The outcome of the cementless tapered SL-Plus stem: an analysis of arthroplasty register data

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Abstract

Purpose The aim of this study is to evaluate the outcome of the cementless SL-Plus stem in worldwide arthroplasty register datasets.

Methods A structured analysis was conducted the registered data about the SL-Plus stem manufactured by Smith&Nephew including published data from Australia as well as previously unpublished datasets from the Registers of Lombardia, Italy and Valdoltra, Slovenia. A total of 75% of the data analysed had not been published so far. The primary outcome measure was the revision rate, calculated in revisions per 100 observed component years. We evaluated a total of 10,684 primary and 122 revision surgeries with an average follow-up period of four years.

Results All datasets showed good and reproducible results for treatment with the SL-Plus stem. An average of 0.31 revisions per 100 observed component years had been reported, which is considerably below the worldwide average (1.29) found for total hip arthroplasty independent of the product. The results of a large centre did not essentially deviate from the revision rates in Lombardia, where the numbers of cases per department are relatively low on average.

Conclusions There were no indications for product defects or relevant errors in application. The SL-Plus stem can be considered a high-quality product that ensures good results also in the hands of less experienced surgeons. Data from even young registers can substantially contribute to the assessment of implants, even with the short follow-up periods. These datasets particularly allow for valid assessment of safety issues and can therefore make an essential contribution to the solution of problems of current relevance.

Introduction

Tapered stems according to the Zweymüller principle rank among the most widely used cementless implants worldwide. The basic concept was developed by Professor Karl Zweymüller in the late 1970s. The first generation of this stem was first implanted in 1979 and then continuously refined. After the first variants had been developed and marketed in collaboration with Sulzer/Centerpulse (now part of Zimmer Inc., Warsaw, IN), a further modification called SL-Plus stem (Fig.1) was brought on the market in cooperation with Plus Orthopedics (now Smith & Nephew, Memphis, TN).

A meta-analysis regarding the outcome of these implants revealed that the major part of published data referred to the Alloclassic stem (Zimmer Inc, Warsaw, IN), whereas relatively few studies have actually been published on the SL-Plus stem. About 50% of these studies deal with the Sikomet metal-on-metal bearing, which is no longer on the market [1].

In 2009 users of the SL-Plus stem in Austria reported incidences of aseptic loosening with this implant, which was in contradiction with the implant's good reputation.

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Fig. 1 SL-Plus Stem, Copyright: Smith & Nephew

As is common in such cases, structured analysis and assessment of the situation were restricted due to the way the incidents were presented. Series of individual cases were presented without a structured follow-up of patient cohorts, or no information was given on the number of primary cases associated with the revision surgeries described. Therefore, serious assessment was hardly possible.

In view of the legal requirement to assure the quality of its products, the implant manufacturer (Smith & Nephew, Memphis, TN) made a request for a survey to be performed in arthroplasty registers worldwide. The aim of the study was to examine the revision rate of this implant in large, well-monitored cohorts and search for indications that would confirm the cases of failure reported.

Materials and methods

A structured survey of annual reports of national arthroplasty registers was conducted using the collection of arthroplasty register links available on the EFORT portal and the links provided on the individual registers' websites.

All national reports available were analysed to find out whether they contained data on the SL-Plus THA system. Published data on this implant were only available from the AOANJRR 2010, the Australian Orthopaedic Association National Joint Replacement Registry [2].

In addition data from high-quality, at least category A.1.x.1.1 registers, according to the criteria developed in the EU project EUPHORIC, were analysed to check whether unpublished data were available [3, 4] (Table 1).

The regional Arthroplasty Register of Lombardia (Milano, Italy) and the local Register of Valdoltra (Slovenia) were found to include unpublished data. A special analysis focusing on the revision rate was conducted on the basis of a standardised protocol.

The main outcome parameter for this study was revision for any reason. The values for direct comparison were calculated using the indicator revisions per 100 observed component years in accordance with the guidelines of the Australian Arthroplasty Register and the European Commission's EUPHORIC project (1st Health Programme, DG SANCO) [2–4].

For interpretation of data based on this indicator it is important to be aware that, on a longitudinal scale, the revision rate is presented as a linear function, which is a mathematical approximation to the real situation. In reality about 50% of all revisions after THA are recorded in the first three years after primary surgery [3, 5]. The average value of revisions per 100 observed component years is therefore slightly overestimated for short follow-up periods in direct comparisons, while the revision rates published gradually decrease due to mathematical reasons' as average follow-up periods become longer and more and more patients leave the "high risk area".

The Australian register only publishes revision rates of individual components in special evaluations if they have turned out higher than anticipated, which does not apply to the SL stem. Otherwise, revision rates of implant combinations are published in the annual report. An analysis of those registers that actually present the components affected in revisions has shown that in about two thirds of cases the stem is concerned as well [1, 6]. These values were used for data adjustment to allow for comparative assessment of the Australian data.

In addition to the AOANJRR, two further datasets were included in the analysis.

At the time of our analysis, the regional Arthroplasty Register of Lombardia (Registro Ortopedico Lombardo

Table 1 Rating system of datasets according to the EU-project EUPHORIC

Aim / purpose	Outcome (A)	Process (B)	Structure (C)
Conformity between aim of data collection and aim of evaluation	Data collection performed for the specific purpose of evaluation (1)	Data collection not performed for the specific purpose of evaluation (2)	
Coverage	Nationwide (1)	Regional (2)	Local (3)
Data collection	Comprehensive (1)	Incomprehensive (2)	Sample-based (3)
Conformity dataset for assessment	Representative (1)	Not representative (2)	

Protesi, ROLP) contained comprehensive and reliable data covering the period from 1 January 2001 to 31 December 2008. Until 2007 the causes of revision surgery were recorded based on the national DRG code. Since the beginning of 2007 the causes of revision have been collected in more detail. For 2007 and 2008 these individual items had also been analysed at the time of this study. The entire dataset is usually cross-checked with administrative data (collected for reimbursement), which show a coverage of 98%. There is an additional level of cross checks with national datasets to detect patients who have undergone revision surgery in other regions of Italy. In the particular case of Lombardia, however, these cases are rare because in Italy patients usually move to the north for revision surgery if they are not revised in the original region.

All tests showed good coverage. The datasets can therefore be rated as reliable.

Valdolta Hospital in Ankarana, Slovenia, is specialised in orthopaedic surgery. It is the largest arthroplasty unit in Slovenia and a major referral centre. Valdolta covers a major proportion of the Slovenian arthroplasty market. An arthroplasty register was set up for internal quality control and scientific purposes which, besides conventional arthroplasty register activities, runs a current collection of retrievals and tissue samples from revisions.

Due to its isolated geographical location on the Adriatic coast, the structure of Slovenian arthroplasty service with this hospital as the largest unit, and the hospital's status as a major referral centre for revision surgery in Slovenia, Valdolta provides good conditions for running a comprehensive register.

The reliability of the database was also examined in a test case and resulted in accurate matching [7].

Arthroplasty register datasets in general show superior quality compared to meta-analyses of clinical studies, but some specific requirements should be taken into consideration for interpretation [8, 9].

The possibilities for comparative evaluation are restricted due to differences in data structures and evaluation procedures. To avoid over-interpretation, we present mainly descriptive data from the individual registers included.

Statistical significance was tested by calculating confidence intervals.

Results

In Australia the market share of the SL-Plus stem is increasing and, being used in 560–700 operations per year, it has become one of the ten most commonly used implants on the market over the last few years. The Australian Registry does not publish the outcome of individual implants, but of implant combinations. In the Registry's 2010 annual report the SL-Plus stem is mentioned in combination with the EPF-Plus and the R3 cup [2].

With 1,710 primary cases and 44 revisions at 3,850 observed component years, the average follow-up is 2.25 years. In the unadjusted table the results appear slightly inferior to the average, but there is no statistically significant difference to the national average.

