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Coronal Micro-leakage Of Temporary Filling Materials

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Dedication

To:

My dear parents for their continuous love and care

To:

My brothers and sister for their support

To:

My dear uncle for his help
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Abstract

Objectives: Temporary filling materials are used in endodontics to prevent contamination of the root canal system during intertreatment visits. The objectives of this study were to evaluate coronal microleakage of four temporary filling materials Cavisol, Litark, Zinc Phosphate, reinforced zinc oxide-eugenol{IRM}) and to compare the sealing ability of the ready made temporary filling materials (Cavisol, Litark) and hand mixed materials (IRM, Zinc phosphate).

Materials and methods: standardized class I access cavities (4 x 4mm) were prepared in 80 intact human mandibular and maxillary permanent premolar teeth. They were divided randomly into four groups consisting of 20 samples. Cotton pellets were placed in the pulp chamber assuring that the opening could accommodate at least 4mm of the temporary filling material.

Each group was restored with one of the test materials and placed in incubator for 48 hours at 37°C. The specimens were then thermocycled (5 to 55°C for 500cycles). Then the specimens were painted with two layers of nail varnish, with the exception of cavity margins and immersed in 2% methylene blue dye for 10 days for leakage assessment. The teeth were sectioned mesio-distally, and the degree of dye penetration was evaluated under stereomicroscope. Grading of the microleakage pattern was from 1 to 3, with 3 providing the best seal. Result were analyzed using one way ANOVA test to determine if a statistically significant difference existed between the groups of the tested materials.

Results: The result indicated that microleakage along Cavisol and Litark samples was within grade 3; whereas IRM and zinc phosphate samples absorbed the dye into the bulk of the materials. Cavisol was found to exhibit
the best seal amongst the four tested materials followed by Litark, Zinc phosphate and IRM.

**Conclusion:** Among the four materials tested, Cavisol was observed to provide a consistently tight seal followed by Litark, zinc phosphate and IRM. This indicated that the ready made temporary filling materials have the best sealing ability over hand-mixed ones. These emphasize further need for the importance of correctly placing a sufficient thickness of temporary filling materials in endodontic access cavities to ensure a tight seal.

**Recommendations:** However, because it is not known how the sealing properties will be affected over longer observation periods, or when the material is exposed to the oral environment, this study must be considered preliminary. Further clinical and laboratory experiments are recommended.
الهدف من هذه الدراسة هو تقييم التسرب الجرثومي الناجي لأربع أنواع من مواد الحشوات المؤقتة (cavisol, litark, IRM, Zinc phosphate)

ومقارنة الحشوات المؤقتة الجاهزة مع تلك المحضرة يدوياً والطرق والمواد: تم تحضير حفرة دخول صنف أول (4 ملم) في ثمانين ناجذ سليم علوي وسفلی وتقسيم عشوائياً إلى أربع مجموعات؛ في كل مجموعة عشرون سنار ووضع كرات قطبيه في الحجرات الليبية لتنمو 4 ملم من المواد الحاشيه المؤقتة.

تم ترميم كل مجموعة بمادة حاشية مؤقتة مختارة، ووضعت في الباذنة لمدة 48 ساعة. وبعد قمبتة المجموعات الى 500 دورة تبريد وتسخين من 5 إلى 55 درجة حرارة سبيليزيه وتم صبغة الأنسان بطلاء الأظافر باستثناء حواف الحفرة، وغمزت في 2% صبغة أزرق الميثيلين لمدة 10 أيام لتقييم التسرب، وشترطت الأنسان أنصياً وحشياً وقيم التسرب بواسطة المجهر الإلكتروني المدرج قسمت أنماط التسرب المجهري من 1-3، حيث القيمة 3 تمثل أفضل التساق. واستخدم اختبار t في قيم t VAANOA حيث قيمة p أقل من 0.05 تمثل علاقة إحصائية معينة بين المجموعات.

نتائج البحث: تشير النتائج إلى أن التسرب الحافي حول الكفيزول و الليتارك قيم ب 3 بينما الزنك كفصات احتضنت الصلبة ووجد أن الكافيزول كان أفضل المواد من حيث الالتصاق الحافي. IRM، الليتارك ثم الزنك كفصات وأخيراً visolaC

الخلاصة: تخلص هذه الدراسة إلى أن أربع مواد الحشتي المؤقتة بلييه kratiL ثم IRM، visolaC، kratiL و AlessaC هذا يشير إلى أن مواد الحشتي المؤقتة الجاهزة تكون التصاق حافي أفضل من تلك المحضرة يدياً. من ذلك تؤكد على أهمية استخدام مادة حشتي مؤقتة سماكة كافية في المعالجات الليبية لتتأثر الالتصاق الحافي.
توصيات البحث: على الرغم من أن هذه الدراسة لا تشير إلى خصائص الالتصاق الحافي للمواضع المختبرة لفترة زمنية أطول أو تعرضها للبيئة الفموية فيجب إعتبارها دراسة أولاً وعليه توحيد باختبارات سريرية ومخبرية مماثلة مستقبلا.
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1.1. Introduction and literature review.

The major factors involved in the development of pulpal and periapical diseases are loss of integrity of coronal tooth substances and the entry of microorganism into dentine and pulp space. Coronal microleakage appears to be of equal or greater clinical relevance as a factor in endodontic failure than apical leakage(1-4).

The chemomechanical removal of microorganism, their substrate and products from the dentine and pulp space, is the first aim of root canal treatment with the second being the three-dimensional obliteration and sealing of the pulp space to prevent bacterial re-contamination(5).

The role of micro-organism in pulpless teeth was recognized more than a century ago. During 1930 microbiological techniques were used to re-establish the scientific basis of root canal treatment. However, techniques at that time had identified aerobic bacteria only with mechanical removal of microorganism, their substrate and products from the dentine and pulp space. The development of anaerobic culturing allowed many unknown microorganisms present in root canals to be grown. Although anaerobic culturing of root canal is not a technique for every day clinical use; the research has given rational explanation for pulp disease and its treatment.

With this rapid increase in knowledge, the anaerobic root canal bacteria are continually being reclassified from bacteriod to two new genera prevotella and porphyromonas (6).

Bacteria are normally confined to the root canal system in pulpless teeth and it is unusual for periapical lesions to contain bacteria unless there is an acute abscess. At the orifice of the root canal a large number of inflammatory cells are normally found and they prevent the bacteria from entering the tissues(6).

The pulp chamber must be free of medicament and clean to receive the temporary filling. The dressing should be protected from saliva by a 3-4mm thick layer of sealing material, when the temporary filling is at particular risk of fracture or
dislodgement extra precautions should be considered, a dual filling is then advisable. The first filling creates internal sealing. An additional filling for dressing of the external occlusal surface helps provide better function and aesthetics. Should the temporary filling fail, the root canal will be at risk of recontamination(7).

The use of temporary restorative material between appointments is one of the factors that determine the success or failure of root canal treatment. These materials serve to seal the tooth temporarily, preventing the entry of fluids, microorganisms and other debris into the root canal space. In addition they also prevent the escape into the oral cavity of medicament placed into pulp chamber(8).

A coronal filling material is considered effective when it is able to fulfill certain properties including good sealing of tooth margins, lack of porosity and dimensional stability to thermal changes, good abrasion and compression resistance, ease of insertion and removal, compatibility with intra-canal medicament and good aesthetic appearance(9-11).

Many studies revealed that Intermediate restorative materials (IRM) exhibited gross microleakage(12). This finding could probably be attributed to the instability of zinc oxide when subjected to extreme of temperatures(13). Although other studies indicated that IRM has good sealing properties in comparison with other new temporary materials (14). While many noted that ready made temporary filling materials such as Cavit has best sealing properties (15), being a hygroscopic material that expands when it comes in contact with moisture (16, 17).

The objectives of this study is to evaluate the sealing ability of Cavisol, Litark, polymer reinforced zinc oxide eugenol (IRM), Zinc phosphate by conducting microleakage tests using methylene blue dye penetration test(12).
1.2. **Justification**

- Recently, in Sudan a higher utilization of ready made temporary filling materials have been observed in inter appointment root canal treatment as well as other restorative procedures.
- Patient’s negligence in replacing temporary fillings lead to an increased duration of the temporary phase resulting in undesirable effects.

1.3. **Objectives**

- **General**
  
  To evaluate sealing ability of temporary filling material (Cavisol, Litark, IRM, Zincphosphate) using a dye penetration test.

- **Specific**
  
  To compare the sealing ability of the ready made (Cavisol, Litark) and hand mixed materials (IRM, Zinc phosphate).
1.4. Literature Review

Temporary filling materials are used in endodontics to prevent contamination of root canal system during intertreatment visits. Microleakage between restorative materials that are placed in endodontic treated tooth has been extensively studied and several methods were in use such as:

1.4.1. Dye penetration method:-

Many studies revealed that IRM (Intermediate Restorative Material) exhibited gross microleakage. Barkhordar and Starkv (12) in 1990 evaluated the efficacy of this resin as an interim restoration and possible effect of access cavity design with respect to its sealing ability compared with other temporary restorative materials, and indicated that Cavit (ready made restorative material) had the best sealing ability whereas IRM (handmix restorative material) showed the maximum methylene blue dye penetration.

On the same year, other study by Hagemeier et al (18) used sixty extracted human molars prepared for initial endodontic therapy via an occlusal access preparation to assess microleakage. The access preparations were sealed with one of the following materials or combinations: TERM (new light cure composite product), Cavit, IRM, Ketac-Silver, or an IRM-Cavit "sandwich" restoration. The specimens were thermocycled for 24 hours (800 cycles), immersed in methylene blue dye for 4 hours, sectioned, and evaluated under a microscope for microleakage. TERM, Cavit, and the IRM-Cavit "sandwich" had virtually no microleakage, while Ketac-Silver and IRM exhibited gross microleakage.

Lee et al in 1993(19) assessed micro-leakage on 140 non-carious non restored molars by basic fuchsin dye penetration after thermal cycling and indicated that Caviton provided the best seal, followed by cavit which demonstrated better sealing than IRM.

Pameijer et al (20) in 1995 assessed microleakage of "surface-sealing" materials, ten teeth per group were assigned at random to six experimental and six control groups.
In the experimental groups, a resin composite was surface-sealed with IRM, glass ionomer, amalgam, dentin bonding agent and resin composite, experimental hybrid cement, or zinc oxide and eugenol. The six surface-seal materials were placed in bulk in the control group. After cavity preparation, restoration, cut back and application of the surface-seal material, the teeth were subjected to thermal cycling, embedded and sectioned. A score of 0-3 was given to the amount of dye leakage observed, it was shown that Zinc oxide and eugenol demonstrated the most leakage, where as the resin composite system TPH had the least, this in vitro study render the recommendation of zinc oxide and eugenol as a surface-seal material questionable.

In 1997 Mayer and Eickholz (13) investigated the microleakage in prepared classs I cavities in 44 extracted human molars filled either with Cavit, Kalsogen (polymerized reinforced zinc oxide eugenol), IRM, or TERM. After setting of the restoration, and thermocycling procedure, Cavit showed less microleakage in the dye penetration test and fewer marginal crevices in the quantitative marginal analysis.

Tewari et al (21) restored access cavities with Kalzinol and a zinc oxide eugenol (ZOE) intermediate restorative material which were then immersed in 2% freshly prepared methylene blue dye, and its penetration was evaluated at 1, 2, 4, and 7 day intervals. ZOE cement displayed dye penetration throughout the complete depth of the restoration, reaching the pulp chamber by the second day, whereas Kalzinol produced leakage reaching the pulp chamber on the fourth day, indicated that none of the ZOE formulations tested could predictably produce a fluid-tight seal even up to the fourth day. Researchers recommended the early replacement of these restorations during and after endodontic treatment to produce a better prognosis.

The sealing properties of three temporary restorative materials, Cavit, IRM, and polycarboxylate-based cement were investigated by Zmener et al(22) . Standardized access cavities were prepared in 45 intact extracted human molars. The teeth were randomly assigned to three groups and the access openings filled with one of three temporary filling materials. In five teeth (negative control), no restorative material
was placed but the preparations were coated entirely with sticky wax. The five teeth of the positive control group had no restorative material and no sticky wax applied. After thermocycling for 500 cycles (5-55°C), the experimental teeth were dipped in molten sticky wax to the CEJ. The coronal enamel was subsequently coated with two layers of nail varnish, leaving an area of 1 mm around the filling material uncovered. The samples were then immersed in 2% methylene blue dye solution for leakage assessment. The teeth were sectioned and the greatest depth of dye penetration was recorded. Positive control sections exhibited complete dye penetration, whereas negative controls had none. All materials leaked at the interface (material-dentin), whereas IRM specimens absorbed the dye into the bulk of the material.

However, other studies show that IRM has good sealing properties in comparative with other new temporary material.

In 1992 Mc Inerney and Zillich (23), prepared thirty-six maxillary central incisors in a manner similar to non-vital bleaching procedures. They were examined with respect to the degree of procion green dye penetration of dentin with and without heating. Cavit, IRM, and zinc phosphate cement were used to evaluate their sealing ability. Cavit and IRM provided better internal sealing of the dentin than did zinc phosphate cement.

Kazemi et al(14) in 1994, assessed the marginal stability and permeability of a new interim restorative endodontic material (Tempit) and compared the findings with the results of two commonly used restorative endodontic materials, Cavit and IRM (Intermediate Restorative Material Capsules). Cavit and Tempit showed a substantial amount of dye diffusion into the body of the materials. Cavit exhibited the best sealing ability at all times. IRM demonstrated the least body penetration of all three materials but had a substantial marginal leakage not significantly different from that of the Tempit material.

Uctasli and Tinaz (24) in 2000, studied the coronal access of 10 teeth per group which were filled with Coltosol, Algenol, IRM, Fermit (Composite resin material) or
Fermit-N (Composite resin material). After storing the teeth in demineralized water for 48 hours, they were immersed in 2% methylene blue dye for 24 hours. All the teeth were sectioned longitudinally and the linear depth of dye penetration was evaluated under a stereomicroscope. It was found that there was no significant difference in the microleakage observed in the composite resin groups (Fermit & Fermit-N).

The effect of repeated vertical loads on microleakage of IRM and calcium sulfate-based temporary fillings was determined by Liberman et al (25). It was suggested that even though calcium sulfate-based materials may be useful when not subjected to any occlusal forces, IRM was preferable whenever occlusal loads may be applied.

Zaia et al (26) in 2002, assessed the ability of IRM, Coltosol, Vidrion R and Scotch Bond to seal the pulp chamber following root-canal treatment on 100 extracted human mandibular molars. The teeth were divided into five groups of 20 teeth each, one group for each barrier material and one control group without barrier material. It was shown that all groups showed dye penetration. Coltosol and IRM sealed significantly better than the other groups, preventing the coronal leakage in 84% and 75% of the specimens, respectively. Scotch Bond exhibited the highest leakage (54% of specimens with dye penetration), which did not differ significantly from the positive control group (62% with dye penetration). It concluded that none of the materials were able to prevent microleakage in all specimens. Vidrion R and Scotch Bond demonstrated the poorest results when used as barriers to coronal microleakage, whilst IRM and Coltosol were significantly better in preventing micro-leakage.

Rafeek et al (27) compared the coronal microleakage of three restorative materials used to seal the access cavity in root treated teeth by using IRM (Intermediate Restorative Material), Fuji II (Glass ionomer cement) and Dyract AP (Compomer). Microleakage was assessed by using Indian ink penetration. There was significantly more dye leakage in teeth restored with Dyract AP compared to those with Fuji II or IRM.
A large number of in vitro leakage studies appear in the endodontic literature, especially those studies that produce relevant information to the clinician to judge new materials and compare them with traditional existing filling materials. Webber et al (8) in 1978 studied the effect of thickness of filling material on microleakage. The access cavities were obturated with Cavit; the data suggested that at least a 3.5 mm thickness of Cavit should be used in order to prevent leakage. Examination under the scanning electron microscope showed areas in which the constituents of Cavit were improperly mixed, which lead to increased penetration.

Oppenheimer and Rosenberg (28) determined the effect of temperature change on the sealing properties of Cavit and Cavit G, by using dye penetration at room temperature and when subjected to temperature change. Under the test conditions, Cavit G and Cavit were resistant to penetration by aqueous methylene blue dye.

In 1990 Noguera and McDonald (29) had investigated the sealing properties of Cavit, Cavit-G, Cavit-W, and IRM-Caps, with TERM, Hard-TERM, and showed that Dentemp TERM exhibited the least leakage, while Hard-TERM demonstrated the greatest leakage, at the tooth restoration interface.

Uranga, et al (30) studied four coronal obturating materials used in endodontic treatment to evaluate the ability of temporary versus permanent materials to seal the access cavity. Eighty human maxillary single-canal teeth were prepared biomechanically and obturated with gutta-percha and an endodontic cement AH Plus, using the warm vertical compaction technique. All access cavities were sealed with 1 of 4 materials (Cavit, Fermit, Tetric, or Dyract). Microleakage was assessed by 2% methylene blue dye penetration. The teeth were subjected to 100 thermocycles, with temperature varying from 0 to 55 °C. The greatest degree of leakage was observed with the temporary materials (Cavit and Fermit). There was a significant difference in leakage between all materials except between Dyract and Tetric. It was suggested that it may be more prudent to use a permanent restorative material for provisional restorations to prevent inadequate canal sealing and the resulting risk of fluid penetration.
A laboratory study to compare the sealing abilities of Fermin and Canseal with the more popular temporary coronal filling materials, Cavit and Caviton was conducted by Cruz et al (31) in 2002. Standardized access cavities were prepared in intact human permanent molar teeth which were restored using one of the temporary filling materials, namely: Fermin, Canseal (at two powders to liquid ratios), Caviton and Cavit. Thermal cycling and/or load cycling were applied on the samples. Assessment of microleakage was evaluated by utilizing methylene blue dye penetration. Grading of the microleakage pattern was from 1 to 3, with 3 providing the best seal. It was found that microleakage along Fermin, Caviton and Cavit samples did not go beyond leakage Grade 2. Dye penetration into these materials was noted. Also, Fermin was found to exhibit the best seal amongst the four materials tested followed by Caviton, and Cavit. Thermal cycling influenced the seal of certain types of temporary filling materials more than load cycling.

Other researcher examined different materials in teeth previously received coronal restoration. The efficacy of Cavit and TERM (a new light-cured composite product) and compared them with the use of a carbon black coronal microleakage protocol was studied by Melton et al (32) in 1990. Teeth with previous coronal restorations were used. After the teeth were accessed, restored with Cavit or TERM, and exposed to the dye, they were cleared. Three-dimensional assessment revealed that Cavit more consistently provided an effective seal. In addition, a great deal of microleakage was observed around the permanent restoration-tooth interface. This indicates that perhaps leaking permanent restorations should be removed in their entirety before initiation of endodontic treatment.

Pai et al (33) in 1999 compared microleakage at three areas: 1) between an access opening restorative material and the cavity wall; 2) between an additional material placed later to patch a secondary opening in the first restorative material and the original restorative material itself; 3) and between the secondarily placed material and the cavity wall. The endodontic access cavities were restored with either IRM or amalgam as the primary restorative material. After 14 days, half of the primary
restorations was removed, and this was filled with a secondary restorative material: IRM. It was noted that significantly less microleakage between primary and secondary restorative materials placed at different times than that between primary temporary restorative materials and the access cavity wall, regardless of the type of primary restorative material used (IRM or amalgam).

The influence of ZOE temporary restorations on microleakage in composite restorations was determined by Yap et al(34) in 2002. It was shown that the groups pretreated with IRM exhibited no significant difference in dye penetration scores that observed between enamel and dentin. Pre-treatment with IRM mixed at P: L ratio of 10g: 2g significantly increased microleakage and is not recommended clinically.

A more recent study in 2005, Tulunoglu et al(35) evaluated microleakage at the interface between various temporary restorative materials and existing amalgam or composite restorations, and dental tissues in previously restored teeth after partial removal of the restoration. After thermal cycling, microleakage was measured microscopically as the penetration of basic fuchsine according to a four-unit-scale: The data evaluated showed that: in almost all groups except the Composite-IRM and Amalgam-CLIP interface, lower microleakage values were observed in temporary restoration-permanent restoration interfaces compared to temporary restoration-tooth interfaces. The use of a resin based temporary restorative material over partially removed resin composite restorations could be beneficial in achieving better resistance to marginal leakage. Within the limitations of this recent study, maintaining partially removed permanent restorations does not seem to cause a problem with achieving marginal seal.

Other researcher conducted the experiment in bleached teeth, Hansen–Bayless et al(36) in 1990 determined sealing ability of two intermediate restorative materials in bleached teeth. Divided into three groups: 1) Cavit base, 2) IRM base and 3) no base. The control group demonstrated dye penetration to the apex, indicating that a base is required to prevent leakage of bleaching agents. when this combination of
bleaching techniques is used. The mean distance of leakage was 3.43 mm (±1.14) for the Cavit group and 5.94 mm (±72) for the IRM group. Results revealed that Cavit was a more effective barrier to leakage than IRM.

Hosoya et al.(37) in 2000 tested two hydraulic filling materials, a photo-activated resin composite, a zinc oxide-eugenol cement, and a zinc oxide phosphate cement with/without the placement of a piece of rubber sheet that was placed as a barrier to isolate filling material from the bleaching agent. Significantly less dye microleakage was observed in the two hydraulic materials than in the photo-activated resin. Both zinc oxide-eugenol and zinc phosphate cements showed a considerable amount of microleakage.

1.4. 2. Microbiological marker:-
Many studies have revealed that regardless of the obturation technique or filling materials employed, entire recontamination of the root canal can occur after a short period of microbial challenge. Once the coronal seal is lost, microorganisms and their products may reach the periradicular tissues and thereby jeopardize the outcome of root canal treatment(38).

Beach et al(39) in 1996 conducted a clinical study for bacterial leakage of Cavit, Intermediate Restorative Material (IRM), and TERM on 51 teeth. Bacterial leakage was evaluated by sampling from beneath the temporary restoration and then culturing the samples both aerobically and anaerobically. Positive growth occurred in 4 of 14 TERM samples and in 1 of 18 IRM samples. Cavit did not demonstrate leakage in any of the teeth in which it was used. Thus it provided a significantly better seal than TERM over the study period.

A study was conducted by Pisano et al in 1996(40) to evaluate Cavit, Intermediate Restorative Material, and Super-EBA as intra-orifice filling materials to prevent coronal microleakage. Root canal instrumentation and obturation was done on 74 extracted single-rooted teeth. Three and one-half millimeters of the gutta-percha was removed from the coronal aspect of the root canal and replaced with one of the three filling materials. The teeth were suspended in scintillation vials containing trypticase
soy broth, and human saliva was added to the pulp chambers. Microbial penetration was detected as an increase in turbidity of the broth corresponding to bacterial growth. At the end of 90 days, it was noted that 15% of the Cavit-filled orifices leaked, whereas 35% of the Intermediate Restorative Material and Super-EBA-filled orifices leaked. The gutta-percha obturated root canals that received an intraorifice filling material leaked significantly less than the obturated, unsealed control group that all leaked in < 49 days.

Deveaux et al (41) in 1999 prepared access cavities in premolars and filled them with cement and then immersed in culture medium in the model system. Half of the teeth were thermocycled on day 2. Bacterial percolation into the upper compartment was measured at regular intervals (days 2, 7, 14, and 21). Cement thickness was measured at the end of the study. In the non thermocycled group, Cavit was more leak-proof than the other cements at day 2, than TERM and IRM at day 7. Fermit was more leak-proof than IRM at day 7. In the thermocycled group, Cavit was more leak-proof than the other cements at day 7. Thermocycling did not significantly affect leakage. Cement thickness averaged 4.1 mm and did not significantly affect leakage. These observations should be considered when using cements as temporary fillings.

On the same year Barthel et al (42) conducted an experiment on human teeth coronally sealed with either Cavit, IRM, glass-ionomer cement, Cavit/glass-ionomer cement, or IRM/glass-ionomer cement, respectively.

The coronal chamber harboring soy broth with 108 colony-forming units of Streptococcus mutans/ml. The apical chamber containing sterile soy broth. The latter was checked daily for turbidity, indicating corono-apical penetration of bacteria. The Cavit group, the IRM group, and the Cavit/glass-ionomer cement group showed significantly more leakage than the glass-ionomer cement group of the IRM/glass-ionomer cement group.

Balto (15) in 2002 evaluated the microbial leakage of Cavit, IRM, and Dyract, on a set of 15 maxillary premolars that were prepared chemomechanically and obturated with thermoplasticized gutta-percha. A 3.5-mm thick layer of one of the three
temporary filling materials was inserted in the access cavities of the teeth from each group (each group was compromised of five teeth). The control teeth (four positive and four negative) lacked any filling material over the gutta-percha, whereas the orifice and the apical foramen of the negative control were completely sealed with nail polish.

It was noted that all positive control teeth leaked within 1 week, whereas those that served as negative control remained uncontaminated throughout the test period. With both organisms, IRM started to leak after 10 days, whereas Cavit and Dyract leaked after 2 weeks.

To evaluate the hypothesis that food-borne viable Enterococcus faecalis cells could enter the root canal space via coronal leakage, the capacity of a calcium sulphate-based temporary filling material (Cavit W) to prevent leakage of E. faecalis from a cheese through the endodontic access cavity into the pulp chamber was assessed by Kampfer et al (43) in 2007. Standardized class I access cavities were prepared in human maxillary molars. These were filled with Cavit of either 2 or 4 mm thickness (n=16, each). Empty access cavities served as positive, teeth filled with a light-curing composite material acted as negative controls (n=8, each). A cheese containing viable E. faecalis cells was placed on the occlusal aspects of test and control teeth. Leakage of E. faecalis from the cheese into the pulp chamber was assessed by culture on a kanamycin aesculin azide agar and compared between groups. All of the positive controls showed pure growth of E. faecalis. In addition, one of the negative control teeth leaked. The 4 mm application of Cavit prevented leakage of E. faecalis significantly better than the corresponding 2 mm application: 1 of 16 specimens compared with 6 of 16 specimens had leakage, respectively concluded that food-derived microbiota could enter the necrotic root canal system via microleakage.

1.4.3 Fluid filtration technique

Fluid filtration technique is an alternative method of thermocycling. Bobotis et al (44) 1989, evaluated the sealing properties of various temporary restorative
materials by using a newly introduced fluid filtration method, the materials tested were Cavit Cavit-G term, glass ionomer cement, zinc phosphate cement, polycarboxylate cement, and IRM. Extracted human incisor canine and premolar teeth were used immediately after placement of 4mm restoration the teeth were immersed in ringer's solution and incubated at 37°C. It was observed that cavit, Cavit-G term, and glass ionomer cement provided leak proof seals during the 8 week testing period, while leakage was observed in 4 of the 10 teeth restored with zinc phosphate cement. IRM and polycarboxylate cement were the least effective of the materials tested for preventing microleakage.

The microleakage allowed by three temporary restorative materials used for the sealing of teeth with both endodontic access and multi-surface cavity preparations was measured and evaluated by Anderson et al (45) in 1989. Extracted human incisor, canine, and premolar teeth with extensive carious involvement were prepared and restored with either Cavit, IRM, or TERM. Microleakage was measured by a fluid filtration technique at various time intervals and after thermal stress. It was shown that the TERM restorations provided excellent seals and were statistically superior to Cavit and IRM for restoring complex endodontic access preparations. The IRM restorations demonstrated significantly greater microleakage after thermal stress, while the Cavit restorations were deemed clinically unacceptable because of extensive cracks, expansion, and extrusion from the tooth preparations. These defects were not observed with the IRM and Term restorations.

Turner (46), in 1990, determined microleakage of temporary endodontic restorations in teeth restored with amalgam. Ten teeth were used for each of the seven materials: Cavit, Cavit-G, TERM, zinc phosphate cement, polycarboxylate cement, glass ionomer cement, and IRM. Microleakage was evaluated using a fluid filtration technique. The amount of microleakage was quantitated by measuring the fluid flow at 15 min, 1 h, 24 h, 1 wk, and 2 wk after insertion of the temporary restoration. Cavit, Cavit-G, TERM, IRM, and glass ionomer cement. All provided excellent
seals while zinc phosphate cement and polycarboxylate cement provided less effective seals.

Lim(47) in 1990 investigated the microleakage of several materials and the result listed in decreasing order were Cavit-W, Ketac Fil inserted without cavity conditioning, Kalzinol, and the control group of Ketac Fil inserted into conditioned cavities.

Jacquot et al (48) in 1996 investigated the quantity of changes in the water tightness of temporary filling materials by a new electrochemical technique by using teeth obturated with Cavit G, Fermit-N, and Intermediate Restorative Material (IRM). The changes in the resistance were measured first just after obturation (time 0), then after days 1, 2, 3, 4, and 7. It was shown that the IRM group was significantly more watertight than the Fermit-N group and much more than the Cavit G group.

A more recent study by Galvan et al(49) in 2002 compared the sealing effectiveness of IRM with other material (Amalgabond, C&B Metabond, One-Step Dentin Adhesive with AEeliteflo composite, One-Step with Palfique composite). Fifty-two extracted mandibular molars were experimented each tooth was affixed to a fluid filtration device and the seal was evaluated at 0, 1, 7, 30, and 90 days. A significant difference in leakage was noted between the materials. At 7 days, IRM, AEliteflo, and Palfique leaked significantly more than Amalgabond or C&B Metabond. Amalgabond consistently produced the best seal of all the materials throughout the duration of the study.

The effect of thermocycling on a colored glass ionomer intracoronal barrier used for the prevention of microleakage was evaluated by Maloney et al(50) in 2005. The samples randomly assigned to three groups with Group 1 received 1 mm intracoronal barrier of Triage glass ionomer, group 2 received 2 mm Triage barrier, and group 3 received no barrier. Microleakage was measured using the fluid transport model. Groups 1, 2, and 3 demonstrated 1.68 mm, 0.60 mm, and 23.24 mm of movement, respectively. One or two (mm) intracoronal barrier of Triage
significantly reduced coronal microleakage in thermocycled endodontically treated teeth.

The following studies compared IRM with other materials as root end filling material.

The microleakage after retro fillings of amalgam, amalgam, silver-containing glass ionomer cement, and intermediate restorative material was compared in vitro by Inoue et al(51) in 1991. The silver-containing glass ionomer cement and intermediate restorative material groups showed significantly less coronal leakage compared with the amalgam group at 1.5 hour.

Crooks et al (52) in 1994 evaluated the seal of IRM root end fillings prepared with various powder to liquid ratios (P:L) at extended time intervals using a fluid filtration method. The P: L of IRM evaluated included 2, 3, 4, 5, and 6 g/ml and the P: L which resulted from the manufacturer's recommended scoop and dropper, suggested that higher P: L of IRM than those previously recommended for temporary restorations and for endodontic access preparations may be acceptable for root end fillings. IRM of higher P: L has other advantages such as ease of placement and decreased setting time, toxicity, and solubility.

Fischer et al (53) in 1998 assessed bacterial leakage of mineral trioxide aggregate as compared with zinc-free amalgam, intermediate restorative material, and Super-EBA as a root-end filling material. Most of the samples filled with zinc-free amalgam leaked bacteria in 10 to 63 days. IRM began leaking 28 to 91 days. Super-EBA began leaking 42 to 101 days. MTA did not begin leaking until day 49.

Fogel and Peikoff (54) in 2001 examined the microleakage of the root-end filling materials (amalgam, Intermediate Restorative Material (IRM), a dentin-bonded resin, Super-EBA, and mineral trioxide aggregate). The results showed that amalgam root-end fillings demonstrated significantly more micro leakage than Super-EBA, dentin-bonded resin, or mineral trioxide aggregate. There was no significant difference between amalgam and IRM, however IRM was also not significantly different from the rest.
In an in vitro study to compare the methylene blue dye leakage linked to retrofillings in human and sheep teeth, with the degree of dye penetration, when intermediate restorative materials and Chemfil were used as retrofillings, was conducted by Roux et al(55) in 2002. It was shown that Chemfil had significantly less leakage than intermediate restorative material.

Torabinejad et al(56) in 1994 compared the amount of dye leakage (in the presence versus absence of blood) in root end cavities filled with amalgam, Super EBA, IRM, and a mineral trioxide aggregate. It was noted that there was a significant leakage difference between the root ends filling material. Mineral trioxide aggregate leaked significantly less than other materials tested with or without blood contamination of the root end cavities.

Steenkamp et al(57) in 2006 assessed and compared in vitro sealing ability of 3 different dental restorative materials, intermediate restorative material (IRM); a resin-modified glass ionomer; and amalgam used as apical sealants during equine surgical endodontics. IRM, a resin-modified glass ionomer and amalgam all showed comparative features as apical sealants when used in vitro in equine teeth. IRM is currently regarded as the superior material in clinical situations due to its ease of handling and lesser sensitivity to environmental moisture during placement compared to the other 2 materials.

A quantitative assessment of the sealing ability of Super-EBA, IRM, and Pro Root MTA root-end fillings subjected to 3 different finishing techniques was investigated by Gondium et al(58) in 2006. The results revealed that Pro Root MTA displayed significantly less mean dye microleakage than Super-EBA and IRM root-end fillings.

Another study on the same year by Malcic et al(59) aimed to determine the leakage of SuperEBA and intermediate restorative material (IRM) in root canal samples, with or without orthograde filling, by evaluating bovine serum albumin (BSA) microleakage using spectrophotometry. Significantly less leakage occurred in
samples filled with orthograde and root-end fillings than did in samples filled only with an orthograde approach and the samples with IRM root-end fillings.

The antibacterial activity of leachable components of selected root-end filling materials: amalgam, ProRoot MTA (mineral trioxide aggregate), Intermediate Restorative Material (IRM), Super Bond C&B, Geristore, Dyract, Clearfil APX composite with SE Bond, or Protect Bond was studied by Eldeniz et al (60) in 2006. It was found that IRM and ProRoot MTA were generally more potent inhibitors of bacterial-growth than the other tested materials.

A latest study by Tobon-Arroyave et al (61) in 2007 was conducted to investigate the effect of rapid exposure to a water-soluble dye of Intermediate Restorative Material (IRM), Super Ethoxybenzoic Acid (sEBA) and Mineral Trioxide Aggregate (MTA), on the marginal adaptation and microleakage of root-end fillings. sEBA and IRM had better adaptation and less leakage compared with MTA. Although sEBA and IRM had better behaviour than MTA regarding microleakage and marginal adaptation, it is possible that exposure of MTA to a water-soluble dye before achieving full set and its porous microstructure contributed to the results.
**Materials & Methods**

2.1. **Study Design:**
An in vitro randomized experimental study.

2.2. **Study Population:**
Caries free, extracted, human premolars collected from orthodontic clinics.

2.3. **Inclusion Criteria:**
Caries free, extracted human premolars.

2.4. **Sample size:**
A total of 80 premolars teeth (40 per group) were selected based on previous studies estimation.

2.5. **Method:**
The Eighty Caries free, extracted, human maxillary and mandibular premolars were stored in 10% formalin at room temperature. The teeth were cleaned off soft tissue and debris before use, rinsed overnight in running water and then immersed in deionized water for 24 hours.

Standardized Coronal access cavities to the pulp chamber were prepared in the occlusal surfaces with the aid of a template measuring 4mm x4mm, access was made using a high speed air turbine under water coolant with a round bur (Maruto, Japan) for initial entry and a diamond fissure bur to extend the preparation to the desired occlusal outline. All teeth were irrigated using 5% sodium hypochlorite (Hyposol, Prevest Denprol and Jammu, India) to remove remaining smear layer, pulp tissues and other debris inside the pulp chambers. The prepared openings were air dried and cotton pellet were placed on the floor of the pulp chamber. A periodontal probe was used to measure the depth of the opening assuring that it could accommodate at least 4mm of the temporary filling material (table 1) (8).

The teeth were divided randomly into two groups of 40 teeth each, ready made [Cavisol (zinc oxide, calcium sulphate, zinc sulphate, glycol acetate, poly vinyle
chloride acetate, triethylolamine and white pigment - (Golchay Co, I.R.I), Litark (zinc oxide, plaster of paris, vinyl acetate, white pigment - (LTK 700, Italy)) were used in group 1 and hand mixing [IRM P: L 20:10 g/ml (ZICONOL, India), zinc phosphate P: L 40:20 g/ml (DENTAM, United Kingdom)] in group 2 (Figure 1). All materials were mixed and handled according to the manufacturers instructions. The filling materials were incrementally introduced into the access opening from the bottom up with the use of a plastic instrument. Every effort was made to ensure that the filling materials were carefully pressed against the cavity walls. The surfaces of filling materials placed in specimens in group 1 were smoothed with normal saline (Himedia, India) to initiate the setting of the materials. The specimens were then placed in normal saline and stored in an incubator (Gallen Kamp, England) for 48h with the temperature maintained at 37°C to ensure setting of the materials.

The specimens were then thermocycled for 500 cycles in distilled water at 5 and 55°C with a dwell time of 30 sec in each bath using thermocycling machine (Techne, Flexigene, Staffordshire, UK) (Figure 2).

In preparation for leakage assessment, the specimens were painted with two layers of nail varnish except of 1mm around the restoration margin and placed in 2% methylene blue dye solution (pH 7.4) and kept for 10 days at 37°C in an incubator (Gallen Kamp, England).

The specimens were washed under running water and dried, then the teeth were longitudinally sectioned in a mesio-distal direction using a low speed diamond disc under constant water lubrication to remove debris and smear layer created by cutting. The sections were stored at 37°C in an incubator until microleakage assessment. Dye penetrations were measured in millimeters, using a calibrated stereomicroscope (WILD Heerbrugg, Switzerland) at a 4x magnification.

The measurement of dye penetration was jointly carried out by two researchers using a modification of scoring technique introduced by Lee et al. (1993) (Figure 3).
2.6 Data collection:
Data was collected using data collection sheet (Appendix 1).

2.7 Data Analysis:
Result analyzed using one way ANOVA test (p<0.05) to determine if a statistically significant difference existed between the groups of the investigated materials.

Table 1: Details of temporary filling materials investigated.

<table>
<thead>
<tr>
<th>materials</th>
<th>constituent</th>
<th>manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cavisol</td>
<td>(zinc oxide, calcium sulphate, zinc sulphate, glycol acetate, poly vinyl chloride acetate, triethylolamime and white pigment</td>
<td>Golchay Co, I.R.I</td>
</tr>
<tr>
<td>Litark</td>
<td>zinc oxide, plaster of paris, vinyl acetate, white pigment</td>
<td>LTK 700, Italy</td>
</tr>
<tr>
<td>IRM</td>
<td>P: L 20:10 g/ml</td>
<td>ZICONOL, India</td>
</tr>
<tr>
<td>Zinc phosphate</td>
<td>P: L 40:20 g/ml</td>
<td>(DENTAM, United Kingdom)</td>
</tr>
</tbody>
</table>
Figure 1: Material used in this investigation: (a) Cavisol & Litark (b) Zinc phosphate (c) Zinconol (IRM).

Figure 2: Thermocycling machine
Figure 3: Grades of dye penetration

Grades of dye penetration (Lee et al, 1993)
1: Dye penetration is over half of the pulp chamber.
2: Dye penetration is within half of the pulp chamber.
3: Dye penetration is within the dentino-enamel junction.
RESULTS

All the samples were screened visually and then under the stereomicroscope, amongst the four materials tested, Cavisol showed the least microleakage, it was followed by Litark, zinc phosphate and IRM.

The results of the one-way ANOVA are shown in Table 1. There were statistically significant differences between the tested materials (p < 0.05).

Result of homogenous subsets used Duncan test for mean separation showed that there were no significant difference between cavisol and Litark, while there were highly significant difference between IRM, zinc phosphate and the ready made temporary filling materials (Figure 4).

By using Chi-square Tests, crosstabs relation between the grades and different materials tested showed that cavisol and Litark samples showed the least microleakage and consistent leakage grade 3 (100%), followed by zinc phosphate cement which consistent leakage grade 1(85%) and grade 2 (15%), while all IRM samples were within grade 1(100%) (Figure 5).

Among all the materials tested, Grade 1 was exhibited in all of IRM samples (100%); 85% in zinc phosphate and 0% in both Litark and cavisol (Figure 6), while grade 2 was exhibited in only 15% of zinc phosphate samples and 0% in the rest of the materials tested (Figure 7). grade 3 was exhibited 100% of both Litark and cavisol samples and 0% in IRM and zinc phosphate samples (Figure 8).

When the relation of each materials was compared to different grades cavisol showed 100% grade 3 (Figure 9), Litark showed 100% grade 3 (Figure 10), zinc phosphate 85% grade 1 (Figure 1) and IRM 100% grade 1 (Figure 12).

Cavisol showed a mean leakage value of $0.98 \pm 0.24$ mm. Litark showed mean leakage value of $1.22 \pm 0.24$ mm, zinc phosphate showed mean leakage value of $5.50 \pm 0.78$ mm and IRM revealed highest mean leakage value of $6.95 \pm 0.84$ mm (Figure 13) (table 2). Micrograph were used to show the leakage of the tested materials. Dye penetration into the material was noted in Cavisol (Figure 14a), Litark (Figure 14b),
zinc phosphate (Figure 14c), all IRM specimens exhibited total leakage i.e. absorbed the dye to the bulk of the material (Figure 14d).
Table 1: Oneway ANOVA Analysis

<table>
<thead>
<tr>
<th></th>
<th>Sum of Squares</th>
<th>Df</th>
<th>Mean Square</th>
<th>F</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Between Groups</td>
<td>70.33</td>
<td>3</td>
<td>23.44</td>
<td>661.94</td>
<td>.000</td>
</tr>
<tr>
<td>Within Groups</td>
<td>2.55</td>
<td>72</td>
<td>.035</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>72.88</td>
<td>75</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table (2) Depth of dye penetration in the cavities restored with the different materials (mm)

<table>
<thead>
<tr>
<th>Materials</th>
<th>Sample size</th>
<th>Total tooth length (mm)</th>
<th>Dye depth (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Litark</td>
<td>20</td>
<td>4.76 ± 0.96</td>
<td>1.22 ± 0.24</td>
</tr>
<tr>
<td>IRM</td>
<td>18</td>
<td>7.50 ± 0.70</td>
<td>6.95 ± 0.84</td>
</tr>
<tr>
<td>Cavisol</td>
<td>18</td>
<td>6.38 ± 0.98</td>
<td>0.98 ± 0.31</td>
</tr>
<tr>
<td>Zincphosphate</td>
<td>20</td>
<td>7.02 ± 0.91</td>
<td>5.14 ± 0.78</td>
</tr>
</tbody>
</table>
Mean with different letters was significantly different.
Fig. (5) Relation between the micro leakage grade and different materials

