Cortical lamina: a new device for the treatment of moderate and severe tridimensional bone and soft tissue defects

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Abstract

Ridge defects are a very common finding after tooth extraction. Recent literature has shown that the pattern of bone and soft tissue remodeling can obtain up to 50% of the original volume. Many different surgical approaches have been proposed over the years to correct ridge defects, but the results have often been inconsistent or difficult to reproduce on a daily basis. For some time, surgeons have relied on the guided bone regeneration (GBR) technique, taking advantage of a barrier membrane to protect the blood clot, combined with different combinations of autogenous bone and bone grafts from various sources. If some kind of understanding has been reached and certain guidelines adopted for the treatment of horizontal defects, those for tridimensional and vertical defects still present a challenge. About a decade ago, a new biomaterial became available on the market – a membrane made of collagenated porcine bone called cortical lamina – which proved to be reliable and easy to handle for both horizontal and vertical defects. The aim of this article is to review the current literature on the topic and to discuss the material in its three forms through the presentation of three patient cases of differing complexity, each with its unique indications and characteristics.

Introduction

Tooth extraction is very often a traumatic experience for the patient, not only because it is something of a mutilation but also because it triggers a phenomenon of bone and soft tissue remodeling that can vary from moderate to severe.\textsuperscript{1-4} The first case presented in this article shows severe 3D defects resulting from an accident, the second a vertical root fracture, and the third generalized stage III periodontitis.

From a clinical point of view, the focus for the clinician in all three cases was to find the best surgical option to treat the lesions. The most recent systematic review in 2015 by Sanz-Sánchez et al\textsuperscript{5} pointed out how the treatment of horizontal lesions by means of a xenograft protected by a bioabsorbable membrane seems to be the most predictable option. Rocchietta et al\textsuperscript{6} and Esposito et al\textsuperscript{7} asked questions about the reliability and reproducibility of procedures for vertical ridge augmentation. One of the most popular techniques for vertical ridge augmentation utilized the combination of bovine-derived anorganic bone with autogenous bone chips together with titanium-reinforced, dense polytetrafluoroethylene (PTFE) membranes. For several years, this was considered a standard procedure, and in 2014, Urban et al\textsuperscript{8} reported an average gain of 5.45 mm on 19 patients treated with this technique. The use of PTFE membranes proved to be very demanding, and their early exposure was one of the weaknesses of the technique. Fontana et al\textsuperscript{9} described seven different kinds of complications. A recent publication by Gallo et al\textsuperscript{10} described the management of 80 complications (exposures and infections) related to the use of these membranes. The authors also reported very useful information, with the majority of complications appearing before the second month after surgery. The use of d-PTFE membranes still represents a viable option for the resolution of horizontal and vertical bony defects, but the high incidence of complications suggests that research into new biomaterials may result in alternatives that are less prone to complications.

Cortical lamina

OsteoBiol Lamina (Tecnoss) is a membrane made of collagenated porcine cortical bone. The scanning electron microscope (SEM) image in Figure 1 shows how it could be compared with a semi-permeable membrane due to the holes and channels on its surface that clearly favor the revascularization of the grafted area, from both the flap side and the grafted site.

The lamina is produced in three different versions. The first is curved (Fig 2), which is very stiff but also very elastic, with a size of 35 × 35 mm and a thickness of 1 mm. OsteoBiol Curved Soft Lamina can easily be adjusted to the local anatomy of the defect. The suggestion is to use it dry to take advantage of its stiffness in order to maximize its ‘dome’ effect.

The second version, OsteoBiol Lamina Soft (Fig 3a), is very rigid and square-shaped, measuring 25 × 25 mm in size with a 0.5-mm thickness. It should be hydrated with warm sterile water for 5 min to gain flexibility so that it can be cut and adjusted over the grafted defect. While it behaves and should be used as a collagen membrane to protect the grafted area, it has all the benefits of being made of bone. Due to its elasticity and flexibility, it needs to be anchored to the bone for stability by means of screws or pins. It is suggested to use 3- or 4-mm pins that should always be placed at least 2 to 3 mm from the edges of the membrane, and 5- to 7-mm tenting screws to create the ‘dome’ effect and support the lamina above the graft (Fig 3b).
The third version is a ‘bone layer’-type rigid OsteoBiol Lamina that represents a piece of cortical bone and is used to replace one or more of the wall’s defects, similar to what was described by Khoury with autogenous cortical bone. The advantage of this version is that it spares the patient from the need for a donor site, which saves time and reduces morbidity and postoperative pain and swelling. The bone layer needs to be stabilized using screws of the desired length to keep the lamina stable and rigidly fixed to the residual bone (Fig 4).
Literature review

