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ORIGINAL RESEARCH

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Effect of a U-shaped toothbrush in removing plaque among pre-school children: a randomized controlled trial

Kamar Abdulrahman[1], Yasser Alsayed Tolibah[1,*], Mohammaed N. Al-Shiekh[1], Nada Bshara[1]

[1]Department of Pediatric Dentistry, Damascus University, 3062 Damascus, Syria

***Correspondence**
yasser94.tolibah@damascusuniversity.edu.sy
(Yasser Alsayed Tolibah)

Abstract

Background: With the emergence of U-shaped manual toothbrushes, it has become necessary to evaluate their effectiveness in preschool children when used independently. Accordingly, this cross-over randomized controlled trial aimed to evaluate the effectiveness of a manual U-shaped toothbrush for dental plaque removal among preschool children, compared with a manual traditional toothbrush, and to assess the ease of use of both toothbrushes and children's preferences. **Methods**: Thirty children aged 4–5 years were randomly divided into two groups: Group 1 (n = 15), in which children used a manual traditional toothbrush for 21 days followed by a manual U-shaped toothbrush for another 21 days, and Group 2 (n = 15), in which children used a manual U-shaped toothbrush for 21 days followed by a manual traditional toothbrush for 21 days. Plaque accumulation was evaluated by two blinded examiners using Turesky modification of the Quigley-Hein plaque index (TMQHPI) at seven-time points; pre-brushing (T0), immediately after using the first toothbrush (T1), 7 days after using the first toothbrush (T2), 21 days after using the first toothbrush (T3), immediately after using the second toothbrush (T4), 7 days after using the second toothbrush (T5), and 21 days after using the second toothbrush (T6) to determine which toothbrush achieved better plaque removal. At T3 and T6, children were asked about the ease of use of both toothbrushes, while at T6, they were asked about their preferred toothbrush. **Results**: At T2, T3, T5, and T6, plaque accumulation was significantly lower with the use of the U-shaped toothbrush. Both toothbrushes were reported to be easy or moderately easy to use by the children. Most children preferred the U-shaped toothbrush. **Conclusions**: U-shaped toothbrushes significantly improved preschool children's plaque control ability. **Clinical Trial Registration**: NCT06288581.

Keywords

Dental plaque; Oral hygiene; Preschool children; Primary teeth; Toothbrushing

1. Introduction

Oral health is integral to overall health and is crucial for a child's life. Dental caries is one of the most significant oral health problems worldwide, often beginning in infancy [1]. Several factors contribute to the development of the oral microbiome, including the potential influence of the mode of delivery, nutrition, eating habits, salivary flow, and the changes in oral microbiome differentiation during the first four years of a child's life. These complexities in the oral environment make the progression of dental caries a highly intricate process in infants [2].

The prevalence of caries in children is continuously increasing, with caries prevalence among Syrian children reaching 79.1% in 2019 [3]. Early childhood caries poses substantial threats to the physical, psychological, and social health of young children, leading to issues such as tooth pain and subsequent tooth loss, which can result in difficulties with eating, speaking, sleeping, and social interactions [4].

Dental plaque is a biofilm formed by the accumulation of microorganisms on tooth surfaces. It is a primary factor in the development of dental caries and periodontal diseases. One of the most effective ways to control plaque is through proper and regular mechanical tooth cleaning using a toothbrush, along with other chemical and preventive adjuncts [5].

The type of toothbrush used, its appropriate design, the correct brushing technique, and the suitable brushing duration are essential factors for achieving effective plaque control [6]. Moreover, effective and consistent brushing allows for the routine removal of dental plaque, thereby preventing its progression to a pathogenic form and reducing the risks of caries and gingivitis [7]. Additionally, effective tooth cleaning depends on patient compliance; however, most children exhibit poor compliance because they consider it a tedious and

repetitive task [8].

It is worth noting that children face difficulties in brushing their teeth as the process requires specific manual skills that are not fully developed until the age of eight years [9]. In unsupervised children, brushing time is often less than 60 seconds per session, and the lingual surfaces are the most frequently neglected areas [10]. Sarvia *et al.* [11] recommend that preschool-aged children (3–6 years old) need parental assistance with toothbrushing due to insufficient motor skills. However, few parents consistently brush their children's teeth, likely due to the demands of daily life. Additionally, one of the main challenges parents encounter is difficulty accessing all areas of the child's mouth, along with limited knowledge regarding the appropriate age to initiate toothbrushing. Effective toothbrushing for children involves the correct technique, the proper frequency, sufficient duration, and the use of a properly designed toothbrush [12]. Therefore, there is a need for alternative, user-friendly tools to improve oral health in children.

The U-shaped toothbrush features silicone bristles and a horseshoe shape, designed to work simultaneously on both the upper and lower jaws. It is suitable for children who lack the skills to use a traditional toothbrush. The brush consists of two plates with silicone bristles arranged in four rows on the buccal and lingual surfaces of the upper and lower jaws. The bristles are aligned at a 45-degree angle with the gingival margin to simulate the Bass toothbrushing method [13].

