Dextrose Prolotherapy For Unresolved Neck Pain

An observational study of patients with unresolved neck pain who were treated with dextrose prolotherapy at an outpatient charity clinic in rural Illinois.

Dr. Hauser has been doing prolotherapy on patients for over 15 years and has treated thousands of arthritic knees, backs, necks, and other joints with remarkable success. In this study, 97 out of 98 patients with chronic neck pain—including subsets of patients who had exhausted all other options (43) or were told by their doctors that surgery was the only option (21)—showed substantial improvement in numerous outcome measures. The improvements in these patients continued through follow up—18 months after conclusion of prolotherapy treatments—and demonstrates the efficacy of this treatment modality.

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By Ross A. Hauser, MD and Marion A. Hauser, MS, RD

Neck pain is a common condition affecting about 10% of the general population of North America at any given time, over a year up to 45%, and over a lifetime 70%.[1-3] Neck pain results in a significant amount of disability and health care use in the United States, with large personal and economic consequences.[4,5] As the duration of neck symptoms increases, especially beyond six months, one's mental health is negatively affected. Younger patients are more impacted by neck and referral arm symptoms more than older patients.[6] It is well documented that the longer the pain persists, the more likely it will become chronic—with up to 7% of patients ending up with chronic neck pain.[7,8]

While there is some consensus on how to treat acute painful neck episodes, there is much debate on how to treat chronic neck pain. Most monotherapies either do not work or have limited efficacy.[9] Non-steroidal anti-inflammatory drugs and anti-depressants have some short term benefit but no published data vindicate their long-term use.[10] Manipulative therapy, physiotherapy, and massage therapy all show some temporary benefit but do little to curb long-term pain.[11,12,13] Some people turn to more invasive therapies like percutaneous radiofrequency neurotomy or surgery, but long-term results have been poor and surgeries are fraught with complications.[14-17] Because of the limited response to traditional therapies, many people are turning to alternative therapies including prolotherapy for pain control.[18-20]

Prolotherapy is becoming a widespread form of pain management in both complementary and allopathic medicine.[21,22] Its primary use is in pain management associated with tendinopathies and ligament sprains in peripheral joints.[23-25] It is also being used in the treatment of spine and joint degenerative arthritis.[26,27] Prolotherapy has long been used for chronic low back pain arising from the sacroiliac joints and as an alternative to surgery.[28-30] Prolotherapy has been shown in low back studies to improve pain levels and range of motion.[31,32] In double-blinded human studies, the evidence on the effectiveness of prolotherapy has been considered promising but mixed.[33-36]

Current conventional therapy for unresolved neck pain include: medical treatment with analgesics, non-steroidal anti-inflammatory drugs, anti-depressant medications, epidural or other steroid shots, trigger point injections, muscle strengthening exercises, physiotherapy, weight loss, rest, massage therapy, intradiscal electrothermal therapy, manipulation, neck braces, implanted spinal cord stimulators or morphine pumps, surgical treatments that range from disc replacements to fusions, multidisciplinary group rehabilitation, education, and counseling. The results of such therapies often leave the patients with residual pain.[9-17] Because of this, many patients with chronic neck pain are searching for alternative treatments for their pain.[18] One of the treatments they find promising is prolotherapy.[37]

Background

Prolotherapy is the injection of a solution for the purpose of tightening and strengthening weak tendons, ligaments or joint capsules. Prolotherapy works by stimulating the body to repair these soft tissue structures. It starts and accelerates the inflammatory healing cascade by which fibroblasts proliferate. Fibroblasts are the cells through which collagen is made and by which ligaments and tendons repair. Prolotherapy has been shown in one double-blinded animal study over a six-week period to increase ligament mass by 44 percent, ligament thickness by 27 percent, and the ligament-bone junction strength by 28 per-

cent.[38] In human studies on prolotherapy, biopsies performed after the completion of treatment showed statistically significant increases in collagen fiber and ligament diameter of 60 percent.[39,40] Fluoroscopically-guided cervical prolotherapy for instability has shown statistically significant results in regard to pain relief and correlates with improvements in the instability with blinded pre- and post-radiographic readings.[41] Prolotherapy for chronic spinal pain and the neck has also been shown to improve one's ability to work.[42]

George S. Hackett, MD, coined the term prolotherapy.[43] As he described it, "The treatment consists of the injection of a solution within the relaxed ligament and tendon which will stimulate the production of new fibrous tissue and bone cells that will strengthen the 'weld' of fibrous tissue and bone to stabilize the articulation and permanently eliminate the disability."[44] Animal studies have shown that prolotherapy induces the production of new collagen by stimulating the normal inflammatory reaction.[45,46] In addition, animal studies have shown improvements in ligament and tendon diameter and strength.[47,48] Dr. Hackett himself reported good to excellent results in 90% percent of 82 consecutive patients he treated with neck and/or headache pain using prolotherapy. He surmised the neck pain and referral headaches were from ligament damage from whiplash-type injuries.[49,50] Dr. Kayfetz and associates confirmed these results in a similar group of patients.[51,52] Recent research, using flexion/extension x-rays to document cervical spine instability and fluoroscopically-guided cervical prolotherapy, demonstrated statistically significant correlations between a reduction in both cervical flexion and extension translation and improvement in the patients pain level.[37] While these results are promising, they looked primarily at neck pain control.

The observational study described in this article was undertaken to evaluate the effectiveness of Hemwall-Hackett dextrose prolotherapy not just for neck pain but also quality of life measures.

