Protocol Writing:

THE EFFECTS OF APICAL DEBRIS EXTRUSION ON POST-OPERATIVE PAIN

A NARRATIVE REVIEW

Word Count:

Date of Submission:

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1. Introduction:

A prevalent dental procedure, endodontic therapy, also known as root canal treatment, is designed to alleviate pain and eliminate the infected dentin of a tooth (Siqueira et al., 2011). Although this technique is efficacious in the management of pulpal and periapical diseases, it frequently results in postoperative distress that negatively affects the quality of life of the patient (Latham et al., 2019; Morse et al., 2020; Smith et al., 2021).

(Peters et al., 2016) Successful root canal therapy depends on selecting instruments and materials, each serving a unique purpose. The mechanical contouring and cleaning of root canals is facilitated by endodontic files, such as K-files, H-files, and rotary NiTi files (Pataky et al., 2018; Johnson et al., 2019). To eliminate residual tissue and detritus, chemical disinfectants, including sodium hypochlorite, chlorhexidine, and EDTA, are indispensable (Martins et al., 2018; Davis et al., 2020).

Apical debris extrusion, in which microorganisms, dentinal fragments, and irrigants migrate into periapical tissues, is an unintended consequence of root canal therapy (Al-Omari & Dummer, 1995). This can result in local inflammation, which may impede healing (Oliveira et al., 2022; Alani et al., 2023).

Achieving success in endodontics requires an in-depth knowledge of tooth anatomy, careful selection of instruments, and exacting techniques. Initial canal negotiation employs K-files, whereas H-files are utilized to shape canals further. In difficult circumstances, rotary NiTi files offer resistance and flexibility (Wang et al., 2019). A sterile environment is maintained by disinfectants such as chlorhexidine, sodium hypochlorite, and EDTA (Gulabivala et al., 2018).

Debris Extrusion remains a concern despite meticulous procedures, underscoring the urgency for endodontics to advance through research and innovation (Huang et al., 2021). Ongoing progress will contribute to improved patient outcomes and reduced postoperative discomfort.

1.1 Rationale:

Given the prevalence of root canal treatment and its implications for oral health, it is imperative to understand the factors influencing postoperative discomfort. Despite advancements in endodontic techniques, postoperative pain remains a significant concern for patients (Su et al., 2015). Thus, understanding the impact of apical debris extrusion on postoperative pain could optimize endodontic procedures, improving patient comfort and treatment outcomes.

The paper focuses on presenting "The effects of apical debris extrusion on postoperative pain". “Apical debris extrusion” is considered to be a general occurrence during the treatment of any root canal and it is reported that no technique has been able to resolve this issue. This paper looks to build a robust base for a future project analyzing the impacts apical debris extrusion can give on postoperative situations

1.2 Research Question (RQ):

Does the amount of apical debris extruded during endodontic treatment have an effect on post-operative pain experienced by patients?

Using PICO formula System to explain Research Question.

P: Patients undergoing endodontic treatment (Root canal treatment)

I: Amount of apical debris extruded during treatment

C: No Extruded apical debris during treatment

O: Post-operative pain experienced by patients

2. Background:

The complex inflammatory and immunological processes involved in post-operative pain following endodontic treatment suggest a correlation between apical debris extrusion and discomfort. Therefore, a comprehensive and systematic evaluation is needed to understand this relationship better.

The primary objective of endodontic operations is to eliminate infected pulp tissue, sanitize the root canal, and fill it with an inert material for obturation. Nevertheless, the use of mechanical forces during the process of instrumentation has the potential to generate debris. The debris consists mostly of pulp tissue, dentin, and bacteria, and it is crucial to eliminate it to prevent subsequent infections and facilitate the process of healing (Siqueira & Rocas, 2009).

The term "apical debris extrusion" pertains to the unintentional displacement of debris beyond the apex of the tooth. Apical debris extrusion is attributed to two basic mechanisms, namely hydraulic and mechanical. The hydraulic mechanism utilizes irrigants and their hydraulic force to facilitate debris removal by pushing it through the apical foramen. Mechanical extrusion arises as a result of the intrinsic configuration of endodontic instruments, which possess the capability to function as wedges, hence exerting apical force on debris (Kustarci et al., 2013).

