ABSTRACT

The optimal long-term, symptomatic therapy for unresolved knee pain has not been established. Accordingly, we investigated the outcomes of patients undergoing Hackett-Hemwall dextrose Prolotherapy treatment for unresolved knee pain at a charity clinic in rural Illinois. We studied a sample of 80 patients, representing a total of 119 knees, that were treated quarterly with Prolotherapy. On average, 15 months following their last Prolotherapy session, patients were contacted and asked numerous questions in regard to their levels of pain and a variety of physical and psychological symptoms, as well as activities of daily living, before and after their last Prolotherapy treatment. The results of this study showed that patients had a statistically significant decline in their level of pain, stiffness, crunching sensation, and improvement in their range of motion with Prolotherapy. More than 82% showed improvements in walking ability, medication usage, athletic ability, anxiety, depression, and overall disability with Prolotherapy. Ninety-six percent of patients felt Prolotherapy improved their life overall. Conclusion: In this study, patients with unresolved knee pain, treated with dextrose Prolotherapy, showed improvements in many clinically relevant parameters and overall quality of life.

KEYWORDS: anxiety, crunching, depression, knee pain, medication, Prolotherapy, range of motion, retrospective study, stiffness.

INTRODUCTION

The optimal long-term, symptomatic therapy for unresolved knee pain has not been established. Accordingly, we investigated the outcomes of patients undergoing Hackett-Hemwall dextrose Prolotherapy treatment for unresolved knee pain at a charity clinic in rural Illinois. Knee pain is a common problem facing many patients, presenting in up to 20% of the adult population. Currently in the U.S., osteoarthritis of the knee results in chronic knee pain in approximately 17 million people. According to the American Academy of Orthopaedic Surgeons, between the years 1998 and 2005, the number of knee replacements doubled, resulting in an estimated 533,808 procedures done in the year 2005. By the year 2030, this number is projected to be 3.48 million. With this one form of surgery already accruing over $17 billion in hospitalization charges in 2005, and 90% of these needing to be repeated in 10 years, we suggest that the Hackett-Hemwall dextrose Prolotherapy technique for treating the injured knee is a safe, effective, and less expensive solution to a portion of this rising trend.

Prolotherapy is becoming a widespread form of pain management in both complementary and allopathic medicine. Its primary use is in pain management associated with tendinopathies and ligament sprains in peripheral joints. Prolotherapy is also being used in the treatment of spine and joint degenerative arthritis. In double-blinded human studies, the evidence on the effectiveness of Prolotherapy has been considered promising, but mixed. Prolotherapy treatments are now done at some major medical centers and universities. George S. Hackett, MD, Prolotherapy pioneer, coined the term Prolotherapy in the 1930s. 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.” Animal studies have shown that Prolotherapy induces the production of new collagen by stimulating the normal inflammatory reaction. In addition, animal studies have shown improvements in ligament and tendon diameter and strength. Human studies have shown improvements in pain symptoms.
Studies on the effectiveness of Prolotherapy on knee pain have been promising. One of these studies showed the benefits of three bimonthly injections of dextrose as the proliferant into the degenerated knees. To evaluate the effectiveness of dextrose Prolotherapy, not just on knee pain but on quality of life measures, this observational study was undertaken.

**Objectives**

To investigate the outcomes of patients undergoing dextrose Prolotherapy treatment for unresolved knee pain at a charity clinic in rural Illinois. To develop selection criterion for who might be a good candidate for Prolotherapy in patients with unresolved knee pain.

**Methods**

Patients with unresolved knee pain who were treated with dextrose Prolotherapy every three months were included into an observational study. The patients were called on the phone, on average, fifteen months following their last Prolotherapy session and asked to answer detailed questions related to the level of knee pain, stiffness, range of motion, medication usage, anxiety, depression, activities of daily living, and other quality of life measures before and after receiving dextrose Prolotherapy.

