**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"

Document Date:

2 March 2026

Principal Investigator:

Christelle Moubarak

Resident, Orthodontic Department – Faculty of Dental Medicine, Saint Joseph University of Beirut, Beirut, Lebanon

Saint Joseph University of Beirut

Faculty of Dental Medicine

Craniofacial Research Laboratory

TITLE

# "Evaluation of enamel surface and pulpal temperature for ceramic bracket removal using two laser intensities versus conventional technique: A Split-Mouth Clinical Study."

Research protocol

Presented by:

**Christelle MOUBARAK**

Under the supervision of:

Pr. Lina MEDAWAR

Department of Orthodontics and Dentofacial Orthopedics

## 1. INSTITUTIONAL FRAMEWORK

- Orthodontic Department, Faculty of Dental Medicine, Saint Joseph University of Beirut.
- Laser Unit, Faculty of Dental Medicine, Saint Joseph University of Beirut

## 2. PROJECT TYPE

Master's thesis.

## 3. PROJECT STUDY

- A comparative and experimental study.
- A cross-sectional, clinical study.

## 4. PROJECT TITLE

Evaluation of enamel surface and pulpal temperature for ceramic bracket removal using two laser intensities versus conventional technique: A split-mouth clinical study.

## 5. RESEARCH AND PUBLICATION TEAM

- **Lead Researcher**: **Christelle Moubarak**

  *Affiliation:* Resident at the department of Orthodontics, Faculty of Dental Medicine, Saint Joseph University of Beirut.
- **Project Director: Pr. Lina Medawar**

  *Affiliation:* Clinical Professor and Program Director, Department of Orthodontics and Research associate, Craniofacial Research Laboratory, Faculty of Dental Medicine, Saint Joseph University of Beirut.

**Publication Team and roles in publication:**

- **Christelle Moubarak**: DDS. Resident at the department of Orthodontics, Faculty of Dental Medicine, Saint Joseph University of Beirut.

  *Role: Principal investigator. Responsible for study conceptualization and design, clinical procedures, data collection and analysis, manuscript editing.*

  Email: christelle.moubarak1@net.usj.edu.lb
- **Pr Karim Corbani:** DDS, MSc, PhD. Assistant Professor, Restorative and Esthetic dentistry department, Head of the Laser Unit and the Emergency Unit, Faculty of Dental Medicine, Saint Joseph University of Beirut.

*Role: Co-director of the research project. Responsible for overseeing the laser debonding procedures and reviewing the manuscript sections related to laser use.*

Email: karim.corbani@usj.edu.lb

- **Dr Roland Kmeid**: DDS, DUO. Head of the Orthodontic Department and Research Associate, Cranio-Facial Research Laboratory. Faculty of Dental Medicine, Saint Joseph University of Beirut.

  *Role: Project guidance and critical manuscript revision.*

  Email: roland.kmeid@usj.edu.lb
- **Pr Elie Khoury**: DDS, DESO, MSc, PhD. Department of Orthodontics, Faculty of Dental Medicine, Saint Joseph University of Beirut.

  *Role: Structure visualization and manuscript revision.*

  Email: khoury.es@gmail.com
- **Dr Adib Kassis:** DDS, MSc, DEA. Department of Orthodontics, Faculty of Dental Medicine, Saint Joseph University of Beirut.

  *Role: Manuscript revision and editing*

  Email: adib.kassis@usj.edu.lb
- **Pr Roula Akl**: DDS, MSc, PhD. Department of Orthodontics, Faculty of Dental Medicine, Saint Joseph University of Beirut

  *Role: Structure visualization and manuscript feedback.*

  Email: roula.akl@usj.edu.lb
- **Dr Emilie Hayek:** DDS, DESO, MSc. Department of Orthodontics, Faculty of Dental Medicine, Saint Joseph University of Beirut.

  *Role: Review of the manuscript.*

  Email: emihayeck@hotmail.com
- **Pr Carla Zogheib.** DDS, DESE, MSc, PhD. department of Endodontics, Saint Joseph University of Beirut.

  *Role: Pulpal thermal changes supervision and control.*

  Email: Carla.zogheibmoubarak@usj.edu.lb
- **Pr Lina Medawar:** DDS, MSc, MAS, PhD. Department of Orthodontics and Research associate, Craniofacial Research Laboratory, Faculty of Dental Medicine, Saint Joseph University of Beirut.

*Role: Directing, Guiding in Research study Design and implementation, Planning and managing the project execution, manuscript refinement*

Email: lina.medawar@usj.edu.lb

## 6. BUDGET

Personal financing.

## 7. KEYWORDS

Adhesive remnant index, laser, orthodontic bracket, pain, temperature, tooth enamel.

## 8. GENERAL CONTEXT

Orthodontic brackets are bonded to the enamel surface to assist tooth movement and must be carefully removed at the end of treatment to restore the enamel as closely as possible to its pretreatment condition while minimizing iatrogenic damage. Inefficient debonding methods may increase enamel damage, prolong the procedure, and cause patient discomfort leading to a negative final perception of treatment. Thus, the importance of having an optimal protocol (1,2).

