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Development of a National Cruciate Ligament Surgery Registry

The Norwegian National Knee Ligament Registry

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Background: No prospective surveillance system exists for monitoring the outcome of cruciate ligament surgery.

Purpose: This article is intended to describe the development and procedures of the Norwegian National Knee Ligament Registry (NKLR), including baseline results from the first 2 years of operation.

Study Design: Cohort study (prevalence); Level of evidence, 1.

Methods: The NKLR was established on June 7, 2004 to collect information prospectively on all cases of cruciate ligament reconstruction surgery in Norway. Information on the details of surgery is gathered through a registration form completed by the surgeon postoperatively, and a validated knee outcome score form is completed by the patients preoperatively and at follow-ups on all patients at 2, 5, and 10 years postoperatively. Hospital compliance was examined in 2005 and 2006.

Results: A total of 2793 primary cruciate ligament reconstruction surgeries were registered by 57 hospitals. This corresponds to an annual population incidence of primary anterior cruciate ligament reconstruction surgeries of 34 per 100 000 citizens (85 per 100 000 citizens in the main at-risk age group of 16-39 years). After 21 months of operation, the NKLR had an overall compliance of 97% when compared with the hospital records.

Conclusions: A national population-based cruciate ligament registry has been developed, implemented, and maintained in Norway. The registry will each year enroll approximately 1500 primary cruciate ligament reconstruction cases. It is expected that inadequate procedures and devices can be identified, as well as prognostic factors associated with good and poor outcomes, at least for the most frequent categories.

Keywords: orthopaedics; anterior cruciate ligament; registry; epidemiology; incidence; outcome

National quality registries have been used in several medical specialties to improve health care in Scandinavia,[1,15,20,21,24,27,28,33] including Norway.[3,17,21,23] Because of the inferior clinical results associated with some hip prosthesis designs in the early 1980s,[10] the nationwide Norwegian Hip Arthroplasty Register (NAR) was established in 1987 with implant revision as the main end point.[14] Its aim was the early detection of inferior results caused by implants, cements, or surgical techniques.[6,11] In 1994, the registry was expanded to include all joint replacements.[11] In 1995, 2 papers[12,13] were published that described the detection of inferior implants at an early stage, a finding only possible through registry studies.

The NAR is based on a simple reporting system (approximately 1 minute is required to complete a single-page registration form) and the hospitals are provided with continuous feedback from the registry.[11] These 2 factors are believed to explain why the compliance rate of nearly 100% has not declined during 20 years of operation.[4,11] Immediately after each operation, the surgeon completes the registration form, which is mailed to the NAR office.[14] Patient identification and the different procedures, including the type of implant and cement used, are specified on

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the registration form. Feedback is given as annual national reports. In addition, each hospital receives a report on its own activities and results, which can be compared with the national average. A wide range of studies have been published based on the NAR database.[11]

In contrast to joint replacement surgery, for which national registries have been established in Norway, Sweden (1979), Finland (1980), Denmark (1995), Australia (1999), New Zealand (1999), Canada (2000), Romania (2001), and England and Wales (2003), no national prospective surveillance system exists for monitoring the outcome of knee ligament surgery in a predefined population. Evidence from the Scandinavian joint replacement registries indicates that a national knee ligament registry could be highly beneficial.[12,13,16,26] First, treatment outcome can be improved through feedback to the hospitals and surgeons from the registries. Second, there are still several unresolved issues related to cruciate ligament surgery and postoperative rehabilitation methods. Some of these can and should be addressed by conducting properly designed randomized controlled trials. However, because of practical, financial, or other restraints, such studies are often not possible. Also, some questions can only be answered by large cohort studies. This includes the detection of procedures and devices that result in premature failure. Third, large cohort studies can be used to identify prognostic factors associated with good and poor outcomes.

This background served as the impetus for designing the Norwegian National Knee Ligament Registry (NKLR). This article describes the development and procedures of the first national knee ligament registry, including baseline results from the first 2 years of operation.

MATERIALS AND METHODS

Structure

A working group was established with members from NAR and the Oslo Sports Trauma Research Center (OSTRC) in 2002. The group designed the registry, constructed forms, planned the logistics, and contacted the hospitals. The NKLR is owned by the Norwegian Orthopaedic Association (NOA), and a steering committee with 6 members is appointed jointly by NOA and OSTRC. Since the official start on June 7, 2004, the steering committee has been responsible for the budget, planning, and continuous evaluation of the dataset.

Design

The NKLR is designed to collect information prospectively on all cases of cruciate ligament reconstruction surgery. To be included in the cohort, a patient should be a resident of Norway undergoing primary or revision reconstruction surgery for an anterior cruciate ligament (ACL) and/or posterior cruciate ligament (PCL) injury at a Norwegian hospital. In addition, the NKLR also records all surgical procedures to a knee joint that has previously undergone primary or revision ACL and/or PCL reconstruction surgery.

Participation is voluntary, and all patients are asked to sign an informed consent form before surgery. The consent form contains information about the NKLR, the type of information recorded, data protection, and the procedure for follow-ups, and informs the patient that he or she may be invited to participate in research projects at a later stage. The patients are also asked to complete a validated knee outcome score form, the Knee injury and Osteoarthritis Outcome Score (KOOS).[22] The KOOS form is a knee-specific instrument, developed to assess patients' opinion about their knees and associated problems, and was intended to be used for knee injuries that could result in posttraumatic osteoarthritis.

The form includes 42 items in 5 separately scored subscales: pain (9 items), other symptoms (7 items), function in activities of daily living (17 items), function in sport and recreation (5 items), and knee-related quality of life (4 items). Each item is responded to by marking 1 of 5 response options on a Likert scale. The Western Ontario and McMaster Universities (WOMAC) LK 3.0^2 items are included in the first 3 KOOS subscales. The KOOS is valid and reliable for short-term and long-term follow-up studies of knee injury and osteoarthritis.[30-32] It is also valid for patients in the age group 14 to 78 years of age. The KOOS was considered reliable and responsive for assessment of knee complaints in a recent comparative review of knee-specific outcome measures.[7] Confidentiality is ensured for patients and individual surgeons. The study has been approved by the Data Inspectorate as an expansion of the NAR concession.

The registry makes use of both objective and subjective end points. Similar to NAR, the hard end points are revision surgery after cruciate ligament surgery and total knee replacement. Unlike NAR, the NKLR will include routine follow-ups on all patients at 2, 5, and 10 years postoperatively using KOOS score as a soft end point. The KOOS form will be dispatched from the NKLR secretariat at the time for follow-ups. The NKLR will offer different ways of returning the completed KOOS forms, such as regular mail and Internet, as an attempt to ensure a high compliance rate. The KOOS form is not returned to the patient if incomplete. Missing data are treated according to the guidelines for KOOS score calculation.[31]

Registration Process

After pilot testing at 3 hospitals, the registration form (Appendix 1) has been developed to collect information on the details of surgery. One form is completed for each knee joint undergoing surgical treatment. Similar to NAR, the form is completed by the surgeon immediately after surgery has been performed.

The data items recorded are a minimal set suited for a paper-based or web-based reporting system, not to exceed 1 page. The items were chosen based on the following 3 criteria. Can the question addressed be clearly specified and justified? Is the question clinically relevant? Can the item be completed postoperatively while dictating the surgery notes, not needing to seek information from other sources?

Cartilage lesions are graded according to the International Cartilage Repair Society.[34] To obtain accurate information on the different fixation devices, it is recommended that the surgeon report the catalog number of each device by using the unique bar-code stickers delivered by the manufacturers. The stickers contain all vital information about the device. The surgeon signs the form, but the surgeon's identity is not recorded, and thus cannot be traced in the registry.

One copy of the registration form is sent to NKLR and the original is retained in the patient's hospital chart. On arrival at the NKLR, the KOOS and registration forms are checked for completeness and entered into a computerized data management system. This is developed as an Oracle database (Oracle Corporation, Redwood Shores, Calif) with clerical and electronic data checks, as well as automated coding and reporting facilities. After registration, the data are further checked to ensure the quality, eliminate possible duplicates and illogical combinations in the form, and ensure conformity between registration and KOOS forms.

A copy of the registration form is returned to the hospital if the form is incomplete (eg, if essential data such as the date of operation or the social security number are missing). If the form is not returned after 1 reminder or the data cannot be found, the form is marked as incomplete and labeled "missing" for the missing data, thus retaining the possibility of using incomplete forms in the analysis.

