

#### JOURNAL of PROLOTHERAPY [for Doctors & Patients]

#### **VOLUME ONE | ISSUE TWO | MAY 2009**

www.journalofprolotherapy.com

CORTICOSTEROID

PROLOTRADORIZADOS The Regeneration & Degeneration OF ARTICULAR CARTILAGE

#### **ALSO IN THIS ISSUE**

- The World Needs This Journal
- Letters from Our Readers
- Trauma Surgeon Turned Prolotherapist: An Interview with José Eleazar Calderón de la Fuente, MD
- A Retrospective Study on Hackett-Hemwall Dextrose Prolotherapy for Chronic Hip Pain
- Prolotherapy for Pelvic Ligament Pain: A Case Report

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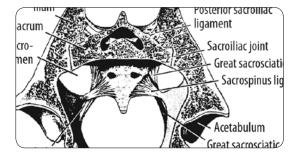
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#### ISSN 1944-0421 (print) ISSN 1944-043X (online)

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#### MICHELLE MURPHY

Michelle Murphy is a long distance runner who, over a number of years, developed sacroiliac joint pain, iliotibial band problems, piriformis syndrome, patella femoral syndrome, and pain all along her entire right side. She sought out treatment as these problems progressed in severity, from both the allopathic community as well as extensive chiropractic and physiotherapy. Unfortunately, these treatments were all minimally successful at best, providing no real relief. In spite of her best efforts to seek medical attention for this problem, she was offered nothing by allopathic medicine, except an assessment of a pulled groin muscle, and to stop running. Since walking was a serious problem, their advice was of no help. Months of dedicated, daily physiotherapy treatments proved mostly futile until finally the physiotherapist, a marathoner herself, informed her of a treatment called Prolotherapy.



#### RODNEY S. VAN PELT, MD

Rodney S. Van Pelt, MD received his medical degree from Loma Linda University Medical School and completed his family practice residency in Florida. He practiced family medicine for several years until falling in love with the specialty of Orthopedic Medicine which uses all the different modalities for pain with conservative treatments. Dr. Van Pelt then received specialized training in the Cyriax technique of Orthopedic Medicine, taking some of his training in Oxford, England. He is one of the few American physicians who is a member of the Society of Orthopedic Medicine of London, England. Dr. Van Pelt practices full time Prolotherapy in northern California. Dr. Van Pelt may be contacted at Orthopedic Wellness Center Plaza Del Sol, 776 S State St., Ukiah, CA 95482; Tel: 707.463.1782; <u>www.sfpmg.com</u>.

GREAT NEWS CORNER



## **The World Needs This Journal**

Ross A. Hauser, MD

elcome to the second issue of the Journal of Prolotherapy<sup>TM</sup>! It was a long road to get here, and I thank all who worked so hard to accomplish that goal! I am more convinced now than ever that the world needs this journal. Pain is destroying a lot of lives and many of them in the prime of life! One of those lives is Terri, who I just met in November, 2008 as a new patient in my office. She has three teenage boys and is happily married. She has suffered with neck pain for 16 years. She attributes the development and continuation of her pain to holding the phone between her neck and left shoulder for her job. In the course of 16 years, she had the following treatments: several hundred high velocity chiropractic manipulations, at least 15 separate courses of physical therapy, about eight trigger point injection sessions, more than five cortisone-type facet injections under fluoroscopy, 20 different medications, and visits to over 50 different health care practitioners.

Though only in her forties, Terri looks much older than her stated age. Pain does that to a person. She and her husband have literally spent tens of thousands of dollars out of pocket for her care. Her MRI does show extensive degeneration, but she has no nerve involvement. On physical examination, Terri exhibited numerous trigger points and tender points throughout her neck and upper back. She received her first Prolotherapy session on her first visit and I gave her a 90% chance of getting rid of all or greater than 75% of her pain with Prolotherapy.

The next week after seeing Terri, I saw another client, Joan, who has had at least 15 separate cortisone shots in her shoulder. By the time she saw her first Prolotherapist (me), she was suffering with a nearly completely frozen left shoulder. She had no abduction (moving the arm away from the body) and no external rotation. When I say none, I mean none. I told her it was doubtful Prolotherapy was going to help her with her range of motion at this stage in the game, but we should be able to decrease her pain. She was okay with that. I should mention the fact that she had massive muscle atrophy in the front of her shoulder. I am confident the doctors who had been treating her had no idea just how much damage the cortisone shots have done to this woman. Had she first seen a Prolotherapist with her shoulder problem, she would most likely be back to full function already.

William is another interesting case. He has experienced successful Prolotherapy to his ankle, and both feet, shoulders, and knees, yet the treatment to his neck was only partially able to cure his neck pain. But he is very pleased with his progress nonetheless, as he is no longer left to live a life of total body pain and pain meds. Here is what he told me, "Many, many times I've talked to my other doctors about Prolotherapy and there was no interest whatsoever! They advised me not to pursue Prolotherapy as a treatment because it isn't proven!"

You can see why the world needs this journal. What I am about to say may sound odd, but once I explain it, it will make sense. *The same reason doctors give cortisone shots is the same reason they don't do Prolotherapy. Let me say it again: The same reason doctors give cortisone shots is the same reason they don't do Prolotherapy injections!* The reason you ask? Because you cannot sacrifice human beings! Yes, that is the reason. Let me explain.

If a panel of traditional doctors reviewed the animal research on corticosteroid injections and the animal research on Prolotherapy, the conclusion would have to be that corticosteroid injections directly into joints **causes articular cartilage degeneration.** In degenerated joints, cortisone injections further the degeneration. I am talking about degenerative arthritis (or commonly known as osteoarthritis), not inflammatory arthritis (like rheumatoid arthritis). The animal evidence on Prolotherapy, on the other hand, is overwhelming that this injection therapy **stimulates regeneration of structures**, such as ligaments or tendons. The

obvious question becomes, "Why don't more traditional doctors do Prolotherapy and why do they give so many corticosteroid shots to already degenerated joints?" The reason is as before, you can't sacrifice human beings.

This issue of the *Journal of Prolotherapy*<sup>TM</sup> contains a scientific review on what corticosteroid shots do to animal and human articular cartilage. Corticosteroids degenerate articular cartilage. Unfortunately, because of the acceptance of corticosteroid injections in traditional allopathic medicine, it is just assumed that, for the most

part, they are safe. As it relates to osteoarthritis, the preponderance of evidence is to the contrary. It is generally accepted that over time a degenerated joint becomes more and more degenerated until a person needs a knee or hip replacement. This begs the question, "Why?" What is causing

so much cartilage breakdown? Why haven't more researchers or doctors thought to make the correlation that perhaps the substance(s) that are degenerating these knees and hips at such an alarming rate, are in fact that very substances that have been injected into the joints and are prescribed to relieve the pain of osteoarthritis?

It is easy to prove that anti-inflammatory injections or medications are damaging to the articular cartilage in animals because you can biopsy or sacrifice the animals and look at the articular cartilage under a microscope. The problem is you can't sacrifice a human being to look at his/her articular cartilage under the microscope a month or two, six or twelve months after a corticosteroid shot! Likewise, it is difficult to prove Prolotherapy because modern medicine wants to see microscopic or X-ray data. What if most ligaments do not show up on X-ray and what if we cannot look at the Prolotherapy-treated ligaments under the microscope? Shouldn't the resolution of patients' symptoms be proof enough? The *Journal of Prolotherapy*<sup>™</sup> welcomes and hopes that future microscopic

Animal studies prove that Prolotherapy stimulates regeneration of ligaments and tendons.

**Corticosteroids degenerate** 

articular cartilage, yet they

are generally accepted as

safe by traditional medicine.

and X-ray data will show that Prolotherapy in human beings to the various structures, such as cartilage, ligaments, menisci, labrum and tendons regenerates them. But let us not forget that the most important evidence in all of this is whether the patients' pain

and lives improve? Does in fact, regenerative injection therapy cause people to achieve long-term pain relief to the point that they regain exercise ability and enjoy life again? We believe at  $\mathcal{J}OP$  that the resolution of a patient's symptom (especially those who have suffered with pain and other symtomatology for years and even decades) is the best kind of proof! You do not need a double-blind study because the patient is basically their own control. Degenerative joint disease or disc disease is a progressive condition. These conditions do not spontaneously remit. For the person suffering from knee pain for 10 years who

> receives Prolotherapy, what more proof does one need if the pain stops and the patient is back to playing tennis?

This second issue of the *Journal of*  $Prolotherapy^{TM}$  is packed with great articles, remarkable recoveries, and experiences with Prolotherapy

from around the world! Here is what you will find in this issue: Two doctors' personal Prolotherapy journeys, a Remarkable Recovery story from an endurance athlete, Prolotherapy study on chronic hip pain, Prolotherapy skill enhancement for hip treatments, a review of the literature on elbow tendinopathies, and much more!

Thanks for all of your comments on the first issue. Remember that our goal is to educate the world about the life-changing effects of Prolotherapy. This will only happen by you telling how your life was changed with Prolotherapy. Tell us **your** story!

Until the next injection,

Ross q. Houser M.D.

## **Letters from Our Readers**

Ross A. Hauser, MD

#### LETTER FROM READER

I am a layman but found the journal to be very readable and understandable. I would like to see some controlled double-blind studies done.

I can certainly see and appreciate the anecdotal evidence but think that the credibility of the field can only be enhanced by some rigorously controlled studies.



I enjoyed the diversity of the authors particularly the

veterinarian. I found the short abstract on the various growth factors most interesting – IGF, TGF, VEGF, PDGF and bFGF. Controlled studies showing the efficacy of these growth factors would be amazing to me.

Yours faithfully, Andrew Spargo

#### EDITOR'S COMMENTS

#### Dear Andrew,

Thanks for your input. We are being diligent on making the journal readable and profitable both to the doctor and the lay public. I would like to refer you to my editorial on page 71 that addresses the issue of double-blind studies for progressive conditions. Yes, we are hopeful that future research will show what we already know, that Prolotherapy stimulates the repair of injured structures and that it is one of the best therapies out there! We too can't wait for the growth factors!

#### LETTER FROM READER

#### Dear Dr. Hauser,

I very much enjoyed the *Journal of Prolotherapy*<sup>TM</sup>, as it addresses doctors and patients, the kind of patient that seeks out healing options. I searched through the internet to research my treatment options, and educated myself on Prolotherapy and its benefits. The *Journal of Prolotherapy*<sup>TM</sup> is another resource for people making informed choices in their health care.

I can see that you almost have the perfect circle in the health care system, as noted on Page 63. It would be helpful to see more professionals listed on this page. Hopefully, the *Journal of Prolotherapy*<sup>TM</sup> will be able to educate more traditional physicians, who as a group I find to be resistant to integrative therapies. When speaking to my physician before coming for my first Prolotherapy treatment, I was surprised to learn that he knew of Prolotherapy. He stated that Prolotherapy "works differently" and continued to discuss the treatment he would provide. He did not discourage me from pursuing Prolotherapy, which was refreshing.

The *Journal of Prolotherapy*<sup>TM</sup> makes everything crystal clear. Both the benefits of Prolotherapy and the mechanism of connective tissue were explained very well. As patients, I know we are often full of worry and in a rush. However, something I have learned with my injury is that when it comes to connective tissues, muscle and bones, healing can be baby steps.

One thing injured people may not realize, but should consider, is that the money they invest in Prolotherapy Treatment is truly a "Life Investment," and once they are better they will see the world with different eyes. The money they invest will come back to them, as they will be physically able to be active again.

"Welding" is an appropriate and helpful term, and is the term I keep in mind as I receive the Prolotherapy treatment. I am looking forward to more "welding," moving towards a strong and healthy body!

Letter submitted from outside the U.S., requesting anonymity.

#### EDITOR'S COMMENTS

#### Dear Anonymous,

Thanks for your letter. Thank you also for reading the first issue. As you know it is our hope to get more doctors interested in Prolotherapy, but honestly a lot will happen if you and others who have received Prolotherapy spread the word! You are right, the word "weld" is a good word as it pertains to Prolotherapy strengthening an area.

#### LETTER FROM READER

Dear Dr. Hauser and Staff,

Congratulations on your *JOP* Volume #1 Issue #1. It evidently reveals a lot of time and hard work. Thank you for continuing to fight the battle to promote Prolo. Remember as time passes your army will grow with more and more painfree soldiers but the army of failed arthroscopes and needless joint replacements will diminish. The good that you sow will not go unrewarded. David beats Goliath because God is sovereign.

The article on Alek Jakich and his post Prolo X-ray in December 2007 reminded me of my first visit with you that very same month. In June 2005 an orthopedic surgeon had given me "exercises" to do for my bilateral chondromalacia patellae and said I would need surgery someday to correct the chronic pain I was in. I remember lying in bed in pain and thinking there had to be a better way. In Feb 2006 my wife and I were touring Italy and we decided to climb St Peter's Basilica, well I climbed back down the 451 steps backwards due to my pain. I looked silly and I

realized I had to find relief to my pain. Prolo provided that relief to both knees in 9 treatments from your skilled hands and capable staff. The fact that Alek's former physician wasn't receptive to Prolo's success doesn't surprise me. I am in the healthcare field as a dentist and I have come across some big egos from



the dental and medical community, in the private and military sectors, who are close-minded. I say shake the dust from your sandals or syringes and move on to the next city. You will find others who support Prolo, perhaps even the next new Surgeon General will be open to Prolo like Dr. Koop was. I'm looking forward to the next *JOP*.

Thanks for your belief in Prolo and faith in God.

Sincerely, Randy Siber, DDS Canton, Ohio

#### EDITOR'S COMMENTS

#### Dear Randy,

Thanks for you kind words. As you know it isn't just the doctor's fight to get Prolotherapy accepted but you, the patients, who have utilized Prolotherapy to get yourself back to the "land of the active." Thanks for joining the fight for Prolotherapy. We hope you will multiply yourself manifold!

IN THE SPOTLIGHT

## **Trauma Surgeon Turned Prolotherapist** An Interview with José Eleazar Calderón de la Fuente, MD

Joseph J. Cukla, LPN

**D** r. José Eleazar Calderón de la Fuente is a well known orthopedic/trauma surgeon in the city of Monclova, Mexico, who has been doing Prolotherapy for over ten years. **He was performing fifteen to twenty surgeries per week before he discovered Prolotherapy.** He primarily operated on knees and low backs, but also did his fair share of shoulder and elbow surgeries. The diagnoses for these arthroscopic and non-arthroscopic procedures would frequently be osteoarthritis and/or degenerative or ligament insufficiency.

Dr. Calderón met Ross Hauser, MD in Mexico when Dr. Hauser was there teaching a seminar on Prolotherapy at the invitation of pathologist Dr. Pepe Salazar, whose wife, Sophia Gutierrez, DDS, was treated by Dr. Hauser in the United States. When she was seen by Dr. Hauser, she was incapacitated by her pain. Drs. Calderón and Salazar were very good friends and Sophia had been a patient of Dr. Calderón for her severely degenerated knees. Her case was non-surgical, thus she was given no more treatment options, as he or others doctors she had seen could do nothing more for her.

Dr. Calderón was invited to the seminar in Toluca, a suburb of Mexico City, but was very skeptical of these syringes with the "magical water" that could cure pain. He was more interested in visiting Toluca than in hearing Dr. Hauser speak, but he decided to drop by as a favor to Dr. Salazar. He had became more interested in Prolotherapy after he observed the dramatic improvements in Sophia, thinking maybe there was something to it, but also realizing that there could be other reasons behind her improvement.

With Dr. Salazar's urging, he decided to bring Prolotherapy into his practice, still not fully believing Prolotherapy could become a successful treatment option for his patients. Dr. Calderón treated his first patient with Prolotherapy, a man with a terribly arthritic back who was not a surgical candidate. What did he have to lose? Lo and behold, the man returned a few weeks later reporting 75% improvement. **Ten thousand Prolotherapy patients later, Dr. Calderón is now Mexico's leading proponent of Prolotherapy, with his own popular website:** <u>www.proloterapia.com</u>. (See Figure 1.)

"Ninety-five percent of the patients I see now are for Prolotherapy. In fact, my arthroscopic equipment is for sale," stated Dr. Calderón. (*See Figure 2.*) "I truly believe



Figure 1. Dr. Calderón performing Prolotherapy on a lumbar pain patient with spondylolithesis at L4, L5.

Dr. Calderón reports a

90% success rate and

treats patients from all

over Mexico, the US, and

South America.

that this treatment can stop the arthritic process. I am only doing surgery now for traumas such as fractures and ruptures. I no longer do arthroscopies or osteotomy alignments. No more surgeries for degenerative conditions." Dr. Calderón has a 90% success rate treating

people from the United States, South America, and from all over Mexico. His patients typically need three to four treatments, depending on their age and severity of their condition.

"My orthopedic colleagues at first thought I was practicing voodoo or witchcraft. Now they refer their own family members to me. Prolotherapy

still is not very common in Mexico, as there are about ten practicing Prolotherapists here, all trained by me. I perform about 50 treatments per week, with low back, knees, shoulders, necks, and ankles being the most common areas."

"If Prolotherapy becomes more accepted, there will be harsh effects to the surgical industry and even the medical business in general," opines Dr. Calderón. "Compared to surgery and other treatment options, Prolotherapy is very cost effective."

"I have trained a couple of orthopedists in Prolotherapy, one who had severe pain as a sequela to two back surgeries. I treated him five times at my clinic during his training, and he is so happy that he is almost pain free now. I am really happy and excited for my colleague. When I first started doing Prolotherapy I was amazed at the results, but now ten years later, it is part of my life.

Dr. Calderón shared that when he was doing traditional medicine he had patients he did not want to see anymore because it would bother him that he could not cure them. "Sometimes I would end up sending them to a psychologist. Now I welcome everyone to my office. I am so happy to cure someone who was told they would never walk again or were confined to bed."

Prolotherapy has actually made his professional life easier. "Not only do I perform 95% less surgeries than I used to, when I do get a patient that may need a spinal column surgery, I refer them to a colleague. Now I do not have to deal with the problems that sometimes occur after a

surgery."

"I am basically using the same solution for my Prolotherapy treatments that Dr. Hauser taught me, distilled water, dextrose, lidocaine, and Sarapin, sometimes adding procaine or sodium morrhuate as he does. I have started to use ozone along with the Prolotherapy solutions. I call it

Prolozone. I use it for patients who have severe pain who I know that their pain will not be resolved quickly with Prolotherapy alone. The ozone can relieve their pain while the Prolotherapy is working."



equipment that he no longer needs because Prolotherapy has been so successful.

"I am very happy to have met Dr. Hauser and am very thankful to him," says Dr. Calderón. I am very grateful to he and his wife Marion as my life has changed completely since I started doing Prolotherapy. He taught me another view of medicine, a medicine I never knew. I will always keep the Hausers in my heart. With Prolotherapy and if God is willing, I would like to keep practicing Prolotherapy until I am 80, far longer than I could have as an orthopedic surgeon."

FANTASTIC FINDINGS

#### A B S T R A C T

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

**Design:** Sixty-one patients, representing 94 hips who had been in pain an average of 63 months, were treated quarterly with Hackett-Hemwall dextrose Prolotherapy. This included a subset of 20 patients who were told by their medical doctor(s) that there were no other treatment options for their pain and a subset of eight patients who were told by their doctor(s) that surgery was their only option. Patients were contacted an average of 19 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 94 hips, pain levels decreased from 7.0 to 2.4 after Prolotherapy; 89% experienced more than 50% of pain relief with Prolotherapy; more than 84% showed improvements in walking and exercise ability, anxiety, depression and overall disability; 54% were able to completely stop taking pain medications. The decrease in pain reached statistical significance at the p<.0001 for the 94 hips, 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 five years of unresolved hip pain were shown to improve their pain, stiffness, range of motion, and quality of life measures even 19 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 hip pain.

Journal of Prolotherapy. 2009;2:76-88. KEYWORDS: alternative to hip surgery, hip pain, ligament injury, Prolotherapy, retrospective study.

## A Retrospective Study on Hackett-Hemwall Dextrose Prolotherapy for Chronic Hip Pain at an Outpatient Charity Clinic in Rural Illinois

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

#### INTRODUCTION

Chronic hip pain is a common condition resulting in over 383,000 hip replacements annually in the United States and the number is increasing every year.<sup>1</sup> The high rates of wear and tear, attributable to normal use of the hip, can result in long term problems. This makes sense when one considers that patients move their hips at least one million times per year during activities of daily living.<sup>2,3</sup> Population-based surveys of patients who have arthritis of the hip document a large untapped need for these procedures, suggesting that the rates of total hip arthroplasty will likely increase in the future.<sup>4</sup> Not everyone who is a candidate for a new hip will choose this option, as the operation has inherent risks including poor outcome, osteolysis and need for revision, deep vein thrombosis and limited life span.<sup>5,6</sup> Because of the limited response of chronic hip pain to other traditional therapies, many people are turning to alternative therapies, including Prolotherapy, for pain control.<sup>7,8</sup>

Prolotherapy is becoming a widespread form of pain management in both complementary and allopathic medicine.<sup>9</sup> Its primary use is in the pain management associated with tendinopathies and ligament sprains in peripheral joints.<sup>10-12</sup> It is also being used in the treatment of spine and joint degenerative arthritis.<sup>13,14</sup> Prolotherapy has long been used for chronic low back pain arising from the sacroiliac joints and as an alternative to surgery.<sup>15-19</sup> Prolotherapy has been shown in low back studies to improve pain levels and range of motion.<sup>20,21</sup> In doubleblinded human studies the evidence on the effectiveness of Prolotherapy has been considered promising but mixed.<sup>22-25</sup>

George S. Hackett, MD, coined the term Prolotherapy.<sup>26</sup> 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."27 Animal studies have shown that Prolotherapy induces the production of new collagen by stimulating the normal inflammatory reaction.28,29 In addition, animal studies have shown improvements in ligament and tendon diameter and strength.<sup>30,31</sup> While Prolotherapy has been used for chronic hip pain, no study has been published to date to show its effectiveness for this condition.<sup>32</sup> To evaluate the effectiveness of Hackett-Hemwall dextrose Prolotherapy, not just on hip pain but on quality of life measures, as well as its ability to reduce or eliminate the need or other medical therapies including total hip replacement this observational study was undertaken.

## Patients and Methods

#### FRAMEWORK AND SETTING

In October 1994, the primary authors started a Christian charity medical clinic called Beulah Land Natural Medicine Clinic in an impoverished area in southern Illinois. The primary treatment modality offered was Hackett-Hemwall 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 compared to other proliferants, and has a high safety profile. The clinic met every three months until July 2005. All treatments were given free of charge.

#### PATIENT CRITERIA

General inclusion criterion were an age of at least 18 years, having an unresolved hip pain condition greater than six months that typically responds to Prolotherapy, and a willingness to undergo at least four Prolotherapy sessions, unless the pain remitted with less number of Prolotherapy sessions.

#### INTERVENTIONS

The Hackett-Hemwall technique of dextrose Prolotherapy was used. Each patient received 40 to 60 injections of a 15% dextrose, 0.2% lidocaine solution with a total of 50 to 60cc of solution used per hip. Each patient was given an intraarticular injection of 5 to 10cc of solution via the lateral or posterior approach. Injections were given at the bony attachments of the following structures around the hips including: the greater trochanter, intertrochanteric crest, neck of femur and dorsal ilium; ischiofemoral and ilofemoral ligaments; tensor fasica lata; and gluteus medius, pyriformis, gemellus superior, quadrates femoris, obturator internus, gemellus inferior and vastus lateral muscles. These typical tender spots each injected with 0.5 to 1cc of solution, can be seen in Figure 1. No other therapies were used. As much as the pain would allow, the patients were asked to reduce or stop other pain medications and therapies they were using.



Figure 1. Typical injection sites for Hackett-Hemwall dextrose Prolotherapy of the hip.

#### DATA COLLECTION

Patients who received Prolotherapy for their chronic hip pain in the years 2001 to 2005 were called by telephone and interviewed by an independent data collector (D.P.) who had no prior knowledge of Prolotherapy. 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, psychological factors and whether the response to Prolotherapy continued after their last Prolotherapy session.

#### STATISTICAL ANALYSIS

For the analysis, patient percentages of the various responses were calculated using Microsoft Excel by an independent computer consultant (D.G.), who also had no previous knowledge of Prolotherapy. These 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 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. 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, stiffness, and range of motion in the above three groups (total hips and two subgroups above).

#### PATIENT CHARACTERISTICS

Complete data was obtained on 61 patients representing 94 hips. Of the 61 patients, 72% (44) were female and 28% (17) were male. The average age of the patients was 62 years-old. Patients reported an average of five years, three months of pain. Fifty-four percent had pain longer than four years and 39% had pain longer than six years. The average patient saw three doctors before receiving Prolotherapy. Twelve percent saw six or more doctors and another 22% saw four or five doctors for their chronic hip pain. The average patient was taking 1.1 pain medications. Thirteen percent stated that the consensus of their doctor(s) was that surgery was the only answer to their pain problem, and 33% of patients were told by their doctor(s) that there were no other treatment options for their chronic pain. (*See Table 1.*)

#### TREATMENT OUTCOMES

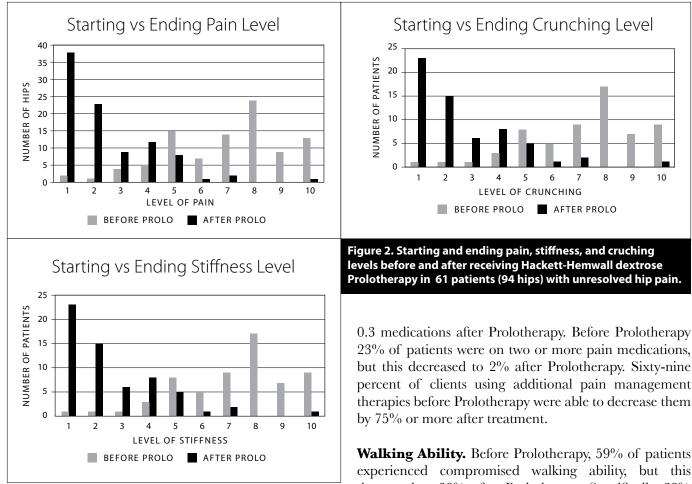
Patients received an average of 4.7 Prolotherapy treatments per hip. The average time of follow-up after their last Prolotherapy session was 19 months.

Table 1. Patient characteristics at baseline.		
Total number of patients treated	61	
Total number of hips treated	94	
Average age of patients	62	
Percent of male patients	28%	
Percent of female patients	72%	
Number of prior physicians seen	3.1	
Average years of pain	5.3	
Informed surgery only treatment option	13%	
Informed no other treatment option for their chronic hip pain	33%	
Average number of pharmaceutical drugs taken for pain	1.1	

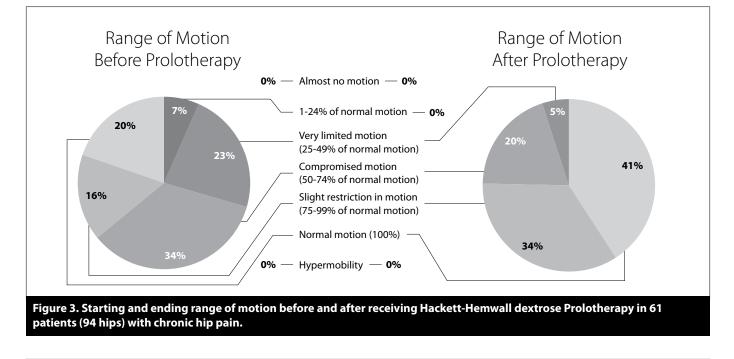
**Pain, Crunching Sensation, Stiffness.** Patients were asked to rate their pain, crunching sensation and stiffness on a scale of 1 to 10 with 1 being no pain/crunching/ stiffness and 10 being severe crippling pain/crunching/ stiffness. The 61, representing 94 hips had an average starting pain level of 7.0, crunching sensation of 2.0 and stiffness of 4.4. Their average ending pain, crunching and stiffness levels were 2.4, 1.2, and 2.0 respectively. Fifty-four percent had a starting pain level of eight or greater, while only 5% had a starting pain level of three or less, whereas after Prolotherapy only 2% had a pain level of eight or greater while 77% had a pain level of three or less. (*See Figure 2.*)

**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 4.3 and ending range of motion was 5.1. Before Prolotherapy 30% had very limited motion (49% or less of normal motion), this decreased to only five percent after Prolotherapy. Prior to Prolotherapy only 36% had 75% or greater of normal range of motion but this improved to 75% after Prolotherapy. (*See Figure 3.*)

Utilization. Pain Medication Sixty percent discontinued pain medications altogether after Prolotherapy. In all, 75% of patients on medications at the start of Prolotherapy were able to decrease them by 75% or more after Prolotherapy. None of the patients had to increase pain medication usage after stopping Prolotherapy. Before Prolotherapy the average patient was taking 1.1 pain medications but this decreased to



experienced compromised walking ability, but this decreased to 39% after Prolotherapy. Specifically, 38% could walk three blocks or less before Prolotherapy,



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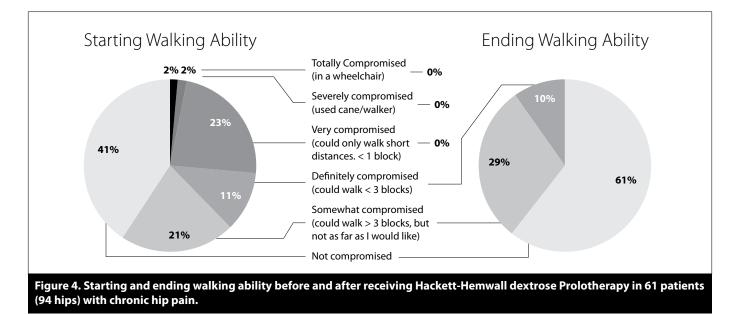
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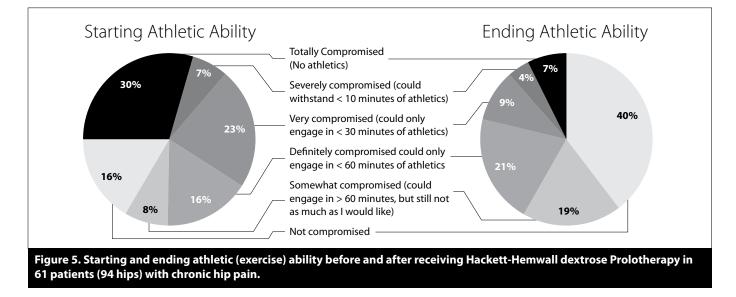
but this decreased to 10% after Prolotherapy. While 27% of patients could walk less than one block before Prolotherapy, all could walk greater than that distance after Prolotherapy. (*See Figure 4.*)

**Exercise and Athletic Ability.** In regard to exercise or athletic ability prior to Prolotherapy, 30% reported totally compromised ability (couldn't do any athletics), seven percent ranked it as severely compromised (less than 10 minutes), 23% ranked it as very compromised (less than 30 minutes) and a total of 84% ranked it as at least somewhat compromised. After treatments, 80% of patients were able to do 30 or more minutes of exercise with 40% not being compromised at all. (*See Figure 5.*)

**Disability.** In regard to quality of life issues prior to receiving treatment, 40% had an overall disability of at least 50% (could only do about half of the tasks they wanted to). This decreased to 11% after Prolotherapy. Sixty-seven percent noted they had at least a 25% overall disability prior to treatments and this decreased to 24% after.

Before receiving Prolotherapy, five of the patients were dependent on someone for activities of daily living (dressing self and additional general self care). All five regained complete independence after Prolotherapy. Before Prolotherapy 11% considered themselves completely disabled in regards to their work situation, but this decreased to seven percent after Prolotherapy.





**Depression and Anxiety.** Prior to Prolotherapy, 46% of patients had feelings of depression and 52% had feelings of anxiety. After treatments, only 13% had depressed feelings and 21% had feelings of anxiety.

**Sleep.** Seventy-two percent of patients reported their pain interrupted their sleep prior to Prolotherapy treatments and 71% subsequently experienced improvements in their sleeping ability.

**Quality of Life.** To a simple yes or no question: *Has Prolotherapy changed your life for the better?* 98% of patients treated answered "yes." In quantifying the response:

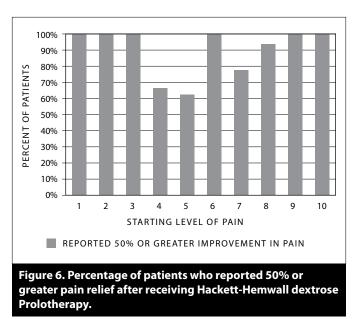
- Seventy-five percent felt their life was at least very much better from Prolotherapy.
- Sixty percent stated that the results from Prolotherapy have very much continued (>75%) to this day.
- Ninety-eight percent felt that they still have some benefits from the Prolotherapy they received.

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?" 81% answered "yes." The patients noted the reasons for some of their returning pain were:

- stopped Prolotherapy treatments too soon (before pain completely gone) – 50%
- re-injury 12%
- new area of pain 14%
- had increased life stressors 10%
- had other explanations for the pain -14%

Of the patients whose pain recurred after Prolotherapy was stopped, 80% were planning on receiving additional Prolotherapy treatments.

**Patient Satisfaction.** Eighty-five percent of patients knew someone who had received and benefited from Prolotherapy. In fact, seventy-five percent came to receive their first Prolotherapy session because of the recommendation of a friend. Eighty-nine percent of patients treated considered the Prolotherapy treatment to be very successful (greater than 50% pain relief). (*See Figure 6.*) Ninety-seven percent noted the Prolotherapy was at



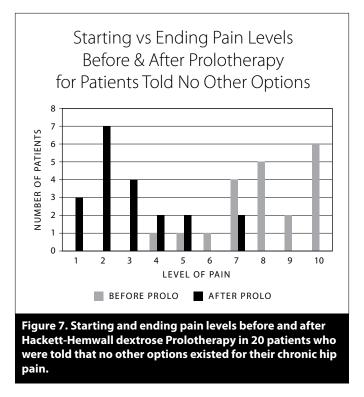
least somewhat successful (greater than 25% pain relief). All 100% noted some benefit in their pain with treatment. None indicated that the Prolotherapy treatments made them worse. Ninety-five percent have recommended Prolotherapy to someone.

#### 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 to get rid of my chronic pain." and
- 2. "Before starting Prolotherapy my only other treatment option was surgery."

**"No Other Treatment Options" Subgroup.** Twenty patients had been told by their doctors that there were no other treatment options for their pain prior to presenting for Prolotherapy. As a group they suffered with pain on average 69 months, saw 3.2 physicians and were on 1.5 medications for pain. Sixty percent of these patients had pain longer than six years. In analyzing these patients, they had a starting average pain level of 8.1 and after Prolotherapy 3.1. Prior to Prolotherapy, 65% of the patients rated their pain as a level eight or higher and none rated it a three or less. After Prolotherapy none rated it an eight or higher and 70% rated it a three or less. (*See Figure 7.*)



Starting levels of stiffness and crunching levels were 5.9 and 3.1 and ending levels of 2.7 and 1.4, respectively. In regard to range of motion, prior to Prolotherapy only 33% had 75% or greater normal range of motion, but this increased to 75% after Prolotherapy. As a group, prior to Prolotherapy, 60% noted in regards to activities of daily living, they could not do at least 50% of the tasks they wanted to do. This decreased to 15% after Prolotherapy. Twenty percent of patients before Prolotherapy could

walk one block or less, but all could walk over a block after Prolotherapy. Only 35% percent said they were not compromised in regard to walking before Prolotherapy, but this increased to 60% after Prolotherapy. Before Prolotherapy 30% could not exercise at all, whereas after Prolotherapy this was down to three percent. Only five percent ranked their exercise ability as not compromised before Prolotherapy, but after Prolotherapy 67% rated it as not compromised. (*See Figure 8.*) For those patients on pain medication, 80% were able to decrease them by 50% or more after treatments. Twenty-five percent of patients on pain medications were able to stop taking them after Prolotherapy. Eighty-five percent were able to decrease their need for additional pain therapies by 50% or more.

Eighty percent of these patients noted the Prolotherapy treatment gave them greater than 50% pain relief with 50% of them receiving 75% or greater pain relief. In response to the question *Has Prolotherapy changed your life for the better?* 100% answered "yes." All 100% have recommended Prolotherapy to someone else. (*See Table 2.*)

**"Surgery is the Only Treatment Option" Subgroup.** This group represents 13% of the patients (eight in number). As a group they saw on average 4.2 physicians and were taking 1.8 pain medications prior to Prolotherapy. They had pain for an average of 44 months. Initial average pain level was 8.4, which decreased to 2.4 after Prolotherapy. Eighty-eight percent had a pain level of eight or more before Prolotherapy. None had a pain level under a seven before Prolotherapy. After Prolotherapy, all had a pain level of five or less with 63% of them having

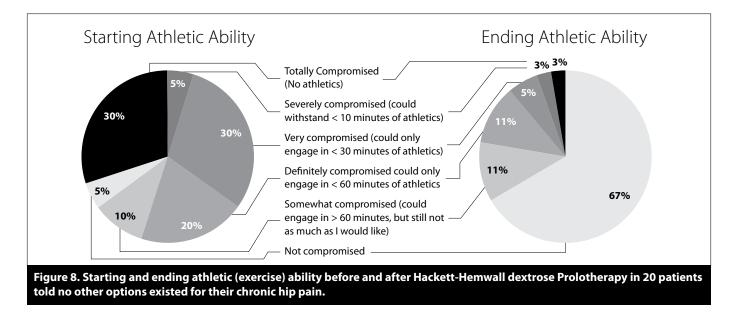
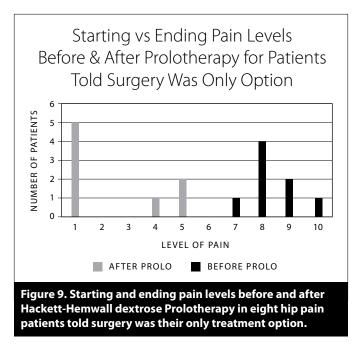


Table 2. Outcome measures for 20 patients told no other treatment options were available for their condition prior to undergoing Prolotherapy treatment.

