Treatment of Peri-implant Defects with Guided Bone Regeneration: A Comparative Clinical Study with Various Membranes and Bone Grafts

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In this clinical study, a bioabsorbable membrane (Biofix) and two augmentation membranes made of expanded polytetrafluoroethylene (Gore-Tex) were tested for their osteopromotive potential. Forty-six implants were augmented with Gore-Tex membranes, 45 implants with titanium-reinforced Gore-Tex membranes, and 38 peri-implant defects with a resorbable polyglycolid membrane (Biofix). Autogenous bone (n = 85) and bovine bone matrix (Bio-Oss, n = 16) were used as filling materials beneath membranes. The results showed that bone repair is significantly improved by the use of membrane techniques. The average rate of bone regeneration with non-resorbable membranes was 84% (GTAM) and 81% (TR-GTAM). The use of Biofix membranes resulted in an average bone gain of 60%. The differences in efficacy established for the three types of membranes were found to be statistically significant ($P < .001$). Barrier membranes represent a valid technique for the treatment of peri-implant defects. Clinical and histologic results showed that Bio-Oss is an osteoconductive scaffold that promotes new bone formation.
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Key words: bone grafts, e-PTFE membranes, guided bone regeneration, polyglycolid membranes

The use of dental implants that are anchored in the jawbone with direct bone-implant contact[1,2] has greatly enhanced the scope of prosthetic-restorative treatment. The success of implants essentially depends on a sufficient volume of healthy bone at the recipient site during implant placement. In a number of experimental and clinical studies,[3–6] membranes were tested for their ability to facilitate the regeneration of bone around implants. Membrane techniques employ the principle of guided tissue regeneration,[7] that is, membranes are used as mechanical barriers to exclude connective tissue and epithelium from the defects. With the use of membranes, osteoprogenitor cells populate the protected space between the membrane and the implant or bone and regenerate peri-implant dehiscences[8] or increase the width of the alveolar crest prior to placement of the implants.[9] Dahlin et al[10] were able to show that the degree of bone formation at fenestration defects in the maxilla is significantly improved when the membrane technique is employed; they concluded that the periosteum alone in adult humans is not capable of generating new bone around exposed implants.

Soft tissue pressure can lead to a collapse of expanded polytetrafluoroethylene (e-PTFE) and resorbable barrier membranes, and consequently to reduced osseous regeneration. The use of augmentation materials beneath membranes for defects in which the membrane tends to touch the implant surface has been shown to improve bone regeneration.[11] Gher et al[12] conducted a clinical study to analyze the efficacy of a bone allograft and Gore-Tex mem-

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Table 1 Treatment Indications and Distribution for Each Group (n = 129)

	Treatment indication*								
Group†	a	b	c	d	e	f	g	h	Total
1 (n = 46)	4	3	2	4	11	3	7	12	46
2 (n = 45)		3	4	5	13	3	2	15	45
3 (n = 38)	1	6	8	3	5	4	1	10	38
Total	5	12	14	12	29	10	10	37	129

*a = edentulous maxilla; b = edentulous mandible; c = gap maxilla; d = gap mandible; e = single tooth maxilla; f = single tooth mandible; g = distal extension maxilla; h = distal extension mandible.
†Group 1 = GTAM; group 2 = TR-GTAM; group 3 = SR-PGA.

branes. They demonstrated that the use of membranes in combination with grafts resulted in complete filling of the bone defect in 15 of 22 patients, whereas the same result was achieved in only 9 of 21 patients when no transplant was employed.

Most implant systems involve a two-stage approach that allows membrane removal at second-stage surgery; therefore, the need for reentry is not considered a disadvantage. However, resorption of a bioabsorbable membrane could result in limited gingival flap reflection, partial-thickness flap elevation, and, consequently, better adaptation of the gingival tissues to the titanium abutments.[13] In a clinical investigation using a new resorbable membrane in combination with bovine augmentation material, Hürzeler et al[14] showed that bone regeneration of the former defect can be expected with high probability. Complete reconstruction of the dehiscences was achieved with 22 of 35 newly placed implants. Lundgren et al[15] reviewed four cases with six implants and concluded that a resorbable matrix barrier (Guidor) can be used for guided bone regeneration. However, in their paper it was strongly emphasized that the barrier requires separate support to prevent its collapse.

