The Norwegian Joint Registry

Leif I. Havelin MD PhD

Key words: arthroplasty, statistics, epidemiology, outcomes assessment

Abstract

The Norwegian Orthopaedic Association established The Norwegian Arthroplasty Register in 1987, first as a hip prosthesis register, but from January 1994 it was extended to include all artificial joints. The main aim has been to survey the results of joint replacement surgery. The orthopaedic surgeons in all hospitals in the country of Norway have agreed to participate. More than 60,000 total hip replacements have been registered so far.

Both primary operations and revisions are reported, and by using the patients’ national identification numbers, we can link the revisions to the primary operation and perform survival analysis of the implants, with adjustment for potential confounding by factors such as age, gender, and diagnosis. As the prosthesis components are registered on an individual basis, survival of components such as the cup or the stem can be calculated separately, with revision used as an end-point. The reason for revision is registered, and we can assess the rate of revision due to aseptic loosening of the stem or cup, infection, dislocation, wear, osteolysis, or other reasons.

For the safety of the surgeons, and to obtain a complete reporting of failures, we do not register the name of the surgeons and we keep the individual hospitals’ results confidential. The operating costs of register are covered by the state and the register is not dependent on grants from the industry. The cost per registered implant is approximately $18 (US). With this system we have been able to detect inferior results of implants as early as after three years of use. Several brands of uncemented prostheses and two brands of cement have been withdrawn from the market mainly based on our findings.

The arthroplasty register is a valuable tool both in quality control and for research in the field of joint replacement surgery.

Hip surgery in Norway in the early 1980s was marked by inferior long-term results with the popular Christiansen prosthesis, which were reported after the prosthesis had been used for 10 years and in more than 10,000 patients in Scandinavia. The patients with double cup prostheses had started to return for revision procedures, and as a reaction to the inferior cemented implants, many orthopaedic surgeons had started to use uncemented hip prostheses with completely unknown results.

With this background the members of the Norwegian Orthopaedic Association established the Norwegian Arthroplasty Register in 1987. The main purpose of the register was to discover inferior results as early as possible in order to avoid inferior implants from being used in large numbers of patients. The system was made nationwide; all hospitals and all members of the Norwegian Orthopaedic Association agreed to participate. The registers in Sweden and Finland were taken as models, but with important differences. From the start, our register was designed with the purpose of performing survival analyses of the prosthetic components, and a cooperation with the Division for Medical Statistics at the University of Bergen was established early.

When the register was started in 1987 only total hip replacements were included. However, in 1994 the register was expanded to include all artificial joints.

Methods

Data Collection

The recording of data is done with individual reporting of each joint replacement operation, comprising both primary operations and revisions. A one-page form is filled

Leif I. Havelin, M.D., Ph.D., is from the Department of Orthopaedic Surgery at Haukeland University Hospital, Bergen, Norway.

