Safety and effectiveness of carbon fiber reinforced polyetheretherketone (CFR PEEK) implants in patients with bone tumors: an international multicenter retrospective registry

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24588

Source
Nationaal Trial Register

Brief title
CFR PEEK registry

Health condition

Patients with bone tumors

Sponsors and support

Primary sponsor: LUMC
Source(s) of monetary or material Support: LUMC

Intervention

Outcome measures

Primary outcome

Determine the implant safety of CFR PEEK implants in patients with bone tumors using the complication rate according to the Henderson classification at 6 months, 1, 2, 5 and 10 years

Secondary outcome

Determine risk factors for complications

Study description

Background summary

Rationale: Carbon-peek is a novel innovative implant material increasingly used in orthopaedic oncology. Potential advantages are enhanced fatigue strength, high elasticity modulus, absence of scatter artefacts, field inhomogeneity and interference on imaging and improved radiotherapy planning. Because of the increased use of carbon fiber reinforced polyetheretherketone (CFR PEEK) implants we propose to evaluate the safety and effectiveness of CFR PEEK implants in patients with bone tumors.
Objective: Determine the complication rate of CFR PEEK implants in patients with bone tumors according to the Henderson classification at 6 months, 1, 2, 5 and 10 years.
Study design: This is an international multicenter online registry (Castor). Starting from 2010, patients who have received or will receive a CFR PEEK implant will be included retrospectively. According to guidelines as part of good clinical practice, all patients will have a planned follow up at 6 months, 1, 2, 5 and 10 years.
Study population: Patients (≥ 18 years) with a bone tumor that received or will receive a CFR PEEK implant in the participating centers.
Main study parameters: Primary parameter is the complication rate according to the Henderson classification at 6 months, 1, 2, 5 and 10 years. Secondary parameters are used to identify risk factors for complications.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients in this online registry (Castor) will not benefit directly from their participation. Their participation will contribute to improve treatment modalities for future patients with bone tumors. Risks and burden associated with participation can be considered negligible due to the observational nature of this registry.

Study objective

Due to the increased use of CFR PEEK implants and the potential benefits of CFR PEEK over metal we propose to evaluate the safety and effectiveness of CFR PEEK implants in patients with bone tumors in this international multicenter retrospective registry.

Study design

According to guidelines as part of good clinical practice, all patients who received or will receive a CFR PEEK implant at each participating center will have a planned follow-up at 6

months, 1, 2, 5 and 10 years. Data concerning patient-, treatment characteristics and outcome will be collected from the electronic health record and pseudonymized by each participating center every year. Subsequently, all participating centers will enter their pseudonymized data yearly into the CFR PEEK online registry (Castor).

Intervention

In all participating centers, patients will be treated according to standard care. The choice for the use of a CFR PEEK implant will be as is standard for the participating surgeon.

Contacts

Public
LUMC
Zeger Rijs

+31641637074
Scientific
LUMC
Zeger Rijs

+31641637074

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this registry, a patient must meet all of the following criteria. The patient:
• Is aged 18 years or older
• Has received or will receive a CFR PEEK implant
• Is diagnosed with either a primary bone tumor, metastatic bone lesion, soft-tissue sarcoma, benign bone tumor or multiple myeloma.

Exclusion criteria

A potential patient who meets any of the following criteria will be excluded from participation in this study:
• Metabolic bone disease
• History of Paget’s disease or other osteodystrophy’s whether acquired or congenital,

including renal osteodystrophy, hyperthyroidism, hypothyroidism, hyperparathyroidism, Ehrler's- Danlos-syndrome, osteogenesis imperfecta, achondroplasia, tuberculosis.
• History of mental disorder or current psychiatric treatment.
• Infection in the location of the operative site, discitis, osteomyelitis, fever and/or leukocytosis (as diagnosed based on the results of CBC and ESR tests).
• Lack of willingness to make a commitment to return for required follow-up visits.
• Drug and/or alcohol abuse

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-08-2020
Enrollment:	1100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
Data concerning patient-, treatment characteristics and outcome will be collected from the electronic health record and pseudonymized by each participating center. Subsequently, all participating centers will retrospectively enter their pseudonymized data into the CFR PEEK online registry (Castor). Each participating center has access to their own pseudonymized data. A note will be made in the electronic health record of the included patients. The coordinating center (LUMC) is the only center that has acces to the data of all participating centers.

