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Clinical efficacy of two toothbrushes with different bristles

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Abstract: *Objective:* The purpose of this single-blind clinical study was to evaluate the efficacy of an innovative manual toothbrush versus a traditional one. *Methods:* The toothbrushes were randomly assigned to 30 volunteers in a student population of the Dental School of the University of Bologna, Italy, divided into 15 test and 15 control subjects. A clinical examination assessing Plaque Index (PI), Gingival Index (GI) and buccal Gingival Recessions was performed at baseline, 3 and 6 months. During the baseline examination, each subject received dental debridment, oral hygiene instructions and a standard kit containing: three standard tubes of toothpaste, 1 hourglass (2 min) and one plaque disclosing solution; each subject of the test group received three innovative toothbrushes, while each subject of the control group received three traditional toothbrushes. *Results:* During the 6 months of observation both groups presented a PI and GI decrease. A more evident improvement of both indices was observed in the test group (PI $P = 0.0001$, GI $P = 0.0001$). The greatest part of recessions remained stable (0–3 months: 70% test group, 60% control group and 3–6 months: 86% test group, 94% control group). Some amplitude modifications (0.5 mm) were mainly detected in the first 3 months (control group $\chi^2 = 17.55$, $P = 0.0001$ and test group $\chi^2 = 3.31$, $P = 0.07$). They always increased in the control group and decreased in the study group. *Conclusions:* The innovative manual toothbrush is more likely to be effective in reducing PI and GI compared to the traditional one and widely safe on periodontal tissues during the period of observation.

Key words: bristle; gingival index; gingival recession; manual toothbrush; plaque index

Introduction

The use of manual toothbrushes plays a fundamental role in oral hygiene for the primary prevention; in fact, the mechanical removal of plaque from dental surfaces is considered to be an essential prerequisite to avoid excessive accumulation (1, 2) and it has been demonstrated that correct plaque control can be obtained with regular use of a toothbrush (1, 3–7) .

Tooth brushing removes food residue and bacterial plaque from dental surfaces, massages the gums and reduces inflammation of tissue (5).

Authors such as Saxer and Yankell (5) have demonstrated that 99–100% of the American population owns a toothbrush and that 95–98% of them regularly brush their teeth, although not always effectively. The same article also described the basic requisites a toothbrush must have in order to effectively remove dental plaque. These basic features include the shape of the handle and of the head (8) as well as the quality of the bristles (9–12).

However, some studies demonstrated that an aggressive use of the toothbrush, especially without rounded filaments, can damage both soft and hard oral tissues (6, 7, 13, 14). Brushing trauma and incorrect cleaning habits can cause gingival recessions in soft tissues (15) and abrasions in hard tissues, especially below the cementum-enamel junction (13).

The development and the severity of dental abrasions and gingival recessions depend on various factors, such as brushing techniques, the pressure employed, the time and frequency of brushing, chemical characteristics and abrasive power of the toothpaste, hardness and morphology of the toothbrush filaments (5, 16, 17). According to Breitenmoser *et al.* (7), there is a relationship between filament morphology and gingival lesions, depending on the shape of the toothbrush filaments: filaments with sharply cut ends cause more lesions than those with soft rounded ends.

In a study on different types of manual toothbrushes, Checchi *et al.* (18) evaluated the percentage acceptability of non-traumatic filaments (rounded filament ends) according to Silverstone and Featherstone's criteria (19). The results demonstrated that only six brushes out of the 62 examined and four brands out of the 31 tested showed a percentage of acceptable rounded ends greater than 50%.

Recently, a special toothbrush with innovative bristles (Meridol® GABA International, Münchenstein, Switzerland) was designed to efficiently clean and reduce gingival damage (Fig. 1). The original design of this toothbrush had conical filaments with extra-thin ends. Those innovative filaments, according to the manufacturer, remove plaque thoroughly yet gently, thereby helping patients who presented gingival problems (recessions and post-surgical healing), reducing the mechanical tissue damage and maintaining a good hygienic level.

Fig. 1. Profile and overhead view of Meridol® toothbrush.

The aim of this research was to evaluate the clinical efficacy of the Meridol® toothbrush in comparison with a standard reference flat profile toothbrush with round bristles, approved by the American Dental Association (ADA, Chicago, IL, USA).

Study population and methods

Thirty students, from the Dental School, University of Bologna, Italy, without either periodontitis or history of periodontal surgery, were recruited for the study. They were divided into two groups: 15 in the test group and 15 in the control group. Random allocation was carried out using numbered containers, each subject was assigned to the test group if he/she was identified by an even number and to the control group if he/she was identified by an odd number. This study was carried out according to the Helsinki Declaration.

This study was performed in single blind so the operator did not know which type of toothbrush was assigned to the subject. Subjects did not know the aim of the study. The study was carried out over a period of 6 months and clinical examination was performed at baseline, 3 and 6 months. Two expert operators with similar professional training examined the subjects. Clinical procedures were calibrated and a reproducibility analysis between the operators was carried out. A sensor probe was used during the clinical examination (PDT Sensor Probe Type Roy/STM 2-3-4-5-7-8). O'Leary *et al.* PI (20), Löe and Silness Gingival Index (GI) (21), number and width of gingival recession were recorded at baseline and at control visits. At baseline, each subject of the study

received a kit containing: three standard tubes of toothpaste, one hourglass (time: 2 min) and one plaque disclosing solution: Red Cote (Sunstar Butler, Chicago, USA). At the same time each subject of the test group was given three Meridol® toothbrushes, while each subject of the control group was given three ADA toothbrushes. Each subject of the sample had a dental debridement and was instructed on Bass oral hygiene technique (22). Each one was asked to clean the teeth twice a day for at least 2 min every time and to replace the toothbrush and the toothpaste every month; each one was finally instructed on the use of the disclosing solution.

Statistical analysis

In order to define the sample size, we set $\alpha = 0.05$, $\beta = 0.10$ and the minimum clinical relevant difference of plaque index (PI) between the two groups at 0.125. The sample size, hypothesising a gaussian distribution of PI, was obtained applying the formula $n = 2\{[(1.645 + 1.282).\sigma]/0.125\}^2$, where σ (standard deviation) was estimated by dividing the range of PI in a student population for six (i.e. 0.70/6) (23).

Parametric analysis of variance for repeated measures was carried out in order to analyse the differences in PI and GI between the two groups across the three times. As the scores of GI were mainly 0 or 1, we chose the highest values of each dental element in order to evidence a minimal significant difference. As for recessions, chi-squared test and Fisher exact test were used in order to evaluate the significance of the differences between the two groups. The alpha-level was set at 0.05 (23).

Results

Distribution of the sample

The distribution of the sample was similar in the two groups as for age (21.7 ± 1.12 and 21.8 ± 1.15 respectively) and sex (eight and seven males respectively). All the participants completed the study protocol.

Plaque index

The comparison of PI across the times between test and control group was always statistically significant ($F = 59.91$, $P = 0.0001$) (Table. 1). PI decreased during the 6 months in both groups, however the improvement was more evident in the test group (relative reduction 45.4 ± 12.86% versus 29.2 ± 11.74%). A decrease in relative reduction of PI was observed in control group (0–3 months 18.8 ± 10.09% and 3–6 months 12.8 ± 8.63%), while in test group an increase was reported (0–3 months 24.4 ± 11.10% and 3–6 months 27.8 ± 11.60%).

Table 1. **PI mean values in the two groups by time**

	Mean	Standard error	Confidence interval 95%
Baseline			
Test	68.53	5.02	58.69–78.37
Control	72.47	4.37	63.90–81.04
3 months			
Test	51.80	4.49	42.99–60.61
Control	58.87	4.51	50.03–67.71
6 months			
Test	37.40	3.02	31.48–43.32
Control	51.33	4.05	47.27–57.25

Significance of the comparison across time between test group and control group: $P = 0.0001$.
PI, plaque index.

Gingival index

An improvement of the GI during the study period was observed in both groups (Table. 2); the comparison between the two groups across the times was statistically significant in all instances ($F = 138.16$, $P = 0.0001$). The improvement was more relevant in the test group than in the control group, respectively 67.9 ± 2.28% versus 46.3 ± 2.43%. A decrease in relative reduction of GI was observed in the control group (0–3 months 31.3 ± 2.28% and 3–6 months 21.7 ± 2.01%), while in the test group an increase was reported (0–3 months 41.1 ± 2.40% and 3–6 months 45.5 ± 2.43%).

Gingival recession

At baseline, the number of recessions was 43 in the test group and 52 in the control group; no new recessions were observed during the study period (Table. 3). The difference in the

Table 2. **GI mean values in the two groups by time**

	Mean	Standard error	Confidence interval 95%
Baseline			
Test	0.56	0.03	0.50–0.63
Control	0.67	0.03	0.62–0.73
3 months			
Test	0.33	0.02	0.28–0.38
Control	0.46	0.02	0.41–0.51
6 months			
Test	0.18	0.02	0.14–0.22
Control	0.36	0.03	0.30–0.41

Significance of the comparison across time between test group and control group: $P = 0.0001$.
GI, gingival index.

Table 3. **Modified and unmodified gingival recessions in the two groups across the time**

	Number of unmodified recessions		Number of modified recessions	
	Test	Control	Test	Control
0–3 months	30	31	13	21
3–6 months	37	49	6	3

The significance of the differences inside the two groups was respectively: control group: $P = 0.0001$ and test group: $P = 0.07$.

number of recessions between the two groups across the time was always not statistically significant ($P > 0.05$). As reported in Table 3, during the observation time the major part of recessions remained stable in both groups, some amplitude modifications (0.5 mm) were mainly detected in the first 3 months (respectively in control group $\chi^2 = 17.55$, $P = 0.0001$ and in test group $\chi^2 = 3.31$, $P = 0.07$). During the period of observation the modified recessions in the test group (0–3 months 30% and 3–6 months 14%) displayed always a 0.5 mm width reduction. In the control group, the modified recessions (0–3 months 40% and 3–6 months 6%) displayed always a 0.5 mm width increase. No signs of gingival damage were observed during the period of observation.

