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Trigger Point Dry Needling, Manual Therapy and Exercise versus Manual Therapy and Exercise for the Management of Achilles Tendinopathy: A Feasibility Study

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Trigger Point Dry Needling, Manual Therapy and Exercise versus Manual Therapy and Exercise
for the Management of Achilles Tendinopathy: A Feasibility Study

by

Alex Michael Koszalinski

A dissertation submitted in partial fulfillment of the requirements
for the degree of Doctor of Philosophy

Nova Southeastern University
College of Health Care Sciences
Physical Therapy Department

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Abstract

Background: The effect of trigger point dry needling (TDN) on myofascial trigger points (MTP) in Achilles tendinopathy are unknown. **Objectives:** To determine the feasibility of a large randomized controlled trial (RCT) to compare the effects of TDN to exercise in a patient population with Achilles tendinopathy. **Methods:** This single-factor, pretest-posttest control group design included 22 subjects between the ages of 24 and 65 years with Achilles tendinopathy. Subjects were randomly assigned to either a control group (MT+Ex) or experimental group (TDN+MT+Ex). Subjects in both groups completed 8 physical therapy treatment sessions over 4 weeks. The intervention for the TDN+MT+Ex group included TDN to MTPs in the gastrocnemius, soleus or tibialis posterior each session while the same soft tissue mobilization and exercise program was conducted in both groups. **Results:** Within group analysis was performed for each group at 4 week and 90 day follow up. Significant improvement ($p < .05$) was achieved for FAAM, NPRS, pain pressure threshold and strength in both groups at 4 weeks and 90 days. The GROC was significant for MT + Ex at 90 days. The MCID for the FAAM, GROC were surpassed in both groups at 4 weeks and 90 days. NPRS surpassed the MCID for the MT + Ex group at 4 weeks. **Conclusion:** A large RCT to investigate the effects of TDN on MTP in Achilles tendinopathy is feasible with modifications. **Recommendations:** Special considerations for data collection sites should be given to the health care system, insurance payor, and financial burden to subjects.
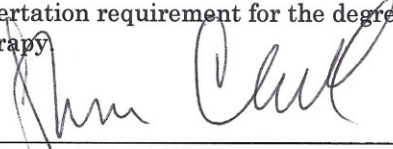
Approval Page

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We hereby certify that this dissertation, submitted by Alex Koszalinski, conforms to acceptable standards and is fully adequate in scope and quality to fulfill the dissertation requirement for the degree of Doctor of Philosophy in Physical Therapy.

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Dedication

For my Dad who taught me to work hard and never sell myself short.

For my Mom who repeatedly told me I could accomplish anything I set my mind too.

For my son, Tyler, who is my inspiration for everything.

Most importantly, for my wife, Julie, who stood by me over the years and gave me the support

and encouragement I needed to continue to push through the many challenges I faced.

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Finally, I want to thank my wife and son for their unending support throughout this dissertation. Through all the late nights, long weekends and numerous challenges this dissertation created, you were there for me. You gave me the strength I needed to push forward. I truly could not have completed this dissertation without you.

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Chapter 1: Introduction

Introduction to the Chapter

Achilles tendinopathy affects people with an active or sedentary lifestyle.[1–5] There are several causes to the development of Achilles tendinopathy as well as surgical and conservative treatment options.[6-8] Mechanical loading through exercise is one specific intervention that can stimulate a healing response in tendons.[9,10] Several studies have reported the effectiveness of managing Achilles tendinopathy from exercise alone without additional therapeutic interventions following short and long term follow up.[11-14] Physical therapists incorporate eccentric strengthening and modalities for pain management for Achilles tendinopathy.[6,15] In addition, physical therapists are also trained in manual therapy interventions that have been effective for Achilles tendinopathy.[16] Treatment programs including only eccentric exercise have reported effectiveness, but the healing rate and functional improvements are slow.[11,13,14] In addition, many of the recommended treatment options for Achilles tendinopathy have questionable efficacy.[6,15] Trigger point dry needling, TDN, is a treatment used by physical therapists that is gaining in widespread use.[17,18] This intervention includes the insertion of a monofilament into a myofascial trigger point without an injectate, referred to as dry needling. There are several studies reporting significant improvement in pain and return to functional activities following TDN.[19-43] In addition, these results occur in much shorter timeframes than what has been reported for eccentric exercise and other interventions for Achilles tendinopathy.[13,14,44] There are 2 published studies that have investigated the effect of needling the Achilles tendon but no clinical studies published on the outcomes of TDN for myofascial trigger points in Achilles tendinopathy. Given the prevalence of Achilles tendinopathy and the reported effectiveness of TDN, a large

randomized controlled trial is warranted to investigate the effect on pain control and functional outcomes.

Statement of the Problem

Pain in the Achilles tendon and posterior heel is a condition that is common to the athletic as well as sedentary populations. Injuries to the Achilles tendon in athletes is often classified as an overuse injury and is estimated to occur in 7 to 11% [1,2] of runners but a lifetime risk of 52% for elite marathon runners.[45] Achilles tendinopathy is not limited to the athletic population. Rolfe and Movin report an incidence of 31% of subjects in their study had a sedentary lifestyle.[46] Achilles tendinopathy and posterior heel pain can develop from multiple causes [47-50] and early histological changes occur before pain is reported.[5] A large number of non-surgical treatment options exist to manage the pain and restore normal activity tolerance[8,15,51,52]; however, research is largely inconclusive on the effectiveness.[15,53,54] Physical therapy is one treatment option with interventions including eccentric exercise and modalities.[15] However, there is limited evidence to support the effectiveness with these interventions for Achilles tendinopathy.[6,15] Trigger point dry needling is an intervention that has become more prevalent among physical therapists.[17,18] This has been found to be an effective intervention for several conditions.[19-43] There are no published studies investigating the effect of TDN to myofascial trigger points in patients with Achilles tendinopathy. Although, there are 2 published studies that have investigated the effect of needling the Achilles tendon. One study injected lidocaine into the Achilles tendon prior to dry needling [55] and the second study did not have appropriate controls rendering the results questionable.[56] Therefore, the effect of TDN without an injectate on pain and functional outcomes is still unknown.

Changes in health care in the United States may be influencing provider practice patterns and patient decisions on specific treatment options for managing Achilles tendinopathy. Trends over the past few years have resulted in a rise in out of pocket costs for health care.[57] Health insurance premiums and deductibles are generating a rise in out of pocket costs that are unaffordable for many people.[57-59] There is evidence that this is negatively impacting utilization of health care services[60] including provider referrals to physical therapy as well as reducing the frequency and duration of physical therapy services.[61] Developing a large, high quality trial may be challenging due to the current status of the health care system in the United States. Given these changes, a large high-quality study may not be feasible.

Studies on the effects of TDN do report significant improvement in pain, ROM, strength and performance on functional outcomes measures.[19-43] There are limitations with this research including: 1) these studies have investigated the short-term effects of TDN and long-term high-quality methodological trials are needed[35,62]; 2) study protocols are not consistent across the TDN studies and therefore, it is not known if specific parameters of interventions in the treatment protocol are required to achieve the reported results; 3) treatment variables are also not consistent across these studies; 4) not all of these studies were completed in the United States and results may not be generalizable to the US population. Thus, the study design may not be replicable with the health care system in the United States.

These limitations do pose a challenge to the development of a randomized controlled study design that will have a sufficient number of subjects, a treatment protocol that is manageable in a high-volume physical therapy clinic and variables that provide meaningful data on a long-term effect. Therefore, a preliminary feasibility study is warranted to provide data to

determine if a large high quality randomized controlled trial could be performed in private outpatient physical therapy clinics.

Relevance and Significance for the Study

The term posterior heel pain can consist of injuries to the Achilles tendon at the insertion site or in the middle portion of the tendon. "Posterior heel pain is multifactorial and includes paratenonitis, tendinosis, tendinosis with partial rupture, insertional tendinitis, retrocalcaneal bursitis, and subcutaneous tendo-Achillis bursitis. Each of these entities is distinct, but they often occur in combination."[4 (p.287)] Clinical presentation often includes subjective report of pain localized to the Achilles tendon or insertion site that increases with standing and walking following prolonged sitting, squatting or running.[63] Common findings on clinical examination of the ankle reveal swelling of the tendon and/or the insertion site, pain with active and passive dorsiflexion, direct palpation of the tendon or insertion site on the calcaneus, positive arc test and Royal College of London Test.[6,64,65]

The onset of posterior heel pain may be due to histopathological changes locally in the Achilles tendon or pain that is referred from muscles in the lower leg or hip.[46,47,66-70] A multitude of factors are believed to contribute to the development of Achilles tendinopathy including intrinsic and extrinsic factors[48]; gender differences[49,71]; biomechanics of the ankle[66]; histological changes in the tendon[49]; central neuronal factors[72]; and neurovascular changes.[73,74] However, posterior heel pain may also be the result of pain referred to the posterior heel from myofascial trigger points in the muscle belly of the gastrocnemius or soleus, tibialis posterior or gluteus minimus.[70] A myofascial trigger point is "a hyperirritable spot in a skeletal muscle that is associated with hypersensitive palpable nodules in a taut band". [75(p 4)] Pain from trigger points

develops from local physiologic mechanisms as well as alterations in the spinal cord.[72]

Microdialysis procedures of an active trigger point reveal the presence of several chemicals that

contribute to nociception and inflammation which can produce pain locally in the muscle.[76]

Referred pain from myofascial trigger points is likely due to alterations in motor, sensory and

autonomic mechanisms of a muscle that develop from the chronic pain and inflammation present

in the trigger point.[72] The increase in pain from a trigger point can produce adaptations at the

neuromuscular junction as well as in the dorsal horn of the spinal cord resulting in either

peripheral or central sensitization which then produces referred pain.[72]   Referred pain patterns

from trigger points have been identified and may not follow the established pain pathways from

nerve entrapment.[72] Pain from active trigger points in the gastrocnemius, soleus, tibialis

posterior and gluteus minimus have been shown to refer pain to the posterior heel.[70]

Treatment Options for Achilles Tendinopathy

There are many treatment options for management of Achilles tendinopathy. Medical

management of Achilles tendinopathy by physicians and podiatrists includes a variety of

treatment options including immobilization, orthotics, plasma-rich injections, steroid injections,

sclerosing agents and surgery.[7,51] Despite the common use of these procedures, there is limited

evidence to support the use of these approaches.[7,12,15,53,76,77] Extracorporeal shockwave therapy

has been found to be more effective than eccentric training alone. However, this procedure is

expensive, not widely used and may not be an option for all patients.[76]

Achilles tendinopathy is commonly treated by physical therapists.[15]   Clinical practice

guidelines for treatment of Achilles tendinopathy have been published by the orthopedic section

of the American Physical Therapy Association, APTA, in 2010 [6] and revised in 2018. [15]

According to these guidelines, there is strong evidence for effective management with eccentric exercise. However, there are reviews suggesting the research on the effectiveness of eccentric exercise to effectively manage Achilles tendinopathy is insufficient and largely of low quality.[78,79]   According to the systematic review by Meyer,[78] there was brevity of quality research on eccentric exercise and those studies that did meet the criteria had different exercise protocols and a determination for the most effective exercise protocol could not be made. Meyer reported only 3 out of 276 studies were judged to have the required minimum score for the review. The APTA clinical practice guidelines only analyzed each study according to the study design and therefore, did not grade the same studies on eccentric exercise as stringently as Meyer. Furthermore, a Cochrane Review for treatment of Achilles tendinopathy was initiated but was later suspended, reporting that there was a lack of quality trials to complete the review.[80] This conflict raises question as to the reliability of the results reported on with the studies for eccentric exercise on Achilles tendinopathy and that the evidence may not be as strong as determined for the APTA clinical guidelines.

Manual therapy is a common intervention performed by physical therapists for treatment of soft tissue and joint restrictions that are often present with Achilles tendinopathy.   Based on current guidelines there is insufficient evidence to support the use of manual therapy for treating Achilles tendinopathy.[15] However, manual therapy procedures including joint and soft tissue mobilization have been found to be effective for pain relief and improved functional outcomes for heel pain.[81,82]

Despite inconsistencies in the recommendations of current clinical guidelines for treatment of Achilles tendinopathy, a "favorable" long term prognosis is expected after 6-12 weeks of treatment.[44] However, treatment programs that include trigger point dry needling for

other musculoskeletal impairments have reported significant improvements in a shorter timeframe.[19-43] However, the long term effects of TDN have not been reported. Additional long-term studies investigating the effect of TDN are needed.[35,62]

Trigger Point Dry Needling

Trigger point dry needling, TDN, is a treatment approach that was not included in the APTA treatment guidelines[6,15] and has been advocated for treatment of myofascial pain in a multitude of diagnoses.[19-43] Dry needling is an invasive procedure in which a small diameter monofilament needle is inserted into the skin and muscle directed at the trigger point with no medication injected into the tissues.[17] It is an intervention that has a low risk for complications.[83] Dr. Lewit was the first to publish a study on use of trigger point dry needling to treat low back pain.[26] Since this paper was published additional studies have reported on the effectiveness of dry needling to treat shoulder pain[30,157]; adhesive capsulitis[29]; neck pain[24,31,32]; cervical dizziness[39]; cervicogenic HA[157]; TMD[20,21]; LBP[19,28,40]; lateral epicondylalgia[21,41]; knee pain[42,155,158] ; and heel pain.[33] However, there are no published studies investigating the effect of TDN for myofascial trigger points in patients with posterior heel pain.

Mechanism of Action for TDN

The mechanism of action of dry needling is not well understood, but several mechanisms have been described in the literature. Dry needling can decrease the tension in the trigger point and allow for an increase in blood flow through the muscle.[74] Shah demonstrated a decrease in nociceptive chemicals in the trigger point following dry needling.[84] Studies using EMG report a decrease in end plate noise in the trigger point following dry needling.[85] This has been found in

the muscle that the needling procedure was performed in as well as muscles in remote sites to the muscle that was needled. Performing needle rotation in the trigger point may also produce a stimulus for collagen production which is needed to repair the degenerative changes to muscle tissue found to occur in trigger points.[75] Additional findings on TDN needling includes changes in somatosensory activity in the brain, anti-nociceptive effects, pain and widespread sensitivity.[66,74,86,87] Substance P is a neurotransmitter that contributes to pain transmission. Substance P was shown to decrease locally in the muscle and in the dorsal root ganglion as well following brief application of dry needling.[75,88]

The mechanism of dry needling on substance P may have relevance to the management of posterior heel pain. High levels of substance P have been detected in Achilles tendons that have signs of degeneration and reports of pain.[66,76,89,90] Substance P is also found in high levels in myofascial trigger points.[31] Trigger point dry needling may provide pain relief by reducing levels of substance P in trigger points and the Achilles tendon. However, there are no published studies that have investigated the effect of TDN on Achilles tendinopathy to determine if this intervention will effectively reduce pain in the posterior heel.

Conclusion

Due to the brevity of quality trials showing effectiveness of management for Achilles tendinopathy, additional studies are needed to determine the most effective treatment program. Prior published studies on TDN on myofascial trigger points as well as tendon needling have reported significant improvements in pain, ROM and functional outcomes.   However, many of these studies are conducted internationally and there are inconsistencies in study methodology that may not able to be replicated in the United States   The primary aim of this study is to test

the feasibility of a randomized controlled trial investigating the effects of TDN to myofascial

trigger points along with manual therapy and eccentric exercise in comparison to a treatment

with manual therapy and eccentric exercise alone for subjects with Achilles tendinopathy.

Research Objectives

The absence of published studies reporting the effect of TDN on myofascial trigger points for

Achilles tendinopathy justifies the need for a study. In addition, studies investigating the effects

of TDN on myofascial trigger points need to include long term follow up. A preliminary study

can provide data that could potentially be used to develop a large, randomized controlled trial.

Therefore, the present study will be a feasibility study design. This study can provide data to

determine method for subject recruitment, design treatment protocol, and determine outcome

measures and conducted to provide data that will be used to determine if a large randomized

controlled trial with long term follow up will be feasible.[91,92]   As this is a feasibility study,

statistical analysis for a between group comparison will not be conducted.[91]

The primary objectives for this study will be to:

1) report the access to participants with Achilles tendinopathy in private, outpatient

   physical therapy clinics

2) identify barriers for subject participation (injury severity, fear of needles, cost of care,

   time to complete study protocol and follow up)

3) describe the suitability of treatment protocol and assessment procedures

4) report the participants adherence to treatment

5) report the attrition rate with follow up data collection

6) calculate within-group treatment effects

The determination of the feasibility for a randomized controlled trial will be adopted from a feasibility study reported by Tough et al. [93] A randomized controlled trial will be feasible if: 1) the 4 week attrition rate less than 20%; 2) no adverse responses reported; and 3) at least 75% of patients complete follow up assessment data. In addition, eligibility and willingness of patients to participate in this trial will be reported.   This data may factor in to the feasibility of a study based on the availability of patients with Achilles tendinopathy in a specific clinic for data collection.

Summary

Achilles tendinopathy is a common diagnosis that affects people with an active or sedentary lifestyle. There are a multitude of treatment options yet the evidence for effectiveness of most of these options is inconclusive. Trigger point dry needling has been an effective treatment for many musculoskeletal conditions, but a study has not been published exploring the effectiveness of this treatment for Achilles tendinopathy. This study will compare the effect of trigger point dry needling to the recommended treatment approach by the ATPA guidelines with eccentric exercise.   However, the escalating health insurance deductibles and rising cost of healthcare are resulting in changes to practice management for patients in physical therapy. Therefore, the feasibility of conducting a high-quality randomized trial with long term follow up is not known.

Definition of Terms

Achilles tendinopathy -- pain, swelling and limitation of function common to many overuse syndromes, as well as the histopathological entities of paratenonitis and tendinosis[94]

Posterior heel pain – pain located in the back of the heel, also referred to as the posterior calcaneus. Posterior heel pain is multifactorial and includes paratenonitis, tendinosis,

tendinosis with partial rupture, insertional tendinitis, retrocalcaneal bursitis, and subcutaneous tendo-Achillis bursitis.[1]

Dry needling – an invasive procedure in which a small diameter monofilament needle is inserted into the skin and muscle directed at the trigger point [75]

Trigger point—a hyperirritable spot in a skeletal muscle that is associated with hypersensitive palpable nodules in a taut band[95]

Needle rotation – a technique used in trigger point dry needling where the needle is turned in a clockwise or counterclockwise direction thereby producing an increase in tension of the muscle and connective tissue[75]

Manual therapy – also known as orthopedic manual physical therapy, OMPT, which is defined as "any "hands-on" treatment provided by the physical therapist. Treatment may include moving joints in specific directions and at different speeds to regain movement (joint mobilization and manipulation), muscle stretching, passive movements of the affected body part, or having the patient move the body part against the therapist's resistance to improve muscle activation and timing. Selected specific soft tissue techniques may also be used to improve the mobility and function of tissue and muscles." [96]

Eccentric exercise -- a voluntary muscle activity in which there is an overall lengthening of the muscle in response to external resistance.[78]

Substance P – a neurotransmitter that contributes to pain transmission, cell growth, angiogenesis and vascular permeability [50]

Plasma-rich injections -- a volume of plasma that has a platelet count above the baseline of whole blood[49] "Platelet-rich plasma has been used clinically in humans for its healing properties attributed to the increased concentrations of autologous growth factors and secretory proteins that may enhance the healing process on a cellular level. The hope is that PRP enhances the recruitment, proliferation, and differentiation of cells involved in tissue regeneration." [97,98]

Sclerosing agents – a compound that acts by irritation of the venous intimal epithelium; used in the treatment of varicose veins.[53,99]

Iontophoresis – a process that uses bipolar electric fields to propel molecules across intact skin and into underlying tissue. The purpose of this study was to describe and experimentally examine an iontophoresis drug delivery model.[94]

Chapter 2 - Review of the literature

Introduction

Tendinopathy is the most common disorder of the Achilles tendon, accounting for 55-65% of the reported cases.[63] Achilles tendinopathy is generally considered a chronic condition and is common to runners[1,4] but also reported in non-athletes as well.[5,46] Non-insertional tendinopathy is more common to runners than insertional tendinopathy.[1,4] Eccentric exercise has been extensively studied for the management of tendinopathy and is included in the APTA Clinical Practice Guidelines as a strongly recommended intervention for Achilles tendinopathy.[6,15] However, systematic reviews on eccentric exercise indicate that there are an insufficient number of quality studies on eccentric exercise for Achilles tendinopathy to determine treatment parameters that are most effective for managing this disorder.[78,79] While eccentric training is effective, the results are delayed with studies reporting evidence of continued healing at the 4 and 5 year follow up with eccentric training alone.[13,14] The slow response has led to the implementation of other interventions for managing Achilles tendinopathy. The combined effects of eccentric training with corticosteroid injections,[54] extracorporeal shockwave therapy[76,100] and tendon needling [56,101] have been reported to be more effective than eccentric training alone.

Myofascial pain syndrome is a chronic condition commonly present in chronic pain including tendinopathies.[75,95] Trigger points are present in the gastrocnemius and soleus with Achilles tendinopathy and may contribute to the pain and limitations in ROM and strength commonly reported with tendinopathy. Research on trigger points indicates presence of chemical mediators that contribute to hypersensitivity, weakness and loss of function.[76,89] There is limited research describing the effect of manual therapy interventions on trigger points in the

lower leg for the management of Achilles tendinopathy.[15] Dry needling has been reported to be

effective for shoulder pain[30,157]; adhesive capsulitis[29]; neck pain[24,31,32]; cervical dizziness[39];

cervicogenic HA[157]; TMD[20,21]; LBP[19,28,40]; lateral epicondylalgia[21,41]; knee pain[42,155,158] ; and heel

pain;[33] as well as needling to the Achilles tendon with and without injection. [157,158]   However, no

studies have been published investigating the effect of dry needling on myofascial trigger points

in the lower leg with Achilles tendinopathy.

