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Knee function and sports participation after nonoperative and operative treatment of anterior cruciate ligament injuries

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A great deal more is known than has been proved

Richard Feynman

Acknowledgments

As I am writing the last words of this PhD dissertation, there are over 12,000 published papers on various topics concerning the ACL. The four papers included in the dissertation are both the result of a substantial amount of research already done, and ground work necessary to complete future research plans. Similarly, my role in the work we have done and will continue to do on this project is one of many. The work presented in this dissertation is a result of the research collaboration between the Norwegian Research Center for Active Rehabilitation (NAR) and the University of Delaware. Collectively, the Delaware and Oslo principal investigators, professors Lynn Snyder-Mackler and May Arna Risberg, have contributed to over 100 publications on ACL injuries. It is hard to imagine a better research environment for a PhD student.

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Abbreviations

ACL – Anterior cruciate ligament
ANOVA – Analysis of variance
AR1 – First order autoregressive
BPTB – Bone patellar tendon bone
CI – Confidence interval
GEE – Generalized estimating equations
GPS – Global positioning system
GRRAS - Guidelines for reporting reliability and agreement studies
GRS – Global rating scale
ICC – Intraclass correlation coefficient
IKDC 2000 - The International Knee Documentation Committee Subjective Knee Form
KOOS – Knee Injury and Osteoarthritis Outcome Score
KOS-ADLS – Knee Outcome Survey – Activities of Daily Living Scale
LCL – Lateral collateral ligament
LSI – Limb symmetry index
MCL – Medial collateral ligament
MDC – Minimum detectable change
MERIT – Method to extend research in time
MRI – Magnetic resonance imaging
MVIC – Maximal voluntary isometric contraction
NAR – Norwegian Research Center for Active Rehabilitation
NIH – National Institutes of Health
NIMI – Norwegian Sports Medicine Clinic
PCL – Posterior cruciate ligament
ROC – Receiver operating characteristic
ROM – Range of motion
SD – Standard deviation
SEM – Standard error of measurement
STROBE - Strengthening the reporting of observational studies
SURF – Surgical risk factor
UDel – University of Delaware
US – United States

List of papers

This PhD dissertation is based on the following four papers, which will be referred to in the text by their roman numerals:

- I Grindem H, Eitzen I, Moksnes H, Snyder-Mackler L, Risberg MA. A pair-matched comparison of return to pivoting sports at 1 year in anterior cruciate ligament-injured patients after a nonoperative versus an operative treatment course. *Am J Sports Med* 2012;40(11):2509-16.
- II Grindem H, Eitzen I, Snyder-Mackler L, Risberg MA. Online registration of monthly sports participation after anterior cruciate ligament injury: a reliability and validity study. *Br J Sports Med* 2013 May 3 [Epub ahead of print]
- III Grindem H, Eitzen I, Snyder-Mackler L, Engebretsen L, Risberg MA. Nonsurgical or surgical treatment of anterior cruciate ligament injuries: knee function, sports participation and knee reinjuries. The Delaware-Oslo ACL Cohort Study. Submitted to *J Bone Joint Surg Am*, July 11 2013
- IV Grindem H, Logerstedt D, Eitzen I, Moksnes H, Axe MJ, Snyder-Mackler L, Engebretsen L, Risberg MA. Single-legged hop tests as predictors of self-reported knee function in nonoperatively treated individuals with anterior cruciate ligament injury. *Am J Sports Med* 2011;39(11):2347-54

Summary of papers I-IV

Paper I was a pair-matched cohort study of return to sports at one year in nonoperatively and operatively treated patients with an anterior cruciate ligament (ACL) injury. Sixty-nine nonoperatively treated patients were pair-matched with 69 operatively treated patients based on specific preinjury main sport, age (± 3 years) and sex. All patients underwent functional testing at baseline and the 1 year follow-up. There were no baseline differences in patient descriptive characteristics, concomitant injuries, sports participation prior to injury, clinical measures or functional measures. Even though patients were routinely advised not to return to level I sports without undergoing ACL reconstruction, there were no significant differences in return to sport rates at the one year follow-up. Nonoperatively treated patients had significantly higher anterior knee laxity, and significantly better hop test symmetry indexes, Knee Outcome Survey-Activities of Daily Living Scale (KOS-ADLS) scores, and International Knee Documentation Committee Subjective Knee Form (IKDC 2000) scores. The differences in knee function outcomes were too small to be considered clinically relevant.

In Paper II we assessed the reliability and validity of an online activity survey used to monitor sports participation after ACL injury and surgery. Test-retest reliability was assessed in a sample of 90 nonoperatively and operatively treated patients. The patients responded to the online activity survey twice, with two to four days between responses. Seventy-four ACL reconstructed patients were included in the validity part of the study. Content validity was assessed by examining how many patients reported activities that were not included in the online activity survey on a routine questionnaire they completed six and 12 months postoperatively. Concurrent validity was assessed by examining the agreement on return to preinjury main sport as determined by the online activity survey and the routine activity questionnaire six and 12 months postoperatively. We also assessed the completeness of the collected data by examining differences between the two methods in the number of sports patients participated in, and the number of patients who participated in specific sports 12 months postoperatively. The online activity survey was found to be highly reliable, to contain all major sports relevant to the patient sample, to show substantial agreement with the routine activity questionnaire on return to preinjury main sport, and may collect more complete data on sports participation compared to the routine activity questionnaire.

In Paper III we described knee function, sports participation and knee reinjuries over two years in 143 ACL-injured patients. Forty-three patients underwent nonoperative treatment and 100 patients underwent ACL reconstruction. Nonoperatively treated patients were significantly older, less likely to have participated in level I sports prior to injury, and more likely to have participated in level II sports prior to injury. Knee functional outcomes included the IKDC 2000 and concentric isokinetic knee extensor and flexor strength. Sports participation was assessed monthly using the

online activity survey. Knee reinjuries were reported by the patients either at a follow-up visit or using the online survey, and subsequently diagnosed clinically, and/or with magnetic resonance imaging (MRI) and arthroscopy. Nonoperatively and operatively treated patients did not have significantly different changes in functional outcomes from baseline to the 2 year follow-up. Operatively treated patients were significantly more likely to participate in level I sports in the 2nd year of the follow-up, and to sustain knee reinjuries; however, these differences were not significant after adjusting for the group differences in age and preinjury sports participation. The adjusted analysis showed that a higher number of nonoperatively treated patients participated in level II sports in the 1st year of the follow-up, and in level III sports during the full two years. After two years, 30 % of all patients exhibited quadriceps strength deficits, 31 % had hamstrings strength deficits, 21 % had self-reported knee function below normal ranges, and 19 % had sustained a knee reinjury.

The purpose of Paper IV was to evaluate if single-legged hop tests conducted in the early phase after ACL injury were predictive of self-reported knee function one year after baseline testing in nonoperatively treated patients. Furthermore, we assessed if a combination of two hop tests would be more accurate than one hop test alone. The hop tests consisted of the single hop for distance, the crossover hop for distance, the triple hop for distance, and the 6-meter timed hop test. At the one year follow-up, patients completed the IKDC 2000. Patients with IKDC 2000 scores equal to or above the 15th percentile from previously published age- and sex-specific data from uninjured individuals were classified as having self-reported knee function within normal ranges. A total of 81 nonoperatively treated patients were included in the analyses, whereof 60 (74 %) were classified as having self-reported knee function within normal ranges at the one year follow-up. The single hop for distance was the only significant predictor of self-reported knee function, and combinations of two hop tests did not yield higher predictive accuracy than the single hop test alone.

Preface

The story of how this PhD dissertation came to be starts with the individual work of my main and co-supervisors, professors May Arna Risberg and Lynn Snyder-Mackler, and the work of their respective research groups at the Norwegian Research Center for Active Rehabilitation (NAR) and the University of Delaware (UDel). In particular, shared research interests in neuromuscular function and early subclassification of ACL-injured patients spurred a research collaboration between NAR and UDel. This research collaboration was established in 2002, and in 2006 the National Institutes of Health (NIH) awarded us a five year grant to perform the study “Dynamic stability of the ACL-deficient knee”, subsequently named the Delaware-Oslo ACL Cohort Study. This study is a prospective cohort study with two year follow-up, including 150 patients from Norway and 150 from the US. After applying for a five year renewal of this grant, the application, with Lynn Snyder-Mackler as the principal investigator, received an NIH MERIT (Method to Extend Research In Time) award in 2012. This award is a tremendous recognition of both the long-standing research achievements of our principal investigator and of the importance of our future research plans. With the support of this new grant, we are now performing five year follow-ups in the Delaware-Oslo ACL Cohort Study, providing data which will enable us to better understand how patients respond differently following ACL injury and ultimately develop clinically applicable tools that can be used to better tailor the treatment to the individual patients.

This dissertation is funded by the initial five year NIH research program grant (R01HD37985) and the NIH MERIT grant (R37HD37985). The main data material consists of patients from the Norwegian arm of the Delaware-Oslo ACL Cohort study (all papers). In addition, data from a previously conducted study from NAR, headed by professor May Arna Risberg and Håvard Moksnes, are included in Papers I and IV. This study was funded by the South-Eastern Norway Regional Health Authority. Furthermore, an additional paper on the predictive characteristics of hop tests in ACL reconstructed patients has been published, based on the Norwegian and the US arms of the Delaware-Oslo Cohort Study.¹⁴⁰ This study is closely related to the work presented in this dissertation, but not included here because it was part of David Logerstedt’s PhD dissertation.

Introduction

ACL anatomy and injury patterns

The ACL is an intraarticular and extrasynovial ligament located in the tibiofemoral joint.²⁰² It originates from the anterior intercondylar area of the tibia and fans out posterolaterally to attach on the posteromedial aspect of the lateral femoral condyle.⁸³ The ACL is the primary restraint to anterior tibial translation and a secondary restraint to internal/external rotation and varus/valgus motion.^{30,230} Two bundles of the ACL have been identified by dissection, and are named after their respective tibial attachments. While the anteromedial bundle of the ACL is tight when the knee is flexed, the posterolateral bundle of the ACL tightens when the knee extends.^{56,57}

ACL injuries have an estimated incidence of 78-81 injuries per 100,000 person-years;^{73,166} although, this is likely an underestimation as some patients may not seek medical care. Athletes aged 15-25 years have been found to compose more than 50 % of all ACL-injured patients, with injuries frequently occurring in pivoting sports such as soccer, alpine skiing, basketball and handball.^{66,84,101} Women have a 2-3 fold risk of sustaining an ACL injury, and sustain their injuries at a lower age than men.²²³ In female elite soccer, athletes are found to sustain 2.2 ACL injuries per 1000 match hours, or about one injury per team each season.⁶⁵ While some injuries occur in contact situations, most injuries occur without contact. In pivoting sports, ACL injuries typically occur during a sudden deceleration prior to a change of direction, or during a landing motion.^{34,129} In alpine skiing, ACL injuries frequently occur while the skier is out of balance during a turn, and the outer ski catches on the snow surface and forces the knee into flexion, internal rotation and valgus.²⁸

Diagnosis

Although diagnostic arthroscopy is considered the gold standard for diagnosing an ACL injury, it is regarded as an unnecessarily invasive and expensive procedure. The diagnosis is therefore based on the patient's injury history, clinical examination, and, in some cases, MRI. A patient with an ACL injury will most often present with a clear history of when and how the injury occurred, will have had acute hemarthrosis, and may also have heard a pop in the knee at the time of the injury.⁶⁷ Of the clinical diagnostic tests, the Lachman test is the most accurate, with a pooled reported sensitivity of 85 % and a specificity of 94 %.²⁶ This test is performed with the patient lying in a supine position with the knee in 20-30° of flexion. The clinician stabilizes the femur with one hand and directs an anterior force to the proximal tibia with the other hand, and judges the amount of tibial displacement and the quality of the end point. The pivot shift test is also performed with the patient

supine. The clinician holds the patient's leg at the ankle, and internally rotates the tibia and flexes the knee from full extension while applying a valgus stress on the lateral side of the proximal tibia with the other hand. In a positive pivot shift test, the initial posterior subluxation of the lateral femoral condyle, caused by the internal rotation of the tibia, will suddenly be reduced by the iliotibial tract when the knee moves into flexion. The pivot shift test has a very high sensitivity (98 %), but only 24 % specificity.²⁶ A positive pivot shift test is therefore a very clear indication of an ACL rupture, but a negative pivot shift test is not sufficient to exclude the diagnosis. A third test, the anterior drawer test, is performed with the patient in the supine position with the hip flexed to 45°, the knee flexed to 90°, and the tibia in neutral rotation. Placing both hands around the proximal tibia with the thumbs on the tibial plateau, the clinician applies an anterior force and judges the amount of tibial translation and the end point. This test has shown high sensitivity and specificity in chronic conditions, but the accuracy is lower in acute cases.²⁶ The KT-1000 arthrometer, an objective instrument for measuring anterior tibial motion relative to the femur, is commonly used in studies on ACL-injured patients. Using a diagnostic cutoff of ≥ 3 mm side-to-side difference in tibial displacement, 89 % sensitivity and 95 % specificity has been reported.⁷⁹ In spite of the available clinical diagnostic tests, every other patient with an acute ACL injury may be sent home from an orthopaedic emergency unit with a diagnosis of an uncomplicated knee sprain, and MRI in the subacute phase may be necessary to detect the injury.⁷³ The diagnostic accuracy of MRI is found to be comparable to the Lachman test.^{161,218} Additionally, the diagnostic accuracy is influenced by the experience of the assessor, and the presence of effusion will make it harder to detect the injury.

ACL injuries rarely occur in isolation, and are frequently associated with other ligament sprains, meniscus tears, articular cartilage injuries, bone marrow lesions, and intra-articular fractures.³¹ As imaging procedures have grown more advanced, the number of reported associated injuries has increased. While as many as 50-70 % of patients may have associated ligament and meniscus injuries,^{31,75,87} using quantitative MRI, Frobell et al.⁷⁵ reported that 57 % of ACL-injured patients also had cortical depression fractures and 98 % had bone marrow lesions. Exact diagnosis of both the ACL injury and all associated injuries is complicated as the accuracy of the different diagnostic tools varies from one injury to another. Clinically, the specific diagnostic tools are chosen based on a preexisting suspicion of which injuries may be present. Because far from all injuries are symptomatic, the total structural damage of the knee is therefore likely to be underestimated. The short and long term clinical relevance of asymptomatic structural damage of the knee is, however, still unknown.

Consequences of an ACL injury

The total economic burden of these injuries is not easily quantified, as indirect long-term costs likely overshadow the more readily quantifiable direct costs. However, it has been estimated that direct hospital costs alone exceed \$1 billion each year in the US.⁸⁸ For the individual patient, consequences of an ACL injury include decreased knee function, a reduced activity level,^{11,153} an increased risk of sustaining new knee injuries,²²⁸ and an increased risk of early onset of knee osteoarthritis.¹⁶⁸ The prevalence of knee osteoarthritis has been estimated to 0-13 % after isolated ACL injuries, and 21-48 % after combined ACL and meniscus injuries.¹⁶⁸

Knee function

While ACL-injured patients exhibit increased passive knee joint laxity as a result of the disruption of the ligament, the degree of passive joint laxity has not shown to correlate with the functional limitations experienced by the patients.¹⁹⁸ In addition to the increased passive joint laxity, ACL-injured patients also show varying degrees of muscle strength deficits,^{4,119,215} altered neuromuscular strategies^{40,139,184,188} and decreased knee joint proprioception.^{21,44} Dynamic knee stability is defined as the ability of the knee joint to remain stable when subjected to rapidly changing loads during activity,²²⁷ and includes the combined contribution of passive knee stabilizers (ligaments, menisci, cartilage, joint capsule) and the muscular system. Dynamic knee instability is thus thought to result from the collective impact of the aforementioned impairments.

Quadriceps strength deficits have been stated to be one of the hallmarks of an ACL-injured knee, and are usually more pronounced and persistent over time than hamstrings deficits.^{4,119,215} The loss of quadriceps strength can be attributed to both disuse atrophy and muscle activation failure.^{33,48,106,227} The muscle activation failure is suggested to be caused by abnormal gamma loop function, where the loss of afferent feedback from the mechanoreceptors in the ACL inhibits recruitment of high-threshold motor units in the quadriceps muscle.¹²²⁻¹²⁴ After 2-5 years, 30-50 % of patients exhibit less than 90 % quadriceps strength of the injured leg compared to the uninjured leg.^{4,6,214} Comparable hamstrings strength deficits are found in 20-35 % of patients in the same studies.

ACL-injured patients also show altered movement patterns after injury, characterized by reduced internal knee extensor moments,^{139,184,188} reduced knee flexion angles,^{40,139,184,188} and increased cocontraction of the muscles surrounding the knee.^{40,188} While quadriceps dysfunction is found to contribute to altered movement patterns,¹³⁹ limited evidence also suggests that the injury may cause a joint de-efferentation due to a reorganization of the central nervous system where the

activity in sensorimotor areas is reduced and the activity in the presupplementary motor area is increased.^{116,117} The resulting knee stiffening strategy is thought to increase knee joint compressive forces and joint loading, and also to reduce the patient's ability to withstand unexpected challenges to knee stability.¹⁸⁸ However, while there is a positive relationship between altered movement patterns and functional limitations,^{41,50} joint compartmental forces have recently shown to be reduced and equally distributed between the medial and lateral compartment early after ACL injury.⁸⁰ Nonetheless, alteration of movement patterns is proposed as one of multiple factors that may drive the progression of knee osteoarthritis; both directly, through prolonged changes in joint loading, and indirectly, through an increased risk of traumatic cartilage and meniscus injuries as a result of dynamic knee instability.^{170,188}

Sports participation

Because ACL injuries most often occur in athletically active people, great importance is placed on the resumption of sports participation after injury. A qualitative study⁹⁸ reported that, early after injury, patients can experience the potentiality of not being able to resume preinjury sports as a threat to personal self-value and self-respect. Still, far from all ACL-injured patients resume their preinjury sports participation. In a meta-analysis of 48 studies, it has been estimated that 18 % do not return to any kind of sports participation, 37 % do not return to their preinjury level of sports participation, and 56 % do not return to competitive sports.¹¹ However, there is an extreme variation in study results on this topic, suggesting that factors other than the injury itself highly influence the reported rates. Furthermore, Söderman et al.¹⁹⁹ reported that, 2-7 years after their injury, 80 % of ACL-injured female soccer players who had retired did so due to the ACL injury. Thus, both returning to sport and sustaining participation in sports is a challenge.

While resumption of sports participation is associated with the functional status of the knee,¹⁵⁷ whether or not the patient resumes sports depends on several factors. Problems with the injured knee is reported to be the third most frequently cited reason for not returning to sport, with more patients attributing not returning to sports to a fear of reinjury or to reasons other than knee function (such as family commitments, lifestyle change and fear of job loss with reinjury).¹¹ However, the relationship between knee function, fear of reinjury and sports participation is not fully understood, as patients who have poorer knee function also show a higher fear of reinjury.^{39,131,132} While ceasing or changing sports participation may not directly reflect poor knee function, resuming sports participation may also not reflect an asymptomatic knee. After returning to sport, ACL-injured patients still exhibit increased knee abduction angles and internal abduction moments compared with uninjured athletes,^{168,204} and active soccer players who have sustained a previous knee injury also have

lower self-reported knee function than players with no previous knee trauma.^{77,205} This may suggest that the current treatment is inadequate in restoring knee function and/or that athletes return to sport prior to completing rehabilitation. Steffen et al.²⁰⁵ further reported that both a history of a previous knee injury and lower self-reported knee function increased the risk of sustaining a new knee injury during soccer, lending support to authors advocating caution in the decision of if and when a patient should return to sport.^{19,82,158,185} Thus, knee function, sports participation and new knee injuries are important parts of assessing the outcome of ACL-injured patients, and more knowledge is needed on the expected outcome in regard to these three factors.

Assessments of outcome

To understand the specific impairments, activity limitations, and participation restrictions of the patients, multiple outcome measures are needed in the assessments of outcome after ACL injuries.^{16,27} The different outcome measures can be categorized based on the method of data acquisition, as self-reported or clinician-reported outcome measures.²⁷ Self-reported outcome measures have gained particular importance over the last decades, as medicine has become increasingly patient-centric. These measures comprise an array of questionnaires typically assessing the patient's perspective on constructs such as function in activities of daily life, function in sports, and quality of life. Clinician-reported measures include performance-based tests, where the clinician records the performance of the patient on a test. In ACL-injured patients, single-legged hop tests and muscle strength tests are frequently utilized performance-based tests. Clinical tests, such as arthrometer measurements of passive knee laxity, comprise another category of clinician-reported outcome measures. During these tests, the patient is passive while being examined by a clinician. Within each of these three categories, a plethora of measures exists. The selection of the specific outcome measures should be based on the relevance of the outcome measure with respect to the study aims and the population, as well as the psychometric properties of the outcome.²⁷

Historically, the Lysholm knee score¹⁴³ and the original IKDC form from 1993⁹⁶ have been the most frequently used rating systems in ACL-injured patients. However, the Lysholm knee score has later shown to have considerable ceiling effects and a lack of sensitivity to change,^{35,182} and the original IKDC form will classify well-functioning knees as 'abnormal' or 'severely abnormal' based on increased passive knee laxity alone. In 1997, the IKDC decided to revise the original IKDC form, and subsequently developed the IKDC 2000.¹⁰⁷ While numerous knee-specific self-reported outcome measures exist, the IKDC 2000 is found to contain the most items important to ACL-injured patients, followed by the Knee Injury and Osteoarthritis Outcome Score (KOOS).²⁰⁹ These two self-reported outcome measures are used in studies worldwide,^{54,62,74,76,141,144,151} and the IKDC 2000 is

suggested to be the most useful of the two when evaluating ACL-injured patients in the first years after injury.²²⁰

Muscle strength testing can be performed for several different purposes.² In ACL-injured patients, the purpose is usually to identify specific deficiencies in muscular function and to monitor the effect of rehabilitation interventions. The gold standard for muscle strength assessments is dynamometry.² While several testing modes can be applied, isometric and isokinetic testing are most frequently utilized. Isometric testing measures the amount of force that can be exerted against an immovable object, quantified by the maximal voluntary isometric contraction (MVIC). During isokinetic testing, the torque is measured through a range of motion where the limb moves at a constant angular velocity. Concentric testing is generally more reliable than eccentric testing, and the reliability is higher at lower speeds. Isokinetic concentric strength testing at 60°/sec is the most common test procedure in ACL-injured patients,^{59,103,175} and considered an easy way of measuring muscle strength with high reliability.² The main criticism against dynamometry is based on the discrepancy between the specific and controlled nature of the testing and the functional demands in sports and daily activities. Dynamometry is therefore very useful in quantifying exactly what it purports to measure, muscle strength, but should be utilized in adjunct with other measures if the purpose is to assess the function of the patient.

Compared to muscle strength testing, single-legged hop testing provides a more functional testing alternative.¹⁶⁷ Hop tests are intended to identify lower limb functional limitations. These functional limitations may be caused by muscle strength deficits, neuromuscular deficits, or a patient's lack of confidence in the injured limb. During hop tests, the patient performs one or several hops on one limb, and the result of the injured limb is typically compared with that of the uninjured limb. A variety of tests exist, and the horizontal distance, the vertical distance, the number of hops, or the time is recorded.^{14,18,55,70,110,112,115,118,167,171,179,189} The most frequently utilized hop test in ACL-injured patients is the single hop for distance. In 1991, the single hop for distance, the crossover hop for distance, the triple hop for distance, and the 6-meter timed hop test were described by Noyes et al.,¹⁶⁷ and these four tests have subsequently frequently been used. More recently, there has been an increased focus on developing hop tests that are demanding and sensitive enough to identify functional limitations in patients who want to return to sport.^{91,213} However, employing more demanding tests is also likely to introduce a higher risk of injury during testing. Thus, it may be impossible to develop one test that is safe and demanding both early after injury and prior to return to sports.

Recording sports participation after ACL injury

There are at least three different purposes for recording sports participation after ACL injury. The most common perspective in the literature is that return to sport reflects the functional outcome of the patients.^{11,69,154} Following this perspective, the treatment outcome is better the more patients participate in high level sports. This view is challenged by several authors because returning to high level sport entails a high risk of reinjury, and it is argued that protecting future joint health, not returning to sport, should be the main aim of the treatment.^{82,158,185} Assessment of reinjuries has therefore become an increasingly important part of evaluating the outcome. However, the interpretation of the rate of reinjuries is challenging without knowing the sports exposure of the patients.⁴⁹ Thus, the second purpose of recording sports participation is to enable interpretation of the reinjury rate, and, optimally, to adjust for sports exposure in the analysis of new injuries. Lastly, continued sports participation is also important from a general health perspective. Yet, not much attention is paid to whether patients become inactive after quitting their preinjury sports or if they substitute their preinjury sport with other, less knee-demanding sports.

