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Patellofemoral design enhancements reduce long-term complications of postero-stabilized total knee arthroplasty

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Abstract

Purpose Few studies investigated whether trochlear and patellar design enhancements improve long-term outcomes of total knee arthroplasty (TKA). This study aimed to compare the long-term survival and complication rates of two consecutive generations of the same TKA system with identical tibiofemoral geometry, but different patellofemoral designs.

Methods The authors retrieved the records of 93 patients (104 knees) operated with the HLS II system and 116 patients (122 knees) operated with HLS Evolution system. Patients were evaluated preoperatively and at a minimum of 10 years noting all complications. Kaplan–Meier (KM) survival was compared for two endpoints: (1) revision of all components and (2) revision of any component.

Results From the HLS II series, the incidence of revision of all components was 6.4%, and of any component was 9.8%. From the HLS Evolution series, the incidence of revision of all components was 4.1%, and of any component was 5.1%. Comparing the survival at equivalent follow-up of 14 years, considering revision of all components, the HLS II had higher survival than the HLS Evolution (98.9% vs 95.9%), while considering revision of any component, the HLS II had lower survival than the HLS Evolution (93.0% vs 94.9%). The differences in survival of the two implants were not significant, neither at equivalent follow-up of 14 years (n.s.), nor at maximum follow-up of each cohort (n.s.). The complication rate was higher for the HLS II series compared to the HLS Evolution (28% vs 12%, $p=0.009$), but patellofemoral complications were not more frequent (8% vs 6%, n.s.).

Conclusions Though the differences in survival of the two implants were not significant, conflicting findings are observed due to partial revisions for patellar fractures (5 in the HLS II series and 1 in the HLS Evolution series) which could be related to patellofemoral design enhancements. This study highlights the importance of patello-femoral geometry, which is often overlooked in TKA.

Level of evidence Retrospective comparative study, Level III.

Keywords Total knee arthroplasty · Long-term · Survival · Complications · Trochlear design · Patellar button · Patellofemoral joint

Introduction

Long-term survival of total knee arthroplasty (TKA) was demonstrated by landmark studies on historic implants [12, 35]. Despite its success, many patients remain dissatisfied with TKA, often due to patellofemoral complications, which remain reasons for revision [9, 22, 32, 39]. Patellofemoral pain and instability are often caused by extensor mechanism malalignment [7, 31, 39] or inappropriate implant design [10, 17]. Numerous biomechanical studies highlighted the importance of trochlear and patellar geometries [1, 29, 40, 41], which led several manufacturers to develop more

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patella-friendly implants [10, 36], though few studies investigated the clinical benefits of such design enhancements [43].

The HLS (Hôpital Lyon Sud) system is a unique TKA design, postero-stabilized (PS) by a central 'third condyle', that successfully reproduces native knee kinematics [45]. It has provided excellent clinical and radiological short-term outcomes [28, 38], with satisfactory survival up to 10 years [13, 24, 38]. The HLS system underwent several incremental improvements since its introduction in 1987, which appeared to reduce the incidence of short-term patellofemoral complications [13]. Notably, the HLS Evolution™ (third generation) had identical tibiofemoral geometry, but enhanced trochlear design in the inter-condylar region compared to its predecessor, the HLS II™ (second generation), to improve patellar tracking. Furthermore, the HLS Evolution also featured three small fixation pegs for its patellar button, to replace the large central peg of the HLS II that rendered the patella susceptible to fracture [13]. However, the long-term effects of these design changes on implant survival and patellofemoral complications remain unknown.

Few studies reported the survival of the HLS II and HLS Evolution TKAs beyond 10 years, and none investigated whether the design enhancements were effective at reducing patellofemoral complications. The purpose of this study was therefore to report the long-term survival of the HLS II and HLS Evolution TKA systems, and to compare their complication rates, with particular focus on patellofemoral complications.

Materials and methods

The authors analysed the survival and compared the complication rates of two TKA series of the 2nd and 3rd generations of the HLS system (Tornier, St-Ismier, France), HLS II and HLS Evolution.

Patient characteristics and surgical data

The records of all TKAs performed using the HLS II system at the authors' centre between January 1992 and December 1993 were reviewed. From a total of 93 patients (104 knees), 1 patient (1 knee) was excluded due to prior surgery on the patella, leaving 92 patients (103 knees). (Table 1). The indications for surgery were primary osteoarthritis in 68 knees (66%) and rheumatoid arthritis in 20 knees (19%). The surgical approach was medial parapatellar in 93 knees (90%), lateral parapatellar in 4 knees (4%), midvastus in 1 knee (1%), and unspecified in 5 knees (5%).

The records of all TKAs performed using the HLS Evolution system at the authors' centre between January 1998 and December 2000 were reviewed. From a total of 116 patients (122 knees), 1 patient (1 knee) was excluded because the patella was not resurfaced, leaving 115 patients (121 knees). (Table 1). The indications for surgery were significantly different, with primary osteoarthritis in 99 knees (82%). The surgical approach was medial parapatellar in 79 knees (65%), lateral parapatellar in 8 knees (7%), midvastus in 34 knees (28%).

Clinical assessment

All patients were evaluated preoperatively, noting their knee alignment, Charnley score [15, 34] to assess the patients' walking ability, and the preoperative Knee Society Score (KSS). Patients were contacted by telephone and/or mail to update their records. If patients were deceased, their general practitioner or next of kin was contacted to confirm the date and cause of death, and whether any of their TKA components had been revised. All patients living with their original TKA components were invited for a clinical evaluation, and those unable to travel were evaluated by telephone. The clinical questionnaire noted the KSS and Oxford Knee Score (OKS), as well as any complications [16], with particular focus those related to the patella or extensor mechanism.

From the HLS II cohort of 92 patients (103 knees), 3 patients (3 knees) had two or more TKA components revised, and 4 patients (4 knees) had only one TKA component revised (Fig. 1). A total of 51 patients (58 knees) had died with their original components in place, and 7 patients (8 knees) could not be reached, but their most recent follow-up records (at 8.6 ± 1.4 years) indicated that none had revision surgery. This left a cohort of 29 patients (30 knees) living with their original TKA components. Twenty-seven patients (28 knees) were evaluated at a minimum follow-up of 15 years: 15 patients (15 knees) were examined at the clinic, whereas 12 patients (13 knees) were surveyed by telephone as they were unable to travel because of limited mobility or poor health, and 6 were not surveyed as they were bedridden or confined to nursing homes.

From the HLS Evolution cohort of 115 patients (121 knees), 4 patients (4 knees) had two or more TKA components revised, and 1 patients (1 knee) had had only one TKA component revised (Fig. 1). A total of 36 patients (39 knees) had died with their original components in place, and 8 patients (8 knees) could not be reached, but their most recent follow-up records (at 2.5 ± 3.0 years) indicated that none had revision surgery. This left a cohort of 67 patients (69 knees) living with their original TKA components. Sixty-five patients (67 knees) were evaluated at a minimum follow-up of 10 years: 33 patients (35 knees) were examined at the clinic, whereas 32 patients (32 knees) were surveyed by telephone as they were unable to travel because of limited mobility or poor health, and 13 were not surveyed as they were bedridden or confined to nursing homes.

Table 1 Preoperative data

	HLS II 92 patients (103 knees) mean ± SD (range)	HLS Evolution 115 patients (121 knees) mean ±SD (range)	*p values*
Preoperative assessment			
Age at surgery (yrs)	66.7 ±9.6 (22.1–85.1)	69.1 ±8.2 (39.1–84.4)	0.026
BMI	28.6 ±4.5 (15.6–37.0)	30.3 ±5.8 (18.4–47.8)	n.s
KSS knee	28.0 ±15.9 (0.0–63.0)	36.0 ±18.8 (0.0–77.0)	0.004
KSS function	33.4 ±20.0 (0.0–75.0)	45.5 ±19.1 (0.0–100.0)	<0.001
Men	22 (24%)	23 (20%)	n.s
Alignment			n.s
Neutral	16 (16%)	31 (26%)	
Varus	48 (47%)	63 (52%)	
Valgus	22 (21%)	22 (18%)	
Unspecified	17 (17%)	5 (4%)	
Charnley classification			n.s
A	34 (33%)	54 (45%)	
B	45 (44%)	50 (41%)	
C	22 (21%)	16 (13%)	
Unknown	2 (2%)	1 (1%)	
Indication			0.017
Primary OA	68 (66%)	99 (82%)	
RA	20 (19%)	14 (12%)	
Post-traumatic OA	6 (6%)	4 (3%)	
APT with (type I) knee prosthesis Zimmer	4 (4%)	1 (1%)	
Ligament-deficiency OA	4 (4%)	0 (0%)	
Gout	1 (1%)	1 (1%)	
Necrosis	0 (0%)	2 (2%)	
Surgical data			
Lateral patellar release	26 (25%)	29 (24%)	n.s
MCL release	31 (30%)	12 (10%)	<0.001
LCL release	7 (7%)	5 (4%)	n.s
Previous surgery	31 (30%)	18 (15%)	n.s
Surgical approach			<0.001
Lateral parapatellar	4 (4%)	8 (7%)	
Medial parapatellar	98 (95%)	79 (65%)	
Midvastus	1 (1%)	34 (28%)	

All patients provided informed consent to use their data for research and publishing purposes. As the study used retrospective data, collected for routine clinical assessment, the Institutional Review Board (Lille University Hospital, France) waived the standard ethical approval process.

Statistical analysis

Descriptive statistics were used to summarize the data. For non-Gaussian quantitative data, between group differences were evaluated using Wilcoxon rank sum tests (Mann–Whitney *U* test). Categorical data were analysed using Chi-square tests. Survival analysis was performed for 2 different endpoints: (1) revision of all components, and (2) revision of any component. The authors calculated implant survival using the Kaplan–Meier (KM) method and using the cumulative incidence function (CIF), both of which were deemed important for this study. The KM survival is most frequently reported for joint arthroplasty and enables direct comparison with published survival data, whereas the CIF is recommended for reporting survival at 10 or more years, where risks of revision are overestimated by KM because of greater proportions of patients deceased and/or lost to follow-up [4, 11, 20, 21, 33, 44]. The differences between the KM curves of both implants and their endpoints were evaluated using the log-rank tests. The cumulative incidence

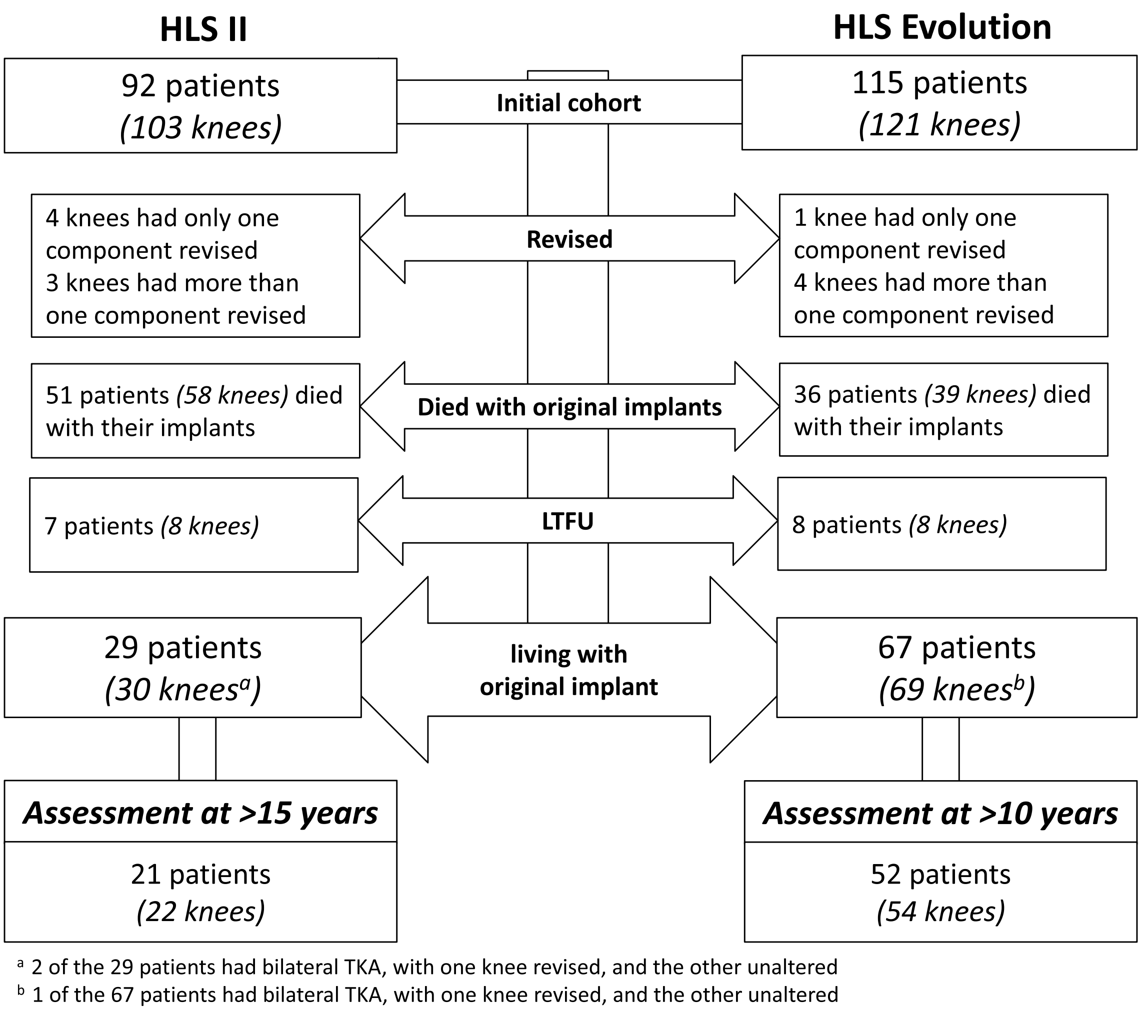

Fig. 1 Flowcharts of the two TKA series

of competing risks of the implants and their endpoints was evaluated using K-sample tests [14]. Statistical analyses were performed using R, version 3.3.2 (R Foundation for Statistical Computing, Vienna, Austria). p values < 0.05 were considered to be statistically significant.

Results

