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Official title: Effect of Cryotherapy on Post-endodontic Pain

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FORMAT FOR SUBMISSION OF RESEARCH PROPOSAL

Title: Effect of Cryotherapy and Occlusal Reduction on Post-endodontic Pain in Patients with Symptomatic Apical Periodontitis

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		Designation: Associate professor of endodontics
		Department: Restorative Dentistry Department
3	Co-supervisor (s)	Name[1]: Dr. Tarek Elsewify
		Designation: Associate professor of endodontics
		Department: Restorative Dentistry Department
4	Name (s) of collaborating Institution/Department (s) *Enclose permission letter (s)*	Gulf Medical University, Thumbay Dental hospital

Signature of Student(s) - _____; _____;

_____; _____;_____

Signature of Supervisor - _____

Signature of Co- Supervisor - 1 _____

Signature of Co- Supervisor - 2 _____

Signature of Statistician - _____

I have gone through the research proposal. The study has been designed to obtain only information relevant to the project and no ethical issues have been identified.

Signature of the Head of the Department/Dean:-_____

Proposal format

1. Title: **Effect of Cryotherapy and Occlusal Reduction on Post-endodontic Pain in Patients with Symptomatic Apical Periodontitis**

2. Background

Post-operative pain is one of the common sequelae after root canal treatment. Pain is triggered by the periapical inflammatory response (1), whose etiology could be mechanical, chemical, and/or microbial (2). This periapical inflammation is referred to as apical periodontitis (3) The prevalence of pain following root canal treatment has been reported to range from 3% to 58%, lasting for several hours or days (4).

Pain could have a deteriorative effect on the patient's quality of life and its management is an integral part of treatment. Several strategies have been presented in endodontics for managing post-endodontic pain such as prescribing analgesics, various mechanical techniques, occlusal reduction (5), and cryotherapy. This research will focus on occlusal reduction and cryotherapy.

Various studies have been performed to evaluate the effects of occlusal reduction on the treatment of pain and discomfort (5-7). However, whether it is an effective intervention in the management of post-operative pain after root canal therapy remains controversial. Although a study by Rosenberg et al. showed that it reduced pain (5) other researchers did not find significant differences in the patients' post-procedural pain (6,7).

Cryotherapy is a treatment in which a particular body segment is exposed to cold temperatures. It aims to decrease the targeted tissue temperature to promote healing and aid in other therapeutic effects such as diminishing edema, inflammation, and pain. Cryotherapy used in dentistry has shown a role in decreasing pain after periodontal surgeries, extractions, and implant surgeries (8). In 2015, intra-canal cryotherapy was introduced in the endodontic field as a successful treatment in reducing post-endodontic pain (9). Cryotherapy in endodontics is applied in the form of applying a final cold irrigating solution into the canal.

Several studies demonstrated that there was a significant reduction in post-endodontic pain after cryotherapy (10-12). Currently, there is no study comparing the effects of

cryotherapy application and occlusal reduction. Therefore, this study will evaluate the effects of cryotherapy applications on post-operative pain on root canal-treated teeth with symptomatic apical periodontitis in comparison to occlusal reduction.

The null hypothesis assumes that there is no difference in the intensity of post-endodontic pain between the control, occlusal reduction, and cryotherapy groups in patients with symptomatic apical periodontitis. Whereas the alternative hypothesis assumes that the intensity of post-endodontic pain will be less in the cryotherapy group than in the occlusal and control group in patients with symptomatic apical periodontitis.

3. Research Question: Is there is a difference in post-endodontic pain intensity following using ccryotherapyy or occlusal reduction in patients with symptomatic apical periodontitis on mandibular first molars?

4. Rationale:

Pain can have an effect of diminishing quality of life regardless of its type and source. When pain is ongoing, it will produce anxiety and emotional distress. Therefore, pain management during treatment is an essential aspect. This study aims to establish if postoperative pain after root canal treatment can be prevented by the application of cryotherapy greater than occlusal reduction. If pain is prevented, the need for analgesics and patient's distress is reduced.

5. Objectives:

To compare the intensity of post endodontic treatment pain following final rinse using cold saline in comparison to room temperature saline and occlusal reduction.

