ORIGINAL ARTICLE

Efficacy of sonic versus manual toothbrushing after professional mechanical plaque removal: A 6-month randomized clinical trial

Magda Mensi[1,2] | Eleonora Scotti[1,2] | Annamaria Sordillo[1] | Valentina Brognoli[1] | Maria Paola Dominici[1] | Stefano Calza[3]

[1]Section of Periodontics, School of Dentistry, Department of Surgical Specialties, Radiological Science and Public Health, University of Brescia, Brescia, Italy

[2]U.O.C. Odontostomatologia – ASST degli Spedali Civili di Brescia, Brescia, Italy

[3]Department of Molecular and Translational Medicine, University of Brescia, Brescia, Italy

Correspondence
M. Mensi, Section of Periodontics, School of Dentistry, Department of Surgical Specialties, Radiological Science and Public Health, University of Brescia, P.le Spedali Civili 1, 25123 Brescia, Italy.
Email: magda.mensi@gmail.com

Funding information
Open Access Funding provided by Universita degli Studi di Brescia within the CRUI-CARE Agreement.WOA Institution: Universita degli Studi di BresciaBlended DEAL: CARE

Abstract

Aim: The aim of this study was to compare the efficacy of two brushing methods (manual vs. sonic) in terms of plaque control after a session of professional mechanical plaque removal (PMPR).

Methods: Subjects with gingivitis underwent a session of PMPR and were randomly assigned to sonic (SB) or manual brushing (MB). Oral hygiene instructions were provided at baseline (BL), 2 (T0a), 4 (T0b) and 6 weeks (T1) and 6 months (T2). Plaque Index (PI), Gingival Index (GI) and bleeding on probing (BoP) were measured at BL, T1 and T2. The proportion of sites with PI, GI and BoP was modelled at site level using a negative binomial regression fitted via generalized linear mixed model accounting for intra-patient correlation.

Results: Thirty-two subjects were selected, 16 assigned to each group and 31 completed the study. PI, BoP and GI were comparable at BL. At T1, PI was successfully maintained at 6.21% for SB and 22.81% for MB, while at T2 reached 11.34% for SB and 28% for MB, favouring the SB group ($p < 0.001$). GI and BoP were significantly lower in the SB group at T1, with a BoP reduction for SB about 3 times higher than MB ($p < 0.001$). These parameters then levelled at T2 between the groups, with BOP reaching 0.14% versus 0.05% ($p = 0.356$) and GI 1.75% versus 3.52% ($p = 0.020$).

Conclusion: Sonic brushing seemed to maintain a lower PI score compared to a manual brush at 6 months. BoP and GI resulted comparable.

KEYWORDS
biofilm, oral hygiene, powered/manual, toothbrush

1 | INTRODUCTION

Oral biofilm is a dynamic bacterial community embedded in an extracellular polymeric matrix adherent to a substrate.[1] Periodontal health is strictly dependent on the daily self-performed disruption of dental biofilm, in combination with regular professional mechanical plaque removal (PMPR).[2,3] Patients able to keep their plaque index below 20% seem to have a lower incidence of caries and tooth loss.[4] Repeated and individually tailored oral hygiene instructions (OHI) provided after a session of PMPR seem to maintain periodontal health for up to three years.[3] Given the positive effect of OHI, particular attention should be paid to the self-care instruments

recommended, especially for areas difficult to reach such as the interdental space and the surface in proximity to the gingival margin.

The most common instrument for home plaque removal is the toothbrush.[5] Both manual and powered toothbrushes are able to remove plaque from the dental surface efficiently when used with the right technique,[6] but the task might not come without difficulties. The efficacy of toothbrushing depends on various factors such as the shape of the brush,[7] brushing frequency[8] and time,[9,10] dexterity[11] and individual education and motivation.[12] Most of the patients do not brush frequently enough and do not apply the correct technique and pressure.[13]

Powered brushes have been introduced to overcome some of the limitations of manual toothbrushing. From the first powered brushes simulating the back-and-forth or the left-and-right manual movements, the technology has improved and led to modern powered toothbrushes applying sonic and ultrasonic vibrations and rotating, oscillating and pulsating heads. Besides, to encourage and enhance patients' compliance, timers have been combined with the brushes, pulsating every 30 s to guide the progression through the quadrants and achieve the most frequently advocated total brushing time of 2 min.[10] When patient compliance is low or when there is a lack of dexterity, powered toothbrushing might help to compensate for a less-than-ideal technique.[14]

An additional challenge is posed by interproximal cleaning. Plaque accumulates differently in different subjects, but interproximal areas seem to be consistently associated with higher plaque scores.[15] Therefore, an efficient plaque disruption at these areas is fundamental for periodontal health.[16] The use of additional interdental devices such as floss or interdental brushes is often advocated,[17] and powered toothbrushes seem to lead to a higher interdental plaque reduction compared with manual ones.[7]

Sonic (side-to-side) toothbrushes utilize rapid bristles vibrations generating acoustic micro-streaming and hydrodynamic forces able to disrupt plaque from the dental surface.[7] The evidence around the use of sonic toothbrushes is still controversial. While many recent studies show that the sonic brushing seems to be more effective in plaque removal than standard manual toothbrushing,[7,9,17,18] a Cochrane review[19] failed to find evidence of their superiority in terms of reduction of plaque and gingivitis in the short and long term. Newly designed sonic brushes are now available, featuring an angled neck and adaptive head to reach difficult areas, and a 3-min 'Deep clean mode' claimed to target-resistant deposits and stains.

