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The GENESIS[◇] II Total Knee System in Primary Total Knee Arthroplasty

A Systematic Literature Review of Clinical Outcomes

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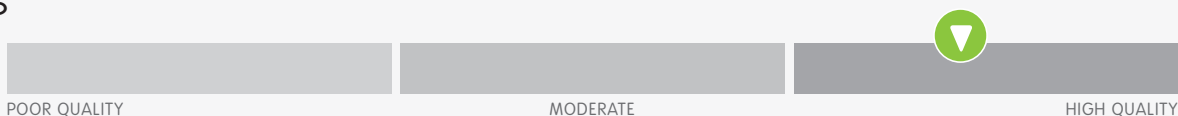
Overview

The GENESIS[◇] II Total Knee System in Primary Total Knee Arthroplasty: A Systematic Literature Review of Clinical Outcomes.

Purpose of review The purpose of the current study was to conduct a systematic review and evaluate the current evidence on the clinical performance of the GENESIS II Total Knee System.

Background Since its introduction in the mid-1990s, several individual studies of the GENESIS II Total Knee System have reported encouraging clinical results. We performed a systematic literature review of the published literature to obtain a more thorough understanding of the overall clinical performance of the GENESIS II Total Knee System. [Read more on page 4](#)

Rating



Why this rating? This is a systematic review of randomized controlled trials, prospective studies, and retrospective studies. The evidence rating is moderate to high, as non-randomized trials are included in the analyses.

Results Nineteen studies featuring data from 2,656 knees met the inclusion criteria for this review. Data was utilized from 1520 total knee arthroplasties at five years, 867 total knee arthroplasties at seven years, and, 769 total knee arthroplasties at nine years postoperatively. [Read more on pages 6–13](#)

Key considerations

- A c review of the literature found:
 - **Low revision rate** (up to 11.9 years follow-up)
 - **99.5% cumulative mean survival rate at five years;** 99.9% at seven years; 98.8% at nine years
 - **Mean implant cumulative survival time of 9.93 years**
 - **Mean postoperative Knee Society knee score 90.6**
 - **Improved mean Knee Society knee scores** (48.2 points from preoperative to postoperative period; average 45.9 months follow-up)
- **GENESIS II Total Knee System is safe and effective** (confirmed by 5 and 10 year survival and national joint registry data)
- **Need for additional studies:**
 - Greater than 10 years follow-up
 - Larger sample sizes
 - Younger patients
 - Investigate health outcomes for total knee arthroplasty for indications other than osteoarthritis

Background

The GENESIS[®] II Total Knee System (Smith & Nephew, Memphis, USA; **Figure 1**) was introduced in 1996 with several new design features to improve clinical function in patients undergoing total knee arthroplasty. The GENESIS II implant has a deeper, more lateralized trochlear groove, thereby enhancing patellar contact and tracking. The system has an externally rotated femoral implant design that optimizes femorotibial rotational alignment and reduces the likelihood of notching the lateral anterior cortex. It has anatomically-shaped tibial baseplates with an improved fin design that enhances coverage of the tibia as compared with symmetrical designs. Wear is reduced by improving contact area and reducing contact stress on all articular surfaces. The femoral components are available in either cobalt chromium alloy or ceramicized metal alloy (OXINIUM[®]). Both posterior cruciate ligament preserving and sacrificing designs are available. Initially ethylene oxide sterilized GUR 1050 resin was used for the original tibial polyethylene inserts; however, due to the introduction of the HiFlex designs and cross-linked polyethylene, a switch has been made to GUR 1020 resin retaining ethylene oxide sterilization [1–4].

Despite more than a decade of use, only one comprehensive systematic review has been conducted to summarize the clinical results of the GENESIS II Total Knee System. Findings of the review were indicative of an implant with a high survivorship (96.0% at 10 years), low complication rates, and good functional scores [5].

We performed a systematic literature review of the GENESIS II implant to improve the understanding of its overall clinical performance. Primary outcomes were implant survival and Knee Society knee scores. These outcomes were selected because both outcomes have time-established utility in evaluating the clinical performance of knee implants. Furthermore, both implant survival [6], and Knee Society knee scores [7] utilize a specific set of commonly used criteria and therefore are ideal for comparing outcomes between studies.

Figure 1: The GENESIS II Total Knee System.



Clinical Studies

The inclusion criteria for this review are clinical studies that utilize the GENESIS[®] II Total Knee System for primary total knee arthroplasty. From 361 potentially eligible studies, identified by a literature search and a content expert, 342 studies did not meet the eligibility criteria for this review, leaving 19 eligible studies [2-4,8-23] (Figure 2).

