Comparison of Periodontal Health, Bonding Time and Failure Between Direct and Indirect Fixed Retainer Placement among Orthodontic Patients– A Modified Split Mouth Randomized Controlled Trial

Approved on 14-12-2023

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TITLE: Comparison of Periodontal Health, Bonding Time and Failure Between Direct and Indirect Fixed Retainer Placement among Orthodontic Patients– A Modified Split-mouth Randomized Controlled Trial

INTRODUCTION:

Orthodontic treatment is an interplay between applied forces and the biological response of teeth. The orthodontic force alters the equilibrium and causes the tooth to move in the desired position. However, there is always a chance of relapse.[1] An interplay of gingival fibres, periodontal fibers and continuous bone growth are responsible for teeth returning to their original positions.[2] Therefore, retention of teeth in their corrected position is necessary for every orthodontic patient. Sperry and Abdulla.[3] attempted retention of teeth after space closure using a fixed retainer in which they found the use of direct bonding material to place the retainer in the mouth conservative and non-invasive.

Fixed retainers forego the need for compliance and are invisible since they are bonded to the lingual surfaces of teeth but in the presence of these retainers, teeth become more susceptible to plaque accumulation.[4] Heier et al.[5] compared the periodontal implications of fixed and removable retainers using plaque and calculus indices. He reported that more plaque and calculus was present on teeth retained with fixed retainer.

There are two ways of placement of fixed retainers, either directly placed intra orally after prior fabrication on a cast or indirectly placed utilizing a cast on which the retainer is placed using composite pads and then transferred into the mouth using a silicon tray.[6] The stability of retainers is of prime importance for maintaining the correct position of teeth in the long run.[7] Egli et al.[8] compared the failure and posttreatment stability of both placement techniques in mandibular arch and found that there was no difference in the risks of failure between mandibular retainers bonded with direct (DB) and indirect methods. (IDB) Bovali et al.[9] compared the placement time and number of failures of fixed retainers bonded via DB and IDB methods and found that the bonding time is significantly shorter for DB along with a higher number of failures using the IDB method.

Levin et al.[10] also assessed the association of orthodontic treatment and fixed retention with gingival health by examining gingival recession, probing depth, and bleeding on probing of anterior teeth. They found the probing depth to be 1.90 ± 0.2 mm, gingival recession to be 0.06 ± 0.02 mm and 20.8% of all sites showed bleeding on probing. He also found that localized lingual gingival recession was significantly greater in teeth with fixed retainers (0.09 ± 0.2 mm) compared to teeth with no fixed retainers (0.01 ± 0.1 mm); $p < 0.05$.

Many people remain cautious of brushing on anterior teeth with retainers because of fear of breakage resulting in more plaque deposits on these teeth and therefore, requiring more scaling visits. The time taken for bonding the direct retainers during outpatient clinics can affect the duration of debonding appointment which is already a lengthy procedure. Thus, its important to assess the periodontal health, bonding time and stability of both maxillary and mandibular fixed retainers placed using DB in one arch and IDB in the other arch in patients who underwent orthodontic treatment.

RATIONALE:

The placement technique of retainers in both maxillary and mandibular arches can influence the time taken for bonding the retainer in the mouth of a patient which can in turn affect the patient´s response to the procedure. The different placement techniques can influence the stability of the retainer wire on teeth and the maintenance of periodontal health during the retention period. Therefore, it is essential to know which technique is better suited for placement and its influence on periodontal health so that in the future it helps clinicians save their time during placement of retainers while benefiting the patients. To our knowledge, this will be the first study both locally and internationally that will include an assessment of periodontal health, time duration of placement and stability of fixed retainer in the maxillary arch as well. Three months period is sufficient for assessment of periodontal health and failure of retainer, long term studies can be at a risk of attrition bias.

OBJECTIVES:

The objectives of this study are:

- The primary objective of this study is to compare the failure of fixed retainers which are bonded either through direct method or indirect method on patients undergoing orthodontic debonding through a modified split-mouth technique over a period of three months.
- The secondary objective of the study is to assess the amount of time taken during placement of retainers via both direct and indirect bonding of fixed retainers and periodontal health of patients undergoing orthodontic debonding through a modified split-mouth technique using mean values for plaque index, gingival index, calculus index follow up appointments over a period of three months.

OPERATIONAL DEFINITIONS:

Fixed Retainer[11]:

Fixed retainers consist of a twisted, flexible wire placed over and bonded to the lingual surface of anterior teeth.

Plaque and Calculus Indices:[12] (Annexure A)

Plaque index is a grading system used to assess the amount of plaque present at the gingival margins and helps in assessing oral health. Calculus index is also a grading system used to assess the amount of calculus present on gingiva. These are measurement indices which consist of four grades namely Grade 0, 1, 2, and 3. The increase in grade indicates the increased amount of plaque, calculus along the gingiva. Grade 0 denotes no plaque, calculus deposits, grade 1 denotes thin layer of plaque, calculus deposits, grade 2 denotes moderate layer of plaque, calculus deposits, grade 3 denotes abundant layer of plaque, calculus deposits.

