ANALYSIS OF PATELLAR TENDINOPATHY RISK FACTORS AMONG INTERCOLLEGIATE ATHLETES

by

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A thesis submitted to the Graduate Council of Texas State University in partial fulfillment of the requirements for the degree of Master of Science with a Major in Athletic Training August 2016

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LIST OF ABBREVIATIONS

Description	Abbreviation
Body Mass Index	BMI
Landing Error Scoring System	LESS
National Collegiate Athletic Association.	NCAA
Patellofemoral Pain	PFP
Quadriceps Angle	Q Angle
Victorian Institute of Sport Assessment – Patella	VISA-P

ABSTRACT

Context: Patellar tendinopathy has a prevalence as high as 50% among athletes involved in jumping sports such as basketball and volleyball. Despite this prevalence, patellar tendinopathy remains a challenging condition for clinicians and researchers alike due to the lack of understanding concerning its etiology. **Objective:** To evaluate the known and hypothesized risk factors for patellar tendinopathy among male and female NCAA intercollegiate athletes to determine which outcome measures are most predictive. Design: Case-Control cross-sectional study. Setting: Laboratory setting. Patients or **Other Participants:** 60 intercollegiate athletes participated in this study (age 20.0 ± 1.2 , height 178.9 ± 9.8 , body mass, 79.7 ± 12.0) A 2:1 ratio of non-injured (n = 40) to injured (n = 20) was employed with participants matched on age and sex. **Interventions:** None. Main Outcome Measures: Static quadriceps angle (Q-angle), body mass index (BMI), waist/hip ratio, and Landing Error Scoring System (LESS) score. **Statistical Analysis:** A Group (2) x Sex (2) MANOVA approach was used to identify differences between the case and control groups, and men and women ($\alpha = 0.05$). Odds ratios were calculated using conditional logistic regression in an effort to identify independent risk factors for patellar tendinopathy. A secondary hypothesis investigated the extent to which a static Qangle, increased BMI, higher LESS score were risk factors associated with the incidence of patellar tendinopathy ($\alpha = 0.05$). **Results:** MANOVA indicated that dominant and non-dominant leg Q angle showed significant differences between the sexes. The average Q angle for female participants was 14.6 ± 3.6 deg compared to 10.1 ± 3.2 deg for male

participants (P < 0.05). The LESS scores in the case group (4.4 ± 1.4 points) were nearly identical to scores in the control group (3.8 ± 1.3 points) (P > 0.05). The Cox regression analysis showed no significant increase in injury risk with the 4 factors analyzed.

Conclusions: Our findings indicate that Q angle, the LESS test, or BMI were not significant predictors of patellar tendinopathy. Future studies should employ prospective, longitudinal designs with larger populations. Further investigation into the LESS test as a potential screening tool for various lower extremity injuries is warranted.

I. INTRODUCTION

Approximately one-third of all injuries treated in outpatient sports clinics involve the knee.¹ Of these, patellar tendinopathy is the most commonly treated disorder, with a prevalence as high as 50% among athletic populations. ²⁻⁵ This overuse injury remains a challenging condition for both clinicians and researchers⁶ despite its high incidence rates.² This difficulty stems from the fact that there is no clear mechanism or physiological process that explains the persistent and recurrent pain experienced by patients with patellar tendinopathy.⁶

To complicate matters further, recent histological studies have shown that "patellar tendinitis", the term previously used to describe this condition, is no longer accurate.⁷⁻⁹ When examined by pathologists, many injured patellar tendons lacked the cells commonly found when an active inflammation response is present.^{9,10} For this reason, there has been a recent push to reclassify chronic overuse conditions such as patellar tendinitis and Achilles tendinitis as "tendinopathies" in an effort to more accurately reflect the underlying pathology.^{11,12}

There are currently two mechanisms believed to combine to cause tendinopathy—repetitive overload of the tendon and a failed healing response.¹³ When a tendon is chronically overloaded, collagen fibers weaken and cross-links fail, resulting in a weakened tendon.¹⁴ Microscopically, tendons of patients diagnosed with patellar tendinopathy appear disorganized instead of aligned in tight, parallel collagen bundles seen in healthy tendons.¹² If the repetitive knee extension forces are not removed in these patients, the affected tendons will not heal properly and enter a cycle of repetitive injury

and failed healing that results in tissue degeneration and subsequent predisposition to further injury.¹⁵

The outcome of this failed healing response is a tendon that is less structured and more prone to injury than a healthy tendon. A decrease in structure at the fibrillar level of a tendon could cause a decrease in its tensile strength that is greater than expected given the actual amount of torn fibers observed microscopically. This change is due to the progressive collapse and disruption of cohesion at the fibrillar level. 16,17

In an effort to understand the etiology of patellar tendinopathy better, researchers have studied numerous variables including strength/flexibility measures, sports-related factors, demographics, and anthropometric measures.^{3,18,19} In their recent systematic review of 11 studies, van der Worp et al² found no strong or moderate causal relationships for patellar tendinopathy. Collectively, the 11 patellar tendinopathy studies they reviewed investigated 40 different clinical measures thought to be associated with patellar tendinopathy. Results of this systematic review were based on the findings of the original studies, as the numbers of variables included made it impossible to run the meta-analysis as the authors had planned.²

Numerous intrinsic and extrinsic risk factors are thought to predispose athletes and other physically-active individuals to patellar tendinopathy. Examples of intrinsic factors that may place a person at risk of developing patellar tendinopathy are height, weight, body mass index (BMI), measures of strength and flexibility, and anatomical alignments such as Q-angle. Extrinsic factors thought to be associated with patellar tendinopathy include playing surface, footwear, repetitive loading, fatigue, and changes in activity levels. However, there is little to no evidence that demonstrates that these

factors actually have any correlation with the incidence or severity of patellar tendinopathy.¹

Due to the unknown etiology, patellar tendinopathy is a frustrating condition for clinicians, athletes, and researchers alike. The collective lack of understanding of patellar tendinopathy makes it hard to develop effective treatment programs for athletes diagnosed with patellar tendinopathy. Suggested therapies include eccentric exercises, ultrasound, extra corporeal shock-wave therapy, and corticosteroid injections. Although evidence of successful treatment of patellar tendinopathy is continuing to grow, there remains a lack of high quality evidence for the efficacy of treatments. Identifying key risk factors that predispose athletes to developing patellar tendinopathy would be extremely helpful for clinicians and sports injury researchers in developing and testing new treatment methods that could have a higher success rate than currently-recommended treatment options.

Therefore, the purpose of this study was to evaluate hypothesized risk factors for patellar tendinopathy among female and male NCAA intercollegiate athletes to determine which outcome measures are most predictive of this condition.

Following the successful oral defense of this thesis, an abstract of these findings will be submitted by the November 15, 2016 deadline for a peer-reviewed presentation at the 68th Annual Meeting of the National Athletic Trainers' Association, to be held in Houston, Texas on June 26-29, 2017. In the interim, we will submit the primary manuscript from this thesis for publication to the *Journal of Athletic Training*.

II. MANUSCRIPT

ANALYSIS OF PATELLAR TENDINOPATHY RISK FACTORS AMONG INTERCOLLEGIATE ATHLETES

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Journal of Athletic Training

Abstract

Context: Patellar tendinopathy has a prevalence as high as 50% among athletes involved in jumping sports such as basketball and volleyball. Despite this prevalence, patellar tendinopathy remains a challenging condition for clinicians and researchers alike due to the lack of understanding concerning its etiology. **Objective:** To evaluate the known and hypothesized risk factors for patellar tendinopathy among male and female NCAA intercollegiate athletes to determine which outcome measures are most predictive. Design: Case-Control cross-sectional study. Setting: Laboratory setting. Patients or Other Participants: 60 intercollegiate athletes participated in this study (age 20.0 ± 1.2 , height 178.9 ± 9.8 , body mass, 79.7 ± 12.0) A 2:1 ratio of non-injured (n = 40) to injured (n = 20) was employed with participants matched on age and sex. **Interventions:** None. Main Outcome Measures: Static quadriceps angle (Q-angle), body mass index (BMI), waist/hip ratio, and Landing Error Scoring System (LESS) score. Statistical Analysis: A Group (2) x Sex (2) MANOVA approach was used to identify differences between the case and control groups, and men and women ($\alpha = 0.05$). Odds ratios were calculated using conditional logistic regression in an effort to identify independent risk factors for patellar tendinopathy. A secondary hypothesis investigated the extent to which a static Qangle, increased BMI, higher LESS score were risk factors associated with the incidence of patellar tendinopathy ($\alpha = 0.05$). **Results:** MANOVA indicated that dominant and non-dominant leg Q angle showed significant differences between the sexes. The average Q angle for female participants was 14.6 ± 3.6 deg compared to 10.1 ± 3.2 deg for male participants (P < 0.05). The LESS scores in the case group $(4.4 \pm 1.4 \text{ points})$ were nearly identical to scores in the control group $(3.8 \pm 1.3 \text{ points})$ (P > 0.05). The Cox regression

analysis showed no significant increase in injury risk with the 4 factors analyzed.

Conclusions: Our findings indicate that Q angle, the LESS test, or BMI were not

significant predictors of patellar tendinopathy. Future studies should employ prospective,

longitudinal designs with larger populations. Further investigation into the LESS test as a

potential screening tool for various lower extremity injuries is warranted.

