



Orthopaedic registries: the German experience

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- National joint registries are gaining more and more importance in the fields of implant monitoring/outlier detection and quality of care.
- The German Arthroplasty Registry (EPRD) was established in 2010 for the purpose of observing the impact of primary hip and knee arthroplasty on the German population.
- Having now over one million documentations, we introduce the structure of the EPRD and detail the process of data collection.
- We report on some preliminary trends and contrast these with findings from other joint registries.
- We introduce the overhauled Arthroplasty Library, that resulted from an international collaboration with National Joint Registry of England, Wales and Northern Ireland.

Keywords: arthroplasty registry; implant monitoring; joint registry, implant library; product database; early results

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Introduction

The German Arthroplasty Registry (EPRD) was established in 2010 as an umbrella organization by surgeons and the German Association of Orthopaedics and Orthopaedic Surgery, comprising hospitals, public health insurance agencies and industry representatives from endoprosthesis manufacturing companies.¹⁻³ The aims of EPRD are:

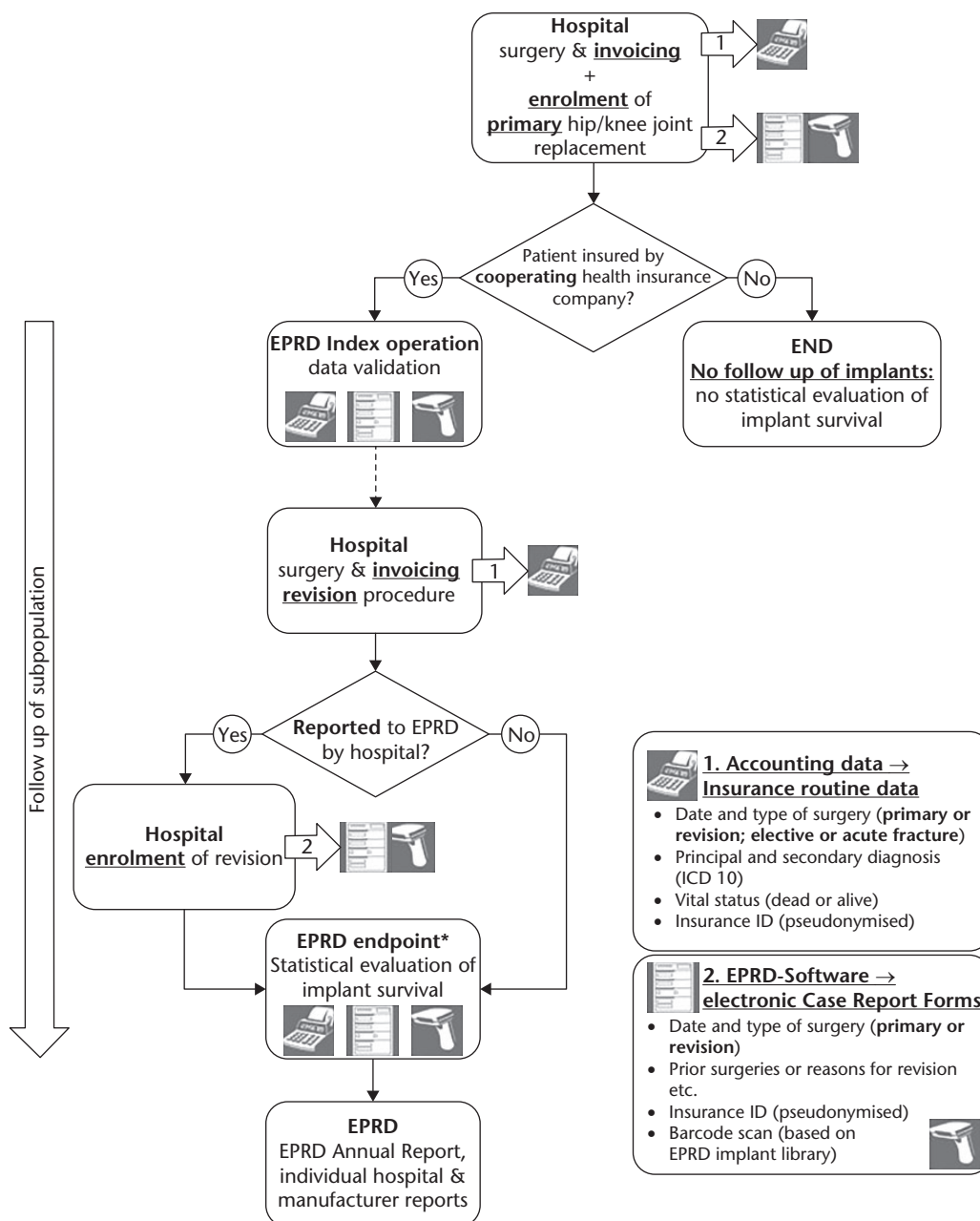
- to maintain a detailed database on all implanted hip and knee endoprostheses in Germany from the index (primary) operation to the end point which is considered to be the revision of any component in Germany;
- to collate and process this data with the aim of improving patient outcome and safety;

- to provide evidence-based guidelines to surgeons and hospitals on a national and international level and;
- to maintain an industry curated database of implant components classifying type, materials, design, size, modularity, fixation method and further attributes.

Since inception, the participation of German hospitals in the arthroplasty registry and, therefore, the number of hip and knee arthroplasty cases contributed, has been steadily growing annually.⁴ Data collection by the EPRD proceeds in Germany on a voluntary basis. Participating hospitals grant consent for patients to be under observation. The event of a revision (or death of a patient) is flagged by the insurer even if the revision takes place in an institution that does not participate in the registry (Fig. 1). Currently, about 65% of the German population are covered by insurance agencies contributing data to the EPRD. This may lead to a bias in the study population, as privately insured patients are not included in the follow-up. Even so, constraining the study population to those insured by the two biggest public health insurance companies in Germany helps uniform data collection. Despite its complexity, arthroplasty patients within this system will be flagged to the EPRD in the event of death or revision of any component of the arthroplasty. Thus, the chance of failing to flag a revision operation is minimized.

Furthermore, health insurers contribute relevant health statistics such as comorbidities, care procedures codes and vital status, allowing sub stratification of collected data.

Currently we are able to provide short-term outcome data on a variety of implants and procedures. Due to the volume and variety of hip and knee arthroplasty procedures performed in Germany, the EPRD generates detailed analysis of these procedures on the whole, as well as



*for survival analysis (revision of any component for any reason) and censoring the data of patients who die or suffer an amputation of the involved limb **just (1) Accounting data → insurance routine data is necessary.**

Fig. 1 Simplified representation of German Arthroplasty Register (EPRD) follow-up data flow from primary hip or knee arthroplasty to revision (ICS, International Classification of Diseases).

providing data on individual components, bearing surfaces and fixation methodologies.

Methods

Data collection

The EPRD commenced in November 2012 gathering prospective data on hip and knee arthroplasty in Germany.

Compliance with the registry remains to date voluntary. Since inception, there has been a steady increase in hospitals participating in gathering registry data. In 2017 the EPRD received documentation relating to the implantation of almost 283 000 hip and knee prostheses from 706 hospitals, representing some 63% of all hip and knee implants for the whole of Germany. At the end of 2018 the clinical and pseudonymized data of over one million hip

and knee arthroplasty procedures had been electronically reported to the EPRD. The submissions of the hospitals include the date and type of surgery (hip or knee arthroplasty; primary or revision; elective or acute fracture), information of relevant preoperative procedures or reasons for revision etc., as well as the scan of barcode information of the implanted arthroplasty components.

In cooperation with Germany's two biggest public health insurers Allgemeine Ortskrankenkasse (AOK) and Verband der Ersatzkassen e. V. (vdek) which together cover some 65% of the German population, the EPRD has secure access to routine patient data which is important for cross-validation verification as well as for complementing the registry data. The flow of pseudonymized data between the health insurers and the EPRD is essential for documentation of relevant health-related cofactors, such as primary diagnosis and relevant comorbidities. Thus, analysis of patient-related risk factors for revision can be evaluated. Furthermore, in the event a revision operation occurs outside of an EPRD registered hospital, all revision surgeries are flagged when the health insurer (AOK and vdek) is billed (Fig. 1).

This collaboration between insurer and registry ensures the inclusion of patients who may otherwise have been revised at a German hospital outside of the data collection system of the EPRD. Just this subpopulation is taken into account in the evaluation of the revision rate. Implant survival status is concluded with the death of the patient or amputation of the affected lower limb, so these events will be regarded as being 'censored' and excluded from implant follow-up, to avoid an underestimation of the revision rate. This is in contrast to some other voluntary registries where despite the death of the patient, the implant continues to 'survive' in the registry. Thus, the outcomes presented here are on overall revision performed on primary procedures after arthroplasty surgery of any component of the arthroplasty, for any reason.⁵ Close monitoring of components in this way forms the platform for the German early warning system, in the event that a component shows signs of significantly underperforming.⁶ With commencement of EPRD data collection, most participating clinics were high-volume tertiary referral university clinics. Hospitals implanting annually fewer than 100 hip and knee prostheses were, and continue to be, under-represented. We expect with increasing hospital participation over time that the statistical evaluation from the EPRD will come to represent a broader perspective of arthroplasty surgery in Germany.

Implant databank

A further function of the EPRD is participation at an international level, where communication with other national registries aims to establish industry standards to better enable accurate classification of implants. This goal was

realized in 2018 with the collaboration between EPRD and the National Joint Registry of England, Wales and Northern Ireland (NJR). Representatives of the 28 orthopaedic implant manufacturers are responsible for maintaining the database of some 57 000 individual components. Collaboration between the EPRD and the NJR has led to the generation of a harmonized classification system covering all components used in both libraries. Each component is classified according to material, measurements, surface finish, type of bony fixation and equipped with a specific article number that is encoded in a barcode for optimizing hospital processing, documentation and completing fill orders for hospitals.¹ This bar code is integral to the process of EPRD documentation and data collection.

Since the beginning of 2018, the product database structure has been completely overhauled and modernized. For hip systems, seven components have been categorized, eight for knee systems. Each component can then be subclassified on the basis of subtype, design specifications, type of fixation, material and size. Thus, the EPRD has at its disposal a highly granular database that enables specific queries relating to implant detail.

Statistical analysis

Kaplan–Meier survival analysis was performed on comparable subgroups with similar patient characteristics (age, sex, acute or elective index procedure and comorbidities) to estimate cumulative incidence for the need of the first revision for any reason. Patients were followed-up with respect to revision, death or amputation including the replaced joint. Patients with incomplete follow-up, those who did not require a revision up to the end of the follow-up period or prior to their death or amputation, have been regarded as being 'censored' at those times. All analyses were performed using R statistical software (R Foundation for Statistical Computing, Vienna, Austria).

Results

Due to the relatively short lifespan to date of the EPRD, many implant survival results are short term (three years) and refer to primary arthroplasty. On the other hand, the structure of the registry is such that no revision operation that takes place within the observed subpopulation in Germany can be lost to follow-up. The conclusiveness of the data means that there is less chance that a failure rate can be underestimated.

General trends and comparison of the EPRD results with other national registries

Comparable with published observations in continental Europe, the EPRD statistics document that hip arthroplasties are more commonly implanted per year than knee prostheses (56% *versus* 44%) and that more hip arthroplasties

