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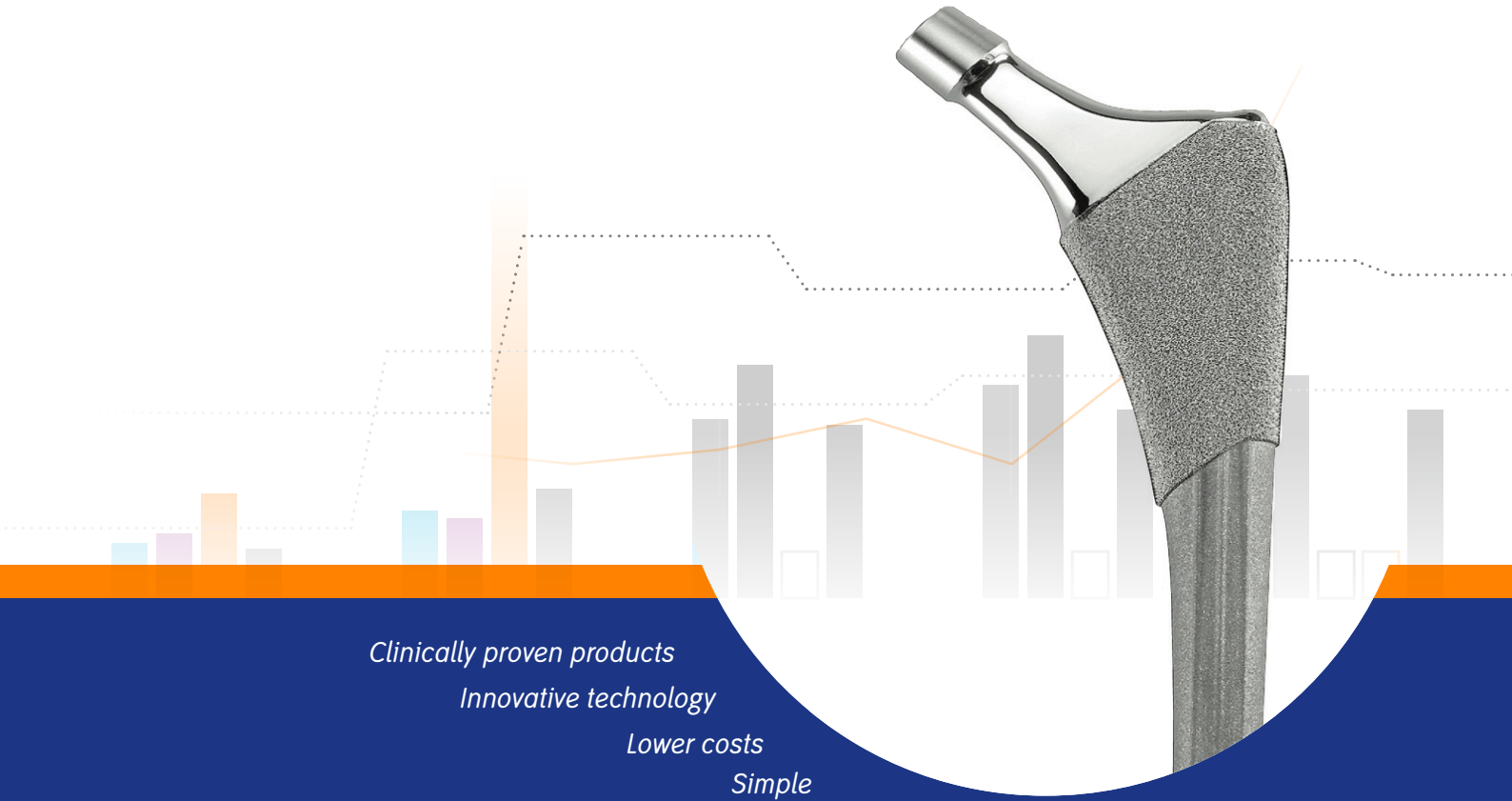
The SYNERGY® Hip System in Primary Total Hip Arthroplasty

A Systematic Literature Review of Clinical Outcomes

Reviewed by: **Robert B. Bourne, Jack M. Bert** | July 2015

Appendices



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Appendix 1: Methods

Eligibility Criteria

The inclusion criteria for this review are clinical studies that utilize the SYNERGY® Hip System for primary total hip arthroplasty. Studies were excluded from the analysis if they met any of the following criteria:

1) Not relevant; studies were identified due to similar terms but were not related to the chosen clinical field (not total hip arthroplasty, orthopaedics, etc.)
2) Focused on secondary or revision procedures;
3) Did not include the primary outcome goals (survivorship, revisions, Harris Hip Scores);
4) Non-peer reviewed meeting abstracts/posters, presentations, book chapters, comments/letters, symposia, unpublished thesis/dissertation reports;
5) Small case studies (<5 patients);
6) In vitro studies/cadaver studies/animal studies;
7) Not published in English;
8) Did not use SYNERGY in study patients;
9) Various implant types were used (<80% SYNERGY used), and the results were not divided by implant type;
10) Ceramic-on-ceramic or metal-on-metal articulation surfaces;
11) Articulation surfaces not specified;
12) SYNERGY used in unapproved/off-label combinations.

Literature Search

A thorough and systematic literature search was conducted using the Google Scholar database. Google Scholar was selected as a search engine because it enables a search of the entire contents of the article, as opposed to only searching keywords/titles/abstracts like many other traditional search databases (e.g. EMBASE, MEDLINE). This capability was important to ensure the comprehensiveness of our search, since the implant type used in clinical studies is often not mentioned in the abstract, title or as a keyword. The Google Scholar search strategy is outlined in **Figure 2**.

