

Assessment of the effectiveness of a rotatable shank toothbrush compared to a conventional handle toothbrush: A multicenter, single-blind, randomized controlled trial

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Abstract

Background. The persistence of dental plaque is attributable to the inaccessibility to all surfaces of the oral cavity. Thus, an integrated team designed an innovative toothbrush comprising a brush head assembly with an upper end and a lower end, and a handle rotatably configured with the lower end of the brush head assembly. The brush head is connected to the handle through a socket–ball joint, which allows the shank and the handle to rotate at any angle between 0° and 360° with respect to one another around an axis. Additionally, the brush head bends toward the handle, maintaining a bending angle of 15°.

Objectives. The aim of the present randomized controlled trial (RCT) was to analyze and assess the effectiveness of a toothbrush with a rotatable shank in comparison to toothbrushes with flexible and straight handles with respect to supragingival plaque and gingival health outcomes. The secondary objective of the study was to evaluate the feedback of individuals who used the rotatable shank toothbrush.

Material and methods. Three toothbrushes – one with a rotatable shank, one with a flexible handle and one with a straight handle – were compared in terms of efficacy in plaque and gingivitis control at 3 clinical centers (a multicenter trial). A total of 270 patients, aged 18–65 years, were included in the study. The collected data was analyzed and compared using the analysis of variance (ANOVA) with Tukey's post hoc test.

Results. All groups demonstrated improvement in gingival health and a reduction in the plaque index (PI) scores. Nonetheless, the improvement was more pronounced in the group that used the toothbrush with a rotatable shank.

Conclusions. The enhanced plaque removal and improved gingival health at all surfaces achieved with the rotatable shank toothbrush are ascribable to the incorporation of 2 features: the ability to rotate the toothbrush neck along its axis; and an inclination that facilitates access to all surfaces.

Keywords: ergonomics, toothbrush, plaque removal, rotatable shank

Introduction

Periodontitis is a chronic multifactorial inflammatory disease that is associated with dysbiotic dental biofilm. It is characterized by the progressive destruction of the tooth-supporting apparatus and, if left untreated, leads to tooth loss. Periodontitis is a vital public health issue due to its high prevalence, which accounts for a substantial proportion of edentulism and masticatory dysfunction, and has a negative impact on general health.¹

Mechanical plaque control is one of the most important health promotion strategies in dentistry, and is of utmost importance in the prevention of gingivitis and periodontitis.² Studies on the subject emphasize the importance of oral hygiene in reducing the incidence of tooth loss, the number of new decayed surfaces, and periodontal attachment loss, thereby reinforcing its importance in preventive dentistry.^{3–6}

Manual toothbrushes are the most frequently used devices for the regular removal of plaque. A wide variety of toothbrushes are currently available on the market.⁷

In conjunction with the appropriately employed brushing technique, a brush should enable complete plaque removal. The advancement of the toothbrush design has been a continual process through the centuries, with the innovations aimed at enhancing efficiency and promoting dental health. The literature on the design of toothbrushes is unequivocal in its assertion that no single design is superior to another in achieving the most effective removal of dental plaque. The analysis of the investigations assessing the cleaning efficiency of different toothbrushes used with the same brushing method does not provide conclusive evidence to determine which toothbrush is superior to others.^{8,9}

The trial conducted by Sripriya and Shaik Hyder Ali, which compared the efficacy of 4 different types of commercially available manual toothbrushes, concluded that although some minor differences in the plaque removal efficacy of the brushes were observed, they were not statistically significant, implying that none of the toothbrush designs was effective in terms of complete plaque removal.¹⁰ In a study evaluating the plaque removal efficacy of 4 different designs of manual toothbrushes, Sial et al. hypothesized that, despite the introduction of various toothbrush designs to the market, no single toothbrush was found to be more effective than the others in removing plaque.¹¹ In a study conducted by Claydon et al., no superior design of a manual toothbrush was identified in the removal of plaque when 8 manual toothbrushes were compared by a professional tooth brusher.¹²

When adults are asked to manually perform oral hygiene procedures with conventional toothbrushes, to the best of their abilities, clinical studies have documented the persistence of a considerable amount of plaque. This is because the majority of the population is either not

trained or suffers from a lack of skill to follow the recommendations, which limits the clinical effectiveness of self-performed oral hygiene.¹³ Most individuals tend to brush surfaces that are easily accessible and neglect areas that are more challenging to reach. The buccal surfaces and the anterior teeth are most thoroughly cleaned and exhibit the lowest plaque accumulation, whereas the lingual/palatal aspects of the teeth demonstrate the greatest plaque accumulation.^{14,15}

In light of these observations, it was pivotal to design a toothbrush that would provide better access to all areas, thereby improving an overall plaque reduction. Hence, an attempt was made to develop and evaluate a novel, ergonomic, rotatable toothbrush. The process of concept generation entailed an insightful understanding of user needs and the conversion of these needs into product requirements. The concept of keeping the bristles in a similar configuration to that of a standard toothbrush and incorporating a ball–socket mechanism at the shank, enabling it to rotate through 360° and bend up to 15°, was developed through a rapid ideation and prototyping process in conjunction with users.

Therefore, the purpose of the present study was to assess the safety and effectiveness of the rotatable shank toothbrush in the elimination of supragingival plaque at all sites of the oral cavity, with a particular focus on gingival health, in comparison to a flexible handle toothbrush and a straight handle toothbrush. The secondary objective of the study was to evaluate the feedback and experience of individuals who used the rotatable shank toothbrush. This could prove beneficial for the general public in selecting the more efficacious toothbrush among all commercially available options. The null hypothesis of the study stated that the rotatable shank toothbrush is equally effective in removing dental plaque by laypeople after 30 days of twice-daily use compared to conventional straight and flexible handle toothbrushes.

Material and methods

Study design

This experimental, multicenter, single-blind, randomized controlled trial (RCT) was conducted at Rural Dental College (Loni, India), Rajasthan Dental College and Hospital (Jaipur, India), and Chhattisgarh Dental College and Research Institute (Rajnandgaon, India). The study was designed in accordance with the CONSORT (Consolidated Standards of Reporting Trials) 2010 criteria (Fig. 1), approved by the Ethics Committee at the Pravara Institute of Medical Sciences (Deemed to be University) (PIMS-DU), Ahmednagar, India (approval No. PIMS/DR/RDC/2022/138), and registered with Clinical Trials Registry – India (CTRI) under the identification No. CTRI/2022/02/049838.

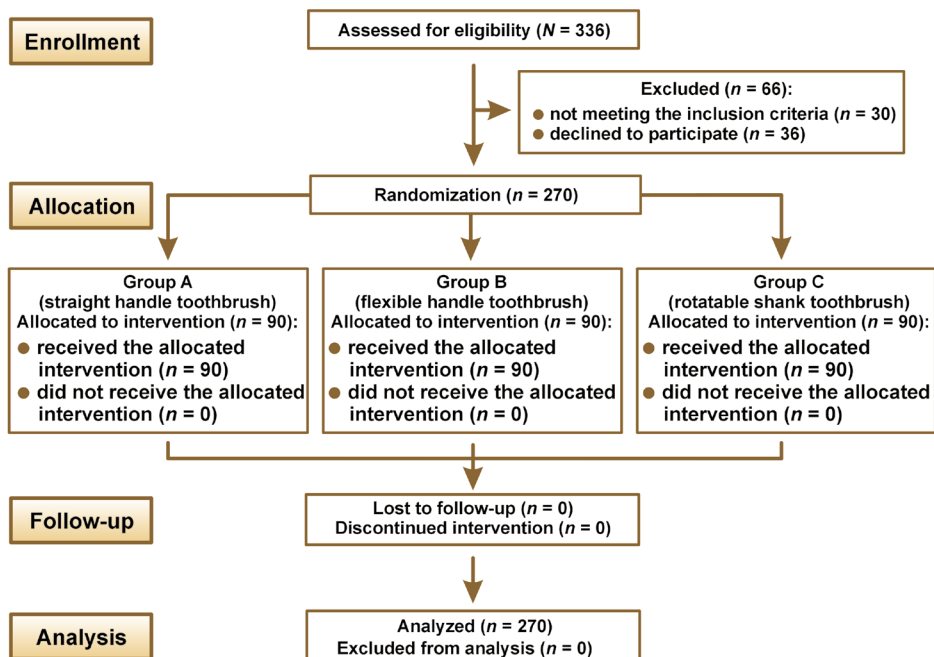


Fig. 1. CONSORT (Consolidated Standards of Reporting Trials) 2010 flowchart

Patient recruitment and eligibility criteria

The participants were recruited from the outpatient clinics of the periodontology departments at Rural Dental College, Rajasthan Dental College and Hospital, and Chhattisgarh Dental College and Research Institute, after signing a fully descriptive informed consent form. The patients were enrolled in the study in accordance with the established eligibility criteria. The participants were dental laypeople (i.e., individuals without any dental background), aged between 18 and 65 years, of either gender, having at least 20 natural, scorable teeth, with visible plaque accumulation represented by a continuous band of plaque (up to 1 mm) at the cervical margin on at least 30% of all facial tooth surfaces. The measurements were made using the Turesky modification of the Quigley–Hein plaque index (TMQHPI) (a score ≥ 2) and the Löe and Silness gingival index (GI) (a score ≤ 2 – redness, edema and glazing with bleeding on probing (BoP)). The participants exhibited signs of moderate inflammation and sought treatment for teeth scaling (cleaning) during the study period. The patients were excluded if they had undergone any surgical, chemical or antibiotic/dental prophylaxis procedures in the experimental area within 3 months prior to the study, had any major tissue lesions, had orthodontic banding or an intraoral prosthesis, or were pregnant. Additionally, bidi or cigarette smokers, oral tobacco or gutkha users, subjects with irregular brushing frequency (≤ 2 times/day), incomplete dentition, carious teeth, and those with periodontitis (probing depth (PD) ≥ 4 mm, clinical attachment loss (CAL) ≥ 1 –2 mm and horizontal bone loss)¹⁶ were excluded from the study.

Sample size calculation

The requisite sample size was estimated using the G*Power software, v. 3.1.9.7 (<https://www.psychologie.hhu.de/arbeitsgruppen/allgemeine-psychologie-und-arbeitspsychologie/gpower>). With an effect size of 0.8, the minimum calculated sample size in each group was 20. With a 10% loss to follow-up, the sample size was 22 in each group. These values were rounded up, and a minimum of 25 participants were included in each group at each center, resulting in a total of 75 participants per center.

The total sample size was calculated to be 225. However, following the screening process, 336 participants were assessed for eligibility to participate in the study. A total of 30 individuals were excluded from the study due to failure to meet the inclusion criteria, while 36 participants declined to participate. Hence, a final excess of 45 participants were included (Fig. 1).

Sample grouping

Eventually, 90 individuals were selected at each center for the current study. The participants were further divided into 3 groups of 30 individuals each, according to the designated toothbrush, as follows: group A – the straight handle toothbrush; group B – the flexible handle toothbrush; and group C – the rotatable shank toothbrush. The assessments were conducted at baseline, and at 15 days and 30 days following the usage of the investigated toothbrushes.

All of the toothbrushes had identical bristles (tapered, round-ended, with a medium thickness diameter of 0.23–0.29 mm)^{17,18} and all the individuals were advised to use the same toothpaste with the Bass toothbrushing technique.

Randomization, allocation concealment and blinding

The participants were randomly assigned to the treatment groups following a simple randomization procedure, specifically the lottery method. A total of 270 chits were created as per the final sample size. Each participant was asked to select a chit following the baseline examination from the investigator. The chits were divided into 3 groups, designated as group A, group B and group C, with 90 participants in each group.

For allocation concealment, the sequentially numbered, opaque, sealed envelope (SNOSE) method was used. The group name was written on a chit and kept in an opaque, sealed envelope. The envelope was labeled with a serial number. Once the patient had consented to participate, the investigator opened the sealed envelope and assigned the treatment group accordingly.