Ceramic brackets offer aesthetic advantages over metal brackets but pose debonding challenges such as increased risk of enamel cracks, fractures, and bracket breakage due to their high strength, bonding resistance, and fragility (2). As patients prioritize aesthetic outcomes, conservative approaches that preserve tooth structure should be emphasized. Advances in materials and technology aim to enhance esthetic results while ensuring enamel integrity (3).

As technology advances, alternative methods such as laser applications are being explored to overcome challenges of the traditional mechanical debonding techniques such as enamel damage or elevated pulpal temperatures due to the mechanical friction (4,5).

The term "laser" stands for "light amplification by stimulated emission of radiation." Its use in dentistry began in the 1980s, initially for soft tissue procedures, and has since expanded to include gingivectomy, frenectomy, surgical exposure of impacted teeth, enamel etching, bonding, bracket debonding, and even pain control and accelerated tooth movement through laser therapy (6,7). In 1997, the U.S. Food and Drug Administration (FDA) approved erbium lasers for hard tissue procedures, followed by diode lasers for soft tissue treatments in 1998 (8).

Laser-assisted debonding works by softening the adhesive resin, reducing the force required for bracket removal and minimizing enamel damage and patient discomfort (9). However, excessive heat diffusion to tooth structures can cause pulpal damage, as research has shown that a temperature

increase of more than 5.5°C above the normal baseline intra-pulpal temperature (i.e., a rise from approximately 37°C to over 42.5°C) is considered critical and may lead to irreversible pulpitis or pulp necrosis. Research suggests that lasers with appropriate power settings can effectively debond ceramic brackets without harming enamel or pulp (10,11).

Among the various laser types, erbium-doped yttrium aluminum garnet (Er:YAG) has gained attention for its safe and efficient application in different dental procedures, making it a strong candidate for laser-assisted bracket debonding (12,13). However, uncertainty remains regarding the influence of different laser wavelengths and bracket systems on debonding outcomes, highlighting the need for further research (14).

Despite recent advancements, significant gaps in the literature remain (15). Notably, most existing studies are limited to either in vitro conditions, which fail to replicate the complex biological environment of the oral cavity, or in vivo studies that lack sufficient clinical standardization. The absence of comprehensive investigations bridging both laboratory and clinical settings leaves critical questions unanswered regarding the safety and efficacy of laser-assisted techniques, and addressing these gaps is of critical importance (16).

Therefore, our present study, through its split-mouth design, offers a unique opportunity to directly compare laser-assisted and conventional methods while minimizing inter-patient variability. By examining enamel surface alterations and monitoring pulpal temperature changes in a clinically relevant context, this research seeks to establish evidence-based guidelines for the safe and efficient use of laser technology in orthodontics. Moreover, by evaluating two different laser power settings, the study aims to identify the optimal parameters, further refining clinical recommendations and ensuring a balanced approach between conservatism and effectiveness; ultimately enhancing patient outcomes and contributing to the development of standardized protocols for laser-assisted bracket removal.

## 9. SUMMARY DESCRIPTION OF THE SUBJECT AND APPROACH

Laser debonding has been proposed as a more conservative alternative to conventional methods, minimizing mechanical stress and enamel damage. Authors such as Mocuta et al. and Aravindaksha et al. highlight the potential of lasers, such as Er:YAG and diode lasers, in reducing adhesive strength effectively while limiting harm to the enamel surface and underlying pulp tissues. However, as indicated in the reviewed studies, existing research often lacks a comprehensive clinical evaluation

of thermal effects and enamel integrity, focusing predominantly on in vitro results without fully replicating the oral environment. Furthermore, there are significant gaps in the development of a standardized clinical protocol for laser-assisted orthodontic debonding, including parameters such as laser type, energy settings, and exposure duration.

This research addresses these gaps by providing clinically relevant data on the safety and efficacy of laser-assisted debonding techniques, aiming to establish evidence-based guidelines for improved orthodontic care. The proposed study evaluates the effect of laser-assisted bracket removal on enamel surface quality and pulpal temperature, based on a split-mouth design to provide robust, comparative data within the same patient. Two different laser power settings will be assessed to determine their impact and optimize laser settings for clinical use. This research aims to assess whether laser technology can offer a more conservative and effective alternative to conventional methods of bracket removal while consistently maintaining pulpal temperature within safe clinical limits. Advanced tools, including microscopy for evaluating adhesive remnant index as well as thermocouples to monitor pulp chamber temperature dynamics, will be employed.

## 10. INNOVATIVE CHARACTER OF THE STUDY

The proposed study represents a novel exploration within the field of orthodontics, applying advanced laser technology for bracket removal. While it builds upon existing research that has demonstrated the potential benefits of lasers in minimizing enamel damage and reducing thermal stress, this study distinguishes itself through its innovative split-mouth design, combining in vivo and clinically relevant methodologies. By using microscopy to assess adhesive remnant index (ARI) alongside thermocouples to measure pulpal temperature dynamics, this approach ensures objective, measurable outcomes that can contribute to the establishment of evidence-based clinical guidelines. Furthermore, this research addresses a critical gap in current knowledge: the lack of a standardized clinical protocol for laser uses in orthodontic debonding. By comparing two different laser power settings, it aims to establish clear, evidence-based guidelines that contribute to the advancement of more conservative and effective orthodontic bracket removal techniques.

