Study Protocol

1. Title of the Study

Clinical Evaluation of Zirconia Occlusal Veneer Bridges: A New Design for Posterior Resin-Bonded Fixed Partial Dentures (RBFPDs)

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2. Background and Rationale

The most frequent failure mode of RBFPDs—regardless of location or material (zirconia or metal)—is debonding, followed by connector or retainer fractures. These limitations have motivated the development of novel, minimally invasive designs that optimize bonding and durability while minimizing abutment preparation. To our knowledge, the present study is the first worldwide to clinically assess posterior zirconia resin-bonded bridges with occlusal veneer retainers, fabricated according to two novel abutment designs and made of two types of zirconia. These designs were developed by the investigator and evaluated in terms of clinical outcomes, including patient and specialist satisfaction with aesthetics, debonding, fracture, and recurrent caries during the follow-up period. Additionally, assessment of the internal and marginal fit of these designs was considered essential.

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3. Objectives

Primary Objective:

To evaluate debonding and fractures during the Follow up period.

Secondary Objectives:

To evaluate patient and specialist satisfaction with aesthetics and recurrent caries.

To evaluate the marginal and internal fit of zirconia occlusal veneer bridges.

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4. Study Design

- Prospective clinical trial.
- Parallel-group design.
- Random allocation using a lottery-based randomization method.

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5. Participants

Inclusion Criteria

- Good general health.
- Good oral hygiene.

- Low caries risk.
- Loss of a single posterior tooth (first molar), either maxillary or mandibular.
- Healthy periodontal tissues surrounding the abutment teeth (probing depth within normal limits, low bleeding index, and absence of abnormal mobility).
- Adequate clinical crown height (at least 4 mm measured on the surface adjacent to the edentulous space, from the gingival papilla to the mesial or distal marginal ridge).
- Vital abutment teeth.
- Abutment teeth free of carious lesions, or presenting only Class I or Class II caries, provided they are adjacent to the missing tooth only (DO on the second premolar and MO on the second molar).
- Abutment teeth free of signs of wear or attrition.
- Absence of parafunctional habits (such as bruxism).
- Abutment teeth with alignment close to normal occlusion (not severely tilted or rotated).
- Absence of supra-eruption of the opposing teeth into the edentulous space, or correction performed when present.
- Patient consent to participate in the study and commit to an 18-month follow-up period.

Exclusion Criteria

- Patient age under 18 years.
- Detection of caries penetration into the dental pulp after excavation, or the need for indirect pulp capping.
- Occurrence of fracture during the cementation procedure.
- Failure of the patient to attend the scheduled follow-up appointments.

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6. Sample Size Calculation

Determined according to previous studies.

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7. Randomization Method

“Participants were allocated to the study groups using a simple lottery-based randomization method to ensure unbiased assignment.”

A folded paper was randomly drawn from a pool of slips specifying the preparation design and the restorative material to be used

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8. Study Groups (n=10):

- D1/3Y: Occlusal veneer bridges prepared with the first design and fabricated of 3Y-TZP zirconia.

- D2/3Y: Occlusal veneer bridges prepared with the second design and fabricated of 3Y-TZP zirconia.
- D1/5Y: Occlusal veneer bridges prepared with the first design and fabricated of 5Y-PSZ zirconia.
- D2/5Y: Occlusal veneer bridges prepared with the second design and fabricated of 5Y-PSZ zirconia.

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9. Clinical Procedure

Preliminary impressions of both arches were taken using alginate and poured in type IV dental stone. For each diagnostic cast, two condensation silicone putty matrices were fabricated in the intended bridge area.

In the first design (D1), occlusal reduction of 1 mm was achieved by creating orientation grooves parallel to the internal cusp slopes using a 0.8 mm diamond fissure bur, followed by outlining with a fine pencil. The remaining enamel between the grooves was removed with the same bur, following the occlusal anatomy, until the grey reference lines of the grooves disappeared. Functional cusps were beveled, and the preparation was smoothed with a finishing bur to achieve a uniform reduction of approximately 1 mm. A tapered flat-ended bur with a rounded edge was then used to prepare a circumferential rounded occlusal shoulder, 1 mm in width, positioned 2 mm apical to the cusp tips. The axial surfaces adjacent to the edentulous space (mesial surface of the molar and distal surface of the premolar) were prepared along the insertion axis, with a 0.5 mm equigingival chamfer finish line. The preparation was extended between the buccal and lingual line angles, forming a longitudinal enamel wing on both buccal and lingual aspects. Refinement was performed with a finishing bur. The thickness of reduction was verified by sectioning one silicone matrix and measuring with a periodontal probe. Areas with less than 1 mm reduction were marked with a pencil and adjusted accordingly. All sharp angles, particularly at the junction between the occlusal shoulder and the enamel wing, were rounded to prevent stress concentration.

