

Association between single leg hop tests and patient reported outcome measures and patellar instability in patients with recurrent patellar dislocations

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To cite: Nilsgård TL, Øiestad BE, Randsborg P-H, et al. Association between single leg hop tests and patient reported outcome measures and patellar instability in patients with recurrent patellar dislocations. *BMJ Open Sport & Exercise Medicine* 2023;**9**:e001760. doi:10.1136/bmjsem-2023-001760

Accepted 29 November 2023



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ABSTRACT

Objectives To assess the associations between the single leg hop tests at two premises; baseline and the change after 12 months, and change in patient reported outcome measures and persistent instability after 12 months in patients with recurrent lateral patellar dislocation (RLPD).

Methods 61 RLPD patients aged 12–30 with a mean (\pm SD) of 19.2 (\pm 5.3) were assessed at baseline, and at 12 months after treatment with either active rehabilitation alone, or medial patellofemoral ligament reconstruction and active rehabilitation. Single leg hop for distance, triple hop for distance, crossover hop for distance and 6-metre timed hop were performed for both legs, and the Limb Symmetry Index (LSI) was calculated. Persistent patellar instability was self-reported as 'Yes' or 'No' at 12-month follow-up. Knee function in sport and recreational activities and knee-related quality of life were assessed at baseline and 12 months follow-up using the Knee injury and Osteoarthritis Outcome Score (KOOS).

Results LSI for the baseline single leg hop for distance and the triple hop for distance was significantly associated with persistent patellar instability at 12 months follow-up with an OR of 0.94 (95% CI 0.88 to 0.99) and OR of 0.91 (95% CI 0.84 to 0.99), respectively. No other statistically significant associations were detected.

Conclusion Individuals with higher LSI values for the single leg hop for distance and triple hop for distance conducted at baseline had lower odds for persistent patellar instability at 12 months follow-up. Clinicians can use results from these hop tests to assess the risk of future recurrent patellar instability prior to treatment.

Study design Retrospective cohort study.

Trial registration number NCT02263807.

INTRODUCTION

Recurrent lateral patella dislocation (RLPD) primarily affects adolescents and young active persons.¹ Patients with RLPD report significantly impaired knee function in sport and recreational activities and reduced knee-related quality of life (QoL) on the Knee Injury and Osteoarthritis Outcomes Score (KOOS).^{2–3} Although patients with RLPD

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Performance-based measures are recommended in evaluating physical function in other knee ligament injuries. However, there exists little knowledge on performance-based measures for patients with recurrent patellar lateral dislocations, and a Cochrane review from 2015 emphasised the need to define more objective criteria to measure individual patient progress and evaluate treatment interventions.

WHAT THIS STUDY ADDS

⇒ Our results indicate that the single leg hop for distance and the triple leg hop for distance can be used to guide clinicians in making more accurate prognoses for which patients would have persisting patellar instability at 12 months follow-up.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Our results should be validated in prediction models of larger data sets.

report similar symptom burden as patients with cruciate ligament injuries, they wait five times longer before treatment is initiated.³ The evaluation of patients with RLPD has mainly included image-based measures identifying anatomical risk factors for recurrent dislocations, and there are no established performance-based measures to evaluate knee function in patients with RLPD.

A clinical challenge is identifying patients who will not regain satisfactory knee function after treatment. A battery of four single leg hop tests is a frequently used performance-based measure to assess knee function in patients with anterior cruciate ligament (ACL) injuries,^{4,5} and the single leg hop tests have shown to predict IKDC scores (International Knee Documentation Committee) in patients treated operatively and non-operatively for ACL injuries.^{6,7} Even though hop tests have been used as an outcome

measure in patients treated for RLPD,^{2 8 9} we have little knowledge of the relationship between the single leg hop tests and patient reported outcome measures (PROMs) in patients with RLPD.

