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SYMPOSIUM: IMPROVING CARE FOR PATIENTS WITH ACL INJURIES: A TEAM APPROACH

Report of the Clinical and Functional Primary Outcomes in Men of the ACL-SPORTS Trial: Similar Outcomes in Men Receiving Secondary Prevention With and Without Perturbation Training 1 and 2 Years After ACL Reconstruction

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Abstract

Background Athletes often are cleared to return to activities 6 months after anterior cruciate ligament (ACL) reconstruction; however, knee function measures continue to improve up to 2 years after surgery. Interventions beyond standard care may facilitate successful return to preinjury activities and improve functional outcomes. Perturbation training has been used in nonoperative ACL injury and preoperative ACL reconstruction rehabilitation, but has not been examined in postoperative ACL reconstruction rehabilitation, specifically return to sport rehabilitation.

Questions/Purposes The purpose of this study was to determine whether there were differences at 1 and 2 years after ACL reconstruction between the male SAP (strengthening, agility, and secondary prevention) and SAP+PERT (SAP protocol with the addition of perturbation training) groups with respect to (1) quadriceps strength and single-legged hop limb symmetry; (2) patient-reported knee outcome scores; (3) the proportion who achieve self-reported normal knee function; and (4) the time from surgery to passing return to sport criteria.

Methods Forty men who had completed ACL reconstruction rehabilitation and met enrollment criteria (3–9 months after ACL reconstruction, > 80% quadriceps strength limb symmetry, no pain, full ROM, minimal effusion) were randomized into the SAP or SAP+PERT groups of the Anterior Cruciate Ligament-Specialised Post-Operative Return to Sports trial (ACL-SPORTS), a single-blind randomized clinical study of secondary prevention and return to sport. Quadriceps strength, single-legged hopping, the International Knee Documentation Committee (IKDC) 2000 subjective knee form, Knee Injury and Osteoarthritis Outcome Score (KOOS)-sports and recreation, and KOOS-quality-of-life subscales were collected 1 and 2 years after surgery by investigators

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Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.
This work was performed at the University of Delaware, Newark, DE, USA.

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blind to group. Athletes were categorized as having normal or abnormal knee function at each time point based on IKDC score, and the time until athletes passed strict return-to-sport criteria was also recorded. T-tests, chi square tests, and analyses of variance were used to identify differences between the treatment groups over time.

Results There were no differences between groups for quadriceps symmetry (1 year: SAP = 101% ± 14%, SAP+PERT = 101% ± 14%; 2 years: SAP = 103% ± 11%, SAP+PERT = 98% ± 14%; mean differences between groups at 1 year: 0.4 [−9.0 to 9.8], 2 years = 4.5 [−4.3 to 13.1]; mean difference between 1 and 2 years: SAP = −1.0 [−8.6 to 6.6], SAP+PERT = 3.0 [−4.3 to 10.3], p = 0.45) or single-legged hop test limb symmetry. There were no clinically meaningful differences for any patient-reported outcome measures. There was no difference in the proportion of athletes in each group who achieved normal knee function at 1 year (SAP 14 of 19, SAP+PERT 18 of 20, odds ratio 0.31 [0.5–19.0]; p = 0.18); however, the SAP+PERT group had fewer athletes with normal knee function at 2 years (SAP 17 of 17, SAP+−PERT 14 of 19, p = 0.03). There were no differences between groups in the time to pass return to sport criteria (SAP = 325 ± 199 days, SAP+PERT = 233 ± 77 days; mean difference 92 [−9 to 192], p = 0.09).

Conclusions This randomized trial found few differences between an ACL rehabilitation program consisting of strengthening, agility, and secondary prevention and one consisting of those elements as well as perturbation training. In the absence of clinically meaningful differences between groups in knee function and self-reported outcomes measures, the results indicate that perturbation training may not contribute additional benefit to the strengthening, agility, and secondary prevention base of the ACL-SPORTS training program.

Level of Evidence Level II, therapeutic study.

Introduction

Upward of 175,000 anterior cruciate ligament (ACL) reconstructions are performed each year in the United States [38] with the goal of restoring the knee anatomy and allowing individuals to resume athletic activities [14, 28]. One year after surgery, only 66% of athletes are participating in modified or full competition [4], and only 55% will eventually return to competition at their preinjury level [3]. Although there are many reasons that athletes do not return to preinjury activities after ACL reconstruction, below-normal knee function is one of the many poor outcomes reported [25, 26].

The Anterior Cruciate Ligament-Specialized Post-Operative Return-to-Sports (ACL-SPORTS) training program [40] was developed as a means to prepare athletes to successfully return to preinjury activities, improve limb symmetry, and address postoperative neuromuscular impairments and predictors of a second knee injury. The training program was derived from successful primary ACL injury prevention techniques [9, 20, 21, 29]. Because prior work found that successful primary programs are multimodal and include strengthening, agility, plyometric, and prevention-focused exercises, these key components all were integrated into this secondary prevention program [39]. The primary objective of the ACL-SPORTS randomized clinical trial was to examine if this return to sport program was successful in improving functional outcomes and limb symmetry after ACL reconstruction [40] and if there was additional benefit of using a neuromuscular reeducation technique called perturbation training [13, 40]. Perturbation training has been shown to normalize movement patterns and improve dynamic knee stability when used in nonoperative ACL injury rehabilitation [7, 10, 18, 22] and shown to improve postoperative patient-reported outcomes when used in preoperative ACL reconstruction rehabilitation [11]. Perturbation training has not been examined as part of postoperative ACL reconstruction rehabilitation. The ACL-SPORTS randomized clinical trial is a single-blind study involving 40 men and 40 women athletes block randomized into a secondary prevention treatment group (SAP: strengthening, agility, and secondary prevention) or a SAP plus perturbation training treatment group (SAP+PERT) and followed for 2 years after ACL reconstruction [40].