From the original HLS II cohort of 92 patients (103 knees), 29 patients (30 knees) were still living with their original implants at a mean follow-up of 20.2 ± 1.1 years (range, 15.3–21.4) (Fig. 1; Table 2). Considering revision of all components as endpoint, the revision incidence calculated using the KM method (1-survival) was 6.4% (CI, 2.0–19.7%), whereas using the CIF it was 3.2% (CI, 0–6.8%) (Fig. 2). Considering revision of any component as endpoint, the revision incidence calculated using the KM method was 9.8% (CI, 4.4–20.7%), whereas using the CIF it was 7.1% (CI 1.9–12.0%) (Fig. 3). For the 7 revised TKAs, the causes of revision were:

- Aseptic patellar fracture in 3 knees, revised at 8 months, 15 months and 11.2 years;
- Septic patellar fracture in 2 knees, revised at 2.9 years and 18.8 years;
- Severe polyethylene wear in 1 knee, revised at 17 years;
- Deep infection in 1 knee, revised at 2 years.

From the original HLS Evolution cohort of 115 patients (121 knees), 67 patients (69 knees) were still living with their original implants at a mean follow-up of 13.3 ± 0.9 years (range 10.0–14.4) (Fig. 1; Table 2). Considering revision of all components as endpoint, the revision incidence calculated using the KM method (1-survival) was 4.1% (CI 1.5–10.5%), whereas using the CIF it was 3.5% (CI 0.1–6.8%) (Fig. 2). Considering revision of any component as endpoint, the revision incidence

Table 2 Clinical outcomes

	HLS II 21 patients (22 knees) mean ±SD (range)	HLS Evolution 52 patients (54 knees) mean ±SD (range)	*p* values[a]
Follow-up (years)	20.0 ± 1.1 (15.3–21.4)	13.3 ± 0.9 (10.0–14.4)	*< 0.001*
Age at follow-up	66.7 ± 8.5 (22.1–85.1)	69.1 ± 8.2 (39.1–84.4)	n.s
Oxford knee score (OKS)[b]	28.7 ± 12.2 (15.0–49.0)	25.9 ± 7.4 (13.0–52.0)	0.006
Knee society score			
KSS knee	74.5 ± 14.2 (0.0–97.0)	83.9 ± 15.6 (53.0–100.0)	*0.004*
KSS function	50.3 ± 27.8 (0.0–100.0)	52.0 ± 25.9 (0.0–100.0)	*< 0.001*

[a]Comparing differences in clinical outcomes may not be appropriate because of different follow-up
[b]Best = 12, worst = 60