Anatomy and Pathology Considerations

Pathology of the Posterior Heel

The term posterior heel pain refers to injuries to the Achilles tendon at the insertion site

or in the middle portion of the tendon.[1] "Posterior heel pain is multifactorial and includes

paratenonitis, tendinosis, tendinosis with partial rupture, insertional tendinitis, retrocalcaneal

bursitis, and subcutaneous tendo-Achillis bursitis. Each of these entities is distinct, but they often

occur in combination." [1]

Injury to the Achilles tendon in athletes is generally described as an overuse injury but is

also common in non-athletes as well.[5,46] There are intrinsic and extrinsic factors that contribute

to the formation of tendinopathy. Extrinsic factors can be grouped into training errors, poor

technique, improper footwear, and running surface can lead to the development of

tendinopathy.[48] Intrinsic factors include weakness, biomechanical dysfunction, gender, age,

genetics and health disorders including diabetes, hypercholerolaemia, hyperlipidaemia and

infection with treatment by fluorquinolone antiobiotics.[48] Biomechanical dysfunction can result

from weakness, loss of flexibility, bone structure (ie tibial torsion, pes cavus or pes planus) and

lead to greater ground reaction force transmitted through the Achilles as well as higher strain to

the tendon.[48] Women may have a lower incidence of tendinopathy due to estrogen having a protective effect on tendon pathology.[49] However, women taking oral contraceptives and hormone replacement therapy have a higher incidence of Achilles tendinopathy.[1,48,49] Alterations in gene expression and regulation is associated with tendon pathology.   Presence of high cholesterol and LDL may also contribute to the presence of Achilles tendon disorders. Klemp reported a decrease or resolution of pain in the Achilles tendon following lipid lowering treatment in 63% of participants.[48]

Several histological changes occur in tendinopathy. Peritendinous changes include thickening and swelling of the paratenon with "widespread proliferation of fibroblasts and myofibroblasts which can cause contracture of the paratenon and constrict the microvasculature".[48,102] Intratendinous changes have been described with tendinosis and chronic tendinopathies.[48]   An increase in the number of blood vessels and nerves has been reported in the area of pain in the Achilles tendon.[103] Doppler ultrasound imaging demonstrates passive dorsiflexion stops blood flow in the area of the neovascularization[104] in CSA with disruption of the ground substance, presence of hypercellularity and collagen fiber disruption.[102] There is a decrease in the type I collagen fibers, increased collagen crimping and ruptures as well as an increase in production of Type III collagen which is structurally weaker than Type I.[102]   These changes will lead to alterations in the tendons mechanical properties and[24] weaken the tendon.[102]

Microdialysis of the intratendinous tissues reveals an increase in neurotransmitters glutamate and substance P but no increase in prostaglandin E which is a marker of inflammation.[50,69]   Tendons with degenerative CT changes also have an irregular hypervascular pattern with an increase in capillaries and arterioles in the peritendinous tissues.[104]

Mechanics of the Achilles Tendon

The mechanics of the Achilles are impacted by the action of the subtalar joint. During midstance of the gait cycle, the foot will move into pronation. This action occurs primarily at the subtalar joint. The tibia responds to the pronation by producing an interior rotation. As the knee extends during this phase of the gait cycle, an external rotation stress is placed on the tibia. This results in an increase of stress to the Achilles at the insertion site[1]. Subtalar pronation or supination can change the shock absorbing quality of the Achilles and lead to rupture.[1]

Stiffness is an important characteristic of a tendon. "The stiffness of a tendon influences force transmission, muscle power and energy absorption and release during locomotion."[102] "A tendon with an optimal level of stiffness will have effective muscle-tendon interactions and reduce the costs of locomotion."[102] The presence of optimal stiffness may also reduce the injury risk and improve the overall response to eccentric training.

Lower tendon stiffness as well as the crimping of the tendon fibers will result in the tendon fascicles to shorten more to reduce the increased compliance that occurs with tendinopathy. This results in reduced extensibility which alters the mechanics of the posterior heel and changes the length tension relationship which reduces the strength of the muscle. This cascade of events will make the tendon susceptible to injury.[102]

Pathological Conditions of the Posterior Heel

Injuries to the posterior heel can be classified as either acute or overuse. [105] Acute injuries involve either partial or complete rupture of the Achilles tendon. Overuse injuries can be further subdivided into acute and chronic phase of injury. The following content will emphasize overuse injuries to the posterior heel.

Overuse Injuries

Acute Phase Mid-Portion Paratenonitis

The paratenon is composed of a single layer of cells referred to as the tenovagium and covers the length of the tendon. The tenosynovium is a connective tissue that has 2 layers of cells. There is a layer of fat in the anterior aspect of the tendon that is rich in blood vessels that nourish the tendon. Inflammation of the paratenon is called paratenonitis and produces pain along the length of the Achilles tendon medially and laterally, but is reportedly more painful on the medial side.[1] Painful nodules may form in the paratenon due to thickening of the paratenon and occurrence of tissue proliferation. Crepitus may also be present. Onset of paratenonitis can be attributed to direct pressure along the Achilles tendon, faulty biomechanics, and training errors in athletes or poorly fitting shoes.[1]

Acute Phase – Distal Bursitis

Distal bursitis involves inflammation of the retrocalcaneal bursa. The anterior surface of the bursa is composed of fibrocartilage, and the posterior aspect merges with the anterior Achilles paratenon. [106,196] When the bursa becomes inflamed, it can further adhere to the Achilles tendon. Forceful contraction of the triceps surae transmits increased force to the distal Achilles at the point of insertion on the calcaneus. This leads to increased strain to the bursa. Over time, inflammation can lead to formation of a larger adhesion and degenerative changes to the Achilles. These changes also often occur with the simultaneous development of a boney Haglund's deformity.[106] When the ankle is moved into dorsiflexion, the adhesion of the bursa to the Achilles and compression of the bursa into the Haglund's deformity lead to further microtrauma to the bursa.[106] As a result, dorsiflexion is minimized to reduce the microtrauma

and the long term result is a progressive decrease in extensibility of the Achilles tendon and triceps surae.

Chronic Phase – Midportion Tendinopathy

The term tendinopathy is defined as a "clinical syndrome, characterized by a combination of pain, swelling (diffuse or localized), and impaired performance" [105] is used to describe the histological degenerative changes in the Achilles tendon. This is a degenerative condition characterized by "mucinoid or fatty degeneration with a disorganized collagen structure." [1] These changes may be the result of microtrauma and can lead to additional injury with partial tear/rupture or inflammation of the connective tissue. The presence of these changes may be due to aging and are not always symptomatic.[1,107] Often the degenerative changes are located in the middle 1/3 of the tendon where the tendon is most hypovascular. Frequently patients report sharp pain and a connective tissue nodule will develop on the medial aspect of the tendon where the stress is greatest.

Studies using microdialysis report an absence of prostaglandins in the Achilles as well as the patellar tendons in human subjects with tendinopathy in the respective tendons.[50,69] In addition, there are high levels of Substance P and glutamate in the tendon in patients with tendonitis. Substance P is associated with vascular proliferation and also a nociceptive chemical that stimulates A-delta fibers. This may explain the presence of an ingrowth of blood vessels and nerves in the middle tendon has been found in patients with Achilles tendinopathy in the mid portion of the tendon. [67,103,104]

Chronic Phase – Distal Achilles Tendinopathy

Distal Achilles tendinopathy is also often referred to as insertional tendinitis.   This condition is characterized by pain and inflammation at the site of attachment of the Achilles tendon on the calcaneus. "There is a high association of insertional tendonitis with retrocalcaneal bursitis or Haglunds deformity." [1] Radiographs often show calcification or ossification at the superior aspect of the calcaneus and insertion of the Achilles. These changes are considered normal to the aging process and may not be the result of injury to the Achilles.[1] The term enthesopathy is also used to describe insertional tendinitis.[65]

Pathophysiology of Painful Achilles Tendinopathy

There is evidence to suggest that a central neuronal mechanism may contribute to the pain reported in the posterior heel.[66,73] Tendinosis was experimentally induced with rabbit tendons resulting in abnormal tenocyte morphology, irregular collagen and disruption of collagen bundles after 3 and 6 weeks of unilateral exercise.   Vascular proliferation occurred after 3 weeks and was also found to have occurred on the uninvolved side as well.[66] This may partially explain the presence of Achilles tendinopathy bilaterally.

Changes occur bilaterally in the spinal cord following unilateral activity results in an increase in substance P and calcitonin gene related peptide (CGRP) in the dorsal horn of the spinal cord. Unilateral strength training leads to an increased capacity of the cortex to drive the homologous untrained muscles.

Studies on the anatomical structure of the Achilles tendon in people with chronic pain report an increase number of new blood vessels are present in the area of tendinosis referred to as a neovascularization.[73]   A high level of Substance P located in the blood vessels of the Achilles

tendon and is believed to contribute to the development of tendinopathy.[67,90] Injection of the

Achilles tendon in the region with the hypervascularization with an analgesic resulted in a short

term improvement in pain.[104]

Treatment Approaches for Achilles Tendinopathy

In 2010, Carcia et al published the Clinical Practice Guidelines for physical therapy

management of Achilles tendinitis[6], and Martin et al published updated guidelines in 2018[15] also

referred to as tendinopathy.[63] According to both reviews, there is strong evidence for the use of

eccentric strengthening. Eccentric training has been effective for improving pain, ROM and

functional outcomes. However, the benefits are reported as early as 12 weeks, but the greatest

effects are reported at a 4 or 5 year follow up.[13,14] The effects of eccentric training on Achilles

tendinopathy have been compared to other interventions including manual therapy,[108] and

medical procedures including PRP,[109] injections [54] and extracorporeal shockwave therapy.[76,100]

Effects of Eccentric Exercise Training

Eccentric muscle contraction occurs when a musculotendinous unit lengthens as a load is

applied to it.[10] Eccentric strengthening is superior to concentric and isometric strengthening for

greater strength gains regardless of the velocity that the eccentric exercise is performed.[110]

However, the gains are velocity specific as the gains were best when the training and testing

were the same velocity.[110] Studies show that concentric training is more effective than eccentric

for improving concentric strength.[110]

There are neurological and mechanical differences between eccentric and concentric

contractions. Neurological adaptations include 1) broader and faster cortical activity during

movements; 2) inversed motor unit activation; 3) increased cross over effect; 4) faster neural adaptations to resistance training; 5) attenuated muscle sympathetic nerve activity; 6) decreased EMG amplitude at similar force levels; and 7) greater EMG signal prior to onset of movement.[110-112]

Mechanical adaptations of eccentric contractions include 1) higher absolute force of contraction; 2) decreased fatigability; 3) lower cardiopulmonary responses; 4) increased metabolic efficiency; and 5) training effect for eccentric exercise with reduced pain following subsequent eccentric training sessions.[110] Changes to the Achilles tendon in healthy subjects have been reported after 4 weeks of training.[113]

Injury can occur to the muscle fiber from eccentric training.[111,113,114] Muscles unaccustomed to eccentric exercise are susceptible to delayed onset muscle soreness which is characterized by soreness and stiffness generally developing 24 hours after the activity. Delayed onset muscle soreness is classified as a minor injury to the muscle and tendon that is expected to last 48-72 hours and then resolve. Repeated bouts of eccentric training leads to a less microtrauma to the muscle and tendon as well as a more rapid recovery following the exercise bout. This change is believed to occur as a result of 1) increased microcirculation to the tendon[115,116]; 2) an increase in stimulus to quiescent cells in the tendon producing more sarcomeres[117,118]; and 3) a shift in the length tension relationship of the sarcomeres in the tendon. The shift occurs to the "over-extension of sarcomeres which produces an increase in compliance in series with active sarcomeres."[111] The protective effects of eccentric training has been reported to last for up to 6 months. [119]

Effect of Eccentric Training on Achilles Tendinopathy

The effects of eccentric training on tendinopathy have been studied extensively.[10,13-15,78] The effects of eccentric training have been reported to produce a healing effect in the degenerative tendons. [13,14] The combined effects of increase in blood flow, sarcomeres and length tendon relationship result in an increase in fiber length allowing for greater dorsiflexion angle.[1,3] Eccentric training has been found to increase the rate of collage synthesis in a chronically painful Achilles tendon with tendinosis.[10] This resulted in reduced pain levels and return to athletic participation. [1,3]

Eccentric exercise also produces a higher frequency vibration than concentric contractions. The effect of vibration on the Achilles tendon has not been widely studied. The effect of whole body vibration has been compared to eccentric exercise on changes in pain in human subjects with chronic Achilles tendinopathy.[195] Horstmann et al randomized subjects into vibration or eccentric training groups. After 12 weeks of training, both vibration and eccentric training resulted in the decrease of pain in the mid-portion of the Achilles tendon. There was no significant difference between groups. Although, only the eccentric training group had a significant improvement in pain at the musculoskeletal junction as well as the insertion site.

Several studies have been conducted that have investigated the effect of eccentric training for the management of tendinopathy.[79] Woodley et al performed a systematic review for eccentric exercise in the management of tendinopathy of the Achilles, patellar and common wrist extensor group in the lateral elbow. Due to an insufficient number of high quality trials, "no strong conclusions could be made regarding the effectiveness of eccentric exercise (compared to control interventions) in relieving pain, improving function or achieving patient satisfaction". [79]

Silbernagle conducted a study investigating the effects of eccentric training alone for patients with Achilles tendinopathy.[120] After 6 months of training with eccentric exercise, a significant improvement in pain was reported by subjects at 1 year follow up. However, only 25% of the subjects reporting significant improvement were able to demonstrate full function as measured by performance on a test battery involving hopping and jumping activities.   Repeated assessment of these subjects in a 5 year follow up indicated that continued healing and improvements in function occur. [13] A similar result was also reported by Gardin et al after a 4 year follow up. [14] This indicates that despite the improvement in pain, the functional improvements are delayed and a long term prognosis for eccentric training to manage Achilles tendinopathy is good.

There are a large number of studies in the published literature investigating the effects of eccentric training for Achilles tendinopathy.[78] However, there is significant variability in the exercise protocols described in the literature. Meyer conducted a systematic review to determine if an optimal dose of eccentric training could be determined.[78] There 276 studies found in the published literature but only 3 of these were determined to have a high methodological quality.[78] All 3 studies used an eccentric protocol based on the Alfredson protocol described below:[121]

> Alfredson protocol: participants perform a single leg heel raise with eccentric lowering of the body with a straight knee putting the involved ankle in a position of dorsiflexion. Then the heel achieves the maximum tolerated lowering, the uninvolved leg performs a concentric contraction to raise the body weight the maximum height putting the involved ankle in a plantar flexed position. This is also performed with the involved knee flexed. The participants performed 3 sets of 15 repetitions, twice a day, 7 days a week x 12 weeks. The exercise was to be performed even if it was painful but should stop the exercise if the pain becomes disabling. Weight is gradually added as tolerated by use of a weighted back pack.

There were variations in the eccentric program as each study modified the Alfredson protocol. Herrington and McCulloch modified the Alfredson protocol to include a variation in speeds

where the participant would gradually increase the speed of the exercise before increasing the

load used for the exercise. [122] Rompe et al gradually increased the exercise volume by advancing

the exercise from one set of 10 to 3 sets of 15 after one week of treatment.[78] Roos et al also

modified the Alfredson protocol by gradually increasing the number of repetitions performed

from one set of 15 repetitions the initial 2 days in the study to 2 sets of 15 on the next 2 days and

then increased to 3 sets of 15 repetitions on the next day and for every day in the study

thereafter.[123] However, each study compared the results of eccentric training to another

treatment approach. Herrington and McCulloch compared the effect of eccentric training to deep

friction massage, ultrasound and stretching.[122] Subjects in this study had a mean duration of

symptoms of 24.5 months. Rompe et al compared the effect of eccentric training to shock wave

treatment or a wait and see program.[76] Participants in this study had a mean duration of pain of

10.8 months. Roos et al compared eccentric training to a night splint.[123] The mean duration of

pain for participants in this study was 5.5 months. The results of these studies do indicate that

eccentric exercise is effective alone in treating Achilles tendinopathy. However due the variation

in exercise protocols, a single best eccentric protocol cannot be developed.[78,79]

Stevens and Tan compared the exercise volume in the Alfredson protocol to a program

consisting of more variability in exercise volume and intensity based.[124] Participants in this study

were able to modify the number of repetitions according to their perceived pain during the

exercise. Results of this study indicate that there is no difference in outcome between the

Alfredson protocol and one that has variable repetitions after 6 weeks of exercise.

Eccentric exercise was compared to concentric exercise for management of Achilles

tendinopathy.[121] A 12 week program was performed using the Alfredson protocol as previously

described for the eccentric component while the concentric component included concentric

contractions only in a straight and bent knee position with exercises progressed to include side jumping and rope skipping for the final 6 weeks of the study to increase the exercise intensity. Results of the study indicate that the eccentric program was significantly more effective than concentric training in reducing pain and allowing return to a walking and jogging program.

Manual Therapy and Eccentric Exercise

The effects of manual therapy on Achilles tendinopathy has not been studied extensively. The effect of eccentric exercise was compared to a combined program of manual therapy and augmented soft tissue mobilization techniques.[108]   Subjects with Achilles tendinopathy were randomized to an exercise only group which consisted of eccentric training twice a day for 12 weeks with the Alfredson protocol. Subjects in the intervention group received augmented soft tissue mobilization twice a week for 12 visits as well as the same exercise program. A significant improvement in pain and functional outcomes were reported for the intervention group compared to the exercise only group a 12, 26 and 52 week measures.   However, results of this study are in question due to low number of participants in the study.

Medical Procedures vs Eccentric Exercise

Platelet-rich plasma (PRP) injections is an intervention used by physicians and podiatrist for the management of Achilles tendinopathy.[98]   A study by deVos et al investigated the effect of PRP injections against 12 weeks of eccentric training for subjects with chronic Achilles tendinopathy.[109] Results of the study indicate there was not a significant difference between groups for pain or return to activity.   In addition, there are other studies that have reported PRP injections are not effective in the management of Achilles tendinopathy.[15,156]

Rompe et al investigated the effect of extracorporeal shock-wave therapy (ESWT) against eccentric exercise for Achilles tendinopathy.[76]   They report a significant improvement in pain and function for ESWT alone compared to eccentric training alone. In a follow up study, they compared ESWT combined with eccentric training to eccentric training alone.[100] Again they report similar findings in that ESWT with eccentric training resulted in a significant improvement in pain and function compared to eccentric training alone.

Corticosteroid injections are another treatment that is provided by physicians and podiatrists.[54] Wetke et al investigated the effect of ultrasound guided corticosteroid injections to the Achilles tendon for subjects who had continued pain and limitations following a program of exercise training alone.[54] In their study, 26% of subjects were able to complete the training program without injections resulting in a significant improvement in pain and functional outcome. The remaining subjects were given 1-3 corticosteroid injections and continued with the exercise program. The result of the exercise plus injection protocol resulted in 94% of subjects reporting improvement in pain and functional outcomes, with 77% achieving good or excellent results.

The effect of eccentric exercise on tendinopathy has been extensively studied.   Eccentric training alone has been found to be effective for the management of Achilles tendinopathy. However, the results are delayed and healing continues to occur even at the 4 or 5 year follow up period. There is significant variation in the exercise protocols and poor methodological quality of the published literature. As a result, the most effective eccentric exercise protocol to use for management of Achilles tendinopathy with this intervention has not been determined.   Eccentric exercise combined with ESWT and corticosteroid injections have resulted in significant improvement in pain and functional outcomes compared to eccentric exercise alone.

Myofascial Trigger Points

Myofascial pain syndrome is a condition in which muscle and musculotendinous pain are the primary symptoms. "It refers to pain and inflammation in the body's soft tissues." [125] "This is a chronic condition that affects the fascia as well as a single muscle or group of muscles". Muscle pain is commonly felt deep in the region and reported as dull, achy and poorly localized. Pain from trigger points often refers to a distant region and may include paresthesia's or dysesthesias. The hallmark of the syndrome is the presence of a myofascial trigger point". [125]

A "myofascial trigger point is a hyper irritable spot in a skeletal muscle that is associated with a hypersensitive palpable nodule in a taut band".[95] Trigger points have also been defined as a "physiologic contracture" and are purportedly due to presence of "local ischemia and hypoxia, significantly lowered pH, chemically altered milieu, local and referred pain and altered muscle activation patterns". [126] The taut band is a localized band of hardened muscle formed by a group of contracted muscle fibers.[125] The taut band does not comprise the entire muscle and includes multiple trigger points. Myofascial trigger points have been determined to be a common source of myalgia[95] and form either independent of other medical conditions or may be associated as an underlying condition with other medical conditions such as osteoarthritis and whiplash.[95,126] "The affected muscles often display increased fatigability, stiffness, subjective weakness, pain in movement, and restricted range of motion that is unrelated to joint restrictions." [127]

Trigger points are classified as either active or latent.[95] Active trigger points are painful and can produce spontaneous symptoms of pain and/or paresthesia. Active trigger points have large referred pain regions.[95] Latent trigger points do not produce spontaneous pain but can be a source of nociceptive input to the dorsal horn of the spinal cord.[114] Latent trigger points can also

contribute to altered mechanics of motion.[128,129] Latent trigger points can also result in a

decrease in AROM, weakness, fatigue and cramping.[130] There is also potential for latent trigger

points to eventually become active trigger points with the appropriate stimulus.[95] Latent trigger

points have been identified in the uninvolved limb in patients with lateral epicondylalgia and

presence of active trigger points.[75]   This may be the result of a central neuronal mechanism.

Motor Aspects of Trigger Points

Motor aspects of active and latent trigger points can include presence of a taut band,

LTR, weakness without atrophy, loss of reciprocal inhibition, EMG end-plate noise, subject to

sympathetic modulation [85] weakness due to inhibition, stiffness and reduced range of

motion.[128,129]

Sensory Aspects of Trigger Points

Sensory aspects of active and latent trigger points can include local pain, pain referred to

distant sites, as well as peripheral and central sensitization.[125] Acute deep-tissue pain that occurs

with trigger points is due to activation of A delta and C-fiber muscle nociceptors.[131]   The

nociceptors can be sensitized by release of substance P and calcitonin gene-related peptide from

nerve endings and are found in high levels in trigger points.[89] "This may eventually lead to

hyperalgesia and central sensitization of dorsal horn neurons manifested as prolonged neuronal

discharges, increased responses to defined noxious stimuli, response to non-noxious stimuli, and

expansion of the receptive field." [131]

The trigger point can transition from a latent to active trigger point and back to a latent trigger point.[132] While latent trigger point does not produce spontaneous pain, mechanical stimulation is painful. The latent TP is still a hypersensitive nodule that can refer pain.[131]

Referred pain is believed to occur through a complex series of events referred to as the central sensitization phenomenon.[125] Due to the chemical mediators in the trigger point and [89] changes at the neuromuscular junction that produce an increase in end plate activity, there is an increase in the stimulation of the afferent nociceptive neurons to the dorsal horn. This produces activation of the single sensory neuron for that motor unit but also stimulates neighboring dorsal horn neurons and thereby expanding on the receptor field in the dorsal horn. The dorsal horn neurons transmit impulses to the brain which then activates the somatosensory cortex. When the dorsal horn is sensitized by an increase in nociceptive input and larger receptor field, the somatosensory cortex will erroneously interpret the sensation as coming from a widespread region.

"Peripheral sensitization can be described as a reduction in the threshold and an increase in the responsiveness of the peripheral ends of nociceptors."[75] The presence of allodynia and hypersensitivity are the hallmarks of peripheral and central sensitization.[75,72]

Autonomic Aspects of Trigger Points

In addition to the effects of motor and sensory aspects of trigger points to pain and dysfunction, there are autonomic aspects as well. The effect of an increase in sympathetic outflow to muscle has been found to result in an increase of EMG activity of trigger points. [133] and a decrease in pain pressure threshold. [134] An increase in sympathetic activity also results in vasoconstriction of capillaries of the trigger point and can increase the superficial blood flow

through the skin in the region of the trigger point.[74] In addition to changes in EMG activity, trigger points can also produce vasodilation, lacrimation and piloerection.[75]

Biochemical Mediators in Trigger Points

Microdialysis of a myofascial trigger point in the upper trapezius indicates a significant increase in the biochemical mediators compared to muscle tissue in the gastrocnemius. Shah et al report an increase in bradykinin, substance P, tumor necrosis factor, CGRP, interleukin beta 1; IL-6 and IL-8, serotonin and nor-epinephrine.[89] In addition, a low pH was present in the trigger point as well as low oxygenation. Additional study indicates the presence of an increase in blood and oxygen in the tissues surrounding the trigger point.[74,125] The presence of these chemical mediators may explain the peripheral and central sensitization that is present with trigger points in myofascial pain syndrome.

Taut Bands

A taut band is a contracture of muscle within which lies a trigger point. [135] Taut bands are not muscle spasms. Muscle spasms are involuntary contractions of the muscle and include electrical activity from alpha motor neuron and motor end plate activity. Taut bands can be seen with sonography and magnetic resonance elastography. [136] Tissue tension is increased in the taut band while vibration is lower than surrounding tissue in the same muscle.

Detecting Trigger Points

Trigger points can be identified by palpation of a muscle perpendicular to the muscle fiber direction where a nodule can be felt within a taut band of muscle tissue.[75,137] Good inter-

rater reliability has been reported and is the common form of identification clinically.[75,114]   The criteria for diagnosing a trigger point with palpation is identifying a taut band and the presence of a tender point in that band.[75]   Trigger points can also be detected with ultrasound imaging,[75] magnetic elastography[125,137] and vibration sonoelastography.[95]   Palpation of a trigger point can elicit a local twitch response which is a brief contraction of the muscle tissue within the taut band alone.[114]   This is differentiated from a golgi tendon reflex where the entire muscle contracts. Trigger points are physiologically distinct from a muscle spasm. A muscle spasm results from an increase in nerve activity and will involve the entire muscle, showing an increase in EMG activity.   A taut band, however, is a localized contracture within a muscle that develops "without activation of the motor end plate". [75]   Vibration sonoelastography can identify trigger points and be used to distinguish between active and latent trigger points.[75]   The localized twitch response may not be palpable in deep muscles. The localized twitch response is theorized to be an important determinant to appropriate placement for the needle in the trigger point. Ultrasound imaging can be used to visualize the LTR in deep muscles during TDN.[138]

Etiology of Myofascial Trigger Points and Taut Bands

The exact mechanism of formation of a trigger points is unknown. There are several theories that have been proposed to explain the formation of a myofascial trigger point, including submaximal muscle contractions, uneven pressure distribution, direct trauma, and unaccustomed eccentric contractions. The integrated trigger point hypothesis by Simons is widely accepted and supported by growing evidence for the motor and sensory aspects of the theory while the autonomic aspect is still unclear.[72,75]

Low Level Muscle Contractions

Hagg developed the Cinderella hypothesis which describes the development of muscle injury and onset of pain due to the overload of small type 1 motor units in skeletal muscle during prolonged, low intensity activity.[95,139] According to Henneman's size principle, small motor units will be activated initially during low intensity, slow paced activities before the larger, fast twitch motor units are recruited.[75] When this type of activity is maintained over a long time frame, there is a decrease in blood flow through the contracting muscle and a reduction in the amount of oxygen available to sustain aerobic metabolism. As this activity continues, anaerobic metabolic activity will become the primary energy source of the muscle fiber. Because this is a less efficient source for ATP production, the muscle will fatigue and the small motor unit becomes overloaded. This results in the increase release of cellular calcium and a continued ischemic response that produces hypoxia and ultimately leads to structural damage of the muscle cell. It has also been reported that ragged red muscle fibers have been detected painful muscle of patients diagnosed with myalgia.[139] As a result these small motor units are overworked and also ragged, resulting in the denotation as the "Cinderella hypothesis". The end result of this activity is muscle pain and formation of trigger points.[85,140] Treaster et al also reported that low level muscle contractions of the upper trapezius during typing for 30 minutes resulted in the formation of trigger points in the upper trapezius.[75] At the present time, no studies have described the formation of trigger points within the gastrocnemius or soleus muscles. These specific muscles have a high percentage of slow oxidative muscle fibers and are subjected to prolonged, low intensity activities such as standing and walking and theoretically could result in the formation of trigger points.

The Cinderella hypothesis may also describe the mechanism of formation of the taut band in response to muscle overload or overuse. Submaximal muscle contractions have been demonstrated to produce trigger points in the upper trapezius of computer operators.[75] The trigger points and taut bands that form from submaximal muscle contraction may be the result of an energy crisis. Submaximal contractions will produce activation of small motor units first and additional motor units are recruited with increased demand for force output. This is not a problem in a normal healthy muscle. However, in a muscle with myofascial pain, the frequent activation of the small motor units produces an excessive release of acetylcholine from the motor end plate at the neuromuscular junction. The release of Acetylcholinesterase is inhibited resulting in the sustained contraction of the muscle fiber leading to a muscle contracture. The presence of calcitonin gene-related peptide (CGRP) can lead to increased sensitivity of Ach receptors that will produce a larger and longer sustaining muscle contraction. In addition, trigger points can produce myofascial tension as well as an autonomic response which stimulates the increased release of Ach. [134]

Eccentric Muscle Contractions

Itoh demonstrated that eccentric exercise can lead to the formation of taut bands in exercised muscle and theorized that eccentric exercise was the cause.[141] Eccentric exercise has been found to produce damage to muscle fibers and muscle pain. Muscle fibers are not uniform in length across a muscle. Angles of pennation and the variation in fiber length will result in some of the fibers being subject to greater length tension than others during an eccentric contraction potentially leading to injury. The gastrocnemius and soleus function primarily in the eccentric mode and are subjected to damage and injury from eccentric contractions. Injury from

eccentric activity has been shown to result in the release of cytoskeletal proteins, evidence of muscle injury.

Integrated Trigger Point Hypothesis

The energy crises hypothesis was introduced in 1981 by Dr. Simons and Dr. Travell and has since been modified by Dr. Gerwin and renamed the integrated trigger point hypothesis.[114] According to this model, the trigger point develops in response to either: 1) "unaccustomed eccentric exercise; 2) eccentric exercise in unconditioned muscle; 3) maximal or submaximal concentric exercise that leads to muscle fiber damage and to segmental hypercontraction within the muscle fiber". [114] This hypercontraction leads to capillary constriction and a decrease in blood flow through the muscle fiber. This results in a decrease in circulating oxygen available for the actin-myoglobin cross bridge formation and the release of the myoglobin to terminate the contraction. Ischemia and hypoxia compound injury to the muscle fiber leading to an increase in SNS adrenergic activity. The pH of the fiber will become more acidic which then results in the release of CGRP and inhibition of acetylcholinesterase activity and thus an increase in the levels of acetylcholine at the neuromuscular junction. Additional changes that occur as a result of the acidic pH and muscle fiber injury include the release of proinflammatory mediators including substance P, K+, serotonin, cytokines and bradykinin. These mediators produce an increase activity at the motor end plate and increase sensitivity of the nociceptors in the region. Additional acetylcholine receptors are produced due to the action of CGRP allowing for more "docking sites for Ach" and increasing the efficiency of the Ach binding to receptors. This in turn produces continuous muscle contraction and leads to the formation of the taut band. This cascade of events leads to increased pain from the increase volume of bradykinin, K+ and H+ as

well as cytokines. Pain becomes chronic as a result of the high levels of CGRP. As the duration of the pain cycle continues, referred pain, hypersensitivity, and allodynia ensue.

Neurophysiological Aspects of Trigger Points

Stimulation of trigger points activates the periaqueductal gray and anterior cingulate cortex in the brain and enkaphalinergic, serotonergic and noradrenergic inhibitory systems associated with A delta fibers through segmental inhibition.[17] "Several studies demonstrated that trigger points activate the anterior cingulate cortex and other limbic structures but suppress hippocampal activity.[75] Increased activity in the ACC is common in chronic pain conditions and is even present when pain is anticipated.

Management of Trigger Points

Trigger Point Dry Needling

"Dry needling is a skilled intervention that uses a thin filiform needle to penetrate the skin and stimulate underlying myofascial trigger points, muscular and connective tissues for the management of neuromusculoskeletal pain and movement impairments." [17] There are 2 types of dry needling techniques, superficial and deep dry needling.[75] Superficial dry needling is performed by inserting the filiform needle into the superficial connective tissue overlying the myofascial trigger point but not penetrating the needle into the muscle. The needle remains in place for 30-60 seconds and then removed. If pain does not reduce during this time, then the needle may need to remain in place for 2-3 minutes. Deep dry needling is performed by inserting the filiform needle directly into the muscle to the depth of the trigger point. Deep dry needling can be performed to the muscle or tendinous tissues.[75]

Mechanism of Trigger Point Dry Needling

There are numerous proposed mechanisms for the effects of trigger point dry needling to manage trigger points, reduce pain and improve the overall function of the muscle. These mechanisms include:

1. Trigger point dry needling can reduce the total concentration of chemicals found in trigger points.[38] Levels of substance P were lower following dry needling.[89]

2. Dry needling produces a local twitch response (LTR) which has been shown to reduce or end plate noise associated with trigger points.[75] Eliciting a local twitch response has been found to be essential for reducing trigger points [17] and achieving pain relief from TDN. Hong demonstrated that the study participants who experienced a LTR reported pain relief while those who did not had no pain relief with the treatment.[131] The presence of the LTR has been the recommended treatment goal for performing TDN with the treatment to the trigger point concluding when an LTR can no longer be produced.[75] Chen et al were able to demonstrate that the spontaneous electrical activity of a trigger point reduces immediately after treatment with TDN.[132]

3. Deep dry needling is associated with reduced local and referred pain, improved ROM and decreased trigger point irritability locally and remotely.[84]

4. Superficial dry needling is believed to activate mechanoreceptors coupled to slow conducting unmyelinated C fiber afferents and indirectly stimulate the anterior cingulate cortex. The effects of superficial dry needling may also be mediated through stimulation of A-delta fibers or by stretching of fibroblasts in connective tissue. Superficial DN is associated with reduced local and referred pain and

improved ROM but unknown if it also reduces the chemical milieu known to be present in trigger points.[142]

5. Dry needling can reduce muscle tension and increase elasticity of scar tissue.[142,143]

6. DN can play a substantial role in the process of mechanotransduction which is the process by which the body converts mechanical loading into cellular responses. This occurs as TDN can stimulate fibroblasts to increase collagen synthesis and cell proliferation by needle rotation.[144,14]5

7. Fibroblast activation with a solid filament has been shown to result in pain neuromodulation.[146,147] "Dry needling is used to treat dysfunctions in skeletal muscle, fascia and connective tissue. Dry needling is used to diminish persistent peripheral nociceptive input and reduce or restore impairments of body structure and function leading to improved activity and participation."[17]

Prognostic Factors for TDN

Multiple studies have been published that show effectiveness of TDN for multiple diagnoses. Huang et al report on the factors that can lead to reduced benefit from TDN.[148] Over an 8 week period, 92 participants were treated with TDN and significant improvement was reported with pain intensity across the group. Further analysis determined that factors associated with poor outcomes include long pain duration, high pain intensity, poor quality of sleep and repetitive work. The authors conclude that the outcomes of treatment with TDN are dependent on the treatment protocol as well as the patient's health characteristics. [148]

Insertion of the monofilament into a myofascial trigger point with TDN often elicits a local twitch response (LTR). There is debate as to the importance of this response for the

beneficial effects reported for TDN.[150] A narrative review by Perreault, there is not a correlation of a LTR with changes in pain or disability. [149]

Dry Needling Reduces Satellite Trigger Points

Hsieh et al compared the change in pain pressure threshold (PPT) of active and satellite trigger points before and immediately after performing TDN to the primary trigger point.[87] Subjects with bilateral shoulder pain and trigger points in the infraspinatus, anterior deltoid and extensor carpi radialis longus were recruited for this study. TDN was performed to the trigger point in the infraspinatus and PPT in each of the muscles was assessed. Significant improvements in PPT and ROM occurred compared to the untreated, contralateral limb.   One session of TDN was able to improve the pain pressure threshold measure in tissues distal to the primary trigger point.

Needling Techniques

Needle Rotation

The needling procedure was studied in normal subjects.[151,183] Functional MRI was used to analyze the effect that needle manipulation had on cerebral activation patterns. Needle rotation was compared to simple insertion of the needle into the trigger point as well as sham needling.   A significant activation of the cerebrum was observed with functional MRI vs simple insertion.

Needle rotation has been studied under a controlled environment with use of robotics to measure the cycles and torque with rotation.[144] A cellular response was found with unidirectional rotation up to several centimeters from the needle. During unilateral and bilateral

needle rotation, changes occur to the shape of the cell and fibroblast in the connective tissue.

These changes are believed to be key components mechanotransduction responses.[144,152,153]

Fast in and Fast out

The fast in and fast out method was described by Hong [154] where the needle was rapidly inserted into the muscle and then withdrawn into the superficial connective tissue but not through the skin. The needle is rapidly inserted into the muscle again. This process is repeated 10-20 times until a local twitch response is no longer elicited. This technique is also referred to as pistoning.[155]

Grasping and Winding Up

Chan Gunn describes a method of needling with the intramuscular stimulation system for treatment of chronic pain referred to as "grasping and winding up".[142] In this system, the needle is inserted into the myofascial trigger point and rotated until tissue tension develops and the muscle then grasps the needle. The needle remains in place 10-20 minutes until the muscle relaxes and thereby releases the needle. A study by Gascon-Garcia et al reported the effects of the winding technique on the transverse carpal ligament which resulted in relaxation and stretching of the tissues.[156]

<div align="center">Outcomes Studies on Trigger Point Dry Needling</div>

The number of studies reporting the effects of trigger point dry needling to myofascial trigger points is rapidly increasing. Multiple studies have investigated the effect of trigger point dry needling various diagnoses. Specifically, TDN has been reported to be effective for shoulder

pain[30,157]; adhesive capsulitis[29]; neck pain[24,31,32]; cervical dizziness[39]; cervicogenic HA[157]; TMD[20,21]; LBP[19,28,40]; lateral epicondylalgia[21,41]; knee pain[42,155,158] ; and heel pain.[33] Specific improvements include decreased pain and increases in ROM, flexibility and strength.[35]

There is variability in the needling techniques performed across these studies. Several studies report performing the fast in and out technique [14,16,117,118,174,178] as described by Hong.[112] This was performed to point of exhausting the local twitch response of each trigger point. Cotchett et al also described keeping the monofilament in the trigger point for 5 minutes after it was evident the LTR were exhausted.[16]   However, the treatment protocol for the number of needle insertions into the trigger point or time point when needling was discontinued after the last LTR are not consistently reported in these studies.

Other studies reported using the needle rotation, or winding, technique with the dry needling. [113,175, 177] Once the LTR was exhausted, the need was rotated and then remained in the trigger point for a time ranging from 10 to 20 minutes.

Dry needling has been reported to effectively treat trigger points in the cervical[62,63] and lumbar regions,[12,47,64]shoulder,[65–67] elbow,[14] TMJ,[13,14] and plantar heel[16] as well as needling to the Achilles tendon with and without injection. [157,158]

Tendon Needling

Prior studies have reported on the effects of needling to the muscle and connective tissues.[77]   Needling to the tendon has also been studied. A systematic review by Krey was conducted were a total of 4 studies met the inclusion criteria for the review.[101] These studies were performed on subjects with lateral epicondylalgia, and tendinopathy of the rotator cuff and Achilles. [101] Results of the review indicate a beneficial effect of tendon needling on pain and

functional outcomes measures.   However, the study by Bell et al on tendon needling for Achilles tendinopathy did have mixed results.[56] In this study, tendon needling was compared to autologous injections to the Achilles.   Subjects in both groups also performed eccentric training for a period of 12 weeks.   Subjects in both groups did have clinically meaningful improvements in the VISA-A scores. However, the improvements in subject's perceived improvement score and return to sport were not statically significant at the 1, 2, 3 or 6 month measures.[56]

TDN vs Injection Therapy

Injection of trigger point is a common intervention for pain relief by physicians. The effect of TDN has been compared to that of injections with Lidocaine and Botulinum toxin. Kamanli et al[34] compared this treatment in patients with myofascial pain syndrome. Participants in this study were treated one time with TDN, Lidocaine or Botulinum toxin injection to trigger points in the upper trapezius. Results of their study indicate that all 3 treatment methods were effective in reducing pain and increasing pain pressure threshold as well as cervical AROM at 1 month post treatment.   However, Lidocaine and Botulinum toxin injections had a greater effect than TDN for pain and pain pressure threshold but additional benefits of treatment included.

Venancio et al also compared the effect of TDN, lidocaine and Botulinum toxin on headaches in patients with myofascial pain syndrome.[160] Patients were injected or needled in one session at 1 to 3 trigger points in the masseter, temporalis, upper trapezius or suboccipitals. TDN was used as the treatment for the control group. Pain was measured at 10 min and weeks 1,4, and 12 post treatment.   TDN resulted in a decrease in pain and rescue medication between week 1 and 4 but not at week 12. Lidocaine and BT resulted in a decrease in pain and rescue

medication at between weeks 1 and 12. However, results of the treatment show no significant

difference between groups.

Ga et al compared the effects of intramuscular stimulation, as described by Gunn, to

trigger point injections with lidocaine to trigger points in the upper trapezius on elderly subjects

with MPS.[161] All subjects were either treated with IMS or TPI one time a week for 3 weeks.

Results of the study indicate that both study groups demonstrated a significant increase in

cervical AROM while the IMS group was more effective than injection with lidocaine for pain

relief after 2 weeks and for reducing depression at 4 weeks.

Manual Therapy for Myofascial Trigger Points

Manual therapy techniques have been effectively used to treat myofascial trigger points.

Studies using trigger point pressure techniques report significant improvement in heel pain[162] and

neck pain with a treatment program including trigger point pressure to trigger points.

Contribution This Study Will Make to the Field of Physical Therapy

There is a growing number of studies in the electronic databases reporting the effects of

TDN on myofascial trigger points and tendons as well as functional improvements in subjects

with various diagnoses. However, the only studies with needling to subjects with Achilles

tendinopathy have been performed to the tendon, with and without injections. There is

significant variability in the needling protocols across these studies and also a low number of

high quality methodological designs. Clinical practice guidelines for physical therapy

management report the strongest evidence for treatment of Achilles tendinopathy is with

eccentric training. However, the results are slow with the most favorable outcomes reporting

improvements over a 4 or 5 year span.[13,14] Continued research is needed to find a more expedient outcome for people with this diagnosis.

There are several potential limitations to conducting a large randomized controlled trial with TDN for subjects with Achilles tendinopathy.   First, the available research does not provide a clear protocol for needling trigger points. Second, there are very few studies that have combined TDN with eccentric training. Both of these factors could lead to errors in determination for the treatment protocol and contribute to ineffective results or even cause aggravation of the injury and thus potentially harm to the subject. Third, potential subjects with needle phobia are not likely to volunteer for this study. Estimates of 10-21% of the population have needle phobia, [163,164] making it more difficult to recruit subjects. Finally, can a large enough sample size be recruited for this study to meet the predetermined power analysis for a randomized controlled trial. Therefore, a feasibility study can help to guide investigators to determine if a large study could be completed and also provide data to help develop the needling and eccentric training protocol.

The results of this study are relevant to all practitioners managing patients with posterior heel pain as well as investigators considering developing a large randomized controlled trial on trigger point dry needling for myofascial trigger points in patients Achilles tendinopathy. This includes physical therapists, primary care physicians, surgeons and podiatrists. The treatment protocol used in this study will guide the clinician in developing the plan of care and may result in a more expedient outcome for the patient.

Chapter 3 - Methodology

Introduction

Clinical practice guidelines for physical therapy management of Achilles tendinopathy report eccentric training for the triceps surae is the most effective treatment for Achilles tendinopathy.[6,15] According to these reviews, there is strong evidence for the use of eccentric strengthening and moderate evidence for laser and iontophoresis with dexamethasone. In addition, weak evidence exists for stretching and manual therapy with soft tissue mobilization. Tendon needling has also been reported as an effective treatment, but there are no studies that have investigated the effect of TDN to myofascial trigger points in patients with Achilles tendinopathy.

While the clinical practice guidelines report strong evidence for eccentric training, there is inconsistency with these studies. Systematic reviews on eccentric exercise indicate that there are an insufficient number of quality studies on eccentric exercise for Achilles tendinopathy to determine treatment parameters that are most effective for managing this disorder.[78,79] A systematic review by Meyer resulted in only 3 of 276 published studies meeting the criteria for the review and there was inconsistency in the exercise protocols among these 3 studies.[78] Therefore, a specific exercise protocol for optimal results has not been identified for Achilles tendinopathy.

Trigger point dry needling is an intervention that is becoming more commonly used by physical therapists.[18] Dry needling has been reported to effectively treat shoulder pain[30,157]; adhesive capsulitis[29]; neck pain[24,31,32]; cervical dizziness[39]; cervicogenic HA[157]; TMD[20,21]; LBP[19,28,40]; lateral epicondylalgia[21,41]; knee pain[42,155,158]; and heel pain[33] as well as needling to the Achilles tendon with and without injection.[157,158] However, no studies have been published

investigating the effect of dry needling on myofascial trigger points in the lower leg with Achilles tendinopathy.

The primary aim of this study was to test the feasibility of a randomized controlled trial investigating the effects of TDN to myofascial trigger points along with manual therapy and eccentric exercise in comparison to a treatment with manual therapy and eccentric exercise alone for subjects with Achilles tendinopathy.   In addition, the objectives for this study included the following:

1) report the access to participants with Achilles tendinopathy in private, outpatient physical therapy clinics

2) identify barriers for subject participation (injury severity, fear of needles, cost of care, time to complete study protocol and follow up)

3) describe the suitability of treatment protocol and assessment procedures

4) report the participants adherence to treatment

5) report the attrition rate with follow up data collection

6) calculate within-group treatment effects

The determination of the feasibility was based in part by meeting the following conditions: 1) the 4 week attrition rate less than 20%; 2) no adverse responses reported; and 3) at least 75% of patients complete follow up assessment data. The research methodology is described along with the description of participants in the study. The treatment was completed by licensed physical therapists that are certified to perform TDN and the recruitment process is outlined as well.

Research Design and Methodology

Study Design

The study is a feasibility study conducted with a single-factor, pretest-posttest control group design. The independent variables were treatment (trigger point dry needling or exercise) and time. Data was collected at three intervals from baseline at the initial examination, at the conclusion of treatment at 4 weeks and follow up at three months. The primary dependent variable was the Foot and Ankle Ability Measure (FAAM) while the secondary dependent variables were pain pressure threshold (PPT) measured with an algometer, global rating of change (GROC), numeric pain rating scale (NPRS), and muscle endurance. CONSORT guidelines were followed for reporting the results of this study.

Participating Investigators - Data Collection

All data collection and treatments were performed by licensed physical therapists certified to perform trigger point dry needling according to the practice act in the state of their employment. All treatments were performed in physical therapy clinics and the participants were asked to maintain an independent exercise program between therapy sessions and for 3 months following the last treatment session. The primary investigator has over 20 years of clinical practice and over 6 years of experience performing trigger point dry needling. There were 7 additional physical therapists who contributed to the data collection. Each clinician maintains practice in separate clinics in the States of North Carolina, Tennessee or Iowa. The clinical experience ranges from 2 to 20 years and all clinicians have been certified to perform trigger point dry needling for over 1 year. The primary investigator will conduct a training session for each clinician contributing to data collection as well as a research assistant in each

clinic who will remain blinded to the group assignment for each participant but will assist with the process of randomization.

Recruitment of Participants

Participants will be recruited by convenience sampling by way of referral to physical therapy from 1) podiatrists, or 2) physicians, physician assistants or nurse practitioners from specialty practices including sports medicine, orthopedic or family medicine in accordance with the physical therapy practice act in the respective state.

