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The effect of total knee arthroplasty (replacement) with the flexion first balancer or measured resection technique

Submission date
07/04/2021

Recruitment status
No longer recruiting

Registration date
23/04/2021

Overall study status
Completed

Last Edited
13/01/2022

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Knee replacement surgery (arthroplasty) is a common operation that involves replacing a damaged, worn or diseased knee with an artificial joint. Adults of any age can be considered for a knee replacement, although most are carried out on people between the ages of 60 and 80.

With the use of a new technique, Flexion First Balancer (FFB), we are able to restore the joint line to its predisease level. We expect better functional outcome for these patients when we compare them to a matched patient group who were operated using the conventional technique, i.e. Measured resection (MR).

The difference between the two techniques is that in MR technique, a standardized amount of bone is resected to accommodate the knee prosthesis. First in extension these bone cuts are made and then in flexion. Resulting in an equal flexion and extension gap and therefore creating a stable knee prosthesis. Since the native medial and lateral side of the knee are not the same this might result in standard error with slight elevation of the joint line as a consequence.
In the Flexion First Balancer technique the bone cuts are first made in flexion and are dictated by the medial collateral ligament tension and therefore restores the medial knee anatomy. Later this flexion gap is copied to the extension gap and these extension cuts are dictated by the natural ligament tension of the knee. Therefore a more natural placement of the knee is possible which might benefit the patient.

Who can participate?
Patients who underwent TKA surgery via the FFB technique for Kellgren-Lawrence grade 3-4 osteoarthritis between September 2015 and November 2016, and patients who were operated on using the standard MR technique between September 2014 and July 2015

What does the study involve?
Two additional X-rays will be made to assess midflexion instability. Furthermore, three functional tests (6 minute walk test, stair climb test, static Quadriceps power test) will be conducted to examine functional outcome.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Amphia Hospital in Breda (the Netherlands)

When is the study starting and how long is it expected to run for?
August 2018 to June 2019

Who is funding the study?
Amphia Hospital Wetenschapsfonds (Science-funding) (the Netherlands)

Who is the main contact?
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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
W18.007

Study information

Scientific Title

Midflexion Instability and Functional Outcome after total knee arthroplasty: flexion first balancer versus measured resection technique. The MIFO study

Acronym
MIFO

Study objectives
Since the FFB technique restores the joint line to its pre-disease height this would result in less coronal mid-flexion laxity. Which, in turn could result in better functional outcome compared to the standard MR technique due to increased stability in the knee.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/09/2018, MEC-U (Koekoekslaan 1, Nieuwegein, 3430 EM, Netherlands; +31(0) 306093580; info@mec-u.nl), ref: NL65535.100.18

Study design
Cross-sectional cohort study single centre

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Total knee replacement for osteoarthritis

Interventions
This cross-sectional study has compared a group of patients operated with the Flexion First Balancer technique to a matched group who were operated using the conventional technique (Measured Resection).
Two additional X-rays were made with either varus or valgus stress in 30 degrees of flexion to assess midflexion instability.
Futhermore, three functional tests (6 minute walk test, stair climb test, static Quadriceps power test) were conducted to examine the functional outcome.

The mean time from TKA was: Follow up, mean (sd) 3.9 yrs (0.2) 2.6 yrs (0.4)
The investigation duration was 1 hour per person.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Mid flexion laxity measured in millimetres on the medial or lateral side with either valgus or varus stress in 30 degrees of knee flexion measured at mean 3.9 years for the Measured resection group and a mean 2.6 years for the Flexion First Balancer group

Key secondary outcome(s))
Functional outcomes measured at mean 3.9 years for the Measured resection group and a mean 2.6 years for the Flexion First Balancer group:
1. 6 minute walk test
2. Stair climb test
3. Static Quadriceps power test

Completion date
01/06/2019

Eligibility

Key inclusion criteria
1. Patients who underwent TKA surgery via the FFB technique for Kellgren-Lawrence grade 3-4 osteoarthritis between September 2015 and November 2016
2. A historical matched cohort of patients who were operated on using the standard MR technique between September 2014 and July 2015 was used

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
55

Key exclusion criteria
1. Ill health
2. Degenerative diseases (e.g. rheumatoid arthritis) or development of severe osteoarthritis influencing functional test outcomes
3. Complications requiring consecutive surgery
4. Hip replacement or contralateral TKA within the past year.

Date of first enrolment
01/09/2018

Date of final enrolment
01/04/2019

Locations

Countries of recruitment
Netherlands

Study participating centre
Amphia Hospital
Molengracht 21
Breda
Netherlands
4818 CK

Sponsor information

Organisation
Amphia Ziekenhuis

ROR
https://ror.org/01g21pa45

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Amphia Ziekenhuis

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		09/12/2021	13/01/2022	Yes	No
Participant information sheet	version v3	09/08/2018	04/05/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes