INFORMED CONSENT

FORM DATED FROM NOV. 22nd 2023

PI: Jamil Awad Shibli

MODULATION OF THE ELECTROMAGNETIC PULSE ON THE ORAL BIOFILM OF INDUCED GINGIVITIS AND MUCOSITIS: PROTEOMIC AND MICROBIAL EFFECTS

GUARULHOS

2023

Informed consent

STUDY TITLE: "ELECTROMAGNETIC PULSE MODULATION ON ORAL BIOFILM OF INDUCED GINGIVITIS AND MUCOSITIS: PROTEOMIC AND MICROBIAL EFFECTS"

PRINCIPAL INVESTIGATOR: Jamil Awad Shibli

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OTHER RESEARCHERS linked to UNG: Prof. Dr. João Gabriel Souza, Rafael Shinoske Siroma and Marcelo Melo.

Participant Initials: |__|__|__|

Participant's date of birth: |__|__| |__|__| |__|__|__|__| dd/mm/yyyy

Participant Number: |__|__|__|

With this informed consent form (ICF), we invite you to participate in the study entitled MODULATION OF THE ELECTROMAGNETIC PULSE ON THE ORAL BIOFILM OF INDUCED GINGIVITIS AND MUCOSITIS: PROTEOMIC AND MICROBIAL EFFECTS.

The objective and main justification of this research will be to evaluate the biological behavior of gingival and peri-implant tissues (tissue present around the tooth and implant) with the accumulation of bacterial plaque on the tooth and implants without brushing only these areas for 21 days.

This study will be conducted at Univeritas-UNG University, and 40 participants with two edentulous spaces (lack of 2 teeth for implant installation) will be selected. To participate in this study, the individual must not be taking antibiotics or using oral antiseptics in the last 6 months, must not have a history of previous periodontal treatment in the last six months, cannot need a bone or gingival graft, and as a woman, cannot be pregnant or breastfeeding.

To carry out the study, the participant will undergo complete examinations of the teeth, implants and gums for a period of 6 months, before and after the installation of the implants, and the consultations will be carried out by professionals trained in Dentistry and specialized in Implantology. In these consultations, a complete periodontal clinical evaluation will be carried out (evaluation of the

condition of the teeth and implants), and a small amount of biofilm (accumulation of bacteria on the implants) will be collected, for microbiological (bacterial identification and quantification) and immunological (inflammation markers) tests. All collected samples will be stored under refrigeration at the Dental Research Laboratory II of Univeritas-UNG for further analysis. The evaluation of the implants and teeth will include an implant surgery (placing 2 implants).

After 60 days of healing the implants, the study participant will receive a healer over the implant. One implant will receive a conventional healer, and the other a healer with electromagnetic pulse (a piece that is installed on the implant and then placed the tooth or prosthesis screwed on the implant) to avoid or reduce the number of microorganisms on the implant. On this same day, the participant will receive an acetate plate (acrylic) that will cover the implants and a tooth right next to it. This acetate plate should be placed over the implants and this tooth to prevent the excavation of these elements for 21 days. This plaque will only be placed on the teeth during normal brushing.

The main benefit of participating in the study will be the installation of the implants and the teeth supported by these implants, in addition to monthly oral hygiene instruction (brushing techniques and care of my teeth and implants). It is important to note that the installation of the prostheses on the implants will not occur immediately after the implants are installed, but approximately after 6 months, when the implants are fixed to the bones.

Participation in this study involves some clinical risks inherent to the procedure. Risks related to local anesthesia are avoided by selecting the most appropriate anesthetic base and constrictor vessel for me. This choice is based on the information provided in the anamnesis. That is why it is very important for the good progress of the treatment that all information about the health of the study participant is accurate and always updated. Another risk, uncommon, but associated with this type of implant surgery is the occurrence of hemorrhages (excessive bleeding). If it cannot be avoided, during the procedure, surgical techniques and specific medications will be used to contain it. If it happens in a postoperative moment, this is rare, the study participant will have all the support of the professionals involved in the research, so that any procedure and or referral (for medical/hospital care) that is necessary to control it can be performed. After the surgical procedure, edema (swellings) and bruises (purple spots) at the surgical site are normal. These clinical signs are controlled with the medication that will be prescribed on the day of surgery and tend to disappear between the 7th and 10th postoperative day, a period that coincides with one of the returns to which the participant must attend to evaluate the postoperative conditions.

If the operated area is not properly cleaned, postoperative infections can occur. In this case, the region will be properly sanitized (cleaned) and systemic antibiotics and individualized and appropriate sites for each case will be prescribed. If the anti-inflammatories and analgesics prescribed soon after surgery cause nausea, headache, gastrointestinal disorders or any other type of discomfort, the medication can be replaced immediately after your complaint and the prescription of gastric protectors will be considered together with diet counseling, after careful evaluation

by the researchers, without prejudice to the treatment. In the event of any undesirable effect, the participant must report it to the responsible researcher, and, if necessary, will brush the area again and will be immediately removed from the study, without compromising free treatment with implants or referrals to other specialties.

The study will last approximately 5 months, and the participant will return approximately 10 times to the research center (UNG) to receive treatment and periodontal maintenance sessions. Each service will last approximately 1 hour.

The study participant will not have any costs for the treatment proposed herein regarding: 1) receiving the implants and prosthesis; 2) with all necessary medications, including antihistamines, anti-inflammatories, and other antibiotics; 3) the evaluation exams during the study, and 4) transportation costs for the return visits determined in the project in addition to snacks. It is important to note that the participant will not receive any remuneration for participating in the study, will have the guarantee of confidentiality that ensures their privacy in the study, and once the data are obtained, they may be published in scientific journals and congresses, but without the identity as a research participant. For the tabulation of the data, each study participant will receive a code, and the collected samples will also be coded before laboratory processing so that only the researchers involved in the data collection will be aware of the identification of the study participants. The study participant will be guaranteed to receive further clarifications that he/she deems necessary before and during the course of the research, at any time.

The survey will be suspended for participants who are unable to attend appointments or who no longer wish to participate in the study. Other eventualities that may interfere with the inclusion criteria and the integrity and well-being of the participants may be considered grounds for suspending the research (e.g., medical impediment to undergo the research procedures). In the case of women who become pregnant, participation in the study will be interrupted. Whatever the reason that suspends or terminates the research for a given participant, this will not be detrimental to his or her rehabilitative treatment. In addition, the volunteer will not have any loss in referrals for treatment in other dental specialties at Univeritas-UNG University. On the other hand, the study participant has the right to withdraw from his participation at any time, without any prejudice or compromise of the treatment.

Participation in the study will not cause expenses to the participant, and there is therefore no provision for reimbursement. Regarding the forms of compensation and the measures to repair eventual damage, it is noteworthy that participation in this study involves a slight risk. Any proven damages that resulted from participation in the research are subject to reparation by the researchers.

TCLE 3-5 Participant Seen:

The result of the treatment will be directed by the principal investigator Jamil Awad Shibli (Telephone 11- 982593438) from Univeritas-UnG, who is also responsible for clarifying any doubts throughout the study. All the ethical norms of the present study are in accordance with the guidelines and norms of the National

Health Council in Resolution No. 466/12. In case of any consideration or doubt, the study participant may contact the Research Ethics Committee (CEP) of UnG at the Graduate and Research Center Building (CEPPE), Praça Tereza Cristina, n.º 229 - Centro – Guarulhos, comite.etica@ung.br and the Secretariat of the Ethics Committee of UnG.

PATIENT CONSENT

I confirm that I discussed until I was satisfied about my decision to participate in this study: ELECTROMAGNETIC PULSE MODULATION ON THE ORAL BIOFILM OF INDUCED GINGIVITIS AND MUCOSITIS: PROTEOMIC AND MICROBIAL EFFECTS. It was clear to me what the purposes of the study are, the procedures to be carried out, its discomforts and risks, the guarantees of confidentiality and permanent clarifications. It was also clear that my participation is free of charge and that I am guaranteed access to treatment or guidance when needed. I voluntarily agree to participate in this study and may withdraw my consent at any time, before or during it, without penalty or impairment or loss of any benefit I may have acquired, or in my attendance at this service. I declare that I have received a copy of this Informed Consent Form

Date:_____/_____/____

_____ _____

Participant's name Signature and ID of the participant

_____ _____

Legal guardian name (if applicable) Signature and ID of the legal guardian

(if applicable)

_____ _____

Name of the person who explained the Signature of the person who explained the consent consent

_____

Jamil Awad Shibli

Principal Investigator

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