



Clinical Evaluation of the Effectiveness and Safety of Cleaning with Toothbrushes “BIOMED”

Baydik Olga D¹, Sysolyatin Pavel G² and Vilikotskiy A^{3}*

¹Siberian State Medical University, Moskovsky tract, Tomsk, Russia

²Novosibirsk State Medical University, Krasny prospect, Novosibirsk, Russia

³SPLAT GLOBAL LLC, Lotte Plaza, Novinskiy Boulevard, Russia

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*Corresponding author:

Vilikotskiy A, SPLAT GLOBAL LLC, Lotte Plaza, Novinskiy Boulevard, Russia;

E-mail: vilikotskiy@splat.ru

Abstract

Objective: Compare the cleaning efficiency of toothbrushes with a conical and rounded bristle shape. To evaluate efficacy and safety of two toothbrushes «Biomed Black» and «Biomed Silver» during tooth brushing. **Methods:** Open-label single-center comparative randomized clinical study in two parallel groups. 52 volunteers at the age of 18 to 65 years participated in the research. The assessment of efficacy was measured by Green-Vermillion and Navy indices. Safety was tested by frequency and severity of side effects.

Results: Toothbrushes «Biomed Black» and «Biomed Silver» showed significant decrease in the amount of dental plaque after 30 seconds of brushing. Also, toothbrushes showed prolonged action of cleaning effect. During the research no side effects were observed in any of volunteers.

Conclusion: The results of the comparison of two toothbrushes with a conical shape of bristles and a cone-shaped one did not reveal any significant advantages of one of them. Both toothbrushes have good cleansing properties and prolonged action.

Clinical relevance: There are no reliable studies on the effect of the bristle shape of toothbrushes on the efficacy and safety of cleansing, as well as on the formation of dental plaque after brushing.

Keywords: Clinical trials; Toothbrush “Biomed Black”; Toothbrush “Biomed Silver”

Introduction

During the Second World Conference on Oral Health Promotion in 1999 it was stated in the oral health care report that bacterial plaque plays decisive role in caries dentistry and etiology of periodontal diseases [1]. For oral health maintenance it is necessary to effectively remove dental plaque. Nowadays a lot of toothbrushes with different brush forms are existing. Despite this variety the main competing forms are round or conical.

Comparison of effectiveness of round bristles and thin conical bristles usage was made in research [2]. Authors proved that round bristles remove dental plaque better than conical ones. Besides that, they do

not cause inflammatory processes unlike conical bristles, since rounded bristles are more rigid and fit tightly to enamel, while the conical ones can be bent. It is notable that in this paper [2] this statement is made only when using toothpastes with abrasiveness (RDA) not higher than 160. When abrasiveness is increasing the rates of cleansing and atraumaticity are almost the same regardless of the shape of the bristles.

Checchi et al. [3] discovered that round bristles in particular clean the teeth plaque better and do not damage gums. However, a big percentage of teeth brushes with round bristles do not match with quality standards and thus they damage enamel and gums.

However, in research it is proven that thinner bristles in particular clean enamel from teeth plaque better [4]. Manufacturer of toothbrushes proves that bristles "Meridol" is effective for cleaning enamel and save for gums because they have ultrathin bristles narrowed at the end. Characteristics of bristles are not disclosed. As a result of clinical tests, hygiene index and inflammatory of gums was lowered.

American dental association (ADA) recommend to use teeth brushes with bristles of round form, yet in the research no differences in cleaning between brushes with round or ultrathin bristles were not found [5].

It is considered bristle construction influence effectiveness of removing dental plaque. But thinner bristles clean teeth plaque from sublingual zone more effectively. In research Stiller et al. [6] it was proven that toothbrush with conical bristles cleans better between teeth than rounded bristles. The influence of both toothbrushes on gums was not evaluated. Similar results were obtained by *in vitro* in research of Hotta et al. [7], and also Yankell et al. [8], who studied the differences in the cleaning ability between modified bristles and simply rounded (modified bristles better cleaned enamel from plaque).

Current oral hygiene measures, appropriately used and in conjunction with regular professional care, are capable of virtually preventing caries and most periodontal disease and maintaining oral health. Toothbrushing and flossing are most commonly used, although interdental brushes and wooden sticks can offer advantages in periodontally involved dentitions [9].

