“Effects of Platelet-Rich Fibrin on Postoperative Outcomes Following Nasosinusal Surgery”

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Study Protocol

This was a prospective, controlled, double-blind study. Data were collected using a standardized medical questionnaire completed by attending physicians during postoperative follow-up visits of patients undergoing sinonasal surgery at the COF center in São Paulo.

1. The study population consisted of patients who underwent sinonasal surgery at COF, São Paulo, and were evaluated at one week and one month postoperatively.

2. Platelet-Rich Fibrin (PRF) was prepared intraoperatively through peripheral blood collection followed by centrifugation performed in the operating room, with an average preparation time of 20 minutes.

3. PRF membrane was topically applied to one nasal cavity, while the contralateral cavity served as the control, according to a randomized allocation protocol.

4. At the end of the surgical procedure, while the patient was still under general anesthesia, the PRF membrane was placed into the designated nasal cavity by an assisting physician, without the presence of the primary surgeon in the operating room.

5. Neither the attending physician responsible for postoperative assessments nor the patient was aware of which nasal cavity had received PRF treatment. Blinding was maintained throughout the evaluations performed at one week and one month after surgery.

6. The questionnaire was completed during routine postoperative follow-up visits after otorhinolaryngological physical examination performed by the surgeons.

7. For comparative purposes, the attending physician completed a separate questionnaire for each nasal cavity of the same patient.

8. Confidentiality of the medical records and questionnaire data was ensured through the signing of informed consent, confidentiality, and commitment agreements by all study participants, including physicians and patients.

9. All collected data were entered into standardized spreadsheets. The study was conducted in accordance with the principles of the Declaration of Helsinki and Resolution No. 466/2012 of the Brazilian National Health Council governing research involving human subjects.

10. A database was created for each patient, including the variables recorded in the questionnaire: descriptive nasal bleeding scale, descriptive crust formation scale, sex, age, and type of surgery performed.