



Treatment time, pain experience and acceptability of the technique for caries removal in primary teeth using the ART approach with or without Brix3000™ papain gel: a preliminary randomised controlled clinical trial

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Abstract

Purpose To compare the Atraumatic Restorative Treatment (ART) associated with Brix3000™ to ART considering treatment time, pain experienced, and acceptability to children.

Methods This study was accepted in Research Ethics Committee in July 2019 (number 3469402). Healthy patients ($n = 20$) aged 3–9 years, with at least one primary molar with occlusal dentine caries without cusp involvement were randomly allocated to either the ART + Brix3000™ group or the ART-only group. The sample was characterised by sex, age, tooth location and caries experience. Time spent and pain experience scores were recorded at prophylaxis, caries removal and restoration. The pain experience (intense, moderate, or mild) was evaluated by the Face, Legs, Activity, Cry, Consolability-revised scale (FLACC-r). Acceptability was assessed by a five-point hedonic facial scale (dichotomised into ‘like’ and ‘indifferent/dislike’ bins) and by an open-question interview. Mann–Whitney, Chi-square, and Fisher’s exact tests were applied to discern differences in time, pain/sample characterisation and acceptability, respectively.

Results The ART + Brix3000™ group required 8.6 ± 3.1 min to remove caries tissue, whereas the ART group required only 4.8 ± 2.0 min ($p = 0.03$). The total time spent with treatments was 13.1 ± 4.0 min for ART + Brix3000™, and 9.8 ± 2.7 min for ART ($p = 0.03$). There was no difference in pain experience and acceptability found among the groups ($p > 0.05$).

Conclusion Although the ART + Brix3000™ technique demanded more treatment time than the ART alone, there were no differences in either pain experience or acceptability.

Keywords Children · Dental caries · Pain · Papain

Introduction

Experiences related to pain and acceptability during dental treatments are important in the successful treatment of young patients (Carvalho et al. 2009; Leal et al. 2009). Also, the duration spent on procedures can directly affect children’s behaviour, making treatment more difficult and,

consequently, causing psychological trauma. It is, thus, important to avoid unpleasant experiences in children’s dental visits, not only for the success of the treatment at hand, but also to avoid the dental phobias that typically emerge during childhood and are associated with future avoidance of dental care (Seligman et al. 2017).

Patients’ discomfort (Carvalho et al. 2009) can be reduced by choosing techniques such as Atraumatic Restorative Treatment (ART). ART is a minimal-intervention technique, consisting of removing the soft carious dentine until firm dentine, using hand instruments, followed by the adhesive restorative procedure with a high-viscosity glass-ionomer cement (Frencken et al. 1996). ART avoids the unnecessary use of rotary instruments and local anaesthesia, reducing distress, anxiety, and fear for patients (Leal et al. 2009).

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Some chemical agents, as the enzyme papain, can be used with ART, resulting in a chemical–mechanical caries removal (CMCR) technique. Papain promotes proteolysis of the exposed collagen fibrils in the carious tissue, which makes the decayed tissue even softer, facilitating its removal with hand instruments (Bussadori et al. 2005), hence enhancing the ART approach.

Brix3000™, released in 2016, presents a high concentration of papain in a gel medium (3000 U/mg), along with Encapsulated Buffer Emulsion (EBE) technology to maintain the pH at a level that immobilises the enzymes immobilised until they meet the decayed tissue (Alkhouli et al. 2020). Studies on Brix3000™ are still scarce; thus, new investigations are needed to discern its mechanism of action, time required for its use, and acceptability to children.

The aim of this preliminary parallel randomised controlled trial was to evaluate treatment time, pain experience and acceptability of caries removal after ART, compared with ART with CMCR using Brix3000™, in children. The hypothesis was that more time would be needed to remove carious tissue with ART plus Brix3000™, and that there would be no difference in pain experience or acceptability between the treatments.

