First exprerience with patient specific custom made total knee allignment guides compared with conventional intramedullary alignment method for total knee arthroplasty.

Gepubliceerd: 08-12-2011 Laatst bijgewerkt: 18-08-2022

We expected operation time and blood loss to be lower in the SPPC group. Alignment, in terms of percentages of outliers, was expected to be superior in the SPPC group, compared to the conventional intramedullary alignment technique.

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27913

Bron
NTR

Aandoening

total knee arthroplasty, allignment, blood loss, patient specific custom made guide,operation time

Ondersteuning

Primaire sponsor: NP Kort, Orthopedic Surgeon (MD, PhD)
Orthopedic Department, Orbis Medisch Centrum
dr H van de Hoffplein 1
6162 BG Geleen, the Netherlands
Overige ondersteuning: self-funded study: fund = provider = Sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Alignment, in terms of percentages of outliers, was expected to be superior in the SPPC group, compared to the conventional intramedullary alignment technique.

Long leg standing x ray:
1. Mechanical axis (both preoperative and post-operative) = angle between the mechanical axis of femur and tibial mechanical axis.
How to measure: Center of rotation of the femoral head (just center of the femoral head on long leg standing x-ray) to center (middle) of distal femur (= femoral mechanical axis) and center (middle) tibial plateau to the center (middle) of the thalus (= mechanical axis-tibia). Here are two angles whose sum is 360 degrees.
Example: The system will give an angle of 182gr and 178gr medial-lateral. Then please note the angle of 178gr. This means that the patient has a 2 degree varus long leg standing x-ray;
2. State of the individual components relative to the femur and tibia mechanical axis of femur and tibia.
Femur: Pulling together on distal condyles of femoral component. Then draw lines previously drawn line for mechanical axis of the femur.
Tibia: line drawing below the tibial plateau. Then draw lines previously drawn line for mechanical axis of the femur.
In both cases there is an additional angle of. Important: Again, like the medial corner record! (See picture).
Ex.: The system provides for the femoral component angle of 87 degrees from 93 degrees laterally and medially. So then like angle of 93 degrees recorded. This means in this case the femoral component in valgus is 3 degrees with respect to the mechanical axis of the femur.
On the lateral picture:
3. Femoral component position relative to anterior cortex.
How to measure: Line through distal femoral component. Tangent of the anterior femoral cortex. Coming back from two angles that are supplementary;
4. Posterior tibial cortex relative position tibiacomponent.
How to measure: Line at the bottom of tibiacomponent. Tangent to posterior tibial cortex. Coming back from two angles that are supplementary.

Toelichting onderzoek

Achtergrond van het onderzoek

Our first 40 consecutive cases and the preliminary results with this new technique will be compared to a matched control group, using conventional intramedullary alignment technique. We expected operation time and blood loss to be lower in the SignatureTM Personalized Patient Care SPPC group. Alignment, in terms of percentages of outliers, is expected to be superior in the SPPC group, compared to the conventional intramedullary alignment technique. All patients were operated by one surgeon in one Dutch Hospital.

Doel van het onderzoek

We expected operation time and blood loss to be lower in the SPPC group. Alignment, in terms of percentages of outliers, was expected to be superior in the SPPC group, compared to the conventional intramedullary alignment technique.

Onderzoeksopzet

6 weeks post operative measurement on x-rays.

Onderzoeksproduct en/of interventie

Recently, a patient specific alignment guide, SignatureTM Personalized Patient Care (SPPC) (Biomet, Inc., Warsaw, IN) was developed, based on a preoperative MRI-scan of the patient's leg. With this alignment guide the intramedullary cavity is not opened, eliminating the risks associated with it. Besides, the new technique theoretically eliminates most disadvantages associated with intraoperative navigation.

Contactpersonen

Publiek

Orthopedic Department, Orbis Medisch Centrum
dr H van de Hoffplein 1
B. Boonen
Geleen 6162 BG
The Netherlands

Wetenschappelijk

Orthopedic Department, Orbis Medisch Centrum
dr H van de Hoffplein 1
B. Boonen
Geleen 6162 BG
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Forty knees in 39 patients (25 women, 14 men) were operated on by means the SPPC procedure between December 2009 and March 2010 and were eligible for inclusion in this case control study. Patients scheduled for primary total knee replacement for osteoarthritis were included.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients with a body-mass-index above 35, patients with active infection, either in the knee or general infection, patients with a history of osteotomy and patients with metal near the knee joint were excluded.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2011
Aantal proefpersonen:	80
Type:	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3054
NTR-old	NTR3202
Ander register	Orbis Medisch Centrum : 2010NK01
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
http://www.ncbi.nlm.nih.gov/pubmed/22880715

http://informahealthcare.com/doi/pdf/10.3109/17453674.2012.711700