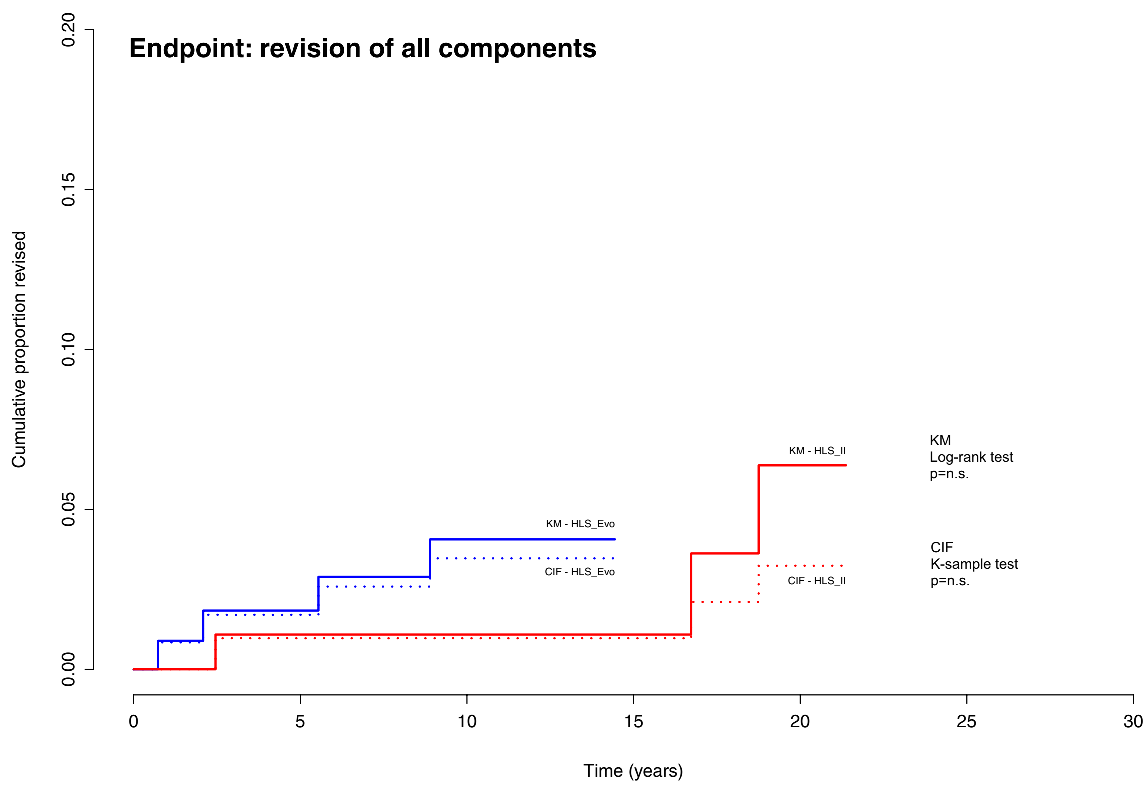

Fig. 2 Risk of revision (1-survival) calculated using the KM and CIF considering revision of all components as endpoint. *CIF* cumulative incidence function, *KM* Kaplan–Meier method

calculated using the KM method was 5.1% (CI 2.2–11.9%), whereas using the CIF it was 4.4% (CI 0.6–8.0%) (Fig. 3). For the 5 revised TKAs, the causes of revision were:

- Deep infection in 2 knees, revised at 8 months and 2 years;
- Aseptic tibiofemoral loosening in 2 knees, revised at 5.5 years and 8.9 years;
- Aseptic patellar fracture in 1 knee, revised at 5.5 years.

Comparing the survival at equivalent follow-up of 14 years, considering revision of all components, the HLS II had higher survival than the HLS Evolution (98.9% vs 95.9%), while considering revision of any component, the HLS II had lower survival than the HLS Evolution (93.0% vs 94.9%). The differences in survival of the two implants were not significant, neither at equivalent follow-up of 14 years (n.s.), nor at maximum follow-up of each cohort (n.s.).

