Polyethylene wear study on the Triathlon Total Knee Prosthesis: a 10 years follow up RSA study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21734

Source
NTR

Brief title
TTK RSA 10 jaar follow up

Health condition

Osteoarthritis

Sponsors and support

Primary sponsor: Stryker
Source(s) of monetary or material Support: Stryker

Intervention

Outcome measures

Primary outcome

In-vivo wear

Secondary outcome

Migration (translation and rotation in 3 directions)
Long-term survival
Knee Society Score (KSS)
EQ-5D-3L
SF-36
Lower-Extremities Activity Scale (LEAS)

Study description

Background summary

The Posterior Stabilized (PS) knee prosthesis is the most implanted total knee prosthesis design, but contribute to additional wear debris. Therefore, an alternative bearing surface in total knee replacements was designed to attempt to reduce wear by applying polyethylene in combination with the successful characteristics of a PS knee. Ultra high molecular weight polyethylene (UHMWPE) is nowadays the standard material used for the articulating surface. X3-polyethylene is a new type of polyethylene with improved mechanical properties and theoretically and in vitro improved wear resistance over conventional and current generation cross-linked polyethylene. In a previous study (NL32489.098.10), we compared the wear obtained using Roentgen Stereophotogrammatric Analysis (RSA) and clinical outcomes of the conventional N2Vac with the X3 highly cross-linked polyethylene in a CS fixed bearing total knee prosthesis (Triathlon Knee System: Stryker, Warsaw, USA) during 5 year follow up. However, the time frame of 5 years seems too short to show a significant difference in wear between the groups. Furthermore, we hypothesize that stronger inserts (X3) might induce small partical wear resulting in loosening of the prosthesis. In this study, we will assess the in vivo wear of the two randomized polyethylene insert types N2Vac and X3 and the migration and long-term survival of the Triathlon CS Peri-Apatite coated titbial component 10 years after surgery.

Study objective

We expect that the X3-polyethylene has animproved wear resistance over conventional and current generation cross-linked polyethylene (N2Vac).This material should theoretically lead to superior wear characteristics and consequently long-term durability and survivorship of the prosthesis.
Furthermore, we expect that the stronger insert (X3) might induce small partical wear, which might further lead to earlier loosening of the prosthesis compared to the N2Vac inlay.

Study design

10 years post-operative

Intervention

1. N2Vac inlay
2. X3 inlay
Both combined with a CS fixed bearing total knee prosthesis (Triathlon Knee System: Stryker, Warsaw, USA)

Contacts

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Eligibility criteria

Inclusion criteria

- Received a Total Knee Joint prosthesis between September 2011 and May 2014;
- Participated in the study assessing the mid-term wear of the N2Vac or X3 insert;
- Sign informed consent of the proposed study.

Exclusion criteria

- The patient was withdrawn from the previous study;
- Revision/Removal of study device;
- Patient withdrawal on patients own request;
- Lost to Follow-Up;
- Death of the patient;
- The patient is unable or unwilling to sign the Informed Consent specific to this study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2021
Enrollment:	87
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	30-06-2021
Application type:	First submission

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
NTR-new	NL9579
Other	METC LDD : P21.056

Study results