

A comparison of two different management techniques for Extensive molar defects in patients suffering from Molar Incisor Hypomineralization (MIH) (Randomized Clinical Trial)

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Background: The molar incisor hypomineralization (MIH) is a developmental enamel defect which affects the first permanent molar and commonly the permanent incisors, the defect can make the patient face a lot of difficulties like sensitivity, rapid caries progression and poor esthetics.

Aim: To Compare two different techniques of management of first permanent molar defects in MIH patients regarding the longevity of the crowns, gingival health, marginal integrity and recurrent caries for nine months. The two techniques are two types of crowns (CAD-CAM milled PMMA versus Cast adhesive Metal Coping (CAC)).

Materials and Methods: 60 molars were selected and randomly allocated into two groups. one received CAD-CAM milled PMMA crown and the second received CAC. The crowns were evaluated for longevity, marginal integrity, recurrent caries and gingival health at 1, 3, 6 and 9 months.

Results: The study showed a highly significant difference between the two groups regarding the longevity in both 1st and 6th months follow ups and no significant differences between the two groups regarding marginal integrity, recurrent caries and gingival health on all follow up visits.

Conclusion: Cast adhesive metal coping can be used as a restoration for first permanent molars affected by MIH and despite the esthetic advantage of the PMMA CAD-CAM milled crown and its excellent marginal fit, it needs more research to increase the retention.

Keywords: Hypomineralized molar, MIH, Molar defects, Molar Incisor Hypominerlization , PMMA

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Introduction

Molar incisor hypomineralization (MIH) is a type of developmental defects of enamel which affects from one to four of the first permanent molars and is commonly associated with the permanent incisors. The affected teeth are characterized by normal enamel thickness. Clinical presentation may be in the form of demarcated and discolored opacities in enamel, post eruptive enamel breakdown (PEB), atypical restorations of the affected molars and incisors, extracted molars due to MIH and failure of eruption of the affected teeth (1). The defect is mostly asymmetrical and the teeth are not equally affected in the same patient (2). The affected enamel is soft, porous and its color range from yellow to brown and has high caries susceptibility (3). The defect severity can be classified according to the European Academy of Pediatric Dentistry (EAPD) as mild which is described as (Demarcated opacities without enamel breakdown, Occasional Sensitivity to external stimulus not teeth brushing, Mild concern about esthetics), or severe which is described as (Opacities with enamel breakdown, Persistent hypersensitivity which interferes with function, Great concern about esthetics) (4).

The etiology is still unknown but likely multiple factors work together to increase risk of MIH (4). The risk factors are divided to prenatal, perinatal and post-natal during the first four years of life (5).

The defect is caused by a disturbance during the transitional or maturation stage of amelogenesis as the ameloblasts are sensitive in those stages to any environmental disturbance (6).

Children with MIH have soft porous enamel and highly sensitive teeth which make maintenance of oral hygiene difficult. Those factors increase plaque formation and caries risk of the patient (7). The MIH patients seek dental treatment for multiple

reasons and they are usually complaining of dental caries, discoloration, sensitivity, malocclusion, periodontal problems and esthetics (8). Because of all the symptoms and complications of MIH the child function, self-image, occlusion, emotional, social life and oral health related quality of life are negatively affected (9,10). The permanent incisors defects are usually less severe and less liable to PEB but the aesthetics is their main problem. On the other hand the first permanent molars are severely affected and commonly have PEB and require multidisciplinary approach in treatment either by restoration or extraction (11).

Possible management options of PEB of first permanent molars can be divided into immediate, short term and long term. The immediate options include controlling tooth sensitivity so the patient can withstand further treatment and maintain good oral hygiene, preventing dental caries as it progresses faster in the hypomineralized teeth, improving enamel quality to decrease the possibility of PEB and improving the bond strength to adhesive restorations, and finally improving the aesthetics as it is very important for child psychological well-being and self-esteem. The short-term options include providing temporary restorations until early adulthood to protect the tooth, maintain good occlusion, maintain good esthetics or extraction of the teeth in some cases based on orthodontic evaluation. Long term options include durable permanent restorations such as partial or full coverage restorations (12).

