SALVIN® Dental Specialties

SALVIN® Regenerative

SALVINOSS®

Xenograft Bone Graft Material

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Mineralized Cancellous Xenograft Material

- *0.25 - 1.0mm Microporous Granules Facilitate Osteoconduction & New Bone Formation*
- *Space Maintaining Material Supports New Bone Regeneration & Healing*
- *SalvinOss® Particles Become An Integral Part Of Newly Formed Bone Framework*
- *Organic Components Removed While Maintaining Characteristics Of Native Bone*
- *Can Be Mixed With Sterile Saline Or The Patients Blood*
- *Radiopaque*

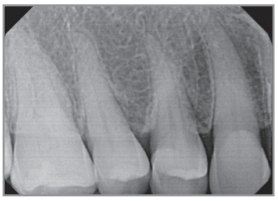
MADE IN USA

60 Second Product Video™ On www.salvin.com

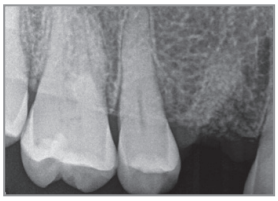
SalvinOss® Technique Guide On www.salvin.com

Case Study - Socket Preservation With SalvinOss®

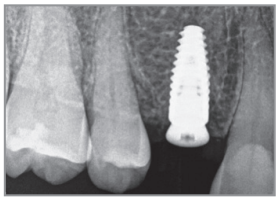
Case & Photos: Dr. Michele Holzinger



Pre-Op



Post-Extraction – 4 Months Healing



Post-Implant – 3 Months Healing

"I trust Salvin Regenerative because they help me produce results that are consistent and reliable for my patients. When I re-enter a site grafted with SalvinOss®, I know exactly what to expect because the results are **predictable**."

–Dr. Michele Holzinger
Periodontist, Middletown, CT

Particle Size	Size	Product #	Price	7 or More	14 or More
250-1000 microns	0.50 cc (0.25g)	**#SALVINOSS-0.50**	**79.00**	**72.60**	**64.50**
	1.00 cc (0.5g)	**#SALVINOSS-1.00**	**119.00**	**108.40**	**98.70**
	2.50 cc (1.25g)	**#SALVINOSS-2.50**	**219.00**	**198.50**	**178.60**

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SALVINOSS®
Xenograft
Bone Graft Material

SalvinOss® Xenograft Bone Graft Material
In Vivo Testing Summary

Summary of In Vivo Use Of Bioresorbable Xenograft Bone Graft Materials
In The Treatment Of One-Walled Intrabony Defects In A Canine Model

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REV. 05-2017

ABSTRACT:

The purpose of this study is to evaluate bone healing within a one-wall periodontal defect following treatment with two different bioresorbable xenograft bone graft materials. Fifteen (15) male beagle dogs at least one year of age (skeletally mature) had second and fourth pre-molars (P2 and P4) extracted from mandible bilaterally. Radiographs were taken 8 weeks following extraction to assess adequate bone healing within the extracted root, with subsequent radiographs taken every two weeks until adequate bone healing was achieved, which was deemed to be at 20 weeks. One-wall critical sized defects were then created at the extraction sites to yield four mandibular defect sites per dog. Treatment of defects were randomly assigned to receive SalvinOss® Xenograft Bone Graft Material or Bio-Oss® Xenograft Bone Void Filler. Following implantation with bone graft materials, the defects were covered with Bio-Gide® Dental Membrane and the gingiva was closed. Evaluations were conducted using Radiographic, Histologic and MicroCT analysis at 10, 16, and 24 weeks post-implantation. SalvinOss®, presenting with 10% more porosity than that of Bio-Oss®, demonstrates increased radio density at 10 weeks post implantation and equivalent radio density at 24 weeks post implantation. Microscopic evaluations confirm that the higher porosity SalvinOss® allows for the defect site to remodel with an equivalent volume of woven bone to that of Bio-Oss® within 24 weeks post implantation. SalvinOss® MicroCT scores show a continuous remodeling by increase in defect fill, and at 24 weeks presents with the maximum histologic score, implying that the material is completely incorporated with woven bone. Bio-Oss® MicroCT scores initially present with a high volume fill that reduces over the 24 week evaluation period.