6. Conceptual/Operational definitions:

- **Dependent factors:** Intensity of post-endodontic pain
- **Independent factors:** Occlusal Reduction, Cryotherapy (cooled saline final irrigant), and room temperature saline.

- conceptual definitions

- Post-endodontic pain: highly unpleasant sensation caused following root canal procedures.
- Occlusal reduction: a procedure in which occlusal interferences are removed using articulating paper, occlusal contacts are highlighted and grinded.
- Cryotherapy: the use of extreme cold in surgery or other medical treatment. Final cold irrigating solution is placed in a refrigerator at 2.5C and applied to the canal.

7. Materials & Methods

7.1. Research design

The research design will be a prospective randomized controlled clinical trial. The patient will be asked to pick an opaque sealed envelope that will contain a number from 1 to 3. The resultant number will determine in which group are the participants to be placed. Single blinding will be maintained in this study as patients will not be aware of their group/used irrigant.

7.2. Study population

The study population consists of 60 participants, aged 18–70 years, who will sign the informed consent. The number of participants is chosen according to a previous study (12).

Inclusion criteria

1. Age: 18–70 years
2. A patient diagnosed with symptomatic irreversible pulpitis/acute apical periodontitis
3. require endodontic therapy
4. Mandibular first molars that are diagnosed with symptomatic irreversible pulpitis/acute apical periodontitis
5. Healthy patients without systemic disease
6. Permanent mature first mandibular molars

Exclusion criteria

1. Medically compromised patients

2. Pregnant patients
3. Teeth with incomplete apex formation
4. Teeth with calcified canals
5. Periapical abscess
6. Patients on antibiotic therapy

7.3. Sample size calculation

The study will be conducted on 60 patients: with 20 first mandibular molars in each group (n=20). The number of participants is chosen as per a previous study by Western et al. (12).

Group I (control group): normal room temperature saline irrigation protocol without occlusal reduction

Group II (occlusal reduction group): normal room temperature saline irrigation protocol with occlusal reduction

Group III (cryotherapy group): final irrigation with cold saline (2.5C-4C) without occlusal reduction

7.4. Study settings

Out-patient clinic, MDS Endodontics postgraduate clinics, Thumbay Dental Hospital

7.5. Sample size estimation:

Sixty healthy patients

$$n = \frac{n_0}{1 + \frac{(n_0 - 1)}{N}}$$

7.6. Duration of study

The proposed research will be conducted over a period of 12 months. Details are given in the Gantt chart.

7.7. Study instrument & validation procedure

- Post-endodontic pain will be measured by a visual analog scale (VAS) from 1 to 10.
- The temperature of the cold saline should be 2-4 °C. The saline will be placed in a refrigerator with a thermometer sensor to confirm the 2 to 4°C temperature range.
- After removal, the temperature of the cold saline will be preserved by keeping the irrigation syringes in a special box filled with ice with a thermometer.
- The thermometer will be calibrated according to the manufacturer's instructions.

7.8. Ethical issues

The proposal will be submitted to the Institutional Review Board of Gulf Medical University Ajman, UAE. After obtaining the approval the research will be conducted. The confidentiality, anonymity, and privacy of the members will be kept up with.

The patient will be asked to sign a printed consent form explaining the aim of the study and to fill the pain scale chart postoperatively at 6, 24, 48, 72 hours, and 7 days, after root canal treatment and return it to the operator at day 8.

7.9. Methodology

Sample selection:

The study will be conducted on 60 first mandibular molars; with 20 first mandibular molars in each group (n=20). The patient will be asked to pick an opaque sealed envelope that will contain a number from 1 to 3. The resultant number will determine in which group are the participants to be placed. Double blinding will be maintained in this study as the operator and the patients will not be aware of their group/used irrigant.

Group I (control group): normal room temperature saline irrigation protocol without occlusal reduction

Group II (occlusal reduction group): normal room temperature saline irrigation protocol with occlusal reduction

Group III (cryotherapy group): final irrigation with cold saline (2.5 C°- 4 C°) without occlusal reduction

Procedural steps:

1) Vitality will be assessed using cold tests and electric pulp testing before the procedure is carried out. Besides, mobility, palpation, and percussion tests will be done to assess periapical health. In order to ensure that the cold and electrical pulp tests are working, and a response is elicited, both tests will be carried out on patients not included in the study.

