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Cleaning Efficacy of Manual Toothbrushes Around Brackets – A Pilot Randomised Control Trial

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Purpose: To test the cleaning efficacy of different manual toothbrushes in orthodontic patients in a single-blind randomised clinical trial. The brushes tested were selected based on previous in vitro tests.

Materials and Methods: Thirty-five regular orthodontic patients with a minimum of six bonded brackets on the maxillary anterior teeth were randomly assigned to three experimental groups: staged (2-level) (Candida Parodin, 12 patients) and V-shaped (Oral-B Ortho, 12 patients) toothbrush head designs were compared in a two-phase study to planar control brushes (Paro M 43, 11 patients). First, all participants were advised to brush their teeth twice daily for 2 min for 3 weeks. Prior to the start and at the end of the study, the gingival index was assessed to evaluate the level of oral hygiene. Afterwards, cleaning efficacy was assessed planimetrically by disclosing the respective teeth after two days of not performing any oral hygiene measures.

Results: Of the initial 35 participants, two did not attend after 3 weeks and had to be excluded. After 3 weeks, the control (5 out of 180 sites or -2.8% with GI ≥ 2) and staged groups (16 out of 216 sites or 7.5% with GI ≥ 2) showed minor improvement in the oral hygiene level. In contrast, the V-shaped group (29 out of 198 sites or 14.6 % with GI ≥ 2) showed a statistically significant improvement of the oral hygiene level. Planimetric evaluation, however, showed no superior cleaning efficacy of any of the tested head designs.

Conclusions: The use of V-shaped and staged toothbrush head designs might be beneficial in patients with inadequate oral hygiene undergoing orthodontic treatment with a fixed appliance. Further large-scale investigations are, however, necessary to validate the presented results.

Key words: bracket, efficacy, orthodontic, RCT, toothbrush

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Patients undergoing orthodontic treatment face greater difficulties maintaining good oral hygiene.[18,29] Despite the post-treatment advantages of orthodontics, the treatment regimen itself creates other problems. The orthodontic appliances and wires impede toothbrushing and the use of dental floss, thus facilitating the accumulation of plaque and consequently compromising gingival health. Dental plaque is the causative factor for the most common oral diseases, i.e. caries and periodontitis; thus, its removal and control are essential for maintaining oral health. This is illustrated by studies showing that orthodontic treatment with fixed appliances is accompanied by an increased risk of demineralisation,[2,4,17,26,28] caries[18,29] and gingivitis.[3,8,10,11] Although it was recently shown that the use of self-ligating brackets may lower the incidence of white spot lesions, the overall oral hygiene level had a greater influence.[1]

The use of fluoride and/or antibacterial agents has been recommended to reduce these unwanted side effects.[15,16]

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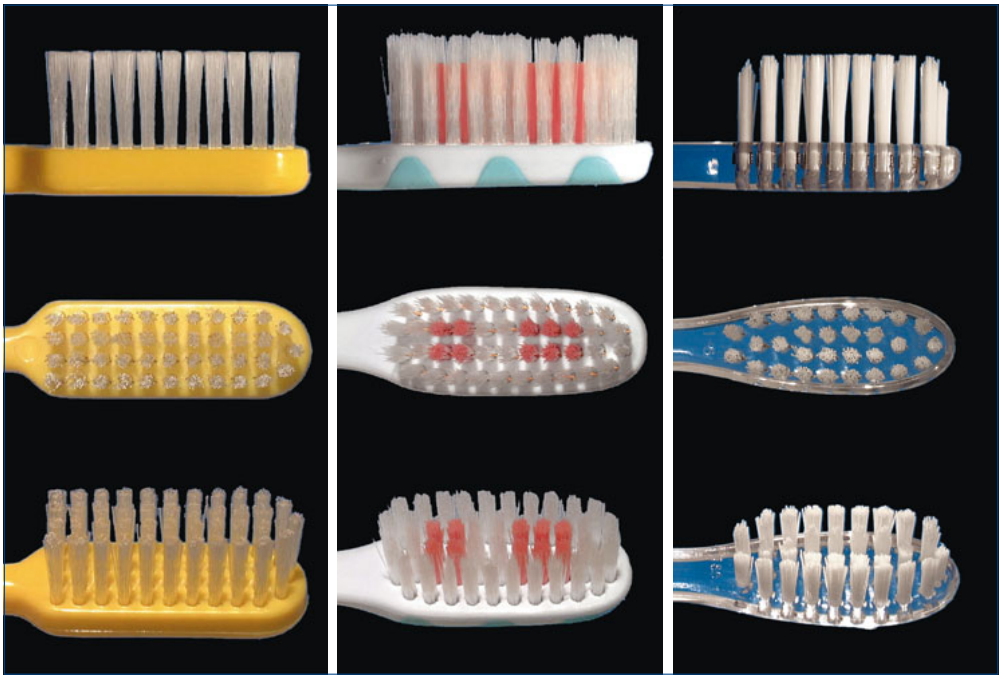

