Plaque removal efficacy of Colgate 360 toothbrush: A clinical study

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Abstract

Aim: The aim of this clinical study was to confirm the plaque removal efficacy of the Colgate 360 Whole Mouth Clean Toothbrush. **Study Design:** This was a single-center, monadic, case–controlled study with the 7 days duration. **Materials and Methods:** A total of eighty participants (56 male and 24 female) aged between 18 and 45 years with a minimum of 20 permanent teeth (excluding the third molars) without any prosthetic crowns and an initial plaque score of minimum 1.5 as determined by Modified Quigley-Hein Plaque Index (1970) participated in the study. There were two dropouts during the study duration, one male and one female. The participants were instructed to brush for 1 min, after which plaque index was recorded again. They were then instructed to brush their teeth twice a day for 1 min with the assigned toothbrush (Colgate 360 Whole Mouth Clean Toothbrush) and a commercially available fluoride toothpaste for the next 7 days. On the 7th day, all the participants were recalled for follow-up and plaque examination. The plaque index scores (pre- and post-brushing) were recorded, tabulated, and analyzed statistically. **Results:** The mean plaque indices reduced after brushing both on day 1 and day 7. There was also a reduction in mean plaque indices from day 1 to day 7. All these reductions were statistically significant ($P < 0.001$). The reduction in plaque scores was independent of the gender of the participants however female participants showed lower scores as compared to male participants ($P < 0.001$). **Conclusion:** The present study demonstrated a significant reduction in plaque scores with the use of Colgate 360 Whole Mouth Clean Soft Toothbrush throughout the study period. Continued use resulted in a further significant reduction in plaque scores irrespective of the gender of participants.

Keywords: Dentifrices, Plaque scores, toothbrush design

Introduction

Dental plaque is the primary etiological factor for dental caries, gingival, and periodontal diseases. Therefore, plaque control and good oral hygiene play a key role in the maintenance of oral health and prevention of these diseases.[1-3] When teeth are brushed with fluoride dentifrice, there is considerable evidence of a caries reduction.[4,5] There are various plaque control methods including mechanical and chemical, but mechanical tooth-brushing method remains the most efficient and commonly used method. Various toothbrush designs have been introduced. These range from variations in shape and size of the head, number of tufts, number of bristles in each tuft, arrangement of the tufts, direction of bristles, material, diameter and length of the bristles, features of the neck like flexibility, etc. Each variant claims its own advantage.[6-8]

The aim of present study was to clinically access the efficacy of manual Colgate 360 Whole Mouth Clean Toothbrush in reducing dental plaque.

Materials and Methods

In this 1-week, single-center, monadic, case–controlled clinical study, a total of eighty (56 male; 24 female) participants aged between 18 and 45 years, with a minimum initial plaque score of 1.5 as determined by Modified Quigley-Hein Plaque Index (1970) were selected and included in the study as

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per the inclusion and exclusion criteria. However, only 78 participants (55 male and 23 female) completed the study as there were two dropouts during the study duration, one male and one female.

Inclusion criteria

- Male and female participants, aged between 18 and 45 years
- Availability for complete duration of the study
- Good general health
- Minimum of twenty uncrowned permanent natural teeth (excluding third molars)
- Initial plaque index of at least 1.5 as determined by the use of the Modified Quigley-Hein Plaque Index
- Signed informed consent form.

Exclusion criteria

- Presence of orthodontic bands
- Presence of partial removable dentures
- Tumor(s) of the soft or hard tissues of the oral cavity
- Advanced periodontal disease (purulent exudate, tooth mobility, and/or extensive loss of periodontal attachment or alveolar bone)
- Five or more carious lesions requiring immediate restorative treatment
- Use of antibiotics any time during the 1 month prior to entry into the study
- Participation in any other clinical study or test panel within the 1 month prior to entry into the study
- Pregnant women or women who are breastfeeding
- History of allergies to dentifrice products and/or personal care products
- Medical condition which prohibits not eating/drinking for 4 h.

Materials used

- Disclosing agent (Alpha Plac; Two-Tone disclosing agent, DPI, Mumbai)
- Colgate 360 Whole Mouth Clean Soft Toothbrush.

Prior to reporting to the testing facility for baseline plaque examination, participants refrained from all oral hygiene measures (i.e., toothbrushes, dentifrices, mouth rinses, dental floss, irrigation devices, etc.) for 12 h and from eating, drinking, or smoking for 4 h. After the application of disclosing agent, each tooth was divided into six surfaces, three facially and three lingually as follows: (1) Mesiofacial, (2) midfacial, (3) distofacial, (4) mesiolingual, (5) mid-lingual, and (6) distolingual. Plaque scores were recorded using Modified Quigley-Hein Plaque Index.