The literature on sports participation after ACL injury is characterized by inconsistencies in individual study results.^{11,156} While some of the heterogeneity in results can be attributed to publication year,¹¹ different lengths of follow-up,¹¹ and sample heterogeneity, differences in the methods of recording sports participation and return to sport are also a potentially large source of study bias. The methods currently used to record sports participation include project-specific questionnaires, patient interviews, and activity rating scales (eg, the Tegner Activity Scale,²¹⁰ the Marx Activity Rating Scale¹⁴⁷ or the Cincinnati Sports Activity Scale²⁰). Sports are also commonly ranked based on the demands the sport places on the knee. The IKDC has proposed a classification of sports activity levels where level I activities include sports characterized by jumping, pivoting and hard cutting (football, soccer), level II activities are sports comparable to heavy manual work (skiing, tennis), and level III sports are comparable to light manual work (jogging, running).⁹⁶ This classification has later been modified to better represent European sports activities, where handball and soccer are typical level I sports, and alpine skiing and snowboarding are typical level II sports.¹⁵⁵ There is also no uniform definition of the term return to sport. The reported rate of patients who return to sport can be influenced by what type of sport patients participated in, seasonal variations, whether studies reported return to preinjury or presurgery sports participation, and if it was required that patients returned to the same frequency of sports participation, to the same level of competition, or that patients regained their former skill level.^{11,150}

With the current methods, the reported outcome is most frequently based on whether or not the patient resumed participation in one sport (return to the preinjury main sport or the preinjury

activity level), or on a score reflecting only the most demanding sports activity patients participated in after injury (eg, Tegner Activity Scale). Because ACL-injured patients often participate in multiple sports both prior to injury and after, these methods do not adequately represent the complexity of sports participation. While no one method may be able to reflect all aspects of sports participation, no existing methods of recording sports participation after ACL injury provide data on how participation in multiple sports changes over time. Thus, detailed knowledge on how sports participation develops over time is lacking. On this background, NAR developed a monthly distributed online activity survey to monitor participation in all major sports that were relevant to the patients treated at our clinic.

Operative and nonoperative treatment courses

The first report on the treatment of ACL injuries has been attributed to Stark in 1850, who advocated immobilization using a cast.²⁰³ In the early 1900s, some reports on surgical repair (direct suture of the ACL) were published.^{22,114} As the results after surgical repair were unsuccessful in the medium and long term, nonoperative treatment again became more common, eventually followed by the advent of surgical reconstruction.¹⁹² Although several contemporary surgeons reported innovative surgical techniques, Hey Groves is often cited as being the first to introduce the concept of reconstruction in 1917. The reported procedure involved detaching a part of the iliotibial tract and rerouting it through drill holes in the tibia and femur.¹⁰² In the last 100 years, the surgical techniques have changed extensively, resulting in faster surgeries with fewer complications and better outcomes. However, surgical reconstruction is still the mainstay of an operative treatment course. Even though surgical treatment has been an option for about 100 years, a variable proportion of patients has been treated nonoperatively. In particular, nonoperative treatment has been common in countries where the surgery is offered through a public health care system.¹¹³ The reasons behind this may include a higher threshold for suggesting surgery when it is paid for by the state. Additionally, countries with extensive public health care systems also have longer surgical waiting lists, which lead to nonoperative management for some amount of time. During this period of time, patients may have regained knee function to the point where they no longer see the need for surgery, and/or adapted to the functional limitations they experience.

Recent studies estimate that 23-36 % of all ACL-injured patients undergo reconstructive surgery,^{43,166} but the surgical rate is markedly higher in the athletically active population.^{61,69,104} During surgery, the ruptured ACL is replaced by a graft which is inserted through bone tunnels in the tibia and femur. In Norway, autografts are almost exclusively used, and hamstrings grafts have gained favor over bone-patellar-tendon-bone (BPTB) grafts over the last 10 years.²¹¹ Although numerous

fixation devices are in use, the most common methods of fixation are an endobutton at the femoral site and an RCI screw at the tibial site.²¹¹ ACL reconstruction is a relatively safe procedure, with 3.7 % reported peroperative complications in 2011.²¹¹ The rehabilitation of these patients can be divided into phases: A preoperative phase, an early postoperative phase, a late postoperative phase, and a return to sport phase.^{3,58} Advancement from one phase to another is not based on time, but on the functional progress of the patient. The reported length of the postoperative rehabilitation varies from 3 to 12 months, and countries with expansive public health care systems report the longest rehabilitation periods.^{3,81,89,99,180} The rehabilitation of all ACL-injured patients should consist of both strength training and neuromuscular training.^{23,180,181} In the preoperative phase, regaining full knee range of motion (ROM), eliminating effusion and normalizing quadriceps strength are advocated.^{48,60,196} In the postoperative rehabilitation, the main challenge is to tailor the rehabilitation program to effectively address the muscle strength and neuromuscular deficits, while also protecting the healing graft and avoiding donor site comorbidity. The strain placed on the graft is controlled by adjusting exercise load and ROM based on the healing phase of the graft.^{78,99} However, we do not know how aggressive the rehabilitation program can be without causing knee damage in the short or the long term. As the postoperative rehabilitation progresses, exercises that more closely resemble the demands of the sport of the patient are introduced.^{3,58} Before the patient returns to sports activities, it is highly recommended that they have passed a set of functional criteria used to determine readiness for return to sport.^{19,213} Although there is lacking evidence for the accuracy of these tests to determine readiness for sports participation, single-legged hop tests and muscle strength testing are commonly used.^{19,213} Furthermore, sports activity restrictions for some amount of time are also advocated postoperatively.¹⁹ While the functional criteria are intended to assess if the knee function of the patient meets the functional demands of the sport, time restrictions are intended to ensure that the graft has had enough time to heal prior to return to sports.¹⁵⁷ The most commonly reported time criteria for return to sports is ≥ 6 months postoperatively, although ≥ 9 months, and even ≥ 12 months postoperatively, are also reported.¹⁹

Substantially less evidence is available to guide a nonoperative treatment course. However, the treatment of these patients mostly follows the same structure as for the operatively treated patients, minus all aspects related to the graft and surgery itself. Similar to the rehabilitation in an operative treatment course, functional criteria for rehabilitation progression should be used.^{71,74} Because nonoperatively treated patients do not experience the additional deficits caused by the ACL reconstruction procedure, the rehabilitation is shorter and can be performed with less restrictions.⁷⁴ The typical reported length of rehabilitation in nonoperatively treated patients is 3^{23,150} and 4 months.^{4,74,208} Although sparsely reported, nonoperatively and operatively treated patients have the same reported functional return to sport criteria.^{74,104} However, nonoperative treatment is more often

advocated in combination with activity modifications, where patients are advised to avoid pivoting sports like soccer, handball and basketball.^{4,162,206} Thus, there are three main differences between an operative and a nonoperative treatment course: The surgical procedure, the length of and restrictions during rehabilitation, and the recommendations for future sports participation.

Choosing a treatment course

The reported reasons to recommend surgical reconstruction of the torn ACL are either to promote dynamic stability,^{25,36,178,185} to prevent future dynamic instability in patients who wish to return to pivoting sports,^{25,36,178,185} to protect the knee from subsequent meniscus injury,^{25,36,178,185} or to decrease the risk of early onset of knee osteoarthritis.^{36,178} However, while ACL reconstruction is shown to decrease the passive laxity of the knee,^{68,69,74,76,120,150,154} it is not shown to lead to improved knee function,^{68,69,74,76,142,150,151,154,159,162,206,207,222} a higher level of sports participation,^{68,69,74,76,120,142,150,151,154,159,162,207} a lower number of meniscus injuries,^{68,69,74,76,150,207} or a lower prevalence of knee osteoarthritis.^{68,69,120,142,150,159,162,163,206,222} The best design for establishing the superiority of one treatment over another is a randomized trial. Following current surgical and rehabilitation practice, there is only one randomized trial comparing initial ACL reconstruction with a nonoperative treatment course (with an option of later reconstruction if needed).⁷⁴ The literature in this field therefore mainly consists of observational studies. These studies are best suited to evaluate outcome following current clinical practice; however, conclusions about the causes of the observed outcome are limited due to the presence of known and unknown confounders. While previous observational studies have not found a significant difference in return to sport rates between nonoperatively and operatively treated patients,^{69,154} it may be easier for nonoperatively treated patients to return to sport as they have shown to participate in less knee-demanding sports than the operatively treated patients.^{46,61,69} So far, no study has reported short term return to sport rates for nonoperatively and operatively treated patients who participated in identical sports prior to injury.

Barring evidence of a superior average outcome following ACL reconstruction, it is thought that some patients will benefit from an operative treatment course, while others will not.^{30,46,68,69,185} Although a recent study from the US indicated that socioeconomic status and the type of health care coverage influence whether or not patients undergo surgery,⁴³ the treatment choice should be guided by the patient's and the clinician's judgment of prognosis following the different treatment courses. A widely accepted treatment strategy is to recommend ACL reconstruction to the patients who want to participate in pivoting sports, while those who have lower demands to knee function are offered a nonoperative course with the option to undergo surgical reconstruction if they have continued problems with knee instability. The rationale for this treatment algorithm is that an ACL

reconstruction will reduce passive knee laxity, thus limiting the risk of subsequent knee injuries, in the patients who subject their knees to the highest loads. On the other hand, patients who have a lower activity level may not need the additional passive knee stability and can therefore be candidates for a nonoperative treatment course. Nonoperatively treated patients who have a high activity level are shown to be at a higher risk of undergoing late surgery than those who have a lower activity level.⁶⁹ Still, some patients successfully return to pivoting sports without ACL reconstruction, while other patients experience functional limitations even with low demand activities. More knowledge is therefore needed to better be able to identify those who benefit from a nonoperative course and those who should undergo surgery.

Predictors of outcome

Prognostic research is defined as the study of associations between outcomes and predictors in defined populations of people with disease, and includes the study of causes of disease progression, prediction of risk in individuals, and individual response to treatment.¹⁰⁰ The ideal design for these studies is a prospective cohort design, and other methodological requirements include a clinically relevant outcome, clinically relevant and reliable predictive variables, and a clearly defined patient group and study setting.^{100,133,224} In order to guide clinical practice, predictive factors should also yield consistent results in different studies.¹³³ However, the studies on predictive factors after treatment of ACL-injured patients is, to some extent, characterized by inconsistent results. One of the main challenges in this area is the disparity in outcomes. The predicted outcomes include several different patient-reported outcome measures,^{60,127,134,200,212} muscle strength measurements,²¹² functional tests,^{48,212} return to sport,⁷⁰ graft rupture or contralateral injury,¹⁹⁰ late meniscus or reconstructive surgery,^{46,69} arthrometer measurements,¹³⁴ ROM deficits¹³⁴ and knee osteoarthritis.^{135,176}

Currently, two algorithms for surgical treatment selection have been devised.^{46,70} While Fitzgerald et al.⁷⁰ reported a high rate of success with short term return to sport for nonoperatively treated patients who passed a functional screening examination, this algorithm was later found to be ineffective in predicting longer term return to sport.¹⁵⁵ The surgical risk factor (SURF) algorithm,⁴⁶ based on preinjury sports participation and passive anterior-posterior knee laxity, has shown to discriminate between groups of patients who have significantly different risks of undergoing late reconstructive or meniscus surgery.^{46,69} Still, the accuracy of this algorithm is questionable as 60-66 % of patients classified as having a high risk of undergoing late surgery did not undergo surgery.

A higher number of studies have predicted the outcome following either nonoperative or operative treatment. These studies may provide valuable information about a patient's prognosis

following the respective treatment. However, they do not provide evidence on which treatment is better for the individual patient, as a poor prognosis of outcome following one treatment does not automatically mean the prognosis will be better with another treatment. In operatively treated patients, the outcome of the patient is found to be associated with smoking,¹²⁷ activity level,¹⁹⁰ educational level,^{127,200} preoperative knee self-efficacy,²¹² preoperative quadriceps strength,^{48,60} ROM deficits,¹⁶⁰ knee pain,^{97,160} concomitant meniscus injuries,^{60,134} and cartilage injuries.¹³⁴ In nonoperatively treated patients, there are indications that concomitant cartilage injuries are associated with increased pain,⁵¹ and that meniscectomy¹⁶² and post injury participation in pivoting sports⁶⁸ are associated with an increased prevalence of knee osteoarthritis. None of these latter studies had a primary aim of identifying predictive factors, and the studies either do not report the strength of the associations, or the sample size is too small to estimate this confidently. Thus, there is a lack of well-designed predictive studies, particularly in nonoperatively treated patients, and there is almost a complete absence of published results that can be applied clinically to refine the prognoses for outcome.

In a clinical commentary published twelve years ago, Fitzgerald et al.⁷² suggested that single-legged hop tests may show promise as predictors of knee function. While these tests are most commonly used to assess the concurrent functional ability of the patients, patients who succeeded with a nonoperative short term return to sport have also shown to have more symmetrical hopping ability at baseline than those who did not succeed.⁷⁰ A limitation of hop tests, however, is that a substantial proportion of patients who experience functional limitations have shown to perform well on individual tests.^{110,167} To increase the concurrent sensitivity, a battery of hop tests is therefore commonly used. In the years after Fitzgerald et al.'s clinical commentary⁷² was published, hop tests continued to be an important part of knee functional assessments;^{4,6,32,81,93,150,154,159,173,180,213} yet, their predictive characteristics remained to be evaluated. With the ultimate purpose of increasing the clinical ability to refine prognoses for outcome after rehabilitation, our research group therefore evaluated the predictive characteristics of four hop tests in nonoperatively (Paper IV) and operatively¹⁴⁰ treated patients. Logerstedt et al.¹⁴⁰ examined if the limb symmetry index (LSI) of the single hop for distance, crossover hop for distance, triple hop for distance, and the 6-meter timed hop test could predict self-reported knee function within normal ranges 1 year postoperatively. The hop tests were conducted both preoperatively and 6 months postoperatively, and self-reported knee function within normal ranges was defined as an IKDC 2000 score equal to or above the 15th percentile from a previously published age- and sex-specific normative material on uninjured individuals.⁸ None of the preoperatively conducted hop tests were significantly associated with 1 year self-reported knee function; however, when conducted 6 months postoperatively, all hop tests significantly predicted self-reported knee function within normal ranges at 1 year. The crossover hop

for distance and the 6-meter timed hop tests were the strongest predictors of the four hop tests. Perhaps most importantly, the probability of having self-reported knee function within normal ranges at 1 year was only 44 % in patients who had a 6-meter timed hop test LSI below 87.8, while the probability of having self-reported knee function within normal ranges was 88 % for patients who had an LSI above 87.8 on this test. It was concluded that hop tests may have considerable implications as clinically applicable measures which inform the clinician and patient about the patients' likely prognosis in the short term.

Aims of the dissertation

The overall aim of this dissertation was to evaluate knee function and sports participation after nonoperative and operative treatment of ACL-injured individuals.

To address this aim, patients were followed for either 1 or 2 years in the four included papers. Sports participation was assessed by return to preinjury main sport in Paper I. We assessed psychometric properties of a new method of recording sports participation in Paper II, and utilized this method in Paper III. The knee functional assessments included hop tests (Papers I and IV), isokinetic concentric knee extensor and flexor strength (Paper III), and self-reported outcome measures (Papers I, III and IV).

The specific aims which were addressed in the four papers were:

1. To describe functional outcomes in nonoperatively and operatively treated ACL-injured patients (Papers I and III)
2. To compare functional outcomes in nonoperatively and operatively treated ACL-injured patients (Papers I and III)
3. To compare return to preinjury main sport in nonoperatively and operatively treated ACL-injured patients (Paper I)
4. To assess the validity and reliability of using an online activity survey to record monthly sports participation in ACL-injured patients (Paper II)
5. To describe monthly sports participation over 2 years in nonoperatively and operatively treated ACL-injured patients (Paper III)
6. To compare monthly sports participation over 2 years in nonoperatively and operatively treated ACL-injured patients (Paper III)
7. To investigate the predictive characteristics of single-legged hop tests in nonoperatively treated ACL-injured patients (Paper IV)

Materials and methods

Ethical considerations

All patients who participated in the studies in this dissertation signed a written consent form prior to inclusion, and all studies passed review by the Regional Committee for Research Ethics in Norway and the Norwegian Data Protection Authority. Special consideration was taken to ensure that patients knew that participation in the project would not influence clinical decision making.

Prior to inclusion, all patients received information about the project from the project leader. If they were interested in participating, they received the written consent form and were instructed to read it thoroughly and bring it back for the next scheduled appointment. At the second appointment, any new questions were answered, and the written consent form was signed. It is our experience that even if patients were well aware of what the project entailed at the time of inclusion, continuous information is needed throughout the course of the project. Patients were therefore reminded of the next follow-up after they had completed a follow-up.

The patient recruitment and data collection were performed at the clinic where patients were treated. Throughout the project, patients were given feedback on their test results and recommendations on how to further improve their knee function. In this setting, ensuring that patients are continually aware that they are research participants, and not exclusively clinical patients, is a particular challenge. To avoid any potential confusion, special attention was paid to several aspects of the project logistics. For example, everyone who called participants was instructed to clearly state they called from the ACL project as opposed to from the clinic, and patients were continually notified of the results from the project.

All patients were also informed that participation in the project entailed slight risks. This mainly concerns the single-legged hop testing, where we have previously experienced episodes of knee giving-way. The hop testing at baseline may be considered the largest risk, as it is the first time patients perform multidirectional plyometrics after injury. Starting in 2003, we have recorded adverse events following the baseline hop tests, and have found that 1 (0.3 %) of 369 patients has experienced a knee giving-way episode that resulted in mild effusion the next day. This patient later underwent ACL reconstruction, and no injuries to the menisci or cartilage were seen during the arthroscopy. Because patients in this project underwent the same functional test and rehabilitation as other patients treated at the clinic, this is also a general risk for all ACL-injured patients, not exclusively those included in research.

Study design

All papers in this dissertation were longitudinal observational studies. In Paper I we sought to compare return to sport rates in nonoperatively and operatively treated patients without the confounding effects of specific preinjury main sport, sex and age. We therefore chose a pair-matched cohort design in which the data were collected prospectively and the patients were matched retrospectively. Retrospective matching was chosen over prospective matching because the latter option would be highly inefficient in a population where we do not know which treatment the patients will receive at baseline. In Papers II-IV we evaluated the reliability and validity of an online activity survey, the clinical course following nonoperative and operative treatment, and the predictive characteristics of hop tests. These aims required a high degree of external validity, and a prospective cohort design was therefore chosen.

Subjects

All patients included in this dissertation have been participants in one of two prospective cohort studies (fig. 1). In Cohort A, 125 consecutive patients were recruited between 2003 and 2005. The main material is from Cohort B, the Norwegian arm of the Delaware-Oslo ACL cohort study. Between 2007 and 2011, 150 consecutive patients were included in this cohort. Cohort A and B had identical inclusion and exclusion criteria (table 1) with one exception: Patients who had sustained an ACL injury within 6 months were included in Cohort A, while this period was 3 months in Cohort B. For Paper I, there was no significant interaction between surgical status and cohort on return to sport ($p=0.69$). For Paper IV, there was no significant interaction between the four hop tests and cohort on self-reported knee function within normal ranges ($p\geq 0.72$). The two cohorts could therefore be merged in the analyses. Papers II and III consist of patients exclusively from Cohort B.

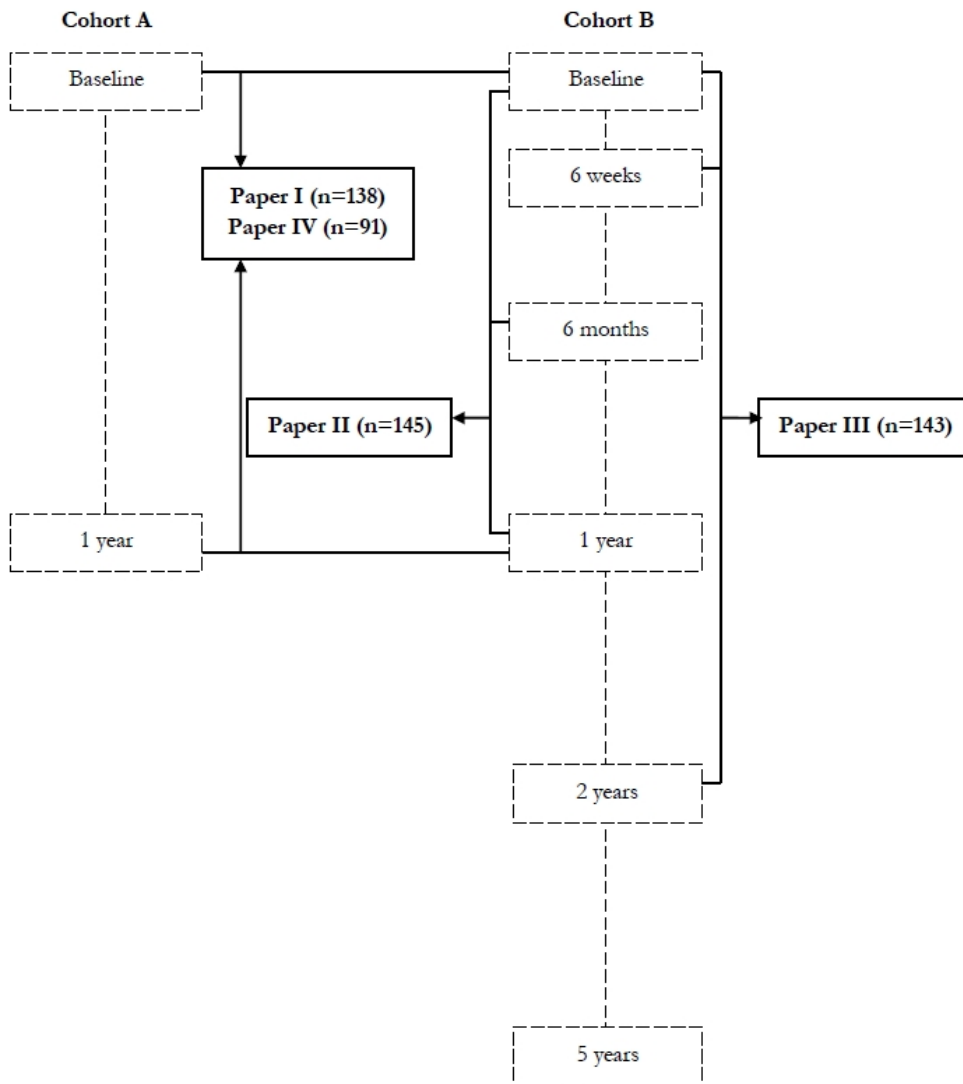


Figure 1 Flowchart showing the originating cohort and follow-up time points for the subjects included in Papers I-IV

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Sustained ACL rupture within 6 months (Cohort A)/3 months (Cohort B), verified by MRI and ≥ 3 mm KT1000 side-to side difference	Bilateral injury
Preinjury participation in level I-II sports \geq twice a week	Previous injuries to either knee
Age 13-60 years	Symptomatic meniscus injury
	Full thickness cartilage injury
	PCL, LCL, MCL injury grade III
	Fracture

Paper I utilized a pair-matched design where the matching criteria were specific preinjury main sport, sex and age (± 3 years). These criteria were set a priori. Matching patients by their specific preinjury main sport was a central aspect of this study because the outcome of interest was return to preinjury main sport. Sex was included as a matching factor because women have been found to be less likely to return to sport.⁹ A stringent age criterion of ± 3 years was chosen because we regarded age to be a potentially strong confounder in the youngest patients of this population.