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

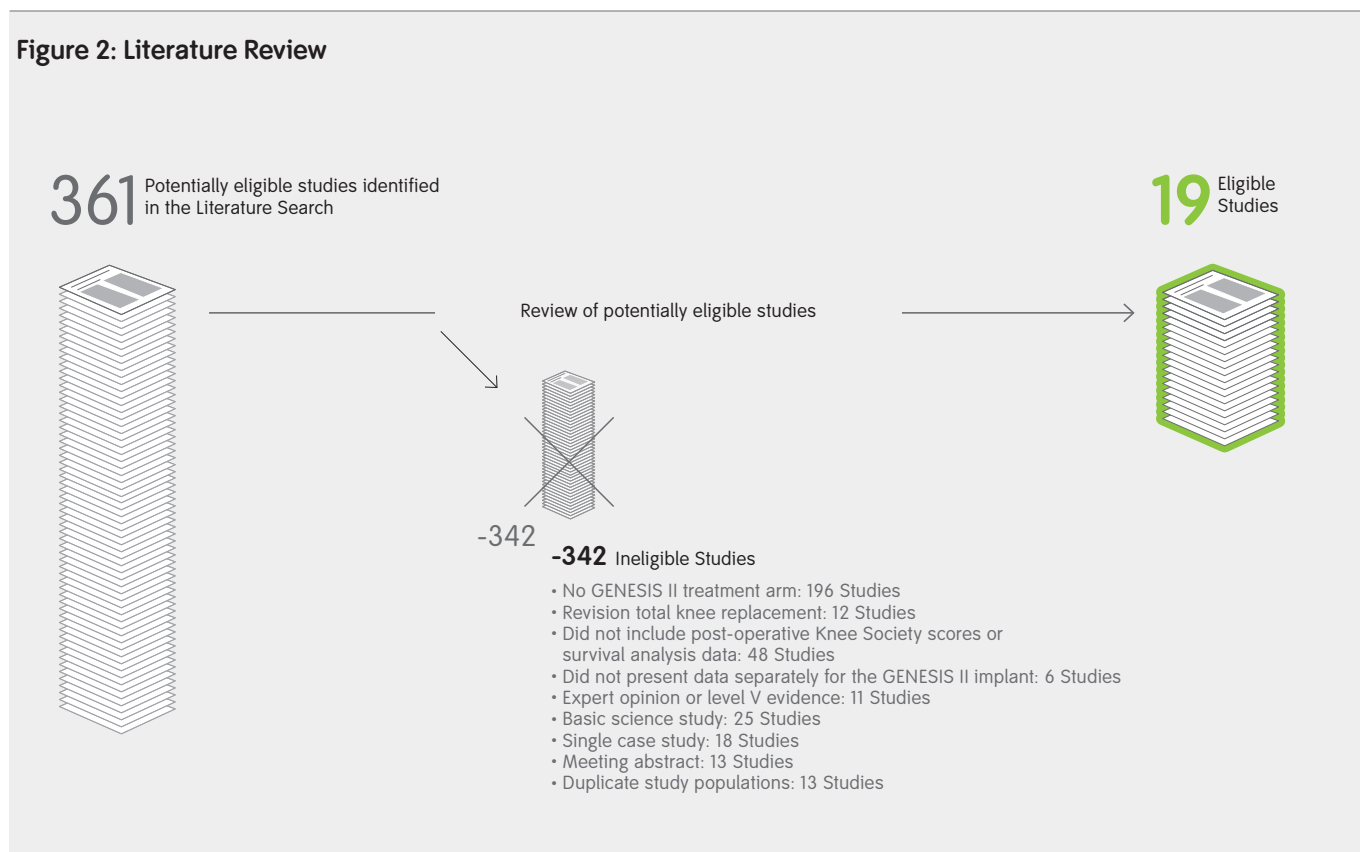
Registry Data

Supplementary to the literature search, the 2010 or most recent national joint replacement registry annual reports from ten countries were also reviewed:

- Excluded (no specific implant data):
Canadian, Romanian, and Scottish registries
- Excluded (GENESIS II Total Knee System not reported):
Danish, Norwegian, Slovakian, and Swedish registries
- Included (provided device specific revision rates):
Australia, New Zealand, and the UK registries [24-26]

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 the GENESIS II implant, and are therefore presented separately in the following analysis.

Figure 2: Literature Review



Study Characteristics

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

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

Figure 3: Study characteristics



Study designs included:

- **Randomized controlled trials**
- **Prospective comparative studies**
- **Case series**



Mean follow-up range:
41.7 months

Mean loss to follow-up rate:
3.7%



Mean age:
68.4 years

Most common reason for TKA:
Osteoarthritis

Sample size range:
34 to 669 knees

Number of knees in study:
2656 knees

Table 1: Study characteristics of the 19 included studies.

Study	Randomised studies	Prospective studies	Case series	Sample Size (Knees)	Mean Age (Range or Std Dev)	% Male	Reason for TKA	Surgical Details	Length of Follow-up (Months)	Loss to Follow-up Rate (%)
Mean				148.9 (N=2656)	68.4	36.1			41.7	3.7
Laskin et al, 2000 [13]				62	74	NR	OA	Posterior-stabilized poly-ethylene component with an intercondylar eminence	NR	NR
				66	71	NR	OA	Deep-dish tibial component, femoral component with recess & cam	NR	NR
				48*	76	NR	OA	Deep-dish tibial component, femoral component without recess & cam	NR	NR
Victor et al, 2005 [15]				17	NR	NR	NR	Posterior-cruciate-ligament-retaining TKA	60	NR
				17	NR	NR	NR	Posterior-cruciate-ligament-substituting TKA	60	NR
Harato, 2008 [9]				111	68.3 (49-89)	34.3	OA	Posterior cruciate-retaining	60-87.6	0.8
				111	66.0 (44-83)	34.4	OA	Posterior cruciate-substituting		16.2
Karachalios et al, 2008 [10]				50	71.1 (52-78)	38	OA	Mini-midvastus approach	24 (23-35)	0.0
				50	70.8 (54-77)	30	OA	Standard anterior midline approach	24 (23-35)	0.0
McCalden et al, 2009 [14]				50	70	46	Degenerative knee disease	High-flex polyethylene tibial insert	32.4 (27.6-37.2)	4.0
				50	72	50	Degenerative knee disease	Standard posterior stabilized polyethylene tibial insert		0.0
Kim et al, 2010 [20]				33	70 (55-79)	3.0	OA	Medial parapatellar approach, cruciate retaining	24	NR
				33				Medial parapatellar approach, posterior stabilized		
Hui et al, 2011 [18]				40	NR	NR	NR	Medial parapatellar incision and anteromedial approach; OXINIUM® femoral component	60	15.0
				40				Medial parapatellar incision and anteromedial approach; OXINIUM femoral component		
Haas et al, 2004 [8]				40	71 (55-82)	24.3	OA (90%), RA (10%)	Minimally invasive total knee replacement	12	NR
				40	70 (52-81)	22.2	OA (95%), RA (5%)	Standard medial parapatellar arthroscopy	12	NR
Laskin, 2007 [3]				40	NR	45	OA	High-flex posterior-stabilized prosthesis	24	2.5
				40	NR	42.5	OA	Standard posterior stabilized implant	24	0.0
Crow et al, 2010 [17]				85	68.3 ± 9.0	41.2	OA or degenerative joint disease	Mini-medial parapatellar arthroscopy; high flexion insert	12	0.0
				79	68.0 ± 8.6	21.8		Mini-medial parapatellar arthroscopy; standard insert		0.0
Laskin, 2007 [11]				14	<75	NR	OA	Oxidized zirconium	60	0.0
				14				Cobalt chromium femoral components		
				76	61 (45-69)	NR	OA	Medial parapatellar approach (58); Mini-midvastus incision (18); PCL resected in all; Oxidized zirconium ceramic femoral component	67.2 (60-103.2)	3.9

NR Not reported

RESULTS

Table 1: Study characteristics of the 19 included studies. (Cont.)

Study	Randomised studies	Prospective studies	Case series	Sample Size (Knees)	Mean Age (Range or Std Dev)	% Male	Reason for TKA	Surgical Details	Length of Follow-up (Months)	Loss to Follow-up Rate (%)
Mean				148.9 (N=2656)	68.4	36.1			41.7	3.7
Laskin & Davis, 2005 [4]				100	67.5 (52-94)	NR	OA	NR	69.6	12
Laskin, 2006 [12]				95	NR	NR	NR	Mini-midvastus approach	24	0.0
Bourne et al, 2007 [2]				100	69 ± 8 (47-88)	40.2	OA (95.9%), Other (4.1%)	Cruciate-retaining, cemented (82); cruciate sacrificing, cemented (18)	120	0.0
Bourne et al, 2007 [23]				669†	68 ± 10 (29-93)	40.0	OA (92.1%), Inflammatory arthritis (5.2%); Other (2.7%)	Cruciate-retaining, cemented; post-and-cam cruciate sacrificing, cemented	114 (60-132)	0.08
Zeh et al, 2009 [22]				64	67.5 ± 9.8	41.3	OA	Mini-midvastus approach, posterior stabilized	12	25.4
Crockarell et al, 2010 [16]				224	73.0 (29-91)	36.3	OA (92.4%); RA (6.3%); Other (1.3%)	Medial parapatellar approach	80.4 (24-96)	0.01
Innocenti et al, 2010 [19]				98	58.8 (36-78)	33.7	OA (86.3%); Hemophilic Arthropathy (5.2%); Secondary OA (3.2%); Osteonecrosis (3.2%); RA (2.1%)	Oxidized zirconium; Medial parapatellar approach; cruciate retaining (62.1%), posterior stabilized (37.9%)	74.4 (60-84)	3.1
Malik et al, 2010 [21]				50	62.8 ± 10.7 (46-87)	24.0	OA (98%); RA (2%)	Standard midline incision, Posterior stabilized	12	0.0
				50	66.4 ± 9.6 (51-85)	24.0	OA	Standard midline incision, High flexion	12	0

