Retrospective Evaluation of Prosthetic Complications and Peri-implant Bone Resorption in Implant-Supported Single Unit Fixed Restorations

Study Protocol

Date: 07.04.2023

Department of Prosthetic Dentistry

Afyonkarahisar Health Sciences University, Faculty of Dentistry

Pre-assignment Details

Participants included in the study were later excluded from the analysis due to reasons such as missing data in patient records, the presence of data outside the specified time frame, patients initially thought to meet the study criteria being incorrectly coded, or medical records being in an unsuitable format or unreadable.

Arm/Group Information

This study does not include any specific study or control groups. The research focuses on the follow-up of participants with certain characteristics over a specified time period.

Type of Units Assigned

- **Period(s):** This is a retrospective study following a 12-month period.
  Period Title: Overall Study
  Started: This study was conducted by including patients 12 months after delivery of the implant-supported restoration. The sample was completed when a total of 100 patients were reached.
  Completed: The number of participants at the end of the study is 100.

Baseline Characteristics

- **Arm/Group Information:** There were no separate groups in the study. The study included a 12-month follow-up of participants with implant-supported single-unit restorations.
  Arm/Group Title: There were no separate groups in the study.
- **Baseline Analysis Population Information**
  Overall Number of Baseline Participants: 100 participants
- **Baseline Measure Information**
  Baseline Measure Title
  Age: Age, Continuous
  Sex/Gender: Female, Male
- **Measure Type:** Count of Participants

- **Measure of Dispersion:** Not Applicable
- **Baseline Measure Data: Not Available.** The study does not have any baseline data, because the data in the study only includes data from participants at the end of the 12-month follow-up.
- **Unit of Measure:** Not Available

Outcome Measures:

- **Outcome Measure Information:** Implant survival and prosthetic complication rate
  Outcome Measure Type: Primary
  Outcome Measure Title: Implant survival and prosthetic complication rate
  Outcome Measure Time Frame: 12 months after delivery of implant-supported restoration
  Arm/Group Information: There were no separate groups in the study. The study included a 12-month follow-up of participants with implant-supported single-unit restorations.

  Analysis Population Information:
  Overall Number of Participants Analyzed: 100 participants
  Outcome Measure Data Table
  Measure Type: Count of Participants
  Measure of Dispersion/Precision: Not Applicable
  Outcome Measure Data: The effect of prosthetic, anatomical and surgical parameters on implant survival rate and prosthetic complications
  Unit of Measure: Implant survival and prosthetic complications rate
  Statistical Test of Hypothesis:
  P-Value: $p<0.05$
  Method: Chi-Squared

Adverse Event Information: Since this is a retrospective analysis, adverse events were not evaluated.

Certain Agreements:

- **Are all PIs Employees of Sponsor?** Yes: The principal investigator is an employee of the sponsor

Results Point of Contact:

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This retrospective study included 100 volunteer patients aged between 30 and 77 who presented at the Department of Prosthetic Dentistry at Afyonkarahisar Health Sciences University Faculty of Dentistry for prosthetic treatment and received a single-unit implant-supported crown. The evaluation of the included patients was conducted during their 12-month follow-up control appointments after prosthetic loading. After obtaining oral and written consent from the patients, demographic data, prosthetic complications related to single-unit fixed implant-supported prostheses, and peri-implant bone loss assessed via radiographic controls were recorded and analyzed. During clinical examinations, the compatibility of the prostheses with adjacent teeth and gingiva, the presence of gingival recession, patient complaints about the prosthesis, and any prosthetic complications were assessed and recorded. Statistical analyses were performed retrospectively after evaluating the collected data.

Ethical Approval for the Study

Since participation in this study was voluntary and conducted with volunteers, it was reviewed by the Clinical Research Ethics Committee of Afyonkarahisar Health Sciences University. The study was unanimously deemed to comply with medical ethical standards (Date: 07.04.2023, Protocol Code: 2023/4). All volunteers signed an informed consent form approved by the ethics committee before participating in the study.

Volunteer Selection

This study included 100 volunteer patients who applied to the Department of Prosthetic Dentistry at Afyonkarahisar Health Sciences University Faculty of Dentistry for prosthetic treatment and received a single-unit implant-supported crown. Patients were selected from archives and evaluated during their 12-month follow-up appointments through clinical and radiographic examinations. To determine the number of volunteers needed for the study, a sample size calculation was performed using G*Power software (G*Power Ver. 3.0.10, Franz Faul, University of Kiel, Germany). With a significance level of $\alpha=0.05$ (95% confidence interval), an effect size (d) of 0.5, and power ($1-\beta$) = 0.80, at least 80 patients were required. To account for potential dropout and data loss during follow-up, an additional 25% (20) patients were added, resulting in 100 patients at the start of the study.

