Quality of Datasets for Outcome Measurement

Quality of Publications regarding the Outcome of Revision Rate after Arthroplasty

Interim Report of the QoLA Project

Presented at the EFORT Congress 2010 in Madrid

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EAR
European Arthroplasty Register
EFORT – JOINT EFFORTS

QoLA*
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***QoLA = Quality of Literature in Arthroplasty**

(Current project conducted by EFORT-EAR)

Quality of Datasets for Outcome Measurement

Contents

Quality of Datasets for Outcome Measurement

Introduction

- This Interim Report comprises the results currently available of the QoLA project (Quality of Literature in Arthroplasty), which has been initiated by EFORT and EAR based on the results of the EUPHORIC project by the EU Commission's Directorate-General for Public Health and Consumer Protection (DG SANCO).

- The methodology applied is largely based on the results of this previous project, which has meanwhile been completed and accepted by the EU Commission. Further information is available via the project website (www.euphoric-project.eu), as well as in a summary report presented during the 2009 EFORT Congress in Vienna. An electronic version of this report has been made accessible via the EAR webpage through the EFORT portal (www.ear.efort.org), section *EAR Publications.*

Rationale

It is a well-known fact that certain circumstances during the conduct of a clinical trial, e.g. patient selection, the surgeons' expertise and experience, or the study design, may have an impact on the results, and the question to what extent the results obtained are reproducible in the total patient population produces on-going critical discussions. This does not only apply to pharmaceutical studies but, of course, also to medical devices such as artificial joint implants.
In principle, two major datasets are available for the assessment of implants or surgical techniques:

1. Sample-based clinical studies that have been published in scientific journals.
2. National and regional arthroplasty registers

Each of these datasets is characterised by specific priorities and requirements that should be taken into account in project planning and when interpreting the results.

Sample-based clinical studies:

- Try to extrapolate the results of a sample to the total patient population;
- Are usually applied to answer a particular question;
- Study design, measuring instruments or patient selection are therefore often very non-homogeneous, which is an essential advantage with regard to the precision in tuning the instruments but, in a meta-analysis, may lead to limitations.
- The characteristics of the collected data substantially affect the validity and possibilities of evaluations. Ordinal and nominal data, such as Yes/No decisions, or the formation of groups (for example: Excellent; Good; Fair; Poor) require relatively large numbers of cases in order to produce statistically significant differences and ensure sufficient statistical power. For example, the question of whether revision surgery has been performed falls into this category.
  In his PhD thesis Leif Ivar Havelin (Lit. 4) 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.
  Also it would still require 3,008 patients to detect the relatively big difference of two percentage points. The execution of studies of that size quickly reaches organisational limits so that one must conclude by implication that the large majority of published studies might be statistically underpowered.
  Metric data, on the other hand, as used in most clinical scores, allow for reasonable evaluations already with a considerably lower number of patients.

Registers:

- Are designed to comprise all surgeries performed in a defined region, e.g. a state, thus providing a very realistic picture of the actual circumstances.
- To achieve completeness, the burden of documentation must not be too great. The questionnaires must therefore be confined to a relatively small core dataset.
- Apart from organisational difficulties, any modification to the dataset entails a depreciation for the evaluation of data already collected. Registers are therefore relatively inflexible.

Rationale

- Data transferred to the register centre by the individual departments can thus be verified to a very limited extent, which should be taken into account when deciding on the contents to be recorded. Only objective and clearly-defined contents should be considered for the core dataset. Many clinical scores, however, contain a variety of data, such as pain or quality of life, that are strongly affected by subjective influences. These contents are less suited for regular data collection, but can be used successfully in projects including register datasets.

- Thus, the two instruments and data sources do not compete with each other, but can sensibly complement one another. Registers offer advantages in recording and evaluation as regards revision rates and causes of revision. They are able to provide a realistic picture of the results in the area covered and considerably alleviate or eliminate effects arising in clinical studies, for example, due to patient selection or personal expertise. Completeness of collection is therefore an essential parameter for the quality of a register dataset.
  Clinical studies, on the other hand, have undeniable advantages in dealing with specific issues and subjectively-influenced answers.

- Registers have been developed with great success in Scandinavia for more than 30 years, and impressive proof has been established of their usefulness for outcome measurement, quality control and quality improvement in many cases (1-15). During the past 10 years similar projects have been set up in quick succession in other countries so that an increasing number of datasets have become available for supranational analyses by now. These datasets can be used as reference values for comparative analyses regarding the reproducibility of published results. The quality, size, geographical distribution and length of follow-up periods of these datasets are only available in very few areas of medicine and for a very small number of indications. Thus, arthroplasty represents a positive exception in the medical field, and we have taken advantage of these positive circumstances for conducting a fundamental and critical analysis of those basic data that decisions have been based on worldwide.

- Revision Rate is a recognised, well-defined and objective parameter after arthroplasty interventions that covers a variety of possible complications. The necessity for revision surgery has serious consequences for the patient's quality of life and causes high health-care expenditure. Decision-making largely follows standard procedures in diagnostic assessment and indication. This indicator is therefore well-suited for comparative analyses, and the conclusions are relevant for all major parties involved in the health-care system.

Materials and Methods

Methodology

When developing the methodology in the course of the EUPHORIC project the main question was how to summarise data based on different numbers of cases and follow-up periods in a single figure and make them directly comparable. We finally decided on the indicator 'Revisions per 100 observed component years', which was introduced in Orthopaedics by introduced the Australian Joint Replacement Registry.

The formula for the calculation is:

$$\frac{\text{Number of cases of revision surgery for any reason}}{\text{Number of observed component years x 100}}$$

The concept of 'Revisions per 100 observed component years' is a recognised standard in epidemiology (16) and was, for example, used as early as the middle of the 20th century in providing evidence of the association between tobacco consumption and the incidence of lung cancer (17).

In principle, this method deals with calculating a correlation between the incidence of a potential risk exposure (e.g. cigarette smoking) and a consequential event (e.g. development of lung cancer). It also allows for considering essential influencing factors (e.g. smoking period or number of cigarettes) in the calculation.

Applied to arthroplasty, this means:

- There is a risk for revision from the moment of implantation. The total number of individual years from implantation (= observed component years) are counted.
- The total number of revisions (for any reason) as the failure end-point are documented and calculated in 'Revisions per 100 observed component years'.
- Back calculation of the calculated value into the usual way of presentation of Revisions/Time is possible by means of a linear function.
- A value of 1 represents a 1% revision rate at 1 year and a 10% revision rate at 10 years of follow-up.
- The advantage of this method is that it allows for comparison of datasets adjusted for the two main factors influencing the value of individual cohorts: number of cases and follow-up period.

This concept and the indicator can easily also be used for clinical studies.

Generous limits were defined for the definition of conspicuous datasets. In view of the multitude of potential influence factors, the possible uncertainty resulting from the calculation method, which will be discussed in more detail in the chapter Interpretation, has only a marginal effect.

Materials and Methods

Materials

A list was compiled of all implants for which data were available from arthroplasty registers, and that were suited for comparative analyses. The respective work packages were distributed among those partners who had evinced interest in collaboration after a call. The individual partners performed a literature analysis of clinical literature, the comparative values from registers were compiled by the EAR Scientific Office at the University Hospital of Orthopaedics in Innsbruck, Austria, which was also responsible for consolidation and comparable analysis of the data.

For the meta-analysis of peer-reviewed publications a structured literature review was performed based on electronic libraries such as Medline, followed by a manual literature research. Conventional meta-analyses were carried out from peer-reviewed journal publications in English and/or the native language of the partner in charge. The pooled results were stratified for potential influencing factors, such as the region of origin or whether the inventor of the respective implant had been part of the study team. The results of these investigations were compared with data from worldwide arthroplasty register reports.

Statistical analyses were performed calculating confidence intervals according to the current standards for meta-analyses.

These were the inclusion criteria for scientific articles to be considered in the subsequent evaluation:

- Unambiguous identification of the implant;
- Revision rate data (for any reason) either presented in the text or unambiguously calculable from the data contained. Unambiguous values were required for all items; an exception was only made in the case of follow-up times where also articles were accepted that merely indicated a time period. In that case a linear function was assumed for patient inclusion.
- Publications in Medline-listed, peer-reviewed journals.

Register data for calculations were obtained from annual reports or, if available, from journal publications. The most recent annual reports available were selected in all cases, and, in accordance with the register categorisation of the EUPHORIC project (18), only A.1.1.1 quality National reports were used. Thus, mainly National registers were included featuring a documentation completeness of more than 90% and published data validation.
In the case of register datasets, precise values were strictly required.

Implant developers were identified through mentions in publications or manufacturers' documentations.

All papers were classified as developers' publications where either the developer of the implant was listed as the author or as a co-author or the developing institution was indicated as address for correspondence.

In cases where no developer was identified or no publications of the respective centre were available, the datasets concerned were not used for specific sub-group analyses.

Materials and Methods

Interpretation

- Surgery outcomes are of course subject to certain fluctuations resulting from factors that are independent of the product used. They could be related to the profile of the patients treated in the respective department, the surgeons' expertise, specific surgical techniques, quality assurance measures, but also due to the influence of the particular public health system.

- The maximum band-widths of the cumulative impact of these factors on the final outcome had to be calculated and evaluated. Various cross-sectional analyses of register data were conducted for this purpose.

- A difference factor 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 estimation of non-implant-related impact factors) shows that the maximum outliers are also lower than a factor of 3:

	S	N	SF	DK	AUS	NZ	GB
AGC	0.94	0.56	0.76	2.39	0.77	0.38	
NexGen	0.37/ 2.71				1.55	1.66	1.27
Oxford Uni	0.86		1.17		0.97		
Duraloc	1.04			1.02	0.86		1.14
PFC	0.91			1.44	1.03	1.02	0.88

- Even though the majority of datasets of both individual departments and individual implants show deviations that remain clearly below a factor of 3, the values of individual outliers are close to this cut-off point.

Materials and Methods

Interpretation

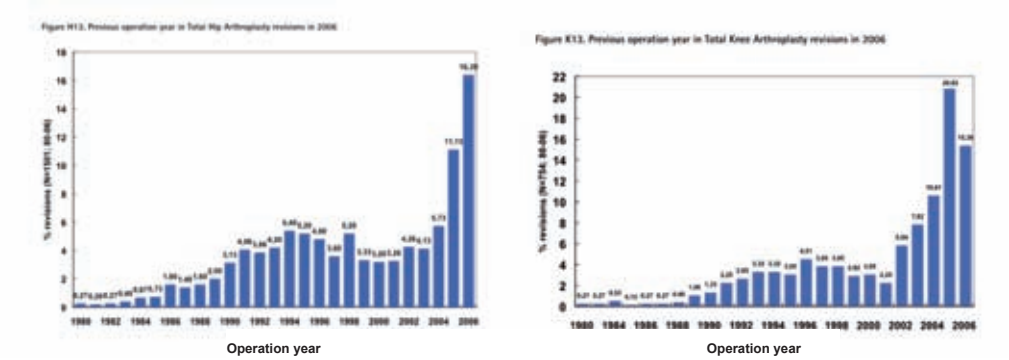
- Particularly when analysing literature from centres of excellence it appears sensible to choose a generous limiting value to significance.

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

1. Deviations from the mean by a factor of 3, i.e. from 33% to 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.

<u>Interpretation of data of the indicator 'Revisions per 100 observed component years':</u>

- The essential simplification behind the calculation of this indicator, which is mathematically inevitable, is the assumption that the distribution of revisions over time is linear. This, however, does not correspond to the actual distribution. For example, the data of the Finnish register show that most revisions occur within the first years after primary surgery.

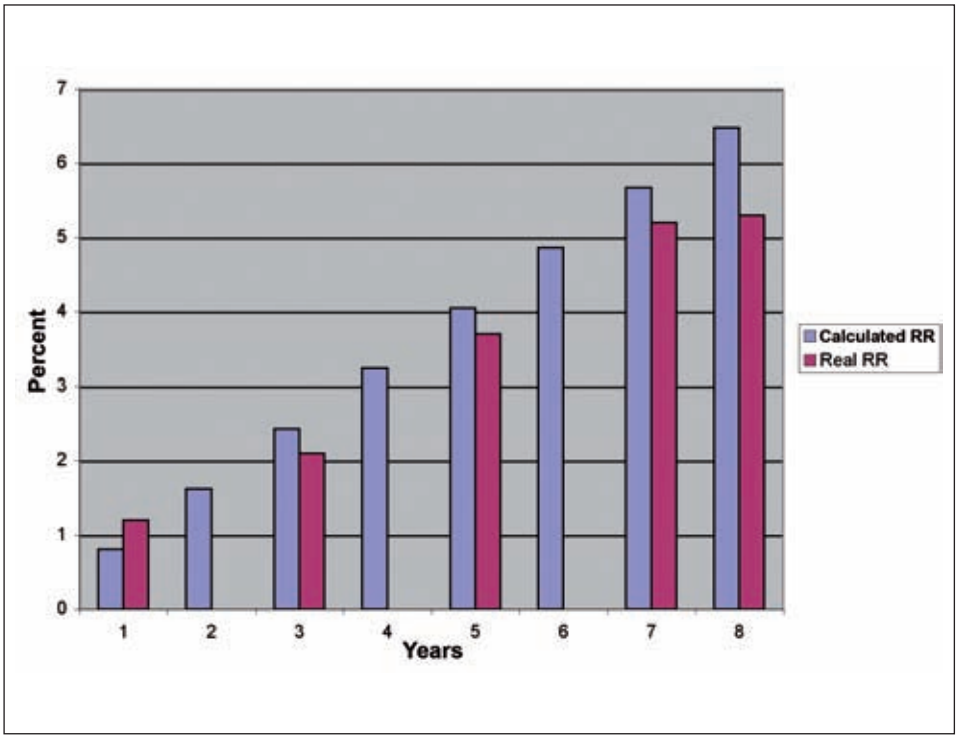


Total Hip Arthroplasty — Total Knee Arthroplasty
Finnish Arthroplasty Register, Annual Yearbook 2006: Year of primary surgery of cases revised in 2006

- The Australian register publishes data for both 'Revisions per 100 observed component years' and the actual incidence of revisions so that the effect can be quantified.

Materials and Methods

Interpretation



Average values of all implants of the Australian Joint Replacement Registry, comparing the back calculation of revision rates calculated based on 'Revisions per 100 observed component years' with the values actually measured. Basis: 2009 Annual Report

- In the first year after primary intervention the real values are slightly above the values calculated while they are slightly below in the long term.

- 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.

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

Results

Evaluation of all Data

- Out of 49 implants and systems included in the comparative analysis, 11 showed statistically significant and relevant deviations from the benchmark: the respective outcome in register data. For another five systems, no revisions were described in the clinical literature.
- The highest value was found for the Optetrak Total Knee system, for which the average revision rates were 41.1 times higher in registers than in the clinical studies published.
- As fas as developers were documented for these 11 systems, they also show statistically significant and relevant deviations from the benchmark.
- The vast majority of these systems, just like the respective studies, stem from North America, above all from the US.
- Developers' publications exhibit statistically significant and relevant deviations for another six systems. In three of these cases –the Taperloc stem, the Oxford Unicompartmental Knee Replacement, and the STAR Total Ankle Arthroplasty– this influence is as large as to lead to a significant and relevant impact on the overall dataset.
- In the case of two systems, Durom and the ABG stem, it is noticeable that the results published in clinical studies show a significantly and relevantly worse picture of the outcome than has been observed in registers. Possible reasons will be addressed in more detail in the Discussion chapter.
- For 40.8% of the implants examined, the clinical literature creates a significantly and relevantly too positive image of the outcome, in 4.1% of cases the revision rates seem to be clearly exaggerated.
- Overall, the datasets of 44.9% of all implant systems examined are not in line with the outcome achieved in average patient service.
- In six cases, the average revision rate given in developers' publications deviates statistically significantly from the benchmark, however, owing to the presence of independent studies, without notably affecting the overall dataset.
- For three of these implants –the Taperloc stem, dem Oxford Unicompartmental Knee system und der STAR Total Ankle Arthroplasty– the publications by the developers do actually have a statistically significant impact on the dataset though, affecting the overall results of a literature analysis.
- If these three implant systems are also considered being compromised by a bias, the published outcomes of a total of 51% of all implants show relevant irregularities.

