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

No registrations found.

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

Summary

ID

NL-OMON27913

Source
NTR

Health condition

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

Sponsors and support

Primary sponsor: NP Kort, Orthopedic Surgeon (MD, PhD)
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Source(s) of monetary or material Support: self-funded study: fund = provider = Sponsor

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

We expected operation time, blood loss and hospitalization to be lower/shorter in the SPPC group than in the conventional total knee alignment group.

Study description

Background summary

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.

Study objective

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.

Study design

6 weeks post operative measurement on x-rays.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2011
Enrollment:	80
Type:	Actual

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	NL3054
NTR-old	NTR3202
Other	Orbis Medisch Centrum : 2010NK01
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

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

