ISRCTN44765636 https://doi.org/10.1186/ISRCTN44765636

A clinical study of the Triathlon knee prostheses using individualized patient matched operation tools

Submission date
09/07/2012

Recruitment status
No longer recruiting

Registration date
12/02/2013

Overall study status
Completed

Last Edited
06/12/2016

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Total knee replacements are one of the most successful joint reconstruction operations used today. The development of the implant design, as well as the improvement of instruments over the last decades have allowed good and reliable results, however with the increasing success of joint replacements and the decreasing age of patients, the expectations of total knee replacements are constantly on the rise. There is still scope to improve the longevity of implant survival as well as improving the function of the implant, giving the patient the ability to not only return to their activities of daily living but also sports and high impact activities. The opportunity exists to provide an alternative approach to total knee replacement surgery which may result in improved patient outcomes. One such approach is to determine the optimal placement of components based on the individual anatomy of patients. The position of the implant can be determined by 3D preoperative planning using an MRI scanning of the knee. Based on this planning custom specific instrumentation is made to position the implant correctly during surgery. Custom cutting guides are generated for each individual patient to enable the surgeon to perform the bone resections in such a way that the resultant construct with the total knee replacement components reproduces the pre-disease limb alignment or natural kinematic knee alignment. The aim of this study is to assess the impact of this new surgical technique aiming at natural kinematic alignment developed by Stryker on the short term functional outcome of patients undergoing primary total knee joint replacement.

Who can participate?
The ShapeMatch study aims to recruit 144 patients, men or non-pregnant women, age 18-80 years, with a diagnosis of Non-Inflammatory Degenerative Joint Disease, candidates for a primary total knee replacement.

What does the study involve?
All 144 patients will receive the same prosthesis but they will be randomly allocated to one of three groups. One third of the subjects will receive the prosthesis performed using the Stryker Patient-Specific Cutting Guides with kinematic alignment; another third of the subjects will receive the prosthesis using the Stryker Patient-Specific Cutting Guides modified to provide

neutral overall limb alignment and the last third of the subjects will receive the prosthesis performed using conventional instrumentation intended to achieve neutral overall limb alignment.

What are the possible benefits and risks for participating?
There are no additional risks associated with participating in this study over and above that of the primary total knee replacement procedure. Complications associated with any total knee arthroplasty procedure have been reported. These include the potential for: injury to the knees neurovascular structures, loosening of the components, heterotopic bone formation, infection, deep vein thrombosis, pulmonary embolism, metal sensitivity reactions, intra-operative or postoperative fracture of the femur, tibia or patella, and the need for re-operation, revision, arthrodesis of the involved joint or amputation of the limb. There is no guarantee that subjects will personally benefit from inclusion in this study. Subjects may undergo more thorough screening and follow-up than non-study patients and may benefit from this increased surveillance. This study seeks to provide clinicians information about this patient specific instrumentation by comparing the results of this instrumentation to the results of conventional instrumentation. Information gathered in this study may benefit others undergoing this procedure and general total knee replacements in the future.

Where is the study run from?
Our patients will be recruited in four different hospitals in Europe: two hospitals in Italy, one hospital in UK and one in Germany.

When is study starting and how long is it expected to run for?
Recruitment started mid-2012 and it is expected that the study will run for two years.

Who is funding the study?
The technique using pre-operative planning and custom made instrumentation has been developed by Stryker, a global orthopaedic company, who is sponsoring, funding and monitoring this clinical study. To gain more information about the company or study you can contact the main Stryker office in Europe, Stryker SA, Grand Rue 92, 1820 Montreux, Switzerland, website: www.stryker.eu

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
K-S-045

Study information

Scientific Title
A prospective randomized multi-centre study of the Triathlon Cruciate Retaining Total Knee System using ShapeMatched Cutting Guides

Acronym
ShapeMatch_EU

Study objectives
There will be a statistically significant improvement in short term kinematics and functional outcome of the Triathlon® CR Total Knee System in combination with natural kinematic aligned ShapeMatch Cutting Guides compared to the Triathlon® CR Total Knee System in combination with ShapeMatch cutting guides modified to provide neutral overall limb alignment or with conventional instrumentation intended to achieve neutral overall limb alignment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Azienda Ospedaliero-Universitaria di Modena, Comitato Etico Provinciale, 05/08/2011, ref: 2765 /C.E

Study design
Post-market prospective randomized single blind multi-centre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Non-inflammatory degenerative joint disease/total knee replacement

Interventions
Study device:
Required Components:
1. Triathlon® Cruciate Retaining Total Knee System with X3® polyethylene insert
2. Resurfaced Patella

Required Instrumentation:
1. Kinematic aligned ShapeMatch Cutting Guide
2. Precision™ saw Blade

Reference device:
Required Components:
1. Triathlon® Cruciate Retaining Total Knee System with X3® polyethylene insert
2. Resurfaced Patella