Materials and methods

Ethics

This preliminary study was approved by the Research Ethics Committee of the Hospital Universitário Clementino Fraga Filho (HUCFF), by project 187/19, number 3469402, accepted on July 25, 2019. This trial is registered in the Brazilian Registry of Clinical Trials (ReBEC) as trial NCT U1111-1243-6328. Parents or legal guardians of the eligible patients received detailed information about the study and signed an informed consent form. An assent form was also given to participants aged 7–9 years, explaining in a comprehensible way to the child, how their participation in the research would be and confirming the child patient's interest to collaborate with the research. After signing the consent terms, the child and their guardian received instructions on the child's oral health care.

Study design

This randomised 2-arm-group active controlled clinical trial, with a 1:1 allocation ratio, followed the CONSORT recommendations (Schulz et al. 2010). Between September 2019 and February 2020 at the Pediatric Dental Clinic of the Federal University of Rio de Janeiro, one examiner selected 20 children with dentine caries lesions in their primary molars ($n = 27$). Children were randomly allocated into two

groups: the test group (ART + Brix3000™) and the control group (ART) to investigate the following outcomes: (1) time required to treat, (2) pain experience and (3) acceptability.

Sample size calculation and interim analyses

The present study is part of a larger study, the primary outcome of which is the evaluation of the longevity of restorations made after ART + Brix3000™ treatment or ART. The sample calculation was based on Motta et al. (2013), in which the standard deviation and mean of the longevity of restorations performed with glass-ionomer cement after using the ART technique (mean 1.63 ± 2.03 months) and mechanical chemical removal with Papacárie™ (mean 2.84 ± 3.03 months), for 18 months, were used. The sample size was calculated using BioEstat 5.3 (Ayres et al. 2007): to attain a power of 80%, assuming $\alpha = 0.05\%$, two-sided Student's *t*-test, and estimating 20% loss, a final sample size of 68 teeth was deemed necessary in each treatment group.

After the trial commenced, it turned out not to be possible to recruit that many eligible children within the practicalities of the clinical context, so it was decided to analyse all the eligible teeth of each child. Thus, when more than one tooth per child fulfilled the inclusion criteria, the subsequent teeth always received the other treatment.

The study was due to the COVID-19 pandemic, which triggered the suspension of clinical activities in the Department of Paediatric Dentistry and Orthodontics from March 2020 up to the present.

Participants, eligibility criteria, and settings

Patients undergoing treatment at the clinic of the Department of Pediatric Dentistry and Orthodontics from September 2019 to February 2020 were recruited by an examiner (LCM). A clinical examination with the child on a dental chair was performed by another examiner (TFS), under artificial light, with a flat mouth mirror. Bitewing radiographs were taken in all cases to confirm that the patient met the inclusion criteria, considering the tooth characteristics. The following eligibility criteria were applied: healthy children aged between 3 and 9 years, with no gender or ethnic restrictions; with at least one active carious lesion on primary molars reaching only the occlusal surface, not exceeding 2/3 of the dentine and without cusp involvement; and with no clinical or radiographic evidence of pulp involvement in the carious molars selected for the study. Children with systemic impairment, or if they were uncooperative during the clinical appointments and with primary molars unable to be restored, or with mobility due to physiological rhizolysis were excluded from the present study.

Baseline characteristics such as sex and age, teeth locations in the arch and dental caries experience were collected by one examiner (TFS).

The dental caries experience was documented through the index of decayed teeth, lost by caries, and restored (dmft/DMFT index) recommended by the World Health Organisation (Petersen et al. 2013) and available in the patients' medical records filled by trained post-graduate students supervised by paediatric dentistry professors.

Randomisation

Children of both sexes were allocated into the two treatment groups using a random numbers table (generated at <https://www.random.org>) and stored in an Excel spreadsheet by a researcher (MLM) different from the operator (TFS). Allocation was concealed using sequentially numbered, opaque, sealed envelopes containing the treatment allocation cards, which were prepared before the trial. When a patient had only one tooth eligible for this study, the treatment was determined accordingly the randomisation. When a patient had two eligible teeth, the first tooth received the randomised treatment and the second tooth, consequently, received the other type of treatment. When the patient had more than two eligible teeth, treatment for the third tooth onwards received a randomised treatment. The operator (TFS) did not open the envelope until the time of the dental appointment. The list was kept confidential until the end of the analyses.