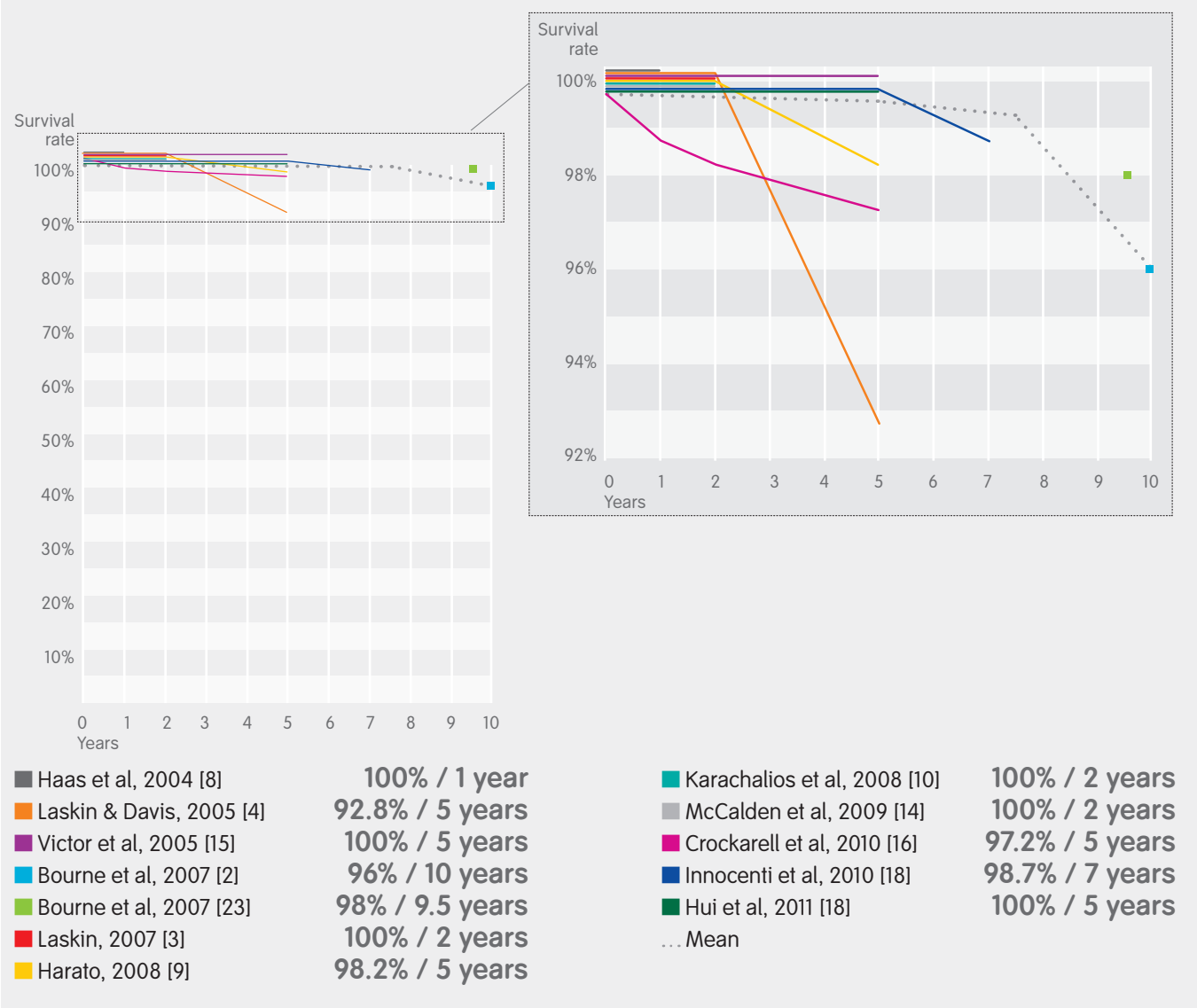
NR Not reported

Survival Rate of the GENESIS® II Total Knee System as Reported in 12 Published Studies

Implant failure was defined by all cause revision due to the variation in implant survival reported in the included literature. Unfortunately, this method does not take into account that causes of failure, such as septic failure and periprosthetic fractures, are often not the result of implant design. Thus the

survival rates reported in this review are less than what would be expected had only implant-related failures been assessed. Implant survival rates for the GENESIS II Total Knee System were reported in 12 studies (Table 2). Using the raw data on failure rates reported in the 12 studies, the authors were able to determine the cumulative survival rates at varying time points, using a Kaplan-Meier analysis (Table 3; Figure 4).

Figure 4: Survival rate of the GENESIS II Total Knee System as reported in 12 published studies



Results Cont.

