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العدد الثاني للمجلد 33 لسنة 2020م

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الحمد لله رب العالمين حمداً كثيراً على نعمته التي أنعم الله بها علينا وألهمنا و وفقنا لإنجاز هذا العمل. والصلاة والسلام على معلم البشرية سيدنا محمد صلى الله عليه وعلى آله وصحبه وسلم تسليماً. إنه لمن دواعي سرورنا أن نشهد بتوفيق من الله صدور العدد الثاني للمجلد 33 من مجلة جامعة بنغازي العلمية والتي مكّنت البَحّاث المهتمين في مجال العلوم الانسانية والتطبيقية والطبية من نشر أبحاثهم على صفحات هذه المجلة لتوفير وإعطاء المعلومة والنتيجة الصحيحة لطلاب العلم والمعرفة، ومن هذا المنطلق فإن هيئة تحرير المجلة تجدد حرصها الدائم على استمرارية صدور المجلة برصانة ومنهجية في البحث العلمي وذلك بإتباع الأساليب العلمية المحكّمة في تقييم البحوث العلمية المقدمة من الأساتذة والبَحّاث بإشراف أساتذة متخصصين أخذين في الاعتبار الطرق المتبعة في المجالات العلمية العريقة ، وبهذه المناسبة يسر هيئة التحرير بالمجلة أن تثمن عالياً جهود جميع البَحّاث والأساتذة المهتمين الذين لم تثنهم الصعاب ولم تؤثر فيهم الظروف الشديدة التي تمر بها بلادنا الحبيبة على تقديم كل ما لديهم من جهد للبحث العلمي واختاروا هذه المجلة لنشر أبحاثهم و أوراقهم العلمية، كما لا يفوتنا أن نتقدم بجزيل الشكر والعرفان لكل من ساهم في تحرير ومراجعة البحوث المقدمة للمجلة وتقديم هذا الانتاج العلمي للوجود.

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تنشر بحوث باللغتين العربية والإنجليزية

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محتويات العدد الثاني للمجلد 33 من مجلة جامعة بنغازي العلمية ( 2020 )

Table of Contents for Volume 33 Issue 2 of the Scientific Journal of University of Benghazi (2020)

الصفحة	المؤلف	العنوان	م
<b>العلوم الإنسانية (Humanities)</b>			
07	مجيد محمّد حبريشة	لفظة (أزر) في القرآن الكريم	1
14	يوسف محمد أبو القاسم الصيد	واقع الطلاق في المجتمع الليبي	2
24	عيسى رمضان محمد مخلوف وعبد الحكيم عبد الحميد بوشنيف موسى وفرّج فرجاني محمد عقيلة	واقع استخدام الوسائل التعليمية في التدريس لتلاميذ الشق الثاني من مرحلة التعليم الأساسي العام ببلدية الأبيار	3
38	إبراهيم أبو عقيل وشهد رفيق نبروخ	ادارة الازمات الاسرية وعلاقتها بإدارة الصف لدى المعلمات الامهات	4
50	بشير محمد العبار وعادل رابح يونس	أثر التغيير التنظيمي على عملية اتخاذ القرارات الإدارية	5
60	على سعيد عبدالله الشريف وعبدالناصر محمد المسلاتي	قياس أهم محددات التضخم في الاقتصاد الليبي	6
70	علي محمود فارس وعبد المطلوب أحمد بوفروة وحنان عبد الرحمن بركة	دراسة جدوى مشروع إنشاء مستشفى تعليمي استثماري بجامعة عمر المختار	7
81	فيصل سالم الكيخيا ومريم محمد حسن	أثر مشاركة العميل على نواتج الخدمات المصرفية المقدمة في المصارف التجارية الليبية العامة العاملة في مدينة بنغازي	8
96	أحمد علي الكاديكي ونرمين خليفة النعاس	إطار مقترح لتطوير دور الأجهزة الرقابية في تقويم أنظمة الرقابة الداخلية بالمؤسسات الحكومية الليبية	9
108	إبراهيم مسعود الفرجاني	اختبار القدرة التنبؤية للنموذج اللوجستي لـ (Estrella et al , 2000) للتنبؤ بتعثر المصارف	10
116	جمال نصر الشيباني	آثار الضرائب على بعض المتغيرات الاقتصادية حسب المنهج الكينزي	11
120	عياد طاهر بن إسماعيل	دعم ثقافة الجودة في مؤسسات التعليم العالي: دراسة حالة جامعة بنغازي	12
130	وليد إبراهيم محمد البرغثي ومنيرة حامد حرم سيدهم	تحليل مستوى الإفصاح عن المخاطر في التقارير المالية السنوية للمصارف التجارية الليبية	13
143	خالد إقليون القطراني	المعوقات التي تحد من التحول نحو الإدارة الإلكترونية في هيئة الرقابة الإدارية دراسة حالة هيئة الرقابة الإدارية فرع إجدابيا	14
152	Abdelsalam M. A. Saad Fathi S. M. Omar Mohamed M. B. Elfallah	The Impact of Incentives on the Performance Level of Nursing Staff in the Libyan Public Health Sector	15

محتويات العدد الثاني للمجلد 33 من مجلة جامعة بنغازي العلمية ( 2020 )

