Innovations

The Effect of Dental Loupes on Quality of Restoration During Restorative Procedure among Age 6-12 Year Old Children – A Randomized Clinical Trial

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Abstract

Background: *Dental caries is a prevalent multifactorial disease affecting individuals globally. The accurate diagnosis and treatment of occlusal caries, particularly in pediatric patients, is crucial for effective restorative procedures.* ***Objective:*** *The purpose of this study was to assess the impact of dental loupes on the quality of restorative procedures and caries excavation in pediatric patients.* ***Methods:*** *A parallel design randomized clinical trial was conducted with approval from the Institutional Ethical Committee and registered with the Clinical Trials Registry-India. Participants included children aged 6 to 12 years with occlusal caries in primary and permanent first molars, recruited from the outpatient clinic of Pediatric and Preventive Dentistry. The sample size was calculated to be 36 per group, total 72 participants. Randomization was performed using a coin toss method, assigning participants to either Group A (treatment with dental loupes) or Group B (treatment without dental loupes). Caries excavation was performed under rubber dam isolation, and restorations were completed using Glass Ionomer Cement (GIC). The quality of restorations was evaluated using modified United States Public Health Service (USPHS) criteria immediately post-operation and at 1 and 3 months follow-up.Statistical analysis was performed using the Chi-square test, with a significance level set at $P < 0.05$.* ***Results:*** *Of the 72 participants, 4 experienced pain within 1 month and were excluded from the study. The remaining 65 participants were evaluated for restoration quality. Marginal integration showed a statistically significant difference ($p = 0.05$).* ***Conclusion:*** *The study aims to provide insights into the effectiveness of dental loupes in enhancing the quality of restorative procedures in pediatric dentistry. Further analysis of the data will contribute to understanding the benefits of magnification in clinical practice.*

Keywords: *Dental caries, pediatric dentistry, dental loupes, restorative procedures, randomized clinical trial, Glass Ionomer Cement.*

Introduction

Dental caries (multifactorial disease) is the most prevalent disease worldwide, regardless of age and gender. Between the ages of 5 and 12, the prevalence is approximately 49%Early loss of primary teeth leads to an imbalance in growth and development [1]. Diagnosis of occlusal caries is a clinical challenge due to the morphological complexity of the groove and fissure system and the frequent presence of pigmentation in the grooves[2].

Visual inspection is still the most popular method for diagnosing caries, despite the development of numerous diagnostic tools, including Quantitative Light Fluorescence (QLF), Electrical Conductivity Measurements (ECM), and Digital Imaging Fiber-Optic Trans-Illumination (DFOTI) [3]. The concepts of minimally invasive dentistry have been extensively advocated in the field since the early 2000s. These ideas are the main drivers behind dentists' use of microscopes.Working with magnification leads dentists to be more conservative with dental tissues.

Dental loupes (DL), one of the optical aids that significantly increases resolution over the human eye, accurately determines the extent of demineralization and the depth of the lesion [4]. A greater range of magnification and improved ergonomics appear to be features of DL [5]. Using a DL has three main benefits: 1) better visualization; 2) better posture while working; and 3) more referrals [6].

Adaptation to the use of loupes takes time, and this can be difficult for some practitioners. The visual and ergonomic advantages of magnification have been highlighted by those who support the regular use of loupes in dental treatment. It has been demonstrated that dentists do superior restorative procedures under a microscope because of accurate diagnosis and appropriate treatment step completion. The dentist can more easily examine cavity preparations, matrix fitting, saliva infiltration, residual dentine debris, occlusal morphology, macro/micro features, restoration surface texture, air voids, and over-contours with the use of a magnified image of the operational field.

According to earlier studies on the use of magnification aids, 70.5% of respondents said that using magnificationwould make child more anxious, 35.9% said that magnificationcan be easily incorporated into pediatric dentistry, and 95.6% said that the restoration method was accurate [5]. Few research have evaluated the use ofmagnificationin pediatric dentistry, despite its relative usefulness in endodontics [4,5]. Therefore, the purpose of the current study was to assess how dental loupes affected the quality of restorative procedures and caries excavation in pediatric patients.

