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Efficacy of sonic vs manual toothbrushing after professional mechanical plaque removal: a 6-months randomized clinical trial.

Short running title: Clinical results and patients' feedback

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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

Disclosure of Potential 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.

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 assigned to sonic (SB) or manual brushing (MB). Oral hygiene instructions were provided at baseline, 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 baseline, T1 and T2. A satisfaction questionnaire was administered. Proportion of sites with PI, GI and BoP was modelled at site level using a Poisson regression fitted via GLMM model accounting for intra-patient correlation.

Results

32 subjects were selected. At T1, average PI was 4.93% ($CI_{95\%}$ 3.57%; 6.81%) for SB and 24.16% ($CI_{95\%}$ 17.56%; 33.25%) for MB ($ratio_{SB/MB}$ 0.20, $CI_{95\%}$ 0.13; 0.32, $p < 0.001$), while at T2 was 9.36% ($CI_{95\%}$ 6.87%; 12.73%) and 29.15% ($CI_{95\%}$ 21.22%; 40.04%) respectively ($ratio_{SB/MB}$ 0.32, $CI_{95\%}$ 0.20; 0.50, $p < 0.001$). GI was lower in the SB group both at T1 ($ratio_{SB/MB}$ 0.34, $CI_{95\%}$ 0.19; 0.61, $p < 0.001$) and T2 ($ratio_{SB/MB}$ 0.35, $CI_{95\%}$ 0.19; 0.66, $p = 0.001$). BoP reduction for SB was about 3 times higher than MB at T1 ($ratio_{SB/MB}$ 0.35, $CI_{95\%}$ 0.19; 0.66, $p < 0.001$) and then levelled at T2. The overall comfort was satisfactory for both techniques.

Conclusion

Sonic brushing allows the maintenance of a significantly lower PI score compared to a manual brush.

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 mechanical 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. Good self-performed plaque control is often tedious, time-consuming and challenging. 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]

Mechanical brushes have been introduced to overcome some of the limitations of manual toothbrushing. From the first mechanical brushes simulating the back-and-forth or the left-and-right manual movements, the technology has improved and led to modern electric toothbrushes applying sonic and ultrasonic vibrations and rotating, oscillating and pulsating heads. In addition, to encourage and improve patients' compliance, timers have been combined with the brushes, pulsating every 30 seconds to guide the progression through the quadrants and achieve the ideal total brushing time of 2 minutes.[10] When patient compliance is low or when there is a lack of

dexterity, mechanical toothbrushing can help to compensate for a less-than-ideal technique and guarantee an appropriate level of oral hygiene.[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 electric toothbrushes seem to lead to a higher interdental plaque reduction compared with manual ones.[7]

Sonic (side-to-side) toothbrushes utilise 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-minute "Deep clean mode" claimed to target resistant deposits and stains.

The present study aims to evaluate the efficacy of a new sonic toothbrush 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), and evaluation of patient comfort and acceptance of the two brushing methods.

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 Specialities, 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). All participants signed a written informed consent before the beginning of the study.

Patients selection

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

- Bleeding on probing (BoP) > 25%;
- Plaque index (PI) > 25%;
- 18 to 40 years of age;
- Presence of at least 5 teeth per quadrant.

The exclusion criteria for the study population were:

- 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]
- Any systemic disease;
- Subjects smoking more than 10 cigarettes per day;
- Presence of orthodontic appliances/retainers or complex prosthetic rehabilitations;
- Presence of crowding or malpositioned teeth;
- Unwillingness to follow the recall and maintenance program.

Outcomes

The primary endpoint of the study was Plaque Index <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 reduction in BoP and Gingival Index

(GI) at T1 and T2, and evaluation of patient comfort through a written questionnaire administered at 2 weeks (T0a), 4 weeks (T0b), 6 weeks (T1) and 6 months (T2).

Clinical assessment and interventions

Clinical examination and collection of periodontal parameters were performed by a trained dentist (E.S) blinded to the intervention, while the treatments and recalls were performed by two trained hygienists (V.B and M.P.D.). Age, gender and smoking status were collected at baseline, along with a complete periodontal charting including 6-points Pocket Probing Depth (PPD), recession (REC), CAL, BoP, PI, GI and mobility. The PI was calculated according to a modified O'Leary index[21] measured on 6 surfaces per tooth (disto-buccal, buccal, mesio-buccal, disto-lingual, lingual and mesio-ligual). The GI was measured at all teeth according to Loe & Silness index.[22] 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).

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:

- Application of a plaque disclosing agent as guidance for plaque removal (Mira-2-Ton® Hager Werken)
- 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)
- Use of an ultrasonic scaler (PS tip, Airflow Prophylaxis Master, EMS, Nyon, Switzerland) where visible or detectable calculus was present
- 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 subjects 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 recommended 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 minutes. The patients were instructed to brush twice a day and details were given about how to:

- Mount the brushing head on the handle
- Set the "Deep clean" mode and medium power level
- 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);
- Move the head of the brush on every dental surface;
- Utilise the 3 minutes of the "Deep clean" mode to cover the 4 quadrants adequately, brushing each of them for 45 seconds.

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:

- 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;

- Position the head perpendicularly to the occlusal surfaces;
- Time the brushing process to 3 minutes per session with a timer.

All the study subjects 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). They received instructions about the amount of toothpaste to be used (pea-sized) and how to use the interdental floss. OHI were 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).

A questionnaire was supplied to the subjects at 2 weeks (T0a), 4 weeks (T0b), 6 weeks (T1) and 6 months (T2). The questionnaire investigated:

- Discomfort on brushing, measured on a Visual Analogue Scale (1-10) (VAS)
- Dental sensitivity after brushing (YES/NO)
- Noise disturbance (for the SB group only, YES/NO)
- Technique difficulty, measured on a VAS scale (1-10)
- Use of the interdental floss, areas covered (anterior only or full-mouth)
- Use of the interdental floss, frequency (times/week)

At 6 months (T2), the patients also received the first PMPR recall session.

Statistical analysis

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, 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%.

Randomisation

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. All data analyses were carried out according to a pre-established analysis plan by a biostatistician blinded to group allocation.

Statistical Analysis

Continuous variables were described with mean and standard deviation, median and median absolute deviation (MAD). Outcome variables (BoP, Plaque, GI) were expressed as the number of sites within patient with the condition (e.g. bleed on probing) over the total number of probed sites (i.e. PI). Analysis were performed considering patient as statistical unit. The variation of the proportion of sites for every outcome between visits was modelled using Generalized Linear Mixed Model (GLMM) with Poisson family, therefore accounting for intra-patient measurement correlation. The dependent variable in all models was the number of sites with the specific outcome (e.g. 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. Potential difference in outcomes baseline values between treatments was adjusted for adding baseline value as a covariate in the model. All analysis assumed a significance level of 5% and were performed using R [R version 3.6.1, R Core Team (2020), Foundation for Statistical Computing, Vienna, Austria].

RESULTS

41 patients were assessed for eligibility. 6 patients were excluded for not meeting the eligibility criteria (presence of orthodontic retainers (n=2), and crowing (n=4)), and 3 patients refused to participate on the basis that they were already using an electric toothbrush and were not willing to change if assigned to the manual brushing group. A total of 32 subjects were selected according to the inclusion criteria, 16 per study group (Sonic vs Manual). 1 patient belonging to the Manual group dropped out at T0a because of onset of oral candidiasis. Statistical analysis was performed on the total 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 regards to gender, smoking status and baseline BoP, GI and PI (Tab.1). Table 2 shows the estimated proportion and relative confidence interval of sites with B0P, GI and PI, respectively at T1 and T2. At T1 both study groups reached the primary outcome showing a PI below 25%. In particular, the PI for the sonic brushing group was 4.93% [3.57;6.81], significantly lower than the PI value of 24.16% [17.56;33.25] for the manual brushing group (p<0.0001). BoP and GI at T1 also show a reduction compared with baseline (Tab.2) and, again, a significantly higher reduction for the SB group, with a BoP of 3.67% [2.81;4.80] vs 10.39% [8.20;13.16] of the MB group (p<0.0001), and a GI of 2.2% [1.45;3.38] vs 6.60% [4.37;9.97] of the MB group (p<0.0001).

Between T1 and T2, PI in the SB group increased but at T2 was still well below the 25% threshold (9.36% [6.87;12.73]) while in the MB group reached a value of 29.15% [21.22;40.04], falling outside the primary outcome range. BoP kept decreasing between T1 and T2 for both groups, reaching comparable values (0.15% [0.06;0.38] for SB and 0.04% [0.01;0.26] for MB), with no significant difference between the groups. GI kept decreasing too, maintaining a lower value for SB (1.55% [0.99;2.41] vs 4.37% [2.86;6.69%], (p=0.001).

Table 3 shows the data collected from the questionnaire administered at T0a, T0b, T1 and T2. In the sonic brushing group, we can notice a reduction of subjects reporting a discomfort at brushing score ≥3 between T0a and T2, with only one patient still experiencing discomfort after 6 months of use. The manual brushing group showed an increase in patients experiencing discomfort ≥3 at use from 3 at T0a to 6 at T2. The number of subjects experiencing dental sensitivity after use seemed

to decrease with time in the SB group (from 3 at T0a to 1 at T2) while it was constant for the MB group. Only one patient reported a disturbance given by the sonic toothbrush noise. The number of patients reporting difficulty in the application of the brushing technique seemed to be lower for the SB group during the observation perio. No inter- or intra-group statistical analysis was performed on the questionnaire results; hence the significance of the observed differences cannot be stated. No side or unintended effects were reported. Tab. 4 shows the data from the questionnaires regarding the patients' flossing habits. The number of patients flossing at least once a day seemed to decrease with time in both groups and most of the subjects floss the entire mouth.

DISCUSSION

The present study aimed to evaluate the efficacy of a sonic toothbrush (Philips Sonicare Flexcare Platinum®) compared with a manual brush (GUM® Technique PRO®, Sunstar gums) in terms of maintenance of a low Plaque Index, Bleeding on Probing and Gingival Index after a single session of PMPR and repeated OHI sessions.

Many publications are available in the literature comparing manual brushing and different kind of mechanic toothbrushes, but the big heterogeneity of protocols makes a comparison 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.[23] In the study from Nightingale et al. (2014)[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. (2014)[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,[24] 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. (2007)[25], 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 hours before the visit and from easting and smoking for the 4 hours prior. A different design was conceived by Pelka et al. (2011)[9] in an attempt to standardise 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 hours. 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 patients' selection and the study protocol probably constitutes part of the reason for the lack of consistent results from different groups.[19,22] Furthermore, whilst all the aforementioned protocols 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.[7,17,25] Therefore, the design included 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. The reason why the GBT protocol was chosen lies in the recent body of evidence showing how air-polishing is able to remove plaque and reduce the gingival inflammation more efficiently than traditional instrumentation.[26-29] The power of the brushing device was then evaluated in terms of ability to keep the PI as low as possible, and below the threshold of 25%. Moreover, the study subjects 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. The diagnosis of gingivitis was made when the BoP was >25%. This differs from the definition of generalised gingivitis included in the current Periodontal Classification[30] (BoP score > 30%) because the study protocol was completed and approved before its release.

The results displayed in Tab.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. 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 (24.16%), also showing a relatively wide intra-group variability (confidence interval =17.56;33.25). 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, 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 (9.36% vs 29.54%), and the MB group has gone above the threshold of 25%, with some patients even reaching values above 40%. BoP showed a reduction in both groups, which was significantly higher for SB at T1 but became comparable at T2. GI decreased in both group following a similar trend.

While the higher percentage of PI might not constitute a considerable risk for the healthy population chosen for this study, patients with a high periodontal or caries risk should aim at the best plaque control possible. Based on the results of this study, the choice of a sonic toothbrush could be an advantage in the maintenance of a proper home oral hygiene.