Data will be handled confidentially and in accordance with the Dutch Personal Data Protection Act (in Dutch: Wet Bescherming Persoonsgegevens, Wbp). All participating centers

are responsible for application of local legislation concerning data transfer. In the signed collaboration letters, participating centers will be asked to declare to follow local and European law concerning privacy and data handling.

Any extracted data from the CFR PEEK registry for further analysis will be anonymized. Access to the source data is only possible for the investigator. Participants' name and all personal data will remain confidential at all times and will not be published in any way. However, representative and regulatory bodies (European Communities EU Notified Body Representatives), inspectors, and auditors may have access to medical files to verify authenticity of collected data.

List of data that will be collected:

Baseline

Gender: Male / Female
Age at surgery in years:
Diagnosis:
1 = Osteosarcoma
2 = Chondrosarcoma
3 = Ewing sarcoma
4 = Soft-tissue sarcoma
5 = Metastasis
6 = Benign
7 = Multiple Myeloma
8 =Chordoma
9 =Giant Cell Tumor
10 = Other
Metastasis at side of surgery:
0 = No
1 = Yes
Primary tumor metastasis:
1 = Bladder
2 = Breast
3 = Colorectal
4 = Endometrial
5 = Ewing sarcoma
6 = Head/neck
7 = Kidney
8 = Liver
9 = Lung
10 = Melanoma
11 = Esophagus
12 = Osteosarcoma
13 = Ovary
14 = Prostate
15 = Stomach

16 = Thyroid
17 = Unknown primary
18 = Urothelial cell carcinoma
19 = Other
Pathological fracture:
0 = No
1 = Yes
Tumor grade:
1 = Low
2 = High
Smoking:
0 = No (definition: stopped at least 6 months ago)
1 = Yes
Diabetes:
0 = No
1 = Yes
If Yes; insulin dependent:
0 = No
1 = Yes
Height: In m
Weight: In kg
BMI: In kg/m2
ASA: 1 / 2 / 3 / 4
Neoadjuvant chemotherapy:
0 = No
1 = Yes
Neoadjuvant radiotherapy:
0 = No
1 = Yes
If Yes; neoadjuvant radiotherapy type:
1 = External Beam Radio Therapy (EBRT)
2 = Proton
3 = Carbon ion
4 = Stereotactic RadioSurgery (SRS)
If Yes; neoadjuvant radiotherapy dose: In Gy
Location lesion:
1 = Humerus
2 = Radius
3 = Ulna
4 = Femur
5 = Tibia
6 = Pelvis
7=spine
Location in bone:
1 = Diaphyseal
2 = Metaphysis
3 = Epiphysis

4 = Spine level
Side:
1 = Left
2 = Right
Date of surgery: dd/mm/yyyy
Surgical margin:
1 = Wide
2 = Marginal
3 = Intralesional
Type of resection and reconstruction:
1 = Intralesional, prophylactic plate
2 = En bloc, Allograft segement
3 = En bloc, Allograft hemicortical
4 = En bloc, Free vascularized fibula autograft
5 = En bloc, Free vascularized fibula autograft combined with allograft
Type of osteosynthesis:
1 = Plate
2 = Nail
3 = Posterior stabilization
4 = Posterior stabilization combined with vertebral body reconstruction
Implant localization:
1 = Spine, cervical
2 = Spine, thoracolumbar
3 = Proximal humerus
4 = Diaphyseal humerus
5 = Distal humerus
6 = Proximal forearm
7 = Diaphyseal forearm
8 = Distal forearm
9 = Proximal femur
10 = Diaphyseal femur
11 = Distal femur
12 = Proximal tibia
13 = Diaphyseal tibia
14 = Distal tibia
Number of locking screws plate:
1 = all
2 = >50%
3 = <50%
4 = None
Type of plate:
1= Proximal humerus
2 = Femoral condyl
3 = Diaphyseal narrow
4 = Diaphyseal broad
5 = Standard distal radius
6 = Narrow distal radius