The single leg hop tests incorporate a variety of movements related to the demands of dynamic knee stability, such as strength, acceleration–deceleration, change of direction, neuromuscular control and confidence in the limb.¹⁰ If these tests of functional performance can identify those who will have an unsuccessful outcome in patients with RLPD, they can be used to inform clinical decision-making and direct interventions to improve knee function.

The purpose of this study was therefore to determine if performance on each of the four single leg hop tests at baseline were associated with the change in self-reported knee function in sport and recreational activities and knee-related QoL from baseline to 12 months, and persistent patellar instability at 12 months. Additionally, we wanted to assess the associations between change in performance on each of the four single hop tests and change in knee function in sport and recreational activities and knee-related QoL from baseline to 12 months and persistent patellar instability at 12 months.

Thus, we hypothesised that conducting the single leg hop tests would reflect the participants self-reported function in sport and recreational activities and knee-related QoL from the KOOS, and persistent patellar instability. One might expect patients who report low function on tasks such as running, jumping and pivoting activities and who report lifestyle modifications, trouble with confidence in their knee and persistent patellar instability to also have poorer performance on the single leg hop tests.

MATERIAL AND METHODS

The data used in this study originate from a randomised controlled trial (RCT) comparing reconstruction of the medial patellofemoral ligament (MPFL-R) and active rehabilitation to active rehabilitation alone for treatment of RLPD.¹¹

The RCT recruited participants aged 12–30 years with RLPD referred to the orthopaedic outpatient clinic at Akershus University Hospital between May 2010 and January 2019. Bilateral cases were excluded to enable comparisons with the non-injured leg. Baseline patient demographic such as age, sex, height and weight were collected. Participants were randomly allocated to treatment with MPFL-R and active rehabilitation (n=30), or active rehabilitation alone (n=31).¹¹ The MPFL-R-group underwent an open isolated MPFL-R procedure with semitendinosus graft modified from Deie *et al.*^{11 12}

Both groups were referred to physiotherapists in primary care for active rehabilitation according to a specific rehabilitation protocol (Appendix 1, Training program for the MPFL study). The rehabilitation goals were to increase muscle strength, restore neuromuscular control and prepare the participants for return to their desired activity level. Active contact sport participation

was not recommended the first 6 months after surgery. Patellar brace or McConnell patellar taping¹³ was recommended during high-risk activity in the first year.

Test procedures

The baseline and 12 months follow-up assessment took place at the orthopaedic outpatient clinic at Akershus University Hospital. A physiotherapist assessed the single leg hop tests.

Single leg hop tests

The four single leg hop tests consisted of the single hop for distance, the triple hop for distance, the crossover hop for distance and the 6-metre timed hop as described by Noyes *et al.*⁵ Hop tests were performed with the healthy limb first, as recommended.⁵ The first eight included patients performed only the single leg hop for distance at baseline. The test battery was then extended to include all four single leg hop tests.

The participants were given one practice trial before two measured and recorded attempts. A successful hop required the participants to maintain the one-footed landing for 3 s. The crossover hop for distance required a 15 cm medial-lateral deviation across the tape measure. Any of the following events classified as an unsuccessful hop: touching the floor with the non-injured foot, touching the walls or floor with either of the upper extremities, loss of balance, double hops or hops that moved too far or not far enough in the lateral direction. No brace or taping was applied during the hop tests. If the hop was unsuccessful, the participants were reminded of the requirement to get the attempt approved, and the hop was repeated. The distance was measured from toe at start to toe at landing. All hop test scores were recorded as absolute distance (in centimetres) or time (in seconds) for both extremities. The longest hop for all three distance hops and the quickest timed hop at baseline and 12 months were used in the analyses. A positive change implies an improvement in hop distance, while a negative change implies an improvement in the 6-meter timed hop.

