Cleaning Efficacy of a Manual Toothbrush with Tapered Filaments

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Purpose: To compare the cleaning efficacy of (A): a newly developed manual toothbrush with tapered filaments (meridol^{*}, GABA International, CH-Münchenstein) with (B): a standard flat trim manual toothbrush (ADA reference toothbrush) in vivo.

Materials and Methods: 87 healthy participants took part in this study. Subjects were asked to abstain from all oral hygiene procedures for 48 hours. After plaque was scored (Turesky modification of the Quigley Hein Index), the subjects brushed their teeth under supervision with the two manual toothbrushes according to a split-mouth design. In total, a cleaning time of two minutes was given for the whole procedure with an alert after every 30 seconds. Immediately after brushing, plaque was scored again by the same investigator, who was blind with respect to the toothbrush used.

Results: Using the non-parametric Wilcoxon test for paired samples (p<0.05) the overall plaque scores were reduced for (A) from 1.95 ± 0.48 to 1.02 ± 0.41 (p<0.001), and (B) from 1.93 ± 0.52 to 1.09 ± 0.44 (p<0.001). At proximal surfaces the plaque scores were reduced (A) from 2.02 ± 0.49 to 1.11 ± 0.43 (p<0.001) and (B) from 2.01 ± 0.52 to 1.20 ± 0.45 (p<0.001). The relative plaque reductions overall were (A) $47.4\pm18.0\%$ and (B) $44.1\pm15.6\%$ (p=0.039), at proximal surfaces (A) $44.2\pm18.8\%$ and (B) $40.5\pm15.9\%$ (p=0.015), and at lingual surfaces (A) $30.6\pm28.1\%$ and (B) $24.0\pm27.1\%$ (p=0.016).

Conclusion: Both brushes removed a significant amount of plaque. Overall and in areas difficult to reach, the meridol[®] toothbrush was superior to the ADA reference brush.

Key words: manual toothbrush, plaque removal, mechanical plaque control, controlled clinical trial

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T ooth brushing manually is far from perfect (Frandsen, 1986). Additionally, most people tend to brush predominantly easily accessible surfaces and neglect areas. Buccal surfaces and anterior teeth are brushed most thoroughly, whereas the lingual aspects of the mandibular teeth remain uncleaned (MacGregor and Rugg-Gunn, 1979; Rugg-Gunn and MacGregor, 1978). More and more

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Iniversity of Heidel-Neuenheimer Feld 221 5636005. Fax: Luni-heidelberg.de 1998), which emerged Promoters of novel to of sensitivity of the p statistically significan ent toothbrush design als therefore still rec trim, multi tufted bru

complex toothbrush designs, therefore, have been developed with the aim to compensate the lack of mechanical skills of the majority of the population. However, paucity still exists on conclusive research on their clinical efficacy. Studies proving a novel toothbrush design to be superior to flat trim brushes (Sharma et al, 1994) were contradicted by the findings of another study (Grossman et al, 1994; Staudt et al, 2001). Recently, this led to the renewal of an old consensus about plaque removal being independent from toothbrush design (Jepsen, 1998), which emerged in 1986 (Frandsen, 1986). Promoters of novel toothbrushes accused the lack of sensitivity of the plaque scores for the lack of statistically significant differences between different toothbrush designs. However, most professionals therefore still recommend short headed, flat trim, multi tufted brushes with end rounded fila-

