Informed Consent Form

Effect of Dynamic Taping on Landing Biomechanical Characteristics in Volleyball and Basketball Players with Symptoms of Patellar Tendinopathy - Motor Control and Biomechanical Characteristics during the Landing Task

NCT number: NCT05454449

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Dec. 1st ,2022

Version 2.0	Date: 12.01.2022

Project name: Effect of Dynamic Taping on Landing Biomechanical Characteristics in Volleyball and Basketball Players with Symptoms of Patellar Tendinopathy - Motor Control and Biomechanical Characteristics during the Landing Task (NCT05454449)

Executing unit: Department of Physical Therapy and Assistive Technology, National Yang-Ming Chiao Tung University

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Contact number：

Emerge contact:

Contact number：

I. Study Purposes:

This study aims to analyze the differences in lower limb biomechanics during landing tasks and observe motor control performance among volleyball and basketball athletes with patellar tendinopathy and those without any symptoms.

II. Research Methods and Procedures

This study is a non-invasive motion testing experiment aimed at recruiting volleyball and basketball athletes aged 18-40 years. If you agree to participate in this study, the relevant tests will be conducted in room 606 of the Biomedical Engineering Building at National Yang Ming Chiao Tung University. During the test, you will need to wear sports shorts and lightweight tops, and the total time required will be approximately 60-90 minutes.

The test content is divided into four parts:

1. Completion of basic information including gender, age, height, weight, weekly exercise hours, sports type, and Victorian Institute of Sport Assessment (VISA) -patellar tendinopathy questionnaire.
2. A five-minute warm-up will be conducted before the test, which may include jogging and stationary jumping at a comfortable pace. After warming up, the highest jump height test will be conducted first, followed by the application of reflective balls and patches required for electromyography (EMG). Reflective balls will be attached to both sides of the anterior superior iliac spine, posterior superior

iliac spine, greater trochanters, and medial and lateral epicondyles of both femurs; patches will be attached to the muscle bellies of the gluteus maximus, biceps femoris, rectus femoris, and vastus lateralis to facilitate motion capture and EMG signal collection, recording motion trajectories and performance.

3. The first part of the formal test is motor control tests. Before the formal start, there will be a video and verbal explanation of how to perform the movements. There can be three practice movements before entering the formal test. The formal test for each movement will be performed three times, with a total of four directional movement tests.

4. The second part of the formal test is the motion analysis of landing tasks, including the 15cm step-down test, drop vertical jump landing from a 30cm height, and countermovement jump. Each landing task will be performed three times with a 3-minute rest between each task. To detect the mechanical parameters of your landing, you need to land squarely on the force plate each time and try to land in the habitual way during the movement.

Inclusion criteria for participants in this study are as follows:

Healthy Participant Group (Asymptomatic group):

1. Aged between 18 and 40 years old.
2. Participated in relevant sports training such as college cup or inducing pain for at least two years.
3. Weekly training time exceeds 90 minutes.
4. No history of patellar tendinopathy and without any lower extremity pain (NRS>3/10) in past 3 months.
5. Victorian Institute of Sport Assessment (VISA)-patellar tendinopathy questionnaire score>80.

Patellar Tendinopathy Group (Symptomatic group):

1. Aged between 18 and 40 years old.
2. Participated in relevant sports training such as college cup or inducing pain for at least two years.
3. Weekly training time exceeds 90 minutes.
4. Pain only in the patellar tendon during lower limb weight-bearing activities for more than 3 months.
5. Victorian Institute of Sport Assessment (VISA) -patellar tendinopathy

questionnaire uestionnaire score≤80.

Exclusion criteria for participants in this study are as follows:

1. Underwent sports physical therapy for knee pain in the past three months.
2. Self-reported pregnancy.
3. Currently have any other chronic or acute lower limb injuries with a pain score >3/10.
4. Had surgery, fractures, or received steroid injections for the patellar tendon in the lower limbs.
5. Have a history of systemic diseases such as rheumatic immune or neurological diseases.

III. Potential Risks, Incidence (Possible Side Effects), and Remedial Measures

All assessment tools used in this study are non-invasive measurements. The patches used to measure electromyography (EMG) signals are medical-grade patches. Before use, the skin of each participant will be cleaned to reduce the risk of contamination. However, there is still a possibility of adverse reactions such as allergies or redness due to individual differences in skin sensitivity. If any allergic reactions or swelling occur, the patches will be immediately removed, and ice application and subsequent anti-allergic treatment will be administered.

During the landing test, there is a potential risk of lower limb skeletal muscle injuries, such as acute sprains or muscle cramps. To minimize the risk of potential injuries, a five-minute warm-up will be conducted before the test. The warm-up includes jogging at a comfortable pace and stationary jumping. Additionally, the test movements will be explained in a video to familiarize you with the test procedures. If any injuries occur during the process, the test will be stopped, and appropriate measures such as ice application and stretching exercises will be provided. If pain persists for more than 24 hours, assistance will be provided for referral to medical care.

IV. Other Possible Research/Treatment Methods and Explanation

In addition to the objective analysis of landing movements and performance using motion analysis systems and electromyography (EMG) signals, it is also advisable to seek professional advice from coaches or physical therapists for relevant recommendations.

V. Expected Research Outcomes

Upon completion of the study, it is anticipated that the use of motion capture systems, force plates, and electromyography (EMG) will provide insights into your landing biomechanics performance and observe motor control to compare differences between athletes with and without patellar tendon pain. Through objective movement observations, participants can gain a clearer understanding of their own landing patterns, facilitating subsequent professional consultations.

The data from this study will also aid clinical practitioners, researchers, and coaches in future efforts toward preventing patellar tendon pain.

