International Journal of Dental Hygiene

Official Journal of the International Federation of Dental Hygienists

ORIGINAL ARTICLE

Safety and efficacy of two manual toothbrushes

NAM Rosema
MF Timmerman
PA Versteeg
WH van Palenstein Helderman
U van der Velden
GA van der Weijden

Authors' affiliations:
NAM Rosema, MF Timmerman, PA Versteeg, U van der Velden, GA van der Weijden, Department of Periodontology, Academic Centre for Dentistry Amsterdam (ACTA), University of Amsterdam and VU University Amsterdam, The Netherlands
WH van Palenstein Helderman, Department of Preventive and Restorative Dentistry, Radboud University Nijmegen Medical Centre, The Netherlands

Correspondence to:
NAM Rosema
Department of Periodontology
Academic Centre for Dentistry Amsterdam (ACTA)
University of Amsterdam and VU University
Gustav Mahlerlaan 3004
1081 LA Amsterdam
The Netherlands
Tel.: +31 20 5980 174
E-mail: n.rosema@acta.nl

Dates:
Accepted 7 June 2010

To cite this article:
Int J Dent Hygiene **8**, 2010; 280–285
DOI: 10.1111/j.1601-5037.2010.00475.x
Rosema NAM, Timmerman MF, Versteeg PA, van Palenstein Helderman WH, van der Velden U, van der Weijden GA. Safety and efficacy of two manual toothbrushes.

Abstract: *Objective:* The purpose of this study was to test the efficacy and safety of a newly designed multi-level manual toothbrush (Profit-Haije-Brush) compared with a control flat-trimmed manual reference toothbrush from the American Dental Association (ADA). *Material and methods:* For this study, 36 healthy subjects without previous experience in the use of the Profit-Haije-Brush (PHB) were selected. Subjects were given a period of 2 weeks to become familiar with both types of brushes and were instructed to use them on alternate days for 2 min twice daily. Prior to their visit, subjects refrained from all oral hygiene procedures for 48 h. Prebrushing plaque and gingival abrasion scores were assessed. Subsequently, two randomly chosen contra-lateral quadrants were brushed with one of both brushes and the other two quadrants with the alternate brush. Subjects were supervised during their 2-min brushing exercise. After brushing, plaque and gingival abrasion were re-assessed. A questionnaire was filled out to investigate the subjects' attitudes towards both brushes. *Results:* The overall mean prebrushing PI was 2.47 for the PHB and 2.44 for the ADA. The reduction in PI was 1.32 and 1.23 respectively ($P < 0.05$). With regard to gingival abrasion the overall mean prebrushing scores were 4.57 (PHB) and 5.34 (ADA). Post-brushing scores were 13.49 and 13.77 for the PHB and ADA respectively. *Conclusion:* Statistically, the multi-level PHB was significantly more efficacious than the flat-trimmed ADA. However, the difference is clinically considered small and the amount of remaining plaque was not significantly different between brushes. No greater potential to cause gingival abrasion to the oral tissues was observed.

Key words: gingival abrasion; multi-level; plaque; toothbrush

Introduction

As dental plaque biofilm is known as an important factor in the onset of gingival disease, plaque control is one of the fundamental requirements for the maintenance of a functional dentition throughout life (1). The presence of high levels of plaque found in most people is largely responsible for the widespread prevalence of gingivitis that is both socially and clinically undesirable. Taking into account that most people reduce plaque scores by only 50%, it is of importance to develop tools for oral hygiene that can help people obtain a higher level of oral hygiene (2). When oral hygiene products are developed, it is of clinical relevance to investigate whether suggested improvements result in a clinical advantage in terms of plaque removal.

A new toothbrush was developed whereby the filaments of the inner and outer rows have different lengths. Until now many different brush head designs have been investigated varying in length, width, number of tufts, etc. However, when focusing on multi-level brush head designs, data on plaque removal are scarce. The idea of a multi-level toothbrush is to provide better plaque removal in areas where a flat-trimmed toothbrush lacks efficacy. As people may find it difficult to brush lingually because of presence of the tongue it is of importance to provide a toothbrush which overcomes this problem. In a clinical study carried out by Bergenholtz *et al.* (3), a V-shaped brush showed some better results compared with a straight brush. Results of laboratory studies suggest that there may be certain advantages of multi-level over flat-trimmed designs (4–7). However, based on limited data and *in vitro* studies, it is difficult to claim that multi-level toothbrushes also have better performance in a real life clinical situation.

The purpose of this study was to test the effectiveness and safety of a newly designed multi-level manual toothbrush (PHB) compared with a control flat-trimmed manual reference toothbrush (ADA). Effectiveness was assessed by means of plaque removal. Safety was evaluated by means of gingival abrasion scores. Furthermore, a questionnaire was used to investigate the subjects' perception of the brushes under investigation.

Materials and methods

Products

The test brush was the Profit-Haije brush (Fig. 1) that has seven rows of tufts in length and six rows in width. The filaments of the middle two rows are of shorter length (approximately 9 mm) than both the outer two rows (approximately 12 mm). This results in a square U-shape design (Fig. 2). The brush has 42 tufts with approximately 18 filaments per tuft. The average filament diameter is 310 μm.

The control brush is the ADA reference brush (Fig. 3). This is a flat-trimmed toothbrush with end-rounded cylindrical filaments and has 47 tufts with approximately 40 filaments per tuft. The filament length is approximately 11 mm and the average filament diameter is 206 μm.

Subjects

In total, 36 subjects (non-dental students), men and women, were selected after screening to take part in the study. Subjects were recruited from different universities and colleges in and around Amsterdam. The volunteers were informed about the study by a recruitment letter and again at their first appointment. All subjects were given a written explanation of the background of the study, its objectives and their involvement. Upon confirmation of their suitability based on predefined inclusion criteria, all subjects were requested to give their written informed consent. Subjects were required to fulfil the following inclusion criteria: ≥18 years of age, a minimum of five evaluable teeth in each quadrant (with no partial dentures, orthodontic banding or wires); an absence of generalized gingival recession, oral lesions and/or periodontal pockets >5 mm; the absence of pregnancy, systemic diseases such as diabetes and the absence of any adverse medical history or long-term medication. The study was approved by the Medical Ethics Committee of the Academic Medical Centre (AMC) of Amsterdam (Approval #: MEC 06/114 # 06.17.0684).

Fig. 1. Profit-Haije brush (PHB).

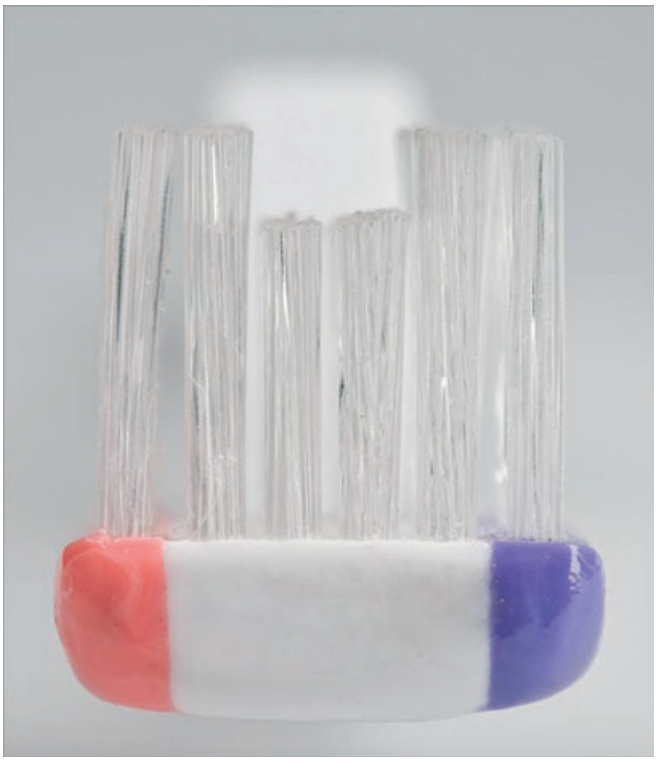

Fig. 2. Close-up frontal view (PHB).