## 11. PROBLEMATIC

To which extent are laser-assisted debonding techniques considered as a viable solution to overcome the challenges of conventional methods, ensuring safe, efficient, and comfortable removal of orthodontic brackets while minimizing enamel damage and pulpal risks?

How do different laser power settings compare in their clinical performance, and which parameters yield the most favorable outcomes in terms of enamel preservation, thermal safety, and overall procedural success?

## 12. RESEARCH OBJECTIVES

*Primary Objective:* To evaluate and compare enamel surface preservation and pulp chamber temperature changes for ceramic bracket removal using two different laser powers versus conventional debonding, within a split mouth design.

*Secondary objectives:*

- To determine which of the two laser power settings (Laser 1 or Laser 2) provides the best balance between an effective and conservative approach, contributing to the development of an optimized clinical protocol for laser-assisted bracket removal.
- To compare the patient's perceived pain and discomfort following each clinical mechanical debonding procedure (Laser 1, Laser 2 and conventional method).

## 13. HYPOTHESIS

*Null Hypothesis ($H_0$):* There is no significant difference between laser-assisted (L1 and L2) and conventional orthodontic bracket removal in terms of enamel surface preservation and patient-reported discomfort.

*Null Hypothesis ($H_0$'):* There is no significant difference between the two laser power settings (L1 vs L2) in terms of effectiveness for orthodontic bracket removal regarding enamel surface preservation, pulp chamber temperature changes, and patient-reported discomfort.

*Alternative Hypothesis ($H_1$):* Laser-assisted orthodontic bracket removal (L1 and/or L2) results in significantly improved enamel surface preservation and reduced patient discomfort compared to conventional bracket removal.

*Alternative Hypothesis ($H_1$'):* There is a significant difference between the two laser power settings (L1 vs. L2) regarding enamel surface preservation, pulp chamber temperature changes, and patient-reported discomfort, allowing for the identification of a more optimal laser setting.

## 14. METHODOLOGY

### A. PILOT STUDY:

An in vitro pilot study was initially conducted on six extracted maxillary teeth with bonded ceramic brackets to assess the feasibility of the methodology and refine the protocol before initiating the main study. In this pilot study we used the same bracket type (3M Clarity™ ceramic brackets) and the same bonding composite materials (TruLock® Light Cure Band Adhesive) as those used in the orthodontic department at Saint Joseph University of Beirut. This preliminary phase aimed to establish a safe and effective debonding protocol using specific LASER parameters—such as power, energy settings, wavelength, and exposure duration. These parameters were selected based on data from peer-reviewed literature to ensure prior validation and clinical safety. For bracket debonding, Er:YAG lasers with around 4 W energy levels and water cooling spray have been demonstrated to be safe (4,10,14). However, due to the absence of a golden protocol, various parameters were evaluated to identify the most effective ones.

***Laser 1***: Er:YAG laser (LightWalker II ST-E Pro+, Fotono, Ljubljana, Slovenia) with a 2,940 nm wavelength, average power of **4W**, pulse energy of 400 mJ, frequency of **10 Hz**, HO2 tipless handpiece, and with a 900mm focal point. A non-contact type handpiece (Turbo) in MSP mode (100 microseconds pulse duration) was applied under air = 1 and water = 1 settings, using a scanning method at a 45-degree angle relative to the bracket surface, maintained at the focal point. Illumination time ranged from approximately 10 to 15 seconds until spontaneous ceramic bracket detachment occurred *(Fig. 1 and 2)*. Three bonded teeth were tested using this protocol to confirm its effectiveness before applying it to the main study.

***Laser 2***: Er:YAG laser (LightWalker II ST-E Pro+, Fotono, Ljubljana, Slovenia) with a 2,940 nm wavelength, average power of **4.5W**, pulse energy of 300 mJ, frequency of **15 Hz**, HO2 tipless handpiece, and with a 900mm focal point. A non-contact type handpiece (Turbo) in MSP mode (100 microseconds pulse duration) was used under **air=1** and **water=1** scanning method, at a 45-degree angle relative to the bracket surface at the focal point and illumination time was around 10 to 15s until spontaneous ceramic bracket detachment *(Fig. 1 and 3)*. Three bonded teeth were also tested using this second protocol to validate its effectiveness.


*Figure 1. Fotona LightWalker II ST-E Pro+ Er:YAG laser unit used for bracket debonding.*


*Figure 2. Parameters Laser 1*


*Figure 3. Parameters Laser 2*

For both intensities the laser tip was positioned at a 45-degree angle and at 1 cm distance from the bracket. The distance was manually verified using a millimeter paper ruler. Laser light was irradiated on the labial surface of brackets at speed of 1mm/sec *(Fig. 4).*

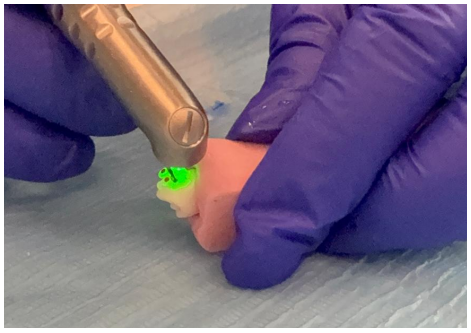


*Figure 4. Laser tip positioning relative to bracket surface.*

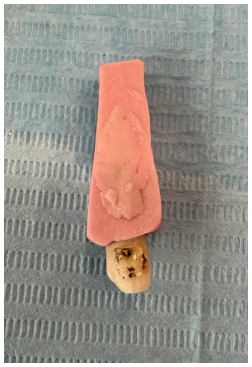


*Figure 5. Tooth surface after bracket removal.*

Following laser irradiation, the brackets were removed according to the manufacturer's instructions. No additional force was required; the brackets either detached spontaneously or were easily lifted from the tooth surface using dental tweezers *(Fig. 5)*.

It's essential to know that the laser unit employed in this study includes a dedicated "bracket debonding" mode with preset parameters specifically developed for orthodontic bracket removal procedure. These manufacturer-recommended settings are based on extensive research and clinical validation to ensure both efficacy and patient safety. Additionally, the device is equipped with intelligent, built-in safeguard with auto-regulated safety features: when one parameter, such as power, is increased, other settings like frequency and pulse duration are automatically adjusted to remain within a clinically safe range. For example, at an average power of 4 W, the pulse energy is set to 400 mJ, whereas increasing the power to 4.5 W results in an automatic reduction of pulse energy to 300 mJ.

## B. CLINICAL STUDY:

### *Collection Procedures*

All clinical procedures and data collection will be conducted at the Orthodontic Department of Saint Joseph University of Beirut, which is equipped with the necessary facilities to ensure standardized conditions for instrumentation use. This controlled clinical setting will enhance the accuracy, consistency, and reliability of the data collected. Standardized imaging and scoring methods will be employed to ensure objective and reproducible assessments.

Patient recruitment will take place at the Orthodontic Department and participants will be selected to meet the inclusion criteria. The study sample will consist of maxillary permanent teeth with orthodontic ceramic brackets in patients who have completed their orthodontic treatment and are ready for debonding. To maintain uniformity across the sample, only patients with the same type of brackets and bonding composite material will be included.

### *Sample Size calculation*

A split-mouth study design will be implemented to compare the effects of laser-assisted debonding and conventional debonding with orthodontic pliers. To limit the heterogeneity associated with the morphology and physiology of the teeth and produce a more uniform sample, we will only include the **upper teeth** which will be equally distributed between right and left quadrants.

Based on statistical power calculations, the study will include **10 patients**, resulting in **20 quadrants**. It will include the **maxillary arch of each patient**, specifically teeth **15 to 25**, for a total of **10 teeth per patient**.

**Each quadrant (5 teeth)** will be randomly assigned to one of the debonding techniques using a computer-generated randomization sequence to minimize selection bias *(Fig.6)*.

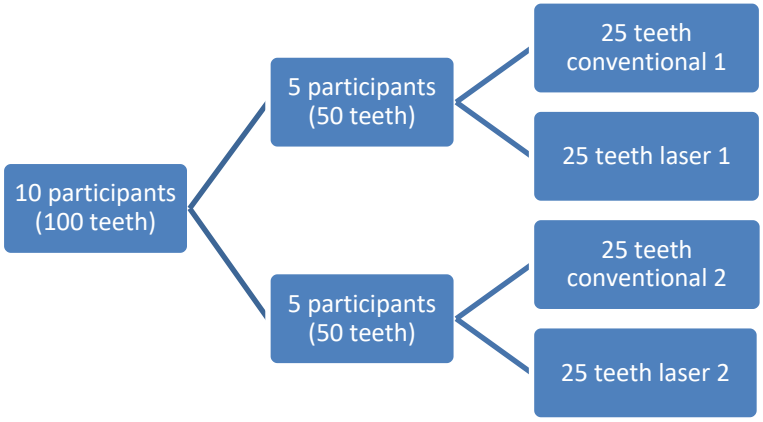



*Figure 6. Split-mouth study design with randomized allocation of debonding technique*

To determine the sample size, a power analysis for Matched-ANOVA: repeated measures within-subject design was conducted using G*Power software 3.1.9.7 for Windows (Heinrich Heine, Universitat Düsseldorf, Düsseldorf, Germany). Using an a priori power analysis: a power of 0.80, an alpha level of 0.05, a medium effect size of 0.25, one group, four measurements, correlation among repeated measures of 0.5 and a nonsphericity correction of 1 (indicating no adjustment needed for correlations among repeated measures) will be adopted. Therefore, the total minimal sample size required will be 24 measurements.