As a result of greater availability of men who underwent ACL reconstruction, enrollment and study of the 40 men in the ACL-SPORTS program were completed before the 40 women. Thus, this article and Capin et al. [6] seek to provide an initial report of the primary outcomes in the 40 men at 1 and 2 years of the ACL-SPORTS randomized clinical trial. The purpose of this study was to examine if there were differences at 1 and 2 years after ACL reconstruction between the male SAP and SAP+PERT groups with respect to (1) quadriceps strength and single-legged hop limb symmetry; (2) self-reported knee scores; (3) the proportion who achieve self-reported normal knee function; and (4) the time from surgery to passing return to sport criteria.

Patients and Methods

The methods of the ACL-SPORTS randomized clinical trial have been previously published by White et al. [40]. The 40 men athletes (mean age ± SD at surgery 23 ± 7

Table 1. Comparison of demographics and anthropometrics for subjects in the SAP and SAP+PERT groups

Demographics/anthropometrics	SAP (mean ± SD)	SAP+PERT (mean ± SD)	Mean difference (95% confidence interval)	p value
Age at surgery (years)	24 ± 9	23 ± 6	0 (−4 to 5)	0.39
Height (cm)	179 ± 7	177 ± 7	2 (−2 to 6)	0.98
Weight (kg)	86 ± 13	86 ± 10	0 (−7 to 7)	0.44
Graft type	Autograft = 14 Allograft = 6	Autograft = 13 Allograft = 7	Odds ratio 0.8 (0.2–3.0)	1.00
Mechanism of injury	Contact 9	Contact 9	Odds ratio 1.0 (0.3–3.5)	1.00
	Noncontact 11	Noncontact 11		
Weeks from surgery to enrollment in ACL-SPORTS training protocol	23 ± 8	22 ± 7	1 (−4 to 5)	0.73

SAP = strength, agility, plyometric, and secondary prevention treatment group; SAP+PERT = SAP + perturbation training group; ACL-SPORTS = ACL-Specialized Post-Operative Return-to-Sports.

years) included in this study underwent an isolated, unilateral ACL reconstruction (autograft = 27, allograft = 13) by 21 different experienced sports orthopaedic surgeons (Table 1). Athletes were between the ages of 15 and 54 years (median = 22 years), participated in Level I or II sports [8] ≥ 50 hours/year before their injuries, and desired to return to their preinjury activity levels. Level I sports involve frequent jumping, cutting, and pivoting such as basketball and soccer [8]. Level II sports involve less frequent lateral movements or jumping such as softball and martial arts [8]. It is common in the United States for athletes after ACL reconstruction to be discharged from physical therapy at the point they achieve activities of daily living goals and basic athletic tasks such as running [1]. Thus, to capture this population and time point as well as allow for the results of this study to be generalizable, rehabilitation before the ACL-SPORTS training program was not standardized and was performed in a number of different community physical therapy clinics.

All athletes had to have completed outpatient rehabilitation, be between 3 and 9 months postsurgery, and met the following criteria for enrollment: ≥ 80% quadriceps femoris muscle strength symmetry, minimal knee joint effusion, full ROM, no reports of pain, and able to complete a running progression [1, 40]. All athletes provided written informed consent at the time of study enrollment, parents/guardians also provided consent for athletes < 18 years old, and the institutional review board approved all research testing procedures for this study.

After it was confirmed that an athlete met the aforementioned inclusion criteria, athletes were randomized to two treatment groups: SAP group (n = 20) and SAP+PERT group (n = 20); a total of 113 athletes were screened to arrive at the desired sample size (Fig. 1). A research administrator (MC), who had no contact with the athletes beyond scheduling, performed the randomization and allocation using a random number generator. All researchers/physical therapists performing data collection and analysis were blind to group assignment. The ACL-SPORTS training program included 10 treatment sessions (two times per week for 5 weeks) for all athletes. The SAP group received progressive secondary ACL injury prevention exercises and agility drills (Appendix 1 [Supplemental materials are available with the online version of *CORR*®.]). Quadriceps femoris muscle strengthening exercises were also included for athletes whose quadriceps strength symmetry measures were between 80% and 90% to help athletes achieve the return to sport criteria of 90% quadriceps strength limb symmetry [40]. Collectively, these exercises were determined to target impairments in balance, dynamic sport-related tasks, and muscle strength, all of which are risk factors for initial ACL injury [29, 30] and subsequent reinjury [9]. Athletes in the SAP+PERT group received all of these exercises augmented with perturbation training [13]. The addition of perturbation training was used to target neuromuscular impairments including muscle cocontraction and abnormal knee kinematics and kinetics [7, 10, 18, 22].

To be cleared for return to their preinjury level of sport, all athletes had to pass strict return-to-sport criteria [40]. These criteria were ≥ 90% quadriceps strength limb symmetry, ≥ 90% limb symmetry on all four single-legged hop tests, ≥ 90% on the Knee Outcomes Survey-Activities of Daily Living scale (KOS-ADLs), and the global rating of perceived knee function. Athletes were first tested for passing return to sport criteria on completion of the ACL-SPORTS training program. If the athlete did not pass the criteria initially, they were regularly tested until they did. The days from surgery to the date an athlete passed these return-to-sport criteria were recorded.

Athletes completed functional testing and motion analysis of their gait biomechanics (results reported in Capin et al. [6]) 1 and 2 years after ACL reconstruction. Of 113 athletes screened, 40 athletes were enrolled into the ACL-

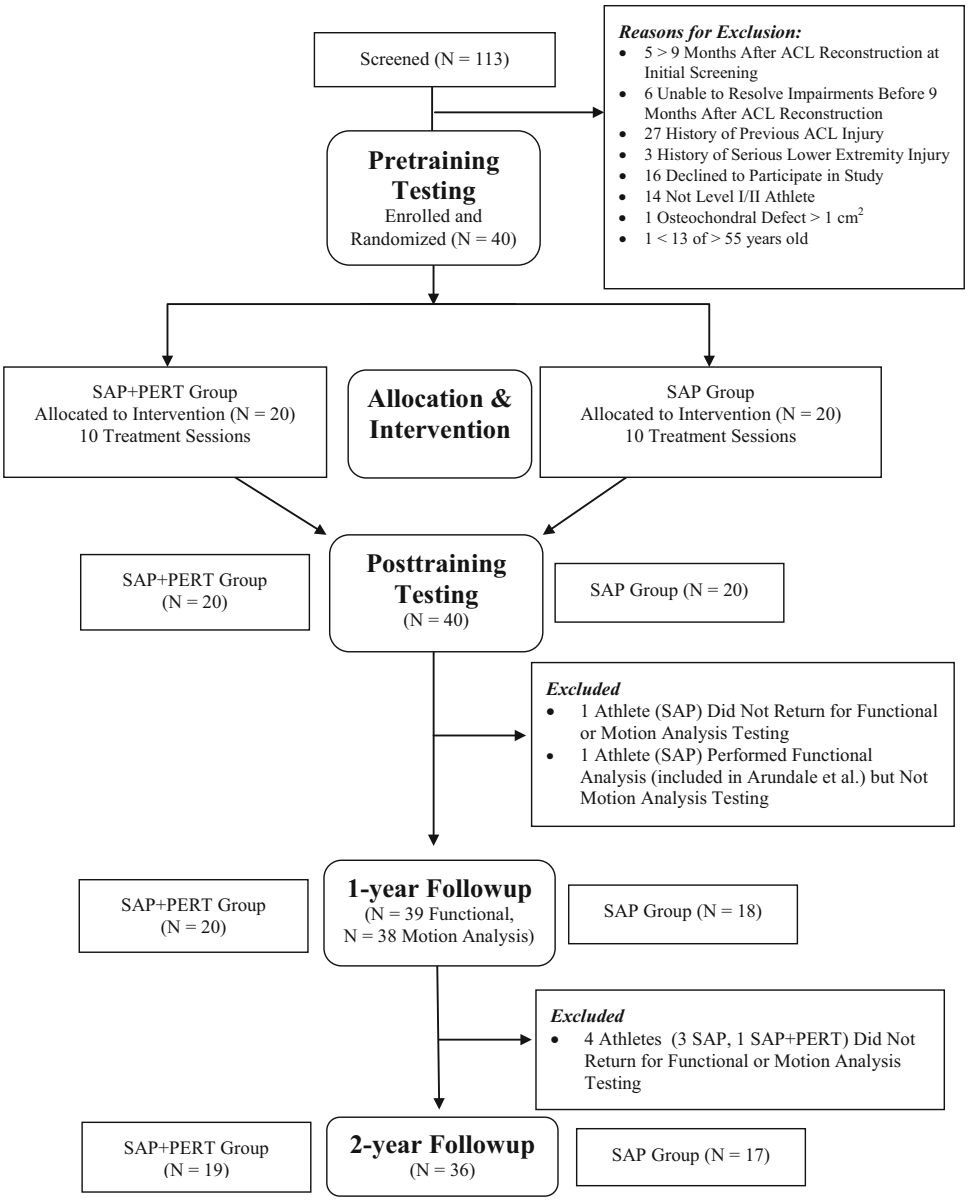

Fig. 1 This figure displays a CONSORT diagram showing athlete flow through the study.

SPORTS training program (Fig. 1) and completed all 10 sessions of training. There were no adverse events during the training program. Thirty-six athletes (17 SAP, 19 SAP+PERT) had functional data at both time points (Fig. 1). One athlete (SAP) did not return for either the 1- or 2-year testing time points. He was willing to speak with researchers regarding his knee but no longer wished to participate in the testing required to be part of the study. Three additional athletes (SAP two, SAP+PERT one) did not return for 2-year testing (one athlete spoke with researchers regarding his activity and knee but no longer wished to participate in the testing required to be part of the study, one athlete had scheduling conflicts that restricted his ability to participate in testing, and one athlete was unable to be contacted). There was no difference at the posttraining time point in International Knee Documentation Committee (IKDC) score between the athletes who had complete data at all four time points and the four athletes who lacked complete data (complete data 86 ± 2, missing data at ≥ 1 time point 90 ± 5, mean difference −4.1 [−14 to 6], p = 0.42). There were no differences between the SAP and SAP+PERT groups in age at the time of surgery, height, or weight at the pretraining time point. There were no differences between groups in the number of weeks from surgery to meeting the enrollment criteria or in graft type or mechanism of injury (Table 1).