Recognizing the anatomy beyond the cemento-dentinal junction is critical for comprehending the possible influence of apical debris extrusion on post-operative discomfort. The periapical region encompasses a complex network of components, including the periapical tissues, nerves, and blood arteries, characterized by their delicate nature. The introduction of material into this region has the potential to trigger an inflammatory reaction, resulting in the occurrence of pain following a surgical procedure. Furthermore, accurately determining the apical foramen and accessory canals can impact the extrusion degree (Plotino et al., 2015).

Extrusion of debris beyond the apex can cause acute inflammation, one of the main causes of post-operative pain after endodontic operations. When debris touches the periapical tissues, it triggers an immunological response and the release of inflammatory mediators. The patient feels discomfort because pain receptors in the afflicted area are activated (Siqueira et al., 2012). The severity of post-operative pain varies depending on the amount of material extruded, the patient's pain threshold, and the clinician's experience level.

Minimizing apical debris extrusion is critical in endodontic treatments for reducing post-operative pain. Several ways, including the employment of nickel-titanium rotating instruments, ultrasonic irrigation, and suitable irrigation solutions, have been proposed to accomplish this (apar & Arslan, 2014). To avoid post-operative discomfort in patients, clinicians must use caution when instrumenting the root canal and use approaches that reduce debris extrusion.

Existing studies suggest various factors leading to debris extrusion, and many have aimed to minimize debris extrusion during therapy. Despite these efforts, conflicting evidence exists regarding the impact of apical debris on post-operative pain. For instance, Gambarini et al. (2017) suggested motor motions during the operation significantly influence apical extrusion and post-operative pain. In contrast, Saber et al. (2020) reported that the kinematics involved during instrumentation does not impact bacterial reduction or post-operative pain. Such divergent perspectives underscore the need for a deeper understanding of the relationship between debris extrusion and post-operative pain, which could inform the design of interventions for patient benefit.

An examined study by Tufenkci et al. (2020) investigated the endodontic access cavity's implications on apical extrusion using various single-file systems. This peer-reviewed material, recently published in PubMed Central, supports our narrative review efforts and underscores the importance of the topic.

2.1 Aims and objectives:

The aim of the research is to assess and evaluate particular problems as well as impacts of apical debris extrusion on postoperative conditions and what type of consequences it holds that is responsible to worsen the situation as well.

The objectives of this research are:

1. To conduct an in-depth analysis of the process of apical debris extrusion and its major characteristics.
2. To assess the impacts of apical debris extrusion.
3. To analyze how apical debris extrusion can act during a postoperative situation.
4. To evaluate some effective ways or techniques which can decrease the pain or suffering during a postoperative condition.
5. To collect and examine some relevant past studies in order to establish a strong base of the research.

3. Methodology:

Methods will aim to find relevant and reliable literature that can be used to answer the research question. A scientific approach indicates the technique the researcher uses to collect, assess, and analyze data. Both "inductive" and "deductive" methodologies make up the majority of study design. Both strategies incorporate pertinent elements that the scientists have used as methodology chosen (Eyüboğlu and Özcan 2019).

3.1 Study Design:

This narrative review uses a thorough methodology to assess how apical debris extrusion affects postoperative pain. It includes research using a range of designs, such as case-control studies, prospective and retrospective cohort studies, and randomized controlled trials (RCTs).

3.2 Search strategy:

The search strategy for the present study refers to the process of sourcing data via analyzing, evaluating and utilizing the existing studies of the experts on apical debris extrusion and impacts on postoperative situations (Spohr *et al.* 2019).

This systematic search strategy was developed to identify relevant studies. Databases considering key journals such as the international endodontic journal. This search will use key terms and phrases including: "Root Canal Therapy"[Mesh], "Pain, Postoperative"[Mesh] , "Pain Management"[Mesh], "Dental Pulp Diseases"[Mesh], "Endodontics"[Mesh], "Dental Leakage"[Mesh] and "Tooth Apex"[Mesh]." These keyword searches will be conducted across numerous databases, including PubMed, Embase, ScienceDirect, and the Cochrane Library. In this scenario, consultations with a librarian can be done to help identify and search the named databases more effectively.

