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Research Article

The Impact of the Novel E-J Biomechanical Footwear System on Lower Limb Biomechanics in Recreational Female Athletes at High Risk of Non-Contact ACL Injury: A Feasibility Study

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ABSTRACT

Anterior Crucial Ligament injury is one of the most severe knee injuries that happens to young athletes who participate in sporting activities that require cutting, pivoting, and sudden deceleration. Prevention programs have proven to lower limb neuromuscular control, which would reflect on dynamic knee stability and functional performance. However, most of those programs have low compliance rates because they require a time commitment and a considerable level of intensity and complexity. The study aims to evaluate the feasibility of performing the intervention on healthy recreational female athletes with the E-J system and to review the current prototype design of the device, according to the user perspective, and finally, to observe any alterations in postural stability. The study was conducted in three phases. Of 15 potential participants, 10 female participants were recruited after being 2D video assessed at the screening phase, as they showed an FPPA exceeding 8.5 degrees while performing a single-leg squat. Participants were assessed using the Y balance test in the pre-intervention phase and after 4 weeks in the post-intervention phase. Compliance rate, Y-balance test outcomes of each limb length, reach for the right and left lower limbs in three directions each (Anterior, Posteromedial, Posterolateral). Results showed a significant (p-value < 0.05) increase in limb length of reach, along with a compliance rate of 89%. The outcomes suggest that performing an intervention with the E-J system is safe and feasible. In addition, the E-J system demonstrated that it may have potential for improving lower limb postural stability.

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1. Introduction

ACL (Anterior cruciate ligament) ruptures account for nearly half of all soft tissue knee sports injuries [1]. ACL injury is arguably one of the most severe and debilitating lower limb injuries associated with athletic participation [2]. According to Sugimoto et al. [3], non-contact mechanisms account for the majority of ACL injuries in sports like landing, cutting, and abrupt deceleration during sprinting in sports such as, football, rugby, volleyball, handball, and basketball.

Neuromuscular and biomechanical changes have been identified as possible risk factors for non-contact ACL (NCACL) injuries among female athletes [4],[5]. The disruption in neuromuscular control and the uneven recruitment of lower limb muscles during athletic movements can lead to heightened lower limb motion and stress, thereby elevating the risk of NCACL injuries in females [6]. When the muscles that govern the dynamic stability of the knee joint in the lower extremities fail to generate the necessary force, there is an increase in stress on the ACL, which raises the likelihood of its injury [7].

Female athletes are reportedly 4–7 times more likely than their male counterparts to sustain an NCACL injury [8]. They appear to have unique neuromuscular strategies when performing motor tasks that place them at a higher risk of sustaining ACL injuries [9]. During athletic movements, female athletes tend to land with a highly extended knee position and an increased knee valgus motion [10]. This lack of neuromuscular control in the lower limb in female athletes during cutting, pivoting sport manoeuvres could lead to valgus collapse, resulting in ACL injury [11].

Academic research has concentrated on developing intervention programs to decrease the frequency of knee ligament injuries, especially ACL injuries, among female players performing risky sport movements [12]. Furthermore, due to improved neuromuscular control of the lower limbs result in modified biomechanical risk variables, it has shown that changes in high-risk lower limb movement patterns resulting in decreasing the chance of sustaining ACL injury while participating in sports which include high-demanding sports manoeuvres, especially among players who show neuromuscular control deficits which may negatively impact their knee dynamic stability [13],[14].

Numerous scholarly investigations have identified a significant disparity between the findings of published research and the practical application of injury prevention strategies [15],[16],[17],[18]. This divergence was underscored by the discrepancies observed between laboratory-derived outcomes and the actual effect on the incidence of injuries among female athletes in high-risk categories [7]. A potential contributing factor to this phenomenon is that the majority of protocols for ACL injury prevention programs demand substantial time commitments, coupled with considerable complexity and intensity. These demands may deter both coaching staff and athletes from active participation, consequently leading to suboptimal adherence rates [17].