Multiple types of full coverage restorations were used to restore badly affected molars with MIH and those crowns were compared with each other and with other types of restorations (13). Multiple studies compared the stainless steel crowns (SSC) with cast restorations of different alloys and those studies showed no

significance difference in both durability and function of both types of crowns (14,15). Cast adhesive coping (CAC) was used in multiple studies using different alloys and it showed a good clinical performance and was considered a useful treatment option for first permanent molars with post eruptive breakdown (15,16). CAC has multiple advantages over SSC that includes less tooth preparation which leads to less chance for pulpal trauma, protection of tooth structure and maintenance of good periodontal health as the margins are supra gingival. It also has high strength and it controls sensitivity. All these factors make it a suitable and durable treatment option for management of PEB of first permanent molars with MIH (15).

In 2003 a study was done by Zagdwon et al. (15) comparing SSC and CAC in defective first permanent molars for 24 months. The study showed no significant difference between the two crowns regarding the longevity of restoration with CAC being more conservative for the remaining tooth structure.

In 2013 Gaardmand et al. (16) have conducted a study evaluating Cast adhesive gold copings that were followed up for a mean time of 38.5 months. Authors stated that the longevity of the crown was excellent and that it can be used as a treatment option for molars affected by MIH.

The CAD-CAM milled Poly Methyl Methacrylate (PMMA) crowns are considered a strong interim and temporary restoration. It can be used for full coverage of hypomineralized molars during adolescence (12). The CAD-CAM milled (PMMA) uses prefabricated polymer material which is fabricated in industrial special conditions that gives the material better mechanical and physical properties (17). These crowns were used also in cases with tooth wear and decreased occluso-vertical dimension and showed no micro leakage, discoloration, plaque accumulation or recurrent caries after 6 months (18).

Therefore, the aim of the current study was to assess and compare CAD-CAM milled PMMA versus Cast adhesive metal coping in the management of first permanent molars with severe molar incisor hypomineralization regarding the longevity of the crowns, gingival health, marginal integrity and recurrent caries for 9 months.

Materials and Methods

Type of the study

The study was designed as a randomized clinical trial with equal allocation ratio between study arms. The study followed CONSORT guidelines and was in line with the principles of the Declaration of Helsinki.

Sample size estimation

A power analysis was designed to have adequate power to apply a statistical test of the null hypothesis that there is no difference would be found between tested groups. By adopting an alpha level of (0.05) a beta of (0.2) i.e. power=80% and an effect size (W) of (0.449) calculated based on the results of a previous study (15); the predicted sample size (n) was found to be a total of (48) cases (i.e. 24 cases per group). Sample size was increased by (20%) to compensate for possible dropouts during follow-up intervals to be (60) cases (i.e. 30 cases per group). Sample size calculation was performed using PASS software.

Ethical approval

The study received an institutional ethical approval from the Research Ethics Committee of Faculty of Dentistry of Ain Shams University (No. IM021818). The Study was also registered on www.clinicaltrials.gov with ID: NCT04209920. All parents or legal guardians provided a signed informed consent before the study.

Study setting and duration

The study was performed in the out-patient clinic of the department of Pediatric

Dentistry, Faculty of Dentistry, Ain Shams University from March 2019 till June 2020.

Study groups

Sixty maxillary and mandibular first permanent molars with MIH in 20 patients were randomly allocated into 2 groups:

Group I (n=30): First permanent molars received CAD-CAM milled PMMA crown (Fig. 1).

Group II (n=30): First Permanent molars received cast adhesive metal coping (CAC) using nickel chromium alloy (Fig. 2).



