

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[®] 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 electrical 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.

While we wait for the results of the long terms tests, expected in the following months, here are the first results.

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

Methodology: This study was conducted 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 days and after 1 month 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
1	44%	33%	34%
2	81%	65%	45%
3	51%	46%	43%
4	34%	23%	21%
5	70%	57%	53%
6	46%	51%	51%
7	18%	19%	19%
8	76%	66%	35%
9	68%	53%	35%
10	42%	44%	39%

Table 1. Subjects' average oral plaque levels at the start of the study, after two weeks of Cwash[®] usage and after a month 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% and after one month of usage it ranged from a minimum of 19% to a maximum of 53%.

The minimum levels belong in all instances to subject n.7 who shows pretty much constant plaque levels (18%-19%) while subject n.4, who started with the second lowest level, shows an appreciable decrease of plaque levels (34% to 21%), thus it is not clear if the efficacy is

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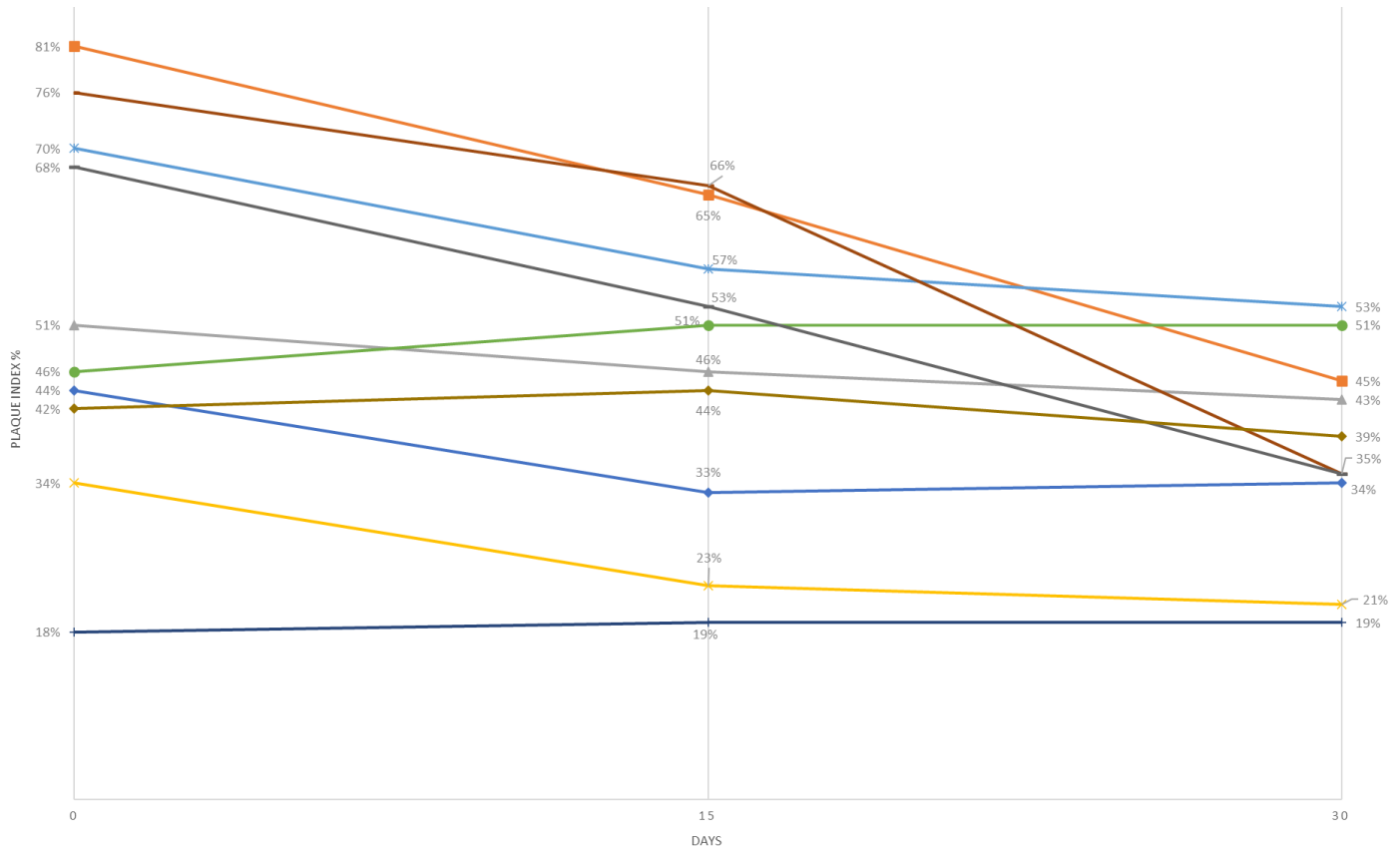


