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, 7x10x10 mm alveolar defects were created and filled with blocks made of collagen & bone-mineral 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.

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.

CLINICAL APPLICATIONS

• OSSIX® VOLUMAX at 12 weeks – Ossification of collagen continues

• OSSIX® VOLUMAX at 24 weeks – Ossification is almost complete

REFERENCES

5. For information on OSSIX® VOLUMAX please refer to the instructions for use available at http://www.ossidental.com/products/ossix-volumax