Original Article

Role Of Prf With Mta And Theracal After Pulpotomy In Relieving Pain And Maintaining The Vitality Of The Remaining Radicular Pulp Tissue In Permanent Posterior Teeth With Closed Root Apices: "Randomized Controlled Trial"

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Abstract

Aim: to evaluate the effect of PRF with TheraCal and MTA in relieving pain, conserving tooth vitality and inducing a dentine bridge barrier after pulpotomy in permanent teeth with closed apices.

Methodology: 98 patients were selected with Symptomatic/ Asymptomatic pulpitis and divided into two groups where, after pulpotomy, in group A: the root stumps were dressed with PRF and MTA while in group B: the root stumps were dressed with PRF and TheraCal. Pain was recorded both preoperatively and postoperatively after 24 hrs and 7 days. Treatment outcome was evaluated after 3, 6 and 12 months clinically and radiographically. After 12 months dentin bridge formation was evaluated by CBCT.

Results: MTA showed (75%) success rate while TheraCal showed (71.43%) after 1 year follow-up.

Conclusions: MTA showed better outcome than that of TheraCal although they showed no significant difference statistically.

Key words: Regenerative pulpotomy, vital pulp therapy, PRF, TheraCal, MTA, Dentin bridge formation, CBCT, pulpotomy.

INTRODUCTION:

The major challenge for the modern approach in restorative dentistry is to induce remineralization of hypo mineralized carious dentine, and therefore, protecting and preserving the pulp vitality. Traditionally, deep caries management often resulted in pulp exposure and subsequent root canal treatment. The promotion of biologically-based treatment strategies has been advocated for partial caries removal which aimed to avoid carious pulp exposure. Indeed, recent consensus reports have stated that the complete or nonselective caries removal is now considered overtreatment (Schwendicke et al., 2016). Treatment of cariously exposed pulp is also shifted toward avoiding pulpectomy, claiming the superiority of vital pulp therapy techniques such as pulp capping, partial and complete pulpotomy (Bjørndal et al., 2019). Preservation of pulp vitality is important as the vital pulp is capable of initiating dentin formation, providing nutrition to the tooth, enabling a defensive function, and also having a reparative capacity. Pulpotomy is one of the major methods of Vital Pulp Therapy that used to maintain the tooth vital, by removing the infected coronal pulp and leaving the radicular part intact. Over the remaining radicular pulp, a suitable material is placed (Eghbal et al., 2009a). Mineral trioxide aggregate (MTA) is a bioactive material that is used in pulpotomy, characterized by a great ability to stimulate reparative dentin formation; however, it has many drawbacks such as; difficult handling, a long setting time and a relatively high cost (Tran et al., 2012). Other materials were introduced in order to overcome these problems such as TheraCal LC, which is considered a light cured, resin modified calcium silicate filled liner designed to be used in direct and indirect pulp capping. It also acts as an insulator/barrier and protectant of the dentin-pulp complex. The formulation of TheraCal LC provides calcium release which stimulates hydroxyapatite and secondary dentin bridge formation which could be placed directly on pulpal exposures after homeostasis is obtained. It is indicated for any pulpal exposures, including carious exposures, mechanical exposures or even due to trauma (Qureshi et al., 2014). In spite of the growing improvements in material sciences, cytotoxic effect of various biomaterials used for pulpotomy still present. Hence, there is a need for biologically based autologous material to neutralize their side effects, reduce the pulpal inflammation and to make the healing faster (Hiremath et al., 2012a). Platelet rich fibrin (PRF), a second generation of platelet concentrate introduced by Choukroun et al. (2006), is an autologous material that helps releasing the growth factors necessary for regeneration of dentin pulp

complex thereby accelerating the healing process (Hiremath et al., 2012a). Therefore, it was placed directly over the pulp stumps after pulpotomy under either MTA or TheraCal. The aim of this study was to compare the effect of PRF with either MTA or TheraCal LC in relieving pain, conserving the tooth vitality and inducing a dentine bridge barrier after pulpotomy in permanent posterior teeth with closed apices.

MATERIALS AND METHODS:

Study design:

The trial design was set as a parallel, randomized, 1:1, double -blinded (outcome assessor- participant) controlled trial. This trial design methodology conforms to the consolidated standard of reporting trials (CONSORT)[1] statement.

Setting and Recruitment:

The trial protocol was registered on www. clinicaltrials.gov (ClinicalTrials.gov Identifier: **NCT03493321**) and was approved by the Committee of Research Ethics, Faculty of Dentistry, Cairo University. Patients were recruited from the outpatient clinics in the Department of Endodontics, Faculty of Dentistry. The study objectives, benefits, risks and follow up intervals were explicitly described to all participants then those accepting participation signed a written consent form.

Sample size calculation:

Based on previous study by *Bakhtiar et al. 2017,* the failure rate among controls (MTA group) is 0.001. If the true failure rate for intervention (TheraCal group) is 0.20, 78 cases (39 cases per group) will be needed to achieve an 80% power using the Fisher's exact test. The Type I error probability associated with this test is 0.05. The number is increased to a total sample size of 98 cases (49 cases per group) to allow for losses of around 25%. Sample size was calculated using PS ***(Dupont and Plummer, 1990).***

Randomization, allocation concealment and blinding:

A random sequence was created on (https:// www.rand.org/), assigning the patients randomly to one of two groups with a 1:1 allocation ratio as follows**:** Group A: PRF with MTA and Group B: PRF with TheraCal**.** To conceal allocations, the randomly generated numbers from the software were written in small 8-time folded papers and inserted into opaque envelopes; the envelopes were sealed, and placed in a container for each patient to withdraw one envelope immediately after placement of the PRF and before placement of either MTA or TheraCal LC to be assigned to either group. Both the patients and the outcome assessor were blinded to the interventions. The steps of the treatment were explained to the patients without knowing which dressing is to be used for pulpotomy. Blinding to the outcome assessor was done by holding back sequence generation, allocation concealment, and the used dressings.

Eligibility Criteria:

Patients free of any systemic diseases that would interfere with normal healing, of both sexes, suffering from Symptomatic or Asymptomatic Pulpitis as well as traumatic pulp exposures in one posterior tooth, with age range between 17-50 years old were included in the study. Whereas patients with bad oral hygiene, necrotic pulps, signs of periapical and/ or periodontal inflammations and those who could/would not participate in a 1-year follow-up were excluded from the study.

Endodontic procedures:

After signing the informed consent, each patient had his/her medical and dental histories recorded by the operator in medical and dental history charts**.** A pain scale chart with numerical rating scale "NRS" was given to each patient to record their preoperative pain level. Then they were asked to fill their postoperative pain levels at 24 hours, and 7 days postoperatively and return t to the operator. Pain level was assigned to one of four categorical scores: None (0); Mild (1–3); Moderate (4–6); and Severe (7–10).

Pulp status was evaluated using thermal (cold) test by Ethyl Chloride and EPT and confirmed clinically thereafter by the presence or absence of bleeding at the exposure. Teeth were included if they responded positively to both the cold test and EPT. Periodontal examination was done clinically using a periodontal probe and radiographically by digital x-ray to evaluate the periodontal status and check for the continuity of the lamina dura. Teeth that had widening of the PDL space, periapical radiolucency or deep pockets were excluded.

Eligible patients were randomly divided into two equal groups (PRF with MTA group) and (PRF with TheraCal group) with 49 patients per group. Patients were anaesthetized using Articaine HCl 4% with Epinephrine. Each tooth was isolated with rubber dam to maintain aseptic field, after isolation any remaining caries was removed by round diamond stone. Access cavities were prepared up to the level of pulp chamber floor using tapered stone with round end in high-speed hand piece with coolant. Haemostasias was achieved by pressing cotton pellet with saline into the cavity for 5 minutes and if bleeding persists, another cotton pellet with saline was placed for another 5 minutes (Figure 1).

[1] (CONSORT) Statement 2010- check list: http://www.concort-statment.org/consort-statment/

(A) **(B)** **(C)**

Figure (1) (A): Access Cavity Preparation Of The Selected Tooth
(B): Control The Bleeding After Using Normal Saline
(C): The Cavity Before PRF Placement Immediately

Preparation of PRF:

After achieving hemostasis; teeth were ready to receive the PRF membrane. PRF was prepared according to Choukroun's technique ***(Choukroun et al., 2006)*** by drawing blood into a 10 ml red capped glass tubes without anticoagulant. The blood sample was immediately centrifuged in an electric powered centrifuge at 3000 rpm for 12 mins. The obtained product consisted of three layers: the top most layer of acellular platelet poor plasma, the middle layer of platelet rich fibrin (PRF), and the bottom most layer of red blood corpuscles, The PRF was segregated and squeezed to form a membrane. The PRF membrane obtained was then placed over the exposed pulp stumps.

In Group A: After hemostasis, PRF was be placed over the exposed pulp followed by 2 mm layer of MTA, a moist cotton pellet was then placed over it, and tooth was temporarily restored with temporary filling for 7 days. After 7 days the patients were recalled, temporary filling was removed. After confirmed MTA setting; teeth were restored with a final DSR Sonic composite resin restoration. **In Group B:** After hemostasis, PRF was placed over the exposed pulp followed by 2 mm of TheraCal, curing of the TheraCal was done for 20 seconds; then teeth were restored with a final composite resin restoration.

Postoperative care and Follow- up:

All patients received postoperative instructions, in case of moderate to severe pain; patients were instructed to call the operator and were allowed to take a prescribed analgesic (Ibuprofen 400 mg). If there was still pain indicating a flare up (emergency), the patients were informed to contact the operator and to come to the clinic for an emergency intervention. The incidence and intensity of pain were recorded on the NRS, after 24 hours and daily up to 7 days.

