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TITLE: **Development and Validation of a Cost-Effective Protocol for Objective Quantification of Muscle/Tendon Function in Chronic Tendinopathy**

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14. ABSTRACT
Purpose: This project examined the safety, efficiency, and psychometric properties of the Comprehensive Tendinopathy Assessment Protocol (CTAP)
Participants: Individuals with Achilles (n=23) or patellar tendinopathy (n=20) and healthy normal individuals (n=102) were enrolled in this study. The combined sample had a mean age of 34 years, 44% were male and 92.4% were right limb dominant.
Methods: The Kiio sensor and CTAP were used to measure muscle plantar flexor and knee extensor strength, power, and endurance in participants with and without tendinopathy. Information on symptoms and function was collected using the LEFS, VISA-P, and VISA-A. Analyses examined reliability, responsiveness, criterion, construct, and convergent validity and the impact of demographic and anthropomorphic characteristics on muscle function.
Results: The findings were strongest for CTAP measuring knee extension strength. Test-retest and inter-rater reliability were excellent on the uninvolved (ICCs=.96 & ICC=.92) and involved sides (ICC= .94 & ICC=.95). Criterion validity for knee extensor test was supported by a strong correlation between CTAP and Biodex knee extension strength measures (r=0.90). Construct validity of the knee strength measure was demonstrated by strength difference between normal subjects and those with tendinopathy on the involved side (507.7 vs 400.5, p=0.01). Construct validity was also supported by a strong correlation between involved side knee extensor strength and the VISA-P score (r=0.56, p=0.02) and a weaker correlation with the LEFS (r=0.27). Stepwise regression models examined the influence of demographic and anthropomorphic factors on non-dominant side knee extensor strength in healthy participants. These analyses found that gender, age, height, and weight explained 52% of the variance (R^2 =0. 5202, p<.0001). Because there were demographic and anthropomorphic differences between participants with and without patellar tendinopathy, an ANCOVA analysis was performed to adjust for these factors in comparing strength of healthy subjects and those with tendinopathy. After adjusting for the demographic and anthropometric characteristics, the differences between normal and tendinopathy participants in knee extensor strength on the involved side increased from (507.7 v 400.5, p=0.01) to (519.6 v 339.7, p<.0001). The psychometric properties of the CTAP measure of knee extensor power and endurance were also supported by these analyses, but the findings were less robust. The results for CTAP measuring plantar flexor strength, power and endurance were mixed.
Discussion: Findings support the reliability and validity of the CTAP for measuring knee extensor strength. The findings also indicate that demographic characteristics may influence CTAP knee extensor strength scores. Research using the CTAP protocol to compare groups may need to adjust for these factors.

15. SUBJECT TERMS
Achilles tendinopathy, patellar tendinopathy, inter-rater reliability, intra-rater reliability, criterion validity, convergent validity, construct validity.

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1. **INTRODUCTION:** This study proposed to develop and validate a Comprehensive Tendinopathy Assessment Protocol (CTAP) using the Kiio sensor to measure muscle and tendon impairments in individuals with chronic Achilles and patellar tendinopathies. The study examined the protocol's feasibility, intra-rater and inter-rater reliability. We also studied the protocol's criterion validity by examining the relationship between data collected with the Kiio sensor and data collected using a Biodex Isokinetic Dynamometer. Convergent validity was tested by examining the relationship between Kiio score and function and construct validity by comparing data collected from individuals with tendinopathy to that from normal healthy individuals. We developed regression models to examine the contribution of demographic variables to muscle function and compared healthy and tendinopathy participants after adjusting for these factors.

2. **KEYWORDS:** Achilles tendinopathy, patellar tendinopathy, inter-rater reliability, intra-rater reliability, criterion validity, convergent validity, construct validity

3. **ACCOMPLISHMENTS:**

    - **What were the major goals of the project?**

        - Aim 2 of this project was to examine the safety, efficiency, and psychometric properties of the CTAP protocol. The following tasks related to this aim will be presented in this report.
            - Task 3: Examine safety & efficiency
            - Task 4: Examine inter-rater & test-retest reliability of the CTAP
            - Task 5: Examine responsiveness of CTAP components
            - Task 6: Examine criterion validity of isometric components of the CTAP
            - Task 7: Examine construct validity of CTAP component scores
            - Task 8: Examine convergent validity of CTAP component scores
            - Task 9: Examine the relationship between CTAP component scores and anthropometric measures
            - Task 10: Determine CTAP decision algorithms

    - **What was accomplished under these goals?**

        - ***Activities during the reporting period***
            - This report addresses the University of Miami SOW beginning 9/30/2022 when Award 15W81XWH-16-1-0789 was transferred to the University of Miami.
            - Consulted with engineer multiple times concerning problems with CTAP, software, hardware and exporting CTAP data from Kiio tablet.
            - Data collection was completed on 9/30/2023.
            - Data entry was completed.
            - Data reconfigured and cleaned for analysis.
            - Data analysis was completed 12/15/2023.
            - Final report was complete 12/20/2023.

- **Methodology-Measures:**
  1. The following data was collected using the Kiio device and following the CTAP protocol for the Achilles and patellar tendons:
     - **Achilles tendinopathy** impacts plantar flexor muscle function, therefore, Achilles tendinopathy was evaluated by measuring plantar flexor strength, power and endurance.
     - **Patellar tendinopathy** impacts knee extensor muscle function, therefore, Patellar tendinopathy was evaluated by measuring knee extension strength, power and endurance.
     - **CTAP Strength: PeakForce** peak force generated on the involved and uninvolved side in N. (∑ Maximum Force achieved on each uninvolved Rep) / # Reps)
     - **CTAP Strength: Weight Adjusted** peak force divided by weight
     - **CTAP Power: TimeTo90PercentPeakForce** Time to 90% of the peak force obtained for involved and uninvolved side (s) (∑ Time to 90% of the Maximum Force achieved on each Rep) / # Reps)
     - **CTAP Endurance: EnduranceU-**Time in target range in seconds on involved and uninvolved sides
  1. A Biodex device was used to measure knee extension and plantar flexion strength, power and endurance.
  2. The following self-report instruments were used to measure symptoms, activity and activity limitations**:**
     - **Tegner:** The Tegner uses a numerical scale ranging from an activity level of 0 (indicating inability to work or participate in sports) to 10 (corresponding to participation in competitive sports, including soccer, football, and rugby at the elite level). Participants are asked to indicate current activity level as well as activity level prior to the injury. We believe that a sample drawn from this civilian population will be representative of the SMs with tendinopathy.
     - **Lower Extremity Functional Scale (LEFS)** The LEFS is a 20 item questionnaire addressing ability to perform everyday tasks. Tasks range from getting out of the bath to making sharp turns while running fast. Items are scored on a 5-point scale where 0 indicates extreme difficulty or inability to perform the activity and 4 indicates no difficulty. Item scores are totaled. Lower scores indicate greater activity limitations
     - **The Victorian Institute of Sport Assessment questionnaires for Patellar and Achilles tendon disorders (VISA-P and VISA-A).** These self-report instruments were developed to specifically assess the severity of patellar and Achilles tendinopathy in terms of stiffness, pain and function. Higher scores indicate greater severity.

- **Methodology-Participants:** Male and female healthy normal individuals and individuals with Achilles or patellar tendinopathy between the ages of 18 and 64 were enrolled in this study.
- **Methodology-Data Analysis:**
  - Descriptive statistics were calculated to characterize the participants.
  - Student's t-tests and Mann-Whitney-U statistics used to compare groups.
  - Correlations and Stepwise Regression used to examine relationships.
  - ANCOVA used to adjust for group differences.

4. ***Specific Objectives and Results***

AIM2: Examine the Safety, efficiency, and psychometric properties of the CTAP
Task 3: Calculate Descriptive Statistics: Demographic and Clinical
The whole sample had a mean age of 33.6 years and 44.3% of the sample was male and 92.4% of the sample was right limb dominant. See Table 1 for demographic and clinical characteristics of all participants and by group.

