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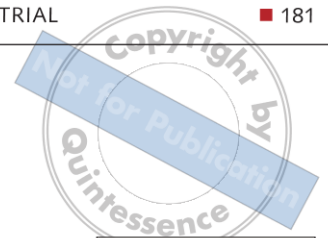
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Efficacy and preference of manual toothbrushes: a randomised, single blind, controlled trial



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Key words *dental plaque, mechanical plaque removal, patient preference, randomised controlled trial, toothbrush*

Purpose: Toothbrushes are manufactured in different designs but it is unclear whether these differences may lead to improvement in the removal of bacterial plaque or make the toothbrushes more appealing to users. The aim of this study is to compare the efficacy of 11 toothbrushes in terms of plaque removal and their acceptance by patients.

Materials and methods: Eleven toothbrushes were randomly assigned to one of the 12 sectors of the mouth of 48 patients. Each patient underwent one plaque recording before and after toothbrushing. Eleven sectors of the mouth were brushed by 11 different toothbrushes, while one sector was used as a control (no toothbrushing). Two questionnaires were also administered to investigate the aesthetic and comfort preference by each participant.

Results: All 11 toothbrushes resulted in effective plaque reduction with respect to the control sector ($P < 0.0001$). No significant differences were found between them. Colgate Massager showed the highest score for aesthetic preference by the patients when compared with Butler 311 and Gum Super Tip 463 ($P = 0.0148$). Oral-B Indicator 35 exhibited the highest score in terms of comfort felt by the patients compared to Colgate Omni and Gum Technique 493 ($P = 0.0095$).

Conclusions: All of the tested toothbrushes, even though different with respect to shape and scope of function, demonstrated efficacious plaque removal.

Conflict-of-interest statement: *The study was completely self-financed with no conflicts of interest.*

■ Introduction

Gingivitis, periodontitis and dental caries represent the most common oral cavity diseases. One important factor for their prevention is the control of pathogenic microorganisms contained in the bacterial biofilm on dental surfaces. This is achieved by the regular correct daily use of a toothbrush at home¹. Consequently, the diffusion of appropriate oral hygiene practices and education for prevention in industrialised countries resulted in the fact that

the toothbrush has become an object possessed and used by everyone, independent of age, gender or social status. Today the toothbrush is not only a tool for domestic oral hygiene, but also an accessory that accompanies people in their daily life, affecting their habits and schedules.

The difference between various manual toothbrushes should lie in the design and new technologies developed by their producers. Toothbrushes have different designs but it is unclear whether these differences lead to improvement in the removal of

Table 1 Sectors of the mouth at which 11 different toothbrushes were randomly assigned.

Sector	Involved teeth	Side
1	12 - 11 - 21 - 22	buccal
2	12 - 11 - 21 - 22	palatal
3	14 - 15 - 16 - 17	buccal
4	14 - 15 - 16 - 17	palatal
5	24 - 25 - 26 - 27	buccal
6	24 - 25 - 26 - 27	palatal
7	32 - 31 - 41 - 42	buccal
8	32 - 31 - 41 - 42	lingual
9	34 - 35 - 36 - 37	buccal
10	34 - 35 - 36 - 37	lingual
11	44 - 45 - 46 - 47	buccal
12	44 - 45 - 46 - 47	lingual

bacterial plaque or to make the toothbrushes more attractive.

In 1988, the Proceedings of the European Workshop on Mechanical Plaque Control discussed the efficacy of the domestic mechanical devices used for oral hygiene, and some characteristics were identified in order to describe an 'ideal' toothbrush. In the Consensus Report, Egelberg & Claffey² stated that 'the ideal design could be specified as a brush which is user-friendly and which efficiently removes plaque with no deleterious soft or hard tissue effects. Attributes of an acceptable toothbrush include: 1) handle size appropriate to user age and dexterity; 2) head size appropriate to the size of the patient's mouth; 3) use of end-rounded nylon or polyester filaments not larger than 0.009 inches in diameter; 4) use of soft bristle configurations as defined by the acceptable international industry standards; 5) bristle patterns which enhance plaque removal in the approximal spaces and along the gum. In general, available short-term studies indicate that many brush designs can potentially fulfil these broad specifications'.

