Introduction

Carpal tunnel syndrome (CTS) has been defined as a compression neuropathy of the median nerve at the wrist, resulting in pain, numbness, and tingling in the thumb, index finger, middle finger, and radial side of the ring finger, and in the lateral half of the palm (1). In 1990, 48% of all reported workplace illnesses were repetitive motion disorders, compared to 18% in 1980 (2). Carpal tunnel syndrome, the most common repetitive motion disorder, is on the rise in the United States (2). Mackinnon and Novack report that 40.8% of upper extremity repetitive motion disorders in 1994 were cases of CTS (3). Harter et al report that lost work time, medical fees, and legal expenses may reach as high as $100,000 per individual case, putting a tremendous financial burden on individuals and employers (4). The incidence of CTS may be underestimated secondary to the number of actual cases that go unreported. According to Cullum and Molloy, patients with CTS often do not report the symptoms that result in a claim of CTS, nor do they accumulate missed days of work. A majority of these individuals choose to make occupational changes when symptoms do occur, rather than file a worker's compensation claim (5).

Currently, there is no treatment for CTS that has proven to effectively and consistently treat the symptoms of CTS. Treatments available range from conservative measures to surgical intervention. However, these treatment options have varied in their success rates, and often patients have recurrent episodes of CTS (6). There are no studies to substantiate the long-term effectiveness of any current clinical interventions.

The purpose of this study is to determine whether the FleXtend™ is effective in treating CTS. The FleXtend™ is an exercise glove designed by Balance Systems, Inc.

with the purpose of decreasing the signs and symptoms of CTS, by increasing the strength and flexibility of the wrist and fingers. The FleXtend™ is relatively inexpensive and can be used in a self-management home exercise program. If it is an effective treatment for CTS, the ramifications for decreasing medical and worker's compensation costs could be quite substantial.

We hypothesize that the FleXtend™ will decrease the signs and symptoms of CTS. The null hypothesis is that the FleXtend™ will have no effect in decreasing the signs and symptoms of CTS.

Literature Review

Anatomy

The carpal tunnel is clearly defined anatomically and formed by an intricate combination of bones, ligaments, tendons and muscles (7). The bones that give the carpal tunnel its structure and make up the wrist complex include the radius, the eight carpal bones, and the five metacarpals. The head of the ulna is not considered part of the wrist complex, because it could be removed without causing any impairment in wrist function (8). The scaphoid, lunate, and triquetrum compose the proximal carpal row and articulate with the radius and the triangular fibrocartilage complex (TFCC) to form the radiocarpal joint (9). Norkin and Levangie include the pisiform anatomically as part of the proximal row, but cite that it does not participate in the radiocarpal articulation. Rather, it functions entirely as a sesmoid bone, with its primary purpose to increase the moment arm of the flexor carpi ulnaris. It also serves as an attachment for the transverse carpal ligament (TCL) (10). The distal row of carpal bones include the trapezium, trapezoid, capitate, and hamate. The proximal and distal row of carpal bones articulate with each other to make up the midcarpal joint.

The curved shape of the carpals combined with several intercarpal ligaments come together to form the carpal arch. The intercarpal ligaments and the transverse carpal ligament (or flexor retinaculum) are oriented transversely across the carpals to help maintain this concavity. The carpal arch and the transverse carpal ligament together are defined as the carpal tunnel (11). The parameters of the carpal tunnel include the carpal bones, the volar radiocarpal ligament, and the volar ligament complex making up the floor (7,12). The TCL, which attaches to the scaphoid tuberosity and part of the

trapezium laterally and the pisiform and the hook of the hamate medially, makes up the roof of the carpal tunnel (7,12).

The carpal tunnel creates a pathway for nine long flexor tendons; the flexor pollicis longus, the four tendons of the flexor digitorum superficialis, and the four flexor digitorum profundus tendons. The median nerve runs superficial to these nine tendons and directly under the TCL. The median nerve goes from deep to superficial just before the wrist complex. It is superficial to the flexor digitorum superficialis and deep to the palmaris longus. In the forearm the median nerve innervates the flexor digitorum superficialis and the lateral half of the flexor digitorum profundus, both of which function in digital movement. In the hand, the median nerve innervates the opponens pollicis, the abductor pollicis brevis, the superficial head of the flexor pollicis brevis, and lumbricals one and two. Cutaneous sensation includes the thumb, first and second digits and the radial 1/2 of the fourth digit on the palmar side of the hand. On the dorsum of the hand, the median nerve cutaneous innervation includes the distal 1/3 of digits one through four, excluding the ulnar aspect of the fourth digit (13). The palmar cutaneous branch comes off the main median nerve in the distal third of the forearm and penetrates the transverse carpal ligament to innervate the skin of the thenar eminance (14). The median nerve separates at the distal edge of the TCL into two main trunks. The lateral trunk gives off the motor branch for the thenar muscles and lumbricals one & two; it also divides into the proper palmar digital branches for cutaneous innervation. The medial trunk divides into the common digital nerves, innervating the second and third webspaces and the adjacent digits (13,14).

Biomechanics

Proper biomechanics at the wrist are essential for efficient function of the hand and fingers. Without correct mechanics at the wrist and hand, an individual's strength, stability and mobility are quickly compromised. The radiocarpal joint is considered a biaxial joint, allowing for the motions of flexion and extension around a coronal axis/sagittal plane, and radial and ulnar deviation around a sagittal axis/coronal plane. Norkin and Levangie define normal ranges of motion for the wrist as the following: 85° of flexion; 70° to 80° of extension; 20° to 25° of radial deviation; and 30° to 35° of ulnar deviation (10).

Several individual anatomic joints comprise what is functionally described as one midcarpal joint. The surfaces of the midcarpal joint are considered a reciprocally concave-convex configuration and classified by most as a condyloid joint allowing for the motions of flexion, extension, radial and ulnar deviation (15). Although these motions are slight, in the midcarpal joint there appears to be increased range in extension over flexion, and radial devatiation over ulnar deviation (16).

The thumb and fifth carpometacarpal joint are considered saddle joints allowing for flexion, extension, abduction and adduction. The thumb also permits some axial rotation that occurs simultaneously with other motions to yield circumduction. The second through fourth carpometacarpal joints are considered plane synovial joints with motions of flexion and extension (10).

The carpal tunnel functions primarily as a protective passageway for the nine flexor tendons and the median nerve. Netscher et al also found that the TCL functions as an important pulley for the flexor tendons through such pathway (17). This same study

reports that when the TCL is transected the excursion of the flexor tendons must increase in order to achieve the same amount of flexion force as was obtainable prior to transection (17). During flexion, an increase in grip force will increase the tension in flexor digitorum tendons. This will increase the pressure on the TCL, which is acting as a pulley for those tendons. Since the median nerve lies between the TCL and the flexor tendons, the pressure on it will increase as well (2).

Pathophysiology

CTS may occur from a variety of biomechanical changes within the wrist and hand; however, the underlying disorder stems from the compression of the median nerve. The compression in the carpal canal diminishes the flow of blood to the epineurium due to an increase in the intracarpal canal pressure. This diminished blood flow is secondary to the disruption of the blood-nerve barrier found at the internal layers of the perineurium and the endothelial cells of the endoneurial microvessels (18). Mackinnon and Dellon state that, "This blood-nerve barrier maintains the internal environment of the peripheral nerve fibers. Breakdown of the blood-nerve barrier at either of these two anatomic sites will result in loss of the normal homeostatic mechanisms" (18). Through a cascade of events, an ischemic reaction occurs to the median nerve and results in clinical symptoms.

As the pressure continues to increase, the endoneurium proceeds to release specific proteins into the tissue, thus amplifying the effect of edema. Slater and Bynum have also noted that the edema becomes trapped within the perineurium due to the dense, highly tensile strength of the perineurium creating a pocket, much like that of a "compartment syndrome" within the nerve (7). Although the carpal tunnel is open at both ends, it has the physiological properties of a closed compartment bound by

synovium proximally and distally (19). As the ischemic environment within the nerve and the proteinaceous exudate promote fibroblast proliferation, it results in the replacement of the epineurium and endoneurium with fibrous scar tissue (7). Mackinnon and Dellon note that the end result is the altered transmission (decreased nerve conduction) of axons through the carpal canal and the decreased glide of the median nerve longitudinally with wrist flexion and extension (19). However, Gelbermann et al found that not all cases of CTS have an increase in carpal tunnel interstitial pressure (20). Therefore, the adhesions of the nerve must play a vital part in the decreased longitudinal gliding of the median nerve as it relates to the decreased nerve conduction during flexion and extension of the wrist. If compression is maintained on the median nerve, the altered effects of the blood-nerve barrier will cause transient ischemia and eventually lead to Wallerian degeneration. Wallerian degeneration can have a detrimental effect on the rehabilitation potential.

