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College of Dentistry

A Clinical Comparison of the Effectiveness of Two Moisture Insensitive Primers on Orthodontic Attachment Bond: A Randomized Clinical Trial

A Protocol Submitted to
The Council of the College of Dentistry, University of Baghdad in Partial Fulfillment of Requirements for the Degree of Master of Science in Orthodontics

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Certification of the Supervisor

This is to certify that the preparation and organization of this protocol entitled **"** A clinical comparison of the effectiveness of two moisture insensitive primers on orthodontic attachment bond: a randomized clinical trial**"** had been made by the master student **Ahmed Abdulelah Abduljawad** under my supervision, at the Department of Orthodontics/College of Dentistry/University of Baghdad in partial fulfillment for the Degree of Master of Science in Orthodontics.

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Introduction

The use of orthodontic bands has many disadvantages; it is time-consuming for the orthodontist, uncomfortable for the patient, the interproximal gaps had to be closed at the end of treatment and decalcification under bands sometimes occurred during treatment. Therefore, the obvious solution to these problems was for the clinician to bond the attachments directly to tooth enamel, thus eliminating the need for bands **(Gange, 2015)**.

The introduction of acid etching technique by Buonocore in 1955 and orthodontic brackets bonding by Newman in 1965 improved the overall orthodontic treatment results **(Buonocore, 1955; Newman, 1965; Kumar et al., 2018)**.

Orthodontic bracket bonding to etched enamel by the use of resin-based materials is a highly technique-sensitive procedure. Moisture control is the most important parameter in this process. Successful bracket bonding highly depends on the provision of a dry field. Contamination may occur after etching the tooth surface or after primer application, compromising the bonding procedure **(Littlewood et al., 2001; Cacciafesta et al., 2004; Safar Ali et al., 2021)**.

Clinical conditions during bonding procedure include a risk of contamination of the etched surface by saliva. Saliva contamination of the enamel surface is regarded as the most common reason for bond failure **(Zachrisson, 1977; Paschos et al.,**

2008). Acid-etched enamel absorbs saliva, which reduces the surface energy and renders the surface less favorable for bonding **(Evancusky and Meiers, 2000; Kumar et al., 2012)**. When the etched enamel is wet, most of the porosities become plugged, and the penetration of the resin is impaired, which results in resin tags of insufficient number and length **(Hormati et al., 1980; Silverstone et al., 1985; Öztoprak et al., 2007)**.

It must be noted, however, that the use of the terms 'moist' or 'wet' implies the presence of water, whilst saliva or crevicular fluid are considered 'contaminants'. Although the presence of water can be prevented by adopting moisture control precautions during bonding procedures, the orthodontist is often faced with the problem of bonding in an environment with increased contamination risk from saliva **(Cacciafesta et al., 1998; Wendl and Droschl, 2004)**. Because of their hydrophobic properties and absence of chemical adhesion, conventional bisphenol A-glycidyl methacrylate (Bis-GMA) adhesives require dry etched enamel for mechanical adhesion **(Hormati et al., 1980; Grandhi et al., 2001)**.

The failure rate of bonding to molars was greater than that of bonding to anterior teeth **(Jung, 2014; Roelofs et al., 2016)**. A possible solution to this problem was offered by the development of the moisture insensitive primers (MIP). These novel bonding materials contain hydrophilic components such as Hydroxyethyl Methacrylate (HEMA), which act as a wetting agent, allowing a lower contact angle and rapid extension of the molecule which bonds easily to the resin composite. In addition, they contain alcohol, which acts as a drying agent that seeks out moisture, evaporates it from the bonding field, and brings the resin in; thus, ensuring an efficient bonding **(Webster et al., 2001; Gange, 2015; Hadrous et al., 2019)**.

These primers are commercially available nowadays as Transbond MIP (3M Unitek Dental Products, Monrovia, CA, USA) and Assure Plus universal bond (Reliance, Itasca, IL, USA). In the cloud, many in vitro studies supports the manufacturers' claim that these two novel orthodontic systems provides sufficient shear bond strength of orthodontic attachments bonded under moisture contaminated conditions **(Goswami et al., 2014; Kumar et al., 2018; Hadrous et al., 2019; Stefański et al., 2019)**.