In this single-blind trial, all procedures were conducted by 2 dental examiners at each center. The first examiner (the primary investigator) was responsible for all clinical procedures, whereas the other one was responsible for the assessment of plaque and gingivitis. The primary investigator and the participants were not blinded in this process. However, to ensure the reliability of the results, 3 examiners (one at each center) were blinded to the type of toothbrush the participants were using.

Intervention

Once the initial assessments and randomization were completed, the participants were led to a separate room, equipped with a washbasin and a mirror. Toothbrushes were given to the subjects by the study coordinator. The same toothpaste was provided to all participants. The use of a toothbrush was demonstrated in accordance with the standard operating procedure (SOP) for toothbrushing. Subsequently, the participants were requested to use the provided toothbrush for the first time at the investigation center under the supervision of a study coordinator to confirm that it was being used correctly. A video demonstrating the proper toothbrushing technique was prepared and shared on the WhatsApp group for the participants to reinforce the technique. The participants were instructed to use the assigned toothbrush with toothpaste in accordance with the demonstrated technique at home on a twice-daily basis for 30 days (D1–D30). At the end of each week, the participants were contacted via telephone for a follow-up interview.

The objectives and procedures of the study were elucidated to the participants in their vernacular language. The study participants were free to withdraw at any point in time, and doing so would not affect the treatment they received at hospital. Throughout the entire duration of the study, the participants were instructed to refrain from any oral hygiene procedures other than brushing. They

were also informed that they would be excluded from the study in the occurrence of any circumstances that might affect plaque accumulation, including oral prophylaxis, the placement of a restoration, any course of antibiotics, the use of mouthwash, the use of dental floss, and any systemic illness.

A follow-up visit for a clinical assessment was scheduled at 15 days (D15) and the participants were asked to return to the study center on D30. It was recommended that the participants refrain from any oral hygiene procedures, as well as from eating, drinking and gum chewing, for a period of 4 h before each visit. The clinical evaluations performed on D1 (the assessment of the plaque index (PI)) were repeated on D15 and D30. On D30, the subjects from group C, who were acquainted with the rotatable shank toothbrush, were invited to respond to a subjective evaluation questionnaire regarding their acceptability of the toothbrush and its efficacy.

The following instructions for use were given to the participants of the study:

- wet the toothbrush bristles and apply a small amount of the assigned toothpaste;
- place the toothbrush bristles in contact with the tooth at an angle of 45° to the gingiva;
- brush each tooth (or 2–3 at a time) using a gentle vibratory motion;
- brush each tooth well and, when finished, flick the toothbrush down the tooth, away from the gum line (rotate the brush shank in case of a rotatable shank toothbrush);
- maintain an inclination of 45° and constant contact with the teeth during brushing;
- be sure to clean all surfaces of your teeth, including the inner and outer surfaces, the chewing surfaces, and the ones behind the back teeth; do not forget about your tongue;
- guide the toothbrush slowly from tooth to tooth, following the curve of the teeth and gums;
- brush your teeth for approx. 2 min.

Assessment

Three dental examiners, one at each center, recorded the participants' dental status, and carried out the assessments of plaque and gingivitis independently. The intra- and inter-examiner reliability coefficients were 0.83 and 0.88, respectively.

The assessments of plaque and gingivitis were conducted using TMQHPI and the Löe and Silness GI, respectively.

According to the TMQHPI assessment procedure,¹⁹ the subject's mouth was rinsed with the plaque disclosing solution (MIRA-2-TON[®]; Hager & Werken, Duisburg, Germany) for 1 min to disclose any accumulated plaque. All natural teeth were assessed. The labial/buccal and lingual/palatal aspects of all teeth were scored on a scale

from 0 to 5, as follows: score 0 – no plaque; score 1 – separate flecks of plaque at the gingival margin of the crown; score 2 – a thin continuous band of plaque at the gingival margin of the crown; score 3 – a band of plaque wider than 1 mm, but covering less than $\frac{1}{3}$ of the crown; score 4 – plaque covering less than $\frac{2}{3}$ of the crown; and score 5 – plaque covering more than $\frac{2}{3}$ of the crown. The PI for the subject was calculated by summing the indices for all surfaces (labial/buccal and lingual/palatal) and dividing the result by the number of surfaces examined. The aforementioned scale was used to score both anterior teeth and posterior teeth (overall PI, PI in the region of first and second molars, and PI for the labial/palatal surfaces of anterior teeth).

The gingival status was evaluated according to the criteria established by L oe and Silness²⁰: score 0 – absence of inflammation; score 1 – a slight change in color and a little change in texture; score 2 – moderate redness, edema and hypertrophy, and BoP; and score 3 – marked redness and hypertrophy, and a tendency to spontaneous bleeding. The GI for the subject was calculated by summing the values for each tooth and dividing the result by the number of teeth examined.

Toothbrushes tested

The toothbrushes tested in the study included a toothbrush with a straight handle, a toothbrush with a flexible handle and a toothbrush with a rotatable shank.

The toothbrush with a rotatable shank comprises a brush head assembly with an upper end and a lower end, a plurality of brush bristles configured on the surface of the upper end, and a handle rotatably configured with the lower end of the brush head assembly. The brush head is connected to the handle through a socket–ball joint, enabling the shank and the handle to rotate with respect to one another (Fig. 2).

The brush head assembly comprises 2 distinct components – a replaceable brush head and a component rotatably configured with the handle. The replacement of the brush head is a simple, plug-and-play process. The brush head assembly is designed to rotate at any angle between 0° and 360° with respect to the handle around an axis. Additionally, the brush head bends toward the handle, maintaining a bending angle of 15° (Fig. 3).

In other words, one of the components – the brush head assembly or the handle – may be in a fixed position, while the other one may rotate with respect to the stationary element. When the brush head assembly rotates with respect to the handle, the rotating axis is parallel to the length of the handle. Holding the handle between the thumb and the index finger while rotating it facilitates three-dimensional (3D) rotation, thereby making the toothbrush more user-friendly.

