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New Carpal Ligament Traction Device for the Treatment of Carpal Tunnel Syndrome Unresponsive to Conservative Therapy

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ABSTRACT: This study evaluated the treatment efficacy and patient satisfaction of a new hand traction device called C-TRAC in patients that failed conservative therapy for carpal tunnel syndrome (CTS). Patients were diagnosed with electromyography and nerve conduction studies. Only patients with a positive Phalens test and a Visual Analog Scale (VAS) of more than 5/10 were eligible for the study. The patients had tried nonsteroidal anti-inflammatory drugs (NSAIDS), resting hand splint during the night, acupuncture, and hand therapy for a minimum of four months. To test C-TRAC as the sole treatment for CTS, patients included in the study stopped all other forms of therapy (NSAIDS, hand therapy, acupuncture, massage, manipulations, and steroid injections). A group of 19 patients used C-TRAC hand traction device for 5 minutes three times daily for four weeks. After the four-week period the device was used as needed. The patients were followed up weekly for four weeks, then at seven months. VAS was used to assess pain, tingling, and numbness in the treated hand. The number of times patients woke up at night and satisfaction with the use of the device were also evaluated. The average VAS for pain decreased from 8.53 to 1.05. The average tingling decreased from 8.15 to 0.95. The average numbness decreased from 8.47 to 0.95. The average number of times patients woke up per night because of CTS symptoms decreased from 3.05 to 0.10. Patients showed significant improvement at four weeks and results were maintained at seven months follow-up. Fifteen patients (79%) rated their treatment as excellent and four (21%) as good and none (0%) as fair or poor. Clinical relevance: This device is very effective and well tolerated in treatment of CTS in patients that failed conservative therapy.

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Carpal tunnel syndrome (CTS) is produced by prolonged compression of the median nerve as it passes through the carpal tunnel (CT) of the hand.[1] The resulting pressure and ischemia of the median nerve produces characteristic symptoms, which include pain, tingling, numbness, and hand weakness. The symptoms disturb sleep patterns and affect performance at work. Many patients have to change jobs or modify activities to decrease their symptoms.[2–4]

Treatments of CTS include conservative modalities and surgical procedures. Conservative therapy is usually reserved for mild to moderate CTS and commonly consists of using a resting hand splint (RHS),[5] nonsteroidal anti-inflammatory drugs (NSAIDs),[6] and hand therapy[7,8] to alleviate symptoms. Surgery can relieve the pressure on the median nerve by sectioning the transverse carpal ligament (TCL),[9] which forms the roof of the CT.[10,11] There is no universal agreement between surgeons on the precise timing[6,12] and the criteria[13,14] for indications of surgery in CTS. The majority of U.S. hand surgeons will try conservative therapy for an average of eight weeks before surgery.[15] 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 preoperative symptoms, most commonly pain, beginning an average

The author has a commercial interest in the products or companies described in this article.

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of two years after surgery. The average time to maximum improvement of symptoms is 9.8 months.[2]

The cost of CTS is a burden on society.[3] When considering lost work time, medical fees, and legal expenses the cost per individual case may reach $100,000,[3,4,6] current costs may be higher.

C-TRAC was invented by the two authors (H.P. and A.P.) in an attempt to treat CTS symptoms more effectively, decrease the overall cost of treatment, and avoid CTS surgery if possible. The device was designed as a custom pneumatic and dynamic hand traction device, which would provide a controlled amount of stretching force or traction force to the TCL and flexor retinaculum (FR). It was hypothesized that this might increase the area of the CT through a progressive stretching program. When the device is on the hand and the air bladder is inflated, a ''three-point'' action force is exerted on the hand: air bladder on dorsum of the hand and the two plates on the thenar and hypothenar areas on the volar aspect of the hand. The resulting force produces a stretching force, a traction force, along the TCL/FR evidenced by increasing the distance between the carpal bones in the thenar side of the hand and the carpal bones in the hypothenar side. X-rays were obtained with and without the C-TRAC in place in two subjects prior to this study. Measurements on the X-rays showed that application of C-TRAC increased the distance between the trapezium and the hook of the hamate and between the scaphoid and the pisiform bones approximately 1–3 mm.