In terms of plaque control, Creeth et al³ recently observed that the efficacy of manual brushing that increased with time and the use of dentifrice did not increase the percentage of plaque removal. However, despite the fact that many manual toothbrushes are available on the market, there is still unclear scientific evidence about the superiority of one type over another⁴. Furthermore, it should be emphasised that

most of the available research has been sponsored by the toothbrush manufacturers, and a possible conflict of interest may affect the results.

The aim of the present independent randomised controlled trial was to compare 11 manual toothbrushes currently present on the market in terms of:

- Efficacy of plaque removal
- Patient satisfaction, considering both aesthetics prior to use and comfort during use of the toothbrushes.

The study was carried out and reported according to the criteria of the Consort Statement⁵, and was completely self-financed with no conflicts of interest.

■ Material and methods

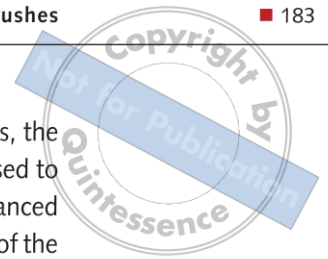
■ Trial design

This is a split-mouth single blind randomised controlled trial. The mouth of the enrolled patients was divided in 12 sectors (Table 1). For each patient, at 11 sectors, 11 manual toothbrushes were randomly assigned to brush the teeth, while 1 sector was not brushed and used as control. Before brushing, a questionnaire was administered to assess the patient's aesthetic rating for each displayed toothbrush. After brushing, a second questionnaire was administered to assess comfort and handiness for each toothbrush. In addition, the efficacy of the 11 tested toothbrushes was evaluated in terms of plaque removal recorded by a blinded examiner.

■ Participants

The present investigation was carried out from October 1st to December 23rd, 2008. During this span of time, 48 volunteers were consecutively recruited for the study in a private office located in Campi Bisenzio, Florence, Italy. The inclusion criteria used for selection were:

- age >18 years
- presence of all natural teeth (with or without the presence of the third molars) or crowns supported by natural teeth or dental implants
- Full-Mouth Plaque Score (FMPS) >50%⁶.



The exclusion criteria were:

- subjects with manual inability to perform tooth-brushing procedures
- pregnant women.

The presence of dental caries, calculus and periodontal diseases did not represent exclusion criteria.

Written informed consent was obtained from all subjects to be entered in the study, during which they were explained the aims and methods of the research. The principles outlined in the Declaration of Helsinki on experimentation involving human subjects were adhered to.

■ Outcomes

The primary outcome was plaque index reduction measured, in a dichotomous manner⁷, on 12 sites (3 sites per 4 dental surfaces) for each sector of the mouth.

The secondary outcomes were subjective evaluations of:

- aesthetic appearance of each displayed toothbrush, measured on a scale from 0 (very bad) to 10 (very nice)
- comfort (comfort, handiness and happiness) for each tested toothbrush, measured on a scale from 0 (very low) to 10 (very high).

■ Sample size

For sample size calculation, a pilot study was conducted on 10 subjects. The subjects utilised only one manual toothbrush on 6 sectors of the mouth. The other contralateral 6 sectors, randomly paired up with the first 6 sectors, were not brushed and served as controls.

The sample size was calculated using $\alpha = 0.005$ and the power $(1-\beta) = 80\%$. For the variability $\sigma = SD$, the calculated value of 3.43 sites (from the previous pilot study) was used, considering the difference in terms of presence of plaque between the brushed and not brushed sites as a variable outcome. The minimum clinically significant difference (δ) considered was of 2 sites with or without plaque. On the basis of these data, the number of patients required to conduct the present study was calculated as 43. However, considering the possibility of per-

forming a randomization with separated blocks, the total number of requested patients was increased to 48 (a multiple of 12) in order to avoid unbalanced comparisons between the investigated regions of the mouth.

■ Training and calibration session

One examiner (GM) was required to attend a training and calibration session on 10 patients aimed at: *i*) instruction and calibration for the measurement of a dichotomous plaque index (presence/absence)⁷, *ii*) instruction for the compilation of the data collection sheets and *iii*) preliminary data recording session. The plaque index was measured twice after an interval of 30 min, corresponding to 6 sectors of the mouth. Therefore, a total of 60 pairs of measurements were recorded and used to evaluate the examiner's reliability using the intra-class correlation coefficient (ρ).

