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Evaluation of a dynamic navigation system for endodontic microsurgery: study protocol for a randomised controlled trial

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ABSTRACT

Introduction Endodontic microsurgery is a very important technique for preserving the natural teeth. The outcomes of endodontic microsurgery largely depend on the skill and experience of the operators, especially for cases in which the apices are located far away from the labial/buccal cortical bone. A dynamic navigation system (DNS) could provide a more accurate and efficient way to carry out endodontic microsurgery. This study is devoted to comparing the clinical outcomes of the DNS technique with those of the freehand technique.

Methods and analysis Sixteen patients will be randomly assigned to one of two groups. For the experimental group, the osteotomy and root-end resection will be performed under the guidance of dynamic navigation. For the control group, these procedures will be performed freehand by an endodontist. The required time to perform these procedures will be used to evaluate the efficiency of the DNS technique. A Visual Analogue Scale will be used to evaluate pain at 1, 3 and 7 days after endodontic microsurgery. Preoperative and postoperative cone beam CT scans will be obtained to evaluate the accuracy of the DNS technique. The global coronal deviations, the apical deviations and the angular deflection will be measured. The root-end resection length deviation, the root-end resection angle deviations, the extent of the osteotomy and the volume change of the buccal cortical bone will also be measured. Periapical radiographs will be obtained to evaluate the outcome at 1 year after microsurgery. The time to execute the study, including follow-ups, will last from 1 June 2022 to 31 December 2025.

Ethics and dissemination The present study has received approval from the Ethics Committee of Peking University School and Hospital of Stomatology. The results will be disseminated through scientific journals.

Trial registration number ChiCTR2200059389.

INTRODUCTION

Endodontic microsurgery is a treatment of last resort for preserving natural teeth. The success rate of endodontic microsurgery has improved from 44.2%–53.5% to 90.5%–91.1% through the use of the endodontic microscope, cone beam CT (CBCT), as well as developments in instruments and materials.[1 2]

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is a randomised, double-blind clinical trial to evaluate the clinical outcomes of the dynamic navigation system (DNS) technique compared with the freehand technique in endodontic microsurgery.

⇒ Minimally invasive procedures of osteotomy and root-end resection may be realised in the group using the DNS technique.

⇒ Only lesions involving a single root will be included in the study, and the labial/buccal cortical bone should be intact according to cone beam CT evaluation in this research.

The procedures of endodontic microsurgery include anaesthesia, flap reflection, osteotomy, root-end resection, root-end preparation, root-end filling, flap repositioning and suturing. There exist challenges for endodontists, including accurate location of the root apex and resection of the root end. An osteotomy with a diameter of 3–4 mm is recommended in modern endodontic surgery. The results of excessive removal of healthy bone could cause slower healing if the root apex was inaccurately located. However, it is difficult to achieve an accurate 3 mm root-end resection and guarantee the resection plane is perpendicular to the long axis of the teeth (no bevel or less than 10 degrees) in many situations. A root-end resection of less than 3 mm may likely not remove enough lateral canals and apical ramifications, resulting in failure of infection control. A root-end resection of more than 3 mm may weaken the root. Bevelling causes damage to the buccal bone and root, leading to elongation of the canal and reduction of the root diameter.[3 4]

Despite advances in microscopy and CBCT, it remains a challenge to perform a minimally-invasive and accurate operation using the procedures of osteotomy and root-end

resection. The outcome is influenced by the experience of the operator, limited field exposure, bleeding in the operative area and interference by anatomic structures (maxillary sinus, mandibular canal), etc.[5]

The concept of 'guided endodontics' has been proposed to guide the operation based on preoperative CBCT. This concept has been applied in location of calcified canals, removal of fibre posts from root canals and endodontic microsurgery.[6–8] Static digital guides are used to realise the concept of 'guided endodontics' and were first applied in endodontic microsurgery in 2007.[9] It has been verified that the accuracy of the location and resection of the root-end is improved by application of a digital guide.[8 10 11] However, there are several limitations of static digital guides, including additional time and economic cost for patients, unstable retention on the soft tissue, increased heat production and limited opening for the posterior teeth.[11 12]

