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Project title: A RANDOMIZED CONTROLLED CLINICAL AND RSA STUDY OF 2 TOTAL KNEE REPLACEMENT DESIGNS A COMPARISON OF NEXGEN CR AND PERSONA CR.
REK-nr: REK: 2015/1740

Introduction:
NexGen is a total knee arthroplasty implant that has been used at great numbers in numerous countries and is well documented in several registries. Persona is a new implant from the same company that produces NexGen, with several changes and modernizations regarding instrumentation and surgical technique. There are a wider range of sizes available, both on the tibia and femur, as well as the menisceal insert. This should allow optimized component fit and less compromise on soft tissue balancing. The tibia is anatomical, with a more medialized keel stem, which should allow for a more accurate fit securing less risk of malrotation and better fixation. The tibial component in the new Persona design, is anatomical, to achieve a better fit than in the old design. Additionally it facilitates proper rotation of the tibia. When a larger surface of bone is covered, it is expected a lesser risk of subsidence and early loosening of the implant. Most countries with well-functioning joint registers are cautious in implementing new designs without studies comparing the new implant to older established implants. There have been several examples of unsuccessful joint replacements introduced to the market without thorough clinical investigation and trials.

Aim of study:

1. To compare the clinical outcome scores in the 4 study groups
    - KSS (Knee Society Score)
    - KOOS (Knee Injury and Osteoarthritis Outcome Score)
    - EQ 5D
    - FJS12 (Forgotten Joint Score 12)
    - Walking speed (4-m static walking speed test)
    - Objective monitoring of free-living physical behaviour (ActivPAL activity monitor)
    - Anchor questions

2. To assess the migration patterns of the components with main focus on the tibia using RSA. Our hypothesis is that early stability of the new Persona is improved with better coverage of the bone plateau. Early stability corresponds to clinical performance at medium term (17, 18).
3. To evaluate revision rates using the Norwegian Arthroplasty Register

Materials and methods:
160 patients have been randomly allocated into 2 groups with 80 in each group, and 30 of the 80 in each group will be randomized for RSA.

Inclusions:
Patients under the age of 80

- Both gender
- Primary osteoarthritis
- BMI ≤ 35

Exclusions:
Patient over the age of 80

- Other diagnoses than primary osteoarthritis
- BMI >35
- ASA 4 patients (American Society of Anesthesiologists)

Clinical evaluation will be performed by independent physiotherapists preoperatively, using EQ5D, Knee Society Score (KSS) and Knee Injury and Osteoarthritis Outcome Score (KOOS). The scoring will be performed by a physiotherapist who is blinded with respect to the assigned study group, and by the patients themselves. An orthopaedic surgeon is consulted in the case of specific clinical problems.

The patients will be examined again at 1, 2, 5 and 10 years with EQ5D, KSS, KOOS, Forgotten Joint Score 12 (FJS12) and Anchor questions.

Preferred walking speed will be measured by timing a 4-meter walk with a stopwatch. Instructions will be given to "walk in your preferred speed" Preferred walking speed has been found valid, reliable, sensitive and specific, and correlates with functional ability and balance confidence (21). Walking speed has also been found to be a consistent predictor of adverse outcomes in different populations (22). Walking speed will be measured at pre-op, 3 months post-op and 1, 2, 5 and 10 years post-op.

The ActivPAL3TM (AP) (PAL technologies Ltd., Glasgow, Scotland) will be used to record free-living physical behavior. The AP is a small, light-weight, three axis accelerometer that will be attached to the anterior aspect of the participants thigh with a hydrogel adhesive (PALStickiesTM, PAL technologies Ltd., Glasgow, Scotland) and covered by waterproof band aid to allow for showering. The AP will be worn continuously 24 h/day to provide seven uninterrupted free-living days of physical behavior data. The participant will be asked to go about their usual activities. A proprietary software-package (PAL Professional) will be used to process acceleration data, and classify the free-living physical activity in sedentary (sitting and lying) and upright (standing and walking) postures, number of transitions from sitting to standing, and number of steps during walking. It has been found that the AP has good accuracy for detecting postures and counting steps during walking in non-impaired people (23-25) and community-dwelling non-impaired elderly (26). It has been found that the AP also was a highly valid measure of postures and transitions in elderly with walking impairments including patients post-stroke. Step counting however, was less accurate for this sample underestimating steps at very slow walking speeds <0.47 m/s (27). The AP monitor will be given to the participant at pre-op, 3 months post-op and 1, 2, 5 and 10 years

post-op. After one week recording the participants will be asked to send the monitor back to the research team in a pre-paid envelope.

Radiography:

- Standard x-rays
    - Preoperatively and at all followup consultations, x-rays will be taken as Anteroposterior (AP) and Mediolateral (ML) views. In addition long axis view (HKA) and patella 45° skyview will be evaluated preoperatively and at 1 year followup. Later these values will be evaluated together with migration- and wear values.

- Radiostereometric analysis (RSA)
    - RSA is a highly accurate and precise method of evaluating implant migration and polyethylene wear (17, 28-31). The precision usually is about 0.1mm (translational migration) and 0.1 degrees (rotation). The radiation dose is low compared to plain x-rays (10-20%). During surgery, tiny spheres of Tantalum are implanted in periprosthetic bone. On day 5-10 postoperatively, two simultaneous exposures of the knee and a co-ordinate system are taken. These films allow three-dimensional definition of the implant and bone relative to the co-ordinate system. Implant migration and rotation are measured on repeat examinations over time. The high precision allows us to detect small differences between groups, and also means that the number of subjects in each group can be restricted. The precision (repeatability) of the measurements in this study will be evaluated by double examinations at the 1-year RSA-visit. Limits for significant differences are calculated as the 99% confidence intervals of the absolute mean values of the double examinations. RSA will be done at day 5-10 post-operatively, at 3months, and at 1,2 and 5 years postoperatively.

Results:
Due to Covid and birth/illness of main researcher, results are not yet published, but are expected during the coming year (2023). This year patients will be admitted for 5 year follow up with clinical tests, PROMs and radiography including RSA x-rays.
Update April 2024: There is an ongoing work for the publication of 2-year RSA data and Active Pal results after 1, 2 and 5 years.

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