

Cwash® Oral Plaque Removal Efficacy Evaluation

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Introduction: We are currently conducting various tests to ensure the performance and the beneficial effects of the $Cwash^{
ensure}$ device, cooperating with various labs and dentists.

Cwash[®], *Figure* 1, is an automated oral care device that utilizes vibrations and a release technology of an antibacterial substance (xylitol) to help in the daily oral hygiene procedures without the need of toothpaste or water.



Figure 1. Cwash[®] device in its two connecting parts. On the left the mechanical and electronical part, on the right the medical grade polymeric Bite.

Oral plaque consists mainly of bacteria that forms and sticks to the teeth and to the gumline, leading to cavities and gum diseases, such as gum bleeding, unless treated by a proper oral hygiene.

The oral plaque index utilised in this study is indicative of the plaque build-up on the teeth and thus of the oral hygiene level.

Objective: Evaluate the degree of efficacy regarding oral plaque removal.

Methodology: This study was conducted between October 2021 and January 2022 by dentist Marina Anselmi and dental hygienist Stelvio di Feo in their dentist office involving 10 non-smoking subjects consisting of 4 males ranging from 37 to 56 years old and 6 females ranging from 19 to 51 years old.

After a first check-up to assess the initial plaque index and gum bleeding index, the subjects were instructed to use Cwash[®] in addition to their usual oral hygiene procedures. Cwash[®] was used daily, twice a day with the 30 seconds cycle and intensity set to factory settings.

Oral plaque and gum bleeding were checked again after 15, 30 and 90 days from the initial check-up.

Each subject's plaque and bleeding indexes were evaluated through a periodontal clinical examination. In the examination the dentists applied a liquid plaque detector using cotton swabs on the lingual and buccal teeth surfaces and evaluated the plaque and bleeding levels utilizing a periodontal probe and *Alfadocs* software. The indexes were evaluated in six sites for each dental element (buccal, mesial-buccal, distal-buccal, lingual, mesial-lingual, distal-lingual) and then converted into a single average value. The examination ends by cleaning away the residual liquid plaque detector.

An example of the data collected can be seen in *Figure 3-4* on the *Attachment A*.

Results: The detected average oral plaque levels are shown in *Table 1*.

	Starting plaque level on the first check-up	Plaque level on the second check- up	Plaque level on the third check- up	Plaque level on the fourth check- up
1	44%	33%	34%	30%
2	81%	65%	45%	46%
3	51%	46%	43%	47%
4	34%	23%	21%	19%
5	70%	57%	53%	56%
6	46%	51%	51%	49%
7	18%	19%	19%	21%
8	76%	66%	35%	38%
9	68%	53%	35%	32%
10	42%	44%	39%	45%

Table 1. Subjects' average oral plaque levels at the start of the study, after two weeks of Cwash[®] usage, after a month of Cwash[®] usage and after three months of Cwash[®] usage.

At the start of the study the subjects' plaque level ranged from a minimum of 18% to a maximum of 81% but after two weeks of Cwash[®] usage as an addition to the usual oral hygiene procedures the plaque level ranged from a minimum of 19% to a maximum of 66%, after one month of usage it ranged from a minimum of 19% to a maximum of 53% and after three months of usage it ranged from a minimum of 19% to a maximum of 56%.

The minimum levels belong to subject n.7 who shows pretty much constant plaque levels (18%-19%) on the first month and a slight increase (21%) after three months while subject n.4, who started with the second lowest plaque level, shows an appreciable decrease of

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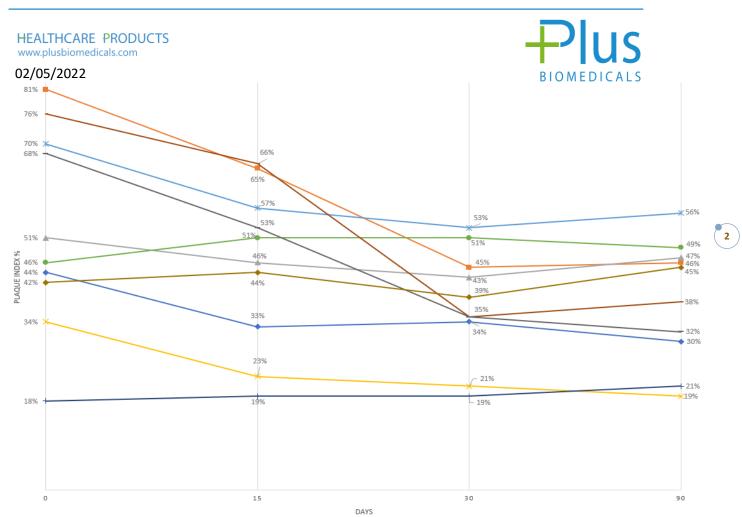


Figure 2. Visual representation of the oral plaque trend for each subject through the four check-ups in three months.

plaque levels (34% to 19%), thus it is not clear if the efficacy is lost if the plaque level is below a certain threshold ($18\% \sim 20\%$) or if the lack of a plaque level decrease is a matter strictly related to subject n.7.

On the other hand, the subjects with the highest plaque levels (n.2 and n.8) showed a great plaque level reduction: n.2 went from 81% to 46% with a decrease of 35% and n.8 went from 76% to 38% with a decrease of 38%.

As we can see in *Figure 2* the great majority of plaque levels decrease with time. Only three subjects present an increasing plaque index value: during the 0-90 days period, subjects n.6, n.7 and n.10 plaque level increased by 3%. All three of them had the initial plaque index below 50%.

On average the plaque levels decreased by 7.3% after the first 15 days period (first check-up/second check-up), decreased by 8.2% after the second consecutive 15 days period (second check-up/third check-up) and increased by 0.8% during the last 60 days period (third check-up/fourth check-up). In the first 30 days the average plaque level variation was -15.5% while the overall average plaque level variation was -14.7% in the three months period.

The detected average gum bleeding levels are shown in *Table 2.*

	Bleeding level on the first check-up	Bleeding level on the second check-up	Bleeding level on the third check-up	Bleeding level on the fourth check- up
1	0%	0%	0%	0%
2	2%	1%	2%	0%
3	15%	6%	2%	1%
4	1%	0%	0%	0%
5	0%	0%	0%	0%
6	3%	0%	0%	0%
7	0%	0%	0%	0%
8	8%	2%	2%	1%
9	8%	2%	2%	1%
10	0%	0%	0%	1%

Table 2. Subjects' average gums bleeding levels during the probing at the start of the study, after two weeks of Cwash[®] usage, after a month of Cwash[®] usage and after three months of Cwash[®] usage.

The gum bleeding levels were low or next to 0% in the great majority of the subjects and stayed as such, on the other hand the subjects with a significant bleeding index showed an appreciable decrease of it over time and usage.

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Conclusion: Assuming the levels detected on the first check-up to be the standard levels the subjects would normally have with their usual oral hygiene practices, our results suggest that the decrease of the plaque and bleeding level can be attributed to the added usage of Cwash[®].

Analysing the data, it is clear that the device it's more effective on subjects with low oral hygiene (high plaque levels) than on subjects with already good oral hygiene (low plaque levels) on which the Cwash[®] usage gave mixed results. Nevertheless, there was an average decrease of 15% of oral plaque after three months of added Cwash usage.

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Attachment A

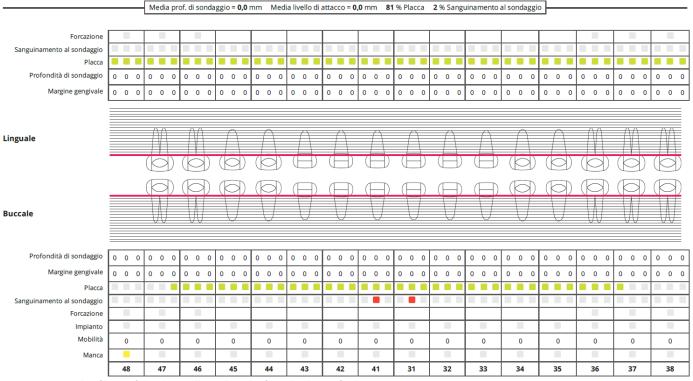


Figure 3. Example of part of the data collected on the first check-up of subject n.2

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Figure 4. Example of part of the data collected on the third check-up of subject n.2

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