The present study aims to evaluate the efficacy of a new sonic toothbrush in patients with gingivitis in terms of plaque control at 6 weeks and 6 months after a session of PMPR, compared with manual toothbrushing. Secondary aims were the assessment of gingival health through bleeding on probing (BoP) and Gingival Index (GI).

2 | STUDY POPULATION AND METHODOLOGY

This randomized clinical trial was conducted in accordance with the ethical principles of the Declaration of Helsinki and took place at the University of Brescia—Section of Periodontics, School of Dentistry, Department of Surgical Specialties, Radiological Science and Public Health, within the ASST Spedali Civili di Brescia, Department of Odontostomatology (Brescia, Italy). The protocol was reviewed and approved by the Ethical Committee of the University-Hospital of Brescia (CE: 2876, approved on 07/11/2017). The study is registered on ClinicalTrials.gov with ID NCT04558606. All participants signed written informed consent before the beginning of the study.

2.1 | Patient selection

The study included systemically healthy participants affected by gingivitis. The participants were selected from the general population afferent to the aforementioned School of Dentistry. The inclusion criteria for the study population were as follows:

1. Bleeding on probing (BoP) >25%;
2. Plaque Index (PI) >25%;
3. 18 to 40 years of age;
4. Presence of at least 5 teeth per quadrant.

The exclusion criteria for the study population were as follows:

1. Diagnosis of periodontitis defined as detectable interdental clinical attachment loss (CAL) at ≥2 non-adjacent teeth, or buccal or oral CAL ≥3 mm with pocketing >3mm detectable at ≥2 teeth[20];
2. Any systemic disease;
3. Participants smoking more than 10 cigarettes per day;
4. Presence of orthodontic appliances/retainers or complex prosthetic rehabilitation;
5. Presence of crowding or malpositioned teeth;
6. Unwillingness to follow the recall and maintenance programme.

Gingivitis patients were selected with the aim of observing how the changes in PI (primary endpoint) might relate to changes in the soft tissues inflammation (secondary aim). The present study was designed before the release for the most recent Periodontal Classification, defining generalized gingivitis as BoP >30%.[21] Therefore, the applied cut-off of 25% is based on previous studies on gingivitis,[22,23] and it was the traditional cut-off level for post-treatment stability in periodontal patients implemented at the aforementioned Dental School.

2.2 | Outcomes

The primary endpoint of the study was variation in Plaque Index, with values reaching <25% at 6 weeks (T1) and 6 months (T2) after the PMPR session, with a linear difference in the treatment effect (sonic vs. manual brushing) of 10% in favour of sonic brushing. Secondary outcomes were the reduction in BoP and Gingival Index (GI) at T1 and T2.

2.3 | Clinical assessment and interventions

Clinical examination and collection of periodontal parameters were performed by a trained and calibrated examiner (E.S—dentist) blinded to the intervention. The treatments and recalls were performed by two trained hygienists (V.B and M.P.D.). The examiner was calibrated through multiple repeated measurements of pocket probing depth (PPD), CAL, BoP and PI in one quadrant with at least 6 teeth on 10 patients. Measurements were repeated after one hour and variability assessed. A data capture system calculated the intra-examiner agreement. Intra-rater agreement was 98.6%, with Cohen's Kappa 0.96 ($CI_{95\%}$ 0.89–1.00). The patients were asked to refrain from brushing starting from the night before the first appointment (around 12 h). Age, gender and smoking status were collected at baseline, along with a complete periodontal charting including 6-point PPD, recession (REC), CAL, BoP, PI, GI and mobility. The presence/absence of bleeding on probing was registered as a dichotomous index (YES/NO) on the periodontal chart. The number of sites positive for bleeding was then divided by the total number of available sites probed expressed in percentage. The PI was measured dichotomously as plaque present/absent on 6 surfaces per tooth (disto-buccal, buccal, mesio-buccal, disto-lingual, lingual and mesio-lingual) with the aid of a plaque disclosing gel and calculated according to a modified O'Leary index.[24] The GI was measured at all teeth according to Loe & Silness index.[25]

In the same appointment, the patients underwent a session of PMPR performed according to the protocol named Guided Biofilm Therapy (GBT), involving the following steps:

1. Application of a plaque disclosing agent as guidance for plaque removal (Mira-2-Ton® Hager Werken).
2. Full-mouth supra-gingival and intra-sulcular biofilm removal via air-polishing (Airflow Prophylaxis Master, EMS, Nyon, Switzerland) with low-abrasiveness erythritol +chlorhexidine powder (PLUS powder, EMS, Nyon, Switzerland).
3. Use of an ultrasonic scaler (PS tip, Airflow Prophylaxis Master, EMS, Nyon, Switzerland) where visible or detectable calculus was present.
4. Re-disclosing with the same agent to detect any residual plaque and its removal with the same air-polishing device.

