INFORMED CONSENT FORM (ICF)

COVER PAGE

Official Title: Periosteal Sutures for Fixation of Composite Bone Graft Substitutes in Guided Bone Regeneration: A Randomized Controlled Clinical Trial

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Sponsor: SigmaGraft Biomaterials

Study Site: Dental Unit, Hospital San Camilo

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Study Title: Periosteal Sutures for Fixation of Composite Bone Graft Substitutes in Guided Bone Regeneration: A Randomized Controlled Clinical Trial

Principal Investigator: Dr. Franco Cavalla

Sponsor: SigmaGraft Biomaterials

Study Site: Dental Unit, Hospital San Camilo

Invitation to Participate

You are being invited to participate in a research study. The purpose of this document is to help you decide whether or not you want to participate. Please take the time you need to make your decision. Read this document carefully and ask any questions you may have.

Purpose of the Study

The purpose of this study is to evaluate whether using a specific stabilization suturing technique improves the outcomes of guided bone regeneration in the anterior maxilla (front upper jaw) when a bone graft is placed together with the installation of a dental implant.

Study Funding and Support

This study is funded by SigmaGraft Biomaterials, which will provide, at no cost to you, the guided bone regeneration biomaterials used in the study and will cover the radiographic examinations and laboratory costs related to the study.

What Will Happen If You Participate

If you agree to participate, the research team will collect and access clinical measurements and data related to your treatment. Your personal information will not be disclosed to third parties.

You will undergo the following study-related procedures:

Two cone-beam computed tomography (CBCT) scans. CBCT involves exposure to ionizing radiation in order to obtain diagnostic images.

To reduce this risk, CBCT will be performed at a private imaging center in the city of San Felipe rather than using the conventional CT scanner currently available at the hospital. This approach reduces the radiation dose approximately five-fold. In addition, you will be protected with a lead apron to minimize radiation exposure.

Other clinical evaluations will be performed according to the study protocol.

Risks and Discomforts

The main risk related to study participation is exposure to ionizing radiation from the two CBCT scans. The study includes measures to reduce radiation exposure as described above.

Benefits

You are not expected to receive any direct benefit from participating in this study. However, the information obtained may help improve future treatment outcomes for patients receiving dental implants in the anterior maxilla who require bone grafting.

Confidentiality

Your personal data will be protected by the research team. Relevant information will be stored securely with restricted access. Information used for analysis will not include identifiers such as your name or national identification number.

Voluntary Participation and Right to Withdraw

Your participation is voluntary. If you decide not to participate, you will not lose any benefits to which you are entitled and you will not experience any negative consequences. If you decide to participate and later change your mind, you may withdraw from the study at any time without needing to provide an explanation.

Questions and Contact Information

If you have questions about this research study, you may contact:

Dr. Franco Cavalla (Principal Investigator)

Telephone: +56 9 3203 5746

If you have questions about your rights as a research participant, you may contact:

Executive Secretary, Scientific Ethics Committee, Servicio de Salud Aconcagua

Telephone: 34-2493499 (Minsal extension 343499)

Email: adriana.rojasp@redsalud.gov.cl

Statement of Consent

I have been informed about the purpose of this study, the procedures, the risks, the benefits, and my rights as a participant. I understand that I may withdraw at any time if I choose.

I sign this document voluntarily, without being pressured to do so.

I understand that I will receive a signed copy of this consent form.

Participant Name: _____

Participant Signature: _____ Date: ___ / ___ / _____

Authorized Witness Name: _____

Authorized Witness Signature: _____ Date: ___ / ___ / _____

Principal Investigator (or Delegate) Name: _____

Signature: _____ Date: ___ / ___ / _____