The Swedish Knee Arthroplasty Project

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25 years ago, members of the Swedish Orthopedic Society, at a meeting in Uppsala, initiated a nationwide multicenter study which should monitor endoprosthetic knee surgery prospectively. The project evolved into the creation of a database, later known as the Swedish Knee Arthroplasty Register (SKAR), the oldest national arthroplasty register. It was a success and comprised more than 65,000 primary knee arthroplasties, with their revisions, at the end of 1999.

Historical review

The term arthroplasty is derived from the Greek arthro = joint and plasty = to form. It was introduced by Gluck (1890), who is credited with having been the first to perform endoprosthetic replacement, using an ivory prosthesis in the hip and knee for patients with tuberculosis. In the beginning, the term arthroplasty was used for several procedures aimed at increasing mobility and function of a joint, such as joint resection, arthrolysis, interposition and replacement.

The initial results of endoprosthetic replacement by Gluck were encouraging but, mainly because of infections, he soon thereafter cautioned against this type of surgery. Infections remained the main obstacle to the further development of endoprosthetic surgery and during the next 50 years, the procedures for patients consisted mainly of knee arthrodesis or operations with interposition of organic tissues or sometimes even metals and other inorganic materials. It was only after antiseptic and aseptic routines were introduced that real progress was made regarding joint replacement. Walldius, in his classic article printed in Acta Orthopaedica Scandinavica in 1957 (reprinted in Clinical Orthopedics 1996), was the first to report encouraging results of total joint replacement of the knee with his hinge prosthesis, originally made of acrylate, which he later changed to stainless steel. Other surgeons were also experimenting with hinged knee prostheses in the 1950s, among others, Shiers, who published a preliminary report in 1954. Along with the development of hinges, interposition arthroplasties with inorganic materials further developed into hemicompartmental procedures with metal spacer blocks that could be used to replace the tibial joint surface.

The real advance came in the 1970s, with the principle of low-friction arthroplasty, initially developed for the hip joint. High-density polyethylene (HDPE) parts were made to articulate against polished metal parts fixed to bone with polymethyl methylacrylate (PMMA) for distribution of load.

Thus, the hemiprostheses evolved into resurfacing unicompartmental prostheses, commonly used in both femorotibial compartments (Gunston 1971, Marmor 1973). By connecting two unicompartmental components, first on the femoral side and later on the tibial side, a bicompartmental prosthesis was created (Freeman & Lewack 1986), which was transformed into a tricompartmental design by adding a patellar flange. In 1974, Insall and Walker successfully introduced the unconstrained total condylar prosthesis with a metal femoral and HDPE tibial component, fixed to bone with PMMA cement (Insall et al. 1976). Hinge prostheses were also redesigned according to the principle of low friction arthroplasty with HDPE bearings.

Göran Bauer (1923–1995), major promoter of the Swedish project, realized that in this environment it would be impossible for an individual surgeon to base his choice of optimal operative treat-

ment on his own experience and that the literature then gave little guidance, since it mainly dealt with descriptions advocating specific methods or implants used in various conditions. The Swedish Knee Arthroplasty Register thus started in 1975 at a time of rapid development of a new type of surgery on patients with many conditions that had led to destruction of the knee. The aim was to give early warning of inferior designs and present average results based on the experience of a whole nation instead of that of highly specialized units.

When the register was started, the main question was what to register. Some variables were easy to define and record, others not. Some definitions seemed clear at a glance, but were in fact very unclear. Therefore we feel impelled to explain in some detail the variables registered in the SKAR.

Items recorded in SKAR

Patient identity

Unique in the Nordic countries is the use of a social security number for all inhabitants. Every Swedish inhabitant has a number (ID) kept in a national census register. It includes information on date of birth and gender and is used by everyone in all contacts with authorities, hospitals and most private companies, when identification is required. The ID is readily available, is printed on id-cards and passports, and permits life-long tracing of patients including date of death. This is in sharp contrast to the situation in most other countries, where such tracing is an immense, if not impossible, task.

Side operated on, date of operation and operating unit

These variables are distinct, and besides mix-up and typing errors cause no problem regarding registration. By adding a letter, representing the side operated on, to the social security number, every knee gets its own unique ID. The registration of the operating unit was not originally intended to evaluate results of individual units, but was to allow for inquiries about patients at a later date.

Primary diagnosis

As mentioned above, at first, the indication for knee arthroplasty was severe destructive changes in the knee, leading to deformity and invalidity, for any reason. It soon became evident that the diseases leading to destruction of the joint varied and could affect the success of the operation. The need to record the diagnosis was therefore patent. Although the diagnosis was clear for most patients who were treated for osteoarthrosis (OA) or rheumatoid arthritis (RA), some cases were difficult to classify under a single diagnosis, especially as a patient can suffer from more than one condition. Although it is possible to record several diagnoses, inevitably a single diagnosis becomes the main one.

