“Finding stability” Experienced and measured function in patients undergoing surgery for patellar instability.

Trine Hysing-Dahl

Thesis for the degree of Philosophiae Doctor (PhD)
University of Bergen, Norway
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Scientific environment and funding

The work leading to this thesis has been performed in the clinical environment of Haraldsplass Deaconess Hospital, Haukeland University Hospital and the Sports Traumatology and Arthroscopy Research (STAR) Group. From December 2020, I was affiliated to the Department of Clinical Medicine (K1) at the University of Bergen.

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Abbrevations

ACL	Anterior cruciate ligament
BMI	Body mass index
BPII	Banff patellofemoral instability instrument
BPII 2.0-NO	Banff patellofemoral instability instrument 2.0 Norwegian version
CI	Confidence interval
CM	Centimetres
COSMIN	Consensus-based standards for the selection of health measurement instruments
ICC	Intra-class correlation coefficient
ICF	International classification of functioning, disability and health
IKDC	International knee documentation committee subjective form
KOOS	Knee injury and osteoarthritis outcome score
KOOS QOL	Knee injury and osteoarthritis outcome score Quality of Life
NM	Newton meters

NPI	Norwich patellar instability score
LOA	Limits of agreement
LSI	Leg symmetry index
MPFL	Medial patellofemoral ligament
MPFL-R	Medial patellofemoral ligament reconstruction
MPFL-RSI	Medial patellofemoral ligament-return to sport after injury
PASS	Patient acceptable symptom state
PCA	Principal components analysis
PI	Patellar instability
PROM	Patient reported outcome measure
QoL	Quality of life
REC	Regional ethic committee
RTS	Return to sport
PT	Peak torque
SEM	Standard error of measurement
SDC	Smallest detectable change
STC	Systematic text condensation
TSK	Tampa scale of kinesiophobia

TTO	Tibial tubercle osteotomy
TT-TG	Tibial tuberosity trochlear groove
YBT-LQ	Y-balance test-lower quarter

Content

1. Theoretical perspective

Both qualitative and quantitative designs were applied to answer the research questions in this thesis. The quantitative method is anchored in natural sciences which is further developed from positivism/empiricism where causal determination, prediction and generalization of findings (e.g. to the entire group of patients with patellar instability (PI)) is the goal. Information is quantified and collected in the form of numbers that are summarised and presented using statistical terminologies (1). Qualitative research is based on constructivism where the researcher typically aims to understand a phenomenon (i.e. PI) from the perspective of those experiencing it. Data are collected through observations, focus groups or interviews and the researcher seeks understanding and illumination (1). Combining these two methodologies allows the researcher to explore several aspects of a phenomenon, seeking both in-depth and in-breadth knowledge.

2. Abstract

Background: Assessment of knee function after patellar stabilizing surgery is a central part of rehabilitation. Therefore, there is a need for valid and reliable tools, including both patient reported outcome measures (PROMs) and functional tests to evaluate treatment and to guide clinicians in for example return to sport decisions. Since conventional return to sport (RTS) assessment currently is lacking for patients with PI, it is important to explore how the patients experience living with this disorder and what functional problems they encounter.

Purpose: To gain new knowledge about functional tests used to assess readiness for RTS and activities after surgery for PI. To examine the psychometric properties of the Norwegian version of the Banff Patellofemoral Instability Instrument 2.0 (BPII 2.0) and to deepen insights on how the patients themselves experience to live with PI before and after surgery.

Methods: The BPII 2.0 was translated into Norwegian (BPII 2.0-NO) before the measurement properties were examined. Patients surgically treated for recurrent PI completed BPII 2.0-NO, related questionnaires and functional tests before and/or six months postoperatively. A sub-group of 50 patients completed the BPII 2.0-NO twice with a two-week interval. We evaluated content validity, internal consistency, test–retest reliability, measurement error and construct validity.

To examine feasibility and appropriateness of the functional assessment, 78 patients from an overlapping cohort (Study I and II) completed PROMs (the BPII 2.0, the NPI and the project-specific activity questionnaire) before they underwent functional testing (Y-balance test-lower quarter (YBT-LQ), single-legged hop tests and isokinetic strength tests). RTS clearance criteria were defined as: ≤4 cm YBT-LQ test anterior reach difference between legs, leg symmetry index (LSI) ≥95% in the YBT-LQ composite score, mean sum score LSI ≥85% of all single-leg hop tests and LSI ≥90% in isokinetic quadriceps strength.

To explore the experience of living with PI, 15 patients from the same cohort participated in a qualitative study, using semi-structured interviews six to 12 months after surgery. The data were analysed by systematic text condensation.

Results: Study I: BPII 2.0-NO demonstrated good face and content validity. No floor or ceiling effects were found, and internal consistency was excellent (α 0.95). Test-retest reliability was high $ICC_{2.1}$ 0.87 (95% CI 0.77-0.93) and measurement error low (SEM 7.1) with an SDC_{ind} of 19.7 points and SDC_{group} of 2.8. Eight of nine hypothesis about construct validity were confirmed.

Study II: Sixty-four patients (82%) were able to complete all functional tests, while only eleven (14%) patients were deemed ready for RTS, passing all return-to-sport clearance criteria. Patients with bilateral problems had higher LSI scores compared to individuals with unilateral instability and demonstrated worse performance in the contralateral leg. The extent of surgery (MPFL-R only versus combined surgery) did not predict self-reported function or functional performance at the follow-up. Further, only normalized anterior reach distance in involved (68.5 ± 5.5 vs 64.2 ± 7.5; *P*=.04) and contralateral leg (71.5 ± 4.0 vs 68.0 ± 7.0; *P*=.01) were affected by the extent of surgery, with a minor correlation (-.234, *P*=.04 and -.208, *P*=.06).

Study III: Participants offered rich and detailed descriptions of the impact and lived experience of PI. A key finding was that PI had a large impact on participants' lives. It was described to affect their mental as well as physical well-being. Their stories display a constant fear of dislocating the patella and for the majority, this was present for years before treatment was commenced and some fear still remained after surgery. The four major themes that emerged from the data were; fear of patella dislocations governs everyday life activities, 2) adaptation to avoidance behaviour, 3) feeling different, misunderstood, and stigmatized affects self-esteem and 4) feeling stronger, but still not fully confident in the knee after surgery.

Conclusion: The BPII 2.0-NO demonstrated good measurement properties. The current combination of functional tests seems feasible to conduct at six months after patellar stabilizing surgery. However, for patients with PI suggested clearance

standards and the use of leg-symmetry-index seems inappropriate. PI had a far-reaching impact in participants` everyday life, affecting ability to participate in social life and physical activities both before and after surgery.

Implications: Appropriate tests and the level of performance that suggests readiness for RTS after surgery for PI needs further exploration. RTS testing at six months postoperative seems premature, and patients should be informed that they probably cannot expect to return to sports at this timepoint. The overall treatment of patients with PI should incorporate increased attentions towards unwanted psychological issues such as adaptive behaviour and raised awareness of the knee both before and after surgery.

Sammendrag

Bakgrunn: Vurdering av knefunksjon er helt sentralt for diagnostikk, behandling og oppfølging av pasienter med ulike kneledds lidelser. Derfor er det behov for gyldige og pålitelige måleverktøy, inkludert pasientrapporterte utfallsmål og funksjonelle tester, for å kunne evaluere behandling og videre veilede pasienter og klinikere i beslutningstagning rundt retur til idrett. I dag mangler det etablerte retningslinjer for hvordan man best vurderer knefunksjon hos pasienter med patellainstabilitet. Derfor er det viktig å utforske hvordan pasientene selv opplever å leve med et ustabilt kneskjell og hvilke funksjonsproblemer de faktisk har.

Formål: Å skaffe ny kunnskap om funksjonelle tester som brukes i avgjørelser om pasientene er klar for å returnere til idrett, i tillegg til å oversette og videre undersøke måleegenskapene til Norsk versjon av spørreskjemaet Banff Patellofemoral Instabilitets Instrument 2.0 (BPII 2.0). Videre har vi ønsket å utforske hvordan pasientene selv opplevde å leve med patellainstabilitet både før og etter kirurgi.

Metoder: BPII 2.0 ble oversatt til Norsk (BPII 2.0-NO) før måleegenskapene ble undersøkt. Pasienter operert med patella stabiliserende kirurgi fylte ut BPII 2.0-NO, relaterte spørreskjema og gjennomførte funksjonelle tester før inngrepet og/eller seks måneder post operativt. Førsteinntrykk og innholds validitet, intern konsistens, test-retest reliabilitet, målefeil og konstrukt validitet ble undersøkt i studie I.

For å undersøke gjennomførbarhet og egnethet av et sett med funksjonelle tester, fylte 78 pasienter fra en overlappende kohort (studie I og II) ut spørreskjema (BPII 2.0, NPI og et prosjektspesifikt aktivitetsskår) før de gjennomførte funksjonelle tester (YBT-LQ, hinketester og isokinetisk styrketest). Pasientene ble klarert for å returner til idrett hvis de passerte følgende kriterier: ≤4 cm sideforskjell i anterior retning og LSI ≥95% i sum skår på YBT-LQ, gjennomsnittlig LSI ≥85% på alle hinketestene og LSI ≥90% i isokinetisk muskelstyrke.

For å utforske pasientenes opplevelser med å leve med patellar instabilitet deltok 15 pasienter i en kvalitativ studie. Intervjuene foregikk seks til 12 måneder etter kirurgi og data ble analysert med systematisk tekst kondensering.

Resultater: Studie I: BPII 2.0 gav et tilfredsstillende første-inntrykk, hadde god innholds validitet og ingen gulv- eller takeffekt ble funnet. Videre hadde skjemaet svært høy intern konsistens (α 0.95) og test-retest reliabilitet $ICC_{2.1}$ 0.87 (95% KI 0.77-0.93). Målefeilen var lav (SEM 7.1) med en SDC_{ind} på 19.7 poeng og SDC_{gruppe} på 2.8. Åtte av ni hypoteser som utgjorde grunnlaget for å bedømme konstrukt validitet ble bekreftet.

Studie II: Sekstito pasienter (82%) gjennomførte alle de funksjonelle testene, mens bare elleve (14%) pasienter ble klarert for retur til idrett. Pasienter med bilaterale problemer hadde høyere LSI-skår sammenlignet med de med unilaterale plager, i tillegg presterte de dårligere på det kontralaterale benet. Omfanget av kirurgi (kun MPFL-R versus kombinert kirurgi) predikerte ikke selvrapportert- eller målt funksjon seks måneder etter kirurgi. Videre var det kun normalisert distanse i anterior retning i det involverte (68.5 ± 5,5 vs. 64.2 ± 7.5; P = 0,04) og det kontralaterale beinet (71.5 ± 4.0 vs. 68,0 ± 7.0; P = 0.01) som var påvirket av omfanget av kirurgi.

Studie III: Deltakerne ga grundige og detaljerte beskrivelser av sine erfaringer med å leve med patellainstabilitet. Et sentralt funn var den omfattende innvirkningen instabiliteten hadde på deltakernes liv. De beskrev både mental og fysisk påvirkning. Historiene deres viste en konstant frykt for at patella skulle luksere. For flertallet var denne frykten til stede i årevis før operasjon, og noe av denne frykten opphørte ikke etter operasjon. De fire hovedtemaene fra analysene var: frykt for patella dislokasjoner påvirker daglige aktiviteter, 2) tilpasning til unngåelsesatferd, 3) å være annerledes, misforstått og stigmatisert påvirker selvfølelsen og 4) føler seg sterkere, men stoler likevel ikke helt på kneet etter operasjonen.

Konklusjoner: BPII 2.0-NO viste gode måleegenskaper. Kombinasjonen av funksjonstester i studie II var gjennomførbar seks måneder etter patella stabiliserende kirurgi, men veldig få klarte testene noe som tyder på at seks måneder er for tidlig for retur til idrett testing. Foreslåtte kriterier og bruk av LSI ser ut til å være uegnet for pasientgruppen. Patellainstabilitet hadde en omfattende innvirkning på deltakernes hverdagsliv, inkludert evnen til å delta i sosiale- og fysiske aktiviteter både før og etter operasjon.

Implikasjoner: Det trengs videre undersøkelser av hvilke tester og kriterier klinikere skal bruke for å vurdere om pasientene har tilfredsstillende knefunksjon for å returnere til idrett. Retur til idrett testing seks måneder etter operasjonen er for tidlig for de fleste pasienter. I tillegg bør behandlingen av disse pasientene inneholde økt oppmerksomhet mot uønskede psykologiske effekter som unngåelsesadferd.

3. List of Publications

I. Hysing-Dahl T, Magnussen LH, Faleide AG, Kjellsen A, Mo, IF, Waaler PA, Mundal R and E. Inderhaug, E: "**Cross-cultural validation of the Norwegian version of the Banff Patellofemoral Instability Instrument 2.0."** Orthopaedic Journal of Sports Medicine. 2023 May; 11(5):23259671231168881.

II. Hysing-Dahl T, Magnussen LH, Faleide AG and E. Inderhaug, E: "**Feasibility of return to sports assessment 6 months after patellar instability surgery"** Hysing-Dahl et al. BMC Musculoskeletal Disorders (2023) 24:662

III. Hysing-Dahl T, E. Inderhaug, E, Faleide AG and Magnussen LH: "**Patients' experiences of living with patellar instability, before and after surgery. A qualitative interview study."** BMJ Open. 2023;13(6):e072141.

4. Introduction

4.1 Patellar instability

The term *patellar instability* is typically used to describe a range of symptoms from an occasional “popping” sensation of the kneecap to an evident lateral dislocation needing acute reposition. PI mostly affects adolescents and young adults, with an annual incidence of 42 per 100,000 - and young women are at highest risk (108 per 100,000) (2). A great variation in injury mechanisms, dislocation rate, underlying risk factors and level of activity makes this patient group highly heterogeneous (3-5).

4.1.1 Anatomy of the patellofemoral joint

The patellofemoral joint is a complex joint where varying joint forces are developed dependent on the degree of knee flexion and whether the foot is in contact with the ground. It consists of the patella, a large triangular sesamoid bone, articulating with the trochlear groove on femur with multiple contact points (Figure 1) (6). Joint stability is determined by the alignment of the lower limb, patellar height on femur, and the congruity of the chondral surfaces. Normal anatomy for functional patellar stability is a deep trochlea groove with early engagement of the patella as the knee starts to flex from a fully extended position. Such stability requires the lower part of the patella to be situated over the proximal part of the trochlear groove when the knee is in full extension. The contact point on the patella progresses from distal to proximal during knee flexion and the patella should ideally be located at the distal end of the femur when at 90° of knee flexion (7). The patella is further stabilised by static and dynamic contribution of its ligamentous and muscular attachments (8, 9). Dynamic stability is provided by the active muscular forces around the joint, primarily exerted by the quadriceps muscle, with secondary dynamic restraints

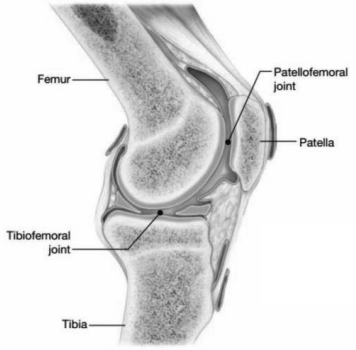

Fig. 1. The patellofemoral joint, Freepik.

from the core muscles and hip flexors. The medial patellofemoral ligament (MPFL) is the most important static restraint on the medial side, while sufficient length of the iliotibial band is important to avoid lateral tracking of the patella (8-10).

4.1.2 Lateral patellar dislocation

Patellar dislocations account for 3.3% of all knee injuries (2) and most frequently occur in the lateral direction (Figure 2). The majority of dislocations are sustained during non-contact trauma, where the knee is subject to valgus stress while extended in a planting or pivoting motion (11). Atraumatic patellar dislocations are mostly seen in individuals with predisposing anatomy where less energy is needed before the patella laterally dislocates (12). Injury to the MPFL, is described in almost all patients after primary dislocation (13-15), leaving patients without the essential medial restraint to the lateral patellar dislocation during the first 30 degrees of flexion (13).

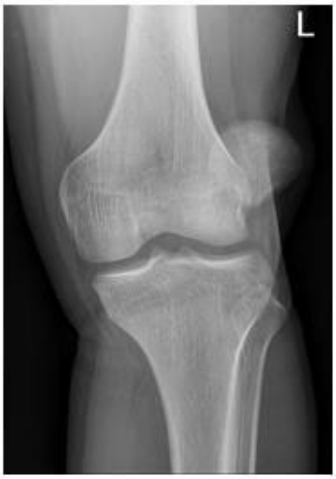

Fig. 2. X-ray of a laterally dislocated patella, with permission from the patient.

After the first event, 23-40% of patients experience recurrent dislocations and are at high risk of developing chronic PI (2, 15-19). Due to lack of evidence, it is uncertain whether risk factors such as younger age (particularly those under 16 years of age), open physes and gender are associated with recurrent instability (20). There is stronger evidence that familial association, different syndromes (e.g. malformations) (20) and anatomic factors increases the risk of repeated dislocations (3, 15, 20, 21). It is assumed that individuals with multiple concomitant predisposing factors have a higher risk of recurrence than those with only one - or few - risk factors (3, 15, 21). The most frequent of the underlying anatomic predisposing factors are trochlear dysplasia, patella alta, and elevated tibial tuberosity to trochlear groove (TT-TG) distance (15). Trochlear dysplasia refers to a flat proximal articular zone and a shallow groove distally, resulting in less bony stability for the patella (22). Patella alta denotes a patella that is positioned higher than ideal in the trochlear groove, also

leading to less stability for the patella. The TT-TG distance is said to be elevated when the distance between the tibial tuberosity and the trochlear groove is above 20 mm as measured on MRI (21).

4.1.3 Living with patellar instability

A lateral patellar dislocation is a painful experience for the individual, and recurrent dislocations are associated with considerably reduced knee function (23, 24), persistent pain (21, 23), kinesiophobia (25) and decreased health-related quality of life (QoL) (23, 26-29). Activity limitations and avoidance behaviour have also been reported in patients with PI (23, 28-31). Young individuals with long-standing symptoms often experience sequelae as they become adults, such as pain caused by chondral damage, lack of confidence in the knee due to recurrent dislocations (21) and an overall negative effect on mental health (32). Early osteoarthritic changes in the patellofemoral joint are often observed after recurrent patellar dislocation leading to patients living with both knee instability and pain (33).

Recurrent PI leads to long-standing symptoms and many patients end up waiting for years before the decision to undergo surgical treatment is made (23). Although surgery provides a structurally more stable patella and improved function (34), several patients still experience pain (33, 35), impaired knee function (24, 36-39) and psychological concerns (40, 41) afterwards. Some studies have reported that surgical treatment leads to an increased incidence of osteoarthritis in the patellofemoral joint postoperatively (33, 42).

The abovementioned descriptions of consequences of PI are based on brief reports from studies with quantitative designs only. Consequently, in-depth knowledge on how the patients themselves experience their condition and how it is to live with PI in the years prior to and after surgery is important for tailoring both treatment strategies and outcome measure instruments for this patient group.

4.1.4 Treatment strategies

The complex aetiology of PI entails that it is a challenging disorder to manage. Non-operative management with exercise therapy is the current standard of care after a first-time dislocation in patients without osteochondral fractures or loose fragments - requiring acute surgery (8, 19, 43, 44). However, this is a subject of ongoing debate, and it has been suggested that individuals with pronounced anatomic risk factors would benefit from surgery after their first dislocation episode (8, 45). Current guidelines recommend patellar stabilising surgery for persons experiencing recurrent dislocations regardless of functional activity level (8, 21, 43, 44).

The growing base of literature about surgical management has led to a better understanding of the functional anatomy of the patellofemoral joint, more accurate assessments of underlying pathophysiology and improved surgical techniques (35). The current mainstay of surgery is to address each patients deviating anatomy with an "à la carte" approach as described by Dejour et al. (22). This approach includes procedures such as tibial tubercle realignment, trochleoplasty, derotational osteotomies in addition to reconstruction of the medial patellofemoral ligament-reconstruction (MPFL-R) (22). However, to this date, data is insufficient to conclude on whether an isolated MPFL-R is superior to combined surgery.

Since the MPFL tears either completely or partially in 87% of all patients with an evident lateral patellar dislocation (15), MPFL-R is performed as part of almost all patellar stabilising surgeries. Different techniques for reconstructing the MPFL are described, without clear superiority of any technique (7, 8, 46). The use of an autograft is recommended, and the most commonly used grafts are gracilis and quadriceps tendons (7, 8, 46). Placement of the femoral tunnel is another area of research interest and currently it is recommended that the placement is checked by fluoroscopy ad modum Schöttle (47). MPFL-R seems to be a preferred treatment strategy for many surgeons, although some complications are reported where loss of knee flexion and medial knee pain is the most common (48, 49).

Tibial tubercle osteotomy (TTO) has been part of the treatment for PI, and related disorders, for decades (7, 8, 46). Common procedures include tibial tubercle

medialisation and tibial tubercle distalisation (21). In the latter, the goal is to reduce the height of patella on femur, allowing patella to enter the trochlea groove earlier in knee flexion while medialisation of the tibial tubercle reduces the lateral vector forces on the patella (46).

Trochleoplasty is a preferred treatment option for patients with prominent trochlea dysplasia (7, 8, 50). Several surgical techniques including sulcus deepening, lateral facet elevation and recession wedge trochleoplasty exist, all focusing on shaping a more normal anatomy in the patellofemoral joint (8, 46). Several studies report good postoperative stability and patient satisfaction (50, 51), however concerns have been raised about complication rates (iatrogenic cartilage damage, overcorrection and arthrofibrosis) and an increased risk of osteoarthritis development after this procedure (5).

If a patient has a femoral anteversion of >20º, femoral derotational osteotomies can be an option (8). However, the use of this procedure in the treatment of PI remains relatively novel, and its role in an "à la carte" approach is still unclear (8, 46).

Both surgical technique and graft choice vary according to patient-related factors (i.e. skeletal maturity and risk factors) and surgeon-related factors (i.e. experiences with the different techniques) and are subject to continuous debate and research (8, 21, 43).

4.1.5 Rehabilitation after patellar stabilizing surgery

There is broad agreement that rehabilitation is essential to achieve successful outcomes after surgery (9, 21, 52-54). The aim of treatment, including surgery and rehabilitation is to stabilise the patella in order to achieve normal functioning in everyday life and participation at preferred level of activity without PI (46). The disorder mostly affects adolescents and young adults and many of these young patients would like to return to or achieve a more active lifestyle after surgery. Adequate pre- and post-operative rehabilitation including regular functional assessments are therefore of great importance so that patients can achieve their goals.

However, there is limited information to guide rehabilitation after surgery; knowledge about appropriate restrictions are lacking, few high-quality studies have examined the optimal content of rehabilitation and there is no consensus on the ideal rehabilitation protocol following patellar stabilising surgery (52, 55). However, some recommendations have been made. These include strengthening exercises for core, hip and thigh muscles in combination with balance and neuromuscular training, addressing functional deficits in the whole kinetic chain and progressing through rehabilitation as functional milestones are reached (7, 9, 21, 52, 56-59).

Whilst some specific aspects of rehabilitation (such as restrictions after TTO) are dependent on the surgical techniques, there are multiple aspects of rehabilitation that needs further research (53). Investigations on accelerated rehabilitation protocols (no or minimal post-operative bracing and weight bearing restrictions) have shown promising results compared to more restrictive protocols (60, 61). Further, there is substantial variability among protocols presented for both isolated MPFL-R and combined stabilizing procedures –related to post-operative restrictions in range of motion, weight-bearing, use of knee brace and time until return to sport (RTS) (54). A British study displays how there is a great variation in the reported care delivered across different centres in the UK (53). We have reason to believe that similar variability exists in the Norwegian Healthcare system.

It has been suggested that impaired core muscle function, weak gluteal muscles and reduced balance prior to surgery might lead to prolonged rehabilitation (21). Hence, preoperative rehabilitation can be of importance for patients with PI, but there are currently no studies that have examined this.

4.2 Measurement instrument

Outcome measures constitute a cornerstone in both clinical practice and health research - forming the basis of diagnosis, prognosis and treatment evaluation (62, p. 1). Appropriate outcome measures are essential for evaluation of changes in symptoms and effect of treatment among others (62). For that reason, it is of great

importance that such instruments are well-designed and appropriate. A measurement instrument can be a questionnaire (patient reported outcome measure, PROM) or a clinical test or a device measuring for example muscle strength.

4.2.1 The International Classification of Functioning, Disability and Health

The International Classification of Functioning, Disability and Health (ICF) was developed by the World Health Organization to provide a common, standardised framework and language for understanding and describing functioning and health conditions (63). Aiming to incorporate all factors that may affect a patient's functioning and health (Fig. 3), the ICF can be useful to ensure that selected outcome measures evaluate all relevant aspects of a patient's function after surgery for PI. The framework describes function according to three levels: 1) body functions and body structures (impairments), 2) activities (activity limitations) and 3) participation (participation restrictions). The first level refers to loss of or deviation from normal body functions and structures, for example muscle strength. Activity limitations represents the difficulties an individual may have performing different activities, such as walking. The last level, participation restrictions, concerns the problems an individual may experience with involvement in life situations, for example school participation.

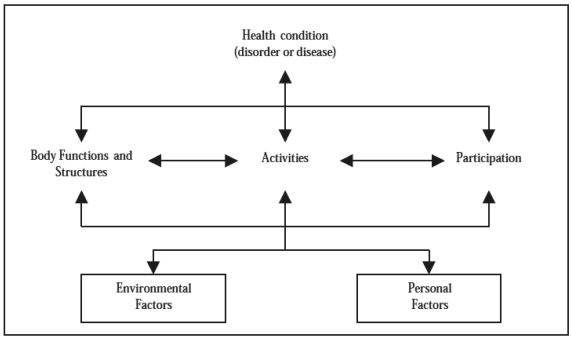

Fig. 3. ICF Diagram, (63).

4.2.2 COSMIN taxonomy

To help clinicians and researchers navigate the jungle of measurement instruments, the consensus-based standards for the selection of health measurement instruments (COSMIN) initiative was started (62, p. 3). These guidelines provide definitions of measurement properties and criteria for evaluating the quality of measurement instruments. The COSMIN taxonomy encompasses three main domains: validity, reliability, and responsiveness.

A measurement instrument should be both valid and reliable, meaning that it should measure what it intends to measure and that the results are reproducible (62). More specifically, validity refers to *"the degree to which an instrument truly measures the construct(s) it purports to measure"* (64, p. 743). COSMIN describes three types of validity; content, construct and criterion validity. Content validity is described as the most important measurement property of an instrument. It concern whether the content of a PROM is an adequate reflection of the concept of interest in terms of how relevant, comprehensive and comprehensible the instrument is for the construct, population of interest and context of use (65). Face validity is an aspect of content validity and refers to *"the degree to which (the items of) a questionnaire appears as an adequate reflection of the construct"* (64, p. 743). Criterion validity refers to how well the scores of for example a PROM agree with the scores from a gold standard instrument (62, p. 150). When no gold standard exists, construct validity can provide information on whether the PROM *"provides the expected scores, based on existing knowledge about the construct"* (62, p. 150). It is often assessed by forming hypotheses and testing them (50 p. 169), for example by investigating relationship with other constructs, both related (convergent validity) and unrelated (discriminant validity). Reliability provides information on the reproducibility of a measurement, and is defined as *"The extent to which scores for patients who have not changed are the same for repeated measurement under several conditions: e.g. using different sets of items from the same multi-item measurement instrument (internal consistency); over time (test-retest); by different persons on the same occasion (inter-rater); or by the same persons (i.e., raters or responders) on different occasions (intra-rater)"* (64,

p. 743). An instruments ability to detect change over time in the construct of interest is referred as *responsiveness* (64). Further concerns i*nterpretability* the *"the degree to which it is clear what the scores or change scores mean*" (62 p.228)

4.2.3 Patient reported outcomes measures for patellar instability

A variety of PROMs are used for evaluation of patients with PI (54). The most used is the Kujala Anterior Knee Pain scale followed by the International Knee Documentation Committee Subjective Knee Form **(**IKDC) 2000, the Knee injury and Osteoarthritis Outcome Score (KOOS) score and the Lysholm score (66). These PROMs were originally developed for use in patients with other knee conditions and few (Kujala and IKDC 2000) have been validated specifically in patients with PI. To provide a questionnaire directly addressing the deficits of patients with PI the Banff Patellofemoral Instability Instrument (BPII) was developed. It is diagnose-specific and validated in this patient group and show promising psychometric properties. However, a Norwegian version is lacking.