Reprint request: Leif I. Havelin, M.D., Ph.D., Department of Orthopaedic Surgery, Haukeland University Hospital, N-5021 Bergen, Norway.
<table>
<thead>
<tr>
<th>Patient ID and date of birth:</th>
<th>TOTAL HIP REPLACEMENTS</th>
<th>Hospital:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous operation in index hip:</td>
<td><strong>Approach:</strong></td>
<td><strong>3 Lateral</strong></td>
</tr>
<tr>
<td>0 No</td>
<td>3 Lateral</td>
<td></td>
</tr>
<tr>
<td>1 Osteosynthesis for prox. femur fracture</td>
<td>2 Anterolateral</td>
<td>4 Posterolateral</td>
</tr>
<tr>
<td>2 Hemiprosthesi</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 Osteotomy</td>
<td><strong>Osteotomy of greater trochanter:</strong></td>
<td></td>
</tr>
<tr>
<td>4 Arthrodesis</td>
<td>0 No</td>
<td>1 Yes</td>
</tr>
<tr>
<td>5 Total hip prosthesis</td>
<td><strong>Bone transplantation:</strong></td>
<td></td>
</tr>
<tr>
<td>Type:</td>
<td>1 No</td>
<td></td>
</tr>
<tr>
<td>Year:</td>
<td>1 In acetabulum</td>
<td></td>
</tr>
<tr>
<td>Number of prostheses in index hip:</td>
<td>2 In femur</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 Bone impaction in acetabulum</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4 Bone impaction in femur (a.m. Ling/Gie)</td>
<td></td>
</tr>
<tr>
<td>Date of operation:</td>
<td><strong>Acetabulum:</strong></td>
<td></td>
</tr>
<tr>
<td>Index of operation is:</td>
<td>Name/type:</td>
<td></td>
</tr>
<tr>
<td>1 Primary operation</td>
<td>Catalogue Number:</td>
<td></td>
</tr>
<tr>
<td>2 Revision</td>
<td>Hydroxyapatite coated:</td>
<td></td>
</tr>
<tr>
<td>Hip:</td>
<td>0 No</td>
<td>1 Yes</td>
</tr>
<tr>
<td>1 Right</td>
<td>1. Cement with antibiotic. Name:</td>
<td></td>
</tr>
<tr>
<td>2 Left</td>
<td>2. Cement without antibiotic. Name:</td>
<td></td>
</tr>
<tr>
<td>3 Right, prosthesis in left hip</td>
<td>3. Uncemented</td>
<td></td>
</tr>
<tr>
<td>4 Left, prosthesis in right hip</td>
<td><strong>Femur:</strong></td>
<td></td>
</tr>
<tr>
<td>Diagnosis (primary operation):</td>
<td>Name/Type:</td>
<td></td>
</tr>
<tr>
<td>1 Idiopathic coxarthrosis</td>
<td>Catalogue Number:</td>
<td></td>
</tr>
<tr>
<td>2 Rheumatoid arthritis</td>
<td>Hydroxyapatite coated:</td>
<td></td>
</tr>
<tr>
<td>3 Sequence after hip fracture</td>
<td>0 No</td>
<td>1 Yes</td>
</tr>
<tr>
<td>4 Sequence after dysplasia</td>
<td>1. Cement with antibiotic. Name:</td>
<td></td>
</tr>
<tr>
<td>5 Sequence after dysplasia with dislocation</td>
<td>2. Cement without antibiotic. Name:</td>
<td></td>
</tr>
<tr>
<td>6 Sequence after slipped capital femoral epiphysis or Perthes disease</td>
<td>3. Uncemented</td>
<td></td>
</tr>
<tr>
<td>7 Ankylosing spondylitis</td>
<td><strong>Caput:</strong></td>
<td></td>
</tr>
<tr>
<td>8 Other:</td>
<td>1 Fixed caput</td>
<td></td>
</tr>
<tr>
<td>Reasons for Revision (one or more):</td>
<td>2 Modular system</td>
<td></td>
</tr>
<tr>
<td>1 Loosening of acetabular component</td>
<td>Name/type:</td>
<td></td>
</tr>
<tr>
<td>2 Loosening of femoral component</td>
<td>Catalogue number:</td>
<td></td>
</tr>
<tr>
<td>3 Dislocation</td>
<td><strong>Systemic antibiotic prophylaxis:</strong></td>
<td></td>
</tr>
<tr>
<td>4 Deep infection</td>
<td>0 No</td>
<td>1 Yes</td>
</tr>
<tr>
<td>5 Fracture of femur</td>
<td>Name:</td>
<td></td>
</tr>
<tr>
<td>6 Pain</td>
<td>Dosage:</td>
<td></td>
</tr>
<tr>
<td>7 Osteolysis in acetabulum</td>
<td>Duration (days):</td>
<td></td>
</tr>
<tr>
<td>8 Osteolysis in proximal femur</td>
<td><strong>Operation theatre:</strong></td>
<td></td>
</tr>
<tr>
<td>9 Other:</td>
<td>1 “Green house”</td>
<td></td>
</tr>
<tr>
<td><strong>Type of revision (one or more):</strong></td>
<td>2 With laminar air flow</td>
<td></td>
</tr>
<tr>
<td>1 Change of femoral component</td>
<td>3 Without laminar air flow</td>
<td></td>
</tr>
<tr>
<td>2 Change of acetabular component</td>
<td><strong>Duration of operation:</strong></td>
<td></td>
</tr>
<tr>
<td>3 Change of all components</td>
<td>Skin to skin (minutes):</td>
<td></td>
</tr>
<tr>
<td>4 Other:</td>
<td><strong>Peroperative complication:</strong></td>
<td></td>
</tr>
<tr>
<td>- Removal of component (e.g., Girdlestone)</td>
<td>0 No</td>
<td></td>
</tr>
<tr>
<td>- Which parts:</td>
<td>1 Yes. Type:</td>
<td></td>
</tr>
<tr>
<td>- Exchange of PE liner</td>
<td><strong>Surgeon</strong> (who has filled in the form):</td>
<td></td>
</tr>
<tr>
<td>- Exchange of cupat</td>
<td></td>
<td>(Surgeon’s name is not registered)</td>
</tr>
</tbody>
</table>

