A RETROSPECTIVE STUDY OF THE EFFECTS OF ADDING ASTYM® TREATMENT TO STANDARD OCCUPATIONAL THERAPY INTERVENTIONS WHEN TREATING INDIVIDUALS WITH LATERAL ELBOW TENDINOPATHY

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By: Anne Crosser, MSOTR/L

Approved by:

Lucinda Dale, EdD, OTR, CHT, FAOTA _____
Committee Chair

Elizabeth S. Moore, PhD _____
Committee Member

Emily J. Slaven, PT, PhD, MS _____
Committee Member

Accepted by:

Laura Santurri, PhD, MPH, CPH _____
Director, DHSc Program
University of Indianapolis

Stephanie Kelly, PT, PhD _____
Dean, College of Health Sciences
University of Indianapolis

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Anne M. Crosser

University of Indianapolis

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Abstract

Different therapeutic interventions are used to manage patients with lateral elbow tendinopathy (LET). Astym treatment is an emerging rehabilitation approach used to promote healing and regeneration of soft tissue conditions; however, there is limited research on its effectiveness for individuals with LET. The purpose of this research study was to determine if the addition of Astym treatment to standard occupational therapy (OT) interventions improved Focus on Therapeutic Outcomes (FOTO) functional status (FS) measures, numeric pain rating scale (NPRS) scores, standard grip strength and provocative grip strength for individuals with LET more than standard OT interventions. A retrospective study using data from 222 individuals with LET was conducted. Patients were placed in two groups for comparison: Astym treatment and standard OT interventions (AG) and standard OT interventions (SG). All outcome scores significantly improved for both groups. Except for higher pain score at the intake evaluation for the AG group, there were no significant differences on all outcomes between groups. Results of this study indicate that standard OT interventions and standard OT interventions with the addition of Astym produce significant improvements in FOTO FS measures, NPRS scores, standard grip strength and provocative grip strength for patients with LET. Further research is needed to determine if the addition of Astym produces superior results when added to standard OT interventions.

Keywords: lateral elbow tendinopathy, Astym treatment, occupational therapy

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A Retrospective Study of the Effects of Adding Astym® Treatment to Standard Occupational Therapy Interventions When Treating Individuals with Lateral Elbow Tendinopathy

Lateral elbow tendinopathy (LET) is the most common cause of lateral elbow pain (Scher, Wolf, & Owens, 2009) causing functional impairment, disability, and lost productivity (Bhabra et al., 2016). It is categorized as a significant clinical problem (Abat et al., 2017), and decision making concerning allocation and prioritization of interventions for the entire spectrum of patients with LET is inconsistent (Coombes, Bisset, & Vicenzino, 2015). Researchers have investigated underlying mechanisms and interventions for the condition; however, LET remains a complex and challenging condition for health care professionals and researchers to manage (Bisset & Vicenzino, 2015).

Despite the high prevalence of LET, there is not a universally accepted effective and consistent algorithm for management of the condition (Vaquero-Picado, Barco, & Antuna, 2016). Patients generally undergo some combination of conservative interventions for the condition, with mixed patient outcomes from the various interventions (Gregory, Wysocki, & Cohen, 2016). Occupational therapists offer multiple standard interventions for the treatment of LET; however, consistent with other healthcare professionals, they have not established a standard treatment protocol. Without an established treatment protocol, variations in administration, duration, frequency and types of interventions provided by medical providers, including occupational therapists, have been identified in clinics and in the literature. In addition, it is impossible to verify adherence to the various treatment protocols that have been recommended (Raman, MacDermid, & Grewal, 2012).

Therapeutic exercise, education, orthoses, and modalities such as ultrasound (US), low-level laser therapy (LLLT), iontophoresis, and manual therapies are among the standard

interventions available to therapists that have been researched (The University of British Columbia, 2016). Another intervention that warrants further research is Astym treatment, an emerging regenerative rehabilitation intervention. Developers and researchers of Astym treatment report that it is a therapy that stimulates the regeneration of healthy soft tissues and resolves tendinopathies, scar tissue problems, and other soft tissue dysfunctions ("What is Astym® Treatment?", 2012). Few researchers have studied the benefits of Astym treatment for individuals with LET, and researchers have yet to publish information on whether adding Astym treatment to standard occupational therapy (OT) interventions would benefit individuals with LET.

The purpose of this retrospective study was to determine if patients diagnosed with LET who received Astym treatment and standard OT interventions (AG) had significantly different outcomes compared to patients who only received standard OT interventions (SG). Specifically, this study addressed the following objectives.

1. To determine if there was a significant difference in Focus on Therapeutic Outcomes (FOTO) functional status (FS) measure scores (which is established from the body part specific patient inquiry (PI) self-assessment survey) between AG and SG at the OT intake evaluation and the OT discharge evaluation.
2. To determine if there was a significant difference in reported pain levels on the numeric pain rating scale (NPRS), standard grip strength, and provocative grip strength between AG and SG at the OT intake evaluation and the OT discharge evaluation.

Literature Review

Tendinopathy is a general term used to describe clinical conditions such as pain and pathology in chronic overuse tendon disorders, and it can develop in any tendon (Bhabra et al., 2016; Maffulli, Lango, & Denaro, 2010; Ode, 2016). As a result of overuse, major tendons such as the wrist extensor tendons are vulnerable to soft tissue lesions at the musculotendinous origin (Maffulli et al., 2010). Researchers have published papers that describe conflicting information on terminology, anatomical constituents, histopathology, pain mechanism, neurochemistry, etiology, and treatment for tendinopathy (Coombes, Bisset, & Vicenzino, 2009; Fredberg & Stengaard-Pedersen, 2008). Results of these publications have left gaps in the literature and have led to more confusion and conflict on how to treat tendinopathies such as LET. With more than 40 published conservative treatment methods for elbow pain and loss of function due to LET (Goguin & Rush, 2003; Shmushkevich & Kalichman, 2013), there is a lack of consensus on optimum management of this challenging condition (Brumell et al., 2016). Abat et al. (2017) further reported that the lack of consensus relative to diagnostic tools and treatment modalities exemplifies a management dilemma for healthcare professionals. The current review of the literature includes terminology, epidemiology, clinical presentation, pathophysiology, and treatment for LET. Descriptions of Astym and FOTO, the main outcome tool used for this study, are also included in this review of the literature.

Terminology

Ahmed et al. (2013) make reference in their publication that Runge, in 1873, first described LET in the medical literature as “writers cramp”. Morris (1882) later renamed “writers cramp” to “lawn tennis elbow”. Coues (1914) was the first to use the term epicondylitis to describe an inflammatory process of the pathological changes of the tendon. Subsequent

researchers have suggested that this condition may not be an inflammatory process but rather a degenerative process. Since "itis" represents inflammation, there is ongoing debate on whether epicondylitis is an appropriate term to use for this diagnosis (Ali & Lehman, 2009; Nirschl & Pettrone, 1979; Rayan, 2002).

Although lateral epicondylitis, lateral epicondylalgia, LET, and tennis elbow are all terms used interchangeably to describe this condition, they each represent distinct stages of the same elbow disorder. Tennis elbow is probably the most commonly accepted label used in clinical practice (Zeisig, Ohberg, & Alfredson, 2006), and it is probably the most commonly used label by patients, clinicians, and the general public (Fedorczyk, 2011). Although this term is not an inappropriate description of the status of the tendon, it is misleading because few people sustain this condition from playing tennis (Fedorczyk, 2011).

There continues to be debate among researchers and clinicians regarding tendon conditions and the appropriate terminology to use when describing chronic tendon disorders (Fedorczyk, 2011; Stasinopoulos & Johnson, 2006). Tendinosis is a term used to describe histological findings identified in an overuse injury to the tendon and the patient may be asymptomatic (Fedorczyk, 2011). Tendinopathy is a term used to describe the spectrum of changes that occur in a damaged or diseased tendon (Ode, 2016; Scott, Backman, & Speed, 2015). The current proposed terminology that may be more appropriate to describe the condition being investigated for this study is tendinopathy (Rayan, 2002; Stasinopoulos & Johnson, 2006) because it incorporates all healing stages of the tendon tissue (Fedorczyk, 2011; Fredberg & Stengaard-Pedersen, 2008; Maffulli, Dhan, & Puddu, 1998; Maffulli et al., 2010; Stasinopoulos & Johnson, 2006). Furthermore, tendinopathy is a term used by experts to signify the clinical

syndrome characterized by pain, pathological characteristics, and impaired performance (Maffulli, et al., 1998); therefore, the term LET will be used for the remainder of this paper.

Epidemiology

Lateral elbow tendinopathy is more common than medial elbow tendinopathy, with researchers reporting a frequency of it occurring 7 to 10 times more often (Hoogvliet, Randsdorp, Dingemanse, Koes, & Huisstede, 2013; Walz, Newman, Konin, & Ross, 2010). There is an annual incidence of four to seven LET cases per 1000 patients in general medical practice (Smidt et al., 2006), prevalence is from 1% to 3% of the general adult population (Goguin & Rush, 2003), 9% to 35% of tennis players (Pluim, Staal, Windler, & Jayanthi, 2006), and up to 14.5% in the working population (Fan et al., 2009). In addition, it is the most common type of upper extremity (UE) tendinopathy in workers (Hopkins et al., 2016).

In the general population, the estimated prevalence of LET is 1.3% in men and 1.1% in women (Walker-Bone, Palmer, Reading, Coggon, & Cooper, 2004). Lateral elbow tendinopathy is predominantly linked to females in the working population (Fan et al., 2009; Shiri, Viikari-Juntura, Varonen, & Heliovaara, 2006). Although the association between gender and LET remains unclear (Fan et al., 2014), Waugh, Jaglal, Davis, Tomlinson, and Verrier (2004) suggested that the disorder can be more severe and more chronic in females. The prevalence of LET peaks at middle age, with the greatest incidence occurs between 45 and 54 years of age (Shiri et al., 2006), and the median age of 41 years (Nirschl & Ashman, 2003). Lateral elbow tendinopathy occurs more frequently among Caucasians (Fan et al., 2009; Nirschl, 1992).

Personal, psychological and physiological factors associated with LET include the following: smoking, obesity, social support, repetitive movement, forceful activities, and job satisfaction (Descatha, Dale, Jaegers, Herquelot, & Evanoff, 2013; Fan et al., 2009; MacDermid,

Wojkowski, Kargus, Marley, & Stevenson, 2010; Shiri et al., 2006; Walker-Bone, Palmer, Reading, Coggon, & Cooper, 2012). High job strain and a history of LET or other UE musculoskeletal disorders, such as rotator cuff injuries or carpal tunnel syndrome, were also strong correlates to cases of LET (Fan et al., 2009; Fan et al., 2014; Herquelot et al., 2013; Shiri & Viikari-Juntura, 2011). Although a single incidence of lifting a heavy object or performing an awkward grasping movement can develop into an elbow tendinopathy, high activity levels involving repetitive UE motion are more often the cause of this condition (Leadbetter, 2016; Fedorczyk, 2011). Researchers report that the most recent research suggest that LET is a degenerative process due to repetitive microtrauma (Sims, Miller, Elfar, & Hammert, 2014).

Clients with LET typically report that the condition is of insidious onset (McMurtrie & Watts, 2012); however, there are also reports where clients recall a history of overuse without trauma (Walrod & Young, 2018). Although the source of LET is often unknown, there is evidence that some cases are due to muscle imbalance, or overuse and/or repetitive strain that overloads the wrist and digit extensors (Goguin & Rush, 2003; Shiri & Viikari-juntura, 2011; Waseem, Nuhmani, Ram, & Sachin, 2012). The intensity, frequency, and hours spent completing a repetitive motion may also contribute to the development of pathological tissue (Cook & Purdam, 2009; Fan et al., 2009). Awkward postures, localized mechanical stress, hand-arm vibration, and highly dynamic movements are occupational factors that have been associated with increased risk of work-related LET (Fan et al., 2009, Fan et al., 2014; Shiri et al., 2006). Office work, assembly work, wood product manufacturing (Fan et al., 2014), construction work, and housekeeping (Descatha et al., 2013) are occupations that have been correlated with LET.

Combined repetitive elbow flexion/extension, wrist bending/twisting and forearm rotating, twisting or screwing motions, duration of forearm supination, and the combination of

forearm supination and forceful lifting are linked to increased incidence of LET (Descatha et al., 2013; Fan et al., 2014; Herquelot et al., 2013; Walker-Bone et al., 2012). Furthermore, Fan et al. (2014) found that forearm pronation and time spent with forceful exertion including pinching, pushing, pulling, or power gripping and/or lifting were significant predictors of the development of LET of the dominant side.

