

# Comparison of Powered versus Manual Tooth Brushing for Safety and Efficacy in Patients with Gingivitis: A Randomised, Multicentre Clinical Trial in China

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**Objective:** To evaluate the effects of powered and manual tooth brushing on gingival inflammation in a Chinese population with mild to moderate gingivitis.

**Methods:** The present randomised, single-blind, parallel clinical trial was conducted in five cities in China. Generally healthy participants aged 18 to 65 years, who were non-smokers and had at least 20 sites of gingival bleeding, were included as eligible subjects. The subjects were randomly assigned to either the powered tooth brushing (PTB) group or standard manual tooth brushing (MTB) group. All subjects were supplied with a fluoride-containing toothpaste. Gingival Bleeding Index (GBI), Modified Gingival Index (MGI) and the Turesky modification of the Quigley-Hein Plaque Index (MPI) were used to evaluate the outcomes.

**Results:** A total of 235 subjects completed the study, 118 in the PTB group and 117 in the MTB group. The mean age and sex distribution for the PTB and MTB groups were  $34.40 \pm 9.99$  years, 89 women and 29 men, and  $34.20 \pm 10.14$  years, 82 women and 35 men, respectively. After 6 months, the percentage decrease in MGI was  $26.150\% \pm 26.897\%$  for the PTB group and  $14.768\% \pm 38.544\%$  for the MTB group ( $P = 0.0092$ ). Statistically significant differences between types of tooth brushing were also observed at 6 months for GBI, and at all time points for MPI.

**Conclusion:** Tooth brushing with a powered toothbrush twice a day was shown to be more effective than use of a manual toothbrush in reducing gingival inflammation, gingival bleeding and surface plaque after a 6-month period. Both kinds of toothbrushes were safe for the oral tissues.

**Key words:** dental hygiene, gingivitis, oral hygiene, public health

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The role of home oral hygiene practices has been studied extensively, with the efficacy and safety of home-use methods, toothbrushes and interproximal cleaning devices being well-documented<sup>1-4</sup>; however, there is limited evidence from clinical trials available to evaluate their impact with a multicentre design and a longer duration. The Fourth National Oral Health Survey of

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China showed a high prevalence of periodontal disease in China, with reported rates of 52.8%, 69.3% and 64.6% in the age groups of 35 to 44 years, 55 to 64 years and 65 to 74 years, respectively<sup>5</sup>. This is important across the entire spectrum of periodontal status, as adequate prevention may reduce the prevalence of periodontal disease and adequate maintenance may minimise its severity. It is important to evaluate the preventative effects of tooth brushing in patients who have not yet experienced periodontitis<sup>6</sup>. The present study aimed to compare the effects of powered versus manual toothbrush use on gingivitis to provide valuable information to help prevent periodontitis.

## Materials and methods

### Subjects

This was a multicentre study conducted on generally healthy adult volunteers aged 18 to 65 years. The Clinical Study Ethics Committee of Shanghai Ninth People's Hospital, Shanghai, China, approved the protocol (SH9H-2018-T60-1) and the trial was registered at [chictr.org](http://chictr.org) (ChiCTR2100050706). Subjects' rights were protected by the Ethics Committee and written informed consent was obtained.

The inclusion criteria were as follows:

- routine manual toothbrush users;
- non-smokers;
- at least 20 natural teeth;
- informed consent provided voluntarily with agreement to fulfil study visits and complete procedures over a 12-month period;
- mild to moderate gingivitis with at least 20 sites of gingival bleeding as assessed by the Gingival Bleeding Index (GBI);
- minimum plaque score of at least 1.5 according to the Turesky modification of the Quigley-Hein Plaque Index (MPI) following an oral hygiene abstention period lasting 8 to 16 hours<sup>8-10</sup>.

The exclusion criteria were as follows:

- fixed orthodontic appliances;
- removable dentures;
- untreated caries lesions;
- significant evidence of periodontal disease and general health problems;
- dental students, dental professionals and others with potential conflicts of interest.

### Study sites and examiners

The study was conducted in five cities in China: Beijing, Shanghai, Chengdu, Wuhan and Guangzhou. All the investigators were oral clinicians with at least 2 years' practice experience.