The purpose of this study is to evaluate the efficacy of C-TRAC in decreasing pain, tingling, numbness, and number of times woken up at night in patients that tried and failed at least four months of conservative therapy for CTS. We present the results of a case series trial designed to test the efficacy of C-TRAC. Patient satisfaction with the use of C-TRAC is also reported.

C-TRAC is an FDA Registered Class I traction device, U.S. multipatented (PATENT NUMBERS 6,146,347; 6,979,305; 6,953,440), and International patent pending device, manufactured by Chesapeake Medical Products LLC, MD, USA.

MATERIALS AND METHODS

Description of the Device

C-TRAC consists of a C-shaped, semirigid frame (Rolyan Aquaplast-T is a trademark of Patterson Medical Products Inc) contoured around the dorsum of the wrist and hand extending from the wrist crease to the metacarpal phalangeal joint area. On the palmar aspect it covers the thenar and hypothenar areas to form two plates between which the device 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 Velcro to the inside of the C-shaped frame there is an air bladder that inflates into a tubular shape parallel to the metacarpals. Deflated, the bladder measures 6 cm × 12 cm and projects from the wrist crease to the distal end of the metacarpals. Attached to the air bladder with two hoses there is a pressure gauge and a hand-pump similar to those found in a medical sphygmomanometer. The two hoses exit the frame toward the ulnar aspect of the hand through a hole (Figures 1–4).

The hand is inserted into the device 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. The device fits loosely (Figures 2 and 3).

Patient Selection

The Internal Review Board of Saint Vincent Catholic Medical Centers of New York, Manhattan Region, approved the research protocol and the consent form used in this study. The patients were referred from Saint Vincent Catholic Medical Centers of New York, Manhattan Region outpatient clinic and from other private clinics. Patients must have failed conservative therapy for CTS to be considered for this study. Failure of conservative therapy was defined as a positive Phalens test, VAS score for pain of 5/10 or more (where 0 is ''no pain'' and 10 is ''worse pain ever experienced'') and complaints of persistence of symptoms of CTS after four months of treatment with RHS, NSAIDS, and hand therapy, which included iontophoresis, stretching, moist heat, and active and passive hand range of motion exercises. Several patients also tried acupuncture, cortisone injections,

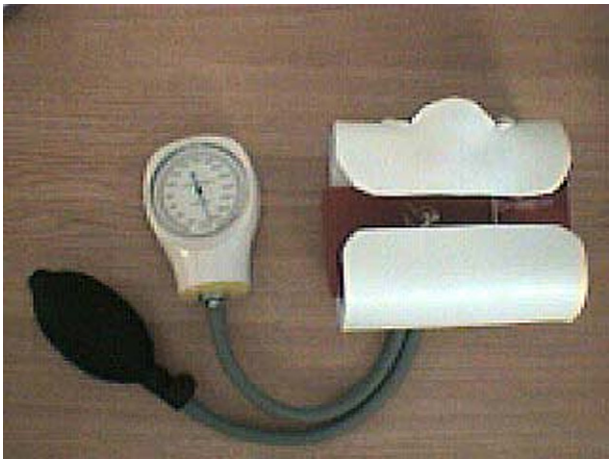

FIGURE 1. *The C TRAC Hand traction unit consists of a C-shaped frame and an air bladder inside the frame attached to a manometer and bulb.*

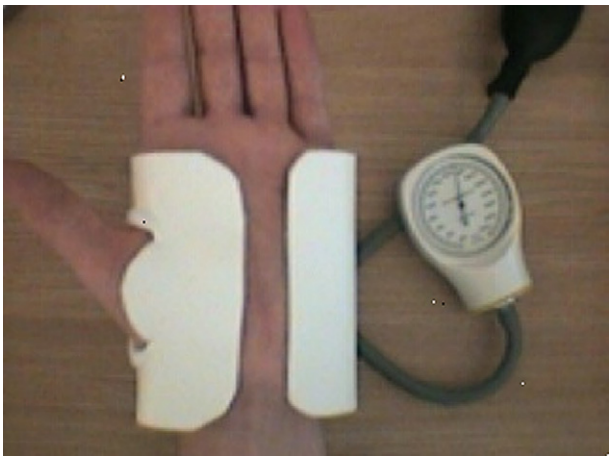

FIGURE 2. *C TRAC device applied to the left hand. As the bladder in the dorsum of the hand is inflated, a 3-point traction force separates the thenar and hypothenar plates, producing traction on the flexor retinaculum.*

and massage as part of their treatment for CTS prior to entering the study.

Exclusion criteria consisted of a VAS for pain of less than 5/10, previous CT release surgery, and 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 more symptomatic limb was chosen for treatment. Only one limb per patient was included in the study.

The patients had electromyographic (EMG) and nerve conduction studies (NCS) for diagnosis of CTS.[16,17]. 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

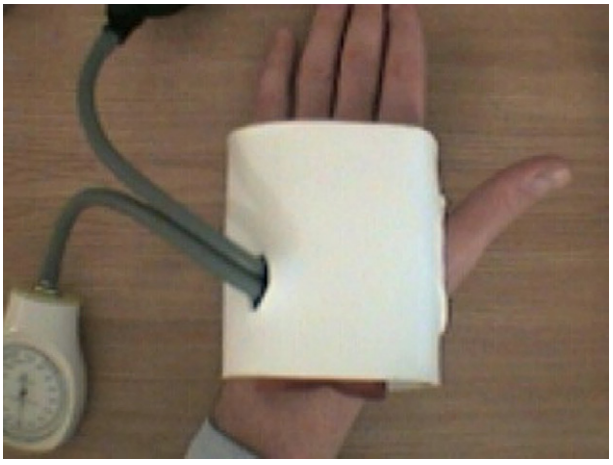

FIGURE 3. *The frame of the C TRAC covers the dorsal aspect of the hand. Notice the air bladder hoses as they exit the frame.*

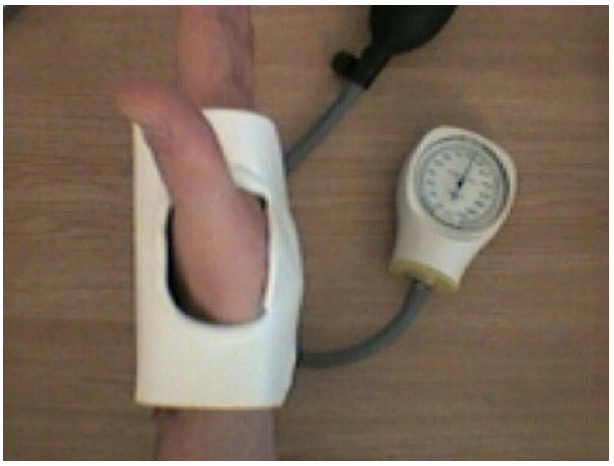

FIGURE 4. *Lateral view showing the thumb exit port and correct placement of the device.*

denervation potentials in the abductor pollicis brevis muscle.

Treatment Protocol

After explanation of the study purpose, the patients signed a consent form. Patients were fitted with a custom C-TRAC and instructed in its use in a session lasting 20–30 minutes. They were shown how to apply the device and how to inflate the air bladder. They were instructed to use the device three times daily for 5 minutes each time in the following manner: place hand in the C-TRAC inflate to 180 mmHg for 2 minutes, deflate and rest for 1 minute, reinflate for 2 more minutes then deflate and remove the device. C-TRAC was used for four weeks. Afterward the patients were instructed to use the device ''as needed'' only if any symptoms reoccurred. They were also instructed not to use NSAIDs, splints or braces, injections, or any other form of therapy for CTS during the study period. Written instructions and a VAS were provided.

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 during the initial visit and by telephone at the end of weeks 1–4. The satisfaction of the patients with their treatment was graded as poor, fair, good, or excellent at the end of the fourth week.

A seven-month follow-up telephone interview was conducted with the treated group and the following data were recorded:

1. Maximum VAS for pain, tingling and numbness at any point in the seven months period.
2. Number of times the device was used per month.
3. Number of times awakened per month by CTS symptoms.

4. Number of physician visits because of CTS symptoms in the seven months period.
5. Number of lost work days because of CTS symptoms.
6. Change of job because of CTS symptoms.

Subjects Demographics

A total of 19 consecutive patients that met the criteria were enrolled in the study. There were two males and 17 females (Table 1). The average age was 51.2 years old (range 37–70 years). The average time with symptoms was 53.6 months (range 4–240 months). Thirteen patients were working at the beginning of the study. Eighteen of the patients had refused CT release surgery in the past.

There were 13 right hands and six left hands, three were classified as mild, 12 as moderate, and four as severe. The group averaged 22.9 months (range 0–60 months) waking up from sleep because of CTS symptoms.

Eighteen patients had EMG/NCS available for review. One EMG/NCS was not available. The patient had an EMG/NCS 10 years prior. She refused repeating it. This patient had clinical diagnosis of CTS, with positive Phalens at 11 seconds, thenar atrophy, hand weakness, and woke up four times a night. She was classified as severe (Table 1).

RESULTS

Four Weeks Follow-up

At the end of four weeks of treatment, no patient was lost at follow-up and there were no reported side effects or complications. Nineteen patients using the C-TRAC were evaluated. Weekly VAS scores for pain, tingling, numbness, and times awakened per night were recorded (Table 2). The average VAS for pain decreased from 8.52 to 1.05 (Figure 5). The average tingling decreased from 8.15 to 0.95 (Figure 6). The average numbness decreased from 8.47 to 0.95 (Figure 7). The average number of times patients woke up per night because of CTS symptoms decreased from 3.05 to 0.10 (Figure 8). At the end of the fourth week the decrease in symptom severity was noted in all measured parameters.

Fifteen of 19 (79%) patients rated their satisfaction with their treatment as excellent, and four of 19 (21%) as good. None rated it as fair or poor (Table 2 and Figures 5–8).

Seven Months Follow-up

The group was followed up at an average of 7.3 months. Of the 19 initial patients, 18 were available for follow-up. One patient was lost to follow-up (Table 3). Eight patients had no symptoms recurrence at seven months. Ten patients had minor symptom recurrence. The average maximum VAS for pain was 0.65/10, for tingling 0.4/10, and for numbness 1.7/10 at the seven-month follow-up. None of the patients reported being awakened 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.

During the 7.3 months three patients did not use the device, nine patients used it less than once a month, and six used it more than once a month. Of the patients that used the device more than once a

TABLE 1. **Patient 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. **Data for Four 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*	*Numbers at Evaluation*	*Numbness Week 1*	*Numbness Week 2*	*Numbness Week 3*	*Numbness Week 4*	*Wake Up/Night at Evaluation*	*Weak Up/Night Week 1*	*Wake Up/Night Week 2*	*Wake Up/Night Week 3*	*Wake Up/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	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	4	0	0	0	0	E
55	F	Moderate	Retired	R	6	6	8	4	2	1	0	9	2	0	0	0	10	4	1	1	0	2	0	0	0	0	E
52	F	Moderate	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	Moderate	Nurse	R	72	2	10	3	0	0	0	10	4	1	0	0	5	1	0	0	0	1	0	0	0	0	E
70	M	Moderate	Engineer	L	4	4	8	4	2	2	0	9	2	2	2	0	9	2	2	1	2	3	2	0	0	0	E
55	F	Moderate	Homemaker	L	84	36	8	6	0	0	0	8	4	3	2	1	8	4	3	1	1	3	3	0	0	0	E
51	F	Moderate	Maintenance	R	36	12	9	5	2	0	0	7	4	2	0	0	10	5	2	2	0	3	1	0	0	0	E
37	M	Moderate	Typist	R	24	6	9	5	2	0	0	6	3	0	0	0	6	3	1	0	0	3	1	0	0	0	E
48	F	Moderate	Clerk	R	12	12	7	4	2	2	0	6	2	0	1	0	7	2	0	1	0	4	2	0	0	0	E
53	F	Moderate	Cook	R	48	24	10	3	3	0	0	10	3	3	0	0	10	3	3	0	0	3	3	2	0	0	G
58	F	Moderate	Clerk	R	72	60	7	7	7	5	4	8	1	6	6	4	8	8	6	5	4	3	2	1	1	1	E
46	F	Moderate	Clerk	L	12	12	10	8	4	0	0	6	6	3	0	0	6	6	3	0	0	5	2	0	0	0	E
49	F	Severe	Typist	R	36	24	10	7	0	0	0	6	8	4	1	0	10	6	4	3	1	4	2	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	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	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	E
50	F	Severe	Clerk	L	240	60	10	6	5	4	4	10	6	6	4	3	10	6	4	4	0	3	3	2	2	0	E

E = Excellent; G = Good.

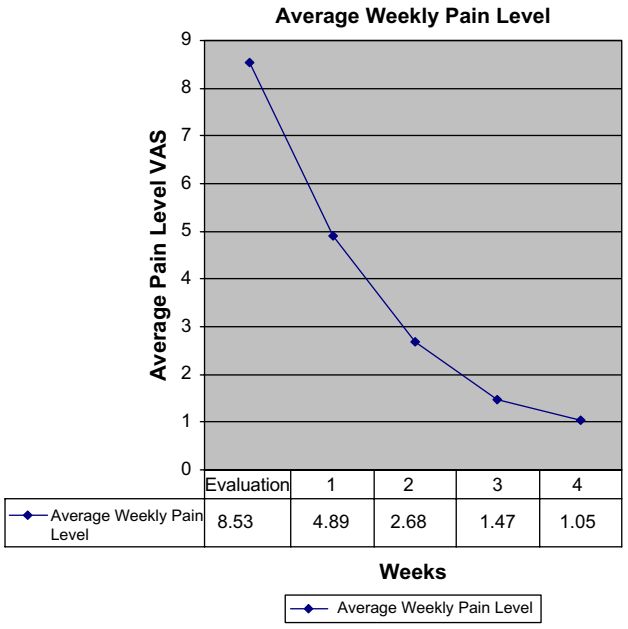

FIGURE 5. *Change in average weekly pain level measured in VAS for 4 weeks.*

month, one patient used it every two weeks and two patients used it once a week. Two patients reported using the device every other day and one reported using it twice a day; they stated they had fear of symptom recurrence. One 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 implanted one month prior to follow-up. After developing CHF, she was using the device twice a day and was the only patient to report not getting relief after one time use. One patient who had symptom recurrence did not use the device for unknown reasons. She denied side effects from the use of C-TRAC 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 (Table 3).

DISCUSSION

C-TRAC was designed to decrease the symptoms of CTS. The proposed mechanism for relief is the noninvasive stretch of the TCL/FR to increase the area of the CT. X-ray evaluation of the effects of the device on the hand prior to this study showed a 1- to 3-mm increase in the distance between the carpal bones in the thenar and hypothenar sides of the hand. After carpal ligament release surgery there is an increase of 1.5–2.7 mm in the diameter of the CT.[18,19] Favorable results of manual manipulations in CTS[20] as well as the properties of the fibrous structures of the wrist[21] support the use of traction for treatment of CTS. The use of C-TRAC for four weeks produced a significant decrease in the symptoms of CTS in our study subjects. The results were maintained at the seven months follow-up.