Word Count: 352

Key Words: etiology, jumper's knee, patellar tendinitis, Victorian Institute of Sport

Assessment – Patella (VISA-P)

6

Introduction

Approximately one-third of all injuries treated in outpatient sports clinics involve the knee.¹ Of these, patellar tendinopathy is the most commonly treated disorder, with a prevalence as high as 50% among athletic populations. ²⁻⁵ This overuse injury remains a challenging condition for both clinicians and researchers⁶ despite its high incidence rates.² This difficulty stems from the fact that there is no clear mechanism or physiological process that explains the persistent and recurrent pain experienced by patients with patellar tendinopathy.⁶

Recent histological studies have shown that "patellar tendinitis", the term previously used term to describe this condition, is no longer accurate. The When examined by pathologists, injured patellar tendons lacked the cells commonly found when an active inflammation response is present. For this reason chronic overuse conditions such as patellar tendinitis and Achilles tendinitis have been reclassified as "tendinopathies" in an effort to more accurately reflect the underlying pathology which is more degenerative than inflammatory. 11,12

In an effort to understand the etiology of patellar tendinopathy better, researchers have studied numerous variables including strength/flexibility measures, sports-related factors, demographics, and anthropometric measures.^{3,18,19} In their recent systematic review of 11 studies, van der Worp et al² found no strong or moderate causal relationships for patellar tendinopathy. Collectively, the 11 patellar tendinopathy studies they reviewed investigated 40 different clinical measures thought to be associated with patellar tendinopathy. Results of this systematic review were based on the findings of the

original studies, as the numbers of variables included made it impossible to run the metaanalysis as the authors had planned.²

Hypothesized risk factors for patellar tendinopathy are generally classified as either intrinsic or extrinsic. Numerous intrinsic and extrinsic risk factors are thought to predispose athletes and other physically-active individuals to patellar tendinopathy. Intrinsic factors that may place a person at risk of developing patellar tendinopathy include height, weight, body mass index (BMI), measures of strength and flexibility, and anatomical alignments such as Q-angle. Extrinsic variables include playing surface, footwear, repetitive loading, fatigue, and changes in activity levels. However, there is little to no evidence that demonstrates that these factors actually have any correlation with the incidence or severity of patellar tendinopathy.

Due to the unknown etiology, patellar tendinopathy is a frustrating condition for clinicians, athletes, and researchers alike. Our collective lack of understanding of patellar tendinopathy makes it difficult to develop effective treatment programs for athletes diagnosed with patellar tendinopathy. Suggested therapies have included eccentric exercises, ultrasound, extracorporeal shock-wave therapy, and corticosteroid injections. Although evidence of successful treatments for patellar tendinopathy is continuing to evolve and grow, there remains a lack of high quality evidence for the efficacy of treatments. Identifying key risk factors that predispose athletes to developing patellar tendinopathy would be extremely helpful for clinicians and sports injury researchers in developing and testing new treatment methods that could have a higher success rate than the currently recommended treatment options.

Therefore, the purpose of this study was to evaluate the hypothesized risk factors for patellar tendinopathy among male and female NCAA intercollegiate athletes to determine which outcome measures are most predictive of this condition.

Methods

Design

This study employed a case-control design in an effort to identify key variables associated with the diagnosis of patellar tendinopathy among NCAA intercollegiate athletes. The purpose of this study was to examine hypothesized risk factors to determine the extent to which selected anatomical and biomechanical measures predisposed athletes to patellar tendinopathy, using both male and female intercollegiate athletes diagnosed with patellar tendinopathy and a control group of healthy intercollegiate athletes.

The two independent variables for this study were Group (intercollegiate athletes with and without a patellar tendinopathy diagnosis), and Sex (male and female). Primary outcome measures were body mass index (BMI), waist-to-hip ratio, static Q-angle measurement, and Landing Error Scoring System (LESS) scores.

Participants

A total of 60 male and female athletes from NCAA Division I and Division III institutions were screened for eligibility to participate in this study. Table 1 summarizes the inclusion/exclusion criteria. All 60 participants (mean age, 20.0 ± 1.2 yrs; height, 178.9 ± 9.8 cm; mass, 81.0 ± 16.5 kg) met all of the inclusion criteria for either the case or the control group, and subsequently completed all aspects of this study. All volunteers for this study were prescreened to ensure that they were NCAA athletes and had no history of ACL reconstruction surgery using a patellar tendon graft. To qualify for inclusion in the case group, participants needed to have either unilateral or bilateral patellar tendinopathy,

Once a volunteer qualified for participation in the study and provided written consent, we obtained participant demographic information. In addition, all participants completed the Victorian Institute of Sport Assessment – Patella (VISA-P) (Figure 1) questionnaire to place them in either the case or control group. Participants who had a VISA-P score less than 80 were assigned to the Case group, while those who had a VISA-P score equal to or greater than 80 were assigned to the Control group. Each participant suffering from patellar tendinopathy was matched with 2 healthy control participants based on their age (± 5 years) and sex. Using these criteria, all 20 athletes in the patellar tendinopathy group were matched with 40 uninjured athletes to form the 20 triads that were used in our conditional logistic regression analysis.

Volunteers who satisfied the inclusion/exclusion criteria provided written consent prior to participation in any part of this study, which was approved by the Texas State University Institutional Review Board (IRB #2015X6665). We explained the possible risks and benefits of this study to the participants prior to any formal data collection. The data for each participant were obtained during a single, 30-minute visit to a university athletic training clinical facility. Participants who completed all aspects of this study received a \$15 gift card to a regional grocery store as an incentive.

Instrumentation

A commercially-available 30 cm high wooden box was used for administration of the drop landings associated with the Landing Error Scoring System (LESS) test.

Two digital tablets (iPad 3, Apple, Inc., Cupertino, CA) were mounted on tripods and were used to obtain digital video recordings of the Landing Error Scoring System (LESS) trials for later analysis. We positioned each iPad 3 meters away from the

individual's landing zone; one iPad was placed perpendicular to the frontal plane while the other was placed perpendicular to the sagittal plane of motion.

Table 1. Inclusion and Exclusion Criteria						
Patellar Tendinopathy Group (Case)		Non-Injured Athlete Group (Control)				
Inclusion Criteria Exclusion Criteria		Inclusion Criteria	Exclusion Criteria			
Unilateral or bilateral patellar tendinopathy	History of ACL reconstruction using patellar tendon graft	No previous history of patellar tendinopathy	History of ACL reconstruction using patellar tendon graft			
NCAA Athlete	Not an NCAA Athlete	NCAA Athlete	Not an NCAA Athlete			
18 to 35 years old	<18 or > 35	18 to 35 years old	< 18 or > 35			
VISA-P Score < 80	VISA-P Score ≥ 80	VISA-P Score ≥ 80	VISA-P Score < 80			

A goniometer with extendable arms (Model 01135, Lafayette Instruments, West Lafayette, Indiana) was used to measure participants' static Q angle in both limbs.

We used a fiberglass tape measure equipped with a Gulick handle to measure our participants' waist-to-hip ratio. The Gulick handle ensures that the same amount of tension was used for each waist and hip circumferential measurement.

The LESS test was developed in 2004 by Padua et al, and has subsequently been shown to be a valid and reliable test for lower limb drop landing biomechanics.²⁴ Prior to the LESS test development, the most common means of evaluating landing biomechanics was through the use of 3-dimensional motion analysis that required expensive laboratory equipment and was time consuming to perform.²⁵ The LESS test provides researchers with an inexpensive, practical measure of lower extremity kinematics and injury risk.²⁴⁻²⁶ This is accomplished by recording an athlete performing a drop-landing task 3 times.

Each trial was later scored using a 17-point checklist to calculate a total score that indicates the level of anterior cruciate ligament (ACL) injury risk based upon the individual's drop-landing biomechanics.

VICTORIAN INSTITUTE OF SPORT

 For how many minutes can you sit pain free? 					
0 mins Doints Points					
0 1 2 3 4 5 6 7 8 9 10					
 Do you have pain walking downstairs with a normal gait cycle? 					
strong severe					
3. Do you have pain at the knee with full active non-weightbearing knee extension?					
severe no pain Points no pain 0 1 2 3 4 5 6 7 8 9 10					
4. Do you have pain when doing a full weight bearing lunge?					
strong severe					
5. Do you have problems squatting?					
Unable no problems Points					
0 1 2 3 4 5 6 7 8 9 10					
6. Do you have pain during or immediately after doing 10 single leg hops?					
strong severe					
0 1 2 3 4 5 6 7 8 9 10					
7. Are you currently undertaking sport or other physical activity?					
0 🗇 Not at all					
4 ☐ Modified training ± modified competition					
7					
10 Compating at the came or higher level as when compatent began					

Figure 1. Victorian Institute of Sport Assessment – Patella (VISA-P) questionnaire

8. Ple	8. Please complete EITHER A, B or C in this question.							
·If y	 If you have no pain while undertaking sport please complete Q8a only. 							
	• If you have pain while undertaking sport but it does not stop you from completing the activity, please complete Q8b only.							
• If you have pain that stops you from completing sporting activities, please complete Q8c only.								
8a. If	you ha	ve no pain w hi	le undertaking	sport, for how	long ca	n you train/practise?		
	NIL	1-5 mins	6-10 mins	7-15 mins	>151	nins		
						Points 🗌		
	0	7	14	21	30			
OR								
			vhile undertakir actice for how l			t stop you from tise?		
	NIL	1-5 mins	6-10 mins	7-15 mins	>15 r	nins		
	0	0	0	0	0			
	0	4	10	14	20	Points		
OR								
8c. If you have pain which stops you from completing your training/practice for how long can you train/practise?								
	NIL 1-5 mins 6-10 mins 7-15 mins >15 mins							
0 2 5 7 10 Points								
		TOTAL VIS	SA SCORE	,				

Figure 1. Victorian Institute of Sport Assessment – Patella (VISA-P) questionnaire - Continued

While the LESS test is primarily used to screen for deficits that may predispose an athlete to an ACL injury, it has been suggested that deficits found by a LESS screening

could be useful for predicting athletes' risk for other lower extremity injuries.²⁶ In their study using 3-dimensional motion capture technology to assess horizontal and vertical jump landing biomechanics, Mann et al²⁷ suggested that the LESS test may be a useful 2-dimensional tool for clinicians to use to screen for patellar tendinopathy risk.

