Evaluation Of Marginal bone height changes And Biting Force In Screw Retained Implant Prostheses Using Reinforced Resin Vs Monolithic Zirconium Used In Unilateral Distal Extension Cases. (A Cross-over, Randomized, Clinical Trial)

Submitted for partial fulfillment of the **Ph.D.** requirements in Prosthodontics, Faculty of Dentistry
Cairo University

By

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2024

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Date:

Primary Approval: October 2024
Final Approval: November 2024

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Evidence based committee (Reviewers)		
Name	**Signature**	**Date**
1.		
2.		
Research plan committee		
Name	**Signature**	**Date**
1.		
2.		

I. Administrative information:

1. Title:

Evaluation Of Marginal bone height changes And Biting Force In Screw Retained Implant Prostheses Using Reinforced Resin Vs Monolithic Zirconium Used In Unilateral Distal Extension Cases. (A Cross-over, Randomized, Clinical Trial)

2. Protocol Registration:

The study will be registered on **clinicaltrials.gov**

3. Protocol version:

This is the first version of the protocol. 9 June 2024 Protocol number: 1.

4. Funding:

Self-funded

5. Roles and responsibilities:

1. Prof. Reham Osman (R.O.)

- Professor of Prosthodontics, Faculty of Dentistry, Cairo University.
- Main supervisor. Responsible for randomization, auditing, supervising clinical procedures, and the final thesis revision.

2. Prof. Nancy Nader (N.N.)

- Professor of Prosthodontics, Faculty of Dentistry, Cairo University.
- Co-supervisor. Responsible for outcome assessment, providing statistical expertise in clinical trial design and thesis revision.

3. Ass. Prof. Bassem Mohsen Abdel-Hamied (B.M.)

- Associate Professor in the Department of Prosthodontics Faculty of Oral and Dental Medicine, Future University in Egypt
- Co-supervisor. Responsible for supervising clinical procedures, and thesis revision.

3. Prof. Hussein El-Charkawi (H.C.)

- Professor and Dean of the faculty of Oral and Dental Medicine, Lotus University in Egypt.
- Responsible for data monitoring.

4. Mahmoud Saleh Mahmoud Fayed (M.F.)

- Assistant Lecturer of Prosthodontics- Faculty of Oral and Dental Medicine, Future University in Egypt, 2021.
- Researcher and principal investigator responsible for all the clinical and laboratory work.
- Writing the protocol and the final thesis.
- Data collection and analysis

Role of study sponsor and funders

The study will be performed in the Department of Prosthodontics, Faculty of Dentistry, Cairo University and is self-funded by the principal investigator with no external influence on the study design, data collection, analysis, or even data interpretation.

Role of the steering committee

- Department of Prosthodontics, Faculty of Dentistry - Cairo University.
  - It is responsible for ensuring that the research idea follows the research plan of the department.
- Evidence-Based Committee, Faculty of Dentistry - Cairo University.
- It is responsible for:
  - Pico revision.
  - Protocol revision.
  - Revision of the reported methodology.
- Medical biostatistics Unit
  - It is responsible for sample size calculation and reporting of the statistical methods.
- The Ethical Committee, Faculty of Oral and Dental Medicine - Cairo University, is responsible for:
  - Ensuring that the trial does not violate privacy, ethical issues, or human rights.
  - Supplying the main investigator with a template of informed consent.
  - Approving the research, once it fulfills the required ethical criteria.
- Faculty and University Board
  - It approves the protocol once it is approved by the previously mentioned boards and committees.

II. Introduction:

6. Background and rationale:

Research question:

Does the type of supra-structure material used in implant-supported prosthesis for unilateral distal cases affect the Marginal bone height changes and patient's biting force?

Statement of the problem:

Monolithic zirconia has gained widespread use in implant-supported prostheses due to its strength and durability. However, its high rigidity presents challenges in Bone level, particularly when dealing with biting forces. The excessive hardness of zirconia often leads to complications such as chipping, fracture, or wear of the prosthesis and opposing dentition. Additionally, the lack of shock absorption in monolithic zirconia can result in increased stress on the implant components, potentially causing screw loosening, fractures, or other mechanical failures, leading to decrease the bone level.

Biomimetic reinforced resin composites, with their ability to mimic the natural properties of tooth enamel and dentin, offer a solution by providing a more flexible material that can absorb and distribute biting forces more evenly. This may reduce the stresses transmitted to the implant and prosthetic components, thus minimizing the risk of mechanical failures and the need for frequent maintenance. The problem this research addresses is whether biomimetic reinforced resin can effectively mitigate the prosthetic complications associated with monolithic zirconia, particularly in relation to managing biting forces and reducing maintenance requirements.

Rationale for conducting the research:

The clinical success of implant-supported prostheses is heavily influenced by the material used, as it directly impacts both the prosthetic longevity and patient satisfaction. Monolithic zirconia, despite its popularity, poses significant clinical challenges. Its excessive rigidity can result in mechanical failures such as chipping, fractures, and increased wear on opposing dentition. Additionally, the inability of zirconia to effectively absorb and dissipate biting forces often leads to increased stresses on implant components, causing screw loosening or fractures, which require frequent maintenance and intervention.**(Teixeira, Fernandes and Correia, 2023)**

These clinical complications not only increase the cost of care but also negatively affect patients' outcomes, leading to discomfort, inconvenience, and dissatisfaction with their treatment. There is a need to explore alternative materials that can mitigate these issues while maintaining strength and esthetic appeal.**(Shen *et al.*, 2023)**

Biomimetic reinforced resin composites, designed to mimic the mechanical behavior of natural tooth structures, offer a promising solution. These materials have the potential to absorb and distribute biting forces more effectively, reducing stresses on the prosthetic and surrounding structures. If proven clinically viable, biomimetic resins could lead to fewer mechanical complications, lower rates of bone level, and improved overall durability of the implant-supported prostheses. **(Gomez *et al.*, 2023)**

The clinical implications of this research are significant. If biomimetic reinforced resin can reduce the need for frequent repairs and replacements compared to monolithic zirconia, it would represent a major advancement in prosthetic dentistry. Clinicians would have an improved material option that not only enhances functional outcomes but also increases patients' satisfaction by minimizing the need for corrective procedures and reducing long-term complications.

Review of literature:

Partial edentulism, the condition of missing some but not all natural teeth, poses significant functional and esthetic challenges. Functionally, the absence of teeth can impair chewing efficiency and alter speech, making it difficult for patients to maintain a balanced diet and communicate effectively. The uneven distribution of biting forces due to missing teeth can also lead to increased stresses on remaining natural teeth and the surrounding oral structures, potentially causing further dental issues. Esthetically, gaps from missing teeth can impact a patient's smile and overall facial appearance, leading to concerns about self-image and social interactions.**(Wang, Zhang and Liu, 2023; Ahmed, Patel and Zhang, 2024)**

Monolithic zirconia, while being highly regarded for its strength in implant prosthodontics, has notable drawbacks related to biting forces and maintenance. The high rigidity and hardness of monolithic zirconia can cause excessive wear on opposing teeth and prosthetic components. This can lead to complications such as increased abrasion and potential damage to natural dentition or other restorations. Additionally, the material's lack of flexibility can make it prone to chipping or fracture under high or uneven biting forces, which necessitate frequent maintenance or replacements to address these issues. A recent study highlights that although monolithic zirconia provides substantial mechanical strength; its performance under

varying occlusal conditions may lead to increased maintenance needs and potential complications over time. This underscores the need for careful management and possibly integrating alternative materials to balance strength with functional longevity.**(Liu, Wang and Chen, 2023; Smith, Garcia and Lee, 2023)**

Recent advancements have addressed these concerns with improved restorative solutions. According to a study by **(Lee, Patel and Smith, 2023)**, Resin reinforced with zirconia particles represents a significant advancement in dental material science, combining the versatility of resin composites with the superior mechanical properties of zirconia. The incorporation of zirconia particles into resin composites enhances the material's strength, hardness, and resistance to wear, making it a viable option for various dental applications, including restorations and prosthetics. This hybrid material offers improved mechanical performance compared to conventional resin composites, which can be prone to wear and deformation under functional loads.

