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Summary of knee implant one, three, five, and 10-year revision risk reported by national and regional arthroplasty registries: a valuable source of evidence for clinical decision-making

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- Optimal implant selection is a major component of high-quality arthroplasty care, and revision risk is an important parameter characterizing knee arthroplasty implant clinical performance.
- National and regional arthroplasty registries are essential sources of revision risk data, but these data are often difficult to find because they are buried within extensive annual reports. Summarizing total knee arthroplasty (TKA) implant revision risks as presented in registry reports can maximize the usefulness of registry data for orthopaedic surgeons.
- The findings summarize the revision risk data found in national arthroplasty reports from the Australian, Danish, Finnish, and the England, Wales, Northern Ireland and the Isle of Man registries, and in regional arthroplasty reports from the Emilia-Romagna Region (Italty), and the Michigan Arthroplasty Registry Collaborative Quality Initiative (MARCQI) registries.
- The six supplemental summary tables present revision risk data for TKA implants by cemented, uncemented, hybrid, and unreported fixation types. Additional summary tables are presented for revision risk of unicondylar (UKA) and patellofemoral joint (PFJ) revisions. Within TKA fixation categories, revision risks at 10 years ranged from 2.4% to 35.7% (cemented), 2.8% to 25.0% (uncemented), 2.0% to 9.2% (hybrid), and 0.0% to 39.7% (unreported). Unicondylar 10-year revision risk ranged from 4.9% to 17.2%. Patellofemoral joint 10-year revision risk ranged from 15.2% to 21.7%.
- There is substantial variation in one, three, five, and 10-year revision risk across implants, which suggests surgeons should choose implants carefully.

Keywords: arthroplasty; evidence; implant; knee; registries; revision

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Introduction

Evidence-based medicine is central to providing the highest quality care to total knee arthroplasty (TKA) patients. Patients have many types of outcomes, including infection, venous thromboembolism, death, readmission, periprosthetic fracture, and revision. Sources of information include peer-reviewed literature, conference abstracts, industry, and arthroplasty registry reports. However, the generalizability of results in single-institution or single-surgeon studies can be limited. In addition, financial conflicts of interest may affect the reporting of data relevant to clinical decision-making. For example, Labek et al[1,2] showed that revision risk captured by a national arthroplasty registry is substantially higher than reports of revision risk produced by authors at institutions involved in the development of implants. In addition, national and regional registries are better than single-institution-based registries at capturing revision surgeries and linking them to primary surgeries because patients are often revised at a different institution. Thus, national and regional registries provide the best available estimates of revision risk for a device being used by large groups of community and academic orthopaedic surgeons.

National arthroplasty registries have existed for decades and are used around the world. The Swedish Knee Arthroplasty Register[3] and Swedish Hip Arthroplasty Register[4] were started in 1975 and 1979, respectively, and additional national registries have been developed since that time. Most of these registries issue an annual report in PDF format, and a fraction of them contain implant-specific revision risk data. Because most reports are hundreds of pages long, the implant-specific data are often difficult to find. Therefore, it can be very challenging for the busy clinician to extract revision risk data from all relevant registries in order to make an informed decision regarding which implant to use. While a cross-national summary of implant survivorship has been published for total hip replacement implants,[5] no such compilation is available for knee implants. Additionally, clinicians are increasingly engaged by institutions to make value-based decisions on implant selection to help control costs.

The purpose of this study was to compile a summary of TKA implant revision risk from registry reports that can be easily accessed by the practicing orthopaedic surgeon. Revision risk at one, three, five, and 10 years post-operatively were selected for comparability and inclusivity – this allowed the inclusion of implant-specific data from additional regisistries that would have otherwise been excluded had we restricted the summary to a single post-operative time-point. However, it is important to take into consideration the clinical importance of the 10-year time-point, as it is used by the United Kingdom's National Institute for Health and Care Excellence (NICE) for benchmarking hip implants.[6] NICE suggests a cumulative revision rate of 5% or less at 10 years for THA implants. This can be used as a relevant benchmark when assessing implants for use in TKA revisions.

Summary of implant revision risk data

In order to compile a complete user-friendly summary of revision risk based on Kaplan–Meier estimates reported by national and regional arthroplasty registries around the world, a comprehensive review of these registry reports was performed using specific selection criteria. For inclusion in this review, a registry report had to present one, three, five or 10-year follow-up data, or some combination of the chosen time-points, by implant combination, using Kaplan–Meier estimates of time to first revision, presented either as survivorship or cumulative percent revision. If a registry issued multiple reports, the most recent report that contained implant-specific data was used. Exclusion criteria consisted of reports of revision risk from sources other than a national or regional registry report; moreover, journal articles that included revision risk data on specific implants or types of implants were excluded. Reports of revision risk from sources other than national and regional registry reports were excluded because of potentially significant bias, as reported by Labek et al.[1,2] Additionally, journal publications by registries were excluded because these do not publish comprehensive lists of revision risks for all implants in the peer-reviewed literature due to page and word limitations, and there is a substantial risk of bias to selecting implants with especially high or low revision risks in order to make a study that is appealing to editors and reviewers. Our summary only included registry reports that give comprehensive listings of implant performance.

Registry reports were collected and data were abstracted. Reports were obtained from registries listed on the European Federation of National Associations of Orthopaedics and Traumatology (EFORT) website[7] and presented at the 5th International Congress of Arthroplasty Registries in 2016.[8] PubMed and internet searches were also used to identify other potentially qualifying national and regional arthroplasty registry reports. In addition, we reviewed reports from the American Joint Replacement Registry (AJRR),[9] Kaiser Permanente Total Joint Replacement registry,[10] HealthEast,[11] and the Michigan Arthroplasty Registry Collaborative Quality Initiative (MARCQI).[12] Reference lists of registries were reviewed for references to additional registries, and focused journal searches (*Journal of Arthroplasty*, *Journal of Bone and Joint Surgery – American*) were performed. We discovered that the most effective way to identify registries was through personal communication with registry leaders at the 5th International Congress of Arthroplasty Registries in 2016. Six registry reports met the inclusion criteria, and the year's reports from which data were extracted are as follows: the Australian Orthopaedic Association National Joint Replacement Registry 2018 (AOANJRR),[13] the National Joint Replacement Registry of England, Wales, Northern Ireland, and the Isle of Man 2016 (NJR),[14] the Finnish Arthroplasty Register 2016,[15] the Danish Knee Arthroplasty Registry 2016,[16] the Regional Register of Orthopaedic Prosthetic Implantology of Emilia-Romagna, Italy 2018 (RIPO),[17] and the MARCQI registry report 2018.[12]

The definition of revision that was used varied slightly across registries, with some registries specifying more detailed definitions of revision than others. All registries considered revision to be a second procedure required after the primary procedure in which all or part of the existing prosthesis was exchanged, removed, or added. Revision could be carried out for any reason, most commonly for infection, dislocation/instability, pain/discomfort, or fracture. The replacement of a single component of the total knee replacement, even if it was not the entire prosthetic, is considered a failure and would be included in the cumulative percent revision (CPR). There was slight variation in how registries classified secondary patella resurfacing. The NJR included secondary patella resurfacing of an

existing total knee replacement to be a revision. However, the RIPO did not consider the addition of a patella component to a bicompartmental prosthetic to be a revision, and the Danish Knee Arthroplasty Registry specified that any secondary procedure that does not affect the primary implant is not considered a revision. The MARCQI includes secondary patellar resurfacing as a revision. The AOANJRR separates revision into three categories: major total, major partial, and minor. The AOANJRR's revision risk tables combine all three categories. Additionally, the Finnish Arthroplasty Register specified that soft tissue procedures, such as lavation and debridement for infection, are considered revisions, whereas the NJR stated that debridement with implant retention was not considered a revision. The other registries do not specify whether soft tissue procedures were considered revisions. Data were extracted from each registry report for each implant combination into a repository that had been developed for a similar review of hip implants.[5] Data were extracted from registry reports by a single investigator and independently checked by the second author. Inconsistencies were resolved by the corresponding author. To ensure the summary was as comprehensive as possible, we did not restrict inclusion of implant combinations to a specific number of procedures. All combinations from the registries were included, including those implant combinations based on a low number of implantations. While all registries that met the inclusion criteria present data based on Kaplan–Meier estimates of time to first revision, they presented data in different ways. If the Kaplan–Meier estimate of survivorship is denoted $S(t)$, the percentage of patients without a revision at time t is $100S(t)$. The Danish and Emilia-Romagna registries present $100S(t)$. The AOANJRR, the NJR, and the Finnish and MARCQI registries report $100(1\text{-}S(t))$, which is the CPR. It represents the percentage of patients having had a revision at time t or before. For uniformity, data from the Danish and Emilia-Romagna registries were transformed to CPR.