Functional testing consisted of quadriceps strength testing, single-legged hop testing, the IKDC subjective knee form, the Knee Injury and Osteoarthritis Outcome Score (KOOS)-sports and recreation, and KOOS-quality-

of-life subscales. Quadriceps strength testing was assessed using an electromechanical dynamometer (Kin-com; DJO Global, Chula Vista, CA, USA; or System 3; Biodex, Shirley, NY, USA) to measure maximal volitional isometric contractions. Athletes were seated on the machine with their hips and knees positioned at 90° and the machine's lever arm axis of rotation aligned with the axis of rotation of the athlete's knee. Straps held the athletes pelvis, thigh, and shank in place while the athlete performed maximal volitional contractions. A quadriceps strength limb symmetry was calculated by dividing the involved limb maximum torque by the maximum torque of the uninvolved limb and multiplying by 100%. The single, crossover, and triple hops for distance and the 6-m timed hop tests [32] were also performed bilaterally. Athletes performed two practice trials of each hop followed by two trials that were recorded, and the tests were always performed in the same order (single, crossover, and triple hops for distance and then the 6-m timed hop) on the uninvolved limb followed by the involved limb. Limb symmetry indices were calculated for the three distance hops by dividing the mean of the two recorded trials on the involved limb by the mean of the two recorded trials on the uninvolved limb. Because a shorter time represents a better score, the limb symmetry indices for the 6-m timed hop were calculated by dividing the mean of the two recorded trials on the uninvolved limb by the mean of the two recorded trials on the involved limb.

The IKDC was used to quantify knee symptoms, knee function, and sports activity on a scale from 0% to 100% [2, 24]. Athletes were rated as having normal knee function if their IKDC score was above or equal to the 15th percentile of age- and sex-matched healthy individuals [2]. This dichotomization has been used in previous studies to classify individuals as having normal or abnormal knee function after ACL reconstruction [25, 27]. The KOOS-sports and recreation subscale includes questions regarding the degree of difficulty individuals are having with tasks such as squatting, running, jumping, and kneeling. The KOOS-quality-of-life subscale includes questions about awareness of knee problems, any modifications athletes may have made to their lifestyle because of their knee, and how much difficulty they are having with their knee. Both subscales are calculated as a percentage on a scale from 0% to 100%.

Statistical Analysis

All statistical analyses were performed in SPSS Version 24 (Microsoft, Redmond, WA, USA). T-tests and chi-square tests were used to determine differences in athlete demographics between athletes in the SAP and SAP+PERT groups. A repeated-measures analysis of variance with planned least-squares comparison of the interaction effect was used to determine if there were differences between groups over time in quadriceps strength limb symmetry. The same analysis was used for single-legged hop limb symmetry, IKDC scores as well as KOOS-sports and recreation and KOOS-quality-of-life scores. Minimally clinically important difference (MCID) scores have been reported as 11.5% for the IKDC [23, 24] and 8% for all KOOS subscales [36] and were used to identify true clinically meaningful changes in the measures that were not the result of measurement error. Chi square tests were used to determine differences between groups in the number of athletes who achieved normal knee function 1 and 2 years after ACL reconstruction. An independent t-test was used to assess if there was a difference between groups in the number of days from surgery to passing the return-to-sport criteria. A significance level of $p \leq 0.05$ was set a priori.

A power analysis was performed to determine the needed sample size using G*Power software (Version 3.1.0; Universtät Düsseldorf, Düsseldorf, Germany) [12]. To remain consistent with the sample size calculations performed for the entire ACL-SPORTS study, and because of its well-established MCID, sample size calculations were performed based off of the IKDC. With $\alpha = 0.05$ and $1-\beta = 0.90$, effect size was calculated using the sample mean and SD IKDC scores using preliminary data from this study. The MCID of 11.5% [23, 24] was used to determine how many athletes would be needed to identify a meaningful difference between groups in IKDC score. A minimum of 12 athletes in each group (total of 24 athletes) was determined to adequately identify a clinically meaningful difference between groups in IKDC scores.

Results

The change in quadriceps limb symmetry from 1 to 2 years was not different between athletes in the SAP group and athletes in the SAP+PERT group nor was there a difference between groups at each time point (1 year: SAP = 101% ± 14%, SAP+PERT = 101% ± 14%; 2 years: SAP = 103% ± 11%, SAP+PERT = 98% ± 14%; mean differences between groups: 1 year = 0.4 [−9.0 to 9.8], 2 years = 4.5 [−4.3 to 13.1]; mean difference between 1 and 2 years: SAP = −1.0 [−8.6 to 6.6], SAP+PERT = 3.0 [−4.3 to 10.3], p = 0.45) (Table 2). There was also no difference in change over time or between groups at either time point for any of the single-legged hop tests (single hop for distance: 1 year: SAP = 99% ± 9%, SAP+PERT = 98% ± 6%, 2 years: SAP = 99% ± 6%, SAP+PERT = 100% ± 6%; mean differences between groups: 1 year = 1.4 [−3.5 to 6.2], 2 years = −0.8 [−5.4 to 3.7]; mean difference between 1 and 2 years: SAP = −0.1

Table 2. Results from quadriceps and single-legged hop test limb symmetry repeated-measures analysis of variance

Variables and time point	SAP (mean % limb symmetry ± SD)	SAP+PERT (mean % limb symmetry ± SD)	Mean difference (95% confidence interval)	p value
Quadriceps strength limb symmetry	Time × group interaction p = 0.45			
1 year	101 ± 14	101 ± 14	0.4 (−9.0 to 9.8)	0.93
2 years	103 ± 11	98 ± 14	4.5 (−4.3 to 13.1)	0.31
Single hop for distance limb symmetry	Time × group interaction p = 0.31			
1 year	99 ± 9	98 ± 6	1.4 (−3.5 to 6.2)	0.57
2 years	99 ± 6	100 ± 6	0.8 (−5.4 to 3.7)	0.71
Crossover hop for distance limb symmetry	Time × group interaction p = 0.81			
1 year	103 ± 9	99 ± 6	4.0 (−1.6 to 9.8)	0.16
2 years	103 ± 9	99 ± 4	4.6 (−0.3 to 9.6)	0.07
Triple hop for distance limb symmetry	Time × group interaction p = 0.65			
1 year	100 ± 7	97 ± 7	3.1 (−1.6 to 7.8)	0.19
2 years	102 ± 6	99 ± 5	2.1 (−2.1 to 6.3)	0.33
Six-meter timed hop limb symmetry	Time × group interaction p = 0.91			
1 year	103 ± 7	103 ± 6	0.2 (−4.8 to 5.3)	0.92
2 years	100 ± 6	100 ± 7	0.1 (−4.8 to 4.6)	0.97

SAP = strength, agility, plyometric, and secondary prevention treatment group; SAP+PERT = SAP + perturbation training group; the time × group interaction describes if the two groups change differently over time; for example, a significant time × group interaction could occur if one group increased over time while the other group decreased over time.

[−3.5 to 3.1], SAP+PERT = −2.4 [−5.2 to 0.5], p = 0.31; crossover hop for distance: 1 year: SAP = 103% ± 9%, SAP+PERT = 99% ± 6%, 2 years: SAP = 103% ± 9%, SAP+PERT = 99% ± 4%; mean differences between groups: 1 year = 4.0 [−1.6 to 9.8], 2 years = 4.6 [−0.3 to 9.6]; mean difference between 1 and 2 years: SAP = 0.01 [−3.8 to 3.8], SAP+PERT = 0.6 [−2.7 to 4.0], p = 0.81; triple hop for distance: 1 year: SAP = 100% ± 7%, SAP+PERT = 97% ± 7%, 2 years: SAP = 102 ± 6, SAP+PERT = 99 ± 5; mean differences between groups: 1 year = 3.1 [−1.6 to 7.8], 2 years = 2.1 [−2.1 to 6.3]; mean difference between 1 and 2 years: SAP = −2.4 [−5.8 to 0.9], SAP+PERT = −3.4 [−6.3 to −0.5], p = 0.65; 6-m timed hop: 1 year: SAP = 103% ± 7%, SAP+PERT = 103% ± 6%, 2 years: SAP = 100% ± 6%, SAP+PERT = 100% ± 7%; mean differences between groups: 1 year = 0.2 [−4.8 to 5.3], 2 years = −0.1 [−4.8 to 4.6]; mean difference between 1 and 2 years: SAP = 2.8 [−1.9 to 7.5], SAP+PERT = 2.5 [−1.7 to 6.6], p = 0.91) (Table 2).

There were no clinically meaningful differences between the SAP and SAP+PERT groups in patient-reported outcome scores. The change in IKDC score between 1 and 2 years was different for the SAP compared with the SAP+PERT group (mean difference between 1 and 2 years: SAP = −3.7 [−8.6 to 1.3], SAP+PERT = 3.9 [−0.8 to 8.5], p = 0.03) (Fig. 2). The groups were not different from each other at either time point (mean difference between SAP and SAP+PERT: 1 year = 2.5 [−9.1 to 4.1] p = 0.44; 2 years = 5.0 [−1.5 to 11.5], p = 0.13); however, the SAP group had an increase in mean IKDC score between 1 (93% ± 2%) and 2 years (96% ± 2%), in which the SAP+PERT group had a decrease in mean IKDC score (1 year 95% ± 2%, 2 years 91% ± 2%). None of these changes in mean IKDC score exceeded the MCID of 11.5%. The changes in KOOS-sports and recreation (Fig. 3) and KOOS-quality-of-life scores (Fig. 4) were not different between groups nor was there a difference between groups at either 1 or 2 years (KOOS-sports and recreation: 1 year: SAP = 94% ± 8%, SAP+PERT = 95% ± 9%, 2 years: SAP = 96% ± 12%, SAP+PERT = 93% ± 13%; mean difference between groups: 1 year = 0.4 [−6.1 to 5.4], 2 years = 2.7 [−5.6 to 11.1]; mean difference between 1 and 2 years: SAP −1.8 [−7.1 to 3.5], SAP+− PERT 1.3 [3.7–6.3], p = 0.40; KOOS-quality of life: 1 year: SAP = 86% ± 11%, SAP+PERT = 82% ± 18%, 2 years: SAP = 88% ± 13%, SAP+PERT = 87% ± 16%; mean difference between groups: 1 year = 3.4 [−7.0 to 13.9], 2 years = 0.7 [−9.3 to 10.6]; mean differences between 1 and 2 years: SAP = −1.8 [−8.5 to 4.8], SAP+PERT = −4.6 [−10.9 to 1.7], p = 0.54).

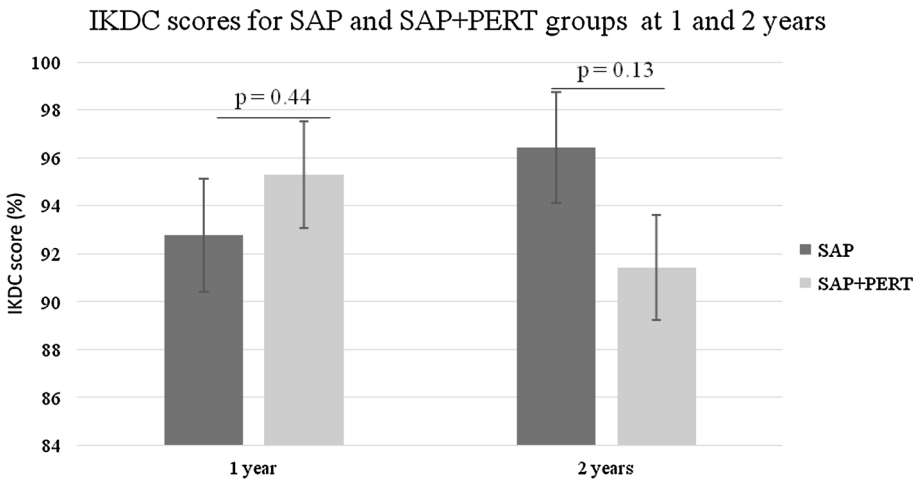

Fig. 2 This figure shows the results of the repeated-measures analysis of variance examining IKDC scores for each group over time. There was a time × group interaction (SAP mean difference between 1 and 2 years −3.7 [−8.6 to 1.3]; SAP+PERT mean difference between 1 and 2 years = 3.9 [−0.8 to 8.5]; p = 0.03) indicating that the change in IKDC score between 1 and 2 years is different between the SAP and SAP+PERT groups. There were no differences between groups at each time point (mean difference between SAP and SAP+PERT; 1 year = 2.5 [−9.1 to 4.1], p = 0.44; 2 years = 5.0 [−1.5 to 11.5], p = 0.13).

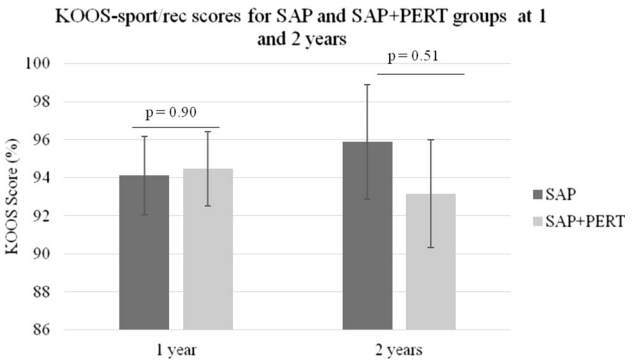

Fig. 3 This figure shows the results of the repeated-measures analysis of variance examining KOOS-sports and recreation (sports/rec) scores for each group over time. There was no time × group interaction (mean difference between 1 and 2 years; SAP = −1.8 [−7.1 to 3.5], SAP+PERT = 1.3 [−3.7 to 6.3]; p = 0.40) indicating that the change in IKDC score between 1 and 2 years is different between the SAP and SAP+PERT groups. There were no differences between groups at each time point (mean difference between groups; 1 year = 0.4 [−6.1 to 5.4], p = 0.90; 2 years = 2.7 [−5.6 to 11.1], p = 0.51).

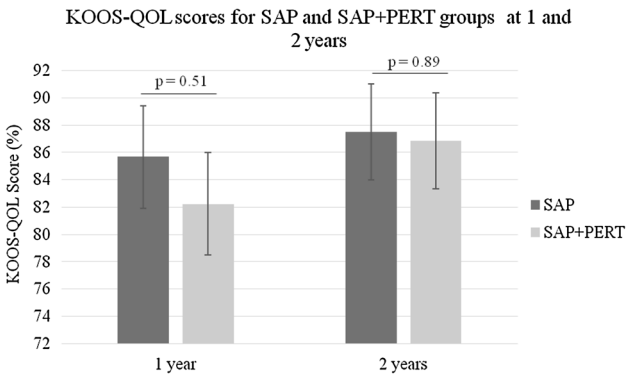

Fig. 4 This figure shows the results of the repeated-measures analysis of variance examining KOOS-quality-of-life (QOL) scores for each group over time. There was no time × group interaction (mean differences between 1 and 2 years: SAP = −1.8 [−8.5 to 4.8], SAP+PERT = −4.6 [−10.9 to 1.7]; p = 0.54) indicating that the change in IKDC score between 1 and 2 years was not different between the SAP and SAP+PERT groups. There were no differences between groups at each time point (mean difference between groups: 1 year = 3.4 [−7.0 to 13.9], p = 0.51; 2 years = 0.7 [−9.3 to 10.6], p = 0.89).

There was no difference between the groups in the number of athletes who had normal knee function, as classified by their IKDC score, at 1 year after ACL reconstruction (SAP 14 of 19, SAP+PERT 18 of 20, odds ratio 0.31 [0.5–19.0], p = 0.18) (Table 3). At 2 years, all 17 athletes in the SAP group achieved normal knee function; however, five of the 19 in the SAP+PERT group did not meet the age- and sex- matched normative normal knee function values, indicating that athletes in the SAP group were more likely to have normal knee function at 2 years than the SAP+PERT group (odds ratio cannot be calculated because no SAP group athletes had below-normal knee function, p = 0.03).

There were no differences between the SAP and SAP+PERT groups in the time from surgery to passing return to sport criteria. The SAP group passed in 325 ± 199 days, whereas the SAP+PERT passed in 233 ± 77 days (mean difference 92 [−9 to 192], p = 0.09).

Table 3. The number of athletes with normal knee function at each time point and results of chi square comparison

Categorization	One year				Two years			
	SAP	SAP+PERT	Odd ratio (95% confidence interval)	p value	SAP	SAP+PERT	Odds ratio (95% confidence interval)	p value
Normal knee function	14 (74%)	18 (90%)	0.31 (0.5–19.1)	0.18	17 (100%)	14 (74%)	N/A*	0.03
Below normal knee function	5 (26%)	2 (10%)			0 (0%)	5 (26%)		

The values presented in the table are the number of subjects (percentage); *because there were no subjects in the SAP group with below normal knee function at 2 years, an odds ratio could not be calculated; SAP = strength, agility, plyometric, and secondary prevention treatment group; SAP+PERT = SAP + perturbation training group.