Daily usage of toothbrush and other oral care products was the safest method to maintain oral health. The combination of toothbrushing plus interproximal oral hygiene aids proves the optimal method of controlling plaque accumulation, whilst gingivitis can be prevented by daily toothbrushing [10]. There are many toothbrushes with different bristle forms but, unfortunately, their effectiveness is not fully scientifically proven. The purpose of the study is to clinically prove effectiveness and safety of toothbrushes «Biomed Black» and «Biomed Silver» with round and conical thin form of bristles respectively (Figures 1 and 2).

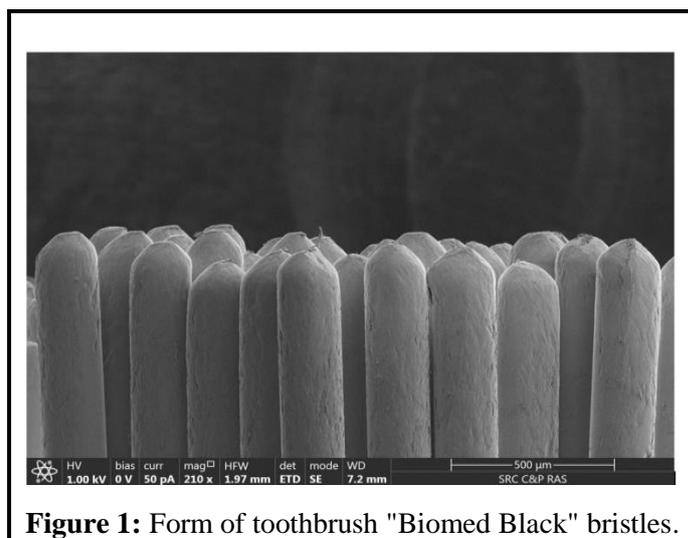


Figure 1: Form of toothbrush "Biomed Black" bristles.

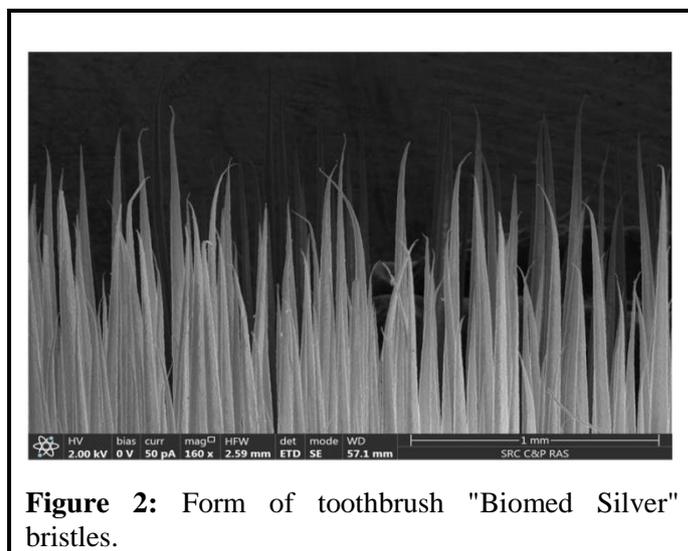


Figure 2: Form of toothbrush "Biomed Silver" bristles.

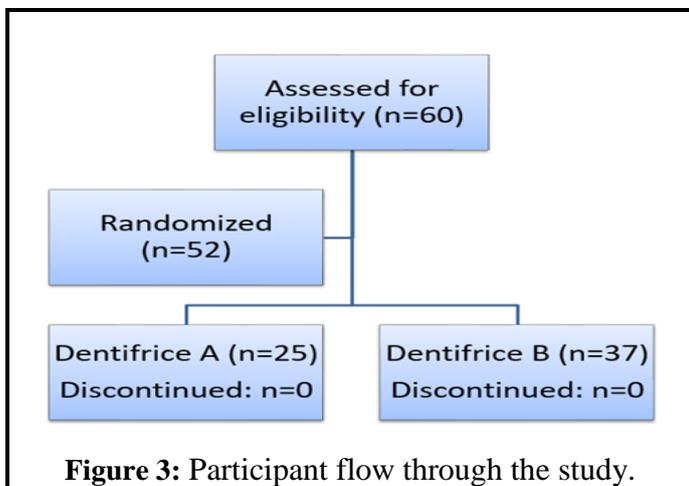
Materials and Methods

Study design

An open-labeled single-center randomized comparative study in parallel groups. In the trial compared 2 groups. All volunteers got toothbrush «Biomed Black» or «Biomed Silver» using toothpaste «Biomed Biocomplex» produced by SPLAT GLOBAL LLC. Volunteers were prohibited from using any other toothbrushes, toothpastes or mouthwashes during the research. Comparison was performed with initial parameters values.

