

FANTASTIC FINDINGS

Dextrose Prolotherapy for Unresolved Low Back Pain: A Retrospective Case Series Study

Ross A. Hauser, MD & Marion A. Hauser, MS, RD

Introduction

Low back pain is one of the leading causes of physical limitation and disability in the United States today. Each year, 65,000 patients are permanently disabled by conditions associated with back pain, and 80% of the U.S. population is estimated to suffer back pain at some point in their lives.^{1,2} Though acute back pain is believed to be self-limiting, it recurs at a rate of approximately 90%.³ In one study, only 25% of the patients who consulted a general practice about low back pain had fully recovered 12 months later.⁴ For those who do recover, relapses can be frequent and severe, with two to seven percent developing chronic pain.⁵

There is some consensus in the medical community on how to treat acute low back pain, but treatment of chronic pain presents many challenges and little agreement on standard of care. Nonsteroidal anti-inflammatory drugs and antidepressants provide some short-term benefit, but no published data warrant their long-term use.⁶ Manipulative therapy, physiotherapy, and massage therapy studies have also shown only temporary benefit.^{7,8} Long-term results on more invasive therapies, such as intradiscal electrothermal therapy (IDET) or surgery, have been poor.^{9,10} Some believe the poor results for the treatment of chronic low back pain stem from the fact that too much emphasis has been placed on pain arising from the intervertebral discs and not enough on chronic low back pain originating from the sacroiliac joint and ligaments.^{11,12} Because of the limited response to traditional therapies, many people have looked to other approaches for pain control. Prolotherapy (proliferative therapy), also known as regenerative injection therapy, is a nonsurgical

ABSTRACT

Objective: To investigate the outcomes of patients undergoing Hackett-Hemwall dextrose Prolotherapy treatment for chronic low back pain.

Design: One hundred forty-five patients, who had been in pain an average of four years and ten months, were treated quarterly with Hackett-Hemwall dextrose Prolotherapy. This included a subset of 55 patients who were told by their medical doctor(s) that there were no other treatment options for their pain and a subset of 26 patients who were told by their doctor(s) that surgery was their only option. Patients were contacted an average of 12 months following their last Prolotherapy session and asked questions regarding their levels of pain, physical and psychological symptoms and activities of daily living, before and after their last Prolotherapy treatment.

Results: In these 145 low backs, pain levels decreased from 5.6 to 2.7 after Prolotherapy; 89% experienced more than 50% pain relief with Prolotherapy; more than 80% showed improvements in walking and exercise ability, anxiety, depression and overall disability; 75% percent were able to completely stop taking pain medications. The decrease in pain reached statistical significance at the $p < .000001$ for the 145 low backs, including the subset of patients who were told there was no other treatment options for their pain and those who were told surgery was their only treatment option.

Conclusion: In this retrospective study on the use of Hackett-Hemwall dextrose Prolotherapy, patients who presented with over four years of unresolved low back pain were shown to improve their pain, stiffness, range of motion, and quality of life measures even 12 months subsequent to their last Prolotherapy session. This pilot study shows that Prolotherapy is a treatment that should be considered and further studied for people suffering with unresolved low back pain.

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injection therapy used to treat unresolved musculoskeletal pain and has shown some promise in relieving lower back pain.¹³ The procedure involves injecting soft connective tissue with one or more proliferants designed to provoke local inflammation, stimulating the body's production of collagen at the injection site. The resulting growth of new ligament and tendon tissue is believed to alleviate pain.

Prolotherapy has a long standing history of use with tendinopathies and ligament sprains in peripheral joints.¹⁴⁻¹⁶ Treatment of degenerative joint and spinal disease, including chronic low back pain arising from the sacroiliac joints, has also been reported with Prolotherapy.¹⁷⁻²¹ These reports have concentrated on Prolotherapy's ability to decrease chronic pain. To evaluate Hackett-Hemwall Prolotherapy's ability to decrease not only pain, but improve range of motion, exercise ability, and other physical and psychological factors important to those with chronic low back pain, this retrospective pilot study was undertaken on a large patient population with chronic low back pain.

HACKETT-HEM WALL PROLOTHERAPY FOR LOW BACK PAIN

George S. Hackett, MD, a pioneer in the field of regenerative injection therapy, is credited with coining the word *Prolotherapy* (from *proliferant* and *therapy*). He brought the procedure into the mainstream and he, along with Gustav Hemwall, MD, developed current injection protocols.²² Their procedure is unique in that it involves treating a maximum number of structures in an area of pain with a substantial amount of solution, typically between 60 and 90ccs per treatment.

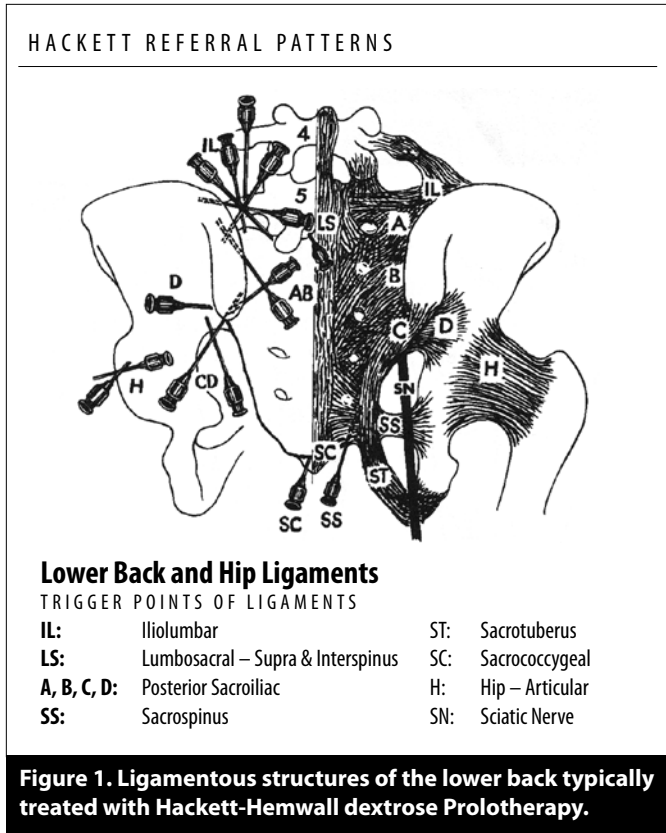
Prolotherapy works by tightening and strengthening weak tendons, ligaments or joint capsules, stimulating the body to repair these soft tissue structures. It starts and accelerates the inflammatory healing cascade by which fibroblasts—the cells through which collagen is made and by which ligaments and tendons repair—proliferate. Hackett held that the procedure “stimulates 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.”²³