The dynamic navigation system (DNS) is a new approach to achieving accuracy during operation and it could overcome the limitations of the static digital guide. At the beginning, this technology was adopted from implant dentistry.[13] In the field of endodontics, this technology was demonstrated to be safe, fast and accurate in preparing the access cavity,[14 15] locating calcified canals,[16–18] intraosseous anaesthesia,[19] removal of fibre posts from root canals[7] and endodontic microsurgery.[20 21] It has several advantages: (1) reducing time and cost; (2) conducive to cooling and avoiding damage to tissue due to heat production; (3) performing operations with insufficient space; (4) increased safety, accurate and predictability and (5) real-time visualisation of the position and angulation of the drill.[12] Gambarini *et al* first reported the use of a DNS in endodontic microsurgery for precise localisation of the root and precise apicoectomy with a minimally invasive cavity. The DNS facilitated the operator's manoeuvres and reduced the risk of iatrogenic errors.[21] Dianat *et al* and Aldahmash *et al* investigated the accuracy and efficiency of guided root-end resection using a DNS in a human cadaver study. Compared with the freehand technique, the DNS technique improved the accuracy and efficiency of root-end resection with minimally invasive osteotomy.[20 22] Martinho *et al* reported that the DNS technique improved the accuracy and efficiency in osteotomy and root-end resection of novice endodontists and experienced endodontists in cadaver heads.[23] Fu *et al* presented excellent case reports of posterior teeth with the assistance of DNS technique. In one case, the distance between the apex of the palatal root of tooth #3 and buccal cortical plate was 14.53 mm, which would pose great challenges for the endodontists. Minimal invasive and efficiency could be realised with the help of DNS technique.[24] To date, there is still a lack of randomised controlled studies on the clinical effects of a DNS compared with the freehand technique in endodontic microsurgery.

We hypothesised that the DNS technique is more accurate and effective than the freehand technique in clinical endodontic microsurgery. This hypothesis will be tested in the present double-masked randomised controlled clinical trial, the design of which is described below.

METHODS AND ANALYSIS

The study is a prospective, single-centre randomised controlled trial. It has been approved by the Ethics Committee of Peking University School and Hospital of Stomatology (PKUSSIRB-202170182). Research procedures including assessments, interventions and follow-ups will be carried out in Peking University School and Hospital of Stomatology (Beijing, China). This study has been registered with the registry of International Clinical Trials Registry Platform (ICTRP) (ID: ChiCTR2200059389). The main objective of this randomised controlled clinical trial is to compare and evaluate the clinical effects of the DNS technique compared with the freehand technique in endodontic microsurgery cases with intact labial/buccal cortical bone. The primary hypothesis is that the DNS technique will improve the accuracy and efficiency of endodontic microsurgery compared with the freehand technique.

Inclusion criteria

Patients attending the Department of Cariology and Endodontology for routine planned endodontic microsurgery will be evaluated for inclusion in this clinical trial. The age of patients to be recruited will range from 18 to 65 years. Patients will have received periodontal treatment before endodontic microsurgery. Only lesions involving a single root will be included in the study. The labial/buccal cortical bone and the palatal/lingual cortical bone should be intact according to CBCT evaluation. Lesion involving palatal root will be included if the surgery could be performed from the labial/buccal side. The osteotomy of 4.5 mm diameter in the DNS group should guarantee to remove all granulation tissue in preoperative evaluation.

Exclusion criteria

1. Smokers.
2. Pregnant women.
3. Patients with systemic diseases.
4. Resurgery.
5. Unqualified coronal restoration.
6. Teeth with deep periodontal pockets (probing depth ≥5 mm).
7. Large periapical lesions (>10 mm diameter).
8. The third molar.

Recruitment

Patients who are willing to participate in this study will be recruited from the Department of Cariology and Endodontology, Peking University School and Hospital of Stomatology. A signed informed consent form will be obtained and stored confidentially in a cabinet. The procedures of this clinical trial are shown in figure 1.

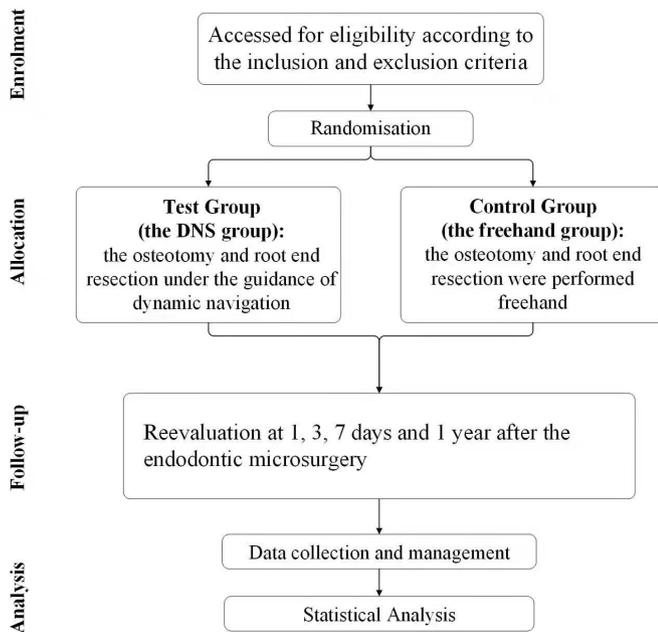**Figure 1** The flow chart of this clinical research.

Groups, randomisation and blinding

An experienced endodontist will perform the examination, diagnosis and assessment procedures after clinical and radiographic examinations. The randomisation sequence will be computer generated by statisticians in the data coordinating centre in Research Center of Clinical Epidemiology in Peking University Third Hospital. Blocked randomisation will be done with dynamic block sizes of 2, 4 or 6. This sequence will be entered into the central online database to achieve the allocation concealment, which will be secured by the username and password. The DNS technique will be applied to operate on the roots of the experimental group, while the freehand technique will be used for the roots of the control group.

Interventions

All enrolled roots will be randomly divided into two groups after examination. The endodontic microsurgery will be performed by the same experienced endodontist using an endodontic microscope (F40, Leica Microsystems, Wetzlar, Germany). The procedures and principles of the endodontic microsurgeries will follow the guidelines proposed by Kim and Kratchman.[3] A vertical and a horizontal incision will be used to reflect the flap. CBCT (VGi EVO, NewTom, Imola, Italy) will be performed and the DICOM dataset will be imported into dynamic navigation software (DCARER, Suzhou, China) to establish navigation path programming. The drilling entry point, angle and depth will be virtually planned. Under dynamic navigation guidance, a trephine bur with a diameter of 4.5 mm on a handpiece at 5000 RPM will be used to complete the osteotomy and 3 mm of root-end resection. Position matching, the proficiency in using the handpiece with trephine bur, initial calibration, registration process would be done before the osteotomy in the DNS

group. The experienced endodontist with over 5 years of endodontic microsurgery experience will be well trained before the microsurgery. For the DNS group, the time required for osteotomy and root-end resection was calculated in seconds with a stopwatch beginning at drilling depth calibration and continuing until the end of the planned path according to previous study.[22] For the freehand group, the osteotomy and root-end resection will be performed freehand with a 45° surgical handpiece with a Lindemann bone cutter bur at 40 000 rpm according to the preoperative CBCT after flap elevation. The time will be recorded with a stopwatch from the beginning of osteotomy and ending of root-end resection.

After 3 mm of the root apex has been resected for the two groups respectively, retropreparation and retrofilling with iRoot BP (Innovative BioCeramix, Burnaby, British Columbia, Canada) will be performed. The flap will be repositioned with 5–0 sutures. These procedures will be operated uniformly for the two groups. Postoperative CBCT will be performed. Amoxicillin and a 0.2% chlorhexidine gluconate rinse will be prescribed to prevent postoperative infection. Sutures will be removed 5 days after the endodontic microsurgery.

Examination

At baseline, preoperative CBCT scans will be obtained for each participant. During endodontic microsurgery, the required time to perform the osteotomy and root-end resection procedures will be recorded and used to evaluate the efficiency of the DNS technique and the freehand technique. A Visual Analogue Scale (VAS) will be recorded at 1 day, 3 days and 7 days after endodontic microsurgery for the evaluation of postoperative pain. Postoperative CBCT scans will be performed to evaluate the accuracy of the DNS technique and the freehand technique. The DICOM data will be imported into MIMICS 21 software (Materialise, Leuven, Belgium) to reconstruct the preoperative and postoperative three-dimensional structures. The reconstructed models will be exported to Geomagic Control software (3D Systems, Rock Hill, South Carolina, USA) in STL format. The global coronal deviations, the apical deviations and the angular deflections will be measured by a blinded technician with superimposition of the pre-established navigation path plan and postoperative images. The root-end resection length deviation, the root-end resection angle deviations, the extent of the osteotomy and the volume change of the buccal cortex will also be measured with superimposition of the preoperative and postoperative images.

