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Safety and performance of high-risk medical devices: the role of real-world data

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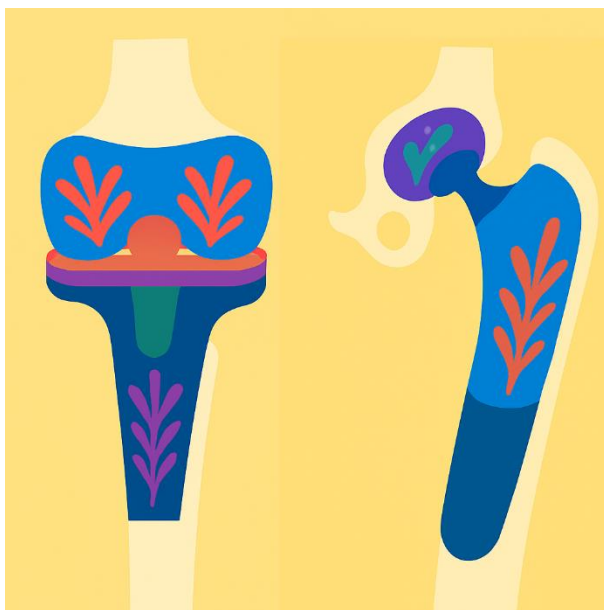
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Chapter 7 – Pooling data for primary total knee implants across national registries: is the same implant used in multiple registries and for the same patient group? - An observational study



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Abstract

Background: Pooling data on the performance of total knee (TK) implants across registries is only possible if the same TK implant is used across multiple registries and if used in patients with similar characteristics. We assessed to what extent specific TK implants: i) are used across multiple registries or only in a single registry; and ii) differ in patient characteristics between registries.

Methods: All primary TK implants implanted between January 2020 and December 2021 in the Danish, Dutch, German, and Italian registries were included. We determined the number of registries using a specific TK implant (based on combined femoral-tibial component brand name and fixation/congruency/mobile bearing insert/patella usage). Patient characteristics (age/body mass index [BMI]/sex/diagnosis osteoarthritis) were compared across registries for TK implants used in ≥ 2 registries ≥ 100 times.

Results: 813 different TK implants (577,351 procedures) were used across the four registries, of which 53 TK implants (7%) were used in one registry (8,000 procedures). 760 different TK implants (569,351 procedures; 99%) were used in ≥ 2 registries of which 47 different TK implants (393,954 procedures; 68%) were used in ≥ 2 registries and ≥ 100 times. Statistically and clinically significant differences in age for the same TK implant across registries were observed for 29 TK implants (62%) and 3 TK implants (6%), respectively; for other characteristics these were for BMI 30 (64%) and 0 (0%) TK implants; for male proportion 23 (49%) and 17 (36%) TK implants; and for diagnosis of osteoarthritis 42 (89%) and 34 (72%) TK implants, respectively.

Conclusion: Most specific TK implants and TK procedures were used across multiple registries, but they were often used in patients with different characteristics. This has an impact on comparing implant performances between registries.

Background

Arthroplasty registries are well suited to assess the safety and performance of total knee (TK) implants, as most registries publish annual reports including survivorship data of specific TK implants.¹⁻³ Many registries have outlier procedures in place to detect implants with significantly higher revision.^{1,2,4} Several factors may influence TK-implant performances, including implant-related factors such as implant materials or the production process, for which the Optetrak case showed that implant-related factors resulted in significantly worse performance.⁵⁻⁷

Patient characteristics (e.g. age, sex, and body mass index (BMI)) can also affect the performance of TK implants.⁸⁻¹⁰ To compare performance of a specific TK implant across registries, characterised by brand name and implant characteristics to avoid camouflage, it is thus important to consider the characteristics of patients receiving that specific TK implant. Few studies have assessed differences in patient characteristics across countries¹¹⁻¹³, with most studies only focusing on variations in preoperative pain and function. Importantly, all studies analysed the entire group of TK implants (e.g. all cemented TK implants) rather than analysing differences for specific TK implants (characterised by a specific brand and implant characteristics like fixation and congruency). Hence, a more comprehensive analysis of the similarities and differences in patients receiving a specific TK implant is required to better understand possible differences in safety and performance of TK implants across registries. Such a comprehensive analysis is also needed to pool data across countries/registries or when performing distributed meta-analyses, where ensuring the same patient mix is crucial for fair comparison of safety and performance.