It is reported in the medical literature that damage to ligaments accounts for up to 70% of all cases of low back pain.^{24, 25} The most common ligament injury in the low back involves the sacroiliac joints.²⁶ Sacroiliac ligament

injury can refer pain down the posterior thigh to the lateral foot, simulating sciatica.^{27, 28} The lumbar vertebrae and the pelvis (sacrum and two iliac bones) are held together by the lumbosacral and iliolumbar ligaments. Connecting the adjoining spinus processes of two lumbar vertebrae are the interspinus and supraspinus ligaments. The interspinus ligaments, extending from the root to the apex of each process, are powerful and thick ligaments in the lumbar region. The supraspinus ligaments are attached to the tips of the spinus process and reinforce the interspinus ligaments.^{29, 30} The interspinus and supraspinus ligaments are designed to be taut when the lumbar spine is bent forward, thus preventing excessive separation from occurring between the spinus processes and vertebrae at the lumbar spine during this movement.³¹

When the interspinus and supraspinus ligaments are injured due to trauma, excessive movement occurs at the involved spinal segment. Injury to these ligaments alone can refer pain down to the heel, groin, or the perineum.^{32, 33} Once damaged, these ligaments can no longer protect the disc and facet joint of the involved lumbar segment and excessive pressures occur. When too much separation of the spinus processes is allowed on forward bending, what results is a bulging disc. If the separation is excessive, a herniated disc will occur.³⁴ The most common area where the above events take place is between the fifth lumbar vertebra and the sacrum.³⁵ The fifth lumbar vertebra sits on the sacrum. Given that the upper surface of the sacrum is inclined downward and forward at an angle of approximately 40 degrees with respect to the horizontal plane, the physiology of such injury is apparent. When the lumbosacral ligaments between these two structures are stretched, the fifth lumbar vertebra begins to move down the sacrum. This causes undue stress on the outer layer of the disc (annulus) and, with time, fissures develop in the annulus, making the disc more prone to herniation. The interspinus, supraspinus, and iliolumbar ligaments are some of the ligaments that prevent this from happening.³⁶ (See *Figure 1*.) The above scenario is the most common cause of ligament injury and is responsible for the majority of unresolved low back pain.

In one analysis of 146 consecutive cases of undiagnosed low back disability, 94% of the patients were found to have ligament injury.³⁷ A similar survey of 124 consecutive cases of unresolved low back pain revealed that 97% of patients possessed joint instability from ligament weakness.³⁸ The sacroiliac ligaments were involved in 75% of the cases; the lumbosacral ligaments in 54%. In these cases, 50% had already undergone low back surgery for a previous diagnosis of a disc problem.



months until July 2005, and all treatments were provided free of charge. Follow-up with patients was completed, on average, one year following treatment.

Dextrose Prolotherapy, using the Hackett-Hemwall technique, was used on all patients for an average of one year. All lower-back ligaments were treated with a dextrose solution chosen as the proliferant because of its ready availability, low cost, and high safety profile. Each patient received 60 to 90 injections of a 15% dextrose, 0.2% lidocaine solution with a total of 60 to 90cc of solution per lower back treatment. Injections were given into and around the sacroiliac joints, as well as tender areas in the lower back. Thus, all soft tissue structures responsible for the intervertebral disc and skeletal stability at the vertebral-sacrum-iliac junction were treated on each patient at each visit.

Injected sites included the sacroiliac, iliolumbar, sacrotuberous, lumbosacral, supraspinus and interspinus, sacrococcygeal and sacrospinus ligaments, as well as the gluteal and piriformis muscle attachments on the iliac crest. Each site was injected with 0.5 to 1cc of solution. (See Figure 2.) An average of four lower back treatments, given every three months, was provided to each patient.

Because nonsteroidal anti-inflammatory drugs (NSAIDs) inhibit the expected inflammatory process, patients were asked to discontinue use of pain medications during therapy, if possible.

Methods

A. PATIENT DATA

A total of 145 patients agreed to participate in the study. Of these, 63% (92) were female and 37% (53) were male, with an average age of 57 years. Patients reported an average of four years and ten months of pain prior to treatment; 55% reported four or more years of pain; and 39% reported six or more years. As a group, they were taking an average of 1.1 pain medications with 27% taking one and 27% taking two or more pharmaceutical drugs for pain. The average patient saw three medical doctors before receiving Prolotherapy. General inclusion criterion included unresolved low back pain, a willingness to undergo at least four Prolotherapy sessions unless the pain resolved with less treatment sessions, and age of at least 18 years. (See Table 1.)

