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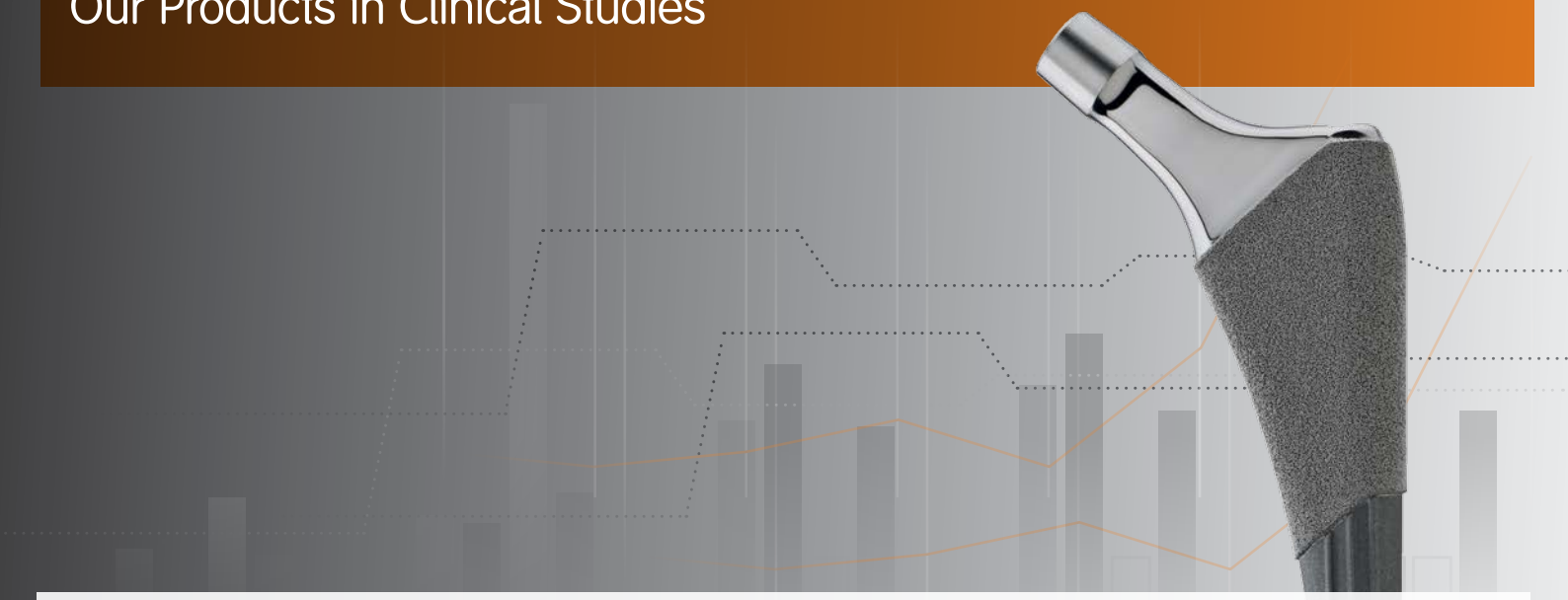

The SYNERGY◇ Hip System in Primary Total Hip Arthroplasty

A Systematic Literature Review of Clinical Outcomes

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

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The SYNERGY° Hip System in Primary Total Hip Arthroplasty: A Systematic Literature Review of Clinical Outcomes

Overview

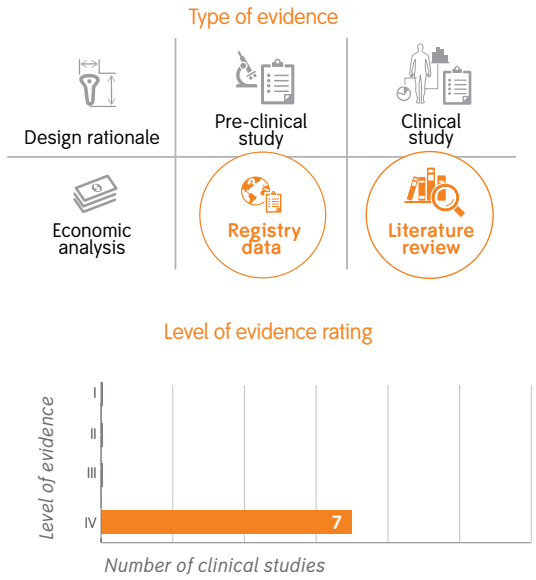
Purpose of review

The systematic review was performed to evaluate and summarize the current evidence on the clinical performance of the SYNERGY Hip System.

Background

Since its introduction more than 15 years ago, several studies have reported positive clinical results with SYNERGY. In order to obtain a more thorough understanding of this device's performance, we conducted a systematic review of the literature to collect data from studies reporting implant survivorship estimates, cumulative revision rates, and Harris Hip Scores (HHS) in patients receiving SYNERGY in primary total hip arthroplasty (THA). In addition, we also conducted a supplementary review of the most recent data available from national joint registries. *Read more on page 4*

Evidence



Why this rating?

This review includes only Level IV evidence, and is therefore rated fair. Although Level I randomized controlled trials (RCTs) are among the studies used, only one arm of the RCTs was included. They were therefore considered to be equivalent to case series and of a lower level of evidence (Level IV).

Study characteristics

Number of studies: **7**

Study designs included:
- **Case series**
- **Individual arms of higher-quality evidence, treated as case series**

Mean follow-up: **4.6 years**
Mean lost to follow-up rate: **0.17%**

Mean age: **64.7 years**
Most common reason for total hip arthroplasty: **osteoarthritis**
Mean sample size (range): **81.9 hips (40 to 198)**
Number of hips in study: **573**

Key results and considerations

A systematic review of the literature found:

- **Low overall revision rate of 0.28% at 4.99 years mean follow up** (three studies with 355 hips reporting; all revisions related to the femoral component)
- **Mean postoperative HHS of 89.6** (seven studies with 573 hips reporting)
  - **Mean HHS improvement of 45.3** points from preoperative to postoperative period

A supplementary review of registry data showed:

- **Data on SYNERGY were available in the annual reports of four separate national joint registries (12,599 devices in total). Final revision rates/survival times were better than the separate registries' class averages in all six categories**

- In conclusion, **SYNERGY is safe and effective** (confirmed by both published clinical data and national joint registry data)
- Need for additional studies:
  - High-quality RCTs
  - Greater than 10 years follow up
  - Focus explicitly on the performance of the SYNERGY Hip System
  - Consistent reporting of outcomes relevant to implant safety and performance across studies
  - Investigate outcomes for THA in indications other than osteoarthritis

The SYNERGY® Hip System (Smith & Nephew, Memphis, USA; **Figure 1a–b**) was introduced in 1997 with design features intended to improve clinical function in patients undergoing primary THA, including:

- Three-point fixation (posterior proximally, anterior midway down and posterior distally) to enhance stability
- Fins to provide enhanced rotational stability
- Two true dual offsets that provide a method of biomechanical restoration without a change in leg length
- Circulotrapezoidal neck design to improve range of motion

A comprehensive systematic review of the published evidence with SYNERGY, the first of its kind, was conducted to improve our understanding of this device's overall clinical performance. The primary outcomes reviewed were cumulative percentage revision rate and HHS.[1] These outcomes were selected because all have time-established utility in evaluating the clinical performance of hip implants. Furthermore, both implant survival and HHS utilize a specific set of commonly used criteria and therefore are ideal for comparing between studies.