- *Inclusion criteria:*
  - Age Range: Patients aged 20–30 years, ensuring mature dentition.
  - Orthodontic Treatment Stage: Patients who have completed their orthodontic treatment and have reached the final stage where brackets are ready for removal (debonding stage).
  - Medication Use: Patients who have not used analgesic medication in the last 7 days or other drugs that could influence pulpal vascular dynamics or pain perception during the procedure.
  - General Health: Patients free from systemic health conditions that could affect dental health.

- *Exclusion criteria:*

- Patients with a history of using medications influencing pulp vascular dynamics or pain perception within the last week.
- Smokers, due to the potential impact on oral and pulpal health.
- Patients with systemic conditions affecting oral health, such as diabetes, osteoporosis, or immune disorders.
- Incompatible Treatments: Teeth with signs of pulp necrosis or bacterial infection, identified through radiographic or clinical examination (e.g., positive percussion test).
- Teeth treated with crowns, large restorations, or other dental materials that interfere with enamel analysis or laser performance.

***Debonding techniques and Group Allocation:***

A total of 100 orthodontic ceramic brackets, bonded to the upper teeth (15 to 25) of 10 patients (10 brackets per patient), will be included.

Participants will first be randomly divided into two main groups of equal size (n = 50 each):

- **Group 1:** Split mouth comparison between Er:YAG Laser 1 and Conventional Debonding
- **Group 2**: Split mouth comparison between Er:YAG Laser 2 and Conventional Debonding

Each group will be further divided into two subgroups based on the method used for debonding on each side of the mouth: *(table 1)*

***Group 1: Laser 1 vs. Conventional Debonding***

- **Subgroup L1 (n = 25):** Debonding with Er:YAG laser using Parameters 1.
- **Subgroup C1 (n = 25):** Debonding with conventional orthodontic plier (3M™ Unitek™ Deboning Instrument).

***Group 2: Laser 2 vs. Conventional Debonding***

- **Subgroup L2 (n = 25):** Debonding with Er:YAG laser using Parameters 2.
- **Subgroup C2 (n = 25):** Debonding with conventional orthodontic plier (3M™ Unitek™ Deboning Instrument).

*Table 1: Groups distribution and debonding method of each group*

| Groups | Debonding Method | Total nb 100 |
|---|---|---|
| L1 | Er:YAG Laser - Parameters 1 | 25 |
| C1 | Conventional debonding | 25 |
| L2 | Er:YAG Laser - Parameters 2 | 25 |
| C2 | Conventional debonding | 25 |

In order to allow comparison between two laser-assisted debonding protocols and the conventional mechanical technique, the groups will be allocated as follows:

- **Group L1 – Laser Parameters 1 (n = 25 brackets):**

Brackets in this group will be debonded using an Er:YAG laser (LightWalker II ST-E Pro+, Fotona, Ljubljana, Slovenia) operating at a wavelength of 2,940 nm. The laser will be applied at a 45-degree angle to the bracket slot from a fixed distance of 1cm. A cylinder-shaped resin-printed mold will be built **to** standardize the laser tip distance during ceramic bracket debonding. Laser Parameters 1, established in a pilot study and supported by existing literature, will be used to ensure both safety and clinical effectiveness.

*Assessments:* Adhesive Remnant Index (ARI), Thermal analysis, Pain evaluation.

- **Group L2 – Laser Parameters 2 (n = 25 brackets):**

Another 25 brackets will be debonded using the same laser and irradiation protocol as Group L1, but with Laser Parameters 2. These parameters were also determined during the pilot phase to explore variations in laser output and their effects on debonding outcomes.

*Assessments:* Adhesive Remnant Index (ARI), Thermal analysis, Pain evaluation.

- **Group C1 – Conventional Debonding (n = 25 brackets):**

Brackets will be removed using the standard mechanical technique. Orthodontic debonding plier (3M™ Unitek™ Deboning Instrument) will be used to apply torsional force to the lateral wings of the brackets, by slightly squeezing the mesial and distal extensions, in accordance with established clinical protocols (3,6).

*Assessments:* Adhesive Remnant Index (ARI), Pain evaluation.

- **Group C2 – Conventional Debonding (n = 25 brackets):**

The remaining brackets will also be removed using the same mechanical technique which

involves orthodontic plier (3M™ Unitek™ Deboning Instrument) applying torsional force to the lateral wings of the brackets and slightly squeezing the mesial and distal extensions (3,6).

*Assessments:* Adhesive Remnant Index (ARI), Pain evaluation.

As for the clinical workflow procedure: Upon the patient's arrival to their debonding appointment, the following clinical procedure will be implemented in a systematic and precise manner. Each quadrant receiving either a laser or conventional debonding technique, as per the study design. During the laser-irradiation procedure, the temperature of the teeth undergoing irradiation will be continuously monitored with the thermocouple device to ensure accurate and real-time temperature registration while the laser is active. Temperature data will be recorded on a tooth-by-tooth basis throughout the procedure to maintain precision. Upon completion of the debonding process, the patient will be immediately asked to assess their level of discomfort using a Visual Analog Scale (VAS) for each debonding technique employed. Finally, images of all teeth surfaces will be obtained using a microscope to evaluate the Adhesive Remnant Index (ARI).