Clinical presentation

The primary symptom of LET is localized pain and tenderness over or near the lateral humeral epicondyle, which often extends into the dorsal forearm (Mora-Relucio et al., 2016; Shmushkevich & Kalichman, 2013). Patients may report their symptoms as acute or chronic. Patients who have symptom duration greater than 12 weeks, such as the individuals in the Sevier and Stegink-Jansen (2015) study, are considered to have a chronic condition (Scott et al., 2015). Brummel, Baker, Hopkins, and Baker (2014) reported that patients with LET generally experience insidious onset and gradual progression of pain and weakness. Patients' accounts of pain differ from an intermittent ache to a constant severe sharp pain (Brummel et al., 2016). Patients' descriptions of pain may vary with activities. A patient may report that using hand tools causes mild pain, or a patient may report that picking up a coffee cup causes severe pain (Walrod & Young, 2018). Pain from LET may be incapacitating, and it has been reported to negatively affect the patients' quality of life (Kawa & Kowza-Dzwonkowska, 2015).

The pain at the lateral epicondyle of the humerus is often aggravated with resisted extension of the wrist (Arif, Sharif, & Khalid, 2017), gripping, forearm rotation, digital extension and wrist radial deviation (Cooper, 2014; Fan et al., 2014). Lateral elbow tendinopathy mainly affects the dominant UE (Kheradmandi, Ebrahimian, Ghaffarinejad, Ehyaii, & Farazdaghi, 2015) and may result in functional deficits that interfere with activities of daily living (ADL),

occupational tasks (Fan et al., 2009), and leisure activities (Kawa & Kowza-Dzwonkowska, 2015). An average episode of LET lasts 6 to 24 months (Jariwala, Dorman, Bruce, & Rickhuss, 2012), with the vast majority of patients (70-80%) recovering by one year (Boyer & Hastings, 1999).

Pathophysiology

Unraveling the complex etiology of LET and identifying contributing mechanisms of the condition remain an ongoing challenge. The etiology associated with degenerative tendon changes of LET is unknown, with many opposing opinions as to the origin of the condition (Abate et al., 2009; Bagayoko & Brockmeier, 2012; Bostan, Balta, Asci, Aytekin, & Eser, 2016; Sevier & Stegink-Jansen, 2015). Researchers have reported alterations in tendinous tissue around the elbow, but it is not known if the pathological tissue changes are the result of LET or if the condition caused the tissue to change (Chen, Wang, Xu, & Zheng, 2010; Kraushaar & Nirschl, 1999). Complexities associated with the etiology of LET have led to confusion and differing opinions about optimal treatment for the condition (Coombes et al., 2015).

Mechanism of degeneration. Faro and Wolf (2007) reported that tendons that transmit loads under elastic and eccentric conditions, such as the extensor carpi radialis brevis (ECRB), are prone to injury. Researchers have implicated hypoxia, ischemic damage, oxidative stress, hyperthermia, and matrix metalloproteinase imbalance as mechanisms leading to tendon deterioration (Sharma & Maffulli, 2006). An invasion of dense, immature, hypertrophic, tendon fibroblasts (tenocytes), haphazard proliferation of tenocytes, and intracellular abnormalities in tenocytes have been found in the abnormal tendinosis tissue (Fredberg & Stengaard-Pedersen, 2008; Kraushaar & Nirschl, 1999; Nirschl & Ashman, 2003; Nirschl, 1992). These degenerative

components appear to cause a disturbance of the internal structure of the tendon, and cause degeneration of the cells and matrix (Coombes et al., 2009.)

An increased rate of matrix remodeling may lead to a mechanically less stable tendon (Arya, 2010; Cook & Purdam, 2009), and collagen cross-linking, non-collagenous matrix, and vascular elements may also weaken the tendon (Fredberg & Stengaard-Pedersen, 2007). Rees et al. (2009) reported that when the internal stress in the tendon fibers is greater than the ultimate tensile strength of the tendon tendinous micro-tears occur. These researchers further identified that when stretching exceeds the tendon tolerance, a micro-tear occurs and the adaptation of the tendon to multiple micro-tears leads to tendinosis. Inflammatory mediators (Maffullli et al., 2010), corticosteroids, and fluoroquinolones have also been linked to tendon weakening (Fu, Rolf, Cheuk, Lui, & Chan, 2010; Le Huec et al., 1995; Rees et al., 2009).

Histopathology. Seminal articles by Goldie (1964) and Coonrad and Hooper (1973) provided evidence that acute inflammatory cells were lacking and degenerative pathologic tissue existed in LET. These researchers discovered that a degenerative process was occurring in the tissue due to an abandoned or immature healing response after an injury or repetitive microtrauma from overuse. Rees, Maffulli, and Cook (2009) further explained that inflammation appears to be involved in the initiation of tendinosis, and irregular inflammatory cells may be present in the tissue, but it does not seem to spread or progress the condition.

Nirschl and Pettrone (1979) published a pivotal study on LET that coined the term angiofibroblastic hyperplasia to describe degenerative tissue in chronic tendinopathy. Increased cell numbers and ground substance, vascular ingrowth, capillary budding, disorganized and immature collagen, and angiogenesis (neovascularization) were identified in the pathological tissue examined in their study (Nirschl & Pettrone, 1979). Maffulli et al. (2010) identified

loosely woven, altered structure, and a succeeding increase in non-collagenous matrix in abnormal tendinosis tissue. An invasion of immature fibroblasts (Bagayoko & Brockmeier, 2012), an increase in proteoglycan content, and a disruption of normal orderly tendon fibers from granulation tissue have also been identified (Longo, Ronga, & Maffulli, 2009). Additional findings from histopathological studies include thickened blood vessels, hyaline degeneration, fibrosis, focal areas of adipose tissue and calcific deposits in the origin of the ECRB (Cohen, Romeo, Hennigan, & Gordan, 2008; Goguin & Rush, 2003; Leadbetter, 1992; Nirschl, 1992; Regan, Wold, Coonrad, & Morrey, 1992). Increased glucosaminoglycans, extra cellular matrix deterioration, reduced type I collagen synthesis, elevated apoptotic and autophagic cell death rates of tenocytes were elements that have also been found in chronic LET (Chen et al., 2010; Kazanjian, 2010; Zeisig et al., 2006).

Anatomy and morphological changes. Nirschl and Pettrone (1979) identified the ECRB as the most frequently affected tendon of the common extensor tendon in LET, followed by the extensor digitorum communis (EDC). Researchers who studied cadaveric specimens of the origin of the ECRB described the pathological tissue as grayish, edematous, and friable (Khan, Cook, Bonar, Harcourt, & Matsastrom, 1999; Nirschl & Ashman, 2003; Tosti, Jennings, & Seward, 2013). Similarly, Khan, Cook, Taunton, and Bonar (2000) and Fredberg and Stengaard-Pedersen (2008) described this abnormal tendon tissue as dull in appearance, brownish, and soft when compared to normal whitish, glistening and firm healthy tendon tissue. Researchers who biopsied pathologic ECRB tissue also identified moth-eaten fibers, mitochondrial redistribution, fibrous necrosis, signs of muscle fiber regeneration over the entire muscle, and higher percentages of the fast twitch oxidative muscle fiber type (Coombes et al., 2009; Goguin & Rush, 2003).

Neurogenic inflammation and neovascularization. Maffulli et al. (2010) clarified that neovascularization is an element of tendinosis and reported that the pain fibers accompanying the neovessels contain neurochemicals involved in neurogenic inflammation. Further contributing to the symptoms of pain with LET, neovessel ingrowth, microvasculature, and neurochemicals have been identified in the tendinous origin of the ECRB (Coombes et al, 2009; Fedorczyk, 2012; Fredberg & Stengaard-Pedersen, 2008; Nirschl, 1992; Regan et al., 1992). Moreover, vasculo/neural ingrowth and multiple blood vessels in the extensor origin in chronic painful ECRB tendinosis have been identified through color Doppler (Zeisig et al., 2006).

Anatomical location and its effect on vascularity contribute to the degeneration of the ECRB and pain symptoms. Anatomically the ECRB is located underneath the extensor carpi radialis longus and attached directly on the lateral epicondyle (Stoeckart, Vleeming, & Snijders, 1989). With this arrangement, Stoeckart et al. (1989) found that every time the elbow moves, the ECRB absorbs abrasive forces, which may contribute to the micro-tears found in the abnormal tissue. The vascularity and healing of the ECRB are compromised due to two avascular zones on the volar side of the ECRB (Zeisig et al., 2006). Additionally, due to regional anoxia, chemical irritation from neurochemicals in the neural tissue of ECRB tendon may contribute to pain symptoms (Alfredson & Lorentzon, 2002; Alfredson, Ljung, Thorsen, & Lorentzon, 2000; Ljung, Alfredson, & Forsgren, 2004; Schneeberger & Masquelet, 2002).

Tendinopathy staging or grading. Due to the evolving research on tendinopathies and LET, there has been a paradigm shift in underlying concepts for treating the condition. Researchers have recommended staging or grading tendinopathies to assist clinicians with clinical decision-making (Cook, Rio, Purdam, & Docking, 2016; Kraushaar & Nirschl, 1999). Because interventions may not be effective if they are not specific to the degenerative stage of

the tendon (Cook et al., 2016) proposed algorithms based on chronicity of the disorder have been developed (Bhabra et al., 2016; Coombes et al., 2015).

Clinical researchers continue to study interventions without knowledge of the stage of tendon pathology; therefore, optimal interventions for each stage remains unknown (McCreesh & Lewis, 2013). Symptom resolution may take longer if interventions do not facilitate appropriate healing of the degenerative stage of the tendon (Bhabra et al., 2016). The diverse presentation of symptoms and the diverse responses to healing continue to make it difficult for researchers and clinicians to find the best treatment protocol for LET. Whether or not a staging model is used to guide interventions, there is heterogeneity in clinical presentation and pathology of individuals with LET (Cook & Purdam, 2009; Coombes et al., 2015), which continues to make it difficult to determine an optimal treatment protocol.

Treatment

In the literature there are a host of interventions available for the treatment of LET, and a variety of practice patterns are used in clinics. Multimodal, (a term used to describe a combination of interventions), manual treatments, exercise, and Astym treatment are just a few treatment options that healthcare providers include for individuals with LET.

Treatment options and practice pattern variations. There have been more than 200 scientific papers describing LET since 1996, with various conclusions about suitable therapy (Brismee, 2014). Multiple treatment options for this condition have been implemented with varying levels of efficacy and cost effectiveness (Bostan et al., 2016; Olaussen, Holmedal, Lindbaek, Brage, & Solvang, 2013). Physical interventions for LET have been widely investigated, and conservative management has been recommended as an initial approach to treatment of the condition (Bisset & Vicenzino, 2015). However, there is not a single treatment

that has been identified as the most effective intervention for long term relief of LET (Bagayoko & Brockmeier, 2012; Bisset, Paungmali, Vicenzino, & Beller, 2005; Elmajee & Pillai, 2016; Sevier & Stegink-Jansen, 2015) and different treatment protocols are used to rehabilitate patients with LET (Fedorczyk, 2012; MacDermid et al., 2010; Waseem et al., 2012).

The therapeutic interventions have different theoretical mechanisms of action for achieving the goals of reducing pain and increasing function (Stasinopoulos & Stasinopoulos, 2017). Conservative treatment for LET is often effective (Walz et al., 2010), but there does not appear to be a clear understanding of the natural course of the condition. Without clinicians and researchers having a clearer understanding of the cause and the progression of the condition, it is difficult to determine if treatments for LET are actually effective or if the disorder just improves spontaneously.

Given that LET is a common condition associated with significant individual and societal costs (Chourasia, Buhr, Rabago, Kijowski, & Sesto 2013), it is imperative to establish optimal prevention and treatment approaches from evidence-based management of LET (MacDermid et al., 2010). Currently there are no clinical practice guidelines for the treatment of LET. Additionally, a standardized classification model for this condition has not been incorporated into clinical practice (Wixom & LaStayo, 2012). There are many and highly varying standard therapeutic intervention options available for LET yet limited scientific support for the incorporation of these interventions in clinical practice exists. In addition, few high-level quality studies supporting interventions for LET have been published, and the outcomes of these studies vary widely (Hoogvliet et al., 2013; Raman et al., 2012). As a result, treatments for LET are continuously being investigated to establish support for the efficacy of the interventions.

Therapists frequently provide conservative treatment to individuals with LET, with MacDermid et al. (2010) identifying 49 interventions used in hand therapy practice. Additionally, there are more than 16 practice patterns implemented in various combinations for acute and chronic conditions (Wixom & LaStayo, 2012). Strength of evidence to support the management of mild-to-severe LET through these practice patterns is limited (Wixom & LaStayo, 2012). Interventions differ widely in the theoretical mechanism of action (Viswas, Ramachandran, & Anantkumar, 2012). Moreover, interventions for the condition are as divergent as resting the wrist and elbow joints to inducing high musculotendinous forces across the lateral aspect of the elbow joint (Wixom & LaStayo, 2012). To complicate matters, training of clinicians is inconsistent, and the interventions selected are often based on the type of discipline training the clinician has received (MacDermid et al., 2010).

Multimodality treatment reviews. Anthony et al. (2013) created an evidence informed aid to assist clinicians with decision-making regarding the management of patients with LET. In their report, they provided a summary of published evidence on non-surgical interventions commonly used to manage LET. Studies of various levels were included in their review on manual therapies, exercise, acupuncture, modalities (LLLT, US, and iontophoresis), orthoses, and taping. The researchers described variations in exercise prescription, and variations in the dosages of treatments. The result of the Anthony et al. (2013) appraisal of the literature was that there were different levels of evidence and different levels of support for the various interventions.

Sims et al. (2014) published a systematic review of non-surgical interventions for LET. Randomized controlled trials on injections, iontophoresis, bracing, exercise, friction massage, extracorporeal shock wave therapy (ESWT), and laser therapy were examined. No substantial

evidence supported the use of one intervention over another. Several other researchers published reviews on available interventions for LET (Bhabra et al., 2016; Bisset & Vicenzino, 2015; Boiragi & Kaur, 2015; McMurtrie & Watts, 2012); Vaquero-Picado et al., 2016). Rest, orthoses, counterforce bracing, strengthening, stretching, US, corticosteroid injections, dry needling, acupuncture, and ESWT were among interventions that were appraised in their reports. These researchers all reported that not one intervention was identified as superior (Bhabra et al., 2016; Bisset & Vicenzino, 2015; Boiragi & Kaur, 2015; McMurtrie & Watts, 2012; Vaquero-Picado et al., 2016).

Sutton et al. (2016) completed a systematic review of musculoskeletal disorders, including LET and reported that beneficial multimodal care for the management of LET included variations in the following: combinations of interventions, number of visits (range from 3 to 12) and duration of episode of care (range from 4 to 6 weeks). They also reported that superior outcomes for the management of LET were associated with multimodal programs that included education, exercise (strengthening, stretching, occupational exercises) manual therapy (manipulation) and soft tissue therapy (deep friction massage). It was found that clinicians often combined interventions in a program of multimodal care for their patients; however, there was minimal research available on the best combination of interventions. The authors recommended that to ascertain the best combination of interventions, future research of multimodal programs should begin with evidence-based interventions for the management of specific musculoskeletal conditions, such as LET. It was also stated that to determine the best combination of modalities, higher quality studies need to be completed, and researchers should compare one group with a full program of multimodal care to one group with a full program of multimodal care minus one of the interventions (Sutton, 2016).

In 2016, the British Columbia Physical Therapy Task Force updated their published summary of evidence regarding standard physical therapy interventions for treatment of LET (The University of British Columbia, 2016). This task force reviewed published studies on manual interventions, exercise, acupuncture, LLLT, US, ESWT, iontophoresis, orthoses and taping. The task force found no clinical evidence to support elbow joint mobilizations, spinal mobilizations, ESWT, or taping for treatment of individuals with acute LET. Weak support was identified for soft tissue techniques, exercise, acupuncture, laser, US, iontophoresis, and orthoses for treatment of individuals with acute LET. There was strong support for elbow joint mobilizations, spinal mobilization techniques, exercise, LLLT, and taping for treatment of individuals with chronic LET. Weak evidence was identified for use of soft tissue techniques, acupuncture, US, and orthoses for treatment of individuals with chronic LET (The University of British Columbia, 2016).

Manual therapy interventions. There are a host of manual interventions used to treat LET. Kumar and Jetly (2016) reported that manual interventions facilitate healing and pain reduction by increasing blood flow to an area for the removal of chemical irritants and for the transport of endogenous opiates. Collagen reorganization, stimulation of fiber orientation, fascial tissue lengthening, and restoring alignment and mobility of joints were reported as additional benefits of manual therapy (Kumar & Jetly, 2016).

Elbow joint mobilizations, spinal mobilization techniques, and soft tissue techniques are manual interventions that have been reviewed (The University of British Columbia, 2016; Trivedi et al., 2014). Researchers have also examined the effectiveness of deep transverse friction massage, mobilization with movement, myofascial release (MFR), active release techniques (ART), and instrument assisted soft tissue mobilization (Balasubramaniam &

Kandhasamy, 2016; Blanchette & Normand, 2011; Chung-Yuan et al., 2016; Dasm, 2012; Hoogvliet et al., 2013; Joseph, Taft, Moskwa, & Denegar, 2012; Prabhakar & Kage, 2013; Prabhakar, Kage, & Anap, 2013). Collectively, the conclusions of publications on manual therapy indicate that techniques are effective, but future studies need (a) larger sample sizes, (b) longer term follow ups, and (c) more rigor (Kim, Choi, & Moon, 2012; Vicenzino, Cleland, & Bisset, 2007).

Herd and Meserve (2008) published a systematic review on mobilization with movement (MWM), cervical spine mobilization, Cyriax physiotherapy, and other manipulative techniques used for treatment of LET. These researchers reported that the manipulative techniques and the comparison treatments varied. The quality of the studies also varied, but the authors found that all of the manipulative therapies had favorable outcomes when used to treat patients with LET. It was also determined that MWM was the most frequently studied, with supporting evidence for short and long term benefits. Herd and Meserve (2008) concluded that future studies with larger sample sizes, valid outcome measures, and long-term follow up were needed.

Khuman et al. (2013) examined MFR compared to conventional therapy (US, exercise, and stretching) for the treatment of LET, and they found that MFR had superior outcomes. Ajimsha, Chithra, and Thulasyammal (2012) compared two groups of individuals with LET, and they found greater improvement in outcomes in a MFR group versus a sham US control group. Another group of researchers examined MFR, active release techniques (ART) and conventional therapy (US, stretching and strengthening), and found that MFR and ART were more effective than conventional therapy for the treatment of LET (Trivedi et al., 2014). The collective recommendations from these researchers were that higher quality studies with larger sample

sizes and longer observations were needed to increase the understanding of the optimal methods to manage LET (Ajunsha et al., 2012; Khuman et al., 2013; Trivedi et al., 2014).

Exercise. Researchers have supported exercise as a conservative treatment for LET. Stasinopoulos (2016) reported that an exercise program is the most common treatment for the management of LET. Stasinopoulos and Stasinopoulos (2017) determined that eccentric-concentric training combined with isometric contraction was more effective than was only eccentric training or eccentric-concentric training for LET. Tyler, Thomas, Nicholas, Malachy, and McHugh (2010), supported the efficacy of adding eccentric strengthening to standard treatment for LET. Raman et al. (2012) found that individuals with LET had improvement in pain levels, grip strength, and function when resistive exercise was used.

In a systematic review of the effectiveness of eccentric exercise (EE), Cullinane, Boocock, and Trevelyan (2013) reported that EE improved outcomes when used as a part of a multimodal therapy program for treatment of LET. Soderber, Grooten,and Ang (2012) found positive effects of EE on pain free grip and wrist extensor strength. It was found that a group that completed EE as part of their rehabilitation had significantly higher pain-free hand grip and wrist extension strength at their final follow up evaluation (Soderber et el., 2012). Despite researchers supporting the use of exercise for LET, not one type of exercise or exercise dosage has been identified as superior (Bisset & Vicenzino, 2015; Raman et al., 2012). Furthermore, Stasinopoulos (2016) reported that exercise alone has low rehabilitative success when treating LET but when combined with other interventions the effectiveness has been heightened.

Regardless of the type or dosage prescribed, every therapeutic intervention in musculoskeletal LET rehabilitation introduces a mechanical force or load that is believed to begin the healing cascade (Hammer, 2008; Thompson, Scott, Loghmani, Ward, & Warden

2016). Mechanotransduction is the result of these mechanical forces on the musculoskeletal system (Khan & Scott, 2009; Lorenz, 2010). Khan and Scott (2009) and Lorenz (2010) described mechanotransduction as a process by which the body converts mechanical loading into cellular responses. It is believed that through mechanotherapy (the application of mechanical forces used by therapists) cellular activities that influence the tissue-level process of growth, modeling, remodeling, and repair will occur (Thompson et al., 2016). Thompson et al. (2016) stated that the ultimate goal of musculoskeletal regenerative rehabilitation is the restoration of function through musculoskeletal tissue regeneration and repair.

Astym. To facilitate healing, Astym treatment includes the use of specific instruments for manual treatment of the soft tissue in conjunction with exercise. Astym treatment is a type of noninvasive soft tissue regenerative therapy that stimulates the healing of acute and chronic musculoskeletal pathological conditions such as LET (Astym, 2012; Sevier & Stegink-Jansen, 2015). Researchers at Performance Dynamics in Muncie, Indiana report that on a cellular level Astym treatment causes (a) dysfunctional capillary exudation, (b) local fibroblast activation and recruitment, (c) phagocytosis, and (d) release of growth factors ("How Astym Treatment Works," 2012). Researchers have determined that patients with post-operative scar tissue (Davies & Brockopp, 2010), chronic or refractory tendinopathies, or repetitive over-use injuries should be considered for this treatment ("What is Astym Treatment," 2012).

Astym treatment began gaining recognition and popularity in the early 2000s, with more recent evidence-based research supporting its effectiveness (Sevier & Stegink-Jansen, 2015; Performance Dynamics, 2009). For more than 20 years, Astym treatment protocols have been developed and refined by a multi-disciplinary research team consisting of scientists, therapists, and physicians at Performance Dynamics, Inc. ("Better Research, Better Results," 2012). These

researchers continue to refine Astym treatment protocols based on statistics from outcome data that are constantly being updated ("Better Research, Better Results," 2012; Sevier & Stegink-Jansen, 2015).

The Astym treatment is categorized as a regenerative medicine that professionals use to stimulate the regeneration and remodeling of healthy muscles, tendons, and ligaments (Kivlan, Carcia, Clemente, Phelps, & Martin, 2015). The application of hand-held instruments with a custom designed edge, functional activities, and exercise stimulate the body to resorb fibrotic scar tissue and to regenerate healthy tissue (Davies & Brockopp, 2010). Clinicians use Astym treatment to decrease pain, reduce impairments, lessen movement restrictions, and improve patient function ("What is Astym?," 2012; Kivlan et al., 2015). Clinicians also use Astym treatments to desensitize and remodel scar tissue and to facilitate increases in strength and range of motion (Davies & Brockopp, 2010).

Application of the Astym hand- held instruments is primarily in a parallel fashion along the involved kinematic chain. By treating in a longitudinal manner, the instruments glide over the normal tissue and engage only the abnormal or dysfunctional tissue (Davies, Brockopp, & Moe, 2016). A lubricant is utilized to reduce the friction from the instruments, while stroking motions are applied to the skin (McCormack, 2012a; McCormack, 2012b). The stroke direction, treatment edge, angle, speed, pressure, and application of shear forces imparted by Astym instruments are systematic (Davies & Brockopp, 2010; Sevier & Stegink-Jansen, 2015; Sevier et al., 2009). The instrument edges are held at a 60° to 80° angle in relation to the skin surface, allowing the Astym custom designed instrument edge to "catch" on dysfunctional soft tissues and the irregular fibrosis. The instruments are designed to assess the presence of dysfunctional

tissue by amplifying the tactile sensation of the underlying improperly organized tissues (Davies et al., 2016).

Studies that support the use of Astym treatment to improve function have been published. Tyler and Slaven (2013) found that systematically induced stretching and strengthening combined with the Astym instrumentation led to gains in self-perceived function, walking speed, and a reduction in pain when treating osteoarthritis of the knee. The effect of Astym treatment on bilateral high hamstring tendinopathy and the mid-portion Achilles tendinopathy was examined by McCormack in 2012. When Astym instrumentation was combined with stretching and eccentric strengthening, individuals had decreased pain and increased function (McCormack, 2012a; McCormack, 2012b). Management of chronic ankle pain using joint mobilization and Astym treatment also revealed beneficial outcomes (Slaven & Mathers, 2011). Furthermore, Davies and Brockopp (2010) completed a retrospective study and found that Astym treatment coupled with manual lymph drainage, gentle massage, stretching, and strengthening had positive results when treating individuals who had scar tissue following surgical treatment for breast cancer.

