

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

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<b>Registration date</b> 23/04/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/01/2022	<b>Condition category</b> Surgery	<input type="checkbox"/> 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?

W. van Lieshout, wvanlieshout@gmail.com

## Contact information

**Type(s)**

Public

**Contact name**

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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

## **Secondary study design**

Cohort study

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

See additional files (in Dutch)

## **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.

Furthermore, 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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

01/08/2018

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

60

**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

**Sponsor details**

Amphia Wetenschapscommissie

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**Sponsor type**

Research council

**Website**

<https://www.amphia.nl/opleiding-en-wetenschap/wetenschap/indieningsproces-wetenschappelijk-onderzoek>

**ROR**

<https://ror.org/01g21pa45>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Amphia Ziekenhuis

## Results and Publications

**Publication and dissemination plan**

Planned publication in high -impact peer-reviewed journal.

**Intention to publish date**

01/05/2021

**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?
<a href="#">Participant information sheet</a>	version v3	09/08/2018	04/05/2021	No	Yes
<a href="#">Results article</a>		09/12/2021	13/01/2022	Yes	No