IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 23, Issue 9 Ser. 1 (September. 2024), PP 19-27
www.iosrjournals.org

Comparative evaluation of coronal sealing ability among commercially available three endodontic temporary restorative materials by using methylene blue dye penetration test : an in-vitro study

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ABSTRACT
Aim: *To evaluate and compare the coronal sealing ability among commercially available three endodontic temporary restorative materials by using methylene blue dye penetration test.*

Methods and Material: *90 extracted mandibular and maxillary premolar teeth were taken. Samples were divided into four experimental groups of 20 each (n-20). In the experimental group, endodontic access cavity was created, and in each group, then the teeth were restored with Orafil G, Coltosol F and IRM. A positive control group was taken (n -5), access cavities were prepared, but not resored. A negative control group was taken (n-5), access cavities were not prepared. Samples were placed in normal saline for 2 hours and thermocycled at 5 ± 2ºC to 55 ± 2ºC for 30 seconds for 100 cycles. Then samples were immersed in methylene blue dye for 7 days. Longitudinal sectioning (mesiodistally) of samples were done with diamond disc and dye penetration was graded using a stereomicroscope at 10 x magnification.*
Statistical analysis used*: The statistical analysis used was Kruskal-Walli's test and one way ANOVA test to compare the Microleakage.*
Results: *Microleakage was observed in Orafil G followed by Coltosol F. No significant difference was seen between two groups of IRM.*
Conclusions: *Orafil G showed considerably good results compare to Coltosol F and IRM.*
Key-words: *Dye penetration method, Microleakage, Temporary restorative material*.

Date of Submission: 24-08-2024 Date of Acceptance: 03-09-2024

I. INTRODUCTION

Microleakage is defined as the "diffusion of the bacteria, oral fluids, ions and molecules into the tooth and the filling material interface" OR "defined as the clinically undetectable passage of bacteria, fluids, molecules or ions between tooth and the restorative or filling material."[1]. It is generally accepted that long-term endodontic success is dependent on proper cleansing and shaping to eliminate tissue debris and microorganisms from the root canal system and to seal the root canal system. Temporary filling material must provide an adequate seal against ingress of fluids, organic material ,or bacteria from the oral cavity to the root canal system.[2]

In endodontics, the aim of treatment is to durably isolate the root canal system. This is achieved after the final stage of three-dimensional filling.[3] The role of these cements is to prevent the root canal system from

becoming contaminated during treatment by food debris, buccal fluids, and microorganisms. They also serve to prevent intracanal drugs from leaking from the tooth.[4]

One of the key factors in predicting the failure or success of the root canal treatment is the use of an appropriate temporary restorative material during the course of root canal therapy. As these materials provide a temporary seal for the tooth preventing any percolation of fluids or microorganisms from the oral cavity during the course of root canal therapy. A temporary material should be easy to manipulate as well as dimensionally stable with good compressive resistance, abrasive resistance and it should be compatible with the intracanal medicament used during the root canal therapy.

The properties that a temporary material has to Possess are:

(1) good sealing of the cement-tooth joint (against marginal infiltration)
(2) good sealing of the cement itself (against porosity),
(3) dimensional variations close to those of the tooth,
(4) good resistance to abrasion and compression,
(5) ease of insertion and removal
(6) compatibility with the drugs used
(7) good aesthetic appearance.[4]

Antiseptic medications must be applied to many clinically infected canals over a multi-visit course of treatment, during which voluntary temporization for varying lengths of time becomes required. The primary goals of endodontic treatments should be to eradicate all bacteria from the tooth. Following this, the tooth should be kept as sterile as possible by avoiding any more bacterial influx both before and after treatment.[5] A coronal filling material is considered to be effective when it is able to fulfill certain properties, including good sealing of tooth margins, lack of porosity and dimensional changes to hot and cold temperatures, good abrasion and compression resistance, easy insertion and removal, compatibility with intracanal medicaments, and good aesthetic appearance.[6]

Duration of usage of a temporary filling material also plays a vital role in determining the degree of coronal microleakage of the material used. Recent studies have proposed that immediate restoration should be done in an endodontically treated tooth as microleakage might occur within few days[7] and according to a study done by Torbinejad et al it was said that bacteria can pass along a root canal filling from coronal to the apical end within a period of 5 to 73 days[8] , in another study conducted by Khayat et al by using fresh human saliva it was said that extensive leakage was seen in an unfilled cavity and it was completely penetrated by microorganisms within 48 days.[9]

Sometimes multiple visits are necessary during endodontic treatment as it is not possible to prepare, shape and obturate the tooth during a single appointment.[10] Therefore, selection of an ideal inter appointment temporary restorative material which provides a fluid impervious seal to prevent microleakage which can lead to failure of the root canal treatment is very important during multiple visit endodontic therapy to prevent bacterial infection.

One of the main causes of endodontic failure is microbial infection. Consequently, every attempt should be made to shield the pulp space from microbial contamination. Hence coronal seal for root canal fillings has been recommended.[11]

A number of materials are available for usage as temporary endodontic restorative materials and can be classified as, non-eugenol containing materials such as zinc oxide-calcium sulphate, zinc oxide-eugenol based materials and light-cured resin-based composite.

Currently, Orafil-G is widely used as a temporary seal in endodontics, although its compressive strength is less than that of ZOE and zinc phosphate cement. It has, the advantage of ease of manipulation because it is a single paste that requires no mixing.[12]

Orafil-G is a premixed temporary filling material that contains zinc oxide, calcium sulfate, zinc sulfate, glyacoacetate, polyvinyl acetate resin, polyvinylchloride acetate, triethanolamine, and red pigment . Orafil-G is easy to introduce in the access cavities and also is easy to remove after hardening.[13]

Several studies have used Intermediate restorative material (IRM), as a temporary filling material. IRM is a polymer-reinforced zinc oxide-eugenol material that requires mixing the powder and liquid before using.[14]

Coltosol F is hygroscopic cement which expands twice as much as zinc oxide-eugenol when in contact with moisture (linear expansion); this is due to water sorption. This extension offers excellent compatibility between cavity walls and the restorative material.[15]

The coronal sealing ability of several materials have been studied over a period of time in search for an ideal temporary filling material to be used during endodontic therapy.

Hence this following invitro study is contemplated to compare the coronal microleakage of three temporary filling materials Orafil-G , IRM , coltosol F.

II. MATERIALS AND METHODS

SAMPLE SELECTION

Ninety freshly extracted non-carious, non-restored human premolar teeth were selected for this in-vitro study which were collected from the Department of Oral and Maxillofacial Surgery of Desh Bhagat Dental College and Hospital, Mandi Gobindgarh. The teeth were cleaned to remove soft tissues remnants and debris and were stored in normal saline solution at room temperature until required.

Inclusion criteria includes:

- Teeth should have fully formed apices.
- Teeth should be non-carious, non-restored .
- There should be presence of one or two root canals.

Exclusion criteria includes:

- The presence of any type of internal resorption.
- The presence of any external resorption.
- The existence of root caries and cracks.
- Any calcification and open apices.
- Teeth which are carious or fractured.

ACCESS CAVITY PREPARATION

Access cavities were prepared with a high-speed airotor under water coolant with a no.4 round diamond bur for initial preparation and the cavity preparation were extended using a diamond fissure bur. After removal of the pulp tissues in the chamber, each cavity was air dried and a small dry cotton pellet were placed on the floor of the chamber. The depth of the cavity was measured from the cavosurface margin with a periodontal probe such that it could accommodate 4mm thickness of temporary restorative material.

TEMPORARY RESTORATION

GROUP 1: Coltosol F temporary filling material was introduced into the cavity incrementally by a plastic filling instrument and condensed to achieve maximal adaptation of the material against the cavity wall .The surface was smoothed with a wet cotton pellet.

GROUP 2: Orafil-G temporary filling material was introduced into the cavity incrementally by a plastic filling instrument and condensed to achieve maximal adaptation of the material against the cavity wall .The surface was smoothed with a wet cotton pellet.

GROUP 3: Teeth were restored with IRM (powder to liquid = 6 g/ml) one scoop of powder and one drop of liquid thoroughly mixed on paper pad with the help of agate spatula.

GROUP 4: Teeth were restored with IRM with a powder to liquid ratio of 2 g/ml made by mixing one scoop of powder and three drops of liquid mixed on paper pad with the help of agate spatula.

GROUP 5: consisted of 5 positive control teeth, in which access cavity were prepared but not restored with a temporary filling material.

GROUP 6: consisted of 5 negative control teeth which have intact crowns and no access opening.