In cases where more than one diagnosis has been given by the operating surgeon as being the cause for operation, the most specific has usually been recorded as the main one (i.e., osteonecrosis is preferred to OA, fracture to disease, malignancy (local) to fracture). RA, when present in the absence of severe diagnoses, such as infection, fracture or malignancy, is given as the main cause of operation, regardless of a local specific diagnosis, such as gonarthrosis or osteonecrosis. Further, when recorded in one knee, RA can change a more nonspecific diagnosis in the other knee (sooner or later).

Type of arthroplasty and endoprosthesis

The definitions used by SKAR for the various types of knee prostheses bear the mark of their evolution, and sometimes seem a little odd to the uninitialited. However, most of these are still used today, with some modifications.

Prostheses without mechanical links between the components (resurfacing prostheses):

Femoropatellar prostheses are used only in the patellar joint.

Unicompartmental prostheses are used in replacing the medial and/or the lateral tibiofemoral compartment. In unicompartmental arthroplasty (UKA) only one compartment is replaced. A bicompartmental arthroplasty can be achieved using two unicompartmental prostheses, both medially and laterally (or one bicompartmental) but these

Knee arthroplasty entry form

Send to: **The Swedish knee arthroplasty register**
Dept. of Orthopedics
University Hospital
SE-221 85 LUND

From: **(####) Hospital name**

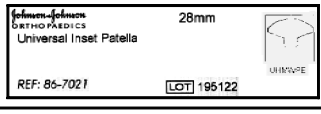
Stamp with patient ID badge or print patient ID below

Patient ID (10 digits)	1,0,1,0,1,0, – 1,0,1,0		
Side (use two forms for bilateral cases)	☒ Right	☐ Left	
Primary diagnosis	☒ Arthrosis	☐ Rheum. arthritis	or (ICD) .....
Date of surgery (yr-mo-day)	9,9,1,2,2,4,		
Primary op.	☒ Yes	☐ No, revision	
Only Uni prostheses, type	☐ Medial	☐ Lateral	☐ Medial + lateral
Only Uni prostheses, incision	☐ Mini	☐ Standard, not mini	(mark comp. Med/Lat below)
Prosthesis (plain text)	PFC		
Cemented parts			
Femur	☒ Yes, cemented	☐ No, uncemented	
Tibia	☒ Yes, cemented	☐ No, uncemented	
Patella	☒ Yes, cemented	☐ No, uncemented	
Bone cement (plain text)	Palacos gentamycin		
Surgeon, coded (voluntary)	J,D,O,E		

Implanted femoral components (attach one sticker with part no. per component used, mark with Med or Lat, as needed)

Implanted tibial components (attach one sticker with part no. per component used, mark with Med or Lat as needed)

Implanted patellar component (attach one sticker with part no. per component used)



In case of revision (attach a copy of the operation report and the discharge letter, mark one or more alternatives below)

Removed components	☐ Femoral comp.	☐ Tibial comp.	☐ Plastic insert
	☐ All comp.	☐ Patellar comp.	☐ Patellectomy
Other	☐ Arthrodesis	☐ Amputation	☐ or .....
Reason (plain text)	.....		

Figure 1. Present Entry Form. The form is filled in during surgery and is mailed to the project center in Lund for registration. The main reason for centralized registration is to check all part numbers against a database provided by the manufacturers to monitor the validity of that database and to update it, as needed.

are rarely performed nowadays.

Bicompartmental prostheses are used to replace both the lateral and medial compartments with a single component (on the tibial and femoral sides), but the femoral side has no patellar flange (thus the patellar joint is not affected). Nowadays these are not commercially available as unlinked prostheses.

Tricompartmental prostheses are used to replace all 3 joint compartments of the knee (i.e., femoropatellar and lateral and medial femorotibial with or without a separate patellar button). Thus, the coverage of the femoral component decides the type of implant. Modern designs are either unconstrained (posterior cruciate retaining) or constrained by highly conforming components or a cam axis design that forces a roll back of the femur on the tibia (posterior stabilized). The latter are used after removal of the posterior cruciate ligament.

Prostheses with mechanical links between the components:

Hinged prostheses are fixed axis total knee designs with stem fixation.

Linked prostheses (mechanically-coupled prostheses that permit more than fixed axis rotation). They are either modified (i.e., rotating) hinges or reinforced cam axis designs that also control varus–valgus stability (i.e., superstabilized). Both are available with or without a patellar flange.

Endoprosthetic model

When recordings started, each type of prosthesis had relatively few models, often named after their designers. The name of the implant was like that of the model. This classification of models by their names has since led to various problems, of which examples can be given.

Implants changed regarding design and material, but not the name. As a unit often used a particular model at a given time, it was well known to the local surgeons who often referred to an implant by a generic name, instead of a more specific one, and even kept using the same generic name when a new variety was introduced (e.g., St. George when EndoLink was introduced). Thus, implants by the same name might be different varieties of the implant (e.g., PCA was used for different variations of the Porous-coated Anatomic prosthesis). Similarly, changes in surface properties (metal backing, coating) were introduced that did not affect naming. Interchangeability permitted use of different models on the femoral and tibial sides (hybrids), and there are examples where the popularity of a hybrid became so great that after a while it was introduced as a standard. This has severely reduced the possibility of analyzing the effect of mechanical properties of implants on results. With the newly adopted recording of the manufacturer's part number of components, we hope to improve this.

