
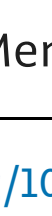


Clinical evaluation of a new chemically-cured bulk-fill composite in posterior restorations: 6-month multicenter double-blind randomized clinical trial

Alessandro D. Loguercio ^{a, b}, B Carpio-Salvatierra ^a, R Naupari-Villasante ^a, M Wendlinger ^a, Ana Armas-Vega ^b, S Cavagnaro ^c, A León ^c, R Aliaga-Galvez ^c, MF Gutiérrez ^c, 

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Abstract

Objective
To evaluate the postoperative sensitivity (POS), as well as the clinical performance of posterior restorations using a new chemically-cured bulk-fill composite (Stela Automix and Stela Capsule, SDI) comparing with a light-cured bulk-fill composite after 6 months.

Methods
Fifty-five participants with at least three posterior teeth needing restoration were recruited. A total of 165 restorations were performed on Class I or Class II cavities. After the application of Stela primer, the chemically-cured composite (Stela Automix or Stela Capsule) was inserted. For the light-cured composite group, a universal adhesive (Scotchbond Universal) was applied with a bulk-fill composite (Filtek One). Participants were evaluated for spontaneous and stimulated POS in the baseline, after 48 h, 7 days, and 6 months. Additionally, each restoration was assessed using the updated version of FDI criteria after 6 months. The differences in the proportions of the groups were compared by Cochran test statistics ($\alpha = 0.05$).

Results
Both chemically-cured composites showed a lower risk of POS compared to the light-cured composite at baseline and up to 48 h ($p < 0.04$). A significantly lower surface luster and texture was observed for the Stela Capsule composite compared to the light-cured bulk-fill composite (baseline and 6 months; $p = 0.03$). A significant color mismatch was observed for the light-cured bulk-fill composite compared to the chemically-cured composites (baseline and 6 months; $p = 0.03$). No significant differences were observed in any other item evaluations ($p > 0.05$).

Conclusion
Chemically-cured composites exhibit lower postoperative sensitivity and less color mismatch compared to a light-cured bulk-fill composite after 6 months of clinical service.

Clinical significance
The chemically-cured composites appear to be an appealing option for restoring posterior teeth, as they exhibit lower postoperative sensitivity compared to a light-cured bulk-fill composite, both at baseline and up to 48 h, and less color mismatch.

Introduction

Although the significant decrease of caries as a disease worldwide, the majority of cavitated dentin carious lesions in posterior teeth remain unrestored in several poor communities throughout the world [1]. In addition to the above, despite the increasing use of resin composites in posterior teeth [2,3], amalgam continues to be the preferable restorative material for filling cavities in posterior teeth in public health, mainly in low- and middle-income countries due to its effectiveness and relatively low cost [4].

Although the use of dental amalgam is widespread, dental and scientific communities generally believe amalgam is safe and effective, though concerns have been raised about the adverse effect on human health and the environment, based on the United Nations Minamata Convention on Mercury [5]. Due to all these facts, the demand for a true amalgam alternative kept on increasing. Although modern restorative materials, particularly resin composites, are reasonable alternatives to amalgam, it is difficult for them to compete with the beneficial characteristics of amalgam, such as easy handling, no requirement for expensive equipment like light-curing devices, and extended durability [6,7]. Despite many attempts to develop an alternative to amalgam [8], currently, no “perfect” alternative is available [9].

Recently, a chemically-cured (self-cured), bulk-fill restorative material has been introduced in the market (Stela, SDI, Victoria, Australia). This product is offered in two application forms (Stela Automix and Stela Capsule) and features an adhesive feature that does not require light-curing, as it polymerizes upon contact with the restorative material. A few in vitro studies have evaluated this new material with promising results [[10], [11], [12]].

However, the most appealing aspect of chemically cured composite materials is their ability to generate minimal shrinkage stress [[13], [14], [15]]. This is due to their low shrinkage, prolonged pre-gel phase, and gradual polymerization, which can reduce stress development at the adhesive interface, and minimize the formation of voids and gaps [13,16]. These characteristics can be crucial, since increased postoperative sensitivity (POS) may clinically manifest as a result of such issues. Indeed, a recent in vitro study indicates that employing chemically-cured composites leads to a resin-dentin interface less prone to gaps and voids when compared to light cured bulk-fill composite, even following extended storage in artificial saliva [11]. Nevertheless, the authors acknowledged that, due to the limitations of in vitro studies, clinical trials are necessary for a more comprehensive evaluation of the clinical behavior of this new material [17,18]. This is the objective of the present study.

The aim of this double-blinded, randomized controlled trial was to compare the clinical performance, which focused on postoperative sensitivity, and posterior restorations placed with chemically-cured bulk-fill composite (Stela Automix and Stela Capsule), to light-cured bulk-fill composite after 6 months of clinical service. The null hypotheses tested were: 1) the use of chemically-cured composite (Stela Automix and Stela Capsule) does not influence the spontaneous postoperative sensitivity (POS) of posterior composite resin restorations; 2) the use of chemically-cured composites (Stela Automix and Stela Capsule) does not influence the stimulated postoperative sensitivity (POS) of posterior composite resin restorations; 3) the use of chemically-cured bulk-fill composites (Stela Automix and Stela Capsule) does not influence any evaluated clinical parameter of posterior resin composite restorations.

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Ethical approval and protocol registration

The Ethics Committee of the State University of Ponta Grossa (Ponta Grossa, PR, Brazil) and Universidad de los Andes (Santiago, Chile), reviewed and accepted the proposed protocol, and gave its consent for the participation of people in this study (protocol #5.972.758 and #CEC2024049, respectively). All participants were informed of the study’s objectives and nature, and signed a consent form before their acceptance in the study. This clinical study was registered in the Brazilian Clinical ...

Results

In total, one hundred and fifty (150) participants were screened for eligibility, and 95 participants were excluded from the study for not meeting the inclusion criteria (Fig. 1). Therefore, one hundred and sixty-five restorations were performed on 55 participants, 20 males and 35 females (Table 1). Each participant had three restorations within the experimental groups ($n = 55$) in a split-mouth design. The restorative procedure was applied precisely as planned, and no modification was ...

Discussion

The present randomized clinical trial evaluated the POS and the clinical performance of a new chemically-cured resin composite applied in two forms (Automix and Capsules) compared to light-cured resin composite restorations. The results of the study showed that the application of the chemically-cured resin composite, regardless of the form, significantly decreased the occurrence of spontaneous POS in resin composite posterior restorations compared to light-cured bulk-fill resin composite ...

Conclusion

The chemically-cured composites appear to be an appealing option for restoring posterior teeth, as they exhibit lower postoperative sensitivity compared to a light-cured bulk-fill composite, both at baseline and up to 48 h, and less color mismatch. However, lower surface luster and texture were observed for the chemically-cured composites applied in Capsule compared to the light-cured composite. ...

Declaration of competing interest

The authors declare that they have no conflicts of interest. ...

Acknowledgments

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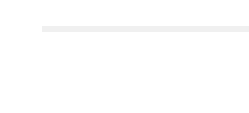
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