The first evidence of the use of OsteoBiol Lamina on humans was published in a multicenter study by Pagliani et al.\textsuperscript{12} These authors reported on the efficacy of the lamina in protecting grafted defects over implants. Reporting on 19 patient cases, the authors described how they utilized cortical lamina for lateral bone augmentation, for augmentation of the sinus floor, to heal bone defects, and to replace the bone window in a sinus lift. They reported a success rate of 97.1%, as one maxillary sinus procedure resulted in insufficient bone gain. The histology in this study revealed bone condensation properties and indicated that the lamina resorbed with time.

Festa et al\textsuperscript{13} carried out a randomized controlled clinical study to compare the preservation of the alveolar ridge dimensions following tooth extraction using porcine-derived xenograft (OsteoBiol GenOs) combined with OsteoBiol Lamina Soft versus extraction sites alone. After 6 months, the extraction sites showed a greater reabsorption of the buccolingual dimension than the grafted sites, and the mean vertical ridge height reduction in the control sockets was significantly higher than that in the grafted sites. The authors concluded that the combination of OsteoBiol Lamina Soft and xenograft was effective in minimizing the effects of extraction.

Wachtel et al\textsuperscript{14,15} published a case series describing the use of the bone lamina technique to perform lateral ridge augmentation. In their report, the authors presented four patient cases with inadequate ridge width. All the patients were treated with a combination of OsteoBiol Lamina Soft and xenogenic bone particles (OsteoBiol mp3). The authors measured the volumetric variation by means of CBCT and took biopsies at the placement of the dental implants. The results revealed a sufficient bone structure for implant placement without any further augmentation procedure. Histological analysis demonstrated new bone formation, and the bone shield resorbed entirely. The conclusion was that bone lamina has the biologic and mechanical properties to successfully achieve hard tissue augmentation.

Various authors (Happe and Slotte\textsuperscript{16} and Lopez et al\textsuperscript{17}) proposed the use of OsteoBiol Lamina instead of the autogenous bone plates described in Khoury’s\textsuperscript{11} technique. Rossi et al\textsuperscript{18} carried out a clinical and histological study on a series of patients who were first treated in the posterior resorbed mandible by means of collagenated porcine bone grafts (OsteoBiol GenOs) mixed with the patients’ own blood clots covered with the OsteoBiol Curved Soft Lamina. After healing periods of 6 to 8 months, implants were placed in the regenerated bone only after biopsies were taken. All the implants succeeded in reaching osseointegration and showed no modification at the crestal level up to 1-year post-loading. Biopsies demonstrated that the areas augmented with OsteoBiol Lamina presented new live bone.

Rossi et al\textsuperscript{19} described in detail how to address and plan cases of combined (horizontal and vertical) ridge augmentation using OsteoBiol Curved Soft Lamina. In another article in 2019, Rossi et al\textsuperscript{20} pointed out, importantly, that lamina made of bone can actually be stabilized to the local anatomy by being stuck between adjacent teeth. None of the membranes used previously had allowed for this function; it was actually considered a contraindication to place membranes close to the natural dentition. This further aspect makes OsteoBiol Lamina very peculiar. In the reported case, a 2-mm-thick ridge was augmented to accommodate 4.2-mm implants, and a follow-up of 5 years showed perfect maintenance of osseointegration and crest stability.
Rossi and Foce\textsuperscript{21} reported that when the OsteoBiol Lamina becomes exposed for various reasons, it slowly melts. This favors the granulation of the surrounding tissue, thus protecting the graft. In addition, it is very rare for the early exposure of the membrane to compromise the final outcome of the augmentation.

Ozel et al\textsuperscript{22} showed that OsteoBiol Lamina also has extraoral uses due to its capability to address maxillofacial problems. The orbital floor is one of the most frequently injured areas during facial trauma. Between 2010 and 2014, 21 patients with traumatic orbital floor defects underwent successful reconstruction with cortical lamina. The authors suggested that the lamina was a good alternative for the reconstruction due to its plasticity and biocompatible structure.

