Study Synopsis

Title:
Ridge Preservation for Dental Implant: A Clinical and Histomorphometric Comparison Study

Purpose:

The purpose of this clinical study is to evaluate the effect of growth factors mixed with a bone substitute on the healing of the gum and bone formation at the tooth extraction site. Approximately 24 patients will be included in the study.

Objective(s)

The primary objective of this study is to:
Evaluate the histological effect of adding growth factors to a bone graft material.

The secondary objective of this study is to:
Evaluate the effect of adding growth factor on wound closure rate.

Study Design and Methodology:

This is a single center, two-year, randomized clinical study.

Planned Number of Subjects:

It is estimated that 24 subjects will be enrolled in the two-year study. It is expected that few enrolled subjects will withdraw prematurely.

Diagnosis and Main Criteria for Inclusion:

This study will evaluate male and female subjects 18-70 years in need of a single tooth extraction with a desire to receive a dental implant.
Study Treatment:

Each subject will undergo extraction of a single tooth. The following parameters will be evaluated:

- Soft tissue closure
- Vital bone formation at the time of implant placement

Study Duration:

The study will last 24 months. Evaluation will be done at the following time periods:

- Baseline
- One week
- Two weeks
- Three weeks
- Four weeks
- Twelve weeks (at the time of implant placement)

Criteria for Evaluation and Statistical Methods:

- Efficacy:

Digital photographs, clinical research forms, and periodontal chart forms will be used as methods of documentation in this study. Subjects will be examined by the co-investigator at baseline, 1 week, 2 weeks, 3 weeks, 4 weeks, and 12 weeks. A mirror, a periodontal probe, a caliper, and digital photographs will be the tools used for the examinations. Soft tissue closure will be assessed using the periodontal probe. Percentage of vital bone will be assessed in the histology lab after taking bone samples. One examiner, who is calibrated, will perform the evaluation. ANOVA will be used to calculate the difference between the test and control groups.
• Safety:

The dental examiner will conduct oral soft and hard tissue examinations before and after treatment, adverse events spontaneously reported by the subjects will be captured.
Ridge Preservation for Implant: A Clinical and Histomorphometric Study Comparing PRF+ CS, PRP+Cs, and Un-rafted (Collaplug) Sites

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