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Clinical Time of the Self-Adhesive Bulk-fill Composite versus Nanohybrid Composite in Cervical Lesions: A Randomized Controlled Clinical Trial

Riham K. El-Shazly[1], Mohamed E. Labib[2], Inas M. El-Zayat[3], Mohamed M. AbdelMohsen[4]

ABSTRACT

Introduction: Restorative materials have evolved toward simpler, faster applications. Incrementally-layered composite resins, while improved, still face long chair-side issues. Self-adhesive bulk-fill resins offer a solution by allowing thicker layers and reducing procedure time. ***Aim:*** To assess the clinical time of the novel material, Surefil One (SuO), against the conventional composite, Neo Spectra (NS), in cervical cavities. ***Materials and Methods:*** Fifty-four cervical cavities were prepared and divided into right and left sides in a split-mouth design, and one side was filled with SuO and the other side received NS. Operatory time (Minutes) was measured and compared between both materials, starting from cavity preparation and terminating after polishing was done, utilizing a stopwatch. ***Results:*** SuO showed a lower mean clinical time than NS. ***Conclusion:*** Utilizing a material that has both advantages of being self-adhesive and bulk-filled reduces the chairside time. ***Recommendation:*** Further long-term clinical studies are warranted to assess the stability and clinical performance of this material.

Keywords: Surefil One, Self-Adhesive, Bulk-Fill, Nano-Hybrid, Operatory Time

INTRODUCTION

The pursuit of simplifying restorative procedures without compromising quality, but rather enhancing the outcomes has remained a constant endeavor. This ongoing quest is evident in the periodic release of new technological advancements by dental material manufacturers. A clear reflection of this continuous pursuit can be observed in the research and development efforts dedicated to adhesive systems.

In recent times, significant progress has been made in the field of adhesive dentistry. This advancement can be attributed to a deeper comprehension of the principles and limitations associated with bonding to dental substrates, as well as remarkable breakthroughs in the chemistry, composition, and technology of dental adhesive systems.

1-Postgraduate Researcher, Restorative Dentistry Department, Faculty of Oral & Dental Medicine, Misr International University, Cairo, Egypt.
2-Lecturer of Restorative Dentistry, Restorative Dentistry Department, Faculty of Oral & Dental Medicine, Misr International University, Cairo, Egypt.
3-Associate Professor of Restorative Dentistry, Restorative Dentistry Department, Faculty of Oral & Dental Medicine, Misr International University, Cairo, Egypt.
4-Professor of Conservative Dentistry, Conservative Dentistry Department, Faculty of Dentistry, Cairo University, Cairo, Egypt.

There has been a notable shift in the dental industry, moving away from complex, multi-component bonding and restorative systems that rely solely on chemical-set processes. Instead, there is a growing preference for simplified adhesive systems that are easier to apply and require fewer bonding steps. To meet the demand for time-efficient chairside treatments, recent developments have led to the introduction of commercially available restorative materials, including low-shrinkage, bulk-fill, and self-adhesive resin-based materials. These materials have been specifically developed with the goal of simplifying restorative procedures and reducing treatment time.[1]

Composite resins have undergone significant advancements, with manufacturers focusing on improving their composition, filler particles, and light-curing properties. These modifications aim to enhance the overall performance and longevity of dental restorations.[1] However, a persistent challenge remains: the contraction of the material during the hardening process. This polymerization shrinkage can lead to various clinical issues, including tooth sensitivity, marginal staining, and recurrent decay.[2]

Consequently, the conventional incremental technique has become the favored choice among dentists aiming to minimize or prevent such issues. Nevertheless, despite its widespread adoption, the incremental technique is not without its own set of challenges. One of the primary concerns revolves around the time-consuming nature of completing larger volume restorations,[3] as well as the possibility of incorporating voids within the restoration.[4] To address these issues and further streamline restorative procedures, the industry has introduced bulk-fill resins. These innovative materials allow for the efficient placement of thicker increments, typically around 4 to 5 mm in thickness, without compromising their mechanical properties.[5,6] The reports from clinical evaluations of bulk-fill resins have shown great promise, indicating their potential to simplify and expedite restorative procedures while maintaining satisfactory outcomes.[7,8]

Composite restoration plays a crucial role in the treatment of cervical cavities due to its numerous advantages and the unique challenges posed by these types of cavities. Cervical cavities, also known as Class V cavities, occur at or above the cemento-enamel junction or root surface of the tooth, making them highly visible and susceptible to various factors such as abrasion, erosion, abfraction, and stress.[9] Furthermore, it is

proposed that the development and progression of carious cervical issues result from the synergistic effect of naturally produced acids by bacteria, which act on a compatible substrate.[10]

