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Clinical Performance of Occlusal and Occlusoproximal Restorations in Primary Teeth Using Glass Ionomer Cement Without 25% Polyacrylic Acid Preconditioning: Protocol of a Randomized Controlled Non-Inferiority Clinical Trial With 2-Year Follow-Up

Desempenho clínico de restaurações oclusais e oclusoproximais de dentes decíduos com ionômero de vidro sem pré condicionamento com ácido poliacrílico à 25%: Protocolo de um Estudo Clínico Controlado e Randomizado de não inferioridade com 2 anos de acompanhamento

Desempeño clínico de restauraciones oclusales y ocluso-proximales en dientes deciduos con ionómero de vidrio sin preacondicionamiento con ácido poliacrílico al 25%: Protocolo de un estudio clínico controlado, aleatorizado y de no inferioridad con seguimiento de 2 años

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Abstract
Current literature lacks robust evidence on the benefits of omitting polyacrylic acid pre-conditioning in glass ionomer cement (GIC) restorations for primary teeth. *The present article aims to describe a randomized controlled non-inferiority trial which sought to evaluate* the clinical performance of occlusal and occluso-proximal restorations using encapsulated glass ionomer cement without prior application of 25% polyacrylic acid. Methodology: Children aged 3 to 9 years, enrolled in public schools in Rio de Janeiro, were randomly assigned to two groups: experimental and control. In the experimental group, encapsulated Riva Regular® glass ionomer cement (SDI – Australia) will be applied after a placebo simulating polyacrylic acid. In the control group, the same material will be used following standard pre-conditioning with 25% polyacrylic acid. The groups were further stratified according to cavity type (occlusal or occluso-proximal), and all procedures were performed using the Atraumatic Restorative Treatment (ART) technique. Follow-ups were conducted at 6, 12, 18, and 24 months, with the primary outcome being the restoration survival rate at 24 months. Conclusion: Omitting the pre-conditioning step with 25% polyacrylic acid may be a viable alternative for GIC restorations in primary teeth, potentially without compromising clinical efficacy compared to the conventional technique. Additionally, this simplified approach may enhance acceptance among professionals by reducing clinical procedure time.
Keywords: Glass Ionomer Cements; Polyacrylic Acid; Dental Cements, Child, Pediatric Dentistry.

Resumo

Objetivo: A literatura ainda carece de evidências sólidas sobre os benefícios da omissão do pré-condicionamento com ácido poliacrílico em restaurações de cimento de ionômero de vidro (CIV) em dentes decíduos. O presente artigo tem como objetivo descrever um ensaio clínico randomizado de não inferioridade que buscou avaliar restaurações oclusais e ocluso-proximais realizadas com ionômero de vidro encapsulado, sem a aplicação prévia de ácido poliacrílico a 25%. Metodologia: Foram incluídas crianças de 3 a 9 anos, matriculadas na rede pública de ensino do Rio de Janeiro, alocadas aleatoriamente em dois grupos: experimental e controle. No grupo experimental, o cimento de ionômero de vidro Riva Regular® encapsulado (SDI – Austrália) foi aplicado após um placebo simulando o ácido poliacrílico. No grupo controle, o mesmo material foi utilizado com o pré-condicionamento convencional com ácido poliacrílico a 25%. Os grupos foram subdivididos conforme o tipo de cavidade (oclusal ou ocluso-proximal), e os procedimentos seguiram a técnica do Tratamento Restaurador Atraumático (ART). O acompanhamento foi realizado aos 6, 12, 18 e 24 meses, sendo a taxa de sobrevivência das restaurações aos 24 meses o desfecho primário. Conclusão: A ausência do pré-condicionamento com ácido poliacrílico a 25% pode representar uma alternativa viável para restaurações em dentes decíduos com CIV, possivelmente sem comprometer a eficácia clínica em comparação à técnica convencional. Além disso, a simplificação do protocolo pode favorecer a aceitação da abordagem por profissionais, reduzindo o tempo clínico do procedimento.

Palavras-chave: Cimentos de Ionômero de Vidro; Ácido Poliacrílico; Cimentos Odontológicos; Criança; Odontopediatria.