Recently, a Gore-Tex augmentation membrane with a titanium net (TR-GTAM) was introduced. This reinforcement stabilizes the position of the membrane after adaptation for the entire duration of the healing period. Jovanovic et al[16] demonstrated increased bone formation with TR-GTAM compared to a standard Gore-Tex membrane (GTAM) in dogs. Simion et al[17] also reported successful vertical augmentation and showed histologically verified osseointegration with titanium-reinforced e-PTFE membranes.

The aim of this study was to investigate the use of different membranes for guided bone regeneration around implants. A resorbable membrane, a standard e-PTFE membrane, and a titanium-reinforced e-PTFE membrane were compared in terms of their capacity to induce new bone formation. Moreover, the clinical and histologic findings of regeneration using bovine bone matrix as a filling material beneath the membrane were evaluated.

Materials and Methods

Eighty-two patients, aged 21 to 70 years and with a mean age of 43.7 years, were included in the study. All patients were in good health, and routine examination demonstrated no systemic or local contraindications to surgical treatment. Prior to the start of the study, each subject received a detailed description of the treatment and the study purpose and signed surgical consent forms. Over the course of this study, a total of 129 Frialit-2 stepped screws (Friatec AG, Mannheim, Germany) were evaluated; of these, 55% were placed in the mandible and 45% in the maxilla. The treated patients required replacements for single teeth and for partially edentulous and completely edentulous arches (Table 1).

Membranes. The augmentative efficiency of three different membranes was evaluated: the standard Gore-Tex membrane (e-PTFE, GTAM, W. L. Gore, Flagstaff, AZ), the titanium-reinforced membrane (e-PTFE, TR-GTAM, W. L. Gore), and the resorbable Biofix membrane (polyglycolid, self-reinforced–PGA, Biocon Ltd, Tampere, Finland). Forty-six implants were placed in conjunction with the Gore-Tex augmentation membrane (GTAM oval 6 or 9), representing group 1. The defects of 42 of these implants were filled with autogenous bone, while the dehiscences of 4 implant sites were augmented with Bio-Oss (Geistlich Söhne AG, Wolhusen, Switzerland). In group 2, a titanium-reinforced membrane (TR-GTAM, TRN2 or TR6Y) was used for a total of 45 implants. For 28 implants, the dehiscences were augmented without any additional material under the membrane, while Bio-Oss was placed in 12 implant sites and autogenous bone was placed into the defect in five patients. In group 3, autogenous bone and a resorbable SR-PGA membrane (Biofix) were used in 38 implant sites.

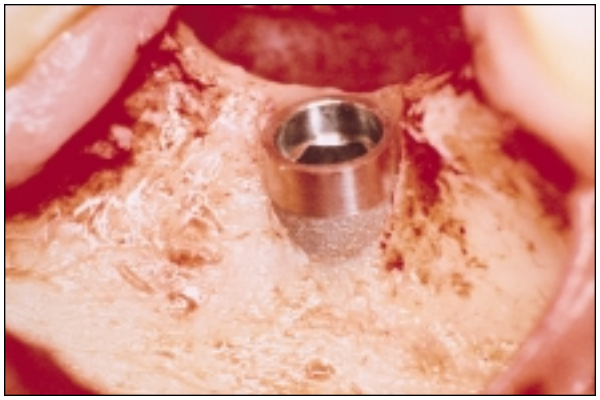


Fig 1a A Frialit-2 implant has been placed. Because of horizontal atrophy, the buccal coronal implant surface is exposed, creating a 4-mm dehiscence-type defect.