A significant gap in knowledge exists regarding the clinical time efficiency comparison between self-adhesive bulk fill and conventional composite materials**.** While numerous studies have explored their mechanical properties and clinical outcomes, direct comparisons of chairside time consumption are relatively scarce. This lack of data hinders dental practitioners in making informed decisions about material selection based on time efficiency, a crucial factor in practice management. Comprehensive research is needed to accurately quantify the time savings offered by self-adhesive bulk fill composites compared to their conventional counterparts.

PATIENTS AND METHODS

Study Design, Study Setting, Ethical Approval and Trial Registration

The current study is a split-mouth design aiming to compare the restorative materials with standardized factors. This study was conducted at the clinic complex of Misr International University. The study commenced on the 27th of October 2022 and ended on the 26th of April 2024. Teeth in participants with cervical lesions were randomly assigned into two (right/left) groups (n=27). All procedures were explained to participants and written informed consent was obtained prior to trial commencement. Ethical approval was obtained on 22nd of October 2022, prior to the commencement of the study. The study was approved by the Ethical Committee, Misr International University, with IRB number: MIU-IRB-2223-177. This clinical trial is reported according to the CONSORT guidelines 2010. The protocol of this study was registered on clinical trials (www.clinicaltrials.gov) with ID number: NCT06394440.

Sample Size Calculation

This power analysis used color match scores after six months as the primary outcome. According to Perdigão J et al. in 2012, the percentages of Alpha scores were 81.5% and 100% in the two groups, respectively. Using an alpha (α) level of (5%), power = 80%; the effect size (w) was 0.476, and the minimum estimated sample size was a total of 43 restorations. Sample size was increased to a total of 54 restorations to compensate for a drop-out rate of 25%. Sample size calculation was performed using G8Power Version 3.1.9.2.[11]

Randomization

Simple randomization for treatment allocation was carried out using website-generated randomization (www.randomizer.org) for treatment assignment for the right teeth. The left teeth received the alternate restoration. The random number sequence was generated by an independent contributor (R.H.)[1] who was not related to the study. The random number generated was only disclosed to the principal investigator (operator) before the placement of the restoration procedure.

Eligibility Criteria:

Inclusion Criteria:

Patient-related Factors: adult patients aged 18-60 years with at least two cervical lesions, able to tolerate required restorative procedures, and can provide informed consent.

Tooth-related Factors: anterior or posterior teeth with vital cervical lesions of at least 1 mm in depth; to include enamel and dentin, and no more than 3 mm. The presence of teeth to be restored in occlusion and normal periodontal status.

Exclusion Criteria:

Patient-related Factors: medically compromised patients, as they will not be able to attend multiple appointments or may require special management; pregnant women as radiographs cannot be taken for them; allergy to any of the restorative materials, including anaesthetics; uncooperative patients who will not abide by the instructions or attend the appointments; extremely poor oral hygiene; heavy bruxism, which was evaluated through the dental history during the patient interview.

Tooth-related Factors: Teeth showing signs of pulpitis or periapical pathosis. Carious cervical lesions extending to proximal surfaces. Carious cervical lesions on the palatal/lingual surfaces, teeth with root caries, and endodontically treated teeth.

Materials

Materials used in this trial are summarized in **Table (1)**.

Procedures

The clinical procedures were done by the principal investigator, which was initiated by scaling and polishing of the teeth. Cavity preparation was done using a 330 Carbide bur (Meisinger GmbH, Germany) using a high-speed handpiece (Pana Air, NSK, Japan) with copious water spray rotating at a speed ranging from 380,000-450,000 rpm. to achieve a proper outline of the cavity.[12] Enamel margins of all cavities were beveled

[1] Reham Hesham, Resident, Restorative Dentistry Department, Misr International University.

approximately 1-1.5 mm at the incisal aspect. Beveling was performed using a diamond red-coded fine grit finishing instrument (Meisinger GmbH, Germany). **(Figure 1)**

(Meisinger Dental Burs, GmbH, Germany) and a sharp excavator (Dentsply® Maillefer, Switzerland) until only healthy dentin remained.[13] A dry retraction cord (Ultrapak

Table (1): Materials Description, Composition, Manufacturer and Lot Number.

Brand Name and Description	Composition	Manufacturer	Lot Number
Neo Spectra ST HV (Nano hybrid) Composite	Methacrylate modified polysiloxane (organically modified ceramic) dimethacrylate resins, ethyl-4 (dimethylamino) benzoate, and bis(4-methyl-phenyl) iodonium hexafluorophosphate. Filler load: 78–80% by weight: Spherical, pre-polymerized SphereTEC fillers ($d_{3,50} \approx 15$ µm), non-agglomerated barium glass and ytterbium fluoride.	Dentsply, Konstans, Germany	Shade A2: 2109000073 Shade A3: 2203000642
Prime&Bond Universal Adhesive (Selective-Etch Mode)	PENTA (dipentaerythritol pentacrylatephosphate), 10-MDP (10-methacryloyloxydecyldihydrogen phosphate), Active GuardTMTechnology crosslinker.	Dentsply, Konstans, Germany	2204000699
Meta Etchant (37% Phosphoric Acid Etching Gel)	Phosphoric acid, H_2O,Xanthum Gum	Meta Biomed, Chungcheongbuk-do, Korea	MET2301021
Surefil One (Self-adhesive Bulkfil Composite)	**Powder:** Silanated aluminum-phosphorus-strontium-sodium-fluoro-silicate glass, dispersed silicon dioxide, ytterbium fluoride, and pigments **Liquid:** acrylic acid, polycarboxylic acid, bifunctional acrylate, self-cure initiator, camphorquinone, and stabilizer	Dentsply, Konstans, Germany	Shade A2: 2205000565 Shade A3: 2206000300

In accordance with American Dental Association (ADA) recommendations, decayed tooth material was eliminated using a sterile low-speed round carbide bur

CleanCut Size 00, Ultradent Products, Cologne, Germany) without a hemostatic agent was used to gently displace the gingiva and provide access to the subgingival or

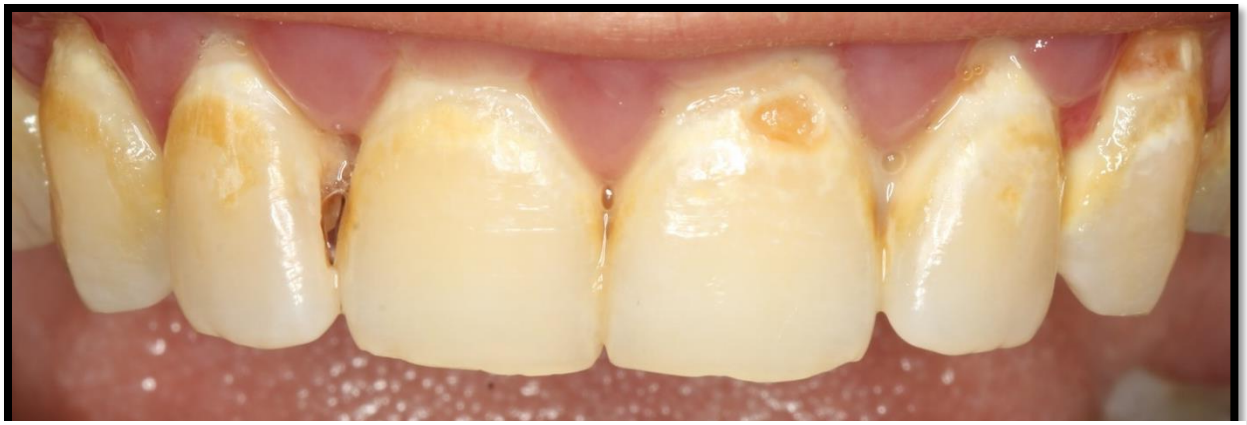

Figure (1): Cervical caries in upper central incisors, right canine and left lateral incisor.

intrasulcular preparation margins. Rubber dam (Sanctuary, Perak, Malaysia) isolation was done using a multiple-teeth isolation sequence. Clamps to retract gingival tissues around cervical cavities were Brinker #4 and Clamp #9 (Coltene, Switzerland). **(Figure 2)**

Dental; Pistoia, Italy) and mixed for eight seconds, followed by its application in cavities that were allocated to receive SuO. Excess material was removed using composite sculpting instruments (#1051/109 and #1051/15, Carl Martin GmbH,