Limb Symmetry Index (LSI) was calculated for each of the four hop tests where the injured leg was compared with the non-injured leg, expressed as a percentage score (injured leg divided by non-injured leg, multiplied by 100). An LSI $\geq 90\%$ has been defined as good functional recovery and return to sport clearance in the ACL literature.¹⁴ The single leg hop test results are presented as both a continuous variable and a dichotomous variable with the number of patients over a cut-off of 90%. In the analyses, LSI were handled as a continuous variable.

PROMs

The participants reported their knee function through the Norwegian version of the KOOS at baseline and 12 months follow-up.¹⁵ Only the subscales; function in sport and recreational activities (KOOS Sport/rec) and knee-related QoL (KOOS QoL) were included in the analyses,

since these have shown to be most responsive and relevant for this young patient group.^{3,16} The score goes from 0 (worst) to 100 (best). Calculation of the score of each subscale and missing data were treated according to the guidelines provided by Roos *et al.*¹⁷

Persistent patellar instability

Patellar knee instability was reported by the patients with a dichotomous answer option of Yes or No at 12 months follow-up. The patients were asked, 'have you experienced any events of partially or completely kneecap dislocations?'. Both were classified as persistent instability.

Data management and statistical analyses

Statistical analyses were performed using SPSS 22 (SPSS, Chicago, Illinois, USA). Descriptive statistics were presented as means (SD) or median (IQR) depending on the distribution of the data.¹⁸

The four single leg hop tests were assessed at two different premises; baseline performance (LSI) and change from baseline to 12 months (LSI). In both cases linear regression analyses were used to calculate the regression coefficient and significance level for the associations between each of the four single leg hop tests (LSI) and change in KOOS Sport/rec and change in KOOS QoL from baseline to 12 months.¹⁸ The associations between respectively baseline hop tests (LSI) and change from baseline to 12 months (LSI) and patellar instability were assessed with logistic regression analysis to calculate the ORs and CIs.¹⁹ Normal distribution was assessed based on the central tendency by comparing the mean and median, and visually assessed on the histogram, Q-Q and box plots. No imputation of missing data was conducted. The linear relationship between the continuous independent variables and the logit transformation of the dependent variable for the logistic regression was assessed using the Box-Tidwell procedure.^{20,21} The results were checked for outliers. The assumptions for linear regression were verified by visual assessment of the distribution of the residuals in three plots: histogram, the probability plot (P-P) and the scatterplot of the residuals.

All regression analyses were adjusted for age, gender, body mass index (BMI) and intervention. The regression analyses for the change from baseline to 12 months was also adjusted for baseline hop test performance. A *p* value of ≤ 0.05 was considered statistically significant.¹⁸ All tests were two-sided.

The study was registered at www.clinicaltrials.org.

RESULTS

A total of 61 patients, 31 managed with MPFL-R and active rehabilitation, and 30 managed with active rehabilitation were assessed at baseline and 12 months follow-up (figure 1). Most of the patients were women ($n=44$, 72%) with a mean age of 19.2 years at inclusion (table 1).

The baseline single leg hop tests were conducted at a median of 31 (range 3–230) months from first-time

dislocation. At baseline, 42 (81%) of the participants had an LSI $\geq 90\%$ on one or more of the four single leg hop tests. At 12 months follow-up, 53 (91%) of the participants had an LSI $\geq 90\%$ on one or more of the four single leg hop tests. Fifteen (24%) participants reported persistent patellar instability at 12 months follow-up.

The improvement from baseline to 12 months follow-up was on average of 17.4 and 25.4 points on KOOS Sport/rec and KOOS QoL. There were no significant associations between the LSI for the single leg hop tests at baseline and the change in function in sport and recreational activities or knee-related QoL. The LSI for the single leg hop for distance and the triple hop for distance at baseline were significantly associated with persistent patellar instability at 12 months with an OR of 0.94 (95% CI 0.88 to 0.99) and an OR of 0.91 (95% CI 0.84 to 0.99), respectively (table 2). Indicating that one unit increased LSI value at the single leg hop for distance and the triple hop for distance, showed 6% and 9% lower OR for reporting patellar instability at 12 months follow-up.

The change in LSI for the crossover hop for distance was positively associated with the change in sport and recreational activities from baseline to 12 months follow-up in an unadjusted analysis (table 3). The association was not statistically significant in a multiple linear regression analysis adjusted for age, gender, BMI, baseline hop test performance and intervention. We found no significant associations between the change in LSI for the single leg hop tests and change in knee-related QoL or persistent patellar instability at 12 months follow-up (table 3).

DISCUSSION

The main finding of this study was that the LSI for the single and triple leg hop for distance at baseline was associated with persistent instability at 12 months follow-up. The patients with RLPD improved their hop test performance and reported better PROM scores at 12 months. However, the improvement in LSI performance was not associated with persistent patellar instability at follow-up. Neither baseline nor change in hop performance (LSI) was associated with the change in PROM scores.

To our knowledge, this study is the first to demonstrate an association between performance on the single leg hop tests prior to treatment and persisting patellar instability at 12 months follow-up in patients with RLPD. The single leg hop tests have been most commonly used to evaluate knee function at a set point in time in patients with RLPD.^{2,8,9} Our results indicate that the single leg hop for distance and the triple leg hop for distance can be used to guide clinicians in making more accurate prognoses for which patients would have persisting patellar instability at 12 months follow-up, however, this should be validated in prediction models of larger data sets.

This study does not explain why the associations between the single leg and the triple hop for distance at baseline and persistent patellar instability were significant while the other hop tests were not. One explanation could be the order of the tests. We did not randomise