Participants were instructed to brush for 1 min, after which they were examined again for recording the plaque index. They were then instructed to brush their teeth twice a day for 1 min with their assigned toothbrush (Colgate 360 Whole Mouth Clean Soft Toothbrush) and commercially available

fluoride toothpaste for the next 7 days. On the 7th day, the participants were recalled for follow-up and plaque examination (similar to baseline assessment). These plaque scores were recorded, tabulated, and subjected to statistical analysis.

Results

Table 1 shows the demographic distribution of participants enrolled for the study. $P = 0.18$ demonstrated the equality of mean age of male and female participants by t-test. Table 2 shows the pre- and post-brushing mean plaque scores of all the participants on day 1 and day 7. The initial plaque score (prebrushing) on day 1 was held as the baseline reference for comparison. The mean plaque scores had comparable variance. Progressive reduction in mean plaque scores was observed across all participants as depicted in Graph 1. Table 3 (two-way ANOVA) shows the difference in mean plaque scores between male and female participants which were statistically significant ($P < 0.0001$). The reduction in mean plaque scores was also highly significant ($P < 0.0001$). In general, the female participants recorded lesser plaque scores at all-time intervals. Tables 4 and 5 show the individual differences and percentage reductions in mean plaque scores. By brushing for 1 min with Colgate 360 Whole Mouth Clean Soft Toothbrush, a mean plaque score ranging from 21% to 28% was seen. With continuous use of this toothbrush for 1 week, a further reduction from 38% to 44% was observed before brushing on the 7th day. A 66–67% reduction was observed after brushing on day 7. Table 6 (Tukey honest significant difference [HSD] test) compares individual mean

Table 1: Age- and gender-wise distribution of participants

	Number of participants	Age (years)		
		Mean	SD	Range
Male	56	28.93	6.33	18-44
Female	24	26.83	6.38	18-45
Total	80	28.3	6.38	18-45

P value by *t*-test for equality of means=0.18 (two-tailed). SD: Standard deviation
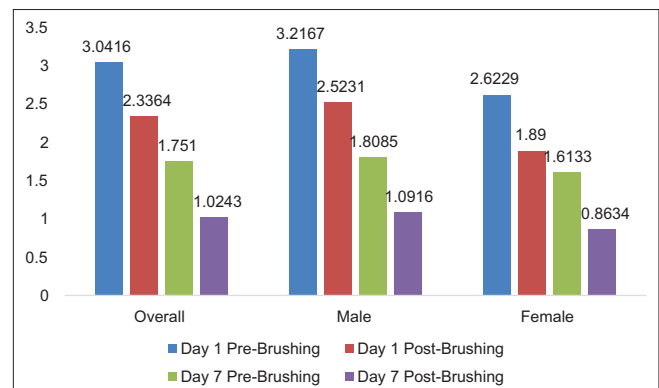
Graph 1: Mean plaque scores

Table 2: Mean plaque scores

	Day 1		Day 7	
	Prebrushing	**Postbrushing**	**Prebrushing**	**Postbrushing**
Overall				
Mean	3.0416	2.3364	1.751	1.0243
SD	0.733	0.822	0.7567	0.5691
Male				
Mean	3.2167	2.5231	1.8085	1.0916
SD	0.7129	0.7956	0.7962	0.5951
Female				
Mean	2.6229	1.89	1.6133	0.8634
SD	0.611	0.7182	0.6479	0.4755

SD: Standard deviation

Table 3: Two-way ANOVA for significance of difference in mean plaque score between genders and time intervals

Source	SS	df	MS	*F*	*P*
Rows (gender)	11.04	1	11.04	22.56	<0.0001
Columns (time)	172.09	3	57.36	117.23	<0.0001
r × c	2.64	3	0.88	1.8	0.1472
Error	148.75	304	0.49		
Total	334.52	311			

SS: Sum of square, MS: Mean square

scores and demonstrates statistical significance of individual differences between mean plaque scores ($P < 0.01$).

Discussion

Dental plaque is a major etiological factor in the causation of dental caries and plaque-induced gingival diseases. Mechanical removal by means of toothbrush, toothpaste, and mouth rinses helps in checking pathogenic plaque build-up; thereby, preventing these diseases. Effective and therapeutic plaque control is an important aspect of personal hygiene. The use of an appropriately designed toothbrush has been documented as an effective tool among plaque control measures. Colgate 360 Whole Mouth Clean Soft Toothbrush is one such attempt to revolutionize the mechanical plaque control among the home-based personal care regimens. The advent of newer toothbrushes with technological advances and infinitesimal modifications in designs is a constant addition to the already existing toothbrush consumer market.[9,10] Thus, a well-designed clinical trial to test a newer brush design is a primary requirement to validate the effectiveness in mechanical plaque removal. Therefore, this study was undertaken to assess the clinical effectiveness of Colgate 360 Whole Mouth Clean Soft Toothbrush in reducing plaque score in study participants over a follow-up of 1 week. The study design was designed to be short-term, single-center, and monadic to reduce the bias error and to control confounding variables like subject compliance.[11] Another major problem associated with these studies is "Hawthorne

effect,"[12] that is, participants brush more consciously and overzealously on the day of examination. To overcome such a problem, participants were refrained from all oral hygiene measures (i.e., toothbrushes, dentifrices, mouth rinses, dental floss, irrigation devices, etc.) for a standardized period of at least 12 h prior to plaque score estimation.

