Original Article

Comparative evaluation of dual-cure resin (TheraCal PT) and Biodentine in coronal pulpotomy of patients with symptoms indicative of irreversible pulpitis: A randomized clinical trial

Harakh Chand Baranwal, Neelam Mittal, Silviya Samad, Aiyman Ayubi, Harshitaa Aggarwal, Shubham M. Kharat

Department of Conservative Dentistry and Endodontics, Faculty of Dental Sciences, Institute of Medical Sciences, BHU, Varanasi, Uttar Pradesh, India

Abstract

Background: New and innovative materials are being marketed for the treatment of coronal pulpotomy. It is crucial to compare their efficacy with already-established materials. TheraCal PT (TP) is such a new material that studies are scarce.

Aim: This study aim to compare and evaluate the outcome of coronal pulpotomy using Biodentine and a newly introduced calcium silicate-based dual-cure resin cement, TP, in patients with symptoms of irreversible pulpitis.

Materials and Methods: Sixty patients with exposed carious pulp and symptomatic irreversible pulpitis were included, aged 18–40, randomly allocated to two groups: TP (group I) and Biodentine (group II). Coronal pulpotomy was performed following a standardized protocol, with TP or Biodentine applied accordingly. The pain was recorded using Visual Analog Scale preoperatively for up to 1 week. Success was assessed clinically and radiographically for up to 12 months.

Statistical Analysis Used: The data were analyzed using the Friedman test and the Mann–Whitney *U*-test. Intragroup pain was analyzed using the Wilcoxon signed-rank test.

Results: Among 60 patients, intervention was done in 53. By removing dropout patients, 47 were analyzed, with 38 available for follow-up at 3, 6, and 12 months. The Biodentine group exhibited a 12-month success rate of 84%, while the TP group revealed 77.3%, with statistically insignificant difference ($P = 0.563$).

Conclusion: TP can be effectively utilized as a pulpotomy material in cases of symptomatic irreversible pulpitis in mature permanent teeth, offering rapid setting and ease of use, although Biodentine yielded slightly better results in this study.

Keywords: Biodentine; coronary pulpotomy; TheraCal PT

INTRODUCTION

Dental caries, an infectious condition, is the most common cause of pulpal inflammation. The term "reparative dentinogenesis" describes the display of several physiological defense mechanisms of the dentin–pulp complex against this.[1] Maintaining pulp viability is the paramount objective of biologically based, minimally invasive treatments. In this aspect, vital pulp treatment (VPT) procedures such as partial and full pulpotomies and direct and indirect pulp capping have become increasingly popular.

Address for correspondence:
Dr. Silviya Samad,
Department of Conservative Dentistry and Endodontics,
Faculty of Dental Sciences, Institute of Medical Sciences, BHU,
Varanasi - 221 005, Uttar Pradesh, India.
E-mail: silviyasamad@gmail.com

Date of submission : 12.05.2024
Review completed : 20.06.2024
Date of acceptance : 22.06.2024
Published : 07.08.2024

Access this article online

Quick Response Code:

Website: https://journals.lww.com/jcde

DOI: 10.4103/JCDE.JCDE_280_24

How to cite this article: Baranwal HC, Mittal N, Samad S, Ayubi A, Aggarwal H, Kharat SM. Comparative evaluation of dual-cure resin (TheraCal PT) and Biodentine in coronal pulpotomy of patients with symptoms indicative of irreversible pulpitis: A randomized clinical trial. J Conserv Dent Endod 2024;27:822-7.

VPT is a collection of conservative methods that count on the natural reparatory mechanisms of the dentin–pulp complex.[2] Because of this, pulp vitality maintenance with VPT treatments has attracted interest as a more cautious substitute for root canal therapy in patients with pulpal inflammation.[3] VPT relies on an appropriate medicament and sealed coronal restoration to create a biologically favorable atmosphere for pulp tissue healing and protection against bacterial contamination. According to some theories, the medication's effectiveness in preventing microleakage had a greater impact on dental pulp healing than its kind.[4] For years, calcium hydroxide (CH) was often used but fell out of favor due to complications such as tunnel defects in dentinal bridges, poor adhesion, lack of long-term sealing, reabsorption, solubility, and mechanical stability.[5,6] Moreover, it is found that the reparative tissue induced by CH is found to be more porous which ultimately causes bacterial ingress compromising the vitality of the tooth.[7] Mineral trioxide aggregate (MTA) cement, composed of calcium silicate compounds, is now popular in endodontic therapy for its efficient interaction with pulp tissue, reducing inflammation compared to CH-based materials.[8] Innovations such as Biodentine (Septodont, Saint-Maurdes-Fosses, France), with similar benefits to MTA but addressing handling difficulties and prolonged setting time, have emerged in the field.[9] The development of resin-modified calcium silicate-based materials such as Theracal LC and Theracal PT aims to enhance bioactivity and reduce cytotoxicity.[10] Theracal LC combines silicate-based properties with improved resin handling, while Theracal PT (Bisco Dental Products, Schaumburg IL, USA), released in 2019, targets pulpotomies and pulp capping.[11] Even though TheraCal LC has considerable bioactivity due to the presence of silanol and resin groups, contrary results also have been reported in terms of reduced success rates on long-term follow-up.[12]

This study compares Theracal PT with Biodentine in coronal pulpotomy of teeth with irreversible pulpitis, considering Theracal PT's recent market entry and lack of prior VPT studies. The null hypothesis of this study was that TheraCal PT (TP) can be used as a successful material for coronal pulpotomy, and there is no difference in success rate when compared with Biodentine.

MATERIALS AND METHODS

This *in vivo*, interventional, parallel arm double-blinded randomized clinical trial (approved by the institute's ethical committee under approval number 2022/EC/3473 and registered with CTRI/2022/11/047727) conducted in the Department of Conservative Dentistry and Endodontics focused on developed permanent molars with clinical symptoms of irreversible pulpitis due to caries. Sixty patients aged 18–40 years, experiencing strong and prolonged reactions to cold and spontaneous dull pain, were screened as per CONSORT guidelines [Chart 1]. Exclusion criteria included nonrestorable teeth, no response on cold testing, the existence of a sinus tract or swelling, uncontrollable bleeding following a pulpotomy, insufficient bleeding due to necrosis, and medically compromised patients. Eligible participants provided informed consent after being briefed on the procedure, associated risks, benefits, and alternative treatments.

A pilot study with six patients per group compared TP and Biodentine in coronal pulpotomies of patients with irreversible pulpitis, followed up for 3 months. Biodentine showed a 100% success rate with no reported pain, while TP had a 66.67% success rate with 2 patients reporting pain. Using G*Power 3.1.9.2 (Heinrich-Heine-Universitat, Dusseldorf, Germany), the sample size calculation yielded 21 per group with 95% power and a 5% alpha error, rounded up to 22 per group, accounting for a 10% dropout rate.

A single operator conducted all endodontic procedures. Group assignment was random using a chit system, facilitated by a dental assistant. While blinding the operator was not feasible, patients and assessors remained unaware of group allocation. Teeth were anesthetized using 2% lignocaine hydrochloride with epinephrine 1:80,000 (Indoco Remedies Ltd, India) and isolated with a Rubber dam (Coltene, Switzerland). All the procedures were done under magnifying loupes (Zumax SLE Loupes 3.5x, Orikam Healthcare India Pvt. Ltd). Carious lesions were excavated using a #2 round diamond bur and spoon excavator (GDC, India). Pulp tissue was removed up to the canal orifice using a sterile round bur with underwater coolant, and bleeding was controlled with a cotton pellet soaked in 3% sodium hypochlorite solution (Paracan, Septodont, USA) for 5 min. In group I, TP (Bisco Dental Products, Schaumburg IL, USA) was applied over the pulp at a thickness of 2–3 mm, light-cured for 20 s, and covered with a layer of glass ionomer cement (GC Corporation). After 10 min, composite restoration (Ivoclar Vivadent) was performed, followed by a postoperative periapical radiograph. In group II, Biodentine (Septodont, Saint-Maurdes-Fosses, France) was gently placed over the pulp tissue at 2–3 mm thickness, allowed to set for 12 min, and followed the same restorative procedures as in group I.

