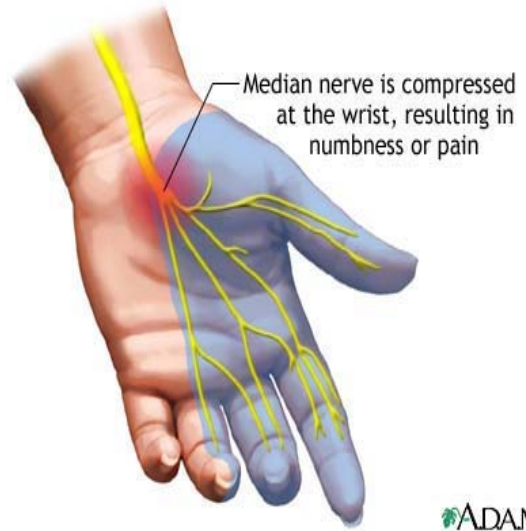


Clinical Trial of Carpal Solution Therapy

Non-Surgical Therapy for Carpal Tunnel Syndrome

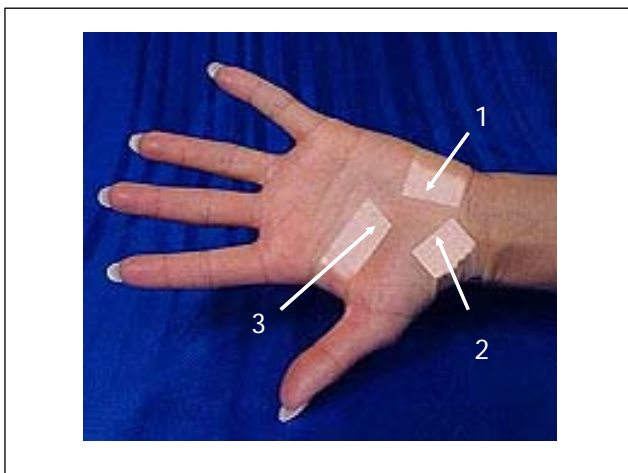
By Dr. Clyde Morgan

Carpal tunnel syndrome occurs when the median nerve is impinged and blood vessels are constricted in and around a narrow passage called the carpal tunnel at the base of the hand near the wrist. Symptoms result from swelling of irritated tendons and soft tissue which crowd the tunnel. Common symptoms are pain and numbness in the hand and forearm. The blue shaded area in the illustration to the right shows the specific areas that are usually affected. Symptoms are most intense at night when the hand is relaxed. Routine sleep interruption and sleep loss is a major concern which has wide ranging health implications. Chronic pain also leads to loss of hand functionality and muscle atrophy which limits use of hands at home and work. The Occupational Safety and Health Administration (OSHA) recognize Carpal Tunnel Syndrome as the leading cause of lost time at work.



ADAM.

The Carpal Solution is intended to be used over a six week protocol. To determine the effectiveness of the Carpal Solution in treating the common symptoms of Carpal Tunnel Syndrome a trial was performed monitoring grip strength measurements over a two week period. This initial study documents the early success that many patients have experienced in taking control of their Carpal Tunnel Syndrome symptoms over two weeks. While the author has extensive experience working with patients who have successfully treated their symptoms in six weeks with the Carpal Solution and followed them over several years, additional work and resources will be needed to formally document the long-term results of the Carpal Solution following the full six-week protocol and tracing the patients over several months.



How the Carpal Solution Works

The Carpal Solution gently tugs simultaneously at three key points surrounding the carpal tunnel during sleep.

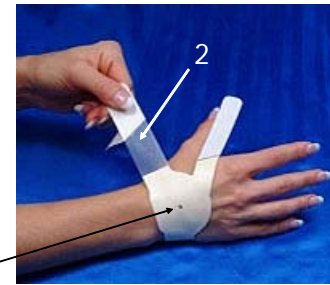
Consistent gentle pulling action applied for 7 to 8 hours per night, while the hand is completely relaxed, decompresses and reshapes the soft tissue around the carpal tunnel and relieves symptoms associated with Carpal Tunnel Syndrome.

Step 1 - Attach 1st strap below little finger securing it on the palm



Step 2 - Self Apply Appropriate Tension with 2nd strap below thumb

Adjust tension by stretching circular cut-out on back of hand in the elastic centerpiece to an oval shape. The diameter should be at least 1.5 times the original.



Circular cut-out stretched to an oval

Step 3 – Stretch and apply 3rd strap between thumb and Index finger to palm



s

Relief is most often noticed within a week in mild cases and six weeks when CTS is chronic.

Gentle decompression of soft tissue during sleep combined with active use during the day results in an ideal rhythmic therapy for relief from CTS symptoms with no muscle atrophy. Soft tissue therapy is a slow process. The optimum protocol that has been effective for many chronic sufferers of CTS is to wear the Carpal Solution every night for two weeks and then every other night for four weeks.