■ Interventions

Experimental phase

All of the patients were instructed to discontinue toothbrushing 24 h before the appointment in which the experimental phase would be performed. At the appointment, no information about the type of brushing technique was given to the participants. The dental hygienist (GM) recorded the plaque index according to O'Leary⁶ on 6 sites per tooth, using a staining solution for dental plaque (GUM® Red-Cote® Liquid, Sunstar Suisse, Etoy, Switzerland).

After the measurements, two other operators (VM and VP) showed the patients 11 different toothbrushes and administered the questionnaire for the aesthetic judgement (from 0 [very bad] to 10 [very nice]) on the same 11 toothbrushes by each patient.

Afterwards, each patient was asked to brush his/her teeth without any toothpaste for 10 s (timed with a chronometer) per sector, considering the mouth divided in 12 sectors (buccal and lingual sides for each sextant) as follows (Table 1):

- Sector #1: buccal aspect, from left upper lateral incisor to right upper lateral incisor
- Sector #2: palatal aspect, from left upper lateral incisor to right upper lateral incisor

- Sector #3: buccal aspect, from first upper right premolar to second upper right molar
- Sector #4: palatal aspect, from first upper right premolar to second upper right molar
- Sector #5: buccal aspect, from first upper left premolar to second upper left molar
- Sector #6: palatal aspect, from first upper left premolar to second upper left molar
- Sector #7: buccal aspect, from left lower lateral incisor to right lower lateral incisor
- Sector #8: lingual aspect, from left lower lateral incisor to right lower lateral incisor
- Sector #9: buccal aspect, from first lower left premolar to second lower left molar
- Sector #10: lingual aspect, from first lower left premolar to second lower left molar
- Sector #11: buccal aspect, from first lower right premolar to second lower right molar
- Sector #12: lingual aspect, from first lower right premolar to second lower right molar.

Cuspid teeth were excluded from the analysis since they represented a limit area between the different treated sectors.

A different manual toothbrush was assigned at each region, with the exception of one region that was considered as the control.

Eleven manual toothbrushes were selected to be tested, 6 among the most commonly available in Italy: AZ Complete (Procter & Gamble, Cincinnati, OH, USA), Colgate Massager (Colgate Palmolive, New York, NY, USA), Colgate Omni (Colgate Palmolive), Gum Super Tip 463 (Sunstar Americas, Chicago, IL, USA), Gum Technique +, (Sunstar Americas), Mentadent Integral Perfection (Unilever, London, UK); and 5 among the most tested toothbrushes in randomised controlled trials published in the last 10 years. In particular, in order to identify these toothbrushes, an electronic search by means of MEDLINE was performed on September 1st, 2008 using the following strategy:

- Free search with 'manual toothbrush' as keywords
- Limits: dates from 1998/06 to 2008/06, humans, dental journals, randomised controlled trial.

Based on this searching strategy, the following 5 toothbrushes were identified: Gum Butler 311 (Sun-

star Americas), Colgate Navigator (Colgate Palmolive), Elmex Inter X (GABA International, Munchestein, Switzerland) Oral-B Cross Action 35 (Procter & Gamble), Oral-B Indicator 35 (Procter & Gamble).

At the end of the experimental phase (brushing phase), a second questionnaire was administered to all subjects to evaluate (from 0 [very low] to 10 [very high]) comfort, handiness and happiness felt using all of the tested toothbrushes.

Afterwards, the blinded examiner (MG) performed a second recording of the plaque index⁶ with respect to the used toothbrushes.

■ Randomisation and allocation concealment

In each patient, the 12 sectors of the mouth were randomly assigned to be treated by each of 11 toothbrushes and in 1 sector no treatment was performed (control sector).

A computer-generated randomisation list assigned the 12 treatments (11 test toothbrushes and 1 no treatment as control) to the 12 sectors of the mouth. Randomisation was performed in separated blocks, to avoid an unbalanced comparison between the different tested toothbrushes and the investigated regions of the mouth.

Treatment assignment was noted in the registration and treatment assignment form that was kept by the central registrar (NM, statistician).

Allocation concealment was performed by using opaque sealed envelopes, sequentially numbered. The central registrar prepared the allocation sequence by means of a computer-generated random permuted block (patient) and instructed the secondary investigators (MV and PV) to assign to each patient a sealed envelope containing the treatments for the 12 sectors of the mouth and to supervise the exactness of all 11 manual brushing steps (10 s per single step). The opaque envelope was opened immediately before the beginning of the manual brushing phase.