3.3 Selection Criteria:

This Narrative review will examine the association between apical debris extrusion during endodontic procedures and post-operative discomfort. To provide a comprehensive understanding of the topic, our review will integrate various study designs to synthesize the available evidence thoroughly.

3.3.1 Inclusion Criteria:

To ensure a comprehensive and extensive investigation of the topic, we will employ a variety of study designs. These will include:

Randomized Controlled Trials (RCTs) provide the highest quality of evidence and are the gold standard of scientific research. We will include RCTs comparing the association between various endodontic techniques, apical debris extrusion, and subsequent post-operative pain.

Prospective and retrospective cohort studies of patients undergoing endodontic treatment and experiencing varying degrees of post-operative discomfort will be included. These investigations can provide valuable insights into real-world situations and long-term patient outcomes.

Case-Control Studies: These studies that compare patients who experienced significant post-operative discomfort (cases) with those who did not (controls) can provide valuable insights into the potential role of apical debris extrusion.

Cross-Sectional Studies: These studies analyzing the prevalence and determinants of post-operative pain at a particular point can also provide relevant information.

Given the advancements in endodontic techniques and comprehension of post-operative pain over the years, we will concentrate on studies published in the last 20 years (2003–2023) to provide the most current and pertinent insights into the research question. Nonetheless, any seminal work conducted before this period regarded as essential to comprehending the topic will also be considered.

3.3.2 Exclusion Criteria:

This will include studies that do not cover apical extrusion and the influence that it has on postoperative pain. In addition, the documents that do not have adequate evidence to back their assertions will be excluded as part of the criterion for exclusion. In addition to that, it will include research that needs to be written in English. Even though more weight will be given to more recent studies, the number of pertinent publications will be unrestricted by the year they were first published. The evaluation will cover all articles written on this topic from 1980 up until the present day.

3.4 Study Selection:

After determining the inclusion and exclusion criteria, the next step is to analyze the titles of the studies that were obtained. This involves reading and assessing the titles and abstracts to see if they contain the necessary keywords and are relevant to answering the research question. Analyzing the titles and abstracts of articles is an essential step in identifying relevant research materials and filtering out those that do not pertain to the main issue being investigated. It is crucial to select only the relevant articles to streamline the assessment process and focus on those that are significant and worthy of thorough analysis.

3.5 Quality Assessment:

For the articles selected for this narrative review, a risk of bias assessment will be conducted using the relevant techniques, such as the Newcastle-Ottawa Scale for observational studies, the Cochrane Risk of Bias tool for RCTs, systematic reviews, cohort studies. The purpose of this evaluation was to guarantee the reliability and validity of the chosen studies.

3.6 Data Extraction:

In this narrative review, a standardized data extraction form will be employed. The study design, participant demographics, procedures, interventions, and outcomes will all be covered in this form. Because this is a narrative review, there will be no statistical data analysis, only a summary of the important findings from these investigations.

This analysis will focus on several variables that may influence the answer to the research query. Specific data will be extracted from the chosen studies with the following factors in mind: Different endodontic systems, including manual, rotary, and reciprocating files, Irrigants have varying propensities for apical debris extrusion.

Irrigation Techniques and Solutions: Techniques such as syringe irrigation, ultrasonic activation, and various irrigants (e.g., Sodium hypochlorite and chlorhexidine) may affect the quantity of detritus extrusion.

Different methods, such as cold lateral condensation, warm vertical compaction, and carrier-based obturators, can influence detritus extrusion.

Patient Factors: Initial diagnosis (e.g., pulpitis versus necrosis), preoperative pain levels, age, sex, and tooth type (anterior versus posterior, vital versus non-vital) may influence postoperative pain perception.

In addition to the study design, sample size, outcome measures, and critical findings, data will be extracted regarding the effect of apical debris extrusion on post-operative pain.

4. Possible/Expected outcomes:

4.1 “Feasibility:

Cost Analysis and Practicality:

In terms of the project, this narrative review is useful. It depends on the capacity to search for and retrieve appropriate papers that address the research subject. Using the institution's library can do this without incurring additional costs. The narrative design also eliminates the necessity for complicated statistical studies. Regardless, the institutional library was expected to only have access to some required publications and databases. This potential constraint would have detrimental consequences for this narrative evaluation. To address this worry, a recommendation to use what was referred to as interlibrary loan services, which may charge some fees, can be used to retrieve materials that cannot be accessed through the institution's library.

Time Management:

Time management is important in ensuring that projects are finished within the specified time frame (Chase et al., 2013). This narrative evaluation will be broken down into little doable chores without losing sight of the overall goal of this story. Topic approval, completion, and submission of the proposal search for relevant studies to include in the narrative review, assessment and analysis of selected articles, synthesis of the results, and completion of the narrative review are the primary activities. Each task will be assigned a two-week time frame, with some leeway allowed for unexpected setbacks and delays during the project. This narrative evaluation is expected to take two months to complete.

TASK NAME/ MONTHS	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEPT	OCT	NOV
DISCUSSION WITH SUPERVISOR										
WRITING THE PROPOSAL										
PROPOSAL SUBMISION										
FORMAT THE RESEARCH PROTOCOL										
PARTS OF THE DISSERTATION										
ABSTRACT										
INTRODUCTION										
LITERATURE										
METHODS										
RESULTS										
DISCUSSION										
CONCLUSION										
REFERENCES										
SUBMISSION										

4.2 Contingency Plan:

If unprepared for unforeseen problems, your efforts to complete the narrative review may be hampered. One potential concern indicated in earlier sections that is a real possibility is the difficulty in obtaining access to numerous papers that may be critical to this evaluation. In this situation, the researcher will contact the author to acquire general information about the item. If this is not possible, other articles will be utilized in their place. Furthermore, unexpected delays can make reaching the specified timeframe difficult. To avoid this, the researcher will endeavor to achieve goals that can be effectively fulfilled quickly. This will enable extra time for more difficult activities, guaranteeing that the narrative review can be finished despite unforeseen delays.

4.3 Impact Assessment:

This review will contribute substantially to understanding the role of apical debris extrusion in post-operative pain. It may identify potential modifications to endodontic techniques to reduce post-operative discomfort, resulting in better patient outcomes. This review can also guide future research and inform endodontic clinical practice guidelines.

5. References:

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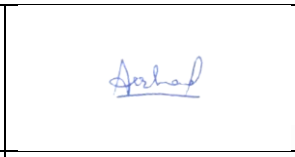
6. Appendices:

6.1 Supervision Agreement Form:

Student's name	ARSHAD AFROZ KHAN			
Supervisor's name	DR. RAFAELA ZANCAN			
Project title				
APICAL DEBRIS EXTRUSION ON POST-OPERATIVE PAIN				
Method of communication	✓ Email	Phone	Online (Adobe connect, Skype, Webex, etc.)	Other (specify): Microsoft Teams
Method of feedback				
Copies of written feedback of all communications should be retained by students and supervisor throughout the whole supervision period. The College retain the right to ask to obtain a copy from this record at any time during the supervision or afterward. Please submit supervision agreement as appendix in the protocol along with at least one supervision record. Please submit at least two supervision records as part of the appendices of Review 1 appendices, and at least two supervision records as part of Review 2 appendices.				
Other arrangements	*Please specify periods of non-availability and any other points or special needs that may affect the supervision.*			
Supervisor Student	No such instance. Have attended all the supervision meetings			
Project feasibility	*Please confirm the feasibility of the project and comment on access to data and resources including equipment, literature and any other practicalities arising from the proposed methods and timescale.*			

Supervisor Student : Yes I can do it on time given. I get to access the data that I need from institutional library and other relevant articles from Pubmed , Google scholar.	
Ethical considerations & Research Governance	*Please consider any ethical and governance issues such as REC approvals, appropriate permissions, institutional sponsorship and indemnities.*
Supervisor Student No ethical issues as it is a Narrative Review	
Health and safety issues	*Conduct a preliminary risk assessment and inform the College if you think there is a Health & Safety concern involved in this project.*
Supervisor Student No health and safety concern issues as it is a Narrative Review	

Signatures		**Date**
Student		25/07/2023
Supervisor		25/07/2023

Student and supervisor should all have a copy.