Given that air-polishing involves both removal of plaque and polishing at the same time, and the ultrasonic scaler was used only to spot-clean areas with detectable calculus with minimal impact on the enamel surface, no re-polishing of the treated surface was performed.

At the end of the treatment, the participants were allocated to one of the study groups—sonic brushing (SB) or manual brushing (MB)—via randomization list and numbered opaque envelopes.

The patients in the sonic brushing group (SB) were supplied with a sonic toothbrush (Philips Sonicare Flexcare Platinum®) with a standard head (AdaptiveClean) and were instructed to use it on 'Deep clean' mode, with a medium power level (level 2). The brushing

time for the 'Deep Clean' mode is set to 3 min. The patients were instructed to brush twice a day and details were given about how to:

1. Mount the brushing head on the handle.
2. Set the 'Deep clean' mode and medium power level.
3. Position the head at a 45 degrees angle towards the gingival margin and delicately insert the bristle tip in the sulcus with a light pressure, enough to allow the bristles to be projected into the sulcus without causing any discomfort (the brush pulsates if too much pressure is applied).
4. Move the head of the brush on every dental surface.
5. Utilize the 3 min of the 'Deep clean' mode to cover the 4 quadrants adequately, brushing each of them for 45 s.

The patients in the manual brushing group (MB) were supplied with a manual toothbrush (GUM® Technique PRO®, Sunstar gums) to be used with a Bass technique. The patients were demonstrated the technique and instructed to brush twice a day, and details were given about how to:

1. Position the head at a 45 degrees angle towards the gingival margin and delicately insert the bristle tip in the sulcus with light pressure, enough to allow the bristles to be projected into the sulcus without causing any discomfort, and then perform small vibratory movements followed by an apico-coronal rotation;
2. Position the head perpendicularly to the occlusal surfaces;
3. Time the brushing process to 3 min per session with a timer.

All the study participants were provided with the same regular sodium fluoride 0.24% w/w toothpaste (GUM® Hydral, Sunstar gums, RDA < 40) and floss (GUM® Expanding®, Sunstar gums). Flossing technique was demonstrated by the hygienist. They received instructions about the amount of toothpaste to be used (pea-sized) and how to use the interdental floss. OHI was provided and reinforced at 2 weeks (T0a), 4 weeks (T0b), 6 weeks (T1) and 6 months (T2) after the PMPR session. Periodontal parameters were re-collected at evaluated at 6 weeks (T1) and 6 months (T2). At 6 months (T2), the patients also received the first PMPR recall session. Complete study protocol is outlined in Figure 1.

2.4 | Statistical analysis

2.4.1 | Sample size determination

We assumed that the count of sites with plaque within the patient can be described by a Poisson distribution. Assuming a fixed number of sites per patient ($N = 48$), we can model the data using a Poisson rate model and therefore estimate the number of patients needed to achieve approximately 10% reduction (as a difference between rates) in the PI rate between the two treatments,
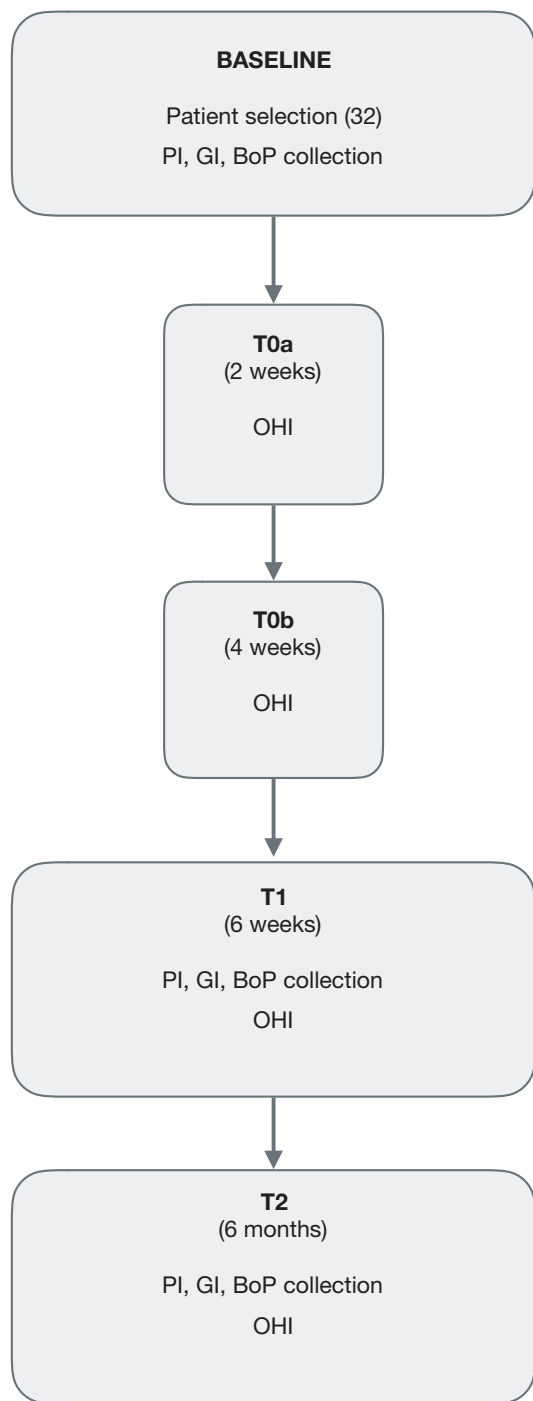
BASELINE