In an effort to enhance recruitment, podiatrists in the region each clinic resides were contacted by phone and informed of the study and asked if they will be willing to refer patients with Achilles tendinopathy to the specified clinics. Every effort was made by the primary investigator or research assistants to perform a site visit to each podiatrist to discuss the background information and research methodology. An information flyer was sent to all the physicians in the region for each clinic that are considered common referral sources by each physical therapist collecting data. See Appendix A for the template of the physician letter.

Description of Participants

Participants were between the ages of 18 and 70 years with a primary complaint of posterior heel pain. Consecutive patients presenting to the data collection facilities were eligible to participate in the study. Participants were informed of the study by the office coordinator and given a flyer that describes the study. This gave the participant an opportunity to consider their interest in consenting to the study and to reduce the potential for persuasion by the physical

therapist during the examination. See appendix B for the template of the participant recruitment letter.

The physical therapist completed a patient interview and pre-screen for any participant willing to give consent to the study. Informed consent was given for review and once signed, self-report measures was completed and then the examination was conducted. See Appendix C for the flow sheet of the participant recruitment process.

Inclusion Criteria

The following conditions were met for the participant to be eligible to participate in the study:

1. Participants were between the ages of 18-70 years
2. subjective report of the primary location of pain at any point along the in the Achilles tendon
3. Pain present ≥ 4 weeks
4. positive Achilles palpation test
5. positive Royal London test
6. decreased plantar flexion endurance test vs non-involved leg

Exclusion Criteria

Any of the following conditions excluded subjects from participating in the study:

1. fear of needles or unwilling to have needling performed due to fear or personal beliefs[75]

2. vascular or sensory disturbances in the lower leg which included but was not limited to injury to the nerve root or peripheral nerve in the affected lower leg, inflammatory diseases, bleeding or clotting disorders, lymphedema, peripheral vascular or peripheral arterial disease. Diabetes was included in this group due to the progressive changes to the sensation and circulation in the lower extremities.

3. recent infection

4. previous surgery to the foot/ankle

5. steroid by injection or transdermal delivery to the posterior heel within three months

6. full rupture of the Achilles tendon

7. pregnant or may be pregnant

8. Tampa Scale for Kinesiophobia > 37[13]

9. participants with a work related injury insured by the bureau of worker's compensation or involved in litigation related to injury of the lower leg, foot or ankle

Self-Report Measures

The FAAM, TSK, GROC and NPRS are the self-report measures selected for this study. Each of these measures can be found in Appendix D.

The FAAM has been determined to be a valid measure for ankle disorders, including Achilles tendinopathy.[6,165] This measure has a 21 question ADL and an 8 question sports subscale. Only the ADL subscale was used for this study as participants in this study were not limited to an athletic population. Each question was scored with a Likert scale ranging from zero ("unable to do") to four ("no difficulty") with the higher number representing a higher level of function. There is an option for no response in the scale and not all questions need to be

answered. The maximum score on the ADL subscale is 84 if all questions are answered. If one of the 21 questions is not answered, then the maximum score would be 80. The total points of the participant's responses will be added and then divided by the maximum possible score and then multiplied by 100 to determine their level of ability. The MCID for the ADL subscale is 8.[165] During the development of the FAAM and testing for reliability and validity, only those responses that answered 90% of the questions were included in the analysis.[165] Therefore, the same criteria was used for the present study.

The TSK was used to assess the level of fear of movement. This is a 17-item questionnaire scored on a 4 point Likert scale with total test scores ranging from 17 and 68. Higher scores indicate higher levels of fear of movement. This test was included in this study based on the recommendation of Silbernagle et al. from the results of 5 year follow up on eccentric strengthening for Achilles tendinopathy.[13] Silbernagle reported subjects in this follow up trial that had high levels of kinesiophobia has less recovery with the muscle endurance measures and therefore, a cut off score of 37 on the TSK was recommended.[13] The Swedish version of the TSK was used in the Silbernagle et al study which is reliable and valid for the Swedish population but the English version will be used for this present study.

The global rating of change is a 15 point scale developed by Jaeschke[166] that is used to determine the patient's judgment of the amount change they have achieved over a period of time. The score ranges from -7 ("a very great deal worse") to +7 ("a very great deal better") with 0 as the mid-point representing no change. In this study, the GROC was used to record the patient's determination of the amount of change they perceive between the initial examination and the discharge exam after completing 8 treatment sessions and again at the three month follow up. The minimally clinically important difference is 3 points.[166]

The NPRS was used to obtain the subjective pain intensity rating. This is a valid measure with an MCID of 2. Three scales will be used to determine: 1) worst level of pain in the last 24 hours, 2) best level of pain in the last 24 hours, and 3) pain at the present time. The average of these three ratings will be used for data analysis. The NPRS was included along with a body diagram which was used in part to determine inclusion to the study.

Physical Examination

The clinician conducted a comprehensive physical examination to the lower leg, ankle and foot to determine the diagnosis of Achilles tendinopathy as well as the presence of myofascial trigger points. Tests and measures were performed for differential diagnosis to rule out conditions that would exclude participants from the study. In addition, a screen was conducted for impairments in the lumbar spine, hip and knee that could contribute to the complaint of posterior heel pain or interfere with the participant's ability to perform the interventions outlined for this study.

Examination for Achilles Tendinopathy

The physical examination to test for Achilles tendinopathy include the following tests:

1. Observation for swelling and tendon thickening in the region of the tendon and insertion.

2. Palpation: Palpation along the Achilles tendon for inflammation, tendon thickening and pain report. The therapist will palpate the tendon beginning at the insertion site at the calcaneus and gradually move proximally along the tendon asking the patient to indicate the location of the greatest pain. This area will be marked with a pen and

then measured from the most distal point of the calcaneus. This measure will be recorded and used for pain pressure threshold testing at the initial examination as well as at the discharge and follow up examinations.

3. The Royal London test. The therapist palpates the Achilles tendon while the participant is lying prone. The most painful area of the Achilles tendon is located while the patient is at rest. The participant is asked to actively dorsiflex the ankle and the precise location of the tendon is palpated again. A positive test for tendinopathy occurs when pain is reduced in the full dorsiflexed position. This test has a sensitivity of .54 and specificity of .91.[6,167]

4. Arc sign: with the patient prone, the therapist observed and palpated the Achilles tendon to determine the area of greatest swelling. The patient was asked to perform active dorsiflexion and plantar flexion. The test is positive if the region of swelling moves proximal and distal and the ankle dorsi- and plantar flexes. This test has a sensitivity of .52 and specificity of .83 for Achilles tendinopathy and can assist in ruling out retrocalcaneal bursitis.[6,167]

5. Plantar flexion endurance test: This test was recommended in the APTA clinical practice guidelines[6] and has good reliability.[167] This test includes a unilateral heel raise with the patient standing and the knee straight and able to lift the heel to a height of 5 cm.[162] The patient will perform as many repetitions as possible at a pace of 40 beats per minute monitored with the use of a metronome.[162] The test concludes when the patient is unable to complete a full heel raise due to either pain or fatigue. The number of completed repetitions were recorded and included in the data analysis at the initial examination, discharge and follow up examinations at three months.

6. The PPT test: Pain threshold was assessed with the PainTest^{TM} algometer by Wagner Instruments.[168] This pain pressure algometer was used to determine the amount of pressure the participant can tolerate on the Achilles tendon before the onset of pain. Each clinician was supplied with a FPK 20 PainTest^{TM} Algometer by Wagner Instruments. The algometer has a 1 cm^2 tip with rubber pad, a dial with graduated increments in lbs and kg along with a push button lock to maintain maximum pressure measurement to ensure accuracy of recording. The rubber tip of the algometer was placed on the posterior aspect of the Achilles tendon, directly over the mark indicating the most painful location. The protocol for PPT measure was adopted from Renan-Ordine.[162] Pressure was applied gradually by the therapist until the patient indicated they begin to feel pain. A total of 3 trials were performed and the mean was used in the data analysis. The amount of pressure was recorded and included in the data analysis. There are no published reports found in the published literature that describes a normative value for pain pressure threshold with Achilles tendinopathy. Therefore, the mean of the 3 measures was used for the within group analysis rather than calculated against a normative value. This test was the last procedure performed in the examination due to the potential for producing more irritation to the tendon which could then affect the participant's ability to perform any of the remaining examination procedures. Pain pressure threshold measures were taken at the initial examination, at discharge as well as the three month follow up examination.

Examination for Myofascial Trigger Points

Palpation has been found to be a reliable measure for locating myofascial trigger points without the use of MRI or ultrasound imaging.[75,114,137] Palpation was performed for myofascial trigger points in the gastrocnemius and soleus with the participant in the prone position while the tibialis posterior can be accessed better with the participant laying on the involved side. Either a pincer or flat palpation method were used for trigger points throughout these three muscles. Criteria for diagnosing a trigger point include: presence of a taut band; a hypersensitive nodule within that taut band; local twitch response with a snapping maneuver over the trigger point; reproduction of referred pain.[70,75] The location of the trigger points were recorded on the examination data sheet and were the sites for TDN and manual therapy during the treatment sessions.

Travell and Simons have identified trigger points located in the proximal region of the lateral and distal region of the medial gastrocnemius that can refer pain to the central aspect of the posterior lower leg and posterior heel.[70] Additionally, trigger points in the medial soleus and the tibialis posterior may also refer pain to the posterior heel and centrally in the posterior lower leg.[70] Trigger points in the gastrocnemius and soleus can alter the flexibility and strength of these muscles resulting in altered biomechanics that may have contributed to the onset Achilles tendinopathy.[48]

Differential Diagnosis

According to the recommendations in the Clinical Practice Guidelines, the following conditions should be ruled out[6]:

- Acute Achilles tendon rupture
- Partial tear of the Achilles tendon

- Achilles tendon ossification
- Retrocalcaneal bursitis
- Posterior ankle impingement
- Os trigonum syndrome
- Accessory soleus muscle
- Irritation or neuroma of the sural nerve
- Systemic inflammatory disease

a. Acute Achilles tendon rupture: The clinic practice guidelines from the American Association of Orthopedic Surgeons recommends that 2 of the following 4 tests be performed to determine the presence of an acute Achilles tendon rupture[7]:

- clinical Thompson test
- presence of a gap or defect upon palpation
- weakness with plantar flexion strength testing
- increased dorsiflexion with gentle passive testing

The clinical Thompson test is performed by the patient standing with the involved leg flexed at the knee and the lower leg resting on a chair. The clinician squeezes the gastrocnemius and soleus. If the foot does not plantar flex, then the test is positive for a rupture.[169] The AAOS recommends this based on consensus and expert opinion. Garras et al performed a retrospective analysis comparing the results of the clinical examination and MRI to surgical observations for acute Achilles tendon ruptures.[170] In this study, the clinical examination tests including the Thompson test, decreased resting tension of the ankle and a palpable defect in the Achilles tendon were 100% accurate when all three were positive while MRI was 90.9%.[170] Therefore, the clinical examination is accurate and can be completed without use of radiological imaging to determine the presence of a rupture. Participants who test positive for an acute Achilles rupture will not be included in this study.

b. Partial tear Achilles tendon: The Achilles tendon is comprises of three bundles of tendons, from the soleus, medial and lateral gastrocnemius, one from each.[171] Partial tears are often acute but may also result from overuse. Smigielski developed a classification for partial tears. A type 1 tear occurs when injury occurs within one bundle. A type 2 tear occurs with injury within two bundles while type 3 has injury within all 3 bundles.[171] Diagnosis by clinical examination is difficult and may depend on the duration of symptoms and location of the tear. Reliability and validity statistics for clinical tests on Achilles rupture are based on the presence of a complete rupture, not a partial rupture.[170] Defects may or may not be palpable depending on the size of the tear, location within the tendon bundle or the duration of injury as scarring may have filled in a defect.[171] The Thompson test alone may not be able to distinguish full from partial tears.[169] Ultrasound imaging or MRI are both valid imaging tests for detecting partial tears. However, in the primary investigators clinical experience, many health insurance companies will not approve payment for radiologic imaging unless physical therapy has been initiated. There is general disagreement in the medical community on the clinical pathway for management of the partial tear, surgical or conservative.[172] There were three meta-analyses published in 2012 that report no significant difference in functional outcomes between surgical and conservative management of Achilles tendon ruptures.[173–175] Recent clinical trials report no differences in the re-rupture rate of the Achilles between the surgical vs non-surgical treatment when early controlled motion was initiated.[12,176,177] At the present time, the clinical examination may not be able to detect a partial tear. However, initiating physical therapy with early controlled motion as previously

described, which is included in the treatment protocol for this study, does not pose added risk for re-rupture of the Achilles tendon compared to treatment following surgery. Therefore, presence of a partial tear of the Achilles will not automatically exclude a participant from this study.

c. Ossification of the Achilles tendon: Ossification is a rare event and has been reported to occur primarily following previous injury to the Achilles tendon where partial or full thickness rupture occurred, in the presence of metabolic conditions or sero-negative arthropaties.[178,179] Pain can be reported with ossification but often the condition is not painful and no treatment is warranted. However, surgical excision and tendon reconstruction is performed in cases of fracture of the bony tissue.[178,179] The clinical examination for tendon ossification is limited as there are no special tests identified for this condition. However, the ossified tendon will be hard on palpation and may be correlated with history of previous injury or medical conditions. If the physical therapist suspects the presence of Achilles tendon ossification, the patient will be referred back to the physician or podiatrist for further examination and radiologic imaging to rule out ossification prior to participation in the study.

d. Retrocalcaneal bursitis: This condition can be identified by the presence of swelling distally at the Achilles insertion along with tenderness lateral to the tendon are common with retrocalcaneal bursitis.[7] A Haglund's deformity is often present and is also located lateral to the Achilles insertion. Pain increases with prolonged walking or standing and additionally, pain may increase at rest while wearing shoes with a closed heel.[7,51] This diagnosis can be ruled out with a clinical examination.

e. Os trigonum: The os trigonum is an accessory bone that develops posterior to the lateral tubercle of the tibia primarily in children between the ages of 8 and 11.[180] In 14% of cases, this accessory bone develops a synchondrosis joint with the tibia.[180,181] Pain and inflammation may develop with forceful or repeated plantar flexion. Pain remains in the posterior heel and is often present with posterior ankle impingement. Palpation of the posterior talocrural joint and the posterior ankle impingement test (described below) can reproduce pain due to the presence of os trigonum.[180] Although, x-ray or bone scan may be needed to determine if a fracture has occurred.

f. Posterior ankle impingement: The onset of posterior ankle impingement is due to forced plantar flexion and often presents as a chronic injury.[180] Impingement occurs as the posterior tubercle of the talus contacts the distal end of the calcaneus during plantar flexion. Repetitive plantar flexion produces inflammation and may also lead to inflammation of the synchondrosis joint or the tendon of flexor halluces longus.

g. Accessory soleus muscle: This is a rare congenital anomaly is located anterior to the soleus.[182]   It is estimated to be present in 0.7 to 5.5% of the population but only 70 symptomatic cases have been reported between 1965 and 1996 and 100 cases from 1869 to 1995.[182] Reported symptoms often include pain and soft tissue swelling in the medial aspect of the distal lower leg that increases with exercise and relieves with rest.[182] Reported cases have also presented with symptoms similar to compartment syndrome.[182] There are no reports describing clinical tests to identify the presence of an accessory soleus muscle found in the published literature. Therefore, radiological imaging is needed when this is suspected.

h. Irritation or neuroma of the sural nerve: presence of neurologic symptoms will immediately exclude participation from this study.

i. Systemic inflammatory disease: patients with known systemic inflammatory disease will not be included in this study.

Remaining Examination Tests and Measures

1. Range of Motion: tri-planar active ROM will be measured with a universal goniometer for the ankle but only the dorsiflexion measure will be included in the data analysis. For the dorsiflexion measure, the patient will be laying supine with measures taken while the knee is extended to 0 degrees and flexed to 45 degrees. This measure will indicate the flexibility of the gastrocnemius and soleus muscles respectively and used for consideration for modifying the ROM during eccentric strengthening.[6]

2. Strength assessment: manual muscle testing will be performed for myotomes L4-S2 to assist in ruling out nerve injury.

3. Sensory testing: response to light touch will be assessed for L4-S1 dermatomes in the involved lower leg.

4. Vascular testing: assessment of the dorsal pedal pulse as well as observation for changes in skin condition, toe nails, and capillary refill.

5. Screening the lumbar spine, hip and knee to determine if any deficits or impairments are present that may interfere with the participant's ability to perform the interventions and exercises outlined in this study.

Random Group Assignment

Data was collected in eight outpatient physical therapy clinics: Breakthrough Physical Therapy in Morehead City, NC; two Breakthrough Physical Therapy clinics in Fayetteville NC, Dunn Physical Therapy in Apex, NC; two Benchmark physical therapy clinics in metro region of Knoxville, TN; and Eastern Iowa Physical Therapy in Wilton, IA. The process for random assignment were the same for each clinic and were done independent of each respective clinic. Each participant was assigned to the dry needling or exercise group by random assignment by a blinded research assistant. A blocked randomization procedure was used to balance the participants among groups. Prior to beginning the study, a blinded research assistant who was not involved in the treatment or data collection, produced a computer generated blocked randomization sequence[188] using 20 numbers with 3 block sizes of 4, 6, and 8. The research assistant wrote the group number (group 1 for TDN + MT + Ex and group 2 for MT + Ex) on an index card, folded it and place it in an envelope. A number, 1-20, was placed on the outside of the envelope that corresponds to the order that participants are entered into the study. The participant was assigned to a group through concealed allocation at the conclusion of the examination. The physical therapist informed the research assistant that an envelope was needed, and that assistant selected the envelope and presented it to the participant who would then open in the presence of only the treating physical therapist, allowing the assistant to remain blinded to the group assignment. Each clinic was encouraged to continue with data collection until a combined total of a minimum of 33 participants for each group have completed the study and was notified by the primary investigator when data collection for the study can be concluded. Each clinic was not limited to the total number of participants that could be included into the study. If a clinic was able to collect data on more than 20 participants, they would need to repeat the process as described. A total of 66 participants were needed to meet the power analysis for this study. Therefore, data collection was planned to continue until a minimum of 33 participants in each group combined from each clinic have completed the treatment protocol.

Interventions

Participants began treatment on the day of the examination. Once the participant was randomized into a group, treatment began. If the participant was unable to complete the treatment on the day of the examination, then treatment began on the day of the next scheduled appointment. For those participants, the physical therapist answered questions and educated the participant about Achilles tendinopathy which is standard practice for physical therapy. However, no interventions were performed, and no exercise was instructed for an independent home program until the participant returned for the next treatment. This session was their second visit to the clinic, but it was recorded as treatment number one.

Participants in **both groups** were treated in the clinic twice a week for four weeks for a total of eight treatment sessions. Each treatment session for Group 1 (MT + Ex) included the following interventions in order: 1) stationary bike x 5 minutes; 2) soft tissue mobilization for trigger points in the gastrocnemius and soleus; 3) stretches for gastrocnemius and soleus in standing and hamstrings in supine or sitting with towel assist; 4) eccentric unilateral heel raises; 5) resisted ankle adduction for tibialis posterior emphasis; 6) resisted towel crunches for intrinsic strengthening; and 7) application of gel ice pack x 15 minutes. Each treatment session for Group 2 (TDN + MT + Ex) included the following interventions in order: 1) stationary bike x 5 minutes; 2) trigger point dry needling to a maximum of 4 trigger points in any or all of the following muscles: tibialis posterior, soleus, medial and lateral gastrocnemius. See Appendix E for detailed TDN protocol. 3) soft tissue mobilization for trigger points in the gastrocnemius and soleus; 4) stretches for gastrocnemius and soleus in standing and hamstrings in supine or sitting with towel assist; 5) eccentric unilateral heel raises; 6) resisted ankle adduction for tibialis posterior emphasis; 7) resisted towel crunches for intrinsic strengthening; and 8) application of

gel ice pack x 15 minutes.   See Appendix F for description of the soft tissue mobilization technique and each exercise in the treatment protocol.

A discharge examination was completed immediately following all interventions during the eighth treatment session.   At this visit, participants completed the FAAM, PPT, TSK, GROC, NPRS, and muscle endurance testing. The gel ice pack was applied at the conclusion of all examination procedures and self-report measures at the eighth treatment session. Participants were instructed to continue with the exercise program independently and return for a follow up examination at three months after the completion of the last treatment session.   The three month follow up examination included the FAAM, PPT, TSK, GROC, NPRS, and muscle endurance tests.   See appendix G for a flow diagram and detailed description of each intervention and exercise.

Data Analysis

The independent variable in this study was trigger point dry needling and time while the primary dependent variable was FAAM and the secondary dependent variables were PPT, GROC, NPRS and plantar flexion endurance test. Descriptive statistics were used to analyze data including participant adherence to treatment, attrition rate and baseline demographics. This data includes gender, age, and estimated duration of symptoms measured in days. Categorical variables were calculated with frequency counts while continuous variables were calculated with measures of central tendency.

Friedman's Test / Two Way Analysis of Variance by Ranks was conducted to assess effect size, changes in FAAM, PPT, GROC, NPRS and plantar flexion endurance measures for within groups interaction at baseline, 4 weeks and 3 months. Level of significance will be set a p

= .05. Data analysis was performed with SPSS. An intention to treat analysis was utilized for drop outs and the previous number recorded was used to replace any missing data. An explanation is provided pertaining to the reason for each participant that dropped out of the study.

Race, Gender, Religion and Ethnicity

Participants were not discriminated against for their race, gender, religious affiliation, ethnicity, or sexual orientation. There is no plan to have an equal number of men and women in this study.

IRB

Approval for this study was sought with the IRB at Nova Southeastern University. Data was not collected until the board granted approval.

Risks and Benefits

Participants in this study achieved the benefit of reduced pain and improved function as a result of the proposed treatment protocol for both groups. While there are no studies found in the published literature on the effects of TDN on myofascial trigger points in Achilles tendinopathy, there are several studies reporting on the beneficial effects of TDN for the cervical, TMJ, shoulder, elbow and lumbar regions. Therefore, the treatment protocol was expected to benefit participants in both groups.

There are known risks with trigger point dry needling. The majority of published data reporting adverse events with dry needling contain data from acupuncturists.[52,184,185] However,

Brady et al published the results of their prospective trial including 39 physiotherapists in Ireland.[83] In this study, 39 physiotherapists trained from the same institute performed a total of 7629 treatments including TDN for myofascial pain over a span of 10 months. Adverse events were categorized as either mild or significant adverse events. In this study, no significant adverse events were reported while a total of 1463 mild adverse events occurred which amounted to 19% of the treatments. The specific mild adverse events were reported and include: bruising at 7.55%; bleeding at 4.65%; pain during treatment 3.01%; pain after treatment at 2.19%. Additional adverse events were reported and classified as "uncommon" and include aggravation of symptoms at 0.88%, drowsiness 0.26%, headache 0.14%, and nausea 0.13%.[83]

Park performed a systematic review with meta-analysis on acupuncture for ankle sprain.[52] A total of 17 trials were included in the analysis. In this review, only 2 studies reported adverse events, and each were the result of an allergy to medication or herbs while no adverse event was reported to result from the acupuncture treatment.

