COMPARATIVE EVALUATION OF A NOVEL CALCIUM SILICATE BASED MATERIAL WITH MTA AND CALCIUM HYDROXIDE AS PULP CAPPING AGENTS IN ADULTS: AN IN VIVO STUDY

DISSERTATION

Submitted to

BABU BANARASI DAS UNIVERSITY, LUCKNOW, UTTAR PRADESH

In the partial fulfillment of the requirements for the degree

Of

MASTER OF DENTAL SURGERY

In the subject of

CONSERVATIVE DENTISTRY & ENDODONTICS

Submitted by

DR. ATUL KRISHNAN

Under the guidance of

DR. PRAVEEN SINGH SAMANT

DEPARTMENT OF CONSERVATIVE DENTISTRY & ENDODONTICS

BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES, LUCKNOW

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BATCH: 2020-2023 **Enrollment No.: 12003220318**

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DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled **"Comparative evaluation of a novel Calcium Silicate based material with MTA and Calcium Hydroxide as pulp capping agents in adults: An In Vivo Study"** is a bonafide and genuine research work carried out by me under the guidance of **Dr. Praveen Singh Samant**, Professor & Head, Department of Conservative Dentistry & Endodontics, Babu Banarasi Das College of Dental Sciences, Babu Banarasi Das University, Lucknow, Uttar Pradesh.

Date: 15/2/23

Place: LUCKNOW

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CERTIFICATE BY THE GUIDE/CO-GUIDE

This is to certify that the dissertation entitled **"Comparative evaluation of a novel Calcium Silicate based material with MTA and Calcium Hydroxide as pulp capping agents in adults: An In Vivo Study"** is a bonafide work done by **Dr. Atul Krishnan**, under our direct supervision & guidance in partial fulfilment of the requirement for the degree of **Master of Dental Surgery (M.D.S.)** in the speciality of Conservative Dentistry and Endodontics.

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ENDORSEMENT BY THE HEAD OF THE DEPARTMENT

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ENDORSEMENT BY THE HEAD OF THE INSTITUTION

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DEDICATED TO

MY

PARENTS

for their love and endless support

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ACKNOWLEDGEMENT

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Dr. ATUL KRISHNAN

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LIST OF ABBREVIATIONS

ABBREVIATION	FULL FORM
&	And
%	Percentage
BECs	Bioactive endodontic cements
$Ca(OH)_2$	Calcium hydroxide
Ca-P	Calcium phosphate
CEM	Calcium- enriched mixture cement
CH	Calcium hydroxide
CO_2	Carbon dioxide
CSCs	Calcium silicate-based cements
DPC	Direct pulp capping
EMD	Emdogain (enamel matrix protein)
EPT	Electric pulp tester
Er,Cr:YSGG	Erbium, chromium-doped: yttrium, scandium, gallium, and garnet
FP	Full pulpotomy
GIC	Glass ionomer cement
IPC	Indirect pulp capping
IRM	Intermediate restorative material
KI	Potassium iodide
LASER	Light amplification by stimulated emission of radiation
MP	Miniature pulpotomy
MTA	Mineral trioxide aggregate
NaOCl	Sodium hypochlorite
NEC	Novel endodontic cement
PAI	Periapical index
PDL	Periodontal ligament

PMC	Pulpdent Multi-Cal
PRF	Platelet Rich Fibrin
PRP	Platelet Rich Plasma
PSP	Photostimulable phosphor
RCT	Root canal treatment
rhPDGF	Recombinant human platelet-derived growth factor
RMGIC	Resin-modified glass ionomer cement
SBAS	Single Bond Adhesive System
SMPP	Scotchbond Multi-Purpose Plus
SPSS	Statistical Package for Social Sciences
TBS	Tensile bond strength
TOP	Tender on percussion
VPT	Vital pulp therapy
WMTA	White Mineral trioxide aggregate

ABSTRACT

ABSTARCT

AIM: The present study was performed to compare the effectiveness of calcium hydroxide liner (Dycal); mineral trioxide aggregate (MTA) and TheraCal PT as direct/indirect pulp capping agents in adult molars.

DESIGN: In-vivo comparative study.

MATERIALS AND METHODS: Sixty-nine adult molars, fulfilling the eligibility criteria were randomly divided into three groups: Group I, Group II and Group III.

Direct/indirect pulp capping was done using Dycal, MTA and TheraCal PT in Group I, II and III respectively. Clinical and radiographic examination was done at the end of 1 and 3 months

STATISTICAL ANALYSIS: The intergroup comparison for the difference of frequencies between two independent groups was done using the Chi Square test.

RESULTS: Overall success rate was highest with MTA, followed by TheraCal PT and least with Dycal, although statistically significant differences were not seen. MTA showed significantly lesser post-operative pain compared to both the other groups. Thicker dentine bridge formation was shown by MTA and TheraCal PT at the end of three months.

CONCLUSION: Within the limitations of this study, it was concluded that no significant difference in overall success rates were observed when performing direct/indirect pulp capping using Dycal, MTA and TheraCal PT within a follow up period of 3 months. All the agents showed significant success rates.

Keywords: Vital pulp therapy, TheraCal PT, MTA, Dycal, Pulp capping, Direct pulp capping, Indirect pulp capping.

INTRODUCTION

One of the main goal of operative dentistry is to preserve the health of dental pulp. Normal pulp is a coherent soft tissue, dependent on its normal hard dentin shell for protection and hence, once exposed, extremely sensitive to contact and temperature. Pulp can get affected by various irritants including caries, trauma and iatrogenic causes and it possesses an intrinsic capacity for healing through cell reorganization and reparative dentin formation, when a proper biological seal is provided and maintained against microbial leakage.[1] In order to preserve the vitality of the pulp, completely removing the carious-firm dentin followed by placement of a material would enable the firm dentin to remineralize by stimulating the underlying odontoblasts to form tertiary dentin. Studies have shown that physiological remineralization can occur only if the firm dentin layer contains sound collagen fibers and living odontoblastic processes.[2] The sound collagen fibers function as a base to which apatite crystals attach. The living odontoblastic processes supply calcium phosphate from the vital pulp for physiological remineralization.

Vital pulp therapy (VPT) comprises a series of conservative procedures that rely on the intrinsic reparatory mechanisms of the dentin-pulp complex.[3] It consists of four distinct therapeutic approaches including indirect pulp capping, direct pulp capping, partial pulpotomy or complete pulpotomy, the latter two which are usually preferred in paediatric patients.[1] The clinical decision to choose between direct and indirect pulp capping would be based on the associated clinical conditions including extend of soft dentin (formerly known as Infected dentin) and firm dentin (formerly known as affected dentin) as well as correlating with clinical and radiographic signs and symptoms. Direct pulp capping is the method of covering the exposed vital pulp tissues with a protective dressing or base in an effort to maintain the pulp vitality.[4] Indirect pulp capping is defined as a procedure wherein the deepest layer of the remaining firm carious dentin is covered with a layer of biocompatible material in order to prevent pulpal exposure and further trauma to the pulp. The ultimate objective is to preserve the vitality of the pulp by completely removing the carious dentin followed by placement of a material that would enable the firm dentin to remineralize by stimulating the underlying odontoblasts to form tertiary dentin.

If the pulp is inadvertently exposed as a result of operator error or misjudgement (mechanical pulpal exposure), it must be decided whether to proceed with root canal treatment or to attempt

clinical management using direct pulp capping or pulpotomy (partial/full) procedure. A clinical evaluation should be made regarding health of the pulp.[5] According to Seltzer and Bender, carious pulpal exposure is normally associated with inflammation and subsequent necrosis. Hence, mechanical exposures always have a better prognosis than a carious exposure.[6] The next most important prognostic factor is the sizes of exposure, with larger exposures having lower healing potential than smaller pinpoint exposures.[7] Other factors for a favourable prognosis for the pulp after direct pulp capping may include easily controllable haemorrhage from exposure site, minimal physical irritation to the pulp tissue, uncontaminated operating field (i.e., a rubber dam isolation) and time gap between exposure and pulp capping.[7,8]

To protect the pulp, various pulp protecting agents are used. Some of the ideal requirements of a pulp capping agent as proposed by Cohen and Combe[1] are that it should maintain pulp vitality, stimulate reparative dentin formation, bactericidal or bacteriostatic in nature, adhere well to both the dentin and the overlying restorative material, able to resist the forces under the restoration and preferably be radiopaque.

Many materials have been employed as potential pulp capping agents. These include calcium hydroxide, mineral trioxide aggregate (MTA), zinc oxide eugenol, tricalcium phosphate, tetracalcium phosphate, calcitonin, bonding agents, growth factors, resin-modified glass ionomer cement (RMGIC), intermediate restorative material (IRM), and dentin shavings. However, the three most common materials that are currently recommended on the basis of in vitro and clinical research are calcium hydroxide, MTA (mineral trioxide aggregate) and other calcium silicate-based cements (CSCs).[1]

Calcium hydroxideis the most commonly used direct pulp capping agent, having good antibacterial properties and reparative dentin stimulation. In 1920, Hermann introduced calcium hydroxide in the treatment of exposed pulp, which induced reparative dentin formation. The pH of commercial products has been measured at between 9.2 and 11.7.[9] Commercially available calcium hydroxide formulations for vital pulp therapy includes Dycal (Dentsply Caulk, USA) and Pulpdent paste (PULPDENT Corporation, Watertown, USA). Calcium hydroxide possess the unique ability to induce mineralization even in tissues which are not programmed to undergo mineralization. However considerable limitations were associated with calcium hydroxide including longer appointments, microleakage, pulp cell apoptosis, poor marginal adaptation to

dentin, causing pulpal irritation, pulpal calcification and potential canal obliteration.(10)(1) Previous studies has shown that $Ca(OH)_2$ is associated with presence of tunnel defects in dentin bridge, high solubility in oral fluids, poor sealing ability and degradation over time, responsible for variable and unpredictable results.[11,7]Therefore, further studies continues to search newer materials with improved biocompatibility and dentin bridge formation.

MTA was introduced by Torabinejad in early 1900s.[12] Majority of the literature reviews and studies reported that MTA induced less pulpal inflammation and more predictable hard tissue barrier formation in comparison to calcium hydroxide.[13,14,15] Some of the other major advantages associated with MTA include high biocompatibility, antibacterial properties, nontoxic or non-mutagenic, radio opacity and release of bioactive dentin matrix proteins.[15,16] Hence MTA remains a highly acceptable material for vital pulp therapy due to its high clinical success rates. Drawbacks associated with MTA are difficulty in manipulation and handling, longer setting time facilitating the need for multiple appointments, disclouration (grey MTA) and higher solubility.[17]

TheraCal PT is a newer biocompatible, dual-cured, resin-modified calcium silicate material which is indicated for pulp capping, with better handling properties, making placement easier and predictable compared to MTA and calcium hydroxide. Also higher biocompatibility and better tissue response makes TheraCal PT a better contender against MTA and calcium hydroxide in terms of pulp capping.

Therefore this in-vivo study is aimed to evaluate the clinical and radiographic efficacy of a TheraCal PT with MTA and calcium hydroxide as pulp capping agents in adults. However, till date no in-vivo studies have been done comparing its pulp capping ability with other pulp capping agents.