This study evaluates the efficacy of C-TRAC in decreasing the symptoms of CTS by using it for 5 minutes three times a day for four weeks. Visual Analog Scale (VAS) was used for grading and follow-up of the severity of symptoms. Several authors favorably established the validity of VAS.[22–26] While other authors have used a functional disability scale to grade the severity of clinical manifestations of CTS, [27,28] we preferred to use VAS to evaluate the effect on each symptom through time. The number of times the patients woke up per night was also

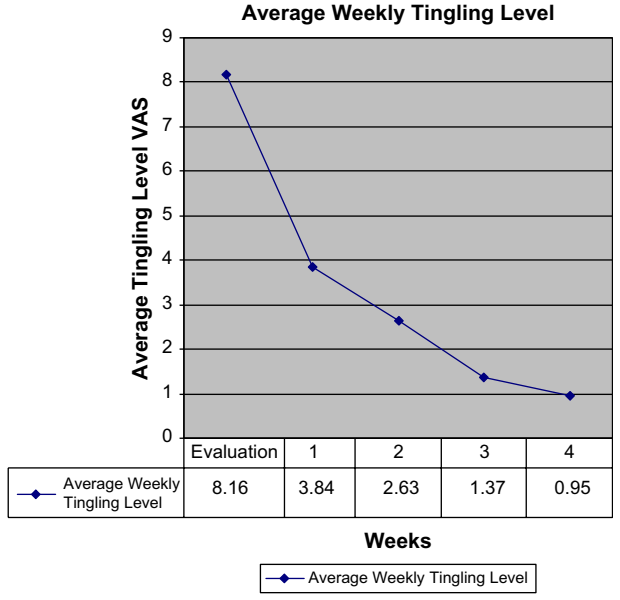

FIGURE 6. *Change in average weekly tingling level measured in VAS for 4 weeks.*

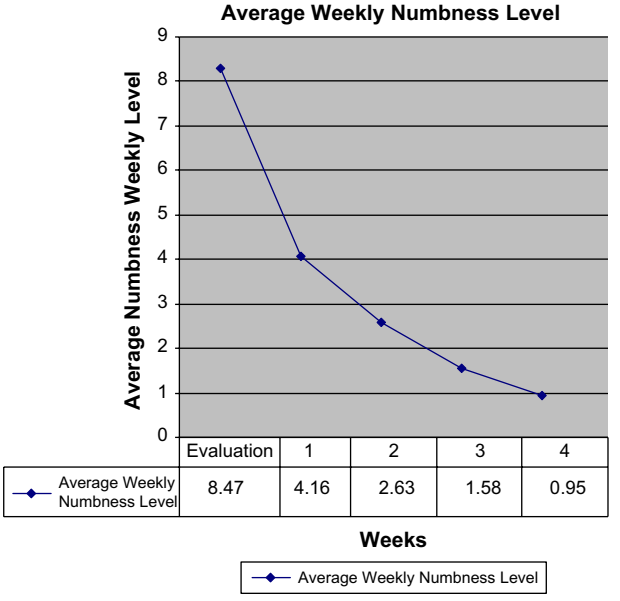

FIGURE 7. *Change in average weekly numbness level measured in VAS for 4 weeks.*

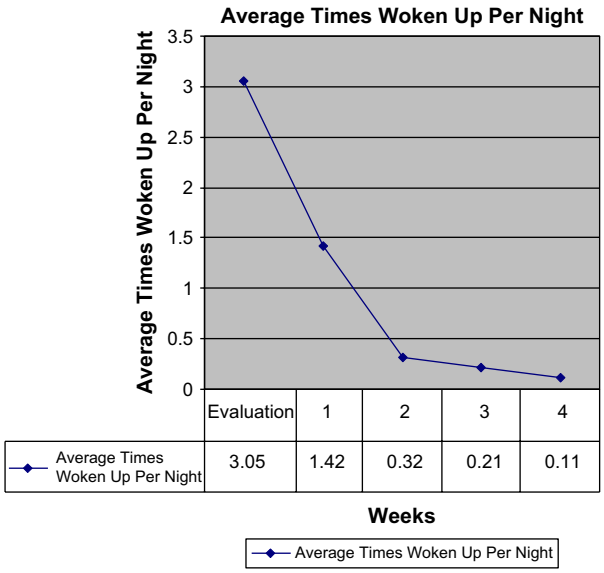

FIGURE 8. Change in average times awakened per night measured weekly for 4 weeks.

recorded as most of the patients considered this to be a very disturbing aspect of CTS. C-TRAC was used as the only therapy for patients in this case series to eliminate the possibility of improvement from a combination of treatment modalities. A seven months follow-up evaluated the recurrence of symptoms, side effects, and the effectiveness of the treatment over time.

