

EAO 2016 Oral Communication - Basic Research

25th Annual Scientific Meeting of the European Association for Osseointegration

September 29th - October 1st, 2016, Paris

2016 Research Forum Poster Session

102nd Annual Meeting of the American Association of Periodontology

September 10-13th, 2016, San Diego, California

Alveolar Ridge Augmentation and Ossification of Thick vs. Thin Sugar Cross-linked Collagen Membranes in a Canine L-shape Defect Model

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Introduction

Guided bone regeneration is widely used today to augment or preserve alveolar bone. In many cases, it yields insufficient bone quantity and quality that may in part, account for the high prevalence of peri-implant infections, esthetically compromised restorations and implant failures.

Collagen regenerative products are used extensively to augment hard and soft tissues. Limited barrier function *in vivo*, due to short resorption time, limits some

products' ability to actively promote new bone and soft tissue formation.

GLYMATRIX® technology, based on sugar cross-linking of collagen, was used to produce a collagen membrane (OP) for guided bone regeneration procedures.

Recently, a new thicker GLYMATRIX® based device (OV) was developed to augment both soft and hard tissues' volume, in periodontal and implant surgeries.

A two-arm study was designed to compare OV to OP.

Methods

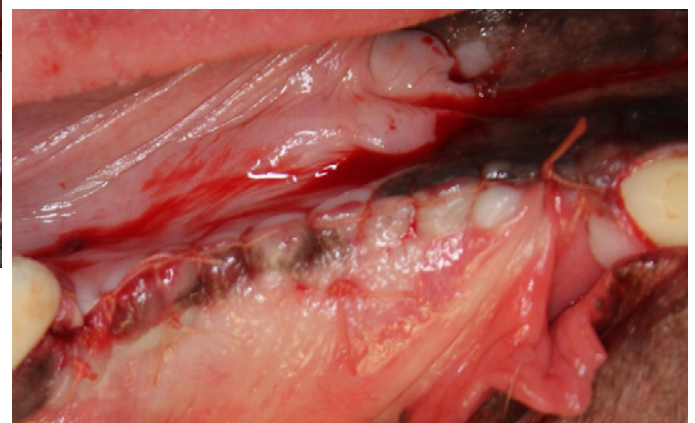
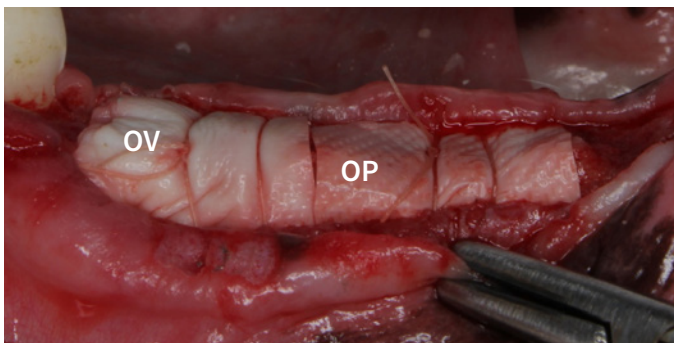
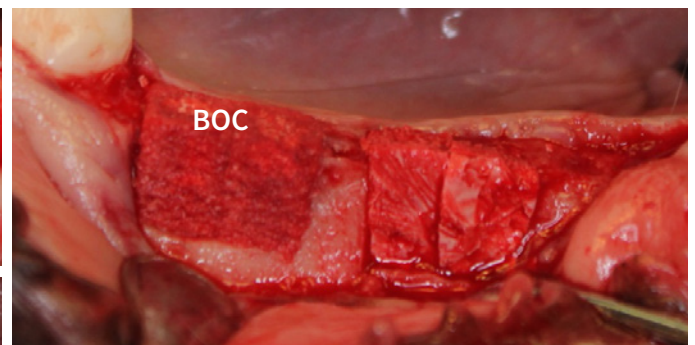
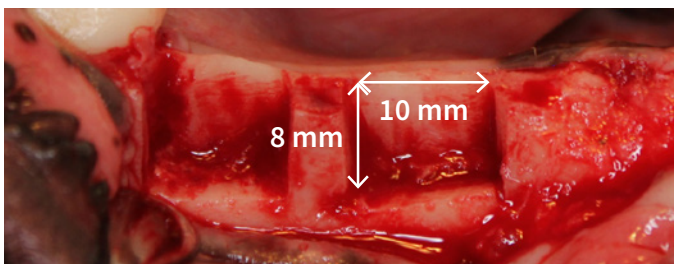
In the two-arm study designed to compare OV to OP, 19 male beagle dogs underwent a surgical procedure in which 4 mandibular premolars were extracted.