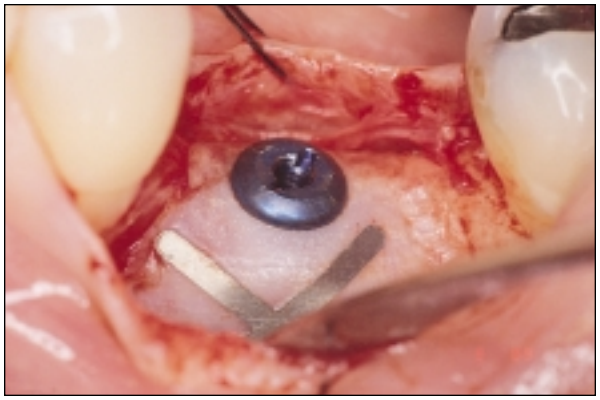


Fig 1b Second-stage surgery after 26 weeks of submerged healing. The membrane is firmly adapted to the underlying tissue.

Surgical Procedure. Surgery was performed under local anesthesia (Ultracain Dental forte, Hoechst AG, Frankfurt am Main, Germany). After implant placement, a calibrated periodontal probe was used to establish the maximum defect dimensions in the apicocoronal direction (Figs 1a and 2a). The probe allows accurate measurements of vertical defect dimensions to 0.5 mm. The membranes were trimmed to shape to ensure complete defect coverage and secured to the buccal bone by Frios titanium pins (Friatec AG) (Fig 2b), thus creating a protected space that could subsequently be filled with the bone graft (Fig 2c).

Autogenous corticocancellous grafts were obtained from sites within the surgical area by means of a trephine bur. In 16 patients, natural cancellous bovine bone mineral (Bio-Oss) was employed. Primary wound closure was achieved with interrupted suture after horizontal incision of the periosteum to release the flap, if necessary. Orthopantomograms were taken after surgery, and patients were given instructions for proper oral hygiene. A 0.1% chlorhexidine solution (Chlorhexamed, Blendax, Mainz, Germany) and an antibiotic (Augmentin 625 mg, three times a day, SmithKline Beecham Pharma, Vienna, Austria) were prescribed for 8 days postoperative; a nonsteroidal anti-inflammatory drug (Diclomelan 50 mg, three times a day, Lannacher Heilmittelwerke, Lannach, Austria) was also prescribed.

Wound healing was carefully monitored throughout the healing period, and patients were recalled for examination every 3 weeks. If patients with nonresorbable membranes showed signs of soft tissue dehiscence, the exposed portions of the membrane were cleaned with a 0.1% chlorhexidine solution, and a second operation was carried out within 2 weeks to remove the membrane. In the patients fitted with Biofix membranes, dehiscence did not require the removal of the membrane, since none of the patients showed signs of infections along the wound margins.

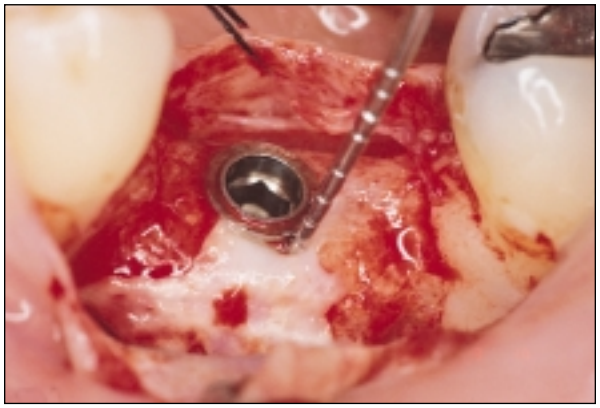


Fig 1c Six-month reentry demonstrating complete fill of the dehiscence defect. A layer of fibrous tissue covers the newly formed hard tissue.

Reentry Procedure. After an average healing period of 24 weeks, radiographs were again taken, and reentry was performed under local anesthesia. Incisions of the ridge mucosa and relieving vestibular incisions were made to raise the mucoperiosteal flap (Figs 1b and 2d). The same reentry procedure was used in the patients treated with bioabsorbable membranes, where the flap was raised to permit removal of the titanium pins and to evaluate the results. The defect dimensions were again measured using a periodontal probe. The extent of fibrous regeneration was excluded from the measured size of new bone formation (Figs 1c and 2e). Finally, a gingiva former was connected, Periotest values (Siemens AG, Bensheim, Germany) were obtained, and the wound was

