone comprises more or less solely of the tooth-related bundle bone, a substantial horizontal/vertical reduction of the buccal bone crest is always seen.[34,35] This ridge alteration may have a significant impact on the aesthetic outcome if it is not dealt with surgically. Another important issue for the final and lasting aesthetic outcome are the choices of prosthetic components. In a series of studies, Abrahamsson and colleagues[36–38] demonstrated the importance of working with biocompatible components in order to maintain a

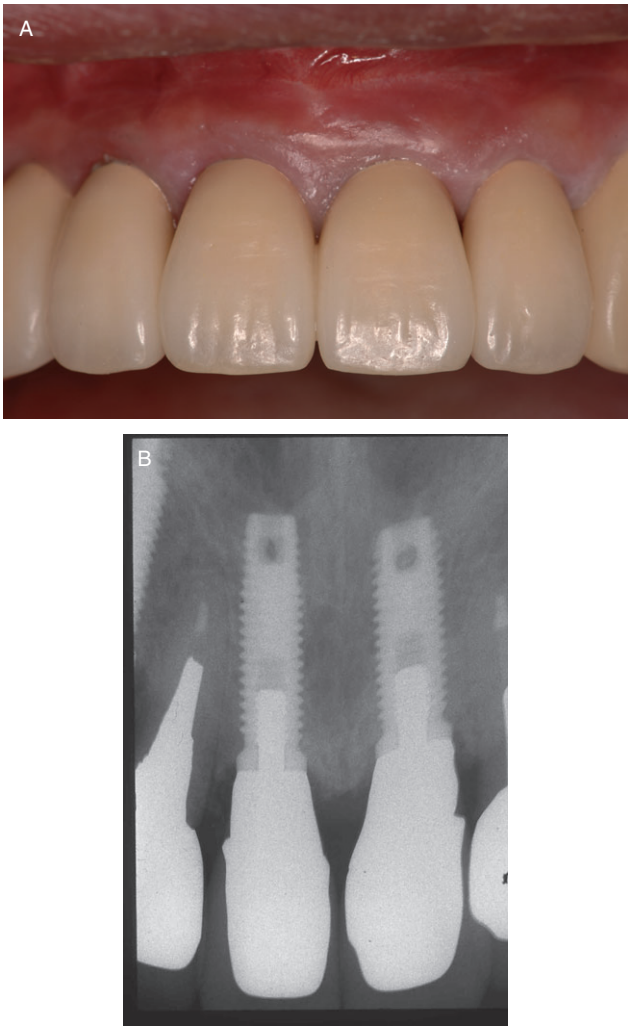

Figure 8 *A,* Five-year follow-up. Frontal view. Note the stable level of the peri-implant tissue. *B,* Radiograph at the 5-year follow-up. Only minor remodeling of the hard tissue is seen. Note the stable bone level well above the level of the fixture head.

TABLE 1

Variable	Baseline	5 years	No	*p* Value
Survival (%)	97.5	97.5	40	n.s.
MBL (mm)	−3.51 (0.55)	−2.38 (0.48)	40	<.0001
MSTL (mm)	−1.52 (0.47)	−1.15 (0.53)	40	<.004

Values in parentheses represent standard error for the values MBL and MSTL. The negative values represent that the bone level is located above the abutment junction (MBL) and that the mucosal margin is located above the crown margin (MSTL).
MBL = marginal bone level; MSTL = marginal soft tissue level.

stable peri-implant mucosa around the implants and their suprastructures.

In the present study, a striking finding was the maintained height of the MBL values, although there was a statistically significant reduction over the 5-year follow-up period. All patients demonstrated a stable bone level well above the level of the fixture head. The stable bony platform supported the MSTLs which maintained clinically a submucosal crown margin and optimal papillae appearance throughout the study period. Also, the MSTL values demonstrated a subsequent reduction. The hard and soft tissue remodeling over time seemed to be of less clinical consequence for the long-term aesthetic outcome. Hence, the physiological pattern of ridge resorption as described earlier in experimental studies, clearly occurred also in this material although with minor clinical consequences.

Several studies have reported on the efficacy of various graft materials in bone augmentation.[39,40] In the present study, bovine hydroxyapatite (BHA) (BioOss) was used as a space-filling material. During the last decade, this material has been widely used because of its similarity to human bone, and has also been considered to be osteoconductive.[41,42] The material was originally considered a slow resorbing bone substitute. However, Schlegel and Donath[43] found no signs of resorption of BHA particles after 6 years, a finding that is also supported by others.[44]

In our opinion, the fact that this material does not seem to resorb might actually be of importance for the successful and stable long-term results. In the present study, the BHA particles probably acted as a scaffold, which gave ample time for stabilization of the newly augmented bone, created by the GBR technique.

Based on the data from this study, we conclude that the application of GBR technique either with Bio-Gide or GORE-TEX® membranes, and a xenogeneic material is a predictable treatment modality in the treatment of localized defects in conjunction with oral implant treatment. The regenerative outcome using the surgical protocol preserved both the hard and soft tissues throughout the duration of the study with only very limited amount of resorption.

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