***Studied variables***

The evaluation of enamel integrity and thermal effects will be conducted using specialized instrumentation to ensure precise and standardized measurements.

- **Adhesive Remnant Index (ARI)**: After each debonding, the teeth will be examined under a microscope (Leica M320 Dental Microscope) at 40× magnification. Images of each debonded tooth of both quadrants will be captured through the microscope to analyze the Adhesive Remnant Index (ARI) *(Fig. 7).* The ARI evaluates the amount of adhesive remaining on the enamel surface and is used to assess the site of bond failure. A higher ARI score indicates that more adhesive remained on the tooth, suggesting the bond failed at the bracket–adhesive interface rather than at the enamel surface, which is favorable for enamel preservation. Therefore, **higher ARI scores are associated with reduced risk of enamel damage and reflect a more conservative debonding method** (5,10).

  The ARI will be scored according to Artun and Berglund's scale (3):

  *Score 0* - Indicated that no adhesive was left on the tooth in the bonding area.

  *Score 1* - Less than half of the adhesive was left on the tooth in the bonding area.

  Score 2 - More than half of the adhesive was left on the tooth in the bonding area.

Score 3 - The entire adhesive was still on the tooth with distinct impression of the bracket mesh on the remaining adhesive surface.

To minimize bias, the operator evaluating the ARI scores will be blinded to the group allocation.


*Figure 7. In vitro pictures showing Adhesive remnant index according to ARI indices*

- **Pulp Temperature Variation**: To evaluate the thermal effects of laser-assisted bracket debonding, a calibrated K-type thermocouple will be used to monitor temperature changes in the pulp chamber in degrees Celsius (°C). The tip of thermocouple will be placed in direct contact with **the cervical third of the palatal surface of each debonded tooth**, as this region is closest to the pulp chamber and offers optimal contact. Temperature will be recorded continuously **before, during, and after** the laser application. All measurements will be expressed as mean ± standard deviation (SD) and will include minimum and maximum values to assess variability *(Fig. 8)*.

  It is important to note that according to previous studies, the **temperature rise associated with this laser protocol remains well below the critical 5.5°C threshold**, which is considered the limit beyond which irreversible pulpal damage may occur**.** Because the Er:YAG laser targets water-containing tissues, its radiation can be directly absorbed by the adhesive resin, particularly the residual monomer**,** allowing for effective debonding without generating excessive heat (12) .This procedure ensures that the laser protocol remains within safe thermal margins throughout the study .


*Figure 8. Thermocouple device*.

- **<u>Pain Perception:</u>** Following all debonding procedures, each patient will be asked to complete a Visual Analog Scale (VAS) to evaluate pain intensity. The VAS is widely used in clinical research due to its sensitivity and ability to detect subtle variations in perceived pain. It is a color-graded scale that consists of a 10 cm (100 mm) horizontal line with endpoints labeled "no pain" (blue) and "worst possible pain" (red). Participants mark the point on the line or bar that corresponds to their pain level, with values ranging from 0 to 10. Participants will rate their pain **immediately after debonding of each quadrant** to allow for localized assessment of discomfort. Each number is associated with descriptors like mild, moderate, or severe pain. The pain score is determined by measuring the distance in millimeters from the "no pain" end to the marked point, allowing for a standardized and quantifiable assessment of pain intensity *(Fig. 9)*.

  It is important to note that any pain or discomfort reported by the patients will be attributed to the mechanical procedure of debonding during bracket removal, and not to thermal changes, as temperature will be maintained within clinically safe limits.

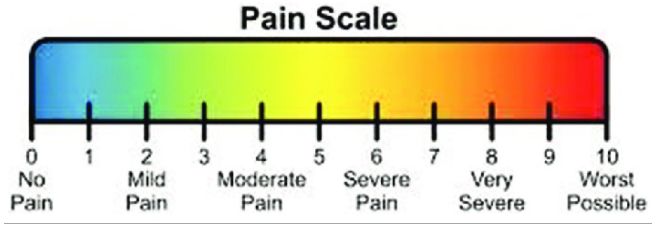



*Figure 9. Visual Analog Scale showing scores ranging from 0 to 10.*

***Comparative Analysis, Data recording and storage:***

Studied factors will be analyzed to assess differences between

- **L1 vs. C1:** Laser Parameters 1 vs. Conventional
- **L2 vs. C2:** Laser Parameters 2 vs. Conventional
- **L1 vs. L2:** Laser Parameters 1 vs. Laser Parameters 2

Data will be documented on standardized forms to ensure consistency and reproducibility. It will be stored on a secured digital platform with restricted access for research personnel only. All measures will be noted in an excel sheet for statistical analysis.

***Statistical Analysis:***

Data will be analyzed using IBM SPSS Statistics for Windows (Version 27) (IBM Corp., Armonk, NY, USA). All tests are two-tailed, and the significance level is set to 0.05: if $p \leq 0.05$ the result of the test is statistically significant.