The effectiveness of a traditional toothbrush and a manual U-shaped toothbrush in removing dental plaque in children was evaluated in a prior study involving children aged 8–10 years, where the U-shaped toothbrush demonstrated superior plaque removal and improved gingival and oral health. Although the U-shaped toothbrush manufacturer states that it is easy to use, there are not enough studies evaluating its effectiveness in plaque removal in preschool children [14]. Therefore, this study aimed to evaluate the plaque removal efficacy of the traditional toothbrush and the manual U-shaped toothbrush when used by preschool children without parental assistance. Additionally, it aimed to assess the children's self-reported ease of use of both toothbrushes and determine which type of toothbrush they preferred more. This article was previously posted on Research Square as a preprint on 02 September 2024.

2. Materials and methods

2.1 Study design, settings, and ethical approval

From February 2024 to June 2024, this study was conducted in a private kindergarten in Damascus, Syria. The study was a single-center interventional, single-blinded, randomized clinical trial that employed a cross-over design. The study adhered to the ethical guidelines outlined in the Declaration of Helsinki and obtained ethical approval from the Local Research Ethics Committee, Faculty of Dentistry (Approval No. 2795, dated 27 March 2023). The project was funded by Damascus University (funder No. 501100020595) and registered with the ClinicalTrials.gov registry under ID number NCT06288581 on 25 February 2024.

2.2 Sample size calculation

The sample size was calculated using G*Power version 3.1.9.4 (Heinrich-Heine-Universität, Düsseldorf, NRW, Germany) based on a previous study that had a similar design and plaque accumulation assessment method (TMQHPI index) [15]. Based on a significance level of 0.05, a power of 80%, and an effect size of 1.10, a minimum total sample size of 30 subjects (15 subjects in each group) was required.

2.3 Recruitment and eligibility criteria

• Inclusion criteria

Healthy children aged 4–5 years, with complete primary dentition (no missing primary teeth), and with parental consent for participation in the study.

• Exclusion criteria

Children with limited communication abilities, children with motor disabilities, children with gingivitis or periodontitis, children with dental caries or tooth mobility, and children whose parents declined participation in the study.

2.4 Blinding

In the current study, a single-blind design was adopted due to the physical differences in the designs of both toothbrushes, which prevented blinding of the participating children. Additionally, the primary researcher (KA), who provided the children with both types of toothbrushes and later applied the plaque-disclosing agent and took photographs of the children's teeth during the follow-up periods, was not blinded. Only the evaluators (two PhD students in the Department of Pediatric Dentistry who were well-trained in using the TMQHPI index) were blinded during the analysis of the children's dental photographs obtained before brushing and at follow-up time points.

2.5 Randomization

Children were allocated to either the traditional or the U-shaped toothbrush group using a simple randomization method with a 1:1 allocation ratio. On 01 February 2024, the principal researcher (KA) generated a random sequence using the website www.random.org. Opaque, sealed envelopes containing a card indicating the type of toothbrush were prepared (15 per study group). The children were instructed to randomly select an envelope, resulting in assignment to one of two groups: Group 1, children used a traditional toothbrush in their daily oral hygiene maintenance for 21 days and then used the U-shaped toothbrush for 21 days (n = 15), and Group 2, children used a U-shaped toothbrush in their daily oral hygiene maintenance for 21 days and then used a traditional toothbrush for 21 days (n = 15). Consequently, each child included in this study used both types of toothbrushes, and each child was counted in both groups: either as a control first and then as a study subject, or as a study subject first and then as a control.

2.6 Clinical procedure

After explaining the study's objectives and methods to the child's guardian, written consent was obtained. Upon agree-

ment, parents were asked to fill out the informed consent form. Subsequently, the principal researcher (KA) provided each included child with the appropriate toothbrush according to the assigned group.

Each child received instructions during the first visit and was taught brushing techniques using an educational model and a magnified toothbrush.

Children in Group 1 were instructed to brush their teeth themselves with a traditional toothbrush, using the horizontal brushing technique with a rotating motion for 2 minutes, with a musical timer that ended the brushing session, twice per day (once in the morning and once before sleep) for 21 days [16]. In the second stage, they were asked to use the U-shaped toothbrush, making approximately twenty motions for approximately 30 seconds in a semi-closed mouth position to allow the toothbrush handle to move from the right buccal angle to the left buccal angle two times per day (once in the morning and once before bedtime) for 21 days. It is worth noting that the rotation of the U-shaped toothbrush from right to left, followed by a return from left to right, was considered a single movement. As for the children in Group 2, they were instructed to use the U-shaped toothbrush first. After 21 days, they were asked to use the traditional toothbrush for another 21 days, following the same instructions.

The chosen traditional toothbrush used in this study was a commercially available, age-appropriate, soft-bristled manual toothbrush (JollyDent, Damascus, Syria), specifically designed for children aged 3–6 years (Fig. 1A).

A single child-sized U-shaped toothbrush was used for all participants. The brush was selected based on its overall fit and suitability for the dental arches of 4–5-year-old children, although the manufacturer does not specify exact dimensions (Fig. 1B).

Both groups used a standardized non-fluoridated toothpaste, an amount equivalent to a pea. Children were instructed to brush their teeth twice a day: once in the morning before eating and once just before going to bed.

Parents were instructed to remind the children of their brushing time and to observe them during the brushing process without intervening, to assess the children's independent brushing abilities. It is worth noting that parents were provided with a wall-mounted checklist featuring daily reminder phrases, on which they could place a checkmark next to each reminder to ensure that all children completed their brushing.