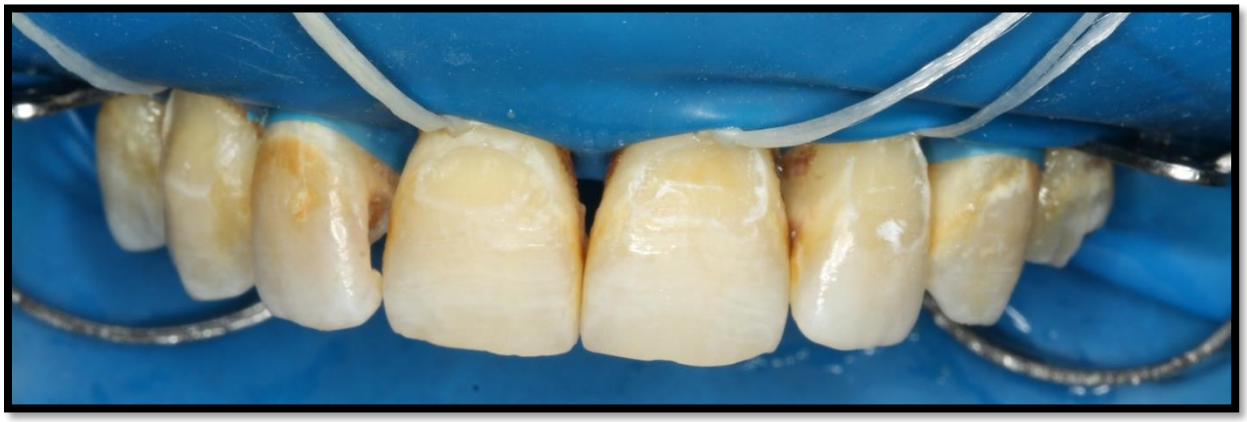

Figure (2): Cavity preparation & rubber dam isolation.

Cleaning of the cavities was done using an air-water spray, leaving a moist appearance. Restorative procedures started by using the left/right eligible teeth to fill with either Surefil One (SuO) or Neo Spectra ST HV (NS). The SuO capsule was put in the Linea Tac 400/M automatic mixer (ATS

Germany), a layer of modeling resin was applied (Signum Liquid; Kulzer, Hanau, Germany) on the top of the self-adhesive composite, and restoration was cured using 1200 mW/cm^2 LED Light Curing unit (Woodpecker, China) for 20 seconds following manufacturer's instructions. The

curing light was calibrated with a radiometer prior to each restoration, and its output was verified every 10 applications.

The alternative teeth that were to receive NS were etched using 37% Phosphoric Acid utilizing the 'Selective-etchig' protocol; enamel margins were only etched for 15 seconds. The 10-MDP containing universal adhesive Prime&Bond (Dentsply, Konstans, Germany) was used in two coats to ensure proper bonding on dentin and enamel.[14] Light curing of the adhesive was done for 20 seconds following the manufacturer's instructions. The nanohybrid composite (NS) was then placed incrementally, and the ch applied increment.

Restorations on both sides were finished using an extra fine grit yellow-coded needle stone (Meisinger GmbH, Germany). Two-step polishing of both restorations was done simultaneously using the pre-polishing and the high polishing brushes of Eve Diacomp Twist Plus (Eve, Germany) under intermittent water spray to attain a smooth glossy appearance of both restorations **(Figure 3)**. Participants were given a follow-up appointment and instructed to report any pain or concerns about the restoration to the principal investigator.

