

NEW BRACE FOR CTS

Title: New Splint for Carpal Tunnel Syndrome Unresponsive to Conservative Therapy.

Authors:

Humberto Porrata, M.D. *

Alejandro Porrata, M.D. *

Julian Sosner, M.D.* **

Affiliation: * Department of Physical Medicine and Rehabilitation,
Saint Vincent's Hospital and Medical

Centers of New York, New York City, New York, USA.

** Associate Professor of Clinical Rehabilitation Medicine, New York Medical College.

Grant: None

Corresponding author:

Julian Sosner M.D., Faculty Practice,

36 Seventh Avenue, Suite 411, New York, N.Y. 100 11, USA.

Running Title: New Brace for CTS.

Title: New Splint for Carpal Tunnel Syndrome Unresponsive to Conservative Therapy.

ABSTRACT

This study evaluated the treatment efficacy and patient satisfaction of a new splint called Porrata Brace (PB) in patients that failed conservative therapy for Carpal Tunnel Syndrome (CTS). A treatment group of 19 patients that used the PB 5 minutes 3 times daily for 4 weeks was compared to a control group of 12 patients that continued other conservative therapy.

The changes in visual analog scale values for pain, tingling, numbness and 'in the average number of times patients woke up at night were statistically significant ($p < 0.005$) only in the treatment group. (Figures 1,2,3,4)

In the treatment group 15 (79%) patients rated their treatment as excellent and 4 (21 %) as good and none as fair or poor. In the control group 3 (25%) patients rated their treatment as fair and 9 (75%) as poor. (Figures 3,4)

Clinical Relevance: This splint is very effective and well tolerated in treatment of recalcitrant CTS symptoms.

Keywords: Carpal Tunnel Syndrome, Splint, Wrist

INTRODUCTION

Carpal Tunnel Syndrome (CTS) is produced by prolonged compression of the median nerve as it passes through the Carpal Tunnel (CT) of the hand²⁵. The resulting pressure and ischemia of the median nerve produce characteristic symptoms, which include pain, tingling, numbness, and hand weakness. The symptoms disturb sleeping patterns and affect performance at work. Many patients have to change jobs or modify activities in order to decrease their symptoms.^{18, 21, 27}

Treatments of CTS include conservative modalities and surgical procedures. Conservative therapy is usually reserved for mild to moderate CTS and it commonly consists of using a Resting Hand Splint (RHS)⁶, Nonsteroidal Anti-inflammatory Drugs (NSAIDs)¹⁰, and Occupational Therapy (OT)^{11, 30}, to alleviate symptoms. Surgery can relieve the pressure on the median nerve by sectioning the Transverse Carpal Ligament (TCL)¹³, which forms the roof of the CT^{12, 20}. There is no universal agreement between surgeons on the precise timing^{5, 10}, and the criteria^{29, 31}, for indications of Surgery in CTS. The majority of US hand surgeons will try conservative therapy for an average of 8 weeks before surgery.⁷ The long-term results of surgery show a large incidence of symptom recurrence and morbidity. Up to 30% of patients report poor to fair strength and long-term scar discomfort and 57% have recurrence of some pre operative symptoms, most commonly pain, beginning an average of 2 years after surgery. The average time to maximum improvement of symptoms is 9.8 months.¹⁸

The cost of CTS is a burden on society ²¹. When considering lost work time, medical fees and legal expenses the cost per individual case may reach \$100,000. ^{10, 21, 27}

We've designed a new splint to more efficiently treat CTS, decrease the overall cost of treatment, the discomfort to the patients, and to avoid surgery, if possible. It is a custom pneumatic and dynamic hand splint designed to provide a controlled amount of stretching force on the Transverse Carpal Ligament and Flexor Retinaculum (TCL/FR) in a short time. We called it the Porrata Brace (PB) (Patent number 6,146,347).

We present the results of a prospective, controlled, randomized trial designed to test the efficacy and patient satisfaction with the PB. The aim of the study was to compare the efficacy of the PB versus conservative therapy in alleviating the symptoms of CTS in patients who failed conservative therapy.

MATERIALS AND METHODS

Description of the splint:

The PB consists of a C-shaped, semi-rigid frame made of Duraplast (Smith & Nephew™) contoured around the dorsum of the wrist and hand extending from the wrist crease to the metacarpophalangeal (MCP) joint area. On the palmar aspect it covers the thenar and hypothenar areas to form two plates between which the brace remains open. There is a circular opening on the thenar plate through which the thumb can pass and can be maintained in an abducted position. Attached with a Velcro to the inside of the C-shaped frame there is an air bladder, which inflates into a tubular shape parallel to the metacarpals. Deflated, the bladder measures 6 x 12 cm and projects from the wrist crease to the distal end of the metacarpals. Attached to the air bladder with two hoses are a pressure gauge and a hand pump similar to those found in a medical sphygmomanometer. The two hoses exit the frame towards the ulnar aspect of the hand through a hole. (Picture 1).

The hand is inserted into the splint from proximal to distal passing the thumb through the “thumb hole” and the adducted fingers exit through the distal opening. The dorsum of the hand comes in contact with the air bladder and the thenar and hypothenar come in contact with their corresponding areas of the brace. The device fits loosely. (Pictures 2, 3)

Patient selection:

The patients were referred from Saint Vincent's Hospital of New York City outpatient clinic and from other private clinics. All patients included in the study had failed conservative therapy.

Failure of conservative therapy was defined as persistence of symptoms of CTS and a Visual Analog Scale (VAS) score for pain of 5/10 or more (where 0 is “no pain” and 10 is “worse pain ever experienced”) after at least 4 months of treatment.

Exclusion criteria consisted of a VAS for pain of less than 5/10, previous CTS surgery, history of osteoporosis, gout, hypothyroidism, osteoarthritis of the hand, septic or rheumatoid arthritis of the hand, renal disease, wrist fracture, pregnancy, ongoing involvement in compensation cases and contact allergy to rubber or plastics.

In patients with bilateral CTS, the most symptomatic limb was chosen for treatment. Only one limb per patient was ‘included ‘in the study.

The patients had electromyography (EMG) and nerve conduction studies (NCS) for diagnosis of CTS.^{8, 19} They were randomly divided into either the treatment or the control group. Within each group of patients the severity of the CTS was classified as mild moderate and severe by EMG/NCS criteria. Mild: prolonged sensory latency of the median nerve. Moderate: prolonged sensory and motor latencies of the median nerve. Severe: same as moderate plus denervation potentials in the Abductor Pollicis Brevis muscle.

Treatment protocol:

After explanation of the study purpose, the patients signed a consent form. Patients in the treatment group were fitted with a custom PB and instructed in its use in a session lasting about 30 minutes. They were shown how to apply the PB and how to inflate the air bladder. They were instructed to use the brace 3 times daily for 5 minutes each time in the following manner: inflation to 180 mmHg for 2 minutes, deflation for 1 minute re-inflation for 2 more minutes then deflation and removal of the PB. The brace was used for 4 weeks. Afterwards the patients were instructed to use the device “as needed” only if any symptoms reoccurred. They were also instructed not to use NSAIDs, splints, injections or any other form of therapy for CTS during the study period.

The patients in the control group used NSAIDs, occupational therapy and RBS as instructed by their treating physician.

Data collection:

Pain, tingling and numbness graded on a VAS (0 none and 10 the most intense symptom sensation) as well as the number of times awakened per night were recorded for all patients in both the treatment and the control groups during the initial visit and by telephone at the end of weeks 1, 2, 3, 4. The satisfaction of the patients with their treatment was graded as poor, fair, good or excellent at the end of the fourth week.

A 7-month follow-up telephone interview was conducted with the treatment group patients and the following data was recorded:

- Maximum VAS for pain, tingling and numbness at any point in the 7 months period.
- Number of times the device was used per month.
- Number of times awakened per month by CTS symptoms.
- Number of physician visits because of CTS symptoms in the 7 months period.
- Number of lost workdays because of CTS symptoms.
- Change of job because of CTS symptoms.

Statistical analysis:

Statistical analysis of the data collected was performed utilizing a Manova Fit and Sphericity test. The data was checked for the variables of pain, tingling and numbness comparing the treatment group to the control group. The data was tested for a null hypothesis value of “0” and for two samples assuming unequal variance. Statistical significance was considered for “p” value less than 0.05 ($p < 0.05$).

Protocol Approval:

The Internal Review Board of Saint Vincent’s Hospital and Medical Center of New York City approved the research protocol and the consent form used in this study.

RESULTS

Subjects Demographics:

38 patients were interviewed. 7 patients were excluded from the study, 2 because of hypothyroidism, 1 because of surgery in the opposite hand and 4 patients had VAS for pain of less than 5/10. A total of 31 patients were enrolled in the study. In the treatment group there were 19 patients, 2 males and 17 females (Table 1). In the control group there were 12 patients, 1 male and 11 females (Table 2).

The average age in the treatment group was 51.2 years old (range 37 to 70 years) and in the control group was 57.2 years old (range 44 to 76 years). The average time with symptoms was 53.6 months (range 4 to 240 months) for the treatment group and 48 months (range 12 to 180 months) for the control group. 13 patients in the treatment group and 6 patients in the control group were working at the beginning of the study.

In the treatment group there were 13 right hands and 6 left hands. 3 were classified as mild, 12 as moderate and 4 as severe. In the control group there were 8 right hands and 4 left hands. 2 were classified as mild, 7 as moderate and 3 as severe. The treatment group had an average of 22.9 months (range 0 to 60 months) waking up from sleep because of CTS symptoms while the control group had an average of 22.6 months (range 0 to 72 months).

In the treatment group 18 patients had EMG/NCS available for review. One EMG from 1990 was not available. This patient had clinical diagnosis of CTS, with thenar atrophy and weakness; she was classified as severe. In the control group one EMG was not available. This patient had clinical diagnosis of CTS, with thenar atrophy and weakness; she was classified as severe (Tables 1, 2).

4 weeks followup:

At end of 4 weeks of treatment, no patient was lost at follow up and there were no reported side effects or complications. 19 patients using the PB and 12 controls were evaluated. Weekly VAS scores for pain, tingling, numbness and times awakened per night were recorded for the PB group (Table 3) and the control group (Table 4). The average VAS for pain in the treatment group decreased from 8.52 to 1.05 ($p < 0.0001$). In the control group it changed from 8.41 to 7.75 ($p > 0.05$) (Graph 1). The average tingling in the treatment group changed from 8.15 to 0.95 ($p < 0.0001$). In the control group it changed from 8.08 to 7.75 ($p > 0.05$) (Graph 2). The average numbness in the treatment group changed from 8.47 to 0.95 ($p < 0.0001$), while in the control group it changed from 8.16 to 8.00 ($p > 0.05$) (Graph 3). The average number of times patients woke up per night because of CTS symptoms in the treatment group changed from 3.05 to 0.10 ($p < 0.0001$), while in the control group it changed from 3.00 to 2.91 ($p > 0.05$) (Graph 4). At the end of the fourth week the decrease in symptom severity or the treatment group was significantly higher ($p < 0.0001$) than in the control group for all measured parameters.

In the treatment group, 15 of 19 (79%) patients rated their satisfaction with their treatment as excellent, and 4 of 19 (21 %) as good. None rated it as fair or poor. In the control group, 9 of 12 (75%) rated their treatment as poor and 3 of 12 (25%) as fair. None rated it as excellent or good. (Table 3, 4 and Figures 1, 2, 3, 4)

7 months follow up:

Only the treatment group was followed up at an average of 7.3 months (4 to 11). 18 patients were available for follow-up. One patient lost his splint and one patient was lost to follow up (Table 5). 2 patients did not use the splint after the initial 4 weeks of treatment. They reported no symptom recurrence. 9 patients (50%) used the splint between once a month (5 minutes) and once every 4 months. Some of these patients reported using the splint as a “preventive measure”. One patient used it every 2 weeks and 2 patients used it once a week. Two patients reported using the splint every other day and one reported using it twice a day; they stated they had “fear of symptom recurrence”. 12 patients (67%) used the splint an average of once (5 minutes) every 2 months.

One patient who had symptom recurrence did not use the splint for unknown reasons. She denied side effects from the use of the PB and reported a maximum VAS for pain, tingling and numbness of 7/10.

She reported the only visit to a physician for CTS in the seven month period. Another patient who reported a maximum VAS for pain, tingling and numbness of 6- 7/10 stated she developed Congestive Heart Failure (CHF) and had a pacemaker placed one month prior to follow up. After developing CHF, she was using the splint twice a day and was the only patient to report not getting complete relief after one time use during the ten month period.

Of the 17 patients who used the PB as needed, 8 (47%) reported no symptom recurrence in the seven month period. The most commonly reported symptom was numbness in 8 of 17 patients (47%). 6 of the 8 (75%) patients had a maximum VAS of 4/10 or less and 2 had maximum VAS of 7/ 10 and 9/10. Two of 17 patients (11.7%) reported tingling recurrence. One had maximum VAS of 1/10; the other had a maximum VAS of 6/10. 4 of 17 patients (23.5%) reported pain recurrence. 3 had a maximum VAS of 3/10 or less and one had a maximum VAS of 6/10. The average maximum VAS for pain was 0.65, for tingling 0.4, and for numbness 1.7 at the seven month follow up. 16 of the 17 (94%) patients reported that the symptoms returned to 0/ 10 after one time use (5 minutes) of the PB. None of the patients reported being woken up from sleep by CTS symptoms in the seven month period and none of the patients had to change jobs or lost days from work because of hand symptoms. There were no reported side effects. (Table 5)

The calculated “p” values for the variables of pain, tingling, numbness and times awakening from sleep, were smaller than 0.001 and therefore were very significant statistically.

DISCUSSION

Our study was designed to evaluate the efficacy of the PB in decreasing the symptoms of CTS by using it for only 5 minutes 3 times a day for 4 weeks. We used a 0-10 VAS for grading and follow up of the seventy of symptoms. Several authors favorably established the validity of VAS.^{1, 17, 22, 28, 23} While other authors have used a functional disability scale to grade the severity of clinical manifestations of CTS^{2, 16} we preferred to use VAS to evaluate the effect of the PB on each symptom over time. The number of times the patients woke up per night was also recorded as most of the patients considered this to be a very disturbing aspect of CTS.

The PB was used as the only therapy for patients in the treatment group to eliminate the possibility of improvement from a combination of treatment modalities. A 7 months follow-up evaluated the recurrence of symptoms, side effects, and the effectiveness of the treatment over time. The severity of symptoms and duration of CTS in our study compares well with previous studies done on surgically treated patients.^{2, 29}

We found impressive improvement in all symptoms of CTS in patients of the PB treatment group including significant decrease of the times patients woke up per night. After 4 weeks of treatment with the PB there was an average of 80-90% decrease in pain, tingling, numbness and times the patients woke up at night. The values were maintained at 7 months follow-up. These results were positive in all patients treated with PB independently of the initial EMG seventy group.

Our results are better than those obtained by Burke et al.⁶ who evaluated the use of RHS for CTS and found that after 2 weeks, 17 of 45 (38%) patients whose wrists were splinted in neutral position reported good or complete relief of symptoms and only 7 of 45 (15.5%) wrists splinted in extension reported a good or complete relief. Their data also showed that continuation of splinting beyond 2 weeks would result in either no improvement in symptoms or a worsening of symptoms (in 76% of the patients). Burke found no correlation between the number of months that the symptoms were present and the subjective relief of splinting. Our statistical analysis showed the same lack of correlation between time with symptoms and decrease in symptoms.

Katz compared operative to non-operative treatment for using a 1 to 5 symptom severity scale¹².¹⁵ The non-operative group received conservative therapy. At 6 months follow-up there was an average decrease in symptom severity scale from 2.8 to 2.7 in the control group, and no further change after 18 and 30 months. This correlates with the lack of change in symptoms in our control group. In the operative group, Katz found a decrease in the severity scale from 3.2 to 1.7 (47%) at 6 months follow up. In our PB treated group, there was better percentage of improvement in symptoms when compared to the operative group described by Katz. The change in the PB group was from 8.2 to 0.65 (92%) for average pain, 8.05 to 0.4 (95%) for average tingling, from 8.16 to 1.7 (79%) for average numbness and from 3.0 per night to 0 per month for average times woken at night at 7 months follow-up.

Atroshi et al reported that 6 months after endoscopic CT release 23 of 121 (18%) patients complained of daytime numbness and tingling, 15 of 116 (12%) complained of nocturnal paresthesias, 14 of 97 (11%) complained of pain and 25 of 121 (19%) complained of palmar tenderness. He used a “present or absent” questionnaire.^{2,3}

Bessette et al. reported that the single most important reason for CTS patients to have surgery from was relief of night pain (37%).⁴ Our results showed decrease in times the patients woke up at an average of 3 to 0.16 after 4 weeks use of the PB. At 7 months the times patients woke up per night was 0 per month.

There was a high level of satisfaction with the use of the PB. This may be due to multiple factors: The effectiveness of the device in decreasing the symptoms in patients who had failed multiple forms of therapy; the short periods of time the PB was used during the day; not having to use a splint during sleep; and not having to use pills, injections, or surgery. All patients continued their usual activities during the study period and none reported complications or problems after 7 months.

The PB was designed to noninvasively stretch the TCL/FR and we believe this splint decreases the symptoms of CTS for multiple reasons. When the splint is on the hand and the air bladder is inflated a “3 point” action force is exerted on the wrist: airbladder on dorsum of the hand and the two plates on the thenar and hypothenar areas on the volar aspect of the wrist. The resulting force presumptively acts to enlarge the carpal tunnel area. It produces an effective, safe, constant and controlled stretching force on the proximal, medial and distal sections of the TCL/FR. This was demonstrated using Xrays of 2 wrists of volunteer subjects with the PB on. Measurements on the X-rays showed that application of the PB increases the distance between the Trapezium and the Hook of the Hamate and between the Scaphoid and the Pisiform bones approximately 1-3 mm (Unpublished data).

Favorable results of manual manipulations in CTS²⁶ as well as the properties of the fibrous structures of the wrist¹⁴ supports our belief that daily use for 4 weeks causes consistent elongation of the TCL/FR that persists in time. This increases the cross area of the CT thus relieving pressure off the median nerve and abating symptoms of CTS. Indeed, at 7 months follow up, 12 of 18 patients reported the need to use the PB an average of once (5 minutes) every 2 months. We believe that patients should use the device once a month after the initial 4 weeks of daily application in order to avoid recurrence of symptoms. We think that the stretching of TCL/FR produces an effect similar to that produced by surgery. After surgery for carpal ligament release there is an increase of 1.5-2.7 mm in the diameter of the carpal tunnel.^{9,24}

CONCLUSIONS

The hand splint we called the Porrata Brace, proved to be extremely effective in decreasing the symptoms of CTS in patients who failed conservative therapy. Used as the sole therapy, the efficacy of this device can be compared with surgery in decreasing the symptoms of CTS at four weeks and 7 months. The brace was easy to use and inexpensive. None of the patients had problems or complications using the brace and the satisfaction with its use was very high.

ABBREVIATIONS

- CHF: Congestive Heart Failure
- CT: Carpal Tunnel
- CTS: Carpal Tunnel Syndrome
- EMG: Electromyography
- MCP: Metacarpal Phalangeal Joint
- NCS: Nerve Conduction Studies
- NSAID: Non Steroidal Anti-inflammatory Drugs
- OT: Occupational Therapy
- PB: Porrata Brace
- RHS: Resting Hand Splint
- TCL: Transverse Carpal Ligament
- TCL/FR: Transverse Carpal Ligament / Flexor Retinaculum
- VAS: Visual Analog Scale

REFERENCES

1. Alderson M, McGall D. The Alderson McGall hand function questionnaire for patients with Carpal Tunnel syndrome: a pilot evaluation of a future outcome measure. *J Hand Ther* 1999 Oct;12(4):313-322.
2. Atroshi I MD, Breidenbach W.C. MD McCabe S.J. MD: Assessment of Carpal tunnel outcome instrument in patients with nerve compression symptoms. *The Journal of Hand Surgery Vol 22A No 2, March 1997.*
3. Atroshi I MD, Johnson R. MD, PhD, Ornstein E. MD: Patient satisfaction and return to work after endoscopic carpal tunnel surgery. *The Journal of Hand Surgery. Vol. 23A No. 1 January 1998.*
4. Besette L. MD, Keller R. MD, Liang M.H. MD, Simmons B.P. MD, Fossel A.H., Katz J.N. MD: Patients' Preferences and their relationship with satisfaction following carpal tunnel release. *J Hand Surg Vol. 22A No. 4 July 1997.*
5. Bland J., FRCP: Do nerve conduction studies predict the outcome of carpal tunnel decompression?. *Muscle and Nerve, July 2001.*
6. Burke DT, Burke MM, Steward GW, Cambre A: Splinting for Carpal Tunnel Syndrome: in search of the optimal angle. *Arch Phys Med Rehabil Vol 75, November 1994.*
7. Destefano F.MD, Nordstrom D. PhD, Vierkant R. MAS, Long term Symptom Outcomes of Carpal Tunnel Syndrome and its Treatment. *Journal of Hand Surgery. March 1997, Vol. 22A, No.2 p220-210.*
8. Dimitru D. *Electrodiagnostic medicine. Philadelphia: Hanley & Belfus; 1995. P 867-885.*
9. Gartman GM, Kovach JC, Crouch CC, Noble PC, Bennett JB. Carpal arch alteration after carpal tunnel release. *Journal of Hand Surgery. Vol. 11A:372374, 1986.*
10. Harter B.T. Jr. MD, McKiernan J.E. Jr. MD, Kirzinger S.S. MD, MS, Archer F.W. MBA, Peters C.K. BS, Harter K.C. MD: Carpal Tunnel Syndrome: Surgical and nonsurgical treatment. *The Journal of Hand Surgery. Vol. 18A, No. 4, July 1993.*
11. Kaplan SJ, Gickel SZ, Eaton RG: Predictive factors in the non surgical treatment of Carpal Tunnel Syndrome. *J Hand Surg 15 B: 107, 1990.*
12. Katz JN, Keller RB, Simmons BP, Rodger C, Besette L, Foy S, Fossel AH, Mooney NA: Maine Carpal Tunnel Study: Outcomes of operative and nonoperative therapy for Carpal Tunnel Syndrome in a community based cohort. *J Hand Surg Vol. 23A No. 4 July 1998.*
13. Kline S.C., Moore JR. The transverse carpal ligament: An important component of the digital flexor pulley system. *Journal of Bone and Joint Surgery. Vol 74A. 1478-1485, 1992.*
14. Kuhlmann J.N., Luboinski J., Laudet C., Boasbhigghi A., Landjerit B., Guerin Surville H., Baux S.: Properties of the fibrous structures of the wrist. *The Journal of Hand Surgery Vol 15B No.3 August 1990.*
15. Largay A.M. MPH, Soule D.N. BA, Katz J.N. MD: Maine Carpal Tunnel Study: Small Area Variations. *The Journal of Hand Surgery. Vol. 23 No. 4, July 1998.*
16. Levine D.W. MD, MPH, Simmons B.P. MD, Koris M.J. MD, Daltroy L.H. DRPH, Hohl G.G. BA, RN, Fossel A.H. Katz J.N. MD, MS: A self administered questionnaire for the assessment of severity of symptoms and functional status in carpal tunnel syndrome. *Journal of Bone and Joint Surgery. Vol. 75A No. 11, November 1993.*
17. Midha R, Noble J, Patel V, Ho PH, Munro CA, Szalai JP. Prospective analysis of relationships of outcome measures for ulnar neuropathy at the elbow. Department of Surgery and Trauma Research Program, Sunnybrook & Women's College Health Sciences Centre, University of Toronto, ON, Canada. *Can J Neurol Sci 2001 Aug;28(3):239-244.*
18. Nancollas MP, Peimer CA, Wheeler DR, Sherwin FS. Longterm results of carpal tunnel release. *J Hand Surg [Br] 1995 Aug;20(4):470-4*
19. Oh SJ. Nerve conduction in focal neuropathies. *Clinical Electromyography: Nerve Conduction Studies 2 d Ed Baltimore: William and Wilfins 1993. p 496-574.*
20. Palmer A.K. MD, Toivonen D.A. MD.: Complication of endoscopic and open carpal tunnel release. *The Journal of Hand Surgery. Vol. 24A No. 3 May 1999.*
21. Pinkman J. Carpal Tunnel Syndrome impacts thousands and costs are skyrocketing. *Occup Health Safety. 1988; 57:52-53.*
22. Poiraudreau S, Chevalier X, Conrozier T, Flippo R, Liote F, Noel E, LefevreColau MM, Fermanian J, Revel M, Rhumato R. Reliability, validity, and sensitivity to change of the Cochin hand functional disability scale 'in hand osteoarthritis. *Osteoarthritis Cartilage 2001 Aug;9(6):570-577.*
23. Poyhia R, Da Costa D, Fitzcharles MA. Pain and pain relief 'in fibromyalgia patients followed for three years. *Arthritis Rheum 2001 Aug;45(4):355-361*
24. Richman JA, Gelberman RH, Rydevick BL, Hajek PC, et al. Morphologic changes after release of the transverse carpal ligament. *Journal of Hand Surgery. Vol 14A:852-857, 1989.*
25. Rosenbaum R.B. MD, Ochoa J.L. MD: Carpal Tunnel Syndrome and Other Disorders of the Median Nerve. Butterworth and Heinemann 1993.
26. Sucher BM DO, Henrichs RN PhD. Manipulative treatment of carpal tunnel syndrome: Biomechanical and osteopathic intervention to increase the length of the transverse carpal ligament. *JAOA. Vol 98, No. 12 December 1998.*
27. US Department of Labor, Bureau of Business statistics. US Bureau of Labor Statistics reports on survey of occupational injuries and illness in 1989. Washington DC; US department of Labor, 89:548.
28. Valle JH, Mathers DM, Ramos Remus C, Russell AS. Generic health instruments do not comprehensively capture patient perceived improvement in patients with carpal tunnel syndrome. *J Rheumatol. 1999 May;26(5):1022-3.*
29. Wintman BI MD, Winters S.C. MD, Gelberman R.H. MD, Katz J.N. MD: Carpal Tunnel Release: Correlations with symptomatology. *Clinical Orthopaedics and Related Research. Num 326, p 135-145.*
30. Yamagushi S. MD, Beppu M MD, Matsushita K. MD, Takahashi K DDS: The Carpal Stretch Test at the Scapholunate Joint. *The Journal of Hand Surgery Vol 23A No4 July 1998.*
31. You H. MS, Simmons Z. MD, Freivalds A PhD, Kothari M.J. DO, Naidu S.H. MD: Relationship between clinical symptom severity scales and nerve conduction measures in carpal tunnel syndrome. *Muscle and Nerve, April 1999.*

Table 1 PB Treatment Group Demographics

Age	Gender	Classification	Occupation	Hand Treated	Months w/ Symptoms	Months affected sleep
37	F	Mild	Data Entry Clerk	R	24	0
44	F	Mild	Computer Clerk	R	48	6
60	F	Mild	Homemaker	R	12	3
55	F	Moderate	Retired	R	6	6
52	F	Moderate	Unemployed	R	120	36
49	F	Moderate	Nurse	L	72	2
70	M	Moderate	Engineer	L	4	4
55	F	Moderate	Homemaker	R	84	36
51	F	Moderate	Maintenance	R	36	12
37	M	Moderate	Typist	R	24	6
48	M	Moderate	Data Entry Clerk	R	12	12
53	M	Moderate	Cook	L	48	24
58	F	Moderate	Clerk	R	72	60
46	F	Moderate	Clerk	L	12	12
49	F	Moderate	Typist	R	36	24
49	F	Severe	Typist	R	48	36
63	F	Severe	Typist	L	60	36
48	F	Severe	Nurse	R	60	60
50	F	Severe	Clerk	L	240	60
51.26 *					53.58 *	22.89 *

* Average

Table 2 Control Group Demographics

Age	Gender	Classification	Occupation	Hand Treated	Months w/ Symptoms	Months affected sleep
60	F	Mild	Homemaker	R	12	3
61	F	Mild	Unknown	R	36	36
56	M	Moderate	Unemployed	R	96	72
44	F	Moderate	Laundry	R	24	8
59	F	Moderate	Homemaker	L	24	18
62	F	Moderate	Homemaker	R	36	0
67	F	Moderate	Retired	L	24	12
54	F	Moderate	Clerk	R	180	60
60	F	Moderate	Retired	R	12	12
68	F	Severe	Retired	L	60	12
76	F	Severe	Retired	R	18	2
63	F	Severe	Typing	L	60	36
60.83 *					48.50 *	22.58 *

* Average

Table 3

PB Treatment Group: Data for 4 weeks of treatment

Age	Gender	Classification	Occupation	Hand Treated	Months w/ Symptoms	Months sleep affected	Pain at Evaluation	Pain Week 1	Pain Week 2	Pain Week 3	Pain Week 4	Tingling at Evaluation	Tingling Week 1	Tingling Week 2	Tingling Week 3	Tingling Week 4	Numbness at Evaluation	Numbness Week 1	Numbness Week 2	Numbness Week 3	Numbness Week 4	Wakeup @ Night @ Evaluation	Wakeup @ Night Week 1	Wakeup @ Night Week 2	Wakeup @ Night Week 3	Wakeup @ Night Week 4	Satisfaction	
37	F	Mild	Data Entry Clerk	R	24	0	6	2	1	1	1	6	2	1	0	0	6	0	0	0	0	0	0	0	0	0	E	
44	F	Mild	Computer Clerk	R	48	6	8	5	3	0	0	8	0	0	0	0	8	1	0	0	0	0	2	1	0	0	0	E
60	F	Mild	Homemaker	R	12	3	5	0	0	0	0	6	0	0	0	0	10	5	0	0	0	0	4	0	0	0	0	E
55	F	Mod	Retired	R	6	6	8	4	2	1	0	9	2	0	0	0	10	4	1	1	0	0	2	0	0	0	0	E
52	F	Mod	Unemployed	R	120	36	10	7	5	4	4	10	9	5	4	4	8	6	6	4	4	3	1	0	0	0	G	
49	F	Mod	Nurse	L	72	2	10	3	0	0	0	10	4	1	0	0	5	1	0	0	0	0	1	0	0	0	0	E
70	M	Mod	Engineer	L	4	4	8	4	2	2	0	9	2	2	2	0	9	2	2	1	2	3	2	0	0	0	0	E
55	F	Mod	Homemaker	R	84	36	8	6	0	0	0	8	4	3	2	1	8	4	3	1	1	3	3	0	0	0	0	G
51	F	Mod	Maintenance	R	36	12	9	5	2	0	0	7	4	2	0	0	10	5	2	2	0	0	3	1	0	0	0	E
37	M	Mod	Typist	R	24	6	9	5	2	0	0	6	3	0	0	0	6	3	1	0	0	0	3	1	0	0	0	E
48	F	Mod	Clerk	R	12	12	7	4	2	2	0	6	2	0	1	0	7	2	0	1	0	0	4	2	0	0	0	E
53	F	Mod	Cook	L	48	24	10	3	3	0	0	10	3	3	0	0	10	3	3	0	0	0	3	3	2	0	0	G
58	F	Mod	Clerk	R	72	60	7	7	7	5	4	8	1	6	6	4	8	8	6	5	4	3	2	1	1	1	1	E
46	F	Mod	Clerk	L	12	12	10	8	4	0	0	6	6	3	0	0	6	6	3	0	0	0	5	2	0	0	0	E
49	F	Mod	Typist	R	36	24	10	7	0	0	0	6	8	4	1	0	10	6	4	3	1	4	2	0	0	0	0	E
49	F	Severe	Typist	R	48	36	10	5	4	2	0	10	7	6	0	0	10	7	6	0	0	0	5	2	0	0	0	E
63	F	Severe	Typist	L	60	36	9	4	4	4	4	10	3	3	3	3	10	3	3	3	3	4	0	0	1	1	1	G
48	F	Severe	Nurse	R	60	60	8	8	5	3	3	10	7	5	3	3	10	7	6	5	3	3	2	1	0	0	0	E
50	F	Severe	Clerk	L	240	60	10	6	5	4	4	10	6	6	4	3	10	6	4	4	0	0	3	3	2	2		E

E = Excellent ; G = Good

Table 4

Control Group: Data for 4 weeks of treatment

60	F	Mild	Homemaker	R	12	3	6	6	6	6	5	6	6	6	6	6	8	9	10	10	10	3	3	4	4	4	4	P
61	F	Mild	Unknown	R	36	36	36	10	10	10	9	9	8	6	6	7	7	8	6	6	7	7	3	3	3	3	4	P
56	M	Mod	Unemployed	R	96	72	9	9	9	9	7	8	8	8	8	7	8	8	8	8	5	6	6	5	5	4	F	
44	F	Mod	Laundry	R	24	8	9	10	8	9	9	9	9	7	9	10	9	9	7	8	9	3	3	3	3	4	P	
59	F	Mod	Homemaker	L	24	18	10	10	10	9	9	10	10	10	9	9	9	9	9	8	9	3	3	3	3	3	3	P
62	F	Mod	Homemaker	R	36	0	9	9	8	7	8	5	5	5	5	6	9	9	9	9	9	0	0	0	0	0	0	P
67	F	Mod	Retired	L	24	12	10	10	10	9	9	10	10	10	9	9	8	10	8	8	8	3	3	3	3	3	3	P
54	F	Mod	Clerk	R	180	60	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	3	3	3	3	3	3	F
60	F	Mod	Retired	R	12	12	10	10	10	9	9	10	10	10	9	9	9	8	8	8	8	7	5	4	5	4	4	F
68	F	Severe	Retired	L	60	12	8	8	8	8	8	9	9	9	9	8	8	8	8	8	7	1	1	1	1	1	1	P
76	F	Severe	Retired	R	18	2	6	6	6	6	6	7	7	7	7	7	7	7	7	7	7	2	2	2	2	2	2	P
63	F	Severe	Typing	L	60	36	9	9	9	9	9	10	10	10	10	10	10	10	10	10	10	4	4	4	4	4	4	P

P = Poor ; F = Fair

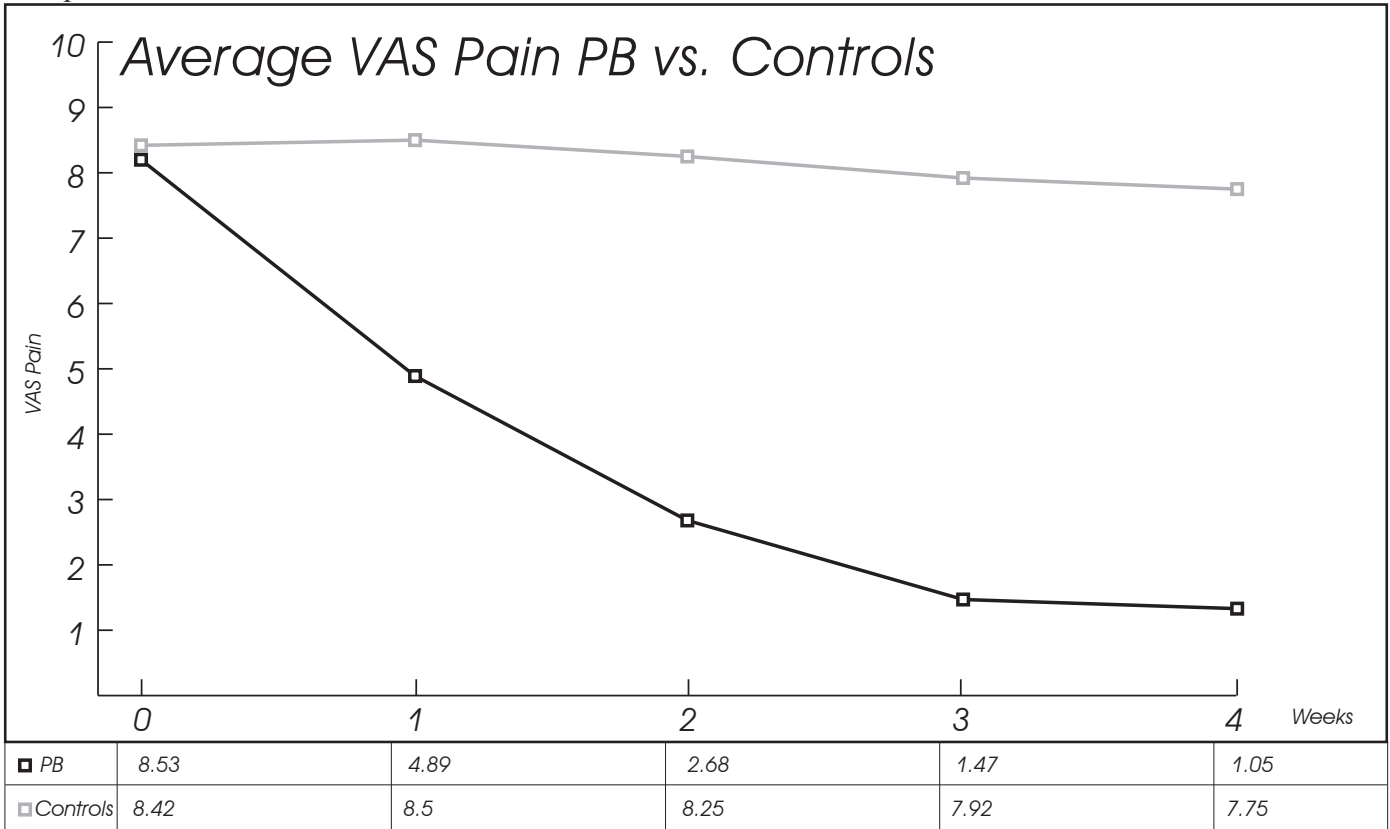
(Headers continued from Table 3)

Table 5

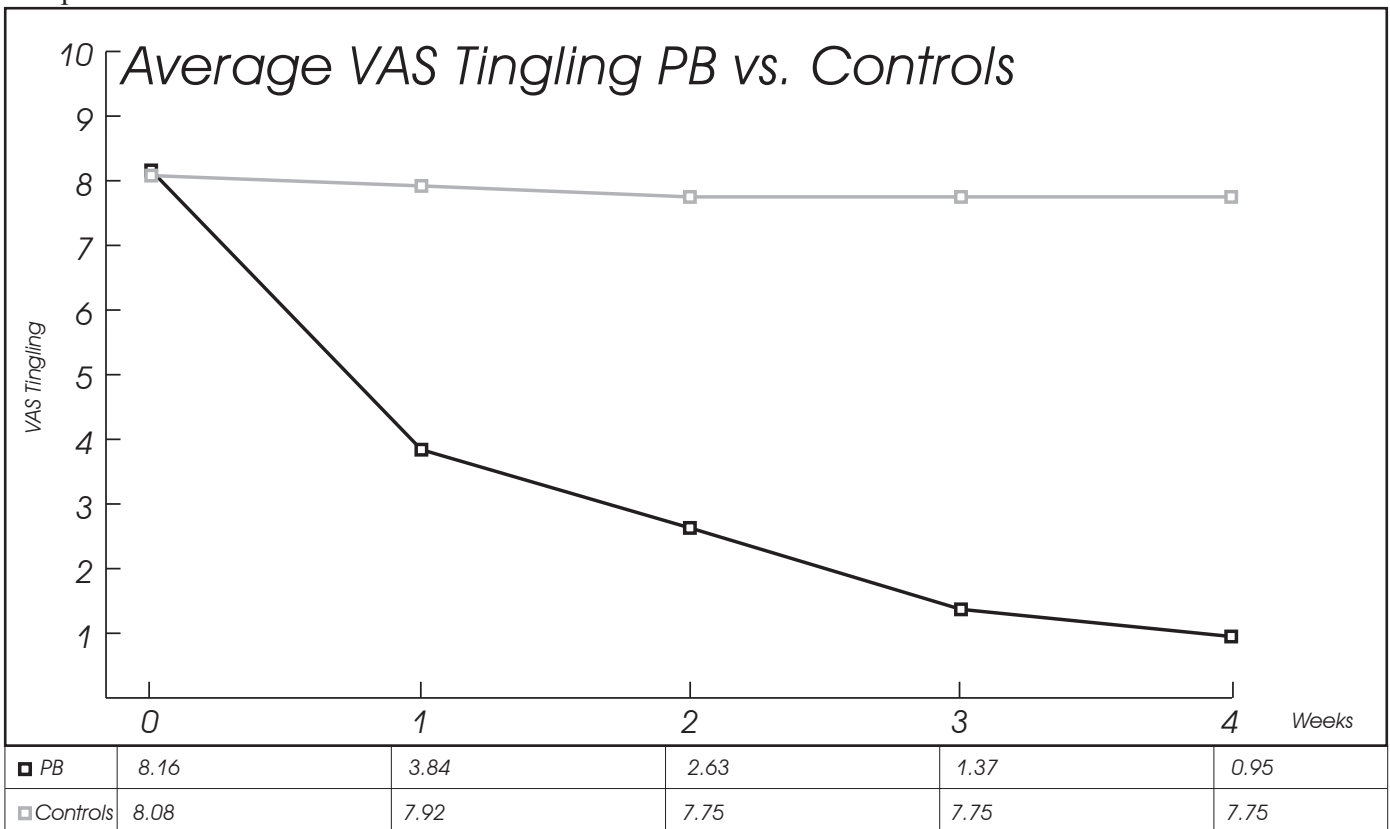
PB treatment group: 7 months follow-up

EMG Classification	Complications	Months with Device	Times used per Month	Times woekn up per Month	Worse pain VAS	Worse tingling VAS	Worse numbness VAS	# Doctor Visits	# Lost work days	Change jobs
Mild	None	4	0	0	0	0	0	0	0	0
Mild	None	4	1	0	0	0	0	0	0	0
Mild	None	10	0	0	0	0	0	0	0	0
Moderate	None	9	0.33	0	0	0	1	0	0	0
Moderate	None	5	0.5	0	0	0	0	0	0	0
Moderate	None	11	4	0	1	0	2	0	0	0
Moderate	None	4	0.5	0	0	0	0	0	0	0
Moderate	None	8	2	0	1	1	1	0	0	0
Moderate	None	11	4	0	0	0	0	0	0	0
Moderate	None	7	0	0	7	7	7	1	0	0
Moderate	None	5	0.5	0	0	0	4	0	0	0
Moderate	None	6	0.25	0	0	0	0	0	0	0
Moderate	None	7	0.5	0	0	0	9	0	0	0
Moderate	None	10	60	0	6	6	7	0	0	0
Moderate	None	5	15	0	0	0	4	0	0	0
Severe	None	8	0.25	0	3	0	0	0	0	0
Severe	None	8	15	0	0	0	0	0	0	0
Severe	None	9	0.33	0	0	0	1	0	0	0

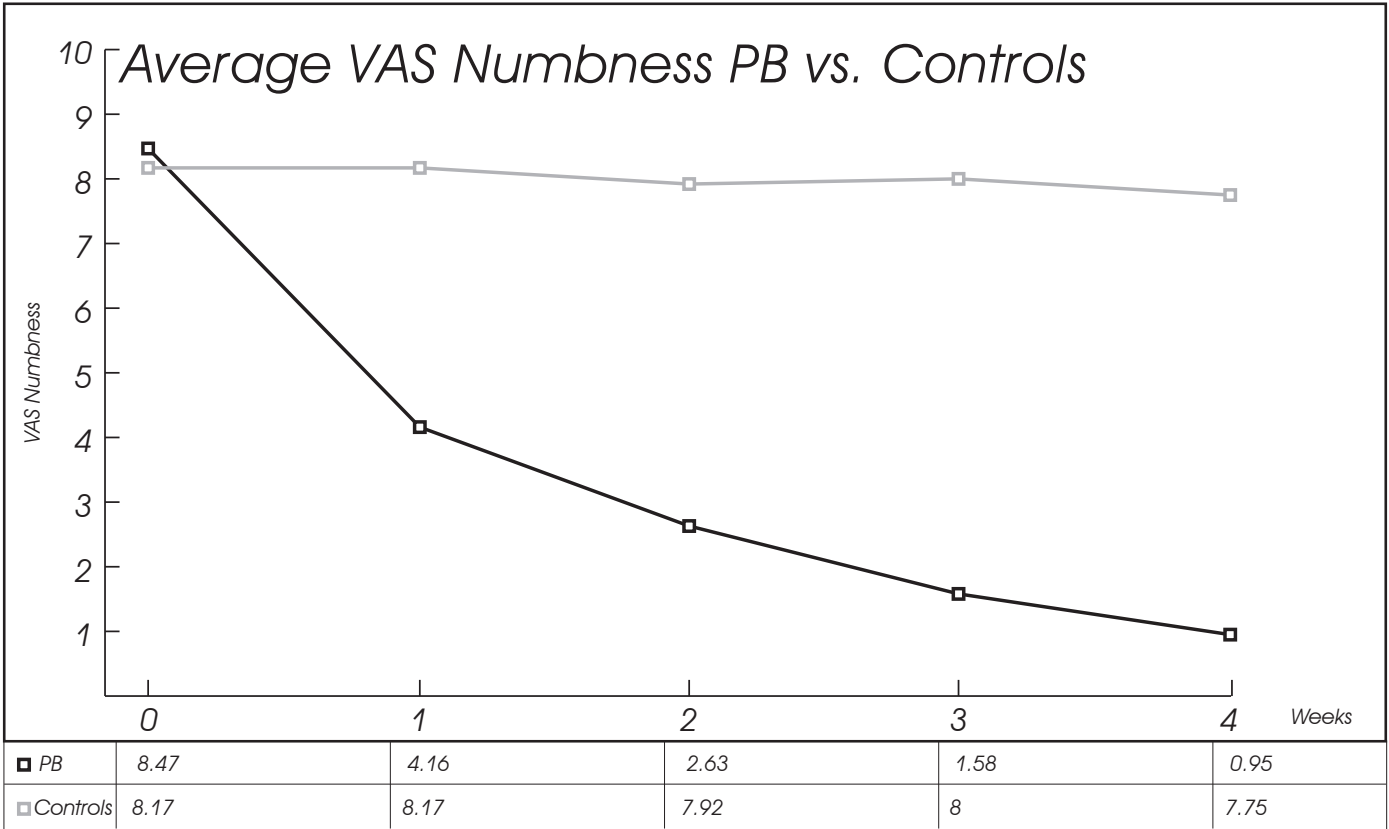
Graph 1



Graph 2



Graph 3



Graph 4