B. TREATMENT PROTOCOL

This pilot study was conducted at Beulah Land Clinic, a free medical clinic located in southern Illinois, between the years 2001 and 2005. The clinic met every three

C. DATA COLLECTION

Pre- and post-study data was collected via telephone questionnaire by an independent data collection provider with no prior knowledge of Prolotherapy. Evaluation

Table 1. Patient characteristics at baseline.	
Total number of back patients	145
Average age of back patients	57.2
Average number of MD's seen prior to Prolotherapy	3.2
Average years of pain	4.7
Average number of pain meds at start of Prolotherapy	1.1
Average number of pain meds after Prolotherapy	0.3
Percentage of male patients	37%
Percentage of female patients	63%
Average number of Prolotherapy treatments	4
Percentage told no treatment options	38%
Percentage told surgery was only option	18%



Figure 2. Typical areas injected with Prolotherapy during low back Hackett-Hemwall dextrose Prolotherapy.

included current levels of pain/stiffness, disability, range of motion, medication use, quality of life measures, psychological factors, and whether the benefits of Prolotherapy continued after the treatment was stopped. Follow-up data was collected an average of 12 months following each patient’s final treatment.

Patients were asked to rate the following: (1) level of pain and stiffness on a numerical scale from 1 to 10, with 1 indicating no pain/stiffness and 10 indicating severe crippling pain/stiffness; (2) level of disability as a percentage of normal daily activities they could perform prior to and following treatment; (3) range of motion on a numerical scale from 1 to 7, with 1 indicating no motion, 2 through 5 ranges of low-normal motion, 6 completely normal motion, and 7 excessive motion; (4) mobility ; (5) exercise time; (6) depressed and anxious feelings and (7) pre- and post-study use of pain medication.

D. ANALYSIS

Patient percentages of the various responses were calculated before and after Prolotherapy. The patient percentages were also calculated for clients who answered yes to either of the following two questions: *Before starting Prolotherapy it was the consensus of my medical doctor(s) that there were no other treatment options that he or she knew of to get rid of my chronic pain?* and *Before starting Prolotherapy my only other treatment option was surgery?*

Results

A. PAIN/STIFFNESS

Pre-study data of all 145 subjects revealed an average pain level of 5.6 and stiffness level of 6.1 on a 10-point numerical pain scale. Post-study data showed pain and stiffness levels were 2.7 and 2.6, respectively. Prior to Prolotherapy, 58% of the patients rated their pain as a level 8 or higher. After Prolotherapy, only 4% rated it that high. Eighty-one percent had a pain level of 3 or less after Prolotherapy, and 69% reported greater than 75% relief of their pain. A full 96% dropped their pain levels by half or more. (See Figure 3.) The improvements in both pain and stiffness levels were significant. (See Figures 4 & 5.)

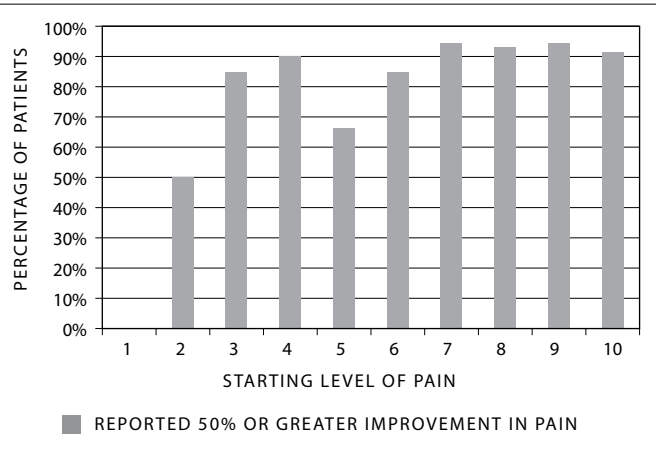


Figure 3. Percent of patients who reported 50% or greater pain relief after receiving Hackett-Hemwall dextrose Prolotherapy.

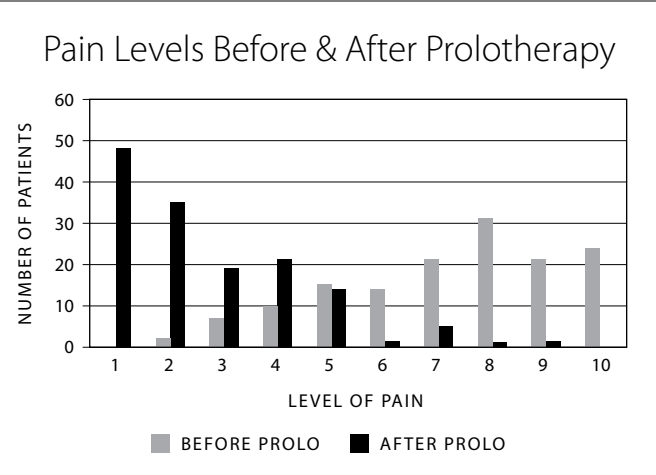


Figure 4. Pain levels before and after Hackett-Hemwall dextrose Prolotherapy.

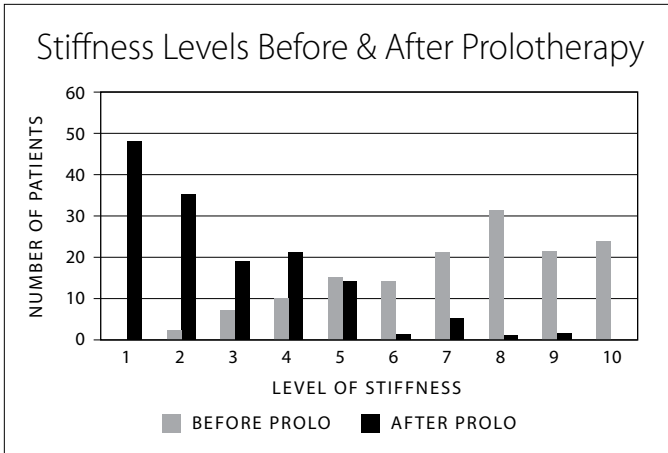


Figure 5. Stiffness levels before and after Hackett-Hemwall dextrose Prolotherapy.