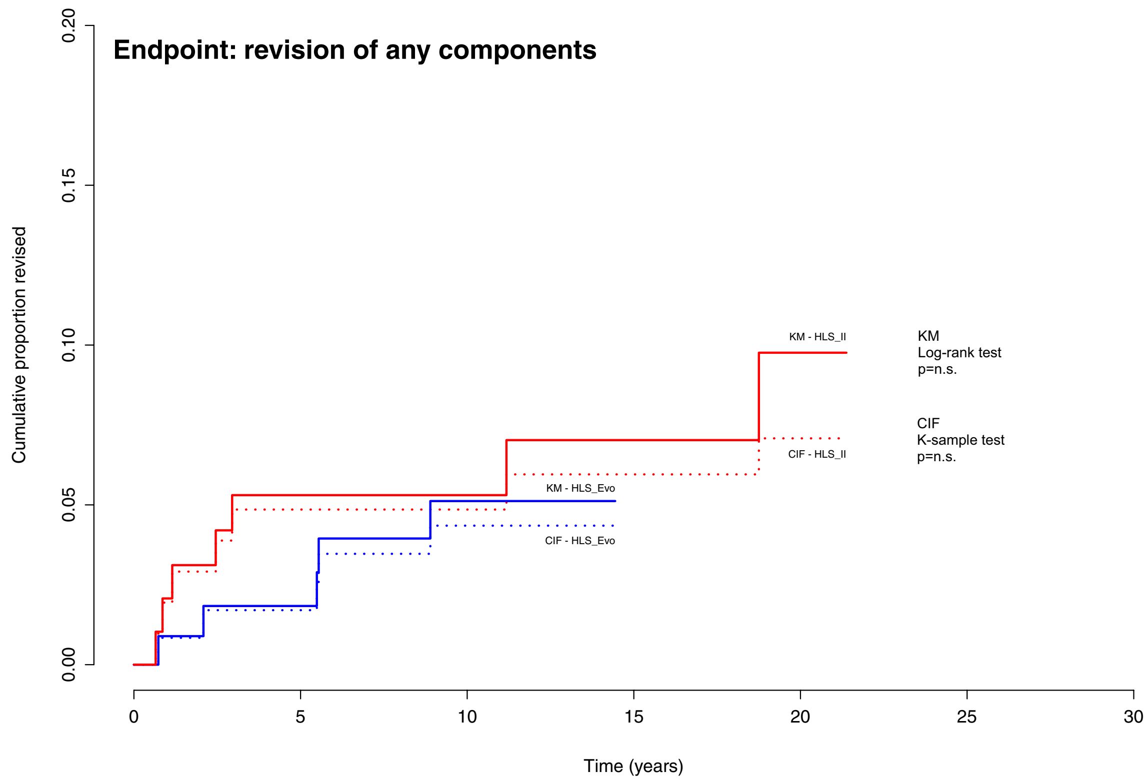

Fig. 3 Risk of revision (1-survival) calculated using the KM and CIF considering revision of any component as endpoint. *CIF* cumulative incidence function, *KM* Kaplan–Meier method

Complications

Comparing complications at equivalent follow-up of 14 years, the complication rate was significantly higher for the HLS II series compared to the HLS Evolution series (26% vs 12%, $p = 0.024$) (Table 3), notably stiffness (11% vs 2%, $p = 0.007$), patellar fracture (5% vs 2%, n.s.) and tibial or femoral fracture (4% vs 1%, n.s.). The overall incidence complications related to the patellofemoral joint or extensor mechanism was only slightly greater for the HLS II than the HLS Evolution (7% vs 6%, n.s.). Post hoc analysis (using $\alpha = 0.05$) revealed that the study was slightly underpowered (2-tailed, $\beta = 0.76$) to detect significant differences in complication rates.

Table 3 Postoperative complications at equivalent follow-up of 14 years

	HLS II 92 patients (103 knees)	HLS Evolution 115 patients (121 knees)	*p* values *
Patellar clunk	0 (0%	2 (2%)	n.s
Patellar dislocation	1 (1%)	0 (0%)	n.s
Extensor mechanism failure	1 (1%)	1 (1%)	n.s
Patellar fracture	5 (5%)	2 (2%)	n.s
Patellar loosening	0 (0%)	2 (2%)	n.s
Tibial/femoral fracture	4 (4%)	1 (1%)	n.s
Stiffness	11 (11%)	2 (2%)	0.007
Infection	4 (4%)	3 (2%)	n.s
Aseptic loosening/polyethylene wear	0 (0%)	1 (1%)	n.s
Hyperlaxity	1 (1%)	0 (0%)	n.s
Patellofemoral complications	7 (7%)	7 (6%)	n.s
Any complication	27 (26%)	14 (12%)	0.024

Discussion

The main finding of the present study was that, although the difference in overall survival for either endpoint was not statistically significant, comparing KM survivals of the HLS II and HLS Evolution at equivalent follow-up of 14 years, the perceived superiority of one model over the other depends on the endpoint of interest. Considering revision of all components, the HLS II had higher survival than the HLS Evolution (98.9% vs 95.9%, both at 14 years), while considering revision of any component, the HLS II had lower survival than the HLS Evolution (93.0% vs 94.9%, both at 14 years). The differences in KM survivals of the two models was not statistically significant, possibly due to insufficient cohorts or events, though it remains interesting to understand the reasons behind our seemingly paradoxical findings. While the rates of patellofemoral complications did not differ significantly among the two series, the HLS II had five partial revisions due to patellar fracture, compared to the HLS Evolution which had only one partial revision due to patellar fracture.

The decrease in the incidence of patellar fracture observed is likely due to the design improvements from one implant generation to the other. The HLS Evolution was designed to prevent the patellofemoral complications observed with its predecessor, the HLS II, notably patellar loosening and fracture. The design improvements included a deeper trochlear groove in the inter-condylar region, and a patellar button with three small fixation pegs instead of one large central peg. Our findings, therefore, suggest that the design enhancements were effective at preventing patellar fractures that require revision, though they did not eliminate less severe patellofemoral complications, such as patellar instability and failure of the extensor mechanism. Our data does not enable us to determine which of the design enhancements contributed to preventing patellar fractures. The replacement of the large patellar fixation peg seems likely to prevent weakening the patellar bone after resurfacing [27], though it is possible that the enhanced trochlear groove prevented patello-femoral overload and fracture.

The HLS II series had significantly more overall complications than the HLS Evolution series. While it is possible that the design improvements are partially responsible for this reduction, we found significant differences in the cohorts which could explain this difference. First, the patients in the HLS Evolution cohort had better preoperative KSS knee and function scores than those in the HLS II cohort. Second, the surgical technique differed between the series, as HLS Evolution patients had fewer MCL releases. Finally, the postoperative rehabilitation for HLS Evolution cohort could have been improved from that of the HLS II cohort, with shorter immobilization and more effective exercises, which may have reduced the incidence of stiffness.

The survival rates beyond 15 years of the HLS implants were satisfactory: considering revision of all components as endpoint, the KM survival was 93.6% for the HLS II, compared to 95.9% for the HLS Evolution. Likewise, considering revision of any component as endpoint, the KM survival was 90.2% for the HLS II, compared to 94.9% for the HLS Evolution. Thus, the 15–20 years survival of the HLS implants is well within the range of 90–98.1% reported for postero-stabilized TKA [2, 7, 13, 21, 26, 28, 37, 42] and of 81.7–91% for cruciate-retaining TKA [3, 5, 8, 18], as well as of 85.7–98.9% for other TKA systems [2, 6, 19, 23, 30] (Table 4).

Both the KM survival of the implants and the cumulative incidence of revision using the CIF are reported in this study. Since our cumulative risk of mortality was greater than the cumulative risk of revision, the traditional KM estimates could be somewhat misleading because the competing risks exaggerate the perceived revision rates [4, 44]. The CIF is, therefore, recommended as an alternative or complement, although this method was recently introduced in arthroplasty studies [21, 25, 44]. Comparing revision rates for the present series using the KM and CIF estimates reveals that the former exaggerates the revision rates by an average of 17.2–18.2% for the HLS Evolution series at 14 years and by an average of 38.4–97.5% for the HLS II series at 20 years. Despite its limitations, especially on longer follow-up periods, KM remains the most commonly reported measure of survival in arthroplasty studies and the only option for comparison with other TKA studies on the literature.

The present study has several limitations inherent to long survival studies involving patients of advanced age at index surgery: (1) despite efforts to reach these patients, 9% of HLS II patients and 7% of HLS Evolution patients were lost to follow-up, which remains acceptable for long-term survival studies, (2) the small number of patients evaluated postoperatively, (3) the patients who were unable to travel to the clinic because of advanced age or limited mobility and had to be assessed by means of telephone consultations, which does not permit full appreciation of the range of motion and function, and (4) the small cohort sizes that rendered insufficient observations to determine statistical significance. It is also worth noting that the comparisons made between the two HLS series may not be valid, considering the differences in preoperative demographics, surgical techniques and time lapse between their inclusion periods. Nevertheless, the study has a number of strengths: (1) its long follow-up, being the first study to report results of the HLS TKA system beyond 15 years, and (2) that all surgeries were performed at one center by the same surgical team using