Table1: Demographic and Clinical Characteristics of Study Participants

Characteristic	Full Sample Mean (sd) Min-max N=145	Achilles Tendinopathy Mean (sd) Min-max N=23	Patellar Tendinopathy Mean (sd) Min-max N=20	Combined Normal Mean (sd) Min-max N=102
Age	33.6 (12.7) 19 - 64	46.9 (13.6) 22 - 64	38.2 (14.2) 20 - 64	29.8 (9.6) 19- 64
Height (cm)	168.1 (11.1) 124-203	168.6 (8.3) 154 - 185	174.7 (10.6) 155 - 195	166.6 (11.4) 124 - 203
Weight (kg)	75.9 (22.3) 47.5 - 194	84.8 (27.4) (56.2 -177)	80.9 (12.7) 65.4 – 107.5	72.9 (21.9) 47.5 -194.0
BMI	26.9 (8.2) 18.1-83.9	20.5 (9.0) 20.5-61.2	26.5 (3.1) 21.4 -33.9	26.4 (8.6) 18.1-83.9
LEFS	75.6 (8.9) 30-80	65.5 (11.8) 30 - 80	66.0 (11.7) 38-80	79.6 (1.5) 72-80
Achilles VISA	91.1 (18.0) 28-100	59.3 (15.9) 28-97	[redacted]	99.5 (1.4) 94-100
Patellar VISA	93.5 (14.4) 39-100	[redacted]	64.8 (16.0) 39-97	99.1 (2.3) 87- 100
Tegner Prior*	6.2 (1.5) 1 -10	5.5 (1.8) 1-9	6.7 (2.2) 3 - 10	6.3 (1.2) 3 - 10
L Leg Length	89.5 (7.6) 38 -112	89.2 (5.9) 82 - 102	91.9 (7.5) 80.0 -107	89.1 (8.0) 38.0 – 112.0
R Leg Length	89.4 (7.6) 38 -110	89.2 (6.0) 82 - 102	92.3 (7.5) 80.0 -107	88.9 (7.9) 38.0 -110.0
Gender Male Female N (%)	98 (44.3%) 123 (55.7%)	10 (43.5%) 9 (56.5%)	14 (70.0%) 6 (30.0%)	38 (37.2%) 64 (62.8%)
Footedness Right Left N (%)	134 (92.4%) 11 (07.6%)	22 (95.6%) 01(04.4%)	19 (95.0%) 01 (05.0%)	93 (91.2%) 09 (08.8%)

Task 3: Calculate Descriptive Statistics: Muscle function

Table 2: Presents plantar flexor and knee extensor strength, power and endurance for the whole sample and for the Normal, Achilles Tendinopathy and Patellar Tendinopathy groups. Strength was measured as the peak force generated in Newtons. Power was measured as the time in seconds required achieve 90% of the peak force. Endurance was measured as the time in seconds force was generated within the target range.

Table 2: Strength, Power and Endurance of Study Participants by Group

Characteristic	Full Sample Mean (sd) Min-max N=122	Achilles Tendinopathy Mean (sd) Min-max N=23	Patellar Tendinopathy Mean (sd) Min-max N=20	Combined Normal Mean (sd) Min-max N=99
Achilles Tendon Plantar Flexor Strength Uninvolved	454.6 (201.5) 42.3-1332.8	325.3 (103.1) 197.5 -544.8		484.6 (207.1) 42.3 – 1332.8
Achilles Tendon Plantar Flexor Strength Involved	431.1 (167.8) 27.0 – 929.5	325.3 (99.4) 161.00 -506.7		455.7 (171.6) 27.0 – 929.5
Achilles Tendon Plantar Flexor Power Uninvolved	0.63 (0.35) 0.02 -1.81	0.75 (0.34) 0.2 – 1.8		0.61 (0.34) 0.02 -1.6
Achilles Tendon Plantar Flexor Power Involved	0.67 (0.43) 0.08 - 2.2	0.90 (0.48) 0.2 – 2.1		0.62 (0.40) 0.08 - 2.2
Achilles Tendon Plantar Flexor Endurance Uninvolved	127.8 (104.4) 0 -622.2	177.7 (126.3) 18.5 –622.2		116.2 (95.7) 0-574.1
Achilles Tendon Plantar Flexor Endurance Involved	131.6 (112.0) 0 -803.2	181.1 (164.6) 38.4 – 803.2		120.1 (93.3) 0 -546.2
Patellar Tendon Knee Extensor Strength Uninvolved	523.9 (247.9) 3.3 – 1989.70		472.9 (180.2) 193.6 -924.8	533.9 (258.6) 3.3 – 1989.70
Patellar Tendon Knee Extensor Strength Involved	490.1 (214.2) 3.1 – 1217.90		400.5 (147.2) 159.8 –722.7	507.7 (221.3) 3.1 – 1217.9
Patellar Tendon Knee Extensor Power Uninvolved	0.68 (0.42) 0.01 – 2.3		0.73 (0.37) 0.29 – 1.6	0.67 (0.43) 0.01 – 2.3
Patellar Tendon Knee Extensor Power Involved	0.66 (0.40) 0.01-1.9		0.71 (0.32) 0.04 – 1.4	0.65 (0.40) 0.01-1.9
Patellar Tendon Knee Extensor Endurance Uninvolved	48.2 (31.3) 0 –203.5		61.9 (44.3) 13.8 – 201.2	45.6 (27.6) 0 – 203.5
Patellar Tendon Knee Extensor Endurance Involved	48.3 (36.4) 0– 278.1		65.2 (51.3) 14.8 – 198.7	45.0 (32.0) 0 – 278.1

<u>Task 3: Examine safety & efficiency:</u> Overall, 80% of testing sessions did not report any adverse events. Only 1 normal participant reported any problems with 2 of the testing sessions. The proportion of sessions reporting problems was somewhat high for KIIO Software/Hardware than for non-KIIO equipment. Overall, 12.6% of testing sessions reported problems with KIIO Software or Hardware. The percent of sessions reporting problems ranged from 8.1% to 16.2%. Only 5.4% of the total sessions reported problems with non-KIIO equipment. **(See Table 3)**

Table 3: Adverse Events During CTAP Testing by Visit and Rater

	Visit 1 & Rater 1 N (%)	Visit 2 Rater 1 N (%)	Visit2 Rater 2 N (%)
No Adverse Event	29 (78.4%)	29 (78.4%)	31 (83.8%)
Non KIIO Equipment Problem	1 (2.7%)	4 (10.8%)	1 (2.7%)
KIIO Software/Hardware Problem	6 (16.2%)	3 (8.1%)	5 (13.5%)
Participant Problem	1 (2.7%)*	1 (2.7%)*	0 (0%)
Total	37 (100%)	37 (100%)	37 (100%)

*Problem occurred in a healthy normal Participant

<u>Task 3: Examine safety & efficiency:</u> The hypothesis that time to perform CTAP testing would be less than that for Biodex testing was not supported. CTAP testing required more time than Biodex testing for both the Achilles and Patellar tendon tests for all participants, normal participants and tendinopathy participants. **(See Table 4)**

Table 4: Time to Perform KIIO and Biodex Tests by Groups

Time	CTAP KIIO Time Mean (sd) N	Biodex Time Mean (sd) N	Biodex Time-KIIO Time Time Mean (sd) N (p-value)*
Achilles Tendon Test Whole Group	35.7 (13.75) N=24	25.6 (5.9) N=23	-14.1 (12.6) N=22 **(p<.0001)**
Achilles Tendon Test Normal Group	34.6 (18.2) N=11	22.4 (10.7) N=10	-14.9 (15.7) N=9 **(p=0.020)**
Achilles Tendon Test Tendinopathy Group	36.6 (9.1) N=13	24.9 (10.2) N=14	-13.5 (10.7) N=13 **(P=0.0006)**
Patellar Tendon Test Whole Group	34.45 (12.9) N=23	18.15 (5.3) N=20	-16.3 (12.6) N=20 **(p<.0001)**
Patellar Tendon Test Normal Group	31.6 (14.0) N=10	17.7 (6.8) N=10	-13.9 (13.8) N=10 **(P=0.01)**
Patellar Tendon Test Tendinopathy Group	37.3 (11.7) N=10	18.6 (3.7) N=10	-18.7 (11.5) N=10 **(P=0.0006)**
*Students t-test			

Task 3: Examine safety & efficiency: Satisfaction with Plantar Flexor Tests

Satisfaction was generally very good, however, there were differences between the healthy normal and tendinopathy participants in their satisfaction with some aspects of the CTAP testing protocol. There were differences between normal and tendinopathy participants in level of agreement with statements that the *"Strength test was painful"* ("strongly disagree" v "disagree", p=0.02), *"Power test was painful"* ("strongly disagree" v "disagree", p=0.01), *"Endurance test was painful"* ("strongly disagree" v "neutral", p=0.004). These findings suggest that participants with tendinopathy experienced more discomfort during testing than did the healthy normal participants. **(See Table 5)**

Table 5: Comparing Test Satisfaction of Normal and Achilles Tendinopathy Participants

	Normal Participants N=122 Median (min – max)	Achilles Tendinopathy Participants N=23 Median (min – max	p-value*
The test position instructions were easy to understand.	5 (3 -5)	5 (4-5)	P=0.70
It was easy to assume test positions.	5 (3-5)	5 (3-5)	P=0.03
Strength test position instructions were easy to understand.	5 (4 -5)	5 (2-5)	P=0.74
The strength test required a lot of effort.	4 (1 -5)	4 (2 -5)	**P=0.04**
The strength test was painful.	1 (1 -5)	2 (1-4)	**P=0.009**
The power test position instructions were easy to understand	5 (2 -5)	5 (2-5)	P=0.72
The power test required a lot of effort.	4 (1-5)	4 (2-5)	P=0.03
The power test was painful.	1 (1-5)	2 (1-5)	**P=0.006**
The endurance test position instructions were easy to understand	5 (3-5)	5 (2-5)	P=0.98
The endurance test required a lot of effort.	5 (1-5)	4 (2-5)	P=0.72
The endurance test was painful.	1 (1-5)	3 (1-5)	**P=0.002**
I was able to understand real time info on screen	5 (3-5)	5 (3- 5)	P=0.61
The visual display was clear and easy to understand	5 (3-5)	5 (1-5)	P=0.88
Verbal instructions were loud and clear	5 (4-5)	5 (3-5)	P=0.54
Response categories: 1=strongly disagree, 2=disagree, 3=neutral, 4=agree, 5=strongly agree			
*Mann-Whitney-U Statistic			

