Revision rates after total joint replacement

CUMULATIVE RESULTS FROM WORLDWIDE JOINT REGISTER DATASETS

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In a systematic review, reports from national registers and clinical studies were identified and analysed with respect to revision rates after joint replacement, which were calculated as revisions per 100 observed component years.

After primary hip replacement, a mean of 1.29 revisions per 100 observed component years was seen. The results after primary total knee replacement are 1.26 revisions per 100 observed component years, and 1.53 after medial unicompartmental replacement. After total ankle replacement a mean of 3.29 revisions per 100 observed component years was seen.

The outcomes of total hip and knee replacement are almost identical. Revision rates of about 6% after five years and 12% after ten years are to be expected.

Revision rate is one of the most important outcome measures of joint replacement surgery. However, the results published in clinical studies show considerable variation owing to a number of factors, such as the implants and surgical technique used, the expertise of the surgeons involved, the impact exerted by the public health system, and the design of the study. Consequently, it is often impossible to determine which factor is causing an effect in an individual study or meta-analysis. However, the scientific community rightly expects to be able to draw conclusions from an individual study and to be able to extrapolate these to the whole population.

In joint replacement, as in many areas of surgery, it can be very difficult to carry out well-designed studies. Placebo-controlled studies are often impossible for ethical reasons, and the blinding of patients or investigators is not feasible in practice. It is, therefore, virtually impossible to design and implement a study of the outcome of implants that bears comparison with pharmaceutical studies. Havelin has shown that, to comply with the usual standards of a 95% confidence interval and a statistical power of 80%, a prospective study would require 13 474 patients in order to determine a 1% difference in outcome between two implants, and 3008 patients to detect a difference of 2%.

Studies of such size quickly overwhelm the organisational capacity of the investigator. This inevitably means that most clinical studies are underpowered. As a result, studies on the outcome of joint replacement are often of inferior quality and potentially more susceptible to bias. Revision surgery, which is an accepted and clearly defined endpoint, occurs either early or late. Consequently, cross-sectional analyses at fixed points in time, such as five or ten years after the primary intervention, may come too early or too late and underestimate the rate of loosening.

Joint registers are organised in a different way from sample-based studies. Ideally, they comprise all cases from a particular country and thus provide a good overview of the true revision rate and causes of revision, without having to rely on extrapolation from a sample. Accordingly, a basic requirement is the highest possible completeness of recording for all cases. This has been achieved in a number of countries where the national register follows the Scandinavian model. A range of publications are available from Scandinavia which demonstrates the feasibility and positive effects of comprehensive data collection.

However, national registers reflect the circumstances under which the data have been collected. The resulting differences, as well as the way in which the data have been analysed and presented, may give rise to misinterpretation without a detailed knowledge of these circumstances. It is therefore advisable to tread carefully and consider the possible underlying differences when applying another country’s data to one’s own population. There are now a number of well-established joint registers in Europe and the Pacific with
high-quality data and sufficient follow-up that can be used for supranational calculations.

The aim of this study was to calculate the mean revision rates to be expected for primary joint replacements, independently of the product used.

Materials and Methods
A systematic review was performed of all published annual reports of national joint registers, as well as of the literature. The search was carried out using the summary webpage listing of the EFORT portal, Google, and the links sections of the websites of the National Joint Registers. Publications were identified by searching Medline for keywords and using the references listed that could be accessed on the webpages of national registers.

We used the following methodology:
1. Datasets from the national joint registers. 2. A minimum of 90% of a country’s total number of cases had to be recorded in the register, or a publication had to be available validating the quality of the data. 3. In order to avoid double-counting of national data, evaluations were always based on the most recent and largest dataset. 4. As a minimum requirement, information had to be available on the number of primary operations, the number of revision operations, and the follow-up periods.

