RANDOMIZED CONTROLLED STUDY COMPARING THE TAPERLOC COMPLETE VERSUS THE TAPERLOC COMPLETE MICROPLASTY.

PROTOCOL NUMBER: ORTHO.CR.GH60

NCT NUMBER: NCT03409666

PROTOCOL VERSION

2017-07 – REV.1.5

STUDY SPONSOR

ZIMMER GMBH
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SWITZERLAND

Complete Protocol Title	Randomized controlled study comparing the Taperloc Complete versus the Taperloc Complete Microplasty
Protocol Number	ORTHO.CR.GH60
Short Protocol Title	Randomized controlled study comparing the Taperloc Complete versus the Taperloc Complete Microplasty
Sponsor	Zimmer GmbH, Zählerweg 4, 6300 Zug, Switzerland
Manufacturer	Biomet Orthopedics, 56 East Bell Drive, Warsaw, Indiana 46581 USA
Study Device(s)	Taperloc Complete Microplasty PPS-Bonemaster Taperloc Complete Reduced Distal PPS- Bonemaster
Technical Documentation Reference Number	Reference can be found on Post-market surveillance Plan (PMSP)
Study Objectives/Endpoints	Primary endpoint: Migration of the prosthesis over two years based on RSA data. Secondary endpoints: a. The prevalence of malalignment, incorrect sizing, subsidence and intraoperative fractures at the direct postoperative visit. b. Survival of the hip prosthesis within 2 years. c. Clinician based outcomes (HHS and radiological evaluation) and patient based outcomes (HOOS, EQ5D, Oxford Hip score, Forgotten Joint score) at each visit.
Indications/Target Population	Subjects with osteoarthritis of the hip scheduled for a primary total hip arthroplasty (THA) who are willing to participate in the study. Subjects have to meet all the in- and exclusion criteria of the study.
Inclusion/Exclusion Criteria	<u>Inclusion criteria</u> In order to be eligible to participate in this study, a subject must meet all of the following criteria. These are standard indications for usage of the Taperloc Complete and Taperloc Microplasty stem. Subjects with one of the following indications: • Non-inflammatory degenerative joint disease including osteoarthritis, avascular necrosis and rheumatoid arthritis. • Correction of functional deformity. Additional inclusion criteria include: • Male or female • ≥ 18 and ≤ 70 years of age • Subjects willing to return for follow-up evaluations. • Subjects able to read and understand Dutch language. <u>Exclusion criteria</u> A potential subject who meets any of the following criteria will be excluded from participation in this study.

	• active Infection (or within 6 weeks after infection) • Sepsis • Osteomyelitis • Uncooperative patient or patient with neurologic disorders who are incapable of following directions • diagnosed Osteoporosis or Osteomalacia • Metabolic disorders which may impair bone formation • Distant foci of infections which may spread to the implant site • Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram • Vascular insufficiency, muscular atrophy or neuromuscular disease.
Study Design	A single-centre, randomized controlled post market surveillance study: • Group 1: Taperloc Complete PPS-Bonemaster, Reduced Distal, Type 1 Taper (n=25) • Group 2: Taperloc Complete Microplasty Reduced Distal, PPS-Bonemaster, Type 1 Taper (n=25) In both groups, the G7 acetabular cup is used with Polyethylene E1 articulation.
Clinical Phase	Post-market
Sample Size	50 subjects in total, 25 study subjects implanted with the study device per cohort.
Length of Study	3 years (1 year of enrolment and 2 years of follow-up)
Materials and Methods	All included patients will be assessed preoperatively and directly postoperative. Follow-up will take place at 6-weeks, 1 and 2 years postoperatively.
Data Collection	Electronic
Statistical Reporting	Data collected will be summarized and reported to the participating investigator. Zimmer Biomet or its designee will conduct statistical analysis. Survivorship will be evaluated using Kaplan-Meier. Implant migration will be evaluated using Roentgen Stereogrammetric Analysis (RSA).
Scores/Performance Assessments	HHS, HOOS, EQ5D, Oxford Hip score, Forgotten Joint Score.
Standards	The PMCF is compliant with the below: • ISO 14155: 2020 - Clinical investigation of medical devices for human subjects - Good clinical practice. • The Declaration of Helsinki (DoH) - Ethical principles for medical research involving human subjects.
Study Funding	Zimmer Biomet makes funding for this clinical study available to support clinical data collection, IRB/EC review fees and other expenses associated with the conduct and execution of this study protocol as outlined in the fully executed Clinical Trial Agreement.

STATISTICAL METHOD

Data will be analyzed using the “Statistical Package for the Sciences” version 20.0 or higher. Differences will be 2-tailed tested and alpha is set on 0.05. Data will be presented as per protocol (intention-to-treat) and as treated analysis (treatment eventually received).

Descriptive analysis

Descriptive analysis will be performed to report baseline characteristics and outcome measures. Continuous data (e.g. age, BMI,): mean ± SD or medians and IQR (depending on normality). Categorical data (e.g. gender, ASA): number and frequencies will be reported for treatment groups.

The quantitative variables obtained from the clinical evaluation (HHS, HOOS, EQ-5D, Oxford Hip Score and Forgotten Joint Score) will be tabulated and analysed as mean, standard deviation, minimum and maximum values. Complications and other clinical relevant information will be documented as known variables. All outcomes will be reported with 95% confidence intervals.

Primary and Secondary Endpoint Analysis

Analysis for primary and secondary endpoints will use the patient population which consists of those cases with complete data for one or more of the primary and secondary endpoints.

Survivorship

Hip prosthesis survivorship will be assessed using a Kaplan-Meier analysis.

Study Safety

All adverse events will be recorded, described, and compared for the groups. Comparisons will use standard statistical tests (chi-square, Fisher’s exact). Adverse events resulting in device removal and/or revision and those not requiring device removal and/or revision will be summarized. Device related serious adverse events will be collected and evaluated for differences in the population.