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Comparison of haptic assisted versus non-assisted uni-compartmental knee arthroplasty

Submission date
26/01/2010

Recruitment status
No longer recruiting

Registration date
05/02/2010

Overall study status
Completed

Last Edited
03/03/2023

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Partial knee replacements are a common surgical treatment for knee arthritis and most patients are satisfied with manual surgery. However, robotic-assisted surgery has the potential to offer more precise implant placement with higher accuracy in bone removal and less blood loss during surgery. However, more evidence is needed to know whether manual or robotic-assisted surgery was of more benefit to patients. This study aims to compare the short and long-term patient-reported clinical outcomes from robotic-assisted or manual surgery in partial knee replacements.

Who can participate?
Patients with osteoarthritis who require a partial knee replacement

What does the study involve?
Participants will be randomly allocated to either receive manual or robotic-assisted partial knee replacement surgery. The study will also involve the completion of questionnaires at the start of the study and at 3 months, 1, 2, 5 and 10 years following their surgery. Participants will also need to undergo CT scans and x-rays which are required for surgical planning when using the robotic arm in surgery. Participants have an additional pre-operative, 3-month, 1-year and 5-year appointment with the human performance lab which will undertake clinical motion analysis to determine whether either type of intervention has an impact on how they walk.

What are the possible benefits and risks of participating?
Currently, clinicians do not know whether manual or robotic-assisted partial knee replacements offer better outcomes for patients. Manual partial knee replacements are currently the gold standard surgical option for patients needing a partial knee replacement with well-reported implant survivorship and good patient outcomes. However, robotic-assisted surgery offers improved implant placement, less blood loss and a more refined approach to bone removal when determining the implant size to be used. The benefits of robotic surgery have the potential to improve long-term implant survivorship and fewer long-term reinterventions. However, in order to have robot-assisted surgery patients need to undergo CT scans which carry an increased risk of radiation exposure.

Where is the study run from?
Glasgow Royal Infirmary (UK)

When is the study starting and how long is it expected to run for?
April 2010 to January 2023

Who is funding the study?
This study is funded by Stryker Ltd, the company that makes the robot which is used in this study. The study is sponsored by the NHS Greater Glasgow and Clyde and is run independently from the company and funder.

Who is the main contact?
1. Dr James Doonan, James.Doonan@glasgow.ac.uk
2. Mr Mark Blyth, Mark.Blyth@ggc.scot.nhs.uk

Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Comparison of post-operative function following MAKOplasty® unicondylar knee arthroplasty, using MAKOplasty® and the MAKO RIO® System, versus OXFORD® partial knee arthroplasty

Acronym
MAKO RCT

Study objectives
MAKOplasty® performed with assistive haptic arm technology will result in less variability in post-operative mechanical knee alignment, and an associated improvement in post-operative function, activity and satisfaction, as compared to the standard unicompartmental knee arthroplasty.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/04/2010, West of Scotland Research Ethics Service REC 4 (Clinical Research and Development, West Glasgow Ambulatory Care Hospital, Dalnair Street, Glasgow, G3 8SJ, UK; +44 (0)141 232 1808; WoSREC4@ggc.scot.nhs.uk), ref: 10/S0704/12

Study design
Prospective single-blind single-centre randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Early-mid stage osteoarthritis of the knee

Interventions
1. Treatment group: MAKOplasty® unicondylar knee arthroplasty, using the RESTORIS implant and the MAKO RIO® Robotic Arm Interactive Orthopaedic System
2. Control group: OXFORD® Partial Knee Arthroplasty

Total duration of treatment will be 1 - 2 hours. Total duration of follow-up will be 10 years.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Mechanical knee alignment (tibiofemoral angle, degrees) - measured from long-leg scans at 3 months post-operatively