21 days later, 7x8x10 mm alveolar defects were created and filled with blocks made of collagen & bovine-bone mineral. The defects were covered with either the test or control membranes or were left empty. At 4, 12, and 24 weeks the lower mandibles of all animals were removed, stripped of soft tissue, bisected at the anterior midline and blindly analyzed using micro-CT. Total mineralized volume (implant + bone) and total mineralized densities were quantified. Thin undecalcified sections were stained with H&E, and ground sections with Stevenel's Blue. Blinded analysis included semi-quantitative histology scoring (healing, ridge restoration and biocompatibility) and

histomorphometry (bone area, alveolar ridge width, residual implant, membrane mineralization and ossification).

4 slides from each implant site were evaluated for histology (H&E and SB) and histomorphometry (SB slides only). Least squares means and standard errors for continuous endpoints were reported on the original scale. Results of all pair-wise comparisons are reported at the 0.05 and 0.01 significance levels, following adjustment for multiple comparisons using the methods of Edwards and Berry.

All endpoints were analyzed using two-tailed tests.



*OP - OSSIX® PLUS, OV - OSSIX® VOLUMAX, BOC - Bio-Oss® Collagen

Results

By all parameters assessed healing and general biocompatibility profiles of OV and OP treated defects were similar.

No statistically significant differences were found between OP and OV in regards to ridge restoration. Membrane mineralization was observed more often in OV at all time points, but membrane ossification (cell mediated remodeling of the membrane into bone) was similar between both, with OV having higher instances of ossification at 24 weeks.

OV had a significantly higher percent membrane at 12 weeks.

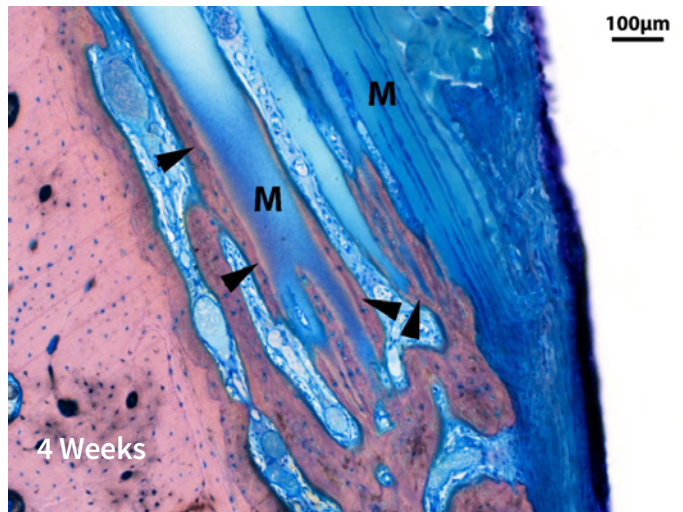
By 24 weeks both had very similar amounts of original membrane remaining of 3- 5%.

Both OP and OV outperformed the empty control, demonstrating statistically significant improved bone growth.

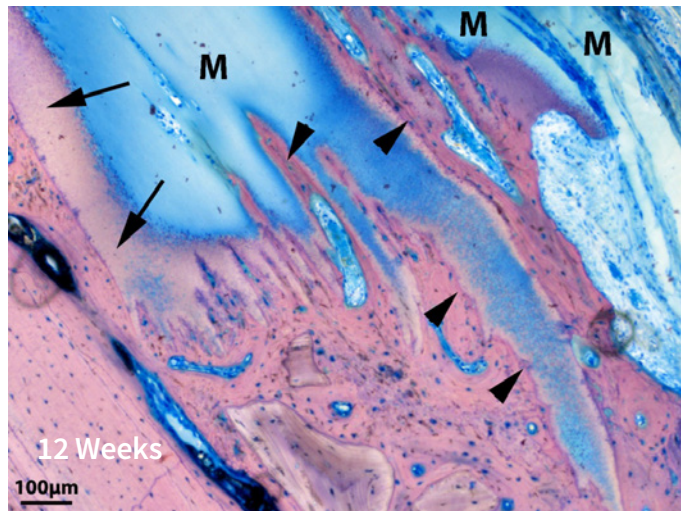
Conclusions

Both OP and OV were effective barriers for 6 months, gradually integrating into adjacent tissues, and promoted restoration of the defects with a bone filler. In contact with bone, both products share a unique quality of mineralization progressing into ossification.