Table of Contents for Volume 33 Issue 2 of the Scientific Journal of University of Benghazi (2020)

العلوم التطبيقية (Applied Sciences)			
164	ناصر محمد المسلاتي وسالم هلال الشريف وسميرة عبد الرازق الكواش	دراسة أثر الانفتاح الاقتصادي على النمو الاقتصادي في ليبيا باستخدام نموذج (ARDL) خلال الفترة (1990-2014)	1
169	Osama R. Shaltami I Fares F. Fares Farang M. EL Oshebi Hwedi Errishi Mohammed S. Aljazwi Abdurabbah. S. Saleh Ali F. Muftah Rachelle R. Favalaro Abla. A. Rhouma	Primarily Assessment of Mamuniyat Formation Sandstones for Glass Industry, Idri Area, SW Libya	2
174	Idress A. Al Gehani Sami A. Alasheebi Ali M. Kalifa Hwedi Errishi Adim A. Hamad	Physiological Responses of Squash (Cucurbita pepo L.) to Humic Acid Treatment under NaCl Stress Conditions	3
180	Osama R. Shaltami Ahmed M. Muftah Moftah, H. El-Shawaihi Osama A. El-Fallah	Geochemical Characterization Of the UI Member, Sahabi formation In Northeast Sirt Basin, Libya	4
189	Hanan Salem Abd Alhafid	Existence and unique of the mild solution of stochastic integro differential equation	5
193	Sumaia E. Eshim Amer A. Boushaala Mohammed M.Hamed	Hybrid Genetic Simulated Annealing Algorithm for Job Shop Scheduling Problem	6
العلوم الطبية (Medical Sciences)			
199	Salem Elfleleh Mohammed shultami Halima A.Bargaty Hussain AlKhamry Salem Omaer Salah JABER	Risk of Middle Ear Complications in Intubated Patients on Mechanical Ventilation Versus Non Intubated	1
203	Naeima Betamar Esra Burgeia AbdulGafar Fareg	Evaluation of the Success Rate of Indirect Pulp Capping Treatment using Different Materials: A Clinical Study	2
211	Hoda Mansur Patricia Murray	Investigating The Effect Of Serum Concentration On The Expression Pattern Of Pluripotency And Lineage-Specific Markers In Mouse Embryoid Bodies Using Immunofluorescence	3
220	Rugea Mahmud Mahmmed Namah AL-Sadik EL-Houni	Effect Of Maternal Iron Deficiency Anemia On The Baby Anthropometric Measurements And Hematological Indices	4
226	Gadalla R.M Muftah H.M Aljelane L.K Aldresy A.H Abdualsalm S.F Mohamed N.S Alfrjane H.H1	The Role of Total Quality Management (TQM) in Improving the Health Services Provided at the Benghazi Medical Center (BMC)	5
233	Abdelraouf A. A. Khatal Akram Y. Yasear Laila R. A. Eljreiby Salh S.Muftah	Micromorphological Studies On Implantation Of Albino Rat Endometrium	6

العلوم الطبية

**Medical Sciences**

## Evaluation of the Success Rate of Indirect Pulp Capping Treatment using Different Materials: A Clinical Study

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### الملخص:

الهدف من هذه الدراسة السريرية هو تقييم معدل نجاح علاج تغطية اللب غير المباشرة (IPC) باستخدام ثلاث مواد؛ Dycal و Biner LC و TheraCal LC في أسنان الضواحك والأضراس الدائمة. في هذه الدراسة تم اختيار عدد 200 من الأسنان الخلفية الدائمة ذات التسوس العميق موصوفة لعلاج اللب غير المباشر (IPC). عدد المرضى 130 مريضاً من كلا الجنسين تتراوح أعمارهم بين 18-55 عاماً. تم تقسيم الأسنان إلى ثلاث مجموعات حسب المادة المستخدمة في تغطية اللب. تم إجراء علاج IPC باستخدام Dycal و Biner LC و TheraCal LC في 67 و 68 و 65 سنناً على التوالي. تم ترميم الأسنان باستخدام مركب راتينج نانو. تم تقييم المرضى سريريًا في 8 أسابيع و 6 أشهر و عام واحد لتقييم نجاح علاج IPC. تم تحليل البيانات إحصائياً باستخدام برنامج SPSS. لوحظ ارتفاع معدل نجاح علاج IPC مع مواد تغطية اللب الثلاثة ولم يكن هناك فرق معتمد به إحصائياً بين المجموعات الثلاث التي تم فحصها ( $P>0.05$ ). في فترة تقييم لمدة عام واحد كان معدل نجاح Dycal و Biner LC و TheraCal LC 97% و 97.1 و 98.5% على التوالي. أظهرت المواد الثلاثة نسبة نجاح عالية ووجدت أنها ناجحة جداً كمادة IPC؛ ومع ذلك، أظهر TheraCal LC أفضل النتائج حتى فترة متابعة لمدة عام واحد. حافظت معالجة IPC على حيوية اللب ووظيفة الأسنان الدائمة، وأن نجاح علاج IPC لا يعتمد على مادة تغطية اللب.

### الكلمات المفتاحية:

تسوس عميق، تغطية غير مباشرة لللب، هيدروكسيد الكالسيوم، Dycal، Biner LC، TheraCal LC.