### Interventions and home hygiene instructions

Two interventions were planned in this home oral hygiene study. The subjects were divided randomly into two groups and provided with either a powered toothbrush (Sonicare DiamondClean Smart used in Gum Health mode with Premium Gum Care brush head [both Philips, Amsterdam, The Netherlands], PTB group) or a manual toothbrush (American Dental Association reference toothbrush with flat-trim nylon bristles, MTB group). All subjects used the assigned toothbrush twice daily, once in the morning and once in the evening, with a standardised fluoride-containing toothpaste. The subjects assigned to the PTB group brushed their teeth according to the instructions provided by the product manufacturer, whereas those assigned to the MTB group brushed their teeth according to their routine habits. All other oral hygiene measures were prohibited. Compliance with the assigned tooth brushing regimen was tracked in a home diary record that was supplied to each subject and reviewed at each study visit by designated staff.

### Outcome measurement

Modified Gingival Index (MGI) was evaluated at four sites on the gingival margin and papillary units of each tooth, with severity rated on a scale of 0 to 4. Gingival Bleeding was assessed using a Community Periodontal Index (CPI) probe. Severity was rated as binary, i.e., bleeding present or not. GBI is part of the empirical clinical algorithm<sup>11</sup>. MPI was scored at six sites, including the labial and lingual side (mesial/centric/distal). All teeth were stained with plaque disclosing dye and then scored.

### Description of study procedures

The subjects attended eight visits to complete the study over a 12-month follow-up period and were enrolled from February 2019 to July 2020. Table 1 presents the study visit intervals and the procedures conducted at each visit.

**Table 1** Timing of study visits and procedures carried out.

Visit 1: Screening (up to day 14)	Informed consent, medical and dental history, concomitant medications, oral examination, preliminary eligibility assessment, enrolment
Visit 2: Baseline/day 0	Oral examination, adverse events/concomitant medications, MGI, GBI and MPI <sup>a</sup> for final eligibility determination, randomisation, product dispensation and instruction, issuing diary
Visit 3: Day 5	Oral examination, adverse events/concomitant medications, compliance review, MPI, dispensing new diary
Visit 4: Week 6	Oral examination, adverse events/concomitant medications, compliance review, MGI, GBI, MPI, dispensing new diary, product use questionnaire
Visit 5: Month 3	Oral examination, adverse events/concomitant medications, compliance review, MGI, GBI, MPI, dispensing new diary, dispensing new brush head or MTB, product use questionnaire
Visit 6: Month 6	Oral examination, adverse events//concomitant medications, compliance review, MGI, GBI, MPI, dispensing new diary, dispensing new brush head or MTB, product use questionnaire
Visit 7: Month 9	Adverse events/concomitant medications, compliance review, dispensing new diary, dispensing new brush head or MTB
Visit 8: Month 12 <sup>b</sup>	Oral examination, adverse events//concomitant medications, compliance review, MGI, GBI, MPI, product use questionnaire

<sup>a</sup>Subjects were required to abstain from administering oral hygiene between 8 and 16 hours prior to each visit at which MPI was assessed.

<sup>b</sup>The clinical measurements of MGI, GBI and MPI were not collected due to the COVID-19 outbreak preceding the scheduled visit.

### Sample size determination

The sample size determination was based on the results of a prior study with similar eligibility criteria in which the primary efficacy endpoint, MGI, was measured in a comparison between a powered toothbrush and a manual toothbrush<sup>12</sup>. After adjustment according to the linear model, the difference in percentage decrease between treatments at week 6 was 46.50%<sup>12</sup>.

In the absence of pilot data for any of the planned clinical sites used, the present authors adopted a conservative estimate of a difference between products of 10% at month 3 (standard deviation 20%, 0.05 significance level, with 90% power). Based on these assumptions, the minimum sample size required to detect the proposed difference was 86 subjects per group, to give a total of 172 subjects. To allow for a 15% dropout rate, the sample size was increased conservatively to enrol 240 subjects (120 per group).

### Randomisation

Subjects were randomised at visit 2 by designated unblinded study personnel. These personnel were not responsible for any efficacy and safety endpoint assessment. As this was a multicentre study, enrolment and randomisation were independent among sites. Each site aimed to enrol 50 subjects (25 per group), except for one site, where the target was 40 subjects (20 per group). Each site's randomisation schedule was paper-based and was provided by a third-party research organisa-

tion. Randomisation was stratified by age: 18 to 34 years and 35 to 65 years.

