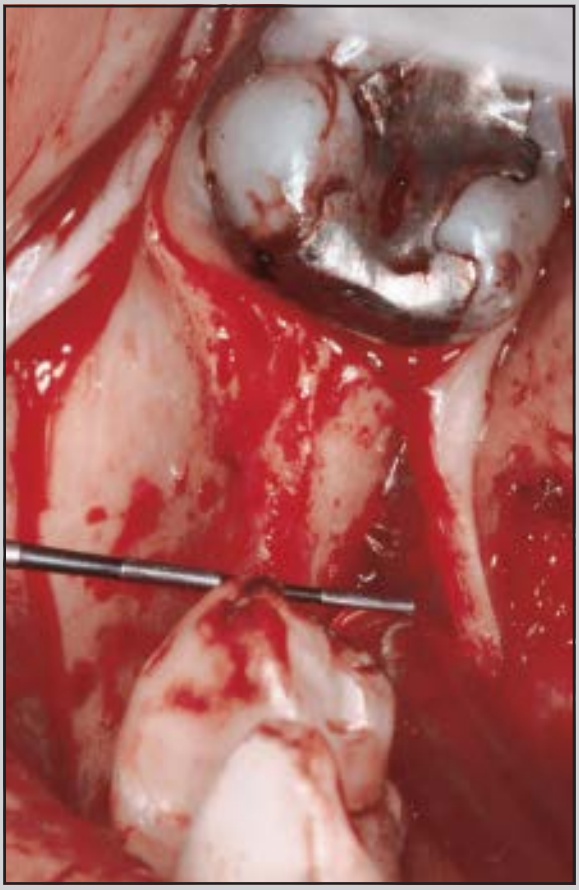

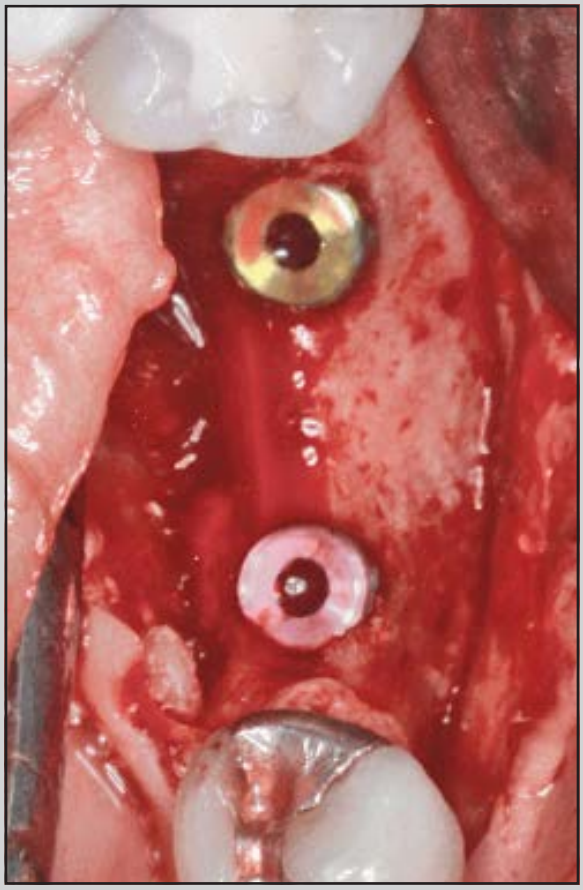

Horizontal Ridge Augmentation with a Novel Resorbable Collagen Membrane: A Retrospective Analysis of 36 Consecutive Patients

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The aim of this investigation was to evaluate a new resorbable, monolayer, noncross-linked collagen barrier membrane for immobilizing bone augmentation material during horizontal guided bone regeneration (GBR) procedures. GBR was performed on 36 consecutive patients in 49 sites, with 103 implants placed either simultaneously or after a healing period. Healing time, suture retention, postoperative complications, and functional outcome after GBR, implant placement, and prosthesis loading were assessed. A wound dehiscence rate of only 12% and a graft failure rate of 4% occurred. Mean healing time was 5.8 months for simultaneous placement and 7.9 + 4.8 months for two-stage procedures. The implant survival rate was 100% after a mean follow-up of 18.3 months from implantation. These early data demonstrate a low dehiscence rate and excellent potential of this new noncross-linked collagen membrane for use with horizontal ridge augmentation.
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Bone augmentation techniques using guided bone regeneration (GBR) before and during implant insertion have been shown to deliver reproducible and excellent success rates.[1–3] However, there are some limitations to GBR in cases demanding extensive bone augmentation, such as vertical alveolar ridge augmentation or treatment of atrophied knife-edged ridges. In such situations, the use of autogenous bone blocks (ABB) has been the preferred procedure.[4] Although the osteoconductive and osteogenic properties of these grafts support their use, resorption rates of over 50% are not unusual.[5,6] Furthermore, harvesting such extensive grafts is highly invasive and the additionally needed surgery in the donor site region can result in considerable postoperative complications.[7,8] The disadvantages of using autogenous bone block grafts have been the impetus for developing novel GBR approaches for bone augmentation.[3,9,10] GBR procedures for large horizontal or even supracrestal augmentations were initially performed with nonresorbable membranes like the titanium-reinforced polytetrafluoroethylene (PTFE) membranes, and have been comprehensively studied.[3,10] In the absence of membrane exposure during the healing phase, very good results have been described.[11–13] However, removal

of a nonresorbable membrane requires a second, rather extensive, surgical reopening.[14,15] Therefore, alternative techniques and materials to avoid use of these nonresorbable membranes are being developed. Nonchemically cross-linked bioresorbable membranes provide good tissue and cell compatibility and lower dehiscence rates compared with PTFE membranes.[2,14,16] Secure mechanical immobilization of the graft particulate under the spanned membrane is one of the keys to successful bone regeneration.[17] Hämmerle et al[18] used a special GBR technique to treat critical size defects such as the so-called knife-edge-ridge where a resorbable collagen barrier membrane is fixed and spanned with the aid of resorbable polylactid acid pins over a graft of anorganic bovine bone mineral (ABBM). This combination of a collagen membrane, graft material, and pin fixation led to a sufficient maintaining space under the membrane with an immobilized graft and resulted in a mean horizontal bone gain of 3.6 mm ± 1.5 mm (standard deviation [SD]). Urban et al[19] demonstrated a horizontal bone regeneration gain of more than 5 mm (5.56 mm ± 1.45 mm) with a resorbable membrane, the use of autogenous bone chips (ABC) with or without particulate ABBM as graft material, and titanium pins for the fixation. This promising technique for horizontal ridge augmentation requires a mechanically stable resorbable membrane with high tensile strength under moist conditions, which will be fixed and spanned by titanium pins to maintain graft stability. One suitable membrane for GBR seems to be the new bioresorbable, monolayer, non-cross-linked, collagen membrane Remaix (RX) (Matricel), distributed as creos xenoprotect (CXP) (Nobel Biocare) since May 2013. First study results (in vitro, in vivo, and mechanical testing) were very promising.[20] This membrane offered the highest degree of stability in mechanical strength testing among similar products tested.[21] The present retrospective study was conducted to further evaluate the performance of this new membrane in a series of clinical cases that underwent horizontal bone augmentation.

Materials and methods

The records of 36 consecutive patients who received the new membrane for alveolar ridge augmentation were analyzed. The applied surgical technique involved horizontal bone augmentations according to the GBR technique detailed below.

All surgical procedures were performed in a private clinical practice in Aachen, Germany, in a hospital-standard, sterile operating room between October 2010 and December 2012. This retrospective analysis is based on existing data collected from every patient who underwent such a surgical procedure in the practice. All patients consented to have their data used in this analysis. The inclusion criterion was an absolute requirement for bone augmentation prior to implant therapy (ie, patients with the ridge thickness of less than 6 mm) (Figs 1 and 2). A two-stage procedure with a healing phase between bone augmentation and implant placement and a procedure with simultaneous augmentation/implantation were allowed. Simultaneous procedure was applied in cases where it was possible to place an implant with a minimal primary stability of 20 Ncm and the defect was not too large. Defects such as a one-wall defect or a bone dehiscence over the implant surface larger than 6 mm in vertical dimension or 3 mm in horizontal dimension were treated in a two-stage procedure. The goal in all cases was to obtain a sufficient alveolar ridge with at least 6 mm for implant insertion of implants with diameters of at least 3.5 mm and 4.3 mm.

Preoperative treatment consisted of 1 day oral amoxicillin (500 mg tid) or clindamycin (600 mg bid) in case of amoxicillin allergy, 1 day bromelain (500 FIP units, bid; Ursapharm Arzneimittel) and a 1-minute mouthrinse with a 0.12% chlorhexidine digluconate preparation (Paroex Gum; Sunstar Suisse) immediately prior to the procedure. All operations were carried out under local anesthesia, using articaine containing epinephrine (1:100.000, Ultracain D-S Forte, Sanofi-Aventis). Postoperative treatment included pain management with ibuprofen (400 mg PRN, maximum 1,200 mg/day) or paracetamol (acetaminophen; 500 mg PRN, maximum 2,000 mg/day), 1 week of antibiotic regimen with oral amoxicillin (500 mg tid) or clindamycin (600 mg bid) in case of amoxicillin

allergy, 1 week of tid mouthrinse with a 0.12% chlorhexidine digluconate preparation, and up to 3 days of bromelain 500 FIP units, bid, to mitigate swelling. All surgical procedures were conducted in healed sites at least 3 months after tooth extraction.

Surgical access was performed by a crestal incision to the keratinized gingiva with formation of a mucoperiostal flap. In the esthetic region, vertical releasing incisions were avoided where possible; if necessary, care was taken to locate incisions at a minimal distance of one tooth away from the augmented region. Decortication was performed using a 1-mm-diameter hard metal round bur (Busch). The augmentation material consisted of ABBM (Bio-Oss, Geistlich) alone or in a 1:1 mixture by volume with ABC harvested either from the surrounding region or from a distant donor site such as the retromolar region (Fig 3). Bone chips were harvested using the Safescraper Twist (Imtegra). All patients were offered the ABBM and bone chips mixture; those who refused autogenous material received ABBM alone. All augmentations were carried out with a resorbable collagen membrane (RX/CXP). The membrane was hydrated with sterile saline solution and then fixed over the graft using titanium pins (Ti-System; Riemser Pharma) inserted mesiodistally and buccolingually into the cortical bone (Fig 4). In some cases, it was possible to stabilize the supracrestal space under the membrane with a higher inserted implant or a longer titanium pin.[10] To ensure tension-free wound closure, one or more periostal releasing incisions were made, as necessary. Sutures were placed with ePTFE sutures (Gore-Tex CV5, W.L. Gore & Associates)

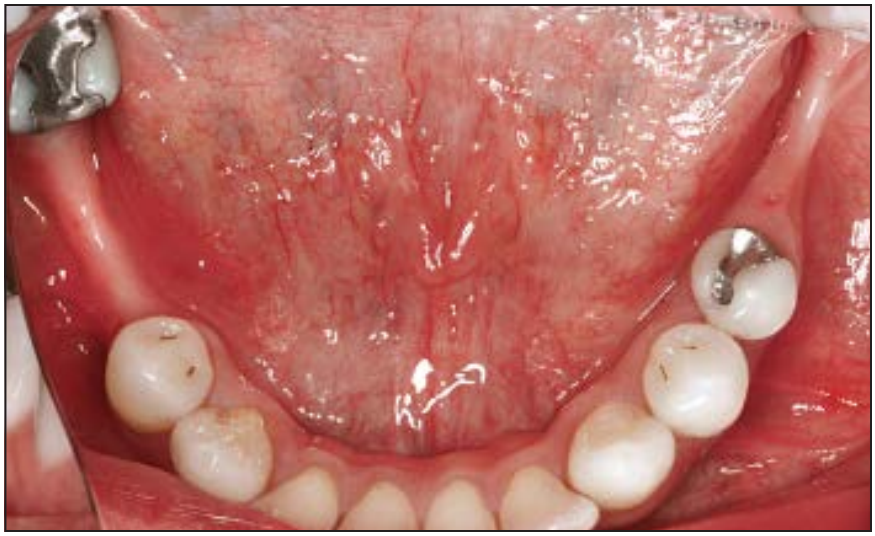


Fig 1 *Resorbed ridge in regions 36, 37 and 45, 46.*

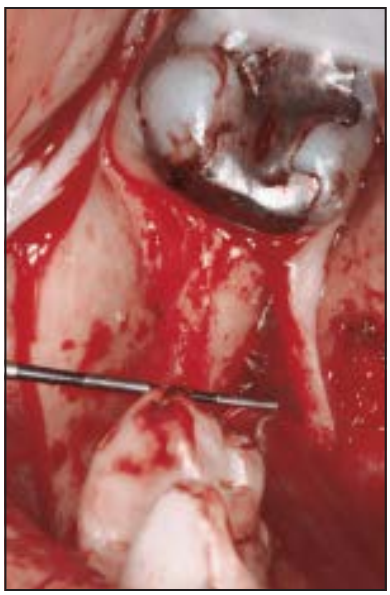
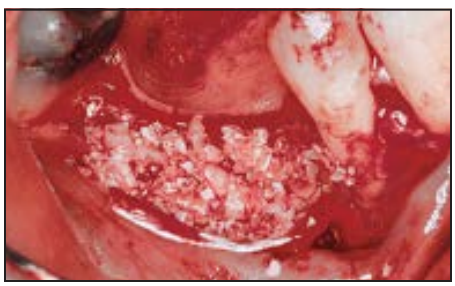