Although these in vitro measurements provide useful information about the bonding efficiency of different types of materials, they should be interpreted with caution because of inherent limitations and because they cannot take into account a number of factors that play an important role in the mouth **(Eliades and Brantley, 2000)**. For your information, no previous clinical study was conducted to evaluate the efficacy of these primers on bond failure rate, therefore; this randomized clinical trial will be conducted to be more representative of the clinical reality.

Aim and Objectives

Aim

To evaluate the clinical effectiveness of moisture insensitive primers in bonding molar tubes under moisture contaminated conditions.

Objectives

1- To evaluate and compare the clinical bond failure and survival rate of molar tubes using two moisture insensitive primers under moisture contaminated condition.

2- To compare the effectiveness of these primers between different arches, sides, gender and age differences.

The null hypothesis is that "there is no significant differences in the bond failure rate of molar tubes using Transbond MIP and Assure Plus universal bond under moisture contamination during the function of archwires used during leveling and alignment stage of orthodontic treatment".

Methodology

Study design

A single-operator, a split-mouth, cross-quadrant, randomized controlled trial (RCT), with 1:1 allocation ratio.

Settings

Orthodontic patients seeking for orthodontic treatment with fixed orthodontic appliance will be recruited for this study. The study will be conducted in the Orthodontic Clinic at the College of Dentistry/University of Baghdad in addition to private dental clinics and Bab Al-Muadham specialized dental center in Baghdad, Iraq. Clinicians will be either specialist orthodontists or under training to become specialist orthodontists.

Ethical approval will be obtained from the Ethics Committee of College of Dentistry/University of Baghdad prior to study commencement. The patients were first evaluated by the principal investigator (A. A. A) to see if they were eligible for the research. Those who meet the inclusion criteria will be asked to assigned a comprehensive consent form prior to the start of trial.

Subjects/Materials

Subjects

Patients seeking for orthodontic treatment and their treatment will be planned with metal fixed orthodontic appliance (0.22" for both arches).

Materials

A- Orthodontic materials:

1-Moisture insensitive primers: Transbond MIP (3M Unitek Dental Products, Monrovia, CA, USA) and Assure Plus universal bonding resin (Reliance, Itasca, IL, USA).

2-Orthodontic adhesive: CONTEC lc (Dentaurum GmbH & Co. KG, Turnstr, Ispringen, Germany).

3-Molar tubes: Stainless steel Classic Roth Tube with 0.022 slot (IOS International Orthodontics Services, Capricorn St, Stafford, TX, USA).

4- 37% phosphoric acid: N-Etch (Ivoclar Vivadent, Schaan, Liechtenstein).

5- Metal fixed orthodontic appliance with 0.022 slot and a universal sequence of orthodontic archwires used to finish leveling and alignment stage of orthodontic treatment. Orthodontic archwires used with brackets during orthodontic treatment.

B- Other materials:

oil- and fluoride-free coarse pumice powder, a rubber prophylactic cup, distilled water, bond brush, dental cotton pellets, articulating paper (ArtEXACT, Becht, Offenburg, Germany).

Instruments/equipment

Instruments

Cheek retractors, tube tweezers, bracket position gauge, dental mirror, probe and tweezers.

Equipment

Light curing unit: (Light emitting diode, Eight teeth curing pen; Changzhou city, Jiangsu, P.R.China) Specification of light curing unit: Light intensity: 1500 mW/cm2, Output wavelength: 380–515 nm.

Sample Size

To have adequate power (80%) to show a statistically significant difference ($P < 0{\cdot}05$) in proportions with at least one failed molar tube after 6 months, the RCT needed 33 patients in each group using a log rank test ignoring the matching. This assumes a difference of 35 percentage points (45% versus 80%, hazard ratio = 3·6). As an approximate allowance for the effect of matching, an estimated 33 patients in total were required using a stratified log rank test for analysis **(Littlewood et al., 2001; Wenger et al., 2008)**.

