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IP Annals of Prosthodontics and Restorative Dentistry

Journal homepage: <https://www.aprd.in/>

Original Research Article

Role of hermetic coronal seal on the long term success of apexification in immature permanent teeth induced by calcium hydroxide based regenerative materials- A pilot study

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ARTICLE INFO

Article history:

Received 17-01-2024

Accepted 20-02-2024

Available online 16-03-2024

Keywords:

Coronal seal

Apexification

Temporary restoration

Calcium Hydroxide

Immature permanent teeth

ABSTRACT

Context: Calcium hydroxide with or without iodoform is commonly used for apexification in immature permanent teeth. Before permanent restoration, temporary restorative material is used for ensuring coronal seal at the tooth orifice. An ideal coronal sealing agent prevents micro-leakage and maintains aseptic root canal environment.

Aim: This study aims at assessing the role of coronal seal on the long term success of apexification in immature permanent teeth by calcium hydroxide.

Materials and Methods: 51 children between the age group of 8-10 years having open apex in permanent upper anterior(s) secondary to trauma were divided into three groups, each receiving calcium hydroxide based material for apexification. Children were evaluated clinically and radiographically and followed up for a period of nine months. Cavit was used as temporary restoration in all three groups. Cases with loss of coronal seal, failure in apexification and clinical flare ups were identified. The data were statistically analyzed by Z-test and Chi-square test.

Results: Presence of good coronal seal was directly related with successful and uneventful apexification. Loss of coronal seal was mostly related with increased evidence of clinical flare up and failure in or delayed apexification. Both the results were found to be statistically significant.

Conclusion: Temporary restorative materials providing meticulous coronal seal is as important as the permanent restoration, for the long term success of apexification.

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1. Introduction

Calcium hydroxide is a material, which has been used, for a variety of purposes since its introduction into Dentistry by Hermann in 1920.¹

In 1959, Granath first reported the use of calcium hydroxide for apical closure.² The technique was given impetus by the description of three cases of apexification by Frank in 1966.³ Frank's rationale was based on the

assumption that the Hertwig's root sheath retains the capacity to function after pulpal injury.³

Apexification is a method to induce development of root apex of an immature pulp less tooth by formation of osteo-cementum or other bone like tissue. The objective is elimination of periapical infection, promotion of root end growth and closure, enhancing the periodontal tooth support.⁴

Coronal seal is produced by a temporary restorative material that is placed at the orifice of tooth access to

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seal the root canal between endodontic visits.⁵ The ideal requirements of temporary restorative material includes the ability to be easily manipulated, to protect the root canal from bacterial contamination of the oral cavity by rendering hermetic coronal seal, dimensionally stable in extremes of temperature and resistant to abrasion or corrosion.⁶

Studies by Ray et al have demonstrated that the quality of the coronal seal is as important as the permanent filling for the periapical health of the tooth concerned after endodontic treatments like root canal treatment (RCT), apexification, pulpectomy etc.⁷

A poor coronal seal will facilitate extensive coronal leakage, and studies by Tronstadet al, Heling et al and Saunder et al have confirmed that extensive coronal leakage can compromise the outcome of endodontic treatments like apexification, RCT etc.^{8–10}

There is a need to understand the effect that a hermetic coronal seal has on the outcome of endodontic treatments like Apexification as well as on the periapical health of the tooth. No such studies have been done in the past.

Hence, this in-vivo study is the first of its kind that aimed at estimating the effect of meticulous coronal seal in inducing apexification in immature permanent teeth using three different calcium hydroxide based preparations in the 8-10 years age group.

2. Materials and Methods

A total of 51 children were selected randomly for this study irrespective of their caste, creed, gender and socio-economic status from the outpatient department of a tertiary care center in Eastern India. The selection was made based on specific set of inclusion and exclusion criteria.

Children of 8 to 10 years of age, having full complement of teeth, having completed their immunization schedule and who had sustained trauma to 11 and/or 21 with Ellis and Dewey Class III traumatic injury were included. The injured teeth would be free from root fracture or dento-alveolar fracture and must not be in traumatic bite.

Children undergoing orthodontic treatment, having deleterious oral habits and/or congenital abnormalities were excluded from this study.

The entire population of children was divided into 3 groups of 17 children each. Group I received calcium hydroxide powder mixed with distilled water, Group II received calcium hydroxide paste without iodoform and Group III received calcium hydroxide paste with iodoform (Table 1). Informed consent was obtained from the parents of the children included in this study.

Access cavity preparation was done to provide straight line access to the root canal. An accurate working length was of utmost importance in our study. After arbitrary estimation of working length from pre-op radiographs, #25 Gutta-percha of the same length was inserted into the root canal, followed by another radiograph, for reconfirmation of

working length (Figure 1).



Figure 1: Showing the measurement of working length in the immature permanent upper anterior teeth. (Pre-operative)

Pulp extirpation was done using barbed broaches, copious irrigation was done with isotonic normal saline. Group I patients received calcium hydroxide by endodontic pluggers and Group II and III patients received the same by means of constant pressure through syringe. In both the cases, the calcium hydroxide was deposited 2 mm short of the radiographic apex (Figure 2).

Table 1: Showing the sample distribution in this study.

Group	Number
Cases treated with setting type of calcium hydroxide	17
Cases treated with non-setting type of calcium hydroxide without iodoform	17
Cases treated with non-setting type of calcium hydroxide with iodoform	17
Total	51

The teeth were evaluated clinically and radiographically, with observation made in the pre-operative, per-operative and post-operative stages. Follow up was done in all the groups at intervals of 24 hours, 3 months, 6 months and 9 months (Figure 3). Coronal seal was achieved with non eugenol based inter-rim restorative material (Cavit) for all the three groups.

Once apexification was complete and the same was evidenced by radiographs, obturation was performed with resin sealer and gutta-percha by lateral compaction technique, after the follow up period of 9 months. Most authors suggested that the process of apexification usually takes about 6-9 months to complete, with an average of 34.2 weeks. Hence we considered 9 month follow up in our

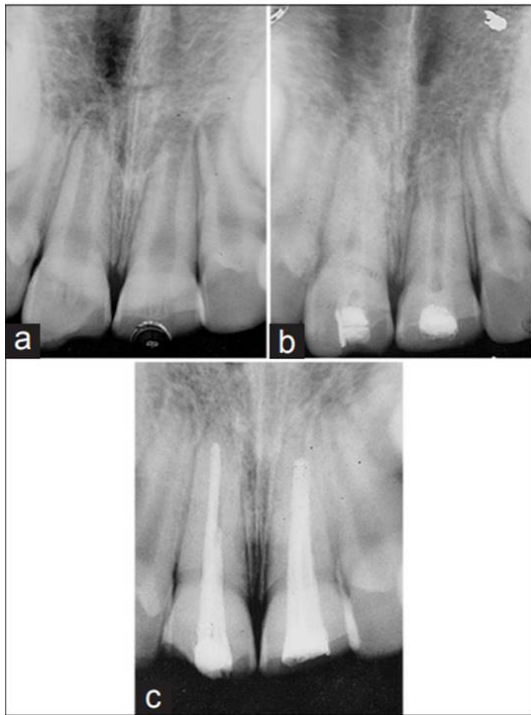


Figure 2: Showing the (a): Pre-operative, (b): Per-operative and (c): Post-operative radiographs in the Group I patients where setting type of calcium hydroxide was used.

