Vertical Ridge Augmentation with Autogenous Bone Grafts: Resorbable Barriers Supported by Ostheosynthesis Plates Versus Titanium-Reinforced Barriers. A Preliminary Report of a Blinded, Randomized Controlled Clinical Trial

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Purpose: *To compare the efficacy and complications of 2 different techniques for vertical bone augmentation at implant placement: particulated autogenous bone grafts covered either by resorbable collagen barriers supported by osteosynthesis plates (test) or by nonresorbable titanium-reinforced e-polytetrafluoroethylene (e-PTFE) barrier (control).* ***Materials and Methods:*** *Twenty-two partially edentulous patients requiring vertical bone augmentation were randomly allocated to 2 treatment groups of 11 patients each. Early implant failures, the amount of vertically regenerated bone measured intrasurgically, and biologic complications were recorded by an independent assessor blinded to the group allocation. The implant site requiring the most vertical bone regeneration was selected in each patient for the bone gain assessment. Patients were followed from implant insertion with simultaneous augmentation procedure to insertion of the provisional restoration. Paired and independent* t *tests and Fisher exact tests were conducted to compare means and proportions at the .05 level of significance.* ***Results:*** *No patient dropped out or was excluded. Both procedures obtained significant bone gain and achieved the desired results, 2.2 mm (SD 1.5;* P < *.001) on average for resorbable barriers and 2.5 mm (SD 1.1) for nonresorbable barriers (*P < *.001). There was no statistically significant difference in bone gain between the 2 procedures (*P = *.58). Complications occurred in 40% of the patients. There was no difference in occurrence of complications between the procedures (*P > *.99). Three major complications occurred, 2 in the resorbable group and 1 in the nonresorbable group, which determined the complete failure of the augmentation procedure.* ***Conclusions:*** *Both techniques were effective in augmenting bone; however, both were associated with complications. Clinicians and patients must carefully weigh risks and benefits when considering the use of vertical guided bone regeneration.* Int J Oral Maxillofac Implants 2007;22:373–382

Key words: *bone augmentation, bone grafting, dental implants, guided bone regeneration, vertical augmentation*

It would be desirable to regenerate bone vertically in a predictable way; such a technique would allow for a more favorable implant-crown ratio and better esthetics for implant placement. Several techniques have been proposed[1–4]; however, the efficacy of these techniques has not been firmly established.[5]

In a retrospective case series, it was demonstrated that it is possible to regenerate bone vertically, using various techniques; however, a few complications occurred.[6] In a randomized controlled clinical trial, a guided tissue regeneration technique for vertical ridge augmentation was compared with distraction osteogenesis.[2] However, it is difficult to draw firm conclusions, as the sample size was small. In a controlled retrospective study,[7] autogenous bone grafts protected by resorbable collagen barriers supported by osteosynthesis plates were compared with autogenous bone grafts protected by nonresorbable titanium-reinforced expanded polytetrafluoroethylene (e-PTFE) barriers. No statistically significant differences were observed in terms of efficacy and compli-

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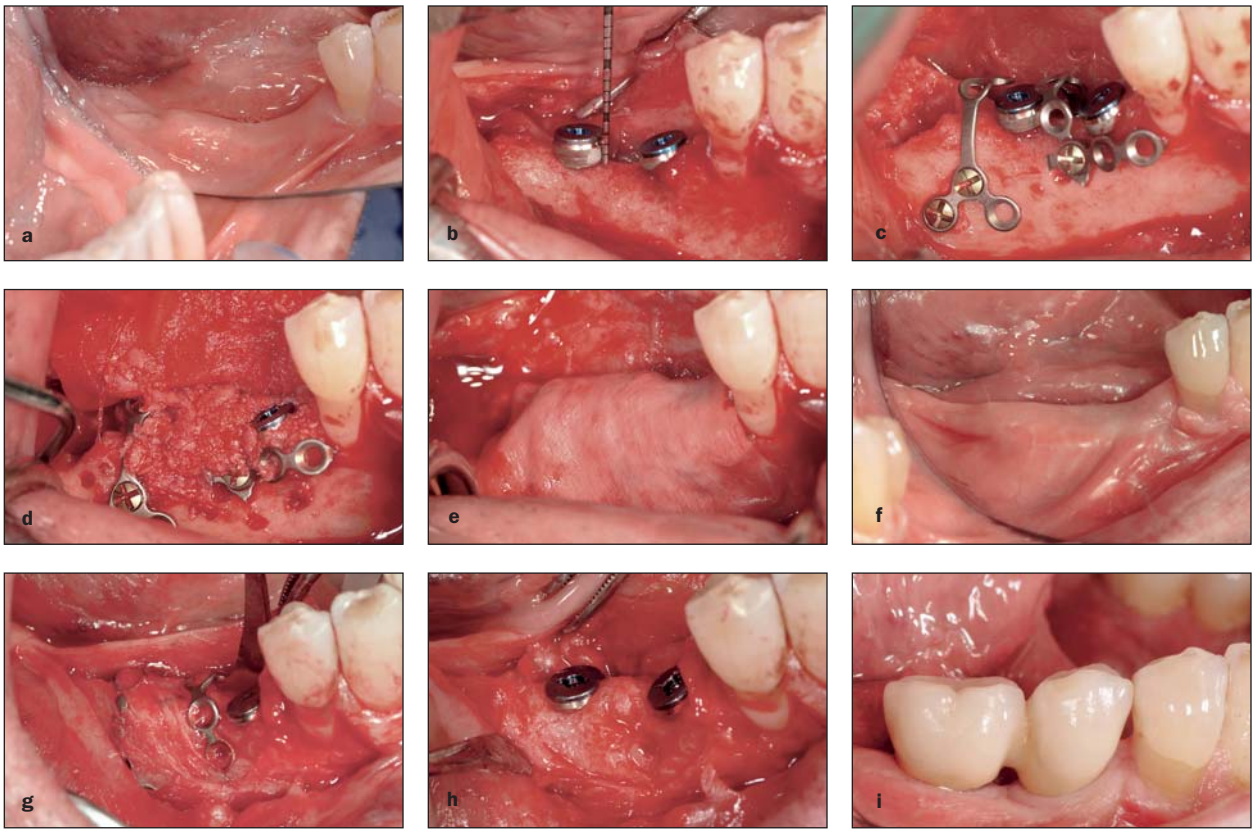