The present invention provides an improved toothbrush design, as the rotation and bending of the brush

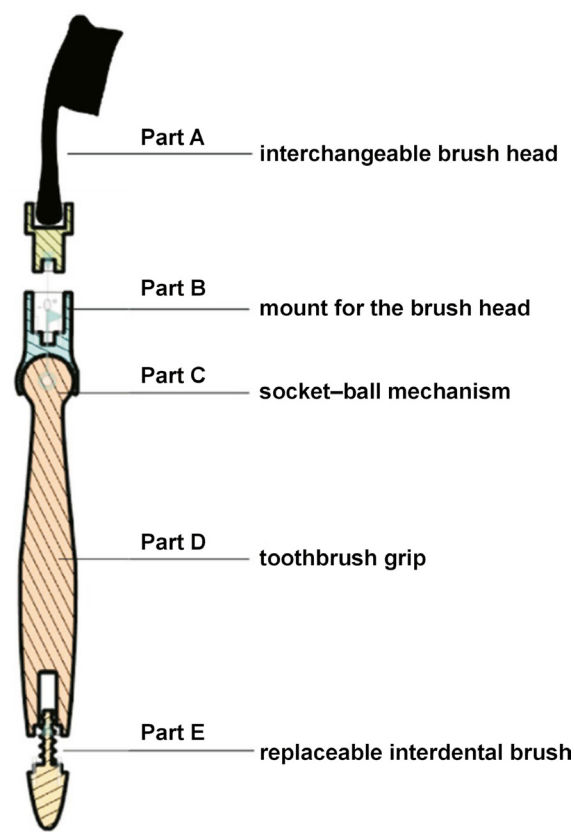


Fig. 2. Components of the rotatable shank toothbrush

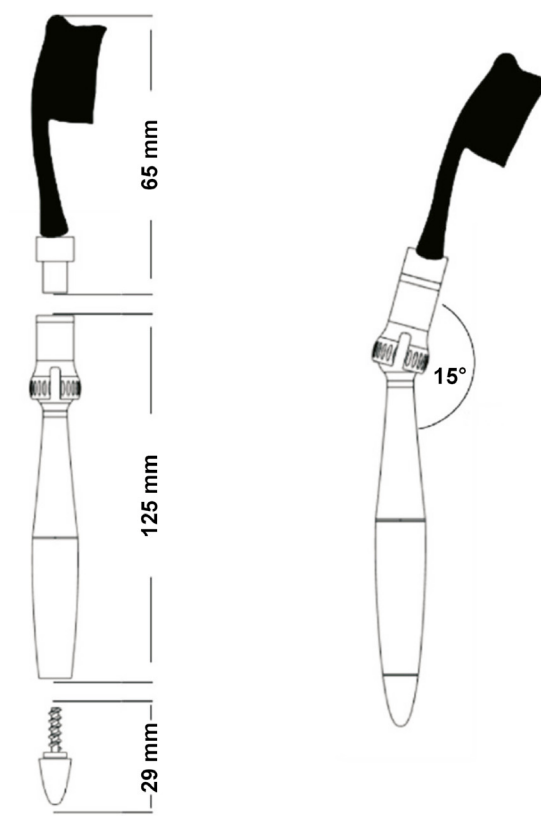


Fig. 3. Size of the components of the rotatable shank toothbrush and the bending angle

head enables adaptation and facilitates the brushing of the lingual/palatal surfaces of teeth, which are difficult to reach with a wrist and arm motion. The improved toothbrush with an ergonomic grip enables users to maneuver the toothbrush with their thumb and index finger while the other 3 fingers are used to press the handle against the palm to acquire a firm grip of the toothbrush. As a result, sweeping the brush downward and upward through a wrist and arm movement is avoided.

Statistical analysis

The obtained data was entered into Microsoft Excel, v. 13 (Microsoft Corporation, Redmond, USA). The data was subjected to statistical analysis using the IBM SPSS Statistics for Windows software, v. 21.0 (IBM Corp., Armonk, USA). For categorical data, the frequency and percentage values were obtained, and for continuous data, the mean and standard deviation ($M \pm SD$) values were obtained.

The primary endpoint was the comparison of groups A, B and C for changes in PI (overall, in the molar region and on the lingual/palatal surfaces of the anterior teeth) and GI at baseline, day 15 and day 30. The mean reduction in the plaque and gingival scores from baseline to 15 days and from baseline to 30 days was assessed. To analyze the data, we used the analysis of variance (ANOVA) with Tukey's post hoc test for pairwise comparisons. The analysis was conducted based on the pre-post values obtained for each group.

All statistical tests were performed with a 95% confidence interval (CI). A p -value < 0.05 was considered statistically significant.

Results

In the present study, there were 160 (59.3%) male participants and 110 (40.7%) female participants. The difference in the proportion of male and female participants was statistically significant ($p < 0.05$) (Table 1). The majority of the participants were in the age group of 18–34 years, and only 10 patients were above 65 years of age (Table 2).

The participants from group C (the rotatable shank toothbrush group) completed a questionnaire, which revealed that most of them had previously used a straight handle toothbrush, followed by a flexible handle toothbrush.

Table 1. Distribution of the study participants according to gender ($N = 270$)

Gender	n (%)	p -value
M	160 (59.3)	0.000*
F	110 (40.7)	
Total	270 (100.0)	

M – male; F – female; * statistically significant (χ^2 test).

Table 2. Distribution of the study participants according to age ($N = 270$)

Age [years]	n (%)	p -value
<18	35 (13.0)	0.000*
18–24	70 (26.0)	
25–34	70 (26.0)	
35–44	33 (12.2)	
45–54	33 (12.2)	
55–64	19 (7.0)	
≥ 65	10 (3.7)	

* statistically significant (χ^2 test).

Following the use of our toothbrush, the individuals indicated a preference for the rotatable shank toothbrush, as it offered them an overall better experience. They also reported that the rotatable shank toothbrush provided greater accessibility to posterior teeth. The majority of the study participants ascertained that the rotatable shank toothbrush was more effective in removing the lodged food. On the other hand, the participants reported bleeding when using the straight handle toothbrush (Table 3).

In the present study, we compared PI (overall, in the molar region and on the lingual/palatal surfaces of anterior teeth) and GI at baseline, day 15 and day 30 in all 3 groups (Table 4).

In group A, the mean values for PI (overall, in the molar region and on the lingual/palatal surfaces of anterior teeth) and GI at baseline were 2.42 ± 0.30 , 2.42 ± 0.59 , 2.42 ± 0.59 , and 1.65 ± 0.17 , respectively. The results of ANOVA showed that after using the straight handle toothbrush for a period of 30 days, the PI and GI values decreased to 1.43 ± 0.58 , 1.36 ± 0.46 , 1.38 ± 0.50 , and 1.43 ± 0.16 , respectively. The reduction in the PI and GI values was statistically significant ($p < 0.05$).

In group B, the mean values for PI (overall, in the molar region and on the lingual/palatal surfaces of anterior teeth) and GI at baseline were 2.38 ± 0.35 , 2.57 ± 0.55 , 2.57 ± 0.55 , and 1.57 ± 0.33 , respectively. A reduction in the PI and GI values was observed between baseline, day 15 and day 30. The results of ANOVA stated that at day 30, the PI and GI values decreased to 1.18 ± 0.41 , 1.23 ± 0.56 , 1.30 ± 0.67 , and 1.23 ± 0.33 , respectively. The reduction in the PI and GI values was statistically significant ($p < 0.05$).

Similarly, in group C, the results of ANOVA showed that the mean PI (overall, in the molar region and on the lingual/palatal surfaces of anterior teeth) and GI values had decreased from 2.40 ± 0.29 , 2.17 ± 0.55 , 2.16 ± 0.55 , and 1.59 ± 0.30 at baseline to 0.53 ± 0.33 , 0.80 ± 0.45 , 0.80 ± 0.45 , and 0.69 ± 0.14 at day 30, respectively. The reduction in the PI and GI values was statistically significant ($p < 0.05$).

The overall comparison of groups A, B and C revealed statistically significant differences in the values measured ($p < 0.05$).

Table 3. Feedback provided by the study participants who used the toothbrush with a rotatable shank ($n = 90$)

Questions inquired	Straight handle toothbrush	Flexible handle toothbrush	Rotatable shank toothbrush	p -value
Type of toothbrush used before	54 (60.0)	36 (40.0)	–	–
Toothbrush with better handle and grip	10 (11.1)	22 (24.4)	58 (64.4)	0.000*
Preferable neck design	11 (12.2)	26 (28.9)	53 (58.9)	0.000*
Toothbrush with better accessibility to posterior teeth	6 (6.7)	22 (24.4)	62 (68.9)	0.000*
Toothbrush better in removing the lodged food	3 (3.3)	31 (34.4)	56 (62.2)	0.000*
Toothbrush causing bleeding while brushing	47 (52.2)	29 (32.2)	14 (15.6)	0.000*
Toothbrush with an overall better experience	13 (14.4)	26 (28.9)	51 (56.7)	0.000*

Data presented as frequency (percentage) (n (%)).

* statistically significant (ANOVA).

Table 4. Comparisons within and between the study groups with regard to the plaque index (PI) and gingival index (GI) scores

Variable	Group A			Group B			Group C			p -value	
	baseline	day 15	day 30	baseline	day 15	day 30	baseline	day 15	day 30		
Overall PI	$M \pm SD$	2.42 \pm 0.30	1.92 \pm 0.47	1.43 \pm 0.58	2.38 \pm 0.35	1.67 \pm 0.38	1.18 \pm 0.41	2.40 \pm 0.29	1.19 \pm 0.39	0.53 \pm 0.33	0.000*
	min	2.00	0.90	0.20	1.90	0.50	0.30	2.00	0.30	0.06	
	max	2.97	2.80	2.50	3.50	2.80	2.40	2.96	2.40	1.70	
	p -value	0.000*			0.000*			0.000*			
PI in the molar region	$M \pm SD$	2.42 \pm 0.59	1.84 \pm 0.52	1.36 \pm 0.46	2.57 \pm 0.55	1.64 \pm 0.60	1.23 \pm 0.56	2.17 \pm 0.55	1.21 \pm 0.48	0.80 \pm 0.45	0.000*
	min	1.00	0.60	0.50	1.30	0.50	0.40	1.00	0.30	0.10	
	max	3.70	3.00	2.60	3.80	3.10	2.80	3.50	2.10	2.00	
	p -value	0.000*			0.000*			0.000*			
PI on the lingual/palatal surfaces of anterior teeth	$M \pm SD$	2.42 \pm 0.59	1.84 \pm 0.52	1.38 \pm 0.50	2.57 \pm 0.55	1.70 \pm 0.62	1.30 \pm 0.67	2.16 \pm 0.55	1.22 \pm 0.50	0.80 \pm 0.45	0.000*
	min	1.00	0.60	0.50	1.30	0.50	0.40	1.00	0.30	0.10	
	max	3.70	3.10	3.00	3.80	3.10	3.00	3.50	2.40	2.00	
	p -value	0.000*			0.000*			0.000*			
GI	$M \pm SD$	1.65 \pm 0.17	1.54 \pm 0.16	1.43 \pm 0.16	1.57 \pm 0.33	1.41 \pm 0.32	1.23 \pm 0.33	1.59 \pm 0.30	0.87 \pm 0.19	0.69 \pm 0.14	0.000*
	min	1.20	1.00	0.80	1.00	0.90	0.80	1.10	0.50	0.40	
	max	2.00	1.90	1.80	3.20	3.10	2.90	2.90	1.70	1.10	
	p -value	0.000*			0.000*			0.000*			

Groups: A – straight handle toothbrush; B – flexible handle toothbrush; C – rotatable shank toothbrush; M – mean; SD – standard deviation; min – minimum; max – maximum; * statistically significant (ANOVA).

The pairwise comparisons of the mean PI (overall, in the molar region and on the lingual/palatal surfaces of anterior teeth) and GI values for straight, flexible and rotatable shank toothbrushes with regard to baseline, day 15 and day 30 were performed using Tukey's post hoc test (Table 5).

In group A, there was a statistically significant reduction in the PI (overall, in the molar region and on the lingual/palatal surfaces of anterior teeth) and GI values from baseline to 15 days (0.50, 0.58, 0.58, and 0.11, respectively) ($p < 0.05$). Similarly, Tukey's post hoc test displayed a reduction in the PI and GI values from baseline to 30 days (0.99, 1.06, 1.04, and 0.22, respectively), which was statistically significant ($p < 0.05$). The comparison of the PI and GI values between 15 and 30 days also depicted a decrease (0.49, 0.48, 0.46, and 0.11, respectively), with the difference being statistically significant ($p < 0.05$).

The post hoc analysis of group B revealed a statistically significant reduction in the PI (overall, in the molar region and on the lingual/palatal surfaces of the anterior teeth) and GI values from baseline to 15 days (0.71, 0.93, 0.87, and 0.16, respectively) ($p < 0.05$). The reduction in the PI and GI values from baseline to 30 days was also statistically significant (1.20, 1.34, 1.27, and 0.34, respectively) ($p < 0.05$). Additionally, the post hoc analysis revealed that the plaque and gingival scores decreased significantly between 15 and 30 days, and the mean difference was 0.49, 0.41, 0.40, and 0.18, respectively ($p < 0.05$).

In group C, the post hoc analysis revealed a mean reduction in the PI (overall, in the molar region and on the lingual/palatal surfaces of anterior teeth) and GI values from baseline to 15 days (1.21, 0.96, 0.94, and 0.72, respectively), from baseline to 30 days (1.87, 1.37, 1.36, and 0.90, respectively), and between 15 and 30 days (0.66,

Table 5. Pairwise comparisons of the plaque index (PI) and gingival index (GI) scores within the study groups

Dependent variable			Overall PI		PI in the molar region		PI on the lingual/palatal surfaces of anterior teeth		GI	
			mean difference	<i>p</i> -value	mean difference	<i>p</i> -value	mean difference	<i>p</i> -value	mean difference	<i>p</i> -value
Group A	baseline	15 days	0.50	0.000*	0.58	0.000*	0.58	0.000*	0.11	0.000*
		30 days	0.99	0.000*	1.06	0.000*	1.04	0.000*	0.22	0.000*
	15 days	30 days	0.49	0.000*	0.48*	0.000*	0.46	0.000*	0.11	0.000*
Group B	baseline	15 days	0.71	0.000*	0.93	0.000*	0.87	0.000*	0.16	0.000*
		30 days	1.20	0.000*	1.34	0.000*	1.27	0.000*	0.34	0.000*
	15 days	30 days	0.49	0.000*	0.41	0.000*	0.40	0.000*	0.18	0.000*
Group C	baseline	15 days	1.21	0.000*	0.96	0.000*	0.94	0.000*	0.72	0.000*
		30 days	1.87	0.000*	1.37	0.000*	1.36	0.000*	0.90	0.000*
	15 days	30 days	0.66	0.000*	0.41	0.000*	0.42	0.000*	0.18	0.000*

Groups: A – straight handle toothbrush; B – flexible handle toothbrush; C – rotatable shank toothbrush; * statistically significant (Tukey's post hoc test).

0.41, 0.42, and 0.18, respectively). The reduction in the PI and GI values at different time intervals was statistically significant ($p < 0.05$).

The ANOVA comparisons of the pre–post scores between baseline and day 15 depicted that group C (rotatable shank toothbrush) exhibited the greatest reduction in the PI and GI values. Similarly, the comparisons of the pre–post scores between baseline and day 30 demonstrated the greatest reduction in the PI and GI scores in the rotatable shank toothbrush group, followed by the flexible handle toothbrush group and the straight handle toothbrush group ($p < 0.05$) (Table 6).

The pairwise comparisons of the pre–post changes in the PI and GI values from baseline to 15 days and from

baseline to 30 days were conducted using Tukey's post hoc test (Table 7).

The results indicated that in the pre–post comparison at day 15 between groups A and B, the overall PI was reduced significantly in the flexible handle toothbrush group (mean difference: -0.21). With regard to groups A and C, the latter exhibited a greater reduction of the overall PI (mean difference: -0.71). The difference in mean between groups B and C demonstrated that the reduction was more pronounced for the rotatable shank toothbrush group (mean difference: -0.50). All the differences were statistically significant ($p < 0.05$).

The mean differences in PI in the molar region depicted a similar observation, whereby the pre–post comparisons

Table 6. Mean pre–post change in the plaque index (PI) and gingival index (GI) scores for the study groups

Variable		Reduction between baseline and 15 days			Reduction between baseline and 30 days			<i>p</i> -value
		group A	group B	group C	group A	group B	group C	
Overall PI	<i>M</i> ± <i>SD</i>	0.50 ± 0.39	0.71 ± 0.38	1.21 ± 0.42	0.99 ± 0.50	1.20 ± 0.44	1.87 ± 0.42	0.000*
	min	0.05	0.04	0.28	0.10	0.20	1.00	
	max	1.90	2.46	2.42	2.24	2.56	2.70	
	<i>p</i> -value	0.000*			0.000*			
PI in the molar region	<i>M</i> ± <i>SD</i>	0.58 ± 0.28	0.93 ± 0.56	0.96 ± 0.30	1.06 ± 0.36	1.34 ± 0.62	1.37 ± 0.40	0.000*
	min	-0.50	0.10	0.40	0.20	0.20	0.50	
	max	1.40	2.40	1.70	1.90	1.60	2.20	
	<i>p</i> -value	0.000*			0.000*			
PI on the lingual/palatal surfaces of anterior teeth	<i>M</i> ± <i>SD</i>	0.58 ± 0.28	0.87 ± 0.60	0.94 ± 0.29	1.04 ± 0.36	1.27 ± 0.65	1.36 ± 0.40	0.000*
	min	-0.50	0.10	0.10	0.20	0.20	0.50	
	max	1.40	1.10	1.70	1.90	1.60	2.20	
	<i>p</i> -value	0.000*			0.000*			
GI	<i>M</i> ± <i>SD</i>	0.11 ± 0.06	0.16 ± 0.13	0.72 ± 0.30	0.22 ± 0.09	0.34 ± 0.24	0.90 ± 0.31	0.000*
	min	-0.20	0.03	0.10	-0.12	0.00	0.15	
	max	0.30	0.20	1.80	0.80	0.50	2.32	
	<i>p</i> -value	0.000*			0.000*			

Groups: A – straight handle toothbrush; B – flexible handle toothbrush; C – rotatable shank toothbrush; * statistically significant (ANOVA).

Table 7. Pairwise comparisons of pre–post changes in the plaque index (PI) and gingival index (GI) scores between the study groups

Dependent variable			Overall PI		PI in the molar region		PI on the lingual/palatal surfaces of anterior teeth		GI	
			mean difference	p-value	mean difference	p-value	mean difference	p-value	mean difference	p-value
15-day pre–post change	group A	group B	–0.21	0.001*	–0.35	0.000*	–0.29	0.000*	–0.05	0.216
		group C	–0.71	0.000*	–0.38	0.000*	–0.36	0.000*	–0.61	0.000*
	group B	group C	–0.50	0.000*	–0.03	0.050	–0.07	0.050	–0.56	0.000*
30-day pre–post change	group A	group B	–0.21	0.004*	–0.28	0.000*	–0.23	0.000*	–0.12	0.001*
		group C	–0.88	0.000*	–0.31	0.000*	–0.32	0.000*	–0.68	0.000*
	group B	group C	–0.67	0.000*	–0.03	0.050	–0.09	0.050	–0.56	0.000*

Groups: A – straight handle toothbrush; B – flexible handle toothbrush; C – rotatable shank toothbrush; * statistically significant (Tukey's post hoc test).

at day 15 between groups A and B, groups A and C, and groups B and C exhibited a reduction, with the rotatable shank toothbrush group demonstrating the greatest reduction, followed by the flexible handle toothbrush group and the straight handle toothbrush group. The differences were found to be statistically significant (–0.35, –0.38 and –0.03, respectively) ($p \leq 0.05$).

The pre–post 15-day pairwise comparisons between the groups showed that PI on the lingual/palatal surfaces of anterior teeth was reduced to the greatest extent by the rotatable shank toothbrush, followed by the flexible handle toothbrush and the straight handle toothbrush. The differences between the groups were statistically significant (–0.29, –0.36 and –0.07, respectively) ($p \leq 0.05$).

Tukey's post hoc comparison of GI with regard to different types of toothbrushes revealed a significant reduction in the GI scores for the rotatable shank toothbrush group, followed by the flexible handle toothbrush group and the straight handle toothbrush group. However, despite the superiority of the flexible handle toothbrush over the straight handle toothbrush in reducing GI, the difference in mean was not statistically significant ($p > 0.05$). Conversely, the comparison between groups A and C, as well as between groups B and C, demonstrated that the rotatable shank toothbrush exhibited a significantly elevated performance in GI reduction (mean difference: –0.61 and –0.56, respectively) ($p < 0.05$).

The pre–post 30-day pairwise comparisons between groups A and B, groups A and C, and groups B and C revealed a mean difference in the overall PI of –0.21, –0.88 and –0.67, respectively. With regard to PI in the molar region, the mean differences were –0.28, –0.31 and –0.03, respectively. In the case of PI on the lingual/palatal surfaces of anterior teeth, the mean differences between the toothbrush groups were –0.23, –0.32 and –0.09, respectively. As far as GI is concerned, the mean difference values for the respective toothbrush groups were –0.12, –0.68 and –0.56. Tukey's post hoc analysis demonstrated that at 30 days, the PI and GI scores exhibited a superior reduction with the rotatable shank toothbrush, followed by the flexible handle toothbrush ($p \leq 0.05$).

Discussion

The major rationale for daily oral hygiene is to maintain teeth devoid of plaque, which is essential for preserving healthy periodontal tissues. As suggested by Armitage, the presence of supragingival plaque is not a good predictor of disease progression; however, its absence has a good negative predictive value.²¹ A toothbrush represents the most common tool for daily plaque removal and it plays a pivotal role in plaque control.

A wide variety of toothbrushes is available on the market. Most of them are capable of adequately removing plaque from the accessible surfaces of the teeth. However, they face limitations in reaching areas that are difficult to access.^{22,23} Interventional studies have explicitly demonstrated the persistence of plaque despite good levels of plaque control, underscoring the importance of developing tools that can assist individuals in maintaining a higher level of oral hygiene.^{24,25}

A scientifically and ergonomically designed toothbrush with a rotatable shank was developed to address the limitations of a generic toothbrush in reaching all areas of the mouth. The design aims to provide patients with optimal cleaning regardless of the brushing technique, and to maximize user comfort and acceptability, thereby fostering compliance with the recommended brushing time and frequency during normal home use. Once the product had been developed and validated, a multicenter clinical study was conducted to ascertain the clinical benefits of its usage.

The present RCT compared the efficacy of the rotatable shank toothbrush with that of the flexible handle toothbrush and the straight handle toothbrush in the elimination of supragingival plaque at all sites of the oral cavity and in the development of gingival health.

The results of the present study should be interpreted in light of the toothbrush design, as the study aimed to verify its efficacy. They should be understood as an indication of the efficacy of the toothbrushes in removing dental plaque. The study outcomes – plaque and gingivitis resolution – were measured by means of TMQHPI and GI (Löe and Silness), similar to previous studies.^{26–30}

The strength of these indices lies in their application in clinical trials of preventive and therapeutic agents.

Plaque was assessed on the facial and lingual/palatal surfaces of all teeth after the application of a disclosing agent. The whole-mouth plaque scores were calculated, as well as the scores for inaccessible areas (in the molar region and on the lingual/palatal surfaces of anterior teeth). Plaque examinations were conducted at 3 experimental time points (baseline, 15 days and 30 days) to assess whether a learning curve affected the results.