Patients and Methods

Framework and Setting. In October 1994, the primary authors (R.H., M.H.) started a Christian charity medical clinic called Beulah Land Natural Medicine Clinic in an impoverished area in southern Illinois. The primary modality of treatment offered was Hemwall-Hackett dextrose prolotherapy for pain control. Dextrose was selected as the main ingredient in the prolotherapy solution because it is the most common proliferant used in prolotherapy, is readily available, is inexpensive when compared to other proliferants, and has a high safety profile. The clinic met every three months starting in 2000 until July 2005. All treatments were given free of charge.

Patient Criteria. General inclusion criteria include being at least 18 years old, having an unresolved neck pain condition that typically responds to prolotherapy, and a willingness to undergo at least four prolotherapy sessions (unless the pain remitted with a lesser number of sessions).

Interventions. Each patient received 40 to 70 injections of a 15% dextrose, 0.2% lidocaine solution with a total of 30 to 60 cc of solution used per neck and upper back. Injections were given into and around the back of the head, neck and upper back. The typical spots injected each with 0.5 to 1cc of solution are illustrated in Figure 1. Tender areas injected included the superior and inferior nuchal ridge, occiput, mastoid process, facet joints, transverse processes, supraspinous processes, scapular border, and clavicle. Typically the attachment of the suboccipital muscles, upper trapezius, levator scapulae, and vertebral ligaments were injected. No other therapies were used. The patients were asked to cut down or stop other pain medications and therapies they were using as much as the pain would allow.

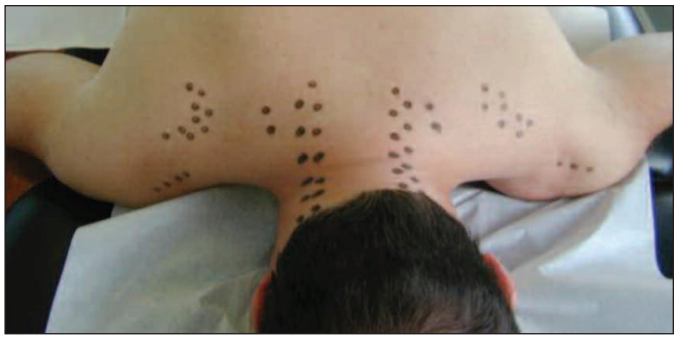


FIGURE 1. *Typical Injection Sites for Hemwall-Hackett Dextrose Prolotherapy of the Neck*

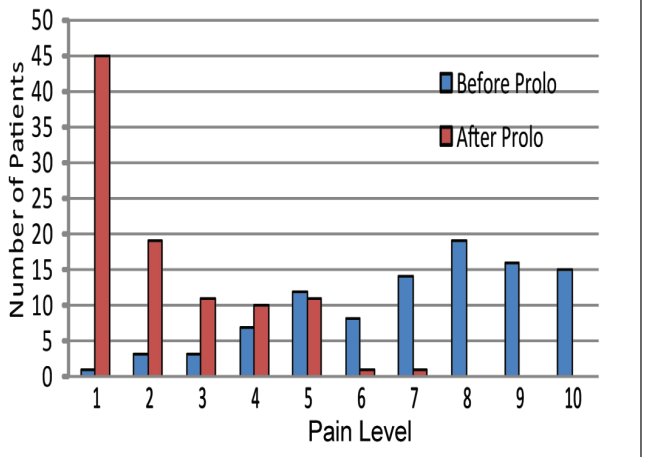
Data Collection. Patients were called by telephone and interviewed by a data collector (D.P.) who had no prior knowledge of prolotherapy both before and after conclusion of treatments. D.P. was the sole person obtaining the patient information during the telephone interviews. The patients were asked a series of detailed questions about their pain and previous treatments before starting prolotherapy. Their response to prolotherapy treatments was also documented in detail with an emphasis on the effect the treatments had on their need for subsequent pain treatments and their quality of life. Specifically, patients were asked questions concerning years of pain, pain intensity, overall disability, number of physicians seen, medications taken, stiffness, walking and exercise ability, activities of daily living, quality of life concerns, and psychological factors. Also noted was whether the post-treatment benefits continued substantially after the sessions concluded.

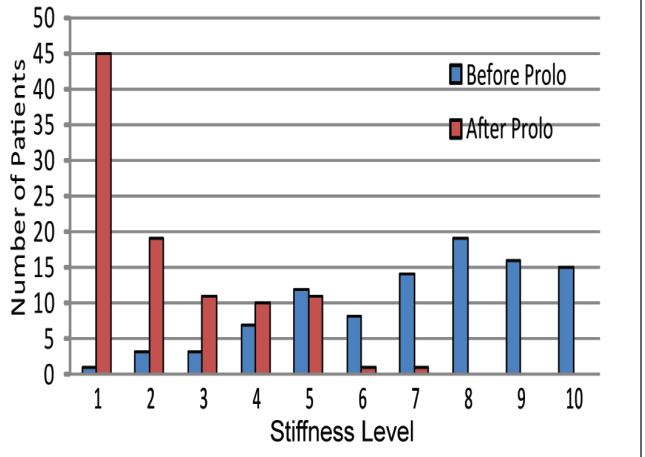
Statistical Analysis. For the analysis, patient percentages of the various responses were calculated. These responses gathered from clients before prolotherapy were then compared with the responses to the same questions after treatment.

Patient Characteristics. From a total of 133 patients eligible for the study, complete data was obtained on a total of 98 patients who met the inclusion criteria. Of those excluded, the main reasons for were:

- inability to come for treatments primarily because of travel/distance/scheduling (38%),
- stopped treatments because of MD recommendation (i.e. needed treatments more frequently), other medical problems, or of their own volition (24%),
- inability or unwillingness to answer survey (9%),
- had prolotherapy treatments at other locations (6%), and
- other (23%).

Of the 98 study participants, 70% (69) were female and 30% (29) were male. The average age was 55 years-old. Patients re-





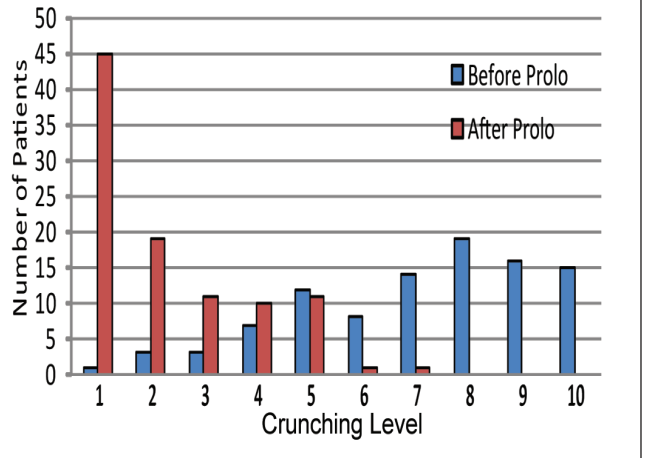


FIGURE 2. *Starting and ending pain, stiffness and crunching level before and after receiving Hemwall-Hackett dextrose prolotherapy in 98 patients with unresolved neck pain.*

Table 1: Patient Characteristics

Total Number of Patients	98
Female	70%
Male	30%
Average Age of Patient	55 years old
Average pain > 4 years	58%
Average pain > 6 years	42%
Average number of M.D.'s	4
Surgery was only option to chronic pain	21%
No other treatment options available for chronic pain	44%
Taking 1 pharmaceutical drug for pain	23%
Taking 2 or more pharmaceutical drugs for pain	33%

ported an average of 4.9 years of pain. Fifty eight percent had pain longer than four years and 42% had pain longer than six years. The average patient saw 4 medical doctors before receiving prolotherapy. Twenty-one percent stated that the consensus of their medical doctor(s) was that surgery was the only answer to their pain problem and 44% of patients were told by their physicians that there were no other treatment options for their chronic pain. Twenty-three percent were taking one pharmaceutical drug, while 33% were taking two or more drugs for pain (see Table 1).

Treatment Outcomes

Patients received an average of 4.2 prolotherapy treatments. The average time of follow-up after their last prolotherapy session was 18 months.

Pain, Crunching Sensation, Stiffness. Patients were asked to rate their pain and stiffness on a scale of 1 to 10, with 1 being no pain/stiffness and 10 being severe, crippling pain/stiffness. The 98 patients had an average starting pain level of 5.6, crunching sensation of 5.1, and stiffness of 6.7. Their average ending pain, crunching and stiffness levels were 2.3, 2.1, and 2.4 respectively (see Figure 2). Over seventy percent said the improvements in their pain, crunching, and stiffness since their last treatment session had very much continued. Eighty-nine percent of patients reported that pain relief was at least 50% of their pain while 60% reported greater than 75% pain relief. Only one patient had less than 25% of their pain relieved with prolotherapy.

Range of Motion. Patients were asked to rate their range of motion on a scale of 1 to 7 with 1 being no motion, 2 through 5 were fractions of normal motion, 6 was normal motion, and 7 was excessive motion. The average starting range of motion was 3.9 and ending range of motion was 5.1. Before prolotherapy, 38% had very limited motion (49% or less of normal motion). This decreased to only 2% after treatments were concluded (see Figure 3).

Pain Medication Utilization. Seventy two percent discontinued pain medications altogether after prolotherapy. In all, 83% of patients on medications at the start of prolotherapy were able to decrease them by 75% or more. None of the patients had to increase pain medication usage after stopping prolotherapy. Seventy-eight percent of patients who had been using addition-

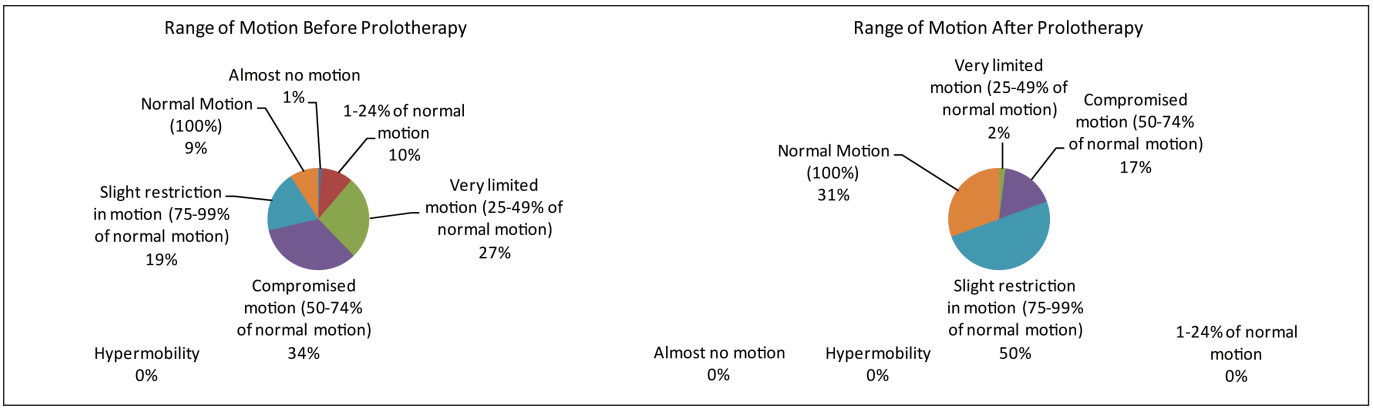


FIGURE 3. *Starting and ending range of motion before and after receiving Hemwall-Hackett dextrose prolotherapy in 98 patients with unresolved neck pain.*