2) All the patients will receive local anesthesia: 2% lidocaine with 1:100,000 epinephrine.

3) Each tooth will be isolated using a rubber dam, and the access cavity will be prepared using a round bur (no.4) and tapered fissure diamond bur (NO173) under copious water.

4) After removal of coronal pulp tissues using a sterile excavator, the working length will be determined with stainless steel hand K-files size #10 and the use of an apex locator and confirmed using intraoral periapical radiographs.

5) Hand instrumentation till 15 size K file.

6) All the canals will be prepared using Protaper Gold rotary files till the file F2 (20/0.06) using the X-Smart Plus endodontic motor.

7) Apical patency will be maintained throughout the shaping procedure using the #10 file between each instrument.

8) All the canals will be irrigated with 10 mL of 3% NaOCl between each file during the whole preparation procedure.

9) After completion of cleaning and shaping in groups I and II, all the canals will be flushed with a final rinse of saline and dried using appropriate size paper points and obturated using the appropriate technique by gutta percha, and permanent composite restoration will be given.

10) After completion of cleaning and shaping in group III, 20 ml cryo-treated saline maintained at a temperature of 2°C–4°C will be irrigated for 5 min in each canal.

11) All the participants will receive a sheet containing VAS after the procedure. After 6, 24, and 48h, patients are to record the intensity of pain in the area of the root canal (using VAS

from 1 to 10). Analgesic pills that had been taken by the patient are to be recorded on the patient's

7.10. Feasibility of the proposed research

The study material and methods technique are available and feasible in Thumbay Dental Hospital.

7.11. Details of data storage

The data gathered from this research will be securely stored in Thumbay Dental Hospital. Preoperative data for each patient will be recorded in the predesigned patient's chart, which includes age, sex, and tooth number before the treatment.

7.12. Data analysis

Data obtained will be tabulated and statistically analyzed by the SPSS software to compare the effect of cryotherapy and occlusal reduction on the level of post-endodontic pain. Patient characteristics will be assessed using numbers, percentages, and mean scores for pain severity. Regarding the type of further statistical test, the decision will be taken later after discussion with the biostatistician regarding the best method for data analysis.

7.13. Timeline

Responsibility	**Phases**											
	1	2	3	4	5	6	7	8	9	10	11	12
Supervisor meeting	■											
Submission of thesis protocol to obtain the Ethics approval		■										
Revising the protocol if necessary.			■									
Data collection				■								
Data entry					■							
Data analysis						■						
Writing a draft thesis							■	■				
Submission of completed thesis for approval							■	■				

Presentation of thesis												
Make changes if needed as per the advice of the Committee												
Submit thesis along with submission form to the university and copies to the department and library												
Defense – Thesis Evaluation Committee												

7. Expected outcome:

the research is expected to reveal the following:

- Compare the effect of cryotherapy and occlusal reduction on postoperative pain after root canal treatment in patients with acute symptomatic periodontitis.

8. References

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9. Consent form

Gulf Medical University, Ajman, UAE **CONSENT FORM**	**جامعة الخليج الطبية، عجمان ، الإمارات العربية المتحدة** **نموذج الموافقة**
Title: Effect of Cryotherapy and Occlusal Reduction on post-endodontic pain in patients with Symptomatic Apical Periodontitis	**العنوان**: . تأثير العلاج بالتبريد والحد من الإطباق على آلام ما بعد اللبية لدى مرضى التهاب دواعم السن
Investigator: Dr. Lana Walid Almasoud……..	**الباحث: لانا النسعود**
Supervisor: Dr. Bassem Mohamed Eid. **Co-Supervisor:** Dr. Tarek Elsewify	**المشرف:** د. باسم محمد عيد **المشرف المشارك**: د. طارق السويفى
Study site: Thumbay Dental hospital, Ajman.	**موقع الدراسة:** مستشفى ثومبي للاسنان عجمان
Contact Number: +971 67431333 Your consent is being sought to take part in the research. Please read the following instructions carefully before making the decisions whether to	**رقم الاتصال:+971 67431333** نسعى جاهدين للحصول على موافقتك للمشاركة في البحث.

consent to participate.