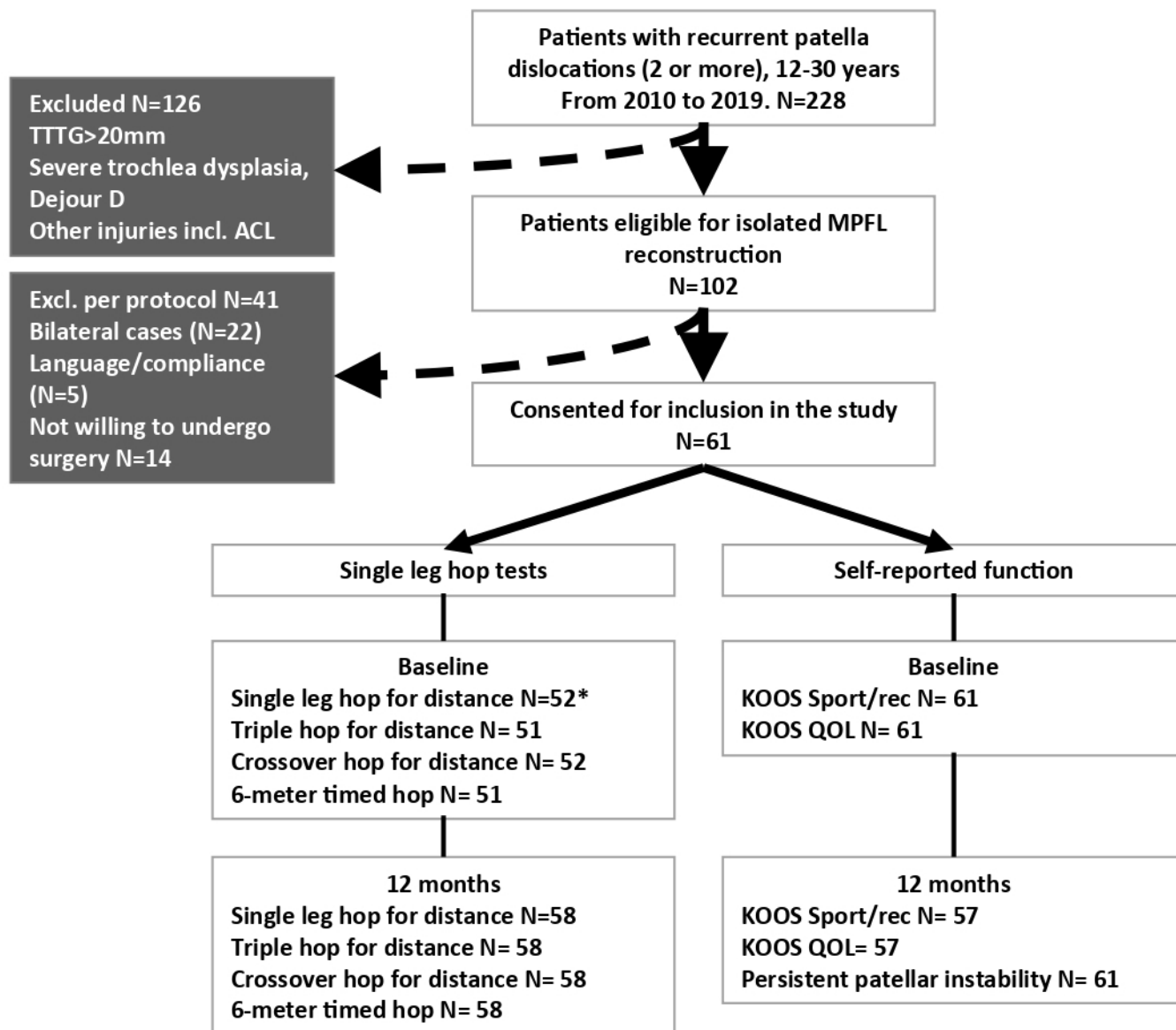


Figure 1 Study participant flow chart. *The first 8 patients only performed the single hop for distance. ACL, anterior cruciate ligament; KOOS, Knee injury and Osteoarthritis Outcome Score; MPFL, medial patellofemoral ligament; QoL, quality of life.; TTTG, tibial tuberosity to trochlear groove.

the order of the tests, which may have given a systematic bias in test results. We repeated an unsuccessful hop until we had two approved attempts, and the number of failed attempts was not recorded. Repetitive testing has been linked to increased fatigue,⁵ and reduced hop performance has been reported during fatiguing conditions.²² This could have led to poorer performance on the remaining single leg hop tests. Another explanation could be psychological factors such as lack of confidence in the knee, which are seen in patients with RLPD.²³ Patients with RLPD could be more apprehensive about hops in the transverse plane or fast hops. The single leg and triple hop for distance may be seen as less apprehensive single leg hop tests, making patients with RLPD able to facilitate maximum effort that challenges the dynamic knee stability.

Interestingly, we found no associations between change in the LSI hop performance from baseline to 12 months follow-up and persistent patellar instability. One-fourth of the participants reported persistent patellar instability at 12 months follow-up. However, our study of 61 patients may be underpowered to detect an association with change in LSI hop performance for the single leg hop tests. The main result from the RCT was that patients treated with MPFL-R had a significantly lower risk of persistent patellar instability.^{3 11} Still, after correcting for treatment with MPFL-R in the analyses, no association was found. The clinical value of these hop tests in a follow-up setting after treatment for RLPD is therefore limited.

The improvement in the LSI for the single leg hop for distance, the triple leg hop for distance, the crossover hop for distance and 6-metre timed hop was on average

Table 1 Characteristics of the participants at baseline and 12 months follow-up, n=61