Systemic and dental anamneses of the volunteers were thoroughly evaluated, and inclusion and exclusion criteria were established. Patients meeting the inclusion criteria were provided detailed information about the study plan before the start. Those who agreed to participate signed the

Inclusion Criteria

1. Patients who had received single-unit dental implant treatment and had 12 months elapsed since prosthetic loading.
2. Patients aged 18 and older, regardless of gender.
3. Patients with no systemic health issues.
4. Non-smokers.
5. Patients for whom radiographic bone loss, mobility, and prosthetic complications data were recorded and evaluated.
6. Patients who signed the informed consent form voluntarily after being fully informed about the study's purpose, duration, and requirements.

Exclusion Criteria

1. Patients diagnosed with osteoporosis and/or undergoing bisphosphonate treatment during or after treatment.
2. Patients with uncontrolled systemic diseases (e.g., diabetes mellitus, heart diseases, liver diseases).
3. Patients with a history of head or neck radiotherapy.
4. Patients on chronic medication (e.g., steroids, antidepressants).
5. Smokers.
6. Patients without radiographs immediately after prosthetic loading.
7. Patients with psychiatric problems.
8. Patients with missing data on radiographic bone loss, mobility, prosthetic complications, or implant dimensions.
9. Patients with short implant designs.
10. Patients who lost implants before the 12-month follow-up.

Data Collection

The evaluations conducted during the patients' 12-month follow-up appointments were recorded and analyzed. The parameters assessed during these appointments include:

A. Demographic Data

1. Age of the patient.
2. Gender of the patient (Male/Female).
3. Education level (Primary School, Secondary School, High School, Undergraduate, Graduate).

B. Clinical Parameters

1. Tooth brushing habits (None, Once daily, Twice daily, More than twice daily).
2. Presence of functional pain (Yes/No).
3. Mobility (Yes/No).
4. Presence of exudate (Yes/No).
5. Attached gingiva (≥3 mm) (Yes/No).
6. Reason for tooth extraction (Endodontic, Periodontal, Other).
7. Immediate implant placement after extraction (Yes/No).
8. Implant diameter (Narrow <3.75 mm, Standard ≥3.75 mm and <5 mm, Wide ≥5 mm).
9. Implant length (Short implants excluded; Standard ≥10 mm).
10. Implant type by tissue relationship (Bone Level, Tissue Level).
11. Anatomical location of the implant (Maxillary Anterior/Posterior, Mandibular Anterior/Posterior).
12. Type of abutment (Standard, Screw-Retained, Ti-Base).
13. Status of the opposing arch (Natural Tooth, Tooth-Supported Fixed Prosthesis, Implant-Supported Fixed Prosthesis, Implant-Supported Removable Prosthesis, Tooth-Supported Removable Partial Prosthesis/Full Denture).
14. Occlusal table dimensions (Normal/Reduced by 30-40%).
15. Superstructure material (Metal-Ceramic, Monolithic Zirconia, Monolithic Glass Ceramic).
16. Presence and history of screw loosening (Yes/No).
17. Presence and history of cementation loss (Yes/No).
18. Framework-ceramic separation (Chipping) (Yes/No).

Data Evaluation

Evaluation of Implant Success and Survival

The success and survival of the implants were evaluated based on the 2007 consensus criteria established by the International Congress of Oral Implantologists (ICOI). The data were categorized

into four groups: Healthy-Successful, Sufficient Survival, Compromised Survival, and Unhealthy-Failed.

Evaluation of Radiographic Bone Loss

Digital radiographs (periapical and panoramic films) taken at the end of prosthetic treatment and during the 12-month follow-up were analyzed using Planmeca Romexis® software (Planmeca, Helsinki, Finland). Marginal bone loss was measured using ImageJ software (ImageJ 1.54g, NIH, USA). Measurements were calibrated based on the actual implant length. The mesial and distal marginal bone loss was calculated separately by subtracting the values obtained immediately after prosthetic loading from those at the 12-month follow-up.

Statistical Analysis

The collected data were analyzed using SPSS Statistics V.26 (IBM SPSS Statistics, USA). The normality of parameters was assessed using the Kolmogorov-Smirnov and Shapiro-Wilk tests. Descriptive statistical methods (mean, standard deviation, median, frequency) were employed. Quantitative data and intergroup comparisons were evaluated using the Kruskal-Wallis test, with Dunn's test for post hoc analysis. The Mann-Whitney U test was used for pairwise comparisons, and the Fisher-Freeman-Halton Exact Chi-Square test was employed for qualitative data comparisons. A significance level of $p<0.05$ was considered statistically significant.