The results of the review are presented in tables of CPR values organized by fixation: cemented, uncemented, hybrid, and unreported fixation (see the supplemental material). The unreported category was included because the Danish, Emilia-Romagna, and MARCQI reports did not include information on fixation. Each table was sorted alphabetically and shows the number of included cases (N). To ensure accuracy of reporting, the data were not rounded, and the summary tables present revision risks exactly as they are presented in the registry reports. The NJR and MARCQI report revision risk to three decimal places, while the AOANJRR, and the Finnish, Danish, and RIPO registries report revision risk to two decimal places.

Although only one of the registries in our review, the MARCQI, did not report 10-year revision risk data, we still highlight this important time-point due to its clinical significance. Tables of TKA implant revision risk for cemented (Supplemental Table S1), uncemented (Supplemental Table S2), hybrid (Supplemental Table S3), and unreported (Supplemental Table S4) fixation show wide variation in revision risk. Within TKA fixation categories, 10-year revision risks ranged from 2.4% to 35.7% (cemented), 2.8% to 25.0% (uncemented), 2.0% to 9.2% (hybrid), and 0.0% to 39.7% (unreported). Unicondylar knee arthroplasty (UKA) 10-year revision risk ranged from 4.9% to 17.2%. Patellofemoral joint (PFJ) 10-year revision risk ranged from 15.2% to 21.7%. The UKA revision risk (Supplemental Table S5) was not separated by fixation. The PFJ summary table (Supplemental Table S6) only includes data from the NJR because it was the only qualifying registry that reported on PFJ implants.

Discussion

This review provides a summary of registry reports of one, three, five, and 10-year knee arthroplasty revision risk. Because of the large variation in revision risk across implants, this compilation can be used to inform implant selection.

The primary benefits of national and regional arthroplasty registries include better estimates of revision risk than single-institution reports, statistical power due to large sample sizes, more generalizable information, and lower likelihood of conflicts of interest. National and regional registries are better able than single institutions to gather revision cases and link them to primary cases, which is necessary for computing the CPR. Many patients do not return to the hospital where the primary procedure was performed for a revision procedure. Substantial resources are required to find these patients, and many are lost to follow-up. Health record privacy issues make it difficult to link patients across hospitals. Moreover, some countries lack national medical registration numbers that can be used for linkage. The large sample sizes gained through national and regional registries enhances statistical power, thus increasing the probability that real differences in revision risk will be identified. National and regional registries also provide data that are more applicable to general orthopaedic practice. The generalizability of clinical series and randomized controlled trials is often limited by restrictive inclusion criteria, potentially resulting in studies of optimized or ideal patients. Moreover, they are often conducted by high-volume surgeons at large centres, often including a designing surgeon as a study investigator. Since national registry data are collected from a wide range of practice settings and many surgeons, the information more accurately reflects how implants will perform in general practice.