STUDY PARTICIPANTS:

The Carpal Solution Study involved eleven pre-qualified patients suffering from the symptoms of Carpal Tunnel Syndrome. Seven participants were experiencing Carpal Tunnel Syndrome symptoms in both hands and involved both hands in the study. The CTS symptoms are most pronounced at night while patients are sleeping. At the onset of the trial all patients participating in the clinical trial reported classical symptoms of Carpal Tunnel Syndrome with routine sleep interruption due to hand pain and numbness. All patients reported some degree of hand dysfunction and loss of grip strength and the resulting inhibition of full capability of hand use in their daily activities due to the pain and weakness they experienced in their hands.

OBJECTIVE OF THE STUDY:

The objective of the Study was to determine the effectiveness of the Carpal Solution in relieving carpal tunnel symptoms. Two primary symptoms were tracked in the study:

- 1) Relief of nighttime hand pain and numbness and interruption of sleep.
- 2) Improvement in hand muscle strength and functionality as measured by the Jamar Grip Strength Dynamometer and Jamar Pinch Test.

EQUIPMENT USED:

Mfg. Sammons Preston, Inc. Jamar Pinch Tester
Mfg. Sammons Preston, Inc. Jamar 5 Position Dynamometer Grip Tester

The Dynamometer is the gold standard in measuring rehabilitation progress and for routine evaluation of hand and finger muscle function. It is particularly useful for patients with hand trauma and dysfunction due to Carpal Tunnel Syndrome. The Dynamometer represents an excellent way to track the hand's response and progress associated with any hand muscle related therapy. The Jamar Pinch Tester is a great way to isolate muscle strength of specific digits such as the thumb which can be missed in the testing with the Dynamometer (See Exhibit I for more information on the Jamar hand muscle functionality testing equipment).

PROCEDURE:

Pinch Tester Test is accomplished by applying pressure while the tester is between the distal pad of the first digit (thumb) and two distal joint of the second digit (index finger). Three readings were taken, the average of the three readings were recorded.

5 Position Grip Tester Test: Positions 1, 3 and 5 were selected to give the full range of muscle action. The Participants are instructed to squeeze 3 times at each position; the average of the 3 grip tests is calculated and recorded. By taking the average of three tests at each position, we minimize any skewing of the data due to a one-time high intensity squeeze or a particularly weak one-time squeeze.

All participants were instructed to wear the Carpal Solution every night for two weeks, using a new Carpal Solution each night. Normal activity was not to be altered, except if the patient was wearing a Cock-Up Splint, they were asked to discontinue the use of the splint during the study.

Base readings were recorded prior to the beginning of testing. Participants returned 3 times (Monday, Wednesday, Friday), to have the Pinch Tester and 5 Position Grip Tester performed and recorded. In exchange for participation the volunteers received free samples of the Carpal Solution for use in the trial and also received feedback on the grip strength study, but received no other compensation for their participation. A total of 18 hands from 11 patients participated in the study.

OVERALL SUMMARY OF RESULTS:

At the end of the two weeks, 82% of participants in the study experienced relief from symptoms of Carpal Tunnel Syndrome and a significant improvement in hand functionality as measured by the grip strength testing. One participant did not experience any relief from symptoms and a second experienced only minor relief from the symptoms of Carpal Tunnel Syndrome.

SLEEP INTERRUPTION RESULTS

- 18% of the patients eliminated sleep interruption due to hand pain after just two weeks of treatment.
- 64% of participants reported significant reduction in the frequency of the interruption of sleep due to hand pain.
- 9% of the participants reported minor improvement, but still experienced sleep interruption.
- 9% of the participants reported no improvement.

Sleep interruption is a major issue for Carpal Tunnel Syndrome sufferers. Based on the results of this limited study, we are optimistic that the Carpal Solution will offer Carpal Tunnel Syndrome sufferers relief from the intense pain and interruptions that often occur during sleep.

GRIP STRENGTH RESULTS

Tables 1 through 5 summarize the test data generated with the Jamar Pinch Test and the Jamar Dynamometer 5 Position Grip Strength Device in the attached pages 11 through 15 of **EXHIBIT II**. Table 5 on page 15 summarizes all of the data for rapid review and comparison.

As demonstrated in **EXHIBIT II**, areas of improved grip strength varied between position 1, 3, 5 and the pinch test using the Jamar hand functionality testing equipment. This is attributed to the variation of participant's job functions and hand use patterns leading to soft tissue injury, tendon strain, median nerve impingement and corresponding muscle atrophy. Each patient's hand muscles are uniquely affected by carpal tunnel syndrome. As the pain is relieved and the patient returns to full activity, the unique hand use pattern also results in custom results for each patient in the restoration of hand grip strength as muscle atrophy is overcome. Also, the different use pattern from the right and left hand in the same patient will result in different improvement rates in the muscle functionality. The size of the individual's hand and muscle mass are other variables that contribute to the variation in absolute readings from person to person at each of the various positions tested.