B. RANGE OF MOTION

The average pre-treatment range of motion was 4.2, and the final range of motion was 5.0. Before Prolotherapy, 36% had 49% or less of normal motion, decreasing to only 6% after Prolotherapy. Eighty percent of patients surveyed in the follow-up reported that the improvements in their pain and stiffness levels were still evident one year after treatment. In regard to range of motion, prior to Prolotherapy, 35% noted less than half of normal back motion, but this improved to 7% after Prolotherapy. Before Prolotherapy only 42% noted a slight restriction of motion or normal motion, whereas after Prolotherapy this increased to 80%. (See Figure 6.)

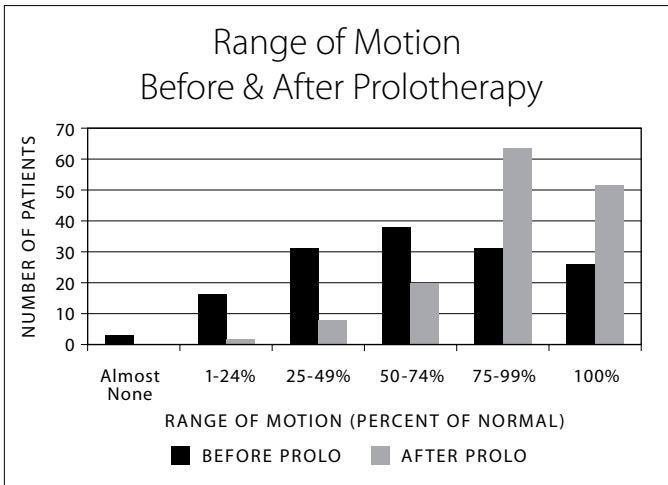


Figure 6. Starting vs ending range of motion levels before and after Hackett-Hemwall dextrose Prolotherapy.

C. MOBILITY

More than 81% of participants showed improvements in mobility following therapy. Prior to treatment, 53% reported difficulty walking and 18% reported they could walk less than one block before Prolotherapy. After Prolotherapy, these numbers dropped to 32% and 2%, respectively. (See Figure 7.)

Pre-treatment, 14% of the patients were dependent on someone for activities of daily living (dressing and other general self-care). This went down to 4% after Prolotherapy. There were 12 patients prior to Prolotherapy that rated their dependency on someone else as greater than “minimum” assistance (i.e., needing help with greater than 25% of daily activities). Following treatment, only one patient reported needing that level of help. At one year follow-up, all patients stated that their initial improvements in mobility had continued since receiving Prolotherapy.

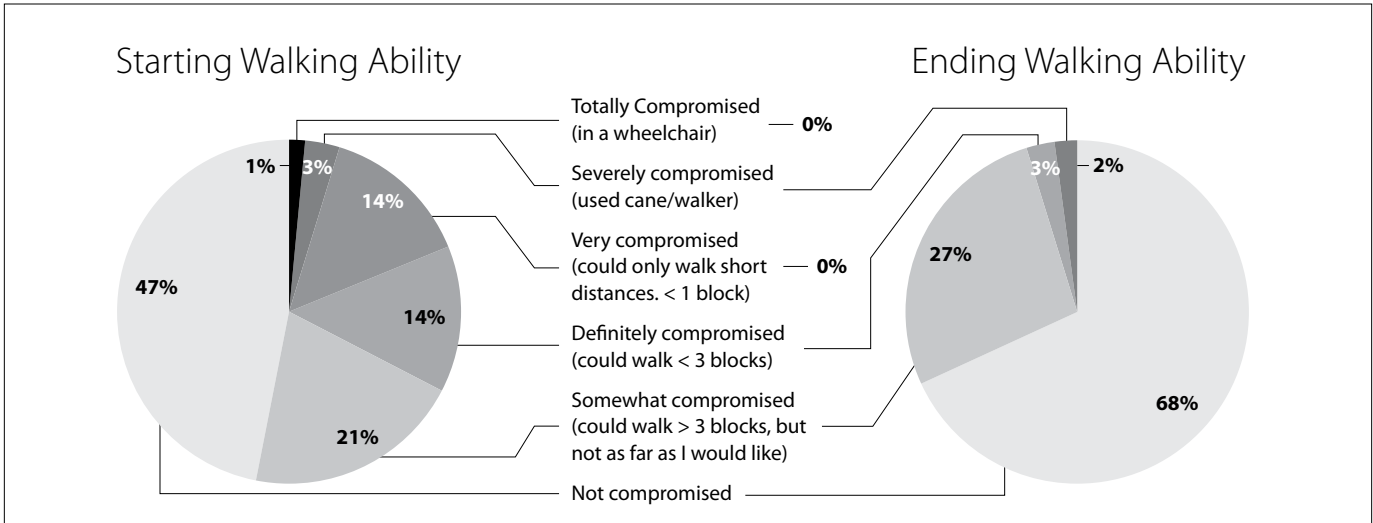


Figure 7. Walking ability before and after Hackett-Hemwall dextrose Prolotherapy.

D. EXERCISE TIME

In regard to exercise or athletic ability prior to Prolotherapy, 31% said they could do no athletics, 14% said they could engage in less than 10 minutes, 19% said they could engage in less than 30 minutes, and a total of 83% ranked it as at least somewhat compromised. After Prolotherapy, 78% of patients were able to do 30 or more minutes of exercise with 38% not being compromised at all. Seventy-three percent of clients stated that the improvement they received with Prolotherapy, in regard to athletic ability, has very much continued. (See Figure 8.)