In order to evaluate the outcome, patients will be recalled for a follow-up examination 1 year after microsurgery. At the recall examination, the results of percussion tests, sinus tract and mobility will be recorded. Periapical radiographs will be obtained to evaluate the outcome according to the criteria of Rud et al and Molven et al.[25 26] All the data will be recorded, imputed and processed in the computer simultaneously. Due to lack of a data monitoring committee in our hospital, the data will be kept

in the cabinet by two different researchers to ensure the accuracy and completeness of the data. An independent inspector will review the incoming data every 3 months. There will be no harms caused by the trial.

The primary outcomes are efficiency and accuracy of the DNS technique and the freehand technique. The secondary outcomes are the VAS evaluation after endodontic microsurgery and the outcome evaluated with periapical radiographs at 1-year follow-up.

Sample size
The sample size of this clinical trial is determined by the following formula:

$$N1 = N2 = 2\left[\frac{\sigma\left(Z_{\alpha/2}+Z_{\beta}\right)}{\delta}\right]^2$$

According to the data of a published clinical trial concerning bone grafting in periapical osseous defects,[27] the σ/δ is around 0.49. The inspection level (α) is set to 0.05, and the power is set to 0.9. For bilateral tests, the required sample size in each group is six. Considering a missed follow-up rate of 20%, the sample size should be 7.2. Consequently, 16 participants will be needed.

Statistical analysis
Data will be analysed using SPSS 25.0 software (IBM SPSS Statistics for Windows). Statistical significance will be accepted for p values lower than 0.05. Normality and variance equality will be analysed using the Shapiro-Wilk test and the Levene variance homogeneity test, respectively. Normally distributed data will be shown as the mean±SD, while non-normally distributed data will be shown as the median (lower to upper quartile). Student's t-tests will be used to compare differences between the two groups for data with both normality and variance equality. Otherwise, the Mann-Whitney U test will be used.

Withdrawal
Patients will have the right to withdraw from this clinical trial without any reason at any point during the treatment. Follow-up treatment will not be affected by the withdrawal.

Dissemination of results
The results of this clinical trial will be registered at the ICTRP. In addition, the results will be published in a peer-reviewed journal.

Patient and public involvement
Neither patients nor the public have been or will be involved in the design, recruitment, assessment, conduct or reporting of this research. The results will be disseminated through scientific journals.

DISCUSSION
According to previous studies, the DNS technique could provide a more accurate and efficient method of performing endodontic surgery. As a new digital technology, the basic principle of dynamic navigation technology is to use trackers to locate surgical instruments and patients in real time. This has been verified in dental implant placement,[12 28] injection of intraosseous anaesthesia,[19] location of calcified canals,[17 18] planning and executing ultraconservative access cavities[15] and removal of fibre posts.[7]

Although there has been great progress in endodontic microsurgery with developments in instruments and biomaterials, the accuracy and efficiency of osteotomy and root-end resection still need to be improved to minimise surgical trauma. With the development and application of digital technology, the concept of 'guided endodontics' has been proposed. The DNS technique has several advantages in realising 'guided endodontics', especially in endodontic microsurgery. It could help operators to avoid important anatomical structures such as the maxillary sinus, mental foramen and nasal floor.[7 20] For endodontic microsurgery, accurate osteotomy and resection of the root-end is difficult if the apices are located far away from the labial/buccal cortical bone. For these cases, the DNS technique could play an important role in guiding the operator to achieve minimally-invasive surgery and an accurate clinical outcome.

Under the guidance of dynamic navigation, a trephine bur with a diameter of 4.5mm will be used to complete the osteotomy and root-end resection simultaneously. Compared with conventional carbide and diamond burs, a trephine bur can also lead to successful outcomes.[29 30] In a study by Hawkins et al, a trephine of 4.4mm outer diameter was used in targeted endodontic microsurgery. It was verified that increased accuracy and efficiency was possible with the guide–trephine combination.[31] Osteotomy diameters <5mm could improve osseous healing. The osteotomy is also large enough to accommodate an ultrasonic tip.[31] In order to match the shape of the implant in the navigation software, a trephine of 4.5mm will be used in this study.

Ethics and dissemination
Ethical approval had been granted by the Ethics Committee of Peking University School and Hospital of Stomatology (PKUSSIRB-202170182). The data of the clinical trial will be input and kept in a specific computer and a locked cabinet by two designated members of staff. The results will be published in a peer-reviewed journal.

Trial status
The trial has been registered at the International Clinical Trials Registry Platform (ICTRP). The identifier number is ChiCTR2200059389. Recruitment will begin in June 2022 and will end in June 2024.

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