

**"QUANTITATIVE ANALYSIS OF ENAMEL SURFACE  
ROUGHNESS AFTER USING A COLOUR CHANGING  
ADHESIVE FOR BONDING : A COMPARATIVE STUDY"**

**Dissertation**

**Submitted to**

**BABU BANARASI DAS UNIVERSITY,  
LUCKNOW, UTTAR PRADESH**

*In the partial fulfillment of the requirements for the degree*

**of**

**MASTER OF DENTAL SURGERY**

**In**

**ORTHODONTICS AND DENTOFACIAL ORTHOPEDICS**

**By**

**Dr. Akshita Agarwal**

**Under the guidance of**

**Dr. Tripti Tikku**

**Professor and Head**

**Department of Orthodontics and Dentofacial Orthopedics**

**BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES, LUCKNOW**

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“When you have too much to say you become speechless and when you have too much to write your pen fumbles”

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ADHESIVE FOR BONDING : A COMPARATIVE STUDY"**

**Dissertation**

**Submitted to**

**BABU BANARASI DAS UNIVERSITY,  
LUCKNOW, UTTAR PRADESH**

*In the partial fulfillment of the requirements for the degree*

**of**

**MASTER OF DENTAL SURGERY**

**In**

**ORTHODONTICS AND DENTOFACIAL ORTHOPEDICS**

**By**

**Dr. Akshita Agarwal**

**Under the guidance of**

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**BBD City, Faizabad Road, Lucknow – 226028 (INDIA)**

**Dr. Lakshmi Bala**

Professor and Head Biochemistry and  
Member-Secretary, Institutional Ethics Committee

**Communication of the Decision of the VII<sup>th</sup> Institutional Ethics Sub-Committee**

**IEC Code: 03**

**BBDCODS/01/2019**

**Title of the Project:** Quantitative Analysis of Enamel Surface Roughness After Using a Colour Changing Adhesive for Bonding: A Comparative Study.

**Principal Investigator:** Dr. Akshita Agarwal      **Department:** Orthodontics & Dentofacial Orthopedics

**Name and Address of the Institution:** BBD College of Dental Sciences Lucknow.

**Type of Submission:** New, MDS Project Protocol

Dear Dr. Akshita Agarwal,

The Institutional Ethics Sub-Committee meeting comprising following four members was held on 10<sup>th</sup> January 2019.

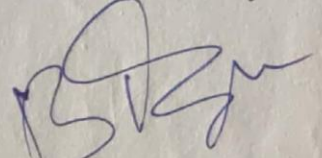
- |   |  |
|---|--|
| 1. Dr. Lakshmi Bala<br>Member Secretary | Prof. and Head, Department of Biochemistry, BBDCODS,<br>Lucknow                    |
| 2. Dr. Amrit Tandan<br>Member           | Prof. & Head, Department of Prosthodontics and Crown &<br>Bridge, BBDCODS, Lucknow |
| 3. Dr. Rana Pratap Maurya<br>Member     | Reader, Department of Orthodontics & Dentofacial Orthopedics,<br>BBDCODS, Lucknow  |
| 4. Dr. Sumalatha M.N.<br>Member         | Reader, Department of Oral Medicine & Radiology,<br>BBDCODS, Lucknow               |

The committee reviewed and discussed your submitted documents of the current MDS Project Protocol in the meeting.

The comments were communicated to PI thereafter it was revised.

**Decisions: The committee approved the above protocol from ethics point of view.**

Forwarded by:



**(Dr. B. Rajkumar)**

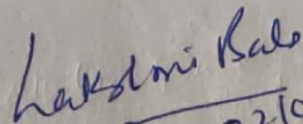
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(Babu Banarasi Das University)

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22/01/19  
**(Dr. Lakshmi Bala)**  
Member-Secretary  
Institutional Ethic Committee  
IEC  
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Web: <http://home.iitk.ac.in/~kbalani/>



Jun. 20, 2021

To Who So Ever It May Concern

This is to certify that **Dr. Akshita Agarwal**, a graduate student pursuing her Masters at Babu Banarasi Das College of Dental Sciences has carried out optical profilometry (images and surface roughness calculations) and elemental mapping of dental brackets at Advanced Centre for Materials Science (ACMS) at IIT Kanpur for her thesis. For 3-D optical profilometry, 3D-optical GT-K0 model from Bruker (UK) is used, whereas for elemental mapping, Tungsten-Electron Microscope (W-SEM) Model/Supplier: JSM-6010LA, JEOL, is utilized.

I her the very best for her future endeavours. Should you require any further details, please do not hesitate to contact me.