Fig 1 Patient 6 (resorbable group): *(a)* defect prior to the intervention; *(b)* probe showing the amount of bone to be regenerated around the selected implant; *(c)* 3 osteosythesis plates are opportunely bent and fixed with screws; *(d)* the particulated autogenous bone graft is placed; *(e)* a resorbable barrier is placed over the graft; *(f)* tissues during the healing phase of the graft just before implant exposure; *(g)* exposure of the regenerated area with the plates still in situ; *(h)* tissue after removal of the plates (regeneration was not 100%; impressions of the plates are clearly visible on the regenerated bone); *(i)* prosthesis in place.

cations between the 2 procedures. It is still unknown which is the most effective and reliable technique, as the sample sizes were small and there is higher risk of bias in retrospective studies. Nevertheless, there is some evidence that resorbable barriers over bovine-derived graft (Bio-Oss) may allow healing with fewer complications than nonresorbable barriers.[8]

The aim of this randomized controlled clinical trial was to compare 2 techniques for vertical bone augmentation: autogenous bone grafts protected by resorbable collagen barriers, supported by osteosynthesis plates (test) versus autogenous bone grafts protected by nonresorbable titanium-reinforced e-PTFE barriers (gold-standard control). These 2 techniques were compared with respect to efficacy and number and severity of complications.

The present investigation is a preliminary report focusing on the amount of vertically regenerated bone and the postoperative complications that occurred up to the insertion of the provisional prosthesis. In the protocol it was planned to prolong the follow-up to the fifth year of function in order to evaluate the stability of the obtained results over time. The present article is reported according to the CONSORT statement for improving the quality of reports of parallel-group randomized trials (http://www.consort-statement.org).

MATERIALS AND METHODS

Any patient in which vertical bone augmentation was desirable for esthetic, prosthetic, or functional reasons prior to the placement of single or multiple implants was eligible for inclusion in this trial. Patients were not admitted in the study if any of the following exclusion criteria were met: *(1)* general contraindications to implant surgery, *(2)* irradiation in the head and neck area, *(3)* poor oral hygiene and motivation, *(4)* uncontrolled diabetes, *(5)* pregnancy or lactation, *(6)* substance abuse, or *(7)* smoking more than 20 cigarettes per day.

Patients were recruited in a single private dental clinic with extensive experience in the treatment of complex implant cases in Rimini, Italy (Figs 1 and 2). Initially, patients referred from other clinics only for