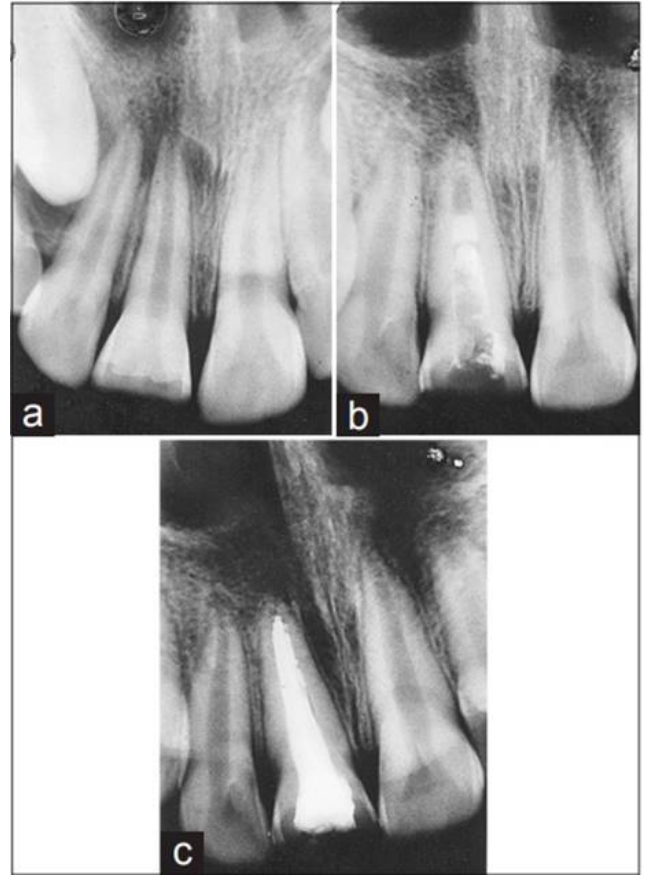


Figure 3: Showing the (a): Pre-operative, (b): Per-operative and (c): Post-operative radiographs in the Group I patients where non-setting type of calcium hydroxide was used.

study.¹¹

During each follow up, the following parameters were assessed-

1. Intactness of coronal seal throughout the treatment period and success or failure of apexification.
2. Incidence of clinical flare ups associated with the respective subgroups.

The data were statistically analyzed by Z-test and Chi-square test and distribution tables and charts were made.

3. Results

Table 2: Showing the intactness of coronal seal and the success of apexification.

Coronal Seal	Successful cases	Failure cases	Total
Intact	42 (82.4)	2 (3.9)	44 (86.3)
Lost	2 (3.9)	5 (9.8)	7 (13.7)
Total	44 (86.3)	7 (13.7)	51(100)

4. Discussions

Coronal seal is achieved by inter-appointment restorative material that is tightly placed at the tooth orifice to

Table 3: Showing the type of material used and clinical flare ups associated with them.

Type of Calcium Hydroxides	No. of cases with clinical flare ups	No. of cases without clinical flare ups	Total	Statistical evaluation
Setting type	6 (35.3)	11 (64.7)	17 (100)	Z = 1.21 (N.S.)
Non-setting without iodoform	4 (23.5)	13 (76.5)	17 (100)	Z = 2.18 (p<0.05)
Non-setting with iodoform	1 (5.9)	16 (94.1)	17 (100)	Z=3.64 (p<0.001)
Total	11	40	51	

Table 4: Showing the correlation between coronal seal and clinical flare up.

Type of Calcium Hydroxides	Loss of coronal seal with clinical flare ups	Intact coronal seal with clinical flare ups	Total
Setting type	4	2	6 (100)
Non-setting without Iodoform	2	2	4 (100)
Non-setting with Iodoform	1	0	1 (100)
Total	7	4	11 (100)

maintain an aseptic environment inside the root canal and/or before placement of permanent restoration. The importance of a hermetic coronal seal lies in its ability to prevent the microleakage of food-debris, foreign particles, saliva, bacteria etc into root canal, thereby creating a favorable environment for the intra canal medicament to work optimally and efficiently which in turn enhances the chances of root end development in apexification.

In situations where meticulous coronal seal could not be rendered by the inter-rim restorative material, consistent and extensive microleakage into the root canal took place, thereby reducing the long term prognosis of the endodontic therapy.¹²

Coronal seal with Cavit is used routinely in multiple sitting endodontic procedures like root canal therapy, pulpectomy, apexification etc. Although large variant of temporary restorative materials are available, in a low resource setting, Cavit has multiple advantages considering the ease of availability and the cost of therapy.^{13,14}

Being hydroscopic in nature, Cavit readily expands when it comes in contact with moisture, thereby, allowing better adaptation of the material against the dentinal walls.¹² This helps to create hermetic coronal seal at the tooth orifice. Cavit, also known to endure unfavorable conditions like thermocycling, is better than other temporary restorative material and still provide a good coronal seal.¹⁴

At the same time, Cavit comes in ready to use consistencies, thereby reducing the inconveniences associated with materials that require mixing.¹⁴ One drawback of Cavit is that, it being a non-eugenol based temporary restorative material it lacks the bactericidal properties of eugenol.¹⁵

Balto H et al compared the micro leakage of Cavit, IRM and Temp Bond as temporary restorative material and results showed that there was no significant difference in terms of coronal leakage between the three materials.¹⁶

This study aimed to understand the direct effect of intact coronal seal induced by Cavit with successful apexification. The criteria of success would be the completion of

apexification in the presence of intact coronal seal and delayed or incomplete apexification in the absence of intact coronal seal.

