

ORIGINAL RESEARCH

Plaque removal efficacy of an innovative U-shaped power toothbrush: a pilot study

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Abstract

Background: This study evaluated the plaque removal efficacy of a novel U-shaped sonic power toothbrush compared to a manual soft toothbrush. **Methods:** Twenty-two children (aged 5–8 years) participated in an examiner-blinded, two-period crossover trial. Each child used a standard soft manual toothbrush (for 2 minutes) and the U-shaped AutoBrush® device (for 30 seconds) in random sequence, with each use separated by a two-day at-home washout period. Before each brushing, dental plaque was disclosed and scored using the Lobene-Soparkar Modification of the Turesky–Quigley–Hein Plaque Index. After 12–16 hours of no oral hygiene, baseline plaque levels were recorded, followed by supervised brushing with the assigned toothbrush and a post-brushing plaque assessment. Plaque reduction (whole-mouth and hard-to-reach sites) was analyzed by baseline-adjusted Analysis of Covariance (ANCOVA). **Results:** All 22 participants (13 males, 9 females), average age of 6.5 years (± 1.1), completed both study periods with no product-related adverse events; both toothbrushes were well tolerated. Both the manual and U-shaped toothbrush significantly reduced plaque from baseline on a whole-mouth level ($p < 0.001$). However, the manual toothbrush showed minimal plaque reduction at certain areas (e.g., proximal and lingual surfaces), whereas the U-shaped toothbrush achieved substantial plaque removal across all regions. The U-shaped toothbrush yielded significantly greater mean plaque reductions than the manual brush for whole mouth, (all facial and lingual tooth surfaces), (50.6%), gumline (71.2%), proximal (40.7%) and other difficult-to-clean sites ($p < 0.001$). **Conclusions:** A 30-second brushing with the U-shaped sonic toothbrush was significantly more effective at removing plaque in children than a 2-minute brushing with a standard manual toothbrush, including at hard-to-reach sites. These findings suggest that the innovative U-shaped powered toothbrush may help improve oral hygiene efficiency for young children. **Clinical Trial Registration:** NCT06300073, <https://classic.clinicaltrials.gov/ct2/show/NCT06300073>.

Keywords

Toothbrushing; Child; Dental devices; Home care; Oral hygiene; Cross-over studies; Dental plaque; Mouth

1. Introduction

Dental caries remains one of the most prevalent chronic diseases in children worldwide [1]. A major contributing factor is the insufficient removal of dental plaque, which harbors cariogenic bacteria. Effective toothbrushing is critical for plaque control and caries prevention from early childhood [2, 3]. Yet the global incidence of caries in permanent teeth has consistently remained elevated among children aged 5 to 14 years from 1990 to 2019 [4]. This data suggests the necessity of enhancing oral home care techniques and guidelines. While most professional dental organizations agree that daily toothbrushing with a fluoride containing toothpaste is essential for the pediatric population, there has been no global professional consensus on toothbrushing techniques and behaviors, such

as frequency and duration [5, 6]. Recent work by Glenney *et al.* [5], presented international professional recommendations for oral hygiene practices for adults and children. Strong recommendations were provided to brush teeth twice daily with fluoride toothpaste containing at least 1000 ppm fluoride and the last brushing should occur at bedtime. The duration of brushing was not definitive except to recommend to brush long enough to ensure that all tooth surfaces are cleaned effectively, which may take around two minutes. No specific recommendations were provided regarding the best toothbrush or brushing technique. The recommendation for device type was undefined, suggesting that individuals may use either powered or manual toothbrushes, as effectiveness is contingent upon user technique.

There is no clear evidence for the most suitable toothbrush

types or brushing techniques that can address the needs of pediatric populations of varying ages, levels of fine motor skills and interest in home care compliance. Researchers recognize that barriers to toothbrushing efficiency in young children have been attributed to challenges with manual dexterity, parental supervision, motivation, toothbrushing duration and cooperation [7–10]. These challenges have stimulated interest in the design of powered toothbrushes aimed at improving plaque removal efficiency in pediatric populations [11].

Systematic reviews have determined that powered toothbrushes, such as oscillating-rotating and sonic movement brush heads, offer superior plaque reduction compared to manual brushes in both adults and children [12–14]. Graves *et al.* [13] examined pediatric populations that included 38 studies, 11 orthodontic and 27 non-orthodontic patients, with ages that ranged from 2 to 17 years. Davidovich *et al.* [14] conducted a systematic review and meta-analysis on plaque reduction in nine studies involving non-orthodontic pediatric populations aged 4 to 13 years over 2 to 12 weeks. They concluded that power toothbrushes achieved better plaque removal than manual toothbrushes. In these reviews, post-brushing plaque removal was not completely achieved, ranging from 0.23% to 35.4%. These findings highlight the opportunity to develop tools to enhance plaque removal efficiency and motivation among children of different age groups.

Designs and models of power toothbrushes have evolved over the past few decades with the objective to improve user motivation and plaque removal efficiency. Innovations have focused on changes in brush head sizes, ergonomic handles for better grip and comfort, variable modes of action, and applications that assist with user instructions and feedback to improve cleaning in different areas of the mouth. Recently, U-shaped automatic toothbrushes have been marketed for children and adults, promising to clean all tooth surfaces simultaneously in a short time, usually within 5 to 60 seconds. In theory, these devices may assist children achieve better plaque removal with less technique-sensitive effort. Recent studies on these devices in adults have shown varied outcomes [15–19]. Two studies assessed the efficacy of different U-shaped automatic toothbrushes using a single-use, two-period crossover design. The findings indicated that U-shaped brushes equipped with silicone bristles were not effective in plaque removal when compared to manual toothbrushes or even to no brushing [15, 16]. The effectiveness of plaque removal by a Y-shaped toothbrush design has produced varied results. In single-use crossover studies, the two-sided design (covering both the upper and lower arches) did not demonstrate significantly better plaque removal compared to a manual toothbrush [17, 18]. In a recent 30-day study, the Y-shaped automatic brush reduced plaque levels at Days 7 and Day 30 compared to baseline. However, there were no differences compared to the sonic toothbrush at any timepoint [19]. These initial observations could indicate design deficiencies in the product that may have led to its inadequate plaque removal effectiveness. Several design factors have been identified that may need consideration such as adequate bristle alignment, choice of bristle composition, fit accuracy with diverse dental arches and sufficient brushing duration [15–19].

The purpose of this feasibility study was to evaluate the

plaque removal potential of an innovative U-shaped sonic toothbrush (AutoBrush® 360°) in 5- to 8-year-old children, compared to an American Dental Association (ADA) standard manual soft bristle toothbrush. We also monitored safety and tolerance of the new device.

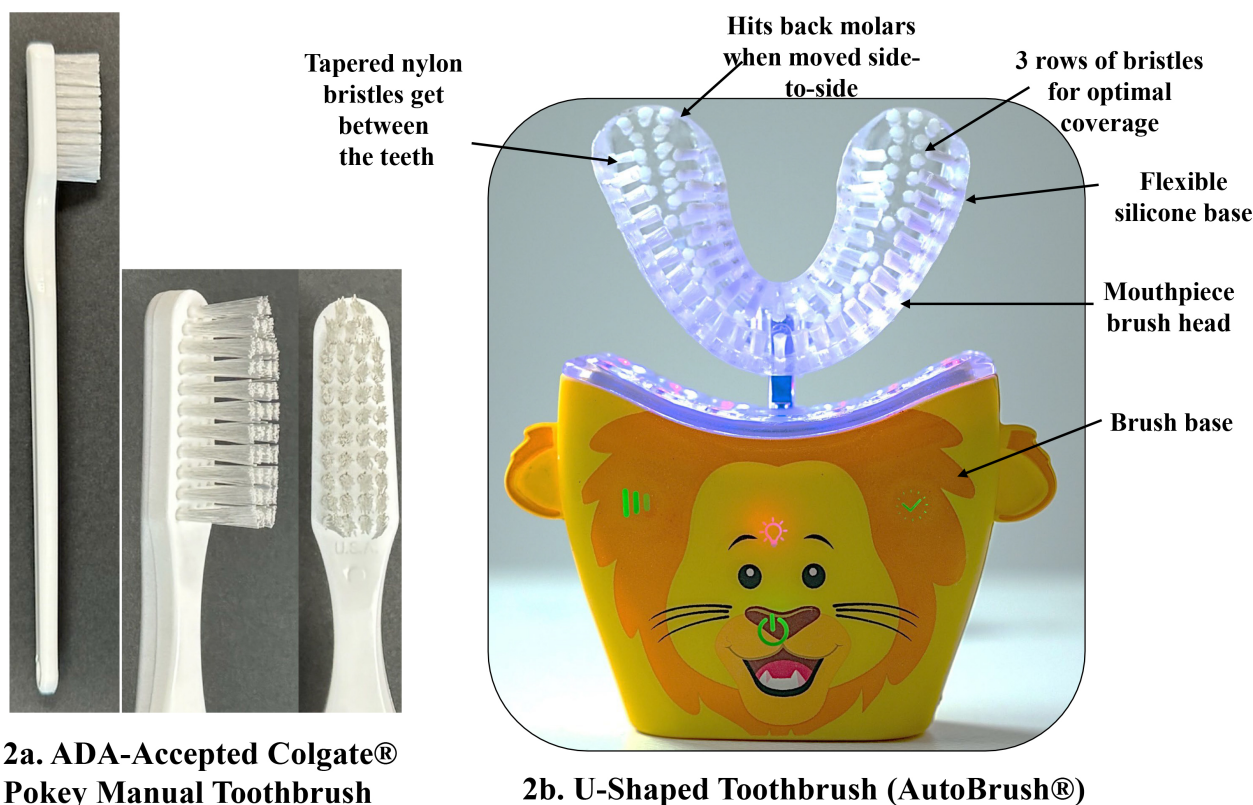
2. Materials and methods

2.1 Study design and participants

This trial was a single-center, examiner-blinded, randomized two-period crossover clinical study design. The study was conducted in accordance with the International Conference on Harmonization Good Clinical Practice Guidelines (ICH-GCP) E6(R2). Prior to the initiation of the study, the protocol, informed consent document, assent document and subject instructions received ethical review and approval from U.S. Investigational Review Board, Inc., an appropriately constituted Institutional Review Board (IRB) as outlined in U.S. 21 CFR Part 56 and is registered with the US Department of Health and Human Services (DHHS) as #IRB00007024. After receiving both consent from parent or guardian and assent from the child, we enrolled 22 healthy children, aged 5–8 years, in this study during 14 February to 17 February 2022. Participants were included if they were regular manual toothbrush users, able to brush their own teeth, had at least 12 natural teeth with facial and lingual scorable surfaces, a baseline plaque index score ≥ 1.8 according to the Lobene-Soparkar Modification of Turesky Modified Quigley-Hein Plaque Index (LSPI) [20, 21] after refraining from oral hygiene for 12–16 hours. Tooth count did not include partially erupted permanent teeth and primary teeth that were in the process of exfoliation. Children were excluded from the study if they had sensitivities or allergies to toothpaste ingredients, presence of grossly carious, fully crowned or extensively restored teeth, orthodontic appliances, or any health condition that could affect oral hygiene or study compliance. By using a crossover design, each child served as their own control to enhance statistical power despite a relatively small sample size.

Participants were randomly assigned to one of two sequence groups: the AutoBrush® 360° (AB) in the first treatment period followed by the ADA-accepted manual toothbrush (MTB) in the second period, or MTB in the first period and AB in the second period. The crossover period was followed by a two-day washout period which is a sufficient time to control for the influence of the previous toothbrush assignment and limit the potential for a carryover effect. During the washout period, the children brushed in their usual manner with the ADA standard manual toothbrush and Crest® Cavity Protection fluoride toothpaste. After each washout period, participants returned to the clinic having abstained from any oral hygiene for the previous 12–16 hours (to allow plaque accumulation) and did not eat 30 minutes prior to the visit. The main clinical activities are presented in Fig. 1 for the crossover study design.