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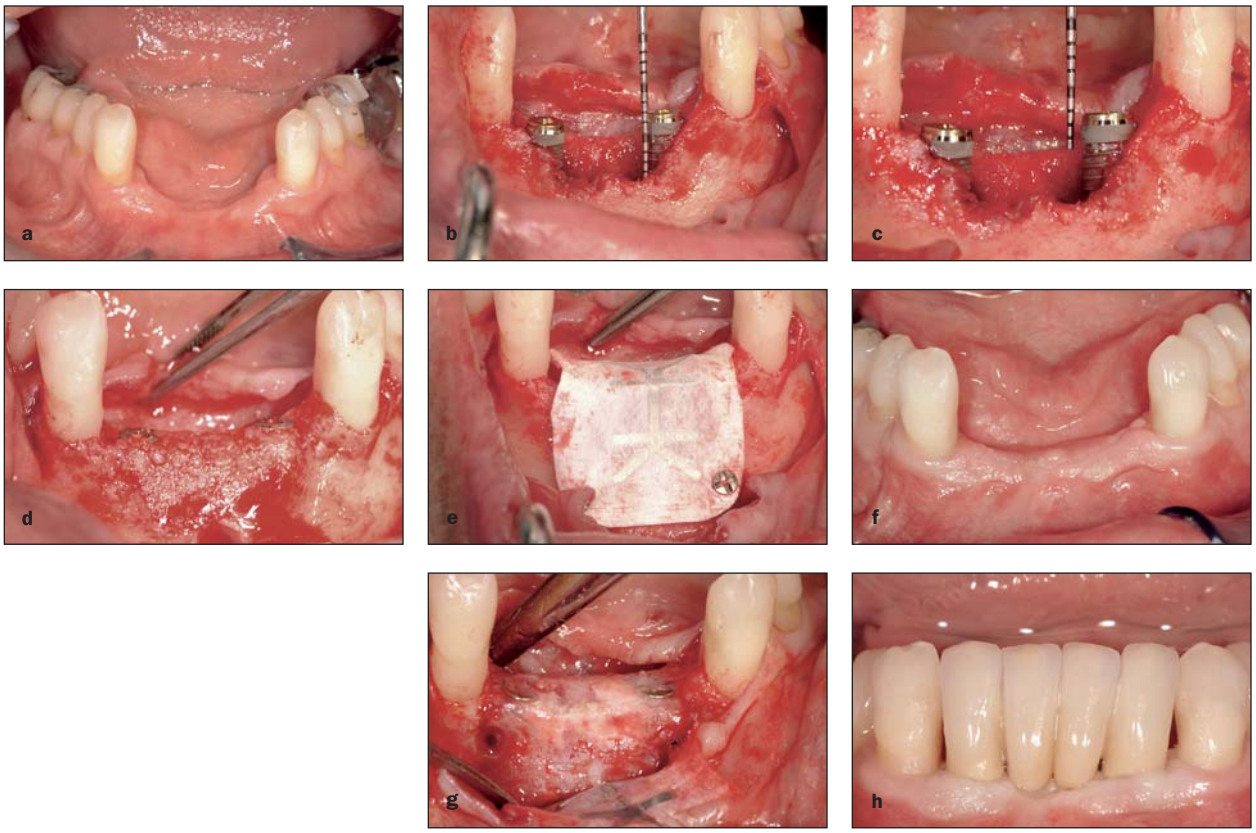

Fig 2 Patient 8 (nonresorbable group): *(a)* defect prior to the intervention; *(b)* intrasurgical baseline measurement DL-AJ (the infrabony component of the defect was not considered for the bone gain assessment); *(c)* intrasurgical baseline measurement HL-AJ; *(d)* the particulated bone graft is placed and modeled over the defect; *(e)* titanium-reinforced barrier is placed over the graft and fixed with miniscrews; *(f)* photograph obtained just before the abutment connection; *(g)* tissue after barrier removal, with the newly regenerated bone covering the titanium screws; *(h)* placement of the prosthesis.

the surgical interventions were also included in the trial, but the follow-up of those patients proved to be difficult. Therefore, this method of recruitment was discontinued after including the first 6 referred patients.

No ethical or institutional review board approval was sought; however, all patients signed a written informed consent form.

Patients in which a vertical ridge augmentation around dental implants was deemed necessary (Fig 1a and Fig 2a) using particulated autogenous bone grafts taken intraorally were randomized to receive either titanium-reinforced nonresorbable e-PTFE barriers (W.L. Gore & Associates, Flagstaff, AZ; control group; Fig 2) or resorbable collagen barriers (Bio-Gide; Geistlich Pharma, Wolhusen, Switzerland) supported by osteosynthesis plates fixed with 1.5-mm diameter screws (Gebrüder Martin, Tuttlingen, Germany; test group; Fig 2).

Surgical templates with hollow titanium cylinders guiding implant placement in the ideal position for the prosthetic rehabilitation were used. Stents were built from study casts obtained with an individual face-bow. All patients received prophylactic antibiotic therapy. Patients subjected to local anesthesia alone were prescribed amoxicillin per os for 8 days (1 g twice a day), starting 1 hour prior to surgery. In case of allergy to amoxicillin, macrolide antibiotics such as doxycycline hyclate (100 mg twice a day) or clarithromycin (Klacid; Abbott Laboratories, Abbott Park, IL; 500 mg twice a day) were given instead for 8 days. Patients subjected to intravenous sedation received 1 g cephalosporin (ceftriaxone [Rocephin]; Roche Laboratories, Nutley, NJ) intravenously followed by amoxicillin (administered as described). Intravenous sedation was induced by fractioned administration of 0.5 to 1 mg benzodiazepine (midazolam) with 0.5 mg atropine. Intravenous analgesics were also administered. Local anesthesia was induced with Articain 4% with adrenalin 1:100,000. Full-thickness flaps were raised to fully expose the area to be regenerated after a buccal incision in inferior posterior areas or a crestal incision, with releasing incisions when needed, in the remaining situations. The choice of the implant diameter and length was left up to the surgeon according to the anatomic limitations and