The patients were recruited from the Norwegian Sports Medicine Clinic (Nimi). All patients underwent active rehabilitation before a treatment decision was made.⁶² During this time, the patients were informed about nonoperative and operative treatment courses. The responsible orthopaedic surgeon made the final decision on whether or not to offer the patient ACL reconstruction, after close communication with the treating physical therapist and the patient. Factors which positively influenced a surgical treatment decision were a wish to return to level I sports, young age, dynamic instability, and the patient's preference for surgery. If a nonoperative treatment course was chosen, the patient underwent continued rehabilitation as needed, typically for 3-4 months after the initial impairments (effusion, pain and ROM deficits) were resolved. Patients who chose to have ACL reconstruction first underwent preoperative rehabilitation to optimize knee function prior to surgery, then postoperative rehabilitation for 6-12 months. All patients were advised not to resume level I or II sports prior to having ≥ 90 LSI on four hop tests,¹⁶⁷ and quadriceps and hamstrings strength LSI ≥ 90 . Nonoperatively treated patients were advised not to participate in level I sports, while operatively treated patients were advised not to participate in level II sports in the first 6 postoperative months, and not to participate in level I sports in the first 9 postoperative months.

A priori sample size calculations were performed for all studies, denoting the minimum number of patients needed prior to perform the analyses. The data collection in Cohort B has been ongoing over the course of this dissertation, and all patients eligible at the time of analysis were included in the papers. All sample size calculations were performed with a beta level of 0.20 and alpha

level of 0.05. For Paper I, 50 pairs (n=100) were needed to detect a 15 percentage point group difference in the return to sport rates. The same sample size calculation was used in the validity study in Paper II, where 50 patients were needed to detect a 15 percentage point differences in sports participation rates between the two methods. For the reliability study and the concurrent validity aim of Paper II, 50 patients were needed to detect a κ of ≥ 0.4 . The sample size calculations for the within-between interaction effect in a repeated ANOVA (Paper III) revealed that 33 patients per group were needed to detect a Cohen's f of 0.2, given an estimated between-measures correlation of 0.6. With a surgical rate of 70 % and 80 % follow-up rate, 138 patients needed to be included. Sample size analysis for logistic regression (Paper IV) showed that 59 patients were needed to detect an effect size of 0.2. This effect size is defined as the difference between the probability of the outcome at the mean of the predictor variable and the probability of the outcome at the mean plus one standard deviation of the predictor variable.

Paper I

From a total of 233 ACL-injured patients (125 patients from Cohort A and the first 108 patients included in Cohort B), 69 pairs (n=138) of nonoperatively and operatively treated patients were formed based on specific preinjury sport, sex and age (± 3 years). Both the nonoperatively and operatively treated group included 32 (46 %) women and 37 (54 %) men. The mean \pm standard deviation (SD) age at baseline was 27.9 ± 7.3 in the nonoperatively treated group and 27.3 ± 6.9 in the operatively treated group.

Paper II

Two different samples were used for analysis in this paper. In the reliability part of the study, all 145 patients enrolled in Cohort B who had agreed to participate in the online activity survey were eligible. The final reliability sample consisted of 90 patients (62 %) who responded to both the test survey and the retest survey 2-4 days later. There were 44 (49 %) women and 46 (51 %) men with a mean age of 29.1 ± 8.4 at the time they responded to the online activity survey. Sixty-seven patients (74 %) had undergone ACL reconstructive surgery 30.9 months (range 3-58) prior to responding to the survey. The remaining 23 patients were nonoperatively treated and responded to the survey 38.2 (range 12-62) months after sustaining their ACL injury.

In the validity part of this study, the 88 patients who had undergone ACL reconstruction in 2007-2010 were eligible. Seventy-four (84 %) patients attended the 6 and 12 month postoperative

follow-ups and responded to the online activity survey 6 and 12 months postoperatively. This group of patients included 39 (53 %) women and 35 (47 %) men, and had a mean age of 24.5 ± 6.9 years at baseline.

Paper III

The first 143 enrolled patients in Cohort B were included in this paper. Of these, 141 (99 %) attended the 6 week test, 135 patients (94 %) were included in the analysis of the monthly online activity survey data, and 128 patients (90 %) patients attended the 2 year follow-up. Of the 143 patients, 100 (70 %) had undergone ACL reconstruction and 43 (30 %) were nonoperatively treated at the 2 year follow-up. The nonoperatively treated patients were 24 (56 %) women and 19 (44 %) men, with a mean age of 30.2 ± 8.8 at baseline. The operatively treated patients were 56 (56 %) women and 44 (44 %) men, with a mean age of 24.2 ± 7.2 .

Paper IV

Ninety-one nonoperatively treated patients were included in this study, whereof 81 (89 %) attended the 1 year follow-up. The patients were 40 (49 %) women and 41 (51 %) men, with a mean age of 29.2 ± 8.8 years at baseline.

Outcome measures

The same outcome measures were used in Cohort A and Cohort B, with the exceptions of the online activity survey and isokinetic muscle strength measurements. The online activity survey was developed after the data collection in Cohort A was completed, and is therefore only included for Cohort B. Our institution did not have access to an isokinetic dynamometer prior to 2007, and these measurements are therefore only included for Cohort B.

Self-reported outcome measures

Three self-reported measures of knee function and two self-reported measures of sports participation were used in this dissertation.

The IKDC 2000 (Papers I, III and IV) is a measure of knee symptoms, function and sports activity.¹⁰⁷ The KOS-ADLS (Paper I) is a measure of knee symptoms and disability with activities of daily living.¹⁰⁹ The global rating scale (GRS) for knee function (Paper I) requires the patients to assess their functional level on a scale ranging from the preinjury level of function to a complete loss of function due to the knee injury.¹⁰⁹ The IKDC 2000, KOS-ADLS and GRS for knee function all have a score from 0 (worst) to 100 (best), and both the IKDC 2000 and the KOS-ADLS were translated from English to Norwegian by NAR following established guidelines.^{24,90} The IKDC 2000 has been found to be valid and reliable in ACL-injured patients.^{92,107,108,121,169} The IKDC 2000 is so far the only self-reported outcome measure of knee function with an evidence-based reported clinically important difference¹⁰⁸ and a normative population material consisting of uninjured individuals.⁸ The reported minimal detectable change (MDC) of the IKDC 2000 is 12.8¹⁰⁷ and the clinically important difference is 11.5.¹⁰⁸ Van Meer et al.²²⁰ recently reported an MDC of 12.2 points in a group of ACL injured patients, further supporting the robustness of using 12 points as a cutoff for true changes in this population. There are no reports of the psychometric properties of the KOS-ADLS exclusively in ACL injured patients. The KOS-ADLS has shown to be highly reliable in patients with various knee problems;¹⁰⁹ however, it likely has ceiling effects and is less responsive to changes in ACL-injured patients,¹⁴¹ as it encompasses activities of daily living, not sport. Based on the reported standard error of measurement (SEM),¹⁰⁹ the MDC of the KOS-ADLS is 8.9.²²⁵

The routine activity questionnaire was used in all papers to establish preinjury sports participation, and in Papers I and II to assess sports participation at 6 and 12 month follow-ups. It was a project-specific questionnaire where patients were asked to list the sports they participated in, and state how many times per week they participated in sports or exercise. As is typical for project-specific questionnaires that measure sports participation, the psychometric properties have not been evaluated.

All four aforementioned questionnaires were completed by the patients without supervision while they sat in the waiting room. At the conclusion of each follow-up, the questionnaires were checked for missing responses and patients were asked to complete the entire questionnaire if items had been overlooked. Ticking off between two boxes was not allowed, and if patients were unsure of what to respond they were asked to provide their best estimate.

The online activity survey (Papers II and III) was developed by NAR to prospectively record monthly participation in all major sports activities relevant to ACL-injured patients treated at our clinic. The registration was carried out with an online survey tool (Questback v. 9.6, Questback AS, Oslo, Norway). The patients received a standardized e-mail each month which explained the purpose of the survey and contained a link to the online activity survey. If patients had not responded within a

week, an automatic reminder was sent out. The activity survey consisted of the question: “Which of the following sports have you participated in during the last 4 weeks?”, followed by a standardized list of sports (table 2) that was intended to cover all major sports that are relevant to ACL-injured patients in our geographical region. The list of sports was derived from previously published studies on ACL-injured patients, discussions with experienced physical therapists who treat ACL-injured patients, and reviewing the sports previous patients (from Cohort A) had listed on the routine activity questionnaire. After reporting which sports they had participated in, patients were asked how many times (on average) they had participated in those sports per week. Psychometric properties of the online activity survey were evaluated in Paper II.

Table 2 Sports recorded in the online activity survey, classified according to activity level^{62,96,155}

Sport	Activity level
Handball	Level I
Soccer	
Basketball	
Floorball	
Volleyball	Level II
Martial arts	
Gymnastics	
Icehockey	
Tennis/squash	
Alpine/telemark skiing	
Snowboarding	
Dancing/aerobics	Level III
Cross-country skiing	
Running	
Cycling	
Swimming	
Strength training	

Muscle strength assessments and single-legged hop tests

All patients performed a standardized 10-minute warm-up on a stationary bicycle prior to functional testing.

Muscle strength of knee extensor and flexors (Paper III) was measured concentrically at 60°/sec using an isokinetic dynamometer (Biodex 6000, Shirley, New York, USA). Isokinetic testing at low velocities is considered to be a valid and relevant method of assessing muscle strength.^{103,174,175} A knee ROM from 90° to 0° of flexion was used, and gravity correction was performed by weighing the tested limb at 10° of knee flexion. The patient sat in an upright position with two shoulder stabilization straps, a pelvic stabilization strap and a thigh stabilization strap. The patient’s arms were crossed over their chest during the test. All patients performed four practice repetitions followed by one minute rest and five recorded test repetitions at maximum effort. To minimize intra- and interrater bias, verbal feedback during the testing was restricted to counting the repetitions. Peak

torque, the highest torque achieved during all repetitions, was reported. Intraclass correlation coefficient (ICC) values of the peak knee extensor and flexor torque range from 0.93 to 0.98, with MDC values of 12-19 %.¹⁰⁵

Four single-legged hop tests were used in Papers I and IV: The single hop for distance, the crossover hop for distance, the triple hop for distance and the 6-meter timed hop test.¹⁶⁷ Single-legged hop testing is an established method of assessing function in ACL-injured patients.^{55,72,177,198} In ACL-reconstructed patients, the limb symmetry indexes of these tests have shown ICC values of 0.82-0.93 and MDC values of 8-13 %.¹⁷⁷ The starting position for all hop tests was behind a marked line with the patient standing on one leg. The single hop for distance required the patient to execute one horizontal hop as far as they could. The crossover hop for distance consisted of three horizontal hops where the patient crossed a line on the floor in the medial, lateral and then medial direction. The triple hop for distance consisted of three horizontal hops. During these first three hop tests, it was required that the patient maintained a stable landing after the final hop. If the patient touched the floor or wall with their hand, performed an additional hop at landing, or their other foot made contact with the floor, the hop was ruled invalid and repeated. The horizontal distance hopped was recorded in centimeters with a tape measure from the starting line to the heel of the patient. The 6-meter timed hop test required the patient to hop a distance of 6 meters as fast as possible. A stop watch was used to record the time to the nearest 100th of a second. The test started when the patient initiated the movement and ended when they crossed the 6-meter line. For all tests, the uninjured leg was always tested first, and, for both limbs, the patient had one practice trial before two test trials were recorded.

Knee laxity measures

Passive anterior-posterior knee laxity was measured with a KT-1000 knee arthrometer (MedMetrics, San Diego, California). A thigh strap was used to ensure anterior orientation of the patella, and special attention was paid to ensure that the patient's thigh muscles were relaxed. The side-to-side difference using the maximal manual test was used for diagnosis at inclusion and reported at follow-ups in Papers I and IV. The manual max test was chosen as it is shown to be the most accurate test for discriminating between injured and uninjured knees.¹⁵ For diagnostic purposes, a cutoff of ≥ 3 mm was used.⁴⁷ The KT-1000 has primarily been validated as a diagnostic tool.¹³ Although KT-1000 measurements have shown to be reliable when performed by experienced raters,^{29,37} the continuous outcome reported in Papers I and IV should therefore be interpreted with some caution.

Assessment of knee injuries

Prior to inclusion, all patients had their ACL rupture verified using conventional MRI. During the follow-up period, the patients reported knee reinjuries either at a follow-up or through the online survey (Paper III). All patients who reported a knee reinjury underwent clinical examination by a physical therapist or an orthopaedic surgeon. Following standard practice at our institution, MRIs and arthroscopy were performed only when clinically indicated. Thus, the knee reinjury was diagnosed solely based on clinical examination in some patients, while other patients were examined with a combination of clinical examination, MRI, and/or arthroscopy. All MRIs were read by the attending radiologist at the institution where the imaging was performed.

Data management and statistics

In Papers III and IV, self-reported knee function within normal ranges was defined as an IKDC 2000 score equal to or above the age- and sex-specific 15th percentile from data on uninjured individuals.⁸ The normative data material consisted of IKDC 2000 scores on 3568 uninjured knees which were collected from a stratified random sample of a preexisting panel.⁸ This panel comprised 1.3 million individuals who were matched to represent the US population using US Census Bureau data. The 15th percentile corresponds to a Z score of approximately minus 1, and was chosen to ensure that patients with scores below the cutoff point had scores that differed from what could be considered a normal variation in IKDC 2000 scores. Following comments from the editor and reviewers, Paper IV included an appendix with results from additional analyses where the 30th and 50th percentile were used as cutoff points for the IKDC 2000 score.

In Papers I and IV, hop test LSIs were calculated as (the best result on the injured leg)/(the best result on the uninjured leg) x100. In Paper III, the muscle strength LSI was calculated similarly, as the percentage peak torque of the injured leg over the peak torque of the uninjured leg. A muscle strength LSI below 90 has frequently been regarded as an unsatisfactory level of muscle strength,^{5,119,214} and the number of patients with muscle strength LSI below 90 was therefore also reported in Paper III.

For all papers, tests of nominal data included the χ^2 tests for unpaired comparisons, Fisher's exact test for unpaired comparisons when the expected count was lower than 5, and McNemar's test for paired comparisons. Unpaired comparisons of scale data were performed with two-sided independent t-tests and Mann-Whitney U tests if the assumption of normality was violated. Paired comparisons of scale data were performed with two-sided paired t-tests with Wilcoxon's test as the nonparametric alternative.

In Paper I, the Mantel-Haenszel estimate of the risk ratio was used to quantify the probability of returning to preinjury main sport in nonoperatively versus operatively treated patients. While this estimate, like the McNemar test, is based on the number of discordant pairs, it also takes into account the number of concordant pairs that did not return to sport, thus providing a true risk ratio.

In Paper II, Cohen's κ was used to determine the agreement between the test and the retest responses, and between the two methods on assessing return to preinjury main sport. Linearly weighted Cohen's κ was used for the ordinal data on how many times per week patients participated in sports. Linear weighting was chosen because the response options were largely linearly spaced. In addition to Cohen's κ , the absolute proportion of agreement was also reported as a measure of agreement that does not depend on prevalence.

The analyses of self-reported outcome and muscle strength in Paper III were performed with a repeated measures ANOVA. Significance for the within-between interaction effect was tested with Wilk's lambda as this test is more robust for violations of the sphericity assumption than the univariate ANOVA tests.

To analyze differences in level I, II and III sports participation, and weekly frequency of sports participation (Paper III), generalized estimating equations (GEE) models were fitted, which adjust for the correlation between months. A logit link function and binomial variance function were used in the analyses of participation in level I, II and III sports, and an identity link function and Gaussian variance function was used in the analysis of weekly frequency of sports participation. A first order autoregressive (AR1) correlation structure and robust standard error estimates were used in all analyses. The correlation structure was chosen based on the assumption that the responses from adjacent months would show the highest intracorrelations. Inference about the beta parameters was found to be robust after comparing models using AR1, exchangeable and unstructured correlation structures. Crude odds ratios/betas for group with 95 % confidence intervals (95 % CI) were presented, as well as adjusted odds ratios/betas where covariates for all analyses included age. Preinjury participation in level I and level II sports were additional covariates in the adjusted analyses of level I and II sports participation, respectively. In the analysis of nonoperatively and operatively treated patients, there were significant group by time interactions for participation in level I and II sports. These analyses were therefore stratified by the 1st and 2nd year of the follow-up period. Prior to running the GEE logit models, we examined the possibility of performing a simpler analysis using the proportion of months each patient participated in level I, II and III sports, respectively, as the dependent variable in a weighted linear regression. However, this summary variable showed a substantial clustering on 0 for level I and level II sports, caused by patients who never participated in

these sports. This distribution would not be improved with transformation and would heavily distort the linear regression results; thus we chose not to utilize a summary measure in the analysis.

In Paper III, the incidence of knee reinjuries was reported as the number of injuries per 100 patient-years. A Cox regression model was used in the analysis of knee reinjuries. The hazard function denoted the probability that an individual would sustain a knee reinjury within an interval of the follow-up time, given that the patient had not yet sustained a reinjury. The reported hazard ratios are then interpreted as the change in the hazard for operatively treated patients compared to nonoperatively treated patients. The analyses were adjusted for age and preinjury participation level I and II sports. The Wald test was used to test for statistical significance, and robust estimation of standard errors were used.

In Paper IV, the main analyses consisted of univariable and multivariable logistic regression, and the area under the receiver operating characteristic (ROC) curve was used as a measure of discriminative accuracy. Utilizing the parameters of the ROC curve, a cutoff point for the hop test LSI was identified by the LSI with the highest product of sensitivity and specificity. The sensitivity, specificity, positive likelihood ratio and negative likelihood ratio at this cutoff point were then reported with 95 % CI.

Data were analyzed using either SPSS (SPSS for Windows, versions 17-20, SPSS Inc, Chicago, USA) or Stata (Stata/IC 12.0 for Windows, StataCorp LP, Lakeway Drive, Texas, USA) In all papers, the two-tailed alpha level was set to 0.05.

Discussion

Study design

An observational study design was chosen in all papers in this dissertation, meaning that the changes in outcomes were observed as they naturally occurred following the treatment of the patients.³⁸ The advantages of utilizing an observational design include a high feasibility and external validity.³⁸ While randomized trials are superior when assessing the efficacy of an intervention, observational studies provide knowledge on the prognosis of outcome following specific treatment algorithms. In other words, randomized trials answer the question “can it work?” and observational studies answer the question “does it work?”.⁹⁵ The observational design was chosen to best answer the research aims of this dissertation, which included evaluating the clinical course of nonoperatively and operatively treated patients, evaluating psychometric properties of an outcome measure, and determining the predictive characteristics of hop tests. These research aims all require a high degree of external validity.

While Papers II, III and IV were prospective cohort studies, Paper I utilized a pair-matched cohort design in which the data were recorded prospectively, but the patients were matched retrospectively. This design may easily be mistaken for a case control design.¹⁴⁸ However, as opposed to a case control study, patients were grouped on different levels of the exposure factor (treatment course) instead of the outcome (return to sport). This also has consequences for the data analysis and interpretation, as the prevalence of the outcome in the sample is known.⁴⁵

Interpretation of study results are frequently hindered by inadequate reporting.^{126,221} Increasing the quality of reporting has therefore been a recent area of focus, and guidelines for reporting study results have been developed for various research designs. The Strengthening the Reporting of Observational Studies (STROBE) statement has been developed for observational studies,²²¹ and, more recently, Guidelines for Reporting Reliability and Agreement Studies (GRRAS) have also been proposed.¹²⁶ To ensure transparent and accurate reporting of the studies included in this dissertation, the STROBE checklist was used when preparing manuscripts for Papers I-IV, and the GRRAS checklist was additionally used for the reliability part of Paper II. The STROBE and the GRRAS checklists can be found in the appendix.

Loss to follow-up is an important potential source of bias in any study design.³⁸ While a random loss to follow-up leads to lower statistical power, systematic losses lead to both lower statistical power and selection bias. It is suggested that a systematic loss to follow-up of 20 % can introduce bias, while a random loss to follow-up of up to 60 % may not lead to biased results.¹²⁸

Whether the follow-up rate is above or below 80 % is an often used criterion when determining the level of evidence of a study. The follow-up rate was 90 % in Paper I, 84 % in Paper II, ≥ 90 % for all follow-ups in Paper III, and 89 % in Paper IV. Loss to follow-up in the included studies is thus not considered to be a threat to the validity of the results.

The major limitation of an observational design is the inability to completely control for confounding variables, making it a suboptimal design for determining the isolated effect of a specific treatment.¹⁴⁶ In Papers I and III, matching and statistical adjustment, respectively, were performed to limit the confounding bias. The aim of both methods is to remove the effect of extraneous factors that are related to both exposure (group) and outcome, but are not in the causal pathway between exposure and outcome. As a result of the matching process in Paper I, the patients selected for analysis were comparable in terms of sex, age and specific preinjury main sport, ensuring that the observed outcome in both groups was equally affected by these factors. In Paper III, all patients in the cohort were included in the analyses, and variables which were significantly different between groups and potentially related to outcome were adjusted for in the analyses. Compared to matching, statistical adjustment has the benefit of retaining the full sample size and has therefore a lower risk of selection bias. However, statistical adjustment also has limitations. In Paper I, matching was chosen because the purpose of the study was to remove the confounding effect of the *specific* preinjury main sport. Including this aspect in a multivariable model would not be feasible because the patients participated in too many different sports. Despite the measures taken to reduce the potential confounding effects of sex, age and preinjury sports participation, the observational design will never fully elude potential bias from confounding – be it from known or unknown factors.¹⁴⁶ In Papers I and III, an obvious group difference is that the operatively treated patients fulfill the treating surgeon's criteria for undergoing surgery while the nonoperatively treated patients either do not, or do not agree with the surgeon's advice. While age and preinjury activity level are the largest reported differences between nonoperatively and operatively treated patients,^{46,61,154} treatment preference should also be considered as a major confounder. Although not explored in ACL-injured patients, pharmacological studies report that concordance between the treatment recommendation and the patient's preferred treatment increases patient satisfaction,^{136,216,217} which in turn is associated with greater treatment adherence.^{138,231} It is likely that this also applies to the treatment of ACL-injured patients, where compliance to rehabilitation and activity restrictions is of great importance. Thus, an important limitation of Papers I and III is that we cannot conclude that the operatively treated patients would have achieved outcomes comparable to what was observed in the nonoperatively treated group had they not undergone surgery, or vice versa. It should, however, be noted that even a randomized design would not solve the problem of treatment preference, as patients with strong treatment preferences will not participate in studies where the treatment allocation is randomized.

Subjects

In line with the inclusion criteria, the target population of this dissertation was ACL-injured patients who participated in pivoting sports prior to injury. The subjects included in this dissertation are generally very similar to subjects in other prospective cohort studies on ACL-injured patients.^{4,104,162,207} While less is known about the nonoperatively treated part of the general ACL-injured population, ACL registries provide detailed knowledge on the ACL reconstructed population. In terms of age, sex and surgical procedures performed at the time of ACL reconstruction, the operatively treated patients included in this dissertation are similar to the patients included in the Scandinavian registries.⁸⁶ The age and sex of the included patients are also comparable to those included in the Kaiser Permanente ACL reconstruction registry and the Multicenter Orthopaedic Outcomes Network cohort in the US, although hamstrings autografts are used substantially less while allografts are used more, and the time from injury to ACL reconstruction is lower in the US.^{86,144} There were no professional athletes included in the data material. While most patients were recreational athletes, some were semi-professional and some competed at a national junior level. Thus, the included patients may be more athletically active than the ACL-injured population at large. This is likely one reason why our rate of ACL reconstruction was substantially higher than what is estimated for the general ACL-injured population,^{43,166} and why the time from injury to surgery in our material is lower than in the Scandinavian registries.⁸⁶ Consequentially, the results of this dissertation should not be generalized to either professional athletes or to patients who do not regularly participate in pivoting sports.

In Paper I, the matching process inevitably reduced the studied sample substantially compared to the original cohort. Of the patients from the original cohort who had complete data, 19 (22 %) nonoperatively treated and 53 (43 %) operatively treated patients were not included in the analyses. To make the two groups comparable in terms of age and preinjury sports participation, the analyzed sample likely consisted of nonoperatively treated patients that were slightly younger and more active in level I sports than the nonoperatively treated population, while the operatively treated patients were likely slightly older and less active in level I sports compared to the operatively treated population. Compared to patients included in Paper III, the mean age of the nonoperatively treated patients in Paper I was two years lower, and the mean age of the operatively treated patients was three years higher, while the standard deviations in age were seven to eight years in both papers. Caution is always advocated with respect to generalizability, and the results may not apply to the youngest patients of the operatively treated population and the oldest patients of the nonoperatively treated population. However, the analyzed sample in Paper I is likely more selected in terms of preinjury main sports level, as preinjury main sport was the primary factor on which we could not match patients. For that reason, explorative analyses were performed where we stratified the return to sport

analysis based on whether patients had a preinjury main sport of level I or II. Lastly, patients with preinjury main sports that are less common in Norway, such as cricket (n=1), skateboarding (n=1) and improvisational dance (n=1), could not be matched. However, these patients also make up a small part of the ACL-injured population.