Oral safety was monitored to detect any adverse deviations from baseline that might be related to the toothbrushes or that occurred in the oral cavity irrespective of cause, and included any adverse changes in the subject's medical and/or dental



2a. ADA-Accepted Colgate® Pokey Manual Toothbrush

2b. U-Shaped Toothbrush (AutoBrush®)

FIGURE 2. Images of the two toothbrush products. (2a) Colgate Pokey ADA-accepted standard soft bristled, flat trimmed, manual toothbrush. (2b) U-Shaped AutoBrush® sonic power toothbrush with two-sided mouthpiece that is designed in various sizes based on individual ages.

facial gumline and lingual gumline. A single qualified and experienced examiner performed all plaque assessments at each visit. After the baseline evaluation, each child brushed with the assigned toothbrush in front of a mirror and under direct supervision of study staff. The brushing procedures were performed out of the view of the study examiner and data recorder to maintain examiner blinding to the assigned toothbrush. Post-brushing plaque scores were then recorded using the same plaque index. After the first period, participants crossed over to the alternate toothbrush, preceded by its 2-day washout period. An overnight no-brushing period, and the same measurements were repeated for the 2nd period exams.

2.4 Sample size and statistical analysis

A sample size of 20 subjects per group in this study was estimated to provide 90% power to detect a treatment difference in whole mouth plaque reduction of 0.4 with an observed variability of 0.7, based on a two-sided test at the 5% significance level.

Plaque reduction from baseline was calculated for each toothbrush for whole mouth surfaces and each of the 8 hard-to-reach site categories. Within-group comparisons were performed by comparing pre- and post-brushing mean LSPI scores using paired *t*-tests. Because each subject experienced both toothbrush conditions, a crossover analysis was employed. An analysis of covariance (ANCOVA) was used to compare post-

brushing plaque scores between the U-shaped toothbrush and the manual toothbrush, adjusting for baseline plaque scores. The model included terms for treatment (brush type), period, sequence and subject (random effect). Statistical significance was set at $p < 0.05$ (two-sided). Post ANCOVA pairwise comparisons between the U-shaped toothbrush and the manual toothbrush control were made using a two-sided Dunnett's test, which controls the error rate for the simultaneous comparisons.

The crossover design inherently controlled for inter-subject variability, increasing the power to detect differences with a smaller sample size [22]. No carryover effect was observed, as plaque levels returned to baseline levels after each no-hygiene period. Safety was assessed by monitoring adverse events or oral tissue abnormalities at each visit.

3. Results

3.1 Participant characteristics

There were no withdrawals from this study; all 22 enrolled children completed both brushing periods. Demographic information is presented in Table 1. The mean age was 6.5 years (± 1.1), with 59.1% males and a majority of children were white (86.4%) and all were non-Hispanic and non-Latino. Baseline plaque levels achieved after the overnight no-brushing period were ≥ 1.8 , by design, and did not differ significantly between the two sequence groups, indicating successful randomization and no significant carryover.

3.2 Plaque evaluations

The pre-brushing (baseline) average whole mouth LSPI scores were similar for both toothbrushes, 3.5 for the manual toothbrush and 3.4 for the AutoBrush® (AB). Both toothbrushes produced a statistically significant reduction in mean whole mouth plaque scores after a single-use brushing ($p < 0.001$ for AB, $p = 0.025$ for MTB). Compared to baseline pre-brushing levels, whole mouth plaque reductions for AB was 50.6% ($p < 0.001$) whereas MTB achieved a 1.9% reduction ($p = 0.025$). See Table 2 for a summary of the within group comparisons of pre- to post-brushing whole mouth plaque reductions. We observed significant reductions from baseline in plaque scores for AB for all hard-to-reach sites that ranged from 38.4% to 72.0% ($p < 0.001$). Changes from pre-brushing scores for MTB ranged from -2.6% to 7.1%. These changes were statistically significant for only four of the hard- to-reach sites (gumline, facial, facial gumline and facial proximal), $p < 0.05$. Mean post-brushing reductions are illustrated in Fig. 3.

Statistical analysis confirmed that AB's plaque reductions were significantly greater than the MTB for all endpoints (whole mouth, gumline, proximal, facial, lingual, facial gumline, lingual gumline, facial proximal, lingual proximal), $p < 0.001$ (Table 3).

3.3 Safety results

There were no adverse events reported or oral abnormalities observed during this short-term study. Both toothbrushes were well-tolerated.

