# PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

### **ARTICLE DETAILS**

# Title (Provisional)

An Investigator-blinded, 24-month, Parallel-group, Non-inferiority Study to Compare Aesthetic Restorations in Primary Anterior Teeth in a Pediatric Dental Clinic: Study Protocol for a Randomized Controlled Trial

## **Authors**

Gimenez, Thais; Sobral, Ana Paula Taboada; Santos, Elaine Marcilio; Gonçalves, Marcela Letícia Leal; Ferri, Elza Padilha; Gallo, Juliana Maria Altavista Sagretti; Horliana, Anna Carolina Ratto Tempestini; Motta, Lara Jansiski; Imparato, José Carlos Pettorossi; Bussadori, Sandra Kalil

# **VERSION 1 - REVIEW**

Reviewer 1

Name Afraa, Salah

Affiliation Ajman University

Date 16-Apr-2024

COI none

An investigation-blinded, 24-months, parallel-group, non-ibferiority study to compare Aesthetic restoration in primary anterior teeth: study protocol for a randomized controlled trial

Bmjopen- 2024-086200

Review report

# **General feedback:**

The study represent a new and valuable idea to study, however the study not presented in correct scientific way for publication. The article had many missing areas, bad structure and no clear research results identified. It need major changes throughout the whole manuscript.

Final decision: rejected

Manuscript comments:

1- abstract:

Abstract sections not structured in sequence as Introduction, method, results, conclusion. Many unnecessary information were there while no results or conclusion was there.

#### 2-introduction:

Introduction section was so short and need more explanation about the restoration used and not only the crowns.

## 3- methods:

This section is very long and many unnecessary details were mentioned. Objectives were mentioned in this section (why?).Participants' recruitment repeated twice. Long procedure description.

## 4- Outcomes

Many information written here which should be mentioned in the method section like variable, assessments, data collection, statistical analysis.

Where are the results, the tables the figures for the outcomes? Nothing is there. Nothing I get from the study results. Which way is better and by numbers?

#### 5- Discussion

Nothing mentioned about the two procedure, and why one procedure is better than the other one.

Reviewer 2

Name Paolone, Gaetano

Affiliation IRCCS San Raffaele Hospital

Date 22-Apr-2024

COI none

The paper "An Investigator-blinded, 24-month, Parallel-group, Non- inferiority Study to Compare Aesthetic restorations in primary anterior teeth: study protocol for a randomized controlled trial" presents a protocol for a clinical trial to compare rehabilitative techniques of primary anterior teeth.

### Protocol is clear,

the reviewer suggests some minor improvements:

There are polyvinyl crowns on the market that have been used to facilitate this type of restoration, since they return the anatomy of the teeth more quickly and without the need for the operator's ability to perform dental sculptures.

Since materials are important, but shape is even more important, he authors could add also another reference that is related to the ability that the operator should have to reproduce the simmetry in anteriors:

https://doi.org/10.3390/sym13050797

This skill is not required using polyvinyl crowns.

"Likewise, the development of new restorative materials that allow the use of thicker layers and unique coloration, promoting an effect called as chameleon, because it mimics the color of the tooth."

Please support this sentence with a reference.

Page 10 lines 12-15: please state that an etch and rinse approach (ER) will be used for the Universal adhesive

"photoactivation of the adhesive and restoration by incremental technique and photoactivation of each layer of resin for 20 seconds. "

please report curing light that will be used and intensity.

Reviewer 3

Name Elheeny, Ahmad Abdel Hamid

Affiliation Minia University

Date 09-Aug-2024

COI None

• The authors stated at the end of the introduction that "There are no studies that have compared rehabilitative techniques of primary anterior teeth regarding patient-centered outcomes and even longevity of restoration". This generalization is not correct/ There are two examples of anterior teeth rehabilitation in pediatric patients

Elheeny, A.A.H., Abdelmotelb, M.A. Oral health—related quality of life (OHRQOL) of preschool children's anterior teeth restored with zirconia crowns versus resin-bonded composite strip crowns: a 12-month prospective clinical trial. Clin Oral Invest 26, 3923–3938 (2022). https://doi.org/10.1007/s00784-021-04359-9

Elheeny, A.A.H. and Sermani D. H. Prefabricated zirconia crown versus resin-bonded composite strip crown in the restoration of primary incisors: A 36-month parallel randomized controlled trial. Ped Dent J 34(1), 19-26 (2024). https://doi.org/10.1016/j.pdj.2023.12.004

- The study hypothesis should be stated
- Sample size needs to be calculated on the basis of repeated measures

• Dental procedures will be carried out under local or general anesthesia?

• Why non-inferior design was adopted? Why equivalence is not considered?

• Explain the rationale of the selected non-inferiority margin

• Statistical analysis is deficient:

The absolute risk difference and the level of confidence need to be added Specify the statistical test for each outcome

# **VERSION 1 - AUTHOR RESPONSE**

Reviewer: 1

Dr. Salah Afraa, Ajman University

**Comments to the Author:** 

the article need to be structured from A to Z to publish this good work.

**Our response:** We thank you for the opportunity.

Reviewer: 2

Dr. Gaetano Paolone, IRCCS San Raffaele Hospital

Comments to the Author:

The paper "An Investigator-blinded, 24-month, Parallel-group, Non- inferiority Study to Compare Aesthetic restorations in primary anterior teeth: study protocol for a randomized controlled trial" presents a protocol for a clinical trial to compare rehabilitative techniques of primary anterior teeth.

Protocol is clear,

the reviewer suggests some minor improvements:

Our response: We thank you for the opportunity.

There are polyvinyl crowns on the market that have been used to facilitate this type of restoration, since they return the anatomy of the teeth more quickly and without the need for the operator's ability to perform dental sculptures.

Since materials are important, but shape is even more important, he authors could add also another reference that is related to the ability that the operator should have to

reproduce the simmetry in anteriors:

https://doi.org/10.3390/sym13050797

This skill is not required using polyvinyl crowns.

Our response: Thank you for the recommendation of the article. We have added this reference to the introduction.

"Likewise, the development of new restorative materials that allow the use of thicker layers and unique coloration, promoting an effect called as chameleon, because it mimics the color of the tooth."

Please support this sentence with a reference.

Our response: We have added this reference to support this statement: Bakti, I., Santosa, A., Irawan, B., & Damiyanti, M. (2018). Chameleon effect of nano-filled composite resin restorations in artificial acrylic teeth of various shades. Journal of Physics: Conference Series, 1073. https://doi.org/10.1088/1742-6596/1073/5/052011.

Page 10 lines 12-15: please state that an etch and rinse approach (ER) will be used for the Universal adhesive

Our response: We have added this information.

"photoactivation of the adhesive and restoration by incremental technique and photoactivation of each layer of resin for 20 seconds. " please report curing light that will be used and intensity.

Our response: It will be used the Radii Xpert (SDI, Melbourne, Vic, Australia), peak 1500 mW/cm2. We have added this information. We have added this information.

**Reviewer: 3** 

Dr. Ahmad Abdel Hamid Elheeny, Minia University

Comments to the Author:

• The authors stated at the end of the introduction that "There are no studies that have compared rehabilitative techniques of primary anterior teeth regarding patient-centered outcomes and even longevity of restoration". This generalization is not correct/ There are two examples of anterior teeth rehabilitation in pediatric patients

Elheeny, A.A.H., Abdelmotelb, M.A. Oral health-related quality of life (OHRQOL) of

preschool children's anterior teeth restored with zirconia crowns versus resin-bonded composite strip crowns: a 12-month prospective clinical trial. Clin Oral Invest 26, 3923–3938 (2022). https://doi.org/10.1007/s00784-021-04359-9

Elheeny, A.A.H. and Sermani D. H. Prefabricated zirconia crown versus resin-bonded composite strip crown in the restoration of primary incisors: A 36-month parallel randomized controlled trial. Ped Dent J 34(1), 19-26

(2024). https://doi.org/10.1016/j.pdj.2023.12.004

**Our response:** Thank you for your review, suggestions, and the opportunity to clarify. As stated in the sentence immediately preceding this one, we are discussing minimally invasive techniques involving selective removal of carious tissue without the need for operative preparation, which is not the case with the use of zirconia crowns. We have made an effort to clarify this statement.

## • The study hypothesis should be stated.

**Our response:** Thank you for your suggestion. We have added the study hypothesis at the end of the introduction. Our hypothesis is that restorations with polyvinyl crowns are not inferior to conventional restorations.

## • Sample size needs to be calculated on the basis of repeated measures

Our response: Thank you for your observation. However, the sample size calculation was not based on repeated measures, as we do not intend to perform intra-group comparisons over time. Instead, our analysis focuses on comparing the groups at different follow-up times. Therefore, the sample size was calculated based on between-group comparisons at these specific time points, rather than repeated measures within the same group.

## • Dental procedures will be carried out under local or general anesthesia?

**Our response:** None of the above. Since we will be performing selective removal of carious tissue and treating teeth without pulp involvement or painful symptoms, neither local nor general anesthesia will be required.

• Why non-inferior design was adopted? Why equivalence is not considered? Explain the rationale of the selected non-inferiority margin.

Our response: Thank you for your question. The non-inferiority design was adopted because our primary objective was to demonstrate that the new treatment is not significantly worse than the conventional treatment within a predefined margin. Equivalence was not considered because our goal was not to prove that the new treatment is equivalent but rather that it does not fall below a threshold of acceptability compared to the standard. We chose a non-inferiority margin of 5% because this difference is considered small enough to be clinically acceptable. Our rationale is that even if the new treatment is slightly less effective, it is likely to be faster and more efficient, which could offset any potential drawbacks. Therefore, the 5% margin reflects our judgment that the benefits of the new treatment in terms of speed and practicality make it a viable alternative.

• Statistical analysis is deficient:

The absolute risk difference and the level of confidence need to be added Specify the statistical test for each outcome

Our response

: Thank you for your suggestion. We have restructured the statistical analysis section to address it.

"The efficacy of each treatment will be evaluated through three primary outcomes:

- 1) Control of Cavitated Active Lesions: Kaplan-Meier survival analysis will be used to estimate the probability of lesion control over time, with the Log-Rank test employed to compare survival curves between the two groups. The absolute risk difference will be calculated to quantify the difference in lesion control rates, with a 95% confidence interval reported.
- 2) Longevity of Restorations: Kaplan-Meier survival analysis will also be used to evaluate restoration longevity, with comparisons made using the Log-Rank test. Cox regression analysis will be performed to assess the influence of additional variables on restoration longevity. The absolute risk difference and its 95% confidence interval will be provided to highlight the comparative effectiveness of the treatments.
- 3) Patient-Centered Outcomes: For comparing patient-centered outcomes between the two groups, the Student's t-test will be used for normally distributed data, while the Mann-Whitney U test will be applied for non-normally distributed data. The absolute risk difference for

patient-centered outcomes will also be calculated, and a 95% confidence interval will be reported.

For all statistical analyses, the significance level will be set at 5%."

## **VERSION 2 - REVIEW**

Reviewer 2

Name Paolone, Gaetano

Affiliation IRCCS San Raffaele Hospital

Date 18-Oct-2024

COI

An Investigator-blinded, 24-month, Parallel-group, Non-inferiority Study to Compare Aesthetic Restorations in Primary Anterior Teeth in a Pediatric Dental Clinic: Study Protocol for a Randomized Controlled Trial

The study addresses a clinically relevant issue in pediatric dentistry, aiming to evaluate the effectiveness of two restorative techniques for anterior primary teeth. The design of a 24-month randomized controlled trial (RCT) comparing polyvinyl crowns with conventional opaque resin restorations is commendable. The study protocol is well-structured and adheres to the SPIRIT guidelines. However, there are some areas that require clarification and refinement to enhance the overall rigor of the study.

The study mentions caries progression as the primary outcome. While the study uses well-established radiographic methods to measure progression, the criteria for defining progression should be elaborated more clearly. This could include a more specific definition of what constitutes "progression" and the expected minimal clinically important difference. This clarification is crucial for assessing the success of non-inferiority in the study.

Parental satisfaction and perception of aesthetic outcomes are important secondary outcomes, but they are subjective and prone to bias. The manuscript could benefit from a more detailed discussion of how this bias will be managed. For instance, will there be any blinding of parents/guardians to the specific intervention their child receives?

The sample size calculation appears to be appropriate for the non-inferiority design. However, the assumptions underpinning the calculations (e.g., retention rate of 80% for restorations and a 10% difference) should be explicitly justified, possibly with references to relevant literature or pilot data.

The strengths and limitations section is comprehensive, but one additional point could be discussed: the study relies heavily on a single examiner's assessment of radiographic outcomes. While calibration efforts are mentioned, variability in radiographic interpretation could still introduce bias.

The manuscript is generally well-written, but there are occasional minor grammatical issues that could benefit from careful proofreading.

The authors could also outline (Introduction or Discussion) the importance of symmetry in the aesthetic restorations. Please refer to: Paolone G. Direct composite restorations in anterior teeth. Managing symmetry in central incisors. Int J Esthet Dent. 2014;9(1):12-25.