Method of fixation

The use of bone cement is recorded separately for each component. In the beginning, this information was relatively self-evident and based on the implant model used, but with increasing popularity of coated implants intended for use both with or without cement, the availability of this information became crucial. Because of the delay in realizing this, the records of cementing were sometimes incomplete during the mid-1980s.

Use of antibiotics

Originally the use of antibiotics, both systemic and mixed in the cement, was recorded, but was very often left out on the returned forms, and the practice was abandoned permanently when forms were made without questions regarding antibiotics. Designed as a strictly prospective register, the SKAR has hitherto not chosen to make a separate database regarding the "profile" of units, based on their commonest treatment at a given time.

Radiographic examination

The amount of destruction in the knee before operation, as well as the fitting and alignment of components may affect outcome. Therefore, pre- and postoperative radiographs were first analyzed and graded. Radiographs from the operating units were reviewed centrally. However, in these early times of prosthetic surgery, problems with standardization became evident. Routines differed regarding centering, weight bearing, extent of flexion/extension and provocation during the radiographic examination. After reviewing about 1,500 cases, the classification was abandoned and never

resumed, mainly because the workload became prohibitive with the sharp increase in number of operations.

Recording of postoperative results

Short-term clinical benefits

Initially, the disability required for endoprosthetic surgery was so severe—with no suitable alternative treatment—that any short-term benefit was regarded as a success, if it did not cause later complications for the patients. It is therefore understandable that the main interest focused on failures and complications, rather than the degree of benefit. The first forms, regarding the primary operation, thus included recording of immediate general complications (during the hospital stay), but specific problems were rarely reported and such records were abandoned when reporting on computer diskettes was introduced in 1990.

Long-term clinical benefit

When knee arthroplasty became accepted as a safe and reliable treatment (even for patients with less disability), the degree of success became an issue. Back in 1979, a clinical evaluation was included at the 3-year follow-up, using the British Orthopaedic Association (BOA) Assessment Chart. This failed, because the clinicians found the extra workload unacceptable. It is only during recent years that data have again been gathered on clinical results, apart from failures, with the help of postal inquiries.

Longevity of the procedure

Although knee function deteriorated with time, it was hard to distinguish what was due to the procedure and what by confounding diseases and aging. The longevity of the procedure thus became measured by the absence of failure, which raised the problem of defining a failure and when it occurred.

Failure

Although commonly used, the terms success and failure were difficult to define in the context of surgical intervention, where the primary objectives of a treatment can be different. Thus a postoperative result for a given patient might be called a success, while for another it would be a failure. Even seemingly obvious failures (e.g., loosening, instability, wear) were not easily distinguished from normal postoperative conditions.

In view of the work with clinical follow-up examinations and lack of definitions for all types of failure, other simpler means became used as indicators of failure. Grossly unsuccessful cases were often caused by implant and fixation problems, or by local complications, requiring surgical intervention. An additional operation, a revision, therefore indicated that both the patient and surgeon agreed that the original problem had not been solved, so that a revision meant a failure of the primary operation.

Revision

Any later operation after primary knee arthroplasty could be called a revision, including soft tissue operations, transpositions, extraction of bone or cement fragments and arthroscopy. However, as these could be of minor nature and not related to the primary procedure, it could be debated if they meant failure. Therefore, it was decided to use a stricter definition of revision. Thus, only those involving addition, exchange or removal of prosthetic components (including amputations and arthrodeses) were said to be failures.

Most revisions are preceded by a period of clinical failure and some of these are never revised. However, unlike clinical parameters, a revision is a well-defined event as to when or whether it occurred and thus the revision and the time-to-revision can be recorded. However, in spite of the stricter definition, revisions can be more or less severe (e.g., a patellar button vs. an arthrodesis).

As for the primary operation, the type of revision and, in case of a new implant, the implant and the method of fixation were also recorded.

Reason for revision

The main reason for revision is recorded. The operation reports regarding revision have been gathered and reviewed at the project center in the Department of Orthopedics in Lund. Among the reasons normally stated by the operating surgeon, one has been selected as the main reason for revision. As for the primary diagnoses, the most spe-

cific (most serious) reason is normally chosen, but unlike for the diagnoses, the different reasons for revision are often interconnected in various ways. In an end-stage of malalignment, wear, instability, loosening and prosthetic fracture, it can be hard to decide about the first or primary reason for failure. To amend the registration, during the recent change in routines, we began to record the state of individual components (when available in the operation report) as well as one main reason.

Organization of the register

Number of participating units and operations

In the first couple of years after the start, 36 units were reporting to the register. In 1980, the number had reached 47, in 1990, 68, and the maximum was 82 units reporting in 1994. Since then, the number has declined, due to streamlining of the medical care system, with merging and closing of hospitals. During 1999, 74 units performed knee arthroplasties, all reported to the register.

The number of primary arthroplasties has increased from fewer than 1,000/year in the first 2 years to nearly 6,000/year in 1998. Revisions of failed arthroplasties soon followed, and since 1980, they have constituted approximately 10% of the total number of arthroplasties performed (Figure 2).