Fig 2 (left) *Occlusal situation of the area 45, 46 shows a 1.5- to 2-mm-wide crest.*

Fig 3 (below) *Positioning of the composite graft consisting of about 50% ABBM and 50% autogenous bone chips from the adjacent area by extending the mucoperiostal flap to the retromolar area in region 38.*



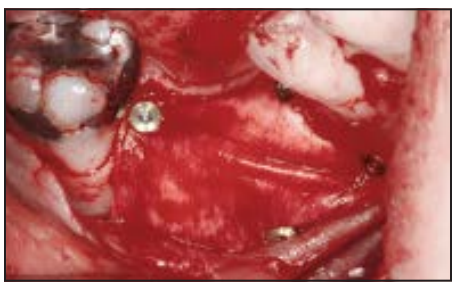


Fig 4 (right) *The tensed membrane fixed with five titanium pins over the graft.*

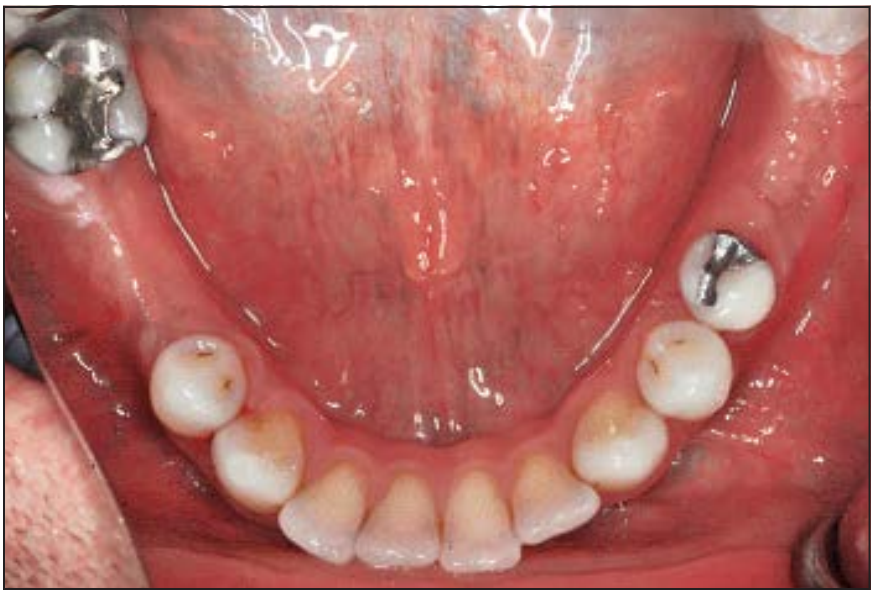
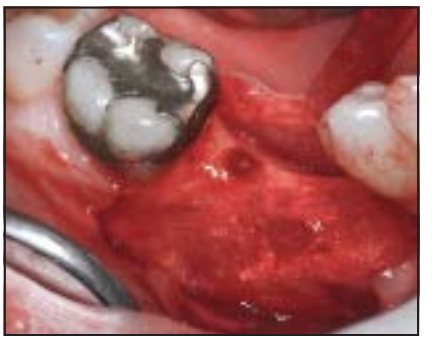


Fig 5 (left) *Occlusal view of the augmented ridges after healing.*

Fig 6 (below) *Ridge in region 45, 46 is more than 6 mm wide after augmentation procedure.*