The objective of toothbrushing is to eliminate dental plaque from all surfaces of the teeth, including the gingival crevice, while minimizing damage to the teeth and the surrounding structures. The American Dental Association (ADA) recommends positioning the toothbrush against the buccal and palatal surfaces of the teeth so that the bristles are at a 45-degree angle to the gingiva, and performing a slight vibratory motion for thorough plaque removal.³¹ Vibratory action has been proposed to contribute to a gingival massage effect at the gingival sulcus, potentially alleviating gingivitis. Thus, in the present study, the patients were instructed to position the toothbrush at a 45-degree angle relative to the gingiva. The plaque and gingivitis scores were evaluated and compared across all surfaces of all teeth at baseline, and at 15 and 30 days.

At baseline, the highest plaque scores were observed in the molar region and on the lingual/palatal surfaces of anterior teeth, probably due to the difficulty in accessing these sites during toothbrushing. In contrast, the lowest plaque accumulation was observed on the facial surfaces of anterior maxillary teeth, presumably due to better and easier access during toothbrushing.

The null hypothesis, which stated that there would be no difference in the efficacy in plaque removal between the examined toothbrushes, was rejected in the analysis.

The mean PI and GI scores, evaluated for groups A, B and C at baseline, and at 15 and 30 days, demonstrated a statistically significant reduction. A comparable statistically significant reduction in the PI and GI scores was observed in the post-hoc analysis from baseline to day 15, from baseline to day 30, and from day 15 to day 30, thereby proving the efficacy of all toothbrushes in plaque removal.

The comparison of the pre–post reduction in the PI and GI values from baseline to day 15 and from baseline to day 30 revealed that group C (the rotatable shank toothbrush) exhibited the greatest reduction in the PI and GI scores ($p < 0.05$).

The pairwise comparison of the pre–post change in the PI and GI scores from baseline to 15 days and from baseline to 30 days between the 3 types of toothbrushes demonstrated the highest reduction in overall plaque, and also in plaque in inaccessible areas for the rotary handle toothbrush, followed by the flexible handle toothbrush and the straight handle toothbrush. This difference was statistically significant.

The results of our study indicate that the rotatable shank toothbrush is most effective in eliminating plaque from all sites, followed by the flexible handle toothbrush. These findings consequently reject the null hypothesis, which asserts that there is no difference in the efficacy in plaque removal between different types of toothbrushes.

The superior plaque elimination demonstrated by the experimental product (the rotatable shank toothbrush) – overall and in inaccessible areas (in the molar region and on the lingual/palatal surfaces of anterior teeth) – is likely related to the brush design, with the 360-degree rotation of the neck around its axis, along with an inclination up to 15°, allowing reachability to all surfaces of the oral cavity (labial/buccal and lingual/palatal tooth surfaces). This could be considered as a clinically relevant advantage.

The fringe benefit of incorporating a rotatable and inclinable neck into the toothbrush design is a significant reduction in handle stiffness in the neck and head regions. This results in a lesser movement, which allows the placement of the brush bristles at 45° to the gingival surface, and the reduction of the force applied to the oral mucosa and tooth surfaces as compared to other toothbrush types. These modifications result in a more gentle brushing action, which may prevent overbrushing and injury to the gingiva.

The product design enables the manipulation of the device by solely using the thumb and the index finger, which overcomes the limitations of a wrist and arm movement, and offers better reachability. This innovation represents a significant advance in the field of manual toothbrush design.

The superiority of the flexible handle toothbrush over the straight handle toothbrush could be due to the incorporation of a flexible component in the neck of the toothbrush, which increases neck flexibility under typical toothbrushing forces and provides comparatively improved simulated plaque control at all risk areas when compared to their rigid-neck counterpart. Theoretically, this could contribute to the prevention of dental caries and gingivitis, and potentially improve dental health. The results of our study align with those of the clinical trial conducted by Acherkouk et al., who, after comparing flexible and rigid neck designs, suggested that flexible toothbrushes might provide superior plaque removal, even in at-risk sites.³²

Gingivitis, a non-destructive disease associated with the accumulation of plaque, causes the inflammation of the gingiva and can be reversed through the implementation of good oral hygiene practices. The removal of plaque from sites with gingivitis results in the resolution of soft tissue inflammation.³³ Our investigation divulged that the rotatable shank toothbrush brought pronounced improvement in the gingivitis scores in comparison with flexible and straight handle toothbrushes. The rationale is based on the premise that the device provides superior plaque control at all risk areas. Consequently, this could

contribute to the amelioration of gingivitis and potentially improve dental health.

The assessment of the suitability of each toothbrush was conducted on all subjects who used the tested toothbrush. The number of reactions related to the toothbrush was documented, and the final assessment was subsequently conducted. The rotatable shank toothbrush was found to be well tolerated and received high levels of appreciation. We hypothesize that such a commendation of the new product may facilitate long-term compliance with oral health recommendations and improve global oral wellness.

Limitations

A limitation of the present study was the unequal gender distribution of the participants. Additionally, we could not monitor the brushing habits of the participants. However, this may also be considered a main strength, as the utilization of the rotatable shank toothbrush resulted in a higher reduction in the plaque and gingival scores, irrespective of the surveillance.

Furthermore, the effectiveness of the rotatable shank toothbrush was not evaluated in individuals with special needs or in comparison with powered toothbrushes, due to the high market cost of the latter, which was identified as a potential limitation.

Conclusions

The present investigation provides evidence that the ergonomically designed rotatable shank toothbrush effectively removed plaque from all surfaces of the teeth, including inaccessible areas. This substantiates its potential to improve oral hygiene when compared with flexible and straight handle toothbrushes. The rotatable shank toothbrush is a safe and effective brushing aid that can be used by anyone, irrespective of manual dexterity or training. It is an innovative addition to the field of manual toothbrush design.

Trial registration

The trial was registered with Clinical Trials Registry – India (CTRI) under the identification No. CTRI/2022/02/049838.

Ethics approval and consent to participate

The study was approved by the Ethics Committee at the Pravara Institute of Medical Sciences (Deemed to be University) (PIMS-DU), Ahmednagar, India (approval No. PIMS/DR/RDC/2022/138). The respondents provided written informed consent prior to completing the questionnaire.

Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Consent for publication

Not applicable.

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