



Informed Consent

**Volumetric digital analysis on the effect of a customized
healing abutment with or without connective tissue
graft in maxillary immediate implant sites.
A randomized clinical trial.**



Informed Consent

DECLARATION OF INFORMED CONSENT, FREE AND INFORMED TO PARTICIPATE IN RESEARCH

Please, read the following information carefully. If you think something is unclear, do not hesitate to ask for more information. If you agree with the proposal made to you, please sign this document.

Title: Volumetric digital analysis on the effect of a customized healing abutment with or without connective tissue graft in maxillary immediate implant sites – A randomized clinical trial.

Explanation: Academic research to be carried out at the Dental Clinic of Universidade Católica Portuguesa, under the responsibility of Prof. Dr. Tiago Borges, Assistant Professor at Faculty of Dental Medicine of Universidade Católica Portuguesa.

Clarification of the study and treatment: This study aims to assess the evolution of the peri-implant tissues after immediate implants, collecting data of peri-implant marginal bone changes, soft and hard tissues volumetric alterations and their relation to the different patient's variables and habits. This investigation will collect data in patients with hopeless tooth, being treated with tooth extraction and immediate implants placed in the fresh sockets at the day of the same surgery. This treatment modality does not consist in any experimental technique nor it is intended to test devices or products without registration or certification by the competent authorities. Data collection will be carried out using an optical scanner that is not subject to radiation emission.

Terms: This study does not involve procedures that do not fall within normal clinical practice. Participation in this study is completely voluntary, without any costs, and patients may withdraw their consent at any stage of the study, without the need to provide any explanation and with total absence of consequences if they do not wish to participate. When deciding to participate, you can ask any questions you consider necessary for clarification at any stage of the study.

Accidental findings: Any accidental finding not related to the anatomy of the jaw and alveolar bone, whose discovery is made during the study, will be mandatorily and immediately communicated to the participant. The patient can express the wish to the same information be communicated to his assistant doctor, informing him of the participant's health condition.



Informed Consent

Confidentiality: The data collected in this study are exclusively used by the researcher and treated in order to guarantee its maximum confidentiality. The data analysis will be conducted guaranteeing their privacy, which will be used only by the researcher involved in this study. Patient identification will be performed using a numeric code, not being identifiable by third parties besides responsible investigator. All legal provisions described in the new General Data Protection Law of 25 May 2018 will be respected.

Signature(s) of main investigator:

THE INVESTIGATOR: _____

I declare I have read and understood this document, as well as the verbal information provided by the main investigator that signs above. I was guaranteed the possibility, at any time, to refuse to participate in this study without any consequences. Thus, I accept to participate in this study and allow the use of the data that I voluntarily provide, trusting that it only be used for this investigation in confidentiality and anonymity given to me by the researcher.

Name: _____

Signature: _____ Visau, ____ / ____ / ____

THIS DOCUMENT IS COMPOSED OF 2 PAGES AND MADE IN DUPLICATE: ONE COPY FOR THE INVESTIGATOR, ANOTHER FOR THE PERSON WHO CONSENTS