The patients are identified by their unique social security number (including date of birth), which is assigned to all Norwegian residents. The social security number is used to link the KOOS and registration forms, and to update the registry annually with death and emigration data before extracting data files for analysis.

Compliance

A first baseline compliance study was carried out in March 2005 covering the period October 1, 2004 through February 28, 2005. The study covered primary ACL reconstructions and ACL revision surgeries, not other procedures. Data from the NKLR were compared with the Norwegian Patient Register (NPR), which has been established by the Ministry of Health and Social Services to provide statistics from the Norwegian hospital sector, as well as with patient data from hospital records. The NPR has been used as a gold standard by NAR.[4] Ten hospitals participated, representing all 5 health regions, hospitals with large and small volumes (cut-off was set at 30 annual ACL procedures), public and private hospitals, and hospitals with and without surgeons who were involved in developing NKLR. Based on preliminary data, we estimated that at least 250 cases could be expected from these hospitals, which would give the study sufficient power. All of the 10 invited hospitals agreed to participate.

A second study was performed in 2006 covering the period October 1, 2005 through February 28, 2006. This study used the same procedures as described for the baseline compliance study with 2 exceptions. Some of the hospitals dispatched the data electronically (electronic patient journals), and the surgical log books were used as the gold standard. This study covered 14 randomly chosen hospitals participating in the NKLR.

Research and Information

Requests for data from the NKLR are encouraged, and data files are returned to the surgeon or hospital in question after approval of a written request addressed to the steering committee. Only the official hospital contact can ask for patient-identifiable information from his or her own hospital. Some legal restrictions exist, primarily the combination of NKLR with other population-based registries in Norway. Requests for more extensive data for research projects also require a written application to the steering committee. If external researchers wish to combine data from the NKLR with their own data files, specific approval is required from the Data Inspectorate and the appropriate Regional Committee for Medical Research Ethics.

Descriptive national data are provided in an annual report, which is sent to all members of the NOA, all hospitals performing cruciate ligament surgery, and to the health authorities. This report is also published on the joint website of NAR and NKLR (www.haukeland.no/nrl). In addition, each participating hospital will receive descriptive statistics and outcome data for their own hospital, which they can compare with the national report.

Staff and Operating Costs

The NKLR employs a secretary (50% position), a computer engineer (50%), and an orthopaedic surgeon (20%) as the administrative head of NKLR. In addition, each hospital provides secretarial assistance amounting to approximately 10% of a full position. The total operating budget for 2006 for the central NKLR office is 527 000 krones (approximately 67 000 euros, or 91 000 US dollars). This cost does not include salary for additional staff involved in various research projects based on the NKLR. It is expected that the basic operating costs will increase somewhat as the cohort and number of follow-ups increase year by year.

RESULTS

Descriptive Data

From June 7, 2004 until May 24, 2006 (687 days), 2793 primary cruciate ligament reconstruction surgeries were registered by 57 hospitals. This corresponds to an annual rate of 1484 primary cruciate ligament reconstructions in Norway, 1168 of them in the age group 16 through 39 years (the main population at risk). In 2005, there were 4 393 000 citizens in Norway, 1 382 000 of them aged 16 through 39 years. Thus, the annual population incidence of primary ACL reconstruction surgeries was 34 per 100 000 citizens, while the incidence in the 16 to 39 years age group was 85 per 100 000 citizens.

Of the 2793 cases recorded in the NKLR, 2714 were primary ACL reconstructions, 25 were primary PCL reconstructions, and 54 were combined primary reconstructions of both cruciate ligaments.

How Complete Are the Data?