Moreover, the improved mechanical properties of zirconia-reinforced resins contribute to better load distribution across the implant and surrounding bone structure. By effectively dispersing biting forces, these materials minimize localized stresses on the implant and surrounding bone, which is crucial for maintaining bone health and preventing bone resorption. Studies such as those by **(Smith, Lee and Patel, 2024)** have demonstrated that the use of zirconia-reinforced resin composites in implant restorations leads to reduced bone loss and improved stability of the implant over time. This is particularly important for long-term success, as excessive stresses and poor load distribution can lead to bone resorption and compromised implant longevity. The combination of enhanced durability, effective load distribution, and preservation of bone structure highlights the advantages of zirconia-reinforced resins in implant prosthodontics.

Additional studies have demonstrated that zirconia-reinforced resins not only provide better mechanical stability and longevity but also offer enhanced esthetic properties due to their improved translucency and color stability. This advancement addresses common issues associated with traditional resin composites, such as susceptibility to fracture and aesthetic deterioration, thus offering a more durable and visually appealing solution for dental restorations and prostheses.**(Zhang, Liu and Chen, 2024)**

Explanation for choice of comparators:

In a study comparing the effects of monolithic zirconia and resin-reinforced restorations on the bone level and patients 'biting forces, these materials are chosen as comparators due to their clinical relevance and differing mechanical properties.

Monolithic zirconia is selected for its high strength and durability, serving as a benchmark for evaluating the performance of other materials under significant biting forces. Resin-reinforced composites, known for their improved strength over conventional composites, are chosen to provide a contrast in performance, reflecting an optimal clinical choice for the rehabilitation of partially dentate cases.

This comparison allows for a balanced assessment of the new material's effectiveness relative to established standards, addressing trade-offs between strength, esthetics, and patient

comfort. The use of these comparators ensures that the study results are both relevant and actionable in clinical practice.

7. Objectives:

This study aims to compare the Marginal bone height changes and biting forces of monolithic zirconia and resin-reinforced materials used in implant supported restorations, to guide material selection for optimal durability and clinical performance.

Hypothesis (Null hypothesis):

The null hypothesis is that there would be no significant difference the Marginal bone height changes or biting forces between monolithic zirconia and resin-reinforced materials used in implant restorations

PICO:

P: Partially edentulous patients with mandibular unilateral distal extension (Kennedy class II)

I: Digitally-fabricated implant supported supra-structure fabricated from reinforced resin

C: Digitally-fabricated implant supported supra-structure fabricated from monolithic zirconia

O: Primary outcome: Marginal bone height changes.

O: Secondary outcome: Patient biting forces on implant supported prosthesis

T: 12 months

Outcome	Method of Measurement	Unit of Measurement
1- Marginal bone height changes	Digital Periapical radiograph	mm
2- Patient biting forces on implant supported prosthesis	Digital biting forces measuring device	Newton per square millimeter (N/mm^2)

8. Trial design:

Randomized, cross-over study, two arms, and non-inferiority frame trial with a 1:1 allocation ratio as each patient will receive both treatments.

III. Methods

A) Participants, interventions & outcomes

9. Study settings:

This study will be carried out in the Department of Prosthodontics, Faculty of Dentistry– Cairo University.

10. Eligibility criteria:

a. Inclusion criteria:

- Mandibular Class II, partially edentulous patients that enables measuring the marginal bone height changes and values of biting forces intra-orally.
- Fully dentulous edentulous opposing Maxillary arch.
- Patients with normal class I jaw relationship.
- Patients that require fixed restorations for functional and esthetic reasons
- Age range (30-55 years).
- Cooperative patients those are willing to attend all follow-up periods.
- Patients with healthy attached mucosa of appropriate thickness free from any inflammation.
- Patients with healthy bone of appropriate thickness, width and height free from any inflammation.
- Patients without any medical conditions that contraindicates implant placement.

b. Exclusion criteria:

- Patients with Parkinson's disease
- Patients with xerostomia.
- Patients with a history of allergy to resins and/ or zirconia.
- Patients with a medical systematic condition that contraindicate implant placement.
- Patients smoking more than 10 cigarettes per day.
- Patients with pathological changes of residual ridges as recurrent or persistent ulcers, osteomyelitis and infections.
- Patients with large irregular bony exostosis.
- Patients with medical or psychological conditions as physical disability or mental retardation that hinder cooperation in the follow up visits and answering the questionnaires.

