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Review article

Powered toothbrushes: a review of clinical trials

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Abstract. There is now a vast range of powered toothbrushes (PTBs) available on the market and the efficacy of each product is usually determined in one, or a series of controlled clinical trials. This article reviews briefly the design of PTBs, some of the proposed indications for their use, and the principal observations from published studies of these products. The important issues regarding the regulation and design of trials involving PTBs are discussed and some recommendations are proposed with a view to developing a more structured approach to testing these products.

Key words: powered; electric toothbrushes; clinical trial design

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As an introduction to a review of the problems and results of studies on manual and powered toothbrushes, Ash (1964) wrote "Although power toothbrushes are not particularly recent in origin, advanced designs, intensive promotion and widespread use of many types and manufacture have stimulated considerable interest and research into their safety and effectiveness". This introductory statement remains perfectly valid 35 years later and as the number of marketed products increases, the volume of published clinical research data pertaining to the efficacy of these new designs also continues to expand.

The principal aims of this article are to present a brief overview of the clinical trials which have been undertaken to evaluate the efficacy of powered toothbrushes and to consider design elements of trials which may be standardised so that more meaningful comparisons of data from different studies can be made. Firstly, however, the design and actions of powered toothbrushes will be reviewed together with the clinical indications for the use of these brushes.

Design and actions of powered toothbrushes

Generally, the brushheads of powered toothbrushes tend to be more compact than those of conventional, manual brushes. The bundles of bristles are arranged either in rows (as for a conventional toothbrush) or in a circular pattern mounted in a round head. Bristles are also arranged as more compact, single tufts which facilitate interproximal cleaning and brushing in less accessible areas of the mouth. All brushes rely primarily upon the abrasive, mechanical contact between the bristles and the tooth surface to effect cleaning. The traditional designs of head operate with a conventional side-to-side, arcuate or back and forth motions whereas circular brushheads have oscillating, rotational or counter-rotational movements.

A number of the new generation powered toothbrushes also incorporate design features which are aimed at improving the efficacy of cleaning and reducing the likelihood of toothbrush abrasion and gingival trauma in the long term (Heasman 1998a). These features include;

- an active brush tip to facilitate plaque control around posterior teeth and at interdental sites;
- an orthodontic head for brushing around and beneath the components of fixed orthodontic appliances;
- rotating/spiralling filaments for interproximal cleaning;
- an audible clicking mechanism to warn the brusher when a pre-set brushing force has been reached;
- timers.

Movement of the brushheads is powered from simple battery units, magnetostrictive devices or piezo-electric elements which are mounted in the handles or stems of the brushes (Hotta & Aono 1992, Terezhalmy et al. 1995a). In addition to the effect of mechanical brushing, the concept of utilising low-frequency acoustic energy to generate dynamic fluid activity and perhaps a mild cavitation effect has been developed to provide a 'beyond the bristle tip' cleaning activity (Engel et al. 1993, Johnson & McInnes 1994, Emling & Yankell 1997, Stanford et al. 1997). Acoustic vibrations produced in vitro have been shown to have significant effects in reducing the abilities of oral bacteria to adhere to hard surfaces (McInnes et al. 1990, 1992, 1993, Wu-Yuan et al. 1994). In a recent review, Walmsley (1997) questioned whether even transient cavitation can be generated by powered toothbrushes and suggested that acoustic microstreaming is the more likely physical phenomenon whereby relatively large hydrodynamic shear forces that are capable of disrupting dental plaque, are produced from relatively low streaming velocities

Table 1. Studies comparing the efficacy of powered and manual toothbrushes

Study	Design/PTB type	Indices	Observations
McKendrick et al. (1968)	Parallel groups 103 University students (18–33 years) 24 months Arcuate movement of PTB with conventional head design Each brush used both with, or without verbal instruction	Oral Hygiene Index (Greene & Vermillion 1969) Periodontal Index (modified) (Russell 1956) Gingival recession	No evidence that the PTB was more effective than MTB in reducing oral debris, calculus formation or periodontal disease. Influence of instructions minimal.
Walsh & Glenwright (1986)	Split mouth, crossover 10 dental students with healthy gingival 14 day period Rotary brush	Plaque index[a)]	No differences in efficacy of plaque removal between MTB and PTB.
Glavind & Zeuner (1986)	Parallel groups matched for plaque 40 adults with CAPD (22–67 years) 20 patients used PTB with verbal instructions 20 patients used oral hygiene kit with self teaching manual 3 month follow-up Rotary toothbrush	Plaque score (% surfaces after disclosing) Gingival bleeding	Improvements in plaque score and gingival bleeding were comparable between both groups at 3 months. All patients using PTB indicated that they would recommend the brush to others.
Killoy et al. (1989)	Parallel groups 24 patients 4 weeks Rotary toothbrush 3 episodes of oral hygiene instructions given verbally	Plaque indices[b,c)] Surface area plaque assessment (digitization of photographs) Bleeding index (Barnet et al. 1980)	Significantly better plaque removal with PTB compared to MTB when measured using O'Leary and Turesky indices. No differences with surface area index – lack of discrimination at interproximal sites. Significant between – and within – group reductions in gingival index.
Walsh et al. (1989)	Parallel groups 108 subjects (18–65 years) 6 months Conventional head, alternate up/down movement. Toothbrushing ±irrigation	Plaque index[a)] Gingival index[d)] Bleeding after probing (% sites) Probing pocket depth Attachment loss Stain (Yankell et al. 1982)	PTB and MTB (±irrigation) were equally effective in reducing plaque, stain, bleeding to probing depth ratio and % of pockets greater (or equal to) 4 mm.
Boyd et al. 1989b (Murray et al. 1989)	Parallel groups 40 subjects with moderate CAPD (age and sex matched) in maintenance phase 12 months Rotary toothbrush MTB used with floss and woodsticks	Plaque index[a)] Gingival index[b)] Bleeding tendency[e)] Probing pocket depth Culture and darkfield microscopy of subgingival microflora	PTB is equally effective in removing plaque and controlling gingivitis as the MTB (with adjunctive aids) in patients on a maintenance programme. No differences between groups with respect to creating a less pathogenic microflora.
Baab and Johnson (1989)	Parallel groups 40 adults with moderate gingivitis (mean age 31 years) 4 weeks Rotary toothbrush with instructions given verbally All subjects given PTB at end of the study	Plaque index[c)] Gingival index[d)] Gingival bleeding index[d)]	PTB more effective in removing plaque and controlling gingivitis than MTB although at the end of the trial, scores for the groups were Plaque index: PTB – 28% MTB – 50% Gingival index: PTB – 1.28 MTB – 1.43 6 months after the study the majority of subjects no longer used the PTB.