	Baseline	12 months
Demographics		
Gender, n (%)		
Female	44 (72.1)	
Age	19.2 (±5.3)	
BMI, median (range)	23.3 (16.9–39.0)	
The single leg hop tests in centimetres or seconds		
Single hop for distance (cm)		
Injured	109.9 (±34.2)	118.7 (±29.3)*
Non-injured	120.4 (±32.1)	123.7 (±26.3)*
Triple hop for distance (cm)		
Injured	334.6 (±111.8)	351.5 (±84.9)*
Non-injured	362.9 (±102.5)	363.5 (±77.5)*
Crossover hop for distance (cm)		
Injured	289.0 (±103.2)	305.7 (±80.1)*
Non-injured	305.4 (±90.1)	319.0 (±74.7)*
6-metre timed hop (s)		
Injured	3.3 (±2.1)	3.0 (±1.2)
Non-injured	2.8 (±0.8)	2.8 (±0.9)
Single leg hop tests as LSI		
Single leg hop for distance	91.0 (±16.3)	95.6 (±10.3)
Triple hop for distance	92.1 (±12.8)	96.6 (±10.0)
Crossover hop for distance	94.1 (±16.7)	96.0 (±12.3)
6-metre timed hop	91.5 (±18.0)	96.1 (±12.0)
Number of patients with LSI over 90 in n (%)		
Single leg hop for distance	28 (54)†	38 (66)‡
Triple hop for distance	31 (61)†	42 (72)‡
Crossover hop for distance	32 (62)†	39 (67)‡
6-metre timed hop	30 (59)† ^a	42 (72)‡
Knee injury and Osteoarthritis Outcome Score (KOOS)		
KOOS Sport/rec (0–100)	56.0 (± 27.6)	73.4 (± 22.2)*
KOOS QoL (0–100)	39.0 (± 19.8)	64.4 (± 23.0)*

Results are in mean (± SD), unless stated otherwise.
 *Significant change from baseline to 12 months follow-up (p<0.05).
 †52 participants had LSI for the single and crossover hop for distance at baseline. 51 participants had LSI for the triple hop for distance and the 6-meter timed hop at baseline.
 ‡58 participants had LSI for all four hop tests at 12 months follow up.
 BMI, body mass index; LSI, Limb Symmetry Index; QoL, quality of life.

5.1%, 4.9%, 2% and 4.8% after 12 months of treatment. Already at baseline, over 80% of the participants had an LSI ≥90% on one or more of the four single leg hop tests.

Relevant clinically improvement may be different for someone with an LSI score at 50% and someone with LSI score at 90%. We speculate that the improvement in LSI from baseline to 12 months may have been too small for the association to patellar instability.

Single leg hop tests are a much-preferred performance-based outcome measure due to the utilisation of the non-injured leg as a control for comparisons.²⁴ However, some criticism for using LSI in the interpretation of hop tests has been the assumption that the non-injured leg is healthy and that any reduced activity level has not affected the function of this leg.²⁵ Decreased knee flexor strength in both the injured and non-injured leg has been reported for patients suffering from RLPD.²⁶ Our participants had a median of approximately 2.5 years from first dislocation to hop test assessment at baseline. It is likely that the non-injured leg also experienced limited physical activity and decreased muscle strength in our study, and a high LSI score would then exaggerate actual function.

Actual numbers have been reported on by Biesert *et al*, who found significantly poorer performance on the single leg hop for distance in patients suffering from RLPD than in healthy controls.² Several of the participants in our study were in or left puberty during study participation. During pubertal development, one would expect physical changes to improve hop tests due to the processes related to biological maturation, such as height and muscle strength.²⁷ An advantage of using LSI is that the participants are their own perfected matched control on age, gender and BMI.

The participants reported low KOOS scores at baseline, and the improvement from baseline to 12 months follow-up was double the reported clinically relevant change for both KOOS Sport/rec and KOOS QoL.²⁸ Even though both KOOS scores and LSI hop performance improved, our results showed no statistically significant associations. The single leg hop tests differ from two of the tasks on the subscale Sport/Rec, kneeling and squatting, in need of acceleration–deceleration, change of direction, neuromuscular control and confidence in the limb. One could manage these tasks well, but still have poor performance on the single leg hop tests, and opposite. The KOOS QoL subscale assesses knee-related QoL and does not directly measure knee function as tested with the single leg hop tests.

Several studies have investigated various functional measurements to determine whether a single test could be sufficient for describing self-reported function.^{29–31} But in general, they found that information from functional or clinician observed measurements differs from what is obtained from patient reported measurements. Participants in our study who rarely challenge themselves physically may not have difficulties with their knee function at their activity level and could therefore potentially score themselves better on PROMs, although they have poor LSI score. On the other hand, patients with a high activity level may score poorly on the PROMs, although

**Table 2** Associations between each single leg hop tests (LSI) at baseline, and functional outcome and patellar instability

Unadjusted analyses						
Baseline	Change in KOOS Sport/rec		Change in KOOS QoL		Instability at 12 months	
	B (95% CI)	P value	B (95% CI)	P value	OR (95% CI)	P value
Single hop for distance	-0.82 (-0.50 to 0.33)	0.694	-0.04 (-0.41 to 0.34)	0.837	0.96 (0.91 to 0.99)	0.041*
Triple hop for distance	-0.14 (-0.68 to 0.41)	0.615	-0.07 (-0.56 to 0.41)	0.767	0.94 (0.90 to 0.99)	0.036*
Cross over hop for distance	-0.29 (-0.75 to 0.17)	0.211	-0.24 (-0.66 to 0.18)	0.262	0.97 (0.92 to 1.01)	0.115
6-metre timed hop	-0.03 (-0.40 to 0.34)	0.856	0.19 (-0.14 to 0.51)	0.254	0.99 (0.95 to 1.02)	0.409
Adjusted analyses						
Baseline	Change in KOOS Sport/rec		Change in KOOS QoL		Instability at 12 months	
	B (95% CI)	P value	B (95% CI)	P value	OR (95% CI)	P value
Single hop for distance	-0.05 (-0.47 to 0.36)	0.798	-0.09 (-0.46 to 0.31)	0.642	0.94 (0.88 to 0.99)	0.043*
Triple hop for distance	-0.07 (-0.64 to 0.51)	0.815	-0.16 (-0.70 to 0.38)	0.548	0.91 (0.84 to 0.99)	0.020*
Cross over hop for distance	-0.20 (-0.71 to 0.31)	0.444	-0.37 (-0.85 to 0.12)	0.133	0.96 (0.91 to 1.03)	0.241
6-metre timed hop	-0.07 (-0.32 to 0.46)	0.736	0.20 (-0.17 to 0.56)	0.287	0.97 (0.92 to 1.02)	0.232

P value: significance level. *: significant values (p<0.05).
Adjusted analyses adjusted for age, gender, BMI and intervention.
B, regression coefficient; BMI, body mass index; KOOS, Knee injury and Osteoarthritis Outcome Score; LSI, Limb Symmetry Index; QoL, quality of life.

Table 3 Associations between change in each single leg hop tests (LSI) and functional outcome and patellar instability

Unadjusted analyses						
Change from baseline to 12 months	Change in KOOS Sport/rec		Change in KOOS QoL		Instability at 12 months	
	B (95% CI)	P value	B (95% CI)	P value	OR (95% CI)	P value
Single hop for distance	-0.02 (-0.53 to 0.49)	0.952	-0.15 (-0.16 to 0.30)	0.503	1.02 (0.97 to 1.07)	0.540
Triple hop for distance	0.13 (-0.46 to 0.47)	0.994	0.06 (-0.35 to 0.48)	0.769	0.98 (0.94 to 1.02)	0.321
Cross over hop for distance	0.54 (0.08 to 1.01)	0.024*	0.30 (-0.13 to 0.74)	0.167	1.01 (0.97 to 1.06)	0.630
6-metre timed hop	0.02 (-0.33 to 0.37)	0.919	-0.10 (-0.41 to 0.22)	0.541	1.00 (0.97 to 1.03)	0.903
Adjusted analyses						
Change from baseline to 12 months	Change in KOOS Sport/rec		Change in KOOS QoL		Instability at 12 months	
	B (95% CI)	P value	B (95% CI)	P value	OR (95% CI)	P value
Single hop for distance	-0.01 (-0.89 to 0.78)	0.891	-0.50 (-1.27 to 0.29)	0.210	0.94 (0.85 to 1.04)	0.213
Triple hop for distance	-0.04 (-0.74 to 0.68)	0.914	0.25 (-0.42 to 0.92)	0.455	0.99 (0.92 to 1.08)	0.982
Cross over hop for distance	0.64 (-0.03 to 1.30)	0.060	0.61 (-0.48 to 0.81)	0.166	0.96 (0.88 to 1.05)	0.353
6-metre timed hop	0.03 (-0.60 to 0.65)	0.923	-0.65 (-0.45 to 0.71)	0.132	0.98 (0.92 to 1.05)	0.576

