Faculty of Dentistry
The British University in Egypt

Clinical Performance of a Novel Self-cured Resin Composite Compared to a Light-cured Bioactive Resin Composite Restoration in Proximal Cavities of Posterior Teeth: A 2-year Randomized Controlled Clinical Trial

الأداء السريري لمركب راتنج جديد ذاتي التصلب مقارنة بمركب الراتنج النشط حيوياً و المُصلّب ضوئياً في التجاويف البينية للأسنان الخلفية: دراسة سريرية عشوائية منضبطة لمدة عامين

Protocol submitted to the Operative Dentistry Department
Faculty of Dentistry, The British University in Egypt
for partial fulfillment of the requirements for the Master's Degree in Operative Dentistry

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Faculty of Dentistry
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I. Administrative information:

1. Title:

Clinical Performance of a Novel Self-cured Resin Composite Compared to a Light-cured Bioactive Resin Composite Restoration in Proximal Cavities of Posterior Teeth: A 2-year Randomized Controlled Clinical Trial

2. Protocol Registration:

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3. Protocol version:

Original scientific research (Clinical Trial)

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II. Introduction:

Dental caries is a complex multifactorial disease characterized by cycles of demineralization and remineralization. According to the WHO; dental caries is considered as a major public health problem globally affecting almost 2 billion people with permanent teeth and 510 million children with deciduous teeth. The prevalence of the disease varies across different regions with the higher percentage observed in less developed countries. (Warreth)

The development of dental caries is multifactorial mainly due to the presence of 4 elements which are: dental biofilm (plaque), fermentable carbohydrates (glucose, fructose, sucrose), dental hard tissue and time. Other additional social and environmental factors can have a substantial impact on the onset and course of the disease. Dietary habits, oral hygiene, salivary flow and fluoride exposure are key factors that influence the susceptibility to dental caries. If dental caries is properly managed, it is a preventable and reversible disease. (Warreth)

The occlusal and proximal surfaces are the most susceptible sites for demineralization from the acidic byproducts. Proximal carious cavities are carious lesions that develop on the smooth surfaces between adjacent teeth often known as interproximal surfaces. Due to their hidden location, these cavities are often discovered by the aid of radiographic investigation especially bite wing radiographs. (Tuculina)

Resin-based composite (RBC) was first introduced by Dr. Rafael Bowen in the late 1950s. The bonding concept along with the invention of the resin matrix; bisphenol A-glycidyl methacrylate; known as Bis-GMA in 1962 were both major breakthroughs in the modern esthetic dentistry. It quickly became a widely used restorative material in modern dentistry especially known for its outstanding aesthetics and high mechanical properties. The beginning of RBC was composed of a combination of an organic polymer matrix, inorganic filler particles with the addition of a coupling agent to enhance bonding and durability. (Ferracane)

Organic matrix is made of monomers that bond into polymers and form a three-dimensional network due to polymerization. This network is filled with fillers to improve its physical and mechanical properties. Filler materials include either glass, quartz particles or fused glass particles. An organic- nonorganic adhesive is added to

the filler particles with the nonorganic end of the molecule tends to bond with the fillers and the organic end of the molecule tends to bond with the resin matrix unifying the whole chemistry of the composite material. (Milosevic)

Initially, the traditional dental composite materials were two-part paste systems with one containing a peroxide initiator and the other an amine activator. The 2 pastes were mixed to result in polymerization in minutes through an auto or self-curing process. Later on in the 1970s, light-curing technology was introduced to improve the curing process by enabling better handling and manipulation of the material. Ultraviolet light was first utilized as an activator for sealants and composites containing benzoin methyl ether eliminating the need to mix two pastes and without the requirement to place the composite material within a confined working time. Ultraviolet light was later replaced by visible light activation technology for curing dental composites due to limitation in depth of penetration of UV light as well as risk of overexposure to relatively high- intensity UV radiation. (Ferracane)

In modern restorative dentistry, clinicians always seek solutions that streamline procedures, improve outcomes and reduce chair time for patients. Traditional light-cured composite systems often involve a complex seven step process which includes etching, priming, bonding and curing which consumes from 90 to 120 seconds to be completed. With each additional step, the risk of technique errors increases, potentially compromising the longevity of the restoration. Self-cure composites, with their simplified application process, are emerging as a preferred choice over the traditional seven-step composite materials. (Logurecio)

Recently, a novel self-cured bulk-fill restorative material has been introduced into the market (Stela, SDI, Victoria, Australia). It is offered in two application forms (Stela Automix & Stela Capsule) that is used in combination with a proprietary adhesive primer (Stela Primer), which does not require light curing, but it undergoes polymerization upon contact with the restorative material in addition to its ability to generate minimal shrinkage stresses. (Logurecio)

Monitoring dental restorations and their performance throughout life is very important but uneasy to undertake. Today, the main difficulty is defining accurate and reliable indicators that help in making right decisions. The FDI criteria is a standardized evaluation system developed by the Fédération Dentaire Internationale to comprehensively assess direct and indirect dental restorations. The criteria are

divided into three main domains: aesthetic, functional, and biological, with multiple specific parameters under each category to evaluate the restoration's clinical performance. (Maillet)

Therefore; the aim of this randomized controlled clinical trial is to evaluate the clinical performance of self-cured composite (Stela, SDI, Australia) in comparison to light-cured bioactive nanohybrid composite (Beautifil II, Shofu, Japan) regarding proximal contact tightness (F3) and post-operative hypersensitivity as primary & secondary outcomes respectively using the FDI criteria in adult population with proximal carious cavities in posterior teeth over 2 years. The null hypothesis tested is that in proximal cavities of posterior teeth, there is no significant difference in clinical performance between self-cured composite and light-cured nanohybrid composite restorations.

III. Review of literature:

Loguercio et al., 2025 executed an 18-month multicenter double blind randomized clinical trial to evaluate the clinical performance of self-cured bulk-fill composite (Stela Automix & Stela Capsule, SDI) in comparison to a light-cured bulk-fill composite (Filtek One Solventum, 3M). The clinical trial involved 55 participants with a total of 165 class I & class II posterior restorations divided into two groups. The self-cured composite groups received Stela Primer followed by either Stela automix or capsule forms while for the light-cured group, the cavities received Scotchbond Universal adhesive followed by Filtek One composite. The restorations were evaluated at the baseline, after 12 and after 18 months using the updated FDI criteria. The results revealed at the 12-month recall, 17 restorations exhibited marginal staining with no differences between groups. Regarding surface luster & texture, 30 restorations were considered clinically good with a significant favoring toward the light-cured group and for color match 32 restorations were rated as good with a significant result favoring both self-cured composite groups. At the 18-month recall, the restorations were rated as good; 22 for surface luster & texture, 27 for marginal staining & 40 for color match. The study's authors concluded that the self-cured bulk-fill composite (Stela) either in automix or capsule forms showed comparable biological and functional performance to the light-cured composite and can be considered as a reliable alternative for posterior restorations.

Guarneri et al., 2025 conducted an in vitro study to evaluate the degree of conversion (DC) and polymerization kinetics of a new self-cure bulk-fill resin-based composite (Stela Automix, SDI). The study was divided into 7 groups (1) Stela Primer (2) Stela Automix (3) Stela Automix exposed to light for 20 secs (4) Stela Primer with Stela Automix (5) Stela Primer with Stela Automix exposed to light for 20 secs (6) Scotchbond Universal with Stela Automix (7) Scotchbond Universal with Stela Automix exposed to light for 20 secs. The real time reaction rates and DC at the bottom of 2mm thick specimens were measured at 720 secs after insertion using a spectrophotometer. The results concluded that the highest DC rate at 2mm depth was achieved when Stela Primer was used in combination with Stela Automix. On the contrary, exposing Stela to light for 20 secs didn't improve the final DC of Stela as much as using the Stela Primer.