For patients with LET, Sevier and Stegink-Jansen (2015) completed a two group, prospective, randomized controlled trial study. Participants were randomized into either a group that completed EE and stretching or a group that completed EE and stretching plus the application of the Astym instruments. Using the Patient and Physician Global Rating of Change Scale to determine the resolution of symptoms, Sevier and Stegink-Jansen (2015) identified that 78.3% of the elbows in the Astym treatment group met resolution criteria at four or eight weeks of the initial treatment. In contrast, only 40.9% of the elbows in the EE group met the resolution criteria at four or eight weeks of the initial treatment. Of the individuals who did not respond to

EE and chose to receive four weeks of Astym treatment, 95.7% of these participants met the resolution criteria. Overall, of the individuals who received Astym treatment 83.6% met resolution criteria.

Further outcome results from the Sevier and Stegink-Jansen (2015) study were that the Astym treatment group's functional gain scores on the Disability of the Arm, Shoulder and Hand (DASH) outcome questionnaire had a greater reduction in disability ($p = .047$) at four weeks. In addition, compared to the EE group, the Astym treatment group had greater gains in grip strength ($p = .008$). However, statistically significant differences were not found between the two groups when assessing pain with activity ($p = .08$) and function ($p = .55$). An additional analysis was completed after the eight to twelve-week treatment period of the participants who received Astym treatment after not responding to EE. The researchers found decreased disability on the DASH by 13.43% ($p < .005$), decreased pain with activity by 26.1 mm on a visual analogue scale (VAS) ($p = .002$), increased grip of 6.3 pounds, and increased function by 17.0 mm on a VAS ($p = .004$). The researchers showed that DASH scores, pain with activity, and function at six and twelve-month assessments continued to improve compared to the baseline measurements (Sevier & Stegink-Jansen, 2015).

Slaven (2014) also established that Astym instrumentation may be effective for treating individuals with LET when combined with a program of stretching and strengthening. The researcher utilized a single case study A-B-C-B-C format. The A phase was the baseline, B was the stretching and strengthening phase, and C was the Astym instrumentation combined with the stretching and strengthening regime of the B phase. In the first phase B the patient experienced high levels of pain that resulted in inability to generate any grip force. With the introduction of Astym treatment into the therapy protocol, the individual with LET had an increase in pain-free

grip strength and a decrease in pain levels, which continued through both C phases and the second B phase (Slaven, 2014).

Functional Outcomes

In addition to common therapy interventions used to treat LET, there are standard outcome measures that are utilized to assess the condition and monitor the effectiveness of standard therapeutic care. These assessments may include grip strength, range of motion, pain pressure threshold, patient reports of pain, and provocative tests (Fedorczyk, 2011). These elements of the clinical evaluation, such as range of motion, have poor reliability and decreased responsiveness when compared to self-report measures (Von der Heyde & Droege, 2015).

Patient reported outcomes (PRO). Supplemental to the traditional standard outcome measures, PRO measures are now being included in the assessment process (Anthony et al., 2013; Werneke, 2016b). Given that traditional assessment tools used in therapeutic practices may not be optimal for measuring patients' function, there is strong support to include the use of PRO measures (Werneke, 2016b). Moreover, PRO measures are used to determine condition severity, prognosis, and response to therapeutic intervention. They are also used as a benchmark to assist with making clinical decisions (MacDermid & Silbernagel, 2015). With the paradigm shift in clinical practice to use PRO measures, and adding to the published support for the use of PRO measures in clinical practice, MacDermid and Silbernagel (2015) reported that these outcome measures are necessary for assessing physical impairments, activity performance, and patient-reported symptoms and function.

Werneke (2016a) suggested that frequent and objective feedback from PRO measures is essential for therapists to confirm the effectiveness of their therapy services. Patient reported outcome measures can be used to improve the quality of care, and improve value of healthcare

services. Furthermore, they can be used to monitor improvements in the patient's quality of life and function. Patient reported outcome measures are considered to be the gold standard for measuring patient outcomes and are endorsed by the World Health Organization, Centers for Medicare and Medicaid Services, National Quality Forum, the Institute of Medicine and other policymakers, payers, professional associations, and clinical practice guidelines (Werneke, 2016b).

The PRO measurement tools are evolving in health care (Hart, Wang, Cook, & Mioduski, 2010b). They define degrees of success in treatment, and PRO measures are increasingly being utilized in the assessment process. MacDermid and Silbernagel (2015) reported that tendinopathy-specific PRO measures were shown to be superior to more generic tools for some conditions, such as LET. Moreover, PRO measures that are used by clinicians to identify pain and functional limitations should be fundamental to outcome evaluation in patients with tendinopathy (MacDermid & Silbernagel, 2015).

As with the traditional measurements, the PRO measures can be used at the intake evaluation, throughout the episode of care, and at the completion of care. The generated outcomes from the PRO measures have been found to complement traditional clinical tools. They also serve as a link between a patient's task performance in the clinic and actual function in real-world situations (Wang, Hart, Cook, & Mioduski, 2010). Furthermore, many PRO measures have been found to be reliable, valid, and sensitive to change (Cook, Roddey, O'Malley, & Gartsman, 2005; Haley et al., 2006).

Focus on Therapeutic Outcomes. Publications that included the PI report of the elbow were not found in the literature; however, publications on the PI of the UE were discovered. Hart et al. (2010b) found that the shoulder PI reduced patient and clinician burden for outcomes data

collection while producing precise and responsive measures of patients' levels of activity dimension. Sindhu et al. (2012) examined the influence of fear avoidance beliefs on functional status outcomes for people with musculoskeletal conditions of the shoulder. Fear avoidance is defined as the avoidance of movement or physical activity based on the belief that the movement or activity will hurt and make the condition worse (FOTO Functional Status Measure Risk Adjustment Procedures, 2013). If a person has a fear of pain or has anxiety around pain this may have a negative impact on his or her physical and functional behaviors.

The findings of the Sindhu et al. (2012) study were that elevated fear avoidance beliefs on the PI report correlated with poorer recovery in individuals with UE muscle, tendon, or soft tissue disorders, or in individuals with UE osteopathy, chondropathy, or acquired musculoskeletal deformity. The results of this study led Sindhu et al. (2012) to suggest that individuals with shoulder conditions may benefit from treatment that specifically addresses fear avoidance beliefs. Wang et al. (2010) evaluated the meaningful interpretation of PI report of individuals with shoulder impairments. The researchers concluded that clinical interpretations of the PI report generated outcome measures that may be useful to clinicians in clinical practice, and may advance clinical science of rehabilitation of the UE (Wang et al., 2010).

FOTO functional status measures outcome data have been utilized to establish the effectiveness of treatment with individuals with adhesive capsulitis (Jewell, Riddle, & Thacker, 2009). In this retrospective study, participants' FOTO questionnaires at intake and at discharge from therapy were analyzed to determine a meaningful improvement of disability. The FOTO system was also used to generate statistically created intervention categories to aid in determining that joint mobility and exercise produced superior outcomes compared to US, massage, iontophoresis, and phonophoresis (Jewell et al., 2009).

Similarly, Hart, Tepper, and Lieberman (2001) completed a retrospective study to analyze health status changes in individuals with wrist or hand impairments. Through the use of FOTO data outcomes, these researchers identified that patients had improvements in perceived physical health status during their treatment episodes that were congruent with the difference between intake and discharge on their FS measure. Their findings also supported the responsiveness of the FOTO instrument for the collection of health status measure in patients with wrist and hand impairments and confirmed the ability to differentiate changes through time in this population (Hart et al., 2001).

There have been an increasing number of studies demonstrating the effectiveness of conservative treatments for LET, yet there is a large heterogeneity among trials, and no one intervention can be generalized to an entire population (Agostinucci, McLinden, & Cherry, 2012; Coff, Massy-Westropp, & Caragianis, 2009; Joseph et al., 2012; Kohia, 2008; Radpasand & Owens, 2009; Tyler, et al., 2010). The results from studies on physical interventions are varied, inconclusive, and conflicting (Bisset & Vicenzino, 2015). Additionally, there remain gaps in the literature, and study limitations impede the use of optimal evidence-based practice, and hamper the development of comprehensive clinical practice guidelines (MacDermid et al., 2010). Furthermore, MacDermid et al. (2010) reported that no treatment protocol that has been identified as being superior for managing LET, improving function, and reducing pain. Although studies have shown promising results for Astym, only a few of the published reports have evaluated the effectiveness of treatment with UE conditions, and no studies have linked Astym treatment with FOTO functional status measures for patients with LET.

This study was designed to compare standard therapeutic interventions to standard therapeutic interventions coupled with Astym treatment for individuals with LET who received

OT. The aim of the study was to determine if the addition of Astym treatment to standard OT interventions yields superior FOTO FS measures when treating individuals with LET. An additional purpose of this study was to determine if the addition of Astym treatment to standard OT interventions yields superior outcomes on the NPRS, and on standard grip strength and provocative grip strength measures. In addition, the results of this study may provide support for effective evidence-based treatment interventions for professionals who treat individuals with LET.

Method

Study Design

A non-experimental retrospective cohort study was completed using data extracted from medical records of patients diagnosed with LET who received OT at three outpatient clinics in New Mexico. Data from patient charts were categorized into one of two groups: AG or SG. This study was determined to be exempt by the Human Research Protections Program at the University of Indianapolis and the Presbyterian Healthcare Services (PHS) Institutional Review Board in Albuquerque, New Mexico.

Participants

A convenience sample of outpatients who received OT for LET through one of three outpatient clinics between January 1, 2014 and June 30, 2016 was used for this study. Two of the outpatient clinics were located in Albuquerque, NM, and the third clinic was located in Rio Rancho, NM. Inclusion criteria for participants were the following: aged 18 years or older, referred for treatment of LET, OT episode of care (intake evaluation, any number of follow-up treatments, and a discharge evaluation with objective measurements and outcomes), and completed FOTO for the episode of care. Exclusion criteria included FOTO episode of care (a)

for body part other than the elbow, (b) impairment other than muscle/tendon or soft tissue, and (c) not categorized as orthopedic.

An a priori sample size estimation was calculated based on comparing differences between two independent means using the G*Power software program (Faul, Erdfelder, Lang, & Buchner, 2007). For an effect size of 0.50, an alpha of .05, and a power of 80%, it was estimated that a sample size of at least 128 participants was needed. To determine if a medium value for the effect size applied to this study was valid, calculations were completed using the means and standard deviations of two groups (Nagrale, Herd, Ganvir, & Ramteke, 2009) and a similar effect size was obtained.

Data

Data were operationalized as follows:

- FOTO diagnosis of an elbow condition. Confirmed diagnosis of LET: Based on the physicians' referral, and the OT evaluation and treatment for LET.
- Age in years.
- Gender: male or female, based on the patient self-report.
- FS measure score at intake (based on the patient responses to the body part specific PI self-assessment survey that was completed on the first day of OT).
- FS measure score at discharge (based on the patient responses to the body part specific PI self-assessment survey that was completed on the last day of OT).
- Chronicity: Designated as acute or chronic. Acute category was assigned if the LET symptoms were present for less than three months at the initial exam, while chronic was assigned if the LET symptoms were present for greater then three months at the initial exam.

- Hand dominance: Based on patient report of using his or her right or left hand or both hands (ambidextrous), to complete the majority of daily activities.
- Involved UE: Based on the side (right or left) reported to have elbow pain.
- Mechanism of onset: Categorized as either trauma or overuse. Trauma was present if the patient reported the injury occurred from a one-time incident. Overuse was present if the patient reported the injury occurred from overuse.
- Severity of the condition: The severity of the condition was automatically calculated from the PI reports, and categorized as slight, moderate, severe, and very severe.
- Symptom acuity: The symptom acuity was based on the number of calendar days between date of onset of symptoms and date of initial intake: 8-14 days, 15-21 days, 22-90 days, 91 days to 6 months, and over 6 months (FOTO Functional Status Measure Risk Adjustment Procedures, 2013).
- Number of visits: The number of OT sessions that a patient participated in.
- Episode of care: The number of days in therapy, starting from the day of the OT intake and ending on the day of OT discharge evaluation.
- Type of work: Six categories were used: clerical, manual labor, professional, homemaker/caretaker, semiprofessional, and not applicable (N/A). Clerical category was used for patients who spent at least 80% of their day using a computer. Manual labor category was assigned for construction workers, painters, house cleaners, cooks, and maintenance workers. The professional category was used for the jobs that included engineers, therapists, and nurses. Homemaker/caretaker was used for those who performed nonpaid work in the home. Semiprofessional was used for hair dressers, and

law enforcement. N/A category included any patient who did not meet criteria for other categories.