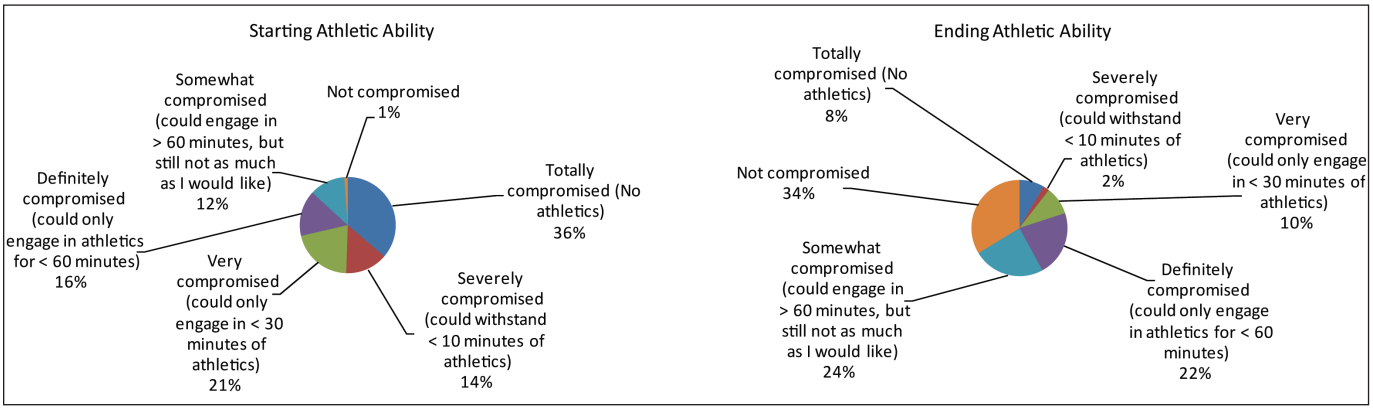


FIGURE 4. *Starting and ending and Improvement in athletic ability before and after receiving Hemwall-Hackett dextrose prolotherapy in 98 patients with unresolved neck pain.*

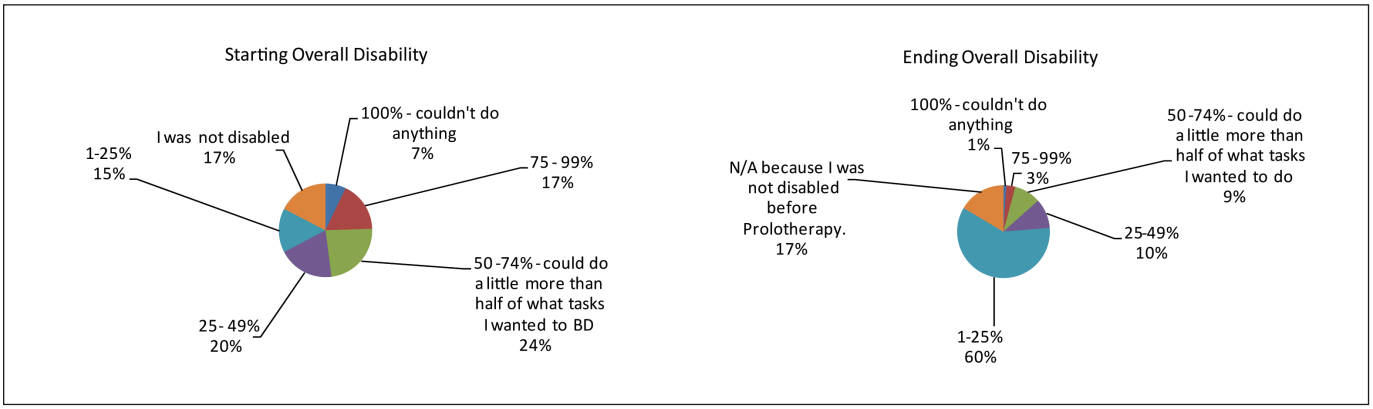


FIGURE 5. *Starting and ending overall disability before and after receiving Hemwall-Hackett dextrose prolotherapy in 98 patients with unresolved neck pain.*

al pain management therapies before prolotherapy were able to decrease them by 50% or more after.

Exercise and Athletic Ability. In regard to exercise or athletic ability prior to prolotherapy, 36% said it was totally compromised (couldn't do any athletics), 14% ranked it as severely compromised (less than 10 minutes), 21% ranked it as very compromised (less than 30 minutes), and 28% ranked it as at least somewhat compromised. After treatments, 80% of patients were able to do 30 or more minutes of exercise with 34% not being compromised at all. Eighty percent of the patients stated that the improvements in regard to exercise ability had continued with an over 75% improvement (see Figure 4).

Disability. In regard to quality of life issues prior to receiving treatment, 48% had an overall disability of at least 50% (could only do about half of the tasks they wanted to). This decreased to 13% after prolotherapy. Sixty-eight percent noted they had at least a 25% overall disability prior to treatments and this decreased to 23% after (see Figure 5).

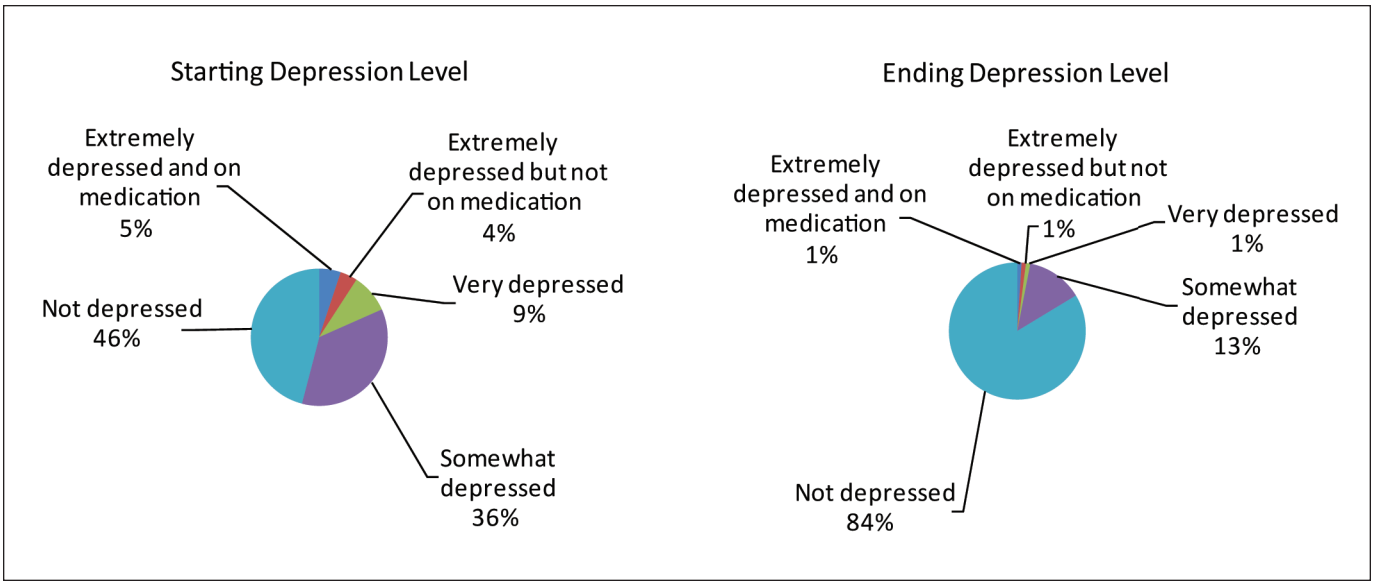


FIGURE 6. *Starting and ending depression level before and after receiving Hemwall-Hackett dextrose prolotherapy in 98 patients with unresolved neck pain.*

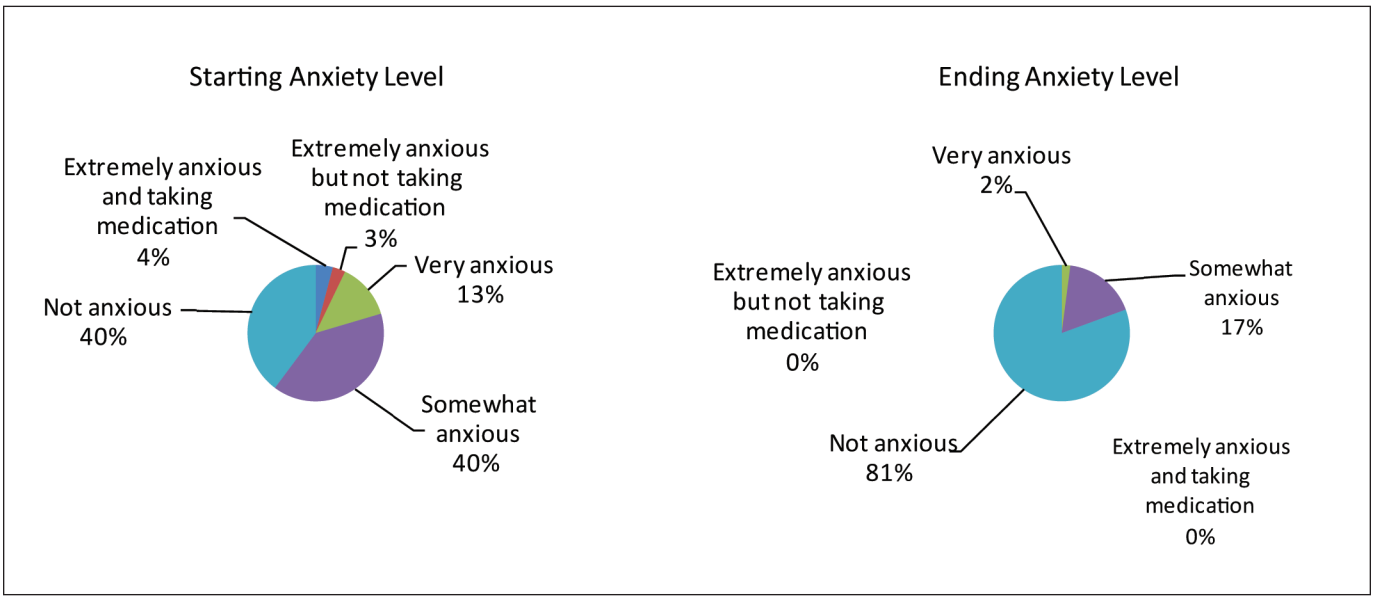


FIGURE 7. *Starting and ending anxiety level before and after Hemwall-Hackett dextrose prolotherapy in 98 patients with unresolved neck pain.*

Before receiving prolotherapy, 14% of the patients were dependent on someone for activities of daily living (dressing self and additional general self care) with 12 patients that rated their dependency on someone else as greater than minimum assist (25% or greater assist). This went down to 4% after treatments with only one patient needed that much assistance after treatment. Sixteen percent of patients had some prior dependency in activities of daily living but this went down to 6% after prolotherapy. Fourteen percent had considered themselves completely disabled as far as their work situation but this decreased to 6% after prolotherapy. All patients stated these improvements had continued since conclusion of prolotherapy sessions.

Depression & Anxiety. Prior to prolotherapy, 54% of patients had feelings of depression and 60% had feelings of anxiety. After treatments, only 16% had depressed feelings and 19% had feelings of anxiety (see Figures 6 and 7). According to the patients, 78% of the improvements in depression and anxiety had continued and that a greater than 75% improvement remains at follow up.