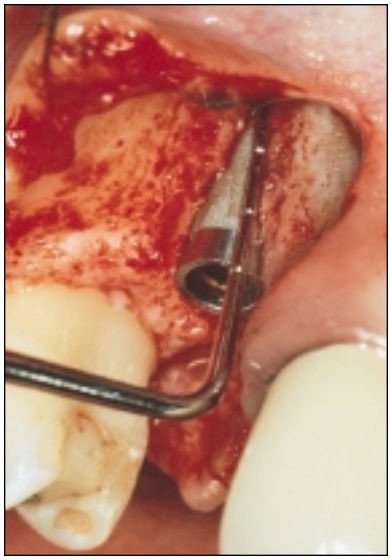


Fig 2a Eight weeks after extraction of the maxillary right canine, a Frialit-2 implant has been placed. The height of the buccal baseline defect is 9 mm.

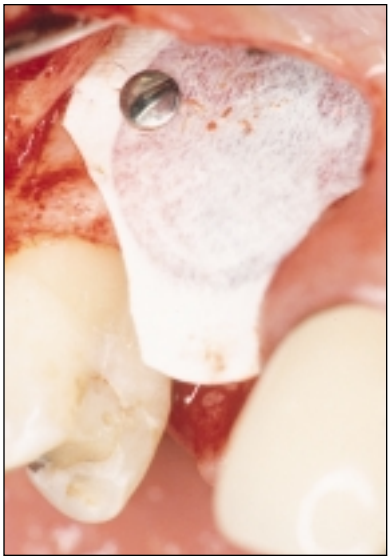


Fig 2b A standard GTAM has been trimmed to shape and buccally fixed with a Frios titanium tag.

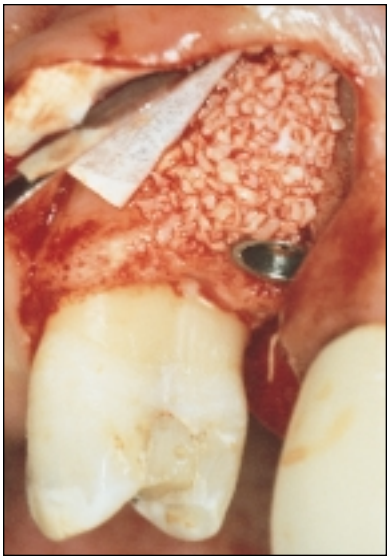


Fig 2c The dehiscence defect has been filled with Bio-Oss granules.

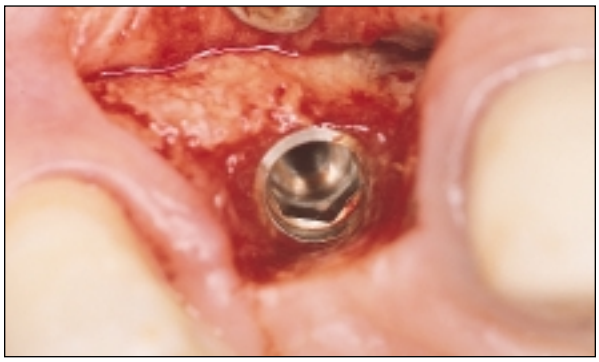
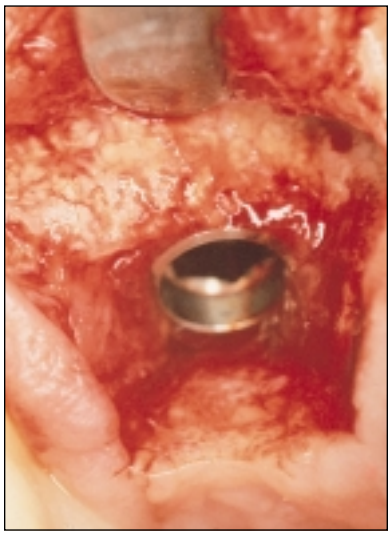


Fig 2d After a healing period of 27 weeks, regenerated hard tissue was present beneath the membrane.