AIM & OBJECTIVES

AIM OF THE STUDY:

The aim of this in-vivo study is to compare the effectiveness of conventional calcium hydroxide liner (CH); mineral trioxide aggregate (MTA) and a novel dual cured resin modified calcium silicate cement (TheraCal PT) as direct/indirect pulp capping materials in adult molars.

OBJECTIVES OF THE STUDY:

1. To evaluate the success rate of novel dual cure calcium silicate-based cement, TheraCal PT as pulp capping agent for deep caries based on clinical and radiographic findings.

2. To evaluate the success rate of calcium hydroxide as pulp capping agent for deep caries based on clinical and radiographic findings.

3. To evaluate the success rate of mineral trioxide aggregate (MTA) as pulp capping agent for deep caries based on clinical and radiographic findings.

4. For inter-comparison of success rate using TheraCal PT, MTA and calcium hydroxide and as pulp capping agents in deep caries based on clinical and radiographic findings.

REVIEW OF LITERATURE

1. **Fitzgerald M & Heys R J (1991)** conducted a clinical and histological evaluation of conservative pulpal therapy in using a zinc oxide-eugenol liner (Cavitec) and two calcium hydroxide liners (Life and Dycal) and results showed that there were no significant differences in clinical symptoms between the materials after indirect or direct pulp capping.[18]

2. **Heitmann T & Unterbrink G (1995)** performed a study with a glutaraldehyde-containing dentinal adhesive for direct pulp capping on eight permanent premolars and molars and found that all teeth remained vital and without symptoms during the initial observation period of 2 to 6 months.[19]

3. **Matsuo T, Nakanishi T, Shimizu H et al. (1996)** performed a study in which direct pulp capping of carious-exposed pulp was done using fast setting calcium hydroxide cement (Dycal) and suggested that adequate postoperative follow-up was to be 21 months after direct pulp capping.[20]

4. **Moritz A, Schoop U and Goharkhay K (1998)** evaluated the CO_2 laser as an aid in direct pulp capping in comparison to conventionally used calcium hydroxide preparation, where in the group of pulps treated with the CO_2 laser showed a success rate of 89% and the calcium hydroxide group showed a success rate of 68%. [21]

5. **Blanco L & Cohen S (2002)** performed treatment of crown fractures with exposed pulps in which partial pulpotomy (Cvek's technique) was done to amputate the exposed pulp tissue to a depth of 1 to 2 mm below the point of pulp exposure and covered by Dycal and then restored using GIC. They found that all of the cases showed successful outcome after treatment. [22]

6. **Scarano A, Manzon L, Di Giorgio R et al. (2003)** evaluated direct pulp capping using dentin bonding agent (Solist); dental adhesive (Prompt); traditional calcium hydroxide (Dycal) & light-curing calcium hydroxide (Ultrablend Plus) and observed that in all

groups, there were active odontoblasts near the composite resins and no newly formed dentin. [23]

7. **Olsson H, Davies J R, Holst K E et al. (2005)** investigated the effect of Emdogain Gel (Biora AB, Malmo, Sweden) on experimentally exposed human pulps to register postoperative symptoms and found that in the EMD gel-treated teeth, postoperative symptoms were less frequent and the amount and pattern of hard tissue formation were markedly different than in the teeth treated with calcium hydroxide. [24]

8. **Sübay R K & Demirci M (2005)** investigated the response of human pulp tissue to a dentin bonding agent, Scotchbond Multi-Purpose Plus (SMPP), in comparison to Dycal and found that SMPP may cause inflammatory changes when applied directly to exposed pulp tissue. Direct capping with Dycal with subsequent sealing with SMPP may show favorable results in pulp tissue. [25]

9. **De Lourdes Rodrigues Accorinte M, Reis A, Dourado Loguercio A et al. (2006)** evaluated the influence of rubber dam isolation on the response of human pulps capped with calcium hydroxide and an adhesive system and it was concluded that Calcium hydroxide showed better pulpal response than adhesive system with or without rubber dam isolation. [26]

10. **Farsi N, Alamoudi N, Balto K et al. (2006)** observed the efficacy of MTA as a direct pulp capping agent in young permanent teeth and found that at long term follow up of 24 months, the clinical and radiographic success rate was 93% with evidence of continued root growth.[27]

11. **Iwamoto C E, Adachi E, Pameijer C H et al. (2006)** evaluated the clinical, radiographical and histological findings in which mechanical pulp exposures were capped with white ProRoot mineral trioxide aggregate (WMTA) compared to calcium hydroxide and found no significant differences during clinical examination and MTA developed better calcific bridge histologically.[28]

12. **Silva G A, Lanza L D, Lopes-Júnior N et al. (2006)** evaluated the pulpal response to direct pulp capping with the Single Bond Adhesive System (SBAS) and capping with Calcium Hydroxide (CH). It was concluded that SBAS should be avoided for vital pulp therapy, while CH remains the capping agent of choice for mechanically exposed human dental pulp.[29]

13. **Elias R V, Demarco F F, Tarquinio S B et al. (2007)** evaluated the pulp response to direct capping with self-etching adhesive or calcium hydroxide. Results showed that calcium hydroxide produced better biological performance (dentine barrier formation) than the self-etching adhesive.[30]

14. **Qudeimat M A, Barrieshi-Nusair K M & Owais A I (2007)** compared the clinical success rate of partial pulpotomy treatment in permanent molars using calcium hydroxide (CH) and mineral trioxide aggregates (MTA) as pulp capping agents and found that no significant difference was shown in the success rates of CH (91%) and MTA (93%).[31]

15. **Lu Y, Liu T, Li H et al. (2008)** evaluated human pulp tissue response following direct pulp capping with a self-etching adhesive Clearfil SE BOND (SB) and it was concluded that Clearfil SB had good biocompatibility with human pulp tissue, but its ability to induce reparative dentine was significantly lower than that of calcium hydroxide.[32]

16. **Min K S, Park H J, Lee S K et al. (2008)** evaluated the pulpal response to direct capping with either mineral trioxide aggregate (MTA) or calcium hydroxide (CH) cement and observed that 100% of the MTA group and 60% of the CH group developed dentin bridges with MTA group having higher mean thickness of the dentin bridges.[33]

17. **Sawicki L**, **Pameijer CH**, **Emerich Ket al. (2008)** compared white MTA (WMTA) with calcium hydroxide as a direct pulp capping agent on human immature permanent teeth

and found that white ProRoot MTA produced slightly more favourable results than calcium hydroxide based on histologic assessment.[34]

18. **Accorinte M L, Loguercio A D, Reis A et al. (2009)** conducted a study to evaluate the histomorphological response of human dental pulps capped with two grey MTA compounds, ProRoot (Dentsply) or MTA-Angelus (Angelus). They found no significant difference between the two materials based on either total or partial hard tissue bridge formation.[35]

19. **Ogisu T, Yamauchi J, Suzuki S et al. (2009)** evaluated the micro tensile bond strength (microTBS) to human dentin of bonding agents containing calcium phosphates for direct pulp capping and found that calcium phosphate-containing adhesives did not adversely affect the microTBS to dentin.[36]

20. **Bjørndal L, Reit C, Bruun G et al. (2010)** conducted randomized clinical trials in treatment of deep caries lesions in adults comparing stepwise vs. direct complete excavation, and direct pulp capping vs. partial pulpotomy and concluded that stepwise excavation resulted in fewer pulp exposures compared with direct complete excavation.[37]

21. **Peters M C, Bresciani E, Barata T J et al. (2010)** evaluated the in vivo remineralization capacity of resin-based calcium-phosphate cement (Ca-P) used for indirect pulp-capping and found that the Ca-P cement has the capacity to promote remineralization of caries-affected dentin to a depth of 30 micrometers.[38]

22. **Zarrabi M H, Javidi M, Jafarian A H et al. (2010)** conducted a histologic assessment of pulp capping with mineral trioxide aggregate (MTA) and a novel endodontic cement (NEC), both of which showed significantly better pulp response, with no significant difference between the two groups in dentinal bridge formation.[39]

23. **Bai J, Qin M & Ji A P (2011)** performed pulpotomy in young permanent incisors with Pulpdent Multi-Cal (PMC) applied as a pulp capping agent and revealed radiographic evidence of dentin bridge formation within 1 to 3 months after pulpotomy.[40]

24. **Banomyong D & Messer H (2013)** conducted a study to observe the effects of glass-ionomer cement (GIC) lining in deep occlusal cavities followed by restoration with resin based restorations and found that the GIC lining does not have any effect on pulpal complications in deep occlusal cavities.[41]

25. **Hilton T J, Ferracane J L, Mancl L & Northwest Practice-based Research Collaborative in Evidence-based Dentistry (NWP) (2013)** conducted a study evaluating the success of direct pulp capping in permanent teeth with MTA (mineral trioxide aggregate) or CaOH (calcium hydroxide) and observed that after 2 year follow up, the probability of failure was higher for $Ca(OH)_2$ than MTA. Hence resulted that MTA had a superior performance as a direct pulp-capping agent as compared with $Ca(OH)_2$.[42]

26. **Nowicka A, Lipski M, Parafiniuk M et al. (2013)** compared the response of the pulp-dentin complex after direct capping with Biodentine (new tricalcium silicate-based cement) with MTA and observed that there were no significant differences between the two groups. Hence stated that Biodentine may be considered an alternative to MTA during vital pulp therapy.[43]

27. **Hashem D, Mannocci F, Patel S et al. (2015)** evaluated the effectiveness of Biodentine (calcium silicate cement) versus glass ionomer cement (GIC) as indirect pulp capping materials. Results showed that there was no statistically significant difference in the clinical efficacy of Biodentine and GIC group but CBCT revealed a significant difference in healed lesions with Biodentine compared with GIC.[44]

28. **Nowicka A, Wilk G, Lipski M et al. (2015)** conducted tomographic evaluations of reparative dentin bridge formation after direct pulp capping with calcium hydroxide, mineral trioxide aggregate (MTA), Biodentine and Single Bond Universal and found that reparative dentin formed in the calcium hydroxide, MTA, and Biodentine groups was significantly superior to that in Single Bond Universal group.[45]

29. **Jang Y, Song M, Yoo I S et al. (2015)** assessed the long-term clinical outcomes of direct pulp capping with ProRoot MTA and Endocem as pulp capping materials and both ProRoot MTA and Endocem exhibited similar cumulative successes as direct pulp capping materials up to 1 year follow up.[46]

30. **Song M, Kang M, Kim H C et al. (2015)** evaluated the short-term clinical outcomes of direct pulp capping using ProRoot MTA or Endocem as capping materials and found that the success rates in ProRoot MTA and Endocem groups were 95.5% and 90.5%, respectively after 3 month follow up.[47]

31. **Yazdanfar I, Gutknecht N & Franzen R (2015)** compared the effectiveness of conventional (calcium hydroxide) and diode laser-assisted methods in direct pulp capping of carious teeth and found that laser-assisted procedure was more effective than conventional technique in enhancing the outcomes of pulp-capping therapy. (48)

32. **AlShwaimi E, Majeed A & Ali A A (2016)** evaluated the response of human dental pulp to direct capping with betamethasone/gentamicin (BG) cream and mineral trioxide aggregate (MTA) and concluded that MTA resulted in a significantly better pulpal response, with less inflammation and a thicker dentin bridge than betamethasone cream.[49]

33. **Cengiz E & Yilmaz H G (2016)** evaluated the efficiency of erbium, chromium-doped: yttrium, scandium, gallium, and garnet (Er,Cr:YSGG) laser irradiation combined with a resin-based tricalcium silicate material (TheraCal LC) and calcium hydroxide in direct pulp capping and found that the Er,Cr:YSGG laser-irradiated TheraCal and Er,Cr:YSGG

laser-irradiated CH groups showed statistically higher success rates than the TheraCal LC and CH groups alone.[50]

34. **Kundzina R, Stangvaltaite L, Eriksen HM et al. (2016**) conducted a study to compare the effectiveness of mineral trioxide aggregate (MTA) and a conventional calcium hydroxide liner (CH) as direct pulp capping and observed that Mineral trioxide aggregate performed more effectively than a conventional CH liner as a direct pulp capping material. [51]

35. **Bakhtiar H, Nekoofar M H, Aminishakib P et al. (2017)** evaluated the clinical efficacy of TheraCal LC as compared with Biodentine and ProRoot mineral trioxide aggregate (MTA) for partial pulpotomy and results showed that Biodentine and MTA performed better than TheraCal LC when used as partial pulpotomy agent and, presented the best clinical outcomes.[52]

36. **Brizuela C, Ormeño A, Cabrera C et al. (2017)** conducted a study evaluating direct Pulp capping with calcium hydroxide, Mineral Trioxide Aggregate, and Biodentine in permanent young teeth and concluded that Biodentine and MTA better response than Calcium hydroxide.[53]

37. **Asgary S, Hassanizadeh R, Torabzadeh H et al. (2018)** conducted a study to evaluate and compare clinical and radiographic success of four vital pulp therapy techniques - indirect pulp capping [IPC], direct pulp capping [DPC], miniature pulpotomy [MP], and full pulpotomy [FP] using calcium-enriched mixture cement for deep caries management and concluded that the 4 VPTs were associated with favorable/comparable clinical and radiographic outcomes.[54]

38. **Al-Hezaimi K, Naghshbandi J, Alhuzaimi R et al. (2020)** conducted an vivo study assessed calcium hydroxide's effect as a matrix carrier for recombinant human platelet-derived growth factor (rhPDGF) and enamel matrix protein (EMD) on pulp tissue healing

following pulp capping. It showed that addition of EMD to CaOH2 can result in multiple root canal calcifications, mostly in the coronal and apical thirds of the canals. The calcified tissue does not appear to resemble secondary dentin in form, shape, amount, or density. Also addition of rhPDGF to $Ca(OH)_2$ may not cause root canal calcifications. The newly formed structure differs from secondary dentin in degree of mineralization, porosity, and density.[55]

39. **Alazrag MA, Abu-Seida AM, El-Batouty KM et al. (2020)** evaluated the marginal adaptation, solubility and biocompatibility of TheraCal LC compared with mineral trioxide aggregate (MTA-Angelus) and Biodentine and observed that TheraCal LC showed the highest frequency of presence of marginal gaps followed by the MTA-Angelus and Biodentine. Solubility of the material after one week showed Biodentine > MTA-Angelus > TheraCal LC. TheraCal LC showed the highest inflammatory response and some degree of cytotoxicity.[56]

40. **Yazdanfar I, Barekatain M & Zare Jahromi M (2020)** conducted a study to evaluate efficiency of diode 808-nm (Picasso-AMD, USA) laser irradiation combined with a resin-based tricalcium silicate material (TheraCal LC, Bisco, USA) and a tricalcium silicate based material alone as direct pulp capping agents. Clinically, diode laser group showed better results and radiographically, no significant difference was observed.[57]

41. **Peskersoy C, Lukarcanin J and Turkun M (2021)** conducted a study to compared the efficacy of Dycal, light cured calcium hydroxide, TheraCal LC, Biodentine and MTA+ as pulp capping agents. Results showed that MTA+ and Biodentine had the highestclinical and radiographic success followed by TheraCal LC and Dycal.[58]

42. **Sanz JL, Doria SA, García SL et al. (2021)** conducted an in-vitro study comparing the biological properties and mineralization potential of Theracal PT, Theracal LC, and Biodentine for Vital Pulp Therapy on Human Dental Pulp Stem Cells and observed that the newly introduced TheraCal PT offers an improved in vitro cytocompatibility and mineralization potential than TheraCal LC and comparable to Biodentine.[59]

43. **Shobana S, Kavitha M & Srinivasan N (2022)** evaluated the effectiveness of Platelet Rich Plasma (PRP), Platelet Rich Fibrin (PRF) and Mineral Trioxide Aggregate (MTA) as direct pulp capping materials using cone beam computed tomography and found that the volume of dentine bridge formed by PRP and PRF was significantly higher than the volume of dentine bridge formed by MTA.[60]

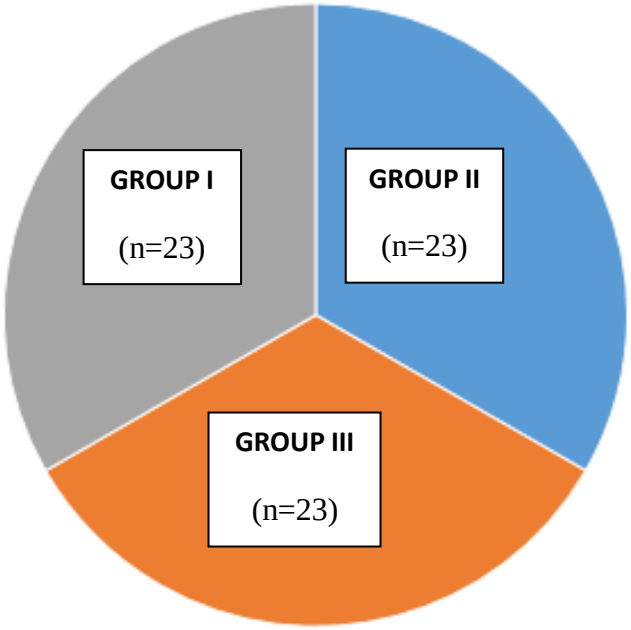
44. **Baraka M, Tekeya M, Bakry N S et al. (2022)** conducted a study to assess clinical and radiographic effectiveness of 38% silver diamine fluoride (SDF) with and without potassium iodide (KI) compared to resin-modified glass ionomer cement (RMGIC) in indirect pulp capping of deep carious lesions in young permanent molars and found no significant differences among the groups for secondary caries, postoperative pain, tooth vitality, clinical abscess, radiographic signs of pulpal pathology, restoration's marginal adaption, anatomic form, and surface roughness.[61]

MATERIAL & METHODOLOGY

The present in-vivo study was conducted in the Department of Conservative Dentistry and Endodontics, Babu Banarasi Das College of Dental Sciences, Lucknow.

Sixty-nine adults aged 18–40 years, who fulfil the eligibility criteria and following written informed consent, was randomly allocated to three groups:

- Group I: Calcium hydroxide (n=23)
- Group II : Mineral Trioxide Aggregate (n=23)
- Group III: TheraCal PT (n=23)



Graph 1: Distribution of participants for the study.

INCLUSION & EXCLUSION CRITERIA

Inclusion criteria:

1. Patients aged between 18 – 45 years.
2. 1st or 2nd maxillary or mandibular permanent molar with a proximal carious lesion.
3. No history of pain or the presence of pain indicating, utmost, reversible pulpitis.
4. Positive response to cold test or EPT.
5. Intraoral periapical radiograph showing carious lesion involving 1/3rd of dentin.
6. Periapical radiograph showing closed apex/ normal periapex.
7. No radiolucency or widening of the periodontal ligament space.
8. Attachment loss not exceeding 4mm.
9. Non-contributory medical history (including pregnancy).
10. No use of medication (no antibiotics during previous month).

Exclusion criteria:

1. Teeth showing clinical and radiographic evidence of pulp degeneration such as history of spontaneous or nocturnal pain, tenderness to percussion or palpation, necrosis of the pulp (negative to vitality testing).
2. Swelling / fistulous tract.
3. Pathologic mobility due to aggressive periodontitis.
4. Internal/external root resorption.
5. Furcation radiolucency/inter-radicular bone destruction and/or periapical bone destruction.
6. In cases of pulpal exposure, if bleeding was not controlled within 10 min using cotton pellets soaked in 3% NaOCl.
7. Teeth with any wasting diseases (attrition, abrasion, erosion, abfraction).
8. Patients with deleterious oral habits.
9. Endodontically treated teeth.

TABLE-1

MATERIALS AND ARMAMENTARIUM

Sl. No.	Material & Armamentarium	Manufacturer
1.	Mouth mirror	Hahnenkratt FS Rhodium, Germany
2.	No.23 Sheperds Hook Explorer	Hu-Friedy, Chicago
3.	Williams probe	Hu-Friedy, Chicago
4.	Spoon excavator	Hu-Friedy, Chicago
5.	Round carbide burs and diamond burs	SS White, New Jersy
6.	Airotor handpiece	NSK, Japan
7.	Micromotor handpiece	NSK, Japan
8.	Loupes (3.5x X 450mm)	Zumax, China
9.	Rubber dam	Coltene/Whaledent, USA
10.	Caries detector dye (Reveal® caries indicator)	Prevest DenPro Limited, Jammu-181133, India
11.	3% Sodium hypochlorite	Septodont Parcan, Lancaster USA
12.	GIC (GC Fuji Type IX)	GC, Japan
13.	Composite	Coltene SwissTec, Coltene Whaledent, USA
14.	Calcium hydroxide (Dycal)	Dentsply Caulk,USA
15.	Pro-root MTA	Dentsply Tulsa, USA)
16.	TheraCal PT	Bisco Inc.,USA

17.	Electric pulp tester	Waldent, New Delhi
18.	Coltene vitality control Endo-Frost	Coltene Whaledent, USA
19.	PSPIX²®Acteon PSP	Acteon group Ltd, Norwich, UK
20.	Rinn XCP film holder	Densply Sirona, USA
21.	MTA carrier	Waldent, New Delhi
22.	Randomizer software	Online version (www.randomizer.org)

TABLE-2

DISTRIBUTION OF SAMPLES

Sixty-nine adults aged 18–45 years, who fulfil the eligibility criteria and following written informed consent, will be randomly allocated to three groups:

GROUP I	GROUP II	GROUP III
Calcium Hydroxide (Dycal, Densply Sirona, USA) n=23	MTA (White ProRoot, Dentsply Tulsa, USA) n=23	Theracal PT (BISCO, Inc., USA) n=23

Fig. 1- Mouth mirror, Excavator, Explorer, Williams Probe

Fig. 2 - Airotor

Fig. 3 - Micromotor

Fig. 4 – Round carbide burs and diamond burs

Fig. 5 - Loupes

Fig. 6 – Rubber dam set

Fig. 7 - Caries detector dye

Fig. 8 - 3% Sodium hypochlorite

Fig. 9 - GIC (GC Fuji Type IX)