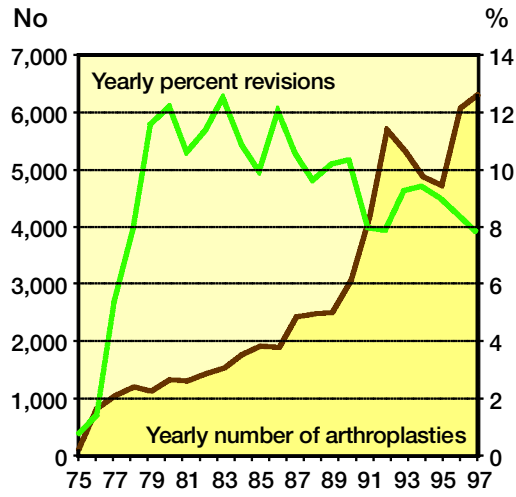


Figure 2. Yearly number of arthroplasties, primary and revisions, reported to SKAR and the percentage of revisions.

Staffing

The register is administratively headed by a committee of 3 persons chosen by the Swedish Orthopedic Association. Every operating unit has a secretary and physician as contact persons for questions regarding the register. Data ar forwarded to the project center in Lund, where they were processed and computerized. Until 1995 there was no regular staffing, but researchers maintained the database with the help of secretaries, and until 1990, with hired computer technicians. This meant that work was done very sporadically, with maximum activity concerning specific scientific projects and less about others. With regular staffing since 1995, the register has been maintained more regularly.

Research based on the register has, for practical reasons, mainly been performed by orthopedic surgeons doing full- or part-time clinical work at the Department of Orthopedics in Lund, but also by guest-researchers staying in Lund temporarily. At present, there are 3 orthopedic surgeons doing active research on the register, which is supervised by 2 senior researchers attached to the project since the start. Statistical advice has been given by professional biostatisticians.

Reporting to the register

During the first 15 years, printed forms were used for reporting an operation. Numbers were inserted in appropriate squares, giving the ID, date of operation, codes for the operating unit, side operated, no. of operation (primary or later revision), type and manufacturer of prosthesis, use of antibiotics and cement. Standard WHO codes were used for diagnoses and complications. Shortly after the start, a drawing of a knee was added to allow surgeons to mark the surfaces replaced and, with increasing experience, lists of the most common diagnoses, types and complications were added when, as in most cases, a choice could be made. In the early 1980s, the register began to gather copies of operation reports on revisions. Until 1989, a follow-up form at 1, 3, 6 and 10 years postoperatively was sent to the participating units to inquire if the patient had a reoperation or perhaps complications and, between 1979 and 1981, the 3-year form also included a clinical evaluation with

SKAR contact persons

City	Orthopedic surgeon	Secretary	Hospital
Alingsås	Pär Dahlkvist	Ing-Britt Gustavsson	Alingsås lasarett
Arvika	Lars Enskog	Britt-Inger Karlsson	Arvika sjukhus
Boden	Arne Henrikson	Carin Isaksson	Bodens sjukhus
Bollnäs / Söderhamn	Lars Golvik	Eva Blomberg	Bollnäs-Söderhamns sjukhus
Borås	Krister Sundholm	Birgitta Gunneriusson	Borås lasarett
Danderyd	Olle Muren	Gunilla Stenséll	Danderyds sjukhus
Eksjö-Nässjö	Stellan Wijkström	Bodil Frank-Hansen	Höglandssjukhuset Eksjö-Nässjö
Enköping	Sten Karlström	Elaine Skirgård	Enköpings lasarett
Eskilstuna	Lars-Gunnar Brobäck	Monica Lindberg	Mälarsjukhuset
Falköping	Ulf Svärd	Britt-Inger Modig	Bassjukhuset
Falun	Anders Henricson	Irene Gradén	Falu lasarett
Gällivare	Jan Minde	Barbro Smedberg	Gällivare sjukhus
Gävle	Lars Linder	Birgitta Hansson	Länssjukhuset Gävle
Göteborg	Björn E. Albrektsson	Anneli Gustavsson	Östra Sjukhuset
Göteborg	Lars Regnér	Jannika Rönnblad	Sahlgrenska sjukhuset
Halmstad	Stefan Elmerson	Lena Alpedal	Länssjukhuset
Helsingborg	Leif Ceder	May-Christine Friberg	Helsingborgs lasarett
Huddinge	Anders Herrlin	Ann-Christin Eriksson	Huddinge sjukhus
Hudiksvall	Sven-Erik Keisu	Laila Pettersson,Grethe Lökken	Hudiksvalls sjukhus
Hässleholm	Martin Sundberg	Helena Ridderstedt	Hässleholms sjukhus
Jönköping	Nils Oretorp	Ann Marie Andersson	Länssjukhuset Ryhov
Kalmar	Carl-Henrik Hybbinette	Catharina Lindgren	Länssjukhuset Kalmar
Karlshamn	Christer Olsson	Lillemor Cehlin	Blekingesjukhuset Karlshamn
Karlskoga	Anders Lindbäck	Ulla Laursén	Karlskoga lasarett
Karlskrona	Ronny Lövdahl	Elisabeth Malmberg	Blekingesjukhuset
Karlstad	Urban Hedlund	Carina Bååth	Centralsjukhuset i Karlstad
Katrineholm	Thomas Hultén	Monica Lindberg	Kullbergska sjukhuset
Kristianstad	Stefan Lewold	Helena Ridderstedt	Centralsjukhuset
Kristinehamn	Rolf Andersson	Birgitta Häggroth	Kristinehamns sjukhus
Kungälv	Lennart Gustavsson	Anita Bengtsson	Kungälvs sjukhus
Köping	Carl Linton	Anette Lindberg	Köpings lasarett
Landskrona	Reiner Brümmer	Anita Sörensson	Landskrona lasarett
Lidköping	Per-Åke Ericsson	Ann-Britt Berling	Sjukhuset i Lidköping
Lindesberg	Sune Hallberg	Birgitta Bergström	Lindesbergs lasarett
Linköping	Lars Good	Anna-Britta Gustavsson	Universitetssjukhuset
Ljungby	Mats Wilhelmsson	Christina Björklund	Ljungby lasarett
Lund	Otto Robertsson	Mariann Hökmark	Lunds Universitetssjukhus
Lycksele	Christer Eriksson	Carina Brännlund	Lycksele lasarett
Malmö	Lennart Sanzén	Margit Friberg, Gunnel Nilsson	Universitetssjukhuset MAS
Mora	Håkan Bjerneld	Margaretha Larsson, Nelly Jonsson	Mora lasarett
Motala	Ulf Larsson	Evalena Stråât	Motala lasarett
Mölndal		Kerstin Karlsson/Marie Mattsson	Sahlgrenska Univ. sjh. Mölndal
Norrköping	Lars-Erik Sylvin	Ingrid Pettersson	Vrinnevisjukhuset i Norrköping
Norrtälje	Kjell Persson	Inger Grandin	Norrtälje lasarett
Nyköping	Leif Pettersson	Victoria Neuman	Nyköpings lasarett
Oskarshamn / Västervik	Håkan Sterling	Helene Toots	Oskarshamns lasarett
Piteå	Stig Eriksson	Lena Forsman	Piteå älvdals sjukhus
Skellefteå	Torbjörn Hedlund	Irene Marklund	Skellefteå lasarett
Skene	Josh Monastyrski	Annalisa Karlsson	Skene lasarett
Skövde	Björn Tjörnstrand	Lena Åberg, Maria Lilja	Kärnsjukhuset
Sollefteå	Bo-Göran Widman	Birgit Ramén	Sollefteå lasarett
Stockholm	Gunnar Westerlind	Rita Djordjeviz	S:t Görans sjukhus
Stockholm	Lucas Annissian	Kerstin Saegebrecht	Karolinska sjukhuset
Stockholm	Kurt Haas		Ortopediska huset, Stockholm
Stockholm	Erik B Mathiesen	Annika Stalebrant	Sabbatsbergs Närsjukhus
Stockholm	Ulf Lindén	Marlene Näslund	Sophiahemmet AB
Stockholm	Per Hamberg	Kerstin Thiel	Södersjukhuset
Sundsvall	Margaretha Rödén	Birgitta Hellrup/Margareta Öhman	Länssjh Sundsvall-Härnosand
Säffle	Hans Lyrholm	Eivor Karlsson	Säffle sjukhus
Södertälje	Stig Lindequist	Britt Marie Blomqvist	Södertälje sjukhus
Torsby	Odd Kleppenes	Mariette Sälgvik	Torsby lasarett
Trelleborg	Birger Bylander	Harriet Nilsson, Kerstin Eriksson	Trelleborgs lasarett
Uddevalla	Rhagnar Myrhage	Lise Lotte Olofsson	Uddevalla lasarett
Umeå	Kjell-Gunnar Nilsson	Margareta Hagström	Norrlands Universitetssjukhus
Uppsala	Gunnar Adalberth	Zerny Paulsen	Akademiska sjukhuset
Varberg	Sven Björkström	Karin Gerdemark	Sjukhuset i Varberg
Visby	Åke Karlbom	Eva Pettersson	Visby lasarett
Värnamo	Åke Deiver	Ann-Margret Norrman	Värnamo sjukhus
Västervik	Anders Svanström	Lotta Törngren	Västerviks sjukhus
Västerås	Maria Hilding	Vanja Karlsson	Centrallasarettet
Växjö	Torben Neergaard-Richa	Carola Sjögren	Centrallasarettet
Ystad	Peter Abdon	Agneta Wahlman	Ystad lasarett
Ängelholm	Anders Nordqvist	Britt-Marie Tilling	Ängelholms sjukhus
Örebro	Per Essving	Britt-Marie Nordin	Regionsjukhuset i Örebro
Örnsköldsvik	Bernt Jonsson	Astrid Kallin	Örnsköldsviks sjukhus
Östersund	Villum Christensen	Helen Ledin Sundstad	Östersunds sjukhus

Output from SKAR

Annual reports to participating units
- Printed annual survey
- Own data with full lists of input
- Own cumulative revision rates
- National cumulative revision rates
- Annual meeting with contact persons