Fig. 3. Control brush (ADA).

Clinical parameters

In this study, plaque and gingival abrasion were assessed in two randomly chosen contra-lateral quadrants (8) by an experienced (9–12) examiner (PAV). Both parameters were assessed prior to brushing and after brushing. All teeth were examined; however, third molars and first incisors were excluded. The

rationale not to include central incisor regions is to avoid overlapping of adjacent quadrants during brushing. Both plaque and gingival tissues were disclosed using a new cotton swab with fresh disclosing solution (Mira-2-Ton®; Hager & Werken GmbH & Co, KG, Duisburg, Germany) for each quadrant. After disclosing, plaque was assessed using a modification of the Quigley & Hein plaque index (13) as described in detail by Paraskevas *et al.* (14). After assessing the plaque, gingival abrasion was assessed according to the method as described in detail by Van der Weijden *et al.* (9).

Study design

To test the efficacy and safety of the PHB brush a randomized single blind, split-mouth, single use study design was employed (Fig. 4). All subjects received both the PHB and the ADA approximately 2 weeks prior to the day of assessments to become familiar with the use of both brushes. Subjects were instructed to use each toothbrush every other day twice daily for 2 min according to a provided brushing calendar, for the duration of the pretrial phase (2 weeks). To keep track of brushing time they also received a timer. Written instructions according to the Bass technique (15, 16) were provided together with a standard, fluoride-containing dentifrice (Zendium® frismint, RDA ±76; Sara Lee H&BC, Veenendaal, The Netherlands). Subjects were asked to refrain from all oral hygiene procedures for 48 h prior to the assessment to allow plaque to accumulate freely. At the brushing visit, all subjects received a prebrushing assessment for both plaque and gingival abrasion. After the prebrushing examination subjects brushed under supervision with one allocated toothbrush in two randomly selected contra-lateral quadrants (being either 1st & 3rd or 2nd & 4th), whereas the remaining two quadrants were brushed with the alternative toothbrush. The randomization list was created using generated random numbers whereby atmospheric noise is used as source outside the computer (http://www.random.org). Randomization was performed in such a way that half of the population started with the PHB and the other half started with the ADA. The allocation of products was carried out by the study coordinator who was responsible for allocation concealment assuring blindness of the examiner. Brushes were moistened with cold running tap water prior to use. An amount of approximately 1 cm of the dentifrice was applied on each brush. A timer was used to make sure that the brushing time per quadrant was 30 s, 15 for the buccal and 15 for the lingual side. Brushing took place in front of a mirror covered with a red foil, so subjects were unable to see the disclosed areas of plaque. All brushing took place in a separate room from the examiner to retain blindness of the study. After the brushing procedure, both parameters were re-assessed after a second disclosing with Mira-2-Ton®. Throughout the study all examinations were performed by one and the same experienced examiner under the same conditions. After the clinical examinations all subjects were asked to complete a questionnaire designed to evaluate their attitudes to both toothbrushes used. Questions comprised effectiveness, pleasantness in use, stiffness of the filaments and preference to either one of the brushes.