The second design (D2) followed the same protocol, with two modifications. First, the adjacent preparation was extended lingually beyond the line angle to the mid-lingual surface, thereby shifting the enamel wing and extending the lingual chamfer to this level. Second, a proximal groove was added at the buccal extremity of each abutment’s proximal preparation, parallel to the insertion axis, using a tapered bur. This resulted in a preparation depth of approximately 1 mm at the gingival portion of the groove area.

Chamfer finish line exposure was achieved with retraction cords. Final impressions were obtained using a putty-wash technique with putty and light-body condensation silicone. Bite registration was performed in maximum intercuspation with addition silicone placed over the prepared abutment areas to ensure occlusal accuracy. Provisional restorations were fabricated using self-curing acrylic resin and the second preformed silicone matrix. Shade selection for the definitive prostheses was carried out with the Vita Classic shade guide, matching adjacent teeth and abutments.

Master casts were scanned with a laboratory scanner and mounted on a non-adjustable articulator to reproduce the intraoral occlusion. A subsequent scan transferred this relationship to CAD software, where the occlusal veneer bridges were digitally designed. Software settings ensured a minimum occlusal thickness of 0.8 mm, with allowance for greater thickness where required to maintain occlusal contact. Connector dimensions were standardized at 12 mm^2. The cement space was set at 90 μm across the abutment surfaces, except within 1 mm of the finish line, where it was reduced to 30 μm. A modified surgical-lap pontic design was used, ensuring passive soft-tissue contact without excessive pressure.

Bridges were fabricated with a five-axis milling machine from either 3Y-TZP or 5Y-PSZ zirconia blocks. After milling, frameworks were separated, manually stained with brush-applied colorants, and sintered in a zirconia furnace at 1450 °C, following the manufacturer's recommendations. Fit was verified on the master cast, and external surfaces were glazed.

During clinical try-in, provisional restorations were removed and the zirconia bridges were evaluated intraorally. Necessary adjustments were made until a proper fit was achieved.

The first step was to verify the absence of proximal interferences at the contact points between the bridge and adjacent teeth. Any interfering proximal contacts were adjusted and polished to ensure neutrality and to avoid influencing bridge seating. Marginal fit was then evaluated visually and with a sharp explorer, as the buccal and lingual margins of the retainers were supragingival.

If inadequate marginal adaptation was observed, internal fit was assessed using a blue-colored light-body addition silicone material. Base and catalyst were mixed and applied to the intaglio surface of the retainers, after which the bridge was seated on the dried abutments using finger pressure and held in place until the material had fully set. The bridge was then removed, and the silicone film was examined under the dental unit light. Areas of perforation or excessive translucency in the silicone layer were marked with a pencil and selectively adjusted with a diamond bur. This procedure was repeated until a uniform thickness of the silicone film was obtained, confirming adequate internal adaptation and complete seating, which was further verified both visually and with a sharp explorer. Bridge stability was confirmed by applying alternating pressure on each retainer individually to exclude rocking.

A second layer of yellow light-body addition silicone was applied over the previously formed blue uniform silicone film, which was retained on the intaglio surface of the retainers. After setting, both layers were removed as a single piece, forming a replica of the prepared abutments and the surrounding cement space (Replica Technique). The two replicas of each bridge were placed in labeled bags, indicating the preparation design and the zirconia generation used.

Each replica was then sectioned into two pieces using a no.15 blade. The sectioning line extended in a mesiodistal direction, passing through the midpoint of the internal slope of the buccal cusps in both preparation designs, as well as through the axial groove in the second design. Twelve measurement points were defined in the mesiodistal direction.

Specimens were examined under a light microscope located in the Materials Science Laboratory, Department of Mechanical Design, Faculty of Mechanical and Electrical Engineering, Damascus

University. The microscope was equipped with a graduated scale capable of measuring in dosimeter units (0.01 mm) at a magnification of ×100. Marginal and internal fit values were determined by measuring the perpendicular distance between the intaglio surface of the restorative material and the abutment at each point of the study.

Intaglio surfaces of the restorations were sandblasted with 50 μm aluminum oxide for 10 seconds at a pressure of 2.5 bar. The sandblasting nozzle was held vertically, at a distance of 10 mm from the internal surfaces. The bridges were then cleaned in an ultrasonic bath with distilled water for 5 minutes. After drying, an MDP-containing primer was applied to the intaglio surfaces and left to evaporate, as per the manufacturer's instructions

After the abutments were isolated for bonding, the prepared enamel surfaces were selectively etched with 37% phosphoric acid for 30 seconds, rinsed thoroughly with water, and then the enamel margins were dried until a chalky appearance was achieved, while maintaining the moisture of the exposed dentin. A universal bonding agent was applied to both enamel and dentin using a microbrush, gently spread with air flow to ensure a thin, uniform layer, and light-cured for 20 seconds.

A dual-cure resin cement was applied to the intaglio surfaces of the bridge, which was then carefully seated on the abutments. Light pressure was applied to the abutments to hold the bridge in place. Excess resin was removed with a brush, and the cement was light-cured for 3 seconds, followed by removal of any remaining resin excess. The cement was then fully cured for 20 seconds on each side to ensure complete setting up. The gingival retraction cords were removed, and the margins were finished using rubber finishing tips. Post-operative oral care instructions were provided to the patient, emphasizing areas most susceptible to plaque accumulation, including the margins and concave connectors on the buccal and lingual aspects. The patient was instructed to avoid using the bridge for biting on hard objects (e.g., nuts, bones, etc.).

Patients were followed up for 18 months, data were recorded at follow-up intervals of one month, six, twelve, and eighteen months. The investigations focused on debonding or fractures of the bridge and the presence of secondary caries at the specified observation intervals. Additionally, after one month, scores of patient satisfaction and the satisfaction of the fixed prosthodontist (a specialist other than the researcher) with the aesthetics of the restoration were recorded using a Visual Analogue Scale (VAS) ranging from 0 (completely dissatisfied) to 100 (completely satisfied), without knowledge of the restorative material. Data were entered into Microsoft Excel v.2307, and statistical analysis was conducted using SPSS software v.27, with a significance level set at 0.05.

10. Outcome Measures

Primary Outcomes:

No cases of debonding were recorded in any of the study groups during the different monitoring periods.

No significant statistical differences in the fracture of occlusal veneer bridges across the monitoring periods within each study group.

Secondary Outcomes:

No cases of secondary caries were recorded in any of the study groups across the various monitoring periods.

No statistically significant difference was observed in the general patient satisfaction scores regarding the aesthetics and translucency of the restorations across the study groups.

no statistically significant difference in the specialist satisfaction scores regarding the aesthetics and translucency of the restorations across the study groups.

No statistically significant differences in fit values among the study groups at any of the evaluated points.

. Follow-Up

- 1 month.
- 6 months.
- 12 months.
- 18 months.

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12. Data Collection

- Clinical examination.
- Photographs.
- Visual Analogue Scale (VAS).
- Light microscope.
- Standard evaluation criteria (USPHS or FDI)

13. Statistical Analysis

- Tests used (Shapiro-Wilk test, One-way ANOVA, Fisher's Exact Test, Kruskal-Wallis, Cochran's Q test, Student T-test, Mann-Whitney U test).
- Software (SPSS).
- Significance level 0.05.

14. Ethical Considerations

- Ethical approval was obtained from the Damascus University Research Ethics Committee (Resolution No. 2812, 16/08/2021).
- "All methods were performed in accordance with relevant guidelines and regulations."

15. Clinical Trial Registration

- Registry name
- Registration number
- Date of registration

16. Confidentiality

All participant data were handled with strict confidentiality. Personal identifiers were removed and replaced with coded numerical identifiers to ensure anonymity. The data were stored in password-protected electronic files accessible only to the principal investigator and authorized research team members. No personal information was disclosed in any part of the study, and all data were used exclusively for research purposes. The procedures for data protection complied with institutional policies and relevant ethical guidelines

17. Risks and Benefits

From an ethical standpoint, there were no concerns regarding the clinical testing of occlusal veneer bridges prior to extensive in-vitro trials, as the literature supports the effectiveness of zirconia adhesive bridges for single-tooth replacements—whether anterior or posterior—in various designs modified by previous researchers. No catastrophic or irreparable failures have been reported regarding RBFPDs, as the conservative nature of the partial preparation preserves tooth structure throughout the clinical service period.

18. Funding and Conflict of Interest

Competing interests: The authors declare no competing interests.

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19. Timeline

Start date: January 2021.
End date: December 2023.