Postoperative evaluation included clinical assessments using the Visual Analog Scale (VAS) preoperatively and after 7 days for pain, and radiographic assessments at 3, 6, and 12 months. Clinical criteria comprised pain assessment, pulp vitality tests, palpation, percussion, swelling, sinus tract examination, and coronal restoration integrity. Radiographic criteria included periodontal ligament space widening, periapical radiolucency, root resorption, and dentine bridge formation. Treatment success meant no signs of irreversible pulpal disease, positive pulp vitality

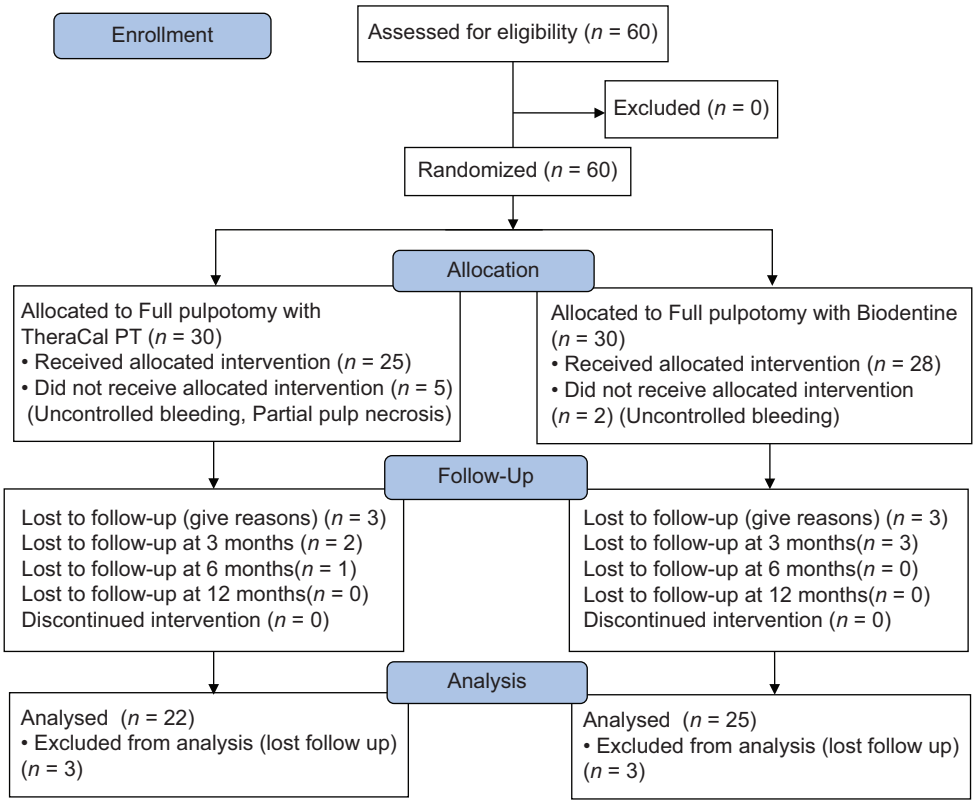

Chart 1: Consort flow diagram of the 66 eligible patients up to 12-month follow-up

tests, no resorption, and no pathosis on radiographs, with complete healing or Peri apical index (PAI) score reduction. Treatment failure included pain, tenderness, sinus tract, radiolucency, lack of improvement or increased PAI score, and root resorption signs.

For statistical analysis, data after evaluation were entered into Microsoft Excel and transferred to SPSS software (Version 21.0; IBM Corp., Armonk, NY, USA). The Mann–Whitney test and Friedman test were employed for intergroup and intragroup evaluations, respectively, to compare success rates, pain incidence, percussion sensitivity, hypersensitivity, dentine bridge formation, root canal calcification, and PAI scores. For VAS scores, intragroup evaluation was done by the Wilcoxon signed-rank test and intergroup evaluation by the Mann–Whitney test.

RESULTS

Out of 60 enrolled patients, the intervention was performed on 53 due to sample loss from uncontrolled bleeding and pulpal necrosis. Analysis was done on 47 patients at the end of 12 months because 6 patients dropped out due to unknown reasons. Based on 12 months of clinical and radiographic evaluation, Group I (TP) showed a success rate of 77.3%, while Group II (Biodentine) had a success rate of 84%. However, the difference was statistically insignificant between the groups ($P = 0.563$) [Table 1]. Hence, the null hypothesis was accepted. Biodentine pulpotomy had an earlier and higher occurrence (20%) of dentin bridge formation compared to TP pulpotomy (18%), but this was statistically insignificant ($P = 0.632$). The number of cases with dentin bridge formation increased significantly over time in both groups [Table 1]. PAI scores improved significantly over time in Group I ($P = 0.002$). However, no significant difference was there between the groups [Table 1]. Both groups showed a highly significant reduction in mean preoperative and 7-day pain scores ($P < 0.05$) [Table 2].