Fig. 10 - Nanocomposite

Fig. 11 – Calcium hydroxide

Fig. 12 – TheraCal PT

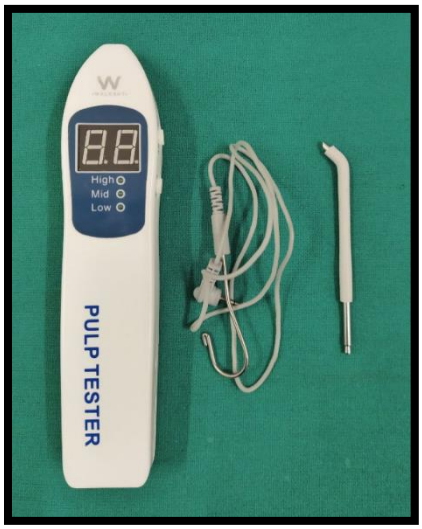


Fig. 13 - Electric pulp tester

Fig. 14 - Endo-Frost spray

Fig. **15**–ProRoot MTA

Fig. **16**– PSPIX²® Acteon PSP

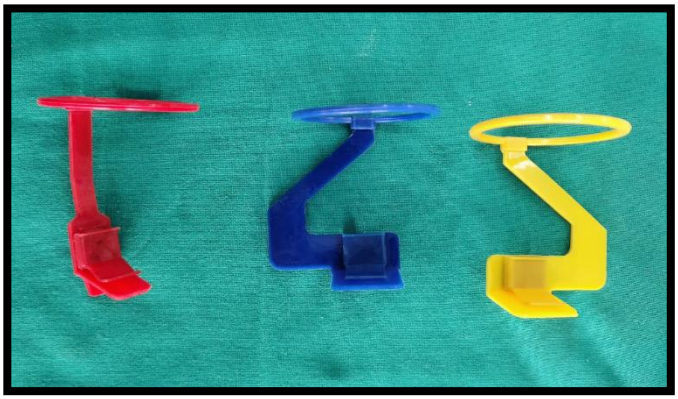


Fig. 17 - Rinn XCP film holder

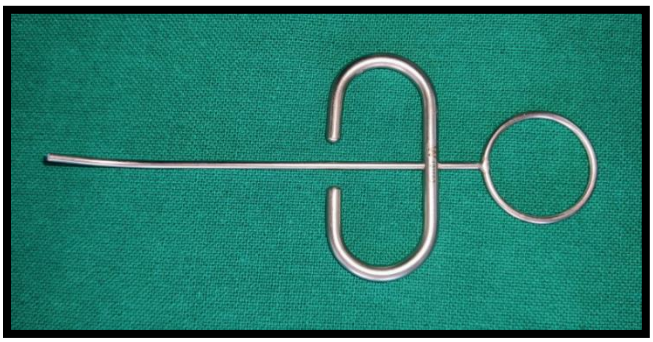


Fig. 18 - MTA carrier

METHODOLOGY

The selected teeth will be anaesthetized and isolated with a rubber dam to avoid salivary contamination of the operating field, and the caries will be removed using a complete excavation strategy (Bjørndal et al. 2010).[62] The cavity outline (Class II) will be prepared till sound enamel is achieved using a high-speed sterile carbide bur under water cooling.

All cavity margins should be on sound tooth structure. Caries free-condition were verified by clinical examination (mirror/explorer) and a caries detector dye (Reveal® caries indicator, Prevest DenPro Ltd, Jammu, India). On the pulpal wall, a sharp sterile hand excavator was used to remove the carious dentin until no or little dye staining is seen. The cavity is then carefully cleansed with 3% buffered sodium hypochlorite solution.

In cases of pulpal exposure, the bleeding was controlled using cotton pellets soaked in 3% sodium hypochlorite. Only a single operator performed all the treatments using a dental loupe at every step.

Table 3: Clinical interventions in each group

GROUP I	A thin layer of a commercial liner (Dycal, Densply Sirona, USA) was applied to the pulpal floor or pulpal exposure site and left to set.
GROUP II	White ProRoot (White ProRoot, Dentsply Tulsa, USA) powder is mixed according to the manufacturer's instructions and a 2- mm-thick layer was placed directly over the pulpal floor or pulpal exposure site and the surrounding dentine, leaving at least 2 mm of dentine and enamel available circumferentially for the bonded composite restoration.

GROUP III	TheraCal PT was applied directly to the cavity floor and manipulated into a smooth surface covering all deep dentin areas and then light cured for 10 seconds. In case of pulp exposure, TheraCal PT was applied directly to the exposed pulp, extending at least 1mm onto sound dentin surrounding the exposure and light cured for 10 seconds.

Then the cavities in all three groups then received a temporary filling (Fuji IX glass–ionomer cement; GC Corp, Tokyo, Japan).

After 1 week, any postoperative pain was recorded; pulpal status was checked using cold or electric pulp testing, and if there were no symptoms, the temporary filling was reduced to a base and teeth were permanently restored with a nanohybrid composite resin using sandwich technique.

Bitewing and periapical radiographs were taken to evaluate the quality of the restoration. At successive follow ups at 1 and 3 months, radiographic assessment of the periapical status of the tooth and dentine bridge formation were assessed using a PSP (photo stimulable phosphor) sensor (PSPIX²® Acteon).

Follow-up Examination:

The clinical examination performed consisted of inspection, palpation, percussion and sensitivity tests (coldtest and EPT). The pocket depth was recorded and restoration was examined visually. Intraoral periapical radiographs were taken to evaluate the status of the periapical tissues and the

continuity of the periodontal ligament space. The pulpal space was checked for calcific alterations and dentin bridge formation.

All radiographic evaluations were performed by two reviewers who were blinded to the material group assignments by masking the coronal part of the radiographs (while evaluating periapical changes).

Criteria for Success or Failure at Follow-up:

1. Postoperative pain within or after 1 week of the treatment.
2. Survival of capped pulps. Survival defined as asymptomatic tooth that responded to sensibility testing and did not exhibit any periapical changes radiographically. Follow- up included pulpal testing and periapical radiograph at 1 and 3 months.

Method of randomization:

Each patient meeting the inclusion criteria were assigned a number from 1 to 69 (in the order of reporting) and then randomized using Research randomizer software.

Table 4: Results from Research Randomizer software

Set #1	48, 43, 63, 47, 52, 67, 55, 16, 61, 22, 65, 18, 13, 60, 31, 19, 29, 57, 11, 66, 33, 40, 4
Set #2	32, 26, 40, 5, 17, 21, 67, 7, 55, 62, 25, 20, 13, 60, 11, 41, 44, 69, 1, 57, 27, 50, 9
Set #3	55, 26, 47, 8, 16, 1, 27, 19, 36, 20, 29, 6, 14, 2, 66, 35, 37, 12, 42, 23, 4, 28, 69

Three sets (for three respective groups) of 23 unique numbers per set, ranging from 1 to 69.

CLINICAL SCORING CRITERIA:(Clinical scores of 1 or 2 suggestive of success of the treatment and scores of 3 or 4 suggestive of failure)**(Table 5)**

CLINICAL SCORE		DESCRIPTION
1	Asymptomatic	**Pathology:** Absent **Functioning**: Normal **Percussion** and **sensitivity**: Asymptomatic **Mobility**: Nil
2	Slight Discomfort	**Pathology**: Questionable **Functioning**: Chewing sensitivity, short-lasting **Percussion** and **Sensitivity**: TOP -ve and sensitivity only to cold **Mobility**: Grade I
3	Minor Discomfort	**Pathology**: Initial changes present **Functioning**: Chewing sensitivity, long-lasting **Percussion** and **Sensitivity**: TOP +ve and sensitivity only to cold **Mobility**: Grade I or II
4	Major Discomfort	**Pathology**: Late changes present **Functioning**: Spontaneous pain **Percussion** and **Sensitivity**: TOP +ve and sensitivity to cold & hot **Mobility**: Grade II or III

RADIOGRAPHIC SCORING CRITERIA: (Radiographic scores of 1 or 2 suggestive of success of the treatment and scores of 3 or 4 suggestive of failure) (**Table 6)**

CLINICAL SCORE		DESCRIPTION
1	No changes present	**PDL**: Normal Width **PAI Index***: 1 **Root & Alveolar Bone Status**: Normal
2	Questionable Pathological changes present	**PDL**: Widened PDL **PAI Index**: 1 or 2 **Root & Alveolar Bone Status**: Normal
3	Minor Pathological Changes present	**PDL**: Widened PDL **PAI Index**: 3 or 4 **Root & Alveolar Bone Status**: Minor external root resorption or bone resorption.
4	Major Pathological changes present	**PDL**: Widened PDL **PAI Index**: 4 or 5 **Root & Alveolar Bone Status**: Definite radiolucency seen w.r.t root/ periapical bone.

*Periapical Index by Orstavik et al.(1986) [63]

DENTIN BRIDGE FORMATION SCORING CRITERIA (RADIOGRAPHICALLY): (Dentin bridge formation scores of 1 or 2 suggestive of success of the treatment and score of 3 suggestive of failure) (**Table 7)**

CLINICAL SCORE		THICKNESS OF DENTINE BRIDGE
1	Complete dentin bridge formation	More than 0.25 mm thickness
2	Partial dentin bridge formation	0.1mm - 0.25 mm thickness
3	Initial/ No dentin bridge formation	Less than 0.1 mm thickness or no evidence of dentin bridge formation

Fig. 19–Pre-operative clinical picture

Fig. 20–Rubber dam isolation

Fig. 21–Application of caries detector dye

Fig. 22–Application of pulp capping agent (TheraCal PT)

Fig. 23–Post-operative image after composite restoration

RESULTS

In this in- vivo study, results showed based on the clinical, radiographic and dentin bridge formation assessment after direct and indirect pulp capping that the overall success rates were highest with MTA(91.3%), followed by TheraCal PT (86.95%) and Calcium hydroxide (78.26%).

Assessment of the pulp capping ability of a particular material was based on 3 different criterias:

a) Clinical scoring criteria – to assess the clinical signs and symptoms after the procedure
b) Radiographic criteria – to assess the periapical changes after pulp capping
c) Dentin bridge formation criteria – to assess the thickness of dentin bridge formed after 3 months of the procedure

CLINICAL SCORING IN CALCIUM HYDROXIDE, MTA AND THERACAL PT

	Score 1	Score 2	Score 3	Score 4
Calcium hydroxide	7	11	3	2
	30.43%	47.82%	13.04%	8.69%
MTA	16	5	1	1
	69.56%	21.73%	4.35%	4.35%
TheraCal PT	8	13	2	0
	34.78%	56.52%	8.69%	0%

