STUDY PROTOCOL

Official Study Title:

Evaluation of Enamel Surface Integrity and Pulpal Temperature During Ceramic Bracket Removal Using Two Er:YAG Laser Intensities Versus Conventional Technique: A Randomized Split-Mouth Clinical Study

NCT Number:

"Pending"

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Principal Investigator:

Christelle Moubarak

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INFORMATION AND CONSENT FORM

Introduction

My name is Christelle Moubarak, and I am a resident in the department of orthodontics at the Faculty of Dental Medicine at Saint Joseph University (USJ). I invite you to participate in my research project entitled: *" Evaluation of enamel surface and pulpal temperature for ceramic bracket removal using two laser intensities versus conventional technique: A split-mouth clinical study"*. The supervisor for this research is Dr. Lina Medawar, whom you can contact at the following address: dr.medawar@inco.com.lb

You are invited to participate in a study conducted at the dental center of FMD, USJ to evaluate an innovative method for removing ceramic brackets using Er:YAG laser technology. This study aims to improve patient comfort and the effectiveness of debonding brackets with laser compared to conventional methods. Your case meets the selection criteria for this study, and your participation will contribute to the advancement of orthodontic techniques.

If you agree to participate, the debonding of your ceramic brackets will be performed using the Er:YAG laser under controlled conditions. The procedure will be explained in detail, and your safety and comfort will be ensured throughout the process. There are no additional costs or risks associated with your participation.

This document provides information about the study. If you have any questions, please feel free to ask. If you agree to participate, you are asked to sign this consent form.

Project Objective

The objective of this research is to evaluate the effectiveness and advantages of using the Er:YAG laser for the debonding of ceramic brackets. Traditional methods can sometimes cause discomfort, enamel damage, or prolonged treatment times. The use of the Er:YAG laser offers a more advanced approach, aiming to reduce discomfort and protect the dental enamel.

Study Procedure

Only one visit will be required.
Debonding of brackets:

A. Half of the upper arch: brackets will be removed with the Er:YAG laser.
B. The other half: brackets will be removed with the conventional method.

After the procedure you will be asked to complete a pain scale to indicate your level of discomfort for each technique used.
This study does not involve any blood sampling or additional examinations.

Advantages and Disadvantages Advantages:

- Reduction of discomfort due to the softening of the adhesive with the laser.
- Increased enamel protection: reducing the risk of microfractures.

- Faster and more efficient procedure.
- Contribution to orthodontic advancements to improve future treatments.
- There are no additional costs or risks associated with your participation.

Participant's freedom and right to withdraw

- Your participation in this research project is completely voluntary.
- You are free to accept or refuse participation in this study. You may withdraw your participation at any time without having to justify your decision or suffer any prejudice whatsoever.
- To access your data, to rectify them, to ask for their deletion, to exercise your right to limit the processing of your data, or for any question about the processing of your data, you can contact us either on my email address or on the email address of my research director.

Information confidentiality

- During your participation in this research project, I will collect and securely record, in a research file (computer and/or paper), information about you necessary for the proper conduct of the research project. This may include the following information: name, gender, date of birth, lifestyle habits, results of all tests, examinations and procedures you will undergo during this project, etc.
- All information collected during the research project will be strictly kept confidential. In order to preserve your anonymity and the confidentiality of this information, you will be identified only by a code number. I will only use the data for research purposes in order to meet the scientific objectives of the project.

Purpose of the treatment

- The data collected will only be used for this research project. It will not be communicated to any other entity. The legal basis for the treatment is your consent.

Photography

This research involves photography of the teeth uniquely.

- Do you allow photography of your teeth? ☐ Yes ☐ No
- Do you allow the use of this material for scientific purposes? ☐ Yes ☐ No

Data Retention and Publication

- Your personal data will be destroyed two years after the study ends.
- You will be informed of the research results if you wish.
- No identifying data will be published.
- In the case of subsequent studies, would you like to be contacted? ☐ Yes ☐ No

Data storage and destruction deadline

- I undertake to store all data collected during the research project in a secure and confidential location. Your personal data will be destroyed two years upon completion of the study. However, the results of the research will be retained and will not be deleted.

Publication of data and data recording

- You will be informed of the results of the research and the publications that will result from it, if you so wish.
  Data from the research project may be published in scientific journals or shared with other people in scientific discussions. No publication or scientific communication will contain any information that could identify you.

Subsequent studies

- It is possible that the results of this study may lead to further research. If so, would you allow me to contact you again and ask if you would like to participate in this new research?
- Yes ☐ No☐

Understanding the information

- You may obtain additional information regarding the research from my research sponsor. You can also ask the representative of the Ethics Board (Tel. 01421000 - ext. 2229), at any time, for further information, explanation of your rights and help in case of conflict.

Participant Consent

I declare that I have read the above research and that it has already been accepted by the Research Ethics Board of Saint Joseph University.

I acknowledge that the project has been explained to me, that my questions have been answered, and that I have been given sufficient time to make a decision. I agree to participate in this research project under the conditions stated herein.

Name: _____

Date: _____

Signature: _____

(For minors: consent of legal representative)

As the father/mother/legal guardian of Name: _____, I authorize their participation in this study.

Name of representative: _____

Signature: _____

Date: _____

Investigator's Declaration

I certify that I have explained the objectives and procedures of the study to the participant. I have answered their questions and emphasized that they can withdraw freely at any time. My research team and I commit to respecting the conditions outlined in this information and consent form and will provide a signed copy to the participant.

Name: Christelle Moubarak

Date: _____

Phone: 0096176411971

Email: christelle.moubarak1@net.usj.edu.lb

Signature: _____