Document Date: 03-Aug-2024

Annexure G: Adolescent Assent to Participate in Research (Age from 13 to <18)

Project Information

Project 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	**Project Number:**
ERC Ref No:	**Sponsor:** The Aga Khan University Hospital
Principal Investigator: Dr. Rashna Firoze Aga	**Organization:** The Aga Khan University Hospital
Location: Section of Orthodontics, Department of Surgery. The Aga Khan University Hospital	**Phone:** 021-34930051
Other Investigators: Dr. Rizwan Khalil	**Organization:** The Aga Khan University Hospital
Location: Section of Orthodontics, Department of Surgery. The Aga Khan University Hospital	**Phone:** 0309-0421462

You are being asked to participate in a research study conducted by **Dr. Rizwan Khalil:** an orthodontic resident supervised by **Dr. Rashna Firoze Aga** from the Section of Orthodontics, Department of Surgery at The Aga Khan University. You were selected as a possible participant in this study because you are undergoing fixed braces treatment and fulfilling the inclusion criteria of our study. Your participation in the research study is voluntary.

Why is this study being done?

This study aims to compare the bonding strength, soft deposits accumulation around braces and gums health between braces bonded with bulk fill composite and light cure conventional composite.

What will happen if I take part in this research study?

Please talk this over with your parents before you decide whether or not to participate. We will also ask your parents to give their permission for you to take part in this study. Even if your parents say "yes" you can still decide not participate.

If you agree to take part in this study, you can quit at any time without any problems and you are not giving up any legal rights. If you don't want to answer a question, you can say so and still stay in the study.

If you volunteer to participate in this study, the researcher will ask you to do the following:

- Your fixed braces treatment will be initiated as per standard protocols. It will be decided by chance which side of each participant's teeth (right or left side quadrants) will get the bulk-fill composite used to bond the braces in both upper and lower jaw. Number of bond breakages will be analyzed in a duration of three months in order to compare bond strength of both bonding materials

- Let the dentist perform a dental examination for soft deposits accumulation around braces and gums health

How long will I be in the research study?

This study will take **3 months of time and a total of 3-5 follow-up visits which will be the routine treatment visits** and there will be [58] of other people in this study.

Are there any potential risks or discomforts that I can expect from this study?

Braces wire might shift more to one side due to bracket bond failure and prick 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. No other serious side effects are expected from participating in this research.

Are there any potential benefits if I participate?

If bulk fill composites prove to be effective, they could reduce braces treatment time by preventing unwanted tooth movements and eliminating the need to go backward on light wires due to breakages. This would improve the treatment experience as a whole, which is an important factor for patients.

Will I receive any payment if I participate in this study?

No, you will not receive any type of payment for participating in this study

Will information about me and my participation be kept confidential??

Any information that is obtained in connection with this study and that can identify you will remain confidential. It will be disclosed only with your permission or as required by law. All the recoreded data of patients will remain confidential. Data will be stored in locked cabinet and password protected files. 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.

Who can answer questions I might have about this study?

If you have any questions, comments or concerns about this study, you can talk to one of the researchers. Please contact **Dr. Rizwan Khalil** at **03326078008** or send an email to **rizwan.khalil@aku.edu** or **Dr. Rashna Firoze Aga** at **rashna.aga@aku.edu** for any questions or if you feel that you have been harmed. This study has been reviewed and approved by AKU Ethics Review Committee**.**

SIGNATURE OF STUDY PARTICIPANT:

I understand the procedures described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

Name of Participant: _____

Signature of Participant: _____ 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: _____