

Hackett-Hemwall Dextrose Prolotherapy for UNRESOLVED ELBOW PAIN



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In this retrospective pilot study at an outpatient charity clinic in rural Illinois, Hackett-Hemwall dextrose prolotherapy helped reduce pain and stiffness and clinically improved the quality of life in people with unresolved elbow pain.

Chronic elbow pain is a common condition affecting 15% of the population at any one time.¹ Lateral epicondylitis (tennis elbow) is the most common form of elbow pain and the most common reason patients with elbow pain come to a physician's office.² It is usually an overuse injury. Elbow injuries in sports with overhead or repetitive arm actions are frequent and often severe. Epicondylitis is an acute injury that results in inflammation and is usually the result of large valgus forces with medial distraction and lateral compression. Epicondylosis develops over a longer period of time from repetitive forces and results in structural changes in the tendon.³ Other diagnoses for elbow pain include olecranon bursitis, biceps tendinitis, ulna and radial collateral ligament sprain, and degenerative arthritis.

The typical treatment for elbow conditions is conservative and includes oral NSAIDs, physical therapy, botulinum injections, pulsed low-intensity ultrasound, repetitive low energy shock wave therapy,

corticosteroid injections, bracing, ergonomic modification of work stations, and rest.^{4,5,6,7,8,9,10,11} Although these therapies are prescribed, convincing evidence to support their use is lacking.¹² It appears the longer the condition persists, the more it becomes resistant to traditional therapies. It has been documented that prolonged symptoms and relapses are frequently observed after having many conservative treatments. In one survey analysis, the elbow complaint resolved in 13% of the patients at three months and in 34% at 12 months.¹³ Because of the limited response to traditional therapies,^{14,15} many patients with chronic elbow pain are turning to alternative therapies such as prolotherapy—including platelet rich plasma (PRP) prolotherapy injections.^{16,17}

George S. Hackett, MD coined the term prolotherapy.¹⁸ 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."¹⁹ Animal studies have shown that prolotherapy induces the production of new collagen by stimulating the normal inflammatory reaction.^{20,21} In addition, animal studies have shown improvements in ligament and tendon diameter and strength.^{22,23}

Prolotherapy is becoming a widespread form of pain management in both complementary and allopathic medicine. Prolotherapy is commonly used for unresolved elbow pain.^{24,25} In double-blinded human studies, the evidence on the effectiveness of prolotherapy has been considered promising but mixed.^{26,27,28} More studies need to be done utilizing larger groups with validated clinical and diagnostic measures to show its effectiveness.

While the normal proliferant used in prolotherapy is dextrose-based, PRP prolotherapy is gaining in popularity. In PRP prolotherapy, a concentrated amount of one's own platelets which contain growth factors are injected into the injured tissue

to promote and speed up the body's natural healing process.³² There have been numerous studies and papers written regarding use of platelet rich plasma (PRP) therapy to induce healing of elbow injuries—specifically for epicondylitis.^{29, 30, 31}

While prolotherapy has a long history of use with chronic elbow problems, no study to date using dextrose as the proliferant has been documented. This observational pilot study was undertaken to evaluate the effectiveness of Hackett-Hemwall dextrose prolotherapy not just on unresolved elbow pain but on quality of life measures and its ability to reduce or eliminate the need for pain medications.

PATIENTS AND METHODS

Framework and setting

The primary authors of this paper started a Christian medical clinic called Beulah Land Natural Medicine Clinic in an impoverished area in southern Illinois. Hackett-Hemwall dextrose prolotherapy was the primary modality of treatment offered for pain control at the clinic. All treatments were given free of charge and the clinic was staffed by volunteer MDs, RNs, MAs and administrative staff. The clinic met every three months from October, 1994 through July, 2005.

Patients

Patients who received prolotherapy for their unresolved elbow pain in the years 2000 to 2005 were called by telephone and interviewed by a data collector (D.P.) who had no prior knowledge of prolotherapy. General inclusion criteria were an age of at least 18 years, having an unresolved

elbow pain condition that typically responds to prolotherapy, and a willingness to undergo at least four prolotherapy sessions (unless the pain remitted with fewer prolotherapy sessions). Typical elbow conditions that respond to prolotherapy include medial and lateral epicondylitis or tendinosis, bicipital tendinitis, elbow osteoarthritis, as well as elbow ligament sprains. Patients not included in this study were those who were thought to have ulnar nerve entrapment.

Interventions

The Hackett-Hemwall technique of prolotherapy was used. Each patient received 20 to 30 injections of a 15% dextrose and 0.2% lidocaine solution. Dextrose was selected as the main ingredient in the prolotherapy solution since it is readily available, inexpensive (compared to other proliferants), has a high safety profile and is the most common proliferant used in prolotherapy. A total of 15 to 30cc of solution was used per elbow. Injections were given into and around the areas on the elbow that were painful and/or tender to touch. The typical spots injected, each with 0.5 to 1cc of solution, can be seen in Figures 1a and 1b. Tender areas injected included the epicondyles and ligament attachments around the elbows. In general, the most tender spots were basically 3/4 inch from the medial and lateral epicondyle where the various ligament attachments are located. These elbow ligaments were the primary focus of the treatment (see Figure 2). The patients were asked to reduce the amount of, or eliminate, the pain medications they were taking.

Data Collection

D.P. was the sole person obtaining the patient information during the telephone interviews. The patients were asked a series of questions about their pain and various symptoms before starting prolotherapy. Their response to prolotherapy was also detailed with an emphasis on the effect prolotherapy had on their elbow pain, stiffness, and quality of life. Specifically, patients were asked questions concerning years of pain, pain intensity, stiffness, number of physicians seen and medications taken, quality of life concerns, psychological factors, and whether the response to prolotherapy continued after the prolotherapy sessions stopped.

Statistical Analysis

For the analysis, patient percentages of the various responses were calculated by an independent computer consultant (D.G.) who also had no previous knowledge of prolotherapy. The responses gathered from patients before prolotherapy were then compared with the responses to the same questions after prolotherapy. The patient percentages were also calculated for patients who answered "yes" to the following question, "Before starting prolotherapy was it the consensus of your MD(s) that no other treatment options existed to cure your chronic elbow



FIGURE 1a. Typical prolotherapy injection sites for Hackett-Hemwall dextrose prolotherapy of the lateral elbow.



FIGURE 1b. Typical prolotherapy injection sites for Hackett-Hemwall dextrose prolotherapy of the medial elbow.

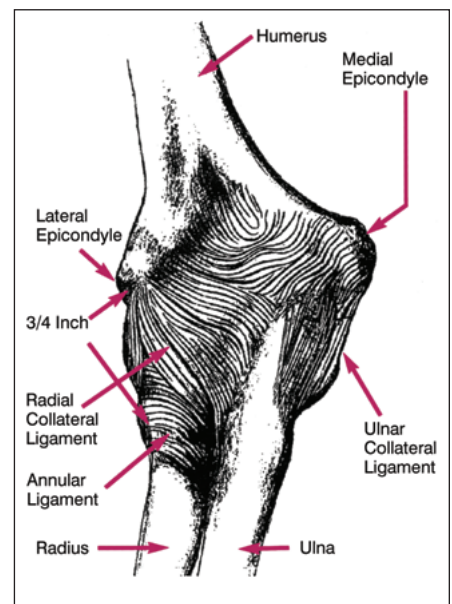


FIGURE 2. Ligament structures of the medial and lateral elbow. For illustration purposes the annular ligament is shown here three-quarters of an inch distal to the lateral epicondyle, a common site treated with prolotherapy.

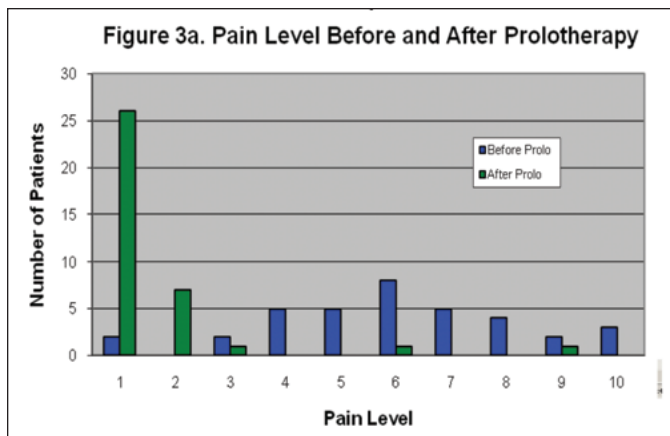


FIGURE 3a. Starting and ending pain levels before and after receiving Hackett-Hemwall dextrose prolotherapy in 36 patients with unresolved elbow pain.