Additional studies reporting adverse events related to acupuncture treatment included treatment to all body regions rather than to the ankle only as reported with Park. White et al reported no serious adverse events in 31,822 treatments.[184] Bleeding or hematoma had an incidence of 310 per 10,000 treatments while needling pain and aggravation of symptoms had an incidence of 110 and 96 per 10,000, respectively.

Witt et al reported on the frequency of adverse events from patient experience over a span of treatments.[185] In their study, 229,230 patients had received a mean of 10.2 acupuncture treatments. Of these patients, 8.6% reported experiencing at least one minor adverse event throughout the course of all the treatments while 2.2% reported one serious adverse event that required medical treatment. Bleeding or hematoma accounted for 58% of the total adverse

events and was reported by 6.1% of the patients. An increase in pain was reported by 1.7% of

the patients. More serious adverse events include infection was reported in 0.014%, nerve injury

by 0.26%, and broken needle by 0.001% of the patients.[185]

Given the large number of patients and treatments in these published reports, the majority

of adverse events from TDN or acupuncture are judged to be mild. Serious adverse events

including but not limited to infection, nerve injury and broken needles are rare and the risks can

be minimized by following proper guidelines for TDN and following proper hygiene and safety

methods.[75] In this study, OSHA guidelines for proper hygiene and disposal of needles or bloody

dressing will be followed.

Data Safety Monitoring Plan and Subject Confidentiality

Every effort was made to maintain confidentiality for each participant in the study. Each

participant was given an identification code that was used on all data collection documents. The

identity of each participant was known only to the physical therapist performing the treatment,

the primary investigator and dissertation committee. This information will remain confidential

and will not be used in any of the reports or publications pertaining to this study. The data

collection paper documents are stored in a locked file in the physical therapy clinic where the

treatments are performed. Electronic files with data collection documents are stored on data

storage devices that are stored in a locked cabinet along with the files and transmitted

electronically to a secured Dropbox account of the primary investigator. Each physical therapist

submitted to the primary investigator the data collected for each participant after the examination

is complete, at the discharge examination and the 90 day follow up exam. The primary

investigator kept electronic files on a storage disk and keep paper copies in a locked, fireproof storage bin at his personal residence.

Adverse events were to be immediately reported to the primary investigator. The primary investigator would conduct a phone interview of the participant. Photos could be taken with permission by the participant for documentation of skin irritation or bruising. If medical attention was needed, the physical therapist who performed the treatment would contact the referring medical provider to report the event and allow the medical provider to determine the appropriate action. The IRB would be informed of any adverse event that was judged to be greater than the severity described in the informed consent document.

Funding for the Study

There was no external funding for this study. Grants have not been applied for to cover the costs associated with this study. Costs associated with purchasing supplies and travel were funded personally by the primary investigator.

Compensation

There was no compensation for the participants in this study. Each participant received treatment for their diagnosis which was expected to be of benefit to the participant. There were no additional fees assessed to the participant for the treatment supplies used throughout this study. The physical therapists participating in data collection volunteered their participation and no compensation was provided for them.

Summary

This chapter describes the research method and data analysis for the study. The results of this study are expected to benefit investigators who are considering developing a large, randomized controlled trial on the effects of TDN on myofascial trigger points in patients with Achilles tendinopathy. In addition, this study is intended to provide physical therapists, podiatrists and physicians additional information to aid in the development of an effective treatment plan for managing Achilles tendinopathy.

Chapter 4 - Results

Introduction

The primary aim of this study was to test the feasibility of a randomized controlled trial investigating the effects of TDN to myofascial trigger points in addition to manual therapy and eccentric exercise in compared to manual therapy and eccentric exercise alone for individuals with Achilles tendinopathy.   In addition, the objectives for this study included the following:

1) report the access to participants with Achilles tendinopathy in private, outpatient physical therapy clinics

2) identify barriers for subject participation

3) describe the suitability of treatment protocol and assessment procedures

4) report the participants adherence to treatment

5) report the attrition rate with follow up data collection

6) calculate within-group treatment effects

The determination of the feasibility was based in part by meeting the following conditions: 1) the 4 week attrition rate less than 20%; 2) no serious adverse responses reported as described by Brady et al[83]; and 3) at least 75% of patients complete the 3 month follow up assessment data. The research methodology is described along with the description of participants in the study. The treatment was completed by licensed physical therapists that are certified to perform TDN and the recruitment process is outlined as well.   Data analysis was conducted with SPSS version 25. Simple means were calculated with MS excel 2016.

Study Objectives

Access to Participants

Data collection began in May 2015 and commenced on August 1st, 2018. During this

time a total of 70 subjects were referred with Achilles tendinopathy and 34 subjects met the

inclusion criteria. Data on referrals is shown in Table 4.1. There were 36 subjects (51.6% of

referrals) who were not eligible to participate in the study. There were 34 subjects (48.6%) who

met the inclusion and 22 subjects (31.4%) who agreed to participate and signed informed

consent. The flow diagram of subject recruitment and retention is described in Figure 4.1.

Table 4.1: Referrals to Participating Clinics

Year	Referred for Achilles	Met Inclusion	Entered Study	Completed Study
2015	33	8	5	5
2016	19	16	13	10
2017	9	4	3	2
2018	9	6	1	1
Total	**70**	**34**	**22**	**18**

Barriers to Subject Participation

There were 12 patients (17.1% of referrals) who were eligible to participate in the study

that declined. These patients declined participation for the following reasons:

- averse to needle stick to painful trigger points (4)

- time commitment (2)

- finances (6)

These patients did continue to seek physical therapy treatment at the data collection sites. Data

on the outcomes of these patients was not collected.

Figure 4.1: Flow Diagram of Subject Recruitment and Retention

Assessed for Eligibility (n=70)

Excluded (n=36)
- Insertional tendinopathy (2015 only) (25)
- Injections (4)
- PMHx Diabetes (2)
- PMHx fracture/surgery (1)
- Fear of needles (4)

Eligible (n = 34)

Declined to participate (n=12)
- Averse to needle stick to painful trigger point (4)
- time commitment (2)
- finances (6)

Randomized (n = 22)

Allocated to Group 1 (Ex+MT)
- (n=10)

Allocated to Group 2 (TDN+Ex+MT)
- (n = 12)

Discharge at 4 weeks
- N = 9
- 1 subject dropped out

Discharge at 4 weeks
- N = 9
- 3 subjects dropped out

3 month follow up
- N = 4
- 5 subjects lost to follow up

3 month follow up
- N = 3
- 6 subjects lost to follow up

There were 4 subjects who voluntarily discontinued participation in the study resulting in a drop out rate of 18.1%. Reasons for drop out include family emergency that resulted in extended delay upon return to treatment; time commitment due to family responsibilities; slow progress and returned to referring provider; one subject did not return for the final treatment session and discharge data collection despite reports of improved pain and functional activity tolerance.

There was a gradual decline in referrals for Achilles tendinopathy to data collection sites over the period of data collection. The first year had a total of 33 referrals which included 25 diagnosed with insertional tendinopathy. The inclusion criteria at this point in the study was limited to non-insertional tendinopathy. Therefore, these subjects were not eligible to participate. The second year of the study (2016), the inclusion criteria was expanded to include insertional and non-insertional Achilles tendinopathy. There was a total of 19 referrals with both diagnoses combined in the second year and then 9 for each of the third (2017) and fourth year (2018) of the study.

Suitability of Study Assessment and Treatment Protocol

Feedback from the research assistants collected from interviews indicate that the time commitment associated with this study was reasonable for the initial examination and completing all required study measures. Research assistants reported that all components of the initial exam, informed consent and completion of self report forms were completed in less than 1 hour. Patient volumes for each research assistant ranged from 1.5 to 2.5 patients per hour during the period of data collection. They reported that subject recruitment and data collection did not

interfere with their ability to maintain their responsibility to patient care in their respective clinics.

Subject Adherence to Treatment

Subjects reported compliance with the home exercise program during the 4 week intervention period. However, there were no compliance forms for the subjects to complete or other mechanism to verify accuracy with the subject report.   There were no reported serious adverse events to the treatment protocol for subjects in either group. Subjects in both groups reported soreness in the lower leg following treatment sessions that ranged between 1-2 points higher in the NPRS from the pain level at the start of each treatment session. All subjects in the needling group, reported soreness at the needling sites during and at the conclusion of each treatment session. The research assistants reassessed the subjects each treatment session to verify the location and severity of soreness did not indicate injury to the Achilles tendon or muscles in the lower leg. There were no drop outs from the study as a result of soreness that occurred due to TDN.   There were no drop outs from the exercise group due to soreness occurring from the treatment protocol.

Attrition Rate with Follow Up Data Collection

There were 7 subjects who returned for the 3 month follow up and 11 subjects did not return. The attrition rate for the 3 month data collection was 61%. The 11 subjects who were lost to follow up could not be reached by phone and did not respond to email.

There were four subjects who dropped out of the study, three were in the needling group and one in the exercise group. This resulted in an 18.1% drop out rate. The subject in the

exercise group reported slow progress and requested dropping out of the study after three treatment sessions. There was a phone call follow up with this subject who reported they did return to the referring provider for continued medical management. Surgery was not performed, and no additional follow up data is available on this subject. Of the three subjects in the needling group, one subject reported a family emergency that required extended travel and was not able to attend treatment at the participating physical therapy clinic to meet the study requirements for treatment frequency and duration. This subject completed three treatment sessions and did not return to the data collection site for treatment. A second subject completed six treatments and was reporting slow progress with pain intensity and return to commonly performed ADL's. She returned to the referring provider for further examination and did not return to complete the remaining 2 treatments. Multiple attempts were made to contact this subject over a period of 2 weeks. A phone log was not recorded on this subject for a precise account of the attempted contacts. No additional information on the status on this subject is available. The third subject dropped out after one treatment reporting time constraints due to family obligations and could not meet the conditions for participation. This subject did not return to the data collection site for continued treatment.

Within-Group Treatment Effects

Table 4.2 presents the demographic data on subjects in both groups. Means are presented for each group. Height was measured in inches, weight in pounds and pain duration in weeks. There is similarity in all characteristics between groups. There was a 10 week difference in the pain duration between groups. However, this difference is not likely to contribute to differences in presentation or results since the pain duration exceeds 6 months for both groups.

Table 4.2: Demographic Data

	Group 1 (MT+Ex)	Group 2 (TDN+MT+Ex)
Age	45.7	41.9
Height	69.9	66.9
Weight	187.9	189.3
BMI	27.3	29.7
Pain Duration	31.0	41.2

Frequency counts for the pain location are shown in Table 4.3. For the 18 subjects who completed the four week treatment protocol, 7 were diagnosed with insertional and 11 with non-insertional tendinopathy.

Table 4.3: Diagnosis

	Frequency	Percent
0	7	38.9
1	11	61.1
Total	**18**	**100**

0 = insertional tendinopathy
1= non-insertional tendinopathy

Dependent variables were FAAM, NPRS, GROC, PPT and plantar flexion strength. The primary dependent variable was the FAAM. A within group analysis for both groups included means and Friedman's Two Way Analysis of Variance by Ranks test were computed for all dependent variables. Significance was set at $p < .05$. An intention to treat analysis was performed. Missing data was recoded by using the mean for the group for initial examination. All other missing data was carried forward from the previous reported measure. Missing data for the Friedman's test was replaced by the mean of the ranks. For subjects who completed the 4 week treatment protocol but did not return for the 3 month follow up data collection, the missing data was the mean of 2 ranks which equates to either 1.5 or 2.5. For subjects who dropped out, the missing data was replaced by the mean of 3 ranks, which equates to a rank of 2.

The within group means, and significance for all tests and measures are provided in Tables 4.4

and 4.5 as shown below.

Table 4.4: Group 1 (MT+Ex) mean scores for tests and measures, change
scores from baseline to 4 weeks and baseline to 3 months

Tests and Measures	Group 1 (MT+Ex group)					
	Baseline	4 week	3 Month	Mean Within Group Change (Baseline to 4 weeks)	Mean Within Group Change (Baseline to 3 Months)	p-value
FAAM	59	86	85	24.0	28.0	*0.002
NPRS	5.8	2.7	1.7	3.1	4.0	*0.001
GROC	NA	4.8	6.1	NA	1.3	*0.046
PPT	2.3	4.7	5.3	2.4	3.3	*0.000
Strength	17.2	24.5	26.2	7.3	9.0	*0.008

Table 4.5: Group 2 (TDN+MT+Ex) mean scores for tests and measures,
change scores from baseline to 4 weeks and baseline to 3 months

Tests and Measures	Baseline	4 week	3 Month	Mean Within Group Change (Baseline to 4 weeks)	Mean Within Group Change (Baseline to 3 Months)	p-value
FAAM	59	78	78	19	19	*0.006
NPRS	5.2	3.3	3.2	1.9	2.0	*0.018
GROC	NA	5.3	5.3	NA	0	1
PPT	2.5	4	4.8	1.8	2.3	*0.006
Strength	9.4	15.3	17.6	5.9	8.2	*0.007

The MCID, for the FAAM is 8 points for the ADL subscale. The sports subscale was not

included in this study. The means for the change score between the baseline to the discharge at 4

weeks as well as the baseline to 3 month follow up exceeded the MCID for both data collection

points in both groups. The means for change scores between baseline and 4 weeks as well as

baseline and 3 months was 24.0%/28.0% for MT+Ex group and 19.0%/19.0% for TDN+MT+Ex

group, respectively. Friedman 2-way rank analysis resulted in a significant difference for the

FAAM for MT+Ex group (p = .002) and TDN+MT+Ex group (p = .006). The individual subject

results for the FAAM are reported in tables 4.6 and 4.7 and graphically in figures 4.2 and 4.3.

Table 4.6: FAAM Scores for Subjects in
the MT+Ex Group

Subject ID	IE	DC 4 (weeks)	3 Months
E1	90%	90%	90%
E2	48%	89%	97%
E3	66%	97%	94%
E4	93%	100%	100%
E5	83%	84%	84%
E6	37%	66%	66%
E7	64%	93%	100%
E8	22%	84%	84%
E9	30%	70%	70%
E10	60%	60%	60%

Figure 4.2:

FAAM Scores For Subjects in MT+Ex Group
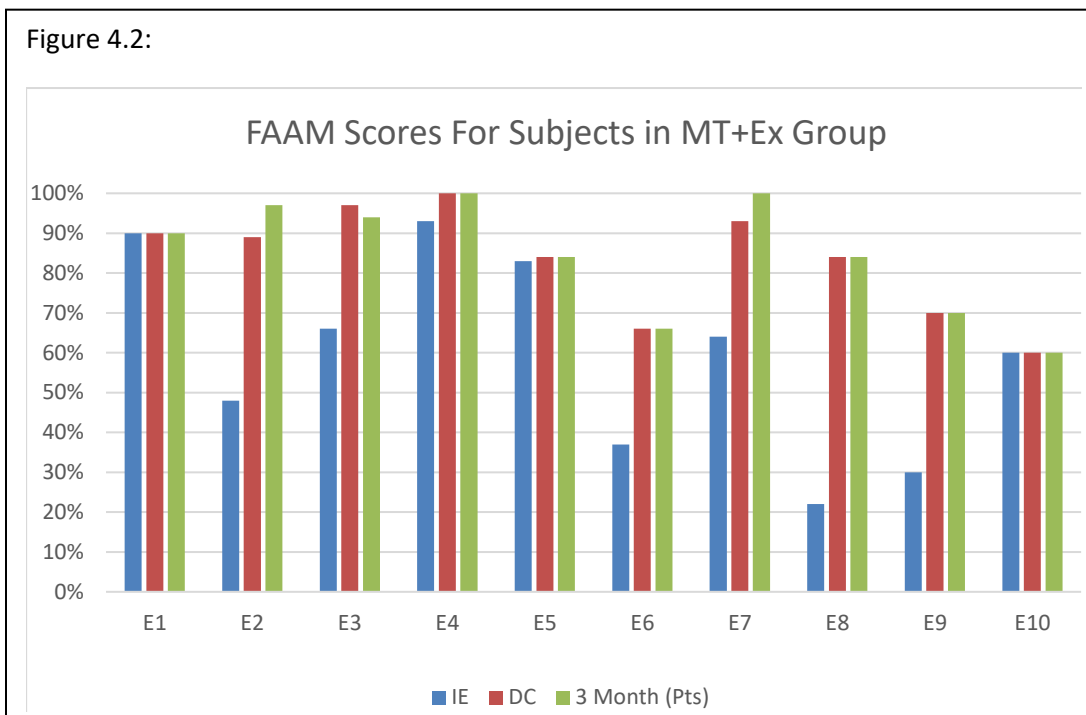
Table 4.7: FAAM Scores for Subjects
in the TDN+MT+Ex Group

Report ID	IE	DC (4 weeks)	3 Month (Pts)
N1	76%	99%	99%
N2	65%	88%	88%
N3	69%	90%	96%
N4	61%	54%	54%
N5	95%	96%	98%
N6	24%	78%	88%
N7	92%	97%	97%
N8	45%	65%	65%
N9	30%	100%	100%
N10	56%	56%	56%
N11	37%	37%	37%
N12	60%	60%	60%

Figure 4.3:

FAAM Scores for Subjects in TDN+MT+Ex Group
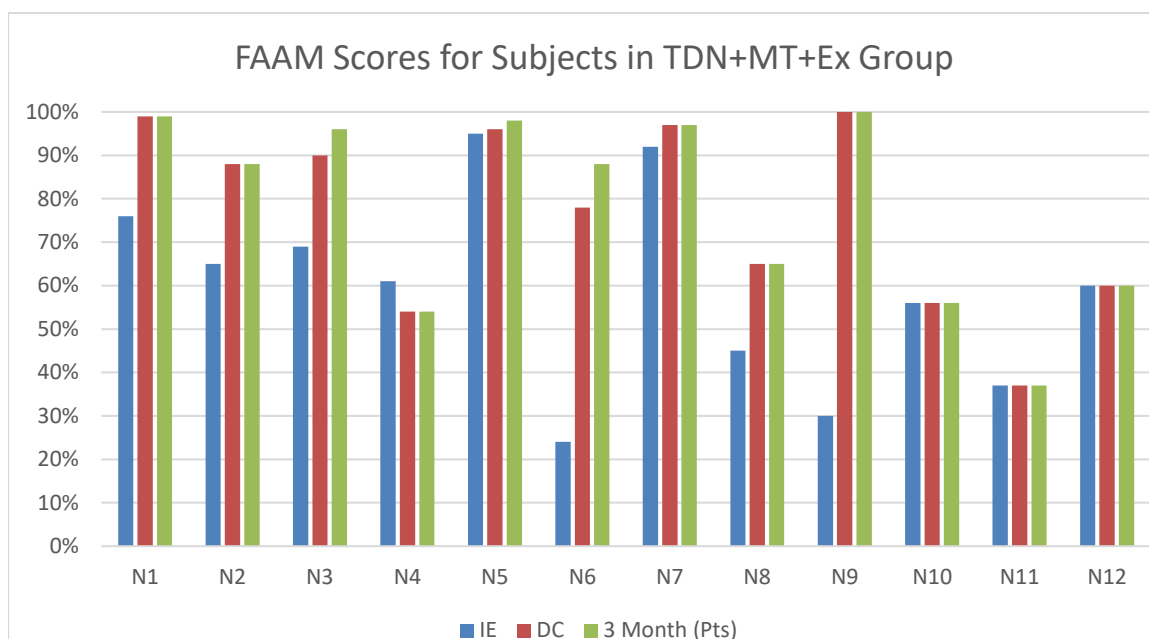
The MCID for the NPRS is 2 points. The means for the change score between the baseline to the discharge at 4 weeks as well as the baseline to 3 month follow up exceeded the MCID for MT+Ex group at 3.1 and 4.0, respectively. The TDN+MT+Ex group means for change from baseline to 4 weeks was a fraction below MCID with a mean of 1.9 while the mean from baseline to 3 month follow up was 2.0. Friedman 2-way rank analysis resulted in a significant difference for the NPRS with both groups at .001 for MT+Ex group and .018 for TDN+MT+Ex group. Individual subject results for the NPRS are reported in tables 4.6 and 4.7 as well as graphically in figures 4.4 and 4.5. The individual subject results for the NPRS are reported in table 4.8 and 4.9 and graphically in figures 4.4 and 4.5.

Table 4.8: NPRS Scores for Subjects in the MT+Ex Group

Report ID	IE	DC (4 weeks)	3 Months
E1	5	3	0
E2	9	5	0
E3	8	1	1
E4	7	7	7
E5	1	0	0
E6	7	3	3
E7	7	2	0
E8	4	0	0
E9	4	0	0
E10	6	6	6

Figure 4.4

NPRS Scores For Subjects in MT+Ex Group
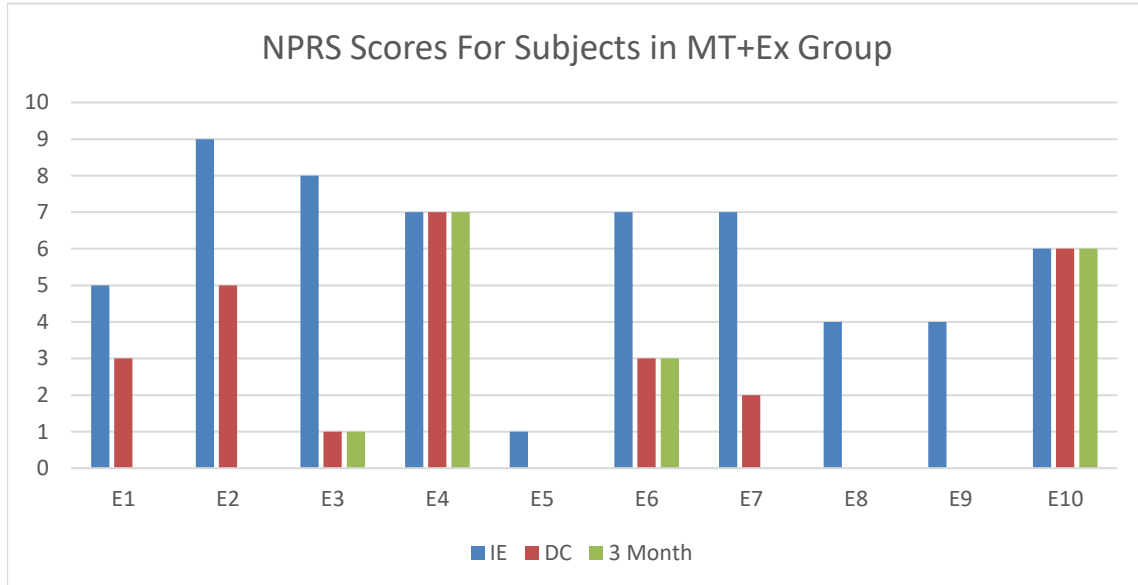
Table 4.9: NPRS Scores for Subjects in the
TDN+MT+Ex Group

Subject ID	IE	DC (4 weeks)	3 Month
N1	4	2	2
N2	5	2	2
N3	4	3	1
N4	5	6	6
N5	1	0	0
N6	8	3	4
N7	2	1	1
N8	7	0	0
N9	4	0	0
N10	4	4	4
N11	9	9	9
N12	9	9	9

Figure 4.5

NPRS Scores for Subjects in the TDN+MT+Ex Group
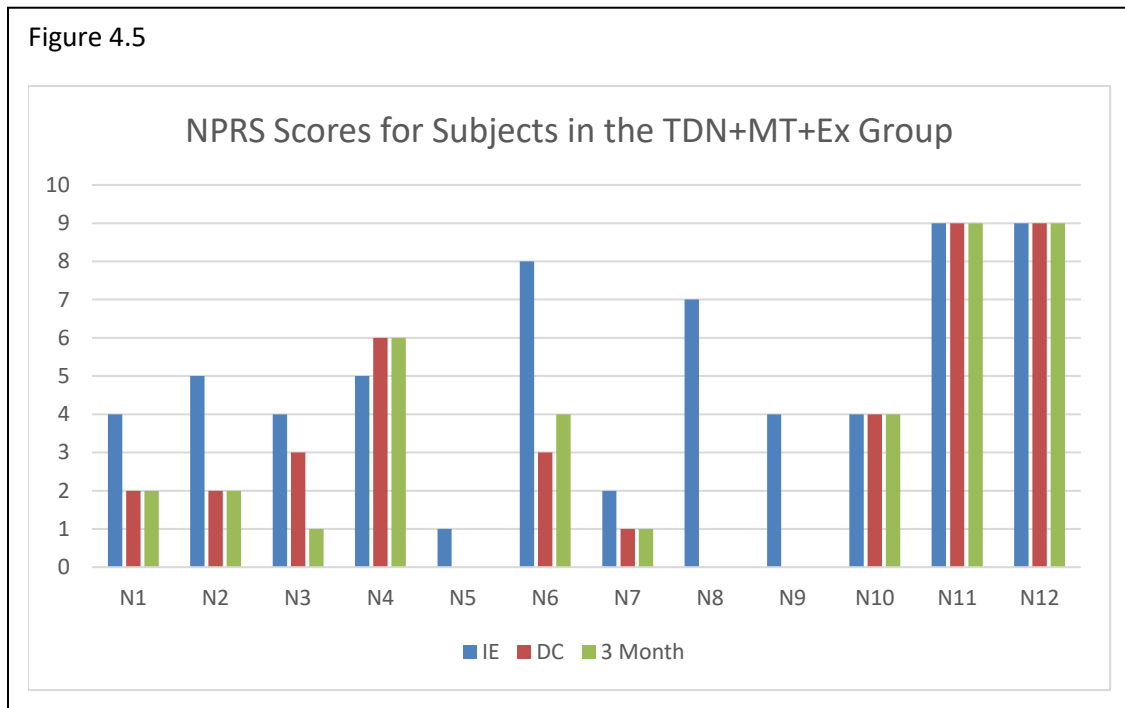
The GROC was administered at the 4 week and 3 month data collection points. The MCID for the GROC is +4 (moderately better). The means for both groups exceeded the MCID at both the 4 week and 3 month measures at 4.8/6.1 for MT+Ex group and 5.3/5.3 for TDN+MT+Ex group. Friedman 2-way rank analysis was significant for MT+Ex group ($p = .046$) but not for TDN+MT+Ex group ($p = 1$).