The LESS test has not been validated for use in screening for the risk of any other acute injury or chronic condition beyond than ACL injury, but we hypothesized there may be a relationship between an athlete's jump landing biomechanics and their likelihood of developing patellar tendinopathy. Muscular insufficiencies in the lower extremity kinetic chain can cause poor jump landing biomechanics. If an athlete has gluteal weakness or hamstring/quadriceps muscular imbalances, a greater amount of force could be translated through the patellar tendon than in an athlete with more efficient biomechanics. This higher rate of tendon loading may predispose the athlete to patellar tendinopathy.

Experimental Procedures

Once consent was obtained, participants completed the Victorian Institute of Sport Assessment – Patella (VISA-P) questionnaire to assist in their placement in either the case or the control group. After completion of the VISA-P questionnaire, participants completed a brief demographic information questionnaire. Participants who scored less than 80 on the VISA-P were assigned to the Case group, and a score of 80 or greater placed them in the Control group. A VISA-P score below 80 has historically been used to differentiate between patients with and without patellar tendinopathy. ^{28,29}

To calculate each participant's body mass index (BMI), body height (cm) was measured using a standard, wall mounted anthropometer, and body mass (kg) was

measured using a standard scale. We calculated BMI using the standard formula: $BMI = mass (kg)/height (m)^2$.

Next, static standing quadriceps angle (Q angle) was measured while the participant stood on an examination table. Participants stood in a natural stance with feet shoulder width apart, and were instructed not to move until Q angle measurements were completed. Participants stood in a relaxed posture with their knees in full extension. A felt-tipped pen was used to put marks on the skin overlying the participant's anterior superior iliac spine (ASIS), center of their patella, and tibial tubercle.

Participants in the case group were asked if their tendinopathy was unilateral or bilateral. For unilateral cases, they were asked if the patellar tendinopathy affected their dominant or non-dominant leg. In bilateral cases they were asked if their dominant or non-dominant leg hurt worse. If their knees were equally painful, their dominant leg was used for measurements. Q angle was measured 3 times and the results were averaged to find the measurement used (Figure 2). Leg dominance was established by asking the participant which leg they would use to kick a soccer ball.



Figure 2. Assessment of Quadriceps Angle (Q Angle)

To obtain the participant's waist-to-hip ratio, a standard fiberglass tape measure with a Gulick handle was used to ensure equal tension was applied to the tape for all measurements. The most superior aspect of participant's iliac crest were marked bilaterally using a felt tipped pen, and the waist circumference was obtained using these marks as reference. Hip circumference measurements used the greater trochanters of the femur as the reference points. Since felt-pen marks placed on the greater trochanters would not be seen under the participants' clothing, participants held the tape measure in place while measurements were taken at the opposite side. Between measurements, the principal investigator (TCR) ensured that the tape measure had not moved off the palpated landmarks.

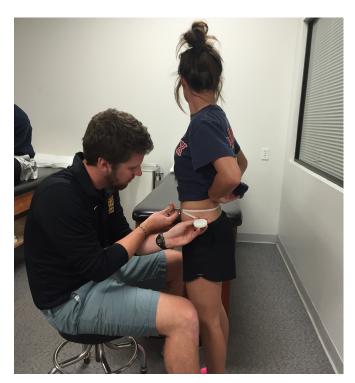


Figure 3. Measuring Waist Circumference

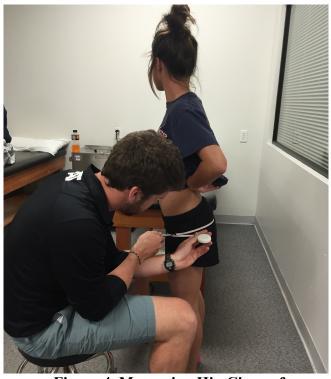


Figure 4. Measuring Hip Circumference

After waist and hip circumference measurements were obtained, participants were asked to pedal a stationary bicycle for 5 minutes as a warm up prior to completing the LESS test. As they were pedaling, the LESS procedure was explained to them, and they were asked if they understood the protocol, and if they had any questions. Participants were given 1 practice jump to verify that they understood the procedure, then the iPad recordings began, and the participant completed 3 consecutive LESS test trials. (Figure 5)

We created an Excel-based scoring matrix to record and simplify the analysis of the 17-point LESS test with data from two cameras. (Figure 6).



Figure 5. Representative Frontal and Sagittal Plane Screen-Capture Views of the LESS test.

Statistical Analyses

Prior to formal data collection, we conducted a pilot study with 10 healthy, physically active volunteers (5 men, 5 women; mean age = 22.7 ± 3.1 yrs) in order to establish intrarater test-retest reliability of the principal investigator (TCR) on all outcome measures. A minimum test-retest intraclass correlation coefficient (ICC) value of 0.75 was set as the goal for all clinical measures included in this study. According to Shrout and Fleiss²⁹, an ICC of 0.75 or higher indicates "excellent" intrarater reliability. We were successful in achieving "excellent" test-retest reliability of all clinical measures prior to commencing with the formal assessment of the participants recruited to this study. The ICC values achieved for all outcome measures are presented in Table 2.

Participant ID:							
Date:							
			Camera				
Landing France Condens Contact College			View	Trial 1	Trial 2	Trial 3	3-Trial Average
Landing Error Scoring System Criteria	4	1					
1. Knee flexion angle at initial contact (> 30 degrees?)	yes = 0	no = 1	S				
2. Hip flexion angle at initial contact (thigh flexed on trunk?)	yes = 0	no = 1	S				
3. Trunk flexion angle at contact (trunk flexed on hip?)	trunk flexed = 0	not flexed = 1	S				
4. Ankle plantar flexion at contact (toe to heel?)	toe to heel = 0	heel to toe = 1	S				
12. Knee flexion displacement (knee position before jumping), > 45 degrees	yes = 0	no = 1	S				
13. Hip flexion at maximal knee flexion angle (hip flexed more than at initial contact?)	yes = 0	no = 1	S				
14. Trunk flexion at maximal knee angle (trunk flexed more than at initial contact?)	yes = 0	no = 1	S				
5. Knee valgus at initial contact (knees over midfoot? Draw straight line thru patella)	yes = 0	no = 1	F				
6. Lateral trunk flexion angle at initial contact?	trunk vertical = 0	not vertical = 1	F				
7. Stance width at foot flat - Wide? (Greater than shoulder width?)	no = 0	yes = 1	F				
8. Stance width at foot flat - Narrow? (Less than shoulder width?)	no = 0	yes = 1	F				
9. Foot position at initial contact - Toe In? (more than 30 degrees internal rotation?)	no = 0	yes = 1	F				
10. Foot position at initial contact - Toe Out? (more than 30 degrees external rotation?)	no = 0	yes = 1	F				
11. Symmetric initial foot contact?	yes = 0	no = 1	F				
15. Knee valgus displacement (before jump), error = knee inside great toe	no = 0	yes = 1	F				
16. Joint displacement (trunk/hips/knees) sagittal plane (Soft = 0; Average = 1; Stiff = 2)	0 = soft	1 = average; 2 = stiff	S				
17. Overall impression (Excellent = 0; Average = 1; Poor (stiff) = 2)	0 = excellent	1 = average; 2 = poor	S, F				
		TOTAL POINTS			0	0	

Figure 6. LESS Test 17-Point Scoring System

Table 2. Pilot Study Results for Test-Retest Reliability for All Clinical Measures				
Outcome Measure	ICC Value	ICC Category		
BMI	1.00	Excellent		
Waist/Hip Ratio	0.99	Excellent		
Dominant leg static Q angle	0.98	Excellent		
Non-Dominant leg static Q angle	0.99	Excellent		
LESS Scores	0.99	Excellent		

A Group (2) x Sex (2) MANOVA approach was used to identify the presence of statistically significant differences between the patellar tendinopathy patients and those in the healthy control group, as well as between men and women (α = 0.05). Four outcome measures, specifically, body mass index (BMI), waist/hip ratio, static Q-angle, and LESS Test scores were analyzed for significant main effects and interactions.

The increased risk of patellar tendinopathy associated with 4 risk factors will be estimated by calculating odds ratios with the use of conditional logistic regression. In this way we were able to describe the odds that a participant with patellar tendinopathy has been exposed to the risk factor, e.g., increased static Q-angle, divided by the odds that an athlete in the control group had been exposed to that same risk factor, after adjusting for all other variables in the model.

We used IBM SPSS software (version 23) for all statistical tests.

Results

Sixty participants were included in the study, and their demographic data are summarized in Table 3. The case group was comprised of 20 participants, who met all of the inclusion criteria, and were currently suffering from patellar tendinopathy. The control group was comprised of 40 matched participants who met the inclusion criteria, and all were injury free at the time of data collection.