Fig 2e The magnification shows a completely regenerated buccal alveolar plate. On clinical examination, the newly formed hard tissue appears to be bone.



closed with interrupted sutures. The conditioning period of the soft tissue around the implants was extended to 8 to 12 weeks so as to permit a maximum degree of differentiation of the newly formed bone into lamellar bone before the implant was finally subjected to functional loading.

Histology. In four patients treated with GTAM and Bio-Oss, a biopsy specimen was obtained from the fringe zone of the grafted area by means of a trephine bur. The material was fixed in 10% formalin, decalcified with rapid bone decalcifier (RDO) (eurobio laboratoires, Les Ulis Cedex B, France), and embedded in paraffin. Sections of 4 to 7 µm were cut and stained with hematoxylin-eosin.

Statistical Evaluation. The Kolmogorov-Smirnov distribution test was used to evaluate the normal distribution of the three parameters: *(1)* baseline defect, *(2)* second-stage defect, and *(3)* defect reduction. Since no normal distribution of the percentage bone gain (D in %) was found, the Kruskal-Wallis test was used to determine significant differences of regeneration between the three groups. Values of $P < .05$ were judged as significant. Pairwise comparisons with the Mann-Whitney *U* test, with an

adjusted α, were used to localize the statistical differences within the three groups. Pairwise comparisons of the results in relation to submerged healing versus premature membrane exposure were evaluated with the Mann-Whitney *U* test (Wilcoxon test).

Results

All implants achieved osseointegration, which was assessed by means of radiographic examination and Periotest measurements. The majority of defects were buccal dehiscences (n = 100) as a consequence of physiologic alveolar atrophy in longstanding edentulous parts of the jaws or because of former large endodontic lesions. A buccal fenestration of newly placed implants was found in 8 patients, all of them located in the maxilla as a consequence of the alveolar bone atrophy pattern. With the placement of 17 implants, mesial (n = 2) and distal (n = 3) defects or buccal defects with additional vertical bone reduction (n = 12) were found. These lesions are typical for delayed immediate implantation 6 to 8 weeks after tooth extraction. In 4 patients, vertical defects of atrophic mandibles were augmented with a total bone height of less than 10 mm (Table 2). Defect height at first-stage surgery (M_1) ranged from 2 to 10 mm, with a mean value of 4.4 mm. Altogether, Bio-Oss was used in 16 patients, autogenous bone in 85 patients, and in 28 patients, TR-GTAM was used with no additional augmentation material.

Clinical Assessments. The vertical height of the defects around the newly placed implants was 4.5 mm (± 2.0) in group 1 (GTAM), 4.6 mm (± 1.6) in group 2 (TR-GTAM), and 3.9 mm (± 1.5) in group 3 (SR-PGA). The second measurement was performed during reentry after a mean healing period of 24 weeks. The dehiscences around the implants were reduced to a mean remaining defect height of 0.9 mm (± 1.6) in group 1, 0.9 mm (± 1.1) in group 2, and 1.7 mm (± 1.3) in group 3. Correspondingly, this represented a defect reduction of 3.6 mm (± 1.9) or 84% in group 1, 3.7 mm (± 1.6) or 81% in group 2, and 2.2 mm (± 1.3) or 60% in group 3. Mean bone gain for all 129 implants was 3.2 mm (M_1 = 4.4, M_2 = 1.1) or 76% (Table 3). Results of the Kruskal-Wallis test revealed a significant difference in bone gain between the three groups ($P < .001$, Table 3). Pairwise comparisons with the Mann-Whitney *U* test with an adjusted α showed a statistical difference between groups 1 and 3 ($P < .001$) and between groups 2 and 3 ($P < .001$), whereas no difference between groups 1 and 2 was found.