Task 3: Examine safety & efficiency: Satisfaction with Knee Extensor Tests

Satisfaction was generally very good, however, there were differences between the healthy normal and tendinopathy participants in their satisfaction with aspects of the CTAP testing protocol. There were differences between normal and tendinopathy participants in level of agreement with statements that the *"Strength test was painful"* ("strongly disagree" v "neutral", p=<.0001), *"Power test was painful"* ("strongly disagree" v "neutral", p=<.0001), *"Endurance test was painful"* ("strongly disagree" v "neutral", p=0.0007). Findings suggest participants with tendinopathy had more discomfort during testing than healthy normal participants. **(See Table 6)**

Table 6: Comparing Test Satisfaction of Normal and Patellar Tendinopathy Participants

	Normal Participants N=122 Median (min – max)	Patellar Tendinopathy Participants N=20 Median (min – max	p-value *
The test position instructions were easy to understand.	5 (3 -5)	5 (4-5)	P=0.64
It was easy to assume test positions.	5 (3-5)	5 (5-5)	P=0.12
Strength test position instructions were easy to understand.	5 (4 -5)	5 (3-5)	P=0.81
The strength test required a lot of effort.	4 (1 -5)	4.5 (1-5)	P=0.80
The strength test was painful.	1 (1 -5)	3 (1-5)	**P<.0001**
The power test position instructions were easy to understand	5 (2 -5)	5 (4-5)	P=0.64
The power test required a lot of effort.	4 (1-5)	4 (2-5)	P=0.64
The power test was painful.	1 (1-5)	3 (1-5)	**P<.0001**
The endurance test position instructions were easy to understand	5 (3-5)	5 (4-5)	P=0.87
The endurance test required a lot of effort.	5 (1-5)	5 (2-5)	P=0.50
The endurance test was painful.	1 (1-5)	3 (1-5)	**P=0.0007**
I was able to understand real time info on screen	5 (3-5)	5 (4-5)	P=0.69
The visual display was clear and easy to understand	5 (3-5)	5 (4-5)	P=0.40
Verbal instructions were loud and clear	5 (4-5)	5 (3-5)	P=0.05
Response categories: 1=strongly disagree, 2=disagree, 3=neutral, 4=agree, 5=strongly agree			
*Mann-Whitney-U Statistic			

Task 4: Examine inter-rater & test-retest reliability of the CTAP:

Inter-rater reliability was tested by having two raters administer the CTAP protocol usually but not always on the same day. Inter-rater reliability was excellent for measures of knee extensor strength for both the involved and uninvolved extremities. However, inter-rater reliability for the knee extensor power and endurance measures was moderate to poor. Inter-rater reliability was good to moderate for plantar flexor strength, power and endurance measures.

Test-retest reliability was examined by having the same rater administer the CTAP protocol on two different days. It therefore represents both intra-rater and test-retest reliability. Test-retest reliability was excellent for knee extensor strength on both sides and good to excellent for plantar flexor strength on both sides. Test-retest reliability was good excellent for knee extensor power and endurance. Test-retest reliability was good to poor for plantar flexor power and endurance. **(See Table 7)** The fact that test-retest reliability was stronger than inter-rater reliability suggests that the raters may have been the larger source of error.

Table 7: Inter-rater and Test-Retest Reliability of the Strength, Power, and Endurance Measures

Measure	**Inter-Rater ICC (95% CI)**	**Test-Retest ICC (95% CI)**
Achilles Tendon Plantar Flexor Strength Uninvolved	.736 (.496 -.863)	.900 (.796-.951)
Achilles Tendon Plantar Flexor Strength Involved *	.615 (.264 - .799)	.822 (.638 - .913)
Achilles Tendon Plantar Flexor Power Uninvolved *	.510 (.062 -.745)	.681 (.351 - .844)
Achilles Tendon Plantar Flexor Power Involved *	.653 (.337 -.819)	.752 (.495 - .878)
Achilles Tendon Plantar Flexor Endurance Uninvolved	.832 (.702-.909)	.436 (.112 - .677)
Achilles Tendon Plantar Flexor Endurance Involved	.734 (.546 – .852)	.771 (.584 - .881)
Patellar Tendon Knee Extensor Strength Uninvolved	.921 (.831 -.963)	.959 (.909-.981)
Patellar Tendon Knee Extensor Strength Involved *	.951 (.896- .977)	.942 (.871 - .974)
Patellar Tendon Knee Extensor Power Uninvolved *	.270 (-.562 - .661)	.744 (.435 - .885)
Patellar Tendon Knee Extensor Power Involved *	.490 (-.091 - .763)	.887 (.751 - .949)
Patellar Tendon Knee Extensor Endurance Uninvolved	.331 (-.037 - .621)	.874 (.741 - .941)
Patellar Tendon Knee Extensor Endurance Involved	.636 (.354 - .812)	.922 (.836 - .964)

- ICC calculated based on the mean of 3 trials
- ICC < 0.5 = poor reliability
- ICC 0.5 to 0.75=moderate reliability
- ICC 0.76 to 0.9=good reliability
- ICC > 0.9=excellent reliability

Task 5: Examine responsiveness of CTAP components
The Standard Error of Measurement (SEM) and Minimal Detectable Difference were calculated based on ICCs for test-retest reliability and standard deviations for the muscle function measures for participants in the reliability studies. In spite of good test-retest reliability for some measures, the high level of variability in the data produced relatively large SEMs and MDDs indicating that large changes in muscle function would be required to exceed variability.
(See Table 8)

Table 8: Responsiveness of CTAP Components

Measure	Test-Retest Reliability ICC	Mean (SD) N	SEM	MDD
Achilles Tendon Plantar Flexor Strength Uninvolved	.900	364.37 (102.0) 32	32.23	89.34
Achilles Tendon Plantar Flexor Strength Involved *	.822	363.67 (101.85) 32	43.18	119.61
Achilles Tendon Plantar Flexor Power Uninvolved *	.681	0.87 (0.32) 32	0.18	0.50
Achilles Tendon Plantar Flexor Power Involved *	.752	0.88 (0.45) 32	0.22	0.61
Achilles Tendon Plantar Flexor Endurance Uninvolved	.436	180.21 (100.90) 32	75.78	209.91
Achilles Tendon Plantar Flexor Endurance Involved	.771	182.38 (128.32) 32	61.40	107.08
Patellar Tendon Knee Extensor Strength Uninvolved	.959	450.04 (143.03) 26	28.89	80.03
Patellar Tendon Knee Extensor Strength Involved *	.942	409.28 (125.89) 26	30.84	85.43
Patellar Tendon Knee Extensor Power Uninvolved *	.744	0.93 (0.38) 26	0.19	0.53
Patellar Tendon Knee Extensor Power Involved *	.887	0.88 (0.42) 26	0.14	0.39
Patellar Tendon Knee Extensor Endurance Uninvolved	.874	55.83 (36.18) 26	12.84	35.57
Patellar Tendon Knee Extensor Endurance Involved	.922	58.14 (35.50) 26	9.9	27.42

Task 6: Examine criterion validity of isometric components of the CTAP: Correlation between CTAP and Biodex measures.

