

## Efficacy of two soft-bristle toothbrushes in plaque removal: a randomized controlled trial

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**Declaration of Interests:** The authors certify that they have no commercial or associative interest that represents a conflict of interest in connection with the manuscript.

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DOI: 10.1590/1807-3107BOR-2016.vol30.0134

Submitted: Jul 6, 2016  
Accepted for publication: Oct 10, 2016  
Last revision: Oct 25, 2016

**Abstract:** The aim of this study was to compare the efficacy in supragingival plaque removal of two soft-bristle toothbrushes. Seventy volunteers were allocated randomly to the Colgate SlimSoft or Curaprox CS5460 toothbrush groups. At baseline appointment, volunteers underwent plaque examination using the Rustogi Modification of the Navy Plaque Index. Under supervision, they then brushed their teeth for 1 minute with their assigned toothbrushes and the plaque examination was repeated. Volunteers performed daily oral hygiene with their assigned toothbrush and a regular dentifrice provided by the researchers for 7 days. The baseline experimental procedures were then repeated. Separate analyses of variance were performed for the whole-mouth, interproximal, and gumline plaque scores ( $p < 0.05$ ). No difference in baseline pre-brushing scores was found between groups. After a single toothbrushing, the mean plaque score was significantly reduced in both groups ( $p < 0.05$ ), with greater reduction of whole-mouth and interproximal plaque scores observed in the SlimSoft group compared with the Curaprox group ( $p < 0.05$ ). After 7 days, the SlimSoft group showed greater reduction of the whole-mouth and interproximal plaque scores compared with the Curaprox group ( $p < 0.05$ ). In conclusion, the SlimSoft toothbrush presented greater efficacy in supragingival plaque removal than did the Curaprox CS5460 toothbrush, as reflected by whole-mouth and interproximal plaque scores.

**Keywords:** Toothbrushing; Dental devices, Home care; Dental plaque; Oral hygiene.

### Introduction

Supragingival plaque removal is considered to be one of the most important health promotion strategies in dentistry. It has been considered to be of utmost importance in the decline of the prevalence of caries (especially with the concomitant use of fluoride dentifrices), as well as gingivitis and periodontitis.<sup>1</sup>

Longitudinal studies have consistently demonstrated that good standards of oral hygiene and regular maintenance reduce the incidence of caries, periodontal disease, and tooth loss, and, more recently, that they improve the outcomes of treatment with dental implants.<sup>2,3,4,5</sup> A classical study related to this topic was performed in Sweden; it demonstrated that a strict oral hygiene regimen reduced tooth loss, the number of new decayed surfaces, and periodontal attachment loss.<sup>3</sup> Other studies have



also demonstrated the effects of supragingival plaque control on different oral health parameters, reinforcing its importance as the core of preventive dentistry.<sup>6</sup>

Although the importance of supragingival plaque control is generally recognized, oral hygiene practices demand time, dexterity, and motivation; these factors limit the clinical effectiveness of self-performed oral hygiene. Clinical studies have documented the presence of remaining biofilm despite good levels of plaque control.<sup>7,8</sup>

The consumption of oral hygiene products has increased worldwide. For example, less than one toothbrush per capita was consumed in the 1990s in Brazil.<sup>9</sup> In 2010, consumption had practically doubled.<sup>10</sup> Importantly, however, increased consumption does not necessarily translate to better clinical results in terms of effective plaque control.

Toothbrushing is the most widely used method for plaque control, and a wide variety of toothbrushes is available in the market. Studies comparing the efficacy of available toothbrushes are scarce. The use of soft bristles has been recommended to improve plaque reduction while minimizing harm to the gingival tissues. Therefore, comparisons of available instruments are necessary to provide better support for the indication of any given toothbrush. To our knowledge, no study has compared the efficacy of two available soft-bristle toothbrushes – SlimSoft (Colgate-Palmolive Co., New York, USA) and Curaprox CS5460 (Curaden AG, Kriens, Switzerland). The aim of this study was to compare the efficacy of these toothbrushes in plaque removal. The pre-established hypothesis was that no difference in efficacy would be found between the two brushes.