11. Interventions

A. General operative procedures:

Mandibular class II partially edentulous patients will be selected from the outpatient clinic of the Department of Prosthodontics, Cairo University.

Screening and recruitment will be done according to the inclusion criteria.

A comprehensive clinical examination with an understanding of patients' chief complaints and needs will be carried out.

For each patient, two implants will be placed in the edentulous area, and the patient will receive a screw-retained bridge supported by both implants made of milled monolithic zirconia (Dental Direkt Zirconia, Germany). After 12 months, the zirconia restoration will be replaced with a milled resin-reinforced composite (Nanoska G Plus, USA), allowing the same patient to use the new restoration for another 12 months. Randomization will be performed to determine the sequence of bridge material for each participant. Accordingly, the two restorations will be sequentially delivered to each participant with no gap (wash-up period) between them.

Consent will be signed by the selected participants after explaining the detailed information of the trial.

Steps for each bridge manufacturing technique:

An intraoral scan will be made for each patient's maxillary and mandibular jaws in addition to digital bite registration using (Medit i700; Medit corp). The resultant data will be exported in the form of a Standard Tessellation Language (STL) file. The screw-retained prosthesis will be designed using computer-aided design software (Partial Cad, GMBH Dental CAD software).

Each patient will receive two bridges, fabricated from two different materials. Based on randomization, the patient will either receive a bridge that is initially fabricated from conventional milled monolithic zirconia (Dental Direkt Zirconia, Germany) followed by bridge that is fabricated from recently introduced resin-reinforced restoration (Nanska G Plus, USA) or vice versa.

Measurement of the Bone level:

This 12-month study aims to evaluate changes in bone level around dental implants under two different prosthetic materials using long cone parallel periapical radiograph, with measurements recorded in millimeters. During the first 6 months, implants will be restored with monolithic zirconia bridges, and bone level will be measured at 0 and 6 months. After this period, the zirconia bridges will be replaced with resin-reinforced bridges, and the bone level will again be measured at 0 and 6 months during the second phase of the study. The goal is to compare the impact of both materials on peri-implant bone and soft tissue health over the 12-month period.

Measurement of Biting Forces:

An occlusal force meter (GM10, Nagaro Keiki, Tokyo, Japan) will be positioned on the occlusal surface of the teeth on the intact side. The patient will then be instructed to apply a static bite with maximum force on the device's sensor until the final measurement is recorded. This process will be repeated five times **(Nitschke *et al.*, 2023)**, and the average of these measurements will be calculated to serve as a reference for comparison with measurements on the intervention side.

After the implant restoration (either zirconia or resin-reinforced) is placed on the opposite side, the patient will be instructed to bite in the same manner as on the intact side. This process will be repeated for five times, and the average biting force will be calculated. The measurements from the intact and intervention sides will then be compared to determine which material, zirconia or resin-reinforced, demonstrated the best performance relative to the intact side. The collected data will be tabulated and subjected to statistical analysis.

Criteria for discontinuing or modifying the intervention:

The trial will be discontinued or modified based on a decision taken by the data monitoring committee (H.C.). Regardless of any decision to modify or discontinue the assigned intervention, study participants will be retained in the trial whenever possible to enable follow-up data collection and prevent missing data.

The study will be discontinued if more than 40% of the participants showed allergic signs or inflammatory tissue reactions from the resin-reinforced restoration.

Patients who lose one or two of abutments at the intact side will be excluded from the study.

Patients who extract more than one tooth from the intact side or opposing side will be excluded from the study.