Fig.1 (a) showing a preoperative photo of the hypomineralized lower first permanent molars (b) showing the molars after treatment and receiving CAD-CAM milled PMMA crown on 9 months follow up

The inclusion and exclusion criteria were as follow:

Inclusion criteria

- 1- Patients with molar incisor hypomineralization having at least one permanent first molar affected and indicated for full coverage.

- 2- Healthy and medically free patients.
- 3- Patient's age ranges from 6 to 12 years old.
- 4- The molar is free from any symptoms of pulp inflammation or has reversible pulpitis (Provoked pain).



Fig.2 (a) showing a preoperative photo of the hypomineralized lower first permanent molars (b) Showing the molars after treatment and receiving cast adhesive metal coping (CAC) on 9 months follow up

Exclusion criteria

- 1- Molars with irreversible pulpitis or pulp necrosis.
- 2- Molars with periapical radiolucency and/or abscess or fistula or any periapical pathosis.

Randomization, allocation concealment and blinding

Randomization was done using online generated randomization (www.randomizer.com). The generated numbers of random sequence were kept in individual sequentially numbered opaque sealed envelopes to ensure allocation concealment. Randomization and concealment were done by a study independent individual.

Neither the patient nor investigator were blinded due to the type of intervention. However, the statistician was blinded.

Study procedure

1. A detailed medical and dental histories were taken that was followed by clinical and radiographic examination.
2. Sensitivity was identified using history, an explorer, and air spray.
3. Local anesthesia articaine 4% with 1:100.000 epinephrine, (Artinibsa ,Inibsa Dental, Spain) was administrated and then teeth were prepared under rubber dam isolation. All soft enamel and dental caries were removed and the tooth was filled with glass ionomer filling (Medifil ,Promedica, Germany).
4. impression was taken using sectional perforated metal tray and putty impression material (Express™, 3M, USA) for fabrication of temporary crown for the indicated molar between visits using (Alpha-Crown, Alpha Dent, USA) and between visits the temporary crown was cemented using eugenol free cement (Cavex, Netherlands).

5. Tooth preparation

For CAD-CAM milled

PMMA crown:

- Axial reduction: The axial walls were prepared using a tapered diamond stone with a round end to create a chamfer finish line of 0.8: 1 mm thickness. Finish line was located supragingivally on sound enamel.
- Occlusal reduction: With a wheel diamond stone, the occlusal surface was reduced by 1:1.5 mm to create an occlusal clearance (19)(20).
- An impression was taken using elastomeric vinyl poly siloxane putty material (Express™, 3M, USA) in a metal perforated tray for the arch containing the prepared tooth then a

light body impression material (Express™, 3M, USA) was injected around the prepared tooth and the tray with the putty impression was reinserted. While an impression was taken for the opposing arch with an alginate material (Cavex, Netherlands).

- The final impression was cleaned and disinfected and sent to the laboratory for fabrication of stone cast.
- After fabrication of the casts the preparation were scanned from the casts using (Exocad, Germany) system and the crown was manufactured and designed using PMMA disk (YAMAHACHI, Japan).

For cast adhesive metal coping (CAC):

- Axial reduction: The axial walls were prepared using a tapered diamond stone with a round end to create a chamfer finish line of 0.5: 0.7 mm thickness. Finish line was located supragingivally on sound enamel.
- Occlusal reduction: With a wheel diamond stone, the occlusal surface was reduced by 1:1.5 mm to create an occlusal clearance (15).
- An impression was taken using the same method and materials used for the PMMA crown.
- The final impression was cleaned and disinfected and sent to the laboratory for crown fabrication.
- Crowns were sandblasted and surface treated with Al₂O₃ powder.

6. Delivery and Cementation

After crown fabrication, each tooth was cleaned and dried. Then the crown was tried in the oral cavity for fitting, occlusion, margins and contacts. Crowns were then then cemented using dual cure self-etch resin cement (Panavia SA Cement Plus, Kuraray, Japan). After cementation the patient was instructed to

maintain good oral hygiene and to avoid eating sticky food.