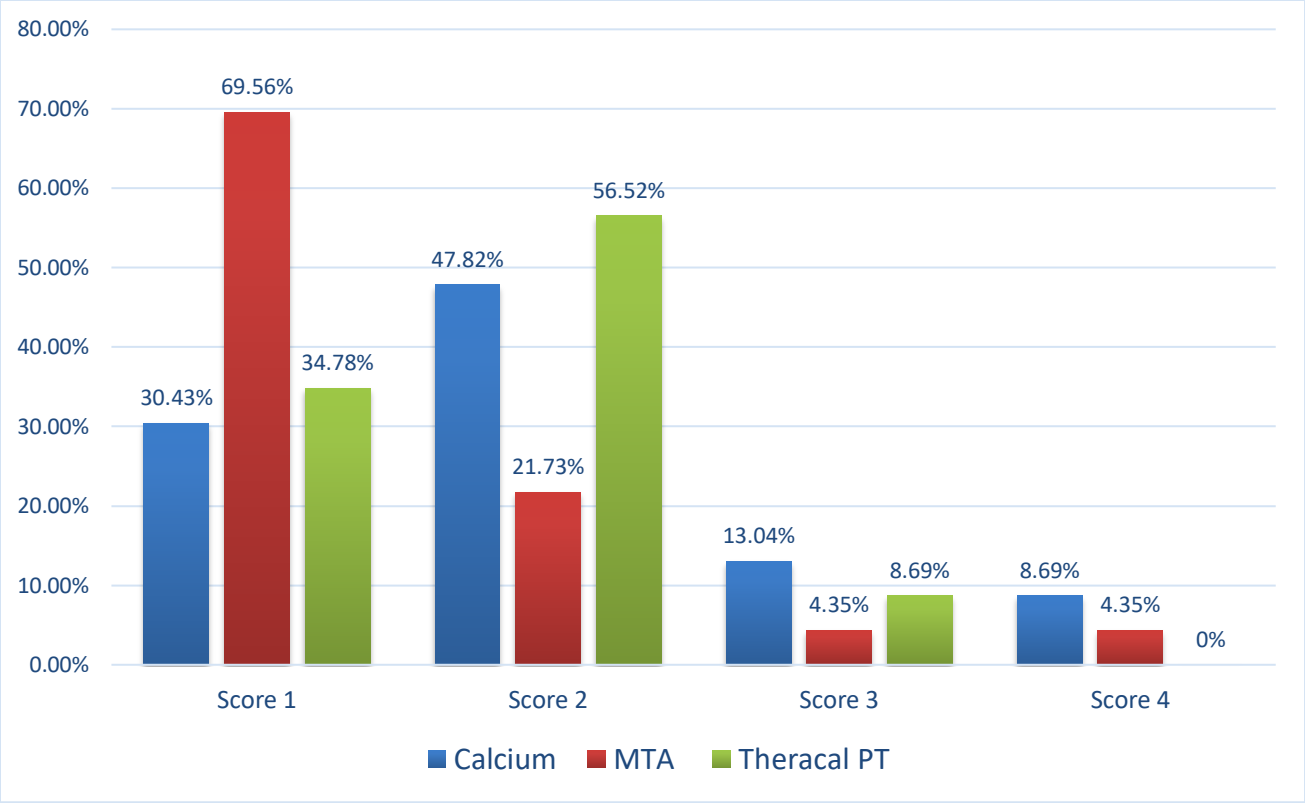
Table 8: Results of clinical scoring in Calcium Hydroxide, MTA and TheraCal PT

Table 9: INTERGROUP COMPARISON BETWEEN THE GROUPS CLINICALLY

Comparison Groups		P value	Significance
Calcium hydroxide	MTA Group	0.045	Significant
Calcium hydroxide	TheraCal PT	0.487	Non-Significant
MTA Group	TheraCal PT	0.049	Significant

Chi square test at 0.05 significance level

Based on clinical scoring, the intergroup comparison between Calcium hydroxide and MTA & TheraCal PT and MTA were statistically significant with p value of 0.045 and 0.049 (significant) respectively.



Graph2: Intergroup comparison between the three groups based on clinical scoring criteria.

RADIOGRAPHIC SCORING IN CALCIUM HYDROXIDE, MTA AND THERACAL PT

	Score 1	Score 2	Score 3	Score 4
Calcium hydroxide	10	9	4	0
	43.47%	39.13%	17.40%	0%
MTA	15	6	2	0
	65.22%	26.09%	8.69%	0%
TheraCal PT	14	7	2	0
	60.87%	30.43%	8.70%	0%

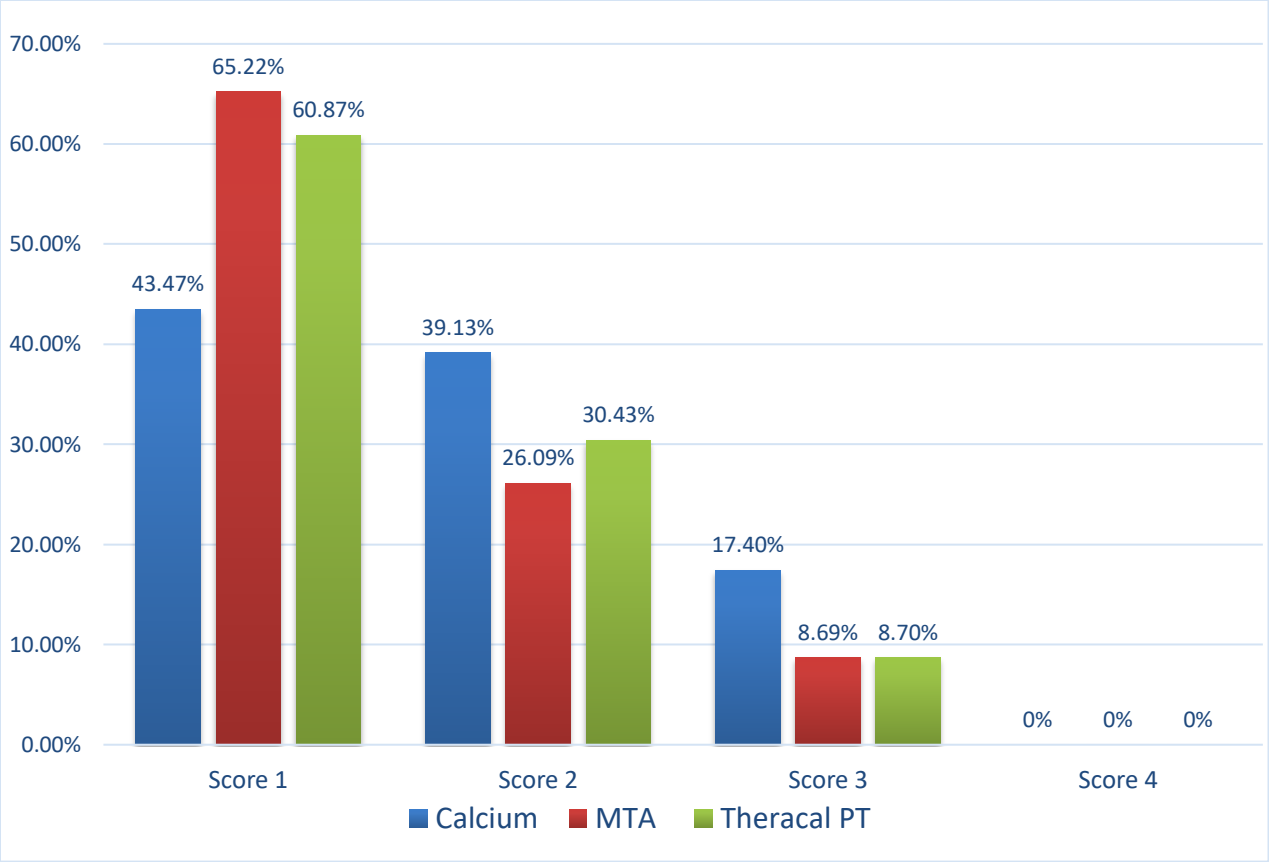
Table 10: Results of radiographic scoring in calcium hydroxide, MTA and TheraCal PT.

Table 11: INTERGROUP COMPARISON BETWEEN THE GROUPS RADIOGRAPHICALLY

Comparison Groups		P value	Significance
Calcium hydroxide	MTA Group	0.518	Non-Significant
Calcium hydroxide	TheraCal PT	0.663	Non-Significant
MTA Group	TheraCal PT	0.990	Non-Significant

Chi square test at 0.05 significance level

Radiographically the intergroup comparison between Calcium hydroxide and MTA; calcium hydroxide and Theracal PT & MTA and Thearacal PT were statistically non-significant with p value of 0.518, 0.663 and 0.990 respectively.



Graph 3: Intergroup comparison between the three groups based on radiographic scoring criteria.

SCORING BASED ON DENTIN BRIDGE FORMATION IN CALCIUM HYDROXIDE, MTA AND THERACAL PT

	Score 1	Score 2	Score 3
Calcium hydroxide	6	10	7
	26.08%	43.48%	30.44%
MTA	15	6	2
	65.22%	26.09%	8.69%
TheraCal PT	14	7	2
	60.87%	30.43%	8.70%

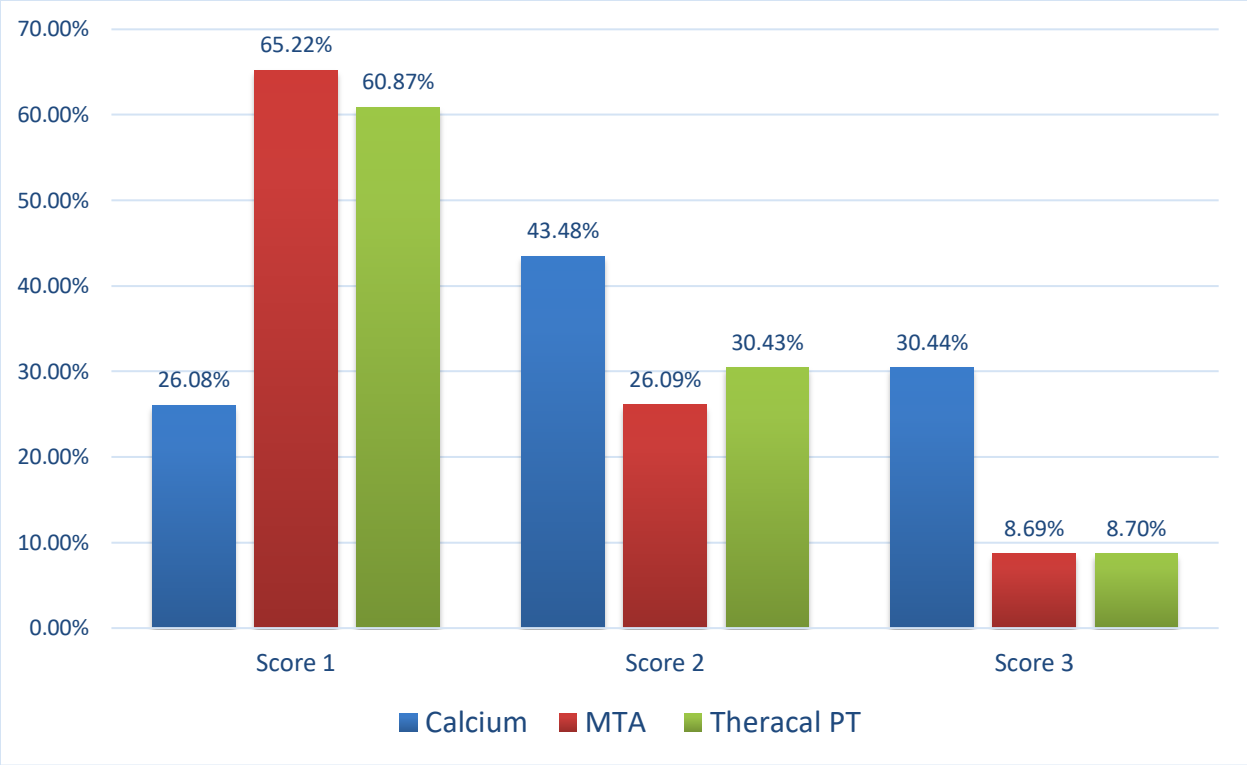
Table 12: Results of scoring based on dentin bridge formation in calcium hydroxide, MTA and TheraCal PT.

