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CORONAL BACTERIAL LEAKAGE ASSESSMENT OF DIRECT INLAY COMPOSITE VERSUS INDIRECT CERAMIC RESTORATION IN (MOD) CAVITY OF ENDODONTICALLY TREATED MAXILLARY PREMOLARS WITH A SINGLE ROOT

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Abstract:
Aim: To evaluate the bacterial coronal leakage assessment of direct inlay composite versus indirect ceramic restoration of (MOD) cavity in endodontically treated maxillary premolars with single root.

Method: 30 human maxillary premolars with single root of fully developed apex extracted were selected. Every tooth has decoronated to 3 mm coronal to cementoenamel junction using diamond disc bur for standardization. ProTaper rotating tools were employed to chemo mechanically prepare the root canals and for radicular preparation to size F3 finishing file. ProTaper obturators #F3 were employed to obturate the canals and resin sealer (ADSEAL) were used for filling the canals via the lateral condensation method. Two mm apically of the coronal gutta percha was removed to make a space for liner material. Above the gutta-percha to the level pulp chamber floor, glass ionomer restorative was utilized as a liner material. The premolars were allocated into 2 identical test groups (group 1&2) of 10 premolars each in accordance with the final restoration techniques (**direct & indirect)** with other two groups of **positive control** with 5 intact teeth, and **negative control** with 5 teeth with empty (MOD) preparation of the cavity following endodontic therapy without placement of the final restoration. The specimens were subjected to thermocycling then bacterial coronal leakage assessment was done for all teeth by using two-chamber.

Results: Group 1: Direct Inlay (Composite Resin) recorded 43% leakage versus 57 % without leakage. On other hand **Group 2: Indirect (Ceramic Inlay)** recorded 34% leakage versus 66 % without leakage, but without statistically significant differences.

Conclusion: Ceramic Inlay as indirect technique of coronal restoration of endodontically treated teeth gives superior results in relation to direct Inlay Composite Resin in coronal bacterial leakage assessment.

Introduction:

The general consensus is that the root canal system must be completely obturated and decontaminated for endodontic treatment to be successful [(1)]. Inadequate coronal sealing, bacterial survival both within and outside the root canal, underfilling the canals, irregular canal geometry, and iatrogenic mistakes are typically the causes of endodontic failures [(2)].

Both a strong apical seal and an entire coronal seal are necessary for endodontic treatment to be successful. It is necessary to consider coronal microleakage as a potential cause of root canal treatment failure. Patients need to be made aware of the importance of the coronal seal through and following obturation because inadequate coronal restoration results in higher failures [(3)].

The results of endodontic therapy and teeth preservation are enhanced by the insertion of a final filling. The chances of a successful outcome of endodontic therapy are significantly reduced in the absence of a permanent filling. To maintain the coronal and radicular dental structure, anterior teeth undergoing endodontic operations that result in minimum tooth structure destruction could be conservatively restored using bonded restorations. For the rebuilding and rehabilitation of teeth that have undergone endodontic treatment, materials that could adhere properly to the dentin are always a viable possibility [(4,5)].

To conserve the most of hard tissue as feasible, the kind of restoration is often determined by the location of the tooth on the dental arch and the amount of residual tooth structure. A crown can more effectively preserve posterior teeth that have undergone endodontic treatment, whereas a direct composite restoration is the material preferred for anterior teeth that have undergone tiny to moderate restoration. Additional materials and methods utilized for a long time post endodontic filling materials consist of ceramic full/partial crowns, gold and ceramic on-lays, and amalgam restorations [(6)].

Clinical studies have demonstrated that post endodontic coronal microleakage might permit bacterial infiltration into the filled root canal system, leading to reinfection and endodontic therapy failures. A sufficient coronal seal is necessary for endodontic treatment to be successful. Following the obturation process is finished, a tightly sealed coronal filling is necessary to stop oral bacteria from getting inside [(2)].

The reasons for the improvement in endodontic success by placement of proper coronal restoration are firstly the coronal seal that prevents re-infection of bacteria into the filled root canals, secondly the protection of the remaining tooth structure from fracture. For this reason, a selection of coronal restoration after endodontic treatment must be considered to protect or reinforce the remaining tooth structure. In daily practice, several dental practitioners usually prefer to select cuspal or full-

coverage restorations for the root-filled teeth after endodontic treatment. However, not every tooth that has had endodontic treatment needs the cuspal-coverage restorations [7].
So, the current research was directed to assess the bacterial coronal leakage assessment of direct inlay composite versus indirect ceramic restoration of (MOD) cavity in endodontically treated maxillary premolars with single root.

