Effect of Different Heating Protocols of Resin Composites on Pulp Condition (Randomized Controlled Trial)

دراسة تأثير بروتوكولات التسخين المختلفة للراتنجات المركبة على حالة اللب المقاس (تجربة عشوائية محكومة)

Thesis/Research Protocol

Submitted to the Department of Endodontics

Faculty of Dentistry Ain Shams University

In partial fulfillment of the requirements of Masters in Endodontics specialty

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B.D.S - Suez Canal University - 2018

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I. Abstract

Restorative dentistry aims to restore and preserve tooth health and function, but the method of applying restorative materials, particularly resin composites, can influence the inflammatory response in surrounding tissues. This study focuses on evaluating the impact of different heating protocols on the concentration of tumor necrosis factor-alpha (TNF-α) in inter crevicular fluid , using it as a biomarker for localized pulpal inflammation. Inter crevicular fluid samples will be collected using Periopaper strips from 30 periodontally healthy patients with deep caries in molars. Patients will be randomly assigned to three groups based on the heating protocol applied to the resin composite. TNF-α levels will be measured at three time points: before treatment, immediately after the procedure, and one week post-treatment. The collected data will be statistically analyzed to determine how different heating protocols affect the inflammatory response, providing valuable insights into optimizing resin composite application to minimize post-operative inflammation.

II. Background

Restorative dental materials are essential for treating tooth decay and repairing damaged teeth, particularly when pulp inflammation is present. The relationship between these materials and dental pulp is vital, as the material selection can greatly affect pulp health. Certain substances aid in the healing process and reduce inflammation, whereas others may worsen the situation. For instance, materials such as glass ionomer and resin-modified glass ionomer create a beneficial setting for pulp regeneration by aiding in pulp cell function [1,8]. On the other hand, using materials with low biocompatibility can cause increased irritation, emphasizing the need to choose suitable materials to protect pulp vitality and uphold oral health [2].

Selecting the right restorative material is crucial for reducing pulp inflammation. Even though traditional amalgam is long-lasting, it can cause irritation to the pulp because of its thermal characteristics and mercury content, which may lead to inflammatory reactions [3]. Composite resins, recognized for their beauty and strong bonding, have the potential to create inflammation if not properly cured, as unreacted monomers can seep into the pulp. Glass ionomer materials are appreciated for their ability to release fluoride and bond with dentin, leading to decreased inflammation and improved remineralization, though their use in posterior restorations is limited due to their mechanical strength [4,6]. Bioactive and resin-modified glass ionomer materials are specifically designed to reduce inflammation and promote healing, making their interaction with the pulp crucial for achieving optimal restorative results [1,8].

Inflammation of the pulp is strongly associated with cytokine secretion, which plays a crucial role in the inflammatory response. In cases of dental pulp injury or infection, immune cells release pro-inflammatory cytokines like IL-1, IL-6, and TNF-α, enhancing the immune reaction by attracting more immune cells and boosting inflammation, often causing discomfort [5,7]. Chronic inflammation resulting from persistent high cytokine levels can harm pulp tissue and jeopardize its vitality, whereas anti-inflammatory cytokines like IL-10 help regulate the response and promote tissue healing [9]. Maintaining a balance between pro-inflammatory and anti-inflammatory cytokines is essential for resolving inflammation, and any imbalance can affect dental procedures [6,10].

Heating composite materials has been shown to influence pulp inflammation, primarily by enhancing their physical and chemical properties. Preheating composite resins improves their flow characteristics, reduces polymerization shrinkage, and enhances marginal adaptation, all of which may reduce microleakage and subsequent pulpal irritation. Moreover, preheating has been demonstrated to increase the degree of monomer conversion, leading to fewer residual monomers that could potentially diffuse into the pulp and provoke an inflammatory response. These modifications in material properties can positively influence the interaction between restorative materials and pulp tissues, reducing inflammation and improving treatment outcomes [14,16].