As would be expected the people with the weakest readings experienced the largest percentage improvements. All patients experienced some improvement in at least one of the tests. However, patient number 10 experienced only a 14% improvement in position #1 and no improvement in the other three hand muscle positions tested on the left hand and only minor improvement on the right hand. This patient also did not experience an improvement in symptoms during sleep. It is concluded that the Carpal Solution was not effective for this patient. It seems clear that there are other medical conditions in addition to carpal tunnel syndrome affecting patient number 10. It has been well documented in the literature that many other conditions often complicate the treatment of Carpal Tunnel Syndrome including: diabetes, auto immune disorders such as arthritis, Gout, Hypothyroidism, tenosynovitis of the flexor tendons, ganglion cyst, musculotendinous variants, and various soft tissue tumors, etc. It was beyond the scope of this study to identify other complicating disorders. The Carpal Solution is best suited for relief of CTS symptoms that are brought on by repetitive stress injury.

While physicians often only test one grip strength position to monitor results of therapy due to time constraints, only looking at one position gives limited validation of progress. Patient 10 demonstrates the effectiveness of the test procedure used in this study. In testing multiple hand strength positions, including the pinch test, and by taking the average of three tests at each position, we have a complete look at hand functionality and have avoided potential false positives. The most meaningful data point to focus on is in Table 5 on page 15 of **EXHIBIT II**, the **Average Improvement All Tests** for each hand. We will refer to it as the **Average Improvement** from here on.

In the patients that experienced significant relief from the symptoms of CTS, the Average Improvement results for each hand of each patient ranged from 15.22 % Average Improvement in the right hand of patient number 8; to 125.36% Average Improvement in the right hand of patient number 5. Patient 3 had a 97.22% Average Improvement in the right hand while experiencing only an 80.83% Average Improvement in the left hand. This difference is attributed to the difference in use pattern for each hand in the same patient. As the pain of CTS is relieved, the dominant hand will usually respond more quickly to improvement in grip strength testing.

Six patients of the eleven (55%) experienced a greater than 40% Average Improvement in their grip strength in the two week trial. Fourteen, of the eighteen hands treated (78%), experienced a 20% or greater Average Improvement in grip strength. Since the protocol is six weeks for chronic cases of CTS, we would conclude that that the patients who were responding more slowly were the more chronic cases. We would expect that as these more chronic cases continue the Carpal Solution therapy, they will experience continued improvement in grip strength and eventually eliminate the interruption of sleep due to hand pain.

ADDITIONAL OBSERVATIONS

Some participants reported that in the area where the wrist and hand join on the palm side, a slight increase in discomfort occurred after 2-5 nights, of wearing the Carpal Solution. It is thought that this discomfort is due to decompression of the soft tissue around the tendons, blood vessels and nerve passing through the Carpal Tunnel. The increase in discomfort lasted only for one or two nights before consistent CTS symptom relief was achieved from the Carpal Solution therapy.

Over several years of successfully treating patients with the Carpal Solution therapy, it has also been observed that patients continuing with their regular duties at work, which brought on the original symptoms of Carpal Tunnel Syndrome will often find that over several months their symptoms may return, even after a successful treatment protocol with the Carpal Solution therapy. In those cases, the patients have been able to check the progression of their symptoms by applying the Carpal Solution for only two to three nights per month. This allows them to carry on with their regular routines without interruption of sleep or lost time at work. The Carpal Solution enables proactive control of the progression of the symptoms of CTS with a non-invasive therapy.

MECHANISM OF ACTION

Cold extremities are a well known indicator of restricted blood circulation in medicine. When blood vessels are constricted or even slightly obstructed due to outside pressure on the vessel, it causes a reduction in the passage of blood to the extremity. The skin surface is where the temperature reduction is most pronounced. When the air temperature (most comfortable at 70 degrees Fahrenheit (F) for normal activity) is well below the average body temperature (about 98 degrees F) the skin temperature of the extremity will be marked by reduced temperature and a chilled sensation if blood vessels feeding the extremity are constricted and physical activity is minimal. This is a well know phenomenon in medicine. The majority of blood feeding the hand passes through three key arteries in and around the carpal tunnel. These include the Median artery passing through the carpal tunnel, and the Ulnar and Radial arteries which pass through the soft tissue proximate to the carpal tunnel (see notes below).

We relied on the above phenomenon to demonstrate the immediate impact and mechanism of action of Carpal Solution therapy. A patient's hand skin temperature was monitored before and after the application of the device. The patient suffering from Carpal Tunnel Syndrome was asked to lie completely still fully clothed in a comfortable position on an exam table. The arms were positioned to lie still horizontally across the patient's abdomen with the hand slightly elevated and resting in the air to stabilize metabolic activity and eliminate possible contribution to increased circulation due to physical activity, gravity or body heat. The temperature in the clinical visitation room was held constant at a comfortable 69 degrees Fahrenheit. Thermocouples were fastened to the palm of the hand and the underside of the forearm using surgical tape. After five minutes in this position, the initial temperature of the hand was recorded at 80.8 degrees F and the forearm position was recorded at 86.4 degrees F. There was a 5.6 degree F temperature gradient between the forearm and the hand recorded before therapy at time zero.

A Carpal Solution was placed on the hand experiencing carpal tunnel syndrome. After twenty minutes, a five degree temperature elevation was recorded on the hand's skin surface. The forearm temperature decreased 0.6 degrees F, leaving the forearm and the hand at the same temperature of 85.8 degrees Fahrenheit. Consistent with the concept reviewed above, it is concluded that improved blood circulation in the extremity resulted in relatively rapid increase in skin temperature of the hand with other factors being held static.