Figure 1: The SYNERGY Hip System (a) standard offset and (b) high offset versions

Clinical Studies

This review reports on clinical studies presenting data on the use of the SYNERGY® Hip System for primary THA only. From the 250 potentially eligible studies identified from a literature search by a content expert, 243 did not meet eligibility, leaving 7 eligible studies.[2–8] (**Figure 2**).

All seven studies included in this review are considered case series. Of these, six were carried out prospectively, indicating that the majority of included studies were well suited to assess prognosis. Although many of the studies in the current review were of greater than Level IV evidence (e.g., some RCTs were included), their research question(s) generally did not focus on the outcomes of using SYNERGY implants. They focused instead on unrelated variables (e.g., the surgical technique performed, cement type used) associated with the use of the 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.

Please refer to *Appendix 1: Methods* for further detail on the eligibility criteria and literature search.

Registry Data

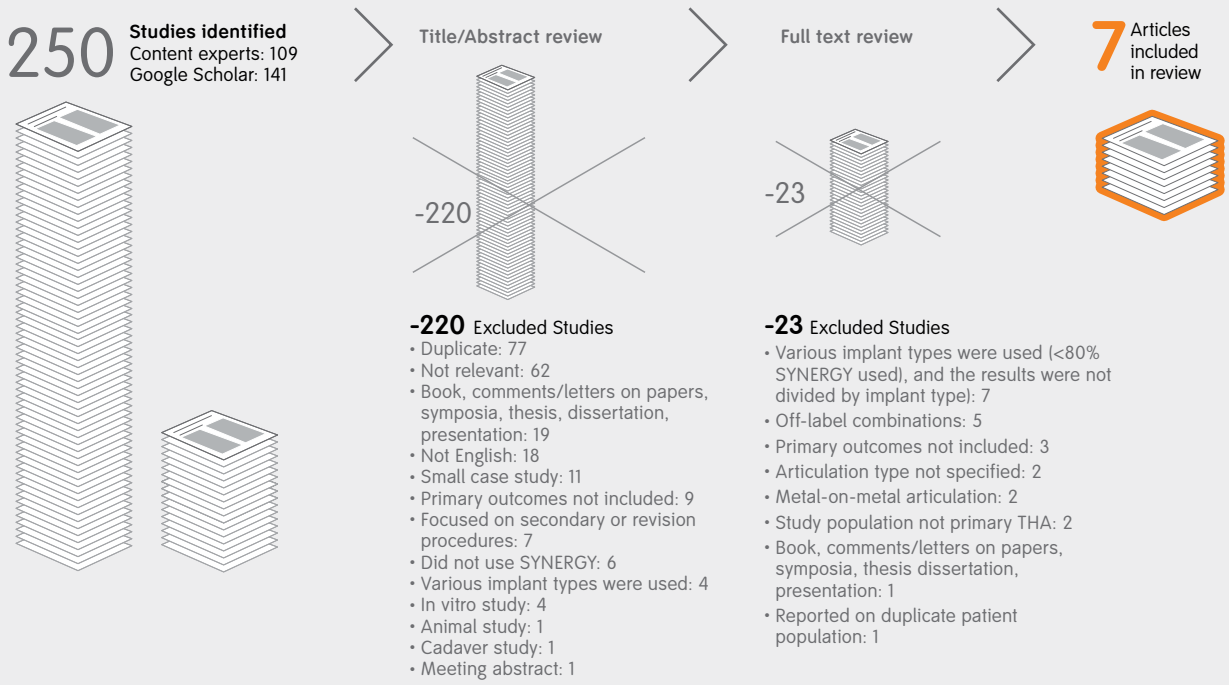
Supplementary to the literature search, the most recent annual reports from the national joint registries that offer device-specific outcomes were also reviewed. Registry data are not subject to the same level of analysis as data found in the published literature. They are only included to provide ancillary information on SYNERGY, and are therefore presented separately in the following analysis. The following exclusions and inclusions were performed for this portion of the analysis:

- Excluded registry reports:
  - Denmark
  - National Joint Registry for England, Wales and Northern Ireland
  - Norway
  - Slovakia

- Included registry reports (provided device-specific revision rates):
  - Australia[9]
  - New Zealand[10]
  - Registro dell'implantologia Protesica Ortopedica (RIPO)[11]
  - Sweden[12]

Please refer to *Appendix 2: Results* for further detail on how outcomes are reported in the various registries, including the separate methods employed to determine revision rates in the Australian and New Zealand registries.

Figure 2: Literature Review



Study Characteristics

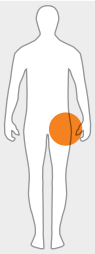
Study characteristics are summarized in **Figure 3** with further detail found in **Tables 1**.

Please refer to *Appendix 2: Results* for additional details on the study results.

Figure 3: Study characteristics

Number of studies:	7
Study designs included:	• Case series • Individual study arms taken from higher-quality studies, considered equivalent to case series

Mean follow-up:	4.6 years
Mean lost to follow-up rate:	0.17%



Mean age:	64.7 years
Most common reason for total hip arthroplasty:	Osteoarthritis
Mean sample size (range) :	81.9 hips (40 to 198)
Number of hips in study:	573 hips

Table 1: Study characteristics of the seven included studies

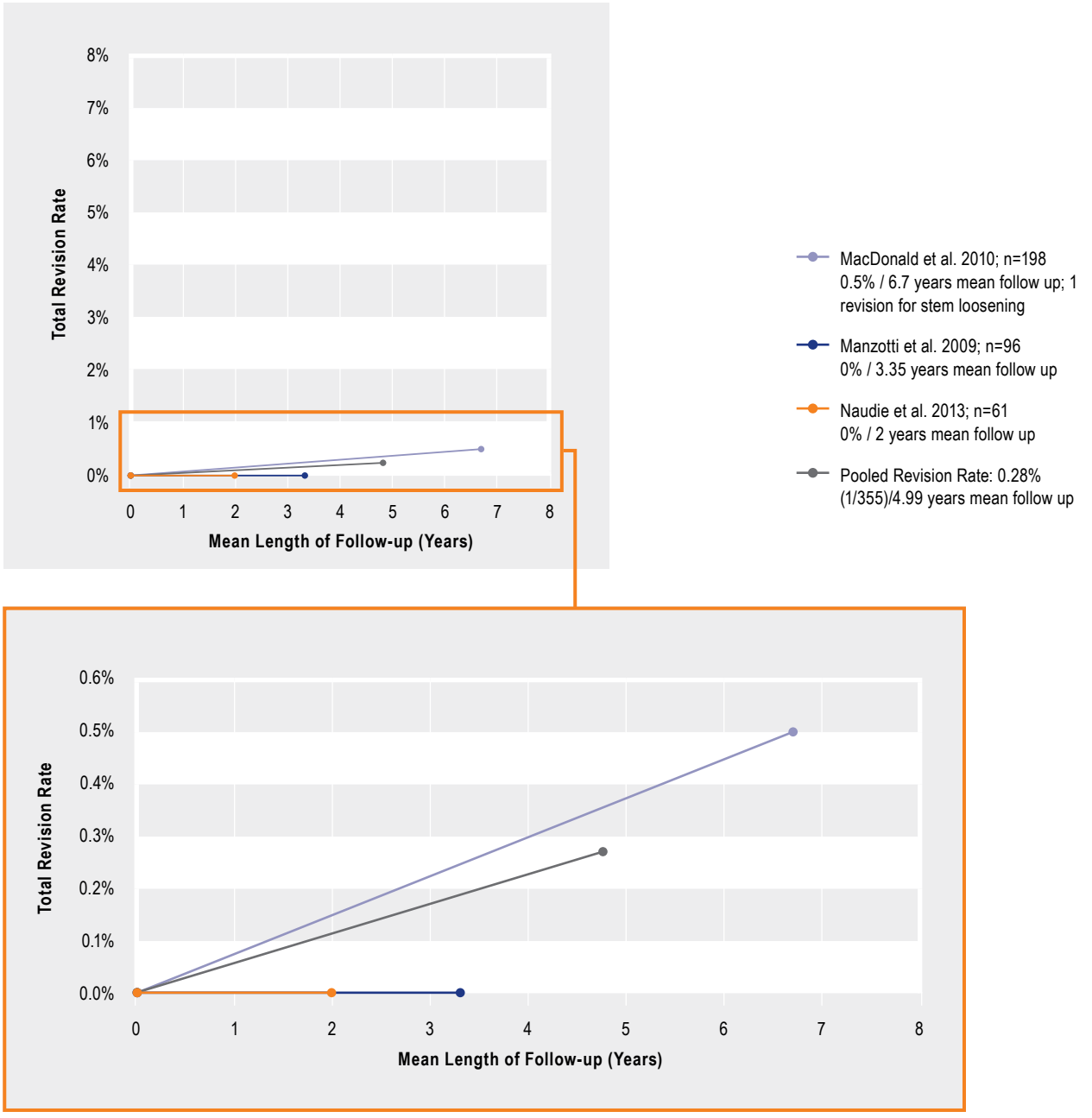
Study, Year	Level I: RCTs	Level II: Prospective comparative	Level III: Retrospective, comparative	Level IV: Case series	Sample size (Hips)	Mean age, years (Range)	% male	Reason for THA*	Other implant components	Length of follow-up, years (Range)	Loss to follow-up rate (%)
Pooled Means					**81.9 (573)**	**64.7**	**47.0**	**Most common: OA (72%), developmental dysplasia (5%), femoral neck fracture (4%), post-traumatic arthritis (3%), AVN (3%), other (13%)**	**–**	**4.6**	**0.17**
MacDonald et al. 2010[4]	■				198	61.0 (NR)	54	OA (100%)	REFLECTION° uncemented	6.7 (2–8.7)	0
Naudie et al. 2013[6]	■				A: 29 B: 33	A: 77.0 (NR) B: 73.8 (NR)	A: 28 B: 33	NR	A: REFLECTION uncemented (Roughcoat) B: REFLECTION uncemented (StikTite)	A: 2.0 (0.3–2) B: 2.0 (0.1–2)	A: 0 B: 3
Konan et al. 2009‡[3]		■			20 20	64.3 (54–86)	30	All femoral neck fracture in one group All OA in control group	REFLECTION uncemented	NR (2–5)	0
Nawabi et al. 2010[7]		■			A: 15 B: 47	A: 72.0 (52–89) B: 71.0 (45–87)§	A: 27 B: 40	OA (100%)	REFLECTION uncemented	A: 0.5 (0.5) B: 0.5 (0.5)	A: 0 B: 0
Nikolaou et al. 2012[8]		■			36∞ 32€	53.0 (20–64)∞ 55.0 (41–64)€	50∞ 56€	OA (64%), RA (3%), developmental dysplasia (6%), AVN (17%), other (11%)∞ OA (59%), RA (3%), developmental dysplasia (6%), posttraumatic arthritis (3%), AVN (16%), other (13%)€	REFLECTION uncemented	5.0 (0.25–5)∞ 5.0 (0.25–5)€	0 0
Whittaker et al. 2010[9]		■			47	58.9 (40–86)	60	OA (100%)	REFLECTION uncemented	6.4 (5–8)	0
Manzotti et al. 2011[5]			■		A: 48 B: 48	A: 72.0 (45–88) B: 72.2 (48–86)	A: 46 B: 46	OA (44%), development dysplasia (Crowe 1-II, 25%), posttraumatic arthritis (17%), AVN (8%), sequelae of septic arthritis (4%), sequelae of Perthes disease (2%)	REFLECTION uncemented	A: 3.4 (0.60–6.3) B: 3.3 (0.70–6.4)	A: 0 B: 0

Please note that although some studies in the current review were of greater than Level IV evidence (e.g., some randomized controlled trials were included), their research question(s) generally did not focus on the outcomes of using SYNERGY°. They focused instead on unrelated variables (e.g., the surgical technique performed, cement type used, etc.) associated with the use of the 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.
Cohorts are only identified in footnotes if considered to be important to the analysis. Otherwise, they are identified as cohorts A and B.
Abbreviations: AVN = avascular necrosis; NR=Not Reported; OA = osteoarthritis, RA = rheumatoid arthritis
‡Hydroxyapatite-coated SYNERGY used.
∞ Ultra-high-molecular-weight polyethylene liner used; € Highly cross-linked polyethylene liner used
*Percentages may not add to 100% due to rounding.