2.7 Outcomes measurements

To evaluate plaque accumulation before using the toothbrush (T0) and plaque removal efficacy immediately after using the first toothbrush (T1), 7 days after using the first toothbrush (T2), 21 days after using the first toothbrush (T3), immediately after using the second toothbrush (T4), 7 days after using the second toothbrush (T5), and 21 days after using the second toothbrush (T6), the Mira-2-Ton plaque disclosing solution (Hager Werken, Duisburg, NRW, Germany) was applied to the teeth to enhance color differentiation, making the plaque more visible. Intraoral photographs were taken at each time point in a frontal view, oriented as perpendicular as possible to the anterior teeth, using plastic mouth retractors to ensure optimal exposure. The photographs were then assessed by two external evaluators blinded to the group assignments. Plaque accumulation was evaluated using the Turesky Modified Quigley Hein Plaque Index (TMQHPI) [17], as shown in Table 1.

FIGURE 1. Toothbrushes used in the current study. (A) Traditional toothbrush and (B) U-shaped toothbrush.

TABLE 1. The Turesky modified Quigley Hein plaque index.

Score	Description
0	No plaque present
1	Separate flecks of plaque at the cervical margin
2	A thin continuous plaque (up to 1 mm) at the cervical margin
3	A band of plaque wider than 1 mm but covering less than one-third of the side of the crown of the tooth
4	Plaque covering at least one-third but less than two-thirds of the side of the crown of the tooth
5	Plaque covering two-thirds or more of the side of the crown of the tooth

The TMQHPI was calculated by first dividing the teeth into anterior (central and lateral incisors and canines) and posterior groups (first and second primary molars) in both the maxilla and mandible. After staining the buccal surfaces of the teeth with a plaque disclosing agent, each tooth was individually assessed. The mean TMQHPI score for the buccal surface of anterior and posterior teeth was calculated separately by summing the scores within each group and dividing by the number of teeth evaluated.

Notably, plaque accumulation in the included children was assessed in the morning before they had eaten breakfast or brushed their teeth at each time point, as this timing allows for a more accurate assessment of plaque buildup on the teeth [18].

At T3 and T6, children were also asked to rate the ease of use of the toothbrush they used by categorizing it as easy, moderate, or difficult. This self-assessment aimed to determine the ease of brushing from the children's perspective.

At the end of the study period (T6), both toothbrushes were placed in the child's cup to determine which toothbrush the child preferred. The child was then asked to choose one toothbrush to use.

Two pediatric dentistry examiners, calibrated independently, assessed all plaque scores from standardized intraoral photographs. To ensure consistency, inter- and intra-examiner reliability were evaluated using Cohen's Kappa on a random sample of 15 images scored twice, 48 hours apart. Kappa values exceeded 0.85 for both inter- and intra-examiner agreement, indicating excellent consistency.

2.8 Statistical analysis

The collected data were analyzed using SPSS software (Version 20, IBM SPSS Inc., Armonk, NY, USA). The Kolmogorov-Smirnov test was used to determine the data distribution and revealed a non-normal distribution; therefore, nonparametric tests were used for the statistical analysis of the outcome. The Mann-Whitney U test was used to compare the overall plaque accumulation between toothbrushes at each time point. Moreover, the Kruskal-Wallis test was used to compare the plaque accumulation between toothbrushes in both regions at each time point. Finally, the Chi-square test was used to compare the ease of use of both toothbrushes. The significance level was set at $\alpha = 0.05$ for all analyses.

3. Results

Participant flow through the study is illustrated in the Consort flow diagram shown in Fig. 2.

Thirty participants were enrolled in this study: sixteen girls (53%) and fourteen boys (47%). The participants' age ranged from 4 to 5 years, with a mean of 4.53 years and a standard deviation of 0.516. Notably, no side effects were observed. No gingival irritation or trauma was noted during brushing with either toothbrush at any follow-up period.

3.1 Overall plaque accumulation assessment using TMQHPI index in follow-up timepoints

3.1.1 Between groups

Tables 2 and 3 present the inter-group and within-group comparisons of TMQHPI scores of overall plaque accumulation, respectively.

3.1.2 Among groups

For Group 1, the Wilcoxon test revealed significant differences between T0 and T1, T1 and T2, and T3 and T4, with p-values < 0.05. Notably, T4, T5, and T6 did not show significant differences.

For Group 2, the Wilcoxon test revealed significant differences between T0 and T1 and between T4 and T5, with p-values < 0.05. Notably, T1, T2, T3, T4, T5, and T6 did not show significant differences. In both groups, T1 and T4 did not show significant differences. In other words, using different toothbrushes at different time intervals resulted in significant changes in scores, especially during the early stages of use.

In conclusion, the previous tables indicate high plaque accumulation before the start of brushing procedures (T0) in both groups, without significant differences. However, when brushing instructions for either the traditional or U-shaped toothbrush were applied to both groups at time points T1 and T4, the average TMQHPI scores decreased, with no significant difference between groups. However, TMQHPI scores mean values increased in both groups at time points T2 and T5; in both instances, plaque TMQHPI mean values were significantly lower with the U-shaped toothbrush than with the traditional toothbrush. This pattern was also observed at time points T3 and T6.

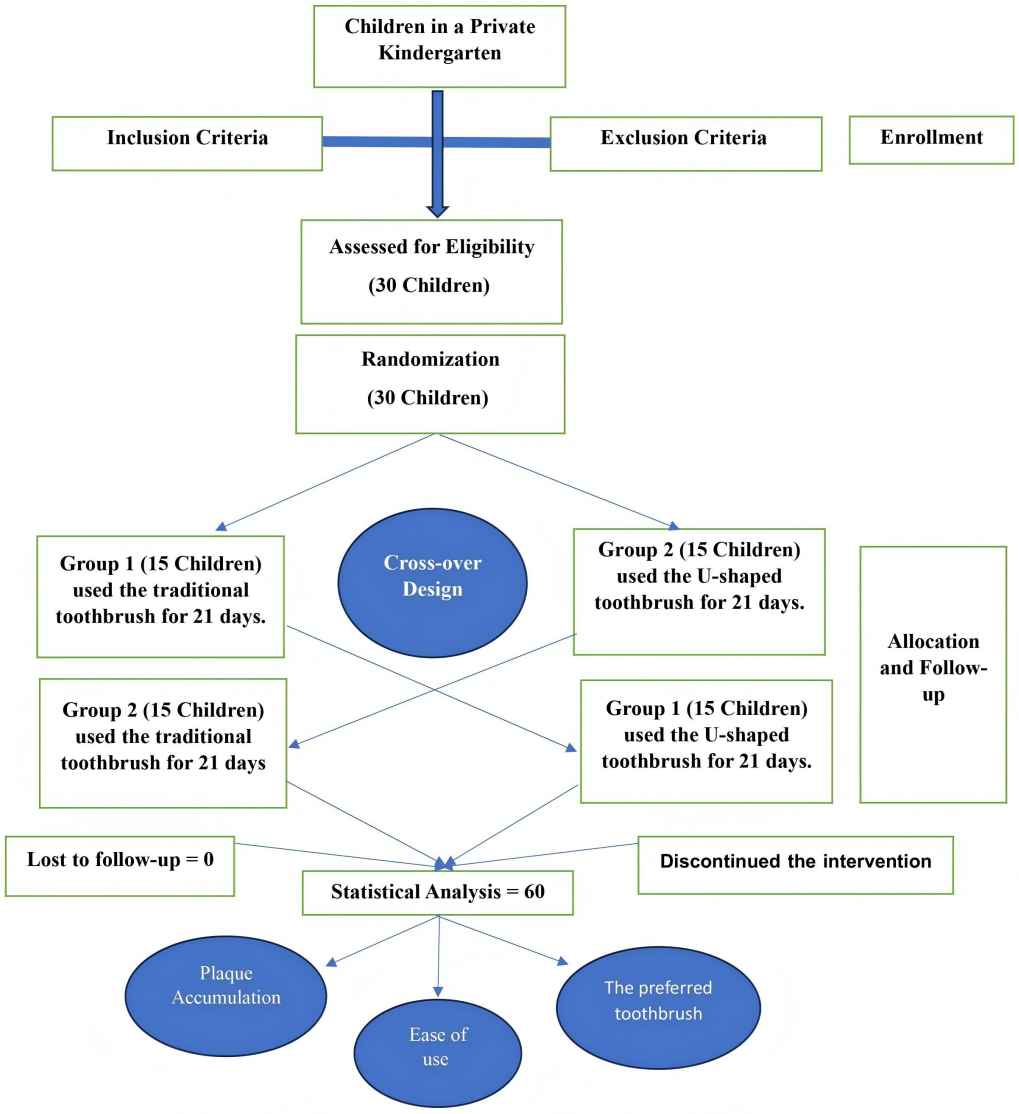

FIGURE 2. Flow chart of the study protocol.

TABLE 2. Inter-group comparison of TMQHPI scores of overall plaque accumulation.

	Group 1: Traditional toothbrush, then U-shaped toothbrush			Group 2: U-shaped toothbrush, then traditional toothbrush			*p*-value^
	Number of children	Median	Range	Number of children	Median	Range	
Before using the toothbrush (T0)	15	3.00	1–4	15	3.00	1–5	0.744
Immediately after brushing with the first toothbrush (T1)	15	1.00	0–2	15	1.00	0–2	0.871
After 7 days of using the first toothbrush (T2)	15	3.00	1–4	15	1.00	0–2	0.001*
After 21 days of using the first toothbrush (T3)	15	2.00	0–3	15	0.00	0–1	0.0001*
Immediately after brushing with the second toothbrush (T4)	15	0.00	0–1	15	0.00	0	0.150
After 7 days of using the second toothbrush (T5)	15	0.00	0–2	15	2.00	1–3	0.0001*
After 21 days of using the second toothbrush (T6)	15	0.00	0–1	15	1.00	0–3	0.0001*

*^Mann-Whitney U test. *Significant difference.*

TABLE 3. Among-group comparison of TMQHPI scores of overall plaque accumulation.

	T0	T1	T2	T3	T4	T5	T6	*p*-value^
	Median	Median	Median	Median	Median	Median	Median	
Group 1: Traditional toothbrush, then U-shaped toothbrush	3.00	1.00	3.00	2.00	0.00	0.00	0.00	<0.001*
Group 2: U-shaped toothbrush, then traditional toothbrush	3.00	1.00	1.00	0.00	0.00	2.00	1.00	<0.001*

*^Friedman test. *Significant difference.*

3.2 Plaque accumulation according to region assessment using TMQHPI index in follow-up timepoints

The median, range of TMQHPI scores for plaque accumulation, and the Kruskal-Wallis test results are described in Table 4.