Patient selection (32)

PI, GI, BoP collection

T0a
(2 weeks)

OHI

T0b
(4 weeks)

OHI

T1
(6 weeks)

PI, GI, BoP collection

OHI

T2
(6 months)

PI, GI, BoP collection

OHI

FIGURE 1 Study protocol

corresponding to approximately 30% proportional reduction. For simplicity, we considered only the effect at the latest time point. We simulated Poisson counts for a set of candidate sample size assuming a drop from a 25% rate (12/48) to 17% (8/48) and modelled the data using Poisson regression (GLM with Poisson family). We performed the simulation 500 times and computed the proportion of time the coefficient for the two groups comparison had a *p*-value lower than 5%. A sample size of 16 for each group allowed a power of at least 90%.

2.4.2 | Randomization

Patients were randomized using a computer-generated randomization list. The random allocation sequence was generated with uninformative labels (A and B) and using block (size = 4) randomization algorithm in order to guarantee a balanced assignment. Clinicians were blind to all randomization parameters. All data analyses were carried out according to a pre-established analysis plan by a biostatistician blinded to group allocation.

2.4.3 | Data analysis

Continuous variables were described with mean and standard deviation, median and median absolute deviation (MAD). Outcome variables (BoP, Plaque and GI) were expressed as the number of sites within patient with the condition (eg bleed on probing) over the total number of probed sites (ie PI). PI and BoP were collected and analysed as a dicotomically (yes/no). For ease of statistical analysis, the GI collected was analysed dicotomically (yes/no) assigning a 'no' to the sites scoring 0 (absence of inflammation) and 'yes' to the sites scoring 1, 2 or 3 (inflammation present). The analysis was performed considering patient as statistical unit, aggregating the outcome variables (BoP, Plaque and GI) as the total number of sites within patient with condition coded as 'yes'. The variation in the proportion of sites for every outcome between visits was modelled using multi-level models fitted via generalized linear mixed model (GLMM) with negative binomial family; a multilevel approach allows to account for intra-patient repeated measurements correlation. A negative binomial distribution was assumed to account for potential overdispersion in outcome counts.

The dependent variable in all models was the number of sites with the specific outcome (eg bleeding on probing), while the total number of sites per patient was used as offset; this allowed to model the rate of occurrence of the outcome. Differences between treatments at baseline were compared using Fisher exact test for sex and gender and Poisson regression for number of teeth.

All analysis was two-sided and assumed a significance level of 5%. All calculations were performed using R [R version 4.0.3, R Core Team (2020), Foundation for Statistical Computing, Vienna, Austria].

3 | RESULTS

Forty-one patients were assessed for eligibility. Six patients were excluded for not meeting the eligibility criteria (presence of orthodontic retainers [*n* = 2], and crowding [*n* = 4]), and three patients refused to participate on the basis that they were already using a powered toothbrush and were not willing to change if assigned to the manual brushing group. A total of 32 participants were selected according to the inclusion criteria, 16 per study group (Sonic vs. Manual). One patient belonging to the Manual group dropped out at BL because of onset of oral candidiasis. Statistical analysis was

performed on the total of 16 patients for the SB group and on the 15 patients completing the study for the MB group. The drop-out patient was excluded from the analysis due to lack of data, not having completed any follow-up.

The two groups were comparable in regard to gender, smoking status and baseline BoP, GI and PI (Table 1). Table 2 shows the percentage value and relative confidence interval of BoP, GI and PI, respectively at baseline (BL), T1 and T2. At T1, both study groups reached the primary outcome showing a PI below 25%. PI for the sonic brushing group was well below the 25% desired target (6.21%) and significantly lower than PI for the MB group ($p < 0.001$). The difference in reduction from BL and T1 (ratio T1/BL) is also in favour of the sonic group ($p < 0.001$). BoP and GI at T1 show a significant reduction compared with BL. For both parameters, the reduction is significantly higher for the SB group, with a BoP which is almost a quarter of the one for the MB group, and less than half the GI of the MB group ($p < 0.001$).

