Randomized Controlled Trial to Compare Two Bone Substitutes in the Treatment of Bony Dehiscences

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ABSTRACT

Aim: This in vivo split-mouth randomized controlled trial compared a synthetic bone substitute with a bovine bone mineral to cover bone dehiscences after implant insertion.

Materials and Methods: Fourteen patients received four to six implants to support an overdenture. Two comparable dehiscences within the same patient were first covered with a layer of autogenous bone, followed by a layer of either Bio-Oss® (group 1; Geistlich Pharma AG, Wolhusen, Switzerland) or Straumann BoneCeramic® (group 2; Institut Straumann AG, Basel, Switzerland) and sealed by a resorbable membrane. The change in vertical dimension of the defect was measured at implant placement and at abutment connection (6.5 months). Clinical and radiological parameters were evaluated up to 1 year of loading.

Results: The vertical size of the defect at surgery was 6.4 ± 1.6 mm for group 1 and 6.4 ± 2.2 mm for group 2 sites, measured from the implant shoulder. After 6.5 months, the depth of the defect was reduced to 1.5 ± 1.2 mm and 1.9 ± 1.2 mm for group 1 and group 2 sites, respectively ($p > 0.05$). No implants failed during follow-up. Mean marginal bone loss over the SLActive surface was 0.94 mm (group 1), 0.81 mm (group 2), and 0.93 mm (group 3, no dehiscence) after 1 year of loading.

Conclusion: Both bone substitutes behaved equally effectively.

KEY WORDS: bone augmentation, guided bone regeneration, maxilla, SLActive, two stage

INTRODUCTION

The presence of a horizontal ridge defect may result in a dehiscence or fenestration defect after implant placement. Dahlin and colleagues[1] were the first to apply guided bone regeneration (GBR) to generate bone over the exposed implant surface. Nowadays, GBR procedures can be performed using resorbable or non-resorbable membranes, in association with a variety of graft materials, such as autogenous bone, allografts, xenografts, and alloplastic materials.

Despite the large amount of papers dealing with the treatment of bony dehiscences,[2–6] much controversy still exists regarding both the need for such augmentation procedures and the most effective GBR procedure/material. This, especially, is due to the lack of well-conducted randomized controlled trial (RCT) studies.

Autogenous bone has not demonstrated the promotion of greater bone regeneration compared with other grafting materials in the treatment of dehiscences.[7,8] Intraoral donor sites for autogenous bone are frequently unavailable or do not always provide a sufficient amount of bone. Harvesting of autogenous bone may also lead to donor site.[9] Research into alternatives has been directed toward the use of biomaterials as substitutes for alveolar bone. Today, many bone substitutes exist, but one of the

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most studied materials, and accepted as the gold standard, is a deproteinized, anorganic bovine bone-derived substitute (Bio-Oss®, Geistlich Pharma AG, Wolhusen, Switzerland). This material is also referred to as natural bone mineral, because proprietary processes are suggested to remove all cells and proteinaceous material, leaving behind an inert bone scaffold, with a specific three-dimensional surface structure.[10] The survival rate of implants placed in conjunction with a xenogeneic collagen membranes (Bio-Gide®, Geistlich Pharma AG) in combination with Bio-Oss (135 implants) ranged from 95.4 to 100%.[11–13] No relevant modifications of probing depth and/or variation of clinical attachment level around implants were observed between implant loading and the end of observation period (ranging from 1 to 9 years of follow-up).[11–14] These results seem to demonstrate that stability and health of peri-implant soft tissues may be expected with GBR procedures after correction of dehiscences and fenestrations.

A new fully synthetic bone substitute (Straumann BoneCeramic®, Institut Straumann AG, Basel, Switzerland), composed of 60% hydroxyapatite (HA) and 40% beta-tricalcium phosphate (β-TCP), might provide a better scaffold for predictable bone volume gain than either HA or TCP alone.[15] All batches are homogenous and consistent. Immunohistologic analysis in dogs of GBR treatment using Straumann BoneCeramic and Bio-Oss, showed similar new bone-to-implant (BIC) contact, bone fill, and percentage of osseointegrated bone graft particles after 4 and 9 weeks of healing for both substitutes, indicating that both materials may provide an osteoconductive scaffold to support GBR at dehiscence-type defects.[16] This has been confirmed by histology after sinus lift augmentation[17,18] and healing of filled extraction sockets[19] in humans in RCTs.

The present split-mouth randomized prospective study compared the capacity of Straumann BoneCeramic and Bio-Oss to cover dehiscences around implants.

MATERIALS AND METHODS

Patients

Consecutively, 14 patients (mean age of 55 years (range: 39–73), 12 women and two smokers, one of whom was a man) in need of an overdenture in the upper jaw, were recruited (2006–2007) and followed up to 1 year after loading. Ten patients were already edentulous at all implant sites for a longer period (mean: 20.1 years, range: 8–35 years); in four patients, the main reason for last tooth extractions (4–11 teeth) were bad quality of roots (endodontic/restorative/periodontal) for prosthetic reconstruction.

Based on multislice computed tomography scans, the patient was included if at least four maxillary implants (≥8 mm in length) could be placed, of which two needed horizontal augmentation. Exclusion criteria from a medical point of view were alcohol or drug abuse, psychiatric problems, uncontrolled diabetes, or uncontrolled systemic disease. From a prosthetic point of view, patients were only included if at least 8 mm of vertical height, measured from the gingiva toward the plane of occlusion, was present.

A healing period of 6 months after extraction was respected before implant installation. Periodontal treatment of the remaining teeth in the lower jaw was performed. Heavy smokers (>20 cigarettes/day) were excluded, while smokers were included but advised to reduce or to refrain from smoking. Follow-up visits were scheduled at 6 and 12 months after prosthesis placement.

Ethical approval was obtained (Ethical committee of the Catholic University Leuven, ref ID: 13409).

Surgery

Implant Installation and Treatment of the Defect. Under local anesthesia and in sterile conditions, a palatal incision with two distal releasing incisions was made and the flap was reflected buccally. The periosteum was released to subsequently allow tension-free primary closure. The knife edge ridge was reduced in height using a bone scraper (Safescrapers®, Meta, Reggio Emilia, Italy) to collect autogenous bone. Implant cavities were prepared following the guidelines as defined by Buser and colleagues,[20] but because a two-stage procedure was intended, the implants were installed subcrestally. Two dehiscences occurred during the preparation of the osteotomy. Chemically modified, sandblasted, and acid-etched surface implants with a smooth collar of 2.8 mm or 1.8 mm (Standard or Standard Plus SLActive, Institut Straumann AG) were used.

Several perforations of the cortex were made in the vestibular bone plate near the defect. The harvested autologous bone primarily covered the implant surface. A sealed envelope was then opened to determine which dehiscence had to be covered with Bio-Oss (group 1) or

Straumann BoneCeramic (group 2). Both substitutes were moistened with blood collected from the patients. The augmentation covered the complete vestibular site including the implant collar. Both augmented areas were sealed by a trimmed/individualized resorbable membrane (Bio-Gide), which rest 2–3 mm on intact bone to ensure stability of the augmentation. Individual silk sutures closed the flap. Areas where no dehiscence was apparent (group 3) were also measured for comparison.

Patients were not allowed to wear the temporary removable prosthesis during the first week. Antibiotics (amoxicillin 500 mg three times a day) were prescribed for 4 days, and painkillers were taken as required by the patient. The patient was asked to rinse twice a day with a 0.12% chlorhexidine solution. Follow-up visits during the osseointegration phase were scheduled until complete closure of the flaps was achieved. All complications (e.g., exposure of membrane, eventual irritation at augmented site, infection) were recorded.

Reentry and Abutment Installation

After a healing period of 6.5 months, a crestal incision was made, and the vestibular flap and pseudoperiosteum were raised for clinical and photographic documentation of the bone regeneration. Healing abutments were placed, and the flaps were sutured with silk ligatures.

Defect Measurement

After implant installation and at abutment surgery, different parameters of the bony defect were measured using a periodontal probe XP23 15 (HuFriedy, Chicago, IL, USA). Implant exposure was assessed in an apico-coronal direction measuring the longest distance of the denuded implant surface (vertical defect height [VDH]). The implant shoulder was the coronal reference point for measurements. Afterward, the exposed implant surface was calculated as the measurement minus the smooth collar height (VDH_{rough}). Other vertical parameters measured were the distance from bone crest to bottom of defect and from implant shoulder to bone crest. The horizontal defect depth (HDD) (Figure 1, B and C) describes the position of the implant in the alveolar bone. If the HDD is negative, the defect is not self-containing, and the implant surface is standing outside the bone. In addition, the width of the defect was calculated at several levels of the dehiscence:

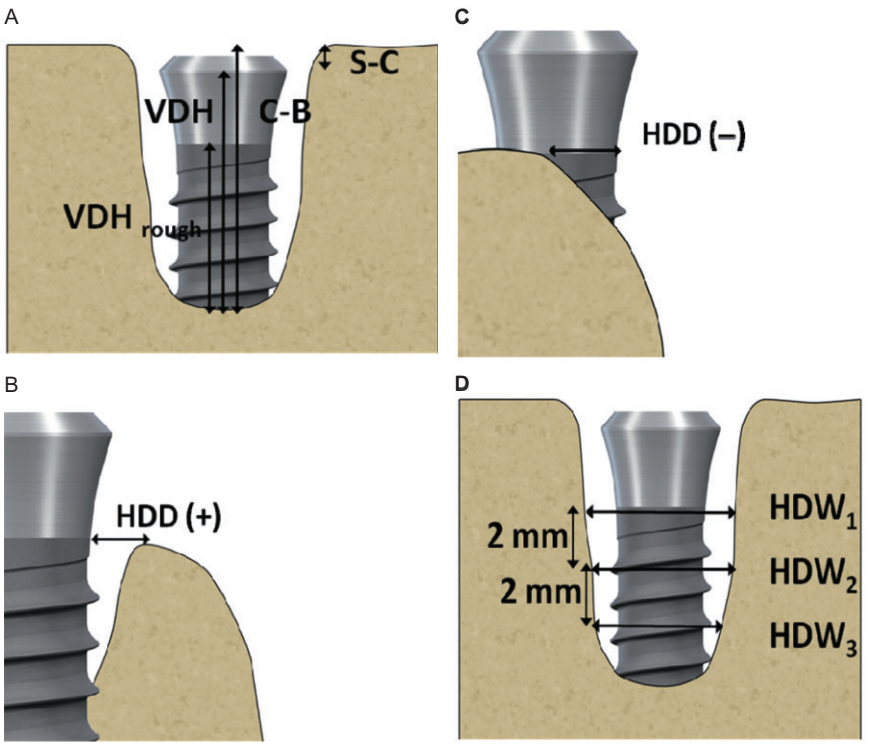

Figure 1 Illustration of the defect measurements at implant insertion and at abutment connection. *A*, Vertical parameters. (C-B = bone crest to bottom of defect; S-C = implant shoulder to bone crest; VDH = vertical defect height; VDH_{rough} = vertical defect height at the rough implant surface. *B–D*, Horizontal parameters. (HDD = horizontal defect depth; HDW = horizontal defect width).

HDW_1 = horizontal defect width at level of smooth – rough border, HDW_2 = width 2 mm below HDW_1, and HDW_3 = width 2 mm below HDW_2 for the entire dehiscence (see Figure 1D).

At second stage surgery, the height of the newly formed bone-like tissue was assessed by measuring the remaining exposure below the implant shoulder by the same parameters as mentioned before.

The percentage of defect reduction (DR) with respect to the original vertical dimension was calculated according to the formula: $(VDH_{impl} - VDH_{ab})/VDH_{impl}*100$

Because bone augmentation per se was not expected on the smooth implant collar, the healing capacity was also calculated in relation to the exposed rough implant surface $(VDH_{rough\ impl} - VDH_{rough\ ab})/VDH_{rough\ impl}*100$.

Prosthetic Procedure

One week after implant installation, the vestibular border of the prosthesis was completely relieved at the inner side at the augmented sites and the denture was relined and repeated each 4 weeks with a soft lining material (Coe-Comfort™, GC America Inc., Alsip, IL, USA).

Two weeks after abutment connection, final impressions were taken. At prosthesis delivery, SynOcta abutments (Institut Straumann AG) were installed together with a screw-retained bar. The abutments were torqued to 35 Ncm. The horseshoe-shaped overdenture was cobalt-chromium reinforced, and resin acrylic teeth were used. Teeth were set according to a balanced occlusion and articulation pattern.

