Validity of published outcome data concerning Anatomic Graduated Component total knee arthroplasty: a structured literature review including arthroplasty register data

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Received: 19 February 2011 / Accepted: 23 March 2011 / Published online: 13 April 2011
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Abstract

Purpose Total knee arthroplasty (TKA) as a treatment for end-stage osteoarthritis of the knee shows good results in terms of patient satisfaction. For the assessment of outcome and revision rate after total joint arthroplasty, there are two major data sources: clinical studies and national arthroplasty registers. The purpose of this study was to analyse the outcome of Anatomic Graduated Component (AGC) TKA reported in clinical studies and to perform a comparison with the outcome reported by national arthroplasty registers.

Methods A systematic literature review was performed using standardised methodology in order to determine the outcome and revision rate of AGC TKA. In a comprehensive meta-analysis of clinical studies and worldwide register results we examined the quality of the basic data and the occurrence and influence of potential bias factors. Confidence intervals were calculated to determine the statistical significance of differences.

Results We found significant differences as regards the revision rate measured in revisions per 100 observed component years. Compared to worldwide register data it turned out to be significantly lower in clinical studies published by the implant development team. Actually, they reported a revision rate of 0.18 revisions per 100 observed

component years, whereas annual reports of national arthroplasty registers report 0.74 revisions per 100 observed component years. A comparison of the results from national arthroplasty registers of different countries revealed a significantly higher revision rate for Denmark in relation to worldwide register data.

Conclusions A conventional meta-analysis of clinical studies is affected by the influence of the development team and therefore subject to bias. For the assessment of outcome arthroplasty register data should be rated as superior and, being used as reference data for the detection of potential bias factors in the clinical literature, could make an essential contribution to the quality of scientific meta-analysis.

Introduction

Total knee arthroplasty (TKA) is a common, successful and safe surgical treatment for end-stage osteoarthritis of the knee that achieves a high percentage of satisfied patients [1, 2]. The Anatomic Graduated Component (AGC) (Biomet, Inc., Warsaw, IN, USA) system was originally introduced in 1983. Since 1986 the design has essentially remained unchanged with an anatomical femoral component with a 7° patellofemoral track, a one-piece direct compression-moulded metal-backed tibial component and a dome-shaped compression-moulded patellar component. The design of this posterior cruciate ligament-sparing knee has a nearly ‘flat-on-flat’ articulation with an anterior lip and central eminence, which allows for complete interchangeability of tibial and femoral components. In 1993 the implant manufacturer introduced gamma sterilisation of the components with argon gas in order to reduce oxidation and enhance the wear properties of the polyethylene [3]. Two

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kinds of tibial components are available. One is a moulded tibia component which has compression-moulded ultrahigh molecular weight polyethylene directly attached by the manufacturer to a cobalt chrome metal tray with a central stem. The other is a modular component including a base plate of titanium and a separate modular power-milled polyethylene component. Nowadays the patellar component is all-polyethylene, whereas in the 1980s a component with metal-backed polyethylene was also used.

Two major data sources are available for the assessment of the outcome and revision rate of arthroplasty, sample-based clinical trials and national arthroplasty registers.

Clinical studies are mainly conducted in specialised centres. These, however, are not representative for average patient treatment in all aspects, for example as regards the number of patients treated, and, consequently, the training of staff and their personal expertise. The study design or patient selection may imply further bias factors. Even a potential publication bias may have an impact on the data published.

By contrast, national arthroplasty registers include all operations performed in a certain country and can thus avoid or considerably reduce these confounders [4]. On the other hand, data from registers reflect the conditions under which they were collected, such as the prevailing surgical procedures performed in a country or the respective public health system involved, which again may influence the outcome. Moreover, different evaluation procedures or the lack of consistency in the designation of implant variants may potentially lead to misinterpretations [5]. Registers focus on outcome regarding the revision rate, as do most outcome studies that are related to specific implants.

The purpose of this study was to perform a critical analysis of the outcome of the AGC total knee replacement and the quality of literature referring to this implant.

Materials and methods

A web-based literature search was conducted via PubMed, followed by a manual literature search as well as a direct request for literature to the implant manufacturer.

The inclusion criteria consisted in the unambiguous identification of the implant; revision rate data had to be either presented in the text or accurately calculable from the data contained; and the papers evaluated had to be in the English or German language and published in MEDLINE-listed, peer-reviewed journals.

The subsequent detailed analysis included a total of 30 papers [6–35]. All publications were analysed in full text and according to the criteria of revision rate, follow-up period, numbers of cases, scores used and general statements about the product.

The clinical follow-up studies were then compared to data sets from arthroplasty registers. Our analysis included journal publications as well as annual register reports that could be accessed via the Internet at <http://www.efort.org/education/registers.aspx>. Three journal publications were available from national arthroplasty registers in Sweden, Norway and Finland [14, 20, 35]. In addition, annual reports of the national joint replacement registers of Sweden (Annual Report 2008), New Zealand (Annual Report 2006), Denmark (Annual Report 2006) and Australia (Annual Report 2008) were analysed for derivation of the values required for indicator calculation.

The main criterion for outcome assessment in this study was the revision rate. It was calculated using a standardised methodology based on the parameter ‘revisions per 100 observed component years’. This indicator is an adaptation of the well-known calculation of ‘years of exposure to certain risks in correlation with complications’, for instance, to specify the interrelation between tobacco consumption and lung cancer [36]. It was introduced in arthroplasty by the Australian National Joint Replacement Registry. The calculations in this study were carried out according to the investigators’ guidelines published in the Registry’s annual reports [37]. This method, which is routinely used in the reports of the Australian and the New Zealand arthroplasty registers, allows for the summarisation of data from different follow-up periods in one value. At the same time it is possible to consider not only the numbers of cases in the weighting process, but also the risk for revision depending on different follow-up periods.

For comparison, publications and annual reports from comprehensive national arthroplasty registers were assessed in meta-analyses using the same methodology. Statistical analysis was carried out by calculating confidence intervals (CI) using the statistics software calculator V.4. In addition, to compare the global data, detailed evaluations were performed to check individual literature sources for bias factors. Particular consideration was given to the methodological quality of the clinical studies.

Results

The mean follow-up period of the published original and review articles examined was 8.4 years, ranging from one to 17 years. The average follow-up of register data and annual reports was 5.7 years (range 3.8–10 years).

Of 30 publications, 26 were conventional clinical follow-up studies and four were review articles; 16 journal articles came from European centres, 12 from the USA, one from South America and one review article included data from European, North American and Australian centres. Of

the 12 original articles published from US centres, nine were authored or coauthored by Merrill A. Ritter, the surgeon contributing to the development of the prosthesis [6–35].

The basic data of the statistical analysis are presented in Table 1.

Studies by contributing surgeon

The mean follow-up period of the studies published by M.A. Ritter was 9.5 years. These publications include a total of 26,261 cases requiring a total of 441 revision operations (Fig. 1). This corresponds to a proportion of revisions of 1.68%. With a value of 0.18 (CI 0.16–0.19), the probability of re-operation according to the revisions per 100 observed component years indicator is statistically significantly lower than suggested by the values obtained from national arthroplasty registers. Thus, the revision rate published by the contributing surgeon is 4.15 times lower than in data based on arthroplasty registers.

Studies from North American centres

The average follow-up period from the entire US literature was 10.7 years. It comprises a total of 27,936 cases with 485 requiring revision surgery. This corresponds to a revision rate of 1.74%, or to a value of 0.16 (CI 0.15–0.18) in terms of revisions per 100 observed component years. Similar to the results published by M. A. Ritter, the probability of re-operation according to this indicator is statistically significantly lower than suggested by national arthroplasty register data. Of the remaining 6% (three papers) one was published by an author declaring conflict of interest for receiving royalties and giving paid presentations on behalf of the company that manufactures the AGC system.

European literature

The mean follow-up in publications dealing with data from European centres was 5.1 years (range 2.0–10.1 years). Of

a total of 2,527 cases 82 required revision surgery (Fig. 1), which corresponds to a proportion of revisions of 3.24%. There is no statistically significant difference between the revisions per 100 observed component years reported from European centres and those reported in national arthroplasty registers.

Annual reports

The average follow-up in the annual reports of the National Arthroplasty Registers of Sweden, New Zealand, Denmark and Australia was 4.8 years with a range from 3.8 to 10 years. Register data comprised a total of 35,284 cases with 1,245 cases requiring re-operation (Fig. 1). The revision rate was 3.53%. The resulting average of 0.74 (CI 0.70–0.78) revisions per 100 observed component years represents the highest revision rate of all publications analysed. There is a statistically significant difference in the revisions per 100 observed component years parameter between the register data and the results reported by M.A. Ritter or other US centres.

Moreover, we observed statistically significant inter-group differences, with the highest deviation being reported by the Danish Knee Arthroplasty Register. In fact, the number of revisions per 100 observed component years for Denmark was 1.76, which implies a revision rate of 4.4%. The comparative values for revisions per 100 observed component years were 0.69 for Sweden, 0.38 for New Zealand and 0.77 for Australia, thus remaining significantly below the figures from Denmark (Table 2).