At T2, PI increased in both groups, reaching an average of 11.34% in SB and 28.00% in MB, the latter being significantly higher and falling outside the primary outcome range. BoP kept decreasing between T1 and T2 for both groups, reaching comparable values, with no significant difference between the groups. Similar trend was observed for GI.

4 | DISCUSSION

The results of the present study (Table 2) show that both sonic and manual brushing were effective in reaching the primary outcome at T1: the PI is kept below 25% for both SB and MB, and BoP and GI show low values both at 6 weeks and 6 months after the initial PMPR session.

Comparing the two treatment groups, we can observe that the sonic brushing was significantly more effective than manual, both at a statistical and clinical level for PI, BoP and GI. In particular, for the manual brushing group, PI at 6 weeks was very close to the cut-off value (22.8), also showing a relatively wide intra-group variability (confidence interval = 18.82–27.65). At T2, we observed an increase in the PI for both groups, especially in the MB group. This could be seen as a normal trend moving further away from the initial PMPR session, especially because the visit at T1 was very close to the three additional sessions of OHI at baseline (BL), T0a and T0b while, during the months between T1 and T2, the patients did not receive any reinforcement and had to rely on their own compliance alone. Nevertheless, the SB group still shows a significantly lower PI, and the MB group has gone above the threshold of 25%, with some patients even reaching values above 30%.

The initial discrepancy between BoP and GI levels BoP showed a reduction in both groups, which was significantly higher for SB at T1 but became comparable at T2. GI decreased in both groups following a similar trend. Analysing BoP, GI and PI as an overall, it is clear that, despite the difference in plaque levels, gingival health was successfully achieved and maintained in both groups. According to a Cochrane Review,[19] the clinical relevance of PI and gingivitis indices as proxies for long-term stability of periodontal health is still unclear, and to estimate a threshold for clinically important PI and gingivitis level is difficult. Nevertheless, one must keep in mind that the participants of the present study did not present any evident risk for caries and periodontal disease. While residual PI might not constitute a considerable risk for this healthy population, patients with a high periodontal or caries risk should aim at the best plaque control possible and could benefit from a better plaque control. Moreover, there is still a scarcity of data on the benefits of power brushing over more than three months.[19] One might argue that BoP would have been a better primary endpoint for the evaluation of resolution of gingivitis.

TABLE 1 Study population demographics and baseline characteristics

	Sonic (N = 16)	Manual (N = 15)	p-Value
Males (%)	9 (56.3%)	4 (26.7%)	0.15[a]
Smokers (N)	8 (50.0%)	9 (60.0%)	0.72[a]
Number of teeth			
Mean (SD)	28.5 (1.12)	28.9 (1.44)	0.84[b]
Median (MAD)	28 (0)	28 (0.74)	

Abbreviation: MAD, median absolute deviation.
[a]Fisher exact test.
[b]Poisson regression.

TABLE 2 Percentage and [confidence interval] for Plaque Index (PI), bleeding on probing (BoP) and Gingival Index (GI) at baseline (BL), 6 weeks (T1) and 6 months (T2) after treatment, ratio between study groups and reduction expressed as ratio between baseline (BL) and T1 and T2. Data were modelled using a GLMM with negative binomial distribution

	BoP (%)				GI (%)	
Time	Sonic	Manual	Ratio	p-Value	Sonic	Manual
BL	27.93 [25.31–30.81]	28.58 [25.68–31.79]	0.98 [0.85–1.13]	0.753	14.01 [11.47–17.12]	11.89 [9.42–14.99]
T1	3.98 [3.20–4.95]	11.34 [9.75–13.18]	0.35 [0.27–0.46]	**<0.001***	3.24 [2.31–4.54]	7.25 [5.50–9.54]
Ratio T1 / BL	0.143 [0.107–0.189]	0.397 [0.324–0.486]	0.36 [0.27–0.47]	**<0.001***	0.231 [0.149–0.359]	0.610 [0.415–0.897]
T2	0.14 [0.04–0.42]	0.05 [0.01–0.34]	2.90 [0.30–28.13]	0.356	1.72 [1.08–2.72]	3.52 [2.38–5.20]
Ratio T2 / BL	0.005 [0.001–0.020]	0.002 [0.000–0.020]	2.97 [0.31–28.83]	0.346	0.123 [0.068–0.221]	0.296 [0.175–0.501]

Bold indicates statistically significant values.

While the authors agree with this statement, the reader must keep in mind that the main aim of the present study was to evaluate the ability of the different devices/technique to remove plaque, not the ability to solve gingivitis.