52 volunteers participated in the research – 25 in a group obtained toothbrush «Biomed Silver» and 27 - toothbrush «Biomed Black». Participant flow through the study is shown in Figure 3. Assessment of teeth plaque was made using Green-Vermillion Index and

Navy Index on Visit 1 after 30 seconds of brushing and on Visit 2 after 12 hours after the brushing.



Toothbrushes

In the trial two toothbrushes were tested: «Biomed Black» with black opaque bristles and «Biomed Silver» with light-grey bristles produced by SPLAT GLOBAL LLC.

Patient selection criteria

Inclusion criteria were

1. Volunteers aged from 18 to 65.
2. Amount of natural teeth not less than 20.

Exclusion criteria were

1. Professional teeth cleaning or whitening procedures conducted less than 90 days before inclusion.
2. Other dental manipulations, including surgical and orthodontic, less than 30 days before inclusion.
3. Pregnancy or breast-feeding period.
4. Wearing braces.
5. Smoking within 6 months before inclusion.
6. Signs of untreated caries.
7. Conditions and diseases that may interfere with the participation of the patient in the study or may affect the evaluation of the investigated parameters.

Statistics

Statistical analysis was performed using IBM SPSS 22 for Windows. The data were analyzed using Mann-Whitney U test with 5% alpha-level. The level of significance was set at 0.05.

Results

52 volunteers participated in the study – 25 in a group «Biomed Silver» and 27 in a group «Biomed Black». Assessment of teeth plaque was performed by Green-Vermillion Index and Index Navy on Visit 1 after 30 seconds of brushing and on Visit 2 after 12 hours after this brushing. Results for both indices are shown in tables 1 and 2 below.

Table 1: Comparison of dental plaque index (Green-Vermillion index) (\pm SD).

Toothbrush	Pre-Brushing (Base line) Before visit 1	Post-Brushing after 30 Seconds brushing visit 1	Post-Brushing after 12 hours brushing visit 2
Biomed Black	1.47 \pm 0.59	0.70 \pm 0.48*	1.37 \pm 0.56*
Biomed Silver	1.48 \pm 0.62	0.82 \pm 0.52*	1.48 \pm 0.57*

*p<0.05 compared to baseline

Table 2: Comparison of Navy Index in 2 groups (p).

Toothbrush	Pre-Brushing (Base line) Before visit 1	Post-Brushing after 30 Seconds brushing visit 1	Post-Brushing after 12 hours brushing visit 2
Biomed Black	1.42 \pm 1.01	0.51 \pm 0.60*	1.21 \pm 0.80*
Biomed Silver	1.54 \pm 0.96	0.78 \pm 0.61*	1.27 \pm 0.79*

*p<0.05 compared to baseline

For toothbrush «Biomed Black» Green-Vermillion index showed decrease in the amount of teeth plaque after 30 seconds by 47%. Index Navy decreased by 36% in comparison with baseline. Also after 12 hours forming of teeth plaque was lower than at the baseline by 7% and 14% for Green-Vermillion and Navy indices respectively [11,12]. Toothbrush «Biomed Silver» showed similar results after 30 seconds of brushing - the amount of teeth plaque decreased by 55% index Navy lowered by 50%. After 12 hours forming of teeth plaque was insignificantly lower than at baseline. No side effects were detected during the research with any of participants.