Results

Evaluation of all Data

Implant	Factor Difference between Outcome in Registers and comprehensive Publications in peer-reviewed journals	Factor Difference between Inventor Outcome and Register Outcome	Inventor Bias	Inventor Bias leading to Bias in aggregated Assessment	Region of Origin
Optetrak KTEP	41.10	Not a single revision published	Yes	Yes	USA
Buechel-Pappas OSG-TEP	10.15	14.29	Yes	Yes	USA
C Stem	8.69	n/a	n/a	n/a	USA,D,GB
CPT stem	7.33	n/a	n/a	n/a	USA
Synergy	6.79	n/a	n/a	n/a	USA
Charnley cup	5.28	n/a	n/a	n/a	GB
Trilogy	4.36	n/a	n/a	n/a	USA
AGC	4.01	4.15	Yes	Yes	USA
Genesis II	3.86	3.70	Yes	Yes	US, Can
Fitmore cup	3.22	n/a	n/a	n/a	EU
Accolade Trident	3.17	n/a	n/a	n/a	USA
Citation stem	Not a single revision published	n/a	n/a	n/a	
Contemporary cup	Not a single revision published	n/a	n/a	n/a	
SecurFit cup	Not a single revision published	n/a	n/a	n/a	USA
Summit	Not a single revision published	n/a	n/a	n/a	USA
Versys stem	Not a single revision published	n/a	n/a	n/a	USA
Taperloc	2.90	10.81	Yes	Yes	USA
Bicontact	2.80	2.11	No	No	EU
Oxford Uni	2.71	4.37	Yes	Yes	GB
Avon	2.18	2.17	No	No	GB
Charnley stem	2.17	n/a	n/a	n/a	GB
Spotorno CLS cup	2.11	9.05	Yes	No	EU
Definition stem	1.95	n/a	n/a	n/a	

Results

Evaluation of all Data

Implant	Factor Difference between Outcome in Registers and comprehensive Publications in peer-reviewed journals	Factor Difference between Inventor Outcome and Register Outcome	Inventor Bias	Inventor Bias leading to Bias in aggregated Assessment	Region of Origin
Hintegra	1.94	1.94	No	n/a	EU
Alloclassic	1.84	0.87	No	No	EU
Durom Resurfacing	1.71	n/a	n/a	n/a	USA
STAR	1.56	4.63	Yes	Yes	EU
Harris-Galante cup	1.53	2.22	No	No	USA
ABG I cup	1.50	n/a	n/a	n/a	USA
LCS	1.46	1.17	No	No	USA
NexGen	1.45	n/a	n/a	n/a	USA
Conserve Plus	1.43	1.47	No	No	USA
Profix	1.39	n/a	n/a	n/a	USA
BHR	1.33	4.33	Yes	No	GB
Triathlon TKA	1.29	n/a	n/a	n/a	USA
AML cementless stem	1.22	4.74	Yes	No	USA
Duraloc	1.21	n/a	n/a	n/a	USA
Romanus cup	1.15	n/a	n/a	n/a	
Natural Knee	1.12	1.07	No	No	USA
ASR	1.06	n/a	n/a	n/a	USA
Agility	1.02	2.43	No	No	USA
SPII	0.99	n/a	n/a	n/a	EU
Spotorno	0.98	1.84	No	No	EU
PFC	0.70	0.64	No	No	USA
Müller stem cemented	0.70	0.59	No	No	EU
Lubinus cup	0.58	n/a	n/a	n/a	EU
ABG stem	0.27	n/a	n/a	n/a	USA
Durom THA	0.25	n/a	n/a	n/a	USA

Results

Implant Developers

Analysis of publications by implant developers has yielded the following results:

- 10 out of 22 implants exhibit statistically significant and relevant deviations from register data and can therefore not be regarded as reproducible in average patient treatment.
- With seven of these 10 systems, the developer's influence on the results published in peer-reviewed journals is so large that it entails a statistically significant impact on the overall dataset.
- Six of the developers concerned come from the US, two from the UK, and another two from continental Europe. Significant bias of the overall dataset has been observed for five developers from the US, one from the UK, and one from continental Europe (Denmark).

Implant	Factor Difference between Inventor Outcome and Register Outcome	Inventor Bias	Inventor Bias leading to Bias in aggregated Assessment	Region of Origin
Optetrak TKA	Not a single revision published	Yes	Yes	USA
Buechel-Pappas TAA	14.29	Yes	Yes	USA
Taperloc stem	10.81	Yes	Yes	USA
Spotorno CLS cup	9.05	Yes	No	EU
AML cementless stem	4.74	Yes	No	USA
STAR TAA	4.63	Yes	Yes	EU
Oxford Uni	4.37	Yes	Yes	GB
BHR Resurfacing	4.33	Yes	No	GB
AGC TKA	4.15	Yes	Yes	USA
Genesis II TKA	3.70	Yes	Yes	USA, Can
Agility TAA	2.43	No	No	USA
Harris-Galante cup	2.22	No	No	US
Avon retropatellar KA	2.17	No	No	GB
Bicontact stem	2.11	No	No	EU
Hintegra TAA	1.94	No	No	EU
Spotorno stem	1.84	No	No	EU
Conserve Plus Resurfacing	1.47	No	No	USA
LCS TKA	1.17	No	No	USA
Natural Knee TKA	1.07	No	No	USA
Alloclassic stem	0.87	No	No	EU
PFC TKA	0.64	No	No	USA
Müller stem cemented	0.59	No	No	EU

Results

Implant Developers

Implant developers' influence on literature published in peer-reviewed journals:

- Implant developers generally have a large share in the literature published on their product.
- However, it is noticeable that, at least in the US, developers who have published less than 25% of the total of observed component years for their product on average have published reproducible outcome.
- All developers publishing outcome showing significant and relevant discrepancy with register data –and thus evoking an injustifiably positive picture– make up a proportion of more than 40% of all cases described for this product, hence dominating the publications about their own development.
- On the other hand, particularly in the case of specialty implants, such as total ankle arthroplasties or resurfacing implants, there are also examples where the developer exerts a comparable influence while the published results are reproducible.
- Cases of developers publishing conspicuously positive outcomes also occur outside of the US. However, except for the group from Oxford, their share of total publications is always below 40%. Consequently, sufficient information is also available from independent clinical studies to allow discrepancies being recognised even in a conventional literature analysis not involving register data.