Resumen

Objetivo: La literatura actual carece de evidencia sólida sobre los beneficios de omitir el preacondicionamiento con ácido poliacrílico en restauraciones con cemento de ionómero de vidrio (CIV) en dientes primarios. El presente artículo tiene como objetivo describir un ensayo clínico aleatorizado de no inferioridad que buscó evaluar restauraciones oclusales y ocluso-proximales utilizando cemento de ionómero de vidrio encapsulado sin la aplicación previa de ácido poliacrílico al 25%. Metodología: Niños de 3 a 9 años, matriculados en escuelas públicas de Río de Janeiro, fueron asignados aleatoriamente a dos grupos: experimental y control. En el grupo experimental, se aplicará cemento de ionómero de vidrio encapsulado Riva Regular® (SDI – Australia) después de un placebo que simulaba el ácido poliacrílico. En el grupo control, el mismo material se utilizará tras el preacondicionamiento estándar con ácido poliacrílico al 25%. Los grupos se subdivididirá según el tipo de cavidad (oclusal u ocluso-proximal), y todos los procedimientos se realizará utilizando la técnica de Tratamiento Restaurador Atraumático (ART). Se realizaron seguimientos a los 6, 12, 18 y 24 meses, siendo la tasa de supervivencia de las restauraciones a los 24 meses el desenlace primario. Conclusión: La omisión del preacondicionamiento con ácido poliacrílico al 25% podría ser una alternativa viable para restauraciones con CIV en dientes primarios, potencialmente sin comprometer la eficacia clínica en comparación con la técnica convencional. Además, este enfoque simplificado podría mejorar la aceptación entre los profesionales al reducir el tiempo clínico del procedimiento.

Palabras clave: Cementos de Ionómero de Vidrio; Ácido Poliacrílico; Cementos Dentales; Niño; Odontopediatría.

1. Introduction

Polyacrylic acid pre-conditioning before the application of glass ionomer cement is recommended by manufacturers to enhance the adhesive interface between the material and the dental structure (Munck et al., 2004; Bayrak et al., 2010). However, in clinical practice, this step is often omitted, particularly in pediatric dentistry, where it may increase procedure time and impact patient care.

There are still controversies regarding its actual necessity, as some studies suggest that PAA conditioning improves substrate wettability and bond strength (Mitchell Ca, 1998; Glasspoole EA et al., 2002), while others have found no significant benefits in adhesion after this pre-treatment (Tanumiharja M et al., 2000). Additionally, incorporating this step can complicate the clinical procedure, increasing susceptibility to technical errors, costs, and chair time (Coutinho E et al., 2006).

The available literature on this topic is predominantly based on laboratory studies, with only two randomized controlled clinical trials conducted in the 1990s, both on permanent teeth (Tyas M, 1993; Van Dijken, 1996). A recent systematic review indicated that pre-conditioning with 25% polyacrylic acid may not be essential for the adhesion of glass ionomer cement to dentin, suggesting that simple mechanical cleaning might be sufficient (Hoshika S., 2015). However, this review also highlighted significant methodological limitations in the analyzed studies and the lack of investigations on primary teeth (Lopes LELS et al.,

2021).

Given these gaps, it is crucial to conduct more rigorous clinical studies, particularly on primary teeth, to assess the performance of glass ionomer cement in different cavities and substrate types. In this context, this will be the first randomized controlled clinical trial on primary teeth, comparing the clinical efficacy of occlusal and occluso-proximal restorations with and without 25% polyacrylic acid pre-conditioning. The findings will contribute to evidence-based clinical recommendations, ensuring greater safety and predictability in the application of this technique.

The present article aims to describe a randomized controlled non-inferiority trial which sought to evaluate the clinical performance of occlusal and occluso-proximal restorations using encapsulated glass ionomer cement without prior application of 25% polyacrylic acid

2. Methodology

2.1 Ethical Principles and Registration

This study adhered to strict ethical and regulatory principles. The research was approved by the Research Ethics Committee of UERJ under opinion number 5.534.478. To ensure institutional compliance, the project was submitted to the Municipal Health Department, accompanied by a letter of consent signed by the directors of the participating schools. After approval, the study was forwarded to the Regional Education Council of each subprefecture, obtaining a favorable opinion and being registered under the code SME-PRO-2023/52474.

Participant inclusion will be conditioned upon obtaining informed consent, with parents or legal guardians signing the Informed Consent Form. Additionally, children provided their Assent, either in written form or, for those unable to read and/or write, through verbal assent.