Table 13: INTERGROUP COMPARISON BETWEEN THE GROUPS BASED ON DENTIN BRIDGE FORMATION

Comparison Groups		P value	Significance
Calcium hydroxide	MTA Group	0.050	Significant
Calcium hydroxide	TheraCal PT	0.089	Non-Significant
MTA Group	TheraCal PT	0.990	Non-Significant

Chi square test at 0.05 significance level

The intergroup comparison between Calcium and MTA based on dentin bridge formation were statistically significant with p value of 0.050. However other groups comparing the dentine bridge formation between MTA and TheraCal PT & Calcium hydroxide and TheraCal PT showed no statistically significant differences with p values 0.990 and 0.089 respectively.



Graph 4: Intergroup comparison between the three groups based on dentine bridge formation.

OVERALL SUCCESS RATE AMONG THE GROUPS

	Successful outcome	Non successful outcome
Calcium hydroxide	18	5
	78.26%	21.74%
MTA	21	2
	91.30%	8.69%
TheraCal PT	20	3
	86.95%	13.04%

Table 14: Overall success rates in calcium hydroxide, MTA and TheraCal PT.

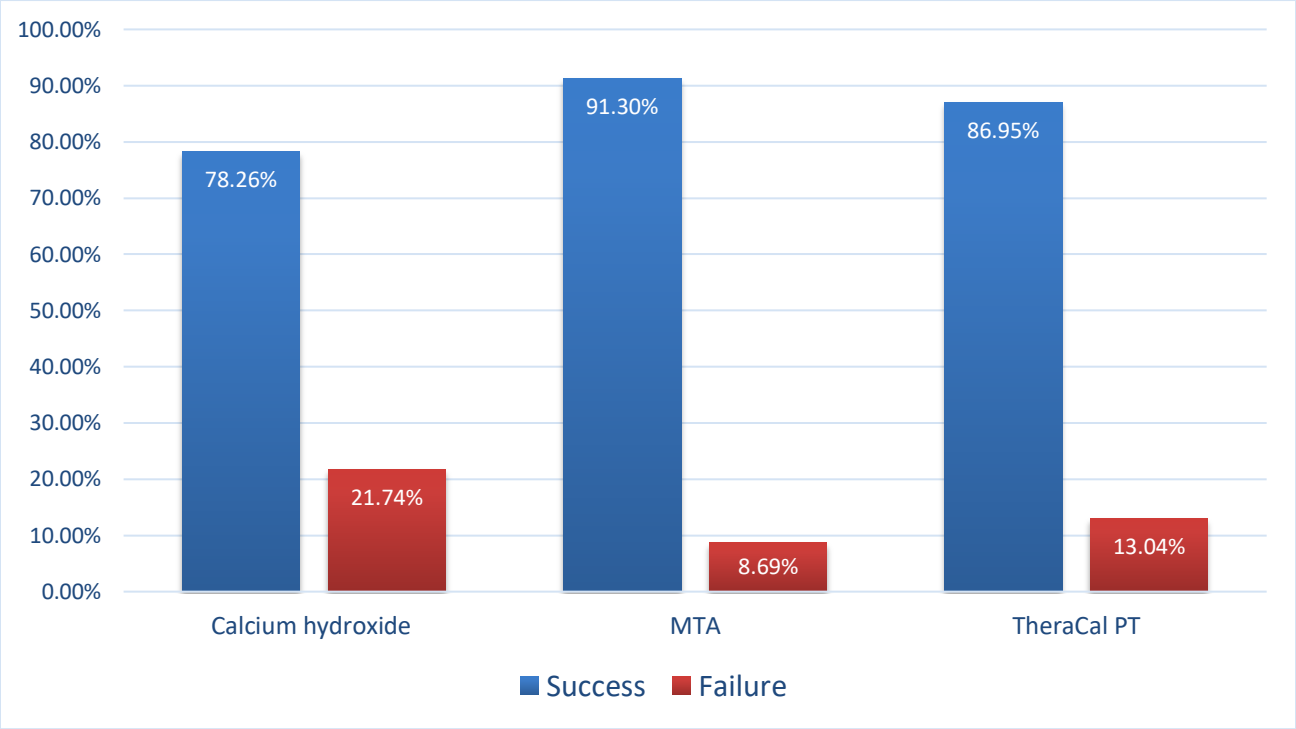
Table 15: INTERGROUP COMPARISON BETWEEN THE GROUPS BASED ON OVERALL SUCCESS RATES

Comparison Groups		P value	Significance
Calciumhydroxide	MTA Group	0.218	Non-Significant
Calciumhydroxide	TheraCal PT	0.436	Non-Significant
MTA Group	TheraCal PT	0.636	Non-Significant

Chi square test at 0.05 significance level

Overall success rate were seen to be 78.26% in the Calcium Group, 91.30% in the MTA Group and 86.95% in the TheraCal PT Group. The intergroup comparison between Calcium and MTA based on overalls success rate was statistically non-significant with p value of 0.218. The intergroup comparison between Calcium and TheraCal PT based on overall success rate was statistically non-significant with p value of 0.436 The intergroup comparison between TheraCal

PT and MTA based on overall success rate was statistically non-significant with p value of 0.636.



Graph 5: Intergroup comparison between the three groups based on overall success and failure rates.

STATISTICAL ANALYSIS

Data were analyzed using the SPSS software Version 19.0. The descriptive statistics included frequency and percentages. The level of the significance for the present study was fixed at 5%.

The intergroup comparison for the difference of frequencies between two independent groups was done using the Chi Square test.

Chi Square Test

Chi-square is a statistical test commonly used to compare observed data with data we would expect to obtain according to a specific hypothesis. When an analyst attempts to fit a statistical model to observed data, he or she may wonder how well the model actually reflects the data. How "close" are the observed values to those which would be expected under the fitted model? One statistical test that addresses this issue is the chi-square goodness of fit test. This test

is commonly used to test association of variables in two-way tables, where the assumed model of independence is evaluated against the observed data. In general, the ***chi-square test statistic*** is of the form

$$X^2 = \sum \frac{(\text{observed - expected})^2}{\text{expected}}.$$

If the computed test statistic is large, then the observed and expected values are not close and the model is a poor fit to the data

DISCUSSION

Vital pulp therapy (VPT) is a viable option which relatively have high success rate when strict aseptic protocol is followed along with proper case selection. It offers great benefits over conventional root canal treatment (RCT). In cases with immature apices, preserving the vitality of the tooth is beneficial for the continuation of root development which enhances the strength of the affected tooth.[64] Another advantage offered by VPT over conventional RCT is better protective resistance against masticatory forces. [65]

Factors which favour vital pulp therapy are; the type of pulpal exposure, which plays a critical role in the successful treatment weather it is a carious exposure, mechanical exposure or traumatic pulp exposure. These factors, combined with the clinical situation like size and time of exposure and other details including past history of pain, radiographic evaluation and pulp sensibility response together decides the treatment plan as well as prognosis of the treatment in vital pulp therapy. Pulp capping of vital mechanical and traumatic exposure of the pulp under aseptic conditions has a reasonably higher chance of success than cariously exposed pulp due to already existing inflammation of the pulp.

The correct diagnosis of the pulp tissue status before direct pulp capping plays an important role in the outcome of vital pulp therapy, thus assessing the degree of infection and inflammation of the pulp tissue is crucial.[66] It is challenging to assess the pulpal health accurately through clinical symptoms to distinguish between altered and healthy pulp.[67] In order to receive information about the status of the pulp, a combination of pulp sensibility testing using CO2 spray (endo ice) and electric pulp tester was used. Several studies have suggested that assessment of pulp sensibility would be more accurate when EPT and cold test are used in combination.[68,69,70]

Bogen et.al (2008) and Parinyaprom N et.al (2018) reported in their studies that pulpal healing can be achieved even after a carious exposure if the inflammation is no more severe than reversible pulpitis.[71,72] Therefore in the present study, asymptomatic teeth or teeth with atmost signs and symptoms of reversible pulpitis were selected.

Beside pain and sensibility testing, the bleeding of the pulp tissue after exposure was also assessed to further evaluate the status of the pulp. The degree of pulpal bleeding may be a more reliable way to determine the status of pulpal infection than preoperative sensibility testing and clinical signs and symptoms.[73] The amount of bleeding when exposing the pulp tissue may

reflect the level of inflammation of the pulp. Christensen GJ (1998)suggested that excessive bleeding of the pulp tissue usually indicates inflammation of the pulp with little or no chance of recovery during vital pulp therapy. [74] Matsuo et.al (1996) also stated that with increased bleeding on exposure, the possibility of irreversible pulpitis is high.[73] Inflammation involves most of the pulp tissue when there is carious pulp exposure since bacteria can easily penetrate deep into the pulp in such conditions in comparison to mechanically exposed pulp where the inflammation is superficial.[75,76] Pulps with profuse and lingering bleeding had a significantly poorer outcome than those with moderate or bleeding of short duration.[73] Clinically, pulp bleeding should be controlled within 5 min.[77,78]

Research conducted by Taha et al. (2017) showed that gaining haemostasis may play an important role in the higher success of VPT, and 10 to 15 minute time was required to achieve control of bleeding.[79] Bogen et al. (2012) studied direct pulp capping with MTA stated that the amount of time needed for haemostasis were between 1 to 10 minutes.[80]

In another study, Chailertvanitkul (2012) demonstrated that haemostasis could be controlled within 1–2 minutes.[81] Also Ricucci D et.al (2019) has recommended 2 minutes as the decisive time for control of bleeding in the determination of "reversible and irreversible pulpitis".[82]

Therefore, in the present study, teeth with pulp exposure showing uncontrolled bleeding 2-5 minutes after wiping with 3% sodium hypochlorite were excluded from the study.

In VPT, the application of haemostatic agents to stop bleeding is recommended; nevertheless, some agents have to be further studied. Sodium hypochlorite (NaOCl) at a concentration of 5.25% can be applied for 30 seconds to stop bleeding as shown by Dammaschke et al. (2019)(83) and Asgary et al. (2018).[84] In addition, NaOCl demonstrated moderate to high rate of pulp survival.[83,84] In this study 3% sodium hypochlorite (NaOCl) was used to control bleeding in cases of pulpal exposures.

Vital pulp therapy showed higher success rates in the younger age group (10 to 20 years) according to many authors.[85] The success rate decreased with increasing age, but studies showed that differences were not statistically significant for upto 45 years of age.[85] Thus it can be claimed that age apparently did not influence the prognosis of direct pulp capping in the age

group of 20-45 years.[86,87,88] Therefore in present study, adults in the age group ranging from 20-45 years were selected.