Gingival Index:[12] (Annexure B)

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

of gingiva. Grade 0 indicates no gingival inflammation, grade 1 indicates mild inflammation, grade 2 indicates moderate inflammation and grade 3 indicates severe inflammation.

Retainer Failure:[13]

Detachment of the retainer wire either at the wire-composite interface or at the adhesive-enamel interface with either movement of teeth or no movement of teeth into a new position.

Periodontal Health:[14]

A state free from inflammatory periodontal disease.

Modified Split-mouth Technique:

A randomized control trial in which experimental and control interventions are randomly allocated to different areas in the oral cavity. In our study, experimental and control interventions will be randomly allocated to the upper and lower dental arches.

HYPOTHESIS:

- **Null Hypothesis**: There is no difference in placement technique of fixed retainers that can influence the failure of fixed retainers.
- **Alternate Hypothesis:** There is a 54% difference in placement technique of fixed retainers that can influence the failure of fixed retainers.

MATERIAL & METHODS:

Study Design: A modified split-mouth randomized controlled trial

Settings: Department of Surgery**,** Dental clinics at the Aga Khan University Hospital.

Study Duration: Minimum six months after ethical review committee (ERC) approval, two months will be used for recruitment of participants in this study.

SAMPLE SIZE:

The size of sample was measured using Open-epi software by using the findings of Gokce et al.[15], keeping α as 5%, the power of study as 80% and confidence level at 95%. To calculate sample size, we used the mean and standard deviation values of gingival index at one week interval (0.54 ± 0.64) and (1.02 ± 0.67) for two different bonding techniques i.e direct and indirect, of fixed retainer placement. A sample size of 30 was achieved in each group accounting for the total sample size of 60.

Sampling Technique: Non-probability consecutive sampling

Sample Selection:

Inclusion Criteria:

- Patients aged between 18 - 40 years
- Patients who read, write and understand English language
- Patients undergoing fixed orthodontic treatment
- Patients with good oral hygiene, with grade 1 or below on plaque and gingival indices at the time of debonding of brackets.
- All patients who will sign the informed consent form

Exclusion Criteria:

- Patients with periodontal disease
- Patients with any systemic disease
- Pregnant or nursing females
- Patients who cannot come for follow up appointments for a retainer check up

DATA COLLECTION PROCEDURE:

Before the initiation of the study, ethical approval will be taken from the institutional Ethical Review Committee of AKUH. This study will be carried out as per guidelines of the World Medical Association's Declaration of Helsinki 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 participants will be given the choice to either accept or refuse their inclusion in the study after providing them with complete detailed information. Only those patients signing the informed consent **(Annexure E)** will be recruited as study participants. All the data recorded 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 15 years as per regulatory requirements and institutional guidelines.

Participants will be assigned to one of the two study groups using a computer-generated randomization list using a random permuted block sampling of 6. The investigators of the study will not be blinded. The recruitment of the patients will be performed by the investigator who will explain the objective, the two arms of the study and the allocation to the participants. Patients will be recruited by principal investigator Dr. Rashna and co-investigator Dr. Fizzah on the basis of the above-mentioned inclusion and exclusion criteria. A proper thorough history and examination will be taken by the principal investigator and co-investigator for the purpose of appropriate

recruitment of patients. Sequentially numbered, opaque, sealed envelopes method will be implemented for allocation concealment, which will conceal the sequence until interventions are being assigned. Allocation of one of two retainer placement techniques will be assigned using closed sealed envelopes. Randomization will be done by closed sealed envelopes. The randomization will be performed by CTU. The study investigators and patients will not be blinded. The eligible upper and lower arches in each subject will be randomized to one of two groups at a 1:1 allocation ratio. Randomization will aid in minimizing selection bias. Envelopes must be stored in a secure place and opened one by one, only after the subject has been found eligible to be randomized.

A fixed retainer wire will be placed either through direct method or indirect method on randomely selected either of the maxillary and mandibular teeth of orthodontic patients after debonding procedure. All the measurements will be recorded by the investigator on a plaque index **(Annexure A)**, gingival index **(Annexure B)** and calculus index **(Annexure C)**.

Data will be collected on an organized study proforma **(Annexures D)**. The patients will be recruited from the Dental clinics, AKUH. All patients who will sign the informed consent form **(Annexure E)** will receive detailed information regarding the study. Data will be collected at three points in time. First, at the time of placement of retainer (T-0), their periodontal health will be recorded on the chart using the plaque, calculus and gingival indices and bonding time will be recorded using a timer. At the follow-up appointments at 1 month (T-1), 3 months (T-2), retainer breakage, gingival and periodontal health findings will be assessed clinically.