Results

Implant Developers

Implant	Region of Origin	Follow-up	Number of Primary Cases	Number of Revision Cases	Observed component years	Revisions per 100 observed compo-nent years	Factor Difference Inventor/ Register	% Primary Cases by Inventor	% Observed component years by Inventor
Optetrak TKA	USA	5.10	448	1	2283.50	0.04	No Revision published	74.78	81.43
Buechel-Pappas TAA	USA	6.10	517	36	3152.60	1.14	14.29	57.25	58.63
Taperloc stem	USA	8.35	1929	36	16114.86	0.22	10.81	44.53	39.19
AML cementless stem	USA	10.39	577	23	5992.17	0.38	4.74	62.43	67.61
AGC TKA	USA	8.67	30596	571	310872.85	0.18	4.15	85.93	79.86
Genesis II TKA	USA, Can	6.34	15049	136	95433.36	0.14	3.70	47.51	45.89
Agility TAA	USA	4.28	682	82	2917.33	2.81	2.43	31.96	54.87
Harris-Galante cup	USA	9.31	7352	393	68481.41	0.57	2.22	31.46	24.37
Conserve Plus Resurfacing	USA	5.00	2023	140	10134.00	1.40	1.47	96.24	96.95
LCS TKA	USA	11.43	14196	863.00	162271.22	0.53	1.17	5.67	5.56
Natural Knee TKA	USA	7.16	1514	68	10847.70	0.63	1.09	91.88	97.17
PFC TKA	USA	6.13	14363	617	88090	0.70	0.64	7.21	4.03
Spotorno CLS cup	EU	8.19	3833	90	31387.80	0.29	9.05	7.80	4.76
STAR TAA	EU	4.60	1233	149	5676.61	2.62	4.63	14.92	17.94
Bicontact stem	EU	8.54	1264	17	10790	0.16	2.11	43.20	66.48
Hintegra TAA	EU	2.42	403	25	975.90	2.56	1.94	100.00	100.00
Alloclassic stem	EU	6.70	8576	194	57445.74	0.34	0.87	7.63	6.83
Müller stem-cem.	EU	6.92	6551	266	45315.50	0.59	0.59	1.88	2.55
Oxford Uni	GB	7.31	3311	175	24202.56	0.72	4.37	46.00	65.30
BHR Resurfacing	GB	4.40	2104	52	9253.00	0.60	4.33	26.43	25.18
Avon Retropatel-lar KA	GB	4.87	663	30	3231	0.93	1.27	93.06	96.36

Results

Quality of the Literature: Analysis of Region of Origin

- It must generally be stated that the majority of publications usually come from the developer's region, which is, of course, also reflected by the distribution of the respective implants in patient treatment.

- For the products developed in North America, a considerable number of publications is also available from other continents. Conversely, there are rarely any US publications dealing with European developements.

Quality of Literature from North America

- Of 29 products developed in the USA and Canada, 12 (=41.4%) show statistically significant and relevant deviations from register data in the overall dataset, presenting an overly positive picture of the outcome.
  For five (=17.24%) of these 12 products no individual developer or clearly defined group of developers can be identified; hence the publications do not come from a particular group that is associated with specific circumstances (which will be addressed in more detail in the Discussion chapter).

- Two products (=6.9%) show increased revision rates in clinical studies.

- For another two products (= 6.9%) the developers' publications show statistically significant and relevant deviations, which leads to a statistically significant impact on the datasets in one case (Taperloc stem). Due to the influence of developer-independent studies, however, the overall datasets are within the limits where deviations are explicable by specific circumstances.

- Only 13 (=41.4%) of the datasets from North America can be attested that the published outcome is reproducible in routine patient treatment as is reflected in worldwide register data.

- An overall analysis of all 29 implant datasets shows that 39.42% of all published cases come from developing hospitals. The value for observed component years even reaches 42.98%, which can be explained by the longer follow-up periods of these studies. 23.84% of all re-operations are published by this group.

Results

Quality of Literature from North America

Implant	Factor Difference between Outcome in Registers and comprehensive Publications in peer-reviewed journals	Factor Difference between Inventor Outcome and Register Outcome	Inventor Bias	Inventor Bias leading to Bias in aggregated Assessment	Region of Origin
SecurFit cup	Not a single revision published	n.a.	n.a.	n.a.	USA
Summit	Not a single revision published	n.a.	n.a.	n.a.	USA
Versys stem	Not a single revision published	n.a.	n.a.	n.a.	USA
Optetrak TKA	41.1	Not a single revision published	Yes	Yes	USA
Buechel-Pappas TAA	10.15	14.29	Yes	Yes	USA
C Stem	8.69	n/a	n/a	n/a	USA,D,GB
CPT stem	7.33	n/a	n/a	n/a	USA
Synergy	6.79	n/a	n/a	n/a	USA
Trilogy	4.36	n/a	n/a	n/a	USA
AGC	4.01	4.15	Yes	Yes	USA
Genesis II	3.86	3.7	Yes	Yes	US, Can
Accolade Trident	3.17	n/a	n/a	n/a	USA
Taperloc	2.9	10.81	Yes	Yes	USA
Durom Resurfa-cing	1.71	n/a	n/a	n/a	USA
Harris-Galante-Pfanne	1.53	2.22	No	No	USA
ABG I cup	1.5	n/a	n/a	n/a	USA
LCS	1.46	1.17	No	No	USA
NexGen	1.45	n/a	n/a	n/a	USA
Conserve Plus	1.43	1.47	No	No	USA
Profix	1.39	n/a	n/a	n/a	USA
Triathlon TKA	1.29	n/a	n/a	n/a	USA
AML cementless stem	1.22	4.74	Yes	No	USA
Duraloc	1.21	n/a	n/a	n/a	USA
Natural Knee	1.12	1.07	No	No	USA
ASR	1.06	n/a	n/a	n/a	USA
Agility	1.02	2.43	No	No	USA
PFC	0.7	0.64	No	No	USA
ABG stem	0.27	n/a	n/a	n/a	USA
Durom THA	0.25	n/a	n/a	n/a	USA