Data was utilized from:

- 1520 total knee arthroplasties at five years postoperatively
- 867 at seven years
- 769 at nine years

The corresponding Kaplan-Meier survival rates were:

- 99.5 % (95% CI: 98.7 – 99.6) at five years postoperatively
- 99.9% (95% CI: 98.5 – 99.5) at seven years
- 98.8% (95% CI: 97.0 – 98.8) at nine years (**Figure 5**).

The mean cumulative survival time for the GENESIS[®] II Total Knee System was 9.93 ± 0.02 years (95% CI: 9.90-9.96).

Only one study, Bourne et al, reported on survivorship for greater than 10 years. They reported a Kaplan-Meier survival rate of 96.0% (95% CI: 90.1 – 90.8) at 11.9 years [2]. The cumulative revision rate was 1.5%.

Table 2: Estimated survival of the GENESIS II Total Knee System (implant failure was recorded as all-cause for revision surgery).

Study	Number of Knees	Minimum Follow-Up (Months)	Survival Rate at 1 Year	Survival Rate at 2 Years	Survival Rate at 5 Years	Survival Rate at 10 Years	Total Revision Surgeries
Mean	157.3 (N=1887)	48.3	99.8	99.9	99.2	96.0	28
Haas et al, 2004 [8]	80	12	100	NR	NR	NR	0
Laskin & Davis, 2005 [4]	100	60	100	100	92.8	NR	4
Victor et al, 2005 [15]	34	60	100	100	100	NR	0
Bourne et al, 2007 [2]	100	120	NR	NR	NR	96	4
Bourne et al, 2007 [23]	669 [†]	60	NR	NR	NR	98*	9
Laskin, 2007 [3]	80	24	100	100	NR	NR	0
Harato, 2008 [9]	222	60	100	100	98.2	NR	4
Karachalios et al, 2008 [10]	100	24	100	100	NR	NR	0
McCalden et al, 2009 [14]	100	27.6	100	100	NR	NR	0
Crockarell et al, 2010 [16]	224	24	98.7	98.2	97.2	NR	6
Innocenti et al, 2010 [18]	98	60	100	100	100	98.7**	1
Hui et al, 2011 [18]	80	60	100	100	100	NR	0

NR Not reported

* Survival Rate at 9.5 years.

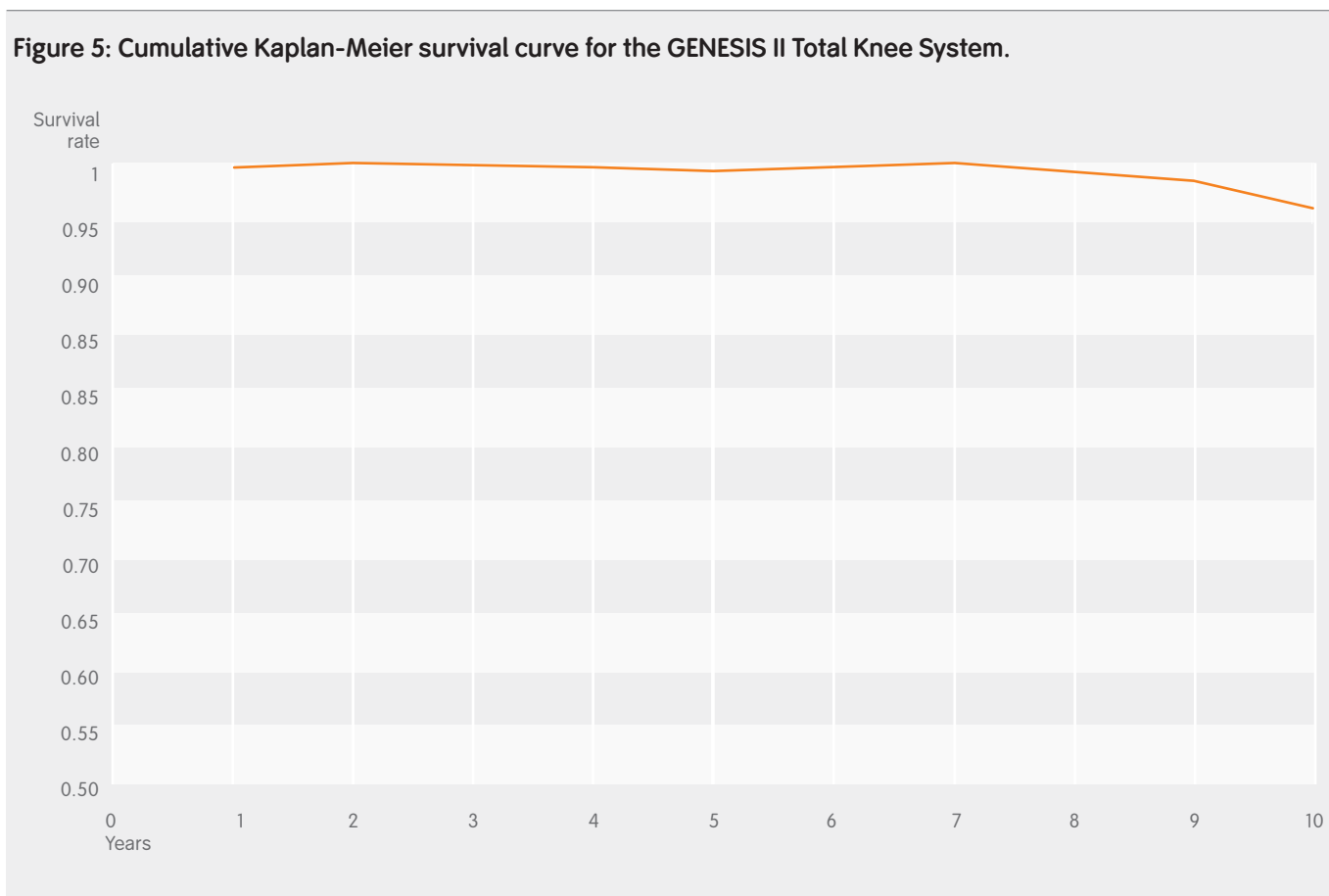
** Survival Rate at 7 years.

[†] Patients who died were not included in analysis; 100 of these patients were followed for over 10 years in Bourne et al, 2007 [2].

Table 3: Kaplan-Meier implant survival table for the GENESIS[®] II Total Knee System.

Year	At Risk	Failed	Censored	Survival Rate	Standard Error	Lower Bound (95%)	Upper Bound (95%)
1	1887	3	80	0.998	0.001	0.997	1.000
2	1804	1	280	0.999	0.001	0.996	1.000
4	1523	3	0	0.998	0.002	0.993	0.999
5	1520	7	646	0.995	0.002	0.987	0.996
7	867	1	97	0.999	0.003	0.985	0.995
9	769	9	660	0.988	0.005	0.970	0.988
10	100	4	96	0.960	0.020	0.901	0.978

Figure 5: Cumulative Kaplan-Meier survival curve for the GENESIS II Total Knee System.



RESULTS

Registry Data

Both the Australian and New Zealand Orthopaedic Association joint registries presented survival data as a rate of revision per 100 observed implant years. Data from the Australian registry also stratify survival data by fixation method (cemented, cementless, hybrid). The UK registry data presented survival data as the revision rate at three and five years. The Australian, New Zealand, and UK registries feature data from September 1999 to December 2009, January 1999 to December 2009, and April 2003 to November 2009, respectively [24-26].

Annual revision rates according to data from the Australian National Joint Replacement Registry [24] are summarized in **Figure 6**. GENESIS® II Total Knee System revision rates per 100 observed implant years from the Australian and New Zealand National Joint Registries [24, 25] were compared to national averages and displayed in **Figure 7**. Detailed values on revision rates from the Australian, New Zealand, and UK National Joint Registries [24-26] are available in the *Appendix 2: Results*.

Figure 6: Revision rates of the GENESIS II Total Knee System from the Australian National Joint Replacement Registry data