Molars are the most significantly affected teeth with carious lesions and also the proximity of pulp horns in relation to the mesial/distal proximal surfaces made mandibular or maxillary molars with proximal carious lesions were the choice of teeth for this study.[89]

A wide range of materials have been suggested in the literature to be used as pulp capping protective dressing materials. Since its introduction into literature in 1920 by Hermann, calcium hydroxide was considered as the gold standard material for pulp capping.[90] Schröder explained that the superficial layer of necrosis caused by calcium hydroxide is believed to be responsible for the irritation of the pulp and stimulating its defense mechanism and repair. [91,92] The repair process begins with vascular and inflammatory cell migration and proliferation, followed by the migration and proliferation of mesenchymal and endothelial pulp cells and the formation of collagen. Subsequently odontoblast differentiation occurs and the formation of tertiary dentine underneath the protective agent takes place.[92] Calcium hydroxide also has potent antibacterial properties, which were believed to be the main reason for using it successfully in pulp capping as it eliminates bacterial penetration and future injury to the pulp tissue.[93] Direct pulp capping (with calcium hydroxide) is reported to be the most common method used to treat carious exposure in young adult patients.[94,95] Hence calcium hydroxide was considered in this study as a pulp capping agent. Although, drawbacks are associated with calcium hydroxide which includes pulp surface inflammation and necrosis, the presence of tunnel defects in the newly formed tertiary dentine, which fails to provide an adequate seal against recurrent infections, high solubility in oral fluids, lack of adhesion [96,97] and inability to kill Enterococcus faecalis in the dentine.[98]

Introduction of Mineral trioxide aggregate (MTA) in the 1990s by Torabinejad as an experimental calcium silicate based material [99] has broadly led to the use of the material to seal pulpal cavities and external root surface communications [100]. MTA is composed of Portland cement, which is mainly composed of tri-calcium and di-calcium silicate, and bismuth oxide as a radiopacifier [101]. The commercialized forms of MTA introduced into the market were ProRoot®

MTA and tooth coloured ProRoot® MTA, (Dentsply Tulsa Dental Specialties, Tulsa, OK, USA), and later, MTA Angelus® and MTA Bianco®, (Angelus, Londrina, Brazil).

MTA has been suggested as the material of choice in cases of pulp capping, pulpotomies, perforative root resorption defects, surgical root end filling (retrograde filling), root and pulp chamber perforations and in cases undergoing revascularization treatment.[102] MTA has been reported to be a biocompatible material, which has inductive and conductive abilities for hard tissue formation.[103] It is bactericidal, stimulates cementum-like hard tissue formation and bone regeneration.[104]

Nair et al., (2008) stated that MTA was clinically easier to use, resulted in less pulpal inflammation and had more predictable outcomes regarding hard tissue barrier formation when compared to calcium hydroxide.[105] In a meta-analysis (2015), investigators reviewed researches done since 2003 wherein, MTA reported significantly superior success rates to calcium hydroxide. MTA specimens showed less pulpal inflammation in comparison to the calcium hydroxide specimens [96] and histologically a better calcified dentine bridge formation was noticed in the MTA capped groups. [105,106,107,108] The pulp survival rate was 95% for a group that was followed for at least 5 years, indicating a high success rate regardless of the patient's age.[109] Hence it was considered as the second material of choice for pulp capping in this study.

Few drawbacks of MTA when used clinically are: difficulty in handling together with a long setting time, high cost and potential discolouration to the tooth were reported.[110] Therefore further research needs to be done for better alternatives.

Recently, a number of bioactive endodontic cements (BECs) have been introduced to the market. Most of these materials have calcium and silicate in their compositions; however, bioactivity is a common property of these cements. These materials include the following: BioAggregate, Biodentine, BioRoot RCS, calcium- enriched mixture cement (CEM), Endo-CPM, Endocem, EndoSequence, EndoBinder, EndoSeal MTA, iRoot, MicroMega MTA, MTA Bio, MTA Fillapex, MTA Plus, Neo MTA Plus, Ortho MTA, Quick-Set, Retro MTA, Tech Biosealer, and TheraCal LC. It has been claimed that these materials have properties similar to those of MTA but without the associated drawbacks.[111]

TheraCal PT is a newer biocompatible, dual-cured, resin-modified calcium silicate material which is indicated primarily for pulpotomy treatments but also as a direct/indirect pulp capping agent. Its predecessor, Theracal LC was associated with some degree of cytotoxicity [112], whereas the initial in-vitro studies with the newer TheraCal PT reveals improved in vitro cytocompatibility and mineralization potential compared to the latter.[113] Initial in-vitro investigations have also shown similar cytocompatibilty and bioactivity of Theracal PT and MTA [114]. This novel calcium silicate based material combines all the advantages of bioceramic cement ie: alkaline pH, biocompatibility and calcium release, while eliminating some of the disadvantages associated with MTA like longer setting time and difficult handling. Hence TheraCal PT was selected as the third material for this study. Even though it's a relatively newer material, more in vivo and in vitro studies are to be done to assess the clinical efficacy of TheraCal PT.

Results of this in-vivo study, considering the overall success rate after performing direct/indirect pulp capping, MTA showed the highest success rate of 91.30% followed by Theracal PT (86.95%) and then calcium hydroxide (78.26%). However, statistically significant differences were not observed during inter group comparison of overall success between the three groups. The higher success rates associated with MTA can be due to its better biocompatibility and superior dentin bridge formation ability compared to the other groups used. Also similar results were seen in a study done by Fatou Leye Benoist et.al (2012) in which they reported higher success rate in the MTA group relative to the Dycal (calcium hydroxide) group after 3 months, which was statistically significant. [115]

Comparison between Group I (Calcium hydroxide) and Group II (MTA):

Comparing the clinical signs after VPT, patients in the MTA group had lesser incidence of postoperative discomfort in terms of pain and tender on percussion, relatively during first 2 weeks. Similarly, radiographic analysis of dentin bridge thickness also showed more complete and thicker bridge formed at the end of 3 months in the MTA group. In the calcium hydroxide group, only 70% of the teeth showed partial or complete dentin bridge formation compared to 91% in the MTA group. This shows the higher reparative dentin formation potential of the

calcium silicate based MTA. Similar results were observed in the study done by Mohanty S and Ramesh S (2020) which showed superior quantity and quality dentin bridge formation by the bioceramic based MTA and Biodentine when compared to propolis. [116]

Almost 70% of the patients in the MTA group and 47.82% patients of calcium hydroxide group had no post-operative pain. Both clinical and dentin bridge formation analysis showed statistically significantly better results with MTA. It could be due to lesser pulpal inflammation associated with MTA compared to calcium hydroxide. [96,105]

The radiographic analysis of the periodontal ligament space and periapical area showed similar results with MTA and calcium hydroxide.

Overall success rates were better with MTA, but statistically insignificant differences were seen on comparing it with calcium hydroxide for a follow up period of 3 months.

Similar results were shown in study done by Mathur VP et al. (2016) who compared the indirect pulp capping ability of MTA, calcium hydroxide and glass ionomer cement and concluded that all three materials were found to be equally suitable as indirect pulp capping agents in terms of clinical success, periapical healing and dentin bridge formation.[117] Also Petrou MA et.al (2014) showed that similar clinical and radiographic success at the end of 6 months were seen at the end of 6 months comparing MTA, medical Portland cement, and calcium hydroxide when used as indirect pulp capping agent.[118]

Comparison between Group II (MTA) and Group III (TheraCal PT):

TheraCal PT showed clinical signs of mild pain and tender on percussion statistically more compared with MTA. It could be due to resin components incorporated in Theracal PT, which may be responsible for the post-operative pain, mainly in case of direct pulp capping.

MTA and TheraCal PT group showed better dentine bridge thickness radiographically compared to calcium hydroxide group when observed at the end of three months, wherein more than 90% of the teeth receiving either MTA or TheraCal PT showed complete or partial dentin bridge formation

On periapical radiographic examination and dentine bridge formation, both TheraCal PT and MTA has shown similar results. MTA and TheraCal PT showed better periapical index (PAI) scoring with lesser incidence of periodontal ligament space widening.

The overall success rates were also comparable with MTA and TheraCal PT showing 91.30% and 86.35% respectively.

Comparison between Group I (Calcium hydroxide) and Group III (TheraCal PT):

Comparison of postoperative pain, radiographic analysis of periodontal ligament space, thickness of dentin bridge formation and overall success rates showed better results with TheraCal PT, but statistically significant differences were not seen between two groups.

Higher incidence of post-operative pain is associated with calcium hydroxide and Theracal PT. Even though Theracal PT shows better in-vitro cytocompatibility than Theracal LC(113), some other studies have shown cytotoxicity and residual monomer release associated with Theracal PT and Thearacal LC. [119] More in-vitro and in-vivo studies need to be done to establish the cytotoxic potential and effects on cell viability associated with Theracal PT.

In the present study, all pulp capping agents showed significant success rates when used as direct/indirect pulp capping material in adult molars. A large number of pulp capping agents are available in the market today. More in-vivo and in-vitro studies comparing them are still required to evaluate and to relate the findings of the present in-vivo study, especially assessing long term outcomes clinically and radiographically.

CONCLUSION

The present in-vivo study compared the direct/indirect pulp capping pulp capping potential of calcium hydroxide, MTA and TheraCal PT when used in adult molars with deep carious lesions.

Within the limitations of the study, the following conclusions were drawn:

1. All the pulp capping agents showed significant success rates when used as a direct/indirect pulp capping material in adult molars.
2. MTA showed the highest overall success rate with least incidence of post-operative pain, lesser periodontal ligament space widening and thicker dentine bridge formation when observed radiographically.
3. TheraCal PT showed statistically similar results in terms of overall success rate, periapical radiographic assessment and thickness of dentin bridge formed when compared to MTA.
4. Calcium hydroxide showed the least overall success rate. Dentin bridge formation and clinical scoring assessment were inferior to that of MTA and was statistically significant. Although there were no significant differences seen in clinical or radiographic outcome compared to TheraCal PT.

However, further in-vivo and in-vitro studies are required to compare and establish the pulp capping potential of different newer agents.

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ANNEXURES

ANNEXURE-I

Babu Banarasi Das University
Babu Banarasi Das College of Dental Sciences,
BBD City, Faizabad Road, Lucknow – 226028 (INDIA)

Dr. Lakshmi Bala
Professor and Head Biochemistry and
Member-Secretary, Institutional Ethics Committee

Communication of the Decision of the IXth Institutional Ethics Sub-Committee

IEC Code: 29 **BBDCODS/04/2022**

Title of the Project: Comparative evaluation of a novel calcium silicate based material with MTA and calcium hydroxide as pulp capping agents in adults: An in-vivo study.

Principal Investigator: Dr Atul Krishnan **Department:** Conservative Dentistry and Endodontics

Name and Address of the Institution: BBD College of Dental Sciences Lucknow.

Type of Submission: New, MDS Project Protocol

Dear Dr Atul Krishnan,

The Institutional Ethics Sub-Committee meeting comprising following four members was held on 07th April, 2022.

1.	Dr. Lakshmi Bala Member Secretary	Prof. and Head, Department of Biochemistry, BBDCODS, Lucknow
2.	Dr. Amrit Tandan Member	Prof. & Head, Department of Prosthodontics and Crown & Bridge, BBDCODS, Lucknow
3.	Dr. Rana Pratap Maurya Member	Reader, Department of Orthodontics, BBDCODS, Lucknow
4.	Dr. Akanksha Bhatt Member	Reader, Department of Conservative Dentistry & Endodontics, BBDCODS, Lucknow

The committee reviewed and discussed your submitted documents of the current MDS Project Protocol in the meeting.
The comments were communicated to PI thereafter it was revised.

Decisions: The committee approved the above protocol from ethics point of view.

Forwarded by:

Lakshmi Bala

(Dr. Lakshmi Bala)
Member-Secretary
IEC

Member-Secretary
Institutional Ethic Committee
BBD College of Dental Sciences
BBD University
Faizabad Road, Lucknow-226028

(Dr. Puneet Ahuja)
Principal
BBDCODS

PRINCIPAL
Babu Banarasi Das College of Dental Sciences
(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow-226028

ANNEXURE-II

BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES (FACULTY OF BBD UNIVERSITY), LUCKNOW

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled **"Comparative Evaluation of a Novel Calcium Silicate Based Material with MTA and Calcium Hydroxide as Pulp Capping Agents in Adults: An In-Vivo Study"** submitted by **Dr Atul Krishnan** Post graduate student from the **Department of Conservative Dentistry and Endodontics** as part of MDS Curriculum for the academic year 2020-2023 with the accompanying proforma was reviewed by the Institutional Research Committee present on **11th October 2021** at BBDCODS.

The Committee has granted approval on the scientific content of the project. The proposal may now be reviewed by the Institutional Ethics Committee for granting ethical approval.

Prof. Vandana A Pant
Co-Chairperson

Prof. B. Rajkumar
Chairperson

ANNEXURE-III

Babu Banarasi Das College of DentalSciences

(Babu Banarasi Das University)

BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

Consent Form (English)

Title oftheStudy:**Comparative Evaluation of a Novel Calcium Silicate Based Material with MTA and Calcium Hydroxide as Pulp Capping Agents in Adults: An In Vivo Study**

Study Number……..

Subject's Full Name…….

Date of Birth/Age ……

Address of the Subject…….

Phone no. and e-mail address……

Qualification ……

Occupation: Student / Self Employed / Service /

Housewife/ Other (Please tick as appropriate)

Annual income of the Subject……

Name and of the nominees(s) and his relation to the subject.....(For the purposeof compensation in case of trial related death).

1. I confirm that I have read and understood the Participant Information Document dated……..for the above study and have had the opportunity to ask questions.

OR

I have been explained the nature of the study by the Investigator and had the opportunity to ask questions.

2. I understand that my participation in the study is voluntary and given with free will without any duress and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.

3. I understand that the sponsor of the project, others working on the Sponsor‘s behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. However, I understand that my Identity will not be revealed in any information released to third parties or published.

4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).

5. I permit the use of stored sample (tooth/tissue/blood) for future research. Yes[] No[]
NotApplicable[]

6. I agree to participate in the above study. I have been explained about the complications and side effects, if any, and have fully understood them. I have also read and understood the participant/volunteer’s Information document given to me.

Signature (or Thumb impression)of the Subject/Legally acceptable representative:…….

Signatory‘s Name…….…….…... Date …….…….

Signature of the Investigator…… Date……..

Study Investigator‘s Name..... Date……..

Signature of the witness……..... Date…….

Name of the witness……

Received a signed copy of the PID and duly filled consent form

Signature/thumb impression of the subject or legally acceptable representative: ……...

Date: ……

ANNEXURE-IV

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University)

BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

Guidelines for Devising a Participant / Legally Acceptable Representative Information

PARTICIPANT INFORMATION DOCUMENT (English)

1. Study Title

Comparative Evaluation of a Novel Calcium Silicate Based Material with MTA and Calcium Hydroxide as Pulp Capping Agents in Adults: An In Vivo Study.

2. Invitation Paragraph

You are being invited to take part in a research/trial study. Before you decide it is important for you to understand why the research/study is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your treating physician/family doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

3. What is the purpose of the study?

The aim of this in-vivo study is to compare the effectiveness of conventional calcium hydroxide liner (CH); mineral trioxide aggregate (MTA) and a novel dual cured resin modified calcium silicate cement (TheraCal PT) as direct/indirect pulp capping materials in adult molars.

4. Why have I been chosen?

You have been selected for this study because you are meeting the criteria required for this study.

5. Do I have to take part?

Your participation in the research is completely voluntary. If you do, you will be given this information sheet to keep and asked to sign a consent form. You are free to withdraw during the study at any time and without assigning any reason.

6. What will happen to me if I take part?

In this study, the clinical efficacy of three pulp capping agents in protecting your pulp (innermost portion of tooth which contains nerves and blood vessels) from deep caries is evaluated separately, where caries is removed from the deepest portion of your tooth and a lining of these pulp protecting materials is placed as a protection, over which other filling materials are placed. All these procedures will be performed under local anesthesia, so no pain / discomfort will be felt.

Once the treatment is performed, clinical and radiographic examination will be will be done for 1 week, 1 month and 3 months from the date of procedure performed and you will need to visit the clinic during these three recalls.

Initial procedure will take approximately 30 minutes to 1 hour, and the recall appointments will take approximately 15 to 20 minutes.

7. What do I have to do?

The study will include sixty-nine adults aged 18–45 years, who fulfil the eligibility criteria and following written informed consent, will be randomly allocated to three groups. After the treatment, the patient or volunteer should check if they have any pain immediately after the treatment or during the recall period of the study. Patients/volunteers are also requested to avoid hard and very hot/cold food.

8. What is the procedure that is being tested?

Adults aged 18–45 years, who fulfil the eligibility criteria and following written informed consent, will be randomly allocated to three groups, for comparing the effectiveness of conventional calcium hydroxide liner (Ca(OH)2); mineral trioxide aggregate (MTA) and a novel dual cured resin modified calcium silicate cement (TheraCal PT) as direct/indirect pulp capping materials in adult molars.

Clinical and radiographic examination will be done. Any postoperative pain and amount of tertiary dentin formation will be evaluated.

9. What are the interventions for the study?

Patients/ volunteers who fulfil the eligibility criteria and following written informed consent, will have direct/indirect pulp capping treatment done using conventional calcium hydroxide liner (Ca(OH)2; Dycal, DENTSPLY SIRONA, USA); mineral trioxide aggregate (MTA; White ProRoot, DENTSPLY TULSA, USA) and a novel dual cured resin modified calcium silicate cement (TheraCal PT; BISCO, USA).

10. What are the side effects of taking part?

Although there are no reports of serious side effects of the procedure. The participant may have postoperative sensitivity/ pain.

If participant have any postoperative pain, they are advised to take prescribed medications for relieve pain and report to the operator immediately.

Contact details in case of any symptoms:

Dr. Atul Krishnan

Ph.: 9544087823

11. What are the possible disadvantages and risks of taking part?

There are no disadvantages to participating in this study

12. What are the possible benefits of taking part?

The participant will benefit because treatment is done with newer and more biocompatible materials intended for the purpose of direct/indirect pulp capping.

13. What if new information becomes available?

If additional information becomes available during the course of the research you will be informed of these and you are free to discuss it with your researcher, letting you know if you

want to continue with the study. If you decide to withdraw, your researcher will arrange for your return. If you decide to continue studying, you may be asked to sign an updated consent form.

14. What happens when the research study stops?

If the study finishes/stops, this will be explained to the patient/volunteer.

15. What if something goes wrong?

Problems/complaints will be handled by HOD or IRC. If something serious happens the institute will take care of the problems.

16. Will my taking part in this study be kept confidential?

Yes it will be kept confidential.

17. What will happen to the results of the research study?

The results of the study will be used to determine and compare the effectiveness of calcium hydroxide liner (CH); mineral trioxide aggregate (MTA) and a novel dual cured resin modified calcium silicate cement (TheraCal PT) as direct/indirect pulp capping materials in adult molars. Your identity will be kept confidential in case of any report/publication.

18. Who is organizing the research?

This research is done at the Department of Conservative Dentistry and Endodontics, BBDCODS, Lucknow. The research is self-funded. The participants have to pay the procedural fee as given by the institution.

19. Will the results of the study be made available after study is over?

Yes.

20. Who has reviewed the study?

The HOD of the respective department and members of the IRC/IEC has reviewed and approved the study.

21. Contact for further information

Dr. Atul Krishnan

Department of Conservative Dentistry and Endodontics,

Babu Banarasi College of Dental Sciences. Lucknow-226028

Phone - 9544087823

Email: atulkrishnan878@gmail.com

Dr. Laxmibala

Member Secretary of the Ethics Committee of the Society,

Babu Banarasi College of Dental Sciences, Lucknow

Email: bbdcods.iec@gmail.com

Name of patient –

Address –

Email –

Tel no. –

Signature of PI……

Name……..

Date……..

The participant will be given a copy of the information sheet and the signed consent form.Thank you for taking part in the study.

ANNEXURE-V

MASTER CHART

GROUP 1

CLINICAL SCORING

SCORE 1	7 TEETH
SCORE 2	11 TEETH
SCORE 3	3 TEETH
SCORE 4	2 TEETH

RADIOGRAPHIC SCORING

SCORE 1	10 TEETH
SCORE 2	9 TEETH
SCORE 3	4 TEETH
SCORE 4	0 TEETH

DENTINE BRIDGE SCORING

SCORE 1	6 TEETH
SCORE 2	10 TEETH
SCORE 3	7 TEETH
SCORE 4	0 TEETH

GROUP 2

CLINICAL SCORING

SCORE 1	16 TEETH
SCORE 2	5 TEETH
SCORE 3	1 TEETH
SCORE 4	1 TEETH

RADIOGRAPHIC SCORING

SCORE 1	15 TEETH
SCORE 2	6 TEETH
SCORE 3	2 TEETH
SCORE 4	0 TEETH

DENTINE BRIDGE SCORING

SCORE 1	15 TEETH
SCORE 2	6 TEETH
SCORE 3	2 TEETH
SCORE 4	0 TEETH

GROUP 3

CLINICAL SCORING

SCORE 1	8 TEETH
SCORE 2	13 TEETH
SCORE 3	2 TEETH
SCORE 4	0 TEETH

RADIOGRAPHIC SCORING

SCORE 1	14 TEETH
SCORE 2	7 TEETH
SCORE 3	2 TEETH
SCORE 4	0 TEETH

DENTINE BRIDGE SCORING

SCORE 1	14 TEETH
SCORE 2	7 TEETH
SCORE 3	2 TEETH
SCORE 4	0 TEETH

ANNEXURE-VI

Formulas used for analysis

Data were analyzed using the SPSS software Version 19.0. The descriptive statistics included frequency and percentages. The level of the significance for the present study was fixed at 5%.

The intergroup comparison for the difference of frequencies between two independent groups was done using the Chi Square test.

Chi Square Test

Chi-square is a statistical test commonly used to compare observed data with data we would expect to obtain according to a specific hypothesis. When an analyst attempts to fit a statistical model to observed data, he or she may wonder how well the model actually reflects the data. How "close" are the observed values to those which would be expected under the fitted model? One statistical test that addresses this issue is the chi-square goodness of fit test. This test is commonly used to test association of variables in two-way tables, where the assumed model of independence is evaluated against the observed data. In general, the ***chi-square test statistic*** is of the form

$$X^2 = \sum \frac{(\text{observed - expected})^2}{\text{expected}}.$$

If the computed test statistic is large, then the observed and expected values are not close and the model is a poor fit to the data

ANNEXURE-VII

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INTRODUCTION

95% **MATCHING BLOCK 1/9** W

One of the main goal of operative dentistry is to preserve the health of dental pulp. Normal pulp is a coherent soft tissue, dependent on its normal hard dentin shell for protection and hence, once exposed, extremely sensitive to contact and temperature. Pulp can get affected by various

irritants including caries, trauma and iatrogenic causes and it possesses an intrinsic capacity for healing through cell reorganization and reparative dentin formation, when a proper biological seal is provided and maintained against microbial leakage. CITATION Gro \l 1033 (1) In order