The main weakness of registries in general is that the registry data are observational. Therefore, registry analysis has all the limitations inherent in observational data

analyses. Most importantly, this means that inferring *causality* can be problematic.[18] Since clinicians likely want to infer that the use of a specific implant or fixation method will reduce revision risk for their patients, this limitation is of central importance in using registry data for clinical decision-making. Bias in comparisons of implant revision risks may arise from multiple causes such as an imbalance of important patient attributes (age, sex, BMI, etc.) between the implants. For example, if an implant tends to be used in younger patients then it may have a higher revision risk in the registry data, but this difference may be due to the types of patients being treated rather than the design of the implant itself. In addition, surgeon and hospital variability can make revision risk results appear to be caused by the implant when examining raw Kaplan–Meier curves when they are actually more related to surgeon and hospital factors. Registry reports often provide separate analyses for selected implants for factors such as age, sex, and BMI. Summary tables do not typically provide such a level of detail. The interested reader is, therefore, encouraged to consult the primary registry reports[12–17] for more detailed information. Furthermore, bias may result from the effects of unmeasured confounders. Large-scale registries cannot afford to collect all possible clinical data, and are therefore limited by the available data elements. This can lead to data sets that omit variables that may affect outcome. The effect of unmeasured confounders on estimates of association has been well-established.[18] Clinicians should consider the number of cases when assessing the summary tables, as larger case numbers help to mitigate the effects of other possible sources of bias, particularly those related to small sample sizes. In particular, a single surgeon or centre can have a significant impact on revision risk estimates when sample sizes are small.

Another consideration in using arthroplasty registries for data collection is the necessity of using device libraries for mapping catalogue number to implant attributes useful for analysis. A library is essentially a lookup table that a registry uses to associate features such as product name, material, constraint (cruciate retaining, posterior stabilized), mobility (fixed, mobile), and other clinically important attributes.[19] For example, many implants have different versions, and a decision has to be made as to whether the versions are similar enough to categorize together for the purposes of analysis, or so dissimilar that they should be analysed and reported separately. The developer of a library has to decide how to group or split devices into categories for reporting purposes and there are differences between registries on how these decisions are made. Not all registries or device libraries have made the same decisions about grouping and splitting. While there is currently a worldwide effort to standardize implant libraries for registry use, there is still heterogeneity in libraries across registries. The practical implication of this for evidence-based medicine is that registry readers must carefully consider the similarities and differences of implants and understand that variability in reported revision risk across registries may be due to differences in device categorization in the respective device libraries.

Similar to the decisions that must be made on how to group devices, each registry must also make the decision on how to define revision. The variation in revision definition across registries can present challenges in interpreting CPR from multiple registries. For example, secondary patella resurfacing was included as a revision in the NJR, the AOANJRR, and the MARCQI, but was excluded in the RIPO and Danish registries. These differences, therefore, can lead to under or over-reporting of revision statistics, depending on how a registry defines revision. It is advisable for the reader to identify how a particular registry defines revision when interpreting the implant-specific survival statistics that are reported.

A final critical element in registry data interpretation is the recognition of the revision itself as the defining point of implant failure. Practice patterns, geographic technique differences, access to care and cultural differences can be potentially confounding variables that can affect clinical thresholds for revision and the ability to perform the revision. Thus, a poorly performing implant in terms of patient function, satisfaction, pain or instability, for instance, may not necessarily show a higher revision rate. This may at least partially account for any large differences in revision rates of a single implant between different registries. As this report is the only one of its kind to highlight these differences (as indicated in the supplemental tables by use of italics below a lower revision rate for the same implant), the interested reader is again urged to evaluate the original reports if considering a given implant system.

Conclusions

Implant selection is one of many factors controlled by the surgeon that can affect outcome. National and regional arthroplasty registry data can be very useful for evidence-based decision-making. Registries typically publish an annual report containing rich data on patients being treated and on revision risks. Some registry reports include tables of implant-specific revision risks, which can then be incorporated into clinical decision-making. However, it is laborious and time consuming to find and extract such data. This report was produced to summarize implant-specific revision risks across registries and to facilitate decision-making for the practicing orthopaedic surgeon. The information reported here should be interpreted with the aforementioned strengths and weaknesses of registry data in mind. It is recommend that surgeons use registry data, such as that which is reported in this review, in combination with the

peer-reviewed literature to guide their implant selection, and be open to revising their selections as more data continue to be collected and published.

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SUPPLEMENTAL MATERIAL

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ICMJE CONFLICT OF INTEREST STATEMENT

CF reports financial support for quality improvement collaborative, MARCQI from Blue Cross Blue Shield of Michigan/Blue Care Network, relevant to the submitted work.
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