

CLINICAL EVIDENCE

2021- CLINICAL STUDY #1

Leadereed by Dr. David Herrera & Dr. Mariano Sanz, Universidad Complutense de Madrid
Product: Balene's manual prototype.

Objective: Validate the functionality of the concept and its ability to remove plaque effectively.
Product with unfinished geometries / material did not include antibacterial additive.
Key results: Balene proved to be as safe and effective as the manual control toothbrush.
Subjects rated satisfactorily efficiency and effectiveness of Balene.
Results published in the International journal Antibiotics.

2022- CLINICAL STUDY # 2

Leadereed by Dr. Fabián Pérez, Universidad Complutense de Madrid
Product: Balene's manual final product.

Objective: Demonstrate the superior effectiveness of Balene in plaque removal.
Key results: Balene showcased a 74% greater plaque removal compared to conventional toothbrushes.
Results published in the International Journal of Dental Hygiene.

2023- CLINICAL STUDY # 3

Leadereed by Dr. Pedro Diz, Universidad Santiago de Compostela
Product: Balene's manual final product.

Objective: Evaluate Balene's usability for individuals with reduced mobility.
Key results: Balene emerged as a more comfortable and easily manageable solution for individuals with reduced mobility and their caregivers during assisted brushing.
Results published in the International Journal Springer Nature.

2023- CLINICAL STUDY # 4
























Leadereed by Dra. Paloma Planells, Universidad Complutense de Madrid
Product: Balene Junior.

Objective: Evaluate the effectiveness of Balene Junior in children aged 6-11.
Key results: Balene Junior demonstrated its superiority over conventional toothbrushes in removing plaque across the eight measured areas. Both parents and participating children highly praised Balene Junior for its clean feeling, ease of use & enjoyable experience.

Key results: Balene proved to be as safe and effective as the manual control toothbrush. Subjects rated satisfactorily efficiency and effectiveness of Balene.

CLINICAL STUDY PUBLISHED IN MDPI SCIENTIFIC JOURNAL

Dental Biofilm Removal and Bacterial Contamination of a New Doubled-Side Thermoplastic Polyurethane-Based Toothbrush: A Crossover Study in Healthy Volunteers

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(This article belongs to the Special Issue **Antimicrobial Strategies against Oral Pathogenic Bacteria and Biofilm**)

Abstract

Multiple toothbrush designs have been developed to enhance dental biofilm removal and decrease bacterial contamination and retention over time. Therefore, the aim of this clinical study was to compare the efficacy of a prototype of a new double-sided thermoplastic polyurethane-based toothbrush with that of a conventional nylon-bristle toothbrush. A crossover study was conducted in systemically healthy volunteers ($n = 24$) for two one-week periods plus one washout week. As outcome variables, plaque and gingival indices, total bacterial contamination of the toothbrushes by quantitative polymerase chain reaction (qPCR), and patient-reported outcomes were measured. Clinical and microbiological variables were analysed using a general linear model and Friedman and Wilcoxon signed-rank tests. No statistically significant differences between toothbrushes were detected neither for full-mouth PII ($p > 0.05$) nor for GI ($p > 0.05$). Similarly, no statistically significant differences were detected for bacterial contamination after 40 seconds or 1 week of use, with results expressed either in CFU/mL or in CFU/mm² ($p > 0.05$). In conclusion, the tested prototype toothbrush was as effective and safe as the control toothbrush, and the participating subjects did not experience any adverse effects from its use and rated its efficiency and effectiveness in cleaning their teeth as satisfactory.

Keywords: dental biofilm; toothbrush; bacterial contamination; plaque index

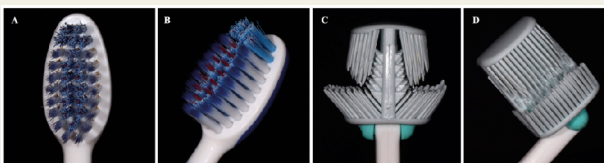


Figure 1. Photographs of control (A,B) and test (C,D) toothbrush heads.

Key result: Balene showcased a 74% greater plaque removal compared to conventional toothbrushes.

SCIENTIFIC ARTICLE PUBLISHED IN THE INTERNATIONAL JOURNAL OF DENTAL HYGIENE

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ORIGINAL ARTICLE

Comparison of the effectiveness of two manual toothbrushes: Conventional design versus double-sided toothbrush design. A pilot study

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Abstract

Objectives: Dental hygiene is the most effective method in the prevention of oral diseases. However, most patients do not use the recommended teeth brushing techniques and/or time brushing is insufficient. With this objective, modifications in conventional toothbrushes have been developed to deal with these findings. The aim of this study was to compare plaque removal effectiveness of a manual toothbrush with a modified head (MTMH) with a wrap-around design versus a conventional manual toothbrush.