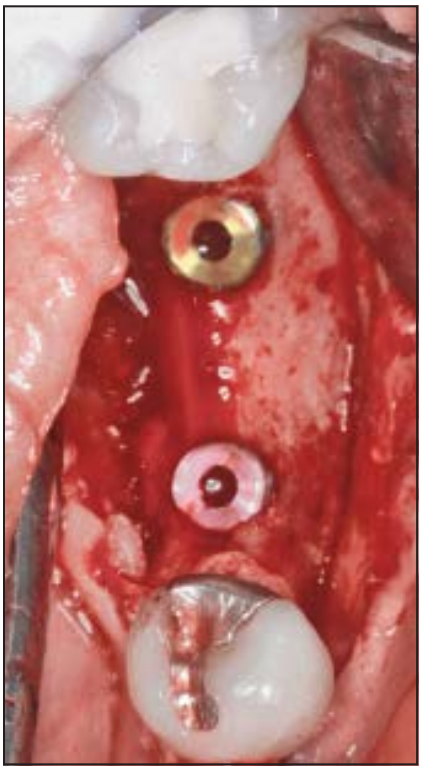
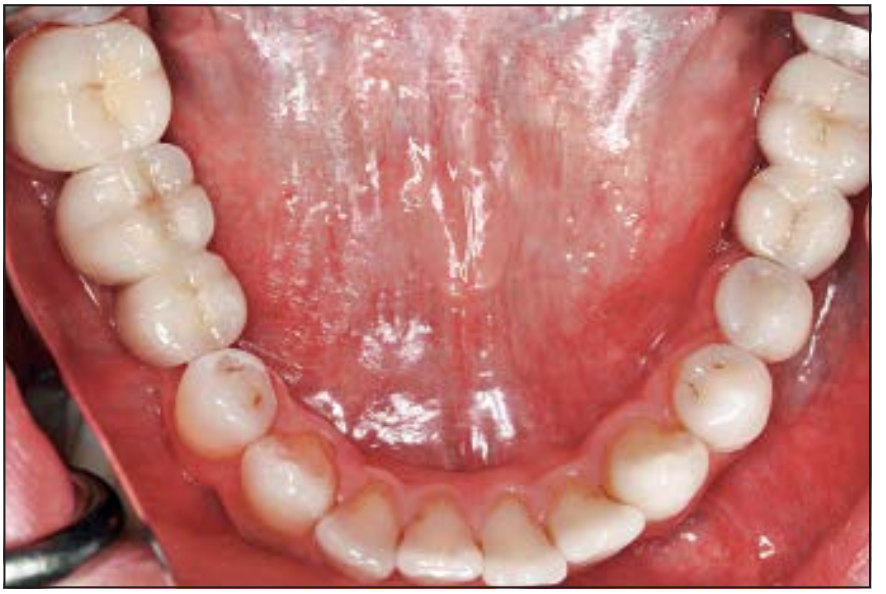


Fig 7 (left) *Clinical view post–implant insertion. Ridge in region 36, 37 is more than 6 mm wide after augmentation procedure.*

Fig 8 (below) *Occlusal view of porcelain-fused-to-metal crowns on 36, 37 and 45, 46.*



using mattress and interrupted sutures, and removed approximately 7 to 10 days later. Healing time for bone regeneration was planned for at least 6 months with or without simultaneous implantation (Figs 5 to 9). Postoperative follow-up assessments according to clinic routines consisted of an initial perioperative evaluation 1 day after surgery, assessment and suture removal 7 to 10 days postoperative, and return visits 6 weeks, 3 months, and 6 months after suture removal. All patients were asked to fill out a

questionnaire during their follow-up visits to record all relevant information on wound healing. Based on these questionnaires, swelling was observed in 17 patients (47%) and resolved no later than 3 days postoperative in all cases. All patients received oral and written instructions on how to monitor for problems with wound healing (dehiscences) and were requested to call the practice for an appointment if they observed any such problems. In these cases the patients were asked to visit the practice every second day for control and wound disinfection until the exposure was closed. Assessment parameters included dehiscence during healing, healing time (months) of the augmentation and/or implants, and implant loss and graft failure rates. Bone augmentation failure was defined as poor esthetic result as per patient satisfaction recorded in a questionnaire, functional failure as per Misch et al's criteria,[22] or no possibility of implantation after previous augmentation. Ongoing follow-up postprosthetic loading consisted of examination and routine prophylaxis with one to four visits per year depending on the periodontal health status of the patient. The implant success rate was evaluated according to the PISA Consensus Conference from 2008.[22] Statistical analyses were performed using Microsoft Excel 2010, and data are presented as mean ± SD. Comparisons between subgroups were performed using Student *t* test, and *P* values < .05 were considered indicative of statistically significant differences.

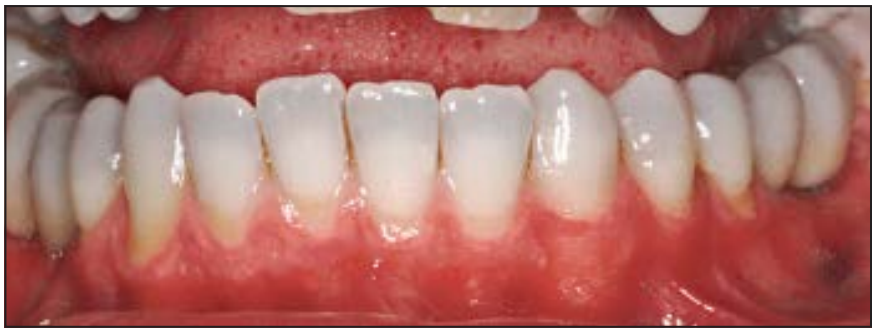


Fig 9 *Anterior view of the prosthetic device.*

Results

A total of 36 consecutive patients underwent horizontal bone augmentation of the alveolar ridge in 49 sites. Based on the Seibert classification criteria, 40 sites had a Class I defect (horizontal or buccal tissue loss with normal ridge height), and the remaining 9 sites had a Class III defect (combined horizontal and vertical bone loss).[23] The 36 patients included 20 males (56%) and 16 females (44%). Patient average age was 57.7 ± 12.0 years (range: 32 to 76 years), which was very close to the median age of 57 years. Only one patient (3%) was diabetic (a 70-year-old man). However, this patient suffered no episodes of dehiscence, graft failure, or other complications, and his diabetes status did not appear to impair single-stage graft/implant surgery healing time (4.7 months), which was below average. Five patients (14%) were smokers, and 21 patients (58%) had a history of periodontitis treatment. Seven patients (19%) received the GBR procedure prior to implantation, whereas the remaining 29 patients (81%) received the GBR procedure during the implantation process. Bone augmentation using ABBM alone was performed in 57% of patients, while 43% were treated with a mixture of ABBM and autogenous bone chips. In total, the patients received 103 implants: 62 NobelReplace Straight (Nobel Biocare), 35 ICX-Templant (Medentis Medical), 4 NobelActive, and 2 NobelReplace CC (Nobel Biocare). All patients were available for postoperative examinations and underwent regular follow-up according to the authors' clinic routine. They were asked to complete a questionnaire based on pain, swelling, fever, general well-being, and food consumption for the time between appointments. Postoperative pain was controlled using mild nonsteroidal anti-inflammatory drugs. Minor extraoral swelling no greater than normally seen in such surgeries was observed in 17 patients (47%) and resolved no later than 3 days postoperatively in all cases. For simultaneous procedures, the average healing time was 5.8 ± 2.8 months. In the cases where GBR was performed prior to implantation, the healing time was 7.9 ± 1.5 months plus

Table 1 Clinical data for bone augmentation using a new collagen membrane with simultaneous or