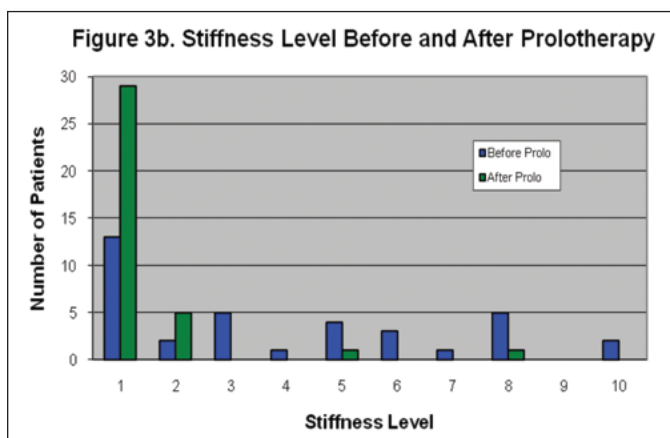


FIGURE 3b. Starting and ending stiffness levels before and after receiving Hackett-Hemwall dextrose prolotherapy in 36 patients with unresolved elbow pain.

pain?” A matched sample paired t-test was used to determine if there were statistically significant improvements in the before-and-after prolotherapy measurements for pain and stiffness in the above two groups (total elbows and subgroup above).

Patient Characteristics

Complete data was obtained on a total of 36 patients who met the inclusion criteria. Of these, 69% were female (25) and 31% were male (11). The patients’ average age was 53 years-old. Patients reported an average of four years and one month of pain and, on average, patients saw 2.4 MDs before receiving prolotherapy. The average patient was taking one pain medication. Forty two percent (15) stated that the consensus of their medical doctor(s) was that there were no other treatment options for their chronic pain. The demographics of the patients can be seen in Table 1.

Treatment Outcomes

Patients received an average of 4.3 prolotherapy treatments per elbow. The average time of follow-up after their last prolotherapy session was 31 months.

Table 1. Patient Characteristics Prior to Prolotherapy	
Elbow patients	n=36
Percentage of female patients	69%
Percentage of male patients	31%
Average age of elbow patients	53
Average years of pain	4.08
Average number of MD’s seen	2.4
Average number of pharmaceutical drugs	1.0
No other treatment options available	42%

Patients were asked to rate their pain and stiffness levels on a scale of 1 to 10, with 1 being no pain/stiffness and 10 being severe crippling pain/stiffness. The 36 patients had an average starting pain level of 5.1 and stiffness of 3.9. Their ending pain and stiffness levels were 1.6 and 1.4 respectively. Sixty-one percent had a starting pain level of 6 or greater, while only 11% had a starting pain level of three or less whereas, after prolotherapy, only 5% had a pain level of 6 or greater and 94% had a pain level of three or less (see Figures 3a and 3b).

One hundred percent of patients stated that the pain and stiffness in their elbows was better after prolotherapy. Over 78% percent said the improvements in their pain and stiffness since their last prolotherapy session have continued 100%. Sixty-three percent received greater than 75% pain relief. Ninety-four percent of patients stated prolotherapy relieved them of at least 50% of their pain (see Figure 4). Ninety-seven percent of patients reported at least 25% relief of their pain with prolotherapy. In regard to pain medication usage: before prolotherapy, the average patient was taking one pain medications but this decreased to an average 0.2 medications after prolotherapy. Of the 22 people taking medications, 21 of them were able to eliminate them or reduce their usage after receiving prolotherapy. No one had to subsequently resume on medications because of elbow pain.

Twenty people stated their elbows did not have normal range of motion before prolotherapy. After prolotherapy, only six patients still did not have normal range of motion (see Figure 5).

In regard to quality of life issues prior to receiving prolotherapy: 77% were totally independent in activities of daily living, but this increased to 94% after prolotherapy. In regard to exercise ability before prolotherapy, only 33% could exercise greater than 30 minutes but, after prolotherapy, this increased to 87% (see Figures 6a and 6b).

Prior to prolotherapy, 44% of patients expressed feelings of depression and 56% feelings of anxiety. After prolotherapy, only 14% reported depressed feelings and 19% feelings of anxiety (see Figures 7a and 7b and Figures 8a and 8b).

