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Short-term results and review of the literature after femoral fractures in patients with total hip replacements

Submission date
19/11/2019

Recruitment status
No longer recruiting

Registration date
14/01/2020

Overall study status
Completed

Last Edited
05/08/2021

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Periprosthetic fractures (Vancouver type B2/B3) after total hip arthroplasty (hip replacement) are an increasing and challenging problem. Only limited evidence is available for this type of fracture treated with modular stems. Therefore, this study evaluated the outcome of Vancouver type B2/B3 fractures treated with a modular hip revision stem using a subproximal/distal anchorage and compared it with the current literature.

Who can participate?
Patients with Vancouver B2 and B3 fractures recorded between 2013 and 2016 and treated with a cementless, modular, fluted, tapered revision stem (Prevision®, B. Braun Aesculap AG, Tuttlingen, Germany)

What does the study involve?
The clinical and radiographic outcomes of patients with femoral fractures around their total hip replacements are evaluated after surgical treatment. Furthermore, complications are evaluated as well. The study involves a clinical examination as well as scores and regular x-rays of the affected hip.

What are the possible benefits and risks of participating?
There are no risks in participating as the follow-up is similar to a regular follow-up in clinic with the benefit of informing the patient and treating possible complications.

Where is the study run from?
Eberhard Karls University Tübingen (Germany)

When is the study starting and how long is it expected to run for?
October 2015 to December 2018

Who is funding the study?
B. Braun, Aesculap

Who is the main contact?
Dr Florian Schmidutz
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
621/2015BO2

Study information

Scientific Title
Hip revision arthroplasty of periprosthetic fractures Vancouver B2 and B3 with a modular revision stem: short-term results and review of literature

Acronym
Prevision

Study objectives
Periprosthetic Vancouver type B2 and B3 fractures are challenging to treat and there is no consent about the stem design and technique. Furthermore, there is only limited number of studies with moderate number of cases for fractures Vancouver type B2 and B3.

The researchers therefore analyzed the outcome of Vancouver B2 and B3 fractures using a cementless, modular revision stem with a subproximal and distal fixation using a modified transfemoral approach. The aim was to show that the modular revision stem inserted via a transfemoral approach would lead to good or at least comparable results in terms to fracture

healing, fixation of the stem, subsidence and functional outcome compared to stems with proximal fixation and the current literature.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/10/2015 by the local ethics committee at the Faculty of Medicine at the Eberhard Karls University and the Medical Center, Tübingen (Gartenstrasse 47, 72074 Tübingen, Germany; Tel: +49 (0)7071 29-77661; Email: ethik.kommission@med.uni-tuebingen.de), ref: 621/2015BO2

Study design
A consecutive series of periprosthetic Vancouver type B2/B3 fractures treated with a modular revision stem via a modified transfemoral approach was retrospectively (2013-2016) evaluated (observational study).

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Orthopaedic surgery: Vancouver B2/3 periprosthetic fractures

Interventions
A consecutive series of periprosthetic Vancouver type B2/B3 fractures treated with a modular revision stem via a modified transfemoral approach was retrospectively (2013-2016) evaluated. The assessment included the clinical (HHS, pain, ROM) as well as the radiological outcome (subsidence, loosening, fracture healing).

Intervention Type
Procedure/Surgery

Primary outcome(s)
Clinical and radiological outcome, measured using the Harris Hip Score and a regular clinical examination comprising palpation of the site as well as evaluation of ROM (range of motion) and standardized radiographs of the affected hip in two planes at the time of the patients' individual postoperative follow-up

Key secondary outcome(s))
Complications, measured by analyzing clinical and radiological outcome combined with data from the digital clinical information charts regarding subsequent surgeries as well as any kind of complication occurred for the duration of the study

Completion date
31/12/2018

Eligibility

Key inclusion criteria
All consecutive Vancouver B2 and B3 fractures that were recorded between 2013 and 2016 and treated with a cementless, modular, fluted, tapered revision stem (Prevision®, B. Braun Aesculap AG, Tuttlingen, Germany) were included and retrospectively analyzed. The patients who could be contacted were examined clinically and radiologically within the study.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
18

Key exclusion criteria
1. Insufficient data or follow-up at less than 3 months
2. Patients who suffered from dementia
3. Insufficient knowledge of the study language
4. incapable of participating in the study due to severe health conditions

Date of first enrolment
01/01/2016

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
Germany

Study participating centre
BG Trauma Center Tübingen,
Department of Arthroplasty
Eberhard Karls University Tübingen
Schnarrenbergstrasse 95
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72076

Sponsor information

Organisation
BG Trauma Center Tübingen

ROR
https://ror.org/04wwp6r22

Funder(s)

Funder type
Industry

Funder Name
B. Braun, Aesculap

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Florian Schmidutz (fschmidutz@bgu-tuebingen.de) and Dr Anna J. Schreiner (annajschreiner@yahoo.de). The data comprises Excel spreadsheets, consent from participants was obtained.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/08/2020	05/08/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes