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Annexure H: Parental Consent Form for Children 0 < 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: 021-34930051

INTRODUCTION

The purpose of this form is to provide you (as the parent of study participant) information that may affect your decision as to whether or not to let your child participate in this research study. The person performing the research will describe the study to you and answer all your questions. Read the information below and ask any questions you might have before deciding whether or not to give your permission for your child to take part. If you decide to let your child participate in this study, this form will be used to record your permission.

Purpose of the Study:

The purpose of this study is 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 is my child going to be asked to do?

If you allow your child to participate in this study, she/he will be asked to:

- His/her 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

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.

NOTE:

This is a research study and, therefore, not intended to provide a consult for medical, diagnosis or treatment. The intervention provided in the course of this study is not necessarily equivalent to the standard method of prevention, diagnosis, or treatment of a health condition. You can continue

see your child's doctor if desired.

What are the risks involved in 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.

What are the possible benefits of this study?

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.

Does my child have to participate?

No, your child's participation in this study is voluntary. Your child may decline to participate or to withdraw from participation at any time. Withdrawal or refusing to participate will not affect their treatment/procedure or relationship with Aga Khan University in anyway. You can agree to allow your child to be in the study now and change your mind later without any penalty.

What if my child does not want to participate?

In addition to your permission, your child must agree to participate in the study. If your child does not want to participate they will not be included in the study and there will be no penalty. If your child initially agrees to be in the study s/he can change their mind later without any penalty.

Will there be any compensation?

Neither you nor your child will receive any type of payment participating in this study.

How will your child's privacy and confidentiality be protected if s/he participates in this research study?

Your child's privacy and the confidentiality of his/her data will be protected by keeping all the data 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. Your child's research records will not be released without your consent unless required by law or a court order. If it becomes necessary for the Ethics Review Committee to review the study records, information that can be linked to your child will be protected to the extent permitted by law. The data resulting from your child's participation may be made available to other researchers in the future for research purposes without identification. In these cases, the data will contain no identifying information that could associate it with your child, or with your child's participation in any study.

Whom to contact with questions about the study?

Prior, during or after your participation you can contact the researcher **Dr. Rizwan Khalil** at **03326078008** or send an email to rizwan.khalil@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

You are making a decision about allowing your child to participate in this study. Your signature below indicates that you have read the information provided above and have decided to allow them to participate in the study. If you later decide that you wish to withdraw your permission for your child to participate in the study you may discontinue his or her participation at any time. You will be given a copy of this document.

Child's Printed Name: _____

Printed Name of Parent(s) or Legal Guardian: _____

Signature of Parent(s) or Legal Guardian _____

Date: _____

Printed Name of Person Obtaining Consent: _____

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: _____