**Results**

A total of 80 patients representing 119 knees were treated in 2003-2005. The average starting knee pain level was 6.5 and ending knee pain level was 2.3. Using the matched sample test, statistically significant improvements in pain, stiffness, and crunching sensation were observed. Ninety-five percent of patients exhibited improvements in their pain levels after treatment with Prolotherapy. Long term improvements in stiffness occurred in 99% of patients. Ninety percent of patients were able to decrease their medication usage by 50% or more. More than 87% of patients were able to decrease their additional pain treatments by 50% or more. Anxiety and depression symptoms were present in 49% and 41% before Prolotherapy and only in 15% and 10%, respectively, after Prolotherapy. Ninety percent of patients who were told, prior to receiving Prolotherapy, that surgery was their only option, had 75% or greater relief of their chronic pain. While no patients stated they could walk normally before Prolotherapy, 65% stated they could walk normally after Prolotherapy.

**Conclusions**

In this observational study, patients with unresolved knee pain reported clinically relevant improvements in their pain levels and quality of life after receiving dextrose Prolotherapy.

**Methods**

**Framework and Setting**

In October 1994 the two authors started a Christian charity medical clinic, called Beulah Land Natural Medicine Clinic, in an impoverished area in southern Illinois. Prolotherapy was the primary modality of treatment offered for pain control. Dextrose was selected as the main proliferant in the Prolotherapy solution because of its availability, relative inexpensiveness (compared to other proliferants), and its high safety profile. The clinic met every three months until July 2005, and all treatments were given free of charge.

**Patients**

Patients who received Prolotherapy for their unresolved knee pain in the years 2003, 2004, and 2005 were called by telephone and interviewed by an independent data collector who had no prior knowledge of Prolotherapy. General inclusion criteria were an age of at least 18 years, presence of an unresolved knee condition that typically responds to Prolotherapy, and a willingness to undergo at least four Prolotherapy sessions, unless the pain remitted with less Prolotherapy sessions.

**Interventions**

The Hackett-Hemwall technique of Prolotherapy was used and each patient received 20 to 40 injections of a 15% dextrose, 0.2% lidocaine solution with a total of 20 to 30cc of solution used per knee. Each patient was given an intraarticular injection of 5 to 10cc of solution. Around the knee, tender areas were also injected, and 0.5 to 1.0cc of solution was used per extra-articular injection. Tender areas injected included the medial and lateral collateral ligaments, patellar ligament, and pesanserine tendon attachments. (See Figure 1.) No other therapies were used. As much as the pain would allow, the patients were asked to reduce or stop non-steroidal anti-inflammatory and narcotic medications.
Results

PATIENT CHARACTERISTICS

From a total of 120 patients with unresolved knee pain whose charts were analyzed and who were interviewed via phone, 80 met the inclusion criteria. The main reasons for exclusion were inability to complete treatments due to travel/distance (45%); stopped treatments because of their medical doctor’s recommendation (i.e. needed treatments more frequently or other medical problems) or on their own (30%); inability or unwillingness to answer survey (15%); and other (10%).

A total of 119 knees from 80 patients met the inclusion criteria. Of these, 60% were female and 40% were male. The average age of the patients was 54 years-old. Patients reported an average of five years of pain, 30% had pain for greater than six years, and 19% had pain for between four and six years. Forty-seven percent of patients came because of financial concerns and 43% came upon the recommendation of a friend or family member. The average patient saw 2.3 M.D.’s before receiving Prolotherapy. Thirteen percent were told by one of their physicians that surgery was the only answer to their pain problem, and 38% of patients were told by their physicians that there were no other treatment options for their chronic knee pain. Twenty-one percent were taking one pharmaceutical drug for pain. Twenty-three percent were taking two or more drugs for pain. (See Table 1.)