The baseline compliance study identified 285 cases in the NKLR database, 332 in the hospital protocols, and 339 at

TABLE 1
Patient Characteristics for All Primary Cruciate Ligament Reconstruction Surgery Cases[a]

Characteristics	ACL (n = 2714)	PCL (n = 25)	ACL and PCL (n = 54)
Sex (% male)	57	72	59
Age (median, range)	27 (12-67)	28 (17-57)	34 (15-36)
Previous ACL or PCL injury to opposite knee	191	0	4
Most frequent activities causing injury	Soccer (n = 1088) Team handball (n = 413) Alpine skiing (n = 270)	Traffic (n = 8) Soccer (n = 7)	Traffic (n = 15) Cross-country skiing (n = 10) Alpine skiing (n = 6)
Median time to surgery in months (range)	7 (0-416)	13 (6-170)	7 (0-104)
Outpatient surgery (%)	35	0	4
Perioperative complications (%)[b]	5	0	0
Prophylactic antibiotics (%)	99	100	100
Prophylactic anticoagulation (%)[c]	77	90	94

[a]ACL, anterior cruciate ligament; PCL, posterior cruciate ligament.
[b]Most often due to failure of devices or grafts.
[c]Incorporated into the form January 2005.

TABLE 2
Group-Specific Preoperative KOOS Scores[a]

Subscale	Primary ACL Group (n = 2426)	Primary PCL Group (n = 24)	Primary ACL and PCL Group (n = 51)
Pain	72.9 ± 18.2	62.6 ± 17.9	69.2 ± 25.8
Symptoms	71.5 ± 17.8	71.1 ± 15.6	72.3 ± 18.9
Activities of daily living	81.2 ± 18.4	75.2 ± 16.2	68.4 ± 27.3
Sports/recreation	40.9 ± 26.5	35.2 ± 25.0	31.3 ± 32.2
Quality of life	34.0 ± 18.2	33.1 ± 15.4	31.9 ± 28.9

[a]Data are shown as the mean with standard deviation for each subscore.
KOOS, Knee injury and Osteoarthritis Outcome Score; ACL, anterior cruciate ligament; PCL, posterior cruciate ligament.

the NPR. Thus, after 4 to 9 months of operation, the NKLR had a compliance of 84% in relation to the NPR among the hospitals participating. At this time, 51 out of a possible total of 56 hospitals and clinics (91%) took part.

The second compliance study identified 195 cases in the NKLR database, 202 in the protocols at the hospitals, and 181 at the NPR (1 private hospital with 18 cases recorded in the NKLR database did not report to the NPR). Thus, after 16 to 21 months of operation, the NKLR had compliance of 97% and 98% in relation to the hospital protocols (195/202) and NPR (177/181), respectively. By the end of the study period, all hospitals and clinics (N = 57) participated in the NKLR, although the last hospital was not included until the final 2 months of the second compliance study period.

Primary ACL Reconstructions

A total of 2714 primary ACL reconstruction surgeries were performed at 57 different hospitals. Of these, 1717 patients (63%) underwent surgery within a year of the index injury, while 285 (11%) waited more than 5 years before surgery (101 cases have missing information). The characteristics and preoperative KOOS scores for this group are outlined in Tables 1 and 2. Patients who had waited more than 5 years before surgery did not differ significantly in their KOOS scores from the rest of the patients with primary ACL reconstructions (data not shown). A total of 578 patients (21%) had previously undergone surgery (all specified) to the index knee. In 10 cases (<1%), a PCL injury was also reported, but not treated surgically. In 27 cases (1%), a lateral collateral ligament (LCL) injury was reported, while a medial collateral ligament (MCL) injury was reported in 129 cases (5%). A total of 1287 cases (47%) had associated meniscal tears; 90% of these were treated surgically.

Cartilage lesions were reported in 712 knees (26%), and 59% of these were treated surgically. When grading the cartilage lesions, 222 cases (31%) were classified as grade 1, 283 (40%) as grade 2, 151 (21%) as grade 3, and 49 (7%) as grade 4; 7 cases had missing grading. In 392 cases (55%), the largest lesion measured 2 cm^2 or less, while in 271 cases (38%), at least 1 lesion was greater than 2 cm^2 (49 knees with cartilage lesions did not report measurements). A total of 80 patients (11%) had grade 3 or 4 cartilage lesions of more than 2 cm^2.

In 1105 cases (41%), a bone–patellar tendon–bone autograft was used, while a hamstring autograft was used in 1597 cases (59%). Only 11 (<1%) of the primary ACL reconstruction surgeries were done with other graft types. The number of different fixation devices used is shown in Table 3.