Univariate analysis: Descriptive statistics will be summarized and presented as means ± standard deviations and medians (interquartile ranges) for the quantitative variables: pulpal temperature variation ΔT and ARI score. The graphical representation: histogram as well as the Shapiro-Wilk test will be used to assess the normality of distribution of quantitative variable within the groups. Mauchly' sphericity test is used for sphericity assumption otherwise we will be using the Greenhouse - Geisser test.

Bivariate analysis: Repeated measures ANOVA is used to test the difference in thermal change between the four groups: conventional 1, conventional 2, Laser 1, Laser 2. In case the dependent variable is not normally distributed within the groups the non-parametric test Friedman will be adopted.

The pain perception variable will be computed as a new variable: PPM and treated as continuous. Freidman test is used to compare PPM between the four groups.

**15. ETHICS**

- *Ethical Approval and consent:* Prior to the start, the study was submitted and approved for ethical clearance at the Institutional review board (IRB) of the Saint Joseph University of Beirut. Written informed consent was received and signed by all participants after they have been fully informed about the study's purpose, procedures, and their rights. Participants were also informed of their right to withdraw from the study at any point without any negative consequences or prejudice.

-*Patient Data Privacy***:** Patient information was anonymized, and data was collected and securely stored in compliance with data protection regulations for safeguard confidentiality.

*-CRFMD A32/35*

*-CER -2025-233*

## 16. STRENGTH OF THE STUDY

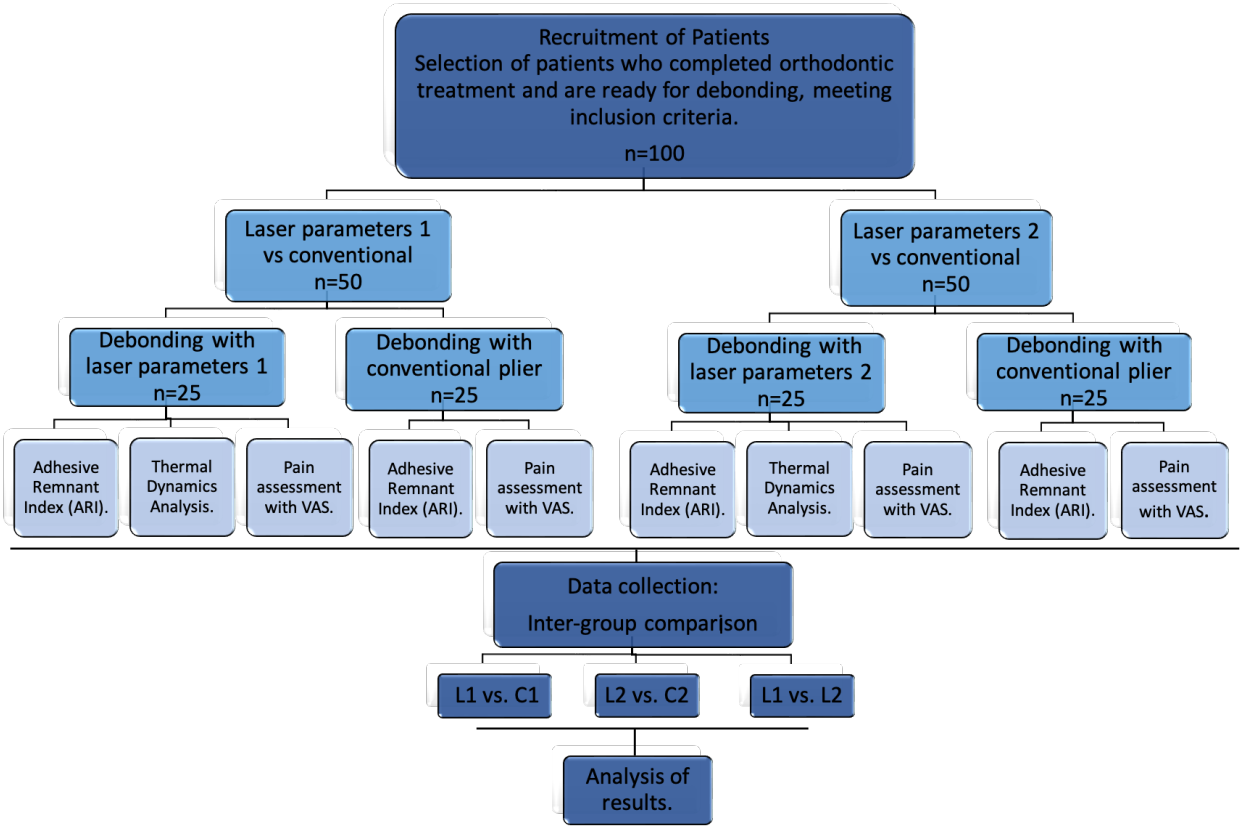
*Clinical Relevance:*

- The study addresses a critical gap in orthodontic research by evaluating the impact of laser-assisted orthodontic bracket removal on enamel integrity and pulpal health.
- By incorporating clinical scenarios, the study provides valuable insights into a more conservative and efficient method for bracket debonding, potentially reducing enamel damage and enhancing patient experience.
- The findings could aid in establishing a clear, evidence-based protocol for laser-assisted debonding, promoting its use in clinical orthodontic practice.