**Case presentations**

**Case 1: OsteoBiol Lamina Soft**

A 49-year-old male patient was referred after a bicycle accident that had occurred 2 months prior to his first consultation. He presented multiple root fractures. Root extractions of teeth 14, 13, 12, 11, 21, and 22 were performed shortly after the accident; tooth 15 was already missing before the accident. CBCT scans (Fig 5) showed alveolar defects ranging from teeth 14 to 22, with the maximum extent of bone loss in...
the area of teeth 11 and 13. The entire area represented a large tridimensional defect, with severe horizontal and vertical components (Fig 6). Another factor aggravating the clinical situation was the complete loss of keratinized gingiva in the buccal aspect of the edentulous area.

**Materials and methods**

The plan was to augment the bone volume and to improve the soft tissue in order to restore the shapes and improve the esthetics. A ridge augmentation procedure was performed under local anesthesia (Supracain; Zentiva) by using the cortical lamina technique. Full thickness buccal and lingual flaps were elevated to expose the underlying large lesion. Two pieces of OsteoBiol Lamina Soft measuring 30 × 30 mm were moistened with sterile saline and shaped to fit the defect area (Figs 7 to 9). The lamina was fixed to the palate by means of 3-mm–long titanium screws (Pro-fix; Osteogenics), and the defects were grafted by mixing 50% autogenous bone, harvested from the external oblique line by means of a rotary chip maker (AutoBone Collector; Osteon). This was mixed with anorganic bovine bone (Bio-Oss; Geistlich) in a 1:1 ratio, and moistened with the patient’s blood clot collected from the operative area. Titanium osteo-fixation screws (Helmut Zepft) of 9 mm in length were used to firmly fix the cortical lamina to the underlying bone (Fig 10). As the lamina is brittle and tends to break easily when fixed with screws, long screws are preferred to allow their placement further away from the edge and so that they pass through the more voluminous part of the bone graft. Wound closure was achieved without tension by mucosal flap activation and separation from the underlying muscle fibers (Fig 11). This procedure coronally advanced the buccal flap and therefore severely reduced the depth of the vestibule. Flaps were sutured with a monofilament suture (Chiralen monofil, blue 6-0; Chirmax). The patient was instructed to take antibiotics (Augmentin, 1 g) twice a day for a week. Healing was uneventful, and the sutures were removed 2 weeks postsurgery. The reentry and implant surgery was planned after 9 months; at that time the ridge looked squared and the soft tissue healthy in color and texture. Four implants (DIO UF (II); DIO Implant) were placed into the regenerated bone 1.5 mm subcrestally, with a torque of 35 Ncm (Fig 12). Two months after implant installation, a procedure aimed to create more vestibule depth and increase the quantity of keratinized gingiva was performed using the strip technique. Mucograft dermal matrix membranes (20 × 30 mm; Geistlich) were used and fixed with resorbable sutures (Monocryl 5-0; Ethicon; Fig 13). Four months later, after maturation of the newly formed keratinized tissue, second-stage surgery was performed and an impression taken. Conditioning and shaping of the peri-implant soft tissue was gained by the placement of a temporary bridge and by increasing the thickness of the marginal mucosa through a connective tissue graft harvested from the palate bilaterally (Figs 14 and 15). Treatment was completed by performing prosthetic rehabilitation with two screw-retained zirconia bridges. The post-procedure CBCT highlights the quantity and quality of the regenerated bone (Figs 16 and 17).

The final outcome of the treatment not only reestablished function but also greatly improved the esthetics of this traumatized patient. In this specific case, OsteoBiol Lamina favored both horizontal and vertical augmentation and offered good implant and soft tissue support (Fig 18).
Fig 7a to c  Defect exposed.

Fig 8a to c  Preparation of the graft (50% autogenous, 50% xenograft).

Fig 9a to c  OsteoBiol Lamina adapted to the anatomy.

Fig 10a to c  Fixation of OsteoBiol Lamina with tenting screws and pins.
**Fig 11a to c** Sutures.

**Fig 12a to f** Healing of the soft and hard tissue and implant placement.

**Fig 13a to c** Strip technique to widen the vestibule.
Fig 14a to c  Connective tissue grafts to enhance thickness.

Fig 15a to c  Tissue conditioning with temporary crowns.

Fig 16  CBCT images after restoration.

