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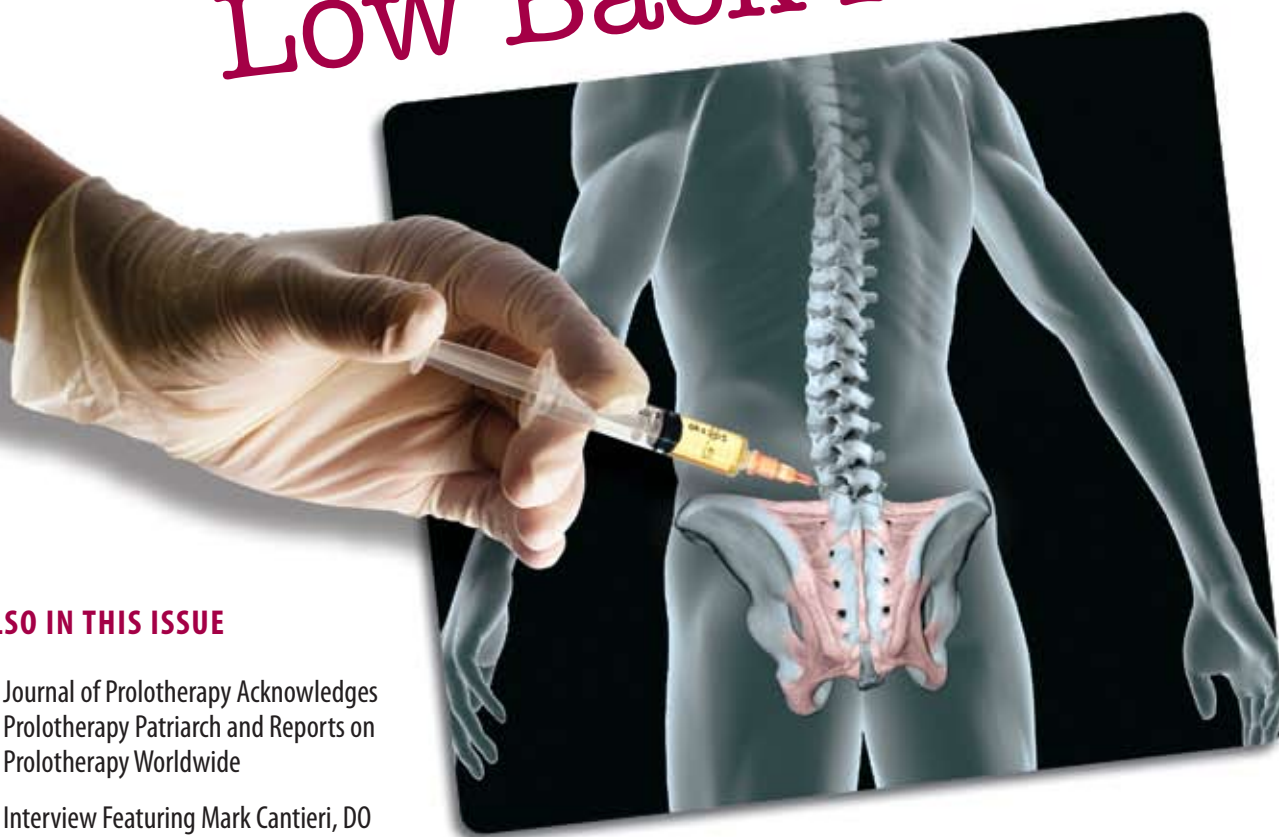
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Prolotherapy for Low Back Pain



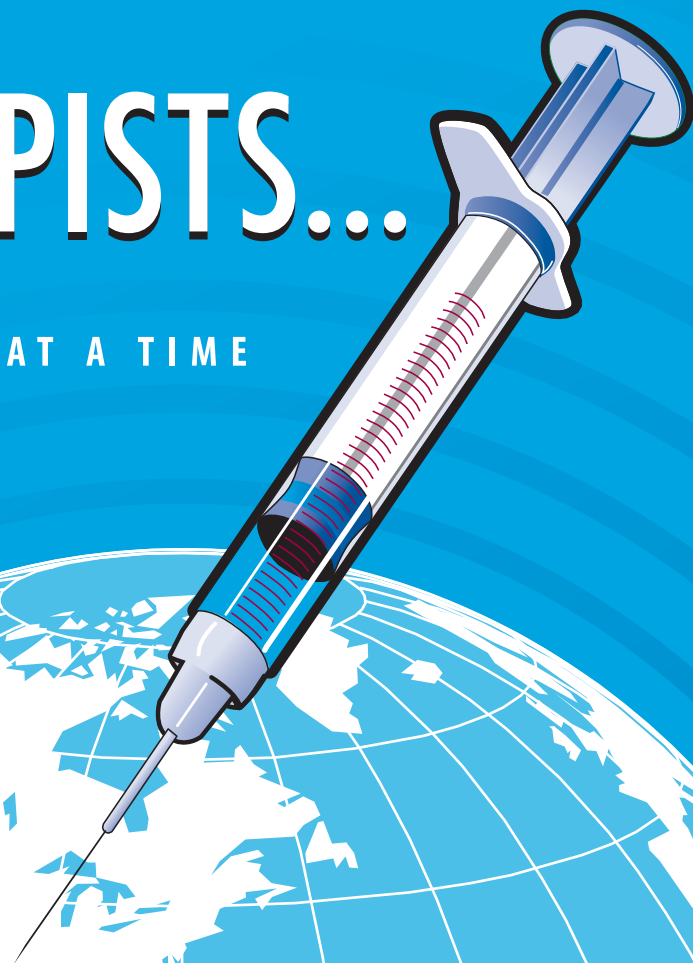
ALSO IN THIS ISSUE

- Journal of Prolotherapy Acknowledges Prolotherapy Patriarch and Reports on Prolotherapy Worldwide
- Interview Featuring Mark Cantieri, DO
- In Memory of Thomas Dorman, MD
- Dextrose Prolotherapy for Unresolved Low Back Pain: A Retrospective Case Series Study
- Increase in Cross Sectional Area of the Iliolumbar Ligament using Prolotherapy Agents: An Ultrasonic Case Study
- Three Cases of Chronic Pain Relieved with Prolotherapy in Hong Kong Clinic
- The Use of Prolotherapy in the Treatment of Chronic Overuse Shoulder and Neck Pain, Neurogenic Pain and Hip Degeneration in an Incomplete C4-C5 Spinal Cord Injury Patient
- The Making of a Prolotherapist
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- Practical Application of Prolotherapy in Canines: Case Studies
- A New Approach for Injecting Patients with Low Back Pain using Prolotherapy Agents: Functional Prolotherapy
- Platelet Rich Plasma (PRP) Injection Technique
- Platelet-Rich Plasma (PRP) Therapy Literature Reviews
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The *Journal of Prolotherapy*™ is unique in that it has a target audience of both physicians and patients. The purpose of this journal is to provide the readers with new cutting-edge information on Prolotherapy, as well as provide a forum for physicians and patients alike to tell their stories.

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G R E A T N E W S C O R N E R



Journal of Prolotherapy Acknowledges Prolotherapy Patriarch and Reports on Prolotherapy Worldwide

Ross A. Hauser, MD

With each study published on Prolotherapy including those in this issue of the *Journal of Prolotherapy*[™], Prolotherapy is making history. But recently Prolotherapy lost one of its pioneers who did his best to get Prolotherapy into the mainstream. That man was Thomas Dorman, MD, who died at the age of 72 on March 15, 2009. In this month's issue, please take a moment to read Richard Gracer, MD's heart-felt tribute to Dr. Thomas Dorman. Besides running a private practice over the years, Dr. Dorman collaborated on a Prolotherapy text book and double-blind studies, as well as published his own data on the remarkable success of Prolotherapy.¹⁻³ Dr. Dorman was one of the main physician teachers of Prolotherapy for many years. In a 1989 study, he noted, "I biopsied individuals before and after treatment with Prolotherapy and submitted the biopsy specimens to pathologists. Using modern analytic techniques, they showed that Prolotherapy caused regrowth of tissue, an increased number of fibroblast nuclei (the major cell type in ligaments and other connective tissue), an increased amount of collagen, and an absence of inflammatory changes or other types of tissue damage."⁴

Most of us involved with Prolotherapy had various interactions with Thomas Dorman over the years and were impacted by his words. Some of his words are on a plaque that hangs in my office – "Prolotherapy stimulates the growth of normal ligament tissue." In the early 1990s, I remember one discussion we had over lunch at a Prolotherapy seminar, during which we were discussing insurance coverage of Prolotherapy. He told me, "I thought when *The Lancet* published our first double-blinded study showing the benefits of Prolotherapy for low back pain that there would have been international coverage on it."⁵ A new treatment for low back pain? What could be more

newsworthy? In the end, there was almost no publicity. Insurance companies don't want to cover Prolotherapy or any other natural remedies, because these are very cost-effective compared to surgeries. As long as people think they might need expensive surgeries, the insurance companies will continue to collect their premiums." The *Journal of Prolotherapy*[™], as well as humanity, owes a debt of gratitude to Thomas Dorman for his remarkable work on promoting and teaching Prolotherapy.

Dr. Dorman, like his predecessors, students, colleagues, and patients, believed wholeheartedly that Prolotherapy should be utilized on a much broader scale for the pain patient. In an effort to do just this, we bring you studies and personal stories of Prolotherapy from around the world, as well as in our own corner of the globe. In this issue, you will find case reports from Dr. Lam treated with Prolotherapy from his Hong Kong Clinic.

Prolotherapy continues to grow in the United States including veterinary medicine where physicians such as Babette Gladstein, DVM, treat not only hip dysplasias, but also spinal conditions, including myelopathy with Prolotherapy on animals.

We are also pleased to present the personal stories of some outstanding Prolotherapy physicians. Scott Stoll, MD, explains his journey to becoming a Prolotherapy physician and Mark Cantieri, DO, one of the most skilled and vocal osteopathic physicians utilizing Prolotherapy, provides us with a candid interview, as he continues to lead the osteopathic medical profession in regards to Prolotherapy.

Marion and I again report on independent data collected on the treatment of low back pain treated with Prolotherapy from a charity clinic we spearheaded for ten years. The data revealed statistically significant results to the $p < .000001$ level. In other words, Prolotherapy gets rid of back pain!

The *Journal of Prolotherapy*™ wants to continue to provide innovative writers and researchers with an outlet to publish work related to Prolotherapy and other therapies that help the chronic pain patient. Scott Benjamin, PhD, PT, has collaborated talents with several colleagues to present a case study using ultrasound to prove that Prolotherapy stimulates ligament growth in a back pain patient.

What is cutting edge pain medicine? It is quite possibly Prolotherapy using your own growth factors. Growth factors can now be used in Prolotherapy by utilizing a patient's own platelet rich plasma (also known as PRP). Featured in *It's a Wide Wide World*, Gary Clark, MD, reports on some of the PRP research, as PRP is emerging in the future of Prolotherapy.

Also in this issue, a *Remarkable Recovery* is featured detailing a patient who used Prolotherapy to stabilize a degenerated hip so he could stand independently, though a quadriplegic. In addition, read about a woman's long-term success story with Prolotherapy in multiple areas of her body, allowing her to regain her life that was destined to be miserable were it not for Prolotherapy.

As good as Prolotherapy is at relieving chronic pain, sometimes patients possess such deep hurt in their subconscious, that something else is needed to help them achieve pain relief, or just regain the ability to sleep at night. For this reason Gina Orlando, MS, Certified

Hypnotherapist, wrote a nice piece on using hypnosis for the chronic pain patient. At the end of the day, whether you are a physician who utilizes Prolotherapy, manipulation, or other modalities, what we want for our patients is quality of life along with pain relief. Hypnosis can be a powerful tool for achieving this goal.

As always, let us hear from you! Thank you to the authors who have sent manuscripts for the upcoming issues. We appreciate the broad range of papers we are receiving. Remember that no one will ever be blessed by your story until you tell it!

Until the next injection,



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IN THE SPOTLIGHT

Interview Featuring Mark Cantieri, DO

Ross A. Hauser, MD

The world of Prolotherapy is thrilled to have many talented physicians in their midst. The *Journal of Prolotherapy*[™] is an avenue to introduce our readers to some of them. This issue features an interview that I conducted via telephone with Mark S. Cantieri, DO, FAAO who practices in Mishwaka, IN and recently released a textbook that he co-authored called *Principles of Prolotherapy*.

First let's hear a little more about Dr. Cantieri's background:

Dr. Cantieri: I did my undergraduate work at Creighton University in Omaha, Nebraska. I have a BA in Psychology. I then moved to Des Moines, Iowa and went to medical school at what is now the Des Moines University, College of Osteopathic Medicine and Surgery. I graduated in 1981 and then did an Osteopathic Manipulative Medicine Fellowship. I then did a rotating internship at Des Moines General Hospital and then I did General Practice in Des Moines for three years. Then I became a member of the Department of Osteopathic Manipulation in Phoenix General Hospital in Arizona. In 1990, I moved to South Bend, Indiana. I came here to create a Department of Osteopathic Manipulative Medicine and to also be the Director of Medical Education, overseeing the internship and Family Practice residency programs. In 1993 I went on my own forming Corrective Care, PC. Dr. Brad Sandler joined me in 1995. In 1997 Dr. Sandler and I began performing Prolotherapy to complement the osteopathic manipulation and rehabilitation work we were already doing. I've continued doing that since.

Q = Dr. Hauser

A = Dr. Cantieri

Q: Your associate, Dr. Brad Sandler is also an osteopathic physician, right?

A: Right. He also attended Des Moines University and then did a residency in Neuromusculoskeletal Medicine (NMM/OMM) at Michigan State University.



Mark S. Cantieri, DO examining a patient.

Q: Do you have any teaching appointments anywhere?

A: Yes. You're considered adjunct clinical faculty when you're taking medical students into your practice. I have this relationship with Des Moines University. I also see residents from various NMM/OMM programs throughout the country. I take residents as well from the two Family Practice residency programs here in South Bend – Memorial Hospital and St. Joseph's Regional Medical Center.

Q: Those programs are for both MD's and DO's, correct?

A: Yes. And they all rotate with me—both the MD's and DO's. I also go monthly and teach over at their continuity clinics.

Q: Is your practice strictly pain management or do you do some family medicine also?

A: It's a broad musculoskeletal medicine practice. I see some children for osteopathic manipulation. Children may have issues such as failure to thrive, difficult deliveries,

difficulty with feeding problems and other types of problems. I also see women with chronic pelvic pain, who are referred from OB/GYNs. We have a pretty broad referral base that includes OB/GYN, neurosurgery, spinal orthopedic surgery, general orthopedic surgeons, sports medicine, family practice, rheumatology and neurology.

Q: Fantastic! You have some appointments in regards to professional organizations, right? Because you've been basically in osteopathic associations, you've been politically active and very involved.

A: Yes, I've done a Health Policy Fellowship through the American Osteopathic Association, Ohio University and Michigan State University. I graduated from that in 1996. I am board certified in Osteopathic Manipulative Medicine. I am a past president of the American Academy of Osteopathy and the current Secretary/Treasurer of that same organization. I'm a past President of the Osteopathic Medical Foundation of Michiana. What we did is manage funds to promote Osteopathic Medicine in the Michiana area, an area that is within a 60 mile radius around South Bend, IN. I am a member of the Legislative Committee for the Indiana Osteopathic Association and am a member of the Board of Trustees of that organization. I am the Vice-Chairman of the Commission on Osteopathic College Accreditation, which accredits all osteopathic medical schools in this country and hopefully throughout the world in a number of years if things continue as they appear to be.

Q: How many osteopathic medical schools are there now?

A: Ross, there are 28. Several are branch campuses.

Q: So you're saying that you see having osteopathic medical colleges in other countries then?

A: It's going to happen. We've already been approached by a few places and so we're starting to look at how we would accredit medical schools, osteopathic medical schools, outside of this country. There are some osteopathic medical schools now in some places like New Zealand and England. There are federations and different types of osteopathic educational programs throughout Europe but they are not full practice and if we accredit these schools, what we want to look at is full licensure like DO's have in the United States. In Britain for instance, osteopaths strictly do manual medicine, osteopathic manipulation.

Q: They don't have injection rights is what you're saying?

A: They don't have injection, prescription or surgical rights.

Q: In regard to osteopathic schools in the United States, is Prolotherapy taught in the medical schools or in the residency programs affiliated with those schools, or is it just certain ones?

A: In the residency program for NMM/OMM, (such a long title) it is a requirement that Prolotherapy is a component of the education. The amount that is taught varies from program to program. It is the only residency in the United States where there is a requirement for exposure to it. When we re-wrote the residency documents a number of years ago, I believe in the year 2000, we included Prolotherapy as a component of the education. It is then a component of the board examination now. You will have questions relative to it (Prolotherapy) on the board (exam). There may only be several questions because of the depth of the board examination, but Prolotherapy is on the board exam.

Q: Is it fair to say that it is possible to go through an osteopathic medical school experience and not get exposure to Prolotherapy?

A: That is correct. It is not a part of the curriculum of an osteopathic medical school.

Q: I understand. You almost have to be an osteopathic physician who has an interest in pain management, then you would get experience.

A: Well, the residency in NMM/OMM is a broad program that includes internal medicine, occupational medicine, preventive medicine, rheumatology, internal medicine, family medicine, and within that there is also a requirement, besides osteopathic manipulation, that they also have exposure to Prolotherapy.

Q: In regard to the amount of doctors who have gone through this kind of residency, do you have any idea of how many numbers?

A: The doctors that are certified in NMM/OMM with the certification? There are about 600.

Q: Oh fantastic! Wow! How many of those programs are there in the country? Like 10 or so?

A: No, there are about 30 programs.

Q: You are saying there are 28 osteopathic schools and there is a certain residency where Prolotherapy experience is basically required. I was just asking about, of the 28, do about one third offer this residency?

A: This residency isn't only offered through a school. You could also go to a hospital based program just like for surgery or family medicine.

Q: Okay. I understand. Obviously you graduated from osteopathic medical school in the early '80s. Then you learned Prolotherapy in 1997, so you obviously practiced osteopathic medicine for many years before you learned Prolotherapy. What got you interested in learning Prolotherapy?

A: What got us interested was several patients that we just felt like, we've done manipulation, we've done a really appropriate rehabilitation, but we couldn't progress them. It's like you've got a low back case where once you really start loading it or trying to encourage rehabilitation, the patient could not progress. You think to yourself, "What's the missing link?" And so that first patient we referred out for Prolotherapy. We referred several patients previously for Prolotherapy, but we really didn't get good results. We didn't have the feedback and kind of results we would have hoped to see. We sent one down to a Dr. Ross Hauser in Chicago, who had a chronic SI joint problem. After two treatments, this patient who had had pain for a number of years was 95% better. So at that point we said, "all right," you know? "We need to consider this as a modality to add to what we're doing."

How's that for a plug, Ross? (they laugh)

Q: Interesting! I obviously remember that Brad (Dr. Sandler) came down to Thebes, IL (for the charity clinic where we taught doctors Prolotherapy), but I just wondered what exactly ended up happening with that. So in 1997 you actively started doing Prolotherapy.

A: Right.

Q: So in your experience, what would you say is the role of Prolotherapy in regard to the chronic pain patient and/or acute pain patient?

A: Well, I think I look at it more in the sub-acute phase when talking about acute pain patients. In other words, the patient has something that's been present for more than four weeks. For the chronic pain patient, we're looking at cases where the patient has something greater than three months. It is an integral part of treating these people. I think the person that knows Prolotherapy, (and I'm not a big fan of the word Prolotherapist—I like to think of us as physicians performing Prolotherapy) has a better understanding, if they're properly trained, of the

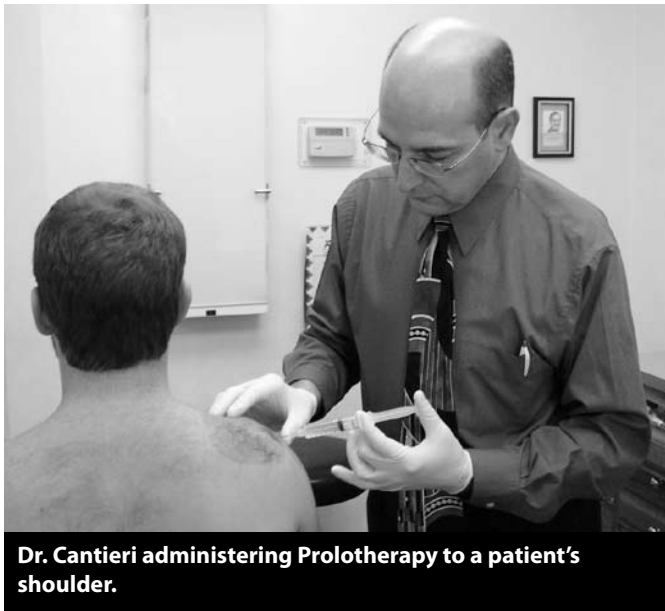
breadth of musculoskeletal medicine. They have a good understanding of discogenic pain and when these patients may need to see someone for a possible discography and fusion. I think they have a better understanding of when an epidural is indicated, or a facet block. They also have a better understanding to know when this is a ligament issue, or a tendon issue, or a joint instability issue. That's what I see is really the role that we play in educating people to add Prolotherapy to their regimen—to the tools they have in their toolbox. Because it just escalates your differential diagnosis so dramatically. The other component of that is we have to teach these physicians who are doing Prolotherapy how to assess musculoskeletal strength and movement and prescribe appropriate rehabilitation. That's one of the problems I see when I see some of the other doctors doing Prolotherapy. They're chasing pain and not really assessing well. They're saying "oh, you hurt here so let's inject," versus using good standard orthopedic evaluation to go through joint by joint, look at stability, and assess whether it is an issue. And then how do you address muscular inhibition and muscular weakness that results from chronic joint instability?

Q: I know in the past you have collaborated with various physicians like Dr. Tom Ravin to teach courses. Are you still doing that?

A: Yes. George Pasquarello, DO and I. He practices in Providence, RI. We teach a course annually at the University of New England in Biddeford, Maine. We've done that since 1999. Previously I taught courses three times per year with Dr. Ravin in Denver. We have gotten away from that and have focused more in the last six years on writing our textbook, *The Principles of Prolotherapy*.

Q: Tell us a little bit about your book. What lead to that, tell us about the process, and tell us about the finished product.

A: When we were educating people, I had the opportunity to work with and see other organizations who were teaching Prolotherapy. What we felt was that there was a need to standardize in order to bring consistency to how we diagnose and treat people with tendonosis, ligament laxity, and joint instability issues. So if we standardize that, it would help to promote Prolotherapy, and also make it easier, I think, to do research. If you have a standardized protocol, it's going to bring more validity to research. So that was our initial goal, as well as to have a tool that we could use, the students could use, Dr. Patterson could use, the American Association of Orthopedic Medicine



Dr. Cantieri administering Prolotherapy to a patient's shoulder.

(AAOM) could use, and other organizations such as the American College of Sclerotherapeutic Pain Management could use to teach from. So that was our goal. So we started with the materials we were using to teach our courses and designed a textbook that introduced the history of Prolotherapy, then reviewed the science of wound healing and why Prolotherapy works. Not the theory of why Prolotherapy works, but why Prolotherapy works. We're very adamant that we know why Prolotherapy works. In the 3rd chapter we discuss posture and how it relates to ligamentous changes in the body and why people have ligamentous instability issues. And finally in chapters 4 through 12 we go through the body, region by region of the body and address how you diagnose tendonitis, ligamentous laxity, and joint instability. What kind of danger areas you have in those areas, what kinds of precautions you should take when treating, and then how you treat those problems.

Q: Are you happy with the final product?

A: I'm ecstatic with it. After six years, it's nice to have it done and I think we have something that will benefit the medical community and patients in general.

Q: Congratulations on finishing that project.

A: Thank you. I know you can relate from writing your own books.

Q: Obviously 2009 marks a historic turning point in the history of America as we have a new political regime. Let's just say theoretically you got a call from Human

Health and Resource Services who really wanted you, Mark Cantieri, to take over as it relates to the propagation of Prolotherapy and musculoskeletal medicine. What vision would you have? I know that you have certain viewpoints and you would like to see Prolotherapy and pain management head in this certain direction. What exactly would you do?

A: Thanks Ross. I would love to see us go back to doing a better job of educating our medical students on physical examination. My greatest angst when I interact with medical students, residents, and physicians is, many of them have a poor understanding of anatomy, poor understanding of the musculoskeletal system and how it functions. I think we've gotten too reliant on ultrasounds, MRIs, X-rays. There's an important place for those, but we've put total reliance on those and gotten apathetic about doing a good physical examination. As a result of that, I think that is what has led to the exorbitant costs associated with medicine. I think we need to address how much medical expense is related to defensive medicine and what we can do to improve tort laws throughout the country. And then I would emphasize better education relative to Prolotherapy and understanding tendon and ligament injuries, and normal tissue repair. We tend to buy into this pharmaceutical idea that all pain is inflammation, when in fact it's not. If we taught wound healing and wound repair better, and people understood it, I think there would be much more insights into how you need to treat people with chronic pain difficulties. Those would be my starting points, Ross.

Q: Say you have a medical or osteopathic doctor who is interested in family medicine who wants to get into Prolotherapy and he/she called you wanting to have the skill set that you just described in regard to knowledge of anatomy, pathophysiology, and learning the technique. In a step-by-step format, what kind of advice would you give the doctor?

A: It's kind of interesting. I recently had a gentleman who does occupational medicine ask me that very same thing. He was frustrated with the tools he had to help his patients. He asked me what I do and how I evaluate these kinds of patients. I suggested several things to him. I think you have to get some basic injection skills. I recommended he consider some of the various Prolotherapy courses that are out there, whether AAOM or AAO, or Dr. Patterson's Course (Hackett-Hemwall Foundation), his introductory course, or having the opportunity to go to Honduras with Dr. Patterson. I think all of those are

excellent opportunities to get hands on experience. I said you've got to spend time back in your anatomy books. You've got to know the anatomy and what goes on with this. Not a plug for our textbook, but I said you have to know wound healing. You have to understand that and I do recommend that people study that component, either on their own or out of our textbook. I also recommend very strongly that they take the Exercise Prescription Course taught at either Michigan State University or through the American Academy of Osteopathy, as most doctors do not understand how to give an appropriate exercise prescription. I think Prolotherapy done without appropriate rehabilitation does not lend itself to give as of high quality results as it does if you give appropriate rehabilitation.

Q: At *Corrective Care*, do you have physical therapists on staff or do you refer them out?

A: We have our own physical therapy department. We have MedX equipment, which is used to isolate cervical lumbar range of motion and strength. We can measure range of motion and strength as compared to normal for a person based on their age and size. Then we do a lot of movement retraining. A lot of it built on Vladimir Janda's work, the Czechoslovakian PM&R doctor, as well as on the work of Phil Greenman, DO, out of Michigan State.

Q: Would you say that the majority of the clients at *Corrective Care* get osteopathic care, Prolotherapy, and exercise rehabilitation?

A: It varies. In the chronic pain patient, I think there are some real limitations to what you can accomplish with osteopathic manipulation. If they have not had that, I'll treat them several times. If they're refracting and I'm seeing obvious signs of joint instability, tendon issues, muscle tightness that I feel is due to underlying tendonosis, I'll tell a person that we need to address the cause of the problem. If they have not been through appropriate rehabilitation first, let's say they have not had trauma, I'll very strongly emphasize manipulation and rehabilitation before I'll do the Prolotherapy. So it's all based on your history and physical exam. That's what's going to be the caveat to how you may progress with treatment and direct treatment. If they've had trauma, many times I go straight to Prolotherapy, particularly if it's a chronic pain problem. They need the joint stabilization addressed before you can begin rehabilitation. Once I've initiated treatment with Prolotherapy, I'll immediately start them on movement retraining and flexibility work. Most of

these people have a lot of muscular inhibition, they're not firing muscles properly. They're compensating, using their body improperly. You have to retrain movement before you do any strengthening work. If you strengthen these people prior to movement retraining, all you do is reinforce abnormal movement and they're going to break back down again later.

Q: Mark, what would you say, in regard to the chronic pain patients, that your success rate is?

A: Well, I think I'm like most doctors doing Prolotherapy. I like to think that 8 out of 10 people are significantly helped. I don't have hard, fast numbers. We're putting in some new electronic medical records at this time so that we can track these things. We're going to track people's pain response using a visual analog scale, as well as functional measurements.

Q: One thing I don't think you mentioned today is this. I saw somewhere where you are a member of the AOA House of Delegates.

A: Yes. That's the policy making body for the association. I'm sure you're familiar with it from the AOA site.

Q: Yes.

A: This last year I was just asked to chair all the committee having responsibility for looking at all resolutions related to education.

Q: Ah, I understand. You know, back to my original question. You answered a couple things as it related to getting medical schools to have a better grip on physical exam and anatomy. Is there anything else that you would institute as it relates to Prolotherapy? Or anything else as it relates to healthcare in the United States? If the government gave you a position and your job was to help many things, like decrease the number of narcotic prescriptions, anti-inflammatory medications, MRIs ordered, etc. I am just wondering, if you had free realm and the policies you instituted would actually come to fruition, what would you do? I know you're obviously very politically active and have experience in this realm.

A: I guess the thing I'd look at Ross, is I would establish a national policy relative to Prolotherapy. There has been completed a policy statement regarding Prolotherapy that is being submitted to the Bureau of Socioeconomic Affairs of the AOA. What bothers me is the fact that the quality of research done for Prolotherapy is as good as, and possibly better than, that which has been done

for epidurals, facet injections, and a lot of the standard steroid injection techniques. Insurance companies pay for all of those things, yet many do not pay for Prolotherapy. It's not cost effective to the insurers. The first thing, if I was in the political position to do it, would change the Medicare policy that Prolotherapy would be a covered service. I think that's an imperative first step. I don't think you're going to have any problems with the private insurers also going along with it. In a recent edition of *Spine*, they published an article that talks about sub-acute and chronic pain and the fact that there's no proven efficacy of epidurals, facet injections, and these things that are done routinely for back pain. It's a multi-billion dollar industry in this country, and growing, but we're not seeing consistent outcomes from it. I contend that if we have done good physical exams, we can differentiate what that patient needs. Whether it be an epidural, whether it be facet injections, whether it be Prolotherapy, and that's why I think we have to open up that window, that Prolotherapy be covered just like these other services are so physicians can add it to their differential as part of what they want to do when they assess and possibly treat a patient.

Q: Yes. And to the lay person, basically what you're saying is that all the procedures that you mention, whether it's facet injection, epidural, Prolotherapy, that they all have a place. The physician who does pain management and has the skills that you alluded to, would know when it's best to apply each of these procedures.

A: Right. We shouldn't have our hands tied. Unrightfully we are restricted from offering Prolotherapy to those needing to utilize their insurance when there is as much evidence for the utilization of Prolotherapy as there is for these other techniques.

Q: In regard to the National Policy relative to Prolotherapy, you said you're working on something. Is it through an organization that you're working on it?

A: I was asked to write a position paper regarding Prolotherapy by the Division of Socioeconomic Affairs of the AOA. A certain malpractice insurance provider covers more DO's than any other insurer in the United States. Their policy with regards to Prolotherapy was in need of updating.

Q: We didn't talk about certification of physicians performing Prolotherapy. You've had some interest in regard to the training of Prolotherapy and possibly having some kind of certifying body.

A: What I hope to see is the creation of a CAQ, a Certificate of Added Qualification, much like you have now for Sports Medicine or Geriatrics. Those aren't board certifications, a residency type certification, but they're certificates. That means that you've shown that you've done appropriate training, your peers have watched you do this and essentially they've signed off and said "Yes, you are competent at this procedure." I think that raises the bar so people, when they go to someone and they say, "I do Prolotherapy" you know what you're getting, based on a standard. I think that's important. Just as we've seen the growth in these pain fellowships where people are doing interventional pain work Prolotherapy also has to hold itself to a set of standards so we know what we're delivering is quality.

Q: So, if you were in charge of coming up with a program of Certificates of Added Qualifications, what would your recommendation be?

A: With regards to the amount of training required?

Q: Yes. And the process.

A: CAQs are done through groups that already oversee board certification. For example, let's say we did it through the one residency that has Prolotherapy as part of their education. The NMM/OMM Residency within the AOA. What that branch could do is develop a CAQ open to DO's and MD's alike, and develop the prerequisites you have to have in order to sit for the examination. You would need so many CME hours in particular courses given by recognized educators. Requirements could include a set numbers of hours with a lecture/discussion format as well as didactic format, maybe injection training with ultrasound, under fluoroscopy, those things that are deemed appropriate. There might be a requirement for so many hours in an anatomy lab. You might have to have so many contact hours working with a person who has done Prolotherapy therapy for so many years. We'd need to get the people together that would help us design this. This is what I hope to see.

Q: So there's nothing right now that you know of that's in the works in regard to that?

A: The only thing I know of is AAOM has a certificate that they give. Ross, you could probably speak to that better than I can. I am not familiar with its requirements. I am not aware if they have a standardized beta tested examination and pre-examination requirements.

Q: I understand.

A: Just like with a need for standardized research a CAQ needs to be instituted that meets the standards of accreditation of the medical community. People get upset about “Well, we have all this Prolotherapy research.” The problem is we haven’t standardized the research protocols. This team of researchers is using one solution, another group is using a different solution. We need to standardize solutions, we need to standardize protocols, we need to standardize diagnosis, numbers of treatments, and these kinds of things in order to bring validity to Prolotherapy research.

Q: Those are good points. As you know, this journal is also read by the lay public. Often regular doctors, when they’re treating people, want to use steroids because that’s basically the standard of care for most conditions. If you were giving a lecture, and the lecture involved the lay public and you were trying to explain when you would use Prolotherapy versus when you would use a steroid injection, what would be some of the highlight points that you might make?

A: I would educate to the public the indications for a steroid. A steroid is to treat inflammation or swelling. So if my patient exhibits marked pain, signs of obvious nerve root inflammation such as a positive straight leg raising test I would recommend a lumbar epidural steroid injection. It would be a very appropriate thing to do. If a person has a joint with marked bursitis pain a steroid injection is appropriate. But it’s only symptomatic treatment. It doesn’t address how that person got there. Do they have underlying instability at those segments? Do they have, as you know, with hip bursitis hip muscle weakness. If you strengthen their hips, they are much less likely to get bursitis again. I think there’s a place for steroids in the treatment of some acute pain problems so that you can calm down a patient’s pain, then move forward and treat what caused the problem originally. And that’s where I think some of us fail. We treat the pain problem but we don’t take what I like to define as the Osteopathic philosophy and say what got them there. What led to the pain that created the problem that they’re having?

Q: Yes. That’s a very good explanation. I appreciate your time. Your answers are outstanding.

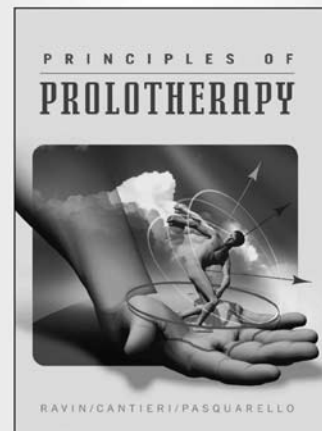
A: Oh thanks Ross. That’s very gracious of you.

Q: Thanks for talking to me today, Mark. I really appreciate your efforts in the field of Prolotherapy.

A: Well, thanks Ross. I do appreciate this. It is very nice of you to include me in this effort.

Q: With the *Journal of Prolotherapy*™, like with any journal, we’re just trying to give people state-of-the-art information. You’re definitely state-of-the-art! So thanks, Mark. Thanks for everything that you do.

A: Thanks. You guys have a great afternoon. Keep up the good work. ■



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IN THE SPOTLIGHT

In Memory of Thomas Dorman, MD

Richard Gracer, MD

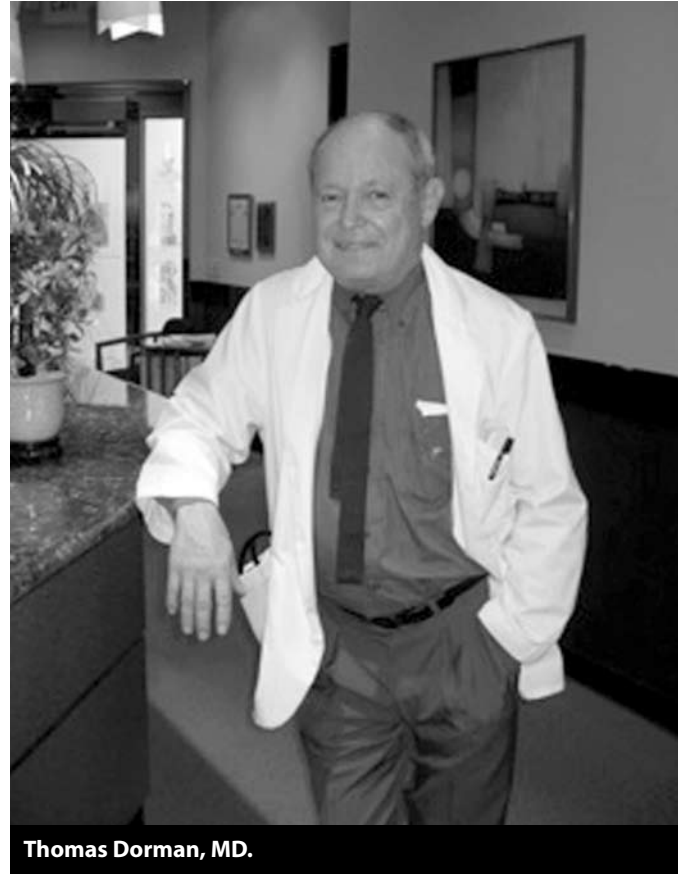
Those of us in the field of Prolotherapy owe a great debt to Dr. Tom Dorman, whose work and dedication to the field of Prolotherapy and Orthopedic Medicine paved the way for many to follow. We mourn his loss, but celebrate his life and life-work. The following is a memorial written by Dr. Richard Gracer.

From all involved in the Journal of Prolotherapy

I was shocked and dismayed, as were all of us who knew him, to hear of the death of my dear friend and colleague, Thomas Dorman, MD on March 10, 2009 at the age of 72. Tom was one of the most influential and important persons that I have had the honor to know. The news sent me reeling and back to many memories of the times and events that we shared. I cried, and between the tears I felt his presence, as I often do. When I see a difficult patient or come across an ethical dilemma, Tom is in my thoughts. He had an invariable scientific honesty and moral compass that often helps to see the best course of action.

Many know his name, but may not really know who he was and what he stood for. Many have read his prolific writings and have gained from his insights, but may not know where they came from or the thought process behind them.

Tom was born in Kenya, while it was still under British rule. His father was a coffee merchant. When Kenya gained its independence, Tom's family moved to Israel. He was in the Israeli army in a paratroop unit during the 1956 war. He attended the University of Liverpool and although his father wanted him to be a businessman, he then went on to medical school in Edinburgh. He moved his family to Canada where he began practice as an internist and cardiologist. In 1978 he moved to San Luis Obispo on the central California coast where he practiced until 1996 when he moved to the Seattle area to work with Jonathon Wright, MD at the Tahoma clinic. A few years later Tom



Thomas Dorman, MD.

opened the Paracelsus Clinic in Federal Way, Washington where he practiced until his death. Those are the facts, but there is much much more.

While practicing cardiology Tom often saw patients with chest pain that was neither cardiac nor gastrointestinal. The diagnosis in these cases can often be obscure. Tom searched for other causes and found that many of these patients had musculoskeletal pain. He studied with James Cyriax, MD, the late British physician who is considered by many to be the "Father of Orthopaedic Medicine." Dr. Cyriax developed a systematic diagnostic method to quickly and reliably find the exact tissue source of musculoskeletal pain. This study started Tom on his life long interest in furthering our understanding of

and treating these problems. Tom became interested in ligaments as a source of tissue pain, a much overlooked problem. In 1994 Tom, with important contributions in radiology from Tom Ravin, MD, published his textbook, *Diagnosis and Injection Techniques in Orthopedic Medicine* on Prolotherapy. This was the first book that combined Cyriax's orthopedic principles with the treatment of ligamentous problems. Tom is not only famous for the concepts he developed, but for his logical methods and his amazing ability to "connect the dots." He saw patterns that everyone else missed. I would often have an "aha" moment when I would think about what he would tell me. When Tom and I taught orthopedic medical courses together, I often learned more than the students.

Tom was well-known within the orthopedic medical community as an exceptional physician, as well as a pivotal thinker, writer and teacher. He had a majestic command of the English language. He also was a major thinker in the preventative/nutritional medicine arena. In fact, he introduced me to this whole area of medicine, and he influenced the orthopedic medical community to shift their thinking to include this vital area.

Besides all of this, Tom was a well-known libertarian thinker and writer. He held strong beliefs in personal freedom and independence. He decried the invasion of insurance companies in medical decisions and never accepted insurance payments. He opposed any governmental control over medical practice. He used alternative medical therapies when he thought that they were the best treatment for his patients. He was the consummate physician.

Tom is survived by his wife of 38 years, Alison, four children – Jill Coletti, Michael, Andrew, and Erin Hadley, and six grandchildren – Jill's Benjamin and Joshua; Michael's Mackenna and Micaela; and Erin's Zoe and Sam.

- To learn more about Tom Dorman please go to his website: <http://www.dormanpub.com/index.htm>
- To see a video interview on Prolotherapy: <http://www.paracelsusclinic.com/Video/>
- To hear his very recent interview with Lew Rockwell go to: <http://www.lewrockwell.com/blog/lewrw/archives/025803.html>

The family has asked that those who wish to honor Tom make a donation to the Ludwig von Mises Institute in his memory (<http://mises.org/>).

Tom Dorman was a great man. He was my colleague. He was my teacher. He was my friend. God rest his soul. ■

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FANTASTIC FINDINGS

ABSTRACT

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

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

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

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

Journal of Prolotherapy. 2009;3:145-155.

KEYWORDS: alternative to low back surgery, ligament injury, low back pain, Prolotherapy.

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

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

Introduction

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

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

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

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

HACKETT-HEMWALL PROLOTHERAPY FOR LOW BACK PAIN

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

Prolotherapy works by tightening and strengthening weak tendons, ligaments or joint capsules, stimulating the body to repair these soft tissue structures. It starts and accelerates the inflammatory healing cascade by which fibroblasts—the cells through which collagen is made and by which ligaments and tendons repair—proliferate. Hackett held that the procedure “stimulates the production of new fibrous tissue and bone cells that will strengthen the ‘weld’ of fibrous tissue and bone to stabilize the articulation and permanently eliminate the disability.”²³

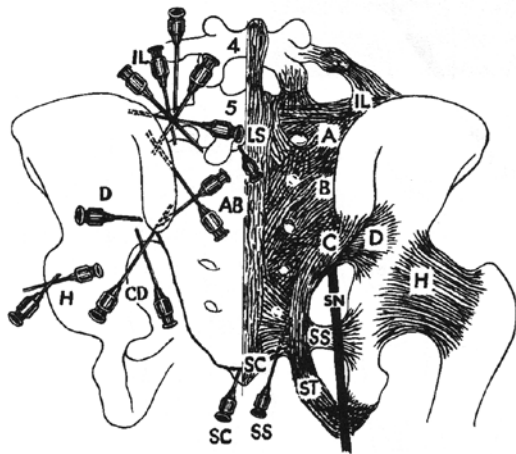
It is reported in the medical literature that damage to ligaments accounts for up to 70% of all cases of low back pain.^{24, 25} The most common ligament injury in the low back involves the sacroiliac joints.²⁶ Sacroiliac ligament

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

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

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

HACKETT REFERRAL PATTERNS

**Lower Back and Hip Ligaments**

TRIGGER POINTS OF LIGAMENTS

IL:	Iliolumbar	ST:	Sacrospinous
LS:	Lumbosacral – Supra & Interspinus	SC:	Sacrococcygeal
A, B, C, D:	Posterior Sacroiliac	H:	Hip – Articular
SS:	Sacrospinus	SN:	Sciatic Nerve

Figure 1. Ligamentous structures of the lower back typically treated with Hackett-Hemwall dextrose Prolotherapy.

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

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

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

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

Methods

A. PATIENT DATA

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

B. TREATMENT PROTOCOL

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

C. DATA COLLECTION

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

Table 1. Patient characteristics at baseline.