A controversial cause of CTS is the occupational stresses of repetitive overuse. While up to a 20% prevalence of CTS in chain saw operators, meat cutters, and poultry processors clearly implicates work related activities as a contributing factor (21), other studies find little evidence that occupation contributes to CTS (22). Cullum and Molloy report that trauma caused by repetitive motions of the wrist and fingers can lead to CTS, especially in patients that work with vibratory machinery, or use forceful finger and wrist flexion/extension (5). Szabo has reported that with repeated wrist flexion and extension, the pressure with in the carpal tunnel took longer to return to resting value then in individuals without CTS (19). This also supports the theory that repetitive use in the occupational setting can directly cause CTS. As repetitive overuse causes muscle to

fatigue, the muscle fibers may become inflamed resulting in a decreased amount of space within the tunnel, or the irritation may bring swelling into the area, causing an increase of contents within the canal.

Other conditions can also lead to an increase in the contents of the carpal canal, and a relative decrease in available space within the canal. Mooney states that individuals with abnormally long lumbricals are prone to CTS due to the muscle mass invading the carpal tunnel (23). Pregnancy is also shown to be a cause of CTS, primarily during the third trimester when retention of fluids is greatest. However, CTS severe enough to warrant treatment occurs infrequently in pregnancy, and normally resolves spontaneously postpartum or responds to conservative treatment (24,25). Both Wand and Stolp-Smith et al have studied the effects of pregnancy on CTS and found that CTS is reported in patients who present with general edema related to the pregnancy (24,25).

Fractures of the radius, such as Colles' or Smith's, and dislocations, especially perilunar dislocations, have also lead to the development of CTS. In Colles' fracture, the immobilized wrist is placed in flexion and ulnar deviation immediately after reduction has taken place. This positioning may acutely compress the median nerve within the carpal tunnel (26).

Systemic disorders such as obesity, rheumatory arthritis, Raynaud's disease, amyloidosis, thyroid dysfunction, and diabetes mellitus may all be associated with CTS. In a study by Stallings et al, obesity was found in 46% of all CTS cases (27). Lam and Thurston demonstrated that females are twice as likely to have CTS, and that patients greater than 55 years of age are more likely to experience CTS (28). Patients with peripheral neuropathy, secondary to disorders such as diabetes and renal failure, may

have increased susceptibility to CTS due to the body's inability to regulate interstitial pressure.

Symptoms

The symptoms associated with CTS vary from patient to patient. Symptoms can have an insidious onset, and patients may wait for weeks, months, or years before seeking treatment. Patients may present with numbness and tingling in the median nerve distribution of the hand, which is aggravated by movement of the wrist and/or fingers (24). The median nerve distribution includes the lateral two-thirds of the palm, the palmar aspects of digits one through three and the radial half of digit four (13). Kaplan et al reported that activity induced and constant paraesthesia were each present in 57% of patients with CTS (29).

The patient may also report nocturnal pain that causes sleep disturbance (14,22,23). According to Kaplan et al, 80% of patients with CTS complained of nocturnal pain and paraesthesia (29). During the night, because of decreased muscular activity, venous return is reduced and as a result carpal tunnel pressure may increase, leading to pain and sleep disturbance (30). Another possible explanation is that during sleep, patients hold their wrists in a flexed position, thus compressing the median nerve and resulting in pain and numbness (7).

Kaplan et al also reported that 22.2% of patients with CTS complain of weakness or clumsiness (29). While numbness at first is only intermittent, it eventually becomes a continuous symptom for the patient. Once continuous numbness occurs the patient may note an increased amount of clumsiness with fine motor tasks.

The report by Kaplan et al also found thenar atrophy in 22.4% of patients with CTS (29). Muscle weakness is associated with the entrapment of the median nerve, and comparing individual muscles bilaterally may reveal muscle atrophy. The patient may not note the decrease in muscle strength due to the insidiously progressive nature of the atrophy. Wasting away of the muscle is seen after the strength loses have occurred. If there is compensation by accessory muscles, this compensation may mask the severity of the muscle loss.

Conservative Management

Prevention

With 1.5% of the U.S. population self-diagnosing CTS, the prevalence has become a significant problem in the workplace (31). Prevention of CTS should include such factors as work site modifications for ergonomic and body mechanic correction, along with patient education of proper body mechanics and posture. Work site modifications may also include task variation and tool alteration.

Conservative treatments incorporate a variety of options. These conservative measures include the following: exercises to increase strength and flexibility with the goals of preventing muscle fatigue and increasing blood flow; splinting to maintain a neutral position of the wrist in order to decrease the intracarpal pressures (30,32); anti-inflammatories to reduce edema (7,33); and diuretics to decrease fluid retention.

Exercise

Multiple treatments have been attempted for strengthening the musculature surrounding the wrist and increasing the flexibility of the connective tissue in the wrist and hand; however, to this date only yoga has shown to be effective with any short-term outcomes. In a recent study Garfinkel et al, 12 poses from Hatha yoga were implemented to increase strength and flexibility. Symptom reduction during exercise is typical of CTS (34). However, Garfinkel et al reported a maintained reduction of symptoms post exercise at the end of an eight-week training session (34). Findings demonstrated an increase in grip strength, with decreases in pain intensity and sleep disturbance. Median nerve motor and sensory conduction time was also improved; however, as noted…

> The official clinical policy statement of the American Academy of Orthopaedic Surgeons states that the use of (nerve conduction velocity and electromyography) are helpful when positive but they can be negative in some patients with this disorder. Therefore, the tests offer supporting evidence but are not essential to making the diagnosis (34).

Tendon gliding is an exercise to decrease the amount of friction found in the carpal tunnel secondary to adhesions of the surrounding connective tissues. With the use of tendon gliding the individual tendons can be freed from scarring tissue by implementing a four step fisting formation (from neutral start, progress to a hook fist, to a straight fist, finishing with a true fist). With the use of tendon gliding the increased movement will increase the blood flow and decrease the interstitial fluid.

Splinting

Splinting has been a common treatment of CTS for many years. Wrist splinting has been used to decrease the nocturnal symptoms in the early stages of CTS (30). Pressures within the carpal tunnel in normals in comparison to patients with CTS are

24mmHg/43mmHg in resting, 79mmHg/97mmHg in wrist flexion, 101mmHg/119mmHg in extension, and after exercise the pressures have been measured at 14mmHg/25mmHg (35). After measuring the canal pressures during sleep without the splints, it was found that splinting did decrease the pressure levels during use; however, these levels were not below the critical pressure level to reduce the symptoms of median nerve compression. During nocturnal use of splints, the pressures continued to decrease as the night went on, showing that maintenance of a neutral wrist position can reduce pressure in the carpal tunnel. When positioning the splinted wrist, there are no standard ranges to use; however, there are studies showing that wrist extension will decrease the amount of canal pressure within the first ten degrees. Thus, the immobilization of wrists in these positions minimizes the compression forces upon the median nerve and maximizes the volume of area within the carpal canal (36). The recurrence rate for CTS after treatment with splinting alone has varied from 34% to 90% (32).

Anti-inflammatory Agents

Weiss et al compared steroid injection to splinting and found that there is a large variance of success in reducing the reoccurrence rate of CTS symptoms (32). Typically, splinting is used in conjunction with other treatments such as corticosteroids or anti-inflammatories. However, according to Banta, splinting and the use of non-steroidal antiinflammatory drugs (NSAIDs) have been relatively disappointing (33). Weiss et al stated that splinting was often used in conjunction with simultaneous steroid injection and that symptom reduction averaged 11 months (32). Banta (33) reported that during a 6-month test of early-mild CTS, the use of splinting and NSAIDs proved to be beneficial for 17% hands (4 of 23).

The corticosteroid injection also has a dual role of establishing a diagnosis and determining the prognosis after surgery with CTS (32). Slater and Bynum noted that 90% of patients would have a reoccurrence of CTS symptoms post-steroid injection normally before four months (7). They also reported that 11% of injections were symptom free for up to 45 months and of the patients that had a reoccurrence of CTS, only 46% of them required surgery for their symptoms (7).

However, Banta found iontophoresis was successful in 58% of those that failed the splinting and ibuprofen treatment on a 3-week protocol, at a 6-month follow up (33). Iontophoresis is becoming another alternative to the oral and injected delivery of corticosteroids due to its noninvasive, painless, and site-specific delivery system. Iontophoresis utilizes a transdermal administration of ionized drugs forced across the permeable skin layer with the assistance of an electrical field.

Pyridoxine (vitamin B6) has been used as a therapeutic agent in CTS. Although no research has validated the effectiveness of its benefits, some patients believe their symptoms are improved (4). No causal links have been noted with the deficiency of vitamin B6 and the presence of CTS. Some physicians are now concerned that the use of excessive amounts of pyridoxine may be linked to the damage of nerve fibers.

Currently, Kaplan et al have identified five factors that may be attributed to the likelihood of failure from non-surgical intervention:

·patient age greater than 50 years,
·the duration of symptoms for greater than 10 months,
·constant paraesthesias,
·stenosis flexor tenosynovitis (presence of trigger finger),
·a positive Phalen's Test in less than 30 seconds (29).

Kaplan also reported that for the five risk factors listed above….

> approximately 60% of patients having only one risk factor were symptom free without operation, but 93% of those having three factors and 100% of those having four or more risk factors failed non-operative management (29).

Surgical Intervention

When conservative measures are unsuccessful in relieving the symptoms of CTS, many patients elect surgery. Palmer and Hanrahan estimated the number of carpal tunnel release (CTR) surgeries to be between 400,000 and 500,000 annually, with a total price tag exceeding two billion dollars each year (37). The first CTR may have actually occurred as early as 1924 (38), but since then there have been many advances in surgical technology, resulting in the development of several techniques, all varying in their potential benefits and risks.

Open Technique

The decompression of the median nerve requires that all impinging structures be released. The structures include the transverse carpal ligament (TCL), the volar radiocarpal ligament, and the deep fascia of the forearm (14). The standard surgical technique is an open carpal tunnel release (OCTR). OCTR allows direct visualization of the carpal tunnel and its contents. A longitudinal incision is made in line with the axis of the fourth finger, which is thought to best protect the palmar cutaneous branches of the median and ulnar nerves from accidental laceration (39). The incision extends from just proximal to the superficial palmar arch to the distal wrist crease, and then continues for another 1 centimeter (cm) in a 45° angle toward the ulnar border. After dissecting the

skin, subcutaneous fat, and superficial palmar fascia, the TCL becomes visible. The

ligament is then cut, along with the radiocarpal ligament, and the deep fascia of the

forearm (14). Although this is a general description of the OCTR, it should be noted that

there is a great deal of variety in the technique itself, in terms of location, length, and

shape of the incision (40).

Modified Open Technique

Scar tenderness and decreased strength are common complaints following OCTR

(6). In an effort to minimize these characteristics, a modified incision length, one of 2.5

cm or less, may be used. This shorter incision starts at the same distal point as the

conventional incision, but ends 1 cm distal to the distal wrist crease. The surgery

continues in the same manner as the long incision approach, and the TCL is sectioned

under direct visualization (14). This modification to the length of the incision can

decrease postoperative discomfort and shorten the amount of time until the patient is able

to resume activities of daily living (ADL) (41).

Endoscopic Technique

In OCTR, the direct visualization of the TCL decreases the risk of accidentally

transecting neural and vascular structures. However, in efforts to minimize painful

scarring and decrease recovery time, endoscopic carpal tunnel release (ECTR) techniques

have been developed, with results that indicate success in achieving those objectives (40).

In ECTR, surgeons use a blunt instrument that divides the TCL from within the canal

itself. Though direct visualization is not possible with this procedure, the endoscope does

provide some visualization. One of the benefits of ECTR is that the skin and palmar fascia remain intact. The incision(s) used in ECTR is shorter than the standard longitudinal incision and results in a less painful, faster healing scar, which blends into the wrist crease itself. There are two ECTR techniques most commonly used in the United States (42). There are variations within each technique, but the described procedures that follow are the most widely performed and reported for each method (40).

The dual-portal method developed by Chow requires two incisions (43). The proximal incision, approximately 1 cm in length, is made transversely in the distal forearm. The second incision is made in the palm just distal to the TCL, and a cannula is inserted under the TCL. The endoscope is inserted in the cannula, allowing the surgeon to visualize the TCL. A sequence of cuts is then performed to transect the TCL (40).

The single-portal method developed by Agee uses one transverse incision, approximately 2 cm in length at the wrist crease between the tendons of the flexor carpi radialis and the flexor carpi ulnaris (44). A pistol grip device is inserted into the cannal along the line of the axis of the fourth finger. The endoscope window near the tip of the device's blade allows the surgeon to visualize the TCL. The blade is then elevated and the TCL is transected by withdrawing the device (44,45). Agee states that more than one pass may be necessary to completely transect the TCL (44).

Carposcopic Technique

Another device has been introduced to further decrease the risk of complications or injury to surrounding neural and vascular structures. Lee and Jackson (46) have developed a fiberoptic light retractor called a carposcope, which is used in conjunction

with a dissector, a guider, and a V-blade knife. The procedure requires one short incision

(1.5 to 2 cm) along the wrist flexion crease, between the palmaris longus and the flexor

carpi ulnaris. Transection of the TCL occurs under direct visualization, while the

carposcope and the carpal tunnel guider protect surrounding structures.

Postoperative Management

Postoperative care may vary depending on the surgical technique used. Some

surgeons elect to splint the hand in neutral or slight extension for one to three weeks

following surgery to prevent bowstringing of the flexor tendons or entrapment of the

median nerve in scar tissue (14,39). However, Cook et al suggest that immobilization

results in the increase of pain and stiffness, and delays recovery (47). Instead, Cook et al

recommend early mobilization and a home exercise program in which the fingers and

wrist are exercised separately to avoid simultaneous flexion and possible bowstringing.

In a study of 216 subjects who had undergone OCTR with an incision of 2.5 cm or less,

all of the subjects started physical therapy on the first postoperative day (47). The

regimen consisted of active range of motion, exercises to promote strength and

endurance, and passive nerve gliding. Though none of the subjects were splinted, there

was no incidence of bowstringing or wound complications (47).

Surgical Outcomes

The outcomes of carpal tunnel release surgery vary widely. Complications do

occur with both the traditional open method and the more recently developed endoscopic

technique. These complications include transient paresthesias of the ulnar and median

nerves, vessel lacerations, nerve lacerations, reflex sympathetic dystrophy, flexor tendon lacerations, and incomplete TCL division (40,48). Some proponents claim that the OCTR is the safest, most effective technique (42). However, Nancollas et al reported that 57% of patients who had undergone OCTR had a return of symptoms within two years following surgery (6). Still others cite ECTR as a superior technique, with a less painful scar and faster recovery time (44,45). In contrast, Hulsizer et al suggest a higher incidence of incomplete release of the carpal tunnel is found with ECTR as opposed to OCTR, thus resulting in persistent or recurrent symptoms (49). Moreover, Palmer and Toivonen surveyed hand surgeons who had surgically treated complications of ECTR and OCTR. They concluded "that carpal tunnel release, be it endoscopic or open, is not a safe and simple procedure. Major, if not devastating, complications can and do occur with both procedures, of which surgeons should be ever cautious" (48). While there are several opinions regarding the effectiveness of current CTS interventions, there is very little scientific support for these treatments (50).

Methods

Subjects

In order for this study to occur, the Pacific University Institutional Review Board (IRB) granted approval for meeting all ethical and moral standards of research. The procedure was described to each subject and written confirmation of informed consent was obtained prior to any testing for exclusion or inclusion into the study. Volunteers were recruited to participate in this study from Spirit Mountain Casino in Grande Ronde, Oregon. Individuals were screened and biographical information consisting of date of birth, weight, height and occupation was obtained from each subject. Participants were then excluded from the study for any medical or musculoskeletal condition that prevented them from participating fully in the testing procedures, such as pregnancy, diabetes mellitus, previous surgeries for CTS, injections of corticosteriods within the last two months, or any inflammatory arthritis. Study participants were included into the study if two of the following five clinical signs or symptoms were present: numbness/tingling; weakness in the forearm, wrist and/or hand; pain in the forearm, wrist and/or hand; sleep disturbance secondary to pain in the wrist and hand; or positive Phalen's Test or Reverse Phalen's Test.

It is important to note that five participants had bilateral involvement, and thus may have had both hands in the study. The individual hands were randomly assigned to either the control group or the FleXtend™ intervention group consisting of 13 individual hands each. Participants who were already receiving some form of treatment from a physician, other than surgery, were non-randomly assigned to the medical group, which consisted of 8 hands. At the end of the study, the control and FleXtend™ groups each

had 11 hands, and the medical group consisted of 4 hands. Subjects whom completed the

study ranged from 26 to 58 years of age, with 15 females and 6 males (Table 1).

