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Comparing functional recovery after custom or standard total knee replacement

Submission date
28/01/2021

Recruitment status
No longer recruiting

Registration date
22/02/2021

Overall study status
Completed

Last Edited
15/01/2025

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Knee osteoarthritis (OA) is a common degenerative process of the joint that occurs with age. Knee OA often results in joint pain, stiffness, and restricted movement. Patients are often advised to participate in regular exercise, wear suitable footwear, lose weight if they are overweight, and reduce the strain on the affected joints. If these methods are not effective patients may require joint replacement surgery to replace the joint.

Currently, total knee replacement (TKR) procedures use a one-size-fits-most design for the implanted joint as the standard of care. Previous studies suggest that while the function of the knee improves following these operations, patients do not achieve normal movement patterns. The knee is a complex joint and the patient's individual anatomical characteristics of the knee are not replicated in conventional off-the-shelf implant designs. In contrast, custom implant designs have been developed which match a patient’s anatomical structure to maximize the recovery of the function of the knee.

However, there is currently a lack of information regarding the recovery after a custom total knee replacement. The aim of this study is to determine if there are any differences in the recovery of joint movement and muscle activation patterns between patients who receive a standard implant or a custom implant during their TKR procedure. Knee function after surgery will also be compared to healthy volunteers who have not had a TKR.

Who can participate?
Adult healthy volunteers and adults due to undergo total knee replacement on a single knee due to osteoarthritis

What does the study involve?
Participants who are due to undergo a total knee replacement (TKR) procedure will be allocated randomly to one of two groups, with an equal chance of being in either group (like tossing a coin). Participants and researchers will not have a choice in the treatment given. One group will receive a non-customized (off-the-shelf) TKR which is the current standard of care. The

participants allocated to the other group will receive a custom TKR produced by Symbios. A further group of healthy volunteers, who do not require a total knee replacement, will also be included for comparison.

The patients receiving TKRs will undergo X-rays and CT scans prior to the operation in order to guide the placement and alignment of the TKR, as well as to guide the design for the custom TKR. TKR participants will be invited to attend three testing sessions at Edge Hill University (EHU) biomechanics laboratory, once before the procedure, and 3 and 12 months following the procedure. At each of the testing sessions, participants will participate in a variety of tasks based on activities of daily life which will be assessed under a 3D motion capture system. Participants will also be assessed for their range of motion and report on their pain, knee function, confidence in using their knee, and quality of life at each session.

The group of healthy volunteers will attend two testing sessions, where the same assessments will take place, no more than six weeks apart. Each testing session will last for approximately 2 h and assistance will be provided in making travel arrangements.

What are the possible benefits and risks of participating?
Participants may not directly benefit from the study, but they and others may benefit in the future as the findings will inform potential treatment pathways in the future. The disadvantages in agreeing to take part in this study are that of time commitment in attending Edge Hill University and completing the tests. There is a potential risk of falling whilst undertaking the testing however, handrails will be in place for all tasks to help to reduce this risk.

Where is the study run from?
Wrightington Hospital and Edge Hill University Biomechanics Laboratory (UK)

When is the study starting and how long is it expected to run for?
From October 2019 to November 2024

Who is funding the study?
Symbios (Switzerland), the John Charnley Trust (UK), and Wrightington Wish (UK)

Who is the main contact?
Prof Tim Board, Tim.N.Board@wwl.nhs.uk

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
268866

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 45597, IRAS 268866

Study information

Scientific Title
The Origin Study: A randomised control trial comparing functional recovery after custom or standard total knee replacement

Acronym
Origin Knee

Study objectives
Custom Total Knee Replacement (TKR) will result in faster and larger magnitudes of functional recovery compared to off-the-shelf TKR, resulting in more normal joint motion and loading patterns during walking and functional activities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/05/2020, North of Scotland Research Ethics Committee 1 (Summerfield House, 2 Eday Road, Aberdeen AB15 6RE; +44 (0)1224 558458; gram.nosres@nhs.scot), ref: 20/NS/0057

Study design
Double-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
This study will use a double-blinded (participants and assessors at EHU), randomised control trial using a qualitative, experimental design to investigate:
1. How does functional recovery (joint movement and loading, and muscle activation patterns) compare after standard off-the-shelf or custom total knee replacement (TKR) during walking and activities of daily living?
2. How do joint movement and loading patterns compare between individuals who have undergone TKR and healthy controls during walking and activities of daily living?
3. How do muscle activation patterns compare between individuals who have undergone TKR and healthy controls during walking and activities of daily living?

