Anatomical Shoulder Fracture Post-Market Clinical Follow-Up (PMCF) Study

A multi-centre, non-comparative, prospective post-market surveillance study to obtain clinical and radiographic outcome data on the Anatomical Shoulder Fracture System when used in primary shoulder replacement.

Protocol number: 06-U03
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STUDY SPONSOR

Zimmer GmbH

Zählerweg 4

P.O. Box

CH-6300 Zug

Switzerland

Phone: +41 52 262 60 70

1 STUDY SYNOPSIS

Complete Protocol Title	Anatomical Shoulder™ Fracture Post-Market Surveillance Study A Multicenter, non-comparative, prospective post-market surveillance study to obtain clinical and radiographic outcome data on the Anatomic Shoulder™ Fracture System when used in primary shoulder replacement.
Protocol Number	06-U03
Short Protocol Title	Anatomical Shoulder ™ Fracture Post-Market Surveillance Study
Sponsor	Zimmer GmbH, Sulzer-Allee 8, 8408 Switzerland
Manufacturer	Zimmer Switzerland Manufacturing GmbH, Sulzerallee 8, 8404 Winterthur, Switzerland
Study Device(s)	Anatomical Shoulder ™ Fracture System
Study Objectives/Endpoints	The objective of the study is to obtain outcome data on the Anatomical Shoulder ™ Fracture System by analysis of standard scoring systems and radiographs.
Indications/Target Population	The Anatomical Shoulder ™ Fracture System is specialized for anatomical reconstruction in case of proximal three or four part fractures. The goal of hemiarthroplasty for fracture is to replace the humeral head with a prosthetic component and to restore function by reconstructing the tuberosities to both, the shaft and the prosthesis.
Inclusion/Exclusion Criteria	Inclusion Criteria: • Patient is skeletally immature. • Patient is pregnant. • Patient is unwilling or unable to cooperate in a follow-up program. • Patient is planned for a bilateral shoulder replacement. • Patient shows one or more of the following medical conditions: - Pathological Fracture - Active Infection • Patient requires one or more of the following medical interventions: - Revision surgery (non-union) - Inverse fracture prosthesis Exclusion Criteria: • Patient is skeletally immature.

	• Patient is pregnant. • Patient is unwilling or unable to cooperate in a follow-up program. • Patient is planned for a bilateral shoulder replacement. • Patient shows one or more of the following medical conditions: - Pathological Fracture - Active Infection • Patient requires one or more of the following medical interventions: - Revision surgery (non-union) - Inverse fracture prosthesis
Study Design	A multicenter, non-comparative, prospective post-marketing study.
Clinical Phase	Post-market
Sample Size	52 cases (shoulders) shall be included in the study
Length of Study	11 years (1 year enrollment plus 10 years follow-up): follow-up visits at 6 to 12 weeks, at 6 months, and thereafter at 1, 2, 3, 4 (optional), 5, and 10 year (optional) years post hospital discharge.
Materials and Methods	Case report forms will be completed either in-office or hospital at Pre-op, Surgery, Discharge, and at the 6 to 12 weeks, at 6 months and thereafter at 1, 2, 3,4 (optional)5 and 10 year (optional) post-operation intervals.
Data Collection	Paper/Electronic
Statistical Reporting	Data collected will be summarized and reported to each participating investigator. Statistical analysis will be conducted by Zimmer Biomet or its designee. Survivorship will be evaluated using Kaplan-Meier.
Scores/Performance Assessments	Constant-Murley, Oxford Shoulder Score, EuroQol (EQ-5D), Revisions, Adverse Events, Radiographic Assessment.
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. • European Regulation (EU) 2017/745.

Study Funding	Funding for this clinical study is made available by Zimmer Biomet 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.

2 STATISTICAL ANALYSIS PLAN

2.1 Sample Size

The primary endpoint of this study is the performance of the Anatomical Shoulder™ Fracture System, which is assessed by the Constant and Murley Score (CM) at five years.
The historical CM score of patients treated with similar implants was calculated as an average from four published study results. This historical CM consists of the resulting average (53.25) and its 95% confidence interval (± 4.38).
A claim of non-inferiority to the historical value will be made if the CM obtained in the experimental group is greater than the historical CM lower 95% confidence limit at 48.87. Thus, the null hypothesis of non-inferiority will be rejected if the lower 95% confidence limit of the CM of the experimental group is not greater than 48.87.
A sample size of 37 achieves 80% power to detect non-inferiority using a one-sided ttest when the margin of non-inferiority is -4.38 to the historical CM mean and the true difference between the CM of the AS Fracture Prosthesis and the historical CM is 3.0.
The data are drawn from a single population with a standard deviation of 17.6.
The significance level (alpha) of the test is 0.05.
Fifty-two patients enrolled in the study allow for a yearly attrition rate of 5.8% over the estimated five-year period.
Calculations have been performed with PASS 2011 (NCSS, LLC. Kaysville, Utah)

2.2 Statistical Analysis

Data collected in the study will be summarized descriptively. Descriptive summaries will be the basis of study reports to participants, as well as to generate an overall summary of the clinical performance of the various implants captured within the database and may be used for reports and to support presentations and publications as needed.
Summaries will routinely describe categorical data as counts and percentages, and ninety-five percent confidence limits will be generally used to assess differences between different implant configurations. Routine summaries describing continuous data will be in the form of means, medians, standard deviations, minima, and maxima, and ninety-five percent confidence intervals will be used to contrast differences.
Routine summaries of implant survival, return to function, etc. (e.g. time to event) will generally be described via the Kaplan-Meier method and these will generally be accompanied with the corresponding crude rates (expressed as percentages). Routine summaries of complication data will be in the form of frequencies and percentages.
Summaries may be further generated for strata within the study population, (e.g. males and females, at different cut-points in the body mass index continuum, etc.).
Patient confidentiality will be protected at all times, and patient identifiers will not be included in study summaries.