Cumulative Percentage Revision Rate of SYNERGY° Hip System, as Reported in Three Published Studies

Out of 355 hips across three studies,[3–5] the overall revision rate was 0.28% (all of which were related to the femoral component; **Figure 4**) over a mean of 4.99 years follow up.

Figure 4: Revision Rate of SYNERGY Hip System in Primary THA (n=3)



Harris Hip Scores

Seven studies[3–9] (573 hips) reported data on the HHS; six studies[4–9] provided both pre-operative and post-operative scores, with all reporting an improvement over time in the scores (**Figure 5; Table 2**). A score equal or above the benchmark (80–100) after surgery is considered an indication of good-to-excellent clinical outcome.[1]

Figure 5: Mean Increase from Preoperative to Postoperative Harris Hip Scores (n=7)

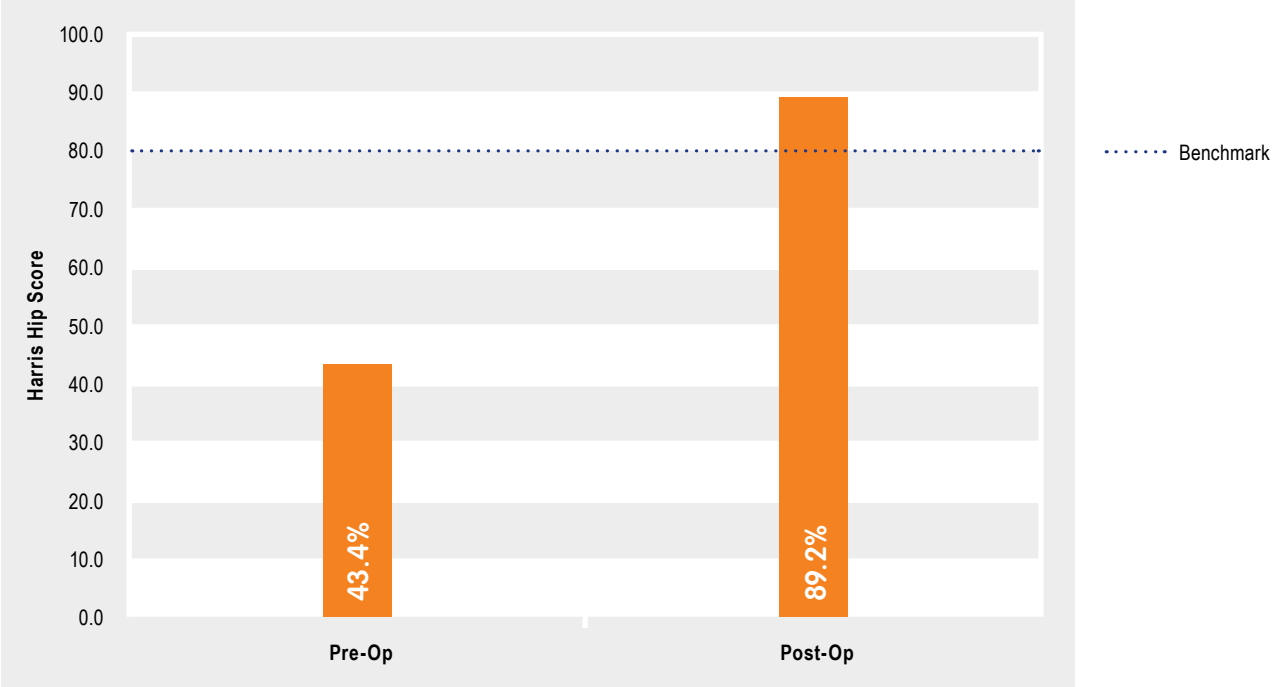


Table 2: Harris Hip Score from the seven studies that reported at least post-operative scores

Study	Number of Hips	Mean Pre-Operative HHS (SD; Range)	Mean Post-Operative HHS (SD; Range)	Mean change in score
Pooled Weighted Means	**81.7**	**43.4**	**89.2**	**45.3**
Konan et al. 2009‡	20 20	NR NR	94.4 (7.73; 87–100) 97.6 (4.31; 92–100)	– –
MacDonald et al. 2010	198	42.3 (NR; NR)	86.4 (NR; NR)	44.1
Manzotti et al. 2011	A: 48 B: 48	A: 40.0 (4.63; 30–46) B: 39.8 (5.13; 32–48)	A: 89.7 (7.10; 72–100) B: 88.9 (7.51; 74–100)	A: 49.7 B: 49.1
Naudie et al. 2013	A: 29 B: 32	A: 54.2 (11.09; NR) B: 44.8 (12.52; NR)	A: 91.3 (7.63; NR) B: 87.6 (7.15; NR)	A: 37.1 B: 42.8
Nawabi et al. 2010	A: 15 B: 47	A: 32.0 (13.0; NR) B: 42.0 (13.0; NR)	A: 85.0 (9.0; NR) B: 89.0 (11.0; NR)	A: 53.0 B: 47.0
Nikolaou et al. 2012	36∞ 32€	47.1 (NR; 22–63) 51.9 (NR; 23–90)	87.9 (NR; 61–98) 91.5 (NR; 63–100)	40.8 39.6
Whittaker et al. 2010	47	44.1 (13.17; NR)	96.0 (5.30; NR)	51.9

Abbreviations: HHS = Harris Hip Score; NR = not reported; SD = standard deviation
Cohorts are only identified in footnotes if considered to be important to the analysis. Otherwise, they are identified as cohorts A and B.
‡Hydroxyapatite-coated SYNERGY® used.
∞ Ultra-high-molecular-weight polyethylene liner used; € Highly cross-linked polyethylene liner used

Registry Data

Device-specific data with the SYNERGY° Hip System were presented by the various registries as either revision rates (**Figures 6 & 7**) or survival times (**Figure 8**). Data with SYNERGY were available in the annual reports of four separate registries,[9–12] with findings on 12,599 devices in total. Revision rates and survival times at final follow-up were below the separate registries' class averages in all six categories.