Procedure/Intervention

1-Sample Selection:

Thirty-three consecutive patients will be eligible for the study if they fulfill the following inclusion criteria:

1. Patients need metal fixed orthodontic appliance with 0.22";
2. Complete set of permanent dentition with fully erupted molar teeth on both arches;

3. Intact 1st molars and mainly their buccal surfaces are free from caries, fillings, or gingival hyperplasia;
4. No occlusal interferences that can affect the ideal position of molar tubes, especially in the lower arch.

2- Randomization:

The primers will be randomly allocated using a split-mouth, cross-quadrant design. In each patient, two diagonal quadrants (i.e. upper right and lower left, or vice versa) will be randomly assigned to each primer group. The split-mouth design has several advantages over a complete randomization design: it compares treatments within patients so that variation between patients is eliminated (e.g. effect of the chewing habits of the patient). Furthermore, in terms of patient recruitment, which is always difficult to accomplish in clinical trials, at most half of the patients are needed in a split-mouth design compared with the corresponding whole-mouth design **(Lesaffre et al., 2009)**. A potential disadvantage of the split-mouth design is that the treatment applied to one side can have a carry-across effect on the contralateral side of the mouth. This problem is limited with randomization **(Thiyagarajah et al., 2006)**.

In order to ensure an equal distribution of primers between the right and the left side of the dental arches, the mouth of each patient will be divided into quadrants and the contralateral bonding pattern will be randomly alternated from patient to patient using a random plan generator (Randomization.com). A CONSORT diagram showing the flow of patients through each stage of the trial is shown in Figure 1.

3-Blinding:

This study will be Double-blinded in which neither the patients nor the trial staff know which one of the primers a patient has received. This can be achieved by placing the two primers in two similar masked bottles and giving them numerical coding i.e. number one and number two coding for either type of primer **(Schulz and Grimes, 2002)**.