Interventions

The interventions were performed by one operator (TFS), who is a specialist in paediatric dentistry and a master's student in paediatric dentistry, and who was previously trained by a gold-standard (paediatric dentistry) expert in both techniques (CMTS). The training process was carried out in the six primary molars of four children who did not take part the final sample.

The ART group was treated based on the fundamentals suggested by Frencken et al. (1996), according to the following steps: (A) prophylaxis to clean the tooth to be treated, removing dental biofilm, and increasing visibility; (B) relative isolation of the tooth with cotton rolls; (C) removal of softened decayed tissue until firm dentine, this using dentine excavators 1, 2 and 3 from an ART-customised kit (Duflex®, S.S. WHITE Brazil) in all cases; (D) checking remaining softened tissues and the consequent need to repeat the removal of decayed tissue. Treatment for the ART + Brix3000™ involved additional steps: (A) prophylaxis; (B) relative isolation with cotton rolls; (C) application of Brix3000™ (Brix Medical Science, Carcañá, Argentina) in the cavity with a dentine excavator, according to the manufacturer's instructions, with a contact time of 2 min; (D) removal of softened

decayed tissue until firm dentine with pendular movements, without exerting pressure, also using dentine excavators 1, 2, and 3 from the ART kit (Duflex®, S.S. WHITE Brazil); (E) tactile and visual inspection, checking the dentine hardness and the presence of remaining softened tissues; (F) if necessary, the gel application was repeated 2 or 3 times until the complete removal of soft tissue; reapplications were registered for accounting.

After caries tissue removal, both groups received restoration with a high-viscosity glass ionomer, Ketac Molar Easy-mix™ 3 M ESPE (St. Paul, MN-USA). The following protocol was applied: (A) conditioning of the cavity and occlusal surface using a drop of the glass-ionomer cement liquid, on a cotton ball, rubbing both the cavity and the occlusal surfaces for 10 s; (B) washing the conditioned surface; (C) drying the surface; (D) mixing glass ionomer according to the manufacturers' instructions; (E) insertion of the mixed glass ionomer into the cavity, overfilling slightly; (F) pressing the ionomer with the petroleum jelly-coated gloved finger (on the top of the entire occlusal surface), exerting slight pressure for 30 s; (G) checking the bite and, if necessary, removing excess material with a manual instrument; (H) covering the filling with petroleum jelly; (I) instructing the patient not to eat for at least one hour.

Outcomes

The sample was characterised (sex, age, tooth location and caries experience) to verify data homogeneity between the two treatment groups.

The time required for each procedure was assessed by three independent examiners (KMS, MAW and AOS), who are oral health technicians in the clinic. Time was measured using a digital timer, which was triggered at the beginning of each phase: prophylaxis, caries tissue removal and dental restoration. The timer was stopped at the end of each procedure.

Pain experience was assessed at the same three moments (start of prophylaxis, caries removal and dental restoration), by the same examiners who measured the time (KMS, MAW and AOS). The Face, Legs, Activity, Cry, Consolability-revised scale (FLACC-r) developed to assess postoperative pain (Bussotti et al. 2015; Silva and Thuller 2008; Malviya et al. 2006) was used for evaluation: evaluators scored the child's body expressions—via (F) face; (L) legs; (A) activity; (C) crying; and (C) consolability—from 0 to 2, summing to a total score from 0 and 10. A total of 0–3 was classified as mild pain, 4–6 as moderate pain, and 7–10 as severe pain (Table 1).