The annual reports of the National Arthroplasty Registers of Sweden, Norway, Finland, Denmark, Australia and New Zealand fulfilled these criteria and were used for the calculation of revision rates after total hip and knee replacement. For the knee, the Australian18 and Swedish17 registers provided a detailed breakdown of total and unicompartmental replacements. These data were used to calculate the results of medial unicompartmental knee replacement. For the ankle, annual reports were available from the National Registers of Norway14 and New Zealand. In addition, there was one journal publication from Sweden.20 Data on shoulder and elbow replacement were available from the reports of the Norwegian14 and New Zealand Registers.19 Replacement of the small joints of the hands and feet was recorded in only the Norwegian register, and has not therefore been considered in this paper, which is concerned with supranational results.

Reports from the national registers are not standardised and differ in structure and statistical analysis. Follow-up, for example, is not standardised. Consequently, a uniform method of calculation had to be found to ensure that data from the various countries were comparable. This was achieved using the indicator ‘revisions per 100 observed component years’, a method of calculation originally introduced by the Australian Arthroplasty Register.18,21 The methodology is basically a standard epidemiological procedure which was used in the classic study of British doctors which showed that smoking causes lung cancer and other illnesses.22 In order to compare different exposures to a certain risk factor (i.e. smoking) and the occurrence of side-effects (i.e. lung cancer), individual exposures to risk are counted and compared to the number of observed events. In this way, datasets with different numbers of cases and follow-up periods can be compared directly with each other. The calculation is based on the fact that, basically, the risk of re-operation exists from the time a prosthesis is implanted until the patient’s death or revision surgery. The individual follow-up periods of all patients included are combined, and this cumulative figure of ‘observed component years at risk’ is then compared with the number of revision operations actually observed. By means of a linear function, the values received can be transferred into the usual way of representation of revision rates per follow-up period. A value of 1 corresponds to a revision rate of 1% at one year and a 10% revision rate at ten years.

All evaluations were performed irrespective of the products used, but none the less reflect the performance of the implants used in the countries involved, the surgical procedures, and the impact exerted by the respective public health system. The results are presented descriptively. We refrained from calculating statistical significance, as our aim was to define benchmarks, not to study significant differences in outcome between individual implant groups or countries.

Results
Based on the datasets from six countries, the mean rate of revision for any reason after total hip replacement (THR) is 1.29 (1.28 to 1.30) revisions per 100 observed component years. This corresponds to a revision rate of 6.45% after five years, and 12.9% after ten years. These values are based on a cumulative number of 689 608 primary operations and 79 231 revision operations, with a mean follow-up of 8.91 years (8.89 to 8.93) (Table I).

Among the countries studied, Sweden showed the best results, with revision rates that were 1.8 times below the mean worldwide figure. Finland exceeds this value by a factor of 3.15. There is a 5.63-fold difference between the extreme values of national outcome.

The mean revision rates after total knee replacement (TKR) were 1.26 which were comparable to those of THR (1.29) (Table II). Here too, Sweden had the best national outcome (1.8 times below the mean) whereas Denmark showed nearly double the revision rate compared with the mean worldwide figure. Irrespective of the product used, the revision rate for medial unicompartmental knee implants (1.53) shown in the national datasets was clearly higher than for TKR (1.53 vs 1.26). Compared with the outcome of TKR in Sweden and Australia, the mean revision rate for unicompartmental replacements is 1.96 times higher. The difference was 1.62 times in Sweden and 2.29 times in Australia (Table III).

The mean revision rate after shoulder replacement is comparable to those of hip and knee replacement, with 1.39 revisions per 100 observed component years. Norway has slightly better results than New Zealand. However, in Norway, shoulder hemi-arthroplasty, which gives a better mean outcome in both countries, is used more frequently (Table IV).
For ankle replacement, a mean of 3.29 revisions per 100 observed component years is to be expected. When the different countries are compared it is noticeable that New Zealand reports better outcomes than Sweden or Norway. However, the data from New Zealand refer to shorter follow-up periods than those from Scandinavia, and the Scandinavia data reflect an increase in revision rates starting five years after primary surgery. Cumulatively speaking, one must expect that after ten years, approximately one-third of all patients will already have had to undergo revision surgery (Table V).