In addition to the Median artery the carpal tunnel contains the Median Nerve which provides feeling sensation to the hand and tendons which facilitate steady controlled wrist movement. We conclude that this rapid rise in skin temperature of the hand resulted from less restricted flow of blood due to decreased external pressure in and

around the carpal tunnel. We would suggest that this effect is achieved through decompression of the soft tissue around the carpal tunnel relieving external pressure on the arteries. We also conclude that just as a slight reduction in external pressure in the soft tissue around the tunnel allowed an increase in blood circulation, that it will also relieve external pressure on the median nerve by the same mechanism. This is how the Carpal Solution therapy alleviates the pain and symptoms of carpal tunnel syndrome and revitalizes the hand naturally with well circulated blood that is rich in oxygen and nutrients.

This demonstration is a simple, but powerful, proof of principle for the Carpal Solution. It offers strong supporting evidence of the potential to decompress and reshape the soft tissue in the Hand to relieve pressure on vessels, nerves and tendons passing through and around the carpal tunnel. It also provides valuable insight and validates the mechanism of action behind the Carpal Solution therapy. Using readily reproducible non-invasive skin temperature measurements, independent investigators can confirm this phenomenon on patients suffering from CTS.

WHO IS AT RISK:

Repetitive stress activities bring on Carpal Tunnel Strain which can lead to Carpal Tunnel Syndrome in people predisposed genetically for the Syndrome. Any activity that requires vigorous repeated hand use will often lead to Carpal Tunnel Syndrome. Below is a list of common occupations and activities that have been identified with the onset of Carpal Tunnel Syndrome.

Some of the Jobs & Activities Common to CTS Onset

- | | |
|------------------------------------|-----------------------------------|
| 1. Typing / Computer work | 9. Homemaking / Needlepoint |
| 2. Sorting mail / Courier Services | 10. Grocery checking |
| 3. Meat cutting | 11. Musicians, Pianist, Violinist |
| 4. Driving vehicles | 12. Golfers |
| 5. Tool handling | 13. Carpenters |
| 6. Machinist / Mechanics | 14. Chefs |
| 7. Construction work | 15. Massage Therapists |
| 8. Landscaping | 16. Tennis players |

Common symptoms of Carpal Tunnel Syndrome follow:

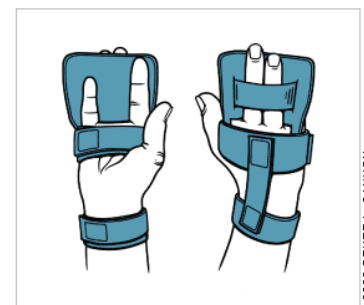
- Pain and weakness in the hand and wrist, radiating up the forearm.
- Poor circulation, numbness, hands fall asleep regularly, loose sensation in fingers and grip strength.
- Dropping objects, forearm pain, inhibits use of hands.
- Symptoms increase at night when the hand is relaxed interrupting sleep.

These symptoms often lead to accidents and declines in quality at work if people are slow to pick up on the symptoms and proactively prevent the progression of the Syndrome.

CONVENTIONAL TREATMENT:

There are three basic types of conservative conventional treatments. These are:

- Wrist supports or splints
- Oral corticosteroid therapy
- Local corticosteroid injections



Wrist supports or splints may be helpful, but these can result in muscle atrophy and other complications. Oral corticosteroid therapy and local corticosteroid injections can offer short-term relief, but have long-term side effects. Also, oral therapy has the disadvantage of treating the whole body rather than just the point where it is needed. Most people would rather not deal with routine injections.



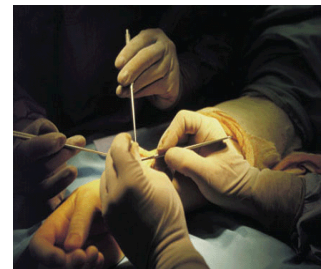
OTHER ORAL MEDICATIONS

Diuretics, nonsteroidal anti-inflammatory drugs (NSAIDs), pyridoxine (vitamin B₆), and orally administered corticosteroids have been used with some temporary success in relieving symptoms in patients with carpal tunnel syndrome. A systematic review of conservative treatments for carpal tunnel syndrome the authors concluded that NSAIDs, diuretics, and pyridoxine are no more effective than placebo in relieving the symptoms of carpal tunnel syndrome.¹⁻⁵

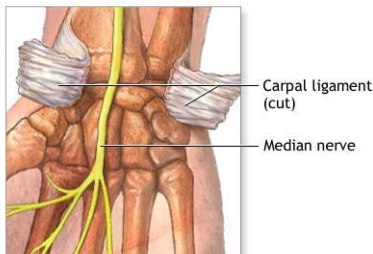
It can generally be concluded that symptoms return in over 80 percent of patients with conventional conservative treatments.⁶ Better options are needed that allow daily activity, relieve pain, allow uninterrupted sleep and stop the progression of the syndrome without side effects such as muscle atrophy or steroids use.