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treatment plan. XiVE CELLplus (Friadent, Mannheim, Germany) implants were inserted according to the manufacturer's instructions. The implant diameters used were 3.8 and 4.5 mm, whereas the lengths used were 8, 9.5, 11, 13, and 15 mm. The surgeon was free to choose the bone harvesting technique and the intraoral donor site. Bone was obtained from areas close to the implant sites. In addition, particulated bone from the implant preparation sites was always collected using a bone trap (Quality Dent; Dental Trey, Forlí, Italy) in a separate suction device used only for that purpose. According to the outcome of the randomization, the surgeon cut and shaped 1 or more osteosynthesis plates in the desired form to maintain the amount of space to be regenerated and fixed the plates with screws (Fig 1c). The bone from the prepared implant site collected with a bone trap and particulated autogenous bone harvested from various intraoral locations were used as grafting material (Figs 1d and 2d). Decortication of the ridge was performed to increase bleeding. Nonresorbable (Fig 2e) or resorbable barriers (Fig 1e) were positioned, and particulated bone was placed on the area to be regenerated. The graft was modeled to completely surround the implants and to fill the site to the desired height and shape. The barriers were then folded over the grafts. Barriers were shaped and positioned to avoid direct contact with the adjacent dentition. Titanium-reinforced e-PTFE barriers were stabilized with miniscrews 1.5 mm in diameter (Gebrüder Martin; Fig 2f). Resorbable barriers were not fixed with miniscrews or tags but were laid on well-fixed osteosynthesis plates. Two resorbable barriers were placed 1 on the top of the other in a few sites. Periosteal incisions were made to release the flaps as coronally as needed. When judged useful, a periosteal flap was raised, reflected over the alveolar crest, and inserted below the opposite flap.[9] Flaps were sutured with horizontal mattress sutures (4-0) plus single sutures (5-0) (Supramid; Aesculap, Tuttlingen, Germany) until the incisions were perfectly sealed. Patients were instructed to use chlorhexidine mouthwash 0.12% (Corsodyl; GlaxoSmithKline, Research Triangle Park, NC) twice a day for the following 2 weeks and chlorhexidine gel 0.12% (Corsodyl) twice a day for a month. They were also instructed to avoid brushing and trauma to the surgical site and to avoid smoking for a few days postsurgery. Analgesics (nimesulide 100 mg) were prescribed to the patients twice a day for 2 days and then as needed. Ice packs were given to the patients. Sutures were removed after 2 weeks. Patients were seen 1 and 2 weeks and 1, 2, 3, and 4 months after surgery. Abutment connection was carried out after 5 months of healing (Fig 1f and Fig 2f). During flap incision, care was taken to evenly divide the keratinized tissue buccally and lingually. Once the barrier (Fig 2g) or the osteosynthesis plates were removed (Fig 1h), the implants were tested for stability, and healing abutments were placed. After about 2 weeks, an impression with a polyether material (Impregum; 3M/ESPE, St Paul, MN) was made using a transparent resin impression tray (Set Dental, Dental Trey, Fiumana-Predappio, Italy). Casts were mounted in a standard articulator. Provisional screw-retained restorations were manufactured using acrylic resin (Ivocron; Ivoclar Vivadent, Schaan, Liechtenstein) and inserted. After 2 or 3 months, definitive metal-ceramic restorations were screw-retained or cemented with provisional cement (Fig 1i and Fig 2h). Intraoral radiographs were obtained with the paralleling technique at abutment connection and at insertion of the provisional prosthesis. In cases where the bone levels around the study implants were hidden or difficult to be read, a second radiograph was obtained.

All surgical interventions were performed by a single experienced operator. The prostheses of 6 patients were fabricated by the referring dentists; all other patients regularly attended the center where the investigation took place.

This study tested the null hypothesis that there were no differences in success rates, bone gain/resorption, or complications between the 2 procedures against the alternative hypothesis of a difference.

Outcome measures were:

1. Implant failure: Implant mobility was an indication of failure. Mobility of each implant was measured manually. Any infection dictating implant removal at abutment connection or at insertion of the provisional prosthesis was an indication of failure.
2. The amount of tissue regenerated in vertical direction. The tissue was measured intrasurgically in mm (rounded to ½ mm) with a graduated periodontal probe (XP23/UNC15; Hu-Friedy, Chicago, IL) at implant surgery (baseline) and at abutment connection. If the bone had to be vertically regenerated at several implants in the same area, only the implant with the largest vertical amount of bone to be regenerated was included in the trial. When present, the infrabony component of the defect was not considered in the measurements.

   For each study, implant 2 measurements were made using the top of the implant-abutment junction (AJ) as a fixed reference point (Fig 3; Fig 1b; Fig 2b; Fig 2c):
   - The maximum vertical depth of the marginal bone to be vertically regenerated (DL-AJ), measuring both the vertical and the horizontal component.