Several studies have indicated that employing balance training apparatus, including unstable surfaces and wobble boards, can substantially enhance the proprioception of lower limb joints musculature during rehabilitation [18], [19],[20]. Documentation from various studies suggests that balance and proprioception training regimens can function as supplementary training elements, offering a minimal risk of injury or fatigue, and thereby improving the neuromuscular control, resulting in better stability and biomechanics of the lower extremities [21],[22],[23],[24],[25],[26]. These programs are predicated on the understanding that the human body operates as an integrated system of interconnected muscles, joints, and linkages, with the entire limb perceived as a singular kinetic functional chain that originates from the foot and extends throughout the entire body [27],[28].

A significant number of unstable footwear designs exhibit several disadvantages. Primarily, they are constrained by the manufacturer's predetermined configuration, precluding any adjustments to lower limb alignment or joint loading [29],[30],[31]. Furthermore, these devices lack the capacity for modification or calibration to accommodate specific therapeutic requirements. A third considerable limitation is their typically high cost, which substantially restricts their widespread application in injury prevention initiatives. Finally, it has been observed that most footwear-based balance devices are effective in influencing only a single plane of motion [32],[33],[34].

The objective of this study was mainly to explore the safety and feasibility of performing the intervention on healthy recreational female athletes wearing a prototype biomechanical device (E-J system), and reviewing the current design of the device, according to user perspective, and finally observe any alterations in postural stability in the lower limbs.

It is hypothesized that the E-J system, functioning as a wearable biomechanical device for the foot, it may foster enhanced lower limb stability. Furthermore, it is anticipated that users will be able to incorporate this device into their daily routines without disruption to their demanding schedules, potentially leading to improved adherence rates. Consequently, the E-J system may serve as a valuable component in risk mitigation programs for lower limb injuries.

2. Methodology

Repeated measurements were taken at two different times in this feasibility study. Every measurement was taken both before and after the four-week intervention. The usage of the Y balance test for measuring postural stability has been approved to be a reliable and valid method for assessing postural stability [35] and has been identified as a measurement to identify high- risk mechanics for sustaining lower limb injuries in the athletic population [36, 37,38].

2.1. Participants

All potential participants for the study needed to be aged 18 to39 years old to qualify participating in the study. They also had to engage in recreational sports involving over 30 minutes of physical activity at least three times a week consistently for the last six months [39].

None of the participants had injuries to their lower limbs in the past three months nor did they have a previous ACL or any long-term problem with their lower limb or surgeries. All participants were also required to have a Beighton score of < 4 for general laxity. Those who experienced musculoskeletal issues that kept them from their usual exercise routine for over 6 weeks before the beginning of the intervention was not included. Furthermore, participants who were already part of another injury prevention program were not permitted to take part. The study received ethical clearance from the Institutional Ethics Committee of the University of Benghazi, School of Physical Activity and Sports Science by Reference and committee: [2025-3-10/112]. All participants reviewed and signed a consent form.

2.2. Procedures

Of 15 female footballers' participants attended the screening phase of the study, performing Single-Legged Squat (SLS) in 2D video frontal plane projection angle (FPPA) [40]. Ten (10) participants were recruited as they showed (FPPA) exceeded 8.5 degrees, which may indicate poor neuromuscular control of their lower limb [1].

2.3. Calibration

Each participant received personalized calibration of their E-J system from the lead researcher before the initial data gathering. The E-J system consists of one modular component fixed to a shoe platform. This component is secured in a way that permits adaptable positioning of the foot's center of pressure. Due to intellectual property protection held by Salford University, UK and the University of Benghazi, Libya and drawings and specific calibration process cannot be disclosed in this document for confidentiality reasons. The calibration of the E-J system was directed by visual 2D FPPA for every participant to achieve as low knee valgus angle as possible during the SLS task.

2.4. First Session

Prior to the first session, participants were asked to perform five minutes of low-intensity warm-up stretching. Afterwards, participants performed the Y balance test. Participants had the chance to become acquainted with the Y balance test in order to reduce systematic bias, which typically required three or four attempts before they were sure they were doing it correctly. It was required of each participant to complete four trials. To reduce the impact of fatigue on participant's performance, they were also given a 60-second break in between each session. A copy of the study intervention program handbook and instructions on how to follow it and document their adherence for each participant. For four weeks, the participant was required to adhere to the research intervention protocol.