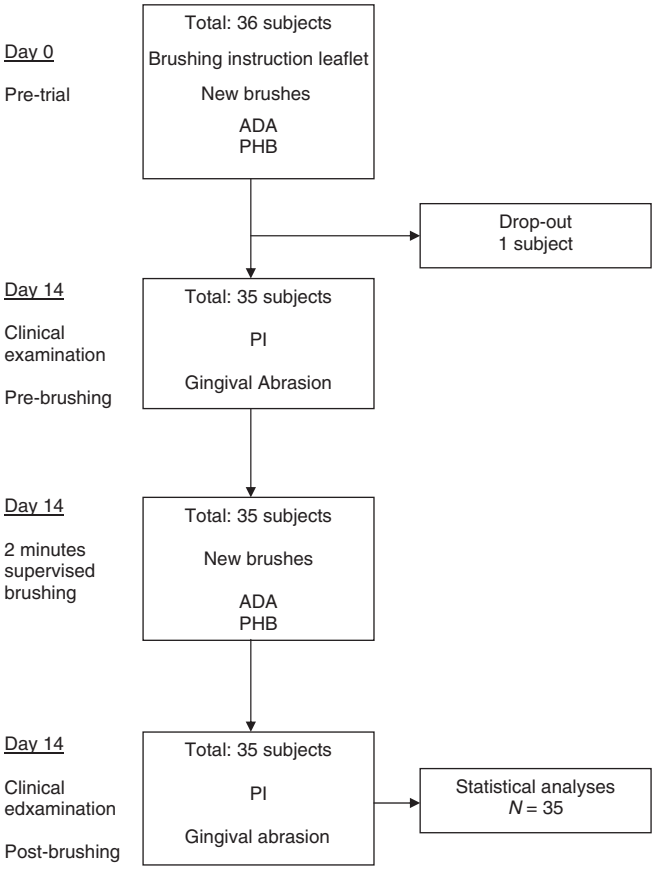

Fig. 4. Flowchart.

Data analyses

For each individual, half mouth prebrushing and post-brushing scores were calculated by brush, and by subtracting the post-brushing scores from the prebrushing scores the amount of removed plaque was determined. Similarly, the increment in gingival abrasion lesions was determined for each individual by subtracting the prebrushing scores from the post-brushing scores. Differences between brushes were compared using the Wilcoxon test for matched pairs. An explorative analysis was performed to assess the origin of possible differences observed between both brushes. Values of $P < 0.05$ were considered as statistically significant. With the present sample size this study was able to discern a difference between plaque scores after brushing of 0.10 with a standard deviation of 0.20 of this difference at a power of >80%.

Results

Of 36 enrolled subjects 35 completed the protocol. One subject did not attend the examination visit because of a scheduling conflict. After the 48 h that subjects abstained from any form of oral hygiene, the mean prebrushing plaque score was

2.47 for the quadrants to be brushed with the PHB and 2.44 for those assigned to the ADA. Mean post-brushing plaque scores were 1.15 for the PHB and 1.21 for the ADA (Table 1a). These values resulted in a difference between prebrushing and post-brushing plaque scores of 1.32 for the PHB and 1.23 for the ADA. This difference was statistically significant in favour of the PHB. Table 2 shows plaque values sorted by tooth type and for approximal, vestibular and lingual regions. With respect to gingival abrasion, the overall prebrushing scores were 4.57 for the PHB and 5.34 for the ADA. Mean post-brushing scores were 13.49 for the PHB and 13.77 for the ADA (Table 1b). The differences between prebrushing and post-brushing did not result in a statistically significant difference between both brushes. Table 3 shows the outcomes of the questionnaire. It appeared that, compared with the ADA, the PHB was considered less pleasant in use and the filaments were considered as being too stiff. Most of the subjects expressed their preference to the ADA.

Table 1. **(a) Mean overall plaque scores (Q&H) for PHB *versus* ADA, and 95% CI of the reduction in plaque scores. (b) Mean overall gingival abrasion for PHB *versus* ADA, and 95% CI of the increment in gingival abrasion scores**

Overall (n = 35)	Prebrushing	Post-brushing	Reduction	95% CI
(a)				
PHB	2.47 (0.49)	1.15 (0.40)	1.32 (0.46)	1.17 <> 1.48
ADA	2.44 (0.48)	1.21 (0.36)	1.23 (0.43)	1.08 <> 1.38
P-value	0.126	0.095	0.028*	
(b)				
PHB	4.57 (4.80)	13.49 (6.46)	8.91 (4.42)	7.40 <> 10.43
ADA	5.34 (5.12)	13.77 (7.87)	8.43 (4.75)	6.80 <> 10.06
P-value	0.256	0.911	0.707	

Standard deviation in parentheses.
P-values from Wilcoxon test.
*Significant.

