

# Prognostic factors evaluation for clinical outcome after indirect pulp capping using Hydrocal LC and Biner LC – an in-vivo study

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**Abstract- Aim:** This study aimed to evaluate the prognostic value of factors with regard to the treatment outcome of indirect pulp capping using Biner LC (METABIOMED Co. LTD) and Hydrocal LC (Medicept Co. Ltd) in permanent posterior teeth having Remaining Dentin Thickness (RDT) of less than or equal to 1.5 mm. **Material and method:** 42 teeth with deep carious lesions and RDT of  $\leq 1.5$ mm underwent indirect pulp capping. Patients were randomly divided into Biner LC and Hydrocal LC groups (n=21 in each group). The patients were followed up at interval of 1 week, 1 month, 3 months and 6 months with a routine examination on all recall visits. Periapical radiographs were taken, lack of patient complaints, positive reactions to electric pulp testing, no sensitivity to percussion, and no widening of the periapical ligament indicated success.

**Statistical Analysis:** The results were analysed via One way ANOVA test, Chi square test and Paired t- test in SPSS version 27.0 software.

**Results:** The overall success rate of IPC in the present study was 95.45% at the end of 6 months. There was no significant difference in the outcome between the Biner LC and Hydrocal LC groups ( $P \leq 0.05$ ), suggesting that both the materials are equally effective as an IPC agent. Factors such as the patient's age and status of the pulp can be considered as prognostic factors in the IPC procedure.

**Conclusion:** This study has shown that Hydrocal LC is equally effective in IPC when compared to Biner LC and has higher viscosity and lower time of light curing, unlike Biner LC. Factors such as the patient's age and status of the pulp can be considered as prognostic factors in the IPC procedure.

**Clinical Significance:** The results of the present study strongly confirms the tendency towards less vigorous caries removal in a more biological, pulp-preserving approach.

**Keywords:** Indirect pulp capping, Hydrocal LC, Biner LC, Remaining Dentin Thickness (RDT)

## INTRODUCTION

Pulpitis is the inflammation of the dental pulp. Potential pathways for pulpal inflammation are dental caries, trauma, dentinal cracks, exposed dentinal tubules or the main apical foramen.<sup>1,2</sup>

Pulpitis can be reversible and irreversible based on the extent of the lesion in pulp. *Reversible pulpitis* means pulpal inflammation which resolves once the etiology is removed and patients shows symptoms like non-

lingering pain or sensitivity to temperature or osmotic changes.<sup>3</sup>

It can be diagnosed through case history, clinical and radiographic examination<sup>4</sup> where clinical examination includes different procedures such as inspection, pulp sensitivity to thermal or electric stimuli, and tenderness on palpation or percussion<sup>4</sup> and radiographically estimation of remaining dentin thickness (RDT) is necessary for protection of the dental pulp against injury or inflammation.<sup>5</sup> It is an important factor to ensure long-term clinical success in pulpal protection.<sup>6</sup>

Healthy pulp has a crucial role throughout the life of a tooth due to the various responses elicited by the pulp to different stimuli of biological and pathological origin leading to the production of peritubular, secondary, and reparative dentin.<sup>7</sup> Retention and maintenance of the pulp is an important aspect in the management of deep carious lesions.<sup>8</sup>

Treatment planning to resolve reversible pulpitis includes removal of the irritant, repair tooth structure, vital pulp therapy and continue to monitor the patient's symptoms.<sup>3</sup> Vital pulp therapy should always be the treatment of choice in teeth with healthy or reversibly inflamed dental pulp. The long-term survival rate of any tooth after undergoing any vital pulp therapy increases tooth's life.<sup>9,10</sup>

Indirect pulp capping (IPC) procedure form of vital pulp therapy is used in deep cavity preparations, with or without carious dentine remaining which is in close proximity to the pulp but showing no visible pulp exposure.<sup>11,12</sup> Placement of liners and bases on the unexposed pulp to maintain its health and to stimulate defensive repair by tertiary dentine deposition.<sup>13</sup> Cavity liner is a cement or resin coating with minimal thickness (usually <0.5 mm) to achieve a physical barrier to bacteria or a therapeutic effect.<sup>14</sup>