■ Blinding (masking)

The examiner (GM) selected the patients and was maintained blinded for the assigned treatment (toothbrushes).

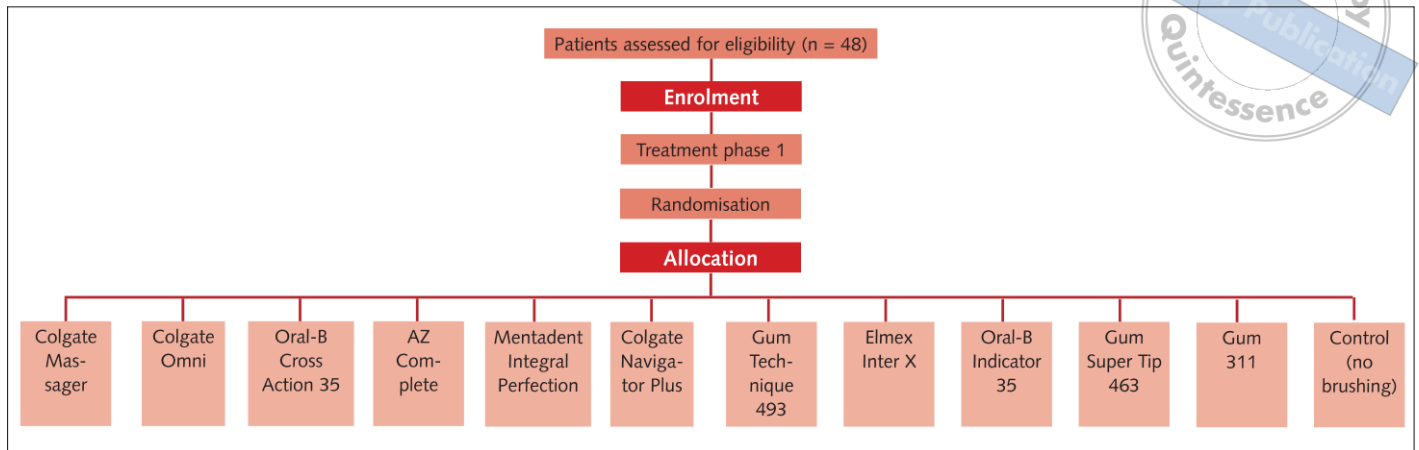
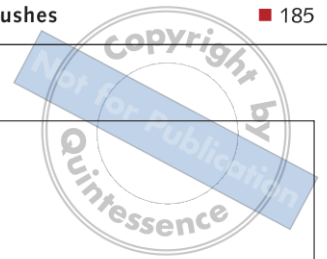


Fig 1 Flow-chart diagram of the study (according to the CONSORT statement).

■ Statistical analysis

The null hypothesis of the study was that there would be no difference in results between the 11 tested toothbrushes and the control sites in terms of plaque removal. In addition, it was hypothesised that no difference would be observed regarding the aesthetic appearance and comfort, handiness, and happiness felt using all of the tested toothbrushes.

Descriptive statistical analysis was performed using frequency and percentage for the qualitative variables, while mean and standard deviation were computed for the quantitative variables.

A restricted maximum likelihood (ReML) method for fitting a mixed model was performed, using the difference in plaque index values recorded between the baseline and the end of the follow-up as an outcome variable, and the type of toothbrush as an explicative variable. Baseline plaque index was used as a covariate and the patient as a random effect.

The Tukey test for post hoc multiple comparisons was used to analyse the differences between the toothbrushes in terms of plaque removal, taking into consideration the fact that the examined sectors were located within the patient.

The secondary variable aesthetic appearance was used as an outcome variable in a mixed-effect model where the type of toothbrush was the explicative variable and the patient was the random effect. The same model was used for the variable outcome comfort. Differences in terms of aesthetic appearance and comfort were examined using the

Table 2 Efficacy of different toothbrushes in terms of plaque removal. Plaque index according to O'Leary⁶.

Toothbrush	Sites (standard deviation)*
Oral-B CrossAction 35	7.2 (2.7)
AZ Complete	7.0 (3.2)
Mentadent Integral Perfection	6.8 (3.2)
Colgate Omni	6.7 (2.9)
Gum Super Tip 463	6.4 (3.0)
Gum Technique 493	6.0 (3.2)
Oral-B Indicator 35	5.9 (3.1)
Colgate Navigator Plus	5.6 (3.2)
Elmex InterX	5.6 (3.6)
Gum 311	5.5 (3.1)
Colgate Massager	5.4 (3.5)
Control	1.0 (2.4)

*The values related to the different toothbrushes linked by a continuous bar do not show a significant difference.