Figure 6: Australian Orthopaedic Association National Joint Replacement Registry, Annual Report 2014[9]

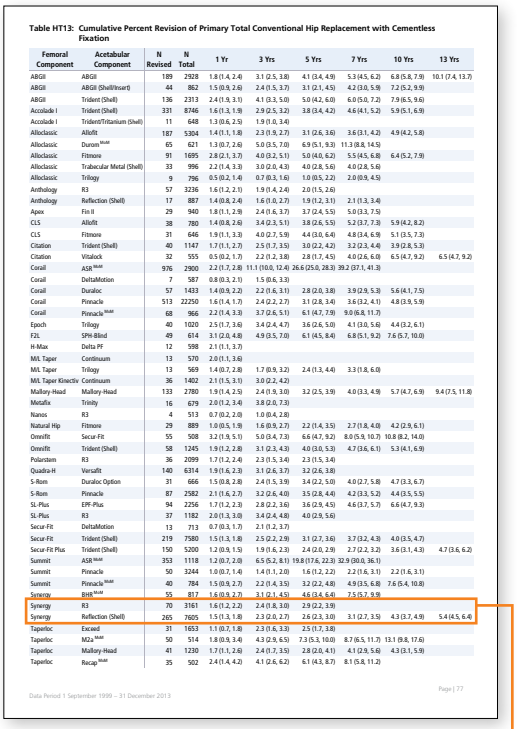


Table HT13: Cumulative Percent Revision of Primary Total Conventional Hip Replacement with Cementless Fixation