Fig 1 The three toothbrush types tested. Left: control; center: staged; right: V-shaped.

Such measures are, however, dependent on frequent professional oral hygiene and perfect patient compliance. Sealing the enamel surface with resin-based bonding agents or even the application of veneers have been proposed to protect enamel against demineralisation.[5,14,24]

Nevertheless, effective toothbrushing still remains the least expensive and most effective preventive measure, if correctly performed. Various types of toothbrushes, both manual and electric, have been designed and promoted for orthodontic patients. In vitro studies[21,22] have recently evaluated the efficacy of different 'orthodontic toothbrushes' under standardised conditions using a well-established test method[9] to quantify enamel areas with inadequate filament contact in a custom-made model of an anterior maxillary dental arch with bonded brackets. Staged (2-level) and V-shaped toothbrushes showed significantly superior cleaning values compared to planar toothbrushes. Although there was no significant difference between the V-shaped and staged toothbrushes, the latter tended to achieve better results in vitro in terms of cleaning ability. However, extrapolation to the clinical situation was not possible, and hence no conclusive clinical statements could be drawn.

Therefore, the purpose of this study was to clinically verify the cleaning efficacy of the most effective in vitro designs, V-shaped and staged toothbrushes[21] compared to a planar control toothbrush. A pilot study was designed over an observation period of 3 weeks to assess the cleaning efficacy of two test toothbrushes and a planar control brush, as expressed by periodontal parameters and quantified enamel areas with inadequate filament contact. The null hypothesis was that the use of the two test toothbrush designs does not lead to better clinical performance.

MATERIALS AND METHODS

A single-blind, randomised controlled clinical study with two test groups and one control was conducted at the Department of Orthodontics and Paediatric Dentistry, Centre of Dental Medicine, University of Zurich, Switzerland. The study protocol was approved by the local ethics committee (StV 08/01; State of Zurich, Switzerland) and informed consent was obtained from all participants or their parents/legal guardians.

Subjects

Thirty-five regular orthodontic patients ages 12.3 to 24.6 years (mean age: 15.7; SD: ±2.8 years; 20 females, 15 males) volunteered for this study. As inclusion criteria, they had a minimum of six bonded brackets in the anterior maxillary teeth (13, 12, 11, 21, 22 and 23), were physically healthy, not participating in another clinical study and were willing to carry out all study procedures and be available for all planned visits.

A standard toothpaste, Elmex Junior (GABA; Lörrach, Germany) containing 1400 ppm of sodium fluoride, was provided to be used with all of the toothbrushes. Subjects were randomly assigned (Microsoft Excel, Version 12; Redmond, WA, USA) to one of 3 experimental groups of different manual toothbrushes based on the results of the in vitro study mentioned above[21] (Fig 1, Table 1).