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- The minimal vertical depth of the marginal bone to be vertically regenerated (HL-AJ), measuring exclusively the vertical component.
- All measurements were photographed with a periodontal probe in situ to identify the exact points from which intrasurgical measurements were taken. To minimize assessment errors, all measurements were then checked on clinical photographs by a second blind and independent assessor using the known fixed distances between threads and the height of the implant collar as reference points. The 2 measurements (DL-AJ and HL-AJ) were then averaged to provide the mean value of the vertical component of the defect.

3. Any biological complications and adverse effects, such as barrier exposure, requiring an additional operation or additional interventions, such as the administration of systemic antibiotics. Related side effects were recorded. These outcomes were recorded at 1 and 2 weeks and 1, 2, 3, and 4 months after surgery.

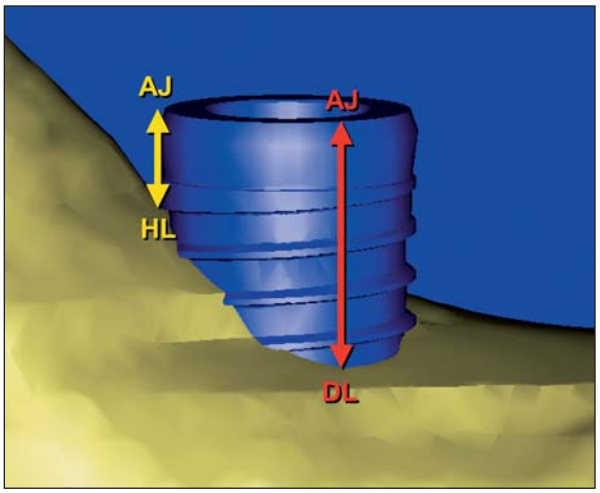

Fig 3 Illustration of the measurement reference points at baseline. HL = minimal vertical depth of the marginal bone to be vertically regenerated (HL-AJ); DL = maximum vertical depth of the marginal bone to be vertically regenerated (DL-AJ); AJ = abutment junction. The same intrasurgical measurements were obtained at implant exposure. The 2 measurements made of each implant were averaged in the calculations.

A clinician experienced in periodontics who was not involved in the treatment of the patients made all assessments; this clinician was unaware of the treatment group. The clinical measurements of the marginal bone level of the study implants were made before the sealed envelope containing the randomization code was opened. In the case of doubt of a measured outcome, a second outcome measurer was contacted, and, in the case of different interpretation, consensus was reached by discussion.

Sample size calculation was based on the number of complications that occurred in another RCT on guided bone regeneration (GBR).[8] To detect a difference between a proportion of complications from 0.27 to 0.80, 21 patients were needed in each group. However, this study was prematurely ended after enrolling 11 patients per group.

A manually generated restricted randomization list was used to create 2 groups with an equal number of patients. Only 1 of the investigators, an investigator who was not involved in the selection and treatment of the patients, was aware of the randomization sequence and had access to the randomization list stored in his password-protected portable computer. The randomized codes were enclosed in sequentially numbered, identical, opaque, sealed envelopes. Envelopes were opened sequentially only after the implants to be included in the trial were inserted and the clinical bone level heights were measured. Therefore, treatment allocation was concealed to the investigator in charge of enrolling and treating the patients included in the trial.

Participants were informed of the nature of the study but not about which procedure they would receive. During the augmentation operation, the patient's eyes were covered. The surgeon obviously could not be blinded, but the outcome assessor was blind to the group allocation and independent of the delivery of the interventions. However, in some cases, when complications occurred, for instance when a soft tissue dehiscence developed over a surgical plate, the outcome assessor could identify the group to which the patient belonged. In addition, the impressions of the surgical plates on the newly formed tissue could be observed in some cases at abutment connection (Fig 1h). Since numerous complications occurred, the blinding of the outcome assessor was not successful in all cases. Also, the statistician was kept blind and performed all analyses without knowing to which group the patients were allocated. The treatment groups were given a code known only by the trial coordinator, who monitored data recording and was not blinded.

Statistical Analysis

All data analysis was carried out according to a preestablished analysis plan. The patient was the statistical unit of the analyses, and the implant in need of the most vertical bone augmentation was used (Figs 1b, 2b, and 2c). A biostatistician with expertise in dentistry analyzed the data without knowing the group codes. Differences in bone levels between baseline and at surgical exposure were compared for

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Table 1 Patient and Intervention Characteristics

	Resorbable (n = 11)	Nonresorbable (n = 11)
Males to females	3 to 8	1 to 10
Mean age in years at the time of implant insertion (range)	44.6 (29–59)	49.9 (36–69)
Smokers	2	2
Intravenous sedation	6	5
GBR in intercalated dentition	4	3
Total number of implants inserted in same surgical session	42	55
Total number of implants subjected to GBR	34	43
Study implants in mandibles	10	11
Study implants with 3.8-mm diameter	7	9
Bone grafts taken from implant site/neighboring area	5	7
Bone graft from mandibular ramus	5	3
Bone graft from chin	0	1
Bone graft from maxillary tuberosity	1	0
Buccal incision	10	10
Crestal incision	1	1
Months from implant placement to exposure (range)	4.6 (1–7)	4.6 (1–6)
Months from exposure to implant loading (range)	2.1 (0–8)	2.0 (1–8)

each group by paired *t* tests, and differences between the groups in bone height were compared using an independent sample *t* test. Differences in the proportion of failures and other complications were compared between the groups using the Fisher exact test. All statistical comparisons were conducted at the .05 level of significance.

