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ORIGINAL RESEARCH

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Comparison of the effectiveness of the hall technique and orthodontic bands in managing extensive of carious lesions in deciduous molars of children with cognitive impairments—randomized clinical trial

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Abstract

Background: This study investigated the efficacy of the Hall Technique (HT) compared to orthodontic band cemented with glass ionomer (BGIC) in managing caries in primary molars of children with disabilities. A total of 58 children aged 4 to 10 years were included. **Methods**: Participants were randomly divided into two groups (n = 50 each): control group—HT and experimental group—BGIC. Block randomization was used. Follow-ups were conducted at 6 and 12 months. Caries progression was assessed using the Chi-Square test between groups and the McNemar test for intra-group comparisons over time. Procedure time was analyzed using the Shapiro-Wilk and Mann-Whitney tests due to non-parametric data distribution. **Results**: After 6 months, no significant differences were observed in caries progression between groups. However, at 12 months, HT showed 92.1% success *vs.* BGIC 67.6% ($p = 0.009$). This group's progression was significantly greater at 12 months compared to 6 months ($p = 0.025$). No significant differences in procedure time was observed between the groups. **Conclusions**: Although BGIC represents a viable alternative for treating extensive caries in primary molars, the HT technique significantly reduced caries lesion progression over 12 months. **Clinical Trial Registration**: The study protocol was registered in the Brazilian Clinical Trials Registry (ReBEC), available at https://ensaiosclinicos.gov.br/rg/RBR-825qxqw and under the identification: U1111-1311-7698.

Keywords

Dental caries; Dental restoration; Children with disabilities

1. Introduction

Patients with special needs often present with physical and/or cognitive impairments that require specialized dental care, particularly due to uncertainties surrounding their limitations. In Brazil, dental care is frequently not prioritized in public health policy, which contributes to a higher prevalence of oral diseases in this population [1].

Several factors predispose individuals with disabilities to oral diseases, especially dental caries. These include poor oral hygiene, improper masticatory function, diets rich in sugars and fermentable carbohydrates, chronic use of sugar-containing pediatric medications, altered salivary flow and limited access to dental services [2, 3].

In pediatric dentistry, minimally invasive techniques have gained traction. One such technique, the Hall Technique (HT), involves cementing preformed stainless-steel crowns (Shofu brand) with glass ionomer cement over deciduous molars without removing carious tissue or any dental preparation, thus eliminating the need for local anesthesia. Initial retrospective analyses showed that the longevity results of treatments performed using this technique were comparable to those obtained with conventional restorations [4].

However, applying the HT in individuals with disabilities requires a highly individualized approach. Factors such as the degree of physical or mental impairment, the level of cooperation, and the extent of carious lesion are determinants for therapeutic planning [5].

Orthodontic bands have recently been recommended as an alternative to conventional restorations to enhance the longevity of restorations in primary teeth with extensive lesions classified as ICDAS (International Caries Detection and Assessment System) scores of 5 or 6 [6–8]. However, no studies have compared the use of bands to the HT in extensive

carious lesions in primary molars, whether in patients with or without disabilities.

Therefore, this study aimed to compare two treatment approaches: the use of the HT with preformed and pre-contoured metal crowns and bands cemented with conventional glass ionomer cement (BGIC) in cases of extensive carious lesions with an ICDAS score of 5 and 6, for the treatment of children with disabilities. The study monitored the performance of these approaches over 6 and 12 months. We hypothesized that there would be no significant difference between the two approaches over time.

2. Materials and methods

2.1 Sample and study design

This study was conducted at Universidade Paulista (UNIP), in Goiânia (GO, Brazil), and Centro Universitário INTA—UNINTA, in Sobral (CE, Brazil), both recognized as reference centers for pediatric dental care and treatment. The trial was registered (ReBEC: U1111-1311-7698) and approved by the Ethics Committee (CAAE 60887816.20000.5374). The study adhered to Consolidated Standards of Reporting Trials (CONSORT) guidelines and was conducted from August 2022 to April 2024. The study employed a randomized clinical trial design and involved children with disabilities who sought dental care. The two study locations were selected based on convenience, as they were in close proximity to the researchers. The calculated sample size was 100 teeth (50 HT, 50 BGIC) obtained from 58 children. The study design was a randomized clinical trial examining children with disabilities who sought dental care.

For the sample size estimation, a success rate of 96% for the HT in patients with learning disabilities after 12 months of follow-up was considered [9]. A clinically significant difference of 20% in the success rate of the orthodontic band technique was adopted, with a significance level of 0.05 and a power of 0.80. Considering a one-tailed test and adding a 10% rate for potential losses and 10% for the cluster effect, the final sample size was determined to be approximately 100 teeth (G*Power 3.1.3; Institute of Psychology, Heinrich Heine University Düsseldorf, Düsseldorf, NRW, Germany).

2.2 Inclusion criteria

This study included children aged 4 to 10 years with cognitive impairment and a diagnosis of learning disabilities (mild to moderate) who presented extensive carious lesions involving more than one surface of the tooth with an ICDAS score of 5 or 6. All participants were required to be available for 12-month follow-up, and inclusion was contingent on the signed informed consent form (ICF) provided by their legal guardians.

2.3 Exclusion criteria

Children's teeth were excluded if they presented with any of the following: pulp exposure; spontaneous pain; advanced root resorption with mobility; presence of edema or fistula near the affected tooth; periapical abscess or furcation involvement; prior restorations or sealants; or enamel formation defects.

2.4 Data collection

2.4.1 Randomization

Two parallel groups were formed based on the selected teeth: a control group treated with the HT and an experimental group treated with the BGIC technique. Randomization was performed using MedCalc Software (MedCalc Software Ltd, version 15.8, Acacialaan 22, 8400 Ostend, Belgium), employing block randomization with varying block sizes. Randomization sequences were concealed in opaque, sealed envelopes and were only revealed at the time of intervention, ensuring allocation concealment between the HT control and BGIC experimental groups. Operators who underwent calibration and theoretical-practical training conducted the clinical procedures for both interventions in Goiânia, GO. The training covered ICDAS classification and a step-by-step process for selecting orthodontic bands and metal crowns up to their cementation and installation. Calibration achieved a Kappa of 0.85 through duplicate examinations of 20 non-study teeth.

Two operators, ACBBP and CSR, executed the study and the same examiners, ACBBP and CSR, conducted the subsequent phases, including the baseline, 6-month and 12-month follow-ups. In cases where a patient had more than one eligible tooth with a carious lesion involving two or more surfaces, each tooth was independently randomized to determine the treatment modality. Thus, a single patient could contribute one or more teeth to the sample.

2.4.2 Blinding

Due to the distinct differences between the interventions, blinding of patients, operators and examiners was impossible. Due to logistical constraints, operators also served as evaluators. However, statistical analysis was conducted under blinded conditions to reduce assessment bias.

2.4.3 Experimental groups

Table 1 summarizes the distribution of groups and techniques used in the study.

TABLE 1. Distribution of experimental groups and techniques.

Groups	N	Technique
Experimental (BGIC)	50	Band cementation using conventional glass ionomer cement.
Control (HT)	50	Utilization of preformed and pre-contoured metal crowns.

BGIC: Band cementation using conventional glass ionomer cement; HT: Hall technique.

Two trained operators (ACBBP and CSR) were responsible for administering the interventions for both groups and for conducting follow-up evaluations at baseline, 6 months and 12 months.

2.5 Clinical procedures

An initial clinical examination was performed to assess primary molars with cavities involving two or more surfaces

of the teeth, showing ICDAS scores of 5 or 6. Following the clinical examination, a radiograph was obtained for each selected tooth. If a child presented with multiple teeth that met the inclusion criteria, each eligible tooth was randomly assigned to one of the treatment techniques. Thus, a patient could contribute one or more teeth to the sample. This initial examination was conducted to screen the children and diagnose carious lesions according to the research criteria, allowing for Randomization and identifying other possible treatment needs to plan the patient's complete treatment.

The researchers allocated the selected molars into two groups, (A) HT control group and (B) BGIC experimental group, using a random sequence list.