Clinical Recordings

Implant stability was measured immediately after implant installation at abutment connection and 1 year after loading using the Periotest (Siemens AG, Bensheim, Germany) and Osstell devices (Integration Diagnostics, Savedalen, Sweden). Osstell measurements were assessed both in mesio-distal as well as in a bucco-oral direction. Each time, the final abutments were torque to 35 Ncm. Pocket probing depth (PPD), gingival recession (Rec), and plaque (yes or no) were measured at six sites per implant at each visit. The implant shoulder was used as reference point. A negative recession value indicates subgingival positioning of the implant shoulder. Bleeding on probing (BoP) was registered after probing the six sites. The results were presented as number of implants without any bleeding site.

Radiographic Follow-Up

Standardized radiographs were taken after implant placement at loading and 1 year after loading. A film holder, beam-aiming device (Rinn, XPC Instruments, Elgin, IL, USA) was used with the film placed parallel to the implants. Threads had to be clearly visible. The known distance between the threads was used for calibration of each radiograph. All radiographic analyses were performed at the University of Bern by a single investigator blinded to the protocol. Radiographic bone level measurements were calculated as the distance from the implant shoulder to the first visible BIC contact. Results on bone level, reported further, are in relation to the smooth/rough interface at the implants. Bone level measurements were therefore deducted by the height of the smooth collar.

Success Criteria

An implant was successful if there was lack of mobility, absence of peri-implant radiolucency, absence of recurrent peri-implant infection with suppuration, absence of continuous or recurrent pain, and no structural failure of the implant.[21]

Statistical Analyses

A sample size of 12 patients was estimated to have an 80% power to detect a difference in vertical height of buccal defects >15% between the treatment groups at a one-sided error level of 2.5%. The study enrolled 14 subjects to account for potential dropout patients.

For data processing and statistical evaluation, SPSS software package version 13 (SPSS, Chicago, IL, USA) was used. The primary outcome variable was the change in vertical height of buccal defects measured during first- and second-stage surgery. The study was designed to show non-inferiority between the two augmentation materials. The null hypothesis claimed that the change in vertical height of buccal defects was more than 15% lower in the test group compared with the control group. Confirmative statistical testing of this hypothesis was done by computing a 95% confidence interval for the mean change in vertical height at abutment connection in the test group and comparing it with the mean change in vertical height at abutment connection in the control group minus 15%. Secondary variables were

compared descriptively for treatment groups and visits. The significance level was set at $p < 0.05$.

RESULTS

Surgical and Prosthetic Procedure

A total of 75 implants were placed (group 1 = 14, group 2 = 14, group 3 = 47) with both 3.3 and 4.1 mm diameters (Table 1). No serious adverse events occurred. Three sites (one group 1 and two group 2) with a soft tissue dehiscence were noted, with subsequent membrane exposure in two patients. The patients were asked to disinfect the area with chlorhexidine spray until complete closure, which took approximately 4 weeks. One cover screw (group 2) remained exposed. The mean vertical coverage was 75% for group 1 and 68% for group 2 when the dehiscence was measured from implant shoulder (including all implants, Table 2) and 78% for group 1 and 76% for group 2 without sites with early membrane exposure (see Table 2). In relation to the SLActive surface, the percentage of DR with and without early membrane exposure sites was 94 and 89% for group 1 and group 2, respectively, and 98 and 98% for group 1 and group 2, respectively.

There was no statistically significant difference between both substitutes for any of the parameter. Complete coverage of the rough implant surface was shown for 8/14 group 1 sites and for 7/14 group 2 sites (Table 3). Sites with >1 mm exposure of the rough surface were correlated with premature exposure of the membrane (see Table 3). Remaining loose bone substitute particles was especially observed at those sites.

Clinical Measurements

Implant stability quotient (ISQ) at implant placement was never different between the three subgroups (Table 4). The values, especially for bucco-oral direction, increased slightly between implant placement, abutment surgery, and 1 year after loading. The change during the first year of loading was seven ISQ units for group 1 and six ISQ units for group 2 ($p > 0.05$). Periotest values also improved for both subgroups between abutment connection and 18 months after implant placement ($p > 0.05$).

PPD, Rec, BoP, and plaque index did also differ significantly between both subgroups (Table 5) ($p > 0.40$). No implants failed, resulting in a 100% survival rate for the three subgroups.

