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.

GLYMATRIX® technology, based on sugar cross-linking of collagen, was used to produce a collagen membrane (OP) for guided bone regeneration procedures. The newly developed OB (OSSIX™ Bone) is a resorbable sponge-like matrix of collagen cross-linked by sugar and hydroxyapatite. Developed to augment hard tissue in periodontal and implant surgeries, it also features GLYMATRIX® technology.

A two-arm study was designed to compare OB to BOC.
Materials and Methods

Nineteen male beagles underwent a surgical procedure in which 4 mandibular premolars were extracted. 21 days later, 7x8x10 mm alveolar defects were created and filled with OSSIX™ Bone (OB) or BioOss Collagen (BOC) blocks, covered with OSSIX® PLUS (OP) membrane, fixated with sutures or 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. Samples were then processed for undecalcified (MMA) histology. 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 quantitative 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, OB - OSSIX™ BONE, BOC - Bio-Oss® Collagen

OBx200

OBx1000

OSSIX™ Bone Subcutaneous Implantation Study - 2 Weeks Vascularization
Results

Healing and biocompatibility profiles of OB treated defects were equivalent to those treated with BOC. OB outperformed the empty control demonstrating statistically improved bone growth and ridge restoration (height and width) at 24 Weeks. OB sites showed significantly larger overall ridge restoration and ridge widths compared to BOC. Additionally, OB maintained its cohesive integrity within the site (no migration) as opposed to BOC, in which migration was seen in 12 out of 19 animals.

Conclusions

OB and BOC outperformed the control (empty) with statistically significant improved bone growth and ridge restoration (height and width) at 24 weeks. Healing and biocompatibility profiles of OB were equivalent to BOC. OB treated sites had a larger overall ridge restoration compared to BOC. No migration of OB particles was seen as compared to BOC. OB may effectively augment alveolar bone around teeth and implants without graft remnants or migration.
References


Clinical Applications

- OSSIX™ Bone is intended for successful use as a bone filler in socket preservation, lateral and vertical augmentation, sinus augmentation, peri-implantitis and periodontal bony defects.
- OSSIX™ Bone is pending 510(k), not available for sale within the United States.

© All rights reserved Zubery et al, 2017