The patients were recalled at 1-, 3-, 6- and 9-months post cementation. The same investigator evaluated the crown for longevity by the crown being present, well cemented and without fracture. The marginal integrity was evaluated by clinical examination using dental probe. While, recurrent caries was evaluated by bitewing radiographs. Gingival health was evaluated using gingival index (GI) (21) with the following scores :

0: normal gingiva

1: mild inflammation: a slight change in color, slight edema, no bleeding on probing

2: moderate inflammation: redness, edema, and glazing, or bleeding on probing

3: severe inflammation: marked redness and edema, a tendency toward spontaneous bleeding, ulceration.

Categorical data were presented as frequency and percentage values and were analyzed for intergroup comparisons using Chi-square test. Ordinal data were presented as median and range values and were analyzed for intergroup comparisons using Mann-Whitney U test. The significance level was set at $p \leq 0.05$ within all tests. Statistical analysis was performed with IBM® SPSS® Statistics Version 20 for Windows.

Results

Participants' demographics are presented in (Table 1)

Two crowns in group I and one in group II were not available for all follow ups and two other crowns in group II dropped out after the 1st month follow up. (Fig.3) represents the study flow chart.

Group I At 1st month of evaluation 7 crowns were lost. On the 3rd month another 3 crowns were lost. On the 6th month another five crowns were lost and on the 9th month follow up 13

crowns were present cemented and sound (Table 2).

Group II At one month only 29 were available for evaluation. Two crowns dropped out after the 1st month follow up and only 2 crowns were lost on the 3rd months follow up. On the 9th month follow up 25 crowns were present cemented and sound (Table 2).

All the crowns fell off intact and sound with no fracture in the crowns.

Results showed a significant difference between the two groups in the 1st month follow up (P-value =0.004) and on the 6th month follow up (P-value=0.005) (Table 2).

Results also showed that there were no significant differences between the two types of crowns regarding marginal integrity (Table 3), recurrent caries (Table 4) and gingival health (Tables 5,6).

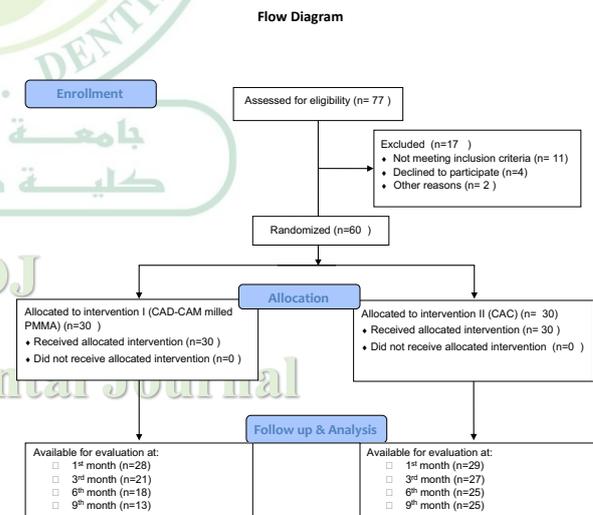


Fig.3 Study flow chart

Table 1: Showing number of individuals in each group and their mean age.

	Gender		Mean Age (Years)
	Male	Female	
Group I	16	14	9.6
Group II	19	11	9.8

Table 2: Showing crown longevity in both groups at 1, 3, 6 and 9 months follow up

		Group						Chi-Square	
		Group I		Group II		Total		X ²	P-value
		N	%	N	%	N	%		
Longevity 1 Month	Success	21	75.00	29	100.00	50	87.72	8.265	0.004*
	Failure	7	25.00	0	0.00	7	12.28		
Longevity 3 Months	Success	18	85.71	25	92.59	43	89.58	0.599	0.439
	Failure	3	14.29	2	7.41	5	10.42		
Longevity 6 Months	Success	13	72.22	25	100.00	38	88.37	7.858	0.005*
	Failure	5	27.78	0	0.00	5	11.63		
Longevity 9 Months	Success	13	100.00	25	100.00	38	100.00	-	-
	Failure	0	0.00	0	0.00	0	0.00		

Table (3): Marginal integrity in both groups at 1, 3, 6 and 9 months follow up.