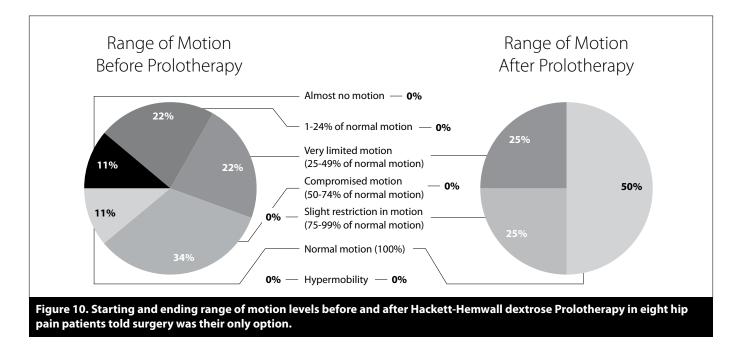
Outcome Measures	Starting	Ending
Average pain level	8.1	3.1
Percentage of patients w/pain level 8 or greater	65%	0%
Percentage of patients w/pain level 3 or less	0%	70%
Average stiffness	5.9	2.7
Average crunching sensation	3.1	1.4
Patients with 75% or greater range of motion	33%	75%
Patients with less than half normal hip motion	30%	5%
Patients not able to do at least 50% of tasks they wanted to do	60%	15%
Inability to exercise	30%	3%
Uncompromised ability to exercise	5%	66%
Patients felt at least some depression	50%	20%
Patients felt at least some anxiety	65%	20%

no pain. (See Figure 9.) On average, 19 months after their last Prolotherapy treatment, as a group they stated that 100% of their improvement in daily pain had continued. Before Prolotherapy their starting stiffness and crunching levels were 4.0 and 1.8 respectively, whereas the ending stiffness and crunching levels were 2.0 and 1.2. Sixty-two percent stated they had greater than 75% pain relief and a full 100% (eight of eight) had 50% or greater pain relief with Prolotherapy. In regard to range of motion, before Prolotherapy 89% of the patients had 74% or



less of normal motion, whereas after Prolotherapy, 75% had 75% or greater of normal motion. Fifty percent had normal range of motion. (*See Figure 10.*)

Before Prolotherapy 87% noted an overall disability of 25% or greater, but this decreased to 13% after Prolotherapy. Sixty-two percent could walk one block or less before Prolotherapy, but all of these patients could walk greater than one block after Prolotherapy. All 100% could only exercise 30 minutes or less before Prolotherapy,



but after Prolotherapy 74% could exercise more than 30 minutes per day. Before Prolotherapy, 100% were taking pain medications, but after Prolotherapy 75% were taking no medications. Since their last Prolotherapy treatment 75% (six of eight) are still not on any pain medications and the other two patients are just on one medication. 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, stiffness and range of motion for the 94 hips, including the subgroup of twenty patients who before starting Prolotherapy were told there were no other treatment options and the eight patients told by their medical doctor(s) there was no other treatment option but surgery. Using the paired t-test, all p values

for pain for all subgroups reached statistical significance at the p<.0001 level. For the 94 hips, the p values for pain, stiffness, and range of motion all showed statistically significant improvements at the p<.0001 level.

## 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 chronic hip pain. Decreases in pain and stiffness and improvements in range of motion reached statistical significance even in patients whose medical doctors said there were no other treatment options for their hip pain or that surgery was their only option. Ninety-five percent of patients stated their pain was better after Prolotherapy. Over 70% said the improvements in their pain, crunching and stiffness since their last Prolotherapy session have very much continued (75% or greater). Eighty-nine percent of patients stated Prolotherapy relieved them of at least 50% of their pain. Fifty-nine percent received greater than 75% pain relief. Only two patients had less than 25% of their pain relieved with Prolotherapy.

More than 82% showed improvements in walking ability, exercise ability, anxiety, depression, sleep and overall disability with Prolotherapy. Eighty-five percent of patients who were on medications were able to cut their medication usage by 50% or more after Prolotherapy. They were able to lessen additional pain management care by 50% or more in 69% of cases. Ninety-eight percent said that dextrose Prolotherapy changed their life for the better. (*See Table 3.*)

#### 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 hip pain to the Hackett-Hemwall technique of dextrose Prolotherapy at a charity medical clinic. 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

Prolotherapy hip study	All	No Other	Surgery
Demographics	Hip Patients	Treatment Option	Only Option
Total number of patients	61	20	8
Months of pain	59	69	44
# of pain meds used before Prolotherapy	1.1	1.5	1.8
# of pain meds used after Prolotherapy	0.3	0.5	0.2
Pain level before Prolotherapy	7.2	5.0	7.1
Pain level after Prolotherapy	2.6	3.0	2.4
Stiffness level before Prolotherapy	4.4	6.0	4.0
Stiffness level after Prolotherapy	2.1	2.7	2.0
Greater than 50% pain relief	89%	80%	100%
Athletic Ability > 30 Minutes of Exercise before Prolotherapy	40%	35%	0%
Athletic Ability > 30 Minutes of Exercise after Prolotherapy	83%	88%	74%
Prolotherapy changed life for the better	100%	100%	100%

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 chronic hip pain. Decreases in medication usage and additional pain management care were also documented. The improvement in such a large number of hips who were treated solely by Prolotherapy is likely to have resulted from the treatment. Many of the above parameters are objective 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 experienced unresolved hip pain for over five years and saw over three physicians prior to Prolotherapy treatment. Twenty-eight (46%) of the patients were either told by their doctor(s) that there were no other treatment options for their pain or that surgery was their only option. So clearly this patient population represented chronic unresponsive hip pain. A follow-up time of nineteen months 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 that was offered was Prolotherapy 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 strengthened or the patient 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/or other medical care. Patients are typically weaned immediately off of anti-inflammatory and narcotic medications that inhibit the inflammatory response that is needed to achieve a healing effect from Prolotherapy. Since none of these were done in this study, the results of this study are expected to be the least optimum level of success achievable with Hackett-Hemwall dextrose Prolotherapy. This makes the results even more impressive.

A shortcoming of our study is the subjective nature of some of the evaluated parameters. Subjective parameters of this sort included pain, stiffness, 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. What was documented was the change in pain levels 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 parameters impossible.

#### POTENTIAL IMPLICATIONS OF FINDINGS

While the exact cause of chronic hip pain is still debated, this study did show that the Hackett-Hemwall technique of dextrose Prolotherapy improves not only pain and stiffness levels of those with chronic hip pain but also a host of other quality of life measures. Current conventional therapies for unresolved hip pain include medical treatment with analgesics, non-steroidal antiinflammatory drugs, anti-depressant medications, steroid shots, trigger point injections, muscle strengthening exercises, physiotherapy, weight loss, rest, massage therapy, manipulation, orthotics, surgical treatments including total hip replacement, multidisciplinary group rehabilitation, education and counseling. The results of such therapies often leave the patients with residual pain.<sup>33-35</sup> Because of this many patients with chronic hip pain are searching for alternative treatments for their pain.<sup>36,37</sup> This is especially true for those who have been told they need a hip replacement in the future. They realize that total hip replacement surgeries carry with them significant risk including prosthesis failure, sciatic nerve injury, infection, post-op blood clot and potential for continued pain.<sup>38,39</sup> For younger clients especially those under the age of 50, the notion of a second more complicated revision hip replacement in the future is not a very appealing prospect.<sup>40</sup> Six to 12 months after a hip joint replacement, pivoting or twisting on the involved leg should be avoided. As there are over 120 hip replacement systems, the hip replacement market is driving more and more conservative surgeries.<sup>41</sup> Despite much fanfare, there is little scientific evidence of the purported advantages of minimally invasive joint replacement and hip resurfacing over conventional joint replacement.42 One of the treatments that chronic hip pain patients are trying instead of surgery is Prolotherapy.43

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

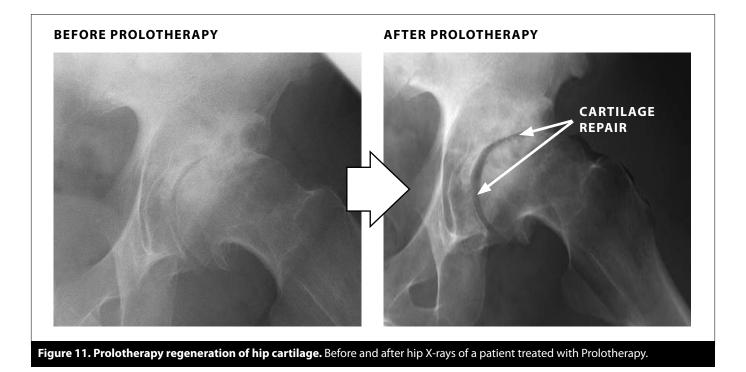
fibroblasts proliferate. Fibroblasts are the cells through which collagen is made and by which ligaments and tendons repair. Prolotherapy has been shown in one double-blinded animal study in a six-week period to increase ligament mass by 44%, ligament thickness by 27% and the ligament-bone junction strength by 28%.44 In human studies on Prolotherapy, biopsies performed after the completion of Prolotherapy showed significant increases in collagen fiber and ligament diameter of 60%.45,46 This is significant since degenerative osteoarthritis has been in many cases known to be caused by joint instability caused by ligament injury.<sup>47</sup> Thus, Prolotherapy has the potential to stop the degenerative joint disease process and some preliminary and anecdotal evidence shows that in some cases it can reverse it.48,49 (See Figure 11.)

For most cases of chronic hip pain, the cause of the pain is presumed to be cartilage degeneration. Because the average person moves his/her hip one million times per year during activities of daily living, it is no wonder that over time this wear and tear can begin to break down the joint.<sup>50</sup> Besides the pain and disability that degenerative arthritis causes, there is a tremendous cost. About 20% of the costs result from ambulatory care services and up to one third from pain medications. Forty-five percent of costs are hospital charges, as an estimated 400,000 people each year undergo a hip replacement alone.<sup>51</sup> The

### Table 4. Average cost of total hip replacment in the Chicagoland health care system.

Description of Cost	Cost (in 2007 dollars)
Cost of hip replacement (total)	\$45,000 +
Cost of surgeon	\$10,000
Cost of prosthesis	\$8,000
Cost of MRI and/or X-rays	\$3,500
Cost of rehabilitation	\$6,000
Annual economic burden per year for disabled hip client	\$20,000

average hospital costs in Chicago per hip replacement is over \$45,000 each. Surgeon and prosthesis costs are between \$15,000-18,000 with total costs per hip including hospital stay, surgeons fee, MRI and X-ray studies and post-operation rehabilitation being over \$75,000.<sup>52,53</sup> Compare those figures to the average cost per Prolotherapy treatment to the hip of \$300 to \$400.<sup>54</sup> (*See Table 4.*) If, as in this study, the average person receives four to five Prolotherapy sessions to complete therapy, the total cost of Prolotherapy for a chronic hip patient would be on the order of \$1500 to \$3000. Thus, each person who received Prolotherapy instead of a hip replacement would, at minimum, save the health care system on the order of \$72,000. These costs do not include patients whose hip replacements fail or need to



be revised. This also does not include the lifetime cost savings in medication and ancillary pain management usage, as well-as the cost savings for patients who would not need a hip replacement because of the Prolotherapy treatment received. It has been shown that hip pain is the major predictor of radiographic hip osteoarthritis that progresses to eventual hip replacement.<sup>55</sup> If this group of patients were to receive Prolotherapy at the start of their pain, prior to significant radiographic hip osteoarthritis, the potential cost savings would be tremendous if these patients were to no longer need a hip replacement. Thus, the actual costs savings over a lifetime with Hackett-Hemwall dextrose Prolotherapy in patients with unresolved hip pain would most likely be well in excess of \$100,000 per hip patient. If this occurred for 250,000 patients per year, the cost savings to the United States health care system could potentially be over 25 billion dollars per year. Future studies should be done to determine if indeed Prolotherapy can keep chronic hip pain sufferers from needing total hip replacements.

## Conclusions

The Hackett-Hemwall technique of dextrose Prolotherapy used on patients who presented with over five years of unresolved hip pain were shown in this retrospective pilot study to improve their quality of life even 19 months subsequent from their last Prolotherapy session. The 61 patients with 94 hips treated reported significantly less pain, stiffness, crunching sensation, disability, depressed and anxious thoughts, medication and other pain therapy usage, as well as improved walking ability, range of motion, sleep, exercise ability, and activities of daily living. This included patients who were told there were no other treatment options for their pain or that surgery was their only option. The results confirm that Prolotherapy is a treatment that should be highly considered for people suffering with chronic hip pain. Future studies will be needed to confirm this pilot study and to document if Prolotherapy can keep chronic hip pain sufferers from needing hip surgeries including hip replacements.

#### ACKNOWLEDGEMENTS

Doug Puller (D.P.), independent data collector.

Dave Gruen (D.G.) independent data analyst from www.bolderimage.com.

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FANTASTIC FINDINGS

#### A B S T R A C T

**Background Content:** This case study examines the effect of the addition of Prolotherapy to manual therapy, and pelvic and trunk exercises, in a treatment regime for a patient with pelvic and chronic low back pain (CLBP) who had previously failed manual therapy and exercise alone and in combination. We hypothesized that with continued exercise and the combination of Prolotherapy and manual therapy, there would be better improvement than any single intervention to reduce pain and improve stability in the lumbar spine and pelvis.

Purpose: The purpose of our case study was twofold.

- 1. If the tenderness in the above ligaments would be reduced using the combination of Prolotherapy, therapeutic exercise, and manual therapy.
- 2. Whether our subject would show functional improvement after treatment.

#### Study Design: Single case study.

**Methods:** One subject, a 44 year-old male with a history of left L5-S1 laminectomy and ligamentous laxity in the pelvis and sacral ligaments, was assessed and treated by the primary author, using Prolotherapy and manual therapy. Therapeutic exercise was performed five days a week with an emphasis on the pelvic and deep trunk stabilizers.

**Results:** After treatments, the patient demonstrated less tenderness, improved ligamentous stiffness, and displayed improved pelvic joint stability. Function also improved as measured by his ability to work, exercise, and perform home activities with less stiffness and pain than previously noted.

**Conclusion:** Patients with LBP may benefit from Prolotherapy to aid in reducing pelvic and lumbar instability in conjunction with manual therapy and exercise to improve dynamic pelvic stability.

#### Journal of Prolotherapy. 2009;2:89-95.

KEYWORDS: chronic low back pain, Prolotherapy, ligamentous laxity, multifidus, sacroiliac joint.

## Prolotherapy for Pelvic Ligament Pain: A Case Report

Ann Auburn, DO Scott Benjamin, PT, DScPT & Roy Bechtel , PT, PhD

#### INTRODUCTION

t has been postulated that 80% of Americans will experience low back pain sometime in their lives.<sup>1</sup> • One estimate is that 40% of all visits to health care professionals are due to low back pain (LBP).<sup>2</sup> Approximately 10-20% of these cases will become chronic, resulting in long-term pain and disability, making low back pain the largest cause of worker compensation claims in the US and Canada.<sup>3</sup> Among industrial workers, the incidence is as much as 60% of all claims.<sup>4</sup> When discussing LBP, one problem is to determine the origin of the pain, which in many cases is not known objectively.<sup>5</sup> The origin of the CLBP (chronic low back pain) will help to determine whether or not the patient needs a multi-disciplinary approach,<sup>6</sup> and whether or not there are some significant psychological factors that will either enhance or worsen the situation.<sup>1</sup>

There appears to be a growing consensus that a significant portion of CLBP cases have an element of segmental instability present.<sup>7-8</sup> As defined by Panjabi, <sup>9</sup> the intrinsic stabilizing system of the spine consists of three interrelated components:

- 1. The passive stabilizing system, consisting of ligaments, intervertebral discs, and joint capsules.
- 2. The myofascial system, consisting of muscles and fascia.
- 3. The motor control processing system, consisting of the central and peripheral nervous systems.

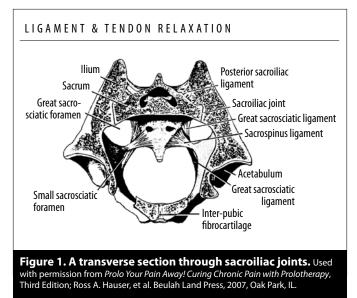
A deficit in the motor control or myofascial systems can result in damage to the passive stabilizing system from poorly controlled segmental movements in the spine and pelvis.<sup>10</sup> If the muscles become weak due to inhibition<sup>11</sup> loads will be transferred to the disc and ligamentous structures and may lead to repetitive wear, causing a breakdown in this passive support system.<sup>12-13</sup>

#### ANATOMY AND FUNCTION:

The pelvis is a bony ring, composed of two hip (innominate) bones, which are made up of the fused ilium, ischium and pubis, and the sacrum, which is in the center between the innominates posteriorly. There are two sacroiliac (SI) joints, and the sacrum and innominates are joined posteriorly by the synovial-lined sacroiliac joints, and the innominates are joined anteriorly by the symphysis pubis, a fibrocartilaginous articulation.<sup>14</sup> The pelvis is a highly significant part of the body that transfers loads between the ground and the spine, as well as transfers loads between the upper and lower extremities, through the spine and thoracolumbar fascia.<sup>15</sup> The shape and orientation of the articular surfaces has been described by Vleeming et al., as contributing to the relative passive stability of these joints, known as "form closure."16 Normal forces applied to the SI joints can enhance stability, dubbed "force closure" by Vleeming et al<sup>17</sup> but poor stability in the SI joint can lead to dysfunctions in the lumbar spine and hip.

### ROLE OF THE LIGAMENTOUS SYSTEM AS IT OCCURS IN LBP:

One of the major low back stabilizers is the iliolumbar ligament (IL), which unites the low lumbar spine with the ilium and sacrum.<sup>18</sup> The ligament will resist the motion of L4 and L5 on the ilium and sacrum.<sup>19-20</sup> The IL has been described as one of the most important ligaments for sacroiliac stability.<sup>19</sup> It will also resist anterior motions of the ilium on L5 and will also help in stabilizing the L5 segmental level.<sup>21-22</sup> The IL is also able to check side bending to the contralateral side.<sup>22</sup> The IL can also aid in reducing the stresses on the low lumbar discs.<sup>23-24</sup> The long dorsal sacro-iliac ligament (LD) joins the sacral crest inferiorly, with the PSIS and iliac crest superiorly.<sup>18,</sup> <sup>25</sup> It functions to keep the sacrum from moving dorsally (counternutation) with respect to the ilium. The LD is linked to pain in the SI joint and also with patients who experience pain in the posterior portion of their pelvis.<sup>26</sup> The sacrospinous ligament (SS) is a triangular band of tissue that connects the ischial spine laterally, to the sacrum.<sup>27</sup> The SS also separates the lesser and greater sciatic notch and resists anterior rotation of the sacrum at the SI joint.<sup>27-28</sup> (See Figure 1.) Painful stimulation of ligaments or joint capsules on the other hand, can reduce or eliminate muscle activity.8 We are just beginning to



understand the complex interplay between Panjabi's passive and active subsystems in providing spine stabilization. Physical damage to a ligament, i.e. a tear, is associated with pain. This pain can also inhibit muscles designed to protect joints which the ligament crosses, and can lead to joint instability and further ligamentous damage, in a vicious cycle.<sup>13</sup> In these cases, the protective ligaments can become stressed and sore, leading to reduced function and potential joint instability<sup>19-20, 12, 22, 25, 29</sup> which can affect a person's job function or an athlete's level of performance. Besides injury due to trauma, subtle factors which may lead to compromise of the ligamentous system include the patient's posture in both a sedentary and active environment.<sup>30</sup> Studies show that if a person slouches, stress on the iliolumbar ligament can lead to creep, which can compromise the stability of the sacroiliac joints and the lumbar spinal segments.<sup>31</sup> Cyclists for example, may not maintain their maximally flexed posture during the course of a ride. Studies show that it can take up to 8 hours to reverse the effects.<sup>31-32</sup> After prolonged flexion, the muscular system takes time to rebound (minutes to hours) leaving the fascia, ligaments, and joints vulnerable to the stresses of functional activities.<sup>11</sup> A dysfunctional sacroiliac joint will impact activities involving hip motions such as squatting, kneeling, adduction, and external rotation of the hip.34

#### PROLOTHERAPY

Background: In the 1950s and 1960s Dr. G. S. Hackett discovered that he could reduce the back pain that a person was experiencing by injecting a hypertonic sugar solution around supporting ligaments.<sup>35-37</sup> Prolotherapy is

defined as "the strengthening of a disabled ligament or tendon by stimulating the production of new bone and fibrous tissue cells".<sup>35, 38-39</sup> Prolotherapy is most appropriate for patients who have CLBP and pelvic instability, ligamentous laxity and for those patients who retain a particular correction for too short a period of time to be functional. There is a paucity of longitudinal studies for alternative medical treatments and Prolotherapy is one of those alternatives. The adjunctive use of Prolotherapy was shown to help reduce the pain from CLBP over a 16 year period.<sup>40</sup> Studies also support the growth factors used as components of Prolotherapy to stimulate the affected tissues.<sup>41</sup> Prolotherapy has helped patients with unstable sacroiliac joints, knee pain, hip pain, plantar fasciitis and even lateral epicondylitis.<sup>41-45, 35-37, 39</sup>

#### HOW DOES THE PROLOTHERAPY PROCESS WORK?

The Prolotherapy procedure for the low back and sacroiliac joint is individualized depending on the patient's presentation. In general, Prolotherapy injections of a sclerosant solution are designed to promote ligament hypertrophy to better sustain the inherent stresses that are placed on them.<sup>47-48, 39</sup> The ligament, or ligaments, to be targeted can be injected with a mixture of solutions that can consist of dextrose, Phenol Quinine and Urea (PQU), human growth hormone, Sarapin (the extract of the pitcher plant), Zinc sulfate, Silica Crystals, Sylnasol, and glycerine-phenol solution.<sup>39</sup> (*See Table 1 for a description of the expected effects of each component.*)

The solution is injected into the fibrosseous junction and has been shown to cause an infiltration of fibroblasts<sup>37,</sup> <sup>39, 49-50</sup> following the inflammation caused by the injected solution. Prolotherapy can be a useful treatment when the patient's ligamentous laxity causes a loss of stability within a specific joint.<sup>49</sup> The fibroblasts will proliferate and this will lead to the re-organization of these cells to lay down a new matrix of collagen.<sup>41, 47, 51</sup> Thus, the inflammation in this case is considered good and will aid in repairing the tissue, whether it be ligament or tendon.<sup>37, 49</sup> When the cellular layer is re-established, the ligament and/or tendon will become stronger and give support to a specific joint.<sup>38-39</sup> This healing process takes about six weeks, with most of the tendon strengthening occurring in weeks two through four after the Prolotherapy treatment.<sup>36-37, 39</sup> During the six weeks period of healing, in our protocol, treatments are usually every other week and there are between 20-25 injections per session.<sup>36-39</sup> Total number of treatments is usually between three and six in a series.<sup>39</sup>

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The reported side effects are minimal, including injection site discomfort for a few days after the treatment.<sup>52</sup> The treatments usually continue until the patient experiences pain relief, function increases, and the ligaments are not tender during the palpation exam. In some cases, treatments are ended if there is no progress after four series of injections.<sup>39</sup>

The purpose of this case study was to determine whether or not our subject, who demonstrated specific ligamentous laxity in the iliolumbar, supraspinous, sacrospinous, and dorsal sacroiliac ligaments on clinical examination, would show improvement in ligamentous stiffness and tenderness after the Prolotherapy injections.