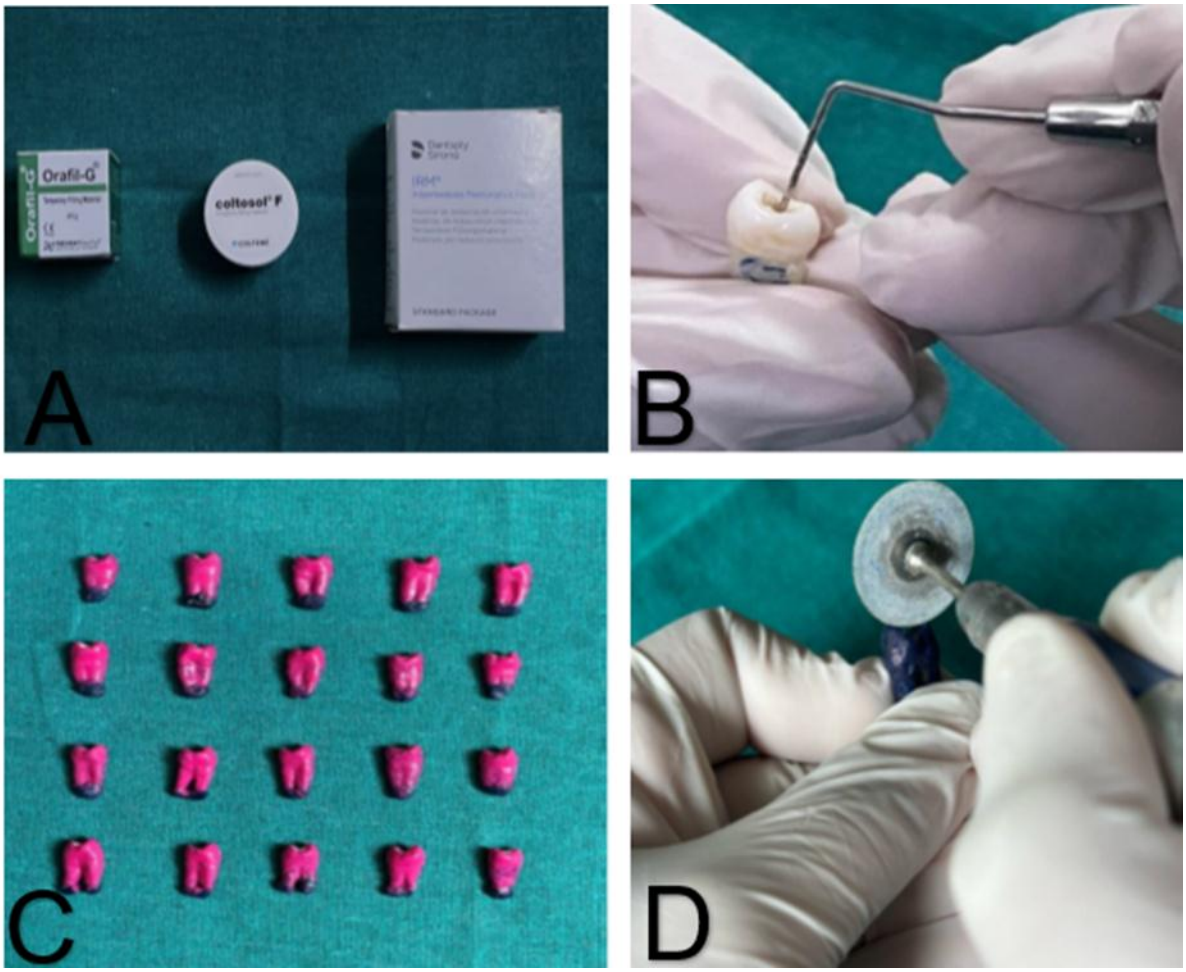

Figure 1. (a) Experiment materials **(b)** 4mm cavity depth determination **(c)** Samples after inlay wax and varnish application **(d)** Mesiodistal sectioning of tooth

After the access cavity filling, the specimens were immediately placed in saline at 37°C for 2h to ensure setting of the material. The apical foramina were sealed by melted inlay casting wax in all specimens.
All of the teeth were then be subjected to thermal stress by placing them alternatively in water baths at 5+-2°C and 55+-2°C for 30 sec each for 100 cycles. After thermal cycling, the teeth were air dried and covered by two layers of nail polish with the exception of the access areas.
Then the specimens were immersed in methylene blue dye solution at 37°C and 100% humidity for 7 days. After this all the specimens were washed under tap water and dried. Teeth were sectioned just apical to the cementoenamel junction with the help of the disc.
Specimens were then sectioned with a low-speed diamond disc and the crown were split into two parts mesiodistally through its longitudinal axis.

