RESEARCH PROTOCOL

DECIDE-AI

The Impact of Artificial Intelligence on Dentists' Decision-Making Process During Caries Detection: A Randomized Controlled Study

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PROTOCOL TITLE The Impact of Artificial Intelligence on the Decision-Making Process of Dental Professionals During Caries Detection: A Randomized Controlled Study

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Subsidising party	Prime Dental Alliance, Eindhoven
Counrty of Participant recruitment	The Netherlands
Study type	Randomized controlled study
Primary outcome	Differences in treatment decisions with and without Artificial Intelligence support during caries detection using bitewings (dental radiographs).
Secondary outcome	Differences in diagnostic performance with and without Artificial Intelligence support during caries detection using bitewings.

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ABSTRACT

Rationale: Artificial Intelligence (AI) based tools can support dental care providers' diagnosis of dental X-rays, promising increased accuracy. However, the influence of AI on dental professionals' decision-making process must be further investigated to ensure it complements the practitioner's abilities without diminishing their clinical judgment. Moreover, the potential

Objective: The aim of this study is to evaluate the impact of AI-based diagnostic tools on the decision-making process of dental care providers compared to non-AI-supported decisions during caries detection. Specifically, the aim is to determine whether there are differences in non-invasive or invasive treatment recommendations, and diagnostic accuracy, when AI is utilized versus when it is not. Additionally, it will be explored how AI affects participants' confidence levels.

Study design: This study is a randomized controlled study with a crossover design examining the impact of AI on the decision-making process with caries lesions detection on dental radiographs (bitewings).

Study population: Dentists from the Department of Dentistry at Radboud university medical center or private dental practices some affiliated with Prime Dental Alliance.

Study parameters:

1. Treatment Decisions: Assessment of treatment recommendations (e.g., no therapy, non-invasive interventions, or invasive treatments) with and without AI assistance.
2. Diagnostic Accuracy: Measured by sensitivity and specificity in detecting caries lesions with and without AI assistance.

Nature and extent of the burden and risks associated with participation, benefit, and group relatedness: There are no risks associated with participating in this study, since it includes standard diagnostic evaluations routinely performed by dentists, with the addition of using AI-based tools for some assessments. All evaluations are done in a controlled, non-clinical setting with no changes in patient care. The study is designed collect information from dentists, simulating their clinical performance without patient data. Diagnostic performance and decision-making will be explored, posing no risk to patients or participants' professional standing.

1. INTRODUCTION AND RATIONALE

AI-based tools are becoming more present in dentistry by supporting diagnostic processes, such as caries detection, while promising enhanced diagnostic accuracy [1]. However, even with the increased performance of AI technologies, there still appears to be a lack of knowledge about its influence on practitioners' decision-making, which is critical if the goal is to integrate

it further into dental practices [2]. Research shows that dentists tend to be more invasive with conditions that may not progress if only observed or treated non-invasively [3]. AI, being highly sensitive to flagging initial lesions, may contribute to these decisions with the potential result of overdiagnosis and overtreatment.

A study conducted in 2021 recruited 20 dentists to analyse a set of 20 bitewings (dental x-rays used to diagnose caries), 10 with the support of AI and ten without. The results showed that using AI led to higher detection rates as well as more non-invasive and invasive treatment suggestions for enamel caries, shifting from 32% to 36% for non-invasive and 17% to 24% for invasive treatment ($p<0.05$) [4]. On the other hand, studies have also emphasized the educative factor of using AI. In a different study the caries diagnosis performance of students was investigated after training with AI, showing that accuracy, sensitivity, and specificity were significantly higher for the trained group compared to the non-trained group ($p < 0.05$) [5].

Incorporating a support medium, such as AI-based diagnostic programs, may enhance accuracy in detecting caries lesions and introduce potential risks, such as overtreatment. Therefore, in contrast to other studies focusing on AI's accuracy or the resulting increase in dentists' accuracy, this study will focus on differences in dentists' treatment recommendations when supported by AI versus when they are not during caries detection. Researching these aspects of AI in dental diagnostics is crucial to enhance the responsible integration of Artificial Intelligence into dental practice.