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



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

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

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

D. ANALYSIS

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

Results

A. PAIN/STIFFNESS

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

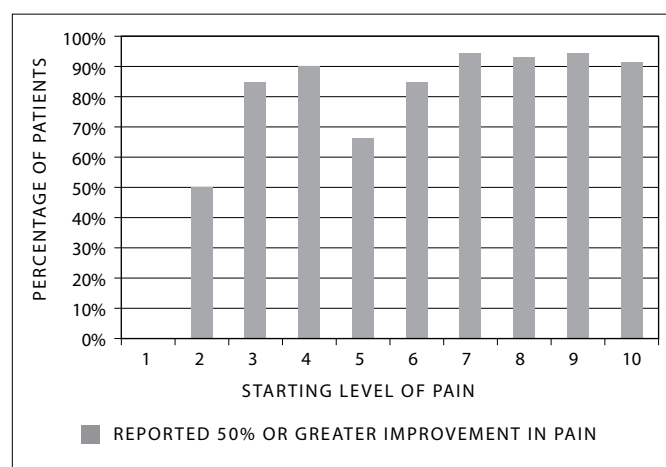


Figure 3. Percent of patients who reported 50% or greater pain relief after receiving Hackett-Hemwall dextrose Prolotherapy.

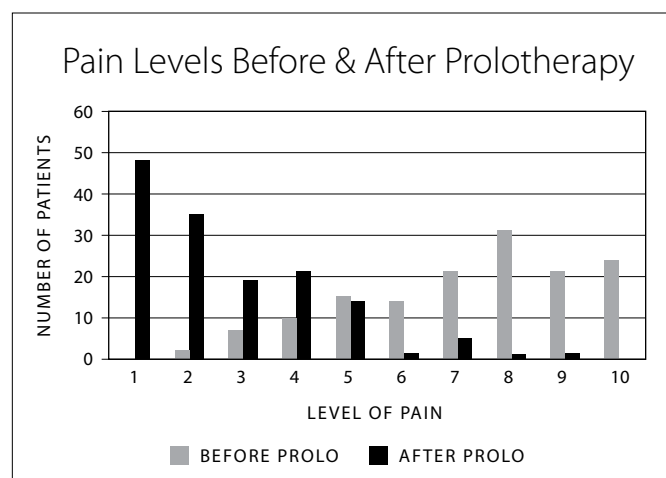
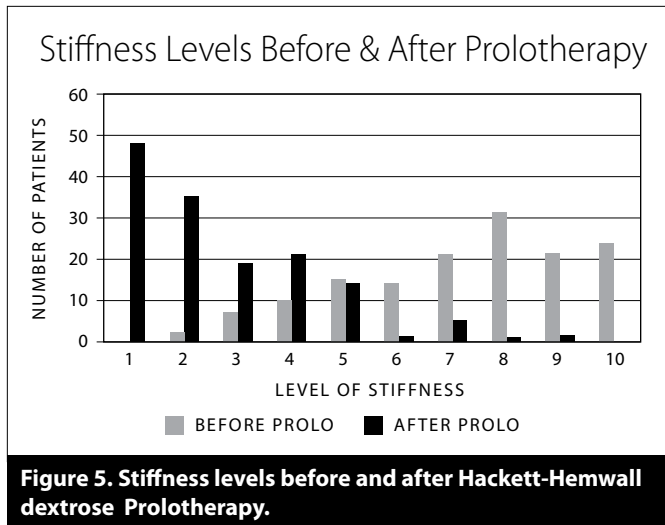


Figure 4. Pain levels before and after Hackett-Hemwall dextrose Prolotherapy.



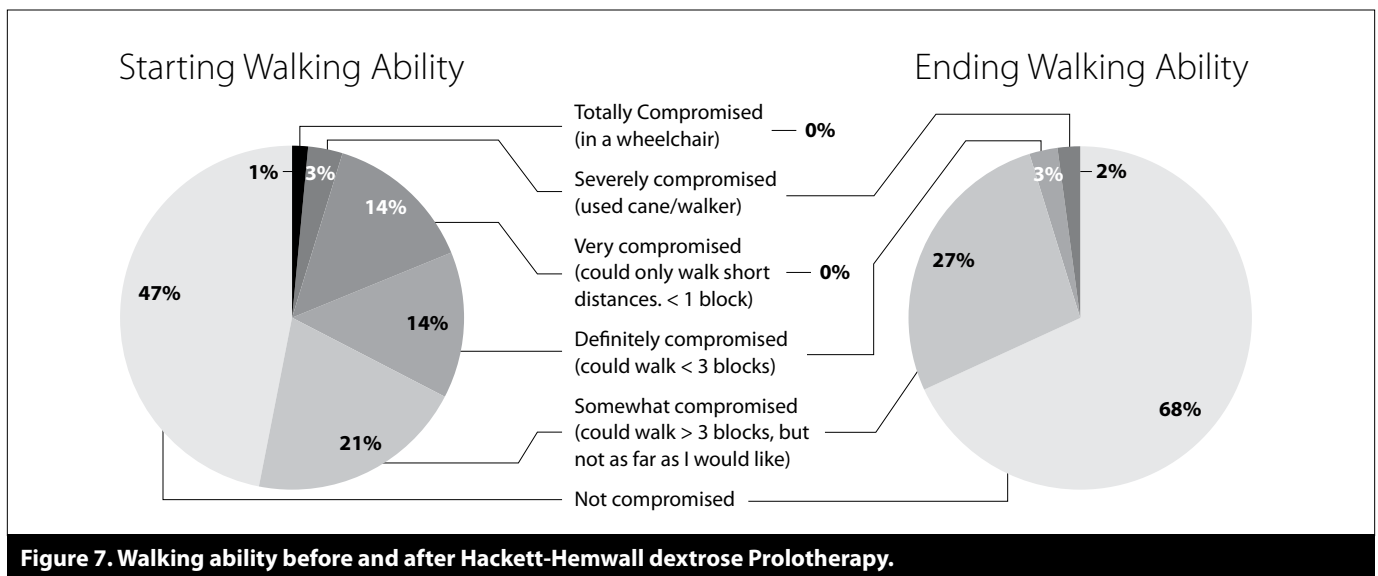
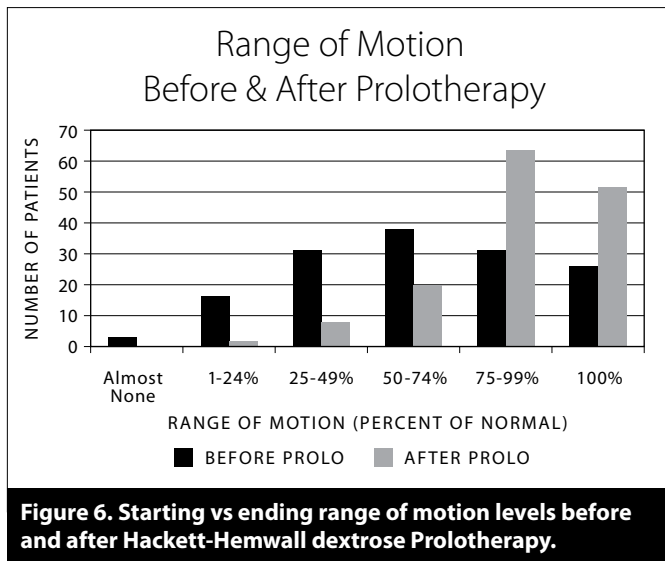
B. RANGE OF MOTION

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

C. MOBILITY

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

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



D. EXERCISE TIME

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

E. ANXIETY AND DEPRESSION

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

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

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

F. MEDICATION USE

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

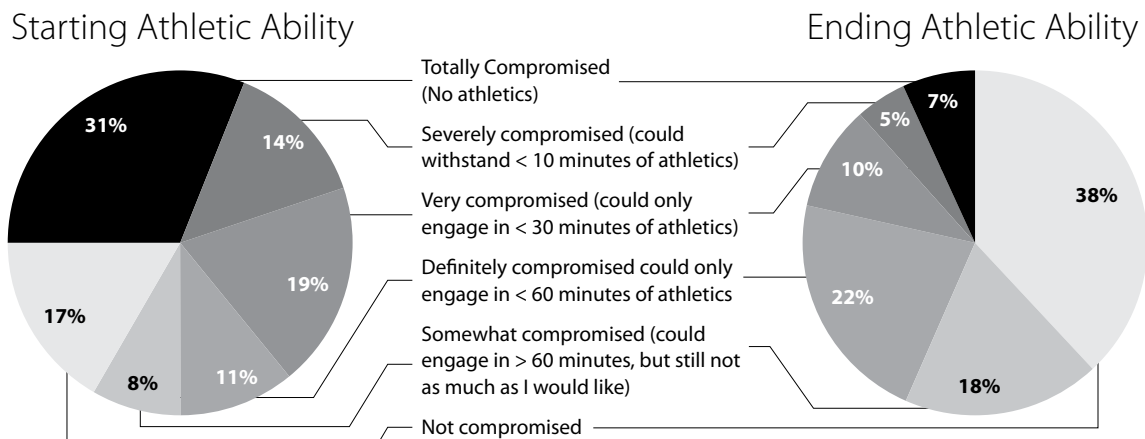


Figure 8. Athletic ability before and after Hackett-Hemwall dextrose Prolotherapy.

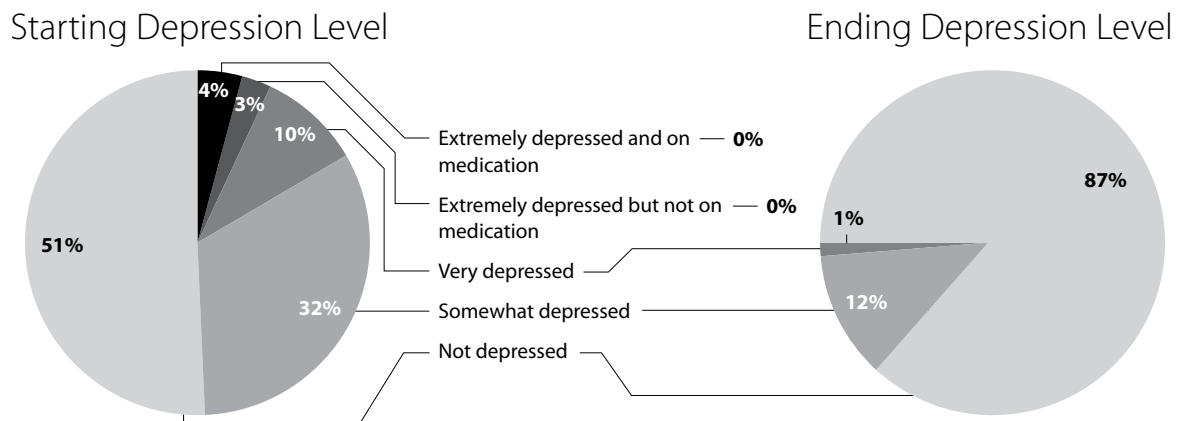


Figure 9. Depression levels before and after receiving Hackett-Hemwall dextrose Prolotherapy.

G. OVERALL RESULTS

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

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

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

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

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

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

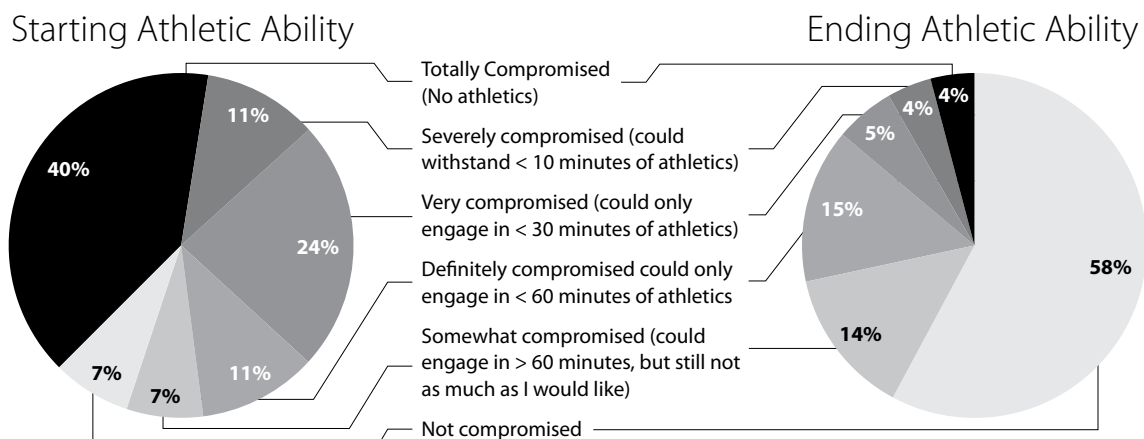


Figure 10. Exercise ability before and after Hackett-Hemwall dextrose Prolotherapy in patients told that no other treatment options existed for their back pain.

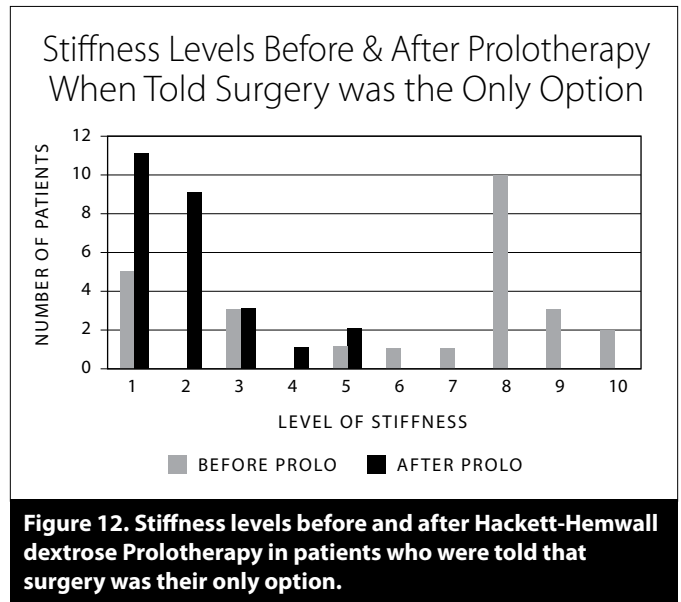
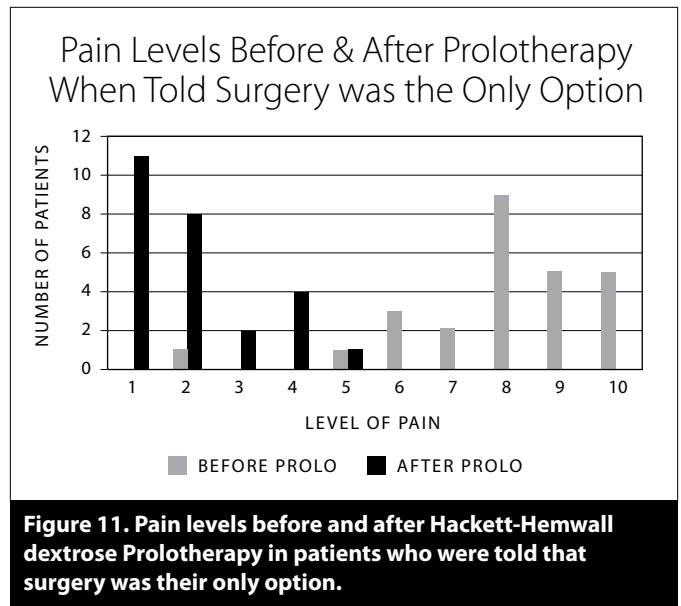
(greater than 50%). Eighty-nine percent of these patients rated the Prolotherapy treatment to be very successful with 62% receiving 75% or greater pain relief. Eighty-nine percent received greater than 50% pain relief with Prolotherapy. In response to the question “*Has Prolotherapy changed your life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

RESULTS IN SURGERY ONLY OPTION GROUP

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

Statistical Analysis

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



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

Discussion

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

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

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

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

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

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

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

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

Study Strengths and Limitations

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

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

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

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

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

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

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

Conclusions

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

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FANTASTIC FINDINGS

ABSTRACT

Background Content: This case study examined the effects of a single Prolotherapy injection series on the left iliolumbar ligament. The ligament measurements were split between medial and lateral portions of the iliolumbar ligament and we hypothesized that growth would occur increasing the cross sectional area and thus provided added stability to the pelvis and lumbar spine.

Purpose: The purpose of our study was to answer two questions: 1) how do you know that the Prolotherapy injectant actually reaches the ligamentous structure you are attempting to heal; and 2) how long does it take for the ligament to recover?

Study Design: Single case study.

Methods: One subject, 32 year-old female with no history of lower back pain (LBP) participated in our study. Her job tasks as a physical therapist required her to twist turn and bend; putting pressure on her pelvis and ligamentous system. The primary author (A.A.) assessed her pelvic ligaments which lead to using a specified Prolotherapy solution for the left iliolumbar ligament. Ultrasound (US) guided imaging was used to take baseline measurements of the left iliolumbar ligament prior to Prolotherapy. Bi-weekly US measurements were up to six weeks to determine cross-sectional area (CSA) changes within the ligament.

Results: The results indicated that after the initial Prolotherapy treatment, there was growth in the left iliolumbar ligament at both the medial and lateral sites. The CSA increased by 27% for the medial measurement and 21% for the lateral measurement compared to baseline. The left iliolumbar ligament also appeared to change its characteristics and looked more uniform as a result of one Prolotherapy treatment.

Conclusion: Patients that experience lower back pain and or pelvic shifting may benefit from the usage of Prolotherapy to strengthen the ligaments surrounding their pelvis. Our study also brings out the positive effects of using US to capture changes that occur within specific tissue.

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KEYWORDS: iliolumbar ligament, Prolotherapy, sacroiliac joint, ultrasound.

Increase in Cross Sectional Area of the Iliolumbar Ligament using Prolotherapy Agents: An Ultrasonic Case Study

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Roy Bechtel, PT, PhD, & Stacey Matthews

Introduction

In order for information to become pertinent and cogent to a specific medical community, it needs to become valid, reliable and reproducible.¹ The complaints of lower back pain (LBP) are frequent at a physician's office² and as the body ages so do the structures that support it (i.e. disc, muscles and ligaments).³ Degenerative disc disease is still the leading lower back diagnosis in the United States.⁴ However, the lack of a specific patho-anatomic diagnosis in many cases of low back pain has led to the development of alternative diagnostic schemes. One example is the treatment-based classification system proposed by Delitto et al.⁵⁻⁶ We too suspect that diagnostic accuracy is improved by determining what structure or structures are responsible for the origin of the patient's symptoms. Auburn, et al⁷ has shown that ligamentous structures can generate pain and cause referral patterns that mimic discogenic pain patterns, as originally reported by Hackett in the 1960s and replicated by Hauser in 2004. Ligament involvement can be confirmed by the changes in symptoms following treatment by Prolotherapy.

The passive ligament system of the pelvis is very strong and will stabilize the sacrum and pelvis against unwanted motion.⁸ The ligaments that are primarily responsible for control of lumbopelvic motion are the iliolumbar ligament (IL), the long dorsal sacroiliac ligament (SI), the sacrospinous ligament (SS) and the sacrotuberous ligament (ST). (See *Figure 1*.) The iliolumbar ligament

will stabilize L4 and L5 on the ilium and sacrum and is considered a very important pelvic stabilizer.⁹⁻¹⁰ The SI, SS and the ST help stabilize the pelvis and subsequently will keep the lumbar spine in check as well.^{9, 11} When there is a disruption in one of the lumbopelvic ligaments, poor control of lumbopelvic motion and muscular imbalances are the result.¹² When this disruption occurs, the clinician needs to determine which ligament is affected so that effective treatment can be applied to help restore normal stability and decrease pain.

Effective treatment for ligament strengthening via cell restoration is called Prolotherapy. This treatment dates back to the 1950s and 1960s when its pioneer Dr. G.S. Hackett discovered that by injecting a hypertonic sugar solution into a painful ligament, a patient's LBP was reduced.¹³⁻¹⁵ Two questions that arise from the cell proliferation procedure are 1) how do you know that the Prolotherapy injectant actually reaches the ligamentous structure you are attempting to heal; and 2) how long does it take for the ligament to recover? The purpose of our study is to answer these questions using the iliolumbar ligament as a model. We used Ultrasound (US) technology to inject the ligament under guidance and to quantify the changes in ligament shape and substance from week to week.

ULTRASOUND IMAGING

Ultrasound consists, simply, of very short wavelength sound waves with a frequency that is higher than 20000 Hz.¹⁶⁻¹⁸ The wavelengths are so short that these waves cannot travel through air, but require a denser coupling medium, usually a gel. Ultrasound imaging (US) has been reported in the recent literature as a reliable and useful way to look at the muscular structures in the body.^{16, 19} Whitaker discusses, for example, that to accurately determine changes in the tissue structure, the clinician needs to understand the ligament's baseline appearance and how its appearance changes after Prolotherapy procedures.²⁰ US technology allows direct visualization of changes in tissue density and structure. Previous researchers have used ultrasonic techniques to identify changes in muscle and ligamentous structures. (See Figure 2.)^{18-19, 21-25} Ultrasound imaging has also been used to look specifically at multifidus muscle atrophy²⁶ after an injury to its nerve supply. US is easier and more cost effective than MRI, thus making it possible for clinicians to assess the integrity of the active (muscle) and passive (ligamentous) stability system.^{17, 27} We chose to use the

iliolumbar ligament due to its relationship with the pelvis⁸ and ease of imaging compared to the sacroiliac or the dorsal sacral iliac ligaments. With a paucity of human studies on the US imaging of the sacral ligaments and only a few using animal (Goff, 2006) we decided that being able to use the ilium as a landmark would give us good insight as to where the iliolumbar ligament was located for our imaging. In our case, the B-mode US was used to measure the cross sectional width of the iliolumbar ligament.¹⁶⁻¹⁷ Whittaker et al¹⁶ determined that the mode in which you use the US is important to determine what you will see. For example, to look at the thickness, length and diameter of a muscle or structure, the B-mode is most efficient. The M-mode which is used most of the time for visualizing internal organs is not as effective for our purpose, but recently researchers²⁸⁻³⁰ have been using the M-mode to study muscle motion during locomotion due to its ability to detect changes in structure during movement.³¹

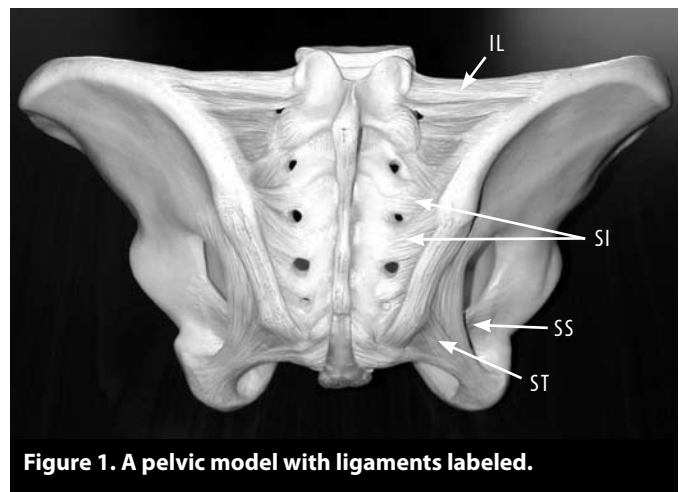


Figure 1. A pelvic model with ligaments labeled.