Before enrolling the first participant, the clinical trial was registered in the Brazilian Registry of Clinical Trials (ReBEC) under the number RBR-102yzxnt. The registration strictly followed the Spirit Checklist guidelines, ensuring transparency and alignment with internationally recognized standards in clinical research (Qureshi R et al., 2022).

2.2 Study Design and Setting

This is a randomized controlled trial with a parallel two-arm design, following the principles of non-inferiority and conducted in a triple-blind manner (Toassi & Petry, 2021; Pereira et al., 2018; Estrela, 2018) using statistical analysis (Vieira, 2021; Bekman & Costa Neto, 2009). The follow-up period will extend over two years, providing a comprehensive assessment of the clinical performance and longevity of the treatments under investigation.

Clinical procedures were meticulously carried out in four public schools in Rio de Janeiro, allowing for the evaluation of restorations in a school-based environment, which represents a realistic and accessible setting, distinct from conventional clinical environments.

The study will be reported in following the CONSORT guidelines, ensuring standardization and high-quality presentation of the findings.

2.3 Sample Size Calculation

For the sample size calculation, 5% of type I error and 80% statistical power was considered. Adopting a non-inferiority hypothesis and defining the primary outcome as a binary categorical variable (success or failure), a success rate of 89.4% for the control group (with conditioning) and 81.8% for the experimental group (without conditioning) was estimated, based on a previous clinical study on permanent teeth (Van Dijken, 1996). Given this success rate and a non-inferiority margin of 20%, a

total of 116 teeth per group was calculated. To account for potential losses during follow-up, a 20% increase was applied, resulting in a minimum of 140 teeth per group, totaling 280 teeth, distributed into 70 teeth per subgroup.

2.4 Eligibility Criteria

The study will include children aged 3 to 9 years, enrolled in public schools in urban areas of Rio de Janeiro, who present at least one primary molar with an active carious lesion on the occlusal or occluso-proximal surfaces, without clinical signs of pulpal involvement or pain symptoms.

In cases where more than one tooth is eligible, a random selection process will determine which tooth is included in the study. For two eligible teeth, a coin flip method (heads or tails) will be used. If more than two teeth are eligible, a random number generator (https://sorteador.com.br/) will be employed to ensure randomization, minimizing selection bias.

Even if only one tooth is included in the study, all eligible teeth will be treated using the Atraumatic Restorative Treatment (ART) technique. Cases requiring additional treatments, such as spontaneous pain, pulp capping, endodontic therapy, or extractions, will be referred to specialized care within the public health system.

Only primary molars with occlusal and occluso-proximal lesions will be considered, provided that: The cavity is accessible to manual restorative dentistry instruments; there is no spontaneous pain, fistula, abscess, pulp exposure, or tooth mobility; the occluso-proximal cavity opening does not exceed 2.00 mm in the mesiodistal direction, 2.00 mm in the occlusocervical direction, and 2.5 mm in the buccolingual direction, as measured with a periodontal probe (Kemoli AM et al., 2009).

The size limitation of occluso-proximal cavities is based on evidence from randomized controlled trials, which suggest a higher survival rate for alternative techniques compared to the Atraumatic Restorative Treatment (ART) technique in managing occluso-proximal lesions (Tedesco TK et al., 2018). For occlusal cavities, no specific measurements regarding size or depth will be taken.

Children with special needs, enamel defects, orthodontic appliances, and/or systemic diseases, as well as those who do not cooperate or refuse to participate in the initial clinical examination, will be excluded from the study. Additionally, teeth with previous restorations, sealants, developmental defects, advanced root resorption, deep carious lesions with potential pulpal involvement, fistulas, abscesses, or spontaneous pain will not be considered.

2.5 Sequence generation and allocation concealment

The teeth included in this study will undergo randomization, using a stratified permuted block design with block sizes of 2 and 4 samples. The randomization unit will be the child, while the analysis unit will be the tooth. The randomization process will consider two stratification factors: cavity classification and intervention type. The randomization sequence will be generated using a dedicated website (www.sealedenvelope.com). To ensure allocation concealment, the generated sequences will be placed in sealed black envelopes, sequentially numbered, and distributed among the different strata.

The envelopes will be prepared, numbered, and sealed by an individual not involved in the study and with no contact with the operator. Patient inclusion will be carried out, determining the group corresponding to the cavity to be treated. The envelope will only be opened after the removal of the surrounding carious tissue.

