ISRCTN83875016 https://doi.org/10.1186/ISRCTN83875016

Effectiveness of Super-Floss® (Oral-B) and the Waterpik® water flosser in plaque removal for patients undergoing orthodontic treatment

Submission date
23/08/2021

Recruitment status
No longer recruiting

Registration date
12/09/2021

Overall study status
Completed

Last Edited
13/09/2022

Condition category
Oral Health

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Patients who wear fixed orthodontic appliances must maintain high standards of oral hygiene; otherwise, they will experience a range of complications.
Various devices are available to help orthodontic patients maintain good oral hygiene, including essential manual toothbrushes and toothpaste, electronic toothbrush, dental floss, brushes for interproximal hygiene, and oral irrigators, such as dental water floss.
This trial aimed to evaluate the effectiveness of super floss (Oral-B Super Floss) and water flosser (Waterpik Cordless Freedom Water Flosser) in plaque removal in orthodontic patients.

Who can participate?
Male or female between 18-35 years old who are approaching the end of their orthodontic treatment

What does the study involve?
Super-Floss ® (Oral-B) will be used on one side of the mouth, while the Waterpik® water flosser will be used on the other. All participants will have around two minutes to brush their teeth and another two minutes to clean in between their teeth.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Princess Nourah Bint Abdulrahman University (Saudi Arabia)

When is the study starting and how long is it expected to run for?
October 2018 to January 2021

Who is funding the study?
Deanship of Scientific Research at Princess Nourah Bint Abdulrahman University (Saudi Arabia)

Who is the main contact?
Dr. Eman Alsagob, EIALSAGOB@pnu.edu.sa

Contact information

Type(s)
Scientific

Contact name
Dr Eman Alsagob

ORCID ID
https://orcid.org/0000-0002-3206-3167

Contact details
Preventive Dental Sciences Department
College of Dentistry
Princess Nourah bint Abdulrahman University
Riyadh
Saudi Arabia
13414
+966 555 178 877
EIALSAGOB@pnu.edu.sa

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
H-01-R-059

Study information

Scientific Title
Comparison between the effectiveness of dental floss and water floss in plaque removal: a controlled clinical trial in orthodontic patients

Study objectives
Studies investigating the efficacy of dental water floss on oral hygiene control of orthodontic patients are limited, and its impact on reducing supragingival plaque biofilm remains unclear. This determines the need for studying the effect of this device on an orthodontic patient sample in particular and whether it is superior or as effective compared to super floss. Hence, this randomized control trial aimed to evaluate the effectiveness of super floss (Oral-B Super Floss) and water flosser (Waterpik Cordless Freedom Water Flosser) in plaque removal in orthodontic patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was reviewed and exempted on 01/10/2018, by the Institutional Review Board (IRB) of Princess Nourah Bint Abdulrahman University (Riyadh, Saudi Arabia; +966118240861; irb@pnu.edu.sa), ref: IRB:18-0241

Study design
Single-blind randomized controlled parallel clinical trial with a split-mouth protocol

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Removal of dental plaque in orthodontic patients

Interventions
In a single visit, the split-mouth technique is performed to compare consistency in both groups. In addition, RMNPI is adapted to measure plaque levels of all subjects at baseline with the use of the WHO probe. A separate researcher will explain oral hygiene instructions to all subjects, using the modified bass technique and a standard toothbrush (soft-bristled brush with fluoridated toothpaste) and explain to the patients the correct method of using interdental cleaning techniques manufacturer's instructions. The type of floss used will be randomly assigned to each side of the oral cavity; Super-Floss ® (Oral-B) will be used on one side, while the Waterpik® water flosser will be used on the other. All participants will have around two minutes to brush their teeth and another two minutes to clean their interproximal teeth. There was no follow up period.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Super-Floss® (Oral-B), Waterpik® water flosser

Primary outcome(s)
The plaque index of each side will be taken before and after the intevention. Examiners who are recording the plaque index before and after the trial will be blinded regarding the type of
floss used for each side of the mouth). Respectively, a canine, one premolar, and one molar are selected for evaluation. Plaque is assessed for each tooth area and is scored using the following scale: 0 = absent, and 1 = present.

Key secondary outcome(s))

There are no secondary outcome measures

Completion date
01/01/2021

Eligibility

Key inclusion criteria
1. Male or female between 18-35 years
2. Approaching the end of their orthodontic treatment
3. Undergoing braces from the right first molar to the left first molar with pocket depth ≤3mm
4. Not used any floss type for the last 24 hours

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
35 years

Sex
All

Total final enrolment
34

Key exclusion criteria
1. Systemic diseases
2. Craniofacial anomalies
3. Periodontal problems
4. Spacing or missing teeth in the examined arch
5. Smokers

Date of first enrolment
01/02/2019

Date of final enrolment
01/05/2019

Locations

Countries of recruitment

Saudi Arabia

Study participating centre
Riyadh Specialized Dental Center
Imam Abdullah Bin Saud Ibn Abdulaziz RD
Ishbiliyah
Riyadh
Saudi Arabia
13226

Sponsor information

Organisation
Princess Nourah bint Abdulrahman University

ROR
https://ror.org/05b0cyh02

Funder(s)

Funder type
University/education

Funder Name
Princess Nourah Bint Abdulrahman University

Alternative Name(s)
Princess Nora University, Princess Nora Bint Abdulrahman University, PNU

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Saudi Arabia

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		31/08/2022	13/09/2022	Yes	No
Protocol file			09/09/2021	No	No