2. OBJECTIVES

2.1 Primary Objectives:

To evaluate the impact of AI-based diagnostic tools on the decision-making process of dental care providers using dental radiographs (bitewings).

1. Treatment decisions: Compare the treatment recommendations of dentists (e.g., no therapy, non-invasive interventions, or invasive treatments) for caries lesions detected with and without AI support.

2.2 Secondary Objectives:

1. Diagnostic performance: Measured by sensitivity and specificity in detecting caries lesions with and without AI assistance.

2.3 Hypotheses

1. The use of an AI-based diagnostic tool increases non-invasive and invasive treatment decisions of dentists during caries detection on bitewing radiographs.
2. The diagnostic sensitivity of dentist in detecting caries lesions increases when using AI support, while the diagnostic specificity does not differ with or without AI support.

3. STUDY DESIGN

This study is a crossover randomized controlled study investigating the influence of artificial intelligence on the decision-making process for intervention after caries lesion detection. Participants will be dentists randomly divided into two groups. Each group will be randomized to receive a set of bitewing radiographs, which should be evaluated with or without AI assistance. The participants will examine caries lesions on the radiographs according to their group and formulate treatment plans accordingly. Then, after a wash-out period of one month, all participants will re-examine the same radiographs, but in the opposite condition of AI assistance (Figure 1). The primary outcome will be classified into no treatment, non-invasive treatment, and invasive approaches. The secondary outcomes include diagnostic performance, assessed through sensitivity and specificity of caries detection.

The impact of AI assistance will be evaluated by comparing the frequency and type of treatment recommendations, as well as diagnostic accuracy (sensitivity and specificity), between conditions with and without AI support. Additionally, these decisions will also be evaluated against a reference standard.

4. STUDY POPULATION

4.1 Inclusion criteria

The study's target population are dental professionals who are authorized to detect caries on bitewing radiographs and indicate treatment in clinical practice, according to the Dutch professional profiles [6]. Dentists who meet the eligibility criteria will be recruited from the dentistry department and dental practices. They will be invited to perform two rounds of bitewing evaluation. Participants will be asked to sign an informed consent form within CastorEDC before the start of the survey.

1. Graduated, practising dentists.
2. At least three years of experience

4.2 Exclusion criteria

1. Retired dentists.
2. Specialized practitioners (e.g., orthodontists and oral surgeons) if their typical practice does not involve routine caries diagnostics and treatment planning.

4.3 Sample size calculation

By means of simulations, a sample size was determined that allows us to find a difference in treatment decisions when using AI assistance during caries detection. Simulations were based on data from a pilot study conducted on last-year dental students. Sensitivity for detecting all stage lesions without AI was 85.2%, and sensitivity with AI was 90.4%, so a difference of 5.2%.

As a result of the study's crossover design, where each dentist evaluates both with and without AI, the study controls for individual differences and increases statistical power. The power analysis assumes statistical testing at a 5% significance level, and we aim to be able to detect a difference of 5% in sensitivity with AI, assuming a baseline sensitivity of 85% without AI. Therefore, to achieve 80% power, the study requires 25 dentists, each evaluating 25 surfaces (total of 625 surfaces), to enable detecting a 5% difference in sensitivity. Therefore, assuming one bitewing includes 2-3 surfaces that require treatment, 25 dentists would each have to analyse 8-10 bitewings.

5. METHODS

The SPIRIT reporting guideline was followed to report this protocol. This protocol will be submitted to the appraisal through the niet-WMO (Wet Medisch-wetenschappelijk Onderzoek)-plichtig route and registered at PaNaMa. The intention is to register further at ClinicalTrials.gov. Additionally, it will be accessible through the Open Science Framework.

5.1 Study parameters

5.1.1 Main study parameter

1. Treatment Recommendations: The main study parameter is the differences in treatment recommendations for caries lesions with and without AI assistance. The given options will be "no treatment", "non-invasive treatment" (fluoride varnish, polishing, sealing), and "restoration".

