

Effects of Training Program wearing Balance Shoes to Reduce Knee and Lower Extremity Injuries in Junior Athletes: A Randomized Controlled Trial

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Abstract

Objective: The purpose of this randomized controlled trial was to compare the effectiveness of an original 15minute exercise program wearing the ReaLine Balanceshoes (RBS) and a conventional injury prevention program in reducing lower extremity injuries.

Methods: We recruited athletic club teams from local junior high schools. Inclusion criteria were adolescents who were a member of their interscholastic athletic club team. Players with an injury within 6 weeks that prevented full participation in sports, a history of systemic disease or neurologic disorder at the start of the intervention, and those already using an injury prevention program were excluded. Participants were individually randomized within a team into one of the study groups (RBS or control). The RBS group used the RBS, a shoe-type training device designed for correcting dynamic knee valgus. A 6-staged progressive exercise program was developed, including slow closed kinetic chain strengthening, joint realignment, balancing, feedforward, feedback, and plyometric components. The control group performed an injury prevention program previously used to reduce injury risk. One 15-minute session was performed 3 days/week for 12 months. The primary outcome was incidence of anterior cruciate ligament (ACL) injury and acute knee injuries.

Results: One hundred twenty three players completed the study (RBS, n=65; control, n=58). No ACL injury or acute knee injury occurred among RBS athletes versus 1 ACL injury [RR 0.298, 95% CI (0.012, 7.175)] and 3 acute knee injuries [RR 0.127, 95%CI (0.007, 2.421)] among control athletes.

Conclusion: The RBS program was not significantly more effective than a conventional injury prevention program in reducing the incidence of ACL injury and other acute lower extremity injuries in junior athletes.

Keywords: Prevention; Sports; ACL; Knee

Introduction

Anterior Cruciate Ligament (ACL) injury is one of the most common lower extremity injuries that occur during many sports [1,2]. Its time loss from sports [3], impact on financial burden [2,4], increased risk of premature knee osteoarthritis [5-7], and a higher rate of non-contact ACL injury over contact injury have led to great interest in developing optimally effective ACL injury prevention programs. While several programs have successfully incorporated one or more exercise components to prevent ACL injury [8-13], most of them require significant time commitments. Additionally, we currently lack an understanding of how these programs prevent injury, due to their multi-component interventions. Furthermore, the current prevention strategy is severely flawed, as it fails to consider that ACL injury is likely to occur within the first 30-40 milliseconds after foot strike [14-16], and we contend that the technique training that corrects lower extremity alignment during the early landing phase should be emphasized. Gaining better understanding of ACL injury prevention strategy would be needed.

ACL injury is most common among individuals between the ages of 16-18 years [17], but the frequency of ACL injury increases steadily from ages 11-12 years [17], and gender differences in ACL injury rates emerge after children encounter puberty [18,19]. Interestingly, there is some evidence demonstrating developmental differences in knee kinematics and kinetics during landing and potential effects of maturation on ACL injury risk. Hass et al. [20] reported that the postpubescent participants exhibited reduced knee flexion at initial foot ground contact and increased mediolateral knee joint forces during the drop jump landing compared with their pre-pubescent counterparts. Hewett et al. [21] reported that following the onset of maturation, female athletes landed with greater total medial motion of the knees and a greater maximum lower extremity valgus angle during the drop vertical jump than did the male athletes. Although there is reason to believe intervening with junior athletes may result in better long-term ACL injury prevention outcomes, it is unclear whether young age groups respond to prevention programs.

To develop an effective and efficient ACL injury prevention program, the exercises should be focus on dynamic valgus correction. In a prospective cohort study by Hewett et al. [22], the dynamic valgus alignment of the lower extremity predicted future ACL injury in female high school athletes. It would be advantageous if the daily training and the dynamic valgus correction exercises could be combined. For this purpose, a training device called the ReaLine Balanceshoes (RBS, GLAB Corp., Higashihiroshima, Japan) has recently been developed. The RBS is a sandal-like balancing device that attaches to the athletes' shoes. Because the balancing axis of the RBS is located underneath the fourth lay of the foot (4th metatarsal and cuboid), the "knee over toe" position is invariably reproduced when the sole of the RBS is maintained in a horizontal position during various weight-bearing exercises. Unstable training devices are often used to compensate for the missing training effects improving ankle and knee strength and proprioception [23,24]. Standing balance training has been reported to be effective for prevention of musculoskeletal injuries [25-27]. Gamada et al. [28] also reported that the exercise program wearing the RBS (the RBS program) was effective in inducing greater activation of the medial hamstrings and vastus medialis during the single-leg landing and the drop vertical jump which seems beneficial for dynamic valgus correction. We therefore expect that the RBS program would integrate proper technique, body mechanics and neuromuscular control, which may reduce ACL injury.

