Evaluation of Zimmer® iASSIST™ vs. conventional instrumentation in Total Knee Arthroplasty: radiographic, clinical and economic outcomes

Multicenter, prospective, randomized, non-controlled, and comparative

PROTOCOL NO. CSE2012-05K

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SPONSOR:
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Title:	Evaluation of Zimmer® iASSIST™ vs. conventional instrumentation in Total Knee Arthroplasty: radiographic, clinical and economic outcomes
Protocol No.	CSE2012-05K
Sponsor	Zimmer Inc.
Study Type	Clinical
Objectives:	The purpose of this prospective study is to evaluate *Zimmer*® iASSIST™ with respect to radiographic, clinical and economic outcomes and compared to conventional instrumentation in primary total knee arthroplasty (Persona®LPS).
Endpoints:	Primary endpoint: • The primary endpoint is defined as component alignment as determined using long leg X-Rays and/or CT-scan Secondary endpoints: • Knee Society Score • EuroQol-5D scoring system • Operating room time • Blood loss and complications
Target Population:	Patients over 18 years old with indication of primary knee arthroplasty and meeting the inclusion/exclusion criteria stated in the protocol.
Study Design:	Multicenter, prospective, randomized, non-controlled, and comparative
Number of Cases:	25 cases (15 iASSIST and 10 conventional) per site. Minimum 3 sites. Total 75 cases (45 iASSIST and 30 conventional).
Length of Study:	24 months, giving 6-7 months of enrollment and 12 month follow-up of each enrolled subject. All subjects will be assessed pre-operatively, operatively, and at 3-month (±2 weeks) and 12-month (±1) post-operatively
Study Device:	Zimmer® iASSIST™ Knee
Scores:	a. Knee Society Score b. EuroQol-5D - Version EQ-5D-3L
Performance Assessment:	Quarterly: evaluating number of surgeries, patient's follow-up and post-op imaging. Electronic data transmission as required.
Statistical Reporting:	Descriptive statistics for the values of the angles (N, mean, median, min, max, SD) will be calculated by treatment group as well as success rates. Significance level of 0.05 will be considered

Statistical Methods

An independent statistician will perform the statistical analyses. Unless otherwise noted, all inference tests will be performed at alpha = 0.05.

Primary endpoints:
The primary angle endpoint will be component alignment as determined using long leg X-Rays and/or CT-scan. Secondary angle endpoints will be Knee Society Score, EuroQol-5D scoring system, operating room time, blood loss and complications. For each subject, each of these angles will be classified as either falling within an acceptable range (i.e. success) or not falling within an acceptable range (i.e. failure). Descriptive statistics for the values of the angles (N, mean, median, min, max, SD) will be calculated by treatment group as well as success rates (percent successes). The null and alternative hypotheses for each of these angle endpoints are respectively as follows:

i.e. v/v angle
H_o: The iASSIST v/v angle success rate is less than or equal to the conventional v/v angle success rate.
H_a: The iASSIST v/v angle success rate is greater than the conventional v/v angle success rate.

A secondary analysis will be conducted for each endpoint using a one-sided variance ratio test on the following secondary null and alternative hypotheses, respectively.

H_o: $V_1 \leq V_2$
H_a: $V_1 > V_2$

Where:
V_1 = The variance of the conventional surgery group
V_2 = The variance of the iASSIST group

Secondary Endpoints:

Secondary non-angle endpoints will include Knee Society Scores and EQ-5D. Total scores for each will be tested for treatment group differences using a two-way ANOVA model with terms for treatment, site and treatment-by-site interaction. If the treatment-by-site interaction term is non-significant at alpha=0.10 it may be dropped from the model for the final analysis.