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# Is ACL reconstruction a prerequisite for the patients having recreational sporting activities?\*



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## ABSTRACT

*Objective:* Whether surgical or conservative treatment is more effective in allowing patients to return to physical activity after anterior cruciate ligament (ACL) injury is controversial. We sought to compare midterm outcome measures between isolated ACL tear patients who underwent reconstruction followed by closed kinetic chain exercises and those who underwent neuromuscular training only.

*Methods:* We retrospectively evaluated patients with ACL tears who underwent post-surgery CKC strength training after ACL reconstruction (Group A), and patients who only underwent neuromuscular training (Group B) with a minimum follow-up time of 5 years. Surgical techniques, rehabilitation, assessment of subjective knee function, one-leg hop test, assessment of joint position sense, muscle strength, and the health profile of the patient were evaluated.

*Results:* Overall, 43 patients were included in Group A (mean age,  $32.56 \pm 4.89$ ; Tegner activity scale, 5) and 39 patients in Group B ( $31.67 \pm 7.27$ ; 5). Patients in both groups returned to their regular physical activity level after a similar time frame (Group A: average, 12 months; Group B, average, 13.4 months). The mean Lysholm knee score was  $88.52 \pm 7.65$  in Group A and  $86.21 \pm 13.72$  in Group B. Mean distances for the one-leg hop test for Group A were  $135.21 \pm 31.66$  and  $145.36 \pm 42.10$  mm in the reconstructed and uninjured knees, respectively. In Group B, the mean hop distances were  $132.47 \pm 28.13$  and  $147.89 \pm 21.45$  mm in the rehabilitated and uninjured knees, respectively. No statistical difference was observed between the groups for any of the parameters evaluated, including assessment of subjective knee function, one-leg hop test, assessment of joint position sense, muscle strength, and the health profile. *Conclusion:* Our data suggest that early surgical reconstruction may not be a prerequisite to returning to recreational physical activities after injury in patients with ACL tears. *Level IV*, therapeutic study.

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#### Introduction<sup>1</sup>

Anterior cruciate ligament (ACL) reconstruction has a high success rate, although patient outcomes depend upon injury characteristics and patient activity.<sup>1.2</sup> Many factors affect the decision for surgical treatment versus conservative management, including the injury pattern, patient's sport, injury severity, potential surgical lesions, and possibility for spontaneous healing.<sup>2–6</sup> Reconstruction is usually recommended for patients with high activity levels or side-to-side laxity.<sup>6–8</sup> However, reconstruction is neither a prerequisite nor a guarantee for restoration of athletic activity or muscle function,<sup>3,9–11</sup> and whether early reconstruction or neuromuscular training better restores knee kinematics is

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<sup>&</sup>lt;sup>1</sup> ACL: anterior cruciate ligament; BMI: body mass index; CKC: closed kinetic chain; JPS: joint position sense.

debatable.<sup>12</sup> Additionally, self-reported assessment scores show no significant differences between patients who undergo ACL reconstruction and those do not,<sup>2–4,6,7,13</sup> even in high-level athletes.<sup>14</sup>

Neuromuscular training, based on biomechanical and neuromuscular principles, aims to improve sensorimotor control and achieve compensatory functional stability. It is guided by the patient's neuromuscular function, not by the time since injury, and starts with the uninjured extremity, initiating normal movement, applying the bilateral transfer effect of motor learning to the uninjured leg, in contrast to traditional rehabilitation programs. Closed kinetic chain (CKC) exercises are the traditional exercises after ACL injury or reconstruction, and they are believed to be safe and functional.<sup>15</sup> However, its crucial role is not only the mechanical aspects but also sensorimotor integration through motor learning in functional training.<sup>16</sup> Furthermore, neuromuscular training is superior to traditional strength training programs alone as measured by global knee function and functional scores.<sup>17</sup>

We compared mid-term outcome measures, proprioception abilities, functional outcomes, subjective outcomes, and time to return to pre-injury activities between patients with isolated ACL tears who underwent reconstruction followed by CKC exercises and those who underwent neuromuscular training only. We hypothesized that neuromuscular training alone might provide good knee function and satisfactory activity level similar to ACL reconstruction in selected cases with isolated ligament injury.

#### Patients and methods

With local ethics committee approval (05.06.2013, No: 139), we retrospectively evaluated patients who underwent post-surgery strength training by CKC exercises after ACL reconstruction (Group A) and patients who only underwent neuromuscular training (Group B) with a minimum follow-up time of 5 years.