Results

Outcome Literature by Implant Developers from the USA

- Examining exclusively implants for which developers or groups of developers are documented leads to a similar result: six (=50%) out of 12 products show statistically significant and relevant deviations in the overall dataset or in publications authored by the developer.

- Overall, in North America 47.91% of all primary surgeries reported on in sample-based journal publications stem from developing centres, the value for observed component years is at 48.38%. Thus, follow-up studies from developing centres on average do not show longer follow-up periods. The value for revision surgeries amounts to 30%. Developing centres hence publish slightly fewer revisions on average than independent studies.

Implant	Factor Difference between Outcome in Registers and comprehensive Publications in peer-reviewed journals	Factor Difference between Inventor Outcome and Register Outcome	Inventor Bias leading to Bias in aggregated Assessment	Region of Origin
Optetrak TKA	41.10	Not a single revision published	Yes	USA
Buechel-Pappas TAA	10.15	14.29	Yes	USA
AGC TKA	4.01	4.15	Yes	USA
Genesis II	3.86	3.70	Yes	US, Can
Taperloc stem	2.90	10.81	Yes	USA
Harris-Galante cup	1.53	2.22	No	US
LCS TKA	1.46	1.17	No	USA
Conserve Plus Resurfacing	1.43	1.47	No	USA
AML cementless stem	1.22	4.74	No	USA
Natural Knee TKA	1.12	1.07	No	USA
Agility TAA	1.02	2.43	No	USA
PFC TKA	0.70	0.64	No	USA

Results

Quality of Literature from the UK

- The analysis generally shows an non-homogeneous picture that is dominated by a few research groups.
- Presumably owing to the long history, no studies by Sir John Charnley could be included, although a multitude of studies with large numbers of cases were published about his developments. While in the publications by users the results of the stem on average did not show any irregularities, the revision rates described for the cup were considerably below those available from registers – in spite of the fact that registers also include recent cases and the data therefore more strongly reflect the further development in Orthopaedics.
- The publications about the Oxford Unicimpartmental prosthesis are largely dominated by the group of developers. The published results to a significant and relevant extent deviate from the comparable values in registers and have a statistically significant impact on the overall dataset. A detailed analysis regarding this product is going to be published shortly (19).
- McMinn's publications concerning the BHR system exhibit statistically significant and relevant deviations from register data and should therefore be subject to critical analysis. However, since only 20% of the published cases stem from this group and independent literature on average even publishes slightly higher rates of revision than shown in the register dataset, the overall dataset on average shows reproducible values.
- Even though publications almost exclusively come from the developing hospital, the revision rates published for the Avon system are well-reproducible. The fact that the average revision rate documented in registers is approximately twice as high can be sufficiently explained by personal expertise and the learning-curve effect.
- Overall, 5.92% of the primary cases and 4.87% of the revision cases published for products from the UK stem from developing institutions. The value for observed component years is 3.14%, which is due to the long follow-up periods of several large studies about the Charnley system.
- For those systems for which publications from developing institutions are avalable, the mean values are: 44.36% of primary cases; 40.61% of revisions; and 57.91% of observed component years. However, the average values are stronlgy influenced by publications concerning the Oxford Unicompartmental implant.

Results

Quality of Literature from the UK

Implant	Factor Difference between Outcome in Registers and comprehensive Publications in peer-reviewed journals	Factor Difference between Inventor Outcome and Register Outcome	Inventor Bias	Inventor Bias leading to Bias in aggregated Assessment	Region of Origin
Charnley cup	5.28	n/a	n/a	n/a	GB
Oxford Uni	2.71	4.37	Yes	Yes	GB
Avon	2.18	2.17	No	No	GB
Charnley stem	2.17	n/a	n/a	n/a	GB
BHR	1.33	4.33	Yes	No	GB

Results

Quality of Literature from continental Europe

- Only one out of 10 systems developed in continental Europe shows significant and relevant deviations in the global data. However, for this system (Fitmore) no publications are available by the developer.
- Otherwise, all data show reproducible average values.
- For the CLS Spotorno cup, there is one developer study with a small number of cases that differs significantly and relevantly from all other data. These data therefore have no major impact on the overall dataset, the discepancy would have been quickly noticed in a conventional meta-analysis.
- As regards the STAR Total Ankle Arthroplasty, the developer's publications also differ considerably from independent studies and register data. Here,14.9% of the cases published come from the developing hospital, which, together with the large difference, has a statistically significant impact on the average outcome of the overall dataset. However, there are also sufficient data available from independent studies to recognise the exceptional nature of the results of this single centre in a critical analysis.
- Regarding all datasets, approximately 8% of all published cases originate from developing hospitals (primary cases: 7.38%; revision surgeries: 8.60%; observed component years: 8.02%). Among the regions under examination, Europe is the only one where the proportion of revisions from developing institutions is slightly higher than the proportion of primary surgeries. This means that implant developers on average publish slightly higher rates of revision than ordinary users. However, the differences within Europe are not statistically significant.
- Analysis of those datasets for which developers' publications are available shows that for the implants in question on average 9.32% of primary surgeries, 10.15% of revision cases, and 9.48% of observed component years come from developing hospitals.