#### TREATMENT

While many treatment alternatives have been proposed for pelvic pain and CLBP, few have demonstrated overwhelming efficacy. In a systematic review,<sup>53</sup> Bronfort et al. found moderate evidence to support the use of spinal manipulative therapy for chronic low back pain. Similarly, Slade and Keating<sup>56</sup> found support for trunk strengthening exercises for patients with CLBP. We chose to use a treatment model which included manual therapy (manipulation/mobilization) and Prolotherapy as the primary treatment regime with the patient exercising on his own. Prolotherapy treatment has been used for the treatment of pelvic and CLBP<sup>48</sup> and has been shown to target the affected ligamentous tissues.<sup>54, 36</sup> Although the results of previous double blinded studies on Prolotherapy for LBP have been mixed<sup>50</sup> more recent evidence suggests that when combined with manual therapy and exercise, the efficacy of the Prolotherapy treatment may be enhanced.<sup>55</sup>

#### METHOD/MATERIALS

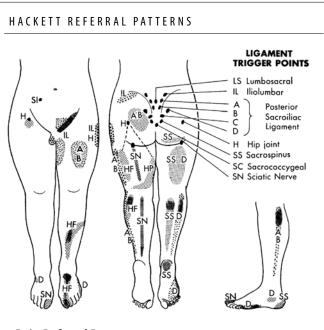
One male subject, 43 year-old, 69.5 cm tall, and 85.9 kg was included in this case study. The patient had a history of playing competitive hockey for 20 years with multiple associated pelvis and lower back injuries. He wore a onehalf inch lift in the left shoe due to a presumed leg length inequality. He underwent successful decompression laminectomy in December of 1999 to remove an L5-S1 left posterior-lateral disc fragment, which was compressing the S1 nerve root. He also was an avid cyclist during his hockey years and continued to cycle competitively until a recent increase in his pelvis and LBP. On some occasions, especially after hard biking or working out, he reported a sensation of "something shifting" in his pelvis, and afterwards was unable to walk normally or to work without pain. The patient was also not able to sit, flex his trunk, and side flex to the left without discomfort. Driving, cycling, and transitions from sitting to standing and from supine to sitting caused pain. For these reasons, he sought treatment from the primary author.

#### PHYSICAL EXAMINATION

The primary author performed a biomechanical examination<sup>57-58</sup> and determined that the patient had pain and limitation of motion with side flexion to the left and flexion of the lumbar spine. The lumbar segmental levels were checked for motion restrictions to determine if there were any segmental dysfunctions, which can be defined as a segment that is hypomobile, usually in some flexion or extension. The biomechanical examination allows a clinician to check the passive intervertebral motion of a specific segmental level to test for hypomobility.<sup>57-58</sup> The patient also presented with a leg length discrepancy (LLD) of <sup>1</sup>/<sub>2</sub> inch on the left side. (*See Table 2.*)

lumbar spine, pelvis and ligament systems.		
Male, 43 y/o		
Segmental dysfunctions:	L4 extended right side L5 extended right side	
llium:	Upslip right side	
Sacrum:	Right extended	
Thoracic spine:	T8-T10 extended left	
Muscle tightness:	Right psoas Right hamstrings Bilateral piriformis Right quadratus Lumborum	
Ligament tenderness: Positive pain sign	Left and right Iliolumbar Left dorsal sacroiliac Left sacrotuberous Bilateral sacrospinous L4-L5 supraspinous L5-S1 supraspinous	

The primary author noted that the patient had a positive pain or "jump sign"<sup>39</sup> when palpating the ligaments around the lumbar spine and pelvis. It was determined through a thorough history that the patient reported symptoms consistent with unstable sacroiliac joints. These symptoms included a sacrum that was rotated to the right and was painful with palpation. The sacrum would not stay in place and would pop out during work, moving in bed, and even getting out of the car. Even though segmental dysfunctions were noted on the right side, (See Table 2.) the pain was mainly experienced on the left side of the buttock, down the lateral side of the left leg and sometimes down to the calf. When the primary author palpated the ligamentous structures, (first on the left, then the right side) there was a reproduction of the referral pattern on the left side and there was tenderness on the left at the L5 transverse process, in the lumbosacral junction, over the IL, LD, SS and the sacrotuberous ligaments. The referral pattern was very similar to the ligament referral pattern in the pelvis and lumbar spine reported by Dr. Hackett.<sup>39</sup> (See Figure 2.) During the physical examination, it was noted that with lumbar extension, the patient reported a "catch" during movement. This "catch" was presumed to indicate lumbar instability associated with segmental dysfunction and/ or lax ligamentous support of the spine. X-ray findings indicated that there were mild degenerative changes in the lumbar spine with mild disc space narrowing at L5-S1. All the segmental dysfunctions were corrected using manual therapy techniques (i.e. muscle energy and/or



#### Pain Referral Patterns FROM LUMBOSACRAL AND PELVIC JOINT LIGAMENTS

Abbreviation	Ligament	Referral Pattern
IL:	lliolumbar	Groin, Testicles, Vagina,
		Inner Thigh
AB:	Posterior Sacroiliac	Buttock, Thigh, Leg
	(upper two-thirds)	(outer surface)
D:	Posterior Sacroiliac	Thigh, Leg (Outer Calf)
	(lower outer fibers)	Foot (Lateral Toes)—
		Accompanied by Sciatica
HP:	Hip—Pelvic Attachment	Thigh—Posterior & Medial
HF:	Hip—Femoral Attachment	Thigh—Posterior & Lateral
		Lower Leg—Anterior & into
		the Big Toe & Second Toe
SS:	Sacrospinus & Sacrotuberus	Thigh—Posterior Lower
		Leg—Posterior to the Heel
SN:	Sciatic Nerve	Can Radiate Pain Down the Leg

Figure 2. Ligament referral pain patterns. Used with permission from *Prolo Your Pain Away! Curing Chronic Pain with Prolotherapy*, Third Edition; Ross A. Hauser, et al. Beulah Land Press, 2007, Oak Park, IL.

manipulation) prior to the Prolotherapy procedure. The patient also relayed that using an SI belt was very helpful and took away some of the popping and pain.

#### PROLOTHERAPY INJECTABLE PROCEDURE

The lumbosacral region was prepped with sterile alcohol and landmarks were identified prior to the injection procedure. The primary author located the areas of pain or tenderness noted by the patient. Once all the painful ligamentous locations were marked, author one drew up the Prolotherapy solution into a syringe, using a 2 inch, 27

gauge needle. The injection procedure is supported by the work of,<sup>35-36, 39, 52</sup> where they stated to inject the needle into the affected area until bone was approximated. Once the bone was found, the needle was drawn out and then the Prolotherapy solution was put into the affected ligament. The Prolotherapy solution used with this patient consisted of 2cc of 50% dextrose, 1cc of PQU (2.43 ml Phenol liquefied, 5.73 GM Quinine HCL, 1.26GM Urea USP), 1cc of Sarapin, and 6cc of 2% Procaine. (Fabricated at the Compounding Pharmacy of Wyoming Park, 2301 Lee Street SW, Wyoming, MI 49519) After the injections, the patient was asked to move into lumbar extension to see if the motion still reproduced "catching" or pain in the pelvis or lumbar spine. If the "catching" was present, the physician (author one) reassessed to determine which ligamentous structure needed to be addressed and injected. Post-injection, the patient was instructed to avoid a hard workout for that day, but to perform usual exercises as long as they did not overstress the treated area. The exercise programs we focused on the trunk and "core" muscles.

#### RESULTS

The outcome measures recorded were pain and improvement of functional activity. Treatment consisted of 16 sessions over a six month period. All treatment and assessments were provided by the primary author.

#### PAIN MEASURES

Prior to the Prolotherapy treatment, the patient had moderate pain with palpation to the iliolumbar, dorsosacroiliac, sacrotuberous, and the supraspinous ligaments. This was determined by the patient's subjective rating using a four point Likert scale ranging from zero, to minimal, moderate, and severe. During palpation from the primary author, the pain level was described as moderate. Once the combined treatment of manual PT and Prolotherapy were fully completed, all 16 sessions, the pain was reduced to a minimal level.

#### FUNCTION

Functionally the patient could perform pain-free biking, exercise without the lumbar "catching" sensation and was able to return to work without having his SI joint move out of place. The patient could also perform activities of daily life such as yard work, without pain and stiffness which had been present prior to the Prolotherapy sessions. Besides the improvement in function, there was a reduction in hip popping, SI irritation and lumbar spine pain. The popping, pain and loss of function all improved over the course of the treatment. The combination of very specific ligamentous Prolotherapy treatments with the inclusion of manual therapy and exercise resulted in a successful outcome for this patient with pelvic pain and CLBP.

#### DISCUSSION

Chronic low back (CLBP) and pelvic pain can deter a person from functioning at their optimal level, thus leading to poor productivity and increasing health care costs.<sup>5</sup> In order to determine what the cause of the LBP is one must evaluate if the problematic area is a ligament, muscle, disc, or nerve root problem.<sup>9</sup> In this case study, we argue for a departure from the traditional pathoanatomical model of dysfunction by emphasizing the interrelationship of the passive and dynamic stabilizing systems of the spine. Attempting to address the weakness without understanding its cause can lead to frustration, poor outcomes, and patient dissatisfaction.<sup>58</sup> Our case study supports previous researchers 35-36, 38-39 who showed that the traumatized LD and IL can demonstrate the same referral pattern as a nerve root irritation. We conclude that when patients present with leg pain, injury to the lumbopelvic ligamentous system must not be excluded from differential diagnosis. Our case study also supports the use of Prolotherapy for ligament disorders. <sup>41, 45, 47</sup> Despite previous studies by Yelland<sup>50</sup> et al, which showed that the injections where not much better than control, our case points up the benefits of today's Prolotherapy compounds and the synergy of combining manual therapy and exercise with Prolotherapy (Dagenais, et al). Our patient did not see long term lasting effects from just manual therapy and exercise alone or in combination. Once we included Prolotherapy, his recovery was improved and also the positive effects from stabilization exercises and also from manual manipulation were enhanced. By itself, Prolotherapy is an ancillary agent to help tissues heal<sup>39, 46-</sup> <sup>47</sup> and with the inclusion of manual PT and exercise there is a strong beneficial stabilization effect.<sup>55-56</sup> Our patient needed the Prolotherapy treatments to improve the integrity of the tissues so that they could respond in a more beneficial manner to the exercise and manual therapy treatments. Researchers have shown that beneficial stress, as provided by carefully supervised exercise, is essential to promote long term positive effects for tissues in the lumbar spine and pelvis.<sup>59</sup> Further research is warranted to explore the combination of manual therapy and exercise

with Prolotherapy in a scientifically-rigorous way, using blinding and a control group.

In this case, it was not until the element of ligamentous insufficiency was addressed by Prolotherapy treatment that the patient experienced significant relief of his pelvic and lumbar spine pain. We take this as evidence that the ligamentous system, at least in this case, was a primary contributor to this patient's CLBP and further supports the notion that Prolotherapy can be an effective tool in the management of pelvic pain and CLBP in the presence of ligamentous instability.

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#### REMARKABLE RECOVERIES

#### A B S T R A C T

I am a long distance runner, who, over a number of years, developed sacroiliac joint pain, iliotibial band problems, piriformis syndrome, patella femoral syndrome, and pain all along my entire right side. I had sought out treatment as these problems progressed in severity, from both the allopathic community as well as extensive chiropractic and physiotherapy. Unfortunately, these treatments were all minimally successful at best, providing no real relief.

During the last run of a taper prior to running the Toronto Waterfront Marathon in September 2006, I heard a crack, and felt searing pain through the inner thigh and groin. In spite of my best efforts to seek medical attention for this problem, I was offered nothing by allopathic medicine, except an assessment of a pulled groin muscle, and stop running. Since walking was a serious problem, their advice was of no help. Months of dedicated, daily physiotherapy treatments proved mostly futile until finally the physiotherapist, a marathoner herself, informed me of a treatment called Prolotherapy. She believed this would address the laxity of the ligaments of my right SI joint, which had culminated in what was in fact a fracture of the inferior pubis ramus resulting from multiple biomechanical problems, and laxity of the ligaments of the SI, exacerbated by many miles of runnina.

My story takes a small turn from the typical "sports injury and Prolotherapy" route, after I was introduced to Dr. Rob Banner in the Pain Clinic at St. Joseph's Hospital in London, Ontario. Based on his experience and my previous lack of success with other approaches in trying to correct my biomechanical problems and the resulting pain, several other therapies in addition to Prolotherapy were first necessary to create an environment in my body more receptive and favorable to treatment. This article encompasses several other treatments that were essential to the ultimate success of my Prolotherapy treatments. I felt this would also present an article somewhat more unique in nature for your readers, and other practitioners as well.

*Journal of Prolotherapy*. 2009;2:96–98. KEYWORDS: headache, knee pain, low back pain, neck pain, Prolotherapy, shoulder pain, running injury, thoracic pain.

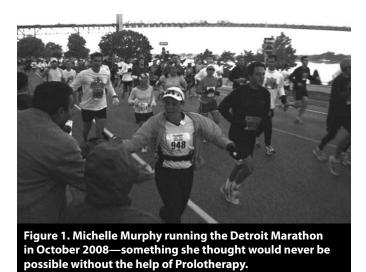
## **Road to Prolotherapy:** An Athlete's Prolotherapy Story

Michelle Murphy

he road to Prolotherapy has been long and winding. At least for me, it has been. It may have begun some 13 years ago with 40 plus hours of unproductive child labor, and the impact that had on my pelvis. I will likely never know for sure. But it certainly was exacerbated by the countless miles of endurance training through sacroiliac (SI) pain, piriformis syndrome, iliotibial (IT) band problems, patella femoral syndrome, and entire right side pain, for which no amount of allopathic medicine, chiropractic and physiotherapy could help. It reached its point of no return on a beautiful, sunny autumn day I called my 39th birthday. During the last 100m sprint of an easy 5 km run, the final of a taper that was to culminate in the running of the Toronto Waterfront Marathon two days later, I heard a crack, quickly followed by a searing pain through the inner thigh and groin. Barely able to walk home, and bed-ridden in pain, after 1200+ kms of training, I was forced to abandon my goal.

When after several days of resting, RICE (rest, ice, compression, elevation), and ibuprofen provided no relief whatsoever, I approached not one, but four local MDs, and two orthopedic surgeons, desperately searching for anyone with some experience in sports injuries to help me with the severe and very uncomfortable pain of what I believed at the time must be a pulled groin muscle. To my dismay, these doctors provided me with nothing more than "if it hurts, don't run," which was least helpful considering even walking was a serious problem, and the ever useless RICE once again.

In spite of the lack of medical advice nor suggestions for rehabilitation, I was fortunate enough to be directed to a local physiotherapist, also a marathoner, who herself had suffered her share of injuries. I worked almost daily with her for four months to discover that I had a "wonky pelvis" as she put it, i.e. loose ligaments of the right SI joint. No matter how hard we worked to stabilize my SI, through



various exercises, breathing, pelvic stability belt, my pelvis kept slipping out. When she had done all she could, she referred me to a pain clinic in London, Ontario where I met an MD. Dr. Rob Banner, who also trained in various complementary and integrative therapies, worked with me for over a year to get me back to running form.

At the same time, complaining of the constant groin pain, my family physician sent me for an X-ray of the pelvis, which revealed that my pulled groin muscle was actually a fracture of the inferior pubis ramus that had gone unidentified until now. Doctors and physiotherapists told me to forget long distances completely, and even to stop running altogether. My offset, twisted pelvis, leg-length discrepancy, IT band and knee problems and laxity of ligaments of the right SI joint were not the makings of a marathoner, so I was told.

What makes a person look for answers when all doors appear closed is the making of another article, but life is too short to abandon with ease those things which not only bring us pleasure, but keep us happy and healthy. In the pain clinic in London, Dr. Banner worked with me through a variety of less-than-conventional therapies to get me back to training, and in the process, decrease my pain.

And so began the road to Prolotherapy in earnest. I went to the pain clinic in hopes of receiving Prolotherapy treatments and getting back to running as quickly as possible. Unfortunately, the doctor's experience and my impatience did not see eye to eye on the approach to healing. The road took a sharp turn when he pointed out that prior to receiving any treatment, I would first need to rid my mouth of the mercury filled amalgams that had been releasing this toxin throughout my body with each bite, essentially clogging up my cells and preventing my body from responding favorably to the many treatments I had sought to rectify my multiple biomechanical problems over the previous years. After removing all amalgams, it took 10 months of chelation using NDF- nanocollodial detox factors, which eliminates heavy metals in the body through urination, to remove enough of the mercury from my system for other treatments to have their desired effect. Once the mercury level was low enough, Dr. Banner used acupuncture to perform vital alignment, to bring about a more neutral realignment of my body after years of favoring the previously strong left side, versus the weakened and misaligned right.

In addition to these, several different treatments were involved to bring about the healing necessary to get me moving again, most notable amongst them were neural therapy and Prolotherapy. Neural therapy is a process by which procaine is injected into scar tissue to unblock interference fields (barriers in the body's natural ability to heal itself). Approximately four treatments injecting scars including ear piercings, a childhood vaccine, a c-section scar and a scar on the knee resulting from a bike accident were required to return the resting membrane potential of these scar tissues to their normal -70 mv, and again, create within my body an environment more receptive to treatment.

At some point during these treatments, my pains had decreased enough that I was able to slowly and gradually return to running, all the while noticing other areas of pain in my body had also started responding favorably to these many treatments. Unfortunately it wasn't long before I discovered that the right SI joint was still causing significant pain and discomfort radiating down the leg, indicative of the continued laxity of those ligaments.

Finally, on to Prolotherapy, what I had been waiting for all along. Prolotherapy involves injections of procaine, bupivacaine and glucose into lax or torn ligaments causing an inflammatory response, resulting in the growth of new and stronger ligaments. At this point, in addition to the SI joint laxity, I had injured my left Achilles tendon while turning to cycling in the absence of running, and had also torn the anterior talo fibular ligament in the same foot. The patella femoral syndrome of the right knee was still troublesome, so come time for Prolotherapy, all of these four areas were treated. The Achilles tendon was by far the most painful injection, followed by the SI.

I was informed to refrain from all vigorous activity for 48 hours as to not add any additional stress during that healing period, followed by no impact activities for two weeks. In the two days or so immediately following, I walked with a slight limp from the injection in the Achilles, and at night, could feel the sharp pain of the needle poking around in the region of my SI. For the first few nights, a three-point turn was necessary to roll over in bed because of the burning sensations radiating deep at the injection sites. (Anyone who has ever been pregnant knows what a three- point turn is.) Having trained for many endurance events and knowing well the "good" feeling of muscular pain, versus the "bad" feeling of pain associated with biomechanical discrepancies, I was constantly questioning which of these two categories of pain the Prolotherapy sensations fell into.

In spite of the initial discomfort, I was able to get around mostly with ease, and returned to cycling and swimming after 48 hours. Following that, sharp, shooting sensations in the region of the SI often had me wondering if I was again hurting myself through my activity, or if those macrophages which had failed me in the past, were now busy at work creating the new and stronger ligaments that would reunite me with my passion.

After two weeks of refraining from running, I gently eased back into my routine, seeing increased strength and decreased pain. Several months later, I had trained for and completed a half marathon, although with some SI pain. Another Prolotherapy treatment and several more months of smarter training, and I registered for, and completed the marathon that I had fractured out of and was sidelined from almost exactly one year earlier. Arguably, 42.2 kms of impact is about as good a test as you will find anywhere to demonstrate the efficacy of a treatment. (*See Figure 1*.)

In the two years since that pelvic fracture and subsequent Prolotherapy treatments, I have run four marathons, competed in numerous other road races of varying distances, as well as several triathlons. After a year of continuous training, I required one isolated Prolotherapy treatment for the same SI joint. Considering the amount of stress I have put on it with my running, if a minor tune up is called for in order to keep me moving and being an active participant in my own life, then so be it.

Mine is not the typical story of sports injury followed by Prolotherapy. That may be in part because I did not present with only one distinct problem, nor was I treated by a typical doctor. When other medical professionals provided no options, Dr. Banner, through his commitment to healing, education, the value of a multi-disciplinary approach, and unique ability to reach for solutions beyond the boundaries of allopathic medicine, provided the options of which life transformations are made. Although I was skeptical, and impatiently wanted my Prolotherapy and to get back to running, his ability to skillfully and appropriately not only decrease my pain but return me to my life, not as I was forced to live it, but as I choose to, is invaluable. The possibilities for those suffering with needless pain and limited mobility which infringes upon every aspect of their lives can be demonstrated through my experience. In spite of the discomfort associated with all of these treatments, the short term pain has far been worth the long term gains. It is my hope many others will be able to see the true benefits of Prolotherapy far outweigh any of the risks, in reclaiming their lives.

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## 20-Year History of Chronic Body Pain Cured with Prolotherapy

George H. Kramer, MD

#### A B S T R A C T

This article discusses the case of 57 year-old Bill B, a dentist, who suffered from chronic pain from ligamentous laxity and degenerative disc disease in the cervical, lumbar and thoracic spine. His headaches and back pain were treated successfully with Prolotherapy even after many years of other treatments with failed results.

Journal of Prolotherapy. 2009;2:99-100. KEYWORDS: back pain, chronic body pain, headaches, neck pain, Prolotherapy, SI pain, thoracic.

r. William B. is a 57-year-old dentist who had a 15 or 20 year history of low back, thoracic, neck pain and headaches. He had surgery on his spine to relieve pressure on the spinal cord from bone spurs but he was left with a lot of pain below that area, to the sacrum and the hip. He also had chronic neck and thoracic pain. Extensive treatment over the years included attending a pain clinic, multiple medications including OxyContin, Percodan, and Neurontin, radiofrequency ablation of the facets, nerve root blocks, and facet injections that were all of little benefit. He had an SI joint injection at the Mayo Clinic that helped him temporarily. He had a course of acupuncture that helped some. He went through an intensive back and neck strengthening program using computerized strengthening that helped the strength but did not change his pain level. He tried massage and yoga that actually increased his pain. An inversion traction table increased his pain. He had multiple neurology evaluations and EMG's that were negative. He did have hyperreflexia in the lower extremities since his thoracic surgery.

At the time of his first visit what was most bothersome was low back and hip pain, right greater than left near the SI joint. This increased with prolonged standing and sitting. Secondly, his work as a dentist required him to be twisted in a bent over position and turning his head to the right causing left-sided neck pain and right-sided headaches, which were constant for one and a half to two months. He had chronic thoracic pain on the left side below the area of the surgery, which was constant. This was particularly noted with twisting and golf. A night splint for TMJ helped his headaches somewhat. He had difficulty sleeping, had pain in the low back with standing, pain in the neck and thoracic area that affected his work especially bending over patients, and he couldn't exercise in the gym, or play golf without significant pain.

An MRI of the thoracic spine showed some mild disc protrusions in the thoracic area and evidence of surgery. A lumbar MRI showed degenerative changes at multiple levels and some degenerative facet changes at L4-5. His cervical MRI showed C3-4, C4-5 and C5-6 disc degeneration with foraminal narrowing and bridging at C5-6.

He really had no change in pain for several years before his first Prolotherapy visit except for some increase in his neck pain. He had shoulder surgery in the past and multiple knee surgeries including ACL reconstruction and medial and lateral menisectomies. He would get right intermittent knee pain.

On examination he had tenderness typical of ligament instability and attachment pain over the cervical facet columns, right greater than left and at the base of the skull, and right side of the head. He had some anterior shoulder tenderness and some limited range of motion of the shoulder. There were degenerative changes in the knee examination and some evidence of loss of joint space. He had tenderness at the iliolumbar and SI ligaments and facet columns L1 to the sacrum that is typical for ligamentous cause of low back pain. There was evidence of spinous processes removed from previous surgery.

He had Prolotherapy to the head attachments, the neck and the low back. After the first visit, one month later, he had marked improvement that he stated was "vast



improvement or 80% improvement overall." He had very little pain of the vertex of his head and very little neck pain. He started to have some tightness just prior to follow up visit and the low back was also much better. He only had some mild coccyx pain near the tailbone and occasional spasm.

After the second treatment he noticed further improvement. He had almost no headaches since the second Prolotherapy treatment. He was quite pleased with his progress. He reported having some flare in the left lower thoracic and lumbosacral area if he over exercised. The patient was instructed in strengthening exercises. He had a third treatment to the neck and low back after which he had no return of his headaches, and had some mild right SI pain with elliptical exerciser and high resistance training, but he was unable to do much of any exercise before having Prolotherapy. He noted some more left low thoracic area and right shoulder pain. He was treated to the thoracic and right shoulder and noticed very little pain at follow up. He was left with some tailbone residual pain, but was exercising 20-minutes once or twice a day and the shoulder was much improved. He was treated additionally with the shoulder and the thoracolumbar area. He continued to have very little pain in the neck, the low back and mainly pain the mid thoracolumbar junction below his surgery. He had two more treatments on his neck and shoulder. He was able

to golf, play racquetball, do his work as a dentist, and exercise on elliptical, Stairmaster and lift weights without chronic pain.

He was quite pleased with his progress and expressed frustration that he had not found Dr. Kramer and Prolotherapy 15 years earlier. He continues to practice dentistry and exercises regularly managing his mild discomfort well, which was previously incapacitating and was not helped with any multiple medical interventions other than Prolotherapy and exercise.

#### LETTER TO DR. KRAMER FROM DR. WILLIAM (BILL) B:

#### Dr. Kramer,

I would like to tell you about my story. I had back surgery about 15 years ago, along with two shoulder surgeries in the past 10 years. I have been through many programs, steroid injections done in the hospital, physical therapy programs involving strenuous exercise. Despite this therapy I still had constant pain in my back and shoulder. I tried every exercise to strengthen the area, but the result was still constant pain. A Russian friend of mine recommended Prolotherapy which I replied, "I have never heard of it." He was an athlete in Russia and said it was common treatment for athletic injuries.

That's when I did my research and found Dr. Kramer. It took several months and repeated treatments, but I was able to get healing and strength in the area that was causing pain. Now I am happy to say that I can go to the gym several times a week without the painful

after affects I used to suffer. If you have tried many therapies and had no luck, don't give up, I didn't!

#### Bill B., DDS

This is one example of an individual with multiple areas of pain treated with many very invasive treatments and heavy medication without



Dr. Bill working pain-free in his profession as a dentist.

improvement, but improved greatly with Prolotherapy.

This illustrates how chronic pain from ligamentous laxity and degenerative disc disease in the cervical, lumbar and thoracic spine, headaches, neck and low back pain can be treated successfully with Prolotherapy even after many years of lack of improvement with other treatments.

TEACHING TECHNIQUES

## Hip Arthritis Prolotherapy Injection Technique

Rodney S. Van Pelt, MD

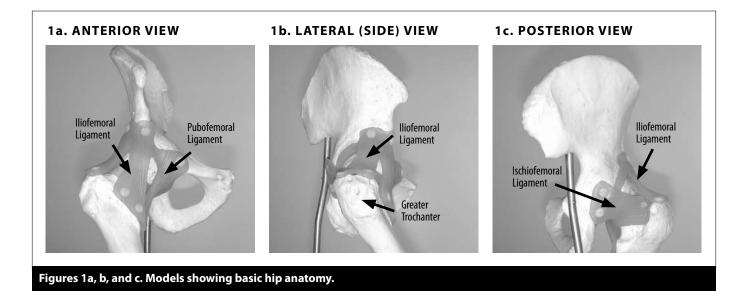
**P** rolotherapy techniques and solutions have improved to the point that even severe degenerative hip osteoarthritis can be helped with Prolotherapy. In general, the number of Prolotherapy treatments will depend on the extent of the arthritis. In my experience it is not uncommon for more advanced cases to need 10 to 14 treatments given one to six weeks apart. Most commonly, I see patients for hip treatments at two-week intervals. One can expect at least a 70% overall success, though with less advanced arthritis the success rate is higher. During the treatment course the patient follows standard post-Prolotherapy instructions. Patients are to be active and exercise to pain tolerance and use heat and avoid ice and other anti-inflammatory medications.

The hip is one of the deepest joints in the body. As is the case with all injections, knowledge of the basic anatomy is important to delivering safe and effective Prolotherapy to the hip joint. (*See Figures 1a-c.*) It is a ball and socket joint with a large range of motion. Directly in front of the hip joint runs the femoral nerve, artery and vein, all structures that obviously I want to avoid with my needles.

I utilize 12cc of solution intraarticular (IA) and 36cc about the joint. The intraarticular syringe contains 1IU of human growth hormone (HGH). The HGH is an important part of the IA cocktail and should be used in every case of moderate or severe arthritis of the hip. The syringe for IA injection should include 5cc 50% dextrose, 2cc 1% lidocaine, and the HGH, then filled to 12cc with saline. Strong proliferants such as sodium morrhuate should not be used IA as they may cause a very strong, and/or prolonged capsulitis.

The injections to the supporting ligaments and capsule of the joint consist of three 12cc syringes. These contain standard Prolotherapy solution and may be supplemented with stronger proliferants such as sodium morrhuate when needed.

Let us proceed with positioning the patient. Have the patient lie on the table with the painful hip up. Draw the knee forward till the hip is flexed at about a 45 degree angle. Next we will palpate the trochanter and outline it for reference. (*See Figure 2.*) Cleanse the skin overlying the injections site.



**The intraarticular (IA) injection** will be administered first. Attach a 22G 3-inch needle to the syringe (a longer needle may be needed for some patients depending on their size). After cleansing the skin, insert the needle through the skin just above the end of the trochanter (proximal to the long axis of the femur). Direct the needle straight down (medially) and advance the needle. The needle will clear the trochanter and you will feel the needle pass through the thick capsule about 2 <sup>1</sup>/<sub>2</sub> inches deep and contact the femoral neck shortly after. (*See Figure 3.*) Typically the patient will experience pain as the needle passes through the capsule as this is a well innervated



structure. The needle should be withdrawn about 1mm. The contents of the syringe are injected intraarticularly here. It should flow freely. If it takes a strong pressure on the plunger then you have not positioned the needle intraarticularly. Reposition the needle and proceed. Following the IA injection the hip should be repeatedly flexed and extended to distribute the Prolotherapy solution throughout the joint.

The iliofemoral and ishiofemoral ligaments and capsule are treated proximally and distally next (these three are almost the same structure). **The first syringe** is inserted just above the posterior-superior aspect of the trochanter. (*See Figure 4.*) The needle is advanced and clears the trochanter and touches bone at the acetabular rim. Injection of 0.5 to 1.0cc of solution is made here. The needle is partially withdrawn and reinserted cephalad and caudad injection made at each side thus "peppering" the posterior/inferior acetabular rim. Approximately 9cc of fluid are injected here. The needle is again partially



Figure 3. Intraarticular Prolotherapy injection of the hip.

withdrawn and redirected toward the distal portion of the neck where the capsule and ishiofemoral ligament insert at the junction of the neck and trochanter. The remaining 3cc are "peppered" here.

**The second syringe** is inserted at the same location as the IA injection. The needle is directed slightly cephalad and advanced. (*See Figure 5.*) It will clear the trochanter and touch the bone at the posterior/superior acetabular rim. 9ccs of proliferant are "peppered" along the posterior/ superior acetabular rim where the capsule and iliofemoral



Figure 4. Prolotherapy injection of the superior/posterior iliofemoral ligament.

ligament attach proximally. Then the needle is redirected toward distal insertion of the iliofemoral ligament and capsule at the junction of the neck and trochanter. The remaining 3cc of Prolotherapy solution are "peppered" here.





Figure 6. Prolotherapy injection technique for treating the anterior portion of the iliofemoral ligament.

To insure treatment of the iliofemoral ligament a third and last syringe is inserted at the anterior/superior aspect of the trochanter. (See Figure 6.) The reason for this is with a tensile strength greater than 350N, it is the most powerful ligament in the human body and provides an important constraint for the hip joint. It keeps the pelvis from tilting posteriorly in upright stance, without the need for muscular effort. It also limits adduction of the extended limb (particularly the lateral elements of the ligament) and it stabilizes the pelvis on the stance during gait, ie, it acts with the small gluteal muscles to keep the pelvis from tilting toward the swing side.<sup>1</sup> In regard to the injection technique, the needle is advanced and clears the trochanter and touches bone at the acetabular rim. Approximately 9cc of solution are "peppered" at this site. The needle is again partially withdrawn and redirected toward the superior anterior portion of the femoral neck where the capsule and (anterior portion) iliofemoral ligament insert at the junction of the neck and trochanter. The remaining 3cc are "peppered" here.

In cases of severe arthritis the "peppering" of injections is very painful. The pain associated with injection tends to decline with subsequent treatments as the underlying inflammation begins to settle down, and the injured structure begins to heal.

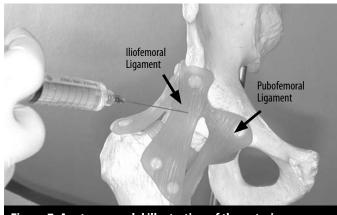
Overall this is a tremendous option for patients to avoid hip surgery. In most cases it is able to accomplish this goal in what patients are routinely told is "impossible." Prolotherapy offers hope for those with hip arthritis.

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#### EDITOR'S COMMENTS

As can be seen in Figure 7, there is greater exposure of the anterior portion of the iliofemoral ligament and pubofemoral ligament from the anterior or front. A greater portion of these ligaments can be injected from the anterior (front) compared to the lateral approach. The clinician needs to be aware that the femoral vein, artery, and nerve lie in front of the hip joint. When the anterior portion of the hip requires injections, care must be taken to avoid hitting these structures with the needle. This involves feeling for the femoral artery pulse and moving three finger breaths laterally, in a line about even with the superior portion of the pubic symphysis. Even so, the needle must be advanced very slowly in case the femoral nerve is "tickled."



**Figure 7. Anatomy model illustration of the anterior hip ligaments.** This picture demonstrates a Prolotherapy injection of the anterior portion of the iliofemoral ligament and pubofemoral ligament from the front of the hip.

WONDER WHY?

## Why Prolotherapy is the Strongest Weapon I have found against Chronic Pain and Sports Injuries

Donna Alderman, DO

hen a person becomes a physician, he or she learns the Hippocratic Oath which sets down the rules for practicing medicine. The first and foremost rule of this doctrine is "to help, or at least, do no harm." Musculoskeletal pain issues, such as low back pain, neck pain, knee pain, shoulder pain, elbow or wrist pain, ankle pain, arthritis pain, and the pain and disability of sports injuries, are common complaints heard by many physicians. As a young doctor practicing family medicine, I had patient after patient come to me with these ailments. Being an osteopathic physician, with extra training in the musculoskeletal system and treatment, I knew more than the average medical doctor regarding these complaints, and had extra tools I could use. I was able to help some of my patients get rid of their pain, but for others, the pain would only go away temporarily and would continue to return.

Because of my belief that a doctor should "do no harm," I was reluctant to prescribe long-term painkillers, which have potential side effects and can be addictive, or to send someone for an invasive procedure such as surgery, unless the need was clear-cut, which is rare. I was getting discouraged. Yet, I did not give up. With all that medical science had to offer, I thought there must be *something* I could do to help these patients. Then I heard about Prolotherapy.

Prolotherapy is a minimally invasive, safe therapy that stimulates the body to heal painful areas. It has a high success rate and strengthens tissue rather than weakening it, as can happen with other treatments such as cortisone, which reduces healing. Cortisone is often injected into painful joints and in the short term can help with pain. However, cortisone can destroy a joint if used too frequently and therefore doctors are instructed not to give more than a few shots a year to a particular joint. Prolotherapy, on the other hand, stimulates the repair of joints.



Dr. Donna Alderman injecting a patient's knee.

Prolotherapy is a logical and simple treatment based on very basic principles. One of these principles is that the body has the ability to heal itself. Another principle is that the body is "programmed" to heal based on "stimulus-response." After an injury, the body will try to heal according to its programming. For soft tissue injuries (ligaments and tendons), the program allows for several weeks of healing, but after that time interval has passed, the healing stops. Think of a sprained ankle. A sprain is an overstretching, twisting and/or tearing of a ligament, the tissue that holds bones together. When a sprain occurs, the body's "program" kicks in and the stimulus to heal begins. At first, this stimulus to heal is strong but over the ensuing weeks diminishes and then eventually stops. Unfortunately soft tissue, specifically joint ligaments and tendons, often do not heal completely after an injury because of limited blood flow to these areas. Therefore if healing is not 100% (and often isn't), the person is left with a remnant of that injury. This remnant makes the joint a little weaker and more prone to another injury. Over time, and repeated injury which is more likely to occur



Dr. Alderman injecting a patient's neck, while teaching doctors from Denmark.

now that joint area weakens more and more. Eventually, an individual may find himself or herself with pain in that area which does not ever seem to go away (chronic pain).

