Multi-Center Clinical Evaluation of the ATTUNE® Cementless Rotating Platform Total Knee Arthroplasty

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Primary objectives:- Investigate the change from pre-operative baseline to two year postoperative functional performance improvement for the ATTUNE Primary, Cementless TKA RP system as measured with the KOOS questionnaire (KOOS-ADL sub-score). This...

Ethical review	Approved WMO
Status	Completed
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON50255

Source
ToetsingOnline

Brief title
14022 ATTUNE(R) Cementless RP Clinical Performance Evaluation

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
osteoarthritis (OA) or post-traumatic arthritis and Non-inflammatory Degenerative Joint Disease

Research involving
Human

Sponsors and support

Primary sponsor: DePuy Synthes Joint Reconstruction Inc

Source(s) of monetary or material Support: DePuy Synthes Joint Reconstruction

Intervention

Keyword: Arthroplasty, Cementless, Knee, Post market

Outcome measures

Primary outcome

Investigate the change from pre-operative baseline to two year postoperative functional performance improvement for the ATTUNE Primary, Cementless TKA RP system as measured with the KOOS questionnaire (KOOS-ADL sub-score). This will be carried out for two configurations: cruciate retaining rotating platform (ATTUNE Cementless CR RP) and posterior stabilized rotating platform (ATTUNE Cementless PS RP).

Secondary outcome

Evaluate change from preoperative baseline in post-operative outcomes using additional patient reported measures at 2 years: PKIP (overall and sub-scores), KOOS (overall and sub-scores), AKS and EQ-5D-3L.

- Evaluate change from preoperative baseline in pain and satisfaction over time as measured using a modified VAS Pain Score (discrete numbers rather than a continual scale) at 2yr.

- Evaluate type and frequency of Adverse Events

- Evaluate survivorship of the ATTUNE Primary Cementless TKA system for the CR RP and PS RP configurations using Kaplan-Meier survival analysis at 2yr and 5yrs.

- Evaluate primary, cementless ATTUNE TKA fixation through zonal radiographic analysis of the bone-implant interface at 6wk, 6mo, 1yr, and 2yr after surgery.

- Evaluate any changes in anatomic tibiofemoral, femoral component and tibial

component alignment at 2 years compared to the first postoperative radiographs.

Study description

Background summary

The ATTUNE Knee System was introduced in 2011 with a goal of addressing the unmet needs of patients, surgeons,
and hospital providers, initially as a cemented system. The goals were to improve function and advance surgical
processes. Some surgeons prefer to treat their patients with a cementless fixation system so the ATTUNE
Cementless Total Knee System has been developed to address their needs.

Study objective

Primary objectives:
- Investigate the change from pre-operative baseline to two year postoperative functional performance improvement for the ATTUNE Primary, Cementless TKA RP system as measured with the KOOS questionnaire (KOOS-ADL sub-score). This will be carried out for two configurations: cruciate retaining rotating platform (ATTUNE Cementless CR RP) and posterior stabilized rotating platform (ATTUNE Cementless PS RP).

Secondary objectives:
- Evaluate change from preoperative baseline in post-operative outcomes using additional patient reported measures at 2 years: PKIP (overall and sub-scores), KOOS (overall and sub-scores), AKS and EQ-5D-3L.
- Evaluate change from preoperative baseline in pain and satisfaction over time as measured using a modified VAS Pain Score (discrete numbers rather than a continual scale) at 2yr.
- Evaluate type and frequency of Adverse Events
- Evaluate survivorship of the ATTUNE Primary Cementless TKA system for the CR RP and PS RP configurations using Kaplan-Meier survival analysis at 2yr and 5yrs.
- Evaluate primary, cementless ATTUNE TKA fixation through zonal radiographic analysis of the bone-implant interface at 6wk, 6mo, 1yr, and 2yr after surgery.
- Evaluate any changes in anatomic tibiofemoral, femoral component and tibial component alignment at 2 years compared to the first postoperative radiographs.