5.1.2 Secondary study parameters/endpoints

1. Diagnostic Accuracy: The secondary parameters include diagnostic accuracy of caries lesions when assessed using AI-based diagnostic tools compared to without AI support. This will be measured by evaluating the sensitivity and specificity of AI-assisted and non-AI-assisted diagnostics. Participants will report on whether a caries lesion is presented and if yes, the extend of it as following:

RA0: No radiolucency - No visible caries.

RA1: Radiolucency confined to the outer half of enamel - Enamel caries.

RA2: Radiolucency extending to the inner half of enamel but not reaching dentin - Moderate enamel caries.

RA3: Radiolucency extending into the outer third of dentin - Dentin caries.

RA4: Radiolucency extending into the middle of dentin - Advanced dentin caries.

RA5: Radiolucency extending into the inner third of dentin - Severe dentin caries.

This classification is conformed to the International Caries Classification and Management System (ICCMS) [7]. However, codes 4 and 5 will be summarized for the study's purpose.

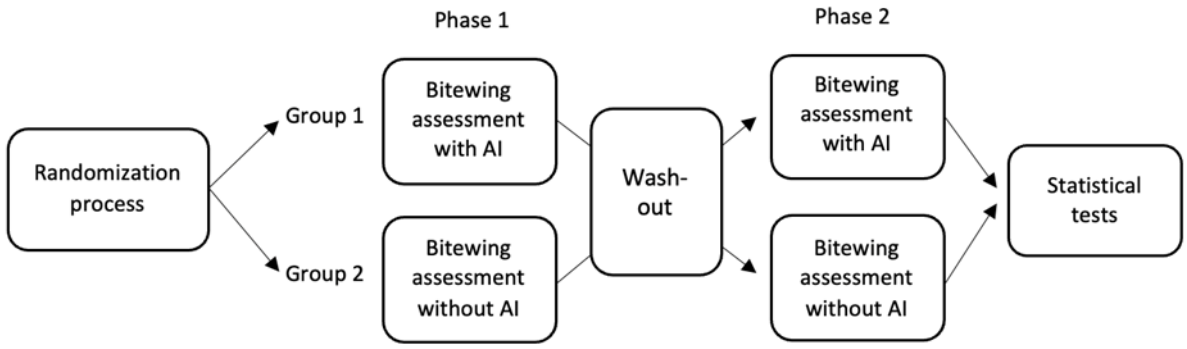
5.2 Randomisation

Dentists will be randomly allocated into two parallel groups in a 1:1 ratio:

1. Group 1: Starting with AI support.
2. Group 2: Starting without AI support.

The allocation sequence will be computer-generated using the randomization module within CastorEDC. Participants will receive a unique identifier and be assigned to a group upon enrolment, ensuring allocation concealment while allowing identification for the second round. The randomization will follow a simple randomization method without stratification. Study personnel involved in enrolment or data collection will have no access to the randomization sequence, ensuring allocation concealment by default. An independent researcher, who is not involved in recruitment, will enrol participants, and start the randomization process within CastorEDC.

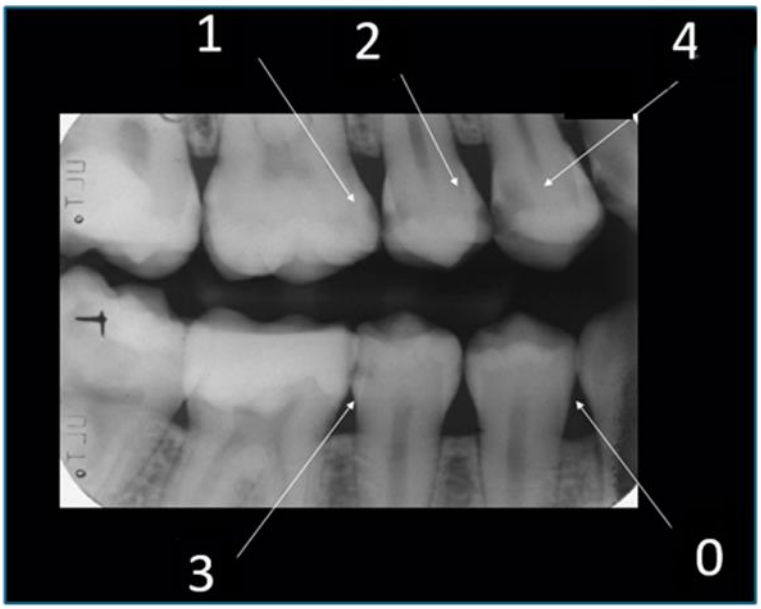
Additionally, to reduce the potential for recognition bias, the sequence in which each bitewing radiograph is evaluated will be randomized individually for each dentist and for both study phases. This randomization will also be performed using functions in CastorEDC.