Materials and methods:
Samples Preparation:
30 human maxillary premolars with single root of fully developed apex extracted were selected. After premolars were thoroughly cleansed to remove any tissue or calculus deposits, isotonic saline was used to keep them.
All premolars were examined under a magnification lens to check for cracks. To guarantee uniform canal shape, radiographs of every tooth were obtained in the bucco-lingual and mesio-distal orientations.

The included criteria of the selected teeth:
The teeth were fully developed apex without interior resorption, decay, calcification of the canal, or history of endodontic therapy.
To standardize, every tooth has decoronated to 3 mm coronal to cementoenamel junction using diamond disc bur for standardization. Also, for standardizations, all teeth were examined radio graphically mesiodistally and buccolingually for selection teeth of similar dimensions of chamber.
To guarantee the apical patency of the canals, a K-file size 10 (Dentsply Maillefer, Switzerland) was transferred to the apex of each canal. The working length (WL) was noted when the identical file was reinserted inside the canal till it was seen through the apical foremen [8].
Using engine ProTaper rotary tools (Dentsply Maillefer, Ballaigues, Switzerland), the root canals were chemo mechanically prepared, and 5,25% NaOCl was used for irrigation. The final tool employed in the apical area was an F3 finishing file. Following preparation, the root canals were irrigated using 15% EDTA (for removal of smear layer), 5,25% NaOCl, and 0,9% NaCl before drying using paper points.
ProTaper obturators #F3 were employed to obturate the root canals and resin sealer (ADSEAL - Root Canal Sealer META BIOMED) were used for filling the canals via the lateral condensation method. Two mm apically of the coronal gutta percha was removed to make a space for liner material.

liner material placement:
Glass ionomer restorative (Ketac™ N100 Light-Curing Nano-Ionomer Restorative Refill (3M™, ESPE, U.S.A) shade A3) was used as liner material over the gutta percha to the level pulp chamber floor.

Teeth grouping:
The premolars were then randomized divided into two identical test groups (group 1&2) of 10 premolars each in accordance with the final restoration techniques (**direct & indirect)** with other two groups of **positive control** with 5 intact teeth, and **negative control** with 5 teeth with empty mesio – occluso – distal (MOD) cavity preparation following endodontic therapy without placing a final filling.

Group 1: Direct Inlay (Composite Resin):
It has premolars with conventional MOD cavity preparation following endodontic therapy. Utilizing a 3M ESPE Single bond universal and a 3M Filtek Z350 XT Universal Restorative Syringe in shade A3, the MOD cavities were directly filled with Composite Resin by following manufacturer directions.

Group 2: Indirect inlay (Ceramic Inlay):
It has premolars with conventional MOD cavity preparation following endodontic therapy. Making an impression using silicone substance on the MOD cavities followed by pouring using a dental stone. Next, in accordance with the manufacturer's directions, the Ceramic Inlay was constructed using an indirect approach from IPS e.max® CAD HT shade A3. The inlays were cemented utilizing DENTSPLY Calibra Universal Dual Cure Auto Mix Syringe Refill, a self-etching adhesive without the need for an extra dentin/enamel adhesive or bonding technique.

Group 3: (Positive control):
It has undamaged premolars that have not had cavity preparation or endodontic therapy.

Group 4: (Negative control):
It has premolars with conventional MOD cavity preparation following endodontic therapy, but no occlusal restoration was placed within the MOD cavities.

***Thermocycling*:**
After that, thermocycling was applied to each sample. With a dwell duration of 30 seconds for every bath, this was performed on 250 occasions across baths that were 5°C, 37°C, and 55°C (9).

Bacterial leakage evaluation:
For testing bacterial leakage, this study used two-chamber design (Figure 1) like that was employed in the work of ***Fathi et al*** (10) to assess coronal microleakage in the current investigation. A cut-ended eppendorf tube was used to hold the occlusal two mm of the root, and the remaining root length was left outside of it.

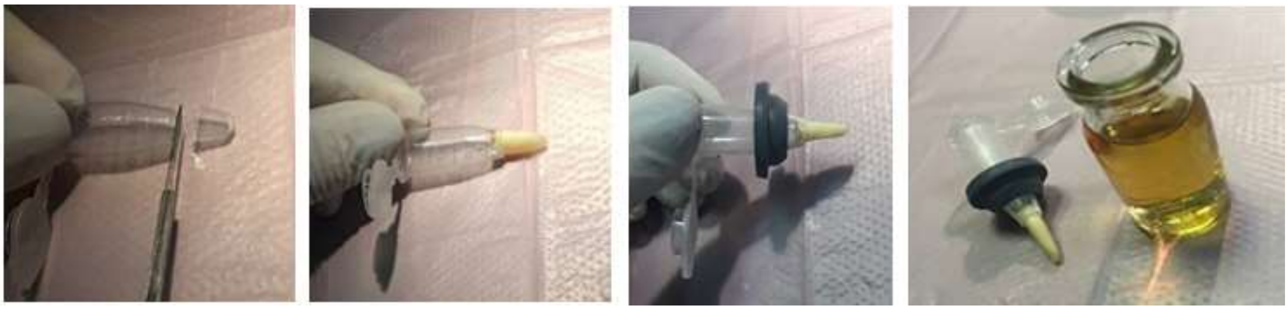

Figure (1): A photograph showing the steps of the two-chamber design construction in order to assess bacterial leakage.

To insert the root within the antibiotic vial top, a handpiece with an acrylic resin finishing bur was employed to drill an opening in the cap of the empty bottle. The tooth/ eppendorf tube and eppendorf tube /rubber cup interfaces were sealed to avoid bacterial leakage in the experiment model using cyanoacrylate adhesive (Loctite 496, Henkel Ltda, São Paulo, SP, Brazil).
Ethylene oxide gas was used for a 12-hour sterilization of the prepared specimens, which included premolars, an eppendorf tube, and the antibiotic vial empty bottle caps. After that, the vials were filled with sterile brain heart infusion (BHI) broth, submerging the specimen's root apexes by two mm. The process was performed in a sterile environment. To stop bacteria from leaking via lateral canals or additional cementum discontinuities, a pair layers of nail varnish were put to the outside surface of every tooth, with the exception of the two-mm area surrounding the apical foramen.
The whole bacterial leakage model equipment was incubated at 37ºC for four days to guarantee sterilization. Subsequently, 2 ml of a 1:10 dilution of *Enterococcus faecalis* at about 5 x 10^8 CFU/ml in brain heart infusion broth BHI (Faculty of Medicine for Girls, Al Azhar University, Cairo) was added to the upper chamber.

Daily assessments of the specimens' turbidity were conducted till turbidity was found in each specimen within the BHI setting. The turbidity of the liquid culture environment suggested a potential leak of microbiological contamination. For a period of 120 days, the specimens were assessed.

Every specimen's observation of turbidity was noted on that day, and the turbid specimens were eliminated. Salt tolerance examination, which suggests *Enterococcus faecalis* leaking instead of the existence of contamination, was additionally used to verify bacterial leakage. An incubator was used to hold a tube with BHI + 6.5% NaCl and a 3 µl portion of the turbid lower broth for a duration of one to two days. *Enterococcus faecalis* would be present if there were signs of turbidity. (Figure2).

The data gathered were tabulated and statistically examined to determine how many samples had been penetrated throughout the course of being exposed to the bacterial source.

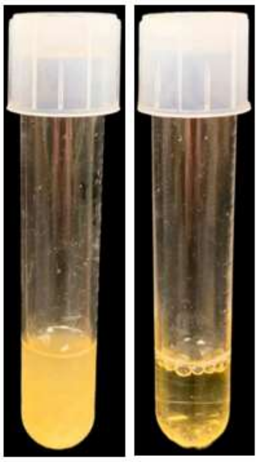

Figure (2): A photograph showing presence of BHI + 6% NaCl both before and following an *E. faecalis* inoculation. Uninoculated control (right tube). Inoculated (left tube) with *E. faecalis.*

Statistical Analyses:

Fisher's exact test was used to examine the percentage of leakage, and the Kaplan-Meier survival with log-rank test was used to analyse the amount of leaking with age. To preserve a general significance level of 0.05 for the log-rank test, post hoc pairwise comparisons were corrected employing Tukey's adjustments. Using the Intention to Treat (ITT) and Per Protocol (PP) analytic techniques, every analysis was performed again. Samples, where it was evident that the leakage had happened as a consequence of an unsuccessful test setup that led to leaking surrounding the tooth rather than within it, were not included in the PP assessment. A significance threshold of 0.05 was used. For all analyses, SAS EG v.6.1 (SAS Institute, Cary, NC) was utilized.

Results:

The coronal bacterial leakage of all groups by numbers, percentages (%), and experimental failures were presented in table (1).

In the positive control group, no contamination was detected during the course of the trial, while contamination happened in the **negative control group** after five days, this indicated the effectiveness and reliability of the experimental model.

Table (1): Showing The coronal bacterial leakage of all groups by numbers, percentages (%), and experimental failures.

Groups	**Number of samples**	**Samples with leakage**		**Samples Without leakage**		**Experimental Failure**	
		NO	**%**	**NO**	**%**	**NO**	**%**
Group 1: Direct Inlay (Composite	10	3	30%	4	40%	3	30%

Resin)							
Group 2:Indirect (Ceramic Inlay)	10	2	20%	4	40%	4	40%
Group 3: (Positive control)	5	0	0%	5	100%	0	0%
Group 4: (Negative control)	5	5	100%	0	0%	0	0%

The numbers of excluded teeth that have indications of experimental failure ware seven teeth while the included teeth in the analysis were 23 teeth. coronal bacterial leakage rates were not significantly variation between the two groups as the p = 0.1235.

Group 1: Direct Inlay (Composite Resin) recorded 43% leakage versus 57 % without leakage. On other hand **Group 2: Indirect (Ceramic Inlay)** recorded 34% leakage versus 66 % without leakage but without statistically significant differences (P = 0.1235). These results were presented in table (2) and shown in figure (3).

Table (2): Showing the percentage (%) of the samples with bacterial leakage, and without bacterial leakage after exclusion of the experimental samples' failure.

Groups	**Number of samples after exclusion of experiment failures**	**Samples with leakage**		**Samples Without leakage**		**P - Value**
		NO	**%**	**NO**	**%**	
Group 1: Direct Inlay (Composite Resin)	7	3	43% [A]	4	57% [A]	0.1235 NS
Group 2: Indirect (Ceramic Inlay)	6	2	34% [A]	4	66% [A]	

NS: non-significant (p > 0.05). *Significant (p<0.05). Different letters indicate a significant difference.