Key secondary outcome(s))
1. Oxford Knee Scores (OKS) - measured pre-operatively and 3 months, 1, 3, 5 and 10 years post-operatively
2. American Knee Society Score (AKSS) - measured pre-operatively and 3 months, 1, 3, 5 and 10 years post-operatively
3. Pain Visual Analogue Score (VAS) - measured daily for 1 week post-operatively, weekly for 8 weeks post-operatively and at 3 months, 1, 3, 5 and 10 years post-operatively
4. Fuctional section of AKSS - measured daily for 1 week post-operatively, weekly for 8 weeks post-operatively and at 3 months, 1, 3, 5 and 10 years post-operatively
5. 12-item short form health survey (SF-12) - measured pre-operatively and 1 year post-operatively
6. Canadian Occupational Performance Score (COPM) - measured pre-operatively and 1 year post-operatively
7. UCLA activity scale - measured pre-operatively and 1 year post-operatively
8. Hospital Anxiety and Depression (HAD) score - measured pre-operatively and 1 year post-operatively
9. Operation times - measured peri-operatively
10. Complications - measured any time following surgery
11. Knee angles during functional tasks - measured 1 year post-operatively
12. Frequency/type of activity - measured over 1 day at 1 year post-operatively
13. Gait velocity, knee angles and moments - measured 1 year post-operatively

Completion date
31/01/2023

Eligibility

Key inclusion criteria
1. Male or female subjects may be recruited to the evaluation
2. Age - there are no restrictions relating to age of the patient. The patient's age must be considered suitable by the clinical investigator for a unicondylar knee arthroplasty using either of the two systems available in the evaluation.
3. Subjects who are able to give voluntary, written informed consent to participate in this investigation and from whom consent has been obtained
4. Subjects who, in the opinion of the Investigator, are able to understand this investigation, co-operate with the investigation procedures and are willing to return to the hospital for all the required post-operative follow-ups
5. Subjects who require a unicondylar knee arthroplasty for primary surgical management of idiopathic osteoarthritis
6. Patients who in the opinion of the Chief Investigator are considered to be suitable for treatment with a MAKOplasty® and OXFORD® unicondylar knee replacement

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
All

Sex
All

Total final enrolment
139

Key exclusion criteria
1. Patients who, in the opinion of the Investigator, have an existing condition that would compromise their participation and follow-up in the study
2. Patients who require revision knee arthroplasty surgery
3. Patients with any tibial deformity requiring tibial component augmentation
4. Patients whom, in the opinion of the Chief Investigator, require a total knee prosthesis
5. Patients with inflammatory polyarthritis
6. Disorders of the feet, ankles, hips or spine causing significant abnormal gait or significant pain
7. Neurological conditions affecting movement
8. Patients with a pathology which, in the opinion of the Chief Investigator, will adversely affect healing
9. Patients with other disorders which, in the opinion of the Chief Investigator, will/could impair rehabilitation
10. Contra-indications for use of the device, as detailed in the package insert
11. Women who are pregnant. If there is uncertainty over pregnancy then a pregnancy test will be conducted.
12. Subjects who are known drug or alcohol abusers or with psychological disorders that could effect follow-up care or treatment outcomes
13. Subjects who are currently involved in another clinical study with an investigational product
14. Subjects who are currently involved in any injury litigation claims

Date of first enrolment
19/04/2010

Date of final enrolment
01/01/2013

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Glasgow Royal Infirmary
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Sponsor information

Organisation
NHS Greater Glasgow and Clyde (UK)

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Industry

Funder Name
MAKO Surgical Corporation

Alternative Name(s)
Mako Surgical

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 06/02/2023:
The datasets generated during and/or analysed during the current study are/will be available on reasonable request and following ethical review from James Doonan (Clinical Trial Manager, james.doonan@glasgow.ac.uk).
The type of data that will be shared: Reasonable anonymised patient data and clinical outcomes.
Dates of availability: Following publication of the 10-year clinical outcomes and health economic outcomes results (approximately Spring 2024).

Whether consent from participants was required and obtained: Consent from participants was obtained but this only pertains to the local sharing of information. And ethical approval would be required for sharing data outside of the current approval.
Comments on data anonymization: No identifiable patient data is available and all patients have been provided with a study ID. Any data that could potentially identify participants will be anonymised.
Any ethical or legal restrictions: Ethical review would be required prior to sharing.

Previous IPD sharing statement:
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/04/2016		Yes	No
Results article	results	01/11/2017		Yes	No
Other publications	1-year outcomes	01/05/2018		Yes	No
Other publications	2-year outcomes	01/07/2018		Yes	No
Other publications	five-year outcomes	01/06/2021	02/06/2021	Yes	No