- Work status: Categories as follows: Full-time work (32 hours a week or more), part-time work (fewer than 32 hours a week), unemployed, disability, retired, student, or volunteer
- The type of OT interventions each patient received.
- The worst, and best/least numeric pain level reported at OT intake and discharge. For increased reliability and validity of the NPRS in the PHS outpatient clinics, the common practice was to administer this instrument in a quiet and private environment.
- Standard grip and provocative grip, mean of three trials for both at OT intake and discharge, using two Jamar dynamometers. Standard grip strength procedures were completed with the patient seated, shoulder adducted, elbow flexed to 90 degrees and the forearm and wrist in neutral (Klein, 2014; Naughton, 2012). Provocative grip strength measurements were taken with the shoulder in 90 degrees of flexion, elbow in 0 degrees of extension, and the forearm in neutral (De Smet & Fabry, 1997; Dorf, Chhabra, Golish, McGinty, & Pannunzio, 2007). Each dynamometer was routinely checked for calibration every six months, which improved the precision and reliability of the devices. All occupational therapists employed by PHS completed rigorous training to ensure consistency of assessment and treatment techniques.

Instruments

Focus on Therapeutic Outcomes. Focus on Therapeutic Outcomes was formed in 1992 by six rehabilitation corporations to create a standardized outcomes measurement and reporting system for outpatient rehabilitation (Hart et al., 2010a). Focus on Therapeutic Outcomes is a proprietary international medical rehabilitation database management system and company

(Hart, Deutscher, Wernekes, Holder, & Wang, 2010a; Swinkels et al., 2008) that partners with clinics to collect and provide outcome measures and data management services (Sindhu et al., 2112; "What is FOTO?," 2016). The FOTO measurement system uses web-based software to analyze information on clinic performance, patient care, and patient satisfaction ("Outcomes Management System + Predictive Healthcare Analytics," 2018). It is a system that reports on characteristics of patients, health care providers, and organizations (Swinkels et al., 2007). The FOTO outcomes database includes standardized assessments of function, along with instruments that collect information on demographic characteristics. The FOTO database is the largest outpatient rehabilitation outcomes databank available to researchers in the United States (Gozalo, Resnik, & Silver, 2016), with the purpose of providing reliable, valid and responsive outcome measures (Swinkels et al., 2008).

The FOTO measurement system uses computerized adaptive testing (CAT) for the PRO. Computerized adaptive testing programs are efficient and feasible to use in outpatient clinics (Jette & Haley, 2005). Outcome scores from CAT programs provide comparable scores and are sensitivity to change, when compared to lengthier outcome evaluations that take longer to administer. The CAT selects items to match individual responses; therefore, the precision of the CAT is believed to be superior to fixed form outcome assessments (Jette & Haley, 2005). With a CAT measure, after the patient answers the first question, each successive item on the assessment is determined by the patient's response to the previous item. Outcome measures that rely on CAT use a computer algorithm to estimate a patient's level of the outcome being measured, update the estimate every time the patient answers another item, and selects the next item to be asked based on its match with the computer's updated estimate of the individual's trait level (Cook et al., 2005).

Patient inquiry self-report survey is a PRO used by FOTO to create a FOTO patient report on the functional level of the body part or impairment that needs treatment. Patients complete the FOTO body part specific PI self-assessment survey prior to participating in the therapy evaluation. Once the initial PI survey is completed, a risk adjustment algorithm predicts outcomes based on patient responses to the PRO (Risk Adjustment & Predictive Analytics, 2018). Examples of the 13 risk adjustment factors in the algorithm include: care type, impairment/body type, gender, age, acuity, surgical history, comorbidities, and medication (Risk Adjustment & Predictive Analytics, 2018).

Although the PI is not specific to tendinopathy, the survey is specific to body parts. The PI survey, the Elbow Wrist Hand (EWH), can be further analyzed by researchers to dichotomize and understand information on specific conditions, such as LET. The EWH was used in this study and was composed of three subsections: function (12 questions), medical history (10 questions), and pain (10 questions). A FOTO patient report is created from the patient responses on the PI survey.

The FOTO report created from the initial PI includes the following: patient name, patient identification number, date of birth, evaluation date, body part, impairment, history, care type, severity, age, acuity, gender, comorbidities, payer, and fear avoidance. The report also includes a FS measure score and a predicted FS measure score. The FS measure score is used to monitor functional improvement of patients. The predicted score is a FS measure score established from episodes of care from previous patients with similar conditions, which provides a baseline for therapist to compare expected outcomes to their patient. At discharge from therapy a FOTO discharge report is created from the patient completing the PI survey again. This report includes the same information as the intake, duration of episode of care in days, the number of therapy

visits, the patient's new FS measure, and points of change on the FS measure. Once the clinician closes a patient's FOTO episode of care a number is assigned for (a) patient's perception of improvement and (b) clinician's perception of improvement (The Power and Value of the FOTO Outcomes Measurement System, 2013).

The reported FS measures are established from the patient's perception of functional limitation before and after the completion of treatment. The FS measure is a score from zero to one hundred that represents a patient's functional ability (one hundred represents no functional impairment). The FOTO system uses functional staging to help clinicians and researchers interpret the FS measure score. Stage 1: exceedingly limited (0-24), Stage 2: poor (25-43), Stage 3: fair (44-59), Stage 4: good (60-80), Stage 5: excellent (81-100) ("Functional Staging," 2018). These FS measures are used by clinicians to monitor the functional changes of patients throughout the course of each patient's therapeutic episode of care (The Power and Value of the FOTO Outcomes Measurement System, 2013). The performance measures can also be utilized for the following: (a) monitor patient satisfaction, (b) identify quality of care (c) identify quality improvement approaches, (d) improve accountability, (e) create clinician and clinic risk-adjusted performance measures, and (f) enhance patient's functional improvement across therapy providers by reducing practice variations (Gozalo et al., 2016).

Specific to the elbow, the FOTO FS measure score is based on the EWH. There are no published studies on UE conditions, including LET, which have used the EWH as an outcome measuring tool. However, as a result of an internal analysis by the FOTO research team, it was concluded the EWH was efficient and produced precise, sensitive and responsive FS measure for patients receiving therapy for elbow, wrist, or hand impairments (Mark Werneke, personal communication July 10th, 2018). Based on 2010 FOTO data ($N = 17$), the EWH had strong test-

retest reliability, with an ICC of .95. The EWH was also found to have good responsiveness. Data from April 2008 to April 2010 ($N = 4863$) from 538 clinics in 26 states, showed that 70% of the patients attained FS measure scores equal to or greater than the minimal detectable change (MDC) at 95% confidence interval, and 70% of patients attained FS measure change scores equal to or greater than the minimal clinically important change (MCID) (Deanna Hayes, personal communication July 11, 2018).

Based on an internal analysis of 4863 patients by the FOTO research advisory board for the 2014 National Quality Forum endorsement, the MCID for the EWH is 4 (Mark Werneke, personal communication July 10, 2018). However, the MCID varies based on the patient's intake score; FS = 0-46 (MCID = 9.0), FS > 46-50 (MCID = 3), FS >50-54 (MCID = 2), and FS >54-100 (MCID is 4) (Mark Werneke, personal communication July 10th, 2018). The MDC for the EWH also varies based on the patient FS score at intake: The FOTO research advisory board established the following MDC: FOTO score: 0-10 (MDC = 23.9), 11-20. (MDC = 9.4), 21-30 (MDC = 6.0) 31-40 (MDC = 4.4), 41-50 (MDC = 4.0), 51-60 (MDC = 4.2), 61-70 (MDC = 4.9), 71-80 (MDC = 6.3), 81-90 (MDC = 9.2), 91-100 (MDC = 21.2) (Deanna Hayes, personal communication July 11th, 2018).

Numeric pain rating scale. The NPRS is the most commonly used tool to assess pain. It is a subjective 11-item unidimensional quantifier utilized in adults (Hawker, Mian, Kendzerka, & French 2011). It is a tool frequently used in clinical and research settings, with evidence supporting the reliability and validity of this measurement tool across many populations (Ferreira-Valente, Pais-Ribeiro, & Jensen, 2011). It has sufficient psychometric strength, with a test-retest stability correlation coefficient of .72 (Jensen, Turner, Romano, & Fischer, 1999).

Ferreira-Valente et al. (2011) published a study comparing the relative validity of four pain scales for detecting differences in painful stimulus intensity and differences between men and women in response to experimentally induced pain. It was found that the NPRS was the most responsive measure of pain intensity with a higher Cohen's effect size (d = .47) (Ferreira-Valente et al., 2011). Furthermore, Hawker et al. (2011) found that the construct validity of the NPRS was highly correlated to the VAS in patients with chronic pain conditions that have lasted longer than six months, with a reported correlation range from .86 to .95.

The reliability and validity of the NPRS has not been established on individuals diagnosed with LET; however, its responsiveness and test-retest reliability has been reported for other UE conditions. In patients with shoulder conditions that resulted in shoulder pain, a MCID of 2.17 for the NPRS was reported suggesting good responsiveness (Michener, Snyder, & Leggin, 2011; Mintken, Glynn, & Cleland, 2009). In a study of patients with shoulder pain, the NPRS had a MCID of 1.1 and a test-retest ICC of .74 suggesting good responsiveness and stability (Mintken et al., 2009). For populations with UE pain, Stratford and Spadoni (2001) reported the MDC of the NPRS at three points. The MCID was established as one point of change for individuals with chronic musculoskeletal pain (Salaffi, Stancati, Silverstri, Ciapetti, & Grassi, 2004).

Jamar dynamometer. The Jamar dynamometer is an assessment device used to measure grip strength in kilograms or pounds. It is considered to be an accurate, reliable, and valid dynamometer for measuring grip strength (Amaral, Mancini, & Marques, 2012), and researchers have used the device to establish grip strength norms in adults in the United States (Klein, 2014). The Jamar dynamometer has been reported to be reliable regardless of the medical condition or aspect of reliability being studied (Mafi, Mafi, Hindocha, Griffin, & Khan, 2012).

When the Jamar dynamometer was used to assess grip strength of healthy individuals, researchers identified good to excellent test-retest reliability, r = .88 to .93 (Mathiowetz, 2002) and excellent inter-rater reliability, r = .99 (Lindstrom-Hazel, Kratt, & Bix, 2009; Mathiowetz, 2002). In community-dwelling older adults, test-retest reliability was also high, with an ICC of .90 on the left hand and .91 on the right hand (Bohannon & Schaubert, 2005). Using the Jamar hand held dynamometer, Smidt et al., (2002) researched intra-observer reproducibility of pain-free grip strength and maximum grip strength with patients diagnosed with LET. It was determined that there was excellent intra-observer reliability, with both grip types (ICC ≥.90).

Kim, Park, and Shin (2014) reported that grip strength reflects functional status of the UE and found that in patients who sustained distal radius fractures, the Jamar dynamometer standard grip strength MCID and MDC was 6.5 kg. Similarly, Lang, Edwards, Birkenmeier, and Dromerick (2008) established an MCID of 5 kg for the affected dominant side and 6.2 kg for the affected non-dominant UE in patients early after stroke.

Procedures

Data collection: Retrospective data were obtained from the FOTO database and from PHS's Epic electronic medical record (EMR).

- The primary researcher, an occupational therapist from one of PHS's outpatient clinics, determined the eligibility of all charts for inclusion in the study. A list of potentially eligible patients with an elbow condition was received from a query of the FOTO database. To determine patients with LET, the primary researcher first established that the physician's referring diagnosis was for one of the following: elbow pain, tennis elbow, lateral epicondylitis, lateral elbow epicondylalgia, or lateral elbow tendinopathy. Second, the terms used by referring physicians were used to identify the treatment

diagnosis: ICD-9: 726.32 (lateral epicondylitis), ICD-10: M77.10 (lateral epicondylitis, unspecified elbow), ICD-10: M25.521 (pain in right elbow), or ICD-10: M25.522 (pain in left elbow).

- To confirm LET, the primary researcher reviewed each patient's OT intake evaluation and verified evaluation and treatment for LET. The primary researcher also confirmed that the EMR included documentation for a complete OT episode of care (initial OT assessment, progress treatment notes for each OT session, final discharge assessment).
- The primary researcher cross-referenced each patient's FOTO identification with the patient's PI report to confirm that each patient's FOTO episode of care included an intake FS measure score and a discharge FS measure score. Data for ineligible patients were deleted.
- Eligible patients were assigned numbers, then all data were entered into an Excel spreadsheet. To minimize data transfer error and for ease of data collection, the columns on the data matrix Excel spreadsheet corresponded to the same sequence as the FOTO data of each individual's PI report on the episode of care. Once all data were entered, the original FOTO query was deleted.

