Full Length Research Paper

# Pain from carpal tunnel syndrome reduced with dynamic splinting: A retrospective study of 156 patients

Stacey H. Berner<sup>1</sup>, F. Buck Willis<sup>2\*</sup> and Ramalingam Shanmugam<sup>3</sup>

<sup>1</sup>Advanced Centers for Orthopaedic Surgery and Sports Medicine, 1380 Progress Way, Eldersberg, Maryland, 21784, USA.

<sup>2</sup>University of Phoenix, Axia College, Adjunct Professor: Health Science, Dynasplint Systems, Inc, Clinical Research, P. O. Box 1735 San Marcos, TX 78667, USA.

<sup>3</sup>School of Health Administration, Texas State University-San Marcos, 601 University Dr., San Marcos, TX 78666, USA.

# Accepted 6 September, 2009

Carpal tunnel syndrome (CTS) affects over six million Americans each year, and the chief complaint are pain and paresthesia. The US Center for Disease Control estimates an expense of \$3.5 billion dollars for this pathology, making CTS the most expensive peripheral neuropathy in the United States. The purpose of this retrospective study was to examine the effect of using dynamic splinting on 156 patients (mean age 55.2  $\pm$  15.6) diagnosed with CTS, (2007 to 2009 May). The Levine-Katz Function/Disability survey is commonly used in diagnosing CTS and this was the outcome measure of this study. This study tracked patients' results during the first two months using this new treatment modality. There was a significant change (reduction) in the scores of the Levine-Katz Function/Disability survey which showed decreased pain of 26%, (P < 0.0001, T = 12.624). Dynamic splinting was effective in reducing pain and associated symptoms for patients diagnosed with CTS in this study.

Key words: Dynasplint, home therapy, Levine-Katz pain survey, rehabilitation.

# INTRODUCTION

Carpal tunnel syndrome (CTS) affects Americans regardless of age, gender or ethnicity. The incidence rate is over 6 million Americans each year (American Association of Electrodiagnostic Medicine, 1999; Atroshi et al., 1997; Atroshi et al., 1999; Banta, 1994; Berner et al., 2008; Burke et al., 2006; de Araujo, 1996); DeStefano et al., 1997; Ettema et al., 2006) and the Center for Disease Control, Occupational Safety Department estimated that a typical CTS claim costs \$5,923.00 (CDC.gov, Occupational Safety web page 2007: http://www.cdc.gov/elcosh/docs/d0300/d000376/summary.html)]. Therefore, the per annum-expense of \$3.5 billion dollars makes this the most expensive peripheral neuropathy in the United

Abbreviations: **CTS**, Carpal tunnel syndrome; **DS**, dynamic splinting.

States (Kaul and Pagel, 2002; Palmer et al., (2007). The chief complaints of patients suffering from CTS are pain and paresthesia. Additional complaints may include dysfunction of the hand in coordination and stamina. Symptoms are often exacerbated by activities and may produce nocturnal awakening.

The biomechanics of the CTS pathology include compression and/or entrapment of the median nerve as it traverses through the carpal tunnel which causes impairment of both motion and/or sensation. Symptoms of numbness, paresthesias and pain as a result of the median nerve compression at the wrist by hypertrophy or edema of the flexor synovium (Atroshi et al., 1999; Kaul and Pagel, 2002; Kerwin et al., 1996; Guyette and Wilgis, 2004; Lee et al., 1999; Mishra et al., 2006; Rotman et al., 2004). The rigid, unyielding nature of the transverse palmar carpal ligament and the flexor retinaculum contribute to this compression.

A recent study by Berner et al. (2008) showed efficacy from use of Dynamic Splinting (DS) on patients diagnosed with CTS (Berner et al., 2008). The dependent

<sup>\*</sup>Corresponding author. E-mail: BuckPhD@yahoo.com. Tel: 512-297-1833. Fax: 866-626-9924.



Figure 1. The Dynasplint carpal tunnel system.

variables in this study were nerve conduction tests (Hilburn, 1996; Hirata and Sakakibara, 2006; Kaufman, 1996; Lee et al., 1999; Marciniak et al., 2005) scores from the Levine-Katz pain/function survey (Levine et al., 1993) which are commonly used in differential diagnosis for CTS. After 60 days in this study the experimental patients showed a significant difference in Levine-Katz scores but this was not seen for the control patients.

Nerve conduction testing was done on both motor and sensory nerve conduction and even the short duration showed a significant change in the frequency of improved nerve conduction. This was attributed to the prolonged duration of stretching employed by the dynamic splinting system (Mishra et al., 2006; Craft et al., 2007; John, 2009: Willis, 2007: Gaspar and Willis, 2009: Shulman et al., 2008). The theory behind the "low-load, prolonged stretching" employed in dynamic splinting originates with the coiled structure of collagen (the primary component in connective tissue). Prolonged stretching at the end-range of motion allows the protein polypeptide binds to realign on the coiled collagen triple helix molecules, thereby elongating the connective tissue. This modality has been shown effective in contracture reduction but analysis of a larger population was recommended.

The purpose of this retrospective study was to examine the effect of dynamic splinting on 156 patients diagnosed with CTS. The dependant variable in this study was the change in Levine-Katz pain/function scores and this study examined a larger population with higher external validity with absence of prescription or category bias (Kooistra et al., 2009). Patients' rights and privacy of their records were maintained throughout this study in accordance with the Helsinki Declaration.

## METHODS

## Testing

Diagnosis of CTS is made from medical history, physical examination, nerve conduction testing and administration of the Levine-Katz survey. The Levine-Katz assessment survey has been validated as a reliable and reproducible outcome measure (American Association of Electrodiagnostic Medicine, 1999; Anto and Aradhya, 1996; Atroshi et al., 1997; Atroshi et al., 1999; Banta, 1994; Berner et al., 2008; Burke et al., 2006; Palmer et al., 2007; Levine et al., 1993).

This survey is a 100 point questionnaire divided into two sections. The first section addresses frequency, intensity and duration of pain, while the second section examines functional abilities hindered by pain. For example a functional question asks to rate 'Difficulty in Writing' on a scale of 0 (unable to do) to 5 (no difficulty). Patients' improvement, as evidenced in reduced Levine-Katz scores, has been correlated to other diagnostic tests including distal motor latency, grip and pinch strength test, Tinel's Sign, Phalen's test and the Semmes-Weinstein monofilament test (Anto and Aradhya, 1996; Atroshi et al., 1997; Atroshi et al., 1999; Banta, 1994; Berner et al., 2008; Burke et al., 2006; Keese et al., 2006; Hirata and Sakakibara, 2006; Wilder-Smith et al., 2006).

#### Subjects

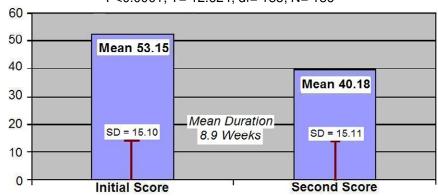
The records of 156 patients diagnosed with CTS were examined for this retrospective study; the mean age was  $55.2 \pm 15.6$ . The duration of treatment examined was eight weeks. Before being fit with the DS each patient completed informed consent (as required by the LifeBridge IRB) and took the initial Levine-Katz pain/function test. (All patient files were held in confidence under the Helsinki Declaration by the World Medical Association). Patient data was retrieved from four prescribing clinics in the USA from 2007 to 2009 May.

A qualified dynamic splinting consultant customized the unit for the patient, by making adaptations for the girth, depth and width of each patient's wrist. The patient was then instructed on the following items: donning and doffing the device, how and when to change tension calibration (based on patient tolerance) and patients were informed of possible side effects.

#### Intervention

The first two weeks of using the DS were an accommodation period for the patient and patients were encouraged to wear the unit twice daily for 15 min each session. Time was then increased by 2 - 4 min each day. After the patient comfortably wore the DS for two 30 min sessions each day for one week, instructions were then given to increase the tension of the DS once every two weeks, based on their tolerance. If the new tension setting caused excess joint fatigue or "soreness", (equivalent to soreness felt after one hour of intense hand therapy) the patient was then instructed to reduce the time to 15 min, twice daily and work the time back up to 30 min, twice daily.

The goal was to wear the DS for two sessions per day lasting 30 min each and to increase the tension twice a month, based on comfort and tolerance. Patients were instructed to communicate about compliance weekly and informed that a second test would be taken after eight weeks, (8.9 weeks) (Figure 1).



P<0.0001; T= 12.624; df= 155; N= 156

**Figure 2.** Changes in Levine-Katz pain/function test (Levine-Katz pain function scale and Dynasplint carpal tunnel system.

#### Statistical analyses

Paired T-tests were calculated to determine if a statistically significant difference occurred for these patients. The dependent variable was the Levine-Katz pain scores and the independent variable was gender. All data analysis was conducted with an alpha value of 0.05. The SPSS program (Chicago, IL) was used for statistical calculations of data transcribed from MS Excel files (Redmond, WA).

# RESULTS

There has been a significant improvement for the 156 patients who completed this study. (P < 0.0001, T = 12.624, SD 15.1, with 155 degrees of freedom). The mean difference between the initial Levine-Katz score and the second score was 13 points, following duration of 8.9 weeks between tests showed that the mean pain change was 26%. The Standard Deviation of both tests were symmetrical, (Pre = 15.10 and Post = 15.11). There was no difference between genders tested with post-hoc T-tests. (P ≥ 0.05) (Figure 2).