TABLE 1 Implants Placed in Each Group According to Diameter and Length

	Implant Diameter (mm)	8 mm	10 mm	12 mm	14 mm
Group 1	3.3	0	1	2	3
	4.1	1	0	4	3
Group 2	3.3	0	0	4	3
	4.1	0	1	2	4

Group 1: Geistlich Bio-Oss, group 2: Straumann BoneCeramic.

Radiographic Evaluation

All implants showed no signs of peri-implant radiolucency. Because of the two-stage protocol, the implants were placed subcrestally with mean bone levels of -1.49 ± 0.95 mm (group 1), -1.41 ± 0.88 mm (group 2), and -1.29 ± 0.73 mm (group 3). The mean bone levels were -0.19 ± 1.05 mm (group 1), 0.14 ± 0.93 mm (group 2), and -0.15 ± 0.62 mm (group 3) at loading and 0.75 ± 0.78 mm (group 1), 0.95 ± 1.16 mm (group 2), and 0.78 ± 0.52 mm (group 3) at 1 year. A more detailed illustration of the cumulative percentage of the mean bone level and mean is shown in Figure 2. Bone loss of ≥1.5 mm during the first year of loading was seen at 1/14 implants in group 1, at 2/14 implants in group 2, and at 4/42 implants in group 3. No statistically significant differences were found between both subgroups with augmentation and the subgroup without dehiscence.

DISCUSSION

For all augmented sites, the defect height decreased during the healing period, with no statistically significant differences between the bone substitutes. Less favorable healing was observed only when early membrane exposure occurred during the first weeks of the two-stage healing.

Soft tissue dehiscences occurred for both substitutes and were therefore not related to the augmentation material. It has also been mentioned by other research groups.[22,23] A plausible explanation in the present study could be necrosis of the edges of the flaps as a result of damage to the vascularization from an excessively palatal incision.[24] The blood supply may come from underlying bone and apposing flap. However, in the presence of a membrane, the unsupported portion of the flap loses its main collateral blood supply from the underlying bone.[25]

TABLE 2 Defect Dimensions (in mm), Measured at Implant Installation (Impl) and at Abutment Connection (Ab). Shown are Mean, Range, and Standard Deviation

	Group 1					Group 2				
	N	Impl (mm)	*N*	Ab (mm)	DR (%)	*N*	Impl (mm)	*N*	Ab (mm)	DR (%)
Including sites with early membrane exposure										
VDH	14/14	6.4 (4.0/9.0, SD: 1.6)	12/14	1.5 (0.0/5.0, SD: 1.2)	75	14/14	6.4 (4.0/12.0, SD: 2.2)	13/14	1.9 (0.0/4.0, SD: 1.2)	68
VDH_{rough}	14/14	4.3 (2.2/7.2, SD: 1.5)	6/14	0.2 (0.0/3.2, SD: 0.8)	94	14/14	4.4 (2.2/10.2, SD: 2.2)	7/14	0.4 (0.0/2.2, SD: 0.8)	89
C-B	14/14	6.1 (4.0/10.0, SD: 1.8)	14/14	0.5 (0.0/3.0, SD: 0.9)		14/14	6.0 (3.5/12.0, SD: 2.3)	14/14	0.5 (0.0/2.0, SD: 0.8)	
S-C	14/14	0.2 (−1.0/1.0, SD: 0.8)	14/14	1.0 (0.0/2.0, SD: 0.8)		14/14	0.3 (−1.0/1.0, SD: 0.7)	14/14	1.4 (0.0/2.0, SD: 0.7)	
HDD	14/14	−0.8 (−2.0/1.0, SD: 1.0)	14/14	1.8 (0.0/2.5, SD: 0.8)		14/14	−0.5 (−1.0/1.0, SD: 0.7)	14/14	2.0 (0.0/3.0, SD: 0.8)	
HDW1	14/14	3.0 (2.0/4.0, SD: 0.6)	2/14	0.4 (0.0/4.0, SD: 1.1)		14/14	2.8 (2.0/4.0, SD:0.5)	2/14	0.5 (0.0/4.0, SD: 1.3)	
HDW2	13/14	2.0 (0.0/3.0, SD: 1.0)	1/14	0.1 (0.0/2.0, SD: 0.5)		10/14	1.6 (0.0/3.0, SD: 1.1)	0/14	0.0 (0.0/0.0, SD: 0.0)	
HDW3	3/14	0.3 (0.0/2.0, SD: 0.7)	0/14	0.0 (0.0/0.0, SD: 0.0)		3/14	0.6 (0.0/3.0, SD: 1.1)	0/14	0.0 (0.0/0.0, SD: 0.0)	
Excluding sites with early membrane exposure										
VDH	13/13	6.2 (4.0/9.0, SD: 1.5)	11/13	1.3 (0.0/2.0, SD: 0.7)	78	12/12	6.4 (4.0/12.0, SD: 2.1)	11/12	1.5 (0.0/2.5, SD: 0.8)	76
VDH_{rough}	13/13	4.2 (2.2/7.2, SD: 1.4)	5/13	0.1 (0.0/0.2, SD: 0.1)	98	12/12	4.4 (2.2/10.2, SD: 2.1)	5/12	0.1 (0.0/0.2, SD: 0.1)	98