Table 1. Patient Characteristics at Baseline.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
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<tbody>
<tr>
<td>Total number of patients treated</td>
<td>80</td>
</tr>
<tr>
<td>Total number of knees treated</td>
<td>119</td>
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<tr>
<td>Average age of patients</td>
<td>54</td>
</tr>
<tr>
<td>Percent of male patients</td>
<td>40%</td>
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<tr>
<td>Percent of female patients</td>
<td>60%</td>
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<tr>
<td>Number of prior physicians seen</td>
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<tr>
<td>Average years of pain</td>
<td>5.0</td>
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<tr>
<td>Average time since last Prolotherapy</td>
<td>15 months</td>
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<tr>
<td>Informed surgery only treatment option</td>
<td>13%</td>
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<tr>
<td>Informed no other treatment option for their chronic knee pain</td>
<td>38%</td>
</tr>
<tr>
<td>Taking one pharmaceutical drug for pain</td>
<td>21%</td>
</tr>
<tr>
<td>Taking two or more pharmaceutical drugs for pain</td>
<td>23%</td>
</tr>
</tbody>
</table>
TREATMENT OUTCOMES

Patients received an average of four Prolotherapy treatments per knee. The average time of follow-up after their last Prolotherapy session was 15 months.

Patients were asked to rate their pain, stiffness, and crunching sensation on a scale of 1 to 10, with 1 being no pain/stiffness/crunching and 10 being severe/crippling pain/stiffness/crunching. The 119 knees had an average starting pain level of 6.5, starting stiffness level of 4.7, and starting crunching level of 3.8. Patients were asked to rate their mobility on a scale of 1 to 7, with 1 being no motion, 2 through 5 were percentages of normal motion with 2 being 1-24%, 3 being 25-49%, 4 being 50-74% and 5 being 75-99% of normal motion. Normal motion was 6, and 7 was excessive motion or hyper mobility. The average starting mobility level was 4.7.

The patients reported, after Prolotherapy, that their average ending pain level was 2.3. (See Figure 2.) Average ending mobility was 5.4, average ending stiffness 2.0, and average ending crunching 2.1. Of the patients who started with serious pain (level 8 or more), 93.5% ended with less than minimal pain (a level of 3 or less). The percentage of patients who had a decrease in their pain level was 95%. Of these patients, 83% had a significant reduction in pain of at least 50% or higher. (See Figure 3.) Eighty-four percent of patients finished with only minor restrictions in motion (75% or greater of normal motion). More than 83% of patients reported a minimal stiffness level (a level of 3 or less) after completion of the treatments. Eighty percent of patients reported improvements in the crunching level of their knees and 90% of patients were able to decrease their medication usage by 50% or more.

In regard to quality of life issues, prior to receiving Prolotherapy, none of the participants reported normal walking ability. Eight percent used a cane/walker or wheelchair for mobility. Twelve percent said they could walk for a block or less. Twenty-three percent could walk between one and three blocks. Fifty-seven percent stated they could walk more than three blocks, but not as much as they would like. All patients reported improvements in walking ability after Prolotherapy with 65% having normal walking ability, and 91% could walk three blocks or more. (See Figure 4.) Eighty percent reported that their progress had very much continued (75-99%) after the Prolotherapy sessions were stopped.

Concerning athletic ability prior to Prolotherapy, 36% said they could do no athletics, 13% said they could engage in less than 10 minutes, 22% reported they could engage in less than 30 minutes, but all 100% ranked athletic ability as at least somewhat compromised. All patients stated they had some improvements in athletic ability, with 38% getting back to completely normal athletic ability, and 80% stating that those improvements very much continued after the Prolotherapy sessions ended. After Prolotherapy, 78% stated they could now do at least 30 minutes of exercise. (See Figure 5.)

Before Prolotherapy, 16% noted some dependency on another person for activities of daily living; 35% worked full-time, 10% worked part-time, 9% were disabled and
Unable to work, and 25% were retired; all participants noted some overall disability with 52% having a greater than 50% disability. After Prolotherapy, 97% of patients were totally independent, 39% worked full-time, 11% worked part-time, 4% were disabled and unable to work, and 23% were retired; 29% had no disability whatsoever, with only 13% having a greater than 50% disability. Ninety-four percent of the patients felt that their improvements in disability have mostly continued (50% or greater) after Prolotherapy.

Seventy-four percent of patients had trouble sleeping prior to Prolotherapy with 82% saying they could sleep much better after Prolotherapy. Ninety-two percent stated that the improvement in sleep has at least mostly continued after Prolotherapy (50% or greater). Before Prolotherapy, 41% of patients were depressed and 49% were anxious. After Prolotherapy, 90% of patients were not depressed, and 85% were not anxious. (See Figures 6 & 7.)

