PRF Membrane and Recovery After Periapical Surgery: A 3D Imaging Study

PRF Membrane and Recovery After Periapical Surgery: A 3D Imaging Study

Study Unique Protocol ID:

3736-1/2022/EKU

NCT Number:
Not available

Date of Document:
2024-12-11

Aim

Comparisation of the swelling, the quality of life and the post operative pain after endodontic surgery with and without of the use of A-PRF+.

Matherials and methods

Patient selection:

- 10-10 per each group

Inclusion Criteria:

- Adults aged 20-65 years, both male and female.
- Diagnosed with periapical disease, including periapical cysts or granulomas.
- Requiring periapical surgery as part of their treatment plan.
- Presenting a tooth needing endodontic surgery with periradicular lesions of strictly endodontic origin.
- Size of the bone crypt between 6 mm and 12 mm.
- Non-surgical retreatment considered unfeasible or previously failed.
- Apical root canal free from posts over a length of at least 6 mm.
- Adequate coronal restoration without coronal leakage.
- Willing and able to provide written informed consent.
- Capable of attending follow-up visits and participating in required assessments.
- Maxillary and mandibular teeth limited to the 2nd premolar to 2nd premolar regions.
- Without general medical contraindications for oral surgical procedures.

Exclusion Criteria:

- Patients with systemic conditions affecting healing, such as:
    - • Uncontrolled diabetes mellitus.
    - • Autoimmune disorders.
    - • Chronic inflammatory diseases.
- Pregnant or breastfeeding individuals.
- Use of medications or therapies that may interfere with healing, including:
    - • Bisphosphonates.
    - • Immunosuppressants.
    - • Radiotherapy.
    - • Oncological therapies (e.g., chemotherapy, immunotherapy).
- Requires antibiotic prophylaxis or therapy.
- History of allergies or adverse reactions to blood-derived products.
- Neuropsychiatric disorders.
- Active infection or severe periodontal disease in the surgical area.
- Periodontal probing depths greater than 5 mm.

- Moderate to severe periodontal bone loss.
- Vertical root fractures.
- Perforation of the furcation area or root canal, except for the apical area.
- Smokers or individuals unwilling to refrain from smoking during the study period.
- Participation in another clinical trial within the last 30 days.
- Absolute or relative contraindications for surgery.

Surgical procedure

- If it is required and feasible endodontic treatment or retreatment maximum 1 week before surgery
- One surgeon perform all operation
- Local anaesthesia 2% lidocaine and ephinephrine 3x2 ml lidocaine
- Trapezoid submarginal flap (Ochsenbein-Luebke flap)
- 15 C surgical blade
- Ball shaped 0,27 mm diameter bone burr, 1:1 straight handpiece
- 3 mm of apical portion is resected- in one piece – perpendicular to the long axis placed in sterile saline
- 3 mm retrograde cavity- with diamond coated ultrasonic instruments
- Micorbiological sample
- MTA retrograde RCfilling
- Mobilisation of the flap
- In the test group the resection cavity was filld and covered with A-PRF+ membrane
- Tension free flap closure with 3-0 Silc suture

PRF preparation

- In the test group before surgery 3 or 2 (depends on size of the cavity) 10ml glass tubes without additives
- 1300 rpm for 8 min centrifugation (Harmonycom)
- Using an A-PRF Duo centrifuge (Process for PRF, Nice, France)
- Placed in sterile container (PRF Box, Process for PRF, Nice, France)

Postoperative instruction

- Diclofecan 50mg (Cataflam 50mg) 2x1 per day, for 3 days
- Rinses with 0,12% Chlorehexidine twice a day for 1 week
- No postoperatic antibiotics was described
- Suture removal after 7 days

Evaluation

- 3D optical scans (Einstar, Shining 3D) were recorded over two time period, T0 (preoperative scan), T1 (day 3 postoperatively)
- VAS (Visula Analogue Scale) pain was graded on a score to 0-10, 0 no pain, 10 maximum intesity of pain, for 7 days
- Likert scale based questionary: ranging from 0 to 4, 0 non 4 very much, for 7 days daily starts ont he operation day
    - Postoperativ limitations in function: Mouth opening, Chewing, Speaking, Sleeping, Daily routine, Work

Statistical Analisys

Statistical Analysis Plan

1. Study Objectives

- **Primary Objective**:
  - To assess the impact of PRF membrane on postoperative swelling and its relationship with quality of life dimensions and pain.
- **Secondary Objectives**:
  - To compare quality of life (QoL) dimensions and pain levels pre- and post-intervention between the PRF membrane group and the control group.
  - To investigate correlations between swelling (volume) and postoperative QoL dimensions.

---

2. Study Design

- **Type**: Preliminary comparative study.
- **Groups**:
  - **PRF Membrane Group** (10 participants): Underwent apicoectomy with PRF membrane application.
  - **Control Group** (10 participants): Underwent apicoectomy without PRF membrane.

---

3. Outcome Measures

1. **Primary Outcomes**:
   - Postoperative swelling (volume): Measured using standardized evaluation methods.
   - Quality of Life (QoL) dimensions: Assessed using a questionnaire with subdimensions (e.g., physical function, pain impact, anxiety, sleep disturbance).
2. **Secondary Outcomes**:
   - Pain intensity: Measured using the Visual Analog Scale (VAS).
   - Correlations between swelling and QoL dimensions.

---

4. Statistical Methods

1. **Descriptive Statistics**:
   - Mean ± standard deviation for continuous variables (e.g., QoL scores, pain, swelling volume).
   - Frequency and percentage for categorical variables.
2. **Normality Testing**:
   - **Shapiro-Wilk test**: Conducted for each variable to determine whether parametric or non-parametric tests will be used.
3. **Comparative Analyses**:

    - **Between Groups**:
        - Independent samples t-test for normally distributed data.
        - Mann-Whitney U test for non-normally distributed data.
    - **Within Groups**:
        - Paired t-test for normally distributed pre- and post-intervention comparisons.
        - Wilcoxon signed-rank test for non-normally distributed data.
4. **Correlations**:
    - Spearman's or Pearson's correlation will be used to evaluate the relationship between swelling (volume) and QoL dimensions depending on data distribution.
5. **Significance Threshold**:
    - A two-tailed **p-value < 0.05** will be considered statistically significant.

---

5. Missing Data

- Missing data will be handled by:
    - **Listwise deletion** for analyses where missing data is minimal.
    - Sensitivity analysis if missing data exceeds 10%.

---

6. Software

- All statistical analyses will be performed using **SPSS** or **R** software.

---

7. Reporting

- Results will include:
    - Comparative tables of pre- and post-intervention outcomes.
    - Statistical significance levels for group comparisons.
    - Correlation matrices for swelling and QoL dimensions.