18-Months Clinical Evaluation of Partial Caries Removal in Permanent Molars with Deep Carious Lesions

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Abstract

Objective: Clinical evaluation of partial caries removal in permanent molars with deep carious lesions over 18-months. **Materials and methods:** 57 patients having permanent molars with deep Class I caries were involved in this study. At the first visit all patients received the treatment of incomplete caries excavation, application of Chitosan-loaded nano-hydroxyapatite (CS/N-HAp) as dentin dressing material and sealing temporarily for a 3-months with a glass ionomer cement (GIC). At the second visit the GIC reduced pulpally leaving 2 mm to act as base under composite resin restoration. Finally, all cavities were restored with selective enamel etching technique by using 35% phosphoric acid gel, followed by application of self-etch adhesive and Nano-filled composite resin according to manufacturer instructions. The clinical and digital radiographic evaluations of the success and failure rates was performed at: baseline (7 days), 3-, 12-, and 18-months. **Results:** Regarding the follow-up periods and, the success rates result showed that there was no significant difference between all different follow-up periods. The success rates were 100% with no signs of clinical and radiographic failure at baseline and after 3 months. While at 12 months and 18 months the success rates were 88.89% and 77.78 % respectively. However, 11.11 % of cases showed failure at 12 months, while 22.22 % at 18 months. **Conclusions:** Complete dentine caries removal with reopening the cavity to remove the residual infected dentine is not essential to control caries progression.

Keywords: Deep caries, Selective caries removal, Chitosan-loaded nano-hydroxyapatite.

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Introduction

Dental caries is a disease showing an estimated worldwide prevalence of more than 2 billion patients in 2013, where dental hard tissues, that is, the superficial enamel and underlying dentine, are destroyed by the metabolites of bacteria with high acidurance and acidogenic activity [(1)].

Primary goal of restorative caries therapy is to preserve pulp vitality and the dentition. Whereas the conventional approach of complete caries removal aims at the elimination of all affected substances without regard to losses of hard tissue or pulp vitality, the innovative concept of selective caries removal (SCR) is characterised by a targeted and non-invasive excavation. It presents a lower risk of accidental pulp exposure, which reportedly has a positive effect on tooth survival [(2)].

Moreover, it was claimed that the caries process becomes arrested in the remaining contaminated dentin, as cariogenic bacteria become nonviable due to absence of the substrate [(3)]. Despite these, there are very few studies on selective removal of soft dentin with long follow up periods [(4)]. In addition, it couldn't be truly stated whether the residual bacteria or their byproducts would be damaging to the pulp or not [(5)]. As there is still controversy regarding the fate of microorganisms, it was claimed that such bacteria could still persist in dentin in cavities treated by either partial caries removal or complete caries removal techniques which affecting the success of the treatment [(6)].

Remineralization capacity of pulp capping materials may not by itself help in management of deep dentinal caries. Antibacterial activity as well as capacity for dentinogenesis play an equally important role. In the previous study, the anti-bacterial efficacy of paste with Chitosan-loaded nano-hydroxyapatite (CS/N-HAp) was evaluated against the most predominant microorganism implicated with the process of dental caries i.e. S. mutans [(7)]

From the previous review, it was postulated that it would be of importance to clinical evaluate the effect of selective (SE) caries removal technique on the success of management of deep carious lesions with using CS/N-HAp paste as dentin dressing material over 18-months.

Materials and methods

I. Materials

1. Dentin dressing material: Chitosan-loaded nano hydroxy apatite (CS/N-HAp). (Naqaa Co. Cairo, Egypt.)
2. Temporary filling material: Glass ionomer cement (Medicem).
3. Acid etch gel: 35% phosphoric acid gel (Scotchbond Universal Etchant, 3M ESPE)
4. Self-etch adhesive (Scotch Bond Universal, 3M ESPE).
5. Final restorative material: Nano-filled composite resin (Filtek Z350 XT, 3M ESPE).

II. Study design:

It was a single centered, double blinded (assessor and patient); two parallel armed randomized clinical trial with an equal allocation ratio (1:1). The trial involved 57 adult patients between the ages of 18 and 50 years who had a posterior permanent tooth with a deep occlusal (Class I) caries that extended to the inner third of the dentin (D3) that have a radiopaque layer separating the carious lesion from the pulp chamber and healthy periapical tissues as determined by a digital sensor radiograph and was clinically and radiographically confirmed.

Patients were selected at the time of their regular dental visits in the outpatient clinics, Department of Operative Dentistry, Faculty of Dental Medicine, Al-Azhar University, Cairo, boys. Clinical selection was conducted using.

II.1. Ethical approval and consent form:

This randomized clinical trial was approved by the institutional Ethics Committee at the Faculty of Dental Medicine, Al-Azhar University Ethics Committee.