Dental plaque is usually colorless, transparent, and not visible to naked eye but can be easily detected by using disclosing solution or tablet. In the present study, a two-tone disclosing solution was chosen as it stains immature plaque as pink and mature plaque as blue or purple.[13]

The sample size of a minimum of 60 was determined based on a standard deviation for the response measure of 0.4, a significance level of alpha = 0.05, and an 80% level of power. The study was powered to detect a minimal statistically significant difference between the study group means of 20%. The sample size calculation utilized historical data from previous studies. Considering a 10% dropout ratio, eighty participants were taken into the study out of which only two dropouts was observed.

Effective tooth-brushing depends on a number of factors including motivation, frequency of tooth-brushing, method, type of dentifrice, and manual dexterity.[14] Thus, in this study, participants were motivated and instructed to use the given toothbrush and fluoridated dentifrice but with the same tooth-brushing method, they have been doing earlier.

In the clinical studies, levels of plaque can be assessed by using various plaque indices, which quantify the amount of plaque present on the surfaces of teeth. Modified Quigley-Hein Plaque Index is the most commonly used plaque index in which plaque is assessed on facial and lingual surfaces of all teeth after disclosing agent. This index is popular due to their ease of use, lesser time, and no specialized equipment requirement.[15]

The results of the study demonstrate an unequivocal efficacy of Colgate 360 Whole Mouth Clean Soft Toothbrush in

Table 4: Difference between mean plaque scores

	Day 1		Day 7	
	Prebrushing	**Postbrushing**	**Prebrushing**	**Postbrushing**
Day 1				
Prebrushing				
Overall	X	−0.7052	−1.2906	−2.0173
Male		−0.6936	−1.4082	−2.1251
Female		−0.7329	−1.0096	−1.7595
Postbrushing				
Overall	−0.7052	X	−0.5854	−1.3121
Male	−0.6936		−0.7146	−1.4315
Female	−0.7329		−0.2767	−1.0266
Day 7				
Prebrushing				
Overall	−1.2906	−0.5854	X	−0.7267
Male	−1.4082	−0.7146		−0.7169
Female	−1.0096	−0.2767		−0.7499
Postbrushing				
Overall	−2.0173	−1.3121	−0.7267	X
Male	−2.1251	−1.4315	−0.7169	
Female	−1.7595	−1.0266	−0.7499	

Table 5: Percentage reduction in mean plaque scores

	Day 1	Day 7	
	postbrushing (%)	Prebrushing (%)	Postbrushing (%)
Overall	23.19	42.43	66.32
Male	21.56	43.78	66.06
Female	27.94	38.49	67.08

Table 6: Critical values for Tukey honest significant difference test for significance of individual differences between mean plaque scores

	HSD (0.05)	HSD (0.01)
Rows (gender)	0.17	0.23
Columns (time)	0.29	0.35
Cells (combined)	0.53	0.62

All individual differences seen in Table 4 are above HSD (0.01); therefore, $P<0.01$. HSD: Honest significant difference

ensuring plaque control. The male participants achieved nearly a 22% reduction in mean plaque scores, while the female participants achieved mean plaque reduction of nearly 28% on day 1. After continuous use of the toothbrush for a week, the male participants showed a further reduction to nearly 44%, while the female participants showed nearly 38% reduction prebrushing on day 7. However, both male and female participants showed a 66–67% reduction in plaque scores postbrushing on day 7. This shows a sustained capability of the toothbrush in improving and maintaining appropriate plaque control. The statistically highly significant ($p < 0.0001$) reduction in plaque index with time and across all participants demonstrates high efficacy of Colgate 360 Whole Mouth Clean Soft Toothbrush in effective plaque control. A two-way ANOVA and individual comparisons by Tukey HSD test were found appropriate in gaining statistical relevance to the analysis.

Conclusion

The present study showed a significant reduction in plaque scores with the use of Colgate 360 Whole Mouth Clean Soft Toothbrush. Continued use resulted in further significant reduction in plaque scores irrespective of gender of participants.

Therefore, it can be concluded that Colgate 360 Whole Mouth Clean Soft Toothbrush has an effective brush design that aids in significant improvement in plaque control, oral hygiene status and therefore, prevention and control of caries and periodontal disease.

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Conflicts of interest
There are no conflicts of interest.

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