Doctors faced with this type of pain sometimes suggest that surgery is the only option, especially if an MRI shows damage. MRI's, however, can be misleading with this type of pain. As evidenced by multiple studies<sup>1-20</sup> MRI's may show abnormalities unrelated to the patient's current pain complaints. Study after study shows that abnormal findings exist in patients who have no pain at all, and therefore surgery directed strictly towards an abnormality on an MRI without being correctly correlated to that patient's history and physical exam may not resolve that person's pain. It is therefore prudent for patients to be as conservative as possible when seeking pain remedies and not go directly for surgery unless there is a very clear need, such as a completely ruptured tendon or ligament (off the bone) or neurological deficits requiring immediate action. Many patients, treated with Prolotherapy, have been able to avoid surgery and have experienced resolution of their pain. This includes patients who have been told they needed back surgery for a disc problem, knee surgery or replacement, ankle surgery, neck surgery, elbow or shoulder surgery and wrist, toe, or other joint surgery.

What about exercise and physical therapy? These are often prescribed for musculoskeletal injuries. It is important to understand that exercise and physical therapy, while helpful to strengthen muscle around a joint, does not have much impact on the tendon part of the muscle which attaches it to the bone, or the ligaments which hold the joint together. Because of the reduced blood flow to

ligament and tendon tissue, these areas do not respond to exercise or physical therapy in the same way that muscle tissue does. Weight training can be employed to build muscles, but again, has very little impact on ligament and tendon growth and repair. Consider bodybuilding and how it works: Body builders use heavier and heavier weights in an effort to create micro-trauma to the muscle. This micro-trauma stimulates the body to go to the injured muscle and make it stronger and bigger (muscle hypertrophy). Again, the stimulus-response of the body at work! However, weight training does not stimulate ligaments and tendons in the same way as it does muscle tissue. Prolotherapy is the only treatment I know of that stimulates the repair and strengthening of ligaments and tendons. You could say, then, that Prolotherapy is "bodybuilding" for the ligaments and tendons.

Prolotherapy works by tricking the body into healing; it provides a "stimulus" which causes the body to "respond" by reactivating and completing the healing process in these previously unhealed areas, reducing or eliminating pain. The stimulus is at the level of the injured ligaments and tendons, and activates growth factors to come to the sites where healing needs to occur. Prolotherapy is an option when physical therapy has failed, but it can also be used in conjunction with physical therapy and exercise. Depending on the injury, Prolotherapy and exercise may be started at the same time, or after a few Prolotherapy treatments have strengthened the joint.

Osteopathic manipulation is also a very effective treatment which can be used in conjunction with Prolotherapy. Sometimes osteopathic treatment can be tried first, if there is no obvious soft tissue injury. Osteopathic physicians are trained in all aspects of body mobilization, not only the spine but also the soft tissues, muscles, nerve flow, blood flow, lymph flow, myofascial release (the release of muscle structures which have a negative impact on body mechanics) as well as specialized techniques such as cranial-sacral (the correct movement and alignment of the cranial bones and sacrum). Osteopathic techniques can be very, very powerful in and of themselves. However, when they do not work to solve a pain issue, they can be combined with Prolotherapy. For instance, I have had patients come in for knee pain, which was treated with Prolotherapy. An analysis of that patient's body mechanics showed a twisting of their back and pelvis was putting undue pressure on his knee and that needed to be addressed. Osteopathic manipulation was then used to



release the twisting and take the strain off the knee, which then was able to return to full function.

Conditions or diagnoses that can be treated with Prolotherapy include degenerative disc disease including herniated discs, low back pain, sciatica, medial and lateral epicondylitis (golfers and tennis elbows), tendonitis or tendonosis, rotator cuff tendon problems, plantar fasciitis or foot pain, knee joint pain, osteoarthritis, hypermobility pain or instability, ankle pain, toe pain or problems including bunion pain or "turf toe", athletic injuries including sprains and strains that do not resolve, sacroiliac issues, neck pain, musculoskeletal headaches and others.

Thanks to the Internet, where a vast amount of information is now available at ones fingertips, our society is shifting from one where patients know little about their health care options, to one where individuals do their own research and take a more active role in making decisions about their medical treatments. The more someone knows about his or her options, the better equipped that person will be to make informed choices that are right for them. While Prolotherapy is not for everyone or for every condition, it has helped thousands of people who might otherwise still be in pain. ■

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#### WONDER WHY? A SCIENTIFIC EDITORIAL

## The Deterioration of Articular Cartilage in Osteoarthritis by Corticosteroid Injections

Ross A. Hauser, MD

#### A B S T R A C T

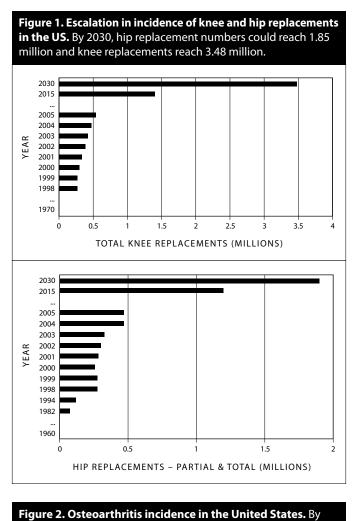
The hallmark feature of osteoarthritis is the breakdown in the articular cartilage of joints such as the knee and hip. Both animal and human research has consistently shown that corticosteroid injections into normal and degenerated knees accelerate the arthritic process. A summary of the effects of the intraarticular corticosteroids on articular cartilage includes: a decrease of protein and matrix synthesis, matrix hyaline appearance becomes fibrotic, clumping of collagen, alteration in chondrocyte cell shape, chondrocyte cell proliferation inhibited, chondrocyte cytoxicity enhanced, loss of chondrocytes, surface deterioration including edema, pitting, shredding, ulceration and erosions, inhibition of articular cartilage metabolism, articular cartilage necrosis, thinning of articular cartilage, decrease in cartilage growth and repair, formation of articular cartilage cysts, and ultimately articular cartilage destruction.

When researchers microscopically and radiologically examine human joints after corticosteroid injections, the same results are found in humans as in animals. Intraarticular corticosteroid injections accelerate the osteoarthritic degenerative process. Because of this possibility, organizations such as the American College of Rheumatology acknowledge, "It is generally recommended, although not well supported by published data, that injection of corticosteroids in a given joint not be performed more than three to four times in a given year because of concern about the possible development of progressive cartilage damage through repeated injection in the weight-bearing joints." It is this author's opinion that there is no doubt that the rise of osteoarthritis, as well as the number of hip and knee replacements, is a direct result of the injection of corticosteroids into these joints.

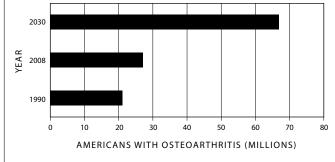
*Journal of Prolotherapy*. 2009;2:107-123. KEYWORDS: articular cartilage, corticosteroid injections, degeneration, osteoarthritis, Prolotherapy, regeneration.

steoarthritis (OA) is a major cause of pain and disability, as well as cost, to both the individual and society. The average direct out-of-pocket expenditure of OA is approximately \$2600 per person per year, but the total annual cost per person (including lost productivity) is between \$5700 and \$9600.<sup>1,2</sup> OA and related conditions cost the U.S. economy nearly \$128 billion per year in medical care and indirect expenses, including lost wages and productivity.3 A major component of the economic burden associated with the treatment of arthritis relates to surgical joint replacements of the hips and knees. In 2004, the national bill of hospital charges for hip/knee replacements was \$26 billion, and the hospital cost was \$9.1 billion.<sup>4</sup> Musculoskeletal procedures, including hip and knee replacements, account for ten percent of all hospital care in the United States. From 1997 to 2005, the number of knee replacements climbed by 69 percent, from 328,000 to 555,800. The number of hip replacements rose from 290,700 to 383,500 procedures.<sup>5</sup> The number of these procedures is increasing at an alarming rate. Nearly 600,000 hip replacements and 1.4 million knee replacements will be performed in the year 2015.6 By 2030, it is estimated that the number of hip and knee replacements annually will increase to 1.85 and 3.48 million, respectively.<sup>7</sup> (See Figure 1.) The question to ask is why has there been such an alarming rate of articular cartilage deterioration necessitating all of these joint replacements? What is causing it?

OA currently affects more than 27 million Americans, up from 21 million in 1990. By the year 2030, it is expected that more than 67 million Americans will have arthritis.<sup>8</sup> (*See Figure 2.*) While much is known about what happens at the level of the joint after the start of OA, there is no consensus as to why the condition starts in the first place. Factors influencing the incidence of OA have been identified through epidemiological and small group studies. These factors include sex (women, especially after entering menopause), low hormone levels,



the year 2030 it is estimated that the number of Americans suffering from osteoarthritis could reach as high as 67 million.

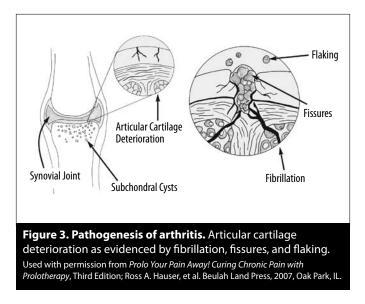


nutritional factors, obesity, inheritance, knee injury, quadriceps strength, ligament laxity, and joint injury due to misalignment, overload or trauma.<sup>9-11</sup> While many of these have been well studied, it is doubtful that they alone could account for the dramatic rise in OA over the last forty years, and the predictions of OA in epidemic proportions for the near future.

The hallmark feature of OA is a breakdown in the articular cartilage of joints such as the knee and hip. The articular cartilage covers the connecting surfaces of two bones where they join, allowing them to glide effortlessly, one bone over the other. The first feature of OA is a fraving and fibrillation of the articular cartilage surface. (See Figure 3.) This coincides with a loss of proteoglycans from the matrix of articular cartilage.<sup>12</sup> Articular cartilage contains chondrocytes embedded in an extracellular matrix composed primarily of type II collagen and proteoglycans. Articular cartilage bulk chemical analysis reveals that it is composed of 10 to 15 percent collagen, 10 to 15 percent protein polysaccharide (proteoglycan), and 70 to 80 percent water.<sup>13</sup> Chondrocytes make up one to five percent of the volume in adult cartilage tissue. Chondrocytes are the cells responsible for the formation, maintenance, and repair, of articular cartilage.14 Despite a poor oxygen tension, limited nutrient supply, and anaerobic metabolism, chondrocytes can still produce large amounts of collagen and proteoglycans.<sup>15</sup> The collagen provides strength to the cartilage, the proteoglycans provide elasticity and stiffness on compression. The proteoglycans are very hydrophilic, meaning they are attracted to water. The proteoglycans form aggregates, which give articular cartilage its unique abilities to act as a shock absorber for joints such as the knee and hip.<sup>16</sup> (See Figure 4.)

OA begins immediately once chondrocyte function is altered. This leads to a decrease in the ground substance, or proteoglycans. This weakens the cartilage structure. The cartilage breaks down further causing fissures in it. Eventually there is enough breakdown of the cartilage that it can be seen on X-ray as joint space narrowing. This causes a transmission of pressures that are too high for the bones to handle. Eventually the space between the bones becomes completely obliterated. This is when the orthopedic surgeon tells the patient he/she has bone on bone and needs a joint replacement. (*See Figure 5.*)

Early in the course of OA, the tissue mounts an attempt at repair. Chondrocytes proliferate with a resulting increase in matrix synthesis. However, in the face of chronic mechanical degenerative forces, degradative enzymes overwhelm the synthetic capability. The net result is too much degradation of cartilage and not enough repair. Traditional pharmacological treatments, including nonsteroidal anti-inflammatory drugs and corticosteroids shots, are typically used to not only decrease symptoms, but also to hopefully improve the physiology of the



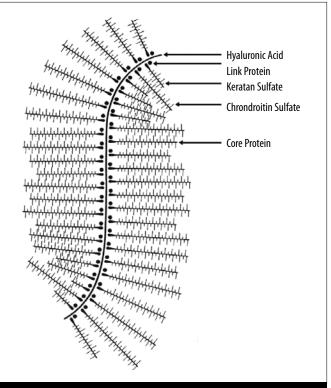
disease process. Unfortunately the preponderance of evidence shows that these treatments actually *accelerate the osteoarthritic process*.<sup>17,18</sup> The rest of this paper will focus on the evidence that corticosteroids deteriorate normal and degenerated articular cartilage.

Intraarticular injections of corticosteroids have been used for the treatment of OA of the knee and other joints for more than 50 years, but there is little controlled evidence to support their use.<sup>19-22</sup> Since 1951, when Thorn first injected hydrocortisone into the knee joint of a patient with rheumatoid arthritis, the anti-inflammatory effects of intraarticular corticosteroid compounds have been established.<sup>23</sup> Cortisol, and the synthetic analogs of cortisol, have the capacity to prevent or suppress the development of the local heat, redness, swelling, and tenderness, by which inflammation is recognized. At the microscopic level, they inhibit not only the early phenomena of the inflammatory process, edema, fibrin deposition, capillary dilatation, migration of leukocytes into the inflamed area, and phagocytic activity, but also the later manifestations of capillary proliferation, fibroblastic proliferation, deposition of collagen, and still later, cicatrization.<sup>24</sup>

The first evidences that steroids injected locally produced adverse effects came a few years after doctors started using corticosteroids. Several

*cicatrization* – the process whereby wound healing forms scar tissue.

corticosteroids. Several case studies reported rapidly progressive degenerative arthritis following intraarticular hydrocortisone injections.<sup>25-27</sup> Researchers then started looking at intraarticular corticosteroid injected joints in



**Figure 4. Proteoglycan aggregate.** The proteoglycans attract water and give articular cartilage its "shock absorbing" properties.

Used with permission from *Prolo Your Sports Injuries Away! Curing Sports Injuries and Enhancing Athletic Performance with Prolotherapy*, Ross A. Hauser, et al. Beulah Land Press, 2001, Oak Park, IL.



**Figure 5. X-ray of a severely degenerated hip.** No cartilage remains in this left hip joint, thus this patient would be a candidate for a hip replacement.

animals, comparing them to similar joints injected with saline (control). The feeling was that these studies should provide a useful indication of the clinical effects of these drugs on normal or diseased joints in man.

#### ANIMAL STUDIES

It is well known and accepted that medications must first be shown to be safe in animals before they are given or injected into human beings. It is also much easier to study the effects of the drugs, or injection of the drugs,

in animals because the animals can be sacrificed, and the tissues examined under a microscope. This allows the researcher to evaluate not only the potential beneficial effect of the medication, but also detrimental effects.

Using tritiated glycine (glycine <sup>3</sup>H) as an indicator of amino acid incorporation in protein synthesis in cartilage matrices, Mankin and Conger injected hydrocortisone acetate into rabbit knees. Their data showed a rapid and profound decrease in glycine incorporation that appeared to depend on dosages. Maximum decline was seen six hours after the injection.<sup>28</sup> They did a similar experiment using glycine <sup>14</sup>C as the radiotracer, which showed a definite decrease in the rate of protein synthesis within two hours of the injection. They

noted that the rate of the inhibitory effect of intraarticular hydrocortisone on cartilage protein synthesis was about twice that of the observed rate for corticosteroids given by intramuscular route.<sup>29</sup> One year later, researchers injected hydrocortisone into normal rabbit knees and produced thinning of the cartilage, and the development of fissures and fibrillations in the articular cartilage. They also found multiple small white deposits within the substance of the articular cartilage, which were found to represent cystic areas of degeneration within the middle zone of the cartilage matrix. These effects were most marked in the animals which had the greatest number of injections.<sup>30</sup> Deleterious effects of cortisone were reported by some

They noted that the rate of the inhibitory effect of intraarticular hydrocortisone on cartilage protein synthesis was about twice that of the observed rate for corticosteroids given by intramuscular route.

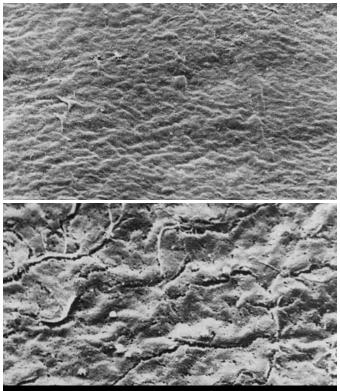
"It must be expected that corticosteroids can retard or prevent recovery in naturally occurring joint diseases. Administration of these drugs must therefore be considered with caution."

researchers who noted that the drug inhibited the synthesis and deposition of chondroitin sulfate in cartilage.<sup>31-33</sup> Many research papers have documented that corticosteroids reduced radiosulfate uptake into chondroitin sulfate, thereby decreasing cartilage growth and repair.<sup>34-37</sup> Other research on the articular cartilage of rabbits showed that the destruction of articular cartilage by corticosteroids worsened with time. Microscopic degenerative changes were progressively more evident, including loss of protein polysaccharide in the matrix, decreased number of chondrocytes, loss of cell shape, distortion of the cell

membrane and nucleus leading to chondrocyte degeneration, multiple fissuring of the matrix, clumping of collagen, and finally by the sixth month, appearance of large cysts containing debris and degenerated chondrocytes.<sup>38-41</sup> (*See Figure 6.*)

In regard to the progression of OA, is the articular cartilage damage seen from the disease or from the steroid injection treatments? One research paper put it this way: "After administration of corticosteroids patients suffering from to arthritis, it is impossible to decide how much damage is due to the steroids and how much is due to the natural progress of the disease. To answer this question, these researchers devised a study to look at what happens to rabbit articular cartilage subjected to

corticosteroid concentrations compatible with what we observed in human patients. They compared this group to normal control animals who received no injections. They also induced an artificial arthritis in one group of animals, used them as another control, and saw what happened to some of these animals if they also were subjected to low dose corticosteroids. Compared to the control groups, the corticosteroids caused severe deleterious effects on the articular cartilage. The articular cartilage became thin, the matrix near the surface lost its hyaline appearance and became fibrous, the surface fibrillated, and the arthritic cartilage lost its ability to repair itself. This last effect caused the researchers to state "It must be expected that



**Figure 6. Electronmicroscopy of articular cartilage after saline injections versus corticosteriod injections.** Articular cartilage injected with saline has a normal, smooth appearance (top), whereas corticosteroid injected cartilage has obvious fissuring and is in the process of deteriorating (bottom). Pictures originally from the *Journal of Anatomy*, volume 127, Oct. 1978, pages 393-402. Article title: Effects of intraarticularly administered corticosteriods and salicylates on the surface structure of articular cartilage.

corticosteroids can retard or prevent recovery in naturally occurring joint diseases. Administration of these drugs must therefore be considered with caution."<sup>42</sup> This last quote was written in 1973. For this review I purposely used "old" research to emphasize the point that the effects of corticosteroids have been known for years. Current research done in 2007 on rabbit cartilage continues to confirm that corticosteroid injections into the knee joints of rabbits causes cartilage necrosis.<sup>43</sup>

#### CORTICOSTEROIDS INDUCE PREMATURE CELL DEATH OF CHONDROCYTES IN ARTICULAR CARTILAGE

Dexamethasone is a corticosteroid commonly used in humans and domestic animals, particularly in the treatment of painful conditions. When articular cartilage cells were subjected to dexamethasone, cell proliferation was inhibited. Even more significant than that was the fact that dexamethasone induced cell apoptosis.<sup>44</sup> Apoptosis is a form of programmed cell death. In simple terms, dexamethasone caused chondrocytes to die a premature death. The mechanism by which corticosteroids does this is most likely through blocking the anti-apoptotic effects of Insulin-like growth factor (IGF-1).<sup>45,46</sup>