Treatment outcome was evaluated clinically after 3,6 and 12 months to evaluate any sensitivity to percussion, presence of a swelling or fistulous tract. At the 12-month follow up tooth vitality was evaluated clinically. The treatment was considered clinically successful in case of absence of pain, swelling and no tenderness to percussion. (Done at 3,6 & 12 months) while radiographically it was considered successful in case of absence of widening in the lamina dura, periapical radiolucency or furcal involvement After 12 months (Estrela et al.).

At the 12-month follow up visit, the pulp status was evaluated by hot and cold test and a CBCT scan was obtained from all patients for evaluation of periapical tissues and detection of dentin bridge formation. The evidence of dentin bridge formation on CBCT was evaluated by two independent observers who were blinded to the groups. In case of disagreement; a discussion was held to reach a consensus about the decision.

Statistical method:

Data were analyzed using IBM SPSS advanced statistics (Statistical Package for Social Sciences), version 23 (SPSS Inc., Chicago, IL). Numerical data was described as median, interquartile range or range or mean and standard deviation, as appropriate, while qualitative data were described as number and percentage. Regarding pain presence, periapical radiolucency, dentin bridge formation and finally tooth vitality; Fisher's exact test was used. Regarding pain intensity measured by NRS score; testing for normality was done using Kolmogrov-Smirnov test and Shapiro-Wilk test. To test the difference between the two groups in case of normally distributed variables, comparisons between the mean of the two independent groups was tested using Student t test. For not normally distributed variables comparisons between the median of the two groups was tested using Mann Whitney U test. A p-value less than or equal to 0.05 was considered statistically significant. All tests were two tailed.

RESULTS

Of 120 patients screened for eligibility, 98 were included, and randomly assigned to either group. Participants' age ranged between 17 and 50 years. The study included upper and lower posterior teeth. There was no statistically significant difference between the two groups regarding all base line data including, age, gender and tooth type (Table1)

	Group A	Group B	P value
Age (mean& SD)	31.65 ± 8.57	28.15± 8.04	0.06344
Gender			
Male %	40%	52.5%	0.2713
Female%	60%	47.5%	
Tooth type			
Upper Molar %	32.5%	17.5%	0.1285
Lower molar %	47.5%	30%	0.1150
Upper Premolar%	15%	37.5%	0.0249
Lower premolar%	5%	15%	0.1436

Pre-operative pain was recorded as cold only, cold and hot and fractured old restoration with no pain for both groups. There was no statistically significant difference between both groups by Chi Square test as P-value > 0.05 (table 2)

Table (2): Pre-Operative Pain Distribution:

	Group A	Group B	P-value
	%	%	
Cold only	30	40	0.3515
Cold and Hot	35	37.5	0.8172
Fractured Old Restoration with No Pain	35	22.5	0.2197

Postoperative pain evaluation:

1.a. Pain Intensity (after 24hrs and through the whole week)
1.b. Pain Incidence (after 24hrs and 7 days)
1.c. Pre-and Post-Operative Pain for each group

1.a. Pain Intensity:

After 24 hours till day 6, there was no statistically significant difference between both groups as P-value > 0.05. Regarding day (7), there was a statistically significant difference between both groups as MTA group showed higher pain intensity than TheraCal group as P-value < 0.05.

Table (3): Results Of Pain Intensity During The 7 Days:

	(MTA) Group		(TheraCal) Group		P-value
	M	SD	M	SD	
Day (1)	4.38	3.17	3.33	2.54	0.1061
Day (2)	3.65	2.83	2.98	2.49	0.2644
Day (3)	3.25	2.64	2.80	2.56	0.4413
Day (4)	3.33	3.15	2.73	2.86	0.3752
Day (5)	2.98	3.28	3.03	3.53	0.9478
Day (6)	2.95	3.43	2.08	3.01	0.2316
Day (7)	2.85	3.87	1.45	2.15	0.049*

1.b. Pain Incidence after 24 hours:

Post-operative pain after 24 hours was ranged as none, mild, moderate and severe. Regarding no and mild pain, there was no statistically significant difference between both groups. While with moderate pain, MTA group showed lower pain incidence (17.5%) than TheraCal group (43.59%). Finally with severe pain MTA group showed higher pain incidence (30%) than TheraCal group (7.69%) as listed in table (4).

Table (4): The Post-Operative Pain After 24 Hours Between Both Groups:

	(MTA) Group		(TheraCal) Group		P-value
	N	%	N	%	
None (0)	9	22.5	10	25.64	0.7456
Mild (1-3)	12	30	9	23.08	0.4892
Moderate (4-6)	7	17.5	17	43.59	0.0122*
Severe (7-10)	12	30	3	7.69	0.012*
Total	40	100	39	100	

Pain Incidence After 7 Days:

Regarding no pain, MTA group showed higher percentage (57.5%) of no pain than TheraCal group (28.21%) with statistically significance difference between both groups as P-value<0.05. While for mild pain, MTA group was (12.5%) and TheraCal group showed (35.9%), with statistically significance difference between both groups as P-value<0.05. For moderate and severe pain, there was no statistically significant difference between both groups as listed in table (5).

Table (5): Pain Incidence After 7 Days:

	(MTA) Group		(TheraCal) Group		P-value
	N	%	N	%	
None (0)	23	57.5	11	28.21	0.009*
Mild (1-3)	5	12.5	14	35.9	0.0156*
Moderate (4-6)	3	7.5	2	5.13	0.6674
Severe (7-10)	9	22.5	12	30.77	0.4085
Total	40	100	39	100	

1.c. Pre- and Post-Operative Pain for Both Groups:

Regarding (**MTA**) group, there was a statistically significant difference between different follow up periods (P-value < 0.01). Also, a Positive statistically Significant moderate correlation between Pre- and Post- operative pain was recorded (P value < 0.01).

Table (6): Pre- And Post-Operative Pain Values For (MTA) Group:

	Pre-Operative Pain		Post-Operative Pain after 24 Hours		Post-Operative Pain after 7 Days		P value
	N	%	N	%	N	%	
None (0)	14	35	9	22.5	23	57.5	
Mild (1-3)	12	30	12	30	5	12.5	
Moderate (4-6)	10	25	7	17.5	3	7.5	
Severe (7-10)	4	10	12	30	9	22.5	0.00742
Total	40	100	40	100	40	100	

*P value < 0.01 **HS**

Regarding (**TheraCal**) group, there was a high significant difference between different follow up periods as P-value < 0.001. Also, a Positive statistically Significant moderate correlation between Pre- and Post- operative pain was recorded (P value < 0.05).

Table (7): Pre- And Post-Operative Pain Values For (Theracal) Group:

	Pre-Operative Pain		Post-Operative Pain after 24 Hours		Post-Operative Pain after 7 Days		P value
	N	%	N	%	N	%	
None (0)	9	22.5	10	25.64	11	28.21	
Mild (1-3)	16	40	9	23.08	14	35.897	
Moderate (4-6)	12	30	17	43.59	2	5.13	0.00094
Severe (7-10)	3	7.5	3	7.69	12	30.77	
Total	40	100	39	100	39	100	

***P < 0.05 **S.**

Follow-up after 3 months:

7 cases recorded pain due to Symptomatic Apical periodontitis which was observed for (MTA) group and (TheraCal) group as (0%) and (17.5%) respectively with a statistically significant difference between both groups (P- value < 0.01), as listed in table (8).

Table (8): Symptomatic Apical Periodontitis Distribution:

	(MTA) Group N(%)	(TheraCal) Group N(%)	P-value
Symptomatic Apical Periodontitis	0(0)	7(17.5)	0.00626

P < 0.01 **HS**

Follow up after 6 months:

The Success rate for MTA group was significantly higher (72.5%) than TheraCal group (43.59%). (P-value < 0.01), as listed in table (9).

Table (9): Success And Failure Rate After 6 Months:

	(MTA) Group		(TheraCal) Group		P Value
	N	%	N	%	
Success	29	72.5	17	43.59	
Failure	11	27.5	22	56.41	0.00919
Total	40	100	39	100	

***P < 0.01 HS**

Follow Up after 1 year:

Dentine Bridge Formation:

MTA group showed higher results than TheraCal group. There was a significant difference between them as P-value < 0.05, as listed in table (10).

Table (10): Dentine Bridge Formation After One Year Follow Up:

	(MTA) Group		(TheraCal) Group		P-value
	N	%	N	%	
Dentine Bridge Formation	15	100	10	60	0.01*

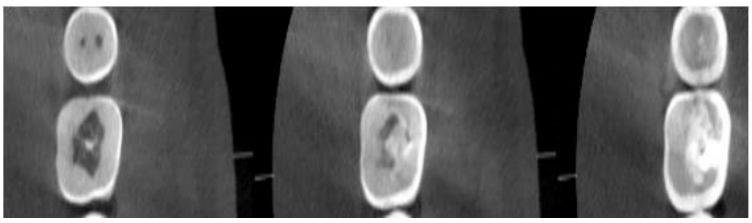

Figure (2): Axial Section By CBCT Showing The Sequential Formation Of The Dentin Bridge In MTA Group

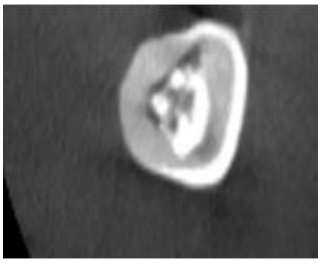

Figure (3): Axial Section By CBCT Showing The Dentin Bridge In Theracal Group

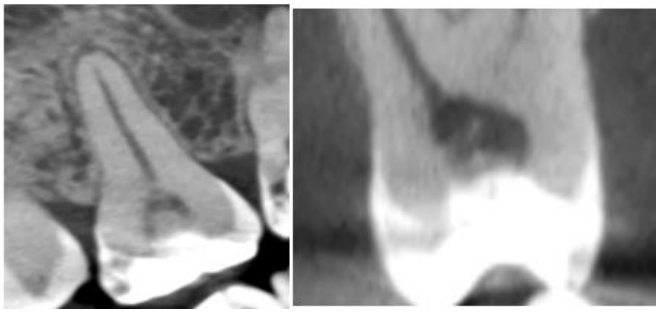

Figure (4): Coronal Section Of Cbct Showing Dentin Bridge Formation In Both Groups

Vitality Test:

MTA group showed higher results than TheraCal group. There was a statistically significant difference between them as P-value < 0.05, as listed in table (11).