Study groups:

The patients will be screened using the inclusion and exclusion criteria by the investigator. Plaque will be assessed using a Community Index of Periodontal Treatment Needs (CPITN) probe before

bonding at T-0, T-1, and T-2. Measurements will be taken for the plaque and gingival indices and bonding time will be assessed using a timer. Retainer failures and periodontal health will be assessed at the follow-up appointments.

Group A (Intervention): Indirect placement of retainer (first making of retainer in lab and then it´s transfer from the cast onto the teeth via silicon key.)

Group B (Control): Direct placement of retainer (no prior lab work).

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

The investigator will unseal the envelope from the CTU, containing information regarding the intervention to be used on the participants based on randomization.

Retainers' management:

Routine oral hygiene maintenance and retainer management instructions will be given to each recruit. The participants will be advised to not bite from their front teeth as it may make retainer wire susceptible to breakage. In case, patient feels wire has moved, tooth has moved or wire is hindering chewing and irritating soft tissues such as tongue, gingiva, patients are advised to report to orthodontic clinics for timely repair of retainer wire.

Interim Analysis/ Stopping Rules:

Interim analysis will be run once after achievement of data collection of 50% of sample size. On the basis of results, it will be decided whether the study will be continued. In case of more than 54% significant difference in failure of fixed retainers, and significant difference in periodontal health and bonding time in two different bonding techniques of fixed retainers, the study will be stopped.

DATA ANALYSIS:

Data will be entered and analyzed in SPSS for Windows (version 23.0, SPSS Inc. Chicago). Frequencies and proportions will be reported for categorical variables such as gender. The 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 such as age, gender, type of malocclusion, duration of retainer placement since two different methods are used. Further, gingival and periodontal health may modify/effect the survival of retainers. Repeated measures Anova will be used for the pairwise comparison at baseline, one month and two months follow up. Independent sample t-test will be used for the comparison between the two groups to compare the values between both groups at T-0, T-1, and T-2. Univariate Cox regression analysis will be used to assess the influence of factors such as age, gender, and type of malocclusion on periodontal health and retainer failures. Significant variables at univariate level will be taken to the multivariable regression. Cox proportional hazard regression will be run for survival analysis to assess the survival time of both, DB and IDB. The significance level will be kept at $p \leq 0.05$ and confidence level will be kept at 95%.

Data management and confidentiality:

Confidentiality regarding patient information will be strictly followed. Except investigators nobody will have access to patient information. There will be no disclosure at any time of participants' name and identity. However, the data may be seen by ERC, or any local regulatory body for monitoring and audit purpose. As per GCP and other guidelines, data will be retained for 10 years.

Publication policy/plan:

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

Data monitoring and quality assurance:

Study PI will randomly check the data for accuracy and completeness on ongoing basis.

Ethical considerations:

Before the initiation of the study, ethical approval will be taken from the institutional Ethical Review Committee of AKUH. This study will be carried out as per guidelines of the World Medical Association's Declaration of Helsinki 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 participants will be given the choice to either accept or refuse their inclusion in the study after providing them with complete detailed information. Only those patients signing the informed consent **(Annexure E)** will be recruited as study participants. All the data recorded 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.

Possible risks or benefits:

There is a risk of breakage of retainer wire. In case of retainer breakage, there can be a risk of flexible retainer wire irritating the gums and hinder chewing and for this reason patients are advised to come to dental clinics for timely repair of retainer wire.

References:

1. Li Y, Jacox LA, Little SH, Ko CC. Orthodontic tooth movement: The biology and clinical implications. Kaohsiung J Med Sci. 2018;34:207-14.
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Annexure: Proforma

TITLE: Comparison of Periodontal Health, Bonding Time and Failure Between Direct and Indirect Fixed Retainer Placement among Orthodontic Patients – A Modified Split-mouth Randomized Controlled Trial

Our team is conducting a clinical trial to compare the health of your gums, time taken for placement of retainer wire and breakage of fixed retainer wire placed either directly by just placing the wire directly on teeth or indirectly by first making it in lab and then transferring it from the cast onto the teeth. Health of your gums will be assessed using plaque and gingival indices. Kindly read the form thoroughly and decide if you want to participate in this study. In case of participation, you must sign the informed consent form. In case of any query, you can ask for an explanation.

Date: **Version:**

Study ID: _____ **Gender:**

Age:_____ **Group:**

✎ Direct retainer

✎ Indirect retainer

At the time of placement of retainer T_0

Type of Placement	**Bonding Time**	**Plaque Score**	**Gingival Score**	**Calculus Score**	**Number of Breakages**
Direct					

Indirect					

Investigator sign_____

Date_____

Possible risks:

There is a risk of breakage of retainer wire. In case of retainer breakage, there can be a risk of flexible retainer wire irritating the gums and hinder chewing and for this reason you are advised to not bite anything from from teeth and maintain proper oral hygiene through brushing and flossing twice a day. In case of breakage, come right away to dental clinics for timely repair of retainer wire.

