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TITLE: Comparison of the Brackets Bonded with Bulk Fill Composite and Conventional Composite in Patients Undergoing Fixed Orthodontic Treatment – A Split-mouth Randomized Controlled Trial

INTRODUCTION:

Fixed orthodontic treatment aims at correcting malocclusion and improving dental aesthetics. It often entails bonding orthodontic brackets to the teeth.[1] The success of fixed orthodontic treatment is highly dependent upon the durable and reliable bond between brackets and the tooth surfaces.[2,3] Bracket bond failure remains a significant concern, leading to compromised treatment outcomes.[4] Bond failure can occur due to various factors, such as inadequate bonding strength, poor oral hygiene and accumulation of dental plaque around the brackets.[5] Bond failure not only compromises treatment effectiveness but also leads to increased chair side time, treatment interruptions and additional costs for patients.[6]

To date, light cure conventional composite resins have been widely used for bracket bonding.[7,8] Mechanical properties of the adhesive resins and resin composites, such as the flexural modulus, compressive strength, and tensile strength, depends on the degree of cure or monomer conversion of the adhesive resin by conventional curing method with light directed from the sides of the bracket.[9] However, the convexity of the labial tooth surface and the bracket material hinder or obstruct direct light propagation resulting in incomplete polymerization of the adhesive at the center of the bracket.[8,9] Light cure conventional composite resin undergoes polymerization shrinkage during the curing process.[10] This shrinkage can generate stress at the bracket-tooth interface, potentially leading to debonding or adhesive failure over time. However, advancements in dental materials have introduced bulk fill composites as an alternative option.[11]

Bulk fill composites are formulated to improve light penetration and depth of cure.[12] This ensures that the composite is adequately polymerized even at the center of the bracket. Bulk fill composites often exhibit lower polymerization shrinkage stress compared to light cure conventional composites.[13] The improved formulation and composition help to minimize the contraction forces during polymerization, reducing the likelihood of adhesive failure of the brackets.[14]

Bracket bond failure is a critical parameter to assess the adhesive strength between brackets and tooth surfaces.[15,16] In addition to bond failure, dental plaque accumulation and gingival health are important aspects to consider during fixed orthodontic treatment.[17] Plaque accumulation around brackets and along the gingival margins can lead to an increased risk of dental caries, enamel demineralization and gingivitis.[18] Therefore, it is crucial to evaluate the impact of different bracket bonding materials on plaque accumulation and gingival health.

To the best of our knowledge, there has been no previous study on this subject. Therefore, the idea of comparing brackets bonded with bulk fill composite and light cure conventional composite in a split-mouth randomized controlled trial intrigued our attention. This study will address a relevant aspect of fixed orthodontic treatment, bracket bonding and compare two adhesive materials that have the potential to impact the efficiency and clinical outcomes of fixed orthodontic procedures.

RATIONALE:

Bulk fill composites have gained popularity as alternative bracket bonding materials due to their potential advantages over light cure conventional composites.[19] Bulk fill composites have the benefit of increased depth of curing and less polymerization shrinkage.[20] However, there is limited research comparing the clinical performance of these materials in terms of bracket bond failure, dental plaque accumulation and gingival health. Bond strength of orthodontic brackets on bulk fill composite surfaces was not found adequate.[21] Understanding the performance of different adhesive materials used in bracket bonding is crucial for orthodontists to make informed decisions regarding material selection, optimizing treatment outcomes and ensuring patients' oral health. By assessing bracket bond failure, dental plaque accumulation and gingival health, this study aims to provide valuable insights into the clinical performance of different adhesive materials, contributing to evidence-based practices in fixed orthodontic treatment.

OBJECTIVE:

The primary objective of this study is to compare the survival rate (days) of orthodontic bracket bond to the tooth, and the secondary objective is to compare the dental plaque accumulation and gingival health using plaque index and gingival index respectively between brackets bonded with

bulk fill composite and light cure conventional composite in patients undergoing fixed orthodontic treatment over a period of three months.

HYPOTHESIS:

Null Hypothesis:

There is no significant difference in the survival rate, dental plaque accumulation and gingival health between brackets bonded with bulk fill composite and light cure conventional composite in patients undergoing fixed orthodontic treatment.

Alternate Hypothesis:

There is a significant difference in the survival rate, dental plaque accumulation and gingival health between brackets bonded with bulk fill composite and light cure conventional composite in patients undergoing fixed orthodontic treatment.