The BPII was originally modified from a questionnaire for patients with ACL deficiency, the Anterior Cruciate Ligament–Quality of Life (ACL-QoL) questionnaire with the rationale that patients with ACL tear and PI displayed similarities related to the injury mechanism (hip and/or knee valgus and external rotation in a decelerating movement) and recurrent episodes of knee instability (67). The first version of the BPII included 32 items (55). After principal component analysis (PCA) and item reduction, a shortened 23 item version, the BPII 2.0, was introduced in 2016 (68). Both versions have demonstrated good measurement properties in surgically and non-surgically treated patients (66-70) - adolescents (70, 71) as well as adults. In the first version of the BPII *face validity* was established by a group of experts orthopaedic surgeons with extensive experience of working with patients with PI (67). The same group evaluated *content validity*, grading the overall relevance of each item (68). In the BPII 2.0, content validity was assessed by interviewing patients about the relevance of each item, wording and overall

importance for their condition (68, 70). No studies have confirmed the underlying factor structure found with PCA of the BPII or the BPII 2.0.

Excellent *internal consistency* has been demonstrated with high α values (> 0.91) for both the BPII (55) and the BPII 2.0 (56) at baseline before surgery and six and 12 months after surgery. No floor or ceiling effects have been found. *Test-retest reliability* has been deemed satisfactory (ICC > 0.89) for both versions(67, 68, 70, 71). *Standard error of measurement,* (SEM), is reported in three studies (68, 70, 71), all calculating the SEM as $SD_{baseline} \times \sqrt{1} - ICC$. No SEM values determined according to current recommendations (calculated from the mean of the variance between tests) have been presented (72). Further, no studies have reported 95% limits of agreement (LoA, Bland-Altman plot) (62 p. 113) for the evaluation of systematic differences and smallest detectable change (SDC) value.

4.2.4 Return-to-sport assessment

Functional assessments refer to any systematic attempt to measure the level of functioning in a variety of domains. It is an important part of rehabilitation, measuring an individual's ability to perform specific tasks in a controlled environment (63). Functional assessment can help clinicians optimize the treatment and guide patients to a safe return to sport and an active lifestyle after surgery.

Until recently, time elapsed from surgery was the only criterium used to clear patients for RTS (73, 74). However, awareness of the importance of both allowing for sufficient biological healing (time-based criteria) and clearance through functional evaluation (functional criteria) is increasing (59, 74, 75). Deciding when patients knee function is sufficient to resume sport and other knee-demanding activities is a challenge for clinicians due to the little evidence on what a functional assessment should include to support the RTS decision. Knowledge on what tests and criteria that will provide the information we seek to advise our patients consists at this point of suggestions from expert groups (76, 77) and studies presenting various tests and test batteries (24, 25, 36-38, 59, 78, 79). There are however several systematic reviews on

the subject, all stating that there is no agreed-upon evidence-based guideline to support the RTS decision following surgery for PI (52, 59, 73, 74).

Because of poorly established RTS guidelines, current recommendations are adopted from another knee condition, namely ACL tear. With similar injury mechanism, neuromuscular impairments, and proprioceptive deficits post-operatively, it is argued that strategies used in RTS assessments after ACL reconstruction can be applied to patients after patellar stabilizing surgery (16, 52, 59, 75, 77). The current suggested RTS assessment for patients with PI therefore includes evaluation of strength, neuromuscular control, and balance to provide insights regarding patients' readiness to RTS.

4.3 Knowledge gaps

Despite increasing research interest in treatment strategies for patients with PI – displayed by the surge of studies on surgical approaches published the past decade - comparison of such treatment strategies are hampered by the lack of appropriate and validated outcome measures for this patient group (80). Therefore, there is a need for valid and reliable tools, including both PROMs and functional tests to evaluate treatment and to guide clinicians in rehabilitation and RTS decisions (73). Further, is it unknow whether the RTS assessment used for patients with ACL injury is feasible for the highly heterogenic patient group with PI - and the evidence on which tests, readiness criteria and the timing of RTS assessment is scarce (36, 75).

Studies using quantitative designs have indicated that having PI negatively affects patients' lives (21, 23-29). Therefore, is it important to explore how the patients have experienced living with this disorder, what functional problems they actually have and what they consider important in relation to returning to an active lifestyle and sport. A deepened understanding of how PI affects patients' lives, how they manage the condition in the years before and after surgery is needed to further develop the treatment course.

5. Aims of the thesis

The overall objective of this thesis was to provide more knowledge on appropriate methods for functional evaluation of patients with PI, including the patient perspective by exploring the experiences of living with this condition.

The specific aims were:

- *To translate, and cross-culturally adapt the BPII 2.0 to Norwegian and examine the measurement properties of the Norwegian version. (Study I)*
- *To examine the feasibility of functional tests assessing readiness for return to sport six months after patellar stabilizing surgery. (Study II)*
- *To explore and describe the experience of living with patellar instability before and after surgery. (Study III)*

6. Material and methods

6.1 Study design

This thesis includes studies of both quantitative and qualitative designs (Figure 4). Study I and II are based on quantitative data, collected at the initial visit before surgery and/or at the six-month postoperative follow-up. The qualitative data for study III was collected in 15 semi-structured individual interviews six to twelve months after surgery.

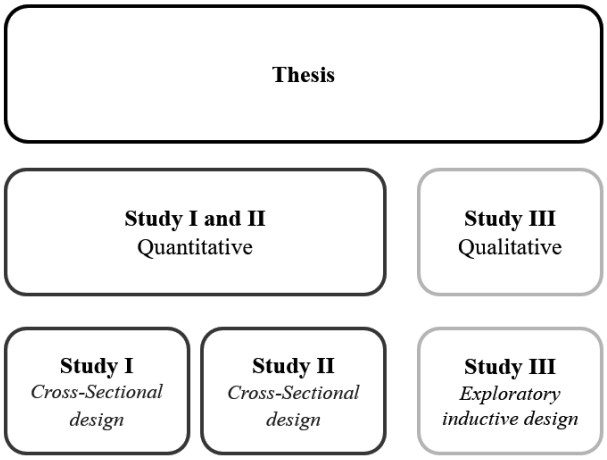

Fig. 4. The thesis` studies, methods and design.

6.2 Patient inclusion and exclusion

From January 2021 to November 2022, patients undergoing treatment for recurrent patellar dislocation were prospectively recruited from three Norwegian orthopaedic centres. Inclusion criteria were ≥ 13 years at surgery and ability to understand and complete the Norwegian questionnaires. Patients with concomitant knee injuries were excluded.

Study I included all eligible patients (N=100), while study II involved only patients who conducted functional assessment six months after surgery (N=78). Study III

included a convenience sample of 15 patients who had completed the postoperative assessment at six months.

6.3 Surgical procedures

Most patients had a MPFL-R by use of a gracilis autograft from the ipsilateral knee. The graft was either harvested from a medial oblique parapatellar incision above the pes anserinus or, in cases of combined tibial tubercle osteotomy, from a central incision. The tendon was inserted in the medial proximal patella through two connected anterior drill holes. Further, the tendon was tunnelled down to its femoral insertion and secured with a PEEK interferences screw (Arthrex, Naples, US). Tunnel placement was checked by fluoroscopy ad modum Schöttle (47). Isometry was verified and graft fixation was done with the knee in 70° of flexion to avoid over constraint of the patellofemoral joint.

TTO with distalisation or medialisation was considered in cases of patella alta or in patients with a lateralisation of the patella. Distalisation was typically considered if the Caton-Deschamps Index was above 1.3 and/or if the Patella Trochlear index was below 0.18. Medialisation of the tibial tubercle was typically considered if the TT-TG distance was ≥15-20 measured on MRI. The osteotomy cut was made on two guidepins placed parallel in a medio-lateral, anterior-posterior direction through the tibial tubercle. After medialisation and/or distalisation was performed, the osteotomy was secured by 2 fully threaded 3.0 mm cortical screws (Synthes, Raynham, US).

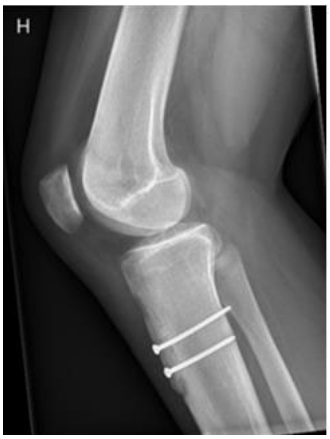

Fig. 5. X-ray of tibial tubercle osteotomy, with permission from the patient.

Finally, a trochleoplasty was considered in cases of a dysplastic patella. Typically, Dejour type B and D dysplastic trochlea with a proximal bump and/or a lateral

trochlear index (LTI) of less than 11° were considered for surgery. A semi-open thin-flap technique was performed through a lateral parapatellar incision. The retinaculum was split to allow for a lengthening procedure at closure. Removal of any suprapatellar bump was performed before an undermining of the cartilage with a 3.2 mm burr was done from a proximal-lateral direction. The undermining was continued until a plastic deformation of the central trochlea could be achieved by applying a manual pressure on the cartilage. Two or more bioabsorbable SmartNail implants (ConMed, Utica, US) were placed to create the new groove of the trochlea.

6.4 Advice and restrictions before and after surgery

Prior to surgery, all patients had been advised to undergo an exercise program targeting neuromuscular deficits. General advice on early neuromuscular control exercises were given upon discharge from the day-care unit, and all patients conducted postoperative rehabilitation by their local physiotherapist. Patients did not wear a brace and were allowed foot-touch weight-bearing from the first postoperative day, supported by crutches for six weeks. From four weeks postoperatively, patients were allowed gradually increased weight-bearing until weaning off crutches.

6.5 Study I and II

6.5.1 Sample size

In study I, sample size was determined according to recommendations from Terwee et al. (62), suggesting a minimum of 50 patients for assessing construct validity, reliability, and floor or ceiling effects, and a minimum of 100 patients for assessing internal consistency (62 p.191).

Study II no formal sample size calculation was performed. However, a target of 75 patients was set to be able to investigate correlations with Pearson`s *r* (81).

6.5.2 Translation and cross-cultural adaptation of the BPII 2.0

Study I started with a translation of the BPII 2.0 into Norwegian. This process was done according to guidelines described by Beaton et al. (82). The first stage involved making two independent translations from English to Norwegian (by a physiotherapist specialising in orthopaedic physiotherapy and an orthopaedic surgeon, both with Norwegian as their native language and fluent in English). In the second stage, the translations were discussed, and a synthesized version was made. Stage three included back translations (from Norwegian to English) by two independent, professional translators both native speakers of English with no medical background. In stage four, an expert committee including the four translators in addition to two orthopaedic surgeons, three physiotherapists specializing in orthopaedic physiotherapy, a researcher with extensive experience in clinimetric research methodology and a teacher specialized in Norwegian was formed to discuss discrepancies and ambiguities resulting in a pre-final version. The original developer of the questionnaire gave permission to perform the translation before the project was started and consulted when needed during the translation process. A twelve-year-old child completed the pre-final version of the questionnaire and commented on difficult wording to ensure readability for adolescents before the pre-final version was tested in the target population at stage five. At stage six, the developer reviewed a table displaying the items from the original questionnaire, the corresponding Norwegian items and the back translations.

The measurement properties of the BPII 2.0 were then evaluated according to recommendations by COSMIN (62, 80). As no gold standard exists to compare the scores of the measurement instrument to, construct validity was evaluated with hypothesis testing (62, p. 169). The following pre-defined hypotheses were therefore based on a former validation study on BPII 2.0 (69), findings from previous translations (83, 84) and clinical experience (Table 1). We expected measures of self-perceived PI (NPI) and kinesiophobia (TSK) to have large negative correlations with the BPII 2.0–No because of the inverse nature of the scales. PROMs that measured similar constructs (KOOS and IKDC) were expected to have large positive

correlations with the BPII 2.0-NO. Further, as knee function is assumed to affect QoL, hypotheses about associations between functional tests (YBT-LQ and hop tests) and the BPII 2.0–NO were also included. We expected functional tests to have a small to medium positive correlation with the BPII 2.0–No, as functional tests only address the physical dimension of QoL.

Table 1. Pre-defined hypotheses on construct validity of the BPII 2.0.

1	A medium to large negative correlation ($-0.30 < r < -1.0$) between NPI and BPII 2.0
2	A large negative correlation ($-0.50 < r < -1.0$) between TSK and BPII 2.0
3	A large correlation ($0.50 < r < 1.0$) between IKDC 2000 and BPII2.0
4	A large correlation ($0.50 < r < 1.0$) between KOOS QoL and BPII 2.0
5	A large correlation ($0.50 < r < 1.0$) between KOOS Pain and BPII 2.0
6	A large correlation ($0.50 < r < 1.0$) between KOOS Sport/Rec and BPII 2.0
7	A large correlation ($0.50 < r < 1.0$) between KOOS Symptoms and BPII 2.0
8	A large correlation ($0.50 < r < 1.0$) between KOOS ADL and BPII 2.0
9	A small to medium correlation ($0.10 < r < 0.50$) between functional tests and BPII 2.0

BPII Banff Patellofemoral Instability Instrument, *NPI* Norwich PI Score, *IKDC 2000* International Knee Documentation Committee Subjective Knee Form 2000, *TSK* Tampa Scale of Kinesiophobia, *KOOS* The Knee injury and Osteoarthritis Outcome Score

6.5.3 Outcome evaluation

Figure 6 provides an overview of measurement instruments used inn study I and II.

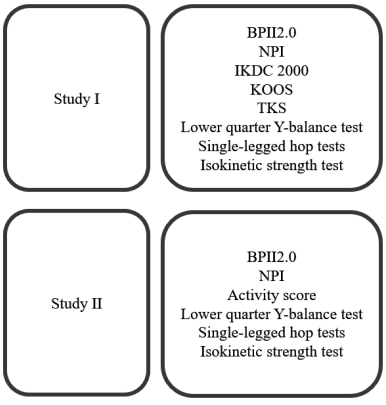

Fig. 6. Measures of function in the patellofemoral joint used in study I and II.

Further, in study II the ICF was used as a framework to ensure the selected outcome measures evaluated relevant aspects of patients knee function (85).

Table 2. RTS criteria categorisation and associated International Classification of Functioning, Disability and Health (ICF) framework classification

Outcome measure	**Corresponding ICF framework classification**
Isokinetic strength	Impairments
Y-balance test	Impairments
Single-legged hop tests	Activity (limitations)
Self-reported function	Participation (restrictions)

Patient-Reported Outcome Measures

The **Banff Patellofemoral Instability Instrument 2.0** (BPII 2.0, Appendix 1) is a disease-specific quality of life (QoL) score covering five domains: symptoms/physical complaints, work-related concerns, recreational activity and sport participation/competition (68). Each of the 23 items are equally weighted and answered on a Visual Analog Scale (VAS). A total score is calculated as an average of the responses on each question, range 0 – 100, where a higher score reflects a higher QoL (68).

The **Norwich Patellar Instability** score (NPI, Appendix 2) is developed to assess patient-perceived symptoms of PI during activity. It includes 19 questions using a five-point Likert scale with options from “never” to “always” (4). The sum score ranges from zero to 100 and is presented as a percentage where a higher score indicates higher instability (31). The NPI has demonstrated good measurement properties in several domains (4, 31, 86), including adequate construct validity (4, 31, 69) high internal consistency and responsiveness (4). The score has recently been translated into Norwegian (translation process completed; provided by the STAR research group).

The **International Knee Documentation Committee Subjective Knee Form** (IKDC) 2000 (Appendix 3) is a knee-specific, patient-reported tool, including 18 questions with varying response format. The questionnaire comprises three domains: symptoms, physical activity, and function. One total score, ranging from 0 - 100, is calculated by summarising all items and dividing them by the maximum possible score x 100. A higher score indicates a better function and high levels of participation (87). The IKDC has demonstrated good psychometric properties for patients with mixed knee pathologies and injuries (88), and is validated in patients with PI (89).

The **Knee injury and Osteoarthritis Outcome Score** (KOOS, Appendix 4) is developed to assess patients' opinions about their knee function and associated problems. It comprises five domains: pain, other symptoms, activities of daily living, function in sports and recreational activities and knee-related QoL. A total sum score is not calculated, rather, scores from each subscale is reported separately and ranges from 0 (low function) to 100 (highest function) (90). The KOOS was developed for patients with knee injuries and/or osteoarthritis but is frequently used in patients with PI. The questionnaire has demonstrated satisfying psychometric properties in a variety of knee conditions (90).

The **Tampa Scale of Kinesiophobia** (TSK, Appendix 5) is developed to measure fear of movement in patients with low back pain (91). It is also widely used to assess kinesophobia after knee injuries such as ACL ruptures (92-95), and has been used to measure fear of re-injury in patients after MPFL-R (25). Patients rate their agreement on each of the 13 included statements using a four-point Likert scale ranging from "strongly disagree" to "strongly agree". The total score is calculated summarizing all items, ranging from 13 – 52, where a higher score indicates more fear of movement (91). The Norwegian version of the TSK is validated for patients with sciatica showing adequate construct validity, test-retest reliability and internal consistency (96).

A project-specific **activity questionnaire** (Appendix 6) was developed by a physiotherapist and an orthopaedic surgeon at Haraldsplass Deaconess Hospital to map patients level and type of activity/sports before and after surgery, including

motivation for returning to sports. First, patients were asked to mark their main pre-injury sport. Next, patients stated at which level they performed their activity/sports before their first dislocation episode. Levels were categorized as elite, high/medium level of competition, low level of competition or recreational level. Then, patients' current level of performance and knee function during activity were registered. Finally, motivation for resuming pre-injury level of performance was registered on a 10 mm VAS scale. No scores were assigned to the answers and no sum score was calculated. The questionnaire was made in Norwegian, therefore an English summary of the content is presented in Table 3.

Table 3. Sports and activity before and after patellar stabilizing surgery

Questions		Answer options
1.	What was your main sport/activity before injury?	Soccer, team handball, basketball etc.
2.	At what level did you perform your sport/activity before injury?	1) Elite, 2) High to medium competitive, 3) Low competitive, 4) Recreational
3.	At what level do you currently perform your main sport/activity?	1) Elite, 2) High to medium competitive, 3) Low competitive, 4) Recreational, 5) Quit, 6) Have not tried yet
4.	How is your knee function during your main sport/activity now?	1) As before injury, 2) With small complaints, 3) With considerable complaints, 4) Quit because of my knee problems, 5) Have not tried due to fear of new dislocations, 6) Quit, other reasons
5.	Grade your current motivation for resuming your main sport/activity at pre-injury level	100 mm VAS scale

English summary of content

Functional tests

All patients were assessed by TH-D, who was not involved in any former treatment of the patients. At the day of testing, questionnaires were completed before patients had a seven-minute warm-up on a stationary bike. To standardise the degree of motivation and feedback provided patients were only given a minimum of encouragement during the functional assessment. The tests used for readiness assessment were selected based on two former expert recommendations and included YBT-LQ, single leg hop tests and isokinetic strength tests (76, 77).

The **Y-Balance test-Lower Quarter** (YBT-LQ) evaluates lower extremity strength, knee stability and dynamic balance in anterior, posteromedial and posterolateral direction (Figure 7) (97). For each direction, three practice trials were allowed before

three test trials were recorded. To reduce fatigue, patients altered legs before continuing to the next direction, starting with the contralateral leg. Attempts were discarded and repeated if the patient failed to maintain hands on hip, unilateral stance or failed to return the reach leg to the starting position under control. Mean reach distances (in centimetres, cm) were normalized to leg length, which was measured from the anterior superior iliac spine to the most distal portion of the medial malleolus. The results are presented as reach values normalized to leg length in all three directions, difference in anterior reach distance (cm) between legs (contralateral – involved) and a composite score determined using the following equation: Composite score = $\frac{anterior\ reach + posteromedial\ reach + posterolateral\ reach}{3\ x\ limb\ length}$ x 100. The YBT-LQ is a reliable test when measuring single leg dynamic balance (97, 98).

Fig. 7. Y-Balance test-Lower Quarter, photo: Trine Hysing-Dahl

The **single-legged hop test** evaluates function, dynamic strength, and lower extremity muscle power (36, 76). It comprises four hop tasks: a single hop as far as possible cm); triple hops as far as possible (cm); triple crossover hops as far as possible (cm); and 6-m timed hops as fast as possible (in seconds) (Figure 8) (99). Starting with the contralateral leg, one practice trial on each test was performed before two test trials were recorded. No rest was allowed between tests. Mean of the two counting tests was calculated before a Leg Symmetry Index (LSI%) value was made with the following equation: $\frac{involved\ leg}{contralateral\ leg}$ x 100. For the 6-m timed hop, LSI was:

$\frac{contralateral\ leg}{involved\ leg}$ x 100. A score of 100% means there is complete symmetry in the performance between the legs. Values <100% indicate a deficit in the involved leg (97, 98). To allow comparison between studies, results were also presented as absolute values (in cm and seconds). Hop tests are reliable and valid for patients with other knee injuries such as ACL ruptures (100).

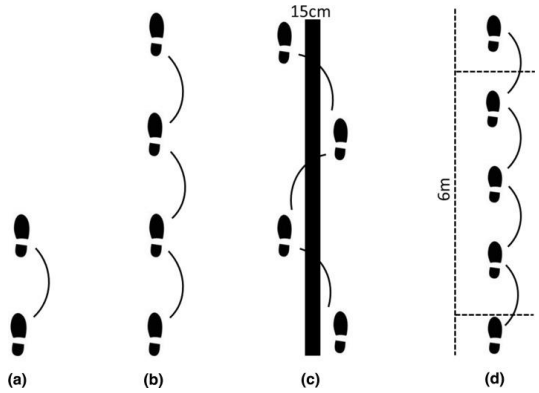

Fig. 8. Illustration of the 4 single leg hop tests: **a** single hop for distance, **b** triple hop for distance, **c** cross-over hop for distance, **d** 6-m timed hop (32).

Concentric muscle strength was evaluated using an **isokinetic dynamometer testing system** (Biodex system 4 dynamometer, Biodex Medical Systems Inc.). The contralateral leg was tested first following the protocol recommended by Undheim et al. (33): Concentric mode of contraction, 5 repetitions at 60º/sec angular velocity with range of motion of 0-90º using gravity correction. Performance is presented as absolute values (in Newton meters (Nm)), and an LSI% in peak torque (PT) Nm (101). Isokinetic strength tests are considered the 'gold standard' for measuring muscle strength (102) and is a reliable and valid outcome measure after other knee injuries (103).

Fig. 9. Isokinetic testing, photo: Ingrid Færøyvik.

6.5.4 Return-to-sport readiness criteria

RTS clearance criteria were defined as previously suggested for patients with PI (59, 76, 77): LSI ≥95% composite score for the YBT-LQ, ≤4 cm YBT-LQ anterior reach difference between legs, LSI ≥85% for all single-leg hop tasks and LSI ≥90% in quadriceps strength. The BPII and NPI were a supplementary part of the RTS assessment, utilized to capture patients self-reported function, including mental readiness for RTS. As no evidence exists regarding clearance cut-off values for these two PROMs, they were not included in the RTS clearance criteria. If patients did not meet the criteria, they were advised to avoid pivoting sports and continue rehabilitation.

6.5.5 Statistics

All statistical analyses were performed using the IBM SPSS Statistics for Windows, version 26.0 (IBM Corp). The a priori significance level was set to ≤0.05. Descriptive analyses were expressed as mean ± SD for continuous variables and frequencies and percentages for categorical variables. Normality of data was tested using the Kolmogorow-Smirnov test and assessed visually by histogram inspection.

Study I: Internal consistency of the BPII 2.0-NO was assessed with the Cronbach's alpha coefficient (α). Test-retest reliability was evaluated calculating Intraclass Correlation Coefficient ($ICC_{2.1}$) with 95% confidence intervals (CI) based on two-way random, single measures with absolute agreement. Standard error of measurement (SEM) was calculated from the mean of the variance between tests with a corresponding 95% CI to suggest the limits of measurement error (1.96*SEM). The smallest detectable change (SDC) at individual level (SDC_{ind}) was calculated based on SEM ($1.96 \times \sqrt{2} \times SEM$) and on group level ($SDC_{group}$) based on SDCind/√n. To evaluate Limits of Agreement (LoA) a Bland-Altman plot was used and inspected for heteroscedasticity. Hypotheses testing was performed using Pearson's r. Finally, the BPII total score was examined for floor and ceiling effects by calculating the number of patients who scored within the lowest or highest 15%.

Study II: Independent samples t-tests were conducted to investigate differences in (1) peak torque (2) reach distance and composite score YBT-LQ and hop tests between the legs and (3) differences in performance based on whether patients had uni- or bilateral problems, extent of surgery, age and level of activity. Associations between measurements were evaluated using Pearson`s *r*. To examine which factors that were associated with performance on functional tests, backward multiple regression was performed with performance (z-scores) at six months postoperative as the dependent variable. Results from each functional test was normalized to z-scores (z = x – population mean/population standard deviation). Independent variables were age, gender, extent of surgery, duration of symptoms and having bilateral or unilateral problems. Only variables with a p-value ≤ 0.10 were included in the final model. In the linear regression analysis multicollinearity was assessed by inspecting the tolerance values.

6.6 Study III

6.6.1 Sample size

Study III is explorative, therefore information power, a pragmatic model of guiding sample size, was found to be appropriate. This model concern the study aim, sample specificity, quality of dialogue and analysis strategy (104). Based on these considerations the initial sample size was set to 10 participants, and evaluation during the research process led to an increased final sample size of 15 participants to reach sufficient information power.

6.6.2 Interviews

This study's aim was to explore personal experiences, and we wanted to give the participants time and space to bring out concrete, detailed and uninterrupted stories. Individual interviews can be experienced as safer and more protective for the participants telling their personal stories compared to focus-group interviews (105, p. 130) and individual interviews were therefore used to explore the patients' experiences of living with PI before and after surgery. The interview guide

(Appendix 7) was developed by TH-D and LHM in cooperation. While TH-D has extensive experience with treating patients with PI, she was inexperienced with qualitative research. Professor LHM is an experienced researcher within the qualitative field. The guide was not pilot tested, but the themes in the interview guide were thoroughly discussed with the other co-authors (EI and AGHF). During the interviews, short fieldnotes were made to capture the atmosphere, and to validate the transcripts and analysis. The interviews were conducted immediately after the six months postoperative assessment or by telephone at up to 12 months after surgery. Before starting the interview, a short introduction of the project was made. It was emphasized that no right or wrong answers existed. Next, we started with an overall question: *"How has it been for you to live with an unstable kneecap?"* The dialogue then involved reflections on how PI had affected patients' lives, including thoughts on the following topics: function in everyday life, sports and leisure activities and changes after surgery. The first four participants were also asked about relevance, comprehensibility, and missing topics in the interview guide. TH-D strove to keep a flexible approach during the interviews to ensure that the conversation could follow the participants stories and that the participants were interrupted only when clarification or elaboration was needed.

