A comparative study of electric toothbrushes for the efficacy of single use plaque removal and the effect on plaque accumulation and gingivitis.

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It is well accepted that the greatest contributor to the health of the periodontium and dentition is regular and thorough dental plaque removal, typically by means of adequate toothbrushing. Although patients are typically informed about the risks of substandard oral hygiene and the contributing factors in oral/dental disease by dental professionals, research has shown that an undesirably high proportion of adults find thorough toothbrushing with a standard manual toothbrush to achieve a plaque-free state challenging, as evidenced by high worldwide levels of gingivitis and/or periodontitis.

The purpose of this study is to clinically evaluate the plaque removal efficacy of two electric powered toothbrushes after a single use, as well as the effect on plaque accumulation and gingivitis after 14 days and 30 days period.

**Materials and Methods**

**Study design:** randomised, single blinded, parallel.

After the screening procedure and based on inclusion requirements, all subjects will receive oral prophylaxis (T0) to ensure a baseline of 0 Plaque Index (PI) prior to the first appointment (T1). The subjects will be instructed not to use a tooth brush or any mechanical cleaning device until the initial PI and Gingival Indexes (GI) are taken at 24 hours after T0. The subjects will be randomized into 3 groups, and the will be provided one of the two evaluated toothbrushes, as well as toothpaste. All subjects will be using identical toothpaste and will receive oral hygiene instructions based on the manufacturer’s recommendations.

At T1 initial GI and PI will be taken prior to brushing followed by a second PI reading immediately after the first use of the power driven toothbrush. The subjects will be instructed to brush twice a day for a period of 2 minutes (following the programmed toothbrush timer) and refrain from using dental floss, tooth pick or any mechanical oral hygiene aid for the period of the study.
On the second visit at 14 days (T2) and third visit at 30 days (T3), additional GI and PI readings will be taken and data will be recorded. All measurements and clinical examinations will be performed by a single blinded examiner. Evaluation on teeth will be made on six teeth #3, 7, 12, 19, 23 and 28 (mesio-buccal, buccal, disto-buccal and mesio-lingual, lingual, disto-lingual) following the Silness-Loe Index.

Other effects on hard and soft tissue will also be recorded such as cervical abrasion, gingival abrasion and effect on dental restorations.

**Toothbrushes:** Oral B (A), BURST Oral care (B), manual toothbrush (C)

**Dentifrice:** Colgate Total

**Duration of study:** 32 days period

**Baseline, data & Indices:** oral prophylaxis will be performed to establish baseline scores to 0. Plaque indices and gingival indices (*Silness-Löe Index*) will be collected 24 hour prior to toothbrush delivery and the subjects will be instructed not to brush or used ant device within this period. After the 24 hours abstinence period an initial G.I records will be collected prior to first use of the brushes followed by a second G.I record immediately after the first use of the toothbrush.

**Sample Size:** 90 healthy subjects age group 18-60 years old. Each group will contain 30 subjects.

**Inclusion criteria**

1. Good overall health
2. At least 20 teeth present, not including 3rd Molars
3. Non-smoker

**Exclusion Criteria**

1. Poor manual dexterity or mentally handicap;
2. Presence of removable intra-oral prosthesis
3. Current orthodontic therapy
4. Severe Periodontal condition or caries teeth in need of immediate attention
5. Pregnant women
6. Subjects that use medications that may effect oral health
7. No Systemic diseases/conditions such as diabetes mellitus, heart disease.
8. Use of plaque inhibiting toothpaste, mouthwash, interdental flossing in the period of the study

Subject Compensation

Study participants will receive $100 for their participation. $50 will be given at T2 and $50 at T3.

Statistical Analysis

ANOVA:
- Compare the plaque level between the three groups after 30 days
- Compare the gingitis level between the three groups after 30 days