Table 4 Survival of primary TKA implants reported in recent literature

Author	Date	Journal	Implant	Manufacturer	Followup (years)	KM survival any component (%)
PS implants						
This study	2018	KSSTA	HLS II	Corin-Tornier	20 (15–21)	90.2
This study	2018	KSSTA	HLS Evolution	Corin-Tornier	13.3 (10–14)	94.9
McCalden	2017	*JoA*	Genesis II	Smith & Nephew	15 (15–16)	97.5
Nakamura	2017	*JoA*	Bi-Surface	Kyocera Medical	18.1 (15–25)	96.2
Schiavone Panni	2017	*Int Orthop*	Nexgen (Legacy)	Zimmer Biomet	16.8 (15–19)	94.7
Victor	2014	*Int Orthop*	Genesis I	Smith & Nephew	15.7 (15–17)	92.4
			Genesis II	Smith & Nephew	15.7 (15–17)	98.1
Argenson	2013	*OTSR*	Fixed PS		10	90
			Mobile PS		10	94
Magnussen	2011	*CORR*	HLS I-IV	Corin-Tornier	(2–20)	96.3
Gaillard	2006	*OTSR*	HLS I-V	Corin-Tornier	3.3 (2–20)	92
Tayot	2001	*The Knee*	HLS I	Corin-Tornier	11.5 (9–14)	93.7
CR implants						
Callaghan	2013	*CORR*	Press-fit Condylar	DePuy	20.6 (20–22)	90.8
Huizinga	2012	*JoA*	AGC	Zimmer Biomet	(15–20)	87
Bistolfi	2011	*J Orthop Traum*	Press-fit Condylar	DePuy	13.5 (11–16)	90.6
Attar	2008	*JoA*	Press-fit Condylar	DePuy	8.8 (0–17)	81.7
Other implants						
Macheras	2017	*The Knee*	aMP	Micro-Port Orthopedics	15.2 (15–17)	98.8
Bouras	2017	*KSSTA*	TC-plus	Smith & Nephew	13.2	90.4
Ouazenar	2016	*KSSTA*	Score (UC)	Amplitude	10.5 (10–)	91
Karachalios	2016	*BJJ*	aMP	Micro-Port Orthopedics	13.4 (11–15)	97.3
Jauregui	2015	*JoA*	Duracon	Stryker	11 (10–13)	95.6
Cholewinski	2015	*OTSR*	Legacy (CCK)	Zimmer Biomet	12.7 (10–14)	97.7
Argenson	2013	*OTSR*	Fixed UC		10	94
			Mobile UC		10	93
			Fixed CR		10	95
			Mobile CR		10	91
Efstathopoulos	2009	*JLTEMI*	LCS (mobile bearing)	Depuy Synthes	10 (5–15)	98
Mangaleshkar	2002	*JoA*	Denham	Zimmer Biomet	11.8 (–10)	92.7
Nouta	2012	*Int Orthop*	APT	Zimmer	11 (1–25)	87.5

KM Kaplan–Meier, *PS* postero-stabilized, *CR* cruciate-retaining, *UC* ultracongruent, *JoA* Journal of Arthroplasty, *KSSTA* Knee Surgery Sports, Traumatology, Arthroscopy, *BJJ* British Joint Journal, *JLETMI* Journal of Long-Term Effects of Medical Implants, Int. Orth., International Orthopedics OTSR, Orthopaedics & Traumatology, Surgery & Research; *CORR* Clinical Orthopedics and Related Research; J. Orthop. Traum., Journal of Orthopaedic Trauma

the same techniques and instruments, which allows a better consistency between the two series, (3) the use of validated outcome assessments including the Oxford knee score that is rarely reported in long-term studies. It is also one of few studies [13, 42] to compare survival and complication rates between several generation of a TKA system. Finally, this study highlights the importance of patello-femoral geometry, which is often overlooked in TKA.

Conclusion

At equivalent follow-up of 14 years, considering revision of all components, the HLS II had better survival than the HLS Evolution (98.9% vs 95.9%), while considering revision of any component, the HLS II had lower survival than the HLS Evolution (93.0% vs 94.9%). Though the differences in survival of the two implants were not significant, conflicting findings are observed due to partial revisions for patellar fractures (5 in the HLS II series and 1 in the HLS Evolution series), which could be related to patellofemoral design enhancements.

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Author contributions NJ participated in study design, data collection and manuscript preparation. CF participated in study design and data collection. JV participated in literature review, statistical analysis and manuscript writing. MS participated in statistical analysis and manuscript writing. HM participated in study design, data collection and manuscript editing. GP Participated in study design and data collection. SP participated in study design, data collection and manuscript editing. All authors read and approved the final manuscript.

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Compliance with ethical standards

Conflict of interest JV and MS received fees for support in study design and manuscript preparation from ReSurg SA (Switzerland).

Ethical approval All patients provided informed consent to use their data for research and publishing purposes. As the study used retrospective data, collected for routine clinical assessment, the Institutional Review Board (Lille University Hospital, France) waived the standard ethical approval process.

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