Date: **Version:**

Study ID: _____ **Gender:**

Age:_____ **Group:**

✎ Direct retainer

✎ Indirect retainer

At the time of one month follow up of retainer T_1

Type of Placement	**Plaque Score**	**Gingival Score**	**Calculus Score**	**Number of Breakages**
Direct				
Indirect				

Investigator sign_____

Date_____

Date: **Version:**

Study ID: _____ **Gender:**

Age:_____ **Group:**

✎ Direct retainer

✎ Indirect retainer

At the time of three months follow up of retainer T_2

Type of Placement	**Plaque Score**	**Gingival Score**	**Calculus Score**	**Number of Breakages**
Direct				
Indirect				

Investigator sign_____

Date_____

Annexure E: Informed Consent Form

Project Information

TITLE: Comparison of Periodontal Health, Bonding Time and Failure Between Direct and Indirect Fixed Retainer Placement among Orthodontic Patients – A Modified Split-mouth Randomized Controlled Trial

ERC Project No:

Principal investigator: Dr. Rashna Firoze Aga

Location: Section of Orthodontics, Department of Surgery. The Aga Khan University Hospital

Co-investigator: Dr. Fizzah Ikram

Location: Section of Orthodontics, Department of Surgery. The Aga Khan University Hospital

Version and Date:

Sponsor: The Aga Khan University Hospital

Organization: The Aga Khan University Hospital

Phone: 021-34930051

INFORMATION SHEET

Our team is conducting a clinical trial to compare the health of your gums, time taken for placement of retainer wire and breakage of fixed retainer wire placed either directly by just placing the wire directly on teeth or indirectly by first making it in lab and then transferring it

from the cast onto the teeth. Health of your gums will be assessed using plaque and gingival indices. Kindly read the form thoroughly and decide if you want to participate in this study. In case of participation, you must sign the informed consent form. In case of any query, you can ask for an explanation.

Purpose of this research study:

This study aims to compare the gum health, time taken for placement of retainer wire and breakage of fixed retainer wire placed either directly onto teeth or indirectly by first making it in lab and then transferring it from cast onto the teeth. Your participation will help us find the technique better suited for placement of fixed retainers after orthodontic treatment.

Procedures:

Your gum health will be assessed using probes and indices at the time of placement of retainer, during follow up appointments at one month and then three months later. Two retainers will be placed in your upper and lower teeth. However, in one jaw the retainer will be placed directly and in the other jaw of your mouth the retainer will be placed which was first made in laboratory and it will be transferred to your teeth via a transfer tray. Selection of jaws for direct and indirect placement of retainers will be random.

Possible risks:

There is a risk of breakage of retainer wire. In case of retainer breakage, there can be a risk of flexible retainer wire irritating the gums and hinder chewing and for this reason you are advised to not bite anything from from teeth and maintain proper oral hygiene through brushing and flossing twice a day. In case of breakage, come right away to dental clinics for timely repair of retainer wire. Retainer repair and management is part of the package of orthodontic treatment, hence, no additional cost exists for this purpose.

Financial considerations:

There is no financial compensation for your participation in this research.

Incentive:

There will be no incentives for your participation in this study.

Adverse events:

Placement of retainer wire on anterior teeth is a routine form of keeping the teeth in their corrected possible. It is essential that a retainer wire holds the teeth in their new position until

soft tissues adapt to this new position, therefore, other than the risk of breakage of retainer wire, there are no known adverse events related to placement of retainers.

Subject withdrawal:

Your participation in this study is voluntary, and you may withdraw from the study at any point due to any valid reason if you wish to do so. This would not affect your treatment or routine care.

Available sources of information:

Any further questions you have about this study will be answered by:

Principal Investigator:

Name: **Dr. Rashna Firoze Aga**

Phone Number: 0333-5141026

Any questions you may have about your rights as a research subject will be answered by:

Name: **Dr. Fizzah Ikram**

Phone Number: 0343-0204809

In case of a research-related emergency, call:

Day Emergency Number:

Night Emergency Number:

AUTHORIZATION

I have read and understand this consent form, and I volunteer to participate in this research study. I understand that I will receive a copy of this form. I voluntarily choose to participate, but I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study.

Name of participant (Printed or Typed):

Date:

Signature of participant:

Date:

Signature of Principal Investigator:

Date:

Name and Signature of person obtaining consent:

Date:

For Participants unable to read

Witness:

I have witnessed the accurate reading of the consent form to the potential participants, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Witness Name: _____ Participant's Thumb Print: _____

Signature: _____

Date: _____