Table (11): The Vitality Test After One Year Follow Up:

	(MTA) Group		(TheraCal) Group		P-value
	N	%	N	%	
Vital Cases	15	100	10	40	0.001*

Success and Failure Rate:

Regarding (MTA) group, it showed 75% which represent 15 cases out of 20 showed no periapical radiolucency with no pain while 25% which represent 5 cases showed Asymptomatic Apical Periodontitis due to restoration fracture. Regarding (TheraCal) group, it showed 71.43% which represent 10 cases out of 14 showed no periapical radiolucency with no pain during function while 28.57% which represent 4 cases out of 14 showed Asymptomatic Apical Periodontitis due to restoration fracture. There was no statistically significant difference between both groups.

Table (12): The Success And Failure Rate Of MTA And Theracal After One Year Follow-Up:

	(MTA) Group		(TheraCal) Group		P Value
	N	%	N	%	
Success	15	75	10	71.43	
Failure	5	25	4	28.57	0.81630
Total	20	100	14	100	

*** P>0.05 NS**

DISCUSSION:

Regenerative Pulpotomy has been introduced recently as a new technique in order to maintain teeth vitality with formation of a new dentin bridge barrier. ***Wang et al. (2010)*** reported that the pulp tissue in teeth clinically diagnosed with irreversible pulpitis still has cells that able to differentiate and proliferate. The regenerative potential of these cells can be controlled by giving them a suitable environment which may become a resource for pulp regeneration.

The aim of the current study was to evaluate the effect of PRF with either MTA and TheraCal in relieving pain, maintaining the teeth vitality and dentine bridge barrier formation in permanent teeth with closed apices.

In the present study, we preferred complete coronal pulpotomy over partial pulpotomy. In complete pulpotomy the entire coronal pulp was removed with sharp spoon excavator till the chamber floor, leaving vital radicular pulp with firm floor sheath which allow proper placement and condensation of the pulp capping agent. Partial pulpotomy, proposed by ***Mejare and Cvek 1993*** was not used in this study, as it is difficult to determine depth of the disease progression clinically so that complete pulpotomy ensure complete removal of the diseased tissue in order to eliminate its confounding effect. Also, lower success rate was found in cases treated with miniature/partial pulpotomy; therefore, it is advisable to perform complete pulpotomy or root canal treatment if the bleeding is hard to control ***(Awawdeh et al., 2018)***. In posterior teeth the caries incidence and pulp exposure were higher than anterior teeth. This could be attributed to their irregular occlusal anatomies that provide areas for bacterial attachment and invasion, therefore in our study posterior teeth were included ***(Van Thompson et al., 2008)***. The amount of remaining tooth structure and coronal restoration plays a key role in the success of VPT; the success rate was higher in molar teeth compared with premolar teeth ***(Awawdeh et al., 2018)***.

Pulpotomy is usually recommended in young patients, as younger pulp is more vascular, cellular, and has enhanced reparative potential ***(Alqaderi et al., 2014)***. Many studies have reported high success rates of pulpotomy in young permanent teeth ***(Alqaderi et al., 2014; Qudeimat et al., 2007)***. However, ***Kunert et al. (2015)***, in a retrospective study in 8- to 79-years-old patients, observed that age had no influence on success rate of pulpotomy. The findings of the current study are in agreement with previous studies ***(Simon et al., 2013)***. These observations suggest that coronal pulpotomy can be practiced in elderly patients as well as in young patients. Success of VPT depends mainly on hemorrhage control after pulp removal. Studies ***(Takashi Matsuo et al., 1996; Mass and Zilberman, 1993)*** have shown that observing the degree of pulp bleeding is better than depending on preoperative clinical signs and symptoms. Bleeding control is considered an important aspect for success of VPT, but they found that these indicators are clinically practical but subjective and cannot reflect the histologic status of the pulp accurately. The need for accurate molecular tests to diagnose pulp status is essential to avoid excessive invasive pulpal treatment ***(Awawdeh et al., 2018).***

NaOCl has been used as a hemostatic agent which also suggested to aid in the formation of dentin bridge ***(Demir and Cehreli, 2007)*** which may interfere in our study in evaluating the action of PRF. So, we avoid using NaOCl and we used Saline instead. Also, ***Hemavathi et al. (2018)*** found that the increased concentration of NaOCl (5%) showed lower success rate when compared to physiologic saline, although this difference was not statistically significant.

Since all pulp capping materials have some degree of toxicity especially in the freshly mixed state ***(Haglund et al., 2003; Balto 2004)*** which could be due to high initial pH ***(Camilleri, 2008)***, it is important to develop biocompatible treatments to maintain pulp vitality and increase tooth longevity ***(Wang et al., 2010)***. Therefore, PRF was used to create a bioactive buffer between those materials and the pulpal wound and also to act as a scaffold for regeneration of new pulp tissue in the pulp chamber. Using PRF in regenerative pulpotomy is useful as the regenerated tissue in the pulp chamber would make the responses to pulp testing more accurate.