Our initial search identified 141 items (note that, given the nature of Google Scholar's search capabilities, not only published articles were retrieved, but book chapters, dissertations, etc.). When combined with 109 potentially relevant articles provided by the content experts, there were 250 studies identified. Upon application of the inclusion criteria, 243 of these did not meet the eligibility criteria for this review. The reasons for their ineligibility are provided in **Figure 2**. Therefore, seven articles were included in the current analysis [2-8].

Data Abstraction

Data were abstracted from the seven included studies on SYNERGY. There were no eligible studies reporting survivorship rates, so this endpoint could not be included. All other studies included the two other endpoints of interest: Harris Hip Scores and/or revision rates in their results. Due to significant heterogeneity among outcomes in the included studies, extraction of specific data was limited to conclusions regarding each outcome measure. Data pooling and meta-analysis of the results was only possible for the study characteristics, revision rates and Harris Hip Score data.

Revision rates were provided in three studies or were calculated from the number of reported complications [3-5]. Harris Hip Scores were reported in seven studies [2-8], six of which [3-8] provided both pre-operative and post-operative scores.

Note

For all figures, tables, and references, please refer to the review, "The SYNERGY® Hip System in Primary Total Hip Arthroplasty: A Systematic Literature Review of Clinical Outcomes."

Appendix 2: Results

Study Characteristics

Included studies were either Level I randomized controlled trials (two studies [3,5]), Level II prospective comparative studies (four studies [2,6-8]), or Level III retrospective comparative studies (one study [4]). However, the research question(s) for these other studies generally did not focus on the outcomes of using SYNERGY° implants; rather they focused on unrelated variables (e.g., the surgical technique performed, cement type used, etc.) and used the aforementioned implant. Therefore, for our purposes, such included studies are considered to be Level IV case series, as only one study arm was included or the study arms were considered independently of one another.

National Joint Registries

Data with SYNERGY were not available in the latest published annual reports of Norway and Slovakia, or the National Joint Registry for England, Wales and Northern Ireland. Findings with this device were available in the annual report of the Danish Hip Registry, however this registry does not permit the commercial use of such data.

Data for SYNERGY were available in the published annual reports of the following national joint registries: Australia [9], New Zealand [10], Registro dell'implantologia Protesica Ortopedica (RIPO) [11], and Sweden [12]. These separate registries differ in their reporting methods.

The latest report from the Australian Orthopaedic Association National Joint Replacement Registry [9] features data from September 1999 to December 2013. The registry provided data with SYNERGY in different acetabular cup combinations at separate time points. The registry publishes cumulative percent revision rates based on Kaplan-Meier estimates of survivorship.

The New Zealand Joint Registry [10] covers a period from January 1999 to December 2013. The registry reports results only in pairings, as revision rates per 100 observed component years.

RIPO [11] provides data from January 2000 to December 2013. The registry uses Kaplan-Meier to estimate survival at different time points. Prosthesis failure is defined as the revision of even one component.

Lastly, Sweden [12] includes data from 1992 to 2012. The registry analyzes survival using the Kaplan-Meier method and reports findings for individual components.

Please note that couples using metal-on-metal articulation surfaces were excluded from the registry search. This resulted only in the exclusion of SYNERGY/BHR from both the Australian and New Zealand registry sections. It should be noted that SYNERGY/R3° was also available in metal-on-metal articulations, which were not approved in certain countries and now globally withdrawn. Because the Australian Orthopaedic Association National Joint Replacement Registry clearly notes when metal-on-metal combinations are included, and did not identify the SYNERGY/R3 combination as being such a combination, it was decided to include data from this pairing. However, the New Zealand Joint Registry provides no such information, and therefore data with this pairing could not be included.

Clinical Definitions

Arthroplasty registries

Collections of data related to patients who undergo an arthroplasty procedure. The registries are often national or regional and track the outcomes of a joint replacement procedure, providing large data sets that can indicate how an implant is performing in the population.

Confidence interval

A range of values (lower and upper) within which it can be assumed that a chosen parameter lies. The power of these assumptions are calculated as percentages, most often as 95% confidence intervals, meaning that if an endpoint is analyzed 100 times, it would fall within this range 95 times. Wider confidence intervals indicate that less certainty can be derived about the finding being measured, whereas smaller ranges indicate a statistically stronger observation.

Cumulative percent revision

A measurement of the total percentage of prostheses that failed/required revision at a given time point. This endpoint is calculated as 100 x [1- S(t)], where S(t) is the survivorship probability estimated by the Kaplan-Meier method and the cumulative percent revision gives the percent of procedures revised up until a certain time (t). In the Australian Orthopaedic Association National Joint Replacement Registry, this measurement accounts for censoring due to death and 'closure' of the database at the time of analysis.

Harris Hip Score

A disease-specific clinical outcome tool using a rating scale of 0 (worst) to 100 (best) points and with separate domains for pain, function, activity, deformity, and motion.

Rate per 100 Observed Component Years

This is a patient-time incidence rate, and is derived by dividing the number of prostheses revised by the observed component years multiplied by 100. It therefore allows for the number of years of post-operative follow up in calculating the revision rate.

Methodological Definitions

Generalizability

The ability of the study findings to be applicable to different populations. Also known as external validity.

Systematic Review

A study design, whereby published literature on a particular topic is combined to increase the power and validity of findings. The ability to combine literature is dependent on the heterogeneity of the included studies. The published literature is identified through a comprehensive review of the published literature in a variety of databases. The quality of a systematic review is dependent on the quality of the individual studies included. If randomized controlled trials are included, a meta-analysis can be conducted to produce relative risk and odds ratios.

Validity

The ability of a trial to accurately assess an outcome. Overall validity includes a number of components that combine to ensure that the findings reported are trustworthy. Validity hinges on reliability, which is the ability of a study to provide consistent results.

Notes

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