Tertiary objectives:
- Evaluate change from preoperative baseline in post-operative outcomes using

additional patient reported measures at 6wk, 6mo, 1yr, and 5yr: PKIP (overall and sub-scores), KOOS (overall and sub-scores), AKS and EQ-5D-3L .
- Evaluate the change from pre-operative baseline in pain and satisfaction as measured using a modified VAS Pain Score (discrete numbers rather than a continual scale) at 6wk, 6mo, 1yr and 5yr.
- Evaluate survivorship of the ATTUNE Primary Cementless TKA system for the CR RP and PS RP configurations using Kaplan-Meier survival analysis at 6mo and 1yr.
- Evaluate correlations between PKIP and each of the following: KOOS (overall and sub-scores) and AKS
- Evaluate primary, cementless ATTUNE TKA fixation through zonal radiographic analysis of the bone-implant interface at 5yrs after surgery.
- Evaluate any changes in anatomic tibiofemoral, femoral component and tibial component alignment at 5 years compared to prior postoperative radiographs.
- Evaluate the impact of pre-operative attitude to pain, assessed using the Pain Catastrophizing Scale, on the post-operative pain profile and post-operative satisfaction at 6wk, 6mo, 1yr, 2yr and 5yr.
- Evaluate the functional outcome (KOOS ADL at all time-points post-op) as a function of posterior cruciate ligament treatment within the CR RP cohort.
- Evaluate the duration of surgery (*skin- to skin* time)
- Evaluate correlations between radiographic interface analysis and patient reported VAS pain and investigator-reported adverse events for severe pain.

Study design

Prospective, multi-center, non-randomized, non-controlled design. Level of evidence: Level II

Study burden and risks

- Pre and post operatively follow up visits. The patient needs to complete some patient reported outcome instruments (Questionnaire eg KOOS-PS, PKIP, EQ5D, pain catastrophizing scale and subject knee outcome. Pre and post operatively visits with AP and lateral X Ray
- Xray AP and lateral will be taken at pre operatively, 6 Weeks, 6 Months, 1 year, 2 year and 5 year. Three visit s have Xray as standard of care and two are outside the standard of care.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

a) Subject is male or female and between the ages of 22 and 80 years at the time of consent, inclusive.
b) Subject was diagnosed with NIDJD and in the opinion of the Investigator, their condition is consistent with the indications detailed in the Instructions For Use.
c) Subject, in the opinion of the Investigator, is a suitable candidate for cementless primary TKA using the devices described in this CIP with either resurfaced or non-resurfaced patellae.
d) Subject that is willing to give voluntary, written informed consent to participate in this clinical investigation and authorize the transfer of his/her information to the Sponsor
e) Subject is currently not bedridden
f) Subject, in the opinion of the Investigator, is able to understand this clinical investigation and is willing and able to perform all study procedures and follow-up visits and co-operate with investigational procedures.
g) Subject is able to read, and comprehend the Informed Consent Document as well as complete the required PROs in either English or one of the available translations.

Exclusion criteria

a) The Subject is a woman who is pregnant or lactating.
b) Contralateral knee has already been enrolled in this study
c) Subject had a contralateral amputation.
d) Previous partial knee replacement (unicompartmental, bicompartamental or patellofemoral joint replacement), patellectomy, high tibial osteotomy or primary TKA in affected knee.
e) Subject is currently diagnosed with radicular pain from the spine that radiates into the limb to receive TKA.
f) Subject has participated in a clinical investigation with an investigational product (drug or device) in the last three (3) months.
g) Subject is currently involved in any personal injury litigation, medical-legal or worker*s compensation claims.
h) Subject, in the opinion of the Investigator, is a drug or alcohol abuser (in the last 5 years) or has a psychological disorder that could affect their ability to complete patient reported questionnaires or be compliant with follow-up requirements.
i) Subject was diagnosed and is taking prescription medications to treat a muscular disorder that limits mobility due to severe stiffness and pain such as fibromyalgia or polymyalgia.
j) Subject has a significant neurological or musculoskeletal disorder(s) or disease that may adversely affect gait or weight bearing (e.g., muscular dystrophy, multiple sclerosis, Charcot disease).
k) Subject is suffering from inflammatory arthritis (e.g., rheumatoid arthritis, juvenile rheumatoid arthritis, psoriatic arthritis, systemic lupus erythematosus, etc.).
l) Subject has a medical condition with less than five (5) years life expectancy.
m) Uncontrolled gout

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	27-06-2017
Enrollment:	65
Type:	Actual

Medical products/devices used

Generic name:	ATTUNE Cementless Rotating Platform Total Knee System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	01-06-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-08-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-09-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT02839850
CCMO	NL60626.100.17