Membrane exposure was found in 22% (n = 10) of the implants in group 1, in 47% (n = 21) of those in group 2, and in 50% (n = 19) of those in group 3

Table 2 Distribution of Defect Types (n = 129)

Type of defect	Number	%
Dehiscence mesial	2	2
Dehiscence distal	3	2
Dehiscence buccal	100	78
Fenestration	8	6
Dehiscence combined	12	9
Vertical defect	4	3

Table 3 Vertical Defect Height at Implant Placement and at Reentry Procedure (mm ± SD)

	Defect height†			
Group	M_1	M_2	Difference	Percentage
1 (n = 46)	4.5 ± 2.0	0.9 ± 1.6	3.6 ± 1.9	84*
2 (n = 45)	4.6 ± 1.6	0.9 ± 1.1	3.7 ± 1.6	81*
3 (n = 38)	3.9 ± 1.5	1.7 ± 1.3	2.2 ± 1.3	60*
Total	4.4 ± 1.7	1.1 ± 1.4	3.2 ± 1.7	76

*Kruskal-Wallis test: $P < .001$.
†M_1 = placement; M_2=second-stage reentry.

Table 4 Numbers and Percentages of Soft Tissue Dehiscences During the Healing Phase

Group	Membrane exposure (%)	Submerged healing (%)	Total
1	10 (22)	36 (78)	46
2	21 (47)	24 (53)	45
3	19 (50)	19 (50)	38

Table 5 Osseous Regeneration as Related to Submerged Healing (mm ± SD)

	Defect height			
Group	M_1	M_2	Difference	Difference (%)
1 (n = 36)	4.5 ± 1.9	0.4 ± 0.8	4.1 ± 1.9	92*
2 (n = 24)	4.5 ± 1.7	0.5 ± 0.9	4.0 ± 1.1	91*
3 (n = 19)	3.8 ± 1.7	1.1 ± 1.0	2.7 ± 1.2	75*

*Kruskal-Wallis test: $P < .009$.

Table 6 Osseus Regeneration as Related to Membrane Exposure (mm ± SD)

	Defect height			
Group	M_1	M_2	Difference	Difference (%)
1 (n = 10)	4.7 ± 2.1	2.6 ± 2.5	2.1 ± 1.2	54*
2 (n = 21)	4.6 ± 1.4	1.3 ± 1.2	3.3 ± 1.9	69*
3 (n = 19)	4.0 ± 1.5	2.3 ± 1.3	1.7 ± 1.1	45*

*Kruskal-Wallis test: $P < .033$.

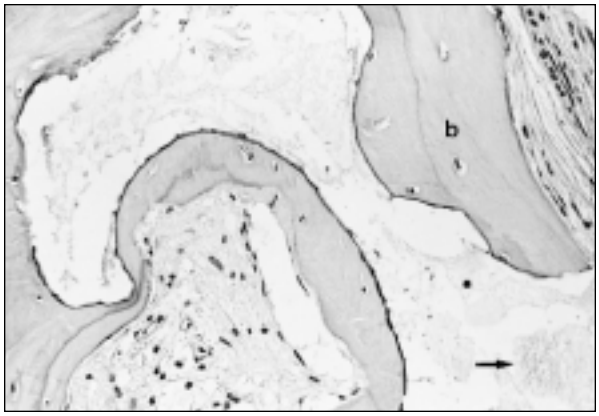


Fig 3 Bio-Oss particles surrounded by lamellar bone 24 months after augmentation. The implanted material shows two different conditions: granular powder *(arrow)* and, in hematoxylin-eosin staining, achromatic amorphous mass *(asterisk)*. The surrounding, slightly irregular lamellar bone (b) seems to use the xenograft particles as a scaffold (original magnification × 250).

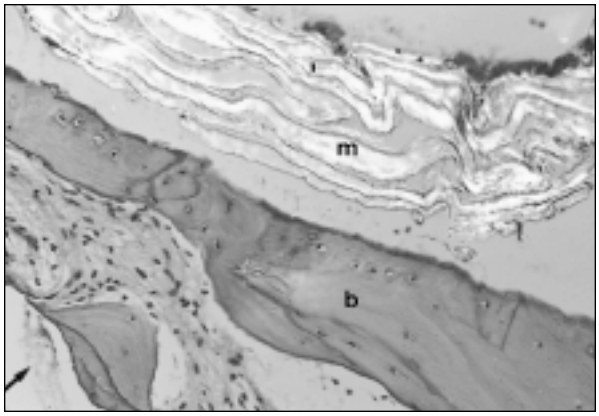


Fig 4 The e-PTFE membrane (m) shows clear birefringence as well as lamellar bone (b) with cement lines and numerous osteocytes and granular powder (*arrow* = Bio-Oss). The retraction phenomena are to be regarded as artefacts in the course of decalcification and of the remaining procedure (hematoxylin-eosin stain; × 250).