Seventeen of the 21 subjects demonstrated dominant hand involvement. Participants'

occupations included the following: cashiers, chefs, dealers, clerks, maintenance workers,

security officers, and office administrators.

Assessment

The Jamar® Hydraulic Hand Dynamometer (Figure 1) was used to measure the

grip strength of participants at the pre-, post- and follow-up test sessions. The Jamar® is

an isometric device that measures grip force in pounds and kilograms. To accommodate

for different size hands, the dynamometer has five grip positions. To determine

appropriate grip position, the handle was adjusted until the participant's PIP joint was

directly over the external handle. The internal handle was placed against the subjects'

thenar/hypothenar eminances. Each participant's grip position was measured, recorded

and used during each testing period to ensure consistency. During grip strength testing

the subject was positioned in the following manner for each measurement: first, the

correct grip position for each included hand was determined as stated above; second, the

subject would then sit comfortably in a chair, with the shoulder relaxed and neutrally

rotated; third, the elbow was flexed to 90 degrees, and the forearm and wrist maintained

in neutral. The red peak-hold needle was reset to zero and the subject was instructed to

squeeze with maximal strength without deviating from this initial arm and wrist position.

The measurement was recorded in one pound increments, the red peak-hold was reset,

and a rest break was given for approximately 30 seconds. The procedure was repeated

Table 1. - Characteristics of Study Subjects by Group

Characteristic	All (n=26)	Control (n=11)	Medical (n=4)	Flextend (n=11)
Age, mean (median)	43.6 (43)	46.9 (46)	41.3 (42)	41.1 (39)
[range]	[26-58]	[37-58]	[26-55]	[27-58]
Gender				
Women	18	10	3	5
Men	8	1	1	6
Weight, mean (median)	177 (180)	172 (180)	164.3 (165)	185.9 (190)
[range]	[125-230]	[130-190]	[125-202]	[140-230]
Height, mean (median)	66 (65)	64 (65)	65.3 (64)	68.2 (71)
[range]	[60-75]	[60-72]	[61-72]	[60-75]

Data are presented as number of involved wrists.

Figure 1. - Jamar® Hydraulic Hand Dynamometer Positioning

two more times and an average for the three trials was recorded. The dynamometer was calibrated for accuracy prior to initial testing and calibration is only necessary on an annual basis, or if error is suspected.

The Visual Analog Pain Scale (VAPS) is an instrument used to obtain a subjective report of pain level at the pre-, post-, and follow-up testing periods. This scale is a horizontal straight line measured 10 centimeters in length and has no markings or numbers. At each testing interval the participants were asked to rate their current level of pain by marking a vertical line to cross the horizontal line at the level they believe coincided with their pain, the left side being no pain at all and the right side of the line being the worst pain imaginable. The length of the horizontal line up to the vertical mark was then measured using a standard ruler and measured to the nearest millimeter.

Phalen's Test (Figure 2) is performed by placing the back of both hands together at chest level, with the wrist flexed at a 90° angle and the fingers pointing downward. This position is held for 30 seconds and the test is positive if it reproduces numbness or tingling in the median nerve distribution of the hand. The length of time that elapsed until these symptoms occurred or worsened was noted. Reverse Phalen's Test (Figure 3) is performed in the same manner as previously described, with the exception of the hand position being palms together, wrists extended to 90° and the fingers pointing upward, as in a prayer position.

A Self-Administered Questionnaire for the Assessment of Severity of Symptoms and Functional Status in Carpal Tunnel Syndrome (survey) (51) is an instrument that is designed to provide a subjective assessment of the severity of symptoms of patients with CTS. This test consists of eleven questions, each with five possible responses. The

Figure 2. – Phalen's Testing Position

Figure 3. – Reverse Phalen's Testing Position

responses have a five point range with one representing mildest symptoms and five representing the most severe. The minimum possible score for this survey is 11 (no symptoms), and the maximum possible score is 55 (severe symptoms).

Procedure

Each participant was evaluated for eight weeks. Once inclusion criteria was met, all participants were then given a pre-test to determine baseline values of signs and symptoms. The pre-test consisted of the following assessments: 1) grip strength measured with the Jamar® Hydraulic Hand Dynamometer using the above stated technique, 2) VAPS, 3) Phalen's Test , 4) Reverse Phalen's Test, and 5) survey questionnaire, *A Self-Administered Questionnaire for the Assessment of Severity of Symptoms and Functional Status in Carpal Tunnel*. A post-test took place after four weeks of intervention, and the participants in the FleXtend™were discontinued from receiving intervention at that time. All groups were tested at the 8-week follow-up test period to determine if there were any changes from the pre-test and post-test values.

The control group was monitored for eight weeks using the above protocol for testing at pre-test, post-test and follow-up time frames to assess changes in CTS signs and symptoms to develop a baseline for comparison of treatment outcomes. Individuals in this group were instructed not to alter their current activities of daily living or exercise routine.

The FleXtend™ glove (Figure 4) is the instrument that was used by the intervention group. It consists of a leather glove, that has metal D-rings sewn to the glove on the ventral surfaces at the PIP joints, the DIP joints, and the wrist joints; a

Velcro® arm band strap that also has D-rings sewn to it that goes just proximal to the supracondylar ridges of the humerus; a tubing clasp to allow for adjustment of tubing tension; and yellow Theraband® tubing which is strung through the Velcro® strap, wrist and DIP joint D-rings to provide resistance.

Subjects in the FleXtend™ group were fitted for the FleXtend™ glove and were instructed in an exercise protocol in which each participant wore the FleXtend™ glove while performing one exercise for three sets of 10 repetitions. Each of the sets took approximately 20 seconds to complete, and then the subject rested for one minute between sets. These exercises were performed twice daily for three days per week and monitored with an exercise log sheet. The subjects were educated on alignment, technique, and proper progression of the exercise protocol. Starting position for this exercise was neutral shoulder, with the elbow fully flexed, forearm supinated to 90°, wrist and fingers fully flexed. Subjects then fully extended and abducted the fingers, followed by wrist extension to approximately 10°, and followed this fluid movement to achieve complete elbow extension. This motion was performed against the resistance of yellow Theraband® tubing. Once reaching full elbow extension, the subject was to return the arm to the original starting position by reversing the motion. The duration of this cycle took approximately one second.

The medical group, under the care of each individual participant's physician, was instructed to continue with whatever treatment or protocol they had been prescribed. This group was tested in the same manner and at the same intervals as the control and FleXtend™ groups.

Figure 4. – Subject Demonstrating FleXtend™

Data Analysis

This study used a two group random sample, with a third non-randomized group (Figure 5). There was one independent variable, which was the alleviation of CTS symptoms. The independent variable had three levels: a control group, and the Flextend™ intervention group, and a medical intervention group. The dependent variable was the individual measurement of five tests: grip strength, VAPS, Phalen's Test, Reverse Phalen's Test, and a survey.

Differences between the pretest, posttest, and follow-up test were examined using a two-factor analysis of variance (ANOVA) with repeated measures. Dynamometer grip strength, the VAPS, and the survey score were analyzed with the StatView version 5.0 for Windows (SAS Institute, Inc., Cary, NC). Paired t-tests were calculated to ascertain pair-wise mean differences where ANOVA results were significant. A Bonferroni correction factor was used to adjust the nominal alpha level from $p \leq 0.05$ to $p \leq 0.008$ to control from overall type I error. Analysis of Phalen's Test and Reverse Phalen's Test was conducted on SPSS for Windows release 9.0.1 (SPSS, Inc., 233 S. Wacker Drive, Chicago IL) with a Pearson's Chi-square test. The level of significance used was $p \leq 0.05$.
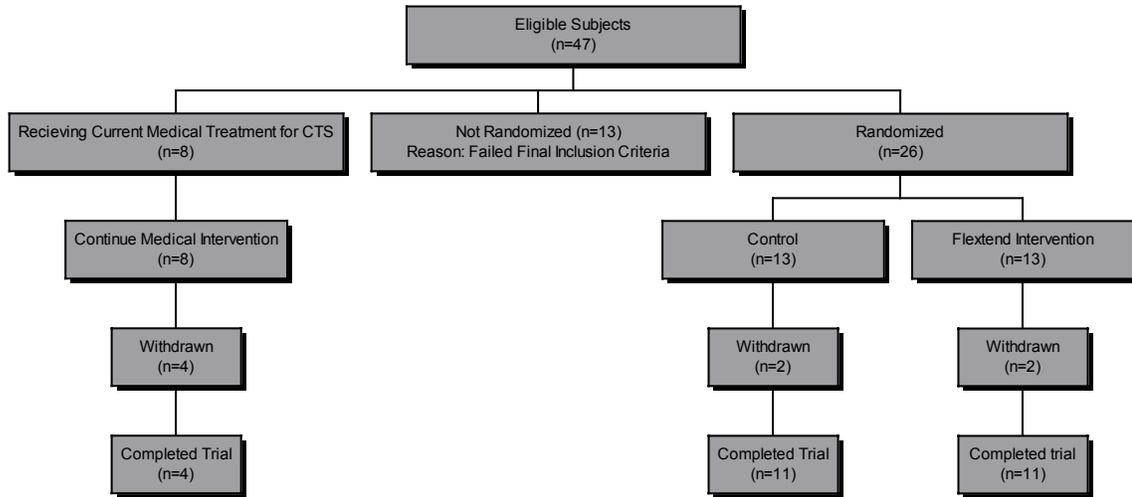
Figure 5. - Randomization into Groups

