Accuracy of Patient Specific Guides for Revision of unicompartmental knee arthroplasty to total knee arthroplasty.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22396

Source
Nationaal Trial Register

Brief title
PSG, UKA

Health condition

The total cohort consisted of 22 patients who have been operated for revision of Oxford UKA with the use of PSG (Signature, Biomet, Warsaw, IN, USA) between October 2010 and October 2014. The data of 10 patients who had a postoperative CT-scan will be indeed included for analysis. All patients were pre-operatively planned with the UKA in situ.

Sponsors and support

Primary sponsor: n.a.
Source(s) of monetary or material Support: n.a.

Intervention

Outcome measures

Primary outcome

Angular component position and absolute deviations of angular component position in three planes from pre-op planning will be determined as well as translational component position along the three axes of the bone and absolute deviations of the planned translational component position.

Secondary outcome

PROMs were obtained pre- and 12 months postoperative including the Dutch validated Oxford Knee Score (OKS; 12 to 60, 12 being the best outcome), Western Ontario and McMaster Universities Arthritis Index (WOMAC; 0 to 100, 100 being the best outcome) and the EuroQol-5D (EQ-5D; 0 to 1, 1 indicates the best health state). Experienced pain was measured by a Numerical Rating Scale (NRS, 0 to 10, 10 being ‘worst pain’).

Study description

Background summary

In het Zuyderland Medisch Centrum, voorheen Orbis MC zijn tussen oktober 2010 en oktober 2014, 22 halve knie prothese gereviseerd naar een totale knie prothese middels de Signature techniek. In de literatuur zijn er weinig tot geen duidelijke gegevens over deze techniek m.b.t. revisies met Signature.

Doormiddel van dit onderzoek willen wij gaan kijken naar de accuraatheid van deze operatie techniek. Er wordt primair gekeken naar de uitlijning van de prothese en secundair naar de kliniek en het functioneren van de patiënten in het dagelijkse leven. Dit willen wij gaan bereiken door de gegevens uit de digitale patiënten dossiers te halen, de vragenlijsten en het radiologische onderzoek te analyseren..

Gezien het retrospectieve karakter van het onderzoek, zijn wij van mening dat het een niet WMO plichtig onderzoek is waarbij patiënten op geen enkele manier belast zullen worden.

Study objective

The hypothesis of this study was that the Oxord UKA will not hamper the accuracy of the CT-based PSG for TKA during revision surgery to restore biomechanical limb alignment and prosthetic component positioning as calculated by the software and the actual alignment in vivo after knee surgery with limited percentages of outliers.

Study design

n.a.

Intervention

Pre-operative CT-scanning of the hip, knee and ankle was performed 6 weeks prior to surgery according to the standard Signature scanning protocol. Software (Mimics, Materialise NV, Leuven, Belgium) was used to create virtual three-dimensional models of femur and tibia. The program was used to determine appropriate implant size and positioning of the knee prosthesis (Vanguard™ Complete Knee System, Biomet, Inc., Warsaw, IN) for each patient individually. A digital, virtual plan of the proposed perioperative positioning was sent to the surgeon. The surgeon was able to adjust the digital plan when deemed necessary. After approving the digital plan, guides for perioperative use were manufactured using a rapid prototype engineering technique. Intraoperatively, the practical form and fit of the guides and all perioperative changes from the pre-operative plan (level of resection, size of prosthesis) are registered in the patients digital operative record.

Contacts

Public
Department of Orthopedic Surgery, Orbis Medisch Centrum
dr H vd Hoffplein 1
M.G.M. Schotanus
Geleen 6162 BG
The Netherlands
+31 (0)88 4597823
Scientific
Department of Orthopedic Surgery, Orbis Medisch Centrum
dr H vd Hoffplein 1
M.G.M. Schotanus
Geleen 6162 BG
The Netherlands
+31 (0)88 4597823

Eligibility criteria

Inclusion criteria

Patients initiated for revision of the Oxford implant.

Exclusion criteria

n.a.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2016
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	26-04-2016
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	NL5691
NTR-old	NTR5835
Other	- : METC 16N96

Study results