### Explanation of any interim analyses or withdrawal/termination criteria

There were no planned interim analyses for this study. All subjects were able to withdraw voluntarily at any time. In addition, the principal investigator at each site was able to terminate a subject's participation for any intercurrent concerning safety issue, or as related to significant non-compliance. Withdrawn subjects were not replaced.

### Blinding

Given the nature of the test products, this was a single-blind study. All examiners of the clinical indices were blinded to the treatment assignment of subjects. Designated unblinded study personnel performed randomisation, product dispensing and instruction, and diary dispensing and review. The study data were merged with randomisation following database lock. Statistical analysis was conducted thereafter.

### Repeatability

Repeat examinations for MGI assessments of three participants were carried out by examiners at each site and a reference examiner at baseline and during the visit at month 3 to evaluate inter-examiner repeatabil-



Screened subjects (N=579)		
Enrolled subjects (N=241)		Screen failures (N=338)
Randomized to PTB (N=121)	Randomized to MTB (N=120)	Lost follow up or withdraw (N=6)
Completion PTB (N=118)	Completion MTB (N=117)	

Fig 1 Subject screening, enrolment and completion.

ity. Replicate GBI examinations were not conducted for the influence of the first examination on the replication. Assessments of each tooth performed at each visit were cross-tabulated and a Kappa coefficient ( $\kappa$ ) was calculated. Repeatability was compared according to pre-defined values as fair to good if it was between 0.40 and 0.75. The Kappa scores for MGI with regard to five examiners were 0.56–0.62 at baseline and 0.57–0.61 at the 3-month visit.

*Statistical methods*

The primary efficacy analysis was conducted including all randomised subjects with a baseline and MGI evaluation at month 3 (modified intention to treat [MITT]). The safety analysis included all randomised subjects who were exposed to treatment. All variables were summarised by descriptive statistics. Standard subject demographics (e.g., age, sex, ethnicity) and baseline characteristics were summarised for all randomised subjects, and for MITT subjects. For continuous subject characteristics, means were compared using a one-way analysis of variance (ANOVA). The incidence of categorical variables was compared using a chi-square test or Fisher exact test, where appropriate.

For each visit, an ANOVA model was used to evaluate product comparisons for efficacy variables. The reduction from the baseline percentage of each efficacy variable (MPI, MGI and GBI) was used as the response variable of the model; the group was used as the independent variable. A sensitivity analysis was performed for central effects. In addition, the time effect of efficacy was tested using a linear mixed-effect model, which considered both time effect and time-group interaction effect.

*Deviations from the planned protocol and analysis*

Clinical examinations were not performed at any of the five clinical sites at month 12 due to the COVID-19 pandemic at that time. Thus, the final efficacy endpoints for MPI, GBI and MGI were analysed with outcomes as recorded at month 6. A telephone interview was completed at month 12 to assess safety. These data are included in the final analysis.

**Results**

*Study subjects: enrolment, randomisation and completion*

A total of 579 subjects were screened for inclusion in this study. Of these, 338 did not meet the inclusion criteria and 241 were enrolled, with 121 randomised to the PTB group and 120 to the MTB group. Upon completion at month 12, there were 118 subjects in the PTB group and 117 in the MTB group. Figure 1 presents the flow of subjects from screening to completion. The baseline values depicting the distribution of age, sex, ethnicity, MGI, GBI and MPI between treatment groups, across all five sites, are presented in Table 2.

*Efficacy outcomes*

Gingival inflammation was found to improve for both treatment groups over the study period. At week 6, both treatment groups had made a modest improvement compared to baseline; however, no statistical intergroup difference was observed, with mean percentage decrease values of  $7.206\% \pm 17.310\%$  and  $7.184\% \pm 22.232\%$  for the PTB and MTB group, respectively. At month 3, the reduction trend continued, with percentage decrease values of  $17.490\% \pm 33.525\%$  for the PTB group and  $11.260\% \pm 35.725\%$  for the MTB group ( $P = 0.1693$ ). In month 6, the reduction trend continued and a statistically significant intergroup difference was observed, with outcomes of  $26.150\% \pm 26.897\%$  for the PTB group and  $14.770\% \pm 38.544$  for the MTB group ( $P = 0.0092$ ).

GBI was also found to reduce compared to baseline for both treatment groups. No statistical difference was observed between groups, however, until month 6, as was also the case for MGI, above. At month 6, the percentage decrease outcomes were  $48.660\% \pm 31.849\%$  for the PTB group and  $31.750\% \pm 39.960\%$  for the MTB group ( $P = 0.0004$ ).

As is customary in Chinese dental practice, an early indication of product efficacy for plaque reduction was

**Table 2** Baseline demographics and clinical values.

Indicator		Study group (PTB), n = 118	Control group (MTB), n = 117	P value
Age, y	Mean ± standard deviation	34.40 ± 9.99	34.20 ± 10.14	0.8778
	Median	33.5	33.0	
	Range	18–63	18–59	
Sex	Female	89 (75.4%)	82 (70.1%)	0.3580
	Male	29 (24.6%)	35 (29.9%)	
Ethnic group	Han Chinese	115 (97.5%)	112 (95.7%)	0.3135
	Manchu	0 (0.0%)	3 (2.6%)	
	Hui	2 (1.7%)	1 (0.9%)	
	Nakhi	0 (0.0%)	1 (0.9%)	
	Mongol	1 (0.8%)	0 (0.0%)	
Baseline MGI	Mean ± standard deviation	1.8264 ± 0.4223	1.8237 ± 0.4328	0.9617
	Median	1.7464	1.8018	
	Range	0.7755–2.9196	0.6667–2.8661	
Baseline GBI	Mean ± standard deviation	0.4676 ± 0.2140	0.4530 ± 0.2138	0.6016
	Median	0.4073	0.3929	
	Range	0.1818–0.9811	0.1786–0.9107	
Baseline MPI	Mean ± standard deviation	3.3110 ± 0.6758	3.3347 ± 0.6704	0.7875
	Median	3.3097	3.3286	
	Range	1.7357–4.8053	1.7071–4.9643	

evaluated on day 5. A reduction from baseline plaque levels was observed at all time points for both groups. In addition, between-group differences were observed to be statistically significant at each time point. The mean percentage decreases were 11.320% ± 14.212% for the PTB group and 6.287% ± 12.904% for the MTB group ( $P = 0.0049$ ) at day 5; 7.030% ± 14.929% for the PTB group and 3.208% ± 14.171% for the MTB group ( $P = 0.045$ ) at week 6; 13.576% ± 20.842% for the PTB group and 7.792% ± 18.472% for the MTB group ( $P = 0.0253$ ) at month 3; and 16.777% ± 20.151% for the PTB group and 5.469% ± 19.409% for the MTB group ( $P < 0.0001$ ) at month 6. Figure 2 presents the trend for the three outcome variables over time.

### Sensitivity and correlation analysis

Sensitivity analysis was conducted for the percentage reduction in MGI, GBI and MPI to investigate the impact of multiple factors, such as age, time and clinical site. There was no statistical difference between the two age groups (18 to 34 years and 35 to 65 years) for reductions in MGI, GBI and MPI at any of the visits, except for MPI reduction at 5 days. The interaction between time and study group was statistically significant ( $P < 0.05$ ), with both groups exhibiting different trends at each visit. Additionally, an interaction was observed between site and group ( $P < 0.05$ ), with the clinical efficacy of both treatment groups in Wuhan found to be inconsistent with those at the other four sites.