Patient (site no.)	Sites (n)	Age (y)	Arch	Augmentation indication	Graft type	Implants (n)	Healing Times (mo)	
							GBR	Simultaneous GBR and/or implant
Simultaneous GBR and implantation								
1 (1,2)	2	70	Maxilla	Horizontal	ABBM	2		5.6
			Maxilla	Horizontal	ABBM	3		5.6
3 (4)	1	54	Mandible	Horizontal	ABBM	2		4.1
4 (5,6)	2	41	Mandible	Horizontal	ABBM	2		4.8
			Mandible	Horizontal	ABBM	2		4.8
5 (7)	1	71	Mandible	Buccal dehiscence	ABBM	1		3.8
6 (8)	1	49	Mandible	Horizontal	ABBM	2		4.9
7 (9,10)	2	59	Maxilla	Horizontal	Autograft + ABBM	2		4.7
			Maxilla	Horizontal	Autograft+ ABBM	2		4.7
8 (11,12)	2	57	Maxilla	Horizontal	Autograft + ABBM	2		5.2
			Maxilla	Horizontal	Autograft + ABBM	2		5.2
9 (13,14)	2	73	Mandible	Horizontal and vertical	Autograft + ABBM	2		7.6
			Mandible	Horizontal and vertical	Autograft + ABBM	1		7.6
10 (15)	1	74	Mandible	Horizontal	ABBM	4		3.8
11 (16)	1	52	Mandible	Horizontal	ABBM	3		3.9
13 (19)	1	70	Mandible	Horizontal	ABBM	2		4.7
14 (20)	1	61	Mandible	Buccal dehiscence	ABBM	1		7.0
16 (23,24)	2	57	Maxilla	Horizontal	ABBM	2		6.0
			Maxilla	Horizontal	ABBM	2		6.0
18 (26)	1	62	Maxilla	Horizontal	ABBM	2		5.8
19 (27)	1	41	Mandible	Buccal dehiscence	ABBM	1		4.1
20 (28,29)	2	45	Maxilla	Buccal dehiscence	Autograft + ABBM	1		5.3
			Mandible	Horizontal	Autograft + ABBM	4		5.3
21 (30)	1	36	Mandible	Horizontal	ABBM	1		4.1
22 (31)	1	40	Mandible	Horizontal	ABBM	1		3.7
23 (32)	1	46	Maxilla	Buccal dehiscence	ABBM	1		3.8
24 (33)	1	71	Maxilla	Buccal dehiscence	ABBM	1		4.4
27 (36)	1	58	Maxilla	Buccal dehiscence	ABBM	1		5.8
28 (37,38,39)	3	49	Maxilla	Horizontal	Autograft + ABBM	3		8.7
			Maxilla	Horizontal	Autograft + ABBM	3		8.7
			Mandible	Horizontal	Autograft + ABBM	4		8.7
29 (40)	1	73	Mandible	Horizontal	ABBM	4		5.5
30 (41)	1	47	Mandible	Horizontal	ABBM	2		5.5
31 (42)	1	57	Mandible	Horizontal	ABBM	1		5.7
32 (43)	1	57	Mandible	Buccal dehiscence	ABBM	1		3.8
34 (44)	1	69	Mandible	Horizontal	ABBM	3		4.2
35 (46,47)	2	73	Maxilla	Horizontal	ABBM	2		6.6
			Maxilla	Horizontal	ABBM	2		6.6
36 (48,49)	2	56	Maxilla	Horizontal	Autograft + ABBM	3		17.4
			Maxilla	Horizontal	Autograft + ABBM	3		17.4
GBR prior to implantation								
2 (3)	1	62	Maxilla	Horizontal and vertical	ABBM	2	9.9	5.6
12 (17,18)	2	76	Maxilla	Horizontal and vertical	Autograft + ABBM	2	8.7	3.6
			Maxilla	Horizontal and vertical	Autograft + ABBM	2	8.7	3.6
15 (21,22)	2	49	Mandible	Horizontal and vertical	Autograft + ABBM		Failure	
			Mandible	Horizontal and vertical	Autograft + ABBM		Failure	
17 (25)	1	54	Maxilla	Horizontal	Autograft + ABBM	3	8.2	7.3
25 (34)	1	66	Mandible	Horizontal	Autograft + ABBM	3	7.4	4.4
26 (35)	1	32	Maxilla	Horizontal and vertical	Autograft + ABBM	2	5.1	3.2
33 (44)	1	69	Maxilla	Horizontal and vertical	Autograft + ABBM	6	7.6	6.0
Mean		57.7					7.9	5.8
Median		57.0					8.2	5.3
SD		12.0					1.5	2.8

ABBM = anorganic bovine bone matrix; GBR = guided bone regeneration.

subsequent implantation	
Prosthetic loading (mo)	**Follow-up (mo)**
6.53	15.03
6.53	15.03
5.03	18.03
5.73	23.53
5.73	23.53
5.20	15.10
6.30	18.10
6.10	18.40
4.70	17.00
7.53	18.03
7.53	18.03
8.53	9.53
8.53	9.53
5.20	6.30
5.30	13.60
5.40	22.20
8.40	9.60
8.33	16.83
8.33	16.83
8.37	28.57
5.03	16.03
6.93	14.73
6.93	14.73
5.97	23.37
4.63	22.03
4.97	13.37
5.57	13.47
7.67	17.17
11.27	27.17
11.27	27.17
11.27	27.17
6.43	18.63
7.13	13.13
6.63	21.43
4.73	19.53
7.00	13.50
7.77	19.67
7.77	19.67
19.27	21.37
19.27	21.37
11.77	14.07
9.63	25.93
9.63	25.93
8.90	26.60
8.33	9.63
6.73	14.43
8.53	25.43
7.8	18.3
7.0	18.0
3.1	5.5

