

A new tooth brushing approach supported by an innovative hybrid toothbrush: Compared reduction of dental plaque after a single use versus an oscillating-rotating powered toothbrush

Submission date 05/02/2018	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 20/02/2018	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 08/10/2019	Condition category Oral Health	☐ Individual participant data

Plain English summary of protocol

Background and study aims:

Oral health is one of the major concerns of dental health care professionals. In Western industrialized countries, the toothbrush is widely accepted as a simple, affordable and effective device to mechanically remove dental plaque in a shorter time. However, a wide diversity in brushing methods does exist depending on the position and motion of the brush. The aim of this study was to evaluate and compare the clinical efficacy of the first hybrid toothbrush (INAVA Hybrid) using combined mode (manual gesture associated to sonic vibrations) to a marketed oscillating-rotating powered toothbrush (Oral-B Vitality) in the reduction of dental plaque after a single use.

Who can participate?

Adult subjects presenting a deposit of dental plaque covering up to 1/3 of the cervical and a mild inflammation of gingival marginal or papillary.

What does the study involve?

On the day of the study, the subjects come to the laboratory after refraining from all oral hygiene procedures for 24 hours and without eating, drinking and smoking for the last four hours before the visit. The dentist performs a clinical examination of the state of the oral cavity, with a "Silness and Loe Plaque Index" (PI) score and "Modified Gingival Index" (MGI) score. After randomization, each participant receives instructions on how to use the assigned toothbrush device. The same toothpaste is provided to all the subjects. A single brushing with the studied product (hybrid toothbrush) or the comparative product (oscillating-rotating device) is performed for exactly two minutes under supervision to ensure compliance with the manufacturer's usage instructions. Immediately after brushing, another clinical examination of

the state of the oral cavity is performed by the dentist and another PI scoring is done. The participants complete a self-assessment questionnaire of the products' acceptability after the first use.

What are the possible benefits and risks of participating?

There are no known benefits with participating in this study. The possible risk is bleeding of the gingiva.

Where is the study run from?

Demscan Poland (Gdansk- Poland)

When is the study starting and how long is it expected to run for?

September 2015 to November 2015

Who is funding the study?

Pierre Fabre Oral Care (France)

Who is the main contact?

Dr JP Gatignol (Public)

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

15E0508

Study information

Scientific Title

Oral and dental efficacy and tolerance of an electric toothbrush versus a comparative electric toothbrush marketed - use test under dental control of the reduction of dental plaque after a single use

Study objectives

The new hybrid toothbrush combining manual gesture associated to sonic vibrations is as efficient as a marketed oscillating-rotating powered toothbrush in the reduction of dental plaque.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval not required: the study takes place in Poland. In that country, an electric toothbrush is considered to be a domestic electric apparatus. Conducting a clinical study with such devices does not require any approval by an ethics committee. However, the study is conducted in compliance with Good Clinical Practices and in accordance with the "Declaration of Helsinki." Written informed consents for participation in the clinical study is obtained for all participants.

Study design

Randomized examiner-blind single-center study parallel group.

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Oral health

Interventions

On the day of the study, participants come to the laboratory after refraining from all oral hygiene procedures for 24 hours and without eating, drinking and smoking for the last four hours before the visit. The dentist performs a clinical examination of the state of the oral cavity. Participants with a "Silness and Loe Plaque Index" (PI) score between 1.0 and 2.0 and "Modified Gingival Index" (MGI) score between 1.0 and 2.0 are included in the study. A randomisation list for toothbrush allocation is generated using the sub routine PROC PLAN of the statistical software SAS 9.4. After randomisation, each participant receives instructions on how to use the assigned toothbrush device. The same toothpaste (Elgydium, Pierre Fabre Oral Care, France) is provided to all the subjects. A single brushing with the studied toothbrush (INAVA Hybrid - Pierre Fabre Oral Care, France) or the comparative toothbrush (Oral-B Vitality 2D Sensitive Clean - Procter & Gamble, USA) are performed for exactly two minutes under supervision to ensure compliance with the manufacturer's usage instructions. Immediately after brushing, another clinical examination of the state of the oral cavity is performed by the dentist and another PI scoring is done. Possible adverse reactions are noted. For this post-brushing evaluation, the dentist is blinded as to the device used. The participants complete a self-assessment questionnaire of the products' acceptability after the first use.

Intervention Type

Device

Primary outcome(s)

Anti-plaque efficacy of the studied toothbrush versus a comparative toothbrush is measured using the "Silness and Loe Plaque Index" immediately after usage.

Key secondary outcome(s)

1. Tolerance of study products is measured using clinical examinations of the oral cavity (teeth, gums, mucous membranes) for physical and functional signs before and immediately after toothbrush use
2. Cosmetic acceptability is measured using a questionnaire filled in by the patients immediately after toothbrush use

Completion date

28/01/2016

Eligibility**Key inclusion criteria**

1. Patients aged between 18 to 70 years old
2. Presenting at least 20 natural teeth, without implants, prosthesis or dental braces on the studied teeth
3. Presenting a "Silness and Löe Plaque Index" between 1.0 and 2.0 and a "Modified Gingival Index" between 1.0 and 2.0. at the time of inclusion
4. Not using preventive dental medications, antibiotics and/or steroids during one week before the beginning of the study
5. Never used an electric toothbrush

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

66

Key exclusion criteria

1. Pregnant or nursing women or not willing to take precautions during the study
2. Subject having an uncompromised manual dexterity
3. Subject having a disease liable to interfere with study data according to the investigator
4. Subject having a cutaneous-mucosal disease liable to interfere with study data according to the investigator, especially: herpes or medical history herpes, aphthosis and medical history of

aphtosis, lichen planus, chronic lupus erythematosus

5. Subject having undergone surgery, chemical or physical treatment to the concerned area in the last 3 months

6. Subject having a background of intolerance or allergy to cosmetics, to drugs or to other substances (fruits, lactose intolerant, nuts, etc.) that makes the subject ineligible or places him/her at undue risk or that forbids him/her not to eat and drink 4 hours before the study

7. Subject planning to have any dental care during the study

8. Subject having applied any topical or local product (dental gel, mouthwash, etc.) the day of the inclusion visit on the study area

Date of first enrolment

20/08/2015

Date of final enrolment

27/11/2015

Locations

Countries of recruitment

Poland

Study participating centre

Dermscan Poland

ul. Kruczkowskiego 12

Gdansk

Poland

80-288

Sponsor information

Organisation

Pierre Fabre Dermocosmetique

ROR

<https://ror.org/04hdhz511>

Funder(s)

Funder type

Industry

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr JP Gatignol (jean.philippe.gatignol@pierre-fabre.com)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	06/11/2018	08/10/2019	Yes	No