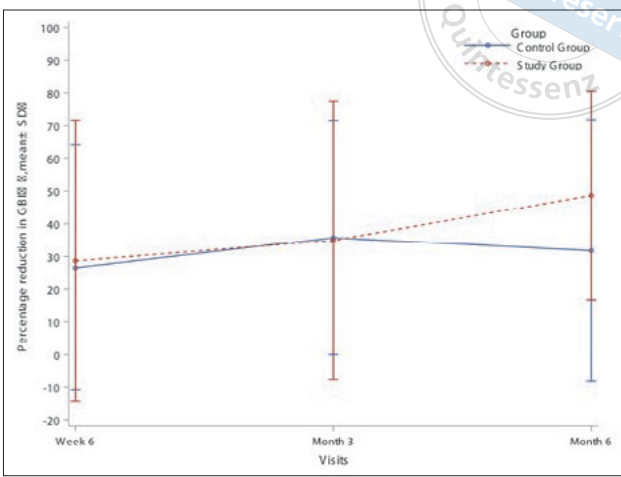
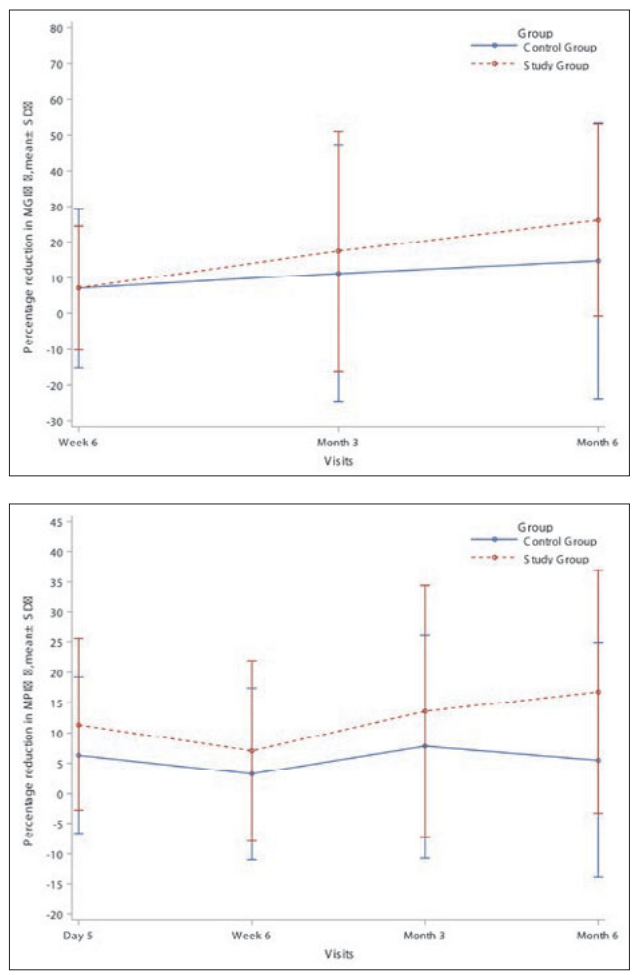
Further, correlation analysis of the percentage reduction in MGI, GBI and MPI with the Pearson method indicates that there was a positive correlation among these three efficacy variables at 3 and 6 months. The correlation coefficient among MGI, GBI and MPI reduction was between 0.25 and 0.45 ( $P < 0.0001$ ) (Table 3). At 6 weeks, the percentage reduction in MPI appeared to correlate with the percentage reduction in GBI, but not MGI.

### Safety outcomes

Over the 12-month period, one adverse event occurred that was possibly related to the study product in each treatment group, both indicated as mild in severity. Neither group reported a severe or greater adverse event possibly related to the study products. A total of 55 subjects reported 69 adverse events that were not related to the study: 27 subjects in the PTB group had 32 adverse events, and 28 subjects in the MTB group had 37 adverse events. There was no statistically significant difference between the two groups.

### Subject deviations

In general, subjects were highly compliant. The most common deviation reported was incidents of missed brushing. Such incidents were infrequent, and therefore deemed insufficiently serious to interfere with the efficacy or safety endpoints.



**Fig 2** Mean percentage decrease for the (a) MGI, (b) GBI and (c) MPI.

**Discussion**

The fourth National Oral Health Survey of China reported high prevalence and severity of periodontal disease among adults in mainland China<sup>13</sup>. The constituents of biofilm are implicated as the source of pathogenesis of periodontal inflammation and disease<sup>14,15</sup>. Adequate home oral hygiene care, such as regular and effective tooth brushing, is necessary for primary periodontal disease prevention. Many individuals use manual toothbrushes as part of their standard home care regimen. Recently published long-term epidemiological research conducted in Germany has shown that use of powered toothbrushes, compared to manual toothbrushes, was found to be significantly associated with a greater number of retained teeth (19.5%), reduced progression of mean pocket depth and reduced clinical attachment level, over an 11-year study period<sup>16</sup>.