6.6.3 Interview analyses

The data material was analysed with Systematic Text Condensation (STC) as described by Malterud (106). Similarities, differences, and variations in experiences from several participants were analysed in this four-step thematic cross-case strategy that offers a framework befitting the explorative aim of the study (106). A stepwise analysis was performed at each level but the process was iterative, allowing for increased understanding at one level to cause a step back and reconsider the content of another level (Figure 10) (106). LHM and TH-D were part of the iterative process, going back and forth throughout the analytical process.

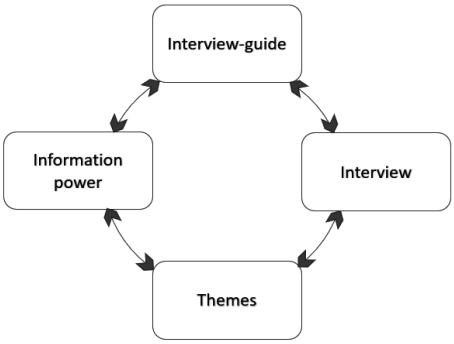

Fig. 10. Illustration of the iterative analysis (indicated with the arrows) of systematic text condensation.

Step 1: *Total impression - from chaos to theme* (106). After four interviews, we (LHM and TH-D) read the transcripts to gain an overview of the data, striving to bracket the preconceptions and still having an interpretative position determined by the research question (106). Preliminary themes were identified and discussed, hence bringing together statements concerning the same topics (it is all in my head (TH-D) and fear of dislocations (avoidance) (LHM)).

Step 2: *Identifying and sorting meaning units – from themes to codes* (106). The transcripts were coded based on the patients' experiences. Coding at this stage started with the themes identified in Step 1, but focused on transcending previous preconceptions (106). An overview of themes and content that LHM and TH-D discussed was used as a decision trail during the analysis if we needed to go back to identify what we assessed during the analysis (106). Before the next step, we revised the meaning units to target the study's aim with a more specific view. For example, if the participants were talking about other problems, not related to PI, we omitted the meaning unit.

Step 3: *Condensation – from code to meaning* (106). The content in each code group was considered an analytic unit and was further abstracted by condensing the content of the meaning units from step 2 (106). The meaning units from each code group were then merged and the essence was summarised in first-person format.

Step 4: *Synthesising – from condensation to descriptions and concepts* (106). TH-D took the role of a re-narrator and wrote the material in the third person (105) before the text was translated into English. This step aimed for a multivocal outcome of stories synthesised through cross-case analysis. An illustrative quote from each code was chosen and used in its original form to elucidate the findings (106). We worked through the material several times, and from the code groups and subgroups in Step 2, we ended up with a results section of four themes, where one had two sub-themes.

6.7 Ethics

A study protocol, describing design, data collection and storage of data was approved by the NSD (Norwegian Centre for Research Data) Data Protection Official for Research (ID: 731409) and the Regional Committee for Medical and Health Research Ethics (REK MIDT(ID: 185067)) before any contact with the patients were made. Data storage on a local research server at Helse Bergen was approved by the Chief Safety Representative. All eligible patients were invited to participate in this study, and information that they could withdraw from the study without consequences for their treatment at any time point were given both verbally and written. Patients aged 13 to 16 years old were invited to participate through their parents, and the adolescents received an information letter with information adjusted to their age (Appendix 8). Informed, written, consent was obtained from all patients prior to data collection. Information and rights about data protection were given in the information letters (Appendix 9 and 10). All investigations were performed free of charge for the patients (funded by the study financing). Potential travel expenses were not covered by the study, but effort was made to guide those who wanted to apply for a refund of travel expenses to a public refund program (Pasientreiser). If the postoperative follow-up revealed knee problems that needed further treatment, patients were offered further follow-up by their surgeon.

7. Summary of papers

7.1 Paper I

Cross-cultural validation of the Norwegian version of the Banff Patellofemoral Instability Instrument 2.0

Aims: To translate, and cross-culturally adapt the BPII 2.0 from English to Norwegian and examine the measurement properties of the Norwegian version (BPII 2.0-NO).

Patients: Patients undergoing surgical treatment for recurrent patellar dislocation were prospectively recruited from two Norwegian Orthopaedic Centres. One hundred and sixteen patients were found eligible for enrolment and 109 agreed to participate. After initial acceptance nine patients never returned the questionnaires. Therefore were one hundred patients included in the analysis, 71 women (71%) and 29 men (29%).

Methods: BPII 2.0 was translated according to internationally accepted guidelines before the BPII 2.0-NO was piloted on ten patients. Face validity was assessed by the expert committee and content validity was assessed by ten patients evaluating the pre-final version. Hypotheses on associations between BPII 2.0-NO and questionnaires and functional tests measuring similar constructs were defined to establish construct validity.

All 100 patients completed the BPII 2.0-NO, the NPI, the IKDC 2000, the KOOS and TSK before and/or six months post-surgery. A subgroup of 50 patients completed the BPII 2.0-NO two weeks before and again at the six months assessment for evaluation of test-retest reliability. Sixty-two participants conducted functional tests consisting of the YBT-LQ test, single-legged hop tests and isokinetic strength tests upon questionnaire completion six months post-surgery.

Results: The BPII 2.0-NO had good face and content validity and no cultural adaptation was necessary. The patients who participated in the pilot testing of the questionnaire expressed that the BPII 2.0-NO was relevant to them and shed light on aspects that no other PROMs covered.

Internal consistency was excellent (α 0.95) and the α value ranged from 0.95 to 0.96 if any of the 23 items were deleted. No floor or ceiling effects were found, and test-retest reliability was high ($ICC_{2.1}$ 0.87 CI 0.77-0.93). A measurement error (SEM) of 7.1 means that for one individual a score change needs to exceed 19.7 points (and 2.8 on a group level) to be interpreted as a true change beyond measurement error.

Support for good construct validity was found as eight out of nine pre-defined hypotheses were confirmed. There was a medium negative correlation (r = -0.48) between the BPII 2.0-NO and the NPI and a large negative correlation (r = -0.57) between the BPII 2.0-NO and the TSK. Further, a large correlation (r = 0.56) between the BPII 2.0-NO and the IKDC 2000, and a medium to large correlation (r = 0.47-0.72) with all KOOS subscales was evident. The hypothesis on a small to medium correlation between the BPII 2.0-NO and functional tests was not confirmed as no statistically significant correlation was found to the YBT-LQ, hop tests and strength tests (all P >0.05).

Conclusion: The BPII 2.0-NO is valid and reliable for assessment of QoL before and after surgery in Norwegian patients with PI.

7.2 Paper II

Feasibility of return to sports assessment 6 months after patellar instability surgery

Aims: To explore the feasibility of functional tests assessing readiness for return-to-sport six months after patellar stabilizing surgery.

Patients: Of 98 patients screened for eligibility, 7 patients were excluded because their indication for surgery was patellofemoral pain, 1 patient had concomitant knee injury, 3 patients were mentally disabled, 2 patients underwent revision surgery and 7 patients declined participation. This left 78 patients (71% female, mean age 22.3 ± 6.9 (range 13-45 years), BMI 25.3 ± 5.2) to be enrolled in this study. Time since first dislocation was 7 years (± 5.9) and 60% reported bilateral instability. Fifteen patients underwent an isolated MPFL-R, while 63 underwent combined surgery (including either TTO and/or trochleoplasty).

Methods: At six months after surgery for recurrent PI with an "a la carte" approach, patients first completed PROMs (the BPII 2.0, the NPI and a project-specific return-to-sport questionnaire) before they underwent functional testing (YBT-LQ, single-legged hop tests and isokinetic strength tests). RTS clearance criteria were defined as: ≤4 cm YBT-LQ anterior reach difference between legs, LSI ≥95% in the YBT-LQ composite score, mean sum score LSI ≥85% of all single-leg hop tests and LSI ≥90% in isokinetic quadriceps strength.

Results: Sixty-four patients (82%) were able to complete *all* functional tests. In the separate tests, all - but 1 - completed the YBT-LQ test, 82% completed the hop tests, and all patients completed the isokinetic strength testing. Only 11 patients (14%) were deemed ready for RTS, passing *all* the RTS clearance criteria. In the YBT-LQ test, 64% passed the two return criteria, while 42% patients reached the RTS clearance criteria (LSI ≥85%) for the single-legged hop test and only 19% of patients achieved the RTS clearance criteria on the isokinetic strength test. The eleven patients who passed all RTS criteria were younger (mean 17.4 compared to mean

22.3 years for the non-passers) and more often had bilateral problems compared to the rest of the cohort. Their level of activity before surgery was equal to the others.

Patients with bilateral problems demonstrated worse performance in the contralateral leg compared to patients with unilateral problems. This resulted in higher LSI scores compared to individuals with unilateral instability.

The extent of surgery (MPFL-R only versus combined surgery) did not affect self-reported function or functional performance at the six-months follow-up except for normalized anterior reach distance in involved (68.5 ± 5.5 vs 64.2 ± 7.5; *P*=.04) and contralateral leg (71.5 ± 4.0 vs 68.0 ± 7.0; *P*=.01), where a minor correlation was found between extent of surgery and reach distance (0.234, *P*=.04 and -0.208, *P*=.06). Meaning that patients undergoing combined surgery had shorter anterior reach distance. Lower age and male gender predicted better performance at six months postoperatively with a shared explained variance of 21%.

Conclusion: The functional assessment used in the current study is feasible to conduct at six months after patellar stabilizing surgery. However, considering the low rates of patients reaching clearance values, the current clearance standards and/or the timing of assessment for RTS is inappropriate. The use of LSI for patients with PI should be questioned. Therefore, further exploration of appropriate tests, RTS clearance criteria and timing for RTS testing is justified.

7.3 Additional analyses Study II (unpublished material)

To explore whether the functional tests and PROM scores measured overlapping constructs, additional analyses on correlations between the measurements in the six months assessment were conducted. A statistically significant correlation was found between knee extension strength in involved leg and performance on all four hop tests (r = 0.58 - 0.70, $P \leq .05$) and YBT-LQ tests (r = 0.29 - 0.33, $P \leq .05$), meaning that those who displayed more knee extension strength performed better on hop performance and had increased dynamic knee stability (see table 4 for correlations).

There was also a significant correlation between performance on YBT-LQ test and hop tests (r = 0.26 - 0.56, $P \leq .05$) However, no correlation was found between self-reported function (NPI and BPII 2.0) and functional performance, except a minor correlation between BPII 2.0 and knee extension strength (r = 0.23, P=.043).

Table 4. Statistically significant correlation between performance and self-reported function in the *involved leg* (N=78)

Measurement	**Measurement**	**Pearson's *r***	***P* value**
BPII 2.0	PT extension 60°/s, Nm	.234	**.043**
PT extension 60°/s, Nm	YBT-LQ, Composite score	.328	**.004**
PT extension 60°/s, Nm	YBT-LQ, Normalized reach (%)	.293	**.011**
PT extension 60°/s, Nm	Single hop for distance, cm	.576	**.001**
PT extension 60°/s, Nm	Triple hop for distance, cm	.698	**.001**
PT extension 60°/s, Nm	Crossover hop for distance, cm	.684	**.001**
PT extension 60°/s, Nm	6-m timed hop, s	-.641	**.001**
YBT-LQ, Composite score	Single hop for distance, cm	.375	**.002**
YBT-LQ, Composite score	Triple hop for distance, cm	.375	**.001**
YBT-LQ, Composite score	Crossover hop for distance, cm	.428	**.001**
YBT-LQ, Composite score	6-m timed hop, s	-.566	**.001**
YBT-LQ, Normalized reach (%) anterior	Single hop for distance, cm	.282	**.017**
YBT-LQ, Normalized reach (%) anterior	Triple hop for distance, cm	.263	**.032**
YBT-LQ, Normalized reach (%) anterior	6-m timed hop, s	-.327	**.008**

YBT-LQ, Y-Balance test-Lower Quarter, PT, Peak Torque, Nm, Newton meter, (P<.05).

Table 5. Performance at six months postoperatively according to level of sports participation.

Test	**All patients**	**Sports active patients (N=29)**	**Not sports active patients (N=48)**	***P* Value**
Performance composite (z-score)	0.003 ± 0.68	0.17 ± 0.65	-0.07 ± 0.68	.063

7.4 Paper III

Patients' experiences of living with patellar instability before and after surgery. A qualitative interview study.

Aim: To explore the experience of living with PI before and after surgery.

Patients: To obtain rich data with a variation in experiences a sample of 15 participants (11 women), aged between 16 and 32 years, with different levels of physical activity, who had undergone functional assessment at six months after surgery for recurrent PI were included.

Method: Individual semi-structured interviews of patients after surgery for PI were conducted with participants recruited from an ongoing trial on functional assessment of PI. The three overall themes in the interview guide were function in everyday life, sports and leisure activities and changes after surgery. Data were analyzed using STC, a four-steps thematic cross-case strategy for analyses of qualitative data. The first step is used to get an overall impression of the material before meaning units are sorted and code groups are established in step two. In step three condensates are abstracted from each code group before a reconceptualised description of each subgroup is presented in step four.

Results: Participants offered rich and detailed descriptions of the impact and lived experience of PI, including fear of new dislocations, increased awareness of the knee and adaptations to avoidance behaviour in everyday life both before and after surgery. A key finding was that PI had a significant impact on participants' lives. It was described to affect their mental as well as physical well-being. Their stories revealed a constant fear of dislocating the patella and for the majority, this fear was present for years before treatment started and some degree of fear persisted after surgery. The four major themes that emerged from the data were: 1) fear of patella dislocations governs everyday life activities, 2) adaptation to avoidance behaviour, 3) feeling different, misunderstood, and stigmatized affects self-esteem and 4) feeling stronger, but still not fully confident in the knee after surgery.

Conclusions: These findings offer new insight into the experience of living with PI. Patients reported that the instability had major impacts on their everyday life, affecting ability to participate in social life and physical activities both before and after surgery. The increased fear, awareness and adaptive behaviour may imply that an increased attention towards cognitive interventions might be useful in the management of PI.

8. Discussion

The knowledge base regarding functional assessment before and after patella stabilizing surgery is scarce. Therefore, the overall aim of this thesis was to gain new knowledge about appropriate methods for functional evaluation of patients with PI and to increase our knowledge on how the patients themself experience their condition. As part of this assessment, the questionnaire BPII 2.0 was translated to and validated in Norwegian. To deepen insights on how the patients experience to live with PI qualitative interviews were conducted.

8.1 Methodological considerations

8.1.1 Method triangulation

Triangulation, often referred to as mixed methods, is a strategy used to add richness and depth to a research topic (107). Study I and II aimed to examine psychometric properties the BPII 2.0 and investigate whether RTS assessment was feasible six month after surgery, while study III sought knowledge on the experience of living with PI. Therefore, this thesis consists of studies of both quantitative and qualitative design. This method triangulation is used to provide a more comprehensive understanding of the phenomenon of interest, PI, and possibly enhance the rigour of the studies. Using different methods represent a strength of this thesis as the quantitative approaches provide width and overview of the issue, whereas qualitative methods provide in-depth descriptions of lived experience and increase our understanding of the phenomenon (105). This became particularly clear when study III revealed that the ripple effects of PI was more comprehensive than expected, further emphasising the relevance of the patient perspective in the treatment of these patients.

8.1.2 Internal validity in study I and II

Study design

Strengths of the designs in study I and II are the prospective inclusion of a population representative of this patient group, sufficient sample sizes and investigations performed by an independent researcher not formerly involved in the patient's treatment. Moreover, following COSMIN guidelines when examining the psychometric properties of the BPII-NO 2.0 and evaluating a RTS test battery consisting of both physical performance tests and self-reported function are strengths of these studies. The goal was to identify relevant and valid tools for clinicians to use when they assess health-related QoL and knee function after surgery. However, as the design in both studies is observational, therefor, conclusions should be drawn with caution.

In study I the BPII 2.0 was translated and evaluated according to international recommendations (64, 80, 82, 108). The interval between test and re-test should be long enough to prevent recall and short enough to minimize the risk of changes in the patient's condition (72). We assumed that a two-week interval between tests, as recommended by de Vet et al. (62, p 125.), was sufficient to fulfil these criteria. However, in the translation process the two translators of the original version, had both a medical background. This represents a minor limitation as it is also recommended to provide translations from a person without a medical background to ensure that the translation is meaningful for patients without medical experience (82). Further, although ten patients were thoroughly interviewed about the relevance, comprehensiveness and understandability of the questionnaire, content validity could have been examined in a qualitative study with a clear methodological approach, for example STC (65).

Study II provides information on what to expect of functional performance six months after surgery, a much-needed supplement since few former studies have reported results from functional tests on patients after patellar stabilizing surgery (24, 25, 37, 38). However, this also entails that selecting tests for the functional

assessment was a challenge. We therefore chose tests based on the available studies (24, 25, 37, 38), expert recommendations (59, 76, 77) and clinical experience. Whether other tests may provide more precise and relevant information about functional performance for these patients is there unknown. Although the functional tests used in study II are recommended for use in RTS decisions following patellar stabilizing surgery we do not know to which degree these tests can predict a safe RTS (76, 77).

The amount of research to inform the choice of RTS readiness clearance criteria in study II was scarce (21, 36, 76). The evidence supporting the chosen criteria consist solely of expert recommendations (73, 76, 77). Though regaining strength and dynamic function comparable to the uninvolved leg seems to be a reasonable measure of being ready for RTS, future studies should critically evaluate whether these criteria make us able to predict a safe RTS and establish appropriate and achievable readiness criteria. No PROMs were included in the RTS readiness criteria as no evidence, nor any expert opinions, exist regarding clearance values and population-based data are not yet available. Consequently, interpretation of the postoperative BPII 2.0 and NPI values remains limited.

The timing of readiness assessment should factor biological healing allowing sufficient MPLF graft integrity and, if bony procedures are performed, bony healing (5, 75). Taking only these factors into account, performing RTS testing at six months after surgery seems reasonable. In support of this, several systematic reviews have reported that most patients have returned to pre-injury level of activity around this time (73, 74, 76). The six-month follow-up time point was therefore chosen. However, looking at the low pass rates, one might suspect that patients need more time to undergo rehabilitation before they consider returning to knee-challenging tasks. As RTS clearance criteria for patients with PI are inspired by research on ACL injuries it is reasonable to look at recommendations in this group where RTS assessments mostly occur at a minimum of nine months after surgery. At this timepoint structural integrity of the ACL graft and sufficient knee function is thought

to be achieved (109). Perhaps this is a more appropriate timing for readiness evaluation in patients with PI as well.

Selection bias

A selection bias occurs when the study sample is systematically different from the population of interest, in this case patients surgically treated for recurrent PI (110). In study I and II, we included both genders with an age range of 13-42, patients with short- lasting - and patients with long-lasting symptoms with a wide span of activity levels and BMI (19–47). This diverse group of patients reflects the population of interest (3-5).

The population in study I and II constitutes a heterogenic population when it comes to activity level and sports participation. In study I this represents a strength, however, in study II it may be considered a limitation as the results can be challenging to interpret due to this diversity in activity level and expected performance on tests. Further, most patients were female in study I and II. This is considered a strength of the current studies as it reflects the distribution among genders who experience PI (2).

Study I included 86% of all surgically treated patients with PI in the two hospitals in question throughout the inclusion period, no selection was done at inclusion. This means that the validity of the BPII 2.0-NO has been examined in a broad spectrum of patients needing surgery for PI, as recommended for such validity studies (62). However, to prevent that local preferences affect the results, the cross-cultural validation should ideally have been conducted in several hospitals spread across the country. It is, however, reasonable to assume that the measurement properties found in the population from Western Norway are applicable to the entire Norwegian speaking population.

Study II included a range of patients in terms of activity level. This implies that the population might not be representative of the more active patients with PI. The aim of Study II was to examine feasibility of the tests in the broad population of patients

with PI as a starting point for further studies on the usefulness of functional assessment for the whole, or a selected group of patients. Interestingly, additional analyses demonstrated that there was no significant difference in performance based on level of activity. Further, looking at the eleven patients who passed all clearance criteria, their pre-surgery level of sports were equal to the rest of the cohort.

Including patients who have undergone different surgical approaches (although that is the current surgical mainstay) in study II, may also be problematic as extent, or type, of surgery may affect performance at six months after surgery. We investigated if the extent of surgery predicted performance and PROMs scores six months after surgery. No significant differences were found, and the extent of surgery did not predict performance, indicating that patients treated with "a la carte" approach can be evaluated as a group. Another study from a similar regional cohort displays similar findings (111). In addition, including "all" patients in the same cohort, regardless of surgical technique, emphasize that results are generalizable to the broad spectrum of patients with PI.

Measurement bias

Prior to each functional testing, patients conducted practice trials to be familiarised with the test procedure. For the YBT-LQ and single leg hop tests the practice included three and one trial, respectively. Despite this pre-test familiarisation, the LSI on the hop tests increased throughout the testing, indicating that there could still be a learning effect. Perhaps a minimum of two practice trials should be recommended for each hop test. No such learning effect was seen in the YBT-LQ, indicating that three trials before testing is sufficient. In the isokinetic strength testing, no practice run was performed (101). A familiarisation of this test could perhaps also have been conducted to minimize such a potential learning effect. For convenience, a tape measure was used instead of the proposed Y-Balance Test Kit^{TM}, whether such an adaption might affect results is not clear – but unlikely.

Although these functional tests are frequently used in RTS assessment after other knee injuries (101, 112) and suggested for patients with PI (52, 75-77) evidence is sparce or lacking on their measurement properties in this patient group.

The measurement properties of the PROMs used in the examination of construct validity in study I may have an impact on the validation process. The IKDC has demonstrated good psychometric properties for patients with mixed knee pathologies and injuries (88) and has been validated in patients with PI (89) with sufficient reliability. However the presence of a substantial ceiling effect in this population (47%) indicates poor validity (89). The existing Norwegian version used in the current study has not been formerly examined with a proper assessment of measurement properties. The KOOS has not been validated in patients with PI (66) and the use of KOOS in this patient group is debated (66) as the scale was originally developed to monitor the long-term consequences of acute knee injuries (meniscus, ACL tear and cartilage damage) (90). Further, the Norwegian version of the TSK is validated for patients with sciatica (96). In addition, has the original version been used to measure fear of re-injuries in patients that have undergone MPFL-R (25). It is also widely used to assess kinesiophobia after other knee injuries (92-95). No information on validity and reliability in patients with PI exists. Additionally, the measurement properties of the Norwegian version of the NPI has not been examined yet. Although limited information is available about most of these questionnaires for patients with PI, the Norwegian versions are in extensive use in research and clinical settings.

Another important aspect to recognise is recall bias from participants. Length of recall period could affect the answers in the PROMs (113) used in study I and II. The BPII 2.0 had the longest recall period of three months, and KOOS the shortest of one week. Meaning that when answering questions in the BPII 2.0 patients were instructed to take the last three months into consideration.

Confounding factors

There are a few potential confounding factors in the current thesis. In study II surgery type, age, gender, length of symptoms and bilateral problem were controlled for. Having a family history of PI, predisposing anatomy and/or repeated dislocation episodes prior to surgery are other potential confounding factors that were not accounted for. Further, in study II information given to patients from the medical caregivers were standardized or reported, meaning that patients may have been given varying advice about restrictions and return to pivoting activities. In addition, all patients were advised to undergo rehabilitation with their local physiotherapist and no standardized rehabilitation protocol was applied. Therefore we do not know the quality and quantity of training performed by each patient. Such potential heterogeneity in rehabilitation may have affected the results. The lack of evidence-based rehabilitation protocol for patients with PI makes it challenging to standardize rehabilitation for this patient group at this point. Establishing evidence-based rehabilitation protocols is therefore a crucial next step and future studies are warranted on this area.

8.1.3 Internal validity in study III

Data collection through interviews

By using semistructured interviews in Study III, the researcher becomes the instrument for data collection (105, p. 41). The effect of an unexperienced interviewer in uncovering relevant thematic areas during the conversations can be questioned (105). To account for the fact that TH-D was an unexperienced interviewer, the interview guide was developed in cooperation with LHM, who has extensive experience with qualitative research. LHM was also present at one of the first interviews to guide TH-D in the interview setting. In retrospect, rehearsal of the semi-structured interview technique with mock interviews could have prepared the unexperienced interviewer better. Further, some researchers suggest that participants are sent transcripts for comment to avoid misinterpretation due to researcher

preconceptions. This was not done in the current since the validity of using this method is questionable (114).

During the interviews, the patients were asked to remember past events, i.e. “How has it been for you to live with an unstable kneecap?”. Time from first dislocation to surgery (recall period) varied from one to 18 years. Although recall bias could occur with such a long recall period in some of the participants, the events of interest (patella dislocations) could be said to be such powerful and invasive experiences that remembering them would not be a problem. There was also a diversity in timing of the interviews, while some were conducted six months after surgery other participants were interviewed 12 months after. As the patients could have had a different level of functional recovery after the surgical treatment is it unknown if timing affected the participants answers.

8.1.4 External validity

Inviting *all* patients surgically treated for recurrent PI in the three orthopaedic units to study I and II increases external validity as an unselected population likely represents the heterogenic spectrum of patients with PI varying from active athletes to inactive adolescents and young adults (3-5). In most previous studies, patients with PI are described as an active populations or athletes (24, 25, 36, 37, 75, 79), implicating that results from these studies are mainly relevant for other athletes and not to the entire population experiencing PI. This may reduce transferability to other, less active populations with PI. In the current study, most patients were not athletes, in fact over 60% reported recreational activity only. However, as we included patients regardless of activity level, we consider the results from study II relevant for the entire spectre of patients, except perhaps elite athletes. Therefore, we interpret the external validity to be high in study I and II.

By using a convenience sampling method in study III, there may be a chance that the invited participants do not represent the entire patient group (105). However, the research findings are likely to be relevant and therefore generalizable outside this context as we included a diversity in gender, age duration of symptoms and level of

activity. A strategic sampling set a priori to data collection would perhaps increase the richness of information (106). However, adjustments were made before the study started to secure sufficient information power, including defining a narrow study aim, sample specific and strong and clear dialogue (104).

8.1.5 Reflexivity

Knowledge is the product of human interaction, interpretation, and perception. Therefore, the scientist will inevitably affect the research process and its results (105). Reflexivity is an active attitude where the researcher self-reflects on potential biases and preconceptions (105, p. 26-27). In study III the reflexive log helped me, as a novice interviewer, to reflect upon my scientific role by for example ensuring that my preconceptions did not influence the analysis of the results. Moreover, extensive clinical experience within the musculoskeletal field, particularly in orthopaedics can be considered both a strength and a potential limitation in study III. My own experiences and preconceptions could implicate a prejudice and thereby prevent a sufficiently comprehensive view. On the other hand, extensive clinical experience was a strength when it came to asking relevant questions.