### Abstract

The aim of this clinical study was to evaluate the success rate of indirect pulp capping (IPC) treatment with three pulp capping materials; Dycal, Biner LC, and TheraCal LC in permanent premolars and molars teeth.

A total of 200 permanent posterior teeth with deep carious lesions indicated for IPC treatment were included in the study. The number of patients was 130 of both genders, age 18-55 years old. Teeth were divided into three groups according to the material used for pulp capping. IPC treatment was performed using Dycal, Biner LC, and TheraCal LC in 67, 68, and 65 teeth respectively. Teeth were then restored with nanohybrid resin composite. Patients were clinically evaluated at 8 weeks, 6 months, and one year follow up period for the success of IPC treatment. Data were statistically analyzed using SPSS software.

A high success rate of IPC treatment was observed with the three pulp capping materials and that there was no statistically significant difference between the three investigated groups ( $P>0.05$ ). At one year evaluation period, the success rate of Dycal, Biner LC, and TheraCal LC was 97%, 97.1, and 98.5% respectively.

The three materials were exhibited a high success rate and found to be very successful as IPC agents; however, TheraCal LC showed the best results up to one year follow-up period. IPC treatment maintained the pulp vitality and function of the restored permanent teeth, and that the success of IPC treatment is independent of the pulp capping material.

**Keywords:** Deep caries, Indirect pulp capping, Dycal, Calcium hydroxide, Biner LC, TheraCal LC.

## 1. INTRODUCTION

The main objective of the modern approach of restorative dentistry is to preserve pulp health of caries teeth, thus reducing the need for root canal treatment and preserve the teeth on the dental arch long-term.<sup>1</sup> Treatment of deep carious lesions is challenging and varied among dental practitioners. The successful treatment is rather a major problem for many of them owing to the complex etiology and pathology of dental caries. Nowadays, based on the biological concept of treatment

strategies along with the development of dental materials; deep caries lesions treated with selective caries removal technique which is recommended by a recent report of European Society of Endodontology.<sup>2-4</sup>

Indirect pulp capping (IPC) is a therapeutic intervention in the treatment of deep carious lesions approximating the pulp of vital teeth with no signs of pulp degeneration, to avoid pulp exposure and preserve pulp vitality.<sup>1, 5-7</sup> IPC is generally used in deep cavity preparation, involves the removal of all soft,

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demineralized infected dentine with or without leaving behind a layer of caries-affected dentine remains in close to the pulp, followed by application of pulp capping material, and a restoration<sup>5,8,9</sup> The idea behind this technique based on the fact that dental pulp can develop inorganic mineralized dentine-like matrix as a part of the repair mechanism in the dentine pulp complex.<sup>7, 10</sup> i.e. preserving the pulp biologic function to stimulate and induce odontoblasts to produce tertiary dentine. The objective of IPC treatment is to discontinue demineralization of carious dentine and thus arresting the carious progression by promoting remineralization and stimulating reparative dentine formation.<sup>10</sup>

Several materials have been used and tested as pulp capping agents.<sup>10-16</sup> Important properties of these materials are biocompatibility, preserve pulp vitality, and antibacterial property.<sup>17</sup> Moreover, other properties being able to promote tissue repair, adhere to dentine and restorative material, as well as sealing capabilities.<sup>18</sup> Among those materials calcium hydroxide Ca(OH)<sub>2</sub> which was introduced by Hermann in 1921 has been considered the "gold standard" of direct and indirect pulp capping for several decades.<sup>16, 17</sup> It is available in several forms such as aqueous suspensions, cements, liners, or filled resins as visible light-cured liner containing calcium hydroxide.<sup>17</sup> For instance; Dycal (Dentsply, Milford, DE, USA) is a Ca(OH)<sub>2</sub> based material, a self-cure radiopaque liner with an alkaline pH (pH 9–11).<sup>19</sup> In clinical practice, it is the first material applied as a liner in patients with deep cavities and remains the most popular material among dentists.<sup>19,20</sup>

Ca(OH)<sub>2</sub>-based materials are reported to display excellent antibacterial properties and induce mineralization and reparative dentine formation because of their chemical irritation nature.<sup>16</sup> However, the conventional two-paste chemical-cure formulation of Ca(OH)<sub>2</sub> cement has several disadvantages that may fail of the treatment such as high solubility in oral fluids that lead to dissolution over time, lack of adhesion to dentine as well as to resin-based restorative materials, poor sealing ability, internal resorption, extensive dentine formation obliterating the pulp chamber, low elastic modulus, and low compressive strength.<sup>8, 17, 19, 21</sup> Furthermore, degradation after acid etching and presence of tunnel defects through reparative dentine bridge.<sup>8, 16, 19</sup> Due to these drawbacks of chemical-cure Ca(OH)<sub>2</sub>; a light-cured,

single component liner contains calcium hydroxide and is polymerized by visible light was introduced in 1988 with improved strength, no solubility in acid, and minimal solubility in water.<sup>22</sup>