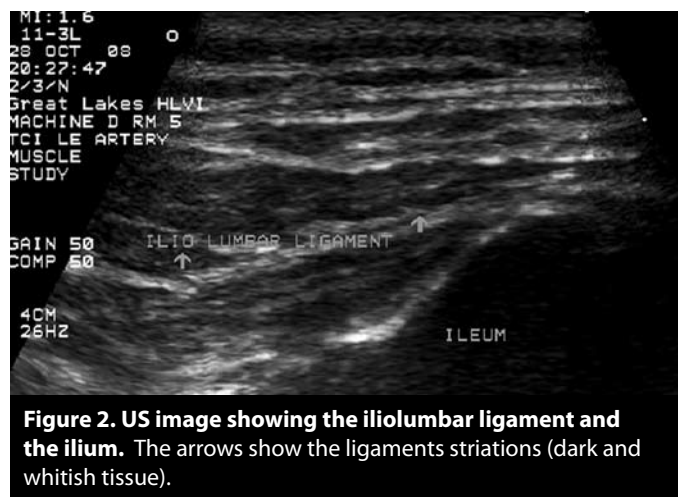


Figure 2. US image showing the iliolumbar ligament and the ilium. The arrows show the ligaments striations (dark and whitish tissue).

Methods/Materials

This study was conducted at Ingham Regional Medical Center in Lansing, Michigan and was reviewed and approved by the board at the Natural Health and Improvement Center. One female, 32 year old, 5'6, and 60 kg was included in this study. She had no history of LBP nor did she have any surgery or lower back procedures performed for pain control. She worked as a physical therapist and performed bending and twisting activities during her daily treatment of patients. She had two children but did not experience lower back pain as a result of her pregnancies.

Procedure

The patient was brought into the examination room, laid prone and the experimental procedure was explained to her. The certified US technician explained how we were going to use US not only measure the iliolumbar ligament changes but also to guide the injection and monitor the Prolotherapy solution as it was injected in and around the ligament. (See Figure 3.) Author two (B.S.) had experience with this US technician from the previous multifidus isolation imaging studies that they conducted. The US technician has 14 years of imaging experience and author two (B.S.) has had over 400 Prolotherapy injections from the primary author (A.A.); (who has over 13 years of Prolotherapy injection experience) thus all principal investigators had the qualifications to examine the ligaments in the spine. The ultrasound technician placed the aqueous US gel onto the patient's skin as a conduction medium and then positioned the US probe (using the

B mode to see the shape and size of the ligamentous structure involved (a 3.5 MHZ curved linear array probe connected to the Phillips Sonos Duplex Imager) to send the sound waves to the computer for observation and recording. (See Figure 3.) Based on the work of Loukas³² the iliolumbar ligament was identified using the US probe. The left iliolumbar ligament was used for analysis. A baseline cross section area measurement of the ligament was obtained. We used medial and lateral measurements to determine how much growth was obtained from the Prolotherapy solution. (See Figures 4a & 4b.) Whittaker³³ points out that the muscle tissue appears darker with US due to the larger amount of blood it contains, and fascia or ligamentous structures appear lighter, reflecting their increased density and lower fluid content. The iliolumbar ligament is thus referred to as hyperechoic compared to the hypoechoic muscle tissue.¹⁶⁻³⁴ In order to determine any changes within the ligament being looked at, we had to apply the above parameters as well as the following, in order to give the study some true quantitative objectives. Each time we imaged, we duplicated the exact settings on the same ultrasound equipment, the Philips Sonos 5500 using the 3.5 MHZ curved linear array probe. We



Figure 3. US technician and subject with the US probe being placed on the left side of the low back.

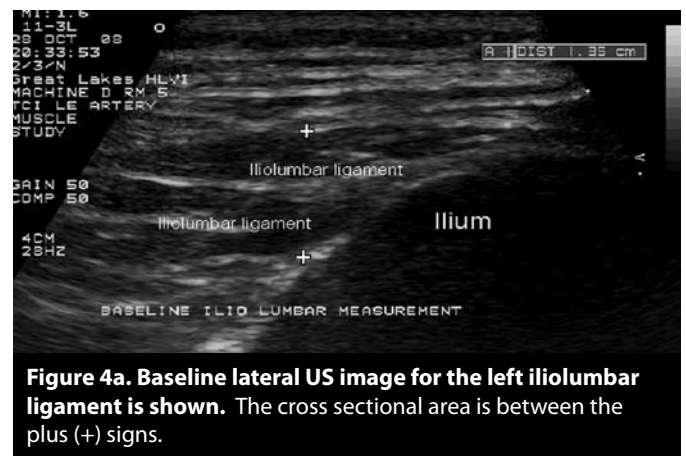


Figure 4a. Baseline lateral US image for the left iliolumbar ligament is shown. The cross sectional area is between the plus (+) signs.

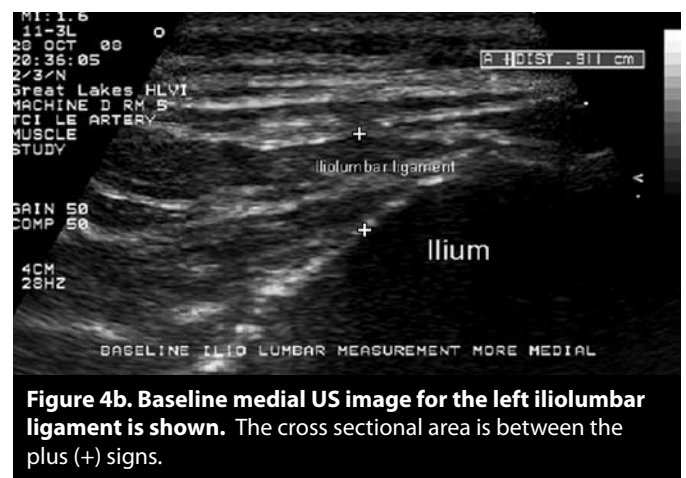


Figure 4b. Baseline medial US image for the left iliolumbar ligament is shown. The cross sectional area is between the plus (+) signs.

used the same gray scale map with B-Mode imaging, consistent depths, as well as consistent patient positioning. When evaluating the ligament for any cross sectional area measurement changes or tissue integrity we made comparable measurements from one session to the next with review of previous imaging.

PROLOTHERAPY INJECTION PROCEDURE

The left and right lower lumbar region was prepped and draped, sterile alcohol was used to clean the area of interest. The primary author (A.A.) then identified landmarks for the posterior superior iliac spine (PSIS), L5-S1 and the left ilium. The primary author (A.A.) then found the attachment site for the left iliolumbar ligament which was verified via US imaging. The US technician isolated the iliac crest and the iliolumbar ligament on the left side so that the primary author (A.A.) could identify the two sites that were used during the procedure. (See Figure 4.) Once the ligament was located, the physician inserted the needle into the affected area until bone was approximated and then the needle was drawn out prior to the solution being injected.³⁵ This procedure is supported by references 14, 15 and 35 and they concurred that the needle is injected into the skin and the bone is approximated in the affected tissues or region prior to the solution being injected. The Prolotherapy solution that was used for this patient was 4cc of procaine, 1cc of 50% dextrose, 0.5cc of PQU (2.43 ml of phenol liquefied, 5.73 GM Quinine HCL, 1.26 GM Urea USP). This material was fabricated at the Compounding Pharmacy of Wyoming Park, 2301 Lee Street SW, Wyoming, MI 49519). Using US, the primary author (A.A.) located the medial injection site on the iliolumbar ligament and injected the Prolotherapy solution. Similarly, the lateral site was identified and the procedure was repeated. (See Figures 5a & 5b)

PROGRESSIVE WEEKLY MEASUREMENTS

The US technician took measurements for the lateral and medial sections of the left iliolumbar ligaments pre-injection, after one week, then, every two weeks. There were four measurements in total for the duration of six weeks from the time of the baseline measurement.

Results

One week after a single series of Prolotherapy injections, there was cross sectional growth in the iliolumbar ligament compared to baseline, although most dramatic growth in the ligament was recorded during weeks two through four. At the six week mark, the growth leveled off for the lateral portion of the left iliolumbar ligament,

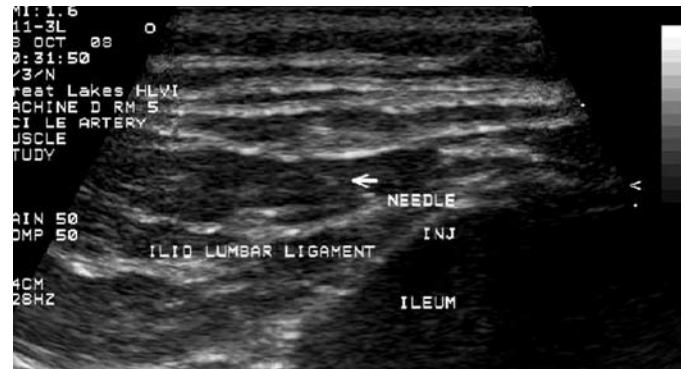


Figure 5a. US illustration showing the needle, ilium, iliolumbar ligament prior to the Prolotherapy injection material moving into the iliolumbar ligament.

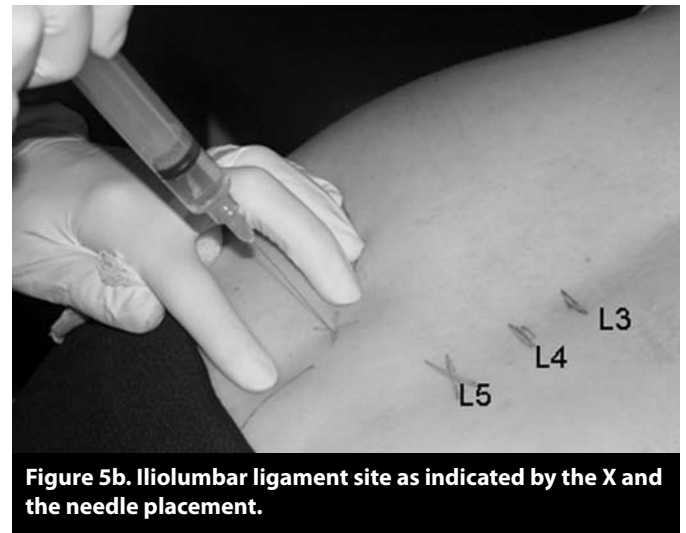


Figure 5b. Iliolumbar ligament site as indicated by the X and the needle placement.

but the medial side of the ligament still showed signs of further tissue proliferation. (See Table 1.) Total growth in the left iliolumbar ligament for the medial portion was a positive 27% from the initial measurement at six weeks post-injection. The lateral section of the ligament also grew by 21% from the initial baseline measurement. (See Table 1.) Thus the cross sectional area of the left iliolumbar ligament in this subject improved from one series of Prolotherapy injection material.

Table 1. Iliolumbar ligament measurements from baseline.

Measurements in CM	Medial	Lateral
Measurement one, baseline	0.91	1.35
Measurement two, 2 weeks	0.995	1.4
Measurement three, 4 weeks	1.25	1.7
Measurement four, 6 weeks	1.2	1.7
Total percentage of growth from baseline to 6 weeks	27%	21%

TISSUE INTEGRITY FINDING

Initially it appeared to us that the iliolumbar ligament tissue was not uniform. Some areas appeared darker and others had a more whitish appearance. We interpreted this to indicate areas of less dense ligamentous tissue and denser ligamentous tissue. As we continued to measure the left iliolumbar ligament, medial and lateral portions, the tissue began to take on an appearance that looked more uniform and hyperechoic (lighter).³⁶⁻³⁷ (See Figure 5a.)

Discussion

Low back pain (LBP) can routinely deter a person from functioning at their optimal level which can lead to poor productivity and increasing health care costs.³⁸ When a clinician determines what the cause of the LBP is one must evaluate if the problematic area is a ligament, muscle, disc or nerve root. Knowing the correct structure to target gives your evidence more credence.³⁹ US technology gives us the validity⁴⁰ and the reliability that is needed to accurately find a structure, and determine its function and or pathology.^{41-42, 43} Fullerton⁴⁴ showed that through US and MRI imaging that a partially torn patellar tendon was repaired through Prolotherapy treatments. He quantified his measurements using US and demonstrated that when using Prolotherapy, the patellar tendon tissue was thickened and healed. He also showed that using Prolotherapy could help restore meniscus tissue which was shown via MRI scans. Rehabilitative clinicians thus can be equipped with a non-invasive technology that allows visualization of deeply-placed structures to determine their state of function and/or pathology.⁴⁵

Other researchers, Young, et al⁴⁶ used US to measure the quadricep muscle comparing tape measure versus US measurement. They concluded that the US proved to be far superior to most clinical measures, specifically, allowing clinicians to visualize quadriceps muscle wasting when very little wasting was demonstrated with the tape measure method. Thus US can help a clinician understand with high sensitivity, if a certain tissue has undergone changes, and whether those changes are positive or negative.

Our findings showed the effectiveness of using Prolotherapy solution to specifically target a designated structure. Our question of whether or not the material actually made its way into the ligament was answered using US technology, since we directly visualized the bolus of injectant entering the tissue. The results showed that the cross sectional area increased in both the medial and lateral portions of the left iliolumbar ligament. The left

iliolumbar ligament was measured on a bi-weekly basis to determine if there was growth in both locations. Loukas⁴⁷ determined how to best visualize the iliolumbar ligament with US, and we employed his ideas to show the changes in the tissue structure over a six week period of time. We did not scan the deep sacroiliac ligamentous structures because of poor visualization of landmarks and inability to accurately measure cross sectional changes. Further research in this area is needed to help identify and treat the ligamentous structures around a person's pelvis that may be contributing to their pain.

Within a week after one Prolotherapy series, the ligament began to increase in cross sectional area and this continued for at least part of the ligament up to the last measurement at six weeks. We hypothesize from this that one series of Prolotherapy (using the reported materials) caused the body to ramp up cellular growth as suggested by Reeves.⁴⁸ Thus, we concluded that one series of injections is sufficient to enhance the stabilizing function of the left iliolumbar ligament and subsequently give the lumbar spine and pelvis increased support. It appears that after six weeks, to maintain ligament hypertrophy, we would need to introduce further solution.

Our finding demonstrated that the iliolumbar ligament appeared to change in how it presented from week one to week six. (See Figures 6a-f.) This finding is separate from the fact that the cross sectional area of the ligament positively increased in size from week one to week six. Our findings are encouraging from many points of view. The first positive effect was that it took only one series of injections to cause a change in a tissue structure. Secondly, we saw that the left iliolumbar ligament appeared differently (more uniform) over the six weeks that the measurements were taken. Lastly, US technology has been shown to be able to visualize the Prolotherapy solution as it is being injected, and can also aid in showing the changes that occur from the Prolotherapy solution. With the array of chemical mixtures for Prolotherapy available today, it would be interesting to see what effects those proliferents would have on various tissues using US technology to monitor cross sectional area changes and tissue growth. In our case, we were not concerned about pain, but only with what effect Prolotherapy would have on the tissues that support the lumbar spine and pelvis. Our positive findings move us one step closer to showing how, for patients with lower back pain, Prolotherapy can prove to be a good adjunct to increase stability in the lumbar spine and pelvis. ■

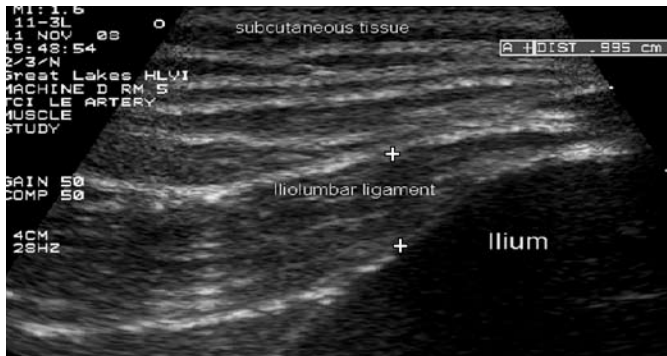


Figure 6a. US illustration of the left iliolumbar ligament, medial portion at 2 weeks from baseline. The cross sectional area is between the (+) signs and the striations are shown in the iliolumbar ligament.

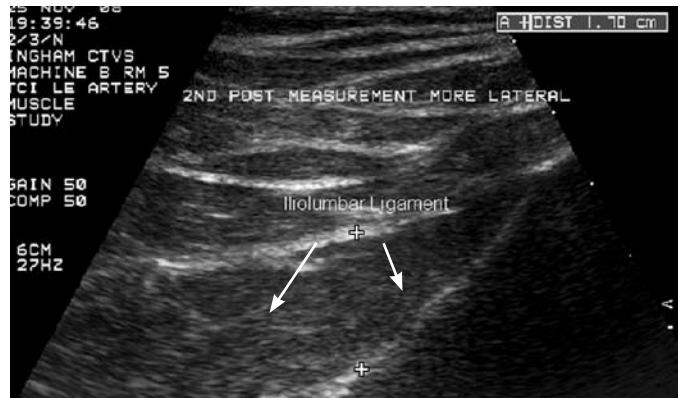


Figure 6d. US illustration of the left iliolumbar ligament, lateral portion at the 4 week mark from baseline. The cross sectional area is shown between the (+) signs and the striations are shown. The delineation line between the ilium and the iliolumbar ligament is shown by the white line; the ligament is becoming more hyperechoic.

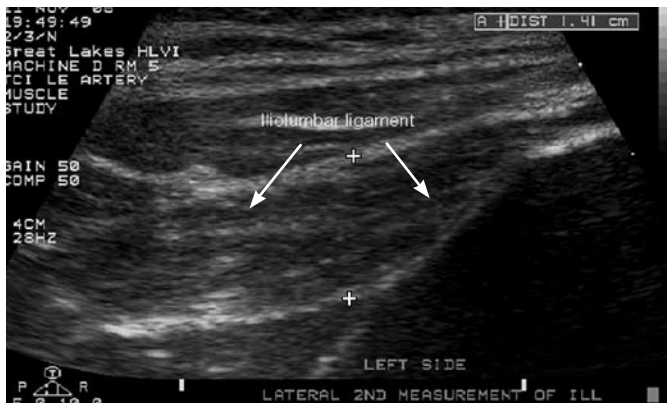


Figure 6b. US illustration of the left iliolumbar ligament, lateral portion at 2 weeks from baseline. The cross sectional area is between the (+) signs and the striations are shown in the iliolumbar ligament.

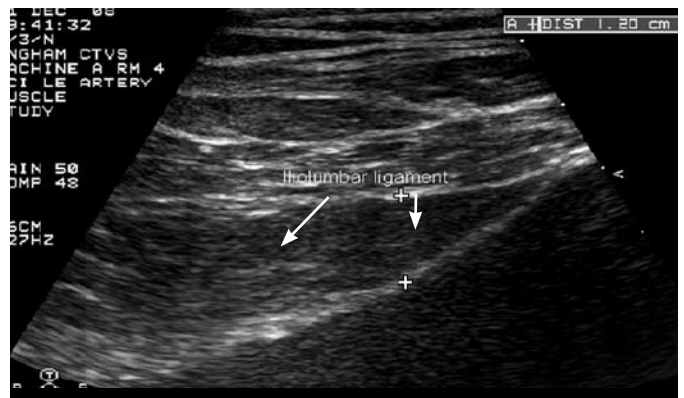


Figure 6e. US Illustration of the left iliolumbar ligament, medial portion at the 6 week mark from baseline. The ligament tissue as shown is more hyperechoic (lighter) and more defined compared to the previous illustrations.

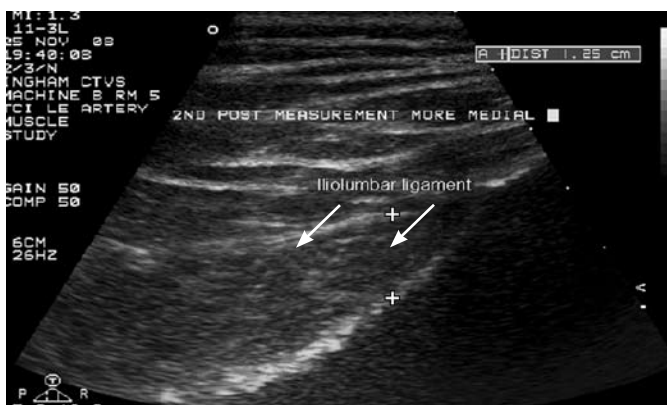


Figure 6c. US illustration of the left iliolumbar ligament, medial portion at the 4 week mark from baseline. The cross sectional area is shown between the (+) signs and the striations are shown. The delineation line between the ilium and the iliolumbar ligament is shown by the white line; the ligament is becoming more hyperechoic.

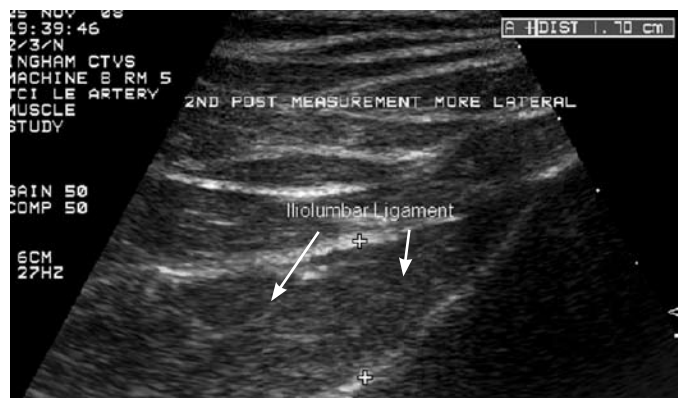


Figure 6f. US Illustration of the left iliolumbar ligament, lateral portion at the 6 week mark from baseline. The lateral portion is also more hyperechoic (lighter) and the delineation line between the Ilium and the ligament is much defined as shown by the white line.