2.5. Follow-Up Session

After the participant finished the study intervention program, the participant performed Y balance test as previously done in the first collection session. The data collection process adhered to all the aforementioned protocols. The entire session lasted between 20-30 minutes.

2.6. Study Intervention program.

Each of the four stages in the study's intervention program lasted for one week. The goal of the first stage was to start with basic two-legged activities, like a two-legged anterior progression exercise that involved a double-legged squat. The second stage introduced single-leg anterior exercise to create greater loads on the hip and knee joints during controlled movements with an emphasis on maintaining a deep knee hold position, such as performing a Single-Legged Squat (SLS). This required sufficient torque production and control from the nearest muscles to manage the movement's direction at the hip.

To enhance the difficulty and concentrate on the flexors and extensors of the knee and hip, the third phase had participants begin with forward lunges, followed by lateral band walks and two-legged squats using a resistance band. The final week of the intervention featured the single-leg deadlift exercise.

Each workout began with three sets of ten repetitions and was gradually increased to a maximum of six sets of ten repetitions, similar to the previous phases.

The purpose of this exercise program was to instate the right technique in both the front and sagittal planes. This intervention program was conducted five days a week over a four-week time frame. Initially, exercise utilizing both legs were introduced to safely acclimate participants to the training movements, followed by a gradual increase of single-leg activities. The intensity and difficulty of the training drills was systematically increased.

Additionally, participants were asked to wear the E-J system for 30 minutes while doing their daily routines at home. To be included in the study, participants needed to complete at least two-thirds of the study intervention program.

3. Results and Discussion

Each participant's physical activity level was 5.6 according to the Tegner Activity Scale (TAS) [42], and they were all recreationally active. Six participants were the right leg dominant, and four were left leg dominant. The participant's adherence level was 89%. The Y balance test outcomes of each limb length reach for right lower limb in three directions, each Anterior, Posteromedial, Posterolateral showed significant increase in limb length ($p = 0.04$, $p = 0.02$, and $p = 0.01$, respectively), which may reflect improvement in the limb stability crease improvement in the lower limb reaching.

Nonetheless, the outcomes of the left side also showed similar improvement in limb length reach at the Anterior, Posteromedial, Posterolateral (P values 0.02, 0.02 and 0.03 respectively). However, due to the lack of a control group, we should be cautioned to claim any improvement in the lower limb's postural stability. There exists a link between poor neuromuscular control and movement patterns that are considered high-risk, which has been shown to increase the chances of experiencing both primary and secondary NCACL injuries [43],[44].

The optimum reasoning behind the potential incorporation of a workable biomechanical device such as the E-J system in injury

Table 1. Illustrate the demographics of the study population.

Variables	Study participants
Age (year)	26.42±9.05
Weight (kg)	64.37±12.06
Hight (cm)	163.28±8.92

Table 2. Illustration the Pre and Post Intervention Y balance test results (cm) for right side lower limb.

Variables	Mean	Std. Deviation	Mean diff	Std. Deviation	*P value*
Anterior/ Pre	85.857	8.529	8.52	2.27	0.04
Anterior / Post	91.571	7.449	7.44	1.99	
Posteromedial/ Pre	80.357	6.766	6.76	1.81	0.02
Posteromedial/ Post	84.357	5.197	5.19	1.38	
Posterolateral /Pre	80.071	8.203	8.21	2.19	0.010
Posterolateral/ Post	85.012	7.980	7.98	2.13	

Table 3. Illustration the Pre and Post Intervention Y balance test results (cm) for left side lower limb.

Variables	Mean	Std. Deviation	Mean diff	Std. Deviation	*P value*
Anterior/ Pre	84.502	8.52	8.52	2.27	0.02
Anterior / Post	91.21	7.87	7.87	2.10	
Posteromedial/ Pre	79.357	7.67	7.67	2.05	0.02
Posteromedial/ Post	83.64	6.05	6.05	1.61	
Posterolateral /Pre	81.153	7.54	7.54	2.07	0.03
Posterolateral/ Post	86.07	7.47	7.47	2.09	

prevention programs are underlined by its flexibility, potentially enhancing its use and wearability, serving as a more time-effective intervention method, while still providing crucial improvements in neuromuscular control. The design of the E-J system aims to adjust lower limb alignment by modifying the foot's center of pressure, which subsequently induces a manageable destabilization. Thus, challenging the muscles responsible for stabilizing the knee dynamically. This change in how the lower limb muscles are activated may enable users to improve their lower limb motor control sufficiently to sustain higher dynamic loads on the knee passive restraints, especially sport activity which require cutting, pivoting and sudden deceleration. [1].