P value: significance level. *: significant values (p<0.05).
Adjusted analyses adjusted for baseline hop test performance, age, gender, BMI and intervention.
B, regression coefficient; BMI, body mass index; KOOS, Knee injury and Osteoarthritis Outcome Score; LSI, Limb Symmetry Index; QoL, quality of life.

they could have a high LSI score. This underlines the idea that while sharing some similarities, the two measurements cannot directly be substituted for the other.

Limitations

The main limitation of this study was multiple testing on a small sample size. Second, our data originates from an RCT, which may not be the ideal study design for answering our objectives. The participants included in the study were those eligible for treatment with isolated MPFL-R, excluding patients with more severe anatomical risk factors. A study assessing the risk of recurrent patellar dislocations found that patients eligible for isolated MPFL-R to likely represent a milder spectrum of the RLPD population.³² This could limit the generalisability of our findings to apply to patients with less severe anatomical factors and those eligible for MPFL-R. Furthermore, we do not have information about leg dominance. The dominant leg might be stronger than the non-dominant leg, and may therefore affect the LSI.

CONCLUSION

Individuals with higher LSI values for the single leg hop for distance and triple hop for distance conducted at baseline had lower odds for persistent patellar instability at 12 months follow-up. Clinicians can use results from these hop tests to assess the risk of future recurrent patellar instability prior to treatment. We found no statistically significant associations between the single leg hop tests and PROMs.

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Acknowledgements The authors would like to acknowledge the physiotherapists Sarah Therese Pedersen and Baard Erik Larsen at the Department of Orthopaedic Surgery, Akershus University Hospital, for performing the follow-up testing.

Contributors TMS-N and AA designed the project. TMS-N, P-HR and AA included patients and collected data. TLN and BEØ analysed the data. TLN and TMS-N wrote the first draft of the paper, and all authors contributed to the final manuscript. All authors read and approved the final manuscript. TMS-N is the guarantor of this study and accepts full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish.

Funding The study has received funding grants through the Norwegian Fund for Post-Graduate Training in Physiotherapy (Grant no. 221441). Data used in this study originates from a randomised controlled trial (clinical trials NCT02263807) which have received funding grants through the Sophies Minde (2011), Aase Bye and Trygve J. B. Hoff's Fund (2011), the Norwegian Association of Sports Medicine, Research Grant 2015, the South-Eastern Norway Regional Health Authority (grant no. 2016094) and Akershus University Hospital (AHUS).

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Consent obtained from parent(s)/guardian(s).

Ethics approval The study was approved by the Research Ethics Committee for South-Eastern Norway (REK South East C 18510) and handled according to ethical standards set by the Data Protection Official at Akershus University Hospital. Written informed consent was provided by every participant or by their legal guardians prior to inclusion. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Our data is stored at Services for sensitive data (TSD) - Oslo University. TSD provides a platform for researchers at UiO and other public research institutions, where researchers can collect, store and analyse sensitive research data in a secure environment.

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