Poly-Ether-Ether-Ketone (PEEK) compared to Multibraided Stainless Steel in Fixed Orthodontic Retention: A Multicenter Randomized Controlled Trial

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The aim of this study is to assess the clinical suitability of PEEK bonded retainers and to evaluate its successes and failures compared to the current clinical *golden standard* multibraided stainless steel bonded retainer wires.Null Hypothesis:...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON57038

Source
ToetsingOnline

Brief title
PEEK as fixed Orthodontic Retention

Condition

- Other condition

Synonym
crooked teeth, malocclusion

Health condition

recent behandelde tandstandafwijking

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Multibraided, Orthodontics, PEEK, Retention

Outcome measures

Primary outcome

Bond failures

Pattern of failures

Secondary outcome

Possibly quantify the extent of undesired tooth movement, relying on intraoral

scans and, if necessary, intraoral photographs.

Study description

Background summary

Retention is a necessity for the stability of any orthodontic treatment outcome. The currently used materials contain risks such as inadvertent activity of stainless-steel bonded retainers, debonding and wire breakage. As the quest for better materials continues, PEEK is emerging as an upcoming candidate worth exploring.
Are the promising results of in vitro studies on PEEK bonded retainer wires translatable to the clinic?

Study objective

The aim of this study is to assess the clinical suitability of PEEK bonded retainers and to evaluate its successes and failures compared to the current clinical *golden standard* multibraided stainless steel bonded retainer wires.
Null Hypothesis: The short-term failure rate of Multibraided Stainless Steel is better than the short-term failure rate of Poly Ether Ether Ketone (PEEK) in

bonded orthodontic retention by the non-inferiorty limit (delta) of 7%.

Study design

A Randomized Multicenter Controlled Trial where the current *gold standard* multibraided stainless steel as a fixed orthodontic retainer is clinically compared to fixed retainers fabricated out of milled Poly-Ether-Ether-Ketone (PEEK).

Intervention

One group will receive fixed orthodontic retention fabricated out of milled Poly-Ether-Ehter-Ketone (PEEK) and the other group will receive fixed orthodontic retention fabricated out of multibraided stainless steel.

Study burden and risks

A risk is that the study could conclude that Poly-Ether-Ether-Ketone (PEEK) is performing insufficiently as fixed orthodontic retention, whereafter the fixed retention could be replaced. Patients are seen frequently after removing orthodontic fixed appliances so there is no suspected affect on tooth movement.

The load for the patient shall be completely comparable to the current protocols, it can be seen as negligible.
Risks concerning the failure of fixed orthodontic retention will stay comparable to the current existing risks using the "golden standard".

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

Subjects with varying pre-treatment PAR-scores who agreed to participate in the follow-up retention protocol

Exclusion criteria

- Congenital anomalies (such as cleft lip and/or palate)
- Missing lower front elements
- Congenital enamel anomalies (such as Amelogenesis and Dentinogenesis imperfecta)
- Pre-existing Periodontal conditions (pockets of more than 3 mm)
- Patients who refuse to participate in the study

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2024
Enrollment:	180
Type:	Anticipated

Medical products/devices used

Generic name:	Poly-Ether-Ether-Ketone
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	07-10-2024
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL85417.091.24