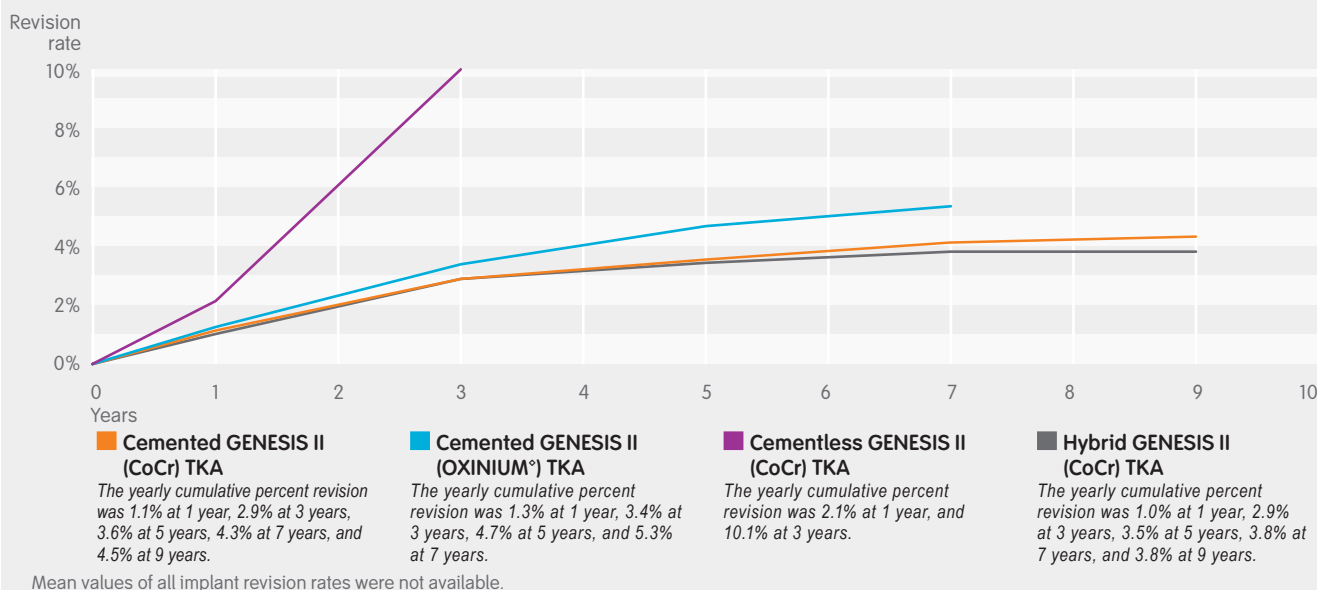
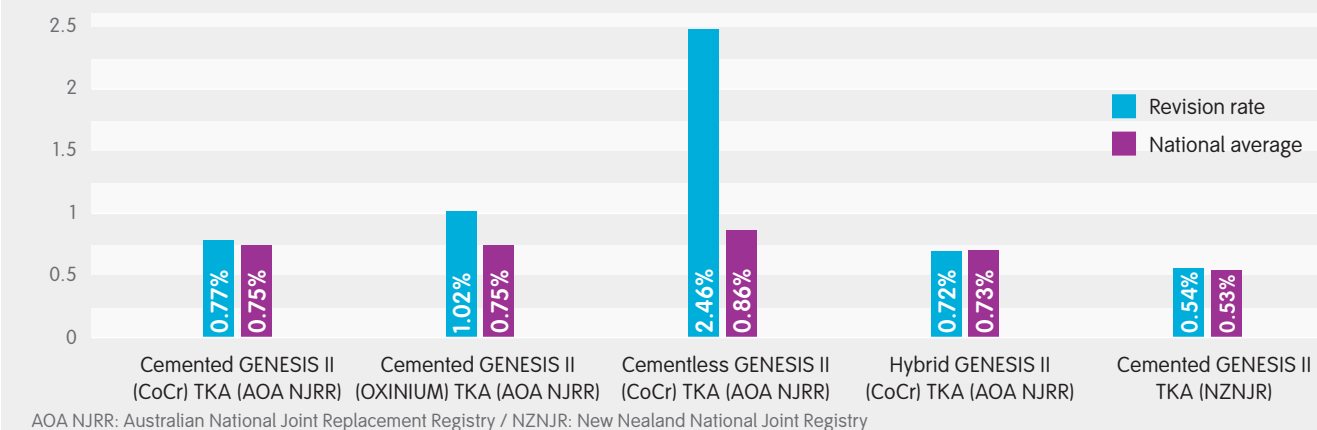


Figure 7: Revision rate per 100 observed years for GENESIS II Total Knee System



Knee Society knee scores

Eighteen studies reported Knee Society knee scores [2-4, 8-13,15-23], with all reporting an improvement over time in the scores (Table 4):

- Mean postoperative Knee Society knee score was 90.6 (range, 76.7 to 97).
- Mean improvement in knee scores from the preoperative to postoperative period was 48.2 (range, 22 to 69) at a mean follow-up period of 45.9 months.

Table 4: Knee Society knee scores from the 18 studies who reported at least post-operative knee scores.

Study	Number of knees in study	Minimum follow-up (Months)	Mean pre-operative Knee Society knee score (Range or SD)	Mean post-operative Knee Society knee score (Range or SD)	Mean change in Knee Society knee score
Mean	142 (N=2556)	45.9	43.1	90.6	48.2
Laskin et al, 2000 [13]	62 66 48	NR NR NR	36 (0-45) 32 (10-40) 35 (5-45)	92 (86-100) 94 (82-100) 94 (84-100)	56 62 59
Haas et al, 2004 [8]	40 40	12 12	28 (18-59) 33 (13-57)	97 (74-100) 91 (68-100)	69 58
Laskin & Davis, 2005 [4]	100	60	NR	Score of >91 in 69% and 81-90 in 31%	NR
Victor et al, 2005 [15]	17 17	60 60	38.0 (15.1) 37.2 (21.7)	81.7 (7.3) 76.7 (12.6)	43.7 39.5
Laskin, 2006 [12]	95	24	NR	95	NR
Bourne et al, 2007 [2]	100	120	38 ± 14	91 ± 11	53
Bourne et al, 2007 [23]	669†	60	NR	NR	48.6
Laskin, 2007 [3]	40 40	24 24	68 66	90 92	22 26
Laskin, 2007 [11]	14 14 76	60 60 60	NR NR NR	91 92 93 (80-100)	NR NR NR
Harato, 2008 [9]	111 111	60 60	46.7 ± 16.9 44.3 ± 17.6	90.8 ± 13.0 90.4 ± 15.7	44.1 46.1
Karachalios et al, 2008 [10]	50 50	23 24	35.7 (14-65) 31.6 (12-70)	97 (92-100) 93.8 (65-100)	61.3 62.2
Zeh et al, 2009 [22]	64	12	52.2 ± 12.2	91.7 ± 15.5	39.5
Crockarell et al, 2010 [16]	224	24	NR	85 (45-100)	NR
Crow et al, 2010 [17]	85 (High Flexion) 79 (Standard)	12	54.8 51.2	86.8 87.4	32 36.2
Innocenti et al, 2010 [19]	98	60	36 (13-57)	89 (64-100)	53
Kim et al, 2010 [20]	33 (CR) 33 (PS)	24	50.0 ± 10.3 44.7 ± 8.4	92.9 ± 7.7 94.3 ± 5.9	42.9 49.6
Malik et al, 2010 [21]	50 (PS) 50 (HF)	12 12	41.7 ± 16.1 43.2 ± 18.1	92 ± 8.2 93 ± 8.2	50.3 49.8
Hui et al, 2011 [18]	40 (OXINIUM®) 40 (CrCo)	60 60	NR NR	89 92	NR NR