Evaluated Toothbrushes

The reportedly best performing toothbrushes[21] with a staged (Parodin plus former Candida Parodin, Bürstenfabrik Ebnat-Kappel; Ebnat-Kappel, Switzerland) or a V-shaped (Oral-B Ortho, Procter & Gamble; Schwalbach a. T., Ger-

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Table 1 Technical data of toothbrushes tested for the three different groups

	Toothbrush	Brush field	Filament diameter (mm)	Filament height (mm)	Number of filaments per hole (n)	Number of filaments per brush head (n)
Planar	Paro M 43 ESRO; Kilchberg, Switzerland	Planar	0.20	11	43	1548
V-shaped	Oral-B Ortho Procter & Gamble; Schwalbach a. T., Germany	V-shaped	0.2	10.5	46	1380
Staged	Candida Parodin Bürstenfabrik Ebnat-Kappel; Ebnat-Kappel, Switzerland	staged	0.17 (conical) 0.15 (round)	9–11.25	54 (conical) 66 (round)	2252–2416

many) brush head design were tested against a planar control brush (Paro M43, ESRO; Kilchberg, Switzerland) for their cleaning efficacy of teeth with fixed orthodontic appliances (Fig 1, Table 1).

Study Design

Prior to the start of the clinical trial, all patients were individually instructed on a model and intraorally in a simple circular brushing technique and received written oral hygiene instructions with respective illustrations.

The study consisted of two phases, the first consisting of 3 weeks of toothbrushing twice daily, timed for 2 min, irrespective of the assigned toothbrush group. In the second phase, the subjects refrained from oral hygiene procedures for 48 h before evaluating the cleaning efficacy of the different toothbrush types (Fig 2). During the study, the patients were advised not to use any additional means of cleaning devices such as interdental brushes, sticks, floss, etc.

Clinical Procedures

All clinical examinations were performed under the same conditions by two experienced, calibrated and blinded clinical investigators (P.S. and V.R.). They were blinded concerning the assignment and sequence of usage of the products. At each clinical examination, all subjects were reminded by the study coordinator not to reveal their group identity to the examiners.

Gingival index

At the start of the study and after phase 1, the gingival index[12] was performed. The gingiva was dried with compressed air and inspected visually. According to this system, complete absence of visual signs of inflammation in the gingival unit was scored as 0, while a slight change in color and texture was scored as 1. Visual inflammation and bleeding tendency from the gingival margin right after briefly running a pressure-sensitive periodontal probe (Hawe Click Probe, Hawe Neos; Bioggio, Switzerland) along the gingival margin was scored as 2, while overt inflammation with tendency for spontaneous bleeding was scored as 3. The probe was run through the gingival sulcus on the mesial, buccal and distal tooth sites of the maxillary anterior teeth