The authors found improvement in all symptoms of CTS in patients using C-TRAC including significant decrease of the times patients woke up per night. After four weeks of treatment 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 seven months follow-up. These results were positive for patients treated in all severity groups, mild, moderate, and severe, as classified by EMG/NCS.

Using C-TRAC the average pain changed from 8.2 to 0.65 (92%), 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 seven months follow-up. Further research using Symptom Severity Scale, Functional Disability Scale, as well as a Satisfaction Scale is recommended since they were designed specifically to address functional improvement in patients with CTS.

Burke et al.[5] who evaluated the use of RHS for CTS and found that after two 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 two weeks would result in either no improvement in symptoms or a worsening of symptoms (in 76% of the patients). The efficacy of C-TRAC in relieving the symptoms of CTS should be compared with the efficacy of RHS, injections, and surgery in short and long-term studies.

Bessette et al.[29] reported that the single most important reason for CTS patients to have surgery was relief of night pain (37%). This study showed the use of C-TRAC decreased the times the patients woke up at night from an average of three to 0.16 after four weeks use. At seven months the number of times patients woke up per night was 0 per month.

There was a high level of satisfaction with the use of C-TRAC. This may be due to multiple factors: the effectiveness of the device in decreasing the

TABLE 3. **Seven Months Follow-up**

EMG Classification	*Complications*	*Months with Device*	*Times Used per Month*	*Times Woken Up per Month*	*Worse Pain VAS*	*Worse Tingling VAS*	*Worse Numbness VAS*	*No. Doctor Visits*	*No. 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

EMG = electromyographic, VAS = Visual Analog Scale.

symptoms in patients who had failed multiple forms of therapy; the short periods of time C-TRAC was used during the day; not having to use a device 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 seven months. Indeed, at seven months follow-up, 12 of 18 patients reported the need to use the device an average of once (5 minutes) every two months. Our feeling is that patients should use the device once or twice a month for six months after the initial four weeks of daily application to avoid recurrence of symptoms, though we have no data to support this impression at this time.

CONCLUSION

The purpose of the study is to evaluate the efficacy of C-TRAC in decreasing pain, tingling, numbness, and number of times woken up at night in patients that failed conservative therapy for CTS. The use of C-TRAC for 5 minutes three times a day for four weeks was beneficial in decreasing the symptoms of CTS. At seven months follow-up the patients continued to show excellent relief from symptoms. C-TRAC was easy to use and inexpensive. None of the patients had problems or complications using the device and reported satisfaction with its use. The efficacy of C-TRAC should be compared with the efficacy of RHS, CT injections, and CT release surgery in future research studies. The cost effectiveness of this device should also be compared with current therapies used for CTS.

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Record your answers on the Return Answer Form found on the tear-out coupon at the back of this issue. There is only one best answer for each question.

#1. A traction force was exerted across the carpal tunnel with X-ray evidence of a separation between the carpal bones in
   a. all patients in this study
   b. 50% of the patients in this study
   c. 50 patients after completion of this study
   d. two patients prior to this study

#2. The C-TRAC applies its force through the
   a. dorsal retinaculum
   b. bases of the 2nd and 5th metacarpals
   c. thenar and hypothenar eminences
   d. distal wrist crease

#3. All patients included in this study
   a. had undergone extensive conservative treatment and failed to achieve significant relief of symptoms before trying the C-TRAC
   b. had undergone failed carpal tunnel release surgery
   c. continued to receive hand therapy while also using the C-TRAC
   d. were seen weekly to monitor progress

#4. The C-TRAC protocol was
   a. 5 minutes 5 times a day for 5 weeks
   b. 5 minutes 3 times a day for 4 weeks
   c. 3 minutes 3 times a day for 3 weeks
   d. 4 minutes 4 times a day for 4 weeks

#5. In this case series, the data are reported
   a. with complete statistical analysis
   b. without statistical analysis
   c. with minimal statistical analysis
   d. as a meta analysis

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