**Figure 1** English translation of the forms used for reporting hip replacements (from 1994) (above) and other types of arthroplasties (right) to the Norwegian Arthroplasty Register.
<table>
<thead>
<tr>
<th>THE NORWEGIAN ARTHROPLASTY REGISTER</th>
<th>KNEES AND OTHER JOINTS (than hips)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient ID and date of birth:</strong></td>
<td><strong>Hospital:</strong></td>
</tr>
<tr>
<td><strong>Patients weight:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Localization:</strong></td>
<td></td>
</tr>
<tr>
<td>1 Knee 6 Elbow</td>
<td></td>
</tr>
<tr>
<td>2 Ankle 7 Wrist</td>
<td></td>
</tr>
<tr>
<td>4 Toe Joints; 8 Finger joints:</td>
<td></td>
</tr>
<tr>
<td>5 Shoulder 9 Others:</td>
<td></td>
</tr>
<tr>
<td>1 Right 2 Left</td>
<td></td>
</tr>
<tr>
<td><strong>Previous operation in index joint:</strong></td>
<td></td>
</tr>
<tr>
<td>0 No 4 Arthrodesis</td>
<td></td>
</tr>
<tr>
<td>1 Osteosynthesis 5 Synovectomy</td>
<td></td>
</tr>
<tr>
<td>2 Osteotomy 6 Other:</td>
<td></td>
</tr>
<tr>
<td>3 Prosthesis. Type:  Year:</td>
<td></td>
</tr>
<tr>
<td><strong>Date operation:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Index operation is:</strong> 1 Primary op. 2 Revision</td>
<td></td>
</tr>
<tr>
<td><strong>Diagnosis (primary operation):</strong></td>
<td></td>
</tr>
<tr>
<td>1 Idiopathic arthrosis</td>
<td></td>
</tr>
<tr>
<td>2 Rheumatoid arthritis</td>
<td></td>
</tr>
<tr>
<td>3 Sequelae after fracture</td>
<td></td>
</tr>
<tr>
<td>4 Ankylosing spondylitis</td>
<td></td>
</tr>
<tr>
<td>5 Sequelae, ligament tear</td>
<td></td>
</tr>
<tr>
<td>6 Sequelae, meniscal tear</td>
<td></td>
</tr>
<tr>
<td>7 Acute fracture</td>
<td></td>
</tr>
<tr>
<td>8 Sequelae, infection</td>
<td></td>
</tr>
<tr>
<td>9 Other:</td>
<td></td>
</tr>
<tr>
<td><strong>Reasons for revision (one or more):</strong></td>
<td></td>
</tr>
<tr>
<td>1 Loose prox. comp. 7 Malalignment</td>
<td></td>
</tr>
<tr>
<td>2 Loose distal comp. 8 Deep infection</td>
<td></td>
</tr>
<tr>
<td>3 Loose patella comp. 9 Fracture</td>
<td></td>
</tr>
<tr>
<td>4 Dislocated patella 10 Pain</td>
<td></td>
</tr>
<tr>
<td>5 Dislocation 11 Defect polyethylene:</td>
<td></td>
</tr>
<tr>
<td>6 Instability 12 Other:</td>
<td></td>
</tr>
<tr>
<td><strong>Type of revision (one or more):</strong></td>
<td></td>
</tr>
<tr>
<td>1 Change of distal component</td>
<td></td>
</tr>
<tr>
<td>2 Change of proximal component</td>
<td></td>
</tr>
<tr>
<td>3 Change of all components</td>
<td></td>
</tr>
<tr>
<td>4 Change of patella component</td>
<td></td>
</tr>
<tr>
<td>5 Change of polyethylene:</td>
<td></td>
</tr>
<tr>
<td>6 Removal. Component:</td>
<td></td>
</tr>
<tr>
<td>7 Insert of patella component</td>
<td></td>
</tr>
<tr>
<td>8 Other:</td>
<td></td>
</tr>
<tr>
<td><strong>Structural bone transplant:</strong></td>
<td></td>
</tr>
<tr>
<td>0 No 3 Bone impaction proximal</td>
<td></td>
</tr>
<tr>
<td>1 Autograft 4 Bone impaction distal</td>
<td></td>
</tr>
<tr>
<td>2 Allograft 5 Other:</td>
<td></td>
</tr>
<tr>
<td><strong>Systemic antibiotic prophylaxis:</strong></td>
<td></td>
</tr>
<tr>
<td>0 No 1 Yes Type: Combinations: Dosage: Duration (days):</td>
<td></td>
</tr>
<tr>
<td><strong>Duration of operation:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Peroperative complication:</strong></td>
<td></td>
</tr>
<tr>
<td>0 No 1 Yes Type:</td>
<td></td>
</tr>
<tr>
<td><strong>KNEE</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Prosthesis type:</strong></td>
<td></td>
</tr>
<tr>
<td>1 Tricondylar 3 Unicondylar</td>