Pires et al., 2025 evaluated the bonding performance of a novel self-curing restorative system (Stela, SDI) compared with a conventional light-cured resin

composite (Ceram.X ONE, Dentsply Sirona) applied on dentin in both etch & rinse (ER) and self-etch (SE) modes. The study's specimens were divided into 2 groups, each group contained of 10 class I prepared cavities in sound dentin and were restored using the two materials. Ceram.X ONE group was used in combination with a universal adhesive system (Prime & Bond Universal, Dentsply Sirona) while Stela group was used along with its adhesive primer. Half of the specimens from each group were bonded in ER or SE mode. The specimens underwent micro-tensile bond strength testing after 24 hours storage in artificial saliva. The results exhibited that both groups in ER mode achieved comparable results (35.8 MPa for Ceram ; 33.6 MPa for Stela). On the other hand, in SE mode Ceram group showed significantly lower bond strength compared with Stela. The researchers concluded that the new self-curing material (Stela , SDI) either used in ER or SE mode represents a promising clinical option to provide adequate interfacial adaptation and strong bonding to dentin.

Laporte et al., 2025 conducted an in vitro study to investigate the performance of the new self-curing restorative material (ST: Stela, SDI) compared to two conventional light-cured composites (TE: Tetric Evoceram, Ivoclar Vivadent & CM: Clearfil Majesty, Kuraray Noritake Dental). The study evaluated compressive strength, mineral deposition, porosity and wettability. The data was statistically analyzed through one-way and two-way analysis of variance (ANOVA). The results revealed higher compressive strength for ST than TE and CM at the baseline and after aging while fracture mode analysis showed brittle fractures for TE and CM whereas ST fractured in multiple smaller fragments. Wettability testing showed that ST had the lowest contact angle compared to TE and CM. Examination by scanning electron microscopy revealed cubical-like crystalline formations on ST's surface indicating some level of bioactivity whereas no changes were observed for TE & CM. The authors concluded that Stela demonstrated promising results across several parameters encouraging it to be a potential candidate for long lasting restorative applications.

Raghip et al., 2025 executed a double-blind split-mouth randomized clinical trial to compare the performance of a bioactive ionic resin restorative (Activa Bioactive-Restorative) to a conventional bulk-fill composite (Filtek One Bulk-fill Restorative) in class I restorations. The clinical trial involved 22 patients who required the restoration of bilateral posterior teeth with ICDAS score 5 lesions. Cavity preparation included selective caries removal and selective enamel etching protocol followed by the adhesive application. A total of 44 restorations were done; 22 used Activa Bioactive Restorative and 22 used Filtek One Bulk-fill Restorative. The study was

evaluated by using modified FDI criteria and the follow up was conducted at 3, 6, 12 and 24 months. The results showed no statistically significant differences were observed between groups at the 3,6 and 12 months recalls and both materials showed excellent performance across all parameters with no failure or secondary caries over the 24-month period. The only significant differences identified were regarding surface luster, occlusal wear and anatomical form at the 24-months follow up in favor of Activa Bioactive group. The authors concluded that bioactive restorative materials exhibit similar performance to a traditional bulk-fill composite showing improved long-term stability and can be considered as a strong alternative for posterior restorations.

Loguercio et al., 2024 performed a multicenter double blind randomized clinical trial to evaluate the clinical performance of a new chemically cured bulk-fill composite (Stela Automix & Stela capsule, SDI) in comparison to a light-cured bulk-fill composite (Filtek One, 3M) over a span of 6 months. The clinical trial included 55 participants (20 males & 35 females) with at least 3 posterior teeth in need of restorations. A total of 165 restorations were performed either on class I or class II cavities and the participants were evaluated for spontaneous and stimulated post-operative hypersensitivity (POS) in the base line, after 48 hours, 7 days & finally at 6 months. Each of the restorations was assessed using the updated version of FDI criteria after 6 months. The researchers concluded that chemically cured composites exhibit much lower POS and less color mismatch in comparison to a light-cured bulk-fill composite after a service of 6 months. The study's clinical significance showed that chemically cured composites appear to be an appealing option for restoring posterior teeth.