## Methodology

### Study design

This study was designed as a phase III single-center, examiner-blind, two-cell, parallel-group randomized clinical trial.

### Ethical aspects

The Institutional Review Board of the Federal University Rio Grande do Sul approved this study (protocol 1.213.343), and all volunteers signed informed

consent forms. The study was conducted according to good clinical practice (GCP).

### Sample size estimation

The sample size calculation utilized historical data from previous studies. Sample size was determined based on a standard deviation for the response measure of 0.12, an alpha level of 0.05, and 80% power. Thirty-five individuals per group were considered to be necessary to detect a minimal statistically significant difference between study groups of 15%.

### Subjects

Seventy healthy adult males and females aged 21–70 years were enrolled in this study. The convenience sample was recruited in October 2015 at the Federal University of Rio Grande do Sul, Brazil. Inclusion criteria comprised good general health; initial mean plaque index  $\geq 0.6$ , as determined by the Rustogi Modification of the Navy Plaque Index;<sup>11</sup> and  $\geq 20$  natural uncrowned teeth, excluding third molars. Subjects meeting any of the following criteria were excluded from the study: orthodontic bands, removable partial denture, tumor or significant pathology in the soft or hard tissues of the oral cavity, moderate or advanced periodontal disease (purulent exudate, tooth mobility, and/or extensive loss of periodontal attachment or alveolar bone), five or more carious lesions requiring immediate care, antibiotic use in the month prior to study entry, participation in any other clinical study or test panel within 30 days prior to the start of the study, pregnant or breast-feeding status, dental prophylaxis in the 2 weeks prior to baseline examination, history of allergy to oral/personal care consumer products or their ingredients, use of any prescription medicine that might interfere with the study outcome, medical condition prohibiting abstinence from eating/drinking/chewing gum for 4 hours prior to the scheduled visit, and history of alcohol or drug abuse.

### Experimental procedures

Qualifying subjects reported to the clinical study site after refraining from the performance of any oral hygiene procedure for 12 hours and from eating, drinking, or smoking for 4 hours. The baseline

examination began with evaluation of the soft tissues of the oral cavity and perioral region, followed by plaque disclosure with 6mL 2% basic fuchsin solution (Eviplac; Biodinâmica, São Paulo, Brazil). A baseline pre-brushing plaque examination was then performed using the Rustogi Modification of the Navy Plaque Index. Supragingival plaque was assessed on the facial and lingual surfaces of each tooth and recorded as present or absent on nine discrete areas of the tooth. From these site-wise scores, a whole-mouth plaque score was determined for each subject by calculating the proportion of sites in the mouth at which plaque was present. The Rustogi Modification of the Navy Plaque Index includes nine areas of each tooth, analyzed from the facial and lingual/palatal aspects. Three areas are near the gingival margin, two are interproximal, and four are on the body of the tooth. This index allows for stratification of area(s) of concern during the analysis.<sup>11</sup>

Participants were then randomized into two groups of 35 individuals each. The randomization list was computer generated. An external researcher was responsible for allocation concealment. The toothbrushes were kept inside numbered opaque plastic bags. The experimental groups were given:

1. Colgate SlimSoft (Colgate-Palmolive Co., New York, USA) group;
2. Curaprox CS5460 (Curaden AG, Kriens, Switzerland) group;

Under supervision, the subjects were instructed to brush their teeth for 1 minute with their assigned toothbrush and a commercially available basic fluoride toothpaste (Colgate Cavity Protection; Colgate, São Paulo, Brazil). Baseline post-brushing plaque evaluation was then performed. Subjects were dismissed from the study site with their assigned toothbrush and toothpaste. They were instructed to use the products at home twice daily (morning and evening) for the next 7 days and to refrain from any interproximal cleaning. Subjects returned to the clinical facility for 7-day pre- and post-brushing plaque examinations using the same index and brushing procedure. The same calibrated examiner (CKR), who was unaware of group allocation, performed all plaque examinations.

### Statistical analysis

The main study outcomes were plaque scores, determined using the Rustogi Modification of the Navy Plaque Index. Separate statistical analyses were performed for whole-mouth, interproximal, and gumline plaque scores. A per-protocol analytical method was used. Baseline and 7-day whole-mouth, interproximal, and gumline plaque scores were compared between groups using analysis of variance. Responses were assessed within and between products using mean pre- to post-brushing and pre- to 7-day differences. Within-treatment comparison of baseline and follow-up whole-mouth, interproximal, and gumline plaque scores was performed using paired *t* tests. All statistical tests were two sided, with a significance level of  $\alpha = 0.05$ . The statistician was blinded to product allocation.

### Results

Three of the 73 subjects screened for study participation were excluded (Figure 1). All 70 randomized subjects completed the 7-day clinical study, and their data were included in the analysis. The two groups did not differ in terms of gender, mean age, or mean baseline plaque score (Table).

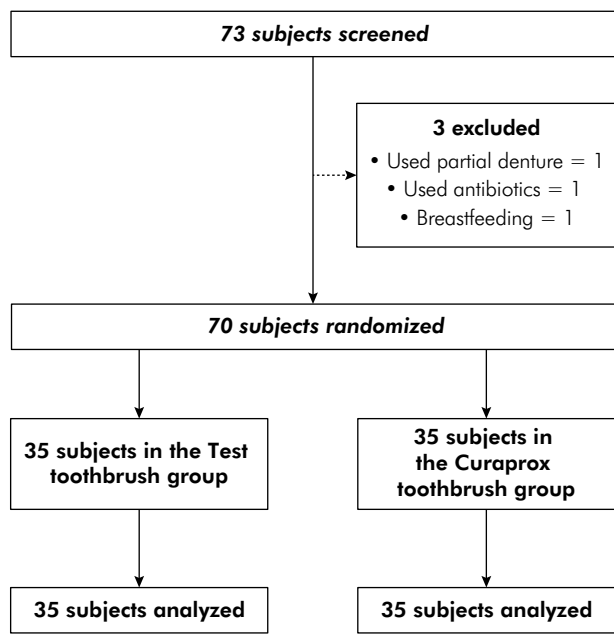


Figure 1. Flow chart of the study.

Baseline pre-brushing whole-mouth, interproximal, and gumline plaque scores did not differ between groups (Figure 2). A single toothbrushing reduced all of these scores significantly in both groups ( $p < 0.05$ ). The SlimSoft group showed significantly greater reduction in the mean whole-mouth and interproximal plaque scores in comparison with the Curaprox group ( $p < 0.001$ ; Figure 2). The reduction in the gumline plaque score did not differ between groups.

At the 7-day assessment, toothbrushing significantly reduced the whole-mouth, interproximal, and gumline plaque scores in both groups ( $p < .05$ ; Figure 3). Subjects in the SlimSoft group exhibited significantly greater reduction in the whole-mouth and interproximal plaque scores compared with

subjects in the Curaprox group ( $p < 0.001$ ), with no significant difference in the gumline plaque score.

During the entire study, five adverse events (one in the SlimSoft group and four in the Curaprox group) were recorded. All five subjects completed the 7-day study. The adverse event reported in the SlimSoft group was tooth sensitivity; the events reported in the Curaprox group were a burning sensation in the mucosa, gingival sensitivity and redness in the upper arch, gingival bleeding for 2 hours after brushing, and development of aphtha in the upper arch.

## Discussion

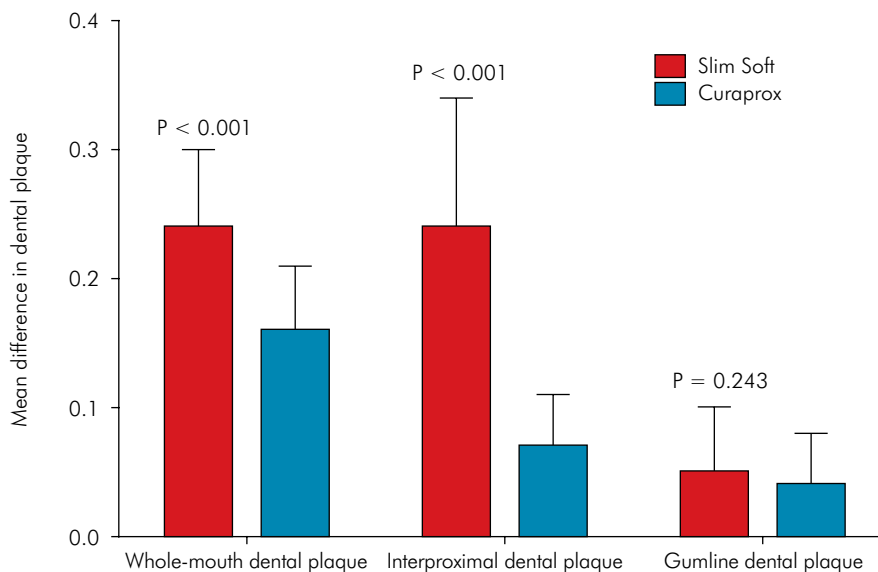
The present randomized controlled clinical trial compared the efficacy in plaque removal of two commercially available toothbrushes. The use of the SlimSoft toothbrush resulted in greater plaque reduction than did the use of the Curaprox toothbrush, as demonstrated by whole-mouth and interproximal plaque scores. The trial was designed according to contemporary clinical epidemiological paradigms and following GCP standards. The report is based on the CONSORT statement.

The results of this study should be considered within the perspective of its design, which aimed to verify efficacy. They should be understood as reflecting the capacity of the toothbrushes to remove dental

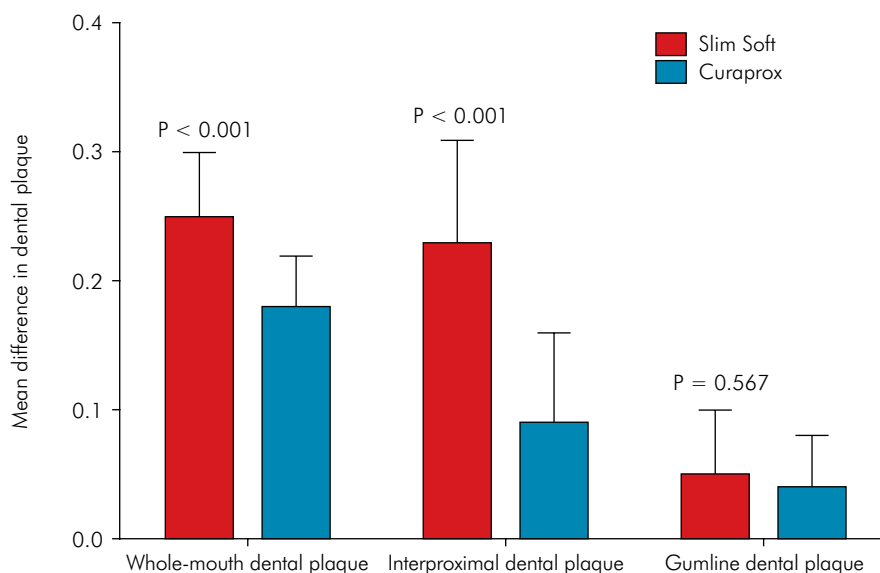
**Table.** Demographical and baseline characteristics of the study subjects.

| Variable                           | SlimSoft group            | Curaprox group            | p-value |
|------------------------------------|---------------------------|---------------------------|---------|
| Male/Female                        | 13/22                     | 19/16                     | 0.149   |
| Mean age $\pm$ SD (range)          | 31.89 $\pm$ 10.21 (21–62) | 33.26 $\pm$ 12.47 (21–63) | 0.616   |
| Mean plaque $\pm$ SD (whole-mouth) | 0.76 $\pm$ 0.07           | 0.74 $\pm$ 0.06           | 0.248   |

SD: Standard deviation.



