The Influence of Alveolar Bone Drilling and Anatomical Position on the Primary Stability, Integration, and Function of an Immediately Placed Dental Implant

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Tooth extraction and subsequent implantation will be performed under local anesthesia. After tooth extraction, an osteotomy is performed in the tooth socket to create a bed for the implant. The patients will be divided into groups based on the bone condition after tooth extraction:

1. Group 1 includes patients with a standard immediate implantation situation, where there is substantial bone apical to the tooth root tip after extraction.
2. Group 2 includes patients where there is no bone apical to the tooth root and the implant is placed without drilling, obtaining mesiodistal stability.
3. Group 3 includes patients where there is bone between the roots of the extracted tooth.
4. Group 4 includes patients where bone is present in the former location of the palatal root.

After implant placement following parameters will be measured:

- Implant insertion depth and horizontal position with a periodontal probe, Implant Stability Quotient (ISQ), scanning of the implantation site with an intraoral scanner, and a 1-year follow-up examination.
- Torque (Ncm) will be measured with a standard implant insertion torque wrench.
- The Implant Stability Quotient (ISQ) will be measured non-contactually with the Ostell Mega ISQ II device. [A magnetic component (SmartPeg) is screwed onto the implant. The Ostell Mega ISQ II device is held 3mm away from the component and sends magnetic impulses to the component. The component vibrates at its resonance frequency, which depends on the amount of bone-to-implant contact. The device records the frequency, converts it into the Implant Stability Quotient (ISQ), and displays a value from 1 to 100 on the screen.]
- Implant depth and horizontal implant position will be measured with a periodontal probe after implant insertion, by gently pressing it against the gingiva.
- Periapical radiographs of the inserted implant will be taken using an X-ray machine.
- Intraoral scanner – teeth, gingiva, and the implant insertion site will be scanned non-contactually.

A temporary healing abutment or a temporary tooth will be attached to the implants, and the gingiva will be sutured. After 8 weeks - the scan for implant prosthetics. The prosthesis is delivered. One-year follow-up visit for examination.

The following data will be collected during the one-year follow-up visit:

- Marginal bone level via radiological examination
- Determination of the Pink Esthetic Score (PES) index
- Determination of the Plaque Index (PI)
- Determination of the Probing Pocket Depth (PPD)
- Determination of the Bleeding on Probing (BOP) index
- Non-contact implant scanning with an intraoral scanner

Primary outcome measures:

1. Implant integration

Secondary outcome measures:

1. Implant insertion torque;

2. Implant insertion depth upon placement and after integration;

3. Marginal bone stability after prosthesis delivery and after one year;

4. Determination of the Pink Esthetic Score (PES) index after prosthesis delivery and after 1 year;

5. Determination of the Implant Stability Quotient (ISQ) value upon implant placement and after integration;

6. Determination of the Plaque Index (PI) after prosthesis delivery and after 1 year;

7. Determination of Probing Pocket Depth (PPD) after prosthesis delivery and after 1 year;

8. Determination of the Bleeding on Probing (BOP) index after prosthesis delivery and after 1 year.

Statistical analysis

The sample size was calculated based on the primary study outcome—implant survival. Based on a large-scale retrospective study, the survival rate of immediately placed implants reaches 98.4% (1). The null hypothesis states that all study groups (N=4) are non-inferior in efficacy, meaning that implant survival reaches 98.4% in all groups. A clinically significant reduction in the implant survival rate will be considered as 10%. Based on this data, to achieve 80% power, with a one-sided α, corrected for multiple comparisons between groups, of 0.0167, a minimum sample size of 104 implants will be required, with a distribution among the study groups of $\sqrt{3}:1:1:1 \approx 38:22:22:22$. The probability of dropout will be compensated by increasing the sample size by 20%, thus a total of 124 implants are planned to be placed in the study (31 implants per group). Statistical analysis will be performed using R software (v. 4.0.4). Measures calculated will include: mean, standard deviation (SD), median, and available number of observations. Categorical variables will be presented as absolute numbers and percentages. To test hypotheses related to the comparison of quantitative variables between two groups, the Student's T-test or the non-parametric Mann-Whitney U test will be used, respectively. To test hypotheses related to the comparison of quantitative variables among more than two groups, one-way analysis of variance (ANOVA) or the non-parametric Kruskal-Wallis test will be used, respectively. Normality will be checked using the Shapiro-Wilk test. For comparing two dependent quantitative variables (baseline measurement and X weeks post-treatment), the paired t-test or Wilcoxon Sign Rank test will be used. Correspondingly, to determine the relationship between torque and ISQ, Spearman's correlation will be used. A P-value less than 0.05 will be considered statistically significant.
The pilot study will not have sufficient power for evidence—all intergroup tests will be exploratory. Power analysis will be calculated to determine the required number of subjects based on the obtained results in order to achieve statistical significance.