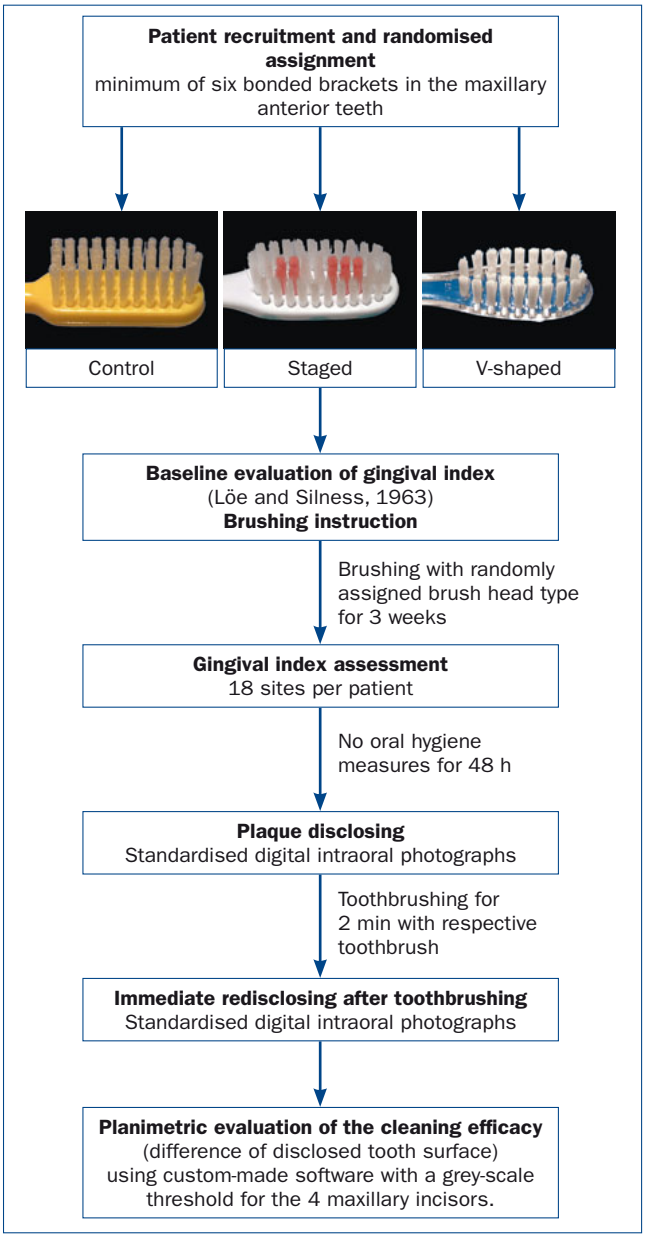

Fig 2 Study design.

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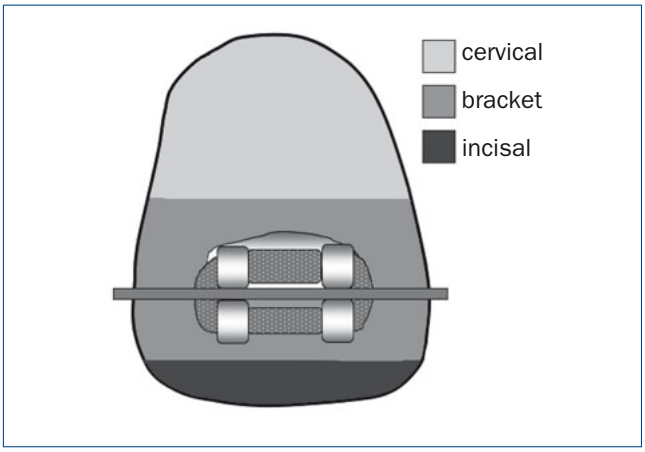

Fig 3 The three zones of interest: cervical, incisal and bracket area. The latter was defined as extending 2 mm around the brackets.

(18 sites per patient) and the mean percentage of bleeding sites per subject was calculated.

Planimetric assessment of cleaning efficacy

After the completion of the 3-week brushing period and after 48 h of no oral hygiene, the tooth surfaces were stained using a plaque-disclosing agent (ESROplaque, ESRO; Thalwil, Switzerland). Afterwards, the patients were advised to brush their teeth with the respective toothbrush for 2 min and the tooth surfaces were then disclosed once again. Standardised digital intraoral photographs were taken after each of the two disclosing procedures.

Tooth surfaces reappearing white after brushing and re-disclosing were considered touched by the filaments. The two pictures were measured planimetrically using custom-made software with a grey-scale threshold under the same conditions by one and the same investigator (B.S.) for the for maxillary incisors. The assessed difference was regarded as potentially cleaned. Measurements were made in three zones of interest: the cervical, the incisal and the bracket area. The latter was defined as extending 2 mm around the brackets (Fig 3).[21]

Statistical Analysis and Data Presentation

Statistical analysis was performed with StatView Version 4.51 (Abacus Concepts; Berkeley, CA, USA) and IBM SPSS Statistics Version 20 (IB; Armonk, NY, USA).

Descriptive statistics for GI scores were computed and the assumption of normality was tested using a Kolmogorov-Smirnov test, which showed that scores of all groups differed significantly from normal distribution ($p < 0.001$). Therefore, non-parametric tests were applied. The Wilcoxon signed-rank test was applied to compare GI scores at the end of the observation period and baseline, and the Mann-Whitney U-test was used to compare the two tested groups and the control group to each other at baseline and at the end of the observation period.