Fig 17a to c  Ridge before and after augmentation and with implants.
Case 2: OsteoBiol Curved Soft Lamina

A 53-year-old female patient was referred to the clinic by her general dentist for generalized stage III periodontitis with severe bone loss in quadrants 1, 3, and 4. Bone loss extended over the apex of teeth 12, 13, 45, and 47, which were deemed hopeless (Fig 19). CBCT showed a severe amount of bone loss and resorption of the buccal plate, with teeth 12 and 13 floating in the soft tissue (Fig 20). Only tooth 12 preserved a minimal amount of periodontal ligament in its apical mesial portion. The occlusal view showed how only a very thin layer of the palatal cortical bone was left in place. The goal for this patient was to reestablish a good regimen of oral hygiene and to restore function where the teeth were lost.

Materials and methods

It was decided to use OsteoBiol Curved Soft Lamina in the maxillary right quadrant. After local anesthesia, buccal and lingual flaps were elevated to expose the defect. All residual granulation tissue was removed, and two tenting screws were positioned where there was still available bone, with the goal of supporting the membrane and maintaining the space. A blood clot from the bleeding area was collected and put aside on a dappen dish. A mixture of xenograft, collagenated porcine bone (OsteoBiol, GenOs), and autogenous bone chips collected from the tuberosity was then moistened and mixed with the patient’s blood clot and inserted into the defect to augment the area. The cortical lamina was prepared, cut with utility scissors,
Nevertheless, a complication arose in the seventh month postsurgery. The patient had been very compliant until the sixth month and had carefully used the temporary removable appliance. However, probably due to excitement at the positive outcome of the 6-month CBCT scan, she began to chew on the area. She presented at 7 months with two ulcers, one in the crestal aspect of the ridge and another in the alveolar mucosa. This called for immediate emergency intervention, where, under local anesthesia, the area of augmentation was cleaned from the inflammatory tissue, some fragments of the contaminated lamina were removed, and the area was disinfected with chlorhexidine and a mixture of sterile saline solution and tetracycline powder (Fig 24). The area was left to heal for another 4 months, and the

and shaped to adapt to the local anatomy. It is important to bear in mind when using Os-teoBiol Curved Soft Lamina to keep it as dry as possible until the sutures are completed in order to maintain its rigidity and shape, maximizing the ‘dome effect’ for the underlying bone graft and blood clot as well as supporting the soft tissue (Fig 21). To complete the procedure, the suggestion is to use PTFE 4-0 sutures due to their strength and flexibility. A normal regimen of antibiotic and anti-inflammatory was prescribed, and the healing was uneventful. The soft tissue showed a completely new volume and shape a few weeks after suture removal (Fig 22).

At 6-months postsurgery, a CBCT scan was taken that showed how the grafted site was changing in volume while the bone graft was mineralizing and integrating (Fig 23).
Implant surgery occurred only 12 months after the completion of the augmentation. In this period of time, the patient refrained from using the temporary removable appliance and adopted a soft diet. One year after augmentation, the two tenting screws were removed, and three 3.5 × 10 mm implants (Ostern Implants) were placed in the now restored ridge. Despite a good implant stability quotient (ISQ) of 73, 76, and 81, the implants were buried for an extra 3 months to allow for further mineralization of the area. The authors were happy with how well the implant fitted into the regenerated bone, and later how well the soft tissue responded to the conditioning with the healing abutments in place (Fig 25). Initially, the implants were loaded with temporaries, and the image of the master cast (Fig 26) shows the volumes of soft and hard tissue achieved. Due to the significant amount of augmentation, the provisional crowns were kept in place for 1 year to ensure that there were no further functional complications. The final restoration was delivered 24 months after bone augmentation and showed a good improvement compared with baseline. Figure 27 shows the 36-month post-loading follow-up radiograph.
Fig 23a to c  CBCT images at 6-months postsurgery.

Fig 24a to c  Complication in seventh month postsurgery: lacerations (crestal and buccal) resulted in the removal of infected parts of the lamina.

Fig 25a to c  Implants in place; soft tissue conditioned with temporaries.
Fig 26a to c  Temporaries in place.

Fig 27a to d  Final restoration and 3-year follow-up radiograph.
Case 3: bone layer rigid OsteoBiol Lamina

A 45-year-old male patient presented at the clinic with a vertical fracture of tooth 24 and an ongoing abscess. The patient was medicated with antibiotics and the tooth extracted, leaving a very large defect. After the healing of the soft and hard tissue, the situation was reassessed with the aid of CBCT (Fig 28). Since the residual defect was a 3D defect with severe vertical (9 mm) and horizontal (8 mm) components, it was decided to use horizontal and vertical ridge augmentation. This kind of defect was elective for the Khoury technique, consisting of two bone layers, one in the buccal aspect and one screwed to the palatal side.