Additionally, a test-retest research design will be used to answer the following research questions:
1. How valid and reliable are knee joint angles recorded by the myrecovery.ai app?
2. How reliable is 3D movement analysis during walking and activities of daily living?
3. What are the smallest differences 3D motion analysis can accurately detect during walking and activities of daily living?

The study team aims to recruit 50 TKR patients to be split equally between standard off-the-shelf and custom implant groups, and 25 age and gender-matched healthy controls to provide an additional control group for the study, to which the TKR groups can be compared to help determine the extent to which joint motion, loading, and muscle activation patterns return to normal post-operatively for each group.

Once patients have provided consent for the study they will be randomly allocated to either the standard off-the-shelf or custom implant groups using an online randomisation and stratification tool (www.sealedenvelope.com) which has been used extensively for medical research. Patients will be assigned to each group will be matched as best as possible for gender, age (<55 years, 55–75 years, >75 years), and previous surgery (total hip replacement or opposite side TKR).

The need for surgery and thus potential eligibility for inclusion within the TKR groups within the study will be determined by orthopaedic clinicians within clinics at the participating NHS Trust using a conventional clinical examination (pain, observational motion, and stability assessments) alongside radiographic images. Participants within both TKR groups will undergo 2 X-Ray (lateral and anterior-posterior) assessments pre-and post-operatively and a low dose CT scan for surgeons to plan the surgical procedure and for the custom TKR to be designed and manufactured (pre-operatively only). Participants within both TKR groups will receive cemented implants, with patella resurfacing in-line with standard practice at the participating NHS Trust. Those within the standard off-the-shelf TKR group will receive an Attune PS total knee replacement manufactured by DePuy Synthes, and those within the custom TKR group will receive a custom Origin implant manufactured by Symbios Orthopaedics. The TKR operation will be performed using standard surgical technique and typically takes approximately one hour. Participants will receive the standard care provided at the participating NHS Trust. During the TKR operations, patients will be asked to wear either earplugs or their own headphones to reduce the chance of them becoming aware of which implant they are receiving, enabling the double-blinding of the study.

Those within each TKR group will be invited to attend 3 testing sessions at the biomechanics laboratory at EHU. These sessions will be scheduled pre-operatively, and 3 and 12 months post-operatively. The healthy control group will be invited to attend 2 testing sessions, no more than 6 weeks apart. Basic information about the participants (age, gender, height, and weight) will be recorded at each testing session, to provide descriptive information about the study population.

Participants within the two TKR groups will be asked to complete the Oxford Knee Score, Forgotten Joint score-12, EuroQol 5-dimension (EQ5D) quality of life questionnaire, and the Activities Specific Balance Confidence (ABC) scale. The scores are well-recognised and well-validated self-completed measures of patient's quality of life, levels of pain, and function relating to activities of daily living. Participants will also be asked to indicate which TKR they believe they have received at each post-operative testing session.

Participants from all groups will be asked to complete the following five tasks associated with daily living; walking, turning, sit-stand-sit, stair ascent and decent, and kneeling (where able). During the walking task, participants will be asked to walk barefoot along a 7 m long walkway

from one chair to another, with support rails alongside the walkway at a self-selected speed. For the turning task, participants will be asked to walk 3.5 m and perform a 180° turn and walk back to where they started. During the sit-stand-sit task, participants will be asked to stand from a seated position, pause briefly and then sit back down. Chair height will be standardised to 45 cm, as this is the typical height of chairs in the UK. Participants will be free to use the arm rest to rise or sit as required. The stair ascent and decent tasks will involve participants walking up a flight of four steps (18 cm depth), with handrails, turning around at the top, and walking back down the same four steps. Participants will be free to use the handrails as they wish and to perform the movement in their own time. The kneeling task will involve participants starting in a standing position and lowering themselves down into a kneeling position, so that one knee is positioned on top of a force plate covered with a foam cushion for comfort. This task will only be undertaken if the participant is comfortable and able to do so. Participants will be asked to complete 6 successful trials per leg during the walking and turning tasks, and 6 successful trials for the sit-stand-sit, stair ascent and decent, and kneeling tasks. A successful trial will be defined as one in which all markers are visible at the beginning and end of the movement, with minimal marker loss throughout.

Four measures will be used to quantify dynamic lower limb function. A 3D motion capture system will be used to track the position of retro-reflective markers, from which hip, knee, and ankle joint motion patterns can be calculated. Specifically, markers will be attached to the following locations using double-sided tape; front and back of the pelvis, inside and outside of the knee's and ankle's, heel, base of the little toe, base of the big toe, and on top of the foot. Clusters (groups) of markers will be placed on the outside of the thigh and lower leg and secured using elasticated bandages. To aid marker placement participants will be asked to wear shorts for the duration of the testing session, these can be provided by the research team at EHU where required. Ground reaction force data will be recorded using two force plates located in the centre of the walk way. Tri-axial accelerometers will be used to record the accelerations of the pelvis, thigh, and lower leg during each of the tasks. Additionally, the activity of the quadriceps and hamstring muscles will be quantified using electromyography (EMG). For this, small boxes which record the electrical activity within a muscle will be attached to the participant using double-sided tape.

Participants will also be asked to maximally bend and straighten their knee joint while lay on a massage bed during each testing session to enable the range of motion available at the knee to be measured. Knee joint range of motion will be quantified using both the 3D motion capture system, described above, and a mobile phone application. Two-dimensional knee joint movement patterns will be calculated by an algorithm developed by myrecovery.ai from a video recorded of the participant (from the shoulders down). The mobile phone will not have a sim card and will be used solely for the purpose of this study.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Perceptions of pain and joint function measured using the following at baseline, 3 and 12 months for those receiving total knee replacement (TKR):
1.1. Oxford Knee Score numerical rating scale
1.2. Forgotten Joint Score-12 questionnaire
1.3. EuroQol 5-dimension (EQ5D) quality of life questionnaire
1.4. Activities and Specific Balance Confidence Scale (ABC) numerical rating scale
1.5. Question asking which TKR they believe they have received

2. Dynamic function measured using the following at baseline, 3 and 12 months for those receiving total knee replacement (TKR), and baseline and 6 weeks for healthy controls
2.1. Hip, knee, and ankle joint motion and loading during walking, sit-to-stand, and stair ascent and descent movement tasks recorded by a 3D motion capture system
2.2. Ground reaction force data recorded using two force plates
2.3. Segmental accelerations throughout the movement tasks recorded by tri-axial accelerometers (Upper Back, Pelvis, and Bilateral Upper and Lower Legs)
2.4. Activity of the quadriceps and hamstring muscles quantified using electromyography (EMG)
3. Range of motion measured using 3D motion capture and 2D video capture of maximal knee flexion and extension whilst lying supine at baseline, 3 and 12 months for those receiving total knee replacement (TKR), and baseline and 6 months for healthy controls

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
13/11/2024

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Able to walk 10 m unaided, rise from a seated position, or walk up 3 steps unaided
3. Willing and able to give informed consent

TKR groups:
1. Due to undergo unilateral TKR due to osteoarthritis

Healthy group:
2. No known conditions which would influence movement patterns

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Body mass index (BMI) >40
2. Knee varus or valgus deformities >15°
3. Severe flexion contracture >15°

4. Known neurological diseases/conditions or impaired balance
5. Dementia or condition which would impair capacity
6. Communication problems that would result in the inability to follow instructions in English
7. Simultaneous bilateral procedure required
8. Active local or systemic infection
9. Immunocompromised
10. Fibromyalgia
11. Loss of bone or musculature, osteonecrosis, or neuromuscular or vascular compromise in the area of the joint to be operated on, to an extent that the procedure is unjustified
12. Prior arthroplasty of the affected knee, including high tibial osteotomy
13. Allergy to implant material
14. Growth restricted patients

Date of first enrolment
01/09/2020

Date of final enrolment
31/07/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Albert Edward Infirmary
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Department of Sport and Physical Activity
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Sponsor information

Organisation
Wrightington, Wigan and Leigh NHS Foundation Trust

ROR
https://ror.org/028mrxf52

Funder(s)

Funder type
Government

Funder Name
The John Charnley Trust

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be included in the subsequent results publication.

IPD sharing plan summary
Available on request, Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	version v1.2	13/05/2020	22/02/2021	No	Yes

Participant information sheet	version v1.2	13/05/2020	22/02/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes