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Review

Revision rates after knee replacement. Cumulative results from worldwide clinical studies *versus* joint registers

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SUMMARY

Objective: To assess revision rates after knee arthroplasty by comparing the cumulative results from worldwide clinical studies and arthroplasty registers. We hypothesised that the revision rate of all clinical studies of a given implant and register data would not differ significantly.
Methods: A systematic review of clinical studies in indexed peer-reviewed journals was performed followed by internal and external validation. Parameters for measurement of revision were applied (Revision for any reason, Revisions per 100 observed component years). Register data served as control group.
Results: Thirty-six knee arthroplasty systems were identified to meet the inclusion criteria: 21 total knee arthroplasty (TKA) systems, 14 unicondylar knee arthroplasty (UKA) systems, one patello-femoral implant system. For 13 systems (36%), no published study was available that contained revision data. For 17 implants (47%), publications were available dealing with radiographic, surgical or technical details, but power was too weak to compare revision rates at a significant level. Six implant systems (17%) had a significant number of revisions published and were finally analysed. In general, developers report better results than independent users. Studies from developers represent an overproportional share of all observed component years. Register data report overall 10-year revision rates of TKA of 6.2% (range: 4.9–7.8%), rates for UKA are 16.5% (range: 9.7–19.6%).
Conclusion: Revision rates of all clinical studies of a given implant do not differ significantly from register data. However, significant differences were found between the revision rates published by developers and register data. Therefore the different data need to be interpreted in the context of the source of the information.

Introduction

The use of artificial joint implants will exponentially grow in the next two decades. The implantation rate of knee prostheses will rise up to 601% until 2030[1]. As life expectancy is growing and the mean age of patients undergoing primary arthroplasty continues to decrease, revision rate and longevity of implants are becoming increasingly important. Medical devices are complex assemblies of multiple components, and the failure of any single component can lead to unexpected and serious safety problems[2]. During the last months quality concerns about arthroplasty have been published[3,4] that were not identified during the pre-marketing tests as stipulated by the regulating authorities. The current study is based on two projects: (1) EUropean Public Health Outcome Research and Indicators Collection (EUPHORIC), performed from 2003 to 2008 funded through the first EU Health Programme by the Directorate-General for Health and Consumers of the European Commission, during which outcome indicators in orthopaedics were defined[5]. (2) Quality of Literature in Arthroplasty (QoLA), performed by EFORT-EAR from 2006 to 2011, during which literature analysis was performed[6].

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We assumed that the world literature about knee arthroplasty would form a "representative sample" providing sufficient data to assess the quality of prostheses using outcome indicators for arthroplasty according to the requirements for outcome measurement and quality monitoring of medical devices. Thus the null hypothesis of the current study stated that the revision rate of world literature of all clinical studies of a given implant and register data would not differ significantly.

Materials and methods

Definition of parameters

The main outcome indicator evaluated was "Revision for any reason". To measure quality, a common set of outcome indicators was tested among the participating European countries in the EUPHORIC project, a multidisciplinary project oriented to public health authorities and policy makers which was funded by the European Commission (DG Health and Consumers; see http://www.euphoric-project.eu). One of our authors (GL) was involved as orthopaedic pilot leader. The outcome indicators "Revision Rate" and "Revision Burden" defined in EUPHORIC were found to be fundamental in evaluating outcomes of prostheses from a health technology assessment point of view. With regard to public health, these are the two most important indicators for comparative evaluation in arthroplasty.

Studies with information restricted to individual reasons for revision (infection, periprosthetic fractures, leg length discrepancy, etc.), re-revisions and case studies were excluded from our analysis.

The parameter "Revisions per 100 observed component years" was used to compare revision rates of individual studies with different follow-up periods and different numbers of implants. This methodology is a modification of a standard procedure in cohort studies used to describe the risk of cancer in tobacco smoking in 1956[7,8]. It describes a defined risk (revision) of a certain procedure (arthroplasty) over time, comparable to the parameter "pack years", and allows adjustment for time, thus making studies comparable[9–13]. A value of one revision per 100 observed component years corresponds to a revision rate of 1% at 1 year and a 10% revision rate at 10 years in a linear function[10,13]. Use of this parameter assumes the revision rate to decrease over time with a linear function. In view of the broad scope allowed for the limit values and the large effects resulting from non-implant-associated impacts on the revision rate, the mathematical uncertainties appear very low and should not affect the overall result[6].