Treatment decisions were based on clinical and patient-related factors including fear of operative complications and occupation-related issues. Patients with little side-to-side laxity (1+) and recreational sporting activity levels were counselled on both treatment strategies. Treatment was determined by the surgeon and patient independent of athletic activity.

We identified 127 cases of ACL reconstruction and CKC strength training (Group A) and 139 patients who underwent neuromuscular rehabilitation without ACL reconstruction (Group B). In Group A, ACL reconstruction was performed 6–8 weeks after the initial injury. All patients first underwent a rehabilitation program consisting of inflammation control, range of motion exercises, quadriceps, and hamstring strengthening exercises. Match-paired groups were formed based on sex, age, body mass index (BMI), and activities.

Inclusion criteria were: 1) male sex; 2) 18–40 years old; 3) BMI < 30 kg/m<sup>2</sup>; 4) Tegner Activity Scale 3–7 and having only recreational sporting activities; 5) no concomitant ligamentous injury at the time of ACL injury; 6) not greater than grade 1 meniscus degeneration at the time of ACL injury; 7) no chondral lesions at the time of ACL injury; 8) no surgical intervention related to the lower extremities before or after the ACL injury or reconstruction; 9) no neurologic or vascular pathology; 10) no symptoms in the contralateral knee; and 11) no psychosocial disorders.

This study was limited to patients with isolated ACL ruptures who wished to return to regular daily activities. Patients with multiple ligament injuries or meniscal tears associated with ACL ruptures were not tested. Existing evidence indicates that patients with multiple structural damage associated ACL rupture are at high risk for further knee damage with continued participation sporting activities particularly high activity levels when managed conservatively.<sup>6</sup> Patients were selected from one sex because of

differences in laxity, proprioception, and muscle strength between sexes.<sup>18</sup>

#### Surgical technique

One surgeon conducted all surgical procedures. After arthroscopic evaluation of the knee joint via standard anterolateral and anteromedial portals, the gracilis and semitendinosus tendons were harvested using a tendon stripper. Femoral tunnels were opened at the 10 or 2 o'clock position through the medial portal with a convenient width to accommodate hamstring tendons folded 4 times. On the tibial side, the ACL guide was set to  $45^{\circ}$  and placed at the stump of the ACL, then reamed over the guide wire after verification of the placement. The ACL stump was preserved to enhance proprioceptive and vascular properties on the tibial side. Notchplasty was not performed in any of the patients. Prepared grafts were embedded intra-articularly through the tibial tunnel and fixed by an EndoButton loop (Smith & Nephew Inc., Andover, MA, USA) at the femoral side and a bioabsorbable screw at the tibial side. After fixation of the grafts, Lachman and pivot shift tests were performed for final verification of graft tension.

Prior to rehabilitation, patients were allowed to ambulate with crutches and a knee brace locked in full extension with weight bearing as tolerated.

## Rehabilitation

Strength training started within 1 week after surgery in Group A. Early range-of-motion exercise was encouraged for the first 3 weeks, with goals of full passive motion in the first week, then full active extension and 90° of flexion. Weight bearing was allowed as tolerated. CKC flexion exercises were performed to increase the degree of flexion. Prone hanging leg extension exercises were conducted to prevent extension limitation. Straight leg raises, isometric quadriceps exercises, and hip abduction and adduction exercises were performed to increase quadriceps control. Cycling, TheraBand<sup>™</sup> strength training, mini-squats, and coordination and balance exercises (on the balance board and soft ground) were initiated 3–4 weeks post-operatively. Standing mini-squats and CKC coordination exercises were continued during this period. Resistive knee flexion and extension exercises were introduced after 6 weeks.

Patients in Group B underwent supervised neuromuscular training 3 weeks after the initial trauma aimed to improve neuromuscular control and compensatory functional stability. Movements were performed in a CKC manner as in strength training to improve functional stability. The specific activities, level of training, and progression schedule were guided by the patient's neuromuscular function including balance, joint position sense, perturbation training, weight shifts on stable and unstable surfaces, plyometric exercises, and landing strategies. Criteria for neuromuscular training were: full and pain-free knee range of motion, minimal joint effusion, at least 70% strength symmetry, and ability to hop in place without pain.

The knee brace was removed 2 weeks after reconstruction in Group A and before beginning neuromuscular rehabilitation in Group B. Clinical follow-up was done after 6, 12, 16, and 24 weeks. Jogging was allowed 12 weeks post-operatively, and pivot sports were allowed 6 months post-operatively in both groups. Contact sports were to be avoided.

