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Electric toothbrush for biofilm control in individuals with Down syndrome: a crossover randomized clinical trial

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Abstract: Poor oral hygiene seems to be the norm in children and teenagers with Down Syndrome (DS). Advances in design and types of toothbrushes may improve biofilm control. This randomized, single-blind, crossover clinical trial evaluated the effectiveness of electric toothbrushes regarding mechanical control of biofilm in children and teenagers with DS and their cooperation. Twenty-nine participants with DS, aged 6 to 14 years, used both types of toothbrushes: electric (ET) and manual (MT). The order of use of the different types of toothbrushes was randomly defined, including a 7-day period with each type with 7-day washout period in between. The Turesky-Quigley-Hein biofilm index was used before and after brushing to assess the effectiveness of the technique. Frankl's behavioral scale was used during toothbrushing to assess the participants' cooperation. Paired T-test, Mann Whitney, Chi-square, and Fisher's Exact tests were applied, with a significance level of 5%. The quantity of dental biofilm was significantly reduced after both brushing techniques ($p < 0.001$). However, no significant difference was found in total biofilm (ET: 0.73 ± 0.36; MT: 0.73 ± 0.34; $p = 0.985$) or % biofilm reduction (ET: 72.22%; MT: 70.96%; $p = 0.762$) after brushing between techniques or in % biofilm reduction between toothbrushes of age groups (6 –9 years, $p = 0.919$; 10–14 years, $p = 0.671$). Participants showed similar cooperation level with the two types of toothbrush ($p = 1.000$). The use of electric or manual toothbrush had no effect on the quantity of dental biofilm removed in children and teenagers with DS, nor did it influence their cooperation during the procedure.

Keywords: Down Syndrome; Toothbrushing; Behavior; Clinical Trial.

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Introduction

Dental caries and periodontal disease are the most prevalent oral diseases in the general population. They are also preventable diseases, as long as one successfully controls supragingival biofilm growth.[1] Mechanical biofilm control is the most traditional method and its effectiveness depends on technique and the type of toothbrush used. Although it might be considered simple, mechanically controlling biofilm is relatively tedious, time-consuming, and hard to achieve, particularly for individuals with special needs,[2,3] such as individuals with Down syndrome.

Down syndrome (DS) is a genetic alteration characterized by trisomy of either all or a critical part of the 21 chromosomes.[4] Its current worldwide occurrence is one in every 1,000 newborns.[5,6] There are many barriers to provide adequate dental care to individuals with DS. Pseudo macroglossia, scalloped, protruded and/or fissured tongue, cleft palate, malocclusions, temporomandibular joint dysfunction (TMD), supernumerary teeth and reduced oral cavity dimensions are some of the oral alterations found in people with DS. All of these conditions favor the accumulation of and hinder biofilm control.[7]

The frequent health problems and intellectual disability of people with DS reduce their manual dexterity for dental biofilm control.[4] Furthermore, the family support for oral hygiene is often given a low priority in detriment of the overall health.[3] Caregivers are usually overloaded with all nature of care tasks and often neglect toothbrushing.[7] Therefore, poor oral hygiene seems to be the norm in children with DS.[8]

Two recent systematic reviews differed regarding the prevalence of caries among children with DS.[8,9] Nevertheless, a less-than-adequate periodontal condition is observed in people with DS: they have a high rate of gingival inflammation and periodontal pockets.[10,11] This is due to difficulties in controlling tongue movements and mouth opening and inadequate behavior during oral hygiene. These characteristics make manual brushing little effective and time-consuming.[12,13]

Although relatively expensive, electric toothbrushes are more efficient, easier to manipulate, and more attractive to patients. Advances in design and types of electrical toothbrushes may improve biofilm control by caregivers and users.[14] These factors can positively contribute to the cooperation of individuals with limited motor skills.[15,16]

Many studies have observed the higher effectiveness of electric toothbrushes compared with manual ones in adult and non-syndromic individuals.[2,13,16,17,18,19,20] However, evaluations in children[21] and individuals with special needs[3,22,23,24] are scarce and no study has been conducted to investigate the use of electric toothbrushes in people with DS.

The purpose of this study was to evaluate the effectiveness of normal and electric toothbrushes and the cooperation of children and teenagers with DS aged between 6 and 14 years. The null hypotheses tested were as follows: a) the two types of brushes have the similarly effective in removing biofilm, and b) the brush type has no influence on the behavior of users during toothbrushing.

Methodology

This study followed the ethical recommendations from the Declaration of Helsinki and Resolution 510/2016 of the Brazilian National Council of Health. The protocol was approved by the Research Ethics Committee (CEP) of the Federal University of Piauí (Procolol number 2.049.490/2017) and registered at the Brazilian Registry of Clinical Trials (ReBEC) (Identification number RBR-2VRQRN). This study was developed according to the Consolidated Standards of Reporting Trials guidelines (CONSORT).

Study design

This was a randomized, single-blinded and crossover clinical trial. The study participants switched treatments (electric and manual toothbrushes) after a washout period. The study took place at the Integrated Center of Special Education (CIES), a multi professional education and healthcare center specialized in individuals with special needs in Teresina, Brazil.

Study participants and sample size calculation

All individuals were enrolled at CIES at the moment of data collection, and had a medical diagnosis of Down syndrome. Medical care is provided by a neurologist who carries out physical and neurological assessment of the individuals and requests laboratory tests in order to reach a diagnosis. All individuals of the center are treated for motor function disabilities by a physiotherapist.

The inclusion criteria of the study were: having good periodontal health confirmed by the dentist responsible for the individuals' oral health care, being between six and 14 years old,[25] and having at least one tooth in each sextant. Individuals with comorbidities, allergy to the biofilm disclosing dye, and those who did not accept the use of electric toothbrushes or the clinical examination were not eligible for the study.

Sample size calculation was based on the ability to detect a difference in total biofilm after toothbrushing of 0.45, with a standard deviation of 0.5016 (greater standard deviation observed in a previous similar study[3]), a 5% significance level and a test power of 80%. A minimum of 28 participants was necessary (OpenEpi online; www.openepi.com). An additional 20% was added to the sample size in order to compensate for eventual losses. The calculation resulted in 32 participants.

Randomization

A list with the names of all individuals with DS enrolled at CIES was provided and the eligible individuals were selected (n = 70). The caregivers who agreed to participate in the study signed the consent form. The final sample consisted of 32 participants.

Each participant used one of the toothbrushes and then, after a seven-day washout period used the other type. The order of the toothbrushes was randomly assigned to each participant using BioEstat version 5.3 for Windows (Instituto Mamirauá, Tefé, Brazil) (Figure 1).

Subsequently, the caregivers were interviewed to register their sociodemographic data (age, gender, parents' schooling, and income) and habits related to oral health (toothbrushing times per day, toothpaste used, and frequency of dental consultations).

After the interview, the participants were given the toothbrush corresponding to the experimental group to which they were assigned and a toothpaste (Colgate Cavity Protection; Colgate, São Paulo, Brazil). However, no guidance was given on the brushing technique. Only in the case of electric brushes were caregivers advised about their operation and how to store them. Guidance was given that all brushings be done with the same toothpaste.

In the first evaluation period, 16 participants used conventional brushes (Dental Brush Medfio Slide Pro, Medfio, Pinhais, Brazil) and 16 used electric rotational-oscillatory brushes (Techline EDA-01, Techline, São Paulo, Brazil). In the second evaluation period, the type of brushes was inverted (Figure 2).

Calibration, pilot study and Interventions

A dentist specialist in special needs patients carried out the calibration of the examiner. For calibration, a single examiner analyzed photos of biofilm accumulation obtained from individuals linked at CIES without DS. Evaluations were performed at two different times, with an interval of 15 days. The intra-examiner agreement score was 1.00 and inter-examiner agreement score was 0.85. Then, a pilot test was conducted with seven individuals with DS to evaluate the methodology. No alteration was necessary, and those individuals were included as participants of the study.