The college could ask to obtain a copy at any time during the supervision or afterward.

Please submit supervision agreement as appendix in the protocol along with at least one supervision record. Please submit at least two supervision records as part of the appendices of Review 1 appendices, and at least two supervision records as part of Review 2 appendices.

The Role of the Supervisor

An important part of the managing the supervision relationship is the completion of the supervision agreement. This agreement should be reviewed periodically and revised if necessary. It should be completed once the supervisor is allocated at the start of Research Methodology II module.

Supervision meetings should be at mutually agreed times and, **as a rule of thumb, the College expects there to be contact between supervisor and student at least once (one hour) every other week.**

Please be aware that students may request to communicate with you in the afternoon, but they are encouraged to arrange this is advance in a mutually convenient time. A brief written record of each supervision meeting should be made on the relevant form. The completed form should be agreed by both the student and the supervisor, and copies retained by both. If supervision meetings are conducted by telephone, a form should be completed by student and sent to supervisor to review and amend as required. Increasing numbers of students and supervisors find email a useful way of maintaining contact and to keep a record of action points required to ensure smooth progress throughout all tasks required to complete the research project. Email has the advantage of automatically providing a record for future reference, but care needs to be taken to be explicit over agreed actions and timescales.

Student Expectations

Whilst individual requirements will vary students can expect supervisors to:

- treat them as an experienced professional, prepared to take responsibility for their own learning and development.
- be available for consultation at a reasonable notice, as negotiated within the supervision agreement, and to **inform them in advance if they will be unavailable for more than a fortnight.**
- read drafts of their work and provide verbal and/or written comments within a reasonable period (normally two weeks, although this should be negotiated in advance and is dependent on the students' adherence to agreed timescales).
- alert them to any areas of their work which needs attention in order for them to submit a successful project, advise on action to be taken and support available.
- provide or advise them on arranging support relevant to specific aspects of their project and key skills (guidance on information technology, development of skills in academic writing). Consulting the Programme Leader and the Dental Research Director is encouraged to personalised develop plan if required.
- advise on the possibility of publishing their work. We encourage publishing the work in conferences and/or peer review journal. Consulting the Programme Leader and the Dental Research Director is encouraged to identify the best way forward for the publication strategy.

Students should not expect supervisors to:

- take the initiative in the direction of the project or in maintaining communication over their progress.
- provide solutions to problems and answers to questions where to do so would be to compromise the students' management of the project and the status of the final product as evidence of the students' capabilities as an independent, self-directed learner worthy of gaining level 7 postgraduate degree.
- correct all errors in spelling, grammar and punctuation, provide tuition in written English, or proof-read their work.

Supervision Record Sheet

Student's name: ARSHAD AFROZ KHAN

Date: 30/05/2023 **Time: 9:00 AM** **From: 9:00 AM** **To: 9:30 AM**

Points discussed:

This should normally include a review of progress on action points agreed at the previous meeting

The points that were discussed in first meeting was about the methodology of the protocol like the things that need to be included (3.1 Study design,3.2 Search strategy,3.3 Selection Criteria, 3.3.1 Inclusion Criteria,3.3.2 Exclusion Criteria,3.4 Study selection,3.5 Quality assessment, 3.6 Data extraction). Also was taught on how make Mesh terms for search strategy.

Action agreed:

Who will be doing what, by when?

After the discussion I was required to complete the methodology part with relevant literature and mesh terms within a span of 10 days.

Date and time for next supervision: 12/06/2023 5:00 PM

Supervisor's signature:

Student's signature:

Student and supervisor should all have a copy.

The college could ask to obtain a copy at any time during the supervision or afterward.

Please submit supervision agreement as appendix in the protocol along with at least one supervision record. Please submit at least two supervision records as part of the appendices of Review 1 appendices, and at least two supervision records as part of Review 2 appendices

6.2 Ethics Review form:

THIS MUST BE SUBMITTED WITH THE PROTOCOL TO AVOID

AN AUTOMATIC FAIL

This application form should be completed by students undertaking any research at the College of Medicine and Dentistry (CoMD). The research ***MUST NOT*** commence until you have received written approval from CoMD Research Ethics Committee (CoMD REC) after checking that the research is compliant with Ulster University Ethics policy & procedures. You should bear this in mind when setting a start date for the project.

PROJECT DETAILS

Project title	APICAL DEBRIS EXTRUSION ON POST OPERATIVE PAIN		
Proposed start date	22/05/2023	Anticipated end date	**01-12-2023**

APPLICANT DETAILS

Name of researcher (applicant)	ARSHAD AFROZ KHAN
Email address	Arshad_Afroz_Khan-AAK@ulster.ac.uk
Name of Supervisor	Dr. RAFAELA ZANCAN
Course	MSc ADVANCED GENERAL DENTAL PRACTICE

DECLARATION

The information contained in this application, including any accompanying information, is to the best of my knowledge, complete and correct. I have attempted to identify all risks related to the

research that may arise in conducting this research and acknowledge my obligations and the rights of the participants.

Applicant Name.	**Supervisor Name.**
Signature 	Signature 
Date **25/07/2023**	Date 25/07/2023

Please categorise your application into on of the four categories

Category A	Category B
No NHS/HSC involvement No new methodologies No human or animal population No vulnerable population No therapeutic interventions No evidence of ethical or health and safety risk to participants or researchers This category involves all reviews, service evaluation/improvement projects and most in-vitro studies.	No NHS/HSC involvement New methodologies Includes human or animal population Includes vulnerable populations Therapeutic interventions Possible ethical or health and safety risk to participants/researchers Data protection act regulated research This category involves all CoMD locally delivered surveys and in-vivo studies, and some in-vitro studies which carries health and safety risk.
Category C	**Category D**
NHS/HSC involvement Research conducted outside the UK Research conducted in collaboration with another institute This category requires prior gate-way approval from the involved third party.	Human Tissue Act regulated research

Category: A

(a) Research Ethics initial risk assessment checklist.

Please answer each question by ticking the appropriate box.

For all applicants:	**YES**	**NO**
(a) Research that may need a review by an external research ethics committee or NHS REC.		
Will the study involve participants who are either patients or staff of the NHS?		✓
Will the study involve the use of NHS data, premises or equipment?		✓
Will the study involve participants over 16yrs who are unable to give informed consent? (e.g. learning disabilities, etc.)		✓
Has external ethics approval been sought for this research for?		✓
(b) Research that may be deemed "above minimal risk" and therefore require a full CoMD REC.		
Does the research involve collaboration with external institutions? (e.g. charitable bodies, other universities, etc.)		✓
Does the research involve vulnerable groups?		✓
Will the study require co-operation of a gatekeeper for access to the groups or individuals to be recruited? (e.g. students at school, Nursing Home residents, etc.)		✓
Will it be necessary for the participants to take part in the study without their knowledge and consent at the time? (e.g. covert observation in non-public places, etc.)		✓
Will the study involve discussion of sensitive topics? (e.g. drug use, sexual issues, etc.).		✓

Will tissue samples (including blood) be obtained from the participants?		✓
Is pain or more than mild discomfort likely to result from the study?		✓
Could the study induce psychological stress or anxiety, or cause harm or negative consequences beyond that encountered in normal life?		✓
Will the study involve prolonged or repetitive testing?		✓
Will the research involve administrative or secure data that requires permission from the appropriate authorities before use?		✓
Is there a possibility that the safety of the researcher might be in question?		✓
Will the research take place outside the UK?		✓
Will the research involve respondents to the internet or other visual/vocal methods where the participants might be identifiable?		✓
Will the research involve the sharing of data or confidential information beyond the initial consent given?		✓
Will financial inducements (other than reasonable expenses and/or compensation for time) be offered to participants?		✓

If you have answered "NO" to all questions, your application may be subject to proportionate light-touch review only. Submit your completed and signed form along with your protocol for assessment REC chair.

*If you have answered "YES" to **any** questions in the first section* (external or NHS review), you will need to send the completed and signed form, along with all relevant associated documentation to the appropriate body for ethical review. Once the ethics approval has been granted by that body, a copy should be submitted along with your protocol for assessment by the College REC chair.

If you have answered "YES" to any questions in the second section (above "minimal risk"), you will need to describe fully how you plan to mitigate the ethical issues raised by your research. **Your protocol will need to be approved by the CoMD REC chair and members**. You should submit your plans for mitigation of the ethical issues in your research using the relevant sections of the following Ethics Review Form. Submit the completed and signed form along with your protocol, as instructed, along with any further associated documents.

PLEASE NOTE:

Please complete this Ethics Review Form **IN FULL**. Failure to complete all section will result in the form being returned to you for completion and consequent delay in approval and commencement of your research study.

It is your responsibility to follow the CoMD and Ulster University Ethics policy & procedures, in addition to any relevant academic or professional guidelines, during conducting your study. This includes providing appropriate information sheets, consent forms, and ensuring confidentiality in the storage and use of the data you collect. Any significant changes to your research protocol (research question, method design or conduct, etc.) should be notified to your supervisor and it may require a new application for ethical approval.

You cannot commence your research project until ethical approval has been given.

(b) Project details for ethical review.

1. Details of the your research

What is the principal research question?
Does the amount of apical debris extruded during endodontic treatment have an effect on post-operative pain experienced by patients?
Summarise the scientific justification for the research (rationale).
Root canals preserve oral health. Patients worry about postoperative pain despite endodontic advances. Apical debris extrusion after root canal treatment is common and unsolved. Apical debris extrusion may cause postoperative discomfort; thus, endodontic techniques must be optimized. Understanding debris extrusion and postoperative pain may improve patient outcomes and comfort. This study lays the groundwork for future research on apical debris extrusion's postoperative effects. The study addresses this issue to improve endodontics for dentists and patients.

Please give a BRIEF overview of the methodology (500 words max.)

During root canal treatment, apical debris extrusion occurs. After removing the infected pulp, the dentist cleans, shapes, and fills the root canals with biocompatible material. Endodontic procedures have improved, but debris still escapes the root apex.

Infected tissue and irrigating fluids may be pushed beyond the apex into the periapical tissues during root canal cleaning and shaping. Debris extrusion can irritate and inflame adjacent tissues, causing postoperative pain.

Patients and dentists worry about postoperative pain from apical debris extrusion. Postoperative pain might damage the patient's quality of life and require further measures, slowing recovery.

Instrumentation, root canal anatomy, and dentist expertise affect apical debris extrusion. Attempts to reduce extrusion have failed.

Optimizing endodontic operations and patient comfort requires understanding how apical debris extrusion affects postoperative pain. Dentists must manage apical debris extrusion. This may require changing sensors, irrigation, or debris-reduction systems.

This research will lay the groundwork for future studies on the postoperative effects of apical debris extrusion. Dentists can adjust treatment to reduce postoperative pain by studying extrusion and pain. This may improve root canal therapy patient satisfaction and outcomes.

Apical debris extrusion is typical during root canal therapy and can cause postoperative pain and discomfort. Endodontic techniques and patient care depend on this research. Dental practitioners study apical debris extrusion to ensure successful and comfortable root canal procedures.

Please list inclusion & exclusion criteria (where appropriate).	
INCLUSION	*EXCLUSION*
The research will comprise descriptive studies including systemic reviews, randomized control trials, in vitro and in vivo investigations , clinical studies , cross sectional studies.	In vitro and in vivo investigations , articles.