**Figure 2.** Mean differences in plaque scores from baseline pre-brushing to baseline post-brushing. p-values refer to inter-group comparisons (analysis of variance).



**Figure 3.** Mean differences in plaque scores from 7-day pre-brushing to 7-day post-brushing. *P* values refer to inter-group comparisons (analysis of variance).

plaque. The study outcomes were measured using the Rustogi Modification of the Navy Plaque Index,<sup>11</sup> which enables the analysis of plaque topography in accordance with the American Dental Association's guidelines for toothbrush studies.<sup>12</sup> We calculated whole-mouth, gumline, and interproximal plaque scores. In addition, plaque examinations were conducted at two experimental timepoints (baseline and 7 days) to assess whether a learning curve affected the results. The same pattern of plaque removal was observed in both groups, independent of the timepoint. Comparison between baseline pre-brushing and post-brushing scores, and 7-day pre-brushing and post-brushing scores revealed the same trend. The lack of a difference in pre-brushing plaque scores between groups indicates that randomization was effective. In addition, the amount of plaque accumulation resulting from the 12-hour periods of refraining from oral hygiene before both evaluations was sufficient to test the efficacy of the toothbrushes.

The null hypothesis that no difference in the efficacy of plaque removal would be observed between toothbrushes was rejected in two analyses (whole-mouth and interproximal plaque scores), the results of which favored the SlimSoft toothbrush. The reduction in the whole-mouth plaque score was 35–50% greater in the SlimSoft group than in the

Curaprox group. The whole-mouth plaque score is a useful measure of the potential of a toothbrush to remove plaque as a whole, which is of great value for the assessment of clinical efficacy. It has been used in previous studies to infer the cleaning potential of toothbrushes.<sup>13</sup> The most interesting result of this study concerns the interproximal plaque score. Studies have clearly demonstrated that the interproximal areas are critical, as the occurrence of gingival inflammation is greater in these areas.<sup>14</sup> Although toothbrushing focuses on the buccal and lingual tooth surfaces, this study showed that it achieved a substantial reduction in interproximal plaque, even without the use of an interdental cleaning device. This finding is of clinical importance, as flossing is not widespread. Therefore, it is interesting that a toothbrush can reach interproximal areas. The reduction of interproximal plaque achieved with the SlimSoft toothbrush was 50–242% greater than that achieved with the Curaprox toothbrush. This result could be attributable to the design of the toothbrush. Participants refrained from interproximal cleaning during the study period, and compliance with this instruction was checked during follow-up visits.

None of the five adverse events reported in the present study was related to the protocol. The burning sensation, eventual bleeding, and hypersensitivity

might be related to a study participation effect, in which individuals may have brushed more vigorously. The use of only 1 minute brushing, as in a previous study,<sup>15</sup> also aimed to avoid excessive brushing.

This study has strengths and limitations that should be noted. Among the strengths is the study design, with randomization of the participants, use of a standardized brushing time, examiner reproducibility, blinding of the examiner and statistician, and 100% compliance with no dropout. The limitation is that effectiveness was not assessed due to the short duration of the study. In addition, the comparative

effect of such brushes on gingival inflammation remains to be studied.

## Conclusion

In conclusion, the SlimSoft toothbrush showed greater efficacy in plaque removal than did the Curaprox toothbrush, as demonstrated by whole-mouth and interproximal plaque scores.

## Acknowledgments

The present study was supported by Colgate Palmolive Inc.

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