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REMARKABLE RECOVERIES

Three Cases of Chronic Pain Relieved with Prolotherapy in Hong Kong Clinic

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ABSTRACT

Hong Kong physician, Dr. Stanley Lam provides the reader with not only his personal story of years of pain from athletic injuries relieved with self-administered Prolotherapy, but those of two other cases—one patient with spinal cord compression and another with undiagnosed Barre-Lieou Syndrome whose pain complaints were cured with Prolotherapy after many traditional treatments failed.

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KEYWORDS: Barre-Lieou Syndrome, low back pain, Prolotherapy, spinal cord compression.

Dr. Lam has a special interest in treating patients with various kinds of pain and sports injuries. He himself is a runner and golfer. He knows very well what it is like to have pain or injuries of various regions of the body, and the importance of living a pain free life. (See Figure 1.)

MY PAIN STORY

I started doing musculoskeletal medicine because I myself suffered from chronic lower back pain radiating down my right thigh on prolonged standing and walking when I was still a resident. The pain responded poorly to the oral medicine of various kinds. It was only partially and temporarily relieved by manual medicine. The pain became more infrequent after I had been found to have a 6mm shorted left leg and over-pronated feet during a lower limb biomechanical workshop. But it was still there because of the long history of ligaments laxity from distorted biomechanics and repeated micro-trauma from sports and practicing manual medicine myself. I finally got total pain relief while participating in a Prolotherapy workshop in Mexico with Dr. Joel A. Berenheim, D.O., when he performed Prolotherapy on my lower back. I also



Figure 1. Dr. Lam performing Prolotherapy for a patient with chronic low back pain.

had a history of bilateral wrist pain on forced extension of my wrists, which I believe a lot of musculoskeletal physicians will commonly have because of ligament laxity from practicing manual medicine. I have performed Prolotherapy on my own wrists twice, each to one side by the other hand. (See Figure 2.) They are pain free now but I still have mild clicking during supination and pronation. I am planning on doing Prolotherapy to them again in the coming few months.

PROLOTHERAPY HELPS PATIENT WITH SPINAL CORD COMPRESSION

Mr. K is a 35 year-old office clerk. He has a long history of neck and shoulder pain due to prolonged usage of a computer with a forward-head posture. He injured his neck one day when he was playing with his son in a playground. While supporting his body weight hanging from a play set, he tried to move forward using both hands from one bar to another. He suddenly felt



Figure 2. Dr Lam injecting his left wrist with his right hand.

a severe pain in his neck and both hands which caused him to fall down to the ground. He had weakness in all four limbs initially making weight bearing impossible. He gradually regained full walking ability 15 minutes later. His neck pain has continued and he has not been able to make firm grips with both hands since the injury. He went to the emergency room in Hong Kong where X-rays were taken and showed no cervical fractures or dislocation. He was then prescribed physiotherapy in a government hospital and was placed on sick leave for seven weeks. This gave him partial relief of the pain and hand weakness. He was lay-referred to see me eight weeks after the injury. Physical exam showed 4/5 gripping power on both hands, and there was diminished pin prick sensation over the C5-7 dermatome. He was admitted to a private hospital and an MRI found a significant protrusion of the C5-6 disc with compression to the spinal cord. But there was no obvious spinal cord edema from this compression. (See Figures 3 and 4.) Nerve conduction velocity test showed normal peripheral nerve conduction. I performed the

first Prolotherapy under fluoroscopic guidance in early February 2009 with 15% glucose (3cc of 50% dextrose mixed with 7cc of 1% lignocaine (lidocaine)). (See Figure 5.) The injection sites include: Both the superior and inferior nuchal lines, the interspinous ligaments from C2-3 down to T3, the facets joints from C2-3 down to T3-4, the origin of the levator scapulae at the superior and medial border of the scapulae, and the origin of the upper trapezius over the spine of scapulae, and the clavicles. After the first Prolotherapy, there was a 60-70% improvement in his pain and his gripping power increased to 5/5. He could resume his usual activities, including work, one week after the first Prolotherapy treatment.

The second Prolotherapy treatment was initially arranged six weeks after the first in mid March 2009, but since he has nearly full recovery to his gripping power, there is no more pain in the neck and upper limbs, and he has resumed all of his usual activities, thus the second Prolotherapy treatment was cancelled.

BARRE-LIEOU SYNDROME RELIEVED WITH PROLOTHERAPY

Ms. A is a 30 year-old financial planner, with a five year history of headaches, vertigo, tinnitus, ear pain, jaw pain, pain on wide-opening of mouth, and neck pain. She also describes a pins-and-needles sensation of the hands and forearms during sleep or prolonged use of a computer. She has difficulty concentrating on her work when she has the



Figure 3. MRI of Mr. K showing compression to the spinal cord.



Figure 4. MRI of Mr. K showing C5-6 protrusion.

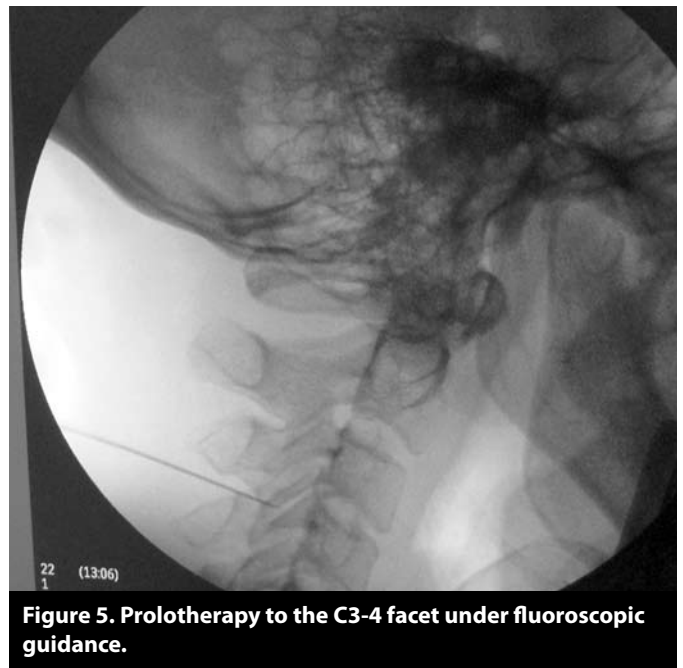


Figure 5. Prolotherapy to the C3-4 facet under fluoroscopic guidance.

attacks. She had seen a lot of doctors for help. Her cervical MRIs were unremarkable. Previous treatments included physical therapy and chiropractic manipulation, each with only temporary, partial relief of the symptoms. She has very poor sleep and was labeled by some doctors to have psychosomatic disorder. So a low dose of antidepressants was given. She was also seeing ear, nose, and throat surgeons for severe allergic rhinitis and sinusitis with facial pain and had been put on intranasal steroid spray for one year with partial relief of the nasal symptoms. She also had gritty and itchy eyes with occasional tearing of eyes with a sense of fullness of the eyeball. She worried that she had glaucoma. She was referred to ophthalmologists for a thorough eye examination, which was normal. She was then labeled to have allergic conjunctivitis and was put on Sodium Cromoglycate eye drops again with partial and temporary relief of the symptoms.

When I first examined her, she had a significantly forward head position with her ear lobe at the level of her sternum. (See Figure 6.)

She had FRSrt C2/3 and C3/4¹, which means there is non-neutral dysfunction with a restriction for extension and for rotation and side bending to the left between C2 and C3, and between C3 and C4. The left facet joint between C2 and C3 and that between C3 and C4 do not close completely. Overall, she had very lax cervical ligaments. Her TMJ had clicking and the lower jaw deviated to right. Very gentle mobilization of the neck using muscle energy technique was done to realign those neck segments and the TMJ, this brought immediate relief of her vertigo and headache. My diagnosis for her was Barre-Lieou Syndrome.² Since Prolotherapy

is still very new to people in Hong Kong and Asia, she had never heard of this kind of treatment. She was advised to go to the internet and look at certain websites including www.prolonews.com; www.treatingpain.com; and www.drreeves.com to get information on Prolotherapy. She came back one week later as her symptoms returned, but this time she received her first Prolotherapy treatment without fluoroscopic guidance in my clinic. (See Figures 7 & 8.) A 15% dextrose solution in lignocaine (lidocaine) was used to treat both the superior and inferior nuchal lines, the interspinous ligaments from C2 down to T1, the facet joints of the cervical spines, the origin of the levator scapulae at the medial and superior border of the scapulae, the mastoid processes and the angles mandibles, and the bilateral TMJs. She felt immediate relief of the headache, nausea sensation, and fullness of head after the injections. Her vertigo subsided one day after the procedure. She followed up four weeks later and stated that her headache, vertigo, tinnitus, nausea and vomiting, fullness in head, and numbness over her upper limbs had subsided. Surprisingly, her allergic rhinitis and conjunctivitis improved a lot. Her sleeping quality also improved and she no longer needed her antidepressant. She is now pain and medication-free after her second Prolotherapy treatment. She was taught the correct typing posture and self stretching techniques. I am hopeful she will remain pain free. ■

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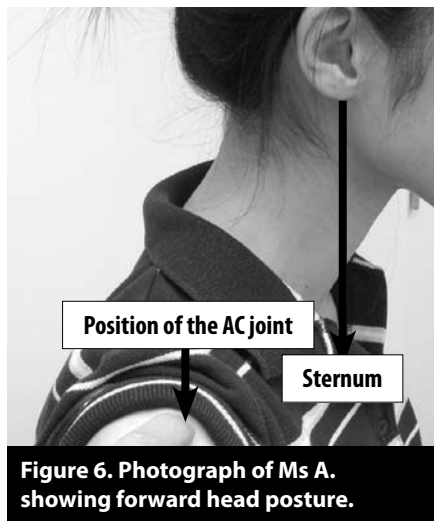


Figure 6. Photograph of Ms A. showing forward head posture.



Figure 7. Dr. Lam injecting the structures that attach to the angle of the mandible.



Figure 8. Dr. Lam injecting the left TMJ.

REMARKABLE RECOVERIES

The Use of Prolotherapy in the Treatment of Chronic Overuse Shoulder and Neck Pain, Neurogenic Pain and Hip Degeneration in an Incomplete C4-C5 Spinal Cord Injury Patient

Ross A. Hauser, MD & Kimberly A. Gruen, BA

ABSTRACT

Chronic pain, osteoporosis, and joint degeneration are common problems facing a spinal cord injury (SCI) patient. To date, there are no published case studies documenting the effectiveness of Prolotherapy in reducing pain and improving joint function in SCI patients. The following is a case study of the use of Prolotherapy to decrease neuropathic, overuse, and pain from joint degeneration as well as improve function in an incomplete C4-C5 quadriplegic.

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KEYWORDS: Prolotherapy, neurogenic pain, overuse injury, quadriplegic, spinal cord injury.

Spinal cord injuries currently affect approximately 450,000 people in the United States with an estimated 8,000 to 12,000 new injuries per year.^{1,2} About half of these injuries result in quadriplegia. One of the major complications associated with all spinal cord injuries is the treatment and management of chronic pain.³⁻⁶ It has been estimated that 40-100% of spinal cord injury (SCI) patients experience chronic pain after a SCI.⁷⁻⁹ Chronic pain greatly impacts the physical, and psychological well-being, as well as the quality of life of the SCI patient.^{10,11} The severity and persistence of pain associated with SCI are, however, of greater significance than its prevalence. It is not unusual for these patients to experience pain for decades because their longevity approaches normal life expectancy owed to early interventions and rehabilitative measures. Treatment of the chronic pain associated with spinal

cord injuries has been an ongoing process, and many clinicians are unsure of how to assess and care for this complication.¹²⁻¹⁵ Some commonly used treatments include occupational and physical therapy, exercise, medication, and surgical procedures.¹⁶⁻²⁰ Unfortunately, most treatments have proved to be relatively ineffective. The lack of effective treatment for SCI pain causes these patients great frustration and, in addition to long-term motor disability, they must endure intractable pain. For this reason, people with SCI and chronic pain are seeking alternative treatments. One of the treatments they are finding is Prolotherapy. Prolotherapy involves injections into injured ligaments, tendons and joints to stimulate repair. Prolotherapy is becoming a widespread form of pain management in both complementary and allopathic medicine.²¹⁻²⁴ It is being used in the treatment of spine and joint degenerative arthritis, as well as for pain management in many areas, such as meniscus tears, fibromyalgia, and a variety of sports injuries.^{25,26}

Another common complication for many SCI patients is osteoporosis and joint degeneration below the lesion level.²⁷ Immobilization secondary to SCI is associated with marked and rapid atrophy of bone. The elimination or decreased use of leg muscle activity causes the loss of calcium and phosphorus which leads to bone loss. The condition can be avoided or lessened if the patient is able to stand using a standing frame or other supportive device.²⁸ The use of a standing frame has many other beneficial effects, such as decreased pressure sores, increased overall strength, and an improved sense of well-being.

The following is a case report on the use of Prolotherapy in the treatment of a quadriplegic with an incomplete C4-C5 spinal cord injury. The goals of the Prolotherapy in this patient were to help eliminate shoulder, neck, and thoracic pain and to stabilize the patient's right hip so he could continue to stand with the aid of a person or a standing frame.

CASE REPORT

Michael Schwass is a 49 year-old Caucasian male who sustained an incomplete C4-C5 spinal cord injury while playing hockey in 1975 at the age of 16. (See Figure 1.) He underwent three surgeries following the injury, which included a cervical spinal fusion at C4-C7 using a bone graft. In 2002, Michael came to Caring Medical and Rehabilitation Services (Caring Medical) at the age of 43, with complaints of upper back, neck, and shoulder pain. His primary concern was his recent inability to stand due to a degenerated right hip as a result of osteoarthritis. He specifically lost the ability to make standing pivot transfers

because his left hip would give out during this movement. Though Michael was a quadriplegic, he prided himself on being able to stand independently without the use of leg braces for up to one minute. He was also able to stand independently for short periods of time with the aid of his standing frame. In late 2001, he lost the ability to stand independently at all and his physicians felt it was because of a collapsing degenerated right hip. (See Figure 2.) He also reported that it was becoming increasingly more difficult for him to sit in his wheelchair because he was losing range of motion of his hip. Sitting was getting unbearable because of the pain. His orthopedic surgeon told Michael that a total hip replacement was his only option. Michael noted that his orthopedist after seeing his X-rays commented "I don't know how you can stand the pain in there!" He and his surgeon discussed that he was at increased risk of wound infection and some other complications because of his spinal cord injury, and subsequently the spasticity in his legs that came with it. Looking for an alternative to total hip replacement, he sought out an evaluation for Prolotherapy.

Michael also wanted an opinion on his right shoulder and thoracic pain. He reported the shoulder pain as achy in quality and located at the front and top of his shoulder, which increased with driving. Michael reported that the thoracic pain was burning in quality and the severity of pain increased with sitting for prolonged periods. On the initial visual analogue scale (VAS) of 0 - 10, his neck pain rated a 7, shoulder an 8, and thoracic a 6.

On initial physical examination he was totally dependent on transfers. He had no movement at all in his legs. He had normal sensation in the face and neck and some in the shoulder region. Below these areas he had about 50% sensation in the torso and on the legs he was able to sense light touch about 20%. In regard his motor system, he had normal neck strength. He had some antigravity movement bilaterally in shoulder abduction and shoulder internal rotation. He could flex his elbows when gravity was eliminated. There was no movement of the hand or wrist. He had no active leg movement. He had tremendous spasticity in both legs. The hip exam was very difficult because of spasticity but hip flexion appeared to be 85 degrees, but internal and external rotation was impossible to assess due to spasticity. He had notable tenderness to palpitation in his posterior neck and upper back specifically along the trapezius and levator scapulae attachments. He also had tenderness at the acromioclavicular joint and at



Figure 1. Michael Schwass at the time this article was written.

the supraspinatus and subscapular tendon attachments in the right shoulder. Severe decrease of range of motion was observed in all planes of his neck. Extension was more affected than flexion. His thoracic exam was unremarkable, as sensation was decreased in this area. His X-rays showed hip dysplasia with flattening of the femoral head with superior migration and a loss of joint space, sclerosis, and large osteophytes bilateral with the right hip being worse than the left.

Treatment with dextrose Prolotherapy was recommended with the objective to decrease or eliminate thoracic, neck, shoulder, and hip pain and improve hip motion. An additional goal for the hip was to increase his ability to retain the erect position with the use of a standing frame for extended periods of time and regain the ability to do standing pivot transfers.

Prolotherapy was started on his hip in September 2002 using the Hackett-Hemwall technique of Prolotherapy. A 15% dextrose, 10% Sarapin, and 0.1% lidocaine solution was injected into and around the following structures: right hip, greater trochanter, and periarticular structures. (See Figure 3.) Eight cc of solution was injected into the joint and another 30 injections with 40cc of solution were used to complete the treatment.

Michael could stand independently for a few seconds by the fifth treatment, and by the fifteenth treatment felt much more stable with his right hip in regard to transfers and standing. He stated at that time that he was 60% of where he wanted to be. In 2006, after 25 treatments of dextrose Prolotherapy, Michael was able to stand completely on his own for almost one minute due to improvement in hip stability. By this time his hip flexion range of motion had improved to 100 degrees. He could now sit for extended periods of time without pain.

In the meantime, Michael began receiving Prolotherapy to his neck, shoulder, and thoracic region. For his neck pain, Prolotherapy was given to his facet joints and



Figure 2. Non-weight bearing AP right X-ray. This X-ray shows Michael's collapsing right hip.

transverse processes of C2-C7, as well as the superior and inferior nuchal ridge on the occiput. The supraspinatus and subscapularis tendon attachments, glenohumeral ligament attachments, acromioclavicular joint and coracoid process were injected in his right shoulder. In regard to his thoracic area, the facet joints and costotransverse joints from T4-T10 were injected.

From 2002 until 2008, Michael received a total of eight treatments to his neck with a 75% pain improvement reported in November 2007, six treatments to his shoulder where an 85% pain improvement was noted in

November 2006, and 10 treatments to his thoracic region where a 90% pain improvement was reported in June 2007. He no longer has shoulder pain with transfers or driving. At his last treatment session, his neck pain was down to a 2 (VAS), shoulder pain 1, and thoracic pain 1.

DISCUSSION

This case study illustrates that Prolotherapy can improve the quality of life for quadriplegics. Michael, like many quadriplegics, suffers from chronic pain in his shoulders and neck, most likely from overuse, and also neurogenic pains in his upper and middle back. What primarily



Figure 3. Injection sites for Prolotherapy to the right hip.

brought Michael to get a Prolotherapy evaluation, however, was his decline in standing transfers because of a degenerating hip. Michael, because of his innate tenacity and personality, has not given up on the idea of a quadriplegic standing on his/her own two feet. (See Figure 4.) It is well known in the rehabilitation field that standing is an excellent exercise for those with spinal cord injury to prevent pressure sores and slow down the onset of osteoporosis.

In the case presented, Michael received Prolotherapy to his right shoulder. His pain level went from an 8 to a 2 (VAS) with Prolotherapy. Because Michael has no voluntary leg motion, like all quadriplegics, his shoulders feel the major force of all transfers as well as physical and daily living activities.²⁹ All of these activities place a great deal of stress on the bones, joints, and soft tissues of the shoulder complex, placing these structures at significant risk for overuse and injury. Overuse-type injuries are the most common cause of shoulder pain in the chronic SCI population.³⁰ The structures most affected are the rotator cuff tendons. Risk factors for shoulder pain in spinal cord injury include duration of injury, older age, higher body mass index, the use of a manual wheelchair, poor seated posture, decreased flexibility, and muscle imbalances in the rotator cuff and scapular stabilizing muscles.^{31,32} Michael had basically all of these risk factors and made only a little progress with traditional physiotherapy to help his shoulder pain. Prolotherapy to his rotator cuff tendons gradually helped him regain his shoulder function. The shoulder joint, specifically the rotator cuff tendons, are commonly treated with Prolotherapy.^{33,34} Traditionally, the main use of Prolotherapy has been on tendinopathies and ligament sprains in peripheral joints.³⁵⁻³⁷

In regard to his neck, Michael was seen about 30 years after his multilevel fusion. His neck CT scan was done before coming to Caring Medical and showed extensive degenerative changes above and below his fusion. This type of response is very common. After a segment of the spine is fused, increased pressure in the vertebral segments above and below the fusion is typically seen. This additional stress on the adjacent segments seems to increase the rate of degeneration at these joints.³⁸⁻³⁹ Michael responded well to the Prolotherapy of his neck. His pain level went from a 7 to a 2 (VAS). Prolotherapy has a long history of being used in the treatment of spine and joint degenerative arthritis.^{40,41} This is especially true in regard to chronic low back pain arising from



Figure 4. Michael can now stand erect with help from his personal assistant, as well as Prolotherapy.

the sacroiliac joints and as an alternative to surgery.⁴²⁻⁴⁴ Prolotherapy has been shown in low back studies to improve pain levels and range of motion.⁴⁵⁻⁴⁸ In double-blinded human studies the evidence on the effectiveness of Prolotherapy has been considered promising but mixed.⁴⁹⁻⁵⁰ In regard to Prolotherapy studies on the neck Prolotherapy has been shown to be effective for facet joint arthropathy, cervicogenic pain and headaches, and cervical instability.⁵¹⁻⁵³

Michael did not get hip replacement surgery, partly because of his fear of the hip replacement dislocating, which is of increased risk when a person has spastic quadriplegia.⁵⁹ In Michael's case, his major goal was standing and transferring better. He feels that his hip stability is much improved after the Prolotherapy.

Also of interest is that Michael's neurogenic thoracic pain was also significantly reduced with Prolotherapy. Most people with spinal cord injury suffer from abnormal

sensations and pain below the injury site.⁶⁰ These abnormal sensations are often “burning” or “freezing” with pain ranging from mild to severe.⁶¹ When the pain is a burning quality the patient is often labeled as having dysesthetic pain syndrome. About 11% of all SCI patients have painful dysesthesias and another five percent have non-painful but chronic and distressing dysesthesia.⁶² The term neurogenic pain presumes that the origin of the pain stems from the SCI.

dysesthesia – an unpleasant abnormal sensation

Regardless of the nomenclature, the condition is difficult to treat even with conventional pain-killing drugs.⁶³⁻⁶⁵ Sometimes SCI patients seek neurosurgical procedures to ablate some of the pain tracts in the spinal cord. This usually fails to relieve chronic SCI pain and frequently produces a higher level of neurological loss and deafferentation.^{66,67} Prolotherapy could offer a non-surgical treatment option also for this condition.

deafferentation – the elimination or interruption of sensory nerve fibers

SUMMARY

This case study exhibited many of the difficult to treat pain issues that occur in quadriplegics. Michael presented with neurogenic thoracic pain, a dysplastic painful hip, neck degeneration above and below the level of his fusion, as well as an overuse injury of his right shoulder. We were able to help Michael with all of these conditions through treatment with Prolotherapy. He regained some hip stability which helped him improve his standing pivot transfers and his ability to stand independently. Prolotherapy treatments provided relief of Michael’s shoulder, neck, and thoracic pain. Chronic pain is common after spinal cord injury and is difficult to treat effectively. Further research into Prolotherapy with this patient population seems warranted. ■

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W O N D E R W H Y ?