Sleep. Eighty percent of patients reported their pain interrupted their sleep prior to prolotherapy treatments and 88% subsequently had improvements in their sleeping ability. Seventy five percent of patients stated that improvement had continued with a greater than 50% improvement still remaining at follow up.

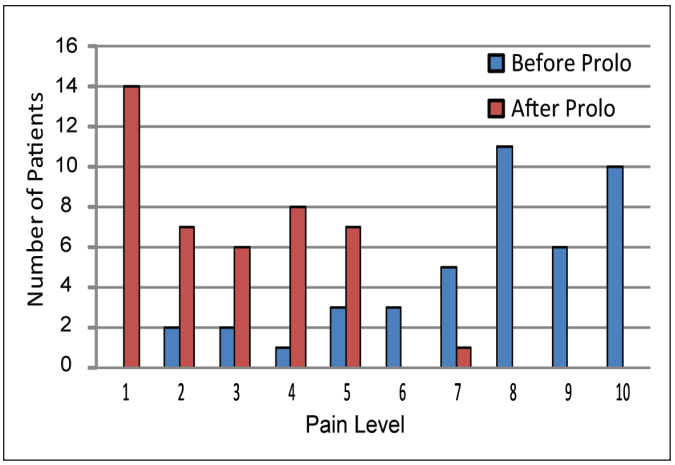


FIGURE 8. *Starting and ending pain level before and after Hemwall-Hackett Prolotherapy in 43 Patients that were Told there No Other Option for their Pain.*

Quality of Life. To a simple yes or no question: 'Has prolotherapy changed your life for the better?' 97% of patients treated answered 'yes.' In quantifying the response:

- Seventy-four percent felt their life was at least very much better from prolotherapy.
- Sixty-nine percent stated that the results from prolotherapy have very much continued to this day.
- Ninety-five percent felt that they still have some benefits from the prolotherapy they received.

When patients experiencing some regression were asked "Are there reasons besides the prolotherapy effect wearing off that are causing some return of my pain/disability?' 84% answered 'yes'. The patients noted the reasons for some of their returning pain were:

- because stopped prolotherapy treatments too soon (before pain completely gone) — 45%,
- re-injury — 21%
- new area of pain — 10%
- had increased life stressors — 6%, and
- had other explanations for the pain — 18%.

Of the patients whose pain recurred after prolotherapy was stopped, 77% were planning on receiving additional prolotherapy treatments.

Patient Satisfaction. Ninety-three percent of patients knew someone who had received prolotherapy. In fact, seventy-one percent came to receive their first prolotherapy session at the recommendation of a friend. Ninety percent of patients treated considered the prolotherapy treatment to be very successful (greater than 50 percent pain relief). Ninety-nine percent noted the prolotherapy was at least somewhat successful (greater than 25 percent pain relief). Only one of the 98 patients noted that there was no change. None indicated that the prolotherapy treatments made them worse. Ninety-nine percent had subsequently recommended prolotherapy to someone.

Subgroup Analysis

Patient percentages were also calculated for patients who answered "yes" to either of the following two statements:

1) "Before starting prolotherapy it was the consensus of my medical doctor(s) that there were no other treatment options that he/she knew of to get rid of my chronic pain." and

2) "Before starting prolotherapy my only other treatment option was surgery."

A matched sample test was used to calculate the difference in responses for all patients between the before and after dextrose prolotherapy measures for pain, crunching sensation, and stiffness in the above two subgroups. Using the matched sample test on all two variables, all p values reached statistical significance at the 1% level. The p values for pain and stiffness were all 0, as some of them were to the 28th decimal.

Outcome Measures	Starting	Ending
Average pain level	7.5	2.7
Percentage of patients w/ pain level 8 or greater	63%	0%
Percentage of patients w/ pain level 3 or less	9%	63%
Average stiffness level	6.8	2.5
Average crunch level	6.3	2.6
Patients with 75% or greater range of motion	26%	74%
Patients able to do at least 50% of tasks they wanted to do	42%	86%
Patients with less than half of normal neck motion	74%	26%
Patients with 75%-99% or normal motion	26%	75%
Inability to exercise	36%	7%
Uncompromised ability to exercise	5%	75%
Patients felt at least some depression	65%	21%
Patients felt at least some anxiety	65%	30%

TABLE 2. *Summary of outcome measures for the 43 patients who had been advised by their doctors that no other treatment options were available for their condition prior to undergoing prolotherapy treatment.*

'**No Other Treatment Options**' **Subgroup.** Forty-three patients had been told by their doctors that there were no other treatment options for their pain prior to presenting for prolotherapy. Forty-seven percent of these patients had pain greater than 6 years and 67% had pain greater than 4 years. Table 2 presents a summary of outcomes at follow up for this subgroup.

Ninety-three percent of these 43 patients noted that prolotherapy treatments gave them greater than 50% pain relief with 58% of them receiving 75% or greater pain relief (see Figure 8). One hundred percent of them had 25% or greater pain relief. Eighty-six percent of those on medications were able to decrease them by 75% or more after prolotherapy. Forty percent were able to get off of prescription medications completely for pain. In response to the question 'Has prolotherapy changed your life for the better?' 95% answered 'yes.' All 43 of them have recommended prolotherapy to someone else. In this group of 43 patients, 91% noted that their overall results from prolotherapy have mostly continued to this day (greater than 50%).