Materials and Method:

Study Design: A parallel design randomised clinical trial was carried out with prior approval from the Institutional Ethical Committee (IEC/TDCH/71/2024), and the trial was registered with the Clinical Trials Registry-India (CTRI/2024/10/075134). The protocol is in compliance with the ethical standards

of the Declaration of Helsinki [6]. Willing participants with informed consent, who satisfied the eligibility criteria, were recruited for the study.

Sample size: The sample size was calculated based on the data obtained from Sayed A et al., with a significance level of 5%, study power of 80%, alpha = 0.05, beta = 0.2. The estimated sample size was 36 per group.

Participants: Participants were recruited from patients who reported to the outpatient clinic in the Department of Pediatric and Preventive Dentistry. Informed consent was obtained from parents/caregivers of the children after explaining the details of the treatment procedure in a designated format in regional and English languages. All the participants in the study were recruited based on the following inclusion and exclusion criteria.

Inclusion criteria : The study participants selected were six to twelve-year-old children reporting for the first time to the Outpatient Department (OPD) of Paediatric and Preventive Dentistry with occlusal caries in primary and permanent first molars. Those with no history of pain and swelling requiring caries excavation followed by Glass Ionomer Cement (GIC) restoration were included in the study.

Children aged six to twelve who had occlusal caries in their primary and permanent first molars and were visiting the Outpatient Department (OPD) of Paediatric and Preventive Dentistry for the first time, without a history of pain or swelling necessitating caries excavation and Glass Ionomer Cement (GIC) restoration, were chosen as study participants.

Exclusion criteria: Children with special health care needs and patients with no consent were excluded from the study.

Randomization and Blinding:

The co-investigator was trained and standardized by the principal investigator to evaluate the restoration using modified United States Public Health Service (USPHS) criteria. Randomization will be performed by a dental assistant not participating in the study by assigning the first patient to either group A or group B by the toss of a coin. After that, the next patient is assigned to the other group. The principal investigator performs the treatment, and the co-investigator evaluates the restoration. The participant and principal investigator are not blinded; the co-investigator and statistician were blinded.

Participants were randomly allocated by the coin toss method into two groups: Group A (n=36): tell-show-do with rotary and hand caries excavation followed by restoration with Dental Loupes, and Group B (n=36): tell-show-do with rotary and hand caries excavation followed by restoration without Dental Loupes.

Clinical procedure:

Caries excavation was done under rubber dam isolation with the round diamond bur no. 6 using a high-speed handpiece and adequate water coolant. The cavities were restored with Type II restorative Glass Ionomer Cement (GIC). Cavity margins were checked for any gaps, and occlusion was checked for any high points. The quality of the restoration was assessed by the co-investigator using

modified USPHS criteria (colour match, marginal discoloration, marginal integrity, fracture, anatomic form) immediately following restoration. The patient was recalled at the end of 1 and 3 months to assess the restoration. During the follow-up visit, if a patient complains of pain/swelling, participants are subjected to pulp therapy procedure.

Statistical methods:

The restorations were evaluated by the co-investigator at immediate postoperative, 1 month, and 3 months using modified USPHS criteria. All the collected data were analyzed statistically using the Chi-square test, and a $P < 0.05$ was considered statistically significant.

Results:

Of 72 participants (36 in each group), 4 participants experienced pain within 1 month and were excluded from the study and underwent appropriate pulp therapy procedures. 65 participants were evaluated due to the loss of follow-up of 3 children. Table 1 shows the demographic distribution of study participants according to gender and teeth: 41 (56.9%) male, 31 (43%) female. They are not equally distributed. Both the first and second molars are included.Figure 1 is a flowchart representation of participants from the initial phase till the 3-month follow-up.

Table 1: Demographic distribution of study participants according to gender and teeth

Variable	Category	n (%)
Gender	Male	41 (56.9%)
	Female	31 (43%)
First molar (n = 31)	Maxilla	11 (15.2%)
	Mandible	20 (27.7%)
Second molar (n = 41)	Maxilla	18 (25%)
	Mandible	23 (31.9%)

The colour changes in both the groups are not statistically significant in all three time intervals (Table 2).

The marginal integration was not significant between groups at immediate postoperative and 1 month, while at 3 months, marginal integration showed a statistically significant difference ($p = 0.05$).

The anatomic form and fracture had a non-significant difference between the two groups at all three time intervals.