Discussion

Only 55% of athletes return to competition at a preinjury level after ACL reconstruction [3], and those who do are at a high risk for a second ACL injury [33]. Below-normal knee function is one reason athletes cite for not returning to sport [25, 26] indicating a need for improved return to sport rehabilitation. Although there are numerous clinical commentaries on rehabilitation aimed at helping athletes return to sport after ACL reconstruction [5, 29], the evidence available is primarily expert opinion. The results of this randomized trial found no differences between the SAP and SAP+PERT groups in quadriceps strength or single-legged hop test scores. There were no clinically meaningful differences between groups in IKDC, KOOS-sports and recreation, or KOOS-quality-of-life scores nor in the time from surgery to passing return to sport criteria. There were differences between groups at 2 years in the number of athletes who had normal knee function according to their IKDC scores, in favor of the SAP group. Together these results indicate that although there may not be additional benefit of perturbation training, the strengthening, agility, and prevention exercises involved in the ACL-SPORTS training program warrant clinician consideration and further study as an addition to criterion-based ACL reconstruction rehabilitation.

One limitation of this study is that it only evaluated men. Women are at higher risk for initial ACL injury and subsequent reinjury [33]; therefore, differences in sex and gender may play an important role in describing knee function after surgery. The current study reports the primary outcomes of the 40 men enrolled in the ACL-SPORTS training program. Data collection and analysis on the 40 women in this cohort are ongoing and will be reported on in future studies. For example, a study examining differences in functional outcomes in both men and women from before to after the ACL-SPORTS training program is currently being compiled, analyzed, and written. Forty athletes could be considered a small sample size; however, an a priori power analysis was completed to determine the number of athletes needed to identify meaningful change with IKDC scores. Although this a priori calculation was not performed for the KOOS-sports and recreation and KOOS-quality-of-life subscales, sensitivity power analyses showed that this study was adequately powered to detect the MCID in these subscales and in fact differences much smaller (effect size of 0.45 with 80% power or 0.52 with 90% power), indicating that this sample size was adequate for the calculations performed and was not the reason for the lack of differences between groups.

The sample of athletes used in this study could be considered selective and a limitation to this study. However, the authors feel the athletes enrolled into the ACL-SPORTS program are representative of many active cutting and pivoting sport athletes, particularly those active athletes who intend to return to sport after ACL reconstruction. The strength, full ROM, absence of pain, and minimal effusion inclusion criteria were set to identify athletes at the point when they would be typically discharged from physical therapy in the United States [1, 41]. As a result of the third party payer system in the United States, many athletes are given a limited number of physical therapy visits and are discharged at the point they have met activities of daily living and basic athletic goals such as running [1, 38]. The ACL-SPORTS program was designed to bridge an athlete from this typical discharge point to their return to sport; thus, identifying athletes at this point was crucial. These inclusion criteria are not dissimilar to the return to sport criteria given by the Multicentre Outpatient Orthopaedic Network (MOON) ACL reconstruction rehabilitation guidelines [41]. Furthermore, the strength, ROM, effusion, and pain inclusion criteria ensured that these athletes were safe (sufficient healing had taken place, the knee was quiet, and they were strong enough) to begin the more advanced return to sport and sport-specific tasks involved in the ACL-SPORTS training program.

By including athletes between 3 and 9 months after ACL reconstruction, the study included athletes who moved both quickly and slowly through their initial course of physical

therapy. This means that even athletes who had more difficulty in the initial stages of their rehabilitation such as trouble achieving full ROM, minimal effusion, or strength goals were still included in this study so long as they met the inclusion criteria by 9 months after ACL reconstruction. No athletes were enrolled before 3 months after ACL reconstruction because the researchers felt that based on tissue healing timelines [31, 34], it was unsafe to perform these higher level activities. Because not all athletes are discharged from physical therapy at the same time after ACL reconstruction, the larger enrollment window allowed the sample to be representative of athletes as they are discharged from physical therapy. One caveat of the long enrollment window was that there was no standard amount of time from the end of training to the 1-year assessment. For example, an athlete who started the program at 3 months after ACL reconstruction would have almost 6 months between finishing the program and completing their 1-year assessment. In contrast, an athlete who started the program closer to 9 months after ACL reconstruction could only have a few weeks between finishing the program and completing his or her 1-year assessment. Based on preliminary results indicating no difference in pretraining functional outcomes between athletes controlling for the time from surgery to starting the ACL-SPORTS program (unpublished results), and the belief that this variation strengthened the sample in terms of generalizability, we did not control for the time between the completion of training and the 1- or 2-year assessments. Finally, there was a wide age range in this study (15–54 years of age), and this could have been a potential confounding variable; however, we did not explore it as such because most athletes in this study were within a few years of the age of 20 years (mean, 23 $\pm$7 years; median, 22 years).

There were no differences between the SAP and SAP+PERT groups in quadriceps strength and single-legged hop test limb symmetry. Such results could indicate that perturbation training does not contribute additional benefit to strength and neuromuscular control limb symmetry at 1 and 2 years after ACL reconstruction. It is also possible that a ceiling effect was observed. Both the SAP and SAP+PERT groups had mean limb symmetry scores for quadriceps strength and single-legged hop testing $>$ 95% at each time point. Previous studies have observed small changes in quadriceps strength between 1 and 2 years after ACL reconstruction [35], and such high scores leave little room to differentiate between groups. Quadriceps strength limb symmetry $\geq$ 80% was also an inclusion criteria. From a safety perspective, this was an important inclusion criterion to ensure the athletes were ready to perform the high-level athletic activities involved in the ACL-SPORTS training program [1, 40]. However, these criteria may have selected for a sample of men who at baseline were already performing highly in quadriceps strength and had less room to make large changes. Further study of the ACL-SPORTS training program is needed to examine if there are differences between the SAP and SAP+PERT groups between the pretraining and posttraining time points. Such information will help establish if perturbation training provides additional benefit to the SAP portion of the ACL-SPORTS training program.