Many publications are available in the literature comparing manual brushing and different kinds of mechanic toothbrushes, but the big heterogeneity of protocols makes a comparison with the present paper difficult.[19] Most of the studies involve the recruitment of patients with mild-to-moderate gingivitis and the use of a disclosing agent to evaluate the amount of plaque, scored at baseline through different plaque indices.[26] In the study from Nightingale et al.[17] comparing the efficacy in plaque removal of a sonic brush with a manual one, patient selection was carried on based on the presence of visible plaque at screening, in particular the presence of a continuous line of plaque of 1mm of thickness at the gingival margin on at least 30% of the buccal surfaces, measured through the use of the Quigley-Hein Plaque Index (score 2). Another study conducted by Nathoo et al.[7] involved the comparison of two different heads of a sonic toothbrush and a manual one, and the patients were selected through the use of the Rustogi Modified Navy Plaque Index,[27] requiring a score of at least 0.6. The plaque on the buccal areas was highlighted with a disclosing agent and registered dicotomically (presence YES/NO) at 9 points on each tooth. In the study conducted by Biesbrock et al.,[28] comparing a sonic toothbrush with a rotating-oscillating one, the same Rustogi Modified Navy Plaque Index was used at screening time (score ≤ 0.6), and the patients were asked to refrain from brushing for 24 h before the visit and from eating and smoking for the 4 h prior. A different design was conceived by Pelka et al.[9] in an attempt to standardize as much as possible the patient population and the brushing technique. They decided to provide the subjects with a PMPR session before the beginning of the study in order to have the lowest amount of plaque possible for all the patients, then asked them to refrain from any oral hygiene manoeuvre for 48 h. At the following visit, the plaque index was calculated following the Turesky-modified Quigley Hein Index score by a blinded investigator before and after a session of brushing provided professionally by the other investigator.

The heterogeneity of the indices and the study protocol could constitute part of the reason for the lack of consistent results from different groups.[19,26] However, a recent Cochrane review[19] could not explain the heterogeneity in the meta-analysis for the primary analysis of powered toothbrushes versus manual brushes.[19]

In the present study, a simpler approach was selected to measure the level of plaque. The presence/absence of plaque was registered with the aid of a plaque disclosing agent according to a modified 6-point O'Leary index.[24] In the author's opinion, Turesky and Quigley Hein indices focus only on the gingival third of the tooth surface and do not allow to distinguish the interproximal areas, while distinguishing 9 areas per facial and lingual surface as per the Rustogi Modified Navy Plaque Index adds an unnecessary level of complexity to the analysis.

While all the study protocols mentioned above are suitable for plaque reduction analysis, they do not take into consideration the fact that oral hygiene instructions and aids are administered in conjunction with PMPR. The authors of the present study think that the power of home-care devices should be evaluated in terms of maintenance of a low amount of plaque after professional plaque removal, rather than reduction of plaque already present, as in some of the aforementioned studies.[7,17,28] Therefore, the design included initial clinical parameters collection, and an initial session of PMPR, carried on following the principles of the GBT protocol. GBT involved the use of an air-polishing device with low-abrasiveness erythritol powder, an ultrasonic device where needed and plaque disclosing agent to guide the removal of the plaque. At subsequent follow-up appointments, clinical parameters were collected and compared to the ones at baseline, as a dental professional would do their clinical routine. When interpreting the data, the PI at baseline (BL) in the selected population might seem very high. This is explained by the fact the participants were asked to refrain from brushing for 12 h before the assessment and treatment at BL. Once completed the PMPR session, the power of the brushing device was then evaluated in terms of ability to keep the PI as low as possible. Finally, the participants of the present study were carefully selected trying to avoid confounding factors that could benefit the results of the test group: all the patients were young (18–40 years of age), highly motivated, without any orthodontic appliance/retainer, prosthetic rehabilitation, crowding or malpositioned teeth.

Regardless of the differences in methodology, the results seem in agreement with previous studies favouring the sonic brushes in terms of plaque removal. Nathoo et al.[7] observed in the patients

Ratio	p-Value	PI (%) Sonic	Manual	Ratio	p-Value
1.18 [0.87–1.59]	0.282	85.84 [75.13–98.09]	73.02 [62.86–84.81]	1.18 [0.96–1.44]	0.112
0.45 [0.29–0.69]	<0.001*	6.21 [4.71–8.19]	22.81 [18.82–27.65]	0.27 [0.19–0.38]	<0.001*
0.38 [0.24–0.61]	<0.001*	0.072 [0.052–0.101]	0.312 [0.253–0.386]	0.23 [0.17–0.32]	<0.001*
0.49 [0.27–0.89]	0.020	11.34 [9.07–14.19]	28.00 [23.34–33.59]	0.41 [0.30–0.54]	<0.001*
0.41 [0.22–0.78]	0.00642	0.132 [0.102–0.171]	0.383 [0.315–0.466]	0.34 [0.27–0.45]	<0.001*

using sonic brush a higher reduction of supra-gingival plaque in the whole mouth, at the gingival margin and interproximally, along with a reduction of gingivitis and gingival bleeding. Pelka et al.[9] found that sonic brushes could clean more tooth surfaces than manual brushes in the same time. Nightingale et al.[17] found their tested sonic brush more efficiently than manual brushing in terms of plaque removal. More cautious conclusions can be found in the Cochrane review from Yacoob et al.,[19] which states that the evidence of superiority of power brushing in reducing plaque in the short term is of moderate quality and high heterogeneity. Moreover, most of the positive evidence included in this review is related to oscillating-rotating brushes, rather than sonic brushes.