2.6 Operator Training

A pilot study will be conducted at a public school in Petrópolis, Rio de Janeiro, to ensure the standardization and reliability of research procedures. This study will allow for the early identification and resolution of potential challenges, enabling

necessary adjustments and refinements before the full implementation of the study. The operator will undergo a three-day clinical training, during which they will perform the Atraumatic Restorative Treatment (ART) on teeth that will not be included in the research.

2.7 Clinical Protocol

Before the eligibility assessment, legal guardians will be informed through a message sent via institutional WhatsApp, explaining the partnership between the school and Rio de Janeiro State University (UERJ) and notifying them of the scheduled visit by the professionals responsible for the screening. The evaluation will take place in the classroom, with the child seated in their chair after performing self-toothbrushing. The examination will be conducted using disposable wooden spatulas and a headlamp, and potentially eligible children will be recorded. After screening, the school will send a WhatsApp message to families containing general information about the research and the possible inclusion of their child in the study. To ensure accessible communication, an animated video explaining the Atraumatic Restorative Treatment in a child-friendly manner will be made available.

Families will receive the required documentation via the school agenda in a sealed envelope, including: An explanatory letter about the research. The Informed Assent Form (TALE), The Informed Consent Form (TCLE), authorization for image use for educational purposes, authorization for data collection and research dissemination, anamnesis and the ECO-HIS questionnaire (for children aged 3 to 4 years). On the scheduled return date, the envelopes will be collected, and the consent forms will be reviewed. Children whose families do not authorize participation will be excluded from study. If the ECO-HIS questionnaire is incomplete, the research team will contact the guardians via institutional WhatsApp to schedule a time to collect the missing information.

Younger children will be given priority in treatment to account for the longer retention of their teeth in the oral cavity. The first consultation will include: Clinical assessment of lesion depth and isthmus breakage, Clinical examination using the DMFT/dmft, IPS, and ICDAS indices and Completion of a quality-of-life questionnaire (CPQ 8-10 or ECO-HIS).

Procedures will be performed in pre-sanitized school rooms, with mats placed on school tables. Portable flashlights (headlamps) will be used for operatory lighting. All cements will be encapsulated, and the same amalgamator will be used across all institutions. The clinical characteristics of the lesion and the child will be recorded in individual files. Data on the restored tooth, including cavity classification and size, dental arch, side, sex, and caries experience, will be systematically collected. Before the procedure, each child will undergo supervised toothbrushing with 1,100 ppm fluoride toothpaste and a toothbrush. The animated video, previously shared with parents, will be shown on a mobile device to reinforce information about the treatment and clarify any remaining doubts.

2.8 Restorative Procedures

Restorations will be performed in strict accordance with the Frencken and Holmgren protocol (Frencken JE, Holmgren CJ, 1999). Randomization and group allocation disclosure will occur immediately after the selective removal of carious tissue from the surrounding walls. Children will be assigned to one of two groups:

- Experimental group – Restorative procedure using encapsulated Riva Regular® glass ionomer cement (SDI – Australia) without pre-treatment with polyacrylic acid, using a placebo instead. This group will be subdivided into two subgroups: occlusal cavities and occluso-proximal cavities.
- Control group – Restorative procedure using encapsulated Riva Regular® glass ionomer cement (SDI – Australia), with cavity pre-treatment using 25% polyacrylic acid. This group will also be subdivided into two subgroups: occlusal cavities and occluso-proximal cavities.

2.9 Outcome Assessment

2.9.1 Primary Outcome

The primary outcome of this study will be clinical success two years after treatment completion. The assessment will be conducted by trained and calibrated evaluators, who will not be involved in the previous study phases and will remain blind to the group allocation of each child. In cases where two possible scores are obtained, the Guidelines for the Evaluation of Restorations using the Atraumatic Restorative Treatment (ART) technique will be followed and the 6-month follow-up, outcomes classified as success or failure will be evaluated according to Roeleveld's criteria, where scores 00 and 10 will be classified as success, scores 11-13, 20-21, 30, and 40 as failure, and scores 50, 60, 70, or 90 as not related to success or failure, considering repairs as failures. However, based on the study design, repairs classified with scores 11 and 12 may later be reclassified as success.

These guidelines, established in previous studies, will provide a systematic framework for evaluating the effectiveness and longevity of restorations, considering factors such as retention, marginal integrity, and the need for repair. Additionally, the evaluation criteria will include specific parameters for classifying restorations, allowing for objective comparisons between different approaches and promoting consistency in clinical outcomes (Frencken JE et al., 2012). These guidelines are crucial for clinical practice, as they ensure the quality of performed interventions and contribute to the evidence base supporting the use of the ART technique in contemporary dentistry.