5.3 Study procedures

Participants will assess bitewings with or without AI assistance according to the assigned group. When caries is detected by the participant, they must select a possible treatment approach: no treatment (includes monitoring), non-invasive interventions (dietary advice, oral hygiene instructions, fluoride varnish, polishing, or sealing), or restoration placement. In addition, participants will be asked to evaluate if caries lesions are present to indicate the level of progression. The example in figure 2 will be provided to calibrate participants answers. After a wash-out period of four weeks, participants will proceed to the second round of assessments. At this point, the groups will assess the bitewings in the opposite AI condition. The same

bitewings will be assessed; however, the sequence will be randomized again.



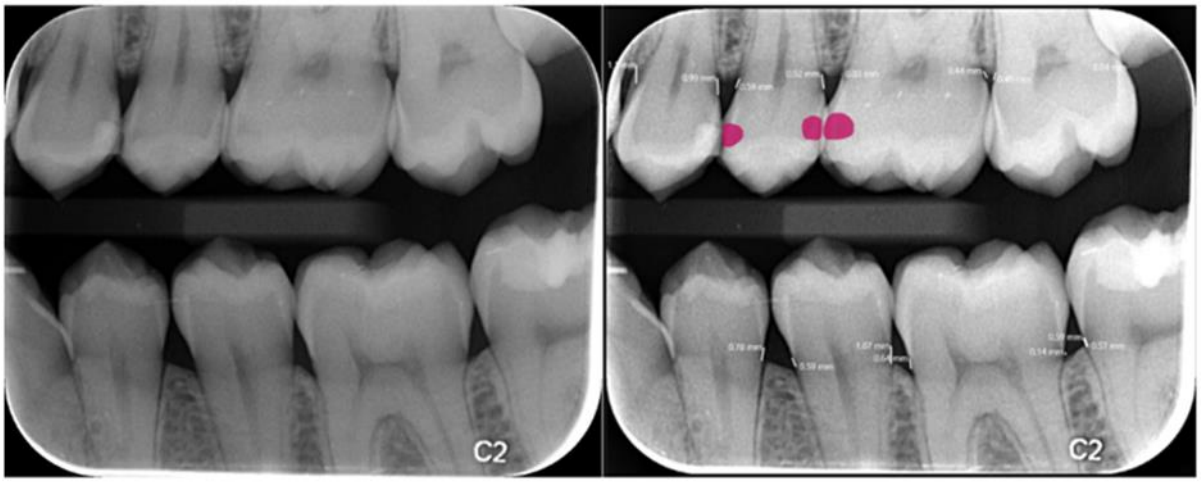
Caries detection
0: No visible caries.
1: Outer enamel caries.
2: Inner enamel caries.
3: Outer third dentin caries.
4: Middle/inner third dentin caries.

Treatment suggestions
0: No treatment (includes monitoring)
1: Non-invasive treatment (dietary advice, oral hygiene instructions, fluoride varnish, polishing, infiltration therapy)
2: Restoration

5.4 Data collection

In this study, bitewings will be used, and Pearl's Second Opinion AI software will detect caries lesions on the radiographs. The bitewings will be collected from open datasets of previous studies and included in a survey using Castor EDC. A link will be provided to each participant, who will complete the survey online. For participants in the AI-group each image will be provided twice. The original image and one with AI flagging. In the non-AI group, each image will be provided without AI flagging. Finally, all the data will be converted into an Excel file, and a. csv file, which will then be reviewed.