*Ease of Publication:*

- The topic is highly relevant to the field of modern orthodontics, as it aligns with the growing interest in minimally invasive techniques and the adoption of laser technologies in orthodontics.
- The use of a split-mouth design; clinical study ensures clinically applicable data, increasing the likelihood of publication in reputable orthodontic journals.

## 17. STUDY DESIGN



**18. REFERENCES**


1) Knaup T, Korbmacher-Steiner H, Braun A, Wenzler JS, Knaup I, Stein S. Effects of 445-nm Diode Laser-Assisted Debonding of Metallic Brackets on Shear Bond Strength and Enamel Surface Morphology. Photobiomodulation, Photomedicine, and Laser Surgery. 2020 Mar 1;38(3):160–6.
2) Ajwa N, Alfayez H, Al-Oqab H, Melibary R, Alzamil Y. The Effect of Erbium-Doped Yttrium Aluminum Garnet Laser in Debonding of Orthodontic Brackets: A Systematic Review of the Literature. Photobiomodulation, Photomedicine, and Laser Surgery. 2021 Nov 1;39(11):725–33.
3) Abdulaziz A, El-Kholy MM, Bushra SS, Ali SM, Shehab KA. Performance of two laser motion modes versus conventional orthodontic ceramic brackets debonding technique on enamel surface topography. Lasers Med Sci. 2024 Jun 13;39(1):156.
4) Mesaroș A, Mesaroș M, Buduru S. Orthodontic Bracket Removal Using LASER-Technology-A Short Systematic Literature Review of the Past 30 Years. Materials (Basel). 2022 Jan 12;15(2):548.
5) Khalil AS, Baowideen FA, Alhujaili AS, Alotaibi NF, Almanjhi WA, Yassin HY, Nasser MM, Alzahrani AF, Alrehaili RS. Efficacy of Lasers in Debonding Ceramic Brackets: Exploring the Rationale and Methods. Cureus. 2024 May 25;16(5):e61050.
6) Rao A, Deenadayalan P, Deepak C, Dilipkumar D, Angrish N, Shetty SS. Effect of ER, CR: YSGG laser debonding on enamel surface changes in stainless steel and ceramic brackets - An *in-vitro* study. J Orthod Sci. 2023 Mar 18;12:7.
7) Hoteit M, Nammour S, Zeinoun T. Evaluation of Enamel Topography after Debonding Orthodontic Ceramic Brackets by Different Er,Cr:YSGG and Er:YAG Lasers Settings. Dent J (Basel). 2020 Jan 9;8(1):6.
8) Mousa MM, Al-Jannan HMG, Sultan K, Ajaj MA, Hajeer MY, Al-Manadili A, Ammar AM, Awawdeh M. Effectiveness of Two Intensity Levels of Diode Laser in Debonding Metallic Brackets Regarding Enamel Surface Integrity and Pulpal Temperature: An Ex-Vivo Study. Cureus. 2023 Jul 4;15(7):e41372.
9) Matos DS, Küchler EC, Borsatto MC, Matsumoto MAN, Marques FV, Romano FL. CO2 laser irradiation for debonding ceramic orthodontic brackets. Braz Dent J. 2021 Mar-Apr;32(2):45-52.
10) Khalil AS, Tamish NM, Elkalza AR. Assessment of chemical, ultrasonic, diode laser, and

Er:YAG laser application on debonding of ceramic brackets. BMC Oral Health. 2022 Mar 19;22(1):79.

11) Demirsoy KK, Kurt G. Use of Laser Systems in Orthodontics. Turk J Orthod. 2020 May 22;33(2):133-140.
12) Mocuta DE, Miron MI, Lungeanu D, Mateas M, Ogodescu E, Todea CD. Laser Er:YAG-Assisted Debonding May Be a Viable Alternative to the Conventional Method for Monocrystalline Ceramic Brackets. Int J Environ Res Public Health. 2022 Nov 6;19(21):14564.
13) Zamzam MK, Hamadah O, Espana-Tost T, Arnabat-Dominguez J. Comparative Study of Transmission of 2940 nm Wavelength in Six Different Aesthetic Orthodontic Brackets. Dent J. 2023 Mar 1;11(3):67.
14) Downarowicz P, Noszczyk P, Mikulewicz M, Nowak R. Thermal effect of Er:YAG and Er,Cr:YSGG used for debonding ceramic and metal orthodontic brackets: An experimental analysis. Adv Clin Exp Med. 2020 May;29(5):557-563.
15) Ngan Ay, Bollu P, Chaudhry K, Stevens R, Subramani K. Survey on awareness and preference of ceramic bracket debonding techniques among orthodontists. J Clin Exp Dent. 2020;e656–62.
16) Woś P, Kiryk S, Dyl T, Kiryk J, Horodniczy T, Szablińska M, et al. Laser Applications in Metal Orthodontic Bracket Debonding: A Systematic Review. Applied Sciences. 2025 Jan 18;15(2):927.