			Group						Chi-Square	
			Group I		Group II		Total		X ²	P-value
			N	%	N	%	N	%		
Marginal integrity 1 Month	Success	21	100.0	29	100.0	50	100.00	-	-	
	Failure	0	0.00	0	0.00	0	0.00			
Marginal integrity 3 Months	Success	18	100.0	25	100.0	43	100.00	-	-	
	Failure	0	0.00	0	0.00	0	0.00			
Marginal integrity 6 Months	Success	13	100.0	23	92.00	36	94.74	1.098	0.295	
	Failure	0	0.00	2	8.00	2	5.26			
Marginal integrity 9 Months	Success	13	100.0	23	92.00	36	100.00	1.098	0.295	
	Failure	0	0.00	2	8.00	2	0.00			

Table (4): Recurrent Caries in both groups at 1, 3, 6 and 9 months follow up.

		Group						Chi-Square	
		Group I		Group II		Total		X ²	P-value
		N	%	N	%	N	%		
Recurrent caries 1 Month	Success	21	100.00	29	100.00	50	100.00	-	-
	Failure	0	0.00	0	0.00	0	0.00		
Recurrent caries 3 Months	Success	18	100.00	25	100.00	43	100.00	-	-
	Failure	0	0.00	0	0.00	0	0.00		
Recurrent caries 6 Months	Success	13	100.00	25	100.00	38	100.00	-	-
	Failure	0	0.00	0	0.00	0	0.00		
Recurrent caries 9 Months	Success	13	100.00	25	100.00	38	100.00	-	-
	Failure	0	0.00	0	0.00	0	0.00		

Table (5): Gingival health in both groups at 1, 3, 6 and 9 months follow up using Mann-Whitney test.

	Group				Mann-Whitney Test	
	Group I		Group II		Z	P-value
	Median	Median	Median	Median		
Gingival health 1 Month	0	0	-	-	-	-
Gingival health 3 Months	0	0	-	-	-	-
Gingival health 6 Months	0	0	-	-	-	-
Gingival health 9 Months	0	0	1.821	0.069	-	-

Table (6): Gingival health in both groups on 1, 3, 6 and 9 months follow up according to chi-square test.

		Group						Chi-Square	
		Group I		Group II		Total		X ²	P-value
		N	%	N	%	N	%		
Gingival health 1 Month	0	21	100.00	29	100.00	50	100.00	-	-
	1	0	0.00	0	0.00	0	0.00		
	2	0	0.00	0	0.00	0	0.00		
Gingival health 3 Months	0	18	100.00	25	100.00	43	100.00	-	-
	1	0	0.00	0	0.00	0	0.00		
	2	0	0.00	0	0.00	0	0.00		
Gingival health 6 Months	0	13	100.00	25	100.00	38	100.00	-	-
	1	0	0.00	0	0.00	0	0.00		
	2	0	0.00	0	0.00	0	0.00		
Gingival health 9 Months	0	10	76.92	24	96.00	34	89.47	3.675	0.159
	1	2	15.38	1	4.00	3	7.89		
	2	1	7.69	0	0.00	1	2.63		

Discussion

In the present study, there was significant difference regarding crown longevity between both groups at 1st and 6th months. Despite utilizing the same cement and having identical tooth conditions, the cast metal coping performed better in terms of retention and longevity than the CAD/CAM milled PMMA crowns. That might be due to the cement type and its different bond strength with the PMMA or the absence of surface pre-treatment or conditioning in PMMA crowns (22).

The same observation of debonding and loss of retention of CAD- CAM milled PMMA crowns was also reported in a study done by (Huettig and Weber,2015)(19). The study also suggested that the bonding could be improved by conditioning of the crown or sandblasting with aluminum oxide.

