- Official Title: Clinical, Radiographic and Histomorphotmetric Analysis of Healing Dynamics in Human Extraction Sockets Grafted With Bio-Oss Collagen®: A Prospective 3-year Post-loading Study
- NCT Number: NCT03659617
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Objective: The purpose of this study is to clinically, radiographically and histologically evaluate the healing sequence of post-extraction sockets grafted with Bio-Oss Collagen® at 3, 6 and 9 months following tooth extraction in single-rooted tooth sites.

Design: This is a randomized clinical trial (*NCT03659617*). The study population consists of adult subjects (ages 18-95) that a single-rooted tooth (except the incisors of the lower jaw) indicated for extraction. Subjects cannot have significant heart, stomach, liver, kidney, blood, immune system disease, or other organ impairment or systemic diseases that would prevent undergoing the proposed treatment or may result in compromised healing (e.g. poorly controlled diabetes, active heavy tobacco use [>10 cigarettes/day])

Methods: Consented subjects will be randomized to one of three groups. Randomization will be done as 1:1:1. Therefore, subjects will have a 33% chance of being randomized to a group where they will have implant placement either after three, six, or nine months after implant placement.

Statistical Analysis Plan: The distribution of the data intergroup is expected to exhibit normality, and for this reason the statistical tests that will be utilized for data analysis are parametric. Nevertheless, prior to the conduction of any parametric test, Wilcoxon Signed Rank tests will be performed to verify the normal distribution of the data. Histomorphometric data will be expressed as the percentage of vital bone, remaining xenograft particles and non-mineralized connective tissue respective to the total sample area. The statistical analyses for these three different compartments will be performed independently: One-way Analysis of Variance (ANOVA) test will be performed to evaluate the differences in the percentage of each specific compartments between the three time points (3, 6 and 9 months). The percentage of each compartment evaluated will be the dependent variable and the time will be the independent variable. This test will probe the null hypothesis that is established as 'no difference in percentage of vital bone, remaining xenograft particles and non-mineralized connective tissue at the different harvesting time points'. The significance level will be set at 0.05 and the Bonferroni method for correction will be applied. False positive rate will be calculated, as well. The volumetric and linear data obtained from the CBCT scans will be analyzed using the same test utilized for the histomorphometric data analyses, setting the significance level at 0.05, the Bonferroni method will be applied and the false positive rate will be calculated. WHI values obtained at the three different time points (3, 6 and 9 months) will be analyzed using the Kruskal-Wallis test. The null hypothesis states that no differences in WHI will be found at different time points. Likewise, the self-

reported level of discomfort will be compared using the Kruskal-Wallis test. The level of discomfort and the post-op visits will be the dependent and independent variable respectively. The significance level will be set at 0.05. Other variables recorded in this study will be expressed as a percentage (i.e. implant survival rate) or presented using descriptive statistics (i.e. marginal bone level). These variables are not expected to be representative of meaningful changes and, consequently, no analytical statistics are initially planned. However, the data will be assessed upon collection and suitability of appropriate analyses will be determined upon data distribution.