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The Journal of Pediatric Dentistry is a peer-reviewed, international, scientific journal published in accordance with independent, unbiased, and double-blinded peer-review principles. Three issues are released every year in April, August, and December.

The aim of the journal is to publish high level clinical and experimental studies conducted in all Pediatric Dentistry reviews comprising the latest research findings, reports on rare and educational cases, and letters to the editor that are prepared in accordance with the ethical guidelines. The journal's publication language is English.

Journal's target audience includes academicians, specialists, residents, and general practitioners working in the fields of pediatric dentistry, medicine and other related fields.

The Journal of Pediatric Dentistry is registered with the following abstracting partners:

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The Journal of Pediatric Dentistry is indexed with, or included in, the following: **EuroPub, DRJI, ASCI-Database.**

The editorial and publication processes of the journal are shaped in accordance with the guidelines of the International Committee of Medical Journal Editors (ICMJE), World Association of Medical Editors (WAME), Council of Science Editors (CSE), Committee on Publication Ethics (COPE), European Association of Science Editors (EASE), and National Information Standards Organization (NISO). The journal is in conformity with the Principles of Transparency and Best Practice in Scholarly Publishing (doaj.org/bestpractice).

Processing and publication are free of charge with the journal. No fees are requested from the authors at any point throughout the evaluation and publication process. All manuscripts must be submitted via the online submission system, which is available at https://jpdent.org/ The journal guidelines, technical information, and the required forms are available on the journal's web page.

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Instructions to the Authors

The Editorial Process

A manuscript will be reviewed for possible publication with the understanding that it is being submitted to Journal of Pediatric Dentistry alone at that point in time and has not been published anywhere, simultaneously submitted, or already accepted for publication elsewhere. The journal expects that authors would authorize one of them to correspond with the Journal for all matters related to the manuscript. All manuscripts received are duly acknowledged. On submission, editors review all submitted manuscripts initially for suitability for formal review. Manuscripts with insufficient originality, serious scientific or technical flaws, or lack of a significant message are **rejected** before proceeding for formal peer-review. Manuscripts that are unlikely to be of interest to the Journal of Pediatric Dentistry readers are also liable to be rejected at this stage itself.

Manuscripts that are found suitable for publication in Journal of Pediatric Dentistry are sent to two or more expert reviewers. During submission, the contributor is requested to provide names of two or three qualified reviewers who have had experience in the subject of the submitted manuscript, but this is not mandatory. The reviewers should not be affiliated with the same institutes as the contributor/s. However, the selection of these reviewers is at the sole discretion of the editor. The journal follows a **double-blind** review process, wherein the reviewers and authors are unaware of each other's identity. Every manuscript is also assigned to a member of the editorial team, who based on the comments from the reviewers takes a final decision on the manuscript. The comments and suggestions (acceptance/ rejection/ amendments in manuscript) received from reviewers are conveyed to the corresponding author. If required, the author is requested to provide a point by point response to reviewers' comments and submit a revised version of the manuscript. This process is repeated till reviewers and editors are satisfied with the manuscript.

Manuscripts accepted for publication are copy edited for grammar, punctuation, print style, and format. Page proofs are sent to the corresponding author. The corresponding author is expected to return the corrected proofs within **three** days. It may not be possible to incorporate corrections received after that period. The whole process of submission of the manuscript to final decision and sending and receiving proofs is completed online. To achieve faster and greater dissemination of knowledge and information, the journal publishes articles online as '**Ahead of Print**' immediately on acceptance.

Authorship Criteria

Authorship credit should be based only on substantial contributions to each of the three components mentioned below:

1. Concept and design of study or acquisition of data or analysis and interpretation of data;
2. Drafting the article or revising it critically for important intellectual content; and
3. Final approval of the version to be published.

Participation solely in the acquisition of funding or the collection of data does not justify authorship. General supervision of the research group is not sufficient for authorship. Each contributor should have participated sufficiently in the work to take public responsibility for appropriate portions of the content of the manuscript. The order of naming the contributors should be based on the relative contribution of the contributor towards the study and writing the manuscript. Once submitted the order cannot be changed without written consent of all the contributors. The journal prescribes a maximum number of authors for manuscripts depending upon the type of manuscript, its scope and number of institutions involved (vide infra). The authors should provide a justification, if the number of authors exceeds these limits.

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Contributors should provide a description of contributions made by each of them towards the manuscript. Description should be divided in following categories, as applicable: concept, design, definition of intellectual content, literature search, clinical studies, experimental studies, data acquisition, data analysis, statistical analysis, manuscript preparation, manuscript editing and manuscript review. One or more author should take responsibility for the integrity of the work as a whole from inception to published article and should be designated as 'guarantor'.

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All authors of must disclose any and all conflicts of interest they may have with publication of the manuscript or an institution or product that is mentioned in the manuscript and/or is important to the outcome of the study presented. Authors should also disclose conflict of interest with products that compete with those mentioned in their manuscript.

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The submitted manuscripts that are not as per the "Instructions to Authors" would be returned to the authors for technical correction, before they undergo editorial/peer-review. Generally, the manuscript should be submitted in the form of two separate files:

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1. Title Page/First Page File/covering letter:

This file should provide;

1. The type of manuscript (Original Article, Review Article, Letter to Editor, Case Report, etc.) title of the manuscript, running title, names of all authors / contributors (with their highest academic degrees, designation and affiliations) and name(s) of department(s) and/ or institution(s) to which the work should be credited, . All information which can reveal your identity should be here. Use only doc files. Do not zip the files.
2. The total number of pages, total number of photographs and word counts separately for abstract and for the text (excluding the references, tables and abstract), word counts for introduction + discussion in case of an original article;
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and all published articles or other manuscripts in preparation or submitted elsewhere that are related to the manuscript must also accompany the manuscript. The material should be sent to any of the two addresses given above.

Types of Manuscripts

Original articles:

These include randomized controlled trials, intervention studies, studies of screening and diagnostic test, outcome studies, cost effectiveness analyses, case-control series, and surveys with high response rate. The text of original articles amounting to up to **3,500** words (excluding Abstract, References and Tables) should be divided into sections with the headings: Abstract (**Structured format: Objectives, Materials and Methods, Statistical analysis, Results, Conclusions**) up to **350** words, Key-words (**3–7** MeSH words), **Introduction, Materials and Methods, Results, Discussion, Conclusions, References** (up to **40** references), **Tables** and **Figure legends**.

Introduction: State the purpose and summarize the rationale for the study or observation.

Materials and Methods: It should include and describe the following aspects:

Ethics: When reporting studies on human beings, indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional or regional) and with the Helsinki Declaration of 1975, as revised in 2000 (available at http://www.wma.net/e/policy/17-c_e.html). For prospective studies involving human participants, authors are expected to mention about approval of (regional/ national/ institutional or independent Ethics Committee or Review Board, obtaining informed consent from adult research participants and obtaining assent for children aged over 7 years participating in the trial. The age beyond which assent would be required could vary as per regional and/ or national guidelines. Ensure confidentiality of subjects by desisting from mentioning participants' names, initials or hospital numbers, especially in illustrative material. When reporting experiments on animals, indicate whether the institution's or a national research council's guide for, or any national law on the care and use of laboratory animals was followed.

Evidence for approval by a local Ethics Committee (for both human as well as animal studies) must be supplied by the authors on demand. Animal experimental procedures should be as humane as possible and the details of anesthetics and analgesics used should be clearly stated. The ethical standards of experiments must be in accordance with the guidelines provided by the CPCSEA and World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Humans for studies involving experimental animals and human beings, respectively). The journal will not consider any paper which is ethically unacceptable. A statement on ethics committee permission and ethical practices must be included in all research articles under the 'Materials and Methods' section.

Study design: Selection and Description of Participants: Describe your selection of the observational or experimental participants (patients or laboratory animals, including controls) clearly, including eligibility and exclusion criteria and a description of the source population. Technical information: Identify the methods, apparatus (give the manufacturer's name and address in parentheses), and procedures in sufficient detail to allow other workers to reproduce the results. Give references to established methods, including statistical methods (see below); provide references and brief descriptions for methods that have been published but are not well known; describe new or substantially modified methods, give reasons for using them, and evaluate their limitations. Identify precisely all drugs and chemicals used, including generic name(s), dose(s), and route(s) of administration.

Reports of randomized clinical trials should present information on all major study elements, including the protocol, assignment of interventions (methods of randomization, concealment of allocation to treatment groups), and the method of masking (blinding), based on the CONSORT Statement (http://www.consort-statement.org).

Statistics: Whenever possible quantify findings and present them with appropriate indicators of measurement error or uncertainty (such as confidence intervals). Authors should report losses to observation (such as, dropouts from a clinical trial). When data are summarized in the Results section, specify the statistical methods used to analyze them. Avoid non-technical uses of technical terms in statistics, such as 'random' (which implies a randomizing devi-

Reporting Guidelines for Specific Study Designs

Initiative	Type of Study	Source
CONSORT	Randomized controlled trials	http://www.consort-statement.org
STARD	Studies of diagnostic accuracy	http://www.consort-statement.org/stardstatement.htm
PRISMA	Systematic reviews and meta-analyses	http://www.prisma-statement.org/PRISMAStatement/Default.aspx
STROBE	Observational studies in epidemiology	http://www.strobe-statement.org
MOOSE	Meta-analyses of observational studies in epidemiology	http://www.consort-statement.org/Media/Default/Downloads/Other%20Instruments/-MOOSE%20Statement%202000.pdf

ce), 'normal', 'significant', 'correlations', and 'sample'. Define statistical terms, abbreviations, and most symbols. Specify the computer software used. Use upper italics (P 0.048). For all P values include the exact value and not less than 0.05 or 0.001. Mean differences in continuous variables, proportions in categorical variables and relative risks including odds ratios and hazard ratios should be accompanied by their confidence intervals.

Results: Present your results in a logical sequence in the text, tables, and illustrations, giving the main or most important findings first. Do not repeat in the text all the data in the tables or illustrations; emphasize or summarize only important observations. Extra- or supplementary materials and technical detail can be placed in an appendix where it will be accessible but will not interrupt the flow of the text; alternatively, it can be published only in the electronic version of the journal.

When data are summarized in the Results section, give numeric results not only as derivatives (for example, percentages) but also as the absolute numbers from which the derivatives were calculated, and specify the statistical methods used to analyze them. Restrict tables and figures to those needed to explain the argument of the paper and to assess its support. Use graphs as an alternative to tables with many entries; do not duplicate data in graphs and tables. Where scientifically appropriate, analyses of the data by variables such as age and sex should be included.

Discussion: Include summary of *key findings* (primary outcome measures, secondary outcome measures, results as they relate to a prior hypothesis); *Strengths* and *limitations* of the study (study question, study design, data collection, analysis and interpretation); *Interpretation* and *implications* in the context of the totality of evidence (is there a systematic review to refer to, if not, could one be reasonably done here and now?, what this study adds to the available evidence, effects on patient care and health policy, possible mechanisms); *Controversies* raised by this study; and *Future research directions* (for this particular research collaboration, underlying mechanisms, clinical research).

Do not repeat in detail data or other material given in the Introduction or the Results section. In particular, contributors should avoid making statements on economic benefits and costs unless their manuscript includes economic data and analyses. Avoid claiming priority and alluding to work that has not been completed. New hypotheses may be stated if needed, however they should be clearly labeled as such. About 30 references can be included. These articles generally should not have more than six authors.

Review Articles:

It is expected that these articles would be written preferably by individuals who have done substantial work on the subject or are considered experts in the field. The prescribed word count is up to **4,000** words excluding tables, references and abstract. The manuscript may have about **75** references. The manuscript should have an unstructured abstract (up to **400** words) representing an accurate summary of the article. The section titles would depend upon the topic reviewed. Authors submitting review article should include a section describing the methods used for locating, selecting, extracting, and synthesizing data. These methods should also be summarized in the abstract. The journal expects the contributors to give post-publication updates on the subject of review. The update should be brief, covering the advances in the field after the publication of the article and should be sent as a letter to editor, as and when major development occurs in the field.

Case Reports/Case Series:

New, interesting and rare cases can be reported. They should be unique, describing a great diagnostic or therapeutic challenge and providing a learning point for the readers. Cases with clinical significance or implications will be given priority. These manuscripts could be of up to **2,500** words (excluding Abstract and references) and manuscript should have an unstructured abstract (up to **350** words), Key-words, Introduction, Case report, Discussion, Conclusion, Reference, Tables and Legends in that order. The case reports could be supported with up to **25** references. The number of images/figures/tables/graphs is to be limited to **7** only.

Editorial:

Editorials are solicited by the editorial board or Editor-in-Chief; should be up to 1,500 words and with no more than 15 references.

Letter to the Editor (LTE):

These should be short and decisive observations. They should preferably be related to articles previously published in the Journal or views expressed in the journal. They should not be preliminary observations that need a later paper for validation. The letter could have up to **300** words and **5** references. It could be generally authored by not more than four authors. It should follow the response of authors with similar word count and references with the reading 'In response.'

Article Types

The following graph shows what types of articles are accepted for publication, and what requirement they may have.

References:

References should be *numbered* consecutively in the order in which they are first mentioned in the text (not in alphabetic order). *Identify references* in text, tables, and legends by Arabic numerals in superscript with square bracket after the punctuation *marks*. *References cited* only in tables or figure legends should be numbered in accordance with the sequence established by the

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Article Type	Abstract Limit	Keywords Limit	Title Limit	Tables/Figures Limit	References Limit
Original Article (up to 3,500 words)	Up to 350 words (Structured: Objectives, Materials and Methods, Statistical analysis, Results, Conclusions)	3 to 7 keywords	Up to 35 words	Approximately 5 tables/figures	Up to 40 references
Brief Report (up to 1,800 words)	Up to 250 words (Structured: Objectives, Materials and Methods, Statistical analysis, Results, Conclusions)	3 to 7 keywords	Up to 35 words	Approximately 5 tables/figures	Up to 20 references
Review Article (up to 4,000 words)	Up to 400 words (Unstructured abstract)	3 to 7 keywords	Up to 35 words	Approximately 5 tables/figures	Up to 75 references
Case Report (up to 2,500 words)	Up to 350 words (Unstructured abstract)	3 to 7 keywords	Up to 35 words	Approximately 7 tables/figures	Up to 25 references
Editorial (up to 1,500 words)	n/a	n/a	n/a	n/a	Up to 15 references
Letter to Editor (up to 300 words)	n/a	n/a	n/a	n/a	Up to 5 references
In Response (up to 300 words)	n/a	n/a	n/a	n/a	Up to 5 references

first identification in the text of the particular table or figure. Use the style of the examples below, which are based on the formats used by the NLM *in Index Medicus*. The titles of journals *should be abbreviated* according to the style used in Index Medicus. Use complete name of the journal for non-indexed journals. Avoid using abstracts as references. Information from manuscripts submitted but not accepted should be cited in the text as "unpublished observations" with written permission from the source. Avoid citing a "personal communication" unless it provides essential information not available from a public source, in which case the name of the person and date of communication should be cited in parentheses in the text.

The commonly cited types of references are shown here, for other types of references such as newspaper items please refer to ICMJE Guidelines (http://www.icmje.org or http://www.nlm.nih.gov/bsd/uniform_requirements.html).

Articles in Journals

1. Standard journal article (for up to six authors):

Albuquerque Guedes AP, Oliveira-Reis B, Catelan A, Umeda Suzuki TY, Fraga Briso AL, Dos Santos PH. Mechanical and surface properties analysis of restorative materials submitted to erosive challenges in situ. Eur J Dent 2018;12:559-565.

1. Standard journal article (for more than six authors): List the first six contributors followed by et al.

Al-Marzooq F, Al Bayat S, Sayyar F, Ishaq H, Nasralla H, Koutaich R, et al., Can probiotic cleaning solutions replace chemical disinfectants in dental clinics?. Eur J Dent 2018;12:532-539.

1. Volume with supplement:

Thosar N, Basak S, Bahadure RN, Rajurkar M. Antimicrobial efficacy of five essential oils against oral pathogens: An in vitro study. Eur J Dent 2013 Sep;7(Suppl 1):S071-S077.

Books and Other Monographs

1. **Books with a Single Author:** Jacobson A, Radiographic Cephalometry: From Basics to Videoimaging, 2nd ed. Birmingham: Quintessence Publishing Co, Inc; 2006
2. **Editor(s), compiler(s) as author:** Garcia LS, Filarial Nematodes In: Garcia LS (editor) Diagnostic Medical Parasitology Washington DC; ASM press; 2007:319-356
3. **Book Chapter:** D'Alpino PH, Svizero NR, Carrilho M, Self-adhering composites. In: Miletic V, ed. Dental Composite Materials for Direct Restorations. Cham: Springer International Publishing; 2018:129–151.

Electronic Sources as reference

Journal article on the Internet: Parija SC, Khairnar K. Detection of excretory Entamoeba histolytica DNA in the urine, and detection of E. histolytica DNA and lectin antigen in the liver abscess pus for the diagnosis of amoebic liver abscess. BMC Microbiology 2007, 7:41.doi:10.1186/1471-2180-7-41. http://www.biomedcentral.com/1471-2180/7/41.

Tables

- Tables should be self-explanatory and should not duplicate textual material.
- Tables with more than 10 columns and 25 rows are not acceptable.

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- Number tables, in Arabic numerals, consecutively in the order of their first citation in the text and supply a brief title for each.
- Place explanatory matter in footnotes, not in the heading.
- Explain in footnotes all non-standard abbreviations that are used in each table.
- Obtain permission for all fully borrowed, adapted, and modified tables and provide a credit line in the footnote.
- For footnotes use the following symbols, in this sequence: *, †, ‡, §, ||,¶ , **, ††, ‡‡
- Tables with their legends should be provided **at the end of the text after the references**. The tables along with their number should be cited at the relevant place in the text.

Illustrations (Figures)

- Upload the images in **JPG** format. The file size should be within 1024 kb in size while uploading.
- Figures should be numbered consecutively according to the order in which they have been first cited in the text.
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Original Article

Assessing the Effectiveness of Virtual Reality vs. Nitrous Oxide in Managing Anxiety and Pain in Pediatric Dental Procedures

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Abstract

Objective: The aim of this study was to compare virtual reality (VR) and nitrous oxide for dental anxiety and pain during a dental procedure in children.

Materials and Methods: This study examined two groups. Group 1 received dental treatment using nitrous oxide. Group 2 received dental treatment while watching a video through a virtual reality headset. Both groups received restorative treatment, including intraoral anesthetic injections, to perform dental restorations, crowns, and/or the extraction of teeth. The participants were asked to rate their pain with the Wong-Baker Faces scale before and after the procedure. After administering local anesthesia, the provider gave the participant a FLACC score. The investigator completed the Houpt Crying and Movement Scale after the procedure. Virtual Reality (VR) may serve as an effective behavior management tool for pediatric dentists by providing distraction and alleviating discomfort during dental procedures. This approach could be a way to enhance the clinical experience for young patients. Additionally, VR may be a valuable alternative when nitrous oxide is contraindicated or unavailable.

Results: Houpt, FLACC, and FACES scores did not demonstrate a statistically significant difference between virtual reality distraction and nitrous oxide in patient reaction to anesthesia, procedure, and post-operative discomfort. The number of participants who claimed they "had fun" during their procedure was statistically higher with VR, demonstrating a p-value of <0.0001.

Conclusion: Virtual reality may be a viable non-pharmacologic behavior management alternative to nitrous oxide.

Keywords: Behavior guidance, children, dental anxiety, nitrous oxide, virtual reality

Introduction

Dental fear and anxiety can significantly limit children's access to dental care. Various triggers, such as the sights and sounds of a dental office, can cause anxiety.[1] To reduce this, dentists have several strategies, including basic behavior management techniques, nitrous oxide, and sedation.[2] Recently, virtual reality (VR) technology has become a promising tool for managing dental anxiety and perceived pain.

Several studies have examined various forms of audiovisual anxiolysis and analgesia through distraction.[3–23] These electronic distractions have ranged from televisions and headphones to pioneering virtual reality systems. VR has been examined not only in dental set-

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tings [3–12,20,21] but also in other medical fields that involve anxiety-inducing or painful procedures, such as burn trauma, chemotherapy, and phlebotomy.[13–19]

Research dating back to 2000 shows that VR can reduce pain more effectively than audio-visual stimuli like video games.[22] For example, when exploring dentistry specifically, a 2001 study claimed that virtual reality is attention-grabbing and allows patients to tolerate painful procedures.[21] Further studies, including one by Atzori in 2018, have shown that modern VR technology can lower "worst pain" and "pain unpleasantness" scores, which children report more enjoyable experiences during dental procedures.[20] In 2019, Rao conducted a study where children using VR during a procedure showed reduced pain and anxiety. Both authors suggested that VR could feasibly be used in dental practice.[3,20]

Standardized systems for measuring behavior and pain perception, such as the FLACC, Wong-Baker FACES, and Houpt Behavior scales, have been validated and are useful in studies demonstrating pain and distress.[24–28]

To our knowledge, this is one of the first randomized controlled trials to directly compare virtual reality distraction with nitrous oxide sedation in pediatric dental procedures, providing novel insights into the comparative effectiveness of these two behavior management strategies.

This study aims to compare the effectiveness of VR and nitrous oxide in relieving dental anxiety and pain during dental procedures.

Materials and Methods

Study Design and Population

This study (IRB#) was an IRB-approved, randomized, controlled, interventional therapy using virtual reality goggles as a method of distraction. The trial adhered to the CONSORT reporting guidelines for randomized controlled trials.

Trial Design: This was a parallel group, randomized controlled trial with a 1:1 allocation ratio comparing standard treatment with nitrous oxide (control) versus distraction therapy (intervention).

Participants: Fifty-three pediatric Dental patients (27 in the control group, 26 in the treatment group) were recruited from the pediatric dental clinic at a tertiary medical center. Data on the type of behavior displayed and the child's responses to standardized questions were collected during and after the procedure.

Inclusion Criteria

- ASA 1 or 2, male or female pediatric dental patients aged 4–12 years.
- Participants who require a restorative procedure that includes the injection of local anesthesia.

Exclusion Criteria

- Participants who could not tolerate the use of a headset, local anesthesia, or nitrous oxide.
- Participants who had hypersensitivity to audio-visual devices that can lead to seizures.

Recruitment and Consent

Participants were enrolled consecutively from the clinic population. Written informed consent was obtained from parents, and assent was obtained from all children aged 7 years and above before study initiation.

Randomization and Allocation

On the day of the appointment, the participant was randomly assigned to either of the following groups by flipping a coin:

1) a control group (treatment using nitrous oxide), or
2) a treatment group (treatment using VR goggles).

Allocation concealment was ensured by performing randomization immediately before the procedure.

Blinding

Due to the nature of the intervention, participants and providers could not be blinded to a group assignment. However, outcome assessment (behavior scoring and post-procedure scales) was conducted by the investigator trained in standardized evaluation to minimize bias.

Interventions

1. **Control Group:** Treatment with Nitrous Oxide.
2. **Treatment group:** Treatment using Oculus Quest 2 VR Goggles. The Oculus Quest 2 is a virtual reality headset designed to give users an immersive experience while watching content or playing games. The headset is strapped to the user's head so that an LCD screen dominates the user's field of vision, blocking all other visual distractions. Built-in audio also projects from the headset. Participants viewed a 45-minute cartoon with an immersive audiovisual distraction during the dental procedure.

Outcomes

Primary Outcome: Self-reported pain using the Wong Baker FACES scale (baseline and post-procedure).[29]

Table 1. Demographics and procedures performed

	Nitrous oxide (N=27)		VR goggle (N=26)		Total (N=53)		p
	n	%	n	%	n	%	
Age at diagnosis (years), mean (SD)	7.70 (1.81)		8.73 (1.66)		8.21 (1.80)		0.037[1]
Sex							0.318[2]
Female	13	48.1	9	34.6	22	41.5	
Male	14	51.9	17	65.4	31	58.5	
Indirect Pulp Cap	2	7.4	1	3.8	3	5.7	0.575[2]
Space maintainer	1	3.7	0	0.0	1	1.9	0.322[2]
Pulpotomy	1	3.7	1	3.7	0	0.0	0.322[2]
Prophy	0	0.0	1	3.8	1	1.9	0.304[2]
Removal of distal shoe	0	0.0	1	3.8	1	1.9	0.304[2]
SDF	1	3.7	0	0.0	1	3.8	0.304[2]
Restorations	19	70.4	15	57.7	34	64.2	0.336[2]
Extraction	12	44.4	10	38.5	22	41.5	0.659[2]
Sealants/PRR	9	33.3	12	46.2	21	39.6	0.340[2]
Stainless Steel Crown	10	37.0	6	23.1	16	30.2	0.268[2]

[1]: Two sample t-test, [2]: Chi-Square p-value

Secondary Outcome

- After administering local anesthesia, the provider gave the participant a FLACC score.[30]
- At the end of the procedure, the participants rated their experience using the Wong-Baker FACES scale, and a survey was given to the participants to be completed.
- The investigator completed the Houpt Crying and Movement Scale[31] after the procedure was completed.

Sample Size Calculation

A prior power analysis on Wong Baker Faces scale was performed to determine the sample size required for this study. The calculation was based on an anticipated effect size of 0.5, a significance level of 0.05, and 5 degrees of freedom for a chi-square test. The analysis indicated that a sample size of 52 participants (26 per group) would provide 80% power to detect the hypothesized effect size. To ensure adequate statistical power, a minimum of 53 participants were included in the study, with 26 participants allocated to the VR goggle group and 26 participants to the nitrous oxide group.

Statistical Analysis

Comparisons were performed using a Chi-square test for categorical variables and two-sample t-test or Wilcoxon rank sum test for numerical (normally and non-normally distributed, respectively). The data distribution was evaluated using the Shapiro-Wilk test and histograms. All tests were 2-sided, and p values <0.05 were considered statistically significant. Statistical analysis was conducted using SAS® Enterprise Guide 8.2 (SAS Institute Inc., Cary, NC, USA).

Statistical Methods

Due to the limited sample size, multivariate analyses were not performed. Comparisons were limited to group-level descriptive statistics and univariate tests.

The statistician was not blinded to group allocation; however, all outcomes were predefined and evaluated using validated behavioral and pain assessment tools to minimize potential bias.

Results

Fifty-three patients were recruited to participate in the study. Table 1 presents the demographic and procedural characteristics of patients who underwent dental procedures using nitrous oxide sedation (N=27) or VR goggles (N=26). The mean age at diagnosis differed between groups, with patients in the nitrous oxide group being younger on average (7.70±1.81 years) compared to those in the VR group (8.73±1.66 years). The gender distribution was similar between groups (p=0.318), with males comprising 51.9% of the nitrous oxide group and 65.4% of the VR group.

The distribution of dental procedures performed was similar between the two groups, with no statistically sig-

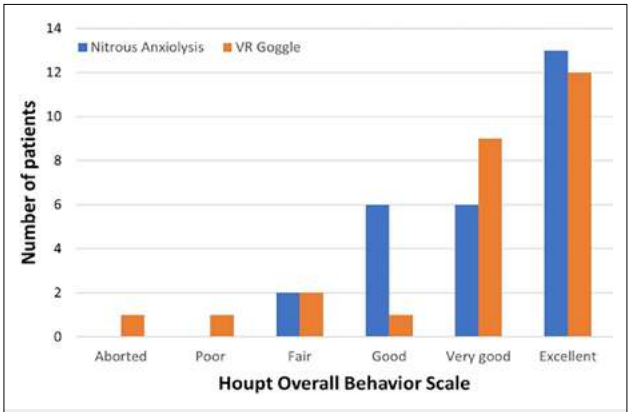

Figure 1. Distribution of Houpt behavior score listed by treatment group

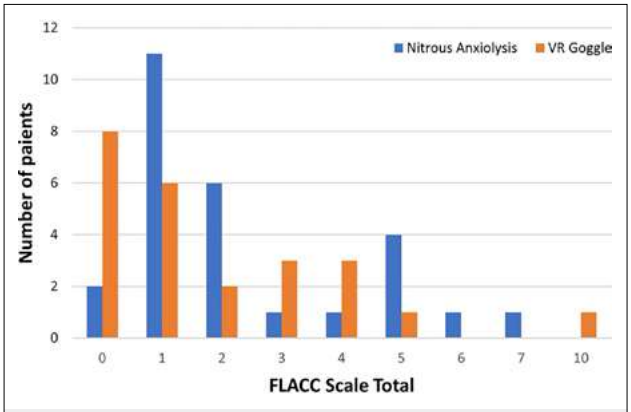

Figure 2. Distribution of total FLACC scale listed by treatment group

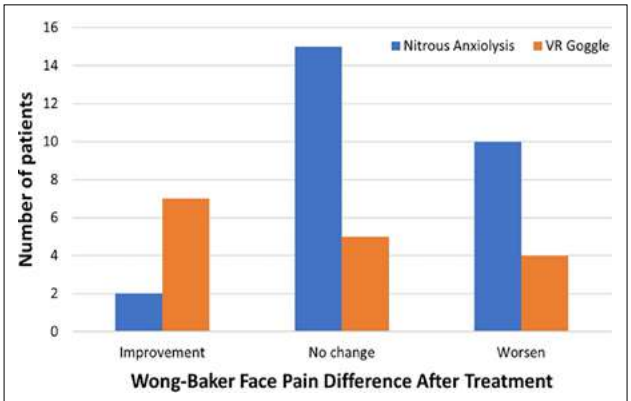

Figure 3. Distribution of Wong-Baker face pain change listed by treatment group. *No significant difference (p=0.069)

nificant difference observed for indirect pulp cap (IPC), pulpotomy, prophylaxis, silver diamine fluoride (SDF) application, extractions, sealants, or stainless-steel crowns (p>0.05 for all). Composite Restorations were the most common procedure, performed in 64.2% of all patients, followed by extractions (41.5%). The number of procedures per patient also did not differ significantly between groups (p=0.437), with most patients undergoing one (41.5%) or two (34%) procedures. We found no statistically significant difference in the Houpt behavior scores between the VR and nitrous oxide groups (p=0.359). Due to the limited sample size, a Houpt score lower than 4 was categorized as poor behavior, and a score of 4 or above was classified as good behavior. A slightly higher rate of good behavior was noticed in the nitrous oxide group (92.6% vs 84.6%). Although the differences were insignificant, Houpt scores (Fig. 1) for movement were similar between the two groups, behavior scores for crying were slightly better among the VR group, and the nitrous oxide group had somewhat better overall behavior.

A FLACC score was given by the provider after the administration of local anesthesia. The mean FLACC score given to patients who received treatment with nitrous oxide was 2.3 (±1.9), while the mean FLACC score given to patients who received treatment with VR was 2.0 (±2.3). These findings are detailed in Figure 2. The mean difference in FLACC score between the VR and nitrous oxide group was 0.3 (95% Confidence interval: -0.9–1.5, p=0.526).

Pre-operative and post-operative pain scales were recorded using the Wong-Baker FACES scale (Fig. 3). An improvement in pain rating after the procedure was more likely to be noticed among the nitrous oxide group (26.9% vs 7.4%), and the VR group was more likely to have a worse pain rating after the procedure (37% vs 15.4%). These differences in Wong-Baker FACES pain scores were not statistically significant (p=0.069).

Although the nitrous oxide group showed a numerically higher proportion of patients reporting post-procedure pain improvement compared to VR group, the difference did not reach statistical significance (p=0.069). These results suggest a potential trend that warrants further study but should be interpreted with caution given the limited sample size.

When asked if the patient had fun after the procedure, the patients responded more in the affirmative with VR than with nitrous oxide (87% vs 19%, p<0.0001).

Discussion

Nitrous oxide, commonly known as laughing gas, has been widely used in dentistry for decades because of its calming and pain-relieving properties. It provides a quick onset of sedation, is easily adjusted, and has a fast recov-

ery time, making it a popular choice for managing dental anxiety in children. Its safety profile is well-documented, and it helps ensure patient cooperation during procedures, which is especially important in pediatric dentistry. On the other hand, virtual reality (VR) offers a new, non-drug approach that has gained interest for its ability to distract and immerse young patients during dental treatments. VR can significantly lower perceived pain and anxiety by shifting the child's focus away from the procedure, creating an engaging and soothing environment. Unlike nitrous oxide, VR is a non-pharmacological modality that removes concerns about drug interactions or side effects. Comparing nitrous oxide and virtual reality in children is important for several reasons.

First, it helps identify which method provides better control of anxiety and pain, leading to a better patient experience and improved cooperation.

Second, it provides insights into the safety profiles, cost-effectiveness, and practicality of implementing these interventions in clinical settings. Third, understanding the differential effects can guide clinicians in selecting personalized management strategies tailored to each patient's needs, preferences, and medical considerations.

Furthermore, this comparison can contribute to the development of integrated approaches that combine pharmacological and non-pharmacological techniques, potentially enhancing overall efficacy. As research advances, establishing evidence-based guidelines for using nitrous oxide and virtual reality can optimize pediatric dental care, reduce dental fear, and promote better oral health outcomes in children. Therefore, a comprehensive comparison of these two modalities is essential for advancing pediatric dental practice and improving patient-centered care.

A recent meta-analysis reviewed and summarized studies on the effectiveness of virtual reality distraction up to 2018. The analysis found that "no differences were observed in anxiety levels during the administration of local anesthesia, use of rubber dam, removal of caries and restorative procedures" and concluded that "the use of virtual reality glasses is an effective tool for improving behavior and reducing pain perception during the dental treatment of children."[32] However, these studies compared the use of VR to dental treatment without the use of any specific form of anxiolysis.

The author aimed to determine if using a virtual reality headset for distraction could serve as a viable alternative to nitrous oxide for managing anxiety and pain in pediatric patients. The results demonstrated no statistically significant difference between VR and nitrous oxide behavior scores. This outcome suggests that VR can be used as a behavior management tool for children in the dental office.

Our findings are consistent with previous reports showing that VR reduces pediatric dental anxiety and pain,[3,20,32] though most prior studies compared VR to no intervention rather than to nitrous oxide. By directly contrasting the VR with an established standard, our trial expands on the literature and provides evidence for VR as a potential alternative. Considering these results, dental providers must evaluate whether VR distraction will benefit their patients after considering the advantages and limitations of both VR and nitrous oxide.

Some advantages of using VR include its ability to distract children and reduce "the unpleasantness and distress that arises during dental restorative procedures."[10] The goggles also prevented the child from seeing intimidating objects such as the dental syringe or dental instruments. Furthermore, to view the VR content, the child needed to keep their head in an optimal position; otherwise, the screen would not be visible. Participants also reported having more fun during the procedure,[20] which could enhance patient satisfaction and retention.

Conversely, virtual reality technology is new and can be challenging to use if the user is not familiar with the technology. On occasion, patients needed repeated commands since they were distracted. If a patient became disengaged or began to cry, tears or closed eyes made VR less effective. Additionally, while there is a possibility that a child could experience an adverse reaction to the VR headset, like headaches or nausea, a 2020 meta-analysis investigating the use of VR in dentistry found no evidence of this in any literature that they compared.[32]

Nitrous oxide has a long history of use and extensive research supporting its benefits, safety, and effectiveness.[33] It can be easily titrated for the individual. If a patient becomes distressed, the nitrous oxide concentration can be increased, and anxiolysis may be achieved after allowing sufficient time for the child to inhale the gas.

However, even with nitrous oxide, basic behavior management techniques are still necessary, for example, the use of distraction. Some children may not tolerate nitrous oxide or may have medical conditions that prevent its use, requiring alternative treatment modalities.

Limitations and weaknesses

This study has potential limitations and weaknesses:

1. Participants underwent various dental procedures, which prevented standardization across the treatments. Some procedures may be more difficult to tolerate than others. For example, a pulpotomy might be more difficult to tolerate than an occlusal composite restoration. If a child receiving an "easier" treatment was assigned to the VR group and a child undergoing a "difficult" treatment was assigned to the nitrous group, the results could be skewed. To mitigate this bias, participants were randomized using a coin toss. Future studies with larger sample sizes are needed to confirm these findings.
2. The statistician was not blind to group allocation; however, all outcomes were pre-defined and evaluated using validated behavior and pain assessment tools to minimize potential bias.
3. While VR offers an engaging, non-pharmacological approach, its limitations include potential intolerance to the headset, occasional distraction from provider instructions, and a reliance on equipment. Conversely, nitrous oxide has a strong safety record and predictable anxiolytics effects, but requires monitoring, carries pharmacological risks, and may not be suitable for all patients.

The results of this study offer valuable insight into virtual reality's usefulness in the dental setting. Most other studies on the topic were designed to evaluate VR's effectiveness in reducing pain and anxiety and its dental application;[4–9] however, few have compared it to existing anxiolytic and analgesic techniques. Although nitrous oxide represents a pharmacologic anxiolytic and VR is distraction based, both serve the same clinical purposes: To reduce anxiety and facilitate cooperation. Our findings suggest that the VR offers a non-pharmacologic alternative with comparable clinical outcomes, particularly in cases where nitrous oxide is contraindicated or declined.

Further research is needed to assess VR's usefulness in the dental setting. One approach could be to have participants experience nitrous oxide and VR on separate occasions to compare their effectiveness. Additionally, comparing VR as a distraction tool to television screens would be beneficial, as it is a common method already employed by many pediatric dentists.

Conclusion

The findings indicate that VR can be as effective as nitrous oxide in managing patient behavior, with no statistically significant differences observed in behavioral responses or perceived pain levels between patients using VR and those receiving nitrous oxide.

Notably, patients reported experiencing greater enjoyment and engagement with the VR experience compared to nitrous oxide, highlighting its potential to enhance patient comfort and cooperation.

These results suggest that VR technology could serve as a viable alternative to traditional sedation methods, offering a distraction technique that may improve the overall dental experience for pediatric patients.

However, further research is necessary to fully understand the scope of VR's effectiveness, optimal application strategies, and long-term benefits within the dental setting. Continued investigation will help establish standardized protocols and determine the practicality of integrating VR into routine dental practice, ultimately aiming to improve patient outcomes and satisfaction.

Disclosures

Ethics Committee Approval: The study was approved by the Geisinger Ethics Committee (no: 2021-0138, date: 10/21/2021).

Informed Consent: Informed consent was obtained from all participants.

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Original Article

Microleakage and Environmental pH Influence in Primary Molars Restored with Self-Curing Bulk-Fill Composite, Light-Curing Bulk-Fill Composite, and Conventional Composite: An *In Vitro* Comparative Evaluation

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Abstract

Objective: The objective of this study was to compare microleakage and the influence on environmental pH of conventional composite (Neo Spectra® ST Universal Dentsply, Sirona, USA), light cured bulk-fill (SDR® Dentsply, Sirona, USA), or self-polymerizing bulk-fill (STELA®, SDI, Australia).

Materials and Methods: Forty-five extracted primary molars were randomly allocated into three groups (n=15) and restored with Neo Spectra® ST Universal, SDR®, or STELA® using an etch-and-rinse protocol. Microleakage was assessed after thermocycling by dye penetration (1% methylene blue), sectioning, and evaluation under a stereomicroscope using a standardized scoring system. For pH analysis, sixty-nine standardized cylindrical specimens of each material (n=23) were immersed in saline, and pH changes were measured at multiple time intervals using a calibrated electrode to evaluate their influence on the surrounding environment.

Results: Fisher's Exact test was performed to evaluate the microleakage score within the three restorative materials. A statistically significant association was found between restorative material and microleakage score (p=0.004), with Neo Spectra® ST Universal showing higher microleakage, while SDR® and STELA® demonstrated improved marginal adaptation. A mixed repeated measures of ANOVA was run to assess the effect of the three types of composite on the environmental pH. pH values changed significantly over time (p<0.0001), with conventional composite Neo Spectra® ST Universal exhibiting the highest pH, SDR® intermediate values, and STELA® the lowest. Significant differences were observed between all groups (p<0.0001).

Conclusion: Bulk-fill and bioactive restorative materials, particularly bulk-fill SDR® and self-polymerizing bulk-fill STELA®, showed superior sealing ability compared to conventional composite Neo Spectra® ST Universal. Additionally, STELA® demonstrated dynamic pH modulation, suggesting potential antibacterial and remineralization benefits, making it a promising material for pediatric restorative dentistry.

Keywords: Acidity, bulk fill composites, composite, dental material, micro leakage, pediatric dentistry, pH, restorative material

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Introduction

Dental caries is a highly prevalent chronic disease in children, particularly affecting primary teeth. Its rapid progression can impair nutrition, growth, and quality of life, leading to pain, infection, premature tooth loss, and malocclusion. Effective prevention includes oral hygiene, dietary control, fluoride use, and regular dental care.[1,2]

Successful restorative treatment in primary teeth depends on selecting materials with good mechanical properties, biocompatibility, fluoride release, and strong marginal sealing ability. Microleakage, defined as the passage of bacteria and fluids at the tooth–restoration interface, is a major cause of restoration failure, leading to secondary caries, sensitivity, and pulpal irritation. This is particularly critical in primary teeth due to their thinner structure and the difficulties of achieving proper isolation in children.[3]

Dental amalgam, historically used for its durability, has recently declined in use due to esthetic concerns and its mercury content.[4] Composite resins are now preferred for their adhesion and esthetics, but they have limitations, such as polymerization shrinkage and technique sensitivity.[5] Bulk-fill composites, such as SDR® (Dentsply Sirona, USA), were developed to improve adaptation and reduce shrinkage stress.[6] Newer self-curing materials, such as STELA® (SDI, Australia), offer additional bioactive benefits, including ion release and remineralization potential.[7] A systematic review concluded that universal adhesives exhibit clinical performance comparable to that of total-etch and self-etch systems in resin composite restorations, with no significant differences in retention or secondary caries over time.[8]

The oral environment also plays a critical role in caries development. An imbalance in the oral biofilm, particularly the proliferation of cariogenic bacteria such as Streptococcus mutans, leads to acid production and demineralization of tooth structure. Secondary caries commonly occurs at the tooth–restoration interface, often due to microleakage and biofilm accumulation. Fluoride-releasing restorative materials can help counteract this process by promoting remineralization and maintaining a favorable pH environment.[9]

Despite advances in restorative materials, comprehensive studies comparing newer materials such as STELA® (SDI, Australia) and SDR® (Dentsply Sirona, USA) remain limited, particularly regarding both microleakage and their influence on environmental pH. This study aims to evaluate STELA® (SDI, Australia), SDR® (Dentsply Sirona, USA), and a conventional composite (Neo Spectra® ST Universal) in primary teeth, focusing on microleakage and their influence on environmental pH.

Materials and Methods

Ethics approval

This *in vitro* study was carried out in the Biomaterial Unit of the Craniofacial Research Laboratory of Saint Joseph University of Beirut. The protocol was approved by the ethics committee of the same university (CER-2025-351).

Sample for microleakage

To determine the minimum required sample size, a G*Power analysis using normalized values yielded a large effect size (w=0.61). Based on this, a minimum sample of 26 specimens (≈9 per group) was required to achieve 80% power at a 5% significance level. To improve reliability and account for potential specimen loss and variability, the sample size was increased to 15 specimens per group, resulting in a total of 45 specimens.

The extracted primary teeth were obtained following approval from the parents or legal guardians, who provided informed consent for the use of the teeth in the present experimental study. The teeth were stored in distilled water and mounted in stone molds before standardized Class I cavities were prepared using carbide burs under water cooling. The samples were randomly divided into three groups (n=15) and restored with Neo Spectra® ST Universal (Dentsply Sirona, USA), STELA® (SDI, Australia), or SDR® (Dentsply Sirona, USA) using an etch-and-rinse protocol and their respective adhesive systems. All procedures were performed by a single operator to reduce bias, and restorations were finished and polished (Fig 1).

The specimens were subjected to thermocycling according to ISO standards 11405 for 500 cycles at 5°C–55°C with a dwell time of 30 seconds, then immersed in 1% methylene blue dye to evaluate microleakage for 24 hours. The tooth specimens were then sectioned in the mesiodistal direction using a high-speed diamond blade (Isomet® Diamond Wafering Blades, No. 11-4244, Buehler Ltd., Lake Bluff, USA) under water cooling (Fig 2). The presence or absence of microleakage was determined by evaluating the extent of dye penetration along the restoration-tooth interface using a stereomicroscope at ×20 magnification.[3] Dye penetration observed under the stereomicroscope was measured according to the following scoring system (Figs. 3, 4):

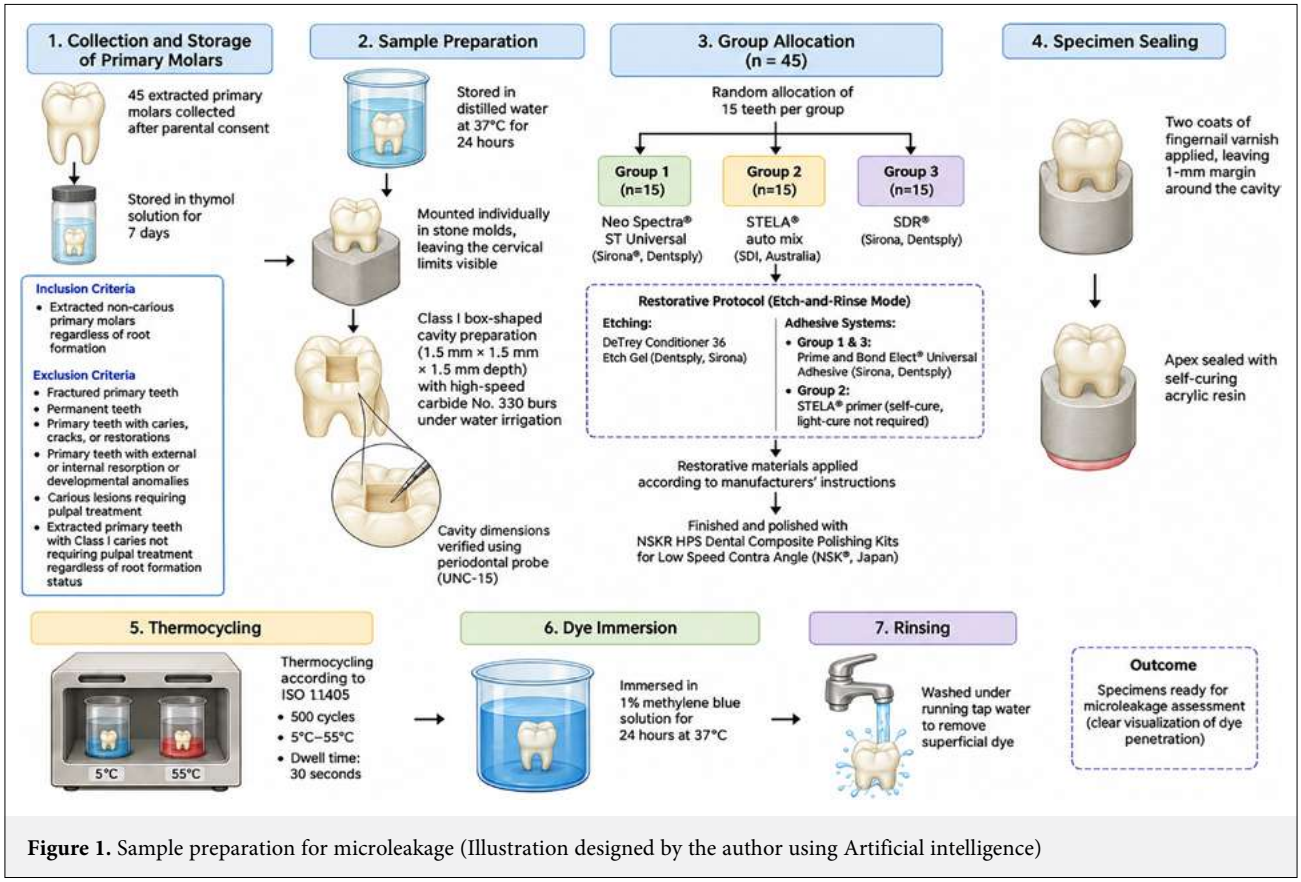

Figure 1. Sample preparation for microleakage (Illustration designed by the author using Artificial intelligence)

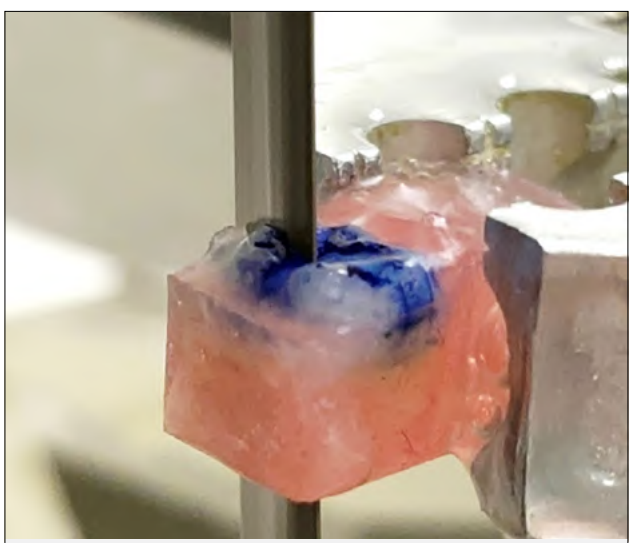

Figure 2. Shows sectioning in a mesiodistal direction



Figure 3. Shows score 1

1. Dye penetration up to one-third of the cavity
2. Dye penetration up to two-thirds of the cavity
3. Dye penetration up to the full cavity depth

Sample for pH evaluation

The sample size calculation was performed using the GPower software (version X.X), applying a one-way ANOVA (fixed effects, omnibus). The parameters entered were: group means=5.3 / 5.4 / 5.5, standard deviation=0.2, alpha=0.05, power=0.80, and number of groups=3. The resulting effect size was f=0.408. GPower indicated that a total of 63 samples would be required to achieve the desired power, or 21 disks per material. To account for potential specimen loss, damage, or measurement exclusion, two additional disks were prepared per group, bringing the total to 23 disks per material.

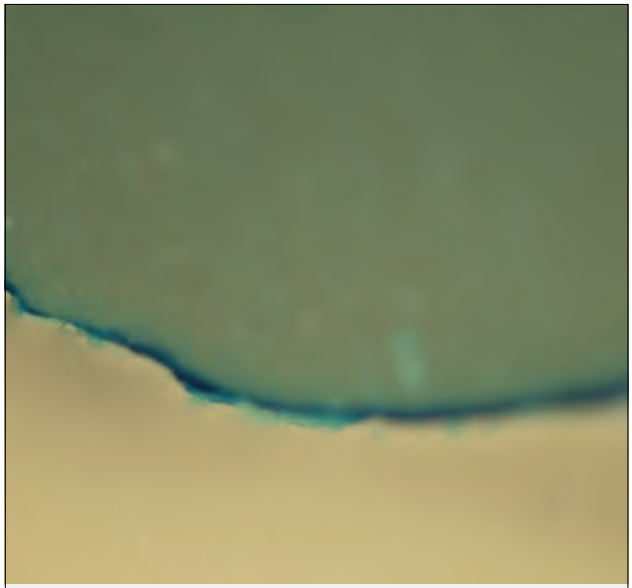

Figure 4. Shows score 3

Standardized cylindrical specimens (6 mm diameter and 2 mm thickness) were prepared using custom-made Teflon molds. The molds were placed on a glass plate and filled with each material. For the conventional composite and SDR®, the molds were light-cured for 30 seconds according to the manufacturers' instructions (light intensity of 1200 mW/cm², Woodpecker®, China). For STELA®, the mold surfaces were pre-coated with STELA® Primer (SDI Ltd., Bayswater, VIC, Australia) prior to filling. STELA® was left to set chemically for 4 minutes to ensure complete polymerization. Each sample was stored individually in saline-filled containers at 37°C. Saline was selected as a standardized and reproducible experimental medium, while recognizing that it represents only a simplified model of the oral environment.[9] The pH was measured using a calibrated electrode at multiple time intervals ranging from 1 hour to 15 days, with measurements performed in duplicate to ensure accuracy (Fig. 5).

Results

Microleakage evaluation

Fisher's Exact test was performed to evaluate the microleakage score within the three restorative materials and revealed a significant association between this score and the type of material ($p=0.004<0.05$).

Within the SDR® and STELA® groups, the most observed microleakage score was score 2 (53.4% and 66.7%, respectively), while the least displayed one was 3 (13.3% and 14.3%, respectively). However, Neo Spectra® ST Universal predominantly exhibited score 3 (66.7%), while the remaining samples showed a score of 2 (33.3%) (Table 1).

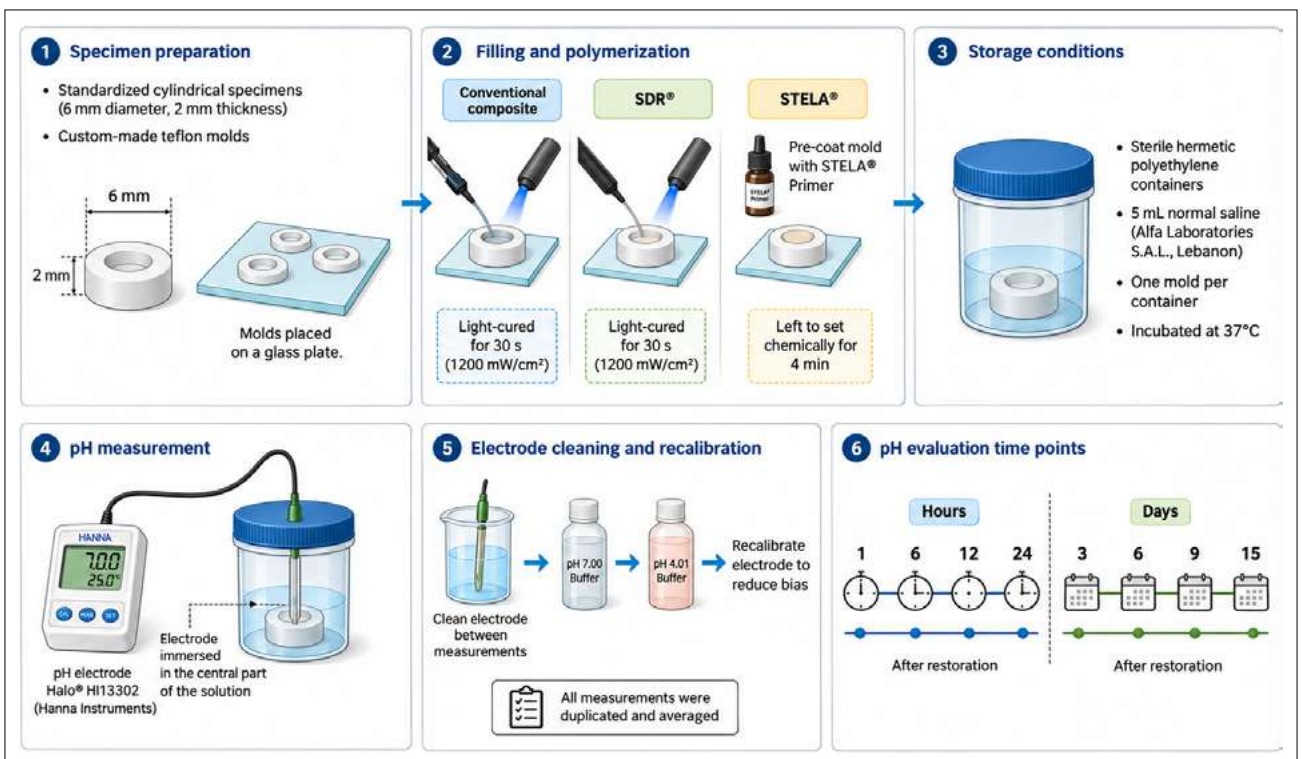

Figure 5. Material and method for pH evaluation (Illustration designed by the author using Artificial intelligence)

Table 1. Fisher Exact analysis to evaluate the association between the type pf restorative material and microleakage score

	Composite n=15 n (%)	SDR® n=15 n (%)	STELLA® n=15 n (%)	p
Microleakage score	5 (33.3)	-	3 (20)	0.004
1				
2	8 (53.4)	5 (33.3)	10 (66.7)	
3	2 (13.3)	10 (66.7)	2 (14.3)	
Total	15 (100)	15 (100)	15 (100)	

p<0.05 is significant. n: Number of samples per group.

Figure 6 illustrates the distribution of restorative materials within each microleakage score. For score 1, the majority of samples belonged to the SDR® group (62.5%), followed by STELA® (37.5%), while Neo Spectra® ST Universal showed no representation. Score 2 demonstrated a more balanced distribution, with STELA® being the most prevalent (43.5%), followed by SDR® (34.8%) and Neo Spectra® ST Universal (21.7%). In contrast, score 3 was predominantly displayed by Neo Spectra® ST Universal (71.4%), while SDR® and STELA® exhibited a minor contribution (14.3% each).

Influence of restorative materials on the environmental pH:

A mixed repeated measures ANOVA was run to assess the effect of time and the type of composite upon pH. Since the assumption of sphericity was violated (based on Mauchly's test), Greenhouse-Geisser corrections were applied (Table 2). The effect of time upon pH was statistically significant (F(4.61, 304.54)=340.29, p<0.0001). Moreover, the effect of the interaction between time and composite type was statistically significant (F(9.23, 304.54)=36.61, p<0.0001), suggesting that pH variations over time were significantly different among the tested composite types.

Table 2. Repeated measures ANOVA evaluating ph changes across time and composite materials

Effect	Df (GG)	F	p
Time	(4.61, 304.54)	340.29	<0.0001**
Time x Composite type	(9.23, 304.54)	36.61	<0.0001**

**: p<0.0001 is highly significant. Df: Degrees of freedom, GG: Greenhouse-Greisser.

For a better interpretation, all results are presented in the form of graphs. Figure 7 show the differences in pH changes over time depending on the dental materials used.

The estimated marginal means of pH values for the three restorative materials were evaluated across eight time points (Table 3). The estimated marginal mean pH values (±standard deviation) of the tested restorative materials were evaluated at 1 hour, 6 hours, 12 hours, 24 hours, 3 days, 6 days, 9 days, and 15 days. Overall, a time-dependent change in pH was observed for all tested materials, indicating a temporal effect on the environmental pH.

The conventional composite Neo Spectra® ST Universal (Dentsply, USA) demonstrated the highest pH values at all time points, with a progressive increase from

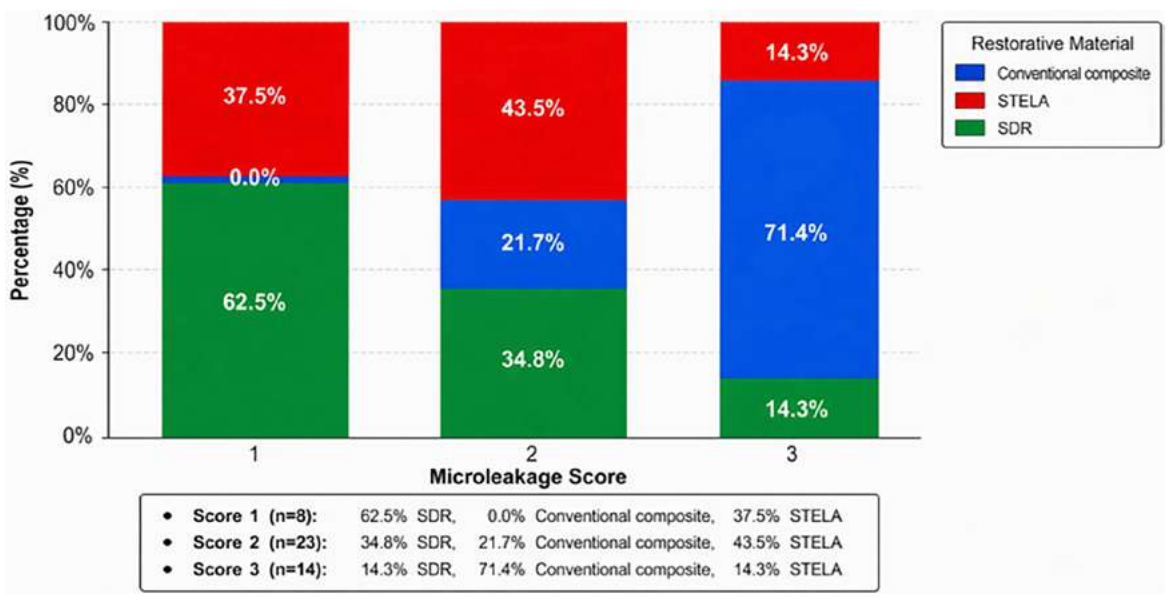

Figure 6. Stacked Bar Chart illustrating the distribution of restorative materials within each microleakage score group

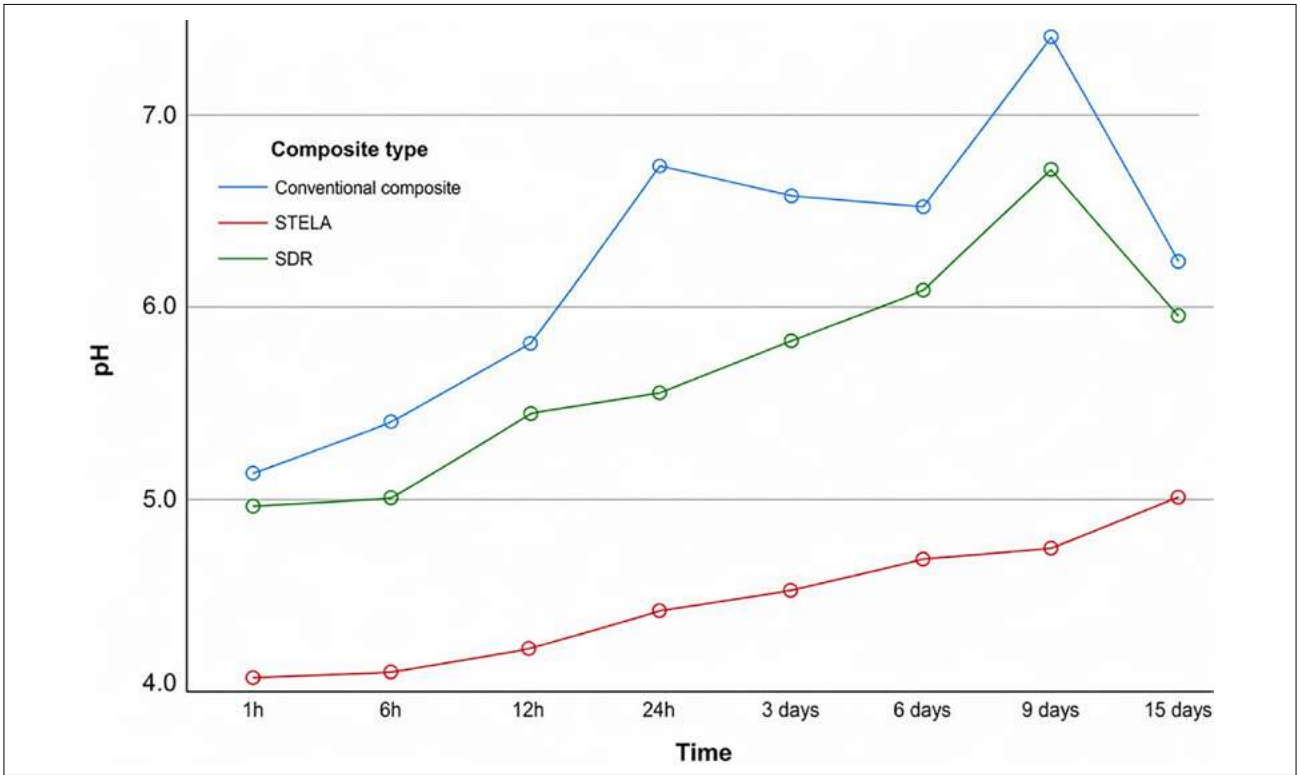

Figure 7. Comparison of pH variation over time among Neo Spectra® ST Universal, STELA®, and SDR®

the initial measurements to approximately the ninth day point, where the highest value was observed. After this peak, a slight decrease in pH was noted at the final measurement.

Table 3. Descriptive statistics of the mean pH values for each composite type across the different time dots

Mean pH values (SD) at	Neo Spectra® ST Universal	STELA®	SDR®
1h	5.14 (0.24)	4 (0.23)	4.97 (0.25)
6h	5.41 (0.14)	3.99 (0.2)	4.99 (0.24)
12h	5.83 (0.2)	4.07 (0.31)	5.44 (0.13)
24h	6.76 (0.2)	4.32 (0.35)	5.56 (0.28)
3 days	6.63 (0.52)	4.38 (0.25)	5.87 (0.35)
6 days	6.59 (0.11)	4.66 (0.52)	6.12 (0.4)
9 days	7.48 (0.21)	4.73 (0.4)	6.82 (0.39)
15 days	6.27 (0.2)	5 (0.41)	5.99 (0.35)

SD: Standard deviation.

Smart Dentin Replacement SDR® (Dentsply Sirona, USA) showed intermediate pH values compared with the other materials. The pH increased gradually over time, reaching its maximum around the 9th day point, followed by a slight decrease toward the end of the observation period.

In contrast, STELA® (SDI, Australia) exhibited the lowest pH values throughout the experiment. However, a gradual and consistent increase in pH was observed over time, indicating a progressive rise in environmental pH. Despite this increase, the values remained lower than those recorded for the conventional composite Neo Spectra® ST Universal (Dentsply, USA) and SDR® (Dentsply Sirona, USA) at all measurement points.

Table 4 displays the results of the post-hoc comparison between composites, using Bonferroni correction, in terms of pH mean difference values with their respective confidence intervals. pH values differed significantly between all composite groups ($p<0.0001$ for all comparisons).

Table 4. Post-hoc comparison between composites with Bonferroni correction

Pairwise comparison	Mean difference (95% CI)	p
Neo Spectra® ST Universal vs SDR®	0.542 (0.378–0.707)	<0.0001**
Neo Spectra® ST Universal vs STELA®	1.868 (1.704–2.032)	<0.0001**
SDR® vs STELA®	1.326 (1.161–1.49)	<0.0001**

**: $p<0.0001$ is highly significant. CI: Confidence intervals.

pH values for Neo Spectra® ST Universal were significantly higher than the ones exhibited by SDR® (mean difference=0.542, CI=0.378–0.707) and STELA® (mean difference=1.868, CI=1.704–2.032). Similarly, SDR® showed significantly higher pH values compared to STELA® (mean difference=1.326, CI=1.161–1.49).

Discussion

In pediatric dentistry, preserving primary teeth until natural exfoliation is a main objective, requiring restorative materials capable of withstanding mechanical wear, bacterial challenges, and environmental variations such as pH fluctuations and temperature changes, while also maintaining aesthetic integrity.[10] However, the longevity of restorations is often compromised by microleakage and secondary caries, which are closely linked to the physicochemical properties of restorative materials.

Secondary caries may develop due to increased bacterial adhesion and biofilm accumulation, particularly at restoration margins where plaque control is difficult. Additionally, polymerization shrinkage and masticatory forces can induce interfacial stresses, especially in deep Class I restorations in primary teeth, leading to marginal gaps, postoperative sensitivity, and eventual restoration failure.[11] In this context, the development of bioactive restorative materials has introduced a promising approach, as these materials can release therapeutic ions such as calcium and fluoride, contributing to antibacterial activity, reduced plaque accumulation, and enhanced remineralization.[12]

The present study aimed to evaluate both microleakage and the influence of restorative materials on environmental pH among three different materials: conventional composite Neo Spectra® ST Universal (Dentsply Sirona, USA), SDR® (Dentsply Sirona, USA), and STELA® (SDI, Australia). Based on the findings, both null hypotheses were rejected, as significant differences were observed among the tested materials in terms of microleakage (p=0.004) and their effect on environmental pH (p<0.0001).

Regarding microleakage, the results demonstrated a clear variation in marginal sealing ability among the materials. SDR® and STELA® predominantly exhibited score 2, indicating moderate microleakage, whereas Neo Spectra® ST Universal showed a significantly higher proportion of score 3, reflecting greater dye penetration and inferior marginal adaptation. This difference can be explained by the inherent characteristics of conventional resin composites, which are associated with higher polymerization shrinkage stress and increased technique sensitivity due to incremental placement. These factors may result in gap formation at the tooth-restoration interface, facilitating microleakage.[4]

In contrast, SDR® demonstrated improved performance, particularly with the highest proportion of score 1 in some samples, suggesting better marginal adaptation. This can be attributed to its flowable consistency and stress-relieving polymerization modulator, which reduces shrinkage stress and enhances cavity adaptation. Similarly, STELA® showed favorable distribution toward lower microleakage scores, likely due to its self-curing mechanism and bioactive composition, which may contribute to improved marginal sealing through physicochemical interaction with the tooth structure.[4,13]

The proportional distribution further confirmed that Neo Spectra® ST Universal was predominantly associated with the highest microleakage score, while SDR® and STELA® were more frequently linked to lower scores. These findings highlight the advantage of bulk-fill and bioactive materials in minimizing microleakage compared to traditional composites.

In addition to marginal integrity, the influence of restorative materials on environmental pH represents another critical factor affecting bacterial activity and caries progression. In the present study, saline was used as the experimental medium to better simulate oral conditions, as distilled water does not adequately reflect the ionic composition of the oral environment. Although artificial saliva is commonly used, its lack of standardization remains a limitation.[14]

The results demonstrated statistically significant differences among the tested materials in their effect on environmental pH, leading to the rejection of the second null hypothesis. All materials exhibited acidic pH values ranging between 5 and 6 after 15 days, with a general trend of gradual increase over time. This behavior may be attributed to ongoing interactions such as water sorption, ion release, and post-polymerization reactions, eventually reaching a stabilization phase.

Among the materials tested, conventional composite (Neo Spectra® ST Universal) consistently exhibited the highest pH values. This can be explained by its chemically stable and highly cross-linked resin matrix, which limits water sorption and ion release, thereby maintaining a relatively neutral environment. These findings are consistent with previous studies reporting minimal environmental interaction and stable pH behavior in Neo Spectra® ST Universal conventional composites.[15,16]

SDR® demonstrated intermediate pH values, reflecting its modified resin matrix and bulk-fill composition. The presence of a polymerization modulator allows controlled shrinkage and improved depth of cure, while also enabling limited water sorption and ion diffusion. This results in moderate interaction with the surrounding medium, explaining the gradual increase in pH over time while remaining lower than Neo Spectra® ST Universal. Similar observations have been reported in the literature, where bulk-fill composites exhibit altered physicochemical behavior compared to traditional composites.[12]

In contrast, STELA® exhibited the lowest pH values throughout the experimental period, which can be attributed to its bioactive nature and enhanced ion-releasing capacity. The material's composition promotes ion exchange processes, including the release of calcium and other reactive species, which may initially lower the pH. Over time, however, this ion release contributes to buffering and remineralization processes, resulting in a gradual increase toward neutral pH. This dynamic behavior reflects the fundamental difference between bioactive and conventional materials. While Neo Spectra® ST Universal remain chemically inert, bioactive materials exhibit time-dependent interactions with their environment, characterized by an initial acidic phase followed by stabilization.[17]

From a clinical perspective, the ability of the restorative material to interact with and potentially modulate its surrounding environment may be relevant in the management of caries-prone primary teeth. Environmental pH is closely associated with the balance between demineralization and remineralization and can influence the activity of cariogenic microorganisms. Therefore, differences in pH behavior among restorative materials may represent an additional factor to consider when evaluating their biological performance. However, the present findings should be regarded as preliminary because the experimental saline model does not reproduce the dynamic and biologically complex oral environment, including salivary buffering, salivary flow, dietary challenges, bacterial biofilms, and host-related factors. Further *in vitro* biofilm studies and clinical investigations are required to determine whether the observed pH differences translate into clinically meaningful effects.

Despite the study's significant findings, several limitations should be considered. The evaluation of microleakage was performed using the dye penetration method, which, although widely used, is a semi-quantitative technique dependent on visual interpretation and may not fully represent clinical conditions. Furthermore, the small molecular size of dye particles may lead to an overestimation of leakage compared to bacterial penetration. In addition, this study was conducted under *in vitro* conditions, which cannot fully replicate the complexity of the oral environment, including salivary flow, occlusal forces, and microbial activity. Therefore, caution should be exercised when extrapolating these findings to clinical scenarios. Moreover, the assessment of environmental pH was limited to a relatively short observation period. Considering the time-dependent nature of ion release and buffering capacity, particularly in bioactive materials, longer-term evaluations would provide a more comprehensive understanding of material behavior. In addition, increasing the sample size in future studies would enhance statistical power and improve reliability.

Overall, the findings of this study demonstrate that restorative materials differ significantly in both their marginal sealing ability and their influence on environmental pH. SDR® and STELA® showed improved microleakage performance compared to Neo Spectra® ST Universal, while STELA® exhibited the most pronounced effect on environmental pH due to its bioactive properties. These results highlight the importance of selecting restorative materials not only based on mechanical properties but also on their biological and chemical interactions within the oral environment.

From a clinical perspective, materials that combine reduced microleakage with beneficial bioactive properties may offer enhanced protection against secondary caries, particularly in pediatric patients where long-term restoration success is critical. Nevertheless, further *in vivo* studies are required to validate these findings and to assess the long-term clinical performance of these materials under functional conditions.

Conclusion

Conventional resin composites in primary teeth are associated with higher microleakage and poorer marginal sealing due to polymerization shrinkage and technique sensitivity, increasing the risk of secondary caries. In contrast, bulk-fill materials like SDR® (Dentsply Sirona, USA) show improved marginal adaptation and reduced microleakage. Self-curing bioactive materials such as STELA® (SDI, Australia) appear promising, combining good sealing ability with ion release that may influence pH, offering potential antibacterial and remineralization benefits. However, further clinical studies are needed to evaluate their long-term performance, underlying mechanisms, and effectiveness under conditions simulating the oral environment.

Disclosures

Ethics Committee Approval: The study was approved by the Saint Joseph University of Beirut Ethics Committee (no: CER-2025-351, date: 11/11/2025).

Informed Consent: Informed consent was obtained from all participants.

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Original Article

Extrinsic Primary Tooth Staining Due to Iron Syrup Medication: Effects of Dilution and Tooth Brushing - An *In Vitro* Study

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Abstract

Objective: Iron deficiency, a leading cause of anemia in children under five, is treated by iron supplementation. However, iron syrups prescribed for children aged 6–24 months, may cause extrinsic staining of primary teeth, raising esthetic concerns. This *in vitro* experimental study aimed to evaluate the impact of syrup dilution and tooth brushing on iron-induced staining of primary anterior teeth.

Materials and Methods: After ethical approval, 90 anterior primary teeth with intact crowns were collected, disinfected, and mounted in acrylic resin molds. Samples were randomly assigned to six groups (n=15). Groups either received undiluted or diluted ferrous sulfate syrup (PediaFer®, 15 mg/mL elemental iron), with or without brushing using a children's fluoride toothpaste (500 ppm) (Aquafresh® milk teeth, GSK Consumer Healthcare, Brentford, UK). Artificial saliva served as control. Immersion simulated three years of clinical exposure by incubating samples for 36 days at 37°C. Color measurements were recorded at baseline and after 12, 24 and 36 days using the CIE Lab* system and a spectrophotometer (VITA Easyshade®, VITA Zahnfabrik, Bad Säckingen, Germany). Color change (ΔE) was calculated and interpreted according to ISO/TR 28642:2016 standards. Analysis was performed using RStudio (version 2024.12.1). Repeated-measures ANOVA or the Friedman tests assessed within-group time effects; t-tests or Wilcoxon tests examined brushing effects; and ANOVA or Kruskal-Wallis tests analyzed dilution effects. Significance was set at $p \leq 0.05$.

Results: Teeth exposed to concentrated iron syrup without brushing showed the highest ΔE values, rising significantly from T1 to T3 ($p<0.001$), indicating progressive staining. Diluted syrup without brushing caused significant discoloration ($p=0.015$). Brushing reduced early staining only in the diluted group at T1 ($p=0.002$), but this effect was not sustained. Pooled analysis showed no significant effect of brushing by T3 ($p=0.08$), while syrup concentration had an overall strong and consistent effect ($p<0.001$). Concentrated syrup led to significantly higher ΔE values than diluted and control groups (adjusted $p<0.001$). Mean ΔE values for concentrated syrup exceeded the clinical visibility threshold ($\Delta E>6$) confirming its marked staining potential.

Conclusion: These findings suggest that dilution is a more consistently effective strategy than brushing alone for minimizing iron-induced staining in primary teeth.

Keywords: Deciduous teeth, iron deficiencies, pigmentation, spectrophotometry, tooth discoloration

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Introduction

Iron is an essential mineral involved in numerous physiological processes, including hemoglobin formation, oxygen transport, immune function, and neurodevelopment.[1] Iron deficiency (ID) is the most prevalent micronutrient disorder globally, affecting over two billion people. Iron-deficiency anemia (IDA) remains the leading cause of anemia in children, especially during the rapid growth phases in the first five years of life.[2,3] To address this, the World Health Organization (WHO) recommends, as a first-line intervention, universal iron supplementation-commonly in the form of syrups or drops- for children aged 6–24 months to support healthy motor and cognitive development.[4] However, the use of iron syrups in children under three years old, coinciding with the eruption of primary teeth, often leads to an undesirable yet common side effect: Extrinsic staining of the teeth.[5,6] This concern is frequently raised by parents and poses an esthetic challenge in pediatric dentistry. Given the increasing esthetic expectations in dental care and the psychosocial impact of visible tooth discoloration on young children, especially in social settings like daycare and preschool, managing such staining is of clinical relevance.[7] Previous *in vitro* studies confirm the staining potential of various iron formulations. Tayebi et al[8] demonstrated that four different types of iron supplements all caused noticeable tooth discoloration, with no significant differences in staining potential among them. Additionally, Pani et al[9] found that while ferrous fumarate (FF) causes less staining than ferric hydroxide polymaltose (FOP), it may not provide adequate iron supplementation; notably, a combination of FF and FOP resulted in significantly less staining than either alone. Abbasi et al[10] demonstrated that a liposomal nano-encapsulated ferrous sulfate drop led to significantly less tooth discoloration compared to commercial iron drops, suggesting nano-encapsulation as a cost-effective alternative. Furthermore, Tüzüner et al[11] reported that iron syrups cause prominent staining on restorative materials, particularly composites, while glass ionomer cements showed greater resistance. Limited research has explored the influence of dilution or preventive oral hygiene measures such as tooth brushing on this staining effect.

Thus, the present study aimed to evaluate the extrinsic staining effects of iron syrup on anterior primary teeth *in vitro*, focusing on two variables: Dilution of the syrup and the effect of tooth brushing. The primary objective was to assess whether dilution reduces staining potential, while the secondary objective was to determine the additional impact of tooth brushing. The primary null hypothesis (H0) posited no significant difference in staining between diluted and undiluted syrups, while the secondary null hypothesis (HS0) suggested no difference between brushed and unbrushed samples.

Materials and Methods

The study is approved by the Saint-Joseph University of Beirut (No: USJ-2024-99, Date: 18/04/2024) and conducted according to Declaration of Helsinki.

Minimal sample size calculation

The present study used an *in vitro* experimental model.

The minimum required sample size was calculated using the G*Power software, assuming a large effect size (f=0.4). With a significance level (α) of 0.05 and six independent groups, a total of 90 units was determined to achieve a statistical power of 80% for detecting differences among groups: This corresponds to 15 units per group.

Sample preparation

Ninety anterior primary teeth were collected, none of which were extracted for reasons related to the present study; all were either recently exfoliated or extracted due to space discrepancy, mobility, or trauma. There were no developmental anomalies, enamel hypoplasia, restorations, extrinsic nor intrinsic stains in the selected teeth. The teeth were sterilized by immersion in 10% formalin for 24 hours and stored in distilled water until usage. Each tooth was thoroughly rinsed and cleaned by a prophylaxis paste (SpectraTM Prophylaxis paste, Prevest DenPro Limited, India) and brush (FlydentTM, China). Each tooth was dissected at the cemento-enamel junction and the pulpal residues were completely removed from the pulp chamber using an excavator (1020/127-128, Carl Martin GmbHTM, Solingen, Germany). Each tooth was then embedded in an acrylic resin mold at the cemento-enamel junction level so that the crown was positioned perpendicularly to the mold (Fig. 1). The teeth were all immersed in artificial saliva containing sodium chloride, potassium chloride, calcium chloride, sodium dihydrogen phosphate, sodium sulfide, and urea with the pH adjusted to 6.75 using potassium hydroxide (KOH).

The teeth were then randomly divided into six groups of 15 each, as follows:



Figure 1. Sample preparation

Group 1: No tooth brushing

Group 2: Tooth brushing

Group 3: Iron supplement without tooth brushing

Group 4: Iron supplement with tooth brushing

Group 5: Iron supplement and water without tooth brushing

Group 6: Iron supplement and water with tooth brushing.

The iron-supplemented solutions contained 6.6 mL of ferrous sulfate oral solution (15 mg iron/mL), equivalent to 100 mg of elemental iron according to the label. The supplement used was a commercially available pediatric iron syrup (PediaFer®, EURO-PHARM International Canada Inc., Montréal, Québec, Canada).

In Groups 5 and 6, 37 mL of bottled drinking water was added to represent the typical daily intake for toddlers. This quantity was based on the American Academy of Pediatric Dentistry (AAPD) recommendation of a minimum daily water intake of 5 oz (148 mL) for children aged 0–3 years, proportionally scaled to reflect consumption patterns throughout the day.

The different solutions containing the samples were placed in an incubator at a temperature of 37°C which represents the human body temperature. To simulate three years of exposure to the iron syrup, the solutions were placed in the incubator for 36 days given the fact that a 24-hour immersion in colorant solutions corresponds approximately to one month of clinical aging.[12] For the groups that required tooth brushing (groups 2, 4 and 6) the teeth were first rinsed with running water before brushing. Tooth brushing was performed three times in each 12-day interval for a duration of two minutes using a manual toothbrush, following the method outlined by Ren et al[13].

Brushing was performed on the labial surface of each specimen according to the modified Bass brushing technique. In this technique, the toothbrush bristles were positioned at approximately a 45° angle to the gingival margin and moved with short vibratory strokes, followed by a gentle sweeping motion away from the gingival margin.[14] Each specimen was brushed individually while maintaining consistent pressure and stroke frequency to simulate routine pediatric toothbrushing conditions.

A toothbrush with extra-soft bristles, suitable for children under three years of age (Aquafresh® Milk Teeth, GSK Consumer Healthcare, Brentford, UK), was utilized. Additionally, a children's toothpaste containing the recommended fluoride concentration (500 ppm) was used (Aquafresh® milk teeth, GSK Consumer Healthcare, Brentford, UK). In accordance with the American Academy of Pediatric Dentistry (AAPD) guidelines, a rice-grain-sized amount of toothpaste was applied for brushing. After brushing, the teeth were rinsed with running water, returned to the solutions and placed in the incubator. All brushing procedures were performed by a single operator to ensure consistency and minimize operator-related variability.

Measurement of color parameters

Prior to all color measurements, all the specimens were rinsed with tap water for 5 seconds and blotted dry using absorbent paper. Color evaluations were conducted using the CIE L*a*b* color space, an internationally recognized color-opponent system defined by the International Commission on Illumination (CIE). Color values were obtained using the Vita Easyshade Spectrophotometer (VITA Easyshade®, VITA Zahnfabrik, Bad Säckingen, Germany) (Fig. 2).



Figure 2. Vita Easyshade® Advance spectrophotometer

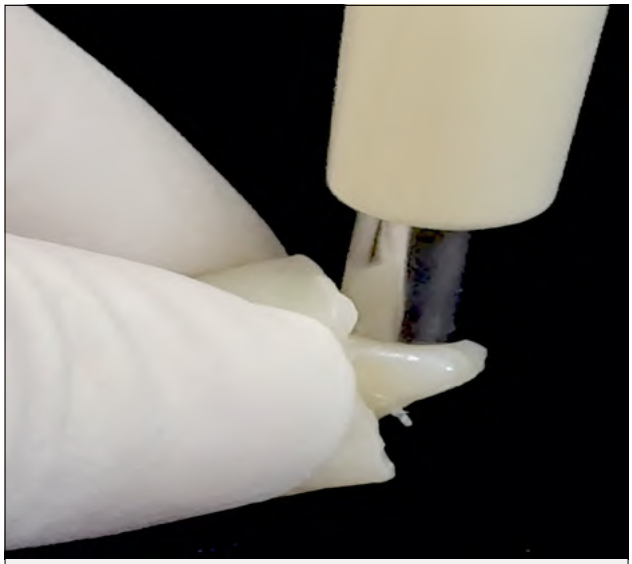

Figure 3. Positioning of the spectrophotometer tip on the labial surface of the tooth



Figure 4. Values obtained by the spectrophotometer

The spectrophotometer was calibrated following the manufacture's guidelines. All the measurements were performed by a single operator under standardized conditions. Measurements were performed on the labial surface with the device tip positioned perpendicularly at the center of the crown's middle third (Figs. 3, 4). For each specimen, three independent measurements were obtained. The mean value was calculated by summing these measurements and dividing them by three, thereby providing a representative value for subsequent analysis. Measurements were recorded at four time points: T0: Baseline (prior to immersion in the solution), T1 (after 12 days), T2 (after 24 days) and T3: Final evaluation (after 36 days). The interval between each time point was set to 12 days to simulate the effects of approximately one year of clinical aging. In groups assigned to tooth brushing (groups 2, 4, and 6), color assessment was conducted after brushing procedures at each time point. Following every measurement session, specimens were returned to freshly prepared solutions.

Color change calculation

To quantify color changes over time, the total color difference (ΔE) between time points was calculated using the standard formula:

$$\Delta E = [(\Delta a)2 + (\Delta b)2 + (\Delta L)2] ½$$

Where:

- ΔL denotes the difference in lightness, with L indicating the degree of lightness/darkness on a scale from 0 (black) to 100 (white)
- Δa represents the difference in the red-green axis (a*), where a* is the chromaticity coordinate along the red-green direction, ranging from -128 (green) to +128 (red)
- Δb represents the difference in the yellow-blue axis (b*), where b* is the chromaticity coordinate along the yellow-blue direction, ranging from -128 (blue) to +128 (yellow)

Interpretation of color differences was based on the ISO/TR 28642:2016 standards: [15]

- a color change of ΔE<1.2 is considered imperceptible to the human eye

Table 1. Descriptive statistics for ΔE by group and time point

Group	Brushing	Dilution	ΔE T1† (Mean±SD)	ΔE T2† (Mean±SD)	ΔE T3† (Mean±SD)	Clinical interpretation‡
G1	No	Control	10.01±5.23	9.56±3.27	10.13±4.09	Clinically perceptible
G2	Yes	Control	8.29±4.06	7.70±5.09	8.87±5.06	Clinically perceptible
G3	No	Concentrated	22.98±14.46	33.86±17.86	44.90±19.39	Clearly noticeable and severe
G4	Yes	Concentrated	31.62±9.96	34.39±12.32	40.90±11.83	Clearly noticeable and severe
G5	No	Diluted	17.58±5.79	23.48±7.54	26.41±9.67	Clinically perceptible
G6	Yes	Diluted	10.14±5.98	13.04±7.76	11.53±7.72	Clinically perceptible but substantially reduced

ΔE: Color difference measured using the CIE Lab system. †: T1, T2, T3: Time points corresponding to 12, 24 and 36 days of immersion, respectively. ‡: "Clinically perceptible" and "clearly noticeable" interpretations follow the thresholds defined by the International Commission on Illumination (CIE).

Table 2. Time effect within each group

Group	Test used	Statistic	p	Interpretation
G 1	rm-ANOVA	F(2,28)=0.098	0.907	No change
G 2	rm-ANOVA	F(2,28)=0.233	0.793	No change
G 3	rm-ANOVA	F(2,28)=9.61	<0.001*	Significant increase
G 4	rm-ANOVA	F(2,28)=2.56	0.095	Trend toward significant increase
G 5	Friedman Test	Chi^2=8.4	0.015*	Significant increase
G 6	Friedman Test	Chi^2=0.533	0.766	No change

(*) indicates statistically significant difference at p<0.05.

- a color change of ΔE=3.7 is considered the acceptability threshold, where approximately 50% of observers perceive the difference as acceptable
- a color change of 3.7<ΔE<6.0 is considered clinically perceptible (mild to moderate)
- a color change ΔE>6.0 is considered clearly visible and aesthetically concerning

Statistical Analysis

Statistical analyses were conducted using RStudio (version 2024.12.1 Build 563). The main outcome was the color change (ΔE) between each post-treatment time point and baseline (T0). Normality was tested using the Shapiro-Wilk test and homogeneity of variances using Levene's test. Depending on these assumptions, the appropriate test (repeated-measures ANOVA or Friedman test for time effect; t-test or Wilcoxon test for brushing; ANOVA or Kruskal-Wallis for dilution) was selected. Statistical significance was set at p≤0.05.

Results

Descriptive statistics

Descriptive statistics for ΔE values at time points T1, T2, and T3 were calculated for all six groups. Table 1 shows the mean ± SD for each group.

Effect of time

To evaluate whether the degree of discoloration statistically increased over time within each group, intra-group comparisons of ΔE values were conducted across the time points. Depending on the results of normality testing, either repeated-measures ANOVA or the non-parametric Friedman test was applied (Table 2).

Effect of tooth brushing

To evaluate the role of brushing, ΔE values were compared between brushed and unbrushed subgroups within each dilution level. These comparisons were performed independently at T1, T2, and T3 using t-tests or Wilcoxon tests depending on distribution (Table 3).

Pooled brushing comparison

To evaluate the overall effect of brushing regardless of syrup concentration, ΔE values were compared between all brushed (groups 2, 4, 6) and unbrushed (groups 1, 3, 5) teeth at each time point. The results are presented in Table 4.

Effect of dilution across groups by time point

To determine the influence of iron syrup concentration on extrinsic staining, comparisons were made across the three dilution levels at each time point, separately for brushed and unbrushed teeth. Due to significant heterogeneity of variances, a Kruskal-Wallis test was used to evaluate the overall group effect (Table 5) and Dunn's Post Hoc was used to show the significant pairwise comparisons within each brushing condition and time point (Table 6).

Table 3. Brushing effect between paired groups

Group pair	Time	Test used	Statistic	p	Interpretation
1 vs 2	T1	t-test	t=1.01	0.32	No effect
1 vs 2	T2	t-test	t=1.19	0.24	No effect
1 vs 2	T3	t-test	t=0.75	0.46	No effect
3 vs 4	T1	t-test	t=-1.90	0.07	Trend toward significance
3 vs 4	T2	t-test	t=-0.09	0.93	No effect
3 vs 4	T3	t-test	t=0.68	0.50	No effect
5 vs 6	T1	t-test	t=3.46	0.002*	Significant effect
5 vs 6	T2	Wilcoxon	W=195	0.12	No effect
5 vs 6	T3	Wilcoxon	W=197	0.15	No effect

T1, T2, T3: Time points corresponding to 12, 24 and 36 days of immersion, respectively. (*) indicates statistically significant difference at p<0.05.

Table 4. Pooled comparison of ΔE between brushed and unbrushed teeth

Time	No Brushing (ΔE±SD)	Brushing (ΔE±SD)	p
T1	16.86±10.72	16.68±12.76	0.943
T2	22.30±14.98	18.38±14.55	0.211
T3	27.15±19.00	20.43±16.94	0.08

ΔE: Color difference measured using the CIE Lab* system. T1, T2, T3: Time points corresponding to 12, 24 and 36 days of immersion, respectively.

Table 5. Kruskal-Wallis results: Effect of dilution by brushing

Brushing	Time	Chi²	p	Interpretation
No	T1	10.6	0.005*	Significant
No	T2	26.6	<0.001*	Significant
No	T3	29.2	<0.001*	Significant
Yes	T1	28.3	<0.001*	Significant
Yes	T2	26.8	<0.001*	Significant
Yes	T3	29	<0.001*	Significant

T1, T2, T3: Time points corresponding to 12, 24 and 36 days of immersion, respectively. (*) indicates statistically significant difference at p<0.05.

Pooled dilution comparison

To evaluate the overall effect of dilution regardless of brushing, ΔE values were compared between the three syrup concentrations at each time point using the Kruskal-Wallis test (Table 7).

To clarify where these overall differences occurred, Table 8 summarizes the pairwise comparisons between dilution levels at each time point, pooling data across all groups regardless of brushing.

Across all time points, concentrated syrup consistently caused significantly more discoloration than both con-

Table 6. Summary of significant pairwise comparisons (Dunn's post hoc)

Brushing	Time	Significant Comparisons	Adjusted p-value
No	T1	Concentrated > Control	0.0105*
No	T2	Concentrated > Control Diluted > Control	<0.001* <0.001*
No	T3	Concentrated > Control Diluted > Control	<0.001* <0.001*
Yes	T1	Concentrated > Control & Diluted	<0.001*, <0.001*
Yes	T2	Concentrated > Control & Diluted	<0.001*, <0.01*
Yes	T3	Concentrated > Control & Diluted	<0.001*, <0.001*

T1, T2, T3: Time points corresponding to 12, 24 and 36 days of immersion, respectively. (*) indicates statistically significant difference at p<0.05.

Table 7. Pooled ΔE (Mean±SD) by dilution level and Kruskal-Wallis p-values

Time	Control (ΔE±SD)	Concentrated (ΔE±SD)	Diluted (ΔE±SD)	p
T1	9.15±4.68	27.30±12.97	13.86±6.91	<0.001*
T2	8.63±4.31	34.13±15.08	18.26±9.20	<0.001*
T3	9.50±4.56	42.90±15.91	18.97±11.45	<0.001*

ΔE: Color difference measured using the CIE Lab* system. T1, T2, T3: Time points corresponding to 12, 24 and 36 days of immersion, respectively. (*) indicates statistically significant difference at p<0.05 as determined by Kruskal-Wallis test.

Table 8. Summary of pooled comparisons (Dunn's post hoc)

Time	Comparisons	Adjusted p-value
T1	Concentrated > Control	<0.001*
	Concentrated > Diluted	<0.01*
	Diluted > Control	0.07
T2	Concentrated > Control	<0.001*
	Concentrated > Diluted	<0.01*
	Diluted > Control	<0.001*
T3	Concentrated > Control	<0.001*
	Concentrated > Diluted	<0.001*
	Diluted > Control	0.0127*

T1, T2, T3: Time points corresponding to 12, 24 and 36 days of immersion, respectively. (*) indicates statistically significant difference at p<0.05.

trol and diluted syrups (p<0.01). The diluted syrup showed intermediate staining and became significantly different from control at T2 and T3, while the difference at T1 remained marginal (p=0.07).

The extrinsic staining observed on primary teeth for each dilution level - control, concentrated, and diluted pediatric iron syrups - regardless of brushing, is shown in (Fig. 5). The differences in staining intensity among the groups are visibly evident, with the concentrated syrup group exhibiting the most pronounced discoloration.

Discussion

The present study explores the extrinsic staining effects of pediatric iron supplements, on primary anterior teeth, focusing on the influence of syrup dilution and tooth brushing. The WHO recommends iron supplementation in the form of drops for children under the age of three to prevent iron deficiency anemia.[1] However, a well-documented side effect is tooth discoloration, which has been reported in over half of children receiving oral iron supplements, leading to concerns among parents.[6] Despite this, limited research has explored the combined effects of syrup concentration, dilution, and brushing on tooth staining, especially in primary teeth. Aiming to fill that gap, the main objectives of this study were to determine whether dilution and brushing mitigate the staining effects of iron syrup and how staining progresses over time.

In this study, the CIELab* color space was employed to objectively evaluate extrinsic staining, as it offers a standardized and widely accepted framework in dental research for quantifying tooth color changes. Color was measured using the L* (lightness), a* (green-red), and b* (blue-yellow) coordinates, while the ΔE value was used to represent the overall color difference over time. This objective method provides greater precision and consistency compared to traditional visual assessments or shade guides. Similar methodologies have been used in dental research, including studies evaluating the color stability of various dental materials subjected to different staining agents, reinforcing the reliability of the CIELab* system in controlled *in vitro* settings.[16,17] To ensure accuracy and reproducibility of the measurements, the VITA Easyshade® spectrophotometer - a device validated in both clinical and laboratory contexts - was utilized. In fact, the use of spectrophotometers in dental research has gained prominence due to their ability to provide objective, reproducible color measure-

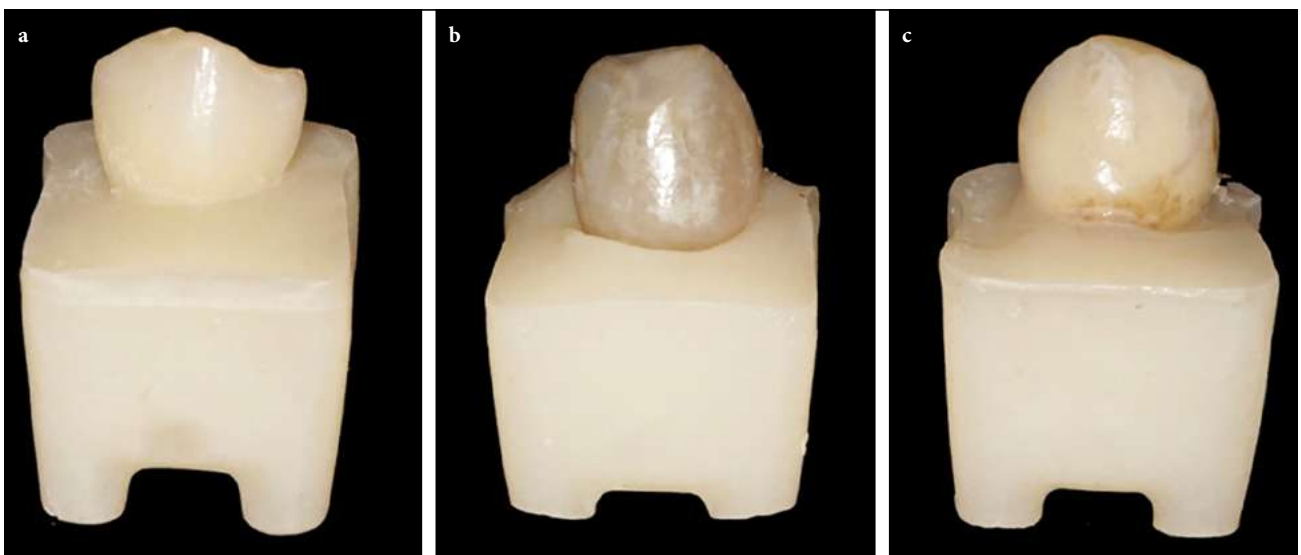

Figure 5. Representative images of primary teeth showing varying degrees of extrinsic staining following exposure to different dilution levels of iron syrup solutions. (a) Control group. (b) Concentrated iron syrup. (c) Diluted iron syrup.

ments, making them especially valuable in studies evaluating extrinsic staining on primary teeth. Recent systematic reviews have emphasized the importance of accurate shade selection and evaluation methods, highlighting spectrophotometry as a reliable tool in both clinical and research settings.[18]

The study's findings revealed a clear progression of extrinsic staining over the three time points, with significant differences between groups. Group 3 (unbrushed, concentrated) exhibited the most severe staining, with ΔE values increasing significantly from T1 to T3 ($p<0.001$). A less intense but still significant increase in staining was observed in Group 5 (unbrushed, diluted), where ΔE values showed an increase from T1 to T3 ($p=0.015$). In contrast, no significant staining progression was seen in the control group (Groups 1 and 2), nor in Group 6 (brushed, diluted), where ΔE values remained relatively stable. These results suggest that the iron syrup concentration played an important role in staining severity, with diluted syrup causing less pronounced discoloration, in line with the results of several studies evaluating the effect of different types of iron drops on the color of primary teeth. For example, Pani et al[9] compared the discoloration potential of the primary teeth exposed to two types of iron syrups, namely, ferrous fumarate (FF) and ferric oxide polymaltose (FOP). They found that the mean ΔE in all groups increased over time and the difference was significant similarly to our study. Another study by Mehran et al[19] evaluated the effect of two types of iron drops on the color of the primary teeth. The results of their study indicated an increase in the mean ΔE over time with statistically significant differences, which corroborates with the results of the present study. Both studies used ferrous sulfate iron supplements but the assessment time points and the immersion protocols differ from the present study.

Further statistical analysis confirmed that syrup concentration significantly influenced staining severity. At all-time points, the concentrated syrup groups (Groups 3 and 4) exhibited the highest mean ΔE values whereas the diluted syrup groups (Groups 5 and 6) had lower but still elevated ΔE values. The control group maintained ΔE values around 9.15 to 9.50, showing minimal discoloration. These differences were statistically significant across all time points (Kruskal-Wallis $p<0.001$), with post hoc tests confirming that the concentrated syrup caused significantly more staining than both the diluted and control groups (adjusted p-values<0.01). These results suggest that while dilution reduces discoloration compared to the concentrated syrup, it does not fully prevent it. Therefore, the primary null hypothesis (H0) is rejected, indicating that iron syrup concentration plays a critical role in staining severity. To the best of our knowledge, this is the first study to evaluate the effect of dilution on iron-induced staining of primary anterior teeth. Previous research has largely focused on the effects of different factors such as different types of iron syrups or the impact of tooth brushing, the role of dilution remaining unexplored. By addressing this gap, our findings allow novel insights into addressing this side effect, highlighting a key strength and innovation of the present study. Proven effective to reduce iron-staining, dilution of iron supplements can be incorporated into the preventive measures given to the parents during the first dental visit. More specifically, special needs children such as children with autism spectrum disorder (ASD) can benefit from this approach as they face difficulty cleaning their teeth or enduring in –office dental prophylaxis due to their poor behavioral activities and complex physiological state.[20]

The effect of brushing on tooth discoloration appeared to be limited and dependent on both iron concentration and duration of exposure. In the diluted syrup group, brushing significantly reduced staining at T1 ($p=0.002$), suggesting an early benefit from mechanical pigment removal. However, this effect was not sustained at T2 ($p=0.12$) or T3 ($p=0.15$), indicating a diminished protective role over time. In contrast, brushing had no significant impact in the concentrated syrup group at any time point. Pooled analysis of all samples supported this trend, showing no overall statistical difference between brushed and unbrushed teeth ($p>0.05$), though a non-significant reduction in staining among brushed samples was noted at T3. These findings suggest that brushing may help limit early pigment buildup when staining intensity is low, as in diluted formulations, but becomes less effective as iron exposure increases and pigments penetrate more deeply into enamel. Thus, the secondary null hypothesis (HS_0) is largely retained, with partial rejection only at T1 in the diluted group where brushing had a measurable effect.

The study also compared its findings to existing literature. Heidari et al[21] examined the removal of iron-induced stains on extracted primary teeth and found that prophylaxis treatment was the most effective in removing iron stains. The present study differed in its use of manual brushing, whereas Heidari et al[21] used an automatic brushing machine, which could explain some of the observed differences in the results. Moreover, the

use of the VITA Easyshade spectrophotometer in this study provided a more precise and reliable measure of color change compared to the Photoshop and iColor software used in Heidari's study.

Further comparisons with studies on restorative materials, such as the one by Almutairi et al[22], revealed similar results to our study, indicating that brushing may have limited impact on staining when exposure is prolonged or when the staining is more intense.

In clinical terms, the ΔE values obtained in this study indicated that all groups experienced clinically perceptible staining, with values exceeding the commonly accepted threshold of ΔE=3.7 used in various studies. [16,18] In some cases, ΔE values surpassed 6.0 representing staining that is clearly visible and likely to be of aesthetic concern. The concentrated syrup groups showed the most severe staining, while the diluted syrup group exhibited moderate discoloration. Interestingly, brushing significantly reduced discoloration in the diluted syrup group, particularly in the early stages, but did not prevent staining from becoming clinically noticeable over time.

The limitations of the present study include its *in vitro* design, which does not fully replicate the dynamic oral environment. Factors such as saliva composition, flow and other oral hygiene habits were not accounted for, which could influence stain formation and removal in real-life scenarios. Additionally, the brushing protocol used in this study was not standardized to the same degree as in some other studies, which may have introduced some variability in the results.

Conclusion

The present study found that the concentration of iron syrup plays a significant role in extrinsic tooth discoloration, with concentrated iron syrup causing the most severe staining. Diluting the syrup reduced staining but did not completely prevent discoloration. Tooth brushing provided only limited, short-term benefits suggesting that while brushing may offer modest protection, especially with diluted formulations, it cannot fully counteract iron-induced staining. Dilution of iron supplements emerges as an effective strategy for reducing discoloration in primary teeth. Pediatricians and pediatric dentists should advise parents to dilute iron supplements and emphasize the importance of early, effective tooth brushing to help minimize staining and maintain oral health.

Disclosures

Ethics Committee Approval: The study was approved by the Saint-Joseph University of Beirut Ethics Committee (no: USJ-2024-99, date: 18/04/2024).

Informed Consent: Informed consent was obtained from all participants.

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Original Article

Longevity of Resin Restorations in MIH Affected First Permanent Molars with and without Deproteinization: A 36- Month Randomized Controlled Trial

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Abstract

Objective: MIH affected molars still pose a restorative challenge to the treating clinician with several authors reporting significantly higher rates of adhesive failures of resin-based restorations compared to their sound counterparts. The objective of the study is to compare the 36 months clinical and radiographic performance of direct resin restorations placed with and without prior treatment with a deproteinizing agent.

Materials and Methods: In this parallel group double blind randomized trial, 50 vital first permanent molars, affected with MIH and requiring restorations of at least 2 surfaces, were randomly allocated by stratified permuted block randomization to receive direct resin restorations either with or without deproteinization using 5% sodium hypochlorite (n=25 each). Clinical and radiographic evaluations of the restored molars were carried till 36 months using the USPHS criteria.

Results: At 36 months, overall retention rate was found to be 100% with complete elimination of any pre-existing sensitivity. Cumulative survival rates were found to be 100% in both groups.

Conclusion: Direct composite restorations served as an adequate restorative measure for first permanent molars affected with moderate to severe MIH where the defect was limited to two surfaces and the preparation involved removal of the defect till detection of reasonable resistance in enamel.

Keywords: Deproteinization, hypomineralization, MIH, MIH affected molars, restoration

Introduction

The term molar incisor hypomineralization (MIH) is used to describe the clinical appearance of enamel hypomineralization of systemic origin affecting one or more first permanent molars (FPMs) that are associated frequently with affected incisors.[1] MIH of first permanent molars (FPMs) is a relatively common condition with a reported prevalence of 4–25 percent.[2,3] Owing to the disrupted ameloblastic function during the maturation stage of amelogenesis, the resultant enamel is qualitatively defective which readily undergoes Post Eruptive Breakdown (PEB) under masticatory forces.[4] Further the porous nature of the defective enamel makes it very sensitive to any kind of stimuli, even brushing. This results in avoidance of brushing of the affected teeth, thereby leading to plaque accumulation, early caries onset and complete breakdown of the enamel exposing the unprotected dentine.[5]

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Based on the severity of hypomineralization, the resultant breakdown and associated symptoms, various treatment options have been suggested for managing these molars.[6] The restoration of MIH affected molars is complicated with repeated loss of restoration owing to the breakdown of hypomineralized enamel at restoration margins necessitating frequent replacements. Moreover, as the pattern of these defects usually does not conform to the normal pattern of pit and fissure caries, failure of restoration on even a single surface may warrant the replacement of the entire restoration. In fact, MIH affected molars undergo dental treatment nearly 9 times more often than non-MIH molars, and every defective tooth on an average is reportedly treated twice.[7,8] The plausible explanation for the poor bond between the enamel–resin interface is the high organic content seen in MIH affected enamel with increased proteins. This has led to similarities being drawn between the composition, treatment, and management of amelogenesis imperfecta (AI)-affected enamel and MIH- affected enamel.[9,10]

In order to overcome the complications of excessive protein content of hypomineralized teeth including MIH affected molars, deproteinization treatment prior to placement of restorations has been proposed as this potentially improves the resin-enamel bond.[11] The use of 5 percent sodium hypochlorite for deproteinization of enamel was first studied by Venezie et al[10] in teeth affected with Amelogenesis Imperfecta. The 'Bleach' pretreatment using 5 percent sodium hypochlorite can potentially have a beneficial effect on the enamel-resin interface of hypomineralized teeth as a result of its protein denaturing ability.[11–13] Various other agents viz. papain gel, bromelain enzyme, calcium hypochlorite have also been proposed for use as deproteinizing agents.[9] Drawing from the similarities between the two types of enamel-affected with Molar Incisor Hypomineralization and Amelogenesis Imperfecta, Wright postulated that a 'bleach-etch-seal' technique could be used for enhancing the resin-enamel interface and ultimately the micromechanical bonding in MIH-affected enamel.[12] The same concept has now been extended to the restoration of MIH affected teeth using composite restorations, as an attempt to improve their clinical performance.[14]

Thus, bearing in mind the suggested potential improvement in the clinical performance and retention of resin restorations in MIH affected FPMs after treatment with a deproteinizing agent (5% NaOCl), and the lack of well-designed prospective randomized controlled trials evaluating the same, the present study was planned to evaluate and compare the effect of deproteinization using 5 percent sodium hypochlorite on the longevity of resin restorations for MIH affected FPMs in 8–14 years old children. The null hypothesis for the statistical evaluation was that no difference exists in the longevity of direct resin restorations on MIH affected molars done with or without deproteinization of the tooth surface.

Materials and Methods

The study was designed to test the null hypothesis that there is no difference in the longevity of direct resin restorations performed on MIH affected molars with or without deproteinization using 5% NaOCl. In the present parallel group double blinded randomized trial, a total of 50 permanent first molars affected with severe MIH in 35 children were restored using direct resin restorations either with or without pre-treatment with 5% sodium hypochlorite. The trial was labelled as a double blinded trial since both the participant and the investigator evaluating the restoration at different time periods were unaware of whether or not the deproteinization treatment was rendered. The pediatric dentist rendering the treatment could, however, not be blinded to the groups for obvious reasons. However, the identical appearance of the restorations and the homogeneity in all other respects apart from an additional step in the procedure made it possible to keep the evaluations of the restorations completely blinded.

The sample size calculation was based on a study conducted by Lygidakis et al[13] Based on this, the minimum sample size was found to be 36 molars at a confidence level of 95% and a significance level of 0.05 with 80% power of the study. Considering the expected 10% attrition rate of the sample a final sample of 50 was selected.

An Institutional Ethical Board approval was obtained before commencing the study (NK/4885/MDS/210) and all procedures were carried out in keeping with the guidelines laid out in the Declaration of Helsinki. The trial was registered with the Clinical Trial registry of India as well (CTRI/2019/03/018005).

Recruitment

Children aged 8–14 years, attending the Out-patient unit of Pediatric Dentistry, Oral Health Sciences Center, Chandigarh between August 2018 and February 2019 were screened for MIH using the criteria proposed by the European Academy of Pediatric Dentistry.[1] Children with at least one first permanent molar (FPM) exhibiting demarcated opacities with or without affected incisors were accepted as MIH affected.

FPMs were further assessed according to the following inclusion criteria: a) MIH affected FPMs that needed restoration of at least two surfaces because of post eruptive breakdown and/or carious involvement, b) MIH affected molars that had been previously restored but required replacement of the existing restoration in accordance with the first criteria, c) No clinical or radiographic sign of associated pulpal/periradicular pathology. Based on the aforementioned criteria, 50 first permanent molars (FPMs) from 35 children, were included in the study after obtaining a written informed consent from the respective parents.

Treatment groups and randomization

Two treatment groups were created for the investigation viz. Group A- Direct composite restoration of included FPMs after their deproteinization treatment using 5% NaOCl, and Group B- Direct composite restoration of included FPMs without subjecting them to the deproteinization treatment.

A stratified permuted block randomization sampling technique was applied using computer-generated sequence of numbers (facilitated by one of the supervisors, MJ) for the random allocation of 50 molars (divided into 9 blocks containing 4, 6, 4, 4, 8, 6, 6, 4, and 8 units, respectively) into one of the two treatment groups in the ratio of 1:1. This was done through sequentially numbered sealed opaque envelopes within the respective block envelope, by one of the supervisors (KG) ensuring that the allocation was completed from one block before moving on the next one. Each tooth was allocated its group on the day of the procedure.

Clinical procedure

All dental procedures were carried out by a single trained pediatric dentist (MR) under local anesthesia and rubber dam isolation. The extent of the cavity preparation was dictated by removal in entirety of the carious tissue and removal of hypomineralized enamel until reasonable resistance was detected. Following the preparation of cavity walls, calcium hydroxide liner (Septodont, France) was applied in deep portions of the preparation that were in close proximity to the pulp. This was followed by application of a protective base of Glass Ionomer Cement to compensate for the lost dentin thickness where needed.

Restorative procedure for group A

Following cavity preparation, the cavity walls were etched with 37 percent Phosphoric Acid (3M™ ESPE™ ScotchbondTM Etchant) for 30 seconds and then rinsed with water. The etched teeth were then air dried. For deproteinization, the etched tooth surfaces were painted with a cotton pellet soaked in 5 percent sodium hypochlorite for 60 seconds and then rinsed with water. The deproteinized surfaces were then air dried for a few seconds till a frosted appearance of the etched-deproteinized surface was evident. This was followed by application of total etch, self-priming, dentin bonding agent (3M™ ESPE™ Adper™ Single Bond 2 Adhesive) using a microbrush, which was then light cured. The teeth were then restored using incremental portions of bulk fill direct posterior composite (3M™ FiltekTM Z350XT, XT Universal Restorative) to re-establish anatomic contours of the tooth. After gross finishing of the restoration, the rubber dam was removed. An articulating paper was used to check for occlusal high points if any, which were then reduced before final finishing of the restoration. Final finishing of the restoration was carried out with composite finishing kit and burs. The restorative procedure is depicted pictorially in Figure 1.

Restorative procedure for group B

The restorative procedure was identical to that followed for Group A, barring the step of deproteinization using 5 percent sodium hypochlorite. The final restorations were similarly checked for occlusion and finished.

Evaluation

Two blinded, calibrated evaluators (KG and MJ) carried out the clinical and radiographic evaluations of the restorations. The first post-restoration recall was at 1 week, primarily for assessment of any immediate discomfort and hypersensitivity resolution. At the subsequent recall appointments at 3, 6, 12, 18, 24 and 36 months, restorations were scored for their retention, marginal integrity, marginal discoloration, anatomic form, secondary caries and hypersensitivity using the modified United States Public Health Services (USPHS) criteria outlined in Table 1.[15] For each criterion, Alpha indicated the greatest degree of clinical acceptability, Bravo represented clinically acceptable scores while Charlie was regarded as a clinically unacceptable score and its assignment to any restoration would have rendered the same a failure warranting re-treatment. Plaque scores and gingival health were assessed using the Loe and Silness index (1963) and the Silness and Loe index (1964), respectively. Sequential radiographic assessment using Intra-oral Peri-apical radiographs was also carried out to monitor continuation of root development and peri-apical health as signs of tooth vitality. Of all the parameters, retention of the restorations formed the primary outcome whilst the rest formed part of the secondary outcomes.

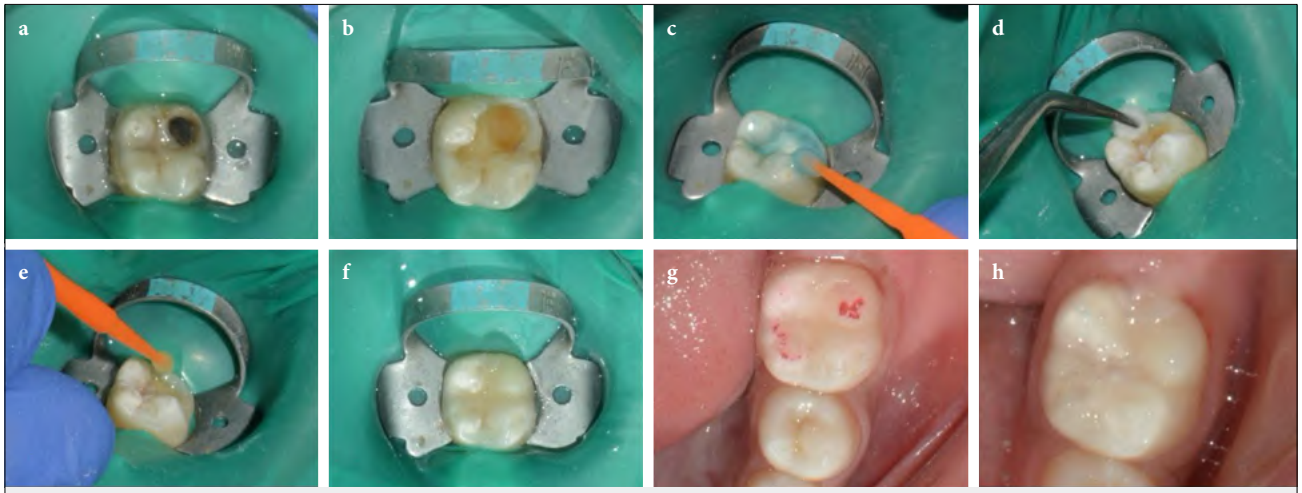

Figure 1. Stepwise procedure followed for restoring the MIH affected Molars in group A; (a) Isolated MIH affected molar with carious defect. (b) Removal of carious and hypomineralized dental tissue till detection of reasonable resistance. (c) Application of acid etchant followed by rinsing. (d) Application of 5% Sodium Hypochlorite-soaked cotton pellet for 1 minute followed by rinsing. (e) Application of bonding agent to etched and deproteinized tooth surface. (f) Restoration with direct composite resin. (g) Reduction of occlusal high points and final finishing of the restoration (h) Restoration at 12 mo follow up

Statistical analysis

Inter-examiner reliability for the two evaluators (KG and MJ) was assessed to be excellent upon the re-evaluation of 15 restorations (Cohen's Kappa coefficient score of 0.8). Data from a single evaluator was then used to carry out the statistical analysis.

Statistical analyses were performed using IBM SPSS Statistics for Windows (Version 25.0. Armonk, NY: IBM Corp.). Results on continuous data are presented as Mean & SD and categorical measurements are presented as Frequency & Percentage. Categorical variables were compared between two groups using Chi-square/Fisher exact test and quantitative using the Mann-Whitney U test. $p<0.05$ was considered statistically significant.

Results

A total of 72 permanent first molars affected with moderate to severe MIH (49 children) were assessed for eligibility between the period of August 2018 and February 2019. Of these, 36 children (n=19 males, 17 females) with 50 affected molars in the age range of 8–14 years (mean 10.2 years) were finally included (Fig. 2). Factors necessitating restorations were the presence of PEB (n=47, 94%), atypical caries (n=43, 86%), defective previous restorations (n=10, 20%) and sensitivity to cold in the affected tooth (n=46, 92%). The unit of allocation was the tooth and not the child. The maximum number of either type of restorations placed in a single child were 4 (in 1 child). Two children received restorations in three molars and 7 children received restorations in two of their four first permanent molars. Table 2 outlines the demographic characteristics of the study sample in both groups. The recall rate of children was 100% (36 children) at 12 months, 97.2% (35/36 children, 49/50 restored FPMs) at 24 months as one child was lost to follow-up in Group A, and 91.6% (33/36, 47/50 restored FPMs) at 36 months as two children from group B failed to report for follow-up thereafter. All the cases lost to follow up were ones that had received restorations in only one of their four FPMs. The number of children and restored FPMs included for the final analysis at 36 months was 33 and 47 respectively (Fig. 2).

Table 3 lists the cavity design for each of the patient enrolled in either of the two groups in terms of the surface involved viz. Occlusal (O), Buccal (B), Palatal/Lingual (P), Mesial (M) and/or Distal (D). The OB cavity design was the most common in both groups separately - Group A- 60%, n=15/25; Group B – 44%, n=11/25; p-value=0.43 and in the total sample (52%; n=26/50). The difference in the number of molars with OB cavity design over the other combinations of surfaces restored was found to be statistically significant ($p<0.05$).

Table 4 compiles the results of the scores allotted to the restorations according to USPHS criteria. The restorations in the two groups did not show any clinical or radiographic differences at the 3- and 6-months period. For anatomic form, scores changed from Alpha to Bravo after 12 months in 1 FPM in Group A and in 4 FPMs in Group B (p=0.34). These scores, however, did not worsen at subsequent reviews. Similarly, Bravo scores

Table 1. Modified USPHS criteria

	Alpha	Bravo	Charlie
Retention	No loss of retention	Partial loss or mobile restoration	Complete loss of retention
Marginal adaptation	No catch or crevice	Catch but no exposure	Explorer reaches DEJ
Marginal discoloration	Matches adjacent tooth structure	Slight mismatch with adjacent tooth structure	Strong mismatch with adjacent tooth structure
Anatomic form	Restoration is contiguous with the original tooth anatomy	Slight discontinuity, clinically acceptable	Discontinuous, failure
Surface texture	Surface of restoration similar to enamel	Surface of restoration gritty	Surface of restoration pitted and coarse
Secondary caries	No caries present	–	Caries present
Post-operative hypersensitivity	No sensitivity	Mild sensitivity with no pain, no retreatment required.	Sensitivity with severe pain, retreatment required

USPHS: United States Public Health Services, DEJ: Dentinoenamel junction

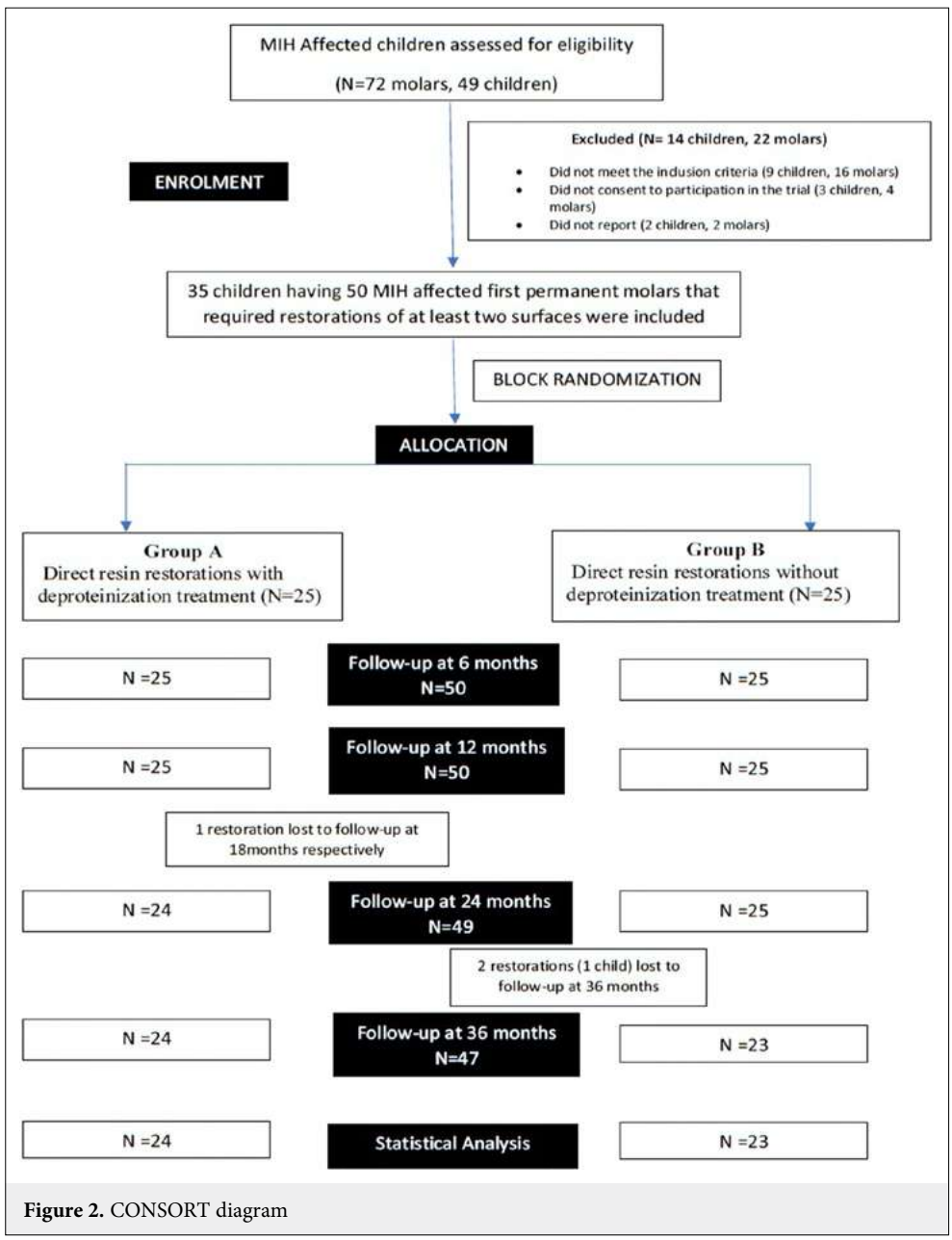

Figure 2. CONSORT diagram

Table 2. Comparative evaluation of baseline parameters

Baseline parameters	Group A	Group B
Mean age	9.92	9.68
Average DMFT+deft	7.56	8.04
Brushing frequency	2.04	2.08
Hypomineralized molars distribution		
Maxillary		
16	3	7
26	9	6
Total	12	13
Mandibular		
36	5	6
46	8	6
Total	13	12
Pre-treatment status		
MIH affected molars	25	25
MIH affected along with caries	22	21
Restored hypomineralized molars requiring replacement	7	4

DMFT: Decayed, missing, filled teeth, MIH: Molar incisor hypomineralization

were recorded for marginal adaptation of 1 restoration in Group A and for 4 restorations in Group B.

2 restorations in Group B began showing marginal discoloration warranting Bravo scores at 12 months. At the end of 36 months, this number had increased to 4. Only 1 restoration in Group A received a Bravo score at 24 months which stayed stable till the end of 36 months (p=0.18 at 36 mo). No restoration received a Charlie score.

Table 3. Cavity design for each of the patient enrolled in either of the two groups in terms of the surface involved

Cavity design	Group A	Group B
	n (%)	n (%)
OB	15	11
OP	5	7
OBD	3	4
OPD	4	1
OBM	0	1
OD	0	1

OB: Occlusal-buccal, OP: Occlusal-palatal, OBD: Occlusal-Buccal-distal, OPD: Occlusal palatal distal, OBM: Occlusal-buccal-mesial, OD: Occlusal-distal

Surface texture was scored to be consistently uniform till the end of 36 months in both the groups. None of the restored teeth in either group was found to develop any evidence of secondary caries.

Pre-operatively, 24/25 teeth in Group A and 22/25 teeth in Group B demonstrated moderate-severe grades of hypersensitivity. Hypersensitivity was found to have resolved in all the restored teeth at the 1-week recall. Thereafter, all the restored teeth continued to remain free of hypersensitivity till 24 months. At 36 months, only one tooth in group A demonstrated mild sensitivity (Bravo score) upon testing with cold air, however it did not warrant re-treatment. The difference of scores for any parameter between the two groups were not found to be statistically significant (p>0.05). The sequential radiographs recorded demonstrated continuous root growth and did not show signs of periapical disease in any of the restored teeth at any point of evaluation (Fig. 3).

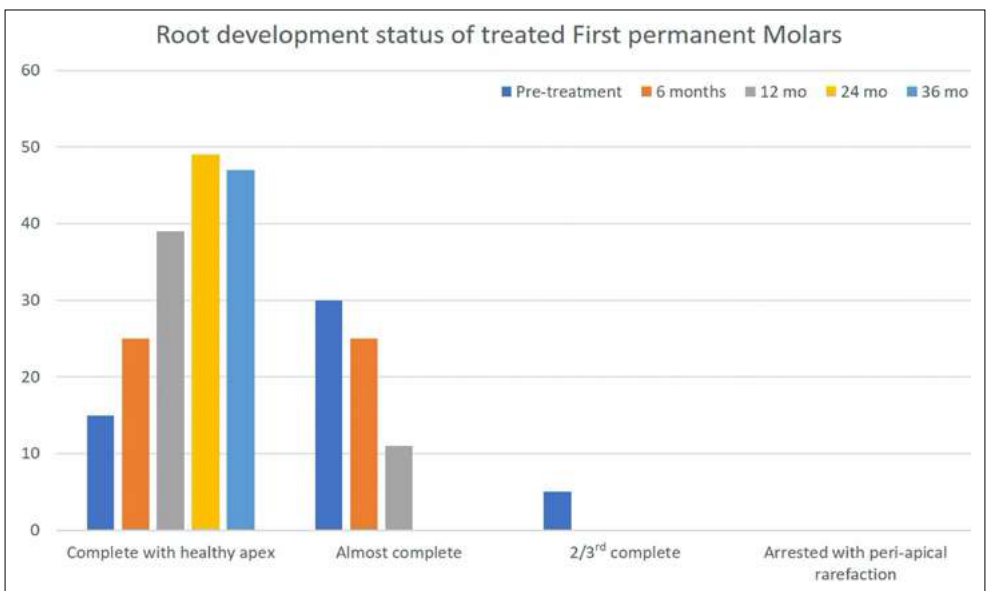

Figure 3. Root development status of restored molars

Table 4. Clinical results of restored teeth in both groups evaluated per the modified USPHS criteria

Evaluation parameters	Time interval									
	Baseline		6 months		12 months		24 months		36 months	
	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
Retention										
Alpha	25	25	25	25	25	25	24	25	24	23
Bravo	0	0	0	0	0	0	0	0	0	0
Charlie	0	0	0	0	0	0	0	0	0	0
p	1.00	1.00	1.00	1.00	1.00					
Marginal adaptation										
Alpha	25	25	25	25	25	24	23	21	22	19
Bravo	0	0	0	0	0	1	1	4	2	4
Charlie	0	0	0	0	0	0	0	0	0	0
p	1.00	1.00	0.49	0.35	0.41					
Marginal discoloration										
Alpha	25	25	25	25	25	23	23	23	23	19
Bravo	0	0	0	0	0	2	1	2	1	4
Charlie	0	0	0	0	0	0	0	0	0	0
p	1.00	1.00	0.48	1.00	0.18					
Anatomic form										
Alpha	25	25	25	25	25	25	23	21	23	19
Bravo	0	0	0	0	0	0	1	4	1	4
Charlie	0	0	0	0	0	0	0	0	0	0
p	1.00	1.00	1.00	0.35	0.18					
Surface texture										
Alpha	25	25	25	25	25	25	24	25	24	23
Bravo	0	0	0	0	0	0	0	0	0	0
Charlie	0	0	0	0	0	0	0	0	0	0
p	1.00	1.00	1.00	1.00	1.00					
Secondary caries										
Alpha	25	25	25	25	25	25	24	25	24	23
Bravo	0	0	0	0	0	0	0	0	0	0
Charlie	0	0	0	0	0	0	0	0	0	0
p	1.00	1.00	1.00	1.00	1.00					
Hypersensitivity										
Alpha	1	3	25	25	25	25	24	25	23	23
Bravo	13	9	0	0	0	0	0	0	1	0
Charlie	11	13	0	0	0	0	0	0	0	0
p	0.36	1.00	1.00	1.00	1.00					

USPHS: United States Public Health Services

Discussion

Hypomineralized young permanent molars, have attracted a lot of interest from pediatric dentists, the world over, owing to the associated clinical problems particularly the hypersensitivity, post-eruptive breakdown and the resultant restorative dilemma they pose. [2,3,6,7] Several strategies have been suggested in literature to facilitate predictable longevity of restorations in MIH affected molars. Several authors have investigated

a spectrum of direct restorative materials for these hypomineralized molars including traditional restorative Glass Ionomer Cement (GIC), Resin Modified GIC, Hybrid GIC and Composite resin restorations.[6,13,16–18] Direct restorations are indicated in MIH affected FPMs where the defect involves 2–3 surfaces, with composite resin restorations showing the best results in terms of longevity compared to all other direct restorative options investigated.[6,8,19] These restorations, however, are not free from concerns regarding inevitable restorative failures owing to the breaches at the tooth-restoration interface.[13,14,20] These failures are attributed to the lower inorganic and higher protein content in the MIH affected enamel along with greater porosity and cracks evident in its ultrastructure.[21,22] These aberrations in MIH affected molars are responsible for atypical etching patterns, limited inter-rod dissolution, high inter-crystal porosity, and poor microtag formation that ultimately translate to an inferior bond strength with resin restorations than what their sound counterparts exhibit.[21,23]

The concept of deproteinizing hypomineralized enamel prior to resin restorations is thus based on the theory that removing the excess protein will lead to better adhesion. First suggested by Venezie et al[10] to improve the bond strength of orthodontic brackets to AI affected enamel, deproteinization using 5% Sodium Hypochlorite was then investigated in MIH affected molars by Gandhi et al[24] to aid in retention of pit and fissure sealants, but with no significant improvement.[10,24] Sonmez et al[14], were the first to investigate deproteinization as a pre-treatment for MIH affected enamel receiving resin restorations. They studied the effect of deproteinization on several cavity designs and reported a significant improvement in the retention of composite resin restorations placed after deproteinization only when the restoration margins rested on hypomineralized enamel. Hitherto, there are no absolute guidelines for cavity preparation in such teeth. Digressing from the recommendations by Fayle et al[25] to limit tooth structure removal to only softened enamel, William et al[5], endorsed the more invasive approach of removing all hypomineralized structure till sound enamel surfaces were reached. In our trial we set out to investigate the longevity of resin restorations in moderate to severe MIH affected first permanent molars placed with and without deproteinization using 5% Sodium Hypochlorite following cavity designs such that the hypomineralized tissue was removed only till resistance was met by the cutting bur. In this way, the final margins would rest on hypomineralized but not structurally compromised enamel.

In the bleach-etch-seal technique by Gandhi et al[24], the tooth surface was treated with 5% Sodium Hypochlorite and then etched. However in our study, the tooth surfaces were first etched with 37% phosphoric acid and then subjected to 5% Sodium Hypochlorite solution via a soaked cotton pellet for 1 minute. This was similar to the approach followed by Sonmez et al[14] and is based on the theory that acid etching the tooth surface to be bonded exposes its collagen framework thus facilitating removal of the excessive protein by the deproteinizing agent.

Upon completion of the restorations, all patients were recalled after a week's interval and assessed for any complaints. Hypersensitivity was the most commonly associated symptom with these molars at presentation. All 50 teeth, irrespective of the treatment received, were found to be free from sensitivity to cold air at their one-week follow-up. At the end of the study, 1 patient in Group B and 2 patients in Group A were lost to follow up at 24 and 36 months respectively. Two of these 3 patients moved out of the city and thus could not visit but they were followed up till 36 months telephonically and reported no signs of restoration loss or irreversible pulpal damage. 1 patient could not be contacted at all for the 36-month follow-up visit.

In terms of overall longevity, we found no significant difference between the restorations in the two treatment groups. No restoration in either group was lost till the end of 36 months. Retention was found to be 100% in both groups. Not one of the restorations in our study was found to be a failure as per the modified USPHS criteria used, nor did any warrant replacement, however, there were differences in clinical performance between the two groups which became evident after 24 months. Although statistically insignificant, a greater number of restorations were found to deteriorate in terms of marginal integrity, color match and anatomic form in the group that did not receive deproteinization. Sonmez et al[14] reported significantly inferior parameters in resin restorations done without deproteinization compared to those restored with deproteinization when the initial cavity design did not remove all the hypomineralized dental tissue. Interestingly, they found that with deproteinization the restorations exhibited similar clinical performance despite the two different approaches of cavity preparation viz removal of the entire hypomineralized dental tissue so that restoration margins rest on sound enamel versus removal of hypomineralized enamel only till resistance to the bur is met.

Limitations

The major limitation to the study, and the technique is the subjectivity of the removal of hypomineralized tissue since it depends on the operator's proprioception.

Conclusion

- Direct composite resin restorations are a good restorative option for MIH affected molars requiring restoration of 2–3 surfaces to prevent debilitative outcomes that result from rapid breakdown and subsequent carious involvement of unrestored MIH affected molars.
- Our results accepted the null hypothesis proposed at the onset of the study for this particular follow-up period as no difference was found to exist in the longevity of direct resin restorations on MIH affected molars done with or without deproteinization of the tooth surface.
- Addressing the dilemma of initial cavity preparation, our study suggests that removing the MIH affected tissue till resistance to the bur is met seems to be enough for the restoration margins to support the oncoming restoration.
- Deproteinizing these cut surfaces after etching and prior to bonding an adhesive resin may aid in improving longevity of these restorations, particularly the integrity of the restoration margins. The fact that this simple pre-treatment with a readily available Sodium Hypochlorite solution may help in enhancing the performance of resin restorations in MIH affected molars while giving allowance for minimally-invasive cavity designs, warrants the need for longer observation of these restores molars and further clinical investigations in this field to draw more conclusive evidence-based results.

Disclosures

Ethics Committee Approval: The study was approved by the Institutional Ethical Board (no: NK/4885/MDS/210).

Informed Consent: Informed consent was obtained from all participants.

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Original Article

Profile of Traumatic Dental Injuries Among Children in NGHA Hospital, Riyadh, Saudi Arabia: A Retrospective Cohort Study

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Abstract

Objective: Traumatic dental injuries (TDIs) are common in the pediatric population in Saudi Arabia and can significantly affect children's oral and overall well-being. While global data are widely available, studies on the prevalence and management of TDIs in Saudi Arabia remain limited. The objective of the study is to assess the prevalence, characteristics, management, and outcomes of TDIs among children treated at the National Guard Health Affairs hospital in Riyadh, Saudi Arabia.

Materials and Methods: A retrospective study evaluated records of pediatric patients (aged 1–16 years) with TDIs treated between January 2019 and January 2024 at King Abdulaziz Medical City and King Abdullah Specialized Children Hospital, National Guard Health Affairs, Riyadh. Data included demographics, injury characteristics, management, complications, and follow-up outcomes. Cases with incomplete records were excluded. Injuries were classified according to International Association of Dental Traumatology (IADT) guidelines. Statistical analysis was performed using IBM SPSS Statistics (version 22.0), with Generalized Estimating Equations used to assess factors influencing treatment decisions, complications, and patient-reported outcomes.

Results: A total of 107 patients with 209 injured teeth were included. Most participants were male (64.5%), as shown in Table 1, with a median age of 6 years and no relevant medical history in 98% of the study population. Falls were the predominant cause (84.2%), mainly occurring at home (81.1%). The upper right central incisor was most affected (25.4%), and uncomplicated crown fractures were the most common injury (20.1%). Most patients (58.1%) presented within 1–24 hours. Conservative management, primarily observation, was the most frequent approach (44.6%). Reported complications included pathological mobility (14 teeth), root resorption (13 teeth), and persistent pain (16 cases). Delayed presentation beyond 24 hours was associated with a higher frequency of complications. Multivariable GEE analysis showed dentition type significantly influenced management decisions ($p=0.024$) and dental anxiety ($p<0.001$).

Conclusion: This study highlights patterns in the management of pediatric TDIs in a tertiary care setting. Early presentation and standardized trauma assessment are important to reduce complications and improve outcomes. Further multicenter prospective studies in Saudi Arabia are recommended to enhance prevention and optimize pediatric oral health care.

Keywords: Retrospective study, traumatic dental injuries, TDIs, children, primary teeth, permanent teeth, etiology, treatment

Introduction

Traumatic dental injuries (TDIs) are a frequent concern in pediatric oral health, significantly affecting children's overall well-being. A recent global study estimated that approximately one billion people have experienced TDIs, with prevalence rates of 22.7% in primary teeth and 15.2% in permanent teeth.[1] However, data on the

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occurrence of TDIs in Saudi Arabia remain limited. A study examining schoolboys aged 5–6 and 12–14 years in Riyadh, the capital city, found prevalence rates of 33% and 34%, respectively.[2] Despite the high frequency of these injuries, many cases either go untreated or receive substandard care.[2,3] This trend is not unique to Saudi Arabia. Research by Hamilton et al[4] revealed that fewer than half (47%) of injured teeth in children aged 11–14 received dental treatment, and of those, over half (59%) were deemed inadequate. Timely and appropriate management of TDIs is crucial, as it greatly enhances outcomes and reduces the risk of complications such as tooth discoloration, necrosis of the pulp, root resorption, increased mobility, and eventual tooth loss.[5,6] Moreover, failure to manage injuries properly at the outset often results in higher long-term treatment costs.[7,8] Understanding the patterns of TDIs is essential for developing preventive strategies, improving treatment protocols, and shaping educational initiatives.[9,10] Given the current lack of comprehensive data on TDIs in Saudi Arabia, the aim of this study is to seek and explore the characteristics, treatment approaches, and complications associated with these injuries in a sample of children in the NGHA hospital in Riyadh, Saudi Arabia.

Materials and Methods

The retrospective study was conducted to evaluate the data records of pediatric patients (aged one – 16 years) who sustained traumatic dental injuries (TDIs) and received treatment at the Pediatric Dentistry Department of King Abdulaziz Medical City (KAMC) and King Abdullah Specialized Children Hospital (KASCH), National Guard Health Affairs (NGHA), Riyadh, Saudi Arabia. Ethical approval was obtained from the King Abdullah International Medical Research Center (KAIMRC), Riyadh, Saudi Arabia (No: 00000178125, Date: 24/06/2025) and the study is conducted according to Declaration of Helsinki. The study covered patients' records for a 5-year period, from January 2019 to January 2024. Patients' data were retrieved electronically. All available cases within the study period were included. All pediatric patients aged 1–16 years who presented with traumatic dental injuries (TDIs) between January 2019 and January 2024 were included. Cases with incomplete or missing key clinical data (e.g., injury type, management, or follow-up outcomes) were excluded. The collected data were extracted from the electronic patients' medical records, covering patients' demographic data, including age, gender, medical history, and the year of injury. Traumatic dental injuries were classified according to the International Association of Dental Traumatology (IADT) guidelines. Injury related details such as the type of dentition affected (primary or permanent), number of injured teeth, cause and location of the incident, and clinical management information, including time of presentation to the emergency department, managing clinician (General dentist, post graduate pediatric dentist, Pedodontist, AGD consultant), immediate treatment provided, and follow up protocols in reference to the International Association of Dental Traumatology (IADT) guidelines. Additional data collected included the number of clinical visits and treatment outcomes, such as the presence of complications (e,g, bone loss, gingival recession, tooth mobility, ankylosis, root resorption), and pulpal status (healing, infected, necrotic), presence of pain, tooth discoloration, tooth loss, and the impact of the developing permanent successor. Clinical outcomes, including pain, pathological mobility, and root resorption, were assessed based on the most recent documented follow-up visit. Patient-centered outcomes, including dental anxiety and patients' aesthetic perception, were also documented when available. Dental anxiety was assessed based on clinician-documented patient behavior recorded in the medical records. Due to the unavailability of total pediatric visit data during the study period, institutional prevalence could not be calculated.

Statistical analysis

All data were entered into a spreadsheet in Microsoft Excel (version 2024), and descriptive and inferential analysis were performed using IBM SPSS Statistics (version 22.0). To assess the association and prediction of injury outcomes, a Generalized Estimating Equations (GEE) model was applied using both multivariable ordinal and binary logistic models, with statistical significance at $p<0.05$.

Results

As reported in Table 1, the analysis included 107 patients, with demographic and injury-related characteristics summarized. The majority of the study population was male (64.5%), and the median age was 6 years. Falls were the most common mechanism of injury, accounting for 84.2% of cases, with most of these injuries occurring in a home setting (81.1%). Primary teeth were most commonly affected (58.9%), with a median of two teeth injured per patient. A relevant medical history was reported in 8.4% of patients. Missing data included the mechanism of injury for 12 patients and the place of occurrence for 33 patients.

Table 2 presents the distribution of the 209 traumatic dental injuries. The most commonly reported injury

Table 1. Demographic and injury-related characteristics of the patients (N=107)

Variables	Category	N	%
Age (years), median (IQR)		6	6
Gender	Male	69	64.5
	Female	38	35.5
Etiology of injury	Car or bicycle accident	3	3.2
	Falling	80	84.2
	Fight	5	5.3
	Hitting	3	3.2
	Playing	2	2.1
	Struck by an object	2	2.1
Place of occurrence	Home	60	81.1
	Playground	2	2.7
	School	7	9.5
	Street	5	6.8
Number of injured teeth, median (IQR)		2	1
Injured dentition	Mixed	2	1.9
	Permanent	42	39.3
	Primary	63	58.9
Medical history	No important medical history	98	91.6
	Important medical history	9	8.4

Data on the etiology of injury were missing for 12 patients. Data on the place of occurrence were missing for 33 patients.

Table 2. Distribution of injury types, severity, and timing (N=209 injuries)

Variables	Category	N	%
Injury type	Concussion	1	0.5
	Subluxation	40	19.1
	Extrusion	7	3.3
	Lateral luxation	15	7.2
	Intrusion	34	16.3
	Avulsion	18	8.6
	Enamel fracture	6	2.9
	UCF	42	20.1
	CCF	21	10.0
	CCRF	4	1.9
	Root fracture	11	5.3
	Alveolar bone fracture	2	1.0
	Complex injury	8	3.8
Time of presentation	<1 h	24	12.6
	>1 h - <24 h	111	58.1
	>24 h	56	29.3

Data on the time of presentation were missing for 18 patients.

type was uncomplicated crown fracture (UCF) (20.1%), subluxation (19.1%), and intrusion (16.3%). In terms of time presentation, the majority of injuries (58.1%) were seen at the clinic between 1- and 24-hours post-incident. A smaller proportion of cases (29.3%) presented after more than 24 hours post-injury. The time of presentation data was missing for 18 injuries.

Table 3 summarizes the frequency of injuries by specific teeth. The distribution shows that maxillary anterior

Table 3. Injured teeth (N=209 injuries)

Variables	Category	N	%
Injured tooth	UR Central Incisor (11)	30	14.4
	UR Lateral Incisor (12)	6	2.9
	UL Central Incisor (21)	34	16.3
	UL Lateral Incisor (22)	9	4.3
	LL Central Incisor (31)	4	1.9
	LR Central Incisor (41)	6	2.9
	LR Lateral Incisor (42)	2	1.0
	UR Primary Central Incisor (51)	53	25.4
	UR Primary Lateral Incisor (52)	8	3.8
	UR Primary Canine (53)	1	0.5
	UL Primary Central Incisor (61)	46	22.0
	UL Primary Lateral Incisor (62)	6	2.9
	LL Primary Lateral Incisor (72)	1	0.5
	LL Primary First Molar (74)	1	0.5
	LR Primary Central Incisor (81)	1	0.5
	LR Primary Lateral Incisor (82)	1	0.5

Table 4. Management provided (N=188 injuries)

Variables	Category	N	%
Immediate treatment	No treatment + monitoring	84	44.6
	Restoration	32	17.0
	Fragment reattachment	2	1.1
	Pulpotomy + restoration	2	1.1
	Extraction	29	15.4
	Repositioning + splint	33	17.6
	Replantation + splint	5	2.7
	Replantation + splint + RCT	1	0.5

teeth were more frequently affected. Among these, primary central incisors were injured more often than permanent central incisors. Specifically, the upper right primary central incisor (tooth #51) was involved in 25.4% of cases, while the upper left primary central incisor (tooth #61) accounted for 22.0% of cases. Permanent maxillary central incisors were also commonly affected, with the upper left central incisor (tooth #21) involved in 16.3% of injuries and the upper right central incisor (tooth #11) in 14.4%. In contrast, injuries to posterior teeth and mandibular teeth were less frequent.

Table 4 presents the immediate management approaches for all 188 injuries. Conservative management was the most common, with "no treatment and monitoring" accounting for nearly half of cases (44.6%). Active management strategies included repositioning and splinting (17.6%), restoration (17.0%), and extraction (15.4%). More invasive procedures, such as replantation and pulpotomy, were performed much less frequently, together representing less than 5% of treatment cases.

Table 5 presents the results of a multivariable Generalized Estimating Equation (GEE) model assessing factors associated with the type of immediate management provided. The analysis revealed that only dentition type emerged as a statistically significant predictor of the management decision (p=0.024). In contrast, time of presentation (p=0.147), gender (p=0.321), and age (p=0.884) were not statistically significant after controlling for all other factors in the model. These findings suggest that, within the context of this study, dentition type appears to be the primary factor influencing the immediate management approach, while time, gender, and age do not significantly contribute to the decision-making process.

Table 5. Multivariable ordinal GEE model for factors associated with the type of immediate treatment

Predictor	Category	Adjusted OR (AOR)	95% Confidence interval (CI)	p
Dentition type				0.024*
	Primary	1.00 (Reference)		
	Mixed	1.304	0.508–3.347	0.581
	Permanent	0.523	0.134–2.041	0.351
Time of presentation				0.147
	<1 hour	1.00 (Reference)		
	1–24 hours	1.571	0.627–3.936	0.335
	>24 hours	3.129	0.982–9.975	0.054
Gender				0.321
	Male	1.00 (Reference)		
	Female	1.480	0.682–3.209	0.321
Age (years)	(per year increase)	1.012	0.861–1.190	0.884

Statistically significant at p<0.05.

Table 6. Multivariable GEE analysis of factors associated with dental anxiety

Predictor	Category	Adjusted OR (AOR)	95% Confidence interval (CI)	p
Dentition type				<0.001*
	Primary	1.00 (Reference)		
	Permanent	0.010	0.001–0.107	<0.001*
Gender				0.029*
	Male	1.00 (Reference)		
	Female	5.167	1.187–22.481	0.029*
Time of presentation				0.585
	<1 hour	1.00 (Reference)		
	1–24 hours	1.428	0.055–37.034	0.830
	>24 hours	0.708	0.029–17.099	0.832
Age (years)	(per year increase)	1.334	0.973–1.828	0.073

Statistically significant at p<0.05.

The Factors related to dental anxiety were assessed using a multivariable ordinal Generalized Estimating Equation (GEE) model, with the results summarized in Table 6. The analysis revealed that dentition type (Overall p<0.001) and gender (Overall p=0.029) were significant predictors of dental anxiety. Specifically, patients with permanent teeth had 99% lower odds of reporting anxiety compared to patients with primary teeth (Adjusted Odds Ratio (AOR)=0.010; 95% Confidence Interval (CI): 0.001–0.107; p<0.001). Gender was found to be a significant factor; Females were over five times more likely to report anxiety than males (Adjusted Odds Ratio (AOR)=5.167; 95% Confidence Interval (CI): 1.187–22.481; p=0.029). Although not statistically significant, there was a noticeable trend suggesting that older age might be associated with an increased likelihood of experiencing anxiety (p=0.073). This might indicate that age could be an influencing factor, although further research would be required to establish a definitive relationship. The time of presentation was not significantly associated with dental anxiety.

A multivariable Generalized Estimating Equation (GEE) model was used to identify factors associated with patients' attendance at follow-up appointments. As shown in Table 7, none of the predictor variables (all p>0.05). However, a trend was observed for dentition type (p=0.056), indicating that patients who sustained a permanent dentition injury were 11 times more likely to attend follow up appointments compared to those with a primary dentition injury (Adjusted Odds Ratio (AOR)=11.358). There were no statistically significant associations found between follow-up appointment attendance and factors such as gender, time of presentation, or age.

Table 7. Multivariable GEE analysis of factors associated with attendance to follow-up clinic visits

Predictor	Category	Adjusted OR (AOR)	95% Confidence interval (CI)	p
Dentition type				0.056
	Primary	1.00 (Reference)		
	Permanent	11.358	0.937–137.748	0.056
Gender				0.330
	Male	1.00 (Reference)		
	Female	1.857	0.535–6.452	0.330
Time of presentation				0.199
	<1 hour	1.00 (Reference)		
	1–24 hours	3.618	0.419–31.275	0.243
	>24 hours	1.288	0.140–11.889	0.823
Age (years)	(per year increase)	0.963	0.685–1.354	0.828

No statistically significant predictors were identified at the p<0.05 level.

The patients' reported outcome of pain at follow-up is summarized in Figure 1. The vast majority of the 102 injuries with recorded pain outcomes were asymptomatic, with 86 patients reporting no pain. In contrast, 16 cases involved persistent pain, suggesting ongoing issues such as inflammation or pathology that required further clinical attention.

Pathological tooth mobility at follow-up is demonstrated in Figure 2. Of the 112 injuries that had data available for this outcome, 98 teeth had no mobility, suggesting a favorable periodontal healing outcome. In contrast, 14 injuries exhibited with continued or new-onset mobility, indicating an unfavorable periodontal outcome.

In Figure 3, the number of cases that presented with root resorption during follow-up is shown. This outcome was assessed in 98 injuries. The majority showed no signs of resorption and were considered to have a stable periodontal outcome. A total of 13 cases were identified with pathological root resorption, highlighting its relevance as a serious posttraumatic dental outcome.

Figure 4 illustrate the prevalence of injuries managed by different types of clinicians. The data reveal that the overwhelming majority of cases (191 injuries) were treated by postgraduate pediatric dentists. In contrast, pedodontists handled 13 injuries, General dentists man-

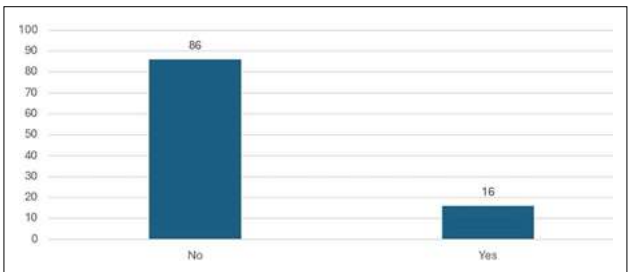

Figure 1. Pain.

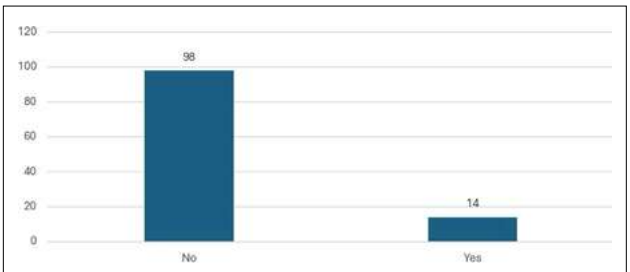

Figure 2. Mobility.

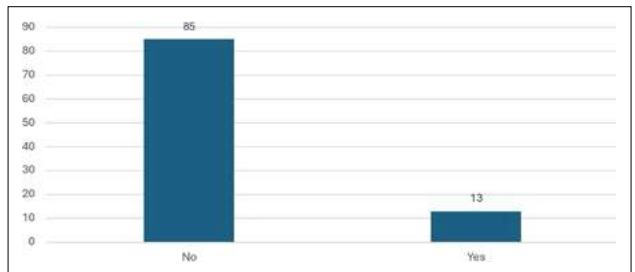

Figure 3. Resorption.

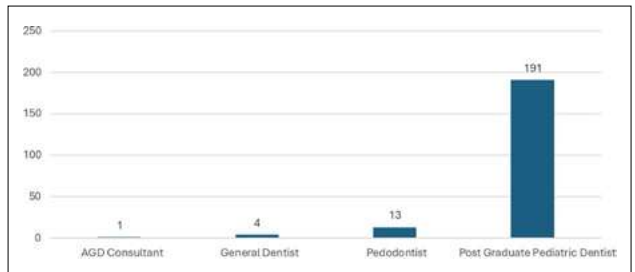

Figure 4. Managing clinician.

aged 4 cases, and an AGD consultant treated just 1 injury. This distribution highlights the dominant role of postgraduate pediatric dentists in managing traumatic dental injuries in this study.

A higher frequency of complications, including persistent pain, pathological mobility, and root resorption, was observed among patients presenting more than 24 hours after injury compared to those presenting earlier, suggesting an association between delayed presentation and adverse clinical outcomes. Institutional prevalence could not be determined due to the lack of available data on total pediatric dental visits during the study period.

Discussion

Due to the lack of TDIs data in Saudi Arabia, this study was carried out to explore the characteristics, management, and associated complications of traumatic dental injuries in a pediatric population treated at the NGHA hospital in Riyadh. A male predominance was observed, supporting findings from previous studies. [2,11–14] This trend is often linked to boys' higher engagement in physically active or risk-prone activities during early childhood. While Gümüş et al[9] found no gender difference in the Turkish population, Patidar et al[11] found that the majority of TDI cases were in boys. The evidence suggests that environmental and social factors may play a role in the different risks of dental trauma between genders.

Our sample indicated that (58.9%) of injuries involved primary dentition, with falls being the predominant cause (84.2%), and the majority of incidents occurring at home (81.1%). These findings closely resemble international trends. Zhang et al[12] in China and Özgür et al[14] both pointed out that falls are the main cause of dental injuries in young children.

Vieira et al[15] similarly found that younger children are more vulnerable to traumatic dental injuries at home, due to inadequate safety precautions and insufficient supervision. Lam[6] corroborated this tendency, demonstrating that most traumatic dental injuries in primary teeth occur due to falls in household environments, particularly among preschool-aged children.

The distribution of injuries in our study exhibited a clear pattern, with maxillary primary central incisors being the most affected. Vieira et al[15] and Gokcek et al[16] also found that maxillary incisors, particularly the primary central incisors, are among the most frequently affected teeth in pediatric dental trauma cases. Studies by Özgür et al[14] and Zhang et al[12] reveal a comparable incidence of trauma linked to anterior primary teeth. This observation aligns with the IADT guidelines supported by the AAPD, which indicate that the maxillary incisors are the most commonly injured teeth in the primary dentition.

The most predominant types of injuries were uncomplicated crown fractures (20.1%), subluxation (19.1%), and intrusion (16.3%). Our findings align with those of Patidar et al[11], who similarly reported an increased prevalence of subluxation and intrusion injuries in children with primary dentition. Lam[6] conducted a comprehensive literature analysis indicating that displacement injuries are significantly more prevalent than fractures in primary teeth, particularly among preschool-aged children. The International Association of Dental Traumatology (IADT) guidelines highlight that luxation injuries occur more frequently in primary dentition because of the thinner cortical bone and incomplete root formation. Clinicians must recognize these patterns, as early identification can directly influence treatment decisions and long-term results.

In our study, the majority of cases (58.1%) were seen between one and twenty-four hours following the injury, while only 12.6% presented within the first hour. A notable proportion (29.3%) arrived after more than 24 hours had passed. Although a significant number of patients received care within a relatively reasonable window, delays beyond the first few hours can still impact healing outcomes. Andreasen et al[5] emphasized that even slight delays in management increase the risk of complications, including pulp necrosis, root resorption, and impaired periodontal healing. Similarly, Al-Jundi[10] reported that delayed presentation is frequently associated with more complex treatment needs and less favorable long-term prognosis. Vieira et al[15] also observed that younger children are susceptible to complications when initial care is postponed. Gokcek et al[16] supported this by identifying a strong association between delayed presentation and the increased possibility of adverse outcomes, including tooth discoloration and mobility. These findings reinforce the need for rapid clinical assessment and public awareness regarding the urgency of dental trauma care.