Discussion:

For the child's overall health, as well as for appropriate mastication, aesthetics, phonetics, space maintenance, growth and development of the craniofacial

structure, and to avoid the formation of abnormal habits, it is critical to keep the primary dentition in good shape [7].Caries lesions, which are the clinical manifestation of dental caries, can be identified by their anatomical location (coronal or root/cementum surface), degree of damage (cavitated or non-cavitated), depth of tissue involvement (pulp, enamel, dentin), andactivity level (active or inactive)[8].Early diagnosis of the carious lesion can prevent the incidence of dental caries[9].

Galilean and Keplerian loupes are the main two loupe systems used in dentistry. Galilean loupes are the most popular due to their light weight, but their magnification factor is limited to 2.5×. Advanced optical devices known as Keplerian loupes have an open magnification factor that is typically restricted to 3.5× to 4.5×.Dentists are less fond with Keplerian loupes because of their greater weight.

Dental loupes have benefits, which include increased vision, improvement in overall quality of the treatment, minimally invasive treatment with less dental hard tissue removal, lesser time for the final occlusion check, ergonomic working position, comfort and motivation of the dentist, better communication with the patient and dental assistant, and avoidance of iatrogenic damage.

GIC is most commonly used as the restorative material of choice. GIC benefits the tooth as a restoration because of its chemical bonding with the tooth, the coefficient of thermal expansion being close to that of dental tissue [10], its biocompatibility as a restoration [11], its anti-caries effect [12], antibacterial properties [13], and its ability to induce remineralization, which prevents secondary caries development [14]. GIC also serves as a rechargeable fluoride release system [15,16].

Posterior GIC restorations were assessed using the modified USPHS criteria. The parameters assessed through both clinical examination and digital photographic images included: (1) colour match, (2) marginal discoloration, (3) secondary caries, (4) anatomical form, (5) marginal adaptation, (6) surface texture, and (7) fracture (Barnes et al., 1995; Celik et al., 2010). The scores were categorised as follows: Alpha (A) indicated clinically acceptable restorations, Bravo (B) represented restorations that were clinically unacceptable but could be repaired (excluding secondary caries), and Charlie (C) signified the need for replacement of the restoration (17).

The benefits of magnification in restorative dentistry treatments are important in the following situations: identification of areas where enamel tissue is demineralized, identification and minimally invasive removal of old restorations, gaps or impurities in restorative materials, inspection of caries borders and remaining caries, management of small & accidental pulp chamber openings without mechanical injury to the pulp, identification of enamel cracks or fractures, especially located on the gingival margin in Class II and MOD cavities, checking of the sectional matrices adaptation and controlled application of liner, sectional matrices adaptation, evaluation of the marginal gaps of the restorations, selective

application of the liner for pulp protection, minimally invasive removal of amalgam restorations, minimally invasive preparation of small Class III cavities, removal of excess composite materials, adhesive excess removal, checking if the composite is flowing into all aspects of the preparation, detecting irregularities, detecting microscopic air bubbles in flowable composite located either inside or on the external surface or margin of the flowable composite bolus, ensuring good finishing of margins, simplifying the finishing and polishing working protocol, and improving the marginal integrity of proximal composite restorations [18].

Illuminating the operating field is beneficial for the operator (19,20). Using a mounted fiber-optic light on the magnifying loupes is advised by loupe manufacturers because it can enhance light levels, when compared to traditional overhead dental lights, by up to four times. The light is usually attached to the center of the forehead, closer to the operating field, reducing the probability of shadowing (21).

One study(22) reported that using magnifying loupes during restoration completion significantly decreased the number of proximal ledges. Mamoun reported that higher-magnification loupes (4×) may work better than unaided entry-level (2.5×) magnifying devices[23]. Therefore, working efficiency is related to the magnification power. The shorter treatment duration creates a positive impact on the child's behavior and cooperation throughout the treatment, thereby reducing operator fatigue [24]. Similar findings were reported by Anusree et al., when magnifying loupes were used for pulpectomy procedures [24]. Wong et al. compared the treatment time for non-surgical endodontic therapy with or without a magnifying loupe and concluded that the use of a magnifying loupe could significantly reduce the endodontic treatment time [25]. Sayed A et al., in their study, found that a greater percentage of patients in the group treated under DOM had improved anxiety scores along with improved overall behavior in children, while an increase in pulse rate was noted [26].