SURGERY


When conventional conservative treatments have been tried and failed for at least six months, it is generally recommended by most surgeons that the patient consider carpal ligament release surgery, but to be considered for reimbursement the diagnosis must be confirmed through nerve conductivity testing. Carpal tunnel strain has to have progressed to carpal tunnel syndrome at that point.



Surgery is done under twilight anesthesia. The drugs cause amnesia so it feels like one has been completely knocked out. Through an incision on the wrist, the carpal ligament is severed to relieve the pressure on the nerve. The incision is sutured closed with the expectation that the ligament tissue will scar back together over several months leaving more space. This is not an exact science. One hopes that there will be no complications.



Relief from pain is likely, but full recovery is uncertain. Patients usually have stiffness, and / or pain at the scar and may have complications with infection or nerve damage. The wrist will often lose strength because the carpal ligament has been severed and scars back together. Surgery requires months of rest and physical therapy after surgery to regain some of the original hand / wrist strength. Some improvement is achieved in 85% of cases with a return to full activity achieved in less than 70% of surgeries.

 When patients return to full activity, it is not uncommon for carpal tunnel symptoms to return within two years of the surgery lowering the success rate further. Surgery can be repeated when symptoms return, but it is generally not recommended to perform this type of surgery more than twice. Before doing surgery a second time most medical professionals will suggest a change of the repetitive activity causing the carpal tunnel syndrome. Often patients with work related CTS will still need to adjust job duties or change jobs after recovery from surgery.

The cost of surgery and rehabilitation is in the range of \$3,000 to \$7,000. The majority of the costs is usually borne by the medical insurer. However, over the last five years insurers and employers have been actively shifting more of the costs of healthcare services to the patient. This trend is accelerating. With increasing co-

pays, the emergence of health saving accounts and much higher deductibles, informed proactive consumers are taking a more active role in self-managing the cost / benefit and the consequences of their medical services. This phenomenon will lead to an acceleration of the development of viable alternatives to conventional conservative treatments.

CONCLUSION:

After two weeks of using the Carpal Solution, 82% of the participants in the study experienced both an improvement in sleep patterns, a reduction in reported hand pain and significant improvement in grip strength as muscle atrophy was overcome. One of the participants did not experience improvement of any of the symptoms. This leads to the conclusion that for the majority of people suffering from the symptoms of Carpal Tunnel Syndrome, the Carpal Solution will provide significant improvement in a relatively short treatment period. It is recommended that people experiencing symptoms associated with Carpal Tunnel Strain or Carpal Tunnel Syndrome visit a license physician knowledgeable in the space to confirm the diagnosis and seek to identify the likely cause.

Several years of working with patients using the Carpal Solution therapy provides the author with ample evidence that the long-term benefits of the therapy are viable for a large portion of the Carpal Tunnel Syndrome population. Based on this experience it is noted that if repetitive stress activity continues people often need to return to using the Carpal Solution for two to three nights per month to control the symptoms and check the progression of the syndrome. For scientific purposes, additional studies evaluating the full six week treatment protocol and following patients over several months is recommended to further document the measurable results of the Carpal Solution therapy. Also, it would be useful to run the next study with a statistically significant patient population. It is recognized that 11 participants do not meet this requirement. However, this study does provide a powerful proof of principle that the Carpal Solution will provide relief of pain and symptoms for a large segment of the Carpal Tunnel Syndrome population, especially those who have developed the condition due to repetitive stress injuries.

This work also documents the mechanism of action in the Carpal Solution therapy in a dramatic demonstration. An easily performed reproducible skin temperature gradient test was used to document less restricted blood flow through the tight passages in the soft tissue in and around the carpal tunnel. If external pressure can be relieved on constricted blood vessels in and around the carpal tunnel with the Carpal Solution treatment in twenty minutes, then by inference, we conclude it will also be relieved on the median nerve through the same mechanism.

Surgery has been the only viable long-term treatment option for Carpal Tunnel Syndrome. Despite the risks associated with invasive surgery, it has only proven effective long-term in less than 60% of cases where repetitive stress activity is continued. Although symptoms may be relieved immediately after surgery, full recovery from carpal tunnel surgery will usually take months of down time and rehabilitation. Some patients have reported infection, nerve damage, stiffness, and pain at the scar. Wrists can lose strength long-term, because the carpal ligament is severed. Patients undergoing surgery often have to change their hand-use pattern to avoid reoccurrence of CTS symptoms. This may require an adjustment in job duties or even changing careers altogether after recovery from surgery.

Alternative less invasive treatment options are urgently needed. Early diagnosis by a trained and licensed professional combined with proactive treatment to minimize damage and muscle atrophy is important to prevent the progression of the syndrome. Also, it is important for sufferers to know that surgery will not be performed and reimbursed unless the symptoms have progressed to a point where Carpal Tunnel Strain has become full-on Carpal Tunnel Syndrome documented with nerve conductivity testing. A general requirement is that severe symptoms must persist for six months before surgery will be performed. The Carpal Solution therapy offers

people suffering from early symptoms of Carpal Tunnel Strain to proactively obtain relief as soon as symptoms are presented. This allows the patient to take control of their symptoms with early preventative therapy. It has been well documented that early treatment of work place injuries is the key to preventing more severe medical complications as well as sleep disruption and reduced earnings.