<td></td>
</tr>
<tr>
<td>2 Bicondylar 4 Patellofemoral</td>
<td></td>
</tr>
<tr>
<td><strong>Femoral component:</strong></td>
<td></td>
</tr>
<tr>
<td>Name/size:</td>
<td></td>
</tr>
<tr>
<td>Catalogue no.:</td>
<td></td>
</tr>
<tr>
<td>Stem/Stabilized/Wedge:</td>
<td></td>
</tr>
<tr>
<td>1 Cement with antibiotic. Name:</td>
<td></td>
</tr>
<tr>
<td>2 Cement without antibiotic. Name:</td>
<td></td>
</tr>
<tr>
<td>3 Uncemented</td>
<td></td>
</tr>
<tr>
<td><strong>Tibial component:</strong></td>
<td></td>
</tr>
<tr>
<td>Name/size:</td>
<td></td>
</tr>
<tr>
<td>Catalogue no.:</td>
<td></td>
</tr>
<tr>
<td>Stem/Stabilized/Wedge:</td>
<td></td>
</tr>
<tr>
<td>1 Cement with antibiotic. Name:</td>
<td></td>
</tr>
<tr>
<td>2 Cement without antibiotic. Name:</td>
<td></td>
</tr>
<tr>
<td>3 Uncemented</td>
<td></td>
</tr>
<tr>
<td><strong>Patella component:</strong></td>
<td></td>
</tr>
<tr>
<td>Name/size:</td>
<td></td>
</tr>
<tr>
<td>Catalogue no.:</td>
<td></td>
</tr>
<tr>
<td>Metal-back 0 No 1 Yes</td>
<td></td>
</tr>
<tr>
<td>1 Cement with antibiotic. Name:</td>
<td></td>
</tr>
<tr>
<td>2 Cement without antibiotic. Name:</td>
<td></td>
</tr>
<tr>
<td>3 Uncemented</td>
<td></td>
</tr>
<tr>
<td><strong>Cruciate ligaments:</strong></td>
<td></td>
</tr>
<tr>
<td>1 Anterior, intact before operation 0 No 1 Yes</td>
<td></td>
</tr>
<tr>
<td>2 Anterior, intact after operation 0 No 1 Yes</td>
<td></td>
</tr>
<tr>
<td>3 Posterior, intact before operation 0 No 1 Yes</td>
<td></td>
</tr>
<tr>
<td>4 Posterior, intact after operation 0 No 1 Yes</td>
<td></td>
</tr>
<tr>
<td><strong>OTHER JOINTS:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Prosthesis type:</strong></td>
<td></td>
</tr>
<tr>
<td>1 Total</td>
<td></td>
</tr>
<tr>
<td>2 Hemi</td>
<td></td>
</tr>
<tr>
<td>3 One-component prosthesis</td>
<td></td>
</tr>
<tr>
<td><strong>Proximal component:</strong></td>
<td></td>
</tr>
<tr>
<td>Name/size:</td>
<td></td>
</tr>
<tr>
<td>Catalogue no.:</td>
<td></td>
</tr>
<tr>
<td>1 Cement with antibiotic. Name:</td>
<td></td>
</tr>
<tr>
<td>2 Cement without antibiotic. Name:</td>
<td></td>
</tr>
<tr>
<td>3 Uncemented</td>
<td></td>
</tr>
<tr>
<td><strong>Distal component:</strong></td>
<td></td>
</tr>
<tr>
<td>Name/size:</td>
<td></td>
</tr>
<tr>
<td>Catalogue no.:</td>
<td></td>
</tr>
<tr>
<td>1 Cement with antibiotic. Name:</td>
<td></td>
</tr>
<tr>
<td>2 Cement without antibiotic. Name:</td>
<td></td>
</tr>
<tr>
<td>3 Uncemented</td>
<td></td>
</tr>
<tr>
<td><strong>Intermediate component (e.g., caput humeri):</strong></td>
<td></td>
</tr>
<tr>
<td>Name/size:</td>
<td></td>
</tr>
<tr>
<td>Catalogue no.:</td>
<td></td>
</tr>
<tr>
<td><strong>Surgeon (who has filled in the form):</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Surgeon's name is not registered)</td>
</tr>
</tbody>
</table>
We apply the Kaplan-Meier method to estimate the prosthesis survival and the long-rank test to test the statistical significance of differences. We also use the Cox model, which is a multiple regression analysis of survival results, to calculate prosthesis survival with adjustment for differences between patients (e.g., age, gender, and diagnosis). In this way we may compare risks for revision for the different prosthetic designs, and assess the impact on the results of confounding factors such as age, gender, and diagnosis. Another way to handle differences between patients is to limit the inclusion of patients in the studies, for instance, to certain diagnostic groups, to only one gender, or most commonly, to a certain age group.