Case001



	Tooth	Surface	Caries depth	Treatment
1	25	m	3	0
2	25	d	3	0
3	26	m	4	1
4				
5				
6				
7				
8				
9				

5.5 Reference standard

Five experts will establish the reference test for caries lesions. The experts will independently evaluate each case regarding the presence and depth of carious lesions (enamel lesion, early dentin lesion, middle dentin lesion, outer dentin lesion), and indicate a therapeutic approach. A discussion round will be held to seek full agreement among the experts.

6. STATISTICAL ANALYSIS

The analysis will focus on treatment decision-making and diagnostic accuracy between conditions with and without AI support. Primary analysis will focus on treatment recommendations, classified into three categories: no treatment (NT), non-invasive treatment (NIT), and invasive treatment (IT). Treatment decisions will be compared across the two

conditions with vs. without AI support. A confusion matrix will be constructed to visualize the direction and quantity of changes between these categories (e.g., NT to NIT, NT to IT, NIT to NT). Differences in proportions will be examined using McNemar's test or paired statistical tests, depending on data distribution and assumptions.

Secondary outcomes will focus on diagnostic performance, specifically the ability to correctly identify the presence or absence of caries and differences between conditions with and without AI support. Again, confusion matrices will be used to visualize the direction and quantity of changes in diagnostic outcomes. Proportions of correct and incorrect classifications will be compared using paired statistical tests. Key metrics, including sensitivity, specificity, precision, and F1 score, will be calculated to quantify diagnostic accuracy.

Descriptive statistics will summarize participant demographics (age, gender, years of experience, training background). In addition, we will conduct exploratory regression analyses to assess whether participant years of experience and training background are associated with treatment decisions and diagnostic accuracy. For treatment decision outcomes (NT, NIT, IT), a multinomial logistic regression will be performed. For diagnostic performance (correct/incorrect classification), a binary logistic regression will be used. These analyses will help identify whether clinician background moderates the impact of AI support. Given the sample size (n=25), these analyses will be considered exploratory and interpreted with caution.

All statistical analyses will be conducted using SPSS or R.

7. ETHICAL CONSIDERATIONS

7.1 Regulations

The Medical Research Involving Human Subjects Act (WMO) is not applicable to this study. Before the start of the study, the study protocol and other related documents were submitted to the Committee on Research Involving Human Subjects (CMO) and declared as "niet-WMO-verplicht" research. Any subsequent protocol amendments will be submitted to the CMO to review. No substantial amendment that requires review by the CMO will be implemented until the CMO grants a favourable opinion for the study.

7.2 Recruitment and privacy

The participants will be dentists working at Radboudumc and practices affiliated with Prime Dental Alliance. Participants who meet the eligibility criteria will be invited via an introductory email and if they wish to participate, an informed consent form will be required. A key file will be kept with participant information so that the invitations for the second round of evaluation can be send. After data collection that file will be deleted to ensure anonymity.

7.3 Dataset

In this study bitewings, will be used for caries detection. The bitewings were collected from several different studies and considered anonymous data because they only provide partial information about a patient, and do not reveal the individual's identity. No additional patient data will be needed for this study.

The participants identity will be kept in a separate key file until after the second round of questionnaires, then all contact information will be deleted, and participant anonymity will be fully secured.

8. ADMINISTRATIVE ASPECTS AND PUBLICATION

8.1 Publication

The arrangements between the sponsor (PDA) and the primary researcher (DSH) regarding the publication of the research data ensure that both parties' interests are respected. The researcher retains the right to publish the research data in scientific journals and present the findings at conferences.

8.2 Handling and storage of data and documents

All data collected during the study, will be securely stored in compliance with data protection regulations, and will be backed up regularly and protected by password authentication to prevent unauthorized access. Access logs will be maintained to track any data access or modifications, by the leading researcher. Data will be stored after the study's completion for verification and research purposes at the Radboud Data Repository. Data, bitewings, and participants’ responses will be anonymized to ensure participant confidentiality, with no personal identifiers linked to the radiographs or survey responses. The anonymized data will be accessible alongside the publication.

9. REFERENCES

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