Survival of the Cementless Spotorno total hip arthroplasty

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON38627

Source
ToetsingOnline

Brief title
CLS

Condition

- Bone and joint therapeutic procedures

Synonym
Hip replacement, total hip arthroplasty

Research involving
Human

Sponsors and support

Primary sponsor: Meander Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: athroplasty, cementless, hip, survival

Outcome measures

Primary outcome

The primairy endpoint is revision of the total hip arthroplasty for any reason.

Secondary outcome

Revision of the total hip arthroplasty because of aseptic loosening, septic loosening, instability or fracture.

Clinical outcome using Charnley*s modification of the Merle d*Aubigné-Postel, Harris Hip score and the EQ5D questionnaire

Radiological geometrical assessment: The acetabular cup inclination angle and degree and angle of linear polyethylene wear and heterotopic ossifications on X-ray.

Effects of preoperative clinical status, patient demographics, prosthetic component size, and polyethylene wear on clinical outcome, aseptic loosening and revision for any reason.

Study description

Background summary

The total hip arthroplasty hugely improves the quality of life and is regarded the most efficient and cost-effective surgical procedure in history1. In

orthopaedic science there is continuing need for evaluation of hip systems used in the past to assess their survival and to determine the factors of failure in order to improve the reliability of orthopaedic implants. Currently a 10-year survival is a benchmark for quality.

During the last thirty years there has been an increase of the use of cementless fixation in total hip arthroplasties (THA). Cementless hip arthroplasties perform well at the mid-term and the long-term. Literature suggests that the fixation of cemented acetabular components is more reliable than that of cementless components beyond the first postoperative decade. Other authors describe a better outcome of the femoral component and on the other hand a lower survival rate of the uncemented acetabular component compared to the cemented type.6 The main excepted reason for the increased use of the uncemented prosthesis was the failure of cemented all polyethylene acetabular component in the 1980*s. At that time the thought was that the use of bone cement caused osteolysis, around the prosthesis. This phenomenon was called *cement disease*. Today we know that polyethylene wear particles originated from the cup are the problem instead of cement-disease*.

In our institution we have used the CementLess Spotorno (CLS) system. Recently, this series was published in a peer reviewed journal, describing clinical outcome after a ten to seventeen year follow-up.9 Our series of n=102 showed a good mid-term to long-term survival.However little is known about the long-term survival of cementless hip systems up to twenty years. By means of this research we want to gain more knowledge about the long term survival of cementless hip systems, in particular the CLS system.

We will evaluate this series again after a five-year interval. We expect that radiologic loosening assessed with conventional X-ray of both the femoral and acetabular component will increase since the last moment of follow up because of an increase of polyethylene wear. Loosening will lead to lower clinical evaluation scores.

Study objective

The main objective of this study is to describe the long term results of a non-designer series of the CLS total hip arthroplasty (with the use of a CLS femoral stem and acetabular cup).

Primary Objective
Survival analysis of the CLS total hip arthroplasty system by assessment of the incidence of revision and time to revision because of aseptic loosening of one or both prosthetic components.

Secondary Objectives
Clinical assessment will be performed by physical examination, interview, and using clinical scores (Charnley*s modification of the Merle d*aubigné-Postel,

Haris Hips Score and the EQ5D).

Radiological assessment will be performed using conventional X-rays of pelvis and proximal femur. Radiogical loosening of the prosthesis is observed and qualified by Gruen and Charnley. The acetabular cup inclination angle and degree and angle of linear polyethylene wear will be measured by the method described by Livermore et. al. Also heterotypic ossifications will be classified with use of the system described by Brooker et. al.

The incidence of revision will be reported and analysed using the Kaplan Meyer method.

Effects of preoperative clinical status, patient demographics, prosthetic component size, and polyethylene wear on clinical outcome, aseptic loosening and revision for any reason will be analysed.

Study design

Prospective cohort study design.
Two surgeons at our institution performed a consecutive series of 120 total hip replacement procedures with the CLS system (CementLess Spotorno; Protek/Zimmer, Zurich, Switzerland) in ninety-six patients between 1989 and 1997. The indications for the procedure were osteoarthritis, rheumatoid arthritis, or femoral head osteonecrosis. Inclusion criteria were an age of sixty-six years or younger; a primary total hip arthroplasty for treatment of osteoarthritis, rheumatoid arthritis, or femoral head osteonecrosis; and a trumpet-shaped femur as defined by the morpho-cortical index (a measure characterizing femoral morphology dysplastic, cylindrical, or trumpet-shaped] and femoral cortical thickness). A trumpet-shaped femur with a thick cortex provides ideal conditions for the CLS press-fit Stem. Exclusion criteria were primary or secondary carcinoma in the last five years, unwilling to participate and a lower extremity with neurovascular compromise. Patients were included in a standardized follow-up protocol until 2007.

Study burden and risks

Patients* risks are negligible and the burden is minimal. All patients underwent surgery 15-22 years ago. We will notify the patient by means of an appointment letter for regular clinical evaluation. Regular clinical evaluation consists of standardized digital X-rays of pelvis and hip, an interview and physical examination.

We believe a routine follow up of patients should be performed every two to three years, because relevant mechanical loosening of the prosthesis can present with few clinical complaints. In these cases early surgery can be a valid option to prevent more difficult revision procedures and the subsequent

risks.

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

Patients who received an uncemented hip prosthesis type Cementless Spotorno between 1989 and 1997 and previously included in the prospective cohort study.

Exclusion criteria

The exclusion criterion for the long-term follow up is not being previously included in the prospective cohort study.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-11-2013
Enrollment:	102
Type:	Actual

Ethics review

Approved WMO

Date:	04-07-2013
Application type:	First submission
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
CCMO	NL44190.100.13