OPERATIONAL DEFINITIONS:

Survival rate of bonded brackets:[22] (Annexure A)

A bracket survived how many days in mouth without detaching from the tooth surface.

Bulk Fill Composite:[23] (Annexure B)

In this study, 3M™ Filtek™ One Bulk Fill restorative will used as intervention.

Light Cure Conventional Composite:[23] (Annexure C)

In this study, 3M Unitek Transbond XT - Light Cure Bracket Bonding adhesive will be used as control.

Plaque Index:[24] (Annexure D)

Plaque index is a grading system used to assess the plaque accumulation around the bonded brackets and gingival margins. It consists of four grades including, Grade 0, 1, 2 and 3. The increase in grade indicates the increased amount of plaque along the gingiva.

Gingival Index:[24] (Annexure E)

Gingival index is a grading system that is used to assess the health of the gingiva. It consists of four grades including, Grade 0, 1, 2 and 3. The increase in grade indicates the compromised health of gingiva.

Split-mouth Technique:[25]

A randomized controlled trial in which intervention and control are randomly allocated to the different quadrants in the oral cavity. In our study, bulk fill composite and light cure conventional composite will be randomly allocated to the right and left quadrants of maxillary and mandibular arches.

MATERIAL & METHODS:

Study Design: A split-mouth randomized controlled single-centered trial

Settings: Dental clinics, Department of surgery, Aga Khan University Hospital, Karachi, Pakistan

Recruitment Time Duration: 01-01-2025 to 30-03-2025

Study Duration: One year after ethical review committee (ERC) approval

Sampling Technique: Non-probability consecutive sampling

SAMPLE SIZE:

The sample size was calculated using standard estimate where $n = 8(CV)^2 /(PC)^2 [1+(1-PC)^2]$, where PC is the proportionate change in means ($PC = (\mu 0 - \mu 1)/\mu 0$) and CV is the coefficient of variation ($CV = \sigma 0/\mu 0 = \sigma 1/\mu 1$). The study required a minimum sample size of 53 (N) patients. With an inflation of 10% for an estimated loss to follow up/non-response rate, we will be including 58 (N) participants in this study to achieve 80% power and to detect at least a 20% change in mean bracket survival rates of 176.75 ± 76.26 days and 197.19 ± 81.78 days with conventional composite and RMGIC, respectively and 40% or less change in coefficient of variation at two sided 5% level of significance. The sample size was calculated by using the findings of Qabool et al.[26] So, we will have 232 quadrants in total. Bulk fill composite will be used for bonding brackets on the teeth surfaces in half quadrants to either right side or left side by using randomization.

SAMPLE SELECTION:

Inclusion Criteria:

- Patients aged between 13 - 40 years
- Patients undergoing fixed orthodontic treatment
- Patients with good oral hygiene, with grade 1 or below on plaque and gingival indices
- All patients who will sign the informed consent/assent form

Exclusion Criteria:

- Patients with enamel surface defects
- Patients with any periodontal disease i.e. gingivitis or periodontitis
- Patients with any systemic diseases i.e. diabetes and hypertension
- Pregnant or nursing females
- Patients with craniofacial syndromes
- Subjects with a previous history of orthodontic or orthopedic treatment

STUDY GROUPS:

The patients will be screened using the inclusion and exclusion criteria by the co-investigator. Bracket bond failure and clinical measurements (plaque accumulation and gingival health) will be recorded at four intervals (T_0, T_1, T_2 and T_3).

Group A (Intervention): Bulk fill composite.

Group B (Control): Light cure conventional composite.

The participants will receive routine instructions for oral hygiene maintenance and care of the appliance verbally.

DATA COLLECTION PROCEDURE:

After obtaining approval from the Ethical Review Committee and taking informed assent and informed consent from the child and parents respectively, **(Annexure F, G and H)**, patients fulfilling the study selection criteria will be recruited in the study as participants. Patients visiting the orthodontic clinic at the Aga Khan University Hospital Karachi will be included in

this study. Detailed information regarding the study will be provided to the participants and they will be given the choice to either accept or refuse their inclusion in the study. Bulk fill composite and light cure conventional composite will be used to bond the brackets in the study participants undergoing orthodontic treatment **(Annexure B and C)**. Bulk fill composite and light cure conventional composite will be randomly allocated to the right and left quadrants of maxillary and mandibular arches. Bracket bond failure and clinical measurements (plaque accumulation and gingival health) will be recorded at four intervals. First, at the time of brackets bonding (T_0), after one month (T_1), two months (T_2) and three months follwow-up (T_3). Data will be collected on an organized study proforma **(Annexure I).**

Interim analysis will be run to ensure that there are no unexpected safety concerns associated with the intervention. The analysis may help determine whether the intervention is effective in achieving its desired outcomes or if there are indications of potential success. If the interim analysis will reveal overwhelming evidence of effectiveness or futility, the trial will be terminated early, saving time, money, and potential exposure to participants.