The economics of Carpal Tunnel Syndrome are compelling. It is the biggest single contributor to lost time at work with workers compensation costs estimated at over \$20 billion per year due to CTS. Medical Insurers would benefit greatly in reducing the cost of treating carpal tunnel syndrome through conventional surgery and conservative treatments. It is estimated that insurers spend over \$5 billion per year in conventional Carpal Tunnel Syndrome therapy.

With the cost of the full Carpal Solution therapy being less than the combined co-pay of a few visits to a physical therapy clinic, the Carpal Solution is a cost effective alternative to other treatment regimens. We concluded that the Carpal Solution provides a reliable, affordable alternative treatment for those who suffer from chronic Carpal Tunnel Syndrome symptoms due to repetitive stress injuries. It is especially appealing to those who are determined to be proactive in preventing the progression of the syndrome to the point where surgery is an option or even a necessity.

Notes: The main supply of blood to the hand for an early stage fetus in the womb is the median artery which passes through the carpal tunnel. This is followed, in development, by the anterior interosseous, which is finally replaced by early childhood, with the ulnar and radial arteries as the principal blood supply of the hand in the majority of the population. Some studies suggest that people suffering carpal tunnel syndrome may also have what is known as a persistent median artery.⁷⁻⁸ The persistent median artery remains unusually large in some people and can be as large as 3 mm in diameter compared to the average found in one study of 1.1 mm. It is the belief of this investigator that a few millimeters of incremental space in and around the carpal tunnel, (where important nerves, vessels and tendons function in close proximity) can be the difference between chronic pain and restful relief leading to active vitality. The above study found that twenty three percent of the population studied had a persistent median artery. A persistent median artery may be a contributing factor in some people suffering from carpal tunnel syndrome.

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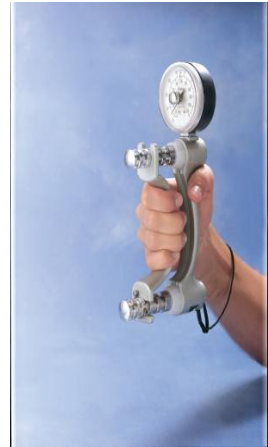
EXHIBIT I

Jamar Hand Muscle Functionality Testing Equipment

JAMAR Hydraulic Hand Dynamometer

The JAMAR Hydraulic Hand Dynamometer is an indispensable tool, to generate accurate and objective data required for reimbursable hand and forearm rehabilitation services. The Jamar Hydraulic dynamometer gives accurate and clinically reproducible grip strength readings. The unit has an adjustable 5-position handle with adjustments from 1 3/8" to 3 3/8", in half-inch increments, allowing for full profile development of muscle, bone and tendon function in the hand, wrist and fingers.

The Peak-hold needle automatically retains the highest reading until reset. This maximum strength indicator facilitates accurate maximum strength readings. Use of average testing of three squeezes assures no anomalies and highly reproducible results. The Jamar Hand Dynamometer is ideal for routine screening of hand muscle function. It is also particularly useful for initial and ongoing evaluation of clients with hand trauma and dysfunction due to carpal tunnel syndrome. The Dynamometer represents an excellent way to track the hand's response and progress associated with therapy. Isometric design ensures accurate, reproducible results. The Jamar Hand Dynamometer is the definitive test for muscle functionality in the hand and has set the standard for measuring and analyzing hand dysfunction.



JAMAR Hydraulic Pinch Gauge

Unlike conventional pinch gauges, the JAMAR Hydraulic Pinch Gauge's unique design allows accurate development of a true pinch pattern. A highly accurate pinch-force measurement, devoid of interference, is the result. The Red indicator needle remains at maximum reading until reset easing the reading of accurate measurements. It measures pinch force up to 45 lbs. The pinch test used in combination with the Jamar Hand Dynamometer provides conclusive data regarding hand functionality with reliable reproducibility.

