



**Evaluating the Effectiveness of Two Manual Toothbrushes for Children: Conventional vs. Double-Sided Design. A Crossover Study Investigating Dental Health in Healthy Odontopediatric Volunteers.**

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## 1. Background

The accumulation of bacteria on dental surfaces is the primary etiological factor for multiple oral pathologies, including dental caries. Therefore, mechanical removal of dental plaque through brushing is considered one of the most effective means to prevent these pathologies (1), (2), (3), (4).

In pediatric patients, reduced fine motor skills, as well as the challenges in maintaining a child's attention during a repetitive task over an extended period, make dental brushing less effective, resulting in a lower plaque removal compared to adults (4).

One of the factors influencing the efficiency of brushing is the type of toothbrush. Currently, the main options available in the market are the conventional manual toothbrush and the oscillating-rotating electric toothbrush, both with nylon bristles.

In a study conducted by Davidovich et al. (2), plaque removal in a group of children aged 3 to 6 years was 25.8% with an electric toothbrush and 19.5% with a manual toothbrush. In the same study, a group of children aged 7 to 9 years removed 23.5% of plaque with an electric toothbrush and 15.5% with a manual toothbrush.

In another study by Francis et al. (5), a group of children aged 8 to 10 years achieved an average reduction in the plaque index of 40.7% when using an electric toothbrush and 24.9% with a manual toothbrush.

One of the materials proposed for toothbrush manufacturing is thermoplastic polyurethane, with good mechanical properties and chemical stability. With this material, a toothbrush with a double-sided head and a rotating handle that adapts to different tooth surfaces has been designed (Balene, Ziz Dental Care, S.L., Madrid, Spain).

This toothbrush design may also be suitable for pediatric or special needs patients who require assistance with brushing. Additionally, it may reduce the time needed to achieve effective brushing, making it suitable for such patients (1), (2).

In Zúñiga et al.'s study (1), the conventional toothbrush showed greater reductions in the plaque index throughout the mouth, on vestibular and non-proximal surfaces. However, there were no statistically significant differences between the conventional and Balene toothbrushes on lingual and interproximal surfaces. Neither of the two toothbrushes

demonstrated significantly greater reductions in the gingival index, and there were no observations of mucosal or soft tissue lesions with either toothbrush. In the same study, the group of dental students in the sample expressed satisfaction with both the conventional and Balene toothbrushes, although the overall rating was higher for the conventional toothbrush.

## **2. Rationale**

The efficiency and effectiveness of dental brushing depend on various factors, including brushing technique, duration, frequency, the type of brush used, its size, and the material and consistency of the bristles (1).

In the pediatric population, limited fine motor skills, difficulty in establishing and maintaining routines, and sustaining attention during brushing due to the time required make plaque removal less effective (2), (3), (6), (7).

As mentioned earlier, the double-sided head brush allows for better access to dental surfaces, which could facilitate brushing by a third person.

Moreover, this brush design, by allowing plaque removal from multiple tooth surfaces simultaneously, could reduce the time needed for effective brushing, thus improving brushing efficiency in pediatric patients.

Furthermore, as observed in Mamat et al.'s study (8), using a "novel" and "different" brush shape with a T-shaped head in a group of children aged 8 to 10 years can increase children's motivation for brushing.

For these reasons, this brush design could potentially lead to better plaque removal in pediatric patients, both in children who brush independently and in children brushed by their parents or caregivers. This improvement in oral hygiene could translate into a decreased risk of oral pathologies, such as caries and gingival and periodontal diseases.

## **3. Working Hypothesis**

The Balene double-sided head brush, made of thermoplastic polyurethane, will achieve plaque removal equal to or greater than that achieved by the conventional manual toothbrush. The null working hypothesis will, therefore, be that the Balene brush will remove less plaque than the conventional manual toothbrush.

#### **4. Objectives**

The main objective of this study is to compare the effectiveness of the Balene brush with the conventional manual toothbrush for dental plaque removal in a pediatric patient population. The secondary objective is to assess satisfaction, both from the patients and their parents or caregivers, with the Balene brush, and to analyze their opinions regarding the brush's ability to achieve efficient plaque removal.

#### **5. Materials and Methods**

To compare both study groups, an observational study with a prospective longitudinal design was conducted to analyze plaque reduction achieved by a pediatric patient population using two different types of brushes.

The sample was obtained from pediatric patients attending routine check-ups at two private dental clinics located in the Community of Madrid and Castilla-La Mancha.

Inclusion criteria for the study were as follows:

- Patients in mixed dentition.
- Presence of at least 16 evaluable teeth.
- ASA I or ASA II patients.
- Patients who regularly brush their teeth (1-2 times daily).
- Patients whose legal guardians agreed to participate in the study and signed informed consent.

Exclusion criteria for the study included:

- Patients with fixed orthodontic appliances, invisible braces, fixed space maintainers, or preformed crowns.
- Patients with any type of systemic pathology.

- Patients who have received antibiotic treatment in the last month.
- Patients using any type of mouthwash or interproximal hygiene device during the study.
- Patients with excessive tooth mobility in any deciduous (baby) tooth, which hinders effective brushing.

Legal guardians provided informed consent for their children to participate in the study. The decision to include children in the mixed dentition, aged between 6 and 12 years, was based on the circumstances of the mixed dentition's onset. Additionally, from the age of six, it is assumed that the patient begins to have better fine motor skills, which allows for more autonomous oral hygiene activities. In the case of children over 12 years, in permanent dentition, it is considered that they should use the double-sided head brush designed for adults, which is not the object of this study.

The children included in the sample were randomly divided into two groups (G1 and G2), depending on the order in which they used the analyzed toothbrushes. Patients in Group G1 used their regular toothbrush as the control brush during the first week and the test brush (Balene) during the second week, while patients in Group G2 used the two brushes in the reverse order.

In the first visit, they were instructed in the use of the toothbrush they would use in the first week. The plaque index was measured and recorded following the Quigley-Hein plaque index modified by Turesky (TMQHPI) (9) after using plaque disclosing solution (PlacControl, Dentaïd, Barcelona, Spain). This examination was performed by two calibrated examiners. Next, instructions for toothbrush use were provided to both the patients and their parents or caregivers, with a reminder to bring the toothbrush to the second visit.

During the second visit, the patient was asked to brush their teeth without supervision, and the plaque index was recorded before and after brushing. Questionnaires regarding the opinions of both patients and parents about the toothbrush used that week were also collected. Subsequently, during the same visit, they were instructed in the use of the toothbrush they would use in the second week, and new questionnaires were provided for them to complete regarding the toothbrush used in the second week.

In the third appointment, to which they must again bring the toothbrush, the procedure for assessing the plaque index and collecting questionnaires was repeated.

Data regarding both the plaque indices and the satisfaction questionnaires were collected in a Microsoft Excel document (version 16.65) for subsequent statistical analysis.

Families included in the sample were given two questionnaires to complete, one for the children and one for the parents, regarding their satisfaction with the test toothbrush (Annex I).

At the beginning of the week when the children were to use the manual toothbrush, they were given brushing instructions following the modified Bass technique. Children were instructed to position the toothbrush at a 45-degree angle with respect to the gumline and make small horizontal movements. Then, the toothbrush should be moved vertically toward the occlusal surface of the tooth to remove bacterial plaque. Finally, after performing this procedure on the vestibular and lingual or palatal surfaces, the occlusal surfaces were brushed with horizontal movements.

For the use of the double-sided head brush, it was indicated that they should insert the brush into the mouth and close it slightly so that the upper and lower arches' teeth contacted the brush head equally. Next, they should make a horizontal sweeping motion across all teeth.

With the conventional toothbrush, children were instructed to divide the mouth into four quadrants (upper right, upper left, lower right, and lower left) and spend approximately the same amount of time on each. In the case of the double-sided head brush, the mouth was divided into the right and left sides. They were instructed to brush twice a day, in the morning and at night. No specific duration for brushing was established to replicate the actual brushing duration in normal conditions as closely as possible.

The modified plaque index (TMQHPI) (9) was calculated after using plaque disclosing solution, providing a score from 0 to 5 for each of the six assessable surfaces of each tooth (mesiovestibular, vestibular, distovestibular, mesiolingual, lingual, and distolingual). Finally, the overall score for the plaque index was calculated by taking the arithmetic mean of the total number of surfaces analyzed. The criteria for scoring the surfaces analyzed are listed in

Table 1. (The maximum value of the index per tooth would be 30, as there are 6 surfaces x 5).

0 - Absence of plaque
1 - Small accumulations of plaque separated along the gumline.
2 - Presence of a fine continuous band of plaque, with a thickness of less than 1 mm, along the gumline.
3 - Presence of a band of plaque along the gumline of the tooth, with a thickness greater than 1 mm but covering less than a third of the tooth's crown.
4 - Presence of plaque covering between one-third and two-thirds of the tooth's crown.
5 - Presence of plaque covering more than two-thirds of the tooth's crown.

Table 1: Modified Quigley-Hein Plaque Index by Turesky

## 6. Statistical Analysis

Sample size calculation was based on the study by Zúñiga et al. (1), with changes in the plaque index as the primary variable, an expected minimum effect of 8.2%, and a standard deviation of 10%, resulting in a requirement of 24 patients to achieve an alpha risk of 0.05% and a beta risk of 0.2 in a two-tailed test.

Before conducting the study, intra- and inter-examiner calibration exercises were performed. For this purpose, clinical photographs of two patients were taken after using plaque disclosing solution, and two examiners were asked to measure the plaque index twice in each patient, with a half-hour separation between the two measurements of the same patient. The Cohen's Kappa coefficient will be used to measure this agreement.

Descriptive statistics were used to present the data obtained from the examination of the patients and the calculation of the plaque indices.

The normality of the data distribution was assessed using the Shapiro-Wilk normality test, after which the t-test for paired samples or the Wilcoxon test was employed to compare the results in the two groups.

For all tests used, a statistical significance level of 95% was established.

## 7. Results

### Plaque control

	INITIAL INDEX		BALENE®		MANUAL	
	Media	DS	Media	DS	Media	DS
<b>TOTAL</b>	8,69	1,15	5,94	0,87	6,37	0,82
<b>LOWER ARCH</b>	7,22	1,09	5,54	0,88	5,99	0,87
<b>UPPER ARCH</b>	10,16	1,4	6,35	0,97	6,76	0,84
<b>QUADRANT 1</b>	10,18	1,46	6,17	1,06	6,83	0,96
<b>QUADRANT 2</b>	10,15	1,37	6,53	0,94	6,68	0,77
<b>QUADRANT 3</b>	7,7	1,14	5,66	0,91	6,25	0,88
<b>QUADRANT 4</b>	6,75	1,14	5,42	0,89	5,74	0,93
<b>ANTERIOR TEETH (1-3)</b>	8,91	1,19	5,99	0,96	6,4	0,89
<b>POSTERIOR TEETH (4-6)</b>	8,47	1,15	5,9	0,86	6,35	0,87

#### Total (whole mouth)

When analyzing the initial plaque indices, we observe that brushing with the Balene 🦷 toothbrush improves dental hygiene (8.69 vs. 5.94), and these differences are statistically significant ( $p < 0.05$ ). The same applies when comparing the initial plaque index (8.69) with the plaque index resulting from manual toothbrush use (6.37), and these differences are also statistically significant.

When comparing the results obtained with the Balene 🦷 toothbrush (5.94) with those obtained with the conventional manual toothbrush (6.37), we see that the plaque index obtained with the Balene 🦷 toothbrush is lower (less plaque) than that obtained with the conventional manual toothbrush (6.37), although these differences are not statistically significant ( $p > 0.05$ ).

#### Lower Arch/Upper Arch

When analyzing the dental arches independently, we observe an improvement in the lower arch with both types of toothbrushes compared to the initial state, although these results are not statistically significant ( $p > 0.05$ ).



When comparing the results of the Balene toothbrush (5.54) with those of the manual toothbrush (5.99), the results are better with the Balene toothbrush, although these differences are not statistically significant ( $p>0.05$ ).

In the upper arch, we observe similar results, better plaque control with both the Balene (6.35) and manual (6.76) toothbrushes when compared to the initial state (10.16). However, the differences in the upper arch are statistically significant ( $p<0.05$ ).

When comparing the Balene toothbrush with the manual toothbrush, although the results are better with the Balene toothbrush, the differences are not statistically significant ( $p>0.05$ ).

#### Quadrant 1/Quadrant 2

When comparing the results obtained by quadrants, we observe that in both quadrant 1 and quadrant 2, the differences between both toothbrushes and the initial state are significant ( $p<0.05$ ), with better plaque control with both the Balene and conventional manual toothbrushes.

Similar to the complete upper arch, when comparing the Balene toothbrush (quadrant 1=6.17; quadrant 2=6.53) with the conventional manual toothbrush (quadrant 1=6.83; quadrant 2=6.68), plaque removal is better with the Balene toothbrush, but without statistical significance.

#### Quadrant 3/Quadrant 4

In the lower quadrants, the results are similar to those obtained when analyzing the complete arch, with better plaque removal with both the conventional and Balene toothbrushes when compared to the initial state, but the differences are not statistically significant ( $p>0.05$ ).

There was also no statistical significance between the conventional manual toothbrush and the Balene toothbrush ( $p>0.05$ ).

#### Anterior Teeth

When analyzing the results obtained in the anterior teeth, we observe that both the Balene toothbrush (5.99) and the conventional manual toothbrush (6.4) remove plaque better than the initial state before hygiene instructions (8.91), and these differences are statistically significant ( $p<0.05$ ).

When comparing the conventional manual toothbrush with the Balene toothbrush, although the plaque index is lower with the Balene toothbrush, the differences are not statistically significant.

### Posterior Teeth

For the study of the posterior teeth, the results are similar to those obtained for the anterior teeth, but the differences were not statistically significant in any of the comparisons ( $p>0.05$ ).