Table 2. **Plaque scores (Q&H) for various regions of interest for PHB *versus* ADA**

Total, n = 35	Prebrushing	Post-brushing	Reduction
Approximal vestibular			
PHB	3.03 (0.40)	1.72 (0.56)	1.31 (0.57)
ADA	3.00 (0.43)	1.68 (0.49)	1.32 (0.50)
P-value	0.383	0.481	0.383
Approximal lingual			
PHB	2.26 (0.51)	1.35 (0.55)	0.91 (0.41)
ADA	2.23 (0.45)	1.46 (0.46)	0.77 (0.50)
P-value	0.249	0.125	0.029*
Mid vestibular			
PHB	2.51 (0.83)	0.26 (0.33)	2.25 (0.81)
ADA	2.49 (0.82)	0.33 (0.36)	2.16 (0.74)
P-value	0.581	0.143	0.158
Mid lingual			
PHB	1.73 (0.80)	0.47 (0.57)	1.26 (0.74)
ADA	1.70 (0.77)	0.64 (0.53)	1.06 (0.57)
P-value	0.621	0.050	0.047*
Molars			
PHB	2.73 (0.52)	1.43 (0.50)	1.30 (0.53)
ADA	2.67 (0.51)	1.56 (0.50)	1.11 (0.50)
P-value	0.134	0.036*	0.007*
Premolars			
PHB	2.33 (0.45)	1.07 (0.43)	1.26 (0.51)
ADA	2.34 (0.46)	1.01 (0.38)	1.32 (0.50)
P-value	0.906	0.467	0.469
Incisors			
PHB	2.35 (0.60)	0.94 (0.40)	1.41 (0.48)
ADA	2.30 (0.59)	1.03 (0.39)	1.28 (0.52)
P-value	0.280	0.042*	0.020*

Standard deviation in parentheses.
P-values from Wilcoxon test.
*Significant.

Discussion

Manual toothbrushes are commonly used for plaque control. Not only a brush itself is of influence of plaque removing efficacy but brushing duration and brushing technique are also important factors in toothbrushing (2, 17, 18). Therefore, a study model was chosen whereby each subject uses both brushes so that each individual acts as his own control. This model has been used in many other studies and proved to be eligible to compare toothbrushes in their capacity to remove plaque (12, 17, 19). Using this design with supervised brushing and a fixed brushing time, has the advantage that the individual technique and brushing time does not interfere with the primary outcome of this study (17, 20).

At present, data on plaque removal with toothbrushes with two-level or multi-level brush head designs are limited. Few laboratory studies have shown some advantages over flat-trimmed designed brush heads (4–7) but most clinical investigations testing new brush head designs are related to angled filament insertion and not to characteristics tested in this particular study. Terézhalmy *et al.* (21) for example used the ADA flat-trimmed toothbrush as control brush versus a prototype manual toothbrush with a multi-level bristle pattern. A statistically significant difference in favour of the prototype brush was observed for overall plaque scores as well as for gingival and interproximal regions. However, this prototype brush had a different bristle configuration as compared with the PHB in this study (difference in filament insertion angle). In another study carried out by Bergenholtz *et al.* (3), a V-shaped brush showed better results compared with a straight brush with respect to interproximal plaque removal in a professional brushing study. This V-shape brush and the U-shape brush from this study have in common that the filaments of the outer rows of tufts are of greater length than the filaments of the inner rows. A study carried out by Yankell *et al.* (22) compared a three sided toothbrush to a traditional flat headed toothbrush (similar to ADA). The results of this study show that after 6 months the three sided brush had better results with respect to lingual plaque removal.