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Inclusion Criteria	Exclusion Criteria
a) Signed informed consent.	a) Dental professionals or dental students.
b) In good general health.	b) Orthodontic banding or intra-oral prosthesis.
c) Aged 18–65 years.	c) Having any physical limitations or restrictions that might pr
d) Minimum of 24 scorable teeth (not including 3rd molars, teeth with bridges, orthodontic appliances, crowns or im-	clude normal oral hygiene procedures (i.e. tooth brushing, etc.).
plants), not less than 5 scorable teeth per quadrant.	 d) Having any evidence of neglected dental health (i.e. severe neriodontal disease or rampant caries)
e) Willing to abstain from all other oral hygiene procedures for the duration of the study, including the use of interdental cleaning products and mouth rinses.	e) Having evidence of major hard or soft tissue lesions or tra ma at the baseline visit.
f) Willing to abstain from brushing for one 48-hour time period	f) Having a known allergy to the test products.
and two overnight periods (14–16 hours). g) Willing to have removed any heavy supragingival calculus that	g) Having received antibiotic therapy within the last 28 days prior to the start of the study.
might impede measurement of probing depth on the outset	h) Pregnancy or lactation.
or the Study.	 i) Having a medical condition or history requiring prophylactic antibiotic coverage prior to dental treatment, (e.g., rheumat fever, rheumatic heart disease, heart murmur, mitral valve prolapse, valvular dysfunction, enlarged heart, bacterial er docarditis, congenital heart defect, or prosthetic replace- ments such as heart valve, hip, etc.).
	 j) A medical history of a bleeding disorder, heart pacemaker, leukemia, cirrhosis, vascular disease, sarcoidosis, diabeter active hepatitis or acquired immunodeficiency syndrome (AIDS).
	k) Current or recent (within the last 30 days) participation in ar other clinical study.

ments as represented by the ADA reference toothbrush, although this type of brush is sensitive to its angulations at use. Not used in the appropriate angulations, the bristles block each other, thus reducing the access to the interdental and paramarginal areas of the teeth (Saxer and Yankell, 1997a; Saxer and Yankell, 1997b). A new type of bristles was used in a recently introduced toothbrush (meridol[®], GABA International, CH-Münchenstein) to avoid these negative effects of conventional flat trimmed toothbrushes. The filaments are tapered and their endings have the shape of an extreme rotational ellipsoid instead of a hemisphere. This is suggested to give the filaments very soft endings combined with the stability of the bristle corpus.

The objective of the study was to evaluate and compare the conventional flat trim ADA reference toothbrush with the tapered filament toothbrush for the reduction of plaque in a clinical single-use single-blind randomized split-mouth study. The hypothesis is that the meridol[®] toothbrush is superior to a conventional flat trimmed manual toothbrush as represented by the ADA reference toothbrush in terms of plaque removal.

MATERIALS AND METHODS

Source and Number of Participants

The study protocol, the participant information sheet and the informed consent form have been approved by the independent Freiburg Ethics Commission International in its meeting on July 16, 2001. A total of 87 healthy male participants were recruited for inclusion in the study. All participants gave fully informed written consent prior to their entry into the study. All participants had to satisfy the inclusion criteria listed in Table 1. If any of the listed exclusion criteria were applicable to a potential participant, that participants completed the study protocol. During the first visit, participants' demographic data, general health status and current medication usage were assessed and recorded. Participants received an oral soft and hard tissue examination to exclude the presence of oral diseases, which needed treatment. Each participant received both toothbrushes to begin a home use acclimatization period of 12 days. Participants were instructed to brush on alternate days with each of the two brushes twice daily for two minutes using an identical dentifrice (Blend-a-med classic, Procter & Gamble, D-Mainz). A calendar was provided delineating the brush/day schedule for the 12-day acclimatization period. The order of use of the toothbrushes was randomly assigned.

After the 12-day acclimatization period, participants reported to the test facility not having brushed their teeth in the previous 48 hours. Participants received oral assessments of all soft and hard tissues. The examination of the oral cavity included lips, tongue, gingivae, sublingual area, inner surfaces of the cheeks, mucobuccal folds, hard and soft palate, and pharyngeal area and cervical areas of all teeth. Assessments were to include color, texture, soft tissue abrasion, and any irregularities. Any irregularities of the hard tissues and dental restorations were noted as well. All tooth surfaces were gently air-dried and disclosed with a dye (Mira-2-Tone, Hager & Werken GmbH & Co.KG, Duisburg, Germany) to stain for presence of plaque. Participants then rinsed their mouths with 15 ml of water, twice, for 15 seconds each. Pre- and post-brushing plaque assessments were obtained from all scorable teeth present at six sites per tooth (mesio-buccal, buccal, disto-buccal, disto-lingual, lingual, and mesio-lingual). Plaque was assessed by the Turesky - Gilmore - Glickman modification of the Quigley and Hein plaque index (Table 2) (Turesky et al, 1970). To avoid carry over effects of each device due to the split-mouth design, the two central incisors and the mesial aspects of the lateral incisors of the upper and lower jaw (buccal and lingual) were not scored. Tooth surfaces were also considered as non-gradable in the presence of a crown, an extensive cervical restoration or a hypoplastic surface that could interfere with cleaning or cause a plaque accumulation. Any surface classified as non-gradable was not included in the data analysis.

Participants received their toothbrush, which was labeled and stored at the test center, and brushed in a split-mouth order using both toothbrushes under supervision out of view of the clini-

Table 2The Turesky modification of the Quigley& Hein plaque index scale (Turesky et al, 1970)

- 0 = No plaque/debris.
- 1 = Separate flecks of plaque at the cervical margin of the tooth.
- 2 = A thin continuous band of plaque (up to 1 mm) at the cervical margin of the tooth.
- 3 = A band of plaque wider than 1 mm but covering less than 1/3 of the crown of the tooth.
- 4 = Plaque covering at least 1/3 but less than 2/3 of the crown of the tooth.
- 5 = Plaque covering 2/3 or more of the crown of the tooth.
- 9 = Missing tooth or non-gradable tooth surface.

cal investigator making the plaque assessments. The groups were stratified by gender, smokers/non-smokers and right/left handed individuals. In a random order, either the 1st and 3rd quadrants or the 2nd and 4th quadrants were brushed by one or the other brush and the two remaining quadrants by the alternate brush. No toothpaste was used. The available time for the brushing procedure was 30 seconds per quadrant. A timeout was given to change the brushes.

Post brushing assessments of soft and hard tissues was obtained by disclosing the plaque again as described above. Any effects on hard and soft tissues were noted. All evaluations were performed by one examiner (E.v.B.) who was calibrated for the Plaque-Index (Dörfer et al, 2001a). The examiner was blinded with respect to the brushes used.

Statistical Analysis

A total of 87 individuals completed the study. As no protocol violation was observed, the data of all 87 individuals were entered into the statistical analysis. All data for each individual were entered twice into the statistical software package SPSS (SPSS Inc., Chicago IL, USA) in order to eliminate errors during this step. The quadrants were assigned to the toothbrushes with which they were cleaned. Index values were calculated overall and for different locations in the mouth. The statistical unit was the single individual. Each individual's achieved plaque removal was characterized by the percentage reductions in plaque index. All analyses were performed with the SPSS statistical software package. Data distribution was proved using the Kolmogoroff/Smirnov test. For comparing the plaque scores pre- and post-brushing and between test and control brush as well as the relative and absolute plaque reduction the non-parametric Wilcoxon test for paired samples was used. The significance level was set at p = 0.05 (Dawson-Saunders and Trapp, 1994). A post hoc power analysis was calculated with the statistical software package SamplePower[®] (SPSS Inc., Chicago IL, USA) on the basis of the variation of the data evaluated during the study and a relative plaque reduction of $\delta 1\%$ that would be desirable to detect (Altman, 1991).

The effect of the different toothbrushes on the participants ability to remove dental plaque were determined by comparing all tooth surfaces in total as well as separate for different locations in the mouth.

The study was monitored by a member of the faculty (T.P.), who was not otherwise involved in the study. The monitoring included the correctness of the randomization procedure, the performance of the split-mouth design, the correctness of all data sheets, and the correctness of the statistical analysis.

RESULTS

The final analysis of single usage cleaning efficacy after the 48-hour plaque regrowth period included 87 male participants. The age ranged from 18 to 63 years of age (27.3 ± 6.8). 2.8% of all sites were not included into the statistical analysis because they were either missing or classified as non-gradable due to restorations, which reached the gingival margin.

On the basis of the variation within the data evaluated during this study, the power analysis showed a power of 99.9% to detect a difference of 1% in relative plague reduction between the two brushes.

The tapered filament toothbrush reduced the plaque overall from 1.95 ± 0.48 prebrushing to 1.02 ± 0.41 postbrushing (p<0.001). This conformed to a relative reduction of $47.4\pm18.0\%$. The overall plaque reduction of the ADA reference toothbrush was from 1.93 ± 0.52 to 1.09 ± 0.44 (44.1±15.6%, p<0.001). The differences between the two brushes in terms of relative plaque reduction in the overall plaque scoring were statistically significant (p=0.039).

In the subgroups of the proximal, mesial, and distal surfaces as well as in the lateral incisors and canines the differences between the relative plaque reductions of the two brushes were statistically significant but missed the pre-set clinical relevance level. The remaining plaque was statistically significant less with the tapered filament toothbrush at the proximal mesial and mesiolingual surfaces compared to the reference toothbrush. In all other subgroups the differences between the two brushes in terms of remaining plaque or relative plaque reduction were not statistically significant. The cleaning efficacy in total and separate for different locations in the mouth are listed with statistical significances in tables 3 to 6.

During the study, no adverse events occurred. No gross oral soft or hard tissue alterations were observed except one case, in which after toothbrushing a small gingival abrasion was observed on the palatal mucosa between the two middle incisors (papilla incisiva). Due to the localization of the defect and the split-mouth design, it was not possible to decide, which brush caused the abrasion.

DISCUSSION

It is well documented, that mechanical plaque control can prevent gingivitis, periodontitis and caries. Sutcliffe found a statistically significant association between caries experience and oral hygiene in children from 3 to 4 years of age (Sutcliffe, 1977; Sutcliffe, 1996). Parvainen et al found in the group of 13–15 years of age a strong correlation between plaque scores and gingivitis (Parvainen et al, 1977). However, the conclusion could be drawn, that there is still a need of improving self-applied brushing. Most subjects were not able to reach the goal of sufficient mechanical plaque control with manual toothbrushes (Frandsen, 1986) and finish their brushing after 45 to 90 seconds (MacGregor and Rugg-Gunn, 1979). Efforts to improve the plaque removal by means of varying the lengths, stiffnesses and orientation of bristles and creating complex brush heads did not show convincing superiority to standard flat trim brushes, and are discussed controversially (Grossman et al, 1994; Sharma et al, 1994; Staudt et al, 2001). Compared to the standard flat trim brush the meridol® toothbrush mainly differs in the filament design, being tapered with a broad base and feather-like tips.

Table 3 Pre- and postbrushing plaque of the tapered filament toothbrush (meridol[®]) and the reference toothbrush (ADA) in total and separately for all buccal and lingual surfaces. Listed are the mean values of the Turesky scoring as well as the absolute and relative plaque reduction (%). The differences are tested for statistical significance by means of the non-parametric Wilcoxon test for paired samples (p).

Surfaces	Brush	Prebrushing	Postbrushing	р	Absolute Reduction	Relative Reduction
total	meridol® ADA p	1.95±0.48 1.93±0.51 n.s.	1.02±0.41 1.09±0.44 n.s.	<0.001 <0.001	0.93±0.41 0.84±0.37 0.014	47.4±18.0 44.1±15.6 0.005
buccal	meridol® ADA p	2.65±0.67 2.60±0.70 n.s.	1.18±0.55 1.25±0.59 n.s.	<0.001 <0.001	1.47±0.66 1.35±0.58 0.027	54.5±19.0 51.9±18.1 n.s.
lingual	meridol® ADA p	1.25±0.45 1.27±0.53 n.s.	0.86±0.43 0.93±0.43 n.s.	<0.001 <0.001	0.39±0.33 0.34±0.38 n.s.	30.6±28.1 24.3±27.1 n.s.