At 3 months, after 7 dropouts, there was no post-operative sensitivity or complications like pain, swelling, and furcal radiolucency in both groups.

Limitations of the study: The evaluation was subjective, with weaknesses in perceiving changes in retention, anatomic form, colour match, marginal integrity, and marginal discoloration that cannot be measured accurately without the use of sophisticated tools. The evaluation by modified USPHS criteria is difficult to distinguish between the scores Alpha and Bravo to arrive at a definitive conclusion. The accurate method to measure these criteria should be objective, which would reduce the manual error caused by fatigue during the evaluation. The short follow-up period resulted in inadequate data on the long-term performance of restorative materials. Thus, many in vivo studies with long-term follow-up are recommended.

Conclusion:

The study demonstrated that the use of dental loupes significantly enhances the quality of restorative procedures in pediatric patients with occlusal caries. The findings indicate improved outcomes in terms of marginal integrity when compared to traditional visual examination methods. Despite the limitations related to subjective evaluations and a short follow-up period, the results suggest that incorporating dental loupes in pediatric dentistry can lead to better clinical results. Future studies with longer follow-up durations and objective measurement tools are recommended to further validate these findings and assess the long-term performance of restorative materials in this population.

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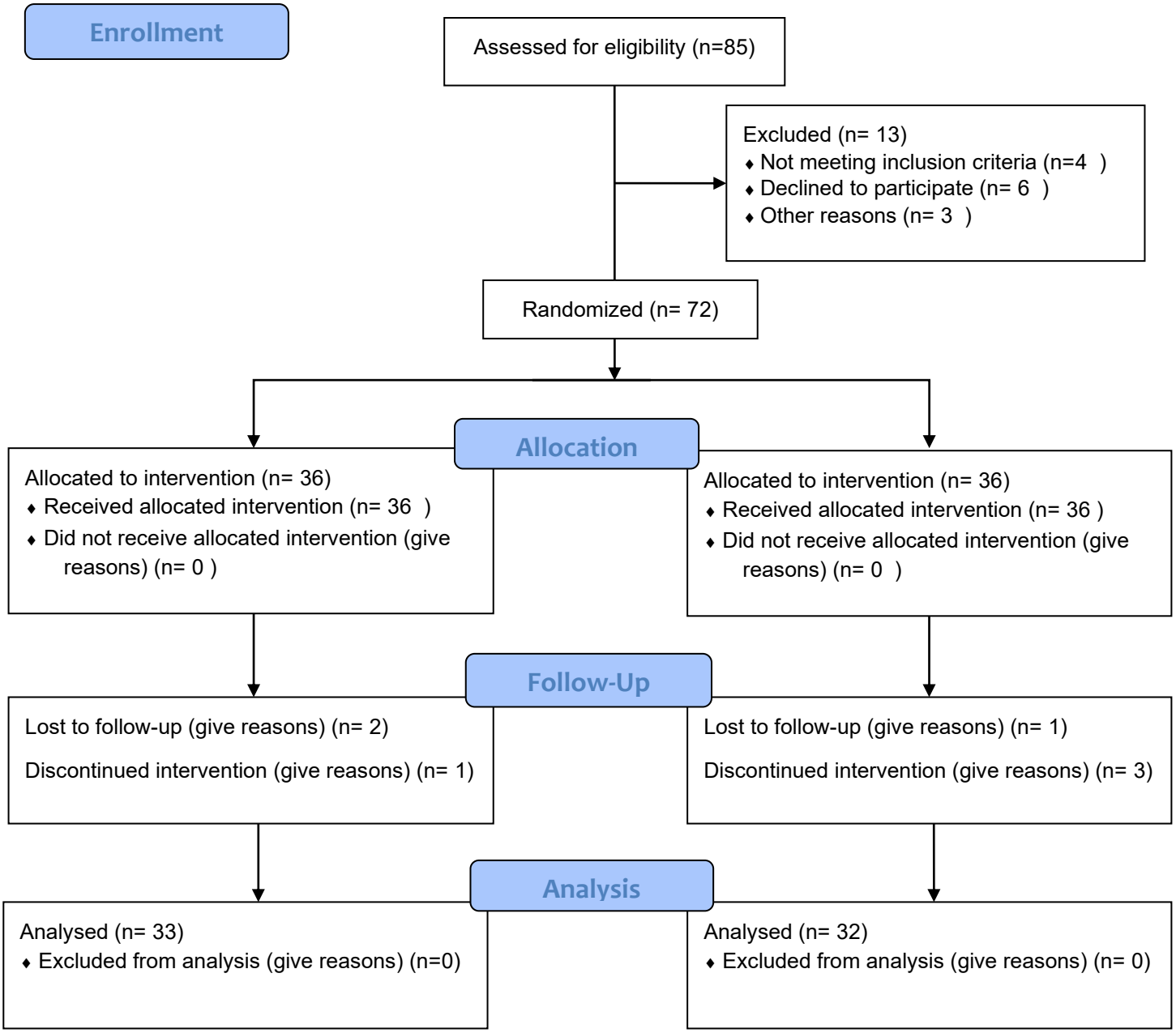
Second molar (n = 41)	Maxilla	18 (25%)
	Mandible	23 (31.9%)