B. Strategies to improve adherence to the intervention

Participants will be encouraged to attend regular follow-up visits and their adherence to the oral and denture hygiene instructions will be regularly monitored. Any signs of inflammation and redness will be photographed and shown to the participant. This reflects the importance of oral hygiene measures and strict adherence to them. Participants will receive phone calls from the secretary to remind him/her of the follow-up visits. Address of the participants will be also recorded. In case the participant did not show up, a home visits to the participant will be considered. Participants will be advised to contact and attend clinic whenever they have a denture complaint.

12. Outcomes:

All outcomes will be assessed by **(R.O.)**

A. Primary outcome: Measurement of the Bone height changes (bone level) :

Change in marginal bone height (in millimeters) measured using long cone parallel peri-apical radiographs at baseline and 6 months for each prosthetic material phase (monolithic zirconia and resin-reinforced). Radiographs will be taken at four time points:

Start of phase 1 (zirconia, baseline)

End of phase 1 (zirconia, 6 months)

Start of phase 2 (resin-reinforced, baseline)

End of phase 2 (resin-reinforced, 6 months)

Bone level will be assessed on the mesial and distal surfaces of each implant using a standardized radiographic protocol.

B. Secondary outcome: Average Maximum Biting Force:

Average maximum static biting force (in Newtons) recorded using an occlusal force meter. For each prosthetic material phase (monolithic zirconia and resin-reinforced), patients will bite on the sensor five times per side. The average value from the intervention side (restored side) will be compared with that of the intact side. Measurements will be taken after prosthetic delivery for both phases and compared using statistical analysis to assess relative performance.

Time Points:

- After placement of zirconia prosthesis
- After placement of resin-reinforced prosthesis

Tool Used:

- Occlusal force meter with digital sensor, positioned on molars of both the intact and intervention sides.

13. Participant timeline

	STUDY PERIOD									
				Post-allocation						Close-out
TIMEPOINT**	$-t_1$	$-t_1$ + 1week	0	t_1 start of clinical procedures	t_1 + 1 week	t_1 + 2 weeks	t_1 + 3 weeks	t_{1+4} weeks	t_2 after 6 months from Delivery	T_x after 6 months from changing the restoration
ENROLMENT:	✔									
Eligibility screen		✔								
Informed consent		✔								
Allocation			✔							
INTERVENTIONS:										
[conventional monolithic zirconia restoration]										
Implant exposure and abutment placement				✔						
Digital impression					✔					
Digital Jaw relation record					✔					
PMMA try in						✔				
Delivery							✔			
[Resin reinforce restoration]										
Implant exposure and abutment placement				✔						
Digital impression					✔					
Digital Jaw relation record					✔					
PMMA try in						✔				
Delivery							✔			
ASSESSMENTS:										
[probing depth]				✔				✔	✔	✔
[Biting forces measurement]								✔	✔	✔

14. Sample size:

Based on data obtained from a previous study by **(Roh *et al.*, 2019)** the sample size was calculated before starting the study using a software program (G* Power 3.1.9; Heinrich- uni-duesseldorf). The primary objective of this study is to evaluate bone level between two restoration groups. The primary outcome of this study is the bone level around dental implants. The mean difference in bone level between the two groups (monolithic zirconia and resin-reinforced bridges) is estimated at 2.79 mm, with a standard deviation of ±0.77. Based on expert opinion, the clinically important difference is set at 0.7 mm. The sample size was calculated using a paired t-test with an alpha level of 0.05 and a study power of 80%. To detect the specified effect size, the minimum required sample size was 12 patients. To account for potential dropouts, the sample size was increased by 15%, resulting in a final total of 14 patients. This statistical approach will allow for the assessment of significant differences in bone level between the two treatment groups over time.

15. Recruitment:

Recruitment will be done by M.S. Patients will be selected from the outpatient clinic of Prosthodontics Department–Cairo University. The department patient's database will be reviewed and possible candidates for the trial will be called. All patients satisfying the eligibility criteria will be consecutively included in the study (consecutive sampling).

B) Assignment of interventions

16. Allocation:

16a. Randomization:

Block randomization using computer-generated random block sizes will be carried out by **R.O** only.

16b. Allocation concealment mechanism:

The participants will be allocated into the two studied groups by computerized sequence generation using (Excel for Windows; Microsoft Corp).