8.1.6 Statistics

Making multiple comparisons between groups increases the risk of a Type I error, making the false conclusion that significant results could have occurred due to chance. To protect against this type of error a Bonferroni test could have been applied (115). However, the Bonferroni test is considered highly conservative when the number of comparisons is small, as in study II (116). This may increase the risk of a Type II error, where obtaining a significant result becomes challenging, even when a difference between the groups exists. Further, the use of multiple backwards regression analyses debated because this approach can be influenced by random variation in the data variables that are automatically included or excluded (automatic variable selection) (116). The current regression analysis were theory driven as only variables assumed to affect the outcome, based on previous research and clinical experience were entered.

8.2 Discussion of results

8.2.1 Psychometric properties of the BPII 2.0

The BPII 2.0-NO demonstrated adequate to excellent content validity, construct validity, test-retest reliability and internal consistency.

The calculation of SEM and SDC for the BPII 2.0-No brings important information about measurement error and smallest amount of change that is needed to be interpreted as a true change beyond measurement error. Responsiveness, i.e. the ability of an instrument to measure change over time in the construct of interest (62) was not addressed in study I. Further, study I was not designed to assess the minimal important change (MIC). To distinguish clinically important changes from measurement error, the SCD should be smaller than the minimal amount of change that is considered to be *clinically meaningful* (MIC) (72). For the BPII 2.0 there is no MIC established with a receiver operating characteristic (ROC) curve as recommended by de Vet et al. (62 p. 258). An estimated MIC of 6.2 is pragmatically suggested using one half the standard deviation of the mean pre-operative score (68). Study I present a higher SDC_{ind} (19.7) than the suggested MIC, implicating that changes smaller than the SDC_{ind} can be attributed to measurement error and further that the BPII 2.0 may have limited ability to detect important changes in health-related QoL over time in individual patients. Establishing a MIC value according to recommended methods made by experts is warranted to enhance interpretation of patients' scores.

8.2.2 Construct validity of the BPII 2.0

The BPII 2.0 includes several items about range of motion, knee strength, pain and difficulties performing movements. Consequently, one could get the impression that the questionnaire is more a measure of self-perceived knee function than a measure of health-related QoL. An important next step is, therefore, to examine the factor structure and determine whether the questionnaire consists of one or several constructs such as health-related QoL *and* knee function. Since there is no clear-cut

ideas about the number of dimensions, exploratory factor analysis is recommended to investigate the factor structure (62 p. 72).

8.2.3 Return to sports assessment

In the process of establishing a valid and reliable RTS assessment for patients with PI is it reasonable to draw on experiences from research after ACL injuries. The findings of low pass rates and reduced performance in the contralateral leg in patients with bilateral instability in study II, demonstrate that adopting test batteries from research on ACL injuries might be problematic. This contradicts previous suggestions (52, 59, 75, 77, 117). Adopting RTS test batteries from ACL research without adjustments to and validation in patients with PI can potentially overestimate of functional recovery in these patients, especially when LISs are used in patients with bilateral instability problems. Therefore, should tests, clearance criteria and timing of RTS assessment ideally be validated in the new patient group to secure that results are robust and trustworthy. The current study lay the ground for further exploration of timing of RTS assessment, which tests to use and how we should interpret them.

Patellar stabilizing surgery aims to regain passive stability of the patellofemoral joint, and through proper rehabilitation to restore the functional stability. The goal is to return the patients to their desired level of activity and sports – or enable patients with long standing problems to increase their activity to a level they have never been able to consider before. The RTS assessment in study II comprehensively evaluates knee stability, dynamic strength and balance and lower extremity muscle power. There is no consensus regarding what such RTS assessment should contain for patients with PI (52, 59, 73-75). Therefore, results from study II could, be considered a starting point in the process of establishing a RTS test battery for patients with PI providing information on achievability and appropriateness of a combination of functional tests and PROMs.

8.2.4 Functional tests

The findings of small to high correlations among the functional tests in study II ($r = 0.26 - 0.70$, $P \leq .05$), indicates that including three different tests, with several subtests might be unnecessary because they seem to measure partially overlapping constructs. In research on patients after ACL reconstruction it is suggested that it is redundant to include all four single-legged hop tests (118, 119). By reducing the number of horizontal hop tests, clinicians could consider including other hop tasks such as a side hops and drop jump so that a wider range of dynamic stability tasks may be assessed (118, 119).

Ebert et al. (118) advocate that hop tests may be used as a pragmatic alternative for quantifying isokinetic knee strength in clinical settings where more sophisticated testing equipment, such as isokinetic dynamometry is unavailable. Findings in the current study II supports this to some degree as patients that displayed more knee extension strength had better performance on the single-legged hop tests ($r = 0.58 - 0.70$). More studies are required to clarify which tests and sub-tests that provide the most information on functional performance and RTS readiness for patients with PI.

Patients with bilateral problems displayed worse performance in the contralateral leg compared to individuals with unilateral instability – and this resulted in higher LSI scores for those with instability in both knees. As 60% of the population of patients with PI has bilateral problems, the usefulness of LSI measures are questionable for these. Problems with comparing to the contralateral leg have also been reported after ACL reconstruction with deficits in hop performance (120) and reduced strength (121) in both the *involved* and the *contralateral* leg compared to age- and sex-matched healthy controls. Information gained from LSI measures such as single-legged hop tests and isokinetic strength tests in the patients with bilateral problems are therefore of limited value. Comparing to age and sex matched normative values present a strategy worth examining (121, 122). Alternatively, intra-individual progression over time may provide a more accurate picture of the patients' recovery and readiness for RTS. Measuring progression, is however, not without challenges as

it is difficult to gain pre-injury (before first dislocation episode) data from most patients.

In all the functional tests in the current project performance is quantified by using numbers. Quality of movement including various compensation strategies, dynamic valgus failure, stiff landings and poor trunk control is not evaluated (118). This oversimplified quantification of performance could affect the tests' ability to provide a comprehensive assessment of the patients knee function. In ACL research the single-leg hop-and-hold test and the countermovement jump with landing error scoring system score are such suggestions for evaluating movement quality (123). These tests are still in the starting phase but will likely play a bigger role in future functional testing. For patients with PI a similar assessment of movement quality can perhaps include appropriate single leg squat mechanics, including adequate depth, without significant knee valgus or hip internal rotation (52). Reliable scoring systems needs to be developed to accurately capture this qualitative aspect. Taking the abovementioned considerations of functional tests into account, further exploration is required to determine what tests to use, how to interpret them and their predictive ability in a population with PI.

8.2.5 Measured and self-reported knee function

The role of self-reported or experienced function in RTS assessment needs to be evaluated. In study II, a minor correlation ($r = 0.23$) was demonstrated between knee extension strength and BPII 2.0 and no other significant correlations were found between self-reported function and performance (Study I and II). This implies that self-reported function capture aspects of functioning that the physical tests do not detect. RTS test batteries should therefore include both functional tests and self-reported knee function to provide a more complete picture of a patients knee function. Currently, the BPII 2.0 and the NPI are the preferred PROMs to include in such assessments because both have demonstrated sufficient measurement properties in patients with PI (4, 31, 66, 68-70, 84, 86, 124) and both measures relevant constructs namely health-related QoL and PI. Unfortunately, the usefulness of these PROMs is

somewhat limited until patient acceptable symptom state (PASS) and RTS clearance criteria are provided to guide interpretation of scores. Therefore, before implementing them, such values need to be established.

8.2.6 Psychological readiness

Fear of new dislocations is reported to be the most common reason for not returning to activities and sports among patients with PI (41, 74, 125, 126). Findings from study III supports this notion and highlights the remaining fear after surgery. Consequently, psychological factors should be evaluated and addressed both before and after surgery. Moreover, RTS decisions should factor how mentally prepared patients feel for challenging their knee again so that the test batteries are informative about both a patient`s physical and psychological readiness for returning to sport.

The importance of mental readiness for resuming sport is increasingly documented after ACL injuries (95, 127-129), resulting in the inclusion of psychological readiness assessment in RTS test batteries (127). How psychological readiness is best evaluated in patients with PI needs to be further examined. Previous studies have evaluated psychological aspects with Tampa scale of kinesophobia (25, 75) and the MPFL-Return to Sport after Injury (MPFL-RSI) score (125, 130, 131). If MPFL-RSI is an appropriate score for patients with PI is unknown as validation of the score according to current standards has not been published at this point. Perhaps the questions in the BPII 2.0 concerning fear for new dislocations and concerns about the knee are more appropriate alternatives as this questionnaire have demonstrated good measurement properties (68-70, 84, 124).

8.2.7 Who needs RTS assessment?

Some professionals will claim that the reason for conducting RTS readiness assessment after ACL reconstruction is to assess graft integrity, and that the relevance of such testing for patients undergoing patellar stabilizing surgery is limited. I would argue that the aim of any RTS assessment is to evaluate a patients` physical and mental readiness for returning to activities and sports and that RTS readiness assessment therefore is relevant for patients with PI who aim to return to sport.

Further, *if* the aim of such RTS testing is to evaluate graft integrity it is reasonable to assume that testing of the MPFL graft integrity is of equal interest as testing of the ACL graft. Furthermore, none of the functional tests in the current study are described to evaluate graft integrity of neither the ACL nor the MPFL ligament. They are described to evaluate the patients knee stability, power, strength, balance and coordination (36, 76, 97, 102).

Whether functional testing is relevant for *all* patients undergoing surgery for PI is however questionable. Those who are not active in sports or who do not have knee demanding activities in their everyday life will perhaps not find RTS testing important. However, fear of new dislocations was presents in all participants regardless of activity level. Systematic and adequate rehabilitation including continued evaluations of physical performance are reported to decrease fear of reinjury (129). Functional testing might therefore be relevant for all patients. Maybe a *return to activity* assessment with different (and less demanding) clearance criteria than those in the *return to sports* assessment would be more appropriate for the patients that are not active in sports. What such *return to activity* assessment should include needs further exploration. Suggestions could be tests that simulate activities of everyday life such as step down tests.

8.2.8 What do we learn from patients experiences?

The effect PI has on patients' entire life was more comprehensive than expected. In particular the fear of new dislocations and adaptive behaviour, was more far-reaching than assumed and it governed everything from daily activities to sports. To address the mental consequences several actions seems reasonable to optimize treatment. Increased attention towards the mental aspects of the rehabilitation process might be beneficial both before and after surgery (129). In the absence of evidence, I would suggest rehabilitation that include building self-confidence, handling thoughts and feelings and expanding the patient`s knowledge about the knee and patellar dislocation. Moreover, as fear seems to intertwine with recovery of function (129) it is reasonable to think that increased confidence in the knee is associated with improved knee function. Therefore, information and regular testing with the aim of

restoring confidence in the knee would also be relevant. How to best address the described barriers and adaptive behaviour is, however, unknown and a crucial next step will, therefore, be to explore the content and timing of such cognitive interventions.

Surgery after the first dislocation episode could be another solution. Although the current mainstay is non-operative management after first time patellar dislocation, some clinicians advocate for early surgery, especially in patients with predisposing anatomy (8, 45, 132). Currently, the interest has been on risk stratification with the objective to identify patients at high risk of recurrence. The increased knowledge about the extent of impact PI has on patient`s lives should be considered in the debate of early versus delayed surgery after first time patella dislocation. Perhaps early surgery can reduce the fear of new dislocations and limit excessive adaptative behaviour.

The findings of extensive fear and adaptive behaviour in study III combined with the number of patients with insufficient performance on functional tests point towards a need for preoperative rehabilitation programs to maximise knee function after surgery. In support of this, Arendt et al. (21) suggests that patients with poor function before surgery might need prolonged rehabilitation. The content of preoperative rehabilitation regimes for patients with PI needs exploration. As evidence is lacking, I would recommend the following in such program; 1) education and information and 2) lower extremity muscle strengthening and neuromuscular training to optimise lower limb alignment in accordance with prehabilitation programs for other knee injuries (133-135). However, the effect of these programs is disputed and there is no consensus on the optimal program (135).

The ripple effect of PI affected all three levels of the ICF framework. Impairments concerning *body functions and body structures* (level 1) were not surprising. Neither was it a surprise that participants expressed some restrictions in *activities* (level 2) However the extent of these restrictions involving everything from for example stair decent to walking and turning around was unexpected. The *participation restrictions*

(level 3) described were also much more serious than anticipated. Participants experienced restrictions in different life situations for example school participation and social life. Many expressed that the comprehensiveness of their knee problems was not taken seriously until they were referred to the specialist healthcare. This knowledge is important in order to deliver patient-centred treatment where shared-decision making is the goal. Meaning the joint process in which a clinicians works together with a patient to reach well-informed decisions about treatment (136). It further highlights a need for increased knowledge about PI among clinicians in both the community- and in specialist healthcare. Hopefully, dissemination of the knowledge gained from the current work, can help enlighten and inform future research on patients with PI.

9. Clinical implications

This thesis is in many ways descriptive, as it provides information about self-perceived and experienced function and functional performance. The findings can be used to improve treatment for patients with PI, both before and after surgery. Providing clinicians with increased knowledge on the appropriateness and validity of RTS testing, together with the improved insight into how patients experience to live with PI both before and after surgery, are important to assist patients in finding stability.

The BPII 2.0-NO provides Norwegian clinicians with a validated questionnaire to evaluate effect of interventions and track progression throughout rehabilitation. The BPII 2.0 can also be used as a conversation starter and to secure that rehabilitation include elements that are important for the individual patient, for example fear of new dislocations or concerns about the knee. However, to allow for evaluation over time – both in a clinical setting and in research – knowledge on responsiveness and predictive validity is needed. An important next step is therefore to establish MIC, PASS values in addition to normative values to make interpretation of the results from this questionnaire more meaningful for both patients and clinicians.

Return to sport testing six months postoperatively seems premature for patients undergoing patellar stabilizing surgery. A suggestion is, therefore, regular testing throughout rehabilitation, and informing patients that they probably cannot expect to return to sport at six months. Furthermore, using LSI measures in RTS assessment of patients with bilateral instability, should be done with caution, as comparing legs when both are impaired possibly overestimates recovery of the knee.

Although further exploration on what tests to use, the timing of their use - and the level of performance that suggests readiness for return to sport is warranted, study II provides results for comparison in future studies and further point the direction of RTS testing in the future.

Recognizing the importance of patients` personal experiences is crucial in assisting them to make well-informed decisions about their health. Because of the comprehensive ripple effect of long-standing symptoms clinicians should consider a more comprehensive rehabilitation that addresses the psychological aspects of PI including preoperative rehabilitation in addition to early surgery.

10. Conclusion

This thesis provides new knowledge to assist patients with PI in finding stability. The Norwegian version of the BPII 2.0 is valid and ready for use to assess QoL in the Norwegian population.

The functional assessment used in the current cohort was feasible to conduct at six months after patellar stabilizing surgery, although achievability of current suggested return-to-sport clearance standards was low. LSI measures seem inappropriate for patients with PI.

PI has a major impact on patients` everyday life. They struggle with an extensive fear of new patella dislocations and develop a heightened awareness of the knee throughout the years living with PI. In addition to excessive adaptive behaviour according to this fear, that further affects ability to participate in social life and physical activities both before and after surgery.

At this point, we need to acknowledge the psychological aspects of PI and that further refinement of readiness assessment for patients with PI is needed.

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Cross-cultural Validation of the Norwegian Version of the Banff Patellofemoral Instability Instrument 2.0

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Background: The Banff Patellofemoral Instability Instrument (BPII) 2.0 is a disease-specific quality of life questionnaire for patients with patellofemoral instability. While good psychometric properties have been demonstrated, the data lack cross-cultural validity, construct validity, and an established measurement error.

Purpose: To (1) translate and cross-culturally adapt the BPII 2.0 to the Norwegian version (BPII 2.0–No) and (2) examine the psychometric properties of the Norwegian version.

Study Design: Cohort study (diagnosis); Level of evidence, 3.

Methods: The BPII 2.0 was translated according to international guidelines. A cohort of 100 patients surgically treated for recurrent patellofemoral instability completed the BPII 2.0–No, related outcome measures (Norwich Patellar Instability Score, International Knee Documentation Committee Subjective Knee Form 2000, Knee injury and Osteoarthritis Outcome Score, and Tampa Scale of Kinesiophobia), and functional tests (Y-Balance Test–Lower Quarter, single-leg hop tests, and knee extension strength) before and/or 6 months after surgery. We evaluated the face and content validity, internal consistency (Cronbach α), test-retest reliability (intraclass correlation coefficient [ICC]), measurement error (SEM and smallest detectable change at the individual [SDC_{ind}] and group levels [SDC_{group}]). Construct validity was assessed by testing 9 hypotheses on the correlation between the BPII 2.0–No and the outcome measures/functional tests (Pearson *r*).

Results: The BPII 2.0–No had good face and content validity. Internal consistency was excellent (α = .95), and no floor or ceiling effects were found. Test-retest reliability was high ($ICC_{2,1}$ = 0.87; 95% CI, 0.77-0.93), and measurement error was low (SEM = 7.1). The SDC_{ind} was 19.7 points and the SDC_{group} was 2.8 points. Eight of the 9 hypotheses regarding construct validity were confirmed.

Conclusion: The BPII 2.0–No was found to be valid and reliable. This study adds further knowledge on the measurement properties of the BPII 2.0 that can be used internationally.

Keywords: Banff Patellofemoral Instability Instrument 2.0; COSMIN; patellar instability; quality of life; reliability; validity

Recurrent lateral dislocation of the patella is a disabling disorder that causes pain and reduces the quality of life.[11] The etiology is diverse but often includes deviant knee anatomy that predisposes the patella to lateral dislocation. Patients experiencing recurrent dislocations are advised to consider surgical treatments that address anatomic risk factors for dislocation and medial retinaculum reinforcement procedures.[18,43] Disease-specific quality of life measurements are commonly used to monitor patients' progression after treatment and determine the success or failure of surgical interventions.[15] Until recently, there was a lack of validated outcome measures for patients with recurrent patellofemoral instability.[11]

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This has reduced clinicians' ability to assess clinical interventions and has limited their ability to understand the daily subjective limitations of these patients. The Banff Patellofemoral Instability Instrument (BPII) was developed to fill this gap in measuring quality of life in patients with patellofemoral instability.[11] The questionnaire comprises 5 domains, covering key aspects of quality of life, including symptoms/physical complaints, work- and school-related concerns, recreational activity, and sport participation/competition.[15] It was originally modified from a questionnaire for patients with anterior cruciate ligament (ACL) deficiency (the ACL–quality of life questionnaire).[11] The first version of the BPII included 32 items. After principal components analysis and item reduction, a shortened 23-item BPII 2.0 was introduced[15] in 2016. Both versions have demonstrated good measurement properties in surgically and nonsurgically treated patients,[10-12,15,17] adolescents,[16,17] and adults. Each of the 23 items of the BPII 2.0 is equally weighted and answered on a visual analog scale. The final score is calculated as a mean of the scores from all answered items (range, 0-100), where a higher score reflects a higher quality of life.[15]

Further psychometric testing is required to build greater scientific soundness for the BPII 2.0. In particular, cross-cultural validity and hypothesis testing have only been performed in 1 other cohort[4] than the original development study.[15] Furthermore, measurement error should be established with a recommended method.[6] Although a few translations have been made,[4,27,39] there is currently no translated and validated Norwegian version available.

The present study aimed to provide Norwegian clinicians with a tool to evaluate quality of life in patients with recurrent patellofemoral instability. Second, this study also aimed to further expand knowledge on the validity of the BPII 2.0 by examining content validity, internal consistency, test-retest reliability, measurement error, and construct validity. We hypothesized that a Norwegian version of the BPII 2.0 (BPII 2.0–No) would be valid and reliable in patients with recurrent patellofemoral instability.

METHODS

Before enrollment and data collection, all patients gave their written, informed consent, and the study protocol received ethics committee approval. This study was performed in 2 stages. First, the BPII 2.0 was translated and cross-culturally adapted. Second, the BPII 2.0–No was examined for measurement properties in a prospective cohort of patients before and/or 6 months after surgery for patellofemoral instability, including a 2-week test-retest interval at the 6-month follow-up.

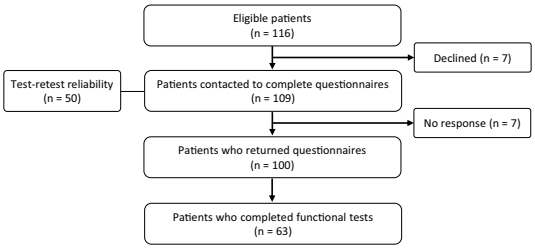

Figure 1. Flowchart of patient participation.

Translation and Cross-cultural Adaption

The BPII 2.0 was translated and cross-culturally adapted into Norwegian according to the guidelines described by Beaton et al.[3] This process involved an expert committee of 3 orthopaedic surgeons (E.I., A.B.K., P.A.S.W.), 4 physical therapists (T.H.-D., A.G.H.F., I.F.M., R.M.) specialized in orthopaedic physical therapy, a researcher (L.H.M.) with extensive experience in clinimetrics research methodology, a teacher specialized in the Norwegian language, and 2 back-translators, both native speakers of English. The expert committee had close contact with the author of the original version throughout the process. To ensure readability for adolescents, a 12-year-old child completed the prefinal version of the questionnaire and commented on difficult wording.

Examination of Measurement Properties

Patients undergoing surgical treatment for recurrent patellar dislocation were prospectively recruited from 2 Norwegian orthopaedic centers from January 2021 to September 2022. Patients were eligible for participation if they were aged $\geq$13 years at the time of surgery, fluent in Norwegian, and able to understand and complete the questionnaires. Patients with concomitant knee ligament injuries were excluded. A total of 100 patients met the inclusion

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criteria and gave their consent for participation in the study. See Figure 1 for the enrollment flowchart.

In addition to the BPII 2.0–No, all patients completed a battery of patient-reported outcome measures (PROMs)—including the Norwich Patellar Instability Score (NPI), International Knee Documentation Committee (IKDC) Subjective Knee Form 2000, Knee injury and Osteoarthritis Outcome Score (KOOS), and Tampa Scale of Kinesiophobia (TSK). Patients also underwent functional testing—including the Y-Balance Test–Lower Quarter (YBT-LQ), single-leg hop tests, and knee extension strength—preoperatively and/or 6 months after surgery.

The NPI was developed to assess patient-perceived symptoms of patellofemoral instability during activity. It includes 19 questions that are rated on a 5-point Likert scale, with options from never to always.[32] The sum score ranges from 0 to 250 and is presented as a percentage, where a higher score indicates higher instability.[34] The NPI has demonstrated good measurement properties in several domains,[32-34] including adequate construct validity,[10,32,34] high internal consistency, and responsiveness.[32] The score has recently been translated into Norwegian (validation process completed; provided by the responsible investigator (T.H.-D.).

The IKDC is a knee-specific, patient-reported tool, comprising 18 questions across 3 domains—symptoms, physical activity, and function.[13] One sum score, ranging from 0 to 100, is made, with a higher score indicating a better function.[13] The IKDC has demonstrated good psychometric properties for patients with mixed knee pathologies and injuries[1] and is validated in patients with patellar instability.[25]

The KOOS was developed to assess patients' opinions about their knee function and associated problems. It comprises 5 subscales—Pain, Symptoms, Activities of Daily Living, function in Sport and Recreation, and knee-related Quality of Life (QOL). Scores from each subscale range from 0 (lowest function) to 100 (highest function).[28] The KOOS was developed for patients with knee injuries and/or osteoarthritis but is frequently used in patients with patellofemoral instability. The questionnaire has demonstrated satisfactory psychometric properties for a variety of knee conditions.[28]

The TSK measures fear of movement in patients with low back pain,[20] but it has also been used to measure fear of reinjuries in patients after medial patellofemoral ligament reconstruction.[31] The sum of the 13 items included provides a score from 0 to 52, with a higher score indicating more fear of movement.[20] The Norwegian version of the TSK is validated for patients with sciatica.[9] It is widely used to assess kinesiophobia after knee injuries such as ACL injuries.[2,14,24,37]

The YBT-LQ evaluates knee stability and 1-leg dynamic balance in 3 directions—anterior, posteromedial, and posterolateral.[26] Reach distance is normalized to leg length, which is measured from the anterior superior iliac spine to the most distal portion of the medial malleolus. Standing on 1 leg, patients reach as far as possible in each direction without losing their balance, and the mean reach distance of 3 attempts is recorded in centimeters. Results are presented as a composite score of all 3 directions (as a percentage).[26,30] The YBT-LQ has proven to be a reliable test for impaired balance symmetry and potentially increased risk for injury.[30]

Single-leg hop tests evaluate the function, dynamic strength, and lower extremity muscle power.[29,41] They comprise 4 tasks—single-leg hop for distance (in cm), triple hop for distance (in cm), triple crossover hop for distance (in cm), and 6-m timed hop (in s). Results are presented as a limb symmetry index (in %), calculated as *surgical limb/uninvolved limb* $\times$ *100* for each test individually and as a sum score (all 4 tests combined).[23] Single-leg hop tests are reliable and valid performance tests for patients with knee injuries.[19]

Knee extension strength (peak torque in N·m) was measured with an isokinetic device (Biodex system 4 dynamometer; Biodex Medical Systems) using a standardized protocol of 5 repetitions at 60 deg/s. Isokinetic strength tests are considered the gold standard for measuring muscle strength[7] and are reliable and valid outcome measures after a knee injury.[35,38]

Data Evaluation and Statistical Analysis

The study sample size was determined according to recommendations from Terwee et al,[36] suggesting a minimum of 50 patients for assessing construct validity, reliability, and floor or ceiling effects, and a minimum of 100 patients for assessing internal consistency.[6] SPSS 26.0 (IBM Corp) was used for data analyses, which included descriptive statistics, testing of normality, examination of internal consistency, test-retest reliability, Bland-Altman plots, hypothesis testing (significance level, $P \leq .05$), and floor and ceiling effects. Continuous variables were reported as means and standard deviations, and categorical variables were reported as absolute values and relative frequencies. The measurement error was calculated in Microsoft Excel 2016.

The COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) were followed when examining the measurement properties of the BPII 2.0–No.[21,36] These guidelines provide definitions and criteria for evaluation of the quality of a questionnaire's validity and reliability. Face validity, the degree to which a questionnaire looks as though it is an adequate reflection of the construct,[22] and cultural adaptation of the Norwegian version were assessed by the expert committee. As no difficulties were encountered, no changes were made to the final version that was used in the validation process. Content validity, the degree to which the content of the BPII 2.0 is an adequate reflection of the construct to be measured,[22] was assessed in a subgroup of 10 patients who tested the prefinal version. "Think aloud" interviewing[42] was applied when completing the BPII 2.0–No followed by questions about patients' interpretation of each item, item relevance, any ambiguous wording, and overall importance for their quality of life.

As no gold standard exists for measuring quality of life in patients with patellofemoral instability, construct validity was assessed by forming and testing hypotheses[6]

TABLE 1
The 9 Study Hypotheses Regarding Expected Associations Between the BPII 2.0–No and Measures of Knee Function[a]

Hypothesis
1. There would be a medium to large negative correlation ($-0.30 < r < -1.0$) with the NPI
2. There would be a large negative correlation ($-0.50 < r < -1.0$) with the TSK
3. There would be a large correlation ($0.50 < r < 1.0$) with the IKDC
4. There would be a large correlation ($0.50 < r < 1.0$) with the KOOS–Pain
5. There would be a large correlation ($0.50 < r < 1.0$) with the KOOS–Symptoms
6. There would be a large correlation ($0.50 < r < 1.0$) with the KOOS-ADL
7. There would be a large correlation ($0.50 < r < 1.0$) with the KOOS–Sport/Rec
8. There would be a large correlation ($0.50 < r < 1.0$) with the KOOS-QOL
9. There would be a small to medium correlation ($0.10 < r < 0.50$) with the functional tests

[a]ADL, Activities of Daily Living; BPII 2.0–No, 23-item Banff Patellofemoral Instability Instrument–Norwegian version; IKDC, International Knee Documentation Committee Subjective Knee Form 2000; KOOS, Knee injury and Osteoarthritis Outcome Score; NPI, Norwich Patellar Instability Score; QOL, Quality of Life; Sport/Rec, Sport and Recreation; TSK, Tampa Scale of Kinesiophobia.