## 8. Satisfaction Surveys

### Parent Survey

	<b>MEDIA</b>	<b>DS</b>	<b>RANGE</b>
<b>MOTIVATION</b>	3,71	0,76	3-5
<b>EASE OF GRUP</b>	4,43	0,53	4-5
<b>EASE OF USE</b>	4,29	0,49	4-5
<b>AESTHETICS</b>	3,43	0,79	2-4
<b>WEIGHT</b>	4,29	0,76	3-5
<b>COMFORT</b>	3,43	0,79	2-4
<b>HYGIENE IN HARD-TO-REACH AREAS</b>	4,14	0,9	3-5
<b>ABSENCE OF DISCOMFORT</b>	4,57	1,13	2-5
<b>TOTAL</b>	4,14	0,69	3-5

Table 3: Parental Satisfaction with the Balene® Brush

The parents of the patients included in the study rated the Balene brush with an average overall score of 4.14 points out of a maximum of 5.

Only one parent reported discomfort related to the use of the Balene brush, scoring these discomforts as 2 out of 5, with 0 being pain that prevented the use of the brush and 5 being the complete absence of discomfort while using it.

### Patient survey

	<b>MEDIA</b>	<b>DS</b>	<b>RANGE</b>
<b>MOTIVATION</b>	4,43	0,79	3-5
<b>EASE OF GRUP</b>	4,29	0,76	3-5
<b>EASE OF USE</b>	4,43	0,79	3-5
<b>AESTHETICS</b>	4,43	0,53	4-5
<b>WEIGHT</b>	4,57	0,53	4-5
<b>COMFORT</b>	3,86	1,46	1-5
<b>HYGIENE IN HARD-TO-REACH AREAS</b>	4,43	0,98	3-5
<b>FEELING OF CLEANLINESS</b>	4,43	0,53	4-5
<b>ABSENCE OF DISCOMFORT IN TEETH</b>	5	0	5
<b>ABSENCE OF DISCOMFORT IN GUMS</b>	4,57	0,79	3-5
<b>TOTAL</b>	4,43	0,53	4-5

Table 4: Patient Satisfaction with Balene® Brush

The children gave a global rating of 4.43 out of 5 points to the brush, with scores ranging between 4 and 5 points.

None of the children included in the study reported discomfort while brushing.

### 9. Conclusions

- Plaque control improves in both the upper and lower arches with both types of brushes after providing hygiene instructions to the patient. However, these differences were statistically significant in the complete mouth, the upper arch, and the anterior teeth.

- The results of this study show that brushing with the Balene® brush achieves better plaque removal in the analysis of the complete mouth, as well as by quadrants or sextants, although these differences are not statistically significant yet ( $p > 0.05$ ).
- Both patients and their parents have reported high levels of satisfaction with the Balene® brush, with overall scores of 4.14 points out of 5 for parents and 4.43 points for patients.

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### Annex I: Satisfaction Survey


Estimadas familias,

En primer lugar, les agradecemos su participación en este estudio. Nos gustaría que cumplimentasen, este cuestionario en el que darán su opinión acerca del cepillo de dientes que sus hijos han estado usando esta semana. En la segunda página, adjuntamos un cuestionario que deben cumplimentar sus hijos.

**Nada (0)      Muy poco (1)      Poco (2)      Normal (3)      Bastante (4)      Mucho (5)**

	Nada (0)	Muy poco (1)	Poco (2)	Normal (3)	Bastante (4)	Mucho (5)
<i>Mi hijo está más motivado a la hora de cepillarse los dientes</i>						
<i>Es fácil de sujetar</i>						
<i>Es fácil de usar</i>						
<i>Es bonito</i>						
<i>Pesa poco</i>						
<i>Es cómodo cepillarse los dientes con él</i>						
<i>Permite limpiar las zonas más difíciles.</i>						

<i>Mi hijo refiere molestias cuando se cepilla con él</i>						
<i>Puntuación global (0-5, siendo el 0 muy malo y el 5 muy bueno)</i>						

		☆	☆ ☆	☆ ☆ ☆	☆ ☆ ☆ ☆	☆ ☆ ☆ ☆ ☆
<i>Me gusta cepillarme los dientes con este cepillo</i>						
<i>Es fácil de sujetar</i>						
<i>Es fácil de usar</i>						
<i>Es bonito</i>						
<i>Pesa poco</i>						
<i>Es cómodo cepillarse los dientes con él</i>						
<i>Puedo limpiar todas las partes de mi boca</i>						
<i>Mis dientes quedan más limpios</i>						
<i>No molesta en los dientes</i>						
<i>No molesta en las encías</i>						

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*Me ha gustado este  
cepillo*

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