NR Not Reported
SD Standard Deviation
PS Posterior Stabilized

HF High Flexion
CR Cruciate Retaining;
† Patients who died were not included in analysis; 100 of these patients were followed for over 10 years in Bourne et al, 2007 [2].

Conclusions

This systematic review indicates that very promising medium- to long-term clinical results have been noted when the GENESIS[®] II Total Knee System is used in primary total knee arthroplasty. Survival findings at 5 and 10 years, as well as national joint registry data, appear to confirm that the GENESIS II Total Knee System is safe and effective. Knee Society knee scores showed

an improvement between the pre-operative and post-operative evaluations. Additional studies of this system with larger sample sizes and longer follow-up periods are required to determine if these initial observations are consistent over time.

Strengths

- A thorough and systematic review of the literature was conducted.
- Eighteen studies met the eligibility criteria for this review.
- Data from 2,656 total knee arthroplasties were included.
- Revision rate data on 40,806 total knee arthroplasties from the Australian, New Zealand, and UK National Joint Registries.
- The indication for primary total knee arthroplasty is consistent throughout the included studies, allowing for extrapolation to the general population.
- The included studies chose designs that produced medium- to high-quality data that helps readers trust the conclusions obtained.
- Most studies collected both baseline and postoperative data, allowing for a broader comparison of study results.
- The results have external validity because the ratio of female to male study participants reflects the gender ratio of patients undergoing total knee arthroplasty in the general population.

Limitations

- Considerable heterogeneity among the chosen studies, with several key differences in study designs, surgical approach, and patient groups did not allow for the conduct of a formal meta-analysis.
- Only implant survival and Knee Society knee scores were analyzed in this review.
- Different definitions of implant survival were used across the studies so the cumulative survival data needs to be interpreted cautiously.
- Device-related causes underlying implant failure, such as polyethylene wear, aseptic loosening, instability, and malalignment or malposition were not obtained.
- Several potentially useful clinical variables were not analyzed including knee pain, patient satisfaction, range of motion, and quality of life.
- The included studies had relatively small sample sizes.
- Only one study reported follow-up beyond 10 years, limiting the assessment of long-term outcomes.
- The average age of the study participants (68.6 years) makes our findings difficult to generalize to younger patients.

Review at a glance

Generalizability

80 out of 100. The included studies predominantly assess survivability in North American, Australian, and European populations, with only one study [20] coming from Korea. Also our study sample was relatively older (mean age 68.6 years), thus results may not be generalizable to younger populations.

Validity

80 out of 100. Systemic review of good quality Level I, II and III clinical studies of the GENESIS[®] II Total Knee System with evidence ratings. A few minimal assumptions were used to obtain the cumulative survival rates, which reduced validity.

Timeliness

90 out of 100. All studies included were published within the past 12 years. Since this system is commonly used globally, current evidence indicating the effectiveness and safety should be readily available.

Importance

90 out of 100. The evidence is important in providing patients, orthopaedic surgeons and healthcare payers the most up to date information on implants in current use.

Strength

75 out of 100. Data from 2,656 total knee arthroplasties were included, along with revision rate data on 40,806 total knee arthroplasties from the Australian, New Zealand, and UK National Joint Registries. The level of evidence in the included studies is medium-to-high. Long-term follow-up up to 11.9 years on the GENESIS II Total Knee System is available.



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Appendices

Visit www.kleos.md/literature/bone-joint-outcome/appendices/v01/n01.pdf for appendices or use this QR code. The following appendices provide further detail:

Appendix 1: Methods

Appendix 2: Results

Please also visit www.kleos.md/literature/background to view an online glossary of technical terminology.

Notes

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