Discussion

A randomized single-blind study was carried out in order to evaluate a new toothbrush (Meridol®) compared to a conventional flat trim one (ADA) over a period of 6 months. To reduce the influence of the variable 'brushing technique', we provided calibrated instructions on supragingival plaque control during the baseline visit. The Modified Bass method (22) applied to the colourimetric technique (24) was recommended. A clinical demonstration of the use of disclosing agent (colourimetric technique) was given at baseline; consequently, each subject received a debridement in order to clean the stained surfaces.

The toothbrush tested has extra-fine conically shaped filaments with a progressively decreasing diameter towards the free end.

A laboratory study on the evaluation of the same toothbrushes used in the present paper, suggests that the Meridol® toothbrush is more likely to be effective in clinical studies on plaque removal compared to other manual toothbrushes with rounded bristles in a flat head design that are similar to the ADA reference standard toothbrush (25).

Another study aimed at the evaluation of the cleaning efficacy of the Meridol® toothbrush against the ADA one, according to a split mouth design on 87 participants, demonstrated that both brushes removed a significant amount of plaque; but overall and in areas difficult to reach, the Meridol® toothbrush was superior to the ADA reference one. After a period of 48 h with no brushing, the Meridol® toothbrush induced a relative plaque reduction of 47.4 ± 18.0%; the corresponding value of the ADA reference toothbrush was 44.1 ± 15.6%. The difference was statistically significant ($P = 0.039$) (26).

A clinical trial regarding gingivitis reduction and potential gingival harm, demonstrated that both Meridol® and ADA toothbrushes can significantly inhibit gingival inflammation when used for several weeks. The Meridol® toothbrush, however, cleans more gently and protectively (27).

In our study, a progressive reduction of the PI was observed in both groups during the 6 months; the reduction was significantly higher in the test group than in the control group in accordance with Dörfer *et al.* (26).

It is interesting to observe how the relative reduction of the PI is progressive in the test group during the 6 months, while in the control group it begins to decrease between 3 and 6 months. It would seem that the traditional toothbrush reaches a threshold of efficacy, while the Meridol® one maintains its effectiveness during the observation period. The reason for this particular behaviour could be the different structural characteristics of the two toothbrushes.

The GI of the two groups denotes a generalized good level of periodontal health. The GI of both groups improves during the periods of observation; these findings agree with the results of a previous 3 month study where the Meridol® toothbrush reduced GI during the trial period by 26.8 ± 18.4% (1.03 ± 0.16 to 0.76 ± 0.24), while the ADA reference toothbrush achieved a relative reduction of 23.1 ± 18.4% (1.02 ± 0.14 to 0.79 ± 0.26). Inhibition during the course of the trial was statistically significant in both toothbrushes ($P < 0.001$) (27).

However, the reduction of GI is higher in our study in both test and control group if compared to the above mentioned study. The reason for this difference could be attributed to additional factors. First of all the particularity of our study sample, being made of young dental students characterized by specific knowledge, high motivation and skill in brushing

Moreover, the debridement at baseline and the use of a disclosing solution certainly could have helped to improve the oral hygiene and the periodontal health.

It is interesting to observe that as for the PI, for the GI, the relative reduction is progressive in the test group during the 6 months, while in the control group the reduction begins to decrease between 3 and 6 months. Therefore, it can be

hypothesized that the structural characteristics of the Meridol® were determinant again.

Notwithstanding the prevalent stability of the recession width during the period of analysis, some modifications were recorded especially during the first 3 months (Table 3). In spite of the limit of the calibration of the periodontal probe used, we hypothesize that the recession modification could be explained by the gingival response during the first 3 months to the dental debridement. It is interesting to observe that width modifications were totally decreased in the test group and increased in the control group. This clinical situation may be due to the different toothbrushes tested, the new bristles of the Meridol® one are more gentle on periodontal tissues but also more effective on dental plaque reaching subgingival areas (25, 28), inducing a probable regenerative response of the gingival contour.

Conclusion

The Meridol® toothbrush compared to the ADA one shows a quicker and stronger effect in reducing plaque and GI, probably because of the thickness and the particular shape of the bristles.

A reduction of the gingival recession width, even if of little entity, was induced by the Meridol® toothbrush suggesting its positive influence on periodontal tissues. The tested brush was demonstrated to be effective and widely safe in a period of 6 months. Consequently, the new toothbrush could be recommended to improve oral hygiene in all patients although further clinical research is required to ascertain its long-term effects.

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