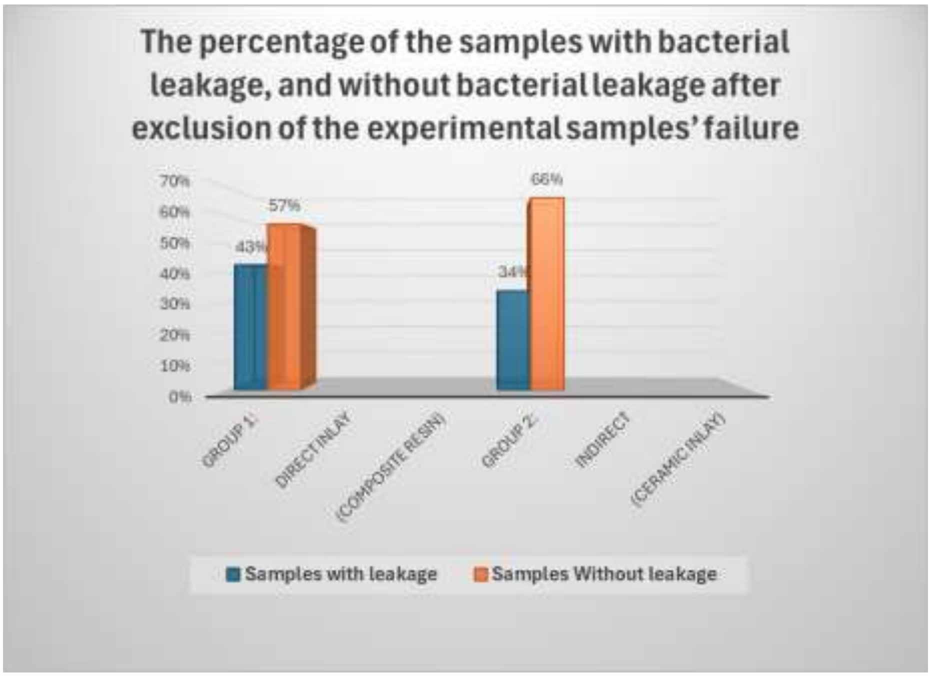

Figure (3): A photograph showing the percentage of the samples with bacterial leakage, and without bacterial leakage after exclusion of the experimental samples' failure.

Discussion:

The dental professions are seeking for achieving strong resin composite adherence to the hard dental structures, as strong bonding ought to result in reduced microleakage and increased

restorative durability [11]. A primary objective of adhesive dentistry has been to establish a securing close bond between the dental fillings and the cavity walls in order to prevent microleakage [12].
Evaluation of the root filling materials' ability to create the best possible coronal seal of its coronal restoration include, the radioisotope electrochemical approach, fluid filtration process, dye penetration procedure, scanning capacitance microscopy, and bacterial microleakage models [13].
There are several models that are not optimally able to replicate the clinical environment. For example, the precision of the data obtained is compromised since dye molecules and electrochemical radioisotopes have smaller dimensions than bacteria and would diffuse more quickly than bacteria. Additionally, air bubbles within the dye penetration technique may hinder dye penetration and therefore might potentially alter the outcome [14,15].
So, the investigational model of our research was directed to evaluate the bacterial coronal leakage resistance of direct inlay composite versus indirect ceramic restoration of (MOD) cavity in endodontically treated maxillary premolars with single root.
In this study we used bacterial coronal leakage to evaluate the adhesion of two techniques of final coronal restoration (direct inlay composite versus indirect ceramic restoration).
Since the bacterial leakage models can more accurately replicate the in the clinical setting and produce outcomes that are more transferable to the clinical scenario, it is frequently used to measure coronal leakage [16]. *E. faecalis* is a biological indication that has been well studied. Numerous laboratory investigations examining *E. faecalis's* sensitivity to endodontic therapy revealed a high level of the bacteria's resistance to antimicrobial medications. Moreover, *E. faecalis* can endure under extremely unforgiving conditions with a low food source and an elevated alkaline pH of up to 11.5. Great resistance to antimicrobial treatments makes E. faecalis an extremely resistant pathogen to root canal treatment because of its ability to proliferate as a biofilm on root canal walls and as a mono-infection in treated canals lacking synergistic assistance from other bacteria [17].
Just 10 out of the 23 specimens in this research (43%) showed leakages after exclusion experimental teeth failure. This is not like the majority of research on bacterial leakage. **Torabinejad *et al***. reported that 50% of the specimens' showed leakages, while **Khayat *et al*.** reported 100% leakage with **Magura *et al***. On other hand the study made by **Eldeniz and Ørstavik's** conducted 72% leakage. The explanations for the current research's lesser leakage percentage than the previous. It might be due to the type of sealer used, and the final coronal restoration [18,19].
The results of our results showed that: **in the positive control group**, no leakage was noted throughout the experimental period, while leakage was occurred within 5 days **in the negative control group**, this supports the experimental model's dependability and efficiency.
In the experimental two groups **Direct Inlay (Composite Resin)** recorded 43% leakage versus 34% leakage **Indirect (Ceramic Inlay)** but without statistically significant differences**.**
On the same direction of the present study, a number of investigations have found that indirect restorations cause fewer microleakage than direct composite resins based on how the dentin system and the restorative work together. Direct and indirect composite approaches exhibited comparable behaviour, according to other experiments [20].
These kinds of partial adhesive restorations may now be made using a variety of materials and technology, including composite or ceramic materials and CAD-CAM machines [21].
Retention loss was most commonly associated with partial indirect ceramic restorations. Thus, the luting agent and restorative material deterioration have a significant impact on the clinical longevity of dentin-bonded restorations [22,23].

Conclusion:

Ceramic Inlay as indirect technique of coronal restoration of endodontically treated teeth gives superior results in relation to direct Inlay Composite Resin in coronal bacterial leakage assessment.

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