A structured literature review concerning every arthroplasty system with sufficient data available in high-level worldwide arthroplasty register datasets was conducted as follows[6,14].

Availability of data, PRISMA statement (Fig. 1)

From 2006 to 2010 a systematic review of the world literature of arthroplasty was performed in the QoLA project, including more than 50 orthopaedic surgeons in more than 40 research centres in 20 countries. The data were subjected to internal and external validation[6,13,15].

In the first step implants were identified by name and producer. The following MeSH descriptor data were used: "Prostheses and implants" (1966–1970), "joint prostheses" (1971–1997) and "Arthroplasty" (E04.555.110), Arthroplasty, Replacement [E04.555.110.110], Arthroplasty, Replacement [E04.650.110].

In a second step, the orthopaedic literature of indexed peer-reviewed journals was screened using MEDLINE. Articles were then reviewed in full text according to a standard protocol.

In a third step, eligibility criteria were applied: unambiguous identification of the implant; data of revision unambiguously given in text, in numbers or in charts.

In a fourth step, prostheses were included if studies contained "revision for all reasons". Studies that focused exclusively on other kinds of revisions alone (mechanical failure, infection, aseptic loosening, etc.), studies without information about revision rate, studies about re-revisions, as well as case studies were excluded. Even though according to the study protocol exclusively clear and objective data like the numbers of patients were evaluated, unclear information or wording was observed in some studies. In these cases a consensus process including the project leader was conducted. Randomly selected datasets were double-checked by an independent reviewer. None of the cross-checks yielded indications for mismatch, several outstanding results concerning individual implants passed an independent review process and were published in various orthopaedic journals[10,15–17].

In a fifth step, selection was made: only studies dealing with total knee arthroplasty (TKA) or unicondylar knee arthroplasty (UKA) were selected. An analysis was performed to assess those implants with sufficient revision data published to compare implants with each other. Implants with no revisions published were excluded. Implants with less than 100 revisions published in all publications together were found to have too few information to be included. Only implants with more than 100 revisions published were included in the current study.

Inclusion period

Literature research was carried out from 2006 until 2010. The oldest available studies were from 1972.

Origin of publication (developer/independent user/continent)

Each study was evaluated separately. The names of the authors and the origin of their affiliation at the time of publication were assessed. If the author contributed to the development of a certain implant, a study in which he was author or co-author was defined as a developer's study. Developers were identified by references in publications, information material by the manufacturers and websites. If a study was published by several authors from different countries, the country of the first author's affiliation was used to classify the country.

Arthroplasty registers

Register data, pooled using the same methodology as described for clinical studies, served as a control group representing the average outcome in average patient care to compare results from publications based on samples. Arthroplasty registers comprise more data (revisions, implants, observed component years) than all published studies together. High-level arthroplasty registers include more than 95% of all procedures in the given area. Primarily, data from all arthroplasty registers with internet access were used as control group, specifically those from the National Joint Registers accessible *via* the summary webpage listing of the EFORT portal[18]. Since key factors for a successful arthroplasty register exist since 2007, we focused only on high-value register reports Type A.1.1.1.1[6,14,18,19]. The data in these registers have gone through internal and external validation.

Statistical significance: Especially when analysing literature from implant developers and centres of excellence it is advisable to choose a generous limiting value to significance. As described in QoLA, surgery outcomes depend on individual expertise, circumstances in the particular hospital and other potential confounders[6].

Therefore, to be rated as a significant value in the analysis, in terms of limited reproducibility in average patient treatment, the following criteria were applied:

(1) Deviations from the mean by the ratio of 3 (i.e., 33–300% as the measure of relevance);
(2) Statistically significant deviation due to non-overlapping of confidence intervals in the main indicator "Revisions per 100 observed component years" as a measure of the quality of datasets;
(3) Or all studies included show a 100% survival rate, which means that not a single revision is documented. In this case it is mathematically impossible to compute confidence intervals, the deviation factor would be infinitely large.

A difference ratio up to 3 (for instance, the revision rates of a dataset are three times as high as in the control group) between the datasets was considered to be explicable by individual expertise, circumstances in the particular hospital and other potential confounders. The value of 3 was chosen because this value covers the variability among individual hospitals in countries where national registers publish these data, such as the Swedish (Hip and Knee) Registers or the Danish National Arthroplasty Register, as well as the deviation from the mean of revision rates of individual implants in various national registers. Calculating the deviation in outcomes achieved with the same implant in different countries covered by a National Arthroplasty Register from the worldwide average of the individual implant (as an estimate of non-implant-related impact factors) shows that the maximum outliers are also lower than a ratio of 3.