Please answer the following question by ticking the relevant box.	YES	NO
Has a detailed research protocol been submitted?	✓	
Will the research involve participants from "vulnerable groups"? Note: If research involves young people or vulnerable adults a CRB check will be required. If you already have current CRB clearance, evidence must be supplied with this Ethics Review Form.		✓
Does the project comply with the relevant professional body Codes of Practice and Standards of Proficiency?	✓	
Have the relevant external permissions and consents been obtained?		✓

If YES, list these permissions and the granting body.
If NO, outline permissions to be obtained.
N/A

2. Consents & withdrawal.

What are your arrangements for obtaining informed consent whether written, verbal or other? *(Please supply copies of participant information sheets and consent forms)*
N/A
What arrangements are in place for participants to withdraw from the study?
N/A

3. Data access, storage & security.

Give details of data to be collected.
A standardized data extraction form will be used in this narrative review. This form will generally focus on five areas: the study design, participant demographics, methods, interventions, and results. Since this is a narrative review, it will not include statistical data analysis but rather just a summary of the key findings from these studies.
Who will act as custodian of the data and control access?
N/A
Who will have access to the data?
N/A
Please detail data storage & security arrangements (including how long data will be kept and how it will be deleted).
N/A

If the research generates personal data, please describe the arrangements for maintaining anonymity and confidentiality.
N/A

4. Risk & Risk Management.

In addition to the Risk assessment in Part (a), will participants face any risk in taking part in this research (e.g. physical, psychological, social, legal or economic)?
N/A
If YES, how will you overcome these risks?
N/A

5. Financial benefit & Conflict of Interest.

Please answer the following question by ticking the relevant box.	YES	NO
Does the student benefit financially from the research?		✓
Does CoMD or Ulster University, or any institution, stand to benefit financially from the research?		✓
Will the participants be incentivised or compensated in any way?		✓
Does the student have any identifiable conflict of interest?		✓
Does CoMD or Ulster University have any identifiable conflict of interest?		✓
If you have answered YES to any of the above, please give details below.		

6. Publication & dissemination of results.

How will the results of the research be reported and disseminated**?** *(Select all that apply)*

- ☐ Peer reviewed journal
- ☐ Conference presentation ✓
- ☐ Internal report
- ☐ Dissertation/Thesis ✓
- ☐ Other publication
- ☐ Written feedback to research participants
- ☐ Presentation to participants or relevant community groups
- ☐ Other (Please specify)

7. Other ethical issues.

Are there any other ethical issues that have not been addressed which you would wish to bring to the attention of CoMD REC?
N/A

Checklist

(Please complete before submitting form)

	Yes/No
Is a copy of the research protocol attached?	**YES**
Have you explained how you will select the participants?	**N/A**
Have you described the ethical issues related to the well-being of participants?	**N/A**
Have you considered health and safety issues for the participants and researchers?	**N/A**
Have you included details of data protection including data storage?	**N/A**
Have you described fully how you will maintain confidentiality?	**N/A**
Is a participant consent form attached?	**N/A**
Is a participant information sheet attached?	**N/A**
Is a copy of your questionnaire/topic guide attached?	**N/A**
Where applicable, is evidence of a current CRB check attached?	**N/A**

CoMD REC USE ONLY.

	Y	N	N/A
Will the main experimental procedure be explained to participants in advance?			✓

Will it be made clear to the participants that this is a student project?			✓
Will the participants be told that their participation is voluntary?			✓
Will a consent form be completed for their participation?			✓
If using questionnaires, will participants be given the option to omit questions that they do not want to answer?			✓
Will participants be told that they can withdraw from the research at any time?			✓
If the research is observational will your participants be asked for their consent to be studied?			✓
Will participants be told that their data will be kept fully confidential?			✓
Will participants be debriefed at the end of their participation?			✓
Will participants be deliberately misled in any way?			✓
Will participants be incentivised and/or compensated in any way?			✓
Are the questions asked potentially upsetting?			✓
Does the project involve working with animals?			✓
Does the project involve working with children (under the age of 18)?		✓	
Does the project involve working with people with learning or communication difficulties?		✓	
Does the project involve working with people in custody?		✓	
Does the project involve people engaged in illegal activities?		✓	
Does the researcher have relevant CRB clearance?			✓

Proportionate review (minimal risk).	-
Pass on for Full REC review (above minimal risk).	-
Approval.	-
Approval subject to amendment(s).	-
Details:	

Rejection.	-
Details:	

Reviewer Name: …….

Designation: ……..

Signed: .....

Date: .....

Supervisor / REC Chair (delete as appropriate)