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HYPERSENSITIVITY AFTER DIRECT COMPOSITE RESTORATIONS VERSUS PREFORMED METAL CROWNS WITH MOLARS AFFECTED WITH MOLAR-INCISOR HYPOMINERALIZATION AMONG A GROUP OF EGYPTIAN CHILDREN (A RANDOMIZED CONTROLLED TRIAL (PART I))

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ABSTRACT

Aim: This study aimed to assess hypersensitivity in molars affected with molar incisor hypomineralization (MIH) after treatment with direct composite restorations versus preformed metal crowns among a group of Egyptian children.

Methodology: The study was conducted on 60 affected permanent molars of Egyptian children selected from Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Cairo University suffering from molar incisor hypomineralization (MIH). The treatment of choice for those cases was either, direct esthetic restorative materials (composite restorations) or preformed metal crowns. Participants were allocated into two groups, group (I) treated by using preformed metal crowns and, group (II) treated by using direct composite resin restorations. Hypersensitivity of the treated molars was measured as a primary outcome. In addition; restoration quality, acceptability of the treatment, health-related quality of life changes by the therapies, parental satisfaction and treatment cost effectiveness were also measured as a secondary outcome. Clinical follow up of the patients was performed for 12 months. The collected data were statistically analyzed .

Results: For hypersensitivity, from baseline to 6 months all cases in both groups were free from hypersensitivity, starting from 9 months the presence of hypersensitivity was recorded in 23.3% of group (II) and 6.7% of group (I), at 12 months follow up, 30.0% of group (II) and 13.3% of group (I) recorded presence of hypersensitivity. Regarding the restoration quality, at baseline and after 1 month all cases in both groups had a (1) score for marginal adaptation (i.e.high quality

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restoration). After 3 months until 12 months, group II had significantly higher scores for marginal adaptation (i.e.less quality restoration). At 12 months, 30% of group (II) recorded unacceptable marginal adaptation in comparison of 13.33% of group (I). For treatment acceptability, 13.3% of group (I) didn't accept the treatment while in group (II) all the cases accepted the treatment. For health related quality of life, at baseline and after 6 months follow up, there was no significant difference between both groups, while within both groups, there was a significant reduction of measured score after 6 months (i.e. improved quality of life). For parental satisfaction, all parents in both groups were satisfied with the treatment. For cost effectiveness, Group (I) had a lower (ACER) (153.00) than group (II) (162.86) (i.e., better effect in comparison to cost).

Conclusion: In molars affected with MIH, direct composite restorations and preformed metal crowns prevented hypersensitivity with no significant difference between the two treatment options. Regarding the restoration quality, after 12 months follow up, preformed metal crowns were significantly higher than DCR. The treatment acceptability was significantly high for the DCR in comparison to PMC. For health related quality of life, both treatment affected positively in patients' health related quality of life after 6 months of treatment, with no significant difference between both groups. All parents in both groups were satisfied with the treatment. For the cost effectiveness after 12 months, PMC had better effect in comparison to cost.

KEYWORDS: Molar incisor hypomineralization; preformed metal crowns; hypersensitivity; direct composite resin; children; Egypt

INTRODUCTION

Molar Incisor Hypomineralization (MIH) has become an area of interest to the pediatric dentists worldwide owing to its negative effect on children's oral self-perceptions and family perceptions of their children's oral health (Sakly et al., 2020).

The main characteristic MIH affected teeth is the presence of porous enamel that can be damaged easily under normal masticatory forces, leading to atypical cavities with rough irregular margins that facilitate the development of caries through the exposed dentinal tissues. Therefore, MIH poses a significant problem for both the patient and the clinicians owing to the presence of hypersensitive teeth that affect the patients' quality of life and represent challenges in restorations (Shaik and Reddy, 2017).

The prevalence of MIH worldwide varies greatly ranging from 2.8 to 40.2%. Regarding the Egyptian population, the prevalence of MIH in a group of Egyptian children aged from 8 to 12 years was (2.3%) with a more female predilection (Saber et al., 2018 and Elzein et al., 2021).

MIH-affected molars show a wide range of clinical presentations and severity grades, depending, for example, on the presence of post-eruptive enamel breakdown and hypersensitivity. The MIH-Treatment Need Index (MIH-TNI) takes both aspects; substance breakdown and hypersensitivity, into consideration and can be linked to therapeutic considerations (Bekes and Steffen 2016; Steffen et al. 2017). The most severe grade, 4c, comes with hypersensitivity and substantial breakdown.

For most severely affected MIH molars direct restorative composite (DRC) or preformed metal crowns (PMC) were the treatments to choose between. A number of aspects could support decision-making, however, are unknown. First, it is not clear if both treatments were similarly acceptable for patients and providers. Second, the effectiveness, restoration quality and treatment costs should be taken in consideration (de Farias et al., 2022)

Given the discussed possible conflict between aesthetics/applicability and clinical performance DRCs possibly being more aesthetic and less invasive, and also being seen as a routine for most

dentists; PMCs possibly being more successful to restore the lesion and to reduce pain/hypersensitivity), acceptability is likely to differ between both treatments (Wuollet et al., 2020)

Therefore, the present study aimed to assess the clinical Management of severe molar-incisor-hypomineralization using DCR or PMC by assessing hypersensitivity, restoration quality, acceptability of the treatment, health related quality of life changes, parental satisfaction and cost effectiveness for both treatment options.

MATERIALS AND METHODOLOGY

The study was conducted on a dental unit in postgraduate clinic of Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Cairo University, Egypt. The participants were selected according to the eligibility criteria of the study.mThe child's guardians were informed about the purpose of the study and asked to sign an informed consent for participation in the study.

Allocation was revealed once the child seated. Then it was recorded if patient and provider accepted this random allocation, or deviated from it (acceptability). Patient diagnostic chart was filled by the operator followed by MIH diagnostic sheet. Child perception questionnaire was taken by the operator (CPQ) before treatment. Participants in group (I) received PMC while participants in group (II) received DCR.

Cases in group (I)

PMCs was placed after infiltration or block anesthesia for a maxillary or mandibular affected molar, respectively, followed by removal of carious dentin and enamel until sound enamel and firm dentin was reached. Tooth preparation for fitting the crown involved minimal reduction of occlusal and proximal surfaces if necessary. Cotton wool rolls and rubber dam isolation was used as required. The correct size of crown was chosen, and then cemented with glass ionomer luting cement.

Cases in group (II):

Anesthesia was similarly provided if needed, also followed by carious tissue removal. Marginal beveling of enamel was performed .A universal adhesive (3M Scotchbond Universal adhesive) was placed after selective enamel etching for 30 s, followed by light-curing for 40's with minimum 1200 mw/s.A bulk-fill composite was used, moisture control was ensured appropriately.

The treatment was expected to take 20-40 minutes and was performed in one appointment. Follow-up the patients for 12 months was sufficient to yield preliminary effectiveness estimates. Secondary outcomes were assessed and measured.

RESULTS:

Demographic data:

The study was conducted on 60 cases that were randomly and equally allocated to each of the studied groups (i.e., 30 cases each). There 12 males and 18 females in group (I) and 11 males and 19 females in group (II). The mean age of the cases in group (I) was (9.17±1.53) years and in group (II) it was (9.33±1.71) years. There was no significant difference between both groups regarding gender (p=0.791) and age (p=0.692) as shown in Table (1), Figure (1):Stacked bar chart showing gender distribution in different groups.

TABLE (1) Intergroup comparisons and summary statistics for demographic data.

Parameter		Group (I)	Group (II)	p-value
Gender [n (%)]	Male	12 (40.0%)	11 (36.7%)	0.791ns
	Female	18 (60.0%)	19 (63.3%)	
Age (Mean±SD) (years)		9.17±1.53	9.33±1.71	0.692ns

P: probability level which is significant at P ≤ 0.05

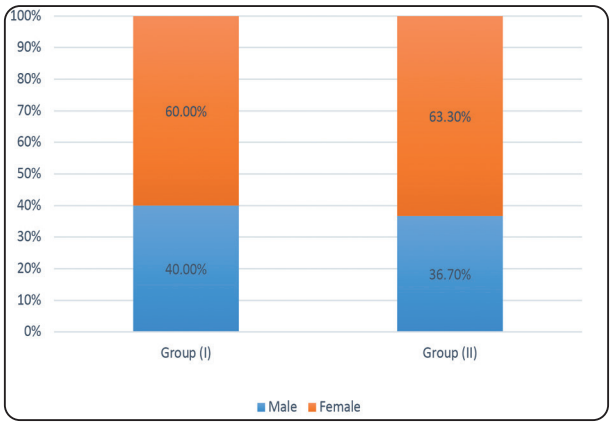

Fig. (1) Stacked bar chart showing gender distribution in different groups

Hypersensitivity

From baseline to 6 months all cases in both groups were free from hypersensitivity. Starting from 9 months majority of cases were free and the difference between both groups was not statistically significant ($p>0.05$). Regarding intragroup comparison, for both groups there was a significant difference between values measured at different intervals ($p<0.05$). For group (I), post hoc pairwise comparisons showed values measured at baseline, 1, 3 and 6 months to be significantly different from 12 months value ($p<0.001$). While for group (II), they showed values measured at baseline, 1, 3 and 6 months to be significantly different from 9- and 12-months values ($p<0.001$)

Restoration quality

At baseline and after 1 month all cases in both groups had a (1) score. After 3 months, there was no significant difference between both groups ($p=0.334$). Starting from 6 months until 12 months, group (II) had significantly higher scores than group (I) ($p<0.05$) which means decrease in marginal adaptation.

TABLE (2) Inter, intragroup comparisons, frequencies, and percentages for hypersensitivity incidence.

Time	Hypersensitivity	n (%)		p-value
		Group (I)	Group (II)	
Baseline	**No**	30 (100.0%)^{A}	30 (100.0%)^{A}	**NA**
	Yes	0 (0.0%)	0 (0.0%)	
1 month	**No**	30 (100.0%)^{A}	30 (100.0%)^{A}	**NA**
	Yes	0 (0.0%)	0 (0.0%)	
3 months	**No**	30 (100.0%)^{A}	30 (100.0%)^{A}	**NA**
	Yes	0 (0.0%)	0 (0.0%)	
6 months	**No**	30 (100.0%)^{A}	30 (100.0%)^{A}	**NA**
	Yes	0 (0.0%)	0 (0.0%)	
9 months	**No**	28 (93.3%)^{AB}	23 (76.7%)^{B}	**0.071ns**
	Yes	2 (6.7%)	7 (23.3%)	
12 months	**No**	26 (86.7%)^{B}	21 (70.0%)^{B}	**0.117ns**
	Yes	4 (13.3%)	9 (30.0%)	
p-value		**0.016***	**<0.001***	

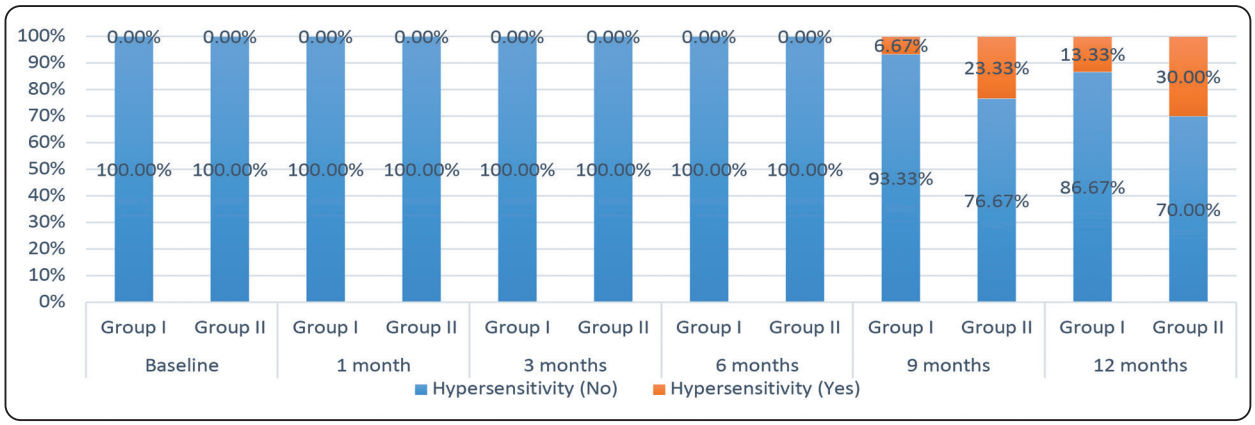

Fig. (2) Stacked bar chart showing hypersensitivity status.

TABLE (4) Inter, intragroup comparisons, frequencies, and percentages for restoration quality score.

Time	Restoration quality score	n (%)		p-value
		Group (I)	Group (II)	
Baseline	**(1)**	30 (100.00%)^{B}	30 (100.00%)^{D}	**NA**
	(2)	0 (0.00%)	0 (0.00%)	
	(3)	0 (0.00%)	0 (0.00%)	
	(4)	0 (0.00%)	0 (0.00%)	
	(5)	0 (0.00%)	0 (0.00%)	
1 month	**(1)**	30 (100.00%)^{B}	30 (100.00%)^{D}	**NA**
	(2)	0 (0.00%)	0 (0.00%)	
	(3)	0 (0.00%)	0 (0.00%)	
	(4)	0 (0.00%)	0 (0.00%)	
	(5)	0 (0.00%)	0 (0.00%)	
3 months	**(1)**	30 (100.00%)^{B}	29 (96.67%)^{CD}	**0.334ns**
	(2)	0 (0.00%)	1 (3.33%)	
	(3)	0 (0.00%)	0 (0.00%)	
	(4)	0 (0.00%)	0 (0.00%)	
	(5)	0 (0.00%)	0 (0.00%)	
6 months	**(1)**	30 (100.00%)^{B}	21 (70.00%)^{C}	**0.001***
	(2)	0 (0.00%)	8 (26.67%)	
	(3)	0 (0.00%)	1 (3.33%)	
	(4)	0 (0.00%)	0 (0.00%)	
	(5)	0 (0.00%)	0 (0.00%)	
9 months	**(1)**	28 (93.33%)^{AB}	7 (23.33%)^{B}	**<0.001***
	(2)	0 (0.00%)	14 (46.67%)	
	(3)	0 (0.00%)	8 (26.67%)	
	(4)	0 (0.00%)	1 (3.33%)	
	(5)	2 (6.67%)	0 (0.00%)	
12 months	**(1)**	26 (86.67%)^{A}	0 (0.00%)^{A}	**<0.001***
	(2)	0 (0.00%)	7 (23.33%)	
	(3)	0 (0.00%)	14 (46.67%)	
	(4)	0 (0.00%)	7 (23.33%)	
	(5)	4 (13.33%)	2 (6.67%)	
p-value		**0.012***	**<0.001***	

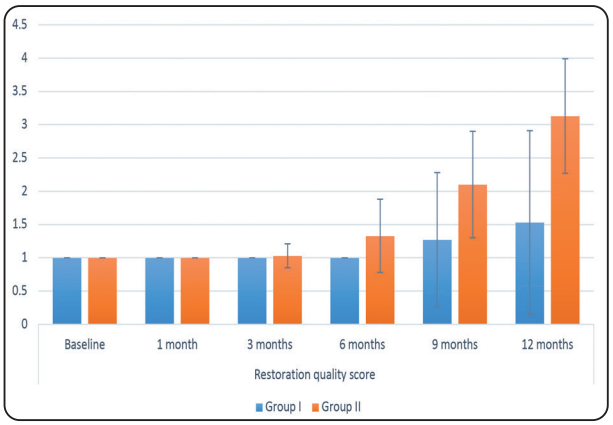

Fig. (3) Bar chart showing mean and standard deviation values of restoration quality score.

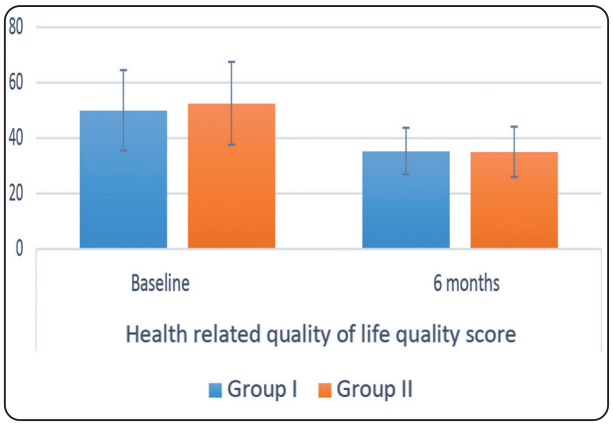

Fig. (4) Bar chart showing mean and standard deviation values of health-related quality of life quality score

Treatment acceptability

Comparisons between groups regarding frequencies, and percentages for treatment acceptability were performed, where only 4 cases didn't accept the treatment in group (I) while to all the cases in group (II) the treatment was acceptable and the difference between both groups was statistically significant (p=0.038).

Health related quality of life quality:

Within both groups, there was a significant reduction of measured score after 6 months (p<0.001).

TABLE (5) Inter, intragroup comparisons, mean and standard deviation (SD) for health-related quality of life quality score.

Time	Health related quality of life quality score (Mean±SD)		p-value
	Group (I)	Group (II)	
Baseline	50.03±14.53	52.57±14.95	**0.389ns**
6 months	35.37±8.37	35.03±9.07	**0.789ns**
p-value	**<0.001***	**<0.001***	

Parental satisfaction

Intergroup comparisons, frequencies, and percentages for parental satisfaction where all parents in both groups were satisfied with the treatment.

Cost effectiveness:

Analysis of cost effectiveness among both groups was performed as presented in **Table (6).**

Group (I) had a lower (ACER) (153.00) than group (II) (162.86) (i.e., better effect in comparison to cost). The incremental cost effectiveness ratio (ICER) (i.e., the average price needed to prevent hypersensitivity in a single case) was (239.52) (EGP).

TABLE (6) Cost effectiveness analysis

Parameter	Group (I)	Group (II)	Incremental cost effectiveness ratio (ICER)
Average total cost	133.00	93.00	
Effect (percentage of cases free from hypersensitivity) after 12 months	86.7%	70.0%	**239.52**
Average cost effectiveness ratio (ACER)	153.40	162.86	

DISCUSSION

The present study was a randomized controlled trial (RCT) conducted to assess the hypersensitivity after treatment with DCR versus PMC with molars affected with MIH among a group of Egyptian children. The study was conducted on a dental unit in postgraduate clinic of Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Cairo University, Egypt. Patients were randomly allocated in two groups (group I and group II). For group I, PMC was placed while for group II, DCR was used to restore the affected molar.

In both groups, assessment of hypersensitivity was performed at baseline using Schiff's Cold Air Sensitivity test based on the supervisor clinical experience, in order to record binary results of presence or absence of hypersensitivity by questioning the child (yes / no) (Clemenus et al., 2017, Gernhardet, 2013). The Secondary outcomes were assessed including: restoration quality (marginal adaptation), acceptability of the treatment, patient health related quality of life, parental satisfaction and cost effectiveness of each treatment. Follow-up the patients for 12 months was sufficient to yield preliminary effectiveness estimates, as risk of failure is generally relatively high in MIH molars (Cuzick, 2023).

In the present study, from baseline to 6 months all cases in both groups were free from hypersensitivity. Starting from 9 months majority of cases were free and the difference between both groups was not statistically significant ($p>0.05$). this was in accordance with the previous studies of Lygidakis et al., 2022 who stated that composite resin restorations had high success rates in restoring MIH affected molars, if placed under rubber dam isolation to ensure good moisture control (Lygidakis et al. 2003; Kotsanos et al. 2005; Mejare et al. 2005; Rolim et al. 2021).

For both groups there was a significant difference between hypersensitivity values measured at different intervals ($p<0.05$). For group (I), post hoc pairwise comparisons showed values measured at baseline, 1, 3 and 6 months to be significantly different from 12 months value ($p<0.001$). While for group (II), they showed values measured at baseline, 1, 3 and 6 months to be significantly different from 9- and 12-months values ($p<0.001$). This is consistent with Singh et al., 2022 who had a 24 month randomized clinical trial to compare results of restorations of MIH affected molars, showed significant difference over the long follow up period at different intervals.

For the restoration quality, in term of marginal adaptation, at baseline and after 1 month all cases in both groups had a (1) score. After 3 months, there was no significant difference between both groups ($p=0.334$). Starting from 6 months until 12 months, group (II) had significantly higher scores than group (I) ($p<0.05$), which interpreted lower restoration quality with less marginal adaptation in DRC comparing to PMC starting from 6 months follow up, this was in line with De Farias et al., 2022 found that in molars with MIH, PMC had a significantly higher survival rate than DCR over 24 months regarding the restoration quality, the survival of SSC and CR restorations after 24 months was 94.4% and 49.2%, respectively. In comparison to the present study, after 12 months follow up, 13.33% of PMC had to be repaired or replaced versus 30 % of DCR