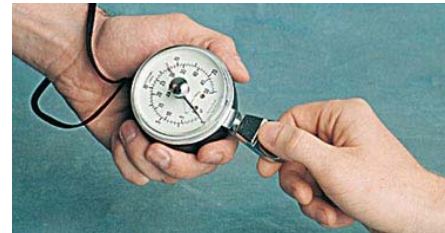


EXHIBIT II

THE CARPAL SOLUTION
TWO WEEK GRIP STRENGTH
CLINICAL DATA SUMMARY

JAMAR PINCH TEST**Table 1**

| PATIENT NUMBER | HAND ID | PINCH FORCE POUNDS LOW | PINCH FORCE POUNDS HIGH | PINCH FORCE POUNDS INCREASE | PERCENTAGE INCREASE |
|----------------|---------|------------------------|-------------------------|-----------------------------|---------------------|
| 1 | R-1 | 10 | 15 | 5 | 50.00% |
| 1 | L-1 | 9 | 12 | 3 | 33.33% |
| 2 | R-2 | 10 | 12 | 2 | 20.00% |
| 2 | L-2 | 8 | 10 | 2 | 25.00% |
| 3 | R-3 | 5 | 17 | 12 | 240.00% |
| 3 | L-3 | 6 | 11 | 5 | 83.33% |
| 4 | R-4 | 12 | 16 | 4 | 33.33% |
| 4 | L-4 | 14 | 16 | 2 | 14.29% |
| 5 | R-5 | 7 | 12 | 5 | 71.43% |
| 6 | R-6 | 13 | 16 | 3 | 23.08% |
| 6 | L-6 | 13 | 16 | 3 | 23.08% |
| 7 | R-7 | 12 | 17 | 5 | 41.67% |
| 8 | R-8 | 11 | 12 | 1 | 9.09% |
| 8 | L-8 | 12 | 13 | 1 | 8.33% |
| 9 | R-9 | 10 | 12 | 2 | 20.00% |
| 10 | R-10 | 10 | 10 | 0 | 0.00% |
| 10 | L-10 | 12 | 12 | 0 | 0.00% |
| 11 | R-11 | 10 | 11 | 1 | 10.00% |

| | | | | | |
|----------------------------|--|--------------|--------------|-------------|---------------|
| TOTAL | | 184 | 240 | | |
| AVERAGE OF 18 CASES | | 10.22 | 13.33 | 3.11 | 30.43% |

EXHIBIT II

THE CARPAL SOLUTION
TWO WEEK GRIP STRENGTH
CLINICAL DATA SUMMARY

JAMAR DYNAMOMETER POSITION # 1

Table 2

| PATIENT NUMBER | HAND ID | GRIP FORCE POUNDS #1 GRIP LOW | GRIP FORCE POUNDS #1 GRIP HIGH | GRIP FORCE POUNDS INCREASE | INCREASE PER PERCENTAGE |
|----------------|---------|-------------------------------|--------------------------------|----------------------------|-------------------------|
| 1 | R-1 | 35 | 50 | 15 | 42.86% |
| 1 | L-1 | 40 | 50 | 10 | 25.00% |
| 2 | R-2 | 30 | 45 | 15 | 50.00% |
| 2 | L-2 | 25 | 40 | 15 | 60.00% |
| 3 | R-3 | 30 | 50 | 20 | 66.67% |
| 3 | L-3 | 20 | 40 | 20 | 100.00% |
| 4 | R-4 | 35 | 50 | 15 | 42.86% |
| 4 | L-4 | 30 | 50 | 20 | 66.67% |
| 5 | R-5 | 25 | 45 | 20 | 80.00% |
| 6 | R-6 | 40 | 50 | 10 | 25.00% |
| 6 | L-6 | 40 | 50 | 10 | 25.00% |
| 7 | R-7 | 40 | 65 | 25 | 62.50% |
| 8 | R-8 | 40 | 40 | 0 | 0.00% |
| 8 | L-8 | 35 | 45 | 10 | 28.57% |
| 9 | R-9 | 20 | 30 | 10 | 50.00% |
| 10 | R-10 | 30 | 35 | 5 | 16.67% |
| 10 | L-10 | 35 | 40 | 5 | 14.29% |
| 11 | R-11 | 40 | 45 | 5 | 12.50% |

| | | | | | |
|----------------------------|--|--------------|--------------|--------------|---------------|
| TOTAL | | 590 | 820 | | |
| AVERAGE OF 18 CASES | | 32.78 | 45.56 | 12.78 | 38.98% |

EXHIBIT II

THE CARPAL SOLUTION
TWO WEEK GRIP STRENGTH
CLINICAL DATA SUMMARY

JAMAR DYNAMOMETER - POSITION # 3

Table 3

| PATIENT NUMBER | HAND ID | GRIP FORCE POUNDS #3 GRIP LOW | GRIP FORCE POUNDS #3 GRIP HIGH | GRIP FORCE POUNDS INCREASE | INCREASE PER PERCENTAGE |
|----------------|---------|-------------------------------|--------------------------------|----------------------------|-------------------------|
| 1 | R-1 | 55 | 75 | 20 | 36.36% |
| 1 | L-1 | 60 | 75 | 15 | 25.00% |
| 2 | R-2 | 35 | 55 | 20 | 57.14% |
| 2 | L-2 | 25 | 40 | 15 | 60.00% |
| 3 | R-3 | 45 | 55 | 10 | 22.22% |
| 3 | L-3 | 25 | 50 | 25 | 100.00% |
| 4 | R-4 | 45 | 70 | 25 | 55.56% |
| 4 | L-4 | 40 | 75 | 35 | 87.50% |
| 5 | R-5 | 20 | 65 | 45 | 225.00% |
| 6 | R-6 | 60 | 75 | 15 | 25.00% |
| 6 | L-6 | 60 | 65 | 5 | 8.33% |
| 7 | R-7 | 70 | 80 | 10 | 14.29% |
| 8 | R-8 | 40 | 55 | 15 | 37.50% |
| 8 | L-8 | 40 | 45 | 5 | 12.50% |
| 9 | R-9 | 40 | 55 | 15 | 37.50% |
| 10 | R-10 | 50 | 55 | 5 | 10.00% |
| 10 | L-10 | 45 | 45 | 0 | 0.00% |
| 11 | R-11 | 60 | 70 | 10 | 16.67% |

| | | | | | |
|----------------------------|--|--------------|--------------|--------------|---------------|
| TOTAL | | 815 | 1105 | | |
| AVERAGE OF 18 CASES | | 45.28 | 61.39 | 16.11 | 35.58% |