Akalin et al., 2023 evaluated the clinical performance of low-shrinkage bioactive resin composite employing Giomer filler technology (Beautifil II LS, Shofu, Japan) in comparison to a conventional nanohybrid resin composite (Clearfil Majesty Posterior, Kuraray, Japan). The authors included a total of 35 participants (18 males & 17 females) which received randomly 35 pairs of fillings restored with either of the two resin composites in class I and II cavities. The restorations were evaluated by two calibrated operators 2 weeks after placement (baseline), at 6 months, at 1 and 2 years using FDI criteria. Data were analyzed using the McNemar test. In both groups, the restorations were rated the best scores (Score 1 & 2) for biological, functional and esthetic parameters. The authors concluded that no fracture, endodontic or hypersensitivity- related complications were observed. Only one restoration from the

nanohybrid composite group showed a small secondary carious lesion that didn't require intervention and was only monitored and one restoration from the low shrinkage Giomer resin composite group showed retention loss. Over the 2-year follow up, both the Giomer and the nanohybrid resin composite restorations' performance was clinically acceptable.

Jacob et al., 2023 conducted an in vitro study to compare the microleakage of two low shrinkage resin composite materials in class II cavities using stereomicroscope. A total of 34 extracted non-carious teeth were randomly divided into two groups; each group included 17 teeth which were restored with either (Filtek Bulkfill, 3M) in bulkfill technique or (Beautifil II LS, Shofu) . Class II cavities were prepared followed by etching and bonding steps in each tooth and then restored following the manufacturer's instructions. The samples were thermocycled, immersed in 1% methylene blue for 24 hours and then finally were sectioned into two halves mesiodistally using a diamond disc at low speed. All the samples were examined under a stereomicroscope at x10 magnification. The results were examined using Mann-Whitney U-test which displayed a statistically significant higher mean rank among Filtek bulk-fill group. The authors concluded that Beautifil II LS resin composite showed less microleakage than Filtek bulk-fill posterior resin composite therefore it can be successfully used with increased longevity.

Pallesen et al., 2015 executed a randomized clinical trial to evaluate the durability of 3 conventional resin composites in class II restorations over a span of 27 years. The study included 30 participants (25 females & 5 males) with age range 25-63 who received at least 3 class II restorations. The 3 cavities were chosen randomly to be restored with chemically cured composite (Clearfil Posterior) and two light-cured composites (Adaptic II) and (Occlusin). The evaluation was done using modified USPHS criteria which were anatomical form, marginal adaptation and discoloration, color match and surface roughness at baseline, 2, 3, 10 and 27 years. The results showed that the overall success rate was 56.5% (55.2% for Adaptic II group), (63% for Clearfil Posterior group) and (51.7% for Occlusin group) with an annual failure rate of 1.6%. It was concluded that the chemically cured bulk-fill resin composite restorations showed lower failure rates than the light-cured composite restorations.

Pallesen et al., 2015 evaluated the durability of 3 conventional resin composites in class II restorations in a randomized clinical trial over a period of 30 years. The study involved 30 participants (21 females and 9 males), each received at least 3 class

II restorations of moderate size. The cavities were restored with 2 chemically cured resin composites (P10, Miradapt) and one light-cured resin composite (P30). Bulk placement was done for the chemically cured group while the light-cured composite resin was inserted in increments. The restorations were evaluated using USPHS criteria at baseline, 2, 3, 5, 10, 15, 20 and 30 years. Results showed that the 3 conventional resin composites showed good clinical performance during the 30-year evaluation period but the chemically cured resin composite showed better performance and less failure rate than the light-cured composite.

IV. Objectives:

Aim of Study:

The aim of this randomized controlled clinical trial is to evaluate the clinical performance of novel self-cured composite (Stela, SDI, Australia) in comparison to light-cured bioactive nanohybrid composite (Beautifil II, Shofu, Japan) regarding proximal contact tightness and post-operative hypersensitivity in proximal cavities of permanent posterior teeth over a span of 2 years.

PICOTs Elements

P: Adult population with class II proximal cavities in posterior teeth
I: Novel Self-cured resin composite
C: Light-cured bioactive nanohybrid resin composite
O1: Proximal contact tightness
O2: Post-operative hypersensitivity
T0: Baseline (After 1 week)
T1: After 6 months
T2: After 12 months
T3: After 18 months
T4: After 24 months

Research question:

In proximal cavities of posterior teeth, do self-cured composite restorations provide similar or better clinical performance than bioactive nanohybrid light-cured composite restorations?

V. Materials & Methods

Materials:

The following materials will be used:

1) Stela self-cured resin composite (SDI, Australia) (capsule form)
2) Beautifil II light-cured nanohybrid resin composite (Shofu, Japan)
3) Beautibond Universal adhesive (Shofu, Japan)
4) Stela Primer (SDI, Australia)

Methodology:

Type of Study: Randomized Controlled Clinical Trial

A- Participants, interventions & outcomes

1) Sample size calculation

The sample size was calculated based on a previous study by T. Toz-Akalin et al., 2023 in which success rate of nanohybrid composites in proximal posterior restorations was 96.6% after 2 years. By implementing a two tailed Z test for difference between two independent proportions with an alpha level of 5% and a power of 80%. The minimum sample size needed was 25 per group in order to detect a difference of 30%. Sample size was increased by 15% to compensate for possible dropouts to reach 29 teeth per group. Sample size was performed using G*Power version 3.1.9.2 for windows.

Statistical analysis:

Data will be analyzed using Medcalc software, version 22 for windows (MedCalc Software Ltd, Ostend, Belgium). Categorical data will be described as frequency and percentage. Intergroup comparisons between categorical variables will be performed using the chi square test, while intragroup comparisons within each intervention will be performed using Cochran's Q test followed by pairwise multiple comparisons. A p-value less than or equal to 0.05 will be considered statistically significant and all tests will be two tailed. Statistical power of the study will be set at 80 % with 95 % confidence level.

Study settings:

The patients will be enrolled from the outpatient clinic of the Conservative Dentistry Department, Faculty of Dentistry, The British University in Egypt.

2) Eligibility criteria

Inclusion Criteria of Participants

1. Subjects between the ages of 18-47 years old
2. Primary caries removal
3. Good or moderate oral hygiene
4. Free of periodontal diseases (probing depth and attachment levels within normal limits/ no furcation involvement/ no mobility)
5. Cooperative patients who agree to keep the scheduled recall appointments for data collection and maintenance

Exclusion Criteria of Participants

1. Composite or amalgam removal
2. Caries extended to the cemento-enamel junction in Class II caries
3. Grade II or III mobility
4. Considerable periodontal disease without treatment
5. Endodontically treated teeth with extensive loss of tooth tissues
6. Severe wear facets and/or parafunctional activities as clenching or nocturnal bruxism.
7. Subjects who are pregnant during the duration of the study
8. Subjects with high caries activity

3) Ethical Considerations (Informed Consent)

The principal investigator will explain the trial to the patients. The operator will discuss the interventions and possible harms with patients on the enrollment day, and obtain written consent (in Arabic) from the patients willing to participate in the trial, and collect it from them. An appendix of the consent form is attached to the protocol.

4) Recruitment:

Patients will be enrolled from the outpatient clinic of the Conservative Dentistry Department, Faculty of Dentistry, The British University in Egypt after explaining the benefits from the research; from which eligible patients will be recruited to fulfill the eligibility criteria until the target population is achieved.

B- Assignment of interventions

5) Randomization and Allocation of Participants:

Sequence generation (Randomization)

Co-supervisor (A.G) will perform simple randomization; numbers will be generated from 1:58 deciding which tooth to receive which intervention in each patient using online software available at www.sealedenvelope.com.

Allocation concealment mechanism

Sequence generation will be concealed using opaque sealed envelopes. Operator S.W will choose between numbers arranged by M.M who will not be involved in any clinical phase.

6) Implementation

M.M will perform sequence concealment. S.W and M.M will carry out allocation concealment.

7) Masking/blinding:

It will be a triple blinded study so that participants, assessors (A.G and M.F), and statisticians will be blinded. (The operator could not be blinded because of the difference in the application procedures of each restorative material. However, the participants, both assessors and the statistician were blinded to the cavity preparation and type of restoration.)

8) Interventions

Grouping

Group A): ***Intervention***: Self-cured resin composite restorations (Stela, SDI, Australia)

Group B): ***Comparator***: Light-cured bioactive nanohybrid resin composite restorations (Beautifil II, Shofu, Japan)

Procedural Steps

Examination and Diagnosis:

Examination and selection of patients will be done according to inclusion and exclusion criteria. Upon confirming medical and dental history, recording patients' chief complaints and dentition, a pre-operative radiograph will be taken using an intraoral

sensor to detect proximal caries and evaluate it against the inclusion criteria. Clinical examination will be done under 4.5 x magnification loupes and dental unit LED light using front-face dental mirror and an explorer.