There were no clinically meaningful differences between the SAP and SAP+PERT groups in IKDC, KOOS-sports and recreation, or KOOS-quality-of-life scores. Using established MCID scores for the IKDC [23, 24] and KOOS [36], these results indicate that the addition of perturbation training may not impact patient-reported functional scores at 1 and 2 years after ACL reconstruction. The IKDC, KOOS-sports and recreation, and KOOS-quality-of-life questionnaires were chosen because these validated questionnaires have previously been used to differentiate athletes at higher levels of function [5, 36]. However, because both the SAP and SAP+PERT groups had IKDC and KOOS-sports and recreation scores $>$ 90% at 1 and 2 years, it is possible that a ceiling effect was observed. The high IKDC, KOOS-sports and recreation, and KOOS-quality-of-life scores reported by the athletes in this cohort could also indicate that by 1 year they had already achieved all of the large, clinically meaningful changes in patient-reported outcomes scores that would occur in their rehabilitation and return to sport. Previous studies have reported IKDC, KOOS-sports and recreation, and KOOS-quality-of-life scores at 1 and 2 years [15, 16, 37]. The MOON cohort was a multicenter cohort that received what is considered the gold standard in criterion-based physical therapy after ACL reconstruction in the United States [37, 41]. At 2 years after ACL reconstruction, the MOON cohort reported a median IKDC score of 75%, KOOS-sports and recreation score of 85%, and KOOS-quality-of-life score of 75% [37]. In comparison, this cohort (SAP and SAP+PERT groups combined) had median scores of 99%, 100%, and 94% on the IKDC, KOOS-sports and recreation, and KOOS-quality of life, respectively. The Scandinavian ACL registries have also published patient-reported outcomes data at 1 and 2 years [16]. In these registries the mean KOOS-sports and recreation scores are between 63% and 64% at 1 year and 66% and 70% at 2 years [16] compared with the 93% and 94% found in this study. The mean KOOS-quality-of-life scores in the Scandinavian registries were 60% at 1 year and between 62% and 69% at 2 years [16]. In contrast, this study found a mean of 83% at 1 year and 87% at 2 years. Although there are differences between these studies in the inclusion criteria, particularly that the ACL-SPORTS program involved only athletes and laid out baseline inclusion

criteria, these comparisons are important for clinicians to be aware of in assessing the value of adding a return to sport program such as the ACL-SPORTS program after a course of criterion-based ACL reconstruction rehabilitation.

There was no difference between groups in the number of athletes who had normal knee function, as assessed by IKDC score at 1 year; however, there was a difference at 2 years. The SAP+PERT group had a smaller number of athletes who had self-reported normal knee function at 2 years. The reason for this result is unclear. Four of the five SAP+PERT athletes had normal knee function at 1 year but had decreases in their IKDC (all larger than the MCID) between 1 and 2 years. Interestingly, two of these athletes had increases in their objective knee measures (quadriceps strength and single-legged hop test limb symmetry). They had not passed return to sport criteria at 1 year, but at 2 years, their limb symmetry scores increased to $\geq$ 90% and they passed all return to sport criteria at 2 years. Further study and closer examination are needed into and what might have happened between 1 and 2 years, because at this time, there is no clear pattern or reasoning. Based on only these 40 men and these preliminary findings, however, these results would seem to favor the SAP group. Further study as well as comparison to the 40 women may help elucidate any trends occurring between 1 and 2 years in the SAP+PERT group.

Athletes in this study were not cleared to return to their preinjury level of activity until they passed strict return-to-sport criteria [1, 19]. These return to sport criteria evaluated both function and self-report allowing for a broad picture of an athlete's readiness to begin a slow reintegration into their preinjury activities. Once cleared, athletes followed guidelines on monitoring and managing effusion and soreness to gradually return to sport. There were no differences between SAP and SAP+PERT groups in the time to passing these return to sport criteria. This indicates that the addition of perturbation may not accelerate an athlete's readiness to return to sport. Quickening an athlete's return to sport, however, may not be a good thing. In a cohort similar to the one in this study, Grindem et al. [17] found a 51% reduction in knee reinjuries for every month return to sport was delayed up to 9 months. Combining the SAP and SAP+PERT groups, the mean time of passing return to sport criteria for the entire cohort was between 8 and 11 months after ACL reconstruction. Grindem et al. [17] also found that athletes passing these same return to sport criteria had an 84% reduction in knee reinjury risk. Looking at the entire male cohort together, 80% of athletes in this cohort met return to sport criteria by 1 year, and 95% of those who completed 2-year testing passed by 2 years. In comparison, only 18 of 73 (25%) athletes in the Grindem et al. [17] cohort, and only 53% of another similar cohort studied by Logerstedt et al. [27], passed the return to sport criteria by 1 year after ACL reconstruction. The results of this study indicate that there may not be additional benefit of perturbation training; however, they do encourage further study examining the effects of time, treatment protocol, and return to sport criteria, particularly on subsequent reinjuries.

The ACL-SPORTS program is a novel sport-specific rehabilitation program designed based on successful primary ACL injury prevention techniques, strength, and agility training. This trial examined whether there was additional benefit of perturbation training, a neuromuscular reeducation technique that has shown benefit in nonoperative ACL injury, and preoperative ACL reconstruction rehabilitation. There were no differences between the SAP group, that received strength, agility, and secondary prevention exercises, and the SAP+PERT group, which received these exercises with the addition of perturbation training, in quadriceps strength and single-legged hop test limb symmetry scores, patient-reported outcome scores, the proportion of athletes with normal knee function as classified based on IKDC score at 1 year, or in the time to passing return to sport criteria. However, these results warrant therapists' consideration of a secondary prevention and return to sport protocol after ACL reconstruction rehabilitation and warrant further study into the benefits of the SAP portion of the ACL-SPORTS training program.

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