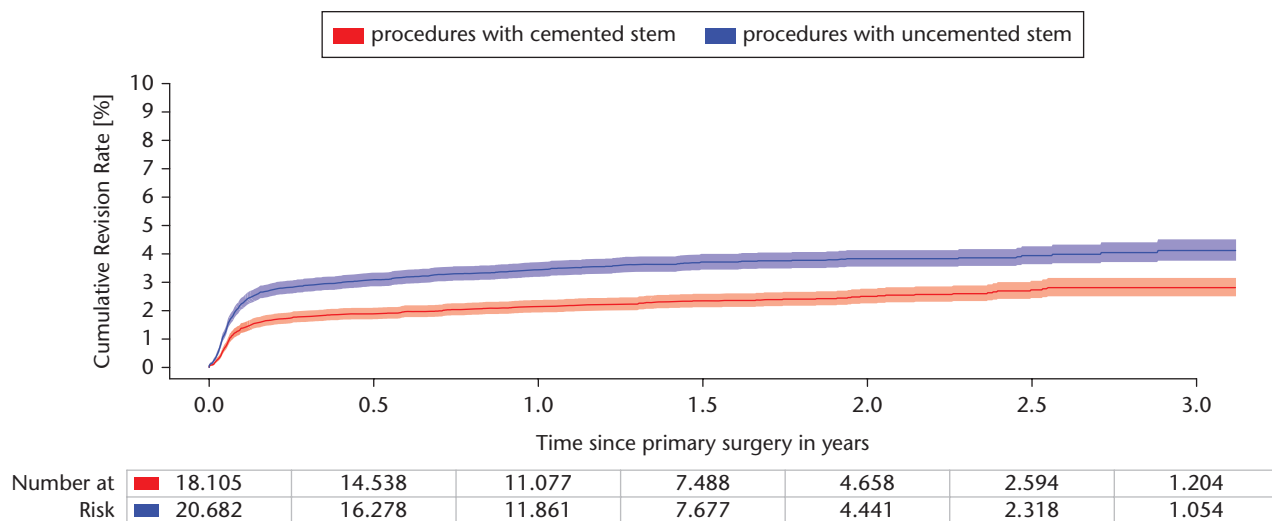


Fig. 2 Kaplan–Meier survival analysis was used to estimate cumulative incidence of overall revision in patients ≥ 75 years old after primary elective total hip arthroplasty.

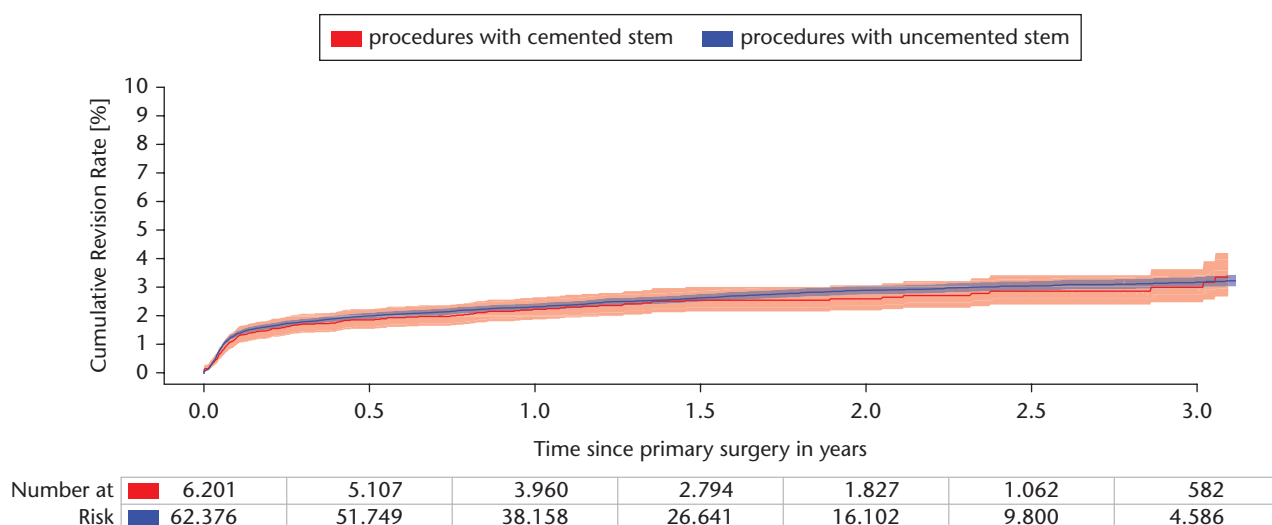


Fig. 3 Kaplan–Meier survival analysis was used to estimate cumulative incidence of overall revision in patients < 75 years old after primary elective total hip arthroplasty.

are implanted in women (59.6% *versus* 40.4%) than men. The failure rate of uncemented femoral stems in elderly patients is in agreement with other national registries with a demonstrably higher revision rate (4.1% *versus* 2.8% at 3 years) in total hip arthroplasty (Fig. 2), while in a younger cohort there is no discernible difference (Fig. 3).

Interestingly, mortality risk in the age group from 75 to 79 years is higher for the six months following implantation for cemented stems (1.2%) compared with uncemented stems (0.7%). Despite analysis of comorbidity data, it remains unclear if this difference represents a selection bias or a true procedural related mortality risk attributable to cementation.

