Ridge augmentation by applying bioresorbable membranes and deproteinized bovine bone mineral: a report of twelve consecutive cases

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Abstract

OBJECTIVE: Lateral ridge augmentations are traditionally performed using autogenous bone grafts to support membranes for guided bone regeneration (GBR). The bone-harvesting procedure, however, is accompanied by considerable patient morbidity. AIM: The aim of the present study was to test whether or not resorbable membranes and bone substitutes will lead to successful horizontal ridge augmentation allowing implant installation under standard conditions. MATERIAL AND METHODS: Twelve patients in need of implant therapy participated in this study. They revealed bone deficits in the areas intended for implant placement. Soft tissue flaps were carefully raised and blocks or particles of deproteinized bovine bone mineral (DBBM) (Bio-Oss) were placed in the defect area. A collagenous membrane (Bio-Gide) was applied to cover the DBBM and was fixed to the surrounding bone using poly-lactic acid pins. The flaps were sutured to allow for healing by primary intention. RESULTS: All sites in the 12 patients healed uneventfully. No flap dehiscences and no exposures of membranes were observed. Nine to 10 months following augmentation surgery, flaps were raised in order to visualize the outcomes of the augmentation. An integration of the DBBM particles into the newly formed bone was consistently observed. Merely on the surface of the new bone, some pieces of the grafting material were only partly integrated into bone. However, these were not encapsulated by connective tissue but rather anchored into the newly regenerated bone. In all of the cases, but one, the bone volume following regeneration was adequate to place implants in a prosthetically ideal position and according to the standard protocol with complete bone coverage of the surface intended for osseointegration. Before the regenerative procedure, the average crestal bone width was 3.2 mm and to 6.9 mm at the time of implant placement. This difference was statistically significant (P<0.05, Wilcoxon's matched pairs signed-rank test). CONCLUSION: After a healing period of 9-10 months, the combination of DBBM and a collagen membrane is an effective treatment option for horizontal bone augmentation before implant placement.
Ridge augmentation by applying bio-resorbable membranes and deproteinized bovine bone mineral

A report of 12 consecutive cases

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Key words: bone regeneration, human, dental implants, membranes, bone substitutes, deproteinized bovine bone

Running title: Ridge augmentation with biomaterials

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Clinical Oral Implants Research

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Conclusion: After a healing period of 9-10 months, the combination of DBBM and a collagen membrane is an effective treatment option for horizontal bone augmentation prior to implant placement.
Introduction

Successful implant therapy is dependent upon an adequate volume of bone at the site of implant placement, since long-term prognosis of dental implants is adversely affected by inadequate bone volume (Lekholm et al. 1986).

Following the increase in the evolution of the dental implants, a multitude of surgical techniques have been developed to enhance the alveolar bone volume for implant placement. These methods encompass grafting techniques, distraction osteogenesis, bone splitting, and guided tissue regeneration (GTR) and are advocated to have the potential for the correction of deficient alveolar ridges (Buser et al. 1993; Oda et al. 2000; Donos et al. 2002a; Cordaro et al. 2002). Guided bone regeneration (GBR) for the treatment of localized jaw bone defects has been documented to be highly successful (for review see Hammerle & Karring 1998).

The GBR procedure allows the regeneration of bone in staged or simultaneous approaches. Regarding the staged approach, a number of clinical studies demonstrated that implants placed in regenerated bone have excellent long-term outcomes (Buser et al. 1996a; Nevins et al. 1998). Unfortunately, partial or full collapse of membranes is a frequent clinical complication leading to compromised results in GBR treatment (Dahlin et al. 1991). Autogenous bone grafts have most frequently been used to support the membranes and are considered as gold standard for GBR in staged implantation procedures (Von Arx et al. 2001a).

Although intraoral or extraoral harvesting procedures are possible, the intraoral sites have been preferred especially for the treatment of localized bone defects in partially edentulous jaws (Misch 1997; Joshi & Kostakis 2004). One main disadvantage of using autogenous bone grafts is the morbidity associated with the harvesting procedure (Nkenke et al. 2004). Intraorally, common donor sites include chin and the area of the retromolar region in the mandible. However, intraoral harvesting procedures have also disadvantages, such as limited availability of bone grafts,
complications including altered sensation of teeth, neurosensory disturbances, wound dehiscences, and infection (Nkenke 2001; von Arx et al. 2005).

Due to these complex disadvantages of bone harvesting procedures, research activities were directed towards the use of biomaterials as substitutes for alveolar bone. In recent clinical studies, it has been demonstrated that the application of bone substitutes in conjunction with the placement of implants lead to successful coverage of the previously exposed implant surfaces (Zitzmann et al. 1997; Hammerle et al. 1998; Moses et al. 2005).

