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Wear of electric toothbrush heads in adolescents with fixed orthodontic appliances

Submission date	**Recruitment status**	[_] Prospectively registered
10/11/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/12/2022	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
14/02/2023	Oral Health	[_] 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

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Additional identifiers

Protocol serial number
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

Study type(s)
Prevention

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.
PB I= 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 sighing 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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
12 years

Upper age limit
15 years

Sex
All

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
University Medical Center of the Johannes Gutenberg University Mainz

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

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