Title: Periodontal Air-Polishing Device Reduces Tissue Damage, Improves Clinical Outcomes, and Exosomal Modulation. A Randomized Clinical Trial in Periodontitis Patients.

NCT Number: Not available

February 1st 2025

PROVINCIAL BIOMEDICAL RESEARCH ETHICS COMMITTEE OF GRANADA (CEI GRANADA-CEIm)

General Information

Any researcher intending to carry out a clinical study must submit a Patient (or Participant) Information Sheet (P.I.S.) to the Clinical Research Ethics Committee (C.R.E.C.) together with the study protocol or project report. In addition, they must comply with the requirements set out in Organic Law 3/2018, of December 5, on the Protection of Personal Data and Guarantee of Digital Rights (Official State Gazette of 06/12/2018).

MODEL OF PATIENT INFORMATION SHEET AND INFORMED CONSENT FORM FOR STUDY PARTICIPANTS

PATIENT OR PARTICIPANT INFORMATION SHEET (P.I.S.)

1. **Title of the Study:**
   Periodontal Air-Polishing Device Reduces Tissue Damage, Improves Clinical Outcomes, and Exosomal Modulation. A Randomized Clinical Trial in Periodontitis Patients.
2. **Objectives:**
   The aim is to compare the levels of pro- and anti-inflammatory exosomes and cytokines in patients treated with manual scaling and root planing versus Airflow®.
3. **Methodology:**
   The study will be conducted in two phases. It is an experimental study with two randomized groups of patients evaluated at two time points.

- First: Gingival examination prior to periodontal treatment, using a periodontal probe to determine bleeding, probing depth, and plaque levels. Gingival crevicular fluid will be collected using size 30 endodontic paper points.
- Second: Repetition of the same process after manual scaling and root planing or Airflow®. Data will be collected at the dental units of the Faculty.

4. **Expected Benefits and Potential Risks of this Study:**
   This study will contribute to improving knowledge of the effects of Airflow® in periodontal treatment compared to manual scaling and root planing. The study does not

involve any potential risks or expected adverse reactions for the patient. Sample collection is completely non-invasive.

5. **Availability of Other Treatments (Alternative Treatments):** The current standard treatment consists of manual scaling and root planing with curettes, which is included in this study.
6. **Use of Biological Samples:** A sample of gingival crevicular fluid will be collected. This will be obtained using size 30 absorbent paper points for endodontics, which will be inserted into the gingival sulcus for 30–40 seconds. The points will then be removed and placed in a sterile container for analysis. The patient will provide consent for this sample to be used only for the purposes described in this study.
7. **Voluntary Participation:** Patient participation is voluntary. The patient may withdraw consent at any time, without the need to provide explanations.
8. **Confidentiality and Data Protection:** Confidentiality and protection of personal data will be ensured. Only one individual, M.B.I., will have access to the subject's data.

Organic Law 3/2018 on the Protection of Personal Data and Guarantee of Digital Rights. The personal data requested (e.g., age, sex, health data) are necessary to meet the objectives of the study. In none of the study reports will your name appear, and your identity will not be disclosed to anyone except for the purposes of the study, or in the event of a medical emergency or legal requirement. Any personal information that may be identifiable will be stored and processed electronically under secure conditions.

Access to such information will be restricted to authorized personnel, who will be obliged to maintain confidentiality. The results of the study may be communicated to health authorities and, eventually, to the scientific community through conferences and/or publications.

The data will be used solely for the specific purposes of this study and, if necessary, may also be used for educational or scientific purposes. In accordance with current law, you have the right to access your personal data; likewise, if justified, you have the right to request its rectification or deletion. If you so wish, you must request this from the physician responsible for your care in this study.

9. The amount of fluid to be collected will be 4–5 microliters, and it will be used exclusively for the specific purposes of the study.
10. Any information obtained from the project that may be needed or intended for future use will require the patient’s information and consent.

WRITTEN INFORMED CONSENT OF THE PATIENT OR PARTICIPANT

Title of the study:
Quantification of Cytokines and Exosomes in Gingival Crevicular Fluid by Flow Cytometry and Periodontal Variables in Patients Treated with Curettes and Airflow®

I, (full name) ....., with National ID No. ……

have spoken with the study's responsible professional, Marco Bonilla Izquierdo, who has provided his contact information for any questions or clarifications regarding the study. **Email:** marcobonilla000@gmail.com

- I have read the information sheet provided to me.
- I have been able to ask questions about the study.
- I have received sufficient information about the study.
- I understand that my participation is voluntary.
- I understand that I may withdraw from the study:
    1. Whenever I wish.
    2. Without having to provide explanations.
    3. Without this affecting my medical care.

I freely give my consent to participate in the study.

The samples obtained in this study will be used exclusively for the specific purposes of the study.

Date ..... **Signature of patient or participant**

Date ..... **Signature of the responsible professional of the study and National ID No.**