Negative values represent a more coronal (**for** S-C) or vestibular (**for** HDD) position toward the reference point.

VDH, vertical defect height; VDD_{rough}, vertical defect height on the rough implant surface; C-B, bone crest to bottom of defect; S-C, implant shoulder to bone crest; HDD, horizontal defect depth; HDW, horizontal defect width; group 1, Geistlich Bio-Oss; group 2, Straumann BoneCeramic; *N*, number of sites for which the indicated dimension was different from zero over the total sites measured; DR (%), percentage of defect reduction; SD, standard deviation.

TABLE 3 Vertical Defect Height of Remaining Dehiscence on SLActive Surface at Abutment Connection

Patient Number	Group 1	Group 2
1	0	0.2
2	0	0
3	0	0
4	0	0
5	0	0
6	0	2.2
7	0.2	0
8	0.2	0.2
9	2.2	3.2
10	0	0
11	0	0
12	0.2	0.2
13	0.2	0.2
14	0.2	0.2

Gray cells represent sites with early membrane exposure.
Group 1, Geistlich Bio-Oss; group 2, Straumann BoneCeramic.

The findings of the present study are in agreement with previous controlled studies using a similar combination of bone substitute (although without autogenous bone) with resorbable barriers in partially edentulous jaws. Zitzmann and colleagues[26] compared the healing of dehiscences, treated with Bio-Oss and covered with either a resorbable or a non-resorbable membrane. For the resorbable membrane, 16% incomplete soft tissue closure and a 92% bone fill was found after 7–10 days. Hämmerle and Lang[27] reported on 10 implants in 10 patients, using Bio-Oss and Bio-Gide and resulted in 86% coverage. Jung and colleagues[23] evaluated bone regeneration at implants with dehiscences for which Bio-Oss/Bio-Gide were compared with Bio-Oss/polyethylene glycol (PEG) hydrogel membrane. Mean defect fills of 94.9 and 96.4% for the PEG and membrane groups, respectively, were observed.

Clinical parameters after 1 year were favorable and comparable for both bone substitutes. No implants failed, which is in line with systematic reviews reporting on survival rates of implants placed in regenerated bone, ranging from 79–100%, with most studies reporting >90% after at least 1 year of function.[3,28] The survival

TABLE 4 Implant Stability Quotient (ISQ, as Measured with the Osstell Device; PTV, as Measured with Periotest Device) Expressed in Mean Value with Ranges

	Group 1			Group 2		
	Impl	Ab	1 yr loading	Impl	Ab	1 yr loading
ISQ MD	71 (59/80)	72 (53/82)	74 (53/81)	74 (55/85)	71 (49/82)	72 (49/84)
ISQ BO	63 (52/80)	69 (51/80)	70 (30/81)	62 (55/79)	66 (42/75)	68 (32/78)
PTV	—	−2 (−6/2)	−4 (−6/0)	—	−2 (−6/3)	−3 (−6/0)

Group 1, Geistlich Bio-Oss; group 2, Straumann BoneCeramic; impl, implant placement; ab, abutment installation; MD, mesio-distal; BO, bucco-oral; PTV, periotest value.

TABLE 5 Clinical Parameters Presented as Mean with Ranges and Standard Deviation per Treatment Group

	Group 1		Group 2	
	6 mo loading	1 yr loading	6 mo loading	1 yr loading
PPD (mm)	2.9 (2.0/4.7, SD: 0.8)	3.5 (2.0/5.2, SD: 0.9)	3.3 (2.0/5.8, SD: 1.1)	3.9 (2.0/6.0, SD: 1.1)
Impl (*n*) with BOP = 0/total Impl (*n*)	7/14	8/14	7/14	9/14
Rec (mm)	−0.4 (−2.0/0.5, SD: 0.7)	−0.7 (−3.0/0.3, SD: 0.9)	−0.5 (−3.3/0.5, SD: 1.0)	−1.2 (−4.7/1.2, SD: 1.7)
CAL (mm)	2.5 (1.3/3.7, SD: 0.6)	2.8 (1.7/4.2, SD: 0.6)	2.8 (2.0/3.8, SD: 0.7)	2.7 (0.8/4.5, SD: 1.0)

Legend: group 1: Geistlich Bio-Oss, group 2: Straumann BoneCeramic, PPD, pocket probing depth, Impl = implants, Rec = gingival recession, CAL = clinical attachment level, SD = standard deviation.

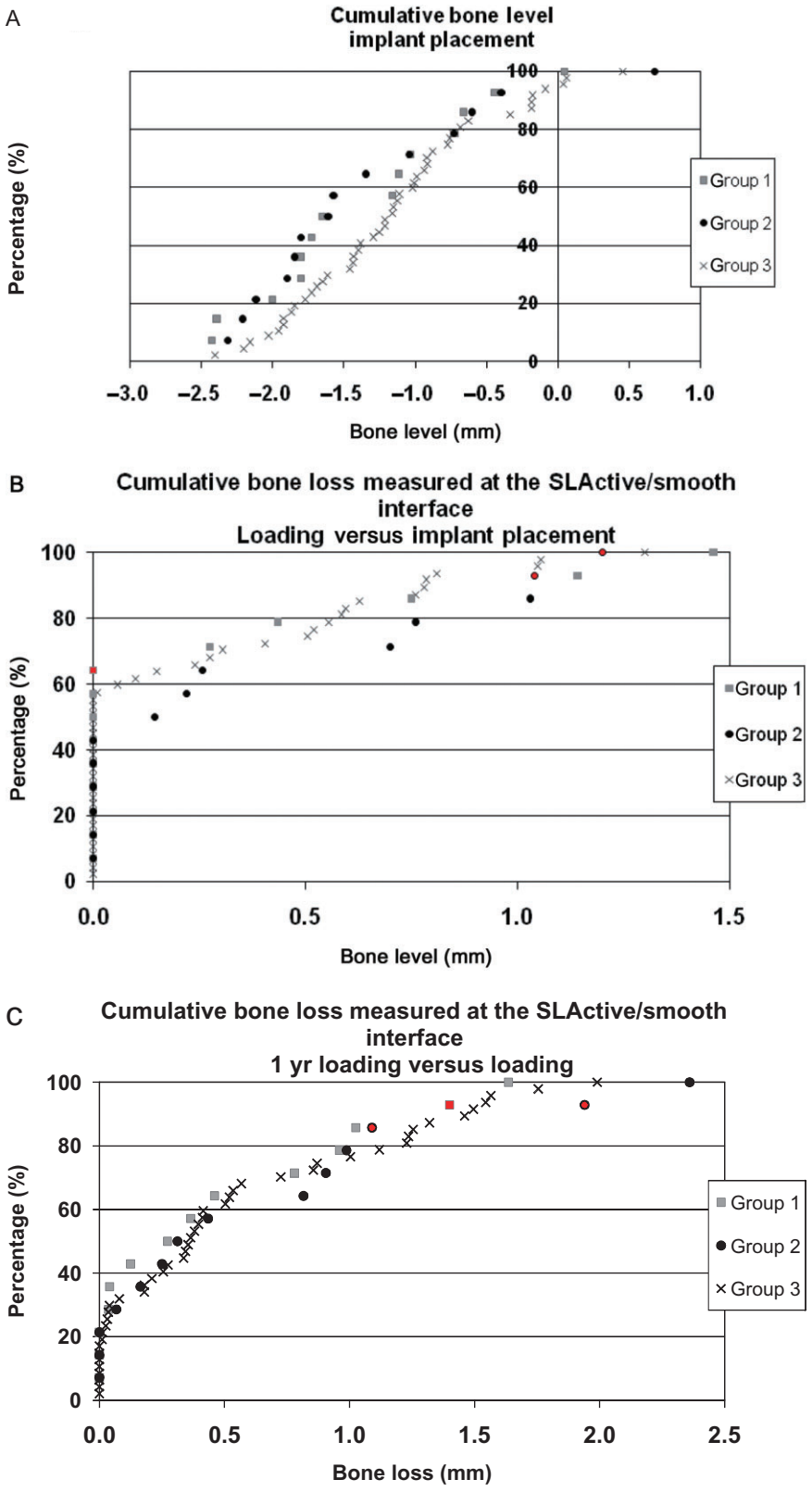

Figure 2 Cumulative percentage of bone level change. The rough (i.e., SLActive)/smooth interface was taken as a reference point for the measurements. *A*, Bone level at implant placement. *B*, Bone remodeling at loading. *C*, Bone loss after the first year of loading. Each symbol represent one single implant. The red points indicate sites with an early membrane perforation. (Group 1 = Geistlich Bio-Oss; group 2 = Straumann BoneCeramic; group 3 = no dehiscence.)

rates and bone levels observed in the present study are comparable with the sites without dehiscences; the latter are also in accordance with studies reporting the outcome of implants in native bone.[29,30] A prospective split-mouth study, compared 112 implants with a GBR-treated dehiscence (Bio-Oss plus a collagen membrane) with 112 implants in native bone after 5 years.[11] The survival rate of implants with a dehiscence was 95%, while the survival of control implants was 97.3%. Marginal bone level changes were higher in patients treated with GBR (mean: 2.2 mm) compared with control implants (mean: 1.7 mm) after 2 years of follow-up.

The knife edge shape of the crest allowed the possibility to collect autogenous bone. Because of the lack of negative controls (i.e., bone substitute without autogenous bone), it was impossible to demonstrate the need for autogenous bone. No evidence is available on whether this layer gives better results,[31] but autogenous bone is known to have osteoconductive and osteogenic properties during the initial healing period.[32,33] Hämmerle and Lang[27] used Bio-Oss alone and concluded that the absence of autogenous bone did not seem to negatively influence the treatment results. Although the need for augmenting a dehiscence is still questioned, it might have a role in aesthetic areas. Exposures of the implant threads, gray areas of the gums, overlying the exposed implants surface, or even the absence of the alveolar prominence, might be prevented when using this technique.