The purpose of this study was to compare the effectiveness of an original 15-minute exercise program wearing the RBS and a conventional injury prevention program in reducing the incidence of ACL injury and other acute lower extremity injuries in junior athletes. We hypothesized that the incidence of ACL injury and other acute lower extremity injuries would be reduced in junior athletes who performed the RBS program compared with the control group. To test this hypothesis, we conducted a randomized controlled trial (RCT).

Methods

Study design

This study was a single-blinded parallel group RCT to compare the effectiveness of the RBS program with a conventional injury prevention program. The players and coaches were not blinded to group allocation, but the researchers who assessed the outcome were. The study period was 12 months. The institutional review board at Sadamatsu Hospital (Omura, Japan) approved the study protocol (#11-09), and permission was obtained from the appropriate school administrators at all of the schools involved in the study. This study complied with requirements of the Declaration of Helsinki.

Participants

We recruited clubs from local junior high schools in Nagasaki, Japan. One author (SS) held instructional regional meetings for coaches at each club, briefing them about the study procedures. Schools were selected on the basis of their willingness to participate. Participants were individually randomized within a team into one of the study groups (RBS or control group) following simple randomization procedures, using a computer-generated list of random numbers (one-to-one allocation ratio) prepared by an investigator with no clinical involvement in the trial (SS). Using opaque, sealed and stapled envelopes, the allocation sequence was concealed from the researchers engaged in enrolling, assessing and interviewing participants. Envelopes were opened only after the enrolled participants had completed all baseline assessments and it was time to allocate them to the respective groups. Inclusion criteria were adolescents who were a member of their respective interscholastic athletic club team (male and female). Exclusion criteria for the study included an injury within 6 weeks that prevented full participation in sports at the start of the intervention, a history of systemic disease or neurologic disorder, and those already using an injury prevention program. All coaches, players, and their parents read and signed informed consent forms before enrollment.

Interventions

The RBS group performed the RBS program, in which the athletes wore the RBS (Figure 1). A 6-staged progressive exercise program was developed, which included slow closed kinetic chain strengthening, joint realignment (restoring screw-home movement of the knee), balancing (biofeedback), plyometric (jumping), and feedforward (landing) components (Table 1 and Figure 2), and the participants were required to do these exercise with wearing the RBS. The control group performed a neuromuscular warm-up program combining progressive strengthening, plyometric, balance, and agility exercises (Table 2 and Figure 3). The training components were selected from programs previously used to reduce lower extremity injury risk in soccer, volleyball, basketball and handball [9,11,12,27,29]. Both programs take 15 minutes per session and were performed 3 days/ week on alternating days for 12 months. Participants started on the first difficulty level and proceeded sequentially to the higher levels every 2 months following an initial training session for that level. All training sessions were designed to be performed prior to daily practice. A minimum of 30 seconds of rest was provided between sets and approximately 1 min of rest between different exercises so that fatigue did not interfere with neuromuscular motor control and performance. Participants were encouraged to perform the exercises using only proper technique with knees comfortably flexed, shoulders back, the "chest over knees", and the "knee over toe". Because we randomized the participants by individual within a team, the coaches monitoring the program were asked to ensure that participants perform the exercises separately in order minimize potential bias introduction. They also reported that they did not routinely use either intervention on field or during off-field practice time, suggesting little outside contamination of the participants. The intervention was introduced to the teams at the beginning of the season, and the research physical therapists gave practical instructions about the exercises every 3 months, and provided verbal and visual feedback to participants during training, if necessary. All participants and coaches received a DVD and a leaflet describing the program. The DVD demonstrated how to perform each exercise with proper biomechanical technique. In the DVD, a physical therapist served as a model to properly demonstrate the exercises. The number of repetitions and sets for each exercise were clearly outlined in the DVD and leaflet.

Procedures

Participants completed surveys at the start of their season to report the following information: name, sex, age, height, weight, and participated sports. Injury surveillance and participation adherence data were collected from coaches between July 2011 and June 2012. All coaches registered individual athlete exposures (AEs) and absences (due to injury or other reasons) for each practice session and game; these data were mailed to researcher by the coach in a monthly summary. An exposure was defined as any practice or game in which

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an athlete was exposed to the possibility of an athletic injury. The coaches also reported compliance with the program on the participation forms.