Calcium hydroxide [Ca(OH)<sub>2</sub>] cements are the most suitable agents for direct and indirect pulp capping which have the ability to release hydroxyl (OH) and calcium (Ca<sup>2+</sup>) ions upon dissolution. Its alkaline pH (pH 9–11) stimulates the formation of secondary/reparative dentin in direct contact with the pulp.<sup>15,16</sup>

For IPC procedure RDT should be of 0.5mm or more upto 2mm to protect the pulp tissues from cytotoxic injuries via calcium hydroxide liner.<sup>17</sup>

To overcome the limitation of the self-cure Ca(OH)<sub>2</sub> cements like high solubility within 1–2 years after

application in tissue fluids which fail to provide a permanent seal against bacterial entry,<sup>18,19</sup> a visible light-cured (VLC) calcium hydroxide liner is introduced.<sup>20</sup>

It consists of calcium hydroxide and barium sulfate dispersed in a urethane dimethacrylate resin alongwith initiators and accelerators activated by visible light<sup>20</sup> It is based on polymeric resins which allows for bonding between (VLC) calcium hydroxide liner and the overlaying composite restoration.<sup>21,22</sup>

Advantages of light cured materials are they set on command, improved strength, essentially no solubility in acid, and minimal solubility in water.<sup>21</sup>

Two light cure calcium hydroxide based liners Biner LC (METABIOMED CO., LTD) and Hydrocal LC (Medicept Co.LTD) are used. Both are light cured, radiopaque and containing hydroxy calcium phosphate in a urethane dimethacrylate resin.<sup>23,24</sup>

Hydrocal LC was found to be the highest Ca<sup>2+</sup> ion-releasing materials among other light cured calcium hydroxide liners.<sup>25</sup> This study aims to evaluate the long-term outcome of Biner LC over Hydrocal LC as an IPC material. The secondary objective of the study is to make patients painfree before getting into irreversible pulpitis leading to pulpectomy procedure.

## MATERIAL AND METHODOLOGY

CTRI number: CTRI/2024/01/061916

Institutional ethical committee number: CDSRC/IEC20210404/29

This prospective, randomized parallel group study was conducted between June 2022 and February 2023 in the Department of Conservative Dentistry and Endodontics, collage of Dental Sciences and Research Center (CDSRC) bopal, Ahmedabad, Gujarat, India. The study was approved by the Institutional Ethics Committee of College of Dental Sciences and Research Centre. A total of 42 patients having complaint of food lodgement and sensitivity were taken as subjects from Department of Conservative Dentistry and Endodontics, CDSRC, Bopal.

Sample Size Calculation:

The selection of teeth for both the groups were done randomly with the help of physical method of simple random selection<sup>8</sup>. The 'Flipping Coin' physical method was used in this study to distribute samples randomly in both groups.

Patient Selection Criteria:

Inclusion criteria:

- Age  $\geq$  18 years
- Posterior teeth with mature root and healthy periodontium having occlusal (Class-1) or proximal (Class-2) deep carious supragingival lesion (Classification of caries followed GV Black classification)
- EPT score should be suggestive of vital pulp according to the scoring criteria of coxo C-pulse pulp tester (Score 0-30 = Vital teeth)
- Teeth having score 1 (Normal Periapical Structures) in periapical radiographic view (according to Periapical Index score system of Orstavik et al)
- Radiographical depth of carious lesion with RDT = 0.5 to 1.5 mm measured through Endo-prep application (accepted by Australian Academy of Endodontics)

Exclusion criteria:

Subjective exclusion:

- Teeth with pulp exposure
- Sinus opening
- Mobility
- Cracked tooth

Radiographic Exclusion:

- PDL widening
- Periapical lesion
- Furcal radiolucency
- Internal/External resorption
- RDT =  $<0.5$  mm or  $> 1.5$  mm

Method:

If all inclusive criteria matched then informed consent was obtained from the participants before enrolling them in the study. And patient was being explained about the whole procedure and they were blinded about the type of material being used. Forty-two patients were recruited for the deep caries

management. RVG (Vatech Digital Intraoral RVG EZ Sensor Classic, South Korea) was taken in bisecting angle technique for all patients and RDT was measured using Endoprep App (Dental Sciences Australia Pty Ltd) after clinical examination and EPT score measurement for examining pulpal condition was done through Coxo C-Pulse Pulp Tester.

For this study, Class -1 and Class - 2 cavities (according to GV Black classification) were included in this study. Caries excavation and pulp capping was started after anesthetizing the tooth using lidocaine 2% with adrenaline 1:80,000 (Indoco Warren Lignox Lignocaine 2%) and rubberdam (Hygienic; Coltene/Whaledent Inc, Cuyahoga Falls, OH) application. Caries removal was done using high speed airtoror (Galaxy Airtor Standard Head Handpiece) along with round diamond bur no. (Mani Diamond round bur no. BR- 31) under running water leaving a layer of affected dentin on the cavity floor.

Now, caries detecting dye (Prevest Reveal Caries indicator Dye) was applied in the cavity to check the presence of remaining infected dentin which was removed using slow speed micromotor (Marathon M4 Micromotor Handpiece) along with carbide round bur no.4. alongwith continuous water flow and rest of the remaining soft infected dentin was removed using spoon excavator (API Spoon Excavator, Ashoosons). Dye was applied upto tooth stop showing presence of any infected dentin. The allotment was done until there were 21 teeth in each group.

Then, pulp capping material (Medicept Dental Hydrocal LC and META-BIOMED Biner LC) from preloaded syringe was placed on the cavity floor in their respective groups was cured using LED light (Woodpecker LED D Curing Light Unit) for 20sec. After that GIC (3M ESPE ketac molar glass ionomer) was manipulated according to manufacturer's instructions using agate spatula and it was placed as a restorative material using plastic filling instrument (API Plastic Filling Instrument). (as shown in figure 1)

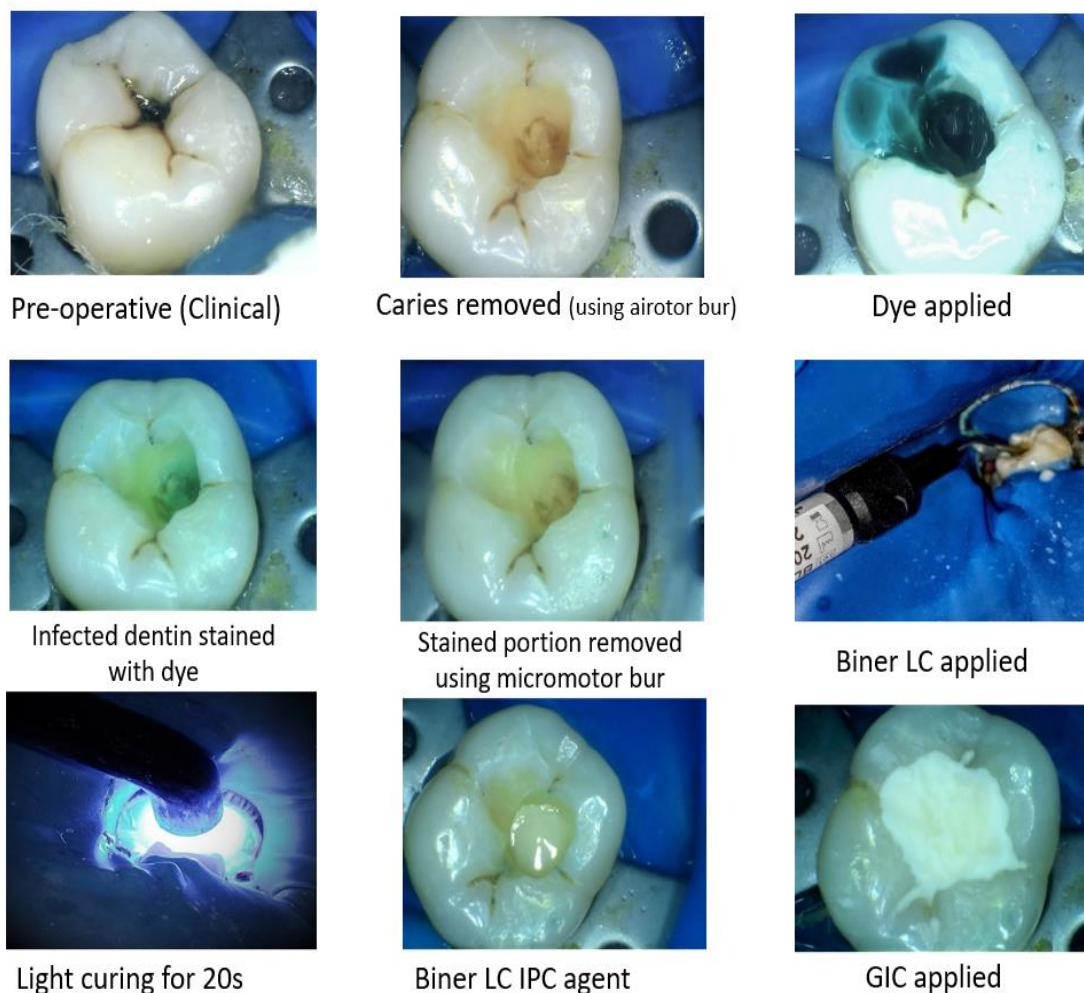


Figure 1: Steps of Indirect Pulp Capping Procedure

Then, cavity varnish (Prevest Denpro Copal, F Cavity Varnish with, fluoride) was applied over GIC restoration.

During the recall visit after 1 week [as shown in fig. 2], RVG was taken to check for furcal radiolucency, root resorption or PAI score and clinically margin's of restoration were checked using explorer, tenderness to percussion and palpation and on absence of above all parameters, GIC was reduced to base and then composite resin (Tetric-E-Ceram Bulk Fill; Ivoclar-Vivadent, Schaan, Liechtenstein) restoration was placed on it and open sandwich technique was done in Class-2 cavities.

A single operator performed the clinical procedure alongwith radiographical evaluation. Before radiographical evaluation, the operator was trained through a session that consisted of comparing few intraoral periapical radiographs representing each of

the 5 PAI scores to the corresponding schematic and radiographic representation.

Patients were recalled at 1 month, 3 months, 6 months interval and clinical and radiographical tests was repeated at every visit and readings were entered in data entry sheet as shown in figure 2. During the clinical and radiographical evaluation, the changes in the periapical and clinical status were recorded, and any disagreement on clinical and radiographical report resulted in joint evaluation until an agreement was reached.

The cases that presented with no history of spontaneous pain or discomfort on chewing, no tenderness to percussion/palpation, absence of furcal radiolucency and root resorption, margins of the restoration were intact and healthy soft tissues around the tooth with no swelling or sinus tract were considered clinically successful.

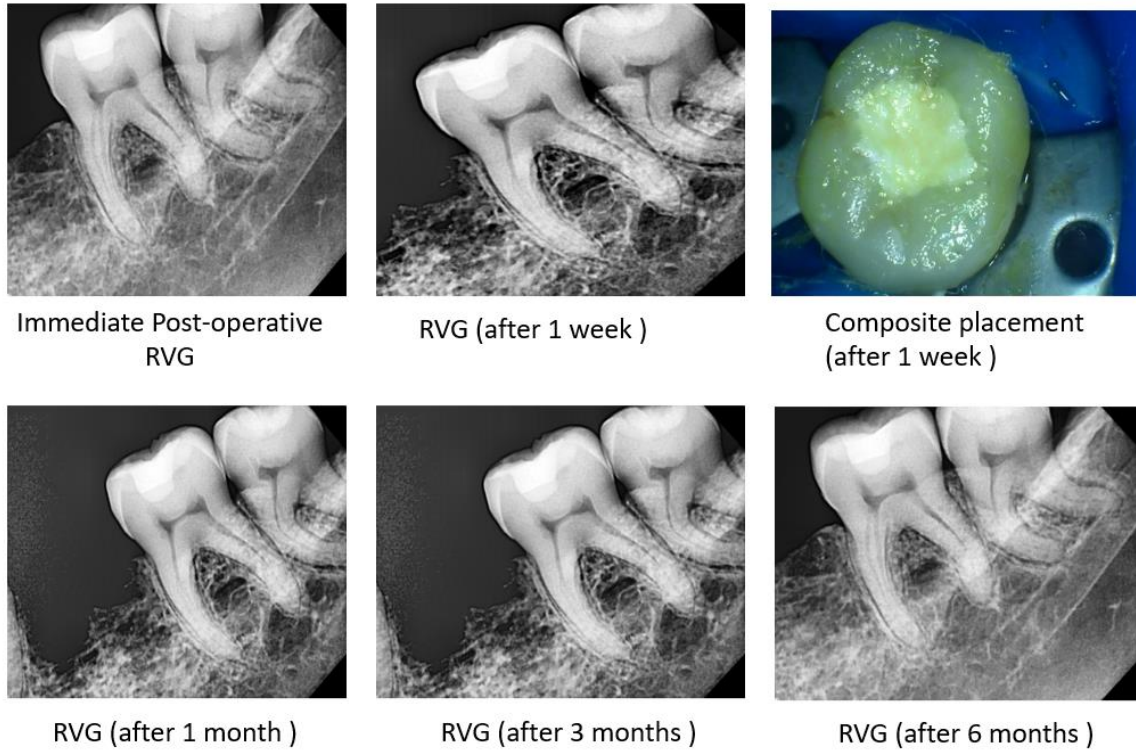


Figure 2: Immediate post operative and follow up radiographs alongwith composite placement after 1 week of procedure completion

STATISTICAL ANALYSIS

The data were collected and analyzed by SPSS Version 27.0 was used to analyze the data. Association among the variables (age, gender, EPT results and pulp capping agents) was examined using the Pearson’s Chi square test, One way ANOVA test and Paired t- test and a P-value of less than 0.05 was considered statistically significant. (P < 0.05).

RESULTS

A total of 42 maxillary and mandibular molars (21 cases for Hydrocal LC and 21 cases for Biner LC) were evaluated. These teeth were examined using various protocols like –

- Tenderness on percussion and palpation
- Pulp sensibility test (EPT score)
- Radiographical success (based on absence of furcal radiolucency, root resorption or PAI score) including 19 males and 23 females. Out of 42 participants, 45.8% were male and 54.8% were female.

Table 1: shows that statistically non-significant difference was observed for in between and within study group comparisons for EPT results pre-operatively, post 1 week, post 1 month and post 3 months. A statistically significant difference was observed for in between and within study group comparisons for EPT result post 6 months.

EPT	STUDY GROUP	N	Mean	Std. Deviation	Lower Bound	Upper Bound	f value	P value
Pre-operative	BINER LC	21	26.4	1.5	25.7	27.1	0.68	0.42**
	HYDROCAL LC	21	26.8	1.5	26.1	27.4		
	Total	42	26.6	1.5	26.1	27.0		
Post 1 week	BINER LC	21	26.8	1.4	26.2	27.4	0.41	0.53**



	HYDROCAL LC	21	27.1	1.0	26.6	27.5		
	Total	42	26.9	1.2	26.6	27.3		
Post 1 months	BINER LC	21	26.7	1.7	25.9	27.5	1.1	0.3**
	HYDROCAL LC	21	27.1	1.2	26.6	27.7		
	Total	42	26.9	1.5	26.4	27.4		
Post 3 months	BINER LC	21	27.1	1.4	26.5	27.8	1.2	0.3**
	HYDROCAL LC	21	27.5	0.9	27.1	27.9		
	Total	42	27.3	1.1	27.0	27.7		
Post 6 months	BINER LC	21	26.9	1.0	26.4	27.3	13.7	0.001*
	HYDROCAL LC	21	27.8	0.6	27.5	28.1		
	Total	42	27.3	1.0	27.0	27.6		

Level of significance  $P$  value  $\leq 0.05$ , \*Significant, \*\*Non-significant

Table 1 :Distribution of study participants based on their study group and EPT results

Table 2: Shows that statistically non-significant difference was observed for in between and within age groups comparisons for EPT results pre-operatively, post 1 week, post 1 month, post 3 months and post 6 months.

EPT	AGE GROUPS	N	Mean	Std. Deviation	Lower Bound	Upper Bound	f value	P value
Pre-operative	20-30	15	26.4	1.7	0.4	25.5	0.3	0.8**
	30-40	15	26.5	1.4	0.4	25.8		
	40-50	12	26.8	1.3	0.4	26.0		
	Total	42	26.6	1.5	0.2	26.1		
Post 1 week	20-30	15	26.7	1.6	0.4	25.8	1.5	0.2**
	30-40	15	26.8	0.9	0.2	26.3		
	40-50	12	27.4	0.8	0.2	26.9		
	Total	42	26.9	1.2	0.2	26.6		
Post 1 months	20-30	15	26.4	1.7	0.4	25.5	1.9	0.2**
	30-40	15	26.9	1.3	0.3	26.2		
	40-50	12	27.5	1.2	0.4	26.7		
	Total	42	26.9	1.5	0.2	26.4		
Post 3 months	20-30	15	26.8	1.5	0.4	26.0	2.8	0.1**
	30-40	15	27.6	0.8	0.2	27.1		
	40-50	12	27.7	0.8	0.2	27.2		
	Total	42	27.3	1.1	0.2	27.0		
Post 6 months	20-30	15	27.2	1.0	0.3	26.6	0.3	0.7**
	30-40	15	27.3	1.0	0.3	26.8		
	40-50	12	27.5	0.9	0.3	26.9		
	Total	42	27.3	1.0	0.1	27.0		

Level of significance  $P$  value  $\leq 0.05$ , \*Significant, \*\*Non-significant

Table 2 : Distribution of study participants based on their age groups and EPT results

## DISCUSSION

The overall success rate of IPC in the present study was 95.45% at the end of 6 months. The results of the present study strongly confirms the tendency towards less vigorous caries removal in a more biological, pulp-preserving approach. There was NO significant difference in the outcome between the Biner LC and Hydrocal LC groups, suggesting that both the materials are equally effective as an IPC agent. Despite the success rate of 95.45% there are certain reasons for failure of this study like improper diagnosis (for eg. irreversible pulpitis can be counted

as reversible pulpitis), dissolution of IPC material, failure of restoration (microleakage, fracture, polymerization shrinkage) leading to discolouration of restoration or its margins and increase in tenderness of tooth converting reversible pulpitis into irreversible pulpitis leaving pulpectomy as the only treatment option

This study was conducted to evaluate the treatment outcome of indirect pulp capping using Biner LC (METABIOMED Co. LTD) and Hydrocal LC (Medicept Co. Ltd) in permanent posterior teeth of central Gujarat subpopulation in the Ahmedabad

region having Remaining Dentin Thickness (RDT) of less than or equal to 1.5 mm.

Factors that contribute to the success of pulp-capping procedure include the type of capping material, age of the patient, periodontal condition of the tooth including root formation and thickness of tertiary dentin formed.

Universal standard for the vital pulp therapy materials - Calcium hydroxide (Ca(OH)<sub>2</sub>) but there are certain drawbacks like degradation and dissolution over time, reparative bridge formation subjacent to Ca(OH)<sub>2</sub> can also characterize tunnel defects, histologically, Ca(OH)<sub>2</sub> demonstrates cytotoxicity in cell cultures and induces cell apoptosis, slow disintegration of the Ca(OH)<sub>2</sub> after hard tissue barrier formation may lead to pulpal degeneration, potential dystrophic calcifications and pulpal necrosis.

To choose the cases for vital pulp therapy diagnosis can be done through case history, clinical and radiographic examination: –

- 1.) Case History – Short, sharp pain lasting few seconds due to cold, sweet or sour stimulus which get relieved on removal of stimulus.
- 2.) Clinically check the tooth with naked eye
- 3.) Determine pulpal vitality via thermal test or electric pulp test
- 4.) Tenderness on percussion and palpation
- 5.) Evaluate the radiograph (reversible pulpitis has NO periapical lesion)

On follow up two cases of proximal caries (Class-2) where restorations were not intact showing fracture, discolouration or chipping off of restoration were excluded from the study before making results.

For IPC procedure RDT should be of 0.5mm or more upto 2mm to protect the pulp tissues from cytotoxic injuries via calcium hydroxide liner. The posterior teeth with mature root and healthy periodontium having occlusal or proximal deep carious lesion were included in the study. The radiological depth of the carious lesion was at least two-thirds of the total dentin thickness.

The standard protocol followed in the study, as mentioned by the American Academy of Endodontics Position Statement on Vital Pulp Therapy (2021), has contributed to the successful outcome in the study.

The success of the vital pulp therapy is based on PAI (Periapical Index scoring) given by Orstavik et al and Penesis et al.<sup>26</sup>

The success of IPC is considered as absence of root resorption, furcal radiolucency or PAI score is 1. The failure of IPC is considered as presence of root resorption, furcal radiolucency or PAI score is >1.

The radiographical depth of carious lesion with RDT of 0.5 to 1.5 mm was measured through Endo-prep application (as shown in Figure 3) [This EndoPrep App (2022) is an Australian Academy of Endodontics based application. Developed by Dr Omar Ikram and Dr William Ha. The application features a measurement tool for measuring canal curvature, tooth inclination and lengths.]

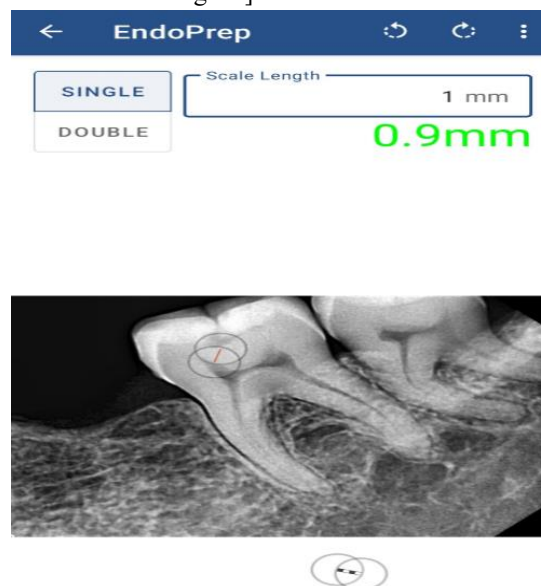


Figure 3 : RDT measured via Endo-Prep App  
Hydrocal LC and Biner LC are composed of Hydroxycalcium phosphate, Urethane dimethacrylate (UDMA) base resin, Photoinitiator, Barium aluminium silicate (radiopacifiers)  
Various advantages of light cured materials are set on command, improved strength, absence of solubility in acid, minimal solubility in water. These polymeric resins based agents allows bonding between light cured Ca(OH)<sub>2</sub> liner and the overlaying composite restoration.<sup>27,28</sup>

Also, there are some disadvantages of resin based pulp capping agents like higher cytotoxicity [according to Jeanneau C. et al (2017)] due to resin monomers, which may remain unpolymerised upon setting. According to Nilsen B.W. et al (2017) cured Theracal LC (resin based pulp capping agent) may release specific toxic additives, camphoroquinone and ethyl-

4-(dimethylamino)benzoate which, probably showed a cumulative toxic effect.<sup>29</sup> Due to the presence of monomers like BisGMA, HEMA, TEGDMA, and UDMA in these agents the biocompatibility is reduced.<sup>30</sup> So, these resin based pulp capping materials may not be used for direct pulp capping or pulpotomy procedures but further studies are required for the support of the above statement.

There are various other light cured resin based pulp capping agents containing calcium hydroxide except Hydrocal LC and Biner LC like Theracal LC, Calcimol LC and Septocal LC. And there are various other pulp capping agents like Pro root MTA, Biodentine and Dycal.

The obtained results were non-significant but Hydrocal LC had some of the advantages over Biner LC like controlled flow due to its higher viscosity, absolute absence of post-operative sensitivity in Hydrocal LC patients after 1 week while two patients with Biner LC showed post operative sensitivity after 2 weeks, some cases of biner LC showed the presence of underlying radiolucency leading to failure of cases, duration of light curing in Biner LC is 40s<sup>27</sup> and that in Hydrocal LC is 20 s for 5mm depth of curing.<sup>28</sup> Hydrocal LC was found to be the highest Ca<sup>2+</sup> ion-releasing materials among other light cured calcium hydroxide liners.<sup>25</sup> But cost-wise Biner LC was cheaper as compared to Hydrocal LC.

Findings obtained from the study are –

- 1.) Hydrocal LC is equally effective in IPC when compared to Biner LC and has higher viscosity and lower time of light curing 20s, unlike Biner LC having 40s for 5mm depth of curing.
- 2.) Hydrocal LC was found to be the highest Ca<sup>2+</sup> ion-releasing materials among other light cured calcium hydroxide liners
- 3.) Post- operative sensitivity was absolutely absent in Hydrocal LC patients after 1 week while in Biner LC, two patients showed NO post operative sensitivity after 2 weeks.
- 4.) In some cases of biner LC underlying radiolucency was present leading to failure of cases suggestive of gap formation which is one of the disadvantages of light-cured pulp capping materials where gap formations occur between dentin and resin based pulp capping materials<sup>31</sup> due to polymerization shrinkage. There are other alternative methods for indirect pulp capping procedure like laser therapy and biomimetic

restoration which are considered as most conservative mode of therapies for reversible pulpitis.

## CONCLUSION

There are certain limitations of this study like this study should include more number of patients and more duration of follow up is required for proper outcome.

Henceforth within limitations of this study it can be concluded that –

Hydrocal LC is equally effective in IPC when compared to Biner LC and factors such as the patient's age and status of the pulp can be considered as prognostic factors in the IPC procedure.

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Conflict of Interest: None declared.

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