The management strategies in this study differed based on the type and severity of the injury as well as the type of dentition. The predominant approach was conservative, with "no treatment and monitoring" provid-

ed in 44.6% of cases, indicating a common tendency to avoid intervention in minor injuries or when spontaneous healing is predicted, particularly in primary teeth.[6,14] This was followed by splinting (17.6%), restorations (17.0%), and extractions (15.4%). Splinting was mostly used for displacement injuries in permanent teeth aligned with IADT guidelines, while restorations were performed primarily for uncomplicated crown fractures.[15,16] Furthermore, extractions were indicated mainly for primary teeth, either non-restorable or with severe displacement injuries, to avoid damaging the permanent successor, a decision also supported by the AAPD guidelines.[16] Replantation, pulpotomy, and root canal therapy were infrequently used, especially in primary teeth, aligning with Patidar et al[11]'s findings and Özgür et al[14], which indicated that invasive interventions are reserved for permanent teeth with a favorable long-term prognosis.

Despite the generally favorable healing results, our study identified numerous complications. Root resorption was reported in 13 cases, persistent mobility in 14 injuries, and 16 patients experienced continuous pain during follow-up visits. These complications were more prevalent in patients' cases presenting after 24 hours, which is consistent with the findings of Andreasen et al[5], who indicated that delayed intervention significantly increases the risk of pulp necrosis, root resorption, and compromised periodontal healing, emphasizing the importance of early intervention. Lam[6], moreover, noted that in primary dentition, higher-risk complications, such as root resorption and mobility, were more frequent in displacement injuries, especially intrusion and severe luxation. Similarly, Vieira et al[15] reported that children who received inadequate or delayed intervention were at higher risk of experiencing persistent symptoms and adverse outcomes. These findings highlight the need for early clinical intervention and follow-up visits to detect and manage these complications at an early stage.

Moreover, our data indicated that follow-up attendance was crucial in the identification and treatment of these complications. Children with permanent dentition injuries were more likely to attend their follow-up visits than those with primary teeth, consistent with the findings of Xu et al[13]. This variation may indicate a parental tendency to underestimate the significance of primary teeth, resulting in poorer compliance with regular follow-ups. These observations highlight the need for not only timely intervention but also structured follow-up and parental education to enhance the outcomes and reduce adverse sequelae in both primary and permanent dentition.

Limitations

Since this is a retrospective study, several limitations should be acknowledged. It relies on existing electronic health records, which may have introduced inaccuracies or missing data, which might limit further complete analysis, particularly regarding the cause of injuries, location of injuries, time of presentation, and dental anxiety. Additionally, the study was conducted at a single health care center (King Abdulaziz Medical City (KAMC) and King Abdullah Specialized Children Hospital (KASCH), National Guard Health Affairs (NGHA), Riyadh, Saudi Arabia), so the findings may not be generalized to Riyadh or other regions of Saudi Arabia. Also, the institutional prevalence could not be calculated due to a lack of access to total pediatric visits. Finally, variability in follow-up attendance and compliance, and the lack of long-term follow-up, may have led to underestimation of long-term complications.

Recommendations

Despite the limitations, the study highlights several opportunities for improving the management of traumatic dental injuries (TDIs) in the pediatric population. First of all, implementing a standardized documentation protocol, including dental trauma assessment and dental anxiety scale in the system, would enhance the quality of the data in regard to diagnoses, management, and future follow-ups. Additionally, conducting a prospective study across Saudi Arabia would provide more comprehensive and accurate results.

Conclusion

This study provides valuable insights into the patterns and management of traumatic dental injuries (TDIs) in the pediatric population within a tertiary healthcare setting. Despite the inherent limitations of a retrospective design, including incomplete records and a lack of long-term follow-up, the findings emphasize the need for improved documentation and standardized protocols. Establishing a unified system for dental trauma assessment and incorporating tools such as dental anxiety scales could enhance both clinical care and research quality. Furthermore, future prospective, multicenter studies across Saudi Arabia are essential to achieve a more accurate understanding of TDIs, their risk factors, and long-term outcomes. Ultimately, addressing these gaps may contribute to optimizing prevention strategies, timely interventions, and overall oral health care for children.

Disclosures

Ethics Committee Approval: The study was approved by the King Abdullah International Medical Research Center (KAIMRC), Riyadh, Saudi Arabia Ethics Committee (no: 00000178125, date: 24/06/2025).

Informed Consent: Not applicable.

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Original Article

Impact of Body Mass Percentile Categorization on Dental Emergence Among a Cross Section of Nigerian Children

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Abstract

Objective: Although multiple studies have highlighted the influence of body mass index (BMI) on the emergence of the dentition, controversies still exist in the body of literature. The purpose of this research was to determine if the categories of body mass percentile have significant predictive effects on dental emergence staging of pre-orthodontic children and adolescents.

Materials and Methods: This was a cross-sectional study, comprising of 424 participants (186 males and 238 females) ages 4 to 15 years. Dental emergence was classified using the Bjork criteria while BMI was used to categorize the body mass percentile using the Centre for Disease Control (CDC) criteria for gender-based BMI-for-age growth chart for 2–20 years. One-way ANOVA was used to compare the mean BMI of the different categories of BMI-percentile in the dentition stages among males and females. Spearman correlation was used to determine the association between body mass percentile and the dentition stages while multinomial logistic regression was thereafter used to ascertain if the body mass percentile had any effect on developmental staging of the dentition. The statistical significance level was set at $p<0.05$.

Results: The category of BMI-percentile significantly predicts the stage of the deciduous dentition and the permanent dentition excluding the permanent molars ($p=0.005$). Underweight participants were more likely to have delayed dental developmental stage compared to overweight participants who were more likely in the advanced late mixed and adolescent dentition stages with greater odds of 0.788 and 0.501 respectively. The category of the BMI-percentile was not a significant predictor of the permanent molars' dentition ($p=0.463$).

Conclusion: Orthodontists and pedodontists could consider the body mass of patients to determine the timing of commencement of intervention.

Keywords: Body mass percentile, dental emergence, children

Introduction

The specific timing of orthodontic interventions such as commencement of orthopedic and functional appliance therapies are closely related to the period of dental emergence.[1–4] In 1981, Hagg & Taranger classified dental emergence into deciduous, early-, intermediate- and late-mixed dentitions, adolescent and the adult dentition stages.[5] Factors that influence the period of attainment of these stages are multifactorial, ranging from genetic, racial, ethnicity, sexual dimorphism and environmental factors such as nutrition and socio-eco-

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nomic factors.[6,7] The impact of nutrition has specifically received the attention of several authors especially with changes in the dietary habit and lifestyle.[8] One of ways that nutritional status can be evaluated is the use of body mass index, which allows an individual to be classified as underweight, normal, at risk of overweight and overweight according to the body mass percentile.[9] Multiple studies have evaluated the relationship between body mass and oral health status with respect to; caries,[10–12] dental eruption and dental maturation[13,14] and periodontal diseases.[15] Body mass percentile has also been reported to be a weak predictor of skeletal maturation stages.[16,17]

Although higher body mass percentile has been reported to be associated to advanced dental development and dental emergence,[16,18–22] delayed eruption of permanent teeth among obese children have also been reported.[23,24] These findings are at variance with reports of early eruption of permanent teeth in overweight and obese children.[20,25,26] On the contrary, Paz-Cortés et al[27] noted that the category of BMI percentile did not affect the sequence of eruption of permanent teeth.

Children that present with extremes of BMI percentile would probably require extra clinical evaluation to determine if the variations are in keeping with their clinical presentations. Also, delayed dental development among underweight could predispose to a high prevalence of malocclusion[28] and accelerated dental development in overweight and obese children could alter the timing of orthodontic intervention.[29] This is so because different observations have been made with regard to overweight/obesity and skeletal maturation.[30,31]

A few studies in Nigeria that have focused on the relationship between body mass percentile and the development of the dentition with little or no attention given to dental emergence stages. Therefore, the aim of the current study was to ascertain if there an association between dental emergence and the body mass percentile among a cross section of Nigerian children.

Materials and Methods

Study design and setting

This was a cross-sectional descriptive study and data were collected from study participants over a fourteen-month period (June 2022 to August 2023) at the orthodontic and paedodontic clinics. A total of 424 participants comprising of 186 males and 238 females ages 4 to 15 years that met the selection criteria were recruited for the study.

Sample size determination and sampling method

The minimum sample size for the study was determined using the formulae below.

$$N=\frac{Z^2P(1-P)}{D2}$$

N=sample size; Z as the statistics for the desired confidence (which is 1.96 at 95% CI). Since the prevalence was not known, P (the prevalence) was set at 50% (that is, 0.5). The acceptable margin of error (D) was set at 0.05. The minimum sample size (N) for participant to be recruited for this study was three hundred and seventy-eight (378). However, a total of 424 was recruited during the study period. Convenience sampling was used to recruit participants for the study.

Selection criteria

Clinically healthy children with no history of orthodontic treatment, no congenital or developmental anomalies like cleft lip and palate, parents who gave informed consent and children who gave assent were recruited for the study. Participants who presented to the clinic appearing chronically ill were excluded from the study.

Ethical consideration

The author obtained ethical approval from the Ethics and Research Committee of the Hospital Management Agency prior to commencement of the study (A732/T/5) and the study follows the principles of the Declaration of Helsinki. Informed consent was obtained from parents. Assent was also obtained from children over 7 years of age.

Data collection

The information obtained from the participants and/or their parents/guardians included chronological age and gender. The weight (kg) and the height (m) were measured in the clinic using the standard stadiometer.

Body mass index (BMI) was calculated by dividing the weight (in kilogram, kg) by the square of the height (in meters, m). The BMI-percentile category of each study participant was determined using the growth chart provided by the Center of Disease Control (CDC) specific for age and gender: 2–20 years.[9]

According to Center of Disease Control (CDC) the growth charts specific for age and gender (2–20 years) are as follows: BMI-for-age; $<5^{th}$ is underweight; $\geq5^{th}$ - $\leq85^{th}$ is normal; $\geq85^{th}$ - $\leq95^{th}$ is at risk of overweight while >95% is overweight.

Assessment of dental emergence

A visual assessment of the dental emergence of the study participants was conducted with the participant seated on a dental chair. Prior to the assessment, each participant was asked to rinse the mouth with water for 30 seconds, and the gingival was cleaned with a sterile gauze for adequate visibility. The oral cavity was then examined by the researcher (AO) using a mouth mirror and periodontal probe to identify an emerging tooth. The dental development of the participants, which in this study is the dental emergence staging, was based on the gingival emergence/visibility of a set of teeth in the oral cavity, corresponding to the dental stages (DS) as described by Bjork et al[32] Assessment of the emergence was conducted the researcher (AO) who is experienced in the field utilizing the assessment tool. Intra-examiner reliability was conducted using kappa statistics. A total of 40 patients were recruited for the pilot assessment of the dentition stages and kappa statistics showed substantial agreement of the anterior dentition stages (k=0.664) while the molar dentition stages showed almost perfect agreement (k=0.945) with p value <0.0001 respectively.

Summary of Bjork et al[32] dental staging assessment tool (Appendix 1).

1. If any part of a tooth is visible in the oral cavity, it is said to have emerged. When a tooth reaches the occlusal level, it is said to be completely erupted.
2. The individual is in DS 02, DS 2, or DS 4 even if not all the teeth concerned are present, provided that the reason for the absence of a tooth is extraction or dentition (developmental) anomaly.
3. Recording only one of the stages implies that all the earlier stages are complete. If a new stage occurs before the previous one is complete – for example when a canine or premolar is visible before all the incisors are fully erupted – this finding will be recorded, as DS 1 and DS 3.

Data analysis

The data collected from the questionnaires were coded and inputted into IBM SPSS statistics 22.0 (SPSS Inc., Chicago, Illinois, USA). Unpaired t-test was used to compare the mean BMI of the participants' dentition stage and the mean BMI of the participants' BMI-percentile according to gender. Also, a comparison of the mean BMI of participants' dentition stages in relation to the body mass percentile according to gender was done using unpaired t-test. One-way ANOVA was used to compare the mean BMI of the different categories of BMI-percentile in the anterior dentition stages among males and females. Tukey post-hoc test was thereafter used to identify specific areas of significant differences. In addition, Spearman correlation was used to determine the association between body mass percentile and the dentition stages. Also, multinomial logistic regression was used to check if the body mass percentile had any effect on the developmental stages of the dentition. The statistical significance level was set at $p<0.05$.

Results

A total of 424 participants were recruited for the study. The anterior dentition stages were assessed for all the participants, with a mean age of 8.64±3.10 years and a mean BMI of 17.12±3.87 kg/m^2. The molar dentition stages were assessment among 363 participants with a mean age of 9.27±2.85 years and mean BMI of 17.55±3.92 kg/m^2, as shown in Table 1.

Table 2 presents the comparison of the mean BMI in the different percentiles. In the anterior dentition, the mean BMI of underweight male participants was higher than the females; 13.20±1.052 kg/m^2 and 13.05±1.53 kg/m^2) respectively, p=0.649. Statistically significant difference was only observed among those at risk of overweight, where the BMI of females (21.46±2.53 kg/m^2) was significantly higher than the male study participants (19.54±1.69 kg/m^2), p=0.006. On the contrary, assessment of the molar dentition stages showed that the BMI of male participants in the underweight category was lower than the female study participants, p=0.361. Again, female study participants had significant higher BMI compared to male in at risk of overweight category, p=0.005. The mean BMI in the normal percentile category in the anterior dentition and in the molar dentition stage were fairly comparable between males and females with no statically significant differences.

Table 3 describes comparison of mean BMI in the dentition stages. In the dentition stages anterior to the molars, the mean BMI of male participants (15.03±1.69 kg/m^2) with fully erupted deciduous dentition was higher in males than females (14.00±2.21 kg/m^2) but not statistically significant p=0.077. In the intermediate mixed, late mixed and adolescent dentition stages, female participants had higher mean BMI but statistical different was only observed in the late mixed dentition (p=0.045). In the molar dentition stages, the mean BMI of females was higher from the eruption of the first molars to the stage of fully erupted second molars, p>0.005. No male participant had a fully erupted third molar while only one female with a mean BMI of 16.55kg/m^2 had a third molar fully erupted.

Table 1. Mean chronological age and body mass index (BMI) of the study participants

Dentition stage anterior to the molars					
Variables	**Gender**	**n**	**%**	**Mean (years)**	**SD**
Chronological age (years)	Male	186	43.9	8.53	3.00
	Female	238	56.1	8.72	3.17
	Total	424	100.0	8.64	3.10
BMI (kg/m^2)	Male	186(43.9)	16.78	3.19	
	Female	238(56.1)	17.39	4.31	
	Total	424(100.0)	17.12	3.87	
Molar dentition stage					
Chronological age (years)	Male	156	43.0	9.16	2.76
	Female	207	57.0	9.35	2.92
	Total	363	100.0	9.27	2.85
BMI (kg/m^2)	Male	156	43.0	17.06	3.93
	Female	207	57.0	17.92	4.300
	Total	363	100.0	17.55	3.92

SD: Standard deviation

Table 2. Comparison of the mean BMI of the different BMI-percentiles of study participants in relation to gender using unpaired t-test

Dentition stage anterior to the molars												
	BMI-percentile		**Male**			**Female**			**MD**	**95% CI**		**p**
	n	**%**	**n**	**Mean-BMI (SD)**	**%**	**n**	**Mean-BMI (SD)**	**%**		**Lower**	**Upper**	
Underweight	68	16.04	30	13.20 (1.05)	44.1	38	13.05 (1.53)	55.9	0.150	-0.505	0.805	0.649
Normal	276	65.09	126	16.53 (1.65)	45.7	150	16.57 (2.10)	54.3	-0.040	-0.494	0.414	0.862
At risk of overweight	49	11.56	18	19.54 (1.69)	36.7	31	21.46 (2.53)	63.3	-1.918	0.669	-3.264	0.006
Overweight	31	7.31	12	24.18 (5.03)	38.7	19	25.87 (6.51)	61.3	-1.694	-6.214	2.827	0.450
Molar dentition stages												
Underweight	46	12.67	22	13.33 (1.09)	47.83	24	13.64 (1.18)	52.17	-0.309	-0.983	0.365	0.361
Normal	241	66.39	106	16.62 (1.67)	43.98	135	16.73 (2.13)	56.02	-0.112	0.594	0.370	0.648
At risk of overweight	48	13.22	17	19.63 (1.69)	35.42	31	21.46 (2.53)	64.58	-1.822	-5.053	-0.591	0.005
Overweight	28	7.71	11	24.70 (4.93)	39.29	17	26.90 (6.05)	60.71	-2.198	-6.689	2.293	0.324

BMI: Body mass index, CI: Confidence interval, SD: Standard deviation, MD: Mean difference

In the fully erupted deciduous dentition, male participants in the underweight, normal and overweight BMI percentile categories had higher BMI compared to the female participants. Statistically significant was only observed in the normal BMI-percentile category, p=0.020. Also, in the early mixed dentition stage, the BMI of male participants in the underweight, normal and overweight BMI-percentile categories were higher in male participants than females, with statistically significant noted in the normal BMI-percentile category, p=0.006. In the late mixed dentition stage, the mean BMI of females in the normal BMI-percentile category was significantly higher than the males, p=0.009. Among participants with fully erupted first permanent molars, females within the normal BMI-percentile categories and those at risk of overweight, had significantly higher BMI compared to the males; p=0.019 and 0.022 respectively (Table 4).

The results in Table 5 and Table 6 showed that there were significant differences in the mean BMI of the various dentition stages in the different categories of BMI-percentile in both the anterior and molar dentition stages. Post-hoc revealed that the mean BMI of underweight male participants in the early mixed dentition stage differ significantly from the normal, those at risk of overweight and those that were overtly overweight, p<0.000. Conversely, there was no statistically significant difference in

Table 3. Comparison of the mean BMI of the different dentition stages of study participants according to gender using unpaired t-test

Dentition stage anterior to the molars												
	Dentition stage		Male			Female			MD	95% CI		p
	n	%	n	Mean-BMI (SD)	%	n	Mean-BMI (SD)	%		Lower	Upper	
Fully erupted deciduous	51	12.03	22	15.03 (1.69)	43.1	29	14.00 (2.21)	56.9	1.023	2.161	-0.116	0.077
Early mixed	128	30.19	60	16.28 (3.137)	46.9	68	15.75 (2.65)	53.1	0.530	1.543	-0.483	0.302
Intermediate mixed	88	20.76	37	16.69 (2.17)	42.0	51	17.12 (3.29)	58.0	-0.431	0.802	-1.665	0.488
Late mixed	63	14.86	36	16.82 (3.05)	57.1	27	18.74 (4.36)	42.9	-1.915	-0.044	-3.786	0.045
Adolescent	94	22.17	31	19.05 (4.12)	33.0	63	20.36 (5.12)	(67.0)	-1.309	0.790	-3.406	0.219
Molar dentition stages												
First molar erupting	113	31.1	52	15.96 (2.29)	46.0	6	16.03 (2.64)	64.0	-0.0757	0.854	-1.005	0.872
First molar fully erupted	204	56.2	89	17.24 (3.33)	43.6	115	18.08 (3.81)	53.4	-0.837	0.167	-1.841	0.102
Second molar fully erupted	45	12.4	15	19.78 (4.374)	33.3	30	21.18 (6.42)	66.7	-1.405	2.216	-5.126	0.451

MD: Mean difference

the BMI of male participants in the early mixed dentition stage that were within the normal BMI percentile and those at risk of overweight, p=0.139. Among the female participants, statistically significant differences were recorded in the BMI between the various BMI-percentile in the early mixed, intermediate mixed, late mixed and adolescent dentitions. In the first molar erupting stage, statistical differences existed between the various categories of BMI-percentile in both gender, p<0.0001; except among male participants between those at risk of overweight and those that were overtly overweight; p=0.178. Statistical differences were recorded between the various categories of BMI-percentile in both gender among those participants with first molars fully erupted. Female participants within the underweight and normal BMI-percentile categories did not show significant different in the stage of fully erupted second molar dentition, p=0.780.

Table 7 showed that the body mass percentile significantly predicts the outcome of the participants' anterior dentition stages, p=0.005. On the other hand, BMI-percentile category did not significantly predict the molar dentition stages (p=0.463). Therefore, further analysis was not conducted for the molar dentition stages.

In Table 8, a unit increase in the underweight individual will increase its log-odds to be in the deciduous dentition stage rather than in the early mixed dentition by 0.952 than individuals that are overweight (p=0.188), with an odd ratio of 2.597, indicting a small effect size. Also, individuals that are at risk of overweight are less likely (with log-odds of -1.003) to be deciduous dentition and more likely going to be in the advanced dental stage (early mixed dentition), although with a small effect, indicated by the OR of 0.369.

The regression model also shows that underweight individuals when compared to overweight participants, are more likely to be in the reference category (early mixed dentition stage) than to be in the intermediate mixed, late mixed dentition and adolescent dentition stages, as the log-odds of been in the aforementioned stages decreases by 0.087 (p=0.903), 0.087 (p=0.895) and 0.662 (p=0.275) respectively. The model therefore explains that participants that are overweight have the tendency of advanced dentition stages of late mixed and adolescent dentition than the underweight participants.

Correlation between body mass percentile and the anterior dentition shows a weak positive (R=0.136) but statistically significant correlation. This shows a small effect size (r2 of 0.019) of the correlation. It however shows that an increase in the category of the BMI percentile would be accompanied by an increase the dental stage of the individual. On the contrary, the molar dentition did not show a statistically significant correlation with BMI-percentile, as shown in Table 9.

Discussion

The findings from this current study add to the evolving field of research which buttresses the notion that a relationship exist between dental emergence and the category of the body mass percentile. This is important because timing is considered critical as far as orthodontics and pedodontics interventions are concern.

Table 4. Mean BMI comparison of dentition stages in different BMI-percentiles according to gender using unpaired t-test

Dentition stage anterior to the molars												
BMI-percentile / Dentition	**Underweight**		**p**	**Normal**		**p**	**At risk of overweight**		**p**	**Overweight**		**p**
Fully erupted deciduous	M: 6 (35.3)	F: 11 (64.7)		M: 15 (50.0)	F: 15 (50.0)		M: 0	F: 1 (100.0)		M: 1 (33.3)	F: 2 (66.7)	
BMI-M(SD)	12.86 (0.88)	11.94 (1.72)	0.245	15.66 (0.83)	14.86 (0.89)	**0.020**	–	17.08	–	18.47 (0.00)	17.18 (2.89)	0.777
Early mixed	M: 12 (50.0)	F: 12 (50.0)		M: 38 (45.8)	F: 45 (54.2)		M: 4 (40.0)	F: 6 (60.0)		M:6 (54.5)	F: 5 (45.5)	
BMI-M(SD)	12.90 (0.87)	13.07 (0.97)	0.657	16.12 (1.36)	15.36 (1.07)	**0.006**	18.10 (0.18)	18.74 (1.65)	0.471	22.90 (4.25)	22.14 (3.40)	0.319
Intermediate mixed	M: 3 (37.5)	F: 5 (62.5)		M: 25 (41.7)	F: 35 (58.3)		M: 8 (50.0)	F: 8 (50.0)		M: 1 (25.0)	F: 3 (75.0)	
BMI-M(SD)	13.16 (0.89)	13.06 (1.22)	0.904	15.99 (1.02)	16.22 (1.58)	0.523	19.66 (0.75)	20.36 (0.91)	0.119	20.98 (0.0)	25.77 (3.51)	0.358
Late mixed	M: 5 (50.0)	F: 5 (50.0)		M: 24 (63.2)	F: 14 (36.8)		M: 5 (50.0)	F: 5 (50.0)		M: 2 (40.0)	F: 3 (60.0)	
BMI	13.13 (1.03)	13.64 (0.85)	0.414	16.27 (0.92)	17.70 (2.24)	**0.009**	19.81 (2.45)	21.42 (1.09)	0.215	25.29 (3.92)	27.61 (2.01)	0.431
Adolescent	M: 4 (44.4)	F: 5 (55.6)		M: 24 (36.9)	F: 41 (63.1)		M: 1 (8.3)	F: 11 (91.7)		M: 2 (25.0)	F: 6 (75.0)	
BMI-M(SD)	14.73 (0.99)	14.84 (1.30)	0.887	18.58 (2.01)	18.44 (2.07)	0.796	22.94 (0.0)	24.15 (1.19)	0.353	31.36 (3.80)	31.07 (7.55)	0.961
Molar dentition stages												
First molar erupting	M: 10 (71.4)	F: 4 (28.6)		M: 34 (42.5)	F: 46 (57.5)		M: 4 (36.36)	F: 7 (63.64)		M: 4 (50.0)	F: 4 (50.0)	
BMI-M(SD)	12.84 (0.91)	12.78 (0.72)	0.899	15.98 (1.06)	15.32 (1.19)	**0.011**	19.00 (1.34)	19.11 (2.05)	0.924	20.50 (0.55)	22.14 (3.93)	0.441
First molar fully erupted	M: 12 (40)	F: 18 (60)		M: 58 (45.7)	F: 69 (54.3)		M: 13 (40.6)	F: 19 (59.4)		M: 6 (40.0)	F: 9 (60.0)	
BMI-M(SD)	13.73 (1.09)	13.56 (0.96)	0.667	16.49 (1.49)	17.30 (2.20)	**0.019**	19.83 (1.77)	21.53 (2.07)	**0.022**	25.94 (3.87)	25.80 (2.72)	0.936
Second molar fully erupted	M: 0	F: 2 (100.0)		M: 14 (42.4)	F: 19 (57.6)		M: 0	F: 5 (100.0)		M: 1 (20)	F: 4 (80)	
BMI-M(SD)	–	15.99 (0.91)		18.76 (1.95)	18.14 (1.91)	0.367	–	24.47 (1.12)		34.05 (0.0)	34.12 (7.54)	0.994

BMI-Body mass index, M: Mean, SD: Standard deviation, M: Male, F: Female

Table 5. BMI comparison of dentition stages in different Percentiles among males and females using One-way ANOVA

BMI-percentile / Dentition	Dentition stage anterior to the molars									
	Underweight	Normal	At risk of overweight	Overweight	p (ANOVA)	Underweight	Normal	At risk of overweight	Overweight	p (ANOVA)
	Male					Female				
Fully erupted deciduous	12.86 (0.88)	15.66 (0.83)	–	18.47 (0.00)	0.000	11.94 (1.72)	14.86 (0.89)	17.08 (0.0)	17.18 (2.89)	0.000
Early mixed	12.90 (0.87)	16.12 (1.36)	18.10 (0.18)	22.90 (4.25)	0.000	13.07 (0.97)	15.36 (1.07)	18.74 (1.65)	22.14 (3.40)	0.000
Intermediate mixed	13.16 (0.89)	15.99 (1.02)	19.66 (0.75)	20.98 (0.0)	0.000	13.06 (1.22)	16.22 (1.58)	20.36 (0.91)	25.77 (3.51)	0.000
Late mixed	13.13 (1.03)	16.27 (0.92)	19.81 (2.45)	25.29 (3.92)	0.000	13.64 (0.85)	17.70 (2.24)	21.42 (1.09)	27.61 (2.01)	0.000
Adolescent	14.73 (0.99)	18.58 (2.01)	22.94 (0.0)	31.36 (3.80)	0.000	14.84 (1.30)	18.44 (2.07)	24.15 (1.19)	31.07 (7.55)	0.000
	Molar dentition stages									
	Male					Female				
First molar erupting	12.84 (0.91)	15.98 (1.06)	19.00 (1.34)	20.50 (0.55)	0.000	12.78 (0.72	15.32 (1.19)	19.11 (2.05)	22.14 (3.93)	0.000
First molar fully erupted	13.73 (1.09)	16.49 (1.49)	19.83 (1.78)	25.94 (3.87)	0.000	13.56 (0.96)	17.30 (2.20)	21.53 (2.07)	25.80 (2.72)	0.000
Second molar fully erupted		18.76 (1.85)		34.05 (0.0)	0.000	15.99 (0.91)	18.14 (1.91)	24.47 (1.12)	34.12 (7.54)	0.000

BMI-Body mass index, ANOVA: Analysis of variance

Although the importance of racial, individual and ethnic variation cannot be overlooked,[33] a vast majority of research findings have followed the trend of advanced dental development with increasing body mass.[16,18–22]

This current study revealed a significant difference in the body mass index in the different categories of BMI-percentile in the various dentition stages. The result of the multinomial regression showed that the stage of a participant's BMI-percentile is a significant predictive factor in the development of the dentition especially the anterior dentition stage, showing that those in the higher BMI-percentile are more likely to be in the advanced dentition stages compared to their peers in the lower BMI-percentile categories.

This finding is in agreement with the observation made by DuPlessis et al[16] The author observed an acceleration in the dental age of participants with increasing BMI-percentile especially among overweight and obese children.[16] Young children in the deciduous dentition stage as early as 4 years with increased BMI-percentile have also been reported to have advanced dental development in the pubertal stage.[29] The study conducted among a Jordanian population made specific reference to dental emergence in phase II mixed dentition where attainment of this stage was much earlier among those with higher BMI.[34] This observation is corroborated by findings in this current study; where attainment of the intermediate mixed dentition occurred earlier among the participants that were overweight compared to those in the normal or underweight categories. This current research also agrees with other results published by previous authors.[20,26] In 2013, Sabharwal et al[25] reported a negative correlation between BMI and eruption time of permanent first molars and incisors, indicating an inverse relationship. Although correlation does not show a cause-effect relationship, it shows that attainment of advanced dental stage occurs at an earlier age compare to individuals with lower BMI. This present study is comparable to the author's[25] report because this current study showed that body mass percentile had a significant positive correction with the anterior dentition stage, indicating an advanced dental staging as the category of BMI-percentile increases. Although this present study shows a positive correlation between BMI-percentile and the molar dentition stages which agrees with inverse relationship that exist between BMI and eruption timing as earlier reported[25] however, the finding was not statistically

Table 6. Tukey Post hoc analysis for significant variables

Dentition stage anterior to the molars							
Dentition	**Gender**	**Under-weight vs normal**	**Under-weight vs at risk of overweight**	**Under-weight vs overweight**	**Normal vs at risk of overweight**	**Normal vs overweight**	**At risk of overweight vs overweight**
Fully erupted deciduous	Male	NA	NA	NA	NA	NA	NA
	Female	NA	NA	NA	NA	NA	NA
Early mixed	Male	0.000	0.000	0.000	0.139	0.000	0.000
	Female	0.000	0.000	0.000	0.000	0.000	0.001
Intermediate mixed	Male	NA	NA	NA	NA	NA	NA
	Female	0.001	0.000	0.000	0.000	0.000	0.000
Late mixed	Male	0.000	0.000	0.000	0.000	0.000	0.000
	Female	0.002	0.000	0.000	0.005	0.000	0.001
Adolescent	Male	NA	NA	NA	NA	NA	NA
	Female	0.046	0.000	0.000	0.000	0.000	0.000
Molar dentition stages							
First molar erupting	Male	0.000	0.000	0.000	0.000	0.000	0.178
	Female	0.014	0.000	0.000	0.000	0.000	0.014
First molar fully erupted	Male	0.000	0.000	0.000	0.000	0.000	0.000
	Female	0.000	0.000	0.000	0.000	0.000	0.000
Second molar fully erupted	Male	NA	NA	NA	NA	NA	NA
	Female	0.780	0.013	0.000	0.002	0.000	0.000

NA: Non applicable: Post-hoc test could not be conducted because at least one group has fewer than 2 cases

significant. Again, this agrees with the non-statistically significant relationship that was observed among the female participants but contrary to the findings among male study participants in the study conducted by a previous author.[25] This current study revealed that BMI-percentile is not a significant predictive variable in determining the dentition stage of the molar dentition.

Our current study is however at variance with the findings reported by some authors.[23,24] The authors conducted the studies among a cross section of Indian population and reported a delayed eruption among obese children compared to their underweight counterpart.[23,24] This is a departure from the established reports of early dental development among overweight and obese children which was also noted in this current study. However, Raghavan et al[23] cited uneven distribution of children among the BMI-percentile group as factor to consider for the variation in their study. It is important to state that the study conducted by Anu et al[24] was specific for the permanent mandibular first molar and incisors unlike the entire dentition that was assessed in this current study. This shows that findings by the author[24] may not be used to generalize the effect of BMI on dental emergence. The category of BMI percentile has been reported not to influence the sequence of eruption of permanent teeth among 4–14 years old children.[27] This present study did not evaluate the sequence of eruption of individual teeth. In addition, Paz-Cortés et al[27] categorized the growth of the children using the International Obesity Task Force classifying it into underweight (BMI<18.5), normal weight (BMI 18.5–24.9), or overweight (BMI 25–29.9) as against the gender-specific BMI-for-age growth charts (2–20 years) recommended by the Centre for

Table 7. Multinomial logistic model fitting information describing the effect of body mass percentile on the dental stages anterior to the molars

Dentition stage anterior to the molars				
	Model fitting criteria	**Likelihood ratio test**		
Model	**-2Log likelihood**	**Chi-square**	**Df**	**Sig. (p-value)**
Intercept only	91.720			
Final	63.456	28.264	12	0.005
Molar dentition stages				
Intercept only	42.452			
Final	33.726	8.726	9	0.463

Df: Degrees of freedom; Sig: Significance

Table 8. Multinomial regression model explaining the impact of BMI-percentile on the dental development stages of anterior dentition stages

Dental stages	B	SE	p	OR	95% CI for OR	
					Lower	Upper
Deciduous dentition fully erupted	-1.299	0.651	0.046			
Intercept						
Underweight	0.952	0.724	0.188	2.597	0.628	10.743
Normal	0.282	0.685	0.681	1.325	0.346	5.077
At risk of overweight	-1.003	1.235	0.416	0.367	0.033	4.123
Overweight	O[b]					
Intermediate mixed						
Intercept	-1.012	0.584	0.083			
Underweight	-0.087	0.712	0.903	0.917	0.227	3.704
Normal	0.687	0.608	0.258	1.988	0.604	6.545
At risk of overweight	1.482	0.710	0.037	4.400	1.095	17.676
Overweight	O[b]					
Late mixed						
Intercept	-0.788	0.539	0.144			
Underweight	-0.087	0.658	0.895	0.917	0.253	3.327
Normal	0.007	0.574	0.990	1.007	0.327	3.101
At risk of overweight	0.788	0.701	0.260	2.200	0.557	8.686
Overweight	O[b]					
Adolescent						
Intercept	-0.318	0.465	0.493			
Underweight	-0.662	0.607	0.275	0.516	0.157	1.695
Normal	0.074	0.493	0.881	1.077	0.409	2.832
At risk of overweight	0.501	0.632	0.428	1.650	0.478	5.693
Overweight	O[b]					

B: Regression coefficient, SE: Standard error, OR: Odd ratio for the predictors, CI: Confidence interval. Overweight (O[b]) is the reference percentile for the body mass percentile groupings; Early mixed dentition was the reference category group for the dental stages: this was used because majority of the participants were in this particular group

Disease Control for children and teens. This could have impacted the outcome of their result.

In this present study, females mean BMI were higher in the intermediate mixed, late mixed and adolescent dentition compared to the male participants. However, statistical significance difference was only observed in the late mixed dentition stage. Raghavan et al[23] reported the eruption timing of the teeth to also be earlier in females compared to the males without specific focus on the dentition stage. This is because majority of the studies only considered the eruption of individual teeth instead of the dentition stage, which has been the focus of this current study.

In the interim, following the outcome of this current study, overweight and obese patients may require early orthodontic treatment intervention as against their peers with normal body mass. With the increasing trend of overweight and obesity among Nigerians,[35] orthodontists and pedodontists should consider it germane in clinical practice to always assess patients body mass in relation to dental emergence.

Table 9. Spearman's Correlation coefficient between body mass percentile and the dentition stage

Variable	R	p
BMI-percentile Vs Anterior dentition	0.136	0.005
BMI-percentile Vs Molar dentition	0.062	0.236

BMI: Body mass index, R: Correlation coefficient

Study limitation and recommendation

This study was cross-sectional research and it was not possible to determine the actual time for the emergence

of the teeth. That is, dental emergence may have occurred prior to the participants' presentation in the clinic. Participants could have switched from one category of BMI-percentile to another due to changes in lifestyle thereby obviating the true reflection of the dental emergence. Also, certain factors like socio-economic factors, dietary habits, genetic and endocrine factors that could independently affect BMI and dental emergence were not accounted for and these could affect the outcome of the study. The sample size of the study could have been larger to accommodate for variables that were tagged non-available.

Conclusion

The category of BMI-percentile significantly predicts the stages of the deciduous dentition and the permanent dentition anterior to the molars (p=0.005). On the contrary, the various categories of BMI-percentile were not significant predictors of the permanent molars' dentition.

Underweight participants were observed to be more likely to have a delayed dentition stage compared to overweight participants who were more likely to be in the advanced late mixed and adolescent dentition stages with greater odds of 0.788 and 0.501 respectively.

Disclosures

Ethics Committee Approval: The study was approved by the Hospital Management Ethics Committee (no: A732/T/5, date: 20/05/2022).

Informed Consent: Informed consent was obtained from all participants.

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Appendix 1. Bjork et al criteria for dental emergence staging (DES)

DES	Description	Stage of dentition	Teeth present
Grading for primary teeth and permanent anterior teeth and premolars			
DS01	Deciduous teeth erupting	Deciduous dentition erupting	
DS02	Deciduous teeth fully erupted	Deciduous dentition complete	
DS1	Permanent incisors erupting	Early mixed dentition	1-7 incisors
DS2	Permanent incisors fully erupted	Intermediate mixed dentition	All incisors
DS3	Permanent canine or premolar erupting	Late mixed dentition	1-11 canines and/or premolars
DS4	Permanent canine or premolar fully erupted	Adolescent dentition	All canines and premolars
Grading for molars			
M0	First permanent molar erupting	First molar not fully erupted	1-3 first molars
M1	First permanent molar fully erupted	First molar fully erupted	All first molars
M2	Second permanent molar fully erupted	Second molar fully erupted	All second molars
M3	Third permanent molar fully erupted	Third molar fully erupted	All third molars

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Case Report

Neonatal Tooth in A Newborn - Case Report

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Abstract

Neonatal teeth are developmental dental anomalies that can be defined as those that erupt in the first 30 days of extrauterine life. This early eruption can lead to breastfeeding difficulties, ulcers on the tongue, and a risk of aspiration and/or swallowing. The objective of this study was to report a clinical case of neonatal teeth in a newborn, as well as the diagnosis and therapeutic approach adopted. A 20-day-old female Caucasian neonate attended the Pediatric Dental Emergency Care Service of the Infant Specialties Clinic of the Baby Clinic of the State University of Londrina (UEL) due to tooth eruption 10 days ago and difficulty breastfeeding. The intraoral physical examination revealed the presence of a tooth compatible with the lower left central incisor, presenting a hypoplastic structure, soft tissue insertion, and a severe mobility. The radiographic examination showed an image compatible with the aforementioned tooth from the normal series of deciduous dentitin and absence of root development. Given the observed dental characteristics, the chosen approach was extraction. It is concluded that clinical and radiographic conditions are fundamental for the assertive diagnosis and therapeutic planning of neonatal teeth, allowing the prevention of damage to maternal health during breastfeeding or early weaning, in addition to reducing the risk of more serious complications to the health of the newborn, such asbroncho aspiration.

Keywords: Infant, natal teeth, newborn, tooth extraction

Introduction

The process of dental eruption of deciduous teeth into the oral cavity generally, begins around six months of age.[1] This phenomenon represents an important milestone in the functional and psychological development of the infant, as well as an event of emotional impact for legal guardians (Cunha et al[2]). However, in certain situations, the eruption chronology may be altered, with the early emergence of teeth in the oral cavity.

Among the most frequently observed dental development anomalies, natal teeth (NT) stand out, defined as those present in the oral cavity at birth. In turn, neonatal teeth (NNT) correspond to those that erupt during the first 30 days of extrauterine life.[2,3] The prevalence of DN and NND is estimated at 34,55:10,000 and 4,52:10,000 births, respectively.[4] Several factors may be related to the etiology and early tooth eruption, including the superficial position of the tooth germ, heredity, poor maternal health, nutritional deficiencies, intrauterine exposure to environmental toxins, endocrine disorders, infections and febrile episodes during pregnancy, among others.[2–5]

As a consequence of the manifestation of NT and NNT, significant structural and functional alterations, includ-

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ing hypoplastic dental structural content, soft tissue insertion, poor root development, increased mobility, and risk of aspiration or accidental swallowing, may be present.[3,6,7] In addition to these characteristics, discomfort may occur during breastfeeding, as well as the appearance of traumatic ulcers in the maternal breast and in the newborn's lingual belly. [2,8,9] Therefore, the identification of NT or NNT requires, without exception, an accurate diagnosis and the choice of the most appropriate therapeutic approach. The first option for the treatment of NT and NNT should always be conservative, avoiding extractions whenever possible.[10] In cases where maintenance of the tooth in the oral cavity is indicated, it is essential to remove possible traumatic agents, which can be done by smoothing the cutting edges using sandpaper strips or polishing discs. This approach aims to prevent the main complication associated with the preservation of these teeth: Riga-Fede disease. However, when the prognosis is unfavorable, extraction is indicated.[7,11]

Considering the scarcity of available literature on natal and neonatal teeth, the present study aimed to report a clinical case involving the presence of a neonatal tooth, addressing the diagnostic process and the therapeutic approach adopted.

Case Report

A 20-day-old Caucasian female infant was brought to the Pediatric Dental Emergency Care Service of the Pediatric Specialties Clinic of the Baby Clinic of the State University of Londrina (UEL), accompanied by her legal guardians, after a referral from a Primary Health Care Unit. The chief complaint reported by the guardians was the recent eruption of a tooth approximately 10 days ago, which was causing difficulties during breastfeeding. During the medical history, the guardians stated that both the pregnancy and delivery were uneventful and that the infant had no systemic conditions to date. They also reported that there were no teeth present at birth and denied any family history of natal, neonatal, or supernumerary teeth. Intraoral examination revealed the presence of a tooth in the region of the mandibular left central incisor. The tooth was hypoplastic and immature, with severe mobility (Fig. 1a, b). Radiographic evaluation, performed using the Mannkopf technique, revealed an image consistent with a normal primary tooth (tooth 81) and soft tissue insertion (Fig. 2).

Based on the clinical and radiographic findings, a diagnosis of neonatal tooth was established, and the clinical team determined the treatment plan for extraction.

For legal and ethical reasons, parents/guardians were fully informed about the procedure and its potential risks, and informed consent was obtained for outpatient tooth extraction. The procedure began with the application of a topical anesthetic ointment containing prilocaine and lidocaine (EMLA® 5% – Aspen Pharma Indústria Farmacêutica Ltda., Serra, Espírito Santo, Brazil) to the mucosa surrounding the tooth, with an application time of two minutes.

Subsequently, terminal infiltration anesthesia was performed with a 2% lidocaine solution with phenylephrine 1:100,000 (Alphacaine – DFL Indústria e Comércio S.A., Rio de Janeiro, Brazil) (Fig 3a, b). The tooth was excised

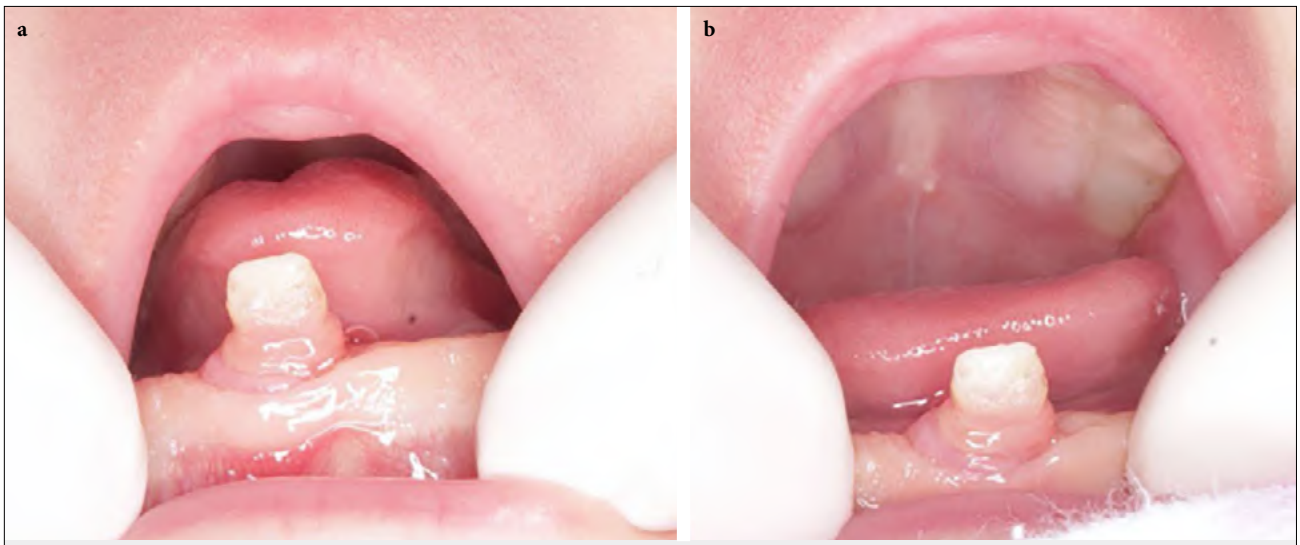

Figure 1. (a, b) Clinical appearance showing the presence of a neonatal tooth



Figure 2. Radiographic exam showing the presence of a neonatal tooth compatible with the normal series. Absence of supernumerary teeth

with curved iris scissors, followed by removal of the remaining dental papilla with a Lucas No. 85 curette (Fig. 4a, b). The area was irrigated with sterile saline, and local hemostasis was achieved by compression with sterile gauze (Fig. 5). At the end of the procedure, the infant was breastfed to provide comfort and aid in local hemostasis.

During the 18-month clinical follow-up period, the absence of tooth 81 confirmed that the extracted tooth corresponded to the normal primary series. The eruption of teeth 71, 72, 74, 82, and 84 occurred without observable functional or aesthetic impairment. No systemic involvement or syndromic diagnoses were identified during the follow-up period (Fig. 6).

Although short- to medium-term follow-up provides valuable information on early childhood clinical outcomes, its limitations must be acknowledged. In particular, the absence of long-term monitoring and data prevents definitive conclusions regarding potential orthodontic implications in the permanent dentition, as well as possible esthetic or functional repercussions, which may only become evident as the child continues to develop.

Discussion

This study reports a clinical case of neonatal tooth loss (NTD) in a newborn, highlighting the importance of early diagnosis and timely intervention to mitigate the risks associated with accidental swallowing or aspiration of the tooth-events that can lead to serious complications and pose a risk to the patient's life. The clinical and radiographic findings supported the healthcare team's decision to extract, rather than retain, the tooth in the oral cavity.

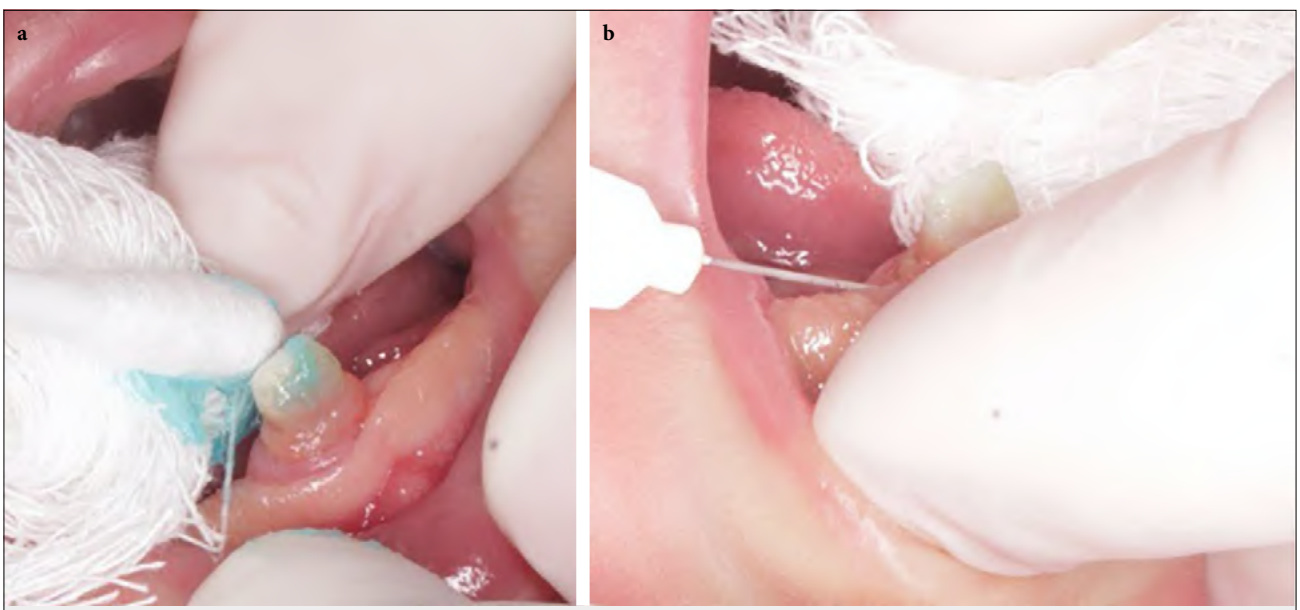

Figure 3. (a, b) Topical anesthesia with an anesthetic based on lidocaine andprilocaine, and terminal infiltrative anesthesia with an anesthetic based on lidocaine 2% and phenylephrine 1:100,000.



Figure 4. (a, b) Surgical removal of tooth 81, i.e., a neonatal tooth compatible with the normal series, with the aid of curved scissors and a fragment of the dental papilla.



Figure 5. The immediate clinical appearance after the removal of tooth 81



Figure 6. Clinical follow-up for 18 months showed the absence of tooth 81. Teeth 71, 72, 74, 82, and 84 erupted

Epidemiological studies have shown that, in approximately 85% of cases, the affected tooth is the mandibular central incisor, with approximately 95% of these teeth belonging to the normal deciduous dentition.[2,3,12] Furthermore, the literature indicates a higher prevalence of natal and neonatal teeth in female newborns.[11,13] In the present case, the patient's sex, the type of tooth affected, and its dental series were consistent with the patterns described in the literature.

The etiology of neonatal teeth remains unclear. The main hypotheses suggest factors such as superficial positioning of the tooth bud, hereditary influence, nutritional deficiencies,[11,14] and the presence of syndromes such as Ellis-van Creveld syndrome.[15] In particular, the occurrence of natal or neonatal teeth in the anterior maxillary region or the involvement of posterior teeth is often considered an indicator of a possible syndromic association.[16] In this case, the patient presented normal systemic conditions at birth and throughout the 18-month follow-up period, with no clinical signs suggestive of syndromic involvement. Furthermore, the legal guardians reported no family history of similar cases,

reinforcing the likelihood of isolated involvement due to the superficial position of the tooth bud.

Although conservative approaches are generally preferred, neonatal tooth extraction is indicated when its retention poses significant clinical risks.[7,11] In the reported case, several factors were observed that justified surgical conduct: tooth insertion in soft tissues, poor root development, marked mobility, potential risk of aspiration or accidental swallowing, and reported discomfort during breastfeeding. These findings alone contraindicate the retention of the tooth in the oral cavity.[3,6,7] Additionally, although no traumatic ulcers were observed in the maternal breast or on the ventral region of the newborn's tongue, Riga-Fede disease should be considered a possible complication in these cases[17] and is also a recognized indication for tooth extraction.[2,8,9] Therefore, given the patient's clinical signs and the tooth's unfavorable prognosis, extraction represented the safest and most appropriate course of action.

It is important to emphasize that tooth extraction in newborns should only be performed when the baby is at least 10 days old or has received a dose of vitamin K shortly after birth, in order to minimize the risk of bleeding associated with the procedure.[18]

Premature loss of primary teeth in cases of neonatal teeth can lead to significant aesthetic, orthodontic, and phonetic consequences. However, in this case, no aesthetic or functional impairments were observed during early childhood.[19] Gingival fibrosis can also occur in the edentulous region, potentially hindering the eruption of the permanent successor, thus reinforcing the need for long-term follow-up.[20]

Given these potential consequences, it is essential that clinicians be able to propose appropriate treatment alternatives that ensure dental rehabilitation, well-being, and quality of life for the patient. Furthermore, clinical and radiographic follow-up should be performed periodically, with careful monitoring of the formation and eruption of the permanent successor. However, in the present case, follow-up was limited to early childhood, which prevents the evaluation of long-term clinical outcomes related to permanent dentition.

Conclusion

Based on the clinical case presented, it is concluded that clinical and radiographic evaluation is essential for defining an individualized therapeutic approach in cases of neonatal teeth. Extraction has proven to be an effective and safe intervention when faced with health risks to the newborn, especially when there is severe mobility and hypoplastic structure. It is noteworthy that, even in the absence of visible lesions, these teeth can compromise breastfeeding and maternal and child well-being, which reinforces the importance of early diagnosis and evidence-based pediatric dentistry.

Disclosures

Ethics Committee Approval: This is a single case report, and therefore ethics committee approval was not required in accordance with institutional policies.

Informed Consent: Written informed consent was obtained from the patient for the publication of the case report and the accompanying images.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

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