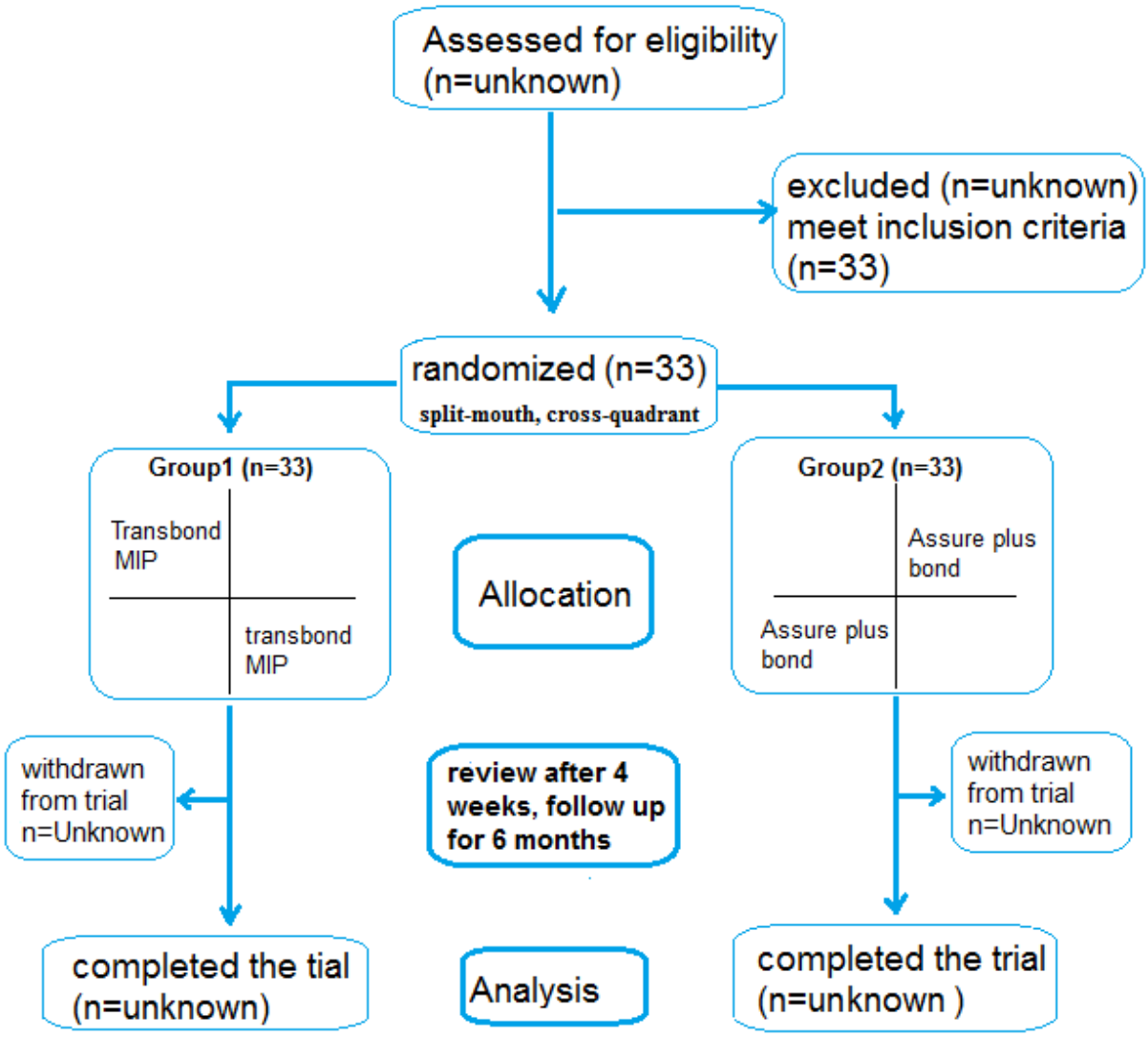

Figure 1 CONSORT flow diagram showing progress of subjects through the trial.

4-Procedure:

A single operator to avoid inter-operator variation will bond all molar tubes. A standardized protocol of tooth preparation and Molar tubes bonding will be adopted for all the patients. All teeth will be isolated and cleansed with a mixture of water and pumice using a rubber-polishing cup on a low speed hand piece. The teeth will be rinsed and dried with an oil-free air syringe, and will be etched with the conventional acid etching technique (37 percent orthophosphoric acid applied for 30 seconds). They will be subsequently rinsed thoroughly with water for 10 seconds to ensure total removal of etchant according to the manufacturer's instructions.

Without drying, one coat of the patient own non-stimulated saliva will be applied to the etched and wet surface using bond brush **(Zeppieri et al., 2003; Endo et al., 2008; Goswami et al., 2014)**. the excess will be blotted with a moist cotton pellet maintaining the surface moist **(Kumar et al., 2018)**.

A liberal coat of the Moisture-Insensitive Primer will be applied to the etched area of the teeth destined for a specific primer (split-mouth) using a nylon bond brush. Air will be gently blown on each tooth for 2 seconds, aiming the air stream perpendicular to the enamel surface then light cured for 20 seconds.

After etching and priming, molar tubes will be bonded to the teeth with CONTEC lc adhesive according to the manufacturer's instructions. The CONTEC lc adhesive will be applied to the molar tube base. The molar tube will be positioned correctly on the buccal surface of the tooth, and pressed firmly into place to express adhesive from the rim of the molar tube base. Excess adhesive will be removed with an explorer before curing. Then, the molar tube will be light-cured with a light curing unit (1500 mW/cm2, 380–515 nm.) for 20 seconds: 5 seconds each from the mesial,

distal, occlusal and gingival aspects of each tube). after curing is complete the molar tubes will be inspected for occlusal interferences using articulating paper. The sample will be excluded from the trial if any occlusal interference was observed. Initial wires will be fitted 10-15 minutes after bonding completion in the context of the straight wire technique.

All patients will receive the same instructions and will be seen at 3-4-week intervals. They will be, however, requested to inform the operator immediately and attend as soon as possible once a bond failure was apparent. They will be instructed to brush with a manual toothbrush using a fluoride-containing toothpaste.

5-Data collection:

Each patient will be monitored for 6 months. If a bond failed, the following will be recorded:

(1) Tooth number where failure occurred;

(2) Type of primer used;

(3) Date of bond failure.

Only the first failure of tubes will be taken into consideration. The teeth with recycled or newer tubes replaced will not be considered.