The PPT measure was conducted with a pain algometer at the most acute point of pain along the Achilles tendon. This was measured by the evaluating physical therapist in the initial examination. This was assessed with the patient in prone and foot hanging off the end of the examination table. The evaluating physical therapist performed a palpation exam along the Achilles tendon. The precise point the patient reported as the most painful during the examination was marked with a pen, and then measured with a flexible tape measure from the most distal point of the Achilles tendon. Points that were ≤ 2 cm were classified as insertional Achilles tendinopathy. Points > 2 cm were classified as non-insertional Achilles tendinopathy. This precise point was used for repeated ppt at 4 weeks and 3 months. Normative data for PPT of the Achilles has not been established. There was similarity in the means for baseline measure of both groups as well as for the 4 week and 3 month measures. Baseline measure for MT+Ex group was 2.3 kg and 2.5 kg for TDN+MT+Ex group. The ppt measures at 4 weeks increased by 104.4% and 71.4% while the 3 month measure increased by 145.1% and 108% for groups 1 and 2 respectively. The Friedman 2-way rank analysis was significant for the PPT measure with MT+Ex group at $p < .000$ and TDN+MT+Ex group $p = .006$.

Strength was determined by the total number of complete repetitions of a single leg heel raise with the knee extended. There was variation between groups for the baseline measure with subjects in MT+Ex group performing a mean of 17.2 repetitions and 9.4 repetitions in

TDN+MT+Ex group. However, the mean change score from the baseline to 4 weeks and baseline to 3 months were similar with increases of 7.3 and 5.9 for groups 1 and 2 respectively. The Friedman 2-way rank analysis was significant for strength at the 4 week and 3 month timepoints for both groups with p = .008 and p = .007 for groups 1 and 2 respectively.

The effect size was calculated for groups 1 and 2 by using Kendall's Coefficient of Concordance. Kendall's W can be used for effect size calculations in SPSS.[186] The effect size for both groups are reported in Table 4.11. Kendall's W interpretation includes the following ranges[187]:

Table 4.10: Kendall's W Interpretation

Kendall's W	Interpretation
$W \leq 0.3$	Weak agreement
$0.3 < W \leq 0.5$	Moderate agreement
$0.5 < W \leq 0.7$	Good agreement
$W > 0.7$	Strong agreement

The interpretation of Kendall's W for effect size of MT+Ex group is rated as good agreement. The effect size for TDN+MT+Ex group is .416 which is moderate agreement.

Table 4.11: Related Samples Kendall's Coefficient of Concordance

	Group 1 (MT+Ex group)	Group 2 (TDN+MT+Ex group)
Total N	10.0	12.0
Kendall's W	0.663	0.416
Test Statistic	86.176	64.888
Degrees of Freedom	13	13
Significance	0.000	0.000

Summary

Data collection for this study was conducted from April 2015 through August 2018. A total of 18 subjects completed the study with a drop out rate 18.1%. Known barriers to the study included fear of needles, finances and time constraints. There was good subject adherence to the study and no serious adverse responses were reported. There attrition rate was high at 61% for the 3 month follow up data collection period.

A within group analysis was conducted. Means for FAAM, NPRS, and GROC did achieve the MCID for the 4 week and 3 month data collection for MT+Ex group. The MCID with these tests were also achieved in the TDN+MT+Ex group except for the NPRS at the 4 week data collection. Friedmans 2-way rank analysis was conducted for each group which resulted in $p < .05$ for all tests and measures except for the GROC at the 3 month data collection for TDN+MT+Ex group. Effect size was calculated with Kendall's W resulting in good agreement for MT+Ex group and moderate agreement for TDN+MT+Ex group.

Chapter 5 - Discussion

Introduction

Achilles tendinopathy is common in athletes as well as non-athletes.[1-5] There are several

non-surgical interventions described for the management of this condition. However, studies

investigating the effectiveness of these interventions have reported a low number of quality

studies and putting the reported effectiveness of these interventions in question.[6,7] Clinical

practice guidelines for physical therapy management of Achilles tendinopathy report strong

evidence for the effectiveness of eccentric training.[6,15] However, a systematic review to

determine the optimal exercise parameters for eccentric training resulted in only 3 of 276 studies

meeting the criteria for a quality study.[78] Trigger point dry needling is an intervention that is

becoming more prevalent in physical therapy. There are several studies reporting the

effectiveness of this intervention for various diagnoses. However, there were no published

studies investigating the effect of TDN on myofascial trigger points in patients with Achilles

tendinopathy.   The primary aim of this study was to test the feasibility of a randomized

controlled trial investigating the effects of TDN to myofascial trigger points in addition to

manual therapy and eccentric exercise in compared to manual therapy and eccentric exercise

alone for individuals with Achilles tendinopathy. A total of 22 subjects were randomized into 2

groups: 1) MT + Ex and 2) TDN + MT + Ex. A within group analysis demonstrated a

significant improvement in FAAM, NPRS, GROC, PPT and strength for the MT + Ex group

while the TDN + MT + Ex group had a significant improvement in FAAM, NPRS, PPT, and

strength. Effect size estimates had good agreement for the MT + Ex group and moderate

agreement for the TDN + MT + Ex group. Conditions to determine feasibility of a large

randomized controlled trial include: 1) the 4 week attrition rate less than 20%; 2) no serious

adverse responses reported as described by Brady et al[83]; and 3) at least 75% of patients complete the 3 month follow up assessment data. Conditions one and two were met, while the third was not as only 39% of subjects completed the 3 month follow up assessment data. There were limitations with this study that would need to be accounted for in the design of a follow up study. However, a large randomized controlled trial may be feasible with modifications.

Discussion and Interpretation of Results

Subject Recruitment

Subjects were recruited by convenience sampling from physicians and podiatrists in the region of each participating physical therapy clinic in this study. Direct marketing was conducted by each clinic to referring providers and flyers were also posted throughout the community in fitness centers and stores with athletic equipment and running shoes.

Subject recruitment was a significant challenge for this study. There was a total of 70 referrals for Achilles tendinopathy to participating clinics in the 3.5 year data collection period. A total of 34 subjects met the inclusion criteria. Referrals to participating clinics was low across the duration of the study and declined significantly from the first year of data collection (2015) to the last (2018). In 2015 there were 33 referrals to participating clinics. The inclusion criteria at the inception of the study was limited to non-insertional tendinopathy. As result, only 8 of these 33 referrals were eligible for the study, of which 5 of these subjects consented to treatment and completed the study. The rationale for including non-insertional tendinopathy was based on the research published on the effects of eccentric training on Achilles tendinopathy. Eccentric training has been found to be more effective for non-insertional than insertional tendinopathy.[13,78] Due to the absence of published literature on TDN for Achilles tendinopathy

at the inception of this study, the decision was made to limit subjects to non-insertional only to have the strongest comparison for TDN to the eccentric training protocol. However, after realizing the low referral rate and recruitment of subjects, the dissertation committee was in agreement that the inclusion criteria should be amended to include insertional tendinopathy. The IRB did approve the proposal to amend the inclusion criteria and in the second year of data collection (2016) there was an increase of subjects recruited that were eligible for the study. In 2016, total referrals did drop off from 33 to 19. However, 16 of the 19 subjects were eligible for the study and 13 did consent. The third (2017) and fourth (2018) year of data collection had a decline of referrals with only 9 for each year. In 2017, 3 of the 9 subjects entered the study while in 2018 only 1 subject entered the study.

There were ongoing effects throughout the data collection period to advertise to referring physicians and podiatrists in the region of each participating clinic. Each participating clinic had a marketing representative that communicated directly with all referring providers to the respective clinics. Reports from research assistants indicate the marketing representative communicated with the primary referring physicians and podiatrists at a minimum of once every 3-4 months of the year. Feedback from the physicians and podiatrists was consistent in reporting that their practice patterns for managing Achilles tendinopathy had not changed. However, patients were less willing to consider a physical therapy referral for treatment due to the changes in health insurance that increased the out of pocket costs for care. Data on the total number of patients from the referral practice patterns for management of Achilles tendinopathy for the physicians and podiatrists was not collected.

Another factor that resulted in low subject recruitment was a change in the primary referral sources for Achilles tendinopathy moving into a new health provider system. The

participating clinics were not in these health systems and referrals to these clinics were classified as out of network. Therefore, patients were responsible for higher copays for treatments at these participating clinics. This is attributed as a significant factor in the absence of referrals in Winston-Salem, NC beginning in 2015 and low referrals in Fayetteville, NC in 2017 and 2018. There were no referrals from these providers after the change in network.

Barriers to Subject Participation

There are several factors that limited the referrals to physical therapy as well as the subjects consenting to participate in the study. There were 12 patients referred to participating clinics that were eligible to participate but declined. A total of six subjects were not willing to consent due to the cost of the physical therapy services. These patients reported a high health insurance deductible and copay resulting in an out of pocket expense they were not willing to pay. Each of these subjects did continue with physical therapy services but were planned to be scheduled for one session per week for four visits or less which is less than the eight visits required to complete the study.   According to reports from referring providers, the total number of referrals were affected by patient reports of high out of pocket costs for physical therapy. However, this data was not collected.

Another factor that limited subject participation was the report of the patient that they were averse to a needle stick to a painful trigger point. It is possible that these patients could have been randomized to the exercise + MT group and thus would have been willing to consent. However, if they were randomized to the TDN + MT + Ex group, they would have dropped out of the study. Therefore, they were excluded from the study. It is not known if these patients would have consented to TDN at a later point in the continuum of care once their pain reduced.

It is also not known if these patients would have consented if the treatment protocol was regional and included TDN to trigger points in the hip or thigh region in addition to the lower leg.

Time commitment for this study was the last explanation given for two patient's refusal to participate in the study. This protocol required two treatment sessions a week for four weeks and subjects were listed as a drop out if they could not maintain this schedule. The NPRS for both of these subjects were high (9 & 6/10) at the initial examination and the FAAM was low (50 points). This may have been a factor in their determination to drop out of the study.

There were 36 subjects that were referred to the participating clinics that did not meet the inclusion criteria. As previously stated, 25 of these patients were diagnosed with insertional tendinopathy in the first year of the study and thus were not eligible. The remaining 11 subjects did not qualify due to injections (4), and fear of needles (4), comorbidity including diabetes (2) and ankle fracture (1). Each of these subjects continued to seek physical therapy treatment at the participating clinics. However, data was not collected on these subjects as they did not consent to the study.

Attrition Rate

There were four subjects who dropped out of this study, a rate of 18.1%. There were no serious adverse events that contributed to the drop outs. Data from the initial examination was carried forward to the discharge and 3 month data collection analysis.

Three of the subjects that dropped out were randomized to the TDN + MT + Ex group. One subject dropped out due to a family emergency that required extended travel out of the region.   The subject did not return to the participating clinic at a later date and did not return phone calls. A second subject dropped out after the second visit reporting family responsibilities

would interfere with the ability to maintain the schedule of the treatment protocol. The third subject dropped out after completing six treatment sessions. This subject was progressing slowly with the treatment protocol with little change in pain and ability to perform the eccentric heel raise exercises. The subject returned to the referring provider and did not return to physical therapy. There was no response to multiple phone calls over a period of three weeks.

There was one subject in the Ex + MT group that dropped out. This subject completed three treatments and then scheduled an appointment with the referring provider for follow up due to slow progress with the treatment protocol. The subject did not return to continue treatment. A follow up phone call was made, and the subject reported continued management with the referring provider with medication and bracing. Surgery was not planned for this subject. The subject did not return for continued physical therapy at a later date.

Analysis of the FAAM and NPRS for the subject that dropped out indicate moderate to severe pain levels and significant functional activity limitations as shown in Table 5.1. The 2 subjects that dropped out due to poor progress, coded as D1 and D3, had initial FAAM scores of 31 points (TDN + MT + Ex group) and 50 points (MT + Ex group). Their NPRS scores were 9 and 6. For subject D1, the mean NPRS for the MT + Ex group was 5.8 and there were 5 subjects who completed the study with initial NPRS scores > 6. For subject D3, their initial NPRS score was 9 while the group mean was 5.2 for the initial examination. Also, for subject D3, the FAAM score was 31 points while the group mean was 50. There was one subject in this group that completed the study with a lower FAAM at the initial examination. This subject had a FAAM score at discharge and 3 month follow up of 66 and 74 respectively. Therefore, there is insufficient data in this study to determine if pain severity at the initial examination could limit the overall effectiveness of the treatment and thus warrant a cut off score.

Table 5.1:	Initial FAAM and NPRS Scores for Dropouts		
Subject	Group	FAAM	NPRS
D1	MT+Ex	50	6
D2	TDN+MT+Ex	47	4
D3	TDN+MT+Ex	31	9
D4	TDN+MT+Ex	50	9

The attrition rate for this study had a significant impact on the data collection for the 3 month follow up. The study protocol required the subjects to return for completion of the self reports, pain pressure threshold measure and the heel raise test for plantar flexion strength assessment. There were 11 subjects who completed the 4 week treatment protocol but did not return for the 3 month data collection, resulting in an attrition rate of 61%. Each subject in this study was informed of the study requirement for a follow up appointment 3 months after the discharge at the initial exam as well as at the discharge appointment. These subjects were scheduled for the return visit at the completion of the discharge treatment session. Attempts were made to contact each subject by phone beginning at 2 weeks prior the schedule appointment as a reminder of the scheduled visit. Numerous attempts were made to contact the subject until 2 weeks after the scheduled appointment. Precise phone logs were not kept to determine the total number of calls made for each of these subjects. Missing data from each of these subjects was carried forward from the discharge visit to the 3 month data collection.

There was one subject in the Ex + MT group that could not return to the clinic to complete the data collection due to extended travel related to the occupation. However, this subject did complete the self reports and mailed them to the clinic. The PPT and heel raise data were not completed was carried forward from the discharge visit to the 3 month data collection.

Study Protocol

The treatment protocol was developed based on prior studies on eccentric training [78,120] and manual therapy[81] for subjects with Achilles tendinopathy. The determination to develop a protocol instead of a pragmatic approach was based on the variability in reporting TDN interventions and to ensure all subjects received a comparable dose of strengthening consistent with the Alfredson protocol as well as the recommendations in clinical practice guidelines.[78] The determination for a four week treatment duration was based on practice patterns for the primary researcher and research assistants in the study.

There were no reported problems with subjects who completed the 4 week treatment protocol maintaining the requirement of treatment twice a week for this period.   Feedback from interviews with research assistants indicated that the time associated with completing the self reports and measurements for pain pressure threshold and the heel raise test was completed in less than one hour.

There were no reported problems with completing the treatment protocol for subjects in both groups. Research assistants report the ability to complete the treatment in less than one hour for all subjects.

Data Analysis

Within Group Analysis for TDN + MT + Ex Group

A within group analysis with Friedman's analysis of variance was conducted. Missing data for subjects who did not return for the 3 month follow up was carried forward from the measures at the discharge. Data from subjects that dropped out before discharge had data carried

forward from the initial examination to the discharge and 3 month follow up. The mean of the 2 rankings was used for each.

A statistically significant improvement was made with the FAAM, NPRS, PPT, and strength. These results indicate the treatment protocol was effective for managing Achilles tendinopathy in this study population. However, a between group analysis was not conducted due to the study design.[91] Therefore, the effectiveness of TDN compared to exercise only cannot be determined from this study.

The PPT measure did increase in this group by a mean of 2.4 kg/cm at the discharge measure. Normative data for PPT in the Achilles tendon is not found in the published literature to compare the results of this study baseline or discharge measures. Renan-Ordine et al did report the PPT changes in their study.[81] In their study, PPT measures were taken in the muscle belly of the gastrocnemius and soleus muscles as well as the Achilles insertion on the calcaneus following a 4 week intervention period. Increases of 1.4, 1.1 and 1.5 kg/cm, respectively were reported. In the present study, there was a mean increase of 1.8 kg/cm along the Achilles at the precise location the patient reported as the most painful. There were no PPT measures assessed in the muscle belly of the present study. The PPT measures of this study cannot be directly compared to Renan-Ordine due to the difference in the location of the measure. Although, this does give a basis for comparison of the measure as the means in both study are similar.

The high attrition rate for the 3 month data collection is an internal threat to the validity of these results. Only 25% of the subjects randomized to this group completed the 3 month data. The data from the remaining subjects was carried forward from the discharge measures.

Due to the high attrition rate with the 3 month data collection measure, an analysis of the mean scores at discharge for the FAAM, NPRS and GROC was conducted and compared to the

MCID for each measure. There were 9 subjects in this group completing the 4 week treatment protocol. The remaining 3 subjects dropped out and their data from the initial exam was carried forward. The mean score for the FAAM improved by 16 points at the discharge measure which is greater than the MCID of 8 points. The GROC did not achieve statistical significance but the mean for the discharge GROC score was 5.3 which is above the MCID of 4. The NPRS had a mean change score of 1.9 at the discharge measure which is slightly below the MCID of the NPRS which is 2. These results indicate the treatment protocol with TDN + MT + Ex did produce a clinically meaningful result in this study population.

Within Group Analysis for MT + Ex Group

A statistically significant improvement was achieved for all study measures in the MT + Ex group. These results indicate the study protocol was effective for this population. This is consistent with the published research of the beneficial effect of eccentric training for reducing pain and improving strength in patients with Achilles tendinopathy.

The attrition rate was high for this group with 50% of the subjects did not return for the 3 month data collection. Missing data was carried forward from the last data collection. The high attrition rate is an internal threat to the validity of the results for this group as well.

The analysis of the mean for discharge measures of the FAAM, NPRS, and GROC with this group was favorable. For this group, 9 of the 10 subjects completed the 4 week treatment protocol with only 1 drop out. There was a mean improvement of 22.4 points on the FAAM which is greater than the MCID at 8. The mean difference score for the NPRS was 3.1 which is greater than the MCID of 2. The mean for the GROC was 4.8 which surpassed the MCID of 4.

The mean change for the PPT measure in this group was 2.4 kg/cm. This is larger than the PPT measures in the Renan-Ordine study.[81] Again, a direct comparison cannot be made due to the difference in the location of the PPT measure between the 2 studies. Although the results of this study are consistent with the report by Renan-Ordine.

Effect Size

The effect size was calculated for each group independently and provides an estimate of the agreement between means for all variables in this study. Effect size is an important measure in nonparametric analyses due to the small sample size. The p -value alone does not allow for the evaluation of the magnitude of the results, but "merely indicates the probability of obtaining a result that is extreme or more extreme than the one that was obtained".[186] It is possible that a large sample size of a study that has a small standard error can lead to a small p - value. Given the small sample size for this present study, the p – value alone does not indicate how meaningful the data is. The effect size, however, can provide the magnitude or agreement of the means for each of the variables.[186]

The nonparametric effect size calculation with data analyzed by Friedmans test can be conducted by calculating Kendalls W.[187] The range for Kendalls W is from 0 which indicates no agreement, to 1 which indicates perfect agreement. The effect size was calculated for each group. The MT + Ex group effect size was 0.663 which is a good agreement of the means. The TDN + MT + Ex group effect size was 0.416 which is moderate agreement of the means.

Feasibility

The primary aim of this study was to test the feasibility of a randomized controlled trial investigating the effects of TDN to myofascial trigger points in addition to manual therapy and eccentric exercise in compared to manual therapy and eccentric exercise alone for individuals with Achilles tendinopathy. To determine the feasibility, three conditions were established: 1) the 4 week attrition rate less than 20%; 2) no serious adverse responses reported as described by Brady et al[83]; and 3) at least 75% of patients complete the 3 month follow up assessment data.

The first condition was met as the 4 week attrition rate was 18.1%. There were 4 subjects that dropped out of the study. Two subjects dropped out due to a family emergency and time commitment, which are not related to the construct of the study. There were 2 subjects who dropped out due to poor progress with treatment, one from each group, resulting in a 9.1% drop out rate due to poor progress.

The second condition was also met. There were no serious adverse events reported in this study. Post treatment soreness was commonly reported from subjects in both groups. However, the research assistant was able to assess each subject each treatment session and determined that the subjects did not sustain injury from the treatment. Based on the criteria from Brady et al, soreness from TDN is considered a minor adverse event and was commonly reported in their study.[83] Post exercise soreness is also a common report with eccentric training for patients with Achilles tendinopathy.[120]

The attrition rate for the 3 month follow up was poor with 61% of subjects not returning for the final data collection. Factors that may have attributed to this include the requirement of subjects to return to the participating clinic. There was also no incentive for the subjects to return. There was incentive for the subjects to attend each treatment session as they were

receiving treatment that was effective in reducing their pain and improving their tolerance for functional activities. However, once they were discharged from treatment there was no further incentive to return aside from their obligation to the study.

