

A Prospective Randomized-controlled Study of Endobon[®] Used in Extraction Sites: A Clinical and Histological Evaluation

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Figure 1. Example of a histological section of a tissue punch sample. A transverse section of the epithelium is visible in the bottom portions. Remnants of the OsseoGuard membrane stain green.



Figure 2. Example of a histological section of a portion of trephine core sample. Upon removal some additional bone material outside of the drill tip was removed illustrating the range of the grafted portion that was taken up by trephine drill. Native bone is darker than the Bio-Oss (straw-colored) collected in this section.



Figure 3. Example of a histological section of a trephined Bio-Oss core sample. On the upper center portion of the core are Bio-Oss particles (buff-colored) and *de novo* bone that stains orange. Native bone is darker than the xenograft and *de novo* bone in this section. Stevenel's blue and Van Gieson's fuchsin (magnification 50x).

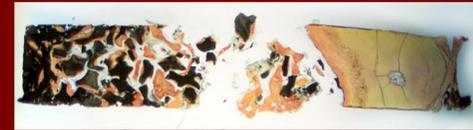


Figure 4. Example of a histological section of a trephine core sample. On the left side of the image is Endobon particles (dark grey) and *de novo* bone that stains orange. Stevenel's blue and Van Gieson's fuchsin (magnification 30x).

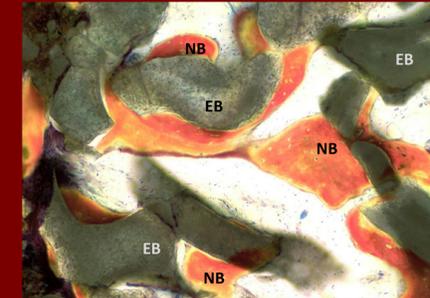


Figure 6. Formation of new bone (NB) demonstrating a cancellous bone network. At 24 weeks of extraction site healing, graft integration and bone bridging with Endobon xenograft material (EB) is present. Stevenel's blue and Van Gieson's fuchsin (magnification 200x).

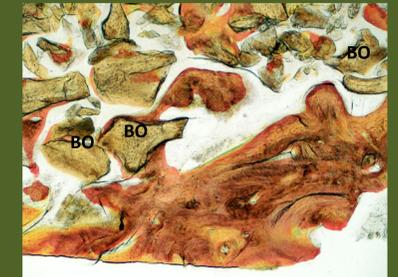


Figure 7. Histologic evaluation of bone samples collected after 24 weeks of extraction site healing. Bio-Oss (BO) graft integration with *de novo* bone formation is observed. Stevenel's blue and Van Gieson's fuchsin (magnification, 100).

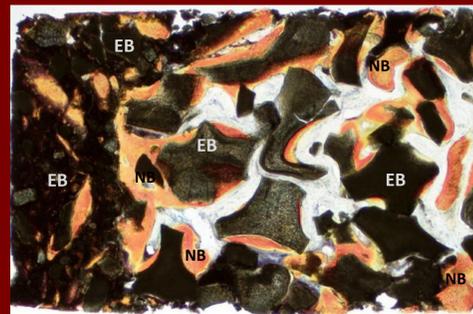


Figure 5. Formation of new bone (NB) after 24 weeks of extraction site healing. Graft integration and bone bridging with Endobon granules (EB) is present. Stevenel's blue and Van Gieson's fuchsin (magnification 100x).

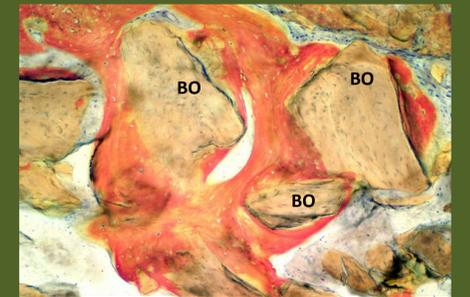


Figure 8. Histologic evaluation of bone samples collected after 24 weeks of extraction site healing. Bio-Oss (BO) particles were found encased in bone matrix or integrated with *de novo* bone. Stevenel's blue and Van Gieson's fuchsin (magnification, 200).

Abstract

OBJECTIVE: This prospective randomized-controlled study compares the quality of *de novo* bone generated in large tooth extraction sites after grafting with two brands of xenograft: Endobon[®] and Bio-Oss[®]. **MATERIALS AND METHODS:** Patients needing at least two tooth extractions in the premolar or molar regions on the same day are included in the study. The sites are randomly assigned to either a test or control group: Endobon (test) or Bio-Oss (control). The grafted sites are covered with a resorbable collagen membrane (OsseoGuard) in order to avoid the loss or movement of any grafting material without the need for releasing incisions to achieve marginal closure. After six months of healing, dental implants are placed. Graft maturation is assessed by the histological analysis of bone samples obtained from the grafted sites during osteotomy preparation. Patients are seen thereafter every six months for another two years to evaluate dental implant performance. **RESULTS:** At this interim analysis a total of 39 patients are enrolled with 78 treated extraction sites. A total of 66 bone cores were suitable for histological evaluation with 30 from test sites and 36 from control sites. A total of 74 Osseotite or NanoTite Tapered implants were placed and are being followed. The percent vital bone for the test group is 29.10% and for the control group 27.31%. Because both test and control cases are in the same patient all baseline variables are similar allowing a comparison of performance and success rates between treatment groups. All but one implant integrated successfully and a total of two implant failures are recorded for an overall success rate of 97.3% at one year. **CONCLUSIONS:** In this study, extraction sites treated with both types of bovine xenografts were found to have *de novo* bone formation and provide a functional anchorage for dental implant placement.

Materials and Methods

Patients requiring removal of at least 2 premolar or molar teeth on the same day had the fresh extraction sites filled with either Endobon[®] (test group)(Biomet3i) or Bio-Oss[®] (control group) (Osteohealth) bovine xenograft sterile granules of 500-1000 µm in diameter. All sites were covered with OsseoGuard (Biomet3i) resorbable collagen membrane to contain grafting material.

After approximately six months of healing, osteotomies were prepared for dental implant placement. A tissue punch was used to expose the implant area and the tissue within the punch was collected and analyzed by histology for evidence of membrane remnants. Bone material collected within trephine drills that were included in the osteotomy preparation were assessed by histological analysis.

Insertion torque force and resonance frequency analysis were recorded. Implant integration and maintenance of integration while supporting a prosthesis is monitored over a total of two years.

Results

A total of 39 patients are enrolled across the five participating centers. Average age at time of enrollment was 51.5 ± 14.7 years. Gender distribution is 53% male and 47% female. Twenty-six percent of patients admitting to a smoking habit of an average of 10 cigarettes per day at screening. A total of 80 tooth sites were extracted and treated.

Most sites (98.2%) are located in posterior regions of the mouth and slightly more in maxillary positions (54.5%). In addition to the bovine xenograft used in the cases, investigators recorded any additional materials used in preparing the graft material for insertion. In all cases there was some pre-hydration with either the patient's blood 25% or with saline 75%. A total of 66 bone cores were suitable for histological evaluation with 30 from test sites and 36 from control sites.

Implants Outcomes

A total of 77 Osseotite or NanoTite Tapered implants were placed into the treated sites and are being followed for maintenance of integration while supporting prostheses. To date, one implant from the control treatment group has been declared a failure prior to loading.

Histological Outcomes

The percent vital bone for the test group is 29.10% and for the control group 27.31%. Because both test and control cases are in the same patient all baseline variables are similar allowing a comparison of implant performance and success rates between treatment groups.

Conclusions The histological and clinical outcomes recorded in this prospective randomized-controlled study of extraction sites treated with bovine xenografts found similar proportions of *de novo* bone formation and functional anchorage for dental implant placement.

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