Timetable

Table 1

	Procedure	Time (months)
1	Material preparation and availability	Two months
2	Patient recruitment	Four months
3	Follow up	Six months
4	Results analysis and interpretation	Two months
5	Thesis writing	Four months
	Total	Eighteen months

The follow up period ends after six months from the start of recruitment of each patient. A clinical trial with similar situations concluded that half (49.8 per cent) of the total bond failures occurred during the first 2 months of treatment **(Mavropoulos et al., 2003)**. The probability of bond failure is greater immediately after bonding and during the first 3 months of bracket life **(Campoy et al., 2010)**.

Stopping Rules:

No stopping rules.

Budget and Funding:

- ❑ The study is self-funded.

Ethical Approval:

- ❑ The protocol will be submitted to ethics committee.

Data Management and Analysis

The data will be analyzed using SPSS software version 28.0.1 (IBM, Chicago, Illinois, USA). To find if there is significant difference, the number of bonding failures will be compared using the chi-square test, the tube survival rate will be estimated using the Kaplan–Meier analysis. The Tube survival distributions with respect to primer material, tooth location (upper/lower, right/left side), patient's gender and age will be then compared by means of a log-rank test. Further analysis to investigate the effects of covariates will be carried out using the frailty Cox regression model with response time to failure.

Further Considerations

Pilot study

- ❑ A pilot study will NOT be conducted

Dissemination

- ❑ Postgraduate Thesis.

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College of Dentistry – University of Baghdad

Patient Information Sheet

You are invited to participate in a scientific research. Please take your time to read the following information carefully before you decide whether or not you wish to participate. You can ask for clarifications or any more information about the study from the researcher and you can discuss this with outsiders.

Information about the research (to be written by the researcher in a simple language answering the following questions when applicable)

1. Study title: A Clinical Comparison of the Effectiveness of Two Moisture Insensitive Primers on Orthodontic Attachment Bond: A Randomized Clinical Trial .
2. What is the purpose of this study? To find a better Moisture insensitive primer to reduce orthodontic attachments bond failure.
3. Where will the study be conducted? University of Baghdad/college of dentistry/orthodontic department .
4. What are the procedures to be followed and what will you be asked to do at each visit? 33 participants will be included in the study. In each participant , two teeth will be primed using the first primer and other two teeth will be primed using the other primer while the rest of the teeth will be primed conventionally then these attachments will be followed up for six months. You will be instructed to Report immediately whenever a bond failure occurs in the involved attachments.
5. How long will the participation in the study last? Six months.
6. If you decided to take part in the study, will the treatment be different from the treatment you would get otherwise? No.
7. Who should not enter the study? If the surface of the target tooth has caries, fillings or stressful contact.
8. What will be the benefits of the study?
   a) To the participant? The bond materials could reduce bond failures and thus, improve the overall treatment for the patient and others.
   b) To the investigator? To find a better orthodontic bond material that reduce bond failure percentage to improve orthodontic treatment and as a Partial Fulfillment of Requirements for the Degree of Master of Science in Orthodontics.
9. What are the possible risks of taking part? There are no risks.
10. If you feel severe discomfort or pain during the study, would you be able to take any relief medication? Yes. (Only Paracetamol).
11. Will your participation in the study interfere with your daily activities? No.
12. Will you be informed of the results of the study? Yes if you request it .

If you agree to participate in this study, we will ensure your confidentiality with no one except the study researchers have the right to access your dental (medical) notes.
Participation in this study is entirely voluntary and you are free to refuse to take part or to withdraw from the study at any time without having to give a reason and without this affecting your future medical care or your relationship with medical staff looking after you.

Thank you for reading this Information Sheet and considering your participation in this study

Consent Form

	Please tick to confirm
I confirm that I have read and understood the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
I understand that my participation is voluntary and that I am free to withdraw at any time without any medical/dental care affected.	
I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the College of Dentistry – University of Baghdad where it is relevant to my taking part in this research. I give permission to these individuals to have access to my records.	
I agree to take part in the above study.	

Regarding any information and records taken during the research please specify your acceptance to share them as you desire:					
	Personal data	X-rays	Extra-oral photographs	Intra-oral photographs	Others
Confidential					
For consultation					
For teaching					
For conferences					
For publication					

	Name	**Signature**	**Date**
Participant			
Parent/guardian (if appropriate)			
Person taking consent			

Person to contact:

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1 copy for the participant; 1 copy for the researcher