E. ANXIETY AND DEPRESSION

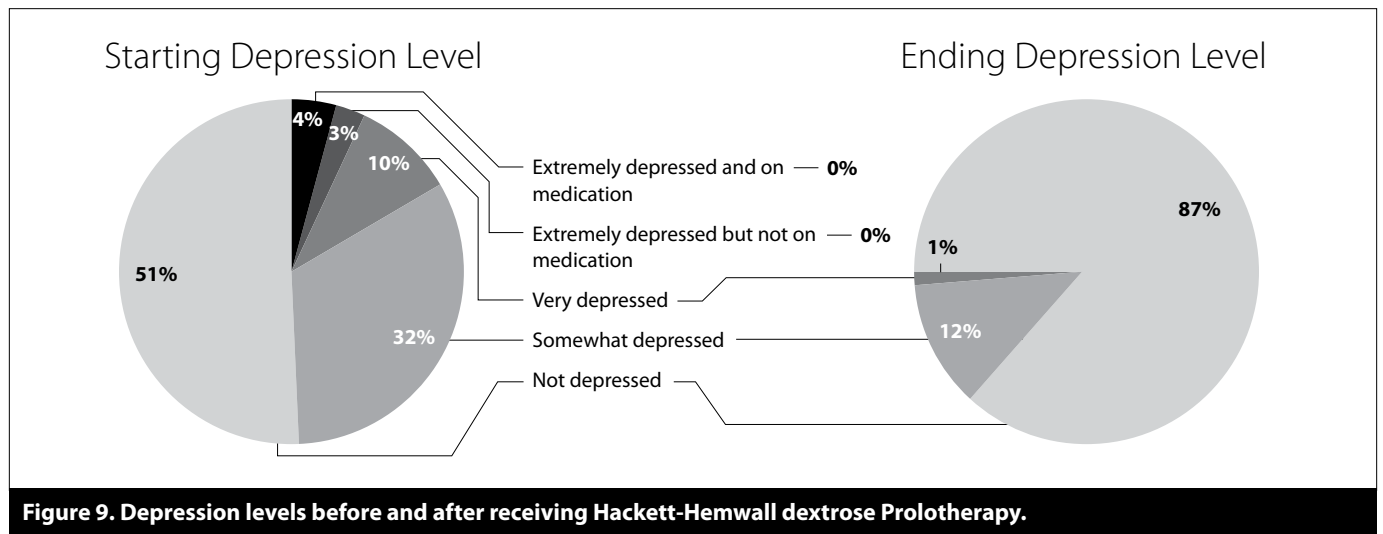
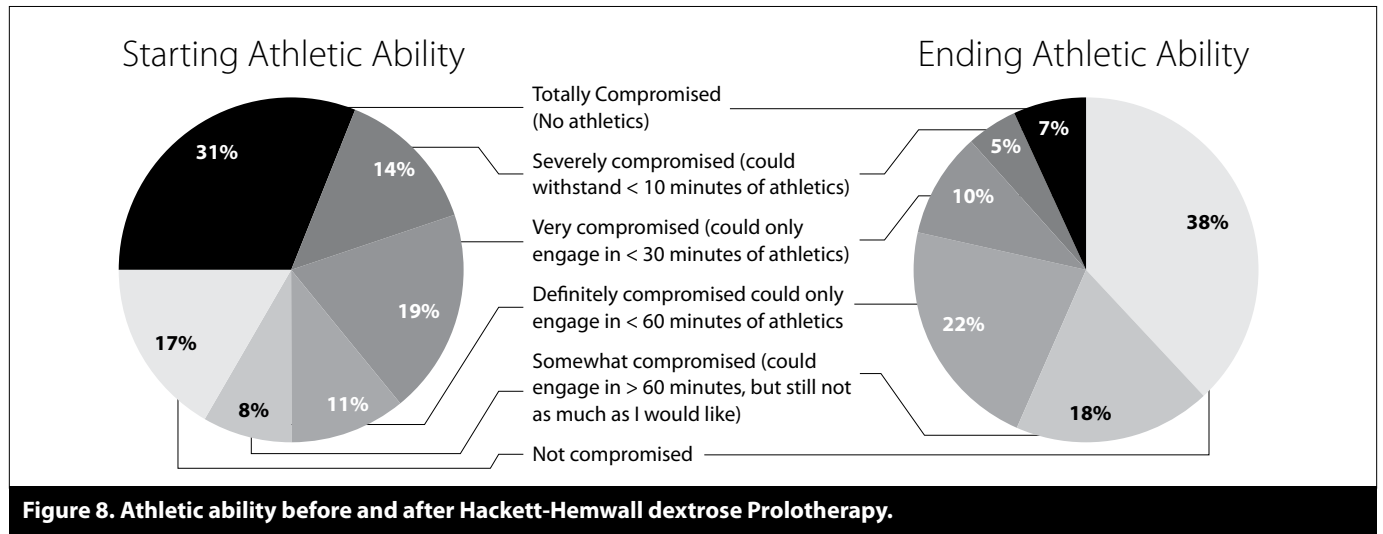
Prior to Prolotherapy, 57% had feelings of anxiety. After Prolotherapy, only 22% had feelings of anxiety. Before Prolotherapy, 49% had feelings of depression and after

Prolotherapy, only 13% had depressed feeling. (See Figure 9.) According to the patients, 75% of the improvements in depression and anxiety have very much continued.

In regard to sleep, 72% of patients felt their pain interrupted their sleep. After Prolotherapy, 86% had improvements in their sleeping ability and 80% of patients stated that improvement has very much continued.

F. MEDICATION USE

Ninety-one percent of patients reported reliance on medication to manage their pain prior to Prolotherapy. Following completion of all injection treatments, 75% reported needing no pain medications. The average number of pain medications used per patient decreased from 1 to 0.3 after the study. For those patients who continued to need medication, 97% of them were able to decrease their use by 50% or more.