The main consideration tackled in this research was mainly health and safety, which included the safe usage of the E-J system while participants engaged in the designated exercise during the research timeline. No injuries or main issues were reported to the researcher. The only concern was muscle discomfort noted during the first week of the study program, which subsided as participants became accustomed to the program. The other considerations are reviewing data collection methods, follow-up effectiveness, dropout rates, and overall acceptability. Additionally, the components of the program were assessed for their efficiency and safety [45],[46]. Moreover, the complete feasibility trial and its design were evaluated in relation to biomechanical outcomes, including the intervention's effect on the lower limb dynamic stability.

The two-dimensional video analysis utilizing FPPA for assessing the knee joint motion proved to be an appropriate and effective method for swiftly screening participants and was convenient for most potential candidates [47],[48],[49],[50]. Furthermore, the researcher employed this 2D video analysis as a tool for calibration purposes. Moreover, each participant required 10 to 15 minutes for calibration, a timeframe they found acceptable.

Each evaluation session spanned twenty to thirty minutes, which participants regarded as reasonable concerning the study intervention, the progressive method and exercise type were found to be suitable by the participants involved in the program that utilized the E-J system. The participants observed that completing the program exceeded fifteen minutes, and sometimes they could not finish all walking trials. Nevertheless, there were no reports of participants dropping out, and the adherence rate, in terms of sessions and time spent, exceeded 89%. Every participant was given a follow-up sheet at the beginning of the trial to monitor their commitment to the study intervention program.

The preliminary results from this feasibility study (Tables 2 and 3) indicated considerable improvements in the Y balance test results for each limb's reach on the right lower limb in all three directions [36]. This might imply that the E-J system has the ability to challenge lower limb stability sufficiently to stimulate improvements in dynamic neuromuscular control, which was believed to be a crucial factor affecting lower limb risk of sustaining injuries [37],[38] which may be related to muscle activation patterns improvement [34].

The findings from this study may lead us to propose that the E-J system may have the ability to alter the lower limb center of pressure, which explain the improvement observed in post-Y test outcomes. Therefore, it may be proposed that it could have an influence on the lower limb postural stability which would justify future studies on the prototype and comparing it in study with the control group.

4. Limitations.

The study findings may have a number of limitations. Firstly, these results pertain solely to young adult females who participate in recreational sports. The findings cannot be generalized to adolescent females' athletes with different skill levels. Secondly, the experiment only explored the immediate effects of the E-J system, a biomechanical device; the duration of its benefits remains unclear. Nonetheless, due to its simple structure and low intensity, it can suggest that users might be able to use the device both in the preseason and throughout the season. Thirdly, there was no control group for comparison included in this research. Lastly, the E-J system, being a prototype, was developed with limited resources, which could have influenced the exploration of it.

Finally, even though there were changes in Postural stability,. However, this must be taken with caution due to the nonstatistical testing adopted in this feasibility study and also whether the exercise program alone, rather than the E-J system, was responsible, which needs to be assessed. Nevertheless, the additional effect of the exercise component needs to be investigated without the E-J system. However, this would be beyond the scope of the present study.

5. Conclusions.

The study outcomes suggest that performing the intervention on healthy recreational female athletes with the E-J system is safe and feasible. The participant's reviewing the current prototype design of the device was positive, as they found it particular and easy to use. Moreover, the methodology applied would be suitable for conducting future studies. Finally, the E-J system demonstrated it may have a potential influence on the lower limb postural stability, which would justify future studies on the prototype and improving it.

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Conflict of interests

NO affiliations with or involvement in any organization or entity with any financial interest or non-financial interest in the subject matter or materials discussed in this manuscript.

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