PRF was preferred over PRP as it was easier in preparation/application with minimal expense and lack of biochemical modification (no bovine thrombin or anticoagulant is required). In an experimental trial, the growth factor content (PDGF and TGF-β) in PRP and PRF was found to be comparable ***(Sánchez, Sheridan, and Kupp, 2003)***. Growth factors play a crucial important role in signaling the tissue formation and repair in the dentine-pulp complex. They are also responsible for signaling tooth morphogenesis and differentiation, and recapitulation of these processes after dental injury which allows tissue regeneration ***(Smith, 2003).*** A number of reports of the in vivo ***(Hu et al., 1998)*** or in vitro ***(Sloan and Smith, 1999)*** placement of exogenous growth factors, particularly TGF-βs and Bone Morphogenetic Proteins, on exposed pulps have demonstrated the potential of these molecules to signal reparative dentinogenic events. Direct application of TGF-1 and BMP-7 to the odontoblasts of unexposed pulps in cultured tooth slices has also shown the ability of these growth factors to signal reactionary dentinogenesis ***(Sloan and Smith, 1999)***.

MTA was successfully used for pulpotomy either in primary or permanent dentitions, it showed good biocompatibility ***(Asgary et al., 2008)***, excellent sealing ability ***(Aqrabawi, 2000)*** and stimulation of healing in the pulpal tissue ***(Asgary et al., 2008)***. In the current study MTA was used as a pulpotomy agent as it was successfully used as a pulpotomy agent for mature permanent molars with irreversible pulpitis where histological examination revealed complete dentinal bridge formation, pulp vitality and absence of inflammation in all the cases ***(Eghbal et al., 2009b).***

TheraCal has been showed calcium release properties ***(Yamamoto et al., 2017)***. This calcium ions plays a key role as it induces the proliferation and differentiation of human dental pulp cells. Also, it is responsible for the new formation of mineralized hard tissues. The amount of calcium ions released from TheraCal LC was in the average range of the stimulatory activity for odontoblasts and the pulp tissue ***(Gandolfi et al., 2012)***. Also, being a light cured material allows placement of the final restoration in the same visit which could provide an advantage over other calcium silicate cements, including MTA, which may ensure a superior seal and eliminate the risk of contamination between visits ***(Arandi and Rabi, 2018)***. Also, the sealing ability of MTA, Biodentine, and TheraCal LC was evaluated. They found that there was no significant difference in the interfacial microleakage between MTA and Biodentine. However, TheraCal LC exhibited better sealing ability and less interfacial microleakage than the other two materials ***(Makkar et al., 2015)***. That's why in the current study we used TheraCal as a comparator.

A two-layer restoration consisting of RMGIC followed by Composite (Bulk fill) was placed to ensure an effective seal. While RMGIC ensured a good seal with minimal marginal leakage, the Composite provided compressive and tensile strength and resistance to dissolution ***(Kleitches, Lemon, and Jeansonne, 1995)***.

In order to evaluate the teeth vitality in the current trail, cold and thermal tests were used. **Villa-Chávez et al 2013** compared between the cold test, heat test and EPT and found that the most accurate test was the cold test (0.94). Also,

the most reproducible was the cold test (kappa = 0.88) followed by the heat (0.86) and finally the EPT (0.76), these results were in agreement with other study by **Bierma et al 2012**.

The follow-up period remains a topic of controversy. Although several studies ***(Calişkan 1995; Matsuo et al., 1996; Zanini et al., 2016)*** stated that follow-up of 6 months seems to be adequate to tentatively assess the outcome of pulpotomy, ***Ng et al. 2008 and Yazdani et al. 2014*** suggested that 2 years of follow-up is required to predict the success of endodontic treatment. While, ***Hørsted et al. 1985*** stated that time needed for dentinal bridge formation is 90 days. But as a rule, long term follow -up is always desirable to reveal late failures; the teeth treated in our study are scheduled for one year ***(Itri, 2017)***.

Patients might have severely inflamed pulp without a history of lingering or spontaneous pain; therefore, a history of pain cannot indicate the degree of pulpal inflammation extension ***(Rajasekharan et al., 2014)***. Recently, a better focus on the healing potential of the dental pulp evidence has revealed the urgent need for a new pulpal disease terminology ***Aguilar and Linsuwanont 2011; Josette Camilleri et al. 2013; Wolters et al. 2017***, with a number of proposed diagnostic categories requiring consideration to reach consensus in this field ***(Camilleri et al., 2013; Wolters et al., 2017).***

In the current randomized controlled trial, patients in both groups had preoperative pain. The pain was recorded from the patient's own words and ranging between no pain, pain with cold only and pain with hot and cold. The mean baseline preoperative pain scores were comparable with no statistically significant difference between both groups (P >.05).