(Table 4). Undisturbed healing, with complete soft tissue coverage during the entire period between first- and second-stage surgery, led to a reduction of the defect height of 4.1 mm (± 1.9) or 92% in group 1, 4.0 mm (± 1.1) or 91% in group 2, and 2.7 mm (± 1.2) or 75% in group 3 (Table 5). Membrane exposure resulted in reduced bone formation. Defect reduction of 2.1 mm (± 1.2) or 54% was found in group 1, 3.3 mm (± 1.9) or 69% in group 2, and 1.7 mm (± 1.1) or 45% in group 3 (Table 6). The statistical comparison with the Mann-Whitney *U* test (Wilcoxon test) showed a significant difference between defect reduction in relation to undisturbed healing versus premature membrane exposure in all three groups (group 1: $P = .017$; group 2: $P = .005$; group 3: $P = .001$).

Histologic Findings. The newly formed bone directly adjacent to the Bio-Oss particles appeared to be lamellar bone and its structure was somewhat irregular. Signs of transformation in the regions of lamellar bone were sparse. Only occasional giant cells could be discerned, and mononuclear cells could be seen either at the smooth bone surface or within resorption pits (mononuclear osteoclasts). The implanted material (Bio-Oss) was evident in two manifestations: in the form of aggregates of granules and, with hematoxylin-eosin stain, in an achromatic and amorphous (negative polarization) structure that filled the hollow spaces of the bone. In all investigated specimens, no objective indication of florid degradation of the granular powder could be found. Rather, in all specimens, the supposition that this granule acts as scaffold for the structuring was confirmed (Figs 3 and 4).

Discussion

In the present clinical study, various barrier membranes, all of which promote bone regeneration around exposed implants, were compared. Schenk et al[18] recently published the healing pattern of regeneration in an experimental study in the canine mandible. They concluded that membrane coverage created a suitable environment for bone regeneration. However, the histomorphometric analysis in their study showed that reinforced e-PTFE membranes (prototypes) maintained a larger space than standard membranes. Buser and Schenk[19] reported four preventive measures to avoid membrane collapse: mini screws or tags, filling materials, titanium mesh, or combinations.

A bone graft was applied in all of the patients in the current study, with the exception of 28 implants in group 2, in which sufficient stability of the membrane during the entire healing time was assumed. Autogenous bone in the form of corticocancellous chips, taken intraorally from the surgery site, was used predominantly (n = 85). Harvesting of small amounts of bone is a safe and simple procedure, and the use of autogenous bone for grafting small periimplant defects is highly predictable. Autogenous bone may retain cell vitality and is generally available adjacent to the implant site.[20]

Cortical or cancellous decalcified freeze-dried bone allograft[12,21] and bovine deproteinized bone matrix (Bio-Oss) present further possibilities for implant use as a filling material under the membrane. A clinical study by Hürzeler et al[14] showed

that Bio-Oss can be used around dental implants as a bone substitute for guided bone regeneration. The biopsy specimen supported the clinical view that the newly formed hard tissue was actually bone. In a histologic study in dogs,[22] the osteoconductive potential of different grafting materials in the sinus area was evaluated. The placement of implants in the sinus cavity simultaneously with Bio-Oss resulted in lamellar bone formation and bone apposition onto the implant surfaces. The authors concluded that natural cancellous bovine bone mineral was osteoconductive and hence suitable for bone formation around implants.

In the present study, 16 implants were treated with Bio-Oss and Gore-Tex membranes. From four patients, a biopsy of the regenerated tissue was taken after the augmentation had been successfully effected in the clinic. Histologic results showed that Bio-Oss acts as a scaffold for new bone formation. The Bio-Oss particles appeared in two different phases: as a birefringent granular powder and—in hematoxylin-eosin stain—as an achromatic, amorphous structure. It is not clear whether these two different appearances represent signs of degradation. In concurrence with the results of other studies,[22,23] the xenograft was found to be present in the graft specimen regardless of the observation time.