Preber et al. (1991)	I Parallel groups 19 dental hygiene students 3 weeks Rotary toothbrush	Plaque scores (% after disclosing)	Median plaque scores lower for PTB group (28%) than MTB group (39%) at the end of the study.
	II Parallel groups 10 dental hygiene students Abstained from oral hygiene for 4 weeks Rotary toothbrush Verbal instructions	Photographs (lower anterior region) of plaque retained after 15, 30, 60 s of brushing	Significantly more plaque removed with PTB than with MTB.
Hotta & Aono (1992)	Parallel group 26 dental students (23–37 years) Piezo-electronic brush Plaque allowed to accumulate overnight and then brushed	Plaque index[c)]	No difference between brushes in their ability to remove plaque.
Silverstone et al. (1992)	Parallel groups 24 subjects matched for age, sex and plaque 6 weeks Rotary toothbrush	Plaque indices[a,b)] Gingival index[d)] Questionnaire	Significant improvement in Quigley & Hein index for PTB group (1.8→0.9) compared to MTB group (1.6→1.2). Both brushes reduced gingival index by a similar, but non-significant magnitude (0.9→0.65). Quigley & Hein index more sensitive than Loe & Silness. No correlation between changes in Quigley & Hein index and gingival index.
Barnes et al. (1993)	Parallel groups 70 adults with gingivitis 12 weeks Rotary toothbrush Instructions by video	Plaque index[a)] Gingival index[d)]	Significant reductions in whole mouth and interproximal gingivitis scores for PTB (but not MTB) No significant differences between groups in plaque reduction.
Howorko et al. (1993)	2-way cross-over Periodontal maintenance patients PTB and MTB each used for 2 weeks Rotary toothbrush Oral and written instructions	Plaque index[b)]	No significant difference in plaque removal between PTB and MTB. PTB more effective on distal surfaces of posterior teeth. PTB may be of less benefit to well-motivated patients on maintenance programmes.
Yukna & Shaklee (1993)	Parallel groups 40 patients (37–81 years) in post surgery maintenance phase 6 months Rotary toothbrush Repeated demonstration with written and verbal instructions	Plaque index[b)c)] Papillary bleeding index (Muhlemann 1977) Modified gingival index[f)]	PTB group had significantly lower mean plaque scores at 6 months than the MTB group. PTB group also demonstrated significantly greater resolution in bleeding than did the MTB group.
Johnson & McInnes (1994)	Parallel groups 51 subjects (18–25 years) 4 weeks Sonic toothbrush Verbal instructions	Plaque index[b)] Gingival index[g)] Sulcular bleeding[g)]	Sonic brush removed more plaque than MTB over 4 week period. No differences over time between groups with respect to gingival and Sulcular Bleeding Indices.

Table 1. Cont.

Table 1 (cont'd)