Various other materials have been introduced into a dental practice and are used as pulp capping agents such as glass ionomer, resin-modified glass ionomer cements and adhesives, and calcium-silicate materials (CSMs).<sup>2, 16</sup> CSMs are recent bioactive materials that can induce regenerative responses in the human body and form hard tissue dentine bridge.<sup>13, 16</sup> These materials are superior in biocompatibility, and sealing of the pulp capped site, and result in more predictable clinical outcomes.<sup>13, 16</sup> An example of these materials is mineral trioxide aggregate (MTA),<sup>16</sup> that has gained an excellent reputation and commonly recommended and preferred by dentists.<sup>23</sup> The second generation of these CSMs are; Biodentine and TheraCal LC.<sup>1, 2</sup> Biodentine is new bioactive tricalcium silicate-based cement, designed to be used as a permanent, biocompatible dentine substitute and stimulates pulp cells to form tertiary dentine.<sup>2</sup> TheraCal LC is a light-cured flowable resin-modified calcium silicate material introduced by Bisco Inc. Schaumburg, IL, USA in 2011, designed to overcome the weaknesses of the previous generation such as poor bonding of CSMs to resin restorations. It is used as direct and indirect pulp capping material that enables the immediate application of final restoration.<sup>1, 2</sup> TheraCal bonds to deep moist dentine, and performs as a barrier and protectant material of the pulp-dentine complex underneath composite, amalgam, and cement.<sup>24</sup> Hence, it acts as a suitable replacement for Ca(OH)<sub>2</sub>, and several other pulp capping materials.<sup>16</sup> TheraCal displayed strong physical properties, high radiopacity, and lower solubility than either ProRoot MTA or Dycal.<sup>1</sup> The aim of this clinical study was to evaluate the success rate of IPC treatment using three materials namely; Dycal, Biner LC, and TheraCal LC in permanent posterior teeth with deep carious lesions.

**2. MATERIALS AND METHODS**

Detailed descriptions and composition of materials used in the study are listed in Table 1.

**Table 1:** Description and composition of the materials used in the study

Material	Components*	Manufacturer
Dycal® Ivory	<b>Base:</b> disalicylate ester, butylene glycol; calcium phosphate; calcium tungstate; zinc oxide; iron oxide. <b>Catalyst:</b> calcium hydroxide; ethylene toluenesulfonamide; zinc stearate; titanium dioxide; zinc oxide; iron oxide.	Dentsply
Binar LC	UDMA resin, calcium dihydroxide, dimethylaminoethyl-methacrylate, barium aluminium silicate, TEGDMA. photoinitiator.	Voco GmbH, Cuxhaven, Germany
TheraCal LC	CaO, calcium silicate particles (Portland cement type III), Sr glass, fumed silica, barium sulphate, barium zirconate, Bis-GMA, HEMA, and PEGDMA.	Bisco Inc., Schamburg, IL, USA
Filtek™ Z250 XT	Zirconia/silica 20 nm, fillers loading 82% by weight. Bis-GMA, UDMA, Bis-EMA, TEGDMA, and PEGDMA.	3M ESPE
Adper™ Single Bond 2	10% by weight 5nm colloidal silica nanofiller. Bis-GMA, ethanol, water, photoinitiator, polyacrylic and polyitaconic acids, HEMA.	3M ESPE

\*According to manufacturers' technique profiles: Bis-GMA: Bisphenol-A-glycidyl dimethacrylate; UDMA: Urethane dimethacrylate; Bis-EMA: Bisphenol A ethoxylate dimethacrylate; TEGDMA: Triethylene glycol dimethacrylate; PEGDMA: Polyethylene glycol dimethacrylate; HEMA; 2-hydroxyethyl methacrylate. CaO: calcium oxide

### Study design:

A randomized clinical trial was conducted at Al-Raja Dental Clinic in Benghazi City. A total number of 200 posterior permanent teeth with deep carious lesion indicated for indirect pulp capping treatment from 130 adult patients were selected in this study. Informed consent from the patients was obtained after giving a brief explanation of the kind of investigation and the clinical procedure that was to be conducted. Inclusion criteria included both genders, age 18 to 55 years old having premolars or molars teeth with a deep carious lesion on the occlusal or occluso-proximal surface with no pain or with very mild sensitivity to cold or discomfort when chewing. Preoperative radiograph shows deep carious lesion extending greater than two-third of dentine thickness approaching pulp,<sup>11</sup> but with a definite radiodense region between the deepest part of caries lesion and the pulp.<sup>25</sup> Teeth with clinical symptoms of irreversible pulpitis, a history of prolonged spontaneous pulpal pain were excluded. In addition, teeth with pulp necrosis or with a negative response to pulp tests, mobility, tender on percussion, presence of swelling, or fistula were also excluded. Furthermore radiographically; if teeth show the presence of periapical or furcation area radiolucency,<sup>11</sup> periapical pathologies, internal or external root resorption, absence of a normal appearance of the periodontal ligament, were also excluded from the study.