The results of the potentially cleaned area, expressed as percentage, were reported using median values and inter-

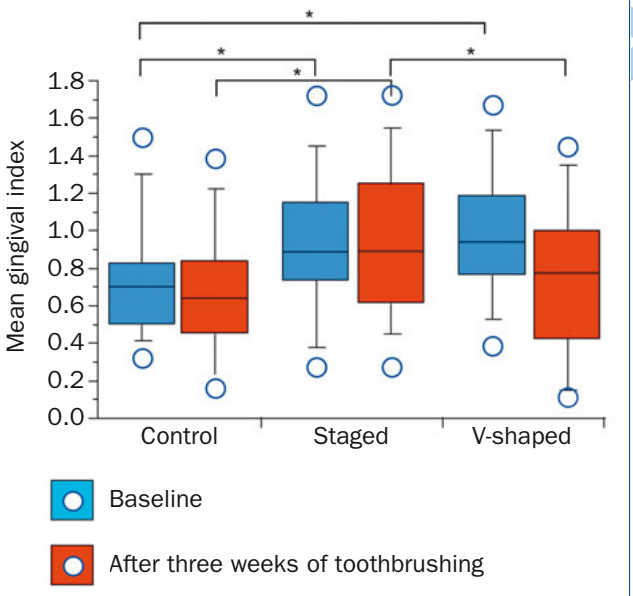

Fig 4 Box plots depicting the mean gingival index score of all selected tooth sites by toothbrush group for planar, V-shaped and staged toothbrushes (horizontal bars: medians; boxes: interquartile areas; error bars: 10th and 90th percentile; dots: extreme values).

quartile ranges (IQR). ANOVA was used for comparison of the brush types. A Bonferroni adjustment was applied for multiple testing. The null hypothesis was that there would be no difference between and within the groups. Significance was set at $p = 0.05$.

RESULTS

Of the 35 persons who started the clinical investigation, two participants (one each from the control and Oral-B Ortho groups) did not attend after 3 weeks and had to be excluded.

At baseline, the 10 subjects (180 sites) of the control group had a significantly better oral hygiene level ($p < 0.05$) with a mean gingival index of 0.76 ± 0.78 compared to the 12 (216 sites) participants of the staged test group (GI: 0.96 ± 0.84) and the 11 (198 sites) participants of the V-shaped test group (GI: 1.04 ± 0.78) (Fig 4).

Gingival Index

The change in mean gingival index score of all selected tooth sites by toothbrush group is illustrated in Fig 4. After 3 weeks of manual toothbrushing with the respective brush, the level of gingival inflammation remained relatively stable

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Table 2 Frequency distribution of gingival index scores of the various toothbrush groups at baseline and after 3 weeks

Gingival index score	Planar toothbrush (control)		Staged toothbrush		V-shaped toothbrush	
Baseline	Number of sites	%	Number of sites	%	Number of sites	%
0	80	44.4	77	35.6	62	31.3
1	64	35.6	73	33.8	75	37.9
2	36	20.0	66	30.6	61	30.8
After 3 weeks						
0	90	50.0	62	28.7	76	38.4*
1	59	32.8	104	48.1	90	45.5*
2	31	17.2	50	23.1	32	16.2*

Baseline to after 3 weeks of toothbrushing with respective toothbrush: control toothbrush: p = 0.305; staged toothbrush: p = 0.890; V-shaped toothbrush: p = 0.003. * Statistically significant.

using the staged (GI 0.96 to 0.93) and control toothbrush (GI 0.76 to 0.67), whereas for the V-shaped brush, it decreased significantly from GI 1.04 to 0.77.

Compared to baseline, no difference was found after 3 weeks in either the control (p = 0.305) or staged (p = 0.890) toothbrush group. However, in the V-shaped group, a statistically significant improvement was observed (p = 0.003); thus, the null hypothesis must be rejected for this group.

At baseline, no statistically significant differences were found between the staged and V-shaped groups (p = 0.554). However, the null hypothesis must be rejected in regard to the control group at baseline, as the controls exhibited statistically significantly better GI scores.

At 3 weeks, the staged toothbrush group differed significantly from the control (p = 0.000) and V-shaped (p = 0.018) groups. No statistical difference between V-shaped and the control was observed (p = 0.098).

The frequency distribution of gingival index scores by toothbrush head type is depicted in Table 2. The relative proportions of the three gingival index scores at baseline showed that the control group had more sites with GI = 0 (44.4%) and significantly less gingival bleeding (GI = 2, 20.0%) than the two groups using test toothbrushes (staged, GI = 0: 35.6%, GI = 2: 30.6% and 31.3%; V-shaped, GI = 0: 31.3%, GI = 2: 30.8%) (Table 2). After three weeks of brushing with the respective toothbrushes, the percentage of healthy gingival sites increased from 44% to 50% of the evaluated tooth sites for the planar toothbrush head type.

In contrast, for the staged toothbrushes, the number of sites that bled on probing as well as the number of healthy tooth sites showing no gingival inflammation decreased significantly by approximately 7%, resulting in an unchanged mean GI level (Fig 3). Patients using the V-shaped toothbrush showed significantly lower gingival inflammation, with an almost 50% decrease in the percentage of GI score 2 sites and a 7% increase of non-inflamed gingival sites.

Planimetric Assessment

Of the 33 participants assessed after 3 weeks of controlled oral hygiene, three could not be re-evaluated after two days of not performing any oral hygiene procedures. One participant in the V-shaped cohort and two from the staged toothbrush group did not attend for disclosing and subsequent planimetric evaluation and were thus excluded; hence, 10 patients in each group were reassessed. Due to optical distortions in the canine areas, only the lateral and central incisors were planimetrically evaluated. Tooth surfaces appearing white after brushing and redisclosing were considered to have been touched by the brush filaments. The respective reduction of uncleaned area in percent for all tested toothbrushes and control was considered as the cleaning efficacy.

After two days of refraining from any oral hygiene procedures, none of the 3 groups differed statistically significantly from each other in terms of accumulated plaque (Table 3).

The cleaning efficacy, calculated as the difference of disclosed area before and after toothbrushing, ranged from 2.8% to 11.8% for the coronal and from 4.3% to 20.3% for the cervical area (Table 3). The overall cleaning efficacy was 22.3% to 26.3% for the control, 13.4% to 28.2% for the staged and 13.9% to 22.0% for the V-shaped brush head type. The performance of all three brush head types was statistically similar.

DISCUSSION

The brushes tested were selected based on the results of an in vitro study evaluating the cleaning efficacy of different manual toothbrush head types.[21] In that study, staged and V-shaped brush head designs outperformed planar brushes in cleaning efficacy of teeth with fixed orthodontic appliances. The purpose of this study was to clinically verify these in vitro results.

Patients undergoing orthodontic treatment with fixed appliances were enrolled in this randomised clinical trial

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Table 3 Percentage of disclosed area for the respective toothbrush head type before and after toothbrushing for 2 min

	Tooth 12			Tooth 11			Tooth 21			Tooth 22		
	% Coronal	% Cervical	% Total	% Coronal	% Cervical	% Total	% Coronal	% Cervical	% Total	% Coronal	% Cervical	% Total
Control												
Before toothbrushing	30.5	34.2	64.8	16.9	40.3	57.3	14.4	39.2	53.5	26.0	35.8	61.8
After toothbrushing	18.7	23.7	42.4	9.1	21.9	31.0	9.0	20.4	29.4	16.5	23.0	39.5
Staged												
Before toothbrushing	23.5	34.0	57.5	14.5	35.3	49.9	15.2	36.4	51.6	23.8	34.1	57.9
After toothbrushing	17.7	24.7	44.2	7.2	17.1	24.9	7.3	16.1	23.5	16.8	20.6	37.4
V-shaped												
Before toothbrushing	32.9	30.0	62.8	14.8	33.6	48.4	17.7	34.6	52.2	31.6	32.8	64.5
After toothbrushing	23.4	25.6	49.0	12.0	17.3	29.2	13.4	16.4	30.3	21.3	23.2	44.5

and were divided into a control and two test groups. The number of drop-outs was reasonable: two subjects were not available after three weeks of controlled oral hygiene procedure and three did not attend 2 days after refraining from toothbrushing. The remaining subjects, however, were unfortunately not homogeneously distributed regarding their level of oral hygiene at baseline, as was evident after statistical evaluation; the control group showed a significantly lower level of gingival inflammation compared to both test groups. Furthermore, the wide age range (12.3 to 24.2 years) might suggest that younger patients would be less conscientious about toothbrushing than adults, which would influence the results. However, as only two patients were older than 20 years (one each in the control and staged groups) and the mean age of all three groups was comparable (control: 15.7 ± 3.4; staged: 16.3 ± 2.8; V-shaped: 15.1 ± 2.1), this effect was considered minimal. The mean gingival index decreased statistically significantly during the first observation period only in the group using the V-shaped brush head type. In the control and the staged brush head groups, however, the mean level of gingival inflammation remained unchanged. These results demonstrated that there is no negative effect on the cleaning efficacy using a planar-head toothbrush in patients with good oral hygiene habits. This is in accordance with several different studies comparing the plaque-removing efficacy of different toothbrushing methods, which found small or no differences.[23,25] Improvement in oral hygiene may not be as dependent upon the development of better brushing methods as upon improving the performance of the individual using any one of the accepted methods[6] and repeated oral hygiene instructions and motivation.[13] This is also in agreement with a systematic literature review,[7] which found oral health promotion during orthodontic treatment to have a positive effect.

On the other hand, the improvement might also be due to the Hawthorne effect,[19] with patients brushing their teeth more thoroughly – regardless of toothbrush type – due to the fact that they were participating in a study, despite receiving oral hygiene instructions at the beginning of their orthodontic treatment.

In an attempt to facilitate plaque control in orthodontic patients, specially designed manual toothbrushes have been developed. Brushes with V-shaped longitudinal grooves trimmed into the bristle field were manufactured to improve brushing around brackets and arch wires, although their effectiveness in reducing gingivitis compared with conventional brushes is questionable.[27] Even though V-shaped brush heads had a significant effect on gingival health, none of the brushes showed superior cleaning efficacy as measured by planimetric evaluation in this pilot RCT. However, the small sample size may have affected the strength of the statistical analysis. A power analysis showed that a minimum sample size of approximately 184 patients would be necessary to achieve 90% power and detect a statistically significant difference at the 5% level with a standard deviations of 0.5. This was far beyond the scope of a pilot RCT study.

Nevertheless, the clinical findings confirm the results of a previous in vitro study[20] which showed that different bristle arrangements such as lowered bristles in the middle of the brush field somewhat improved the cleaning efficacy over planar bristle fields. However, this was not verified by the planimetric assessments. In patients with good oral hygiene, toothbrushes with a flat profile did not prove to be unsatisfactory for the cleaning of teeth with brackets.

It has also been shown that certain toothbrushes have different cleaning effects when used with varying forces of application. At high loads, soft or fine bristles may become twisted resulting in a lower cleaning efficacy. With low force, interaction with the tooth surfaces increases, since soft bristles allow penetration into the interproximal and interbracket area.[20]

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CONCLUSIONS

Based on the present results, it seems that regular orthodontic patients display relatively high gingivitis scores, which might be improved by selecting an appropriate brush design. When teaching a simple circular brushing technique to orthodontic patients with inadequate oral hygiene, the use of a V-shaped brush head design demonstrated a significant improvement in the level of oral hygiene and gingival health after an observation period of 3 weeks. This improvement was only seen in the V-shaped brush group and not in the staged group or in the control, and this difference between the groups could not be substantiated regarding the cleaning efficacy conducted by planimetric evaluation at the end of this pilot RCT. Nevertheless, as in any pilot RCT, this study served to meet three major objectives: test the feasibility of investigating the studied intervention, assess the acceptability of the study design, and facilite the determination of effect sizes for use in sample-size calculations. It is safe to assume that the present study was useful for ascertaining that statistical differences can be discerned between the different interventions and that the study design is suitable for a large-scale investigation. Moreover, a power analysis was performed to calculate the sample size needed for the latter.

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