The highest revision rates for all implants were seen after elbow replacement. The mean value is 5.08 revisions per 100 observed component years. After a mean 6.3 years the two national registers have recorded 808 primary cases and 258 revision operations (Table VI). Here too, the mean revision rates are higher in Norway, the country providing the dataset with the longer follow-up period, than they are in New Zealand.

**Discussion**

The range of outcomes reported from clinical follow-up studies is usually wide, and it is often difficult to interpret individual results correctly. The outcome of joint replacement is affected by a variety of factors. Apart from the implant used, these include the surgeon’s expertise, the hospital environment, and the health-care system generating or preventing factors that influence the outcome. Direct comparison of meta-analyses of clinical studies and register results for the same implants suggest that, at least in certain subfields and with respect to individual implants, there are considerable differences between the revision rates published in clinical follow-up studies and register data.
The fact that there are these differences should prompt critical analysis of the data to detect factors that may potentially affect the outcome. Apart from the study design, these may also be related to surgical technique or the circumstances under which the studies were conducted. For example, it is conspicuous that among the countries studied, Sweden achieved the best results in many areas. It would appear that the long-standing national joint registers, regular feedback and the surgeon’s central involvement have played an essential role. It has been shown\(^{25}\) that there has been an approximation in the performance of individual hospitals, which is presumably also an achievement of the register. This cannot be assumed to occur in every country. Nevertheless, there are considerable differences among individual departments within a country.\(^{12,18-20}\) The department achieving the best outcome shows only one-third of the national average revision rate after ten years, whereas the department with the worst outcome has revision rates that are about 2.5 times higher than average. This simple statement describes but does not explain the observation. In order to determine the reasons behind the differences would require comprehensive detailed evaluations, which are actually included within the scope of registers but are presented directly to the head of department and remain unpublished.

On the other hand, the mere existence of a register is no guarantee of success. Like Sweden, Finland started to develop a national register very early, but organised it differently. The data were compiled by a public health authority and the Orthopaedic Specialty Society was largely excluded from the process. Even though reports were published, active feedback and the discussion of results with surgeons were more or less dispensable. It seems that this has contributed to the significantly worse national results in Finland. To what extent should this provide an impetus for critical discussion? In Finland itself, the decision has already been made to organise the national register differently in the future, with greater involvement of surgeons.

In arthroplasty of the ankle the impact of experience and the learning curve is clearly seen.\(^{20}\) The revision rate drops after the first 30 procedures. The number of cases treated by an individual surgeon are often very low, and this probably contributes to the differences seen in the outcome of individual groups of prostheses.

Hip and knee replacements are of a high standard. A maximum revision rate of 10% after ten years, which is frequently mentioned as a benchmark and also demanded in guidelines by public institutions such as NICE, is ambitious, though, and above average compared to the actual outcomes documented in worldwide registers. Although Scandinavian registers show that this is achievable as a national average, they are only representative of the worldwide situation to a limited extent.

Revision rate is an important, but not the only, outcome measure. In this study shoulder prostheses, for example, give results that compare well with those obtained for hip or knee replacement. However, the fact that no implant was revised does not necessarily mean that a satisfactory clinical outcome was obtained. The frequency of an unsatisfactory outcome without revision differs between joints. Unicompartamental knee prostheses, irrespective of the implant used, gave a higher revision rate than TKR in all datasets compared. Therefore, a critical reconsideration of its indications may help improve the results. Revision, however, may not be an appropriate way of comparing these two types of implants.\(^{26}\) Time will tell whether more subjective ways of assessing outcome will prove more useful.

**Supplementary material**

A table showing performance deviations of an implant from the worldwide average is available with the electronic version of this article on our website at www.jbjs.org.uk

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No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.
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