Note: We would like to explicitly point out that this is a methodological study. All values and factors refer to differences between datasets, i.e., to the inherent quality of these data. They do not refer to absolute revision figures or the outcome of specific products assessed.

Results

Availability of data, PRISMA statement (Fig. 1)

Thirty-six different knee implants were identified having sufficient data in worldwide register datasets. For 13 prostheses not a single study about "revision for all reasons" could be found in clinical sample based studies. In the case of 17 prostheses less than 100 revisions were found to be published in the relevant world literature and, in accordance with the inclusion criteria, were judged as "implants with too few revisions published" to perform calculations with significant power. Six implants (four total and two unicondylar knee replacement systems) with "sufficient revisions published" remained in 168 clinical studies, concerning 83,495 primary cases and 3448 revision cases. These studies were assessed in detail (Figs. 1–3, Tables I and II).

Origin of publication (Figs. 2–4, Table I)

Studies from developers represent an overproportional share of all observed component years. Even though only 18% of all studies worldwide were published by developers, these studies represent 46% of observed component years and 38% of all cases published. In the USA 61% of all cases and observed component years were published by developers. By contrast, in the EU and Asia over 90% of all cases and all studies and over 80% of all observed component years are published by independent users. The majority of studies (91 of 168) were published in the EU, but most cases (47,034 of 83,495) in the USA.

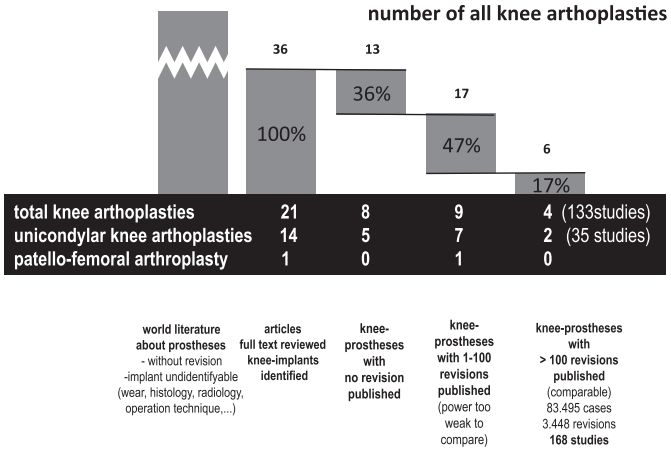

Fig. 1. PRISMA statement.
Number of studies and knee arthroplasties, derived from world literature.

Revision rate (Tables I and II)

All prostheses except two report better revision rates in clinical studies than in registers, but the differences did not reach the criteria of our definition of relevance in all cases. The mean revision rate of TKA in registers is 50% higher than in studies, while the mean revision rate of UKA in registers is more than double. In five of six implants, studies by developers report better results than studies from independent centres. However, the difference is not significant. The revision rate per 100 observed component years for primary knee arthroplasty systems ranges from 0.34 to 1.09 in clinical studies and is comparable to register data, which show revision rates from 0.49 to 1.96[13,17,20].

Sample size: Number of primary implants, length of follow-up and observed component years did not correlate directly nor indirectly with revision rate. Regarding LINK uni, the two largest studies[21,22] have an unexplicable low revision rate of 0.14 at 9 years and 0.09 at 20 years postoperatively *versus* 0.97 in registers. Similar findings were also published for Oxford UKA[17].

Discussion

Clinical studies display results of individual centres with individual prostheses. Even with the large number of cases included in the current analysis – 83,495 from clinical studies and 161,015 from register datasets—revision data from comprehensive clinical

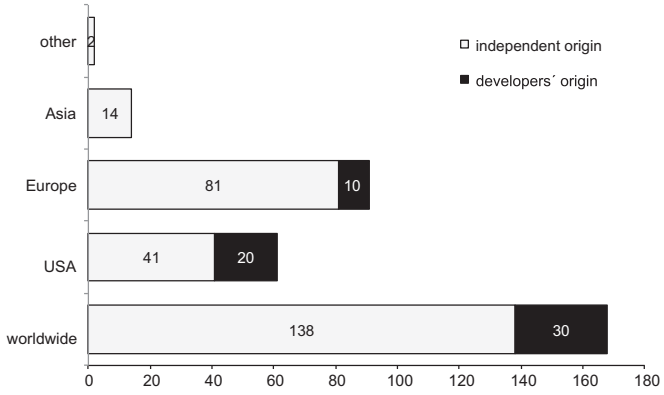

Fig. 2. Observed component years.
Developer contributes to a large proportion of observed component years in USA.

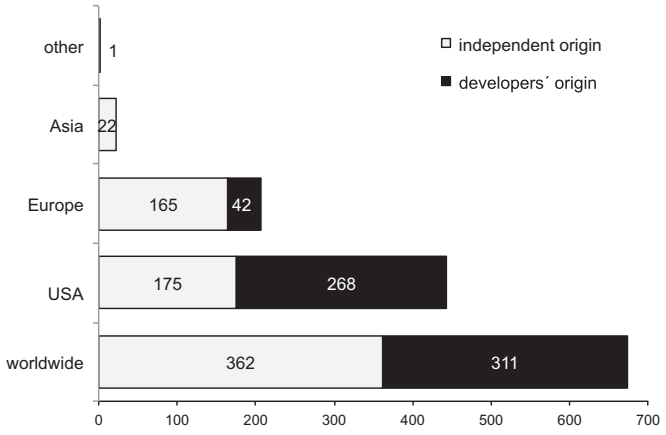

Fig. 3. Primary implants in thousands.
Independent data are found predominantly in Asia and the EU.

studies of a certain implant are in part inconsistent: In two-thirds of all individual clinical studies, data of different origin are controversial and in part not reproducible in register data. In one implant up to 11-fold differences are found between the outcome in arthroplasty registers and the outcome from developers' studies.

Therefore it has to be questioned, how big sample size of an individual clinical study would have to be to obtain relevant data: Using a 95% confidence interval and a statistical power of 80% 13,474 patients would be requested in order to detect a 1% difference in outcome[23]. Not a single publication meets this requirement—this number is only achieved for three implants if all clinical studies are summarised. In contrast, nowadays registers obtain more than twice as many primary cases than clinical studies. Upon rollout of further national registers, data will become even more.

The parameter "revision per 100 observed component years" is one possibility of comparing different studies. The linear function of Revision for any reason is a mathematical simplification of reality, since the risk for septic revision is higher directly postoperatively and aseptic loosening is known to occur later on. But also other methods like Kaplan Meier method (with results often presented in terms of cumulative revision risk), cumulative incidence estimator, the Cox model, hospital-specific rankings of

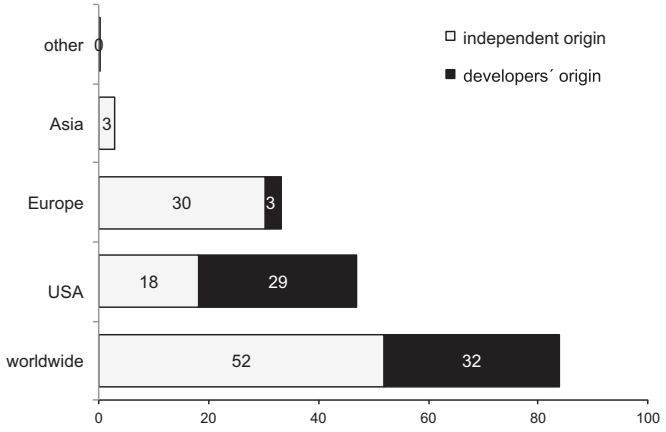

Fig. 4. Number of studies.
Most studies worldwide are of independent origin.

Table I
Origin of publications. Differences between amount of studies, cases and observed component years and revision rate

	Europe	USA	Asia	Other	Worldwide
Studies	54%	36%	8%	1%	168 (100%)
Cases (in 1000)	40%	57%	4%	0.1%	84 (100%)
Revisions (in 1000)	48%	49%	3%	0.3%	3.5 (100%)
Observed component years (in 1000)	31%	66%	3%	0.1%	673 (100%)
Revisions per 100 observed component years	0.79	0.38	0.5	0.61	0.51

revision risks and others have statistical errors as Ranstam describes in a statistical analysis of arthroplasty register data[24].

Certainly, there are differences regarding patient selection, postoperative care, diligence and experience between different departments. But as evidence from registers shows, within one country the best performing department shows revision rates of one-third and the department with the worst outcome shows revision rates that are 2.5 times higher compared to national average revision rate[13]. Therefore deviations from the mean exceeding a factor of 3 were defined to be significant. According to this definition developers' studies tend to report significantly better outcome than independent studies in three cases. Even studies with more patients and longer follow-up do not lead to better predictability for users of the products or administrative bodies: There are large studies[17,21,22] with unexplicably low revision rates compared to registers. If published series by expert centres (e.g., developers) set benchmarks and might have an effect on the submission and acceptance of scientific papers, can be speculated, however, it will be impossible to check for confounders due to lack of access to such information.

Two implant systems were evaluated with very consistent data whose results of both developers and independent users are comparable to register data: LCS and PFC total knee prostheses. It is an interesting observation that the number of component years published by the developer is more than 10 times lower in these products (4–6%) as compared to the other prostheses (43–74%) evaluated in this study.

One limitation of this study might be a possible selection bias, since clinical studies consist of small numbers of primary implants, whereas registers consist of larger data. Another limitation is that it exclusively focuses on revision rate. Revision rate obviously does not necessarily reflect subjective patients satisfaction. Beverland reported that there are 11 times more "very happy" patients following hip arthroplasty (54%) than following knee arthroplasty (4%) although revision data were comparable for both implants[25]. Even patients after knee arthrodesis report between 60% and 100% good and excellent results – depending on previous history of suffering and definition of success[26–29]. Patient satisfaction and sustainable results should be the goal of knee arthroplasty. Revision rate is one major indicator to measure the achievement of that goal since there is a correlation between short-term clinical outcome and mid-term revision rate[30].

Most clinical trials are undertaken in selected centres by a small number of surgeons, usually on a specific patient population. In contrast, register data include many centres, all patients and a large number of surgeons. This can explain the superior results of clinical trials compared to register data. The value of arthroplasty register data and the difficulty of interpreting results were addressed by Graves, who found both to be complementary[31].

In conclusion we found, the different data need to be interpreted in the context of the source of the information. For that reason, registers and clinical studies are complementary scientific tools and they serve different purposes. It is thus not recommended to use

Table II
Revision rates and follow-up periods. Revisions per 100 observed component years shows differences between worldwide clinical studies, clinical studies published by developers and worldwide register

	AGC (TKA)	Kinemax (TKA)	PFC (TKA)	LCS (TKA)	Oxford uni (UKA)	LINK uni (UKA)	Total	All TKA	All UKA
Market introduction	1983	1988	1984	1977	1976	1972			
Company	Biomet	Stryker	De Puy	De Puy	Biomet	Link			
Follow-up (years after market introduction)	28	23	27	34	35	40			
Worldwide clinical studies									
Primary implants	43,465	2159	15,467	13,911	5217	3276	83,495	75,002	8493
Revisions	1141	140	644	903	449	171	3448	2828	620
OCY observed component years	337,131	17,174	91,637	139,289	41,166	46,824	673,220	585,231	87,989
Number of studies	30	10	55	38	25	10	168	133	35
Clinical studies published by developers									
Primary implants	26,261	523	1161	805	1758	1294	31,802	28,750	3052
OCY published by developer (%)	74%	43%	4%	6%	40%	55%	46%	46%	48%
Studies	9	1	7	3	9	1	30	20	10
Worldwide register data									
Primary implants	35,284	3844	74,121	31,984	11,985	3797	161,015	145,233	15,782
Revisions	1245	192	1580	854	825	184	4880	3871	1009
OCY observed component years	169,027	27,968	322,403	110,024	42,037	18,985	690,443	629,421	61,022
Revisions per 100 observed component years									
All studies	0.34	0.82	0.70	0.65	1.09	0.37	0.51	0.48	0.70
Independent studies	0.79	1.24	0.71	0.65	1.53	0.71	0.78	0.72	1.15
Developers' studies	0.18	0.25	0.49	0.66	0.43	0.09	0.20	0.20	0.22
Register data	0.74	0.69	0.49	0.78	1.96	0.97	0.71	0.62	1.65
RATIO register/developer	**4**	3	1	1	**5**	**11**	3	3	**7**

clinical studies or register data alone for outcome measurement and quality monitoring of medical devices.

Author contributions

CP developed the conception and design of the study, acquisition of data, carried out interpretation of data and drafted the manuscript. GL and NB contributed to acquisition of data, analysed register data, and revised the manuscript. AB ran statistical analysis and revised the manuscript. All authors participated in the design, interpretation of results, and approved the final manuscript.

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Conflict of interest

None to declare.

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