Prospective Healing Assessment After Application of Endodontic Microsurgery for Elimination of Apical Pathology, By Use of Either a Rotary Bur for Osteotomy and Apical Root Resection, or Piezoelectric Unit for the Same Clinical Procedures.

09/11/2025

Study Protocol + Statistical Analysis

Introduction

Persistent and recurrent apical periodontitis can be treated predictably by modern endodontic surgery. Unlike traditional surgery, modern microsurgical techniques incorporate the use of an operating microscope, ultrasonic tips for precise root-end preparation, and biocompatible root-end filling materials, such as mineral trioxide aggregate (MTA), and more recently other bioceramic-based materials such as Endosequence Root Repair Material (RRM; Brasseler, Savannah, GA)[1-3]. These materials offer a better seal and apical tissue response[1-3]. Endodontic microsurgery is a minimally invasive procedure. Osteotomy diameter is 3-4mm, just enough to allow for access to the apical lesion, a 3mm apical root resection, root end preparation and root end filling[1,2]. Weighted pooled success rates have been

established in a meta-analysis with cumulative outcomes for the traditional approach of apical surgery at 59.0% and for endodontic microsurgery at 93.5%[4]. The significantly higher success of the modern microsurgical procedure has been repeatedly concluded in several investigations[5,6].

Traditional use of surgical manual instruments or even rotary burs for osteotomy resulted in a significant increase of temperature or even bone injury during surgery, because of the application of excessive pressure on the bone[7]. In order to overcome these limitations, researchers have introduced the application of units that utilize the principles of ultrasonic microvibration to make precise and selective cut on the bone in harmony with the surrounding tissues[7,8]. One of the novel methods to incorporate these properties of ultrasonics is Piezosurgery. This is a relatively new alternative for bone-related procedures introduced in the field of dentistry. It has a wide potential for usage with the devices running according to the piezoelectric principles and capable of cutting by way of ultrasonic vibration[9,10]. These vibrations are low frequency modulated vibrations at 25 to 30 khz which selectively cut the bone without damaging adjacent soft tissues and delicate structures, such as the Schneiderian membrane or a nerve[10].

Aims and Objectives

The aim of this study is to prospectively compare postsurgical healing after the use of microsurgical technique to eliminate apical pathology, either by use of rotary burs for osteotomy and root resection, or by use of piezoelectric surgery for the same clinical procedures. Null hypothesis is that there is no difference in healing and buccal bone thickness reformation between the two surgical procedures.

Another purpose of the study is to prospectively evaluate healing after the application of a novel buccal bone preservation technique, called the 'bone window' technique. The technique will be applied in a subgroup of patients on maxillary and mandibular premolar and molar teeth with an intact buccal cortical bone, and healing and buccal bone reformation will be assessed at follow up. Null hypothesis in this part, is that there is no difference in healing and buccal bone preservation between osteotomy with a bur and the 'bone window' technique.

Khoury and Hensher in 1987 were the first ones who reported a "bone window" (lid) approach, which provided better access and intraoperative visibility to the desired lesion location while avoiding extensive removal of alveolar bone[11]. This was performed in the pre-Cone Beam Computed Tomography (CBCT) era and

relied on clinicians' experience. The primary aim of performing a bone window technique is to preserve more bony structure and to maintain the integrity of the healthy cortical plate[12].

In endodontic microsurgery, a significant reduction of osteotomy size resulted in the preservation of more bony structure while obtaining access to the target roots compared with the pre-microsurgery era[1]. Animal histologic sections showed that the cortical plate is the last component to heal, with a healing rate of 70% at the 6-month follow-up[13]. Furthermore, cone-beam computed tomographic (CBCT) assessment after apical surgery in humans revealed that only 54.1% of cases showed cortical plate healing at a 1-year follow-up[14]. The extent of cortical plate loss and its limited healing potential may require the need of regenerative techniques with graft materials.

Methods and Materials

For this prospective investigation, patients will be randomly allocated into two groups. In group 1 (experimental group), endodontic microsurgery will be performed by use of a rotary bur for osteotomy and apical root resection and in group 2 (control group), piezoelectric surgery will be used for the same clinical procedures. Removal of the periapical pathology, root end preparation and root end filling will be done in both groups following the same protocol, technique and

materials. All surgical procedures will be performed by one operator. Postsurgical healing as well as certain preoperative and postoperative parameters will be assessed and compared in the two groups. Limited field of view (FOV) CBCT scan will be performed presurgically, postsurgically and at follow up examination by use of a Veraviewepocs 3D F40 (Morita, Irvine, CA) unit: Field Of View (FOV) 4 x 4 cm, voxel size = 0.125 mm.

The inclusion criteria will be defined as follows:

1. Age 18 years and older consenting to the surgical procedure as well as agreeing to preoperative, postoperative and at least 1 follow-up CBCT evaluation after 12 months
2. Noncontributory medical history (American Society of Anesthesiologists class I and II)
3. A history of previous endodontic treatment with radiographic presence of apical periodontitis
4. A true endodontic lesion: microsurgical classification A, B, or C according to Kim and Kratchman, 2006[1].
5. Lesion size 10 mm or smaller in diameter measured on preoperative CBCT
6. Coronal restoration should be present at the time of follow up examination.

The exclusion criteria will be as follows:

1. Nonconsenting patients and patients younger than 18 years of age
2. Medical history with American Society of Anesthesiologists class III to V

3. Insufficient coronal restoration

4. Nonrestorability or traumatized teeth

5. Teeth with microsurgical classification D, E, or F according to Kim and Kratchman 2006[1].

6. Mobility I or higher

7. Radiographic presence of nonapical root resorption

8. Teeth with a vertical root fracture or coronal/ midroot perforation

9. Lesion size larger than 10 mm in diameter measured on preoperative CBCT

10. Use of bone graft material for regeneration

All participants will be thoroughly informed on the purpose and the details of the study and a written consent will be obtained.

Apical surgery following the protocol of endodontic microsurgery and the use of an operating microscope as described by Kim S, Kratchman S, 2006[1] will be executed in all patients. Briefly, local anesthesia is performed, flap is reflected and osteotomy and apical root resection is done either by use of a rotary bur or the tip of a piezoelectric unit. Apical granulomatous tissue is removed, followed by root end preparation and root end filling with modern bioactive materials. Flap is repositioned and sutured with resorbable sutures. A limited FOV CBCT will be acquired immediately postsurgically.

In a subgroup of patients having at least 2mm of intact buccal cortical bone thickness preoperatively, piezoelectric surgery will be used to prepare a rectangular

buccal 'bone window'. The buccal bone thickness will be measured preoperatively on the coronal slices of the CBCT. After completing the root end filling, the bone window will be repositioned at the original position and a collagen membrane will be placed in contact with the bone fragment to enhance bone healing and stabilize the fragment.

All patients will be recalled at minimum one year after periapical surgery for follow up examination. At follow up, clinical examination will be performed including percussion, palpation and periodontal probing. Radiographic examination will include a periapical radiograph and a limited FOV CBCT scan. Healing will be evaluated using Molven et al, 1987[2] criteria for two dimensional radiographic assessment and modified Penn 3-dimensional criteria as described by Schloss et al, 2017[3] for the three-dimensional examinations.

A preoperative and postoperative volumetric assessment of the lesions will be performed by using a segmentation and volume measurement software. The sliced image data of cone-beam computed tomographic images before and after surgery and at follow up examination will be imported into the segmentation software and after segmentation, the volumes of periapical lesions will be measured, and the difference in the volume will be calculated

Particularly for the 'bone window' cases, a pair-matching of cases having intact buccal bone plate and similar apical defect volumetric dimensions will be done, utilizing either a bur for osteotomy and root resection or the piezoelectric unit for bone window preparation and apical root resection.

In addition, certain perioperative parameters, such as the time required to execute osteotomy and root resection in all surgeries in the two groups of patients will be calculated.

Statistical Analysis

Data will be analyzed using STATA 18 software (StataCorp LLC, College Station, TX). Descriptive statistics will be calculated as means with standard deviations for continuous variables (volumetric analysis) and as frequencies with percentages for categorical variables (healing scores). Data normality will be tested. Comparisons of means between the two treatment groups will be done using Student's t-test for data with normal distribution, or Mann–Whitney U-test for not normal distributions. Chi-Square or Fisher's exact tests will be used to test the difference between the groups for categorical variables. To evaluate the outcome of the two treatment procedures at the 12-month follow-up, a multivariate binary logistic regression model will be calculated to correlate the independent variables with the success rate. The results will be reported in terms of odds ratios (ORs) with 95% confidence intervals .

Conclusion

This prospective healing evaluation after endodontic microsurgery either by use of a bur or piezosurgery aims to:

- Compare the healing outcome between the two techniques
- Highlight advantages and limitations of piezoelectric units for apical microsurgery
- Evaluate the clinical advantages and the healing outcome of the novel 'bone window' technique.

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