4. Discussion

This randomized, single-use crossover, examiner-blind feasibility clinical study with 22 children aged 5–8 years, demonstrated significant plaque removal with a U-shaped Sonic Toothbrush compared to the ADA accepted manual toothbrush. The U-shaped brush demonstrated significantly greater plaque reductions for whole mouth surfaces (50%, $p < 0.001$) and in all hard-to-reach areas compared to the manual brush, with the most notable benefit being a 70% reduction in all gumline regions, $p < 0.001$. Brushing with MTB lowered whole-mouth plaque scores from baseline with reductions ranging from 1.9% for whole mouth surfaces to 7.1% in the facial gumline sites. Plaque levels at the proximal and lingual surfaces were not significantly reduced after manual brushing for two minutes, reflecting the challenges children have in cleaning those areas thoroughly. In contrast, the U-shaped toothbrush (30-second use) achieved significant plaque removal across all evaluated tooth sites, particularly in areas that prove difficult to reach with a manual toothbrush. Superior plaque removal efficacy of power toothbrushes has been observed in several short-term studies. A two-period, single use, examiner-blind study was conducted in children 8 to 11 years of age to evaluate the plaque removal effect of an oscillating-rotating electric toothbrush compared to a manual toothbrush [23]. Based on the six-surface plaque measurement with the Turesky Modification of the Quigley-Hein Plaque Index [20], plaque scores were analyzed for permanent and mixed dentitions. The oscillating-rotating brush removed 7.5% more plaque in permanent dentitions and 12.9% more in

TABLE 1. Demographic characteristics.

	Mean (S.D.)	Minimum–Maximum
Age, yr (S.D.)	6.5 (1.10)	5.0–8.0
	Frequency	Percentage
Gender		
Male	13	59.1%
Female	9	40.9%
Race		
White	19	86.4%
African American	2	9.1%
Native Hawaiian/Pacific Islander/Other	1	4.5%
Ethnicity		
Non-Hispanic/Non-Latino	22	100.0%

S.D.: standard deviation.

TABLE 2. Comparison of whole mouth LSPI scores.

Group	Pre-brush (S.D.) ¹	Post-brush (S.D.)	% Reduction ²	p-value ³
MTB	3.5 (0.35)	3.4 (0.34)	1.9%	0.025
AB	3.4 (0.36)	1.7 (0.52)	50.6%	<0.001

¹Unadjusted mean (standard deviation) for LSPI score. No significant difference in baseline plaque scores.

²Calculated as (pre-brush score minus post-brush score) divided by pre-brush score.

³Within-group p-value comparing the post-brush mean score versus the pre-brush mean score.

MTB: manual toothbrush; AB: AutoBrush®; S.D.: standard deviation.

