Fixation of custom 3D metal printed pelvic implants. A Clinical RSA study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22611

Source
Nationaal Trial Register

Brief title
RSA-FOCIS

Health condition

Pelvic defects

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

The primary outcome is migration assessment of the 3DPI implant, measured with model-based RSA. Migration is defined as movement (mm / degrees) of the component along and about the three orthogonal axes (x-, y- and z-axes) for translation and rotation. Migration

patterns are obtained/calculated at 2 years (short-term), 5 and 10 years (mid-term) and 20 years (long-term).

Secondary outcome

Clinical parameters

• Patients demographics: age, gender, weight, length, BMI, indication for surgery, Charnley score, pelvic/hip medical history; previous surgery.
• Hip range of motion will be recorded during routine pre- and postoperative follow-up and noted according to common ROM examination: Flexion/Extension, Abduction/Adduction, Internal rotation/External rotation.
• If 3DPI for tumour; tumour and oncological related characteristics: Enneking tumour stage, tumour histology, tumour resection margins, (neo) adjuvant therapy, local recurrences, metastatic status pre and post-operatively, patient survival.
• Surgical data: Type/location of pelvic resection (according to Enneking pelvic resection classification), surgery date, surgical time, blood loss, transfusion requirements.
• Implant specifics: details and type of 3DPI (as described in paragraph 7.1), if applicable: type, make and fixation of used acetabular shell and femoral stem (including bearing materials and head size).
• Complications
o Implant specific complications / (serious) adverse events and patient survival will be recorded according to appearance, severity and management.
o For tumour related cases, the Henderson complication classification (53) will be used.
• 3DPI Revision/mechanical failure; type of revision (total, partial), date, reason for revision.
o A 3DPI revision/mechanical failure will be classified as any operative amendment to the implant, replacement of screws, change of any arthroplasty component or removal/exchange due to (a)septic loosening of the implant.

Radiological parameters
Based on pre-operative x-ray and CT scan:
• For THA revision cases: Paprosky acetabular defect classification score (41)
Based on post-operative x-rays:
• 3DPI implant status: intact screws, signs of loosening based on gross implant migration, acetabular/femoral periprosthetic osteolysis according to the DeLee and Charnley zones (54).

PROMS

Study description

Background summary

Patient specific custom designed and 3D metal printed implants (3DPI) offer an innovative alternative approach to the management of large bone defects in the pelvic area. The latter

are a challenge for reconstruction after extended bone tumour resections or after revision of failed implants at the hip region. Furthermore, high failure rates are reported with current available reconstructions methods. Due to technological advances, large and complex 3DPI designs are now readily available to be used as a reconstructive alternative in pelvic tumour and total hip arthroplasty revision surgery. Early results are promising and multiple centers worldwide have adopted this new technique in recent years (1–10).

Since no innovation should be done without evaluation, the new medical device regulations (MDR) in Europe, impose strict / high standards using clinical evidence on existing implants and on new orthopaedic implant before their market introduction. In the past, the ODEP (Orthopaedic Data Evaluation Panel) and the Dutch Orthopaedic Association (NOV) defined benchmarks, with maximum rates of revision for any hip (cup or stem) and knee implant. This has been adopted by The European Federation of National Associations of Orthopaedics and Traumatology (EFORT) recently. The benchmark of excellent implant performance is defined as a revision percentage, for any reason, below or equal to 10% after 10 year. Because a period of 10 years is too long to introduce new implants in a safe way, other methods can be used which on short term have a high predictive value for long-term failure. Measurements of early micromotion of the implant within the bone, with an accuracy of 0.1mm has such predictive value. The current gold standard for micromotion measurements is RSA (11,12). A safer way of introducing new implants to the market was already proposed in 1995, where RSA studies are performed after pre-clinical testing, but before general market introduction (13). The short-term RSA results are a prognostic value for long term failure for a-septic loosening (14–17). For that matter, the NOV issued a guideline in 2011 that new hip arthroplasty designs should only be used if clinical Radio Stereometric Analysis (RSA) data are available, or when the new design is part of a clinical RSA study (18–21).

