Treatment Decision after Anterior Cruciate Ligament Injury, and Evaluation of Measurement Properties of a Patient Reported Outcome Measure

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Till mina älskade barn och man!

"If your dreams don't scare you, they are not big enough"

- Ellen Johnson Sirleaf

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ABSTRACT

Background: After an ACL injury, treatment aims to restore knee function. Evaluation of treatment progress is important, and adequate measurement methods are necessary. The International Knee Documentation Committee-Subjective Knee Form (IKDC-SKF) is a common patient-reported outcome measure (PROM) used after ACL injury. It evaluates symptoms, function and physical activity. The IKDC-SKF had not been translated to Swedish language for use in Swedish clinical and research settings. The measurement properties of the IKDC-SKF had been tested, but no assessment of methodological quality of the studies investigating it, nor compiling of results, was published.

Sooner or later after an ACL injury, a treatment decision must be made. Treatment options are either ACL reconstruction (ACLR) plus rehabilitation, or rehabilitation alone. There are guidelines stating that a decision for ACLR should be made if the patient has high activity demands and/or knee joint instability. It is unclear which factors orthopaedic surgeons and physiotherapists prioritise when recommending ACLR. It is also unclear when the decision for treatment is taken, on what grounds, and how treatment decision correlates to patients reported symptoms and function.

Aims: The overall aim of this thesis was to evaluate the measurement properties of a patient-reported measure for evaluation of function after ACL injury and treatment, and to overview the treatment decision process after an ACL injury.

Methods: A systematic review was conducted to assess the measurement properties of the IKDC-SKF. The IKDC-SKF was translated from English to Swedish, and the Swedish version was tested for reliability, validity, responsiveness and interpretability.

A survey study was conducted, where 98 orthopaedic surgeons and 391 physiotherapists rated 21 predefined factors based on importance to the decision for ACLR. Orthopaedic surgeons and physiotherapists rated how important they considered their own and each other's assessments and patient's wishes for treatment decision making.

In a prospective cohort study, patients with an ACL injury were followed from within 6 weeks up to 12 months after injury. Data regarding treatment chosen,

when and why, were described and compared to patient-reported pre-injury activity level, knee joint instability and function.

Results:

The English and Swedish version of the IKDC-SKF had good measurement properties and interpretability.

Swedish orthopaedic surgeons and physiotherapists considered young age, high activity demands, knee-demanding occupation, and knee joint instability despite adequate rehabilitation indications to recommend ACLR.

An early decision for ACLR was primarily based on *high activity demands*. A later decision was mainly due to *knee joint instability and high activity demands*. A decision taken later than five months after injury was based mainly on *knee joint instability*.

A decision for *non-operative treatment* taken and maintained during the first 12 months after injury was mainly due to *sufficient function or no knee joint instability problems*, and non-operatively treated patients were older than the other groups.

Conclusions:

The patient-reported outcome measurement IKDC-SKF is suitable for evaluation and assessment in patients with ACL injury.

ACLR as treatment after an ACL injury was recommended for young patients, patients with high activity demands (i.e. knee demanding occupation and/or knee joint instability despite adequate rehabilitation) and/or patients suffering from knee joint instability

An early decision for ACLR was more often based on high activity demands, while later decisions were more often based upon knee joint instability. Non-operative treatment decisions were often based upon lack of knee joint instability problems or sufficient knee function.

Self-reported knee joint instability and function during the first three months after ACL injury were no different in patients who chose ACLR treatment or who chose non-operative treatment.

Keywords: anterior cruciate ligament injury, ACL, ACL reconstruction, ACLR, choice of treatment, IKDC, measurement properties, evaluation

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SVENSK SAMMANFATTNING

Bakgrund: Efter en främre korsbandsskada syftar behandlingen att återställa knäfunktionen. Utvärdering av framstegen är av vikt, och adekvata mätmetoder för detta är nödvändigt. International Knee Documentation Committee Subjective Knee Form (IKDC-SKF) är ett patientskattningsformulär som är väl använt över hela världen vid främre korsbandsskador. Det utvärderar symptom, funktion och fysisk aktivitet. Det har inte funnits tillgängligt på svenska tidigare och det har heller inte funnits någon sammanställning över formulärets mättegenskaper.

Efter en främre korsbandsskada måste förr eller senare beslut om behandling fattas, om patienten ska genomgå en rekonstruktionsoperation för främre korsbandet, med efterföljande rehabilitering, eller enbart rehabilitering. Det finns riktlinjer som gör gällande att en korsbandsrekonstruktion kan vara ett adekvat alternativ när patienten har höga aktivitetskrav eller lider av instabilitet i knäleden. Det är dock ej fastställt vilka faktorer ortopedläkare och fysioterapeuter anser viktiga för att rekommendera rekonstruktionsoperation. Det är inte heller klargjort när efter skada och på vilka grunder faktiska behandlingsbeslut fattas, och hur orsaken till beslutet hänger samman med patientens självrapporterade symptom och funktion.

Syfte: Det övergripande syftet med avhandlingen var att utvärdera mättegenskaper för ett patientskattningsformulär som utvärderar funktion efter en främre korsbandsskada, samt att överblicka beslutsprocessen för behandling efter en främre korsbandsskada.

Metod: En systematisk genomgång utfördes av studier som utvärderat mättegenskaper för IKDC-SKF. Studierna värderades avseende metodologi och resultat. IKDC-SKF översattes till svenska, och den svenska versionens mättegenskaper prövades.

En enkätstudie utfördes där 98 svenska ortopedläkare och 391 svenska fysioterapeuter fick skatta 21 faktors betydelse för valet att rekommendera rekonstruktionsoperation av främre korsbandet. Ortopedläkare och fysioterapeuter fick även skatta vikten av sin egen och varandras bedömning samt patientens önskan, i valet av behandling.

I en prospektiv kohortstudie följdes 219 patienter med en främre korsbandsskada, från 6 veckor och upp till 12 månader efter skadan. Data om vilken behandling patienten genomgått, när behandling valdes och grunder för behandling samlades in från patient och ortopedläkare och jämfördes med patientskattad aktivitetsnivå innan skada, knäledsinstabilitet och funktion.

Resultat: Den systematiska genomgången av IKDC-SKF och prövningen av den svenska versionens mätenskaper visade att IKDC-SKF uppvisar goda mätenskaper och tolkningsbarhet.

Svenska ortopedläkare och fysioterapeuter anser att ung ålder, höga aktivitetskrav, knäkrävande arbete och knäledsinstabilitet trots adekvat rehabilitering är faktorer som indikerar behov av rekonstruktionsoperation av främre korsbandet.

Ett tidigt beslut för rekonstruktionsoperation efter främre korsbandsskada fattas i hög grad på grund av höga aktivitetskrav. Ett senare beslut för rekonstruktionsoperation fattas i hög grad på grund av knäledsinstabilitet och höga aktivitetskrav, medan ett sent beslut fattas i hög grad på grund av knäledsinstabilitet. Ett beslut att enbart behandla med rehabilitering fattas i hög grad på grund av att patienten har tillräckligt god funktion eller inte har några besvär från knäledsinstabilitet. Det var inga skillnader i patientskattad funktion och knäledsinstabilitet mellan de patienter där rekonstruktionsoperation valdes och de som valde att behandla med enbart rehabilitering.

Sammanfattning: IKDC-SKF visar goda mätenskaper och kan rekommenderas för användning hos patienter med en främre korsbandsskada och andra knärelaterade diagnoser.

Efter en främre korsbandsskada fattas ett tidigt beslut för rekonstruktionsoperation på grund av höga aktivitetskrav. Ett senare beslut för rekonstruktionsoperation fattas när patienten lider av knäledsinstabilitet och nedsatt knäfunktion, medan ett beslut för enbart rehabilitering valdes när funktion och knästabilitet var god. Det var inga skillnader mellan patienter där man valt rekonstruktionsoperation och enbart rehabilitering, avseende skattad funktion och knäledsinstabilitet. Både ortopedläkarens och fysioterapeutens bedömning samt patientens önskan är viktig i valet av behandling.

Nyckelord: främre korsbandsskada, främre korsbandsrekonstruktion, val av behandling, IKDC, mätenskaper, utvärdering

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LIST OF PAPERS

- I. **Hanna Tigerstrand Grevnerts**, Caroline Terwee, Joanna Kvist. The measurement properties of the IKDC-subjective knee form. *Knee Surg Sports Traumatol Arthrosc.* 2015 Dec;23(12):3698-706. doi: 10.1007/s00167-014-3283-z. Epub 2014 Sep 6.
- II. **Hanna Tigerstrand Grevnerts**, Karin Grävare Silbernagel, Sofi Sonesson, Clare Ardern, Annika Österberg, Håkan Gauffin, Joanna Kvist. Translation and testing of measurement properties of the Swedish version of the IKDC subjective knee form. *Scand J Med Sci Sports.* 2017 May;27(5):554-562. doi: 0.1111/sms.12861. Epub 2017 Mar 19.
- III. **Hanna Tigerstrand Grevnerts**, Anne Fältström, Sofi Sonesson, Håkan Gauffin, Siw Carlford, Joanna Kvist. Activity demands and instability are the most important factors for recommending to treat ACL injuries with reconstruction *Knee Surg Sports Traumatol Arthrosc.* 2018 Aug;26(8):2401-2409. doi: 10.1007/s00167-018-4846-1. Epub 2018 Feb 6.
- IV. **Hanna Tigerstrand Grevnerts**, Sofi Sonesson, Håkan Gauffin, Clare Ardern, Anders Stålmán, Joanna Kvist. Decision-making for surgical or nonsurgical treatment after an ACL injury: acute and subacute treatment decision is based upon expected future activity demands and later decision on current knee function. Manuscript in process.

DESCRIPTION OF CONTRIBUTION

Study 1

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ABBREVIATIONS

ACL	Anterior cruciate ligament
ACLR	Anterior cruciate ligament reconstruction
ANOVA	Analysis of variance
AUC	Area under the curve
COSMIN	COnsensus-based Standards for the selection of health Measurement INstruments
ES	Effect Size
GRC	Global rating of change
GRADE	Grading of Recommendations Assessment, Development and Evaluation
ICC	Intraclass correlation coefficient
IKDC- SKF	International Knee Documentation Committee Subjective Knee Form
KOOS	Knee injury and osteoarthritis outcome score
MCS	Mental component summary (of SF36)
MCIC	Minimal Clinical Important Change
PCS	Physical component summary (of SF36)
PROM	Patient Reported Outcome Measure
ROC	Receiver operator curve
SD	Standard deviation
SDC	Smallest detectable change
SDCgroup	Smallest detectable change group
SDCind	Smallest detectable change individual
SF36	Short Form 36
SRM	Standardized response mean

PROLOGUE

As a child, I was not interested in sports. I loved to read. I used to beg my mother to tell kids who rang on the doorbell asking to play, that I was sick. I just wanted to be left alone with my books.

As a child I also loved to plan and make lists. I used to make Christmas lists in February, for the presents I would make myself to my family. But I always had a hard time to focus and structure when things were boring. My childhood room was a mess, I've lost plenty of house keys in my life and I can't remember the times I forgot to bring clothes for gymnastics class or forgot an apple or banana in my schoolbag- resulting in having to throw everything in the bag and clean it from rotten fruit...

When I was about 14 year old, a gymnastics teacher in school had a lecture about the importance of strengthening the body with physical activity. It really made me understand that I needed to be more physically active. Since I didn't like team sports, I just felt clumsy and awkward, I begun to work out at the gym. I loved it. I wanted to know everything about the muscles and the body. I wanted to become a body builder.

A natural step to "knowing everything" about the body, I thought, was to become a physiotherapist. I studied in Linköping, and loved it. While writing my bachelor thesis, I had an inspiring supervisor that asked if I wanted to write some further and turn the essay in to a scientific article. I liked the writing, and I liked to challenge myself, so we wrote a manuscript for a scientific journal. It was published.

Some years later, I decided to do the master programme, and quite early into the programme I realised how much I had missed the university world, and the structure. I thought that PhD studies must be the greatest challenge I could ever imagine. So, that was what I wanted to do!

I had the same supervisor for both bachelor and master thesis, and I found that she had a way of mentoring that motivated me in to doing my best. I had the fortune that she agreed to be my PhD supervisor too.

During these years of PhD studies, I have learned so much. I have challenged myself. I have been nervous so many times. I have been full of endorphins and joy when I have overcome my fears. I have developed new sides of myself.

I have had the fortune to co-examine more than 250 patients with an acute knee injury together with two great orthopaedic surgeons. The experience I bring from these sessions will be useful for me for the rest of my career as a physiotherapist.

I have loved (almost) every moment of my years as a PhD student, and I am so grateful that I have had the opportunity to do this. The experiences during these years, are of the kind that money cannot buy.

I quote Forrest Gump; “life is like a box of chocolates”. I think that the years as a PhD student are too. There are some chocolates that go down easily with joy, and some that are bitterer to chew on. But you need the bitter ones to appreciate the most delicious ones, and all together the box is perfectly balanced.

Enjoy reading my box of chocolate!

INTRODUCTION

For as long as people have participated organized sports, there have been reports of sports injuries. There have also been attempts to heal injuries, in one way or another. Since Hippocrates sought to treat sports related injuries ⁶⁶, we have sought to evaluate and improve the treatment methods. To find the best way to help the patient to heal as safely and quickly as possible and to return to sport.

An Anterior Cruciate Ligament (ACL) injury is a serious sports injury ^{59, 96}. The late nineteenth century saw the first attempts to reconstruct the torn ligament ^{66, 109}. Techniques for surgical repair of the ACL have varied ever since ¹⁰⁹. Regardless how a torn ACL is replaced, it seems that function and motor control is not restored to the preinjury state ^{99, 128}.

In the early eighties, Noyes described the ACL injury and corollary. Approximately one third of an ACL injured cohort requires reconstructive surgery, one third seems to manage without surgery, and one third manages with a modification of activity ^{93, 94}. Today, the two major treatment options are ACL reconstruction plus rehabilitation, or rehabilitation alone (non-operative treatment). Patients report satisfactory outcomes following non-operative treatment ^{40, 74}. However, in many countries, ACLR is the standard treatment after ACL injury. We lack evidence about how treatment is chosen. In all medical care approaches, the best treatment possible is desirable.

Treatment decision- from evidence to recommendation

Evidence Based Medicine (EBM) is the foundation of modern health care systems, and the basis for empirical practice of medicine ²⁵. EBM is often divided into two branches: one with more emphasis on clinical experience and judgement, and one with more emphasis on research evidence ¹⁰⁸. Critics of EBM are concerned that research is emphasized too much, and clinical expertise and patients preferences are ignored ¹²³. With constant updates of clinical guidelines and publication of new research, it may be a challenge for clinicians to stay up-to-date and utilize the latest evidence ²¹. The core message of EBM is that good clinical practice should be based upon valid and reliable research. Although, in practice

there is often a gap between the available research and its use in clinical decision making ^{33, 111}.

Evidence Based Practice (EBP), was developed as a response to growing demands in health care organizations for professional practice to be based on research and treatment decisions based on evidence of effectiveness ¹⁸. EBM is the theoretical framework and foundation to EBP, and the result of improving how researchers conduct and clinicians use research ³⁹. Clinical practice and recommendations should be based on up-to-date, valid and reliable evidence from research. However, the disparity between the production of research and the use of research findings in clinical practice –the research-practice gap ⁸⁹ – is hard to bridge.

Researchers have attempted to bridge the gap between research and practice by developing guidelines that include information about the strength of recommendations for different treatments. Several factors impact on clinical recommendations. The more complex the decision, the more important it is that the recommendations are clear, and can lead to clinical guidelines or policies ⁸⁰. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) is a theoretical framework for assessing the quality of guidelines. GRADE aims to ease the translation from evidence to clinical recommendations ⁵⁰. Clinical recommendations can be assessed as “strong” or “weak”. Strong recommendations imply (i) evidence is strong for that treatment, (ii) most patients will want and should receive the treatment, and (iii) recommendations can often be adopted as a policy. Weak recommendations imply (i) evidence is lacking, (ii) many patients should not receive the treatment, and (iii) policies cannot be made without considerable discussions ⁵⁰. After rating the quality of the evidence (considering design and potential biases), there are four key factors that are important to assess whether a recommendation is strong or weak (figure 1) ⁵⁰:

1. There should be a balance between desirable and undesirable consequences (i.e. a valuation of potential adverse effects of the treatment).
2. There should be strong evidence for treatment method and effect (i.e. research of high methodological quality).

- Values and preferences; the more variation in preferences, or high uncertainty in values and preferences, the greater chance of a weak recommendation.
- Cost-effectiveness; higher costs might cause a recommendation to lose impact.

Figure 1. Factors affecting decision making according to GRADE. Reprinted with permission from the U.S. GRADE Network.

Treatment decision- patient contribution

Patient's preference is an important factor and a key component in shared decision making. Shared decision making aims to enhance patients' involvement in the treatment decision. In sports medicine, efforts should be made to consider long-term outcome, especially for young athletes. Cost-effectiveness and risk assessment must be considered, and an assessment of the appropriateness of the stakeholders to make the decision, as well as the appropriateness of the decision itself^{6, 10}.

Choice of treatment after ACL injury

There are no internationally-accepted guidelines on how to treat an ACL injury. There are several guidelines and recommendations ^{9, 78, 84, 112} stating that knee joint instability and high activity demands are indications for ACLR. However, non-operative treatment can be an effective treatment also ^{40, 48}. Although there is uncertainty about which patient is a candidate for ACLR and which patient can be managed with non-operative treatment, there have been attempts to develop decision rules to ease the decision for choice of treatment ^{74, 88}. Studies of these decision rules show that patients who are initially classified as copers (able to manage without surgery) might need ACLR later, and some patients who have surgery might have been able to cope without it.

Little knowledge of patient's perspective of important reasons for choice of treatment

There are few studies of patient's perspective regarding choice of treatment after an ACL injury ^{116, 120}. Patients state that fear of not being able to participate in sports to the same extent as before the injury, disbelief in the ability to perform in physical activity/sports, and knee joint instability/giving way episodes or impaired knee function are important reasons for choosing ACLR treatment ¹¹⁶. We lack knowledge of patient's reasons for choosing a non-operative treatment.

Short- and long-term consequences after ACL injury

The ACL is an important structure in the knee, controlling rotation and anteroposterior displacement of the tibia on the femur ⁷⁷. Patients experience swelling and pain early after ACL injury ¹⁷. Knee joint instability or giving way symptoms often occur after swelling has reduced and the knee is exposed to more strenuous activity ⁹⁷. Giving way episodes can contribute to new injuries. When a decision for ACLR is taken later after ACL injury, the risk for further injuries until the surgery is performed is significantly raised ^{5, 16, 43}. Associated injuries (e.g. meniscus injuries) are important risk factors for developing osteoarthritis ²². ACLR does alter the risk of early onset of osteoarthritis, compared to non-operative treatment ^{22, 122}.

Rehabilitation after ACL injury and after ACLR

Patients benefit from starting knee rehabilitation early after injury, irrespective of the final treatment choice ¹²⁷. Pre-surgical rehabilitation to regain full range of

motion, control swelling and to regain strength in quadriceps are factors that enhance the likelihood of good outcome after surgery ¹²⁷. The pre-surgical rehabilitation period can also serve as education of the patient about how the post-operative treatment will be and the amount of effort that is required. For patients who undergo rehabilitation, the physiotherapist's role is important. Physiotherapists assess functional outcome, inform and educate patient about the nature of the injury and recognize psychological issues that might arise during the process ^{79, 127}.

The first rehabilitation phase aims to “quiet” the knee – reduce swelling and improve range of motion. Balance, neuromuscular control and muscle strength also need to be addressed. Sport-specific exercises are added in a later phase depending on functional progress and the goals of the patient ^{34, 127}.

Evaluation after ACL injury

Evaluation of treatment is a cornerstone in health care ^{24, 34, 127}. Assessments of function are useful in the treatment decision process, to seek to predict who may be able to manage without ACLR ^{11, 29} and to evaluate function ³⁸. Assessing range of motion, swelling, muscle strength and other quantitative measures provide important information to allow physiotherapists to adjust and progress rehabilitation ¹.

Among patient-reported outcome measures (PROMs), the International Knee Documentation Committee Subjective Knee Form (IKDC-SKF) measures symptoms, function and sports activity, and is developed for use in knee injuries and symptoms ⁵⁶. The IKDC-SKF is the third most used patient-reported outcome in ACL injuries ¹³⁰. It has been translated into 20 different languages ¹¹⁹ and consists of 18 items that gives a total score a 0-100 scale, where 100 equals full knee function ⁵⁶.

Patient-reported outcome measures

PROMs identify non-observable characteristics such as confidence in own ability, fears to return to sport and ability to perform ²³. The use of PROMs in clinical practice and research, as well as health-care policies, has increased during the last two decades ⁴². Clinicians seem to be positive about the use of PROMs to improve quality of care, but the time for administration and collection can be a barrier for the use of PROMs in clinic ¹⁰⁰. Using PROMS means:

- Information that cannot be obtained from clinical measures (e.g. how the knee functions in daily life) can be gained ⁴².
- Monitoring changes and effects of treatment in non-observable characteristics can lead to further possibilities to improve and tailor the treatment ⁴².
- Behavioural changes might occur due to addressing unobservable characteristics such as health related quality of life (i.e. patients might become aware of problems and be more adherent to treatment) ⁴⁴.
- Opening a discussion between patient and health care provider about topics that might be sensitive to address ⁷¹.
- Patients can facilitate important questions to be raised in the clinical encounter ⁷¹.
- Improved patient engagement ⁷¹.
- Patients being integrated in clinical care ⁷¹.
- Enhanced shared decision making ⁷¹.

Measurement properties of a patient-reported outcome measure

To successfully use a measurement instrument, it is important to examine its design, and make sure it is appropriate for use in the patient population. The measurement properties should be tested and evaluated, with appropriate methodology ²⁴.

The CONsensus-based Standards for the selection of health care Measurement INstruments (COSMIN) panel is a team of scientists in the Netherlands. They have developed a checklist with a scoring system for evaluation of the methodological quality and result of studies assessing measurement properties of health care-related PROMs. The scoring system and their work aims to improve research and simplify evaluation of PROMs ⁸⁶. The COSMIN group has also defined and described the taxonomy of measurement properties of a health-related patient-reported outcome (HR-PRO) (Figure 2). They have defined reliability, validity and responsiveness for evaluation of PROMs ⁸⁷ and the quality criteria that should be met for a PROM to show good measurement properties, and developed a standardized way to summarize the methodological score and valuation of results

Figure 2. The taxonomy of measurement properties defined by the COSMIN panel ⁸⁷. Reprinted with permission from the COSMIN group.

Reliability

Reliability is “the degree to which the measurement is free from measurement error”. Testing of reliability includes test-retest reliability, measurement error and internal consistency. Test-retest reliability is important to evaluate whether the outcome replicates the same measure when it is tested repeatedly, with the same test surroundings and in the same study population ²⁴. *Test-retest* reliability for a PROM involves patients completing out the form twice, with a short gap (typically 2 weeks) between measurement occasions. The interim time should be appropriate, ensuring that no change in condition has occurred, and that the patient does not recall the answers from last time. Correlations between the first and second score are made, and a high correlation is a sign of good test-retest reliability ¹¹⁷. An ICC or Kappa test result for test-retest reliability of >0.7 is considered good ¹¹⁷. *Measurement error* is the systematic and/or random error of a patient’s score that is not due to true changes in the construct that will be

measured. *Internal consistency* measures the internal relationship among the items included in the score⁸⁷, and is often tested with a Cronbach's alpha, where a value of 0.7-0.95 is considered good¹¹⁷.

Validity

Validity is "the degree to which an instrument measures the construct(s) it purports to measure". *Content validity*, including *face validity*, is assessed by testing that the items are fit for the construct to be measured, for the study population and for the purpose of the measurement instrument. It also includes the comprehensibility of the items⁸⁷. One simple yet effective way to examine face validity of a PROM is the "eyeball test" – simply to look at the questions. Does it look professional? Are the questions too basic or too advanced for the population intended? Are the instructions clear? Is there a good flow in the questions? Does the questionnaire look sloppy or do the questions appear in an unstructured way?²⁴.

Construct validity includes structural validity, hypothesis testing and cross-cultural validity. *Structural validity* for a PROM can be assessed using factor analysis, exploring or confirming whether the score is a reflection of the dimensionality of a construct¹¹⁷.

Hypothesis testing involves testing pre-defined hypotheses (e.g. correlations between the measurement instrument and another measurement instrument). Hypotheses should be well-defined and set a priori, and >75% confirmed hypothesis is a good result for hypothesis testing¹¹⁷. *Cross-cultural validity* refers to translating and culturally-adapting PROMs into another language. Testing cross-cultural validity includes assessing that the translated version reflects the construct to be measured and adequately reflects the original version, and assessing if any cultural changes need to be made in the new version²⁴.

When testing *criterion validity*, the measurement instrument can be compared to another measurement that reflects the same construct – a "gold standard". It is difficult to find an adequate "gold standard" for a HR-PRO. If another HR-PRO is too well correlated to the HR-PRO in question, the use of the HR-PRO being tested can be questioned. Low correlation between two HR-PROs makes the use of the "gold standard" comparison meaningless. The use of a "gold standard" in testing PROMs has been debated²⁴, but is often used as a way to test criterion validity.

Responsiveness

Responsiveness to change is a measurement property linked to validity and reliability. In an instrument with poor reliability, a patient must report a large improvement for a change to be visible. An instrument with poor validity (i.e. does not measure the construct intended) will also have low responsiveness, because the construct that has improved is not the one being measured ²⁴.

Rationale of the thesis

After an ACL injury, treatment aims to restore knee function. Early after injury, patients are often shocked, upset and worried about their future knee function ⁹⁷. To assess the main goal – restoration of function, regardless of treatment – evaluation with outcome measures with good measurement properties is important. The outcome measure should be suitable for the patient population and detect changes in state. The IKDC-SKF is the third most used PROM in ACL populations worldwide ¹³⁰, but there has been no summary of the measurement properties of the IKDC-SKF. There was no Swedish language version for use in Swedish clinics and research settings. A systematic review with assessment of methodological quality and synthesis of results from studies that have tested measurement properties would help clinicians and researchers. Translating and testing the measurement properties of the Swedish IKDC-SKF would be useful in Swedish clinical settings and research.

Sooner or later, patients will, together with orthopaedic surgeon and physiotherapist, decide how their injury should be treated. We lack knowledge about how to help patients make the best treatment decision. To be able to offer patients the best treatment, we must investigate how the treatment decision is taken, when the decision is taken and how the reasons for a decision match patient's activity demands, knee joint instability and function. To map the important factors for treatment choice after ACL injury, a first step is to investigate the factors orthopaedic surgeons and physiotherapists consider important when they recommend treatment, and how they value the importance of their own and each other's assessment, as well as patient's wishes.

To further map how the treatment decision after an ACL injury is taken, extended information about patient's reasons for choice of treatment is needed plus information about how patient-reported symptoms and function are related to

these reasons. By adding clinician's reasons for chosen treatment, we will clarify the picture of the treatment process and reasons for treatment choice.

AIMS OF THE THESIS

Overall aim

The overall aim of this thesis was to evaluate the measurement properties of a patient-reported measure for evaluation of function after ACL injury and treatment, and to overview the treatment decision process after an ACL injury.

Specific aims

1; To evaluate the methodological quality and results of studies reporting on the measurement properties of the IKDC-SKF following the Consensus-based Standards for the selection of health status Measurement INstruments (COSMIN) guidelines and the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines (Study I).

2; To perform translational and cross-cultural adaption for the Swedish version of the IKDC-SKF and to test the validity, reliability, responsiveness, and interpretability (floor and ceiling effect and Minimal Clinical Important Difference) of the IKDC-SKF in patients with an ACL injury undergoing reconstruction surgery, from before reconstruction to up to 1-year follow-up (Study II).

3; To (1) study and compare the factors Swedish orthopaedic surgeons and physiotherapists consider important for recommending ACLR, and (2) to assess how important orthopaedic surgeons and physiotherapists consider their own and each other's, as well as patients', roles are in the treatment decision (Study III).

4; To (1) describe the key characteristics of treatment decisions for patients with an ACL injury; what treatment was chosen, when was the decision made, which reasons do patients and orthopaedic surgeons state that the treatment decision was based upon, and (2) compare key patient reported function measures (pre-injury activity level, knee joint instability and function at baseline, 4 weeks and 3 months after an ACL injury) between patients who had ACLR and those who had non-operative treatment (Study IV)

MATERIALS AND METHODS

Overview of the studies

The four papers included in this thesis are based on four studies (table 1): one systematic review (study I), one methodological study (study II), one cross-sectional survey study (Study III) and one prospective cohort study (study IV).

Table 1. Overview of the studies in the thesis

	Study 1	Study 2	Study 3	Study 4
Design	Systematic review	Methodological study	Cross-sectional survey study	Prospective cohort study
Material/ Participants	Previously published studies with methodological evaluation of the measurement properties of the IKDC-SKF	Patients, 16-40 years old, with an ACL injury, that had or would undergo ACLR	Orthopaedic surgeons and physiotherapists treating ACL deficient patients	Patients, 15-40 years old, with an ACL injury less than seven weeks ago
Methods	Systematic assessment of the methodological quality and results of articles published on measurement properties of the IKDC-SKF, using the COSMIN guidelines	Translation to Swedish, cross-cultural adaption and testing of measurement properties of the Swedish version of IKDC-SKF	Questionnaire to orthopaedic surgeons and physiotherapists active in treating patients with ACL injury. Ranking the importance of reasons for recommending ACLR	Choice of treatment, reason for it and timing, was collected from medical charts and questionnaires to patients and orthopaedic surgeons. Reasons for treatment was compared to patient-reported preinjury activity level, knee joint instability and IKDC-SKF, at 4 weeks and 3 months after injury
Data analysis	Analysis by two independent researchers, using the COSMIN guidelines to assess methodological quality and compile the results	Test for face validity and cross-cultural validity, internal consistency (Cronbach's alpha), test retest reliability (ICC _{2,1}), measurement error (based on reliability measures), correlations for structural validity and construct validity, correlations and ROC-analysis for responsiveness and MCIC, and descriptive statistics	Descriptive statistics	Descriptive statistics and comparisons between acute, subacute and late ACLR decision and non-operative decision, using Chi-Square test, independent sample T-tests and one-way Analyses of variance (ANOVAs), with a post hoc Tukey test.

ACL: Anterior Cruciate Ligament, ACLR: Anterior Cruciate Ligament Reconstruction, ANOVA: Analyses of variance, COSMIN: Consensus-based Standards for the selection of health status Measurement Instruments, IKDC-SKF: International Knee Documentation Committee Subjective Knee Score, ICC: Intra-Class Correlation, ROC: Receiver Operating Characteristic, MCIC: Minimal Clinical Important Change

Study I and II

The COSMIN manual and 4-point checklist was used to assess the methodological quality of studies that evaluated measurement properties of the IKDC-SKF⁸⁵⁻⁸⁷, specifically for study I, but also as criteria for the design and conduct of study II.

Systematic review

A search strategy was developed in consultation with a librarian. A filter developed for searching articles evaluating the measurement properties of patient-reported outcomes was also used¹¹⁸. The search terms were “IKDC” AND “knee” together with the search filter for PubMed, and without the filter for search in Scopus and CINAHL. The search was conducted on March 24, 2013. The search and abstract screening was completed by one researcher (HTG). Full text screening and data extraction was completed by two independent researchers (HTG and JK), with comparison of result and consensus discussion if required.

The inclusion criteria were:

1. The study should aim to develop IKDC-SKF or to evaluate measurement properties of the IKDC-SKF.
2. Studies that aimed to evaluate measurement properties of another measurement instrument, and used IKDC-SKF to compare to (e.g. correlations or hypothesis).
3. Studies should be peer-reviewed publication written in English or Swedish.

The included articles were assessed with the COSMIN 4-point checklist for methodological quality. The methodological score was given according to “worse score counts” system, meaning that the lowest score in any section was the overall score given to the measurement property assessed. The results of the findings of the study were assessed with guidance from the quality criteria proposed by Terwee et al¹¹⁷:

- Strong positive scoring (+++): Consistent positive findings in multiple studies of good methodological quality OR in one study of excellent methodological quality
- Moderate positive scoring (++) : Consistent positive findings in multiple studies of fair methodological quality OR in one study of good methodological quality

- Strong negative scoring (---): Consistent negative findings in multiple studies of good methodological quality OR in one study of excellent methodological quality
- Moderate negative scoring (--): Consistent negative findings in multiple studies of fair methodological quality OR in one study of good methodological quality
- Limited findings (+/-) Positive or negative findings in one study of fair methodological quality
- Indeterminate scoring (?): Results only from studies of poor methodological quality
- Conflicting findings (+/-): conflicting findings

An overall score, based on both methodological score and result for each measurement property, was presented. Further information about the methodology is described in study I ⁴⁶.

Update of the systematic review

The systematic review was updated in June 2019 and covered the time frame from March 24, 2013 to June 2, 2019. The COSMIN 4-point checklist for methodological quality was used as in the original systematic review, with some methodological adjustments for the updated systematic review:

- The increase in studies evaluating measurement properties for the last few years led to an exclusion of the second inclusion criterion (to limit the search and narrow the material, and include the most important data).
- The update was conducted by one researcher (HTG), and the search filter was not used because the search terms “IKDC” AND “knee” were estimated to be specific enough to retrieve all relevant articles.
- For responsiveness, studies with only reports of effect size, standardized response means, minimal detectable change were graded as “poor” due to “other important methodological flaws in the design or execution of the study”. A correct evaluation of responsiveness should include a construct or criterion approach ²⁴, thus, if that was not assessed, the methodological assessment was considered insufficient. In the original systematic review, the same studies were assigned a score for methodology, but the results were interpreted as inconclusive because the assessment method was inappropriate.

Translation of the IKDC-SKF

The translation process of the IKDC-SKF (study II) was completed according to the guidelines by Guillemin et al ⁴⁹ and the recommendations by the COSMIN group. After the translation process, cross-cultural validity was evaluated and minor changes in terminology when describing activities were made ¹²¹.

Participants and data collection

The Swedish version of the IKDC-SKF was tested in 10 patients with ACL injury who evaluated face validity by commenting on relevance, comprehensibility and similarity between the English and Swedish versions.

In total, 179 patients, waitlisted for ACLR, participated in the study. Participants completed a questionnaire package (IKDC-SKF, KOOS, ACL-RSI and study-specific questions) before ACLR and at 6, 15, 24 and 52 weeks after ACLR. A complementary population of 514 patients from the Swedish Knee Ligament Register were invited, and 203 (39%) agreed to participate. Participants completed the questionnaire package once at 6-8 months after ACLR. The second recruitment ensured that the number of participants was sufficient to power the test of measurement properties, strengthening the methodological quality. Data from participants in the additional recruitment were used for the internal consistency, structural validity and criterion validity analyses, thus fulfilling the criterion for excellent score on sample size, according to the COSMIN checklist ⁸⁵⁻⁸⁷.

Analysis

Test-retest reliability was calculated based on data from patients at 6 months after ACLR. The questionnaire was sent out the second time by mail, at five days after the initial questionnaire had been completed and returned. A maximum of 21 days between test and retest was considered adequate. Patients reported whether they considered their knee-related condition had changed since the last time they completed the questionnaire. If so, their answers were excluded. The correlation between the test and retest was analysed with ICC_{2,1}.

Measurement error was analysed using the change scores from the test-retest analysis, and the formula $SD_{diff}/\sqrt{2}$, and calculations for smallest detectable change (SDC) was completed for individuals ($SDC_{ind} = 1,96 \times \sqrt{2} \times SEM$) and groups ($SDC_{group} = SDC_{ind}/\sqrt{n}$) ^{7, 117}.

Internal consistency of the items was analysed with Cronbach's alpha, where a result of 0.7-0.95 was considered good internal consistency ¹¹⁷.

Construct validity was tested with structural validity, hypothesis testing and criterion validity testing. *Structural validity* was tested using factor analysis. The IKDC-SKF had been tested using factor analysis in three previous studies ^{56, 110}, supporting a one-factor solution twice and the possibility for a two-factor solution once ⁵². The two factor solution was "symptom and knee articulation" (14 items) and "activity level" (4 items), leaving three items that failed to fit either factor in the model. Because of the few studies that had evaluated structural validity using factor analysis, we used exploratory factor analysis to explore how the score should be interpreted.

For hypothesis testing, ten predefined hypotheses were developed, with a predefined direction and magnitude for confirmation definitions. For good measurement properties in hypothesis testing, at least 75% of hypothesis should be confirmed ¹¹⁷. The hypotheses can be found in table 3 in study II ¹²¹.

Criterion validity was analysed using the Short Form 36 (SF-36) as a gold standard. We hypothesised that the IKDC-SKF would have a stronger correlation to the physical component summary (PCS) of the SF-36 ($r > 0.5$) than to the mental component summary (MCS) ($r < 0.5$).

For responsiveness, we used the change score from baseline (preoperative) to 4 months post ACLR. Both a construct and a criterion approach were used to analyse responsiveness.

For the *construct approach to responsiveness*, correlations between change scores from baseline and 4 months and baseline to 12 months were calculated between IKDC-SKF and the five subscales of KOOS and the PCS of the SF-36. Effect size (ES) and standardized response mean (SRM) was calculated for change scores from baseline to 12 months. ES and SRM are measures of the magnitude of a change score, not measures of the validity of the change score ²⁴. To calculate the validity of the change score, a comparison to other instruments or strongly grounded hypothesis should be made. We chose to analyse responsiveness using several methods, including reporting ES and SRM because they are commonly used measures, and ES and SRM were complementary results to the responsiveness testing.

For the *criterion approach to responsiveness*, a global rating of change (GRC) question was used. Responses were dichotomized into two groups: “no change” and “improved”. The change score of the IKDC-SKF between baseline and 4 months post ACLR was used, a time frame considered to be sufficient for a change (improvement in most cases) in condition to have occurred. A receiver operating characteristics (ROC) curve was plotted, and the Youden index was used to estimate the most sensitive and specific change value¹³³, which is the minimal clinical important difference (MCID) value. The area under the curve (AUC) was used to interpret the result, and >0.7 was considered appropriate¹¹⁷.

Interpretability is not a measurement property. Although, it is important to evaluate, not the least for clinical implications. Floor and ceiling effects were investigated, with <15% respectively, considered adequate¹¹⁷.

Study III

In this survey study, the questionnaire used was developed by researchers well experienced in ACL injury research, and based on research by Swirtun et al¹¹⁶. The questionnaire was tested for content validity by orthopaedic surgeons and physiotherapists, who reviewed the questions for content, relevance and clarity.

The final questionnaire contained 21 factors that were to be graded on a 0-3 scale, with a higher grade corresponding to higher likelihood to recommend ACLR. Each factor had the heading; “How do the following factors affect your judgement of whether a patient should undergo ACLR?”. The 0-3 grade scale was anchored 0 = “no surgery” and 3 = “surgery” for orthopaedic surgeons. For physiotherapists, 0 = “little probability that I would recommend ACL reconstruction” and 3 = “great probability that I would recommend ACL reconstruction”.

An open question was included; “Are there any more factors you consider important in the recommendation for ACLR?” Participants could add comments or additional factors they believed to be important to recommend ACLR. Orthopaedic surgeons and physiotherapists were asked “To what extent do you believe the decision for ACLR is based on orthopaedic surgeon’s assessment, physiotherapist’s assessment, and patient’s wishes”. Respondents graded the three alternatives from 0 (not important at all) to 3 (very important).

Participants and data collection

More than 90% of orthopaedic surgeons who are active in performing ACLR procedure in Sweden, register data in the Swedish national knee ligament register¹³². All orthopaedic surgeons listed in the register were contacted by email, with information about the study and asked to participate. Of the 235 invitations sent to orthopaedic surgeons, 130 responded and 98 participated. One email address was incorrect. The number of surgeons who were performing ACLR during the time of the survey study was 152-160, according to the Swedish ACL register ¹³², which indicates that some email addresses could have reached surgeons who were not performing ACLR. Among the 32 who declined participation, 25 declined because they did not treat patients with ACL injury, and 7 declined without explanation.

Physiotherapists who could have been active in treating patients with ACL injury were identified through the Swedish Society for Physical Activity and Sports medicine, Swedish Football Physiotherapists Association, at orthopaedic clinics and through professional contacts. They were contacted by email, with information about the study and an invitation to participate. After the first send out, physiotherapists who accepted to participate recommended colleagues who were active in the area of rehabilitation, leading to two complementary rounds of questionnaires. A total of 947 emails were sent to physiotherapists. Of the 595 physiotherapists who responded, 391 participated (205 women and 186 men). Of the physiotherapists who declined participation, 166 were not treating patients with an ACL injury, and 38 declined without explanation.

Up to two reminders were sent to orthopaedic surgeons and physiotherapists. The questionnaire was administered via a secure web-based system (Esmaker version 3.0, Entergate® AB). All data were registered anonymously.

Analysis

Data were analysed after dichotomizing the response options to a combination of 0-1 and of 2-3. A rating of 2-3 indicated that the factor had an important impact on the decision to decide for or recommend surgery.

Responses for each factor were analysed to determine if clinical agreement was reached. Clinical agreement was defined as when 80% of respondents had chosen the same response option (after dichotomizing the answer options) ⁷⁸.

The answers to the open-ended question of which factors that were the most important for choosing ACLR were categorized into six categories; knee joint instability, patient focus, activity demands, other injuries, sociodemographic factors and objective measures). For each category, we examined whether it was described as a sole factor in the decision to recommend ACLR, or part of a cluster of factors that were considered to be important together.

Study IV

A prospective cohort study where patients with ACL injury were included early (0-6 weeks) after ACL injury and followed up to 12 months after injury. If a decision for ACLR was taken, patients were followed until the surgery was performed.

Participants and data collection

The patients were participants of the NATural COrollorary X (Nacox) study ⁶⁹, a prospective cohort study that aims to describe the natural collorary after an ACL injury. The patients who at the time for data analysis had undergone ACLR or had chosen non-operative treatment at 12 months after injury were included.

Patients were included from six different orthopaedic clinics in cities of various size, in urban and rural environments in Sweden, during June 2016 to October 2018. Patients were recruited consecutively ⁶⁹.

Information about the treatment, reason and timing for chosen treatment was derived from medical charts and questionnaires to orthopaedic surgeons and patients. All medical charts regarding the ACL injury were reviewed by the first author, and data about which treatment was decided, when, and why were obtained.

When a treatment decision was made, the orthopaedic surgeon answered a question about which treatment was chosen and described why in free text.

Patients answered electronically-administered questionnaires, distributed via short message service (SMS), about treatment choice and reason for the choice. Patients answered the questionnaires after the visit at the orthopaedic surgeon. When a decision for non-operative treatment was made, patients still received questionnaires with questions about treatment decision at 3, 6, and 12 months after injury to ensure the decision had not changed. If the decision was unchanged at 12 months after injury, the decision was considered to be final.

Analysis

All final reasons for each patient were categorized according to previous research⁴⁵, guidelines^{78, 84, 112} and clinical experience within the research group. Categories were:

ACLR treatment

- knee joint instability/giving way
- high activity demands
- knee joint instability/giving way and high activity demands
- patients' wishes

Non-operative treatment

- lack of knee joint instability/giving way
- low activity demands
- sufficient knee function
- other reasons

The timing for decision of ACLR treatment was categorized as “acute phase decision” when the decision was made between injury day and 31 days after injury, “subacute phase decision” when a decision was made between 32 days and 5 months after injury and “late phase decision” when the decision was made between 5 and 12 months after injury.

Patients-reported data were collected regarding:

- activity participation before the injury (categorized in the Tegner activity scale⁷⁶ according to definitions by Fältström et al³⁶)
- knee joint instability in everyday living and in rehabilitation training, recreational activities or sports activities
- knee function (using the IKDC-SKF)

Group comparisons were made between (i) patients who chose ACLR and patients who chose non-operative treatment, and between (ii) acute phase decision ACLR, subacute phase decision ACLR, late phase decision ACLR and the non-operative group. Variables analysed were age, sex, preinjury Tegner Score, knee joint instability in daily living (baseline, 4 weeks, 3 months), knee joint

instability in rehabilitation physical activities or sports (3 months), and IKDC-SKF (4 weeks, 3 months).

ETHICS

Ethical approvals

Study ethics, where required, was approved by the Ethical Review board in Linköping, Sweden.

Study I: No ethical approval was needed.

Study II: 2011/ 450-31

Study III: 2014 71/31

Study IV: 2016/44-31

Ethical considerations

The general ethical principles for medical research, stated in the Declaration of Helsinki were followed. All study participants received written study information, and approved participation either in writing (study IV) or electronically (study II and III). All participants in all studies were informed that the results would be coded and handled anonymously, that they had the possibility to retrieve information collected about them, and how to retrieve the information collected.

In study II and IV, patients were informed that they could decline or withdraw participation at any time during the study, and that participation or declining to participate would not have any impact on their health care. There is a possibility that patients believed they would receive better care by participating in the study, and would not have otherwise participated.

It is possible that patients in study II and IV could have been affected by replying to questions about their knee, that it could cause both an extended feeling of severeness about the condition, and possibly exaggerate fear. However, no patient made any written or verbal comments about fear.

RESULTS

Study I and II

Systematic review of the measurement properties of the IKDC-SKF

Twenty-six studies were assessed for methodological quality and scored from poor to excellent. Several studies tested more than one measurement property, and there were four studies that had poor methodological quality for all measurement properties they evaluated^{65, 70, 101, 113}. Their results were not included in the assessment of the results of the testing of measurement properties. For some other studies^{4, 54, 58, 62, 67, 121, 124}, we assigned a poor methodological score one or more measurement properties, but fair to excellent methodological score for the other measurement properties. Thus, these studies were included in the assessment of the results, for the measurement properties where they had a fair to excellent methodological score. Based on the results of 22 studies, IKDC-SKF has good internal consistency, test-retest reliability, content and structural validity, responsiveness and interpretability (no floor and ceiling effects). Further evaluation of measurement error, MCID, and hypothesis testing is recommended.

Updated systematic review

There were 14 additional full text articles for evaluation (figure 3), and 4 articles that evaluated interpretability only^{90, 91, 104, 107} (appendix 1).

There was stronger evidence of good measurement properties of the IKDC-SKF. There was new evidence for hypothesis testing, translation validity and criterion validity (table 2). Interpretability in terms of floor and ceiling effects was consistently low, except in two studies^{32, 91}, in a population that had undergone ACLR 2-4 years ago and a population of “children with a history of knee surgery”. Muller et al⁹⁰ defined the threshold for patient acceptable symptoms score as 75.9 points.

Fig 3. Flow chart over the literature search process in the updated review.

Table 2. Studies evaluated in the updated systematic review and assessment of methodological score and result for measurement properties of the IKDC-SKF.

Author/year	Type of study ^a	Internal consistency ^b	Reliability ^b	Measurement error ^b	Structural validity ^b	Hypothesis testing ^b	Cross-cultural validity ^b	Content validity ^b	Criterion validity ^b	Responsiveness ^b
Ahmed 2017	B	G+	G+			P		P		
Celic 2014	B	G+	G+	G+		F+	G+			F+
Ebrahimzadeh 2014	B	F+	F+						F+	
Grevnerts 2017	B	E+	P	P	E+	E+	P		E+	F+
Huang 2017	B	F+	F+	F+		F+	P			F+
Jacobsen 2015	B, C		F+				F+			F+
Jia 2018	B	E+	G+	G+		G+	F?			Pd
Kim 2013	B	F+	F+			F+	F?			Pd
Van de Graaf 2014	B	G+	G+	G+	P	G+		G+		
Van der Velden 2019	B, C		G+	G+		G+	G+	E+		
Ogura 2018	A									G+
Noorduyn 2019	A									G+
Koumantakis 2016	B	F+	F+	F+		F+	P			Pd
Kummel 2018	B	E+	E+	E+	E+	E+		E+		E+
Summarized level of evidence ^c		+++	+++	+++	+++	+++	+++	+++	+++	+++

^a Type of study: A: aimed to investigate measurement properties of the IKDC-SKF, B: investigated the measurement properties of the IKDC-SKF while translating it into another language, C investigated the measurement properties of the Pedi-IKDC-SKF

^b Methodological quality assessed using the COSMIN score: E excellent, G good, F fair, P poor. Studies with a "Poor" rating were not included in the scoring of results of each measurement property. The results for each measurement property in each study were rated as: positive, +; indeterminate scoring, ?; or negative, -

^c Summarized level of evidence: (+++) for strong positive scoring, (++) for moderate positive scoring, (---) strong negative scoring, (+/-) moderate negative scoring, (?) for indeterminate scoring (+/-) for conflicting findings

^d Studies reporting only effect size, standardized response means (SRM), and/or minimal detectable change (MDC) as responsiveness testing, were assigned a poor methodological score

The measurement properties of the Swedish version of the IKDC-SKF

The Swedish version of the IKDC-SKF had good measurement properties in reliability, validity and responsiveness.

Reliability:

- *Internal consistency*: good, Cronbach's alpha: 0.9.
- *Test-retest reliability*: excellent, ICC_{2,1}: 0.92 (95% CI: 0.81- 0.97, P < .001).
- *SEM*: 5.7 points, SDC_{group}: 2.4 points and SDC_{ind}: 15.8 points.

Validity:

- *Structural validity*: A single factor solution accounted for 46.1% of the variance in an exploratory factor analysis. Factor loadings were >0.4 for 17 out of 18 items. The factor loading for item 6 ("during the past 4 weeks, or since your injury, did your knee lock or catch?") was 0.349.
- *Criterion validity*: the correlation between the IKDC-SKF and the Physical Component Summary of the SF36 was strong, $r = 0.73$ ($p < 0.001$). The correlation between the IKDC-SKF and the Mental Component Summary of the SF36 was weak, $r = 0.32$ ($p < 0.001$). Both results were as hypothesized, confirming the hypothesis for criterion validity.
- *Hypothesis testing*: the ten hypotheses¹²¹ were confirmed.

Responsiveness:

- *Construct approach to responsiveness*: The IKDC-SKF change score (baseline to 4 months after ACLR) was positively correlated with the global rating of change (GRC) question ($r = 0.62$, $p < 0.01$). The ROC analysis had an AUC of 0.79.
- *Criterion approach to responsiveness*: The six hypotheses for change scores from baseline to 4 months and baseline to 12 months¹²¹, were confirmed.

Interpretability:

- There were no floor or ceiling effects (<15%) at any occasion.
- MCID at 4 months was 13.9 points (sensitivity: 65.2%, specificity: 95.5%).

- Patients who reported “great improvement but not fully recovered” on the GRC had a mean change in IKDC-SKF from baseline to 4 months of 16.2 points.

Study III and IV

Factors that orthopaedic surgeons and physiotherapists rate as important to recommend ACLR

In study III, the results showed six factors that > 80 % of orthopaedic surgeons and > 80% of physiotherapists rated as important for recommending ACLR:

- Young age
- Wishes to return to contact or pivoting sports (at elite or recreational level)
- A physically demanding occupation
- Knee joint instability in sports or activities of daily living (despite adequate rehabilitation training for >3 months)

Open-ended question for factors considered important to recommend ACLR

Of the orthopaedic surgeons, 56 answered the open-ended question. Of them, 44 reported knee joint instability, often in combination with other factors (e.g. “in relation to activity level” “young age” or “knee joint instability in ADL or working situation”) as the most common combination of factors for recommending surgery. Of physiotherapists, 337 answered the open-ended question. Knee joint instability was reported as a single factor or in combination with other factors, by 331 physiotherapists. “Function” was mentioned in combination with other factors, such as “insufficient function despite adequate rehabilitation”.

Orthopaedic surgeon’s, physiotherapist’s and patient’s contributions to treatment decisions

In study III, orthopaedic surgeons and physiotherapists appraised that their own, each other’s assessments, and the patient’s wishes in the decision making to recommend ACLR were very important (table 4).

Table 4. Result of orthopaedic surgeons and physiotherapists rating for the question: "To what degree do you believe the decision for ACLR is based upon the orthopaedic surgeon's and physiotherapist's assessments, and patient's wishes?". Rating scale: 0-3, anchored; 0 = "to a very low extent" and 3 = "to a very high extent". Reported is the number of respondents that had rated 2 or 3.

	Orthopaedic surgeon rates:	Physiotherapist rates:
The importance of orthopaedic surgeon assessment	99%	75%
The importance of physiotherapists assessment	98%	71%
Patient's wishes	80%	80%

Compliance to rehabilitation; communication about treatment decision recommendations

- 79% of orthopaedic surgeons stated that they *often* sought information about compliance to rehabilitation
- 71% of orthopaedic surgeons stated that they *sometimes* or *often* read the patient's medical record to obtain information about rehabilitation compliance
- 70% of orthopaedic surgeons stated that they *sometimes* or *often* had contact with the treating physiotherapist
- 96% of orthopaedic surgeons *sometimes* or *often* sought information about the rehabilitation outcome by asking the patient
- 78% of orthopaedic surgeons stated that they *sometimes* or *often* obtained information about rehabilitation by reading the patient's medical record
- 81% of orthopaedic surgeons *sometimes* or *often* contacted the treating physiotherapist and asked for information about the patient's compliance to rehabilitation
- 80% of the physiotherapists stated that when they recommended ACLR, they *often* communicated their recommendation to the patient
- 67% of the physiotherapists *sometimes* or *often* communicated their recommendation to the orthopaedic surgeon

Treatment decision after an ACL injury; what decision was made and when?

For the 219 patients included in study IV, the treatment decision was:

- ACLR in the acute phase after injury (0-31 days after injury), n=33
- ACLR in the subacute phase after injury (1 to 5 months after injury), n=85
- ACLR in the late phase after injury (5 to 12 months after injury), n=25
- Non-operative treatment (decision within 12 months after injury, or if no definitive treatment decision was taken), n=76

Reason for treatment decision

In study IV, high activity demands was the main reason for choosing ACLR in the acute phase decision group. Knee joint instability/giving way and high activity demands was the main reason for choosing ACLR in the subacute phase decision. Knee joint instability/giving way was the main reason for choosing ACLR in the late phase decision group.

The main reason for the choice of non-operative treatment was no knee joint instability/no giving way. There were 22 (29%) patients where the choice for non-operative treatment was based on “other reasons” (study IV, manuscript in progress)

Comparisons of patient-reported factors between ACLR and non-operative groups

In study IV, there were few differences between patients where an ACLR treatment decision had been taken and where a non-operative treatment decision had been taken, regarding pre-injury activity level, patient-reported knee joint instability ratings and function.

- Patients in the non-operative decision group were older than patients in the acute phase decision group ($p < 0.031$) and patients in the late phase decision group ($p < 0.001$)
- Patients in the acute phase decision group had a higher pre-injury Tegner score compared to the late phase decision group ($p < 0.031$) and the non-operative group ($p < 0.003$)
- Patients in the subacute phase decision group had a higher pre-injury activity level compared to patients in the non-operative group ($p < 0.023$)

There were no differences between groups regarding patient-reported knee joint instability ratings (rated at baseline, 4 weeks and 3 months after injury) or IKDC-SKF scores (rated at 4 weeks and 3 months after injury).

DISCUSSION

This thesis highlights the evaluation of function from the patient's perspective, and provides evidence that the IKDC-SKF is an appropriate patient-reported outcome measure for evaluating symptoms, function and sports participation after ACL injury. The thesis also summarises the treatment decision process after an ACL injury, from the patient's and the health care personnel's perspectives. Physical activity demands and presence of, or lack of knee joint stability were the factors orthopaedic surgeons, physiotherapists and patients considered important for treatment choice. Yet, patient-reported function and knee joint instability in the early phase after ACL injury did not differ between patients where a decision for ACLR or non-operative treatment had been made, or would be made later. Orthopaedic surgeons, physiotherapists and patients have an important role in the treatment decision process, although the contribution of each part remains clear.

Measurement properties of patient-reported outcome measures

A key aspect in assessing the measurement properties of a PROM, is to acknowledge that the result of a test for measurement properties is not a fixed result. Tests allow the researcher to draw certain conclusions, but the results are specific for the test environment (population, settings, severity of symptoms etc.) and may not be generalized automatically ²⁶. In study I of this thesis, the studies included in the systematic review tested the measurement properties of the IKDC-SKF in different populations with different diagnoses, different symptom severities, in different phases of rehabilitation, before or after a surgical intervention, different ages and with different physical activity demands. This may allow a broader generalizability than when one population is tested. Nevertheless, it is important to interpret and apply the results with caution. It is vital to assess the value and appropriateness of a PROM in the specific population in which it will be used.

The results from study I and study II are important for the use of IKDC-SKF. Study I suggests the IKDC-SKF has good measurement properties in several populations. Nevertheless, before using the IKDC-SKF in clinical or research settings, a

valuation of the evidence for measurement properties of that specific population should be made.

Reliability

The updated systematic review enhanced the strong positive findings for *internal consistency*, with a Cronbach's alpha ranging from 0.77-0.97. *Internal consistency* has been tested in patients with a broad range of diagnoses and symptoms in these studies. The conclusion is that the *internal consistency* for the IKDC-SKF is well explored and has good results for patients with knee injuries. The Swedish version of the IKDC-SKF ¹²¹ had good results for *internal consistency* regarding both methodological quality and result (Appendix 1).

Test-retest reliability shows a strong positive score in the systematic review, and the updated review strengthened the conclusion. The Swedish IKDC-SKF had poor methodological quality, due to low sample size (<30 participants). Because of the poor methodological quality, the ICC result of 0.92 for Swedish IKDC-SKF was not added to the systematic review results. Nevertheless, the result indicate that the Swedish version has a positive result for test-retest reliability.