As hypothesized, there was a strong correlation between Biodex and CTAP scores for knee extension strength, and a moderate correlation for knee extensor power and plantar flexor strength. However, the correlation for knee extensor endurance was weak and the correlations for plantar flexor power and endurance were non-existent. It is possible that the weaker correlations for endurance may reflect differences between the CTAP and Biodex conceptualization of endurance. (**See Table 9)**

Table 9: Relationship Between KIIO CTAP and Biodex Measures		
	Achilles Tendon Plantar Flexors	Patellar Tendon Knee Extensors
Strength	R=0.40 **P=0.04** N=27	R=0.90 **P<.0001** N=38
Power	R=0.14 P=0.48 N=27	R=0.54 **P=0.006** N=24
Endurance Time	R=0.17 P=0.43 N=24	R=0.37 P=0.08 N=23
Spearman Correlation		
R=0.0 to 0.19=no correlation (cells colored white)		
R=0.20 to 0.39 =weak correlation (cells colored light red)		
0.4 to 0.59=moderate. (cells colored light blue)		
0.60 to 1.0=strong (cells colored light green)		
p-values bolded are <0.05		

Task 7: Examine construct validity of CTAP Achilles Protocol component scores: Comparing Normal and Tendinopathy Participants

As expected, the plantar flexor strength of participants with tendinopathy was much less than that of the normal participants on both the involved and uninvolved sides and these differences were statistically significant. Plantar flexor power was measured as *"Time to 90% of the peak force"*. Therefore, longer times indicated lower power. On both the uninvolved and involved sides, the time to 90% peak force was longer for the tendinopathy participants than for the normal group. However, the difference was greater on the involved side. Plantar flexion Endurance was measured as *"Time in target range".* Unexpectedly, the Achilles tendinopathy participants had a longer time in target" than the normal participants. This could be associated with a lower target range in the tendinopathy group. **(See Table 10)**

Table 10: Comparing Plantar Flexor Strength, Power and Endurance of Achilles Tendinopathy and Normal Participants			
Characteristic	Achilles Tendinopathy Mean (sd) Min-max N=23	Combined Normal Mean (sd) Min-max N=102	p-value*
Plantar Flexor Strength Uninvolved	325.3 (103.1) 197.5 -544.8	484.6 (207.1) 42.3 – 1332.8	**p<.0001**
Plantar Flexor Strength Involved	325.3 (99.4) 161.00 -506.7	455.7 (171.6) 27.0 – 929.5	**p<.0001**
Weight Adjusted Plantar Flexor Strength Uninvolved	4.0 (1.3) 1.9-7.2	6.8 (2.5) 0.43-16.4	**<.0001**
Weight Adjusted Plantar Flexor Strength Involved	4.0 (1.2) 2.1-6.95	6.4 (2.1) 0.24-11.3	**<.0001**
Plantar Flexor Power Uninvolved	0.75 (0.34) 0.2 – 1.8	0.61 (0.34) 0.02 -1.6	P=0.07
Plantar Flexor Power Involved	0.90 (0.48) 0.2 – 2.1	0.62 (0.40) 0.08 – 2.2	**P=0.003**
Plantar Flexor Endurance Uninvolved	177.7 (126.3) 18.5 –622.2	116.2 (95.7) 0-574.1	**P=0.01**
Plantar Flexor Endurance Involved	181.1 (164.6) 38.4 – 803.2	120.1 (93.3) 0 -546.2	P=0.09
*Student's t-test			

Task 7: Examine construct validity of CTAP Patellar Protocol component scores: Comparing Normal and Tendinopathy Participants

As expected, the knee extensor strength of participants with tendinopathy was less than that of the normal participants on the involved side. Knee extensor power was measured as *"Time to 90% of the peak force"*. Knee extension power was less for the participants with tendinopathy than for normal participants on both the involved and uninvolved sides but the differences were not statistically significant. Similar to the findings for the CTAP Achilles protocol, the patellar tendinopathy participants had a longer time in target" than the normal participants. Again, this could be due to the lower target range in the tendinopathy group. **(See Table 11)**

Table 11: Comparing Knee Extensor Strength, Power and Endurance of Patellar Tendinopathy and Normal Participants

Characteristic	Patellar Tendinopathy Mean (sd) Min-max N=20	Combined Normal Mean (sd) Min-max N=102	p-value
Knee Extensor Strength Uninvolved	472.9 (180.2) 193.6 -924.8	533.9 (258.6) 3.3 – 1989.70	P=0.32
Knee Extensor Strength Involved	400.5 (147.2) 159.8 –722.7	507.7 (221.3) 3.1 – 1217.9	**P=0.01**
Weight Adjusted Knee Extensor Strength Uninvolved	5.9 (2.4) 2.8-13.2	7.4 (3.2) 0.06-24.4	**P =0.04**
Weight Adjusted Knee Extensor Strength Involved	4.9 (1.5) 2.0-7.7	7.0 (2.5) 0.05-13.6	**P <.0001**
Knee Extensor Power Uninvolved	0.73 (0.37) 0.29 – 1.6	0.67 (0.43) 0.01 – 2.3	P=0.56
Knee Extensor Power Involved	0.71 (0.32) 0.04 – 1.4	0.65 (0.40) 0.01-1.9	P=0.55
Knee Extensor Endurance Uninvolved	61.9 (44.3) 13.8 – 201.2	45.6 (27.6) 0 – 203.5	P=0.12
Knee Extensor Endurance Involved	65.2 (51.3) 14.8 – 198.7	45.0 (32.0) 0 – 278.1	P=0.10
*Student's t-test			

Task 7: Examine construct validity of CTAP Patellar Protocol component scores: Comparing Uninvolved and Involved Sides.

Since we calculated the difference by subtracting the score from the involved side from the score for the uninvolved side, we expected to have large positive mean values. This was only true for knee extensor strength. The difference for knee extensor power was very small and the difference of knee extensor endurance was negative. The differences for plantar flexor strength and endurance were very small or negative. Unexpectedly, there was a statistically significant, negative difference for plantar flexor power suggesting that power was greater for the involved leg. **(See Table 12)**

Table 12: Strength Power and Endurance Difference between Uninvolved and Involved Sides by Group.

	Achilles Tendinopathy (N=23) Mean (sd) p-value*	Patellar Tendinopathy (N=20) Mean (sd) p-value*
Plantar Flexor Strength	0.05 (33.5) P=0.99	
Plantar Flexor Power	-0.15 (0.32) P=0.03	
Plantar Flexor Endurance	-3.45 (98.7) P=0.86	
Knee Extensor Strength		72.4 (165.7) P=0.06
Knee Extensor Power		0.02 (0.31) P=0.77
Knee Extensor Endurance		-3.3 (31.2) P=0.64
Difference calculated as Uninvolved -Involved.		
*paired t-test		

Task 8: Examine convergent validity of Achilles Protocol CTAP component scores: Relationship to Activity Limitation Measure.

Hypothesis 2f: In participants with tendinopathy, the component scores of the CTAP will demonstrate moderate to strong correlation to scores on the LEFS. There was a moderate correlation between the LEFS score and weight adjusted plantar flexor strength on both the involved and uninvolved sides plantar flexor power on the un-involved side. There was also a moderate correlation between the VISA-Achilles score and weight adjusted plantar flexor strength on both the involved and uninvolved sides and plantar flexor power on the un-involved side. **(See Table 13)**

Table 13: The Relationship between Function and Plantar Flexor Strength, Power, and Endurance N=23			
Characteristic	LEFS	VISA-Achilles	Current Tegnar
Plantar Flexor Strength Uninvolved	r=0.07 p=0.77	r=-0.05 p=0.82	r=0.02 p=0.91
Plantar Flexor Strength Involved	r=0.01 p=0.98	r=-0.05 p=0.003	r=0.04 p=0.87
Weight Adjusted Plantar Flexor Strength Uninvolved	r=0.34 p=0.13	r=0.32 p=0.13	r=0.18 p=0.43
Weight Adjusted Plantar Flexor Strength Involved	r=0.30 p=0.18	r=0.34 p=0.11	r=0.16 p=0.49
Plantar Flexor Power Uninvolved	r=0.37 p=0.10	r=0.20 p=0.35	r=-0.02 p=0.92
Plantar Flexor Power Involved	r=-0.11 p=0.62	r=-0.15 p=0.51	r=0.18 p=0.42
Plantar Flexor Endurance Uninvolved	r=-0.02 p=0.94	r=0.04 p=0.85	r=0.16 p=0.47
Plantar Flexor Endurance Involved	r=0.16 p=0.48	r=0.15 p=0.63	r=0.12 p=0.60
R=0.0 to 0.19=no correlation (cells colored white)			
R=0.20 to 0.39 =weak correlation (cells colored light red)			
0.4 to 0.59=moderate. (cells colored light blue)			
0.60 o 1.0=strong (cells colored light green)			
*Spearman Correlation**, p-values bolded are <0.05**			

Task 8: Examine convergent validity of Patellar Protocol CTAP component scores Relationship to Activity Limitation Measure.

As expected, correlations between the activity limitation measures and muscle function measures were much stronger on the involved side. Involved side knee extension strength was moderately correlated with VISA-P (r=0.56). The LEFS was moderately correlated with knee extension power (r=0.60) and knee extension endurance (r=0.52). These relationships support the validity of the CTAP knee extension measures. **(See Table 14).**

Table 14: The Relationship between Function and Knee Extension Strength, Power and Endurance n=20

Characteristic	LEFS	VISA-Patellar	Current Tegnar
Knee Extension Strength Uninvolved	r=0.10 p=0.72	r=0.17 p=0.52	r=0.15 p=0.58
Knee Extension Strength Involved	r=0.27 p=0.32	r=0.56 **p=0.02**	r=0.38 p=0.14
Weight Adjusted Knee Extension Strength Uninvolved	r=0.14 p=0.61	r=0.13 p=0.61	r=0.05 p=0.85
Weight Adjusted Knee Extension Strength Involved	r=0.31 p=0.25	r=0.55 **p=0.02**	r=0.31 p=0.25
Knee Extension Power Uninvolved	r=0.27 p=0.31	r=0.13 p=0.61	r=-0.29 p=0.28
Knee Extension Power Involved	r=0.60 **p=0.01**	r=0.34 p=0.18	r=0.11 p=0.68
Knee Extension Endurance Uninvolved	r=0.49 p=0.05	r=0.28 p=0.28	r=0.18 p=0.51
Knee Extension Endurance Involved	r=0.52 **p=0.04**	r=0.33 p=0.20	r=0.14 p=0.61
R=0.0 to 0.19=no correlation (cells colored white)			
R=0.20 to 0.39 =weak correlation (cells colored light red)			
0.4 to 0.59=moderate. (cells colored light blue)			
0.60 to 1.0=strong (cells colored light green)			
*Spearman Correlation**, p-values bolded are <0.05**			

AIM3: Develop empirical guidelines for interpreting the clinical data produced by the CTAP to guide the clinical management of patients with Achilles or patellar tendinopathy

Task 9: Examine factors that influence CTAP component scores in healthy individuals: Differences in demographic and clinical characteristics between individuals with and without Achilles tendinopathy.