4.1. Intactness of coronal seal throughout the treatment period and success or failure of apexification

In this study, about 86.27% of the total sample population had intact coronal seal. Patients with intact coronal seal had successful apexification. Failure to induce apexification occurred in only 4.55% of the total cases with intact coronal seal. Coronal seal was lost in 13.73% of the total sample population and only 28.57% of the patients without intact coronal seal had undergone successful apexification (Figure 4).

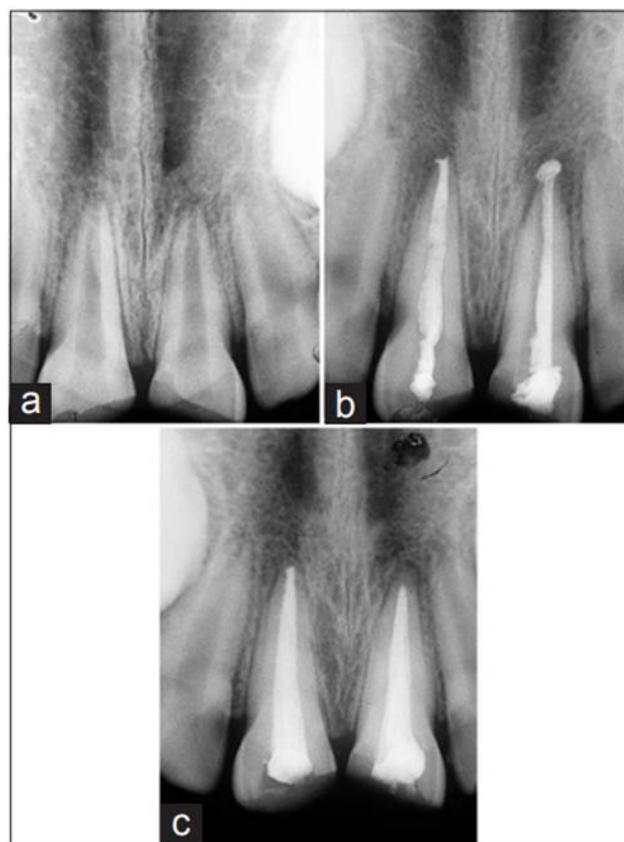


Figure 4: Showing the (a): Pre-operative, (b): Per-operative and (c): Post-operative radiographs in the Group III patients where non-setting type of calcium hydroxide with Iodoform was used.

Chi-square test was performed and it signifies that successful apexification took place in subjects with intact coronal seal. Also the intact coronal seals were significantly higher than the lost coronal seals and that successful cases were significantly higher than the failure cases.

In this extensive review of literature, almost all studies that detected coronal leakage were in-vitro studies. In our in-vivo model study, coronal seal was detected by visual

inspection and clinical evaluation only, as no standardized method was found in existing literature for detection of coronal seal intra-orally.

Torabinejad et al pointed out that, during or after treatment, root canals can be contaminated under several circumstances: -

1. If the temporary seal has broken down;
2. If the filling material and the tooth structure have fractured or been lost.^{16,17}

Thus if the coronal seal is lost, it may lead to contamination of the root canal space by microorganisms thereby leading to retardation or failure in achieving apexification. (Figure 5)

Koagelet al compared the coronal microleakage of Tempit Ultra-F, Tempit, IRM, and Cavit using the fluid transport model. Tempit Ultra-F provided better seal than IRM and Cavit, but no difference was found between Tempit Ultra-F and Tempit and between Tempit, Cavit, and IRM.¹⁸

Lim KC compared the micro leakage of glass ionomer cement (KetacFil) with re-inforced zinc oxide eugenol cement, (Kalzinol). There was no significant difference in the micro leakage observed in Ketac-Fil restorations and Kalzinol at the end of 30 days.¹⁹

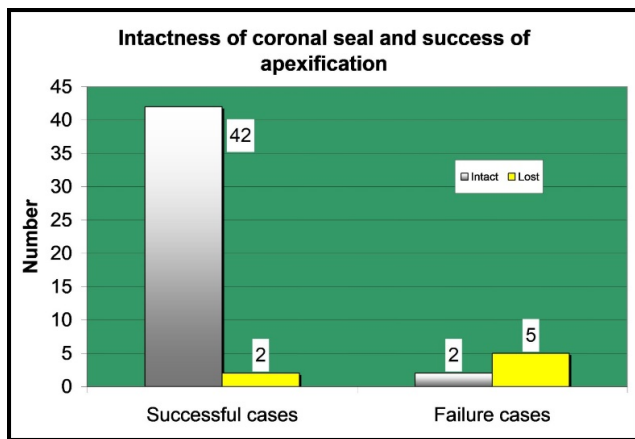


Figure 5: Showing the graphical representation of the intactness of coronal seal and success of apexification.

Though glass ionomer cement is used as permanent restorative material after endodontic treatments, studies by Adouet al reported that when glass ionomer cement was used as temporary restorative material, the coronal microleakage can be reduced to almost negligible values.²⁰ Thus the overall prognosis of the endodontic treatment goes up by many folds.

The biochemical adhesion of the cement with the dentinal walls and the impermeability of the cement due to the glass reinforced structure ensure negligible coronal leakage.

On the other hand, there is no rationale for using glass ionomer cement as an inter-rim restorative material considering the fact that it will be removed in subsequent visits and the increasing cost of therapy.

Thus in the present study Cavit was used as intermediate restorative material and was intact in most of the cases during the treatment period.

4.2. Incidence of clinical flare ups associated with the respective subgroups

In this study, the total number of cases with clinical flare-ups is eleven, which comprises about 21.57% of the total sample. The maximum numbers of cases with clinical flare ups were associated with the use of setting type of calcium hydroxide which is about 11.76% of the total cases. There was minimum clinical flare up with the use of non-setting type of calcium hydroxide with iodoform (Figure 6).

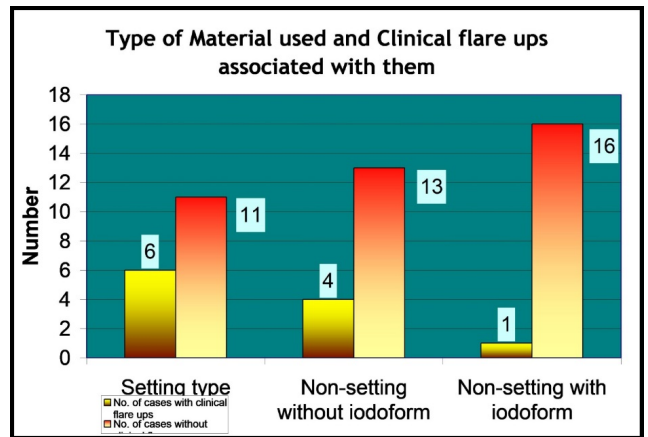


Figure 6: Showing the type of material used and the incidence of clinical flare ups associated with them.

It is apparent that the sample subpopulation receiving non-setting type of calcium hydroxide with iodoform, the incidence of clinical flare-ups was very less. The cases without clinical flare was 94% and highly significant ($Z = 3.64$; $p < 0.001$). In the sample subpopulation in whom non-setting type of calcium hydroxide without iodoform was used the cases without clinical flare ups was 76.5 which is significant at 5% level ($Z = 2.18$; $p < 0.05$).

Koagel et al in their study had concluded that most common cause of clinical flare ups during apexification or failure in endodontic treatment with intact coronal seal is micro-leakage at the tooth material junction or through the material itself.¹⁸

Molander et al suggested that calcium hydroxide often used as a routine inter-appointment dressing fails to consistently produce sterile root canals, even with an intact coronal seal. Enterococcus faecalis persisted even after calcium hydroxide dressing for two months. Synergistic effect was observed between iodine and calcium hydroxide,

when used together in reducing the persistent strains of enterococcus faecalis.²¹

Estrela et al evaluated the antimicrobial activity of calcium hydroxide in infected dentinal tubules with loss of coronal seal. Calcium hydroxide in infected dentinal tubules showed no antimicrobial effect on *S. faecalis*, *S. aureus*, *B. subtilis* or *P. aeruginosa*. Herein lies the relevance of an intact coronal seal, which not only shields off the oral micro-flora and opportunistic pathogens from entering the root canal, but at the same time, it also ensures sterile environment inside the same for the optimum efficacy of calcium hydroxide.²²

In this study, most of the inter-appointment clinical flare ups were due to the presence of residual microorganisms. Seven patients were associated with the loss of coronal seal that made the penetration of microorganisms inside the root canal relatively easier. The relative ineffectiveness of calcium hydroxide to provide antibacterial activity augmented the enhanced clinical and tissue response. Thus, we could establish a direct relationship between the loss of coronal seal and the incidence of clinical flare up.