The most prominent differences between both brushes in this study with respect to plaque removal could be observed in the molar and incisor regions, and at the lingual aspect. In the molar region, known as a 'hard-to-reach area', the PHB

Table 3. **Questionnaire results**

Clean teeth after brushing with PHB	Yes: 24	No: 11	$P = 0.028$*
Clean teeth after brushing with ADA	Yes: 31	No: 4	$P < 0.001$*
Does the PHB harm the gums	Yes: 27	No: 8	$P = 0.001$*
Does the ADA harm the gums	Yes: 4	No: 31	$P < 0.001$*
PHB unpleasant/pleasant in use (VAS: 0–10)	3.55 (2.48)	$P < 0.001$**	
ADA unpleasant/pleasant in use (VAS: 0–10)	7.03 (1.73)		
PHB filaments too soft/too stiff (VAS: 0–10)	8.13 (1.33)	$P < 0.001$**	
ADA filaments too soft/too stiff (VAS: 0–10)	4.73 (1.72)		
Which brush would you keep if you had to choose	PHB: 7	ADA: 28	$P = 0.001$***
Which brush performs best	PHB: 9	ADA: 20	Even: 6

**P*-value from chi-square test.
***P*-value from paired samples *t*-test.
****P*-value from binomial test.

removed more plaque than the ADA. Both the molar region as well as the lingual area is known to be a zone where gingival inflammation is often more pronounced compared with other areas in the oral cavity (23, 24). The designs of the brushes under investigation in the studies of Bergenholtz *et al.* (3) and Yankell *et al.* (22), as well as the design of the PHB brush from this study, have in common a similarity in shape from the frontal point of view which is hollow/concave. This may contribute to a better performance in hard-to-reach areas.

Based on this study, and the *in vivo* and the *in vitro* studies a possible superiority of multi-level toothbrushes over flat-trimmed brushes with respect to plaque removal might be suggested, although the difference plaque scores in this study is not of striking magnitude. The American Dental Association states in its Acceptance Guidelines Program-Toothbrushes (25) that a difference of at least 15% is needed to be of clinical relevance. In this study, the difference between both brushes (7%) does not exceed this limit when calculated as one-sided non-inferiority comparison ($1.645 \times SE$) (26). Another way to interpret the data of this study is by means of 'effect size' according to a 'Cohen's d' [(mean difference1 − mean difference2)/SD]. This results in a Cohen's coefficient of determination of approximately 0.2. Effect sizes <0.3 are to be considered as small and therefore the observed effect in this study may be of minor clinical relevance (27). The statistically significant difference that was observed is likely as a result of the fact that the PHB had good results in areas where the ADA lacks efficacy. With regard to the molar and lingual regions, a difference between brushes in favour of the PHB of approximately 18% was observed, and this could be considered as a clinically relevant advantage. Especially when taken into account that the subjects were not professionally instructed in the use of either brush but only received an instruction leaflet. On the other hand, clinical relevance should also be based on the amount of plaque that remains present after brushing which showed a 5% difference between the PHB and the ADA ($P = 0.095$).

Another aspect of toothbrushes is safety to oral tissues. Excessive brushing force can traumatize soft and hard oral tissues (28, 29). The data of this study did not show a statistically significant difference in gingival abrasion scores between brushes, though the increment between pre and post-brushing was significant. In a study carried out by Versteeg *et al.* (12) whereby the same study design was used in three different toothbrush comparisons similar results could be observed. In this study, prebrushing scores varied from 3.3 to 4.7 increasing to post-brushing scores of 7.4–15.2. Their conclusion was that the brushes under investigation were considered as equally safe to oral tissues.