Results

During the study, subjects representing a total of eight hands dropped out or were excluded (Figure 5). Four subjects from the medical intervention group, two from the control group, and one from the FleXtend™ group were non-compliant with the retesting process, and were dropped from the study. One individual in the FleXtend™ intervention group was excluded midway through the study, secondary to beginning a neurological medication. Final data was analyzed for 26 hands (11 in the control group, 11 in the FleXtend™ intervention group, and four in the medical group) (Table 1).

For grip strength, as measured in pounds, the means (Figure 6) and standard deviations (Table 2) for pre-, post-, and follow-up testing for the control were 57.3±17.8, 57.4±13.6, and 60.1±17.7, respectively. The means and standard deviations for pre-, post-, and follow-up testing for the FleXtend™ group were 69.8±16.5, 79.6±20.7, and 69.0±21.0, respectively. The means and standard deviations for pre-, post-, and follow-up testing for the medical group were 54.3±25.8, 55.0±30.1, and 57.0±41.7, respectively. There was no statistical significance for grip strength for pre-, post-, and follow-up testing within groups (p=0.15), nor between groups (p=0.52), and no interaction (p=0.23) between groups (Table 3).

For the VAPS, as measured in centimeters, the means (Figure 7) and standard deviations (Table 2) for pre-, post-, and follow-up testing for the control were 4.6±2.0, 4.1±1.6, and 4.3±1.8, respectively. The means and standard deviations for pre-, post-, and follow-up testing for the FleXtend™ group were 3.8±2.0, 1.9±1.3, and 2.6±2.4, respectively. The means and standard deviations for pre-, post-, and follow-up testing for

Figure 6. - Comparison of Means for Grip Strength
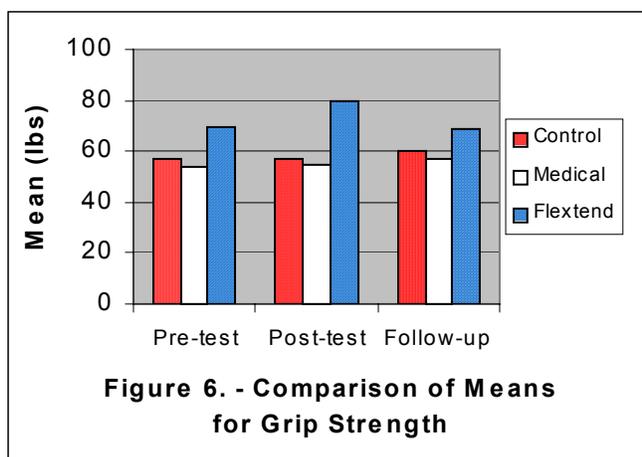
Table 2. - Means and Standard Deviations for Grip Strength, Visual Analog Pain Scale and Survey

Variable	n	Mean (Standard Deviation)		
		Pretest	Posttest	Follow-up test
Dynamometer (lbs)				
Control	11	57.3 (17.8)	57.4(13.6)	60.1(17.7)
Flextend	11	69.8(16.5)	79.6(20.7)	69.0(21.0)
Medical	4	54.3(25.8)	55.0(30.1)	57.0(41.7)
Visual Analog Scale (cm)				
Control	11	4.6(2.0)	4.1(1.6)	4.3(1.8)
Flextend	11	3.9(2.0)	1.9(1.3)	2.6(2.4)
Medical	4	5.0(3.0)	4.8(3.9)	5.2(3.4)
Survey (11-55)				
Control	11	27.7(7.1)	28.8(7.4)	27.1(6.2)
Flextend	11	27.5(8.4)	20.9(5.6)	22.9(8.3)
Medical	4	28.0(7.8)	25.0(12.2)	25.8(10.5)

Table 3. - ANOVA F-Table for Grip Strength

	DF	SS	MS	F-Value	P-Value	Lambda	Power
Groups (Within)	2	4544.06	2272.03	2.10	0.15	4.20	0.38
Subject	23	24907.89	1082.95				
Category for Dyna (Between)	2	132.07	66.04	0.66	0.52	1.32	0.15
Category for Dyna * Groups (Interaction)	4	588.52	147.13	1.47	0.23	5.87	0.41
Category for Dyna * Subjects	46	4610.68	100.23				

F for p=0.05 (df 2, 23) = 3.42

Figure 7. - Comparison of Means for Visual Analog Pain Scale
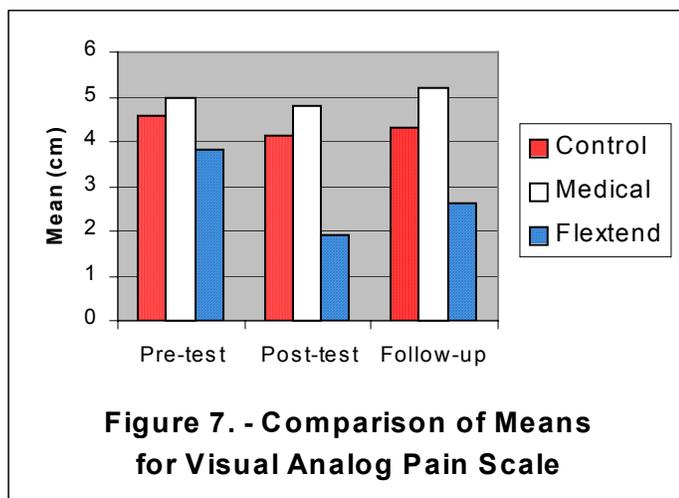
the medical group were 5.0±3.0, 4.8±3.9, and 5.2±3.4, respectively. There was statistical

significance for VAPS for pre-, post-, and follow-up testing within groups (p=0.03);

however, there was no significance between groups (p=0.29), and no interaction (p=0.59)

between groups (Table 4).

The results of the Phalen's Test demonstrated no significance. The Pearson Chi-

Square results were p=0.596 for pre-test, p=0.684 for post-test, and p=0.860 for follow-

up (Table 5). The counts for negative/positive of Phalen's Test results (Table 6) for the

control group for pre-, post-, and follow-up testing were as follows: 8/3 (pre), 5/6 (post),

and 4/7 (follow), respectively. The FleXtend™ results were 6/5 (pre), 7/4 (post), and 5/6

(follow), respectively. The medical results were 2/2 at each testing interval.

The results of the Reverse Phalen's Test demonstrated no significance. The

Pearson Chi-Square results were p=0.866 for pre-test, p=0.169 for post-test, and p=0.066

for follow-up (Table 5). The counts for negative/positive of Reverse Phalen's Test

results (Table 6) for the control group at pre-, post-, and follow-up testing were as

follows: 7/4 (pre), 4/7 (post), and 3/8 (follow), respectively. The FleXtend™ results were

8/3 at each testing interval. The medical results were 3/1 at each testing interval.

However, the post test results demonstrated that the subjects in the control group initially

had seven negatives and four positives, but at follow-up testing the control group had

three negatives and eight positives for the Reverse Phalen's Test. In comparison, the

FleXtend™ group maintained eight negatives and three positives throughout the study.

However, this is not a statistically significant finding.