- **Intervention (Stela self-cured resin composite):**

1- *Cavity Preparation*: Both intervention and control restorations will be placed by the principal investigator in a single visit per participant. Local anaesthetic agent will be administered followed by rubber dam quadrant isolation and pre-wedging using wooden wedges of appropriate sizes. Cavities will be prepared using 330 and 245 burs forming a trumpet-shaped outline; enamel margins will be bevelled, and proximal line angles will be finished using coarse and medium grit strips. Soft caries will be removed using sharp excavators of appropriate shapes and sizes. Finished cavities will be air-water rinsed to remove all blood and contaminants prior to bonding procedures.

2. *Bonding Procedures*: Finished cavities will receive pre-contoured metal sectional matrix bands of appropriate sizes. Suitable wedges and separator rings will be applied accordingly for all cavities. Then the cavity walls and margins will be primed using Stela primer and wait for 5 seconds before the next step. Cavity will be gently air-dried for 2-3 seconds.
3. *Composite resin packing*: the composite will be placed as single increment and injected using capsule tip.
4. Finishing and polishing: restorations will be contoured under copious coolant using medium grit diamond stones, then finished using fine-grit ones. Inter-proximal surfaces will be finished using medium and fine-grit strips. Restorations will further be polished using diamond impregnated rubber points and cups and composite polishing paste.

- **Comparator (Beautifil II light-cured resin composite):**

1. *Cavity Preparation:* cavity preparation procedures will be carried out using appropriate rotary and hand instruments so that the final cavity will be caries free, with rounded internal line angles, saucer-shaped internal outline, and finished external enamel outline. No beveling of enamel margins will take place.
2. Bonding procedures: a sectional matrix system: thin pre-contoured metal matrix bands of appropriate sizes, suitable wedges and separator rings will be applied to all cavities. Selective etching approach will be followed whereas enamel will be etched for 30 seconds using 34-37% orthophosphoric acid, and then rinsed off with a steady shower of air-water for 15 seconds. Cavity will be gently air dried before

universal adhesive application and LED curing according to the manufacturer's instructions.

3. Cavity liner: a very thin layer of flowable composite resin will be applied over the bonded surfaces, gently agitated with an explorer to clear any bubbles, then LED cured according to the manufacturer's instructions.
4. Composite resin packing: composite will be packed in a centripetal pattern using non-sticky metal composite applicators of appropriate shapes and sizes; starting with a 1 mm vertical marginal ridge followed by oblique increments, sculpted to final anatomy, and not-more-than 2 mm thick each. Each increment will be cured according to composite resin manufacturer's instructions using a LED dental lamp checked for intensity before each procedure.
5. Finishing and polishing: restorations will be contoured under copious coolant using medium grit diamond stones, then finished using fine-grit ones. Inter-proximal surfaces will be finished using medium and fine-grit strips. Restorations will further be polished using diamond impregnated rubber points and cups and composite polishing paste.

9) Outcomes:

Prioritization of Outcome	**Outcome**	**Method of Measurement**	**Unit of Measurement**
Primary Outcome	Proximal contact tightness of examined restorations	FDI criteria for direct and indirect restorations	Number and %
Secondary Outcome	Postoperative hypersensitivity	Visual Analogue scale	

Restorations will be given scores 1-5, where 1 is 'clinically excellent', and 5 is 'clinically poor'. Restorations receiving scores 1-3 are considered successful, while 4 and 5 are failed restorations requiring repair or replacement.

One-week post-operative hypersensitivity will be examined using a visual analogue scale following the FDI criteria (absence/presence of hypersensitivity).

C) Data collection, management, and analysis:

10. Data collection methods

10.a. i. Baseline data collection:

For every patient, chief complaint, medical and dental history, and contact information will be recorded in examination charts and outpatient clinic software. Data entry will be done by the principal investigator S.W.