Postoperative pain is a common complication following dental restorations, often attributed to factors such as polymerization shrinkage, microleakage, and residual stresses on the tooth structure. These factors can lead to irritation of the dentin-pulp complex, resulting in transient sensitivity or inflammation. Restorative materials, particularly resin composites, play a critical role in the development and mitigation of postoperative pain. Studies have shown that preheating resin composites may reduce postoperative sensitivity by enhancing material adaptation, reducing polymerization shrinkage, and improving marginal integrity. Additionally, the degree of monomer conversion achieved during polymerization is critical, as unreacted monomers can penetrate dentinal tubules and induce pulpal inflammation. Proper application techniques, including the use of adhesive systems and incremental layering, have been shown to significantly minimize postoperative discomfort. Despite advancements, the persistence of postoperative pain highlights the need for continued research into restorative protocols and material modifications to improve patient outcomes [17,18].

Evaluating pulp inflammation can be effectively done by analyzing inter crevicular fluid, which offers a non-invasive diagnostic method. Increased cytokines and inflammatory markers in inter crevicular fluid indicate pulp inflammation, aiding clinicians in assessing its severity [11]. By observing biomarkers like IL-1, IL-6, and TNF-α, dentists can gain insights into pulpal health and tailor treatment plans accordingly. As research advances, inter crevicular fluid analysis may become a crucial diagnostic tool for early detection and treatment of pulpal inflammation, improving patient outcomes in restorative dentistry [5].

This research focuses on examining how restorative materials affect cytokine expression and pulp inflammation to better understand their impact on dental pulp health and enhance treatment methods.

Review of Literature:

Konradsson et al. (2005) conducted a comparative study examining Class V restorations using calcium aluminate cement (CAC), resin composites, and enamel. Fifteen participants underwent restorations with subgingival margins for CAC and resin composites, while enamel served as the control. Gingival crevicular fluid (GCF) samples were collected at baseline, day 3, and day 7, with IL-1α, IL-1β, and IL-1 receptor antagonist (IL-1ra) levels quantified using ELISA. No significant differences in IL-1 cytokine levels were observed between the three materials. While IL-1 concentrations remained low in the initial phase, they significantly increased during experimental gingivitis (3).

Ilday et al. (2013) explored the impact of silorane composite restorations on GCF levels of TNF-α, IL-6, and IL-8, as well as GCF volume and periodontal parameters. Using Periopaper strips, GCF samples were collected and stored at −80°C for ELISA analysis. Restorations adhered to standard protocols with the Silorane System Adhesive and FiltekSilorane composite (3M ESPE). Two weeks post-restoration, elevated cytokine levels and GCF volumes indicated adverse periodontal effects associated with silorane composites (5).

Celik et al. (2017) investigated the influence of various restorative materials on cytokine levels in GCF in Class V cavities. Sixty participants underwent restorations with Filtek Z250, Dyract XP, Fuji IX, and CavexAvalloy materials. GCF samples were collected at baseline, seven days, and 21 days post-restoration. Mann-Whitney U and Wilcoxon signed-rank tests, along with Spearman’s rank correlation, were employed for statistical analysis. While plaque index (PI) and gingival index (GI) scores improved after treatment, cytokine responses varied: IL-6 and IL-8 levels rose for most materials, but Filtek Z250 and Fuji IX exhibited exceptions. Fuji IX restorations also showed elevated TNF-α levels, highlighting material-specific periodontal responses (2).

Stefanović et al. (2021) evaluated IL-1β and TNF-α levels in GCF in relation to caries severity, tooth location, and restorative materials. Ninety individuals with healthy gums and proximal cavities contributed GCF samples collected before treatment, seven days after, and thirty days after treatment. IL-1β levels showed significant correlation with caries severity pre-treatment, with levels varying across cavity types (C2–C5). Root caries (C5) cases exhibited the highest IL-1β levels 30 days post-treatment. Restorative material choice significantly affected cytokine profiles, although cavity size did not. Notably, canines and molars demonstrated the highest cytokine levels, reflecting inflammation in these structures (1).