Annual meeting with the manufacturers or sales-people
Presentations at national and international meetings
Papers in peer-reviewed journals
Selected reports and reference list on internet: www.ort.lu.se/knee/

Validation of SKAR

Formerly repeated individual inquiries
Yearly lists of data to each participating unit
Manual updates of selected series of primary arthroplasties as part of specific studies
Duoble entry test of secretary accuracy
Postal questionnaire to all living patients (1977)
Analysis of medical charts in revised cases
Cross-checking with a national hospital admission register (the Patient Administrative System)

BOA-charts. In the mid-1980s, we saw a sharp increase in the number of operations performed. This increased the workload at the units when answering postoperative inquiries. In 1989, it was felt that inquiries about individual patients were so time-consuming, and the compliance in reporting by units so adequate, that they were abandoned in favor of yearly lists of revisions performed, including the operation reports. In 1990, a computer program was developed, allowing the units to report their primary operations to the register on diskettes. This method was used by most units until 1999, when the latest major change in the reporting routines was made. At this time, registering the Part No. of the implant components used was started, and in an effort to reduce workload and increase accuracy, reporting by diskette was stopped and new paper forms were produced that also allowed the stickers with the Part No. (included in the implant packages) to be attached, exactly specifying the components (Figure 1). For revisions, the operation report and discharge letter continue to be the main source of information regarding reason for and type of revision.

Statistics

The first reports from the register were mainly descriptive where the number of complications or failures was related to the number of implants.

The problem with this simple method was that the operations were not performed all at once and then followed for a different numbers of years. This, combined with the death of some patients (censored observations), resulted in patients having different lengths of follow-up, which could produce misleading results.

The use of survival (actuarial) methods to produce life tables was started in the 16th century. They allowed for varying periods of follow-up and permitted calculation of cumulative failure rates over time, that could be presented in a graph. The method has been extensively used by epidemiologists and insurance companies to predict the survival of patients with particular diseases. For arthroplasties, Dobbs in 1980 was the first to use it when analyzing failures after hip arthroplasty. Tew and Waugh in 1982, used it for knee arthroplasty and later, SKAR adopted the method (Knutson et al. 1985, 1986). As the method initially had been used to show the proportion of patients surviving a disease, the curve started high on the left hand side, with all patients surviving (100%), falling to the right as patients died (Figure 3). This was also how the register initially showed the curves, but for semantic reasons this was later changed. By subtracting the survival percentage from 100%, the curves, instead of showing the cumulative percentage of patients surviving an arthroplasty (by not being revised), express the cumulative rate (percentage) of revisions (CRR) occurring after arthroplasty, starting at zero and gradually increasing.

At present, when producing curves, the register uses the life table method (monthly intervals) to calculate the cumulative revision rate, with confidence intervals based on the Wilson quadratic equation with Greenwood and Peto effective sample-size estimates (Dorey et al. 1993). When few patients are left at risk, a single revision increases the revision rate dramatically. Therefore, the curves are normally cut off when 40 knees remain (Figure 4).

Regarding the statistical tests, we initially used the Wilcoxon (Gehan), the log-rank and other sim-

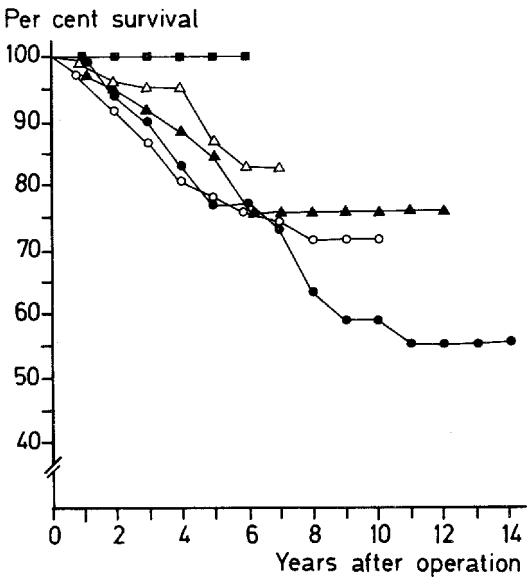


Figure 3. Cumulative prosthetic survival rates in 498 rheumatoid arthritis patients with primary knee arthroplasty, performed in Lund, 1967–1983. ▲ hinged, ▲ stabilized (linked), ■ tricompartmental, ● medial and lateral unicompartmental and ● tibial hemiprostheses (Knutson et al. 1985).