MATERIALS:

XenoGraft Bone Graft Materials:

SalvinOss® Xenograft Bone Graft Material is a non-pyrogenic porous bone mineral matrix for use in periodontal, oral, and maxillofacial surgery. SalvinOss® is produced by removal of organic components from porcine bone utilizing trade-secret multi-step chemical and thermal processes that maintain the chemical and physical (i.e. – porosity) characteristics of native bone. SalvinOss® is sterilized by gamma-irradiation. Scanning Electron Microscope (SEM) imaging and Micro-Computed Tomography (MicroCT) analysis of granules charged into an analytical crucible present an average pore size of 153.8 microns with an estimated overall porosity of 68.06%. (Figure A)

Bio-Oss® is a granular porous bone mineral matrix produced by removal of organic components from bovine bone. Bio-Oss® is physically and chemically comparable to the mineralized matrix of human bone. Bio-Oss® is sterilized by gamma-irradiation. Scanning Electron Microscope (SEM) imaging and Micro-Computed Tomography (MicroCT) analysis of granules charged into an analytical crucible present an average pore size of 164.3 microns with an estimated overall porosity of 56.96%. (Figure B)

Barrier Membrane Material:

Bio-Gide® is a porcine-derived non cross-linked collagen membrane processed by standardized, controlled manufacturing techniques that remove non-collagenous components. Bio-Gide® is provided sterile via gamma irradiation in double blisters.

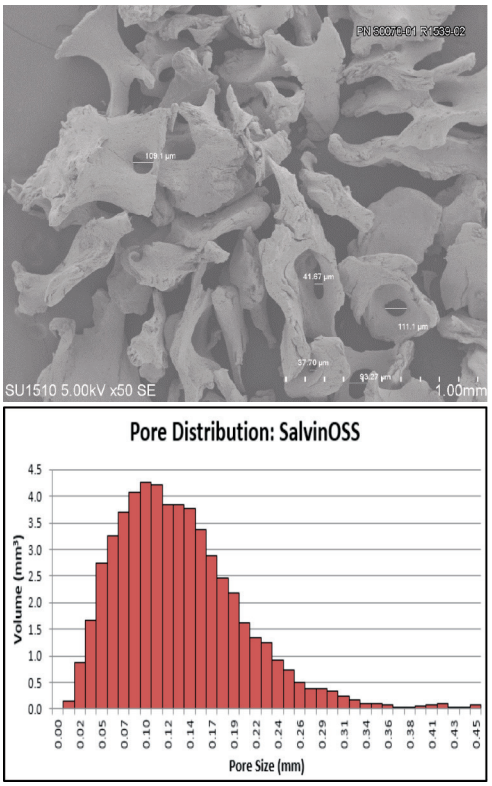


Figure A: *SEM Image of SalvinOss® At 50x magnification & MicroCT Graph Showing Pore Size Distribution*

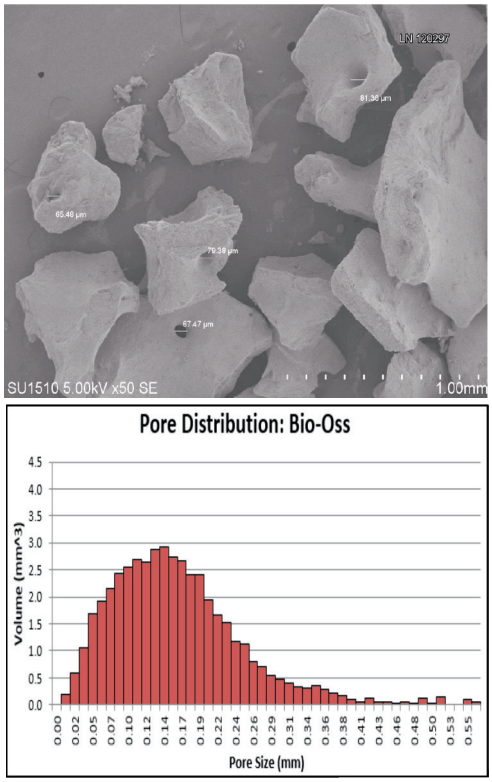


Figure B: *SEM Image of Bio-Oss® At 50x magnification & MicroCT Graph Showing Pore Size Distribution*