The design attributes of powered toothbrushes may help to account for the differences observed in long-term outcomes. In the present study, the PTB group

was found to have gained substantial benefits regarding plaque levels as early as day 5, compared to the MTB group, with gingival inflammatory status observed to improve as well, up to month 6. It is important to note the positive correlation between reduction in dental plaque and gingival bleeding or in dental plaque and gingival inflammation.

The present study corroborates previously published clinical trial outcomes and meta-analyses that show that powered tooth brushing has a clinically measurable benefit on gingival health and plaque management compared to manual tooth brushing<sup>17-20</sup>. In addition to corroborating previously observed effectiveness outcomes, the low incidence of adverse events also adds important evidence to demonstrate that powered tooth brushing is safe for long-term use.

Many of the published prospective trials comparing powered and manual toothbrushes are single-centre<sup>21-23</sup>. The present study had a multicentre design. The five sites involved in the study represent distinct regions of mainland China. Indeed, there may be

**Table 3** Correlation analysis results of percentage reduction in MGI, GBI and MPI.

Visit	Percentage reduction	MGI correlation coefficient	GBI correlation coefficient	MPI correlation coefficient
Week 6	MGI	1.00000	0.04829	0.06468
	GBI	0.04829 ( $P = 0.4613$ )	1.00000	0.25984
	MPI	0.06468 ( $P = 0.3235$ )	0.25984 ( $P < 0.0001$ )	1.00000
Month 3	MGI	1.00000	0.26167	0.40981
	GBI	0.26167 ( $P < 0.0001$ )	1.00000	0.29966
	MPI	0.40981 ( $P < 0.0001$ )	0.29966 ( $P < 0.0001$ )	1.00000
Month 6	MGI	1.00000	0.42481	0.39357
	GBI	0.42481 ( $P < 0.0001$ )	1.00000	0.31771
	MPI	0.39357 ( $P < 0.0001$ )	0.31771 ( $P < 0.0001$ )	1.00000

Note: The correlation analysis of percentage reduction in MGI, GBI and MPI at 6 weeks, 3 months and 6 months was conducted using the Pearson method.

population-based differences between sites, but inter-examiner variation must also be considered. We recommend that subsequent multicentre study designs plan to conduct periodic recalibration exercises during the study period to minimise elements of bias or variation.

However, while the multicentre nature of the study may have presented its own challenges and limitations, the present authors are confident in the value of the generalisability of the observed results. Intragroup statistical differences were observed compared to baseline and intergroup statistical differences were evident. While the control available in a single-centre study may limit variation, such a model may lack the generalisability that a multicentre study affords.

Finally, we acknowledge the limitation presented by the interruption caused to this study by the COVID-19 pandemic. Lacking the data for month 12 makes it difficult to fully capture the drivers of the observed differences. Looking at the study data trends, between-group differences were more marked over time. The difference may also reflect that there is a delay between sustained lowered plaque levels introduced by powered tooth brushing and a subsequent reduction in gingival inflammatory status.

### Conclusion

Within the limits and design of the present study, performing oral hygiene twice a day with a powered toothbrush was shown to reduce plaque levels significantly in the short and long term compared to use of a manual toothbrush. There was a positive correlation among the three efficacy variables (MPI, GBI and MGI) at months 3 and 6. There was a very low incidence of adverse events across all sites, demonstrating the long-term safety of the use of powered and manual toothbrushes among the population.

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### Conflicts of interest

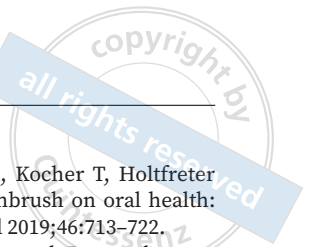
The authors declare no conflicts of interest related to this study.

### Author contribution

Drs Dan Ying TAO, Yan SI, Bao Jun TAI, Xi Ping FENG, Tao HU, Shu Guo ZHENG and Han JIANG designed the study and drafted the manuscript; Drs Ye TAO, Yan ZHOU and Fang Zhi ZHU collected the data and revised the manuscript. All the authors read and approved the final version.

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