2.5.1 HT control group

The teeth assigned to the control group were treated according to the principles of the HT [4]. After conducting clinical and radiographic examinations, prophylaxis was performed on the selected tooth using a prophylactic paste. Due to the specific characteristics of the patient population, the use of separating elastic was omitted. A pre-fabricated and pre-contoured stainless steel crown (Shofu) was selected to ensure optimal fit for the affected tooth. The selected crowns were then filled with glass ionomer cement (Ketac Molar 3M) and positioned over the tooth to be treated. During the material setting phase, patients were instructed to bite on a cotton roll over the crown to ensure satisfactory seating and allow excess cement flow. After the material was set, the dentist removed the excess cement and took a final radiographic image of the treated tooth. The technical sequence is illustrated in Fig. 1.

2.5.2 BGIC experimental group

The procedure began with a clinical examination, radiographic evaluation and prophylaxis on the selected tooth. If proximal contact points hindered band placement, an FF2200 bur was used to remove the contact on the adjacent surface. Next, the most appropriate band for the specific tooth was selected. Dental floss was placed around the band to prevent the risk of the patient swallowing or aspirating it. The band was then adapted to the tooth using an orthodontic plugger for optimal fit, then removed with a band remover to allow handling of the chemically activated high-viscosity glass ionomer cement in powder-liquid form. The dentist applied the restorative material to all internal surfaces of the orthodontic band, positioned it on the tooth and then applied digital pressure. Excess material was removed using a manual instrument. Petroleum jelly was applied around the band-tooth interface to complete the isolation, and the restoration was finalized. After the material was set, the dentist removed the excess cement and took a final radiographic image of the treated tooth. Fig. 2 illustrates the technical sequence.

All participants and their guardians received standardized instructions on oral hygiene and dietary habits, with an emphasis on reducing the frequency of sugar intake. The two operators treated the other teeth, requiring intervention, but were not included in the study.

2.5.3 Procedure time for each technique

The timing of each installation procedure began when glass ionomer was placed into the crown or band and concluded after applying digital pressure to both.