In the light optimal patient care, development of new techniques and innovations like 3DPI’s should obviously be encouraged, but the introduction also closely monitored and evaluated with techniques available for this purpose. Custom 3D metal printed implants are not, but will be subjected to more strict implant criteria set by the EU (MDR effective since July 2018 with transition up to May 2020). In order to improve patient safety, the new MDR anticipates to regulate and quantify the quality of custom 3D metal printed implants. In the light of implant fixation and long-term survival, there is a need to assess primary and secondary fixation by evaluating three-dimensional migration patterns of these implants within the bone by means of RSA. This ought to be done in addition to and in combination with the evaluation of clinical, standard radiological and patient reported outcome measures.

Study objectives: The primary objective of this clinical study is to determine and evaluate the short-, mid- and long-term migration patterns of custom 3D metal printed pelvic implants by means of Radio Stereometric Analysis combined with clinical, standard radiological and patient reported outcome measures (PROMS) results.

Study design: single center prospective cohort study

Study population: all patients eligible for treatment with a custom 3D metal printed pelvic implant (3DPI).

Intervention: Evaluation of a custom 3D metal printed pelvic implant (3DPI) with RSA (i.e.

implant migration software using tantalum markers as bone markers) t.

Main study parameters:
Primary Objective:
The primary objective of this study is to evaluate the short, mid and long-term migration patterns, of custom 3D printed pelvic implants and mechanical loosening patterns.

Secondary Objective:
The secondary objective is to evaluate clinical (e.g complications), radiological (CT) and PROMS outcome of 3D printed pelvic implants.

Study objective

Similar or better fixation, migration and functional outcomes compared to other existing techniques

Study design

Investigation Pre-operative Pre-discharge 6w 3m 6m 12m 24m yearly thereafter
RSA X-ray x (*) x (*) x (*) x (*) x (*) x (*) x (*)
Pelvic CT scan x x
Standard pelvic/hip X-ray
AP + Lateral x x x
Anchor question x (*) x (*)
NRS rest + activity x (l) x (l) x (*) x(l) x (*) x (*)
EQ-5D-5L x (l) x (l) x (*) x (l) x (*) x (*)
Tumour pts:
MSTS x (*) x (*) x (*) x (*) x (*) x (*)
All other pts:
HOOS-PS, OHS X (L) X (L) x (*) X (L) x (*) x (*)

Intervention

3d titanium printed pelvic implant

Contacts

Public
LUMC
Demien Broekhuis

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Scientific
LUMC

Demien Broekhuis

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Eligibility criteria

Inclusion criteria

• Patients eligible to be treated with a 3DPI for:
o Pelvic tumour resection
o Failed total hip arthroplasty with Paprosky type 2C, 3A and 3B defects
o Severe acetabular bone loss due to other reasons with Paprosky type 2C, 3A and 3B defects

• Patients aged 18 years and older
• Patient is able and willing to consent and participate in the study by signing and dating and IRB-approved consent form
• Patient is willing to attend the follow-up evaluations at the LUMC (these evaluations will take place during regular clinical follow-up moments), for a minimum of two years post-operatively.

Exclusion criteria

Primary exclusion criteria:
• Patients who are unable or unwilling to cooperate in routine follow-up program
• Patients who are mentally or cognitively disturbed
• No written and signed Informed Consent
• Active local or systemic infection
• Insufficient Dutch language proficiency

Secondary exclusion criteria:
• Insufficient or poorly distributed RSA markers visible on baseline RSA radiographs which does not improve after repositioning the patient (2 attempts): the patient will be excluded from the RSA study, but patients will have regular clinical follow-up.

Study design

Design

Study type: Interventional

Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-08-2020
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	05-08-2020
Application type:	First submission

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	NL8816
Other	METC : P19.095 / NL71635.058.19

Study results