The three examiners' application of the scale was compared by an inter-examiner calibration, with seven other children examined independently, also using FLACC-r, by the three examiners during their dental treatments; Cohen's

Table 1 Description of FLACC-r scale scoring

FLACC-r scale scoring		0	1	2
Categories				
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested, sad, appears worried	Frequent to contrast quivering chin, clenched jaw, distressed looking face, expression of fright/panic	
Legs	Normal position or relaxed; usual tone and motion to limbs	Uneasy, restless, tense, occasional tremors	Kicking, or legs drawn up, marked increase in spasticity, constant tremors, jerking	
Activity	Lying quietly, normal position, moves easily, regular, rhythmic respirations	Squirming, shifting back and forth, tense, tense/guarded movements, mildly agitated, shallow/splinting respirations, intermittent sighs	Arched, rigid or jerking, severe agitation, head banging, shivering, breath holding, gasping, severe splinting	
Cry	No cry (awake or asleep)	Moans or whimpers; occasional complaint, occasional verbal outbursts, constant grunting	Crying steadily, screams or sobs, frequent complaints, repeat outbursts, constant grunting	
Consolability	Content, relaxed	Reassured by occasional touching, hugging, or being talked to; distractible	Difficult to console or comfort, pushing caregiver away, resisting care or comfort measures	

Note: Each of the five categories (F) Face, (L) Legs, (C) Cry, (C) Consolability is scored from 0 to 2, which results in a total score between zero and ten. Source: Malviya et al. (2006)

statistic for inter-rater reliability was $\kappa = 1.0$. These children did not otherwise participate in the sample of the study.

At the end of treatment, the child was shown a hedonic facial scale (Domene et al. 2002), comprising a sequence of facial expressions by which the children were asked to describe how they felt during the procedures. The hedonic scale ranged over: (1) dislike a lot, (2) disliked, (3) indifference, (4) liked, and (5) loved (Fig. 1). The answers were dichotomised into “liked”, referring to ratings 4 and 5, and “indifferent/disliked”, for ratings 1, 2, and 3.

The children were asked two open questions about what they most liked and disliked in the treatments, to check how patients’ preferences related to the treatment methods and their parts. These open responses were compiled into groups corresponding to the treatment phase to which they referred (prophylaxis, caries tissue removal, and restoration).

Blinding

Neither the patients nor the operator (TFS) could be blinded during the treatment due to the Brix3000™ application being easily perceived by both.

The timekeepers were dental health technicians, who were blinded to the objective of the study, and did not know what Brix3000™ does.

Statistical analysis

Data were stored and analysed using IBM SPSS Statistics 21.0 (SPSS Inc., Chicago, USA), and the significance level adopted for all tests was 5%.

A descriptive analysis of the sample was carried out, evaluating sex, age and caries experience. The χ^2 test was used to assess the distribution, among treatment groups, of the children included in this study based on age, sex, tooth location and experience of caries.

The Kolmogorov–Smirnov test was applied to verify the distribution of data collected. The Mann–Whitney U test was applied to assess differences in treatment duration, pain experience was evaluated using the χ^2 test, and acceptability by Fisher’s exact test.

Results

Participant flow and recruitment are represented in the clinical trial flow chart (Fig. 2). A total of 27 caries lesions were treated, 13 with ART + Brix3000™ and 14 with ART alone.

A total of 20 children participated; 12 were males (60%) and 8 were females (40%). Their average age was 5.5 ± 1.6 years, with a median of five years. The mean caries experience was 6.7 ± 5.0 on the dmft/DMFT index, with a median of 6. For analysis, this variable was dichotomised

Fig. 1 Hedonic scale with five facial expressions that indicates: (1) disliked a lot, (2) disliked, (3) indifference, (4) liked, (5) loved

