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A clinical study on evaluation of a novel power toothbrush in eliminating dental plaque

Submission date
25/02/2018

Recruitment status
No longer recruiting

Registration date
22/03/2018

Overall study status
Completed

Last Edited
01/03/2021

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aimed at comparing the plaque removal efficiency of a novel multi-surface (MS) power toothbrush with a widely used single-surface oscillation-rotation (OR) power toothbrush.

Who can participate?
Zhejiang Chinese Medical University students in good health (updated 04/08/2020, previously: Healthy volunteers aged 18 to 22)

What does the study involve?
Every participant has two visits, at the first visit they use an oscillation rotation toothbrush (OR) in the left half of their mouth for 1 minute and the multi-surface toothbrush (MS) in the right for 1 minute. At the second visit, they use OR in the right and MS in the left. The participant's plaque is assessed without knowing which toothbrush was used. Participants are followed up for 1 week to investigate side effects such as gingival (gum) bleeding.

What are the possible benefits and risks of participating?
Multi-surface power toothbrushes could improve the removal of plaque in areas that are hard to clean and shorten brushing time. Users could achieve almost optimal oral hygiene by using the multi-surface toothbrush without needing to know the professional technique. It could help to save the time the dental hygienist spends on patient education. Possible risks include gingival bleeding and gingival harm.

Where is the study run from?
Stomatology Hospital affiliated to Zhejiang Chinese Medical University (China)

When is the study starting and how long is it expected to run for?
February 2016 to July 2016

Who is funding the study?
Zhejiang Chinese Medical University (China)

Who is the main contact?
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2. Mr Mingjie Wang (public)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
832219A00601

Study information

Scientific Title
Plaque removal efficiency of a multi-surface novel power toothbrush: a clinical study

Study objectives
The multi-surface toothbrush reduces plaque at the same rate as with an oscillation rotation toothbrush.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics board of stomatology hospital affiliated to Zhejiang Chinese Medical University, 01/02/2016, ref: No. 20162001

Study design
Interventional split-mouth single-center study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Gingivitis, dental plaque

Interventions
Current interventions as of 21/04/2020:

Right and left mouth will be randomly allocated to multi-surface power toothbrush (MS) (Y600, Newly, Newly tech Ltd, Zhejiang, China) or oscillation rotation power toothbrush (OR) (Oral-B Vitality Floss Action® with Precision Clean brush head, EB20, P&G Ltd, Guangzhou, China). All the data will be collected in Stomatology School, Zhejiang Chinese Medical University, Hangzhou, China.
Before brushing, drops of plaque checker (Plaque checker, Ci Medical Co. Ltd., Hakusan Ishikawa, Japan) will be dropped onto a cotton swab and then applied on the dentitions for 30 seconds. The mouth will be then rinsed with water. Eight intra-oral photos will be taken from each participant to form a baseline. The photos will be taken at F22, 1/125sec with film speed ISO

1600. Then the participants will be asked to read the manuals of the toothbrushes before using them. Participants will be asked to use MS and OR for one minute in the allocated half mouth. During brushing, a timer will be employed to help the participants to spread their time equally over upper,lower, lingual, buccal and occlusal surfaces. Photos will be taken of the experiment and the control group. Time points for taking photos for the experiment group will be after 0s, 15s, 30s, 45s, 60s and for the control group will be after 0s, 30s, 60s.

The staff managing the study will be not allowed to express any preference for either toothbrush. Two evaluators will examine the results and do not know the assignment of the toothbrush. They will be trained to guarantee the same standard. A calibration test will be employed to evaluate the consistency of scoring the plaque. When they score and calculate the plaque, they will not know which toothbrush had been used.

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Previous interventions:

Every participant has two visits, at the first visit they use an oscillation rotation toothbrush (OR) in the left half of the mouth for 1 minute and the multi-surface toothbrush (MS) in the right for 1 minute. At the second visit, they use OR in the right and MS in the left.