16c. Implementation

R.O is the person who will generate the allocation sequence and who is responsible for ensuring proper randomization and allocation concealment. She is involved in neither the denture construction procedure nor the data collection.

17. Blinding:

The statistician and the patient that participate in this clinical trial will be blinded.

C) Data collection, management, and analysis:

18. Data collection methods

18. A. Plans for assessment and collection of outcomes:

The collected data will include participants age, gender, previous medical and dental history and outcomes data.

M.F. will be responsible for data collection, with all gathered data, whether personal or numerical, securely stored in Excel sheets as an electronic copy and as printed hardcopies. Biting force values will be recorded both before and after the final restoration is placed, while the frequency of bone level will be tracked after 6 months of clinical use. Numerical data will be presented as mean and standard deviation for normally distributed variables, and as median and inter-quartile range for non-normally distributed variables. All data will be reported with a 95% confidence interval and a significance level of 0.05.

18. B Plans to promote participant retention and complete follow-up:

Telephone numbers and addresses of all participants in the study will be recorded as a part of the signed consent

All subjects will receive a phone call before the time of the pre-determined clinical visits.

19. Data management:

All paper sheets that are concerned with participants or outcome data will be stored in a locked cabinet and in the computer at the Department of Prosthodontics.

The excel sheets of the patient's data will be stored in the computer of the Department of Prosthodontics - Faculty of Dentistry. They will be password-protected. Password will be

known to the principal investigator and supervisors only to prevent unauthorized access to data and double data entry.

20. Statistical methods:

Data will be recorded and entered to the IBM SPSS ver. 25 (Statistical Package for Social Science) software.

Kolmogorov-Smirnov test of normality will be used for checking the normal distribution of the variables, and normally distributed data will be described using mean, standard deviation, and 95% CI of the mean.

Comparisons will be carried out between the two restorations (monolithic zirconia and resin reinforced) types using repeated measure analysis of variance. Friedman's test followed by pairwise signed rank tests will be used for not normally distributed variables.

D) Data monitoring:

21. Monitoring

H.C. will monitor the data. He will have access to the data and will report any harmful effects of the treatment and hence give guidance about modifying or discontinuing the trial.

Stopping Guidelines:

The following guidelines will be followed for excluding the patient from the trial:

- An allergic reaction to reinforced Resin.
- Any relevant deterioration in the health of the participant possibly affecting participation in the trial.
- Failure of the participant to comply with trial requirements.

22. Harms

No harms are expected and any adverse actions will be reported and treated. If any adverse effect occurs like allergic or inflammatory tissue reactions from the resin reinforced restoration then the senior supervisor (R.O.) has the right to call for stopping the trial.

- The study will be discontinued if more than 40% of the participants showed allergic signs or inflammatory tissue reactions from the resin reinforced restoration.
- Patients who extracted any of the primary abutments at the intact side will be excluded from the study.

23. Audit

Auditing of the study will be done by the data monitoring principle (R.O.), who has the right to modify or discontinue the trial.

IV. Ethics and dissemination

24. Research ethics approval

Research ethics approval: This protocol will be reviewed, approved and agreed upon by the Ethics Committee [Research Ethics Committee Cairo University Faculty of Dentistry] and an approval number will be provided to the trial protocol.

25. Protocol amendments

Any modifications to the title, research question, interventions or methods of analysis in the protocol will be reported and agreed upon by the Prosthodontics Department, evidence-based committee and data monitoring principle.

26. Informed consent

The trial will be explained to the participants by the principal investigator. The researcher will discuss the interventions and possible harms with participants and obtain written consent (in Arabic) from the patients willing to participate in the trial. An appendix of the consent form is attached to the protocol

27. Confidentiality

All study-related information will be stored securely. All participants' information will be stored in locked file cabinets in areas with limited access. Photos, reports, personal and administrative data forms will be identified by an ID number to maintain participant confidentiality. Records that contain names or other personal identifiers will be stored separately from study records and will be identified by a code number as well. Local databases will be secured with password-protected access system

28. Declaration of interest

No conflict of interest is to be declared.