The aim of this study was to assess, across national registries, to what extent specific TK implants: i) are used across multiple registries or only in a single registry, and ii) differ in patient characteristics between registries.

Methods

Design and setting

The study was designed as a comparative observational study including data from four national European arthroplasty registries. Eight European national registries were asked to participate. Although all registries showed interest in doing so, this required some effort to make the standard script applicable to the registry, conduct the analyses, and send the data, which the following four European registries managed to do: the Danish Knee Arthroplasty Register (DKR), the Dutch Arthroplasty Register (LROI), the German Arthroplasty Register (EPRD), and the Italian Arthroplasty Registry (RIAP). Regarding the EPRD, only registry data with complete linkage to insurance data was included (10.5% of all TK procedures).¹⁴ TK implant-level completeness for the included four registries ranged from 59% (RIAP) to 97% (LROI).^{15,16} Aggregated TK-implant-level data was retrieved from each registry, including all patients receiving a primary TK implant between January 1, 2010 and December 31, 2021. In addition, each registry provided the number of unicompartmental knee (UK) implant procedures in this period, as different use of UK implants across registries may have been impacted by patient characteristics.¹³ The study is reported according to STROBE guidelines.

Categorisation of TK implants

Groups of comparable TK implant constructs were defined based on the following implant characteristics: implant–bone fixation (i.e. fixation), tibial insert–femoral congruency (i.e. congruency), mobile bearing insert, and patella usage (Table 1). Within each TK construct, the brand name of both the femoral and tibial component was used to indicate a specific TK implant.

Patient characteristics

For each specific TK implant in a registry, the number of procedures as well as the following patient characteristics were retrieved: i) mean age (standard deviation (SD)); ii) mean BMI (SD); iii)

percentage male sex, and iv) percentage of patients with the diagnosis osteoarthritis. The registers differed in their classification of the initial diagnosis, and we calculated the percentage of patients with the diagnosis osteo-arthritis in the following way for each registry:

- DKR: the number of patients with primary osteoarthritis as the initial diagnosis, relative to the total number of patients. Other diagnoses include rheumatoid arthritis, sequelae after tibia/femur condyle fracture, sequelae after patellar fracture, secondary arthrosis after meniscectomy, hemophilia, cancer, or other.
- EPRD: the number of patients with primary osteoarthritis as the initial diagnosis, relative to the total number of patients. Other diagnoses include post-traumatic osteoarthritis, secondary osteoarthritis, or other.
- LROI: the number of patients with osteoarthritis as the initial diagnosis, relative to the total number of patients. Other diagnoses include post-traumatic, rheumatoid arthritis, osteonecrosis, or other.
- RIAP: the number of patients with primary osteoarthritis as the initial diagnosis, relative to the total number of patients. Other diagnoses include post-traumatic osteoarthritis, rheumatoid arthritis, neoplasia, osteonecrosis, or other.

Statistics

Descriptive statistics were used to assess the number of registries in which each TK construct (based on implant characteristics: fixation, congruency, mobile bearing insert, and patella usage) was used. We also calculated the percentage of UK-implant procedures reported in each registry relative to all knee (i.e. both TK and UK) implant procedures used. For each specific TK implant used in ≥ 2 registries and used ≥ 100 times in each registry, we compared patient characteristics across registries. The criterion of ≥ 100 TK implants used per registry was added to ensure sufficient sample size for

meaningful analysis. First, we calculated for all patients receiving a TK implant across registries: the mean (SD) age and BMI, as well as the percentage of male sex and patients with osteoarthritis. Thereafter, for each registry and specific TK implant, we calculated a confidence interval around the mean or percentage, using the SD and total number of patient procedures. Statistically significant differences were determined by non-overlapping confidence intervals between registries.¹⁷ As statistical significance does not equal clinical relevance, we applied the commonly used threshold of a $\geq 10\%$ difference (i.e. 10% difference on the 0 to 100% percentage scale) to determine a clinically relevant difference for male sex and osteoarthritis diagnosis, and for the continuous variables age and BMI we used thresholds of a ≥ 5 years difference and a ≥ 5 points difference, respectively.^{18,19} These commonly used thresholds are determined in a large cohort study (including 4,183 patients) and in a Delphi study (i.e. the assessment of quality in the lower limb Arthroplasty “AQUILA” initiative) including 44 orthopedic experts.