Conversely, during the follow-up period, controls were performed only by evaluation of peri-implant soft tissue parameters or intraoral periapical radiographs. This type of evaluation presents a relevant limit; no information of regenerated tissue on the buccal aspect is provided. Cone beam images can be proposed; although, it is not yet possible to detect a thin layer of bone covering the implant surface.[34] Another technique might be to probe with a needle at fixed reference points, to explore the thickness of the buccal bone wall.

The impact of the implant surface was not investigated in this study, but this might have been one of the cofactors leading to such a positive healing result. Previous studies in dogs have indicated that a rougher surface increases BIC contact compared with a turned surface.[35–38] Besides an increased roughness, modified stereolithography (SLA) surfaces (i.e., SLActive) have an increased surface-free energy and hydrophilicity (water contact angle of 0°) compared with SLA. Results from an animal study revealed that this surface improved the adhesion and, subsequently, the stabilization of the blood clot and new bone formation.[38] One must bear in mind that results from animal studies cannot be extrapolated to humans and that created defects are not completely the same as the dehiscences in the present human study where they occurred due to a small ridge (implant standing outside the crest); thus, the defects were never self-containing.

The presence of remaining particles has previously been mentioned for Bio-Oss[26,39] and was also found in the present study at sites augmented by group 2. A histologic analysis[39] revealed that loose xenogeneic particles were clearly identifiable but already surrounded by new bone formation.

To our knowledge, this is one of the few prospective randomized clinical trials to treat fully edentulous patients with a very small alveolar ridge without autogenous bone blocks. For most patients, the alternative treatment was the placement of a hip or cranial graft to allow implant placement, but these patients were not willing to undergo such bone transplantation. Alternatives could have been zygomatic implants,[40] although the crest was often very small, or a ridge splitting technique.[2] Systematic reviews[41,42] could not perform meta-analyses because of limited sample size and heterogeneity of the last techniques.

CONCLUSION

This study showed that both bone substitutes, following a simple surgical protocol, can be used to cover dehiscences along implants.

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