In regard to sleep: prior to prolotherapy, 61% of patients felt their pain interrupted their sleep. After prolotherapy, 79% of this group reported improvements in their sleeping ability.

To a simple yes or no question: “Has prolotherapy changed your life for the better?” 100% of the patients treated answered “yes.” Eighty percent of the patients noted that greater than the

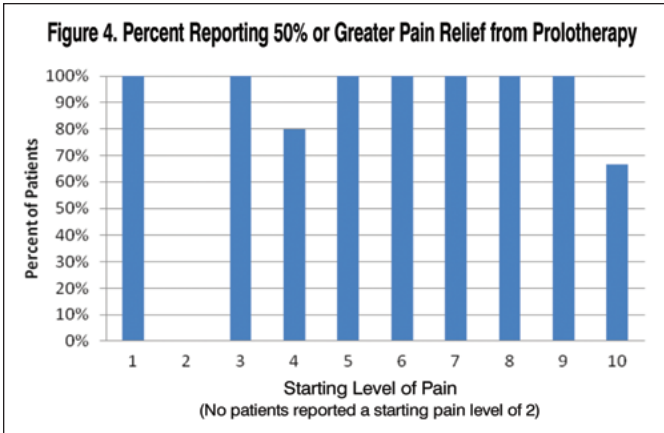


FIGURE 4. Percent of patients who reported 50% or greater pain relief after receiving Hackett-Hemwall dextrose prolotherapy.

75% of the results from the prolotherapy had remained. All of these patients knew someone who had received prolotherapy. Seventy percent of these patients came to receive their first prolotherapy treatment because of a recommendation from a friend. All of these patients report they have recommended prolotherapy to someone else.

Of those whose pain/disability had increased since stopping the prolotherapy, 82% noted there were reasons for this happening. The number one reason being that 55% claimed they stopped the prolotherapy too soon before 100% of their pain was gone.

Results for Those Whose MDs Said No Other Treatment Option Was Available

As previously noted, 42% (15) of patients prior to prolotherapy were told that no other treatment options existed for their pain. As a subgroup, they suffered with pain for an average of 59 months. In analyzing these patients, they had a starting average pain level of 6.9 and, after prolotherapy, a pain level of 2.2. Prior to prolotherapy, they rated their elbow stiffness a level of 4.7 and, after prolotherapy treatment, a level of 1.9. Fourteen of fifteen (93%) had 50%, or greater, pain relief.

In regard to exercise ability for this subgroup, before pro-

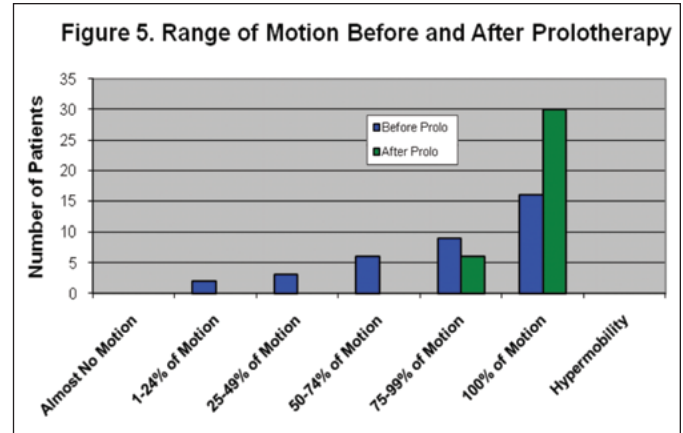


FIGURE 5. Starting and ending range of motion levels before and after receiving prolotherapy in 36 patients with unresolved elbow pain.

lotherapy treatment, only 33% could exercise greater than 30 minutes because of elbow pain, but this increased to 80% after prolotherapy treatment.

Statistical Analysis

A matched sample paired t-test was used to calculate the difference in responses between the before and after measures for pain and stiffness for the 36 patients and the subgroup of 15 patients who were told by their medical doctor(s) that there were no other treatment options available. Using the paired t-test, all p values for pain and stiffness for the two groups reached statistical significance at the $p < .000001$ level (see Table 2).

DISCUSSION

Principle Findings

The results of this retrospective, uncontrolled, observational study show that prolotherapy helps decrease pain and stiffness and improve the quality of life in patients with unresolved elbow pain. The Hackett-Hemwall dextrose prolotherapy gave 64% percent of patients greater than 75% pain relief with 94% of them having 50% or more of their pain relieved. One hundred percent of the patients stated their pain and their life was better after prolotherapy. Notable improvements in other quality

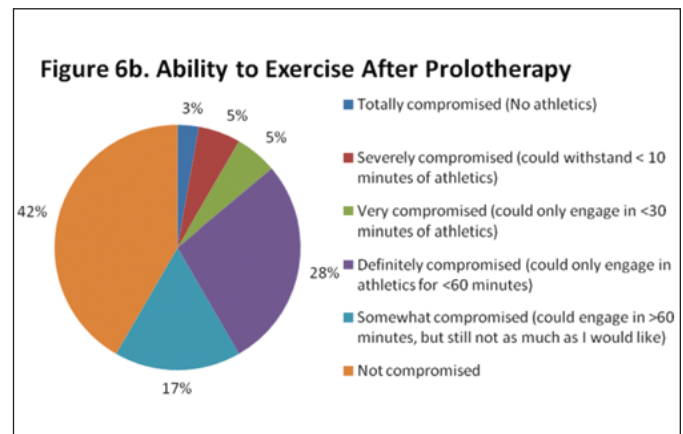
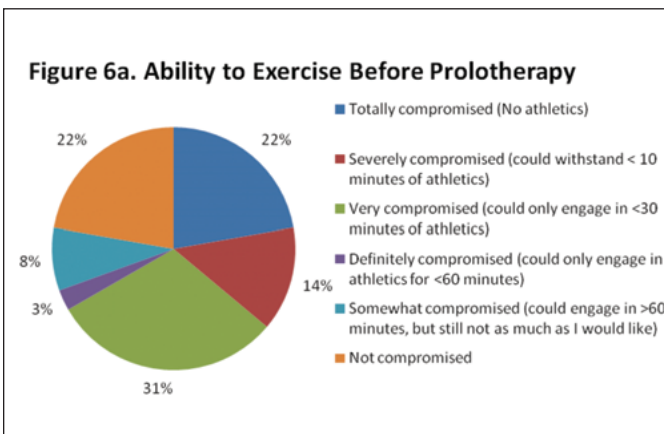


FIGURE 6a AND 6b. Starting and ending ability to exercise before and after receiving Hackett-Hemwall dextrose prolotherapy in 36 patients with elbow pain.

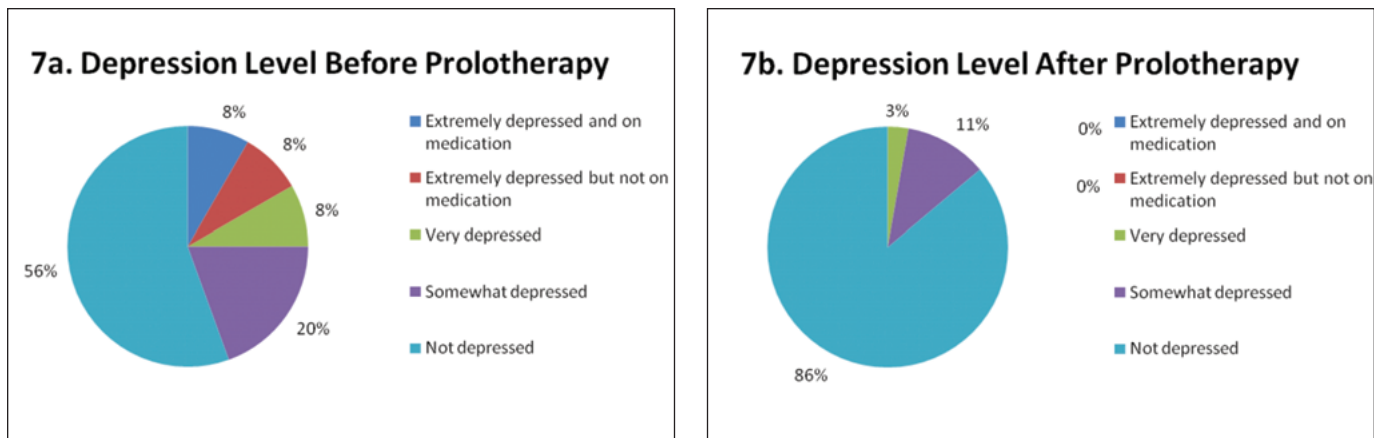


FIGURE 7a AND 7b. Starting and ending depression levels before and after receiving Hackett-Hemwall dextrose prolotherapy in 36 patients with elbow pain.

of life issues—including range of motion, depression, anxiety, sleep, exercise ability and medication usage—was also seen with prolotherapy.