Reference Instrumentation:
1. Conventional instrumentation intended to achieve neutral overall limb alignment
2. ShapeMatch Cutting Guides modified to provide neutral overall limb alignment
3. Precision™ saw Blade

Intervention Type
Device

Primary outcome measure
To demonstrate by means of fluoroscopy and functional evaluation that TKRs performed using a kinematic aligned ShapeMatch Cutting Guide provides better short term kinematic and functional improvement compared to those TKRs performed with ShapeMatch cutting guides modified to provide neutral overall limb alignment or with conventional instrumentation intended to achieve neutral overall
1. Consistent femoral-tibial pivot point location
2. Consistent femoral Anterior-Posterior translation
3. Consistent external rotation during extension
4. Better Get-up-and-go test

Secondary outcome measures
1. To compare pain, function and health related quality of life (QOL) between the kinematic aligned ShapeMatch Cutting Guide group and the neutral overall limb aligned groups using cutting guides and conventional instrumentation, respectively.
2. To evaluate the cost-benefit ratios between those TKRs performed using kinematic aligned ShapeMatch Cutting Guides and those TKRs performed with ShapeMatch cutting guides modified to provide neutral overall limb alignment or with conventional instrumentation intended to achieve neutral overall limb alignment. To meet this objective, the following criteria

will be satisfied:
2.1. Lower procedural and hospital logistic costs
2.2. Lower blood loss
2.3. Less (pain) medication
2.4. Higher activity score on discharge
2.5. Faster functional improvement
3. To compare device-related adverse events between those knees implanted using the kinematic aligned ShapeMatch Cutting Guide and those implanted using ShapeMatch cutting guides modified to provide neutral overall limb alignment or those implanted using conventional instrumentation intended to achieve neutral overall limb alignment.
Published complication rates with similar devices, as well as complications reported in the investigational and control groups, will be reviewed.

Overall study start date
11/06/2012

Completion date
11/06/2014

Eligibility

Key inclusion criteria
1. Patient has signed an EC approved, study specific Informed Patient Consent Form
2. Patient is a male or non-pregnant female, skeletally mature and age 18-80 years at the time of study device implantation
3. Patient has a diagnosis of Non-Inflammatory Degenerative Joint Disease (NIDJD)
4. Patient is a candidate for a primary total knee replacement
5. Patient is willing and able to comply with postoperative scheduled clinical and radiographic evaluations and rehabilitation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
144

Key exclusion criteria

1. Patient has a Body Mass Index (BMI) ≥ 40
2. Patient age ≥ 80
3. Patient has a varus or valgus deformity greater than 10° or flexion contracture greater than 20°
4. Patient has an active or suspected latent infection in or about the affected knee joint at time of study device implantation
5. Patient has received any orthopaedic surgical intervention to the lower extremities within the past year or is expected to require any orthopaedic surgical intervention to the lower extremities, other than the TKR to be enrolled in this study, within the next year
6. Patient requires bilateral total knee replacements, or has a history of contralateral partial or total knee replacement
7. Patient has any implanted device that would be incompatible with MRI procedures
8. Patient has chronic heart failure (NYHA Stage ≥ 2)
9. Patient has a neuromuscular or neurosensory deficiency, which limits the ability to evaluate the safety and efficacy of the device
10. Patient is diagnosed with a systemic disease (e.g. Lupus Erythematosus) or a metabolic disorder (e.g. Pagets disease) leading to progressive bone deterioration
11. Patient is immunologically suppressed or receiving steroids in excess of normal physiological requirements (e.g. > 30 days)
12. Patient requires revision surgery of a previously implanted total knee replacement or knee fusion to the affected joint
13. Patient has a known sensitivity to device materials
14. Patient is a prisoner

Date of first enrolment
11/06/2012

Date of final enrolment
08/04/2013

Locations

Countries of recruitment
England

Germany

Italy

United Kingdom

Study participating centre
University of Modena e Reggio Emilia
Direttore della Struttura Complessa di Ortopedia e Traumatologia
Azienda Ospedaliera-Universitaria di Modena
Largo del Pozzo, 71

Modena
Italy
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Study participating centre
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Study participating centre
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Study participating centre
Orthopädische Klinik der Medizinischen Hochschule Hannover im Annastift
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Sponsor information

Organisation
Stryker SA (Switzerland)

Sponsor details
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Clinical Research Manager Europe
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1820

Sponsor type
Industry

Website
http://www.stryker.eu

ROR
https://ror.org/04t7jet59

Funder(s)

Funder type
Industry

Funder Name
Stryker SA (Switzerland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Due to early study termination, there was limited data available for analysis and therefore insufficient power to provide robust, meaningful results for primary or secondary analysis.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2016		Yes	No
Results article	results	01/02/2018		Yes	No