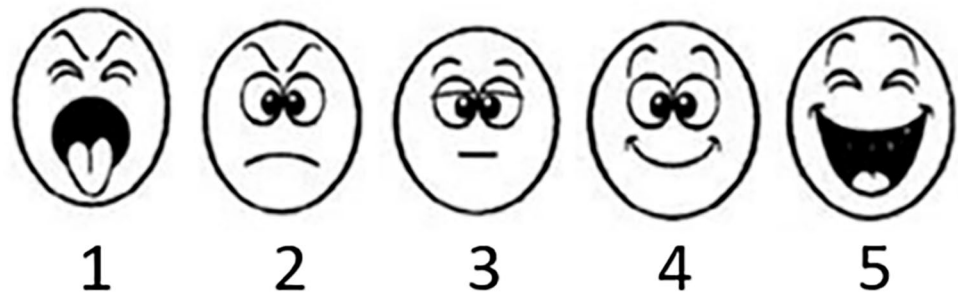
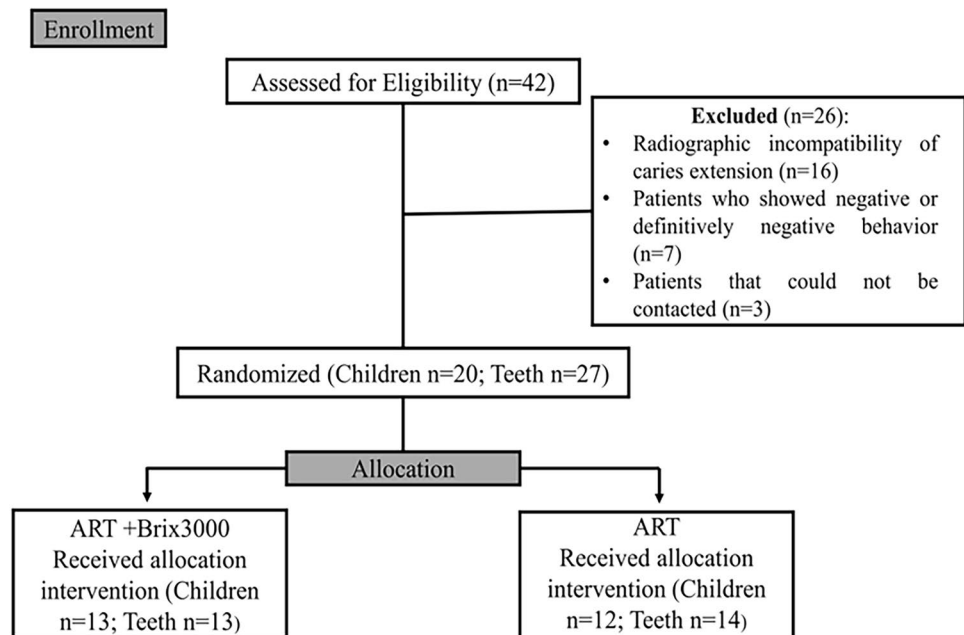


Fig. 2 Consort flow diagram of the trial



by thresholding at the median ($dmft/DMFT \leq 6$ and $dmft/DMFT > 6$).

No significant differences regarding sample characteristics of age, sex, location of the tooth in the arch and caries experience were found between the groups, as shown in Table 2.

The ART + Brix3000™ group required more time (8.6 ± 3.1 min) for caries removal than the ART group (4.8 ± 2.0 min) ($p = 0.002$). Differences were also found in the total treatment time ($p = 0.03$): the ART + Brix3000™ group took four minutes longer (13.14 ± 4.0 min) than the ART group (9.8 ± 2.7 min). Of the patients who received the ART + Brix3000™ technique ($n = 13$), almost half required reapplication of the product ($n = 6$). The periods of prophylaxis ($p = 0.31$) and restoration ($p = 0.13$) showed no difference between the groups (Fig. 3).

Pain experience, expressed using the FLACC-r scale, was found not to differ between the groups during each of prophylaxis, restoration and caries tissue removal (Table 3).

The acceptability ratings showed that 6 (46.2%) patients liked being treated with ART + Brix3000™, and 7 (53.8%)

liked ART. Five patients reported indifference/dislike of ART + Brix3000™ (41.7%) and 7 in ART (58.3%). No statistical difference was found regarding acceptability between the groups ($p \geq 0.26$) (Table 4).