With best regards

K. Balani

**Babu Banarasi Das College of Dental Sciences**  
**(A constituent institution of Babu Banarasi Das University)**  
**BBD City, Faizabad Road, Lucknow – 227105 (INDIA)**

**Participant Information Document (PID)**

**1. Study title**

Quantitative analysis of enamel surface roughness after using a colour changing adhesive for bonding : A Comparative Study

**2. Invitation paragraph**

You are being invited to take part in a research study, it is therefore important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully. Ask us for any clarifications or further information. Whether or not you wish to take part is your decision.

**3. What is the purpose of the study?**

The purpose of this study is to quantitatively evaluate and compare the amount of enamel surface roughness produced following debonding of metal brackets and removal of adhesive while using two different adhesive systems: Grelgloo (Ormco India) and conventional Transbond XT (3M) using a 3D noncontact optical profilometer.

**4. Why have I been chosen?**

You have been chosen for this study as you are fulfilling the required criteria for this study.

**5. Do I have to take part?**

Your participation in the research is entirely voluntary. If you do, you will be given this information sheet to keep and will be asked to sign a consent form. During the study you still are free to withdraw at any time and without giving a reason.

**6. What will happen to me if I take part?**

You will have to give consent to use your extracted premolar teeth.

**7. What do I have to do?**

You do not have to change your regular lifestyles for the investigation of the study.

**8. What is the procedure that is being tested?**

The procedure will involve determining the surface roughness of enamel after debonding of the brackets by means of profilometer bonded using two different adhesives.

**9. What are the interventions for the study?**

Premolar teeth will be collected from patients who will be indicated for premolar extraction during their fixed orthodontic treatment . profilometric analysis will be done in IIT Kanpur. However you will not have any side effect on your health. This will be done only once in the study.

**10. What are the side effects of taking part?**

There are no side effects on patients of this study.

**11. What are the possible disadvantages and risks of taking part?**

There are no risk or disadvantages of taking part in this study.

**12. What are the possible benefits of taking part?**

This study will help us to know that whether the colour changing adhesives helps us in achieving the enamel surface closest to the original surface following debonding. If found so , the usage of these adhesives would increase greatly in dental clinics for Orthodontic treatment, as they can be easily removed without causing damage to tooth surface.

**13. What if new information becomes available?**

If additional information becomes available during the course of the research you will be told about these and you are free to discuss it with your researcher, your researcher will tell you whether you want to continue in the study. If you decide to withdraw, your researcher will make arrangements for your withdrawal. If you decide to continue in the study, you may be asked to sign an updated consent form.

**14. What happens when the research study stops?**

If the study stops/finishes before the stipulated time, this will be explained to the patient/volunteer.

**15. What if something goes wrong?**

If any severe adverse event occurs, or something goes wrong during the study, the complaints will be handled by reporting to the institution (s), and Institutional ethical community.

**16. Will my taking part in this study be kept confidential?**

Yes it will be kept confidential.

**17. What will happen to the results of the research study?**

The results of the study will be used to assess the enamel surface roughness of the teeth before and after bonding . Your identity will be kept confidential in case of any report/publications.

**18. Who is organizing the research?**

This research study is organized by the academic institution (BBDCODS).

**19. Will the results of the study be made available after study is over?**

Yes.

**20. Who has reviewed the study?**

The study has been reviewed and approved by the Head of the Dept, and the IEC/IRC of the institution.

**21. Contact for further information**

Dr. Akshita Agarwal  
Department of Orthodontics and Dentofacial Orthopedics  
Babu Banarasi College of Dental Sciences.  
Lucknow-227105  
Mob- 7619800900

Dr.Tripti Tikku (HOD)  
Department of Orthodontics and Dentofacial Orthopedics  
Babu Banarasi College of Dental Sciences.  
Lucknow-227105  
Mob- 9554832799

Dr. Laxmi Bala,  
Member Secretary,  
Babu Banarasi College of Dental Sciences.  
Lucknow  
[bbdcods.iec@gmail.com](mailto:bbdcods.iec@gmail.com)

Signature of PI.....

Name.....

Date .....



**बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज**  
(बाबू बनारसी दास विश्वविद्यालय का एक घटक संस्थान)  
बीबीडी सिटी, फैजाबाद रोड, लखनऊ - 227105 (भारत)

**प्रतिभागी सूचना दस्तावेज (पीआईडी)**

**1- अध्ययन शीर्षक**

रंग बदलने वाले पदार्थ द्वारा चिपकाए गए ब्रैकेट के निकलने के बाद दांत की ऊपरी परत के खुरदुरेपन का विश्लेषण और नियमित रूप से इस्तेमाल होने वाले पदार्थ से तुलनात्मक मूल्यांकन।

**2- आमंत्रण अनुच्छेद?**

आपको एक शोध अध्ययन में भाग लेने के लिए आमंत्रित किया जा रहा है, इसलिए यह समझना आपके लिए महत्वपूर्ण है कि अध्ययन क्यों किया जा रहा है और इसमें क्या शामिल होगा। कृपया निम्नलिखित जानकारी को ध्यान से पढ़ने के लिए समय दें। किसी भी स्पष्टीकरण या आगे की जानकारी के लिए हमसे पूछें। चाहे आप भाग लेना चाहते हैं या नहीं, आपका निर्णय है।

**3- अध्ययन का उद्देश्य क्या है?**

इस अध्ययन का उद्देश्य रंग बदलने वाले पदार्थ द्वारा चिपकाए गए ब्रैकेट के निकलने के बाद दांत की ऊपरी परत के खुरदुरेपन का विश्लेषण करना और नियमित रूप से इस्तेमाल होने वाले पदार्थ से तुलनात्मक मूल्यांकन करना है।

**4- मुझे क्यों चुना गया है?**

इस अध्ययन के लिए आपको चुना गया है क्योंकि आप इस अध्ययन के लिए आवश्यक मानदंडों को पूरा कर रहे हैं।

**5- क्या मुझे भाग लेना है?**

शोध में आपकी भागीदारी पूरी तरह से स्वैच्छिक है। यदि आप करते हैं, तो आपको यह जानकारी पत्र दिया जाएगा और सहमति फॉर्म पर हस्ताक्षर करने के लिए कहा जाएगा। अध्ययन के दौरान आप अभी भी किसी भी समय बिना किसी कारण के वापस लेने के लिए स्वतंत्र हैं।

**6- अगर मैं भाग लेता हूं तो मेरे साथ क्या होगा?**

आपको इस अध्ययन में अपने फ़िक्स्ड ऑर्थोडॉंटिक उपचार के दौरान निकाले गए दांत देने होंगे।

**7- मुझे क्या करना है?**

अध्ययन की जांच के लिए आपको अपने नियमित जीवन शैली को बदलने की ज़रूरत नहीं है।

**8- परीक्षण की जा रही प्रक्रिया क्या है?**

इस अध्ययन में हम ब्रैकेट को निकालने के बाद, रंग बदलने वाले पदार्थ से होने वाली दांत की ऊपरी परत पर खुरदुरेपन की जांच करेंगे।

**9- अध्ययन के लिए हस्तक्षेप क्या हैं?**

न्यूनतम हस्तक्षेप किया जाएगा।

**10- भाग लेने के दुष्प्रभाव क्या हैं?**

इस अध्ययन के कोई दुष्प्रभाव नहीं हैं।

**11- भाग लेने के संभावित नुकसान और जोखिम क्या हैं?**

इस अध्ययन में कोई जोखिम शामिल नहीं है।

**12- भाग लेने के संभावित लाभ क्या हैं?**

यह अध्ययन के द्वारा हमें ब्रैकेट को चिपकाने वाले रंग बदलने वाले पदार्थ से होने वाले दांत की ऊपरी परत पर खुरदुरेपन के बारे में पता चलेगा। यदि परिणाम सही निकला तो इस पदार्थ का प्रयोग और भी अधिक किया जा सकता है क्योंकि यह दांतों से सरलता से हट जाता है।

**13- क्या होगा अगर नई जानकारी उपलब्ध हो जाए?**

यदि शोध के दौरान अतिरिक्त जानकारी उपलब्ध हो जाती है तो आपको इनके बारे में बताया जाएगा और आप अपने शोधकर्ता के साथ चर्चा करने के लिए स्वतंत्र हैं, आपका शोधकर्ता आपको बताएगा कि आप अध्ययन में जारी रखना चाहते हैं या नहीं। यदि आप वापस लेने का निर्णय लेते हैं, तो आपका शोधकर्ता आपके वापसी के लिए व्यवस्था करेगा। यदि आप अध्ययन में जारी रखने का निर्णय लेते हैं, तो आपको एक अद्यतन सहमति फॉर्म पर हस्ताक्षर करने के लिए कहा जा सकता है।

**14- शोध अध्ययन बंद होने पर क्या होता है?**

यदि अध्ययन निर्धारित समय से पहले समाप्त / खत्म हो जाता है, तो यह रोगी / स्वयंसेवक को समझाया जाएगा।

**15- क्या होगा अगर कुछ गलत हो जाए?**

यदि कोई गंभीर प्रतिकूल घटना होती है, या अध्ययन के दौरान कुछ गलत हो जाता है, तो शिकायतों को संस्था (ओं), और संस्थागत नैतिक समुदाय को रिपोर्ट करके संभाला जाएगा।

**16- क्या इस अध्ययन में मेरा हिस्सा गोपनीय रखा जाएगा?**

हां इसे गोपनीय रखा जाएगा।

**17- शोध अध्ययन के नतीजों का क्या होगा?**

इस अध्ययन के परिणाम से ब्रैकेट को चिपकाने वाले रंग बदलने वाले पदार्थ से होने वाले दांत की ऊपरी परत पर खुरदुरेपन का मुलांकन होगा। आपको यह समझना होगा कि आपकी पहचान किसी भी रिपोर्ट/ प्रकाशन में नहीं की जाएगी।