A limitation of the present study is the decision to compare a powered brush with manual brushing on a strictly selected population. Oscillating-rotating toothbrushes represent a different and popular type of powered toothbrushes and are proven to be an effective option for home plaque control.[29] While a comparison between the two technologies would be of interest, the authors decided to maintain manual brushing in the control group due to the type of patients selected for this study. The subjects were mostly young and with good dexterity, lacking factors that might complicate the brushing procedure. Therefore, manual brushing was facilitated and, in fact, both groups obtained an overall satisfactory control of the plaque level. On the one hand, the selected sample might not be representative of the population attending a general dental practice, but on the other hand, it allowed the focus to be on the technique, rather than on possible patient-related confounding factors. Another limitation is the fact that the definition of gingivitis used in the present study (BoP > 25%) does not match the current Periodontal Classification,[21] due to the fact that the study design was completed before its release. As the cut-off for generalized gingivitis in the current classification is 30%, some of the patients might have mistakenly fallen into the 'healthy' category. Moreover, this might make a comparison with future trials difficult.

5 | CONCLUSIONS

The results of the present study show that the use of a sonic toothbrush after professional mechanical plaque removal allows to maintain a significantly lower plaque level when compared to a manual brush in patients with gingivitis. Bleeding on probing and gingival index seem to reach comparable values between the two brushing methods.

6 | CLINICAL RELEVANCE

6.1 | Scientific rationale for study

To assess the efficacy and patients' perception of a sonic toothbrush, compared to manual brushing.

6.2 | Principal findings

Sonic brushing leads to improved GI and allows better control of the plaque than manual brushing. The patients' acceptance and comfort result high.

6.3 | Practical implications

A sonic toothbrush should be considered when selecting the appropriate home-care tools for the patients.

CONFLICTS OF INTEREST
Dr. Mensi reports personal fees from EMS, personal fees from KULZER, personal fees from SUNSTAR, outside the submitted work. Dr. Scotti reports personal fees from EMS, personal fees from KULZER, outside the submitted work. Dr. Sordillo reports personal fees from EMS, outside the submitted work. Dr. Brognoli reports personal fees from EMS, outside the submitted work. Dr. Dominici has nothing to disclose. Dr. Calza has nothing to disclose.

AUTHOR CONTRIBUTIONS
MM designed the study. SE was the principal investigator. VB and MPD were the other investigators. CS performed the statistical analysis. SA wrote the paper.

DATA AVAILABILITY STATEMENT
Data available on request from the authors.

REFERENCES
1. Donlan RM, Costerton JW. Biofilms: survival mechanisms of clinically relevant microorganisms. *Clin Microbiol Rev*. 2002;15(2):167-193.
2. Needleman I, Nibali L, Di Iorio A. Professional mechanical plaque removal for prevention of periodontal diseases in adults – systematic review update. *J Clin Periodontol*. 2015;42(Suppl. 16):S12-S35. https://doi.org/10.1111/jcpe.12341
3. Tonetti MS, Eickholz P, Loos BG, et al. Principles in prevention of periodontal diseases –Consensus report of group 1 of the 11th European workshop on periodontology on effective prevention of periodontal and peri-implant diseases. *J Clin Periodontol*. 2015;42(Suppl. 16):S5-S11. https://doi.org/10.1111/jcpe.12368
4. Slot DE, Wiggelinkhuizen L, Rosema NAM, et al. The efficacy of manual toothbrushes following a brushing exercise: a systematic review. *Int J Dent Hygiene*. 2012;10:187-197. https://doi.org/10.1111/j.1601-5037.2012.00557.x
5. Davies RM, Davies GM, Prevention ERP. Part 4: toothbrushing: what advice should be given to patients? *Br Dent J*. 2003;195:135-141.
6. Lang NP, Cumming BR, Löe H. Toothbrushing frequency as it relates to plaque development and gingival health. *J Periodontol*. 1973;44(7):396-405.
7. Nathoo S, Mateo LR, Chaknis P, et al. Efficacy of two different toothbrush heads on a sonic power toothbrush compared to a manual toothbrush on established gingivitis and plaque. *J Clin Dent*. 2014;25(4):65-70.

