Informed Consent

Project Information		
Project Title:	Effect of Diode Laser and 20% Benzocaine Anesthetic Gel on Pain Reduction following Tooth Separation with Elastomeric Separators in Fixed Orthodontic Patients: A Randomized Trial in Karachi-Pakistan	Version & Date:01 ; 27/04/2026
ERC Project No:	2025-11599-35214	Sponsor:
Principal Investigator:	Syed Iqbal Azam	Organization:
Location:		Phone:
Other Investigators:	Muhammad Ashfaq, Rashna H shukia	Organization:
Location		Phone:

***Copy of the consent will be provided to the patient**

1. Purpose of This Research Study

You are being asked to participate in a research study designed to evaluate the effectiveness of Low-Level Laser Therapy (LLLT) and benzocaine gel in reducing orthodontic pain associated with bracket placement and adjustments. The study aims to determine the potential benefits and risks of these interventions in managing discomfort during orthodontic treatment.

2. Procedures

- If you agree to participate, you will undergo one or both of the following procedures:
  - **Low-Level Laser Therapy (LLLT):** A painless laser will be applied to the affected areas in your mouth to help reduce pain and inflammation.

    - **Benzocaine Gel Application:** A topical anesthetic gel will be applied to specific areas in your mouth after orthodontic adjustments.
- Each procedure will take approximately 20 minutes.
- Your pain levels will be assessed using a standardized scale before and after treatment.
- You may be asked to complete a short questionnaire regarding your pain experience.

3. Possible Risks or Discomfort

- **LLLT Risks:**
    - LLLT is generally safe, but in rare cases, temporary sensitivity or mild irritation may occur.
- **Benzocaine Gel Risks:**
    - Possible mild irritation or allergic reactions.
    - Rare cases of **methemoglobinemia**, a condition affecting oxygen levels in the blood, have been reported with excessive use.
- If any adverse effects occur, you should immediately inform the research team.

4. Possible Benefits

- You may experience **reduced orthodontic pain** compared to conventional methods.
- The findings from this study may help improve future orthodontic pain management strategies.
- There is no guarantee that you will benefit directly from participating in this study.

5. Financial Considerations

- There is **no financial compensation** for your participation in this research.
- The study will cover any costs associated with LLLT and benzocaine application.
- No additional expenses will be incurred by participants.

6. Available Treatment Alternatives

- If you choose not to participate, you will continue to receive **standard orthodontic pain management options**, including over-the-counter pain medications .

7. Available Medical Treatment for Adverse Experiences

- This study involves **minimal risk**.
- In case of an adverse reaction, appropriate medical care will be provided.
- The research team will assist in referring you for necessary treatment, but the study **does not cover additional medical costs**.

8. Confidentiality

- Your identity will remain **confidential**.
- The study results may be published, but your name and personal information will not be disclosed.
- Only authorized research personnel will have access to your data.

9. Right to Refuse or Withdraw

- Participation is **voluntary**, and you may withdraw at any time without penalty.
- If you choose to withdraw, inform the research team to ensure a proper termination process.
- The investigator may terminate your participation if deemed necessary for medical or ethical reasons.

10. Available Sources of Information

- For questions about the study, contact the Principal Investigator:
  - **Name:** [Syed Iqbal Azam]
  - **Phone Number:** [03212565127]
- For concerns about your rights as a research subject, contact:
  - **Name:** [Muhammad Ashfaq]
  - **Phone Number:** [03212565127]
- In case of a research-related emergency:
  - **Day Emergency Number:** [03142075439]
  - **Night Emergency Number:** [03242139092]

11. Authorization

I have read and understood this consent form, and I voluntarily agree to participate in this research study. I understand that my participation does not waive any legal rights.

Name of Participant (Printed or Typed): _____
Date: _____
Signature of Participant: _____

Signature of Principal Investigator: _____
Date: _____

Name and Signature of Person Obtaining Consent: _____
Date: _____

For Participants Unable to Read:

Witness Statement:
I have witnessed the accurate reading of the consent form to the participant, and they have had the opportunity to ask questions. I confirm that the participant has given consent freely.

Witness Name: _____
Participant's Thumb Print: _____
Signature of Witness: _____
Date: _____