Outcome measures

The IKDC 2000 was the main patient-reported outcome measure of knee function in this dissertation, and was included in Papers I, III and IV. This questionnaire was developed to measure knee symptoms, function and sports activity in patients with a variety of knee problems, including ligament injuries.¹⁰⁷ Although the items in the IKDC 2000 were not derived from patient interviews, several studies have shown that ACL-injured patients find the questionnaire highly relevant.^{92,209,220} Furthermore, test-retest reliability studies show ICC values ranging from 0.90 to 0.99,^{94,107,149,169,220} meaning the amount of random errors associated with this score is minimal. Because the IKDC 2000 utilizes one total score for a multidimensional construct (symptoms, function and sports activity), it is not directly interpretable in which specific domain the patients have problems. This is an important limitation of the questionnaire, and the score should be interpreted as an overall outcome.

In Papers III and IV, we classified patients as having self-reported knee function within or below normal ranges by comparing the IKDC 2000 score of the individual patients with previously published sex- and age-specific normative scores from an uninjured population. The intent behind this classification was to identify patients who very likely had self-reported outcomes below what could be considered normal for their sex and age. By utilizing a cutoff at the normative 15th percentile, the patients who were classified as having self-reported knee function below normal ranges had to score lower than $\geq 85\%$ of individuals without knee injuries. The normative data represented the general US population. This population is also likely to have lower demands to knee function than our athletically active patient population, further strengthening the assumption that a score below the normative 15th percentile represents unsatisfactory knee function. Any use of normative values for classification will be limited by the fact that we do not know the true variation in scores for the patients who have knee problems.⁷ Therefore, we do not know the proportion of patients with scores above the 15th percentile who still have knee problems. In Paper IV, the median IKDC 2000 score of the patients who were classified as having self-reported knee function within normal ranges was 94.3, indicating minimal functional limitations. Still, we cannot exclude the possibility that some patients with IKDC 2000 scores above the 15th percentile experienced knee problems.

In addition to the dichotomizing the IKDC 2000 in Papers III and IV, a dichotomized measure of muscle strength LSI was also reported in Paper III, and the single hop for distance was dichotomized in Paper IV using a data-derived cutoff point. Dichotomizing continuous variables inevitably leads to a loss of information, as the variance within the low and high scoring groups is ignored.¹⁸⁷ In particular, the practice of dichotomizing continuous predictors in regression models has been criticized.¹⁸⁷ In Paper IV, the hop test scores were analyzed as continuous variables, and a cutoff point for the significant hop test was identified after assessing the association between the independent and dependent variables. The main reason for presenting dichotomized results for the IKDC 2000 and the muscle strength LSI was to provide an estimate of the number of patients who did not achieve a satisfactory outcome. Identifying a group of patients with a poor outcome is particularly clinically relevant, as the ultimate goal almost always is to improve the outcomes of these patients. Thomee et al.²¹⁴ also suggest that the variability of reported continuous outcomes may be ignored by readers. Utilizing functional tests in ACL-injured patients, they posited that an interpretation based on the mean results would lead to a conclusion that the treatment was successful, even if only 23 % of patients achieved an LSI ≥ 90 on all six tests. Although clinically useful, this type of dichotomization remains limited as the cutoff points are slightly arbitrary. Additionally, as the definition of a satisfactory outcome will vary from patient to patient, no standardized dichotomization of outcome will be a perfect measure of success and failure. Still, the simplification of the outcome caused by the dichotomization increases the clinical applicability of the results by identifying patients who very likely would need other interventions, or a longer time, to achieve satisfactory knee function.

In addition to the project leaders of Cohort A and B, five physical therapists conducted the KT-1000 measurements, hop tests and muscle strength measurements included in this dissertation. While KT-1000 measurements have shown to be influenced by hand dominance,^{193,195} everyone who performed these tests was right-handed. To diminish the possibility of interrater bias, all physical therapists underwent thorough training before they started collecting data. This training consisted of written and spoken instructions in the test procedures, observation of the testing, and finally, supervised testing. Furthermore, during the course of the data collection, there was frequent joint testing to avoid possible individual differences in the way the tests were performed.

Multiple outcome measures that target different aspects of the overall outcome were included in this dissertation. While multiple outcomes are needed to properly assess the overall status of the patient, multiple analyses also raise the chance of type I errors.¹⁶ Paper III had the most extensive data material of the papers in this dissertation. The repeated measures models used to analyze knee function and sports participation limited the number of comparisons and thereby reduced the risk of type I errors in this paper. The data on sports participation were particularly complex, where both the

temporal activity restrictions and seasonal variations in the participation in winter sports affected the data structure. The analysis was thus a compromise between accurately modeling the intracluster correlation and reducing interaction on one hand, and providing estimates of the overall differences in sports participation with limited type I error inflation on the other hand. As a result, further details in the data, for example according to specific sports or more specific follow-up times, were not explored.

Results

Methodological aspects of measuring sports participation after ACL injury

In Paper II, we utilized a new method of recording sports participation after ACL injury. The online activity survey was found to be highly reliable. The content validity was supported as it contained all sports that $\geq 10\%$ of patients reported to participate in. The concurrent validity was supported by substantial agreement on return to preinjury main sport recorded with the routine activity questionnaire. Finally, the online activity questionnaire seemed to provide more complete data on sports participation compared to the routine activity questionnaire. Although more than 50 studies have reported return to sport rates after ACL injury,¹¹ Paper II is, to our knowledge, the first paper where psychometric properties of a method of recording sports participation after ACL injury have been evaluated. While there are reports on the validity and reliability of activity rating scales,^{35,147} these scales rank sports based on the demands they pose on the knee, as opposed to simply recording what sports the patients participate in.

By recording the participation in all major sports in which patients participate, the online activity survey encompasses a wider perspective on sports participation after ACL injury compared to a more traditional return to sport perspective. In Paper II, we found that patients participated in a mean of 3.7 ± 2.3 different sports 12 months postoperatively. Thus, a large part of the sports participation is neglected if the focus is exclusively on one sport. Furthermore, monthly reports enabled us to more accurately describe the timing of resumption of the different types of sports. The time from ACL reconstruction to resumption of sports has been reported to range from 2 to 24 months,¹¹ but how these data are collected is usually not described. However, it does not seem uncommon to record these data 2-3 years after the patient has returned to sport,^{17,152,229} which introduces a major potential for inaccurate recall.

The online activity survey was delivered by a web-based method where patients received invitations to the survey through a link in an email. The advantages of an online survey over a

traditional paper survey include lower costs, more design options, and that it requires very little time to distribute and collect results.⁶⁴ However, a meta-analysis of 45 studies showed that the average response rate of online surveys was 11 % lower than other survey modes.¹⁴⁵ Online survey response rates are found to be related to who conducts the survey, the relevance of the topic, and how long it takes to complete.⁶⁴ More practical concerns are also important, such as avoiding poor wording and technical flaws, avoiding activation of the email spam filter, and having updated email addresses for all participants. Although low response rates have previously shown to be an issue, our response rate for monthly reports over two years was 87 % (Paper III). Based on feedback from patients, the positive aspects of this form of monitoring included that it was very easy to complete the survey, and that receiving a monthly email from the project manager made it easier for them to contact us with any other concerns they may have. In the reliability study (Paper II), we sent invitations to all patients who had been enrolled in Cohort B, regardless of when they were included in the study. As could be expected, the response rate was lower (71 %) for this survey. When the survey was sent out, we received several automatic replies showing that the email address we had used during the two year monthly registrations was now invalid. However, because the eligible cohort consisted of 145 patients and we only needed 50 responses based on the power calculations, we did not make additional efforts to locate valid email addresses for those who did not respond. Still, the dependency upon having updated email addresses is an important limitation when utilizing this method. While the online survey provided valid and reliable responses, other modes of registering sports participation may also be considered. In currently ongoing studies, text messaging is utilized to record soccer exposure and injuries,¹⁶⁵ and global positioning system (GPS) tracking is utilized to quantify running exposure.¹⁶⁴ Furthermore, smartphone apps could be used to record participation in multiple sports, and also have the possibility of linking GPS data for relevant sports. Thus, several options are available which may be suitable for this relatively young and technologically competent population.

In future use of the online activity survey, some modifications may be considered. An important limitation is the selection of sports, which was found to be valid for our patient population, but will not provide an accurate representation of sports participation in other cultural or geographical settings. We therefore recommend that the survey be modified based on the sports the target patient population participates in. To avoid underreporting, specific sports should be listed. Still, to ensure that no major sports are missed, a free-text choice may be included in the survey. The original survey was designed with a focus on user-friendliness, at the expense of gaining some information. The user-friendliness of the survey was likely a main reason why the monthly response rate was high over the 2 years. Still, important data could be gained if the number of hours patients spend in the separate sports is recorded instead of an aggregate measure of their weekly frequency of sports participation. This modification could enable a quantification of the risk of reinjury in different

sports, which would help clinicians to better advise patients in the return to sport phase. Ultimately, different modifications may be desirable depending on the individual study's perspective on sports participation, the benefit of increasing the amount of details should be carefully weighed against the chance of negatively affecting the response rates, and following any modification, the psychometric properties of the new version must be established.

What is the expected outcome after nonoperative and operative treatment?

The 1 and 2 year outcomes reported in Papers I and III suggest that, following the treatment algorithm at our institution, both groups exhibit clinically relevant improvements in knee function over time. While the mean results for muscle strength symmetry and self-reported function were within what can be considered normal, Paper III showed that 30 % of patients had muscle strength deficits > 10 % compared with the uninjured leg, and 21 % had self-reported knee function below normal ranges at the 2 year follow-up. Regardless of treatment course, almost all patients participated in level III sports every month over the 2 years they were followed. While Paper I showed that 68.1 % of patients returned to their preinjury main sport after 1 year, Paper III showed that the participation in level I and level II sports was relatively constant over the second year. The participation in level II sports in nonoperatively treated patients was an exception, where there was a cyclical pattern which most likely was caused by seasonal variations in winter sports. On average, patients participated in sports 2-3 times per week consistently over the 2 years. The 1 and 2 year functional results and return to sport rates reported in this dissertation are in the mid to upper range of what has previously been reported.^{6,11,53,97,141,214}

Both Paper I and III revealed a high level of noncompliance to the recommended activity restrictions. While nonoperatively treated patients were advised not to resume level I sports, 56 % of patients did so at some point over the two years they were followed; furthermore, 34 % of these patients also intended on resuming level I sports when they made their initial treatment choice. Operatively treated patients also showed noncompliance, as 34 % and 18 %, respectively, returned to level I and II sports sooner than they were recommended after ACL reconstruction. While previous studies report that both nonoperatively and operatively treated patients have some form of activity restriction,^{69,150,206} little attention has so far been paid to whether patients actually follow these restrictions or not. Compliance has, however, been a larger focus in the assessment of the effect of rehabilitation programs, where Beynnon et al.³² showed that the compliance to the prescribed exercises decreased over time, with only half of the prescribed exercises performed 4 months after ACL reconstruction. Noncompliance in general thus poses a challenge when assessing the outcomes after treatment of ACL injuries, as patients may have done something largely different than the

described treatment intervention. The consequences of not following the recommended activity restrictions are not completely implicit. There is no consensus in the literature on the exact amount of time that patients should be restricted from sports participation postoperatively,¹⁹ or on the expected time frame for human graft remodeling.⁴² However, it is indicated that the graft undergoes remodeling for longer than 1 year postoperatively^{1,63,111,186,191} and that participation in sports earlier than 6 months postoperatively is related to a slower recovery of cartilage morphological characteristics after running.²¹⁹ Thus, while too demanding sports participation too early after surgery places the knee at risk for future damage, we do not have the detailed knowledge on how to define “too demanding sports participation” or “too early”. The reasons why some patients did not comply with the activity restrictions were not evaluated in this dissertation. Heijne et al.⁹⁸ described that ACL-reconstructed patients had unrealistic expectations about the time frame of rehabilitation, and considered themselves to be able to recover faster than what they had been told to expect. Patients are also surrounded with conflicting information from their clinicians, news reports on professional athletes, various internet sources, family and friends. Anecdotally, it is also hard to convince patients to refrain from sports participation once they feel they are ready. Still, without knowing the reasons behind the noncompliance, it is difficult to know how to reduce it. Thus, both the consequences of not complying with activity restrictions and the reasons behind this behavior may be areas of future study that ultimately may lead to improved patient outcomes.

Paper III showed that 77 % of patients who initially decided to undergo ACL reconstruction mainly chose surgery because they intended to participate in level I sports. The lower number of patients who chose surgery due to dynamic knee instability shows that, in this population, ACL reconstruction was more often performed to prevent future knee problems than to treat existing knee problems. In the second year after the surgery, the mean percentage of patients who participated in level I sports was only 46 % among those who made an initial decision of undergo surgery. The results of this dissertation, as well as numerous other studies,^{10-12,46,69,74,154} show that an operative treatment course does not guarantee that the patient resumes high level sports. Fear of reinjury is proposed to be the main reason for not returning to sport,^{9,11} and it is therefore advocated that clinicians should help patients build confidence in the injured knee in the return to sport transition phase.¹¹ Herein lays a clinical dilemma, because the clinician also has a responsibility to inform the patient about the risk of reinjury following return to sport. While fear of reinjury may be exaggerated in some patients, for other patients, not returning to sports due to fear of reinjury might actually prevent reinjuries. Using motion analysis, Paterno et al.¹⁷² showed that postural stability and biomechanical measures during landing from a drop jump could predict rerupture of the ACL after reconstruction, highlighting the importance of regaining neuromuscular control prior to resumption

of sports. However, future work is needed to find clinically applicable tools that can accurately discriminate between patients with high and low reinjury risks.

In Paper III we found that 33 % of patients who initially decided on a nonoperative treatment course later underwent ACL reconstruction. Previous studies have reported that 20-37 % of nonoperatively treated patients later undergo ACL reconstruction.^{52,68,74,162} Initially, it seems discouraging that the rate of late ACL reconstruction following our treatment algorithm is comparable to the rate of late reconstruction following randomization.⁷⁴ However, the rate of late ACL reconstruction is not a reliable measure of treatment failure, perhaps most importantly because it depends on the surgeon's willingness to perform the surgery. Nonetheless, it is clear that the accuracy of the current surgical selection criteria has great potential for improvement.

Over 2 years, knee reinjuries were recorded in 9 % of nonoperatively treated and 24 % of operatively treated patients. These injuries were reported by the patients, and it is probable that a systematic MRI at the follow-up would disclose additional cases of asymptomatic structural damage. Comparison of injury rates between studies is challenging as there are large differences in how the injuries are recorded and diagnosed. Most commonly, surgical procedures are reported as a proxy measure of injuries.^{52,74,150,162} In Paper III, only 15 of the 41 injuries were treated surgically, exemplifying the impact differences in methodology can have. Only 6 % of all patients in Paper III underwent meniscal surgery between baseline/ACL reconstruction and the 2 year follow-up. This is a low percentage compared to other studies,^{52,74,150} but also an underestimation of the total number of reinjuries these patients incur. The injuries were reported both at follow-ups throughout the study, but also in the online survey which was sent to the patients each month. While the accuracy of this system is not assessed, all patients were frequently and systematically asked whether or not they had sustained any knee reinjuries. The verification and diagnosis of the reinjury was made according to the standard practice at our institution. In Paper III, five injuries (12 %) were diagnosed solely based on clinical examination (three meniscus injuries, one MCL injury and one patella subluxation), 15 (37 %) injuries were diagnosed after clinical examination and MRI, 13 (32 %) were diagnosed after clinical examination and arthroscopy, and 8 (20 %) were diagnosed after a combination of clinical examination, MRI and arthroscopy. It is possible that the patients who reported a knee reinjury and only underwent clinical examination had additional injuries in the knee that would be detected had they undergone MRI or arthroscopy. However, the analysis of knee reinjuries in Paper III was based on the number of patients with reinjuries, not the total number of reinjuries. Thus, undiagnosed additional injuries would not affect the results of the analysis.

Athletically active individuals are at risk of sustaining injuries, regardless of whether or not they have a previous ACL injury. The risk of sustaining acute meniscus injuries is found to be higher

in individuals who participate in soccer, rugby, and even swimming.¹⁹⁷ However, the consequences of sustaining additional knee trauma are likely even greater in athletes who have residual structural damage from a previous trauma. Thus, implementation of interventions that can reduce the risk of a new knee injury is a key factor to protect future knee health in patients who want to return to sports after an ACL injury. These interventions can be divided into two categories: 1) Devising and implementing more accurate criteria for deciding when and if the patient can resume sports participation with an acceptably low risk of sustaining new injuries, and 2) Improving treatment strategies to address the modifiable risk factors for sustaining injuries following resumption of sports. However, these strategies also rely on the patient complying with activity restrictions and rehabilitation, respectively.

The expected outcome following ACL injury is not easily quantified. It is essential to assess multiple aspects of the overall outcome, and the relationship between the different types of outcomes, especially over time, is not fully understood. Furthermore, the definition of a good outcome also depends on the time of assessment. In the short term, regaining knee function and being able to resume sports participation may be of high importance to the patient. However, resuming sports participation does not guarantee sustained participation in sports, and may increase the risk of sustaining a knee reinjury, ultimately resulting in poor knee function, more extensive structural damage in the knee, and early onset of knee osteoarthritis. A good outcome in the short term is therefore not only an insufficient indicator of a good outcome in the longer term, but may in some cases also indirectly lead to a poor long term outcome. Thus, assessments of outcome in the short, mid and long term are needed to evaluate if a treatment is truly beneficial, and there is a need for more knowledge on how short and mid term outcomes are associated with long term outcomes. This also makes it difficult to provide patients with accurate and thorough information in the early phase after injury.

In any comparison of nonoperatively and operatively treated patients, the patients who initially decide on nonoperative treatment and then undergo late ACL reconstruction represent a dilemma for the researcher. After a patient undergoes ACL reconstruction, their postoperative results cannot provide knowledge on the outcome following nonoperative treatment. However, because nonoperatively treated patients always have the choice of undergoing surgery if they are dissatisfied with the outcome, there is a risk that the group of nonoperatively treated patients ultimately will consist of patients who exclusively have a good outcome. It is not clear how patients who undergo late ACL reconstruction differ from patients that undergo initial ACL reconstruction. A recent meta-analysis reported a 3.5 fold increase in the odds of having a medial meniscus tear at the time of reconstruction in patients who underwent surgery more than 12 months after injury.¹⁹⁷ While it is widely argued that the timing of surgery is associated with the risk of meniscus injuries,^{85,197,201} none

of the cited studies take into account that patients who undergo late ACL reconstruction have also been exposed to risk for a longer time; that is, that the prevalence of meniscus injuries will increase with increased time from injury, regardless of the timing of ACL reconstruction. In a cohort where all patients initially were treated nonoperatively, Kostogiannis et al.¹²⁵ showed that patients who underwent ACL reconstruction had lower self-reported knee function at a 15 year follow-up compared with those who remained nonoperatively treated. Still, it is not clear if this was caused by factors that existed prior to the surgery or after, or, even more importantly, if the outcome of these patients would have been different if they had undergone initial ACL reconstruction. In all papers of this dissertation, the treatment status at the latest follow-up determined whether patients were classified as nonoperatively or operatively treated. In Paper III, we performed additional analyses to explore whether there were substantial differences between patients who initially decided to undergo ACL reconstruction and those who made a late decision to undergo ACL reconstruction. There were no statistically significant or clinically meaningful group differences in baseline characteristics or functional outcomes over the 2 years. There was also a low threshold for recommending ACL reconstruction to nonoperatively treated patients who experienced dynamic instability after rehabilitation and wanted to undergo surgery. The rationale behind this decision was to potentially prevent future knee injury in patients with dynamic instability, and to swiftly treat patients who had already sustained meniscus injuries. Four of these 21 patients (19 %) had sustained new knee injuries prior to ACL reconstruction, all were meniscus injuries and all were treated with surgical repair. The rate of concomitant surgical procedures at the time of reconstruction was lower than previously reported in patients who undergo late surgery,²⁰¹ and not significantly different from the patients who made an initial surgical decision. After adjusting for preinjury participation in level I sports and age, a significantly lower number of patients who made a late decision of undergoing surgery participated in level I sports after surgery compared with those who made an initial surgical decision. The lower participation in level I sports is likely a contributing factor to why only two patients reported a knee reinjury after surgery.

Papers I and III showed that, following the treatment algorithm at our institution, there are few differences in the outcomes between nonoperatively and operatively treated patients. Although statistically significant differences were noted in favor of the nonoperatively treated group for selected functional outcomes (Paper I) and in level II and III sports participation (Paper III), these differences are likely of little clinical relevance. The functional differences were all smaller than the smallest detectable difference of the outcome measures, the differences in level II participation was only present in the first year of the clinical course, and although nonoperatively treated patients were more likely to participate in level III sports, more than 85 % of the operatively treated patients also participated in these sports from the 2nd to the 24th postoperative month. Previous comparative

studies on the outcome after nonoperative treatment and operative treatment with ACL reconstruction report either no significant differences or conflicting results with regard to self-reported knee function, performance-based measures, sports participation, knee reinjuries, and knee osteoarthritis.^{6,46,52,68,69,74,76,120,142,150,151,154,159,162,206,207,222} The only difference between these groups which is consistent across studies is that operatively treated patients have reduced passive anterior-posterior knee laxity. Thus, while nonoperative and operative treatment courses both hold a place in the treatment of ACL injuries, future efforts should be made to better identify the patients who benefit from a nonoperative and an operative treatment course, respectively.

The predictive characteristics of single-legged hop tests

In Paper IV we showed that conducting the single hop for distance early after injury can be useful when providing a prognosis for 1 year outcome after nonoperative treatment. Paper IV had a high focus on clinical utility. Firstly, hop tests have a large potential for implementation in clinical practice, as they are easy to perform and require very little time, space and equipment. Secondly, the reported test statistics were chosen to enable easy interpretation of the clinical usefulness. Based on the expected outcome in our patients, a single hop LSI above 88 indicated an 89 % (95 % CI: 81-96 %) probability of regaining knee function within normal ranges, while there was a 57 % (45-68 %) probability of regaining knee function within normal ranges for patients with an LSI below 88. Although the single hop had very similar sensitivity and specificity at the chosen cutoff, the post-test probabilities revealed that the test can primarily be used to identify patients with a high probability of having self-reported knee function within normal ranges. While using several hop tests in combination is advocated to increase the concurrent sensitivity,^{110,167} Paper IV showed no additional benefit of using two hop tests in combination. Furthermore, the concurrent and predictive characteristics of these tests seem to be different. Hop tests have previously shown low concurrent sensitivity, meaning that patients exhibit high LSIs despite having knee problems. In contrast, the triple hop and crossover hop showed a distinct lack of predictive specificity, meaning the lack of accuracy was caused by patients with low LSIs having self-reported knee function within normal ranges one year later.

Hop tests show low to moderate association with muscle strength^{167,174,179,226} and self-reported knee function,^{167,194,226} and are not shown to be influenced by passive knee laxity.^{55,183,194} As functional performance-based measures, they are thought to reflect the combined contribution of the muscle strength, the neuromuscular control, and the confidence of the patient. Because these tests do not measure specific impairments, the relationship between hop tests and 1 year knee function likely consists of interplay of multiple factors. For example, it may be speculated that some patients have

lower baseline hop test scores because their neuromuscular control is more severely affected, which also worsens the 1 year prognosis. Other patients may perform poorly on the hop test due to psychological factors that also might influence compliance with rehabilitation. Thus, while the single hop test should be performed to provide a more accurate prognosis for knee function, evaluation of the specific impairments of the patients must be conducted to direct the focus of rehabilitation.

Using the same methods as in Paper IV, our research group has also evaluated the predictive characteristics of single-legged hop tests in ACL reconstructed patients.¹⁴⁰ While no association was observed between preoperatively conducted hop tests and self-reported knee function 1 year postoperatively, the crossover hop for distance and the 6-meter timed hop test conducted at 6 months postoperatively were the strongest predictors for 1 year postoperative outcome. A plausible explanation why hop tests were not predictive when conducted preoperatively may be that the patients had undergone extensive preoperative rehabilitation; thus, the variation in LSIs was lower at the preoperative test compared with both the 6 month postoperative test and the baseline test in the nonoperatively treated patients. It is probable that the preoperative variation in hop test LSIs may have been too low compared to the measurement error of these tests. The observed differences in concurrent and predictive characteristics, and the differences between treatment groups and time points, strongly suggest that none of the four hop tests are generally better than the other. Instead, different tests should be utilized based on the purpose and time of testing.

Conclusions

The following conclusions were made for each of the seven aims of the dissertation:

1. Both nonoperatively and operatively treated patients showed large improvements in functional outcomes from baseline to 1 year (Paper I), and baseline to 2 years (Paper III). After 2 years, 23 % of nonoperatively treated patients had knee extensor strength LSI below 90 and 23 % had knee flexor strength LSI below 90 (Paper III). Seventeen percent of nonoperatively treated patients had self-reported knee function below normal ranges. For operatively treated patients, 33 % of patients had knee extensor strength LSI below 90 and 34 % had knee flexor strength LSI below 90, while 22 % had self-reported knee function below normal ranges.
2. At 1 year, nonoperatively treated patients had statistically significantly better hop test scores and self-reported function than operatively treated patients who were matched by preinjury main sport, sex and age (Paper I). None of the differences exceeded the minimal detectable differences of the outcomes. Changes in self-reported knee function and muscle strength over 2 years were not significantly different between nonoperatively and operatively treated patients (Paper III).
3. Nonoperatively and operatively treated patients who were matched by specific preinjury main sport, sex and age did not have significantly different 1 year return to preinjury main sport rates (Paper I).
4. The online activity survey was a highly reliable method of monitoring changes in sports participation after ACL injury. The content and concurrent validity of the online activity survey were supported, and the use of the survey may lead to more complete data on sports participation compared to a routine activity questionnaire (Paper II).
5. Nonoperatively treated patients showed a cyclical development in level II sports which to a large extent coincided with the summer and winter seasons, while the number of patients who participated in level I and III sports was relatively constant over the two years (Paper III). The number of operatively treated patients who participated in level I and II sports increased between 6 and 12 months, and remained relatively constant over the 2nd year. The number of operatively treated patients participating in level III sports increased over the first three months, then remained relatively constant for the rest of the 2 year follow-up period.

6. The unadjusted analysis showed that a significantly higher number of operatively treated patients participated in level I sports in the 2nd year of the follow-up (Paper III). After adjusting for age and preinjury sports participation, a significantly higher number of nonoperatively treated patients participated in level II sports during the 1st year, but not in the 2nd year of the follow-up period. A significantly higher number of nonoperatively treated patients participated in level III sports over the full 2 year follow-up period. However, more than 85 % of the operatively treated patients also participated in these sports from the 2nd to the 24th month.

7. The single hop for distance can be useful when providing a prognosis for 1 year outcome in nonoperatively treated patients, and combinations of two hop tests did not provide more accurate predictions than the single hop test performed alone (Paper IV)

Future perspectives

A vast amount of research comparing the outcome after nonoperative and operative treatment courses suggests no significant differences in the average outcome. Still, the outcome after both treatment courses is variable, with a considerable number of patients having functional deficits, not returning to sport, sustaining new knee injuries, and/or developing knee osteoarthritis. Thus, there is a need to establish more accurate treatment selection criteria by identifying which patients will benefit the most from which treatment. By devising a clinical prediction rule for treatment choice and subsequently validating this rule there is a great potential for improving patient outcomes following both treatment courses. In the Delaware-Oslo ACL Cohort study, we are currently performing 5 year follow-up testing including evaluation of radiological knee osteoarthritis. Pooling the data from the two sites will enable us to devise clinical prediction rules for short and longer term outcome with a high degree of external validity.

The transition from rehabilitation to sports participation poses an important clinical challenge. Future research is needed to guide the clinical decision of when, and if, a patient should resume what type of sports participation. Clinically applicable tests that can predict reinjury risk following return to sport are also lacking. In studies evaluating treatment outcome, compliance to both the rehabilitation and the activity restrictions should be monitored. Lastly, participation in sports should be recognized as both being potentially damaging to future knee health and as a flawed, yet important indicator of a satisfactory outcome. Thus, the limitations of traditional measures of sports participation should be recognized, and valid and reliable methods that utilize a wider perspective on sports participation should be implemented.

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Paper I

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Paper II

Online registration of monthly sports participation after anterior cruciate ligament injury: a reliability and validity study

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ABSTRACT

Background The current methods measuring sports activity after anterior cruciate ligament (ACL) injury are commonly restricted to the most knee-demanding sports, and do not consider participation in multiple sports. We therefore developed an online activity survey to prospectively record the monthly participation in all major sports relevant to our patient-group.

Objective To assess the reliability, content validity and concurrent validity of the survey and to evaluate if it provided more complete data on sports participation than a routine activity questionnaire.

Methods 145 consecutively included ACL-injured patients were eligible for the reliability study. The retest of the online activity survey was performed 2 days after the test response had been recorded. A subsample of 88 ACL-reconstructed patients was included in the validity study. The ACL-reconstructed patients completed the online activity survey from the first to the 12th postoperative month, and a routine activity questionnaire 6 and 12 months postoperatively.

Results The online activity survey was highly reliable (κ ranging from 0.81 to 1). It contained all the common sports reported on the routine activity questionnaire. There was a substantial agreement between the two methods on return to preinjury main sport ($\kappa=0.71$ and 0.74 at 6 and 12 months postoperatively). The online activity survey revealed that a significantly higher number of patients reported to participate in running, cycling and strength training, and patients reported to participate in a greater number of sports.

Conclusions The online activity survey is a highly reliable way of recording detailed changes in sports participation after ACL injury. The findings of this study support the content and concurrent validity of the survey, and suggest that the online activity survey can provide more complete data on sports participation than a routine activity questionnaire.

demanding sport patients participate in postinjury (eg, the Tegner activity scale).⁷

The current methods only provide a limited view of the full complexity of sports participation. Although return to sports is considered indicative of a successful outcome, it does not guarantee normal knee function⁸ or sustained sports participation.⁹ Further, it may expose the athlete to considerable risk of additional injuries or reinjuries.¹⁻¹⁰ In studies reporting reinjuries, sports participation between index and secondary injury can provide valuable data on patient-time at risk,¹¹ although this is rarely reported in the literature. Additionally, the ACL-injured patients often participate in multiple sports both prior to and following ACL injury. While it has been shown that many patients do not return to their preinjury activity level,² less attention has been paid to the extent to which the patients return to, or take up, alternative sports activities. Hence, the assessments of sports participation after ACL injury should include not only if the patients return to sport or not, but also how the full sports activity profile changes. Finally, as sports participation is highly dynamic, optimal quantification requires repeated reports during the observation time. Frequent reporting also limits the risk of inaccurate recall by reducing the retrospective period.

In order to address these concerns, we developed an online activity survey to prospectively record the monthly participation in all major sports activities relevant to ACL-injured patients treated at our clinic. The aims of this study were (1) to assess the test-retest reliability of the online activity survey in a sample of non-operatively and operatively treated ACL-injured patients; (2) to evaluate if the content of the online activity survey provided a valid representation of sports participation at 6 and 12 months after ACL reconstruction; (3) to assess the concurrent validity of the questionnaire with respect to return to preinjury main sport at 6 and 12 months after ACL reconstruction; and (4) to evaluate if the online activity survey provided more complete data on sports participation compared with a routine activity questionnaire.

METHODS

Subjects

All the patients were enrolled in a prospective cohort study conducted at the Norwegian Sports Medicine Clinic (Nimi) between 2007 and 2012.¹² In order to be included in the study, the patients had to have a sustained unilateral ACL rupture within the previous 3 months. Diagnosis was

INTRODUCTION

After an anterior cruciate ligament (ACL) injury, a major concern for athletically active patients is when, if at all, they will be able to return to sports.¹ Return to sports has therefore become a commonly used measure of treatment success.² A multitude of different methods of recording activity level after ACL injury has been reported in the literature, including project-specific questionnaires, patient interviews and activity rating scales.³⁻⁵ The reported outcome is frequently based on whether or not the patient resumes one specific sport,⁶ or on a score reflecting only the most

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confirmed with MRI and a side-to-side KT-1000 difference of ≥ 3 mm.¹³ Other inclusion criteria included age 13–60 years and preinjury participation in level I or level II sports (table 1)¹⁴ \geq twice a week. Patients were excluded if they had bilateral injuries, previous injuries to either knee or if the MRI showed other grade III ligamentous injury, fracture or full-thickness articular cartilage damage. Patients with meniscal injuries were excluded only if they had symptoms during plyometric activities that were not resolved within 3 months from injury. Finally, patients who were not able to understand written and spoken Norwegian were also excluded.

All patients signed an informed consent prior to inclusion. The study was carried out in accordance with the directives given in the Declaration of Helsinki, and was approved by the Regional Ethical Committee for South-Eastern Norway.

Data collection

Online activity survey

An online registration was carried out with an online survey tool (Questback V 9.6, Questback AS, Oslo, Norway). Every month, each patient received a standardised e-mail that contained a unique link to the online activity survey. A reminder was automatically sent to those patients who had not responded after 1 week.

The online activity survey consisted of the question: "Which of the following sports have you participated in during the last 4 weeks?" followed by the sports listed in table 1. The patients were then asked: "How many times per week have you, on average, participated in these sports?" The listed sports were intended to cover all major sports the ACL-injured patients in our geographical region participated in. The selection of sports was based on previously published studies on ACL-injured patients, discussions with physiotherapists with extensive experience in ACL-rehabilitation and the results from a previous cohort study on ACL-injured patients performed at our institution.¹⁵ In this latter study, the patients completed a questionnaire in which they were asked to list all sports they participated in.

Table 1 Sports recorded in the monthly online activity survey classified according to activity level¹⁴

Sport	Activity level
Handball	Level I
Football (soccer)	
Basketball	
Floorball	Level II
Volleyball	
Martial arts	
Gymnastics	
Icehockey	
Tennis/squash	
Alpine/telemark skiing	
Snowboarding	Level III
Dancing/aerobics	
Cross-country skiing	
Running	
Cycling	
Swimming	
Strength training	

Routine activity questionnaire

All the patients attended the follow-up visits at our clinic 6 and 12 months postoperatively. Following an established test battery,¹² they completed a routine activity questionnaire without supervision in the clinic waiting room. On the routine activity questionnaire, the patients listed the types of sports or exercise they currently participated in, and how many times per week they participated in sports or exercise.

Reliability (aim 1)

In February 2012, all patients (n=145) were invited to participate in the test-retest of the online activity survey (figure 1). Based on our power calculations,¹⁶ it was estimated that 50 subjects would be needed to detect a κ of ≥ 0.4 at 0.80 power. The retest was sent 2 days after the test response was recorded. To avoid measuring true changes in sports participation, we decided a priori to exclude patients who responded to the retest ≥ 5 days after their test response.

Validity (aims 2–4)

All patients who had undergone ACL reconstruction between 2007 and 2010 (n=88, figure 1) were included in the comparisons between methods. Non-operatively treated patients were excluded from aims 2 to 4 because a merged sample of non-operatively and operatively treated patients would not allow for clear clinical interpretation of the data. Patients who had undergone ACL-reconstruction after 2010 were excluded due to incomplete follow-up data.

To evaluate if the content of the online activity survey included all common sports, we used the responses from the routine activity questionnaire at 6 and 12 months postoperatively. "Common sports" was operationally defined as sports that $\geq 10\%$ of patients participated in. We examined if the patients reported sports that were not part of the online activity survey, and how many patients participated in those sports. We expected that the routine activity questionnaire would not disclose any sports, in which $\geq 10\%$ of the patients reported to participate, other than those included in the online activity survey.

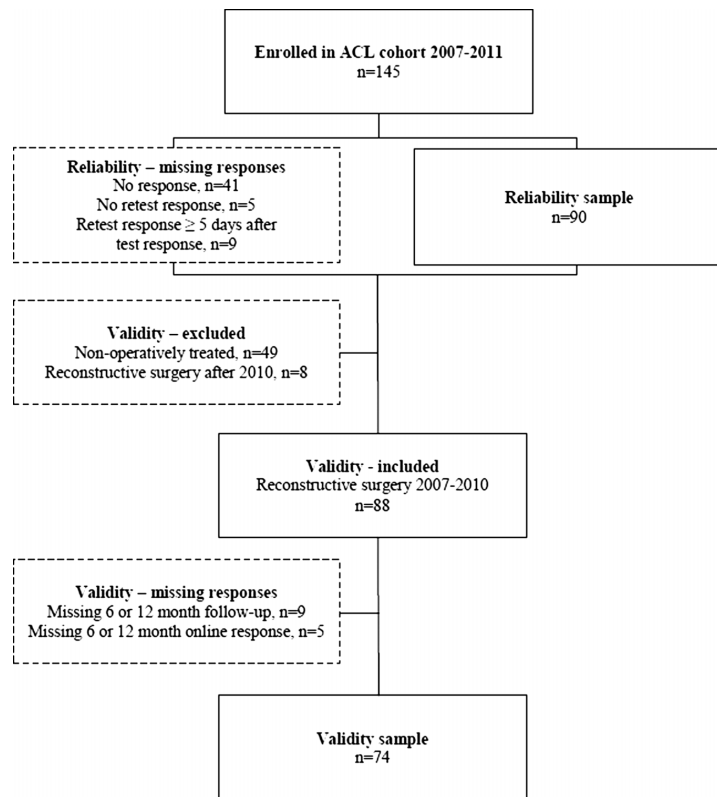
To evaluate the concurrent validity of the online activity survey, we examined the agreement between return to preinjury main sports recorded with the online activity survey and the routine activity questionnaire at 6 and 12 months postoperatively. We expected substantial agreement ($\kappa > 0.6$)¹⁷ between the online activity survey and the routine activity questionnaire.

To evaluate if the online activity survey provided more complete data on sports participation than our routine method, we compared the number of sports patients participated in 12 months postoperatively, the number of patients who participated in each sport 12 months postoperatively, and the number of patients who participated in level I, II and III sports at 6 and 12 months postoperatively. The online activity survey was designed with a list of specific sports in order to avoid bias that may come from patients having to decide which sports are relevant to report. Therefore, we expected that patients would report participation in a higher number of sports, and that more patients would report to participate in some sports, compared with the routine activity questionnaire.

Data management and statistics

Participation in level I, level II and level III activities was defined as the reported participation in at least one sport of the respective level (table 1). The patients were classified as having returned to preinjury main sport if they reported participation

Figure 1 Flowchart of patient participation in the reliability and validity assessment of the online activity survey.



in their preinjury main sport, regardless of their level of participation.

Test-retest reliability was quantified using κ with 95% CIs. Linearly weighted κ was used for the frequency of sports participation. Following recent guidelines for reporting reliability and agreement studies,¹⁸ the proportion of absolute agreement was reported. Agreement between methods in assessing return to preinjury main sports was quantified using κ . Paired *t* test and McNemar's test were used for between-methods comparisons of the number of sports patients participated in, the number of patients who participated in specific sports and the number of patients who participated in sports of different levels. All statistical analyses were conducted with SPSS V. 17 (SPSS Inc, Chicago, Illinois, USA).

RESULTS

Reliability

Of the 145 eligible patients, 101 (69%) responded to the test questionnaire, and 90 (62%) also responded to the retest questionnaire 2–4 days later (figure 1). Sixty-seven patients (74.4%) had undergone reconstructive surgery and 23 patients (25.6%) were non-operatively treated (table 2). The most frequent preinjury main sports were football (28.9%) and handball (25.6%). Both the test and the retest responses showed that most patients participated in sports 2–3 times/week, with the most frequent sports activities being strength training, running, cross-country skiing and cycling (table 3). Data collection was carried out in February, which is reflected by the high number of patients

participating in winter sports. κ ranged from 0.81 to 1, and the proportion of agreement ranged from 0.91 to 1.

Validity

Of 88 ACL-reconstructed patients, 74 (84.1%) completed the monthly online activity survey and attended follow-ups 6 and 12 months postoperatively (figure 1). This group included 39 (52.7%) women and 35 (47.3%) men with a mean age of 24.5 (6.9) years. The most frequent preinjury main sports were football (39.2%) and handball (28.4%). The sixth online activity survey was completed 6.3 (SD: 0.4) months postoperatively, and the 6 month routine questionnaire was completed 6.1 (0.3) months postoperatively. The 12th online activity survey and the 12-month routine questionnaire were completed 12.4 (0.5) and 12.1 (0.5) months postoperatively, respectively.

Table 2 Characteristics of the reliability sample (n=90)

Age, mean (SD)	29.1 (8.4)
Sex, female/male (% female)	44/46 (48.9%)
Treatment, operative/non-operative (% operative)	67/23 (74.4%)
Preinjury activity level, level I/level II (% level I)	65/25 (72.2%)
Months from surgery, mean (SD, minimum–maximum)	30.9 (16.4, 3–58)
Months from injury (non-operatively treated patients), mean (SD, minimum–maximum)	38.2 (17.0, 12–62)
Days from test to retest, mean (SD)	2.5 (0.7)

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Table 3 Test-retest reliability of the online activity questionnaire (n=90)

Item	Test n (%)*	Retest n (%)*	Cohen's κ (95% CI)	Proportion of agreement (95% CI)
Handball	8 (8.9)	10 (11.1)	0.88 (0.71 to 1.00)	0.98 (0.95 to 1.00)
Football	16 (17.8)	16 (17.8)	0.92 (0.82 to 1.00)	0.98 (0.95 to 1.00)
Basketball	3 (3.3)	3 (3.3)	1.00 (1.00 to 1.00)	1.00 (1.00 to 1.00)
Floorball	5 (5.6)	6 (6.7)	0.90 (0.71 to 1.00)	0.99 (0.97 to 1.00)
Volleyball	3 (3.3)	3 (3.3)	1.00 (1.00 to 1.00)	1.00 (1.00 to 1.00)
Martial arts	8 (8.9)	8 (8.9)	1.00 (1.00 to 1.00)	1.00 (1.00 to 1.00)
Gymnastics	2 (2.2)	2 (2.2)	1.00 (1.00 to 1.00)	1.00 (1.00 to 1.00)
Icehockey/bandy	5 (5.6)	5 (5.6)	1.00 (1.00 to 1.00)	1.00 (1.00 to 1.00)
Tennis/squash	5 (5.6)	4 (4.4)	0.88 (0.66 to 1.00)	0.99 (0.97 to 1.00)
Alpine/telemark skiing	14 (15.6)	13 (14.4)	0.96 (0.87 to 1.00)	0.99 (0.97 to 1.00)
Snowboarding	8 (8.9)	7 (7.8)	0.93 (0.79 to 1.00)	0.99 (0.97 to 1.00)
Dancing/aerobics	13 (14.4)	11 (12.2)	0.81 (0.63 to 0.99)	0.96 (0.91 to 1.00)
Cross-country skiing	37 (41.1)	39 (43.3)	0.95 (0.89 to 1.00)	0.98 (0.95 to 1.00)
Running	52 (57.8)	51 (56.7)	0.93 (0.86 to 1.00)	0.97 (0.93 to 1.00)
Cycling	36 (40.0)	38 (42.2)	0.82 (0.70 to 0.94)	0.91 (0.85 to 0.97)
Swimming	8 (8.9)	8 (8.9)	1.00 (1.00 to 1.00)	1.00 (1.00 to 1.00)
Strength training	60 (66.7)	62 (68.9)	0.90 (0.80 to 1.00)	0.96 (0.91 to 1.00)
Times per week			0.94 (0.87 to 1.00)	0.97 (0.93 to 1.00)
0-1	18 (20.0)	18 (20.0)		
2-3	43 (47.8)	44 (48.9)		
4-5	22 (24.4)	22 (24.4)		
>5	7 (7.8)	6 (6.7)		
Level I	28 (31.1)	29 (32.2)	0.92 (0.84 to 1.00)	0.97 (0.93 to 1.00)
Level II	42 (46.7)	40 (44.4)	0.91 (0.82 to 1.00)	0.96 (0.92 to 1.00)
Level III	77 (85.6)	77 (85.6)	0.91 (0.79 to 1.00)	0.98 (0.95 to 1.00)
Return to preinjury main sport	40 (48.2)	39 (47.0)	0.98 (0.93 to 1.00)	0.99 (0.97 to 1.00)

*Number of patients reporting to participate in the respective sports.

Content validity of the online activity survey

Eleven sports activities that were not included in the online activity survey were reported on the routine activity questionnaire (table 4), either at 6 or at 12 months postoperatively. The routine activity questionnaire did not disclose any additional sports in which $\geq 10\%$ of the patients participated.

Concurrent validity of the online activity survey

Six months postoperatively, the return to preinjury main sports rates were 21.9% based on the online activity survey, and

23.4% based on the routine activity questionnaire (figure 2). At 12 months postoperatively, the return to preinjury main sport rates were 59.7% and 55.6% for the online activity survey and the routine activity questionnaire, respectively. The κ between the two methods was 0.71 (95% CI 0.51 to 0.91) and 0.74 (0.59 to 0.90) for 6 months and 12 months postoperatively, respectively.

Table 4 Activities reported on the routine activity questionnaire that were not part of the online activity survey (n=74)

	6 months postoperatively, n (%)	12 months postoperatively, n (%)
Physical education activity	5 (6.8)	2 (2.7)
Rock climbing	2 (2.7)	1 (1.4)
Hiking	1 (1.4)	1 (1.4)
Playing with kids	1 (1.4)	1 (1.4)
Badminton	1 (1.4)	
Snow kiting	1 (1.4)	
Skateboarding	1 (1.4)	
Orienteering	1 (1.4)	
Ice skating		1 (1.4)
Golf		1 (1.4)
Rowing		1 (1.4)

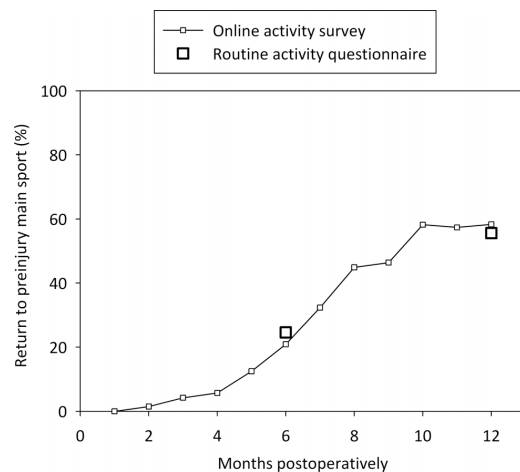


Figure 2 Return to preinjury main sport from 1 month to 1 year postoperatively, as measured with the online activity survey and the routine activity questionnaire (n=74).

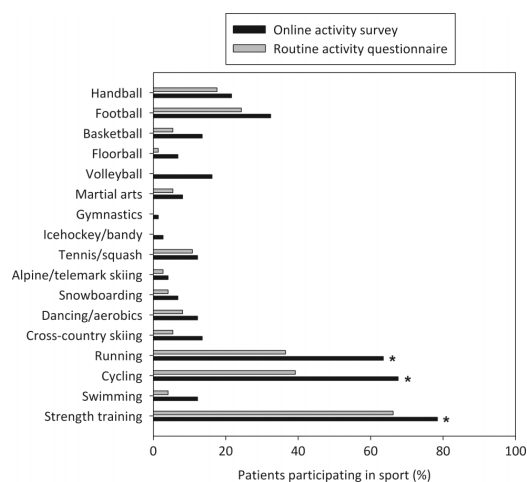


Figure 3 Percentage of patients participating in specific sports activities 12 months postoperatively, as measured with the online activity survey and the routine activity questionnaire (n=74). *p<0.05.

Completeness of the data on sports participation

Twelve months postoperatively, the online activity survey showed participation in a significantly greater number of sports activities (3.7 (SD 2.3)) compared with the routine activity questionnaire (2.3 (1.2), $p < 0.001$). The analysis of specific sports at 12 months postoperatively (figure 3) revealed that a significantly higher number of patients participated in running (online activity survey: 63.5%, routine activity questionnaire: 36.5%, $p < 0.001$), cycling (online activity survey: 67.6%, routine

activity questionnaire: 39.2%, $p < 0.001$) and strength training (online activity survey: 78.4%, routine activity questionnaire: 66.2%, $p = 0.049$).

Six months postoperatively, the online activity survey showed that a significantly higher number of patients participated in level II sports (online activity survey: 18.8%, routine activity questionnaire: 6.8%, $p = 0.040$, figure 4). Twelve months postoperatively, the online activity survey showed that a significantly higher number of patients participated in level II (online activity survey: 39.2%, routine activity questionnaire: 27%, $p = 0.035$) and level III sports (online activity survey: 93.2%, routine activity questionnaire: 81.1%, $p = 0.049$). There were no other significant differences between the methods (all $p > 0.227$).

DISCUSSION

The results of this study showed that the online activity survey was highly reliable. It also included all common sport activities in this patient-group, supporting its content validity. Further, there was a substantial agreement between the methods on return to preinjury main sport, supporting the concurrent validity. Finally, the participation in a greater number of sports and a higher number of patients participating in some sports indicated that the online activity survey offers more complete data on sports participation compared with the routine activity questionnaire.

Sports participation after an ACL injury can be recorded for at least three purposes. Most commonly, the authors report proportions of patients who have returned to sport as a measure of treatment outcome.^{7 15 19 20} However, as returning to sport entails a high risk of reinjury, several authors have questioned if return to sports should be the main aim of the treatment.^{1 21 22} Rupture and subsequent injuries have thus become increasingly important in evaluating treatment outcome. Although sports participation places the patient at a higher risk of injury,^{1 10} few studies on reinjuries after ACL injuries account for sports exposure,^{23 24} a key factor in sports injury epidemiological research.¹¹ The second purpose of recording sports participation should therefore be to adjust for sports exposure in analyses of reinjuries. Lastly, it is unknown how an ACL injury affects general physical activity levels in the long term. While it is well documented that many patients do not return to sports,^{2 25} less attention has been paid to whether patients become inactive after quitting their preinjury sports or if they take up other forms of physical activity. The online activity survey utilised in this study holds the potential of providing data that may elucidate all three areas.

All items in the online activity survey showed almost perfect agreement, defined as $\kappa > 0.80$.¹⁷ Furthermore, all items except participation in cycling and dancing/aerobics showed a $\kappa > 0.87$. The period between test and retest registrations was limited to 2–4 days because participation in some of the recorded sports is highly dynamic. Participation in organised sports, such as football and handball, may be more consistent than participation in unorganised activities. We did not find an overall pattern of differences between organised and unorganised sports. Thus, we believe the results were not largely affected by the changes in true participation rates. A disadvantage of having a short period between the test–retest registrations is the chance that the retest response is influenced by recollection of the test response. Based on the feedback from patients, the online activity survey is very easy to complete and takes no more than 1 min. While the possibility that the results were influenced by patient recall cannot be excluded, the potential for bias is likely smaller with this

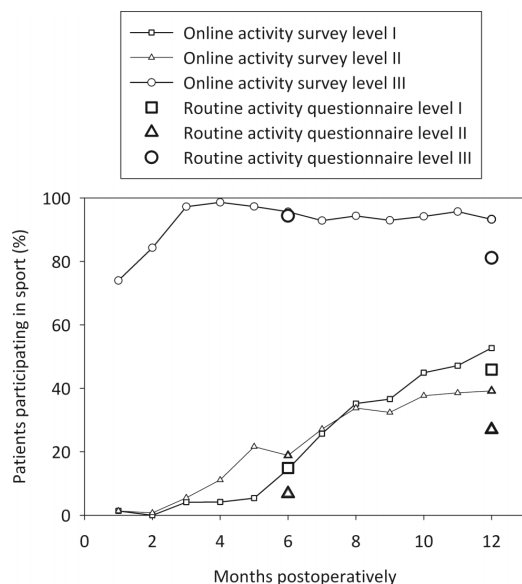


Figure 4 Percentage of patients participating in level I, II and III sports from 1 month to 1 year postoperatively, as measured with the online activity survey and the routine activity questionnaire (n=74).

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method compared with methods that require more time and deliberation to complete.

Regarding the content validity of the online activity survey, the routine activity questionnaire did not disclose any sports activities, in which more than 10% of patients participated, that was not included in the online activity survey. This supports the content validity of the online activity survey, in that it includes all common sports activities in this patient population (table 4). There was also substantial agreement between the two methods on return to preinjury main sport at 6 and 12 months post-ACL reconstruction. This indicates that the online activity survey can be used to determine return to preinjury main sport. The online activity survey also offers a more detailed knowledge on the timing of return to sports (figure 2). How long they will be out of sports is a main concern for the majority of ACL-injured patients,¹ and a detailed knowledge on this topic enables clinicians to provide a more accurate timeline for the resumption of sports participation.

The online activity survey showed participation in a significantly greater number of sports, and also that a higher number of patients reported to participate in low-level sports compared with the routine activity questionnaire. In the online activity survey, patients ticked a box if they had participated in any of the listed activities. In contrast, the routine activity questionnaire contained an open-ended question where patients listed the sports they were participating in. Responses to open-ended questions rely on the assumptions about what constitutes an informative answer, which may lead to under-reporting of sports patients do not come to think of or deem less important.²⁶ Our results are likely explained by patients under-reporting sports that were perceived as less important when filling out the routine activity questionnaire. Thus, the online activity survey seems to offer more complete data on sports participation.

We acknowledge that there are limitations to this study. First, the absence of established, comparable methods inevitably hampers the ability of demonstrating validity of the online activity survey. In this study, we compared the online activity survey with a routine activity questionnaire where patients listed the sports or exercises they participated in. While the psychometric properties of the routine activity questionnaire are unknown, we are not aware of any instruments with established validity and reliability that measure participation in several specific sports. Activity scales such as the Tegner activity scale,⁵ Cincinnati³ and MARS⁴ provide scores based on knee-demanding sports. In contrast, the online activity survey was not designed as a scale, but as an easy-to-use tool that would provide more detailed data on sports participation. Second, the sports recorded were selected to represent all major sports ACL-injured patients at our institution participated in, and do not provide an accurate representation of sports participation in other cultural or geographical settings. Thus, if used in a different setting, the survey should be modified based on what sports the patient-group participates in. To avoid under-reporting, we recommend that the survey includes a list of specific sports. However, adding a free-text choice where patients can report sports that are not included in the survey should be considered to ensure that no major sports are missed. Third, the monthly online activity registration might have led to reporting bias at the 6 and 12 month follow-ups, as patients may have become accustomed to reporting sports listed in the online activity survey. A fourth limitation is the fact that the online activity survey was not intended to measure treatment success, but rather to provide a broader perspective on changes in sports participation after an ACL injury. If return to sport is to be used as a criterion for successful outcome, the survey should be

modified to include questions regarding sport performance and reasons for not returning to sport. Finally, sports frequency was not registered for each individual sport. Recording the number of hours the patients spend in different sports could add important data in future studies. However, if further development of this method is performed, the benefit of increasing the level of detail in the registration should be carefully weighed against the risk of adversely affecting response rates.

CONCLUSION

This study showed that the online activity survey was highly reliable and provided a valid representation of sports participation in a sample of ACL-injured patients. There was a substantial agreement between the online activity survey and a routine activity questionnaire on determining return to preinjury main sport; however, the online activity survey provided more complete data on sports participation. While the existing literature is predominantly focused on activity scales and return to preinjury sport, this method provides a broader perspective on changes in sports participation after ACL injury and surgery.

What are the new findings?

- ▶ The online activity survey utilised in this study can provide more detailed longitudinal data on sports participation after anterior cruciate ligament (ACL) injury than commonly used measures like return to sports and activity rating scales.
- ▶ The use of an online activity survey is a highly reliable way of collecting data on sports participation after ACL injury.
- ▶ In addition to providing a broader perspective on sports participation, the online activity survey can be used to prospectively monitor return to preinjury main sport.

How might it impact on clinical practice in the near future?

- ▶ This study may lead to a change in methods that are used to monitor sports participation following ACL injuries.
- ▶ The online activity survey can provide clinicians with more detailed information about the changes in patients' sports participation after injury.
- ▶ By incorporating more detailed data on sports participation after injury, future studies might provide more accurate prognoses for future sports participation, and more accurate estimates of the risk of reinjuries.

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Contributors All authors contributed to the conception and design, interpretation of the data, critical revision and final approval of the article. IE and HG were responsible for data acquisition, HG was responsible for data analysis.

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Online registration of monthly sports participation after anterior cruciate ligament injury: a reliability and validity study

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Paper III

**NONSURGICAL OR SURGICAL TREATMENT OF ANTERIOR CRUCIATE LIGAMENT
INJURIES: KNEE FUNCTION, SPORTS PARTICIPATION AND KNEE REINJURY.**

THE DELAWARE-OSLO ACL COHORT STUDY

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ABSTRACT

Background: While there are many opinions on the expected knee function, sports participation and risk of knee reinjury in nonsurgically treated ACL-injured patients, knowledge on the clinical course following nonsurgical compared with surgical treatment is lacking.

Methods: This prospective cohort study included 143 ACL-injured patients. Isokinetic knee extension and flexion strength and self-reported knee function (IKDC 2000) were collected at baseline, 6 weeks and 2 years. Sports participation was reported monthly for 2 years using an online activity survey. Knee reinjuries were reported at follow-ups and in a monthly online survey. Repeated ANOVA, GEE models and Cox regression were used to analyze group differences in functional outcomes, sports participation and knee reinjuries, respectively.

Results: The surgically treated patients (n=100) were significantly younger, more likely to participate in level I sports and less likely to participate in level II sports prior to injury than nonsurgically treated patients (n=43). There were no significant group by time effects in functional outcomes. The crude analysis showed that surgically treated patients were more likely to sustain a knee reinjury and to participate in level I sports in the 2nd year of the follow-up period. After adjustment for age and preinjury sports participation, these differences were nonsignificant; however, nonsurgically treated patients were significantly more likely to participate in level II sports the 1st year of the follow-up period, and in level III sports over the 2 years. After 2 years, 30 % of all patients had extensor strength deficits, 31 % had flexor strength deficits, 21 % had self-reported knee function below normal ranges, and 19 % experienced knee reinjury.

Conclusions: There were few differences in the clinical course of nonsurgically and surgically treated ACL-injured patients in this prospective cohort study. Regardless of treatment course, a considerable number of patients have not fully recovered, and future work should focus on improving the outcomes of these patients.

INTRODUCTION

Injuries to the anterior cruciate ligament (ACL) are common in sports, and may lead to reduced knee function, reduction in sports participation, and early onset of knee osteoarthritis.¹ A wish to return to pivoting sports remains the most important indication for ACL reconstruction, with arguments being made that surgery will improve the ability to return to sport as well as reduce the risk of knee reinjury.²⁻⁴ Still, there is lacking evidence that a surgical treatment leads to better outcomes than nonsurgical treatment in terms of knee function, sports participation, or early onset of knee osteoarthritis.⁵⁻⁸

Clinicians are often in the situation where suggesting either a surgical or nonsurgical treatment to a patient both constitutes a reasonable alternative. Nonsurgical and surgical treatment courses differ not only with regard to the surgical intervention, but also in the content and length of rehabilitation, as well as recommendations for future sports participation.⁷ Following current practice patterns, nonsurgically and surgically treated patients have shown to be different populations in terms of age and preinjury activity level,^{9,10} often with different treatment goals regarding return to sport. Additionally, an ACL-injured patient typically participates in multiple sports prior to injury and after;¹¹ yet, postinjury assessments of sports participation are predominantly restricted to reflect resumption of only the sport of the highest activity level.^{12,13} To our knowledge, no studies have reported knee function, knee reinjuries, as well as detailed changes in the participation in different types of sports, following nonsurgical and surgical treatment of ACL-injured patients. Furthermore, there is a concern that the subgroup of surgically treated patients who are initially treated nonsurgically and later undergo ACL reconstruction will have sustained secondary injuries,^{14,15} and will therefore have poorer outcomes than the rest of the surgically treated patients. More knowledge on how the outcomes differ between the patients who make a late decision to undergo ACL reconstruction and the patients who initially decide to undergo reconstruction is therefore of great interest.

Thus, the aim of this prospective cohort study was to evaluate the clinical course over 2 years, measured by knee function, sports participation and knee reinjuries, of ACL-injured patients who chose nonsurgical and those who chose surgical treatment. A subanalysis was included to explore differences between patients who had surgery as their primary treatment decision, and patients who initially were treated nonsurgically, but later made a decision to have an ACL reconstruction.

MATERIAL AND METHODS

Subjects

One hundred forty three consecutive patients who fulfilled the selection criteria were included in this prospective cohort study (fig. 1). All patients were referred to the Norwegian Sports Medicine Clinic (Nimi) and had sustained an ACL rupture within the last 3 months. Diagnosis was confirmed with magnetic resonance imaging (MRI) and ≥ 3 mm side-to-side difference with a KT-1000 arthrometer (MedMetrics, San Diego, CA). Other inclusion criteria were age 13-60 years and participation in level I or II sports¹⁶ \geq twice a week (Table 1). Patients were excluded if they had current or previous injury to the contralateral leg, or if the MRI showed other grade III ligament injury, fracture, or full-thickness articular cartilage damage. Patients with meniscal tears were excluded only if they had pain or effusion during or following plyometric activities.

All patients signed an informed consent form prior to inclusion. The study was approved by the Regional Ethical Committee for South-Eastern Norway.

Treatment algorithm

Before inclusion in this study, the patients underwent rehabilitation to resolve initial impairments. Immediately after inclusion, all patients underwent 5 weeks of rehabilitation following the protocol by Eitzen et al.¹⁷ During these weeks, patients received information about nonsurgical and surgical treatment alternatives. After the 5 week period, the decision on whether or not to undergo ACL reconstruction was made. The decision was made after close communication between the

orthopaedic surgeon, the physical therapist, and the patient. The main reason for the treatment choice was recorded prospectively at the conclusion of the 5 week rehabilitation period. Nonsurgically treated patients then underwent continued rehabilitation as needed, typically for 2-3 additional months. The rehabilitation consisted mainly of strength training, neuromuscular training, and plyometrics. Surgically treated patients underwent ACL reconstruction with bone-patellar-tendon-bone (BPTB) autograft, hamstrings single bundle autograft, or hamstrings double bundle autograft. The postoperative rehabilitation was divided into 3 phases.¹⁸ In the early postoperative phase (0-6 weeks), the rehabilitation aimed to eliminate effusion, regain full range of motion, and minimize muscular atrophy. The 2nd phase (6 weeks-6 months) included strength training and neuromuscular training to regain adequate muscle strength and dynamic knee stability. The 3rd phase (6-12 months) focused on normalizing muscle strength and dynamic knee stability, and to prepare the patient for return to sport with sport-specific training.

All patients were advised not to return to level I or II sports (table 1) until they had $\geq 90\%$ hamstring and quadriceps strength compared to the uninjured side, and limb symmetry indexes (LSI) ≥ 90 on 4 hop tests.⁷ Surgically treated patients were recommended to avoid level II sports the first 6 postoperative months, and level I sports the first 9 postoperative months. Nonsurgically treated patients were advised not to participate in any level I sports.

Data collection

Testing was performed at baseline, after completion of the 5 week rehabilitation program (6 week test), and 2 years later (nonsurgically treated patients) or 2 years postoperatively (surgically treated patients). Isokinetic concentric muscle strength measurements of knee extensors and knee flexors were performed at 60 °/sec with a Biodex 6000 dynamometer (Biodex Medical Systems Inc, Shirley, New York). The patients completed a standardized warm-up on a stationary bicycle. Four trial repetitions were performed with submaximal effort, followed by 1 minute rest, before 5 test repetitions were recorded. The uninjured leg was always tested first. For assessment of self-reported knee

function, the patients completed the IKDC 2000. The IKDC 2000 has been shown to be a valid, reliable and responsive measure of knee function in patients with knee injuries.^{19,20}

An online survey (Questback v. 9.6, Questback AS, Oslo, Norway) was used to record monthly sports participation in the period between the 6 week test and the 2 year follow-up.¹¹ The online activity survey consisted of the question: “Which of the following sports have you participated in during the last 4 weeks?”, followed by the sports listed in Table 1. Patients were also asked how many times per week they had, on average, participated in those sports. This response was categorized as 0-1 times per week, 2-3 times per week, 4-5 times per week, or more than 5 times per week. The online activity survey has been shown to be highly reliable and to provide a valid representation of sports participation in this patient-group.¹¹

Patients reported whether or not they had experienced reinjury in the index or contralateral knee both at follow-ups and in the monthly online survey. The online survey was used to identify patients with a knee reinjury who may not have sought medical attendance at our clinic. Patients who reported knee reinjury underwent clinical examination by a physical therapist or orthopaedic surgeon. Following standard practice at our institution, additional verification of the diagnosis was done using MRI and/or during surgery when clinically indicated (table 5).

Data management and statistical analysis

For muscle strength, peak torque of the involved and the uninvolved leg, and LSI, were reported. The LSI was calculated by $(\text{peak torque involved leg}) / (\text{peak torque uninvolved leg}) \times 100$. The number of patients with LSI below 90 and IKDC 2000 scores below the age- and sex-specific 15th percentile of previously published data on uninjured individuals²¹ was also reported. Participation in level I, II and III sports was defined as reported participation in at least one sport of the respective level.

Group differences in nominal variables were analyzed with chi square tests or Fisher’s exact test. Independent t-tests were used to analyze differences in normally distributed continuous variables, and the Mann Whitney U test was utilized when variables were not normally distributed.

Knee function change over time and group differences in the change over time were analyzed with a repeated measures ANOVA. The a priori sample size analysis showed that 33 patients per group were needed to detect a Cohen's f of 0.2 for a within-between interaction effect, assuming an estimated between-measures correlation of 0.6. Wilk's lambda was used for significance testing. The standardized response mean (SRM) from baseline to the 2 year follow-up was reported for all functional outcomes, and was calculated by the mean change from baseline to the 2 year follow-up divided by the standard deviation of the change.²²

To analyze group differences in level I, II and III sports participation, and weekly frequency of sports participation, generalized estimating equations (GEE) models were fitted, adjusting for dependence between months with a first order autoregressive correlation structure. For participation in level I, II and III sports, the logit link and binomial variance functions were used, while the identity link and Gaussian variance functions were used in the analysis of frequency of sports participation. Robust standard error estimates were used in all analyses. Crude odds ratios or β for group with 95 % confidence intervals (95 % CI) were reported, as well as adjusted estimates where all analyses were adjusted for age. The analyses of level I and II sports participation were additionally adjusted for preinjury participation in level I and level II sports, respectively. The analyses of participation in level I and II sports were stratified by the 1st and 2nd year of the follow-up period due to significant group by time interactions.

Cox regression with robust estimation of standard errors was used to assess group differences in the risk of knee reinjury. The crude and adjusted hazard ratios were reported, and the covariates were age, preinjury participation in level I sports, and preinjury participation in level II sports. Significance was tested with Wald test.

Table 1. Sports recorded in the monthly online activity survey classified according to activity level¹⁶

Sport	Activity level
Handball	
Soccer	
Basketball	Level I
Floorball	
Volleyball	
Martial arts	
Gymnastics	
Icehockey	Level II
Tennis/squash	
Alpine/telemark skiing	
Snowboarding	
Dancing/aerobics	
Cross-country skiing	
Running	Level III
Cycling	
Swimming	
Strength training	

RESULTS

Of the 143 included patients, 43 patients (30.1 %) remained nonsurgically treated and 100 patients (69.9 %) had undergone ACL reconstruction (fig. 1). Seventy-nine patients made a primary decision of undergoing ACL reconstruction and 21 made a late decision of undergoing surgery after initially making a nonsurgical treatment decision. Dynamic instability in level I sports was the main reason for making a late decision of undergoing ACL reconstruction (fig. 1). The rate of undergoing late ACL reconstruction was 3.1 times higher (95 % CI: 1.5-6.3) in patients who chose nonsurgical treatment but still wanted to return to level I sports compared to patients who chose nonsurgical treatment without a wish to return to level I sports (fig. 1).

The nonsurgically treated group was significantly older than the surgically treated group, less likely to participate in level I sports, and more likely to participate in level II sports prior to injury (Table 2). The 2 year follow-up was performed 24.5 ± 0.7 (mean \pm SD) months after the 6 week test for nonsurgically treated patients, and 24.4 ± 0.6 months after surgery for the surgically treated patients ($p=0.493$). There were no significant differences in descriptive characteristics between patients who chose ACL reconstruction as a primary and as a late decision ($p \geq 0.11$).

Patients who made a primary decision of ACL reconstruction underwent surgery 4.9 ± 2.9 months after injury, while patients who made a late decision of undergoing ACL reconstruction underwent surgery 12.7 ± 5.0 months after injury ($p < 0.001$). At the time of ACL reconstruction, 32 patients (32.0 %) had concomitant surgery to one (28 patients) or both (4 patients) menisci. The medial meniscus was repaired in 15 patients (15.2 %) and partially resected in 5 patients (5.1 %). The lateral meniscus was repaired in 1 patient (1.0 %) and partially resected in 15 patients (15.2 %). No surgical procedures were performed in the nonsurgically treated group. There were no significant differences between those who made a primary and a late decision of undergoing ACL reconstruction in the number of patients who had surgical procedures performed to the lateral or medial meniscii, or in the number of patients whose meniscus injuries were treated with repair and resection ($p \geq 0.21$).

Table 2. Descriptive characteristics of nonsurgically and surgically treated patients

	Nonsurgical (n=43)	Surgical (n=100)	p- value
Preinjury participation in level I sports, yes/no (% yes)	19/24 (44.2)	80/20 (80.0)	<0.001
Preinjury participation in level II sports, yes/no (% yes)	30/13 (69.8)	51/49 (51.0)	0.038
Sex, F/M (% F)	24/19 (55.8)	56/44 (56.0)	0.984
Age, y, mean (SD)	30.2 (8.8)	24.0 (7.2)	<0.001
Height, cm, mean (SD)	175.6 (8.9)	173.8 (9.0)	0.278
Weight, kg, mean (SD)	72.7 (11.7)	72.6 (14.5)	0.974
BMI, mean (SD)	23.5 (2.6)	23.9 (3.3)	0.479
Concomitant injuries*			
Medial meniscus	10 (23.3)	25 (25.0)	0.842
Lateral meniscus	6 (14.0)	22 (22.0)	0.266
Medial cartilage	3 (7.0)	3 (3.0)	0.365
Lateral cartilage	4 (9.3)	10 (10.0)	1.000
MCL grade I-II	12 (27.9)	28 (28.0)	0.991
LCL grade I-II	4 (9.3)	1 (1.0)	0.029
Popliteus	0 (0)	2 (2.0)	1.000
No concomitant meniscus, cartilage, ligament or muscle injury	18 (41.9)	44 (44.0)	0.813
Months from injury to baseline test, mean (SD)	2.1 (0.5)	2.0 (0.6)	0.615
Months from injury to 6 week test, mean (SD)	3.3 (0.6)	3.2 (0.7)	0.695

Values are n (%) unless otherwise stated.

*Diagnosed with MRI at inclusion

Knee function

There were no significant baseline group differences in IKDC 2000 scores, knee extension and flexion strength (all $p \geq 0.16$), and no significant group by time effects were found (Table 3). Both groups showed large SRM values for the IKDC 2000, and moderate to large SRM values for extension and flexion strength of the involved leg. At the 2 year follow-up, 7 (17.1 %) nonsurgically treated patients and 19 (22.1 %) surgically treated patients had IKDC 2000 scores below the normative 15th percentile. Nine (22.5 %) nonsurgically treated patients and 27 (32.9 %) surgically treated patients had knee extension LSI below 90 , and 9 (22.5 %) nonsurgically treated patients and 28 (34.1 %) surgically treated patients had knee flexion LSI below 90 .

Patients who underwent ACL reconstruction as a primary and a late decision did not have significantly different changes in any functional outcome ($p \geq 0.15$).

Table 3. Functional outcomes of nonsurgically and surgically treated patients from baseline to the 2 year follow-up

	Baseline		6 week		2 years		Time p-value	Standardized response mean from baseline to 2 year		Group x time p-value
	Nonsurgical	Surgical	Nonsurgical	Surgical	Nonsurgical	Surgical		Nonsurgical	Surgical	
IKDC 2000	72.8 (11.3)	69.8 (11.5)	80.4 (10.4)	77.8 (11.2)	89.2 (11.3)	88.9 (12.1)	<0.001	1.06	1.21	0.650
Knee extension strength										
Uninvolved	186.8 (46.3)	193.6 (52.3)	195.1 (49.6)	204.4 (52.5)	198.4 (55.4)	213.1 (55.3)	<0.001	0.49	0.59	0.472
Involved	167.1 (43.0)	171.7 (48.1)	180.8 (45.4)	190.0 (49.3)	190.3 (51.1)	200.9 (55.5)	<0.001	0.84	0.86	0.676
Limb symmetry	90.0 (10.9)	89.0 (10.5)	93.2 (8.0)	93.5 (10.6)	96.4 (9.8)	99.2 (15.2)	<0.001	0.43	0.46	0.664
Knee flexion strength										
Uninvolved	95.4 (29.1)	95.9 (26.1)	101.2 (29.1)	104.4 (26.3)	104.5 (31.9)	108.6 (29.2)	<0.001	0.55	0.73	0.408
Involved	88.8 (26.2)	91.3 (25.8)	98.3 (26.8)	101.8 (26.9)	102.6 (29.0)	102.6 (29.3)	<0.001	0.80	0.60	0.413
Limb symmetry	88.8 (26.2)	91.3 (25.8)	97.9 (10.8)	97.7 (10.6)	99.2 (15.2)	94.7 (11.5)	0.257	0.21	-0.08	0.165

All values are mean (SD)

Values represent the 41 nonsurgically treated and 86 surgically treated patients who had complete data

Sports participation

The overall response rate for the online activity survey was 87.0 %. In total, 2820 observations from 135 patients were included in the analyses.

Consistent with the differences in preinjury sports participation, nonsurgically and surgically treated patients had different sports activity profiles after injury (fig. 2). The crude analysis showed that a significantly higher number of surgically treated patients participated in level I sports in the 2nd year of the follow-up period; however, there were no significant difference after adjusting for age and preinjury sports participation (table 4). The adjusted analyses showed that a significantly higher number of nonsurgically treated patients participated in level III sports over the 2 years, and in level II sports in the 1st year of the follow-up period. In every month of the 2 year follow-up period, the median frequency of sports participation was 2-3 times per week in both groups, and not significantly different (adjusted β [95 % CI]: 0.10 [-0.11-0.31], $p=0.357$).

Compared to patients who made a primary surgical decision, a significantly lower number of patients who chose surgery as a late decision participated in level I sports over the 2 year follow-up period (adjusted OR [95 % CI]: 0.35 (0.16-0.76), $p=0.008$). No other significant differences were found between patients who chose ACL reconstruction as a primary and a late decision.

Table 4. Monthly participation in sports over 2 years in nonsurgically vs surgically treated patients

	Crude odds ratio (95 % CI), p-value	Adjusted odds ratio (95 % CI) , p-value
Participation in level I sports		
1 st year of follow-up	1.45 (0.76-2.76), 0.265	0.77 (0.39-1.50), 0.440 ^a
2 nd year of follow-up	2.78 (1.40-5.52), 0.004	1.43 (0.69-2.99), 0.340 ^a
Participation in level II sports		
1 st year of follow-up	0.23 (0.14-0.38), <0.001	0.20 (0.12-0.34), <0.001 ^b
2 nd year of follow-up	0.65 (0.37-1.14), 0.131	0.63 (0.35-1.14), 0.126 ^b
Participation in level III sports	0.47 (0.21-1.05), 0.065	0.42 (0.19-0.94), 0.035 ^c

An odds ratio above 1 indicates a higher number of ACL reconstructed patients participating in sports

^a adjusted for age and preinjury participation in level I sports

^b adjusted for age and preinjury participation in level II sports

^c adjusted for age

Knee reinjuries

Four nonsurgically treated patients reported 7 knee reinjuries (Table 5). Twenty-four surgically treated patients reported 34 knee reinjuries from surgery to the 2 year follow-up. Nonsurgically treated patients sustained 8.0 (2.1-13.9) knee reinjuries per 100 patient-years, and surgically treated patients sustained 16.8 (11.1-22.4) reinjuries per 100 patient-years. While surgically treated patients had a significantly higher crude risk of knee reinjury (HR [95% CI]: 2.89 [1.02-8.13], $p=0.045$), there was no significant difference between the groups after adjusting for age and preinjury sports participation (aHR [95% CI]: 1.79 [0.57-5.57], $p=0.317$).

Four patients who made a late decision to undergo ACL reconstruction reported knee reinjuries prior to ACL reconstruction and 2 patients reported knee reinjuries after surgery. During the full study period, these patients sustained 10.5 (2.1-18.9) knee reinjuries per 100 patient-years.

Table 5. Knee reinjuries in nonsurgically and surgically treated patients

	Nonsurgical (n=43)	Surgical (n=100)
Index knee		
ACL rerupture	-	8 (8.0 %)
Medial meniscus	2 (4.7 %)	9 (9.0 %)
Lateral meniscus	2 (4.7 %)	4 (4.0 %)
Medial cartilage	1 (2.3 %)	2 (2.0 %)
Lateral cartilage	1 (2.3 %)	2 (2.0 %)
Patellofemoral cartilage		3 (3.0 %)
Medial collateral ligament		1 (1.0 %)
Patella subluxation		1 (1.0 %)
Contralateral knee		
ACL rupture	1 (2.3 %)	2 (2.0 %)
Lateral meniscus	0 (0 %)	1 (1.0 %)
Medial collateral ligament	0 (0 %)	1 (1.0 %)

n (%)

Of the 41 injuries, 5 (12 %) were exclusively diagnosed clinically, 15 (37 %) injuries were diagnosed by clinical examination and MRI, 13 (32 %) were diagnosed by clinical examination and arthroscopy, and 8 (20 %) were diagnosed by clinical examination, MRI and arthroscopy. The 7 injuries in the nonsurgically treated group were all diagnosed by clinical examination and arthroscopy.

DISCUSSION

In order to provide evidence-based recommendations for treatment choice to ACL-injured patients, knowledge of the clinical course following nonsurgical and surgical treatment is needed. This prospective cohort study suggests that there are few differences in the clinical course of patients who choose nonsurgical treatment and those who choose surgical treatment. After adjusting for age and preinjury sports participation, the only significant differences found in this study were that nonsurgically treated patients were more likely to participate in level II sports in the 1st year of the follow-up period and in level III sports over both two years. The first finding can be explained by surgically treated patients having reduced knee function and activity restrictions early after ACL reconstruction, and the difference in level III sports participation was likely not important as more than 85 % of surgically treated patients also participated in these sports from the 2nd to the 24th postoperative month (fig. 2). This study also showed that surgically treated patients were more active in level I sports in the 2nd postoperative year and had a higher crude risk of knee reinjury, and that this was explained by that patient-group being younger with a higher number of patients participating in level I sports prior to injury.

As there is no evidence-based algorithm that identifies nonsurgically treated patients who can succeed with a long-term return to level I sports, all patients in this study were recommended to undergo ACL reconstruction if they intended to participate in level I sports. As shown in our previous findings,⁷ there was a large degree of noncompliance to the recommended activity restrictions (fig. 2). Thirty four percent of surgically treated patients participated in level I sports, and 18 % participated in level II sports, earlier than recommended, while 55.6 % of nonsurgically treated patients at some point participated in level I sports despite the recommendations to avoid these sports (results not shown). Furthermore, 34 % of patients who chose a nonsurgical approach intended to resume level I sports when they made the treatment choice (fig. 1). The rate of making a late decision to have surgery was also significantly higher in these patients. This finding, however, is based on a small number of patients, and there was a low threshold for recommending ACL reconstruction to nonsurgically treated patients who wanted to participate in level I sports.

In terms of graft choice and meniscal procedures performed at the time of ACL reconstruction, the surgically treated patients in this study were similar to patients included in the Scandinavian ACL registries.²³ Although we did not find significant differences in surgical procedures performed at the time of ACL reconstruction between patients who underwent ACL reconstruction as a primary and as a late decision, studies with larger samples have shown that the prevalence of meniscus tears increases with a longer time from injury to ACL reconstruction.^{14,15} The patients who made a late decision to undergo ACL reconstruction did so due to episodes of dynamic instability, mainly in level I sports (fig. 1). After surgery, a significantly lower number of these patients participated in level I sports compared to those who chose surgery as a primary decision, and only two patients reported knee reinjuries. Fear of reinjury is shown to be a more frequent reason for ceasing sports participation than knee problems.¹² As there were no significant differences in functional outcomes, it is plausible to suggest that patients who made a late surgical decision avoided level I sports to protect their knee from further injury, rather than having a decreased ability to participate in sports.

Participation in sports does not necessarily indicate good knee function,^{24,25} and patients often cite reasons other than knee problems for not participating in sports.¹² The reasons why patients did not participate in sports were not evaluated in this study. However, the cyclical development in level II sports participation in nonsurgically treated patients (fig. 2) coincided to a large extent with the summer and winter seasons. As the variations in seasonal sports participation highly influence results when sports participation is recorded at a follow-up time that also reflects the time from injury, multiple reports during the year are needed to accurately describe the sports participation in this patient-group.

While this study provides knowledge on the clinical course following treatment of ACL injuries, the observational design prohibits solid conclusions on differences in treatment efficacy. Our results may not apply to patients who undergo other surgical or rehabilitation interventions, or to institutions with different criteria for treatment selection. The presence of knee reinjury was only recorded if the patient reported they had a knee reinjury. Thus, future studies including follow-up MRIs of all patients are needed to evaluate the total extent of structural changes in these patient-

groups. Although the average functional outcome of both treatments was good, one fifth of all patients experienced knee reinjury and one third of patients who initially decided on a nonsurgical treatment course later underwent ACL reconstruction. Future studies examining predictive characteristics of patients who succeed and fail following both treatments are therefore needed. Finally, continued follow-up is needed to evaluate longer-term sports participation, reinjury risk, and development of knee osteoarthritis.

CONCLUSION

This prospective cohort study suggests that there are few differences in the 2 year clinical course between ACL-injured patients who choose nonsurgical and surgical treatment. While surgically treated patients had a significantly higher crude risk of knee reinjury, there was no significant difference in the risk after adjusting for age and preinjury sports participation. Patients in both groups showed large improvements in knee function; however, at 2 years, one fifth of patients reported knee reinjuries and a considerable number of patients still exhibited functional deficits. Future work on how to identify and better treat the patients who will have an unsatisfactory outcome is needed.

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Figure 1. Flowchart of patient participation in the study

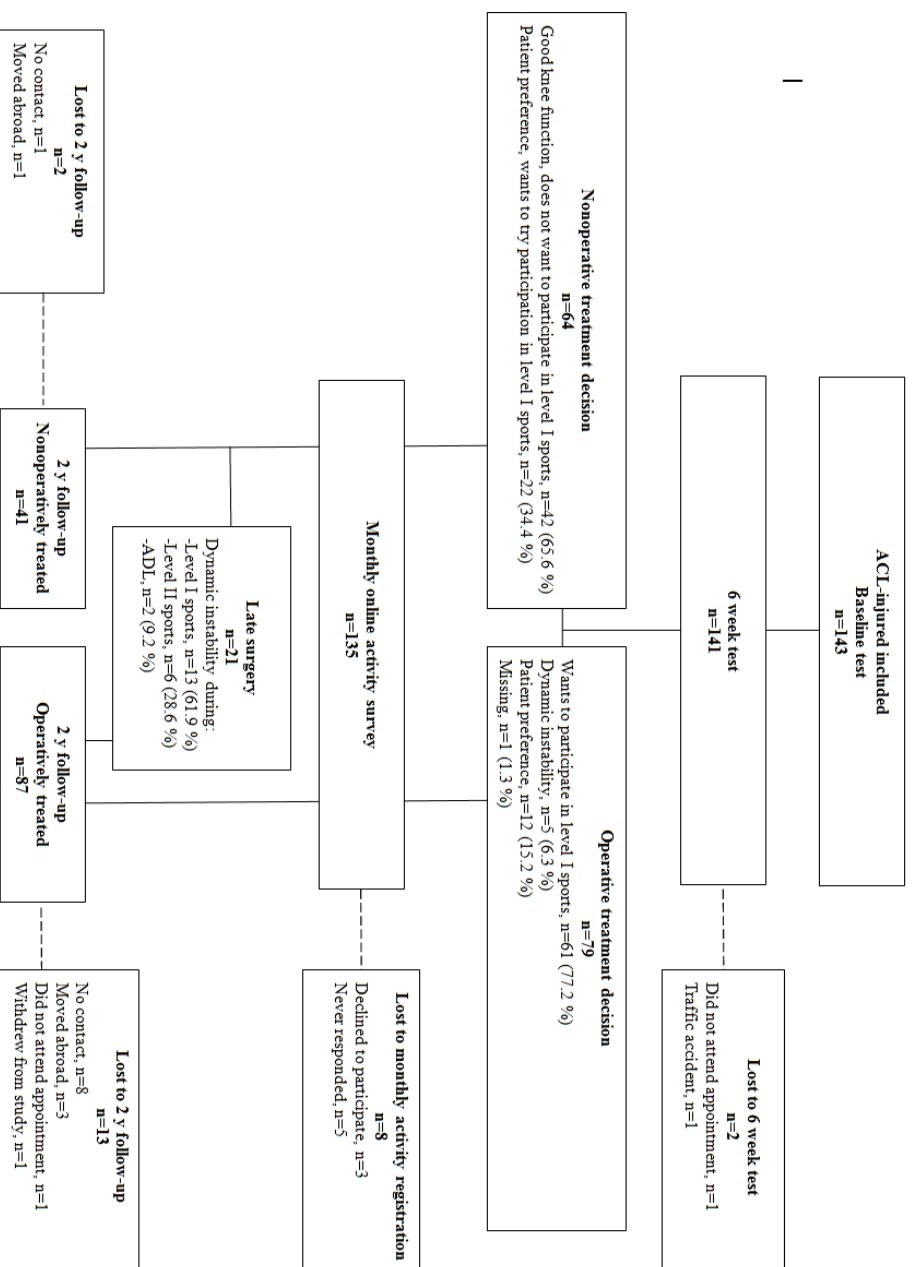
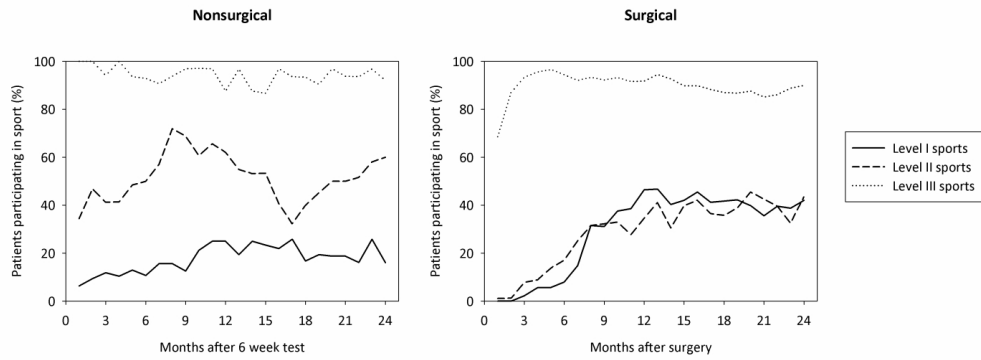


Figure 2. Percentage of nonsurgically (n=37) and surgically treated (n=98) patients participating in level I, II and III sports over 2 years (unadjusted data representing all patients, regardless of preinjury participation in respective level of sport)



Paper IV

Artikkelen er tatt ut av denne versjonen av doktoravhandlingen på grunn av copyright-restriksjoner. Hele artikkelen er tilgjengelig på <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3462240/pdf/nihms404143.pdf>

The paper is removed from this version of the PhD Thesis due to copyright restrictions. The paper is available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3462240/pdf/nihms404143.pdf>

Appendix I

STROBE statement for cohort studies

STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (b) For matched studies, give matching criteria and number of exposed and unexposed
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) If applicable, explain how loss to follow-up was addressed (e) Describe any sensitivity analyses
Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)
Outcome data	15*	Report numbers of outcome events or summary measures over time
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at <http://www.strobe-statement.org>.

Appendix II

Guidelines for reporting reliability and agreement studies (GRRAS)

Guidelines for Reporting Reliability and Agreement Studies (GRRAS).

TITLE AND ABSTRACT	1. Identify in title or abstract that interrater/intrarater reliability or agreement was investigated.
INTRODUCTION	2. Name and describe the diagnostic or measurement device of interest explicitly
	3. Specify the subject population of interest.
	4. Specify the rater population of interest (if applicable).
	5. Describe what is already known about reliability and agreement and provide a rationale for the study (if applicable).
METHODS	6. Explain how the sample size was chosen. State the determined number of raters, subjects/objects, and replicate observations.
	7. Describe the sampling method.
	8. Describe the measurement/rating process (e.g. time interval between repeated measurements, availability of clinical information, blinding).
	9. State whether measurements/ratings were conducted independently.
	10. Describe the statistical analysis.
RESULTS	11. State the actual number of raters and subjects/objects which were included and the number of replicate observations which were conducted.
	12. Describe the sample characteristics of raters and subjects (e.g. training, experience).
	13. Report estimates of reliability and agreement including measures of statistical uncertainty.
DISCUSSION	14. Discuss the practical relevance of results.
AUXILIARY MATERIAL	15. Provide detailed results if possible (e.g. online)

Kottner J, Audige L, Brorson S, Donner A, Gajewski BJ, Hrobjartsson A *et al.* Guidelines for Reporting Reliability and Agreement Studies (GRRAS) were proposed. *J Clin Epidemiol* 2011;64(1):96-106.

Appendix III

Cohort A: Approval South East Regional Committee for
Medical and Health Research Ethics

REGIONAL KOMITE FOR MEDISINSK FORSKNINGSETIKK

Øst-Norge (REK I)

Forskningsleder May Arna Risberg
NAR – Ortopedisk senter
Kirkevn. 166
0407 Oslo

Deres ref.:

Vår ref.: 736-04278

Dato: 21. desember 2004


Screeningtester av pasienter med isolert fremre korsbåndsskade – en etterundersøkelse


Regional komite for medisinsk forskningsetikk, Øst-Norge, vurderte prosjektet på sitt møte 15.12.04.

Komiteen har ingen innvendinger mot at studien blir gjennomført.

I overskriften på informasjonsskrivet må det fremgå at informasjonen også omfatter foreldre med barn under 18 år.

Med vennlig hilsen


Knut Engedal
professor dr.med.
leder


Ida Nyquist
sekretær

Appendix IV

Cohort A: Approval from the Norwegian Data Protection Authority



Ullevaal universitetssykehus HF
Kirkeveien 166

0407 OSLO

Ullevaal universitetssykehus HF	
Saksnummer: 04/10267-1	Saksbehandler: PøPA
Dato: 05 FEB 2004	Sendt til:
APP-Enhet: 529	
Merk: Kopi til Anna Risberg	

Deres ref
M. A. Risberg - FVS

Vår ref (bes oppgitt ved svar)
2003/1708-4 CBR/-

Dato
05.02.2004

KONSESJON TIL Å BEHANDLE HELSEOPPLYSNINGER

Datatilsynet viser til Deres søknad av 11. november 2003, om konsesjon til å behandle helseopplysninger.

Datatilsynet har vurdert søknaden og gir Dem med hjemmel i helseregisterloven § 5, jf. personopplysningsloven § 33, jf. § 34, konsesjon til å behandle helseopplysninger i forskningsprosjekt vedrørende evaluering av knefunksjonen hos pasienter med fremre korsbåndskade og effekten av et rehabiliteringsprogram.

Konsesjonen er gitt under forutsetning av at behandlingen foretas i henhold til søknaden, vedlagte merknader og de bestemmelser som følger av helseregisterloven med forskrifter.

Dersom det skjer endringer i behandlingen i forhold til de opplysninger som er gitt i søknaden, må dette fremmes i ny konsesjonssøknad.

I medhold av helseregisterloven § 5, jf. § 36, jf. personopplysningsloven § 35, fastsettes i tillegg følgende vilkår for behandlingen:

1. Den databehandlingsansvarlige skal hvert tredje år sende Datatilsynet bekreftelse på at behandlingen skjer i overensstemmelse med søknaden og helseregisterlovens regler.
2. Personidentifiserbare data skal slettes/anonymiseres straks oppbevaring ikke er nødvendig, og senest to år etter prosjektavslutning, 31.12.2008.

Med hilsen

Hanne P. Gulbrandsen
Hanne P. Gulbrandsen (e f)
rådgiver

Cecilie L. B. Rønnevik
Cecilie L. B. Rønnevik
rådgiver
(saksbehandler,
telefon 22 39 69 00)

Vedlegg: merknader

Kopi: UUS, Heidi Thorstensen

Postadresse:	Kontoradresse:	Telefon:	Telefaks:	Org.nr:	Hjemmeside:
Postboks 8177 Dep 0034 OSLO	Tollbugt 3	22 39 69 00	22 42 23 50	974 761 467	www.datatilsynet.no

Appendix V

Cohort A: Patient informed consent

Til pasienter som har en isolert fremre korsbåndskade og foreldre/ foresatte med barn under 18 år som har en isolert fremre korsbåndskade

Informasjon om prosjektet:

«Screening tester av pasienter med isolert fremre korsbåndsskade »

Alle pasienter som pådrar seg fremre korsbåndskade gjennomgår screeningtester som del av funksjonsvurdering og kvalitetssikring ved NAR/NIMI. En del av de som pådrar seg en slik skade må gjennom en operasjon der man lager et nytt korsbånd ved hjelp av en sene fra det samme kneet. Men det er også en del personer med korsbåndskade som kan fungere veldig bra uten å operere.

Formålet med dette prosjektet er å undersøke om en screeningtest bestående av 4 kne funksjonstester (hinketester) og to funksjonsspørreskjemaer kan benyttes for å vurdere kne funksjonen etter en korsbåndskade. For å vurdere dette trenger vi å re-teste alle dere som har vært igjennom screening tester i forbindelse med skaden etter 1 år. Videre ønsker vi å kartlegge hvor mye denne skaden koster samfunnet og har derfor utviklet et spørreskjema om helseøkonomi.

Dersom du ønsker å være med i prosjektet og innkalles til en 1 års kontroll må du komme til en screening test ved NIMI.

Det er ingen kjent risiko ved å delta i disse testene. Det har forekommet at pasienter har opplevd noe ubehag ved hinking. Dette er imidlertid ikke aktiviteter som har større belastninger enn det man vanligvis utsetter seg for i løpet av vanlige aktiviteter for aldersgruppen det gjelder.

Du har nøyaktig de samme rettighetene og forsikringsvilkårene som du ville hatt dersom du ikke deltok i denne etterundersøkelsen. Du har rett til å trekke deg fra undersøkelsen når som helst, og du har da rett på å kreve dataene slettet. Dersom feil oppdages har du rett på å få korrigert opplysningene.

Dataene som innhentes på kne funksjonen din vil lagres i manuelle arkiv med personidentifikasjon som låses inn, og du har til enhver tid full innsynsrett i dataene. Dataene aidentifiseres ved elektronisk lagring i sykehusets og NIMIs sikre nettverk for statistiske analyser. Elektronisk lagres dataene kun med nummer. Ingen av dataene sammenholdes med elektroniske registre. Lagringen av data vil foregå i henhold til personsopplysningsloven. Etisk komité har vurdert prosjektet.

Prosjektet planlegges avsluttet i 2008, og alle sensitive persondata vil bli slettet innen 2 år etter at studien er ferdig. Dersom nye studier basert på de innsamlede opplysninger blir aktuelle, ber vi om tillatelse til å henvende oss for nytt samtykke for slik bruk.

Dersom du har spørsmål underveis, kan du ringe fysioterapeut Håvard Moksnes, 2326 5640, havard.moksnes@nimi.no.

Samtykkeerklæring

Jeg har lest og blitt forklart informasjonen på medfølgende informasjonsskriv om prosjektet, og sier meg villig i å delta i etterundersøkelsen.

Jeg har forstått at deltakelsen er frivillig.

Sted

Dato

Underskrift

Underskrift av foresatt
(dersom pasienten er under 18 år)

Appendix VI

Cohort A: Patient informed consent for continued use of
previously collected data

Informasjon til deg som tidligere har deltatt i forskningsprosjektet

«Screening tester av pasienter med isolert fremre korsbåndsskade »

Dette er informasjon til deg som tidligere har deltatt i forskningsstudien «Screening tester av pasienter med isolert fremre korsbåndsskade » der hensikten var å undersøke om en screeningtest bestående av 4 kne funksjonstester (hinketester) og to funksjonsspørreskjemaer kan benyttes for å vurdere knefunksjonen etter en korsbåndsskade.