Ethics, data sharing plan, funding, use of AI, and disclosures

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Results

Inclusion of TK constructs

Based on the combination of implant characteristics (i.e. three fixation types, six congruency types, two mobile bearing insert types (yes/no), and patella usage (yes/no)) 72 TK constructs would be possible theoretically, of which 9 (13%) were not used in any of the four registries or did not exist (Figure). 63 TK constructs (577,351 procedures; 813 different TK implants) were used in the four registries. Of these, 25 (40%) TK constructs were used in a single

registry, including 53 out of 813 (7%) different TK implants and 8,000 out of 577,351 (1%) procedures. 27 (71%) of the remaining 38 TK constructs (175,397 procedures; 713 different TK implants) did not have specific TK implants used ≥ 100 times in ≥ 2 registries. Thus, 11 TK constructs, considering 47 specific TK implants and 393,954 (68%) procedures, were included in the comparison of patient characteristics between registries (Figure, Table 2). Of note, no specific TK implants with mobile/rotating bearing inserts were used ≥ 100 times in ≥ 2 registries. Overall, 206 TK implants with mobile/rotating bearing inserts were used across registries but 183 of these were used in only one registry and 23 TK implants with mobile/rotating bearing inserts were used < 100 times.

Inclusion of TK implants

Table 2 shows the femoral–tibial brand name combinations for the 47 specific TK implants included in each of the 11 TK constructs, as well as the number of procedures in which these TK implants were used. Most included TK-implant procedures were registered in the LROI (n=207,017) followed by the EPRD (n=139,940), the DKR (n=41,526), and the RIAP (n=5,471). In four TK constructs, only one specific TK implant was used, while the TK construct “cemented, minimal congruent, fixed, and no patella usage” included the highest number of specific TK implants, namely 13. Three TK constructs were used in all four registries: i) the cemented, minimal congruent, fixed, without patella (including 13 different TK implants); ii) the cemented, posterior stabilised, fixed, with patella (including seven different TK implants), and iii) the hybrid, minimal congruent, fixed, without patella (including five different TK implants). Five TK constructs were used in three registries, and three TK constructs were used in two registries.

Use of UK implants across registries

The percentage of UK implants used was rather similar across registries: highest in the DKR (15.3%), followed by the LROI (13.3%), RIAP (12.4%), and the EPRD (12.1%).

Comparing patient characteristics for specific TK implants between registries

Overall, patients receiving the 47 specific TK implants were on average 68 years old (SD 7.3 years), with a mean BMI of 30 (SD 3.4), 34% were male, and 81% had the diagnosis osteoarthritis.

Of these 47 TK implants, statistically significant differences in age between registries were found for 29 (62%) TK implants, 30 (63%) had differences in BMI, 23 (49%) in percentages of male sex, and 42 (89%) in percentage of patients with osteoarthritis (Tables 3 and 4). Only one TK implant, Genesis II–Genesis II (hybrid/fixed/posterior stabilised/with patella) had no statistically significant difference between registries for any of these patient characteristics.

As for clinically relevant differences in patient characteristics when the same TK implant was used, age was different in 3 of the 47 (6%) TK implants, percentage of male sex in 17 (36%), percentage of patients with diagnosis of osteoarthritis in 34 (72%), whilst no differences in BMI were found.

Discussion

This is the first multi-registry study to compare the use of specific TK implants across registries and by comparing their use in comparable patients characterised by age, sex, BMI, and diagnosis of osteoarthritis. This is essential for comparison of safety and performance of the implant between registries. Only 53 (7%) of the 813 specific TK implants were used in a single registry, suggesting that pooling data across registries to detect any safety concerns is possible for most (93%) TK implants. Of the 47 TK implants used ≥ 100 times in ≥ 2 registries, statistically significant differences in patient characteristics were found in 62% of the TK implants for age, 77% for BMI, 49% for male sex, and 89% for diagnosis of osteoarthritis. Only a small number of these statistically significant differences in age and male sex were deemed clinically relevant,

none for BMI, but a large proportion (72%) of the differences in osteoarthritis diagnosis. These findings suggest that when comparing the performance for specific TK implants across registries potential differences in patient characteristics should be considered, particularly regarding diagnosis.

Most studies investigating differences in patient characteristics across registries did not consider specific TK implants but analysed all TK implants combined^{11,12}, and found considerable differences between countries in preoperative patient characteristics (e.g. age and BMI) and pain levels. Our study contributes to this literature by providing a more comprehensive analysis of differences in patient characteristics for specific TK implants. For clinicians, such detailed analysis on the TK-implant level will likely be more clinically relevant in guiding implant selection, as clinicians select implants based on their performance but need these patient characteristics to put the performance in context. For example, if the revision risk of a specific implant is good but based on a relatively older population while the patient concerned is much younger, then it is uncertain whether the implant will perform similarly in that patient. Such TK-implant-level information is also relevant for regulators to better interpret the safety and performances of TK implants on the market across registries²⁰, as elderly patients, for example, may have lower remaining life expectancy, and surgeons may be less likely to revise given the higher risks associated with surgery.²¹

Even though we found statistically significant differences in age, BMI, percentage of males, and osteoarthritis diagnosis across registries for many TK implants, the question is whether these differences are also clinically relevant. In a large study population, even very small differences can be detected as statistically significant, though they may not be clinically relevant.²² As clinical differences are more relevant for clinicians, we also determined the clinically relevant differences by applying commonly used thresholds.^{18,19} Only a small number of TK implants showed clinically

relevant differences in age, BMI, and male sex, but differences in osteoarthritis diagnosis remained for a large proportion of TK implants. This suggests that most TK implants are used in similar patient groups except for diagnosis. This is in line with research showing differences in treatment approaches for knee osteoarthritis between countries, influenced by several factors such as variations in healthcare systems, guidelines and preferred approaches, economic factors, and cultural preferences.^{23,24} The relatively high differences in osteoarthritis diagnosis might be caused by differences in definitions or the classification used. While the DKR, EPRD, and RIAP included primary osteoarthritis to calculate the percentage, the LROI included both primary and secondary osteoarthritis. Even though we tried to harmonise as much as possible across registries, these differences reflect the heterogeneity in definitions and methods across registries and show the need for further harmonization for better comparison.

To allow for early detection of safety issues in specific implants, it is often recommended that data across registries should be pooled to increase the number of implants at risk for statistical analysis and thereby statistical power.^{2,25} Another advantage of pooling data across registries is that it might better represent real-world performance of this specific device across all patients in which it is used. On the other hand, if we want to know the revision risk for a specific implant in a specific patient population, we would need to include only specific patients to arrive at the best revision risk estimate, akin to what we do when pooling data in a meta-analysis. In addition, pooling of data is complicated by large heterogeneity in methods used across registries, definitions, and outcomes collected, which negatively impacts the ability to pool data.² The current study shows that if harmonization across registries in methods and collected outcomes can be reached, pooling of data will be possible for the majority of TK implants (93%), as only 7% of TK implants were used in a single registry, and this is particularly valuable for TK implants with limited sample size.

Combining data from multiple registries may also increase the heterogeneity of the included data due to factors other than recorded patient characteristics, where using data from a single registry may limit this heterogeneity, which makes interpretation more straightforward. For instance, revision tendencies can vary between countries, which influences the estimated performance (i.e. revision risks) of specific TK implants. When using data from an individual registry, such differences in tendencies to revise may be smaller, although between-hospital variations in revision thresholds may still exist as well as differences in operative volumes of individual surgeons and hospitals, all known as factors influencing revision risks.^{26,27} Although data pooling has its limitations, we believe that pooling data should be recommended, to increase the number of implants for statistical power and thus to better represent real-world performance of a specific implant.

Limitations

First, we were limited in the patient characteristics that could be compared between registries, where more factors (e.g. American Society of Anesthesiologists (ASA) classification) may affect the safety and performance of primary TK implants, and are therefore important to take into account when comparing the performance of TK implants.²⁸ Second, the frequency of UK implants used in a registry may affect differences found in patient characteristics where it is known that UK implants are more commonly used, for instance in younger patients.²⁹ However, as the variation in UK implants used across registries was relatively small, the impact is likely negligible. Third, there could have been selection bias because not all TK implants used in patients were reported in registries (i.e. TK-implant-level completeness ranges from 58.7% to 97%). Lastly, we limited our analysis to four national registries where a larger number of regional, national, and multi-country registries exist.² Including additional registries could have resulted in a higher number of specific TK implants used across multiple registries for which patient characteristics could be compared.

Conclusion

Most TK implants were used in multiple registries, indicating that if harmonization of data collection across registries is achieved, this will enable pooling of data across registries for detection of safety concerns, particularly for those TK implants with limited sample size within a registry. In addition, differences in characteristics of patients receiving the same TK implant across registries were found, which should be considered when comparing the performance of the same TK implant across registries and may assist clinicians in implant selection for specific patients.

Figures and Tables

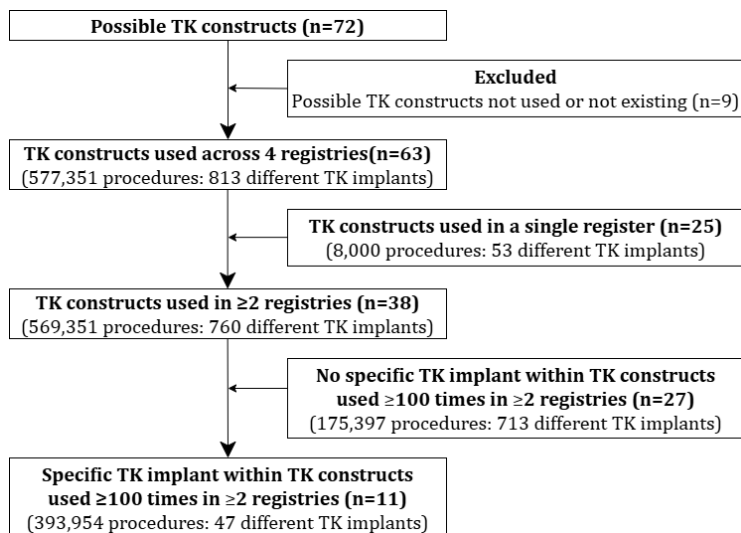


Figure 1. Use of specific TK implants across registries and included TK implants in comparison of patient characteristics

Fixation	Cemented; cementless; hybrid LROI definition: femoral component is cementless, tibial and/or patellar components are cemented
Congruency	Mega prosthesis (i.e. maximal-hinged or mega tumor resection prosthesis) LROI definition of hinged: a component that only allows for flexion and extension through a fixed axis and provides collateral as well as posterior ligament stability Fully congruent (high posterior peg of liner) LROI definition of fully: a component that only allows for flexion and extension through a fixed axis and provides collateral as well as posterior ligament stability Posterior (i.e. posterior stabilised) LROI definition: both cruciate ligaments removed Medial pivot LROI definition of mobile: the medial pivot knee design has a highly congruent medial liner–femoral component contact Minimal (i.e. minimally congruent): retaining of posterior cruciate ligament (CR) LROI definition: retaining of medial CR Bicruciate retaining LROI definition: both cruciate ligaments retained
Bearing insert	Fixed (i.e. non-mobile) LROI definition: component that is not intended to move relative to its interface component Mobile/rotating (i.e. a tibial insert is intended to move on its metal tibial component) LROI definition of mobile: a component that is intended to move relative to its interface component LROI definition of rotating: a component that is intended to move relative to its interface component Rotating: where the component moves in an inward and outward direction
Patella usage	No; yes

Table 1. Implant characteristics used to categorise TK constructs in primary arthroplasty, and their definitions according to the LROI implant library³⁰

TK construct				Number of implants used in registry					TK implant
F	C	M	P	Total	DKR	EPRD	LROI	RIAP	Brand name femoral–tibial component
C	F	F	No	991		794	197		NexGen-NexGen
C	MP	F	No	2,561 546		1,358 438	576 282	627	Evolution MP–Evolution MP Advance-Advance
C	MP	F	Yes	399		117	282		Evolution MP-Evolution MP
C	M	F	No	37,811	1,155	16,628	24,028	339 218 368 147	Vanguard Complete–Vanguard Complete
				31,435	2,805	15,364	13,266		PFC/Sigma-PFC/Sigma
				21,740	852	14,929	5,959		NexGen-NexGen
				18,731		7,044	11,687		Genesis II-Genesis II
				13,757		13,418			Columbus-Columbus
				11,672	1,787	6,691	2,976		Triathlon-Triathlon
				7,517		6,953	196		Persona-Persona
				5,832		3,034	2,798		TC plus-TC plus
				5,678		5,160	518		Attune-Attune
				3,875		1,198	2,677		ACS-ACS
				3,754		3,006	748		Balansys-Balansys
				2,305		2,172	133		Innex-Innex
				427		280			Unity-Unity
C	M	F	Yes	21,468	14,000	3,612	3,856		PFC/Sigma-PFC/Sigma
				10,704	4,944	643	5,117		Vanguard Complete–Vanguard Complete
				5,766	4,207	1,559			NexGen-NexGen
				5,099	1,905	2,947	247		Triathlon-Triathlon
				3,056		662	2,394		Genesis II-Genesis II
C	P	F	No	55,367		15,547	39,820	2,581 396 218	NexGen-NexGen
				37,974		2,243	35,731		Genesis II-Genesis II
				7,665		2,858	4,807		Triathlon-Triathlon
				6,648		1,816	2,251		Persona-Persona
				5,845		1,823	4,022		PFC/Sigma-PFC/Sigma
				3,809		993	2,816		Balansys-Balansys
				2,726		1,904	426		Attune-Attune
				601		396	205		ACS-ACS
				536		318			Columbus-Columbus
				14,523	548	2,004	11,971	325 102	NexGen-NexGen
C	P	F	Yes	12,204		226	11,978		Genesis II-Genesis II
				8,729	977	806	6,946		PFC/Sigma-PFC/Sigma
				1,980		848	1,132		Triathlon-Triathlon
				1,462		1,279	183		Balansys-Balansys
				1,273		299	649		Attune-Attune
				794		149	543		Persona-Persona
H	M	F	No	3,134	164	310	2,660		Vanguard Complete–Vanguard Complete
				3,074	1,630	580	864		NexGen-NexGen

				807 430 478	291 160	516 270 325			PFC/Sigma-PFC/Sigma Triathlon-Triathlon Columbus-Columbus
H	M	F	Yes	4,948 624	4,851 159	133	465	153	NexGen-NexGen Vanguard Complete-Vanguard Complete
H	P	F	Yes	333		123	210		Genesis II-Genesis II
U	M	F	No	2,830	1,091	166	1,573		Triathlon-Triathlon
<i>F = fixation; C = cemented; H = hybrid; U = uncemented; C = congruency; F = fully; MP = medial pivot; M = minimally; P = posterior; M = mobility; F = fixed; P = patella used</i>									

Table 2. TK constructs used ≥100 times in ≥2 registries

TK construct and TK implant	Mean age					Mean BMI			
	n	DKR	EPRD	LROI	RIAP	DKR	EPRD	LROI	RIAP
C/F/F/No patella NexGen	991		72	72			31	29*	
C/MP/F/No patella Evolution MP	2,561		68	69	72 [†]		31	29*	
Advance	546		71	71			31		
C/MP/F/Patella Evolution MP	399		65	68			30	29	
C/M/F/No patella Vanguard Complete	37,811	68	67 [†]	70		29	29 [†]	31	
PFC/Sigma	31,435	68	70 [†]	69		29	31 [†]	30	
NexGen	21,740	68	70 [†]	68		29	31 [†]	29	
Genesis II	18,731		68	69*			31	30*	
Columbus	13,757		69		72		31		
Triathlon	11,672	67 ^d	69	69	72 ^{†,§}	30	31 [†]	30	
Persona	7,517		69	65 ^d	71 ^{†,§}		31*	28	
TC plus	5,832		71*	69			31	31	
Attune	5,678		66 ^d	72* [†]			31	29*	
ACS	3,875		67	66			32	29*	
Balansys	3,754		70*	68			31	31	
Innex	2,305		71	74*			31		
Unity	427		70		71		31		
C/M/F/Patella PFC/Sigma	21,468	70	70	69 [†]		30	31 [†]	30	
Vanguard Complete	10,704	67 [†]	70	68		30	31 [†]	30	
NexGen	5,766	69*	71			30	31*		
Triathlon	5,099	67*	68	68		30	31	30	
Genesis II	3,056		67	68			32*	30	
C/P/F/No patella NexGen	55,367		69	69*			31	29*	
Genesis II	37,974		69	69			31	30*	
Triathlon	7,665		70	70			31	30*	
Persona	6,648		70	68*	71		30	29*	
PFC/Sigma	5,845		70	69*			31	30*	
Balansys	3,809		70	69*			31	29*	
Attune	2,726		69	69	72 [†]		31	30	
ACS	601		69	66*			32	31	
Columbus	536		68		72*		32		

C/P/F/Patella									
NexGen	14,523	68	69*	68		30	32†	29	
Genesis II	12,204		69	67*			30	30	
PFC/Sigma	8,729	68*	69	69		30	32†	30	
Triathlon	1,980		70	68*			31*	30	
Balansys	1,462		69	66*			32	29*	
Attune	1,273		69	69	71†		31	30	
Persona	794		68	66	70		31	29*	
H/M/F/No patella									
Vanguard Complete	3,134	67	68	69		30	31	29*	
NexGen	3,074	69	68*	69		29†	31	31	
PFC/Sigma	807	69	68			29*	31		
Triathlon	430	70	69			30	30		
Columbus	478		70		70		31		
H/M/F/Patella									
NexGen	4,984	68	68			30*	31		
Vanguard Complete	624	67		69		30		30	
H/P/F/Patella									
Genesis II	333		69	66			30	31	
U/M/F/No patella									
Triathlon	2,830	67	66*	68		30	31	29†	
* = Statistically significantly difference from one other registry; † = Statistically significantly difference from two other registries; ‡ = Statistically significantly difference from three other registries; § = Clinically relevant difference									

Table 3. Patient characteristics (age and BMI) across registries for the 47 TK implants analysed in the 11 TK constructs

TK construct and TK implant	Proportion male (%)					Proportion osteoarthritis (%)			
	n	DKR	EPRD	LROI	RIAP	DKR	EPRD	LROI	RIAP
C/F/F/No patella NexGen	991		28	22			83*§	100§	
C/MP/F/No patella Evolution MP	2,561		34	34	29		93†	100	99
Advance	546		41§	10*§			89*§	100§	
C/MP/F/Patella Evolution MP	399		19*§	33§			89*§	100§	
C/M/F/No patella Vanguard Complete	37,811	40	48§	33†§		100§	78†§	93§	
PFC/Sigma	31,435	47†§	36§	34§		83§	85§	100†§	
NexGen	21,740	44	37†	43		85†§	94	100§	
Genesis II	18,731		34	35			93*	100	
Columbus	13,757		33		32		87*§		99§
Triathlon	11,672	45	38§	36§	53†§	79§	82§	100§	98§
Persona	7,517		39§	56†§	38§		93†	100	98
TC plus	5,832		37*	30			80*§	100§	
Attune	5,678		41	38			89*§	100§	
ACS	3,875		29*	37			79*§	100§	
Balansys	3,754		32	32			88*§	100§	
Innex	2,305		35	27			87		
Unity	427		29§		42§		79*§		91§
C/M/F/Patella PFC/Sigma	21,468	39†	34	30		86§	86§	100†§	
Vanguard Complete	10,704	41†§	26§	30§		81§	91§	100§	
NexGen	5,766	38	35			94	85*		
Triathlon	5,099	38§	40§	25†§		81§	77§	100†§	
Genesis II	3,056		30	29			93	100	
C/P/F/No patella NexGen	55,367		32*	36			89*§	100§	
Genesis II	37,974		35	37			89*§	100§	
Triathlon	7,665		36	36			79*§	100§	
Persona	6,684		39	41	38		78§	100§	96§
PFC/Sigma	5,845		33*	41			88*§	100§	
Balansys	3,809		43	36*			96*	100	
Attune	2,726		38	46†§	32§		89†§	100§	98§
ACS	601		36	32			89§	0§	
Columbus	536		34		29		87		94
C/P/F/Patella NexGen	14,523	29	30	31		77†§	93§	100§	

Genesis II	12,204		18*§	31§			86*§	100§	
PFC/Sigma	8,729	40†	32	35		77§	74§	100†§	
Triathlon	1,980		34	34			72*§	100§	
Balansys	1,462		37§	21*§			99	100	
Attune	1,273		39	39	33		57†§	100§	98§
Persona	794		39§	28§	29§		91†	100	98
H/M/F/No patella									
Vanguard Complete	3,134	40	46	38		87§	92	100†§	
NexGen	3,074	42§	50§	29†§		92§	82†§	100§	
PFC/Sigma	807	43	41			86	86		
Triathlon	430	49§	38§			86§	70*§		
Columbus	478		34		34		92*		100
H/M/F/Patella									
NexGen	4,984	41	39			90§	74*§		
Vanguard Complete	624	40§		25*§		74*§		100§	
H/P/F/Patella									
Genesis II	333		44	48			98	100	
U/M/F/No patella									
Triathlon	2,830	43	47§	37*§		87§	93	100†§	

* = Statistically significantly difference from one other registry; † = Statistically significantly difference from two other registries; ‡ = Statistically significantly difference from three other registries; § = Clinically relevant difference

Table 4. Patient characteristics (% male and osteoarthritis) across registries for the 47 TK implants analysed in the 11 TK constructs

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