

**Title:** Diagnostic Accuracy of Artificial Intelligence, CBCT, and Clinical Examination in Detecting Number of Root Canals in Conventional and Retreated Maxillary and Mandibular Molars

**NCT Number:** “Pending”

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**Introduction:** Accurate root canal detection is crucial for successful endodontic treatment, particularly in complex molar cases. Conventional methods, such as clinical examination and cone-beam computed tomography (CBCT), have their limitations, as high radiation exposure. Recent advancements in Artificial Intelligence (AI) have shown promise in improving diagnostic accuracy. This study aims to compare the effectiveness of AI, CBCT, and clinical examination using a dental operating microscope (DOM) in detecting root canals in upper first, upper second, and lower first molars, in both conventional and retreatment cases.

**Methods:** CBCT scans from 210 patients requiring non-surgical root canal therapy or re-treatment were selected. The scans were analyzed using three detection methods: clinical examination via DOM, interpretation by two experienced endodontists using CBCT, and an AI convolutional neural network (CNN) software (Diagnocat). The detected number of root canals was recorded and compared across the three methods. Statistical analysis was performed to evaluate the diagnostic accuracy, including sensitivity, specificity, and agreement between methods.

**Results:** AI detected a significantly higher number of molars with three or four canals compared to clinical examination and CBCT in conventional treatment cases ( $P < 0.001$ ). In retreatment cases, AI demonstrated a similar trend, with one case of five root canals detected clinically but missed by both CBCT and AI. Overall, AI showed higher diagnostic accuracy (88.2%) compared to clinical examination and CBCT. There was no significant difference in AI accuracy between molar types, though the upper first molar had the highest accuracy (93.9%).

**Conclusion:** AI demonstrated higher accuracy in detecting root canals compared to CBCT and clinical examination in both conventional and retreatment cases, particularly in upper molars. These findings highlight the potential of AI as a valuable tool for enhancing diagnostic precision in endodontics, especially in complex cases. However, further research is necessary to address the limitations of AI

## Study Objectives and Hypotheses

- **Objective:** To evaluate and compare the accuracy of AI, CBCT, and clinical examination in detecting the number of root canals in maxillary and mandibular molars.
- **Hypothesis:** AI will demonstrate superior diagnostic accuracy compared to CBCT and clinical examination.

## Study Design

- **Sample Size:** 212 molars.
- **Randomization:** Not applicable (observational study).
- **Blinding:** Independent assessment by two experienced endodontists for CBCT and clinical examination.
- **Control Group:** Not applicable.

## Eligibility Criteria

### Inclusion Criteria:

- Male and female patients who were capable of providing informed consent.
- Age between 18 to 40 years old.
- A restorable tooth.

### Exclusion Criteria:

- Patients that underwent vital pulp therapies.
- Patients with calcifications in pulp space.
- Open apex/immature roots.
- Teeth restored by full coverage crowns.
- Pregnant women by taking adequate history from patient and pregnancy test that was done in the first visit

## Study Procedures

- CBCT scans are analyzed by endodontists and AI software (Diagnocat).
- Clinical examination is performed using a dental operating microscope (DOM).
- The detected number of canals is recorded and compared across methods.
- Statistical analysis is performed to evaluate accuracy.

## Statistical Analysis Plan

- Descriptive analysis of frequencies and percentages.
- Friedman's test for comparison between methods.
- Kappa statistics for agreement between methods.
- ROC curve analysis to determine diagnostic accuracy measures (AUC comparison).

## **Risks and Benefits**

- **Risks:**
  - Radiation exposure from CBCT scans.
  - Potential diagnostic errors leading to treatment challenges.
  - Procedural complications, such as tool breakage or nerve injury.
- **Benefits:**
  - Enhanced diagnostic accuracy and reduced diagnostic errors.
  - Improved treatment outcomes and reduced human error.

## **Study Timeline**

- **Estimated Duration:** 1 visit and subsequent visit to continue the root canal treatment.
- **Key Milestones:**
  - Participant recruitment (2 months).
  - Data analysis and reporting (3 months).

## **Ethical Considerations**

- The study has been reviewed and approved by the Institutional Review Board (IRB) of Misr International University. (IRB Number: MIU-IRB-2425-008)
- Participant confidentiality will be maintained in compliance with ethical guidelines.

## **Funding and Conflict of Interest**

- No external funding has been received for this study.
- The researchers declare no conflicts of interest.