For the survey score, the means (Figures 8, 9, and 10) and standard deviations

(Table 2) for pre-, post-, and follow-up for the control was 27.7±7.1, 28.9±7.4, and

Table 4. - ANOVA F-Table for Visual Analog Pain Scale (VAPS)

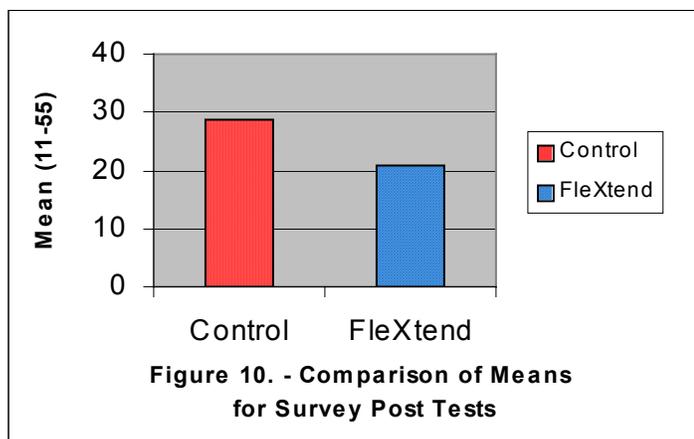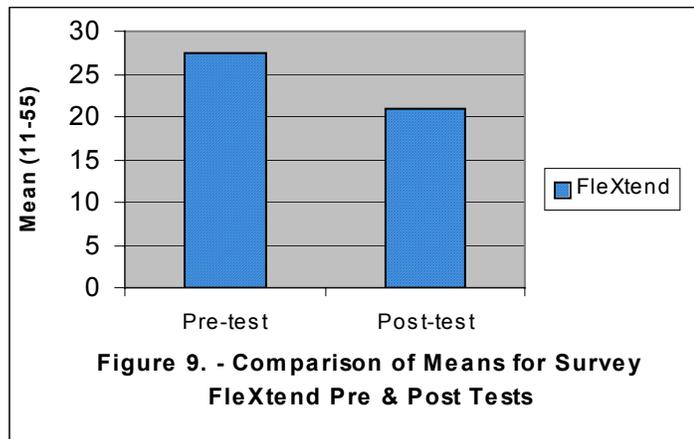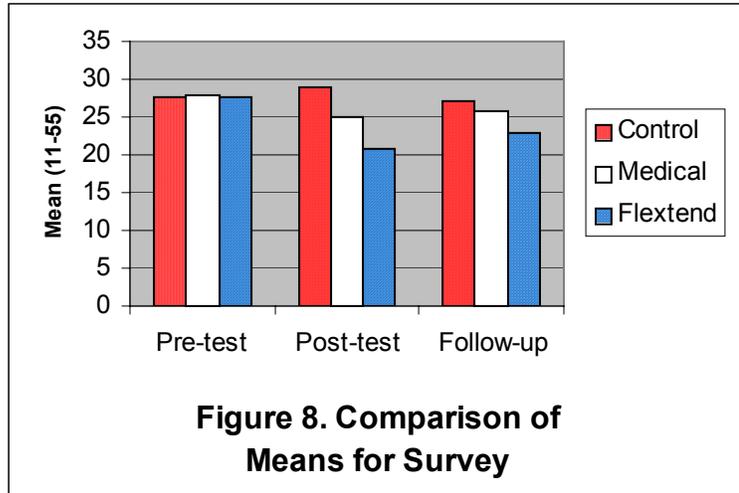|	DF	SS	MS	F-Value	P-Value	Lambda	Power
Groups (Within)	2	60.43	30.21	3.93	0.03	7.85	0.65
Subject	23	176.96	7.69				
Category for VAS (Between)	2	7.46	3.73	1.26	0.29	2.51	0.25
Category for VAS * Groups (Interaction)	4	8.46	2.12	0.71	0.59	2.85	0.21
Category for VAS * Subjects	46	136.66	2.97				

F for p=0.05 (df 2, 23) = 3.42

Table 5. - Chi-Square Results for Phalen's and Reverse Phalen's Tests

	Pre	Post	Follow
Phalen's Test	0.596	0.684	0.860
Reverse Phalen's Test	0.866	0.169	0.066

F for p=0.05 (df=2) = 5.99

Table 6. - Phalen's and Reverse Phalen's Test Results

Phalen Test	No	Yes	Reverse Phalen Test	No	Yes
Pre-test			Pre-test		
Control	8	3	Control	7	4
FleXtend™	6	5	FleXtend™	8	3
Medical	2	2	Medical	3	1
Post-test			Post-test		
Control	5	6	Control	4	7
FleXtend™	7	4	FleXtend™	8	3
Medical	2	2	Medical	3	1
Follow-up			Follow-up		
Control	4	7	Control	3	8
FleXtend™	5	6	FleXtend™	8	3
Medical	2	2	Medical	3	1

Figure 8. Comparison of Means for Survey

Figure 9. - Comparison of Means for Survey FleXtend Pre & Post Tests

Figure 10. - Comparison of Means for Survey Post Tests

27.1±6.3, respectively. The means and standard deviations for pre-, post-, and follow-up

testing for the FleXtend™ group were 27.5±8.4, 20.9±5.6, and 22.9±8.3, respectively.

The means and standard deviations for pre-, post-, and follow-up testing for the medical

group were 28.0±7.8, 25.0±12.2, and 25.8±10.5, respectively. There was no statistical

significance for the survey for pre-, post-, and follow-up testing within groups ($p=0.40$);

however, there was significance between groups ($p=0.05$), and interaction ($p=0.05$)

between groups (Table 7). A paired t-test with Bonferroni correction factor was used as a

post hoc test to determine where the significance existed. The FleXtend™ pre and post

testing was found to be significant ($p=0.0070$, since the Bonferroni correction factor

yielded $p≤0.008$ (Table 8). The survey control and FleXtend™ post-tests also

demonstrated to be statistically significant ($p=0.003$) (Table 9).

Table 7. - ANOVA F-Table for Survey

	DF	SS	MS	F-Value	P-Value	Lambda	Power
Groups	2	277.90	138.95	0.948	0.40	1.90	0.19
Subject (group)	23	3371.95	146.61				
Category for Survey	2	100.86	50.43	3.101	0.05	6.20	0.56
Category for Survey * Groups	4	164.92	41.23	2.535	0.05	10.14	0.67
Category for Survey * Subjects (Group)	46	748.08	16.26				

F for p=0.05 (df 2, 23) = 3.42

Table 8. - ANOVA F-Table for Survey Flextend Pre & Post Tests

	DF	SS	MS	F-Value	P-Value	Lambda	Power
Subject	10	809.364	80.936				
Category for Survey	1	242.227	242.227	11.305	0.007	11.305	0.869
Category for Survey * Subjects	10	214.273	21.427				

Calculated with Paired t-tests and Bonferroni correction from p<0.05 to p<0.008

Table 9. - ANOVA F-Table for Survey Post Tests

	DF	SS	MS	F-Value	P-Value	Lambda	Power
Subject	10	644.091	64.409				
Category for Survey	1	344.045	344.045	15.193	0.003	15.193	0.950
Category for Survey * Subjects	10	226.645	22.645				

Calculated with Paired t-tests and Bonferroni correction from p<0.05 to p<0.008

Discussion

Statistical significance within this study was difficult to ascertain for most of our tests (grip strength, VAPS, Phalen's Test, and Reverse Phalen's Test) secondary to the limited number of subjects; therefore, a type II error may have been committed. In addition, the subjects in the medical group were not randomly assigned, since those participants were already receiving a physician prescribed treatment for their condition.

Subject compliance may have also been a factor in all three groups. It was difficult to assess compliance with physician orders regarding treatment protocols for those subjects in the medical group. It was difficult to monitor whether subjects were self- medicating or changing their daily activities or exercise routines. These confounding factors may have altered the results.

The adjustable resistance of the FleXtend™ was difficult to monitor and maintain because direct supervision of participants during the intervention was not always possible. This may have lead to subjects setting the tension too loose or too tight, and thus affecting the intended purpose of the FleXtend™. A standardized method of setting the resistance of the FleXtend™ is recommended to address the individual strength differences between participants, and their progression throughout the intervention. One suggestion to standardize the resistance of the FleXtend™ for each subject would be to set the resistance at a 10-repetition maximum, at which the subject fatigues the wrist and finger extensors, and mark the Theraband® length that coincides with this resistance.

The changes in grip strength, as measured in pounds by the Jamar® Dynamometer, were not statistically significant (Table 3). Although there was no statistically significant difference between the groups, the mean strength data for the

FleXtend™ group was greater than that of the control and medical groups (Table 2). The duration of the treatment intervention of four weeks may not have been long enough to show physiological strength gains. Increased treatment duration may lead to statistically significant strength increases.

The VAPS showed no statistical significance between groups. The lack of a clear explanation to the subject prior to asking them to rate their pain may have affected the results. Individuals may have understood the instructions to mean the symptoms that they were having instead of the actual pain. In addition, subjects with bilateral symptoms had difficulty reporting the unique symptoms that each hand had separately.

During Phalen's Test and Reverse Phalen's Tests, the protocol used was slightly varied from the traditionally recommended duration of 60 seconds. A 30-second test period was used to avoid exacerbation of symptoms. As with the visual analog scale, these tests were subjective. A script explaining the symptoms that were being qualified and quantified with this test may have provided more accurate responses from the subjects.

Results obtained from this study revealed that there was a statistically significant improvement in the survey score for the FleXtend™ group. There was significance within groups for the FleXtend™ for the pre- and post-tests (p=0.007), and significance between the post-test FleXtend™ and post-test control groups (p=0.003). These were each shown with a paired t-test and a Bonferroni correction (p≤0.008), and points to a decrease in severity of symptoms and an increase in functional status for individuals in the FleXtend™ group. Levine et al stated, "Severity of symptoms and functional status

are the principal reasons that patients seek treatment; therefore, they should be the most critical outcomes used to measure response (51)."

Future studies of the FleXtend™ with similar standards to this study would be beneficial to determine whether these results can be generalized to populations outside of the Casino at which the testing occurred. These studies should consider extending the intervention protocol to at least eight weeks to allow more time for physiological strengthening of the extensor muscles. Another idea for study would be to use the FleXtend™ motion without the Theraband® tubing to determine if the resistance or the motion itself is responsible for symptom relief.

Conclusion

Do to the small power of the statistics used in our study, and the limited number of subjects, it is difficult to ascertain the overall effectiveness of the FleXtend™ in treatment of CTS. Although there was no significant improvement in grip strength, decreased perceived pain on the VAPS, or fewer subjects testing positive for Phalen's Test and Reverse Phalen's Test, the subjects in the FleXtend™ group did have statistically significant improved survey scores as compared to the control and medical groups. Thus, for grip strength, VAPS, Phalen's Test, and Reverse Phalen's Test, we reject the hypothesis, and accept the null hypothesis. However, for the survey, we accept the hypothesis, and reject the null hypothesis. This study has proved beneficial in establishing a basis for using the FleXtend™ as a viable treatment option for CTS, with decreased severity of symptoms and increased functional status as determined by the survey. We believe this warrants further study and testing of this product, under more controlled circumstances, and with a larger number of participants.

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Appendix A

INSTITUTIONAL REVIEW BOARD

I.   Project Title

The Effectiveness of the FleXtend™ in the Treatment of Carpal Tunnel Syndrome.

II.   Abstract

Carpal Tunnel Syndrome (CTS) has become a significant problem in today's workplace, causing pain, disability, lost wages, and increasing worker's compensation costs. To this point only surgery and yoga-based intervention has been proven to have a positive outcome in the remittance of the signs and symptoms that accompany CTS; however, there are no studies to substantiate the long-term effectiveness of any current clinical interventions. The FleXtend™ glove by Balance Systems Inc. was designed to decrease the signs and symptoms associated with CTS by increasing wrist strength and flexibility, which addresses the imbalance between the flexors and extensor of the fingers, wrist and forearm. The purpose of this study is to determine if the FleXtend™ glove is an effective treatment for CTS. Approximately 60 subjects will be recruited to participate in the study, and will be randomly assigned into a control group or one of two test groups, each consisting of 20 participants. The control group will receive no direct intervention, while one test group will receive the FleXtend™ treatment protocol, the second group will receive a treatment that they have been prescribed by their medical provider. The subjects will be followed for a 4-week period, and will be tested for 1.) grip strength with a dynamometer, 2.) a visual analog scale to indicate pain level throughout treatment, 3.) a survey questionnaire, *Severity of Symptoms and Functional Status in Carpal Tunnel*, and 4.) Phalen's Test, which is a test whereby the wrist is held in flexion for 30 seconds. Finally, subjects will be accessed with follow-up testing, for an additional 4-week period, to determine the long-term effectiveness after the treatment has concluded.

III.   Location of the project

Data for this project will be gathered at the Spirit Mountain Casino in Grand Ronde, OR.

IV.   Project Overview

An adult population with CTS, will be recruited to participate in the study. Volunteers will be screened and excluded from the study for any medical or musculoskeletal condition that prevents them from participating fully in the testing procedures, such as: pregnancy, diabetes, previous surgeries for CTS, injections for CTS within the last two months, or any inflammatory arthritis. Study participants will then be included if they have 2 of 5 following clinical signs/symptoms: numbness/tingling, weakness, and pain in the forearm, wrist & hand, sleep disturbance secondary to CTS, or testing positive for Phalen's Test. Volunteers included in the study will then receive a pre-test to determine baseline values of signs and symptoms. The pre-test will consist of the following four assessments: 1.) grip strength will be measured using a Jamar® hand dynamometer, in which the participant squeezes the device as hard as possible, thus indicating the amount of pressure created by the grip; 2.) a visual analog scale, in which the participant will rate their pain from "worst pain" to "no pain" on a 10-cm line; 3.) a survey questionnaire, *Severity of Symptoms and Functional Status in Carpal Tunnel*, in which participants answer eleven questions with 5 responses each. The responses have a 5-point range, based on severity of symptoms. The points are added, and a mean score is determined. This mean is compared to a measure that indicates how severe the participant's symptoms are; 4.) Phalen's Test, which is a diagnostic marker of CTS. This test is done by the participant placing the back of both hands together at chest level, with the wrist bent at a 90° angle and the fingers pointing downward. This position is

held for 30 seconds and the test is positive if it reproduces numbness or tingling in the hands. The length of time that elapses until these symptoms occur or worsen will be noted. These four tests will be performed on each subject every four weeks for a total of eight weeks. Testing will continue for another eight weeks to follow the longevity of the treatment. All participants will be randomly assigned to either a control group or one of the two test groups. All groups will receive the above described testing prior to initiating the exercise protocol, post-protocol, and at a 4 week follow-up visit. The control group will receive no intervention from this study. One test group will be fitted for the FleXtend™ glove and be instructed in an exercise protocol in which each participant wears the FleXtend™ glove while performing one exercise for 3 sets of 10 repetitions. Each of the sets will take 20 seconds to complete, and then the subject will rest for 2 minutes between sets. These exercises will be performed 3 times per week. The other test group will be instructed to continue with their already prescribed protocol from either their physician or physical therapist.

V. Risks

Because these testing procedures are routinely used in the physical therapy clinic, minimal risk is afforded by participation in the study. There is, however, the risk that muscle soreness may result within the first few sessions of the study.

VI. Procedures to avoid the risks

To decrease the risk of soreness from the performance of the exercise protocol, subject will be given precautionary guidelines on how to limit muscle soreness and how to deal with its onset. These precautions will include education on alignment, technique, and the proper progression of exercise protocol. Subjects will be initially supervised to assure that they are correctly following the protocol of the exercises.

VII. Signatures

_____   _____
Janine Boyer   Date

_____   _____
Adam Laraway   Date

_____   _____
Gregory Milles   Date

_____   _____
John Medeiros, Ph.D., P.T.   Date
Faculty Advisor

_____   _____
Jay Salzman, P.T.   Date
Faculty Advisor

VIII. Project Dates: Winter 1999-Spring 2000.

Appendix B

INFORMED CONSENT FORM

Pacific University

A.	The Effectiveness of the FleXtend™ in Treatment of Wrist and Hand Pain.	
B.	Principal Investigators:	
	Janine Boyer	992-9009
	Adam Laraway	533-9795
	Greg Milles	357-5317
	Advisors:	
	John Medeiros, Ph.D., P.T.	359-2149
	Jay Salzman, P.T.	359-2800
C.	Location: Spirit Mountain Casino in Grand Ronde, OR.	
D.	Date: Winter 1999-Spring 2000	

1. Description of the Project

The purposes of this study are to determine whether the FleXtend™ will relieve symptoms associated with wrist and hand pain and to assess the effects of the FleXtend™ exercise program on wrist strength and flexibility. You will be screened and excluded from the study for any condition that prevents you from participating fully in the testing procedures, such as: pregnancy, diabetes, previous surgeries for Carpal tunnel syndrome, injections of corticosteriods within the last two months, or any inflammatory arthritis. You will then be included if you have 2 of the 5 following clinical signs or symptoms: 1.) numbness/tingling; 2.) weakness in the forearm, wrist and hand; 3.) pain in the forearm, wrist and hand; 3.) sleep disturbance secondary to wrist and hand pain; or 5.) increase in symptoms after the wrist is held in flexion for 60 seconds. If you decide to participate in this study, you will be placed in one of three groups that will be followed for 8 weeks. One group will receive the FleXtend™ treatment program, which will consist of performing an exercise of 5 minutes in duration, twice daily, three times per week for the first 4 weeks. The second group will receive treatment that they have been prescribed by their medical provider and the third group will receive no direct treatment. All groups will receive the described testing prior to initiating the exercise program, after the treatment program, and at a 4 week follow-up visit. Testing will take approximately 15 minutes. The testing will consist of the following five assessments: 1.) grip strength; 2.) a visual pain scale; 3.) a survey questionnaire; 4.) Phalen's Test, a test that involves placing the back of both hands together at chest level for 60 seconds; and 5.) Reverse Phalen's Test, a test that involves placing the hands in a prayer position at chest level for 60 seconds.

