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A study to compare three different bristle designs of manual toothbrushes in reducing dental plaque in fixed orthodontic patients

Submission date
11/07/2022

Recruitment status
No longer recruiting

Registration date
14/07/2022

Overall study status
Completed

Last Edited
11/04/2023

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Manual toothbrushes play a fundamental role in oral hygiene for preventing dental plaque. Controlling dental plaque accumulation for preventing gum inflammation (gingivitis), gum disease (periodontitis), and tooth decay, is highly influenced by several factors. The presence of fixed orthodontic appliances on tooth surfaces such as brackets and bands creates difficulties in maintaining good oral hygiene, leading to the build-up of plaque. Although there is considerable literature revealing the superiority of powered toothbrushes, particularly oscillating rotating brushes, when compared to manual toothbrushes in patients with fixed orthodontic appliances, there is limited evidence regarding the effectiveness of advanced bristle designs (multilevel, criss-cross) of manual toothbrushes alone in removing plaque on patients undergoing orthodontic treatment except for a few that have compared manual brush with orthodontic brushes with conflicting reports of effectiveness.
This study aims to compare the level of plaque before and after using three different bristle designs of manual toothbrushes in patients undergoing fixed orthodontic treatment.

Who can participate?
Patients being treated with a fully bonded fixed orthodontic appliance, aged between 18 and 25 years, and in good general and oral health.

What does the study involve?
Participants will be allocated to use one of three types of manual toothbrushes (flat, orthodontic, multilevel pulsar) at random, with an equal chance of being allocated each type (like tossing a coin) during the first visit of the study. In the second visit of the study, participants will use one of the two toothbrush types that they did not use in the previous part of the study, again allocated at random. In the third visit of the study, they will use the type of toothbrush they have not yet used. Each visit of the study will be separated by 1 week. Before and after using each type of toothbrush, participants will be assessed for levels of plaque.

What are the possible benefits and risks of participating?
The risks and inconvenience will be very minimal limited to participants sparing some of their

valuable time. There will be no individual benefit from participation in this study but it may help in the advancement of knowledge and health science progress.

Where is the study run from?
King Abdullah International Medical Research Center (Saudi Arabia)

When is the study starting and how long is it expected to run for?
From April 2020 to April 2022

Who is funding the study?
Investigator-initiated and funded

Who is the main contact?
Dr Fathima Fazrina Farook, fazrinaf@ksau-hs.edu.sa

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A comparative study of three different bristle designs of manual toothbrushes in dental bio-film reduction in fixed orthodontic patients

Study objectives
To compare the level of plaque before and after using three different bristle designs of manual toothbrushes (multilevel, flat trim, and orthodontic) in patients undergoing fixed orthodontic treatment using the modified bass technique.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/03/2020, Institutional Review Board (IRB) Ministry of National Guard - Health Affairs (King Abdullah International Medical Research Center, Ali Al Arini, Ar Rimayah, Riyadh 11481; +966 (0)114294444; irb@ngha.med.sa), ref: RC20/085/R

Study design
Randomized crossover trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

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
Plaque removal in patients with fixed orthodontic appliances

Interventions
The study participants will be randomly divided into three treatment sequences using the computer-generating random method ABC, BCA, and CAB with approximately 10 subjects in each treatment sequence.
Group A: Toothbrush with flat bristles
Group B: Toothbrush with orthodontic bristles
Group C: Toothbrush with multilevel (Pulsar) bristles
The washout period between each visit will be 1 week

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Plaque score measured using the Turesky Modified Quigley-Hein Plaque Index at baseline and following each single brushing exercise

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/04/2020

Completion date
01/04/2022

Eligibility

Key inclusion criteria
1. Aged ≥18 to ≤25 years
2. In good general and oral health
3. Wearing fully bonded fixed orthodontic appliances
4. Good hand dexterity
5. Without any disabilities
6. ≥25 natural teeth with facial and lingual scorable surfaces without any oral lesions
7. Periodontal pockets of 3mm or loss of attachment/recession of 2mm

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
25 Years

Sex
Both

Target number of participants
30

Total final enrolment
34

Key exclusion criteria

1. Evidence of mucogingival problems
2. Smoking
3. Pregnancy
4. Five or more carious lesions requiring restorative treatment
5. Heavy restorations
6. Wearing fixed or removable prostheses
7. Participation in any other elective dental procedure, including prophylaxis, during the study period
8. Evidence of any disease or condition that may interfere with the study procedures

Date of first enrolment
01/10/2020

Date of final enrolment
01/10/2021

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
King Saud Bin Abdul Aziz University For Health Sciences
College of Dentistry
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Sponsor information

Organisation
King Abdullah International Medical Research Center

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Sponsor type
Government

Website

http://kaimrc.med.sa/

ROR
https://ror.org/009p8zv69

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date
01/11/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request. Dr Fathima Fazrina Farook (fazrinaf@ksau-hs.edu.sa) can be contacted for access to the datasets. Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices) will be shared at the beginning 3 months and ending 5 years following article publication, for individual participant data meta-analysis.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/08/2022	11/04/2023	Yes	No