10.a. ii. Outcome data collection:

(A.G and M.F) will be calibrated to 100% agreement on 10 patients- not included in this trial. In cases of disagreement between evaluators, further discussion will take place till reaching consensus. 1^{ry} and 2^{ry} outcomes will be assessed following the FDI criteria and assessment tools. Evaluation will be done at baseline (T_0) (1 week after restoration); (T_1) at 6 months; (T_2) at 12 months; (T_3) at 18 months; and (T_4) at 24 months. Post-operative hypersensitivity, however, will be assessed at 1 week (baseline) only followed by vitality assessment at following recall appointments.

10. b. Patient retention:

S.W. will record telephone numbers and addresses of all subjects in the study as a part of the signed consent. Patients will be contacted by phone one day before the follow-up dates. S.W will also explain to the patient the benefits of follow up and any defective restoration will be managed accordingly.

11. Data management:

S.W will electronically enter all the data. Patients' files are to be stored in numerical order in a secured place. All paper sheets concerned with the personal or outcome data will be stored in a locked cabinet in the Conservative dentistry department, The British University in Egypt. The excel sheets of patients' data will be stored in a computer in the Conservative Department, Faculty of Dentistry, the British University in Egypt. The computer will have a password only known to S.W. and A.G. to prevent unauthorized access to data and double data entry. A back-up will be made online to avoid data loss.

D) Data monitoring:

12. Monitoring

The co-supervisor (A.G) will monitor this study for the risk of bias and to monitor blinding. He will also have full access to the results and to take the final decision to terminate the trial when necessary.

13. Harms

The principal investigator (S.W) will explain possible harms to patients. Zero harms are expected and if there are any adverse actions, the process will be stopped immediately and managed accordingly after reporting it to the co-supervisor (A.G) and main supervisor (M.F).

14. Audit

Auditing of the study design will be done by the main and co-supervisors to assure quality of the research procedures.

Ethics and dissemination

15. Research ethics approval

This protocol will be reviewed, approved and agreed upon by the Ethics Committee (Research Ethics Committee, Faculty of Dentistry, The British University in Egypt) and an approval number will be provided to the trial protocol.

16. Confidentiality

Name and personal data of the participants will not appear on the protocol form and will be maintained secured for 10 years after the trial. This is done for protection of participants' privacy and civil rights.

17. Declaration of interest

There is no conflict of interest, no funding or material supplying from any parties.

18. Access to data

The investigator and the co-supervisor will be given access to the data sets. All data sets will be password protected to ensure confidentiality.

19. Post-trial care

All patients will complete their treatment by the same operator at the outpatient clinic of the conservative department. Further dental complaints and follow-up after the trial ends will be conducted in the related internship clinic.

20. Dissemination policy

SW will publish the full protocol online in www.clinicaltrials.gov to avoid repetition and to keep the integrity of the research work. Thesis will be discussed in front of a judgment committee. SW will publish the study to report the results of this clinical trial. A copy of

the thesis will be available at the library of the Conservative dentistry department- The British University in Egypt; and the official website of the Egyptian Universities Libraries Consortium. Final report of the trial will be also published in an international journal.