Despite of several experimental studies (Araújo et al. 2003; von Arx et al. 2001b) the studies evaluating clinical outcomes of lateral ridge augmentation with GBR procedures in staged implantation, usually used autogenous bone as filler materials in combination with non-resorbable membranes (Nevins et al. 1994; Buser et al. 1996b). Limited data are available reporting on the application of bone substitutes in combination with resorbable membranes for ridge augmentation prior to implant installation (Zitzmann et al. 2001a; Friedmann et al. 2002). Scientific data regarding the amount of bone gain by using biomaterials is scarce.

The aim of the present study was to test whether or not resorbable membranes in combination with bone substitutes will lead to successful horizontal ridge augmentation allowing implant placement under standard conditions.
Material and Methods

From the patient pool of the University of Berne, School of Dental Medicine, 12 patients including 6 women and 6 men with 15 sites in need of implant therapy agreed to participate in the present clinical trial. The patients had a mean age of 44 years, were in good systemic health and presented with no contraindications against oral surgical interventions. The indications for the placement of implants included single tooth gaps, multiple tooth gaps and edentulous distal extension situations (Table 1). The evaluation prior to the placement of the implants revealed a bone volume at the planned recipient site insufficient for the placement of implants according to standard protocols. Whereas the bone height in the edentulous area did not preclude implant placement, the width of the crest was of insufficient dimension. Hence, a GBR procedure aimed at augmentation of the ridge was included in the treatment plan. The patients were thoroughly informed about the foreseen treatment including the advantages and disadvantages of this new procedure in comparison to established augmentations procedures as well as prosthetic treatment options.

Ridge augmentation procedures

Prior to the surgical procedure for ridge augmentation the patients were given 3g of Penicillin (Clamoxy1®, SmithKline Beecham AG, Thörishaus, Switzerland). Following a mouth rinse with 0.1% of an aqueous solution of chlorhexidine, the area intended for surgery was carefully anesthetized using local anesthetics (Ultracain® D-S, Hoechst-Pharma AG, Zurich, Switzerland).

To raise a mucoperiosteal flap, a paracrestal technique was applied placing the line of incision towards the palatal aspect of the ridge in the maxilla. Oblique releasing incisions were used to allow for a wide flap basis as well as sufficient access to the defective ridge area. The flaps were carefully raised using tissue elevators. Sutures (Gore-Tex®, W.L. Gore & Associates, Flagstaff, AZ, USA) were applied for atraumatic retraction of the flaps during the subsequent part of the intervention (Fig. 1 a,b and Fig. 2 a,b). The bone ridge was examined and any soft tissues remaining
on the crest were meticulously removed with a surgical curette. A caliper was used to measure the oro-facial bone width to the nearest 0.5 mm at the prospective implant site. The cortical bone plate was perforated at numerous locations using a round bur in order to allow access of the cells from the bone and bone marrow to the area of regeneration. Subsequently, depending on the size of the defect, blocks, granules (particle size 1-2 mm) of cancellous DBBM (Bio-Oss®, Geistlich AG, Wolhusen, Switzerland) or combinations thereof were placed in the defect area. The aim was to increase the ridge to a size sufficient for standard implant placement, i.e. 6 mm or more. The membrane supporting material was partly stabilized by the morphology of the ridge, partly by the covering membrane. A collagenous membrane (Bio-Gide®, Geistlich AG, Wolhusen, Switzerland) was trimmed to cover the membrane supporting material and to extend 2-3 mm onto the intact bony borders of the defect (Fig. 1c-e and Fig. 2 c,d). Fixation of the membrane was obtained by use of fixation pins made of poly-lactic acid (Resor Pin®, Geistlich AG, Wolhusen, Switzerland) or by use of ligatures tying the membrane borders to the adjacent soft tissues. Releasing incisions were made through the periosteum at the base of the flap in order to allow tension free adaptation of the wound margins. Horizontal mattress sutures as well as single interrupted or continuous sutures (ePTFE) were placed to obtain healing by primary intention (Fig. 1e). The area of regeneration was x-rayed using single tooth films.

The patients received prescriptions for analgesic and anti-inflammatory medications for three days (Ponstan®, Parke-Davis, Baar, Switzerland). Another dose of penicillin (1.5g) was prescribed to be taken 6 hours following the first dose. Patients were instructed to rinse with a 0.1% solution of chlorhexidine twice a day for 2 weeks. The temporary removable partial dentures were checked and adapted if necessary to avoid trauma to the surgical area.