Reviewer 3

Name Elheeny, Ahmad Abdel Hamid

Affiliation Minia University

Date 11-Oct-2024

COI

Thanks for the authors for their revision

# Major concerns:

- 1. Justify the use of minimum invasive technique with with resin composite of anterior primary teeth as a control group, especially the level of evidence regarding the outcomes of this approach in pediatric patients is still low. If this is not the situation, add in the introduction section the previous studies and their outcomes.
- 2. At the end of introduction, the authors stated that "Our hypothesis is that restorations with polyvinyl crowns are not inferior to conventional restorations", This is not accepted. The authors have to defines the null hypothesis (H0) clearly for each outcome independently and please avoid the use of "we, I, he, she, etc".

### Minor comments.

- 3. Children behavior according FBRS have to be stated in the methodology before and after treatment especially, the authors will consider infants and preschool children. How their behavior will be managed? Additionally in the introduction section, please clarify the child behavior as one of important challenges in restoring anterior teeth in pediatric patients.
- 4. Define the clinical and radiographic outcomes clearly in terms of pain, discoloration, radiloucency, recurrent caries, ...etc at each time interval

## Minor concerns

1. The first paragraph in the introduction, add "early" after severe with the abbreviation of severe early childhood caries (sECC). This the definition is according to the AAPD.

2. The authors stated that "Children who suffer from severe caries in childhood may have negative impacts on the growth, development, nutritional problems and quality of life problems related to the oral health of the child and his family." Please rephrase as Children who suffer from severe caries in childhood may affect their growth and development as a result of nutritional problems. Subsequently, this may negatively affect their quality of life related to the oral health of the child and his family. (A reference needs to be added).

## **VERSION 2 - AUTHOR RESPONSE**

Reviewer: 3

Dr. Ahmad Abdel Hamid Elheeny, Minia University

**Comments to the Author:** 

Thanks for the authors for their revision

Major concerns:

1. Justify the use of minimum invasive technique with with resin composite of anterior primary teeth as a control group, especially the level of evidence regarding the outcomes of this approach in pediatric patients is still low. If this is not the situation, add in the introduction section the previous studies and their outcomes.

Response:

We appreciate the reviewer's observation. The choice of minimally invasive techniques using resin composite as a control group was based on existing studies that, despite their limitations, provide foundational evidence supporting its use in pediatric patients. Specifically, studies such as Zulekha et al. (2022) and Ozdemir et al. (2022) highlight the potential of composite resin in achieving acceptable aesthetic and functional outcomes, albeit with limited long-term data in primary anterior teeth.

To address this concern, we revised the Introduction to include references to these, emphasizing their outcomes and relevance to our hypothesis. This adjustment will provide a clearer justification for the selection of this control group, contextualizing its application within the broader framework of evidence-based pediatric restorative techniques.

2. At the end of introduction, the authors stated that "Our hypothesis is that restorations with polyvinyl crowns are not inferior to conventional restorations", This is not accepted. The authors have to defines the null hypothesis (H0) clearly for each outcome independently and please avoid the use of "we, I, he, she, etc".

Response:

Thank you for pointing this out. We acknowledge the need for clarity and precision in formulating the null hypothesis. The Methods were revised to define the null hypothesis ( $H_0$ ) for each primary and secondary outcome independently. For instance:

 $H_0$  for caries lesion progression (primary outcome): There is no difference in the progression of caries lesions between polyvinyl crowns and conventional restorations after 24 months.

 $H_0$  for restoration longevity (secondary outcome): There is no difference in the survival rates of restorations between polyvinyl crowns and conventional restorations after 24 months.

 $H_0$  for patient-centered outcomes (secondary outcome): There is no difference in parental perception, satisfaction, or quality of life impact between polyvinyl crowns and conventional restorations.

These revisions were incorporated into the Methods section, ensuring alignment with scientific standards and avoiding first-person pronouns.

#### Minor comments.

3. Children behavior according FBRS have to be stated in the methodology before and after treatment especially, the authors will consider infants and preschool children. How their behavior will be managed? Additionally in the introduction section, please clarify the child behavior as one of important challenges in restoring anterior teeth in pediatric patients.

### Response:

Thank you for this observation. We revised the Methods section to include a description of how children's behavior will be evaluated using the Frankl Behavioral Rating Scale (FBRS) both before and after the treatment. Additionally, we clarified the behavioral management strategies that will be employed, such as the tell-show-do technique, positive reinforcement, and parental presence when needed, considering the age group and individual needs of the children.