Postoperative evaluation included clinical assessments using the VAS preoperatively and after 7 days for pain and radiographic assessments at 3, 6, and 12 months. Clinical criteria comprised pain assessment, pulp vitality tests, palpation, percussion, swelling, sinus tract examination, and coronal restoration integrity. Radiographic criteria included periodontal ligament space widening, periapical radiolucency, root resorption, and dentine bridge formation. Treatment success meant no signs of irreversible pulpal disease, positive pulp vitality tests, no resorption, and no pathosis on radiographs, with complete healing or PAI score reduction. Treatment failure included pain, tenderness, sinus tract, radiolucency, lack of improvement or increased PAI score, and root resorption signs. For statistical analysis, data after evaluation were entered into Microsoft Excel and transferred to SPSS

Table 1: Evaluation of success rate, dentine bridge formation, and PAI scores

(a) Intragroup and intergroup evaluation of success rate (in percentage) at different follow-up times

Groups	Follow-up			Intragroup (*P*)†
	3 months	6 months	12 months	
I (*n*=22), *n* (%)	18 (81.8)	17 (77.3)	17 (77.3)	0.368
II (*n*=25), *n* (%)	23 (92)	22 (88)	21 (84)	0.223
Intergroup (*P*)‡	0.302	0.334	0.563	

(b) Intragroup and intergroup evaluation of Dentine bridge formation at different follow-up times

Groups	3 months		6 months		12 months		Intragroup (*P*)†
	P	A	P	A	P	A	
I (*n*=22), *n* (%)	0	20 (90.9)	2 (9.1)	16 (72.7)	4 (18.2)	13 (59.1)	0.005*
II (*n*=25), *n* (%)	1 (4)	23 (92)	3 (12)	19 (76)	5 (20)	16 (64)	0.005*
Intergroup *P*‡	0.860		0.738		0.658		

(C) Intragroup and intergroup evaluation of PAI scores at different follow-up time

Groups	Follow-up												Intragroup (*P*)†
	Preoperative			3 months			6 months			12 months			
	1	2	3	1	2	3	1	2	3	1	2	3	
I (*n*=22), *n* (%)	18 (81.8)	4 (18.2)	0	17 (77)	3 (13)	0	17 (77.3)	0	1 (4.5)	17 (77.3)	0	0	0.002*
II (*n*=25), *n* (%)	23 (92)	1 (4)	1 (4)	23 (92)	2 (8)	0	20 (80)	3 (12)	0	20 (80)	0	0	0.158
Intergroup (*P*)‡	0.338			0.796			0.210			0.418			

*$P<0.05$ statistically significant, †Friedman test, ‡Mann–Whitney test. PAI: Peri apical index

Table 2: Intragroup and intergroup evaluation of visual analogue scale scores pre operatively and at 7 days

Groups	Mean±SD		Intragroup (*P*)†
	Preoperative	7 days	
I (*n*=22)	4.77±0.52	0.86±2.03	<0.001*
II (*n*=25)	5.04±0.67	0.60±1.44	<0.001*
Intergroup (*P*)‡	0.153	0.794	

*$P<0.05$ statistically significant, †Wilcoxon signed-rank test, ‡Mann–Whitney test. SD: Standard deviation

software (Version 21.0; IBM Corp., Armonk, NY, USA). The Mann–Whitney test and Friedman test were employed for intergroup and intragroup evaluations, respectively, to compare success rates, dentine bridge formation, and PAI scores. For VAS scores, intragroup evaluation was done by the Wilcoxon signed-rank test and intergroup evaluation by the Mann–Whitney test.

DISCUSSION

VPT is a conservative approach that harnesses the natural healing abilities of the dentin–pulp complex. It is effective even in cases of irreversible pulpitis caused by trauma or carious lesions.[13] Full pulpotomy, where the entire coronal pulp is surgically removed while preserving the vitality of the radicular portion, has gained recognition as a substitute for root canal therapy. Studies show a high success rate of 92.8% for coronal pulpotomy in permanent teeth with symptomatic irreversible pulpitis over a 12-month period.[14] Systematic reviews also support the efficacy of VPTs, especially full pulpotomies, for treating carious pulp exposure, presenting them as an alternative to root canal therapy.