The questionnaire administered during follow-up appointments shows that the discomfort and the noise disturbance associated with the use of a sonic toothbrush are negligible after 6 months of use. Interestingly, some patients reported hypersensitivity after the use of the manual toothbrush. This could be due to some characteristics of the selected brush, such as the big head and the long bristles, designed to reach the interproximal spaces. The data from the questionnaire also show that the initial learning curve of the suggested technique is comparable, with patients reporting a similar level of difficulty of use. At T2 the sonic brush seems to become easier to use, probably because of the fact that the device is more forgiving in terms of dexterity and attention during use.

In both groups the compliance to flossing results average, with a few subjects flossing at least once a day and with a tendency of reduction of the flossing frequency with time. Regardless, the

patients in the SB group showed a significantly lower PI, leading us to the hypotheses that the sonic toothbrush can help in the reduction of interdental plaque as well. A study distinguishing interproximal and buccal/lingual plaque during data analysis could help to clarify the matter. Given the simple descriptive nature of questionnaire results, no conclusion can be drawn in regards to the observed differences within and between groups.

A limitation of the present study is the decision to compare a mechanical technique with manual brushing on a strictly selected population. Oscillating-rotating toothbrushes represent a different and popular type of power toothbrushes, and are proven to be an effective option for home plaque control. [31] Whilst 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 it allowed the focus to be on the technique, rather than on possible patient-related confounding factors.

CONCLUSIONS

The results of the present study show that the use of a sonic toothbrush after professional mechanical plaque removal can allow the maintenance of a significantly lower plaque level when compared to a manual brush.

Clinical relevance

Scientific rationale for study: To assess the efficacy and patients' perception of a sonic toothbrush, compared to manual brushing.

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.

Practical implications: A sonic toothbrush should be considered when selecting the appropriate

home-care tools for the patients.

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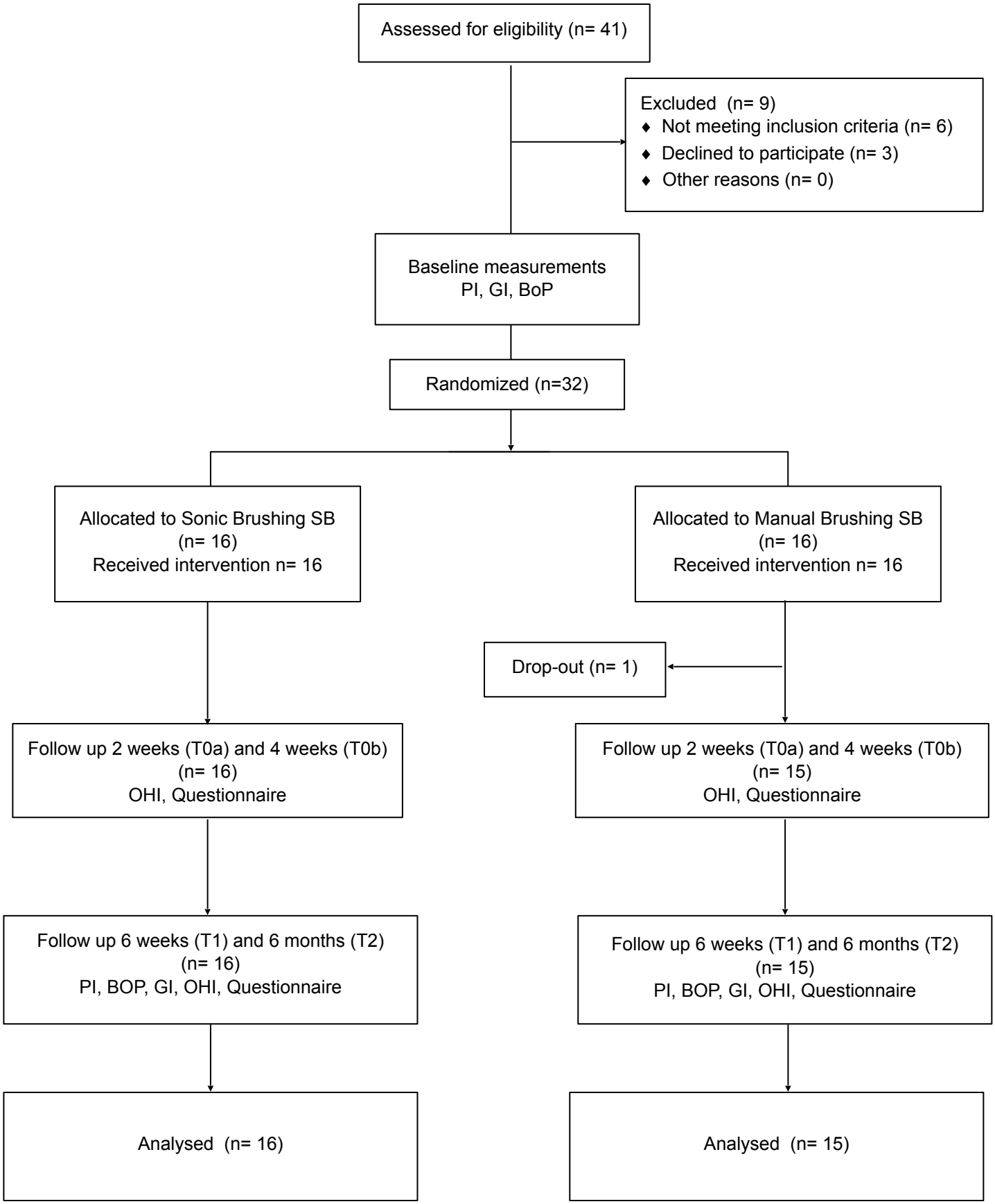
Assessed for eligibility (n= 41)
Excluded (n= 9)
♦ Not meeting inclusion criteria (n= 6)
♦ Declined to participate (n= 3)
♦ Other reasons (n= 0)
Baseline measurements
PI, GI, BoP
Randomized (n=32)
Allocated to Sonic Brushing SB
(n= 16)
Received intervention n= 16
Allocated to Manual Brushing SB
(n= 16)
Received intervention n= 16
Drop-out (n= 1)
Follow up 2 weeks (T0a) and 4 weeks (T0b)
(n= 16)
OHI, Questionnaire
Follow up 2 weeks (T0a) and 4 weeks (T0b)
(n= 15)
OHI, Questionnaire
Follow up 6 weeks (T1) and 6 months (T2)
(n= 16)
PI, BOP, GI, OHI, Questionnaire
Follow up 6 weeks (T1) and 6 months (T2)
(n= 15)
PI, BOP, GI, OHI, Questionnaire
Analysed (n= 16)
Analysed (n= 15)