Femoral Component	Acetabular Component	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	7 Yrs	10 Yrs	13 Yrs
ABGII	ABGII	189	2928	1.8 (1.4, 2.4)	3.1 (2.5, 3.8)	4.1 (3.4, 4.9)	5.3 (4.5, 6.2)	6.8 (5.8, 7.9)	10.1 (7.4, 13.7)
ABGII	ABGII (Shell/Insert)	44	862	1.5 (0.9, 2.6)	2.4 (1.5, 3.7)	3.1 (2.1, 4.5)	4.2 (3.0, 5.9)	7.2 (5.2, 9.9)	
ABGII	Trident (Shell)	136	2313	2.4 (1.9, 3.1)	4.1 (3.3, 5.0)	5.0 (4.2, 6.0)	6.0 (5.0, 7.2)	7.9 (6.5, 9.6)	
Accolade I	Trident (Shell)	331	8746	1.6 (1.3, 1.9)	2.9 (2.5, 3.2)	3.8 (3.4, 4.2)	4.6 (4.1, 5.2)	5.9 (5.1, 6.9)	
Accolade I	Trident/Tritanium (Shell)	11	648	1.3 (0.6, 2.5)	1.9 (1.0, 3.4)				
Alloclassic	Allofit	187	5304	1.4 (1.1, 1.8)	2.3 (1.9, 2.7)	3.1 (2.6, 3.6)	3.6 (3.1, 4.2)	4.9 (4.2, 5.8)	
Alloclassic	Durom Mod	65	621	1.3 (0.7, 2.6)	5.0 (3.5, 7.0)	6.9 (5.1, 9.3)	11.3 (8.8, 14.5)		
Alloclassic	Fitmore	91	1695	2.8 (2.1, 3.7)	4.0 (3.2, 5.1)	5.0 (4.0, 6.2)	5.5 (4.5, 6.8)	6.4 (5.2, 7.9)	
Alloclassic	Trabecular Metal (Shell)	33	996	2.2 (1.4, 3.3)	3.0 (2.0, 4.3)	4.0 (2.8, 5.6)	4.0 (2.8, 5.6)		
Alloclassic	Trilogy	9	796	0.5 (0.2, 1.4)	0.7 (0.3, 1.6)	1.0 (0.5, 2.2)	2.0 (0.9, 4.5)		
Anthology	R3	57	3236	1.6 (1.2, 2.1)	1.9 (1.4, 2.4)	2.0 (1.5, 2.6)			
Anthology	Reflection (Shell)	17	887	1.4 (0.8, 2.4)	1.6 (1.0, 2.7)	1.9 (1.2, 3.1)	2.1 (1.3, 3.4)		
Apex	Fin II	29	940	1.8 (1.1, 2.9)	2.4 (1.6, 3.7)	3.7 (2.4, 5.5)	5.0 (3.3, 7.5)		
CLS	Allofit	38	780	1.4 (0.8, 2.6)	3.4 (2.3, 5.1)	3.8 (2.6, 5.5)	5.2 (3.7, 7.3)	5.9 (4.2, 8.2)	
CLS	Fitmore	31	646	1.9 (1.1, 3.3)	4.0 (2.7, 5.9)	4.4 (3.0, 6.4)	4.8 (3.4, 6.9)	5.1 (3.5, 7.3)	
Citation	Trident (Shell)	40	1147	1.7 (1.1, 2.7)	2.5 (1.7, 3.5)	3.0 (2.2, 4.2)	3.2 (2.3, 4.4)	3.9 (2.8, 5.3)	
Citation	Vitalock	32	555	0.5 (0.2, 1.7)	2.2 (1.2, 3.8)	2.8 (1.7, 4.5)	4.0 (2.6, 6.0)	6.5 (4.7, 9.2)	6.5 (4.7, 9.2)
Corail	ASR Mod	976	2900	2.2 (1.7, 2.8)	11.1 (10.0, 12.4)	26.6 (25.0, 28.3)	39.2 (37.1, 41.3)		
Corail	DeltaMotion	7	587	0.8 (0.3, 2.1)	1.5 (0.6, 3.3)				
Corail	Duraloc	57	1433	1.4 (0.9, 2.2)	2.2 (1.6, 3.1)	2.8 (2.0, 3.8)	3.9 (2.9, 5.3)	5.6 (4.1, 7.5)	
Corail	Pinnacle	513	22250	1.6 (1.4, 1.7)	2.4 (2.2, 2.7)	3.1 (2.8, 3.4)	3.6 (3.2, 4.1)	4.8 (3.5, 5.9)	
Corail	Pinnacle Mod	68	966	2.2 (1.4, 3.3)	3.7 (2.6, 5.1)	6.1 (4.7, 7.9)	9.0 (6.8, 11.7)		
Epoch	Trilogy	40	1020	2.5 (1.7, 3.6)	3.4 (2.4, 4.7)	3.6 (2.6, 5.0)	4.1 (3.0, 5.6)	4.4 (3.2, 6.1)	
F2L	SPH-Blind	49	614	3.1 (2.0, 4.8)	4.9 (3.5, 7.0)	6.1 (4.5, 8.4)	6.8 (5.1, 9.2)	7.6 (5.7, 10.0)	
H-Max	Delta PF	12	598	2.1 (1.1, 3.7)					
M/L Taper	Continuum	13	570	2.0 (1.1, 3.6)					
M/L Taper	Trilogy	13	569	1.4 (0.7, 2.8)	1.7 (0.9, 3.2)	2.4 (1.3, 4.4)	3.3 (1.8, 6.0)		
M/L Taper Kinectiv	Continuum	36	1402	2.1 (1.5, 3.1)	3.0 (2.2, 4.2)				
Mallory-Head	Mallory-Head	133	2780	1.9 (1.4, 2.5)	2.4 (1.9, 3.0)	3.2 (2.5, 3.9)	4.0 (3.3, 4.9)	5.7 (4.7, 6.9)	9.4 (7.5, 11.8)
Metafix	Trinity	16	679	2.0 (1.2, 3.4)	3.8 (2.0, 7.3)				
Nanos	R3	4	513	0.7 (0.2, 2.0)	1.0 (0.4, 2.8)				
Natural Hip	Fitmore	29	889	1.0 (0.5, 1.9)	1.6 (0.9, 2.7)	2.2 (1.4, 3.5)	2.7 (1.8, 4.0)	4.2 (2.9, 6.1)	
Omnifit	Secur-Fit	55	508	3.2 (1.9, 5.1)	5.0 (3.4, 7.3)	6.6 (4.7, 9.2)	8.0 (5.9, 10.7)	10.8 (8.2, 14.0)	
Omnifit	Trident (Shell)	58	1245	1.9 (1.2, 2.8)	3.1 (2.3, 4.3)	4.0 (3.0, 5.3)	4.7 (3.6, 6.1)	5.3 (4.1, 6.9)	
Polarstem	R3	36	2099	1.7 (1.2, 2.4)	2.3 (1.5, 3.4)	2.3 (1.5, 3.4)			
Quadra-H	Versafit	140	6314	1.9 (1.6, 2.3)	3.1 (2.6, 3.7)	3.2 (2.6, 3.8)			
S-Rom	Duraloc Option	31	666	1.5 (0.8, 2.8)	2.4 (1.5, 3.9)	3.4 (2.2, 5.0)	4.0 (2.7, 5.8)	4.7 (3.3, 6.7)	
S-Rom	Pinnacle	87	2582	2.1 (1.6, 2.7)	3.2 (2.6, 4.0)	3.5 (2.8, 4.4)	4.2 (3.3, 5.2)	4.4 (3.5, 5.5)	
SL-Plus	EPF-Plus	94	2256	1.7 (1.2, 2.3)	2.8 (2.2, 3.6)	3.6 (2.9, 4.5)	4.6 (3.7, 5.7)	6.6 (4.7, 9.3)	
SL-Plus	R3	37	1182	2.0 (1.3, 3.0)	3.4 (2.4, 4.8)	4.0 (2.9, 5.6)			
Secur-Fit	DeltaMotion	13	713	0.7 (0.3, 1.7)	2.1 (1.2, 3.7)				
Secur-Fit	Trident (Shell)	219	7580	1.5 (1.3, 1.8)	2.5 (2.2, 2.9)	3.1 (2.7, 3.6)	3.7 (3.2, 4.3)	4.0 (3.5, 4.7)	
Secur-Fit Plus	Trident (Shell)	150	5200	1.2 (0.9, 1.5)	1.9 (1.6, 2.3)	2.4 (2.0, 2.9)	2.7 (2.2, 3.2)	3.6 (3.1, 4.3)	4.7 (3.6, 6.2)
Summit	ASR Mod	353	1118	1.2 (0.7, 2.0)	6.5 (5.2, 8.1)	19.8 (17.6, 22.3)	32.9 (30.0, 36.1)		
Summit	Pinnacle	50	3244	1.0 (0.7, 1.4)	1.4 (1.1, 2.0)	1.6 (1.2, 2.2)	2.2 (1.6, 3.1)	2.2 (1.6, 3.1)	
Summit	Pinnacle Mod	40	784	1.5 (0.9, 2.7)	2.2 (1.4, 3.5)	3.2 (2.2, 4.8)	4.9 (3.5, 6.8)	7.6 (5.4, 10.8)	
Synergy	BHR Mod	55	817	1.6 (0.9, 2.7)	3.1 (2.1, 4.5)	4.6 (3.4, 6.4)	7.5 (5.7, 9.9)		
Synergy	R3	70	3161	1.6 (1.2, 2.2)	2.4 (1.8, 3.0)	2.9 (2.2, 3.9)			
Synergy	Reflection (Shell)	265	7605	1.5 (1.3, 1.8)	2.3 (2.0, 2.7)	2.6 (2.3, 3.0)	3.1 (2.7, 3.5)	4.3 (3.7, 4.9)	5.4 (4.5, 6.4)
Tapeloc	Exceed	31	1653	1.1 (0.7, 1.8)	2.3 (1.6, 3.3)	2.5 (1.7, 3.8)			
Tapeloc	M2a Mod	50	514	1.8 (0.9, 3.4)	4.3 (2.9, 6.5)	7.3 (5.3, 10.0)	8.7 (6.5, 11.7)	13.1 (9.8, 17.6)	
Tapeloc	Mallory-Head	41	1230	1.7 (1.1, 2.6)	2.4 (1.7, 3.5)	2.8 (2.0, 4.1)	4.1 (2.9, 5.6)	4.3 (3.1, 5.9)	
Tapeloc	Recap Mod	35	502	2.4 (1.4, 4.2)	4.1 (2.6, 6.2)	6.1 (4.3, 8.7)	8.1 (5.8, 11.2)		

Data Period 1 September 1999 – 31 December 2013

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Table HT13*: Cumulative Percent Revision of Primary Total Conventional Hip Replacement with Cementless Fixation

Femoral Component	Acetabular Component	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	7 Yrs	10 Yrs	13 Yrs
Synergy	R3	70	3161	1.6 (1.2, 2.2)	2.4 (1.8, 3.0)	2.9 (2.2, 3.9)			
Synergy	Reflection (Shell)	265	7605	1.5 (1.3, 1.8)	2.3 (2.0, 2.7)	2.6 (2.3, 3.0)	3.1 (2.7, 3.5)	4.3 (3.7, 4.9)	5.4 (4.5, 6.4)

Table HT2*: Cumulative Percent Revision of Primary Total Hip Replacement by Class

Total Hip Class	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	7 Yrs	10 Yrs	13 Yrs
Total Conventional	11442	280522	1.6 (1.6, 1.7)	2.8 (2.7, 2.8)	4.0 (3.9, 4.1)	5.2 (5.1, 5.3)	6.8 (6.6, 6.9)	8.9 (8.6, 9.3)
Total Resurfacing	1170	15770	1.8 (1.6, 2.0)	3.3 (3.1, 3.6)	5.3 (4.9, 5.7)	7.5 (7.0, 7.9)	9.8 (9.2, 10.4)	11.6 (10.6, 12.6)
Thrust Plate	12	258	0.8 (0.2, 3.1)	1.2 (0.4, 3.6)	3.9 (2.1, 7.4)	4.5 (2.4, 8.3)	6.2 (3.5, 11.1)	
TOTAL	**12624**	**296550**						

* Tables HT13 and HT2 are taken directly from the AOANJRR Annual Report 2014.