## DETERIORATION OF ARTICULAR CARTILAGE WITH JUST ONE STEROID INJECTION

Regarding the effect of corticosteroid injections, some researchers started looking at the effects of *just one* corticosteroid injection into a joint of an animal. One study, done at University Central Hospital in Helsinki, Finland, showed significant deleterious effects on cartilage via electron microscopy after only one steroid injection into the knee. The authors also found that the higher the dose of steroids injected into the knee, the worse the deterioration.<sup>47</sup> Even one injection into the temporomandibular joint (TMJ) showed tremendous destruction of the articular cartilage and underlying bone.<sup>48</sup> Another study showed that even 16 weeks after a single steroid joint injection, the cartilage remained biochemically and metabolically impaired.<sup>49</sup>

#### CORTICOSTEROIDS CAUSE CARTILAGE DETERIORATION IN EXERCISED HORSES

Corticosteroid injections into equine (horse) joints cause similar effects as those in the rabbit. Equine research has been consistent in that corticosteroids cause a breakdown of the cartilage matrix and protein synthesis.<sup>50-52</sup> It is especially damaging to pony foals where corticosteroids caused joint damage either at the joint surface or deep within the cartilage. Signs of surface deterioration included edema, fibrillation, enlargement of lacunae, pitting, and shredding and erosions of the cartilage. Cartilage ulceration and fracture was common. Glycosaminoglycan content of articular cartilage decreased by 55% in three months. Corticosteroids inhibited articular chondrocyte metabolism which initiated cartilage degeneration. Surface destruction and osteochondrosis dissecans followed continued mechanical stress of compromised cartilage.<sup>53</sup>

(*See Figure 7.*) In another study, articular cartilage and chondrocytes obtained from young adult

**Osteochondrosis dissecans** – a disorder in which a fragment of cartilage and subchondral bone separates from an articular surface.

horses ages 1.5–3.5 years of age were subjected to the corticosteroid methylprednisolone. Chondrocyte cytotoxicity was found as the steroid concentration was



**missing.** Severe damage to articular cartilage surfaces can occur with corticosteriod injections which can be localized as the above picture captures.

increased. This coincided with a decreased and altered chondrocyte expression of matrix proteins, which the authors felt likely contributed to the pathogenesis corticosteroid-induced cartilage degeneration.54 of Researchers at the University of Montreal showed that repeated intraarticular injections into the radiocarpal joint of horses free of OA, compared to controls, induced the breakdown of articular cartilage. Specifically, the biomarkers for proteoglycan and collagen breakdown were significantly elevated in the corticosteroid injected joint fluid.<sup>55</sup> In a similar experiment, chromatographic analysis of joint fluid in corticosteroid injected joints showed fragments of the articular cartilage aggrecan. They were significantly elevated in the steroid injected joints, compared to control joints. The authors summarized their findings by saying, "these results indicate that the repeated use of intraarticular methylprednisolone acetate leads to potentially harmful inhibition of procollagen II synthesis and an increased release of degradation products of the proteoglycan aggrecan from articular cartilage."<sup>56</sup> To see what happens when you inject steroids into a joint and then exercise the joint, researchers at Kansas State University injected the contralateral middle carpal joints of healthy horses with either corticosteroid or diluents (control). The results showed that steroid injected cartilage was 24% thinner and had a 97% decrease in compressive stiffness. The authors concluded that repetitive intraarticular administration of corticosteroid in exercising horses alters the mechanical integrity of articular cartilage.<sup>57</sup> A summary of the effects of the intraarticular corticosteroids as denoted by the above research can be seen in Table 1. (See Table 1.)

#### HUMAN DATA

Temporary and permanent damaging changes in soft tissue, bone, and cartilaginous structures, have long been reported to occur when corticosteroids are administered for human disease.<sup>58-62</sup> In my pain practice, it is relatively common for a person to come in with X-rays or MRIs which demonstrate a rapid deterioration of the articular cartilage after being on a strong anti-inflammatory medication or receiving a corticosteroid shot. (See Figure 8.) One of the first reports of corticosteroid-induced cartilage damage was in 1960, where the authors reported on four cases of steroid arthropathy after patients were given corticosteroids.<sup>63</sup> The authors noted, "Rapid destruction of the femoral head with subsequent disorganization of the hip joint rarely, if ever, occurs in uncomplicated rheumatoid arthritis or osteoarthritis. Recently we have seen four patients, all treated with corticosteroids, in which such destruction developed. The striking feature in each case was the relative freedom from pain in the presence of severe joint disorganization. Before advising treatment with either oral or intraarticular administration of corticosteroid, this possible complication should be borne in mind, and the likelihood of accelerated joint destruction weighed against the benefit which the patient is likely to derive." There are many other reports of corticosteroids dramatically accelerating the arthritic

## Table 1. Known effects of intraarticular corticosteroids on articular cartilage.

- Deleterious effects more serious in animals with the greatest number of injections
- Higher dose leads to worse deterioration
- Destruction worsened with time and exercise
- Inhibition of synthesis and deposition of chondroitin sulfate and glycosaminoglycan
- Breakdown of proteoglycans and collagen
- · Decrease of protein and matrix synthesis
- Matrix hyaline appearance becomes fibrous
- Clumping of collagen
- Alteration in chondrocyte cell shape
- · Chondrocyte cell proliferation inhibited
- Chondrocyte cytotoxicity enhanced
- Loss of chondrocytes
- Surface deterioration including edema, pitting, shredding, ulceration and erosions
- · Inhibition of articular cartilage metabolism
- Articular cartilage necrosis
- Thinning of articular cartilage
- · Decrease of cartilage growth and repair
- · Formation of articular cartilage cysts
- Articular cartilage destruction

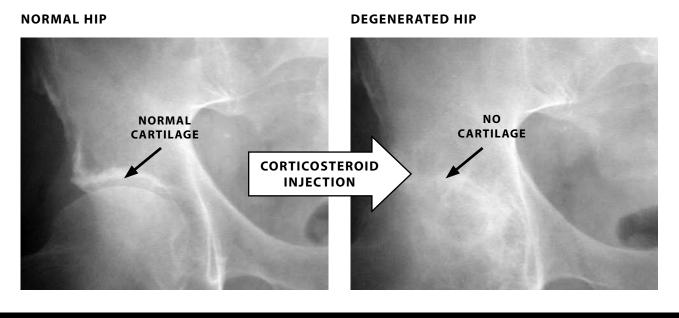


Figure 8. X-ray of a normal hip compared to a steroid-injected degenerated hip. Right hip degeneration in a patient following multiple steroid injections.

process.<sup>63-67</sup> The current literature continues to report on papers whereby intraarticular corticosteroid injections cause this rapid destruction of articular cartilage in various joints including the hips and shoulders.<sup>68-71</sup>

Corticosteroids are injected into joints because they often provide some pain relief. Perhaps it is just this effect, however, that is one of the main reasons corticosteroids deteriorate cartilage. The thought process is simple. A person receives an intraarticular corticosteroid injection because of an injury within and/or around, the involved joint. The corticosteroid provides pain relief, generally lasting for a few weeks. So, some of the articular cartilage damage from steroids can be attributed to analgesia, resulting in microtrauma due to painless overuse. During the period of pain relief offered by the steroid shot, the person resumes normal activities, including athletics. Without the steroid, the person is unable to perform these activities or they are modified because of pain. Now, because the patient does not sense the pain, activities are resumed. This situation is much like the professional football players who receive steroid injections before or during an NFL game. A recent Caring Medical patient told me that during a typical NFL game, five players are receiving injections before or during a game. He said that he has even received two shots in one game. (See Figure 9.) Without a pain signal, the patient has no idea if the activities he is doing, such as running and jumping, are contributing to the deterioration of his cartilage.

Another good example of painless cartilage deterioration is rheumatoid arthritis. Three papers clearly demonstrate the principle that cartilage could be deteriorating even though, clinically, a patient feels better. In the first study involving forty rheumatoid arthritis patients, patients reported feeling better due to medications including steroids, with resultant improvement in their blood tests as well. However, X-rays of their hands and feet over the years revealed worsening of the cartilage.<sup>72</sup> In cases where the patients' rheumatoid arthritis was in complete remission, researchers found that even though the rheumatoid



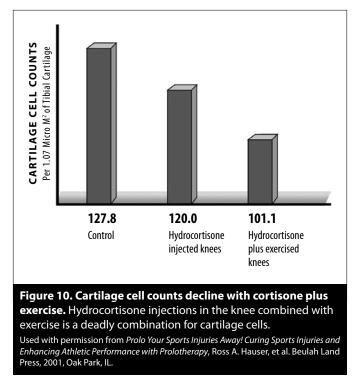
**Figure 9. Steroid injections temporarily block the pain signal.** Without a pain signal, the patient (athlete) cannot determine whether their activities, such as running or jumping, are contributing to cartilage deterioration because the steroid has masked the pain.

arthritis was in clinical remission, articular cartilage deterioration was still reported.73,74 Simply put, pain is our protective mechanism to know something is wrong. Blocking the pain response with anti-inflammatories or corticosteroids overrides this mechanism. Cortisone shots and exercise can be a deadly combination for articular cartilage cells. A good example of this was an animal study where the researchers looked at cartilage cell counts in hydrocortisone injected knees without exercise and those in hydrocortisone injected knees with exercise. This would be akin to patients receiving cortisone shots so they could resume their tennis playing. In this study, all knees injected with cortisone showed cartilage deterioration, but severe cartilage damage was seen in 67% of animals that exercised and also received cortisone. The cortisone and exercise group also showed a significant decline in glycosaminoglycan synthesis and cartilage cell counts compared to the other group. The animals that received a cortisone shot and then ran showed areas of cartilage cell death, which weren't seen in those animals that only exercised or only received a cortisone shot.<sup>75</sup> (See Figure 10.)

### ARTICULAR CARTILAGE DETERIORATION NOT DUE TO AGING

By the time the first changes of radiological osteoarthritis are detected, 13% of knee cartilage has already been lost.76 Articular cartilage volume normally decreases by two to three percent per year.<sup>77</sup> Researchers have already shown that lifelong moderate use of normal joints does not increase the risk of OA.78-80 The degeneration of normal articular cartilage is not simply the result of aging and mechanical wear. Once OA forms, articular cartilage volume decreases at a rate of about four to five percent per year.<sup>81-83</sup> The rate of loss at two years predicts subsequent total knee arthroplasty. For every one percent increase in the rate of tibial cartilage loss there was a 20% increase risk for undergoing a knee replacement at four years.<sup>84</sup> Surely we all should be asking the question what is causing this increase in tibial (joint) cartilage loss beyond that occurring with the normal aging process? Could it be the actual anti-inflammatory medications used by doctors to treat osteoarthritis?

While it is easier to microscopically study the effects of intraarticular corticosteroids in animals and compare them to non-injected joints because animals can be sacrificed, the same is not so in humans. For this reason, less human data exists, but what is available is compelling. *Intrarticular corticosteroids accelerate human articular cartilage deterioration just like in animals.* 



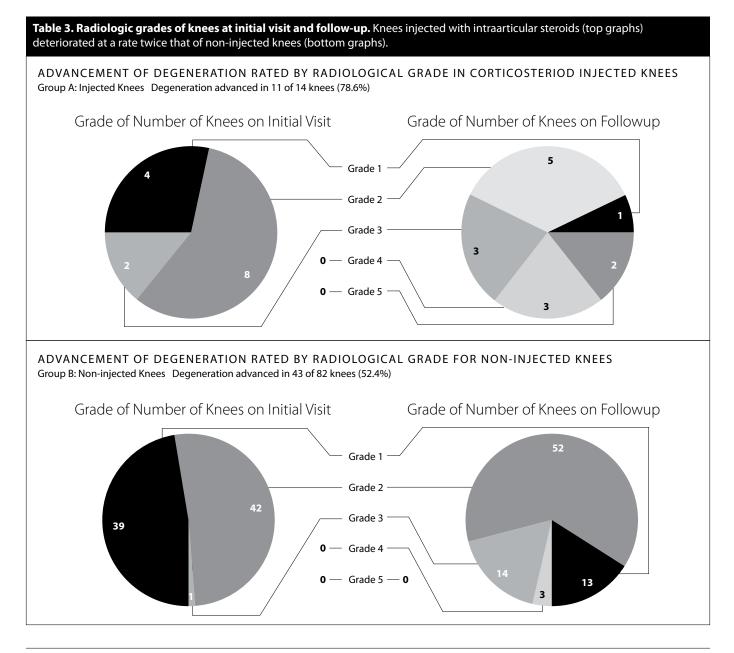
#### NATURAL COURSE OF OSTEOARTHRITIS OF THE KNEE TREATED WITH OR WITHOUT INTRAARTICULAR CORTICOSTEROID INJECTIONS

This heading was the title of an article published in 1993, that compared osteoarthritic knees treated with intraarticular corticosteroid injections to those treated without them.<sup>85</sup> The research was done by four doctors in the Department of Orthopaedic Surgery at Yokohama City University School of Medicine in Yokohama, Japan. They were able to analyze X-rays, pain levels, and functional status of the patients at the start of treatment and after a ten-year period.

The 82 knees not receiving corticosteroid injections were compared to the 14 knees that did receive them. The average age of the patients at the beginning of the study was 60 years-old, and at the end, 70. The median number of corticosteroid injections per joint was 25. Limb alignment was evaluated at the femorotibial angle, measured via an anteroposterior radiograph taken with the patient standing on one leg. The angle is the lateral angle between the femoral axis and the tibial axis. The results of the study revealed a significant difference in the femorotibital angle before and after the corticosteroid injections in the knees of the male patients. Specifically these knees went from 0.6 degrees of valgus at the initial visit, to a varus-angulation of 3.4 degrees. The osteoarthritis of each of the knees was classified into six grades, varying from Grade 0 (normal) to Grade 5 (severe bony defects) using the standing radiograph. (*See Table 2.*) In the corticosteroid-treated group, degeneration of the knee joint associated with bony defects equivalent to Grade 4 or 5 was found in five of fourteen knees, but this was only seen in three of 82 knees that received no injections. (*See Table 3.*) Radiographic degeneration was observed to be more advanced in the group that received corticosteroid injections than in the group that did not receive such injections. In the corticosteroid-injected knees, the radiographic grade worsened by 1.1, whereas the non-injected knees changed by only 0.6 grade. Using

Table 2. Radiologic grades of knee X-rays.		
Grade	Grade of Degeneration	
0:	normal joint	
1:	osteophytes, osteosclerosis	
2:	narrowing of joint space (< 3mm)	
3:	obliteration of joint or subluxation	
4:	bone defect (< 5mm)	
5:	bone defect (> 5mm)	

a paired t-test ratio, these results were statistically significant. In both groups, the clinical evaluation was performed at follow-up according to the knee rating system given in the



Assessment Criteria for the Evaluation on Osteoarthritis of the Knee issued by the Japanese Orthopaedic Association. The criteria is composed of four items, including pain on walking, pain on ascending or descending stairs, range of motion, and joint effusion with a maximum score of 100 for a normal knee. (*See Table 4.*) The average score at follow-up was 69 in the corticosteroid-injected knees and 91 in those not treated with corticosteroid injections. The researchers confirmed that not only do corticosteroids injected into human osteoarthritic knees accelerate articular cartilage degeneration as confirmed by X-ray studies, but they deteriorate joint function compared to non-injected knees.

The researchers confirmed that not only do corticosteroids injected into human osteoarthritic knees accelerate articular cartilage degeneration as confirmed by X-ray studies, but they deteriorate joint function compared to non-injected knees.

#### CORTICOSTEROID INHIBITION OF HUMAN ARTICULAR CARTILAGE BIOSYNTHESIS

An early event in the development of osteoarthritis in a joint is proteoglycan loss from articular cartilage.86,87 Proteoglycans are very large molecules consisting of proteins with attached chains of polysaccharides called glycosaminoglycans. With the exception of hyaluronic acid, glycosaminoglycan units are sulfated, and consequently, highly negatively charged, allowing attraction and binding of water. Because of their great attraction for water, proteoglycans are viscous making them ideal for lubricating fluid in joints. The charges repel each other, which gives them an open structure and is space-filling. These biochemical traits contribute to the mechanical properties of proteoglycans in articular cartilage, such as absorption and distribution of compressive weight, and protect structures in the joints from mechanical damage. Therefore, any decrease in the tissue concentration of proteoglycans, compromises the functional properties of cartilage. Depletion of proteoglycans can result in fibrillation and degeneration of the articular cartilage.<sup>88-90</sup> In all but severe cases of osteoarthritis, the chondrocyte

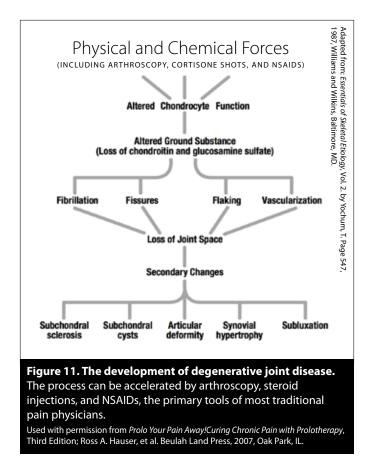
#### Table 4. Assessment criteria for the evaluation on osteoarthritis of the knee.

From The Committee for Assessment Criteria on Knee Diseases and their Treatments of the Japanese Orthopaedic Association.

Pain on walking	Points
Walking 1km or more usually with no pain but without regard to mild pain rarely felt on some activity	30
Walking 1km or more regardless of pain	25
Walking 500m or more, but less than 1km without regard to pain	20
Walking 100m or more, but less than 500m without regard to pain	15
Walking indoors or more but less than 100m without regard to pain	10
Unable to walk	5
Unable to stand up	0
Pain on ascending or descending	Points
No pain	25
Pain but no pain with handrails	20
Pain with handrails, but no pain when step by step	15
Pain when step by step, but no pain when step by step with handrails	10
Pain even when step by step with handrails	5
Unable to ascend or descend	0
Range of motion	Points
Squatting	35
Sideways or cross-legged sitting	30
Flexion of arc of motion of 110 degrees or more	25
Flexion of arc of motion of 75 degrees or more	20
Flexion of arc of motion of 35 degrees or more	10
Flexion of arc of motion less than 35 degrees including ankylosis or severe flexion contracture	0
Joint effusion	Points
No edema, no swelling	10
Puncture required sometimes	5
Puncture required frequently	0
Total score	Points
	100

response to proteoglycan depletion results in an increase in glycosaminoglycan synthesis.<sup>91-93</sup> (See Figure 11.)

In vitro studies of various corticosteroids, including dexamethasone, hydrocortisone, and betamethasone, have shown that they inhibit human glycosaminoglycan biosynthsis in a dose dependent manner.<sup>94-97</sup> Ultimately when human articular cartilage is examined microscopically



after intraarticular steroid injections, signs of degeneration are present.98,99 One human study examined the articular cartilage in the tempomandibular joint (TMJ) after two injections with triamcinolone and compared this to tempomandibular joints that did not receive any steroid injections. The researchers performed microscopic analysis examining the fibrous (top), cartilaginous, and subchondral bony layers of the articular cartilage tissue. The author summarized his results this way, "The results of this study revealed higher destruction to all layers of the joints that received intraarticular injection of triamcinolone acetonide, when compared to the group of joints, which received no steroid injections. This finding firmly supports the hypothesis; intraarticular injection of steroids acts in joints suffering from OA as a lytic agent with the potential to produce a pharmacological arthroplasty."100 The author noted that his study revealed the complete loss of the fibrous layer in the steroid group in 84% of the specimens and that other studies showed a 100% loss.<sup>101,102</sup> He explained it this way, "This is simply because the joints in this investigation received only two injections of steroids, meanwhile the joints in Poswillo's study received six injections of steroids."