Data analysis for the 42% (15) of patients whose doctors reported no other treatment options were available, revealed large improvements in levels of pain, stiffness, and exercise ability following Hackett-Hemwall dextrose prolotherapy treatments.

Strengths and Weaknesses

Our study cannot be compared to a clinical trial in which an intervention is investigated under controlled conditions. Instead, it is aimed to document the response of patients with unresolved elbow pain to the Hackett-Hemwall 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 range of motion, stiffness, athletic (exercise) ability, sleep, anxiety, and depression, in addition to pain level, are important factors affecting the person with unresolved elbow pain. Decreases in medication usage were also documented. The improvement in such a large number of variables treated solely by prolotherapy is likely to have resulted from prolotherapy treatments. So while there is no medical test to document pain improvement or the progress with prolotherapy, an increased ability to exer-

cise, sleep, and use less medications are objective changes.

A strength of this study is the quality of the cases treated. The average patient in this study experienced unresolved elbow pain for four years and one month and had already seen over two physicians for their condition. Fifteen (42%) of the patients were told by their MD(s) that no other treatment option was available for their pain. Clearly, this patient population represented chronic unresponsive elbow pain. Having an average follow-up period of thirty-one months—along with reports of lasting improvements in their quality of life since their last prolotherapy session and an indication that the changes were due to prolotherapy.

Because this was a free clinic with limited resources and personnel, the only therapy provided was prolotherapy. The prolotherapy treatments could only be given every three months. In private practice, the Hackett-Hemwall technique of dextrose prolotherapy is typically given every four to six weeks. If a patient is not improving or has poor healing ability, the prolotherapy solutions may be changed and/or strengthened. The patient may also be advised of additional measures to improve their overall health, which may include advice on diet, supplements, exercise, weight loss, changes in medications, additional blood tests, and/or other medical care. Patients are often weaned im-

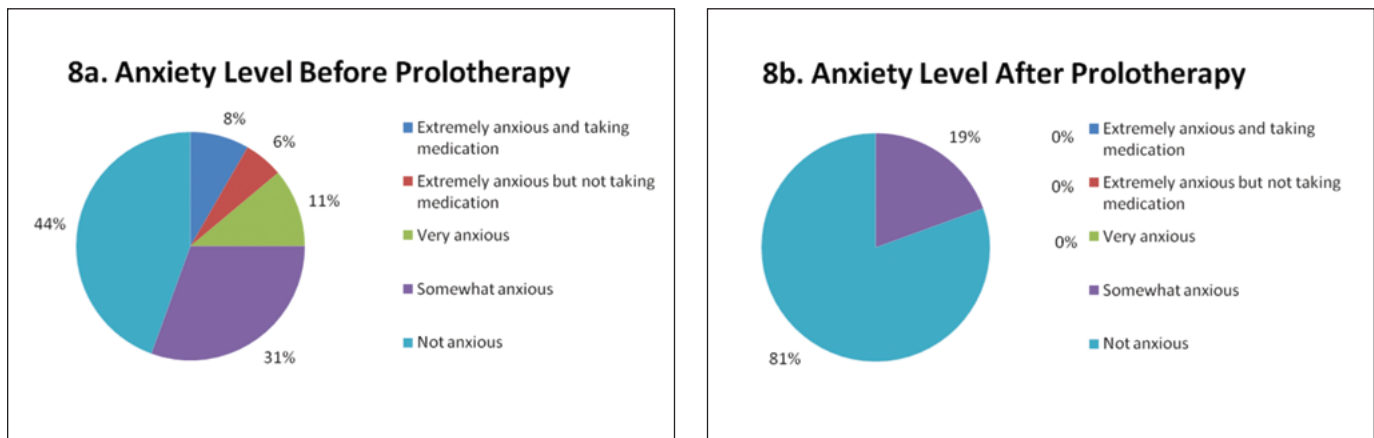


FIGURE 8a AND 8b. Starting and ending anxiety levels before and after receiving Hackett-Hemwall dextrose prolotherapy in 36 patients with elbow pain.

mediately off anti-inflammatory and opioid medications that inhibit the inflammatory response needed to achieve a healing effect from prolotherapy. Since this was not done in this study, the results from this clinic are likely an indication of the lowest level of success with Hackett-Hemwall 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 included pain, stiffness, anxiety, and depression levels since the results relied on the answers to our questions by the patients. What were documented were the changes in these parameters that occurred with prolotherapy.