Among the seven patients who had episodes of clinical flare ups along with loss of coronal seal, four belonged to Group I, two belonged to Group II and one belonged to Group III.

The remaining four patients associated with clinical flare up were associated with an intact coronal seal. One major drawback in this study was that the volume of the temporary restorative material was not standardized, which could have resulted in decreased thickness of the restorative material, allowing penetration of the oral microorganisms and other opportunistic pathogens into the root canal.

The four patients who had clinical flare ups despite having an intact coronal seal, had two patients each from Group I and Group II respectively.

Most clinicians agree that residual microorganisms left in the root canal account for the inter-appointment clinical flare ups and that healing is more likely in the absence of bacteria.²³ In our study, the children who had clinical flare up, had loss of coronal seal, resulting in elevated bacterial population inside the root canals, which eventually leads to increased chances of clinical flare up and also delayed or failure in apexification.

From the statistical analysis it is also evident that the cases with clinical flare ups (64.7%) did not reach the significant level with the use of calcium hydroxide powder mixed with distilled water.

Group I patients received setting form of calcium hydroxide mixed with distilled water. This particular preparation of calcium hydroxide acts by vapor release instead of contact, unlike the other preparations.²⁴ Studies by Omran et al confirmed that with this preparation, there also was severe reduction in the micro-hardness of dentin.²⁵ The vapor release would have created undue

internal pressure forcing the temporary restoration to get dislodged, and the reduced micro-hardness would have made the retention and maintenance of the coronal seal difficult, contributing to more episodes of coronal seal break and clinical flare up in Group I patients.

Siqueira JF suggested that the primary function of calcium hydroxide as a routine intra-canal medicament is its antimicrobial activity. Association with other medicaments like iodine may enhance its efficacy in eliminating residual bacteria in the root canal system.²⁶

In this study, clinical flare ups with loss of coronal seal was observed in 12% children receiving calcium hydroxide paste (Group II) and 5.9% children, receiving calcium hydroxide with iodoform (Group III). It can be inferred that loss of coronal seal may lead to clinical flare ups and delayed apexification even if we augment the antimicrobial activity of calcium hydroxide with iodoform.

However, recent studies fail to standardize the role of an intact coronal seal in the optimum functioning of an intra-canal medicament. This is what actually affects the long term outcome of endodontic treatment including apexification.

This is the first study that tries to establish direct effect that a tight coronal seal might have on the successful outcome of an endodontic treatment. There are many prior studies that compare the coronal leakage between different restorative materials, but none on the eventual treatment outcome. In this study, we considered apexification with calcium hydroxide as that is routinely used and easily available in a low resource setting. However, the present study being a pilot one, apexification with bioceramics and/or advanced regenerative endodontics maybe a significant future direction, on larger sample sizes.

5. Conclusion

Endodontic treatment is a technique sensitive process and good coronal seal rendered by a temporary restoration is an almost indispensable step of regenerative endodontics. The direct correlation between good coronal seal and effective treatment outcome has not been studied previously in real time case scenarios. This study shows that loss of coronal seal was directly related to apexification failure in young immature permanent tooth. This concept can be further extended to more sensitive procedures like root canal therapy, pulpectomy etc.

In this pilot study, we found that the success of apexification in young, immature, permanent incisors was directly related to a good coronal seal, while those associated with loss of coronal seal had incidences of clinical flare ups in between appointments and higher chances of failure of apexification secondary to contamination of the root canal by pathogens.

Another relevant outcome of this study was that when augmented with iodoform, calcium hydroxide showed

increased efficacy in apexification and if supported adequately by good coronal seal, then there were practically no incidence of clinical flare up.

6. Source of Funding

None.

7. Conflict of Interest

None.

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Cite this article: Ghosh S, Sil S, Saha N. Role of hermetic coronal seal on the long term success of apexification in immature permanent teeth induced by calcium hydroxide based regenerative materials- A pilot study. *IP Ann Prosthodont Restor Dent* 2024;10(1):31-37.