Intact implants in dead patients are followed from the primary operation until the date of death when they are censored, and the follow-up times are included in the survival analyses as censored observations. The dates of death are delivered by the Norwegian Population Registry. We have also performed studies on subgroups of patients through questionnaires regarding their function, level of pain, and satisfaction with their surgical outcome. It is, of course, also possible to receive additional information from the hospitals concerning x-ray findings and clinical performance. The statistical packages we most commonly apply are the BMDP (BMDP Statistical Software Inc., Cork, Ireland), SPSS (SPSS Inc., Chicago, IL, USA), and the S-PLUS (Statistical Sciences Inc., Seattle, WA, USA).

Reports to the Surgeons

All members of the Norwegian Orthopaedic Association receive our annual reports, and we provide the hospitals their own production statistics and survival results, which they can compare with the national result and with the results of other hospitals (Fig. 2). The hospitals’ results are confidential; although each hospital receives the results from other institutions for comparison, the names of the other institutions are masked. Results of different implant brands are presented at conferences and in scientific publications in international journals.

Staff and Economy

When the register started in 1987 we had a part-time secretary and the orthopaedic surgeons that participated worked for the register on a voluntary basis. The financial support was derived from funds mainly from the Norwegian Medical Association. Over the years, the staff has been increased and the Norwegian state now covers the operating expenses. At the present time the register has one full-time and one part-time secretary, and one position for an orthopaedic surgeon which is split between three physicians. We have one statistician who prepares our annual reports in addition to counseling the orthopaedic surgeons with their statistical work. The register has also one research fellow, who’s salary is financed from an external source.

Figure 2. Hospital-wise survival curves for primary total hip replacements. Each curve represents the overall prosthesis survival from one hospital. The hospitals are only informed about which curve is their own.

in by the surgeon immediately after each operation (Fig. 1). On the form, the surgeon provides the patient’s national personal identification number and information about diagnosis or reason for re-operation, approach, use of bone transplant, antibiotic prophylaxis, type of operating room, and preoperative complications. We register the acetabular, femoral, and head components separately, on catalogue number level, as many surgeons are using modular prostheses and commonly combine prosthetic parts from different systems. Stickers with catalogue numbers are delivered by the manufacturers along with the implants. The form contains only essential information, and it takes less than one minute to fill in. We register the name of the hospital where the operations are performed, but not the name of the surgeon.

Statistical Methods

In Norway, like in the other Scandinavian countries, each inhabitant has an individual national identification number. By the use of these numbers, we link revisions to the primary operations, and thus perform survival analyses of the implants. Revision is used as an end-point in the analyses, and we do not collect other follow-up data beyond information regarding the revision. As we register the type of revisions, and the reasons for the re-operations, prosthesis survival with revision due to aseptic loosening, dislocation, infection, fracture, osteolysis, or pain as an end-point, can be assessed. Further, we can assess the survival of the prosthesis components separately.
Table 1  Number of Arthroplasties Recorded in the Norwegian Arthroplasty Register* 1987-1998

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Hip:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>1,316</td>
<td>3,921</td>
<td>5,204</td>
<td>4,848</td>
<td>4,487</td>
<td>4,877</td>
<td>4,819</td>
<td>4,600</td>
<td>5,101</td>
<td>4,809</td>
<td>5,294</td>
<td>5,026</td>
<td>54,302</td>
</tr>
<tr>
<td>Revision</td>
<td>178</td>
<td>649</td>
<td>741</td>
<td>732</td>
<td>784</td>
<td>768</td>
<td>844</td>
<td>906</td>
<td>979</td>
<td>998</td>
<td>1,009</td>
<td>969</td>
<td>9,557</td>
</tr>
<tr>
<td>Knee:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>995</td>
<td>1,089</td>
<td>1,074</td>
<td>1,243</td>
<td>1,353</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5,754</td>
</tr>
<tr>
<td>Revision</td>
<td>75</td>
<td>86</td>
<td>107</td>
<td>121</td>
<td>109</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>499</td>
</tr>
<tr>
<td>Elbow:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>70</td>
<td>64</td>
<td>55</td>
<td>56</td>
<td>39</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>284</td>
</tr>
<tr>
<td>Revision</td>
<td>10</td>
<td>10</td>
<td>4</td>
<td>13</td>
<td>8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>45</td>
</tr>
<tr>
<td>Ankle:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>11</td>
<td>8</td>
<td>17</td>
<td>8</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>45</td>
</tr>
<tr>
<td>Revisions</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>9</td>
</tr>
<tr>
<td>Finger joints:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>335</td>
<td>237</td>
<td>193</td>
<td>218</td>
<td>211</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1,194</td>
</tr>
<tr>
<td>Revisions</td>
<td>14</td>
<td>32</td>
<td>34</td>
<td>25</td>
<td>22</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>127</td>
</tr>
<tr>
<td>Shoulder:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>121</td>
<td>116</td>
<td>121</td>
<td>145</td>
<td>114</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>617</td>
</tr>
<tr>
<td>Revisions</td>
<td>7</td>
<td>12</td>
<td>16</td>
<td>8</td>
<td>16</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>59</td>
</tr>
</tbody>
</table>

*Norway: 4.4 million inhabitants.

The total annual budget is about $160,000 US, and the cost per registered joint replacement is about $18.

Results

With our system, the participation of the surgeons has been practically 100%. As far as we have been able to control (with the Norwegian Institute for Hospital Research), we receive reports on more than 95% of the joint replacements that are performed. As the observation period is relatively short (only from 1994 for the other joints) most of our survival analyses and publications so far have been on the results of total hip replacement. The annual number of arthroplasties that have been reported are provided in Table 1.

Hip Replacements

The annual number of total hip replacements in this country (4.4 million inhabitants), is approximately 5,000 primary operations and 900 revisions. The annual incidence of primary total hip replacement is 114 per 100,000 inhabitants. The median age of the patients is 70 years for the primary operations, and 69% of the patients are women. In primary hip replacement, the uncemented acetabular cups have constituted about 18% and the uncemented stems about 12% of cases. In primary surgery, uncemented implants are mostly used in the younger age groups. In revisions, the use of uncemented cups has increased from 18% in 1987 to 29% in 1997, and uncemented stems from 15% in 1987 to 25% in 1997. Also the use of the bone impaction technique has been increasing in revisions during the last four to five years, and this technique is now used in 13% of cup revisions and in 21% of revisions of the femoral stems. A trochanteric osteotomy was performed in 26% of the operations in 1987, and this technique is now used in only 7% of the operations. With the cemented implants, the use of antibiotic containing cement, which is delivered by the manufacturers in Europe, has been increasing, and this type of cement is now used in about 90% of the cemented primary operations and in nearly 100% of the cemented revisions. The low-viscosity cement constituted about 4% in 1991, but low-viscosity cement has been abandoned in Norway after a publication from our register. Since 1994, systemic antibiotic prophylaxis has been used in practically 100% of the patients both in primary and revision total hip replacement.

The Charnley prosthesis has been the dominating hip implant in Norway and has been used in 50% of the primary operations. Except for the Charnley prosthesis, femoral heads with a diameter of 32 mm dominated during the first years of the register, but in 1997 this diameter was used in only 4% of the operations.

Concerning reasons for revision, aseptic loosening is still the dominating cause. However, there has been an increasing numbers of revisions performed due to osteolysis and wear of uncemented cups, and these were the reasons for 5% and 3% of the revisions in 1997, respectively.

Uncemented Hip Replacements

Short-term Results

When the hip register was established in 1987 it was important to assess the results of the many undocumented uncemented implants. In 1994 we compared the overall results of the uncemented implants that had been used from 1987 to 1993 with the overall results of the cemented implants. We found that the uncemented implants had inferior results compared to the cemented implants. Further,
we found the poorest results for the uncemented compared to cemented implants in the younger age groups, the patient groups in which the uncemented implants had been most commonly used.

Already in 1991, after three years of operating the register, we found inferior results for the uncemented smooth surfaced press-fit prostheses, such as the Bio-Fit. Also the threaded femoral stem, the Femora, and the uncoated threaded cups had inferior results, and these implants were abandoned.10,11 We found good short-term results for the uncemented femoral stems with circumferential porous coating or with hydroxyapatite coating. Of uncemented cups, we found good short-term results for those with either hydroxyapatite coating or porous coating. The designs with porous-coating or HA-coating are still used, mainly in the younger patients groups, whereas other designs of uncemented implants have been abandoned in Norway.

0-10 Years of Follow-up of Uncemented Acetabular Components

In a recent study presented at the 1999 SIROT meeting in Sydney, we assessed the results of uncemented cups again.12 In that study, uncemented cup designs that had been in use for more than five years were included. As a control we used the results from Charnley cups that had been inserted with high viscosity cement in patients of the same age. Endpoints in the survival analyses (Kaplan-Meier method) were revision of the cup due to any cause and revision due to aseptic loosening of the cup. Follow-up was 0-10 years. In patients under 60 years, we found that cups with HA coating on a smooth metal surface (n = 2,144) had inferior results compared to the Charnley cups (n = 1,754) with 8.5-years cumulative cup survival of 89% [95% confidence limits (CL): 87% to 91%] and 94% (95% CL: 92% to 96%) respectively (p = 0.001) (Fig. 3). Also with only revision due to aseptic loosening of the cup as an end point, the HA coated cups had inferior results compared to the Charnley cups (Fig. 4). The threaded HA-coated cups had better results than the hemispheric HA-coated cups (p = 0.05).

The porous-coated hemispheric cups (n = 1,197), had an 8.5-years survival of 92% (CL: 88% to 95%) which was slightly inferior to, but not statistically significantly different from, the Charnley cups (p = 0.06). Within the group of porous-coated cups there were large differences among the brands.

The uncoated threaded cups (n = 985) were statistically significantly inferior to all the other designs (p < 0.0001).

Cemented Hip Prostheses

Many different types of cemented total hip replacements have been in use in Norway. The Charnley prosthesis has dominated and has been used in more than 50% of total hip replacements. The short-term results of the 10 most commonly used cemented implants were published in 1995.13 For the cemented prostheses, the type of cement was more important to the results than the implant brand. A cement called the "Boneloc" was used in most European countries from 1991 to 1995. We demonstrated that already after 2.5 years, near 5% of the Charnley prostheses implanted with the Boneloc cement had been revised, compared to only 2% of the Charnley prostheses inserted with other types of cement.8 These results were important for the withdrawal of this cement from the market in Europe, and they were important for avoiding it from being introduced on the American market. Longer follow-up has yielded a revision rate of about 25% at five years for Charnley prostheses fixed with the Boneloc cement.14 With the smooth surfaced Exeter prosthesis, the results with Boneloc cement was better than when Boneloc was used with the Charnley prosthesis, however, it seems that even when used with the Exeter prosthe-
sis Boneloc cement provides inferior results. In Norway, only one type of low-viscosity cement (the CMW 3) had been in use. The results of this cement were significantly inferior compared to the high-viscosity cements, probably because of technical difficulties in maintaining a high cement pressure during the operation. The use of this cement has now been abandoned in Norway.

Prevention of Sepsis
In a study on the effect of different antibiotic prophylaxis regimens, we found that the combination of antibiotics given systemically and embedded in the cement gave a lower risk for revision due to sepsis than when antibiotics were given only systemically, only in the cement, or when no antibiotics were administered. Further, we found that the risk for revision due to aseptic loosening was lower if antibiotics were given as a combination, both systemically and in the cement, most probably because some low-grade infections were prevented.

Patient Related Risk Factors
In a study on the patient-related risk factors, we found that risk for revision of the total hip replacements was increased in older male patients above average height. An increased use of alcohol was associated with an increased risk for dislocation, and patients on anti-diabetic drugs or steroids had an increased risk for revision. Patients performing regular exercise and female patients performing strenuous work also had an increased risk for revision.

Hospital Category and Patient Volume
We analyzed the impact of hospital size and patient volume on the risk for revision of hip implants. In Norway the majority (52%) of the total hip replacements are performed in local county hospitals, 31% are performed in larger central hospitals, and 16% in university hospitals. We found that the risk for revision was lower in the local hospitals and in the central hospitals than in the university hospitals. This difference was related to a more common use of uncemented implants with inferior results in the university hospitals during the early years of the observation period. However, when we adjusted for the use of these inferior implants and for other known confounding factors, we also found slightly inferior results in the university hospitals. The reasons for this difference may be related to the lower number of hip replacement operations per surgeon in the university hospitals and to the training of young surgeons in these hospitals.

Patients' Function and Satisfaction
In a case-control study of patients reported to the Norwegian Arthroplasty Register we obtained information through a mailed survey that addressed the patients' satisfaction and function after primary and revision total hip replacement surgery. The 84% of the patients who did not undergo a revision during the period rated their overall satisfaction as good or very good, compared to 61% of the patients who had undergone both a primary operation and a revision. These findings underline the importance of a successful primary operation with a good prosthesis.

Diagnosis and Survival of Hip Prostheses
In unadjusted analyses of the total patients in the register, we found significant differences in revision rates among the diagnostic groups. However, after adjustment for prosthesis type and other confounding factors, and when we studied only patients with Charnley prostheses, most of the differences disappeared. Some smaller differences remained: increased revision risk among patients with sequelae after hip fractures and in patients with dysplasia with total dislocation; a lower risk was found among patients with dysplasia without dislocation. Reports of inferior results for other patient categories, therefore, seem to be related to the common coupling between young patients and use of inferior or undocumented uncemented implants.

Mortality of Patients with Total Hip Replacements
With data from the Arthroplasty Register and the Norwegian Population Registry, mortality for 35,938 patients with primary total hip replacement (THR) was compared with the mortality in the population with the same composition of age, sex, and date of birth. Overall the THR-patients had a lower mortality than the population [standardized mortality ratio (SMR) = 0.8], but a higher mortality than in the population was observed for THR patients under 60 years (SMR = 2.7), and for THR patients with rheumatoid arthritis (SMR = 1.6). During the first 60 postoperative days the mortality was increased for all patient groups. Patients with a primary operation and a later revision had the same mortality as patients with only a primary operation, and patients with a second primary operation had a lower mortality than those with only one primary operation, probably because of the selection of healthy patients.

Cost of Inferior Implants
The economic impact of the use of different inferior implants in hip replacement surgery in Norway was assessed in a study by Funes and colleagues.

Knee Replacement
The annual number of primary knee replacements in Norway was 1,228 in 1997, which is only 23% of the number of hip replacements in Norway. Thus, the number of knee replacements is much lower in the Norwegian population than in most other countries. Rheumatoid arthritis and ankylosing spondylitis was the reason for knee replacements in 19% of cases, but was the reason for primary hip replacements in only 4% of cases. Of the knee replacements, a cemented femoral component was used in 87% of cases and a cemented tibial component in 97%, thus 11% were
hybrids. Eight percent of the total knee replacements were revisions. The reason for revision was a loose femoral component in 16% of cases, a loose tibial component in 26%, patella problems (loosening, dislocation, or pain) in 14%, instability in 11%, polyethylene problems in 11%, and infection in 19% of the revisions.

Replacement of the Shoulder, Elbow, Ankle, and Finger Joints
In replacements of the elbow, ankle, and finger joints rheumatoid arthritis was given as the dominant diagnosis. For shoulder replacements 40% of the operations were performed due to rheumatoid arthritis, 14% due to primary osteoarthritis, 17% due to sequela after fracture, and 15% due to an acute fracture. For shoulder replacements, the hemi-arthroplasties dominated, constituting 90% of all shoulder replacements.

Discussion
Our approach to maintaining an arthroplasty register is through individual reports on every patient and every operation. Only in this way can we get information such as the patient’s age, gender, and diagnosis, which is important as these parameters might be unevenly distributed among the implants. For example, uncemented implants are most often given to young male patients. In our system we are able to adjust for these confounding factors by the use of multiple regression methods, by selecting limited age groups, diagnostic groups, or by assessing the results within male or female patients. By recording the individual data of all patients, the Norwegian Register is similar to the Finnish Implant Register and the Swedish Knee Register. Also in the Swedish Hip Register, individual data have been recorded since 1992.22 Another advantage is that in the Norwegian Register we can separately assess the survival of prosthesis components, such as the cup and the stem.

It can be argued that results from registries are not the same as results from prospective randomized studies. It is a problem that in the field of joint replacement surgery, too few prospective randomized studies are performed. Further, as the short-term results of joint replacement surgery generally are very good, well-designed randomized studies need to draw upon a very large number of patients over an extended follow-up period; therefore it is often many years before clear results can be ascertained and even longer before they appear in the medical literature. With a national register it is usually possible to determine the results earlier than it would be through randomized studies. An added benefit is that the results reflect the outcome for the average surgeon rather than from specialized centers. We have been able to find inferior results of implants at about three years if the differences are large. To find and document smaller differences, larger numbers of patients and longer observation is needed.

It can be questioned if revision is a too crude an endpoint to be used in register studies. Other parameters like pain, function, and x-ray findings might be used in smaller studies, but it would be impossible to get all the surgeons in a country to follow-up every one of their patients regularly and report these findings to the register. In a national register study, revision is therefore the only practical endpoint.

The Norwegian Arthroplasty Register has been a success considering the high level of participation by surgeons and hospitals; more than 95% of the operations performed in Norway are included in the database. The good compliance is probably due to the high motivation among the orthopaedic surgeons in Norway, which may be the result of the prosthetic catastrophes seen in the years before the register was established. However, we also think that the high level of compliance is due to the very simple system used for reporting and that the annual results are provided to surgeons and hospitals. In this way the results concerning the outcome of implants are immediately available and reinforces the need to complete reporting forms for the ongoing analyses performed by the register.

Other reporting systems in addition to a paper form have been considered. It is possible to let the surgeons put the data directly into a personal computer, and then submit the data over the Internet or on diskettes. However, our system is simpler for the surgeons, and some orthopaedic surgeons do not like to use a personal computer. We are, therefore, concerned that such a reporting system could cause a lower rate of reporting, but we are considering it as an optional reporting method in the future.

The economy has been a problem for most joint replacement registries, and certainly it was for ours during the first years. Now, our registry is fully funded by the state. In this way we are independent from the industry sponsorship. We feel that when it comes to publishing objective, non-biased results, it is preferable for a register to be independent from the manufacturers of the prostheses.

The names of the surgeons are not recorded in our registry; this decision was made in order to gain the complete participation from all the surgeons. Lawyers, patients, and health authorities have sometimes asked for the surgeons' individual results, but we are not able to provide this information. We believe that if the surgeons' names and individual results were made available or published, at least some surgeons might fear reporting their failures. The main aim of the register is to control the quality of implants and surgical routines. Our task is not to control the quality of surgeons, which rather must be watched locally in the hospitals.

It is a fact that a large number of the joint implants that are used have undocumented long-term results. The prosthetic catastrophes seen before are not expected for the implants used today, but it is still important to survey the results, especially of the new implants as well as when
modifications are done to the more established prostheses. So far, we have been able to detect clearly inferior results of certain implants in the short-term. It is important that in the future we assess the mid-term and long-term results of those implants that exhibited good short-term results. With longer observation, it will also be possible to find smaller differences. Many patients receive artificial joints each year; even a small increase in the percentage of revision, may indicate large numbers of unnecessary reoperations.

References