Table 2:

Follow up	Criteria	Groups	Alpha, n (%)	Bravo, n (%)	Charlie, n (%)	P value
Immediate postoperative	Color match	Group A	35(97%)	1(2.7%)	0	0.30
		Group B	33(91.6%)	3(8.3%)	0	
	Marginal discoloration	Group A	36(100%)	0	0	NA
		Group B	36(100%)	0	0	
	Marginal integrity	Group A	36(100%)	0	0	NA
		Group B	36 (100%)	0	0	
	Anatomic form	Group A	34(94.4%)	2(5.5%)	0	0.33
		Group B	32(88.8%)	4(11%)	0	
	Fracture	Group A	36(100%)	0	0	NA
		Group B	36(100%)	0	0	
1 month	Color match	Group A	31(94%)	2(6%)	0	0.61
		Group B	28(87.5%)	4(12.5%)	0	
	Marginal discoloration	Group A	31(94%)	2(6%)	0	0.81
		Group B	29(90.6%)	3(9.3%)	0	
	Marginal integrity	Group A	32(97%)	1(3%)	0	0.52
		Group B	29(90.6%)	3(9.3%)	0	
	Anatomic form	Group A	29(87.8%)	4(12%)	0	0.61
		Group B	29(90.6%)	2(6%)	1(3%)	
	Fracture	Group A	31(94%)	1(3%)	1(3%)	0.81
		Group B	28(87.5%)	2(6%)	2(6%)	
3 month	Color match	Group A	29(87.8%)	4(12%)	0	0.301
		Group B	23(71.8%)	7(21.8%)	2(6%)	
	Marginal discoloration	Group A	31(94%)	2(6%)	0	0.413
		Group B	26(81%)	5(15.6%)	1(3%)	
	Marginal	Group A	32(97%)	1(3%)	0	0.05*

	integrity	Group B	27(84%)	4(12.5%)	1(3%)	
	Anatomic form	Group A	28(84.5%)	2(6%)	3(9%)	.629
		Group B	24(75%)	5(15.6%)	3(9.3%)	
	Fracture	Group A	29(87.8%)	2(6%)	2(6%)	.306
		Group B	23(71.8%)	7(21.8%)	2(6%)	


Enrollment
Assessed for eligibility (n=85)
Excluded (n= 13)
♦ Not meeting inclusion criteria (n=4)
♦ Declined to participate (n= 6)
♦ Other reasons (n= 3)
Randomized (n= 72)
Allocation
Allocated to intervention (n= 36)
♦ Received allocated intervention (n= 36)
♦ Did not receive allocated intervention (give reasons) (n= 0)
Allocated to intervention (n= 36)
♦ Received allocated intervention (n= 36)
♦ Did not receive allocated intervention (give reasons) (n= 0)
Follow-Up
Lost to follow-up (give reasons) (n= 2)
Discontinued intervention (give reasons) (n= 1)
Lost to follow-up (give reasons) (n= 1)
Discontinued intervention (give reasons) (n= 3)
Analysis
Analysed (n= 33)
♦ Excluded from analysis (give reasons) (n=0)
Analysed (n= 32)
♦ Excluded from analysis (give reasons) (n= 0)