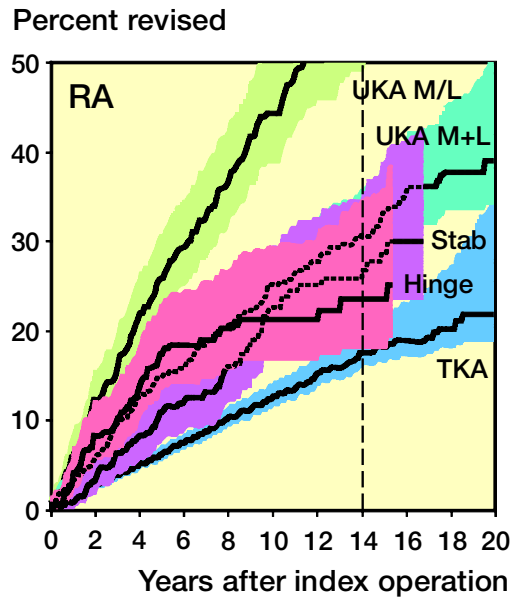


Figure 4. Cumulative prosthetic revision rates in 294 hinged, 363 stabilized (linked), 8,062 tricompartmental, 849 medial and lateral unicompartmental, and 456 medial or lateral unicompartmental knee arthroplasties performed for rheumatoid arthritis in Sweden since 1975.

ilar tests to test crude (empirical) survival between groups. However, these methods have the disadvantage that when comparing groups (i.e., implant type), the effect of other factors (i.e., age, gender) is not taken into account. Therefore, in recent years, we have chosen Cox's regression to estimate differences in survival, allowing adjustment for external factors.

Equipment

In 1979, computerization was introduced using a terminal connected through a modem to a university computer, a Univac 1100/80. This was fed with data and output was mainly in the form of lists of selected data to researchers, letters to the participating units, regarding the 1- and 3-year follow-ups, and later also statistical calculations. Use of the equipment required trained non-medical personnel until the personal computer was introduced, which enabled orthopedic researchers to access and analyze data without help from outside technicians. The really significant change came in 1990 when the database itself was moved to a PC at the department to a database designed and maintained exclusively by orthopedic surgeons. The software used during this period has mainly been Paradox (database), SPSS (statistics) and Microsoft Excel (graphs).

Output from the register

Reporting from the register has been done in various ways, in spoken, written and computerized form. During the first years, reports were made annually at meetings of the Swedish Orthopedic Society. These annual reports developed into separate annual meetings with contact persons on the register and specific annual reports to the participating units. These included the data of each unit (but not of others), allowing for control and correction, if needed. When computerization permitted relatively easy production of graphs representing the cumulative revision rate (CRR), each unit was given a graph where the CRR of the unit (but not of other units) could be compared to that of the country as a whole. No information regarding results of individual units has been provided to official or administrative bodies, such as the National Board of Social Welfare. These bodies receive ag-

gregated data concerning important aspects of the register, such as demographic data, complications, patient-related factors, failure rates, etc. Because of a legal debate as to whether printed reports (and thus CRR curves) to individual units were official material that could be claimed by anybody, the production of individual curves has been stopped. A computer program has now been developed which, when used in combination with a diskette (sent from the register) containing data from the actual unit, allows the contact physician to produce his own CRR curves that can be compared with curves for the country as a whole.

Besides yearly reports to participants and authorities, the register continuously makes available articles in peer-reviewed scientific journals and presentations at national and international meetings. Seven larger presentations have been given at annual meetings of the AAOS, the latest in 1999.

A comprehensive list of publications is available on the worldwide web homepage of the register at **www.ort.lu.se/knee/** .

Financing

The register was started with a contribution from the Swedish Medical Research Council (MFR) that gave financial support for several years. The last 15 years' annual funding has come from the Council of Counties (Landstingsförbundet), and later the Board of Social Welfare (Socialstyrelsen), through a special grant provided by the Swedish Government. Much of the financing has been, and still is, provided by individual research grants and indirectly by Lund University Hospital.

In 1999, the direct cost of running the register in Lund amounted to 150,000 USD.

Validation of data

During the period with 1-, 3-, 6- and 10-year follow-up forms, the inquiries contained information on the primary operation which could be checked and corrected, if needed, by the surgeon. When individual inquiries were stopped, the units were provided annually with lists regarding primary and revision arthroplasties reported the previous year (including patient ID, type of operation), giving opportunities for checking and correction.

Figure 5. The validation process which involved handling of 30,000 enquiries.

Some units have been separately approached several times with requests for manual updates on specific implants used during a certain period. Besides making for more exact records, this has shown the accuracy of the data and permitted changes in the register.

Errors in data entering were checked several times to ensure that typing errors were within acceptable limits.

The most elaborate check was performed in 1997, when all registered living patients were sent a questionnaire to inquire whether revision had been made without a report to the register (Figure 5). After validation and the subsequent update of the register, the revision status was correctly registered in 94% of cases (Robertsson et al. 1999).

To improve further the quality of reporting, the register has been checked annually against the Patient Administrative System (PAS) since 1997, a database run by the health authorities that records hospital admissions, and has included all hospital units in Sweden since 1987. The PAS is nonspecific and only gives an indication as to whose medical record needs to be checked.

Advantages of SKAR

The register has proved useful in many ways beyond the scope of this article and only general examples will be given.

Research benefits

The register gives data for separate studies on the population of patients with knee arthroplasty.

Outcome analyses have been the main purpose of the register since its start. Hitherto, outcome has mainly been confined to the rate of revisions and most of the research has focused on this. By providing analyses based on nationwide experience has drawn attention to problems as regards indications, methods and material. Due to the low failure rate, further studies, especially on subsets of patients or implants, can be based only on large-scale multicenter studies.

Epidemiologic and demographic analyses are obvious needs for a national register, and are often included in reports.

Spin-off research projects, based on the register, have proved valuable, for example, salvage of failed arthroplasty by knee fusion (Knutson), prosthetic infections (Bengtson), risk of cancer after knee arthroplasty (Lewold), patient satisfaction (Robertsson) and selection of appropriate questionnaires to use for patients treated with knee arthroplasty (Dunbar).

Quality benefits

Warnings. Surgeons have been warned of inferior implants (e.g., Dean, PCA), technically demanding implants (e.g., Oxford), diseases not to be treated with certain methods (e.g., unicompartmental arthroplasties in rheumatoid arthritis) and treatments (e.g., revision of a failed unicompartmental arthroplasty with a new one, instead of a TKA).

Control and comparison. By giving individual results of units, general failure rates and demographic data, comparisons can be made between units, between implants, regarding patient selection and availability of surgery. This helps decision-making and increases the probability of suitable choices. Further, it reveals differences, between regions or patient groups, regarding results and availability or type of treatment being offered.

Stimulation. The knowledge that the data obtained are being monitored encourages units and individual surgeons to do their best. When units compare their results to those reported nationally, units with inferior results should be stimulated to analyze the reasons and improve, while units with good results should be motivated to stay at the top. Having access to nationwide results, surgeons are stimulated to select well-documented methods and implant types.

Benefits of advice

Surgeons are being advised regarding optimal methods, implants and selection of patients.

Patients are being guided when information from the register is used to explain what they can expect (risk evaluation), why specific methods are preferred and when to wait or proceed with surgery.

Political/economic benefits

Purchasers of medical treatment, authorities or clients are more willing to give financial support when effects of previous financing can be shown, the results of the treatment can be documented, improvement in quality with time can be demonstrated and future trends can be predicted. The register has provided this information which helps the orthopedic profession in the struggle for meager medical resources. Further, this will benefit not only knee surgeons, but orthopedics as a whole.

The future

The newly introduced registration of part numbers, exactly describing which implant components have been used, will facilitate analysis of implant properties. Instead of a relatively rough distinction between implants based on model types and names, it will be possible to evaluate the effect of different sizes/thicknesses, surfaces, materials and other design factors, such as mode of fixation, length of pegs or stems, symmetrical versus asymmetrical designs, fixed versus mobile bearings, degree of articular constraint, posterior cruciate retention versus sacrifice, depth of the patellar groove, patellar replacement, and so on.

In recent years, we have begun studying other types of outcome measures, not based on failures, such as patient satisfaction, general and site/disease-specific health scores. Thus, in most patients who do not experience failure, grading of the success may be possible, further enhancing the choice of implants and methods maximally benefiting patients.

Although we feel that knee arthroplasty has come a long way, its evolution has not stopped. So long as there is room for improvement, new implants and methods will be introduced. Some of these will be beneficial, others not. It is important that the effects of changes are quickly recognized, minimizing exposure to inferior methods and maximizing the use of superior ones. Continuing the 25 years of work with SKAR is the best way to do this.

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Dobbs H S. Survivorship of total hip replacements. J Bone Joint (Br) 1980; 62: 168-73.

Dorey F, Nasser S, Amstutz H. The need for confidence intervals in the presentation of orthopedic data. J Bone Joint Surg (Am) 1993; 75: 1844-52.

Freeman M A, Lewack B. British contribution to knee arthroplasty. Clin Orthop 1986; 210: 69-79.

Gluck T. Die Invaginationsmethode der Osteo- und Arthroplastik. Berl Klin Wschr 1890; 19: 732.

Gunston F H. Polycentric knee arthroplasty. Prosthetic simulation of normal knee movement. J Bone Joint Surg (Br) 1971; 53: 272-77.

Knutson K, Lindstrand A, Lidgren L. Survival of knee arthroplasties. A nationwide multicenter investigation of 8,000 cases. J Bone Joint Surg (Br) 1986; 68: 795-803.

Knutson K, Tjörnstrand B, Lidgren L. Survival of knee arthroplasties for rheumatoid arthritis. Acta Orthop Scand 1985; 56: 422-5.

Insall J, Ranawat C S, Scott W N, Walker P. Total condylar knee replacement: preliminary report. Clin Orthop 1976; 120: 149-54.

Marmor L. The modular knee. Clin Orthop 1973; 94: 242-48.

Robertsson O, Dunbar M, Knutson K, Lewold S, Lidgren L. Validation of the Swedish Knee Arthroplasty Register: A postal survey regarding 30,376 knees operated on between 1975 and 1995. Acta Orthop Scand 1999; 70: 467-72.

Shiers L G. Arthroplasty of the knee. Preliminary report of new method. J Bone Joint Surg (Br) 1954; 36: 553-560.

Tew M, Waugh W. Estimating the survival time of knee replacements. J Bone Joint Surg (Br) 1982; 64: 579-82.

Walldius B. Arthroplasty of the knee using an endoprosthesis. Acta Orthop Scand (Suppl 24) 1957.

Walldius B. Arthroplasty of the knee using an endoprosthesis. Clin Orthop 1996; 331: 4-10.