Results

Quality of Literature from continental Europe

Implant	Factor Difference between Outcome in Registers and comprehensive Publications in peer-reviewed journals	Factor Difference between Inventor Outcome and Register Outcome	Inventor Bias	Inventor Bias leading to Bias in aggregated Assessment	Region of Origin
Fitmore cup	3.22	n/a	n/a	n/a	EU
Bicontact	2.8	2.11	No	No	EU
Spotorno CLS cup	2.11	9.05	Yes	No	EU
Hintegra	1.94	1.94	No	n/a	EU
Alloclassic	1.84	0.87	No	No	EU
STAR	1.56	4.63	Yes	Yes	EU
SPII	0.99	n/a	n/a	n/a	EU
Spotorno	0.98	1.84	No	No	EU
Müller stem-cemented	0.7	0.59	No	No	EU
Lubinus cup	0.58	n/a	n/a	n/a	EU

Results

Numbers of Cases: Register Data and Clinical Studies

- Referring to all implants in the respective regions, the data show that the number of primary and revision operations, as well as of observed component years recorded in the high-quality registers included considerably exceed the cumulative number of cases treated in clinical studies worldwide.

- Although there is no operative National register in the United States, 3.15 times as many primary surgeries, 2.17 as many revision surgeries, and 3 times as many observed component years are documented in worldwide Register datasets as in all clinical studies together.

- A similar situation is observed for continental Europe. Registers inlude 2.45 as many primary surgeries, 5.8 as many revision surgeries, and 3 times as many observed component years. The data on primary and revision surgeries are influenced by the large number of SPII implants documented in Scandinavian registers.

- Regarding the numbers of cases, the results from the UK are similar to those from the other regions. Although the British National Joint Registry did not fulfil the exacting inclusion criteria, 2.09 as many primary and 2.34 as many revision cases of British products are documented in registers. The fact that, with 87% of observed component years, clinical studies in this case outnumber register data is due to the impact the publications on the Charnley system have on the mean value.

Discussion and Summary

- A large bandwidth has been observed as to the average values regarding the reproducibility of results published in clinical sample-based studies in peer reviewed journals.

- There are considerable discrepancies at to the reproducibility of published results between North America, notably the USA, and Europe.

- More than 50% of the USA datasets, to a statistically significant and relevant extent, are not reproducible in average patient treatment and/or may lead to misinterpretations in meta-analyses performed according to the procedures currently applied.

- A relevant proportion of published outcome to a statistically significant extent shows overly positive results.

- The possible explanation that the general results after arthroplasty interventions are better in the US cannot be confirmed by comparative analyses between various countries. Compared to Europe, the average outcomes achieved in patient treatment are worse in the USA (18).

- On average, published revision rates are lower in clinical studies than in register data. However, this could, for example, be explained by the fact that clinical studies are usually conducted in centres of excellence, whereas register data also include small departments.

- No clear trend towards generally positive outcome publications can be derived, however. Compared to the proportion of datasets potentially compromised by relevant confounders, nearly just as many outcome results actually are reproducible. This is not easy to explain, and it must doubted that there is a general reason.

- Regarding two products from the USA the studies published, contrary to the general trend, show markedly higher revision rates than registers.

  - Durom cup: Two publications met the inclusion criteria. The dataset is strongly influenced by a publication by Long et al from the group led by L. Dorr.
    For some time now, there has been an intensive discussion about increased revision rates regarding this product. Registers also show increased rates of revision as compared to other products, but they are not as high as described in the cited article so that an impact by specific circumstances in the centre concerned cannot be excluded. There are relatively few publications dealing with this implant, and they are by no means adequate to allow for drawing final conclusions.

  - ABG stem: 24 European publications and one from New Zealand are available on this implant. Even though direct relation with this product were only established in few publications, it was involved in a critical discussion concerning the use of the ROBODOC implantation system. Publication activity shows a peak around the time of this discussion and shortly afterwards. Historical cases have shown that the opinion prevailing on a certain product within the

medical community may have an impact on scientific publications (20). It cannot be excluded that this phenomenon was also effective in this case. Apart from this, it is conspicuous that no publications are available from the USA.

- o It should generally be stated that scientific publications reporting on the occurrence of increased revision rates fulfil an important function for all users. In the majority of cases in which registers indicate existing problems with a product or its handling, such articles are missing completely. Moreover, it is striking that in the respective cases –for example, the ASR cup, which has been included in the present analysis– mostly no publications are available from the developers at all.

- Contrary to the data from North America, the vast majority of European results are well-reproducible and show good validity. Even though there are individual groups of developers who draw an unjustifiable, overly-positive picture of their product, sufficient independent publications of good quality are available (except for the group from Oxford) to be able to recognise discrepancies even in a conventional meta-analysis based on scientific publications.

- Whereas outside of the USA the vast majority of developer-independent publications have shown reproducible results, this does not apply to the USA. Here, even a considerable proportion of the independent literature presents significantly and relevantly better outcomes than are shown by the comparative values from worldwide registers.

- Striking differences have been observed in the published data and publication behaviour between the USA and Europe.

  - o Among the products for which developers have been identified, almost 50% of published cases come from the developing hospital. In Europe this applies only to about 10% of cases.

  - o The strong influence of developing institutions on scientific publications in the USA entails that results which are irreproducible in average patient treatment are hardly recognised because comparative data are often unavailable.

  - o Even publications by USA users who are not directly involved in product development cannot be reproduced to a relevant extent – a phenomenon that has been observed only in one single case in Europe.