Study	Design	Indices	Observations
Quirynen et al. (1994)	Split mouth cross-over 6 dental students (20–24 years) 4 months Rotary toothbrush 6 adults (30–59 years) moderate periodontitis 7 months Rotary toothbrush	Plaque index[b)] Sulcus bleeding index (Muhlemann & Son 1971) Probing pocket depths	Significantly less plaque removed with MTB. Greater and significant reduction in gingival inflammation and probing pocket depths with PTB. Decrease in efficiency of both brushes with time indicating a need for reinforcement of oral hygiene instructions and remotivation.
Stoltze & Bay (1994)	Parallel groups 40 medical students (18–30 years) 6 weeks Rotary toothbrush No instructions	Plaque index[a)] Gingival index[d)]	MTB: reductions in plaque over 6w, 1.2→1.1 (all sites), 1.4→1.2 (interproximal sites). Gingival index unchanged. PTB: reductions in plaque 1.2→0.6 (all sites) 1.4→0.8 (interproximal) Gingival index also reduced 1.1→0.9 (all sites) 1.1→1.0 (interproximal sites)
Van der Weijden et al. (1994)	Parallel groups 77 non-dental students (mean age 22 years) Moderate gingivitis 8 months Rotary toothbrush Written instructions at baseline, verbal reinforcements at 1, 2, 5 m.	Plaque indices[a,b)] Calculus index (Volpe et al. 1965) Modified gingival index Bleeding score	Generally, subjects using PTB were removing more plaque and had lower gingival indices at 5 and 8 m. No differences in calculus. Oral hygiene and toothbrush instructions are essential to maximise improvement in gingival health.
Terezhalmy et al. (1995b)	Parallel groups 50 subjects 6 months Ultrasonic toothbrush	Plaque index[b)] Gingival index[d)] Bleeding index (Caton & Polson 1985)	PTB claimed to be more effective than MTB in reducing plaque formation, removing plaque and reducing gingivitis over 6 months
Tritten & Armitage (1996)	Parallel groups 60 subjects (22–59 years) Gingival index >1.5 Sonic toothbrush	Plaque index[b)] Gingival index[d)] Bleeding tendency[e)] Bleeding on probing (%) GCF – volume GCF – [AST]	PTB statistically superior in removing supragingival plaque – an effect noted especially around posterior teeth and interproximal sites. No significant differences between groups for other indices.
Ainamo et al. (1997)	Parallel groups 111 patients (20–63 years) Bleeding at >30% sites. Matched for age, sex, plaque, bleeding. 12 months Rotary toothbrush Professional instructions only at baseline	Visible plaque index[g)] Modified gingival bleeding index[g)] Questionnaire to evaluate compliance	PTB more effective than MTB in improving gingival health. No difference in plaque index between groups at baseline, 3, 6, 12 months. ? Hawthorne effect due to volunteers brushing more diligently on the days of clinical examinations. Site specific data show more effective plaque removal by PTB at anterior sites.
Forgas-Brockman et al. (1998)	Parallel groups 56 adults (20–60 years) with plaque index ≥2 and 50% bleeding 30 days. Ultrasonic toothbrush	Plaque index[b)] Gingival index[d)] Interdental bleeding index (Caton & Polson 1985)	No differences between PTB and MTB in post-brushing plaque scores at 15 and 30 days. Pre-brushing plaque scores were lower in PTB group at both time points. Both brushes reduced gingivitis and bleeding with no significant differences between groups.

(for review see Walmsley 1997). Arguably, an understanding of the precise mechanism of plaque disruption (cavitation or acoustic microstreaming) may be regarded as being of secondary importance providing the device is proven to have clinical efficacy. So far, the results of comparative in vitro and in vivo studies investigating the efficacy of sonic toothbrushes in removing pellicle, plaque and stain have been somewhat equivocal and have failed to confirm superiority for the sonic device (Grossman et al. 1995, Khambay & Walmsley 1995, Moran et al. 1995, Schemehorn & Keil 1995, Schemehorn & Henry 1996, Tritten & Armitage 1996. Van der Weijden et al. 1996a, b).

Indications for the use of powered toothbrushes

There is considerable evidence that powered toothbrushes are of benefit in achieving improved plaque control in specific patient groups; patients with fixed orthodontic appliances (Boyd et al. 1989a, Wilcoxen et al. 1991, Trombeli et al. 1995, Heintze et al. 1996, Ho 1997, Trimpeneers et al. 1997, Heasman et al. 1998b) – for whom there is also evidence that powered brushes are more effective in reducing decalcification (Boyd & Rose 1994), children and adolescents (Risers & Binns 1967, Grossman & Proskin 1997), handicapped and severely retarded children (Lucente 1966, Oldenburg 1966, Steinberg & Steinberg 1982) and institutionalised patients including the elderly who are dependent upon care-providers (Harrison 1968, Kambhu & Levy 1993). Interestingly, however, powered toothbrushes have been shown to be of no significant benefit for patients with rheumatoid arthritis (Read et al. 1981, Risheim et al. 1992), for children who are well-motivated brushers (Crawford et al. 1975) and for patients with chronic adult periodontitis (Boyd et al. 1989b, O'Beirne et al. 1996, Robinson et al. 1997).

Clearly, however, from the industrial viewpoint, 'special groups' alone do not constitute a sufficiently wide market and powered toothbrushes are now recommended on a community wide basis with a view to enhancing interest in oral hygiene practices, improving toothbrushing technique and efficacy, and increasing motivation and compliance with oral hygiene measures (Stalnacke et al. 1995). Consequently, a very significant proportion of clinical trials are designed to evaluate new powered brushes, usually comparing their efficacy against a 'benchmark', established powered brush and/or a conventional, manual toothbrush.

Efficacy studies

Clinical trials of powered toothbrushes have either compared the efficacy of the latter in reducing plaque and gingivitis to that of a conventional, manual toothbrush, or have sought to establish superiority of one model over another whilst including a manual toothbrush as a 'control'. Manufacturers of powered toothbrushes usually quote both inhouse and independent data which in general support the superior effectiveness of PTBs. An extensive review of the early comparative studies reveals that whereas the majority of reports tend to confirm superiority of PTBs (Cross et al. 1962, Hoover & Robinson 1962, Lefkowitz & Robinson 1962, Birch & Mumford 1963, Soparker & Quigley 1964, Lobene 1964a, b), the observation was by no means universal and a number of studies reported only equivalence (Chilton et al. 1962, Elliot 1963, Rainey & Ash 1964, Smith & Ash 1964, McKendrick et al. 1968). Indeed, in his extensive review of the subject Ash (1964) concluded that manual and electric toothbrushes are equally effective.

The data and outcomes of recent studies of PTB and manual brushes tend to confirm the earlier observations that PTBs appear to demonstrate superior efficacy in plaque removal (Table 1). A more detailed review of the studies listed in Table 1 however, reveals an enormous variation in the design of the trials, the cohorts of subjects studied, the outcome measures (indices) used to evaluate efficacy and the overall duration of the studies. These issues will be discussed in more detail in the next section but it is hardly surprising to find inconsistencies in results of different studies (sometimes using the same model of PTB) when such variability in design criteria exist.