RESULTS

Twenty-four patients were considered eligible and were consecutively enrolled in the trial. However, during the surgical procedure, 1 patient did not need any vertical augmentation procedure, while another was subject to a horizontal GBR procedure alone. Therefore 22 patients were fully enrolled and randomized: 11 to the test group and 11 to the control group. All patients were treated according to the allocated intervention. No dropouts or exclusions occurred up to the insertion of the provisional restoration, and the data of all patients were evaluated in the statistical analyses.

Deviations from the operative protocol were as follows. In 1 patient, the second intrasurgical measurements could not be made because a soft tissue graft was placed in the area. Sounding (forced probing until the tip of the probe was stopped by the hard tissues) was performed instead. In another 2 patients, for whom complications occurred, no measurements were made at the anticipated surgical removal of the barriers. Measurements were estimated on the clinical photographs obtained at the intervention. One patient who was allergic to penicillin did not take the prescribed alternative antibiotics. The treated area was swollen at the 1-week follow-up, and finally the patient started to take antibiotics. Implants were prematurely exposed (2 to 10 weeks after implant placement) in 2 patients from each group because of complications. One patient had implants connected to abutments just prior to 4 months postplacement because the provisional prosthesis frequently became loose because the supporting teeth were affected by caries.

Patients were recruited and subjected to vertical bone augmentation from April 2004 to April 2005. The last provisional prosthesis was inserted in December 2005. The follow-up focused on the time between implant placement and insertion of the provisional restoration about 6 months after the augmentation procedure.

The main patient characteristics at baseline are illustrated in Table 1. Patients were in general healthy. Three patients were on medication: 2 in the resorbable group (1 for hypertension and the other for autoimmune hypothyroidism), and 1 in the nonresorbable group for hypertension, depression, and hyperthyroidism. The length of the study implants is presented in Table 2. There were no significant baseline imbalances between the groups. Autogenous bone grafts were always harvested using a bone trap on a dedicated suction device. In 6 patients of the resorbable group and in 8 of the nonresorbable group, local bone had to be supplemented with bone harvested elsewhere in the vicinity of the implant site. For 1 patient in the resorbable group, it was necessary to elevate an additional flap to have access to a sufficient amount of bone for filling the defect (Table 1).

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Table 2 Length of the Study Implants

Implant length	Resorbable (n = 11)	Nonresorbable (n = 11)
8 mm	2	1
9.5 mm	5	4
11 mm	3	4
13 mm	1	1
15 mm	0	1

Table 3 Comparison of Mean Bone Levels (in mm) Around Study Implants Between Baseline and at Surgical Exposure for Each of the 2 Study Groups, and Comparisons Between the Groups

	Resorbable (n = 11) Mean (SD)	Nonresorbable (n = 11) Mean (SD)	*P**
Baseline	2.93 (0.86)	2.73 (0.79)	.57
At surgical exposure	0.77 (1.25)	0.25 (0.62)	.23
Bone level change	2.16 (1.51)	2.48 (1.13)	.58
*P**	< .001	< .001	

*Paired *t* test.

Table 4 Comparison of the Frequency of Complications

	Resorbable (n = 11)	Nonresorbable (n = 11)	*P**
All complications	4	5	> .99
Major complications	2	1	> .99

*Fisher exact test.

No patient dropped out, and all patients were followed through initial loading. No study implant failed up to the placement of the provisional prosthesis. One implant subjected to a vertical GBR procedure in the contralateral side of one patient, failed during healing because of infection.

At baseline the amount of bone needed to be regenerated in vertical height was 2.9 mm in the resorbable group and 2.7 mm in the nonresorbable group (Table 3). Both techniques resulted in a statistically significant vertical bone gain from baseline: 2.2 mm for the resorbable group ($P < .001$) and 2.5 mm for the nonresorbable group ($P < .001$; Table 3). The difference between the 2 groups in the amount of regenerated bone was not statistically significant ($P = .58$; Table 3).

In the group treated with resorbable barriers, complete bone regeneration was obtained for 4 of 11 implants (Figs 1a and 1b). In nonresorbable barrier group, complete regeneration was obtained for 9 of 11 implants. No bone gain or bone loss occurred in 2 patients of the resorbable group, those in which major complications occurred.

Complications were classified as major or minor. Major complications were those that led to the failure of the graft, such as infected dehiscence of soft tissues or abscesses requiring additional surgery and systemic antibiotics. Minor complications were those that did not result in the complete failure of the graft, such as dehiscence of soft tissues requiring no treatment or treatment with chlorhexidine applications and/or systemic antibiotics.