The Quigley Hein Index (modified by Turesky et al.)[26,27] was used to quantify biofilm. Scores range from 0 to 5, where: 0 = no plaque; 1 = separate flecks of plaque at the cervical margin; 2 = a thin continuous zone of plaque (up to 1 mm) at the cervical margin; 3 = a zone of plaque wider than 1 mm but covering less than 1/3 of crown; 4 = plaque covering at least 1/3 but less than 2/3 of the crown; 5 = plaque covering more than 2/3 of the crown. The score index of the participants was quantified as mean and percentage of total biofilm.[16,19] The percent biofilm reduction for each participant was measured using the following formula: % biofilm reduction = (BTbt-BTat)/BTbt X 100, where BTbt = biofilm disclosed before toothbrushing; BTat = Biofilm disclosed after toothbrushing.

Parents/caregivers were asked not to perform oral hygiene procedures 23 to 25 hours before each evaluation, for the purpose of intentional biofilm accumulation. This recommendation was reinforced through a telephone call, on the eve of the clinical examination, when the researcher confirmed the participant's presence for the appointment.

For biofilm disclosure, a basic fuchsin dye solution (Replak®, Dentsply, York, USA) was used before and after each toothbrushing. The solution was applied with swabs on the buccal surfaces of all teeth. The biofilm measurements occurred before and after each brushing performed by the caregivers with the participants in a dental chair under a light reflector and using a flat mouth mirror.

The caregivers were advised that brushing should last around 2 min. During the clinical examinations,