There are many trends in German arthroplasty surgeries that support worldwide trends, while other observations differ from published trends in other national registries. Interpretation of these differences affords care, especially in the early analysis. In 2017, the EPRD documented a rate of 77.2% of all total hip arthroplasties implanted without cement (Table 1). In Switzerland, the proportion was even higher at 83.6%,⁷ while Sweden and Norway choose overwhelmingly cemented fixation.^{8,9}

When it comes to bearing surfaces (tribology), the EPRD reports a slow but developing preference in Germany for a ceramic head articulating on highly crosslinked polyethylene in hip arthroplasty. Ceramic heads are

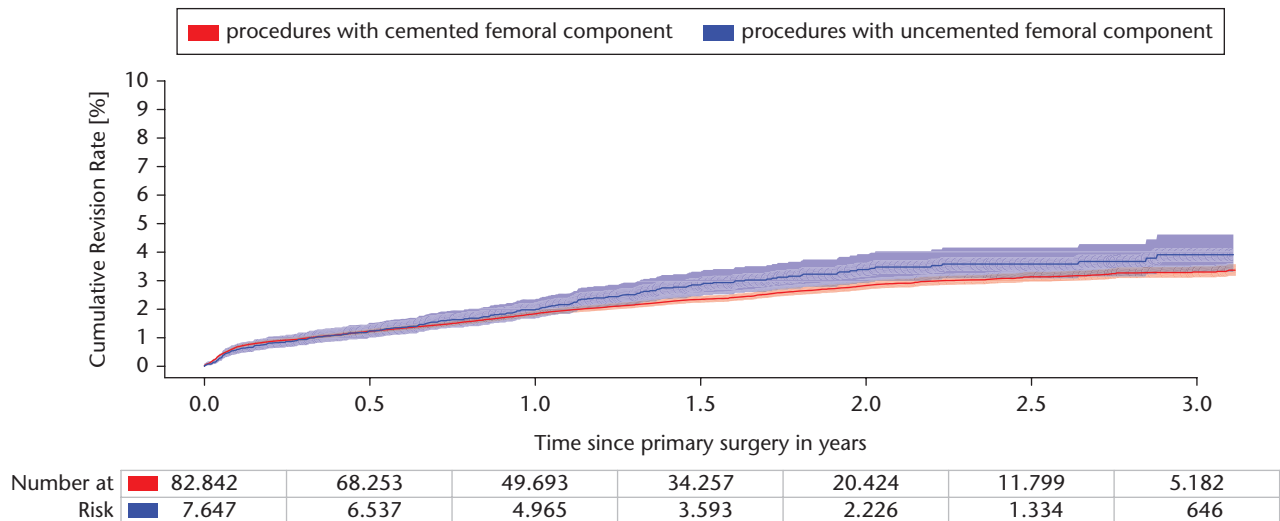
Table 1. Proportions of (bony) fixation types in primary total hip arthroplasty (year 2017)

Fixation type	Proportions, %	Age, yrs	Male:female, %	Body mass index, kg/m ²
Cemented fixation	77.2	67	45:55	27.7
Hybrid fixation	15.9	78	29:71	26.6
Cementless fixation	5.7	80	27:73	26.1
Reverse-hybrid fixation	1.2	75	29:71	26.1

Table 2. Proportions of bearing types in primary total hip arthroplasty (year 2017)

Bearing type	Proportions, %	Age, yrs	Male:female, %	Body mass index, kg/m ²
XLPE/ceramic	53.1	69	42:58	27.4
XLPE+antioxidant/ceramic	16.9	69	43:57	27.6
Ceramic/ceramic	9.2	62	47:53	27.5
PE/ceramic	8.1	75	35:65	27.3
XLPE/metal	6.8	78	37:63	26.7
PE/metal	2.2	80	30:70	26.2
XLPE+antioxidant/metal	0.6	78	35:65	26.4
Metal/metal	0.1	54	99:1	26.3
Not clearly identifiable	3.0	68	43:57	27.8

XLPE, highly crosslinked polyethylene; PE, polyethylene

**Fig. 4** Kaplan–Meier survival analysis was used to estimate cumulative incidence of overall revision in all patients after primary knee arthroplasty.

utilized in 87.3% of all prosthetic total hip joints (Table 2), which represents a growth of almost 2% since 2014. This high penetration of the use of ceramic heads separates Germany from most other countries.

According to the EPRD, most revision knee surgery occurs later than revision hip surgery, being performed between the second and third postoperative years and shows a more linear increase within the early phase. In contrast, revision hip surgery is most often performed in the weeks to months following the index procedure. The risk of revision hip surgery for a total hip arthroplasty is 3.2% at 2.5 years postoperative. At the same timeframe it is higher for hemiarthroplasty (4.5%) and higher still for total hip arthroplasty (7%) after acute fracture.

Following the worldwide trend, knee prostheses in Germany tend to be fully cemented. With respect to femoral fixation technique, we see within the first year of observation no relevant increase in failure rate between the cemented and the uncemented femoral components (Fig. 4). From the second year on, we see a statistical separation of the two groups, such that a survivorship advantage is observed for cemented femoral components. However, after the second year of observation the confidence intervals of the two curves once again overlap, suggesting that at this timeframe, a cemented femoral component no longer shows a survival advantage. Even in this early phase, there appears to be clear advantages to specific components or fixation methods. Not all of these

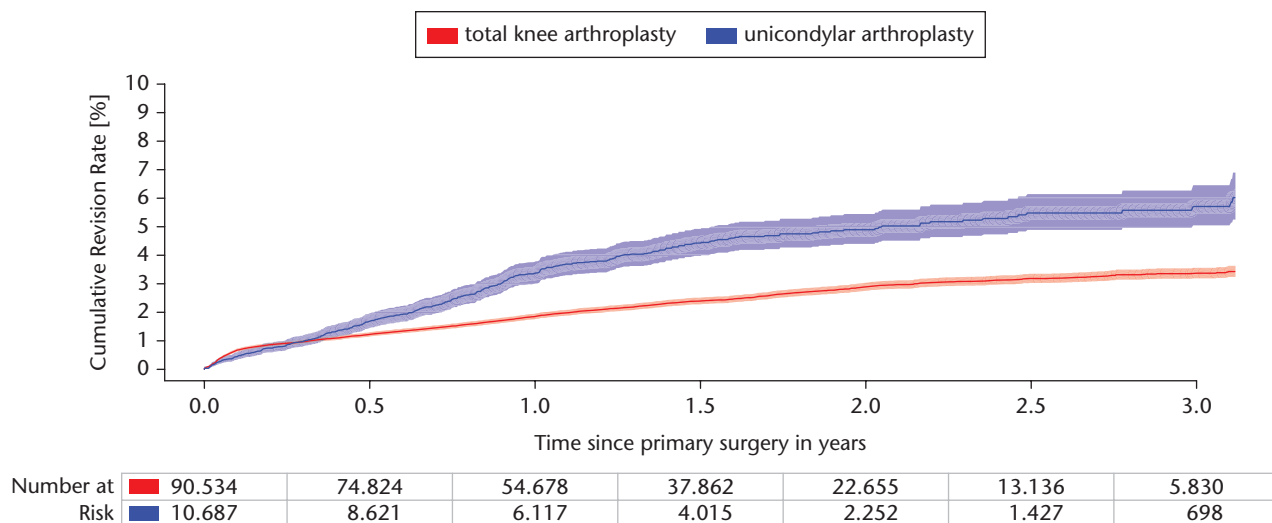


Fig. 5 Kaplan–Meier survival analysis was used to estimate cumulative incidence of overall revision in all patients after primary total knee arthroplasty.

perceived advantages are as easy to interpret and care must be exercised before a specific recommendation can be published.

German facilities have been slowly broadening their experience with unicondylar knee prostheses. In the last few years, the percentage of knee implants that are unicondylar has marginally increased, according to EPRD data. In 2017, the EPRD documented an increase in the proportion of implanted unicondylar knee prostheses of all knee prostheses, to 12.2%, rising 3% above the rate documented in 2014. This retreat from unicondylar knee prostheses is opposite to that observed in the Swedish, Australian and United States national joint registries, who observe that the proportion of unicondylar knee implants is receding. This trend is particularly strong in the United States, where the percentage of all implanted knee prostheses that are unicondylar knee prostheses has receded to under 5%.¹⁰

The general tendency for hospitals with a large arthroplasty turnover to have a lower revision rate is no more clearly demonstrated than when observing the revision rate as it pertains to the implantation of unicondylar knee prostheses. The comparison between total and unicondylar prostheses shows a preferential survival rate for total knee arthroplasty from the sixth postoperative month. Three years after the index operation, the failure rate for unicondylar prostheses is calculated to be 5.7%, clearly above that of 3.4% for total knees (Fig. 5).

Discussion

In terms of international comparison, the EPRD was established relatively late. What it lacks in long-term follow-up, it compensates for with a relatively high volume of hip

and knee arthroplasty procedures, structured data collection and patient follow-up and a comprehensive product database. Due to the short duration of the registry, analysis is restricted to publishing only short-term (three year) results of primary arthroplasty. On the other hand, we want to stress the conclusive data collection across EPRD registered hospitals and health insurers, so that the possibility of underestimating a revision rate is minimized. There is mounting political pressure on all hospitals in Germany to participate in registry observation. With increasing participation from smaller clinics, we anticipate added diversity so that the registry will in future be comprised of a broader representative base. With this development comes an increasingly truer statistical representation of what is clinically observed in Germany.

Complementary data obtained from the combined resources of the EPRD and health insurer documentation of routine patient data, the EPRD is empowered to analyze a reliable database of implanted hip and knee endoprostheses, now delivering data for a period of up to three years follow-up. Even in this early phase, there appears to be clear advantages to specific components. Not all of these perceived advantages are as easy to interpret and care must be exercised before a specific recommendation can be published.

Furthermore, following collaboration with the NJR, the establishment of a comprehensive arthroplasty component catalogue sets up a framework for future component evaluation, refinement and improvement. This product database and its structure is available for further international collaboration and promotes establishment of international standards.

Early data results have provided us with a valuable insight into the performance of common implants. In the example of hip prostheses, we see a survival advantage for procedures with cemented stems in the elderly (75 years and over) patient cohort. There appears to be a significant increase in the early (weeks to months following the index procedure) revision rate for those where a uncemented stem is primarily implanted. On the other hand, we observe in the age group from 75 to 79 years that cementation of the stem in the index procedure is associated with a significantly higher mortality rate at 1.2% six months postoperatively, compared with 0.7% for uncemented femoral stems. Further investigation and follow-up are required before definitive conclusions can be made about stem selection in elderly patients.

There is a general tendency for hospitals with a large arthroplasty output to have a lower revision rate. This trend is apparent for hip and knee, and particularly evident for unicondylar knee arthroplasty. As expected, those clinics that specialize in unicondylar prosthetic implantation demonstrate a failure rate in the early postoperative phase that is comparable with that of total knee arthroplasties. When considering unicondylar prostheses alone, comparing the facilities that most frequently implant these prostheses to the remaining hospitals, there is a clear advantage to be observed with respect to the performance of these prostheses when the operation is conducted in one of these major contributing facilities.

We qualify this data by acknowledging that the statistics collected are only designated to the specific hospital. There is no break down to individual surgeon. It may be that individual surgeons' results vary significantly within respective hospitals.

Limitations

The EPRD acknowledge several limitations of these results. First, the considered periods are relatively short with regard to the life span of implants.

Secondly, we concede that EPRD does not have access to all relevant clinical data. As of 2017, data regarding patient height and weight, and therefore body mass index, has been collected. Thirdly, our data did not include any patient-related outcome measures. It is possible that some of the treated patients are symptomatic but have not been revised. Fourthly, procedures performed outside of Germany cannot be followed by the EPRD. Finally, because participation in EPRD data collection for hospitals is still voluntary, the registry does not have a full coverage of all hip and knee arthroplasties performed in Germany. Therefore, we are limited to those patients who are followed up by cooperating health insurance companies to evaluate valid implant survival analysis. Additionally, the bigger hospitals are those participating in the registry; therefore, the results might be biased by high volume users.

Conclusions

The EPRD is well on the way to providing detailed registry data of international relevance, as is supported by the presented data. To date, the EPRD has collected over one million hip and knee endoprotheses documentations. Due to collaboration with public health insurers, losing revision cases to follow-up is minimized. Censoring the data of patients who die or suffer an amputation of the involved limb helps to avoid underestimation of the revision rate. Furthermore, with growing political pressure on hospitals in Germany to participate in registry observation we anticipate an increase in the national completeness of data collection in the foreseeable future. Incidental to the development of the German registry is the establishment of an integrated and harmonized product database developed in collaboration with the NJR. This now stands as an international classification model and we anticipate further collaboration with other national registries.

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ICMJE CONFLICT OF INTEREST STATEMENT

VJ declares payments from Medacta, Implantcast and Aesculap as well as the Endoprothesen Register Deutschland gGmbH (EPRD).

AG declares employment by EPRD.

OM declares employment by EPRD.

CP declares travel support by EPRD and DG00C, payments by Zimmer, DePuy/Synthes, Link, Smith & Nephew and AOREcon.

AS declares payments and travel support by Medacta, Implantcast and Aesculap as well as the Endoprothesen Register Deutschland gGmbH (EPRD).

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LICENCE

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