Data Analysis

Data were analyzed using IBM SPSS Statistics for Windows, Version 24.0 (IBM Corp., Armonk, NY). Normality of the data was determined using a Shapiro-Wilk, all tests were two-tails, and a significance level of less than .05 was considered statistical significance. Descriptive statistics were conducted on the entire sample and both treatment groups. Nominal data are presented as frequencies and percentages, and interval and ratio data are presented as medians and interquartile ranges if the data were not normally distributed, and means and standard

deviations if the data were normally distributed. To determine if participants in both groups were similar in demographic characteristics, comparisons were conducted using the Pearson chi-square test for nominal data and either an independent *t* test or non-parametric Mann-Whitney *U* test for interval and ratio data, dependent on whether or not the data were normally distributed.

Outcome data (FOTO score, pain, standard grip strength, and provocative grip strength) from intake and discharge were compared between the treatment groups using the non-parametric Mann-Whitney *U* test due to the data not being normally distributed. To determine if there was greater change in one treatment group compared to the other, change scores were created by subtracting the intake score from the discharge score. This method of analysis was used due to the data not being normally distributed. The change scores were compared for significant differences between treatment groups using a Mann-Whitney *U* test for non-normally distributed change scores and an independent *t* test for normally distributed change scores. A positive change score indicates a higher score/ value at discharge, and a negative change score indicates a lower score/value at discharge. If a participant's FOTO FS measure, standard grip strength or provocative grip strength got better over time the change score was positive. If a participant's pain level got better over time the change score would be negative. In addition, change from intake to discharge for the entire sample, the AG, and the SG were compared using the non-parametric Wilcoxon signed-ranks test.

Results

Initially, data from 805 FOTO forms from patients with orthopedic elbow impairment intakes (completed on the first day of OT) collected between January 1, 2014 and June 30, 2016 were obtained. Of the 805 intakes, there were 312 complete episodes of elbow impairment. Of the complete elbow impairment episodes, 90 of the orthopedic elbow impairments were other

conditions such as cubital tunnel syndrome, fractures, or arthritis. The remaining EMR were retained for analysis as the final sample size. See Figure 1 for the CONSORT flow chart.

Patient characteristics

The mean age for the total sample was 55.06 (*SD* = 14.07). The total sample was predominantly female, right hand dominant, right UE was more often involved, with chronic LET, and overuse as the primary mechanism of onset. The AG and SG were similar in gender, hand dominance, chronicity, involved UE, and mechanism of onset. Overuse was more frequently reported and most patients were right-hand dominant with right UE more often involved (see Table 3). The AG was younger than the SG, mean age was 53.26 (*SD* = 13.51) years and 56.65 (*SD* =14.43) years respectively, however, the difference was not statistically significant ($p = .073$). Frequency of condition severity showed twice the number of patients categorized as very severe for the SG compared to the AG (see Table 4); symptom acuity was more frequently greater than 22 days for both groups (see Table 5). Both groups had similar number of OT visits and FOTO episode of care (duration in days); the AG showed more clerical and manual types of work compared to the SG, and both groups more frequently had full-time workers (see Tables 6, 7, and 8). Occupational therapists used multiple types of treatments for patients in both groups with 5 of the 19 differing significantly between groups (see Table 9).

Outcomes

With the exception of pain at intake, there was not a statistically significant difference in any of the outcomes between the treatment groups (Table 1). When change scores were compared between the groups there were no significant differences (see Table 2). There was significant improvement ($p < .001$) in all outcomes for the AG (Table 10) and the SG (Table 11). Both groups surpassed the established Elbow Wrist and Hand MDC by 4.3 times for the AG and

3.8 times for the SG (Deanna Hayes, personal communication July 11th, 2018; Mark Werneke, personal communication July 10, 2018). Both groups surpassed the established Elbow Wrist and Hand MCID by 4.5 times for the AG and by 8 times for the SG (Deanna Hayes, personal communication July 11th, 2018; Mark Werneke, personal communication July 10, 2018). Both groups exceeded the MCID for the NPRS, with point change of -6 and -5 for AG and SG respectively (Farrar, Young, La Moreaux, Werth, & Poole, 2001; Salaffi et al., 2004; Stratford & Spadoni, 2001). Although both groups had improved standard grip and provocative grip, there are no established MDC or MCID for comparison for individuals with LET.

Discussion

Except for AG having higher NPRS scores at intake, no statistically significant difference was found between AG and SG at intake or discharge for the FS measure, NPRS, standard grip strength or provocative grip strength. Although participants differed in that SG had more severity of condition, based on the FOTO system functional staging, both groups were Stage 3 (Fair) at initial intake and both groups improved to Stage 4 (Good) at discharge.

In a study where Astym treatment was compared to EE for LET, Sevier and Stegink-Jansen (2015) suggested that Astym is an effective treatment to improve elbow function. The current study found that AG did not have functional gains that were statistically significant compared to SG. The contradictory results of the two studies may be due to the different assessment tools used to measure outcomes.

Using the self-rated DASH, Sevier and Stegink-Jansen (2015) found that the Astym group and the delayed Astym group had greater gains in function compared to the EE group The DASH incorporates functional statements that focus on use of the shoulder, elbow, wrist, and hand. It has a section that specifically addresses a patient's pain level over the last week. It

also has a couple of more global functional statements such as managing transportation needs and sexual activities. Compared to the DASH, the FOTO FS measure used in this study was calculated using risk adjustment factors such as age, acuity, severity, and co-morbidities. In addition to functional questions that are specific to a body part, the PI self-assessment survey included questions about medication use for the condition and previous treatment or surgeries for the condition. Because of differences in question types between the two outcome tools, it is plausible that the results reported by Sevier and Stegink-Jansen (2015) might have been different from this study due to the diverse measurement features of each tool. In addition, because the DASH does not consider risk adjustment factors when calculating the outcome scores, the scores may improve at greater intervals.

In the current study, the AG had higher pain levels at the initiation of therapy, with their NPRS scores decreasing the same amount as the SG. An established protocol that indicates the best treatment choice for LET based on a patient's pain level does not exist. Therapists in this study may have chosen to implement Astym treatment based on patients' high level of pain; however, due to the retrospective design of this study it is impossible to confirm this. Regardless of the treatment received, both groups in this study surpassed the MDC and MCID that were established for the NPRS for chronic neuropathic and non-neuropathic pain (Farrar et al., 2001), shoulder pain (Michener et al., 2011), and chronic musculoskeletal pain (Saliffi, Stancati, Silvestri, Ciapetti, & Grassi, 2004) confirming clinical improvement in pain levels. The clinical decrease in pain is consistent with the study on the role of Astym treatment in the management of LET (Slaven, 2014) and the Sevier and Stegnik-Jansen study (2015); however, unlike those studies, the current study did not find a statistically significant improvement in pain levels with the addition of Astym treatment.

Dale, Mikuski, and Miller (2016) used the NPRS to assess pain levels of individuals with LET who received either standard intervention or a Pilates-based intervention. Similar to the current study, Dale et al. (2016) confirmed that both intervention groups had clinical improvements in pain that exceeded the MDC and MCID that was outlined in Stratford and Spadoni (2001) and Salaffi et al. (2004). Arif et al. (2017) published a randomized clinical trial that compared two manual therapy techniques for individuals with LET: one group received an ulnar medial-lateral glide and the other group received a radius anterior glide of the elbow. The authors identified similar change in pain scores (NPRS) as the current study. Both groups had decreased pain levels on the NPRS (Arif et al., 2017), with the ulnar medial lateral glide group surpassing the MDC and MCID established by Stratford and Spadoni (2001) and Salaffi et al. (2003). In a randomized, double-blinded, cross-over study that compared Kinesio taping (KT) to sham taping (ST), Cho, Hsu, Lin, and Lin (2018) found that individuals had improved pain levels on the NPRS during resisted wrist extension and pain-free grip strength. These researchers showed that the group that received KT had an average reduction of 2.1 on the NPRS indicating a clinical reduction in pain based on the established MDC and MCID (Cho et al., 2018).

Consistent with the results of the published Slaven (2014), and Sevier and Stegnik-Jansen (2015) studies, there were significant improvements in the pain level of the participants. However, unlike the Slaven (2014) and the Sevier and Stegnik-Jansen (2015) study, the current study did not find the addition of Astym made a significant difference in outcomes between groups. The results of the current study may be due to the different pain outcome tools used in the studies. The researcher in the current study used a verbal NPRS, compared to the VAS used by Slaven (2014) and Sevier and Stegnik-Jansen (2015). This may have affected participant responses, for example, individuals may have had difficulty understanding the numeric rating

scale or had auditory limitations that altered their pain level response. The differences in study conclusions may also be due to the inclusion and exclusion criteria. To be included in the Sevier and Stegnik-Jansen (2015) study, participants had to have chronic pain (pain for greater than 12 weeks duration). The current study did not have that same criterion, with 57% of the participants having chronic pain. This may indicate that Astym treatments are potentially more effective with individuals who present with chronic pain.

The Sevier and Stegnik-Jansen study (2015) exclusion criteria included the following: history of systemic connective tissue diseases or polyarthralgia, history of cervical radiculopathy, degenerative disease of the cervical spine, limited range of motion of the involved elbow, abrasion or direct trauma to the involved lateral elbow, abnormal antero-posterior and/or lateral X-rays of the involved elbow. Participants in the current study were not excluded based on any existing comorbidities. It is plausible that including individuals with more medical comorbidities might have negatively influenced the outcomes. For example, a participant's pain reduction might have been less or the pain reduction might have taken longer to reduce or to resolve with the presence of existing comorbidities such as cervical radiculopathy. An individual's sensation of pain could have been altered or the pain cycle could have been perpetuated longer with a condition such cervical radiculopathy. In addition, if a participant had decreased elbow range of motion this might have interfered with the regeneration healing process, due to decreased circulation to already compromised tendon(s).

Injections and the prescription of pain medication also excluded individuals from being included in the Sevier and Stegnik-Jansen (2015) study. It may be plausible that if the same exclusion criteria used by Sevier and Stegnik-Jansen (2015) were used for this study that the overall outcomes of the latter may have reached statistical significance. For example, individuals

who had received injections or who had been prescribed pain medication may have higher pain levels. Despite receiving one of these interventions, participants may continue to have high pain levels or they may have not responded well to these treatments. In addition, interventions provided years ago versus days ago may no longer be effective, and a participant may continue to have high pain levels. If individuals who had continued high pain levels following injections or following the use of prescribed pain medication had been excluded from the current study, the amount of change in the NPRS might have been different between groups.

In the current study, standard and provocative grip strength improved, consistent with the other outcome measures. Both AG and SG had statistically significant improvements in outcomes, but when comparing the two groups there was no statistical difference. Regarding clinical changes, the standard grip strength and provocative grip strength of both groups showed improvement, suggesting the possibility for improved function. Supporting this suggestion, AG had clinical improvements in both standard and provocative grip strength that met the MDC and MCID outlined in Kim et al. (2014), and Lang et al. (2008), however, LET was not examined in these studies.

The improvement in grip strength found in this study was similar to studies completed by Sevier and Stegink-Jansen (2015) and Slaven (2014), with standard and provocative grips strength of AG and SG showing statistically significant improvements. However, unlike the Sevier and Stegink-Jansen (2015) study there was not a statically significant difference between the groups. Although Fouda and Dewir (2017) did not conduct a study that assessed the efficacy of using Astym therapy to treat those with LET, they found that taping techniques for LET resulted in significant improvements in grip strength and significant decreases in pain intensity in individuals with the mean age of 35.12 years. Similarly, Shakeri, Soleimanifar, Arab, and

Behbahani (2018) in a study on the effectiveness of KT for LET, found that participants with the mean age of 34.61 years had significant improvements in function and significant decreases in pain levels. Comparably, although Stasinopoulos and Stasinopoulos (2017) did not study the effectiveness of Astym therapy, they identified that specific exercise prescriptions for LET resulted in significant improvements in function and significant reduction in pain intensity in individuals with a mean age of 43 years. The results of these studies indicate that regardless of the type of intervention provided for LET, patients have improvements in their outcomes.

Gender may or may not influence the effectiveness of treatment for LET. The authors of a study on taping techniques for LET with an equivalent number of male and female participants found that all participants, regardless of gender, had statistically measurable improvements in grip strength and pain levels (Fouda & Dewir, 2017). Similarly, outcomes for grip strength and pain were similar for males and females in the current study. However, it may be possible that gender could influence the effectiveness of Astym treatment with women being more sensitive to the Astym instrumentation and having a lower pain threshold to the treatment. A literature review on sex-related influences on pain supports the hypothesis that, in general, females have greater pain sensitivity and are more sensitive to pressure pain. Ferreira-Valente et al. (2011) found that following painful stimuli women reported higher pain intensity ratings on three pain scales. In addition, due to the pain and hormone levels or neural connections, physiologically pain levels and responses to treatment for pain may vary between females and males (Fillingim, King, Ribeiro-Dasilva, Rahim-Williams, & Riley, 2008). A study on hormones and pain further support that women and men have different pain sensitivity. Results indicated that women and men may respond differently to pain and to treatments for pain (Schertzinger, Wesson-Sides, Parkitny, &Younger, 2018).

The current study included 118 full time employed individuals and 18 of the participants were left hand dominant; 95 of the participants experienced left elbow pain, and 29 had elbow pain due to a one-time incident. The Sevier and Stegink- Jansen (2015) study and the Shakeri et al. (2018) did not report participant's hand dominance. Fouda and Dewir, (2017) and Stasinopoulos and Stasinopoulos (2017), reported that 85% to 100% of study participants in their studies experienced LET in their dominant arm; however, neither publication indicated if there was a link between hand dominance and outcomes. Although researchers often report hand dominance and the percentage of individuals who have LET in their dominant elbow, correlations between outcomes and UE dominance have not been reported. It may be beneficial for future researchers to study hand dominance and outcomes and LET treatments.

In the current study, both groups received multimodal treatment in OT, consistent with recommendations of Sutton et al. (2016) and the British Columbia Physical Therapy Task Force (The University of British Columbia, 2016). Results of this study confirm that occupational therapists provided multimodal treatments for patients with LET similar to that of physical therapists (Bisset & Vicenzino, 2015; Marcolino et al., 2016; Sutton et al., 2016; The University of British Columbia, 2016). The AG group more often received treatment involving paraffin, moist heat, muscle energy technique, and joint mobilization compared to the SG group. The difference in use of heat could be explained by more than half of the AG group having chronic symptoms and higher pain at the OT intake, both of which responded favorably to the use of heat. Joint mobilization, used more often with the AG group in the current study, was shown to have strong support for treatment of individuals with chronic LET (Marcolino et al., 2016; The University of British Columbia, 2016). Because of the retrospective design of the study, it is not known how occupational therapists determined tendinopathy stage or if stage influenced

decisions for treatment. For the purposes of comparison in the current study, the PI assigned acute and chronic categories as 0-3 months or more than 3 months (Sevier & Stegink-Jansen, 2015), respectively, but there was no difference between the groups. In future studies, researchers should study stage and treatments to clarify which treatments are most effective for stage of tendinopathy. Although the AG had longer duration of treatment compared to the SG this was not statistically different. It may have been that occupational therapists provided longer duration of treatment for the AG because of higher pain at initial intake, with pain reduction requiring more time. Nonetheless, number of OT visits and duration of treatment found in the current study is in line with that of Sutton et al. (2016).

Thirty months of EMR and FOTO data were collected for this study. During this time frame, the number of weeks patients received treatment, the number of treatment sessions each patient received, the number of times outcome measurements were collected, and the time in between each outcome measurements performed by the individual clinician varied. In contrast, the Sevier and Stegnik-Jansen study (2015) was a 12-month study with reassessments of the outcomes at designated times. Perhaps the comparison between group outcomes of this study would have been more consistent with the other study, if the current study had more control over: (a) the types of treatments, (b) number of treatments and the number of measurements, and (c) established measurement times.

Limitations

There are several limitations inherent in a retrospective study (Carter & Lubinsky, 2016), and therefore are present in this study. Numerous internal validity threats limit the interpretation of results. Examples of these threats include the following: lack of a control group or lack of controlled manipulation, the occurrence of history and/or maturation, the occurrence of

instrumentation change, and having a sample size too small to find statistical significance. Additional threats include missing data or unknown data, the investigator having no control over exposure or outcome assessments, and the investigator only being able to indicate association, not causation due to the study design. Significant differences in characteristics and treatment between groups could have masked the treatment effects. There were more people in the AG that had clerical or manual work compared to more people in the SG that were not working or had semiprofessional work. The differences in type of work could have influenced the effectiveness of a treatment. For example, a treatment might not have been as effective for a participant in the AG due to clerical and manual work often being a causative factor of LET (Fan et al., 2014; Descatha et al., 2013); however, there is no way to know if this altered the outcomes of treatment. For work status there were more people in the SG that were retired, unemployed, students or volunteers. It is possible that a participant in the SG could have had better outcomes due to having more time to rest from aggravating factors and having more time to focus on the recommended home exercise program; however, there is no way to determine if this altered the treatment outcomes.

For this study there was not a designated control group; therefore, it was not possible to determine a cause and effect relationship with the addition of Astym treatment to standard therapeutic interventions. There was no random assignment of the participants, resulting in no control over the similarities or differences of the groups. It was also impossible to determine why a participant received Astym treatment in addition to standard therapy. Hence, it is difficult to determine if bias toward placement into one of the treatment groups occurred.

History, maturation, and variations in interventions are added threats that may have significantly influenced the results of this study. In addition, construct validity could have been

impacted by experimenter or participant expectancies, interaction among different interventions, and interaction between testing and treatment. During a participant's OT services, he or she may have received treatments from other disciplines. Treatments from a massage therapist, acupuncturist, chiropractor, or physician, may have contributed to a participant's change scores in his or her outcomes. In addition, each participant received OT interventions that varied in the amount and the length of time. For example, the number of OT treatments, the number of Astym treatments, participant's length of episode of care varied, and the time an individual participated in OT all varied. Moreover, the different types of interventions occurred in numerous sequences, and discrepancies were present in the treatments provided by the different occupational therapists. For example, different therapists may have applied varying amounts of pressure with the Astym instrumentation, or in the event that a therapist used a taping technique, the amount of tension applied by each therapist may have been different. Another example of maturation is that performance with the testing procedures may have improved because of increased comfort and experience with the testing process. In contrast, participants may not have been interested or understood the value of subsequent assessments.

To help minimize some of these threats the investigator used a systematic approach to assign each EMR to a group. The researcher implemented this method to create equal representation of the entire sample, to create an equal sample size of each group, and to decrease bias. Because of the nature of this retrospective study, patients and therapists being unaware of their participation in a study reduced the likelihood of expectancy threat.

To account for missing data, case deletion and variable deletion occurred. The researcher discarded charts if a FOTO episode of care did not have all of the necessary data collected. In addition, deletion of missing variable from analysis transpired if an EMR was missing the

specific demographics or outcome measurement of interest. Although all participants attended an initial OT evaluation and attended an OT discharge evaluation, not all therapists collected data on standard grip strength and provocative grip strength, which may have altered the results of the outcome.

Additional threats to internal validity may include the significant differences in condition severity, number of OT sessions, duration of episode of cares, and type of work between the AG and the SG. In addition, Moist hot pack, paraffin, MET, soft tissue mobilization, and joint mobilization, were interventions that were significantly different between the AG and the SG and could alter internal validity. There was also no control over how therapists completed outcome measurements. For example, there was no control over the sequence of the administration of measurements, the number of times the outcome measurements were completed, or the interval of time between the measurements. In addition, therapists' attitudes on testing procedures may have varied and their opinions on the outcome tools used may have been different. If a therapist did not see the value in using outcome tools this may have had a negative impact on a participant's performance during the assessments. When discussing the outcome tools and the results of the participant's outcome scores, the therapist's lack of enthusiasm may have influenced a participant's perception of the importance of the outcome tools used and it may have influenced a participant's performance on the assessments. In addition, although therapists at PHS are encouraged to discuss the results of the participant's outcome scores with the participants, the therapists may not have discussed the results. This may have caused the participants to question the importance of the assessments, and it may have caused sub-optimal performance by the participant on the assessments.

Staff training may have helped to minimize some of the internal validity threats. First, therapists in this study had completed the same required PHS competency training. The therapists also competently demonstrated therapeutic interventions and assessments prior to implementing them in the clinic. Therapists only implement Astym treatments if they have completed the comprehensive training and certification program provided by Performance Dynamic®. Therapists demonstrated standard procedures when using the clinic's outcome tools. The therapists also had specialized instructions on the FOTO system, and they had training on the use of the PI as an outcome tool. Furthermore, training on standard clinic procedures had occurred with all employees who assisted patients with the FOTO body part specific PI self-assessment survey.

Documentation errors and collection of data by multiple individuals may also threaten the validity of a study. In the current study, therapists used the same EPIC template for the intake evaluation, daily notes, and discharge. Therapists' training on the EPIC documentation system was also standardized, and PHS implemented regular reviews of documentation for quality management. If a therapist's documentation skills did not meet the standard requirements of PHS, the therapist was required to correct errors in all documentation and additional documentation training occurred. To minimize data collection errors, one investigator collected and coded all of the data in the current study. The investigator also cross-referenced and verified all of the data that were collected and coded into the spreadsheet.

Although all of the EMRs were collected on outpatients who were receiving OT from PHS clinics in the same metropolitan area of the same region of the country, the generalizability of this retrospective study was enhanced by including a convenient sampling of participants with diverse demographics. Exclusion from the study did not occur if a participant had any existing

comorbidities. Participants also received standard interventions, such as orthotic devices, physical agent modalities, manual interventions and taping, that the traditional outpatient OT clinics offer. Furthermore, the episodes of care for individuals who received OT services were regulated by Medicare guidelines and customary insurance guidelines that are followed throughout North America. To avoid exceeding the Medicare cap, close monitoring of patient's progress (or lack of progress) and close monitoring of the number of visits occurred.

Despite the limitations of this study, the findings of this research begin to bridge the gap of knowledge on standard OT interventions provided to individuals with LET. The researcher of this study provided support for use of standard OT interventions and Astym in addition to standard OT interventions in an outpatient setting, with the benefits of decreased pain and improved function in individuals with LET. Because of the design of this study it is impossible to determine cause and effect relationships. Further research with more control over confounding variables is warranted to explore the efficacy and effectiveness of Astym treatment in patients with LET.

Conclusion

Lateral elbow tendinopathy is often difficult to treat and may be refractory to treatment. There are often prolonged symptoms, re-occurrences of the pain, and loss of function and strength observed (Sevier & Stegink-Jansen, 2015). In outpatient clinics, patients present with multiple characteristics that may impact the effectiveness of any intervention. The researcher from this retrospective study suggests that standard OT interventions can decrease pain, improve functional abilities and increase grip strength in individuals with LET; however, the addition of Astym treatment to the standard OT interventions may not result in statistically significant improvements in these outcomes than standard care alone.

Recommendations

There are a number of published case studies that support the use of Astym to treat musculoskeletal conditions (Bhave, Corcoran, Cherian, & Mont, 2016; McCormick, 2012; Tyler & Slaven, 2013). A larger study, long-term follow-up, and a prospective study may help determine if the addition of Astym treatment to standard therapeutic interventions for LET reduces pain and increases function. Randomized clinical trials that control more variables should be completed to examine the effectiveness of Astym treatment for the management of patients with LET as compared to standard care. Furthermore, researchers are encouraged to use FS measure scores in their studies to assess the effectiveness of Astym treatment.

Dissemination

The results of this study will be presented in a public forum as a requirement for the student researcher's completion of the Doctorate of Health Science degree. If information learned from this study is published, participants will not be identified by name because all of the information will be reported statistically.

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Table 1.

Comparison of Outcomes from both Intake and Discharge between Treatment Groups

	AG	SG	
	Mdn (IQR)	*Mdn* (IQR)	*p*
FOTO FS measure at intake	56.00 (19.00)	51.00 (21.00)	.086
FOTO FS measure at discharge	69.00 (14.00)	69.00 (18.00)	.447
NPRS at intake	8.00 (2)	7.00 (4.00)	.009
NPRS at discharge	1.00 (2.00)	0 (2.00)	.133
Standard grip at intake	47.84 (55.83)	41.00 (35.50)	.214
Standard grip at discharge	66.66 (51.67)	48.00 (24.65)	.280
Provocative grip at intake	33.50 (49.50)	32.00 (39.00)	.194
Provocative grip at discharge	54.34 (52.50)	45.00 (32.00)	.276

Note. AG = Astym and standard therapeutic intervention group; SG = standard therapeutic intervention group; FOTO FS = Focus on Therapeutic Outcomes functional status; NPRS = numeric pain rating scale.