Table 4 Pre- and postbrushing plaque of the tapered filament toothbrush (meridol[®]) and the reference toothbrush (ADA) for all mesial, central, distal and proximal aspects of the lingual and buccal tooth surfaces. Listed are the mean values of the Turesky scoring as well as the absolute and relative plaque reduction (%). The differences are tested for statistical significance by means of the non-parametric Wilcoxon test for paired samples (p).

Surfaces	Brush	Prebrushing	Postbrushing	р	Absolute Reduction	Relative Reduction
mesial	meridol®	2.03±0.50	1.12±0.43	<0.001	0.91±0.43	44.1±20.5
	ADA	2.04±0.55	1.21±0.48	<0.001	0.83±0.41	40.9±17.4
	р	n.s.	0.013		0.047	0.031
central	meridol®	1.83±0.49	0.85±0.42	<0.001	0.99±0.46	53.6±19.6
	ADA	1.79±0.56	0.89±0.49	<0.001	0.90±0.40	51.3±18.3
	р	n.s.	n.s.		n.s.	n.s.
distal	meridol®	2.00+0.50	1.11+0.44	<0.001	0.89±0.44	44.1+19.6
	ΔΠΔ	1 99+0 52	1 19+0 47	<0.001	0 79+0 41	40 0+17 3
	//B/(1.00±0.02	1.10±0.41	\$0.001	0.005	40.011.0
	μ	11.5.	11.5.		0.025	0.039
mesial +	meridol®	2.02±0.49	1.11 ± 0.43	<0.001	0.90±0.42	44.2±18.8
distal	ADA	2.01±0.52	1.20±0.45	<0.001	0.81±0.38	40.5±15.9
	р	n.s.	0.034		0.015	0.015

It was hypothesized that these bristles show less blocking effects (Saxer and Yankell, 1997b) and more easily will infiltrate the interdental and the subgingival areas and, therefore, improve plaque removal and gingival health. This study was designed to detect any differences between the tapered filament toothbrush and the reference toothbrush. Efforts were taken, therefore, to give the study a very high statistical power. This included first the split-mouth design to exclude Table 5 Pre- and postbrushing plaque of the tapered filament toothbrush (meridol^{\circ}) and the reference toothbrush (ADA) for all six sites evaluated. Listed are the mean values of the Turesky scoring as well as the absolute and relative plaque reduction (%). The differences are tested for statistical significance by means of the non-parametric Wilcoxon test for paired samples (p).

Surfaces	Brush	Prebrushing	Postbrushing	р	Absolute Reduction	Relative Reduction
mesio- buccal	meridol® ADA p	2.73±0.69 2.72±0.75 n.s.	1.27±0.58 1.35±0.69 n.s.	<0.001 <0.001	1.46±0.69 1.37±0.65 n.s.	52.0±22.7 50.6±20.9 n.s.
centro- buccal	meridol® ADA p	2.49±0.74 2.39±0.75 0.048	0.90±0.58 0.95±0.59 n.s.	<0.001 <0.001	1.59±0.75 1.44±0.65 0.021	62.8±20.6 60.2±20.7 n.s.
disto- buccal	meridol® ADA p	2.75±0.67 2.71±0.68 n.s.	1.38±0.63 1.46±0.62 n.s.	<0.001 <0.001	1.36±0.66 1.24±0.61 n.s.	49.1±19.9 45.7±19.4 n.s.
mesio- lingual	meridol® ADA p	1.33±0.47 1.36±0.57 n.s.	0.96±0.47 1.07±0.47 0.007	0.001 <0.001	0.36±0.39 0.29±0.45 n.s.	26.0±33.4 17.1±29.0 0.024
centro- lingual	meridol® ADA p	1.18±0.49 1.19±0.58 n.s.	0.79±0.48 0.82±0.48 n.s.	<0.001 <0.001	0.39±0.38 0.37±0.43 n.s.	33.7±33.9 19.2±96.2 n.s.
disto- lingual	meridol® ADA p	1.26±0.51 1.27±0.55 n.s.	0.84±0.45 0.93±0.49 n.s.	<0.001 <0.001	0.42±0.39 0.34±0.44 n.s.	29.9±39.4 22.6±37.5 n.s.

inter-individual variation with a pre-determined randomized and supervised brushing schedule, which took care of right/left handed individuals. Second, all plaque scoring was done by the same investigator who was blinded in terms of the brush used on the different sites in the mouth of the subject. Third, the number of participants was large enough to detect differences in terms of the relative plaque reduction of 1% between the two brushes with a power of 99.9% (Altman, 1991), meaning that equity between the two brushes could have been proven as well.