For the tooth longevity outcome, failures will only include scores 40 and 50, which refer to pulp inflammation (where the restoration remains in place but is not categorized under other scores), fistula, pain, or tooth extraction. Scores 70 of 90 will not be included in the analysis. The clinical criteria for determining success will be evaluated at 6, 12, 18, and 24 months, focusing on adhesion and restoration survival. In cases of partial restoration loss, repair will be performed using the same restorative material, whereas complete restoration loss will be considered a failure criterion. Partial losses will not be classified as failures. If a high failure rate is observed in one or both groups, suggesting that the harm to participants outweighs the benefits, the study will be discontinued (Tyson et al., 2016).

The primary outcome assessment will be conducted for 24 months, with the month of failure occurrence being recorded. The primary outcome analysis will be performed using survival analysis methods.

2.9.2 Secondary Outcomes

The operative time of the procedure will be recorded using a digital stopwatch, measuring the total duration from the moment the child is positioned on the treatment surface until the final application of the coat. This approach ensures precise tracking of the time required for each procedure.

To evaluate patient discomfort during treatment, the child's behavior will be classified according to the Frankl Behavior Scale, considering the period from relative isolation to the final application of the coat. Additionally, post-treatment discomfort will be assessed using the Wong-Baker Faces Pain Scale, which will be presented to the child at the end of the treatment. This outcome will be recorded after the completion of the treated tooth, even if other teeth still require intervention.

The impact of treatment on the child’s quality of life will be assessed using a quality-of-life questionnaire during the initial consultation. The Brazilian version of the Child Perceptions Questionnaire 8-10 (CPQ8-10) will be applied. Although originally developed for children aged 8 to 10 years, it will also be administered to children aged 5 to 8 years, as supported by

existing literature (Foster Page et al., 2013). For children aged 3 and 4 years, parents or guardians will complete the ECOHIS questionnaire. At the end of treatment, a new quality-of-life questionnaire (CPQ8-10/ECO-HIS) will be conducted (Novaes et al., 2017). The total scores and effect size changes across different domains will be analyzed and compared between groups.

Regarding the cost analysis, the gross cost of each procedure will be calculated per treated tooth, excluding follow-up consultations. A record sheet will be completed during the first appointment, documenting all materials and quantities used. The total cost per child will be determined by summing the treatment costs per tooth at each visit, providing a comprehensive financial evaluation of the procedure.

2.10 Data Analysis

Microsoft Windows Excel 2013 will be used for data entry, and Stata 13.0 for data analysis. The Kolmogorov-Smirnov test will be used to assess the normality of quantitative variables. A significance level of 0.05 will be adopted for all statistical analyses.

Kaplan-Meier survival analysis and the log-rank test will be performed to assess the survival rate of restorations. Cox regression analysis will evaluate associations between restoration survival and variables such as operator experience (experienced/inexperienced), age, sex (male/female), dental arch (upper/lower), side (right/left), tooth type (first/second primary molar), and moisture control during restoration (absence of saliva or gingival bleeding). The hazard ratio (HR) and 95% confidence interval (CI 95%) will be calculated. Intra-examiner reproducibility for restoration evaluation will be measured using the weighted kappa test.

To analyze final discomfort and its association with different groups and variables, ordered logistic regression (CI 95%) will be applied. These results will be presented using descriptive statistics. Missing data will not be imputed, and only complete questionnaires will be analyzed. The number of responses and missing data and their distribution will be reported.

For statistical analysis, only children who complete the questionnaire at baseline, 6 months, and 24 months will be considered. The Wilcoxon test will be used for paired samples (pre- and post-treatment comparisons). The Mann-Whitney test will be used to compare data between groups (unpaired analysis).

Kaplan-Meier survival analysis and the log-rank test will be applied to assess tooth exfoliation. Cox regression analysis will evaluate associations between exfoliation and variables such as age, sex (male/female), dental arch (upper/lower), side (right/left), and tooth type (first/second primary molar). The hazard ratio (HR) and corresponding 95% CI will be derived.