G. OVERALL RESULTS

To a simple yes or no question: “*Has Prolotherapy changed your life for the better?*” 97% of patients treated answered “yes.” When asked, “*Are there reasons besides the Prolotherapy effect wearing off that are causing your continued pain/disability?*” 80% answered “yes.” The patients noted the reasons for some of their returning back pain as the following: 52% said they stopped Prolotherapy treatments too soon (before the pain was completely gone), 16% re-injury, 12% new area of pain, 10% had increased life stressors, and 10% had other explanations for the pain. Of the patients whose pain recurred after Prolotherapy was stopped, 85% are planning on receiving more Prolotherapy.

Ninety percent of patients knew someone who had received Prolotherapy. Seventy-one percent came to receive their first Prolotherapy session because of the recommendation of a friend. Ninety percent of patients treated considered the Prolotherapy treatment they received to be very successful. Ninety-nine percent noted that the Prolotherapy had been at least somewhat successful. Only one patient of the 145 noted that it made no change. No one said the Prolotherapy treatments made them worse. Ninety-four percent have recommended Prolotherapy to someone else.

H. RESULTS FOR THOSE WHO WERE TOLD THERE WAS NO OTHER TREATMENT FOR THEIR PAIN

As previously noted, 38% of patients (55 in number) prior to Prolotherapy were told that there were no other treatment options for their pain. In analyzing these

patients, they had a starting average pain level of 7.1 and after Prolotherapy a pain level of 3.1. Prior to Prolotherapy, 58% of the patients rated their pain as a level 8 or higher. After Prolotherapy only 4% rated it that high. Results with stiffness were similar with an average starting level of 7.0 and an ending level of 3.1. The improvements in both pain and stiffness levels were significant. As a group, prior to Prolotherapy, 55% stated that they could not do at least 50% of the tasks they wanted to do. This decreased to 11% after Prolotherapy. In regard to range of motion prior to Prolotherapy, 35% noted less than half of normal back motion, but this declined to 7% after Prolotherapy. Before Prolotherapy only 42% noted a slight restriction of motion or normal motion, whereas after Prolotherapy this increased to 80%. Sixty-four percent had compromised walking ability and 20% could walk less than one block before Prolotherapy. After Prolotherapy, only 35% had compromised walking ability and 4% could walk less than one block. Before Prolotherapy 40% could not exercise at all, whereas after Prolotherapy this was down to 4%. Only 7% ranked their exercise ability as not compromised before Prolotherapy, but after Prolotherapy 58% rated it as not compromised. (See Figure 10.) For those patients on pain medication, 97% of them were able to decrease it by 50% or more. Seventy-eight percent of them were able to decrease their need for additional pain therapies by 50% or more. Before Prolotherapy, 60% felt at least some depression and 71% some anxiety. This decreased to 20% who felt depression and 31% who were anxious after Prolotherapy.

In this group of patients, 87% noted that their overall results from Prolotherapy have mostly continued to this day

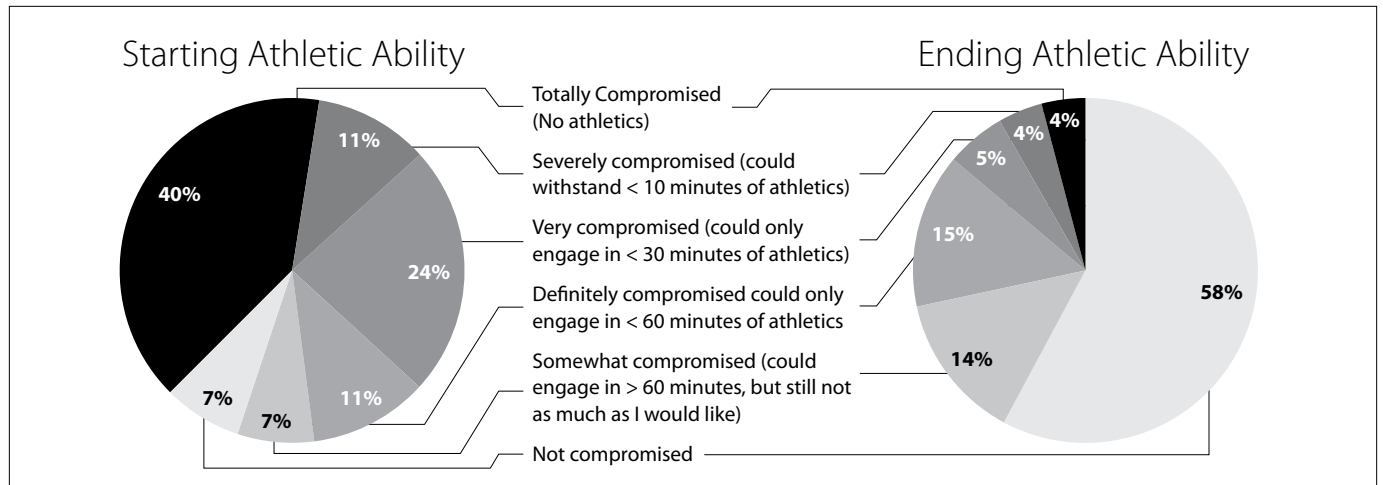


Figure 10. Exercise ability before and after Hackett-Hemwall dextrose Prolotherapy in patients told that no other treatment options existed for their back pain.

(greater than 50%). Eighty-nine percent of these patients rated the Prolotherapy treatment to be very successful with 62% receiving 75% or greater pain relief. Eighty-nine percent received greater than 50% pain relief with Prolotherapy. In response to the question “*Has Prolotherapy changed your life for the better?*” 94% answered “yes.”