The design criteria and observations from studies published during the last 10 years, and each comparing the efficacy of at least 2 PTBs (and in some cases also a manual brush) are presented in Table 2. The design of many of these studies is complex not only be-

Abbreviations

PTB powered toothbrush
MTB manual toothbrush
CAPD chronic adult periodontal disease
GCF gingival crevicular fluid
AST aspartate aminostransferase

a) Silness & Löe (1964)
b) Quigley & Hein (1962) or Turesky et al. (1970)
c) O'Leary et al. (1972)
d) Löe & Silness (1963)
e) Armitage et al. (1982)
f) Lobene et al. (1986)
g) Ainamo & Bay (1975)

Table 2. Studies comparing the efficacy of 2 or more powered toothbrushes

Study	Design/PTB types	Indices	Observations
Breuer et al. (1989)	Cross-over study 9 subjects 1 week 'training' 4 week use of brush with plaque scored twice each week 2 week 'washout' before cross-over Interplak versus Braun D3 No verbal instructions	Plaque index[b)]	Braun D3 slightly more effective in plaque removal than the Interplak, particularly at lingual surfaces on mandibular anterior teeth. Clinical significance of the differences is questionable.
Ciancio & Mather (1990)	Parallel groups 30 high plaque formers 1 week No verbal instructions *Interplak versus Waterpik Automatic toothbrush	Plaque indices[b)] (Grossman & Fedi 1974, Coontz 1985)	No statistically significant differences in plaque removal between the 2 electric brushes.
Knocht et al. (1992)	Parallel groups 96 subjects (18–65 years) PI>1.8; GI>0.9 4 weeks Demonstration of brushes and instruction given Interplak versus Epident At first and final visits, the efficacy of brushing was assessed as a single event.	Plaque index[b)] Modified gingival index (Löe 1967)	After single visit brushing episodes – Epident brush more effective in plaque removal than Interplak. Similar observations over 4 week period for reductions in plaque and gingival indices. Some lack of correlation between GI and PI scores.
Van der Weijden et al. (1993a)	Split mouth 60 dental students 3 experiments; each run after 24 hours abstinence from oral hygiene I Teeth brushed by Professional II Teeth brushed by students (after 3-week learning period) III Efficacy of brushing after professional instructions Brushing time – 2 min *Braun D3 versus Braun D5	Plaque index[a)]	I D5 slightly more effective than D3 in plaque removal II No difference in efficacy of brushes when subjects brushed their own teeth III D5 better than D3, notably at interproximal sites.
Van der Weijden et al. (1993b)	Split mouth 20 dental students and staff in Periodontal Department 24 h abstinence from oral hygiene Professional brushing, one brush/quadrant, for 7.5, 15, 30, 45, 90 s (5 experiments) *Blend-a-Dent versus Interplak versus Braun Plak control	Plaque index [a)]	Increase in efficacy for all powereded brushes with increase in brushing time. Interplak and Braun models more effective than Blend-a-Dent – mainly due to better plaque removal from interproximal sites. Brushing time is an important variable for plaque removal with powered toothbrushes.
Grossman et al. (1995)	Parallel groups 116 subjects from general population 8 weeks Sonicare versus Braun Oral B Plak Remover	Plaque index[a)] Gingival index[d)]	No significant differences in plaque removal and resolution of gingivitis between the groups. Subject preference (100%) for Braun brush greater than for Sonicare (25%).

Moran et al. (1995)	Cross-over 24 subjects (19–51 years) 21 day stain enhancement (chlorhexidine, tea, coffee) *Braun Oral B Plak Remover versus Sonicare	Tooth stain (Addy & Roberts 1981)	Significant reduction in stain with Braun powered brush (but not Sonicare) compared to manual toothbrush. No significant difference between powered brushes. Subject preference for Braun toothbrush.
Van der Weijden et al. (1995)	35 non-dental students Abstain from oral hygiene for 48 hours I Split mouth Professional brushing by examiner 30 seconds/quadrant II Professional instruction and assessment of brushing by students (split mouth) III Brushing force evaluated Brushing time=2 min Braun D7 versus Philips HP500	Plaque indices[a,b)]	I & II D7 removed significantly more plaque than Philips HP500 III Mean brushing force used was comparable for the 2 powereded brushes Subject preference was for the Braun D7 (26 subjects).
Grossman et al. (1996)	Randomised cross-over 24 subjects (18–65 years) 5 day periods: 4 days to induce stain (chlorhexidine/tea) Day 5 – 2 minutes of brushing with allocated brush *Braun D7 versus Braun D9	Extrinsic dental stain assessed after 30 s, 1 min and 2 min of brushing (Lang & Brecx 1986)	D9 was consistently more effective in removing stain than the D7 ($p<0.05$) after 2 min brushing.
Robinson et al. (1997)	Parallel groups 54 subjects with early periodontitis 6 months Sonicare versus Braun D7	Plaque index[b)] Papillary bleeding score (Loesche 1979) Probing pocket depth Attachment level	Significant reductions in favour of the Sonicare brush for interproximal plaque at 6 months, bleeding (4 and 6 months), probing pocket depth (4 and 6 months) and attachment level (6 months).
Shibley et al. (1997)	Parallel groups 66 subjects PI>2.0, GI>1.5, Bleeding ⩾30% sites 30 days Interplak versus Hapika	Plaque index[b)] Gingival index[f)] Interproximal bleeding index (Caton & Polson 1985)	The reduction of plaque and resolution of gingivitis over 30 days was similar for subjects using the Hapika and Interplak powered toothbrushes.
Heasman et al. (1998c)	Parallel groups 75 non-clinical dental students (18–25 years) Supervised brushing after 24-h abstinence from oral hygiene. 6 weeks home use. Toothbrushing forces recorded at baseline and 6 weeks *Philips Jordan HP735 versus Braun D7	Plaque index[b)] Gingival index[d)]	No differences between powered brushes in efficacy of plaque removal. GI scores 'stable' over 6 weeks for HP735 group but increased for subjects using D7. Significantly more force used with HP735 at baseline compared to D7 although the difference had disappeared by 6 weeks.