#### Subjective knee function assessment

The validated Lysholm knee scoring system<sup>19</sup> was used to assess subjective knee function. It was patient-administered to minimise bias.<sup>20</sup> A score of 95–100 points is excellent, 84–94 points is good, 65–83 points is fair, and less than 65 points is poor.<sup>19</sup>

#### One-leg hop test

The one-leg hop test<sup>21</sup> was performed by jumping forward and landing on the same foot with both hands behind the back. Each subject made three attempts, and the longest hop was registered. Measurements were recorded in millimeters (mm).

## Joint position sense (JPS) assessment

An isokinetic dynamometer (Cybex Humac<sup>®</sup> Norm<sup>®</sup> system) was used for all procedures. With the subjects seated, the lateral condyle of the femur was aligned with the axis of rotation of the apparatus and the ankle fixed to an accessory rod for knee evaluation. The popliteal fossa was positioned away from the seat edge to allow complete joint movement and minimise skin stimulation. The precision of the angle measurements was 1°/sec angular velocity. The passive motion test was performed in the continuous passive motion mode at an angular velocity of 1°/sec. During passive and active motion tests, subjects were required to achieve joint position angles of 30°, 45°, and 75°. The direction of movement was from full extension to 90° of flexion. Patients were blindfolded for all procedures. Five attempts in each position were performed after 5 practice attempts to gain familiarity with the procedure. The differences between the perceived angles and the actual angles were recorded. The values are reported as mean ± standard deviation.

#### Muscle strength assessment

An isokinetic dynamometer (Cybex Humac<sup>®</sup> Norm<sup>®</sup> system) was used for all procedures. Measurements obtained using this technique are reliable.<sup>22</sup> Subjects were seated with hips flexed at  $90^{\circ}$  and the lateral condyle of the femur aligned with the axis of rotation of the apparatus. The popliteal fossa was positioned away from the seat edge to enable complete joint movement. A 10-min warm-up period involving cycling at 70-80 rpm was performed before the test. Each participant performed 3 trials to become accustomed to the procedure. Concentric-concentric contraction tests were performed at angular velocities of 60°/sec and 240°/sec in flexion and extension, respectively, from 0° to 90°. Peak torque (best repetition) was measured using isokinetic concentric-concentric testing with 5 repetitions at an angular velocity of 60°/sec. The highest peak torque value for each velocity was compared with the uninjured side, and the ratio was reported as a percentage representing the injured leg strength deficit.

#### Health profile

The SF-36 survey was used to establish each patient's mental and physical health profile. The survey consisted of 8-scaled scores using a scale from  $0-100.^{23}$ 

### Statistical analysis

Results were analysed using the SPSS software package version 20.0 (IBM Corp, Armonk, NY, USA). Variables were expressed as mean  $\pm$  standard deviation. Continuous variables between the two groups were compared using an independent-t test. A chi-squared test was performed for qualitative variables. P-values <0.05 were considered statistically significant.

#### Results

Overall, 43 patients in Group A and 39 patients in Group B met the inclusion criteria (Fig. 1; Table 1). No patients needed surgical intervention during the follow-up period (i.e., there was no crossover and re-injury). All patients returned to near their pre-injury physical activity level after a similar time frame (Group A: average, 12 [10–16] months; Group B: average, 13.4 [10–17] months) (p = 0.375). The mean rehabilitation period was 7 (6–8) months in Group A and 7.2 (6–9) months in Group B. Patient demographics are shown in Table 1. There was no loss of flexion and extension compared with the uninjured leg in either group.