The five-year revision rate in Australia is 4.5% for these implant combinations. Based on several other registers publishing more detailed information on the component involved in revision surgery, it can be assumed that about one third are isolated stem revisions, one third isolated cup revisions, and in one third of cases the entire system is changed [1, 6]. Hence the stem is involved in about two thirds of interventions.

Comparative interpretation of the Australian data is thus limited for methodological reasons due to necessary mathematical adjustments. However, based on the data available for Australia, an estimated 3% rate of revision for

Table 2 Outcome of the SL-stem in Australia

Australia adjusted SL stems	Follow-up period (years)	Number primary cases	Number revisions adjusted	Observed component years	Revisions per 100 observed component years
SL-Plus/EPF-Plus	2.80	1,988	43	5,561	0.76
SL-Plus/R3	0.86	523	6	451	1.45
Total	2.39	2,511	49	6,012	0.82

Fig. 2 Distribution of revisions in Lombardina on a longitudinal scale

any reason after five years seems to be realistic for the stem.

Combination with the R3 cup shows slightly higher cumulative revision rates than with the EPF cup, but the differences are not statistically significant and the numbers of cases much too small to be able to draw conclusions on potential implant-specific relationships. The average value from the Australian data is 0.82 revisions per 100 observed component years (Table 2).

The regional register of Lombardina (ROLP) includes data on 6,158 SL-Plus stems for the period from 2001 to 2008, with 5,534 stems used in THA, 498 in hemi-arthroplasty, 64 in revision operations, and no specification given in 62 cases. These surgeries were carried out in 53 different hospitals.

The average follow-up in this dataset was four years. In total, 51 stems (0.83%) had to be revised. Forty-eight cases were revisions after primary THA (0.87%), including 30 stem revisions, 15 total revisions, one explantation and spacer due to infection, and two were not specified.

This corresponds to 0.2 revisions per 100 observed component years. In revision surgery another SL-stem was used in 22 cases, while another type of implant was used in 29 cases.

Three cases had to be revised after revision THA (4.69%), two after an initial stem revision, one after exchange of both components. Total re-revision was performed in all cases. This corresponds to 1.17 revisions per 100 observed component years.

The total dataset shows 0.21 revisions per 100 observed component years.

Analysis of time to revision shows a distribution similar to Finland [5] (Fig. 2).

In Lombardina, 34 re-operations were performed after 2007, the year when the register introduced the more detailed description of revisions.

Four cases had to be revised for aseptic loosening of both components, nine cases for isolated aseptic loosening of the stem, one case for isolated loosening of the cup, two cases due to recurrent dislocation, one case due to periprosthetic fracture, two cases because of implant fracture, three cases due to pain, and one case due to infection. In 11 cases the documentation available was not sufficient, which may be explained due to restrictions during the implementation of the new data collection procedures.

At the Hospital of Valdoltra, Slovenia, a total of 2,015 SL-Plus stems were implanted with a maximum follow-up of 7.7 years and an average FUP of 4.26 years.

There were 22 revisions, which corresponds to a survival rate of 98.91% at six years and 0.26 revisions per 100 observed component years.

Seven of these 22 revision cases were due to aseptic loosening, which corresponds to a survival rate of 99.65% and 0.08 revisions per 100 observed component years.

The SL-stem was combined with several different cups. In 485 cases it was combined with the Bicon cup. In this cohort seven revisions occurred; all of them included the cup, while the stem was only affected in three cases. There was no aseptic loosening of the stem while there were two involving the cup. The majority of revisions were performed for other reasons.