To a simple yes or no question: Has Prolotherapy changed your life for the better? 96% of patients treated answered yes. In quantifying the response, 43% felt their life was at least radically better with Prolotherapy. Eighty-eight percent rated Prolotherapy at least very successful in treating their condition (50% or greater improvement) with 50% noting the Prolotherapy to be extremely successful (75% or greater improvement). The percentage of patients able to decrease their additional pain-related treatments including chiropractic, physical therapy, acupuncture, and massage after Prolotherapy was 86%. The percentage of patients able to decrease their medication usage by 50% or more was 90%.

Ninety-four percent of patients know of others who have benefited from Prolotherapy. Ninety-seven percent of patients have recommended Prolotherapy to someone. Eighty-seven percent noted that the results of Prolotherapy have mostly continued (at least 50% retained), and 52%
of patients noted that their overall results have very much continued to the present (75% to 99%). Seventy-eight percent noted there were reasons besides the Prolotherapy effect wearing off that were causing their continued pain and/or disability. Of the 78%, 42% of these believe they stopped Prolotherapy too soon (before the pain was totally gone), 20% re-injured the area that had received Prolotherapy, 13% had a new area of pain, 10% had increased life stressors, and 15% had other explanations for the pain. Of the clients whose pain recurred after Prolotherapy was stopped, 81% are planning on receiving more Prolotherapy.

**Statistical Analysis**

A matched sample test was used to calculate the difference in responses between the before and after measures for pain, stiffness, and crunching. Using the matched sample test on all three variables, all p values reached statistical significance at the 1% level. The p values for pain, stiffness, and crunching were all 0. (See Table 2.) Analysis and calculation of the p-value was done by an independent third party who had no previous knowledge of Prolotherapy.

As previously noted, 38% of patients were told prior to Prolotherapy that no other treatment options existed for their pain. In analyzing these patients, 53% achieved least 75% pain relief with Prolotherapy. All patients stated they had achieved at least some relief of their pain with Prolotherapy. Thirteen percent of patients, prior to Prolotherapy, were told by their physician that surgery was their only option and 90% of them received at least 75% relief from their pain.

To further analyze the data, we asked the question “Were there any characteristic differences in patients who had excellent pain relief with Prolotherapy (greater than 75%...
Fantastical Findings: A Retrospective Study on Dextrose Prolotherapy for Unresolved Knee Pain

Table 2. Main outcome measures at baseline and after treatment with Prolotherapy.

<table>
<thead>
<tr>
<th>Outcome Measures</th>
<th>Starting</th>
<th>Ending</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average pain level</td>
<td>6.5</td>
<td>2.3</td>
</tr>
<tr>
<td>Percentage of patients w/ pain level 8 or greater</td>
<td>41%</td>
<td>3%</td>
</tr>
<tr>
<td>Percentage of patients w/ pain level 3 or less</td>
<td>13%</td>
<td>78%</td>
</tr>
<tr>
<td>Average stiffness level</td>
<td>4.7</td>
<td>2.0</td>
</tr>
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<td>3.8</td>
<td>2.1</td>
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<tr>
<td>Patients felt at least some depression</td>
<td>40%</td>
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<td>Patients felt at least some anxiety</td>
<td>39%</td>
<td>12%</td>
</tr>
<tr>
<td>Inability to exercise</td>
<td>33%</td>
<td>9%</td>
</tr>
<tr>
<td>Uncompromised ability to exercise</td>
<td>0%</td>
<td>30%</td>
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Figure 8. Percent of patients with excellent pain relief versus minimal pain relief based on length of pain. The best responders to dextrose Prolotherapy received the Prolotherapy within three years of having pain.

Figure 9. The effectiveness of Hackett-Hemwall dextrose Prolotherapy versus patients’ starting range of motion.