In the aforementioned study, Hürzeler et al[14] illustrated that a resorbable collagen membrane (Bio Gide) with Bio-Oss caused predictable bone gain around exposed threads. After 24 to 48 weeks, the mean bone gain amounted to 92%. Results of a recently published clinical study[13] showed some bone regeneration in specimens treated with resorbable poly(lactic acid) poly(glycolic acid) (PLA/PGA) membranes, but the amount of newly formed bone was less than that seen in specimens treated with e-PTFE membranes. The stiffness of the resorbable material used in the study was not sufficient to guarantee maintenance of an adequate space.

The overall results of the present study showed that bone gain with nonresorbable e-PTFE membranes was in accordance with results of other clinical studies reporting a bone fill between 74.5% and 89.6%.[8,10] Defect reduction with the resorbable SR-PGA membrane was markedly less compared to GTAM-augmented sites (60% versus 81% and 84%, Table 3). In 50% of the patients, soft tissue dehiscences resulted in exposure of polyglycolid membranes. However, surgical treatment was not necessary since an infection did not occur in any of the patients. The absence of postoperative infections could be explained by the development of infection-inhibiting mediators in the course of catabolism of polyglycolid.[24] In the case of soft tissue dehiscence, the SR-PGA membrane progressively resorbed, with consequent spontaneous healing of the soft tissues within 3 to 6 weeks. The absence of soft tissue coverage caused a significant deterioration of the results for resorbable membranes (45% versus 75% bone repair; $P = .001$). To what extent the thickness of the polyglycolid membrane (0.15 mm) and the resorption process itself were factors contributing to the poor rate of membrane coverage during healing are questions that currently defy answers.

In both Gore-Tex groups, the portion of soft tissue dehiscence amounted to 22% (GTAM) and 47% (TR-GTAM). Simion et al[25] showed that complete invasion of the membrane and colonization of its internal surface was observed after 4 weeks of exposure. Topical application of 0.2% chlorhexidine gel was an effective method of reducing plaque and calculus formation. The study, however, failed to demonstrate the capacity of chlorhexidine to prevent bacterial penetration through the inner portion of the membrane. Results of several studies[8,12,21,26,27] illustrate that early exposure of the membrane during the healing phase does impede the effectiveness of guided bone regeneration. The present results indicate that soft tissue dehiscence always had a negative effect on the formation of bone. While the groups with submerged healing showed bone regeneration of 92% with GTAM and 91% with TR-GTAM, the results were significantly reduced in the case of exposure (group 1: 54%, $P = .017$; group 2: 69%, $P = .005$). In light of these results and of other clinical experiences over the course of a 3-year application period, every effort has been made to detect soft tissue dehiscence as early as possible. This is effected by regular examinations (2- to 4-week intervals). The whole membrane has been removed within 1 to 3 weeks. The use of titanium-reinforced membranes, which can maintain space without filling material,[17,28] has retrospectively proved to be effective. Its ease of adaptation and fixation, in particular, are significant advantages. Moreover, clinical experiences confirm that titanium reinforcement guarantees the maintenance of space during the entire healing period.

Although guided bone regeneration has become a predictable surgical technique, some important questions still remain. The most suitable type of graft and the impact of membrane resorption on osteogenesis, the required healing period of an implant in membrane-protected bone regeneration and, above all, the reaction of newly formed bone to functional loading need further investigation if the efficacy of implants as support for restorations is to be reliably predicted.

Conclusion

The results of this study suggest that, given appropriate maintenance by the patient, predictable reconstruction of osseous defects can be implemented with the membrane technique. The use of resorbable polyglycolid membranes results in a significant bone gain, although, statistically, it is to a smaller extent than with the use of nonresorbable e-PTFE membranes. In this patient population, Bio-Oss has proved clinically and histologically to be a suitable osteoconductive scaffold for guided bone regeneration.

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