'**Surgery Is Only Treatment Option**' **Subgroup.** Twenty-one patients had been told by their doctors that there were no other

Outcome Measures	Starting	Ending
Average pain level	6.6	2.1
Average stiffness level	6.3	2.3
Average crunch level	4.3	2.0
Patients with 75% or greater range of motion	29%	86%
Can only exercise 30 minutes or less	86%	19%
Patients felt at least some depression	43%	19%
Patients felt at least some anxiety	38%	10%
Feeling disability - free	5%	76%

TABLE 3. *Summary of outcome measures for the 21 patients who had been advised by their doctors that surgery was their only treatment option prior to undergoing prolotherapy treatment.*

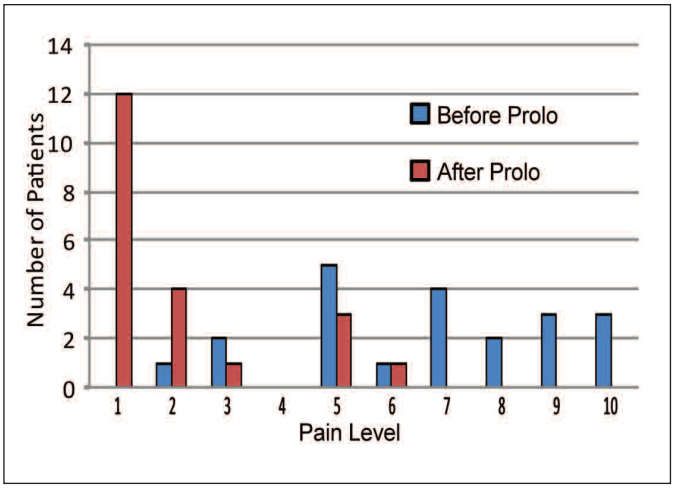


FIGURE 9. *Starting and ending pain level before and after Hemwall-Hackett Dextrose Prolotherapy in 21 Patients that were told there was no treatment option other than surgery.*

treatment options for their pain prior to presenting for prolotherapy. Ninety percent had pain greater than two years with forty-eight percent having pain greater than four years. Eighty-six percent had seen two or more medical doctors. Table 3 presents a summary of outcomes at follow up for this subgroup.

Eighty-one percent of this group of 21 experienced a pain level of 3 or less after prolotherapy (see Figure 9). All pain, stiffness and crunching level improvements reached statistical significance. Sixty-one percent stated they had greater than 75% pain relief and a full 90% (19 of 21) had 50% or greater pain relief with prolotherapy. Eighty-six percent noted they could only exercise thirty minutes or less before prolotherapy but after prolotherapy the percentage decreased to 19% (see Figure 10).

One hundred percent of patients taking pain medication were able to decrease their dosage by 50% or more. Forty-eight percent were able to get off of pain medications all together. The need for additional pain management care also lessened by 50% or more in 81% of the patients after prolotherapy.

Ninety-five percent of these patients stated that their pain was at least somewhat better due to prolotherapy. 50% noted that they were radically better. All twenty-one (100 percent) of the patients knew someone who was helped with prolotherapy and have recommended prolotherapy to someone else. Eight-one percent felt that their lives were very much better because of prolotherapy. All one hundred percent said that prolotherapy changed their life for the better.

Principle Findings. The results of this retrospective, uncontrolled, observational study, show that prolotherapy helps decrease pain and improve the quality of life of patients with unresolved neck pain. Decreases in pain, stiffness, and crunching levels reached statistical significance even in patients whose medical doctors said there were no other treatment options for their neck pain or that surgery was their only option. Sixty percent of patients had greater than 75% of their pain relieved with prolotherapy and 91% of percent of patients stated prolotherapy relieved them of at least 50% of their pain. More than 80% showed improvements in walking ability, exercise ability, anxiety, depression, and overall disability with prolotherapy. Ninety percent of patients who were on medications were able to cut their medication usage by 50% or more after treatment. They were able to lessen additional pain management care by 50% or more in 75% of cases. Ninety-eight percent of patients stated their pain was dcreased with prolotherapy. Ninety seven percent said that dextrose prolotherapy changed their life for the better.

Study Strengths and Weaknesses. Our study cannot be compared to a clinical trial in which an intervention is investigated under controlled conditions. Instead, its aim was to document the response of patients with unresolved neck pain to the Hemwall-Hackett technique of dextrose prolotherapy. Clear strengths of the study are the numerous quality of life parameters that were studied. Quality of life issues such as walking ability, stiffness, range of motion, activities of daily living, athletic (exercise) ability, dependency on others, work ability, sleep, anxiety and depression—in addition to pain level—are important factors affecting the person with unresolved neck pain. Decreases in medication usage and additional pain management care were also documented. The improvement in such a large of percentage of study subjects who were treated solely by prolotherapy is likely to have resulted from that treatment. Many of the above parameters are objective outcomes with progress noted in the increased ability to walk, exercise, work, and the need for less medications or other pain therapies.

The quality of the cases treated in this study is notable. The average person in this study had unresolved neck pain for 4.9 years and had seen four physicians prior to prolotherapy treatment. Sixty-four (65%) of the patients were either told by their medical doctors that there was no other treatment option for their pain or that surgery was their only option. So clearly this patient population represented chronic unresponsive neck pain. Having a follow-up time of eighteen months, on average, since their last treatment session provided a measure of the long-lasting effect of this modality.