[a)] Silness & Löe (1964)
[b)] Quigley & Hein (1962) or Turesky et al. (1970)
[c)] O'Leary et al. (1972)
[d)] Löe & Silness (1963)
[e)] Armitage et al. (1982)
[f)] Lobene et al. (1986)
[g)] Ainamo & Bay (1975)

Abbreviations PI: plaque index
GI: gingival index

* Studies in which a manual toothbrush was included although data not shown.

cause of the greater number of toothbrushes being compared, but also because of additional parameters and variables that have been investigated; time spent brushing, toothbrushing by the subjects versus toothbrushing by professional/examiner, evaluation of toothbrushing forces used with different PTBs and manual toothbrushes.

Clinical trials of powered toothbrushes

Regulatory issues

Clinical trials involving the testing of therapeutic devices such as powered toothbrushes are not currently subject to the same regulatory and audit directives as are trials involving pharmaceutical products. Drug trials, over recent years, have been scrutinised and in some cases criticised for different reasons; inadequate protocols, poor study design and data collection, inappropriate patient (subject) recruitment, unsuitable statistical analysis, failure to obtain ethics committee (IRB) approval or informed consent from the participants (Hutchinson 1993). Clearly, all of these issues are very much applicable to PTB studies which, like drug trials, are frequently undertaken in hospitals, universities and general dental practice (and in some multi-centre trials, all three). Only by independent monitoring is it possible to confirm that a commercially-sponsored trial has been carried out to the highest possible standard and to avoid criticisms of bias or selfinterest being levelled at either the investigators or the sponsors. Certainly, any clinical trial which is undertaken 'at the interface' between industry and academia (irrespective of whether or not drugs are involved) should be directed by guidelines of Good Clinical Practice (GCP) which are defined as "standards by which clinical trials are designed, implemented and reported so that there is public assurance that the data are credible and that the rights, integrity and confidentiality of subjects are protected" (European Community Directive 1991).

In a positive move towards regulating claims of effectiveness and safety of powered toothbrushes, the Council on Scientific Affairs of the American Dental Association (1996) has published acceptance programme guidelines for these devices. The Council encourages manufacturers to submit clinical protocols for review prior to the start of clinical PTB studies. Furthermore, with a view to standardising procedure and obtaining reproducible data, the guidelines stipulate certain criteria that need to be considered when designing PTB studies; sample size, duration, clinical procedure, clinical assessments, safety assessments and statistical analysis. Subsequently, in order to gain a 'seal of acceptance' for the product, all claims of efficacy and safety also need to satisfy specific criteria (Table 3). Claims of equivalence or superiority over a 'benchmark' product must be based upon data from 2 independent trials and predetermined target criteria of proportional efficacy.

Protocol, blinding and bias

The responsibility for writing the protocol should be shared by the clinical investigators and representatives of any sponsoring company with a view to utilising the experience of each party with respect to issues of trial design and the product(s) to be tested. The protocol must describe the subjects to be studied, study design, assessment methods, the power of the study, issues regarding adverse events and withdrawals. Critically, the protocol should also state clearly the targets of proportional efficacy that will be considered necessary to afford clinical significance to the results and also give details of the statistical analysis. The content, format and ultimately execution of the protocol should be controlled by standard operating procedures which are implemented by the sponsoring company (or an independent representative thereof) in accordance with GCP guidelines (Hutchinson 1993).

From the outset, it is important to appreciate that PTB trials pose a number of specific problems which need to be considered if reproducible data are to be realised. It is clearly not possible to design a double-blind PTB-MTB trial although single (operator) blind status is essential. Upholding single blind status and thus eliminating operator bias can however, be quite difficult to achieve. Different personnel are required to carry out separate tasks: clinical examination and data collection; instruction in the use of the toothbrushes; allocating and collecting toothbrushes to, and from the subjects who must also be informed repeatedly not to discuss the brushes they have used with those responsible for clinical examinations and data collection. When toothbrushes are given to trial subjects, instructions for their use are given either verbally, in writing and occasionally on video (Tables 1, 2). Verbal instructions tend to be favoured and there is some evidence to suggest that these maximise the efficiency with which subjects use PTBs (Van der Weijden et al. 1994). When verbal instructions are given, bias is minimised if the instructions for different models are given by different personnel. This is equally important when one PTB is being compared with a manual toothbrush. When more than one PTB model is involved, bias can be further minimised if the clinical investigators (as opposed to the Principal Investigator) are unaware of the sponsor's identity.