# DISCUSSION

The purpose of this retrospective study was to examine the effect of dynamic splinting on 84 patients diagnosed with CTS. The success of this modality is hypothesized to be derived from prolonged, end-range stretching of the transverse palmar carpal ligament and the flexor retinaculum because contracture of these structures contributes to compression in CTS. Dynamic tension and prolonged stretching have been successful in contracture reduction from head to toe, trismus (Shulman et al., 2008) to hallux rigidus (Willis, 2007). The low-load, prolonged duration of end-range stretching is hypothesized to be responsible for elongation of connective tissue. The patients' perspective on this modality was that they found it to be pleasantly comfortable. The bio-mechanics which are engineered into the system enable the patient to make precise adjustments and ensure comfortable usage. Unlike traditional "positioning splints" which are simply designed to prevent the patient from aggravating their CTS condition, the DS patients are instructed to simply rest the device on their lap during these treatment periods for a cumulative 60 min per day.

The results showed efficacy of the DS in reducing pain and associated symptoms for these patients. This report showed that the new modality was effective in reducing symptoms and improving function in patients diagnosed with CTS. This study also answered recommendations for further investigation of non surgical treatments for CTS (Atroshi et al., 1999; Berner et al., 2008; Burke et al., 2006; DeStefano et al., 1997; Palmer et al., 2007; Mishra et al., 2006). The retrospective series manuscript is limited in that it lacked randomization and control group and future research could further measure the efficacy of dynamic splinting in treating CTS by using cross-over trial of this modality.

# ACKNOWLEDGEMENTS

No extramural funding was used in this study and the patients were only compensated with additional care for follow ups and refitting if the Carpal Tunnel Dynasplint system. We wish to acknowledge and thank clinicians who also supplied data for this study: the Meharry Physical Therapy and Dr. John Jernigan from Mulberry Medical Associates.

## REFERENCES

American Association of Electrodiagnostic Medicine (1999). Guidelines in electrodiagnostic medicine. Practice parameter for electrodiagnostic studies in carpal tunnel syndrome. Muscle Nerve Suppl., 8:141-67.

- Anto C, Aradhya P (1996). Clinical diagnosis of peripheral nerve compression in the upper extremity. Orthop. Clin. North Am., 27: 227-236.
- Atroshi I, Breidenbach WC, McCabe SJ (1997). Assessment of the carpal tunnel outcome instrument in patients with nerve-compression symptoms. J. Hand Surg. Am., Mar 22(2): 227-236.
- Atroshi I, Gummesson C, Johnsson R, Ornstein E, Ranstam J, Rosén I (1999). Prevalence of carpal tunnel syndrome in a general population. JAMA July 14; 282(2): 153-158.
- Banta CA (1994). A prospective, nonrandomized study of iontophoresis, wrist splinting, and anti-inflammatory medication in the treatment of early-mild carpal tunnel syndrome. J. Occup. Med., 36(2): 166-168
- Berner SH, Willis FB, Martinez J (2008). Treatment of Carpal Tunnel Syndrome with Dynasplint: a Randomized, Controlled Trial. J. Med., (1): 90-94.
- Burke FD, Wilgis EF, Dubin NH, Bradley MJ, Sinha S.(2006). Relationship between the duration and severity of symptoms and the outcome of carpal tunnel surgery. J. Hand Surg. [Am.], 31(9): 1478-1482.
- CDC.gov, Occupational Safety (2007): http://www.cdc.gov/ elcosh /docs/d0300/d000376/summary.html
- Craft RO, Duncan SF, Smith AA (2007). Management of Recurrent Carpal Tunnel Syndrome with Microneuroloysis and Hypothenar Fat Pad Flap. HAND, (2)2:85-89.
- de Araujo MP (1996). Electrodiagnosis in compression neuropathies of the upper extremities. Orthop. Clin. North Am., 27: 237-244.
- De Stefano F, Nordstrom DL, Vierkant RA (1997). Long-term symptom outcomes of carpal tunnel syndrome and its treatment. J. Hand Surg., 22(2): 200-210.
- Ettema AM, Amadio PC, Cha SS, Harrington JR, Harris AM, Offord KP (2006). Surgery versus conservative therapy in carpal tunnel syndrome in people aged 70 years and older. Plast. Reconstr. Surg.,118(4):947-58.
- Ettema AM, Zhao C, Amadio PC, O'byrne MM, An KN (2006). Gliding characteristics of flexor tendon and tenosynovium in carpal tunnel syndrome: A pilot study. Clin. Anat., 20(3): 292-299.
- Gaspar PD, Willis FB (2009). Adhesive Capsulitis and Dynamic Splinting: a Controlled, Cohort Study. BMC Musculoskeletal Disorders 10: 111-115
- Guyette TM, Wilgis EF (2004). Timing of improvement after carpal tunnel release. J. Surg. Orthop. Adv. Winter, 13(4): 206-209.
- Hilburn JW (996). General principles and use of electrodiagnostic studies in carpal and cubital syndromes. With special, attention to pitfalls and interpretation. Hand Clin., 1(12): 205-221.
- Hirata M, Sakakibara H (2006). Sensory nerve conduction velocities of median, ulnar and radial nerves in patients with vibration syndrome. Int. Arch. Occup. Environ. Health, 80(4): 273-280.
- John MM, Willis FB, Protillo A (2009). Runner's Hallux Rigidus Reduction and Gait Analysis, J. Am. Podiatric Med. Assoc., 99(4):367-370
- Kaufman MA (1996). Differential diagnosis and pitfalls in electrodiagnostic studies and special tests for diagnosing compressive neuropathies. Orthop. Clin. North Am., 27: 245-252.