To fully understand the influence of anthropometric measures on muscle function differences between individuals with and without tendinopathy, we needed to examine the demographic and anthropometric differences between these groups. On average, participants with Achilles Tendinopathy were older and weighed more than healthy normal participants. As expected, participants with tendinopathy had lower LEFS and VISA-A scores than normal participants.

Table 15: Comparing Demographic and Clinical Characteristics of Achilles Tendinopathy and Normal Participants

Characteristic	Achilles Tendinopathy Mean (sd) Min-max N=23	Combined Normal Mean (sd) Min-max N=102	p-value*
Age	46.9 (13.6) 22 – 64	29.7 (9.6) 19- 64	**P <.0001**
Height (cm)	168.6 (8.3) 154 – 185	166.6 (11.4) 124-203	P=0.42
Weight (kg)	84.8 (27,4) (56.2 -177)	72.9 (21.9) 47.5 -194.0	**P=0.03**
BMI	29.7 (9.0) 20.5-61.2	26.4 (8.6) 18.1-35.6	P=0.10
L Leg Length (cm)	89.2 (5.9) 82- 102	89.1 (8.0) 38.0 – 112.0	P=0.94
R Leg Length (cm)	89.2 (6.0) 82- 102	88.9 (7.9) 38.0 -110	P=0.87
Gender Male (N/%) Female (N/%)	 10 (43.5%) 9 (56.5%)	 38 (37.2%) 64 (62.8%)	P=0.58
Dominant Leg Right (N/%) Left (N/%)	 22 (95.6%) 01(04.4%)	 93 (91.2%) 09 (08.8%)	P=0.48
LEFS	65.5 (11.8) 30 – 80	79.6 (1.5) 72-80	**P <.0001**
Achilles VISA	59.3 (15.9) 28-97	99.5 (1.4) 94-100	**P <.0001**

*Student's t-test

Task 9: Examine factors that influence CTAP component scores in healthy individuals: Differences in demographic and clinical characteristics between individuals with and without patellar tendinopathy.

On average, participants with patellar tendinopathy were older, taller, weighed more and were more likely to be male than the healthy normal participants. As expected, participants with tendinopathy had lower LEFS and VISA-A scores than normal participants. **(See Table 16)**

Table 16: Comparing Demographic and Clinical Characteristics of Patellar Tendinopathy and Normal Participants

Characteristic	Patellar Tendinopathy Mean (sd) Min-max N=20	Combined Normal Mean (sd) Min-max N=102	p-value*
Age	38.2 (14.2) 20 – 64	29.7 (9.6) 19- 64	**P=0.02**
Height	174.7 (10.6) 155 – 195	166.6 (11.4) 124-203	**P=0.004**
Weight	80.9 (12.7) 65.4 – 107.5	72.9 (21.9) 47.5 -194.0	**P=0.03**
BMI	26.5 (3.1) 21.4 -33.9	26.4 (8.6) 18.1-35.6	P=0.94
L Leg Length	91.9 (7.5) 80.0 -107	89.1 (8.0) 38.0 – 112.0	P=0.14
R Leg Length	92.3 (7.5) 80.0 -107	88.9 (7.9) 38.0 -110	P=0.08
Gender Male (N/%) Female (N/%)	 14 (70.0%) 6 (30.0%)	 38 (37.2%) 64 (62.8%)	**P=0.007**
Dominant Leg Right (N/%) Left (N/%)	 19 (95.0%) 01 (05.0%)	 93 (91.2%) 09 (08.8%)	P=0.57
LEFS	66.0 (11.7) 38-80	79.6 (1.5) 72-80	**P=0.0003**
VISA Patellar	64.8 (16.0) 39-97	99.1 (2.3) 87- 100	**P<.0001**

*Students t-test

Task 9: Examine the relationship between CTAP Plantar Flexor component scores and anthropometric measures: Relationships among scores in Normal Participants

There was a weak correlation between plantar flexion strength and age, height, and weight. There was also a weak correlation between plantar flexor power and height, weight and BMI. **(See Table 17).**

Table 17: The Relationship between Demographic Characteristics and Plantar Flexor Strength, Power and Endurance in Normal Participants N=99						
Characteristic	Plantar Flexor Strength Dominant	Plantar Flexor Strength Non-Dominant	Plantar Flexor Power Dominant	Plantar Flexor Power Non-Dominant	Plantar Flexor Endurance Dominant	Plantar Flexor Endurance Non-Dominant
Age	r=-0.26 **p=0.01**	r=-0.30 **p=0.003**	r=0.19 p=0.07	r=0.13 p=0.19	r=0.08 p=0.43	r=0.17 p=0.09
Height	r=0.32 **p=0.001**	r=0.29 **p=0.003**	r=-0.02 p=0.81	r=0.08 p=0.42	r=-0.20 **p=0.047**	r=-0.21 **p=0.03**
Weight	r=0.22 **p=0.03**	r=0.23 **p=0.03**	r=0.04 p=0.72	r=-0.02 p=0.86	r=-0.30 **p=0.002**	r=-0.31 **p=0.002**
BMI	r=0.06 p=0.53	r=0.09 p=0.37	r=0.02 p=0.82	r=-0.03 p=0.80	r=-0.21 p=0.03	r=-0.20 **p=0.04**
L Leg Length	r=0.19 p=0.07	r=0.18 p=0.07	r=0.03 p=0.80	r=0.06 p=0.55	r=-0.11 p=0.27	r=0.08 p=0.44
R Leg Length	r=0.18 p=0.08	r=0.17 p=0.09	r=0.02 p=0.85	r=0.08 p=0.44	r=0.02 p=0.81	r=0.01 p=0.93
Achilles Tendon function =Plantar flexor strength, power & endurance						
R=0.0 to 0.19=no correlation (cells colored white)						
R=0.20 to 0.39 =weak correlation (cells colored light red)						
0.4 to 0.59=moderate. (cells colored light blue)						
0.60 to 1.0=strong (cells colored light green)						
Pearson Correlation, **p-values bolded are <0.05**						

Task 9: Examine the relationship between CTAP knee extensor component scores and anthropometric measures

There was a moderate correlation between knee extensor strength and height on both the involved and uninvolved sides. There were weak correlations between knee extensor strength and age, weight, and leg length. Knee extensor endurance was weakly correlated age, and weight. **(See Table 18).**

Table 18: The Relationship between Demographic Characteristics and Knee Extensor Strength, Power and Endurance in Normal Participants n=102

Characteristic	Knee Extensor Strength Dominant	Knee Extensor Strength Non-Dominant	Knee Extensor Power Dominant	Knee Extensor Power Non-Dominant	Knee Extensor Endurance Dominant	Knee Extensor Endurance Non-Dominant
Age	r=-0.17 p=0.09	r=-0.27 **p=0.005**	r=0.12 p=0.23	r=0.05 p=0.59	r=0.22 **p=0.03**	r=0.22 **p=0.02**
Height	r=0.44 **p<0.0001**	r=0.53 **p<0.0001**	r=0.13 p=0.21	r=0.13 p=0.20	r=-0.01 p=0.89	r=-0.08 p=0.41
Weight	r=0.28 **p=0.005**	r=0.36 **p=0.0002**	r=-0.08 p=0.44	r=0.01 p=0.93	r=-0.14 p=0.17	r=-0.20 **p=0.046**
BMI	r=0.05 p=0.60	r=0.08 p=0.39	r=-0.13 p=0.21	r=-0.04 p=0.66	r=-0.14 p=0.17	r=-0.17 p=0.10
L Leg Length	r=0.32 **p=0.0009**	r=0.32 p=0.001	r=0.10 p=0.30	r=0.09 p=0.36	r=0.02 p=0.83	r=0.007 p=0.94
R Leg Length	r=0.31 **p=0.001**	r=0.31 **p=0.002**	r=0.09 p=0.35	r=0.08 p=0.44	r=0.02 p=0.81	r=0.01 p=0.93
R=0.0 to 0.19=no correlation (cells colored white)						
R=0.20 to 0.39 =weak correlation (cells colored light red)						
0.4 to 0.59=moderate. (cells colored light blue)						
0.60 to 1.0=strong (cells colored light green)						
Pearson correlation **p-values bolded are <0.05**						

Task 9: Examine the relationship between CTAP component scores and anthropometric measures: Leg Dominance

To understand the possible influence of leg dominance on CTAP component scores we compared the dominant and non-dominant side scores. Because difference scores were calculated by subtracting the non-dominant side values from the dominant side values positive scores indicated that dominant side was stronger. The dominant side measures were greater for knee extensor strength, power and endurance. Dominant side measures were only greater for plantar flexor strength. Because there was a lot of in the difference scores, most differences were not statistically significant. **(See Table 19)**

Table 19: Strength Power and Endurance Difference between the Dominant and Non-dominant limbs	
	Normal (N=99) Mean (sd) p-value*
Plantar Flexor Strength	29.9 (112.5) **P=0.01**
Plantar Flexor Power	-0.009 (0.31) P=0.77
Plantar Flexor Endurance	-3.9 (75.0) P=0.60
Knee Extensor Strength	26.2 (175.2) P=0.13
Knee Extensor Power	0.02 (0.37) P=0.63
Knee Extensor Endurance	0.61 (16.6) P=0.71
Dominant side values greater	Non-dominant side values greater
Difference calculated as dominant-non-dominant. *Paired t-test **p-values bolded are <0.05**	

Task 9: Examine the relationship between CTAP component scores and anthropometric measures: Gender

To understand the possible influence of gender on CTAP component scores we compared the anthropomorphic characteristics and muscle function of male and female participants. Male and female participants differed on height, weight, leg length and strength measures. **(See Table 20)**

Table 20: Comparing Demographic Characteristics and Muscle Function of Male and Female Healthy Normal Participants

Characteristic	Male Participants Mean (sd) Min-max N=38	Female Participants Mean (sd) Min-max N=64	p-value*
Age	28.8 (6.6) 19 – 46	30.3 (11.0) 19- 64	P=0.37
Height (cm)	175.0 (10.3) 134 – 203	161.6 (8.8) 124-175	**P=<.0001**
Weight (kg)	83.4 (14.8) 59 -134	66.7 (23.1) 47.5 -194.0	**P=<.0001**
BMI	27.3 (5.1) 20.2-47.9	25.8 (10.2) 18.1-83.9	P=0.31
L Leg Length (cm)	92.6 (10.8) 38- 112	87.0 (4.6) 75-100	**P=0.005**
R Leg Length (cm)	92.4 (10.7) 38- 110	86.9 (4.8) 75-101	**P=0.005**
Plantar Flexor Strength Dominant	591.8 (268.4) 42.3-1332	420.6 (123.6) 168.9-697	**P=0.007**
Plantar Flexor Strength Non-Dominant	547.4 (198.0) 27.0-929.5	400.9 (123.5) 152.3-765.8	**P=0.002**
Plantar Flexor Power Dominant	0.64 (0.35) 0.02-1.5	0.59 (0.34) 0.10-1.60	P=0.46
Plantar Flexor Power Non-Dominant	0.68 (0.45) 0.18-2.2	0.58 (0.36) 0.08-2.0	P=0.25
Plantar Flexor Endurance Dominant	83.1(57.0) 0.04 -241.9	135.9 (108.4) 0-574.1	**P=0.002**
Plantar Flexor Endurance Non-Dominant	78.7 (45.5) 0 -198	144.8 (105.4) 0-546.1	**P=<.0001**
Knee Extension Strength Dominant	712.7 (286.7) 257.8-1989.7	427.8 (168.1) 3.3-1093.4	**P=<.0001**
Knee Extension Strength Non-Dominant	685.9 (218.2) 232.9-1217.4	401.9 (141.5) 3.1-747.4	**P=<.0001**
Knee Extension Power Dominant	0.78 (0.50) 0.04-2.3	0.61 (0.37) 0.01-1.81	P=0.07
Knee Extension Power Non-Dominant	0.80 (0.46) 0.05-1.9	0.57 (0.37) 0.01-1.69	**P=0.009**
Knee Extension Endurance Dominant	42.5 (24.4) 0.35 -137.1	47.4 (29.4) 0-203.5	P=0.39
Knee Extension Endurance Non-Dominant	38.7 (18.5) 1.08 -102.2	48.7 (37.5) 0-278.1	P=0.08
*Students t-test			

Task 9: Examine factors that influence CTAP component scores in healthy individuals: Model Predicting Dominant Side Plantar Flexor Strength (See Table 21)

To examine the combined influence of demographic and anthropomorphic measures on muscle function we used stepwise linear regression. In the model predicting dominant side plantar flexor strength, gender was the first variable entered into the model followed by age, height, and weight. Tolerance values demonstrated no problem with collinearity. The final model was statistically significant ($p<.0001$) explained 29% of the variance ($R^2=0.2931$) in dominant side plantar flexor strength.

Table 21: Stepwise Regression Model Predicting Plantar Flexor Strength Dominant Side in Normal Participants N=98, $R^2=0.2931$, $p<.0001$, (df=97)							
Step	Variable	Parameter Estimate	R^2	Partial R^2	Tolerance	F	p-value
0	Intercept	-171.7				0.28	p=0.5995
1	Gender	104.04	0.1968	0.1968	0.6222	5.03	p=0.0273
2	Age	-5.12	0.2398	0.0430	0.9634	7.64	p=0.0069
3	Height	4.05	0.2754	0.0345	0.6730	4.08	p=0.0463
4	Weight	1.37	0.2931	0.0187	0.8591	2.46	p=0.1200
Candidate variables for stepwise regression: gender coded 1=male 2=female, age (years), height (cm), weight (kg), right leg length (cm), left leg length (cm)							

Task 9: Examine factors that influence CTAP component scores in healthy individuals: Model Predicting Non-Dominant Side Plantar Flexor Strength (See Table 22)

In the model predicting non-dominant side plantar flexor strength, gender was the first variable entered into the model followed by age, weight and height. Tolerance values demonstrated no problem with collinearity. The final model was statistically significant ($p<.0001$) explained 33% of the variance ($R^2=0.3290$) in non-dominant side plantar flexor strength.

Table 22: Stepwise Regression Model Predicting Plantar Flexor Strength Non-Dominant Side in Normal Participants N=98, $R^2=0.\ 3290$, $p<.0001$, (df=97)							
Step	Variable	Parameter Estimate	R^2	Partial R^2	Tolerance	F	p-value
0	Intercept	30.74				0.01	p=0.9063
1	Gender	97.74	0.2186	0.2186	0.6222	6.95	p=0.0098
2	Age	-4.93	0.2814	0.0628	0.9634	11.08	p=0.0012
3	Weight	1.28	0.3087	0.0274	0.8591	3.35	p=0.0706
4	Height	2.68	0.3290	0.0202	0.6731	2.80	p=0.0974
Candidate variables for stepwise regression: gender coded 1=male 2=female, age (years) height (cm), weight (kg), right leg length (cm), left leg length (cm)							

Task 9: Examine factors that influence CTAP component scores in healthy individuals: Model Predicting Dominant Side Knee Extensor Strength (See Table 23)

In the model predicting dominant side knee extensor strength, gender was the first variable entered into the model followed by height and age. Tolerance values demonstrated no problem with collinearity. The final model was statistically significant (p<.0001) explained 35% of the variance (R^2 =0.3546) in dominant side knee extensor strength. (**See Table 23)**

Table 23: Stepwise Regression Model Predicting Knee Extensor Strength Dominant Side in Normal Participants N=101, R^2 =0. 3546, p<.0001, (df=100)							
Step	Variable	Parameter Estimate	R^2	Partial R^2	Tolerance	F	p-value
0	Intercept	-384.45				1.06	p=0.3047
1	Gender	212.93	0.3003	0.3003	0.6714	15.93	p=0.0001
2	Height	5.71	0.3366	0.0363	0.6763	6.15	p=0.0148
3	Age	-3.64	0.3546	0.0180	0.9831	2.71	p=0.1030
Candidate variables for stepwise regression: gender coded 1=male 2=female, age (years), height (cm), weight (kg), right leg length (cm), left leg length (cm)							

Task 9: Examine factors that influence CTAP component scores in healthy individuals: Model Predicting Non-Dominant Side Knee Extensor Strength (See Table 24)

In the model predicting non-dominant side knee extensor strength, gender was the first variable entered into the model followed by age, height and weight. Tolerance values demonstrated no problem with collinearity. The final model was statistically significant (p<.0001) explained 52% of the variance (R^2 =0.5202) in dominant side knee extensor strength. (**See Table 24)**

Table 24: Stepwise Regression Model Predicting Knee Extensor Strength Non-Dominant Side in Normal Participants N=101, R^2 =0. 5202, p<.0001, (df=100)							
Step	Variable	Parameter Estimate	R^2	Partial R^2	Tolerance	F	p-value
0	Intercept	-399.30				2.07	p=0.1531
1	Gender	176.99	0.3889	0. 3889	0.6236	18.57	p=<.0001
2	Age	-6.19	0.4393	0.0504	0.9664	13.98	p=0.0003
3	Height	5.40	0.4958	0.0565	0.6709	9.93	p=0.0022
4	Weight	1.73	0.5202	0.0244	0.8487	4.88	p=0.0295
Candidate variables for stepwise regression: gender coded 1=male 2=female, age (years) height (cm), weight (kg), right leg length (cm), left leg length (cm)							

Task 10: Determine CTAP decision algorithms: Adjusted Strength Differences between Participants with and without Tendinopathy

To examine whether the strength differences between participants with and without tendinopathy resulted from differences between groups in anthropomorphic characteristics rather than the CTAP strength measures' ability to identify tendinopathy, we used analysis of covariance (ANCOVA) to compare participants with and without tendinopathy after adjusting for age, gender, height, and weight.

For the plantar flexion measures, adjusting for age gender, height, and weight narrowed the differences in plantar flexor strength between individuals with and without tendinopathy but differences remained and were statistically significant.

For the knee extensor strength measures, adjusting for confounding factors increased differences between participants with and without tendinopathy. Adjusted values were lower for participants with tendinopathy and higher for those without. Before adjusting for the confounding variables, the difference in dominant side strength between those with and without tendinopathy was not statistically significant. After adjusting, the differences increased and were now statistically significant. **(See Table 25)**

Table 25: Unadjusted and Adjusted Comparison of the Strength of Participants with and without Tendinopathy

Strength Measure	Tendinopathy Unadjusted Mean (Standard Error) N	Normal Unadjusted Mean (Standard Error) N	p-value Unadjusted Value	Tendinopathy Adjusted Mean (Standard Error) N	Normal Adjusted Mean (Standard Error) N	p-value Adjusted Value
Plantar Flexor Strength Uninvolved	325.3 (21.49) N=22	484.6 (20.81) N=99	**p<.0001**	356.37 (41.44) N=22	477.37 (17.87) N=99	**P=0.012**
Plantar Flexor Strength Involved	325.3 (20.10) N=22	455.7 (17.24) N=99	**p<.0001**	356.54 ((34.07) N=22	448.41 (14.69) N=99	**P=0.020**
Knee Extensor Strength Uninvolved	472.9 (40.29) N=20	533.9 (25.61) N=102	P=0.32	410.40 (49.59) N=20	546.15 (20.70) N=102	**P=0.015**
Knee Extensor Strength Involved	400.5 (32.92) N=20	507.7 (21.91) N=102	**P=0.01**	339.70 (37.96)	519.58 (15.84)	**p<.0001**

Summary

Achilles Tendinopathy CTAP to Measure Plantar Flexor Muscle Function:

Reliability and Responsiveness: Reliability results were inconsistent**.** Inter-rater reliability was generally moderate for plantar flexor strength, power, and endurance measures. Only endurance on the uninvolved side had good reliability. Test re-test reliability was good to excellent for plantar flexor strength on both sides and plantar flexor endurance on the involved side. Test-retest reliability was generally better than inter-rater. Because test-retest reliability used the same rater for both test sessions, this finding suggests that variability in how the raters administered the test may have been a source of measurement error and reliability might be improved with additional standardization and training. Because of wide variability in data, the SEM and MDD were relatively large.

Criterion and Construct Validity: There was a moderate correlation between the CTAP and Biodex plantar flexor strength measures. The plantar flexor power and endurance measures were not correlated. These findings provided some evidence for the criterion validity of the CTAP plantar flexor strength measure but not for the power and endurance measures. Known groups construct validity of the CTAP plantar flexor strength measures was supported by large and statistically significant differences between participants with and without tendinopathy. There were less robust findings for plantar flexor power and endurance. The unanticipated finding of small and inconsistent differences in strength, power and endurance between the involved and uninvolved sides failed to support the construct validity of the CTAP plantar flexor measures. The unexpected finding of weak or no relationship between LEFS and VISA-A measures and plantar flexor strength, power and endurance failed to support the construct validity of these CTAP measures.

Factors Influencing Scores in Healthy Participants: Participants with and without Achilles tendinopathy differed in age and weight and both were weakly related to CTAP plantar flexor strength. These findings suggested that a combination of demographic and anthropomorphic measures may be important predictors of knee extensor strength in healthy participants. Analysis using stepwise linear regression found that a model containing gender, age height and weight predicted 29% of the variance in dominant side plantar flexor strength and 33% of the variance in non-dominant side plantar flexor strength. These findings supported a relationship between CTAP plantar flexor strength measures and demographic and anthropomorphic characteristics. This suggests that comparisons of plantar flexor strength between participants with and without tendinopathy should consider adjusting for these confounding factors.

Decision Algorithms: Adjusting for age gender, height, and weight, the differences in plantar flexor strength between individuals with and without tendinopathy narrowed somewhat but persisted and were statistically significant. The finding that the adjusted means differed from the unadjusted means supports adjusting for demographic and anthropomorphic factors in making decisions about the impact of tendinopathy on plantar flexor strength.

Conclusion: There is moderate support for the reliability and validity of the CTAP plantar flexor strength measures. There is less support for the reliability and validity of the CTAP plantar flexor power and endurance measures. CTAP plantar flexor strength measures are influenced by demographic and anthropomorphic factors.

Patellar Tendinopathy CTAP to Measure Knee Extensor Flexor Muscle Function:

Reliability and Responsiveness: Inter-rater and test-retest reliability were excellent for knee extensor strength on both sides. Test-retest reliability was good to excellent for the power and endurance measures but inter-rater was moderate to poor for these same measures. This suggests that the rater error is an important source of variance and additional standardization and training might decrease this source of error. Because of wide variability in data, the SEM and MDD were relatively large.

Criterion and Construct Validity There was a strong correlation between the CTAP and Biodex knee extension strength measures, a moderate correlation for power measures and a weak correlation for endurance measures. These findings provided strong evidence for the criterion validity of the CTAP plantar flexor strength measure but less convincing evidence for the power and endurance measures. Known groups construct validity of the CTAP knee extensor strength measures was supported by large and statistically significant differences between participants with and without tendinopathy on the involved side. The known groups validity of the power and endurance measures was not supported. The finding that the uninvolved side extensor strength was substantially greater than the involved supported the construct validity of the CTAP knee extensor strength measure. The finding of a moderate correlation between involved side CTAP knee extensor strength and the VISA-P and involved side knee extensor power and endurance and LEFS provided evidence for the construct validity of these measures.

Factors Influencing Scores in Healthy Participants: Participants with and without patellar tendinopathy differed in age, height, weight, and gender. Age, height, and weight were moderate to weakly related to CTAP plantar flexor strength. In addition, there were significant differences between genders in height, weight, and CTAP knee extensor strength measures. These findings suggested that a combination of demographic and anthropomorphic measures may be important predictors of knee extensor strength in healthy participants. Analysis using stepwise linear regression found that a model containing gender, height and age predicted 35% of the variance in dominant side knee extensor strength and a model containing gender, age, height and weight explained 52% of the variance in non-dominant side knee extensor strength. These findings strongly supported the relationship between CTAP knee extensor strength measures and demographic and anthropomorphic characteristics. This suggests that comparisons of knee extensor strength between participants with and without tendinopathy should consider adjusting for these possible confounding factors.

Decision Algorithms: Adjusting for age gender, height, and weight increased the magnitude of the differences in knee extensor strength between individuals with and without tendinopathy and the differences were statistically significant. The finding that the adjusted means differed substantially from the unadjusted means supports adjusting for demographic and anthropomorphic factors in making decisions about the impact of tendinopathy on plantar flexor strength.

Conclusion: There is strong support for the reliability and validity of the CTAP knee extensor strength measures. There is less support for the reliability and validity of the CTAP knee extensor power and endurance measures. CTAP knee extensor strength measures are influenced by demographic and anthropomorphic factors.

- **Goals Not Met**
    - Although data collection was continued until the end of the funding period, problems with Kiio hardware and software and difficulty recruiting participants with tendinopathy resulted in a smaller number of participants than planned. Data analysis was conducted on the available sample and all data analysis tasks have been completed although the smaller than anticipated sample size made it more difficult to achieve statistical significance.
- **What opportunities for training and professional development has the project provided?**
    - This project was not intended to provide training and professional development opportunities. There is "Nothing to Report".
- **How were the results disseminated to communities of interest?**
    - Final data analysis was completed 12/15/2023 and the final report on the data analysis was completed 12/20/2023. Dissemination of relevant findings will take place in 2024.
- **What do you plan to do during the next reporting period to accomplish the goals?**
    - This final technical report addresses all the tasks identified in the University of Miami SOW from February 2022.

