March 18th, 2022 NCT 04748458 Study ID: 589/2020/Oss/IOR Date of approval: 17/06/2020 Title: Long-term Outcomes of Conical Tapered Stems in Cementless Total Hip Arthroplasty Due to Congenital Hip Pathologies (RetroCone)

Study start: July 17, 2020 Primary completion: October 1, 2021 Study completion: October 2, 2021 Brief summary

A retrospective consecutive population of patients treated with conical tapered stems in cementless total hip arthroplasty for osteoarthritis due to congenital hip pathologies will be selected. The aim of this retrospective study is to evaluate the long-term clinical and radiographic results of this implant and the survival rates in such a specific cohort.

Study description

Congenital hip pathologies may severely alter the local anatomy of the hip, making total hip arthroplasty (THA) due to osteoarthritis after congenital hip pathologies challenging. While it seems that congenital hip pathologies did not significantly influence the outcomes when compared to THA after osteoarthritis, the choice of implant was demonstrated to impact the survival rates of the THA after congenital hip pathologies.

To date, no guidelines exist about the correct choice of hip implant in congenital hip pathologies: only midterm case series are available. Conical tapered stems have been frequently suggested for the most difficult cases.

The aim of this study is to describe the survival rates and the long-term clinical and radiological outcome of conical tapered stems in THAs after congenital hip pathologies.

Population

retrospective, consecutive adult population treated with conical tapered stems in cementless total hip arthroplasty for osteoarthritis due to congenital hip pathologies.

Inclusion Criteria:

Symptomatic hip osteoarthritis due to congenital hip pathologies

Consecutive population with a minimum follow-up of 2 years

Cementless total hip arthroplasty with conical tapered stem

Pre-operative planning using CT

Complete clinical and radiographic assessment

Exclusion Criteria:

Other type of hip osteoarthritis

Other type of implants

Inadequate pre-operative planning (eg: no CT)

Incomplete clinical and radiographic assessment

Methods

Demographics of the patients involved were collected using medical records.

The patients were clinically and radiographically evaluated in the post-operative setting at 1, 6, 12, 24 months and then biennial. Harris Hip score (HHS) was adopted to clinically assess the patients at the final follow-up []. Plain antero-posterior pelvis radiographs were taken at every follow-up: the last X-ray was evaluated for the positional parameters specified in the table []. Osseointegration was evaluated using the criteria of Moore et al. (cup) and Engh et al. (stem) [].

Failures were collected and the survival rates were specified, using a 955 confidnce interval.

Statistical analysis plan

Statistical analysis has been done by using Windows SPSS 14.0, 14.0.1 version (SPSS Inc, Chicago, IL) and JMP, 12.0.1 version (SAS Institute Inc, Cary, NC, 1989-2007).

The quantitative data were expressed as average values, standard deviations and ranges of minimum and maximum. The qualitative data were expressed ss frequencies and percentages. The survivorship of the primary THA implants were calculated and plotted according to Kaplan-Meier method (95% confidence interval). The endpoint was removal or change of any component. The implants were followed until the last date of observation (date of death or 31 December 2019). A p-value less than 0.05 was considered statistically significant.