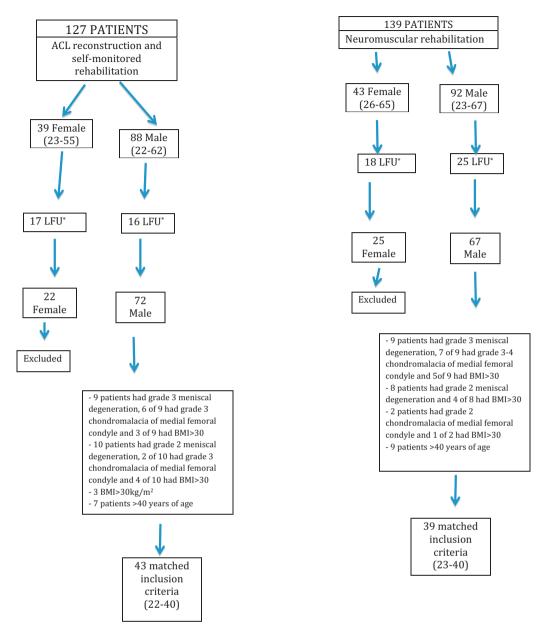
The mean Lysholm knee score was  $88.52 \pm 7.65$  in Group A and  $86.21 \pm 13.72$  in Group B. All scores were considered good, with no statistically significant differences (p = 0.239). Mean distances for the one-leg hop test for Group A were  $135.21 \pm 31.66$  and  $145.36 \pm 42.10$  mm in the reconstructed and uninjured knees, respectively. In Group B, the mean hop distances were  $132.47 \pm 28.13$  and  $147.89 \pm 21.45$  mm in the rehabilitated and uninjured knees, respectively. There was no significant difference in one-leg hop distance between the groups for the injured leg (p = 0.632) or between the injured and uninjured leg for each group (p = 0.258 in Group A and p = 0.217 in Group B).

There were no significant differences in JPS (active and passive motion) between the groups (Table 2) or between the injured and uninjured knees within in each group (Table 3). There were no significant differences in peak torque at an angular velocity of  $60^{\circ}$ / sec (Table 4). There was no significant muscle strength deficit between the injured and uninjured legs in flexion and in extension (Table 5). There was no significant difference in the SF-36 health assessment between groups (Table 6).

### Discussion

The ACL provides sensory information about joint position to regulate joint stability, coordination, and function.<sup>24–26</sup> Rehabilitation after ACL injuries is intended to rebuild muscle strength, improve neuromuscular control, re-establish full range of motion, and allow return to pre-injury activity levels.<sup>17</sup>

This retrospective study indicates that ACL reconstruction combined with strength training in patients with isolated ligament injury who participate in recreational sports yield equivalent results at 8 years after injury compared to neuromuscular training. Successful returns to pre-injury activity levels and to recreational sports activity make neuromuscular training an alternative to ACL reconstruction in selected cases. Following ACL reconstruction with hamstring tendon grafts, deficits in muscular strength are observed,<sup>9</sup> and these deficits are assumed to predict functional outcome.<sup>27</sup> Compared with the healthy population, muscle strength values are lower in ACL deficient knees, especially in strenuous activities, and highly related to re-injury and future function.<sup>27,28</sup> In this study, no asymmetry was noted in HM/QM strength ratio between groups; deficits in extension and in flexion did not exceed 13%. Symmetry in quadriceps and hamstrings strength should be at least 85%, compared with the contralateral limb, prior to returning to physical activity.<sup>28</sup> Sandberg et al. reported better isometric strength in conservatively treated patients 1 year post-injury.<sup>29</sup> Ageberg et al.<sup>9</sup> reported similar results between surgical reconstruction and conservative neuromuscular rehabilitation at mid- and long-term follow-ups. A deficit in the HM/QM torque production ratio is a key variable in ACL injury.<sup>24</sup> Quadriceps peak torque has been reported to decrease by 24% and hamstrings peak torque by 10% in ACL deficient knees.<sup>26</sup> Patients in the neuromuscular training group had a greater percent



\* LFU: Lost in follow-up

Fig. 1. The patients who met the inclusion criteria.

Table 1	
Patient demographics.	

Variable	Group A (reconstructed) $(n = 43)$	Group B (non-constructed) (n = 39)	p*
Age (years)	32.56 ± 4.89	31.67 ± 7.27	0.759
BMI (kg/m <sup>2</sup> )	25.19 ± 3.22	24.76 ± 3.27	0.708
Follow-up (years)	8.25 ± 1.82	8.10 ± 2.43	0.426
Tegner activity scale	5 (4-7)	5 (3-7)	0.762
Football	22	18	n.a.
Jogging	14	16	n.a.

 $^*p < 0.05$  is considered as statistically significant. Values are given as mean  $\pm$  standard deviation.

Independent T-Test is used.

change in isokinetic torque, compared with those in the strength training group, even though both groups' peak hamstring torque time was affected.<sup>30</sup> Neuromuscular and proprioceptive training are highly recommended to increase muscle strength and help avoid proprioception deficits associated with muscle strength deficits as well as fatigue.<sup>10,31,32</sup> ACL reconstruction re-establishes static stability, but dynamic stability is influenced by knee proprioception, muscle strength, and fatigue.<sup>17</sup> Additionally, neuromuscular training can limit successive deterioration of the injured knee and help maintain patient activity.<sup>7,25</sup>

It has been widely suggested that the patients who want to return to their pre-injury activity level should go reconstruction.<sup>7</sup> However disagreement exists about whether surgical or

### Table 2

Assessment of pro	prioception deficits	between the p	perceived and actua	l angle in both groups.