There were no statistically significant differences in the total number of complications or major complications between the 2 groups (Table 4).

In the resorbable group, 4 patients had complications. Two patients had serious complications: 1 patient had 2 abscesses bilaterally both in the augmented sites, and the other patient had an abscess in the augmented site. Both patients were treated with removal of barrier and antibiotics, and the augmentation procedure was a complete failure (18%). The remaining 2 patients had minor complications. One patient had a dehiscence with no suppuration, which was treated with repeated application of chlorhexidine gel. The other patient displayed a swelling in the operated area suggesting an early infection 1 week postoperatively. After reassessment the patient admitted to not having taken the prescribed postoperative antibiotics. Antibiotics were administered 7 days after the augmentation procedure. In both cases the augmentation procedure was considered successful.

In the nonresorbable group, 5 patients had complications. A major complication occurred in a patient who presented with a dehiscence/infection 3 weeks postoperatively. The barrier was removed, and systemic antibiotics were administered. The augmentation procedure was a failure. The following 4 minor complications were observed. A fistula was noticed in 1 patient at abutment connection; it disappeared after cleaning was performed at abutment connection. Another patient had a fistula 2 weeks postoperatively. The complication was successfully treated with another course of systemic antibiotics. Another fistula was observed in another patient 2 months after surgery. The site was treated with removal of the barrier and systemic antibiotics. One patient displayed a lymph node swelling 1 month after surgery. It was treated with systemic antibiotics. In all cases the augmentation procedure was considered successful.

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DISCUSSION

The present investigation was designed to evaluate whether a novel technique for vertical bone regeneration using particulated autogenous bone grafts protected by stable osteosynthesis plates and covered by resorbable barriers could offer some advantage over the use of autogenous bone chips and titanium-reinforced nonresorbable barriers. The technique was based on the clinical impression that more serious infections could develop when using nonresorbable barriers. Some scientific evidence supporting this hypothesis exists. A randomized clinical trial suggested that resorbable barriers over bovine-derived bone graft may allow healing with fewer complications than a nonresorbable barrier.[8] However, the results of the present investigation failed to disclose any statistically significant difference between the 2 techniques. There could be therefore 2 possibilities: either a significant difference does not exist (ie, the 2 techniques actually provide rather similar results, or a difference does exist, but the number of patients included in the present trial was insufficient to show it).

Nine sites in the nonresorbable group versus 4 in the resorbable group achieved 100% vertical augmentation. In addition, the clinical impression was that the bone regenerated under nonresorbable barriers had a more "bony appearance" than that formed under resorbable barriers. A possible explanation for this perceived difference is that the duration of the barrier effect of the resorbable membrane is too short; ie, the barriers are resorbed too fast, not allowing complete bone regeneration in all cases. In contrast, the nonresorbable membranes managed to function as barriers for the entire period. The use of resorbable barriers with a longer degradation time should also be evaluated. In order to solve these issues, this trial shall be continued; additional patients will be included until the planned sample size is fulfilled.

The recruitment of enough patients to fulfill the sample size was not easy, since relatively few patients require vertical bone regeneration. Patients more commonly require horizontal GBR, which can be accomplished using the same techniques. Since the trial center is a reference center for the treatment of more complex implant cases, it was originally planned to include all the referred patients in the trial in order to speed up the enrollment of patients. It was soon realized that it was difficult for the referring centers to carry out the follow-up examinations; they did not have enough experience dealing with biologic complications and with the prosthetic components of the dental implants used. After 6 referred patients had been included, it was decided not to include in the trial patients on a referral basis, unless they could attend all scheduled visits at the treatment center.

Both techniques were able to achieve the planned goal, except in cases where a major complication occurred. In the presence of major complications, the augmentation procedure was a complete failure (2 patients in the resorbable group and 1 patient in the nonresorbable group). Nine of 22 patients had complications (approximately 41%). However, only 3 patients (14%) had serious complications. The remaining complications could be handled and did not compromise the outcome of the intervention. Two of the patients in which major complications occurred were referred.

The majority of complications occurred in the patients who were treated first. It is plausible to explain them with regard to the learning curve of the surgeon. However, the surgeon was trained with this technique and performed more than 100 similar interventions before starting this trial. Therefore, this initial clustering of the complications could be accidental.