7 = Triangular distal radius
8 = 1/3 tubular
9 = Distal fibula
Type of nail:
1 = Humerus nail
2 = Proximal humerus nail
3 = Proximal femur short nail
4 = Proximal femur long nail
5 = Femoral nail
6 = Tibia nail
7 = Ankle arthrodesis
Autograft:
0 = No
1 = Yes
Allograft:
0 = No
1 = Yes
Cement (PMMA):
0 = No
1 = Yes
Adjuvant chemotherapy:
0 = No
1 = Yes
Adjuvant radiotherapy:
0 = No
1 = Yes
If Yes; Adjuvant radiotherapy type:
1 = External Beam Radio Therapy (EBRT)
2 = Proton
3 = Carbon ion
4 = Stereotactic RadioSurgery (SRS)
Adjuvant radiotherapy regimen:
1 = Multifraction
2 = Single fraction
Adjuvant radiotherapy planning available:
0= No
1= Yes
Adjuvant radiotherapy dose: In Gy
Surgery mechanical failure:
0 = No
1 = Yes
Weight bearing protocol:
0 = No
1 = Yes: 15%
2 = Yes: 50%
3 = Yes: 100%

Complications (Henderson classification is explained at the bottom of this list)

Soft tissue failure Henderson1*:
0 = No
1 = Yes
Henderson type 1 subgroup A or B:
1 = A
2 = B
Date Henderson 1 dd/mm/yyyy
Structural_failure_Henderson2**:
0 = No
1 = Yes
Henderson type 2 subgroup A or B:
1 = A
2 = B
Details:
1 = Breakage through screw hole
2 = Breakage plate
3 = Loosening screws
4 = screw breakage
5 = Bending plate
6 = Other
Date Henderson 2 dd/mm/yyyy
Loosening_Henderson3***:
0 = No
1 = Yes
Henderson type 3 subgroup A or B:
1 = A
2 = B
Date Henderson 3 dd/mm/yyyy
Infection_Henderson4****:
0 = No
1 = Yes
Henderson type 4 subgroup A or B:
1 = A
2 = B
Date Henderson 4 dd/mm/yyyy
Oncological_state_Henderson5*****:
0 = No
1 = Yes
Henderson type 5 subgroup A or B:
1 = A
2 = B
Date Henderson 5 dd/mm/yyyy
Peadiatric_Henderson6******:
0 = No
1 = Yes

Henderson type 6 subgroup A or B:
1 = A
2 = B
Date Henderson 6 dd/mm/yyyy
Revision:
0 = No
1 = Yes
Failure:
0 = No
1 = Yes
Date failure dd/mm/yyyy
Failure reason:
0 = No failure
1 = H1A
2 = H1B
3 = H2A
4 = H2B
5 = H3A
6 = H3B
7 = H4A
8 = H4B
9 = H5A
10 = H5B
11 = H6A
12 = H6B
Reconstruction in situ?
0 = No
1 = Yes
If yes, date reconstruction in situ dd/mm/yyyy
Prosthesis?
0 = No
1 = Yes
If yes, date prosthesis dd/mm/yyyy
Amputation
0 = No
1 = Yes
If yes, date amputation dd/mm/yyyy
Girdleston
0 = No
1 = Yes
If yes, date girdleston dd/mm/yyyy
Alive with no evidence of disease?
0 = No
1 = Yes
If yes, date alive with no evidence of disease dd/mm/yyyy
Alive with disease?
0 = No

1 = Yes
If yes, date alive with disease dd/mm/yyyy
Death of disease?
0 = No
1 = Yes
If yes, date deceased dd/mm/yyyy
Death of other cause
0 = No
1 = Yes
If yes, date deceased dd/mm/yyyy
Date final follow up dd/mm/yyyy
Date last update dd/mm/yyyy

Henderson classification background, criteria and definitions

*Type 1 failure: soft-tissue failure

Allograft soft-tissue failures are subclassified as functional failures and failures of cover based on precedents in the literature. Getty and Peabody reported glenohumeral instability or dislocation in 11 of 16 patients who were treated with an allograft or allograft–prosthesis composite for a proximal humeral tumour. Potter et al reported instability in 18% and 19% proximal humeral osteo-articular allografts and allograft–prosthetic composites, respectively, following resection of a tumour. Wound dehiscence requiring further surgery has also been described. Ramseier et al reported significant wound complications in children undergoing allograft replacement following physeal-sparing surgery, although retention of the graft was achieved in all four patients.