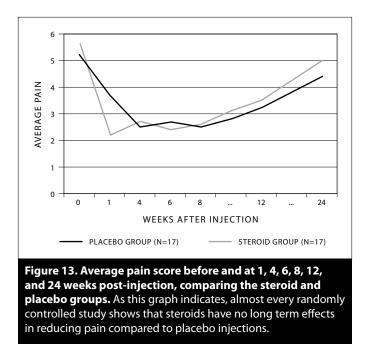
#### INTRAARTICULAR CORTICOSTEROID USAGE IS COMMON

Since its introduction in the early 1950s, the use of corticosteroid compounds by intraarticular injections has become a common practice in orthopedics and sports medicine. (*See Figure 12.*) Prompt and effective reduction of local inflammation occurs after intraarticular injection of corticosteroids. Most of the substances released by the damaged cells to cause inflammation are greatly decreased in quantity. Corticosteroids also inhibit fibroblasts, collagen deposits, and reduce capillary formation, thus limiting the formation of scar tissue. Generally the relief of pain and inflammation is obtained within a few hours after the injection and can last a few days or a few weeks. Because of their pain-relieving effects, corticosteroids are commonly used in both human and veterinary medical practices.

Intraarticular corticosteroids are recommended in several guidelines for the treatment of patients with knee osteoarthritis.<sup>103-105</sup> Rheumatologists in particular when surveyed state that over 95% of them use them at least sometimes and 53% frequently in the treatment of osteoarthritis of the knee and hip.<sup>106, 107</sup>

While most controlled studies have shown that intraarticular corticosteroid injections are superior to placebo injections for osteoarthritis of the knee, the benefit of such injections is short-term generally lasting from one to three weeks.<sup>108-115</sup> (*See Figure 13.*) No improvement in long-term pain or function has been

Figure 12. Commonly used corticosteroid medications.



shown by intraarticular corticosteroid injections into the knee. Even systematic reviews summarizing the evidence of intrarticular corticosteroid injections in patients with osteoarthritis of the knee have confirmed that inadequate data exists related to the beneficial use of corticosteroid injections for knee osteoarthritis besides one to three weeks of pain relief.<sup>116-120</sup> In randomized controlled studies of intraarticular corticosteroid injections of other joints including the hip and carpometacarpal joint of the thumb, again short-term results of a few weeks of pain relief was seen, but no long term benefits could be documented.<sup>121-125</sup> One reviewer called the response to intraarticular corticosteroids "brief and transient," noting that the number of potential adverse effects of intraarticular corticosteroids stresses the importance of their judicious use.<sup>126</sup> Another review summarized it nicely, " Local injections of corticosteroids are commonly used in orthopaedic practice on the assumption that they will diminish the pain of inflammation and accelerate healing. Less often considered is the possibility that their use may delay the normal repair response. Unfortunately, there is a paucity of well-controlled studies that provide definitive recommendations for nonrheumatologic use of corticosteroids. Also troubling are the significant potential complications that can occur with their use. The authors believe that use of corticosteroids should be limited to the few conditions that have been proved to be positively influenced by them."127 In this author's opinion osteoarthritis is not one of them.

#### GENERAL GUIDELINES FOR INTRARTICULAR CORTICOSTEROID USAGE IN OSTEOARTHRITIS OF A JOINT

The guidelines published by the American College of Rheumatology note, "It is generally recommended, although not well supported by published data, that injection of corticosteroids in a given joint not be performed more than three to four times in a given year because of concern about the possible development of progressive cartilage damage through repeated injection in the weight-bearing joints."128 The guidelines given by the International Society of Arthroscopy, Knee Surgery & Orthopaedic Sports Medicine state, "Although an extremely useful technique, the intermittent use of intrarticular cortisone should be deployed with caution. The potential risks of provoking hyaline cartilage degeneration, the hazards as they relate to joint infections, and the limitations of cortisone should be fully discussed and disclosed to the patient."129

These guidelines are a far cry from what used to be the standard of care. What most patients do not realize is that rheumatologists in the 1950s and 60s used to give ten or more steroid injections per joint per year. Some patients receiving more than 150 steroid injections into their joints.<sup>130</sup>

#### S U M M A R Y

From animal studies, corticosteroids have shown to produce a deleterious effect on cartilage metabolism. This is manifested by damage to, and death of, the chondrocytes. The chondrocytes are the cells that synthesize the components of cartilage, mainly the type II collagen and proteoglycans. Because chondrocytes decrease in number and function, collagen and proteoglycan synthesis decline. The net result of these effects is articular cartilage degeneration. The degenerated cartilage loses elasticity, making the joint more stiff. Ultimately, the cartilage thins and there is narrowing of the joint space as evidenced by X-ray. This narrowing is typical of osteoarthritis.

In most of the animal studies, the severe deleterious effects on the joint and articular cartilage, both mechanical and physiological, have been corticosteroid doserelated. Running exercises combined with intraarticular corticosteroids is more detrimental to the articular cartilage than corticosteroids alone. This combination caused a significant enhancement of the loss of chondrocyte cells and matrix compared to corticosteroid injection alone. In regard to human research, it is an established fact that osteoarthritis and subsequent knee and hip replacements are increasing at an alarming rate. Normal job-related activities, regular exercise and normal aging cannot account for such a dramatic increase. The usual and customary treatment for unresolved pain from an osteoarthritic joint often involves a cortisteroid injection. Because of the ubiquitous use of corticosteroid shots, a direct chondrotoxic effect from corticosteroids could explain this increase. Steroid arthropathy and "charcotlike arthropathy" have been reported in the arthritic human knee and hip joints with the use of intraarticular corticosteroid injections. These changes could also be due to the temporary suppression of pain, which encourages excessive and unguarded activities of diseased joints, resulting in rapid progression of joint destruction. This is especially true of athletes who typically return to full intensity sport activities with a few hours to a few days after a cortisone injection.

The results of human studies revealed a higher destruction of articular cartilage in corticosteroid-injected joints than those who received no injections. Corticosteroid-injected joints show a greater deterioration of all layers of the articular cartilage. Long term this is manifested by more advanced osteoarthritis in the joint leading to a decline in joint function. It is this author's opinion based upon the scientific research that this is one of the main factors that explains the tremendous increase in osteoarthritis of the knee and hip coinciding with the dramatic rise in knee and hip replacements.

#### CONCLUSION

There is no clear evidence that corticosteroids injected into the osteoarthritic knee, hip, or other joints have long term benefit. Definite evidence exists, however, primarily from animal studies, that corticosteroids are harmful to the articular cartilage. Intraarticular corticosteroid injections result in severe deleterious effects, both mechanical and physiological, on the joint and articular cartilage. Most of these changes are dose-related. The catabolic effects of intraarticular corticosteroids include a massive decrease in the synthesis of all major articular cartilage matrix components. The loss of glycosaminoglycans, proteoglycans, proteins and matrix collagen leads to the ultimate breakdown of the articular cartilage. The net result of corticosteroid joint injections is an acceleration of the osteoarthritic process which is manifested in the dramatic rise of cases of osteoarthritis of the knee and hip and subsequent joint replacements. Forty years ago, in an Editorial for the British volume of the Journal of Bone and Joint Surgery, Sweetnam stated, "We now have evidence, both clinical and experimental, that apart from the well recognized hazard of infection, intraarticular injections of corticosteroids, certainly, if repeated, may be harmful, yet the practice has continued. We believe that it should now cease."131, 132 This sentiment is reiterated by the International Society of Arthroscopy, Knee Surgery, and Orthopaedic Sports Medicine who state, "Although an extremely useful technique, the intermittent use of intraarticular cortisone should be deployed with caution. The potential risks of provoking hyaline cartilage degeneration, the hazards as they relate to joint infections, and the limitations of cortisone, should be fully discussed and disclosed with the patient."133, 134

In summary, intraarticular corticosteroid injections degenerate articular cartilage in osteoarthritis. Studies have shown no long term benefit in joint osteoarthritis and substantial scientific evidence has been offered to the contrary, that the long-term sequelae of injections of corticosteroids into degenerated joints accelerates the arthritic process. Despite its widespread use, substantial scientific evidence exists to dissuade both clinicians and patients from using intraarticular corticosteroids in the treatment of osteoarthritis. The continued use of intraarticular corticosteroid injections in the treatment of osteoarthritis. ■

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Gary B. Clark, MD, MPA

hronic elbow pain is of interest to many patients and prolotherapists—basically because it seems so often to resist classic forms of treatment. Chronic elbow pain often comes on slowly as an insidious but, eventually, disabling musculoskeletal malady that plagues the elbows of many individuals from all walks of life.

As is so often the case with similar sprain injuries, chronic elbow pain is usually associated with repetitious occupational or sports-related activities, movements, and postures. Thus, it is a common complaint amongst Rolfers, massage therapists and other body work therapists; weight lifters; people constantly involved in computer and word processing work—and, yes, tennis players and golfers. Why, even waiters who constantly bus heavily-laden trays of dishes with food complain of chronic elbow pain! But, just to be on the safe side, keep in mind that dysfunctional elbow pain may also be associated with a more proximal shoulder injury and dysfunction that is affecting the more distal elbow function.

Chronic elbow pain usually presents as that dull to sharp, nagging pain on either the lateral or medial aspect of the elbow that just doesn't want to go away. It can be exceedingly tender to the touch—even keeping one awake at night due to inadvertent pressure on the sore spot.

Quite often elbow becomes refractorypain nonresponsive-to many of the standard therapies, including cortisone injections, nonsteroidal antiinflammatory medication, physical therapy, orthotic devices, massage, electrical stimulation therapy, and acupuncture. At best, these therapies provide only temporary, short-term pain relief. Some may be actually deleterious to tendon health. Seldom do any promote definitive repair and long-term return to pain-free, normal function.

Hopefully, the following articles will shed some light on the current thinking about the cause of chronic elbow pain and the treatments that are available. These reviews offer the readership an expanded view of what's happening out there in that "wide, wide world"—out there where the science and art of proven Prolotherapy meet the more staid, often unproven wisdom of outmoded convention.

We encourage each reader to use the National Library of Medicine's "PubMed" website on the Internet to personally review any of the following articles first hand. You can go directly to the source—it doesn't take a medical diploma to "surf the net!" In this wonderful age of worldwide communication, we are pleased to summarize and interpret for you while you have the grand opportunity to learn more and become better informed about Prolotherapy and your personal aches and pains.

#### Structure-function relationships in tendons: a review.

Benjamin M, et. al. *Journal of Anatomy*. 2008 Mar;212(3):211-28.

Where tendons and ligaments meet bone: attachment sites ('entheses') in relation to exercise and/or mechanical load.

Benjamin M et. al. *Journal of Anatomy*. 2006 Apr;208(4):471-90.

#### ABSTRACT SUMMARY

The authors of these two articles explain some of the more modern, proven conventions regarding tendon attachment to a joint site. They refer to the site of tendon attachment to joint bone as the "enthesis." The excessive overuse injury to that site of tendonto-bone attachment is called an "enthesopathy." It is at the enthesis that most muscle tendon sprain injuries occur if that site has become the epicenter of concentration of chronic stress forces during repetitive, excessive overuse.

The authors describe the key cell of a tendon as the "tenocyte", which is morphologically and functionally distinctly unique compared to other fibroblastic cells—including those of ligaments. It is the tenocyte that generates and lays down new collagen tissue during normal wear-and-tear tendon regeneration— and is a component of the traumatic, sprain injury caused by chronic, excessive stress injury.

#### JOP COMMENTARY

One of the "banes" of our existence as Prolotherapy patients and Prolotherapists are tendon sprain injuries. Why? Because tendons seem to behave so differently from the usual ligament sprain injury and, often, seem so much harder to treat.

These two articles present up-to-date concepts of the biochemical and cellular makeup of tendon tissues, explaining the basis for chronic tendon injury. They emphasize that most repetitive occupational and sports injuries are more degenerative in nature (i.e., they are a "tendonosis")—rather than inflammatory (i.e., not a "tendonitis"). They, also, describe why tendons behave differently under stress-as compared to ligaments. It is more than there being a relative scarcity of blood vessels inciting to injury and hindering healing. It has to do more with the unique biochemical properties of the enthesis, the comparatively increased cellularity of the tendon, and the function of the tenocytes, themselves. The difference of tendon tissue behavior speaks not only to the tendon's somewhat different response to injury-but also to the tendon's responding differently to various treatments, including Prolotherapy. The 2008 offering, particularly, is an elegant review that offers a "unified theory" of myofascial biology for musculoskeletal medicine.

So, the good news is that, thanks to Prolotherapy, tendon sprain injuries of the elbow are no longer such a "bane" of our existence. Chronic elbow tendon sprain is much more. ■

#### Understanding tendinopathies.

Murrell GA. British Journal of Sports Medicine. 2002;36;392-393.

#### Loss of homeostatic tension induces apoptosis in tendon cells.

Egerbacher M, et. al. *Laboratory of Comparative Orthopaedic Veterinary Medicine*. G-387, Michigan State University, East Lansing, MI 48824, USA.

#### ABSTRACT SUMMARY

The authors of these two articles employ another, "new-fangled" term called "apoptosis". Apoptosis is simply a fancy medical label for normal cell deaththe normal cell death that is expected to happen during the normal life span of any given tissue, including a tendon or ligament. Of course, we want the rate of normal cell regeneration to keep up the pace with normal cell death. In disease and injury, apoptosis starts to win that race.

The authors go on to explain that, in the case of tendon degenerative injury, the normal rate of cell death apoptosis is increased over the rate of new cell regeneration. In fact, they demonstrate very good experimental evidence that tendon degeneration is associated with increased tendon cellular apoptosis along with a concomitant loss of collagen fiber integrity, even potentially leading to tendon rupture.

#### JOP COMMENTARY

These two articles provide more insight into the reason for there being a difference between ligaments and tendons in their functional, as well as dysfunctional, behavior—especially in response to injury.

The "Big Question" is what is causing the increased rate of cellular apoptosis or tenocyte death? Are the cellular and collagen matrix changes of tendon degenerative "sprain" injury:

Directly due to excessive, repetitive mechanical load forces—which is the conventional conceit?

Or, at least in some cases, directly due to a loss of "homeostatic tension"—in other words loss of normal postural muscle tone?

Currently, there are cogent arguments that both of these processes may be occurring. In any case, understanding these basic cellular concepts of tendon degeneration goes on to explain why treatment of tendon injuries definitely requires a regenerative approach, such as Prolotherapy. This is because Prolotherapy promotes regeneration of new tendon tissue at the enthesis—the site of degenerative damage. ■

## The efficacy of Prolotherapy for lateral epicondylosis: a pilot study.

Scarpone, M, et. al. Clinical Journal of Sports Medicine. 2008 May;18(3):248-54.

## The systematic review of four injection therapies for lateral epicondylosis: Prolotherapy, polidocanol, whole blood and platelet rich plasma.

Rabago D, et al. British Journal of Sports Medicine. 2009 Jan 21. [Epub ahead of print]

#### ABSTRACT SUMMARY

The authors of these two reports have accomplished three steps that are necessary to produce an acceptable, evidence-based rationale for performing Prolotherapy. Those three steps are achieving:

- 1. Based upon a well-designed study
- 2. Presented as a well-written report-and
- 3. All the above presented in a reputable medical journal.

The first article is a well-designed, randomly controlled pilot study. The second article is a well-designed meta-analysis of five prospective case series and four controlled trials. The information gleaned from these two studies reports provides definite pilot-level, evidence-based support for the use of Prolotherapy, Polidocanol, autologous whole blood, and plateletrich blood for treating lateral elbow epicondylosis (tennis elbow).

#### JOP COMMENTARY

The authors of these two reports demonstrate some of the best examples of carefully thought out and executed scientific studies of the efficacy of Prolotherapy. Everybody asks for "scientific proof" of the efficacy of Prolotherapy? This has been borne out by insurance company response.

As is often the case when such a study is in its early conceptual and developmental stages—funding, resources, and scope of design were limited. Therefore, the numbers of patients studied were relatively few. As they say in the statistics game, the "n" was small. Nevertheless, these two reports pave the way for larger studies in the foreseeable future. More study needs to be accomplished to solidify the original findings and determine the comparative efficacies between the four individual injection therapies—three of which are, basically, variations of the regenerative Prolotherapy theme.

Regardless of their size or differential accuracy, these reports have provided ample evidence to convince some insurance companies to accept Prolotherapy of lateral epicondylosis for reimbursement with preauthorization.

Also, these articles presage the future advent of injecting more specific growth factors via Prolotherapy techniques. Also waiting in the wings is the possible, future adjunctive use of nitric oxide stimulants either topically or by injection to reduce the rate of apoptosis and enhance the rate of collagen regeneration.

Using nitric oxide to treat tendinopathy. Murrell GA. *British Journal of Sports Medicine* 2007 Apr;41(4):227-31.

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#### For more information:

<u>mdoherty@wisc.edu</u> or <u>info@HackettHemwall.org</u> The conference brochure, including registration material, will be available at <u>www.ocpd.wisc.edu</u>.

#### $0\ R\ G\ A\ N\ I\ Z\ A\ T\ I\ O\ N\ S$

#### American Association of Orthopedic Medicine (AAOM)

600 Pembrook Drive, Woodland Park, CO 80863 Phone: 888.687.1920 Fax: 719.687.5184 www.aaomed.org

#### **The Hackett Hemwall Foundation**

2532 Balden Street, Madison, WI 53705 USA www.HackettHemwall.org

#### GetProlo.com

Beulah Land Corporation 715 Lake St. Suite 400 Oak Park, IL 60301 Phone: 708.848.5011 Fax: 708.848.8053 www.getprolo.com

## The American Academy of Osteopathy

3500 DePauw Blvd, Suite 1080 Indianapolis, IN 46268 Phone: 317.879.1881 Fax: 317.879.0563

#### American College of Osteopathic Sclerotherapeutic Pain Management, Inc.

303 S. Ingram Ct. Middletown, DE 19709 Phone: 302.376.8080 Toll Free: 800.471.6114 Fax: 302.376.8081 www.acopms.com

## American Osteopathic Academy of Sports Medicine (AOASM)

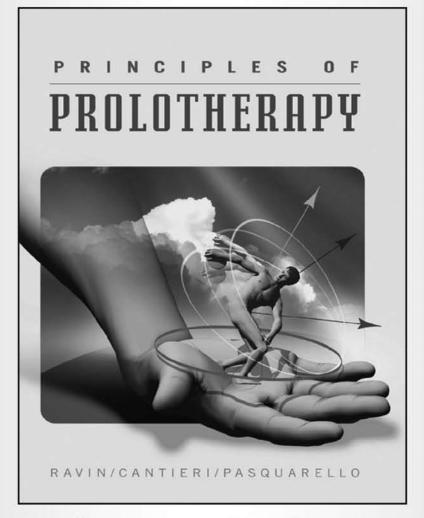
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#### American Holistic Veterinary Medial Association

2218 Old Emmorton Road Bel Air, MD 21015 Phone: 410.569.0795 Fax: 410.569.2346 www.ahvma.org

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Developed by: Ross A. Hauser, M.D.



Formulated to Support Prolotherapy by Promoting the Healing Process and Maintaining the Growth and Integrity of Joints and Connective Tissue.<sup>†</sup>

- Supports Collagen Production and Connective Tissue Growth<sup>+</sup>
- Assists with the Strengthening of Joints<sup>+</sup>
- Promotes the Healing Process<sup>+</sup>

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## Supplement Facts

Serving Size: 4 Capsules Servings Per Container: 30

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4 capsules contain	Amount Pe Serving	
Vitamin C (as Ascorbate)	160 mg	267%
Magnesium (as Ascorbat	e) 40 mg	10%
Manganese (as TRAACS <sup>®</sup> Manganese Gl	2 mg ycinate Che	
Potassium (as Ascorbate	e) 20 mg	<1%
Methylsulfonylmethane	1,000 mg	*
L-Arginine USP	600 mg	*
L-Proline USP	500 mg	*
L-Cysteine HCl Monohydrate USP	250 mg	*
Gotu Kola (aerial portion) Extract 4:1	250 mg	*
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Centella asiatica Purified Triterpenes	30 mg	*

† These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.



\* % Daily Value not established

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