The previous table shows high plaque accumulation before starting the brushing procedures (T0) across groups in both regions, without statistically significant differences between groups ($p = 0.428$). However, when brushing instructions were applied and children in both groups used either the traditional or U-shaped toothbrush at time points T1 and T4, the average TMQHPI scores decreased in both regions, with no significant difference between the groups ($p = 0.344$ and $p = 0.239$, respectively).

At T2, significant differences were observed ($p < 0.001$), with both regions using a traditional toothbrush showing the highest TMQHPI scores. Similarly, at T3, there was a significant difference ($p < 0.001$), with the traditional toothbrush in both regions showing higher scores than the U-shaped toothbrush.

Significant differences were noted again at T5 ($p < 0.001$), with the posterior region brushed with the traditional toothbrush showing the highest scores, followed by the anterior region with the traditional toothbrush. At T6, significant differences were also observed ($p < 0.001$), with the posterior region brushed with a traditional toothbrush showing the highest scores.

Fig. 3 Summarize the changes in the TMQHPI score during the measurement periods based on groups according to the studied toothbrushes and cleaning region.

Figs. 4,5 illustrate the reduction in plaque accumulation in both study groups before brushing and during the follow-up periods.

Further investigation was conducted using the Mann-Whitney test to identify where the differences occured. At T2, significant differences were observed between the anterior region brushed with a U-shaped toothbrush and the anterior region brushed with a traditional toothbrush, favoring the former ($p = 0.001$), the anterior region brushed with a U-shaped toothbrush and posterior region brushed with a traditional toothbrush ($p < 0.001$) favoring the former, a posterior region with a U-shaped toothbrush and anterior region brushed with a traditional toothbrush ($p < 0.001$) favoring the former, and posterior region with a U-shaped toothbrush and posterior region brushed with a traditional toothbrush ($p < 0.001$) favoring the former.

Significant differences also appeared at T3, T5 and T6, with consistent findings between the anterior region with a U-shaped toothbrush and the anterior region brushed with a traditional toothbrush ($p < 0.001$ in all timepoints) favoring the former, the anterior region brushed with a U-shaped toothbrush and posterior region brushed with a traditional toothbrush ($p < 0.001$ in all timepoints) favoring the former, posterior region brushed with a U-shaped toothbrush and anterior region with a traditional toothbrush ($p < 0.001$, $p < 0.001$, and $p = 0.002$; receptively) favoring the former, and posterior region brushed with a U-shaped toothbrush and posterior region brushed with a traditional toothbrush ($p < 0.001$ in all timepoints) favoring the former.

No significant differences were found between the anterior region with a traditional toothbrush and the posterior region with a traditional toothbrush at the T2, T3, T5, and T6 time points, with *p*-values ranging from 0.254 to 0.538.

3.3 The ease of use of both toothbrushes as assessed by children

Table 5 presents children's assessments of the ease of use of both types of toothbrushes at the end of each brushing phase (at points T3 and T6), along with the results of the Chi-square test. There were no significant differences in ease of brushing between the two groups ($p = 0.237$), and no child found either toothbrush difficult to use.

3.4 Determining the preferred toothbrush for children

At the end of the follow-up period, 28 children (93.3%) preferred the U-shaped toothbrush, compared with 2 (6.7%) who preferred the traditional toothbrush.

4. Discussion

Cleaning teeth, like all hygiene habits, is acquired during a child's socialization process. When a child is taught this early in life, it naturally becomes ingrained in their daily routine and continues throughout their life [19]. Moreover, maintaining oral health is key to preventing oral diseases such as caries and periodontal diseases. Since dental plaque is the primary cause of these conditions, effective plaque control is the most effective way to mitigate these diseases [5].

Despite various mechanical and chemical methods for plaque control, toothbrushing remains the most common and safest method. However, children face difficulties with toothbrushing as it requires specific manual skills that do not

TABLE 4. Inter-group comparison of TMQHPI scores of plaque accumulation.

Group	Group 1: Traditional toothbrush, then U-shaped toothbrush					Group 2: U-shaped toothbrush, then traditional toothbrush					*p*-value^
	Number of children	Anterior Area		Posterior Area		Number of children	Anterior Area		Posterior Area		
		Median	Range	Median	Range		Median	Range	Median	Range	
Before using the toothbrush (T0)	15	3.00	1–4	3.00	1–5	15	3.00	1–5	3.00	1–5	0.428
Immediately after brushing with the first toothbrush (T1)	15	0.00	0–2	2.00	0–2	15	0.00	0–2	1.00	0–3	0.344
After 7 days of using the first toothbrush (T2)	15	2.00	0–4	3.00	1–4	15	1.00	0–1	1.00	0–2	<0.001*
After 21 days of using the first toothbrush (T3)	15	2.00	0–2	2.00	0–3	15	0.00	0–1	0.00	0–1	<0.0001*
Immediately after brushing with the second toothbrush (T4)	15	0.00	0–2	0.00	0–2	15	0.00	0	0.00	0–1	0.239
After 7 days of using the second toothbrush (T5)	15	0.00	0	1.00	0–2	15	2.00	0–2	2.00	0–2	<0.001*
After 21 days of using the second toothbrush (T6)	15	0.00	0–1	0.00	0–1	15	1.00	0–2	1.00	0–3	<0.001*

^*Kruskal-Wallis test.* **Significant difference.*

fully develop until age eight [9].