Statistical analysis:
The data were analysed using the Kruskal-Walli's test to determine whether any statistically significant differences existed between groups.

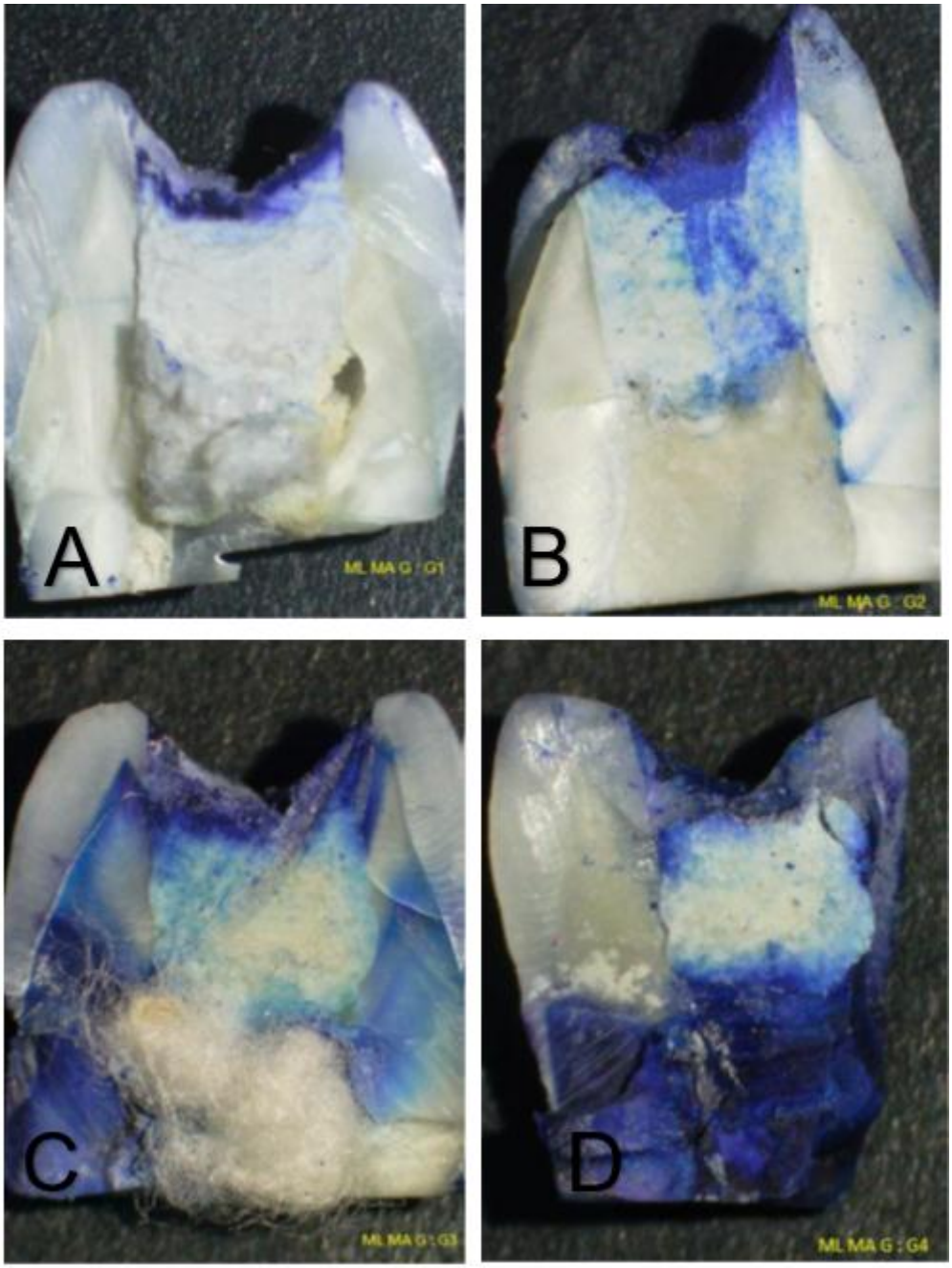

Figure 2. (a) Grade 1 dye penetration **(b)** Grade 2 **(c)** Grade 3 **(d)** Total penetration

III. RESULTS

All the experimental temporary filling materials showed some amount of dye penetration. The positive controls demonstrated complete dye penetration while negative controls showed no dye penetration. The leakage value indicated differences among the materials. Orafil G presented the least microleakage, followed by Coltosol F and IRM (both groups).