(Table 1). The predefined hypotheses were based on former validation studies[10] on the BPII 2.0, findings from previous translations,[4,39] and clinical experience. We expected PROMs that measure similar constructs, particularly the KOOS and IKDC, to have large positive correlations with the BPII 2.0–No. Measures of patellofemoral instability (NPI) and kinesiophobia (TSK) were expected to have large negative correlations with the BPII 2.0–No because of the inverse nature of the scales. Further, as knee function is assumed to affect quality of life, we also included hypotheses about associations between functional tests (YBT-LQ and hop tests) and the BPII 2.0–No. We expected functional tests to have a small to medium positive correlation with the BPII 2.0–No, as functional tests only address the physical dimension of quality of life. All correlations were investigated using the Pearson correlation coefficient (r), where 0.10-0.29 was considered small, 0.30-0.49 medium, and 0.50-1 large.[5]

Internal consistency was assessed by the Cronbach alpha coefficient (α), where .70 is acceptable, $\geq$.80 is preferable, and >.95 might indicate item redundancy.[36] We also examined the floor and ceiling effects, defined as >15% of participants having the minimum or maximum score. Test-retest reliability was examined in a subgroup of 50 patients who completed the BPII 2.0–No at both 2 weeks before the 6-month follow up and at a 6-month follow-up. Reliability was calculated using the intraclass correlation coefficient ($ICC_{2,1}$) with 95% CI based on 2-way random, single measures with absolute agreement.[36] An ICC of 0.70-0.89 indicates a high correlation and 0.90-1 indicates a very high correlation.[6] The standard error of measurement was calculated from the mean of the variance between tests.[36] A 95% CI of standard error of measurement was made to suggest the limits of measurement error ($1.96 \times SEM$). To express the smallest change score (with $P \leq .05$) that can be interpreted as a real change and not measurement error, the smallest detectable change (SDC) at the individual level (SDC_{ind}) was calculated based on the SEM ($1.96 \times \sqrt{2} \times SEM$). The SDC on the group level (SDC_{group}) was calculated as $SDC_{ind}/\sqrt{n}$, where n represents the number of patients returning the BPII 2 weeks before the six months follow-up (N = 50).[36] A Bland-Altman plot was used to evaluate the limits of agreement (LoA).[6]

TABLE 2
Baseline Patient Characteristics (N = 100)[a]

Characteristic	Value
Age at surgery, y	22.7 ± 6.4
Female sex	71 (71)
Years since the first dislocation	7.1 ± 6.1
Bilateral problems	53 (53)
BMI, kg/m^2	25.6 ± 5.4
Surgical procedure[b]	
MPFL-R	21 (22.1)
Combined surgery	74 (77.9)

[a]Data are reported as mean ± SD or n (%). BMI, body mass index, MPFL-R, medial patellofemoral ligament reconstruction.
[b]Data for 5 patients are missing because of postponed surgery.

RESULTS

Patient Characteristics

The 100 study patients had a mean age of 22.7 ± 6.4 years, and 71% were women. The mean time from first dislocation to surgery was 7.1 ± 6.1 years (range, 0-27 years) and 53% of patients had bilateral problems. Patient characteristics are described in Table 2.

Data Quality

Overall, patients were able to complete the BPII 2.0–No without assistance. Only 1 patient had 1 missing item. The mean BPII 2.0 score was 42.7 ± 17.3 before surgery and 65.4 ± 20.2 at the 6-month follow-up. There were no floor or ceiling effects for the overall score, as none of the patients had either the lowest possible score (0) or the highest score (100) at the 6-month follow-up.

Measurement Properties

The expert committee agreed that the BPII 2.0–No had good face validity. Further, support for good content validity was found as interviewed patients reported (1) a high

TABLE 3
Descriptive Statistics at 6-Month Follow-up on Measurements Used in Hypothesis Testing (n = 72)[a]

Hypothesis	Measurement	Mean ± SD (Range)	Correlation Analysis[b]	
			r	*P*
1	NPI	10.5 ± 11.2 (0–39.2)	−0.485	.001
2	TSK[c]	27.7 ± 6.6 (15–44)	−0.579	.001
3	IKDC[d]	69.1 ± 15.0 (35.6–100)	0.564	.001
4	KOOS–Pain[d]	83.4 ± 13.7 (42–100)	0.579	.001
5	KOOS–Symptoms[d]	77.6 ± 13.6 (50–100)	0.448	.001
6	KOOS-ADL[d]	93.6 ± 7.6 (72–100)	0.472	.001
7	KOOS-Sport/Rec[d]	64.6 ± 23.1 (10–100)	0.547	.001
8	KOOS-QOL[d]	58.7 ± 20.7 (6–100)	0.723	.001
9	YBT-LQ, reach distance, %[e]	73.1 ± 8.8 (52.7–100.4)	−0.031	NS
9	Hop test, LSI%[f]	90.8 ± 15.3 (38–124)	−0.109	NS
9	PT extension 60 deg/s, N·m[g]	91.1 ± 41.9 (13–184.5)	0.206	NS
9	PT flexion 60 deg/s, N·m[g]	65.5 ± 24.1 (19.9–134.5)	−0.005	NS

[a]ADL, Activities of Daily Living; IKDC, International Knee Documentation Committee Subjective Knee Form 2000; Sport/Rec, Sport and Recreation; KOOS, Knee injury and Osteoarthritis Outcome Score; LSI, limb symmetry index; NPI, Norwich Patellar Instability Score; NS, not significant; PT, peak torque; QOL, Quality of Life; TSK, Tampa Scale of Kinesiophobia; YBT-LQ, Y-Balance Test–Lower Quarter.
[b]For correlation with the 6-month follow-up BPII 2.0–No..
[c]2 missing TSK questionnaires.
[d]2 missing KOOS and IKDC questionnaires.
[e]62 patients completed the YBT-LQ.
[f]55 patients completed hop tests.
[g]60 patients completed the isokinetic strength tests.

relevance of included items, (2) no missing key aspects of their knee-related QOL, and (3) comprehensible instructions and questions of the BPII 2.0–No. Further, the patients interpreted the instructions and questions as intended.

Construct Validity. The BPII 2.0–No displayed medium negative correlations with the NPI ($r = -0.485$) and a large negative correlation with the TSK ($r = -0.579$). Further, large correlations between the BPII 2.0–No and the IKDC ($r = 0.564$), and medium to large correlations with all KOOS subscales ($r = 0.448$ to 0.723) were evident. There was no correlation between physical tests (YBT-LQ, hop tests, and strength tests) and the BPII 2.0–No. In total, 8 of the 9 predefined hypotheses were confirmed (Table 3).

Internal consistency was excellent for the total BPII 2.0 questionnaire, with a Cronbach α of .95 (n = 99). The α value varied from .95 to .96 if any of the items were deleted. The test-retest reliability of the BPII 2.0–No was high, with an $ICC_{2,1}$ of 0.87 (0.77–0.93) (Table 4). The SEM was 7.1, indicating that a change in score for 1 individual must exceed 19.7 points (SDC_{ind}) and on the group level must exceed 2.8 (SDC_{group}) points to be interpreted as a true change (exceeding measurement error). A graphic presentation of the LoA is presented in a Bland-Altman plot (Figure 2). The upper limit was 16.8 and the lower limit was −21.1 points.

TABLE 4
Test-Retest Reliability, Measurement Error, and SDC of the BPII 2.0–No (n = 50)[a]

Variable	Value
BPII 2.0–No, first administration, mean ± SD	62 ± 18.5
BPII 2.0–No, second administration, mean ± SD	64.9 ± 20.6
Mean difference	2.9
$ICC_{2,1}$ (95% CI)	0.87 (0.77–0.93)
SEM	7.10
1.96 × SEM	13.91
SDC_{ind}	19.67
SDC_{group}	2.78

[a]BPII 2.0–No, Banff Patellofemoral Instability Instrument–Norwegian version; ICC, intraclass correlation coefficient; SDC, smallest detectable change; ind, individual.

DISCUSSION

The BPII 2.0 was, as the first disease-specific PROM, successfully translated and cross-culturally adapted for use in Norwegian-speaking patients with recurrent patellofemoral instability. The present study indicated that the BPII 2.0–No is relevant and comprehensible, and overall it holds acceptable standards when used to assess these patients. Construct validity was acceptable and good test-retest reliability was demonstrated. The SDC was 19.7 points, indicating that changes in scores in 1 individual need to exceed this number to be interpreted as a "true" change.

When analyzing the data quality of the BPII 2.0, no floor or ceiling effects were found. This is in line with findings from the original publication and other language validation studies,[4,15] indicating that the questionnaire can capture changes at both ends of the score range.[36] Support

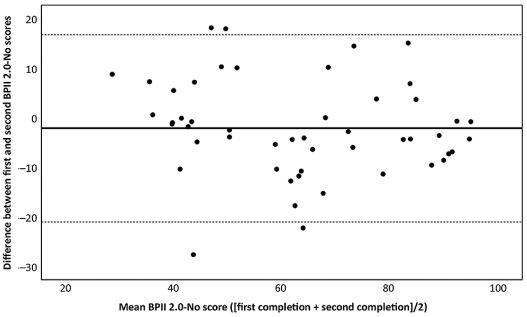

Figure 2. Bland-Altman plot displaying limits of agreement (n = 50). BPII 2.0–No, Banff Patellofemoral Instability Instrument–Norwegian version.

for good construct validity was found, as 8 of the 9 predefined hypotheses were confirmed. The BPII 2.0 showed, as presumed, the largest associations with the KOOS-QOL ($r = 0.723$). This finding is comparable with the Dutch adaptation of the first version of the BPII.[39] The moderate negative association with perceived symptoms of patellar instability (NPI) ($r = -0.485$) seen in the present study also corresponds to results from 2 other studies[4,10] on the BPII 2.0 and the BPII. As assumed, a large negative association between the BPII 2.0 and kinesiophobia measured by the TSK was found ($r = -0.579$). It was expected that fear of reinjuries because of increased movement and physical activity could have a negative impact on quality of life. Shams et al.[31] also reported higher TSK scores in patients who had undergone medial patellofemoral ligament reconstruction compared with healthy adults.

It is reasonable to assume that impaired knee function can have an impact on a person's quality of life through restrictions in daily life and sport/recreational activities, and this is supported by the present large association ($r = 0.56$) between the BPII 2.0 and self-perceived knee function (IKDC). Counterintuitively, this was not the case when knee function was measured using functional tests in the current cohort. As this was the first study to assess the associations between the BPII 2.0 and functional tests, there were no studies to inform what associations to expect. Nonetheless, it was assumed that measured functional performance would have a small, statistically significant association with quality of life. This was not supported in the present study, as no association between the functional tests and the BPII 2.0 was present. A possible explanation for this is that the selected functional tests do not capture aspects of functioning that are relevant for quality of life for patients with patellofemoral instability. Another explanation is that there may be a mismatch between the patient's perception of physical ability and actual performance.

The internal consistency of the BPII 2.0–No was excellent ($\alpha = .95$) and in line with values reported by Lafave et al[15] at the 6-month follow-up after surgery. This indicates that the questionnaire measures 1 single construct. At the same time, the Cronbach α did not change significantly when items were deleted, indicating item redundancy. This was further supported by high interitem correlation values (Supplemental Table S1, available separately). Several of the interitem correlations approached the limit of 0.7 described by de Vet et al,[6] indicating that several items capture the same aspect of quality of life. Hence, a further item reduction may be needed. The first version of the BPII underwent principal component analysis,[15] leading to a shorter version (BPII 2.0), from which the Norwegian version is translated. The principal component analysis is, however, a data reduction method, computed without regard to any underlying structure caused by latent variables. Studies performing exploratory factor analysis would therefore be valuable to determine the dimensionality of the questionnaire.[6]

The present high test-retest reliability is comparable to previous results.[4,11,15-17] The 2-week interval between completions should be long enough to prevent recall and short enough to minimize the risk of changes in the patient's condition.[36] The patients' quality of life was expected to be stable in this relatively short time. Our patients are not completely comparable to those of the study by Lafave et al,[15] as they investigated test-retest reliability before surgery, while we tested test-retest reliability 6 months after surgery. Consequently, in their study, the mean scores on the BPII 2.0 were lower than those in the present study.

This is the first study to report the SEM of the BPII 2.0 with a sufficient method according to recommendations from the COSMIN.[6] Interestingly, our SEM value was considerably higher than previously reported (7.10 vs 2.64 and 2.13).[15,17] Possible explanations for this discrepancy may be the method used to obtain the SEM value. While the SEM in this study is derived from the mean of the variance between tests, the other 2 values are calculated from the standard deviations, a method de Vet et al.[6] warn against using because it does not take into account systematic differences. In addition, the insufficient sample size in the study by Lafave et al[17] might affect their results. This is also the first study to report the 95% LoA and SDC for the BPII 2.0, thereby providing more detailed information on the smallest change in score that can be interpreted as a "real" change above measurement error in 1 individual (SDC_{ind}).[36] The SDC_{ind} estimated in the present study indicates that only a change of >19.7 points on the BPII 2.0 can be considered as a "real" within-person change for patients with recurrent patellofemoral instability. For the BPII 2.0, there is no established minimal important change assessed with, for example, a receiver operating characteristic curve, as recommended by de Vet et al.[6] Consequently, interpretation of changes in the BPII 2.0 must be done with this in mind, and future studies should address this limitation.

The prospective inclusion of patients in the present study represents a strength. The high standard deviations found in the present analysis are in line with previous work[4,15] and indicate that a heterogeneous population was evaluated, as is the case with patellar instability patients.[40] As the Norwegian-speaking population is relatively homogeneous, we assume that the inclusion of 86% of all patients undergoing surgical treatment for recurrent patellar dislocation in 2 orthopaedic units constitutes a representative,

unselected, cohort of this group of patients in Norway. Moreover, mapping quality of life is a reasonable tool to utilize when evaluating the effect of surgery.

Limitations

There are some limitations to consider. This study was conducted in 2 orthopaedic units; however, a multicenter study would increase the scientific value of the results. Few cross-cultural validation studies of the BPII 2.0 to other languages exist; thus, comparison with other studies is limited. Although the IKDC is validated in patients with patellofemoral instability,[25] demonstrating sufficient reliability, the presence of a substantial ceiling effect may compromise the validity of the questionnaire in this population.[25] The existing Norwegian version of the IKDC used in the present study has not undergone a recommended assessment of measurement properties.[8] The KOOS questionnaire is frequently used in patients with patellofemoral instability but has not been validated in this population.[12] In addition, a validated Norwegian version of KOOS has not been published.[8] Even though the TSK measures aspects (fear of movement) that may be relevant for patients with patellofemoral instability, no information on validity and reliability in this patient group exists. Although there is limited information on the measurement properties of the Norwegian versions of the questionnaires, they are in extensive use and well accepted in research and clinical communities. The functional tests are also in extensive use after knee injuries; however, their reliability and validity in patients with patellofemoral instability have not been established. Therefore, limitations in the comparative use of these instruments should be acknowledged.

CONCLUSION

The Norwegian version of BPII 2.0 was successfully translated and cross-culturally adapted into Norwegian. The support for content validity in the present study indicates that the items of the BPII 2.0–No reflect relevant and important aspects of quality of life in patients with patellofemoral instability. The scale has good construct validity and reproducibility. This study also highlights the need to perform an exploratory factor analysis to establish the factor structure of the BPII 2.0. The present study adds to the growing evidence on the validity and reliability of the BPII 2.0 in accordance with the COSMIN guidelines.

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Feasibility of return to sports assessment 6 months after patellar instability surgery

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Abstract

Background The evidence regarding the usefulness of assessment tools to support decisions of return-to-sport after surgery for patellar instability is scarce. The purpose of this study was therefore to explore the feasibility of functional tests assessing readiness for return-to-sport six months after patellar stabilizing surgery. However, there is little evidence on what a functional assessment should include to support these decisions following surgery for patellar instability. Therefore the purpose of this study was to explore the feasibility of functional tests assessing readiness for return-to-sport six months after patellar stabilizing surgery.

Methods In this cross-sectional study a prospective cohort of 78 patients were subjected to a range of return-to-sport readiness tests at six months after surgery for patellar instability with an "a la carte" approach. Lower Quarter Y-Balance Test (YBT-LQ), single-legged hop tests and isokinetic strength tests were performed. In addition, self-reported function was measured with the Banff Patellofemoral Instability Instrument 2.0 (BPII) and Norwich Patellar Instability score (NPI). Return-to-sport clearance criteria were defined as: ≤4 cm YBT-LQ anterior reach difference between legs, leg-symmetry-index (LSI) ≥ 95% in the YBT-LQ composite score, mean sum score LSI ≥ 85% of all single-leg hop tests and LSI ≥ 90% in isokinetic quadriceps strength.

Results Sixty-four patients (82%) were able to complete all functional tests, while only eleven (14%) patients were deemed ready for return-to-sport, passing all return-to-sport clearance criteria. Patients with bilateral problems demonstrated worse performance in the contralateral leg, which resulted in higher LSI scores compared to individuals with unilateral instability. A supplementary finding was that the extent of surgery (MPFL-R only versus combined surgery) did not predict and mainly did not affect self-reported function or functional performance at the follow-up.

Conclusion The functional assessment used in the current study seems feasible to conduct at six months after patellar stabilizing surgery. However, current suggested clearance standards and the use of leg-symmetry-index seems inappropriate for patients with patellar instability. Therefore, further exploration of appropriate tests and return-to-sport clearance criteria is justified.

Trial registration clinicaltrial.gov, NCT05119088. Registered 12.11.2021 - Retrospectively registered, https://clinicaltrials.gov/ct2/show/NCT05119088.

Keywords BPII 2.0, Functional tests, Lateral patellar dislocation, NPI, Patellar instability, Return to sports

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Background

There is a broad agreement that patients with recurrent patellar dislocations who do not achieve satisfactory function with rehabilitation should be offered surgery [1–5]. A common approach is to address each patient's deviant knee anatomy. This so-called "a la carte" method includes procedures such as tibial tubercle realignment, trochleoplasty and/or derotational osteotomies in addition to medial patellofemoral ligament reconstruction (MPFL-R) [6].

The aim of surgery is to stabilize the patella so that patients can regain knee function and participate in the activities/sports they desire. The postoperative rehabilitation is often long and demanding and six months after surgery patients may start to consider returning to sport (RTS) or other knee-challenging activities [7]. It would therefore be helpful to evaluate physical function and RTS readiness at this time point to advise patients on whether they are ready to challenge their knee in sport again or whether they should "hold back" and continue rehabilitation.

Some studies have reported the use of functional evaluations comprising various tests [8–13] and expert groups have proposed RTS clearance criteria for patients with patellar instability (PI) including criteria such as no pain, no effusion, no patellofemoral instability, a full range of motion, nearly symmetrical strength, and excellent dynamic stability [3, 14]. These are often inspired by methods applied on patients with anterior cruciate ligament (ACL) injury, calculating Leg Symmetry Indexes (LSIs) from hop and strength tests to compare function of the involved leg to the contralateral leg. However, at this point, there is little evidence on what a functional assessment should include to support the RTS decision following surgery – what tests and criteria will provide the information we seek to advise the patients [3, 15–17]. Moreover, there is little knowledge about the validity of using such tests for this patient group [16]. Suggested tests and "clearance standards" therefore need further clinical evaluation to ensure the appropriateness for patients after patellar stabilizing surgery, especially since some of the RTS clearance criteria include the use of LSIs in a group of patients where many have bilateral problems.

The aim of the current study was therefore to explore the feasibility of functional tests assessing readiness for RTS six months after surgery for recurrent patellar dislocation, by examining (1) how many patients who were able to complete the tests, (2) achievability of suggested clearance standards for RTS and (3) appropriateness of LSI measures for patients with PI.

Materials and methods

From January 2021 to December 2022, patients undergoing surgical treatment for recurrent (two or more) patellar dislocation were prospectively recruited from three Norwegian Orthopaedic Centres; Haukeland University Hospital, Haraldsplass Deaconess Hospital and Laerdal Hospital. Inclusion criteria were 13 to 45 years at surgery and fluency in Norwegian. Patients with concomitant knee injuries were excluded. Written informed consent was obtained from all patients prior to data collection. For patients under 18 years, legal guardians signed the consent. The study protocol was retrospectively registered and is available at ClinicalTrials.gov (NCT05119088). The study was approved by the Norwegian Centre for Research Data, Data Protection Official for Research, project number 731,409 and the Regional Committee for Medical and Health Research Ethics (ID: 2020/185,067).

Surgical procedures

Prior to surgery, all patients had been advised to undergo an exercise program targeting neuromuscular deficits. Type of surgery was based on findings from the preoperative counselling and radiologic examinations, including radiographs and MRI scans. All patients underwent a MPFL-R by use of a gracilis autograft from the ipsilateral knee. The tendon was inserted in the medial proximal patella through two connected anterior drill holes. Further, the tendon was tunnelled down to its femoral insertion and secured with a PEEK interference screw (Arthrex, Naples, US).

Tibial tubercle osteotomy with distalisation or medialisation was considered in cases of patella alta or in patients with a lateralisation of the patella, measured by the tibial tuberosity- trochlear groove distance (TTTG). Elevated TTTG from 15 to 20 or Caton-Deschamps Index above 1.3 was typically considered an indication for these procedures either alone or in combination.

Finally, a trochleoplasty was considered in cases of a severely dysplastic patella. Typically, Dejour type B and D dysplasia with a proximal bump and/or a lateral trochlear index of less than 11° were considered for surgery. A semi-open thin-flap technique was performed through a lateral parapatellar incision. One or two bioabsorbable SmartNail implants (ConMed, Utica, US) were then used to create the new groove of the trochlea.

Postoperative treatment

General advice on early neuromuscular exercises was given upon discharge from the day-care unit, and all patients conducted postoperative rehabilitation with their local physiotherapist. Patients did not wear a brace and were allowed foot-touch weight-bearing from the first postoperative day supported by crutches for six

weeks. From four weeks postoperatively, patients were allowed gradual full weight-bearing until weaning off crutches.

Readiness assessment

The International Classification of Functioning, Disability and Health was used as a framework to ensure the selected outcome measures evaluated relevant aspects of patients knee function [18]. To capture patients' subjective function, including mental readiness for RTS, Banff Patellofemoral Instability Instrument 2.0 (BPII) and Norwich Patellar Instability score (NPI) were included. The functional tests used for readiness assessment were selected based on two former expert recommendations [3, 14]. All patients were evaluated six months postoperatively. At the day of testing, questionnaires were completed before participants completed a seven-minute warm-up on a stationary bike and underwent the functional tests. All patients were evaluated by the same, independent, examiner not formerly involved in their treatment.

Patient reported outcome measures (PROMs)

The BPII 2.0 is a self-administered, disease-specific quality of life (QOL) score that consists of 23 questions covering five domains: symptoms/physical complaints, work-related concerns, recreational activity and sports participation [19]. Patients grade their answers on a 100 mm VAS scale. A total score is calculated as the average of the responses on each question, range 0-100, where higher scores indicate better QOL [19]. The Norwegian version of the BPII 2.0 is valid and reliable for patients with PI [20].

The NPI score is a 19-item score of self-experienced PI during activity [21]. Patients respond using a five-point Likert scale with options from "never" to "always" [21]. The score is presented as a mean percentage where a higher score indicates more instability. The NPI has demonstrated good measurement properties in several domains [21–23], and has recently been translated into Norwegian.

Functional tests

The *Lower Quarter Y-balance Test* (YBT-LQ) evaluates lower extremity strength, knee stability and dynamic balance in anterior, posteromedial and posterolateral direction [24]. For each direction, three practice trials were allowed before three test trials were recorded. Mean reach distances (in centimetres, (cm)) was normalized to leg length, which was measured from the anterior superior iliac spine to the most distal portion of the medial malleolus. The results are presented as normalized reach values in anterior direction, difference in anterior reach distance (cm) between legs, and a composite score determined using the following equation:

Composite score = [anterior + posteromedial + posterolateral) / (3 x leg length)] x 100

The YBT-LQ has shown predictive validity for injury risk and is a reliable test for measuring single leg dynamic balance [24, 25].

The *single-legged hop test* evaluates functional performance, dynamic strength and lower extremity muscle power [3, 12]. It comprises four tasks: a single hop for distance (cm); triple hops for distance (cm); triple crossover hops for distance (cm); and 6-m timed hops (in seconds) [26]. One practice trial on each hop test was performed before two test trials were completed. No rest was allowed between tests. The results are presented as a mean of the two test trials in absolute values (cm), and a mean LSI%; (involved leg/contralateral leg) x 100%) of the four tests. A score of 100% meant there was complete symmetry in the performance of the legs. Values < 100% indicated a deficit in the involved leg [24, 25]. Hop tests are reliable and valid for patients with other knee injuries such as ACL rupture [27].

Concentric muscle strength was evaluated at 60°/Sect. (5 repetitions) angular velocity using an isokinetic device (Biodex system 4 dynamometers, Biodex Medical Systems Inc.). Performance was presented as absolute values (in Newton meters (Nm)), and peak torque (PT) LSI% [28]. Isokinetic strength tests have been found to be a reliable measure of muscle strength after other knee injuries and are considered the 'gold standard' for measuring muscle strength [28, 29].

"Results from each functional test was normalized to z-scores (z=x – population mean/population standard deviation) and then added, creating a new "performance at six months" composite variable. The approach of adding z-scores to make a single composite score has not been used extensively, but may have its benefit to represent a broader construct of physical performance in PI-patients [30].

RTS clearance criteria

RTS clearance criteria for the functional tests were defined as previously suggested for patients with PI [3, 14]: LSI ≥ 95% composite score for the YBT-LQ, ≤ 4 cm YBT-LQ anterior reach difference between legs, LSI ≥ 85% for all single-leg hop tasks and LSI ≥ 90% in quadriceps strength [3, 12–14, 31]. The BPII and NPI were a supplementary part of the RTS assessment and not included in the RTS clearance criteria as no evidence exists regarding clearance values for these two PROMs.

Statistical analyses

All statistical analyses were performed using the IBM SPSS Statistics for Windows, version 26.0 (IBM Corp).

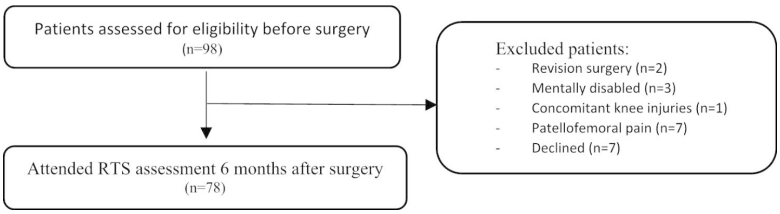

Fig. 1 Flowchart of patient's participation

Table 1 Performance and pass rates on functional tests six months after surgery (n = 78)[a]

Test	Involved Leg	Contralateral Leg	LSI, %	*P* Value	*Passed RTS criteria, % (n)*
YBT-LQ, Composite score	74.3 ± 9.3	77.3 ± 9.0	96.1	**0.047**	64.1 (50)
YBT-LQ, Normalized reach (%) anterior	65.1 ± 7.3	68.7 ± 6.6		**0.001**	
Single hop for distance, cm	72.3 ± 34.2	85.4 ± 30.2	82.0	**0.016**	50.0 (39)
Triple hop for distance, cm	273.2 ± 100.2	305.1 ± 88.2	88.4	0.051	55.1 (43)
Crossover hop for distance, cm	240.4 ± 94.4	255.5 ± 98.4	95.8	0.374	62.8 (49)
6-m timed hop, s	3.3 ± 1.3	3.1 ± 1.1	95.3	0.367	64.1 (50)
LSI ≥ 85% all 4 hop test			91.0		42.3 (33)
PT extension 60°/s, Nm[b]	92.2 ± 41.4	130.9 ± 46.5	72.0	**0.001**	19.2 (15)
PT flexion 60°/s, Nm[b]	64.6 ± 23.2	69.1 ± 23.1	94.3	0.241	63.0 (34)

[a]Data are reported as mean ± SD unless otherwise specified. Bolded P value indicates a statistically significant difference between the legs (P ≤ .05). YBT-LQ, Lower Quarter Y-Balance test, LSI, Leg Symmetry Index, PT, Peak Torque

[i]Information missing in 3 patients n = 75

As this is a feasibility study the focus was on the feasibility of the current assessment and no formal power analysis were performed. The a priori significance level was set to ≤0.05. Descriptive analyses were expressed as mean ± SD for continuous variables and frequencies and percentages for categorical variables. Independent samples t-tests were conducted to investigate differences in [1] PT between the legs, [2] reach distance and composite score between the legs on YBT-LQ and hop tests and [3] differences in performance based on bilateral problems and extent of surgery. To examine which factors that predict performance, backward multiple regression was performed. With performance six months postoperative as the dependent variable, age, gender, extent of surgery, duration of symptoms and bilateral/unilateral problems was entered as independent variables, and only variables with a p-value ≤ 0.10 were included in the final model. Multicollinearity was assessed by inspecting the tolerance values in linear regression analysis, and values < 0.1 were interpreted to indicate correlations that are too high between variables [32].

Results

Patient demographics

Of 98 patients screened for eligibility, 78 patients (71% female, mean age 22.3 ± 6.9 (range 13–45 years), BMI 25.3 ± 5.2) were enrolled in this study after exclusions (Fig. 1). Mean time since first dislocation was 7.0 years (± 5.9), and 60% reported bilateral problems. Functional testing was performed on average 6.1 months (± 0.8) after surgery. 19% (n = 15) of patients underwent an isolated MPFL-R while 81% (n = 63) underwent combined surgery (including either TTO and/or trochleoplasty). Pre-surgery level of activity/sports were competitive in 38% of the patients and recreational in 62%. Mean BPII score was 65.1 (± 19.9), and mean NPI score was 9.9 (± 11.3) at that follow-up.

Ability to complete the tests

Sixty-four patients (82%) were able to complete *all* functional tests at the six-months assessment. Looking at the tests separately, all - but one - completed the YBT-LQ test, 64 patients (82%) completed the hop tests, and all patients completed the isokinetic strength testing. Performance was generally impaired on the involved leg compared to the contralateral leg (see Table 1).

Achievement of suggested clearance standards for RTS

In total eleven patients (14%) passed *all* the RTS clearance criteria and were therefore deemed ready for sport resumption. In the YBT-LQ test, 64% passed the return criteria (composite score LSI ≥ 95% and anterior reach asymmetry ≤ 4 cm). For the four hop tests, a mean sum score of 91% LSI was seen across all patients – but only 33 patients reached the RTS clearance criteria (LSI ≥ 85%) for this test. On the isokinetic strength test, the mean

Table 2 Functional performance *of contralateral leg* in patients with uni- compared to bilateral patellar instability (n = 78)[a]

Test	All patients	Bilateral problems	Unilateral problems	*P* Value
YBT-LQ anterior reach difference, cm	3.2 ± 3.8	2.4 ± 3.3	4.5 ± 4.1	**0.017**
YBT-LQ, Composite score, LSI, %	96.4 ± 5.6	96.9 ± 5.9	95.6 ± 5.1	0.368
Mean sum score hop test LSI, %	90.8 ± 15.6	96.7 ± 12.8	83.8 ± 15.9	**0.001**
PT extension 60°/s, Nm, LSI, %	72.0 ± 25.1	76.6 ± 28.2	65.5 ± 18.6	0.060
YBT-LQ, Composite score	77.3 ± 9.0	77.4 ± 9.2	76.9 ± 9.0	0.796
Single hop for distance, *contralateral leg*, cm	85.4 ± 30.2	84.6 ± 29.6	86.4 ± 31.4	0.812
Triple hop for distance *contralateral leg*, cm	305.1 ± 88.2	294.8 ± 81.4	319.5 ± 96.6	0.267
Crossover hop for distance *contralateral leg*, cm	255.5 ± 98.4	234.3 ± 78.4	289.5 ± 117.9	**0.045**
6-m timed hop *contralateral leg*, s	3.1 ± 1.1	3.2 ± 1.0	3.0 ± 1.2	0.485
PT extension 60°/s, Nm, *contralateral leg*[a]	130.9 ± 46.5	119.1 ± 43.1	147.7 ± 46.6	**0.008**
PT flexion 60°/s, Nm, *contralateral leg*[a]	69.1 ± 23.1	67.1 ± 22.4	72.0 ± 24.1	0.372
Performance composite (z-score)	0.003 ± 0.68	0,05 ± 0.10	-0.06 ± 0.12	0.499

[a]Data are reported as mean ± SD unless otherwise specified. Bolded P value indicates a statistically significant difference between groups (P < .05). LSI, leg symmetry index, PT, Peak Torque

[a]Information missing in 3 patients n = 75

Table 3 Prediction of performance at six months postoperatively. Final multiple regression models after backwards elimination with gender, age, type of surgery, duration of symptoms and bilateral/unilateral problems as covariates (n = 78)

Dependent Variable	Independent variables	B (CI)	Beta	p-value*	R^2
Composite performance (z score)	Gender	−0.314 (-0.627,-0.002)	−0.211	0.049	
	Age at surgery	−0.037 (-0.057, −0.016)	−0.375	0.001	0.208

*Independent variables predicting performance six months postoperatively with p ≤ .10 were retained in the final model. CI, confidence interval

LSI was 72% across all patients - and only 19% of patients achieved the RTS clearance criteria (LSI ≥ 90%) (Table 1). The eleven patients who passed all RTS clearance criteria more often had bilateral problems and were of younger age (mean 17.4 vs. mean 22.3 years) when compared to the other patients. Their pre-surgery level of activity/sport was equal to the rest of the cohort.

Measures of leg symmetry index

Those with *bilateral* problems had higher absolute LSI scores on all functional tests compared to individuals with unilateral problems (Table 2) – but only the hop test LSI sum score and anterior reach difference between legs reached statistical significance ($P \leq .05$). Comparing the *contralateral leg* of those with *bilateral instability* to the *contralateral leg* of those with *unilateral instability*, patients with bilateral instability demonstrated worse performance in knee extension strength and crossover hop distance on what would be defined as the "healthy leg" when calculating LSI's (Table 2). This illustrates how patients with bilateral patellar instability have reduced leg strength and hop ability in *both legs* and therefore is it problematic to use the contralateral leg as a «gold standard» in these patients. No difference in *contralateral leg* performance was found for knee flexion strength, the YBT-LQ test or the other hop tests ($P > .05$).

The extent of surgery

The extent of surgery (MPFL-R only versus combined surgery) affected only normalized anterior reach distance in involved (68.5 ± 5.5 vs. 64.2 ± 7.5; $P = .04$) and contralateral leg (71.5 ± 4.0 vs. 68.0 ± 7.0; $P = .01$), but the correlation was minor (-0.234, $P = .04$ and −0.208, $P = .06$). No other statistically significant difference in functional tests or the PROM scores were seen between patients with MPFL-R only versus combined surgery at the six months assessment (All $P > .05$).

Predictors of performance

In the backward multiple regression, age and gender remained independent significant predictors of performance six months after surgery, with a shared explained variance of 21% (Table 3). Tolerance values were both 0.98, indicating no problems with multicollinearity.

Discussion

The most important finding from the current study – evaluating functional tests six months after surgery for recurrent patellar instability – was a high degree of completion across the different tests. Although completion rates were high, only eleven out of 78 patients passed all the RTS clearance criteria suggested in current literature. Because patients with bilateral problems demonstrated impaired performance in the contralateral leg,

they also displayed higher LSI scores than individuals with unilateral instability. A supplementary finding was that the extent of surgery (MPFL-R only versus combined surgery) mainly did not affect self-reported function or functional performance and only gender and age at surgery predicted performance six months postoperatively.

Most patients were able to perform all tests in the current study when evaluated six months after surgery, indicating that the tests are appropriate for this patient group. However, only 14% met all the RTS clearance criteria at this time point. In comparison, Matassi et al. [10] found a 40% readiness clearance rate at 8 months after MPFL-R. That study, however, applied a slightly different test battery including balance, strength, speed and agility tests – at a later time in the rehabilitation process (range 8–35 months). On the hop-tests, 42% passed all four tests in the current cohort. In comparison, Saper et al. [12] described lower hop-test pass rates (32%) at 7 months after stabilizing surgery in a study including adolescents with unilateral instability only. As illustrated, discrepancies in findings might be due to several factors, such as timing of the RTS evaluation, the type of tests applied and surgical approach. Further comparisons across available published RTS data are therefore difficult.

The current finding of 60% bilateral leg involvement in patients with PI is in line with other reports [33]. As calculating an LSI involves using the contralateral – assumingly "normal" – leg as a reference, its use can be erroneous for patients with PI. Overall, the quadriceps strength in the contralateral leg (not the one that had undergone surgery) was significantly reduced in those with bilateral, compared to those with unilateral instability. When applying LSI, this discrepancy will give the impression of a symmetrical performance and thereby a satisfactory outcome - when in fact - both legs might have inadequate muscle strength. The reporting LSI's adapted from assessment of patients with ACL injury therefore seems inappropriate for patients with PI. Evaluation of absolute values and comparison to normative references populations can - to a certain degree - overcome this issue. Serial measurements of the same leg over time can also contribute to a more appropriate functional evaluation of patients with PI.

Performance on functional tests revealed that the patients in the current study have pronounced functional limitations six months after surgery. This is in line with other studies reporting persistent reduced knee function after surgery for recurrent patellar dislocation [8, 9]. It is indicated that an anterior reach asymmetry of ≥4 cm on the YBT-LQ test may predict an increased risk of future lower extremity injury [34]. The patients who had asymmetry of ≥4 cm, approximately one out of three in the current cohort, may therefore return to sport with an increased risk of further injuries. The isokinetic strength deficits at six months seen in the current and previous studies [12, 13, 35], also implies that patients may not be able to generate the forces needed to stabilize the knee and maximize functional ability, and therefore need more strength training before returning to knee-challenging activities. Interestingly, a recent systematic review reported that more than 90% of patients with PI resumed athletic activity at a mean of 6.7 months after surgery [36]. Based on our experience from the present study, returning to sport at six months seems premature and it may be more appropriate to have the patients exercise more before conducting RTS assessments *nine* months after patellar stabilizing surgery - a time that is well established after ACL reconstruction [37]. This recognition should inspire further investigations of the timing of RTS assessment and maybe more structured exercise programs for the late phase rehabilitation in patients with PI.

The current RTS clearance criteria are similar to widely used criteria applied on patients with an ACL tear [38–40]. Although similarities exist in injury mechanism and neuromuscular deficits between those patient groups, comparison should be done with caution. The amount of patients with bilateral problems is lower, participation at competitive level of sports is higher [40–43] and physical performance is generally better in patients with ACL tears [38, 40, 43]. Faleide et al. [40] reported that 69% of patients with ACL reconstructions competed in elite to lower competitive levels while 31% participated at a recreational level of activity. Other ACL studies report an even higher share of patients performing sports at competitive levels [37, 42]. In contrast, the current study had 38% competing in elite, competitive or lower competitive level while 62% participated in recreational activities only. Furthermore, the current cohort had long-standing symptoms and a mean of 7 years from first dislocation to surgery - indicating that PI should be regarded as a more chronic condition than an ACL tear. This illustrates that the two patient groups are not directly comparable and thereby emphasize how patients with PI need different tests and clearance standards. Further, one may question whether RTS testing is relevant to this heterogeneous population at all. Perhaps is only a selection of patients (aiming to return to pivoting activities) in need of functional RTS testing, while the majority might be better off with a return to *activity* assessment with less demanding clearance standards than those applied for athletes.

When adopting RTS assessment from ACL research to patients who have undergone surgery for PI, it is interesting to note that psychological readiness has not been addressed in any of the former PI-studies [10–12]. The impact of kinesiophobia and mental readiness for resuming sport are increasingly documented after ACL injuries [40]. Lack of mental readiness for challenging the knee,

may also presumably play an important role after patellar stabilization surgery. The two diagnose-specific PROMs included in the current both addresses some psychological factors, and the results indicated that psychological readiness was affected in the current population. This is in line with findings by Platt et al. [36] and Hurley et al. [44] which indicated that the most common reason for patients choosing to lower their level of sport participation after MPFL-R was fear of new dislocations. However, as no clearance standards for the BPII and the NPI exists, future work is warranted to enhance interpretation of the questionnaires and possibly implement them in RTS evaluations.

This far, research on patients with PI has been conducted on relatively small and homogeneous cohorts, often undergoing uniform surgical procedures [8, 10–12]. Due to the diversity in selected populations and surgical procedures it is difficult to compare across studies. All patients in the current study underwent surgery with an "a la carte" approach making the results relevant to a broad spectrum of patients. Our results may, however, not be relevant for competitive athletes following extensive rehabilitation protocols at specialized clinics. Furthermore, one might argue that including patients who have undergone differing procedures in one study pose some challenges. While a recent systematic review reported that combined surgery did not affect time to RTS [36], Krych et al. [13] reported that patients who had undergone combined procedures had inferior quadriceps strength compared to those who had undergone isolated MPFL-R. Interestingly, the extent of surgery in the present study, did not affect neither the PROM scores nor performance on functional tests, except YBT-LQ normalized anterior reach – indicating that patients with differing surgical procedures can be evaluated in the same cohort. This is further supported by the finding that neither the extent of surgery, bilateral/unilateral instability nor the duration of symptoms predicted performance, while gender and age predicted performance. This might not be surprising as it is well-known that performance vary between men and women, and performance is assumed to decrease with increasing age.

All the current patients underwent postoperative rehabilitation, but no standardized rehabilitation protocol was applied - and rehabilitation was performed in several different locations. It is therefore unclear how a potential heterogeneity in rehabilitation might have affected the current outcomes. Future studies should try to control such variables. Other limitations in this study includes no data on number on dislocation episodes and the skewed distribution between genders where the majority of patients were female. This reflects the population experiencing PI as females more often experience this disorder. However, results should be interpreted with this in mind.

Conclusion

The functional assessment used in the current cohort was feasible to conduct at six months after patellar stabilizing surgery. However, achievability of current suggested return-to-sport clearance standards was low and the use of leg symmetry index measures seems inappropriate for patients with patellar instability due to the high proportion of patients with bilateral complaints. More knowledge is needed on what tests to use, the timing of their use - and the level of performance that suggests readiness for return to sport. In addition, one should consider if a majority of this highly heterogeneous group of patients might be better off with a *return to activity* rather than *return to sports* assessment. Our findings indicate a need for further refinement of readiness assessment for patients with patellar instability.

Abbreviations

ACL	Anterior cruciate ligament
BPII	Banff Patellofemoral Instability Instrument 2.0
CM	Centimetres
LSI	Leg Symmetry Indexes
MPFL-R	Medial patellofemoral ligament reconstruction
NM	Newton meters
NPI	Norwich Patellar Instability score
PI	Patellar instability
PROMs	Patient Reported Outcome Measures
PT	Peak torque
QOL	Quality of life
RTS	Return to sport
TTTG	Tibial tuberosity- trochlear groove
YBT-LQ	Lower Quarter Y-balance Test

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Authors' contributions

TH-D: Conception and design of study, acquisition of data, analysis and interpretation of data and drafting of manuscript. LHM: Conception of study and critically revising manuscript. AGHF: Conception of study, interpretation of data and critically revising manuscript. EI: Conception and design of study and critically revising manuscript.

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Data Availability

The datasets used and analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethical approval and consent to participate

The study protocol was approved by the Norwegian Centre for Research Data, Data Protection Official for Research, project number 731409 and the Regional Committee for Medical and Health Research Ethics (ID: 2020/185067). Written informed consent was obtained from all patients prior to testing. The study was conducted according to the Helsinki Declaration and its later amendments.

Consent for publication

Not applicable.

Competing interests
The authors declare no competing interests.

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Patients' experiences of living with patellar instability before and after surgery: a qualitative interview study

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ABSTRACT

Objectives To explore the experience of living with patellar instability before and after surgery.

Design Qualitative individual semistructured interviews of patients with patellar instability using a four-step thematic cross-case analysis strategy (systematic text condensation).

Setting Two orthopaedic units within two large Hospitals in Norway.

Participants A convenience sample of 15 participants, aged between 16 and 32 years, who had undergone surgery for patellar instability within the last 6–12 months.

Results Participants offered rich and detailed descriptions of the impact and lived experience of patellar instability, including fear of new dislocations, increased awareness of the knee and adaptations to avoidance behaviour in everyday life both before and after surgery. The four major themes that emerged from the data were: (1) fear of patella dislocations governs everyday life activities, (2) adaptation to avoidance behaviour, (3) feeling different, misunderstood and stigmatised affects self-esteem and (4) feeling stronger, but still not fully confident in the knee after surgery.

Conclusions These findings offer insight into the experience of living with patellar instability. Patients reported that the instability had major impacts on their everyday life, affecting ability to participate in social life and physical activities both before and after surgery. This may imply that an increased attention towards cognitive interventions may be useful in the management of patellar instability.

Trial registration number NCT05119088.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is the first study to use a qualitative method of inquiry on the patients' experiences of living with patellar instability.
⇒ Data were analysed data by systematic text condensation, a thematic, cross-case strategy suited for exploratory analysis of patients' experiences.
⇒ For pragmatic reasons, a convenience sampling strategy was used.

INTRODUCTION

Patellar instability (PI) is painful and disabling, mainly affecting adolescents and young adults.[1–3] The patient group is heterogeneous regarding symptom burden, type and level of activity and underlying causes for the instability.[4] Some patients experience only a single dislocation as a result of knee trauma, while the majority experience recurrent dislocations due to underlying predisposing factors.[5] This may lead to long-standing complaints such as pain,[1] kinesiophobia[6] and overall functional impairment.[2 3] Mental health[7] and health-related quality of life[1 8–10] are also reported to be negatively affected, making the condition complex.

PI is challenging to manage due to this heterogeneity, but also due to the negative consequences of not being able to trust the knee in everyday life activities.[1 11] However, increased knowledge of functional anatomy of the patellofemoral joint has improved the assessment of underlying pathophysiology and surgical management.[12] Current guidelines recommend patellar stabilising surgery for recurrent dislocations regardless of functional activity level.[11 13–15] Although surgical treatment provides a structurally more stable patella, many patients still experience pain,[12] reduced knee function[2 16–19] and psychological concerns such as fear of new dislocations after surgery.[20 21]

Persistent pain and reduced knee function is reported to reduce physical ability and increase pain-related fear-avoidance behaviour in other long-lasting knee disorders, such as patellofemoral pain[22 23] and anterior cruciate ligament injury.[24 25] Similarly, such activity limitations and avoidance behaviour has been reported quantitatively in cross-sectional studies in PI.[10 26 27] However, knowledge regarding the patients' own experiences of living with an unstable kneecap, and how this affects daily life activities, is scarce. Consequently, there is a need for a deepened understanding of how PI affects patients' lives and how they manage the

Table 1 Participant characteristics at the time of interview

ID number	Hypermobile	Bilateral problems
1	Yes	No
2	No	Yes
3	No	No
4	Yes	Yes
5	No	Yes
6	Yes	Yes
7	Yes	Yes
8	Yes	No
9	No	Yes
10	Yes	Yes
11	Yes	No
12	Yes	No
13	No	Yes
14	No	No
15	Yes	Yes

condition. Therefore, the aim of this study was to provide more detailed descriptions of the experiences of living with PI.

MATERIALS AND METHODS

Recruitment and participants

We conducted a qualitative individual interview study with patients who had undergone surgery for recurrent patellar dislocation at two orthopaedic units in Norway. The participants were recruited from an ongoing clinical trial on PI, either face to face after a postoperative assessment or by telephone. To obtain rich data with a variation in experiences, a sample of 15 participants (11 women), from age 16 to 32 years, with different levels of physical activity and a time span of 1–18 years from their first dislocation episode, were included (table 1). None of the participants had redislocated their patella at the time of interviews. All participants received an information letter before entering the clinical trial, informing them that they could be asked to take part in the qualitative interview study. All participants invited gave their written consent.

All participants attended postoperative rehabilitation with their local physiotherapist and had completed a 6-month follow-up at the hospital.

Data collection

Data were collected between November 2021 and September 2022. All interviews were conducted by first author TH-D, using a semistructured interview guide, inviting the participants to reflect on their experiences of living with PI. We wanted information about the years living with PI before surgery, but also if and how experiences had changed after surgery. The three overall themes in the interview guide were; function in everyday life, sports and leisure activities and changes after surgery (online supplemental file 1). Preconceptions about the participants were extensively discussed between the first (TH-D) and the senior author (LHM) throughout the analysis process. TH-D is a PhD candidate and an experienced physiotherapist working with orthopaedic patients for over 10 years. LHM is professor of physiotherapy with extensive experience within qualitative research. She has 20 years of clinical experience as a physiotherapist, mainly from primary care. AGHF works as an orthopaedic physiotherapist (PhD) and EI works as an orthopaedic surgeon (PhD). EI was the surgeon of one of the participants and TH-D conducted the 6 months postoperative follow-up of all participants. No other direct relationships were present between any of the participants and the authors of the study.

The interviews took place at one of the orthopaedic centres or by telephone from 6 to 12 months postoperatively. LHM was an observer of one interview, otherwise no other people than TH-D and the participant were present during the interviews. The interviews, which had a duration of 16–35 min, were audiotaped before they were transcribed verbatim. In addition, short fieldnotes were made to capture the atmosphere, and to validate the transcripts and analysis. Open-ended questions were used to facilitate the participants to speak freely about their experiences to avoid being influenced by the researcher's assumptions. Transcripts were not sent to participants for comments since the validity of using this method is questionable.[28]

Data analysis

The transcribed text resulted in 57 pages of text. Data were analysed by TH-D and LHM using systematic text condensation (STC) which is a thematic, cross-case strategy suited for exploratory analyses.[29] The analysis has four steps: (1) reading all the material to get an overall impression and to identify preliminary themes; (2) identifying and sorting meaning units concerning the participants' experiences with living with an unstable knee, and establishing code groups and sorting the meaning units correspondingly; (3) abstracting condensates from each code group and subgroups exemplifying essential aspects of each group and (4) synthesising the material and presenting a reconceptualised description of each subgroup. As recommended by Malterud,[29] preliminary analyses were conducted after the first four interviews, allowing for adjustments of the interview guide and aim of the study. No adjustment was made. Data were reported in line with the COnsolidated criteria for REporting Qualitative research checklist.[30]

Patient and public involvement

This research project was driven by the views of participants experiencing recurrent PI. In the first four interviews, participants were consulted for their views and thoughts about the questions asked in the current study.

The participants reported the questions to be relevant, comprehensive and no new topics were raised.

RESULTS

Four key themes emerged from the data analysis. The first three themes are related to the experiences during the years before surgery, while theme 4 concern experiences after surgery: (1) fear of patellar dislocations governs everyday life activities; (2) adaptation to avoidance behaviour; (3) feeling different, misunderstood and stigmatised affects self-esteem and (4) feeling stronger, but still not fully confident in the knee after surgery.

Theme 1: fear of patella dislocations governs everyday life activities

Fear of dislocating the patella was always on the minds of the participants, and this worry was with them all day, every day. Many participants expressed that this fear constituted the main concern of their knee-problem and resulted in a lack of trust in their knee. The unpredictable threat that the patella could dislocate at any moment influenced their ability to carry out many activities. The participants gave detailed descriptions of dislocations during everyday movements such as turning around in bed, straightening the knee and walking downhill. In specific situations, the patella always dislocated. This led to avoidance of these situations. However, the dislocation could also occur suddenly and unexpectedly. This uncertainty led to intrusive fear and a more general avoidance behaviour. Such hyperawareness of the knee was commonly described and the participants felt a need to control any situation to prevent dislocation. Sometimes they felt that the knee had improved so that they could trust it more. However, such periods always ended with a new dislocation aggravating the fear. The experience of dislocation in a variety of situations had a negative impact on their self-confidence and well-being. A male in his 20s expressed:

> I think that the kneecap can pop out all the time, it is almost unconscious, the focus on my knee, it's always in the back of my mind. I think about how I lay weight on the leg, how I walk. It is always an extra focus there, but you get used to it. After so many years, it is almost automatic because it can dislocate in almost every possible situation, you never know. (ID5)

Most participants described fear and avoidance during daily activities, while a few described this fear only in connection with sports, for example, when playing soccer. In those situations, they felt similar awareness towards their knee and put the same restrictions on activity as the others. One young male expressed:

> I don't go into tackling as hard as before with my affected leg. Therefore, my knee limits me in those situations, but the rest of the time, I don't think about it. (ID3)

Theme 2: adaptations to avoidance behaviour

Most participants expressed some level of lifestyle modifications caused by PI. The participants made, both conscious and unconscious, adaptations to daily life activities. A commonly described adaptation strategy was to avoid strenuous activities and to constantly pay attention to the knee. This hyperawareness made the participants consider and plan every movement, avoid sudden movements and try to move as carefully as possible. The hyperawareness could lead to changed movement habits (compensatory movements) and restrictions in daily activities. One participant felt totally immobilised, not even being able to descend stairs without dislocating her patella. Activities such as vacuuming, heavy lifting and pushing heavy trolleys in the supermarket were examples of activities some avoided. Several had stopped doing activities that involved running and/or pivoting and cutting manoeuvres, that is, soccer, alpine skiing and paintball, activities that they previously had appreciated. One participant gave a powerful description of her changed movement pattern:

> My knee dislocated almost every time I fully straightened the leg. So I started walking on my toes to avoid fully to straighten the knee. (ID4)

Other examples were increased awareness when walking on uneven or slippery surfaces and choosing the easiest paths when hiking. A female participant in her 20s described herself as an 'old lady' when descending stairs, if able to walk stairs at all. She had experienced having to slide downhill on her bottom to make it home safe after hiking. This fear-avoidant behaviour led to reduced physically activity. Many quit sports and recreational activities because of the potential consequences. Several expressed that being physically active was not worth the risk, and this activity restriction made them feel frustrated. Activities assumed to be feasible, such as playing with children on the floor or standing on a crowded bus, were mentioned as challenging, in addition to standing and walking in social gatherings and large crowds.

> I did not want people to be near me because if they got too close and pushed me or bumped into me, the kneecap could dislocate. I did not take the bus alone; if there were no seat available and it suddenly stopped, the knee would dislocate. It was extremely unpredictable, and it limited me in several ways. (ID15)

One participant even avoided going places alone throughout her entire childhood because of the fear of dislocating her patella. It should be noted that even though most of the participants reported fear-avoidance, a minority were not afraid of the knee causing problems and they did not adjust their daily life movement habits.