8. Kumar S, Tadakamadla J, Johnson NW. Effect of toothbrushing frequency on incidence and increment of dental caries: a systematic review and meta-analysis. *J Dent Res*. 2016;95(11):1230-1236. https://doi.org/10.1177/0022034516655315

9. Pelka AK, Nagler T, Hopp I, et al. Professional brushing study comparing the effectiveness of sonic brush heads with manual toothbrushes: a single blinded, randomized clinical trial. *Clin Oral Investig*. 2011;15(4):451-460. https://doi.org/10.1007/s00784-010-0411-0

10. Creeth JE, Kelly SA, González-Cabezas C, et al. Effect of toothbrushing duration and dentifrice quantity on enamel remineralisation: An in situ randomized clinical trial. *J Dent*. 2016;55:61-67. https://doi.org/10.1016/j.jdent.2016.10.003

11. Shin NR, Choi JS. Manual dexterity and dental biofilm accumulation in independent older adults without hand disabilities: a cross-sectional study. *Photodiagnosis Photodyn Ther*. 2019;25:74-83. https://doi.org/10.1016/j.pdpdt.2018.11.007

12. Davison J, Mclaughlin M, Giles M. Factors influencing children's tooth brushing intention: an application of the theory of planned behaviour. *Health Psychology Bulletin*. 2019;3:58-66. https://doi.org/10.5334/hpb.8

13. Ganss C, Schlueter N, Preiss S, et al. Tooth brushing habits in uninstructed adults—frequency, technique, duration and force. *Clin Oral Investig*. 2009;13(2):203-208. https://doi.org/10.1007/s00784-008-0230-8

14. Löe H. Oral hygiene in the prevention of caries and periodontal disease. *Int Dent J*. 2000;50(3):129-139.

15. Cumming BR, Löe H. Consistency of plaque distribution in individuals without special home care instruction. *J Periodontal Res*. 1973;8:94-100.

16. Graziani F, Palazzolo A, Gennai S. Interdental plaque reduction after use of different devices in young subjects with intact papilla: a randomized clinical trial. *Int J Dent Hyg*. 2018;16(3):389-396. https://doi.org/10.1111/idh.12318

17. Nightingale KJ, Chinta SK, Agarwal P, et al. Toothbrush efficacy for plaque removal. *Int J Dent Hyg*. 2014;12(4):251-256. https://doi.org/10.1111/idh.12081

18. McCracken GI, Heasman L, Stacey F, et al. The impact of powered and manual toothbrushing on incipient gingival recession. *J Clin Periodontol*. 2009;36(11):950-957.

19. Yaacob M, Worthington HV, Deacon SA, et al. Powered versus manual toothbrushing for oral health (Review). *Cochrane Database Syst Rev*. 2014;6:CD002281. https://doi.org/10.1002/14651858.CD002281.pub3

20. Tonetti MS, Greenwell H, Kornman KS. Staging and grading of periodontitis: framework and proposal of a new classification and case definition. *J Periodontol*. 2018;89(Suppl 1):S159-S172. https://doi.org/10.1002/JPER.18-0006

21. Trombelli L, Farina R, Silva CO, Tatakis DN. Plaque-induced gingivitis: case definition and diagnostic considerations. *J Periodontol*. 2018;89(Suppl 1):S46-S73. https://doi.org/10.1002/JPER.17-0576

22. Jones CL, Saxton CA, Ritchie JA. Microbiogical and clinical effects of a dentifrice containing zinc citrate and Triclosan in the human experimental gingivitis model. *J Clin Periodontol*. 1990;17:570-574.

23. Putt MS, Van der Weijden GA, Kleber CJ, Saxton CA. Evaluation of a 21- day, partial mouth gingivitis model using a chlorhexidine dentifrice. *J Periodontal Res*. 1993;28:301-307.

24. O'Leary TJ, Drake RB, Naylor JE. The plaque control record. *J Periodontol*. 1972;43(1):38. https://doi.org/10.1902/jop.1972.43.1.38

25. Loe H, Silness J. Periodontal disease in pregnancy. I. Prevalence and severity. *Acta Odontol Scand*. 1963;21:533-551.

26. Grender J, Williams K, Walters P, et al. Plaque removal efficacy of oscillating-rotating power toothbrushes: review of six comparative clinical trials. *Am J Dent*. 2013;26(2):68-74.

27. Rustogi KN, Curtis JP, Volpe AR, et al. Refinement of the Modified Navy Plaque Index to increase plaque scoring efficiency in gumline and interproximal tooth areas. *J Clin Dent*. 1992;3(Suppl C):C9-C12.

28. Biesbrock AR, Bartizek RD, Walters PA, et al. Clinical evaluations of plaque removal efficacy: an advanced rotating-oscillating power toothbrush versus a sonic toothbrush. *J Clin Dent*. 2007;18(4):106-111.

29. Grender J, Williams K, Walters P, Klukowska M, Reick H. Plaque removal efficacy of oscillating-rotating power toothbrushes: review of six comparative clinical trials. *Am J Dent*. 2013;26(2):68-74.

APPENDIX 1

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4-5
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	6-7
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7-9
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	10
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	10
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7-10
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	7
	11b	If relevant, description of the similarity of interventions	n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	9-10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	10
	13b	For each group, losses and exclusions after randomisation, together with reasons	10
Recruitment	14a	Dates defining the periods of recruitment and follow-up	/
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Tab 1

Section/Topic	Item No	Checklist item	Reported on page No
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	10-11
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	11
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n/a
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	n/a
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	11
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	15
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	14-15
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	14
Other information			
Registration	23	Registration number and name of trial registry	/
Protocol	24	Where the full trial protocol can be accessed, if available	/
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	2

  *We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.