Intention to treat analysis will be applied to maintain the benefits of randomization and avoid introducing bias due to non-adherence or dropouts. By analyzing participants as part of their original assigned group, the ITT analysis provides a more conservative estimate of treatment effects, reflecting real-world scenarios where not everyone perfectly adheres to the assigned treatment.

Randomization:

Block randomization will be used to determine which side of teeth (right or left side quadrants) the bulk-fill composite will be used to bond the brackets in each participant. This will be controlled by a research faculty member of the Section of Dentistry assigned to the research by the Clinical Trials Unit AKUH.

Random Sequence Generation:

In this two-armed study, fifteen blocks each with a block size of four with any of the following six-possible allocation sequences for two treatment arms will be generated.

(1) AABB, (2) BBAA, (3) ABAB, (4) BABA, (5) ABBA, (6) BAAB

The blocks to be utilized and their order will be determined by the research Faculty member using sealed envelope™ online software.[28]

Allocation Sequence Concealment:

The treatment allocation pattern determined against each participant's ID (01-58, in ascending order) by the research faculty member, will be printed individually on paper. These papers will be sealed in an opaque envelope with the participants' ID mentioned over the envelope by a team member independent of the trial.

Enrollment:

After obtaining approval from the ERC (AKUH), each participant fulfilling the inclusion criteria for the study and consenting to participate in the trial will be assigned a participant ID.

Implementation:

During the recruitment of the participants in the trial, the sealed envelope for a participant ID will be opened to reveal the random sequence by the enrolling team member.

Blinding:

The study investigators, patients and assessors will not be blinded during the trial. The patients will be recruited by the co-principal investigator. All the measurements will be recorded by the co-investigator on the study proforma **(Annexure E)**.

POSSIBLE RISKS OR BENEFITS:

Orthodontic wire might shift more to one side due to bracket bond failure and poke the patient. This will be managed by giving instructions to patients that if this happens then you will have to report immediately to the outpatient orthodontic clinic. There are no other serious adverse effects. In case any serious adverse event happens ERC, CTU and the sponsors will be informed.

DATA ANALYSIS:

Data will be entered and analyzed in SPSS for Windows (version 23.0, SPSS Inc. Chicago). Shapiro-Wilk test will be used to check the normality of the data. Descriptive statistics, such as means and standard deviations for normally distributed or median and interquartile range (IQR) for non-normally distributed data will be reported for all baseline clinical factors. Paired t-test/Wilcoxon test will be used for the pairwise comparison. Gingival index and plaque index will be analyzed as quantitative variables. Gingival and Periodontal health scores will be assessed between the two groups using Paired t test / Wilcoxin sign rank test. The rate of bracket survival and total number of bracket breakages in the two groups will be assessed by Cox proportional hazards model, with stratification on the matched pairs. A p-value ≤ 0.05 at 95% confidence interval will be considered as statistically significant.

ETHICAL CONSIDERATION:

This study will be carried out as per the guidelines of the World Medical Association's Declaration of Helsinki[27] and the principles of Good Clinical Practice (GCP). Any modifications in the protocol will be re-submitted to the ERC. The study will be conducted in compliance with regulations and a copy of the final study protocol will be submitted to ERC. All the recorded data of patients will remain confidential. Access will be provided to no one except the investigators. Participants' names and identities will remain undisclosed; however, data may be seen by ERC or any local regulatory body. Data will be saved for 10 years as per GCP and institutional guidelines.

FINANCE:

The Aga Khan University Hospital, Karachi (Department of Surgery).

PUBLICATION POLICY/PLAN:

For publication the data will be utilized and it could be presented in either national or worldwide forums.

DATA CONFIDENTIALITY:

All the recoreded data of patients will remain confidential. Access will be provided to no one except the investigators. Participants' names and identities will remain undisclosed; however, data may be seen by ERC or any local regulatory body. Data will be saved for 25 years as per GCP and institutional guidelines.

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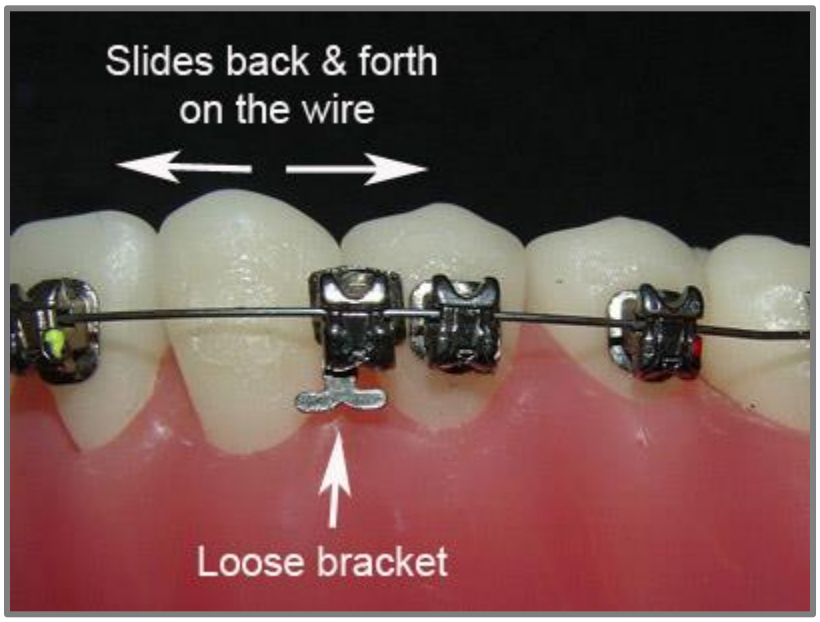
Annexure A: Bond failure[22]



Annexure B: Bulk fill composite resin[23]

Storage: Stored at room temperature in cabinets of dental procedure rooms where other materials are stored and protected from humidity and sunlight.

Usage: Steps for light -cure composite bonding are:

a. Prepare teeth with oil-free pumice, and rinse thoroughly for 15 seconds with water.
b. Air dry tooth surface for 5 seconds until dry field is maintained and isolate with cotton rolls.
c. Etch enamel surface with 37% phosphoric acid for 15 seconds.
d. Rinse the etched surface for 20 seconds to remove the acid and precipitates that might have formed during the etching procedure.
e. Thoroughly dry etched surface with moisture free air. Tooth surface should appear frosty white; if not then re-etch for 5 seconds.
f. Brush thin uniform amount of primer on every tooth surface.
g. Apply a small amount of adhesive paste onto bracket base and position the bracket on tooth surface.
h. After accurately placing bracket on tooth surface, apply visible blue light for 30 seconds on center of bracket.

Annexure C: Light cure conventional composite resin[23]

Storage: Stored at room temperature and protected from humidity.

Usage: Steps for light -cure composite bonding are:

a. Prepare teeth with oil-free pumice, and rinse thoroughly for 15 seconds with water.
b. Air dry tooth surface for 5 seconds until dry field is maintained and isolate with cotton rolls.
c. Etch enamel surface with 37% phosphoric acid for 15 seconds.
d. Rinse the etched surface for 20 seconds to remove the acid and precipitates that might have formed during the etching procedure.
e. Thoroughly dry etched surface with moisture free air. Tooth surface should appear frosty white; if not then re-etch for 5 seconds.
f. Brush thin uniform amount of primer on every tooth surface.
g. Apply a small amount of adhesive paste onto bracket base and position the bracket on tooth surface.
h. After accurately placing bracket on tooth surface, apply visible blue light for 30 seconds on center of bracket.

Annexure D: Plaque Index[24]

0	No plaque
1	Thin plaque layer at the gingival margin, only detectable by scraping with a probe
2	Moderate layer of plaque along the gingival margin; interdental spaces free, but plaque is visible to the naked eye
3	Abundant plaque along the gingival margin; interdental spaces filled with plaque

Annexure E: Gingival Index[24]

0	Normal gingiva; no inflammation; no discoloration (erythema); no bleeding
1	Mild inflammation; slight erythema; minimal superficial alterations; no bleeding
2	Moderate inflammation; erythema; bleeding on probing
3	Severe inflammation; severe erythema and swelling; tendency to spontaneous bleeding; possible ulceration