Title

Efficacy of Philips Sonicare Flexcare Platinum Toothbrush® compared to manual brushing in healthy patients: a 12 mouth randomized clinical trial.

Author

Introduction

Professional oral hygiene has become a customary procedure in everyday dentistry. Both manual and sonic brushes are part of normal oral hygiene education practice. The aim is the removal of biofilm, plaque and calculus from the dental surface. Routine recalls ensure a better oral health and greater protection against caries, gingivitis and periodontitis. Regular attendance to oral hygiene sessions plays an important role but has to be accompanied by the compliance with home oral care instructions. The patients should be adequately instructed to take care of their oral health. Compared with manual toothbrushes, ergonomic instruments, such as sonic toothbrushes, can be a more practical and less demanding mean to remove biofilm and plaque efficiently. Studies in literature investigate the efficacy of toothbrushes in plaque removal, but our study would validate efficacy of toothbrushes post-causal therapy, towards lower plaque accumulation, and reduction in bleeding.

Aim

The objective of this study is to compare two methods (manual VS sonic) of tooth brushing in terms of impact on the gingival index and plaque index after one session of Full Mouth-Erythritol Powder Air Polishing Therapy (FM-EPAPT) in healthy patients.

Materials and Methods

Trial design:

Monocetric, pragmatic, single blinded, randomized clinical trial (RCT) of parallel design.
The trial will have one-year duration.

Participants:

Healthy subject affected by gingivitis are included in the study. The patients are treated at the Department of Surgical Specialties, Radiological Science and Public Health, School of Dentistry, Section of Periodontics, Brescia, Italy between the period 01/10/2017 -

01/10/2019. Presence of gingivitis is defined as bleeding on probing (BOP) > 25%.

Inclusion criteria are:

- Patients affected by gingivitis is defined as bleeding on probing (BOP) > 25%.
- Healthy young patients (18-40 years)
- Patients with almost 5 teeth per quadrant
- Patients smoking less than 10 cigarettes a day

Exclusion criteria are:

- Presence of periodontitis (pocket depth - PPD > 4 mm)
- Patient with BOP and/or plaque index < 25%
- Patient with any systemic disease
- Orthodontic or prosthesis patient
- Patient with split
- Impossibility to come to the recall appointments
- Not willing to follow the agreed protocol

A written informed consent will be obtained from each patient included after explanation of the risks and benefits of participating in this study. No change in the trial design will be made after approval of the Ethics Committee.

Intervention

Age, sex, smoking habits should be recorded. At Baseline examination taken by (RA) the following periodontal index will be recorded at 6 sites per tooth.

- **P.P.D**: measured from the gingival margin to the bottom of the pocket.
- **G.I**. recorded as presence or absence of bleeding after gently run on the surface of the

marginal gingiva.

- **PI**: recorded as presence or absence of plaque. A probe will gently run on the surface of the teeth.

- **REC:** measured from the cement-enamel junction to the gingival margin.

- **CAL:** measured clinically from the base of the pocket to the cement-enamel junction

A PCP-UNC 15 periodontal probe is used on six sites per tooth (mesio-buccal, buccal, disto-buccal, mesio-lingual, lingual and disto-lingual) with a gentle probing force by the same examiner. Measurements are rounded to the nearest millimetre.

Examiner calibration:

The examiner should be calibrated measuring PPD and PAL in one quadrant with at least 6 teeth on 10 patients. Measurements should be repeated after one hour and variability should be assessed

After baseline recording (RA), a professional oral hygiene (full mouth erythritol powder air polishing therapy – FM-EPAPT) will be done by VB.

After ultrasonic debridment the randomization envelope will be open by VB.

Group A: sonic toothbrush (Philips Sonicare Flexcare Platinum Toothbrush®) will be given

Group B: Manual brushing (Technique Pro - GUM® Sunstar Italiana SRL) will be given.

For each group specific instruction of oral hygiene will be done.

For all patient are recommended: toothbrush Hydral Gum (GUM® Sunstar Italiana SRL) and interdental floss (GUM® Sunstar Italiana SRL)

Each patient is recalled at 2 and 4 weeks to reinforce oral hygiene instructions (VB) and do collect GI and PI (RA).

Furthermore, all patients are recalled at 6 weeks 6 and 12 months for update of periodontal folder (RA); at 6 and 12 months professional hygiene will be done by VB.

At the end of the therapy reinforcement of oral hygiene instruction are given by VB.

Primary Outocome:

Change in P.I..: change in 10% of the site in test group.

Secondary Outcomes:

Change in G.I.: change in presence or absence of bleeding after gently run on the surface of the marginal gingiva.

Change in R.E.C.: change in gingival reduction.

Change in C.A.L.: change in clinical attachment level.

Sample size determination

We assumed that count of sites with plaque within 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 P.I. rate between the two treatments, corresponding to approximately 30% proportional reduction. For simplicity we considered only the effect at the latest time point. The 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 a Poisson regression (GLM with Poisson family). We performed the simulation 500 times and computed the proportion of time the coefficient for the two group comparison had a p-value lower than 5%. A sample size of 16 for each groups allowed a power of at least 90%.

Statistical Analysis Plan

Data will be aggregated within patient to compute the number of site with plaque over the total number of probed sites (i.e. P.I.). Counts will be modelled using a Poisson rate model (GLMM with Poisson family) and setting the total number of site per patient as offset. A significance level of 5% will be used and all the analysis will be performed using the software R.

Randomization

Patients will be randomized to either treatment using a computer generated sequence based on a blocked randomization procedure. The software used will be R.

Summary of the procedures:

Baseline:

- clinical measurements: PPD, PI, GI, REC, CAL.
- FM-EPAPT
- randomization
- education and motivation

2/4 weeks:

- education and motivation
- checking compliance
- GI and PI

6 weeks:

- education and motivation
- checking compliance
- clinical measurements: PPD, PI, GI, REC, CAL.

6/12 months:

- clinical measurements: PPD, PI, GI, REC, CAL.
- FM-EPAPT
- checking compliance
- education and motivation

Drop-outs:

All drop-outs should be reported and the reason for dropping out should be investigated and reported per study group.

Publication plan:

2, 6 and 12 months results