2. Description of Risks

The possibility of muscle soreness may result within the first couple of exercise sessions. You will be given precautionary guidelines on how to limit muscle soreness and how to deal with its onset. These precautions will include education on alignment, technique and the proper progression of the exercise protocol. You will initially be supervised to assure that you are correctly following the protocol of the exercises.

3. Description of Benefits

From this study we may learn more about the treatment of wrist and hand pain. It has been proposed that increasing wrist extensor strength can aid in both the prevention of wrist and hand pain, and its rehabilitation after onset. You may or may not have any benefits from the treatment protocol.

4. <u>Alternatives Advantageous to Subjects</u>

Other possible conservative treatments that a person could pursue are yoga, splinting, anti-inflammatory medications, steroid injection, diuretics, vitamin B6, iontophoresis, stretching, exercise, and surgical interventions. However, except for yoga and surgery, no treatment has proven beneficial for relief of symptoms; and yoga has not yet proven to have long-term results to relieve symptoms.

5. <u>Records</u>

Records for this project will be maintained in a confidential manner and no information containing your name will be released without your permission.

6. <u>Compensation and Medical Care</u>

If you are injured in this experiment, it is possible that you will not receive compensation or medical care from Pacific University, the experimenter, or any organization associated with this project. However, all reasonable precautions will be used to prevent injury.

7. <u>Offer to answer any questions</u>

The experimenter will be happy to answer any questions that you may have at any time during the course of the experiment. If you are not satisfied with the answers that you receive, please call Dr. Daiva Banaitis, Director of the School of Physical Therapy at Pacific University at 359-2160.

8. <u>Freedom to Withdraw</u>

You are free to withdraw you consent and to discontinue participation in this study or activity at any time without prejudice to you.

I have read and understood the above. I am 18 years of age or over (or this form is signed for me by my parent or guardian).

Name: (printed)_____

Signature: _____ Date: _____

Address:_____ City: _____

State: _____ Zip: _____

Phone: _____

Appendix C

Inclusion/Exclusion Data Sheet

Name: _____   Date: _____

Physical Testing

Left (pos/neg)	Test	Right (pos/neg)
	Spurling's Test	
	Adson's Test	
	Costoclavicular Test	
	Hyperabduction Test	
	Resisted Flexion/Pronation Test	
	Medial Epicondylitis	
	Lateral Epicondylitis	

"**LET ME KNOW IF ANY OF THESE TESTS CAUSE YOU ANY PROBLEMS**"

Appendix D

General Data Sheet

Name: _____ Date: _____

Age: _____ Gender: Male or Female

Height: _____ Weight: _____

Dominant Hand: (please circle) Left   Right

Involved Hand: (please circle) Left   Right   Both

Work Schedule: (please fill in your normal working schedule)

Monday	_____ am/pm to _____ am/pm
Tuesday	_____ am/pm to _____ am/pm
Wednesday	_____ am/pm to _____ am/pm
Thursday	_____ am/pm to _____ am/pm
Friday	_____ am/pm to _____ am/pm
Saturday	_____ am/pm to _____ am/pm
Sunday	_____ am/pm to _____ am/pm

Currently:

Task: _____ Hours per week: _____

Months with current employer: _____

Previous Job: _____

Months with previous employer: _____

Previous related injuries / symptoms: (optional)

_____

Are you receiving treatment of any of the following types for your wrist or hand pain:
(circle yes or no)

Yes   No   Hydrocortisone Injections
Yes   No   Surgery
Yes   No   Braces/Splinting
Yes   No   Medications_____

Have you ever had: (circle yes or no)

Yes   No   Diabetes
Yes   No   Injections in the wrist and/or hand in the last two months
Yes   No   Inflammatory arthritis
Yes   No   Previous surgery for Carpal Tunnel Syndrome

Appendix E

Testing Data Sheet

Name: _____   Date: _____

I. VISUAL ANALOG PAIN SCALE

No _____ Worst
Pain   Pain

II. DYNAMOMETER (in lbs.)   GRIP SIZE (sm. to lg.): 1   2   3   4   5

TRIAL #	RIGHT HAND	LEFT HAND
1		
2		
3		

III. GLOVE SIZE: XS   S   M   L   XL

IV. SURVEY SCORE: _____/55

V. PHALEN'S TEST:

HAND:	POS.	NEG.	SECONDS
RIGHT	+	-	
LEFT	+	-	

IV. REVERSE PHALEN'S TEST:

HAND:	POS.	NEG.	SECONDS
RIGHT	+	-	
LEFT	+	-	

Appendix F

Severity of Symptoms and Functional Status with Wrist and Hand Pain

The following questions refer to your symptoms for a typical twenty-four hour period during the past two weeks (circle one answer to each question).

How severe is the hand or wrist pain that you have at night?
1   I do not have hand or wrist pain at night.
2   Mild pain
3   Moderate pain
4   Severe pain
5   Very severe pain

How often did hand or wrist pain wake you up during a typical night in the past two weeks?
1   Never
2   Once
3   Two or three times
4   Four or five times
5   More than five times

Do you typically have pain in your hand or wrist during the daytime?
1   I never have pain during the day.
2   I have mild pain during the day.
3   I have moderate pain during the day.
4   I have severe pain during the day.
5   I have very severe pain during the day.

How often do you have hand or wrist pain during the daytime?
1   Never
2   Once or twice a day
3   Three to five times a day
4   More than five times a day
5   The pain is constant.

How long on average does an episode of pain last during the daytime?
1   I never get pain during the day.
2   Less than 10 minutes
3   10 to 60 minutes
4   Greater than 60 minutes
5   The pain is constant throughout the day.

Do you have numbness (loss of sensation) in your hand?
1   No
2   I have mild numbness.
3   I have moderate numbness.
4   I have severe numbness.
5   I have very severe numbness.

Do you have weakness in your hand or wrist?

    1   No weakness
    2   Mild weakness
    3   Moderate weakness
    4   Severe weakness
    5   Very severe Weakness

Do you have tingling sensation in your hand?

    1   No tingling
    2   Mild tingling
    3   Moderate tingling
    4   Severe tingling
    5   Very severe tingling

How severe is numbness (loss of sensation) or tingling at night?

    1   I have no numbness of tingling at night.
    2   Mild
    3   Moderate
    4   Severe
    5   Very severe

How often did hand numbness or tingling wake you up during a typical night during the past two weeks?

    1   Never
    2   One
    3   Two or three times
    4   Four or five times
    5   More than five times

Do you have difficulty with the grasping and use of small objects such as keys or pencils?

    1   No difficulty
    2   Mild difficulty
    3   Moderate difficulty
    4   Severe difficulty
    5   Very severe difficulty

Appendix G

PACIFIC UNIVERSITY

School of Physical Therapy

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PACIFIC UNIVERSITY
School of Physical Therapy

Demonstration/Photo/Video Tape Consent Form

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Demonstrations, photo, and video tapes are excellent tools to help students and professionals understand the practical problems of individuals with movement disabilities. Your cooperation is greatly appreciated.

<u>Consent</u>:

( )　　I, _____, give permission for Pacific University faculty, staff, or students to photograph or video tape me or _____; and/or use
　　　　　　　　　　　　　　　　　　　　　(family member)
me or family member as a subject for demonstrations and presentations. It is my understanding that photographs or videotapes will be used for educational purposes only. These educational purposes may include classroom presentations, presentations at professional meetings, and/or professional education.

_____　　_____
Witness　　　　　　　　　　　　　　　　　　Participant or Guardian

_____　　_____
Date　　　　　　　　　　　　　　　　　　　　Date

( )　　I give permission for this photo to be used in publications.

_____　　_____
Witness　　　　　　　　　　　　　　　　　　Participant or Guardian

_____　　_____
Date　　　　　　　　　　　　　　　　　　　　Date