Methods: This pilot prospective clinical study was designed according to STROBE guidelines. The patients suspended oral hygiene habits for 24 h (baseline). Subsequently, the teeth were brushed for 60 s. Both toothbrushes followed the same study procedure, separated by 1 month. Plaque-removing effectiveness was measured before and after tooth brushing using the modified O'Leary Plaque Index (PI).

Results: Seven patients were included in this pilot study. The mean age was 37.66 ± 10.68 years. PI mean differences between baseline and after brushing were $51.99\% \pm 16.43$ for MTMH and 27.93 ± 6.85 , for conventional toothbrush ($p = 0.0013$). After brushing, mean PI values were $18.36\% \pm 6.95\%$, and $37.61\% \pm 10.57\%$ respectively ($p < 0.001$).

Conclusion: Within the limitations of the present study, it can be concluded that the effectiveness of plaque removal by using MTMH is significantly higher than the conventional manual toothbrush.

KEYWORDS

dental plaque/therapy, dental plaque index, oral hygiene, tooth brushing



Key results: Balene emerged as a more comfortable and easily manageable solution for individuals with reduced mobility and their caregivers during assisted brushing.

CLINICAL STUDY PUBLISHED IN THE SPRINGER NATURE SCIENTIFIC JOURNAL

Plaque removal efficacy of a new toothbrush with a double-sided head and rotating handle—a pilot randomized control trial in acquired brain injury patients

Eliane García Mato¹ · Lucía Sande López¹ · Marcio Diniz Freitas¹ · María Teresa Abeleira Pazos¹ · Jacobo Limeres Posse^{1,2} · Pedro Diz Dios¹ · Berta Rivas Mundiña¹

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Abstract

Objectives To assess the efficacy of a new toothbrush (Balene) for the mechanical removal of dental plaque in patients with acquired brain injury.

Material and methods The study group consisted of 25 adults with acquired brain injury. The participants underwent 2 sessions of toothbrushing lasting 1 min, one with a conventional toothbrush and the other with the Balene toothbrush. This new double-headed toothbrush has 6 active sides, which allows for the simultaneous toothbrushing of both alveolar arches, with elastomer bristles angled at 45°, as well as a handle that rotates up to 180°. Therefore, the user does not need to remove the toothbrush from the oral cavity during the toothbrushing process. Dental plaque accumulation was assessed using the simplified oral hygiene index of Greene and Vermillion.

Results The plaque index was significantly reduced both with the Balene toothbrush ($p < 0.001$) and with the conventional toothbrush ($p < 0.001$). The dental plaque removal efficacy was similar with the two toothbrushes. There were also no statistically significant differences in the removal of plaque with the Balene toothbrush between the autonomous and assisted toothbrushing modalities ($p = 0.345$).

Conclusions For patients with acquired brain injury, the Balene toothbrush was as effective as a conventional toothbrush, regardless of whether the toothbrushing modality was autonomous or assisted.

Clinical relevance The Balene® toothbrush's efficacy in removing dental plaque is similar to that of conventional toothbrushes, both with the autonomous and assisted toothbrushing modality. Given its particular ergonomics, this toothbrush could be indicated for certain select patients with acquired brain injury (i.e., those whose degree of cooperation allows for toothbrushing, with a sufficient mouth opening, with no substantial abnormalities in the intermaxillary relationship, and with no significant edentulous sections).

Keywords Toothbrush · Dental plaque · Ergonomics · Acquired brain injury

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2023- CLINICAL STUDY #4

Leadered by Dra. Paloma Planells, Universidad Complutense de Madrid
Product: Balene Junior.

Key results: Balene Junior demonstrated its superiority over conventional toothbrushes in removing plaque across the eight measured areas. Both parents and participating children highly praised Balene Junior for its clean feeling, ease of use, and enjoyable experience.

Removal of dental biofilm from a new double-sided thermoplastic polyurethane toothbrush for children. A cross-sectional observational study with a prospective longitudinal design.

Dr. Paola Beltri Orta: Collaborating Researcher, Dr. Cristina López Arrastia: Collaborating Researcher, Dr. Alberto José López Jiménez: Collaborating Researcher, Dr. Lara Vivero Couto: Collaborating Researcher, Dr. Paloma Planells del Pozo: Principal Investigator.

CONTEXT AND OBJECTIVE

The accumulation of bacteria on the teeth causes oral problems such as cavities. Brushing is essential to prevent this. In children, brushing is less effective due to limited dexterity and lack of prolonged attention. The choice between a manual brush and an electric brush with an oscillating-rotational movement affects the effectiveness of brushing. The main objective of this study is to compare the effectiveness of the Balene® toothbrush with the traditional manual toothbrush in children. The secondary objective is to evaluate patient and caregiver satisfaction with the Balene® toothbrush and its ability to effectively remove plaque.

METHOD

In order to compare the two study groups, an observational study with a prospective longitudinal design will be carried out, in which the reduction in the plaque index achieved by a population of pediatric patients between 6 and 11 years of age, with two different types of toothbrush, will be analyzed. The plaque index will be measured and recorded according to the Turesky modified Quigley-Hein plaque index (TMQHPI) (9) after using a plaque developer (PlacControl).

CONCLUSIONS AND RESULTS

Within the limitations of this study, the Balene® toothbrush shows superior plaque removal rates in all measurements and could be a valid alternative that allows for more comfortable and effective brushing.

PLAQUE CONTROL

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

SATISFACTION SURVEY

Patient survey:

	MEDIA	DS	RANGO
MOTIVATION	4,43	0,79	3-5
EASE OF ATTACHMENT	4,29	0,76	3-5
EASE OF USE	4,43	0,79	3-5
AESTHETICS	4,43	0,53	4-5
WEIGHT	4,57	0,53	4-5
COMFORT	3,86	1,46	1-5
HYGIENE IN LESS ACCESSIBLE AREAS	4,43	0,98	3-5
FEELING OF CLEANLINESS	4,43	0,53	4-5
ABSENCE OF DISCOMFORT IN THE TEETH	5	0	5
ABSENCE OF DISCOMFORT IN THE GUMS	4,57	0,79	3-5
TOTAL	4,43	0,53	4-5

Chart 4: Patient satisfaction with the Balene® toothbrush.

Both participants and their parents reported high levels of satisfaction with the Balene® toothbrush, with overall scores of 4.14 out of 5 for parents and 4.43 for patients.



MICROBIAL CONTAMINATION*

- The nylon used in conventional toothbrushes is a hygroscopic material that retains moisture, making it an ideal medium for microbial growth from both the environment and the oral cavity itself.

NEW GENERATION TYFLEX BRISTLES

Our new generation bristles are made of a hydrophobic elastomer (TPU-thermoplastic polyurethane) that does not retain moisture.

· They are soaked in a 99,9% effective antibacterial substance during the injection process²⁸.

Table 1. Test result of Anti-microbial effect against Escherichia coli

Sample	Number of living bacteria		Antimicrobial activity value against Blank	Reduction %
	At beginning (Per cm ²)	After 24 hours (Per cm ²)		
1. Blank	1.6 x 10 ⁸	1.1 x 10 ⁸	---	---
2. 0.3%	1.6 x 10 ⁸	1.1 x 10 ⁴	2.0	99
3. 0.5%	1.6 x 10 ⁸	50	4.3	99.99
4. 0.7%	1.6 x 10 ⁸	<6.3	>5.2	>99.999
Control (Film only)	1.6 x 10 ⁸	2.4 x 10 ⁸		

Table 2. Test result of Anti-microbial effect against Staphylococcus aureus

Sample	Number of living bacteria		Antimicrobial activity value against Blank	Reduction %
	At beginning (Per cm ²)	After 24 hours (Per cm ²)		
1. Blank	1.3 x 10 ⁴	7.5 x 10 ⁴	---	---
2. 0.3%	1.3 x 10 ⁴	1.0 x 10 ³	1.8	98.7
3. 0.5%	1.3 x 10 ⁴	25	3.4	99.9
4. 0.7%	1.3 x 10 ⁴	94	2.9	99
Control (Film only)	1.3 x 10 ⁴	1.6 x 10 ⁵		

TOOTHBRUSH LIFESPAN**

-Toothbrushes should be renewed every 2-3 months due to bacterial colonisation and wear of current materials^{23,24}. However, consumers use toothbrushes for much longer than recommended by manufacturers, and toothbrushes with extreme wear are less effective than those with no or mild wear^{25,26}.

· Our bristles have a lifespan of 6 months while maintaining their physical and mechanical properties and doubling the lifetime of other nylon filament brushes.

· Although by the end of the test the internal bristles have a slight deformation, it is not enough to impact the cleaning efficacy. Besides the bristles, the rest of the toothbrush including the shaft is in perfect condition and has no reliability issues.