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' charts made categorization of the patients into various diagnostic categories impossible.

Interpretation of Findings

Hackett-Hemwall dextrose prolotherapy was shown to be very effective in eliminating pain and stiffness and improving the quality of life in this group of patients with unresolved elbow pain in this retrospective pilot study. This included the subgroup of patients told by their MD(s) that no other treatment options for their pain existed. Current conventional therapies for unresolved elbow pain include medical treatment with analgesics, non-steroidal anti-inflammatory drugs, anti-depressant medications, steroid injections, trigger point injections, muscle strengthening exercises, bracing, physiotherapy, weight loss, rest, massage therapy, manipulation, surgical treatments, acupuncture, education and counseling. The results of such therapies often leave the patients with residual pain.^{33,34,35} Because of this, many patients with chronic elbow pain try alternative treatments for their pain. Simply put, patients who either cannot find relief with traditional therapies or do not like their options—especially if surgery is recommended—search for alternatives. One of the treatments such chronic elbow pain patients are trying instead of surgery is prolotherapy.³⁶

Prolotherapy is the injection of a solution for the purpose of tightening and strengthening weak tendons, ligaments or

TABLE 2. Summary of Results of Hackett-Hemwall Dextrose Prolotherapy Elbow Study		
Demographics	All Elbow Patients	No Other Treatment Options
Total number of patients	36	15
Average months of pain	49	59
Average pain level before Prolotherapy	5.1	6.9
Average pain level after Prolotherapy	1.6	2.2
Paired t ratio	14.43	8.367
P value	P < .000000	p < .000001
Average stiffness level before Prolotherapy	3.9	4.7
Average stiffness level after Prolotherapy	1.4	1.9
Paired t ratio	6.285	14.992
P value	p < .000000	p < .000001
Exercise ability > 30 minutes of exercise before Prolotherapy	33%	33%
Exercise ability > 30 minutes of exercise after Prolotherapy	86%	80%
Paired t ratio	-8.371	-6.205
P value	p < .000000	p < .000023
Greater than 50% pain relief	94%	93%

joint capsules. Prolotherapy works by stimulating the body's own mechanisms 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%, ligament thickness by 27% and the ligament-bone junction strength by 28%.³⁷ In human studies on prolotherapy, biopsies performed after the completion of prolotherapy showed statistically significant increases in tendon and ligament collagen fiber and diameter of about 60%.^{38,39} Ligament injury has been implicated as the cause of degenerative osteoarthritis in joints.⁴⁰ This is significant as it relates to chronic elbow pain, because the main potential sources of the pain are presumed to be either of muscle origin, or from a

tendon or ligament that cannot heal. For lateral elbow pain, this is either the biceps tendon, wrist flexor muscle attachments (lateral epicondyle), or radial (lateral) collateral ligament. For medial elbow pain, the structures include the ulnar collateral ligament or wrist flexor muscle attachments (medial epicondyle).^{41,42} Because prolotherapy induces repair of ligaments and tendons at the muscle origin, it can provide a good alternative for those who suffer from chronic elbow pain.

Conclusions

The Hackett-Hemwall technique of dextrose prolotherapy used on patients with an average duration of four years and one month of unresolved elbow pain—and interviewed thirty-one months out from their last prolotherapy session—was shown in this observational pilot study to improve patients' quality of life. They reported less pain, stiffness, depression and anxiety, medication usage, as well as im-

proved range of motion, sleep, and exercise ability. This included patients who were told by their medical doctor(s) that no other treatment options for their unresolved elbow pain existed. Over 73% of participants reported that improvement in their elbow pain and stiffness since receiving their last prolotherapy treatment had continued unabated to the day of being questioned.

Since this pilot study found such significant improvements in these participants with chronic unresolved elbow pain, further studies under more controlled circumstances and with larger patient populations should be done. ■

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