Measurement error was insufficiently evaluated. Only three studies ^{56, 82, 126} had sufficient methodological quality to be assessed. In the updated review seven additional studies were included ^{15, 53, 58, 67, 68, 121, 124, 125} and the updated review result suggests strong positive findings. The Swedish IKDC-SKF had poor methodological quality for *measurement error*, due to small sample size, but the result of the testing is consistent with previous findings.

Overall, the methodological quality score for *reliability* was strong positive, and the results were strengthened in the updated systematic review. *Measurement error* went from having inconclusive results, to strong positive results. The Swedish version shows good *reliability* overall, and all results are in line with evidence. Studies of the Swedish IKDC-SKF, with a higher methodological quality could be valuable to further strengthen the *reliability* of the Swedish version.

Validity

Structural validity was tested in three studies ^{52, 56, 110} in the systematic review. The results were inconclusive, with one study reporting findings that suggested two dimensions of the form. The overall result still showed more evidence for a one-factor solution, and the updated review supported that, with two studies

with an excellent methodological score^{68, 121}. These studies also supported the one-factor solution. The result for *structural validity* is strongly positive, and it is reasonable to conclude that a one-factor solution and summarization of the score into one overall score could be recommended.

The Swedish version was one of the two studies with excellent methodological score for *structural validity*, where all items, except item 6 (During the past 4 weeks, or since your injury, did your knee lock or catch?), had a good factor loading. Item 6 has shown lower loading previously, in the development study⁵⁶. In the testing for the Swedish IKDC-SKF all participants had an ACL injury and were waitlisted for ACLR. Thus, the question about locking might have been less of value for this group of patients, because locking is not a primary symptom of ACL injury. However, it is reasonable to retain item 6 because (i) the IKDC-SKF was not specifically developed for ACL injuries⁵⁶, and (ii) a meniscus injury can manifest in symptoms like catching or locking³⁰.

The result of *hypothesis testing* was assessed in 10 studies^{12, 14, 19, 20, 64, 81-83, 105, 126} in the systematic review. There were six additional studies identified that scored poor for methodological quality^{2, 51, 65, 70, 113, 114}, which were excluded from the result assessment.

Studies that evaluated the measurement properties of other studies, and used the IKDC-SKF to compare, and studies that did not aim to evaluate measurement properties were included in the first systematic review. It may be unreasonable to assess methodological quality with the COSMIN checklist when the study was not designed to assess measurement properties of IKDC-SKF. This may be an explanation for the high frequency of poor scoring, hence a methodological consideration for the thesis. It was also the reason to exclude studies from the systematic review update. Nine additional studies^{15, 53, 58, 62, 67, 68, 121, 124, 125} were added following the updated search, and hypotheses were all confirmed. The former conclusion of conflicting evidence for *hypothesis testing* changed to strongly positive. The Swedish IKDC-SKF had excellent methodological quality and was tested for ten hypotheses, all confirmed.

In the systematic review, *cross-cultural validity* included *translation validity*, reflecting the translation process. The score was intermediate, mainly because no comparisons of similar patient groups in the original language (English) and the target language were made. In the updated review, eight additional studies

15, 53, 57, 58, 62, 67, 121, 125 were assessed; two had a good methodological score, three had fair. The low methodological quality in many studies (the Swedish version included) were mainly due to small samples and no differential function item (DIF) testing. In most studies that translated the IKDC-SKF to different languages, the translation process was described in detail, often with reference to Guillemin's work ⁴⁹. However, there was no tradition to test DIF, or to report it in accordance to COSMIN guidelines. Therefore, the methodological score for *translation* and *cross-cultural validity* was low.

The update for *cross-cultural validity* strengthened the results, and the overall score was strong positive.

Content validity was assessed in three studies ^{68, 124, 125} in the updated review; two were of excellent methodological quality. There was a strong positive score for *content validity* for the IKDC-SKF. One study concluded that of both patients and orthopaedic surgeons who completed the form, >75% considered the content relevant. All items were rated as comprehensible, and 50% of the items as essential. One study reported that the IKDC-SKF (among other tested questionnaires) did not cover topics such as fear of re-injury, worries about the future, and expectations regarding sports participation. However, there are other questionnaires more suitable than the IKDC-SKF for measuring psychological concerns regarding return to sport ¹²⁹.

Compared to other measurement properties, where an assessment of methodology and result can be direct (e.g. test-retest reliability, where there are clear cut-offs for excellent, good, fair and poor ICC scores), *cross-cultural validity* and *content validity* are more arbitrary to assess, and requires extended skills of the assessor. This is a methodological issue that has not been addressed in the literature. Clearer and more specific criteria for *cross-cultural* and *content validity* might be useful to ensure that scores are comparable when assessments are completed according to COSMIN criteria.

Criterion validity was assessed in twelve studies ^{13, 20, 41, 52, 56, 63, 73, 81, 82, 98, 110, 126} of good methodological quality. All studies had correlations to the gold standard used (SF36 was common, and also was in the measurement instrument development article⁵⁶), but the result score was intermediate, since the correlation was not above 0.7. Evaluation of criterion validity against a gold standard for PROMs is difficult. For the update, only two more studies were

assessed ^{27, 121}, one with excellent methodological score (the Swedish version of IKDC-SKF, study II) and one with fair quality. The correlation between the Swedish IKDC-SKF and the physical component summary of the SF36 was 0.73, which confirms the hypothesis and gives a strong positive result. The findings for *criterion validity* changed to strongly positive.

Responsiveness

In the systematic review, *responsiveness* was given a strong positive score, which was further strengthened in the updated review. In the update, seven studies with methodological score fair ^{15, 54, 57, 121}, good ⁹⁵ and excellent ^{68, 92} had good result for *responsiveness*, mainly assessed with measures of area under the curve (AUC) and hypothesis testing.

Some articles used the measure of ES and SRM as test for *responsiveness*. COSMIN considers ES and SRM of limited value for testing *responsiveness* ²⁴. The ES and SRM measure whether the instrument can detect a change, but not whether the change is meaningful to the patient. When testing *responsiveness* with a *criterion approach*, the result gives an implication to whether the instrument can detect changes that are clinically relevant, thus ES and SRM should not be used as a sole measures of responsiveness.

More studies evaluated *responsiveness* with AUC value and hypothesis testing, and fewer reported ES and SRM, compared to the original review. This might indicate that testing for *responsiveness* is moving towards a trend of less reports in ES and SRM, which would mean a quality improvement in *responsiveness* testing from PROMs in research²⁴. In the updated systematic review, studies that did not evaluate with either AUC or hypothesis testing, but only ES or SRM, were assigned a poor methodology score. In the original review, the methodological score was not affected by whether only ES and/or SRM was used, but the studies that did not use AUC or hypothesis testing did get an inconclusive result score. Because the COSMIN guidelines and criteria are more prominent today ⁴², it seems more accepted that correct *responsiveness* testing should not be (only) with the use of ES and SRM. The result of the updated systematic review, with more studies that have used proper methods, also show that. That is why the decision was taken to give a methodological score of poor in the updated systematic review, for studies that failed to use a proper evaluation method, since it is a methodological flaw, and not a reflection of the result. The overall result is

the same, since the studies that had evaluated *responsiveness* in the original systematic review with only ES or SRM, got a result score of inconclusive result, which did not higher or lower the overall result score, and in the updated systematic review, the same study would have gained a poor methodological quality score and thus would not have been included in the result score.

Minimal Clinical Important Difference (MCID) is often considered a measure of *responsiveness*, although it can be considered to be defined as *interpretability*, since it is a clinically useful measure ⁸⁷. Many studies tested MCID in both the original and updated review, with scores between 9.8 to 13.9 points. Although, the use of MCID scores must be regarded with caution, since a meaningful change in state and score can differ depending on diagnosis, treatment method evaluated, where in a rehabilitation phase patients are ⁸, and the score reported must be taken in consideration to the clinical context.

The Swedish version of the IKDC-SKF had an excellent methodological score and the results were good, in both criterion and construct testing for *responsiveness*, thus confirming the overall strong positive score for *responsiveness*.

Interpretability

Although *interpretability* is not considered to be a measurement property per se, it is important to assess and to report, and provides clinicians with data important for interpreting the scores of PROMs in daily use.

Interpretability was reported mainly in terms of presence of floor and ceiling effect. There was seldom any floor or ceiling effect above 15%, indicating a good result. One study ³² showed a 30% ceiling effect, by using a population of patients that had undergone ACLR 2-4 years ago, where such high scores can be expected. A 34% ceiling effect was found in another study, where children with “previous knee disorders” filled out the questionnaire ⁹¹. Since there was no further description of what the knee disorder was, it is difficult to evaluate the importance of that result.

Muller et al ⁹⁰ investigated another part of interpretability, by defining the threshold for patient acceptable symptom state (PASS). The PASS is assessed according to whether the patient is satisfied with current knee function. Compared to investigating MCID, PASS indicates not if patients feel better, but if

they feel well. The IKDC-SKF had a PASS score of 75.9 points, in patients between 1-4 years after ACLR.

The method to define PASS as a meaningful value has been debated, and Roos et al.¹⁰⁶ compared PASS scores to both minimal important change and treatment failure for the same cohort. They found that the PASS value seems to be more adequate as a measure of satisfying result for patients. The PASS score of 75.9 is in line with previous studies that show that a PASS score of 72 on a 0-100 scale should be adequate on a PROM used for young patients after ACLR⁵⁵. In study II in this thesis¹²¹ the IKDC-SKF mean score was 78.1 at 12 months after ACLR, which should indicate a good result in terms of patient satisfaction.

Choice of treatment after ACL injury

The desired effect of an ACLR is to gain stability of the knee⁷². Guidelines state that the presence of knee joint instability should be the reason for choosing ACLR^{3, 9, 84, 112}. The results of study IV show that the main reasons for a decision of ACLR treatment were instability and/or high activity demands. The combined results of study III and study IV shows that orthopaedic surgeons and physiotherapists follow guidelines when describing the grounds for ACLR recommendation.

Reasons for choice of treatment

Age was considered to be an important reason for recommending ACLR (study III). It was not expressed as an important reason in study IV by orthopaedic surgeon and patients, but still patients where a decision for ACLR was taken early, were younger than the patients where a non-operative treatment decision was taken. Age could be an indirect reason for fear of knee joint instability in activity, since younger individuals often have higher activity demands, an explanation that also can be found in the literature⁸⁴. It can also be an expression of fear of knee joint instability in future participation in sports activity¹¹⁶. During knee strenuous situations, patients with an ACL injury can suffer from giving way symptoms, which can be associated to new injuries^{5, 16, 43}. The core dilemma is that some patients can perform in demanding activities without ACLR, but it is difficult to identify which patients require surgery, and which do not⁸⁸.

The absence of conclusive evidence regarding the best treatment places health care professionals in a difficult situation. The risk of performing an “unnecessary” ACLR, includes the risk for post-operative complications²⁸, the costs for surgical procedure and prolonged time for rehabilitation after the surgical procedure. The risk of graft rupture or contralateral ACL injury is higher in young active patients³⁵ and if ACLR is conducted early after injury³⁷. These risks must be weighed against the risk of suffering giving way episodes with possible new injuries, with a non-operative treatment approach. Although re-injuries seem more frequent after ACLR than non-operative treatment⁴⁷, it could be that patients treated with ACLR often are highly active, and have greater exposure to knee strenuous activities that puts their knee into higher risk situations.

With regard to GRADE score for treatment after ACL injury, there is evidence for successful outcome for both treatment methods. There is a delicate balance between desirable and undesirable treatment consequences. Costs for ACLR outweighs costs for non-operative treatment, and an early ACLR is not more beneficial in terms of costs, compared to a delayed ACLR⁶¹. With regard to values and preferences, patients often prefer ACLR, which seems to be founded in beliefs that ACLR is a necessary treatment to allow physical activity¹²⁰. Some patients express wishes for non-operative treatment as a more “natural treatment” or because an ACLR is a definitive treatment decision, while a non-operative treatment can be changed into ACLR later on¹²⁰. Still, evidence for recommendations for either ACLR and non-operative treatment must be considered as weak, and this implies that further research is warranted in that area.

Treatment decision process: patient's, physiotherapist's and orthopaedic surgeon's roles

The treatment decision process after an ACL injury is complex. We have little knowledge of how the treatment decision process after an ACL injury is perceived by patients and health care personnel. In cases of complex treatment decisions with limited evidence for which treatment is superior, the importance of information of options, possible side effects and risks, and exploration of patient's preferences are enhanced¹⁰². There is a fine balance between informing the patient without overwhelming her with information. A shared decision making strategy, where health care personnel balance sharing information that the patient requests, in a clear and comprehensible way, with managing the

emotional responses that might arise, is recommended, but requires a lot from the health care personnel ¹⁰².

The process for choice of treatment after ACL injury is not carefully explored. In this thesis, some aspects of the patient's role in the decision process is reported. Orthopaedic surgeons and physiotherapists rate patient's wishes highly in the treatment decision choice for ACLR (study III), and there were no differences in patients' and orthopaedic surgeons' reasons for choice of treatment (study IV). Patients can tend to rely on health care personnel advice ¹²⁰, which emphasizes the importance of further investigation of the treatment decision process. Patients must receive adequate information about the treatment options as well as pros and cons about either treatment, based on evidence and clinical experience, for evidence based health care and shared decision making to be practised.

Patients, orthopaedic surgeons and physiotherapists all have influence on the treatment decision process after an ACL injury. The decision process is not investigated in detail in this thesis. However, assumptions can be made that there is not an equal contribution to the decision by all three actors. In the decision for ACLR, the orthopaedic surgeon has the final call, and can decide to not perform the ACLR if necessary, just as the patient must consent to surgery.

The majority of orthopaedic surgeons, sometimes or often, state that they have contact with treating physiotherapist in the treatment decision, regarding rehabilitation and compliance to rehabilitation. Almost all of orthopaedic surgeons also rated the importance of the physiotherapist assessment high. Although, physiotherapists do seem to have lower beliefs in the importance of their own assessment. Only 75% of the physiotherapists rated their own assessment as important. Physiotherapists often seem to communicate their assessment of treatment recommendation directly to the patient, but not so many stated that they sometimes or often communicate their assessment to the orthopaedic surgeon. This indicates that there could be a discrepancy between physiotherapists and orthopaedic surgeons regarding how they perceive their communication, a phenomena that has been observed in previous studies ⁷⁵.

Physiotherapists seem to experience a lack of communication between caregivers in discussion about surgical treatment and that rehabilitation and surgical decisions often are taken separately¹³¹. Patients may feel that they are not always heard in the treatment decision process¹¹⁵. Physiotherapists often meet the patient more frequently than the orthopaedic surgeon, thus might have more possibilities to listen to the patient's story and communicate patient's wishes further¹¹⁵, hence, an improved communication between physiotherapists and orthopaedic surgeons might be beneficial for patients in the decision making after an ACL injury.

The results from study IV suggest that the orthopaedic surgeon had less influence in the non-operative treatment decision. Some patients had not been at a follow up at the orthopaedic department, thus had not discussed the choice of treatment with an orthopaedic surgeon. We did not analyse information about whether the physiotherapist was more active in advising in these cases, but it may be the case⁹⁷.

In both study III and study IV, respondents from smaller and larger clinics all over Sweden, representing private and public health care have been included. Still, it is important to recognize that there might be different traditions and health care systems both between and within countries⁶⁰, which makes it important to interpret and generalize the results from study III and study IV with care.

Patient-reported factors in relation to choice of treatment

In study IV, patient reported knee joint instability rating and function (IKDC-SKF) improved during the first 3 months. There were no significant differences between groups in knee joint instability or IKDC-SKF. This indicates that when an early decision for ACLR is made, patient ratings of knee joint instability or function (IKDC-SKF) does not weigh heavily on the treatment decision making. This is supported by the reason for ACLR, which was mainly due to high activity demands. Still it is interesting that patients who decided for ACLR in the late phase did not differ from the non-operatively treated patients in IKDC score and knee joint instability ratings. Perhaps they did not put enough strain on the knee for the first three months after injury to acknowledge knee joint instability? This might imply that when a decision for ACLR is not taken due to high activity demands, several months might be needed to evaluate whether knee function is adequate to sustain non-operative treatment or not.

The similarity in patient-reported knee joint instability and function also raises questions about whether the right choice of treatment was taken. Instead, the stated reasons for chosen treatment may be simplified and represent a more complex process, which was difficult to describe by both patients and orthopaedic surgeons. When medical decisions are taken in complex situations, the decisions tends to be based on emotional and relational grounds, not only for patients, but also for health care personnel and the reason for these decisions can be more difficult to express³¹. This thesis will not provide answers for the details of the treatment decision process for all involved parts, but the results implicates that the process needs to be further described and explored.

Methodological considerations

Study I and II

Study I was a systematic review of mainly methodological studies, and study II was a methodological study. The decision to use the COSMIN guidelines was taken in an early phase of the planning of both studies, and affected the study plan, design and outcome in a direct way. The COSMIN guidelines were used since they are addressing PROMs specifically and exclusively.

The COSMIN guidelines are commonly used for assessment of methodological quality and results of testing of measurement properties. By using a framework specifically developed for patient-reported outcomes, the methodological quality of the assessment can be considered high. Although, in 2013-2014 when the systematic review was conducted, the COSMIN was not as well-known as today, which might be a reason why many studies scored poor on methodological quality. Many studies had been published long before the COSMIN guidelines were developed. The tradition of how to report the translation process and evaluation of validity and reliability, as well as the definitions and terminology of measurement properties, differed and was often inconsistent. By assessing articles that had been published earlier, with the use of newly developed criteria, a possible low methodological score must be interpreted with caution.

At the time for the IKDC-SKF updated review (conducted for this thesis, not published), it was noticeable that more studies referred to the COSMIN guidelines as a theoretical framework in their methodological studies. A common way to report facilitates the interpretation of what has actually been evaluated in the article, and the scoring process for methodological quality.

During 2018, the COSMIN group published a 10-step instruction guide for how to perform a systematic review of measurement properties of PROMs ¹⁰³. These guidelines were not used for the update, due to intentions to be consistent in the methods for both reviews and to enhance the possibilities to add the results from both reviews. Although, this updated checklist will probably be a future important tool to increase the quality the methods of this type of methodological studies. It will hopefully aid in how to report, and also ease the interpretation for clinicians and researchers.

In the original systematic review, the term translation validity was used as a term for cross-cultural validity and content validity. That was a choice made in discussion with the co-author (CT), who also is one of the founders of the COSMIN group initiative. The decision to use the term translational validity was taken to ease interpretation for readers, since the terminology and content of the term cross-cultural validity was defined, but not as commonly used in this area, at that time. For the updated review, cross-cultural validity and content validity was separated, to be more consistent with the checklist but also since the terms often are described in articles today, thus it is easier to interpret and assess.

Since 2013, many papers have been published about translation processes and measurement properties of the IKDC-SKF. For the update, done in 2019, 12 of the 14 assessed articles were articles where the IKDC-SKF was translated into a new language. There is a need to use PROMs of good quality, both in the clinical setting and in research. When a PROM is translated, it is important to ensure the measurement properties of the translation are good ²⁴.

Although many of the articles in the updated review report that they have used the COSMIN guidelines, many score fair and sometimes even poor for methodological quality. The low scores can be due to circumstances that are difficult to control afterwards. For example, sample size can be poor if there was a lower response rate than expected. But a poor score although good intentions could also be due to difficulties in reporting the result of a standardised assessment in a different forum, e.g. assessing according to COSMIN but reporting as a scientific paper with the structure the specific journal requires (word limitation etc.). Perhaps this type of scientific reports needs to be reported in another standardized way? A standardized report for articles that evaluate measurement properties using the COMSIN guidelines, might ease comparisons between papers, and improve interpretation of results for the reader. It might also facilitate knowledge translation to clinicians and researchers who are not experts in the field of measurement properties.

Study II was planned to evaluate the measurement properties and translational process of the Swedish IKDC-SKF, by using the COSMIN as a methodical framework. However, we failed to score excellent in all methodological assessments for all measurement properties.

Test-retest reliability and measurement error scored poor methodological quality due to low sample size (<30 patients), which was due to a lower response rate than expected. For test-retest reliability, there was a balance between including responses from patients who returned the questionnaire late and not including responses where too much time had passed, due to the risk that patients had changed in condition. Patients filled out a question if their knee-related condition had changed since they filled out the first questionnaire. If the knee had changed, the patient's response was excluded. The decision not to include responses with more than three weeks interim time contributed to the low sample size for test-retest reliability and measurement error. By having two more participants, the methodological score would have been fair. The results for ICC_{2,1} was high, but the "worst score count system" in the methodological assessment, and decision to exclude the result from studies with poor methodological quality (according to guidelines) meant that the result did not count in the overall result for test-retest reliability.

Assessment criteria always have a cut off, separating "good" from "bad/poor". Although, there are difficulties in assessing, as well as risks of excluding results that are valid, due to how results are presented. That is a problem that should be addressed in the future developments of reports of methodological studies.

Study III and IV

In study III, the factors/reasons for recommending ACLR were pre-stated. The questionnaire sent to orthopaedic surgeons and physiotherapists was pre-tested by physiotherapists and orthopaedic surgeons presently not active in treating ACL injured patients, but with extended experience in the field. The questionnaire was tested for comprehension, relevance and clarity.

In contrast to testing a PROM, this questionnaire was intended for use in a cross-sectional study to describe a phenomenon, and testing responsiveness was not required. Answers to the questions are reported separated and the questionnaire was not intended to result in a score. A test of criterion validity would have been difficult because the questions were study specific and, to our knowledge, had not been used previously.

Regarding reliability, a test-retest and test for interpretability could have provided useful information about whether there were aspects missing, but it was not practically possible. Because the intention was to reach as many orthopaedic surgeons and physiotherapists who treat patients with ACL injury as possible, a pre-testing of that size necessary would mean that many possible respondents would have already participated, when it was time for the testing. A decision that the pre-testing was enough, was therefore taken.

The intention initially was to grade each factor for importance in the choice to do/recommend ACLR. Although, after data collection, we realized that a score of 0-1, close to “no surgery” could be interpreted as that the factor was not important in the choice to do/recommend ACLR, but also it could be interpreted as that it was a factor that suggested that a non-operative approach was recommended. Due to that ambiguousness, the decision to only report the result for scoring of 2-3 was taken.

We allowed participants to elaborate in free text, both if there were reasons they considered to be missing and to allow to describe other reasons that might influence the choice of treatment. A decision for using only free text option was taken for study IV. With the results of both the third and fourth study in this thesis, we know that the reason for choosing ACLR or non-operative treatment is more complex than stating one or a few factors that are the most influencing. It is difficult to express reasons for a complex decision into one or a few, and perhaps a qualitative approach could bring further light on this complex issue.

In study IV we used the medical chart information to report exact timing of when an ACLR decision was taken. For the group where a non-operative treatment decision was taken, the exact date for decision was not always registered. As discussed before, the reason for non-operative decision was not as exact as the ACLR decision, and subsequently not the timing either. There were cases where no definitive decision was registered, and overall it seems that there exists a group of patients who steers toward non-operative treatment without outspoken reasons, or a preceding medical decision process.

The question of how orthopaedic surgeons and physiotherapists rated their own, each other's assessment, and the patient's wishes when recommending ACLR, could have been more elaborated. That would have given more information about whose assessment and wishes are important and if there were differences who they considered to have more impact on the decision. Further information about how the decision was taken in non-operative treatment situations would

have given a more complete picture of the decision process. Future analysis of the treatment decision process, with regards to patient involvement, communication between patient and health care personnel and how information is given and perceived, are planned to be done for both non-operative and ACLR treatment decision processes.

In study IV, pre-injury activity level, knee joint instability rating, and IKDC-SKF were assessed and compared between patients who had chosen or would choose ACLR or non-operative treatment. Patients reported knee joint instability ratings and IKDC-SKF at several times after their injury. Hence, the patient reported factors could be answered either before or after the treatment decision was taken. The results of the patient-reported factors cannot therefore be used for prediction of treatment decision.

Clinical implications

This thesis gives the prerequisites for Swedish clinicians to use the IKDC-SKF in clinical context. It also provides evidence that the IKDC-SKF is a well-tested and a suitable tool for assessing symptoms, function and sports participation in patients with ACL injury. The IKDC-SKF has good validity, reliability and responsiveness. The systematic review of measurement properties for IKDC-SKF provides clinicians and researchers a compendium of the measurement properties of the IKDC-SKF.

Orthopaedic surgeons and physiotherapists in Sweden make decisions about treatment for ACL injured patients, with consideration of best evidence and the patient's wishes.

The complexity of the treatment decision-making process after an ACL injury supports the need for collaboration between orthopaedic surgeons and physiotherapists. Study III shows that both professions value each other's opinions, and share common ground in which reasons they consider important for recommending ACLR. The result that their values are shared, might contribute to enhance collaboration between the professions, a result that most likely would benefit patients.

The result that patient-reported knee joint instability and function did not reflect the choice of treatment chosen, could serve as a reminder to physiotherapists and orthopaedic surgeons, to interpret knee joint instability and function in an early phase with caution, in regards to choice of treatment.

Future research

The assessment and valuation of the methodological quality of a PROM should be an ongoing procedure. Assessments that are structured, standardized and reported in ways that are easy to interpret are of relevance, and help clinicians and researchers make decisions about which PROM to use. The results of the measurement properties testing for IKDC-SKF, should be completed with further testing of the Swedish version. Future research testing the measurement properties of the IKDC-SKF in patients with other diagnosis, and patients with an ACL injury that are treated non-operatively, would give information about whether the Swedish version is applicable for these groups.

Future research on the treatment decision process after an ACL injury is needed for a deeper understanding of how the decision is taken. It would be preferable to gain deeper perspective from health care personnel (orthopaedic surgeons

and physiotherapists) and the patient's perspective. More information about how patients receive and perceive information about the treatment options, pros and cons and risks about either treatment should be warranted. This could be gained by a qualitative approach and further explored with a quantitative approach, but should include patients', physiotherapists' and orthopaedic surgeons' perspective.

The course of non-operatively treated patients after an ACL injury is less documented compared to the course after ACLR. There is a need to map the process after an ACL injury that leads to a non-operative treatment, clarify the reasons for choice of treatment further and gain deeper knowledge of the decision process after an ACL injury.

CONCLUSIONS

Overall conclusion

- The IKDC-SKF, including the Swedish version, has good measurement properties and can be recommended for use in patients with an ACL injury, as well as other knee diagnoses.
- After an ACL injury, an early decision for ACLR is based on patients' high activity demands. ACLR decision later after injury is more common in the presence of knee joint instability and dysfunction, which cannot be discriminated by patient-reported knee joint instability and function during the first 3 months after injury. Orthopaedic surgeons' and physiotherapists' assessments are important in the choice of treatment decision, as well as patients' wishes.

Study aim specific conclusions

- Several studies that have tested the measurement properties of the IKDC-SKF showed to have excellent methodological quality, and showed good testing results for measurement properties, assessed with the COSMIN guidelines.
- The Swedish version of the IKDC-SKF has good results regarding measurement properties and interpretability for patients with an ACL injury.
- According to Swedish orthopaedic surgeons and physiotherapists, ACLR treatment after an ACL injury should be recommended when patients are young and/or, have high activity demands, have a knee demanding occupation and/or have knee joint instability despite adequate rehabilitation. In the treatment decision after an ACL injury, orthopaedic surgeons and physiotherapists take each other's assessments and patient's wishes into consideration.
- Treatment choice differs depending on when in time after injury the decision is taken. An early decision for ACLR is more often based upon high activity demands, while later decisions are more often based upon knee joint instability. Non-operative treatment decisions are often based upon

lack of knee joint instability problems or sufficient knee function. Self-reported knee joint instability and function during the first three months after ACL injury is no different in patients who chose ACLR or non-operative treatment.