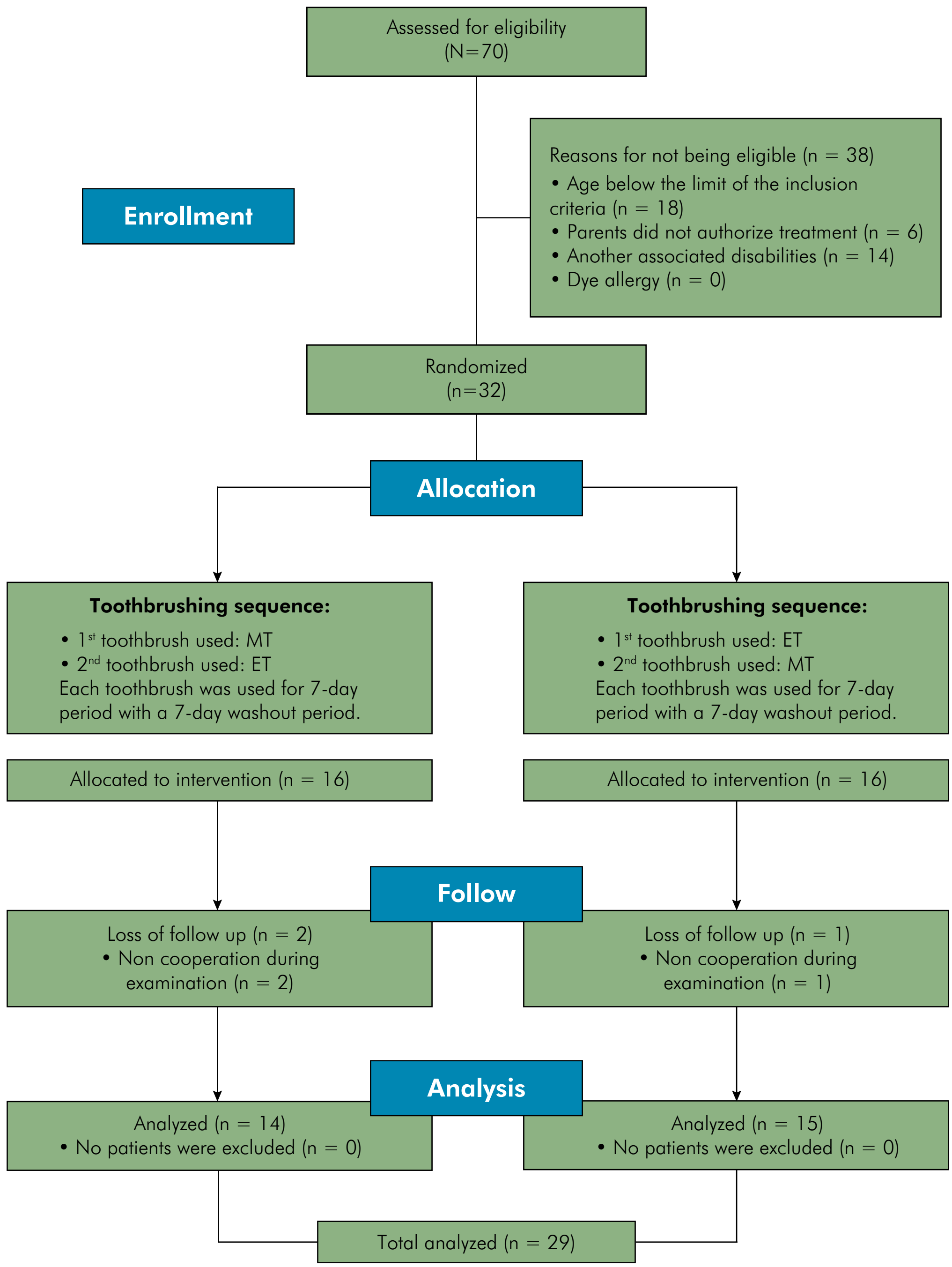


Figure 1. Flow chart of the study recruitment and interventions.

the examiner measured the brushing time and verified that it followed the recommendation, with minimal variations.

On the exam day participants were asked to perform the same technique as they had done during the seven previous days. Then, the toothbrush that had been used was collected and the participant had a seven-day washout period, during which caregivers returned to their usual toothbrushing practice. After the washout period, the participant attended the study site to receive the other type of toothbrush. The second toothbrush was also used

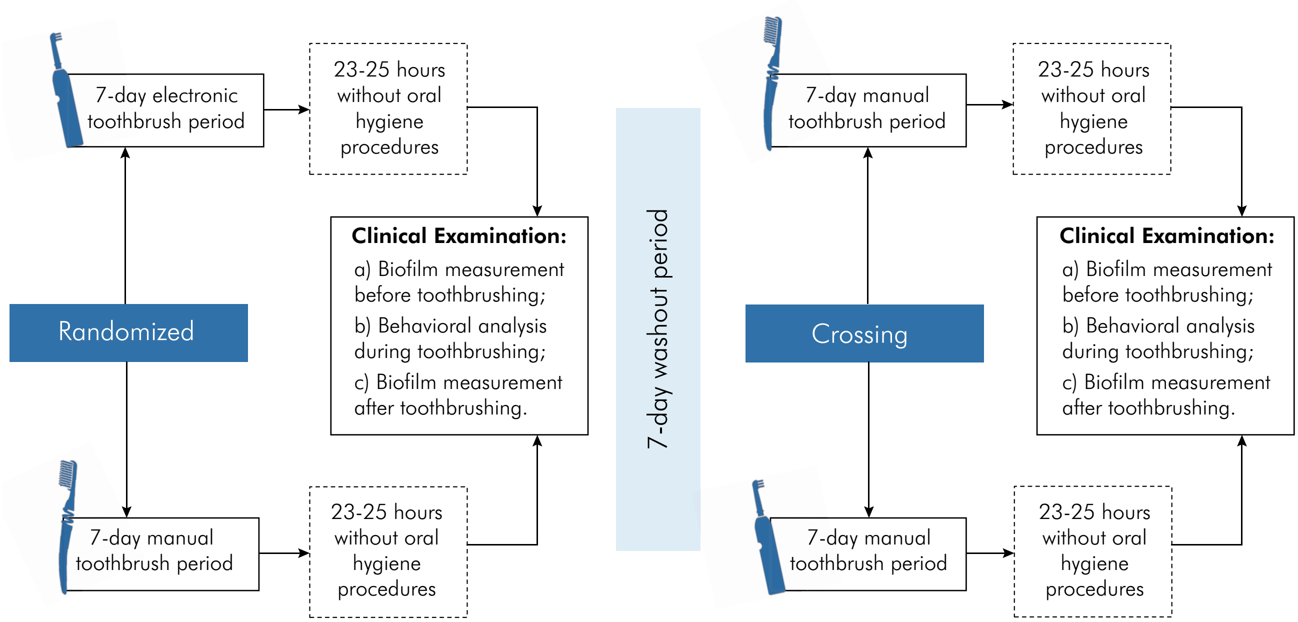


Figure 2. Flow chart of the experimental design.

for seven days, after which the participant returned for a new clinical examination and measurement of dental biofilm. The same precautions were adopted to confirm the appointment, to reinforce the biofilm accumulation period of 23 to 25 hours, and to disclose and measure the biofilm before and after toothbrushing.

Behavioral assessment was carried out using the Frankl Behavior Scale[28] with the two types of toothbrushes during brushing on the day of the clinical examination for biofilm measurement. The scale scores range from 1 to 4, as follows: 1 - definitely negative behavior; 2 – negative behavior; 3 – positive behavior, and 4 - definitely positive behavior. This variable was dichotomized as non-cooperative behavior: scores 1 and 2; and cooperative behavior: scores 3 and 4. The measurements took place in a calm and quiet room, which consisted of an individual dental office, equipped with air-conditioning due to the hot local climate and with as few people as possible inside, in order to minimize the external factors that could interfere in the behavioral analysis.

At the end of the experiment, manual brushes were donated to the participants, and caregivers were guided on the correct brushing and biofilm control technique. This is a routine practice adopted at CIES for all patients seeking dental care.

Outcomes, blinding and statistical analysis

This study's primary outcome was biofilm reduction after toothbrushing. The secondary outcome was the participants' behavior during toothbrushing, which made it impossible to mask the type of toothbrush used by the participants.

Statistical analysis was blindly carried out regarding the evaluated groups. A descriptive data analysis was conducted, and data were presented as frequency, percentage, mean, standard deviation, median and interquartile interval. The Shapiro Wilk test was applied for normality assessment and quantitative variables' distributions. Data were analyzed using the software Statistical Package for Social Sciences (SPSS for Windows, version 21.0, SPSS Inc. Chicago, USA).

Normal distribution was observed for total biofilm score and non-normal distribution, for % biofilm reduction. The Student's paired T-test was used to compare the biofilm mean before and after brushings with the two kinds of toothbrushes. Student's T-test was used to compare the types of toothbrush. Mann Whitney test was used to analyze biofilm reduction after toothbrushing. Fisher's Exact test was used to assess the association between the type of behavior and the type of toothbrush. To measure intra- and inter-examiner agreement, an interclass correlation test for calculation of total biofilm after brushings was used. All of the analyses were carried out at significance level $p < 0.05$.

Results

Thirty-two participants were randomly assigned to the study. One participant was excluded for not cooperating during the initial biofilm evaluation and was subsequently replaced. Three participants were excluded from the data analysis because they were below the age limit of the inclusion criteria. Thus, data from 29 participants who completed the two evaluation periods between May and July 2017 were analyzed.

Table 1 presents the sociodemographic variables of the sample. The majority of participants were female (62.1%) with a mean age of 9.03 years (SD = 2.67). Most of the parents (79% of mothers and 72% of fathers) had more than 11 years of formal schooling, which corresponds to high school in Brazil. The monthly income of 93.1% of participants' families was higher than one Brazilian minimum wage. Most of the participants (65.5%) reported that they usually carry out three or more daily toothbrushings and all of them had previously been to a dental consultation.

Table 1. Socioeconomic data and oral health habits of children and teenagers with Down syndrome.

Variables	n	%
Gender		
Male	11	37.9
Female	18	62.1
Age group		
6–9 years	17	58.6
10–14 years	12	41.4
Mother's schooling		
< 11 years	6	20.7
> 11 years	23	79.3
Father's schooling		
< 11 years	8	27.6
> 11 years	21	72.4
Per capita income		
< 1 MW	2	6.9
> 1 MW	27	93.1
Daily toothbrushing frequency		
up to 2	10	34.5
3 or more	19	65.5
Who performs toothbrushing		
Mother	15	51.7
Participant + caregiver	13	44.8
Another caregiver	1	3.5
Cooperates during toothbrushing		
Yes	24	82.8
No	5	17.2

Table 2 shows the mean reduction of biofilm after brushing, according to the type of toothbrush used. There was a significant decrease of biofilm after brushing ($p < 0.001$), but there was no difference in biofilm before (ET: 2.39 ± 0.62; MT: 2.25 ± 0.58; $p = 0.390$) or after (ET: 0.73 ± 0.36; MT: 0.73 ± 0.34; $p = 0.985$) toothbrushing between toothbrush type. The use of ET resulted in a decrease in biofilm greater than 70% in the majority of participants, with no significant difference compared with a MT ($p = 0.762$).

Analysis by age group also showed no difference between toothbrush types. Figure 3 shows that regardless of age group, the % biofilm reduction of both brushes remained at approximately 70% (6–9 years, $p = 0.919$; 10–14 years, $p = 0.671$).

Table 3 shows that there was no significant difference in the behavior during brushings with the two types of toothbrushes ($p = 1.000$). No adverse effects were reported or observed during the study.

Discussion

Mechanical biofilm control, consumption of free sugars, socioeconomic factors, and family and personal habits are determinant factors for dental caries incidence.[29,30,31,32] A negligent oral hygiene during childhood and adolescence can have several negative impacts, potentially affecting an

Table 2. Analysis of total biofilm (mean ± SD) before and after toothbrushing and the percent reduction of biofilm (median (25th-75th percentile)) after toothbrushing using the Quigley–Hein biofilm index.

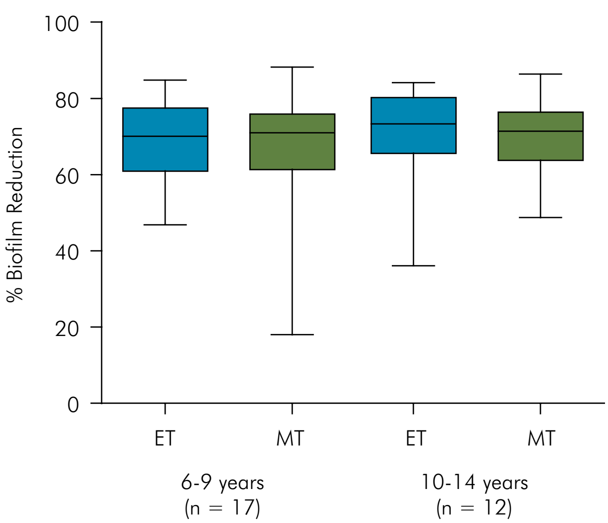
Toothbrushing	n	Biofilm before toothbrushing	Biofilm after toothbrushing	p-value	Reduction of biofilm (%)
Electric	29	2.39 ± 0.62	0.73 ± 0.36	< 0.001[a]	72.22 (60.82–78.21)
Manual	29	2.25 ± 0.58	0.73 ± 0.34	< 0.001[a]	70.96 (62.63–75.80)
p-value		0.390[b]	0.985[b]		0.762[c]

[a]Paired T-Test; [b]Student's T-test; [c]Mann-Whitney test.

Table 3. Distribution of the sample according to behavioral analysis during use of electric and manual toothbrushes by children and teenagers with Down syndrome.

Toothbrushing	n	Behavior		p-value
		Non-cooperative n (%)	Cooperative n (%)	
Electric	29	4 (13.8)	25 (86.2)	1.000[a]
Manual	29	5 (17.2)	24 (82.8)	

[a]Fisher's test.



ET: Electric toothbrush; MT: Manual toothbrush; No significant difference was observed (6–9 years, p = 0.919; 10–14 years, p = 0.671; Mann-Whitney test).

Figure 3. Percent biofilm reduction by age group and toothbrush type.

individual's quality of life.[33,34] Although gingivitis rarely develops into periodontitis during childhood, untreated gingivitis is a determining factor for bone loss during adulthood.[35]

Novel strategies to prevent oral biofilm-dependent diseases for individuals with special needs are desirable because those individuals present behavioral difficulties during clinical procedures.[4,21] In this study, electric and manual toothbrushes had a similar efficiency in reducing dental biofilm. Furthermore, there was no difference in behavior during toothbrushing with the two toothbrushes. Thus, both null hypotheses were accepted.

Brushing practices are considered effective as long as they lead to a biofilm reduction greater than or equal to 60%.[27] In this study, children and teenagers with DS, had a biofilm decrease greater than 70% with the two types of brushes The biofilm reduction observed was higher than that observed in other studies with normotypical individuals who used electric toothbrushes,[19,20] but similar to the results observed with individuals with motor difficulties, intellectual disability,[3,23,24] and pediatric patients.[21]

Ferraz et al.[3] observed that the use of electric toothbrushes enabled biofilm reduction similar to the use of manual toothbrushes in children and teenagers with cerebral palsy whose oral hygiene procedures were performed by caregivers. However, a study with normotypical children responsible for their own toothbrushing reported a superior effectiveness of electric toothbrushes for biofilm control.[21] These results suggest that electric toothbrushes positively impact normotypical children and teenagers, but probably the impact is not as pronounced in individuals with special needs or their caregivers. This could also be the case with our results.

No study has assessed whether the order of using different types of toothbrushes in a crossover study design changes the effectiveness of biofilm control. In this study, the order of toothbrushes did not affect biofilm reduction. We had an expectation that participants who used the electric toothbrush in the first experimental period would have a greater reduction in biofilm due to a possible motivation of using a different and technologically enhanced device. However, toothbrushing was carried out by the participants' caregivers and the impact of using a new device tends to be lower in adults than in children and adolescents. This may explain why there was no difference between groups.

The participants in this study were monitored by an oral health promotion program that develops educational and preventive activities, and this may also have influenced the effectiveness of the brushing performed by caregivers. As a protocol of this program, oral hygiene instructions are routinely provided to patients with intellectual disabilities and their caregivers, and this contributes to a significant biofilm reduction with manual brushing.[23] This reinforces the importance of establishing oral health promotion programs for individuals with special needs, for whom invasive treatment may be more complex. In addition, the long-term insertion of participants and their caregivers in an oral health promotion program, with toothbrushing performed by caregivers even in older ages explains the absence of difference between biofilm control strategies in different age groups. However, during the period of the study the caregivers were asked not to take part in any activities provided by the above-mentioned program.

Oral hygiene procedures are often considered time consuming and problematic in individuals with special needs, due to inadequate behavior and lack of cooperation. One example is keeping the mouth open during hygiene procedures.[36] Electric toothbrushes tend to be more attractive and result in more positive attitudes during oral hygiene procedures in individuals with special needs.[36-38] However, in this study, most of the participants showed a similar cooperation during the use of the two types of toothbrush, in other words, the type of toothbrush was not a behavior determinant.

The duration and movements of toothbrushing are the best predictors of good oral hygiene.[39] This would justify the superior effectiveness of electric toothbrushes in studies with normotypical children and teenagers who brush their own teeth, as the attractiveness of the device may act as a motivation, increasing the duration of brushing and compensating for the low manual dexterity observed when using manual toothbrushes that limits the effectiveness of biofilm removal.[40]

However, when caregivers are responsible for the oral hygiene, these effects are less pronounced.[3] Although the use of electric toothbrushes facilitates and speeds up oral hygiene procedures, the positive impact on behavioral cooperation during toothbrushing had no significant effect on biofilm reduction when compared with a manual toothbrush.

The caregivers did not receive specific instructions on toothbrushing technique as it could bias the study results, since the analysis of the biofilm removal would have to be attributed to the combination of type of toothbrush and brushing technique. For this reason, caregivers were instructed to brush as usual, in order to allow the effect of the different brush types alone to be measured.

In this crossover study, participants acted as their own controls, increasing the efficiency and accuracy of the study and minimizing the inter-individual variation.[38] The adoption of a washout period similar to the experimental period, in order to minimize treatment bias, eliminated residual effects from the previous experimental period. The evaluation by a trained and calibrated researcher for the adopted index increased the internal validity of the study, avoiding possible measurement biases. Blinding during statistical analysis of the results aimed to reduce any possible detection bias.[38] Treatment bias was reduced by not giving any oral hygiene information to the participants.

However, the selection of a sample from a single institution has an effect on the external validity[38] and reduces the generalizability of these results for individuals with DS in other age groups and who do not have access to health services and programs. Randomization among eligible participants and the random allocation of groups strengthened the methodological rigor of this study, reducing confounding and selection biases, so that risks and benefits were equally distributed, and participants had the same chance of being allocated in either group.

Our study provides professionals and caregivers with the ability to confidently decide on the methods to be adopted for oral hygiene practices, taking into account costs and benefits, because electric toothbrushes are expensive and would be an added cost to the already high expenses of a family of an individual with DS.

Conclusion

Based on this study's results, it can be concluded that electric and manual toothbrushes are similarly effective for the removal of biofilm. Children and teenagers with Down syndrome were cooperative with both types of mechanical dental biofilm control.

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