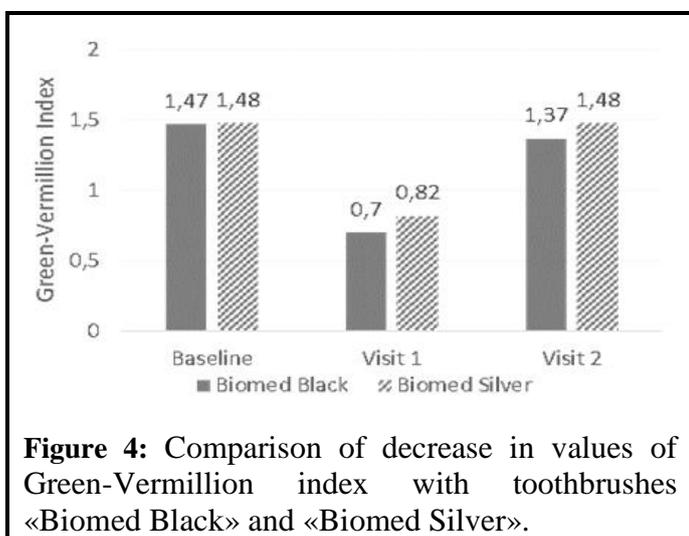


Figure 4: Comparison of decrease in values of Green-Vermillion index with toothbrushes «Biomed Black» and «Biomed Silver».

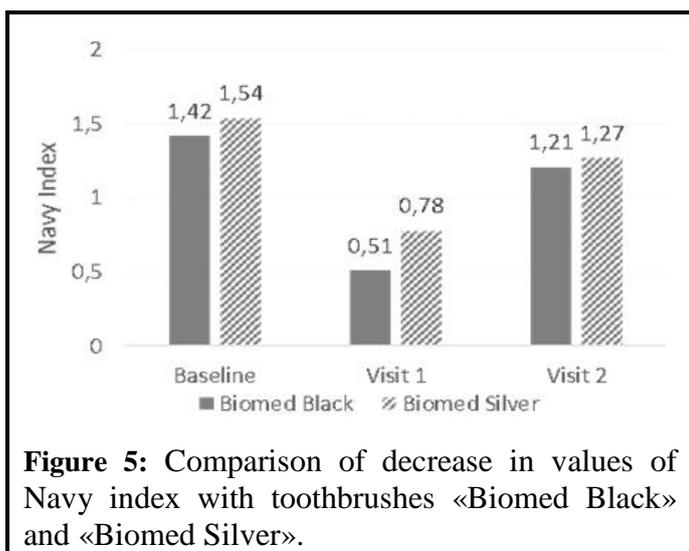


Figure 5: Comparison of decrease in values of Navy index with toothbrushes «Biomed Black» and «Biomed Silver».

Discussion

Toothbrushes «Biomed Silver» and «Biomed Black» appeared to have a good cleaning effect according to results of the trial. It was observed the substantial

decrease in the amount of teeth plaque on enamel and between teeth according to Green-Vermillion Index of and Navy Index. In Figure 4,5 below could be seen the difference between two toothbrushes in the results of Green-Vermillion and Navy indices immediately after brushing (Visit 1) and 12 hours after (Visit 2).

Considering good cleaning effect of both toothbrushes, it was mentioned that forming of dental plaque after 12 hours of cleaning was lower than before brushing. It demonstrates its prolonged cleaning effect of these products. During the study no negative side effects were detected with any of the volunteers that participated in tests.

This clinical trial demonstrated a good cleaning effect and safety of toothbrushes of BIOMED in the treatment of tooth enamel.

Conclusion

In conclusion, results of this study clinically proved the cleaning effect of toothbrushes of Biomed series and safety of their usage. These results show of long acting cleaning effect.

This research is to relevant research for comparison of effectiveness of clarification a conic and roundish bristle. The research proves efficiency, safety and not injury use of toothbrushes with various bristle of BIOMED.

Conflict of Interest

Author Baydik Olga Dmitrievna declares that he has no conflict of interest. Author Sysolyatin Pavel G. declares that he has no conflict of interest.

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Ethical Approval

The trial was performed according to Declaration of Helsinki and Good Clinical Practice (ICH GCP).

Informed Consent

Informed consent was obtained from all individual participants included in the study. All subjects before inclusion had been informed on the study design and procedures and signed the informed consent form.

Author Contributions

All the authors contributed to the design, conduct and reporting of the study. All authors had access to the final study report, made contributions to the development of the manuscript, had final responsibility for the decision to submit, and approved the submitted version.

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