The problems that were encountered with this study may be surmountable and a large randomized controlled study may be feasible with modifications to the study design.

1. It is recommended that the study would be conducted in health systems with a large provider network.

2. The study treatment protocol should be pragmatic and allow for TDN to the hip and thigh region as well as locally to the lower leg to account for subjects who are averse to needle insertions to painful trigger points for each treatment session. Regional TDN has been reported to reduce PPT in satellite trigger points. [87]

3. The treatment frequency and duration should not be limited. This will account for subjects with financial constraints that prohibit their participation in the study.

4. A financial incentive may increase subject recruitment as well as reduce the attrition rate for follow up data collection.

5. Data collection for long term follow up should allow for subjects to complete self report measures over the phone or video conference to verify identity. This would also allow for the researcher to view the subject performing the heel raise exercise and record this data. This does eliminate the PPT variable from the follow up data collection. Normative data has not been published for PPT to the Achilles tendon, nor has data correlating PPT measures to functional activity status. Therefore, the value of PPT to the results of future studies may need to be weighed against the importance of reducing the attrition rate with collecting the follow up data.

Literature Review

Pain Pressure Threshold

The study protocol for assessing pain pressure threshold was adapted from Renan-Ordine et al.[81] One key difference was the PPT assessment in the present study was performed on the most painful point on the Achilles tendon, not the muscle tissue as described by Renan-Ordine. The improvement in pain along the Achilles tendon from TDN to the muscle may indicate that a portion of the pain perceived at the tendon may be referred from the trigger point. Another plausible explanation for pain relief from TDN would be the reorganization that occurs in the muscle fibers with resolution of the trigger point. The presence of the trigger point does reduce strength and extensibility of the muscle. This leads to altered force to the tendon with muscle contraction and also with elongation. Therefore, reorganization of the muscle fibers would alter the stress-strain relationship of the muscle and improve the mechanics of the Achilles tendon during the heel raise activity.

Trigger Point Dry Needling

The improvements in pain, strength and functional activity tolerance in the TDN + MT + Ex group are consistent with results of other published studies on TDN. The needling technique included the fast in and out to exhaust the twitch response as well as needle rotation. There was variation in the needling procedure in the published literature and the absence of a standardized needling technique available in the published literature at the inception of this study. Multiple studies performed either the fast in out or rotation and reported a significant treatment effect.[21,23,30,38,39,41,42,142,155,156,158] The determination for this study was to use both techniques since there was no data to suggest one was more effective than another. The data collected in

this study did not include ultrasound imaging, tissue samples or analysis of blood values. Therefore, the effect of needling in this study is based on the results of the self report measures, strength and PPT measures.

Pain relief that occurred in the TDN group may have been due to the release of the trigger point and taut band. A local increase in blood flow through the region of the trigger point will occur and can remove chemical mediators, exchange of nutrients with the cells and facilitate a healing response to this tissue.[76,89] The TDN procedure can also improve tissue elasticity allowing for greater range of movement during eccentric strengthening and other functional activities the subject would perform. [142,143] Lastly, TDN can also stimulate fibroblasts which may increase the rate of collagen production to heal the tissue following injury. [146,147]

Additional effects from TDN may be related to an increase in tissue extensibility. End plate noise in trigger points decreases in response to TDN.[75] Also, TDN can increase connective tissue extensibility which would improve the overall plantar flexion motion and potentially a larger gain in strength due to a greater mechanical load response to tendons.[142,143]

Eccentric Training

The effects of eccentric training have been reported to produce a healing effect in the degenerative tendons.[13,78,79] The combined effects of increase in blood flow, sarcomeres and length tendon relationship result in an increase in fiber length allowing for greater dorsiflexion angle.[1,3] Eccentric training can also increase the rate of collage synthesis in a chronically painful Achilles tendon with tendinosis.[10] This resulted in reduced pain levels and return to athletic participation. [1,3] The results in this study are consistent with the prior published studies as subjects in the MT + Ex group had a mean improvement in pain and functional activities that exceeded the MCID's for these outcomes measures.

There are several mechanical adaptations that occur to the muscle and tendon in response to eccentric training.[110] Changes in force and cross sectional area have been reported to occur at 4 weeks of eccentric training.[113] These adaptations may have occurred to various degrees in the present study and contributed to the improvements reported in pain, strength and functional outcomes.

The optimum dose of eccentric training for Achilles non-insertional tendinopathy has not been determined. The systematic review by Meyer reviewed 276 studies,[78] but only 3 were determined to have high methodological quality.[76,122,123] Each of these three studies measured pain and functional improvement following the intervention period and compared to another intervention. The exercise program for these studies were based off the Alfredson protocol, but the plantar flexion endurance test was not conducted at the initial examination or discharge visit. As a result, there is not a data set to compare gains in muscle strength in these studies. Therefore, a comparison of progress in strength with the heel raise with this study cannot be made.

For the present study, subjects were instructed to perform the heel raise exercise to the best of their ability, but they could stop the exercise on their own accord either when pain increased during the exercise or if they encountered muscle fatigue and were unable to perform a full repetition. This protocol is consistent with the report of Stevens and Tan who compared the Alfredson protocol to a do-as-tolerated program.[124] Stevens and Tan report that there was no difference between the outcomes of subjects in either group. Therefore, subjects were not required to perform 3 sets of 15 repetitions as advocated in the Alfredson protocol.

Implications

Implications for Practice

The results of this study provide support for the application of TDN to trigger points located in the lower leg in the management of insertional and non-insertional Achilles tendinopathy. Subjects in this study did achieve improvements in the FAAM, NPRS and GROC that greater than the MCID for each respective measure. There were also no serious adverse responses from TDN. There are no published studies in the literature reporting the effect of TDN to the muscles of the lower leg for the management of Achilles tendinopathy. Therefore, this study does provide support for TDN as a viable treatment option and also describes a specific protocol for the TDN procedure that could be replicated in clinical practice.

The results of this study are also consistent with prior studies reporting the effect of eccentric training for Achilles tendinopathy. Both groups in this study performed the same exercise protocol. A between group analysis was not conducted due to the study design.[91] However, subjects in both groups reported improvements providing evidence of effective management for subjects in this study.

Treatment with TDN to trigger points in the muscle combined with eccentric training can reduce pain in the Achilles tendon without a direct application of treatment from thermal or electrotherapeutic modalities or needling with injections to the tendon. This study indicates there is a potentially beneficial effect from managing trigger points and strength deficits. This strengthens the support of physical therapy management for Achilles tendinopathy as a viable treatment option for effective management of pain and facilitate improvement of functional activity.

Implications for Further Research

The results of this study can also be used to guide the development of future studies. The protocol for TDN was described in detail and could be used to standardize the TDN procedure for all researchers and research assistants in a study. In addition, the study design could be replicated in a larger study with the recommended modifications previously stated.

There are several studies reporting the effect of eccentric training on Achilles tendinopathy, including a report of a 5 year follow up. The quality of the majority of these studies is reported to be poor, but the results of these studies are in agreement with the relative effectiveness of this treatment protocol. Future studies should be designed to compare the effectiveness of TDN to other surgical and nonsurgical procedures that are proposed for Achilles tendinopathy such as extra corporeal shockwave therapy and tendon needling with injection. Analysis of the total cost of care for managing Achilles tendinopathy with the comparison of effectiveness for these interventions should also be studied. This data would be meaningful to all patients, especially those with financial constraints.

Limitations

A significant limitation of the study was the occurrence of 2 large podiatry practices undergoing a change in their provider network during the data collection period. This had a profound negative impact on the total referrals to the participating clinics as the participating clinics were not in that provider network. Patients seeking physical therapy treatment at out of network clinics would be responsible for higher out of pocket costs. The data collected in this study does not accurately reflect the impact of this change. Data was collected based on the referrals that were received by the participating clinics but not on the potential subjects that

could have been referred from podiatrists and physicians. These potential subjects may have either declined due to financial constraints or selected a physical therapy clinic that was in network for a variety of other reasons.

The challenges of subject recruitment significantly contributed to the extension of the study to over three and half years. During this time, there was a large increase in the out of pockets costs of health care as large health insurance providers in the regions of the participating clinics had increases in deductibles and co-pays. Grant funding for this study was not available and therefore, financial incentives could not be provided to the patients to offset the costs for participating in this study.

The attrition rate for the 3 month follow up, combined with the drop out rate had a profound impact on the final statistical analysis.   Missing data was carried forward from the last available measure. However, the actual results for these subjects may have been significantly different from the last data collection measure, resulting in a different outcome to the analysis. This increases the risk of a type II error. Low subject recruitment also contributed to this as a larger sample may have resulted in an improved attrition rate and reduce the risk of a type II error.

Another limitation to this study was the patient compliance with the home exercise program of daily eccentric training throughout the duration of the study.   An exercise log was not included in the study and the research assistants were not able to verify accuracy of subject reporting. As a result, an analysis could not be performed to determine if compliance had an impact on overall tests and measures.

There was a total of 7 research assistants collecting data for this study, each practicing in different clinics. Every effort was made to ensure standardization of the examination, data

collection and performance of TDN and manual therapy treatment techniques. The primary investigator met personally with all research assistants to review the techniques for TDN and manual therapy as well as review and demonstrate the eccentric training program. There was an exception with one research assistant. A personal meeting could not be arranged due to the distance between the primary investigator and research assistant and the timing of the scheduled appointment with a patient eligible for the study. The primary researcher conducted two meetings over the phone as well as a video conference to review the study protocol prior to the first subject initial examination. The TDN procedure was demonstrated through video conference. This research assistant had two years of experience with TDN and was familiar with the specific procedure from completing of TDN certification training and reported performing this routinely in clinical practice. Therefore, the primary investigator considered this research assistant to be competent to perform TDN for this study without a live demonstration and assessment of the TDN procedure. This research assist collected data on one subject for the study.

Delimitations

A delimitation of this study was the decision to limit the study population to non-insertional Achilles tendinopathy and exclude insertional tendinopathy. As previously stated, the research results on the improvement of pain and strength with eccentric training was superior for non-insertional tendinopathy. However, there are still benefits reported with eccentric training with insertional tendinopathy. There were a total of 25 patients referred in the first year of the study that may have been recruited for the study. It is not known how many of these subjects would have met the inclusion/exclusion criteria and consented to the study. Although, an increase in subject recruitment may have resulted in a sufficient number of subjects to allow for a

more robust statistical analysis and more clear recommendations on the feasibility of a larger randomized controlled trial.

A second delimitation was the decision to cease data collection despite the low recruitment and high attrition rate for the 3 month follow up. This determination for this decision was based on several factors including the low referrals to the participating clinics and rising out of pocket costs for patients which was reported to be a factor in patients refusal to participate in the study.

Recommendations

Results of this study indicate a large randomized controlled trial investigating the effects of TDN for Achilles tendinopathy may be feasible with changes in the study design. As previously stated, a future study design should consider: 1) conducting this study in a health system with a large provider network; 2) allow pragmatic approach for TDN, manual therapy and exercise with the conditions that eccentric exercise is included in the treatment; 3) do not include a required number of treatments; 4) provide an incentive for subjects to complete the long term follow up data collection; 5) study variables could include measures that do not require subjects to be physically present in the participating clinic to obtain.

Consideration for the Rising Cost of Health Care

The current state of healthcare in the United States could have a negative impact on the ability to conduct a large randomized controlled trial on Achilles tendinopathy. Healthcare costs in the United States continue to rise. Estimated costs on national health spending has increased every year since 1961.[57] In 2018, the estimated cost of health care is projected to amount to nearly $3.5 trillion.[58] This is an increase of 5.4% over the total costs in 2017. There are several

causes to the increase in cost for health care. Every year, the number of people in the United States with chronic diseases increases, people are living longer and the average lifespan continues to climb. These costs are covered in part by the Federal government, but for those who have employer sponsored healthcare, the cost of health insurance and health care is gradually increasing for employers and employees. According the Kaiser Family Foundation report on employer health benefits, the cost of health insurance for employer sponsored plans has risen 3% on a single and 5% on a family plan.[59]   This is a concern as this increase is greater than the rise in wages (2.6%) and inflation (2.5%) for the past year. These statistics become more alarming when factored over a longer period of time. Since 2012, the cost of insurance premiums has outpaced the rise in wages, 25% to 14% respectively.[59]

The out of pocket costs for these employer sponsored plans are also rising. A total of 85% of employer sponsored plans require an annual deductible. Over the past 5 years, these deductibles have increased 53%.[59] Once the deductible is met, other cost sharing fees are billed to the patient in the form of co-insurance and copays. Cost of the copay for physical therapy services may be as high as $75 per visit[60] depending the insurance carrier and network affiliation of the provider.   Most plans have an out of pocket maximum and will cover 100% of the cost once this limit is reached. However, this limit may be unaffordable for some as it is reported to be at $6,000 or more for 20% of the covered employees. [59] Another factor is the network affiliation of the health providers in a region. Health insurance carriers commonly have network of preferred providers for medical services. Rates for services are negotiated and the cost savings is passed down to the patient if they seek services within a network provider. However, out of pocket costs for care will be higher for services from providers that are considered to be out of network and may not be covered at all. [189]

The rising cost of health care is having an impact on the physical therapy profession. Physical therapy is classified as a specialist health care provider, resulting in a higher copay than other health care professions. The high cost of copays for each physical therapy session is often given by patients who request fewer than the recommended number of treatment sessions.[61] The total number of annual visits covered will also very by plan. This may be a limit for all therapy services combined, or a limit per diagnosis.

Planning for a large randomized trial will need to take into consideration the rising cost of health care and the impact it may have on physical therapy. Proper planning will be needed to reduce the impact of the potential financial burden for patients who may be eligible for participation in a trial but do not have the resources to participate.

Additional Recommendations

Additional recommendations for future studies include tracking referrals from providers to determine the practice patterns for managing Achilles tendinopathy. There are several treatment options for managing Achilles tendinopathy including extracorporeal shock wave therapy, PRP, tendon needling, physical therapy with several treatment options. A comparison of treatment outcomes and cost associated with care is needed to determine the most effective treatment for reducing pain, increasing function and tracking cost of care. Rising health care costs and out of pocket expenses are influencing decisions made on treatment. The long range financial costs of care and outcome for each intervention would give providers and patients information that should appropriately guide their selection for the best treatment.

Summary

Achilles tendinopathy is common to athletes as well as non-athletes.[1-5] Clinical practice guidelines recommend management of Achilles tendinopathy with eccentric training. However, studies investigating the effects of eccentric training as a stand alone treatment for Achilles tendinopathy report slow progress and delayed return to functional activity. In addition, systematic reviews report poor methodological quality and inability to determine an optimal exercise dosage to achieve results.[78]

Trigger point dry needling is becoming more prevalent in physical therapy. There are many studies reporting the effects of TDN [19-43] but there are no studies in the published literature that have investigated the effect of TDN to myofascial trigger points in the muscles of the lower leg for the management of Achilles tendinopathy.

The delayed healing response with eccentric training for Achilles tendinopathy can be a financial burden to patients. The cost of health care is gradually increasing in the United States.[57,58] There has been a rise in out of pocket costs to patients as health insurance deductibles and co-pays that make seeking treatment unaffordable.[61] This cost may influence provider behavior and practice patterns when patients are not able to comply with clinical practice guidelines. The risk to the patient is an incomplete treatment plan may result in delays in healing rates and suboptimal results that can impact the quality of life. Research is needed to investigate interventions in combination or in isolation that can facilitate a more rapid healing response and return to function to improve the quality of life for people with Achilles tendinopathy and the reduce the financial burden for those with limited resources to pay for their health care.

There are 4 studies that have reported the effects of tendon needling for Achilles tendinopathy.[77] However, 3 study included injections to the tendon and the other included a treatment protocol that has significant threats to validity and the results are in question.[56] There is

a lack of standardization of TDN procedures in the research resulting in significant variability of the treatment procedures for the TDN technique. A large randomized controlled trial is needed to determine the effectiveness of TDN for Achilles tendinopathy. However, the rising cost of health care is negatively impacting referrals to clinics and it may not be possible to conduct a large trial. Therefore, a feasibility study would help to determine the components of a study that could be effective.

Eccentric training has been shown to stimulate a healing response in degenerative Achilles tendons.[13,78,79] Repeated exercise bouts with eccentric loading can produce an increase in microcirculation in the exercising tendon, increase the number of sarcomeres leading to an increase in tendon extensibility and reduced risk of injury. [1,3,10,119] Long term studies report continued improvement in pain and functional activity tolerance in patients with Achilles tendinopathy 4-5 years after initiating an eccentric training program.[13,14]

A trigger point is a "hyper irritable spot in a skeletal muscle that is associated with a hypersensitive palpable nodule in a taut band".[75] Trigger points are classified as either active or latent. Active trigger points are painful and can produce pain locally as well as referred to a distant region. Latent trigger points do not produce pain spontaneously but contribute to pain and movement impairments. Over time, latent trigger points can transition to active trigger points given the appropriate stimulus. Both types of trigger points can produce a loss of range of motion, weakness, fatigue and cramping.[130]

Microdialysis of trigger points reveals an increase in chemical mediators, low pH and oxygenation along with a pooling of blood in the surrounding muscle tissue.[76,89] These findings are believed to attribute to pain locally as well as that referred to a distant region.

Trigger points can be effectively managed with soft tissue mobilization and TDN. [19-21,30-33,40-42,81,155,157,158,162] Trigger point dry needling involves the insertion of a monofilament into the trigger point. This frequently produce a twitch response. Analysis of the trigger point following a twitch has revealed a significant decrease in the volume of the chemical mediators and also an increase in blood circulating through the region of the trigger point.[76,89] Furthermore, TDN has been found to increase collagen synthesis, increase extensibility of connective tissue and reduce end plate noise which can improve the quality of the muscle contraction and flexibility of the tissues.[17,75,131,132] There is variation in the TDN procedure and a standard of practice has not been established.

This study set out to determine the feasibility of a large randomized controlled trial to investigate the effect of a treatment program including TDN combined with manual therapy and exercise compared to the same manual therapy and exercise program for patients with Achilles tendinopathy. Inclusion criteria included the following:

1. Participants were between the ages of 18-70 years

2. subjective report of the primary location of pain at any point along the in the Achilles tendon

3. Pain present $\geq$ 4 weeks

4. positive Achilles palpation test

5. positive Royal London test

6. decreased plantar flexion endurance test vs non-involved leg

Any of the following conditions excluded subjects from participating in the study:

1. fear of needles or unwilling to have needling performed due to fear or personal beliefs[75]

2. vascular or sensory disturbances in the lower leg which included but was not limited to injury to the nerve root or peripheral nerve in the affected lower leg, inflammatory diseases, bleeding or clotting disorders, lymphedema, peripheral vascular or peripheral arterial disease. Diabetes was included in this group due to the progressive changes to the sensation and circulation in the lower extremities.

3. recent infection

4. previous surgery to the foot/ankle

5. steroid by injection or transdermal delivery to the posterior heel within three months

6. full rupture of the Achilles tendon

7. pregnant or may be pregnant

8. Tampa Scale for Kinesiophobia > 37[13]

9. participants with a work related injury insured by the bureau of worker's compensation or involved in litigation related to injury of the lower leg, foot or ankle

Twenty-two subjects were recruited from convenience sampling from participating physical therapy clinics in North Carolina, Tennessee and Iowa. Subjects were randomized into 2 groups. One group received TDN to trigger points in the gastrocnemius, soleus and tibialis posterior in addition to soft tissue mobilization, stretching and eccentric training. The other group was treated with the same soft tissue mobilization, stretching and eccentric training program. Both groups were seen in private outpatient physical therapy clinics twice a week for 4 weeks. Subjects returned for follow up 3 months after discharge. The independent variables were TDN and time. The dependent variables were FAAM, NPRS, GROC, PPT, and strength of the triceps surae muscle group.

There were 4 subjects that dropped out of the study. Three of these subjects were in the TDN + MT + Ex group and one from the MT + Ex group. Subject attrition at the 3 month follow up was 61%. An intention to treat analysis was conducted and missing data was carried forward from the most recent data collection. A within group analysis was conducted with Friedman's Rank and significant at $p < .05$. A statistically significant difference occurred for the MT + Ex groups with all dependent measures: FAAM, NPRS, GROC, PPT and strength. The TDN + MT + Ex group had a significant improvement in all dependent variables except for the GROC.   In addition, the mean for both groups exceeded the MCID for the FAAM, NPRS and GROC at the 4 week data collection.

In conclusion, the results of this study provide a detailed study design and protocol that could be modified for large randomized controlled trial to investigate the effect of TDN on Achilles tendinopathy. Two of the three conditions for feasibility were met. Several modifications are proposed for a future research design.   Specific results from this study include a significant improvement in pain, strength and functional outcomes in the MT + Ex group as well as the TDN + MT + Ex group. There was a large attrition for the 3 month follow up data which increases the probability for a type II error. However, the mean change scores for the FAAM, GROC and NPRS were clinically meaningful for the MT + Ex group, while the FAAM and GROC were clinically meaningful for the TDN + MT + Ex. Follow up studies are needed to determine the effect of TDN for Achilles tendinopathy and to compare the results of this intervention to other treatment options available to people with this diagnosis.

APPENDIX A

Physician Letter for Recruitment - Sample

Dear Dr. ######

I would like to inform you of a research study that will be conducted at Breakthrough Physical Therapy. We will be comparing the effect of 2 treatment programs on non-insertional Achilles tendinopathy. You may currently have patients that could qualify for inclusion to this study.

Achilles tendon disorders are common to runners as well as those who maintain a sedentary lifestyle. We are conducting a randomized controlled trial comparing the results of trigger point dry needling, manual therapy and exercise to manual therapy and exercise on pain and functional activity tolerance in patients with non-insertional Achilles tendinopathy. There are several published studies reporting benefits of trigger point dry needling for headache and neck pain,[63] temporomandibular disorders,[13] lateral epicondylitis,[14] and back pain.[12] However, there are no published studies reporting the effects of trigger point dry needling for Achilles tendinopathy. The most current clinical practice guidelines for physical therapy recommend eccentric exercise and long term studies report significant improvement in pain and return to activity following a consistent eccentric exercise program.[7] However, systematic reviews on eccentric exercise are not conclusive on the effectiveness of eccentric exercise for Achilles tendinopathy.

We are seeking a total of 66 men and women between the ages of 18 and 60 to participate. The inclusion criteria for this study include:

1. Primary region of pain along the Achilles tendon.
2. Pain ≥ 4 weeks.
3. Subjective pain rating of ≥ 4/10 on the numerical pain rating scale.

Participants will be randomized into 2 groups. One group receiving trigger point dry needling along with soft tissue mobilization and exercise while the second group will have the same soft tissue techniques and exercises. All participants will be treated for 8 sessions and maintain a consistent home program. A follow up examination will be performed at 3 months.

If you have any questions, please do not hesitate to contact me. I look forward to the opportunity to talk with you and your patients about participating in this study.