5. **IMPACT:** *Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*
    - **What was the impact on the development of the principal discipline(s) of the project?**
        - Assessing muscle strength is very important in preventing and rehabilitating many orthopedic problems. Isokinetic dynamometry (Biodex) is currently a "gold standard" for assessing muscle strength. Unfortunately, isokinetic dynamometers are expensive, and very large. Because they are large and not portable, they cannot be used for collecting data outside clinical or lab settings.
        - An affordable and portable system for assessing muscle function in the field would be very useful. The CTAP protocol for assessing knee extensor strength may meet this need because it performs well when compared to isokinetic dynamometry. However, the plantar flexor strength protocol is more problematic. The advantage of large isokinetic testing devices such as the Biodex is their ability to stabilize the limb and joint being tested. While it is relatively easy to stabilize the knee and upper leg to perform CTAP knee extensor strength testing, it is much more difficult to adequately stabilize the ankle.
        - Our experience suggests that CTAP may work well to test the strength of some muscle groups such as the knee, elbow, wrist, and shoulder. Difficulty stabilizing the body above and/or below the tested joint makes CTAP strength testing for muscles functioning at joints such as the ankle and hip less satisfactory.

What was the impact on other disciplines?

- Athletic trainers could benefit from using CTAP to collect information on muscle strength in the field. Occupational therapists could benefit from using CTAP to measure hand muscle function more functionally and precisely than is currently possible.

- **What was the impact on technology transfer?**
  - CTAP software and hardware would require additional development to address the problems we encountered before it could be widely used for either clinical or research purposes.

- **What was the impact on society beyond science and technology?**
  - Because CTAP currently is not available for use beyond this project, it is not anticipated to make an impact beyond the academic world.

6. **CHANGES/PROBLEMS:** *The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

- **Changes in approach and reasons for change**
  - The approach was not changed 10/1/2022 to 9/30/2023.

- **Actual or anticipated problems or delays and actions or plans to resolve them.**
  - 10/01/2021: Kiio ceased operation and 12/2021 Kiio initiated transfer of Award 15W81XWH-16-1-0789 to the University of Miami
  - All activities for Award 15W81XWH-16-1-0789 suspended 10/01/2021 through 9/30/2022.
  - University of Miami accepted Award 15W81XWH-16-1-0789 under a new SOW for the period 10/01/2022 to 9/30/2023.
  - Award 15W81XWH-16-1-0789 transferred finally transferred to the University of Miami 9/30/2022.
  - There were problems in transferring eBRAP access for Award 15W81XWH-16-1-0789 to PI Roach and the University of Miami. Access was finally granted July 2023.
  - The 12-month suspension of the project created the need to retrain on the data collection and data entry protocols.
  - Kiio and Biodex equipment were not used during the period the protocol was suspended 10/01/2021 to 9/30/2022. When funding was available to resume data collection the status of all equipment had to be re-evaluated. The Kiio equipment used at the University of Wisconsin site was transferred to the University of Miami December 2022.
  - Numerous issues were identified including problems with wireless connections between the Kiio sensors, tablets, and computers. Repairs and software updates were required to prepare for data collection.
  - January 2023 UM contacted an engineer who had helped develop the Kiio sensors and software. The number and extent of the software and hardware problems required the engineer to address issues on site in Miami in February 2023. He was able to repair and restore the Kiio equipment. By the

beginning of March 2023 UM had 5 working Kiio units. Unfortunately, additional problems developed with both Kiio software and tablet batteries. Several Kiio Units stopped turning on and software problems interrupted data collection. The engineer was contacted again to facilitate data transfer from the Kiio tables due problems with their age and battery status. By the end of the award period only one Kiio tablet was working properly. All these problems limited our ability to collect data.

    - There were problems with recruitment. Once the problems with data collection instruments had been addressed and training on the data collection protocols had been completed, we attempted to recruit participants with tendinopathy. Although multiple individuals using multiple methods attempted to recruit participants with tendinopathy, we were not able to enroll the target number of this type of participant in the time remaining. Many possible participants with tendinopathy were not eligible because of previous surgery.

- **Changes that had a significant impact on expenditures**
    - We had to expend funds to hire an engineer to address problems with Kiio software and hardware. Because these problems delayed data collection, we continued to collect data until the end of the award period. The data analysis tasks associated with this award were performed unfunded after the award ended.

- **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**
    - There were no changes so there is nothing to report.

- **Significant changes in use or care of human subjects**
    - There were no changes so there is nothing to report.

- **Significant changes in use or care of vertebrate animals. NA**

- **Significant changes in use of biohazards and/or select agents. NA**

7. **PRODUCTS:** *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

    - No products were developed so there is nothing to report.

8. **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

    - **What individuals have worked on the project?**

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change."

Name:	**Kathryn Roach**, PT, PhD.
Project Role:	Principal Investigator (Data Management)
Researcher Identifier (e.g. ORCID ID):	0000-0001-7943-0529
Nearest person month worked:	4.20
Contribution to Project:	Dr. Roach is the Lead Data Management and Analysis for this project. She submitted revisions and reports to the University of Miami HSRO and USARMRC HRPO. Dr. Roach worked with the Data Collection team to ensure the quality of data collection. She created and managed project databases and supervised data entry and data cleaning. In addition, she conducted and interpreted the data analysis for all project aims, and prepared reports.
Funding Support:	**Project Number:** SC200152 • **Source of Support:** Department of Defense (DoD) • **Status of Support:** Active • **Title:** Consumer Perspectives on a Multimodal Approach to Make Neuropathic Pain Manageable • **Major Goals:** The main goal of this proposal is to explore consumers' perspectives on a multimodal pain program to facilitate the development of effective clinical SCI neuropathic pain trials and programs that are tailored to consumers' preferences, underlying mechanisms, and predictors of manageable pain after SCI. • **Name of PD/PI:** Eva Widerstrom-Noga, PhD, DDS • **Role:** Co-Investigator • **Primary Place of Performance:** University of Miami Miller School of Medicine • **Project/Proposal Start and End Date**: 07/01/2021 – 06/30/2024.

Name:	**Eryn Milian**, PT, PhD
Project Role:	Co-Investigator (Data Collection Lead)
Researcher Identifier (e.g. ORCID ID):	0000-0003-1684-1835
Nearest person month worked:	3.00
Contribution to Project:	Dr. Eryn Miliani serves as the Data Collection Lead for this research project. Dr. Milian participates in and supervises all aspects of the data collection, recruiting of subjects, analysis, and dissemination. Maintained communication among the key personnel through regular meetings. In addition, monitored the timeline of the project and ensured compliance with regulatory requirements.
Funding Support:	

Name:	**Michele Raya**, PhD, PT, ATC, Board Certified Sports Clinical Specialist
Project Role:	Co-Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0003-0686-0098
Nearest person month worked:	1.8
Contribution to Project:	Dr. Raya assisted in data collection, and recruitment of subjects, and participated in the interpretation and data analysis.
Funding Support:	

Name:	**Phil Grattan,** PT, DPT
Project Role:	Co-Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0002-8347-0598
Nearest person month worked:	3.00
Contribution to Project:	Dr. Grattan assisted with data collection, recruitment of subjects, data analysis, and interpretation.
Funding Support:	

Name:	**Lauren Butler**, DPT
Project Role:	Physical Therapist Researcher (part-time)
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	3.0
Contribution to Project:	Dr. Butler conducted the data collection for the project. Dr. Butler identified subjects, recruited patients, maintained all program-related documentation, and oversaw the project's progress.
Funding Support:	

Name:	**Robyn Rice**, PT, PhD
Project Role:	Physical Therapist Researcher (part-time)
Researcher Identifier (e.g. ORCID ID):	0000-0002-4077-1040
Nearest person month worked:	3.0
Contribution to Project:	Dr. Rice performed data management and data collection. Data collection is responsible for identifying subjects, recruiting patients, maintaining all program-related documentation, and overseeing the project's progress. Data management assisted with data entry, data cleaning, and data analysis
Funding Support:	.

Name:	**Joseph Girardi**, PT, DPT
Project Role:	Physical Therapist Researcher (part-time)
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	1.2
Contribution to Project:	Dr. Girardi assisted in the data collection and participated in the interpretation and data analysis.
Funding Support:	

Name:	**Julia Wasserman,** PT, DPT
Project Role:	Physical Therapist Researcher (part-time)
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	1.20
Contribution to Project:	Dr. Wasserman assisted in the data collection and participated in the interpretation and data analysis.
Funding Support:	

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**
    - No, there is nothing to Report.
- **What other organizations were involved as partners?**
    - The University of Miami is the only institution involved in the final year of this project so there is nothing to report.

9. **SPECIAL REPORTING REQUIREMENTS**
    - **COLLABORATIVE AWARDS:** This is not a Collaborative Award.
    - **QUAD CHARTS:** The Final Quad Chart will be submitted.
10. **APPENDICES:** *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc. Reminder: Pages shall be consecutively numbered throughout the report.* ***DO NOT RENUMBER PAGES IN THE APPENDICES.***