

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

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<b>Registration date</b> 12/09/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/09/2022	<b>Condition category</b> Oral Health	<input type="checkbox"/> 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

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## Additional identifiers

### Clinical Trials Information System (CTIS)

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 intervention. 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  $\leq 3\text{mm}$
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  
Ishbilyah  
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?
<a href="#">Results article</a>		31/08/2022	13/09/2022	Yes	No
<a href="#">Protocol file</a>			09/09/2021	No	No