Another characteristic analyzed was stiffness. In this study, stiffness was measured on a scale of 1 to 10 with 1 being little to no stiffness and 10 being extreme stiffness. As seen in Figure 10, 76% of patients who rated their starting stiffness level as a 7 or less had excellent pain relief following Prolotherapy. Those who had minimal results with Prolotherapy was only 3.4%. But when the initial stiffness level was 8 or more, 14% had minimal results. Using the same scale, patients with an initial crunching level of 6 or less only 3.5% had minimal results with Prolotherapy, while 30% of those, with a level of 7 or more, reported minimal results. (See Figure 11.)

When patients stated their starting walking level was somewhat compromised (able to walk more than three blocks) or not compromised at all, 80% had excellent results and only 1.7% had minimal results with Prolotherapy. When starting walking ability was definitely compromised or worse (at least 25% or greater compromised), 22% of patients had minimal pain relief. (See Figure 12.)

When a patient’s starting work situation was examined, 36 of the 37 patients that worked had excellent pain relief with Prolotherapy. In regard to those who were disabled at the time of their first Prolotherapy treatment, 44% had excellent pain relief with Prolotherapy. All of the patients who started extremely depressed and on medications reported 100% excellent pain relief with Prolotherapy. Of those who were very depressed, but not on medication, 17% of them reported excellent pain relief.

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**Discussion**

**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 knee pain. Decreases in pain, stiffness, and crunching levels reached statistical significance with Prolotherapy. The percentage of patients with less knee pain was 95%, and 99% reported long term improvements in stiffness after Prolotherapy. Eighty-six percent of patients decreased their need for additional pain therapies, including medication usage by 90% or more, after Prolotherapy. Eighty-two percent showed an improvement in sleep. For those with depression and anxiety, 86% were less depressed and 82% were less anxious. In regard to activities of daily living, Prolotherapy improved walking ability in 84%, athletic ability in 76%, and dependency on another person in 75% of patients treated. Of the patients treated with the Hackett-Hemwall technique of dextrose Prolotherapy, 95% felt an overall improvement in their quality of life. Ninety-four percent of patients noted their improvement in overall disability has mostly continued since their last treatment.

**STRENGTHS AND LIMITATIONS**

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 knee pain to Prolotherapy at a charity medical clinic. Clear strengths of the study are the numerous quality of life parameters that were studied. Such quality of life issues as walking ability, stiffness, range of motion, activities of daily living, athletic ability, dependency on others, sleep, anxiety and depression, in addition to pain level, are important factors affecting the person with unresolved knee pain. The improvement in such a large number of knees treated solely by Prolotherapy, even though subjective, is likely to have resulted from the Prolotherapy.

Another strength of this study is that the study population received only Prolotherapy as a treatment for their knee pain; no other treatment modalities were used. Because of the number of patients coming to each clinic (anywhere from 250 to 500), it was impossible to perform numerous modalities on each of them. The financial constraints on
the patient population also precluded them from getting other therapies. Thus, their improvement most likely stems from the Prolotherapy, not any other treatment.

A weakness of this study is that most Prolotherapists using the Hackett-Hemwall method of Prolotherapy see patients every four to six weeks, which is in tune with the normal healing time of ligaments and tendons. Because this was a charity clinic that required numerous volunteers to run it, it was only possible to provide care once every quarter (every three months). Because of this extended follow-up time, the actual cure rates of pain were below what others have found with Prolotherapy.\textsuperscript{32-34} If the Prolotherapy treatments were received more frequently, we would expect the cure rates of pain to be even greater.

Another weakness of this study is that there was not a control group. Because the average person in this study had pain for an average of five years and was an average age of 54, their unresolved knee complaints most likely stem from a chronic degenerated knee. Since these conditions are almost universally progressive and often don’t spontaneously improve, a control group, while helpful, does not negate the results of the study.

An important limitation of our study is the subjective nature of the evaluated parameters. Another limitation is the lack of X-ray and MRI correlation for diagnosis and response to treatment. There was also a lack of physical examination documentation in the patients’ charts to include in the study.