	Exercises				
Level 1	Squats	Split squats	Front lunges	Side lunges	
Level 2	Squat steps	Side steps	Knee bent walk	Knee lift	
Level 3	Quick squats	Quick split squats	Squat jumps	Split squat jumps	
Level 4	1-step drill (R-L)	1-step drill (F-B)	2-step drill (R-L)	2-step drill (F-B)	
Level 5	4-way lunges	3-step drill	Side hops	Bounding	
Level 6	Block jumps	Spike jumps	Continuous jumps	Single leg jumps	

Table 1: Levels and exercises of the RBS program using the ReaLine Balanceshoes. R-L = right-left; F-B = forward-backward.

	Exercise						
Level 1	Squats	Front lunges	Shuttle run	Sit ups			
Level 2	Squat steps	Side lunges	Diagonal run	Back extensions			
Level 3	Quick squats	Squat jumps	Bounding run	Pelvic lifts			
Level 4	Single leg standing	Single leg squats	Side hops	Bench			
Level 5	Squats with calf raise	Tuck jumps	Repeated side steps	Side bench			
Level 6	Calf raise	Scissors jumps	Lateral hops	Hip abductions			

Table 2: Levels and exercises of the neuromuscular warm-up program as the control intervention.

We defined the primary outcome as ACL injury and any acute injuries to the knee. A secondary outcome was defined as ankle sprain. One research physical therapist (TK) who was blinded to group allocation interviewed any player who sustained an injury. Detailed information related to the date of injury, whether it occurred for the first time or not, mechanism of injury, and diagnosis was documented. Interviewing occurred as soon as possible after injury to minimize recall bias. Classification of lower extremity injuries as contact or noncontact was based on the coach's or athlete's report of the mechanism of the injury. A direct contact injury was defined as an injury sustained as a result of direct blow to the knee or ankle. An indirect contact injury was defined as an injury sustained as a result of contact (being hit, pushed, or held) to the body other than the knee or ankle by another player or object during the course of play. We considered the case where an injured player stepped on someone else's foot while landing after jumping during a basketball or volleyball game as an indirect injury mechanism. A non-contact injury was defined as an

injury sustained by an athlete without extrinsic contact by another player or object on the field. A recordable acute knee or ankle injury was defined as an injury to the area about the knee or ankle, which occurred during a practice or game play, had a sudden onset, and led to the player being unable to participate fully in future practice or game play.

Statistical analysis

We included all acute knee injuries and ankle sprain reported after all clubs had completed the first session of the training to compare the incidence of injury between the two study groups. Injury incidence was calculated as the number of injury cases divided by 1000 AEs. A sample size of 1926 players in each group was estimated to achieve 80% power with α =5% to detect a 50% reduction in acute knee injuries based on expected injury rate in Japanese adolescent basketball players [30], adjusting an anticipated drop-out rate of 5%.

We used logistic regression to examine the effectiveness of the training program in reducing injury, while controlling for other baseline covariates. Relative risk (RR) was calculated as the ratio of incidence rates for the RBS versus control athletes. Baseline characteristics were compared between groups using t tests. Results are presented as means with a 95% confidence interval (CI). All tests were two-tailed, and differences among results were considered significant when P-values were <0.05. We selected an intent-to-treat analysis rather than a per protocol analysis. We used the Statistical Package for the Social Sciences (IBM SPSS Statistics V.22) for analyses.



Figure 1: The concept of the ReaLine Balanceshoes (GLAB Corp., Hiroshima, Japan). (a) A sandal-like balancing device attaches to athletic shoes, enabling performance of variety of weight-bearing exercises including stepping and jumping. (b) The "knee over toe" position is invariably reproduced when the sole of the RBS is maintained in a horizontal position during various weight-bearing exercises.

Results

Inclusion of teams and players

Figure 4 shows the flow of teams and players through the study. All 18 eligible athletic club teams were asked to participate in this study. Initially, 6 teams declined participation in the study, and 128 athletes of 12 teams were randomized to either group. One hundred twenty three players from 6 volleyball teams (n=54), 5 basketball teams (n=59), and 1 tennis team (n=10) completed the study (RBS group, n=65; control group, n=58). The players in the two groups were similar in terms of baseline characteristics (Table 3). Reported compliance with the program varied among teams from 76 to 114 times, with an average of about 104/140 uses per team (74%).



Figure 2: The RBS program aimed for correcting dynamic valgus. (a) Squats, an example of slow closed kinetic chain strengthening exercises. (b) Knee bent walk, an example of stepping exercises. (c) Continuous jumps, an example of explosive plyometric exercises. (d) Single leg jumps, an example of landing exercises.