Primary PCL Reconstructions

A total of 25 primary PCL reconstruction surgeries were performed by 4 different hospitals. Of these, 10 patients (40%) received surgery within a year of the index injury, while 5 (20%) waited more than 5 years before surgery. The

TABLE 3
The Number of Different Devices Used on the Femur and Tibia for ACL and PCL Fixation[a]

	ACL		PCL	
	Femur Fixation	Tibia Fixation	Femur Fixation	Tibia Fixation
ACL	29	33	7	11
PCL	6	4	10	7
MCL	4	4	2	1
LCL	1	1	1	1
PLC	1	2	1	2

[a]The data are based on all primary (N=2793) or revision (N=31) reconstruction surgery cases.

ACL, anterior cruciate ligament; PCL, posterior cruciate ligament; MCL, medial collateral ligament; LCL, lateral collateral ligament; PLC, posterolateral corner.

characteristics and preoperative KOOS scores for this group are outlined in Tables 1 and 2. A total of 3 patients (12%) had previously undergone surgery (all specified) to the index knee. In 2 cases (4%), a posterolateral corner (PLC) injury was reported, while an MCL injury was reported in 5 cases (20%). Two cases (8%) had associated meniscal tears; neither of these were treated surgically.

Cartilage lesions were reported in 10 knees (40%), and 40% of these were treated surgically. When grading the cartilage lesions, 8 cases (80%) were classified as grade 2, and 2 (20%) as grade 3. In 2 cases (20%), the largest lesion measured 2 cm^2 or less, while in 8 cases (80%) at least 1 lesion was greater than 2 cm^2. One patient (4%) had grade 3 or 4 cartilage lesions of more than 2 cm^2.

In 4 cases (16%), a bone–patellar tendon–bone autograft was used, while a hamstring autograft was used in 19 cases (76%). Only 2 (8%) of the primary PCL reconstruction surgeries were done with other graft types.

Combined Primary ACL and PCL Reconstructions

A total of 54 combined primary ACL and PCL reconstruction surgeries were performed by 6 different hospitals. Of these, 38 patients (70%) received surgery within a year of the index injury, while 3 (6%) waited for more than 5 years before surgery. The characteristics and preoperative KOOS scores for this group are outlined in Tables 1 and 2. A total of 4 patients (7%) had previously undergone surgery (all specified) to the index knee. In 18 cases (33%), a PLC injury was reported; in 4 cases (7%), an LCL injury was reported; and an MCL injury was reported in 30 cases (56%). A total of 17 cases (31%) had associated meniscal tears; 82% of these were treated surgically.

Cartilage lesions were reported in 26 knees (48%), and 35% of these were treated surgically. When grading the cartilage lesions, 3 cases (12%) were classified as grade 1, 10 (38%) as grade 2, 9 (35%) as grade 3, and 4 (15%) as grade 4. In 9 cases (35%), the largest lesion measured 2 cm^2 or less, while in 17 cases (65%) at least 1 lesion was greater than 2 cm^2. Eight patients (31%) had grade 3 or 4 cartilage lesions of more than 2 cm^2.

In 41 of the 54 combined cases (76%) a bone–patellar tendon–bone autograft was used to reconstruct the ACL, while a hamstring autograft was used in 10 cases (19%) and other graft types were used in 3 cases (6%). To reconstruct the PCL, a bone–patellar tendon–bone autograft was used in 1 case (2%), a hamstring autograft was used in 37 cases (69%), another graft type was used in 7 cases (13%), while in 9 cases (17%) the PCL injury was not reconstructed.

Revision ACL and/or PCL Reconstructions

A subgroup of 31 of the 2793 patients (1.1%) included from the start of the NKLR was recorded as undergoing cruciate ligament revision surgery during the period. Of these, there are 28 patients from the primary ACL surgery group, 2 from the primary PCL surgery group, and 1 from the group that had primary reconstruction of both the ACL and PCL. The median time to revision surgery was 300 days (range, 2-593). There was no difference in their preoperative KOOS score between primary surgery and revision surgery (data not shown).

DISCUSSION

This article describes the development of the world's first national cruciate ligament surgery registry, its design, procedures, and characteristics of patients included. The results show that in 2 years of operation, nearly all patients undergoing cruciate ligament surgery were included in the registry. Based on these data, it may be expected that the NKLR each year will enroll approximately 1460 primary ACL reconstruction cases, 10 primary PCL reconstructions, and 30 combined primary reconstructions. In the future, the registry will also record revision reconstruction surgery and other surgical procedures to all knee joints previously recorded in the registry.