TABLE 1: NUMBER OF TEETH WITH DIFFERENT LEAKAGE GRADES

FILLING MATERIALS	NO. OF SPECIMENS	LEAKAGE GRADES				TOTAL LEAKAGE
		0	1	2	3	
GROUP 1 : Coltosol F	20	-	02	07	11	0
GROUP 2 : Orafil-G	20	-	17	03	-	0

GROUP 3 : IRM (P:L* = 6 g/ml)	20	-	-	05	08	07
GROUP 4 :IRM (P:L* = 2 g/ml)	20	-	-	03	08	09
POSITIVE CONTROL GROUP	05	-	-	-	05	05
NEGATIVE CONTROL GROUP	05	05	-	-	-	0

The penetration level was the same as the degree of marginal dye penetration. In the IRM group (powder to liquid = 6 g/ml), seven specimens showed total leakage, while in the IRM group (powder to liquid = 2 g/ml) nine specimens showed the same leakage. A summary of the results is presented in Table 1.

TABLE 2: MEAN LEAKAGE OF VARIOUS GROUPS

GP	N	Mean	Std. Deviation	Std. Error Mean
1	20	2.45	.686	.153
2	20	1.15	.366	.082
3	20	3.05	.780	.179
4	20	3.30	.733	.164
5	05	4.00	.000	.000
6	05	00	00	00

On comparison of microleakage grades of various groups the mean microleakage value for Group 1(Coltosol F) group is 2.45,which is more than the Group 2 (Orafil G) i.e 1.15, whereas Group 3 and 4 (IRM) with different powder and liquid ration have mean value of 3.05 and 3.30 which is also more than Group 2. However, Group 3 and Group 4 have non-significant difference. (Table 2)

TABLE 3: INTERGROUP COMPARISON OF MEAN LEAKAGE OF VARIOUS STUDIED GROUPS

GP	N	Mean Rank	chi square	df	p value
1	20	44.02	62.311	5	0.000*
2	20	17.78			
3	20	57.50			
4	20	63.20			
5	5	79.50			
6	5	3.00			

*Statistically significant ** statistically non-significant

There was no statistically significant difference in coronal microleakage between IRM (powder to liquid = 6 g/ml) and IRM (powder to liquid = 2 g/ml), whereas there was a statistically significant difference in leakage between the Orafil G and Coltosol F group and IRM (powder to liquid = 6 g/ml), and also between the Cavit and IRM (powder to liquid = 2 g/ml) group ($p < 0.05$) (Table 3).

IV. Discussion:

Microleakage is one of the most important risk factors associated with endodontic failure in multi visit endodontics. The prognosis of endodontic therapy is also predicted on the basis of the provisional restorative material and the main role of a provisional restorative material is to prevent the seepage of fluids and microorganisms from the oral cavity into the access cavity.[16]

Temporary restorative materials in clinical endodontic practice must possess certain physical properties which allows immediate sealing of the access preparation.[17]

Nowadays, the definitive coronal restoration is not placed at the same appointment as the root filling in many dental practices. As a result, it is crucial that the temporary restorative material used does not compromise the cavity's width, and that the materials chosen will stop bacteria from penetrating the tooth even though they have two interfaces and are subjected to a moderate masticatory load for varying amounts of time. This will help to more predictably achieve a bacteria-free environment within the root canal system.[18]

According to a study conducted by Magura et al based-on saliva penetration rate into the root canals said that if permanent restoration is not done for a duration of more than 3 months following an endodontic therapy root canal retreatment must be performed.[19]

Various factors such as complexity of cases and multiple appointments requires the temporary material to produce a leak proof seal during the duration of the endodontic therapy.[20]

A temporary material should be easy to manipulate as well as dimensionally stable with good compressive resistance, abrasive resistance and it should be compatible with the intracanal medicament used during the root canal therapy.

In our study we compare the microleakage between three commercially available temporary filling materials out of which one we have used in different powder and liquid ratio (Group 3 & Group 4) whereas the remaining two are conventional self-cure temporary restorative materials (Group 1 & Group 2) by using dye penetration test with 1% methylene blue solution.

The most common method used for assessing microleakage is by dye penetration test using methylene blue dye.[21] The methylene blue dye has high water solubility as well as move by simple diffusion and not absorbed by hydroxyl apetite crystals present in the dentin and that it has a molecular size smaller than that of the bacteria so it may be used as a tool to compare relative leakage.[22] Hence in the present study this explains the methodology for using 1% methylene blue dye to verify microleakage.

According to Webber et al a temporary restorative material should have at least 3mm thickness to result in superior marginal sealing ability.[2] Hence the thickness of all the temporary restorative materials used in this present study was standardised to 4mm to test the microleakage present except for the samples in the positive control group in which no restoration was placed.

Rahmat A. Barkhordar and Marvin M. Stark concluded that self-curing hygroscopic materials had the best sealing ability. The reason for this is that these materials when used with the thickness of 3 to 5 mm has the best sealing ability.[10]

Naseri M et al conducted a study to simulate the clinical condition the teeth samples were incubated at 37º celcius in 100% humidity to ensure complete setting of temporary filling material.[22] In this study sealing of the teeth samples was performed by using nail varnish in order to prevent the leakage of the dye through the tooth structure as observed by various authors such as Zmener O et al.[21]

According to a study by Naseri et al, the sealing ability of temporary filling materials were tested for coronal sealing ability after 1 day, 1 week and 4 weeks as these are the most frequently used time intervals during dental practice between root canal therapy appointments or following obturation before the placement of a permanent restoration.[22] but in the present study the time interval considered to compare the difference in microleakage values between the temporary restorative materials was 1 week. S. Deepak, M. done the study which is in corroborated with the present study.[23]

According to the results of the present study all the test materials showed microleakage Orafil G (Group 2) showed the least microleakage scores followed by Coltosol F(Group 1), IRM powder to liquid ratio of 2 g/ml (Group 4) and IRM powder to liquid ratio of 6 g/ml (Group 3) had non-significant difference whereas the maximum microleakage was shown by Group 5 which was a control group.

Orafil G (Group 1) & Coltosol F (Group 2) of present study are conventional self-cure temporary restorative materials which are commercially available in a premixed state which sets under humidity and composed of Zinc Oxide and calcium sulphate. These materials can be quickly placed and adjusted into the access cavity. This reduces the inconsistencies associated with the chair side manipulations. These superior manipulation properties were considered as supplementary factors responsible for good coronal sealing ability which coincides with the results of this present study.

The results of this in vitro study indicate Coltosol F and Orafil G provide a better coronal seal than IRM of both groups. Coltosol F and Orafil G are hygroscopic materials that exhibit linear expansion which results from water absorption on setting.[12] These characteristics might explain why surface penetration was noted in these two materials. This expansion could enhance the contact between the material and the access cavity, resulting in an improvement in the seal. Immediately following cavity sealing, the specimens were submerged in saltwater to replicate the real-world scenario and facilitate the sealing material's hygroscopic expansion. The significantly better sealing property of Coltosol F and Orafil G also might be due to the fact that the materials are premixed. This reduces the inconsistencies related to chairside mixing.

N. S. V. Babu, P. V. Bhanushali et al [24] conducted a study to compare the microleakage of nano silver containing UDMA-based cements with routinely used zinc oxide and calcium sulphate-based temporary cements in primary teeth. The teeth were divided randomly into four groups of 14 teeth each—Group I: IRM, Group II: Cavit G, Group III: Orafl-G and Group IV: Dia-Temp. The manufacturer's recommendations were followed when using temporary restorative products. After thermocycling, the teeth were submerged in 0.5% basic fuchsin for 24h. The specimens were sectioned and evaluated under a digital microscope at 20× magnification under stereomicroscope and were scored for microleakage. The collected data were tabulated and subjected to statistical analysis Dia-Temp presented the least microleakage values. The highest grade for microleakage was shown by IRM followed by Orafil-G and Cavit-G.

Coltosol F and Orafil G did not show leakage to the cavity base while in IRM groups. Seven specimens of IRM (powder to liquid = 6 g/ml) and nine specimens of IRM (powder to liquid = 2 g/ml) showed leakage to the cavity base. This is consistent with the findings reported by Magura et al. [19] In their study using Pelikan ink,

the teeth with IRM temporary restorations showed salivary penetration which was not significantly different from the group without a coronal seal.

