

CerviFit® Home Strengthening and Reconditioning Program Study

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7/01/2020

People with work related injuries are the most difficult to treat and tend to have a less favorable outcome compared to the general population. There are several factors for this with the most obvious being patient motivation (or the lack thereof). Other contributing causes include time constraint, delay in initiating treatment, the quality/consistency of physical therapy, and poor coordination of care between providers and the third-party payors.

Neck and upper body pain, including headache and shoulder pain, represent a substantial number of those injured at work. Though the absolute number may not represent the highest percentage of those injured (20% approx.) based on a 2019 Zurich insurance study comprised of a formal analysis of more than 6,000 yearly worker injury claims in the healthcare industry. Representing about \$30 million in annual claim payments, (entitled The Benchmark Study of Healthcare Workers' Compensation Claims Statistics, it tends to be the most protracted in terms of treatment days and missed workdays. The cause for poor treatment outcome is the current treatment modalities are not designed to properly correct the underlying pathophysiological cause of the injury. Correlating this with the fact that 15% of all work-related injuries account for 85% of the costs, affirms that the CerviFit Home Program is both the medical treatment of choice and the financially prudent course of action for this patient type.

The CerviFit Strengthening and Reconditioning Program is unique in its design and treatment platform. By addressing the underlying fundamental cause of these pain types, it improves treatment outcome, motivates patient compliance, improves functionality, and is cost effective to the insurance carrier.

Clinical Criteria for Entry:

All the enrolled WC patients were referred to the neurologist either by a WC PCP or a specialist (typically from an Orthopedist, occasionally the Pain Interventionist) after failing traditional conservative medical care such as physical therapy and medication. Those that were evaluated by at least one specialist prior to the neurological referral had additional treatments such as a change in medications, renewal of therapy, and/or invasive procedures such as cervical epidurals or shoulder injections. Interestingly, none of the patients were seen in the acute phase of the injury, i.e., not before 3 months post event.

The breakdown of patients:

- 24 Males, 20 Females
- Male Population (Yrs. old) 30% (18-32), 60% (33-47), 10% (50-65)
- Female Population (Yrs. old) 35% (18-32) 55% (33-49) 10% (49-72)

Though the chief complaints were neck and upper body pain, there were associated pain symptoms in their shoulder(s) and head and sensory complaints in the extremity(ies). Over three quarters had radicular symptoms at the onset of their injuries (sensory loss, pain, weakness) into one or both upper extremities. The most common reason for the referral from the treating physician to the neurologist was for the diagnosis of headaches. Other diagnoses were neck pain, radiculopathy, and/or vertigo. Any combination of these symptoms, with an abnormal examination were considered appropriate candidates for the CerviFit Home program.

The examination had to demonstrate a decrease in the ROM of the cervical spine by more than 15 degrees in at least 2 out of the 4 planes (typically there were restricted movements in all four movements to varying degrees). Other findings included asymmetrical weakness of the neck muscles, decreased ROM of one or both shoulders, multiple trigger points bilaterally, and neurological deficits (such as radiculopathy, entrapment brachial plexopathies, CTS, dystonia, occipital neuralgia).

Objective Testing:

Once approved for the CerviFit Home Program, each patient's baseline tensile neck strength was measured by a handheld dynamometer (pounds per square inches) with a custom designed head strap.

The neck movements recorded were:

1. Flexion
2. Extension
3. Left lateral extension
4. Right lateral extension

Part of the initial evaluation with the CerviFit Home Program included rating their pain via the VAS (Visual Analog Scale) and their functional limitations based on the Oswestry Neck Disability Index (see the attached questionnaire).

Of note, all patients had an MRI of the Cervical spine prior to starting the CerviFit Program, but the specific pathology on the imaging study was not tabulated with the other indicators, nor were any neuroimaging parameters established. However, any

type of cervical spinal fracture, spinal cord compression, or recent cervical surgery were excluded. The caveat with the latter is the patients with preexisting spinal surgeries were not considered absolute contraindications. If these patients already had physical therapy during their course of treatment, then they were eligible for the CerviFit Program. Those who had surgery subsequent to the CerviFit program, resumed the program once they were cleared by the surgeon to initiate post op physical therapy.

Electro-diagnostic studies were performed on two thirds of those enrolled, (several had this study performed at an outside facility prior to the referral). The findings varied from negative to cervical radiculopathy. These results were not used as a criterion for the CerviFit Home Reconditioning and Strengthening Program so no determination could be made about the effectiveness of the program regarding the neuropathic abnormalities.

Clinical Data:

Over the course of the 10 Week program, the patients were evaluated in the office every two weeks. In addition to the standard clinical evaluation, the physician utilized the VAS for pain, the Oswestry Disability Neck Index, and the dynamometer.

Of the 44 patients, 86% or (38) were compliant with the 10-week treatment program. Two (2) patients had missed or failed to show-up for their follow-up clinical evaluation on a consistent basis, thus rendering them non-compliant. Three had inconsistent results (in conjunction with other clinical factors) and were deemed malingerers. One discontinued use of the program to undergo Chemotherapy for Breast Cancer. One discontinued, to undergo cervical arthroplasty, but restarted the program in the post-acute phase of their rehabilitation.

- 30% of the patients had one or more level disc protrusion as a result of the injury
- 35% had preexisting chronic pathological changes in the cervical spine or in the shoulder
- 64% of the patient population studied had cervicogenic headaches and 5% had exacerbations of preexisting migraines
- 52% had shoulder pain, typically diagnosed with impingement syndrome.
- All had asymmetric weakness of the cervical neck muscles with weakness in all planes of movement per the dynamometer.

Of those patients who were compliant with the program, all had improvement clinically. Their overall cervicogenic pain improved based on their VAS (Visual Analog Scale) and improved functionality per the Oswestry Index.