The study results of Hakmi & Dashash, 2023 regarding DCR and ICR to restore MIH stated that both DCR and ICR can be considered effective restorations with acceptable clinical performance in the restoration of hypomineralised first permanent molars with a clinical success rate 90% in the ICR group versus 85% in the DCR group after 12 months of follow-up. The difference in success of DCR which was higher than the present study may be attributed to the different technique in DCR application as, in Hakmi & Dashash, 2023, all prepared walls were wiped with cotton moistened

in sodium hypochlorite 5.25% before applying the acid etch and bond. Sodium hypochlorite enabled the removal of proteins from the infected MIH molars, which in turn can promote the inclusion of resin tags, which enhance the micro-mechanical bonding resulting in better marginal adaptation and restoration quality along the follow up period.

Regarding the treatment acceptability and the patient satisfaction, 4 cases didn't accept the treatment after application in group (I) while to all the cases in group (II) the treatment was acceptable and the difference between both groups was statistically significant (p=0.038). This contributes to the superiority of DRC in esthetic than PMC. However by measuring the patient/parental satisfaction, all parents in both groups were satisfied with the treatment.

However, De farias et al., 2022, measured patient satisfaction between patients who received PMC and DCR to restore MIH affected molars, it appears that this difference is more functional than aesthetic, , since they are posterior teeth, the aesthetic commitment is not so high; that is, possibly, for the patients, the benefit surpassed the aesthetic losses. This hypothesis can be reinforced due to the fact that, for those guardians, there were no differences in satisfaction between the two treatments. These findings were in accordance with the present study as the target population were seeking treatment of the condition showing less interest to esthetic.

For health related quality of life changes, it was measured as difference in Child Perception Questionnaire (CPQ) at baseline and after 6 months after treatment. At both intervals, there was no significant difference between both groups (p>0.05). While, within both groups, there was a significant reduction of measured score after 6 months (p<0.001). This was in accordance with Bekes et al., study that aimed to investigate the changes in oral health-related quality of life (OHRQoL) before and after treatment of hypersensitive molars affected by molar incisor hypomineralization (MIH).

Regarding the cost effectiveness, PMC had a lower (ACER) (153.00) than DCR (162.86) (i.e., better effect in comparison to cost). Thus, PMC is more cost effective than DCR because it offered better effectiveness after 12 months however its cost was higher than DRC. This was in agreement with Elamin et al., 2019 concluded that PMC placed using the Hall or conventional techniques had excellent survival and high cost-effectiveness. On the other hand, Bader, 2004 results stated that the direct placement restorations were more cost-effective than the indirect restorations at all-time intervals over the 15-year study period, this difference can be due to the effectiveness to be considered in the study, as in the present study it was the percentage of cases free from hypersensitivity, while in Bader, 2004 it was cases with less discomfort and less removal of sound tooth substance with long-term survival.

LIMITATIONS

The diagnosis of MIH is challenging, especially in the target population because the permanent first molars were much affected with unusual occlusal topography. This could be altered with other developmental enamel defects having similar clinical appearance.

Unlike PMC, DCR is highly affected by the oral hygiene. This could affect the results when comparing both treatment.

The follow up period in the present study was 12 months, a longer follow up would be better to assess both treatment longevity.

Parent/patient bias may be present due to the use of PMC which is considered unaesthetic restoration.

Recommendations:

Based on the results of the present study, the following can be recommended:

1. Further randomized clinical trials comparing PMC and DRC in MIH severely affected molars

among Egyptian children are still required to confirm our findings with a larger sample size and longer follow-up.

2. Further studies should be performed in different areas and governorates of Egypt to generalize the study findings, especially regarding patient acceptance and satisfaction.
3. The early diagnosis of MIH affected molars is recommended for the proper management of the affected molars to control hypersensitivity and PEB.
4. Oral examination and awareness of keeping oral hygiene measures should be included in the routine pediatric examination, this will assist in early diagnosis of MIH and lead to higher restorations success.
5. Further studies for DCR in restoring MIH affected molars should be conducted with the use of sodium hypochlorite prior to etching that may enhance the micro-mechanical bonding resulting in better marginal adaptation and restoration quality with long follow up period.
6. Further studies regarding restoration of anterior teeth affected with MIH are needed.

Conflict of interest

The authors have no conflict of interest to declare.

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