  - o There are marked differences in the published number of cases for individual implant systems. In the USA, it is conspicuous that usually only few studies with low numbers of cases are available in the case of implants for which no developer has been identified.

  - o What is remarkable with respect to European products is that in the majority of cases relatively few studies have been published with low numbers of cases, particularly if the products have been developed in non-English-speaking countries and are not being marketed

by a big international manufacturer.
It should be investigated whether there are specific factors that negatively affect the chances of an article being accepted for publication.

- o On average, the published literature on European products shows considerably better quality and reproducibility than the US literature.

- o Publications from Europe are in general less influenced by particular groups, and convey a more democratic picture and wider scope of experiences.

- o Nevertheless critical evaluation is recommended in individual cases.

- Implant developers have a strong influence in the published clinical literature and therefore, sometimes to a relevant extent, determine the users' assessment of the product as well as product-relevant administrative decisions, for example, in certification procedures, market monitoring, or regarding the choice of a certain system in tendering procedures.
  The developers' influence in these procedures is by far larger with USA products and publications than is is in Europe.
  Usually both the users and public health authorities are interested in outcome data mainly to be able to estimate future quality in treatment or the complication rates to be expected for application in routine patient service.
  However, centres and physicians involved in implant development are not, or only to a limited extent representative for average patient treatment with regard to several aspects.

  - o As a rule, the hospital concerned can rely on a high degree of expertise and a fundamental understanding of the product and its handling.

  - o High personal motivation can be assumed when it comes to the thorough investigation of potential, outcome-relevant flaws in the entire course of therapy, and drawing the consequences.

  - o The final result of a THA implantation depends on a variety of factors, such as the product, instrumentation, operating technique, patient selection, etc. Since every product is developed against a specific background and based on a specific set of experiences, the product might make particular allowance for the factors prevailing at this hospital.

  - o On the other hand, it would be absolutely conceivable that implant developers also test the limits of their products and have to accept revisions due to increased learning curves, for example, while defining the limits of potential product applications, whereas subsequent users profit from these findings in routine patient treatment. This would be a possible explanation why some implant developers on average even publish higher revision rates than are shown in independent studies or register data.

Discussion and Summary

- Finally, one should also bear in mind that implant developers and manufacturers have a fundamental interest in the success of their product.
  The mere fact that a certain author publishes data deviating from the benchmark does therefore not allow for drawing conclusions on the reasons for the discrepancy. However, one should critically consider the value of these data for one's own decisions.

- Arthroplasty registers can essentially support the evaluation of outcome data.
  - They can serve as a benchmark in verifying the reproducibility of clinical studies. The methodology and basic concepts are being developed in the present project.
  - Registers refer to all surgeries performed in a certain region and can therefore reduce or exclude several sample-based bias factors.
  - The results of arthroplasty registers, just as every study, include the circumstances under which the data have been collected. Differences between countries, data collection and evaluation procedures may influence the results and conclusions drawn. This should be taken into account in the interpretation of results.
  - Fluctuations in results from register datasets are generally considerably lower that in clinical studies.

Statement to stimulate Discussion on the preliminary Results

- Up to now, analysis of about 50% of all implants scheduled for examination has been completed and summarised in this report.
  The sample hence appears perfectly representative.

- As a general rule, analyses of clinical literature should only be conducted comprehensively and interpretation should be handled with care.

- Comparative data should be included whenever possible. If applicable, stratifications should be carried out according to the region of origin of the data and studies.

- In the case of contradictory results, register data should be rated as superior since they are less susceptible to sample-based confounders.

- Independent of the product, on average 1.2-1.3 revisions per 100 observed component years must be expected for total hip and knee endoprostheses. This would correspond to an average revision rate of about 6% at five years and of about 12% at 10 years. Data from studies that strongly deviate from this average value, i.e. by a factor of 3-5 or above, should be critically analysed and examined for signs of sample-based confounders, such as

  o Patients lost to follow-up;

  o Strict inclusion and exclusion criteria leading to the selection of patients with a favourable risk profile;

  o Statistical power;

  o Relation to implant developer;

  o Specific expertise or the fact that the study centre mainly treats patients providing very favourable conditions for good outcomes.

- In view of the fact that implant developers have great influence on the published results, efforts should be made in the future to provide the reader with more transparent information on the specific circumstances under which the data have been obtained.
  Since there are definitely implant developers in all continents who are renowned for their surgical skills while their published results achieved with their own developments are well-reproducible by other surgeons, stating a general reason alone, such as higher expertise, does not suffice to explain differences in outcome.

Outlook

- We will proceed with our examinations and hope to present the final project report at the EFORT congress 2011 in Copenhagen.
- Data evaluation will be continued and the scope will be extended.
- The results will also be submitted for journal publication. Since we are dealing with an absolutely controversial issue and also challenge current practices, we will report on our experiences.
- Please address questions or interpretations regarding the data to the EAR Scientific Office.
- Anyone interested in co-operation on this project is very welcome and requested to contact the EAR Scientific Office.

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Abbreviations

EAR	European Arthroplasty Register, an EFORT-affiliated, non-profit scientific society focused on outcome research in arthroplasty and Arthroplasty Registers
EFORT	European Federation of National Associations of Orthopaedics and Traumatology
EUPHORIC	European Public Health Outcome Research and Indicators Collection, project funded by the European Commission (Directorate General for Health and Consumers DG SANCO, Grant Agreement 2003134) under the Community Action Programme for Public Health (2003-2008).
KA	Knee Arthroplasty
RCT	Randomised Controlled Trial
TAA	Total Ankle Arthroplasty
THA	Total Hip Arthroplasty
TKA	Total Knee Arthroplasty

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