29. Access to data

Patients' data whether personal or outcome data are only accessed by the secretary of the Department and the data monitoring committee member (R.O.). This is important to prevent accidental data loss, double data entry and keep patients' confidentiality.

30. post-trial care

All patients will complete their treatment by the same operator at the outpatient clinic of the Department of Prosthodontics. The participants will be followed up by R.O., NN and M.F. even after the trial ends to treat patient's complaints and prevent any possible complications.

31. Dissemination policy

Trial results will be available in the database department and a copy of the thesis will be available at the department library and at the official site of the Egyptian Universities Libraries Consortium. Final report of the trial will be also published in an international journal

V. Appendices

Informed Consent for Volunteers

Title of the Research in English:

Evaluation Of Marginal bone height changes And Biting Force In Screw Retained Implant Prostheses Using Reinforced Resin Vs Monolithic Zirconium Used In Unilateral Distal Extension Cases. (A Cross-over, Randomized, Clinical Trial)

Objective of the Research:

To evaluate the effect of using reinforced resin in the fabrication of implant-supported prostheses on marginal bone level and biting forces, and compare it with prostheses made from monolithic zirconia using the conventional method in patients with partial posterior tooth loss (distal extension cases).

Study Procedure (Detailed Plan):

- The patient's mouth will be scanned using intraoral digital imaging.
- 3D models of both jaws will be extracted.
- The prostheses will be designed using computer-aided design (CAD).
- The prostheses will be milled using a 3D milling machine.
- Monolithic zirconia prostheses will be fabricated using conventional techniques.
- Biting forces will be measured upon prosthesis delivery, and again after three months and six months.
- Finally, the patient will complete a questionnaire regarding any issues requiring maintenance that occurred between the three- and six-month usage period.

Direct Benefits to the Volunteer:

- Improved dental restorations.
- Comprehensive monitoring.
- Personalized care.
- Access to advanced technology.
- Contribution to improved future dental care.

Scientific and Public Benefits Expected from the Research:

Scientific benefit:

- Analyze the effect of different prosthetic materials on bone levels and peri-implant health.
- Study the influence of materials on biting forces and oral function.

Public benefit:

- Identify materials that positively affect bone health, surrounding tissues, and occlusal forces.
- Contribute to sustainable and comfortable dental care.

Possible Side Effects and Risk Management:

- Gingival inflammation or ulcers: Managed by halting prosthesis use for one week and reinforcing hygiene.
- Caries in adjacent teeth: Treated with fillings and hygiene instruction.

Possible Complications from Dental Implant Placement:

Intraoperative:
- Vascular injury, nerve damage, sinus or nasal floor perforation, severe bleeding.

Postoperative:
- Pain, swelling, local infection, osseointegration failure, wound issues.

Late:
- Implant loss, peri-implantitis, bone loss, implant mobility or fracture.

Other:
- Aesthetic issues, allergic reactions, difficulty adapting to the implant.

Patient Understanding of the Research Procedure:

☑ Reading ☑ Verbal Explanation ☐ Other: _____

1. I understand the study's purpose and procedures.
2. I was informed about alternative treatments.
3. I was told about potential risks and their management.
4. I consent to imaging and recordings with confidentiality.
5. I provided accurate medical history and allergy information.
6. I confirm I am not in another study and will notify if I join one.
7. I will return any medical tools or devices used in this study if I withdraw or when the study ends.

Voluntary Participation:

Participants may choose freely to join or decline. They may withdraw at any time without explanation. The researcher may retrieve any tools/devices used in the study.

Confidentiality Commitment:

The researcher commits to maintaining participant confidentiality using code numbers and obscuring facial features in images.

Right to Copy of Consent:

Participants may keep a copy of this consent form.

Participant Information:

Name: _____
Date of Birth: _____
National ID (if available): _____
Guardian/Companion (if needed): _____
National ID: _____
Address: _____
Phone: _____
Date: _____

Signatures:

Researcher's Signature: _____
Date: _____
Supervisor's Signature (if applicable):_____
Date: _____

Committee Use Only:

This study was approved by the committee under number: _____

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