VII. References

1. Țuculină, M. J., Staicu, A. N., Munteanu, M. C., Cumpătă, C. N., Dimitriu, B., Rîcă, A. M., Beznă, M. C., Popa, D. L., Popescu, A. D., & Țîrcă, T. (2023). Study on the restoration of Class II carious cavities by virtual methods: Simulation of Mechanical Behavior. *Journal of Functional Biomaterials*, *14*(7), 354.
2. Ferracane, J. L. (2024). A historical perspective on dental composite restorative materials. *Journal of Functional Biomaterials*, *15*(7), 173. https://doi.org/10.3390/jfb15070173
3. AlShaafi, M. M. (2017). Factors affecting polymerization of resin-based composites: A literature review. *The Saudi Dental Journal*, *29*(2), 48–58. https://doi.org/10.1016/j.sdentj.2017.01.002
4. Warreth, A. (2023). Dental caries and its management. *International Journal of Dentistry*, *2023*, 1–15. https://doi.org/10.1155/2023/9365845
5. Toz-Akalin, T., Öztürk-Bozkurt, F., Kusdemir, M., Özsoy, A., Yüzbaşıoğlu, E., & Özcan, M. (2022b). Clinical evaluation of low-shrinkage bioactive material Giomer versus nanohybrid resin composite restorations: a two-year prospective controlled clinical trial. *Operative Dentistry*, *48*(1), 10–20. https://doi.org/10.2341/21-155-c
6. Pallesen, U., & Van Dijken, J. W. (2015). A randomized controlled 30 years follow up of three conventional resin composites in Class II restorations. *Dental Materials*, *31*(10), 1232–1244. https://doi.org/10.1016/j.dental.2015.08.146
7. Pallesen, U., & Van Dijken, J. W. (2015b). A randomized controlled 27 years follow up of three resin composites in Class II restorations. *Journal of Dentistry*, *43*(12), 1547–1558. https://doi.org/10.1016/j.jdent.2015.09.003
8. Jacob, G., & Goud, K. (2022). A comparative study on microleakage of two low shrinkage composite materials in Class II cavities: A stereomicroscopic analysis. *Journal of Conservative Dentistry*, *26*(1), 83. https://doi.org/10.4103/jcd.jcd_444_22
9. Laporte, C., Bourgi, R., Jmal, H., Ammar, T. B., Hazko, S., Addiego, F., Sauro, S., Haïkel, Y., & Kharouf, N. (2025). Mechanical, Antibacterial, and Physico-Chemical properties of three different Polymer-Based direct restorative materials: an in vitro study. *Polymers*, *17*(9), 1272. https://doi.org/10.3390/polym17091272
10. Raghip, A. G. M., Comisi, J. C., Hamama, H. H., & Mahmoud, S. H. (2025). Two-Year Randomized Clinical Trial to Evaluate the Performance of Posterior Bulk-Fill Resin Composite with Ionic Releasing Restorative Material. *Journal of Dentistry*, 105912. https://doi.org/10.1016/j.jdent.2025.105912
11. Pires, P. M., Neves, A. A., Farrar, P., Cascales, Á. F., Banerjee, A., Feitosa, V. P., & Sauro, S. (2025). Bonding Performance and interfacial Ultra-Morphology/Nanoleakage of a modern Self-Curing Bulk-Fill restorative System: an in vitro study. *European Journal of Dentistry*. https://doi.org/10.1055/s-0045-1804886
12. Guarneri, J. a. G., Maucoski, C., Ghaffari, S., MacNeil, B. D., Price, R. B., & Arrais, C. a. G. (2024). Ability of a novel primer to enhance the polymerization of a self-cured resin composite. *Dental Materials*. https://doi.org/10.1016/j.dental.2024.10.013
13. Loguercio, A. D., Carpio-Salvatierra, B., Ñaupari-Villasante, R., Wendlinger, M., Armas-Vega, A., Cavagnaro, S., León, A., Aliaga-Galvez, R., & Gutiérrez, M. F. (2024b). Clinical evaluation of a new Chemically-Cured Bulk-Fill composite in posterior restorations: 6-Month multicenter Double-Blind randomized clinical trial. *Journal of Dentistry*, *149*, 105246. https://doi.org/10.1016/j.jdent.2024.105246

14. Loguercio, A. D., Carpio-Salvatierra, B., Ñaupari-Villasante, R., Armas-Vega, A., Cavagnaro, S., León, A., R, A., Soares, C. J., & Gutierrez, M. F. (2025). Clinical evaluation of a new Chemically-Cured Bulk-Fill composite in posterior restorations: 18-Month multicenter Double-Blind randomized clinical trial. *Journal of Dentistry*, *162*, 106031. https://doi.org/10.1016/j.jdent.2025.106031
15. De Carvalho, L. F., Silva, M. G. E., Da Silva Barboza, A., Badaró, M. M., Stolf, S. C., Cuevas-Suárez, C. E., Lund, R. G., & De Andrade, J. S. R. (2024). Effectiveness of bioactive resin materials in preventing secondary caries and retention loss in direct posterior restorations: A systematic review and meta-analysis. *Journal of Dentistry*, *152*, 105460. https://doi.org/10.1016/j.jdent.2024.105460