Tab.1 - Study population demographics and baseline characteristics

	SONIC	MANUAL
Males (%)	25	16
Smokers (%)	12	12
BoP (%)		
Mean (SD)	28.0 (3.9)	28.8 (5.0)
Median (MAD)	26.8 (1.2)	26.9 (0.9)
GI (%)		
Mean (SD)	13.7 (4.5)	11.5 (3.0)
Median (MAD)	12.5 (1.9)	11.7 (2.0)
PI (%)		
Mean (SD)	87.1 (16.2)	74.6 (19.7)
Median (MAD)	100.0 (0.0)	77.9 (12.1)

PI - Plaque Index, BoP - Bleeding on Probing (BoP), GI - Gingival Index, SD - Standard Deviation, MAD - median absolute deviation

Tab.2 - Plaque Index (PI), Bleeding on Probing (BoP) and Gingival Index (GI) at 6 weeks (T1) and 6 months (T2) after treatment, and ratio between the two groups. The reduction in time per each group is expressed as ratio between (T1-T2)/T1.

	PI [CI]				**GI [CI]**				**BoP [CI]**			
	Sonic (%) n = 16	**Manual (%) n = 15**	***Ratio Sonic/Manual***	***p*-value**	**Sonic (%) n = 16**	**Manual (%) n = 15**	***Ratio Sonic/Manual***	***p*-value**	**Sonic (%) n = 16**	**Manual (%) n = 15**	***Ratio Sonic/Manual***	***p*-value**
T1	4.93 [3.57; 6.81]	24.16 [17.56; 33.25]	0.20 [0.13; 0.32]	**<0.001**	2.2 [1.45;3.38]	6.60 [4.37;9.97]	0.34 [0.19; 0.61]	**<0.001**	3.67 [2.81;4.80]	10.39 [8.20;13.16]	0.35 [0.25;0.50]	**<0.001**
T2	9.36 [6.87; 12.73]	29.15 [21.22; 40.04]	0.32 [0.20; 0.50]	**<0.001**	1.55 [0.99;2.41]	4.37 [2.86;6.69]	0.35 [0.19; 0.66]	**0.001**	0.15 [0.06;0.38]	0.04 [0.01;0.26]	4.16 [0.48; 35.75]	0.19
Percentual reduction (%)	-89.6 [-125.2; -59.7]	-20.6 [-34.7; -8]			30.2 [4; 49.3]	33.7 [16.7; 47.3]			95.8 [89.8;98.3]	99.6 [97.5; 99.9]		