Peskersoy et al. (2022) investigated the effects of flowable resin composites (FRCs) on noncarious cervical lesion (NCCL) restorations and periodontal tissues over a 12-month period. GCF samples were analyzed for osteoprotegerin (OPG), immunoglobulins (IgA, IgM), and interleukins (IL-1, IL-1β, IL-10) via ELISA. Self-adhering FRCs demonstrated the best clinical effectiveness, while fluoride-releasing FRCs negatively affected GCF volume and cytokine profiles, inducing an inflammatory periodontal response (4).

Campbell et al. (2022) conducted a clinical study to assess preheating resin composites on postoperative sensitivity using a visual analog scale (VAS) in a randomized controlled trial. Findings revealed that preheating composites to 39°C before application significantly reduced sensitivity compared to room-temperature composites, with improvements noted at 24 hours, one week, two weeks, and one month post-treatment (14). The study underscored the potential of preheating to enhance clinical outcomes by improving the mechanical and rheological properties of composites while minimizing microleakage and postoperative sensitivity.

Despite robust laboratory evidence highlighting the advantages of preheating composites, including improved adaptation, reduced film thickness, and enhanced mechanical properties (16, 17), clinical studies remain limited. Broader investigations into real-world applications are essential to validate the long-term benefits and promote wider adoption of preheating protocols in restorative dentistry.

III. Research Question:

For patients with deep carious occlusal cavities , what is the effect of Thermoviscous bulk fill and the heated nanohybrid in comparison to the non-heated nanohybrid resin composites on pulp condition ?	
Population	30 patients have deep occlusal cavities in molars
Intervention 1	Restoring by Thermoviscous bulk fill resin composite (viscalor)
Intervention 2	Restoring by heated conventional nanohybrid resin composite
Control	Restoring by conventional nanohybrid resin composite (incremental packing)
Primary outcome	Pulpal inflammatory responses (Immuno-histological analysis of the crevicular fluid)
Secondary outcome	Post operative pain
Time of Follow up	1 week follow up

Study setting	Faculty of Dentistry, Ain Shams university.

IV. Aim of the Study, Research Objectives and Clinical Relevance:

This research seeks to assess how resin composite heating method affects the levels of pro-inflammatory cytokines— tumor necrosis factor-alpha (TNF-α)—in inter crevicular fluid . The levels of cytokines will be used as biomarkers to gauge the degree of local inflammation in molar teeth with deep occlusal cavities. Furthermore, the research aims to evaluate the impact of various restorative materials and heating procedures on biological and clinical results, improving knowledge of material-related pulpal reactions and assisting in making restorative choices.

Primary Outcome: pulpal inflammatory response (immuno-histological analysis of the crevicular fluid)(TNF-α)
Secondary Outcome: post operative pain

Clinical Relevance:

New restorative materials have gained popularity in recent times as they have little effect on pulpal inflammation.

V.Hypothesis:

Null hypothesis: no statistical difference between different restorative materials on pulpal inflammation.

VI. Ethical considerations:

In clinical trials

Risk Minimization

Efforts will be made to minimize risks associated with the study. Participants will be closely monitored throughout the follow-up period, and any patient who discontinues follow-up or undergoes extraction of the tooth involved in the clinical trial will be excluded from the study.

Benefits to Patients and the Community

The study aims to reduce postoperative pulpal inflammation, benefiting not only individual patients but also contributing to improved clinical outcomes for the wider community.

Privacy Protection

Patient privacy will be safeguarded by limiting access to personal data, including Personally Identifiable Information (PII) and Personal Health Information (PHI). Data such as phone numbers and medical histories will be recorded in an Excel sheet secured with a password accessible only to the principal operator.

Confidentiality

All patient information will be treated as confidential and will not be shared with unauthorized individuals or researchers without the patient's explicit consent.

Data Management

Data will be systematically managed using computer-based Excel sheets and Word documents to ensure accuracy and organization.

Consent Procedures

Patients will receive detailed information about the nature of the treatment, the study's objectives, and potential postoperative pain. Informed consent will be obtained before participation.

Patient Informed Consent Form

The informed consent form will follow the template provided by RECFDASU.