Previous studies have emphasized the importance of parental supervision and assistance in brushing young children's teeth twice daily using a soft-bristled, age-appropriate toothbrush and fluoride-containing toothpaste. This practice is recommended to commence with the eruption of the first primary tooth [20]. However, Huebner *et al.* [21] studied the barriers preventing parents from brushing the teeth of infants or preschool-aged children. These barriers included a lack of knowledge about the importance of brushing their children's teeth, a lack of social support for this behavior, external constraints, and work pressures. Many parents expressed hesitation and fear about their lack of the necessary skills to brush their children's teeth without harming their children's mouths.

Additionally, parental involvement plays a crucial role in children's oral hygiene practices; however, many parents experience challenges in maintaining consistent tooth brushing routines. Parents often encounter difficulties related to children's uncooperative behavior, including resistance, tantrums, and a desire for independence, which can limit effective supervision [22], which may be due to different lifestyles or constraints within each family, highlighting the need to explore additional tools to improve children's ability to brush their teeth effectively [23].

Therefore, this study emerged from the need for a simple, acceptable, and effective method for plaque removal in preschool-aged children to improve their oral health, especially without parental supervision.

Studies on the effectiveness of the U-shaped electric toothbrush have yielded mixed results, with some showing it to be effective and others ineffective [24, 25]. Another study also evaluated the effectiveness of the manual U-shaped toothbrush in children, using a design similar to the present research but in an older age group (8–10 years). The results demonstrated a significant improvement in gingival indices and plaque removal among children using the U-shaped toothbrush [14]. To the best of our knowledge, this study represents the first ran-

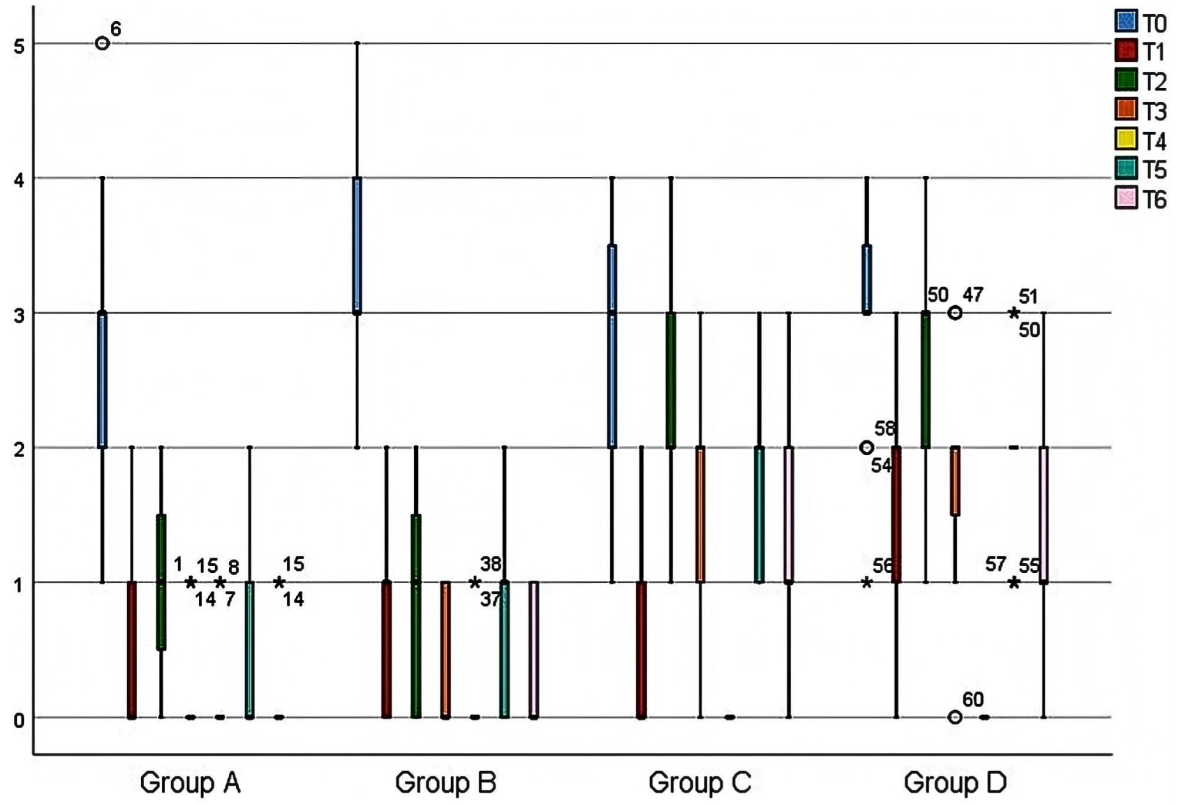

FIGURE 3. A boxplot summarizing the changes in the TMQHPI score during the measurement periods based on groups according to the studied toothbrushes and cleaning region. Group A: Anterior region with a U-shaped toothbrush. Group B: Posterior region with a U-shaped toothbrush. Group C: Anterior region with a traditional toothbrush. Group D: Posterior region with a traditional toothbrush. *symbols mean extreme outlier.

