

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...

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|------------------------------|------------------------|
| 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 |