Sachin Chadgal et al [25] concluded in his study that coronal sealing ability of Cavit G, IRM and Orafil-LC by means of methylene blue dye penetration method. The root canals of fifty mandibular premolars were prepared with Ni-Ti rotary instruments under irrigation with 5% NaOCl and 17% EDTA. The samples were obturated and separated into three experimental and two control groups. All three materials were modified according to the manufacturer's specifications and placed in 4mm deep access cavities. Samples were incubated, thermocycled and then placed in 2 % methylene blue dye for one week. Samples were sectioned bucco-lingually and viewed under stereomicroscope. Degree of dye penetration was evaluated and scored for each group. Significantly lower dye leakage was showed by Cavit and Orafil-LC than IRM. Better sealing ability was observed for Cavit and Orafil-LC than IRM.

Temperature fluctuations can adversely affect the marginal seal of a dental material.[26] To test this factor, thermal cycling was incorporated into this study design. The temperatures, 5°C and 55°C, represented the extremes found in an oral environment.[27] A total thickness of 4 mm for all restorations was used in this study in order to comply with the recommendation of Webber et at.[2], who found that a 3.5-mm thickness of Cavit was the minimum thickness necessary to prevent total leakage of the dye molecule. The technique for inserting these temporary filling materials into the access cavities may also have had an impact on the marginal leakage. In this study, all of the materials were introduced incrementally into the access cavity to ensure good marginal adaptation by one operator to reduce the chances of a manipulative variable.

The present study results were not consistent with those reported by Anderson et at. who indicated that in the IRM-restored group a lower powder to liquid ratio provided a better seal. However, no significant difference was found between the two powders to liquid ratios in this investigation. In the study by Anderson et al, they used a fluid filtration method to evaluate microleakage, whereas in this study the dye penetration method was used. The results obtained in this study refer only to an in vitro condition. Clinically, the results could be influenced by the masticatory forces present in the oral cavity. Marginal microleakage increases in the existence of functional mastication , and it also increases with a longer interappointment interval.[28]

This study done by Himani Shah [29] coincide with the present study as it evaluates the impact of coronal sealing ability of three temporary restorative materials called Orafil LC, Cavit-G, and Coltosol to prevent microleakage. Endodontic access cavities were created in 60 caries-free human removed premolars. All 60 extracted teeth were randomly divided into one of three experimental groups and filled with Orafil LC, Cavit-G, or Coltosol in 4 mm deep cavities. The thermocycling process was performed and then all 60 teeth were immersed in 10% India ink at 37°C for 1 week. The teeth were sectioned buccolingually, and dye penetration was measured using a stereomicroscope. The data was examined using Fisher's exact test. Significant differences were seen between the Orafil LC, Cavit-G, and Orafil LC-Coltosol groups. The experimental groups with the highest and lowest leakage scores were Coltosol and Orafil LC, respectively. This in vitro study has certain limitations such as it does not duplicate the oral environment such as presence of saliva, the data obtained through dye penetration test have been questioned by researchers who claim that this technique has large standard deviations and it is non reproducible.

Clinically in the oral cavity, according to Qvist V micoleakage can be impacted by the masticatory forces which may vary based on the variables such as Sex, location of the tooth, age and bruxism.30 Hence in the present study occlusal load was not used.

V. CONCLUSION

The key factor for the success of root canal treatment depends on the prevention of microleakage of fluids and microorganisms from the oral cavity into the endodontic access through a temporary filling material either during the inter appointment time period or following obturation before the placement of a permanent restoration which can be prevented by using an appropriate temporary filling material which has superior sealing properties.

This study was performed to evaluate and compare the coronal microleakage between commercially available three endodontic emporary restorative materials over seven days' time periods as it might give an insight regarding the quality of these temporary restorative materials.

According to the results of this study:

- All the test materials showed microleakage.
- On comparison orafil G (Group 2) showed the least microleakage.
- The maximum microleakage was shown by both the groups of IRM (Group 3 and Group 4).

This study provides an insight to the clinician regarding the quality of various commercially available temporary restorative materials thereby making it easier to select the suitable material for specific clinical conditions.

Thereby within the limitations of this study we conclude that all the materials devoid of the mode of curing showed microleakage grades between day and that the conventional self-cure premixed temporary filling materials provide less microleakage when compared to the hand mixed powder liquid temporary materials.

Though this study is not clinically evident, it suggests that temporary materials can be used only for a short duration of time and a permanent coronal restoration must be placed after root canal therapy at the earliest to avoid possible failures.

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