Informed Consent Form (ICF)

Project Name：Characteristics of Subgingival Microbiota in Patients with Stage III-IV Periodontitis in Response to Nd:YAG Laser-Assisted Therapy

August 16, 2024

You are being invited to participate in a clinical research study. This informed consent form provides important information to help you decide whether to join this study. Please read it carefully and discuss any questions with the research investigator. Your participation is entirely voluntary. This study has been approved by the Institutional Review Board (IRB) of our research institution.

1. Study Objectives：

Periodontitis is a microbially associated, host-mediated chronic inflammatory disease. Stage III-IV periodontitis, representing the advanced phase of disease progression, is characterized by severe alveolar bone loss and irreversible clinical attachment loss (CAL). According to the latest Global Burden of Disease Study, periodontitis ranks as the sixth most prevalent condition globally, with Stage III-IV cases constituting a significant proportion of affected individuals.

The primary therapeutic objectives in periodontitis management are plaque control and inflammation resolution. Conventional scaling and root planing (SRP), while foundational, exhibits inherent limitations including incomplete biofilm removal and iatrogenic tissue trauma. The neodymium-doped yttrium-aluminium-garnet (Nd:YAG) laser (wavelength: 1064 nm), a near-infrared laser modality, demonstrates selective absorption for melanin and hemoglobin while maintaining low water absorption coefficients (0.61 cm^(-1)). This unique photophysical property enables deep tissue penetration and localized photothermal effects. Recognized for its potent bactericidal, hemostatic, and soft tissue ablation capabilities, Nd:YAG laser has emerged as a minimally invasive adjunct to periodontal therapy. Nevertheless, the response patterns of subgingival microbiomes to Nd:YAG laser-assisted treatment remain insufficiently characterized in the current literature.

This study aims to comparatively evaluate the clinical efficacy of Nd:YAG laser-assisted

scaling and root planing (SRP) versus conventional SRP alone in the treatment of stage III-IV periodontitis. Furthermore, we seek to investigate the effects of Nd:YAG laser adjunctive therapy on the compositional structure and diversity of subgingival microbiota. By elucidating the potential role of Nd:YAG laser in modulating subgingival microbial equilibrium, this research will provide novel theoretical insights and evidence-based guidance for the clinical management of periodontitis.

2. Research Procedures：

From August 2024 to March 2025, 120 patients with stage III-IV periodontitis were recruited from the Department of Stomatology, The First Affiliated Hospital of Sun Yat-sen University, according to predefined eligibility criteria. All participants provided written informed consent. The study subjects were randomly allocated to either the conventional subgingival scaling and root planing (SRP) group (n=62) or the Nd:YAG laser-assisted SRP group (n=63).

3. Risks and Discomforts：

Your personal information will remain strictly confidential. The collection of oral plaque samples will not pose any risks to your health or safety.

4. Potential Benefits：

You will receive a complimentary comprehensive oral examination.

5. Cost Considerations：

All study-related procedures, including: periodontal examinations and oral plaque sample collection will be provided free of charge.

6. Confidentiality：

Your participation in this study and all personal data collected will remain strictly confidential. Blood samples will be coded using study identification numbers rather than personal identifiers. Personally identifiable information will not be disclosed to anyone outside the research team without your explicit permission. All investigators and study sponsors are legally obligated to maintain confidentiality.

Physical records will be stored in locked filing cabinets accessible only to authorized researchers. For quality assurance purposes, regulatory authorities or ethics review board members may inspect study documents at the research site in accordance with applicable

regulations. No individually identifiable information will be published when study results are disseminated.

Participation in this study is completely voluntary. You have the right to decline participation or withdraw at any time by notifying the research team, without any impact on your current or future medical care. Should you choose to withdraw, your collected data will not be included in the final analysis while still retaining all your medical rights and benefits.

The principal investigator reserves the right to discontinue your involvement in the study if medically necessary, such as if you require alternative treatments, experience study-related injuries, or fail to comply with the research protocol. This ensures your safety and the integrity of the study while maintaining ethical standards throughout the research process.

If you decide not to participate, you will still receive a comprehensive oral health evaluation and may discuss alternative treatment options with your study clinician, who will explain their respective benefits and risks. Your decision regarding participation will not affect the quality of care you receive or limit your access to any available treatments.

Informed Consent Form – Signature Page

Participant's Declaration:
I confirm that I have read and fully understood the information provided about this study. All my questions have been answered to my satisfaction. I voluntarily agree to participate in this research and understand that I may withdraw at any time without penalty or loss of benefits to which I am otherwise entitled.

Participant Signature: _____
Date: _____
Printed Name: _____

Investigator's Declaration:
I certify that I have explained the nature, purpose, and potential risks/benefits of this study to the participant in language they could understand. I have answered all questions truthfully and completely.

Investigator Signature: _____
Date: _____
Printed Name: _____

Witness (if required):
I confirm the participant's voluntary consent was obtained appropriately.

Witness Signature: _____
Date: _____