RESULTS

Figure 7: Revisions per 100 Observed Component Years with SYNERGY°, Identified by Acetabular Couple, as Reported in New Zealand Registry[10]

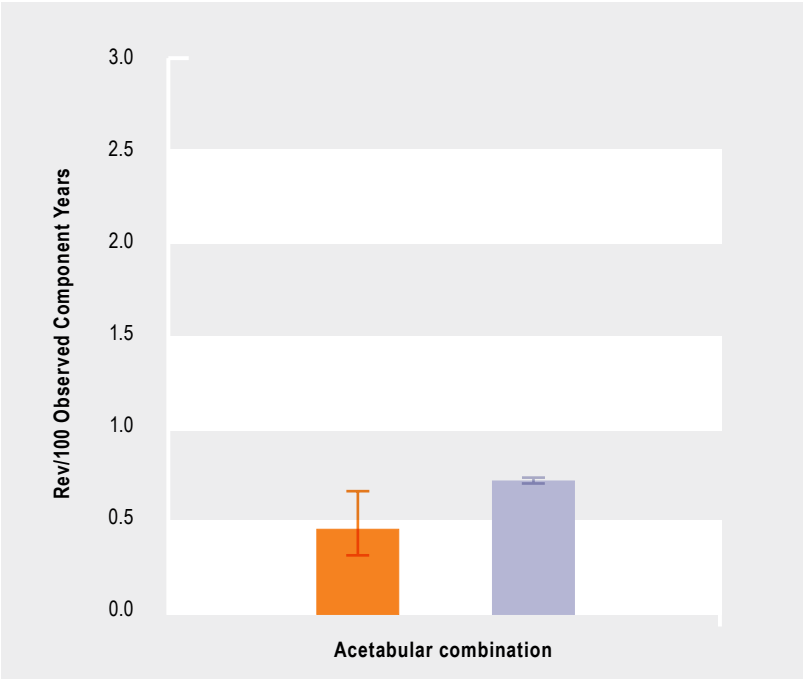
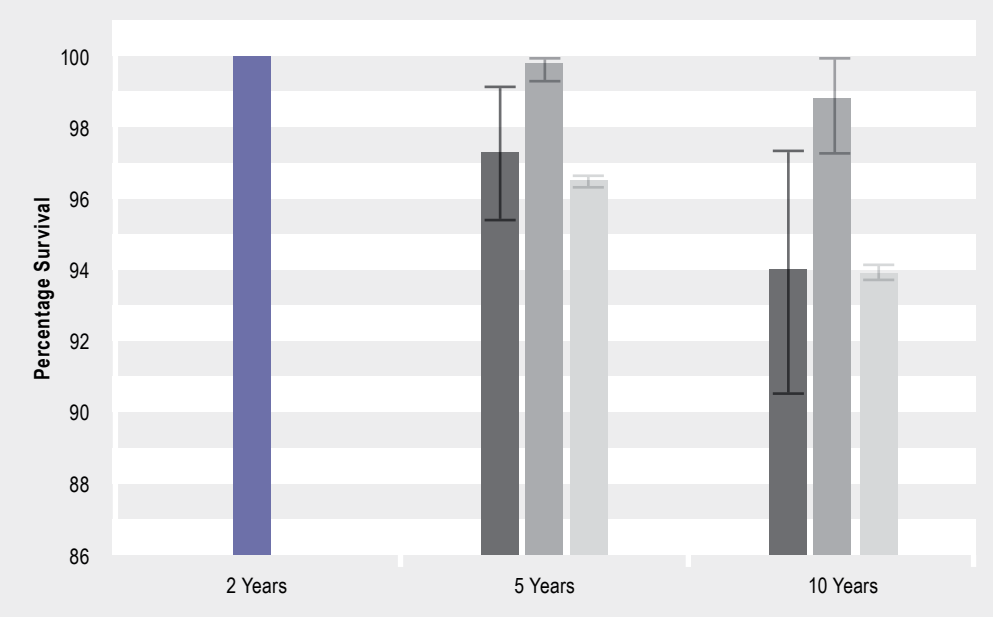


Figure 8. Kaplan-Meier Implant Survivorship Estimate of SYNERGY°, as Reported by Two Registries[11,12]



Sweden*, SYNERGY, 0 revised out of 234 implanted (100% survivorship)

RIPO, SYNERGY/REFLECTION° Uncemented; 13 revised out of 392 implanted (KM survivorship estimate at 5 years, 97.3% [95% CI: 95.4–99.2), and at 10 years, 94.0% [95% CI: 90.5–97.4])

RIPO, SYNERGY; 3 revised out of 445 implanted (KM survivorship estimate at 5 years, 99.8% [95% CI: 99.3–100.0), and at 10 years, 98.8% [95% CI: 97.3–100.0])

RIPO class average, conventional THA; 2,391 revised out of 59,859 implanted (KM survivorship estimate at 5 years, 96.5% [95% CI: 96.3–96.7), and at 10 years, 93.9% [95% CI: 93.7–94.2])

*The Swedish Hip Registry does not provide exact two-year class averages with which to compare against. However, it does state that, "the proportion of total hip replacements to be reoperated within two years diminished during the 1990s and has since 2001 been about 2%."

