Straumann BLT CIR-ECL-2016-03

STATISTICAL ANALYSIS

Study Number: CIR-ECL-2016-03
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Department: Oral and Maxillofacial Surgery
Research Line: Oral Invalidity
Research Title: Evaluation of marginal bone loss in Straumann® BLT implants in patients with posterior partial edentulism. A randomized clinical study comparing direct implant connection vs. intermediate abutment.

1. OBJECTIVES

The primary objective of the study is to compare the radiographic evolution of implants between two surgical techniques: direct connection vs. intermediate abutment.

2. SAMPLE AND STATISTICAL METHODOLOGY

The study sample consists of 30 patients undergoing rehabilitation with implants in two posterior sector positions. The group includes 22 men (73.3%) and 8 women (26.7%), divided into two groups according to the applied technique:

- **Direct connection group (control):** n=12 patients
- **Intermediate abutment group (test):** n=18 patients

The test group is further subdivided into two subgroups based on abutment height:

- **Subgroup H1 mm:** n=7 patients
- **Subgroup H2.5 mm:** n=11 patients

Since each patient contributes two implants (mesial and distal) to the study, the previous figures are doubled at the implant level, totaling 60 implants:

- **Direct connection group (control):** n=24 implants
- **Intermediate abutment group (test):** n=36 implants
- **Subgroup H1 mm:** n=14 implants
- **Subgroup H2.5 mm:** n=22 implants

The study design corresponds to an RCT with multilevel data: patient and implant.

The study collects **bone level (BL) measurements** in the mesial and distal areas of each implant at different time points:

- **T1 (surgery)**
- **T2 (crowns placement)**
- **T3 (4 months)**
- **T4 (6 months)**
- **T5 (12 months)**
- **T6 (24 months)**

Bone loss (MBL) at each time point **Tj** is calculated as the difference between **T1 and Tj**, following the investigator's database example:
Example: **MBL T1T6 = BL T1 – BL T6.**

Descriptive analysis provides key statistics for all variables collected in the study: absolute and relative frequencies (for categorical variables) and mean, standard deviation, range, median, and quartiles (for continuous variables). A complete report of this analysis is available in an appendix, presented in table format.

The radiographic variables **BL and MBL** are described for each zone (mesial and distal) of each implant (mesial and distal) and also averaged for mesial implants, distal implants, and total implants (mean of both).

A **Shapiro-Wilk test** was conducted to verify the normal distribution of **MBL** across different time points and within each group, yielding a confirmatory result (**p>0.05**).

Inferential Analysis

To study the dependent variable **MBL**, linear models under the **GEE (Generalized Estimating Equations) approach** are applied to assess mean differences by group. **Beta coefficient estimates** with **95% confidence intervals (CIs)** are obtained using the **Wald Chi-square statistic**.

The **GEE analysis methodology** is justified due to the intra-subject correlation inherent in the multi-level data structure (patients contribute multiple implants to the study).

The **same GEE methodology** is used to examine the effect of **intermediate abutment height** within the test group.

Similar linear models were applied to evaluate **overall bone loss progression** over the follow-up period and to analyze potential differences between mesial and distal implant positions or between mesial and distal areas within an implant.

Conventional association tests (**Chi-square, Fisher's exact test**) were used at the patient level to assess the **homogeneity of the test and control groups**.

The **significance level** used in the analyses was **5% (α=0.05)**.

A general **linear model** as described achieves **70% power** to detect a mean **MBL difference corresponding to a large effect size (d=0.8)** between groups with **95% confidence**. This power accounts for the dependency between observations, assuming **a total of 60 implants in 30 different patients** and a **moderate intra-class correlation (ICC=0.5)**.