In line with our results, (Stawarczyk et al.,2012)(23) compared tensile bond strength of treated crowns with alumina powder and untreated crowns cemented with either self-adhesive or conventional resin cement. Authors reported that air abrasion of polymeric crowns with alumina powder increased the tensile bond strength with different types of cements containing methacrylate monomer except for the Bis-GMA based conventional resin cement and that this mechanical retention is needed for the bonding of CAD-CAM milled PMMA.

Another study by (Stawarczyk et al., 2015)(24) supported the effect of type of cement on retention. The study tested the tensile bond strength of air abraded CAD-CAM milled PMMA with dentin when using different coupling agents for the crowns and different pre-treatments for the hard dental tissue. Crowns were cemented with two different cements. The study showed that the self-adhesive resin cement containing methacrylate monomers had higher bond strength and the coupling agents had no effect on bond strength.

In the search for a method to improve the bond strength to CAD-CAM milled PMMA, a review done by (Mine et al., 2019)(25) found that some treatments might improve the bond between adhesive cements and CAD-CAM PMMA; and that to improve the bond with CAD-CAM milled PMMA, it is recommended to use methyl methacrylate (MMA) containing materials.

On the contrary from the CAD-CAM milled PMMA the CAC was sandblasted with aluminum oxide as done by (Zagdwon et al., 2003)(15) and cemented with dual cure self-etch resin cement (Panavia SA Cement Plus, Kuraray, Japan) which improved the shear bond strength. It was explained by (Shafiei et al., 2018)(26) that the shear bond strength of self-etch resin cement and base metal alloys is enhanced by sandblasting when compared to shear bond strength between self-etch resin cements and nickel chromium cobalt alloy.

However, the study showed no significant difference between the two crowns regarding marginal integrity. Two CAC showed an open margin at the 6th months follow up. The marginal fit of the CAD-CAM milled crowns was discussed in a study by (Peng et al.)(27) and another study by (Cheng et al.)(28) who found that the CAD-CAM fabricated crowns have better internal fit and less marginal discrepancy than the conventional crowns.

Improper oral hygiene as a result of hypersensitivity, and the presence of hypoplastic enamel lead to faster plaque accumulation and decay process in MIH cases(29). All these complications were found by multiple studies to be well treated by full coverage restorations which protect the tooth structure from caries development and progression(11,15,30). Thus, there were no significant difference between the two crowns regarding recurrent caries formation. Both types showed no recurrent caries in all patients and this result agreed with the previous studies (14,15,18).

At the 9th months follow up, 2 of the crowns of group I showed mild gingival inflammation and one showed moderate inflammation. On the other hand, one crown of group II showed mild gingival inflammation. Gingival inflammation around the crowns is mainly due to bacterial colonization and plaque formation on restoration surface. Bacterial accumulation and plaque formation differ from one restoration to another based on multiple factors like surface texture, and smoothness of the material (31,32). This is thought to be the reason that explains the difference between the two materials regarding the gingival reaction and inflammation as the CAC showed better results related to the gingival health when compared with PMMA. That was supported by (Al Halabi et al)(20) who found that CAD-CAM PMMA crowns showed more plaque accumulation and gingival inflammation than 3D printed photopolymer resin crowns when used as full coverage restorations in pulp treated primary molars.

Further studies comparing different pretreatments and coupling agents for the PMMA are suggested as it has a great advantage over the CAC which is aesthetics, and this advantage is very important for the patient satisfaction, self-esteem and related quality of life especially in the early

adulthood.

Limitations

Sample was drawn conveniently so it might not be representable of the whole population. Further studies are needed with larger sample size.

Lack of prior similar research studies.

Conclusions

Within the study limitations the study concluded that:

- Cast adhesive metal coping can be used as a full coverage restoration for first permanent molars affected by MIH.
- Despite the esthetic advantage of the PMMA CAD-CAM milled crown and its excellent marginal fit, its retention is still compromised and needs more research to reach for a method to increase the retention of the crown.

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