It is now recognised that bias originating from material gain by sponsors, manufacturers and trialists can affect the outcome of clinical trials (Blum et al. 1986) although the use of multiple trial centres and independent auditors are likely to expose both outliers and

Table 3. American Dental Association guidelines for claims of efficacy and safety for powered toothbrushes

- *No comparative claims*
  Data from at least 1 clinical trial of at least 25 subjects must show that the product can be used (unsupervised) by the lay person to give a 15% (statistically significant) reduction versus baseline reduction in both plaque and gingivitis.
- *Comparative claims*
  Superiority claims for a PTB require 2 independent clinical trials each to demonstrate a 25% statistically significant improvement in gingivitis reduction over the products to which it is compared. Equivalence claims in plaque removal or gingivitis reduction need to be substantiated by 2 independent clinical trials designed with sufficient power to detect a 10% difference in performance between the products.
- *Safety*
  Claims of superior safety must be supported by 2 independent clinical trials which demonstrate statistically significant improvement ($p<0.05$) in safety for the PTB versus a compared product.

irregularities. It is evident from the data in Tables 1 and 2 that in the majority of cases, the PTBs evaluated in clinical trials are marketed products rather than prototypes. If 'prototype testing' rather than product testing were to be implemented then many of the pressures to disprove the null hypothesis of equivalence would be unfounded as the design of prototypes could be modified and re-tested if required. Furthermore, the efficacy and actions of prototypes can be evaluated to some extent using robotic systems which simulate clinical toothbrushing (Driesen et al. 1996, Yankell et al. 1997) although clearly, such systems do not allow for individual, behavioural aspects of toothbrushing which can only be assessed clinically.

Design

The advantages and disadvantages of cross-over and parallel design plaque and gingivitis trials which have been discussed previously by Chilton & Fleiss (1986) apply equally well to PTB studies. A review of the studies in Tables 1 and 2 suggests that the parallel group design is favoured for PTB trials and especially those of longer duration (6 months or more) for which cross-over designs are impractical (McKendrick et al. 1988, Boyd et al. 1989b, Walsh et al. 1989, Yukna & Shaklee 1993, Quirynen et al. 1994, Van der Weijden et al. 1994, Ainamo et al. 1997). These longer term, parallel-group studies are appropriate for evaluating the efficacy of a product during ordinary 'day to day' use. Under these circumstances motivation and compliance will become important additional variables but the 'novelty effect' (Ash 1964) for subjects using a PTB will almost certainly have subsided. Blocking or stratification of subjects (patients) into matched sets or predetermined strata is important in PTB parallel design trials, although for long-term studies the withdrawal of subjects can be frustrating and compromises the complete data sets on completion of the trial. The most common prognostic factors which have been used for matching are age, gender, left/right handedness and baseline scores of plaque, gingivitis and bleeding.

The cross-over design is more applicable for short-term PTB studies and because the subjects act as their own controls, manual dexterity, handedness and motivation are inherently controlled, and important inter-individual differences that are impossible to match are eliminated. The problem of carry over effects between brushing periods can be reduced by incorporating a short 'washout period' as well as a 'training period' for using each toothbrush during which no assessments are made as part of the trial (Breuer et al. 1989). Cross-over (and split-mouth) studies are potentially of greatest value in evaluating plaque removal efficacy of new PTB models in the prototype stage of development. After a period of familiarisation with each brush subjects abstain from all oral hygiene measures for 24–48 h. The efficacy of cleaning is assessed after a single episode of toothbrushing (Van der Weijden et al. 1993a, 1995, Grossman et al. 1996, Van der Weijden et al. 1996a,b). These studies are usually undertaken on university students (dental or non-dental) as the cohort under investigation. Provided the investigator (or sponsor) does not extrapolate the results to a more general population or to a long term day-to-day regime of toothbrushing then the value of the design is realised and the integrity of the data maintained.

Scoring plaque

The main outcome measure in studies that are designed to evaluate efficacy of toothbrushing is the presence (or absence) of dental plaque. The indices most frequently used to quantify plaque deposits in PTB studies are those of Silness & Loe (1964), O'Leary (1967) and Quigley & Hein (1962), later modified by Turesky et al. (1970) (Tables 1, 2). Indeed, the Quigley & Hein Index (1962) was developed originally to assess plaque deposits before and after brushing in a comparative, powered versus manual toothbrushing study. With the objective of evaluating most precisely the overall effectiveness of the toothbrushes being tested, plaque indices should be recorded on a full mouth basis and around 6 surfaces on each tooth (mesiobuccal, mesiolingual, buccal, lingual, distobuccal, distolingual). The new generation of powered toothbrushes incorporate specific features that are designed for example, to improve cleaning in posterior and interproximal areas. A number of studies have shown some brushes clean more effectively at certain sites and around particular teeth (Van der Weijden et al. 1993a, Johnson & McInnes 1994, Tritten & Armitage 1996, Van der Weijden 1996b) and it should no longer be considered acceptable to score plaque on selected (Ramfjord) teeth, in 'representative' areas of the mouth, or from photographic records in toothbrushing studies.

One issue which needs to be addressed with respect to scoring plaque in future studies is the importance of scoring subgingival deposits. Ash in his earlier review (1964) commented that effective cleaning of the subgingival crevice might be considered a criterion of effectiveness and that very few studies had evaluated the ability of powered brushes to remove subgingival deposits. It appears that the concept of subgingival brushing has only been assessed in studies on teeth scheduled for extraction (Parfitt 1963, Rapley & Killoy 1994, Taylor et al. 1995) and this method only provides a 'one-off' evaluation. It is somewhat surprising that a clinical index which incorporates a score for subgingival deposits has neither been developed nor incorporated in a powered toothbrush study and indeed, this is one area upon which our group is currently working. Perhaps one reason why clinical researchers apparently remain so enamoured with plaque indices that were devised over 30 years ago was identified by Max Goodson (1986) who commented ... "who are the people who are interested in doing therapeutic trials? Of course, commercial companies are first and foremost. When it comes right down to push and shove, the commercial companies look at what's been done for the last 50 years and they say, we've done gingival indices, we've done plaque indices and, obviously it's tried and tested and therefore this is what we will support. I don't care how sophisticated you are in your measurements this is what we believe in and this is what we believe can convince the FDA is correct". A degree of cynicism perhaps, but nevertheless a view which may well help to explain the apparent inertia in this particular field.