Theme 3: feeling different, misunderstood and stigmatised affect self-esteem

Most participants had lived with PI for many years before surgery, and they shared detailed descriptions of living

with a troublesome knee. This felt extremely stressful, and it affected their lives in many ways like not being taken seriously by parents, friends, teachers and/or healthcare personnel. They felt that the others did not understand the extent of how the knee-problem led to restrictions in leisure and social-activities, or even isolation. They were told not to worry and that their knee-problems would pass by itself.

> I was never taken seriously. I remember my father often said to me this is just a wiggled knee. Just walk it off. (ID4)

Self-esteem

Several participants felt that living with PI had a negative impact on their well-being, with subsequent loss of self-esteem and feeling depressed. Dislocations were explained as extremely painful, but also very embarrassing. Friends and schoolmates became afraid of coming too close and treated them differently. Most participants reflected on how their knee-problem had affected them mentally; they felt different and alone, with knee-problems that no one else had. This, in addition to not being able to participate in leisure and social activities, led to social isolation and a feeling of not belonging to others. For a female participant this was the worst part of her knee-problem. She wanted to participate in activities with her friends, and had tried several times, but always ended up with a dislocated patella. Eventually, she gave up. Not being able to participate in physical activities contributed to lower self-esteem, weight gain and becoming gradually more enclosed. The problem with the kneecap was described as leading to a vicious spiral.

Not being able to do the things they loved were described as a punch in the face and a defeat before surgery. One participant said that she usually was present on the soccer field when her team trained because of the social aspect, but she found it tough not being able to play. Waiting for surgery was also hard, it took a long time and the feeling of not being able to do anything to fix the problem themselves was frustrating. They felt that surgery was their only option to regain a stable patella. A female in her 20s summed up all these negative experiences:

> You feel very alone, really. I knew nobody else with this problems. I felt so different. I could not participate. I repeat myself, but it is the fact that you don't feel like you belong with the others. It sounds horrible when I talk about it, but it led me into a depression in my youth. And I can transfer it to other problems too. You suddenly don't have the confidence to do what you want to do. (ID4)

Social impact

Detailed stories about the social impact of the problems were frequently mentioned. The younger participants were less socially active as they avoided common activities for children and adolescents. Sometimes they were stigmatised and perceived as lazy. Some experienced to be excluded from social events such as birthday parties or leisure activities involving physical activity, due to assumptions that they could not participate. The adult participants also described problems with social activities. Some hesitated to go to social gatherings such as parties, because dancing was impossible. They also hesitated to join friends on a hike or similar activities. Such loss directly affected the participants' role and position within their social network, triggering social isolation and frustration.

> You feel a bit weird, I got embarrassed - it was so painful. I know I should think about the physical aspects, but I was more concerned with the fact that I was different from the others. That was the worst part for me. Not being able to participate in the activities that the others did. I know how important physical activities are for your mental health. (ID4)

Theme 4: feeling stronger, but still not fully confident in the knee after surgery

After the surgery, all participants experienced the patella to be more stable. They perceived that their patella moved differently, it felt safer to use their knee. Despite this, complete confidence in the knee was not regained. Many experienced some degree of guarding, and therefore, continued to avoid knee-strenuous activities even though they felt safer.

> My instability is gone, but my knee is not as expected. Sometimes the pain is worse, and I can't kneel. (ID2)

Even if many participants still had avoidance behaviour and lacked trust in their knee after surgery, several described behaviours that indicated that they gradually exposed themselves to activities they wanted, but previously feared. Examples were hiking alone, walking fast and running. A valuable improvement after surgery was that they no longer had to be aware of how they moved. The fear of dislocation was less prominent, and they had less limitations in their lives. Despite the experience of a 'repaired' knee postoperatively, fear and mental barriers were still present in several as they trusted their knee to a larger extent, but not completely. They were still not able to give full effort in strenuous activities such as running and soccer. A female in her 30s said:

> Now, it is like a dream come true compared to before. It is so weird to fully straigthen the knee without my patella popping out. But it is still a large mental barrier. Especially whenever I walk stairs and down hills. I have not dared to run downhill yet. I try all the time. But downhill, there is still a mental block. So, I constantly work on the mental aspect, to walk downstairs normally. And I feel a progression, little by little. My knee is stable. It is weird and fantastic. (ID4)

DISCUSSION

Main findings

The current study is, to the best of our knowledge, the first study exploring daily life challenges experienced by patients with PI before and after surgery. Four major themes emerged from the current analysis: (1) fear of patellar dislocations governs everyday life activities, (2) adaptation to avoidance behaviour, (3) feeling different, misunderstood and stigmatised affects self-esteem and (4) stronger, but still not fully confident in the knee after surgery.

Methodological considerations

This study employed a clear, transparent and reproducible methodological approach to data analysis following Malterud's STC.[29] We interviewed a broad spectrum of participants experiencing recurrent patellar dislocations, giving them the opportunity to explain in their own words how the condition affects their lives. All participants invited wanted to partake in the study, indicating that they had an interest in, and maybe need for, telling their story. This is a strength of the current study as there is less risk for selection bias. The participants provided vivid and varied information when telling their stories. The higher number of women compared with men, reflects the fact that women have a higher incidence of PI.[31] Participants were asked to remember how this condition affected their lives before surgery. This could have introduced a certain recall bias. However, these intervening experiences were considered to be strong and long-lasting. Therefore, recall bias is most likely not a prominent problem.

Information power from the data was judged to be sufficient[32] with a number of 15 participants. Factors pertaining to high information power included a narrow study aim, sample specificity and strong and clear interview dialogue. We consider the clinical experience within the musculoskeletal field, particularly in orthopaedics, among the authors as a strength when it came to asking relevant questions. On the other hand, this experience could also implicate a prejudice and thereby prevent a sufficiently comprehensive view.

What is previously known: what does this study add?

The results from our study are novel since this is the first study to explore patients' experiences of living with PI. A key finding was that the PI had a large impact on participants' lives. It was described to affect their mental as well as physical well-being. Their stories display a constant fear of dislocating the patella and for the majority, this was present for years before treatment was commenced.

Fear of reinjury and lack of trust in the knee is a dominant theme in research on other knee conditions such as anterior cruciate ligament injury[24 25] and has been described in relation to returning to and/or participating in sports for PI patients.[21] Our study reveals that the consequences of fear have a much more far-reaching impact as many participants expressed that fear governs everything from daily life activities to more strenuous activities. Previous studies have reported that patients more often perceive high-energy activities involving multidirectional movement to cause PI compared with lower-energy uniplanar tasks.[10 33 34] In contrast to this, most participants in our study experienced PI in both low-energy uniplanar tasks (eg, turning around in bed) as well as more knee strenuous activities (eg, playing soccer). The current study, therefore, offers new insight into the comprehensiveness of having PI by telling the patient's own stories.

The fear described was often accompanied by an enhanced awareness and an increased focus on movement patterns in situations spanning from stair descending to being in large crowds. Individuals with a healthy and pain-free body do not notice their body much when they perform different activities.[35 (p.35)] They are not aware of their body parts when moving, making complex activities such as walking downhill in uneven and rough terrain possible. However, when a person experiences a disorder such as PI, the body-part becomes a prominent focus that can be a hinder for unfolding. One participant explained this increased awareness by saying 'it's always in the back of my mind'. She perceived her body as dysfunctional and strange and the knee 'always' had her attention, thereby shifting the focus from the tasks to be performed, to the body as an object. A shift in focus like this may interfere with the patient's daily life activities, leading to modifications and restrictions. This implies that some patients may benefit from a more comprehensive treatment focusing on overcoming these mental barriers and adaptations both before and after patella stabilisation.

Although activity modifications and restrictions are previously described in studies on patients with PI,[26 27] the extent of avoidance behaviour expressed in some of our participants was surprising. The statement that one of our participants did not go anywhere alone throughout her entire youth provides a powerful example of how PI may restrict a person's life. However, those who only experienced dislocations caused by trauma to the knee during sports and/or strenuous activities described only minor adaptations when, for example, playing soccer. This variety in avoidance behaviour is understandable, considering the heterogeneity of the population experiencing PI.[4 26 36]

For some, the fear of new dislocations and the following avoidance of activities and social life led to a feeling of hopelessness and low self-esteem, and they felt different, misunderstood and stigmatised. A few also felt that others did not take their knee-problem seriously and considered them as lazy. This is important for healthcare providers to be aware of in the management of patients with PI. Further, the lack of confidence in both the knee and in oneself was repeated in the participants' stories and underscores the importance of confidence building in these patients.

Postoperative fear of new dislocations has been reported in a recent systematic review examining return to sports after surgery.[21 37] Our findings support this and shed further light on the extent of fear that remains after

surgery. Even though participants felt that the patella had become stable after surgery, many could not shake that feeling of fear and awareness. A goal of stabilising surgery is to improve function and reduce concerns regarding the knee. Interestingly, most participants experienced that a stable patella alone was not enough for the fear to disappear. Accordingly, our findings indicate that post-operative rehabilitation should address psychological as well as functional factors by involving gradual exposure to activities that were previously feared. This is in line with research on other knee injuries, where the psychological factors have gained increased attention in the last years[38] and further research should explore how to address psychological barriers after patellar stabilising surgery.

CONCLUSION

The participants in our study expressed that they struggled with an extensive fear of new patella dislocations and had developed a heightened awareness of the knee throughout the years living with PI. They also described that they had adapted their daily activities according to this fear, leading to social isolation and low self-esteem. A main finding was that the fear and avoidance behaviour were still present after surgery. This increases our understanding of how PI affects the patients' lives and facilitate the development of more targeted interventions that address each patient's needs and barriers for physical unfolding. Our study suggests that an increased attention towards interventions targeting unwanted psychological issues both before and after surgery is warranted.

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Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request. Quotations and further details are available from TH-D at Trine.Hysing-Dahl@haraldsplass.no.

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Appendix 1

BANFF PATELLOFEMORAL INSTABILITETSINSTRUMENT 2.0

Et mål på livskvalitet hos pasienter med ustabilt kneskjell

Pasientens navn (for-/etternavn): _____

Fødselsnummer (11 siffer): _____

Undersøkelsesdato (dd/mm/åå): _____

Hvilket kne blir du undersøkt for i dag?	**Denne undersøkelsen gjelder:**
o Venstre kne	o Første undersøkelse hos spesialist
o Høyre kne	o Operasjonsdag
	o 3 måneder etter operasjon
o Begge knær	o 6 måneder etter operasjon
	o 12 måneder etter operasjon
	o 24 måneder etter operasjon

Veiledning

Vennligst besvar hvert spørsmål med hensyn til din aktuelle status, funksjon, omstendigheter og oppfattelse vedrørende ditt kne som har et ustabilt kneskjell. Ta de siste 3 måneder i betraktning.

Marker med en skråstrek (/) det punktet på linjen mellom 0 og 100, som nærmest beskriver din situasjon. For eksempel følgende spørsmål:

Er dette et godt spørreskjema?

0 —————————————————— **100**
Ubrukelig **Fantastisk**

Dersom skråstreken plasseres midt på linjen, betyr det at spørreskjemaet er av middels kvalitet, eller med andre ord mellom ytterpunktene "ubrukelig" og "fantastisk". Det er viktig å sette skråstreken ved endene av linjen hvis ytterpunktene best beskriver din situasjon.

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SEKSJON A: SYMPTOMER OG FYSISKE PLAGER

1. Hvor plaget er du av at kneskjellet ditt "hopper ut" eller er ustabilt?

0 ——————————————————— 100
Ekstremt plaget — Ikke noe plaget

2. Hvor mye smerte eller ubehag får du i kneet ditt ved langvarig aktivitet (over 30 minutter)? For eksempel: ståing, gåing, idrett og lignende.

0 ——————————————————— 100
Ekstremt mye smerte — Ingen smerte i det hele tatt

3. Hvor mye smerte eller ubehag får du i kneet ditt ved langvarig sitting (over 30 minutter)? For eksempel: kino, bilkjøring, eller lignende.

0 ——————————————————— 100
Ekstremt mye smerte — Ingen smerte i det hele tatt

4. Har du nedsatt bevegelse i kneet ditt?

0 ——————————————————— 100
Svært redusert bevegelse — Ingen tap av bevegelse

5. Hvor svakt føles kneet ditt?

0 ——————————————————— 100
Ekstremt svakt — Ikke svakt i det hele tatt

SEKSJON B: JOBB OG/ELLER SKOLERELATERTE BEKYMRINGER

***Hvis du ikke er i jobb/skole på grunn av kneet ditt, sett en skråstrek helt til venstre (ved 0) for hvert spørsmål.*

6. Hvor store vanskeligheter opplever du med kneet ditt ved vendinger og vridninger på jobb og/eller skole?

0 ——————————————————— 100
Store vanskeligheter — Ingen vanskeligheter i det hele tatt

7. Hvor store vanskeligheter har du med å sette deg på huk på jobb og/eller skole?

0 — 100
Store vanskeligheter — Ingen vanskeligheter i det hele tatt

8. Er du bekymret for å måtte være vekke fra jobb og/eller skole på grunn av ditt kneproblem?

0 — 100
Ekstremt bekymret — Ikke bekymret i det hele tatt

9. Har ditt kneproblem forårsaket økonomiske problemer for deg eller din familie?

0 — 100
Store økonomiske problemer — Ingen økonomiske problemer

SEKSJON C: FRITID / IDRETT / AKTIVITET

10. Hvor bekymret er du for at dine idretts- og/eller fritidsaktiviteter kan forverre ditt kneproblem?

0 — 100
Ekstremt bekymret — Ikke bekymret i det hele tatt

11. Må du være forsiktig ved deltakelse i idrett og/eller fritidsaktiviteter?
(Sett skråstrek helt til venstre (ved 0) dersom du ikke kan delta i idrett og/eller fritidsaktiviteter på grunn av kneet ditt).

0 — 100
Alltid forsiktig — Aldri forsiktig

12. Hvor engstelig er du for at kneskjellet skal «hoppe ut» når du deltar i idrett og/eller fritidsaktiviteter?
(Sett skråstrek helt til venstre (ved 0) dersom du ikke kan delta i idrett og/eller fritidsaktiviteter på grunn av kneet ditt).

0 — 100
Ekstremt engstelig — Ikke engstelig i det hele tatt

13. Hvor bekymret er du for å gå på isete, vått eller ujevnt underlag?

0 ——— 100
Ekstremt bekymret — Ikke bekymret i det hele tatt

14. Kan du gi full innsats i dine idrett og/eller fritidsaktiviteter?
(Sett skråstrek helt til venstre (ved 0) dersom du ikke kan delta i idrett og/eller fritidsaktiviteter på grunn av kneet ditt).

0 ——— 100
Aldri i stand til — Alltid i stand til

SEKSJON D: LIVSSTIL

15. Er generell sikkerhet en bekymring for deg på grunn av kneet ditt? For eksempel: gå opp eller ned trapper, bilkjøring, eller bæring av små barn og lignende.

0 ——— 100
Ekstrem bekymring — Ingen bekymring i det hele tatt

16. Hvor mye har din evne til å trene og opprettholde fysisk form blitt begrenset av ditt kneproblem?

0 ——— 100
Fullstendig begrenset — Ikke begrenset i det hele tatt

17. Hvor mye har din livsglede blitt begrenset av ditt kneproblem?

0 ——— 100
Fullstendig begrenset — Ikke begrenset i det hele tatt

18. Unngår du fritidsaktiviteter med familie og/eller venner på grunn av ditt kneproblem?

0 ——— 100
Unngår alltid — Unngår aldri

19. Fører ditt kneproblem til at du må planlegge sosiale- og fritidsaktiviteter mer enn familie og/eller venner?

0 ——— 100
Må alltid planlegge — Må ikke planlegge

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SEKSJON E: SOSIALT OG FØLELSESMESSIG

20. Er du frustrert over at dine behov for fritidsaktiviteter eller konkurranse ikke lengre kan oppfylles på grunn av ditt kneproblem?
(Sett en skråstrek helt til høyre (ved 100) hvis du oppfyller dine behov. Sett en skråstrek helt til venstre (ved 0) hvis du ikke har konkurransemessige behov).

0 ——————————————————— 100
Ekstremt frustrert — Ikke frustrert i det hele tatt

21. Har du hatt problemer med å håndtere ditt kneproblem følelsesmessig?

0 ——————————————————— 100
Ekstreme problemer — Ingen problemer i det hele tatt

22. Hvor ofte er du nervøs for kneet ditt?

0 ——————————————————— 100
Alltid nervøs — Aldri nervøs

23. Hvor engstelig er du for å skade kneet igjen?

0 ——————————————————— 100
Ekstremt engstelig — Ikke engstelig i det hele tatt

Takk for at du fylte ut dette spørreskjemaet.

Appendix 2

Haraldsplass Diakonale sykehus

Norwich Patellar Instabilitets Skår

Under følger en liste med aktiviteter som kan gi følelsen av at kneskjellet vil «hoppe ut» av ledd eller føles ustabilt.

For- og etternavn:			
Fødselsnummer: (11 siffer)			
Dato for undersøkelse:		Undersøkelse:	☐Første ☐3mnd ☐6mnd ☐1år ☐2år
Kne: ☐Høyre ☐Venstre			

Vennligst les igjennom hver påstand og kryss av i den boksen som best beskriver hvor ofte du opplever at kneskjellet vil «hoppe ut» av ledd eller føles ustabilt når du gjør følgende aktiviteter. Hvis du ***ikke gjør*** aktiviteten på grunn av ditt kneproblem kryss av i ***gjør ikke*** ruten.

#	Spørsmål	Alltid	Ofte	Noen ganger	Sjelden	Aldri	Gjør ikke
1.	Vridning/retningsendring under idrett/aktivitet						
2.	Retningsendring ved løping						
3.	Løpe rett frem på *ujevnt* underlag						
4.	Gå på glatt, vått eller isete underlag						
5.	Løpe sideveis						
6.	Hinke						
7.	Hoppe						
8.	Løpe rett frem på *jevnt* underlag						
9.	Gå ned trapper						
10.	Sette deg på huk og opp igjen						
11.	Knele/sitte på kne						
12.	Gå rett frem på *ujevnt* underlag						
13.	Gå opp trapper						
14.	Gå opp på eller over et høyt trinn						
15.	Krysse beina når du sitter						
16.	Gå rett frem på *jevnt* underlag						
17.	Gå inn eller ut av en bil						
18.	Snu en tung handlevogn rundt en butikkhylle						
19.	Snu deg for å se over skulderen						

Haraldsplass
DIAKONALE SYKEHUS
Bergen Diakonissehjem

2000 IKDC Kneevalueringsskjema

Navn:_____ **Dato:**_____ **Skadedato:**_____

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

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

- ☐ Veldig harde aktiviteter som hopping og vendinger ved basketball eller fotball *5p*
- ☐ Harde aktiviteter som tungt fysisk arbeid, ski eller tennis *4p*
- ☐ Moderate aktiviteter som moderat fysisk arbeid, løping eller jogging *3p*
- ☐ Lette aktiviteter som gange, husarbeid eller hagearbeid *2p*
- ☐ Umulig å foreta seg noen av de overnevnte aktiviteter på grunn av knesmerter *1p*

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

Aldri	0	1	2	3	4	5	6	7	8	9	10	Alltid
	11p	*10p*	*9p*	*8p*	*7p*	*6p*	*5p*	*4p*	*3p*	*2p*	*1p*	

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

Ingen smerte	0	1	2	3	4	5	6	7	8	9	10	Verst tenkelige smerte
	11p	*10p*	*9p*	*8p*	*7p*	*6p*	*5p*	*4p*	*3p*	*2p*	*1p*	

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

- ☐ Ikke i det hele tatt *5p*
- ☐ Litt *4p*
- ☐ Moderat *3p*
- ☐ Veldig *2p*
- ☐ Ekstremt *1p*

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

- ☐ Veldig harde aktiviteter som hopping og vendinger ved basketball eller fotball *5p*
- ☐ Harde aktiviteter som tungt fysisk arbeid, ski eller tennis *4p*
- ☐ Moderate aktiviteter som moderat fysisk arbeid, løping eller jogging *3p*
- ☐ Lette aktiviteter som gange, husarbeid eller hagearbeid *2p*
- ☐ Umulig å foreta seg noen av de overnevnte aktiviteter på grunn av hevelse *1p*

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

JA *1p* NEI *2p*

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

- ☐ Veldig harde aktiviteter som hopping og vendinger ved basketball eller fotball *5p*
- ☐ Harde aktiviteter som tungt fysisk arbeid, ski eller tennis *4p*
- ☐ Moderate aktiviteter som moderat fysisk arbeid, løping eller jogging *3p*
- ☐ Lette aktiviteter som gange, husarbeid eller hagearbeid *2p*
- ☐ Umulig å foreta seg noen av de overnevnte aktiviteter på grunn av svikt av kneet *1p*

IDRETTSAKTIVITETER:

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

- ☐ Veldig harde aktiviteter som hopping og vendinger ved basketball eller fotball *5p*
- ☐ Harde aktiviteter som tungt fysisk arbeid, ski eller tennis *4p*
- ☐ Moderate aktiviteter som moderat fysisk arbeid, løping eller jogging *3p*
- ☐ Lette aktiviteter som gange, husarbeid eller hagearbeid *2p*
- ☐ Umulig å foreta seg noen av de overnevnte aktiviteter på grunn av kneet *1p*

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

	Ikke vanskelig i hele tatt	Litt vanskelig	Moderat vanskelig	Ekstremt vanskelig	Kan ikke i det hele tatt
Gå opp trapper					
Gå ned trapper					
Knele/ gå ned på kne					
Gå ned på huk/gjøre knebøy					
Sitte med bøyd kne					
Reise deg opp fra stol					
Løpe rett frem					
Hinke på ditt skadete ben					
Starte og stoppe raskt					
	5p	*4p*	*3p*	*2p*	*1p*

FUNKSJON:

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

10. FUNKSJON FØR KNESKADEN (sett ring rundt) *(poeng registreres ikke)*:

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

10. NÅVÆRENDE KNEFUNKSJON (sett ring rundt):

Kan ikke gjøre daglige aktiviteter	0 *1p*	1 *2p*	2 *3p*	3 *4p*	4 *5p*	5 *6p*	6 *7p*	7 *8p*	8 *9p*	9 *10p*	10 *11p*	Ingen begrensninger i daglige aktiviteter

IKDC 2000 ((x-18/87)*100)= _____

(Orginalartikkel: Irrgang et al. Development and validation of the International Knee Documentation Committee Subjective Knee Form. The American Journal of Sports Medicine 2001;29(5):600-13 Oversatt av Norsk Senter for Aktiv Rehabilitering, Ullevål Universitetessykehus, Oslo, 2005, til og med trinn 4 etter retningslinjer utarbeidet av: Guillemin F, Bombardier C, Beaton D. Cross-cultural adaptation of health-related quality-of-life measures: Literature review and proposed guidelines. J Clin Epidemiol 1993;46:1417-32)

Appendix 4

Bergen 15 May 2007

Norwegian KOOS, version LK1.0

The KOOS form was translated into Norwegian in the following way.

Translation done at The Norwegian Arthroplasty Register (NAR)

- KOOS was translated from the Swedish version by two researchers in orthopedics. The choice of using the Swedish version was based on the assumption that cultural differences between the two neighbour countries would be minimal due to similarities in language and lifestyle.
- The translation was checked by two bilingual orthopedic surgeons (Swedes with permanent address in Norway).
- The form was tested on knee arthroplasty patients to clarify potential misinterpretations.

Translation done by The Norwegian National Knee Ligament Registry (NKLR)

- A translation from the English version was done by an orthopedic researcher.
- Another translation from the Swedish version was done by a former researcher at the Norwegian School of Sport Sciences who is bilingual in Norwegian and Swedish.
- The translations were compared, and due to only minor differences in the use of synonyms, the NKLR chose a wording as close to the Swedish translation as possible. This is due to the fact that the creators of the KOOS form are Swedish, even though the first form was made in English.

Finally the NAR and the NKLR versions were compared, minor adjustments were done, and the translators agreed upon a common translation. The final validated Norwegian version is named KOOS Norwegian version LK1.0

Nasjonalt Register for Leddproteser
Helse Bergen HF, Ortopedisk klinikk
Haukeland Universitetssykehus
5021 Bergen

The Norwegian Arthroplasty Register
Department of Orthopaedic Surgery
Haukeland University Hospital
N-5021 Bergen, Norway

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http://www.haukeland.no/nrl/

KOOS – SPØRRESKJEMA FOR KNEPASIENTER

DATO: _____/_____/_____ FØDELSENR (11 siffer): _____

NAVN: _____

Veiledning: Dette spørreskjemaet inneholder spørsmål om hvordan du opplever kneet ditt. Informasjonen vil hjelpe oss til å følge med i hvordan du har det og fungerer i ditt daglige liv. Besvar spørsmålene ved å krysse av for det alternativ du synes passer best for deg (kun ett kryss ved hvert spørsmål). Hvis du er usikker, kryss likevel av for det alternativet som føles mest riktig.

Symptom

Tenk på de **symptomene** du har hatt fra kneet ditt den **siste uken** når du besvarer disse spørsmålene**.**

S1. Har kneet vært hovent?

Aldri	Sjelden	I blant	Ofte	Alltid
☐	☐	☐	☐	☐

S2. Har du følt knirking, hørt klikking eller andre lyder fra kneet?

Aldri	Sjelden	I blant	Ofte	Alltid
☐	☐	☐	☐	☐

S3. Har kneet haket seg opp eller låst seg?

Aldri	Sjelden	I blant	Ofte	Alltid
☐	☐	☐	☐	☐

S4. Har du kunnet rette kneet helt ut?

Alltid	Ofte	Iblant	Sjelden	Aldri
☐	☐	☐	☐	☐

S5. Har du kunnet bøye kneet helt?

Alltid	Ofte	I blant	Sjelden	Aldri
☐	☐	☐	☐	☐

Stivhet

De neste spørsmålene handler om **leddstivhet**. Leddstivhet innebærer vanskeligheter med å komme i gang eller økt motstand når du bøyer eller strekker kneet. Marker graden av leddstivhet du har opplevd i kneet ditt den **siste uken**.

S6. Hvor stivt er kneet ditt når du nettopp har våknet om morgenen?

Ikke noe	Litt	Moderat	Betydelig	Ekstremt
☐	☐	☐	☐	☐

S7. Hvor stivt er kneet ditt **senere på dagen** etter å ha sittet, ligget eller hvilt?

Ikke noe	Litt	Moderat	Betydelig	Ekstremt
☐	☐	☐	☐	☐

Smerte

P1. Hvor ofte har du vondt i kneet?

Aldri	Månedlig	Ukentlig	Daglig	Hele tiden
☐	☐	☐	☐	☐

Hvilken grad av smerte har du hatt i kneet ditt den **siste uken** ved følgende aktiviteter?

P2. Snu/vende på belastet kne

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

P3. Rette kneet helt ut

Ingen	Lett	Moderate	Betydelig	Svært stor
☐	☐	☐	☐	☐

P4. Bøye kneet helt

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

P5. Gå på flatt underlag

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

P6. Gå opp eller ned trapper

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

P7. Om natten i sengen (smerter som forstyrrer søvnen)

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

P8. Sittende eller liggende

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

P9. Stående

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

Funksjon I hverdagen

De neste spørsmål handler om din fysiske funksjon. **Angi graden av vanskeligheter du har opplevd den siste uken ved følgende aktiviteter på grunn av dine kneproblemer**.