Professional and material costs will be used to estimate the incremental cost of treatments, which will be compared using Bootstrap regression analysis

3. Results and Discussion

Glass ionomer cement is widely used in pediatric dentistry due to its adhesive properties, good bond strength to dental structures, and relative resistance to moisture. These characteristics make it particularly advantageous in pediatric treatments, where behavioral challenges may hinder conventional restorative procedures. However, to ensure effective adhesion, the material must be properly handled by the operator, strictly following the manufacturer's recommendations. Among these recommendations, surface preconditioning with 25% polyacrylic acid is essential to optimize the interaction between the cement and the dental substrate. Nevertheless, in clinical practice, this step is often omitted to reduce treatment time, which may impact adhesion quality and, consequently, the clinical performance of the restoration.

There is still no consensus on the need for pre-treatment of the dental surface when using glass ionomer cement (GIC). While some studies indicate that applying polyacrylic acid (PAA) before cement insertion improves the wettability of the

substrate, thereby increasing bond strength and clinical retention (Mitchell Ca, 1998; Glasspoole EA et al., 2002), others have found no significant benefits in adhesive strength after pre-treatment (Chen CN, 2002; Tanumiharja M et al., 2000). Furthermore, including this clinical step may increase the complexity of the procedure, making it more susceptible to technical errors and consequently raising costs and the time required to complete the treatment (Coutinho E et al., 2006).

The current literature on this topic consists mostly of laboratory studies, with only two controlled and randomized clinical trials, both conducted in the 1990s on permanent teeth (Tyas M, 1993; Van Dijken, 1996). Some studies suggest that prior conditioning with 25% polyacrylic acid does not significantly influence the adhesion of glass ionomer cement to dentin and that simple mechanical cleaning would be sufficient to optimize this adhesion (Hoshika S., 2015). In a recent systematic review, Lopes LELS et al. (2021) stated that there are no substantial differences between techniques that use or do not use pre-treatment with polyacrylic acid. However, the review highlighted significant limitations in the included clinical studies.

According to the guidelines of the American Dental Association (ADA), for a restorative material to be fully accepted, it must achieve a minimum retention rate of 90% after 18 months (Loguercio AD, Reis A. et al., 2008; Fagundes TC et al., 2014). This criterion indicates that at least one of the studies included in the review would require a longer follow-up period to adequately assess the material's effectiveness. Additionally, limitations were observed, such as the exclusive use of sound dentin in all studies, as the analyzed cavities were limited to cervical lesions caused by abrasion in permanent teeth, restricting the applicability of the results to other clinical conditions.

Although both studies evaluated dentin conditioning with polyacrylic acid, one did not have an adequate sample size, making reliable statistical analyses unfeasible. The main limitations in the bias assessment domains included a lack of clarity in participant selection criteria and insufficient reporting on the randomization and group allocation processes, compromising the quality and validity of the conclusions. Given this, there is a clear need for more rigorous clinical studies that analyze the performance of materials under real clinical conditions, considering different types of substrates, cavities, and primary teeth.

The reduction in clinical time when pre-conditioning is omitted makes the procedure simpler and faster, which is a considerable advantage, especially given the need for children's cooperation during treatment. Regarding the choice of product presentation for the research. Encapsulated glass ionomer cements have a fixed powder-to-liquid ratio predetermined by the manufacturer and are mechanically mixed, which minimizes operator interference in the material's functional properties—its main advantage (Nomoto R et al., 2004). Randomized clinical trials have shown that the longevity of restorations using encapsulated GICs is comparable to that of manually mixed ones (Oliveira RC et al., 2021; Freitas MCCA et al., 2028). Additionally, laboratory studies suggest that encapsulated GICs exhibit lower porosity and greater mechanical strength compared to manually prepared versions (Molina GF et al., 2013; van 't Hof MA et al., 2013).

In addition to the primary outcome, patient-centered secondary outcomes will also be assessed in this study, as patients' perceptions and opinions are fundamental to the decision-making process in evidence-based dentistry. If our non-inferiority hypothesis is confirmed, the indication of the technique without the need for pre-conditioning with 25% polyacrylic acid will be supported. Furthermore, we hope that the present study protocol will encourage researchers to conduct new well-designed randomized clinical trials on the topic to improve the quality of the evidence.

4. Conclusion

The present study will evaluate the clinical performance of occlusal and occluso-proximal restorations using glass ionomer cement, with and without prior conditioning with 25% polyacrylic acid, to determine whether omitting the acid is a viable treatment option for primary teeth

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