Tukey test for multiple comparisons in the mixed-effect models.

■ Results

A total of 48 subjects (26 females) were enrolled in the study (Fig 1). The mean age was 34.4 years, ranging from 18 to 63. No drop-outs were recorded during the experimental phase.

The results of the examiner calibration showed a reliable intra-class correlation coefficient (r) of 0.86 using plaque index as the outcome variable.

Table 3 Patients' aesthetic preference for the different toothbrushes.

Toothbrush	Score (standard deviation)*
Colgate Massager	6.4 (2.4)
Colgate Omni	6.0 (2.1)
Oral-B CrossAction 35	5.9 (2.1)
AZ Complete	5.8 (1.8)
Mentadent Integral Perfection	5.8 (2.4)
Colgate Navigator Plus	5.7 (2.0)
Gum Technique 493	5.7 (2.0)
Elmex InterX	5.6 (1.9)
Oral-B Indicator 35	5.4 (2.0)
Gum Super Tip 463	5.0 (1.8)
Gum 311	5.0 (2.8)

*The values related to the different toothbrushes linked by a continuous bar do not show a significant difference.

The differences in terms of plaque index between baseline and the end of the brushing phase are reported in Table 2. One toothbrush (Oral-B Cross Action 35) achieved a higher efficacy (7.2 ± 2.7 sites with plaque removed) than the other tested toothbrushes, even though no statistically significant difference was observed between the 11 toothbrushes. All of the toothbrushes showed a similar statistically significant efficacy in removing bacterial plaque with respect to the control sector that was not brushed ($P < 0.0001$), which resulted in a value of 1.0 ± 2.4 sites.

Regarding the patient preference for the aesthetic appearance of the displayed manual toothbrushes, a significant difference resulted from the analysis (Table 3). In particular, Colgate Massager obtained the highest score (6.4 ± 2.4) when compared with the other toothbrushes, and this difference was statistically significant with respect to Gum Super Tip 463 and Gum 311 ($P = 0.0148$).

With regard to the variable comfort reported by the interviewed subjects, significant differences resulted from the analysis (Table 4). In particular, Oral-B Indicator 35 achieved a higher score (6.7 ± 1.2) than the other tested toothbrushes and this difference was statistically significant with respect to Colgate Omni and Gum Technique 493 ($P = 0.0095$).

Table 4 Patients' comfort preference for the different toothbrushes.

Toothbrush	Score (standard deviation)*
Oral-B Indicator 35	6.7 (1.2)
AZ Complete	6.4 (1.4)
Elmex InterX	6.4 (1.5)
Gum 311	6.4 (2.2)
Mentadent Integral Perfection	6.4 (2.0)
Colgate Massager	6.3 (2.2)
Oral-B CrossAction 35	6.2 (1.9)
Gum Super Tip 463	6.1 (1.5)
Colgate Navigator Plus	6.0 (1.8)
Colgate Omni	5.6 (2.3)
Gum Technique 493	5.4 (1.9)

*The values related to the different toothbrushes linked by a continuous bar do not show a significant difference.

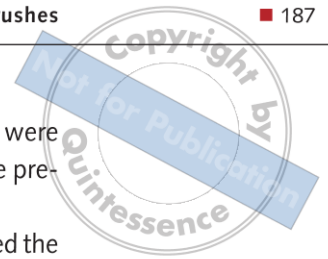
■ Discussion

In the present study, 48 subjects were enrolled to evaluate the efficacy, in terms of plaque removal, of 11 manual toothbrushes commonly present on the market or tested in several studies. Aesthetic appearance and comfort felt during their use were also evaluated by the subjects. It should be noted that, within the current literature, no randomised controlled trials have been published reporting patient-centred data (i.e. aesthetics, comfort) with regard to manual toothbrushes.

The results showed that (a) all tested toothbrushes were able to significantly remove bacterial plaque with respect to the control area ($P < 0.0001$), where no toothbrushing was performed, and that (b) no significant differences were present between them. In contrast, regarding the judgement of the aesthetic appearance and the comfort felt during the use of the toothbrushes, some statistical differences were observed in the analyses. In particular, Colgate Massager showed the highest score in terms of aesthetic satisfaction, while Oral-B indicator 35 showed the highest score in terms of comfort compared to the other tested toothbrushes.