\textbf{INTERPRETATION OF FINDINGS}

It is estimated that 80\% of people over the age of 50 suffer from some degree of progressive osteoarthritis. Generally speaking, weight-bearing joints, such as the hips, spine, knees, and hands are most commonly involved.\textsuperscript{35,36} These joints are especially prone to degeneration as a result of the greater wear and tear they experience than other tissues through the body.\textsuperscript{37}

Current conventional therapy of painful osteoarthritis of the knee include: medical treatment with analgesics, non-steroidal anti-inflammatory drugs, and intraarticular corticosteroid or Hyaluronan injections, muscle strengthening exercises, weight loss, the use of assisted devices, such as canes and orthotics, surgical treatment that range from arthroscopic joint debridement to total joint replacement, and education and counseling. Many times the results of such therapies leave patients with residual pain.\textsuperscript{38,39,40} Because of this; many patients with osteoarthritis are searching for alternative treatments for their pain. One of the treatments they are trying is Prolotherapy.

Prolotherapy is a treatment being performed by more physicians based on positive anecdotal evidence, yet large studies on long term outcomes are limited. From at least one source, some 450,000 Americans have undergone Prolotherapy.\textsuperscript{41} There have been numerous studies on animals’ knees showing the efficacy with Prolotherapy,\textsuperscript{42-46} but only two in humans.\textsuperscript{47,48} The studies showed Prolotherapy resulted in significant improvements in knee osteoarthritis, including improvements in pain, swelling complaints, and knee buckling frequency. Radiographic improvements in the knee osteoarthritis also occurred.\textsuperscript{49} This observational study was the first to show Prolotherapy helps not only the physical components of unresolved knee complaints such as pain, stiffness, range of motion and crunching sensations, but also helps numerous quality of life functions including walking ability, sleep, athletic ability, activities of daily living, and feelings of depression and anxiety. This study also showed that 15 months after their last Prolotherapy session, the vast majority of improvements continued. In this study population, Prolotherapy reduced the patients’ subjective overall disability, medication usage, other pain therapy treatments needed, as well as depressed and anxious feelings. Prolotherapy improved the patients walking and exercise ability, sleep, activities of daily living, and work situation. For the vast majority of the patients, Prolotherapy had a long lasting effect and changed their lives for the better.

In regard to the question, \textit{who is a good Prolotherapy candidate?} this study compared patients who had great pain relief (greater than 75\%) to those that had minimal pain relief (less than 25\%) with Prolotherapy. This observational study showed that patients at initial presentation did better with Prolotherapy if they had pain less than three years, starting range of motion of 50\% or more of normal, stiffness and crunching level of 7 or less, saw three or fewer M.D.’s prior to Prolotherapy, had an overall disability of 50\% or less, could walk greater than 3 blocks, had employment and they were on medications if they were extremely depressed. (See Table 3.)
The Hackett-Hemwall technique of dextrose Prolotherapy used on patients who had a duration of five years of unresolved knee pain was shown in this observational study to improve their quality of life. They reported less pain, stiffness, disability, depressed and anxious thoughts, medication and other pain therapy usage, as well as improved walking ability, range of motion, ability to work and activities of daily living. Therefore, Prolotherapy appears to be a viable treatment option for people suffering with unresolved knee pain.

### Conclusions

The Hackett-Hemwall technique of dextrose Prolotherapy used on patients who had a duration of five years of unresolved knee pain was shown in this observational study to improve their quality of life. They reported less pain, stiffness, disability, depressed and anxious thoughts, medication and other pain therapy usage, as well as improved walking ability, range of motion, ability to work and activities of daily living. Therefore, Prolotherapy appears to be a viable treatment option for people suffering with unresolved knee pain.

### Bibliography


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<td>50% or more of normal</td>
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<tr>
<td>Stiffness and crunching level</td>
<td>7 or less</td>
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<tr>
<td>Number of physicians seen prior to Prolotherapy</td>
<td>3 or less</td>
</tr>
<tr>
<td>Overall disability</td>
<td>50% or less</td>
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<tr>
<td>Walking ability</td>
<td>&gt; 3 blocks</td>
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<td>Employed</td>
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</table>


49. IBID.

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