In 1,413 cases the SL-stem was combined with a spherical press-fit cup. In this group 28 revisions occurred, 12 for aseptic loosening, seven were septic revisions, six due to mechanical problems, and three post-trauma. This corresponds to a survival rate of 97% after six years for the

Table 3 Aggregated data on the revision rate of the SL-stem

Datasets	Follow-up period (years)	Number primary cases	Number revisions	Observed component years	Revisions per 100 observed component years	CI
Valdoltra	4.26	2,015	22	8,583.90	0.26	0.17–0.39
ROLP	4	6,158	51	24,632	0.21	0.16–0.27
Australia	2.39	2,511	49	6,012	0.82	0.62–1.08
Total	3.67	10,684	122	39,228	0.31	0.26–0.37

implant system and revision for any reason. The stem was revised in 15 cases (survival rate, 98.9%), including five times for aseptic loosening (survival rate, 99.6%). The cup was exchanged in 21 cases, which results in a survival rate of 98.5%.

In 117 cases the SL-stem was combined with a cemented cup. Six revisions had to be performed, including four stem and two cup revisions. The survival rate was 92.9%. The reasons for revision were aseptic loosening in four cases, one septic complication, and one revision was due to mechanical reasons.

Regarding the stem revisions, three out of the total of four were carried out for aseptic loosening (survival rate, 94.4%).

Evaluation of the aggregated data reveals an average revision rate of 0.31 revisions per 100 observed component years. This is significantly superior to the worldwide average register value for THA independent of the product, which is at 1.29 revisions per 100 observed component years [10] (Table 3).

Discussion

Analysis of datasets from three different countries and more than 10,000 primary implantations did not reveal signs of product problems with the SL-Plus stem. Moreover, there were no indications of relevant, common or systematic handling problems that could lead to early revisions.

The probability can be considered quite low that the loosening described by individual users are a basic problem related to the product or the instruments.

The SL-Plus stem shows good results. In Lombardia on average 116 primary implantations were carried out per department. The results are similar to those achieved in an experienced centre such as Valdoltra. The SL-Plus stem represents a safe implant with good and reproducible outcome, also in the hands of less experienced surgeons.

The results from Australia are statistically significantly inferior to those achieved in Central Europe. However, this fact should not be overrated. On the one hand, the follow-up period is shorter in Australia than it is in the European datasets, which, from a methodological point of view, results in higher average values due to the relative frequency of revisions in the short term. On the other hand, the type of implant was developed in Central Europe so that a great deal of know-how has been accumulated over decades with regard to the surgical technique and the implant itself.

Anyhow, in Australia there seems to be potential for the improvement of results, even if the implant is not among the underperformers on a national scale.

Like in Central Europe, the concept of rectangular tapered stems does not have a long tradition in Anglosaxon

countries. A few years ago the Australian register also detected problems occurring with products of a similar design distributed by other suppliers [11]. National users should carefully analyse the data, and further training should be considered if required.

The distribution of revisions in all datasets does not indicate handling problems such as a high proportion of early revisions (Fig. 2)

We were not able to confirm high revision rates due to aseptic loosening in the data analysed as reported by single users based on inferior quality database.

The SL-stem has to be rated as a safe implant, even in the hands of less experienced and low volume surgeons.

Revision rate data for the SL-Plus stem were first published in 2003. The first studies available by 2006 mainly dealt with the Sikomet metal-on-metal bearing. All in all, data of about 2,000 primary cases were published [7, 12–14], roughly half of which concerned the Sikomet bearing, which has meanwhile been withdrawn from the market. If the data concerning the Sikomet issue are excluded, the data available confirm good results. Implantation using a mini-invasive approach seems to allow good outcomes too [15].

The present paper based on register data includes significantly higher numbers of cases and to date is by far the largest outcome study conducted on this implant.

Approximately three quarters of the data included have not been published so far. The inclusion of unpublished data is sensible and can substantially enlarge the database for evaluations. Particularly when it comes to safety issues, also registers under development can make valuable contributions. It seems advisable to increasingly use this potential in the future.

Standardisation in data collection and evaluation of arthroplasty registers is reasonable and, together with advanced methodological procedures, could be of great use in the analysis of aggregated datasets.

Conflict of interest The data evaluations of unpublished register data and the organisation of the project were supported by Smith & Nephew. None of the authors received financial or other benefits.

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