RESULTS IN SURGERY ONLY OPTION GROUP

In regard to the question “*Before starting Prolotherapy my only other treatment option was surgery?*” 18% of the patients (26 in number) answered “yes.” In analyzing data on these patients, they started out with an average pain level of 6.0, which decreased to 2.1 after Prolotherapy. Eighty-one percent had a pain level of 3 or less after Prolotherapy. Their starting stiffness level was 6.1 and ending was 2.0. Both pain and stiffness improvements were significant. (See Figures 11 & 12.) Sixty-nine percent stated they had greater than 75% pain relief and a full 96% (25 of 26) had 50% or greater pain relief with Prolotherapy. Sixty-five percent noted they could only exercise 10 minutes or less before Prolotherapy, but after Prolotherapy this decreased to 6%. Before Prolotherapy, 65% considered themselves at least somewhat depressed and anxious. This decreased after Prolotherapy to 19% somewhat depressed and 15% somewhat anxious. Seventy-six percent taking pain medications were able to decrease the dosage by 50% or more. The need for additional pain management care also lessened by 50% or more in 77% of the patients after Prolotherapy. Eighty-eight percent of these patients stated, in regard to their pain, that they were at least somewhat better due to Prolotherapy. Fifty percent noted that they were radically better. Twenty three (88.5%) of the patients recommended Prolotherapy to someone else. Eighty-one percent felt that their lives were significantly better because of Prolotherapy. All 100% said that Prolotherapy changed their life for the better.

Statistical Analysis

A matched sample paired t-test was used to calculate the difference in responses between the before and after measures for pain, for the entire 145 low back patients, as well as the subgroup of fifty-five patients who were told prior to Prolotherapy that nothing else could be done with their pain, as well as the subgroup of twenty-six patients who told by their medical doctor(s) that surgery was their only option. The paired sample t ratio was computed on this pre-post Prolotherapy study. The paired t ratios for

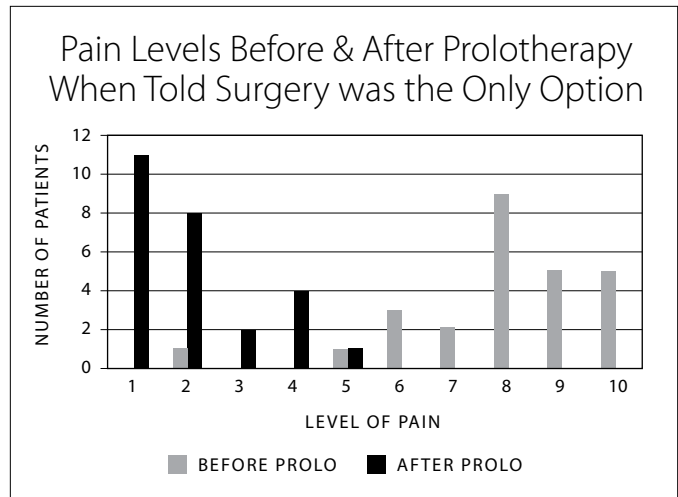


Figure 11. Pain levels before and after Hackett-Hemwall dextrose Prolotherapy in patients who were told that surgery was their only option.

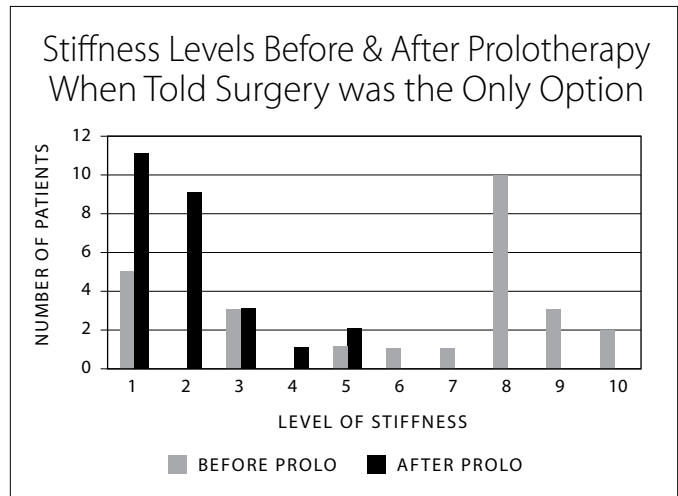


Figure 12. Stiffness levels before and after Hackett-Hemwall dextrose Prolotherapy in patients who were told that surgery was their only option.

all the groups were highly significant, using N pairs minus one as the degrees of freedom. For the entire 145 low back study participants the paired t ratio was significant ($t(144) = 22.5 p < .000001$). For the subgroup of low back patients who were told that there were no other treatment options the paired t was also highly significant ($t(54) = 26.3 p < .000001$). The paired t ratio was highly significant also for the subgroup of low back patients who were told that surgery was their only option ($t(25) = 23.8 p < .000001$). In summary, for all the low back participants, as well as the two subgroups, their low back pain was significantly reduced at the $p < .000001$ level by Hackett-Hemwall dextrose Prolotherapy.

Discussion

Post-study data revealed an average reported drop in pain of 2.9 points on a 10-point scale. This data showed an even greater average drop in pain of 3.9 for those patients who were told prior to Prolotherapy that nothing more could be done for their pain, or surgery was their only option. More than 80% of the study population reported improvements in mobility (walking and daily activities), exercise ability, anxiety, depression, overall disability, and the large majority (75%) were able to discontinue use of pain medication. When subjects were asked at one year follow-up whether their lower back pain improved following Prolotherapy, 98% answered yes.