Because this was a charity medical clinic with limited resources and personnel, the only therapy offered was prolotherapy treatments given every three months. In private practice, the Hemwall-Hackett technique of dextrose prolotherapy is typical-

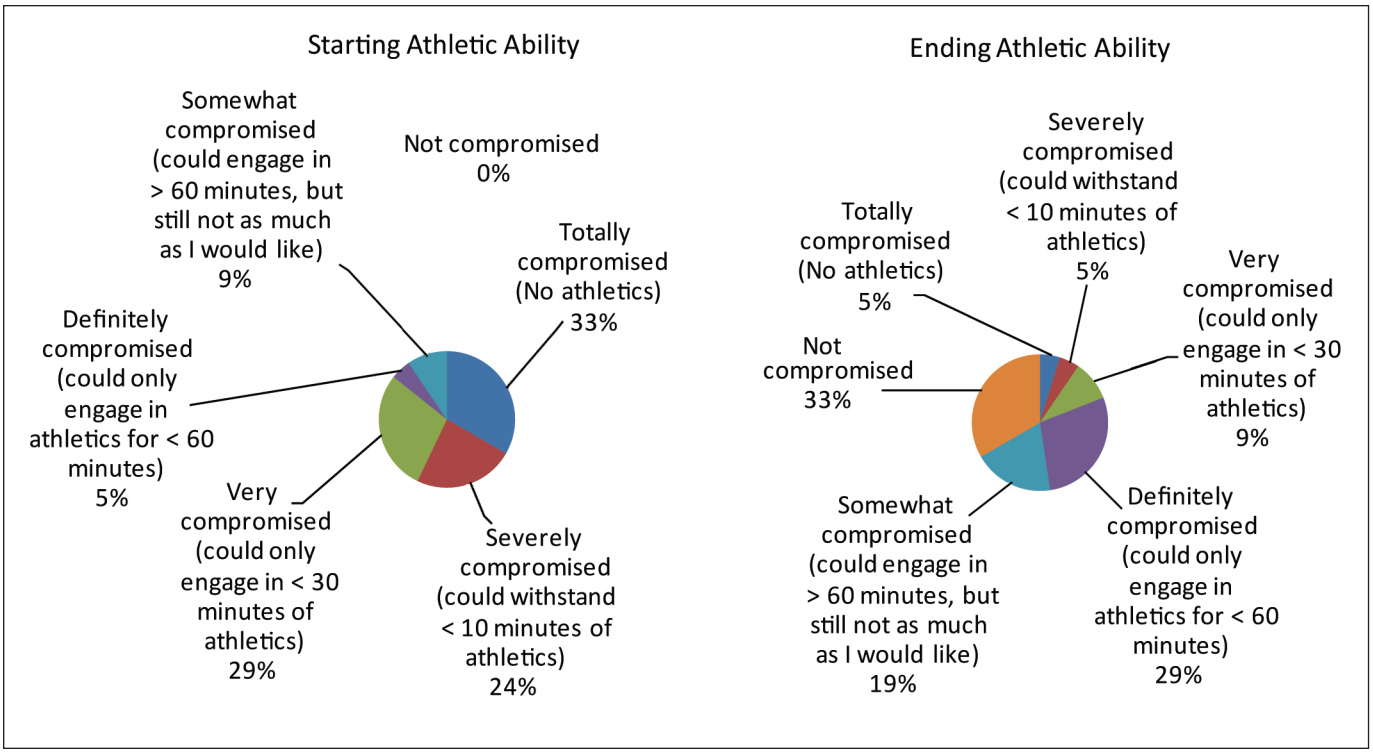


FIGURE 10. *Starting and ending athletic (exercise) ability before and after Hemwall-Hackett dextrose prolotherapy in 21 patients that were told there was no other treatment option other than surgery.*

ly given every four to six weeks. If a client is not improving or has poor healing ability, the prolotherapy solutions may be changed and strengthened or the client is advised about additional measures to improve their overall health. This can include advice on diet, supplements, exercise, weight loss, changes in medications, additional blood tests, and other medical care. Often clients are weaned immediately off any anti-inflammatory and narcotic medications that inhibit the inflammatory response that is needed to get a healing effect from prolotherapy. Since none of these were done in this study, the results of this study are expected to be least optimum level of success achievable with Hemwall-Hackett dextrose prolotherapy. This makes the results even that much more impressive.

A shortcoming of our study is the subjective nature of some of the evaluated parameters. Subjective parameters of this sort included pain, anxiety, depression, and disability levels. The results relied on the answers to questions by the patients. Another shortcoming is that any additional pain management care that they may have been receiving was not controlled. There was also a lack of X-ray and MRI correlation for diagnosis and response to treatment. A lack of physical examination documentation in the patients' chart made categorization of the patients into various diagnostic parameters impossible.

Interpretation of Findings. While the exact cause of chronic neck pain is still debated, this study did show that the Hemwall Hackett technique of dextrose prolotherapy improves not only the pain level and work ability of those with chronic neck pain, but also a host of other quality of life measures. The Hemwall Hackett technique of dextrose prolotherapy to the neck involves injections into all the various trigger points in the neck. Specifically, in this study, injections were given at the fibro-osseous junction of various soft tissues that attach to the superior and inferior nuchal ridge, greater occipital protuberance, as well as the cervical facets and transverse processes. The posterolateral clavicle and superior medial border of the scapula were also injected. It is this thoroughness in each treatment that most likely is responsible for the significant improvements in this patient population, with a statistically significant decline in their unresolved neck pain, stiffness, and crunching sensation.

Conclusions

The Hemwall-Hackett technique of dextrose prolotherapy used on patients who presented with almost five years of unresolved neck pain were shown in this observational study to improve their quality of life even eighteen months subsequent to their last prolotherapy session. With one exception, all patients reported significantly reduced levels of pain, stiffness, crunching sensation, disability, depressed and anxious thoughts, medication, and other pain therapy usage. They also reported improved walking ability, range of motion, sleep, exercise ability, and activities of daily living. The results confirm that prolotherapy is a treatment that should be highly considered for people suffering with unresolved neck pain. ■

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headed the writing of a 900-page epic sports book that discusses the use of prolotherapy for sports injuries, "Prolo Your Sports Injuries Away! Curing Sports Injuries and Enhancing Athletic Performance with Prolotherapy."

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