Figure 2. Visual representation of the oral plaque trend for each subject through the three check-ups in one month.

lost if the plaque level is below a certain threshold (18%~23%) or it 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 the greatest plaque level reduction: n.2 went from 81% to 45% with a decrease of 36% and n.8 went from 76% to 35% with a decrease of 41%.

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: n.7 increase by 1% and then remains stable, n.10 initially increase by 2% then decrease by 5% and n.6 increase by 5% and then remains stable. All three of them had the initial plaque index below 50%.

On average the plaque levels decreased by 7% after the first 15 days period (first check-up/second check-up) and by 8% after the second consecutive 15 days period (second check-up/third check-up). In the 30 days period the total average decrease was 16%.

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
1	0%	0%	0%
2	2%	1%	2%
3	15%	6%	2%
4	1%	0%	0%
5	0%	0%	0%
6	3%	0%	0%
7	0%	0%	0%
8	8%	2%	2%
9	8%	2%	2%
10	0%	0%	0%

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

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

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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 16% of oral plaque after a month of Cwash usage.

Even if ten subjects don't represent a vast statistical sample, it is a first sign that will surely be confirmed on the next tests we are currently carrying out.

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Attachment A

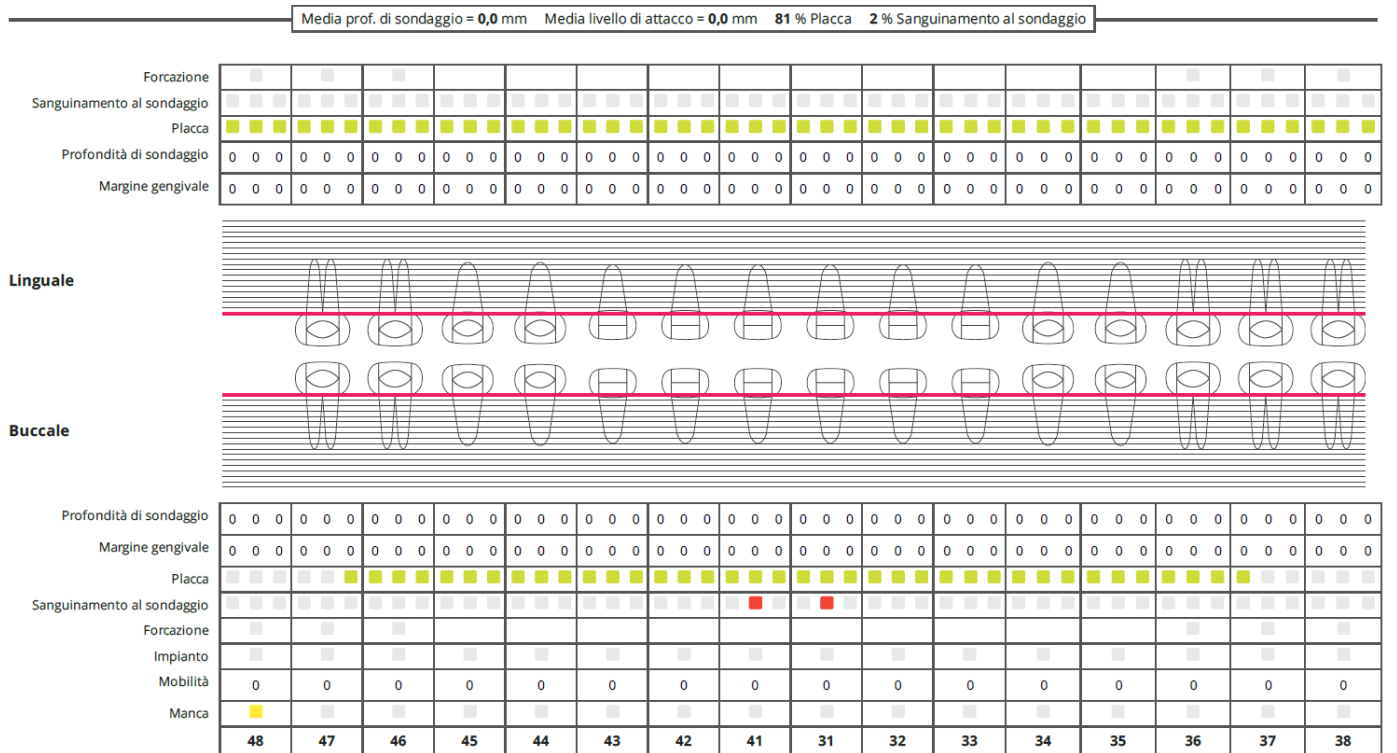


Figure 3. Example of part of the data collected on the first check-up of subject n.2

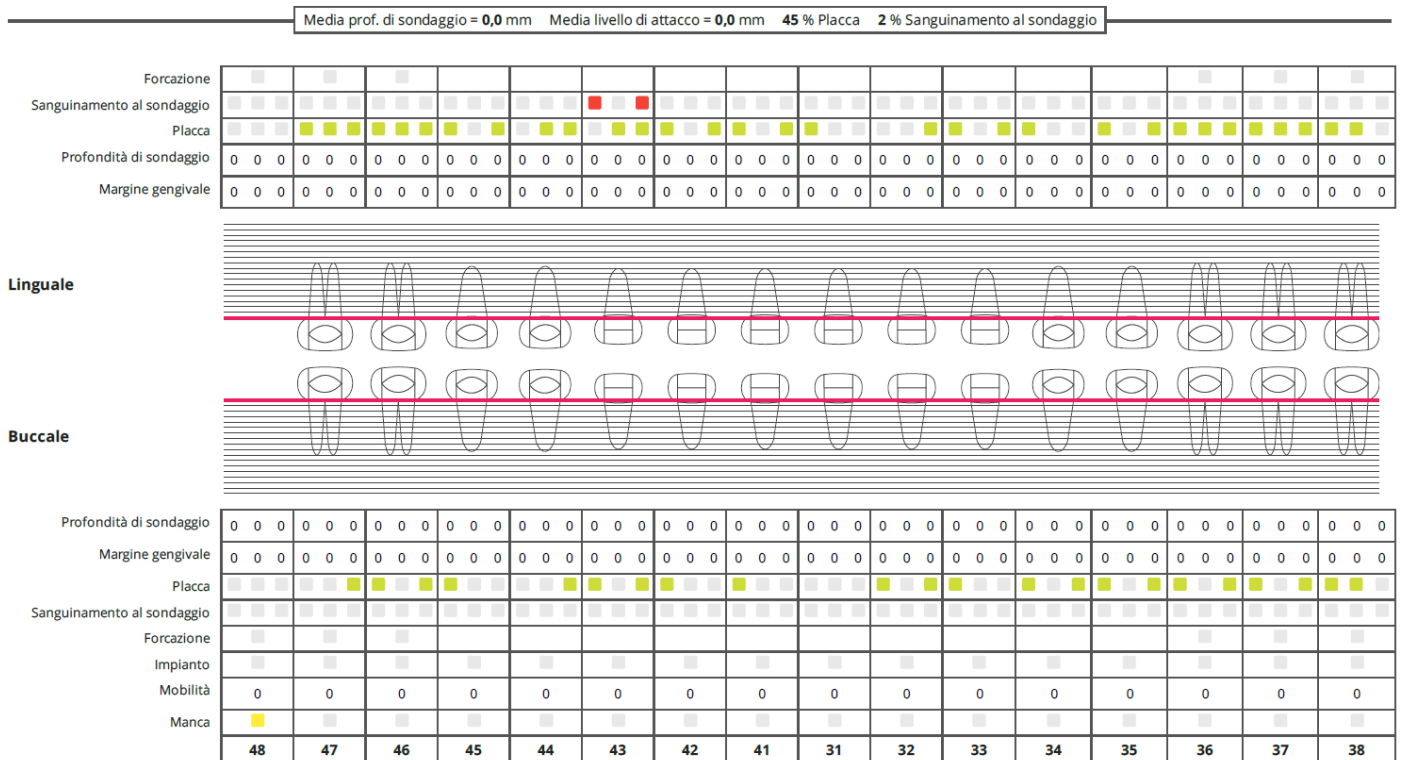


Figure 4. Example of part of the data collected on the third check-up of subject n.2