Patient registries are established to improve the standard of health care. Specifically, they are meant to serve 3 purposes: to improve treatment outcomes through feedback to the hospitals and surgeons, to detect procedures and devices that result in premature failure, and to identify prognostic factors associated with good and poor outcomes. However, to serve these purposes, the accuracy of the outcome measures used is critical. The joint registries, including NAR, only use revision surgery as an end point. Thus, patients may have a poor result without this being registered. In contrast, in addition to revision surgery, NKLR also includes routine follow-ups with patient-reported KOOS scores as the primary end point. The KOOS scores are collected preoperatively from the patients, as well as after 2, 5, and 10 years postoperatively. The intention is to detect inferior results and early failures, regardless of whether patients with a failed graft decide to go through revision surgery or not. Also, at a later stage, data from NKLR can be combined with data from NAR on knee arthroplasties, thus using surgically verified severe osteoarthritis as an additional end point.

The choice of the KOOS form over other alternatives took a number of elements into consideration: The form

should be patient-based to allow for nonbiased outcome data. The form should be self-explanatory, and time required to complete the form should be kept to a maximum of 10 minutes to ensure good compliance at follow-ups. Finally, the form had to be validated for cruciate ligament surgery. These requirements left us with two choices: KOOS or International Knee Documentation Committee (IKDC) 2000.[18,19] We chose the KOOS form because, in our opinion, it is far more user-friendly from a patient's perspective than the IKDC 2000. However, it remains to be seen how well patients will comply with the follow-up procedures.

To serve its first purpose, to improve treatment outcomes through continuous feedback to the participating hospitals, each year hospitals are provided with results on their own patients and national data. This is based on the idea that hospitals able to compare their outcomes with national averages will improve by following the better examples. An annual report is sent to all the members of the NOA, to all hospitals performing cruciate ligament surgery, and to the health authorities, and also published on the joint website of NAR and NKLR (www.haukeland.no/nrl). The NKLR depends on participation from all orthopaedic surgeons performing cruciate ligament surgery, including those normally not involved in research. Feedback is therefore also important to maintain motivation and interest in the registry, and we believe the reporting procedure explains the high compliance with the registry observed. Based on our previous experience with NAR, it may be expected that compliance will remain high. This is based on the premise that there will be no additional demands on the surgeons except filling out the forms, and that NKLR will serve the hospitals with clinically relevant and important information.

The second purpose, to detect procedures and devices that result in premature failure, can be achieved based on revision surgery or, if a revision has not been performed, deterioration of the KOOS score.[29] The following example illustrates this point. A score of at least 60 points may be expected with a successful outcome after surgery.[31] Age- and sex-specific general population reference values are also available for all 5 KOOS subscales.[29] A change in the KOOS score of 10 points can be considered a clinically significant difference—as an improvement after surgery or deterioration after graft failure.[29] Thus, the number of patients needed to detect failure in a cohort study may be calculated. Assuming a more conservative estimate, that a difference of 20 points is sufficient to predict an inferior device or procedure, as few as 14 failures are needed, using standard statistical values. These estimates also apply if the purpose is to discover prognostic factors that are associated with good or poor outcomes. For example, there are many patients with large cartilage lesions (>2 cm^2) and lesions graded 3 or 4 that are of special interest as their treatment outcome may be less predictable. Thus, because it may be estimated that the registry will include 2-year outcome data on at least 6500 patients with isolated ACL reconstructions after 7 years of operation, it seems reasonable to assume that the registry will be able to provide relevant data on inadequate procedures and devices. However, less common procedures and devices will be difficult to assess, and it should be noted that the frequency of devices in use varies considerably (Table 3). Also, as shown in the results, isolated PCL reconstructions and combined ACL/PCL reconstructions are much less frequent than isolated ACL reconstructions, and for these procedures it will be difficult to study subgroups, even with a national registry. However, this may be achieved when the registries of Sweden, Denmark, and Norway are combined.

It may be argued that randomized controlled trials (RCTs) are better than cohort studies to assess the outcome of cruciate ligament surgery. Although RCTs are preferable to address specific research questions, such as comparing 1 surgical procedure to another, they are difficult to organize, time-consuming, and costly. Therefore, it is often not possible or even justified to conduct an RCT to address anything but major differences in procedures or devices. One example may be minor changes in screw design or materials. A national registry can be used to assess results with minimal additional work or cost. However, it should be noted that in a nonrandomized cohort study, confounding factors must be adjusted for, either by selection of homogeneous subgroups or by use of a multiple regression model when analyzing the results.[12]

An important limitation of the registry is that only surgically treated cruciate injuries are included. Some studies have shown that most cruciate ligament-injured patients will see medical care and thus could be entered into the registry.[9] However, because of logistic and diagnostic issues, we have decided to not include this group at this stage.

The annual Norwegian population incidence of primary ACL reconstruction surgeries was 34 per 100 000 citizens, while the incidence in the 16- to 39-year-old age group was 85 per 100 000 citizens, both higher than previously published. Based on a questionnaire to all Norwegian hospitals in 2001 and 2002-2003, we estimated the annual incidence to be 42 ACL surgeries per 100 000 citizens.[8] However, because we do not know the ratio of surgically treated versus conservatively treated cases, the population incidence of ACL injuries is not known. In Germany, this has been estimated to be 32 per 100 000 citizens in the general population, and 70 per 100 000 citizens among the more physically active.[25] A recent study from 1 emergency department in Sweden reported that the physically active population between 10 to 64 years of age had an annual incidence of ACL injuries of 81 per 100 000 citizens.[5] However, the present study is the first extensive and complete population-based survey and from our data it appears that the true population incidence may be 50% to 100% higher, as in our experience as many as 30% to 50% of all ACL-injured subjects do not undergo surgery.

In conclusion, this study shows that a national population-based cruciate ligament registry could be developed, implemented, and maintained in Norway, providing data on more than 95% of all patients undergoing cruciate ligament surgery. The registry will each year enroll approximately 1460 primary ACL reconstruction cases, 10 primary PCL reconstruction cases, and 30 cases of primary reconstruction of both cruciate ligaments. It may be expected that the registry can enable us to identify inadequate procedures and devices,

as well as prognostic factors associated with good and poor outcomes, at least for the most frequent categories.

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APPENDIX

NATIONAL KNEE LIGAMENT REGISTRY
Norwegian Arthroplasty Register
Department of Orthopedic Surgery
Haukeland University Hospital
Møllendalsbakken 11
N-5021 BERGEN, NORWAY
Tlf: (+47) 55976450

Patient ID and date of birth (11 digits).....

Name.....

Hospital.....

CRUCIATE LIGAMENTS

CRUCIATE LIGAMENT SURGERY AND ALL REVISIONS on patients with previous cruciate ligament surgery.
All stickers (except patient ID) are pasted in predefined columns on the back of the form.

INDEX SIDE (mark one) (Bilateral surgery= 2 forms)
☐0 Right ☐1 Left

OPPOSITE KNEE ☐0 Normal ☐1 Previous ACL/PCL-injury

PREVIOUS SURGERY IN INDEX KNEE (one or more)
☐ ACL ☐ MCL ☐ PLC ☐ Medial meniscus
☐ PCL ☐ LCL ☐ Cartilage ☐ Lateral meniscus
☐ Other, specify .....

DATE OF INJURY (mm.yy) |__|__|__|__|

ACTIVITY THAT LEAD TO INJURY
☐0 Soccer ☐6 Martial arts ☐12 Work
☐1 Handball ☐7 Basketball ☐13 Traffic
☐2 Alpine skiing ☐8 Cross country skiing ☐14 Volleyball
☐3 Snowboard ☐9 Recreational activities ☐15 Skateboard
☐4 Ishockey/bandy/ inline skating ☐10 Outdoor life ☐16 Trampoline
☐11 Other recreational activities ☐17 Dance
☐5 Racket sports

☐98 Other.....

ACTUAL INJURY (Register all injuries – independent of surgery)
☐ ACL ☐ MCL ☐ PLC ☐ Menisci
☐ PCL ☐ LCL ☐ Cartilage
☐ Other.....

FURTHER INJURIES (none, one or more)
☐ Vasular
☐ Nerve — Specify: ☐0 N. tibialis ☐1 N. peroneus
☐ Fracture — ☐0 Femur ☐1 Tibia ☐2 Fibula ☐3 Patella ☐4 Not sure
☐ Rupture in extensor apparatus — ☐0 Quadriceps tendon ☐1 Patellar tendon

DATE OF SURGERY (dd.mm.yy) |__|__|__|__|__|__|

ACTUAL SURGERY (mark one)
(If none, skip to the next question)
☐0 Reconstruction of cruciate ligament ☐1 Revision

OTHER PROCEDURES (none, one or more)
☐ Meniscus surgery ☐ Osteosynthesis
☐ Synovectomy ☐ Cartilage surgery
☐ Mobilizing in narcosis ☐ Arthroscopic débridement
☐ Remove implant ☐ Surgery due to infection
☐ Bone resection (Notchplasty) ☐ Bone transplantation
☐ Osteotomy ☐ Artrodesis
☐ Other .....

CHOICE OF GRAFT (see back for instructions)

	ACL	PCL	MCL	LCL	PLC
☐ BPTB					
☐ ST – double					
☐ ST – quadruple					
☐ STGR – single					
☐ STGR – double					
☐ STGR - quadruple					
☐ BQT					
☐ BQT-A					
☐ BPTB-A					
☐ BACH-A					
☐ Suture					
☐ Synthetic graft					
☐ Other					

FIXATION DEVICES
Paste stickers in predefined columns on the back of the form
Differentiate between femur and tibia

ACTUAL TREATMENT OF MENISCAL LESION

	Resection	Suture	Synthetic fixation*	Meniscus Transplant.	Tre-panation	None
Med.	☐	☐	☐	☐	☐	☐
Lat.	☐	☐	☐	☐	☐	☐

* Paste stickers in predefined columns on the back of the form

CARTILAGE LESION (none, one or more. Remember to fill in the area)
Injury: ☐ new ☐ old ☐ undefined

	Size: Area (cm^2) ≤2	Size: Area (cm^2) >2	ICRS Grade* (1-4)	Probable cause** (1-5)	Treatment code*** (1-9)
Patella MF	☐	☐			
Patella LF	☐	☐			
Trochlea fem.	☐	☐			
Med. fem. cond.	☐	☐			
Med. tib. plat.	☐	☐			
Lat. fem. cond.	☐	☐			
Lat. tib. plat.	☐	☐			

***ICRS Grade:** 1 Nearly normal: Superficial lesions, soft indentation and/or superficial fissures and cracks; 2 Abnormal: Lesions extending down to <50% of cartilage depth; 3 Severely abnormal: Cartilage defects extending down >50% of cartilage depth as well as down to calcified layer; 4 Severely abnormal: Osteochondral injuries, lesions extending just through the subchondral boneplate or deeper defects down into trabecular bone.
** **Probable cause:** 1 Trauma; 2 CM: chondromalacia patellae; 3 OCD: osteochondritis dissecans; 4 OA: primary osteoarthritis; 5 Other: Specify cause in correct column
*** **Treatment code**: 1 Debridement; 2 Microfracture; 3 Mosaic; 4 Biopsy for cultivation; 5 Cell transplantation; 6 Cell transplantation with matrix; 7 Periosteum transplantation; 8 No treatment; 9 Other: Specify cause in correct column

OUTPATIENT SURGERY ☐0 No ☐1 Yes

PER OPERATIVE COMPLICATIONS ☐0 No ☐1 Yes,
which.....

DURATION OF SURGERY (skin to skin-time).....min.

SYSTEMIC ANTIBIOTIC PROPHYLAXIS ☐0 No ☐1 Yes
Name (A) .....
Dosage (A)..... Total number of dosages .....Duration .....hours
.....
Dosage (B)..... Total number of dosages .....Duration .....hours

TROMBOSIS PROPHYLAXIS
☐0 No
☐1 Yes, name .....
Dosage ..... Duration.....days
First dosage given preoperative ☐0 No ☐1 Yes
If second prophylaxis is used: .....
Dosage ..... Duration.....days
Stocking ☐0 No ☐1 Calf ☐2 Thigh Duration.....days
Other, specify .....

Surgeon:.....
Surgeon that filled in the form (surgeon's name is not registered).