One week following augmentation surgery, the interrupted sutures were removed and another week later the mattress sutures were removed as well. Follow-up visits were scheduled every 6 to 8 weeks until reentry surgery.
Reentry and implantation surgery

Nine to ten months following augmentation surgery, reentry and implantation surgery were carried out. Following chlorhexidine rinses, the application of local anaesthetics and the exposure of single tooth film radiographs, crestal incisions as well as releasing incisions along the same lines as the ones during augmentation surgery were performed. The flaps were raised to a similar degree as the ones 9 months before in order to visualize the result of augmentation. The width of the crest was again measured with the same caliper in the same locations as prior to the augmentation. Implants of the Straumann® Dental Implant System (Straumann AG, Waldenburg, Switzerland) were placed according to standard protocols in prosthetically ideal position. The flaps were then adapted and sutured around the transmucosal implants using ePTFE sutures.

Statistical analysis

The Wilcoxon matched pairs signed rank test was applied to detect differences between the values obtained for ridge width before therapy and at the time of implant placement. The level of significance was chosen at $\alpha = 0.05$. 
Results

All sites in the twelve patients healed uneventfully. No flap dehiscences and no exposures of membranes were observed.

Upon raising the flaps for reentry the regenerated tissue appeared as mineralized bone tissue. An integration of the deproteinized bovine bone particles into the newly formed bone was observed. Merely on the surface of the regenerated bone some single pieces of the grafting material were only partly integrated into bone. However, these were encapsulated in connective tissue but anchored by the regenerated bone (Fig. 1 f,g and Fig. 2 f,g).

No remnants of the collagen membrane could be detected at reentry surgery. On top of the newly formed bone, however, a thick layer of periosteum-like tissue was found. This area possibly contained remnants of the partly resorbed membrane.

In all of the cases, but one, the bone volume following regeneration was adequate to place the implant type of choice according to the treatment plan in a prosthetically ideal position. In this one case, no gain of bone volume had occurred during the phase of regeneration. The tissue was inflamed and the DBBM granules were encapsulated into connective tissue. Since no adverse reactions were observed during the healing time, the reasons for this lack of bone formation are obscure. The average crestal bone width amounted to 3.2 mm before the regenerative procedure. At the reentry operation 9 to 10 months later, the mean crestal bone width had increased to 6.9 mm (Table 2). This difference was statistically significant (p < 0.005).

During the drilling procedure for implant placement the cutting resistance within the area of regeneration was found to be slightly lower than usually encountered with non-augmented host bone. However, the drill guidance was excellent and no fracture of parts of the regenerated tissue or grafting particles occurred. All implants could be placed with good primary stability.
Four months after placement, all implants were well tissue integrated as demonstrated by clinical measurements regarding the soft tissues and by analysis of single tooth X-rays regarding the bone (Fig.1 h and Fig. 2 h). Final reconstructions were fabricated and placed according to the original treatment plan.
**Discussion**

The results of this clinical trial demonstrated that the combination of DBBM and the collagen membrane may successfully be used for horizontal ridge augmentation in the chosen indications in the present study. Nine to ten months following regeneration surgery, implants could be placed in all sites but one according to the treatment plan. This indicated a high predictability of the procedure. In addition, the success rate found in this series of consecutive cases was similar to the success rates previously published (for review see Hammerle & Jung 2003).

Bone grafting materials in different structures have widely been utilized in bone augmentation procedures (for review see Hammerle & Karring 1998). In animal experiments the osteoconductivity of DBBM has previously been demonstrated (Hammerle et al. 1997). In a recent experimental study, it was shown that DBBM underwent remodeling similar to that of pristine host bone (Berglundh & Lindhe 1997). While in previous clinical studies, small bone defects at implant sites were augmented by use of DBBM (Zitzmann et al. 1997; Hammerle & Lang 2001; Hellem et al. 2003), larger bone defects were predictably augmented in the present case series. All the indications in this study included sites, where the lack of available bone precluded implant installation and hence, bone regeneration combined with implant installation in one single surgical procedure was not possible. Nevertheless, the therapy chosen lead to clinical success and implants could be placed in prosthetically correct position. The reasons for lack of bone formation in one individual are obscure. No adverse reactions were observed neither during initial tissue healing nor during the phase of intended bone regeneration. It can only be speculated that this clinical failure may have been due to micromotions or pressure of the prosthesis onto the edentulous ridge.

In recent clinical and histomorphometric studies it was demonstrated that the combination of DBBM with collagen membranes could successfully be used for staged alveolar ridge augmentation procedures (Zitzmann et al. 2001a; Friedmann et al. 2002). The described indications were very similar to the indications treated in the present study. After 7 months of healing, quantitative and
qualitative histology revealed no difference by using either DBBM with a resorbable collagen membrane or DBBM with a non-resorbable ePTFE membrane (Friedmann et al. 2002).

One main advantage of this technique, i.e. applying biomaterials to support resorbable membranes, is the avoidance of the morbidity associated with harvesting autogenic bone (Nkenke 2001; von Arx et al. 2005). This is a significant benefit to the patient and represents an important step in the development of GBR procedures. Future research should be focused on such patient-centered outcomes. The development of biomaterials, ideally coupled with the incorporation of bone growth factors and bioactive peptides, represents an important line of research (Jung et al. 2003).

Various membrane materials have been used in clinical studies with the aim to augment the ridge prior to implant placement (Buser et al. 1996b, Donos et al. 2002b). In most studies non-resorbable, expanded polytetrafluoroethylene (ePTFE) membranes were applied. Disadvantages associated with such membranes include an extensive surgical exposure needed for removal. In addition, the problem of frequent soft tissue dehiscences and membrane exposure allowing for bacterial contamination and infection of the area intended for regeneration has been reported (Simion et al. 1994). The use of resorbable membranes may avoid some of these disadvantages (Moses et al. 2005). The good outcomes documented in the present study demonstrated the barrier function of the collagen membranes to be adequate to allow for the desired bone regeneration in these indications. The time sequence of resorption and loss of barrier function of the membrane have not been investigated in details. A recent rat study compared alveolar ridge augmentation utilizing a synthetic resorbable and a non-resorbable membranes both combined with autogenous bone grafts (Donos et al. 2002c). It was found that resorbable membranes preserved its integrity and barrier function for at least 30 days following placement. Another study reported on the amount of bone fill in dehiscence defects when applying resorbable collagen membranes and ePTFE membranes combined with DBBM. The amount of bone fill with the resorbable membrane was similar to that obtained with the ePTFE membranes (Zitzmann et al.1997; Zitzmann et al. 2001b).
No flap dehiscences occurred in the present study. This is in agreement with a previous human study using the same grafting materials for alveolar ridge augmentation prior to implant placement (Zitzmann et al. 2001a), but appears to be in contrast with the findings from studies on ridge augmentation with the use of non-resorbable membranes. Most reports have documented a certain percentage of flap dehiscences (Lang et al. 1994; Jovanovic et al. 1992; Zitzmann et al. 1997). Hence, the absence of dehiscences in this initial report on ridge augmentation using the present materials is promising. Apart from the finding that soft tissue dehiscences seem to be less frequent when using resorbable compared to non-resorbable ePTFE membranes, resorbable membranes have additional advantages: i) following regeneration, no extensive raising of flaps is necessary for membrane removal, ii) no exposure of the regenerated bone in the apical areas results, iii) decreased patient morbidity is achieved.

In the present study stability was achieved by fixing the membranes to the local bone by use of miniature pins of polylactic acid and by use of ligatures tying the membrane to the soft tissues adjacent to the site of regeneration. The good outcomes in the present study confirm that the area underneath the membrane, i.e. the supporting material and the initial spaces, was sufficiently stabilized by membrane, pins and sutures to allow successful bone formation.

It is concluded that after a healing period of 9-10 months, the combination of DBBM and a collagen membrane is an effective treatment option for horizontal bone augmentation prior to implant placement with decreased patient morbidity.

**Acknowledgments**

The present experiment was partly funded by the Clinical Research Foundation (CRF) for the Promotion of Oral Health, University of Berne, Switzerland.
Tables

Table 1. Patient and site characteristics as well as local status of all 12 patients treated with GBR for ridge enlargement

<table>
<thead>
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<td>front</td>
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<tr>
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Table 2. Pre- and post-op ridge with of all the sites in the 12 consecutively treated patients

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<th>patient number</th>
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<td>reentry mm</td>
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<td>6.0</td>
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<td>4.5</td>
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<tr>
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Figures

Fig.1 a-h: Bone augmentation procedure at the implant site 22 (patient number 10):

a: occlusal view of the site 22 showing limiting amount of bone
b: buccal view revealed a large bone concavity precluding implant placement
c: occlusal view after grafting with DBBM granules
d: the grafted area was covered with a collagen membrane trimmed and adapted to the defect site
e: horizontal mattress and single interrupted sutures were used to obtain primary wound closure
f: reentry surgery after 9 months revealed a good integration of the DBBM particles into the newly formed bone
g: implant could be placed in prosthetically ideal position
h: radiographs before and after regeneration and implant placement

Fig. 2 a-h: Bone augmentation procedure at a multiple tooth gap in the anterior maxilla (patient number 12):

a: buccal view of the defect site 11, 21 and 22
b: occlusal view showing a thin alveolar ridge which precludes implant placement in a prosthetically ideal position
c: buccal view after grafting with granules and blocks of cancellous DBBM
d: a bioresorbable collagen membrane covering the right side of the augment area
e: with a second collagen membrane the entire area was covered
f: 9 months after augmentation the implants could be placed in prosthetically ideal positions
g: after placement of the implants no remaining bone defects were present
h: implants 11 and 22 after insertion of the fixed partial denture
References


ridge augmentation with biomaterials


