

Document Date: 03-Aug-2024

Annexure F: Informed Consent Form

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: 021-34930051

INFORMATION SHEET

“I am **Dr Rizwan Khalil** from Department of Department of Surgery, Aga Khan University and doing a research on **Comparison of the Brackets Bonded with Bulk Fill Composite and Conventional Composite in Patients Undergoing Fixed Orthodontic Treatment.**” Our team is conducting a study 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. The soft deposits accumulation around braces and gums health markers will be used to check the health of your gums.

PURPOSE OF THIS RESEARCH STUDY:

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.

PROCEDURES:

This study required sample size of 58 (N) patients. 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. The soft deposits accumulation around braces and gums health markers will be used to check the health of your gums. The total time taken for these observations will be negligible as they will be processed along with your regular follow-up.

POSSIBLE RISKS OR DISCOMFORT:

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.

POSSIBLE BENEFITS:

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.

FINANCIAL CONSIDERATIONS:

There is no financial compensation for your participation in this research. There is no any additional costs that might result from participation in this study.

AVAILABLE MEDICAL TREATMENT FOR ADVERSE EXPERIENCES:

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.

CONFIDENTIALITY:

Your identity in this study will be treated as confidential. The results of the study, including laboratory or any other data, may be published for scientific purposes but will not give your name or include any identifiable references to you. However, any records or data obtained because of your participation in this study may be inspected by the sponsor or by AKUH ERC members.

RIGHT TO REFUSE OR WITHDRAW:

You are free to choose whether to participate in this study. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate. You will be provided with any significant new findings developed during this study that may relate to or influence your willingness to continue participation.

AVAILABLE SOURCES OF INFORMATION:

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

Name: Dr. Rashna Firoze Aga

Phone number: 021-34866641

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

Name: Rizwan Khalil

Phone number: 0332-6078008

AUTHORIZATION:

I have read and understood 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. I have received a copy of this document.

Name of participant (Printed or Typed): _____

Date: _____

Signature of participant: _____

Date: _____

Signature of Principal Investigator: _____

Date: _____

Name and Signature of the 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: _____