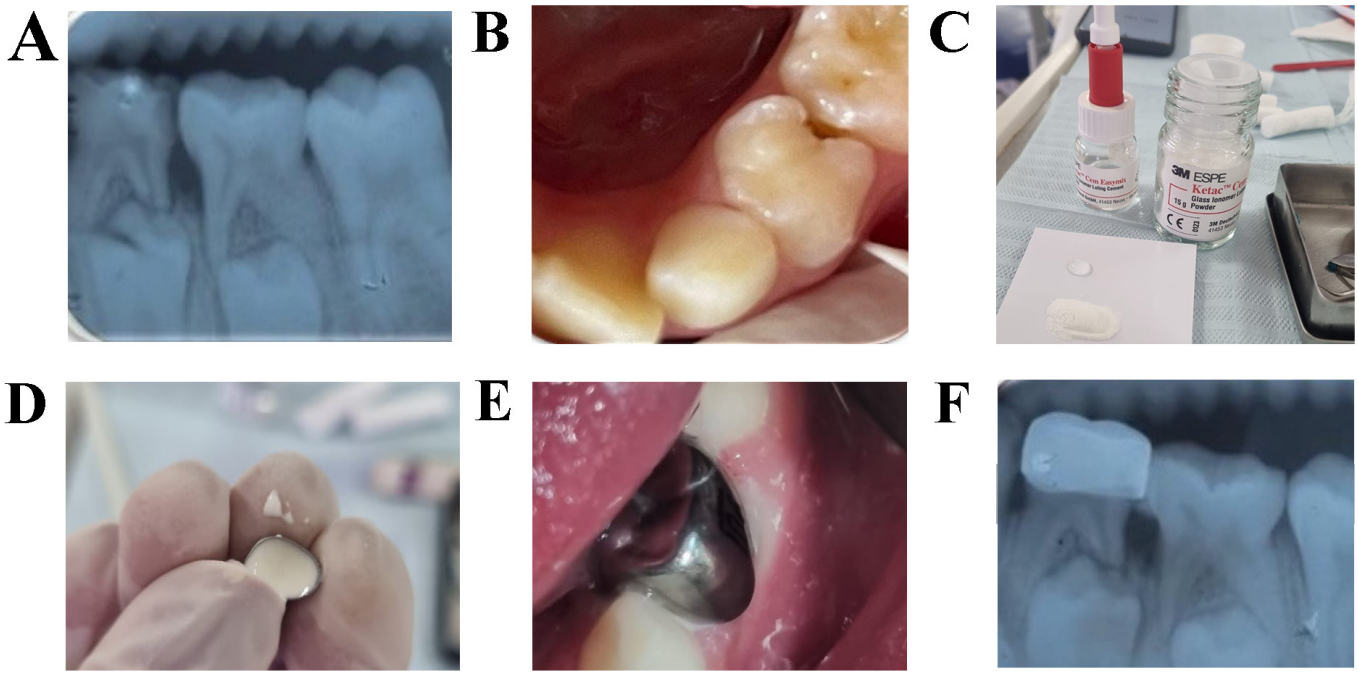
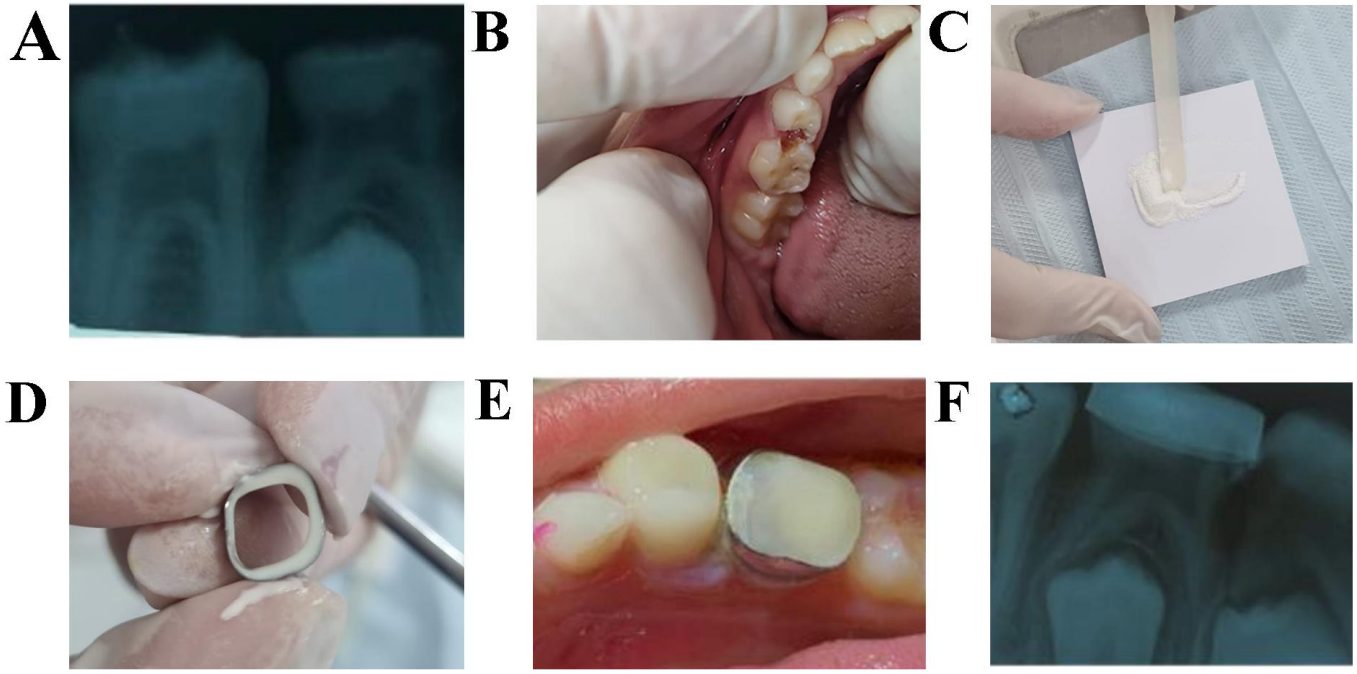


FIGURE 1. Clinical sequence of the hall technique placement. (A) Radiograph of the carious lesion on tooth 74. (B) Prophylaxis on tooth 74. (C) Manipulation of the Ionomer. (D) Placement of the Ionomer in the Hall crown. (E) Installation of the crown. (F) Radiograph after installation.



F I G U R E 2. Clinical image sequence of orthodontic band installation (BGIC). (A) Initial radiograph of tooth 64. (B) Places caries lesion score 5 after prophylaxis. (C) Manipulation of the Ionomer. (D) Placement of the Ionomer in the orthodontic band. (E) Installation of the band on the tooth. (F) Radiograph after installation.

2.5.4 Follow-up protocols

Participants were scheduled for clinical reassessments at 6 and 12 months post-intervention. During each follow-up, they underwent clinical examination, radiographic imaging and photographic documentation. Evaluators assessed them using evaluation forms based on the criteria for the two techniques. The researchers responsible for the interventions contacted participants via WhatsApp to confirm the follow-up appointments 7 days before the scheduled date. Participants who failed to attend were considered dropouts. Follow-up radiographs are available upon request.

2.6 Outcomes analyzed

2.6.1 Caries progression

Caries progression was assessed clinically and radiographically at baseline, 6 months and 12 months following the initial intervention. Evaluators assessed crown integrity and lesion development. The assessment methodology [10] was used for the evaluation of restorations with bands and resin-modified glass ionomer cement, and the evaluation of the stainless-steel crowns followed the HT [11].

2.6.2 Evaluation of time spent for the installation of both techniques

The timing began after placing the glass ionomer cement in both the band and the crown and concluded after their installation on the carious tooth.

2.7 Statistical analysis

Between-group comparisons of caries progression at 6 and 12 months were performed using the Chi-Square test. Within-group comparisons between 6- and 12-month outcomes were analyzed using the McNemar test. The time spent on procedures in both groups was analyzed for distribution using the Shapiro-Wilk normality test and subsequently tested with the Student's *t*-test (parametric data) or the Mann-Whitney test (non-parametric data). All statistical analyses were performed analyses using Jamovi Version 1.2.27.0 (Sydney, Australia), with a significance threshold set at 5%.

3. Results

As illustrated in the flowchart (Fig. 3), 105 children were initially screened for participation. Based on the inclusion criteria, 58 children were ultimately enrolled in the study. If a child presented with more than one tooth showing carious lesions on two or more surfaces meeting the inclusion criteria, multiple teeth from that child could be included. A total of 100 teeth were randomly assigned to either the HT (n = 50) or to cemented bands with BGIC (n = 50), as per the sample size calculation.

Participant recruitment was conducted sequentially from August 2022 to April 2023, with the final follow-up occurring in April 2024. After one year, 72 teeth were successfully re-evaluated, including 38 treated with HT crowns and 34 with banded BGICs. Among these, 3 HT-treated teeth and 4 banded teeth had exfoliated. In total, 100 teeth were evaluated at least once during the study.

Baseline characteristics of the participants by group were summarized in Table 2. Most participants in both groups were male (HT = 64%; BGIC = 52%), with an average age of 6.44 (±1.58) years. No statistically significant differences were observed between the groups.

Among the enrolled children, Autism Spectrum Disorder

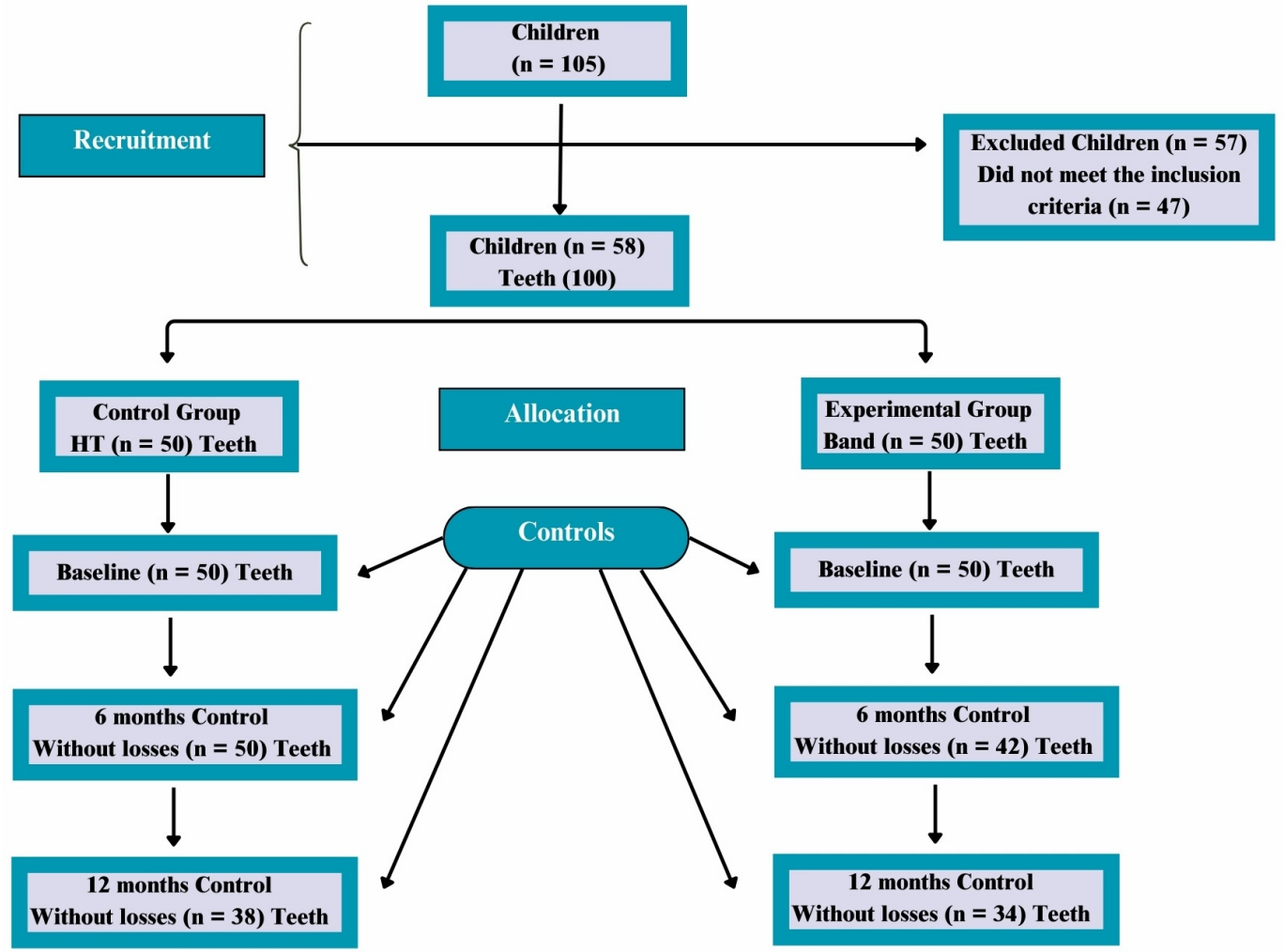


FIGURE 3. Flowchart of participant inclusion and study phases. HT: Hall Technique.

TABLE 2. Baseline characteristics of participants by experimental group.

Characteristics	Groups		
	HT	BGIC	Total
Gender, n (%)			
Female	18 (36%)	24 (48%)	42 (42%)
Male	32 (64%)	26 (52%)	58 (58%)
Average Age (SD)	6.38 (±1.70)	6.50 (±1.47)	6.44 (±1.58)

SD: Standard Derivation; BGIC: Band cementation using conventional glass ionomer cement; HT: Hall technique.

(ASD) and Attention Deficit Hyperactivity Disorder (ADHD) were the most frequently reported neurodevelopmental conditions in both groups. When comparing caries progression between groups at the 6-month mark, no statistically significant differences were found (Table 3). However, by the 12-month follow-up, the BGIC group showed a significantly higher incidence of caries progression ($p = 0.009$).

Within-group analyses revealed a significant increase in caries progression in the BGIC group between the 6- and 12-month evaluations ($p = 0.025$) (Table 4).

In contrast, the HT group did not exhibit a statistically significant change in caries progression between the 6- and 12-month evaluations ($p = 0.317$) (Table 5).

Procedure times for both treatment approaches were presented in Table 6. As the data followed a non-parametric distribution, the Mann-Whitney test was applied. No statistically significant difference in procedure duration was observed between both groups.

4. Discussion

This randomized clinical trial demonstrated significant differences in the effectiveness of caries lesion arrest between the HT and BGIC in primary molars of children with disabilities, particularly at 12-month follow-up. Consistent with previous findings by Innes *et al.* [4], the HT involves sealing carious lesions with preformed metal crowns without caries removal, creating a sealed environment that inhibits lesion progression.

TABLE 3. Comparison of caries progression between groups at 6 and 12 months.

	HT	BGIC	p-value/χ^2 Test
6 months			
Absent Progression, n (%)	46 (92)	36 (85.7)	
Present Progression, n (%)	4 (8)	6 (14.3)	0.335
Total, n (%)	50 (100)	42 (100)	
12 months			
Absent Progression, n (%)	35 (92.1)	23 (67.6)	
Present Progression, n (%)	3 (7.9)	11 (32.4)	0.009*
Total, n (%)	38 (100)	34 (100)	

**Statistically significant difference ($p < 0.05$). BGIC: Band cementation using conventional glass ionomer cement; HT: Hall technique.*

TABLE 4. Within-group comparison of caries progression in the BGIC group at 6 and 12 months.

	12 months			p-value
	Absent Progression	Present Progression	Total	McNemar
6 months				
Absent Progression	23 (82.1)	5 (17.9)	28 (82.35)	
Present Progression	0 (0)	6 (100)	6 (17.65)	0.025*
Total	23 (67.64)	11 (32.36)	34 (100)	

**Statistically significant difference ($p < 0.05$).*

TABLE 5. Within-group comparison of caries progression in the HT group at 6 and 12 months.

	12 months			p-value
	Absent Progression	Present Progression	Total	McNemar
6 months				
Absent Progression	35 (97.2)	1 (2.8)	36 (94.74)	
Present Progression	0 (0)	2 (100)	2 (5.26)	0.317
Total	35 (92.1)	3 (7.9)	38 (100)	

TABLE 6. Comparison of procedure duration between experimental groups (in seconds).

	HT	BGIC	p-Value Mann-Whitney Test
Median	73	77	0.722
25th Percentile	45.8	51.3	
75th Percentile	107	106	
Standard Deviation	57.4	46.8	
p-Value Shapiro-Wilk Normality Test	<0.001	<0.001	

BGIC: Band cementation using conventional glass ionomer cement; HT: Hall technique.

Regarding acceptance, Santamaria *et al*. [12–14] reported that caregivers prefer the HT due to the absence of anesthesia and invasive procedures. Our findings align with these results, with participants showing higher acceptance of the HT compared to BGIC. Additionally, the higher efficacy of the HT in preventing caries progression over 12 months has been corroborated by previous studies [12–14]. These results highlight the protective role of the metal crown against dental biofilm, which delays the progression of carious lesions. Conversely, the BGIC technique exhibited a significantly higher failure rate after one year, in line with prior studies [4, 12–14].

Although both techniques are considered minimally invasive and technically straightforward, the HT demonstrated notably superior outcomes in terms of caries control. This reinforces its recommendation for pediatric populations with oral hygiene challenges [4, 12–14].

At the 6-month evaluation, no statistically significant difference was observed between the HT and BGIC groups ($p = 0.335$), suggesting that both techniques are initially effective in halting caries progression. These findings align with previous studies supporting the effectiveness of minimally invasive approaches in preserving tooth integrity during the

initial treatment periods [4, 12–14].

However, at 12 months, the HT group showed a markedly lower caries progression rate (7.9%) compared to the BGIC group (32.4%), with a statistically significant difference (p = 0.009). This results highlights the HT's protective effect over time, possibly due to the complete isolation of the tooth by the metal crown, which prevents exposure to cariogenic biofilm.

Within-group analyses further emphasized this trend: while the HT group maintained stable results over time (p = 0.317), the BGIC group showed a significant increase in caries progression between 6 and 12 months (p = 0.025), likely related to material degradation or insufficient long-term sealing capability.