**18- शोध का आयोजन कौन कर रहा है?**

यह शोध अध्ययन अकादमिक संस्थान द्वारा आयोजित किया जाता है। आपको शामिल किसी भी प्रक्रिया के लिए भुगतान नहीं करना है।

**19- क्या सेवाएं शोध खत्म हो जाने के बाद उपलब्ध रहेंगी या नहीं?**

हाँ।

**20- अध्ययन की समीक्षा किसने की है?**

इस अध्ययन की समीक्षा विभाग के प्रमुख और संस्थान के आईईसी / आईआरसी द्वारा की गई और अनुमोदित की गई है।

**21- अधिक जानकारी के लिए संपर्क करें**

**डॉ. अक्षिता अग्रवाल**

**ऑर्थोडॉन्टिक्स एवं डेंटोफेशियल ऑर्थोपेडिक्स विभाग**

**बाबू बनारसी कॉलेज ऑफ डेंटल साइंसेज**

**लखनऊ- 227105**

**7619800900**

**डॉ. तृप्ति टिक्कू**

**प्रोफेसर और हेड**

**ऑर्थोडॉन्टिक्स एवं डेंटोफेशियल ऑर्थोपेडिक्स विभाग**

**बाबू बनारसी कॉलेज ऑफ डेंटल साइंसेज**

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**9554832799**

**डॉ. लक्ष्मी बाला**

**सदस्य सचिव**

**बाबू बनारसी कॉलेज ऑफ डेंटल साइंसेज**

**लखनऊ**

**bbdcods.iec@gmail.com**

पीआई का हस्ताक्षर .....

नाम .....

दिनांक .....

**Babu Banarasi Das College of Dental Sciences**

(Babu Banarasi Das University)

BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

Consent Form (English)

Title of the Study -: **Quantitative analysis of enamel surface roughness using a colour changing adhesive for bonding : A Comparative Study**

Study Number.....

Subject's Full Name.....

Date of Birth/Age .....

Address of the Subject.....

Phone no. and e-mail address.....

Qualification .....

Occupation: Student / Self Employed / Service / Housewife/ Other (Please tick as appropriate)

Annual income of the Subject.....

Name and of the nominees(s) and his relation to the subject..... (For the purpose of compensation in case of trial related death).

1. I confirm that I have read and understood the Participant Information Document dated .....for the above study and have had the opportunity to ask questions. OR I have been explained the nature of the study by the Investigator and had the opportunity to ask questions.
2. I understand that my participation in the study is voluntary and given with free will without any duress and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.
3. I understand that the sponsor of the project, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. However, I understand that my Identity will not be revealed in any information released to third parties or published.
4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).
5. I permit the use of stored sample (tooth/tissue/blood) for future research. Yes [ ] No [ ] Not Applicable [ ]
6. I agree to participate in the above study. I have been explained about the complications and side effects, if any, and have fully understood them. I have also read and understood the participant/volunteer's Information document given to me.

Signature (or Thumb impression) of the Subject/Legally Acceptable

Representative:.....

Signatory's Name.....

Date .....

Signature of the Investigator.....

Date.....

Study Investigator's Name.....

Date.....

Signature of the witness.....

Date.....

Name of the witness.....

Received a signed copy of the PID and duly filled consent form Signature/thumb impression of  
the subject or legally Date.....

**Babu Banarasi Das College of Dental Sciences**

(Babu Banarasi Das University)

BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

**Child Assent Form**

Study Title -: **Quantitative analysis of enamel surface roughness using a colour changing adhesive for bonding : A Comparative Study**

Study Number \_\_\_\_\_

Subject's Full Name \_\_\_\_\_

Date of Birth/Age \_\_\_\_\_

Address \_\_\_\_\_

I \_\_\_\_\_, exercising my free power of choice, hereby give my consent for participation in the study entitled: "Quantitative analysis of enamel surface roughness using a colour changing adhesive for bonding – A Comparative Study" I have been informed, to my satisfaction, by the attending physician, about the purpose of the study and the nature of the procedure to be done. I am aware that my parents/guardians do not have to bear the expenses of the treatment if I suffer from any trial related injury, which has causal relationship with the said trial drug. I am also aware of right to opt out of the trial, at any time during the course of the trial, without having to give reasons for doing so

Signature of the study participant \_\_\_\_\_

Date: \_\_\_\_\_

Name of the study participant \_\_\_\_\_

Signature of the Witness \_\_\_\_\_

Date \_\_\_\_\_

Name of the Witness \_\_\_\_\_

Signature of the attending Physician \_\_\_\_\_

Date \_\_\_\_\_

Name of the attending Physician \_\_\_\_\_