Groups	Passive	re		Active		
	30°	45°	75°	<b>30</b> °	<b>4</b> 5°	75°
Group A (n = 43)	4.33 ± 3.16	7.67 ± 3.48	5.28 ± 3.45	5.67 ± 5.2	4.52 ± 3.89	4.29 ± 3.51
Group B (n = 39) $p^*$	5.23 ± 3.68 0.514	10.77 ± 4.49 0.127	$6.76 \pm 4.52$ 0.703	$7.15 \pm 5.83$ 0.627	$6.38 \pm 4.98 \\ 0.356$	$4.19 \pm 3.04$ 0.869

\*p < 0.05 is statistically significant.

Values are given as mean  $\pm$  standard deviation.

Independent T-Test is used.

## Table 3

Significance of proprioception in the reconstructed and conservatively managed knees in both groups.

Propriocept	tion	Group A [Reconstructed vs healthy] (p)	Group B [Rehabilitees vs healthy] (p)
Active	30°	0.064	0.235
	45°	0.378	0.603
	75°	0.737	0.795
Passive	30°	0.966	0.794
	45°	0.162	0.517
	75°	0.568	0.397

\*p < 0.05 is considered as statistically significant.

Independent T-Test is used.

#### Table 4

Assessment of muscle strength in peak torques between groups.

Groups	Extension PT (N-m)	Flexion PT (N-m)
Group A	111.00 ± 24.62	78.54 ± 12.61
Group B	103.81 ± 21.27	71.65 ± 14.53
p <sup>*</sup>	<b>0.279</b>	<b>0.127</b>

p < 0.05 is statistically significant. Values are given as mean  $\pm$  standard deviation. Independent T-Test is used. PT: Peak torque.

conservative treatment more effectively enables patients to return to physical activities.<sup>6</sup> In this study, no difference was seen between the groups in returning to pre-injury activity levels. Myklebust et al.<sup>33</sup> reported that 20 of 22 (91%) competitive handball players without reconstruction returned to pre-injury activity levels after 6-11 years, compared with 58% in the reconstructed group. Similarly, Walla et al.<sup>34</sup> stated that low functional limitations exist in former college and high school athletes with chronic nonreconstructed ACL ruptures. Fitzgerald et al.<sup>14</sup> reported that 79% of patients returning to pre-injury activity levels did so without recurring episodes of giving way after non-operative rehabilitation. These data are similar to those results of Shelton et al.,<sup>35</sup> who evaluated high-level physical activity. Kostogiannis et al. <sup>7</sup> reported 15 years of satisfactory results in patients with non-reconstructed torn ACL who underwent rehabilitation with neuromuscular training. However, not all studies show promising results for nonoperative management. Engström et al.<sup>36</sup> and Anderson et al.<sup>37</sup> reported that 23-30% of patients returned to pre-injury activity levels. Kessler et al.<sup>3</sup> reported similar unfavourable outcomes between surgically reconstructed and conservatively managed patients. To date, no consensus has been reached regarding the management of patients with torn ACL, even in high-level athletes.<sup>3,4,13</sup> Moreover, delayed surgery after rehabilitation must be considered as an alternative to early reconstruction plus strength training.<sup>11</sup> However, all patients in these studies were professionals or had a high level of physical activity, in contrast to our study population. This may account for the high rate of returning to preinjury activity levels in the non-reconstructed patients in our study, which is already lower than that reported by Delince et al.,<sup>6</sup> who

#### Table 5

Muscle strength ratio between flexion and extension and muscle strength deficits between the healthy and injured legs.

Groups	HM/QM (%)	Deficit in extension (%)	Deficit in flexion (%)
Group A	71.56 ± 5.94	12.23 ± 8.17	11.35 ± 7.59
Group B	71.56 ± 6.42	13.02 ± 7.11	11.53 ± 0.93
p <sup>*</sup>	1	0.769	0.921

 $^{*}p$  < 0.05 is considered as statistically significant. Values are given as mean  $\pm$  standard deviation.

Independent T-Test is used. Data are given in percentage.

Table 6	
SF-36 health profiles of the	patients with and without ACL reconstruction.