II.2. Sample size

Sample size calculation was based upon the result of **Franzon et al** [8] using an alpha level of 0.05 (5%) and beta level of 0.20 (20%), i.e. power = 80%, the estimated minimum required sample size (n) was 46 teeth per group, giving a total of 92 teeth, oversampling will be performed to compensate for the 25% dropout rate that may occur so the required sample size is a minimum of 57 teeth per group giving a total number of 57 teeth. Sample size calculation was performed using IBM SPSS Power Release 3.0.1.

II.3 Eligibility criteria

Inclusion criteria were as follows: Class I deep carious lesions in permanent molars which extended to (D3). Teeth with a healthy response to the electrical pulp tester, absence of spontaneous pain and periapical lesions, a negative sensitivity to percussion, and without mobility. Exclusion criteria were: teeth with cuspal loss, cavities below the gingival edge, the existence of previous restorations, periodontal disease, signs of irreversible pulpitis or necrotic pulp, and roots with external or internal resorption.

II.4. First treatment visit

The clinical procedures were carried out step-by-step in two visits. Patients in undergoing the following procedures: anesthesia and rubber dam isolation of the area to be treated; access to the lesion using rotating diamond burs on rotator instruments. Selective removal of soft dentin was carried out by sharp double-ended excavator (No 51-52, Dentsply, Konstanz, Germany). A low-speed fissure bur (HM 21, size #012, Meisinger) was used to remove the caries from the cavity's margins and expose sound dentin. The dentinoenamel junction and cavosurface margins were inspected carefully and made sure to be clean, with at least 1.5 to 2 mm rim of peripheral sound tooth structure to provide a firm marginal adhesion for the restoration. The last layer of soft dentin was left on the pulpal floor to prevent pulpal exposure. The cavity was then rinsed with air/water spray, and the cavity was gently dried with cotton. Followed by application the CS/N-HAp dentin dressing materials paste.

A highly viscous mix of glass ionomer (GI) cement (Medicem) was packed and contoured into proper form and allowed to set as a temporary restoration over the CS/N-HAp.

II.5. Second visit

Patients were contacted for a second treatment appointment after three months. Dental examinations, both clinical and digital radiographic, anesthesia and isolation were repeated. If irreversible pulpitis, pulp necrosis, or periapical pathosis were identified as failure symptoms, the patients were directed to the appropriate departments for retreatment (endodontic therapy).

The temporary restoration reduced pulpally leaving thickness of approximately two mm to act as base under composite resin restoration. The cavities were restored with selective etching of enamel technique for 15 s, followed by coating the entire cavity was a single layer of the self-etch adhesive. Finally, the Nano-filled composite resin was placed according to manufacturer instructions.

II.6. Outcomes and follow-up

Primary outcome: success and failure rates of caries removal method by clinical and radiographic evaluations which was performed independently by the same investigator at 4 different follow-up periods: baseline (7 days), 3 months, 12 months, and 18 months.

The primary success outcome was pulp vitality, which was determined by the combination of the following characteristics: Absence of pain with percussion and palpation or abnormal response with electrical testing. No swelling or fistula formation. Absence of pathological mobility of the tooth and absence of periapical lesion (radiographic examination). If at least one of these signs/symptoms indicated pulp necrosis, failure was defined [(9)].

II.7. Statistical analysis

Statistical analysis was performed using SPSS statistical version 21 (Chicago, IL, USA). The Kolmogorov-Smirnov test was used to verify the normality of distribution. A one-way ANOVA test was used to compare the efficacy of the technique at different follow-up periods. The post hoc Tukey test was used for comparison two intervals. The Significance level was set at $P < 0.05$.

Results

Regarding the follow-up periods, the Chi-Square test results for success rates showed that there was no significant difference between all different follow-up periods (p=0.261). The results showed that the success rates were 100% with no signs of clinical and radiographic failure at baseline and after 3 months.

While at 12 months and 18 months the success rates were 88.89% and 77.78 % respectively. However, 11.11 % of cases showed failure at 12 months, while 22.22 % at 18 months. The data is summarized in **(Table 1)** and **(Figure 1)**.

Table (1): Success and failure rates results of the SE technique at different follow-up periods:

Variable	Baseline		3 months		12 months		18 months		p-value
SE technique	Success; No., (%)	Failure; No., (%)	Success; No., (%)	Failure; No., (%)	Success; No., (%)	Failure; No., (%)	Success; No., (%)	Failure; No., (%)	
	9 (100 %)	0 (0 %)	9 (100 %)	0 (0 %)	8 (88.89 %)	1 (11.11 %)	7 (77.78%)	2 (22.22%)	0.261 NS

Ns; non-significance

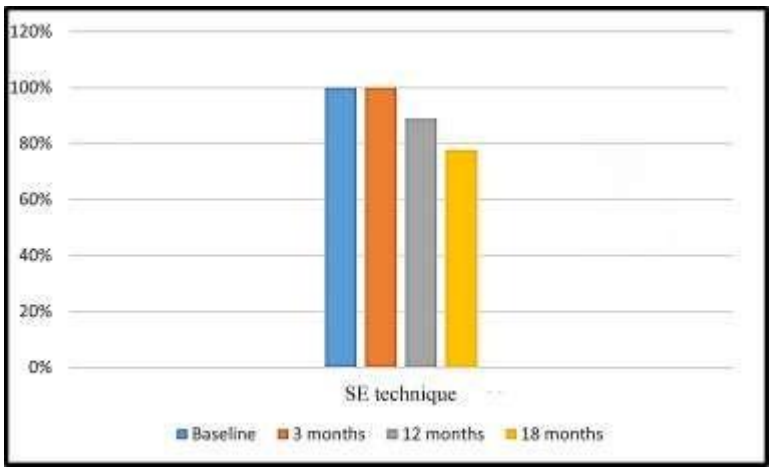

Figure (1): A diagram showing the success rates results of the SE technique at different follow-up periods.

Discussion

At the moment, caries therapy should be based on minimal intervention dentistry principles, including minimally invasive cavity preparations when surgical intervention is necessary [10,11]. However, total excavation in one step, with the hardness of a dental probe used to test caries excavation, is the most frequently utilized method for deep carious lesions [12]. Due to this technique, there is a substantial danger of pulp exposure and a poor outlook for preserving pulp vitality [13]. Therefore, SE was chosen for analysis in this clinical experiment because it is advised against removing carious dentine from deep lesions in this manner.

In this clinical trial, a Class I cavity with only occlusal surface caries was selected to be involved to avoid the higher risk of failure for teeth having multi-surface restorations according to the finding of the systematic review [14].

Our results revealed that there was no significant difference between all different follow-up periods with SE technique, that could be due to the common factor in all these cases is the disturbance of the biofilm, disturbing bacterial adherence, metabolism, and reproduction with a consequent decrease in the production of the acid responsible for the demineralization and toxicity to the pulp. The remaining bacteria do not promote lesion progression after the dentine has been isolated from the oral environment [15]. Our results in agreement with **Singhal et al** [6] who found and concluded that the incomplete caries removal is associated with a marked reduction in bacterial growth.

Moreover, the sealing carious dentin tissues reduces the microbiological load in the infected dentin because of restriction of exogenous nutrient supply by isolating the caries process from the oral cavity [(4)] or due to the CS/N-HAp dentin dressing material which antibacterial activity and reduce the presence of cariogenic bacteria [(16)].

Likewise, our results agreed with the results of a previous study by **Labib et al** [(17)] who concluded that no statistically significant difference in the clinical success rates follow up periods of SE technique for 1 year of clinical follow-up.

Moreover, it is important that the temporary filling used between treatments in a 2-visits o provides a good cavity seal. A restoration of reasonable quality such as a glass-ionomer could be suitable [(18)]. Additionally, with the final restoration the selective enamel etching promoted better marginal integrity for self-etch adhesive showing it to be an efficient technique for Class I composite restorations [(19)].

Furthermore, the desired outcome using SE technique is to favor deposition of tertiary or sclerotic dentine and remineralization of the remaining demineralized dentine [(15)]. Sclerotic dentine is less permeable than primary dentine, thereby preventing toxic agents from microbe metabolism or materials used for sealing cavities from reaching the pulp. This defense reaction controls the inflammation reaction to the caries process allowing the pulp to repair itself. This is proven by the absence of periapical lesion on the radiographic examination and the lack of pain in all cases evaluated during the 18-month period [(20)].

In addition, the treatment with CS/N-HAp as dentin dressing material improved the remineralization potential and mechanical properties of the demineralization dentin. Chitosan due to its biocompatibility, biodegradability, low toxicity, antimicrobial property and more importantly versatile biological activity makes it a desirable material to be used on dental tissues [(21)]

However, our findings disagreed with **Maltz et al** [(9)] who found that SE showed a significantly higher failure rate for 18 months follow up. They stated that failure of patients to attend the second appointment compromised the therapy performance in their study. Due to loss of temporary filling and invasion of bacteria into cavity again.

Conclusions

1. Selective caries removal to soft dentin can be used in the management of deep caries to avoid pulp exposure and preserve tooth structure.
2. Complete dentine caries removal with reopening the cavity to remove the residual infected dentine is not essential to control caries progression.

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