Register-based studies

Amounting to 3.33%, the average revision rate in publications based on register data sets was similar to those reported in annual reports of national arthroplasty registers and in the studies published from European centres. The mean follow-up of these studies was 6.56 years (range 5.0–6.8 years). Unsurprisingly, there

Table 1 Basic data of statistical analysis

Source	Follow-up period	Revision rate (%)	Total primary cases	Total revision cases	Total observed component years	Revisions per 100 component years	CI	Factor difference to register data
US literature	10.65	1.74	27,936	485	297,556.95	0.16	0.15–0.18*	4.52
European literature	5.07	3.24	2,527	82	12,806.0	0.64	0.52–0.79	1.15
Development team	9.45	1.68	26,261	441	248,258.15	0.18	0.16–0.19*	4.15
Register-based publications	6.56	3.33	12,869	428	84,374	0.51	0.46–0.56	1.45
Annual reports	4.79	3.53	35,284	1,245	169,026.5	0.74	0.70–0.78	

*Statistically significant difference to register data

Fig. 1 Number of primary (blue) and revision (red) cases

was no statistically significant difference in terms of revisions per 100 observed component years between the register-based studies and the national arthroplasty register data sets.

Discussion

The purpose of this study was to evaluate the clinical outcome of the AGC total knee replacement and to analyse the quality of the literature dealing with this implant system. The average results of the development team and, as a consequence, the published outcome of North American centres differ remarkably from the outcome of European centres and the results shown by national register data worldwide.

In fact, the development team reported 0.18 revisions per 100 component years, which corresponds to a survival rate of 98.2% after ten years. The analysis of register data revealed a value of 0.74. The factor difference of 4.15 between the reports of the development team and the

register data is statistically significant. Basically, the main reason for revision in all reviewed literature was aseptic loosening.

A value of one revision per 100 observed component years corresponds to a revision rate of 5% at five years or a 10% revision rate at ten years in conventional follow-up studies. To be rated as an outlier data set, the average value had to show a statistically significant difference in the outcome and at least a difference of 300% to the register data sets. The National Arthroplasty Registers of Sweden and Denmark calculate individual department outcomes—with maximum deviations of up to a factor of 3 for the outlier departments. This was rated as ‘regular differences’ that may occur in average patient care due to the cumulative effects of influencing factors, such as surgeons’ expertise, training activities of the department, internal and external quality control activities, patient selection or effects of the individual public health system. Any divergence higher than a factor of 3 is hardly explicable by these factors alone.

At any rate, regardless of the reasons for such deviations, the average surgeon should be aware of the

Table 2 Revision rate of AGC TKA reported in different annual reports

Country	Year	Primary cases	Revision cases	Observed component years	Revisions per 100 observed component years	Factor difference to worldwide data
Sweden	2008	14,653	507	73,265	0.69	0.94
New Zealand	2006	364	5	1,795	0.28	0.38
Denmark	2006	7,037	310	17,592.5	1.76	2.39*
Australia	2008	3,797	81	14,334	0.57	0.77

*Statistically significant difference concerning the revision rate reported in the annual report of a single country to worldwide data

fact that the outcome published by the originating centre seems to be hardly reproducible in average patient care and other institutions. Therefore, the published results of the development group are only of limited value for other users' decisions since they actually cannot expect to be able to reproduce the excellent results. This might be similar with the reported results of high volume clinics.

By contrast, with an outcome of 0.64 revisions per 100 component years, the reported results of European centres do not differ significantly, either from register data or from register-based publications.

However, the evaluation of annual reports of national joint arthroplasty registers revealed statistically significant differences. Showing 1.76 revisions per 100 observed component years, the revision rate reported from the Danish Knee Arthroplasty Register was significantly higher than the rates reported in the registers of Sweden, New Zealand or Australia. Moreover, statistical analysis revealed a significant difference compared with worldwide data.

This could possibly be explained by the fact that training for the use of a particular medical device or certain surgical techniques might differ between countries and regions. Therefore, specific problems associated with the use of a particular device might prevail in a certain country or area.

With eight of 12 publications the majority of the studies dealing with North American centres come from the development team. The papers by the development team include 94% of all reported cases of this region. This might explain why the results of North American centres differ statistically significantly from register data.

In general, register data can be used as a benchmark in the assessment of clinical studies, particularly when it comes to evaluating whether relevant bias factors could possibly have influenced the outcome. Thus, register data can provide a valuable contribution to the assessment and impact of outcome data.

Moreover, a single group's impact on the results is limited by the wider scope of data collection. For the assessment of outcome results of orthopaedic implants, register data are therefore superior to clinical studies. Potential influence of national circumstances can be quantified and narrowed down by comparing data from different countries.

Regardless of the confounding factors detected in the clinical literature, register data concerning the AGC total knee prosthesis indicate competitive performance of this implant in comparison with other products.

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