Reconstructive Surgical Treatment of Peri-Implant Bone Defects: Application of a Bovine Xenograft and Resorbable Membrane With or Without Enamel Matrix Derivatives: A Multicenter Randomized Clinical Trial. 5 years follow up.

TECHNIQUE UNDER INVESTIGATION

Use of a bovine xenograft and a collagen membrane with (test group) or without (control group) the adjunctive application of enamel matrix derivative proteins.

STUDY CENTERS

- Ortiz-Vigón & Carnicero Clinic, Bilbao, Spain.
- PerioCentrum Reina Mercedes, Madrid, Spain.

STUDY PRODUCTS

Straumann Xenograft: Bovine cancellous bone particles.

Straumann GBR Membrane: Native collagen membrane derived from porcine pericardium, developed and manufactured for dental tissue regeneration.

Straumann Emdogain: Enamel matrix derivative proteins.

GENERAL ASPECTS OF THE CLINICAL TRIAL

Number of subjects: 40 patients (20 per group).

Number of centers: 2.

Type of defects: Radiographically identified peri-implant intraosseous defects ≥3 mm in depth. Intraoperatively, defects must present with at least three or four bony walls, a width ≤4 mm, and a depth >3 mm.

STUDY GROUPS

Test Group

- Straumann Xenograft (bone graft)
- Straumann GBR Membrane (collagen membrane)
- Emdogain (enamel matrix derivative proteins)

Control Group

- Straumann Xenograft (bone graft)
- Straumann GBR Membrane (collagen membrane)

STUDY PERSONNEL

Study Director: Alberto Ortiz-Vigón (Arrow Development SL).

Principal Investigator and Sponsor: Alberto Ortiz-Vigón.

Study Collaborators: Ramón Lorenzo, Fabio Vignoletti

Study Coordinator and Monitor: Erik Regidor.

STUDY DURATION

Total duration: 60 months (5 years).

Study start: Following approval by the Ethics Committee.

LEGAL CONSIDERATIONS

This clinical investigation will be conducted in accordance with Spanish legislation governing clinical research involving human participants. Study initiation is based on a research protocol developed by Arrow Development SL and conducted at the Ortiz-Vigón Clinic and PerioCentrum Reina Mercedes.

STUDY DESIGN

Prospective, randomized, multicenter clinical trial with a duration of 60 months.

The objective is to evaluate and compare the effect of enamel matrix derivative proteins used in combination with a resorbable collagen membrane and xenograft during reconstructive surgical treatment of peri-implant bone defects around non-submerged dental implants, compared with treatment using xenograft and collagen membrane alone.

HYPOTHESIS

The use of enamel matrix derivative proteins in conjunction with a resorbable membrane and a xenograft provides additional clinical benefits in the treatment of peri-implant bone defects when compared with treatment using xenograft and membrane alone.

RATIONALE

To date, no randomized clinical trials with sufficiently long follow-up periods have assessed the additional benefit of enamel matrix derivative proteins when used simultaneously with xenograft and collagen membrane reconstruction of peri-implant bone defects.

STUDY OBJECTIVES

Primary Objective

Treatment success defined as:

- Absence of bleeding on probing and/or suppuration;
- Probing pocket depth (PPD) ≤ 5 mm;
- Marginal mucosal recession ≤ 1 mm.

Secondary Objectives

- Evaluate radiographic defect fill on periapical radiographs.
- Assess the risk of complications in both groups.
- Evaluate patient-reported outcome measures (PROMs).
- Measure surgical intervention time and postoperative analgesic requirements.
- Assess volumetric changes through STL file comparisons.

RANDOMIZATION AND BLINDING

Patients will be randomly allocated using computer-generated blocked randomization (block size = 4).

Allocation concealment will be maintained until the time of surgery. The surgeon will know the assigned treatment, whereas the clinical examiner and statistician will remain blinded throughout the study.

FOLLOW-UP PERIOD EXTENDED TO 5 YEARS

6 Months (26 Weeks)

- Intraoral photographs
- Intraoral radiographs
- Intraoral scan
- Probing depth measurements
- Recession measurements
- Plaque index
- Bleeding index
- Width of keratinized mucosa
- Supportive periodontal therapy
- Oral hygiene instructions
- Patient satisfaction questionnaire

12 Months (52 Weeks)

- Intraoral photographs
- Intraoral radiographs
- Intraoral scan
- Probing depth measurements
- Recession measurements
- Plaque index
- Bleeding index
- Width of keratinized mucosa
- Supportive periodontal therapy
- Oral hygiene instructions
- Patient satisfaction questionnaire

2-Year Follow-up

- Intraoral photographs
- Intraoral radiographs
- Probing depth measurements
- Recession measurements
- Plaque index
- Bleeding index
- Width of keratinized mucosa
- Supportive periodontal therapy
- Oral hygiene instructions

3-Year Follow-up

- Intraoral photographs
- Intraoral radiographs
- Intraoral scan
- Probing depth measurements
- Recession measurements
- Plaque index
- Bleeding index
- Width of keratinized mucosa
- Supportive periodontal therapy
- Oral hygiene instructions
- Patient satisfaction questionnaire

4-Year Follow-up

- Intraoral photographs
- Intraoral radiographs
- Probing depth measurements
- Recession measurements
- Plaque index
- Bleeding index
- Width of keratinized mucosa
- Supportive periodontal therapy
- Oral hygiene instructions

5-Year Follow-up

- Intraoral photographs
- Intraoral radiographs
- Intraoral scan
- Probing depth measurements
- Recession measurements
- Plaque index
- Bleeding index
- Width of keratinized mucosa
- Supportive periodontal therapy
- Oral hygiene instructions
- Patient satisfaction questionnaire

PRIMARY OUTCOME VARIABLE

Probing Pocket Depth (PPD)

Measured at six sites per implant at baseline, 6 months, 12 months, 3 years, and 5 years.

Three measurements will be obtained on the buccal aspect (mesial, mid-buccal, distal) and three on the lingual/palatal aspect (mesial, mid-lingual/palatal, distal).

SECONDARY OUTCOME VARIABLES

Radiographic Defect Fill assessed using standardized intraoral radiographs.

Mucosal Recession measured at baseline, 6 months, 12 months, 3 years, and 5 years.

Bleeding on Probing (BoP) measured at six sites per implant at baseline, 6 months, 12 months, 3 years, and 5 years.

Presence/Absence of Plaque assessed using a dichotomous plaque index at baseline, 6 months, 12 months, 3 years, and 5 years.

Complications, including membrane exposure during healing.

Surgical Time recorded in minutes.

Patient Satisfaction evaluated throughout all follow-up visits, including the 3-year and 5-year evaluations.