### Clinical procedures:

A thermal vitality test was done to testify tooth sensitivity; after removal of the stimulus, the response rapidly disappeared. A preoperative periapical radiograph was taken for each patient to assess penetration depth and the extent of the caries lesion, as well as the thickness of the remaining dentine overlying the pulp chamber. All the clinical procedures were performed by the standard method of IPC treatment under a rubber dam. After clinical examination and radiographic assessment, local anesthesia was administered. A sterile diamond bur suitable to the size of the cavity in a high-speed handpiece was used for cavity preparation under constant water cooling. Caries tissue was removed completely from the lateral walls and cavosurface margins of the cavity preparation. Excavation of carious dentine included removal of all active demineralized carious tissue from the peripheral sites to the center or the deepest part of the lesion. Not to mention that it is usually at the pulpal floor or the axial wall in the case of the class II cavity. Selective caries removal was performed with the cautious excavation of soft, wet, and necrotic caries tissue reaching to a non-soft, relatively firm dentine, accompanied by visual inspection and tactile sensation to avoid pulp exposure. A hand instrument spoon excavator was used to remove necrotic fragments of caries tissue followed by a round bur in a low-speed handpiece under water coolant. A new sterile bur is replaced when approaching the deeper area of the caries lesion, to reduce the number of microorganisms in the cavity and to avoid the introduction of infected dentine into the pulp which might lead to irreversible inflammation and treatment failure.<sup>26, 27</sup> The cavity was then washed with normal saline and gently dried. Teeth were then randomly assigned into three groups; Gp:1, Gp:2, and Gp:3 according to the material used for pulp capping. Gp1 consists of 67 teeth allocated to receive treatment with Dycal (chemical-cured radiopaque Ca(OH)<sub>2</sub>). Dycal is available as a two-paste system; a catalyst paste and a base paste. It was mixed with equal quantities of both the catalyst and the base to a homogenous paste and applied with a dycal applicator directly over the deepest spots of

the dentine on the pulpal floor of the cavity preparation. The excess dycal material was removed from the surrounding cavity walls and enamel margins. Gp 2 consists of 68 teeth and treated with Biner LC (Light-curing radiopaque one-component cavity liner containing Ca(OH)<sub>2</sub>). It was applied to the deepest spots of the pulpal floor and then light-cured according to manufacturer instructions. TheraCal LC (Light-curing, resin-modified calcium silicate filled liner) was applied in Gp3 similarly as of Gp2, and consists of 65 teeth. Biner LC and TheraCal LC are supplied by the manufacturer in syringes and disposable tips and requiring no preparation before use. Excess material was removed while still soft and before light curing. The randomization procedure was performed as follows; a number corresponding to each IPC treatment group was written on a piece of paper and kept in a closed box. A paper was selected from the box by a person other than the operator, and the treatment indicated was carried out.<sup>2</sup> The bonding and restorative procedures were performed likewise for the three investigating groups as followed; The cavity walls and margins were acid etched with 37% phosphoric acid semi gel (Meta Biomed Co Ltd., Korea) according to the manufacturer's instructions, then thoroughly rinsed off with water and gently air-dried using compressed air without desiccation. Bonding agent Adper™ Single Bond 2 Adhesive (3M ESPE) was applied with a microbrush in two consecutive layers. A gentle stream of air was applied from an air syringe to allow evaporation of the solvent then light-cured for 10 seconds with LED light-curing unit (Mini LED, Satelec, France). For class II cavity preparation, a Tofflimire retainer with a matrix band was placed before acid etching and bonding procedures. Nanohybrid resin composite restorative material Filtek™ Z250 XT (3M ESPE) was incrementally packed in the cavity preparation. Each increment was polymerized for 20s using the same LED light-curing unit. The occlusal adjustment was then performed in maximum intercuspation and eccentric movements. The identified high spots were carefully removed using extra-fine grit diamond burs EX-17EF, FO-23EF (Toboom Shanghai Precise Abrasive Tool Co., Ltd) with water coolant, and then polished with polishing tips to eliminate any surfaces scratches (Enhance Dentsply Caulk). After completing the treatment, the patient was instructed about preventive measures and maintenance of oral hygiene.

At follow-up evaluation, a detailed clinical examination was performed for every patient at 8 weeks, 6 months, and one year intervals. Periapical radiographs were taken at the end of the clinical trial. However, the patient who returned to the dental clinic with pain or any sign of treatment failure, a periapical radiograph was taken for him/her to evaluate the restoration and periapical region that could be attributed to a failure of the treatment.<sup>20</sup>

The clinical success of the treatment was evaluated by the following criteria: intact restoration, positive (normal) response to cold pulp test, absence of prolonged spontaneous pain, no tenderness on percussion or palpation, no tooth mobility, no abscess or swelling of periodontal tissues of the treated tooth.<sup>9, 14, 28</sup> On radiographic examination; the success of the treatment included intact lamina dura, no periapical radiolucency, no internal or external root resorption.<sup>14, 28, 9, 20</sup> Any tooth presented with one of the above-mentioned criteria was recorded as treatment failure and was root canal treated, or replacement of the restoration when indicated. One tooth was restored at each clinical visit. Restorative treatments, clinical

and radiographic evaluations were performed by the same operator.<sup>14</sup> The data were statistically analyzed using SPSS software (version 16, SPSS Inc. IBM Corp. Chicago, USA). Chi-Square test was applied and the level of significance was set as  $P < 0.05$ .

### 3. RESULTS

At the beginning of the study, 213 teeth received IPC treatment. By the end of the one year, 13 patients were lost to follow up. Hence a total of 200 experimental teeth were evaluated. The mean age was  $30.7 \pm 8.4$  yrs. The numbers of female and male patients were 102 (78.5%) and 28 (21.5%) respectively. From all teeth included in the study, 150 (75%) were molars and 50 (25%) were premolars. Among those, the upper right first molar and lower left second molar received the highest number of restorations; 23 (11.5%) and 22 (11%) respectively (Figure 1). Additionally, 70 (35.5%) restorations were class I, and 129 (64.5%) were class II. A total of 67 (33.5%) teeth treated with Dycal, 68 (34%) teeth treated with Biner LC, and 65 (32.5%) teeth received TheraCal LC.

Statistical analysis revealed no significant differences in the success rate of IPC between the three investigated groups using three pulp capping materials ( $P > 0.05$ ) (Table 2). Clinical and radiographic evaluation revealed that the success rate of IPC treatment at one year evaluation period was 97% for Dycal (GP1), where 56 teeth considered successful and only 2 teeth (3.0%) were failed. These two teeth are UR4 presented with pain during the 8-weeks evaluation period and went for root canal treatment (RCT), and UL6 attended at a one year evaluation period with fractured restoration. The success rate for Biner LC (Gp2) was 97.1%; where 66 teeth were considered successful. Two teeth (2.9%) recorded failure; UL5 and LL6 and hence root canal treated. Whereas for TheraCal (Gp3); the success rate was 98.5%. Sixty-four teeth treated were considered successful and only one tooth (1.5%), UL5 reported failure, and went for RCT. In general, all the failed teeth belonged to class II cavity preparations, in which three of them were premolars and two teeth were molars. Radiographic examination at the end of one year evaluation period exhibited intact lamina dura, absence of periapical radiolucency, no internal or external root resorption.

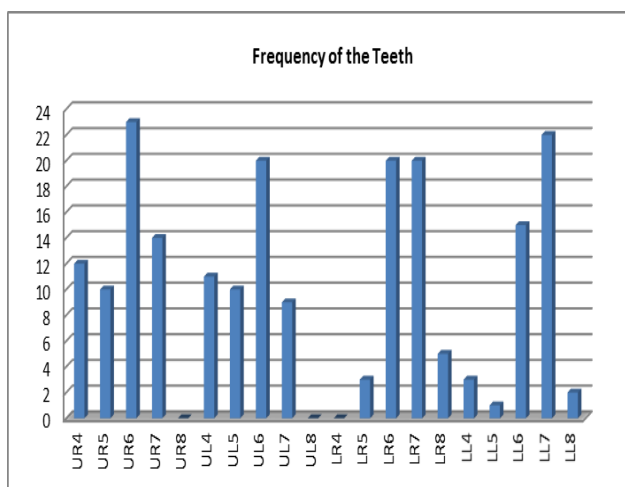


Figure 1: The number and frequency of all restored teeth with the three pulp capping materials

**Table 2:** Results of the success and failure of the three IPC materials

Pulp capping materials (Group)	N	Success	Failure	P-value
Dycal (Gp1)	67	65 97.0%	2 3.0%	0.833
Biner LC (Gp2)	68	66 97.1%	2 2.9%	
TheraCal (Gp3)	65	64 98.5%	1 1.5%	
<b>Total</b>	200	195 97.5%	5 2.5%	

### 4. DISCUSSION

Management of deep caries lesion is an area of continuous amendment and challenge to the dentists, in terms of which treatment will produce the best outcomes and excellent prognosis which is the preservation of pulp vitality of the tooth with no apical pathology.<sup>29</sup> Deep caries can be recognized by two layers: infected dentine which is a superficial layer of soft demineralized destructive dentine tissues infiltrated with a large number of bacteria and denatured collagen fibrils that cannot be remineralized; and the other layer is the affected dentine, which is a deeper layer of partially demineralized dentine with intact collagen fibrils that can be remineralized.<sup>30, 31</sup> It is hard to differentiate exactly these two layers in the clinical reality. However, using some indicators such as the color and consistency of the decayed dentine as well as the operator skills and clinical experience to make the good decision for excavation of the infected dentine, leaving only the affected dentine to avoid pulp exposure.<sup>32, 33</sup> Yet, if the pulp happens to be exposed and infected during caries removal, a successful outcome will be reduced.<sup>29</sup> Therefore, a conservative procedure has been suggested to avoid pulp exposure by using the indirect pulp capping (IPC) treatment, which can be either a one-step or two-steps clinical procedure.<sup>34</sup> It has been suggested to apply a cavity liner and/or base if caries extends close to the pulpal tissue<sup>7, 30, 31</sup> i.e. when the remaining dentine thickness (RDT) is  $\leq 0.5$  mm, as a protective layer under the final restorations and to coat the innermost layer of caries-affected dentine to induce remineralization<sup>7, 12, 20</sup> In the current clinical trial a one-step (one-visit) IPC treatment under controlled isolation was performed. The choice for IPC was based on a careful pulp diagnosis with proper evaluation of the pain history, symptoms, clinical and radiographic findings.<sup>15</sup> In addition, selective and cautious caries removal was done with expectations that reparative dentine would be formed, demineralized dentine would be remineralized, and the number of viable bacteria would be reduced, thus caries lesion is arrested.<sup>3</sup> Evidence has been shown that the two clinical visits IPC treatment would not be necessary, because, through the second visit, the treatment procedure increased the risks of pulp exposure.<sup>35</sup> Additionally, some patients do not attend the second clinical visit which might result in partial or total loss of the temporary filling and therefore failure of the treatment<sup>9</sup> This would add extra cost, time, and discomfort to the patient, and would thus be

detrimental to pulpal health<sup>9, 33, 35, 36</sup> The IPC treatment for each patient was firstly evaluated after 8 weeks, based on the fact that the evaluation period of 8- to 12- weeks post-treatment is considered sufficient period to promote remineralization of carious dentine and pulp recovering<sup>26, 37</sup> In their study, the investigators found a statistically significant increase in total mineral content in the testing samples with a qualitative increase in radiopacity of the calcium hydroxide<sup>26</sup>

In the current study, few cases reported failures among the three investigated groups; Dycal, Biner LC, and TheraCal LC treated teeth. The main reason for the failure could be attributed to a non-diagnostic inflammation in the pulp that could not be precisely diagnosed before starting the treatment. On several occasions, dentists find difficulty in evaluating the true clinical status of the pulpal tissue underneath deep caries lesion, which sometimes makes it hard to reach a precise and accurate diagnosis of pulpal health. In this context, it has been documented that the correct and accurate “gold standard” of pulp health status is the histological analysis, and cannot be determined by clinical signs, symptoms, or radiologic appearance<sup>8</sup> Instead, Bjørndal<sup>38</sup> in 2008 reported that there was no reliable method to determine the degree of pulp inflammation in deep carious lesions, which is the main reason why successful treatment of deep caries is still uncertain. It is worth mentioning that all failure teeth belonged to class II cavity preparations. The multi-surface restorations such as class II (DO, MO, and MOD) produced inferior results compared with one-surface restorations such as Class I occlusal cavity, which is established in a previous study.<sup>39</sup>

Regarding the dycal treated teeth; it has been documented that the older Ca(OH)<sub>2</sub> formulations do not provide a long-term biological seal, protection, and permanent barrier against bacterial infection and microleakage. Because Ca(OH)<sub>2</sub> cement dissolve within 1–2 years, and tunnel defects in the majority of the reparative dentin bridges underneath the capping material.<sup>2, 19</sup> However, according to Accorinte et al.,<sup>40</sup> by the time the Ca(OH)<sub>2</sub> is vanished due to dissolution, dentine bridge has formed. Yet, in the present study up to a one-year follow-up period dycal treated teeth (Gp1) exhibited a high success rate (97%). Dycal has been widely used and commonly preferred in clinical practice as a pulp capping material with the longest track record of clinical success.<sup>8</sup> The high success rate observed with dycal treated teeth could be attributed to its effect on pulp repair by one or more of several mechanisms of action.<sup>8</sup> It is an alkaline material, biocompatible, induces remineralization, and reduces the risk of bacterial infection.<sup>2, 41</sup> In addition to the ability of Ca(OH)<sub>2</sub> to release hydroxyl (OH) and calcium (Ca) ions upon its dissociation into the surrounding environment.<sup>17, 42</sup> These ions caused a chemical injury that stimulates the pulp to perform a defense mechanism where the undifferentiated cells within the pulp distinguish into odontoblasts that form a hard mineralized tissue as a reparative dentine.<sup>42</sup> According to Murray et al.,<sup>43</sup> Ca(OH)<sub>2</sub> liners mediate and maintain the health and vitality of the underlying odontoblasts survival for the deposition of reparative dentine when the RDT is ≤0.5 mm. Furthermore, the hydroxyl ions diffuse into the dentine and create an alkaline pH level, which is an unsuitable environment for remaining bacteria in the cavity, therefore penetration of bacteria into the pulp is minimized.<sup>8, 18, 21</sup> In this context, the high pH of Ca(OH)<sub>2</sub> destroy the bacterial cell membrane and protein structure, and thus sufficiently terminate the residual

bacteria.<sup>17, 19</sup> This may explain the high success rate and the few numbers of failures among this investigating group, which is in agreement with other studies who reported a high success rate with Ca(OH)<sub>2</sub> ranging from 70% to 91%.<sup>9, 20</sup>

Biner LC treated teeth (Gp2) also exhibited a high success rate (97.1%). There were only two teeth reported failures (2.9%) soon after treatment and therefore root canal treated (RCT). Biner LC is a visible light-cured (VLC) liner flow on-demand, easy handling, and dispensing, consists of calcium hydroxide and barium sulfate dispersed in a urethane dimethacrylate resin containing initiators and accelerators activated by visible light.<sup>22</sup> The polymeric resins of this material permit a good bond with the overlying composite restoration, and also reported to be compatible with adhesive systems, dentine, and pulp.<sup>21, 22</sup> However, Gandolfi et al.,<sup>13</sup> found that the amount of calcium released by VLC liner was very small compared to that released by the dycal. Nevertheless, other studies reported that the results of pulp capping with different adhesive resin-based systems are nearly equal to those with Ca(OH)<sub>2</sub> in dentine bridge formation.<sup>44</sup> It has been suggested to use VLC Ca(OH)<sub>2</sub> liner as indirect pulp capping material underneath all types of restorations, and if a dentine bonding agent is preferred to be used, the VLC liner should only be applied on the deepest dentine leaving the rest of the cavity surface free for bonding.<sup>17</sup>