Clinical Results At The End Of The Program:

- Overall, there was a 28% improvement in tensile strength in the compliant patients with 57% (25 people) experiencing an average 40% improvement.
- The average reduction on the Oswestry Index Scale was 8 points with 70% converted from moderate to mild disability.
- The VAS was decreased from 7 to 3.5 on average, though the maximum pain during an exacerbation was reduced by 2 points in the majority of patients.
- All the compliant patients continued to use the CerviFit device at the completion of the study. Most stayed at the 1-to-2-pound weights.
- There were no injuries or complications with the device. Initially a few had recurrence of their pain as they did not understand the principle, technique, or follow the proper exercise instructions of the program.

Conclusion:

All the enrolled patients in the CerviFit Program had been refractory to the standard treatment currently practiced by the medical community in the Workman's Compensation arena. The number of patients who had a positive response, and their success rate, was higher than anticipated. The reason for this was multi-factorial. The patients had input and control in their care, received tangible feedback every two weeks over the course of the program, and expressed improved quality of life as documented by the Oswestry Index scale.

Additionally, Workman's Compensation insurance carriers have the ability to discharge a patient if noncompliance is documented. The physician was able to confirm noncompliance in four patients and all treatment was immediately terminated.

A larger study is needed to determine what factors influence clinical outcome such as underlining pathology, job description and time of onset to treatment with the overall goals of reducing the number of medications such as opiates, and the recurrence rate of exacerbations. Other diagnostic tests such as electrodiagnostic studies, X rays, and neuroimages and neuropsychological evaluations need to be included to determine which abnormalities are predictors of outcome and functionality.

CerviFit Device



Dynamometer



Dr. Jeffrey Steinberg is a Board-Certified Neurologist with over 25 years of clinical experience. Dr. Steinberg completed his residency at Kaiser Permanente Los Angeles University of California, Davis, an Interventional Pain Fellowship at University of Louisville, (Veterans Administration) and Neurophysiology/Sleep Fellowship at Emory University. Dr. Steinberg is the Founder of the Headache and Pain Center of South Florida with a focus on Patient-Centric Care.

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SAMPLE NECK Pain and Disability Questionnaire

Rate the severity of your pain by circling one number: (No Pain) 0...1...2...3...4...5...6...7...8...9...10 (Excruciating Pain)

This questionnaire has been designed to give the doctor information as to how your neck pain has affected your ability to manage everyday life. Read through each section and check only ONE line that applies to you. You may find that two of the statements in a section relate to you, but please **just check ONE line** that best describes your current predicament.

Section 1– Pain Intensity

- I have no pain at the moment.
- The pain is very mild at the moment.
- The pain is moderate at the moment.
- The pain is fairly severe at the moment.
- The pain is very severe at the moment.
- The pain is the worst imaginable at the moment.

Section 2– Personal Care (washing, dressing, etc.)

- I can look after myself normally without causing extra pain.
- I can look after myself normally but it causes extra pain.
- I am slow and careful because it is painful for me to look after myself.
- I need some help but manage most of my personal care.
- I need help every day in most aspects of care.
- I do not get dressed, I wash with difficulty and stay in bed.

Section 3– Lifting

- I can lift heavy weight without extra pain.
- I can lift heavy weight but it causes extra pain.
- I cannot lift heavy weight off the floor, but I can manage if they are conveniently positioned like on a table.
- I cannot lift heavy weight, but I can manage light to medium weights if they are conveniently positioned.
- I cannot lift any weight due to neck pain.

Section 4– Reading

- I can read as much as I want to with no pain in my neck.
- I can read as much as I want to with slight neck pain.
- I can read as much as I want to with moderate neck pain.
- I cannot read as much as I want to due to moderate neck pain.
- I can hardly read at all because of severe neck pain.

Section 5– Headaches

- I have no headaches at all.
- I have slight headaches that occur infrequently.
- I have moderate headaches that occur infrequently.
- I have frequent moderate headaches.
- I have frequent severe headaches.
- I have severe headaches all the time.

Section 6- Concentration

- I can concentrate fully when I want to with no difficulty.
- I can concentrate fully when I want to with slight difficulty.
- I have a fair degree of difficulty in concentrating when I want to.
- I have a great deal of difficulty in concentrating when I want to.
- I cannot concentrate at all.

Section 7- Work

- I can do as much work as I want to.
- I can only do my usual work, but no more.
- I can do most of my usual work, but no more.
- I cannot do my usual work.
- I can barely do any work at all.
- I cannot do any work at all.

Section 8- Driving

- I can drive my car without any neck pain.
- I can drive my car as long as I want with slight neck pain.
- I can drive my car as long as I want with moderate neck pain.
- I cannot drive my car as long as I want.
- I can hardly drive at all because of severe neck pain.
- I cannot drive my car at all.

Section 9- Sleeping

- I have no trouble sleeping.
- My sleep is slightly disturbed (less than 1 hour sleepless)
- My sleep is mildly disturbed (1 hour sleepless)
- My sleep is moderately disturbed (2 to 3 hours sleepless)
- My sleep is greatly disturbed (4 to 5 hours sleepless)
- My sleep is completely disturbed (6 to 7 hours sleepless)

Section 10- Recreation

- I am able to engage in all my recreation activities with no neck pain.
- I am able to engage in all my recreation activities with some neck pain.
- I am able to engage in most, but not all of my usual recreation activities.
- I am able to engage in a few of my usual recreation activities.
- I can hardly do any recreation activities.
- I cannot do any recreation activities due to neck pain.

Patient Name (Print)

Patient Signature

Date

FOR OFFICE USE ONLY:

Total Points $\times 2 =$ _____
Disability Percentage Rating Scale