Resultatene har blitt publisert i internasjonalt tidsskrift. Videre har vi presentert resultatene fra studien ved ulike internasjonale og nasjonale konferanser. I all hovedsak viste studien at dere som var med i studien bedret knefunksjon signifikant, både målt ved spørreskjema og hinke-tester. Det er to hovedfunn som har tilført ny kunnskap innen behandling av pasienter med fremre korsbåndsskade; (1) at pasienter som ikke opereres kan fungere like bra som opererte pasienter ett år etter skaden, men at dette også innebærer redusert grad av deltagelse i vridningsidretter, og (2) at korsbåndsskadede pasienter som presterer lavt på test tre måneder etter skade har like stor sannsynlighet som pasienter med høy score for å ha god knefunksjon etter ett år. De som ønsker detaljer rundt resultatene fra studien, kan få tilsendt den vitenskapelige artikkelen, og de sammendragene som er presentert.

Vi vil informere deg om at vi, etter godkjennelse Personvernombud ved Oslo Universitetssykehus, Ullevål, har fått tillatelse til å oppbevare sensitive persondata fra den nevnte studien til 2020, 2 år etter at prosjektet er planlagt avsluttet.

Den forlengede oppbevaringen av sensitive personopplysninger vil ikke ha noe å si for deg. Informasjonen som er lagret om deg skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene blir behandlet uten navn og fødselsnummer/direkte gjenkjenn-ende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste. Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten, og som kan finne tilbake til deg. Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres. Du har rett til å få innsyn i hvilke opplysninger som er registrert om deg, og du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du trekker deg fra studien, kan du kreve å få slettet innsamlede opplysninger.

I tillegg til de allerede publiserte studiene, har vi flere vitenskapelige studier som vi i de nærmeste årene vil publisere på dette datamaterialet, men kun på bakgrunn av de allerede innsamlede data.

Vi håper på sikt å kunne sette i gang med en langtidsoppfølging av dere som har deltatt i dette prosjektet, noe som vil innebære en del av de samme testene du har gjennomført tidligere. Du vil da bli kontaktet av oss, og vi vil innhente nytt samtykke for videre deltakelse.

Dersom du ikke ønsker at opplysningene om deg kan lagres til 2020, eller har andre spørsmål, ber vi deg ta kontakt med undertegnede.

Med vennlig hilsen

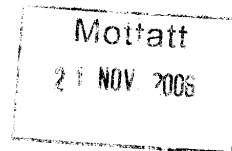
Kristin Bølstad
Forskningskoordinator
Hjelp24 NIMI/NAR
Tlf. 23 26 56 61 / 980 333 26
Epost: kristin.bolstad@hjelp24.no

Appendix VII

Cohort B: Approval South East Regional Committee for
Medical and Health Research Ethics

REGIONAL KOMITE FOR MEDISINSK FORSKNINGSETIKK

Øst-Norge (REK I)



Forskningsleder May Arna Risberg
NAR, Ortopedisk Senter
Ullevål universitetssykehus

Deres ref.:

Vår ref.: 685-06289 1.2006.3281

Dato: 20. november 2006

**Dynamisk stabilitet i et korsbåndsskadet kne – et forskningssamarbeid mellom
Universitetet i Delaware, USA, Ortopedisk senter, Ullevål universitetssykehus**

Regional komité for medisinsk forskningsetikk, Øst-Norge, vurderte det reviderte prosjektet på sitt møte 09.11.06.

Komiteen finner at prosjektlederen har tatt tilfredsstillende hensyn til de merknader komiteen tidligere har gitt, og har ingen innvendinger mot at prosjektet blir gjennomført.

Med vennlig hilsen

A handwritten signature in black ink, appearing to read "Knut Engedal".

Knud Engedal
professor dr.med.
leder

A handwritten signature in black ink, appearing to read "Ida Nyquist".

Ida Nyquist
sekretær

Kopi: Forskningsdirektør Andreas Moan, Ullevål Universitetssykehus

Appendix VIII

Cohort B: Approval from the Norwegian Data Protection Authority

Linn Gjersing

From: Thorstensen Heidi [Heidi.Thorstensen@ulleval.no]
Sent: 29. januar 2007 20:58
To: Linn Gjersing
Cc: Thorstensen Heidi
Subject: Formalisering av personvern i studien - Dynamisk stabilitet i et korsbåndsskadet kne - et forskningssamarbeid mellom Universitetet i Delaware, USA og Ortopedisk senter, Ullevål Universitetssykehus og NIMI

Your mail has been scanned by InterScan VirusWall.

*****_*****

[Ta vare på denne eposten]

Kjære forsker

Viser til melding om behandling av personopplysninger / helseopplysninger. Det følgende er et formelt svar på meldingen. Forutsetningene nedenfor må være oppfylt før rekruttering av pasienter til studien kan starte.

Mandat for tilrådning

Med hjemmel i Personopplysningsforskriftens § 7-12 og Helseregisterlovens § 36 har Datatilsynet ved oppnevning av Heidi Thorstensen som personvernombud ved UUS, fritatt sykehuset fra meldeplikten til Datatilsynet. Behandling og utlevering av person- /helseopplysninger til forskning meldes derfor til sykehusets personvernombud. Konesjonsplikten gjelder fremdeles, men personvernombudet tar stilling til om melding er dekkende eller om det må søkes om konsesjon hos Datatilsynet, se for øvrig www.datatilsynet.no for oversikt over oppnevnte personvernombud.

Tilrådning med forutsetninger

Personvernombudet har vurdert den planlagte databehandlingen av personopplysninger/helseopplysninger og vurderer denne til å tilfredsstillende forutsetningene for melding gitt i personopplysningsforskriften § 7-27 og er derfor unntatt konsesjon, Personvernombudet har ingen innvendinger og tilrår at studien gjennomføres med den planlagte behandlingen av person- / helseopplysninger under forutsetning av følgende:

1. Behandling av personopplysninger/helseopplysninger i studien skjer i samsvar med og innenfor det formål som er oppgitt i meldingen (se vedlagte meldeskjema)
2. Vedlagte samtykke benyttes.
3. Studien remeldes på eget skjema (se www.uus.no/personvern) hvert tredje år, første gang i 2010
4. Melding pr. epost om avsluttet studie sendes personvernombudet senest 2019

Øvrige forutsetninger:

- a. Positiv uttalelse er innhentet fra Regional Komité for medisinsk forskningsetikk ("REK")
- b. Studien er godkjent av avdelingsledelse og forskningsutvalget ved sykehuset og

registrert hos FUS v/Evi Faleide.

Endringer

Dersom det underveis i studien blir aktuelt å gjøre endringer i behandlingen av de aidentifiserte dataene, eller endringer i samtykket, skal dette forhåndsmeldes til personvernombudet.

Lykke til med studien!

<<Samtykkeerklæring endelig versjon.doc>> <<UUSmeldeskjemaforpersonvern Ingrid ACL161106.rtf>>

Mvh

Heidi

IKKE SENSITIVT INNHOLD

Heidi Thorstensen

IKT-sikkerhetssjef/personvernombud, Konsern IT

Ullevål universitetssykehus HF

Mobil: 48016349

Personvern i medisinsk forskning: www.uus.no/personvern

- This footnote confirms that this email message has been swept for the presence of computer viruses.

Appendix IX

Cohort B: Patient informed consent

Informasjon til pasienter som har en isolert fremre korsbåndskade og foreldre/foresatte med barn under 18 år som har en isolert fremre korsbåndskade, omhandlende deltagelse i prosjektet

Dynamisk stabilitet i ett korsbåndsskadet kne

Bakgrunn

Et røket fremre korsbånd vil kunne medføre instabilitet i kneet. Graden av instabilitet har imidlertid vist seg å variere fra pasient til pasient – noen kan stabilisere kneet selv under aktiviteter som involverer hopping, finter og vendinger, andre kan ikke. I Norge er det klinisk praksis at alle pasienter med en fremre korsbåndsskade gjennomgår et rehabiliteringsprogram for å bedre knefunksjonen. Forskning viser at ca 50 % av alle med en fremre korsbåndsrupitur klarer seg uten kirurgisk rekonstruksjon. Aktiv rehabilitering vil da være tilstrekkelig behandling for denne gruppen. Uansett om man velger kirurgisk behandling eller ikke vil det være helt nødvendig at man gjennomfører rehabilitering først. Vi vet fra forskning at pasienter med en fremre korsbåndskade har best prognose, uansett kirurgi eller ikke, dersom pasienten har en så optimal knefunksjon som mulig også før et eventuelt kirurgisk inngrep. Det vil si at dersom det viser seg at pasienten må gjennomgå kirurgisk behandling, vil muskelstyrken og knefunksjonen før kirurgi være avgjørende for resultatet på lang sikt.

Formål med studien

Det overordnede målet med dette prosjektet er å identifisere de med fremre korsbåndsskade og med god evne til å stabilisere kneet fra de med dårlig evne til å stabilisere kneet under aktivitet. Videre er målet å vurdere knefunksjonen før og etter gjennomføring av to forskjellige, spesifikke treningsprogram med vekt på stabilitet- og balanseøvelser, og følge alle med fremre korsbåndsskade, enten man opereres eller ikke, gjennom de to første årene etter skaden.

Generell beskrivelse

Totalt 150 pasienter vil delta i denne undersøkelsen. Deltakelse i denne studien er frivillig, og du kan til enhver tid trekke deg fra denne studien uten konsekvenser for deg selv eller behandlingen din. Undersøkelsen innebærer kliniske og funksjonelle tester, og i tillegg bevegelsesanalyse under gange. Først skal man gjennomføre en screening-undersøkelse, der vi ved hjelp av forskjellige funksjonstester og spørreskjemaer kartlegger din knefunksjon. Etter denne innledende undersøkelsen, vil du få rehabilitering ved Hjelp24 NIMI, parallelt med at du gjennomgår de samme testene på nytt på ulike tidspunkter i løpet av de neste to årene. En del av deltagerne vil også bli testet med bruk av bevegelsesanalyse under gange ved Norges Idrettshøgskole (se detaljer under).

Til slutt i dette informasjonsskrivet finner du en detaljert beskrivelse av rehabiliteringsprogrammet, hver test, omtrentlig tid beregnet for hver test og testprosedyrer.

Inndeling i to ulike treningsgrupper

Balanse- og stabilitetstrening inngår som en viktig del av rehabilitering for alle korsbåndspasienter. Det er imidlertid mange forskjellige måter å utføre denne type trening på. De siste årene har det blitt utviklet en type treningsprogram med stabilitets- og balansetrening på rullebrett og vippebrett. Vi ønsker i denne undersøkelsen å se om det er noen forskjell i effekten av å trene på denne måten eller med andre, etablerte balanse- og stabilitetsøvelser. Vi vet per i dag ingenting om det er noen forskjell i effekt på bruken av de to ulike typer av balanseøvelser. Dette innebærer at du etter den innledende screeningstesten vil bli trukket ut (ved loddtrekning) til å tilhøre én av de to nedenfor nevnte treningsgrupper:

Gruppe A: Balanse- og stabilitetstrening på rulle- og vippebrett

Deltagerne i denne gruppen vil de første 4-6 ukene gjennomgå øvelser på rullebrett og vippebrett i 10 spesifikke treningsøkter. Øvelsene kommer i tillegg til generell rehabilitering.

Gruppe B: Balanse- og stabilitetstrening med etablerte øvelser

Deltagerne i denne gruppen vil i løpet av de første 4-6 ukene også gjøre balanse- og stabilitetsøvelser i 10 spesifikke treningsøkter, men ikke på rullebrett og vippebrett. I stedet brukes matter og puter som gir et ujevnt underlag. Øvelsene kommer i tillegg til generell rehabilitering.

De 10 treningsøktene vil bli avtalt med en hyppighet på 2-3 ganger per uke, avhengig av dine tidsbegrensninger og anledning til progresjon i rehabiliteringen. Pasientene i begge grupper vil få like hyppig oppfølging, og skal trene akkurat like mye, men i disse 10 treningsøktene vil altså de konkrete balanseøvelsene være litt forskjellige, avhengig av hvilken gruppe du trekkes ut til. Rehabiliteringen og oppfølgingen for øvrig er akkurat den samme for alle.

Mer om de ulike testene

Innledende screeningundersøkelse

Undersøkelsen vil finne sted på Hjelp24 NIMI Ullevål Stadion, og vil totalt sett ta ca 1 time. Fysioterapeuten vil gjøre kne-instabilitetstester (KT1000). I tillegg vil du gjennomføre fire forskjellige ett-bens hinketester (ett hink, tre hink i sikk-sakk, tre hink og hink 6 meter på tid).

Etter hinketestene vil du fylle ut fire forskjellige spørreskjemaer, omhandlende din knefunksjon og ditt generelle aktivitetsnivå.

Det vil også gjøres en muskelstyrketest. Testen vil finne sted på Hjelp24 NIMI samtidig med hinketestene, og vil foretas ved hjelp av Biodex 6000, et apparat som gir et objektivt mål på muskelstyrke. Testen måler styrke i quadricepsmuskelen på lårets forside, og hamstringsmuskelen på lårets bakside.

De testene som er beskrevet ovenfor, vil gjentas ytterligere fire ganger i løpet av prosjektperioden:

- Første gang rett etter gjennomføring av de 10 treningsøktene med stabilitets- og balansetrening, (enten på rullebrett og vippebrett eller med generelle øvelser)
- Andre gang 6 måneder etter den innledende screeningundersøkelsen
- Tredje gang 12 måneder etter den innledende screeningundersøkelsen
- Fjerde gang 24 måneder etter den innledende screeningundersøkelsen

Dersom det viser seg at operasjon er den riktige behandlingen for deg, vil testene gjennomføres 6, 12 og 24 måneder etter operasjonen.

Bevegelsesanalyse

Hvis det er aktuelt for deg å delta i bevegelsesanalysen, foregår denne ved bevegelseslaboratoriet ved Norges Idrettshøgskole. Testingen vil ta 2-3 timer, og innebærer vanlig gange og hink. Bevegelsesanalysen vil foregå umiddelbart før og etter gjennomføringen av det spesifikke rehabiliteringsprogrammet. I tillegg skal det gjøres en oppfølgende bevegelsesanalyse etter 1 år.

Bevegelsesanalysen foregår ved at du får festet små reflekskuler (markører) på bena og føttene. Disse refleksene fanges opp av åtte tredimensjonale kameraer, som gir et detaljert bilde av hvordan bena beveger seg ved gange. Du skal gå over tre kraftplattformer som er nedfelt i gulvet. Samtidig vil vi evaluere muskelaktivitetsmønsteret i muskulaturen i lår og legg. Dette gjøres ved å feste små elektroder på huden over muskulaturen, som registrerer musklens aktivitet – såkalte elektromyografiske målinger (EMG).

Risiko/ubehag

Å delta i studiet innebærer ikke at du skal utføre noen andre øvelser eller bevegelser enn de du uansett vil utføre gjennom rehabiliteringen. Du vil i løpet av testingen gå, hinke og gjøre ulike former for styrke, stabilitets- og balanseøvelser. Dette er øvelser som er i daglig bruk av fysioterapeuter for å avgjøre pasienters funksjonsnivå. Det kan være at du kan oppleve noe ubehag i kneet ved gjennomføring av hinke-testene, men det er svært liten risiko for at dette skal føre til forverring av din skade.

Kompensasjon

Du vil motta kroner 200,- for å dekke dine reiseutgifter/parkeringsutgifter og tiden som er involvert i testingen hvis du ikke har andre dokumenterte reiseutgifter.

Anonymitet og data

Dataene som innhentes vil lagres i manuelle arkiv med personidentifikasjon som låses inn, og du har til enhver tid full innsynsrett i dataene. Dataene aidentifiseres ved elektronisk lagring på Oslo universitetssykehus og Hjelp24 NIMIs sikre nettverk for statistiske analyser. Elektronisk lagres dataene kun med nummer. Ingen av dataene sammenholdes med elektroniske registre. Lagringen av data vil foregå i henhold til personsopplysningsloven. Prosjektet er vurdert av den Regionale Etsiske Komité for medisinsk forskning.

Prosjektet planlegges avsluttet i 2017, og alle sensitive persondata vil bli slettet innen 2 år etter at studien er ferdig. Dersom nye studier basert på innsamlede opplysninger blir aktuelle, ber vi om tillatelse til å henvende oss til deg for nytt samtykke for slik bruk.

Har du spørsmål underveis, kan du kontakte prosjektleder Hege Grindem på telefon 95106154, eller e-post hege.grindem@hjelp24.no.

Med vennlig hilsen

Prof. Dr. Med
Lars Engebretsen
Direktør Ortopedisk avdeling

Samtykkeerklæring

Jeg har lest og blitt forklart informasjonen på medfølgende informasjonsskriv om prosjektet, og sier meg villig i å delta i:

Alle tester/ prosedyrer

JA NEI

Alle tester/ prosedyrer UTENOM bevegelsesanalyse

JA NEI

Jeg har forstått at deltakelsen er frivillig, og at jeg når som helst kan trekke meg fra studien uten å oppgi grunn.

Sted

Dato

Underskrift

Underskrift foresatte (dersom deltageren er under 18 år)

Appendix X

International Knee Documentation Committee Subjective Knee Form

IKDC 2000 Kne evaluerings skjema

Navn: _____ Dato: _____ Skadedato: _____

SYMPTOMER:

Grader symptomene på det høyeste aktivitetsnivå som du tror du kan fungere uten betydelige symptomer, selv om du ikke egentlig driver med aktiviteter på dette nivået.

1. Hva er det høyeste aktivitetsnivå du tror du kan drive med uten betydelige knesmerter?

- Veldig harde aktiviteter som hopping og vendinger som ved basket eller fotball
- Harde aktiviteter som tungt fysisk arbeid, ski eller tennis
- Moderate aktiviteter som moderat fysisk arbeid, løping eller jogging
- Lette aktiviteter som gange, husarbeid eller hagearbeid
- Umulig å foreta noen av de overnevnte aktiviteter på grunn av knesmerter

2. I løpet av de siste 4 uker (eller siden kneskaden); hvor ofte har du hatt smerter (sett ring rundt)?

Aldri 0 1 2 3 4 5 6 7 8 9 10 Alltid

3. Hvis du har smerter; hvor intense er de (sett ring rundt)?

Ingen smerte 0 1 2 3 4 5 6 7 8 9 10 Verst tenkelige smerte

4. I løpet av de siste 4 uker (eller siden kneskaden); hvor stivt eller hovent har kneet ditt vært?

- Ikke i det hele tatt
- Litt
- Moderat
- Veldig
- Ekstremt

5. Hva er det høyeste aktivitetsnivå du tror du kan drive med uten betydelig hevelse i kneet?

- Veldig harde aktiviteter som hopping og vendinger som ved basket eller fotball
- Harde aktiviteter som tungt fysisk arbeid, ski eller tennis
- Moderate aktiviteter som moderat fysisk arbeid, løping eller jogging
- Lette aktiviteter som gange, husarbeid eller hagearbeid
- Umulig å foreta noen av de overnevnte aktiviteter på grunn av hevelse

6. I løpet av de siste 4 uker, (eller siden kneskaden); har kneet låst seg (sett ring rundt)?

JA

NEI

7. Hva er det høyeste aktivitetsnivå du tror du kan drive med uten betydelig svikt av kneet?

- Veldig harde aktiviteter som hopping og vendinger som ved basket eller fotball
- Harde aktiviteter som tungt fysisk arbeid, ski eller tennis
- Moderate aktiviteter som moderat fysisk arbeid, løping eller jogging
- Lette aktiviteter som gange, husarbeid eller hagearbeid
- Umulig å foreta noen av de overnevnte aktiviteter på grunn av svikt av kneet

IDRETTSAKTIVITETER:

8. Hva er det høyeste aktivitetsnivå du vanligvis kan delta i (nå)?

- Veldig harde aktiviteter som hopping og vendinger som ved basket eller fotball
- Harde aktiviteter som tungt fysisk arbeid, ski eller tennis
- Moderate aktiviteter som moderat fysisk arbeid, løping eller jogging
- Lette aktiviteter som gange, husarbeid eller hagearbeid
- Umulig å foreta noen av de overnevnte aktiviteter på grunn av kneet

9. Hvordan påvirker kneet din evne til å (sett kryss):

		Ikke vanskelig i det hele tatt	Litt vanskelig	Moderat vanskelig	Ekstremt vanskelig	Kan ikke i det hele tatt
a	Gå opp trapper					
b	Gå ned trapper					
c	Knele (gå ned på kne)					
d	Gå ned på huk					
e	Sitte med bøyd kne					
f	Reise deg opp fra stol					
g	Løpe rett frem					
h	Hinke på ditt skadede ben					
i	Starte og stoppe raskt					

FUNKSJON:

Hvordan vil du gradere din knefunksjon på en skala fra 0 til 10 der 10 er normal, utmerket funksjon og 0 er at du ikke kan gjøre noen av dine daglige aktiviteter som også kan inkludere idrett?

10. FUNKSJON FØR KNESKADEN:

Kan ikke 0 1 2 3 4 5 6 7 8 9 10 Ingen
gjøre daglige aktiviteter i daglige aktiviteter
begrensninger

NÅVÆRENDE KNEFUNKSJON:

Kan ikke 0 1 2 3 4 5 6 7 8 9 10 Ingen
gjøre daglige aktiviteter i daglige aktiviteter
begrensninger

(Original artikkel: Irrgang et al. Development and Validation of the International Knee Documentation Committee Subjective Knee Form. The American Journal of Sports Medicine 2001. vol. 29 no.5 pp. 600-613)

Oversatt av NAR- Ortopedisk senter, UUS, Oslo; 2005, til og med trinn IV etter retningslinjer utarbeidet av:

Guillemin F, Bombardier C, Beaton D. Cross-cultural adaptation of health-related quality-of-life measures: literature review and proposed guidelines. J Clin. Epidemiol 1993. vol. 46 pp. 1417-32.

Appendix XI

Knee Outcome Survey - Activities of Daily Living Scale

Vurdering av kneets tilstand (KOS)

Gradering av daglige aktiviteter

Navn: _____ Dato: _____ Skadedato: _____

Instruksjoner:

Det følgende spørreskjema er laget for å kartlegge symptomene og begrensningene du opplever ved daglige aktiviteter på grunn av din kneskade. Vennligst besvar hvert spørsmål ved å **krysse av for det utsagnet som best beskriver deg i løpet av de 1 til 2 siste dagene**. For hvert spørsmål er det mulig at flere utsagn kan beskrive din funksjon, men vi ønsker at du bare krysser av for det utsagnet som **best** beskriver deg i dine daglige aktiviteter

Symptomer

1. I hvilken grad påvirker hvert av de følgende symptomer nivået på din daglige aktivitet?
(Kryss av for ett svar på hver linje)

	Jeg har aldri symptomet	Jeg har symptomet, men det påvirker <u>ikke</u> min aktivitet	Symptomet påvirker min daglige aktivitet <u>litt</u>	Symptomet påvirker min aktivitet <u>moderat</u>	Symptomet påvirker min aktivitet <u>svært mye</u>	Symptomet hindrer meg fra all daglig aktivitet
Smerte						
Stivhet						
Hevelse						
Svakhet						
Halting						
Glipp, svikt eller kollaps av kneet						
Score	5	4	3	2	1	0

Vurdering av kneets tilstand (KOS)

Gradering av daglige aktiviteter

Side II

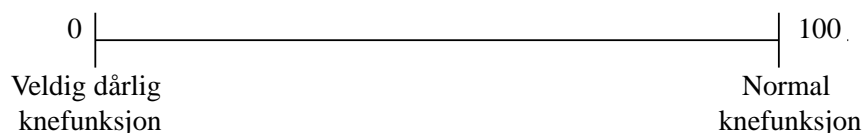
Funksjonelle begrensninger ved daglig aktivitet

2. Hvordan påvirker kneet din evne til å... (kryss av for ett svar på hver linje)

	Ingen problemer med aktiviteten	Aktiviteten er ubetydelig vanskelig	Aktiviteten er litt vanskelig	Aktiviteten er ganske vanskelig	Aktiviteten er veldig vanskelig	Kan ikke gjøre aktiviteten
Gå?						
Gå opp trapper?						
Gå ned trapper?						
Stå?						
Knele (gå ned på kne)?						
Gå ned på huk?						
Sitte med bøyd kne?						
Reise deg opp fra stol?						
Score	5	4	3	2	1	0

3. Hvordan vil du gradere din kne funksjon i dine vanlige daglige aktiviteter på en skala fra veldig dårlig (0) til normal (100)?

Merk av en loddrett strek på linjen.



(Originalartikkel: Irrgang et al. "Development of a Patient-Reported Measure of Function of the Knee" *American Journal of Sports Medicine* 1998. vol. 80 pp. 1132-1145)

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