Outcome

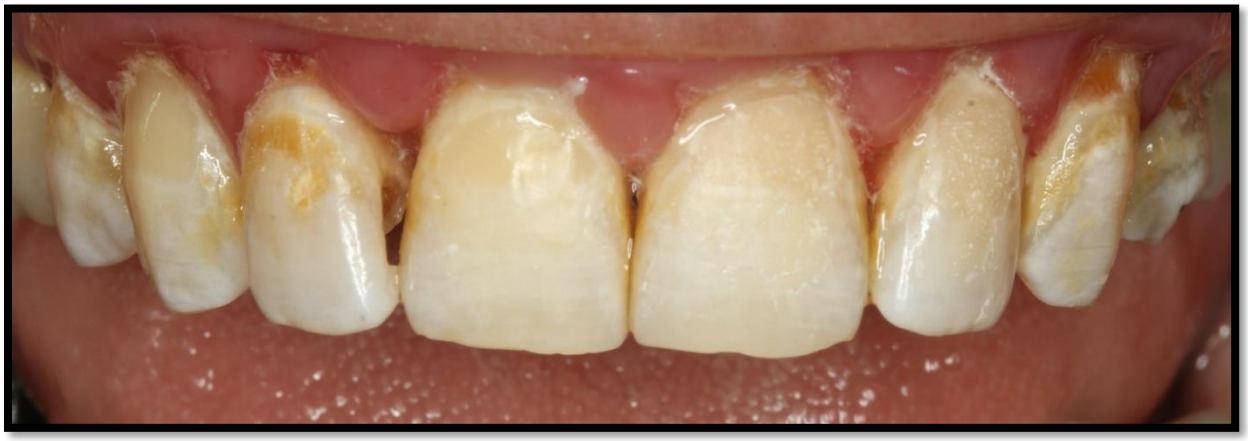

Figure (3): Post-operative (Right side restored by NS & Left side restored by SuO).

increment thickness did not exceed two millimeters. Each increment was coated with a layer of the modeling resin to ensure a smooth surface and to prevent the composite from sticking to the sculpting instruments.[15] Light curing was done for 20 seconds for ea-

This study aimed to determine how long it took to repair dental cavities near the cervical lesions using a self-adhesive bulk fill dental material (Surefil One) against the nanohybrid composite (Neo Spectra) using a stopwatch. The goal was to see if using the

self-adhesive material could save time by eliminating the separate steps of etching and applying a bonding agent, which are typically needed with traditional composites.

In order to determine the clinical efficiency of the self-adhesive bulk fill composite. Time was measured for various lapses in minutes.

Lapse (1): Cavity preparation of all cervical cavities.

Lapse (2): Rubber dam isolation.

Lapse (3): Adhesive steps accompanied by the placement of the nanohybrid composite.

Lapse (4): NS placement and curing of each increment.

Lapse (5): SuO placement and curing.

Lapse (6): Finishing procedure.

Lapse (7): Polishing procedures.

The total time was calculated and documented for comparisons between the tested materials.

Statistical Analysis

Numerical data underwent examination for normality through the assessment of data distribution and the application of normality tests (Kolmogorov-Smirnov and Shapiro-Wilk tests). The data exhibited a normal (parametric) distribution. Data were expressed as mean and standard deviation (SD).

A paired t-test was employed to compare operation times between the two groups, with the significance level established at $P \leq 0.05$. Statistical analysis was conducted using IBM SPSS Statistics for Windows, Version 23.0, by IBM Corp. located in Armonk, NY.

RESULTS

A total of 54 cervical restorations were placed and were preliminarily inspected for their clinical time, starting from cavity preparation until polishing was tackled. The outcome of the study was summarized and tabulated in **table (2)**.

Surefil One showed statistically significantly lower mean operation time than Neo Spectra (P-value <0.001, Effect size = 0.872) **(Figure 4)**.

Table (2): Mean, standard deviation (SD) values and results of paired t-test for comparison between operation times (minutes) in the two groups.

Surefil One (n = 27)		Neo Spectra (n = 27)		*P*-value	*Effect size (d)*
Mean	**SD**	**Mean**	**SD**		
30.9	**7.6**	**37.5**	**7.7**	**<0.001***	**0.872**

**: Significant at P ≤ 0.05*

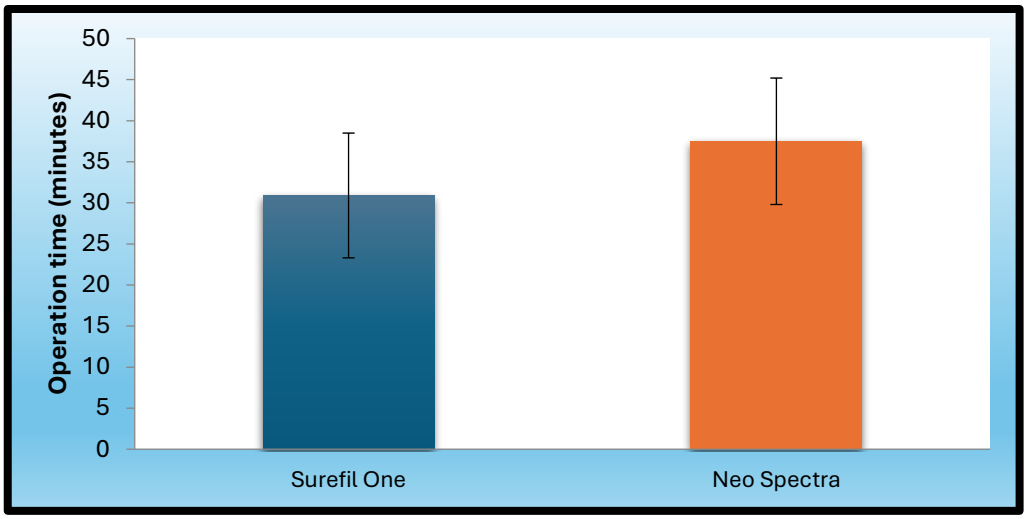

Figure (4): Bar chart representing mean and standard deviation values operation times in the two groups.