FIGURE 4. Assessment of plaque accumulation at different time points in group 1. T0: Before brushing in the group 1; T1: Immediately after brushing using a traditional toothbrush; T2: 7 days after brushing using a traditional toothbrush; T3: 21 days after brushing using a traditional toothbrush; T4: Immediately after brushing using a U-shaped toothbrush; T5: 7 days after brushing using a U-shaped toothbrush; and T6: 21 days after brushing using a U-shaped toothbrush.

FIGURE 5. Assessment of plaque accumulation at different time points in group 2. T0: Before brushing in the group 2; T1: Immediately after brushing using a U-shaped toothbrush; T2: 7 days after brushing using a U-shaped toothbrush; T3: 21 days after brushing using a U-shaped toothbrush; T4: Immediately after brushing using a traditional toothbrush; T5: 7 days after brushing using a traditional toothbrush; and T6: 21 days after brushing using a traditional toothbrush.

TABLE 5. Children's assessment of the ease of using the toothbrushes.

Toothbrushes	The ease of use			Number of voted children	*p*-value^
	Easy	Moderate	Difficult		
Traditional Toothbrush	9	21	0	30	0.237
U-shaped toothbrush	15	15	0	30	

^Chi-square test.

domized controlled trial to evaluate the effectiveness of a manual U-shaped toothbrush in preschool children. The increased prevalence of dental caries among preschool-aged children may be attributed to their underdeveloped manual dexterity [26]. It is essential to find simple and effective alternatives to traditional toothbrushes for this age group. Therefore, this research explicitly targets children aged 4–5 years.

This study was designed as a crossover trial for several reasons. First, the sample size was relatively small. However, the children in this sample shared similar environments, routines, and meal times, which enhanced the credibility of the results, as the adopted study design required a smaller sample size. Second, the crossover design allowed each child to independently evaluate the ease of use and personal preference for each toothbrush after trying both. In contrast, a parallel arm trial design might not provide the same level of reliability for the other variables in the study [27].

A fluoride-free toothpaste was used with both toothbrushes to eliminate the confounding effect of fluoride on plaque reduction. Numerous studies have shown that fluoride independently contributes to plaque reduction [28, 29], improving oral health regardless of the toothbrush's efficiency. Thus, a fluoride-free toothpaste was selected to ensure that the outcomes reflected the effect of the toothbrushes alone.

Although the 45° bristle angulation of the U-shaped brush mimics the Bass principle, the actual brushing movements were strictly horizontal back-and-forth motions. Moreover, the horizontal brushing technique was employed in both groups, as it is simple, easy for preschool children to learn, and effective in plaque removal [30].

The Plaque Index (PI) has been utilized in numerous previous studies; however, it does not apply to our research because the PI is designed to detect plaque on permanent teeth, whereas our study focuses exclusively on primary teeth. Additionally, the PI is limited in its ability to detect plaque, as it considers only the presence or absence of plaque, without accounting for factors such as location and distribution, which makes it less accurate for our purposes.

This study used the TMQHPI plaque index to detect plaque on all buccal surfaces by applying a Mira-2-Ton disclosing solution (Hager Werken, Germany). The solution is preferred over disclosing tablets because the clinician applies it uniformly across all teeth. In contrast, the tablets rely on the child's ability to follow instructions, making the solution more accurate for this study. It is noteworthy that only the buccal surfaces of the anterior and posterior teeth were selected for evaluation using the TMQHPI index. This choice was based on several reasons: plaque tends to accumulate more on buccal surfaces than on lingual surfaces, which are subject to continuous, instinctive cleaning [23]. Additionally, photographing only the buccal surfaces facilitated a more practical and streamlined workflow for subsequent assessment.

Any teeth with caries or mobility were excluded to eliminate factors that could influence the effectiveness of either the traditional or U-shaped toothbrushes in plaque removal. A monitoring protocol was established to assess plaque before brushing, after brushing, after one week, and after three weeks, to ensure the child's adherence to either the traditional or U-shaped toothbrush and to evaluate the potential improvement in oral health. Although many studies have shown that a one-week monitoring period is sufficient to assess plaque control, the extended monitoring was intended to provide more comprehensive data. Photographs were utilized to ensure blinding during the assessment of results. An external evaluator assessed plaque accumulation using photographs taken according to the specified index, both before and after brushing, and at one week and three weeks. Multiple angles of the child's mouth-front and both sides were photographed to facilitate the external assessor's accurate plaque evaluation. It is worth noting that the overall study design involved each child trying both a new type and a traditional type of toothbrush, similar to the study by Youcharoen *et al.* [23].

No washout period was applied between T3 and T4. As dental plaque accumulation is a continuous, progressive biological process, we expected plaque levels to return to baseline quickly if brushing were stopped [31]. However, in this young age group (4–5 years), ethical considerations prevented us from withholding brushing for an extended period.

The current study indicated that plaque accumulation was high in both groups. This finding is consistent with a previous study conducted in Syria [3]. Syrian children generally have low parental awareness of oral hygiene and are frequently exposed to plaque accumulation [32].

The current study also indicated that when brushing instructions were given directly (with both toothbrushes), children in both groups showed a decrease in plaque index in both regions. However, their adherence to the instructions decreased over time, suggesting the need to frequently remind preschool children of the brushing instructions or to have their parents monitor them.

The current study also suggested, after reviewing the results and pairwise comparisons, that plaque removal effectiveness during follow-up periods distant from the time of instruction was highest in the anterior region with the U-shaped toothbrush, followed by the posterior region with the U-shaped toothbrush, and then the anterior region with the conventional toothbrush. The least effective cleaning was observed in the posterior region when using the conventional toothbrush. These findings align with several previous studies that have shown plaque tends to accumulate more on posterior teeth than on anterior ones [23, 33].

Regardless of the region assessed, the results showed that the U-shaped brush outperformed the traditional brush in plaque accumulation reduction at follow-up time points. This could be because the child spent less time cleaning with the U-shaped manual brush, as the movements were easier to remember after one training session. This brush helps the child maintain interest in brushing, thereby improving oral health quickly without causing boredom. A previous investigation presented similar results [14].

Another possible explanation for the superiority of the U-shaped toothbrush over the traditional one is that brushing with a traditional toothbrush requires following the recommended guidelines for at least 2 minutes. On average, the child will spend about four seconds brushing each tooth, one at a time. In contrast, the U-shaped toothbrush covers both dental arches and cleans all tooth surfaces simultaneously. Additionally, children may struggle to consistently angle the traditional toothbrush at 45 degrees to the tooth surface. In contrast, the U-shaped brush's bristles are automatically positioned to achieve this optimal angle. Additionally, the current study found that preschool children preferred the U-shaped toothbrush and found it as easy to use as the traditional toothbrush, which may support the recommendation of using this brush as an alternative to conventional toothbrushes in preschool-aged children. In the study by Kayalvizhi *et al.* [34], which included children aged 8–10 years in the mixed dentition stage, a disposable, single-use toothbrush with chewable silicone bristles was used. The modified Turesky plaque index was employed to evaluate plaque removal over one week. The results indicated that this toothbrush effectively removed plaque and had higher compliance than traditional toothbrushes, as it reduced the time required for brushing. The study concluded that children's ability to use traditional toothbrushes varies significantly by age, motivation, and individual ability and dexterity. The current findings meet the previous results, where toothbrushes that do not require manual dexterity might be more effective for children.

In the study by Schnabl *et al.* [24], the effectiveness of a U-shaped electric toothbrush was examined in individuals with low motivation for brushing their teeth, using the encouraging phrase "clean your teeth in 10 seconds". The sample consisted of individuals aged 14 years or older, including 10 males and 10 females. The results showed that this device was superior in plaque removal only in the upper premolars and molars. However, it was generally less effective than manual brushing. Similarly, Nieri *et al.* [25] found that the U-shaped electric toothbrush was as ineffective as not brushing at all. Both

studies attributed this result to the varying sizes and shapes of participants' jaws, insufficient brushing time, an inadequate number of bristles, or low bristle quality. On the other hand, in the current study, the children were similar in age and likely had comparable jaw sizes, making the U-shaped manual toothbrush more effective. Additionally, the longer brushing time contributed to its increased effectiveness.

A randomized controlled trial demonstrated that an oscillating-rotating electric toothbrush removed 32.3% more plaque than a manual brush in preschoolers aged 3–6 years ($p < 0.01$) [35]. Furthermore, a meta-analysis of nine randomized controlled trials (RCTs) spanning 1980–2019 confirmed a significant overall benefit of powered-over manual toothbrushes in pediatric populations (mean difference = 0.59, 95% CI 0.35–0.83; $p < 0.001$) [36]. These findings suggest that powered, oscillating, and sonic designs may enhance plaque removal in preschool cohorts. We, therefore, recommend that future trials directly compare manual and electric U-shaped toothbrushes to identify optimal strategies for early childhood oral hygiene.

This study's limitation is that it requires longer observation periods to monitor the development of dental caries and the DMFT (Decayed, Missing, and Filled Teeth) index to demonstrate the long-term effectiveness of this toothbrush. Additionally, since children with gingivitis and periodontitis were excluded, it was not possible to assess the impact of either type of toothbrush on gingival or periodontal indices.

Consequently, similar studies with extended observation periods can be conducted across different age groups, as well as among children with special needs and those with reduced motor skills, to provide a more precise evaluation of the effectiveness of this toothbrush on plaque removal and on the healing of gingivitis and periodontitis.

5. Conclusions

Based on the current study's results, the U-shaped toothbrush was more effective at reducing plaque accumulation in children than the traditional toothbrush. Additionally, it was more widely accepted and had a similar level of ease of use to the traditional toothbrush. However, preschool children must be frequently reminded of brushing instructions to maintain reduced plaque accumulation.

AVAILABILITY OF DATA AND MATERIALS

De-identified data are available upon reasonable request to the corresponding author.

AUTHOR CONTRIBUTIONS

KA—conceptualized the idea, provided the clinical procedure, and contributed to the writing and documentation. NB—conceptualized the idea and supervised the research. MNA—performed the statistical analyses. YAT—interpreted the data and revised, formatted, and edited the manuscript. All authors have read and agreed to the published version of the manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study was conducted according to the guidelines of the Declaration of Helsinki and was approved by the Institutional Review Board of Damascus University (Approval No. UDDS-371-27032024/SRC-2795). Informed consent was obtained from all children's parents involved in the study.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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