CI – 95% Confidence Interval

Tab.3 - Questionnaire results at 2 weeks (T0a), 4 weeks (T0b), 6 weeks (T1) and 6 months (T2) about perceived pain, disturbance given by the noise

DISCOMFORT (0-10)		
	SONIC	MANUAL
T0a (2 weeks):		
1	13 (81.25)	12 (80)
≥3	3 (18.75)	3 (20)
T0b (4 weeks):		
1	15 (93.75)	8 (53.3)
≥3	1 (6.25)	7 (46.7)
T1 (6 weeks):		
1	16 (100)	9 (60)
≥3	0	6 (40)
T2 (6 months):		
1	15 (93.75)	9 (60)
≥3	1 (6.25)	6 (40)
NOISE DISTURBANCE (YES/NO)		
T0a - Yes	1 (6.25)	-
T0b - Yes	1 (6.25)	-
T1 - Yes	2 (15.4)	-
T2 - Yes	2 (15.4)	-

DIFFICULTY (1-10)		
	SONIC	MANUAL
T0a (2 weeks):		
1	12 (75)	10 (67)
≥3	4 (25)	5 (33)
T0b (4 weeks):		
1	15 (93.7)	7 (47)
≥3	1 (6.3)	8 (53)
T1 (6 weeks):		
1	15 (93.7)	9 (60)
≥3	1 (6.3)	6 (40)
T2 (6 months):		
1	14 (87.5)	9 (60)
≥3	2 (12.5)	6 (40)
HYPERSENSITIVITY (YES/NO)		
T0a - Yes	3 (17.6)	4 (28.6)
T0b - Yes	1 (5.9)	5 (35.7)
T1 - Yes	2 (12.5)	4 (28.6)
T2 - Yes	1 (5.9)	3 (14.3)

of the electric toothbrush, sensitivity during/after use and difficulty of use.

Tab.4 - Questionnaire results at 2 weeks (T0a), 6 weeks (T1) and 6 months (T2) about frequency of flossing habit (times per week) and area covered

DENTAL FLOSS: WHERE		
	SONIC	MANUAL
T0a (2 weeks):		
anterior area	2 (12.5)	2 (13.3)
entire mouth	14 (87.5)	13 (86.7)
T0b (4 weeks):		
anterior area	3 (18.75)	1 (6.7)
entire mouth	13 (81.25)	14 (93.3)
T1 (6 weeks):		
anterior area	3 (18.75)	2 (13.3)
entire mouth	13 (81.25)	13 (86.7)
T2 (6 months):		
anterior area	2 (12.5)	1 (6.7)
entire mouth	13 (81.25)	14 (93.3)
** 1 patient of the sonic group reports no flossing*		

DENTAL FLOSS: TIMES * WEEK		
	SONIC	MANUAL
T0a (2 weeks):		
1-3	4 (25)	5 (33.3)
4-5	4 (25)	4 (26.7)
≥6	8 (50)	6 (40)
T0b (4 weeks):		
1-3	2 (12.5)	6 (40)
4-5	8 (50)	3 (20)
≥6	6 (37.5)	6 (40)
T1 (6 weeks):		
1-3	4 (25)	5 (33.3)
4-5	8 (50)	6 (40)
≥6	4 (25)	4 (26.7)
T2 (6 months):		
1-3	7 (43.75)	8 (53.4)
4-5	4 (25)	3 (20)
≥6	4 (25)	4 (26.7)

while flossing.