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Effect on dental pulp of different methods of cavity preparation

Submission date	Recruitment status	[ ] Prospectively registered
29/08/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/09/2018	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/11/2019	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Dentist aim to keep the pulp of the tooth (the soft tissue inside the tooth) alive. When a tooth with decay is being prepared for a filling, the pulp can be damaged by substances released by inflamed cells and bacteria, drilling and heat. The aim of the study was to investigate the pulp response to cavity preparation using an ultrasonic device in comparison with a conventional high-speed burr drill preparation using different sealing materials.

Who can participate?
Patients under orthodontic treatment who require premolar tooth extraction as part of their orthodontic treatment.

What does the study involve?
Participants were non-randomly allocated in five groups. Groups 1 and 2 received cavity preparations with high-speed rotation and sealing procedures. Groups 3 and 4 received cavity preparations with an ultrasonic device and the same sealing procedures as in groups 1 and 2. Group 5 did not receive cavity preparation. These intact premolars were used as controls. Finally, teeth were extracted according to the postoperative experimental periods: immediately, 7 and 30 days after the cavity preparation under local anesthesia.

What are the possible benefits and risks of participating?
Participants were able to benefit from having their premolar teeth extracted. There may be some risks such as some discomforts related to the anesthesia sensation, cavity instrumentation or sealing techniques. In cases of pain in the patient, the tooth was extracted.

Where is the study run from?
Bauru Dental School, University of São Paulo, Brazil

When is the study starting and how long is it expected to run for?
February 2008 to December 2008

Who is funding the study?
Department of Restorative Dentistry, Endodontics and Dental Materials of Bauru, Dental School,

University of São Paulo (Brazil) and Postgraduate Research Support Program of Coordination for the Improvement of Higher Education Personnel of Brazil (PROAP-CAPES).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
145/2007

Study information

Scientific Title
Histological evaluation of the human pulp response to different cavity instrumentation and restorative techniques

Study objectives
1. There will be no differences in pulp response between two types of cavity instrumentation.
2. There will be no differences in pulp response between two types of cavity sealing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bauru Dental School Ethics Committee, 13/12/2007, Protocol number: 145/2007.

Study design
Non-randomised interventional study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Dental pulp injury following cavity preparation

Interventions
Participants were allocated in 5 experimental groups. Groups 1 to 4 received local anesthesia with adrenaline (4% Articaine), rubber dam isolation and deep class V cavities as follows:
Group 1: Class V cavity preparations with high speed rotation on intact premolars sealing with gutta-percha as a insulator and glass ionomer cement.
Group 2: Class V cavity preparations with high speed rotation on intact premolars, application of etch and rinse adhesive system then, sealing with gutta-percha as a insulator and glass ionomer cement.
Group 3: Class V cavity preparations with ultrasonic device on intact premolars sealing with gutta-percha as a insulator and glass ionomer cement.
Group 4: Class V cavity preparations with ultrasonic device on intact premolars, application of etch and rinse adhesive system then, sealing with gutta-percha as a insulator and glass ionomer cement.
Group 5: intact premolars as a control group.
Finally, teeth were extracted according to the postoperative experimental periods, immediately, 7 and 30 days after the cavity preparation under local anesthesia and fixed in 10% phosphate-buffered formalin solution for 48 hours. Subsequently, the teeth were decalcified in 4% EDTA (Titriplex III, Merck) solution (pH 7.4) and submitted to histological procedures. Five-micrometer thick serial sections were cut parallel to the main vertical axis of the tooth throughout the cavity preparation, stained with hematoxylin and eosin (H&E) and Brown and Brenn (B&B) and analyzed under an Olympus BX50F4 light microscope. Each series of tooth sections were blind analyzed by one experienced examiner and the data of all morphological features of the pulp tissue were fully recorded.
The volume densities or the fractions of pulp volume occupied by the odontoblasts, collagen fibers and fibroblasts, ground substance, blood vessels, inflammatory process and tertiary dentin adjacent to the cavity preparation was performed with the point-counting relative volumetry method using a 100× immersion objective and a Zeiss Kpl 8× eyepiece containing a Zeiss II integration grid (Carl Zeiss GmbH, Jena, Germany) with 100 points in a quadrangular area. In ten sections per tooth, the grid was successively superimposed on 12 histological fields per section at three different pulp levels. The points that were superimposed on each cell or structure (Pi) were counted and the total number of points (Pt) was obtained. Volume density (Vvi) was calculated by the equation: Vvi = Pi/Pt.
The remaining dentine thickness (RDT) between the cavity floor and the pulp chamber was measured. For each tooth, five histological sections with less RDT were selected. Images of the remaining dentin were captured in a video camera AxioCam HRc (Carl Zeiss MicroImaging GmbH, Göttingen, Germany) coupled to an Axioskop II microscope (Carl Zeiss, Oberköchen, Germany) with 10× objective and analyzed using the AxioVision Release 4.7.2 software (Carl Zeiss Vision Imaging Systems, Oberköchen, Germany). The RDT of each group was the average of the RDT of each specimen.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Morphological features of the pulp tissue. The teeth were extracted according to the postoperative experimental periods, immediately, 7 and 30 days after the cavity preparation under local anesthesia and fixed in 10% phosphate-buffered formalin solution for 48 hours. subsequently, the teeth were decalcified in 4% EDTA (Titriplex III, Merck) solution (pH 7.4) and submitted to histological procedures. Five-micrometer thick serial sections were cut parallel to the main vertical axis of the tooth throughout the cavity preparation, stained with hematoxylin and eosin (H&E) and Brown and Brenn (B&B) and analyzed under an Olympus BX50F4 light microscope. Each series of tooth sections were blind analyzed by one experienced examiner and the data of all morphological features of the pulp tissue were fully recorded.

Key secondary outcome(s)
1. The volume densities or the fractions of pulp volume occupied by the odontoblasts, collagen fibers and fibroblasts, ground substance, blood vessels, inflammatory process and tertiary dentin adjacent to the cavity preparation was performed with the point-counting relative volumetry method using a 100× immersion objective and a Zeiss Kpl 8× eyepiece containing a Zeiss II integration grid (Carl Zeiss GmbH, Jena, Germany) with 100 points in a quadrangular area. In ten sections per tooth, the grid was successively superimposed on 12 histological fields per section at three different pulp levels. The points that were superimposed on each cell or structure (Pi) were counted and the total number of points (Pt) was obtained. Volume density (Vvi) was calculated by the equation: Vvi = Pi/Pt.
2. Remaining dentine thickness (RDT). For each tooth, five histological sections with less RDT were selected. Images of the remaining dentin were captured in a video camera AxioCam HRc (Carl Zeiss MicroImaging GmbH, Göttingen, Germany) coupled to an Axioskop II microscope (Carl Zeiss, Oberköchen, Germany) with 10× objective and analyzed using the AxioVision Release 4.7.2 software (Carl Zeiss Vision Imaging Systems, Oberköchen, Germany). The RDT of each group was the average of the RDT of each specimen.

Completion date
01/06/2009

Eligibility

Key inclusion criteria
1. Sound teeth without signs of cervical lesion
2. Sound teeth without signs of cracks or fractures
3. Sound teeth without signs of periodontal disease
4. Sound teeth without signs of root lacerations
5. Sound teeth with normal response to cold (fast decrease of sensitivity after cold stimuli)
6. Sound teeth without sensitivity to percussion.
7. Patient aged 11-25 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. Teeth with existing caries lesions
2. Teeth with periodontal disease
3. Teeth with cervical lesions

Date of first enrolment
01/02/2008

Date of final enrolment
01/12/2008

Locations

Countries of recruitment
Brazil

Study participating centre
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Sponsor information

Organisation
Bauru Dental School, University of São Paulo

ROR
https://ror.org/036rp1748

Funder(s)

Funder type
Government

Funder Name
Coordination for the Improvement of Higher Education Personnel, CAPES. Government of Brazil

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository