ISRCTN13456471 https://doi.org/10.1186/ISRCTN13456471

Clinical evaluation of polyetherketoneketone (PEKK) post and core system in restoring teeth that have had tooth pulp treatment

Submission date
05/10/2019

Recruitment status
No longer recruiting

Registration date
14/10/2019

Overall study status
Completed

Last Edited
05/03/2024

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Restorations in compromised endodontically treated teeth aim to protect the remaining dental tissue from fracture, prevent the return of sepsis to the root canal system, and compensate for lost dental structures. There are several ways to restore compromised endodontically treated teeth, one of them is called post and core. Several factors affect the fracture resistance of teeth restored with post and core. Fibreglass reinforced resin posts are often prefabricated posts, limiting their fitting of the channel's precise shape. Recently a new dental material has been introduced called polyetherketoneketone (PEKK). This material has similar characteristics to human bone and is shock absorbent and lightweight. The aim of this study is to compare patients receiving treatment with a one-piece milled post and core made from PEKK and prefabricated fibre posts.

Who can participate?
Adults with destroyed lower premolars

What does the study involve?
Chosen teeth are randomly allocated into two groups to undergo restorations supported with either a one-piece milled post and core made from PEKK or prefabricated fibre posts. All teeth are assessed clinically at 3, 6, and 12 months and radiographically at 6 and 12 months after treatment.

What are the possible benefits and risks of participation?
The treatment may introduce a new material for fabricating posts and cores. There are no known risks to participants as any failed treatments will be re-done using another method.

Where is the study run from?
Tishreen University (Syria)

When is the study starting and how long is it expected to run for?
May 2019 to December 2021

Who is funding the study?
Tishreen University (Syria)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Protocol serial number
2164

Study information

Scientific Title
Evaluating the success of post and core system fabricated by polyetherketoneketone (PEKK) material in restoring endodontically treated teeth: a randomized controlled trial

Acronym
PEKK_ post and core_ endodontically treated teeth

Study objectives
Current study hypothesis as of 19/04/2021:
Null hypothesis: There are no differences in survival rates between the two groups: one-piece milled post and core from (PEKK), and prefabricated fiber posts.

Alternative hypothesis: There are differences in survival rates between the two groups: one-piece milled post and core from (PEKK), and prefabricated fiber posts.

Previous study hypothesis:
Null hypothesis: There are no differences in survival rates between the three groups: one-piece milled post and core from (PEKK), one-piece milled post and core from fiber-reinforced composite blocks and prefabricated fiber posts.

Alternative hypothesis: There are differences in survival rates between the three groups: one-piece milled post and core from (PEKK), one-piece milled post and core from fiber-reinforced composite blocks and prefabricated fiber posts.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/04/2019, The Institutional Review Board of Tishreen University (Tishreen University, Faculty of Dentistry, Department of Fixed Prosthodontics), No. 2164

Primary study design
Interventional

Study design
Randomized two parallel-group clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Damaged endodontically treated lower premolars with two or fewer remaining cavity walls that need post and core

Interventions
Current interventions as of 19/04/2021:
A randomized two parallel-groups clinical trial was designed to evaluate the differences in survival rates between the two groups:

Group 1: one-piece milled post and core from (PEKK)
Group 2: prefabricated fiber posts (control group)

According to the patient identification number, stratified random allocation was performed based on a website (Randomization.com) to achieve balance between groups in size. Double blinding will be used (patient and examiner).

The control group is the group of prefabricated fiber posts.

Previous interventions:
A randomized three parallel-groups clinical trial was designed to evaluate the differences in survival rates between the three groups:

Group 1: one-piece milled post and core from (PEKK)
Group 2: one-piece milled post and core from fibre-reinforced composite blocks.
Group 3: prefabricated fiber posts (control group)

According to the patient identification number, restricted random allocation was performed by blocking with a block length of 3 and 6 based on a the website (Randomization.com) to achieve balance between groups in size. Double blinding will be used (patient and examiner).

The control group is the group of prefabricated fiber posts.

The primary endpoint was the loss of restoration for any reason. Secondary endpoints were tooth loss, post debonding, post fracture, vertical or horizontal root fracture, endodontic or periradicular conditions requiring endodontic retreatment, secondary
caries and failure of core build-up, and loss of restoration because of technical failures. The patients were recalled at 3, 6, and 12 months.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The loss of restoration for any reason, conducted by using of an explorer at 3, 6, and 12 months post-treatment and periapical radiographic examination performed by use of a paralleling technique at 6 and 12 months post-treatment

Key secondary outcome(s)
Conducted by visual inspection at 3, 6, and 12 months post-treatment
1. Tooth loss
2. Post debonding
3. Post fracture
4. Vertical or horizontal root fracture
5. Endodontic or periradicular conditions requiring endodontic retreatment
6. Secondary caries
7. Failure of core build-up
8. Loss of restoration because of technical failures

Completion date
01/12/2021

Eligibility

Key inclusion criteria
1. Patients older than 18 years
2. Patients are required to have one mandibular premolar for which endodontic treatment is indicated
3. The remaining cavity walls of the premolar after endodontic treatment two or fewer
4. No or treated periodontitis with a maximum probing depth of 4 mm and no bleeding on probing
5. Tooth mobility not more than score 1
6. The premolar are required to be in occlusal function with a natural tooth following restoration and none are used as abutments for fixed or removable prostheses
7. A willingness to return for a follow-up examination for at least 1 year

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
24

Key exclusion criteria
1. Tooth will aim to serve as an abutment for fixed or removable prostheses
2. Medical contraindications to dental treatment
3. Poor oral hygiene
4. Teeth with failed endodontic therapy
5. Patients with severe parafunctional habits

Date of first enrolment
01/01/2020

Date of final enrolment
01/09/2021

Locations

Countries of recruitment
Syria

Study participating centre
Tishreen University
Faculty of Dentistry
Lattakia
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Sponsor information

Organisation
Tishreen University

ROR
https://ror.org/04nqts970

Funder(s)

Funder type
University/education

Funder Name
Tishreen University

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 due to confidentiality

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/04/2024	05/03/2024	Yes	No