Table 3. Summary of Demographic Data					
Group	N	Age (yrs)	Height (cm)	Body Mass (kg)	
Case	20	20.2 ± 1.6	179.4 ± 9.9	82.8 ± 10.8	
Control	40	19.9 ± 1.0	178.4 ± 9.9	78.1 ± 12.3	
Total	60	20.0 ± 1.2	178.8 ± 9.8	79.7 ± 12.0	

We employed a Group (2) x Sex (2) multivariate analysis of variance (MANOVA) to identify differences between the participants with patellar tendinopathy and the healthy control participants ($\alpha = 0.05$). A total of 4 outcome measures--standing static Q angle, waist-to-hip ratio, Landing Error Scoring System (LESS) score, and body mass index (BMI)--were analyzed for significant main effects and interactions.

The increased risk of patellar tendinopathy associated with the 4 predictors was estimated by calculating odds ratios using a conditional logistic regression. This analysis allowed us to describe the odds that a participant with patellar tendinopathy had been exposed to a risk factor, e.g., a larger Q angle, divided by the odds that a control subject had been exposed to that same risk factor, after adjusting for all other variables in the model.

Factorial MANOVA

To determine whether the Case and Control group participants were statistically different from each other we performed a 2 x 2 MANOVA and Levene's Test for Equality of Error Variances on all 4 outcome measures. None of the outcome measures produced statistically significant results on Levene's Test for Equality of Error Variances meaning that no outcome measure violated the assumption of sphericity (Table 4).

Table 4. Results of Levene's Tests of Equality of Error Variances					
Outcome measure	Levene's Test (F)	Significance (P)			
Dominant Leg Q Angle	0.075	0.973			
Non-dominant Leg Q Angle	0.396	0.756			
LESS Score	19.255	0.508			
Body Mass Index (BMI)	0.494	0.688			

[†] P < 0.05

The MANOVA omnibus F ratio using Wilk's Lambda indicated no significant differences between the case and control groups on any of the 4 outcome measures (P > 0.05).

We did observe significant differences in Q angle between male and female participants in our study. The results of the MANOVA indicated that Q angles were significantly different between women and men. The average Q angle was significantly greater in women $(14.6 \pm 3.6 \text{ deg})$ compared to the men $(10.1 \pm 3.2 \text{ deg})$ (P < 0.05).

When examining LESS scoring items individually, 2 of the 17 scoring categories were significantly different between the groups. Values for Item 5, "knee valgus at initial foot contact", (F = 8.39, P = 0.005) and Item 15, "knee valgus prior to maximum vertical jump", (F = 4.69, P = 0.035) were paradoxically higher in the Control group compared to the Case group. We believe that this finding may be due to the fact that the case group athletes have received some sort of physical therapy or rehabilitation program for their injury. A common element of a rehabilitation program for a knee injury to an athlete in a sport that requires repetitive jumping is landing and jumping training. These injured athletes may have been trained specifically to not allow any knee valgus collapse while jumping or landing, thus explaining the unexpected results.

Conditional Logistic Regression

In an effort to determine the relationship between the outcome variables and the risk of developing patellar tendinopathy, we performed a conditional logistic regression analysis on all variables using a Cox survival analysis. This analysis is designed to quantify the odds that a person exposed to a specific variable or condition will develop patellar tendinopathy. We hypothesized that BMI, waist/hip ratio, Q angle, and LESS scores would be associated with an increased risk of developing patellar tendinopathy. The Cox regression analysis did not reveal any of these outcome measures to be significant predictors of which participants had patellar tendinopathy (P > 0.05) (Table 5).

Table 5. Results of Conditional Logistic Regression Analysis							
					95% CI for Exp (B)		
	B	df	Sig.	Exp(B)	Lower	Upper	
Waist/Hip	2.601	1	0.942	13.480	0.000	5.313E+31	
Ratio							
Dominant Leg	-0.052	1	0.925	0.950	0.323	2.792	
Q Angle							
Non	0.057	1	0.917	1.059	0.363	3.087	
Dominant Leg							
Q Angle							
LESS score	-0.018	1	0.989	0.983	0.082	11.847	

Discussion

We found only one previous study that examined Q angle as a potential risk factor for patellar tendinopathy. Witvrouw et al³¹ conducted a prospective study of 138 undergraduate college students who participated in a variety of sports activities as part of their physical education curriculum. As in our study, Witvrouw et al³¹ found no

significant differences in Q angle between the case and control groups. In contrast to our results, Witvrouw and associates did not report differences in Q angle between sexes, while we did. It is generally accepted that that women have larger Q angles than men.³²

In a related study of adolescent athletes with patellofemoral stress syndrome, Moss et al³³ found that Q angle was a significant predictor of injured versus non-injured participants. The mean Q angle in their study was 16.2 ± 1.3 deg, while our study was 11.4 ± 3.6 deg. The approximately 5 deg difference in means could be explained by the fact that Moss³³ examined exclusively females in his study. As previously stated, females typically have a larger Q angle than males due to their greater pelvic flare, so an exclusively female population would be expected to have larger Q angle measurements. Measurement techniques also differed significantly in the two studies. In our study, we used a hand-held, extendable arm goniometer to obtain 3 measures of each Q angle, and averaged the results. Moss et al³³ used digitized film of participants running on a treadmill to obtain their Q angle measurements. Their measurements were obtained from a dynamic task, while ours were obtained while the participant was standing still. All of these differences in populations, measuring techniques, as well as the fact that they were examining patellofemoral stress syndrome could potentially explain the difference in findings with our study and Moss et al.³³

To the best of our knowledge, this was the first time the Landing Error Scoring System (LESS) test had been used to assess an athlete's risk of developing patellar tendinopathy. The LESS test was designed to be used as a more affordable method of performing a jump landing biomechanical analysis.²⁶ The LESS test has been studied for effectiveness in predicting athletes' risk of sustaining a non-contact ACL injury, but has

not been used in other types of injury screenings. As a general screening of jump landing biomechanics, we hypothesized that the LESS test would show significant differences (P <0.05) between our case and control groups. This was not the case in our study as there was no statistically significant difference in LESS scores between the healthy $(3.8 \pm 1.3 \text{ points})$ and injured $(4.5 \pm 1.4 \text{ points})$ populations (F = 2.671, P = 0.108).

The LESS scores in the control group $(3.8 \pm 1.3 \text{ points})$ were nearly identical to scores in the case group $(4.4 \pm 1.4 \text{ points})$. The lack of variability makes it nearly impossible to find any statistical significance between groups.

When examined individually, 2 of the LESS scoring items did show statistical significance. Item 5 "knee valgus at initial foot contact" (F = 8.391, P = 0.005) and item 15 "knee valgus displacement (before jump)" (F = 4.685, P = 0.035) were the two significant categories. These values for item 5 (0.260) and item 15 (0.329) were paradoxically lower in the case group than the control group scores (0.533, 0.660) respectively. A lower score indicates less errors, meaning the control group actually had more valgus collapse than the case group did. As discussed previously, we hypothesize this is due to rehabilitation programs the case group athletes may have completed which trained them to resist knee valgus collapse while jumping and landing.

In a related study in 2012, Foss et al³⁵ found no relationship between BMI and patellofemoral pain (PFP). Patellofemoral pain and patellar tendinopathy are different conditions that have potentially similar causes and are common in similar populations. Patellofemoral pain is common in younger athletes, and hypothesized risk factors include increased BMI, a small intercondylar notch, sex, and training levels.³⁵ We found similar results, with BMI showing no statistically significant between group relationship.

van der Worp et al⁴ also found no significant difference in BMI between healthy athletes and athletes with patellar tendinopathy.

No significant differences were found between the Case and Control groups for the waist-to-hip ratio. Like several of our other outcome measures, our waist-to-hip ratio data were not normally distributed. Because all participants were active members of NCAA teams at their respective universities, their morphologies were quite similar. All of our participants had either ectomorphic or mesomorphic body types, with no endomorphic participants in our study. Thus, there was little to no variability in our waist/hip ratio measurements. Gaida et al²⁰ found similar results when examining participants with bilateral patellar tendinopathy. In their study of 39 elite female basketball athletes, there was no significant difference in waist/hip ratio between athletes with bilateral patellar tendinopathy and the control group.²⁰

We performed a conditional logistic regression on all variables to determine if any of the outcome measures was associated with an increased risk of patellar tendinopathy. However, none of our 4 outcome measures examined showed any statistically significant predictive value. The lack of statistical significance found could be because the participants were not normally distributed. Because intercollegiate athletes exclusively made up our sample population, after accounting for differences between the sexes, their anthropometric measures were very similar.

In the Cox regression analysis, we did not find any significant increase in the odds of developing patellar tendinopathy associated with waist to hip ratio (OR = 13.48, P = 0.942). In 2012 van der Worp et al⁴ found no association between waist to hip ratio and patellar tendinopathy in basketball and volleyball players. They had 2,363 responses to a

survey initially sent to an estimated 12,000 Dutch basketball and volleyball athletes. We included waist to hip ratio in our study despite the lack of evidence in the previous study because of the survey methodology. We hypothesized there might have been different findings if the waist and hip measurements were obtained by a skilled investigator instead of a novice evaluator.

Conclusions

Our findings did not reveal any significant associations among Q angle, waist/hip ratio, BMI, or LESS scores and the incidence of patellar tendinopathy in our sample of NCAA intercollegiate collegiate athletes. The causal factors for patellar tendinopathy remain elusive, as was previously concluded by van der Worp et al.² The multifactorial etiology of this condition makes it difficult to definitively determine which factors have a causal relationship with patellar tendinopathy. We suggest that future researchers conduct prospective, longitudinal studies using a larger sample of college and/or high school athletes to study the epidemiology of patellar tendinopathy. Specifically, these studies should recruit equal percentages of women as participants. In addition, future studies should differentiate between those individuals with unilateral and bilateral patellar tendinopathy. Lastly, for improved scoring and understanding of LESS test results in this population, researchers should document the dominant lower limb of their participants and look for side-to-side differences in landing mechanics in effort to establish causal relationships with patellar tendinopathy.