Abbreviations: KM = Kaplan-Meier

95% confidence interval

RESULTS

Discussion

Literature review

The main findings of the systematic literature review were as follows:

- Mean revision rate of 0.28% after a mean 4.99 years follow up from three studies (only one revision[3] from 355 hips) was well below the benchmark for well-performing hip prostheses of no more than 0.5% cumulative revision rate per annum established by the UK National Institute for Health and Care Excellence (NICE),[13] as were the individual revision rates reported in all three of these studies. The previous NICE benchmark established a benchmark of 1% per annum[14]
- The six studies (532 hips)[3–8] providing both pre-operative and post-operative HHS showed mean improvements from 43.4 preoperatively to 89.2. A post-operative HHS above 80 indicates good outcomes with respect to pain, function, absence of deformity, and range of motion following primary THA[1]

Registry data

The main findings from the four registries[9–12] offering relevant data, with up to 13 years of follow up in some cases, were as follows:

AOANJRR

- SYNERGY® combined with both the R3® and REFLECTION® Uncemented Acetabular System was below the class average for cumulative percent revision at all available follow-up periods[9]

New Zealand

- SYNERGY combined with REFLECTION Uncemented had a revision rate per 100 observed component years well below the overall class average[10]

RIPO

- Kaplan-Meier survivorship estimates for SYNERGY/REFLECTION Uncemented combination and for the SYNERGY alone was above the class average at both five years and 10 years[11]

Sweden

- No class averages could be found in the latest report of the Swedish Hip Arthroplasty Register. However, as the SYNERGY has had no revisions to date (234 hips followed for up to two years), it has the best possible performance for its specific follow-up point[12]

Conclusions

When results from the peer-reviewed literature are considered along with the results reported by the national joint registries (12,599 cases), there is considerable evidence that SYNERGY is safe and effective at follow-up periods of up to more than a decade.

Strengths	Limitations
• A thorough and systematic review of the literature was conducted using Google Scholar. Using Google Scholar allowed for full text searches, ensuring comprehensiveness. Content experts also provided a list of relevant articles. • High degree of external validity, with data from seven different studies across a variety of countries.	• There is a lack of high-quality evidence (Level I randomized controlled trials). • Limited number of studies which focus specifically on the outcomes of the implants of interest. • Studies often used a variety of implants and did not present the results according to implant type, which excluded many studies. • Heterogeneity in outcome reporting across the studies did not allow for pooling of the data for some outcomes. • Collectively, these limitations suggest that caution should be exercised when applying the findings of this review to clinical decisions.

Review at a glance

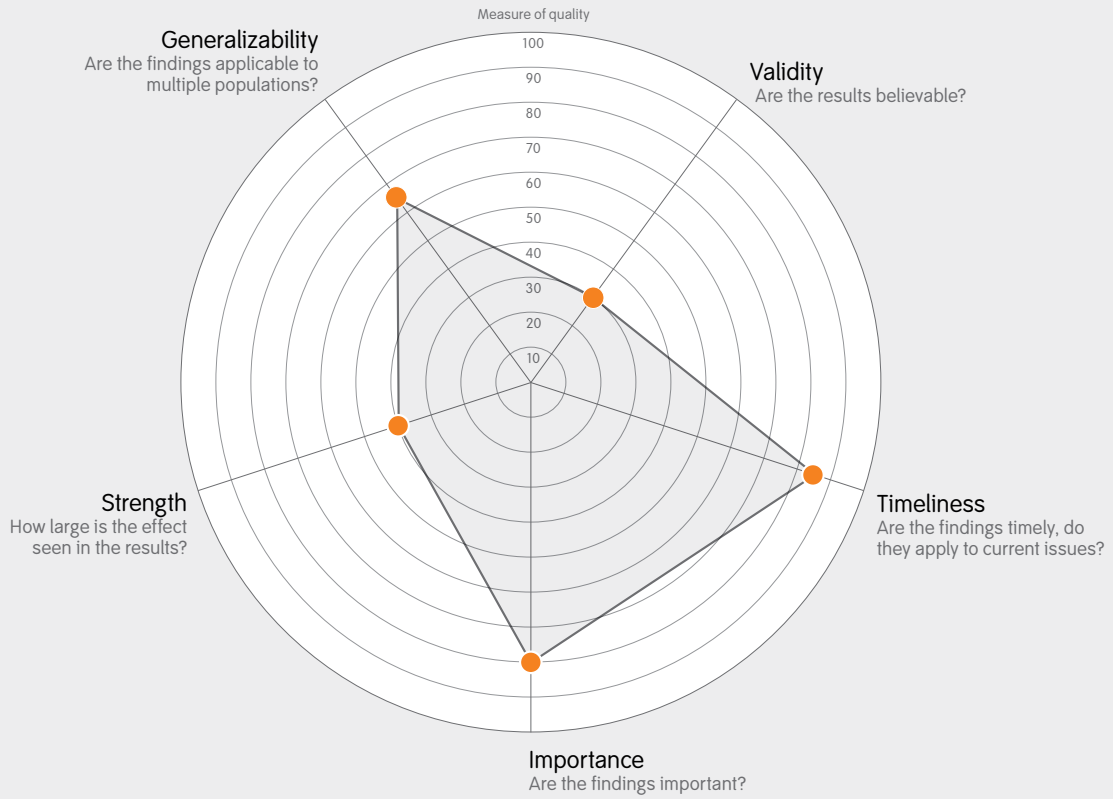
Generalizability
65 out of 100. All included studies considered patients who underwent primary THA with SYNERGY°, allowing the findings to be applied to a larger population with similar characteristics. However, the wide variety of surgical techniques used, indications for THA and fixation methods, limit the generalizability of the findings.

Validity
30 out of 100. Systematic review of fair evidence, with somewhat inconsistent reporting of outcomes across included studies. Study questions often did not focus explicitly on the outcomes of the implants of interest (e.g., they were focusing on surgical technique or cement type).

Timeliness
85 out of 100. This review assesses the survivorship, revision rates, and Harris Hip Scores of SYNERGY used in primary THA for varying indications. All studies in this review were published within the past eight years (75% were published within the last four years).

Importance
80 out of 100. The evidence is important in providing patients and orthopaedic surgeons with information regarding the successful clinical outcomes of SYNERGY. This information is important since these implants have been in use for over 15 years, and this is the first comprehensive systematic review to summarize the clinical results of this total hip prosthesis.

Strength
40 out of 100. Data from seven studies were included in this study. The quality of evidence is fair. Meta-analytic statistical analysis was only possible for select variables (study characteristics, revision rates and Harris Hip Scores), due to heterogeneity in the reporting of study outcomes.



For detailed information see **www.kleos.md/literature/background**

REVIEW

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Products in this literature review may not be available in all countries. Indications for use may vary from country to country.

Appendices

Visit **www.smith-nephew.com/education** and search for the appendices or use this QR code. The following appendices provide further detail:

The SYNERGY® Hip System in Primary Total Hip Arthroplasty, A Systematic Literature Review of Clinical Outcomes, Reviewed by: Robert B. Bourne, Jack M. Bert.
Appendices
Appendix 1: Methods
Appendix 2: Results

Notes

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