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Clinical trial of zirconia bridges for back teeth

Submission date 04/12/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 17/12/2025	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 17/12/2025	**Condition category** Oral Health	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
The most frequent failure mode of resin-bonded fixed partial dentures (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.

Who can participate?
Patients aged between 18 and 47 years with loss of a single posterior tooth (first molar), either maxillary or mandibular.

What does the study involve?
Design 1 (D1)
Occlusal reduction: 1 mm using orientation grooves (0.8 mm diamond fissure bur).
Functional cusps beveled; preparation smoothed with finishing bur.
Circumferential rounded occlusal shoulder: 1 mm width, 2 mm apical to cusp tips.
Axial surfaces adjacent to edentulous space prepared with 0.5 mm equigingival chamfer.
Buccal and lingual enamel wings formed.
Thickness verified by sectioning silicone matrix; adjusted where <1 mm.
All sharp angles rounded to prevent stress concentration.

Design 2 (D2)
Same as D1 with two modifications:
Lingual extension beyond line angle to mid-lingual surface.
Addition of proximal groove at buccal extremity of each abutment (≈1 mm depth at gingival portion).

What are the possible benefits and risks of participating?
Dental literature has concluded that zirconia adhesive bridges can be used effectively to replace

single missing anterior or posterior teeth. No reports have documented catastrophic or unrestorable failures affecting the abutment teeth, regardless of the design modifications proposed by previous researchers. Furthermore, in cases where resin-bonded fixed partial dentures fail, they can be replaced with conventional full-coverage bridges. The conservative nature of these preparations preserves tooth structure during clinical service, thereby allowing the teeth to be easily re-prepared according to recommended academic standards for conventional fixed dental prostheses.
The new design of occlusal veneer bridges offers several advantages. It requires minimal tooth preparation, with a reduction of approximately 1 mm, thereby protecting sound dental tissues from the extensive removal associated with traditional bridges and inlay-retained designs. This preparation remains distant from the vital pulp and from most of the dentin surface, significantly reducing the potential pulpal consequences of aggressive tooth reduction. Full coverage of the occlusal surface and the proximal surfaces adjacent to the edentulous area increases the bonding surface available for resin cement. Additionally, the design maintains all preparation margins entirely within the enamel. Preparing the occlusal and axial surfaces at approximately 1 mm depth also preserves a large portion of enamel, thereby enhancing resin-cement bonding strength. The retainer design, which resembles anatomical occlusal veneers and parallels the occlusal plane, is oriented perpendicularly to functional occlusal forces and reduces shear forces acting on the luting resin.
The use of monolithic zirconia results in a homogeneous and highly fracture-resistant restoration despite the minimal material thickness. Connector areas of at least 12 mm^2, fabricated entirely from zirconia, further increase the fracture resistance of occlusal veneer bridges under masticatory loading.
In the second design variation of occlusal veneer bridges, the addition of axial grooves and lingual extensions reduces the paths of insertion and enhances the available bonding surface with the dental tissues.

Where is the study run from?
Damascus University, Syria.

When is the study starting and how long is it expected to run for?
January 2021 to December 2023.

Who is funding the study?
Investigator initiated and funded.

Who is the main contact?
Ramah Makieh, rmakkieh@yahoo.com

Contact information

Type(s)
Principal investigator

Contact name
Dr Yasmeen Abdul Kader Ghalawingy

ORCID ID
https://orcid.org/0000-0003-3027-2093

Contact details

Al Mazzeh
Damascus
Syria
00931
+963956881078
yassamine.alsham@gmail.com

Type(s)
Scientific

Contact name
Prof Mohammad Luai Morad

Contact details
Al Mazzeh
Damascus
Syria
00931
+963956881078
luai.morad@damascusuniversity.edu.sy

Type(s)
Public

Contact name
Dr Yasmeen Ghalawingy

Contact details
Al Mazzeh
Damascus
Syria
00931
+963956881078
yasmeen92.ghalawingy@damascusuniversity.edu.sy

Additional identifiers

Study information

Scientific Title
Clinical evaluation of zirconia occlusal veneer bridges: a new design for posterior resin-bonded fixed partial dentures (RBFPDs)

Study 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.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 16/08/2021, Damascus University (Faculty of Dentistry/ Department of Fixed Prosthodontics, Damascus, 00931, Syria; +963933449668; dr.laflouf@hotmail.com), ref: 2812

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Loss of a single posterior tooth (first molar), either maxillary or mandibular.

Interventions
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 bevelled, 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 additional silicone placed over the prepared abutment areas to ensure occlusal accuracy. Provisional restorations were fabricated using self-curing acrylic resin and a 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 50μm aluminium oxide for 10 seconds at a pressure of 2.5bar. The sandblasting nozzle was held vertically, at a distance of 10mm 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, and data were recorded at follow-up intervals of one, 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.

Intervention Type
Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Zirconia occlusal veneer bridges

Primary outcome(s)
1. Debonding or fracture of occlusal veneer bridges measured using data collected on the number of debonding and fracture cases recorded during different monitoring periods at 1, 6, 12 and 18 months

Key secondary outcome(s))
1. Incidence of secondary caries, patient satisfaction, specialist satisfaction, and fit values of occlusal veneer bridges measured using data collected on the number of secondary caries recorded, general patient satisfaction scores, specialist satisfaction scores at 1, 6, 12 and 18 months

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Good general health
2. Good oral hygiene
3. Low caries risk
4. Loss of a single posterior tooth (first molar), either maxillary or mandibular
5. Healthy periodontal tissues surrounding the abutment teeth (probing depth within normal limits, low bleeding index, and absence of abnormal mobility)
6. 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)
7. Vital abutment teeth
8. 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)
9. Abutment teeth free of signs of wear or attrition
10. Absence of parafunctional habits (such as bruxism)
11. Abutment teeth with alignment close to normal occlusion (not severely tilted or rotated)
12. Absence of supra-eruption of the opposing teeth into the edentulous space, or correction performed when present
13. Patient consents to participate in the study and commit to an 18-month follow-up period

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
47 years

Sex
All

Total final enrolment
35

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

Date of first enrolment
01/01/2021

Date of final enrolment
30/12/2023

Locations

Countries of recruitment
Syria

Sponsor information

Organisation
Damascus University

ROR
https://ror.org/03m098d13

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			16/12/2025	No	No