Table 2

Comparison of Outcome Change Scores between Treatment Groups

	AG	SG	P
FOTO	18.00 (9.50)	16.00 (21.00)	.674
NPRS	-6.00 (3.75)	-5.00 (3.00)	.086
Standard grip	10.20 (19.82)	10.67 (12.00)	.794
Provocative grip	14.33 (22.00)	13.00 (17.34)	.874

Note. AG = Astym and standard therapeutic intervention group; SG = standard therapeutic intervention group; FOTO FS = Focus on Therapeutic Outcomes functional status; NPRS = numeric pain rating scale.

Table 3

Participant Characteristics by Sample and Group with Group Comparisons

	Total (*N* = 222)	AG (*N* = 104)	SG (*N* = 118)	
		N (%)	*N* (%)	*p*
LET Diagnosis		104 (47)	118 (53)	
Gender				.708
Female	138 (62%)	66 (63.5)	72 (61.0)	
Male	84 (38%)	38 (36.5)	46 (39.0)	
Hand Dominance				.948
Right	198 (89.2%)	106 (89.8)	92 (88.5)	
Left	18 (8.1%)	9 (7.6)	9 (8.7)	
Ambidextrous	6 (2.7%)	3 (2.5)	3 (2.9)	
Chronicity				.780
Chronic	126 (57.8)	58 (55.8)	68 (57.6)	
Acute	96 (43.2)	46 (44.2)	50 (42.4)	
Involved UE				.500
Right	127 (57%)	67 (30.2)	60 (27.02)	
Left	95 (43%)	51 (22.97)	44 (19.81)	
Mechanism of onset				.551
Traumatic	29 (13.1)	18 (8.11)	11 (4.95)	
Overuse	193 (86.9)	100 (45.50)	93 (41.44)	

Note. AG = Astym and standard therapeutic intervention group; SG = standard therapeutic intervention group; LET = lateral elbow tendinopathy; UE = upper extremity.

Table 4

Descriptives for Condition Severity by Sample and Group with Group Comparison

	Slight	Moderate	Severe	Very severe
	N (%)	*N* (%)	*N* (%)	*N* (%)
AG	38 (36.5)	33 (31.7)	22 (21.2)	11 (10.6)
SG	46 (39.0)	24 (20.3)	20 (16.9)	28 (23.7)
Total	84 (37.8)	57 (25.7)	42 (18.9)	39 (17.6)

Note. AG = Astym and standard therapeutic intervention group; SG = standard therapeutic intervention group.

Table 5

Descriptives for Symptom Acuity by Sample and Group with Group Comparison

	8-14 days	15-21 days	22-90 days	91 days-6 months	> 6 months
	N (%)	*N* (%)	*N* (%)	*N* (%)	*N* (%)
AG	5 (4.8)	0 (0)	41 (39.4)	23 (22.1)	35 (33.7)
SG	3 (2.5)	8 (6.8)	39 (33.1)	31 (26.3)	37 (31.4)
Total	8 (3.6)	8 (3.6)	80 (36.0)	54 (24.3)	72 (32.4)

Note. AG = Astym and standard therapeutic intervention group; SG = standard therapeutic intervention group.

Table 6

Descriptives of Number of Occupational Therapy Visits and Focus on Therapeutic Outcomes Duration by Sample and Group with Group Comparison

	Total	AG	SG	
	Mdn (IQR)	*Mdn* (IQR)	*Mdn* (IQR)	*p*
Number of visits	7 (5)	7.00 (4)	7.50 (5)	.818
Number of days	44.50 (22)	50.00 (28)	41.00 (21)	.086

Note. AG = Astym and standard therapeutic intervention group; SG = standard therapeutic intervention group.

Table 7

Descriptives for Type of Work by Sample and Group and with Group Comparison

	Clerical	Manual	Professional	HC	N/A	SP
	N (%)	*N* (%)	*N* (%)	*N* (%)	*N* (%)	*N* (%)
AG	27 (26.0)	22 (21.2)	2 (1.9)	3 (2.9)	39 (37.5)	11 (10.6)
SG	19 (16.1)	12 (10.2)	3 (2.5)	2 (1.7)	59 (50.0)	23 (19.5)
Total	46 (20.7)	34 (15.3)	5 (2.3)	5 (2.3)	98 (44.1)	34 (15.3)

Note. HC = Homemaker/Caretaker; SP = Semiprofessional; AG = Astym and standard therapeutic intervention group; SG = standard therapeutic intervention group.

Table 8

Descriptives of Work Status by Sample and Group with Group Comparison

	Full-time	Part-time	Retired	Unemployed	Disability	Student	Volunteer
	N (%)	*N* (%)	*N* (%)	*N* (%)	*N* (%)	*N* (%)	*N* (%)
AG	58 (55.8)	9 (8.7)	24 (23.1)	7 (6.7)	3 (2.9)	3 (2.9)	0 (0)
SG	60 (50.8)	7 (5.9)	32 (27.1)	9 (7.6)	3 (2.5)	5 (4.2)	2 (1.7)
Total	118 (53.2)	16 (7.2)	56 (25.2)	16 (7.2)	6 (2.7)	8 (3.6)	2 (0.9)

Note. AG = Astym and standard therapeutic intervention group; SG = standard therapeutic intervention group.

Table 9

Descriptives of Treatments by Sample and Group with Group Comparisons

	Total (*N* = 222)	AG (*N* = 104)	SG (*N* = 118)	
	N (%)	*N* (%)	*N* (%)	*p*
Paraffin	111 (50.0)	70 (67.3)	41 (34.7)	.001
Moist heat pack	147 (66.2)	83 (79.8)	64 (54.2)	.001
Fluidotherapy	22 (9.9)	9 (8.7)	13 (11.0)	.655
Ultrasound	142 (64.0)	72 (69.2)	70 (59.3)	.161
Infrared	3 (1.4)	3 (2.9)	0 (0)	.101
Ice	54 (24.3)	19 (18.3)	35 (29.7)	.060
Positional release	17 (7.7)	11 (10.6)	6 (5.1)	.137
Deep transverse friction massage	108 (48.6)	47 (45.2)	61 (51.7)	.349
Myofascial release	57 (25.7)	29 (27.9)	28 (23.7)	.539
Soft tissue manipulation	157 (70.7)	61 (58.7)	96 (81.4)	.001
Muscle energy technique	29 (13.1)	21 (20.2)	8 (6.8)	.005
Trigger point release	86 (38.7)	47 (45.2)	39 (33.1)	.073
Joint mobilization	57 (25.7)	35 (33.7)	22 (18.6)	.014
Dry needling	17 (7.7)	9 (8.7)	8 (6.8)	.623
Manual edema mobilization	7 (3.2)	2 (1.9)	5 (4.2)	.452

Electrical stimulation	51 (23.0)	23 (22.1)	28 (23.7)	.873
Iontophoresis with dexamethasone	77 (34.7)	42 (40.4)	35 (29.7)	.120
Taping	154 (69.4)	75 (72.1)	79 (66.9)	.466
Orthosis	75 (33.8)	32 (30.8)	43 (36.4)	.396

Note. AG = Astym and standard therapeutic intervention group; SG = standard therapeutic intervention group.

Table 10

Comparison of Outcomes between Intake and Discharge for the Astym and Standard Therapeutic Group

		Intake	Discharge	
	N	*Mdn* (IQR)	*Mdn* (IQR)	*p*
FOTO FS Measure	104	56.00 (19.00)	69.00 (14.00)	.001
NPRS	104	8.00 (2.00)	1.00 (2.00)	.001
Standard Grip	69	47.84 (55.83)	66.66 (51.67)	.001
Provocative Grip	43	33.50 (49.50)	54.34 (52.50)	.001

Note. FOTO FS = Focus on Therapeutic Outcomes functional status; NPRS = numeric pain rating scale; AG = Astym and standard therapeutic intervention group.

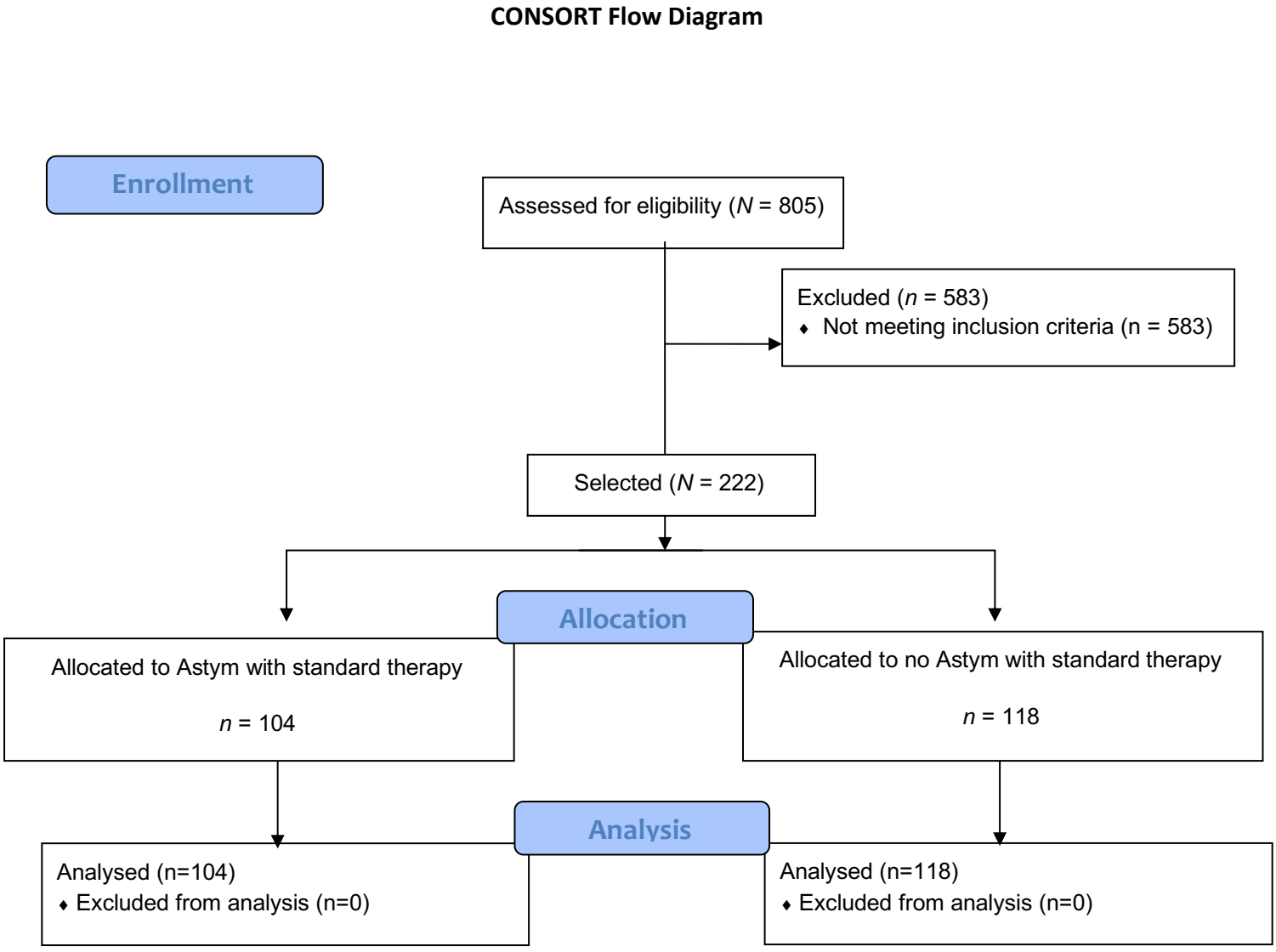
Table 11

Comparison of Outcomes between Intake and Discharge for the Standard Therapeutic Group

		Intake	Discharge	
	N	*Mdn* (IQR)	*Mdn* (IQR)	*p*
FOTO FS Measure	118	51.00 (21.00)	69.00 (18.00)	.001
NPRS	118	7.00 (4.00)	0 (2.00)	.001
Standard Grip	73	41.00 (35.50)	48.00 (24.65)	.001
Provocative Grip	31	32.00 (39.00)	45.00 (32.00)	.001

Note. FOTO FS = Focus on Therapeutic Outcomes functional status; NPRS = numeric pain rating sale; SG = standard therapeutic intervention group.

Figure 1


CONSORT Flow Diagram
Enrollment
Assessed for eligibility (N = 805)
Excluded (n = 583)
♦ Not meeting inclusion criteria (n = 583)
Selected (N = 222)
Allocation
Allocated to Astym with standard therapy
n = 104
Allocated to no Astym with standard therapy
n = 118
Analysis
Analysed (n=104)
♦ Excluded from analysis (n=0)
Analysed (n=118)
♦ Excluded from analysis (n=0)