**Type 2 failures: nonunion at the graft–host junction

Nonunion of the allograft–host bone junction is reported to occur in 4% to 50% of cases, making it the most common cause of failure of massive allografts used for limb salvage surgery. Nonunion at this site has been subclassified to reflect the local biological healing capacity of the host, using the terms hypertrophic (type 2A) and atrophic non-union (type 2B), thereby indicating whether an improvement in stability is likely to result in union at the allograft–host junction. Nonunion is affected by radiation therapy and chemotherapy. After the course of chemotherapy is complete, healing should occur. However, radiation has longer-term effects and may reduce healing at the allograft–host junction permanently. Nonunion may not only reflect local biological factors but also the intimacy of the allograft to the host bone, as gapping can prevent healing. Nonunion often manifests as breakage of internal fixation devices due to repetitive micromovement at the junction site. Observations in experimental animals and human trials consistently demonstrate the importance of rigid fixation of the allograft–host junction. Others have reported significantly higher rates of allograft fractures in patients undergoing chemotherapy.

***Type 3 failures: structural failure

Structural failures of allograft occur in 6% to 42% of cases and are usually fractures of the graft. These failures have been subclassified as failure of fixation (type 3A) and fracture of the allograft (type 3B). Failures of fixation typically occur early in the post-operative period, prior to union at the allograft–host junction, and may be treated by revision of the fixation. These failures have been subclassified accordingly. Failures of fixation occurring with an allograft–host nonunion should be considered type 2 failures because fatigue failure is an expected result of nonunion.
Allograft fractures occur both early and late. Typically, early fractures occur at the allograft–host junction; peri-articular fractures can arise at various times. These fractures occur in the subchondral region of the osteo-articular allograft, resulting from subchondral resorption of bone causing inadequate support of the articular surface. These fractures are commonly seen in osteo-articular grafts of the tibia.
Late allograft fractures occur secondary to creeping substitution and revascularization of the graft, typically near or around screw holes. Allografts are devoid of periosteum and undergo little or no remodeling. These fractures may occur many years after the initial procedure. Not all allograft fractures require replacement of the allograft, as some may heal with revision of the fixation and autograft placement.

****Type 4 failures: infection

Allograft infections are subclassified as early (A) and late (B), defined as within or beyond six months of implantation, as described first by Loty et al and later by Donati et al. Most allograft infections are early and caused by Staphylococcus organisms. Donati et al reported a higher rate of late infections than Loty et al. However, 50% of late infections reported by Donati et al occurred after re-operation for allograft fracture, and therefore cannot be considered late infections as defined by Loty et al.
Late infections that occur in patients undergoing revision surgery are commonly observed in those receiving adjuvant chemotherapy or radiation treatment. Treatment of allograft infections generally requires removal of the graft and a two-stage revision procedure using another allograft, a prosthesis, a vascularized autograft or a combination of these implants.

*****Type 5 failures: recurrent disease

Failure caused by recurrent tumour is the type which is most likely to result in amputation or death and is therefore assigned type. Similar to endoprostheses, failures due to recurrent tumour are subclassified according to the site of recurrence owing to differences in the treatment required for each location. Soft-tissue recurrences abutting an allograft (type 5A), which are infrequent, may be treated with revision of the graft without resection of additional bone, whereas bony recurrences, which are more common, require further resection and portend a poorer prognosis, particularly in the presence of a skip lesion. The decision to resect and perform limb salvage or to amputate depends on a number of factors: the presence or absence of metastases, the response to chemotherapy, soft-tissue considerations, and neurovascular involvement.

******Type 6 failures: salvage after failure in paediatric patients

Similar to type 6 paediatric limb salvage failures for endoprostheses, paediatric allograft failures are subclassified as premature physeal arrest (type 6A) and joint dysplasia (type 6B). Allograft reconstruction in adolescent patients in whom one physis must be sacrificed offers the advantage of sparing an adjacent physis. Equal limb lengths can be maintained with contralateral epiphysiodesis. Although higher rates of non -union are not necessarily increased in this patient population, short segment instrumentation around a joint can result in limitation of movement. Functional limitations can occur owing to a limitation of movement at the joint and altered levels for the joint lines.

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL8717
Other	LUMC science commission and METC : LUMC science commission number W2020.06, METC number will follow

Study results