4.8 ± 2.0 months for GBR and implant placement, respectively. The main patient characteristics and their clinical outcomes are listed in Table 1. The average dehiscence rate was 12%, occurring in 6 out of 49 augmentation sites, in five patients. Of the dehiscences, 3 were detected in three patients with simultaneous GBR and implant placement, and the other 3 dehiscences occurred in two patients with GBR prior to implantation (Table 2). Spontaneous closure with no full membrane degradation and no graft exposure was observed in 4 surgical sites within about 2 weeks. The two remaining dehiscent sites were on opposite posterior aspects of the mandible in a single patient with severe bony erosion. In this patient, the initially placed augmentation material consisted of ABBM and autogenous bone but due to unsuccessful wound closure the material and the membrane had to be removed. After 8 weeks, a second operation was performed on the patient using the same technique with a different resorbable collagen membrane (Bio-Gide, Geistlich). However, this graft also had to be removed. In a third attempt 4 months later, only autogenous bone blocks and chips were transplanted and fixed with the creos xenoprotect membrane. This final augmentation procedure was successful. In sum, the initial augmentation failure rate was 4%, with 2 failures in 49 total augmentation procedures performed on 1 of 36 (2.8%) patients. All 103 implants inserted were fully osseointegrated after the proposed healing period. At the reentry operation after bone augmentation healing, the sites were visually inspected and no membrane remnants were seen, indicating that it was fully biodegraded. At the final prosthetic fitting, all prosthetic devices withstood the 25 Ncm torque required. All inserted implants received a prosthetic reconstruction as described in Table 1 and were loaded on average 7.4 months after implantation. The implant survival rate is 100% at a mean follow-up of 18.3 months (range: 6.3 to 28.6 months) from date of implant placement. Prosthetic survival was 100% at last follow-up. Implant success rate according to Misch et al was also 100%.[22]

Discussion

The present retrospective case series shows very promising results with regard to alveolar ridge bone augmentation using a mechanically stable collagen membrane combined with ABBM or a mixture of ABBM and ABC. Application of this technique prior to or simultaneous with implant placement and followed by prosthetic loading led to complication-free treatment in 31 of 36 patients (42 of 49 operation sites).

The augmentation failure rate was 4%, representing two failures occurring in a single patient (2.8%). The dehiscence rate of 12% in the present case series is lower than the published values using membranes in GBR.[12,13,24,25] The dehiscence rate for nonchemically cross-linked bioresorbable collagen membranes reportedly ranges from 22% to 32%.[13,21,25] Additional

Table 2 Dehiscence characteristics

Patient (site no.)	Age (y)	Sex	Arch	Graft type	Two-stage surgery	Dehiscence	Size (mm)	Graft failure
9 (13,14)	73	F	Mandible	Autograft + ABBM	No	Yes	3 × 2	No
15 (21,22)	49	F	Mandible	Autograft + ABBM	Yes	Yes	10 × 5	Yes
			Mandible	Autograft + ABBM	Yes	Yes	15 × 5	Yes
22 (31)	40	M	Mandible	ABBM	No	Yes	3 × 3	No
26 (35)	32	M	Maxilla	Autograft + ABBM	Yes	Yes	4 × 2	No
34 (44)	69	M	Mandible	ABBM	No	Yes	5 × 2	No

F = female; M = male; ABBM = anorganic bovine bone matrix.

chemical cross-linking leads to greater membrane stability against biodegradation, but also results in higher dehiscence rates of 39% to 64%.[12,13,24,25] The higher success rate shown in this analysis might be attributable in part to the good tissue integration and vascularization of the collagen membrane.[20] Surgical technique may also have contributed to the good results reported in this study. One major advantage of the investigated collagen membrane is its inherent resistance to tearing when using titanium pins for the graft stabilization, a requirement of this technique.[19] Comparative tensile and suture-pull-out testing provided evidence that this membrane possesses the highest mechanical strength of all tested collagen membranes in both wet and dry states and is superior in this performance with respect to (non-titanium-reinforced) PTFE membranes.[21] However, there are still cases where titanium-reinforced ePTFE membranes are favorable, especially when no slow-resorbing bone substitute material is used to maintain the space under the membrane or when vertical bone augmentation is needed. The results of this ongoing clinical case series and the described bone augmentation technique are very promising, with a 100% implant survival rate for 103 implants, to date. However, the mean follow-up period is still relatively short. Thus, the available clinical data are limited, particularly relating to success of long-term outcomes, bone loss in the augmented region, and crestal remodeling, as demanded by Tonetti and Hämmerle.[26] Further follow-up investigations including randomized controlled studies are required to validate these findings.

Conclusions

These early data demonstrate a low dehiscence rate and excellent potential of the RX/CXP monolayer, noncross-linked collagen membrane for use with horizontal ridge augmentation. Further clinical studies are needed to determine if the results seen in this case series report can be generalized over a larger patient population being treated by other clinicians.

Acknowledgments

The authors reported no conflicts of interest related to this study.

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