Materials and methods

After local anesthesia with lidocaine with adrenaline 1,100,000, full-thickness buccal and lingual flaps were elevated to expose the defect. The anatomy was well known from the CBCT scan; nevertheless, the defect was measured with PCP periodontal probes to validate its extent (Fig 29).

The OsteoBiol Lamina was cut into two portions, one buccal (18 x 10 mm) and one lingual (13 x 10 mm), moistened with warm sterile saline, dampened with the patient’s blood clot, and screwed into position with 3-mm titanium screws to replace the missing buccal and lingual cortical bone. The placement of the two bone walls created a defined four-wall defect that was grafted with a xenograft (OsteoBiol GenOs). Then, the soft tissue was closely approximated with 4.0 PTFE sutures to ensure primary closure (Fig 30). The radiograph taken at the end of the procedure shows how the defect was repaired (Fig 31).

Six months later, the area was ready for the reentry, and after the elevation of the buccal and lingual flaps and removal of the fixation screws, it was noticed that the anatomy of the area had completely changed, and that the defect was completely regenerated. The two bone plates showed a good degree of integration and produced a new anatomy, with a 90-degree ledge supporting the soft tissue (Fig 32). This new anatomy facilitated the placement of a 4.3 x 13 mm implant (Replace Select; Nobel Biocare) that was later restored with an individual zirconia crown (Figs 33 and 34). Both the clinical photographs and radiograph taken 3 years after the restoration show the integrity and stability of both the soft and hard tissue.
Fig 29a and b  Defect assessment: bone layer held in place by pins.

Fig 30a and b  Occlusal views showing the two bone plates.

Fig 31  Postoperative radiograph.

Fig 32a and b  Reentry procedure: the lamina is fully integrated.
The procedure. Even where the lamina was exposed earlier than expected, its behavior was always very positive. Enzymes and saliva in the oral cavity lead to slow resorption, and the surrounding soft tissue usually granulates and leads to secondary healing that does not compromise the maturation of the underlying bone graft. Basically, the lamina integrates if remained covered until the second stage, but behaves as a resorbable membrane once flaps do not protect it well, and still produces some degree of regeneration. It is suggested that surgeons focus on

**Conclusion**

In the three complex cases presented here, the cortical lamina technique showed the versatility of a product that enables a surgeon to tackle simple and complex cases of GBR with multiple options. The number of reports in the literature about this technique are increasing year by year because it reduces the complications related to GBR. In one of the three cases presented here, the complication experienced by the authors did not affect the final outcome of the procedure. Even where the lamina was exposed earlier than expected, its behavior was always very positive. Enzymes and saliva in the oral cavity lead to slow resorption, and the surrounding soft tissue usually granulates and leads to secondary healing that does not compromise the maturation of the underlying bone graft. Basically, the lamina integrates if remained covered until the second stage, but behaves as a resorbable membrane once flaps do not protect it well, and still produces some degree of regeneration. It is suggested that surgeons focus on...
1. OsteoBiol Lamina Soft in any situation, horizontal or a combined defect, where one would use a resorbable membrane.

2. OsteoBiol Curved Soft Lamina in situations where the anatomy is favorable (ie, where the lamina would fit and stabilize without the need for pins and/or screws), with the goal to augment both horizontally and vertically.

3. Bone layer rigid OsteoBiol Lamina as a substitute for the autogenous bone in a modified Khoury technique.

Further ongoing clinical research continues to evaluate the performances of different mixes of autogenous bone and biomaterials with the different types of lamina and will provide more detailed information in the near future.

The following specific indications for the use of cortical lamina are suggested:

In the three cases presented here, the clinicians used different approaches, different materials, and different mixes (anorganic bovine bone, autogenous bone, collagenated porcine bone); nevertheless, all three procedures resulted in successful outcomes. This seems to suggest that, even though it would be best to pair the lamina with a product of similar origin, it performs well even when paired with xenogenic bone of another origin (bovine) as well as with autogenous bone.

The correct management of the soft tissue and on preserving primary closure of the wound. This would protect the regenerative process and guarantee a safe implant procedure once healing is completed.

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