Furthermore, the Introduction were updated to emphasize that managing child behavior is a significant challenge in restoring anterior teeth, particularly in infants and preschool children, due to factors such as fear, limited cooperation, and the complexity of the procedures.

4. Define the clinical and radiographic outcomes clearly in terms of pain, discoloration, radiloucency, recurrent caries, ...etc at each time interval

## Response:

We updated the Methods section to explicitly define the clinical and radiographic outcome.

#### Minor concerns

1. The first paragraph in the introduction, add "early" after severe with the abbreviation of severe early childhood caries (sECC). This the definition is according to the AAPD.

### Response:

We appreciate this suggestion. The Introduction were revised to reflect the correct terminology.

2. The authors stated that "Children who suffer from severe caries in childhood may have negative impacts on the growth, development, nutritional problems and quality of life problems related to the oral health of the child and his family." Please rephrase as Children

who suffer from severe caries in childhood may affect their growth and development as a result of nutritional problems. Subsequently, this may negatively affect their quality of life related to the oral health of the child and his family. (A reference needs to be added).

### Response:

Thank you for this suggestion. We revised the sentence as you suggested. To support this statement, we will include the following references:

Alanzi et al. (2023): "Does the severity of untreated dental caries of preschool children influence the oral health-related quality of life?"

Lembacher et al. (2023): "The Impact of Dental Pain on the Oral Health-Related Quality of Life (OHRQoL) of Preschool Children in Austria."

#### Reviewer: 2

## Dr. Gaetano Paolone, IRCCS San Raffaele Hospital

The study mentions caries progression as the primary outcome. While the study uses well-established radiographic methods to measure progression, the criteria for defining progression should be elaborated more clearly. This could include a more specific definition of what constitutes "progression" and the expected minimal clinically important difference. This clarification is crucial for assessing the success of non-inferiority in the study.

### Response:

Thank you for this suggestion. We expanded the description of caries progression criteria in the Methods section. "Clinical outcomes: The association between exfoliation and/or the maintenance of restorations without extensive structural failures, such as marginal integrity, absence of recurrent caries, and restoration retention, will determine the success, or absence of caries progression, of restoration longevity and tooth survival in the restored tooth. These outcomes will be assessed at 6, 12, 18, and 24 months, ensuring comprehensive follow-up data."

Regarding the minimal clinically important difference (MCID), this is defined as the smallest change that would indicate a meaningful difference in clinical management. For this study, the MCID is set at 10%, based on previous studies evaluating restorative longevity and caries progression in primary teeth (e.g., Zulekha et al., 2022; Pardi et al., 2005). We revised the manuscript to clarify these definitions and justify the MCID with references.

Parental satisfaction and perception of aesthetic outcomes are important secondary outcomes, but they are subjective and prone to bias. The manuscript could benefit from a more detailed discussion of how this bias will be managed. For instance, will there be any blinding of parents/guardians to the specific intervention their child receives?

#### Response:

We appreciate this observation and agree that subjective outcomes, such as parental satisfaction and perception, are prone to bias. To mitigate this, the parents/guardians will be

blinded to the intervention performed. They will not be informed whether their child received a conventional composite restoration or a polyvinyl crown. Additionally, satisfaction and perception will be evaluated using validated questionnaires with structured Likert-scale questions to standardize responses and minimize reporting bias. This information were included in the revised Methods section.

The sample size calculation appears to be appropriate for the non-inferiority design. However, the assumptions underpinning the calculations (e.g., retention rate of 80% for restorations and a 10% difference) should be explicitly justified, possibly with references to relevant literature or pilot data.

# Response:

Thank you for pointing out the need for further justification of our sample size assumptions. The assumption of an 80% retention rate is based on literature reporting similar outcomes in primary teeth restorations (Zulekha et al., 2022, already cited in the text). The 10% difference in retention and the 5% non-inferiority margin are considered clinically relevant, as suggested by previous studies in pediatric restorative dentistry. We added these references and their relevance to the study design in the revised manuscript.

The strengths and limitations section is comprehensive, but one additional point could be discussed: the study relies heavily on a single examiner's assessment of radiographic outcomes. While calibration efforts are mentioned, variability in radiographic interpretation could still introduce bias.