The presence of (unrecorded) subgingival plaque may, to some extent, help to explain those instances where there is a lack of an association between plaque and gingivitis scores in toothbrushing studies. Van der Weijden et al. (1994) suggested that the observed differences in plaque-gingivitis relationships when comparing toothbrushes would be expected to follow the sequence; plaque in-

dices, bleeding on probing and then visual signs of gingivitis. This sequence has not however been observed universally as some longitudinal studies have demonstrated (for manual and powered brushes) reductions in plaque scores without a commensurate or expected resolution in gingivitis (Spindel et al. 1986, Khocht et al. 1992, Stoltze & Bay 1994, Tritten & Armitage 1996, Ainamo et al. 1997). Reasons for this lack of association are difficult to corroborate but may include the presence of undetected subgingival or interproximal plaque, intersubject variation in the 'pathogenicity' of plaque and an exaggerated 'effect' of plaque reduction which results from volunteers paying particular attention to cleaning their teeth on the days of clinical examination (Ainamo et al. 1997). The so-called Hawthorne Effect, which results from a change in behaviour in a subject who anticipates involvement in a clinical study, can be a confounding source of variability in cross-over trials giving rise to different conditions between the first and succeeding experimental periods (Robertson et al. 1989). We have identified a Hawthorne Effect in our own comparative toothbrush studies (Heasman et al. 1998 b,c) and therefore agree with the suggestion of Robertson et al. (1989) that a period of stabilisation should be included between screening and baseline so that the Hawthorne Effect can, as far as possible, 'run its course'.

Finally, the need to match groups (pairs of subjects) for plaque at baseline should be mentioned. In their evaluation of a sonic toothbrush, Johnson & McInnes (1994) observed that larger amounts of plaque may be more easily removed than small quantities, and Heintze and co-workers (1996) demonstrated that the perceived advantage of powered over manual toothbrushes in patients with 'poor' oral hygiene was in fact 'neutralised' in patients with 'good' oral hygiene. These observations further demonstrate the potential difficulties in using results from studies using one selected cohort of subjects (or patients) for the basis of recommending products to an overall broader more general population.

Compliance

Compliance can be monitored quite easily in short term studies and those involving university staff and students who can be contacted readily on campus. When the latter are recruited from a dental faculty it is possible to establish total compliance as well as the maximum effectiveness of any device by supervising the brushing episodes in the research unit. This clearly becomes impractical for studies lasting more than a few weeks.

In longer-term studies compliance becomes an important inter-subject variable and can be assessed by telephone calls, questionnaires and by entering into a calendar or log diary, the time and duration of toothbrushing on a daily basis (McKendrick et al. 1971, Walsh et al. 1989, Stalnacke et al. 1995, Forgas-Brockman 1998). An assessment of potential compliance in long-term studies can be made from the study of comparative frequency of use of PTB and manual toothbrushes reported by Muhler (1969). 280 subjects who had purchased PTBs were contacted and monitored over 12 months. The frequency of brushing (daily) increased from 1× to almost 3×/day over the first 2 months and then fell steadily to 1 brushing episode/2 days at 9 months. The pattern of this decline suggests that any 'novelty effect' of using a PTB wears off at between 5 and 6 months of use and by 12 months, fewer than 50% of subjects were still using their PTB. The subjects questioned had not participated in a clinical trial and so the observations probably provide a fairly accurate assessment of PTB use in a general population. In other words, with respect to withdrawals, 50% should be the 'worst case scenario' for long term PTB trials.

A more favourable compliance rate for PTB use was reported by Stalnacke et al. (1995) who found that of 124 patients who had bought a PTB in the 'previous 3 years', 62% still used them on a daily basis. The authors acknowledged however that their crosssectional design study with a questionnaire and a small sample was always likely to incur bias and overestimate the true compliance rate.

One important point which is relevant to long term studies with relatively infrequent recall intervals is the reliability of the PTBs themselves. There is evidence from both longterm (McKendrick et al. 1971) and short term study recruits who were followed up 6 months later (Baab & Johnson 1989), that PTBs which develop technical problems are a likely cause of poor compliance.

Analyses and outcomes

Specific details regarding appropriate methods for data analysis in plaque, gingivitis (Chilton & Fleiss 1986) and PTB studies (Ash 1964) have been dealt with elsewhere and do not warrant further discussion.