- Kaul MP, Pagel KJ (2002).\_Value of the lumbrical-interosseous technique in carpal tunnel syndrome. Am. J. Phys. Med. Rehabil., 81(9): 691-695.
- Keese GR, Wongworawat MD, Frykman G (2006). The Clinical significance of the palmaris longus tendon in the pathophysiology of carpal tunnel syndrome. J. Hand Surg., 31(6): 657-660.
- Kerwin G, Williams CS, Seiler JG III (199. The pathophysiology of carpal tunnel syndrome. Hand Clin., 12: 243-251
- Kooistra B, Dijkman B, Einhorn TA, Bhandari M. (2009). How to design a good case series. J. Bone Joint Surg. 3: 21-26.
- Lee D, van Holsbeeck MT, Janevski PK, Ganos DL, Ditmars DM, Darian VB (1999). Diagnosis of carpal tunnel syndrome. Ultrasound versus electromyography. Radiol. Clin. North Am., 37(4): 859-872.
- Levine DW, Simmons BP, Koris MJ, Daltroy LH, Hohl GG, Fossel AH, Katz JN (1993). A self-administered questionnaire for the assessment of severity of symptoms and functional status in carpal tunnel syndrome. J. Bone Joint Surg. Am., 75(11): 1585-1592.
- Marciniak C, Armon C, Wilson J (2005). Practice parameter: utility of electrodiagnostic techniques in evaluating patients with suspected peroneal neuropathy: an evidence-based review. Muscle Nerve, 31(4): 520-527.
- Mishra S, Prabhakar S, Lal V, Modi M, Das CP, Khurana D (2006). Efficacy of splinting and oral steroids in the treatment of carpal tunnel syndrome: A prospective randomized clinical and electrophysiological study. Neurol. India, 54(3): 286-290.
- Nuismer BA, Ekes AM, Holm MB (1997). The use of low-load prolonged stretch devices in rehabilitation programs in the Pacific northwest. Am. J. Occup. Ther., 51(7): 538-543.
- Padua L, LoMonaco M, Aulisa L, Tamburrelli F, Valente EM, Padua R, Gregori B, Tonali P (1996). Surgical prognosis in carpal tunnel syndrome: Usefulness of a preoperative neurophysiological assessment. Acta Neurol. Scand., 94: 343-346.
- Palmer KT, Harris EC, Coggon D (2007). Carpal tunnel syndrome and its relation to occupation: a systematic literature review. Occup Med., 57(1):57-66.
- Rotman MB, Enkvetchakul BV, Megerian JT, Gozani SN (2004). Time course and predictors of median nerve conduction after carpal tunnel release. J. Hand Surg., 29(3): 367-372
- Shulman DH, Shipman B, Willis FB (2008). Treating Trismus with Dynamic Splinting: a Cohort, Case Series. Adv. Ther., 25(1):9-15
- Wilder-Smith EP, Seet RC, Lim EC (2006). Diagnosing carpal tunnel syndrome--clinical criteria and ancillary tests. Nat. Clin. Pract. Neurol., 2(7): 366-374.
- Wilgis EF, Burke FD, Dubin NH, Sinha S, Bradley MJ (2006). A prospective assessment of carpal tunnel surgery with respect to age. J. Hand Surg., 31(4): 401-406.
- Willis B (2007). Dynamic Splinting Increases Flexion for Hallux Rigidus (Pilot Study). BioMech., 14(9):49-53.