VI. Activities to Avoid During the Study

Participants are encouraged to maintain their regular exercise routines, but it is advised to avoid excessive training that may result in prolonged muscle soreness in the three days leading up to the experiment.

VII. Confidentiality

The principal investigator will treat any identifiable records and your personal privacy information as confidential in accordance with the law, and they will not be disclosed publicly. Your identity will remain confidential when the research results are published. By signing the consent form, you agree that your original records may be reviewed directly by monitors, auditors, institutional review boards, and regulatory authorities to ensure that the research process and data comply with relevant legal and regulatory requirements. The aforementioned individuals also commit not to disclose any information related to your identity, thereby ensuring the confidentiality of your identity.

VIII.Compensation for Damages

If adverse reactions or injuries occur as a result of the planned research, National Yang-Ming Chiao Tung University will be responsible for compensation. However, anticipated adverse reactions listed in this consent form will not be compensated. Signing this consent form will not affect any of your legal rights.

IX. Handling and Storage of Specimens and Data:

All research data from this study will be preserved for 10 years. At the end of this period, data will be destroyed using a paper shredder and by formatting hard drives. During the study, participant identities will be replaced with codes for identification purposes. Basic participant information (such as name, date of birth, etc.) will only be recorded on paper-based data sheets, which will be stored in a locked file

cabinet in a laboratory. The keys to the file cabinet will be kept by the principal investigator to maintain the privacy of the participants. The results of this study will only be used for academic publication and will not be used for other purposes. Participant privacy will not be disclosed except for investigations conducted by relevant authorities in accordance with the law.

X. Authorized Users of Specimens and Data

According to the "Human Research Act," only the principal investigator, co-investigators, and personnel included in the project are allowed to use your research data (or specimens) during the course of the study according to the research plan.

XI. Post-study Handling of Specimens and Data

Methods of handling research-related data:

□ Destruction by National Yang-Ming Chiao Tung University

□ Willing to continue: After the study ends, research-related data will be preserved by National Yang-Ming Chiao Tung University in accordance with the law for future studies related to volleyball and basketball athletes with patellar tendon symptoms. The data will be preserved for ten years, after which it will be destroyed. All new research projects must first be approved by the Institutional Review Board of National Yang-Ming Chiao Tung University. If the data are to be used beyond the original scope, a separate consent form will be required to be signed by you before proceeding with another research. Furthermore, any use beyond the original scope must be approved by the Institutional Review Board of National Yang-Ming Chiao Tung University.

Signature: _____ Date: _____

XII. Mid-study Withdrawal Procedure and Handling of Specimens and Data

You are free to decide whether or not to participate in this study, and you may withdraw your consent or discontinue participation at any time during the research process without providing any reasons. Declining to participate or withdrawing will not result in any unpleasant consequences, affect the evaluation of you by the principal investigator in future research projects, nor compromise any of your rights. Your specimens will be handled according to your decision, but please note that data concerning you obtained prior to withdrawal will be retained and analyzed. Regarding the handling of specimens after withdrawal from the study:

□ Destroyed by National Yang Ming Chiao Tung University.

□ Willing to continue, specimens will be legally preserved by National Yang

Ming Chiao Tung University for future research related to volleyball and basketball athletes with symptoms of patellar tendinopathy. The specimens will be preserved for ten years after the conclusion of the study and must be destroyed upon expiration. All new research projects must be approved by the Institutional Review Board of National Yang Ming Chiao Tung University. If the usage exceeds the original scope, another consent form will be required before conducting further research. Additionally, any usage beyond the original scope must be approved by the Institutional Review Board of National Yang Ming Chiao Tung University.

Signature: _____ Date: _____

XIII. If the research outcomes of this project are published in academic literature, or if any intellectual property or tangible benefits are obtained, National Yang-Ming Chiao Tung University may utilize them for medical purposes, including disease diagnosis, prevention, treatment, and research.

XIV. Rights:

1. As a participant in this study, upon completion, you are entitled to receive a transportation allowance of NT$200.
2. You have the right to not participate in the study, and you may withdraw from the study at any time without causing any discomfort or affecting your rights.
3. If you experience any discomfort or have any questions related to your participation in this study, you may contact the principal investigator, Yi-Fen Shih, at 2826-7340.
4. If you have any questions regarding your rights as a participant in this study, you may contact the Institutional Review Board (IRB) of National Yang-Ming Chiao Tung University for consultation at 02-2823-9753 or via email at irb@ym.edu.tw.
5. The principal investigator, Yi-Fen Shih, has provided you with a copy of the consent form for your records. The researchers have thoroughly explained the nature and purpose of the study to you and have answered any questions you may have had. The researchers have also explained your right to withdraw from the study at any time without causing any discomfort or adverse consequences.

XV. Signature

1. I have provided an explanation to the participants regarding the purpose,

procedures, as well as the potential risks and benefits of participating in this study. All inquiries raised by the participants have been addressed satisfactorily.

Research Explainer: _____

Relationship to the Research: □ Principal Investigator □ Co-Investigator □ Researcher

Explanation Date: _____

2. The participants have thoroughly understood the research methods mentioned above and the potential risks and benefits they may entail. Any questions regarding the research project have been thoroughly explained by the research team. I hereby consent to participate voluntarily in the research project.

   Subject: _____

   Date: _____

   *This consent form is applicable to adults aged twenty years and above and must be signed by the participant themselves with the date specified for it to take effect.

   *In the case of research involving fetuses, consent should be provided by the mother.

3. I certify that one member of my research team has already explained the research to the individuals mentioned above, including the purpose, procedures, and potential risks and benefits of participating in this study. All questions raised by the participants have been answered, and the participants meet the enrollment criteria for this study.

   Principal Investigator/Co-Investigator: _____

   Date: _____