One issue of relevance with respect to outcomes and data interpretation is the need to differentiate between statistical and clinical significance (Ash 1964). In short term studies, it is perfectly reasonable to claim that 'Brush A cleans better than Brush B' provided that baseline plaque levels have been matched and that the applied statistical test confirms the difference at the $p=0.05$ level. A brief examination of published data however (Tables 1, 2) reveals that the more efficacious brush (statistically) is often seen to remove around 10% more plaque than its comparitor. After comparing the efficacy of 2 PTBs in reducing Silness & Loe (1964) plaque scores, Van der Weijden et al. (1995) correctly questioned the clinical significance of differences of this magnitude; the prebrushing scores were 1.91 for each PTB group, whereas post brushing scores were 1.03 and 0.83 ($p<0.05$). In an earlier 8 month study, the same group showed that after 2 months, plaque scores of 1.01 (MTB) versus 0.87 (PTB) ($p=0.06$) did not result in a significant difference between groups for either gingival index or bleeding scores. Statistically significant differences in bleeding scores were noted at 5 and 8 months however, at which times the differences in plaque scores between the groups were around 25% (Van der Weijden et al. 1994). Interestingly, these latter data would permit superiority claims according to the ADA Guidelines (1996) and it seems reasonable to suggest that for claims of clinical significance or clinical benefit to be made, proportional efficacy data should confirm a 25% (minimum) improvement in the reduction of clinical parameters (in addition to plaque removal) for one brush against the comparitor, and the clinical parameters may then be specified in future marketing claims. Such data should also emanate from the same study to avoid hypothetical claims being made by 'association' using data from different clinical trials.

Analysis issues of wider significance and which pertain to all industry sponsored clinical trials are also relevant to PTB studies. There is some agreement between industry and academics/clini-

cians that sponsors and trialists should be separated in the process of data analysis in order to further reduce the effects of bias and self-interest (Blum et al. 1986). It is important that a study protocol clearly defines not only the proposed methods for statistical analysis but also all aspects of intellectual property including ownership of the data, who is the responsible party for analysis, and who will undertake the preparation of the final report and any subsequent submission for publication.

Toothbrushing forces

One of the advantages of PTBs is their ability to maintain or improve plaque control whilst using significantly less toothbrushing force than is required for manual toothbrushes (McLey & Zahradnik 1994, Van der Weijden 1996c, Heasman et al. 1998b). This advantage is most probably relevant to observations from in vitro, animal (histopathological) and clinical studies which suggest that PTBs cause less dental and gingival abrasion than do their manual counterparts (Hoover & Robinson 1962, Niemi et al. 1986, Niemi 1987, Engel et al. 1993, Schemehorn & Zwart 1996, Tritten & Armitage 1996).

Toothbrushing forces can be measured using a strain gauge attached to the handle of the PTB (Van der Weijden et al. 1995, 1996), and clearly depend upon a number of factors including the brushing technique. arrangement and stiffness of the bristles, and shape and movement of the brushhead. The most recent evidence suggests that the forces used with PTBs are in the 80–190 g/f range, compared to forces in excess of 250 g/f which are used for manual toothbrushes (Van der Weijden et al. 1995, 1996, Heasman et al. 1998b, Van der Weijden et al. 1998). As these forces may depend upon the size and shape of the brushhead and therefore any new features incorporated into the design, it becomes evident that subjects should receive specific tooth-brushing (and operating) instructions with new devices to ensure their correct use, and that the 'learning curve' for effective powered toothbrushing has been achieved (Heasman et al. 1998d).

Conclusions

The majority of recent, short-term, proof of principle clinical trials confirm that PTBs demonstrate greater plaque removal efficacy than their manual counterparts (Hancock 1996). The extent to which the statistical superiority translates to clinical benefit in the longer term warrants further investigation. Criteria of proportional efficacy should be preset so that the magnitude of clinical benefit and the level of superiority of one brush over another can be determined unequivocally after analysis of the data.

The testing of new prototypes should be structured. Initially, in vitro model or robotic systems can be used to optimise design features before progressing to short term (3–6 weeks) volunteer studies to evaluate plaque removal in vivo. A favourable outcome at this stage would lead to long-term studies of at least 6 months duration, targeting the general population or perhaps a more restricted cohort of patients with specific periodontal problems. Logically, a new design should be evaluated against the model which it will supersede and most studies also look to evaluate benchmark efficacy against an 'accepted' product of proven efficacy. If the integrity of these studies is to remain intact however, it is crucial that the number of PTBs tested in any one trial is not expanded simply as a potential means of gaining commercial advantage over competitor products.

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Zusammenfassung

Elektrische Zahnbürsten. Eine Übersicht klinischer Studien

Zur Zeit ist eine große Vielzahl elektrischer Zahnbürsten auf dem Markt erhältlich. Für jedes Produkts existieren normalerweise eine oder mehrere kontrollierte klinische Studien, die dessen Wirksamkeit nachweisen. Das Ziel des vorliegenden Artikels ist es, eine Übersicht über den Aufbau der elektrischen Zahnbürsten, einige der vorgeschlagenen Indikationen für ihre Anwendung und die Hauptergebnisse der zu diesen Produkten publizierten Untersuchungen zu geben. Die wichtigen Punkte in der Regelung und im Aufbau von Studien, die sich mit elektrischen Zahnbürsten beschäftigen, werden diskutiert und es werden einige Empfehlungen für ein strukturierteres Herangehen an die Testung dieser Produkte gegeben.

Résumé

Brosses à dents électriques: une revue des essais cliniques

Il y a actuellement un grand nombre de brosses à dents électriques disponibles sur le marché et l'efficacité de chaque produit est d'habitude déterminé dans un ou une série d'essais cliniques contrôlés. Cet article revoit brièvement le modèle des brosses à dents, quelques indications proposées pour leur utilisation et les observations principales des études publiées sur ces produits. Les problèmes importants concernant la régulation et le modèle des essais analysant ces brosses à dents électriques sont discutés et quelques recommendations sont proposées en vue de développer une approche plus structurée lorsque ces produits sont analysés.

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