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The impact of diamond burs on pulpal blood flow during crown preparation

Submission date	Recruitment status	[_] Prospectively registered
26/05/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
29/05/2024	Completed	[X] Results
Last Edited	**Condition category**	[X] Individual participant data
05/08/2024	Oral Health	

Plain English summary of protocol

Background and study aims
This study investigates how blood flow within a tooth's pulp (the innermost layer of the tooth) is influenced during its preparation for a crown. The study will compare the impact of using brand-new dental burs with those that have been used repeatedly. Advanced laser technology will be used to assess the blood flow before the procedure, immediately afterwards, 24 hours later, and 1 week after the procedure. This study will shed light on whether the wear and tear of dental tools has implications for tooth health during dental treatments.

Who can participate?
Patients aged 20-50 years who need prosthetic dental restorations (crowns)

What does the study involve?
Each participant receives both treatments for each pair of symmetrical teeth: (A) teeth prepared with new burs; (B) teeth prepared with burs at their fifth use. Pulpal blood flow is measured before the preparation, immediately after, at 24 hours and at 7 days after the prosthetic preparation for the crown.

What are the possible benefits and risks of participating?
Participants will benefit from the prosthetic restoration. There are no foreseen risks associated with the intervention.

Where is the study run from?
Victor Babes University of Medicine and Pharmacy (Romania)

When is the study starting and how long is it expected to run for?
March 2022 to February 2024

Who is funding the study?
Victor Babes University of Medicine and Pharmacy (Romania)

Who is the main contact?
1. Dr Edmond Ciora (Principal investigator), ciora.edmond@umft.ro
2. Dr Mariana-Ioana Miron, miron.mariana@umft.ro

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Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
UMFT No 40 / 04.04.2022

Study information

Scientific Title
Analysis of the pulpal blood flow microdynamics during prosthetic tooth preparation using diamond burs with different degrees of wear

Study objectives
During tangential preparation for zirconia crown, wear of diamond burs increases the vascular microdynamics at the level of the dental pulp.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/04/2022, Ethics Committee of Scientific Research of “Victor Babes” University of Medicine and Pharmacy (Piata Eftimie Murgu 2, Timisoara, 300041, Romania; +40 (0)256466001; cecs@umft.ro), ref: 40/04.042022

Study design
Proof-of-concept single-center interventional single-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Safety

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Patients who need oral prosthetic dental crowns

Interventions
A randomized, single-blinded clinical study was performed with a split-mouth design. The selected teeth were prepared for full coverage monolithic zirconia prosthetic restorations and were approximately the same dimensions, with no carious lesions or prosthetic treatment. Each participant received both treatments for each pair of symmetrical teeth: the teeth were randomly assigned to two study groups: (A) to be prepared with new burs; (B) to be prepared with burs at their fifth use. Allocation of treatments to the left or right was randomized. Randomization was single-blind and performed with the R package "blockrand" version 1.5.

The burs used for teeth preparation were from Komet dental, cylindroconical bur 859UF dimensions/sizes: 14; size diameter: 1/10 mm; length: 9.0 mm; maximum speed: 300,000; angle: 3.7°. The diamond burs included in the study were used for the first time (new) in the 1st group and for the 5th time in the 2nd group that is the burs had already been previously used four times for other dental preparations, at five minutes per use.

Teeth preparation was done using the SMARTtorque LUX S619L turbine manufactured by KAVO®, which has a built-in push-button mechanism for securing the drill bit and a 4-hole spray design to ensure efficient cooling during operation. This handpiece was linked to the dental unit via a MULTIflex™ LUX connection by KAVO®. It had a maximum bur rotation speed of 400,000 rpm. The preparations were performed under a water flow rate of 50 mL/min and the cooling water reservoir was filled with water at a temperature of 20 °C +/- 0.5. To maintain hygiene standards, the turbine underwent sterilization at a temperature of 135 °C.

The laser Doppler signal was assessed with a MoorLab laser Doppler device for general medical use (laser Doppler MoorLab instrument VMS-LDF2, Moor Instruments Ltd., Axminster, UK) and a straight optic probe VP3 with a length of 10 mm, built to be used on the oral mucosa/teeth. The MoorLab laser Doppler monitor (Moor Instruments) uses laser radiation generated by a semi-conductor laser diode operating at a wavelength of 780 + 10 nm and a maximum accessible power of 1.6 mW. The programmed bandwidth of the recorded laser Doppler signal was 20 Hz-20 kHz, while the sampling frequency displayed a value of 40 Hz. Probe calibration was performed according to the instructions of the manufacturer.

Between the appointments, teeth were protected by provisional acrylic crowns, in order to eliminate other factors that may influence the results of the testing, such as temperature, direct occlusal forces applied on the polished teeth, and contamination with bacteria from the oral cavity.

Four consecutive determinations of the pulpal blood flow were taken for each tooth included in the study: before the preparation (control values), immediately, at 24 h and at 7 days after the prosthetic preparation for crown.

Intervention Type
Procedure/Surgery

Primary outcome measure
Pulp blood flow measured with a laser Doppler signal using a general medical laser Doppler device at four timepoints: at baseline, after the intervention, at 24 hours, and at 7 days.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/03/2022

Completion date
01/02/2024

Eligibility

Key inclusion criteria
Adults who need prosthetic restorations

Participant type(s)
Patient

Age group
Adult

Lower age limit
20 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
6

Total final enrolment
6

Key exclusion criteria
1. Smoking
2. Any systemic disease
3. Any sign of pulpal inflammation

Date of first enrolment
04/04/2022

Date of final enrolment
10/11/2022

Locations

Countries of recruitment
Romania

Study participating centre
Victor Babes University of Medicine and Pharmacy
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Funder type
University/education

Funder Name
Victor Babes University of Medicine and Pharmacy Timisoara

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/09/2024

Individual participant data (IPD) sharing plan
The dataset generated during this study will be made available upon institutional contact and reasonable request from Dr Edmond Ciora (ciora.edmond@umft.ro). These dataset-sharing plans will include individual patient data meta-analysis (IPD meta-analysis).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Patient informed consent (English)		29/05/2024	No	No
Other files	Patient informed consent (Romanian)		29/05/2024	No	No
Statistical Analysis Plan			29/05/2024	No	No
Results article		07/06/2024	28/06/2024	Yes	No
Dataset			05/08/2024	No	No