III. SUMMARY AND RECOMMENDATIONS

Summary

Patellar tendinopathy affects up to 50% of athletic populations,^{3,4,5} and is often a difficult condition to completely resolve.⁶ This difficulty seems to stem from the fact that the mechanism(s) and/or underlying physiological processes that create the persistent and recurrent pain experienced by patients with patellar tendinopathy are not clearly understood.⁶

Current evidence suggests that failed healing response and repetitive overload of the patellar tendon are the primary mechanisms contributing to patellar tendinopathy in athletes. ¹³ In sports requiring forceful repetitive knee extension forces, the patellar tendon enters into a cycle of repetitive injury and failed healing, and thus becomes predisposed to injury ¹⁵. Despite multiple studies examining both anthropometric and sport-related variables in athletes, the reason why this cascade of events occurs in some physically active individuals but not others is not well understood. ^{2,4} The purpose of this study was to evaluate hypothesized risk factors for patellar tendinopathy among NCAA Division I, II and III athletes to determine which outcome measures are most predictive of incurring this condition.

Two of the 17 scoring categories of the LESS test showed significant differences between the case and control groups, but the overall total LESS score did not. None of the other main outcome measures were statistically significant different between those with and without patellar tendinopathy.

Recommendations for Future Research

Future research should differentiate between unilateral and bilateral patellar tendinopathy, and note which leg is the dominant leg for each case. Matching between the case and control groups should be done not only on age and sex, but also sport, leg dominance, BMI, and/or single/bilateral patellar tendinopathy. Further investigation is warranted into knee valgus collapse during drop landing tasks and its implications for knee injuries, specifically patellar tendinopathy. Future studies should also employ a longitudinal, prospective design with bigger populations in order to increase statistical power. As this was the first time the LESS test was used as a potential screening tool for patellar tendinopathy, further investigation in this area, as well as screening for other lower extremity injuries is warranted.

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APPENDIX SECTION

OVERVIEW OF THE STUDY

Purpose of Study: The primary purpose of this study will be to evaluate the known and hypothesized risk factors for patellar tendinopathy among female and male NCAA intercollegiate athletes and determine group differences. Second, we look to determine which outcome measures identify group membership, those with and without patellar tendinopathy.

Experimental Hypotheses:

- Specifically, we hypothesize that significance will be established between group differences (p < 0.05).
- We also hypothesize that the following outcome measures will be identified as significant risk factors associated with the incidence of patellar tendinopathy ($p \le 0.05$):
 - ➤ Increased Q angle
 - ➤ Increased LESS scores
 - ➤ Increased waist/hip ratio
 - ➤ Increased BMI

Assumptions:

- This study assumed that participants were healthy and were collegiate athletes.
- This study assumed that participants fully complied with all aspects of the research protocol
- This study assumed that participants answered honestly for all questions
- This study assumed that all testing equipment used were reliable and accurate

Delimitations:

• This study is delimitated by the recruitment of collegiate athletes

Limitations:

- Time constraints
- Longitudinal Effects
- Truthful responses to VISA-P questionnaire.

• Lacking good previous research on patellar tendinopathy risk factors

Operational Definitions:

Patellar Tendinopathy- pain in the patellar tendon, most commonly at the inferior pole of the patella

Collegiate athletes – currently competing on an NCAA Division I, II, or III sports team

Recommendations for Future Research

- Increase the amount of total study participants to increase statistical power of the study.
- Study these variables in a longitudinal study
- Differentiate between unilateral and bilateral patellar tendinopathy
- Investigate the role leg dominance may play
- Blinding of the researcher to those who have and do not have patellar tendinopathy

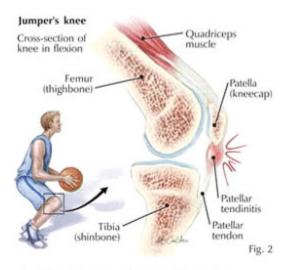
IRB SYNOPSIS

ANALYSIS OF PATELLAR TENDINOPATHY RISK FACTORS AMONG PHYSICALLY-ACTIVE ADULTS

1. Identify the sources of the potential subjects, derived materials or data. Describe the characteristics of the subject population, such as their anticipated number, age, sex, ethnic background, and state of health. Identify the criteria for inclusion or exclusion. Explain the rationale for the use of special classes of subjects, such as fetuses, pregnant women, children, institutionalized mentally disabled, prisoners, or others, especially those whose ability to give voluntary informed consent may be in question.

A total of 60 physically-active adults participating in NCAA Division I, II and III athletics teams at universities in the central Texas area will be recruited to this study. Participants who are currently suffering from unilateral or bilateral patellar tendinopathy (see **Figure 1**) will be matched with 2 healthy adults in a control group. A 2:1 ratio of non-injured (n=40) to injured (n=20) individuals will be sought, and participants with patellar tendinopathy will be matched on sex, age (± 5 years), and current physical activity levels.

Figure 1. Patellar tendinopathy, known as "jumper's knee" in layman's terms.



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The inclusion criteria for membership in the patellar tendinopathy group of this clinical study include: (a) a clinical diagnosis of patellar tendinopathy, (b) meeting the minimum amount of weekly physical activity, and (c) age between the 18 and 35 years. The exclusion criteria for the patellar tendinopathy group include: (a) a history of knee reconstructive surgery that used the patellar tendon as a graft, (b) not meeting the weekly physical activity standard, or (b) being younger than 18 or older than 35 years.

The inclusion and exclusion criteria for membership in the healthy, physically-active (control) group will be the same as for the patellar tendinopathy group, with the obvious exception of not having a clinical diagnosis of patellar tendinopathy.

We will not recruit any members of the special classes of subjects as participants in this study.

2. Describe the procedures for recruitment of subjects and the consent procedures to be followed. Include the circumstances under which consent will be solicited and obtained, who will seek it, the nature of information to be provided to prospective subjects, and the methods of documenting consent. (Include applicable Consent Form (s) for review.) If written consent is not to be obtained, this should be clearly stated and justified.

Participant recruitment will begin following IRB approval of this research proposal and will continue through February 2016, or until all 60 participants have been recruited. Recruitment efforts will utilize both emails and flyers. We will collaborate with our athletic training colleagues employed at central Texas NCAA institutions to help recruit individuals who have been diagnosed with patellar tendinopathy. Each volunteer will complete a Volunteer Screening Questionnaire, which we will use to determine his or her eligibility for participation in this study. If a volunteer satisfies the inclusion and exclusion criteria, we will obtain written consent for participation. (See attached **Consent Form)**

3. If your planned recruitment process involves emailing Texas State students, staff, faculty or other individuals using their active Texas State email address, provide details in the Synopsis. (In addition, the IRB will require a draft of your recruitment email, using the enclosed template and formatted as illustrated in the example in this document, submitted in addition to other required documents.

We will specifically recruit athletes from Texas State University's active team rosters for this study. This will be accomplished using referrals from Texas State University athletic training staff members. Please refer to the attached recruitment **email template.**

4. If you plan to distribute a survey to collect information directly from individuals who comprise a significant proportion of one or more Texas State affiliation groups, as defined in Section 04 of UPPS No. 04.01.02, Information Resources Identity and Access Management, you must follow the review and approval procedures outlined in UPPS No. 01.03.05, Administrative Surveys, and provide information in your Synopsis regarding review and approval.

We will employ a survey in this study, but not as described in Question 4 of this synopsis. The Victorian Institute of Sport Assessment Patella (VISA-P) questionnaire will be used to help the principal investigator place subjects in the injured or control group. (See attached VISA-P Questionnaire)

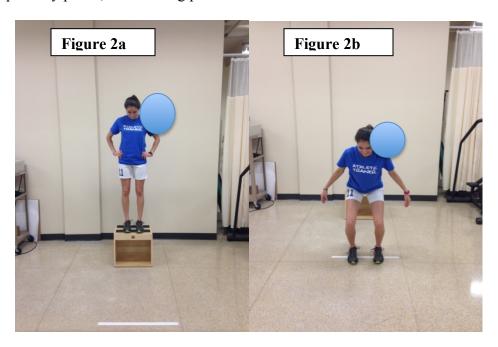
5. Describe the project's methodology in detail. If applicable, detail the data collection procedures, the testing instruments, the intervention(s), etc. If using a survey, questionnaire, or interview, please provide a copy of the items or questions.

This study will employ a cross-sectional, case-control experimental design to identify variables associated with the diagnosis of patellar tendinopathy in physically-active populations. Participants who have been diagnosed with patellar tendinopathy will be assigned to the case group while healthy participants will be assigned to the control group.

There will be two independent variables in this study: **Group** (2), i.e., Patellar Tendinopathy, Healthy Controls, and **Sex** (2), i.e., Male, Female. The key outcome measures will be body mass, body mass index (BMI), Victorian Institute of Sport Assessment--Patella questionnaire score, waist/hip ratio, standing quadriceps angle (Q angle), and Landing Error Scoring System (LESS) test score.

After obtaining written consent from the participant, all data will be collected during a one-time visit to either Texas Lutheran University's Exercise Physiology Laboratory in Seguin, or Texas State University's Biomechanics/Sports Medicine Laboratory in San Marcos. This single session will take approximately 60 to 90 minutes to complete, and involves several whole body and lower extremity anthropometric measurements, as well as a series of 3 drop landings evaluated with the Landing Error Scoring System (LESS) test (see *Figures 2a and 2b*), (Padua et al., 2009).

Figures 2a and 2b. The Landing Error Scoring System (LESS) test. 2a. Preparatory phase; 2b. Landing phase.



Once the volunteer is found to be eligible for participation, she/he will engage in a 5 minute warm-up period that will involve stationary cycling and dynamic stretching of the lower extremity muscles. After the warm-up period has been completed, the participants will be asked to perform the LESS test—a series of 3 two-footed landings from a 12" high box (*Figures 2a and 2b*).

Two iPad cameras mounted on tripods will be used to record the landings for later analysis with a 17-point scoring system. The zoom lens feature on the iPad cameras will be adjusted so as to capture lower extremity motion at the hips, knees and ankles, as the outcome measures of interest in this study are all related to landing mechanics. With different landing strategies, e.g., landing in an extremely flexed-knee position, it is possible that a participant's facial features may be captured on the recording. If this occurs, and that participant's landing is used as an example in a public forum, e.g., thesis defense, medical conference presentation, peer-reviewed manuscript, that participant's facial features will be covered using a computer-generated opaque oval (see Figures 2a, 2b, for examples).

Further, all participants will be assigned code numbers, and all data captured on the recording devices will be identified and stored using these codes. All personal identifying information will be removed. These coding procedures will help protect the identities of each participant.

Pilot Study

Prior to formal data collection, we will conduct a pilot study with 10 physically-active volunteers to establish the intra-rater, test-retest reliability of the principal investigator (CR) on all of the clinical outcome measures to be obtained in this study, e.g., body mass, waist/hip ratio, standing Q angle. According to Shrout and Fleiss (1979), intraclass correlation coefficients (ICC_{3,1}) values \geq 0.75 are indicative of "excellent" intra-rater reliability, while ICC values between 0.40 and 0.74 are considered "good and fair" reliability, and ICC values \leq 0.39 are viewed as "poor". Our goal is to achieve intraclass correlation coefficients (ICC_{3,1}) values \geq 0.75 or higher prior to commencing data collection with the 60 participants to be recruited to this study.

MANOVA

A two-way MANOVA approach will be used to identify the presence of any significant differences on the outcome measures between the case and control groups. Five outcome measures — body mass, body mass index, waist/hip ratio, static quadriceps angle, and landing error scoring system (LESS) score — will be analyzed for significant main effects and interactions. The *a priori* alpha level is set at 0.05. We will use IBM SPSS software (version 23) for all statistical tests.

Logistic Regression

The increased risk of patellar tendinopathy associated with the 5 hypothesized risk factors will be estimated by calculating odds ratios with the use of logistic regression. In this way we will be able to describe the odds that a participant with patellar tendinopathy has been exposed to the risk factor, e.g., a specific body mass, a poor LESS

score, divided by the odds that a control subject had been exposed to that same risk factor, after adjusting for all other variables in the model.

6. Describe any potential risks — physical, psychological, social, legal or other — and state their likelihood and seriousness. Describe alternative methods, if any, that were considered and why they will not be used.

The potential risks for this study are minimal, as the LESS test—the only dynamic physical activity in this study—is actually a lower extremity injury screening tool. That said, the risks of performing the LESS test include lower extremity muscle strain, and/or muscle and joint soreness the day after performance of the LESS tests.

It is also conceivable that participants might somehow slip and fall while landing on both feet from a 12" high box, a requirement of the Landing Error Scoring System (LESS) testing. However, since all participants will be skilled athletes participating on NCAA-sponsored sports teams, the likelihood of this sort of occurrence in very low. To further reduce the already low risk of falling, the LESS testing will be completed in a controlled laboratory environment with minimal noise and distractions. The LESS test has been employed and validated in many other published research studies and thus no alternative test will be considered. Specific exclusion criteria have been created to avoid adding potential risks and/or discomforts to the volunteers participating in the study.

The principal investigator, a licensed athletic trainer (AT) employed by Texas Lutheran University, is skilled in sports injury prevention and emergency medical care, and will be present to provide the participants with any acute medical care needed.

7. Describe the procedures for protecting against or minimizing any potential risks and include an assessment of the likely effectiveness of those procedures. Include a discussion of confidentiality safeguards, where relevant, and arrangements for providing mental health or medical treatment, if needed.

All participating athletes will be asked to sign a HIPAA waiver form that will allow the principal investigator (TCR) to view their existing athletic medical history form that will be on file at their respective universities.

All participants will be assigned a numeric identification code, which will be used instead of their name for all record keeping and during data analysis to maintain their confidentiality and privacy. Volunteer screening, consent, and demographic questionnaires will be completed. A previous medical history will be completed as a component of the volunteer screening form.

8. Describe and assess the potential benefits to be gained by the subjects, as well as the benefits that may accrue to society in general as a result of the proposed study.

Our study is one that can help identify key risk factors pertinent to the diagnosis of patellar tendinopathy, as well as assist in the development of new clinical decision rules that could improve clinical practices and treatment protocols for this chronic medical condition. This condition is frustrating for athletes and clinicians alike as its symptoms can persist for months at a time. An increased understanding of the risk factors for patellar tendinopathy will allow preventative measures to be implemented and potentially decrease the incidence of this patellar tendinopathy among future intercollegiate athletic populations.

9. Clearly describe any compensation to be offered/provided to the participants. If extra credit is provided as an incentive, include the percentage of extra credit in relation to the total points offered in the class. Also, if extra credit is provided, describe alternatives to participation in your research for earning extra credit.

Completion of all aspects of this study will require one (1) visit to our research laboratory for screening, consent and subsequent data collection. The total time commitment to complete all aspects of this study will be 60 to 90 minutes. As an incentive for participation, we have proposed a \$15 HEB gift card as appropriate compensation. With 60 participants to be recruited, the total cost of these gift cards will be \$900.

10. Discuss the risks in relation to the anticipated benefits to the subjects and society.

The data collected from this study will provide benefits to the athletic community and health care system that outweigh any risks. Patellar tendinopathy can be a debilitating injury for athletes and this study will provide insight on appropriate diagnostic tools. There are no significant risks associated with the proposed methods of this study.

11. Identify the specific sites/agencies to be used as well as approval status. Include copies of approval letters from agencies to be used (note: these are required for final approval). If they are not available at the time of IRB review, approval of the proposal will be contingent upon their receipt.

All data collection sessions will take place at either Texas Lutheran University's Athletic Training Clinic or at Texas State University's Biomechanics/Sports Medicine Laboratory.

12. If you are a student, indicate the relationship of the proposal to your program of work and identify your supervising/sponsor faculty member.

The principal investigator and lead author is a graduate student in the Master of Science degree program in Athletic Training at Texas State University. This project is being completed as a master's thesis and my supervising faculty member is Dr. Rod Harter.

13. In the case of student projects, pilot studies, theses, or dissertations, evidence of approval of Supervising Professor or Faculty Sponsor should be included. Thesis and dissertation proposals must be approved by the student's committee before proceeding to the IRB for review.

The committee for this thesis consists of Dr. Rod Harter (chair), Dr. Jeff Housman and Dr. Marie Pickerill—all graduate faculty members in the Department of Health and Human Performance at Texas State University. A formal proposal meeting was held on December 9, 2015, at which time my committee members approved my thesis proposal as written, and signed the required Graduate College form.

14. If the proposed study has been approved by another IRB, attach a copy of the letter verifying approval/disapproval and any related correspondence. If the proposed study has not been reviewed/approved by another IRB, please state this explicitly.

Not applicable. This research proposal is only being submitted to the Texas State University IRB.

15. Identify all individuals who will have access, during or after completion, to the results of this study, whether they be published or unpublished.

No persons, other than the principal investigators, will have access to the raw data or personal identifying information generated from this study. All interested individuals or groups may contact the principal investigators for the results of this study.

16. Provide date of completion of the required CITI training on the protection of human subjects. Applicants must provide training dates for themselves and for supervising faculty member. All training must be current and not expired.

Timothy Colin Reisler Biomedical Research Medical Students Course (Graduate Student) Passed on 12/4/2014, Expiration date 12/3/2016

Reference ID: 4544001

Rod A. Harter Biomedical Research Investigator Refresher Course/2 Passed on 02/14/2014, Expiration date 02/11/2016 (Faculty)

Reference ID: 7054667

Consent Form to Be in a Research Study

(In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study. In this form "we" means the researchers and staff involved in running this study at Texas State University.)

Principal Investigator:

T. Colin Reisler, ATC, LAT Graduate Assistant Researcher Dept. of Health & Human Performance 601 University Drive San Marcos, TX 78666 tcr37@txstate.edu

Mobile: 802-558-4163

Rod A. Harter, PhD, ATC, LAT, FNATA Professor of Athletic Training Dept. of Health and Human Performance A132 Jowers Center San Marcos, TX 78666 rod.harter@txstate.edu

Office: 512-245-2972

What is the purpose of this form?

This form will help you decide if you want to participate in the research study. You need to be informed about the study, before you can decide if you want to be involved. You do not have to be in the study if you do not want to. You should have all your questions answered before you give your permission to be involved in the study.

Please read this form carefully. If you choose to participate in the study, you will need to sign this form. You will receive a copy of this signed form.

Why is this research being done?

The primary purpose of this study will be to identify key anatomical and biomechanical risk factors that predispose physically-active persons to patellar tendinopathy, also known as "jumper's knee", a common condition involving the knee. We are seeking volunteers between the ages of 18 and 35 who are intercollegiate athletes who are interested in helping us answer this research question. If you are an athlete at an NCAA Division I, II, or III university, you may qualify for participation in this study, regardless of whether you have patellar tendinopathy or not.

How long will this study take?

Your participation in this study will require one (1) laboratory visit lasting approximately 60 to 90 minutes. After you have read and signed this consent form, your participation in the study will occur at either Texas Lutheran University's Kinesiology Laboratory or Texas State University's Biomechanics/Sports Medicine Laboratory. You will be asked

to complete a participant demographic form and a paper-and pencil questionnaire known as the Victorian Institute of Sport Assessment Patella. Once completed, we will then assess your height and weight in order to calculate your body mass index (BMI). Finally, we will measure your waist/hip ratio, quadriceps angle, and then ask you to perform the Landing Error Scoring System (LESS) Test. The LESS Test is a lower extremity injury risk screening procedure that involves a drop landing from a 1-foot high box that is followed by a maximum vertical jump.

What will happen if you are in the study?

If you volunteer to participate in this study, you will be screened for eligibility to participate in this study by completing a volunteer screening form that will ask about your general health and knee conditions. If you meet all of the inclusion criteria and agree to participate, you will need to sign this Consent Form before any study procedures take place.

During data collection, you will first be asked to step on the scale so that your weight can be measured. We will also measure your height, and use these two values to calculate your body mass index (BMI).

Next, we will measure your quadriceps angle (Q-angle) and waist/hip ratio while standing. The Q-angle is a measurement of the angle formed where an imaginary line from your hip bone to the middle of the kneecap intersects a line from the shinbone to the middle of the kneecap. A protractor-like device called a goniometer will be used to measure your Q-angle to the nearest degree. The waist/hip ratio is a simple ratio between waist and hip size, and will be obtained with a standard tape measure.

After these static measures have been taken, you will be asked to complete a simple 5-10 minute warm-up program consisting of riding a stationary bicycle for 5 minutes and lower extremity stretching exercises to prepare for the LESS test. To perform the LESS test, you will stand on a 1-foot high box, jump forward a distance of one-half of your body height, and land on both feet. Immediately after landing, you will perform a maximum vertical jump and then land again on both feet. The LESS Test protocol requires that you perform 3 trials, each of which will be recorded on video for scoring at a later date.

What are the benefits of being in the study?

There are minimal benefits associated with participation in this study. However, you will learn about your current body mass index, as well as other clinical orthopedic information about your lower extremity and your drop landing biomechanics. Your data will also help

us to learn more about the factors that predispose physically-active persons to patellar tendinopathy.

What are the risks of being in this study?

There are no significant risks associated with being a participant in this study. Nearly all the data being obtained do not involve any physical activity on your part. The LESS test—the only dynamic physical activity associated with this study—is actually a lower extremity injury screening tool. The risk of injury while performing the 3 LESS test trials is very low, but do include lower extremity muscle strain, and/or muscle and joint soreness the day after performance of the LESS tests.

What if you are hurt in this study?

Please be advised that medical treatment is available upon the event of physical injury resulting from the study. Medical treatment will be limited to first aid and ice. In the event that you sustain an injury needing medical treatment beyond that of first aid and ice, you will need to seek appropriate medical attention. We will report any adverse events per institutional policy. In the event that you believe you have suffered injury not apparent immediately after testing, please contact the IRB chairperson Dr. Jon Lasser at 512-245-3413, who will review the matter with you and identify any other resources that may be available to you.

Will you be compensated/helped for being in this study?

You will receive a \$15 HEB gift card if you complete all aspects of this study during your one visit to our research laboratory. In addition to being compensated for your time in the study, you will learn more about your knee anatomy and biomechanics, and how it might impact your risk of future orthopedic injury.

Who funds the study?

The study will most likely be funded by a \$500 grant from Texas State University's College of Education Graduate Student Research Grant program.

Who will see your information?

Your participation in this study is confidential. Only the investigators will have access to your personal identifiers and to any information that may be linked with your identity. All information that you provide will be assigned an identification number rather than your name to ensure your confidentiality. All coded data will be stored in a locked filing cabinet in Texas State University's Biomechanics/Sports Medicine Laboratory for up to 3 years following the conclusion of this study before being destroyed. In the event of this study being published, none of your personal identifying information will be disclosed.

If you want to know about the results before the study is done:

We cannot disclose any information about your results to you until the end of the study, after all results have been analyzed. At that point, we will be happy to discuss and interpret your individual clinical findings, and the overall results of this study with you.

Right to ask questions:

You may ask questions about the research procedures at any time and will receive immediate responses. If you have any further questions, please direct these to T. Colin Reisler (Graduate Student Researcher) at tcr37@txstate.edu or Dr. Rod Harter (Professor/Thesis Supervisor) at rh56@txstate.edu.

Voluntary Participation

Your participation in this study is completely voluntary. You may withdraw from this study at any time without any negative consequences from anyone associated with this study.

What if you have concerns about a study?

This project (Insert IRB #) was approved by the Texas State University IRB on (Insert IRB approval date). Pertinent questions or concerns about the research, research participants' rights, and/or research-related injuries to participants should be directed to the IRB chair, Dr. Jon Lasser (512-245-3413 - lasser@txstate.edu) and to Becky Northcut, Director, Research Integrity & Compliance (512-245-2314 - bnorthcut@txstate.edu).

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you understand the information given to you about the study and in this form. If you sign the form, it means that you agree to participate in the study.

You have been given an opportunity to ask any questions that you may have and all have been answered to your satisfaction.

You must be 18 years of age or older to consent to this study. If you consent to participate in this study and to the above state terms, please sign your name and date below.

You will be given a copy of this consent form for your records.

The second secon	·
Participant Name (please print in all caps)	
Participant Signature	Date
I, the undersigned, verify that the above info followed.	ormed consent procedure has been
Investigator Signature	Date

IRB RESEARCH APPROVAL



Institutional Review Board Application

Certificate of Approval

Applicant: Timothy Reisler

Application Number: 2015X6665

Project Title: Analysis of Patellar Tendinopathy risk factors among intercollegiate athletes

Date of Approval: 02/01/16 15:50:58

Expiration Date: 01/31/17

Assistant Vice President for Research

and Federal Relations

Chair, Institutional Review Board

Participant Screening

1.	Are you between 18 and 35 years old? Yes No
2.	Are you an NCAA athlete? Yes No
3.	Do you have anterior knee pain that gets worse with activity? Yes No
4.	Have you had this pain for > 3 months? Yes No
	Have you had an ACL reconstruction surgery that used a patellar tendon graft?

VICTORIAN INSTITUTE OF SPORT

1.	For how many minutes can you sit pain free?				
0 mins		100 mins	Points		
	0 1	2 3 4 5 6 7 8 9 10			
2.	Do you	u have pain walking downstairs with a normal gait cy	cle?		
strong severe pain	0 1	2 3 4 5 6 7 8 9 10	Points		
3.	Do you	u have pain at the knee with full active non-weightbe	aring knee extension?		
strong severe pain	0 1	2 3 4 5 6 7 8 9 10	Points		
4. Do <u>:</u>	you hav	e pain when doing a full weight bearing lunge?			
strong severe pain		1 2 3 4 5 6 7 8 9 10	Points		
5. Do :	you hav	e problems squatting?			
Unable			Points		
	severe	re pain during or immediately after doing 10 single leg	g hops? Points □		
	-	rrently undertaking sport or other physical activity?			
0		Not at all			
4		Modified training ± modified competition	vilson avmentoma k		
7 10	o o	Full training ± competition but not at same level as v Competing at the same or higher level as when symp			
10		Competing at the same of higher level as when symp	noms began		

• If yo	• If you have no pain while undertaking sport please complete Q8a only.						
• If you have pain while undertaking sport but it does not stop you from completing the activity, please complete Q8b only.							
\bullet If you have pain that stops you from completing sporting activities, please complete Q8c only.							
8a. If you have no pain while undertaking sport, for how long can you train/practise?							
	NIL	1-5 mins	6-10 mins	7-15 mins	>15 mins		
						Points	
	0	7	14	21	30		
OR							
8b . If you have some pain while undertaking sport, but it does not stop you from completing your training/practice for how long can you train/practise?							
	NIL	1-5 mins	6-10 mins	7-15 mins	>15 mins		
	О						
	0	4	10	14	20	Points	
OR							
8c. If you have pain which stops you from completing your training/practice for how long can you train/practise?							
	NIL	1-5 mins	6-10 mins	7-15 mins	>15 mins		
	0	2	5	7	10	Points	
TOTAL VISA SCORE							

8. Please complete **EITHER A, B or C** in this question.

Review of Literature

Introduction

Patellar tendinopathy (PT) is an injury with high prevalence among active populations.¹ About one-third of all injuries treated in outpatient sports clinics involve the knee.² Of these, PT is the most commonly treated disorder.² The prevalence of patellar tendinopathy in sports requiring repetitive jumping activities such as volleyball and basketball is as high as 40% to 50% ^{3,4,5}

Anatomy/histology of tendons

Tendons are a form of connective tissue in the same subcategory as bone and ligaments that is known as "dense, parallel-fibered connective tissues." The function of all tendons is the same: to attach muscle to bone. Tendons can be divided into 3 sections: the muscle-tendon junction (MTJ), the bone-tendon junction (BTJ), and the tendon midsubstance. Microscopically, collagen is the major load-bearing component of tendon.

Throughout the body, many different types of collagen can be found. Within tendons, 95% of the collagen is typically type I and the remaining 5% is primarily type III.⁸ For collagen to be able to bear any load, it must be cross-linked with other collagen fibers, and it must be organized.^{9,10} Organized collagen fibrils are arranged "head to tail" and are linked with each other. If not organized correctly, collagen loses its entire load bearing capability. Collagen fibrils can be organized into groups or bundles surrounded by loose connective tissue called a fascicle.¹¹ Fascicles are associated with individual motor units at their MTJ. Evidence suggests that this organization is not standard across all tendons, or even at all points within the same tendon, explaining why there is no universally accepted standardized tendon organization model.¹²

At rest, tendons have a microscopic wavelike appearance ("crimp") that straightens out and becomes parallel when loaded.⁶ On a load-deformation curve, this straightening of collagen fibrils occurs in the toe region as the "slack" of the tendon is taken up. Moving past the toe region, the collagen fibrils stretch as more load is applied, creating the linear region of the load-deformation curve.

The total load a tendon can withstand is dependent on its cross-sectional area, length, and composition. Typically, the higher concentration of type I collagen a tendon contains, the greater load a tendon will be able to withstand before sustaining damage. Thicker, longer tendons are able to withstand higher load before rupture than thinner, shorter tendons can. Tendon strength can also be increased by a greater number of cross-links between collagen fibrils. Tendons typically experience total mechanical failure at about 8-10% elongation from their starting length. Under normal physiological conditions, the stress on a tendon doesn't leave the linear region of the load-deformation curve.

Load-deformation curves of normal and repaired supraspinatus tendons at twelve weeks.

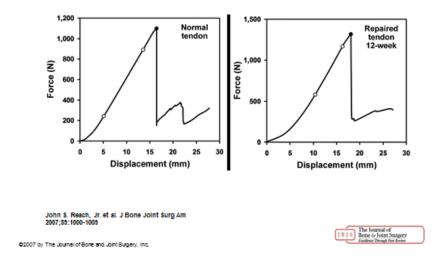


Figure 1. Load-deformation curves of normal and repaired supraspinatus tendons at 12 weeks. The tendons were tested to failure at a displacement rate of 100 mm per second. Note that the toe, linear, and yield regions of the curve for the repaired tendon are similar in morphology to those in the curve for the normal tendon. The solid black circle on each curve indicates the point taken as ultimate strength, and the open circles indicate the region from which construct stiffness was determined.

The mechanism currently believed to cause tendinopathy is a failed healing response combined with repetitive overload of the tendon. When a tendon is overloaded, collagen fibers are weakened, cross-links fail, and other normal structures are affected causing the tendon to weaken. If the damaging forces are not removed, the tendon is not allowed time to heal properly and it enters a cycle that causes tissue degeneration. The end result of this failed healing response results in a tendon that is less structured, thicker, and more prone to injury than a healthy tendon. Italian is a failed healing response results in a tendon that is less

History of Patellar Tendinopathy

Previously known as "patellar tendinitis" or "jumpers knee", there has been a movement to change the name for this condition as neither truly conveys the nature of the condition. Authors have moved away from the term "tendonitis" as it is misleading about the nature of the injury, which was previously believed to be an inflammatory condition. The lack of inflammatory cells found in tendons when examined by pathologists has rendered the "itis" suffix incorrect. This re-classification from "itis" to "opathy" is true for all tendons throughout the body, not just the patellar tendon.

Injuries previously termed "tendinitis" such as Achilles tendonitis and lateral epicondylitis, are now referred to as "tendinopathy" due to the degenerative process occurring in the tendon. ^{14,15} For injuries involving the patellar tendon specifically,

"jumpers knee" has also been a commonly used term. This terminology is also incorrect for two reasons: it is too vague, and does not include athletes not involved in jumping sports. "Jumpers knee" does not specify the tissue involved in the condition, and thus could include other conditions causing anterior knee pain. Repetitive jumping athletes are not the only ones to be diagnosed with patellar tendinopathy so "jumpers knee" is not a good descriptor of this condition.

Epidemiological Concerns

The prevalence of patellar tendinopathy among high level athletes who place their knee extensor mechanisms under repeated, violent stresses is approximately 40 to 50%. The sports that require these stresses most commonly are basketball and volleyball, but soccer and some track and field jumping events can also have a high incidence of patellar tendinopathy.

The general population has an incidence of only 10 to 15% of people involved in recreational sports.^{24,5} The difference in prevalence between competitive and recreational athletes is logical because of the difference in load placed on the knee extensor mechanism. Recreational athletes rarely stress those structures enough to cause damage, and thus are far less likely to experience patellar tendinopathy.

It is not likely that athletes diagnosed with patellar tendinopathy will be able to quickly return to pain free activity. A 2005 study found that the average length of pain and reduced function associated with patellar tendinopathy is almost three years.³ With athletes dealing with pain and dysfunction for such an extended period of time, it is no

surprise that patellar tendinopathy is the primary cause of the end of some athletic careers.¹⁵

Hypothesized Risk Factors

Though many risk factors for patellar tendinopathy have been hypothesized, there has not been any strong or moderate evidence showing a relationship. Hypothesized risk factors include measures of strength/flexibility, sports-related factors, demographics, and anthropometric measures, none of which have shown strong evidence of being related to patellar tendinopathy. Measures of weight, BMI, waist-to-hip ratio, leg-length difference, arch height of the foot, quadriceps and hamstring flexibility, quadriceps strength, and vertical jump performance all showed some potential association with patellar tendinopathy, but all evidence for other factors was inconclusive.

Landing Error Scoring System

The Landing Error Scoring System (LESS) is a free, public-domain field test of drop landing biomechanics. An individual begins the LESS test by standing on a box 30 cm high and performs a double leg landing on a target area designated 50% of their height away from the box. They land on the target area and immediately perform a maximal vertical jump.²⁵ Two cameras, set up in the frontal and sagittal plane, record the subject who performs 3 separate trials. The examiner later reviews the video and scores the subject on 17 different jump-landing characteristics.²⁵ A lower overall score indicates a subject with better jump-landing biomechanics.

The LESS test was developed and tested in 2009 by Padua et al and has been shown to be a valid and reliable test for lower limb drop landing biomechanics. The only way to test landing biomechanics prior to its development was through the use of 3-

dimensional motion analysis that required expensive laboratory equipment and was time consuming to perform. Primarily used to screen for deficits that may predispose an athlete to an anterior cruciate ligament (ACL) injury, it has been suggested that deficits found in the screen could be useful for predicting athletes' risk for other lower extremity injuries. We hypothesize there may be a relationship between an athlete's jump landing biomechanics and their likelihood of developing patellar tendinopathy. We believe the LESS test may be able to predict those athletes at risk for patellar tendinopathy based on their scores on the jump landing task. Poor jump landing biomechanics can be caused by muscular insufficiencies in the lower extremity kinetic chain. If an athlete has gluteal weakness or hamstring/quadriceps muscular imbalances, a greater amount of force could be translated through the patellar tendon than in an athlete with good biomechanics. This higher rate of tendon loading may predispose the athlete to patellar tendinopathy.

Quadriceps Angle

First described in 1964 by Brattström,²⁸ Q-angle is an index of the vector of pull of the knee extensor musculature and the patellar tendon.^{29,30} To measure Q-angle, a line is drawn from the middle of the tibial tubercle to the middle of the patella and from the anterior superior iliac spine (ASIS) to the middle of the patella. The angle at which the lines intersect is considered to be the Q-angle.^{31,32} Traditionally measured with the patient laying supine, Q-angle can also be measured with the patient standing. Typically, Q-angle is measured as an indicator of patellofemoral dysfunction such as patellofemoral pain syndrome (PFPS) and patellar instability.^{33,34,35} As the lateral angle of pull of the

extensor mechanism increases, the patella tracks more laterally in the trochlear groove. This mal-tracking of the patella increases pressure on the patella's articular cartilage, causing the person to be predisposed to PFPS and potential lateral patellar dislocations due to the resulting instability. 31,36

Smith et al (2008)³⁷ found that there is a high level of disagreement about both the inter-tester and intra-tester reliability for Q-angle measurements. In their systematic review of 10 articles, they found inter-tester reliability intra-class coefficient (ICC) scores from 0.20-0.70 and intra-tester reliability ICC scores from 0.22-0.75. These ranges are very broad, and demonstrate a significant lack of agreement on the reliability of the Q-angle measurement.

VISA-P

The Victorian Institute of Sport Assessment – patella (VISA-P) is a 10-point questionnaire used to quantify the severity of patellar tendinopathy. The VISA-P questionnaire assesses severity of symptoms, simple function, and ability to play sport on a 0-100 scale by asking questions about the patient's pain during certain daily activities, sport specific activities, and their ability to practice for certain lengths of time. Unlike most common pain scales such as the Visual Analog Scale (VAS) or the Numeric Rating Scale (NRS) for pain where 0 is equivalent to no pain, and 10 means extreme, severe pain, the VISA-P questionnaire is opposite. A score of 0 on the VISA-P means the patient is experiencing strong, severe, debilitating pain, and a score of 100 means they are completely pain free and totally functional. Visentini et al. (1998) demonstrated this questionnaire to be a valid and reliable test for the severity of patellar tendinopathy with good inter-tester and short-term test-retest reliability.

Patellar tendinopathy is a highly debilitating injury which, due to duration and intensity of the pain, could be the primary cause for some athletes to end their careers.^{3,15} In sports requiring repetitive, forceful knee extension such as basketball and volleyball, incidence rates can be as high as 40-50%.^{3,4,5} Despite the high incidence rates, very little is known about potential risk factors for patellar tendinopathy. Van der Worp et al¹ examined potential hypothesized sports-related factors, demographics, and anthropometric measures, none of which have shown strong evidence of being related to patellar tendinopathy.

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