DISCUSSION

The development of self-adhering restorative materials (self-adhesive resin composites) for self-etch adhesives and self-adhesive resin cements can be attributed, in part, to advancements in the chemistry of acidic functional groups. Initially, acidic functional monomers were incorporated into self-etching adhesives as ligand components, facilitating a chemical interaction with the hydroxyapatite present in dental hard tissues.[16]

MOPOS, a modified polyacid, is the crucial element in Surefil One. Its unique structure and characteristics enable innovative formulations for creating a self-adhesive restorative material. MOPOS plays a significant role in promoting adhesion to tooth structure and facilitating network formation, thereby enhancing the mechanical strength of the material. In contrast to conventional methods that involve modifying polyacids with hydroxyethyl-methacrylate (HEMA) in a manner that is not resistant to hydrolysis, MOPOS offers a hydrolytically stable alternative.[17]

The step-by-step application of composite resin in layers of ≤2 mm thickness has been recommended to reduce shrinkage stress, enhance the degree of conversion, prevent breakdown at the restoration margin, and ensure satisfactory aesthetics. Despite its benefits, this incremental approach to applying resin composite is known to be time-intensive, particularly when dealing with larger cavities, and it poses a risk of contamination. Additionally, this method leaves room for unintentional air entrapment between sequential layers, potentially leading to adhesive failure between these layers. The

difficulties associated with incremental layering have spurred the creation of bulk-fill composite materials that can be applied in layers ranging from 4 to 5 mm in thickness. This innovation presents advantages such as decreased treatment duration, lowered volumetric shrinkage stress, enhanced curing depth, and the preservation of desired micromechanical properties.[18]

Surefil One's unique advantage lies in its ability to chemically bond directly to tooth structure, eliminating the need for separate etching and bonding steps required by traditional composite materials. This chemical adhesion mechanism significantly simplifies the restorative process, contributing to a reduced clinical application time. By bypassing these additional procedures, separate etching and bonding, dental professionals can achieve efficient and effective restorations, ultimately saving valuable chair time. Moreover, being a bulk fill material offers a significant advantage in terms of time efficiency.

One goal of the current randomized clinical trial was to assess the average time required to utilize a restoration using composite resin in cervical cavities using two technological innovations, self-adhesive and bulk-fill composite resin. While it intuitively appears reasonable that restorations utilizing bulk-fill composite resin would be carried out more swiftly, up to this point, there has only been in vitro evidence and one clinical trial supporting this claim.[3,19] As a result, there was no sufficient means of determining the potential time savings in completing entire procedures, encompassing rubber dam isolation, adhesive system application, finishing, and polishing in vivo, aspects that were not assessed in the in vitro study mentioned but were scrutinized in this investigation. It is crucial to mention that the in vivo study done measured the time of a conventional bulk-fill composite without the self-adhesive property. [19] This study took into account the necessity to calculate the time required to accomplish the entire restoration process and test the self-adhesive technology added to the bulk fill material.

In this study, utilizing a self-adhesive bulk-fill composite required an average duration of 30.9 ±7.6 minutes in clinical settings. In contrast, the conventional procedure, involving the use of traditional composite resin applied through the incremental technique, along with a universal adhesive system and selective etching of the enamel, necessitated an average time of 37.5 ±7.7 minutes. This outcome was in accordance with Tardem et al. in 2019 and Vianna-de-Pinho in 2017.[3,19]

CONCLUSION

Within the limitations of this study, the findings demonstrate that utilizing Surefil One resulted in a significantly reduced treatment time compared to the conventional incremental layering technique with a nano-hybrid composite. These results suggest that Surefil One has the potential to optimize clinical workflow and improve patient satisfaction.

RECOMMENDATIONS

Further long-term clinical studies are warranted to evaluate the durability and clinical performance of this material.

FUNDING

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CONFLICTS OF INTEREST

The author declares no conflict of interest.

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