Discussion

Traumatic emotional experiences during young patients' dental treatment could affect how they will deal with their dental problems during their entire lives and might result in avoidance of dental treatment (Leal et al. 2009). In the literature, the clinical application of Brix3000™ has been reported only in comparison with rotary instruments (Alkhouli et al. 2020; Vila-Sierra et al. 2019), but conventional methods of caries tissue removal are already associated with increased anxiety and fear in young patients. This occurs due to vibration and heat produced, which can migrate into the pulp, causing pain and a consequent negative experience (Kumar et al. 2016). The ART technique, in contrast, is known as a method that reduces child discomfort (Leal

Table 2 Description of age, sex, tooth location and caries experience of children included in the study

Variables	ART + Brix3000™ (n = 13)	ART (n = 14)	p value*
<i>Age</i>			
≤ 5 years	8	9	0.88
> 5 years	5	5	
<i>Sex</i>			
Male	6	8	0.56
Female	7	6	
<i>Tooth location</i>			
Maxilar	7	4	0.18
Mandibular	6	10	
1st primary molar	5	4	0.58
2nd primary molar	8	10	
Right molar	10	9	0.47
Left molar	3	5	
<i>Caries experience</i>			
dmft/DMFT ≤ 6	8	6	0.33
dmft/DMFT > 6	5	8	

Note: Statistical analyses were performed using Chi-Square test and the significance level was $p < 0.05$

et al. 2009). Although some studies have combined the ART approach with the CMCR technique, they have evaluated only anxiety (Topaloglu-Ak et al. 2007) and the survival of

restorations (Mandari et al. 2001). Thus, this randomised controlled clinical trial compared the ART + Brix3000™ and ART by considering the pain experience, as well as treatment duration and acceptability among children undergoing these different procedures.

Systematic reviews show that, despite being used to facilitate the selective removal of softened caries tissues, papain-based CMCR products tend to require longer dental appointments than rotary instruments (Schwendicke, 2018; Deng et al. 2018), but they also can be considered a faster option when used in isolation versus the manual excavation of ART technique (Schwendicke 2015). In this study, the ART + Brix3000™ combination proved, statistically, to require more time to remove caries tissue than the ART approach. The time increase due to Brix3000™ was expected, since this product required 2 min of direct contact with the soft carious tissue for proteolytic action (Vila-Sierra et al. 2019). Furthermore, reapplication of the product was necessary in almost half of the sample that received this type of treatment (46.1%), which directly contributed to the greater time spent. However, even if CMCR products entail greater clinical time, it can also assist professionals by guiding the selective removal of only soft, infected dentine, avoiding the unnecessary removal of further tissue, promoting the preservation of affected dentine, and reducing pulp exposure risks during the removal of carious tissue (Alkhouli et al. 2020; Busadori et al. 2005).

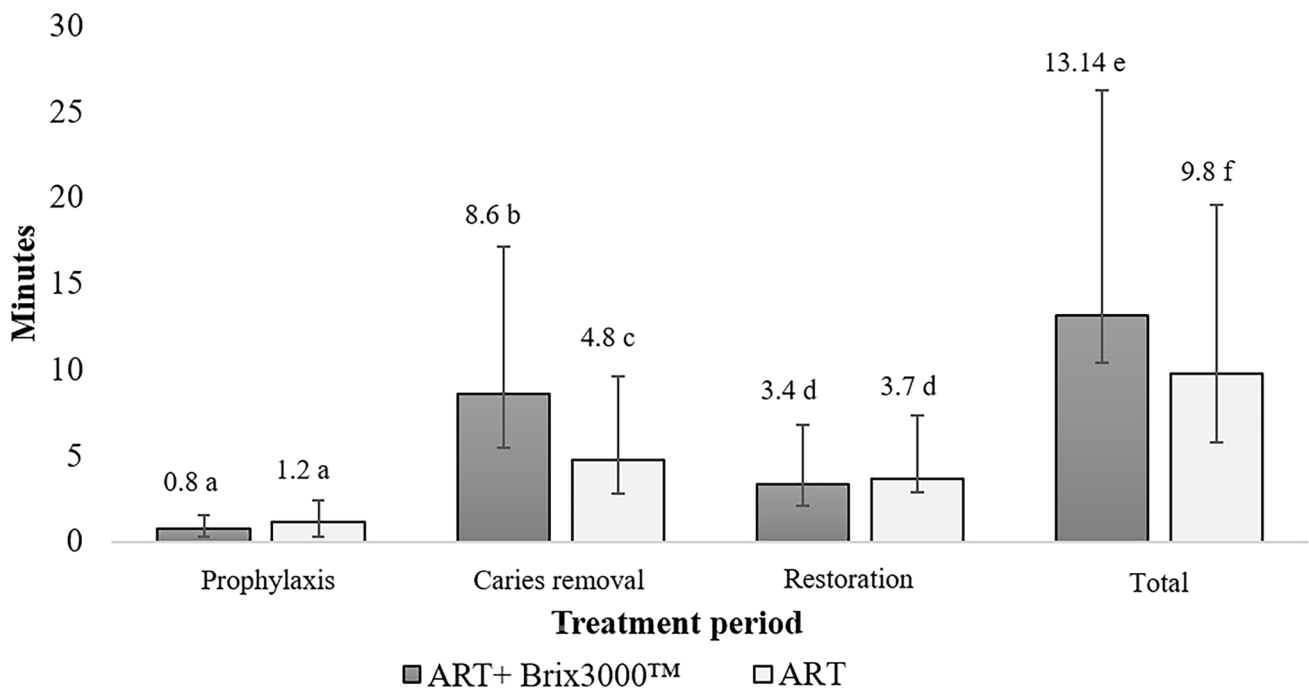


Fig. 3 Mean time of the prophylaxis, caries removal, restoration, and total of dental treatment. Statistical analyses were performed using Man-Whitney test and the significance level was considered as

$p < 0.05$. Different lowercase letters show statistically significant differences between groups

Table 3 Effect of the treatments on pain expressions by FLACC-r scale

Moments	Treatment	Mean \pm SD	Mild	Moderate	Intense	<i>p</i> value*
Prophylaxis	ART + Brix	1.15 \pm 0.55	12	0	1	0.29
	ART	1.00 \pm 0.00	14	0	0	
Caries removal	ART + Brix	1.00 \pm 0.00	13	0	0	–
	ART	1.00 \pm 0.00	14	0	0	
Restoration	ART + Brix	1.00 \pm 0.00	13	0	0	–
	ART	1.00 \pm 0.00	14	0	0	

Note: (–) Not applicable (Constant values). (*) Statistical analyses were performed using Chi-Square test and the significance level was considered as $p < 0.05$

Table 4 Patients' acceptability expressed by what they most liked and indifferent/disliked during the different treatments

Patient impressions		Brix3000™	ART	<i>p</i> value*
Liked	Prophylaxis	0	0	0.26
	Caries removal	3	1	
	Restoration	3	6	
Indifferent/ Disliked	Prophylaxis	2	1	0.77
	Caries removal	1	3	
	Restoration	2	3	

Note: (*) Statistical analyses were performed using

Fisher's exact test and the significance level was considered as $p < 0.05$

Although time is important during the dental treatment of children, other outcomes as pain and acceptability are also bases of a good experience (Schwendicke 2015). Assessment of pain in children can be difficult, especially given children's natural levels of cognitive and verbal development (Bussotti et al. 2015). The children's pain was hence assessed using the FLACC-r observational pain scale. Pain was assessed not only during caries removal, but also during prophylaxis and restoration, with the aim of observing whether they child's pain expressions differed between the treatment phases. Pain assessments between the three examiners were checked for agreement using Cohen's κ coefficient, and blinding the examiners about the aims of the study and the product used prevented bias due to prior knowledge about the experiment.

The lowest pain scores (mild pain) were found in most of the caries tissue removal procedure and during restoration, without any difference between the techniques, supporting our hypothesis that both techniques are equal in terms of pain experience. Intense pain was only found during prophylaxis in one patient. This result may be explained by the fact that rotary instruments were used only during prophylaxis, which probably caused fear and discomfort due to the vibration and sound. Other studies that evaluated pain with the use of Brix3000™, compared this technique to rotary

instruments and found a reduction in pain (Alkhouli et al. 2020; Vila-Sierra et al. 2019).

Ladewig et al. (2018) showed that chemical–mechanical caries removal involves less pain than other types of caries removal, including ART. Some randomised clinical trials (Abdul Khalek et al. 2017; Kchorar et al. 2011) compared pain related to the use of Papacárie™ to ART and other chemical caries removal products with different main chemical agents such as Carisolv™, finding better results with the Papacárie™. This may indicate the potential for painless treatment using papain enzyme-based products, such as Brix3000™, that should be investigated with large samples.

The hypothesis that there would be no difference between the groups regarding the acceptability of the techniques was also supported. In addition, the open interview question on what patients most liked and disliked during the treatments of caries lesions showed no statistically significant differences between the groups. An interesting finding was that some patients complained about caries removal using the ART approach ($n = 3$; 75%), suggesting a possibility of greater discomfort during ART without the Brix3000™ technique.

Other studies that accessed children's acceptance of papain-based products also found more acceptance for CMCR than for ART and rotary techniques (Kumar et al. 2016; Venkataraghavan et al. 2013). These findings may reflect the easier removal of decayed tissue: it is made even softer by CMCR products, thus potentially resulting in less discomfort than removal by mechanical means alone.

The absence of statistical differences in age, sex, and the treated tooth's location in the arch between the groups shows the homogeneity of the selected sample. Nevertheless, a major limitation of this study is its small sample size, which directly influences the significance, interpretation and generalisability of the results. This study should hence be considered a preliminary investigation, and any generalisation and further use of its findings should be done cautiously.

Still, this study brings original, new information about Brix3000™ as it is, to the authors' knowledge, the first randomised clinical trial that compares treatment duration, pain

and acceptability of Brix3000™ together with ART relative to purely mechanical ART technique.

Conclusion

Within the limitations of the present study, ART with Brix3000™ was found to require longer treatment times, which can be considered an inconvenience in children's dental treatment. Regarding pain and acceptability, ART technique associated with Brix3000™ showed no statistically significant difference from than isolated ART, which is well accepted by children and has been proven to reduce pain experiences during the removal of decayed tissue.

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Author contributions TFS: Designed the study, performed the experiment, analysis, interpretation and wrote the manuscript. MLM Designed the study, was responsible for the randomization of the groups, contributed for the writing of the manuscript and critically reviewed the final version. CMTS: Contributed to the training of the operator to perform the experiment. AFG: Designed the study, contributed for data conception and analysis and critically reviewed the manuscript and its final version. LCM: Designed and contributed for data conception, assisted in the selection of the sample, and critically reviewed the manuscript and its final version. All authors declare that they contributed to critical review of intellectual content and approve the final version to be published.

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Availability of data and material Not applicable.

Code availability Not applicable.

Declarations

Conflict of interest The authors declare that Brix3000™ was donated for the study but any researcher have direct connection with the company involved in the donation. Besides, the company did not interfere in the analysis and results of this research.

Ethics approval All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study was approved by the Research Ethics Committee of the Hospital Universitário Clementino Fraga Filho (HUCFF), by project 187/19 under the number 3469402, accepted on July 25, 2019.

Consent to participate Parents or legal guardian of the patients treated received detailed information about the study and signed an informed consent form. An assent term was also given to participants aged 7–9 years, explaining in a comprehensible way to the child, how their participation in the research would be and confirming the child patient's interest to collaborate with the research. After signing the consent terms, the child and their guardian received instructions on child's oral health care.

Consent for publication Not applicable.

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