Figure 1
Fig. (6) Incidence of micro leakage grade 1 in different materials

Fig. (7) Incidence of micro leakage grade 2 in different materials
Fig. (8) Incidence of micro leakage grade 3 in different materials

Materials

IRM  Zinc phosphate  Cavisol  Litvak
Fig. (9) Degree of dye penetration grades within the Cavisol

Fig. (10) Degree of dye penetration grades within the Litrak
Fig. (11) Degree of dye penetration grades within the zincphosphate

Fig. (12) Degree of dye penetration grades within the IRM
Fig (13) Depth of dye penetration (mm) in the different materials.
Fig 14: Micrograph of dye penetration within different materials.

a) Cavisol exhibited grade 3 dye penetration. b) Litark exhibited grade 3. c) Zinc phosphate exhibited grade 1. d) IRM exhibited grade 1.
4.1. DISCUSSION

Cavisol and Litark are premixed temporary filling materials. This reduces mixing inconsistencies commonly encountered with chair side manipulation of cements. In addition, they set on contact with moisture and possess hygroscopic properties. This enables these materials to provide a tight seal in endodontic access cavities, thereby preventing seepage of bacteria, oral fluids and other debris into the pulp chamber, which is essential for the success of root canal treatment.

In this in vitro study, cavisol and Litark (ready made filling materials) were compared to IRM and zinc phosphate (hand mixed) temporary restorative materials. As per the design of this study, all temporary restorative materials were allowed to set for 48 hours in an incubator and then subjected to thermocycling followed by immersion in 2% methylene blue dye. Caution should be exercised in extrapolating conclusions from this study; because the experimental design did not totally mimic actual clinical conditions (e.g. the present study evaluated these materials with four dentinal walls for support). However, the data provide useful preliminary information on the sealing properties of the materials tested.

Extracted intact premolars (n=80) were used and a thickness of at least 4 mm of restorative material was inserted. This is in conformity with what had been reported (8, 46), that a minimum of 3.5 to 4 mm of restorative material is necessary to prevent microleakage. However, clinically a 4 to 5 mm thickness of temporary restorative material cannot always be achieved, in particular not in severely broken-down teeth requiring endodontic therapy. Access preparations can frequently be made in premolars with minor loss of coronal structure or with existing four-surface class I or three-surface class II restorations. To prevent weakening of the tooth, coronal structure should be preserved whenever possible (41), whereas temporary restorative materials
need adequate retention to prevent dislodgement between appointments. Therefore, a 4 mm thick temporary restorative material is desirable. Certainly, there are teeth that require endodontic therapy that have lost so much tooth structure that less than the minimum recommended thickness of access preparation is sometimes available.

A number of methods have been used to evaluate the microleakage of temporary endodontic filling materials(13, 14, 19, 29). The present study utilized thermal cycling procedure to simulate intraoral conditions. The temperature range of 55±2C and 5±2 C used in this study corresponds to the extremes of temperatures that could be experienced in the oral environment (29).

The rationale for selecting a 10-day observation period was based on the premise that this is an adequate time-lapse for a temporary restoration between endodontic appointments, at which no or minimum leakage to occur. Our observations revealed that all the tested materials leaked to some extent.

Different authors have reported conflicting results concerning the ability of ready made temporary filling materials such as Cavit and hand mixed materials (IRM and zincphosphate) to prevent coronal microleakage. Some revealed that cavit a ready made material had the best sealing ability whereas IRM as hand mixed showed the maximum dye penetration (12). Other indicated that Cavit showed less microleakage in dye peneteration (20), and act as a barrier to leakage than IRM (36). Additional study indicated that IRM speciemens absorbed the dye into the bulk of the materials(22). A similar finding was noted in this study in which Litark and Cavisol as ready made temporary filling materials has better sealing ability than zinc phosphate and IRM, as hand-mixed temporary materials absorbed the dye into the bulk of the materials. This finding could probably be attributed to the instability of
zinc oxide when subjected to extreme of temperatures (13), as well as inconsistencies in the mixing process and the resulting lack of homogeneity (41).

This observation is different from other studies which showed that IRM demonstrated the least body penetration when compared with Cavit and Tempit (new interim restorative materials)(14).

On the other hand, some reported that Cavit and IRM provided better internal sealing than did zinc phosphate cement (23), whereas our findings showed that the mean leakage value of zincphosphate (5.14\pm0.78\text{mm}) was less than IRM(6.95\pm0.84 \text{mm}).

IRM seems to be more difficult to pack into an access cavity than other materials. The penetration of the dye in the bulk of the IRM may be caused by the presence of air bubbles and voids, which did not seem to affect the overall leakage patterns. These defects of IRM and zincphosphate may be the result of mixing and insertion procedures. Cavisol and Litark are a premixed, ready-to-use, hygroscopic material that expands when it comes in contact with moisture (17) , and presumably this expansion permits the material to adapt more tightly to dentin walls, thus providing a good seal under different conditions, including thermocycling (16, 17).

Dye microleakage and penetration in all Cavisol and Litark samples did not extend beyond the dentino-enamel junction (Figure 3). Cavisol was observed to exhibit better sealing ability as compared with Litark. However, no statistically significant difference was noted between them (p>0.05), while there is significant difference (p<0.05) between these materials and hand-mixed groups.
4.2. CONCLUSION
Among the four materials tested, Cavisol was observed to provide a consistently tight seal followed by; Litark, zincphosphate and IRM. This indicated that ready made temporary filling has best sealing ability over hand-mixed. These emphasize further stress for the importance of correctly placing a sufficient thickness of temporary filling materials in endodontic access cavities to ensure a tight seal.

4.3. RECOMMENDATION
However, because it is not known how the sealing properties will be affected over longer observation periods, or when the material is exposed to the oral environment, this study must be considered preliminary. Further clinical and laboratory experiments are recommended.
References


## Appendix I

**Data collection sheet:**

1. Tooth # □
2. Types of materials □
3. Cavisol □
   a. Litark □
   b. IRM □
   c. Zinc phosphate cement □
3. Microleakage depth
   a. Grade 1 □
   b. Grade 2 □
   c. Grade 3 □