Only one tooth (1.5%) reported failure with TheraCal LC treated teeth, which consider a very high success rate (98.5%) of the treatment. This material is recently available in the market, designed for use in indirect and direct pulp capping. The main advantages of this material are the high biocompatibility, bioactivity property, and intrinsic osteoconductive activity which is the ability to induce a biological and regenerative response in the human body, resulting in the formation of a bond between the material and the tissue which is the dentine bridge of improved quality and superior sealing ability of the pulp capped site.<sup>2, 13, 24</sup> Additionally, TheraCal LC consists of tricalcium silicate particles in a hydrophilic monomer that displayed higher and significant calcium release and lower solubility than Dycal making it a stable and durable material as a liner or base.<sup>24, 32</sup> These good properties could clarify the excellent results obtained with TheraCal treated teeth in this study. On the other hand, this material is “white” in color and opaque hence it should be placed in a thin layer so as not to show through composite materials and affecting the shade of restoration.<sup>16</sup>

Since this material has been recently presented to the dental practitioners and researchers, only a few clinical studies were evaluating its performance, and the majority of them were investigated primary teeth, or when TheraCal was used as direct pulp capping. Clinical studies have shown that TheraCal LC can encourage reparative dentine and dentine bridge formation when used as direct and indirect pulp capping material.<sup>45, 46</sup> Another study reported that all experimental teeth (20) treated with TheraCal LC remained vital after 2 years.<sup>47</sup> Petrolo et al.,<sup>48</sup> found that most vital teeth were seen in the TheraCal group after a 2 years evaluation period when they investigated the effects of TheraCal on pulp with a self-etching adhesive system.

It is worth mentioning that very few teeth reported failures with resin-contained pulp capping materials; i.e. Biner LC and TheraCal LC. Literature reported that the components of the adhesive resin-based liners are found to be toxic in cell cultures

which may threaten the pulp in the short-term,<sup>49</sup> in addition to the temperature rise during photopolymerization of these materials.<sup>50</sup> It has been documented that the presence of resin in the components of pulp capping material which may remain unpolymerized is often accompanying by adverse pulpal reactions that lead to pulp toxicity and inflammation even in the absence of bacteria.<sup>49, 51</sup> Thus inflamed pulp due to caries would have decreased healing capability.<sup>49</sup> Moreover, TheraCal could induce adverse pulpal effects when applied in pulp capping procedures despite the low heat generation of the photopolymerization process.<sup>50</sup> These are the possible explanations for the failures that occurred with the resin-contained pulp capping materials though they were very few cases.

A high success rate of IPC treatment was observed among the three experimental groups regardless of the material used throughout the study. This success can be principally related to several factors such as; the careful selection of the cases, proper pulpal diagnosis, adequate and proper excavation of caries infected dentine, good isolation, and prevention of contamination. In addition to a good choice of IPC medication as well as the restorative material used for the permanent restoration.<sup>32, 52</sup> The good quality bond between the restorative material and tooth structure which in turn provide an effective seal of the lesion from the oral environment is very important to prevent bacterial substrate infiltrating into the dentine and to control the progression of caries.<sup>8, 52</sup> Studies have demonstrated a significant decrease in the count of bacterial under sealed restorations.<sup>41, 53</sup> In addition, other studies have reported that; clinical, radiographic, and microbiological evaluations have demonstrated that sealing the cavity properly could lead to arrest the deep active carious lesions even when inert materials such as wax or gutta-percha were used as liners.<sup>54, 55</sup>

Finally, it is sensible to consider that pulp capping material individually did not influence the clinical success of treatment for deep caries lesions of permanent teeth, which is also specified in the Cochrane review that indicated that the difference in base materials did not show any changes.<sup>29</sup> It's a combination of several factors as mentioned formerly in the discussion section which is in agreement with other studies.<sup>3, 7, 20, 32</sup> In addition to the correct diagnosis of the health status of the pulp before starting the treatment and maintain the pulp vitality after treatment.

## 5. CONCLUSIONS:

Within the limitations of this study, the following conclusions can be drawn: IPC treatment maintained the pulp vitality and function of the restored permanent teeth, and that the success of IPC treatment seen in the present study is independent of the pulp capping material. Proper and careful case selection included healthy pulp and correct pulpal diagnosis, good isolation, a good marginal seal of the cavity preparation with a suitable restoration are important factors for successful treatment. All three materials were exhibited a high success rate and found to be very successful as IPC agents, however, TheraCal LC seems promising material and exhibited the best results up to a one year follow-up period. Additional research including controlled clinical studies with larger sample size and longer-term follow up evaluation periods is required to better assess and understand the clinical performance and efficiency of these relatively new materials in the long run.

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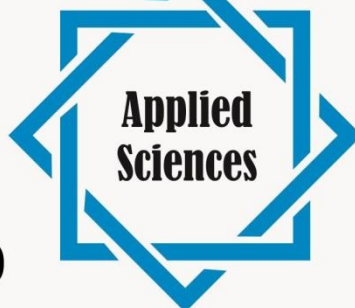
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