Section I: Introduction

I, Dr. Lana Almasoud, student of 2nd year MDS endodontics program, at Gulf Medical University, Ajman. am conducting research entitled: Effect of Cryotherapy and Occlusal Reduction on post-endodontic pain in patients with Symptomatic Apical Periodontitis under the supervisor Dr. Bassem Mohamed Eid.

As a part of the curriculum. This research will be carried out on healthy individuals indicated for root canal treatment. Detailed information will be provided to you. Your consent will be sought to participate in the research. Upon your acceptance, feel free to ask me if any question or word is not clear to you. If you feel discomfort at any moment or you have any doubts concerning the research, you can stop me at any time and ask me to provide more details. You can also withdraw from the study at any point of time. Your decision on whether you want to participate or not is completely voluntary.

Section II: Details of the study

Purpose of the Research: This research is aimed to evaluate postoperative pain following final irrigation using cold saline in comparison to occlusal reduction

Why am I being asked to participate in this research?

your participation will add a value to our research. This research is mainly concerned to investigate In the effect of cryotherapy on postoperative pain compared to occlusal reduction

……...

How long will I be in this study?
About 1 weeks

How many other people will be participating in

يرجى قراءة التعليمات التالية بعناية قبل اتخاذ القرار بشأن الموافقة على المشاركة أم لا.

القسم الأول: مقدمة

أقوم أنا الدكتورة لانا المسعود، طالبة السنة الثانية في البرنامج ماجستير جراحة اللبية، جامعة الخليج الطبية، عجمان ، بإجراء بحث: تأثير العلاج بالتبريد والحد من الإطباق على آلام ما بعد اللبية لدى مرضى التهاب دواعم السن تحت إشراف الأستاذ لدكتور باسم محمد عيد. يعتبر هذا البحث جزء من المقرر الدراسي. سيتم إجراء هذا البحث على شريحة من المرضي الاصحاء الذين يحتاجون معالجة قناة الجذر. سيتم تزويدك بمعلومات مفصلة في حال موافقتك للمشاركة في البحث .

فضلا لا تتردد في أن تسألني إذا كان أي سؤال أو كلمة غير واضحة، أو إذا شعرت بعدم الراحة في أي لحظة أو كانت لديك أي شكوك بشأن البحث، فيمكنك إيقافي في أي وقت للتوضيح. يمكنك أيضًا الانسحاب من الدراسة في أي وقت. برجاء العلم بأن قرارك فيما إذا كنت ترغب في المشاركة أم لا هو عمل تطوعي تمامًا.

القسم الثاني: تفاصيل الدراسة

الغرض من البحث:

سيتم إجراء هذا البحث للتحقيق في: هدف هذا البحث إلى تقييم آلام ما بعد الجراحة بعد الري النهائي باستخدام محلول بارد بالمقارنة مع تقليل الإطباق

لماذا يطلب مني المشاركة في هذا البحث؟

، ستضيف مشاركتك قيمة لأبحاثنا، حيث يهتم هذا البحث بشكل أساسي بالتحقيق في تأثير العلاج بالتبريد على آلام ما بعد الجراحة مقارنة بتقليل الإطباق

كم من الوقت ستسغرق هذه الدراسة؟
حوالي أسبوع واحد

كم عدد الأشخاص الآخرين الذين سيشاركون في هذه الدراسة؟
٦٩ شخص

this study?
69 individuals

What I will be asked to do?
Before you participate in this study, I will ask you to give a written consent after explaining to you the purpose of the research. I will ask you to participate in the research by accepting to perform necessary radiographic images, receiving root canal treatment and returning back the survey given to you after 1 week.

What benefits can I expect from participating in the study?
The benefit of participating in the study is that you will get a free root canal treatment.

What possible risks/ discomforts can I expect from participating in this study?
Yes, root canal treatment might have some complications such as instrument fracture, tooth perforations, post operative pain.

Are there costs for participating?
We don't require you to pay us and neither will you be paid.