SF-36#	Group A	Group B	p*
GH	72.78 ± 12.20	63.58 ± 18.43	0.162
PF	80.22 ± 13.87	71.74 ± 14.79	0.148
RP	$70.65 \pm 32.67$	55.23 ± 41.05	0.287
RE	73.79 ± 40.18	$63.54 \pm 40.46$	0.573
SF	$63.74 \pm 24.22$	70.76 ± 17.63	0.304
BP	61.72 ± 22.33	$56.68 \pm 23.43$	0.441
VH	66.19 ± 12.65	59.43 ± 13.61	0.127
MH	$67.65 \pm 17.34$	$61.42 \pm 17.31$	0.365

p < 0.05 is considered as statistically significant.

#Abbreviations: GH: General health perceptions, PF: Physical functioning, RP: Role limitations due to physical functioning, RE: Emotional function, SF: social function, BP: Bodily pain, VH: Vitality, MH: Mental Health.

suggested that conservative treatment may be satisfactory for individuals participating in non-competitive activities.

Hop tests are the most commonly reported functional tests. accurately reflect the number of instability episodes patients experience, and are objective criteria for returning to sports.<sup>8,18,26,38</sup> The European Board of Sports Rehabilitation recommends less than 10% asymmetry in the hop test between the healthy and the injured legs, whereas over 10% asymmetry can be seen in healthy individuals.<sup>39</sup> Additionally hop tests are positively correlated with quadriceps isokinetic peak torques.<sup>30</sup> We found no differences in the one-leg hop test between groups or injured and uninjured legs within each group, consistent with previously published data.<sup>8,9,31</sup> Better hop tests were also reported in neuromuscular rehabilitated patients than in traditional self-monitored patients.<sup>15</sup> Impairment in neuromuscular system JPS causes a shorter hopping length.<sup>18</sup> Moksnes and Risberg reported better hop test results in nonreconstructed individuals who did not play professional sports, with a 69% rate of returning to pre-injury activity levels. Their treatment algorithm recommended non-operative treatment first.<sup>8</sup> Hop tests are also correlated with self-reported knee function tests.<sup>18,38</sup>

In our study, Lysholm knee scores were used as a self-reported assessment; the results were inconsistent with published literature.<sup>7</sup> However, there was no significant difference in Lysholm knee scores between the groups. But the mean knee score alone is not sufficiently sensitive to detect small changes over time. Patients with lower activity levels would likely perform better on the Lysholm scale than a patient with the same instability but higher demands on knee function.<sup>7</sup> Activity level is an important issue when considering overall score on the Lysholm scale.<sup>7</sup>

Subjective factors such as rehabilitation prospects, social and family situations, lifestyle changes, concomitant injuries, chondral lesions, meniscal and ligamentous injuries, and fear of re-injury must be considered when deciding on a treatment approach.<sup>6,7,10</sup> Patients have reported a serious fear of re-injury during activities, despite tests showing sufficient muscle strength.<sup>39</sup> Athletes returning to high-level sports need to be mentally prepared and confident that their knee is successfully rehabilitated.<sup>8</sup> Factors that can negatively affect psychological and physical outcomes after ACL injury, such as patient mood changes, should be monitored throughout rehabilitation.<sup>8,10</sup>

We acknowledge several limitations. Our results are representative of only a small selected group of patients since subjects with concomitant ligament or meniscus injury were excluded. We had to adhere to strict patient selection criteria in order to obtain two homogeneous patient samples whose only difference would be treatment protocols. Including cases with additional injuries would confound the factors affecting the patient outcome. This resulted in a small sample size which can not represent all potential outcomes after ACL rupture. The retrospective study design, potential bias associated with patients choosing their treatment, and lacks of follow-up arthroscopy or MRI are additional limitations. Well-designed randomized clinical trials are therefore needed. Nevertheless, we created groups similar in age, sex, and BMI to retrospectively compare the midterm results of 2 treatment methods.

#### Conclusions

Based on previous literature and the results of the present study, early surgical reconstruction does not appear to be advantageous over neuromuscular rehabilitation for treatment of patients who participate in recreational sports activities. Despite the small sample size and aforementioned limitations, this study brings new insight regarding decision making in treatment of isolated ACL injuries since there is no other study comparing these two treatment methods in terms of performance based or patient reported outcomes. Nevertheless, our data cannot be generalised to all ACL injuries, particularly those with concomitant injuries of the knee and patients with higher activity levels but the treatment choice must take into consideration the patient's activity level and the pros and cons of surgical reconstruction and conservative treatment.

#### **Conflict of interest**

The authors declare that there is no actual or potential conflict of interest in relation to this article.

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