Two staff scored the plaque without knowing the allocation of toothbrush. Participants are followed up for one week to investigate adverse events like gingival bleeding and damage to gingival margin.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Multi-surface power toothbrush (Y600, Newly, Newly tech Ltd, Zhejiang, China) or oscillation rotation power toothbrush (Oral-B Vitality Floss Action® with Precision Clean brush head, EB20, P&G Ltd, Guangzhou, China)

Primary outcome measure
Current primary outcome measure as of 04/08/2020:

1. Plaque removal efficiency at lingual, buccal, gingival marginal and proximal areas measured by RMNPI at 0,15,30,45 and 60 seconds for MS group and 0 ,30, 60 seconds for OR group
2. Plaque removal efficiency at occlusal areas measured by IPP at 0,15,30,45 and 60 seconds for MS group and 0 ,30, 60 seconds for OR group
3. User feedback on the toothbrush measured by questionnaires after two visits. Participants are asked to score the different aspect of using the two kinds of toothbrushes: noise, vibration, convenience, difficulty to brush the posterior tooth and the whole satisfaction

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Previous primary outcome measure:

1. Plaque removal efficiency in the lingual, gingival marginal, buccal and approximal areas: plaque reduction rate = (plaquet0 – plaquetn) / plaquet0. t0 represents baseline, while tn represents different timepoints
2. User feedback on the toothbrush: questionnaires were distributed to participants, they are asked the following questions and score the different aspect of using the two kinds of toothbrushes: noise, vibration, convenience, difficulty to brush the posterior tooth and the whole satisfaction
3. Difference in plaque removing efficiency between upper and lower dentition: evaluated using t test
Measured at baseline/first visit and 2 months/second visit

Secondary outcome measures
Current secondary outcome measures 04/08/2020:

Adverse effects (gingival bleeding) measured using an adverse event questionnaire just after the application and 1 week after visits

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Previous secondary outcome measures:

1. Plaque removal efficiency between brushing time: method the same as the first visit
2. Adverse effects (gingival bleeding), measured using an adverse event questionnaire 1 week after visits
3. Difficulty in brushing the posterior teeth, assessed using questionnaires and t test measured at baseline/first visit and 2 months/second visit

Overall study start date
01/02/2016

Completion date
01/07/2016

Eligibility

Key inclusion criteria
Current inclusion criteria as of 24/02/2021:
1. In good general health
2. Right-handedness
3. University students (not dental students)
4. Mouth opening over three fingers
5. Teeth number 1 to 6 exist in each quadrant

Previous inclusion criteria from 04/08/2020 to 24/02/2021:

1. In good general health
2. Right-handedness
3. University students
4. Enough mouth opening and lingual frenulum to let the oral cavity contain an orthodontic

photograph mirror
5. A minimum of 6 teeth in each quadrant

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Previous inclusion criteria:

1. Aged from 18 to 22 years old
2. Normal lingual frenulum to let the oral cavity contain a dental mirror
3. A minimum of 6 teeth in each quadrant
4. In good general health

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Total final enrolment
21

Key exclusion criteria
Current inclusion criteria as of 24/02/2021:
1. Inability to participate due to severe diseases
2. Cardiovascular diseases
3. Blood disease (hemophilia, pernicious anemia)
4. Hypertension
5. Metabolic diseases (diabetes mellitus)
6. Renal insufficiency
7. Infectious diseases (hepatitis A/B/C, HIV)
8. Seizure or neurological disorders
9. Need antibiotic prophylaxis due to immunosuppression or endocarditis; addiction (alcohol, drugs)
10. Allergic to toothpaste or other materials used in this study
11. Pregnancy
12. Presence of dental (carious lesion with cavity) and/or periodontal diseases (periodontal probing depth >3.5 mm
with CPI probe)
13. Having taken antibiotics in the preceding 2 weeks
14. Having a crown, implant, or orthodontic appliances

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Previous exclusion criteria:
1. Taken antibiotics in the preceding 2 weeks
2. Participants having a crown, implant or orthodontic appliances
3. Drinking alcohol or smoking tobacco within 4 hours before the experiment
4. Performing any oral hygiene care in the 12 hours before the visit, including brushing their teeth, chewing gum or using dental floss. In that period only small sips of water were allowed

Date of first enrolment
01/02/2016

Date of final enrolment
01/05/2016

Locations

Countries of recruitment
China

Study participating centre
Stomatology Hospital affiliated to Zhejiang Chinese Medical University
No. 529, Binwen Rd., Binjiang District
Hangzhou
China
310000

Sponsor information

Organisation
Zhejiang Chinese Medical University

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School of Stomatology
Binwen Road 548, Binjiang District
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Sponsor type
University/education

Website
http://zzdkq.zcmu.edu.cn/page/hf/index.jsp

ROR
https://ror.org/04epb4p87

Funder(s)

Funder type
University/education

Funder Name
Zhejiang Chinese Medical University

Alternative Name(s)
ZCMU

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/12/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Mingjie Wang (543347419@qq.com) for 5 years.

IPD sharing plan summary
Available on request