The published literature on this topic, which is sparse, also seemed to indicate that problems with nonresorbable barriers are common. For instance, a retrospective trial including 32 patients treated for vertical ridge augmentation with autogenous bone chips and titanium-reinforced barriers showed that vertical augmentation could be considered a failure in terms of regenerated tissues in 4 of 6 patients whose barriers became exposed.[1]

In another recent randomized clinical trial,[2] a group of 11 patients were treated with vertical ridge augmentation using autogenous bone chips and reinforced-titanium barriers. In 3 patients barriers were exposed. In 2 of these patients, the barriers had to be removed some weeks postoperatively, and the amount of regenerated bone was partially compromised. In a recent retrospective controlled study comparing the same techniques in 19 patients, 3 complications occurred—1 major complication in the resorbable group and 2 minor complications in the nonresorbable group.[7]

From the available scientific literature, including the present trial, it can be estimated that 9% to 17% of the interventions[1,2,7] in patients treated for vertical ridge augmentation with autogenous bone chips and nonresorbable titanium-reinforced barriers will not be completely successful. Based on the literature (data from the present trial combined with data from another retrospective study[7]) the use of resorbable barriers supported by osteosynthesis plates results in a complete failure in about 18% of cases. Therefore the predictability of such procedures may be ques-

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tioned. However, in specific situations, for instance in highly visible esthetic areas, the advantages of those techniques might outweigh the risks. It is up to individual clinicians to evaluate patients on a case-by-case basis and to help their patients make informed decisions.

In order to learn from complications such as those in the present study, some speculation is permissible. The first patient who was treated, a healthy young woman, developed bilateral abscesses in both mandibular posterior hemiarches, which were treated with resorbable barriers in the same surgical session. Since the outcome was highly disappointing, the patient history was rescrutinized in greater detail. Not long before GBR, the patient had been subjected to 3 periodontal surgeries (open-flap debridement) by the referring dentist, and in all cases the patient received a course of prophylactic antibiotics (amoxicillin) for about 8 days. The last exposure to antibiotics was about a month before the augmentation intervention. It is suspected that penicillin-resistant bacteria survived in the patient's mouth; this might explain why 2 simultaneous abscesses developed. One of the implants on the side not included in the trial failed, but it was replaced and the patient was successfully restored. However, both GBR procedures resulted in complete failure.

The other case was that of a patient who was allergic to penicillin. At the 7-day postoperative check-up, a swelling suggesting an early infection was observed. After questioning the patient, it was learned that the prescribed postoperative antibiotics had not been taken. Antibiotic therapy was immediately started, and the swelling soon disappeared. At abutment connection, the outcome of the therapy was 100% bone gain.

Despite the use of extensive prophylactic antibiotic coverage, all of the complications that occurred in this investigation appeared to have an infection-related etiology. In a recent Cochrane systematic review[5] evaluating the efficacy of various bone augmentation procedures, it was hypothesized that the collection of autogenous bone grafts with bone traps might be associated with increased infection rates. It is in fact known that considerable amounts of bacteria can be found in the particulated bone collected with bone traps also when dedicated suction devices are used.[10]

In the present investigation, all treated patients were accounted for with no exclusions, and the intrasurgical assessment of bone gain was not done by the operator but by blinded independent assessors using 2 different methods of recording the data. Both assessment systems (the clinical measurements obtained intrasurgically with a periodontal probe and those made on clinical pictures using the known fixed distances of the implants) provided similar results, and both assessors agreed on the final measurement. Therefore, the bone gain data can be considered reliable. It should also be observed that bone overgrowth occurred around many implants, requiring bone removal in order to remove the healing screws and to place the abutments. However, the clinical measurements did not take this into account since the maximum score 1 implant could receive was 0 mm. A score of 0 mm indicated that the bone was at the level of the upper portion of the implant. Conversely, it is not certain that the tissue regenerated was always bone. In some instances (generally after a complication and possibly more commonly under resorbable barriers), it was difficult to discriminate clinically between immature bone and connective tissue. Radiographic evaluation may give a clearer indication of the bone height and the extent of mineralization. Since intraoral radiographs were made at abutment connection and when implants were loaded, it will be possible to monitor marginal bone level changes over time.

The mean time from the abutment connection to the insertion of the provisional prosthesis was quite long. In 6 cases it took more than 3 months for the patients to receive the prosthesis. There were 2 main reasons for this delay: *(1)* the implants that were prematurely exposed because of complications were loaded as originally planned (about 6 months after implant placement), and *(2)* the referring clinicians were not familiar with the implant system used. The components had to be ordered, and the dentists as well as the technicians had to be trained with the new system.

This trial did not intend and was not designed to establish when vertical GBR may be indicated, or to evaluate factors associated with success or failure of the interventions, but rather to evaluate which could be the most effective approach, and in the presence of similar results, to identify the technique providing fewer complications. The investigators were also interested in learning which technique was the simplest to use, and which was the least expensive.

With respect to the generalizability (external validity) of the findings, it should be recognized that both techniques were tested in real clinical conditions and that patient inclusion criteria were broad. Therefore, the results can be easily generalized to a wider population. However, the surgeon was highly experienced with both techniques, and this factor may limit extrapolation of the present results.

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CONCLUSIONS

No statistically significant differences for the amount of regenerated tissue or number of complications were observed between the 2 techniques; however, the number of included patients was too low to detect a difference, if any. To establish what might be the most effective therapeutic approach for vertical ridge augmentation, a greater number of patients needs to be included. With both techniques, complications were common, major complications compromised the outcome of the intervention; therefore, both clinicians and patients should carefully evaluate the pros and cons in relation to the desired outcome before deciding whether to use vertical GBR techniques.

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