Methods for In Vivo Study:

In Vivo Study Subjects and Surgical Procedure:

Fifteen (15) male beagle dogs at least one year of age (skeletally mature) had second and fourth premolars (P2 and P4) extracted from the mandible bilaterally. Radiographs were taken 8 weeks following extraction to assess adequate bone healing within the extracted root, with subsequent radiographs taken every two weeks until adequate bone healing was achieved, which was deemed to be at 20 weeks. One-wall critical sized defects were then created at the extraction sites to yield four mandibular defect sites per dog. Reference notches were made into the root surface, at the base of the defects, of the adjacent P3 and M1 rostral roots. Treatment of the defects were randomly assigned to receive SalvinOss® or Bio-Oss®. Following implantation with bone graft material, the defects were covered with Bio-Gide® Dental Membrane and the gingiva was closed.

In Vivo Study Evaluation Methods:

Radiographic – Post-implantation radiographs were taken to evaluate new bone formation and any other radiographically visible changes immediately following implantation, and at 10 and 24 week evaluation time points. All radiographic images were taken using a Progeny VetVision DC (digital capture) machine. Radiographic observations are summarized in this report for the periodontal defect at time of Defect Creation, 10 and 24 week intervals. Representative radiographic images are included for 10 and 24 week intervals.

MicroCT – At 10, 16, and 24 weeks post-implantation, animals were euthanized and a total of 60 mandible specimens containing defect sites were harvested and forwarded for MicroCT analysis. Quantitative analysis of MicroCT images was used to determine average regenerated area within the defect sites in mandible specimens. Region of interest subsections were isolated from the data sets, thresholded, and analyzed. The metric of average regenerated area was used to compare the SalvinOss® test group to the Bio-Oss® test group.

Histology – After MicroCT analysis at 10, 16, and 24 weeks post-implantation, mandible specimens containing the defect sites were fixed and histologically processed for evaluation. For each defect site, an approximately 2 mm thick segment was collected in a central plane along the axis of the tooth/jaw (mesial-distal vertical plane). This segment was placed into a cassette and allowed to fix further in 10% neutral buffered formalin. Tissues were then decalcified using a buffered formic acid solution. After decalcification, tissues were processed for paraffin embedding. Sections approximately 5 microns thick were collected from the cut surface of the section at the first full block face. Multiple step sections were collected as necessary to capture/demonstrate the center of the tooth root canal and other landmarks (i.e. notch in tooth root, periodontal ligament, cementoenamel junction). Whenever possible, sections from three levels of the defect area were obtained, and at least 2 levels were obtained from each defect site. Slides were stained with Masson's trichrome. A board certified veterinary pathologist performed the histologic examination using incandescent and polarized light microscopy. Woven bone regeneration was evaluated via Masson's trichrome staining at 10, 16, and 24 weeks. The amount of bone regeneration was scored on the following scale:

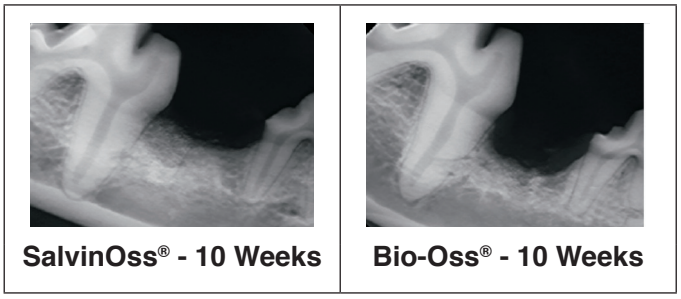
0 = regeneration not evident;
1 = some regeneration is evident;
2 = regeneration is evident, but not complete;
3 = regeneration appears complete

Results for In Vivo Study:

Radiographic Evaluation:

Defect Creation – Dental radiographs were taken following the creation of the one-wall critical sized periodontal defect and placement of the test articles. Both test articles were radiographically visible. The adjacent P3 and Ml roots associated with each defect appeared healthy, and the defect notch was visible within the rostral roots.

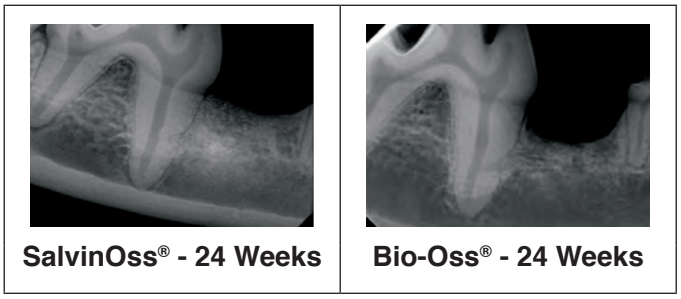
10 Week Interval – Both test articles were visible. Adjacent P3 and M1 roots notched during defect formation were visible and showed no evidence of root resorption. The SalvinOss® sites had an increased amount of radio density, suggesting more bone formation than the Bio-Oss® sites at this time point. (Figure C)



SalvinOss® - 10 Weeks	Bio-Oss® - 10 Weeks

Figure C:
Radiographic Images of SalvinOss® & Bio-Oss® (10 Weeks)

24 Week Interval – By this interval, all defect sites had become difficult to distinguish radiographically from surrounding bone due to new bone formation within the defect with remodeling and associated article absorption. All test sites had noticeably increased radio density and development of interradicular bone by the 24 week interval compared to the 10 week time point. Adjacent P3 and Ml roots notched during defect formation were visible and showed no evidence of root resorption. (Figure D)



SalvinOss® - 24 Weeks	Bio-Oss® - 24 Weeks

Figure D:
Radiographic Images of SalvinOss® & Bio-Oss® (24 Weeks)

MicroCT Evaluation:

The Bio-Oss® test group initially exhibited a high average regenerated area of 18.9 mm^2 at 10 weeks, which reduced to 16.1 mm^2 at 16 weeks and to 14.9 mm^2 at 24 weeks. This decrease in regenerated area is likely due to the resorption of the Bio-Oss® material. The average regenerated area for the SalvinOss® test group increased between 10 and 16, and 16 and 24 weeks. Average regenerated area for the 16 and 24 week time points are statistically equivalent for the two materials. (Table A)

Table A: *Average Regenerated Area At 10 weeks, 16 weeks, And 24 weeks.*

SalvinOss®	***Regenerated Area (mm^2)***	***Percent Regenerated Area (%)***
10 Weeks	*13.5 ±5.4*	*52.8 ±21.4*
16 Weeks	*13.8 ±2.7*	*54.3 ±10.6*
24 Weeks	*17.1 ±5.2*	*67.5 ±20.3*
Bio-Oss®	***Regenerated Area (mm^2)***	***Percent Regenerated Area (%)***
10 Weeks	*18.9 ±1.3*	*74.3 ±5.0*
16 Weeks	*16.1 ±5.0*	*63.2 ±19.7*
24 Weeks	*14.9 ±4.2*	*58.8 ±16.7*

Microscopic Evaluation:

The average woven bone regeneration for SalvinOss®, Bio-Oss®, and a baseline control are presented in Figure E. Average woven bone regeneration scores for SalvinOss® increased throughout the study period, achieving a score of 3 at the final 24 week time point. Bio-Oss® average woven bone regeneration score decreased between 10 and 16 weeks and then increased to 2.5 by the final 24 week time point. Both SalvinOss® and Bio-Oss® supported formation of new woven bone within the treatment site with the final volume of woven bone between the two treatment modalities being similar. (See Figures F & G)

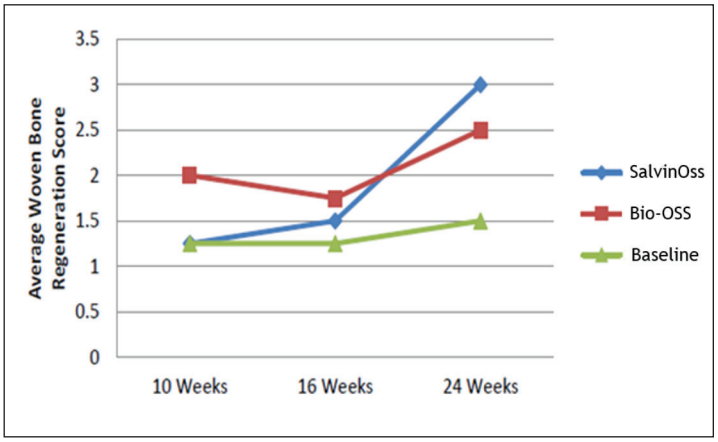


Figure E: *Woven Bone Regeneration Scores From Microscopic Evaluation*

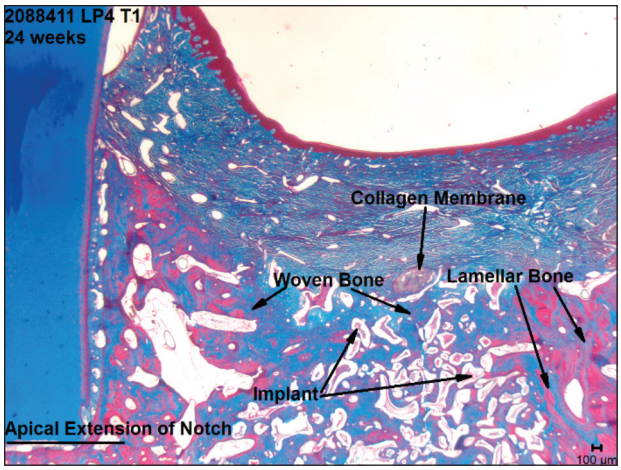


Figure F: *SalvinOss® – (T1) – 24 Weeks Post-Op*

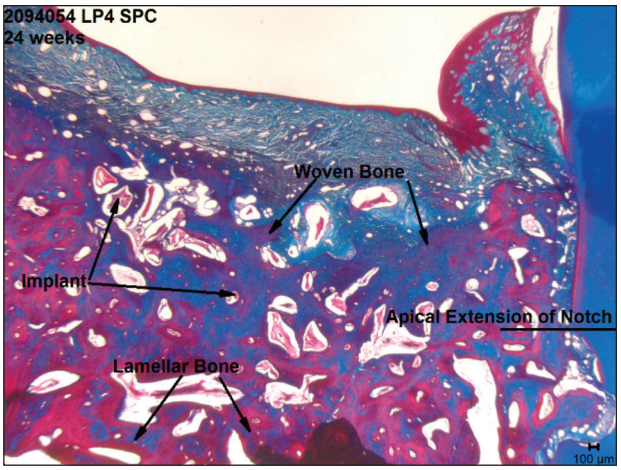


Figure G: *Bio-Oss® – (SPC) – 24 Weeks Post-Op*

DISCUSSION:

SalvinOss® Xenograft Bone Graft Material, manufactured using a proprietary multi-step chemical and thermal process, presents with 10% more porosity then that of Bio-Oss® within the implantation site. Even though substantially more porosity exists within the SalvinOss® surgical site, radiographic evaluations demonstrate increased radio density at 10 weeks post implantation and equivalent radio density at 24 weeks post implantation.

Microscopic as well as MicroCT evaluations, confirm that the higher porosity SalvinOss® Xenograft Bone Graft Material allows for the defect site to remodel with an equivalent volume of woven bone to that of Bio-Oss® within 24 weeks post implantation. In fact, SalvinOss® MicroCT scores show a continuous remodeling by increase in defect fill, and at 24 weeks presents with the maximum histologic score, implying that the material is completely incorporated with woven bone. In contrast, Bio-Oss® MicroCT scores initially present with a high volume fill that reduces over the 24 week evaluation period.

It is apparent from the above summary of testing that use of the porous SalvinOss® Xenograft Bone Graft Material will result in an increasing volume of new bone formation within the surgical site throughout 24 weeks of healing time.

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