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APPENDIX 1

Appendix 1. Result of methodological evaluation and results from studies: Internal Consistency						
Author/Year/Country	Type of study ^a	N=	Age:	Gender	Diagnosis or other disease characteristics	COSMIN score and reason for score
Ahmed et al 2019 Egypt	B	100	Mean: 38.7, range: 18.70	55% male	Ligament injuries, meniscus injuries or osteoarthritis, at 15 days and 1 day pre- and at 6 months postoperatively	Good. Good sample size (50-99). Not described, but it can be deduced how missing items were handled Cronbach's alpha: 0.89
Celik et al 2014 Turkey	B	103	Mean: 34.9, SD: 11.9	50.5% male	Knee pathology (including 38.8% PFPs, 11.8% ACL injury, and other knee diagnosis)	Good. Good sample size; 5*#items and ≥ 100 OR 6-7* items but <100 Cronbach's alpha 0.89
Ebrahimzadeh et al 2014 Iran	B	145	Mean: 30.9 SD: 10.4	77% male	ACL injured patients	Fair. Not clear how missing items were handled Cronbach's alpha 0.845
Grevnerts et al 2017 Sweden	B	245	Mean: 24, SD 9	50% male	ACL injured patients that had undergone ACL reconstruction 6-8 months ago	Excellent Cronbach's alpha 0.90
Huang et al 2017 Taiwan	B	173	Mean: 44.4, SD: 19	54.3% female	Various knee problems, of them 22, 5% ACL injured patients.	Fair. Not clear how missing items were handled. Cronbach's alpha 0.87
Jia et al 2018 China	B	103	Mean: 49.4, SD: 17.6	36.9% female	Various knee problems	Excellent Cronbach's alpha 0.92
Kim et al 2013 Korea	B	150	Mean: 30.5, Range, 9-68	98 males, 52 females	Various knee problems	Fair. Not clear how missing items were handled Cronbach's alpha: 0.91

Koumantakis et al 2016 Greece	B	80	Not reported	80% male	Patients with ACL injury (51.2%), meniscus injury (30%) and various knee injuries (18.8%).	Fair. Not clear how missing items were handled	Cronbach's alpha: 0.87
Kummel et al 2018 Germany	B	423	Mean: 38, SD: 14	62% men	Patients undergoing surgery for anterior cruciate ligament, meniscus and/or cartilage injuries	Excellent	Cronbach's alpha: 0.87
Van de Graaf et al 2014 The Netherlands	B	Wait-listed for surgery n=28, postop n=43	Waitlisted for surgery: mean: 48.8 Postop: mean: 57.7	Male n=31	Patients on the waitlist for meniscal surgery and patients between 6 weeks and 6 months after meniscal surgery	Good. Good sample size (50-99)	Cronbach's alpha: 0.90

^a Type of study: A: aimed to investigate measurement properties of the IKDC, B: investigated the measurement properties of the IKDC while translating it into another language, C investigated the measurement properties of the Pedi-IKDC

Appendix 1. Result of methodological evaluation and results from studies: Test-retest reliability							
Author/Year/Country	Type of study ^a	N=	Age:	Gender	Diagnosis, other disease characteristics	COSMIN score and reason for score	Findings of study
Ahmed et al 2019 Egypt	B	100	Mean 38.7, range 18.70	55% male	Ligament injuries, meniscus injuries or osteoarthritis, at 15 days and 1 day pre- and postoperatively at 6 months.	Good. Good sample size (50-99). Assumable that patients were stable during the interim time	ICC: 0.95
Celik et al 2014 Turkey	B	58	33.7 +/- 10.6	28 men	Knee pathology (including 38.8% PFPS, 11.8% ACL injury, and other knee diagnosis)	Good. Not described, but it can be deduced how missing items were handled	ICC: 0.91.
Ebrahimzadeh et al 2014 Iran	B	145	Median age 30.9, range 14-65	76% men	ACL injured patients	Fair. Doubtful whether time interval was appropriate (interim period 3 days). Not clear how missing items were handled	ICC: 0.845 (P<0.001)
Grevnerts et al 2017 Sweden	B	28	Not reported	Not reported	ACL injured patients that had undergone ACL reconstruction 6 months ago	Poor. Small sample size (<30)	ICC 2.1: 0.92 (confidence interval 95%: 0.81-0.97 (P<.001))
Huang et al 2017 China	B	31	Not reported	Not reported	Various knee problems	Moderate sample size (30-49) Not clear how missing items were handled	ICC: 0.97 (p<0.001)
Jacobsen et al 2015 Denmark	B,C	52	Median: 15, Range 11-18	28 boys	Various knee problems	Fair. Not clear how missing items were handled	Bland Altman plots with 95% limits of agreement revealed no systematic differences between the two responses
Jia et al 2018 China	B	103	Mean age: 49.4 ± 17.6	36.9% female	Various knee problems	Good. Assumable that patients were stable during the interim time	ICC 0.94
Kim et al 2013 Chorea	B	126	Not described	Not described	Various knee problems	Fair. Not clear how missing items were handled. Unclear if patients were stable during the interim time	ICC: 0.94, (p<0.01)

Koumantakis et al 2016 Greece	B	35	88.5% male	Mean: 33.2, SD: 11.6	Patients with ACL injury (51.2%), meniscus injury (30%) and various knee injuries (18.8%)	Fair. Not clear how missing items were handled. Moderate sample size (30-49)	ICC: 0.95 (CI 0.91-0.98).
Kummel et al 2018 Germany	B	181	38 (SD14)	62% men	Patients undergoing surgery for anterior cruciate ligament, meniscus and/or cartilage injuries	Excellent	ICC: 0.94 (0.91; 0.95)
Van de Graaf et al 2014 The Netherlands	B	Wait-listed for surgery n=28, postop= 43	Waitlisted for surgery: mean: 48.8 Postop: mean: 57.7	Male n=31	Patients on the waitlist for meniscal surgery and patients between 6 weeks and 6 months after meniscal surgery	Good. Good sample size (50-99)	ICC: 0.92 CI:0.89-0.96
Van der Velden et al 2019 The Netherlands	B,C	59	Mean 15, SD 1.85	34% male	Various knee symptoms	Good. Good sample size (50-99). Assumable that patients were stable during the interim period	ICC:0.0

^a Type of study: A: aimed to investigate measurement properties of the IKDC, B: investigated the measurement properties of the IKDC while translating it into another language, C investigated the measurement properties of the Pedi-IKDC

Appendix 1. Result of methodological evaluation and results from studies: Measurement error							
Author/Year/Country	Type of study ^a	N=	Age:	Gender	Diagnosis, other disease characteristics	COSMIN score and reason for score	Findings of study
Celik et al 2014 Turkey	B	103	Mean: 34.9, SD: 11.9	50.5% male	Knee pathology (including 38.8% PFPs, 11.8% ACL injury, and other knee diagnosis)	Good. Not described, but it can be deduced how missing items were handled	SEM: 6.0, MDC: 16.4
Grevnerts et al 2017 Sweden	B	28	Not reported	Not reported	ACL injured patients that had undergone ACL reconstruction 6 months ago	Poor. Small sample size (<30)	SEM:5.7 p, SDC _{group} : 2.4 p, SDC _{ind} :15.8 p.
Huang et al 2017 China	B	31	Not reported	Not reported	Various knee problems, of them 22, 5% ACL injured patients. All patients received physical therapy treatment	Fair. Moderate sample size (30-49), Not clear how missing items were handled	SEM: 3.2, MDC: 8.9
Jia et al 2018 China	B	103	Mean: 49.4, SD: 17.6	36.9% female	Various knee problems	Good. Assumable that the patients were stable during the interim time	SEM: 3.9, MDC:10.9
Koumantakis et al 2016 Greece	B	35	Mean: 33.2, SD: 11.6	88.5% male	Patients with ACL injury (51.2%), meniscus injury (30%) and various knee injuries (18.8%).	Fair. Not clear how missing items were handled. Moderate sample size (30-49)	SEM: 4.4 p, SDC:12.2 p
Kummel et al 2018 Germany	B	181	Mean: 38, SD: 14	62% male	Patients undergoing surgery for anterior cruciate ligament, meniscus and/or cartilage injuries	Excellent	SEM: 5.4p SDC: 14.9p
Van der Velden et al 2019 The Netherlands	B,C	59	Mean 15, SD 1.85	34% male	Various knee symptoms	Good. Good sample size (50-99). Assumable that the patients were stable	SEM: 8.6p, SDC: 23.8 p

Van de Graaf et al 2014 The Netherlands	B	Wait-listed for surgery n=28, postop = 43	Waitlisted for surgery: mean: 48.8 Postop: mean: 57.7	Male n=31	Patients on the waiting list for meniscal surgery and patients between 6 weeks and 6 months after meniscal surgery	Good. Good sample size (50-99)	SEM: 5.3, SDD: 14.6
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^a Type of study: A: aimed to investigate measurement properties of the IKDC, B: investigated the measurement properties of the IKDC while translating it into another language, C investigated the measurement properties of the Pedi-IKDC

Appendix 1. Result of methodological evaluation and results from studies: Content validity							
Author/Year/Country	Type of study ^a	N=	Age:	Gender	Diagnosis, other disease characteristics	COSMIN score and reason for score	Findings of study
Ahmed et al 2019 Egypt	B	100	Mean: 38.7, range: 18.70	55% male	Ligament injuries, meniscus injuries or osteoarthritis, at 15 days and 1 day pre surgery and postoperatively at 6 months	Poor. NOT assessed if all items together comprehensively reflect the construct to be measured. NOT assessed if all items are relevant for the study population. NOT assessed if all items refer to relevant aspects of the construct to be measured	There was a pretesting of the first version of the questionnaires, by a group of 4 orthopaedic surgeons and 30 patients to confirm that the draft could be understood. One hundred patients were studied for feasibility, of which 97 (97%) filled out the entire questionnaire, while 3 (3%) left either item number 6 (In past 4 weeks, or since injury, did knee your catch?) or item number 7 (What is the level of activity that you can do without giving way?) without answering
Kummel et al 2018 Germany	B	61	Mean: 38, SD: 14	Comprehensibility rating: 52% men, relevance rating: 43% men	Patients undergoing surgery for anterior cruciate ligament, meniscus and/or cartilage injuries	Excellent.	50% of the items were rated as essential and all items as comprehensible

Van de Graaf et al 2014 The Netherlands	B	Wait-listed for surgery n=28, postop= 43	Waitlisted for surgery: mean: 48.8 Postop: mean: 57.7	Male n=31	Patients on the waiting list for meniscal surgery and patients between 6 weeks and 6 months after meniscal surgery	Good. Good sample size (50-99)	None of the PROMs (IKDC, KOOS, WOMAC), covered topics such as expectations regarding sports and recreation performance, difficulty in participating in favourite or second-favourite sport, fear of reinjuring the knee, worries toward the future, frustration regarding the knee, or influence of knee pain on performing heavy physical labour. The only major difference between the IKDC and the KOOS was the coverage of apprehensiveness and an item regarding the modification of lifestyle, in favour of the KOOS.
Van der Velden et al 2019 The Netherlands	B,C	59	Mean 15, SD 1.85	34% male	Various knee symptoms	Excellent	75% of content was relevant. The Pedi-IKDC and all KOOS- Child subscales were all found relevant by patients (> 75%). The orthopaedic surgeons rated the Pedi-IKDC and KOOS-Child subscales as relevant (all > 75%), except the KOOS-Child ADL (64%). Feedback from both groups showed that the KOOS- Child has a higher patient burden, since it has multiple subscales

^a Type of study: A: aimed to investigate measurement properties of the IKDC, B: investigated the measurement properties of the IKDC while translating it into another language, C investigated the measurement properties of the Pedi-IKDC

Appendix 1. Result of methodological evaluation and results from studies: Structural validity							
Author/Year/Country	Type of study ^a	N=	Age:	Gender	Diagnosis, other disease characteristics	COSMIN score and reason for score	Findings of study
Grevnerts et al 2017 Sweden	B	249	24 years (SD 9 years, range 15-45 years)	50% men	ACL injured patients that had undergone ACL reconstruction 6-8 months ago.	Excellent	A single factor solution accounted for 46.1% of the variance. Factor loadings were >0.4 for 17 of 18 items. The factor loading for item 6 ("during the past 4 weeks, or since your injury, did your knee lock or catch?") was 0.349
Kummel et al 2018 Germany	B	423	38 (SD14)	62% men	Patients undergoing surgery for anterior cruciate ligament, meniscus and/or cartilage injuries	Excellent	Confirmatory factor analysis for a unidimensional score showed that the lowest factor loading for item 6 was 0.15, and over 0.4 for all other items
Van de Graaf et al 2014 The Netherlands	B	Waitlisted for surgery n=28, postop=43	Waitlisted for surgery: mean: 48.8 Postop: mean: 57.7	Male n=31	Patients on the waiting list for meniscal surgery and patients between 6 weeks and 6 months after meniscal surgery	Poor. Participants less than 5 x #items	A single dimension model covered 41.5% of the total variance.

^a Type of study: A: aimed to investigate measurement properties of the IKDC, B: investigated the measurement properties of the IKDC while translating it into another language, C investigated the measurement properties of the Pedi-IKDC

Appendix 1. Result of methodological evaluation and results from studies: Hypothesis testing							
Author/Year/Country	Type of study ^a	N=	Age:	Gender	Diagnosis, other disease characteristics	COSMIN score and reason for score	Findings of study
Ahmed et al 2019 Egypt	B	100	Mean: 38.7, range: 18.70	55% male	Ligament injuries, meniscus injuries or osteoarthritis, at 15 days and 1 day pre surgery and postoperatively at 6 months	Poor. Unclear whether hypothesis regarding correlations or mean differences formulated a priori (i.e. before data analysis), unclear what was expected	Correlation to KOOS: r=0.58
Celik et al 2014 Turkey	B	103	Mean: 34.9, SD: 11.9	50.5% male	Knee pathology (including 38.8% PFPs, 11.8% ACL injury, and other knee diagnosis). 3-14 days between administrations of the IKDC-SKF form	Fair. Hypothesis vague or not formulated, but possible to deduce what was expected	Turkish IKDC-SKF correlates well to Turkish Kujala Anterior Knee Pain Scale, Lysholm score and PCS of SF36. Weak correlation between IKDC-SKF and MCS of SF36.
Grevnerts et al 2017 Sweden	B	249	Mean: 24, SD: 9	50% men	ACL injured patients that had undergone ACL reconstruction 6-8 month ago	Excellent for all items	Ten out of ten hypothesis were confirmed
Huang et al 2017 China	B	173	Mean age 44.4 SD: 19.0	54.3% female	Various knee problems, 22, 5% ACL injured. All patients received physical therapy treatment	Fair. Not clear how missing items were handled	Correlations between Chinese IKDC-SKF and Chinese KOOS and SF36 were made. Hypothesis stated that a strong correlation (> 50) should be seen to physical subscales in both measures, and a weak correlation (<.35) to mental subscales. Hypothesis were confirmed.
Jia et al 2018 China	B	103	Mean: 49.4, SD: 17.6	36.9% female	Various knee problems	Good. Expected magnitude of the correlations or differences for the hypothesis were NOT stated a priori.	Correlation to Lysholm score: r0.81 (p<0.01) Correlation to SF36; Physical function: r0.72 (p<0.01) Bodily pain: r.07 (p<0.01) Role-emotional: r0.31 (p<0.01) Mental health: r.024 (p<0.01) Hypothesis confirmed