A1. Gå ned trapper

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

A2. Gå opp trapper

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

Angi graden av **vanskeligheter** du har opplevd ved hver aktivitet den **siste uken**.

A3. Reise deg fra sittende stilling

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

A4. Stå stille

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

A5. Bøye deg, f.eks. for å plukke opp en gjenstand fra gulvet

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

A6. Gå på flatt underlag

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

A7. Gå inn/ut av bil

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

A8. Handle/gjøre innkjøp

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

A9. Ta på sokker/strømper

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

A10. Stå opp fra sengen

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

A11. Ta av sokker/strømper

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

A12. Ligge i sengen (snu deg, holde kneet i samme stilling i lengre tid)

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

A13. Gå inn og ut av badekar/dusj

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

A14. Sitte

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

A15. Sette deg og reise deg fra toalettet

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

Angi graden av **vanskeligheter** du har opplevd ved hver aktivitet den **siste uken.**

A16. Gjøre tungt husarbeid (måke snø, vaske gulv, støvsuge osv.)

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

A17. Gjøre lett husarbeid (lage mat, tørke støv osv.)

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

Funksjon, sport og fritid

De neste spørsmålene handler om din fysiske funksjon. Angi graden av vanskeligheter du har opplevd **den siste uken** ved følgende aktiviteter på grunn av dine kneproblemer.

SP1. Sitte på huk

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

SP2. Løpe

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

SP3. Hoppe

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

SP4. Snu/vende på belastet kne

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

SP5. Stå på kne

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

Livskvalitet

Q1. Hvor ofte gjør ditt kneproblem seg bemerket?

Aldri	Månedlig	Ukentlig	Daglig	Alltid
☐	☐	☐	☐	☐

Q2. Har du forandret levesett for å unngå å overbelaste kneet?

Ingenting	Noe	Moderat	Betydelig	Fullstendig
☐	☐	☐	☐	☐

Q3. I hvor stor grad kan du stole på kneet ditt?

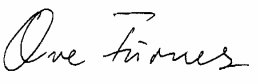
Fullstendigl	I stor grad	Moderat	Til en viss grad	Ikke i det hele tatt
☐	☐	☐	☐	☐

Q4. Generelt sett, hvor store problemer har du med kneet ditt?

Ingen	Lette	Moderate	Betydelige	Svært store
☐	☐	☐	☐	☐

Takk for at du tok deg tid og besvarte samtlige spørsmål!

Until otherwise is decided it is recommended that future revisions of the Norwegian KOOS form are done by The Norwegian Arthroplasty Register. If someone find that any questions from the questionnaire is difficult to understand or difficult to answer, we will be thankful to receive information on this.



Ove Furnes

Director,
The Norwegian Arthroplasty Register

Chairman,
Department of Orthopaedic Surgery,
Haukeland University Hospital,
N-5021 Bergen, Norway

Stein Håkon Låstad Lygre

Research Fellow,
The Norwegian Arthroplasty Register

Appendix 5

Navn

Personnr Dato for utfylling

"TAMPA"
Spørsmål om smerte og fysisk aktivitet

Vennligst svar på de følgende spørsmål. Svar i forhold til dine egne følelser, ikke i forhold til hva andre synes du skal mene. Sett ring rundt det tallet ved siden av hvert spørsmål som best tilsvarer dine følelser.

	SVÆRT UENIG	LITT UENIG	LITT ENIG	SVÆRT ENIG
1. Folk tar ikke min medisinske tilstand alvorlig nok……	1	2	3	4
2. Kroppen forteller meg at noe er alvorlig galt…….	1	2	3	4
3. Skaden har gjort at kroppen min vil være utsatt resten av livet……...	1	2	3	4
4. Jeg er redd for at jeg kan skade meg ved et uhell...……	1	2	3	4
5. Smertene ville blitt verre hvis jeg hadde prøvd å overvinne dem……	1	2	3	4
6. Det sikreste jeg kan gjøre for å hindre at smertene blir verre, er å unngå unødvendige bevegelser…….	1	2	3	4
7. Jeg ville ikke hatt så mye smerte hvis det ikke foregikk noe potensielt farlig i kroppen min…….	1	2	3	4
8. Smerter betyr alltid at jeg har skadet kroppen……	1	2	3	4
9. Smertene sier fra når jeg skal stoppe treningen, slik at jeg ikke skader meg……..…..	1	2	3	4
10. Det er faktisk ikke trygt for en person med min tilstand å være fysisk aktiv…….	1	2	3	4
11. Jeg er redd jeg kan komme til å skade meg hvis jeg trener……...……	1	2	3	4
12. Jeg kan ikke gjøre alle de tingene folk flest gjør, fordi jeg har så lett for å bli skadet…….…….	1	2	3	4
13. Ingen burde være nødt til å trene når han eller hun har smerter……...…….	1	2	3	4

(The Tampa scale. Kori, Miller & Todd
oversatt av Haugen, AJ og Grøvle, L 2004)

Idrett og aktivitet ved patellofemoral instabilitet

Haraldsplass Diakonale sykehus

Navn:	*Fødselsnr:*	*Dato for utfylling:*

1. Hva regner du som din hoved-idrett/aktivitet? Sett et kryss bak din idrett/aktivitet.

Fotball	Aerobic	Svømme
Håndball	Styrketrening	Turn/Rytmisk gymnastikk
Basketball	Alpint/Telemark	Sykle
Volleyball	Langrenn	Gange i terreng
Tennis/badminton	Dans	Gange jevnt underlag
Kampsport	Løp i terreng	Annet
Trampoline	Løp jevnt underlag	Beskriv annen idrett:

2. På hvilket nivå utførte du din idrett/aktivitet før plagene oppstod? Sett kun ett kryss.

Elitenivå	☐	Konkurranse middels til høyt nivå	☐
Konkurranse lavere nivå	☐	Mosjonsnivå	☐

3. På hvilket nivå utfører du idrett/aktivitet nå? Sett kun ett kryss.

Elitenivå	☐	Konkurranse middels til høyt nivå	☐
Konkurranse lavere nivå	☐	Mosjonsnivå	☐
Sluttet/driver ikke lenger med	☐	Ikke prøvd ennå	☐

4. Hvordan fungerer kneet ditt nå ved din idrett/aktivitet?

Som før plagene oppstod/uten plager	☐	Med små plager eller begrensninger	☐
Betydelige plager eller begrensninger	☐	Forsøkt, men gitt opp grunnet kneplagene	☐
Ikke forsøkt pga frykt for nye plager	☐	Ikke gjenopptatt, annen årsak	☐

5. Hvor stor er din motivasjon for å gjenoppta din idrett/aktiviteter på samme nivå som før plagene oppstod?

(Sett skråstrek helt til venstre (ved 0) dersom du ikke er motivert for å gjenoppta din idrett/aktivitet på samme nivå som før plagene oppstod).

0 ——————————————————— 100

Ikke motivert — Ekstremt motivert

Appendix 7

Intervjuguide

Innledning:

Jeg kommer til å styre samtale, det er ingen riktige svar, vi er ute etter dine erfaringer og opplevelser. Det er veldig fint hvis du klarer å gi eksempler når du svarer på spørsmålene.

Kort om hvorfor vi ønsker å vite mer om deltagernes erfaringer.

Temaer

ADL

- Hvordan har det vært for deg å leve med ustabilt kneskjell?
- Hvilke forventninger hadde du til hvordan kneet skulle fungere etter operasjonen?
- Hvilke forventninger hadde du til funksjon etter operasjon.
- Hvordan har du tilpasset livet ditt til et kne med ustabilt kneskjell?
- Hvordan fungerer kneet ditt på jobb/skole?
- Hvordan fungerer kneet i ADL?
    - Eksempler
- Noe du unngår?
    - Hvorfor?
- Hva er det som gjør at du ikke kan gjøre den aktiviteten?
- Hvordan har det påvirket deg sosialt?
- Følte du at du ble tatt på alvor

Aktiviteter

- Hva er ønskene dine for aktivitet?
- Hva hindrer deg i å drive med den (de) aktivitetene du ønsker?
- Har du eksempler på hvorfor de ikke kan drive med den aktiviteten?
- Hvilke aktivitet og idrett driver du med i dag?
- Hvor ofte driver du med aktivitet og eller idrett i løpet av en vanlig uke?
- Er det aktiviteter du ikke driver med pga ditt kneproblem? I såfall hvilke?
- Hvor motivert er du for å kunne drive med alle aktivitetene du ønsker?
- Når følte du deg klar for aktivitet igjen?
- Hvordan har det påvirket ditt aktivitetsnivå å ha ustabilt kneskjell?'
- Hva skal til for å komme tilbake i aktivitet?

RTS testing

- Er det relevant for deg å teste om kneet ditt er klar til å drive idrett/ krevende aktivitet?
- Ja/nei – hvorfor?
- Hva synes de om testene, er de relevant for deg og dine problemer?
- Hvordan opplevde du testingen?

Rehabilitering etter kirurgi (fysioterapi)

- Hva har du gjort for å gjenvinne funksjon etter operasjonen?
- Har du gått til fysioterapeut etter operasjonen din?
- Hvor ofte hadde du timer?
- Hva gjorde du hos fysioterapeuten?
- Hadde du hjemmeøvelser?
    - Hvilke? Hvor ofte?
- Er det noe du savner i oppfølgingen hos fysioterapeut?

Appendix 7

- Hvorfor sluttet du med behandlingen?

Postoperativ oppfølging fra sykehuset

- Hvordan opplevde du oppfølgingen fra sykehuset?
- For mye/lite kontroller?
- Hva savner du?

Hva var det som endret seg etter operasjonen?

- Gir frykten seg?

Hva gjør det med deg at du har hatt disse problemene siden barndommen?
Har det påvirket deg som person at du har levd med et ustabilt kneskjell?
Hva er det viktigste/den største påvirkningen på livet ditt ved å leve med instabil patella?

Noe annet du vil tilføye?

INFORMASJONSSKRIV TIL BARN/UNGDOM 12-16 (- 18) ÅR:

USTABILT KNESKJELL - UTVIKLING AV ET TESTBATTERI OG AKTIVITETSREGISTRERING

BAKGRUNN OG HENSIKT

Dette er et spørsmål til deg om å delta i en forskningsstudie for å undersøke nytten av ulike tester og spørreskjema etter stabiliserende kirurgi for ustabilt kneskjellet.

Du er operert eller skal gjennomgå stabiliserende kirurgi ved Haraldsplass Diakonale Sykehus eller et av sykehusene i Helse Vest og vi inviterer deg derfor til å delta i studien. Haraldsplass Diakonale Sykehus er ansvarlig for prosjektet. Prosjektet gjennomføres i samarbeid med de andre sykehusene i Helse Vest.

HVA INNEBÆRER STUDIEN?

Deltakelse innebærer at du ved første undersøkelse på sykehuset gjennomgår 4 fysiske tester og 6 spørreskjema i etterkant av undersøkelse hos legen. Spørreskjemaene omhandler plager fra kneet, hvor ustabilt kneet oppleves og bekymringer vedrørende kne plagene. I tillegg til hvilke aktiviteter/idrett du deltok i før kneproblemene oppstod, dagens deltakelse og motivasjon for å gjenoppta samme nivå som tidligere. Denne undersøkelsen vil ta omtrent 60 minutter. Omkring seks måneder etter operasjonen vil du bli innkalt til en ekstra kontroll. Vi vil da be deg gjenta de fysiske testene samt fylle ut 3 av spørreskjemaene. Du vil også bli spurt om å fylle ut 3 av spørreskjemaene 2 uker før seks måneders kontrollen. Når det er gått 1 og 2 år siden operasjonen vil vi sende ut spørreskjemaet som omhandler aktivitet og idrett i posten for utfylling, med vedlagt frankert returkonvolutt. Fra journalen din vil vi hent følgende opplysninger om deg: fødselsnummer, operasjonsmetode, tidligere skader i kneet, vekt og høyde. Skulle du ikke ønske å delta i studien vil du følge våre standard kontrollrutiner.

MULIGE FORDELER OG ULEMPER

Ved å delta i studien vil du få mulighet til å belyse viktige sider ved vår evaluering om du er klar for retur til fritidsaktiviteter og/eller idrett. Videre vil du få tettere oppfølging enn vanlig. Undersøkelsen på sykehuset tar litt lengre tid enn vanlig. Testene du skal gjennomføre gjør ikke vondt eller er ubehagelige.

Du vil ikke bli utsatt for noen andre undersøkelser eller behandlinger enn det som er beskrevet over.

HVA SKJER MED PRØVENE OG INFORMASJONEN OM DEG?

Alle personopplysninger vil bli behandlet konfidensielt. Det betyr at informasjonen som registreres om deg skal kun brukes slik som beskrevet over studien og at alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste. Det betyr at opplysningene er avidentifisert.

Det er kun autorisert personell i prosjektgruppen som har adgang til navnelisten og som kan finne tilbake til deg. Opplysningene vi har samlet om deg vil bli slettet innen 01.01.2033.

Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Appendix 8

DELTAKELSE

Det er frivillig å delta i studien. Du kan når som helst og uten å oppgi noen grunn trekke deg fra deltagelse i studien. Alle opplysninger om deg vil da bli anonymisert. Dette vil ikke få konsekvenser for din videre behandling.

KONTAKTOPPLYSNINGER

Dersom du har spørsmål til prosjektet eller ønsker å trekke deg fra deltakelse, kan du kontakte:
Prosjektleder: Trine Hysing-Dahl, tlf. 469 03 740, trine.hysing-dahl@haraldsplass.no
Forskningskoordinator: Ingun Fleten Mo, tlf. 469 03 961, ingunn.fleten.mo@haraldsplass.no.

Appendix 9

Forespørsel om deltakelse i forskningsprosjektet

Ustabilt kneskjell
- utvikling av et testbatteri og aktivitetsregistrering

FORMÅLET MED PROSJEKTET OG HVORFOR DU BLIR SPURT PÅ VEGNET AV DITT BARN

Dette er et spørsmål til deg om deltagelse for ditt barn i en forskningsstudie for å undersøke gjennomførbarheten til et testbatteri til bruk etter stabiliserende kirurgi for ustabilt kneskjell.
Ditt barn er operert eller skal gjennomgå stabiliserende kirurgi ved Haraldsplass Diakonale Sykehus eller et av sykehusene i Helse Vest og vi inviterer derfor han/henne til å delta i studien. Haraldsplass Diakonale Sykehus er ansvarlig for prosjektet. Prosjektet gjennomføres i samarbeid med de andre sykehusene i Helse Vest.

HVA INNEBÆRER DELTAKELSE I PROSJEKTET FOR DITT BARN?

Deltakelse innebærer at barnet ved første undersøkelse på sykehuset gjennomgår 4 fysiske tester og 6 spørreskjema i etterkant av undersøkelse hos legen. Spørreskjemaene omhandler plager fra kneet, hvor ustabilt kneet oppleves og bekymringer vedrørende kne plagene. I tillegg til hvilke aktiviteter/idrett barnet deltok i før kneproblemene oppstod, dagens deltakelse og motivasjon for å gjenoppta samme nivå som tidligere. Denne undersøkelsen vil ta omtrent 60 minutter. Omkring seks måneder etter operasjonen vil barnet bli innkalt til en ekstra kontroll. Vi vil da be barnet gjenta de fysiske testene samt fylle 3 av spørreskjemaene. Barnet vil også bli spurt om å fylle ut 3 av spørreskjemaene 2 uker før seks måneders kontrollen. Noen uker etter 6 måneders kontrollen vil vi invitere barnet til et intervju som vil vare om lag 30 minutter. Vi vil da spørre om hvordan kneet fungerer i aktivitet og idrett, hvilke aktiviteter barnet driver med og hvordan oppfølgingen fra sykehus/fysioterapeut har vært Vi vil også spørre om hvordan det har påvirket barnet å leve med et ustabilt kneskjell. Når det er gått 1 og 2 år siden operasjonen vil vi sende ut 3 av spørreskjemaene i posten for utfylling, med vedlagt frankert returkonvolutt. Vi vil i tillegg registrere følgende opplysninger om barnet, fødselsnummer, operasjonsmetode, tidligere skader kneet, vekt og høyde. Skulle ditt barn ikke ønske å delta i studien vil han/henne følge våre standard kontrollrutiner.

Foreldre som samtykker på vegne av barn kan på forespørsel få se spørreskjemaene og beskrivelse av de fysiske testene før samtykke gis.

MULIGE FORDELER OG ULEMPER

Ved å delta i studien vil deltakeren få mulighet til å belyse viktige sider ved vår evaluering om han/hun er klar for retur til fritidsaktiviteter og/eller idrett. Barnet vil få tettere poliklinisk oppfølging enn vanlig. Vi vil ikke gjennomføre noen andre undersøkelser eller behandlinger enn det som er beskrevet over.

FRIVILLIG DELTAKELSE OG MULIGHET FOR Å TREKKE DITT SAMTYKKE

Det er frivillig å delta i prosjektet. Dersom barnet ønsker å delta, undertegner du samtykkeerklæringen på siste side. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke. Det vil ikke ha noen negative konsekvenser for barnet eller han/hennes behandling hvis dere ikke vil delta eller senere velger å trekke samtykket. Dersom du trekker tilbake samtykket, vil det ikke forskes videre på barnets helseopplysninger. Du kan også kreve at barnets helseopplysninger i prosjektet slettes eller utleveres innen 30 dager, og at det biologiske materialet destrueres. Adgangen til å kreve destruksjon, sletting eller utlevering gjelder ikke dersom materialet eller opplysningene er anonymisert eller publisert. Denne adgangen kan også begrenses dersom opplysningene er inngått i utførte analyser. Dersom du senere ønsker å trekke samtykket eller har spørsmål til prosjektet, kan du kontakte prosjektleder (se kontaktinformasjon på siste side). Dette vil ikke få konsekvenser for barnets videre behandling.

HVA SKJER MED OPPLYSNINGENE OM BARNET?

Alle personopplysninger vil bli behandlet konfidensielt. Informasjonen som registreres om barnet skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter barnet og barnets opplysninger gjennom en navneliste. Det betyr at opplysningene er avidentifisert. Det er kun autorisert personell i prosjektgruppen som har adgang til navnelisten og som

kan finne tilbake til barnet. Opplysningene vi har samlet om barnet vil bli slettet innen 01.01.2033. Det vil ikke være mulig å identifisere barnet i resultatene av studien når disse publiseres.

Opplysningene som registreres om barnet skal kun brukes slik som beskrevet under formålet med prosjektet, og planlegges brukt til 01.01.2028. Eventuelle utvidelser i bruk og oppbevaringstid kan kun skje etter godkjenning fra REK og andre relevante myndigheter. Du har rett til innsyn i hvilke opplysninger som er registrert om barnet og rett til å få korrigert eventuelle feil i de opplysningene som er registrert. Du har også rett til å få innsyn i sikkerhetstiltakene ved behandling av opplysningene. Du kan klage på behandlingen av barnets opplysninger til Datatilsynet og institusjonen sitt personvernombud. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger (=kodede opplysninger). En kode knytter barnet og barnets opplysninger gjennom en navneliste. Det er kun prosjektleder, Trine Hysing-Dahl og forskningskoordinator, Ingun Fleten Mo, som har tilgang til denne listen.

Opplysningene om ditt barn vil bli oppbevart i fem år etter prosjektslutt av kontrollhensyn.

FORSIKRING

Ved deltakelse i prosjektet vil barnet være dekket av pasientskadeloven.

ØKONOMI

Prosjektet er finansiert av forskningsmidler fra Helse Vest. Barnet vil ikke motta økonomisk kompensasjon for deltakelse. Egenandel ved tilleggs kontrollen vil dekkes av prosjektet.

GODKJENNINGER

Regional komité for medisinsk og helsefaglig forskningsetikk har gjort en forskningsetisk vurdering og godkjent prosjektet (ID:185067). Haraldsplass Diakonale Sykehus og prosjektleder Trine Hysing-Dahl er ansvarlig for personvernet i prosjektet. Vi behandler opplysningene basert på ditt samtykke.

KONTAKTOPPLYSNINGER

Dersom du har spørsmål til prosjektet eller ønsker å trekke deg fra deltakelse, kan du kontakte:

Prosjektleder: Trine Hysing-Dahl, tlf. 469 03 740, e-post trine.hysing-dahl@haraldsplass.no
Forskningskoordinator: Ingun Fleten Mo, tlf. 469 03 961, e-post ingunn.fleten.mo@haraldsplass.no.

Dersom du har spørsmål om personvernet i prosjektet, kan du kontakte personvernombudet ved institusjonen: Personvern@haraldsplass.no

Datatilsynets e-postadresse er: Postkasse@datatilsynet.no

Som foresatte til_ (Fullt navn) samtykker vi til at hun/han kan delta i prosjektet

Sted og dato

Foresattes signatur

Foresattes navn med trykte bokstaver

Sted og dato

Foresattes signatur

Foresattes navn med trykte bokstaver

Appendix 10

Forespørsel om deltakelse i forskningsprosjektet

Ustabilt kneskjell
- utvikling av et testbatteri og aktivitetsregistrering

FORMÅLET MED PROSJEKTET OG HVORFOR DU BLIR SPURT

Dette er et spørsmål til deg om å delta i en forskningsstudie for å undersøke nytten av ulike tester og spørreskjema etter stabiliserende kirurgi for ustabilt kneskjellet.
Du er operert eller skal gjennomgå stabiliserende kirurgi ved Haraldsplass Diakonale Sykehus eller et av sykehusene i Helse Vest og vi inviterer deg derfor til å delta i studien. Haraldsplass Diakonale Sykehus er ansvarlig for prosjektet. Prosjektet gjennomføres i samarbeid med de andre sykehusene i Helse Vest.

HVA INNEBÆRER DELTAKELSE I PROSJEKTET?

Deltakelse innebærer at du ved første undersøkelse på sykehuset gjennomgår 4 fysiske tester og 6 spørreskjema i etterkant av undersøkelse hos legen. Spørreskjemaene omhandler plager fra kneet, hvor ustabilt kneet oppleves og bekymringer vedrørende kne plagene. I tillegg til hvilke aktiviteter/idrett du deltok i før kneproblemene oppstod, dagens deltakelse og motivasjon for å gjenoppta samme nivå som tidligere. Denne undersøkelsen vil ta omtrent 60 minutter. Omkring seks måneder etter operasjonen vil du bli innkalt til en ekstra kontroll. Vi vil da be deg gjenta de fysiske testene samt fylle ut 3 av spørreskjemaene. Du vil også bli spurt om å fylle ut 2 av spørreskjemaene 2 uker før seks måneders kontrollen. Noen uker etter 6 måneders kontrollen vil vi invitere deg til å delta på et intervju med prosjektleder. Vi vil da spørre deg spørsmål om hvordan kneet fungerer i idrett og aktivitet, hvilke aktiviteter du driver med og hvordan oppfølgingen fra sykehus/fysioterapeut har vært etter operasjonen, vi vil også spørre om hvordan det har påvirket deg å leve med et ustabilt kneskjell. Når det er gått 1 og 2 år siden operasjonen vil vi sende ut 3 av spørreskjemaene i posten for utfylling, med vedlagt frankert returkonvolutt. Vi vil i tillegg registrere følgende opplysninger om deg, fødselsnummer, operasjonsmetode, tidligere skader kneet, vekt og høyde. Skulle du ikke ønske å delta i studien vil du følge våre standard kontrollrutiner.

MULIGE FORDELER OG ULEMPER

Ved å delta i studien vil du få mulighet til å belyse viktige sider ved vår evaluering om du er klar for retur til fritidsaktiviteter og/eller idrett. Videre vil du få tettere poliklinisk oppfølging enn vanlig.
Du vil ikke bli utsatt for noen andre undersøkelser eller behandlinger enn det som er beskrevet over.

FRIVILLIG DELTAKELSE OG MULIGHET FOR Å TREKKE DITT SAMTYKKE

Det er frivillig å delta i prosjektet. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke. Det vil ikke ha noen negative konsekvenser for deg eller din behandling hvis du ikke vil delta eller senere velger å trekke deg. Dersom du trekker tilbake samtykket, vil det ikke forskes videre på dine helseopplysninger. Du kan også kreve at dine helseopplysninger i prosjektet slettes eller utleveres innen 30 dager, og at det biologiske materialet destrueres. Adgangen til å kreve destruksjon, sletting eller utlevering gjelder ikke dersom materialet eller opplysningene er anonymisert eller publisert. Denne adgangen kan også begrenses dersom opplysningene er inngått i utførte analyser. Dersom du senere ønsker å trekke deg eller har spørsmål til prosjektet, kan du kontakte prosjektleder (se kontaktinformasjon på siste side). Dette vil ikke få konsekvenser for din videre behandling.

HVA SKJER MED OPPLYSNINGENE OM DEG?

Alle personopplysninger vil bli behandlet konfidensielt. Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste. Det betyr at opplysningene er avidentifisert. Det er kun autorisert personell i prosjektgruppen som har adgang til navnelisten og som kan finne tilbake til deg. Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Opplysningene som registreres om deg skal kun brukes slik som beskrevet under formålet med prosjektet, og planlegges brukt til 01.01.2028. Eventuelle utvidelser i bruk og oppbevaringstid kan kun skje etter godkjenning fra REK og andre

relevante myndigheter. Du har rett til innsyn i hvilke opplysninger som er registrert om deg og rett til å få korrigert eventuelle feil i de opplysningene som er registrert. Du har også rett til å få innsyn i sikkerhetstiltakene ved behandling av opplysningene. Du kan klage på behandlingen av dine opplysninger til Datatilsynet og institusjonen sitt personvernombud. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger (=kodede opplysninger). En kode knytter deg til dine opplysninger gjennom en navneliste. Det er kun prosjektleder, Trine Hysing-Dahl og forskningskoordinator, Ingun Fleten Mo, som har tilgang til denne listen.

Opplysningene om deg vil bli oppbevart i fem år etter prosjektslutt av kontrollhensyn.

FORSIKRING
Ved deltakelse i prosjektet vil du være dekket av pasientskadeloven.

ØKONOMI
Prosjektet er finansiert av forskningsmidler fra Helse Vest. Du vil ikke motta økonomisk kompensasjon for deltakelse. Egenandel ved tilleggs kontrollen vil dekkes av prosjektet.

GODKJENNINGER
Regional komité for medisinsk og helsefaglig forskningsetikk har gjort en forskningsetisk vurdering og godkjent prosjektet (ID:185067). Haraldsplass Diakonale Sykehus og prosjektleder Trine Hysing-Dahl er ansvarlig for personvernet i prosjektet. Vi behandler opplysningene basert på ditt samtykke.

KONTAKTOPPLYSNINGER
Dersom du har spørsmål til prosjektet eller ønsker å trekke deg fra deltakelse, kan du kontakte:

Prosjektleder: Trine Hysing-Dahl, tlf. 469 03 740, e-post trine.hysing-dahl@haraldsplass.no
Forskningskoordinator: Ingun Fleten Mo, tlf. 469 03 961, e-post ingunn.fleten.mo@haraldsplass.no.
Dersom du har spørsmål om personvernet i prosjektet, kan du kontakte personvernombudet ved institusjonen: Personvern@haraldsplass.no

Datatilsynets e-postadresse er: Postkasse@datatilsynet.no

JEG SAMTYKKER TIL Å DELTA I PROSJEKTET OG TIL AT MINE PERSONOPPLYSNINGER OG MITT BIOLOGISKE MATERIALE BRUKES SLIK DET ER BESKREVET

Sted og dato

Deltakers signatur

Deltakers navn med trykte bokstaver

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