Several factors impact the success of pulpotomy procedures. Age does not significantly affect success rates, but the state of the pulp, especially in irreversible pulpitis cases, is crucial. Rubber dam isolation reduces leakage risk compared to cotton roll isolation.[15] Proper coronal sealing with bioactive material is essential to prevent bacterial microleakage.[16] Applying a definitive restoration at the same appointment significantly impacts success rates, as well as restores tooth esthetics.[17] Biodentine, a calcium silicate-based material introduced in 2009, has gained attention for its improved sealing ability and faster setting time. Recent studies highlight the significance of growth factors like TGF-b1 in dental processes, especially in promoting reparative dentine synthesis when Biodentine is applied directly to the pulp. It creates a "mineral infiltration zone" along dentin–cement interface, releasing ions that enhance sealing performance and disinfect surrounding tissues.[18] Biodentine's high alkaline pH inhibits bacterial growth and promotes OD21 cell proliferation, contributing to its bioactivity and suitability for dentin–pulp complex regeneration.[19] The alkalizing capability of calcium silicate cements arises from the generation of CH on exposure to moisture, which releases hydroxyl ions. Increased Ca2+ release suggests enhanced hydroxyl ion transport. The differing compositions of TP and Biodentine likely contribute to variations in Ca2+ release.

TP is a novel dual-cure calcium silicate material infused with resin, designed for vital pulp therapy. The manufacturer promotes its ease of handling compared to Biodentine and its ability to protect the tooth's pulp complex, thus maintaining pulp vitality.[20] TP sets via a dual polymerization reaction and is hydrophilic. TheraCal LC is another variant of the same family, which is a calcium silicate-based light-cure resin cement, marketed before the introduction of TP. Both exhibit similar effects in terms of alkalizing activity due to

their resinous structure. Their low solubility and limited resin matrix water sorption hinder the hydration of calcium silicate into CH, bringing down the alkalizing activity. Biodentine is mainly composed of tricalcium silicate powder (80.1%), with a liquid containing calcium chloride as a water-reducing agent, ensuring ample calcium sources. TP is a resin-modified calcium silicate cement composed of a resin matrix including bis-GMA (5%–10%) and polyethylene glycol dimethacrylate (10%–30%). Interestingly, TP's safety datasheet does not mention calcium's presence in its composition. Biodentine's highly porous and hydrophilic structure facilitates hydration, resulting in significant volumes of calcium silicate hydrate and CH, contributing to increased Ca2+ release. In contrast, TP's resinous structures lack sufficient porosity for this hydration reaction and rely primarily on constrained water sorption and diffusion within the hydrophobic resin matrix. The scanty moisture diffusion in the set resin material may lead to inadequate Ca2+ release.[21] Biodentine exhibits a stronger alkalizing potential compared to TP across all time intervals, consistent with previous research.[22]

Although research on TP is limited due to its recent introduction, it shows promise for treating exposed dentin. This is the rationale behind the current study. This study shows a promising success rate of 84% and 77.3% in coronal pulpotomy using Biodentine and TP respectively after 1 year. The presence of periapical involvement might not always be associated with pulp necrosis and some part of the pulp tissue may still be vital. Various case reports of the resolution of periapical radiolucencies after indirect pulp capping and pulpotomy have been published. 77.3% of cases of the Theracal PT group and 80% of cases of the Biodentine group showed healing of periapical lesion or improvement in PAI score on IOPA evaluation. When subjected to intragroup analysis the PAI scores gradually got reduced over 12 months in both the groups. However, there was a statistically significant difference in the intra-group analysis among the subjects in TP group.

One of the main reasons for which the patient seeks endodontic treatment is pain. In the present study, patients in both groups had preoperative pain scores ranging between 4 and 6 on a 10-cm VAS. The mean postoperative pain scores after 7 days demonstrated considerable reduction in both groups with no statistically significant difference between the groups ($P > 0.05$). Thus, it can be concluded that both materials when used for pulpotomy, help in reducing pain considerably. There are previous studies that prove the effectiveness of pulpotomy in mitigating pain.[23] In this study, all patients initially presented with acute, spontaneous, or persistent pain. Pulpotomy treatment significantly reduces pain by severing nociceptive sensory neurons and reducing local tissue pressure and inflammatory mediators. Compared to root canal treatment, pulpotomy results in greater pain reduction.[24] Studies have shown that coronal pulpotomy has a good track record of immediate and better pain relief.[25] Here, both materials used significantly demonstrated pain alleviation, possibly due to their biological properties.

CONCLUSION

This study concludes that the newly introduced calcium silicate-based dual cure material, TP, can be successfully used in coronal pulpotomies of symptomatic irreversible pulpitis cases like Biodentine, with the advantages of rapid setting time and ease of use.

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

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