Kim et al 2013 Chorea	B	150	30.5 years of age (range, 9 to 68 years).	98 males and 52 females	Various knee problems	Fair. Not clear how missing items were handled. Some information on measurement properties (or a reference to a study on measurement properties) of the comparator instrument(s) in any study population	Hypothesis confirmed. Correlation to Lysholm: r 0.82 ($p < 0.01$) Correlation to SF36: Physical Component summary r 0.61 ($p < 0.01$), Mental component summary r 0.35 ($p < 0.01$)
Koumantakis et al 2016 Greece	B	80	80% male	Not reported	Patients with ACL injury (51.2%), meniscus injury (30%) and various knee injuries (18.8%).	Fair. Not clear how missing items were handled. Hypothesis vague or not formulated, but possible to deduce what was expected.	Correlation to SF36: PCS: $r = 0.77$ ($p < 0.01$) MCS: $r = 0.22$ ($p < 0.01$) One or more hypothesis were not confirmed, but hard to derive a percentage of confirmed hypothesis.
Kummel et al 2018 Germany	B	423	Mean: 38, SD: 14	62% male	Patients undergoing surgery for anterior cruciate ligament, meniscus and/or cartilage injuries	Excellent.	90% of hypothesis were confirmed
Van de Graaf et al 2014 The Netherlands	B	Waitlisted for surgery $n = 28$, postop = 43	Waitlisted for surgery: mean: 48.8 Postop: mean: 57.7	Male $n = 31$	Patients on the waiting list for meniscal surgery and patients between 6 weeks and 6 months after meniscal surgery	Good. Good sample size (50-99 per analysis)	100% hypothesis confirmed. IKDC correlation to SF36: To PCS: $r = 0.78$ To MCS: $r = 0.11$
Van der Velden et al 2019 The Netherlands	B, C	10	Mean 15, SD 1.85	34% male	Various knee symptoms	Good. Percentage of missing items NOT described	75% of hypothesis were confirmed

^a Type of study: A: aimed to investigate measurement properties of the IKDC, B: investigated the measurement properties of the IKDC while translating it into another language, C investigated the measurement properties of the Pedi-IKDC

Appendix 1. Result of methodological evaluation and results from studies: Cross-cultural validity							
Author/Year/Country	Type of study ^a	N=	Age:	Gender	Diagnosis, other disease characteristics	COSMIN score and reason for score	Findings of study
Celik et al 2014 Turkey	B	20	Mean: 27.4 SD: 6.3	20% male	Knee pathology (including 38.8% PFPS, 11.8% ACL injury, and other knee diagnosis).	Good. Not described, but it can be deduced how missing items were handled. There was no DIF conducted, i.e. no full cross-cultural analysis, and there for the sample size was not rated.	There was a difficulty translating the words pivoting and giving way. Pivoting was left as is because it could not be replaced by a Turkish word, and it is also used by Turkish medical professionals and athletes. “Giving way” was translated as boşalma, which means “loss of control.” The pilot study indicated that some patients still had difficulty understanding the words “pivoting,” and “giving way.” Therefore, an explanation was provided in parentheses for “pivoting” that described the situational term as “the external or internal rotation of the body while the foot is stable on the ground.” “Giving way” was also explained in parentheses as “anterior translation, slipping, or sense of looseness within the knee.” These phrases helped the patients understand the questions. The patients required approximately 5 minutes to complete the Turkish IKDC Subjective Knee Form.
Grevnerts et al 2017 Sweden	B	10	Range: 17-31	50% men	ACL injured patients	Poor. Poor sample size and no DIF testing	All patients stated that the versions were similar and that the questions were relevant. The scores the patients showed on the Swedish and English forms were coherent.

Huang et al 2017 China	B	10	Not described	Not described	Patients with various knee problems	Poor. Poor sample size and no DIF testing	All subject completed the IKDC- SKF without missing items and demonstrated a clear understanding of the scale items. No major conceptual or cultural differences were found.
Jacobsen et al 2015 Denmark	B,C	15	Median: 14, range: 10-15	Not described	Patients with various knee problems	Fair. Not clear how missing items were handled	The following changes were made in order to adapt the Pedi- IKDC to the Danish language. The most you could do in items 1, 6, 9, and 10 was changed to the Danish word of toughest. Basketball in items 1, 6, 9, and 10 was changed to handball. Heavy lifting in items 1, 6, 9, and 10 was changed to lift of heavy objects. In item 5 puffy (or swollen) was merged to swollen. Get stuck in place (lock) was changed to the Danish phase of got stocked (locked) in item 7. Feeling like it can't hold you up in item 9 was changed to giving away. Squat in item 11D was changed to crouch down.
Jia et al 2018 China	B	103	Mean: 49.4, SD: 17.6	36.9% female	Various knee problems	Fair. Sample used in the pre-test NOT (adequately) described.	The translation procedure was conducted in five steps according to suggestions proposed by American Academy of Orthopaedic Surgeons Outcome Committee. Forwards and backwards translation, expert committee, and tested on 20 patients. No results outspoken from testing on patients, neither for potential cultural changes or adaptions.

Kim et al 2013 Chorea	B	30	Median: 30.5 (range: 9- 68)	98 males and 52 females	Various knee problems	Fair. Sample used in the pre-test NOT (adequately) described. Not clear how missing items were handled.	No results reported, but that 30 patients (not further described) filled out the form and were interviewed for comprehensibility. Good description of translation process that was conducted according to guidelines.
Koumantakis et al 2016 Greece	B	30	Not described	Not described	Patients with various knee pathologies that were referred for physical therapy	Poor. Sample used in the pre-test NOT (adequately) described	Content and face validity between source and target versions assured, as all patients completed the IKDC-SKF in Greek without omissions and demonstrated a good understanding of the scale items.
Van der Velden et al 2019 The Netherlands	B,C	10	Mean: 15, SD: 1.85	34% male	Various knee symptoms	Good. Percentage of missing items NOT described. Stated (but not shown) that samples were similar for all characteristics except language/cultural	The questionnaires were pilot tested in a group of 10 children, aged 10–15 years who received treatment for orthopaedic-related knee problems. Respondents were asked about item difficulty. In case of indistinctness or incomprehensibility adjustments were made. Overall, the forward-backward translation revealed minor differences in translation. Small adaptations in structure and tense were made. No cross-cultural adaptations were necessary.

^a Type of study: A: aimed to investigate measurement properties of the IKDC, B: investigated the measurement properties of the IKDC while translating it into another language, C investigated the measurement properties of the Pedi-IKDC

Appendix 1. Result of methodological evaluation and results from studies: Criterion validity							
Author/Year/Country	Type of study ^a	N=	Age:	Gender	Diagnosis, other disease characteristics	COSMIN score and reason for score	Findings of study
Ebrahimzadeh et al 2014 Iran	B	145	Mean: 30.9, (SD 10.4)	77% men	ACL injured patients	Fair. Not clear how missing items were handled	Correlation to SF36: PCS: R = 0.626**, P<0.00. MCS: R = 0.159, P = 0.055
Grevnerts et al 2017 Sweden	B	249	Mean: 24 (SD 9)	50% men	ACL injured patients that had undergone ACL reconstruction 6-8 months ago.	Excellent scoring for all items	There was a positive correlation between IKDC-SKF and the SF36. The correlation between the IKDC-SKF and the PCS was high, $r=.73$ ($P<.001$). There was a weak correlation between the IKDC-SKF and the MCS $r=.32$ ($P<.001$), thus confirming the hypothesis for criterion validity.

^a Type of study: A: aimed to investigate measurement properties of the IKDC, B: investigated the measurement properties of the IKDC while translating it into another language, C investigated the measurement properties of the Pedi-IKDC

Appendix 1. Result of methodological evaluation and results from studies: Responsiveness							
Author/Year/Country	Aim of study*	N=	Age:	Gender	Diagnosis, other disease characteristics	COSMIN score and reason for score	Findings of study
Celik et al 2014 Turkey	B	33	Mean: 30.8 (SD: 8)	70% male	Knee pathology (including 38.8% PFPS, 11.8% ACL injury, and other knee diagnosis). 3-14 days between administrations of the IKDC-SKF form	Fair. Moderate sample size (30-49)	Effect size: 2.09; CI1.61, 2.59
Grevnerts et al 2017 Sweden	B	47	Mean: 24 years (SD: 9)	50% male	ACL injured patients that had answered questionnaires at baseline (before ACL reconstruction) and at 4 months after ACL reconstruction	Fair, due to low sample size.	The ROC analysis showed an AUC of 0.79. All ten hypothesis were confirmed. The effect size of the change from baseline to 12 months was 1.8, and standardized response mean was 1.9.
Huang et al 2017 China	B	173	Mean: 44.4 (SD:19)	54.3% female	Various knee problems, 22, 5% ACL injured. All patients received physical therapy treatment.	Fair. Not clear how missing items were handled	An effect size of 0.37 was seen at baseline, 0.46 at 4 weeks, 0.61 at 8 weeks and 0.95 at 12 weeks after physiotherapy intervention. Area under the ROC curve: 0.83 (CI 0.76-0.89) MCID: 9.8 (sensitivity 0.79, specificity 0.72)
Jacobsen et al 2015 Denmark	C	52	Median 15 (range: 11-18)	54% male	Various knee problems	Fair. Not clear how missing items were handled	Area under the ROC curve was 0.7. The MCIC was 12.0 (SD 13.5) points. SRM showed a large effect size in children reporting improvement (SRM = 0.9, n = 67) and a small effect size in children reporting deterioration (0.2, n = 25).
Jia et al 2018 China	B	103	Mean age: 49.4 ± 17.6	36.9% female	Various knee problems	Poor. Other important methodological flaws in the design or execution of the study	SRM: 2.39, ES: 1.33

							Not described what happened during the interim period, no description of how many patients that were changed or unchanged. Statistical analysis did not include neither construct nor criterion based testing for responsibility.	
Kim et al 2013 Chorea	B		104		Not described for this sub cohort	Not described for this sub cohort	Various knee problems	SRM 0.689
Noordyun et al 2019 The Netherlands	A		298		Mean: 57.5 (SD: 6.7)	50.3% female	Older patients treated for a meniscal tear by arthroscopic partial meniscectomy or physical therapy	7 of 10 hypothesis confirmed. MIC: 10.9 points.
Ogura et al 2018 USA	B		86		unclear	unclear	Pre- and postoperatively for autologous chondrite implantation.	MCID 34.4, AUC: 0.74
Koumantakis et al 2016 Greece	B		80		No reported	80% male	Patients with ACL injury (51.2%), meniscus injury (30%) and various knee injuries (18.8%).	ES: 1.26
Kummel et al 2018 Germany	B		312		38 (SD14)	61% male	Patients undergoing surgery for anterior cruciate ligament, meniscus and/or cartilage injuries	AUC: 0.82- 0.89 Hypothesis: 76% of hypothesis were confirmed

^a Type of study: A: aimed to investigate measurement properties of the IKDC, B: investigated the measurement properties of the IKDC while translating it into another language, C investigated the measurement properties of the Pedi-IKDC

Appendix 1. Result from studies: Interpretability						
Author/Year/Country	Aim of study ^a	N=	Age:	Gender	Diagnosis, other disease characteristics	Findings of study
Celik et al 2014 Turkey	B	103	Mean: 34.9 (SD: 1.9)	50.5% male	Knee pathology (including 38.8% PPPS, 11.8% ACL injury, and other knee diagnosis). 3-14 days between administrations of the IKDC-SKF form	No floor or ceiling effect.
Grevnerts et al 2017 Sweden	B	277	Mean: 24 (SD:9)	50% male	ACL injured patients that had answered questionnaires before ACL reconstruction and again at 4, 6 and 12 months after ACL reconstruction. Also participants that answered to questionnaires ones at 8 months after ACL reconstruction.	There was 1% ceiling effect at 6 and 8 months and 2% ceiling effect at 12 months. The other measurement occasions showed no floor or ceiling effect. The MCID calculated with score from 4 months was 13.9 points, with a sensitivity of 65.2% and a specificity of 95.5%
Huang et al 2017 China	B	173	Mean: 44.4 (SD:19)	54.3% female	Various knee problems, 22, 5% ACL injured. All patients received physical therapy treatment.	No ceiling or floor effects.
Jia et al 2018 China	B	103	Mean: 49.4(SD:17.6)	38 (37%) female	Various knee problems	No floor or ceiling effect.
Kim et al 2013 Chorea	B	150	Mean: 30.5	98 males, 52 females	Various knee problems	No floor or ceiling effect.
Koumantakis et al 2016 Greece	B	80	Not reported	80% male	Patients with ACL injury (51.2%), meniscus injury (30%) and various knee injuries (18.8%).	No floor or ceiling effect.
Muller et al 2016 USA	A	251	Mean: 26.1, (SD: 9.9)	55.4% female	Patients who were between 1 to 5 years after primary, unilateral, anatomic ACL reconstruction.	Threshold for patient acceptable symptom state was: 75.9 (CI: 0.83, 0.96) for the IKDC-SKF.
Nasreddine et al 2017 USA	A	2000	Mean: 14 (SD: 2.6)	50% female	Examination of differences in scores among children who had a history of knee surgery or limited activity compared with those who did not.	34% ceiling effect. The mean 6 SD score was 86.7 6 16.8.

Ra et al 2014 Chorea	D	134	Mean: 27.2	111 males, 23 females	A total of 134 patients who underwent ACL reconstruction between 2007 and 2011 were enrolled in this study. All patients fulfilled the postoperative 6- and 12-month evaluations.	IKDC-SKF showed a ceiling effect of 5.2% at 6 months and 17.2% at 12 months.
Rothermich et al 2016	D	242	Mean: 14.9	60% female	Patients with various knee disorders and injuries	IKDC-SKF mean score was 50.3 (SD18.3) for all patients. Diagnose specific scores: Isolated meniscal tears: 41.2 (SD16.0) ACL and meniscal injuries: 50.2 (SD13.9) Isolated ACL tears: 48.1 (SD14.1) Symptomatic discoid meniscus: 46.3 (SD17.4) Patellofemoral pain: 49.0 (SD 17.4) Patellar instability: 49.2 (SD22.1) OCD lesions: 62.2 (SD 19.5)
Van de Graaf et al 2014 The Netherlands	D	Patients on the wait-list for surgery n=28, postoperative=43 n total= 71	Waitlisted for surgery: mean: 48.8 Postop: mean: 57.7	Male n=31	Patients on the waiting list for meniscal surgery and patients between 6 weeks and 6 months after meniscal surgery	No floor or ceiling effects.
Van der Velden et al 2019 The Netherlands	A,B,C	59	Mean: 15 (SD: 1.85)	34% male	Various knee symptoms	No floor or ceiling effect.

^a Type of study: A: aimed to investigate measurement properties of the IKDC, B: investigated the measurement properties of the IKDC while translating it into another language, C investigated the measurement properties of the Pedi-IKDC, Type D= compared The IKDC to other measurement instruments without specifically investigating measurement properties,

ACL= anterior cruciate ligament, PFPs= patellofemoral pain syndrome, OA= osteoarthritis, Q= question, n0= number.

Papers

The papers associated with this thesis have been removed for copyright reasons. For more details about these see:

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