One of the most important confounders, which determine the outcome of plaque reduction, is the amount of initial plaque. As there were almost no differences in the initial amount of plaque between the two groups, this source of errors could be excluded. Furthermore, the plaque regrowth resulted in pre-brushing index values, which were similar to those in other studies (Dörfer et al, 2001a; Dörfer et al, 2001b; Dörfer et al, 2001d; Dörfer et al, 2001c; Staudt et al, 2001). This similarity also appeared in the amount of plaque removal, indicating that the participants thoroughly brushed their teeth, therefore, not influencing the outcome of the study.

The differences between the two groups were statistically significant but small and clinical relevance might be doubted. However, plaque was very low after brushing anyway. Therefore, it is rather unlikely to achieve marked differences between different brushes especially when you compare the test toothbrush with a flat trim toothbrush, which still is seen as ideal (Frandsen, 1986; Jepsen, 1998) and Table 6 Pre- and postbrushing plaque of the tapered filament toothbrush (meridol[®]) and the reference toothbrush (ADA) separate for all teeth. Listed are the mean values of the Turesky scoring as well as the absolute and relative plaque reduction (%). The differences are tested for statistical significance by means of the non-parametric Wilcoxon test for paired samples (p).

Surfaces	Brush	Prebrushing	Postbrushing	р	Absolute Reduction	Relative Reduction
lateral incisor	meridol® ADA p	1.91±0.80 1.84±0.78 n.s.	0.94±0.67 1.00±0.60 n.s.	<0.001 <0.001	0.97±0.63 0.84±0.55 0.019	51.1±33.9 45.0±24.3 0.015
canine	meridol® ADA p	1.93±0.68 1.86±0.72 n.s.	0.93±0.52 1.03±0.57 n.s.	<0.001 <0.001	1.01±0.62 0.83±0.55 0.008	52.0±24.0 43.5±25.8 0.009
first premolar	meridol® ADA p	1.73±0.60 1.67±0.57 n.s.	0.77±0.44 0.81±0.45 n.s.	<0.001 <0.001	0.96±0.53 0.86±0.50 n.s.	53.1±31.7 50.7±22.9 n.s.
second premolar	meridol® ADA p	1.69±0.53 1.76±0.60 n.s.	0.77±0.45 0.80±0.48 n.s.	<0.001 <0.001	0.92±0.52 0.95±0.62 n.s.	53.6±25.3 52.0±31.6 n.s.
first molar	meridol® ADA p	2.06±0.52 2.09±0.62 n.s.	1.06±0.51 1.19±0.61 n.s.	<0.001 <0.001	1.00±0.56 0.90±0.49 n.s.	47.5±26.0 44.0±21.3 n.s.
second molar	meridol® ADA p	2.33±0.51 2.31±0.55 n.s.	1.58±0.65 1.62±0.62 n.s.	<0.001 <0.001	0.75±0.58 0.69±0.47 n.s.	31.7±25.7 30.6±19.3 n.s.

proved to be even more effective than some of the battery toothbrushes (Dörfer et al, 2001d; Sharma et al, 2001). Whether or not the higher plaque-removing efficacy of the tapered filament toothbrush will result in improved gingival health has to be evaluated in long-term clinical trials.

From the data of this study it was concluded that both toothbrushes removed a significant amount of plaque. However, the tapered filament toothbrush showed on most surfaces a statistically significant better plaque-removing efficacy compared to a standard flat trim toothbrush.

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