■ Plaque-removing ability

Before the experimental toothbrushing phase of the different sectors of the mouth, no instructions about



the type of technique were given to the participants. In fact, the aim of this study was not to test brushing techniques, but the efficacy in bacterial plaque removal, after a single occasion, of the most commonly used manual toothbrushes.

Generally, it is well-known that the patients do not use the most correct/appropriate technique. In fact, from the results of this study noticeable differences in terms of plaque removal were present among the enrolled subjects. This is to confirm the concept that, nowadays, even with the modern toothbrushes that are more accurate and responsive to the preferences of laypeople, the skill of the patient and the frequency of home toothbrushing are the strong determinants for the maintenance of periodontal health⁸. In addition, up to now, there is no evidence to support the superiority of one manual toothbrush over another^{4,8}.

Reviewing the literature, the results of the present report are in agreement with other studies. In 2007, Sripriya et al⁹ published the results of a randomised, single blind, cross-over controlled trial that had a similar study design as the present study. The aim was to compare the efficacy of the four most commonly used bristle designs of toothbrushes in terms of plaque removal after a single occasion. The results showed a significant reduction in the post-brushing plaque scores for all the brushes and no significant differences in the reduction of plaque scores between the four brushes.

The present results are also in agreement with the conclusion of another intra-individual crossover controlled randomised trial conducted by Bergenholtz et al¹⁰. The authors enrolled 24 adults to compare the plaque-removing ability of straight multi-tufted and V-shaped brushes. The results showed that there was no difference between the two brushes tested in the unsupervised part of the study.

In contrast, a 4-week post-prophylaxis randomised parallel longitudinal double-blind clinical trial conducted by Chava¹¹, with the aim of determining the plaque-removing ability of a curved bristle toothbrush compared to a conventional straight bristle manual toothbrush, showed different results. In fact, the author reported that the curved bristle toothbrush was significantly more effective in removing plaque overall than the conventional toothbrush. However, it must be noted that the

two manual toothbrushes tested by Chava¹¹ were different from the 11 toothbrushes used in the present study.

Another randomised clinical trial¹² compared the Oral-B Cross Action toothbrush with seven leading manual brushes (Mentadent Oral Care, Oral-B Indicator, Reach Advanced Design, Colgate Total, Colgate Plus, Dr. Best InterDent, Colgate Wave) in terms of safety and efficacy. Seven independent clinical studies, each involving approximately 100 healthy subjects from a general population, were carried out using a crossover design.

In each study, the Oral-B Cross Action toothbrush was compared with an alternative brush for plaque removal efficacy. In each study, the Cross Action toothbrush was found to be significantly more effective than the compared brush in removing plaque. The results reported by Cronin et al¹² showed some differences with respect to the data of the present report. In particular, Cronin et al reported significant differences in terms of plaque removal, while in the present study no differences were observed (Table 2). Another important aspect to consider with respect to the study by Cronin et al¹² is the presence of a conflict of interest if compared to the present study that was conducted independently from the toothbrush companies.

■ Aesthetic assessment

Regarding the aesthetic assessment, among the 11 manual toothbrushes, Colgate Massager showed the highest score, with a statistically significant difference with respect to Gum Super Tip 463 and Gum 311. This result may be due to the different heights of the bristle rows set on a rubber head, the lateral rubber bristles and its coloured ergonomic handle.

■ Comfort

Considering the variables of comfort, handiness and happiness felt during the use of the tested toothbrushes, Oral-B Indicator 35 obtained the highest score, resulting in a statistically significant difference with respect to Colgate Omni and Gum Technique 493. This result may be due to its straight ergonomic handle, manageability and its little head with bristle rows at the same level.

Since the purpose of this study was to assess the efficacy of the brushes after a single experimental phase, consisting of a single use and in a single appointment, an important limitation of the present study is the inability to test the safety, efficacy and comfort of the toothbrushes over their prolonged use. Additional studies with at least 3 months of follow-up should be conducted to identify differences between the tested brushes in terms of efficacy, safety, aesthetics and comfort.

■ Conclusions

Although some differences were observed between manual toothbrushes in terms of patients' opinion on aesthetics and comfort, from an objective point of view, all of the 11 tested brushes were effective in removing plaque and no significant differences were observed between them.

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