Sincerely,

Alex Koszalinski, PT, DPT, OCS, FAAOMPT
Physical Therapist
(330)329-1718

APPENDIX B

Participant Recruitment Letter - Sample

(Insert Company Header)

RESEARCH VOLUNTEERS NEEDED

IF YOU HAVE ACHILLES TENDINITIS OR PAIN IN THE BACK OF YOUR HEEL
YOU MAY BE ELIGIBLE TO PARTICIPATE IN A RESEARCH STUDY

Alex Koszalinski, PT, DPT, OCS, FAAOMPT and Breakthrough Physical Therapy are looking for men and women to participate in a research study who are between the ages of 18 and 70 and have been diagnosed with Achilles tendinitis or have pain in the back of the heel. We are comparing the results of treatments commonly performed by physical therapists to help determine the most effective combination of techniques and exercises to reduce pain in the back of the heel.

In order to be eligible for this study, you must be:

- Between 18 and 70 years old
- Have had pain for 4 weeks or longer
- Be able to schedule treatment 2 times a week for 4 weeks
- Return to Breakthrough Physical Therapy for a brief examination 3 months after completing the last treatment

If you are interested in participating in this research study, please inform the Office Coordinator and you will be able to be scheduled with a physical therapist who is involved in this research study.

For additional information, please contact:

Alex Koszalinski
(330)329-1718
alexkoszalinski@yahoo.com

APPENDIX C

Recruitment Flow

Present to Physical Therapy with Primary Complaint of Posterior Heel pain or Diagnosis of Achilles tendinitis or tendinopathy

↓

Complete Medical History Documents

↓

Patient History and Screen for Inclusion/Exclusion Criteria Physical Examination Complete

↓

Sign Informed Consent

↓

Complete Self Report Measures

↓

Complete Physical Exam

↓

Blinded Randomization into Groups

Group 1
MT + exercise

↓

Treatment x 8 sessions

Group 2
TDN+MT + exercise

↓

Treatment x 8 sessions

Return 2-4 days after 8th treatment session for testing
FAAM, PPT, GROC, NPRS, muscle endurance

↓

Return for follow up at 3 months
FAAM, PPT, GROC, NPRS, muscle endurance

APPENDIX D
Self-Report Measures

Foot and Ankle Ability Measure (FAAM)
Activities of Daily Living Subscale

Please answer **every question** with **one response** that most closely describes your condition within the past week. If the activity in question is limited by something other than your foot or ankle mark "Not Applicable" (N/A).

	No Difficulty	Slight Difficulty	Moderate Difficulty	Extreme Difficulty	Unable to do	N/A
Standing	☐	☐	☐	☐	☐	☐
Walking on even Ground	☐	☐	☐	☐	☐	☐
Walking on even ground without shoes	☐	☐	☐	☐	☐	☐
Walking up hills	☐	☐	☐	☐	☐	☐
Walking down hills	☐	☐	☐	☐	☐	☐
Going up stairs	☐	☐	☐	☐	☐	☐
Going down stairs	☐	☐	☐	☐	☐	☐
Walking on uneven ground	☐	☐	☐	☐	☐	☐
Stepping up and down curbs	☐	☐	☐	☐	☐	☐
Squatting	☐	☐	☐	☐	☐	☐
Coming up on your toes	☐	☐	☐	☐	☐	☐
Walking initially	☐	☐	☐	☐	☐	☐
Walking 5 minutes or less	☐	☐	☐	☐	☐	☐
Walking approximately 10 minutes	☐	☐	☐	☐	☐	☐
Walking 15 minutes or greater	☐	☐	☐	☐	☐	☐

Tampa Scale for Kinesiophobia

1 = strongly disagree   2 = disagree   3 = agree 4 = strongly agree

1. I'm afraid that I might injury myself if I exercise	1	2	3	4
2. If I were to try to overcome it, my pain would increase	1	2	3	4
3. My body is telling me I have something dangerously wrong	1	2	3	4
4. My pain would probably be relieved if I were to exercise	1	2	3	4
5. People aren't taking my medical condition seriously enough	1	2	3	4
6. My accident has put my body at risk for the rest of my life	1	2	3	4
7. Pain always means I have injured my body	1	2	3	4
8. Just because something aggravates my pain does not mean it is dangerous	1	2	3	4
9. I am afraid that I might injure myself accidentally	1	2	3	4
10. Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening	1	2	3	4
11. I wouldn't have this much pain if there weren't something potentially dangerous going on in my body	1	2	3	4
12. Although my condition is painful, I would be better off if I were physically active	1	2	3	4
13. Pain lets me know when to stop exercising so that I don't injure myself	1	2	3	4
14. It's really not safe for a person with a condition like mine to be physically active	1	2	3	4
15. I can't do all the things normal people do because it's too easy for me to get injured	1	2	3	4
16. Even though something is causing me a lot of pain, I don't think it's actually dangerous	1	2	3	4
17. No one should have to exercise when he/she is in pain	1	2	3	4

Global Rating of Change

Date: _____

Please rate the overall condition of your injured body part or region FROM THE TIME YOU BEGAN THE TREATMENT UNTIL NOW (Check only one):

__ A very great deal worse	__ About the same	__ A very great deal better
__ A great deal worse		__ A great deal better
__ Quite a bit worse		__ Quite a bit better
__ Moderately worse		__ Moderately better
__ Somewhat worse		__ Somewhat better
__ A little bit worse		__ A little bit better
__ A tiny bit worse		__ A tiny bit better

Body Chart and Numeric Pain Rating Scale

PAIN DIAGRAM AND RATING

Please use the diagram below to indicate the symptoms you have experienced over the past 24 hours. Be VERY precise when drawing the location of your pain. Use the key to indicate the type of symptoms

Key: Pins and Needles   = 000000   Stabbing   = //////////
            Burning   = xxxxxx   Deep Ache   = zzzzzz

Please rate your *current* level of pain on the following scale (circle one)
0   1   2   3   4   5   6   7   8   9   10
(no pain)   (worst pain imaginable)

Please rate your *worst* level of pain in the last 24 hours on the following scale (circle one)
0   1   2   3   4   5   6   7   8   9   10
(no pain)   (worst pain imaginable)

Please rate your *best* level of pain in the last 24 hours on the following scale (circle one)
0   1   2   3   4   5   6   7   8   9   10
(no pain)   (worst pain imaginable)

APPENDIX E

TDN Protocol

The TDN treatment protocol for this study will include treatment locally to the tissues of the lower leg only and not regionally to include tissues throughout the lower quarter and the foot. The study by Cotchett included a regional approach for needling in the lower leg as well as the foot to treat trigger points for the effective management of plantar heel pain.[23]   Clewley also described a regional approach in treatment of adhesive capsulitis.[29]   Travell and Simons report referred pain from trigger points in the gluteus medius and minimus that may refer pain to the lower leg and posterior heel.[70]   Hseih also demonstrated decreased EMG activity in satellite trigger points following needling of active trigger points.[87]   However, the majority of the published reports describing the outcomes of TDN have treated the local tissues.[19-21,30,32,155,157] In addition, the recommendations from the clinical practice guidelines are limited to eccentric exercises of the lower leg rather than a global approach including muscles proximal to the lower leg. Therefore, the TDN protocol for this study will be limited to the muscles of the lower leg and additional muscles of the lower quarter will not be included in this study.

Participants placed into Group 1 will have treatment with TDN + manual therapy and exercise. TDN will be performed at each treatment session to trigger points in the gastrocnemius, soleus or tibialis posterior. At each visit, the physical therapist will perform a palpation assessment as previously described for the physical examination. The therapist will then select up to four trigger points to perform TDN during the session. Priority for needling will be to treat active trigger points first and then latent trigger points but no more than four trigger points can be treated in one session.

Equipment and supplies for dry needling will include Hwa-to needles 0.3 mm x 40 mm or 0.3 mm x 50 mm single use with a tube to reach the trigger points in the gastrocnemius and soleus. A Hwa-to 0.3 x 25mm single use needle with a tube will be provided for trigger points in the tibialis posterior. One needle will be used for each trigger point and will be disposed of in accordance with the OSHA standard procedures for disposal of contaminated needles.[193] A needle disposal container and red bags for blood soaked gauze will be supplied. Individually wrapped alcohol pads will be used to clean the skin over the trigger point prior to performing the TDN procedure and immediately after the needle is removed. Non-latex gloves will be worn on both hands throughout the TDN procedure. Hand sanitizer will be used on the gloves prior to cleaning the skin with alcohol pads.

Once the trigger points have been identified and the determination has been made as to which trigger points will be treated, the therapist will prepare the needles. Either a 25mm, 40mm, 50 mm needle, or longer if necessary, will be selected as determined by the therapist for the appropriate depth of the trigger point. The therapist will don gloves for both hands and select the appropriate needle for each trigger point. The wrapping will be pulled back to reveal the handle of the needle but not to expose the needle. Then the needle, still contained in the wrapping, will be placed on the edge of the needling tray with the handle hanging over the edge so the therapist can pick up the wrapped needle without touching the tray. The therapist will then remove an individually wrapped alcohol pad and clean the skin over and around the region of the trigger points that will be needled. One alcohol pad will be used for each trigger point. The therapist will then clean the gloved hands with sanitizer and select the appropriate needle from the tray and remove the needle from the wrapper.

The therapist will grasp only the handle of the needle while the needle will remain in the protective tube. The blue spacer insert will be removed from the tube and the therapist will hold both the needle and tube to maintain the protective tubing over the needle without any portion of the needle becoming exposed or in contact with any object. The non-needling hand will be placed with the palm flat on the skin and the index and middle fingers placed directly over the trigger point. The needling hand will place the needle and protective tubing in between the index and middle finger of the non-needling hand and sufficient pressure will be applied to hold the tube in an upright position to allow the needling hand to tap the tip of the handle to insert the needle into the skin. Once the needle has been inserted, the needling hand will then hold the tube while the index and middle fingers of the non-needling hand will be separated to produce sufficient tension in the skin to allow the needle to remain in an upright position so the tube can be removed from the needle and not allow the needle to fall and land on the patient's skin or the therapist's gloved hand. The needle will be directed as described below for each muscle.

1. Medial or lateral gastrocnemius

   a. Patient position: trigger points in the gastrocnemius will be treated with the participant in the prone position with the ankle in neutral position and feet suspended from the table. An alternate position to improve relaxation and needle tolerance will be with the patient in prone but a pillow under the anterior aspect of the lower leg to produce 20-30 degrees of knee flexion and the toes resting on the table to produce 20 degrees of ankle plantar flexion.

   b. Therapist position: The therapist will sit on a stool at the edge of the table alongside the affected leg with the participant close to the edge to allow for a comfortable reach to the trigger point.

  c. Needling technique: The needle will be directed posterior to anterior.

2. Soleus:

  a. Patient position: the participant may be positioned in prone or side lying. The prone position remains as described for the gastrocnemius. For trigger points in the lateral soleus, the patient may lay on the non-involved side or on the involved side for trigger points in the medial aspect of the soleus. The participant's knees may be flexed to the degree that is comfortable for the patient and will allow the therapist to maintain a comfortable reach to perform the needling technique. The ankles should be positioned at 20 degrees of plantar flexion

  b. Therapist position: the therapist will be positioned in sitting on a stool at the edge of the table.

  c. Needling technique: Trigger points in the medial aspect of the soleus will be needled in a medial to lateral direction while trigger points in the lateral soleus will be needled in a lateral to medial direction. The direction for needling will be the same in the prone or side lying positions.

3. Tibialis posterior:

  a. Patient position: the participant may be positioned in supine or side lying on the affected side. In the supine position, a pillow may be placed under the leg to allow for knee flexion 20-30 degrees and plantar flexion 20 degrees at the ankle for additional comfort. In the side lying position, the knee may be flexed and ankle plantar flexed to the same degree measures.

b. Therapist position: the therapist will sit on a stool at the edge of the table facing the involved leg.

c. Needle direction: the therapist will apply pressure to the medial aspect of the gastrocnemius and soleus muscles to push them posteriorly to expose the tibialis posterior muscle. This will be maintained throughout the needling procedure. The needle will be placed posterior to the tibia and directed anterior and medially toward the tibia.

d. Precautions: the posterior tibial artery, vein and nerve are located posterior to the tibialis posterior muscle. The needle should be positioned in close proximity to the tibia to avoid contact with these structures.[75]

Each trigger point will be needled in the same manner as described here. Once the needle is inserted into the skin, the therapist will direct the needle as described above for each muscle. The needle will be inserted into the trigger point and then retracted but still maintained in the muscle then inserted again into the trigger point at a rate of approximately one insertion per second. This is referred to as a pistoning technique.   If a twitch occurs, the needle will continue to be inserted in a pistoning manner until a twitch is no longer produced. If no muscle twitch occurs after it is inserted two times into the trigger point, then the needle will be drawn out of the muscle but still maintained in the subcutaneous tissue and then redirected toward the trigger point in a more lateral direction. This will be done in such a manner that a cone shape is made with the needle where the apex of the cone is superficial and the broad diameter of the cone is deep at the location of the trigger point.[190] Once the cone method has been completed, the needle

will again be directed into the middle of the trigger point and then rotated slowly in either a clockwise or counterclockwise direction until the tissue tension becomes taut and additional tension cannot be applied. At this point, the needle will not be able to be removed from the muscle with a gentle pull by the therapist. The needle will remain in this rotated position until the needle can be withdrawn from the tissue with a gentle pull of the needle.[191]

Once the needle is removed from the tissue, the therapist will apply continuous pressure at the site of the insertion to produce homeostasis. This will be maintained for 30 seconds. If any blood is present, it will be cleaned with a gauze pad and disposed of in a red biohazard bag.

Appendix F

Manual Therapy and Exercise Protocol

1. Stationary bike: participants in both groups will begin each session on the stationary bike for 5 minutes. This is a light warm up to increase circulation in the muscles of the lower leg.

2. Soft tissue mobilization: longitudinal stroking will be performed for up to 4 trigger points in the gastrocnemius, soleus or tibialis posterior. The therapist will perform this technique along the taut band by placing the thumbs of each hand at the distal end of the taut band. Deep pressure will be applied by both thumbs, but only one thumb will glide proximally along the taut band while the other thumb will remain in place at distal end of the band. Movement of the thumb will be slow at a rate of approximately 8-10 seconds from the distal to proximal end. A total of 6 repetitions will be performed at each trigger point.[191] This process is believed to assist in relaxation and increase circulation through the taut band.

3. Stretching: passive stretches for the gastrocnemius and soleus will be performed in standing. While the combined hamstring and gastrocnemius-soleus stretch will be performed in long sitting. An alternate stretch position for the hamstring and gastrocnemius-soleus will be in supine. Each stretch will be held for 30 seconds and performed 3 times.

4. Eccentric strengthening: exercises for this study are taken from the Alfredson protocol. These exercises were included in each of the 3 studies that met the requirement for the systematic review by Meyer.[78] Stevens and Tan also used these exercises in their study that compared the Alfredson exercise protocol to a patient driven "do as tolerated"

protocol.[124] Stevens and Tan report no significant difference in VISA-A scores or VAS after 6 weeks of daily exercise. Because of the variability in pain levels and tolerance for exercise, the "do as tolerated" protocol described by Stevens and Tan will be utilized in this study. Participants in this study will perform each exercise within their perceived level of tolerance with the goal of performing 3 sets of 15 repetitions twice a day. Participants will be encouraged to add a weighted backpack to increase the resistance with the same instructions for the frequency and volume of the exercise.

    a. Eccentric strengthening for gastrocnemius and soleus with straight knee
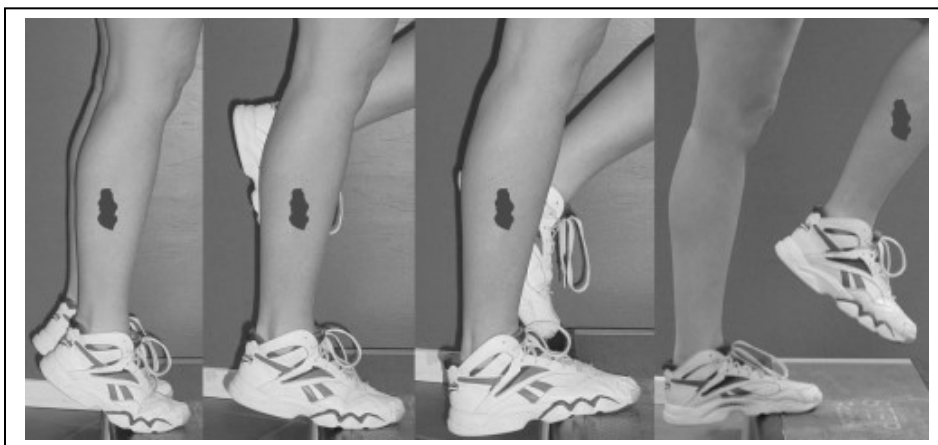
The participant will stand on the edge of the step with the heel hanging over. Only the involved leg will control the lowering of the body. At the end of repetition, the non-involved leg will raise the body and then the involved leg will again perform the eccentric lowering of the body weight.

b. Eccentric strengthening for gastrocnemius and soleus with bent knee

The participant will perform the exercise as described for the straight knee. However, in this exercise the knee will remain in a flexed position to emphasize the soleus muscle.

5. Tibialis posterior strengthening with ankle adduction: the tibialis posterior acts synergistically with the gastrocnemius and soleus during the gait cycle to plantar flex the ankle to achieve the terminal stance and pre-swing phases of the gait cycle. Kulig et al report this muscle is most active during adduction.[192] Trigger points in the tibialis posterior can refer pain to the central posterior lower leg and thus will be strengthened. To perform this exercise, participants will sit on a chair with the forefoot of the involved foot on towel while the heel remains on the floor.   The participant will adduct the foot to move the towel medially. Weight can be added to the end of the towel to achieve the desired level of effort. Participants will perform 3 sets of 15 repetitions and will only perform this exercise during the treatment sessions.

6. Intrinsic strengthening with towel crunches: intrinsic muscles also act synergistically with the gastrocnemius and soleus during the gait cycle to plantar flex the ankle during terminal stance and pre-swing phases of the gait cycle. This muscle group will be
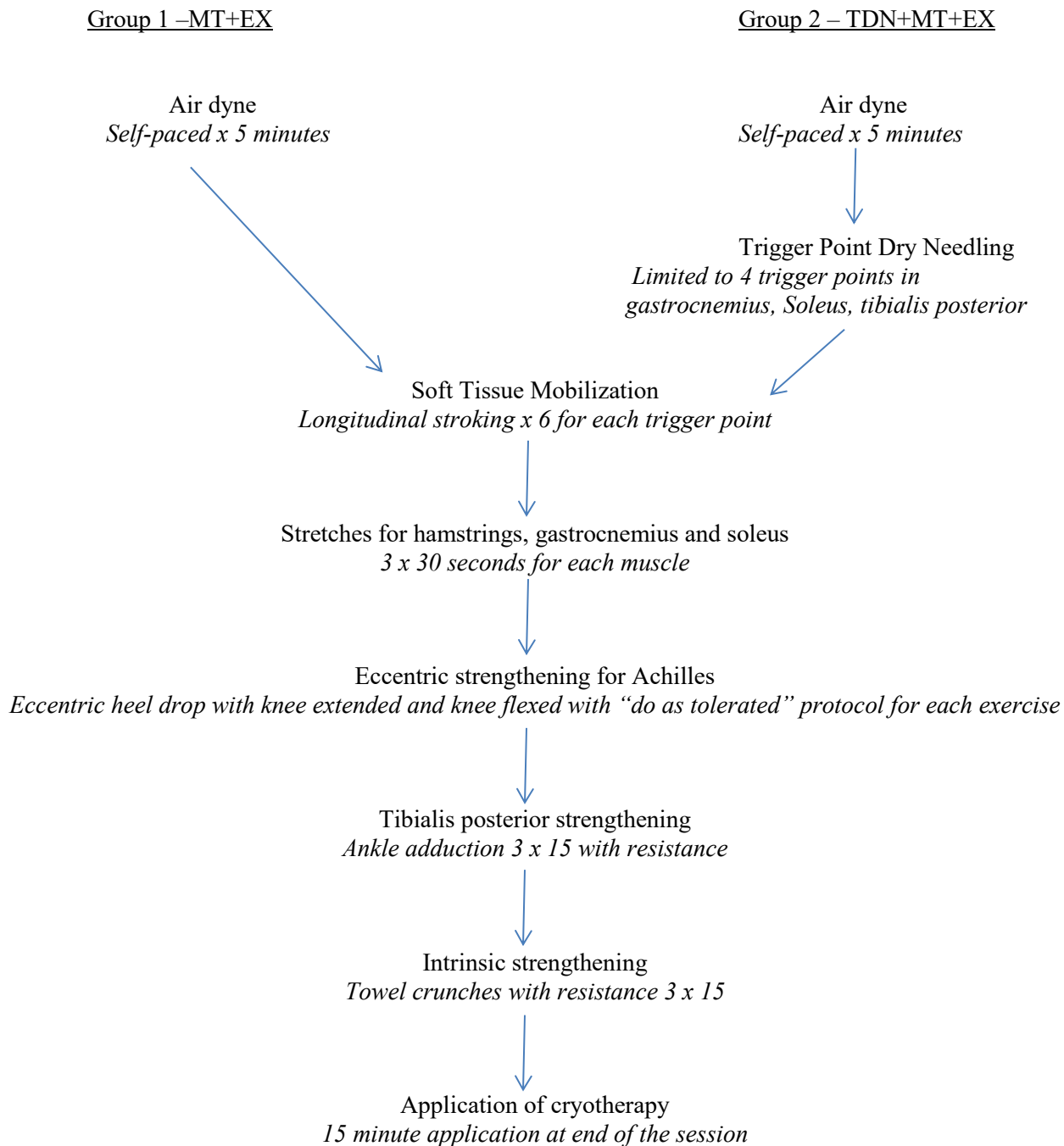
strengthened by performing a towel crunch. The forefoot of the involved leg will be placed on a towel while the heel remains on the floor. The participant will flex the toes to drag to towel toward the heel while the heel remains fixed on the floor. Additional weight can be added to the end of the towel to achieve the desired level of effort. Participants will perform 3 sets of 15 repetitions and will only perform this exercise during the treatment sessions.

7. application of a gel ice pack: a gel pack will be added to the lower leg at the end of each session. The exception will be at the conclusion of the interventions at the eighth session. During this session, the participant will complete all interventions and then undergo the discharge examination including self-report measures, PPT and muscle endurance testing. The gel pack will be applied at the conclusion of the discharge examination procedures. For this intervention, the participant will choose to lay supine or prone and the ice will be applied to the lower leg for a maximum of 15 minutes. The participant will be monitored throughout the application and standard precautions will be followed for cryotherapy.

Appendix G

Sequence of Interventions for Each Session

Group 1 –MT+EX

Group 2 – TDN+MT+EX

Air dyne
Self-paced x 5 minutes

Air dyne
Self-paced x 5 minutes

Trigger Point Dry Needling
*Limited to 4 trigger points in
gastrocnemius, Soleus, tibialis posterior*

Soft Tissue Mobilization
Longitudinal stroking x 6 for each trigger point

Stretches for hamstrings, gastrocnemius and soleus
3 x 30 seconds for each muscle

Eccentric strengthening for Achilles
Eccentric heel drop with knee extended and knee flexed with "do as tolerated" protocol for each exercise

Tibialis posterior strengthening
Ankle adduction 3 x 15 with resistance

Intrinsic strengthening
Towel crunches with resistance 3 x 15

Application of cryotherapy
15 minute application at end of the session

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