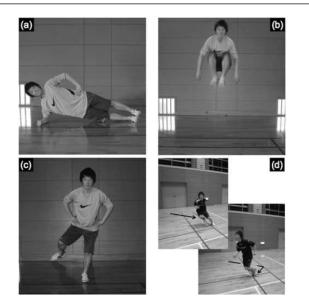


Figure 3: A neuromuscular warm-up program combining progressive strengthening, plyometric, balance, and agility exercises. The training components were selected from programs previously used to reduce injury risk in soccer, volleyball, basketball, and handball. (a) Side bench, an example of strengthening exercises. (b) Tuck jumps, an example of plyometric exercises. (c) Hip abductions, an example of balance exercises. (d) Diagonal run, an example of agility exercises.

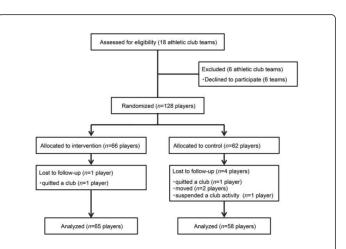


Figure 4: Flow chart of participants through the study.

	RBS n=65 (male: 30, female: 35)	Control n=58 (male: 26, female: 32)	P value
Age (yrs)	12.8 (12.6, 12.9)	12.7 (12.6, 12.9)	0.69
Height (cm)			
male	161.8 (158.6, 164.9)	159.6 (156.9, 162.3)	0.31
female	155.8 (154.1, 157.5)	153.7 (152.1, 155.4)	0.09
Weight (kg)			
male	50.5 (46.6, 54.4)	47.6 (44.3, 50.9)	0.27
female	46.5 (44.3, 48.7)	45.0 (42.9, 47.1)	0.35

Table 3: Demographic data of the subjects (95% CI).

Outcome measure

During the 12-month study period, we collected data on a total of 14245 AEs for the RBS group and 12931 AEs for the control group. One ACL injury occurred in the control group (0.000 injuries/1000 AEs vs. 0.077 injuries/1000 AEs; RR 0.298; 95% CI: 0.012, 7.175) (Table 4). Also, one medial collateral ligament injury and one meniscus injury occurred in the control group, bringing the overall acute knee injury rate in the control group to 0.232 injuries/1000 AEs (RR 0.127; 95% CI: 0.007, 2.421) (Table 4). Fifteen ankle sprains occurred; seven in the RBS group and eight in the control group (0.491 injuries/1000 AEs vs. 0.619 injuries/1000 AEs; RR 0.781; 95% CI: 0.302, 2.020) (Table 4). The odds of injury were equivalent for the two groups and no significant differences were found (Table 4). All injury characteristics are summarized in Table 5. There were no adverse events by the intervention in either group.

Injury type and study group	Injuries per 1000 AEs	Relative risk (95% Cl)	P value
ACL injury			
RBS program	0.000	0.298 (0.012, 7.175)	0.29

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Control program	0.077		
Acute knee injuries			
RBS program	0.000	0.127	0.06
Control program	0.232	(0.007, 2.421)	
Ankle sprain			
RBS program	0.491	0.781	0.61
Control program	0.619	(0.302, 2.020)	

Table 4: Comparisons of injury incidence (injuries/1000 athlete exposures) and relative risk by injury type in the RBS and control groups.

Injury	Study group	Sex	Sports	Onset	Mechanism
ACL injury	Control	Femal e	Volleybal I	1st time	Non-contact (Single-leg landing)
MCL injury	Control	Femal e	Volleybal I	1st time	Non-contact (Slipped while receiving the ball)
Meniscus injury	Control	Femal e	Volleybal I	1st time	Non-contact (Slipped while receiving the ball)
Ankle sprain	RBS	Male	Volleybal I	1st time	Non-contact (Slipped while running)
	RBS	Male	Volleybal I	1st time	Non-contact (Landing)
	RBS	Male	Volleybal I	Unknown	Unknown
	RBS	Femal e	Volleybal I	Recurrenc e (3rd time)	Indirect (Stepped on opposite player's foot while landing)
	RBS	Male	Basketb all	Unknown	Non-contact (Cutting)
	RBS	Femal e	Basketb all	1st time	Non-contact (Running)
	RBS	Femal e	Basketb all	Recurrenc e (2nd time)	Indirect (Being pushed by opposite player while dribbling)
	Control	Femal e	Volleybal I	1st time	Indirect (Stepped on opposite player's foot while landing)
	Control	Femal e	Volleybal I	1st time	Indirect (Stepped on opposite player's foot while landing)

Control	Femal e	Volleybal I	Unknown	Unknown
Control	Male	Basketb all	1st time	Indirect (Stepped on opposite player's foot while landing)
Control	Male	Basketb all	Unknown	Indirect (Being pushed by opposite player while dribbling)
Control	Femal e	Basketb all	1st time	Indirect (Being pushed by opposite player while dribbling)
Control	Femal e	Basketb all	Recurrenc e (2nd time)	Indirect (Stepped on opposite player's foot while landing)
Control	Femal e	Basketb all	Unknown	Unknown

Table 5: Characteristics of injuries recorded in the study. MCL=MedialCollateral Ligament.

Discussion

The principal finding in this RCT was that the exercise program wearing the RBS was not significantly more effective than a conventional injury prevention program in reducing the incidence of ACL injury and other acute lower extremity injuries in junior athletes. However, the participants who performed the RBS program had no acute knee injuries, whereas there were three acute knee injuries, including one ACL injury, in the control group.

To our knowledge, this is the first study to evaluate the effectiveness of different injury prevention programs in reducing lower extremity injuries in junior-specific athletic population. While immediate injury risk may be less during junior age [31,32], knee kinematics and kinetics during landing diverge during puberty [20,21], suggesting puberty may be an ideal time to intervene to reduce future injury risk. Considering the difference of the number of acute knee injuries between 2 groups, it seems that junior athletes can respond to the RBS program. Although we can't simply compare our results with those of previous studies because many of them targeted either collegiate or high school-aged players, the reported incidences in our study were consistently lower than prior studies of older athletes [9,11,33-35].

We hypothesize that feedforward motor control and muscular preactivation could be an underlying mechanism for fewer acute knee injuries in the RBS group. Video analysis estimates that ACL injury occur in approximately 40 milliseconds after ground contact [15,16], whereas the spinal stretch reflex occurs in 50 to 70 milliseconds, with an additional time lag due to the electromechanical delay [36], suggesting that ACL injury occurs too fast to allow a reflexive muscular response to prevent the injury. Thus, during fast movements like landing and cutting, substantial preactivation of the knee joint muscles just before ground contact seems essential. These preparatory patterns may be modifiable and reinforced with specific training designed to simulate sport-specific tasks with an emphasis on safer kinematics [37]. The RBS program was designed specifically to correct

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dynamic valgus alignment of the lower extremity. This program is unique in wearing the balancing devices that allow for stepping and jumping. Emphasis was placed on performing steps, jumps and landings with horizontally maintained the RBS orientation, which inevitably made the athletes maintain the "knee over toe" position. Athletes can receive biofeedback consistently during any weightbearing activities wearing the RBS, and as required with feedforward regulations at stepping and landing. Our study showed increased prelanding activity of the semitendinosus during the drop vertical jump after 4 weeks RBS program [28]. Zebis et al. [38] confirmed that female athletes with reduced preactivation of the semitendinosus during side cutting were at increased risk of future ACL injury. These modifications to existing motor patterns by the RBS program are particularly important because it may help decrease abnormal joint motion and protect an athlete's ACL from high impulse loading. Interestingly, all three acute knee injuries, including one ACL injury, were non-contact in nature and occurred in the control group. Although not statistically significant, this suggests a possible benefit of wearing the RBS program to reduce non-contact ACL injury in junior athletes.

Some important study strengths include its RCT design, individual athletic exposure and injury registration, and blinded analyses. In contrast to most previous intervention studies, we randomized individual players to either the RBS or control group within a team to match AEs, levels of play, and the types of sports the athletes participated in. Whether our results can be generalized to other age groups or other team sports is uncertain.

This study also has some limitations. First, while we saw a trend towards decreased ACL and acute knee injuries in the RBS vs control group, increasing participant numbers may increase our statistical power to a point where these differences become statistically significant. Second, 3-arm design RCT (additional control group with no interventions) may be more appropriate to examine the effectiveness of prevention program on junior athletes. Third, we gave practical instructions about the exercises only once every 3 months and participant compliance with these instructions was uncertain. Thus, our data likely underestimate the effect of the RBS program. Lastly, some athletes may not seek medical care, and therefore medical records were likely nonexistent for some injuries. This may have underestimated more specific diagnoses.

Conclusion

The RBS exercise program, which emphasizes correcting dynamic valgus, was not significantly more effective than a conventional program reported to reduce ACL injury risk in preventing knee injuries in junior athletes. By adding ankle-specific exercise, we aimed to further reduce injury incidence, especially regarding ankle sprain. The next step is to quantify biomechanical and physiological theories to explain the effect of the RBS program to refine and increase the injury-preventive effect of the program. Furthermore, whether intervening with junior athletes would result in better long-term injury prevention outcomes is of interest.

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