

Wear of electric toothbrush heads in adolescents with fixed orthodontic appliances

Submission date 10/11/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 21/12/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 14/02/2023	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Plaque promotes the development of caries, gingivitis and periodontitis. It must be removed regularly and mechanically to prevent this. Patients with fixed orthodontic appliances have an increased risk of caries, as more plaque is accumulated through brackets, arches and other appliance components. These patients often have two to three times more plaque on their teeth than patients without multibracket appliances and a higher risk of white spot lesion development. Due to multibracket appliances increasing the difficulty of achieving a thorough oral hygiene routine, gingivitis is more frequent and usually persists throughout the treatment period. Current research and literature show that there are controversial results on toothbrush wear and its influence on the effectiveness of plaque removal.

The primary objective of this study was to evaluate the degree of wear on electric toothbrush heads used by 12 to 15-year-old subjects with fixed orthodontic appliances over a period of 12 weeks using the wear index. The secondary objective was to examine the development of oral hygiene over time and to clarify to what extent the wear index affects the plaque index.

Who can participate?

Healthy adolescents aged between 12 and 15 years old with generally good oral hygiene and fixed conventional brackets on all eight anterior teeth.

What does the study involve?

At baseline, every test person received the same oral hygiene products. All test persons were instructed to clean their teeth twice a day (morning/evening) for three months for two minutes each, using exclusively the products they received. The study was designed to assess if the participants in the test group experience an improvement in oral health. Plaque index measurements are taken at baseline, and weeks 4, 8 and 12 visits. Subjects are instructed to abstain from any oral hygiene for 12 hours prior to all visits. Only after the plaque index had been collected did the test persons perform their next oral hygiene routine. During the visit, the electric toothbrush head is evaluated and photographed with an assigned number. The papillary bleeding index and the modified plaque index are collected on-site before and after brushing the teeth. If a subject's toothbrush head reaches wear-index grade 4, the study is regarded as finished for the subject at this time for ethical reasons.

What are the possible benefits and risks of participating?

Participation will help with the evaluation of products and their longevity independent of the instructions by the developer to improve oral health in patients with fixed appliances. There are no notable risks involved with participating. This study involves the use of toothbrushes as part of a normal oral hygiene routine. No behaviour with increased risk is requested from participants. The toothpaste provided in this study is currently marketed. The risk from a chemical hazard is negligible, or no greater than what would have been encountered during daily life. Toothbrushes are not anticipated to cause any serious or long-term effects on oral tissue including gum recession.

Where is the study run from?

University Medical Center of the Johannes Gutenberg University (Germany)

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

August 2013 to June 2014

Who is funding the study?

University Medical Center of the Johannes Gutenberg University (Germany)

Who is the main contact?

Prof. Dr. Christina Erbe, erbe@uni-mainz.de

Contact information

Type(s)

Principal Investigator

Contact name

Prof Christina Erbe

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

2013012

Study information

Scientific Title

A clinical trial to evaluate the wear index of electric toothbrush heads and the correlation of the wear index and the plaque reduction among a population with fixed orthodontic appliances

Study objectives

The null hypothesis of this study states that all toothbrush heads remove the same amount of plaque regardless of their wear. The alternative hypothesis states that varying degrees of wear on the toothbrush heads lead to varying degrees of plaque reduction.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved, 27/02/2014, The Ethics Committee of the Rhineland-Palatinate Medical Association (Deutschhausplatz 3, 55116 Mainz, Germany; +49 (0)6131 288220; kammer@laek-rlp.de), ref: (9178-F)

Study design

Single-center 12-week 1-treatment study

Primary study design

Observational

Secondary study design

Case series

Study setting(s)

Dental clinic, Home

Study type(s)

Prevention

Participant information sheet

See trial outputs table

Health condition(s) or problem(s) studied

Evidence of plaque due to the wear of the toothbrush heads in adolescents with fixed orthodontic appliances

Interventions

At baseline, every test person (64 adolescents aged 12-15 years old) received the same oral hygiene products (electric toothbrushes) free of charge. All test persons were instructed to clean their teeth twice a day (morning/evening) for three months for two minutes each, using exclusively the products they received and a prescribed brushing technique. The patients receive a brushing schedule:

Before: anamnesis, which takes place before any general dental treatment.

During: regular plaque checks

After: professional teeth cleaning

The test persons returned to the practice after four, eight and twelve weeks with the toothbrush head received at the beginning. The last oral hygiene before a visit was performed on the evening of the previous day. Until the agreed date on the following day, the test persons had to refrain from cleaning their teeth. Only after the plaque index had been collected did the test persons perform their next oral hygiene routine. During the visit, the electric toothbrush head was evaluated and photographed with an assigned number. The papillary bleeding index and the modified plaque index were collected on-site before and after brushing the teeth. If a subject's toothbrush head had reached wear-index grade 4, the study was regarded as finished for the subject at that time for ethical reasons.

Wear Index of electric brush heads:

The Wear Index is divided into 5 grades that assess the wear of an electric toothbrush brush head.

Plaque index based on Silness and Loë (1964):

Plaque is assessed without staining on all four tooth surfaces (buccal, lingual, mesial, distal) by eye and probe.

Papillary bleeding index (PBI):

The PBI assesses local inflammation in the sulcus.

PBI = sum of bleeding measuring points: total number of measuring points.

With the PBI, it is possible to check whether the patient is practising good oral hygiene on a permanent basis or whether he or she is only practising good dental cleaning before the respective visit to the dentist, while simultaneously recording the plaque index.

Screening methods

Screening-Baseline

Introduction to the clinical trial process

Consent by signing the consent form (by a legal guardian)

Dental examination

Determination of PI and PBI

Independent tooth cleaning by the test subject according to cleaning instructions

Oral Hygiene Instructions

At Home

Only use the electric toothbrush that has been provided

Only use the toothpaste that has been provided

Only use products according to the instructions twice daily

1st appointment, 4 weeks after baseline

Bring the electric toothbrush with the brush head Determination of Wear Index

Oral hygiene status (PI, PBI)

Independent tooth cleaning of the test person according to brushing instructions

Oral hygiene instruction

2nd appointment, 8 weeks after baseline

Bring the electric toothbrush with the brush head Determination of Wear Index

Oral hygiene status (PI, PBI)

Independent tooth cleaning by the test person according to brushing instructions
Oral hygiene instruction

3rd appointment, 12 weeks after baseline

Bring the electric toothbrush with the brush head Determination of Wear Index

Oral hygiene status (PI, PBI)

Independent tooth cleaning by the test person according to brushing instructions

Oral hygiene instruction

Professional tooth cleaning

Duration

The examinations took place every 4 weeks, up until 12 weeks after baseline.

Follow-up activity

The patients received a free electric toothbrush. In addition, their oral hygiene was checked and they received instructions accordingly.

Intervention Type

Device

Phase

Not Applicable

Primary outcome measure

Papillary bleeding after careful dental probing in the papillary region measured using the papillary bleeding index (PBI) at baseline and 4, 8 and 12 weeks

Secondary outcome measures

The secondary objective was to examine the development of oral hygiene over time and to clarify whether, if, and to what extent the wear index affects the plaque index.

1. Plaque quantity measured using the plaque index (PI) at baseline and 4, 8 and 12 weeks
2. Toothbrush head wear measured using the wear index (WI) at baseline and 4, 8 and 12 weeks

Overall study start date

15/08/2013

Completion date

30/06/2014

Eligibility

Key inclusion criteria

1. A signed informed consent from each subject and his/her legal guardian
2. Aged between 12 and 15 years old
3. No serious medical diseases
4. Total of at least 16 teeth
5. All eight anterior teeth present and orthodontic fixed appliances
6. General good oral hygiene

Participant type(s)

Healthy volunteer

Age group

Child

Lower age limit

12 Years

Upper age limit

15 Years

Sex

Both

Target number of participants

64

Total final enrolment

64

Key exclusion criteria

1. No multibracket appliances in situ
2. Suffering from severe periodontal diseases or gingival recession
3. More than three carious defects
4. Active periodontal treatment
5. Use of antibiotics or anti-inflammatory drugs
6. Pregnancy
7. Unreliability, lack of cooperation or other objections with the opinions of the practitioner
8. Professional tooth cleaning had been performed in the past four weeks
9. The presence of any symptoms
10. Any health-related issues
11. Participation in any other study

Date of first enrolment

20/12/2013

Date of final enrolment

14/03/2014

Locations

Countries of recruitment

Germany

Study participating centre

University Medical Center of the Johannes Gutenberg-University
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Sponsor information

Organisation

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Sponsor type

University/education

Website

<http://www.unimedizin-mainz.de/home.html?L=1>

ROR

<https://ror.org/00q1fsf04>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Universitätsmedizin der Johannes Gutenberg-Universität Mainz

Alternative Name(s)

University Medical Center Mainz, Universitätsmedizin Mainz

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

Germany

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

The study protocol, statistical analysis plan, and other additional documents are not intended to become available online.

Intention to publish date

01/03/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available because if the raw data is available but not analyzed appropriately by qualified experts, it may lead to misinterpretation of the results.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			25/11/2022	No	Yes
Protocol file			25/11/2022	No	No