## Response:

We agree that reliance on a single examiner for radiographic assessments is a potential limitation. While calibration efforts will be performed, variability in interpretation cannot be completely eliminated. This limitation will be added to the Strengths and Limitations section, along with a note about the use of standardized radiographic criteria and periodic intra-rater reliability checks to minimize bias.

The manuscript is generally well-written, but there are occasional minor grammatical issues that could benefit from careful proofreading.

## Response:

We appreciate the suggestion. A thorough review of the manuscript were conducted to address any grammatical issues and ensure clarity throughout.

The authors could also outline (Introduction or Discussion) the importance of symmetry in the aesthetic restorations. Please refer to: Paolone G. Direct composite restorations in anterior teeth. Managing symmetry in central incisors. Int J Esthet Dent. 2014;9(1):12-25.

### Response:

Thank you for this valuable suggestion. We included a discussion in the Discussion regarding the importance of symmetry in aesthetic restorations for anterior teeth, referencing Paolone G. (2014). This addition will highlight the challenges and goals of achieving natural-looking

restorations, particularly in primary incisors where anatomical and proportional symmetry is crucial for aesthetic success.

### **VERSION 3 - REVIEW**

Reviewer 2

Name Paolone, Gaetano

Affiliation IRCCS San Raffaele Hospital

Date 01-Dec-2024

COI

The authors have provided all the requested improvements

Reviewer 3

Name Elheeny, Ahmad Abdel Hamid

Affiliation Minia University

Date 06-Dec-2024

COI

### **Dear Authors**

Thank you for your extensive revision. Two main issues should be adjusted

- 1. The null hypotheses are not compatible with the non-inferiority design considred by the authors. The H0 should stated as the new treatment is inferior to the standard treatment and the alternative hypothesid should state the reverse. Please revise
- 2. Please add theses recently published articles to the introduction section that discussed the success rates and longevity of zirconia crowns in the treatment of anterior primary teeth

https://doi.org/10.1016/j.pdj.2023.12.004

doi: 10.1007/s00784-021-04359-9

Thank you

Thank you

# **VERSION 3 - AUTHOR RESPONSE**

**Reviewer: 2** 

Dr. Gaetano Paolone, IRCCS San Raffaele Hospital

**Comments to the Author:** 

The authors have provided all the requested improvements

Answer:

Thank you for your positive feedback and acknowledgment of the revisions made. We appreciate your thoughtful review and are pleased that the changes have addressed your concerns. Your comments have been invaluable in improving the quality and clarity of our manuscript.

Reviewer: 3

Dr. Ahmad Abdel Hamid Elheeny, Minia University

**Comments to the Author:** 

**Dear Authors** 

Thank you for your extensive revision. Two main issues should be adjusted

1. The null hypotheses are not compatible with the non-inferiority design considered by the authors. The H0 should stated as the new treatment is inferior to the standard treatment and the alternative hypothesid should state the reverse. Please revise

Answer:

Thank you for your observation. We have revised the null hypotheses to reflect the non-inferiority design, as suggested. The revised null and alternative hypotheses are as follows:

The null hypothesis  $(H_0)$  for each primary and secondary outcome independently are:

 $H_0$  for caries lesion progression (primary outcome): Polyvinyl crowns are inferior to conventional restorations in preventing the progression of caries lesions after 24 months.

 $H_0$  for restoration longevity (secondary outcome): Polyvinyl crowns are inferior to conventional restorations in the survival rates of restorations after 24 months.

 $H_0$  for patient-centered outcomes (secondary outcome): Polyvinyl crowns are inferior to conventional restorations in terms of parental perception, satisfaction, or quality of life impact.

2. Please add theses recently published articles to the introduction section that discussed the success rates and longevity of zirconia crowns in the treatment of anterior primary teeth

https://doi.org/10.1016/j.pdj.2023.12.004

doi: 10.1007/s00784-021-04359-9

Thank you

Answer: Thank you for your suggestion to include recently published articles discussing the success rates and longevity of zirconia crowns in the treatment of anterior primary teeth. We have reviewed the articles and incorporated their findings into the introduction section of the manuscript. These references provide valuable insights that strengthen the contextual

BMJ Open: first published as 10.1136/bmjopen-2024-086200 on 6 February 2025. Downloaded from http://bmjopen.bmj.com/ on June 13, 2025 at Agence Bibliographique de l Enseignement Superieur (ABES) .
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background and relevance of our study. The revised introduction now highlights the outcomes of recent studies on zirconia crowns, emphasizing their promising results in terms of aesthetics and longevity, as well as their role in minimally invasive restorative dentistry.