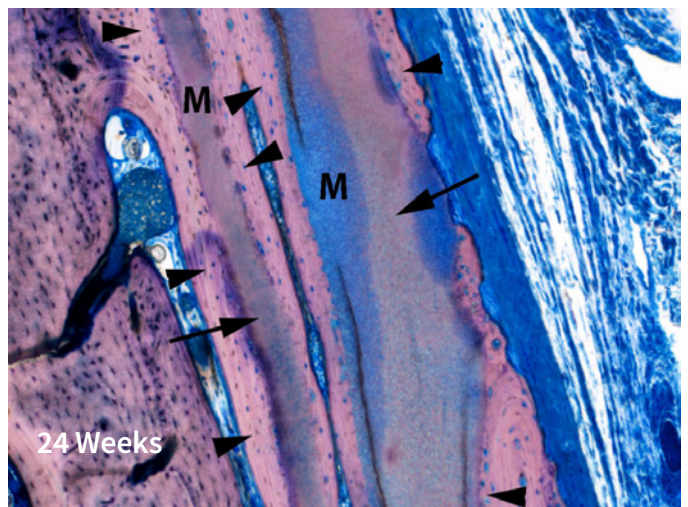
Therefore OV, being a thick membrane (1-2 mm), has the potential to augment thin tissue around implants, esthetic deficiencies, and correct residual dehiscence after regenerative procedures.



OSSIX® VOLUMAX at 4 weeks
De-novo bone formation advancing into the matrix



OSSIX® VOLUMAX at 12 weeks
Ossification of collagen continues



OSSIX® VOLUMAX at 24 weeks
Ossification is almost complete

*M – Membrane, Arrows – New bone

Table 1
Percent Bone Area

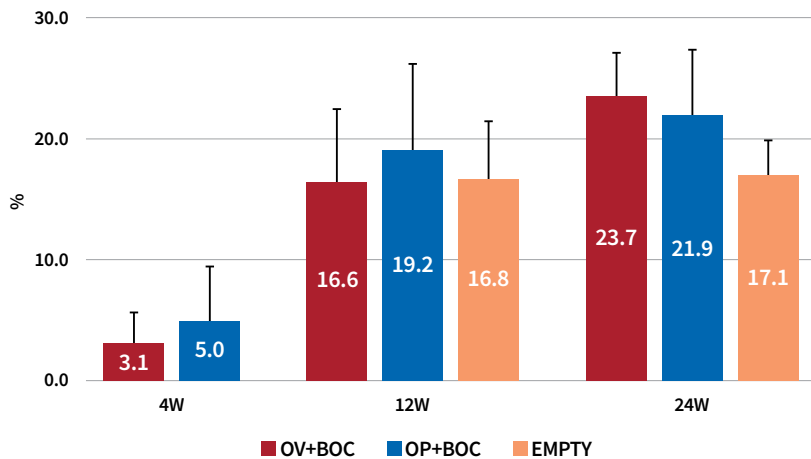
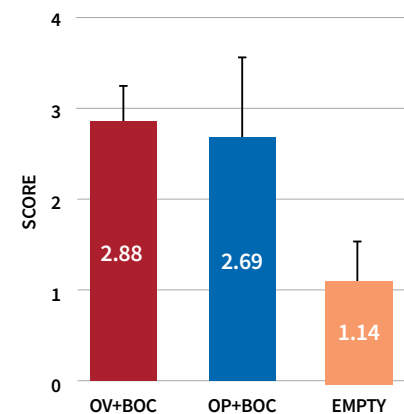


Table 2
Alveolar Ridge Restoration
24 weeks



*OP - OSSIX® PLUS, OV - OSSIX® VOLUMAX, BOC - Bio-Oss® Collagen

References

1. Artzi Z, Weinreb M, Carmeli G, Lev-Dor R, Dard M, Nemcovsky CE. (2008) Histomorphometric assessment of bone formation in sinus augmentation utilizing a combination of autogenous and hydroxyapatite/biphasic tricalcium phosphate graft materials: at 6 and 9 months in humans. *Clin. Oral Impl. Res.* 19; 686–692.
2. Beitlitum I, Artzi Z, Nemcovsky CE (2010) Clinical evaluation of particulate allogeneic with and without autogenous bone grafts and resorbable collagen membranes for bone augmentation of atrophic alveolar ridges. *Clin. Oral Impl. Res.* 21, 2010; 1242–1250.
3. Zubery Y, Goldlust A, Alves A, Nir E. (2007) Ossification of a novel cross-linked porcine collagen barrier in guided bone regeneration in dogs. *J Periodontol.* 78(1):112-121.
4. Zubery Y, Nir E, Goldlust A. (2008) Ossification of a collagen membrane cross-linked by sugar: a human case series. *J Periodontol.* 79(6):1101-1107.

Clinical Applications

- OSSIX® VOLUMAX is a resorbable collagen membrane intended for use during the process of guided bone regeneration (GBR) and guided tissue regeneration (GTR).
- For information on OSSIX® VOLUMAX please refer to the instructions for use available at <http://www.ossixdental.com/products/ossix-volumax>

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