No additional benefit of using a calcium hydroxide liner during stepwise caries removal

A randomized clinical trial

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ABSTRACT

Background. Clinicians often use calcium hydroxide liners during stepwise treatment of advanced caries. In this randomized clinical trial, the authors compared the short-term outcome of stepwise caries removal with and without use of a calcium hydroxide liner in conjunction with provisional resin-modified glass ionomer (RMGI) restorations.

Methods. The authors included in the trial 98 patients aged 15 to 30 years who had a deep carious lesion in a posterior tooth. The authors measured the dentin thickness radiographically and recorded its color, consistency, and moisture, as well as the bacterial count of the lesions. After partial caries removal, the authors assigned patients randomly to have their caries provisionally restored using RMGI with (control group) or without (test group) a calcium hydroxide liner. The primary outcome measure was tooth vitality after 90 days. Secondary outcomes included changes in dentinal, radiographic, and microbiological characteristics of the lesions.

Results. The authors found no statistically significant difference between the test and control groups in tooth vitality after 90 days. Irrespective of calcium hydroxide liner use, the authors observed darker, harder, drier, and less contaminated dentin after the provisional restorations, but dentin thickness remained unchanged.

Conclusions. On the basis of this 3-month clinical trial's results, the use of a calcium hydroxide liner during stepwise caries excavation and provisional restoration did not provide any additional benefit.

Practical Implications. After 3 months, using a calcium hydroxide liner does not appear to offer any additional benefit when clinicians use RMGI provisional restorations during stepwise caries removal. Longer studies are needed to confirm these results.

Key Words. Randomized controlled clinical trials; caries; glass ionomer cements.

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Despite developments in caries prevention and early diagnosis, untreated caries is still the most prevalent disease worldwide, with a global prevalence of 35% for all ages combined.[1] The lack of early intervention leads to the progression of early carious lesions to deep cavities involving the inner one-third of dentin, which poses a recurrent challenge for clinicians.[2-4] Carious dentin removal before a restorative procedure commonly is associated with significant risk of experiencing pulp damage, including pulp exposure and irreversible pulpitis.[5,6] Considering the limited access of the population to endodontic treatment in several countries, pulp damage can be followed by tooth extraction, compromising patient quality of life and becoming an important public health problem.[5,7,8]

Investigators have proposed stepwise caries removal to reduce the risk of pulp

exposure during 2-step carious tissue excavation.[9-11] During the first procedure, the clinician partially removes the carious dentin and provisionally seals the cavity until the second intervention. This method allows the remineralization of the lesion and induces the development of tertiary dentin, thereby reducing the risk of pulp exposure and postoperative complications after the second excavation procedure.[12,13] Between 45 days and 6 months after the first procedure, the clinician performs complete excavation, followed by definitive cavity restoration. Among the provisional restorative procedures, the use of a calcium hydroxide liner on the remaining carious dentin tissue usually is recommended because of its ability to induce dentin remineralization.[13,14]

However, study results have demonstrated that simply sealing the cavity properly may be enough to allow reorganization of carious dentin within a short time, followed by remineralization for longer periods.[15,16] Therefore, simpler provisional restorations with a reduced number of clinical steps can result in outcomes similar to those observed for restorations with calcium hydroxide liners. In addition to being technically simple to use, the restorative material must have adequate biocompatibility with the pulp tissue, considering its insertion into deep cavities; sufficient mechanical properties to withstand occlusal loads; and proper marginal seal. Despite inducing mild pulp damage when used in deep cavities, resin-modified glass ionomers (RMGIs) have acceptable biocompatibility,[17,18] adequate mechanical properties for provisional restorations in occlusal cavities, antibacterial properties, fluoride release, and ability to bond to tooth tissues.[19-21]

Thus, our objective in this trial was to compare the effectiveness of a provisional restoration with RMGI alone or combined with a calcium hydroxide liner in maintaining pulp health in the stepwise caries removal technique. The hypothesis was that restoring the cavity with RMGI rather than with a calcium hydroxide liner would produce similar clinical outcomes.

METHODS

The scientific review committee and the committee for the protection of human study participants of Federal University of Sergipe approved this clinical trial (certification of submission for ethic appreciation 27090414.0.0000.5546). All participants included in the study signed an informed consent form. We registered the study protocol at ClinicalTrials.gov (NCT02494193) and followed the Consolidated Standards of Reporting Trials guidelines.[22]

Study design. This was a randomized, single-blind, controlled trial with a parallel group and an allocation rate of 1:1. After we partially removed carious dentin, we randomly allocated patients with a deep carious lesion on the occlusal surface of a posterior tooth to have the lesion provisionally restored with RMGI either with a calcium hydroxide liner (control group) or without a calcium hydroxide liner (test group). We conducted the study at the dental clinic of the school of dentistry affiliated with the Federal University of Sergipe from June 2015 to September 2016.

Inclusion and exclusion criteria. We recruited participants by means of advertisements placed on the university's premises. We included male and female patients aged 15 to 30 years whose permanent premolars or molars had deep carious lesions involving the inner one-third of dentin. We used the following exclusion criteria: presence of periapical or periodontal lesions; necessity of extensive indirect restorations; any diagnosis of pulp alteration (cold testing with refrigerant spray), root exposure, or noncarious cervical lesion; history of hypersensitivity; and pulp exposure during caries removal.

Sample size calculation. We based the sample size calculation on primary outcome (maintenance of pulp vitality) data. We performed the calculation for the binary outcome equivalence trial, considering a power of 80%, a significance level of 5%, an equivalence limit between the control and test treatments of 20%, and a success rate of 90% for both treatments on the basis of a previous study.[23] The sample size calculation showed that a minimum of 98 patients (49 per group) was necessary.

Random assignment. A person not involved in the study used a computer to generate a randomized list and inserted the treatment allocated to each patient into sequentially numbered, opaque sealed envelopes. We numbered the cavities to be restored according to the order of participant recruitment. The operator in charge of the interventions opened the envelope only at the time of the procedure.

Baseline measurements. At baseline and before the intervention, we obtained bite-wing radiographs to measure the thickness of the remaining dentin under each carious lesion. We used bite-wing film holders to standardize the position of the radiographs obtained throughout the study. We placed self-cured acrylic resin on the film holder and took impressions of occlusal surfaces of the opposing teeth, thus allowing us to relocate the device in the same position in the measurement performed after the intervention. We used Phosphor Plate Systems (Scaneo, Fona Dental) and opened the digitized images by using ImageJ software (National Institutes of Health) to measure the remaining dentin thickness. We drew 5 straight lines linking the cavity floor to the pulp chamber, and we calculated the average length of these lines to estimate the remaining dentin thickness (Figure 1).

ABBREVIATION KEY. **ITT:** Intention to treat. **RMGI:** Resin-modified glass ionomer.