Post-operative pain was scored using NAS after 24 hours and was ranged as none, mild, moderate and severe for both groups (MTA) and (TheraCal). Regarding no pain, there was no statistically significant difference between both groups. Also, for mild pain, there was no statistically significant difference. For moderate pain, it showed a statistically significant difference between both groups with better performance to MTA as pain was related to 7 cases (17.5%) while in (TheraCal) group 17 cases felt pain (43.59%). Finally with the severe pain, there was a statistically significant difference between both groups. In (MTA) group 12 cases showed severe pain by 30%, while with (TheraCal) group only 3 cases showed severe pain by (7.69%). MTA group showed less performance with less pain relief than TheraCal group in severe pain. ***Asgary et al. 2013*** reporting 27% pain in the pulpotomy group on the first day after treatment, another study by ***Galani et al. 2017*** observed 70.3% pain on the first day after pulpotomy. Also, ***Simon et al. 2013*** noted slight to moderate pain in 14 of 17 patients (82%) immediately or 1 day after complete pulpotomy and 71% reported no to very slight pain on the fifth day after treatment. ***Eghbal et al. 2009a***, in a clinical and histological study, observed complete remission of symptoms 24 hours following pulpotomy.

After 7 days, the MTA group showed better performance than TheraCal with significant difference in no pain and mild pain groups with 57.5% and 28.21% for MTA and TheraCal respectively, mild pain for MTA and TheraCal groups were 12.5% and 35.9% respectively. While, in relation to moderate and severe pain there was no statistically significant difference between both groups. MTA showed 7.5% for moderate pain while TheraCal was 5.13%. In severe pain MTA showed 22.5% while TheraCal was 30.77%.

The (TheraCal) group showed better performance (with significant difference) than MTA group in the pain intensity for the first week. This can be due to that TheraCal LC has a pH of 9.30 at 5 hours which gradually decreased to 8.4 at 6 hours and 8 at 25 and 144 hours which was significantly lower than the pH recorded for ProRoot MTA at different time periods. Also, they found that ProRoot MTA released significantly greater amounts of calcium ions than TheraCal LC. They also found that TheraCal LC does not form calcium hydroxide after setting, despite its release of calcium ions and formation of calcium apatite on its surface which reported by ***Yamamoto et al. 2017.***

The MTA group showed only failure in 9 cases after 1 week (18.3%) due to pain. Also, 2 other cases were lost due to restoration fracture (4.08%). The failure of these 9 cases in MTA group may be due to improper case selection from the beginning, suggesting the limitations of the currently available diagnostic aids to correctly diagnose pulpal disease. Although bleeding was controlled within the normal range but the inflammation might be extended toward the radicular part. Still there is no definite diagnostic tool to confirm the pulp status accurately.

The clinical and radiographic criteria for successful VPT includes maintenance of pulp vitality, minimum pulp inflammatory responses, formation of a continuous layer of reparative dentin, absence of postoperative clinical signs and symptoms of pain, or swelling. Also, it includes absence of radiographic evidence of internal or external root resorption, periapical and/or inter-radicular radiolucency, irregular calcification, or other pathologic changes ***Aguilar and Linsuwanont 2011.***

After 3 months of follow-up, the patients suffered from Symptomatic Apical Periodontitis related to teeth treated with TheraCal, and severe pain was recorded (up to 10 in some cases) so RCT was done in those teeth which was 7 cases (17.5%). These results were in agreement with ***Lee et al. 2015***, the results showed that the TheraCal produced less favorable pulpal responses than MTA group. Also, they found that TheraCal induced an extensive pulp inflammatory reaction in 75% of the teeth, which caused a higher degree of inflammation. This result may be related to the acrylic monomer Bis-GMA presented in the material.

Clinical and radiographic evaluation of success rate in this current study after 6 months and 1 year were the same; the cases showed periapical lesions radiographically gave a negative response in vitality test clinically. So, the success rate percentage clinically and radiographically with no difference. The total number of cases after 6 months of follow-up that continued without pain clinically or periapical pathosis radiographically in MTA group was 29 cases out of 40 with 72.5% success rate. For the TheraCal group only 17 cases out of 39 with 42.5% success rate (with significant difference between both groups).

After one year follow-up only 20 cases related to MTA group was showed for the final evaluation. In MTA group, CBCT showed restoration fracture in 5 cases with periapical pathosis with no pain which indicated Asymptomatic Apical

Periodontitis (25%), also these 5 cases gave no response clinically with thermal and cold tests. The remaining 15 cases (75%) showed 100% dentin bridge formation by CBCT with positive response to thermal and cold tests clinically. At the 1-year follow-up, the failure rate was lower because most failures occurred immediately after treatment.

In the TheraCal group only 14 cases out of 17 showed up for the final evaluation. The success rate evaluated radiographically by CBCT showed 6 out of 10 cases with dentin bridge formation with no periapical lesion (60%). Also, it showed 4 out of 10 cases positive response to thermal and cold tests clinically (40%). Teeth showed periapical lesion by CBCT which indicated Asymptomatic Apical Periodontitis due to restoration fracture was 4 cases out of 14 (28.57%) with negative response to thermal and cold tests clinically.

The results of this study were in agreement with those of study by ***McDougal et al. (2004)*** who reported clinical success rate of 90% at 6 months and 78% at 12 months. Radiographic success, however, was only 49% of pain-free teeth at 6 months and 42% of pain-free teeth at 12 months.

Two common causes generally attributed to a decrease in success rate over time which could be coronal leakage or presence of residual infection. Although every attempt was made to achieve satisfactory coronal seal in this study, coronal leakage could still be a possible cause of failures, as current restorative materials do not provide a perfect seal. Another limitation was that the crowns were not placed.

The status of pulp before VPT is also a key factor in determining the success rate of this technique ***(Ward, 2002)***. Although the ability to control bleeding is generally used as an indicator to assess the extent of pulpal inflammation ***(Takashi Matsuo et al., 1996)***, it may, however, not accurately correlate with the extent of inflammation in all the cases ***(SELTZER et al., 1963)***. Thus, many cases having pulpal inflammation at advanced stages may have been included in the study and might have affected the results. A dentine bridge is a deposit of reparative dentine or other calcific substances that forms across the exposed pulp ***(Fransson et al., 2016)***. This barrier can be detected clinically after reintervention by removal of the filling, but this is discouraged to avoid contamination. Pulp capping materials such as MTA and Biodentine, besides their sealing properties, are placed in sufficient bulk to provide a physical barrier even in the absence of a physiological calcific barrier. In our study we used CBCT in order to detect whether the dentin bridge was formed or not. CBCT offers accurate volumetric radiographic analysis for teeth.

Also, a recent systemic review ***(Fransson et al., 2016)*** describing hard tissue formation after pulp capping or partial pulpotomy has found limited evidence of hard tissue barriers with use of calcium hydroxide or MTA. In our study the remaining teeth showed 100% dentin bridge formation in MTA group and 60% with TheraCal group which may be attributed to the presence of PRF beneath the MTA. Previous studies have reported a superior dentin bridge quality and more predictable results with MTA than with CH ***(Asgary et al., 2008)***. The explanation may be due to the clinical and radiographic parameters may not provide information about the histological criteria. The quality of bridge formation may not have a direct correlation with clinical success. A histological study may better explain the influence of these pulpotomy agents on the pulpal healing. Pulp canal obliteration/ calcification was not observed in any of the cases at 1-year follow-up in the current study. Yet, ***Eliyahu Mass and Zilberman 2011*** reported increased pulp calcifications in 28.3% teeth after partial pulpotomy in permanent molars after a mean period of 49 months. However, total pulp obliteration was not found in any of the cases. Root canal calcification is one of the reasons why many clinicians choose immediate pulpectomy over attempting pulpotomy as a conservative treatment approach.

Quality of restoration is one of the most important factors in long-term success of pulpotomized teeth ***(Santini, 1986; Trope et al., 2002)***. The quality of the restoration should be checked every 3 months and integrity of the composite resin to eliminate any confounding of the results on this account. But in our study, some patients refused the periodic check as they were not feeling any pain. Although the gold standard for determining outcome of pulpotomy is histological examination, it could not be performed in this study, as it is a clinical trial and the technique can be considered succeeded if the tooth appears clinically and radiographically normal ***(Coll et al., 2013)***, This is also in agreement with ***Ricucci et al. 2014***

On the other hand, if the radicular pulp is inflamed beyond repair, the pulpotomy will eventually fail either by reappearance of symptoms or development of a new periapical lesion. Furthermore; in reporting failures it should be specified whether it is related to the pulpotomy procedure itself or to restorative procedures and tooth fracture. Based on the low success rates for pulpotomy at one year it seems reasonable to recommend cusp coverage restorations to exclude other biomechanical failures ***(Taha and Abdelkhader, 2018)***. The success of VPT is linked to several factors other than the material used. The coronal seal and coverage are significant contributing factors for VPT survival probability. We noticed that recurrent caries and fractured fillings were directly linked to all reported late failures in this study, especially in premolar teeth. All included teeth had two-wall caries were referred for coronal coverage. Unfortunately, the compliance of most of the patients was low. The comparatively lower success rate for both materials reported in this study could be related in part to coronal restorative causes because both materials might be associated with a certain degree of leakage, and coronal coverage is a must if VPT is performed in a tooth with a proximal cavity ***(Demarco et al., 2005)***.

CONCLUSIONS:

• Within the limitations of the study, it can be suggested that coronal pulpotomy can serve as a suitable alternative treatment option for cariously exposed permanent teeth without apical periodontitis.

• MTA is better than TheraCal LC as a pulpotomy agent, as it was accompanied with less postoperative pain and higher success rates.

• Regenerative pulpotomy using PRF is a promising treatment modality that can make pulp sensibility testing after pulpotomy more reliable.

• Availability of better diagnostic techniques in the future may help in the better selection of the cases and hence increased success rate of this technique.
• It is not recommended to use this technique with upper or lower first premolars as it showed a severe pain in less than 24hrs whether we used MTA or TheraCal.

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