Sample Archiving and Future Use of Specimens

inter Crevicular Fluid samples will be collected by inserting a Periopaper strip into the gingival sulcus for 30 seconds. The inter crevicular fluid volume will be measured using a Periotron6000. Collected samples will then be placed in Eppendorf tubes and stored at -40°C for future analysis using ELISA.

VII. Study Design:

Randomized Controlled Trial (RCT).

In vivo

VIII. Materials and Methods:

A. **Study Setting**

   This Study will be Performed in faculty of dentistry Ain Shams University.

B. **Sample Size**

   Sample size calculated depending on a previous study (***Celik N et al 2013,Abo Elkasem M et al 2023***) as reference. According to this study, the minimally accepted sample size was 5 per group (increased to 7 to compensate for 30% drop out percentage), when mean ± standard deviation of periodontal parameters before restoration in group I was 5.83 ± 0.25 while after restoration was 7.15 ± 0.7, with 2.8 effect size, when the power was 95% & type I error probability was 0.05. Total sample size increased to 10 to increase study power. The independent t test was performed by using G.power 3.1.9.4.

   Total Sample size = 10 Per each group

Thirty patients will be selected from the outpatient clinic of Endodontics Department Faculty of Dentistry Ain Shams university, according to following criteria:

Inclusion criteria:

- Patients of age older than 18 years
- No filling with the related teeth.
- Asymptomatic deep occlusal cavitiesICDAS score [5 or 6].
- Patient with healthy gums (no bleeding when probed and no signs of bone loss in 2D X-rays).
- Normal occlusion.
- Participants must be willing to stay for the whole trial period and sign the consent form after receiving a thorough explanation of the study.

Exclusion criteria:

- At-risk populations like pregnant women, nursing mothers, inmates, individuals with mental illness, and others...
- Smoking cigarettes or using any other form of tobacco.
- Patients with medical issues such as diabetes.
- A tooth that has been treated with endodontic therapy in the past.
- Continual dental or periodontal care in the year leading up to the start of the research.
- Presence of periodontal pockets >3 mm in the affected tooth.
- Antibiotics or any medication that might lead to decreased salivary flow.

Justification of exclusion: In this study we will exclude any other causes that may change the concentration of GCF proinflammatory cytokines such as periodontally affected teeth or cases not committed to treatment plan due to systematic health problem. Or patients who are at higher risk of poor physical, psychological or social health problems such as pregnant women or prisoners (vulnerable).

This Proposal follows the research guidelines of Ain shams University and will be reviewed by the Research ethics committee in the Faculty of Dentistry, Ain Shams University. The procedure will be fully explained to the participants, and they will sign an Informed consent before starting the treatment.

C. **Study procedure:**

1)Materials :

Material	**Thermoviscous Bulk fill resin composite “Vis Calor”**	**Heated Conventional Nanohybrid resin**	**Conventional Nanohybrid resin composite “Ivo Clar”**

		composite "Ivo Clar"	
Mode of Supply	**compules**	**One tube**	**One tube**
Composition	**89% filled universal nano-hybrid composite**	**Di methacrylate and TEGDMA (22 wt.%). The fillers include barium glass, ytterbium trifluoride, silicon dioxide and mixed oxide (76 wt.% or 60 vol%). Additives, initiators, stabilizers and pigments are additional contents (2 wt.%).**	**Di methacrylate and TEGDMA (22 wt.%). The fillers include barium glass, ytterbium trifluoride, silicon dioxide and mixed oxide (76 wt.% or 60 vol%). Additives, initiators, stabilizers and pigments are additional contents (2 wt.%).**
Heating Method	**Vis Calor Dispenser " Device used in combination with Vis Calor Bulk"**	**Composite heater**	**No Heating**

2)Methods :

<u>Treatment Protocol and Interventions</u>

Informed Consent and Patient Data Collection

All participants will be required to sign informed consent forms prior to their inclusion in the study. Demographic data, including age, gender, and tooth number, will be recorded for patients meeting the inclusion criteria. Additionally, preoperative pain levels and Visual Analog Scale (VAS) pain scores will be documented.

Cavity Preparation and Restoration

Caries diagnosis will be performed using a visual-tactile method aligned with ICDAS score, supplemented by radiographic imaging. Cavity preparation will be conducted using a high-speed handpiece with diamond burs under continuous water cooling, adhering to adhesive cavity preparation principles to ensure sound tooth structure preservation.

Local anesthesia will be administered, followed by isolation of the teeth using a rubber dam (Sanctuary). All restorations will be performed by the same operator, with the contralateral intact enamel surface serving as the control and the restored surface as the experimental side., the eligible participants will be randomly allocated for one of the 3 comparative Parallel-Groups; test groups and control groups using computer generated random tables.

Group I: Restoring with thermoviscous bulk fill resin composite (viscalor)

Group II:Restoring with heated conventional nanohybrid resin composite

Group III:Restoring with Conventional nanohybrid resin composite (incrementally packed)

Periodontal Examination

The periodontal condition will be evaluated through both radiographic and clinical parameters. Radiographic assessment will measure bone levels, while clinical parameters will include the gingival index, plaque index, and inter crevicular fluid volume. Gingival inflammation will be assessed through visual inspection and gentle sulcus probing.

Specimen Collection and Inter crevicular fluid Sampling

Inter crevicular fluid samples will be collected from the mesial and distal surfaces of the relevant teeth before the restoration, immediately after, and two weeks post-treatment. Sampling sites will be isolated with cotton rolls, sprayed with water to remove saliva, and air-dried using an air syringe. A saliva ejector will be employed to prevent contamination.

A standardized paper strip (Periopaper) will be inserted 1 mm sub gingivally and left in place for 30 seconds until moderate pressure is felt. Strips contaminated with blood or saliva will be excluded. The absorbent portion of each strip will be trimmed and placed into labeled Eppendorf tubes containing 300 μL of phosphate-buffered saline (PBS) and sealed with parafilm to prevent evaporation. The samples will then be sent for laboratory analysis.

Elution will be performed using 500 µL of PBS with an automatic pipette. To separate Inter crevicular fluid from the Periopaper, the samples will be vortexed for 1 minute and centrifuged at 3,000 g for 10 minutes to remove plaque and cellular debris. The samples will be stored at -80°C until biochemical analysis.

A Periotron 8000, calibrated prior to each measurement, will be used to determine Inter crevicular fluid volume. Conductors will be disinfected with alcohol to ensure accurate readings.

Cytokine Analysis

Pro-inflammatory cytokine levels (TNF-α) in Inter crevicular fluid samples will be measured using enzyme-linked immunosorbent assay (ELISA) kits specific to each cytokine, following the manufacturer's protocol. Results will be read using a microplate reader at a wavelength of 405 nm. Cytokine levels will be expressed in pg/mL.

Assessment of Post-Operative Pain

Postoperative pain will be evaluated using two primary methods: the Visual Analog Scale (VAS) and an evaporative air stimulus.

Visual Analog Scale (VAS)
The VAS is a widely recognized tool for assessing pain intensity. Patients will be asked to indicate their pain level on a 10 cm horizontal line, with "0" representing no pain and "10" representing the worst pain imaginable. This method allows for a subjective yet quantifiable measurement of pain. The VAS will be administered at multiple intervals: preoperatively, immediately postoperatively, and during follow-up visits to monitor changes in pain levels over time.

Evaporative Air Stimulation Test
The evaporative air test involves applying a controlled stream of air to the restored tooth surface to provoke a pain response. This method helps to assess the sensitivity of the treated area, particularly in cases involving postoperative pulpal inflammation. Patients will be asked to rate their pain intensity immediately after air exposure using the VAS, allowing a direct correlation between the stimulus and perceived discomfort.

By combining these two methods, a comprehensive evaluation of postoperative pain will be achieved, providing both subjective and stimulus-specific insights into patient comfort and the effectiveness of the treatment.

IX. Statistical Analysis

Handling of numerical / quantitative variables:

Numerical data will be explored for normality by checking the data distribution using Kolmogorov- Smirnov and Shapiro-Wilk tests. Data will be presented as mean & standard deviation. If data will be normally distributed comparison between 2 different groups will be performed by using Independent t-test, comparison between 2 related groups will be performed by using Paired t-test, while comparison between more than 2 groups will be performed by using One Way ANOVA test followed by Tukey`s Post Hoc test for multiple comparisons.

If data will be non-parametric data comparison between 2 different groups will be performed by using Mann-Whitney test, comparison between 2 related groups will be performed by using Wilcoxon Signed Rank test, while comparison between more than 2 groups will be performed by using Kruskal-Wallis test.

Handling of categorial / qualitative variables:

Data will be presented as frequency and percentages. All comparisons will be performed by using Chi square test.

Statistical analysis:

Data were collected, tabulated, and statistically analyzed using Microsoft Excel ® 2016, Statistical Package for Social Science (SPSS)® Ver. 24. and Minitab ® statistical software Ver. 16.

X. Funding of the Study

The study will be funded by the student herself.

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تأثير بروتوكولات تسخين مختلفة لمواد الحشو الراتنجية على حالة اللبّ

(تجربة عشوائية محكومة)

اقتراح مقدم

استكمالا لمتطلبات درجة الماجستير جامعة عين شمس

من

اميرة عادل محمد حسن

(بكالريوس طب وجراحة الفم والاسنان جامعة قناة السويس (2018

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المقدمة

تهدف علاجات الأسنان الترميمية إلى استعادة صحة الأسنان ووظائفها، ولكن طريقة تطبيق المواد الترميمية، خاصة الراتنجات المركبة، قد تؤثر على استجابة الأنسجة المحيطة للالتهاب. تسعى هذه الدراسة إلى تقييم تأثير بروتوكولات تسخين مختلفة على تركيز عامل نخر الورم ألفا (TNF-α) في السائل بين الأسنان، حيث يُعتبر هذا العامل مؤشراً بيولوجياً على الالتهاب اللبّي الموضعي. سيتم جمع عينات من السائل بين الأسنان باستخدام شرائط **Perio Paper**من 30 مريضًا يتمتعون بصحة دورانية سليمة ويعانون من تسوس عميق في الأضراس. سيتم تقسيم المرضى عشوائيًا إلى ثلاث مجموعات بناءً على بروتوكول تسخين المادة الراتنجية المستخدم. سيتم قياس مستويات عامل نخر الورم ألفا في ثلاث مراحل: قبل العلاج مباشرة، بعد الإجراء مباشرة، وبعد أسبوع من العلاج. سيتم تحليل البيانات إحصائيًا لتحديد كيفية تأثير بروتوكولات التسخين المختلفة على الاستجابة الالتهابية، مما يوفر رؤى قيّمة لتحسين تطبيق الراتنجات المركبة وتقليل الالتهاب بعد العلاج.

تلعب المواد الترميمية دورًا حاسمًا في علاج تسوس الأسنان وإصلاح الأسنان التالفة، خاصة عندما يكون الالتهاب اللبّي مصدر قلق. يؤثر تفاعل هذه المواد مع لب السن بشكل كبير على صحته، حيث يمكن أن تدعم المواد المناسبة الشفاء أو تفاقم الالتهاب. تُعتبر المواد الحيوية مثل الأيونومرات الزجاجية والأيونومرات المعدلة بالراتنج فعالة في تعزيز تجديد لب السن من خلال تحسين وظيفة خلايا اللب، بينما قد تسبب المواد ذات التوافق الأقل تهيجًا، مما يؤكد أهمية اختيار المواد بعناية.

تتميز الراتنجات المركبة بمزايا جمالية وقوة رابطة عالية، لكنها قد تُحدث التهابات إذا لم تُعالج بشكل صحيح، حيث يمكن أن تنتشر المونومرات غير المتفاعلة إلى اللب. من جهة أخرى، تعزز المواد الحيوية والأيونومرات المعدلة بالراتنج من إعادة التمعدن، على الرغم من محدودية استخدامها في الترميمات الخلفية.

يلعب تسخين الراتنجات المركبة دورًا إيجابيًا في الحد من الالتهاب اللبّي. يساهم التسخين المسبق في تحسين الخصائص الفيزيائية والكيميائية للراتنجات، مثل التدفق والتكيف الحدي والبلمرة، مما يقلل من خطر التسرب المجهري والتهيج. كما يعزز معدلات تحويل المونومرات، مما يقلل من المونومرات المتبقية التي قد تسبب الالتهاب.

يعد تحليل السائل بين الأسنان طريقة غير غازية لتقييم الالتهاب اللبّي، حيث توفر المؤشرات البيولوجية مثل عامل نخر الورم ألفا و IL-1 و IL-6 رؤى مهمة حول صحة اللب، مما يساعد في تطوير استراتيجيات علاجية أكثر كفاءة.

هدف الدراسة وأهميتها الإكلينيكية

تهدف هذه الدراسة إلى تقييم تأثير بروتوكولات تسخين مختلفة لمواد الراتنج المركب على مستويات TNF-α في السائل بين الأسنان كعامل حيوي للالتهاب اللبّي.

الأهمية الإكلينيكية:تسعى الدراسة إلى تقديم رؤى جديدة تسهم في تحسين النتائج السريرية وتقليل المضاعفات بعد العلاج.

المواد والطرق

المواد والطرق المستخدمة في البروتوكول

تم تصميم هذه الدراسة لتقييم تأثير بروتوكولات تسخين المواد الراتنجية المركبة على الالتهاب اللبّي باستخدام تقنيات ومواد محددة وفقاً للمعايير السريرية والبحثية المتبعة.

المواد:

1. **المواد الراتنجية المركبة**:
   - **Thermoviscous bulk-fill resin (Viscalor)**: مادة حديثة مصممة للتطبيق باستخدام تقنية الملء الكلي، تُستخدم في المجموعة الأولى دون تسخين إضافي.
   - **راتنج مركب نانوهجيني مسخن مسبقًا**: يُستخدم في المجموعة الثانية بعد تسخينه إلى درجة حرارة محددة.
   - **راتنج مركب نانوهجيني تقليدي**: يُستخدم في المجموعة الثالثة كمعيار للمقارنة
2. **أدوات العزل**:
   - سدادة مطاطية لتوفير بيئة معزولة تماماً أثناء الإجراءات.
3. **الأجهزة التشخيصية**:
   - جهاز قياس عامل نخر الورم ألفا (TNF-α) باستخدام تقنية التحليل المناعي (ELISA).
   - أدوات قياس الألم والتقييم السريري (مقياس بصري للألم VAS).

بروتوكولات العلاج

تم تصميم هذه الدراسة كبحث معشّى ذو شواهد، يتم تطبيقه على 30 مريضًا بمستوى عالٍ من الدقة لتقييم تأثير بروتوكولات التسخين المختلفة.

1. **المجموعة الأولى:**استخدام مادة راتنجية مركبة من النوع **Thermoviscous bulk-fill (Viscalor)**دون الحاجة إلى تسخين إضافي، حيث يتم تعبئتها في خطوة واحدة.
2. **المجموعة الثانية:**استخدام مادة راتنجية مركبة نانوهجينية يتم تسخينها مسبقًا لدرجة حرارة محددة لتحسين خصائصها الميكانيكية والفيزيائية.
3. **المجموعة الثالثة (مجموعة الضبط):**استخدام مادة راتنجية مركبة نانوهجينية تقليدية تُطبّق بطريقة التعبئة المتدرجة دون تسخين مسبق.

سيتم قياس مستويات عامل نخر الورم ألفا في ثلاث مراحل: قبل العلاج مباشرة، بعد الإجراء مباشرة، وبعد أسبوع من العلاج. سيتم تحليل البيانات إحصائيًا لتحديد كيفية تأثير بروتوكولات التسخين المختلفة على الاستجابة الالتهابية، مما يوفر رؤى قيّمة لتحسين تطبيق الراتنجات المركبة وتقليل الالتهاب بعد العلاج.