With respect to outcomes of the questionnaire significant differences could be observed. Interestingly the outcomes do not reflect the results of the clinical parameters in this clinical trial. In contrast, the PHB performed better than the outcomes of the questionnaire would suggest. One could believe that the 'experience' of the brush is highly responsible for the judgement as to which toothbrush is considered to be the best. This 'experience' does not seem to be a representation of the clinical outcome. However, a toothbrush could be developed in such a way that subjects are willing to use the product, but as people's preferences vary, recommendations can not be generalized. After all, the best brush is the brush that the patient likes and will use.

Conclusion

The multi-level PHB was statistically and significantly more effective than the flat-trimmed ADA. However, the difference is clinically considered small and the amount of remaining plaque was comparable for both brushes. No greater potential to cause gingival abrasion to the oral tissues was observed.

Clinical relevance

As new brushes are developed, it is important to evaluate their safety and relative ability to remove plaque and improve gingival health, so dental professionals are informed about the most effective toothbrushes available. The data from the present randomized, single blind, split-mouth, single use study show that subjects only reduced the plaque score with approximately 50%. Though a small but statistically significant difference between both brushes could be observed, the most

distinct differences were found in the molar and lingual region and in favour of the PHB. Taking this into account, it is of clinical relevance to conclude that a multi-level toothbrush may provide a safe advantage over a regular flat-trimmed manual toothbrush.

This study provides the following information: The efficacy of two different manual toothbrushes in the hands of panellists with superficial instruction only, and the effect on the surrounding gingival tissues.

Acknowledgements

The authors would like to thank Dr. J.A.F. Haije, dentist, Haarlem, The Netherlands for providing the Profit-Haije Brushes.

References

1 Löe H, Theilade E, Jensen SB. Experimental gingivitis in man. *J Periodontol* 1965; **36:** 177–187.
2 Jepsen S. The role of manual toothbrushes in effective plaque control: advantages and limitations. In: Lang NP, Attström R, Löe H, eds. *Proceedings of the European Workshop on Mechanical Plaque Control*. Berlin, Quintessenz Verlag, 1998, pp. 121–137.
3 Bergenholtz A, Gustafsson LB, Segerlund N, Hagberg C, Ostby N. Role of brushing technique and toothbrush design in plaque removal. *Scand J Dent Res* 1984; **92:** 344–351.
4 Volpenhein DW, Walsh ME, Dellerman PA, Burkett TA. A new method for *in vitro* evaluation of the interproximal penetration of manual toothbrushes. *J Clin Dent* 1994; **5:** 27–33.
5 Volpenhein DW, Hartman WL. A comparative evaluation of the *in vitro* penetration performance of the improved Crest Complete toothbrush versus the Colgate Total toothbrush and the Oral-B Advantage toothbrush. *J Clin Dent* 1996; **7:** 101–105.
6 Volpenhein DW, Handel SE, Hughes TJ, Wild J. A comparative evaluation of the *in vitro* penetration performance of the improved Crest complete toothbrush versus the Current Crest complete toothbrush, the Colgate Precision toothbrush and the Oral-B P40 toothbrush. *J Clin Dent* 1996; **7:** 21–25.
7 Yankell SL, Shi X, Emling RC, Bucker R, Loudin S. Laboratory evaluation of two bi-level toothbrush products for subgingival access and gingival margin cleaning. *J Clin Dent* 2000; **11:** 20–23.
8 Bentley CD, Disney JA. A comparison of partial and full mouth scoring of plaque and gingivitis in oral hygiene studies. *J Clin Periodontol* 1995; **22:** 131–135.
9 Van der Weijden GA, Timmerman MF, Versteeg PA, Piscaer M, Van der Velden U. High and low brushing force in relation to efficacy and gingival abrasion. *J Clin Periodontol* 2004; **31:** 620–624.
10 Versteeg PA, Timmerman MF, Rosema NA, Warren PR, Van der Velden U, Van der Weijden GA. Sonic-powered toothbrushes and reversal of experimental gingivitis. *J Clin Periodontol* 2005; **32:** 1236–1241.
11 Paraskevas S, Rosema NA, Versteeg P, Van der Velden U, Van der Weijden GA. Chlorine dioxide and chlorhexidine mouthrinses compared in a 3-day plaque accumulation model. *J Periodontol* 2008; **79:** 1395–1400.
12 Versteeg PA, Rosema NA, Timmerman MF, Van der Velden U, Van der Weijden GA. Evaluation of two soft manual toothbrushes with different filament designs in relation to gingival abrasion and plaque removing efficacy. *Int J Dent Hyg* 2008; **6:** 166–173.
13 Quigley GA, Hein JW. Comparative cleansing efficiency of manual and power brushing. *JADA* 1962; **65:** 26–29.
14 Paraskevas S, Rosema NA, Versteeg PA, Timmerman MF, Van der Velden U, Van der Weijden GA. The additional effect of a dentifrice on the instant efficacy of toothbrushing: a crossover study. *J Periodontol* 2007; **78:** 1011–1016.
15 Bass CC. An effective method of personal oral hygiene. *J Louisiana State Med Soc* 1954; **106:** 100–112.
16 Van der Weijden GA, Echeverria JJ, Sanz M, Lindhe J. Mechanical supragingival plaque control. In: Lang NP, Lindhe J, eds. *Clinical Periodontology and Implant Dentistry*, 5th edn. Oxford, Blackwell Munksgaard, 2008: pp. 723.
17 Van der Weijden GA, Timmerman MF, Nijboer A, Lie MA, Van der Velden U. A comparative study of electric toothbrushes for the effectiveness of plaque removal in relation to toothbrushing duration. Timerstudy. *J Clin Periodontol* 1993; **20:** 476–481.
18 Van der Weijden GA, Timmerman MF, Reijerse E *et al.* The long-term effect of an oscillating/rotating electric toothbrush on gingivitis. An 8-month clinical study. *J Clin Periodontol* 1994; **21:** 139–145.
19 Graveland MP, Rosema NA, Timmerman MF, Van der Weijden GA. The plaque removing efficacy of a finger brush (I-Brush). *J Clin Periodontol* 2004; **31:** 1084–1087.
20 Addy M. Measuring success in toothbrush design – an opinion and debate of the concepts. *Int Dent J* 1998; **48(Suppl. 1):** 509–518.
21 Terezhalmy GT, Bsoul SA, Bartizek RD, Biesbrock AR. Plaque removal efficacy of a prototype manual toothbrush versus an ADA reference manual toothbrush with and without dental floss. *J Contemp Dent Pract* 2005; **6:** 1–13.
22 Yankell SL, Emling RC, Perez B. A six-month clinical evaluation of the Dentrust toothbrush. *J Clin Dent* 1996; **7:** 106–109.
23 Lang NP, Cumming BR, Löe HA. Oral hygiene and gingival health in Danish dental students and faculty. *Comm Dent Oral Epidemiol* 1977; **5:** 237–242.
24 Cumming BR, Löe H. Consistency of plaque distribution in individuals without special home care instruction. *J Periodontal Res* 1973; **8:** 94–100.
25 ADA. *Acceptance Program Guidelines – Toothbrushes*. Chicago, IL, ADA Council on Scientific Affairs; 1998.
26 Van Palenstein Helderman WH, Kyaing MM, Aung MT *et al.* Plaque removal by young children using old and new toothbrushes. *J Dent Res* 2006; **85:** 1138–1142.
27 Cohen J. *Statistical Power Analysis for the Behavioral Sciences*, 2nd edn. Hillsdale, NJ: Lawrence Erlbaum Associates; 1988.
28 Alexander JF, Saffir AJ, Gold W. The measurement of the effect of toothbrushes on soft tissue abrasion. *J Dent Res* 1977; **56:** 722–727.
29 Breitenmoser J, Mörmann W, Mühlemann HR. Damaging effects of toothbrush bristle end form on gingiva. *J Periodontol* 1979; **50:** 212–216.