These findings carry significant clinical implications. The HT provides enhanced protection against caries progression in patients with special health care needs, who often face challenges related to oral hygiene maintenance, sugar-rich diets and sugary medication use. The non-invasive nature and simplicity of the HT also make it a practical and less traumatic intervention for these patients, avoiding the need for anesthesia or cavity preparation. Regarding procedural time, no significant differences were observed between the two techniques (p = 0.722), suggesting that time efficiency should not be the decisive factor when selecting a treatment approach. Although crown fitting in the HT group may require slightly more technical skill, this is offset by the technique's superior efficacy.

All included participants had mild to moderate disabilities, and behavior management was conducted using standard pediatric techniques.

This study also presents several limitations. To our knowledge, it is the first to evaluate the sealing of ICDAS 5 and 6 lesions using orthodontic bands in children with disabilities. Additionally, all procedures were performed by two calibrated operators; ideally, follow-up assessments should be conducted by independent evaluators to minimize bias. While chi-square and McNemar tests were suitable for our binary outcomes and study design, they do not account for intra-patient correlations or longitudinal variability. However, given the binary nature of our outcomes and the limited longitudinal time points (two intervals), advanced methods like Generalized Estimating Equations (GEE) or mixed-effects models would likely offer marginal gains in precision for this specific design. Future studies with longer follow-up periods and continuous outcomes may benefit from such approaches. Furthermore, blinding was not feasible due to the visible differences between the treatment techniques, which may introduce performance and detection bias—especially in subjective assessments like clinical evaluations of caries progression. However, we mitigated this risk by standardizing outcome criteria (ICDAS scores) and supporting the primary outcome (caries progression) by radiographic evidence, which is less susceptible to observer bias.

In conclusion, the HT proves to be a superior option in terms of efficacy for managing caries lesions in the primary molars of children with disabilities. Its consistent performance over 12 months and ability to isolate the tooth makes it an ideal choice in complex oral hygiene control cases, such as those with ASD and ADHD.

Future studies should explore the impact of the HT over an even longer follow-up period and investigate the combination of different types of cement with orthodontic bands, aiming to optimize outcomes for patients for whom this approach remains preferable.

5. Conclusions

The HT for treating caries lesions in primary molars of children with disabilities demonstrated greater effectiveness in controlling caries progression after 12 months of follow-up. While both techniques yielded comparable outcomes at 6 months, BGIC remain a viable short-term alternative for managing extensive lesions.

More studies are needed, particularly concerning bands, to provide a scientifically grounded alternative for treating carious lesions with scores of 5 and 6.

ABBREVIATIONS

BGIC, Bands cemented with conventional glass ionomer cement; HT, Hall Technique; ICDAS, International Caries Detection and Assessment System; ReBEC, Brazilian Registry of Clinical Trials; ICF, Informed consent form; ADHD, Attention Deficit Hyperactivity Disorder; ASD, Autism Spectrum Disorder; UNIP, Universidade Paulista; GEE, Generalized Estimating Equations.

AVAILABILITY OF DATA AND MATERIALS

The data analyzed in this study are available upon request. Please write to the corresponding author.

AUTHOR CONTRIBUTIONS

CSR—designed the research study, performed the research, analyzed the data, wrote the manuscript. TG, JCPI, AFBC—designed the research study, analyzed the data. MVA—designed the research study, performed the research. ACBBP—designed the research study, performed the research, analyzed the data, wrote the manuscript. RPSC—designed the research study, performed the research. KMSM—designed the research study. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study was approved by the Ethics and Research Committee of the Postgraduate Center/CPO São Leopoldo Mandic, opinion 1.795888/2016, under CAAE 60887816.20000.5374, meeting the ethical and fundamental requirements of Resolution 466/2012 of the National Health Council (Guidelines for research involving human beings). All study participants signed an Informed Consent Form (ICF). The protocol was registered in the Brazilian Registry of Clinical Trials (ReBEC), available at

https://ensaiosclinicos.gov.br/rg/RBR-825qxqw and under the identification: U1111-1311-7698.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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