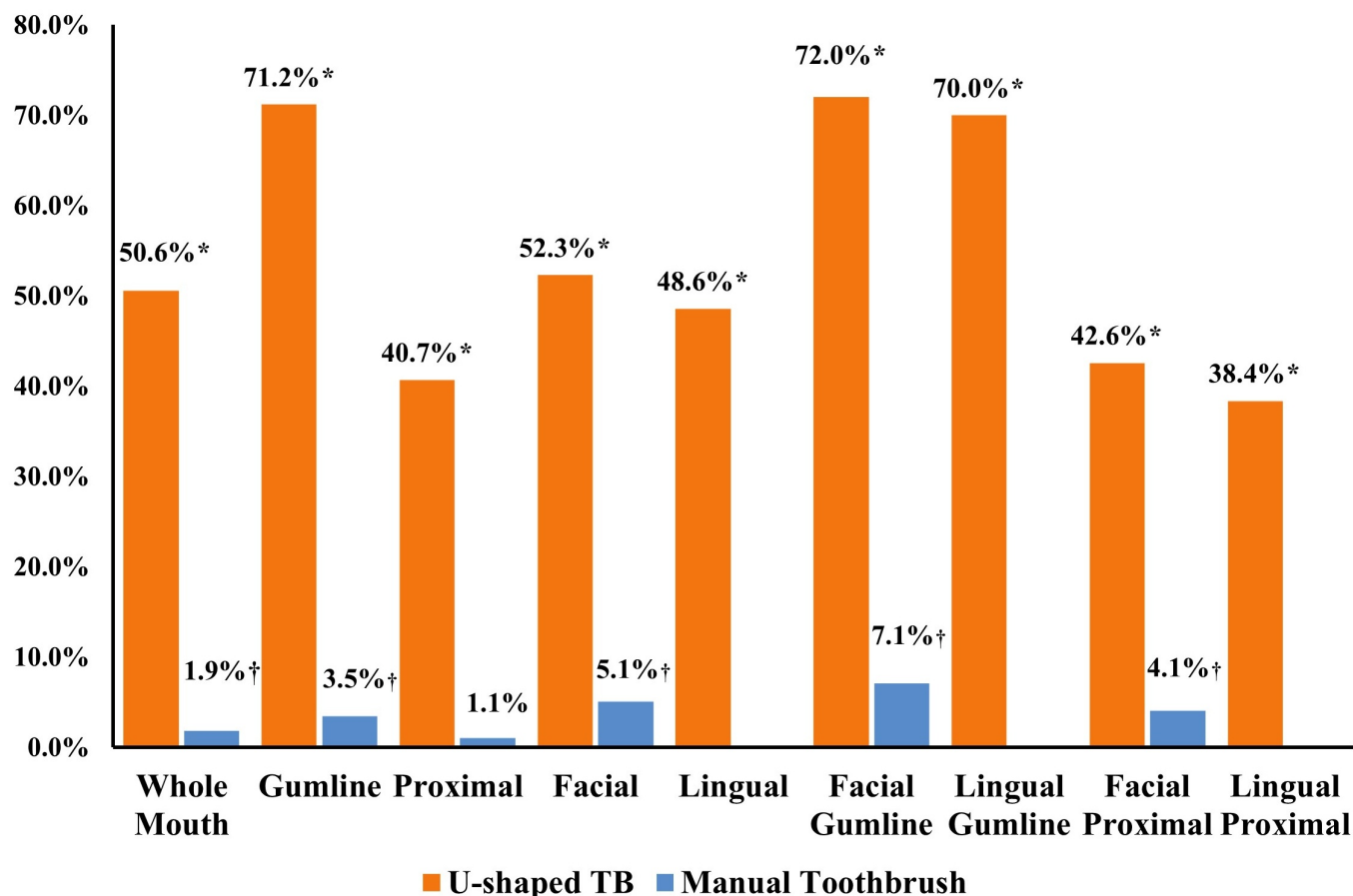


FIGURE 3. Mean post-brushing LSPI percent reductions: whole mouth and hard-to-reach sites. *Significant difference from pre-brushing for U-shaped toothbrush, $p < 0.001$. †Significant difference from pre-brushing for Manual Toothbrush, $p < 0.05$. TB: Toothbrush.

TABLE 3. Differences between toothbrushes: post-brushing mean whole mouth and hard-to-reach areas (summary of ANCOVA results).

Variable	Post-Brushing (s.e.)		Between Treatment Difference (s.e.) [†] (p -value) [*]	2-Sided 95% Conf. Interval [‡]	Between Treatment Difference (%) [⌣]
	MTB	AB			
Whole Mouth	3.4 (0.07)	1.7 (0.11)	1.7 (0.08) (<0.001)	(1.5, 1.8)	50.0%
Gumline	3.3 (0.08)	1.0 (0.10)	2.3 (0.09) (<0.001)	(2.1, 2.5)	69.7%
Proximal	3.5 (0.07)	2.1 (0.13)	1.4 (0.08) (<0.001)	(1.2, 1.5)	40.0%
Facial	3.7 (0.10)	1.8 (0.15)	1.8 (0.11) (<0.001)	(1.6, 2.1)	51.4%
Lingual	3.1 (0.07)	1.6 (0.10)	1.5 (0.07) (<0.001)	(1.3, 1.7)	48.4%
Facial Gumline	3.6 (0.11)	1.1 (0.14)	2.5 (0.13) (<0.001)	(2.2, 2.7)	69.4%
Lingual Gumline	3.0 (0.07)	0.9 (0.10)	2.1 (0.09) (<0.001)	(1.9, 2.3)	70.0%
Facial Proximal	3.8 (0.04)	2.2 (0.16)	1.5 (0.12) (<0.001)	(1.2, 1.7)	42.1%
Lingual Proximal	3.2 (0.08)	1.9 (0.11)	1.3 (0.07) (<0.001)	(1.1, 1.4)	40.6%

s.e.: standard error of the mean; MTB: manual toothbrush; AB: AutoBrush®.

[†]LS Mean for Difference: Mean difference of the covariate adjusted treatment means.

^{*} p -value of the test of the LS Mean difference between treatments.

[‡]LS Mean Difference Lower/Upper CI: 95% Confidence Limit Upper/Lower Bound.

[⌣]Calculated as (U-shaped TB-MTB)/MTB.

mixed dentitions, compared to a manual brush. A two-week, randomized, single-blind, parallel study with 60 adolescents (13 to 17 years) investigated the plaque removal effect of an oscillating-rotating toothbrush compared to a manual toothbrush [24]. Participants who used an oscillating-rotating toothbrush for two minutes showed a 25.9% greater reduction in plaque compared to those who used manual toothbrushes for two minutes following their usual method. Another single-use crossover study was conducted to assess the efficacy of plaque removal using an oscillating-rotating toothbrush compared to a manual toothbrush, involving two age groups: 3–6 years and 7–9 years. In the study, parents brushed the teeth of children aged 3–6 years, whereas children aged 7–9 years brushed their own teeth under supervision [25]. Plaque removal was 32.3% more effective in children aged 3–6 and 51.9% more effective in children aged 7–9 compared to using a manual toothbrush. The findings of these studies agree with the conclusions drawn from systematic reviews and meta-analyses regarding the effectiveness of power toothbrushes in pediatric populations.

The results of our study differ from those of prior investigations of automatic (U-shaped or Y-shaped) electric toothbrushes [15–19]. Two single-use, two-period crossover design studies found that a U-shaped brush with silicone bristles was not effective in plaque removal when compared to manual toothbrushes or even to no brushing [15, 16]. In two single-use crossover studies, a two-sided, Y-shaped design (covering both the upper and lower arches) did not demonstrate significantly better plaque removal compared to a manual toothbrush [17, 18]. A 30-day study found that the Y-shaped automatic brush decreased plaque levels at Days 7 and 30 compared to baseline but showed no differences when compared to the sonic toothbrush at any time point [19]. Short-term studies evaluating different U-shaped or Y-shaped automatic toothbrush were ineffective, with post-brushing plaque levels similar to the no brushing routine. The U-shaped device, with silicone rather than nylon bristles, did not effectively remove plaque, possibly due to inferior brushing force in that protocol. Even after modifications to the both of the U-brush and Y-brush designs, the products failed to outperform the manual toothbrush [16, 18]. The U-shaped and Y-shaped automatic devices were not fabricated for different mouth sizes and the U-shaped brushes contained silicone bristles which lack the flexibility needed to remove plaque and reach the proximal and gumline areas.

The plaque removal effectiveness of manual and power toothbrushes is dependent on the user's brushing behaviors, understanding and commitment to comply with use instructions as well as the manual skills needed to clean all tooth surfaces in the mouth. The performance of the AutoBrush® in our study could be attributed to differences in device design or brushing protocol. The AB features a sonic vibration mechanism, variable sizes to accommodate the mouth fit for children and adults, more than 50,000 nylon tapered bristles placed at a 45° angle to the gumline to simulate the Bass technique and lights with music to help make the experience more enjoyable. Although subjects were given detailed instructions for using the automatic device, proper use does not depend on the individual's manual dexterity. In this single-use crossover study we used a pea size amount of the same standard fluoride toothpaste that was used when brushing with

the manual toothbrush. Our data suggest that not all “U-shaped” automatic toothbrushes are equivalent, and that the AutoBrush® represents a more efficacious iteration of this concept.

In our study, we observed only slight levels of plaque removal for the flat-trim manual toothbrush. This could be seen as a limitation to the study since our results are in contrast to results of a systematic review which indicated that a flat-trim manual toothbrush reduces plaque by 24% to 47% in adults [26] but consistent with reductions of 0.77% to 61.8% with manual toothbrushes reported in a systematic review of studies in children ages 2 to 17 years [13]. The systematic review by Slot *et al.* [26] reported that a flat trim manual toothbrush provides an average plaque removal of about 24% in an adult population, based on the six-surface plaque measurement with the Turesky Modified Quigley-Hein Plaque Index (TMQPI) (actually the LSPI) [20]. The authors noted that a higher magnitude of effect in other research may be associated with plaque measured with the Rustogi Modified Navy Plaque Index (RM-NPI) [27] vs. TMQPI. It was noted by Graves *et al.* [13] that the studies reviewed used a variety of toothbrush types, both power and manual, and brushing instructions varied from parental brushing to supervised brushing, brushing time and varied measurement indices. Some of the manual toothbrush designs included flat trim as well as multi-level and crisscross bristles. In our study, we did not attempt to instruct the subjects on brushing technique with the manual toothbrush since the study was designed to assess the functionality of the U-shaped toothbrush. Plaque removal efficacy with the manual toothbrush may be enhanced if the children are instructed in using a brushing technique, such as modified Bass, and standardized for all subjects. It is important to consider that this population of 5 to 8-year-old children may have different levels of manual dexterity and also reflect dentitions that were either all primary or largely mixed. The varied stages of tooth exfoliation and eruption may create a more difficult plaque removal process with any toothbrush. To address this limitation, future studies in children should stratify subjects by age and primary or mixed dentitions. A limitation of this study design is the lack of an acclimation or familiarization period of at least two days with each toothbrush preceding each crossover period. All participants in this study were current manual toothbrush users and had to be able to brush their own teeth. A familiarization period has frequently been used in other single-use crossover studies to permit practicing with the assigned toothbrushes before the test periods [25, 28–30].

Effective plaque removal in children is a constant challenge since efficiency can be impacted by a child's age, user behavior, manual dexterity and motivation. There is strong evidence that use of an electric toothbrush provides meaningful improvement in plaque levels compared to a manual toothbrush in children as young as 2 years of age and up to 17 years [13]. The introduction of the U-Shaped sonic toothbrush to the power toothbrush market is a creative option since it provides plaque removal benefits with a 30-second toothbrushing versus two minutes with a manual toothbrush and may offset individual disabilities or deficiencies in brushing skills. Incorporating such innovative devices under parental supervision may improve daily oral hygiene and potentially

reduce the risk of early childhood dental caries and gingivitis. Further studies are warranted to confirm long-term safety and efficacy benefits and to determine optimal usage of U-shaped automatic toothbrushes in home care routines. The positive results of this single-use plaque removal efficacy study has prompted interest to investigate the effect of this specialty toothbrush on plaque and gingivitis effect in a population of children and adults, as well as evaluate its safety profile on hard and soft tissues, including gingival abrasion and recession.

5. Conclusions

The results of this single-use, randomized crossover study showed that this novel U-shaped sonic toothbrush enable children to remove significantly more plaque than an ADA accepted standard soft manual toothbrush. Brushing for 30 seconds with the U-shaped automatic toothbrush achieved greater plaque reductions across whole mouth surfaces and especially at hard-to-reach sites (gumline and proximal) compared to a manual brush used for the recommended 2-minute duration. Both toothbrushes were safe and generally well-tolerated by the children. These findings suggest that the U-shaped automatic toothbrush design can assist young children improve plaque control with reduced brushing time irrespective of manual dexterity.

ABBREVIATIONS

AB, U-shaped sonic toothbrush (AutoBrush® 360°); ADA, American Dental Association; ANCOVA, Analysis of Covariance; IRB, Institutional Review Board; ICH-GCP E6(R2), International Conference on Harmonization Good Clinical Practice Guidelines; LSPI, Lobene-Soparkar Modification of Turesky Modified Quigley-Hein Plaque Index; MTB, ADA accepted standard soft-bristle manual toothbrush; DHHS, Department of Health and Human Services; RMNPI, Rustogi Modified Navy Plaque Index; TMQPI, Turesky Modified Quigley-Hein Plaque Index.

AVAILABILITY OF DATA AND MATERIALS

The data that support the findings of this study are available on request from the corresponding author.

AUTHOR CONTRIBUTIONS

SLS, KRM and JLM—designed the research study. CL—reviewed and approved the study protocol. KRM, JLM, ALY, KSW and TLY—performed the research. RS—analyzed the data. SLS—wrote the manuscript. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Prior to the initiation of the study, the protocol, informed consent documents, assent documents and subject instructions

received ethical review and approval from U.S. Investigational Review Board, Inc., #IRB00007024, Reference No. U.S. IRB2022SRI/01. Parents or guardians who agreed to the participation of their children gave their signed informed consent, and children gave their signed assent to participate in the study.

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Not applicable.

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CONFLICT OF INTEREST

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