Though practitioners and patients of the procedure have long touted Prolotherapy’s benefits, placebo-controlled studies have been lacking, and few insurance companies provide coverage. As a result, Prolotherapy is still considered by many to be experimental. In double-blinded human studies, the evidence on the effectiveness of Prolotherapy for low back pain has been promising but mixed.³⁹⁻⁴² Factors that could have contributed to suboptimal results in some of the studies are a limited number of sites were treated and/or a limited amount of proliferant was used. In one study on chronic low back pain, tissue biopsies performed three months after completion of Prolotherapy showed statistically significant increases in collagen fiber and ligament diameter (60%), suggesting clinical evidence of the procedure’s effectiveness.⁴³

Animal studies on Prolotherapy offer more definitive results, and also show that the procedure induced the production of new collagen.^{44,45} In one double-blinded animal study, ligament mass increased by 44%, ligament thickness by 27%, and the ligament-bone junction strength by 28% over a six-week period.⁴⁶ Improvements in ligament and tendon diameter and strength have also been documented.^{47,48}

Former U.S. Surgeon General C. Everett Koop began advocating for insurance coverage of Prolotherapy in 1978 after it alleviated his chronic leg and back pain, but few inroads have been made. Most physicians are not familiar with the procedure, do not practice it, and therefore cannot attest to its benefits. Awareness of the procedure rose in 2005 when Dr. Robert Sheeler, medical editor of the *Mayo Clinic Health Letter*, lent his qualified support to its effectiveness for various types of joint pain, including

that arising from the sacroiliac.⁴⁹ Though several Mayo Clinic physicians now offer Prolotherapy as a treatment option, widespread understanding and acceptance of the procedure in the medical community is still in its infancy, and further research studies are needed to determine the extent of its benefits.

Comparison of pre- and post-study data showed significant improvements across all indicators. The results of this retrospective pilot study therefore suggest that Hackett-Hemwall dextrose Prolotherapy can play a role in decreasing pain, improving mobility and range of motion, reducing medication use, and improve many quality of life parameters in patients with unresolved low back pain. (See Table 2.)

Table 2. Summary of results of Hackett-Hemwall dextrose Prolotherapy back study.

Demographics	All Back Patients	No Other Treatment Option	Surgery Only Option
Total number of patients	145	55	26
Avg. months of pain	58	53	60
# of pain meds used before Prolotherapy	1	0.9	1.1
# of pain meds used after Prolotherapy	0.3	0.3	0.4
Pain level before Prolotherapy	5.6	7.1	6.0
Pain level after Prolotherapy	2.7	3.1	2.1
Stiffness level before Prolotherapy	6.1	7.0	6.1
Stiffness level after Prolotherapy	2.6	3.1	2.0
Greater than 50% pain relief	96%	89%	96%
Athletic Ability > 30 Minutes of Exercise before Prolotherapy	19%	30%	12%
Athletic Ability > 30 Minutes of Exercise after Prolotherapy	78%	81%	90%
Prolotherapy changed life for the better	97%	94%	81%

Study Strengths and Limitations

By virtue of its design, this pilot study cannot be compared to randomized placebo-controlled clinical trials. Instead, its aim was to document the response of patients with unresolved low back pain to the Hackett-Hemwall technique of dextrose Prolotherapy at a charity medical clinic.

Multiple quality of life measures were assessed, including mobility, stiffness, range of motion, and activities of daily living, which, in addition to pain level, are important factors affecting the individual with unresolved low back pain. Decreased reliance on pain-relief medication was also documented.

Because this data was collected from patients at a free clinic, no control group was used to validate the data collected, and no imaging studies are available to corroborate patient reports or provide clinical proof of improvements. Instead, the authors relied on the objective observations of the patients themselves regarding levels of pain and if and how their daily functioning improved. Given the size of the study group, it is likely that Prolotherapy, rather than other, concomitant factors not controlled for, is responsible for the improvements seen.

The individuals participating in this study represent a typical cross-section of chronic low back pain patients, including gender, age, location and levels of pain/stiffness, and years of affliction. Before seeking treatment at the clinic, participants averaged four years and ten months of low back pain and had seen at least three physicians to resolve the problem. Prior to Prolotherapy, fifty-five (38%) of the patients said they were told there were no other treatment options for their pain and twenty-six (18%) of the patients said their medical doctor(s) believed that surgery was their only option. Adding to the study's validity is the length of time between each patient's final treatment and the follow-up interview. In the authors' view, the one-year time frame was sufficient to gauge Prolotherapy's long-term effectiveness.

Because this was a charity medical clinic with limited resources and personnel, the only therapy provided was Prolotherapy, and treatments were given only at three-month intervals. In private practice, the Hackett-Hemwall technique of dextrose Prolotherapy is typically given

every four to six weeks and often used in conjunction with a dynamic whole-body approach to pain relief. In patients who show little progress or who demonstrate poor healing capacity, the injection proliferants may be changed and strengthened, or additional actions recommended to improve overall health. Such complementary measures may include advice on diet, supplements, exercise, weight loss, changes in medications, additional blood tests, and other medical care. Most private-practice clients are also immediately weaned off of anti-inflammatory and narcotic medications that inhibit the inflammatory response needed to obtain a healing effect from Prolotherapy. Though cessation of medication use was highly recommended for all clinic study participants, not all patients were able to comply. Taking into account the lack of complementary therapies used during this pilot study, the results may indicate only the lowest level of success possible with Hackett-Hemwall Prolotherapy.

Like all case studies lacking a control group to limit variables impacting outcomes, our study results are a snapshot only of the parameters evaluated and are necessarily subjective. The results are based solely on the answers provided by the participants to the questions posed by the questionnaire. No radiograph or MRI correlation for diagnosis and response to treatment is available, and a lack of physical examination documentation in the patients' charts made categorization of participants into various diagnostic parameters impossible. Medication use, level of activity, and other pain management care during the course of treatment are variables that could influence results. What was documented were simple outcome measures that occurred prior to and following treatment with Prolotherapy.

Conclusions

The Hackett-Hemwall technique of dextrose Prolotherapy, used on 145 patients who had an average duration of four years and 10 months of unresolved low back pain, was studied in this retrospective case series review for its effectiveness in relieving pain/stiffness and improving mobility. Study participants, interviewed 12 months following their last Prolotherapy session, reported clinically significant lower levels of pain, stiffness, and medication usage, as well as improved mobility and range of motion. Despite the limitations inherent in the study design, the authors believe that Prolotherapy is a viable treatment for unresolved low back pain. Future studies are needed to verify these preliminary findings. ■

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