EXHIBIT II

THE CARPAL SOLUTION
TWO WEEK GRIP STRENGTH
CLINICAL DATA SUMMARY

JAMAR DYNAMOMETER POSITION # 5**Table 4**

| PATIENT NUMBER | HAND ID | GRIP FORCE POUNDS #5 GRIP LOW | GRIP FORCE POUNDS #5 GRIP HIGH | GRIP FORCE POUNDS INCREASE | INCREASE PER PERCENTAGE |
|----------------|---------|-------------------------------|--------------------------------|----------------------------|-------------------------|
| 1 | R-1 | 45 | 60 | 15 | 33.33% |
| 1 | L-1 | 35 | 60 | 25 | 71.43% |
| 2 | R-2 | 20 | 30 | 10 | 50.00% |
| 2 | L-2 | 15 | 35 | 20 | 133.33% |
| 3 | R-3 | 25 | 40 | 15 | 60.00% |
| 3 | L-3 | 25 | 35 | 10 | 40.00% |
| 4 | R-4 | 35 | 50 | 15 | 42.86% |
| 4 | L-4 | 40 | 60 | 20 | 50.00% |
| 5 | R-5 | 20 | 45 | 25 | 125.00% |
| 6 | R-6 | 40 | 55 | 15 | 37.50% |
| 6 | L-6 | 40 | 50 | 10 | 25.00% |
| 7 | R-7 | 40 | 70 | 30 | 75.00% |
| 8 | R-8 | 35 | 40 | 5 | 14.29% |
| 8 | L-8 | 25 | 35 | 10 | 40.00% |
| 9 | R-9 | 30 | 40 | 10 | 33.33% |
| 10 | R-10 | 35 | 40 | 5 | 14.29% |
| 10 | L-10 | 40 | 40 | 0 | 0.00% |
| 11 | R-11 | 40 | 45 | 5 | 12.50% |

| | | | | | |
|----------------------------|--|--------------|--------------|--------------|---------------|
| TOTAL | | 585 | 830 | | |
| AVERAGE OF 18 CASES | | 32.50 | 46.11 | 13.61 | 41.88% |

EXHIBIT II**THE CARPAL SOLUTION
TWO WEEK GRIP STRENGTH
CLINICAL DATA SUMMARY****SUMMARY OF POSITION: #1, #3, #5 AND PINCH TEST****Table 5**

| PATIENT NUMBER | HAND ID | #1 GRIP PERCENTAGE INCREASE | #3 GRIP PERCENTAGE INCREASE | #5 GRIP PERCENTAGE INCREASE | PINCH PERCENTAGE INCREASE | AVERAGE IMPROVEMENT ALL TESTS |
|----------------|---------|-----------------------------|-----------------------------|-----------------------------|---------------------------|-------------------------------|
| 1 | R-1 | 42.86% | 36.36% | 33.33% | 50.00% | 40.64% |
| 1 | L-1 | 25.00% | 25.00% | 71.43% | 33.33% | 38.69% |
| 2 | R-2 | 50.00% | 57.14% | 50.00% | 20.00% | 44.29% |
| 2 | L-2 | 60.00% | 60.00% | 133.33% | 25.00% | 69.58% |
| 3 | R-3 | 66.67% | 22.22% | 60.00% | 240.00% | 97.22% |
| 3 | L-3 | 100.00% | 100.00% | 40.00% | 83.33% | 80.83% |
| 4 | R-4 | 42.86% | 55.56% | 42.86% | 33.33% | 43.65% |
| 4 | L-4 | 66.67% | 87.50% | 50.00% | 14.29% | 54.62% |
| 5 | R-5 | 80.00% | 225.00% | 125.00% | 71.43% | 125.36% |
| 6 | R-6 | 25.00% | 25.00% | 37.50% | 23.08% | 27.65% |
| 6 | L-6 | 25.00% | 8.33% | 25.00% | 23.08% | 20.35% |
| 7 | R-7 | 62.50% | 14.29% | 75.00% | 41.67% | 48.37% |
| 8 | R-8 | 0.00% | 37.50% | 14.29% | 9.09% | 15.22% |
| 8 | L-8 | 28.57% | 12.50% | 40.00% | 8.33% | 22.35% |
| 9 | R-9 | 50.00% | 37.50% | 33.33% | 20.00% | 35.21% |
| 10 | R-10 | 16.67% | 10.00% | 14.29% | 0.00% | 10.24% |
| 10 | L-10 | 14.29% | 0.00% | 0.00% | 0.00% | 3.57% |
| 11 | R-11 | 12.50% | 16.67% | 12.50% | 10.00% | 12.92% |

| | | | | | | |
|----------------------------|--|---------------|---------------|---------------|---------------|---------------|
| TOTAL | | 768.59% | 830.57% | 857.86% | 705.96% | 790.75% |
| AVERAGE OF 18 CASES | | 42.70% | 46.14% | 47.66% | 39.22% | 43.93% |