Can I participate in this study if I do not sign this consent form?
Your refusal to sign this consent form will prevent you from participating in the study. However, if you do sign this consent form, it shows your approval to participate in the study and you will receive a signed copy of this consent form.

Confidentiality
The data gathered from this research will be securely stored in the office of the college of dentistry at Gulf Medical University for a period of three years.

We will not share any information about you which may disclose your identity in any form. In any publications or presentations, any information that makes it possible to identify you as a subject will not be included. The data will be analysed in groups. The information can be only accessed by ethics committee in the University, and the

ماذا سيطلب مني أن أفعل؟
قبل أن تشارك في هذه الدراسة، سأطلب منك إعطاء موافقة خطية بعد أن أوضح لك الغرض من البحث. سوف أطلب منك المشاركة في البحث بقبول إجراء الصور الشعاعية اللازمة، وتلقي علاج قناة الجذر، وإعادة المسح الذي تم تقديمه لك بعد أسبوع واحد.

ما الفوائد التي يمكن أن أتوقعها من المشاركة في الدراسة؟
فائدة المشاركة في الدراسة هي أنك ستحصل على علاج مجاني لقناة الجذر.

ما هي المخاطر / المضايقات المتوقعة من المشاركة في هذه الدراسة؟
نعم، قد يكون لعلاج قناة الجذر بعض المضاعفات مثل كسر الأدوات وثقوب الأسنان وآلام ما بعد الجراحة

هل هناك تكاليف للمشاركة؟
نحن لا نطلب منك أن تدفع لنا أي مبالغ وكذلك نحن لن ندفع لك حيث إن الدراسة تتضمن إجراء علاجي

هل يمكنني المشاركة في هذه الدراسة دون التوقيع على نموذج الموافقة؟
سيمنعك رفضك للتوقيع على نموذج الموافقة من المشاركة في الدراسة. ومع ذلك، إذا وقعت على نموذج الموافقة، فسيظهر موافقتك على المشاركة في الدراسة وستحصل على نسخة موقعة من نموذج الموافقة.

السرية
تُخزن البيانات التي تم جمعها من هذا البحث بشكل آمن في مكتب كلية طب الأسنان بجامعة الخليج الطبية لمدة ثلاث سنوات.
لن يتم مشاركة أي معلومات عنك قد تكشف عن هويتك بأي شكل من الأشكال. في أي منشورات أو عروض تقديمية، لن يتم أيضًا تضمين أي معلومات تجعل من الممكن التعرف عليك كمشارك في موضوع البحث حيث سيتم تحليل البيانات في مجموعات. لا يمكن الوصول إلى المعلومات إلا من قبل لجنة الأخلاقيات في الجامعة، والباحثين (إذا لزم الأمر) مع التنظيم المناسب.

القسم الثالث: شهادة الموافقة
أقر أنني قد قرأت المعلومات الواردة أعلاه وقد أتيحت لي الفرصة لتوضيح كافة شكوكي والرد على أسئلتي بما يتيح لي أن أوافق طوعًا على المشاركة في هذه الدراسة.

researchers (if required) with appropriate regulatory. **<u>Section III: Certificate of Consent</u>** I have read the above information. I have had the chance to clear my doubts and my questions have been answered to my fulfilment. I consent willingly to be a participant in this study. **Name of participant:** Signature of participant: Date: **Statement by the researcher taking consent** A copy of this Informed Consent form has been provided to the participant **Name of Researcher taking the consent:** **Signature of Researcher taking the consent:**	**اسم المشارك:** **توقيع المشارك:** **التاريخ:** **بيان من الباحث أخذ الموافقة** تم تقديم نسخة من نموذج الموافقة المستنيرة إلى المشارك **اسم الباحث الذي أخذ الموافقة:** **توقيع الباحث الذي يأخذ الموافقة:**

10. Draft Questionnaire

Postoperative Pain:

_____6h. _____24h. _____48. _____72h _____7 days

0 = no pain

1-3 = mild pain

4-6 = moderate pain

7-9= severe pain

10=worst pain

11. Budget

- Not available

12. Collaborations (If Any)

1. Two copies (one original & one Xerox) of the research proposals must be sent through the Head of the department/Dean to the research department, Gulf Medical University.