The Making of a Prolotherapist

Scott R. Stoll, MD

Dr. Stoll performing Prolotherapy on a patient's knee.

Enthusiastically, I started my first day of practice as a Physiatrist with all of the tools I learned in training, ready to diagnose and treat all of the sports and spine maladies I had so carefully studied. I worked diligently to practice evidence-based medicine and applied solid, scientifically proven principles to the patients who presented in my office each day. Over the course of time however, my patients did not seem to be getting better and moving on with their lives. I began to recognize that I was accumulating a growing population of patients requiring on-going treatment and medications to maintain their already limited daily activities. I was forced to ask myself, “What am I doing to improve my patients’ conditions and return them to high quality, independent lives?” and “Am I creating a population of patients who are dependent on a system of passive treatment for their quality of life?” Many of these people related stories such

as an inability to pick up their baby out of the crib, or even hold the baby for more than a couple of minutes due to severe pain. Dads, moms, and grandparents were unable to play with their children and often had to say no to those pleading, smiling faces. Some faced economic hardship, as they were unable to return to their jobs due to unremitting pain. Many had significantly reduced the sphere of their quality of life, living to just to get through the day. I began to realize that I did not have an answer for my patients and I refused to settle for the easy answer of “You will just have to live with it.”

Working as a team physician for a Division I University, I also began to see a large number of athletes with “soft tissue” injuries not identifiable on traditional imaging studies, yet limiting their participation, and in some cases preventing them from active play. The trainers, athletes, and parents were frustrated once conservative treatment was exhausted but the pain and impairment persisted. All of the treatment modalities I learned in training fell short and I was forced to ask myself, “What am I treating and is there a better way?”

Finally I began to see a trend of both recurrent and recalcitrant pain in my treatment of low back pain patients. Patients that were seemingly success stories early on, and had returned to their lives after one or two transforaminal epidurals and Physical Therapy, would return to my office reporting the unfortunate return of their low back pain. Further intensive treatment following all of the recommended algorithms for pain management and rehabilitation returned mediocre results and a large number of defeated patients. The best of conservative care, including kinetic chain based physical therapy, fluoroscopic injections, chiropractic treatment, acupuncture, dietary excellence, medications both pharmaceutical and homeopathic, and medium level laser, failed to resolve their pain syndromes. In many of the cases, because of vague and diffuse symptoms, I could not identify the pain generator and could not offer any further treatment options, nor any hope.

Motivated by the stories and faces frequenting my growing practice, I began to intensely research the musculoskeletal system and treatment options. My focus turned toward regenerative and restorative medicine focusing on healing. I postulated that if treatment could stimulate healing and restoration of injured tissues, then patients would not only experience pain relief, but would gain their independence from my disease management based practice and see me only at the restaurant or juice bar.

I recalled hearing during residency, some vague and generally unfavorable reports of “sclerotherapy” treatment for low back pain. So with no other leads, I began to read online articles about this “controversial” treatment. During the research process, I found numerous articles touting the benefits of a more modern concept, Prolotherapy or regenerative injection therapy. The information seemed promising and I contacted Dr. Reeves by email to ask him if these patient histories and success stories were accurate. He confirmed the remarkable benefits and referred me to the American Association of Orthopaedic Medicine, where I attended my first conference in Chicago in 2004. The lectures answered many of my seemingly unanswerable questions, highlighting the importance of collagen and ligament injury as a treatable source of chronic musculoskeletal

pain. The big picture of musculoskeletal medicine started to come into focus for the first time. With eyes wide shut, I watched Prolotherapy performed for the first time during the patient demonstration section, almost not believing what I was seeing. I never imagined that a needle could be accurately passed through the skin so many times without fluoroscopy. Later, I had an opportunity to visit with these patients who shared case histories that reminded me of many of my patients. I was encouraged as they validated the benefits of Prolotherapy, their changed lives, and I was hopeful that I was now on the right path.

I was trained to use fluoroscopy for injections and felt grossly under-trained to perform blind spinal injections. While at the AAOM conference, I learned about the cadaver based program held annually at the University of Wisconsin, through the Hackett Hemwall Foundation, and attended their fall conference later that year. The course thoroughly prepared me to begin safely performing Prolotherapy, and I returned to my office to begin performing some basic Prolotherapy on knees, shoulders, and elbows. With each passing month, patients returned to my office reporting improved pain, function, and quality of life, and substantially decreased use of any pain medications. My confidence grew both in my skills and in the positive outcomes achieved through the regenerative injections. I also noticed that my patients were able to return to their lives and reached a point where they no longer needed to schedule follow-up visits. Enthusiastically, I pursued more training through the University of Wisconsin courses, returned to my anatomy books and discussions with mentors. Prolotherapy and the study of Biotensegrity dramatically expanded the successful treatment of my patients. More than any other treatment I currently employ in my practice. It has become a cornerstone in my conceptual understanding of the musculoskeletal system, led to more accurate diagnoses, and produced consistently successful treatment protocols. Furthermore, this field brought clarity where there was once confusion and uncertainty.

During the past five years, the study and application of Prolotherapy has filled a critical void in my education that has transformed both my practice and the lives of my patients. I also realize that I have just embarked on an exciting journey of continual learning with a tremendous group of like-minded physicians and practitioners whose ideals truly embody the timeless ideals of the Hippocratic Oath. ■



Dr. Stoll using Prolotherapy to eliminate the pain from a hip injury.

Pain Management Using the Power of the Mind

Gina Orlando, MA, CH

ABSTRACT

The purpose of this article is to describe medical hypnotherapy and the role it plays in the management of the pain patient. The author presents three case studies discussing the beneficial effects of hypnotherapy on generalized body pain, as well as two children with RSD.

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KEYWORDS: Emotional Freedom Technique, hypnosis, hypnotherapy, mind-body, pain management, RSD.

Much research shows the positive effects of using hypnotism for acute and chronic pain reduction and management. Hypnosis is the practice of approaching the subconscious mind with simple but powerful positive suggestions and images for changes that the client desires and deserves. When using hypnosis for pain management we remind the client that “pain isn’t pain until the brain translates it as pain.” Another way to say that is “change the mind, change the brain, change the pain.” So we help clients use the power of their minds to reduce “discomfort” and increase “comfort,” words we use instead of saying the word “pain” to avoid bringing the latter to mind and perhaps focusing on it, thus increasing it.

This article will explain what hypnotism really is, and will give some case studies showing its effectiveness for chronic pain reduction and management to encourage you to consider adding this modality, along with Prolotherapy, with your chronic pain patients. Hypnosis is helpful for somatic and visceral nociceptive pain, neuropathic pain and psychogenic pain.

There is much confusion about what hypnosis really is. Hypnotism was approved by the AMA in 1958. Because of its long history, it is considered traditional medicine

rather than alternative medicine. Current JCAHO/NIH standards require hospitals to offer non-pharmacological management for pain. Hypnosis is an appropriate way to meet this standard. Hypnosis is often used in medical environments under the name of “guided imagery,” since that phrase doesn’t carry the baggage that the word hypnosis has wrongly acquired. There are several titles for practitioners, depending on state laws. Some call themselves hypnotherapists, or consulting hypnotists or clinical hypnotherapists. Hypnotism is a certified profession, not a licensed one. So if the practitioner does not have a medical or therapeutic license, they have to get a medical referral to do medical work stating “referring client for hypnotherapy for pain management.” There are highly competent hypnotherapists from a variety of backgrounds. Insurance rarely pays for hypnotherapy so the client is instructed to pay at the time of service in many offices. They are always encouraged to submit the receipt to insurance.

So what is hypnosis? Let me first explain what therapeutic hypnotism is *not*. It is not what you see portrayed on TV, movies, cartoons, and on stage where a hypnotist appears to have control over someone. This couldn’t be further from the truth. A hypnotist has no control over a client. In fact, *all hypnosis is self-hypnosis*. In the state of hypnosis *the client is in control*. The role of the hypnotherapist is to help the client get back into control. In the case of pain management, it is to reduce feelings of discomfort and allow feelings of comfort. In the session the hypnotherapist facilitates a deep state of relaxation where the client’s subconscious mind becomes available for positive suggestions for the change they desire. The hypnotherapist acts like a caring coach. The client will respond to suggestions that they are open to, because the majority of humans are suggestible. There are ways to check for suggestibility. Ask a client if they have ever followed a suggestion to see a certain movie, or go to a new restaurant. Ask the client if they have ever daydreamed, or gotten very involved in a good book or TV show. These are all accurate indications that a client can be hypnotized, along with possessing normal intelligence, having the ability to concentrate, and being willing to change.

The state of hypnosis is a natural mind state in-between waking and sleeping. It is a time when the subconscious mind becomes available for new positive suggestions and

images for desired change. Thought is powerful energy. One's life flows in the direction of the most dominant thoughts. In the hypnotic state the client becomes highly responsive to suggestions for the positive changes they desire. It is very natural, available for clients to use, given to each of us by a Higher Source to help manifest health, joy, and positive changes in your life. It's all good. Nothing bad can happen to you in this state. The reason hypnosis is so effective for improving health, and aiding in pain management, is that the subconscious mind controls the body's millions of functions. It's also the place where habits and emotions live, and where the invisible walls of resistance can reside. Pain becomes a bad habit that can be unlearned in most cases. Some clients can have secondary gain with their pain. This will be discussed later.

Each person uses various mind states every day, described by a number representing the number of cycles per second (Hertz, Hz) that their brain is moving at in that state. You are familiar with all of them.

- Beta** = awake and alert 30-13 Hz
- Alpha** = relaxed 12-8 Hz
(the state of hypnosis)
- Theta** = deeper hypnosis, imagery, near sleep 7-3 Hz
(a deeper state of hypnosis)
- Delta** = sleep, dreaming 2- .5 Hz

The state of hypnosis involves the Alpha and Theta states. Everyone is familiar with these states because we flow through the Alpha and Theta brain wave states each night as we fall asleep. We also drift into either or both of them when daydreaming, during meditation and prayer, when watching TV, when running or playing in the "zone." It is an altered state of consciousness, just like sleep is an altered state of consciousness, but it's not as deep as sleep. So it's deeper, slower and more relaxed than being awake and alert (Beta) but less deep, less slow than sleep (Delta). It is natural, simple and normal and may be employed for every acute and chronic pain client. Yet, people have not been taught how to use this natural mind state. That is the role of a hypnotherapist, specially trained in medical uses of hypnotism.

There are many styles of hypnotism. I use a common style of therapeutic hypnotism, using my trained voice and special licensed relaxing background music, along with encouraging the client to close their eyes, and coach them on the use of abdominal breathing to relax. I don't use any visual objects, such as a watch, nor do I touch the client's



Figure 1. A client (her husband, Marty Berg poses as a client) relaxes comfortably as Gina speaks to him, allowing him to enter trance. Note the biofeedback monitor on client's left hand and graph being created on computer screen.

body. I don't ask questions during sessions. The client has an easy job. After an intake where I gather pertinent and specific information on the client's pain history and create rapport, I ask the client to sit back in a comfortable recliner. (See Figure 1.) When the client's eyes are closed, I begin speaking in a relaxing voice. Some clients need extra time to begin to relax. Deep, rhythmic belly breathing and progressive/autogenic relaxation are important tools for each pain management client to learn. This alone begins to ease the pain. Then I shift to saying positive suggestions, adding in words and statements that they have chosen for their suggestions. Besides relaxation, which reduces cortisol, there are other hypnosis phenomena used to help clients. These are distraction, dissociation, time distortion, desensitization, direct and indirect suggestion, analgesia, glove anesthesia, total anesthesia, and post-hypnotic suggestion. We never override the brain's ability to create pain in order to signal tissue damage. Hypnotherapy and EFT (Emotional Freedom Techniques, a waking hypnosis technique which uses tapping on acupressure points) are also effective ways to change underlying emotional issues with hypnotic approaches.

Clients need not concentrate on the words. Many people hear all the words; for others the words drift away, but the suggestions still get in. Others get some "busy mind" but the suggestions still get in. If "busy mind" occurs, the client is instructed to simply bring their attention back to their breath, the words and the music. In the state of hypnosis, clients feel relaxed. Some people feel so relaxed that their arms and legs feel heavy. Others feel light and

tingly. Some may experience time distortion, images, or some eyelid fluttering. Hypnosis is not being unconscious, in a coma, “out,” “under” or asleep.

To track the level of relaxation which correlates with depth of hypnosis, I use a biofeedback monitor on the client’s left hand. It tracks galvanic skin response, measuring changes in the electrical conductivity of their skin. Moist skin conducts electricity better than dry skin. As the client relaxes, skin moisture content decreases and the electrical conductivity decreases as well—a highly accurate reflection of changes in their physiology. The biofeedback monitor is attached to my computer and creates a stress reduction curve which correlates to the six levels of hypnosis depth, with six being the deepest. (See Figures 2 & 3.) I get immediate feedback and the client receives this quantitative feedback at the end of the session. It is always fascinating to them.

As the body relaxes, the brain waves will automatically slow down and the client drifts into a state of hypnosis. It is natural and very powerful. Some people drift lightly, some people enter a deep state, most are somewhere in the middle. With practice, most people can go deeper. The client always receives their recorded hypnosis session on a CD, which they use every day at home to increase their comfort, feel more relaxed, in control, sleep better and have a more positive attitude. As they use the CD every day, it also improves their self-hypnosis skills. Clients sign up for a series of sessions, with a three-session minimum.

CASE STUDY #1

(CLIENTS ARE NUMBERED FOR PRIVACY REASONS.)

A 65 year-old woman, referred by a physician for pain control who described her pain as generalized body pain, especially back fatigue and pain in her knees. Even with Prolotherapy, she was on medications for pain, muscle relaxation and anxiety, including Vicodin, Norco 10/325, Soma 350 mg, and Klonopin 0.25 mg. Even with medications and Prolotherapy, this client’s pain often was at a 10, which totally disabled her. This client lives hundreds of miles away, so our initial intake was by phone. Upon hearing her story of a series of difficult diseases, conditions and falls, I could hear the deep sadness, trauma and grief of a woman who had lost the vibrant, loving, full life she once had. Upon getting breast cancer in 1990, with two mastectomies and breast reconstruction, her husband cut off from her in every way. This caused great emotional pain, shock, anger,

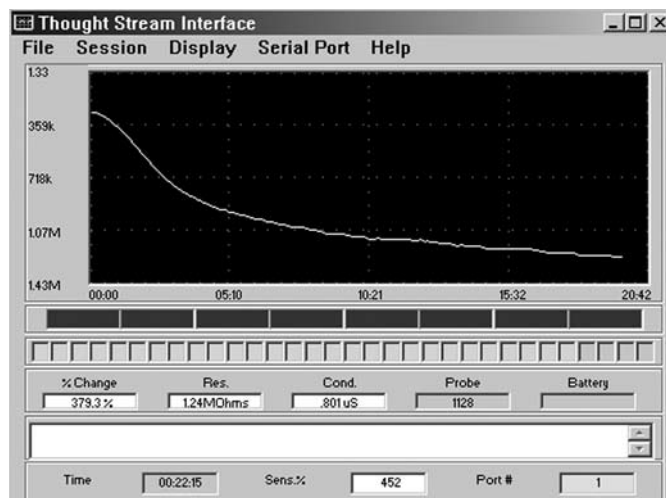


Figure 2. A classic, deep relaxation curve. The client went to a level 6 of hypnosis depth (the deepest). The time span of the session was 20 minutes.

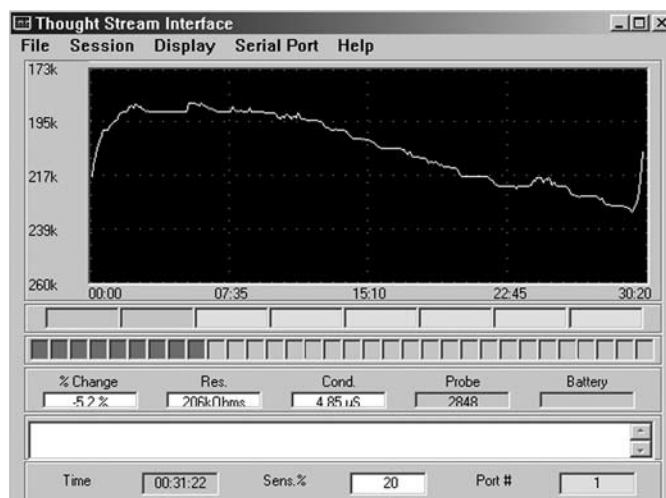


Figure 3. This client initially experienced some stress (upward curve) but then relaxed well and went to a level 2 of hypnosis depth.

sadness, resentment, betrayal and grief. When one of her implants leaked, her health was very impacted in many ways, with immune system problems and much pain. She spun downward and became disabled and was on full disability for years.

She was very open for healing and felt “very excited and confident” of the hypnosis support. In our field, we acknowledge that emotions can lead to physical manifestations of illness and pain. Since I wasn’t going to see her for weeks, and wanted her to begin to get some support and relief, I recommended that she order two guided imagery CDs; one dealing with pain management

and the other to begin healing the trauma and her broken heart. She ordered both and listened to each one every day. These pre-recorded sessions are helpful. I also create such CDs and make them available to my clients for purchase. These guided imagery sessions began a healing process for her. She was a very dedicated, diligent client, with a deep desire to regain some sense of her former self, and feel more comfortable and in control of her body. She was determined to get off pain medications, even though her physician wondered if that were possible.

We had six sessions over a 3½ month period. She scheduled with me each time she was in town for her Prolotherapy sessions with her physician. She steadily improved with these interventions of hypnosis, (including some classic relaxation and breath techniques, Ericksonian approaches, imagery, desensitization, sleep improvement, ego strengthening, healthy boundary setting and problem solving), EFT, and Prolotherapy. The Prolotherapy alone, for this client, helped her, but didn't allow her to be free of the pain medications, or long bouts of intense pain. After the second session, her pain was down to 5-6. It was in this second session that I sensed she was in an abusive relationship with her husband. The hypnosis session dealt with creating healthy boundaries. We talked of options, resources, and a book she could read. She read the book, which helped her gain a lot of strength and a firm reality check. Her pain reduced substantially after that. She regained some of her power and created more safe and healthy boundaries for herself. She was getting herself back.

She was quite the student with the hypnosis CDs and listened to them regularly, incorporating the messages, allowing her body to heal and move into comfort. It was a beautiful process to witness. Again, I function as a caring coach, helping to create a safe and healing environment, honoring mind, body, emotions, energy and spirit. The client does the work. She gets an A+ for effort and determination. Ten weeks into this process, not only had she established newfound healthy boundaries with her husband, but she got off her pain meds and her pain often gets down to 0, sometimes in the 1-3 range. When occasionally it spikes to a 10, she practices belly breathing with a self-hypnosis suggestion, lays down for a few minutes, and brings it down to 0 with her breath and her practiced mind. Her husband is happy and relieved that she is doing better, and has high curiosity about her process, but is not trusting it yet. Her doctor and staff

were delighted that she could get off the pain medications, and have such dramatic pain relief. Her spirituality was an important part of her recovery. She felt that God was also part of her healing. At the end of her sixth session she said, "Awareness is the key. I can find my way. Thank you!"

You may be wondering what part of the recovery could be attributed to the Prolotherapy, the hypnotherapy, the EFT, the caring support. Remember, with Prolotherapy alone, this client didn't get complete relief. *Yet, in a holistic approach, we often have to use several modalities to deal with the complexity of a client's issues. That's the challenge and gift of the holistic field. We deal with the complex terrain of mind, body, energy, emotions and spirit.*

CASE STUDIES #2 AND #3

Both of these clients were children with RSD. They had very different outcomes with hypnosis support. Both had secondary gain with their condition, which allowed them to have special time with Mom and stay out of school.

Client #2 was a 13-year-old girl in 7th grade. She came to see me seven months after a broken arm had healed. Her pain remained. She stated the pain was pretty static at an 8. She could not attend school, so her mother, a nurse, did extraordinary things to be home and present for her youngest daughter. They had a very close relationship. They tried physical therapy and counseling, and then decided on hypnotherapy. The mother stayed with us in the sessions (I have since changed my policy on this). Some traditional hypnotherapy approaches were used to support this client to increase her comfort, and EFT (Emotional Freedom Techniques) was also used. The client did not experience any shift in her discomfort. Yet she and her mother felt encouraged to continue. In the sixth session the issue of secondary gain was explained and she began to get hypnotic support for this common component of chronic disorders. I began to suspect that Mom also had some secondary gain in this situation, which forced her to have some special alone time with her youngest child. This was discussed. In the eighth session, I asked the Mom to wait in the waiting room. I continued to work with the client on the secondary gain of having this special time with Mom, and that if her pain improved, she'd have to lose this special time and go back to school. Her discomfort did not improve, and with the separating of Mom and daughter, this client did not return. I share

this case study to remind that a client needs to want the result in order for it to happen. Secondary gain is very common in all chronic conditions.

Client #3: This girl was a precocious 9-year-old in 4th grade. She had a broken ankle which had healed six months earlier. The pain remained and she was diagnosed with RSD. She also couldn't go to school. Her pain ranged from 5-10. Her mother also did extraordinary things to be present for her oldest daughter and stay home with her. She had a tutor during this time. Her younger sister was in school, so she also had some very special time with Mom. She did miss school, her friends, and she had a major part in their musical *The Wizard of Oz*, and was concerned that she wouldn't be able to perform. So she had some motivation to get better.

She responded beautifully in the first session to classic hypnotherapy and EFT. We discussed the concept of secondary gain. "Could it be that even though you really hate having this ankle pain, that you do get a benefit by having some special alone time with Mom?" She said, "Of course! I get to have Mom all to myself. My life ended the day my little sister was born!" I couldn't help but smile at her clarity and honesty. "Do you think you can come up with some ways that you and your Mom could have special time together during the week when you get better and can go back to school?" She had an immediate and creative list of things she could do with her Mom, including a weekly time to go out and have lunch or tea together. I asked her to write them down, and discuss them with her mother. She did, and Mom agreed.

In between her first and second session, she listened to her hypnosis CD and used the EFT technique; her discomfort fell to zero. She went back to school, practiced in the musical, and enjoyed new and healthy ways to have special time with Mom. She was a hit in her musical. Her pain never returned. People said it was a miracle. The miracle is that the mind is powerful. Children can respond so quickly to hypnotherapy and EFT. They use creative problem solving well, too.

SUMMARY

Most acute and chronic pain management clients respond well to hypnotherapy which increases their comfort substantially. Many have been told that they will have to

live with their pain. They are grateful for hypnotherapy, a holistic modality and relaxing support which utilizes the power of the subconscious mind. Research supports that it is very effective. Clients get their confidence back and usually start feeling better soon. They realize how powerful their mind is and learn how to use it to their advantage to increase their comfort. "Change the mind, change the brain, change the pain."

There are many resources to learn more about hypnotherapy and pain management. A classic text book is *Hypnotic Suggestions and Metaphors* edited by D. Corydon Hammond, Ph.D., an American Society of Clinical Hypnosis Book, W.W. Norton & Company, New York, 1990. There is a whole section dedicated to pain management. You can easily search the Internet and find a wealth of articles and research in your favorite medical journals. Often, medical journals in other countries are more open to this research.

If you wish to train to become a hypnotherapist, you may study with the National Guild of Hypnotists program, or with the American Society of Clinical Hypnosis. You can offer your pain patients pre-recorded pain management CDs as an easy way to introduce this modality. Please contact me for this information. Private clients and sessions by phone are also available.

BIOGRAPHY AND CONTACT INFORMATION:

Gina Orlando, MA, CH works as a certified hypnotherapist and wellness consultant. Gina has a passion for health in body, mind, emotions and spirit and has worked for 28 years as an educator, consultant and writer in the holistic health field, helping people of all ages to make positive changes in their lives and health. She earned her Master of Arts degree from DePaul University in 1998 as an educator and consultant in holistic health promotion and complementary medical approaches to health. She is a Certified Hypnotherapist, also trained in medical uses of hypnotism. She uses hypnosis, relaxation, guided imagery, Emotional Freedom Techniques, other mind-body-spirit-energy techniques as well as wellness education in her private and group work with a wide range of issues and conditions. She facilitates groups through Loyola Hospital at Gottlieb and companies in the Chicago area. She practices in Oak Park, IL and can be reached at (708) 524-9103. Website: www.ginaorlando.com Email: GOrlandoMA@aol.com ■

FOUR-LEGGED PROLOTHERAPY

Practical Application of Prolotherapy in Canines: Case Studies

Babette Gladstein, DVM

The current surge of interest in Prolotherapy—for humans and animals—is gratifying. As a holistic veterinarian and Prolotherapy practitioner in New York City, I have found the demand for treatment increasing, along with the number of successful outcomes. Effective and practical, Prolotherapy can easily be incorporated into modern veterinary practice when physical rehabilitation of chronic joint pain is required. In my experience, it can sometimes obviate the need for orthopedic surgery—especially meaningful in an older animal—yet it can also be used in an adjunctive capacity to some other treatments, including surgery. The common denominator for use is degenerative disease, trauma or injury.

The results are generally predictable and include improved mobility and quality of life for the pet, along with a reduction in—and often elimination of—pain. Yet each individual animal responds differently to Prolotherapy. I usually expect to see significant improvements, if not resolution, in one to three sessions, while more extreme or challenging cases may require a longer series of treatments.

I am happy to share with you some snapshots from my recent caseload.

CASE STUDY 1: “DEGENERATIVE MYELOPATHY AND HIP DYSPLASIA”

Clara, an 11-year-old yellow Labrador weighing in at 60lb, is a beloved family pet. Her owners are committed to maintaining her health and preserving her quality of life. She presented for Prolotherapy treatment with degenerative myelopathy in the hindquarters. She had also been diagnosed with arthritis and hip dysplasia.

At first, Clara had responded well to acupuncture and electric stimulation. However, within five months, the efficacy of her treatment plan declined. At that time, she became noticeably weaker, and walked awkwardly with the hind legs crossing over. She underwent her first

ABSTRACT

Prolotherapy is easily incorporated into the modern veterinary practice and can often obviate the need for orthopedic surgery. This article provides six case reviews of animals successfully treated with Prolotherapy.

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KEYWORDS: animals, hip dysplasia, patella subluxation, Prolotherapy, veterinary medicine.

Prolotherapy treatment and, immediately after, was able to walk without the crossover.

Three weeks later, after her second session, Clara could walk comfortably again. Her balance and stride were markedly more stable, with her hind legs staying parallel, about 9 to 10 inches apart. This pattern was to be seen after every one of Clara’s Prolotherapy sessions. The improvement was sustained for approximately six weeks, when her hind end started to weaken again. A third Prolotherapy treatment focusing on Clara’s back and hips, improved motion and restored the old girl’s vigor. Although other health issues interrupted her Prolotherapy treatments for a few weeks, she was able to have another session about a month later. Again, Clara’s mobility was satisfactorily restored. However, just two days later, Clara skidded on a slippery floor and injured her front elbow. Her recuperation took several weeks and, although she received acupuncture and electric stimulation, she did not receive another Prolotherapy treatment for her hindquarters for more than two months. Again, the results were dramatic, with greatly increased mobility and comfort for Clara.

CASE STUDY 2: “RELIEVING THE RIPPLING EFFECTS OF TRAUMA TO THE PATELLA”

The mixed lab puppy, full of beans, had managed to injure herself somehow. Diagnosed with bilateral medial patella subluxation, four-month-old, 55lb Aria was found to have extreme remodeling on the left patella. The persistence on the patella was attributed to trauma according to prior vet reports. Radiographically both hips were within normal limits.

On physical exam, positive draw was noted on the right but was considerably more marked on the left knee. Palpitation of the knee, left hip and lumbar area demonstrated pain at all three sites. At this point, Aria was holding up her left leg and was completely non-weight bearing on that side.

At her first Prolotherapy treatment, Aria received injections in the painful areas. Following the session, she was able to bear partial weight, no longer held up the leg and was toe touching. The results were even more pronounced after Aria's second Prolotherapy treatment. She was found to have completely restored weight-bearing ability although noticeable stiffness behind remained. This case is ongoing. Aria is scheduled to receive a third Prolotherapy treatment soon.

CASE STUDY 3: "PROLOTHERAPY AND THE POWER OF THREE: THREE SESSIONS, THREE WEEKS APART"

Rory, a black lab mix, had gradually lost hind end stability over the course of his 13 years. The 75lb dog's condition was compounded by congenital dysplasia of the left hip. Weak and with his back legs touching, he would frequently lose his balance and fall over. This situation lasted for about a year until he began Prolotherapy treatment. Rory underwent a total of three Prolotherapy sessions at three-week intervals, targeted to restore flexibility to his back and both hips. There was notable progress after each treatment, with Rory's legs separating and, each time, he showed increasing ability to support himself. After the third treatment, Rory's hind legs were separated by at least 10 inches. No further treatment was necessary.

CASE STUDY 4: "THE PIT BULL AND THE PARTIAL REPAIR ACL INJURY"

Eight-year-old Ernie had been diagnosed with a partial repair ACL on his left knee six months prior. This was not his first ACL injury—he had already undergone ACL repair with a figure 8 on his right knee two years beforehand. Now, 60lb Ernie was presenting with a moderate (2 out of 5) lameness on the left hind leg. The treatment regimen for his left knee was administered as follows: two Prolotherapy treatments three weeks apart, with ultrasound therapy 3–4 times a week in the interval. Ernie is now walking and running normally.

CASE STUDY 5: "THE HUNT FOR RELIEF FOR DUTCH"

Dutch, a large black lab, has been trained as a hunting dog since puppyhood. He is usually active and enthusiastic about his work. At just 2.5 years old, he had undergone knee surgery, with a figure 8 repair, and a small amount of physical therapy. The 90lb dog returned to work, but 18 months later clearly had difficulty bearing weight on the knee. The problem—a reinjury—manifested after a run in the park. Laser therapy, acupuncture and ultrasound were administered to the knee on two separate occasions

but improvement was marginal. Since the knee had no positive draw and the surgery site remained intact, it was recommended that the injured knee should be given time to heal and Dutch was kept on cage rest for two weeks. The results were still not satisfactory. At this point, a Prolotherapy treatment was administered and, immediately, for the first time since the re-injury, Dutch could bear weight comfortably on the leg. The dog was able to walk in a more normal fashion. Dutch's owner was advised that another session would aid Dutch's recovery further.

CASE STUDY 6: "A BETTER QUALITY OF LIFE IN AN EXTREME CASE OF BILATERAL HIP DYSPLASIA"

Thurman, a distinctive 80lb 13-year-old dog, was noticeable for more than his bobtail. He had been diagnosed with two dysplastic hips and presented with severe instability—wobbling and collapsing, with hind legs crossing, and buckling. On examination, he was found to have general weakness, with pain in both hips and in the back area. He was started on a series of three Prolotherapy treatments, three weeks apart. (See *Figure 1*.) The benefits were marked after his second session, when Thurman's aggravated condition was relieved, with an end to the wobbling, buckling and crossing over. The ongoing general weakness also improved somewhat, and became episodic rather than constant. After his third treatment, Thurman's condition responded convincingly again, with complete elimination of pain—as evidenced by palpation—and increased joint stability. Thurman's mobility improved noticeably. ■



Figure 1. Bobtail Thurman has two dysplastic hips and is receiving Prolotherapy treatments to help regain mobility and reduce pain.

TEACHING TECHNIQUES

A New Approach for Injecting Patients with Low Back Pain using Prolotherapy Agents: Functional Prolotherapy

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

ABSTRACT

The spine is a flexible mechanical system and performs several important functions. Performing Prolotherapy to the spine for regenerative purposes often restores function completely. The authors investigated and reported on alternative positioning for injecting the lower back and pelvic ligaments.

Journal of Prolotherapy. 2009;3:181-183.

KEYWORDS: low back pain, lumbar spine, needle position, Prolotherapy.

The spine is a flexible mechanical system and performs several important functions. It must protect the spinal cord and the nerves that allow us to move about. It must bear weight to allow us to stand upright, and it must bend and twist to allow us to function in the environment.¹ For motion to occur, the bones of the spine (the vertebrae) must be separated by a flexible connector. That flexible connector is the intervertebral disc. There are a total of 33 vertebra in the spine.² Knowing all this, the clinician must ask what happens when the flexible rod does not work as well as it needs to and what if one of the support structures is not supporting the spine? Does this give rise to pain? The passive ligament support system of the spine can give rise to pain and cause referral patterns just as nerve impingement can do.³⁻⁴

The passive ligament system of the pelvis is very strong and will stabilize the sacrum and pelvis against unwanted motion.⁵⁻⁶ The ligaments that are primarily responsible for control of lumbopelvic motion are the iliolumbar ligament (IL), the long dorsal sacroiliac ligament (LD), the sacrospinous ligament (SS) and the sacrotuberous ligament (ST). The iliolumbar ligament will stabilize L4 and L5 on the ilium and sacrum and is considered a very important pelvic stabilizer.⁷ The LD, SS and the ST help stabilize the pelvis and subsequently will keep the

lumbar spine in check as well. When there is a disruption or weakness in one of the lumbopelvic ligaments, poor control of lumbopelvic motion and muscular imbalances and pain (usually chronic) are the result.

Once the clinician establishes what structure(s) are compromised and are part of the pain generating system, treatment can proceed. Treatment planning can include manual therapy, stabilization exercises and Prolotherapy to support the ligament systems and joints.⁸ Prolotherapy can directly restore the tissues and provide support to joints, aiding motion and helping with muscular control by stabilization and reducing of pain.⁹⁻¹² When a clinician decides to use Prolotherapy for a patient with low back pain, he/she must decide what solutions to use, but also where and how best to inject the material. Authors (Ann Auburn, DO (AA) and Scott Benjamin, PT, DScPT (SB)) had two years of experimental practice on what may be alternative positions for injecting the lower back and pelvic ligaments. SB had a vast history of sporting injuries which resulted in pelvic obliquities which lead him to see AA initially. Together they determined that stressing the ligamentous system using different angles and joint positions, instead of the prone position, could mimic ligament stresses in everyday situations and thus lead to improved effectiveness of Prolotherapy treatments. Their basic experiments involved having the patient flex forward at different angles for the Prolotherapy treatment to better expose the target ligament.

DETERMINATION OF AN ALTERNATIVE POSITION FOR LUMBAR SPINE INJECTIONS

Based on previous informal experimentation, the authors determined that two angles, 15 degrees and 60 degrees of lumbar flexion would be excellent choices for injection. We determined this, with the notion that in life you move through these angles during a variety of daily activities so AA and SB wanted to see the treatment effects at those angles on the ligaments. We also hypothesized that with

the 15 degree angle, the iliolumbar and the supraspinous ligaments are best reached. We also thought that the dorsal sacroiliac ligament was reachable at the 15 degree mark but wanted to also stress it at 60 since as a person moves the ligaments are stretched in various ways. With the patient forward, we wanted to also inject the iliolumbar, sacroiliac as well as the supraspinous ligaments to create an environment that challenged the ligaments as a person would do so in life. The authors also postulated that this method would allow the Prolotherapy injections to be placed in various parts of the ligamentous structure.

PATIENT DEMOGRAPHICS

For this study, we recruited a female participant who was 39 years old, with a history of low back pain (LBP) due to multiple car accidents and giving birth to three children. She had previous treatment which consisted of manual therapy, exercises, medication and physical therapy modalities. All of the treatments provided relief, but she experienced recurrent pain and “shifting” within her lower back and pelvis. Her pain centered on her sacroiliac joint (SI) and at the L4-L5 and L5-S1 segmental levels on the left side. The ligamentous structures that were painful consisted of the iliolumbar, dorsal sacroiliac, supraspinous and the sacrotuberous ligament. There was more pain on the left side compared to the right.

Ligament injections for lower back and pelvis pain are a very positive adjunct along with manual therapy and stabilization exercises.¹³⁻¹⁵ The ligaments that support the pelvis can help patients stabilize the lumbosacral spine by allowing them to safely perform functional activities and stabilization exercises. Krekoukias pointed out that when the paraspinals are overfiring, the spine appears to move in a stiffer fashion.¹⁶ This facilitation goes hand in hand with poor ligamentous and neuromuscular control of the vertebral segment, and leads to degradation of function and recurrent somatic dysfunction. With Prolotherapy, the muscular system can function more efficiently because the improvement in passive spine stabilizing allows better muscle recruitment and restores normal motor control.¹⁷⁻¹⁹ Patients who present with pain in their lower back and SI joints may benefit from the procedures illustrated. By stressing the ligaments in different planes of motion (more function, if you will) the physician can expose alternate areas of the ligament as well as increasing the tensile load of the ligament when the Prolotherapy is applied. Our experience suggests that Prolotherapy injections in these positions provide better results than injecting in the prone position only. Using this “new” positioning for functional Prolotherapy for injections of the ligaments around the

lower back and pelvis can provide the clinician with another alternative when dealing with patients who experience recurrent lower back and pelvis pain.

PROLOTHERAPY SOLUTIONS USED FOR THIS PATIENT

The Prolotherapy solution used for this patient was made of 2 ccs of 50% dextrose, 1 cc of PQU (2.43 ml Phenol liquefied, 5.73 GM Quinine HCL, 1.26GM Urea USP), 1 cc of Sarapin, and 6 ccs of Procaine. (Fabricated at the Compounding Pharmacy of Wyoming Park, 2301 Lee Street SW, Wyoming, MI 49519).

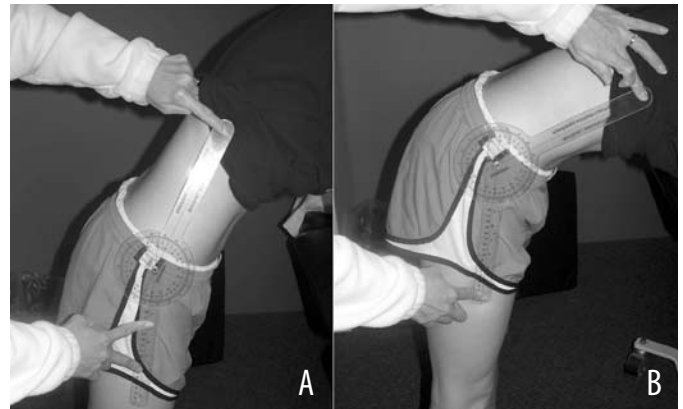


Illustration 1. Patient Positioning. Picture A shows the patient bent over at a 15 degree angle. Picture B shows the patient bent over at a 60 degree angle.

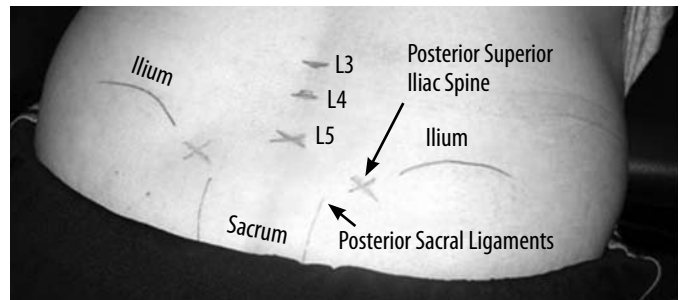


Illustration 2. This figure shows the patient with landmarks identified in the lumbar spine, hip and pelvis.

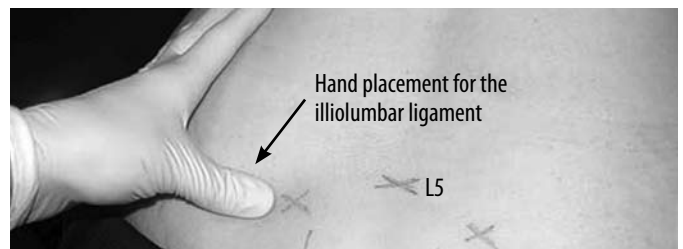


Illustration 3. This figure shows the patient in the bent over position at 15 degrees and is showing palpation of the left iliolumbar ligament over the posterior iliac crest.



Illustration 4. This figure shows the patient bent over at a 15 degree angle and the needle placement for injections of the L3 supraspinous ligament with Prolotherapy solution.

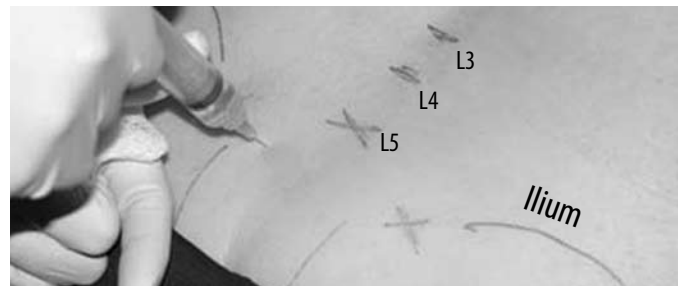


Illustration 6. This figure shows the patient bent over at a 60 degree angle and the needle placement for the left lumbosacral ligaments with Prolotherapy solution.

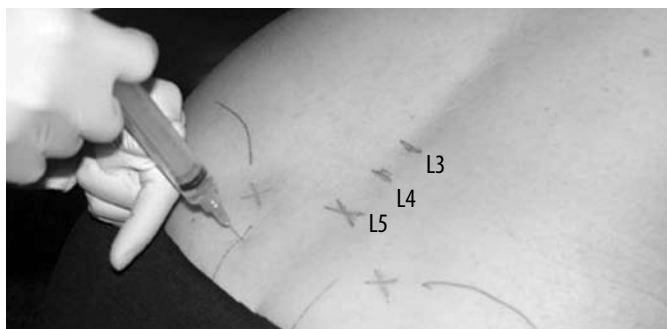


Illustration 5. This figure shows the patient bent over at a 15 degree angle and the needle placement for injections of the left superior portion of the sacroiliac ligament with Prolotherapy solutions.



Illustration 7. This figure shows the patient bent over at a 60 degree angle and the needle placement for injections to the dorsal sacroiliac ligaments (long or short bands). Positioning the patient bent over at a 60 degree angle will provide more of a stretch to this ligament.

LIGAMENTS INJECTED AND POSITION USED

The illustrations will show the ligamentous structures that were focused on and also what treating angle was used. The illustrations are marked for the clinician to see what structures are being focused on. ■

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TEACHING TECHNIQUES

Platelet Rich Plasma (PRP) Injection Technique

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

WHAT IS PRP?

In basic terms, PRP involves the application of concentrated platelets, which release growth factors to stimulate recovery in non-healing injuries. PRP causes a mass influx of growth factors, such as platelet-derived growth factor, transforming growth factor and others, which exert their effects of fibroblasts causing proliferation and thereby accelerating the regeneration of injured tissues. Specifically PRP enhances the fibroblastic events involved in tissue healing including chemotaxis, proliferation of cells, proteosynthesis, reparation, extracellular matrix deposition, and the remodeling of tissues. Bottom line here is that PRP helps the healing process.¹⁻³

HOW IS PRP DONE?

The preparation of therapeutic doses of growth factors consists of an autologous blood collection (blood from the patient), plasma separation (blood is centrifuged), and application of the plasma rich in growth factors (injecting the plasma into the area.) In other words, PRP is done just like any other Prolotherapy treatment, except the solution used for injection is plasma enriched with growth factors from your own blood. Typically patients are seen every four to six weeks like any other Prolotherapy patient. Generally two to six visits are necessary per area. (See Figures 1-4.)

WHERE IS PRP USED?

In the scientific literature are reports of soft tissue injuries treated with PRP including tendinopathy, tendinosis, acute and chronic muscle strain, muscle fibrosis, ligamentous sprains and joint capsular laxity. PRP has also been utilized to treat intra-articular injuries. Examples include arthritis, arthrofibrosis, articular cartilage defects, meniscal injury, and chronic synovitis or joint inflammation.



Figure 1. Draw the appropriate amount of blood from the patient.



Figure 2. Process the blood by first dispensing it into a centrifuge collection container.



Figure 3. Spin blood plus mixing agents in centrifuge to concentrate plasma growth factors.

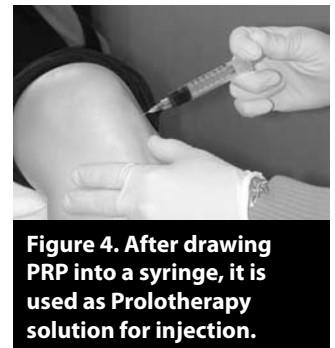


Figure 4. After drawing PRP into a syringe, it is used as Prolotherapy solution for injection.

ABSTRACT

This article provides the JOP reader with some basic information about Platelet Rich Plasma, also known as PRP. PRP as a Prolotherapy proliferant has become increasingly popular in the pain management field. The basic tenants of PRP preparation and use in the Prolotherapy field are discussed.

Journal of Prolotherapy. 2009;3:184.

KEYWORDS: growth factors, platelet rich plasma, PRP, Prolotherapy.

PRP has been used successfully to enhance surgical outcomes in maxillofacial, cosmetic, spine, orthopedic, and podiatric surgery. In regard to its use today, you will see that the majority of doctors using it apply it onto their current knowledge-base of Prolotherapy. In other words, the doctors doing PRP are using it as a proliferant, much like they use other solutions in Prolotherapy. **In simple terms, PRP is a type of Prolotherapy!**

WHAT IS REALLY GREAT ABOUT PRP?

Ultrasound studies before and after PRP are showing that the tissue is healing. This is something we knew all along with Prolotherapy, but the evidence was just not documented aside from anecdotal evidence from our patients. Now that ultrasounds are showing degenerated tendons being regenerated with Prolotherapy PRP, the critics are being answered. Yes, it is true that Prolotherapy stimulates the body to repair painful areas. This can be done by injecting simple solutions such as dextrose in the area, to more complicated solutions using glucosamine, manganese, natural hormones, to a person's own growth factors through the use of PRP. ■

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Platelet Rich Plasma (PRP) Therapy Literature Reviews

Gary B. Clark, MD, MPA

VISIONS OF REGENERATIONS TO COME

“Sometime between the years 1934 and 1936, a random patient with a random disease visited a random doctor and for the first time in recorded human history had a better than 50:50 chance of benefiting from the encounter.”—Anonymous

The above-cited quotation still lies sequestered in the dusty archival stacks of a university library—reminiscent of critical comments on medicine by Oliver Wendell Holmes. This anecdote could be referring to any number of important events that occurred around 1934 to 1936 that profoundly affected modern musculoskeletal medicine as we know it today. For example, there was the industrial development of sulfa and penicillin antibiotics, which benefited all of medicine and humankind. Or was it the advent of Osteopathy through the insight of Andrew Taylor Still? Then, it could have been the development of Prolotherapy by George Stuart Hackett and his circle of colleagues.

It was George S. Hackett who, in that era, asked how we could better treat and heal chronic sprain injuries.¹ Hackett reached out to what little was known about wound healing at the time and came up with the pragmatic realization that **stimulating natural inflammation** could be the answer.

We now know that traumatic wound healing or tissue regeneration occurs in four phases:

- **Inflammatory Phase**, which occurs when initially injured, disrupted cells release chemical agents (i.e., so-called “growth factors”) that cause a localized inflammatory reaction. The creating of an inflammatory reaction is the first of a series of cascading events that constitute the entire healing process. Inflammation further releases more growth factors, which, in turn, cause the migration and division of inflammatory cells

needed for the phagocytosis of cellular debris, setting the stage for the next phase.

- **Proliferative Phase**, which occurs when new blood vessels form (i.e., angiogenesis) and fibroblasts migrate, proliferate, and begin depositing (regenerating) Type II collagen, resulting in the formation of so-called “granulation tissue.”
- **Maturation and Remodeling Phase**, which occurs when the Type II collagen fibers convert to Type I collagen and elastin fibers, followed by the formation of collagen fiber cross-linkage,—and
- **Re-epithelialization Phase**, which occurs when disrupted skin or surrounding connective tissue fascia is closed by scarring or regeneration, respectively.

Medical science, even in Hackett’s time, recognized inflammation as the body’s normal process for initiating the healing of the physical disruption of virtually any tissue. Such “physical disruption” might be due to regular wear-and-tear, traumatic injury, infectious disease, or degenerative disease.

Thus, Hackett surmised that injecting just a small amount of irritative substance into the location of a chronic ligament or tendon sprain injury should create an inflammatory response, which *should* ultimately stimulate the healing of the musculoskeletal injury. He chose glucose as a readily available, inexpensive, osmotic irritant—or “proliferant”—solution. As a result, Prolotherapists have been regenerating injured ligament and tendon tissue and healing chronic sprain pain and dysfunction in that fashion ever since.

In the course of applying Hackett’s practice, we have eventually come to respect the difference between ligament versus tendon injuries—as addressed in the

Literature Review of the previous issue of the *Journal of Prolotherapy*. This current review delves further into the state-of-the-science-and-art of the most cutting-edge of those therapies—Platelet-Rich Plasma Therapy—which has lately surfaced in the popular press as an excellent approach to treating especially stubborn tendon sprain injuries.

Platelet-Rich Plasma (PRP) Therapy is a particularly hot topic, nowadays—in the laboratory, the clinic, and on the street. A very recent *New York Times (NYT)* article describes how two Pittsburgh Steelers “used their own blood in an innovative injury treatment before winning the Super Bowl.”² The article goes on to cite several other sports figures who have also been successfully treated in this fashion. It refers to PRP Therapy as a means of delivering a “growth-factor cocktail” to such injuries as “tennis elbow” or “knee tendinitis” (sic).

It is gratifying—if not somewhat humorous—that the advocates for this “new” PRP treatment describe how this “nonsurgical” therapy works by using “the body’s own cells to help it heal”—as if Prolotherapists have not been doing exactly the same thing since the mid-1930’s. And the same PRP advocates tout their noninvasive technique du jour as providing better cost-effectiveness compared to surgery, thereby making PRP Therapy hugely attractive for preferential insurance reimbursement—while standard Prolotherapy remains non-reimbursed by most healthcare insurance programs!

The truth of the matter is that Prolotherapists have been using the earliest version of PRP Therapy for years—achieving all of PRP Therapy’s basic positive attributes, albeit less potent to some degree but at a very small fraction of the cost.

The *NYT* article goes on to say that PRP Therapy “has the potential to revolutionize not just sports medicine but all of orthopedics”—possibly “obviating surgery and shortening rehabilitation.” Isn’t that one reason why Prolotherapists have been calling our style of practice “Orthopedic Medicine”—treating joint injury and dysfunction while protecting our patients, whenever possible, from more invasive, expensive, and potentially debilitating orthopedic surgery by using the nonsurgical, regenerative approach of Prolotherapy?

It is obvious that PRP Therapy is a logically next progression toward perfecting the Hackett technique for repairing extremely recalcitrant, severe ligament

and tendon tear injury. And PRP Therapy may be just technically attractive enough to catch the public’s, the physician’s (medical, osteopathic, and surgical), the dentist’s, the veterinarian’s—and the insurance company’s eye—finally!

As we mentioned in the last *JOP* literature review, Rabago, D. et. al., described a systematic review of the efficacy of four therapies for lateral epicondylitis (i.e., “tennis elbow” or sprain injury of the proximal tendon of the radial extensor muscle of the forearm).³ Those four therapies—including Platelet-Rich Plasma Therapy—are, very basically, four different types of therapy delivery systems. Each system delivers a growth factor or other therapeutic agent of some form to the injured tendon. To better understand PRP Therapy as a unique delivery system, let’s define some basic players.

First, what is a platelet? A platelet is a normal cellular component of blood. Like the normal circulating red blood cell (erythrocyte), the platelet has no nucleus. If the normal red blood cell is about eight one-thousandths of an inch in diameter, the normal platelet diameter is about one twentieth of that. Although very small, the platelet is loaded with various types of “granules” or sac-like secretory vesicles.

Secondly, what is a growth factor? A growth factor is a growth-enhancing peptide or protein that binds to receptors on a cell surface, activating cellular proliferation into more of the same cell form or differentiation (morphing) into another cellular form. In other words, a growth factor is a cell-secreted peptide or protein that promotes or increases (i.e., “up-regulates”) normal cellular functions, such as cell proliferation, differentiation, and tissue repair.⁴

According to the current literature, there are at least 16 major families of growth factors. A platelet alpha granule, alone, contains over 250 different, evolutionarily-related growth factors.⁵

There have been a large number of research-based journal articles written on the general topic of “regenerative” therapy based on the injection delivery of various sources of growth factors—some of which you will see, below. A main intention of the following literature review is to use some of those articles to familiarize the reader—both Physician and Patient—with the basic concepts and language of PRP Therapy. Also, we want to stimulate reading and increase the general level of understanding of

Prolotherapy. Please use the www.pubmed.gov website of the National Library of Medicine to access the following and other articles.

Determination of endogenous growth factors in human wound fluid: temporal presence and profiles of secretion.

Vogt PM, et. al. *Plast Reconstr Surg.* 1998 Jul;102(1):117-23.

Platelet quantification and growth factor analysis from platelet-rich plasma: implications for wound healing.

Eppley BL, et. al. *Plast Reconstr Surg.* 2004 Nov;114(6):1502-8.

ABSTRACT SUMMARY

These first two articles are representative of an immense volume of basic research already achieved in studying the role of growth factors in superficial, cutaneous wound healing. For example, Vogt, et. al., (1998) identified and measured the growth factors present in open skin wounds, including:

- Interleukin-1 alpha
- Platelet derived growth factor (PDGF)
- Insulin-like growth factor 1 (IGF-1)
- Transforming growth factor beta (TGFbeta)
- Basic fibroblast growth factor (bFGF)—and
- Epidermal growth factor.

They and others have identified the basic roles of these growth factors, such as:

- Interleukin-1 alpha—found to be specifically linked to the stimulatory Inflammatory Phase of healing
- Transforming growth factor beta—found to be linked to the matrix formation of the Maturation and Remodeling Phase—and
- Epidermal growth factor—found to be linked to the Re-epithelialization phase.

Eppley, et. al., (2004) went a step further and measured the degree of concentration of platelets and growth factors in PRP. They reported platelets as being concentrated up to 8-fold. Various growth factors, including PDGF, TGFbeta, and vascular endothelial growth factor (VEGF), were found to be concentrated from 3- to 6-fold.

JOP COMMENTARY

Understanding the science of wound repair or healing has been at the forefront of medical interest since the days of Hippocrates with the earliest recognition of the classic inflammatory signs of *rubor* (redness), *calor* (warmth), *tumor* (swelling), and *dolor* (pain).⁶ Since Hippocrates, most of the initial research on healing understandably addressed the healing of cutaneous (skin) wounds. With a continued stream of discoveries based on the advent of the latest analytical tools at the molecular and submolecular level, there has been a burst of recent activity identifying and understanding the sequential roles of the various growth factors involved in wound repair of all tissues—not just cutaneous tissue. More specific basic research focused on the healing of ligaments and tendons is exemplified by the following articles. ■

The roles of growth factors in tendon and ligament healing.

Molloy T, et. al. *Sports Med.* 2003;33(5):381-94.

Independent and additive stimulation of tendon repair by thrombin and platelets.

Virchenko O, et. al. *Acta Orthop.* 2006 Dec;77(6):960-6.

Low molecular weight heparin impairs tendon repair.

Virchenko O, et. al. *J Bone Surg Br.* 2008 Mar;90(3):388-92.

ABSTRACT SUMMARY

Molloy, et. al., (2003) address specific growth factors encountered in ligament and tendon healing. After reading about the factors found in superficial wounds, above, these should appear familiar, including:

- Platelet derived growth factor (PDGF)—produced shortly after tendon injury, stimulates production of other growth factors such as IGF-1, and is involved in the tissue remodeling phase of healing.
- Insulin-like growth factor 1 (IGF-1)—present in the early inflammatory phase.
- Transforming growth factor beta (TGFbeta)—present in the inflammatory phase.
- Basic fibroblast growth factor (bFGF)—present in the late inflammatory phase, stimulates angiogenesis, and regulates cellular migration and proliferation.

- Vascular endothelial growth factor (VEGF)—present after the inflammatory phase stimulating angiogenesis (neovascularization).

Listed with the factors, above, are various general roles that each factor plays in the process of ligament or tendon repair.

Virchenko, et. al., (2006) introduce the concept that the blood coagulation substance, thrombin, plays an additional role in tendon repair, which is not, yet, well understood. The second Virchenko article (2008) supports the first in showing that continuous heparin (anti-thrombin) treatment significantly impairs tendon wound healing by making thrombin unavailable.

JOP COMMENTARY

Ligament and tendon wound healing is a complicated series or cascade of interlinked, molecular events intertwined with the, likewise complex, coagulation (i.e., hemostasis) cascade. Platelets,—well known components of the hemostasis cascade—are now equally well known to be involved in ligament and tendon repair. Thrombin (another well-known hemostasis component), also, demonstrates properties in wound healing that are similar to those of known growth factors, although the exact nature of thrombin's role in healing yet remains to be fully understood. It can be said that thrombin causes the PRP injection to clot. That clot may act as a biological “scaffolding” or physical infrastructure upon which the healing may progress more readily.

Basic research delving into the intricacies of wound healing has served as a natural spring board for developing application of those basic understandings to real world medical and surgical problems. If basic science has shown the importance of the delivery of growth factors to injured ligament, muscle, and tendon tissues, then how can those factors be delivered most effectively facilitate tissue healing? The following articles reflect such delivery applications to a couple of other-than-ligament-tendon tissue injury issues. ■

Intervertebral disc regeneration using platelet-rich plasma and biodegradable gelatin hydrogel microspheres.

Nagae M, et. al. *Tissue Eng.* 2007 Jan;13(1):147-58.

Effects of intramyocardial injection of platelet-rich plasma on the healing process after myocardial infarction.

Li XH, et. al. *Coron Artery Dis.* 2008 Aug;19(5):363-70.

ABSTRACT SUMMARY

Nagae, et. al., (2007) report on the delivery of PRP-impregnated, biodegradable, gelatin hydrogel microspheres to a rabbit model of intervertebral disc degeneration. The experimental PRP group showed significant healing of the disc degenerative process.

Li, et. al., (2008) describe the delivery of thrombin-activated PRP to a rat model of myocardial infarction (i.e., coronary heart attack). The thrombin-PRP injection resulted in the improvement of several parameters that demonstrated enhanced myocardial remodeling and accelerated myocardial healing.

JOP COMMENTARY

These two articles represent the relatively few existing articles relating to the application of PRP Therapy to musculoskeletal tissue injuries other than ligaments and tendons. As shown in these two articles, wounds need not be just traumatic—they may also be due to wear-and-tear degeneration or a vascular accident. Although there is currently only a smattering of study on the application of PRP technique to such tissues, this literature does provide evidence that PRP Therapy is an extremely potent healing remedy—when delivered in an effective way. ■

Platelet-rich plasma stimulates porcine articular chondrocyte proliferation and matrix biosynthesis.

Akeda K, et. al. *Osteoarthritis Cartilage.* 2006 Dec;14(12): 1272-80.

Buffered platelet-rich plasma enhances mesenchymal stem cell proliferation and chondrogenic differentiation.

Mishra A, et. al. *Tissue Eng Part C Methods.* 2009 Feb 13. [Epub ahead of print]

ABSTRACT SUMMARY

Akeda, et. al., (2006) present an “in-vitro” (i.e., laboratory counter-top) model in which porcine chondrocytes (mature pig cartilage cells) were grown in culture media and PRP was introduced into the culture media. While, the cells remained structurally and molecularly unchanged, including their proteoglycan (e.g., glucosamine) and collagen molecular types, cell proliferation and glucosamine-collagen synthesis were enhanced.

Mishra, et. al., (2009) present an interesting in vitro model whereby mesenchymal stem cells were grown in culture media enhanced with either PRP or non-enhanced (control) media. The PRP-treated cells demonstrated increased proliferation and the development of chondrogenic (cartilage precursor cell) molecular markers.

JOP COMMENTARY

These articles introduce another relatively new concept that is becoming a “household” phrase: **tissue engineering**. If we consider ligaments or tendons as having limited regenerative capacity due to their relative lack of blood vessels and regenerative fibroblasts, certainly articular cartilage tissue is even more limited. The tissue engineering approach uses a natural or synthetic “scaffolding” upon which, in these two cases, chondrocytes (articular cartilage cells) or primitive stem cells are carried and nurtured, enabling cellular multiplication (growth) and regeneration of new tissue in the laboratory—or in the outpatient clinic.

As mentioned above, if clotted, PRP can provide a natural infrastructural scaffolding, which is, by design, rich in growth factors. PRP clots when mixed with thrombin, and can be injected into a patient’s site of articular cartilage defect or the complex can be precisely implanted by arthroscopy—rather than necessitating an open operation for implanting the regenerating cell-scaffold complex!

Thus, PRP technology can be very useful by providing a bio-scaffolding within which injectable, tissue-engineered, autologous cartilage cells may be introduced into a wound space to proliferate. There is a significant volume of research directed toward applying PRP Therapy to the problems of joint articular cartilage degeneration—as seen so often in wear-and-tear osteoarthritis. Further stem cell research is likely to bring us to the next major threshold of discovery in understanding and employing this elegant extension of the standard Hackett Prolotherapy model. ■

Augmented bone regeneration activity of platelet-rich plasma by biodegradable gelatin hydrogel.

Hokugo A, et. al. *Tissue Eng.* 2005 Jul-Aug;11(7-8):1224-33.

Benefit of percutaneous injection of autologous platelet-leukocyte-rich gel in patients with delayed union and nonunion.

Bielecki T, et. al. *Eur Surg Res.* 2008;40(3):289-96. [Epub 2008 Feb 15]

ABSTRACT SUMMARY

Hokugo, et. al., (2005) investigated PRP’s ability to enhance bone repair in a rabbit model. The PRP was incorporated into a gelatin hydrogel. This PRP delivery system was applied topically to rabbit ulna bone defects. They observed that growth factors, such as PDGF and TGFβ, were released directly from the PRP and more slowly released from the hydrogel as it degraded. Successful bone regeneration and bone defect healing resulted.

Bielecki, et. al., (2008) present an application of PRP by injection of autologous platelet-leukocyte-rich gel to delayed-union and nonunion fracture patients—as opposed to employing standard orthopedic surgical open grafting procedures. All delayed union cases demonstrated successful union after an average of 9.3 weeks. The nonunion group demonstrated 13/20 successful unions after an average of 10.3 weeks.

JOP COMMENTARY

There appears to be even more advanced interest in the clinical literature regarding the application of PRP technique to facilitate bone healing, especially in regard to filling large traumatic or post-surgical defects. Again, these studies demonstrate the powerful effect of Platelet-Rich Plasma when used to facilitate tissue repair—essentially for any musculoskeletal tissue. All it takes is the proper delivery system.

SUMMARY

So, the **delivery system** is what it is all about. That is delivering the growth factors and the cellular building blocks (stem cells or mature tissue cells) to the right place at the right time.

Since the 1930s and George S. Hackett’s initial trials, Prolotherapy has been on the cutting edge of modern tissue regenerative therapy and providing that delivery system on-call, any time, any place. As practiced by Hackett

and his followers, Prolotherapy has consistently provided the most basic, inexpensive, effective delivery of the most fundamental wound repairing stimulants or proliferants. Doesn't that fit the definition of "efficacious?" Standard Prolotherapy is both clinically **efficient** and **effective**.

All along, Hackett's Prolotherapy has been the natural forerunner of today's more advanced PRP Therapy! Whenever a Prolotherapy needle penetrates into an injured ligament or tendon enthesis (i.e., the anchoring site of ligament or tendon attachment to bone), a very small, bleeding wound occurs at the needle point. That is why it has always been effective to "pepper" an injection site with numerous, small, gentle needle stabs—to create multiple, tiny wounds, essentially recreating the original sprain injury.

Needle wounding physically disrupts cells and causes cellular release of cellular and tissue-derived growth factors—both healing-specific and hemostatic-specific. Minute needle-wound bleeding results in multiple, equally minute clots immediately occurring at those wound sites—each clot being a local accumulation of circulating platelets, thrombin, and red and white cells. Already released growth factors activate those platelets, other circulating cells, and local tissue cells, all of which release more growth factors and stimulate an inflammatory reaction in a cascading, crescendo fashion.

While performing the minute wounding at needle point, a small amount of proliferant solution is, also, injected into the injury site. This glucose-based, osmotically-active, irritative proliferant causes even more local, physical cellular disruption with the release of more growth factors—causing even further Inflammatory Phase activity.

Thus, standard Prolotherapy causes an enhanced Inflammatory Phase (IP) reaction to ensue. Ultimately, IP-generated growth factors stimulate ligament or tendon fibroblastic cells to lay down (i.e., regenerate) new Type II collagen fibers in the subsequent Proliferative Phase—which is followed by the Maturation-Remodeling and Re-epithelialization healing phases. Ligament and tendon sprain injury healing is the ultimate result with diminished pain and restored function—all this occurring without any PRP necessarily being performed.

So, the difference between standard Prolotherapy and PRP Therapy is just a matter of degree—and the possible provision of an infrastructural scaffolding to fill in a structural void. The increased concentration of platelets and, thus, increased concentration of platelet-delivered growth factors simply makes PRP Therapy appear to be

a more potent treatment, especially for repairing a severe tendon sprain injury involving a significant tear or gross (versus microscopic) tissue defect at the enthesis.

As borne out by Rabago, D., et. al., however, it is yet to be determined what the real difference is between standard Prolotherapy and PRP Therapy. In their systematic review, they were not able to discern a significant clinical difference between the four therapeutic delivery systems over the long haul. Clearly, more study is needed to answer the question of differential long-term effectiveness and safety between standard Prolotherapy and PRP Therapy. Regardless, Prolotherapists and Prolotherapy patients have all along been "back to the future" in the arena of tissue regeneration and healing.

A PRACTICAL NOTE

PRP Therapy is surely here to stay. It will become even more technically embellished and refined, supported by other high-tech modalities, such as ultrasound-based needle guidance. As such, it will also remain much more expensive than routine, standard Prolotherapy, requiring more technological capital and personnel investment. Thus, PRP will garner a relatively higher price tag for insurance reimbursement and on the fee-for-service market.

Currently, PRP Therapy is enjoying a typical "high-tech hype." It is the musculoskeletal treatment *du jour*. An energizing supplement to this PRP high-tech hype is that PRP is often advertised as being supported by ultrasound needle guidance and is enjoying reimbursement by healthcare insurance companies.

But, the chief inherent danger in "high-tech" therapies is that the given procedure often becomes "low-touch" and relatively very expensive. Because of the "*du jour*" popularity amongst physicians and its insurance coverage attractiveness amongst patients, PRP Therapy could unnecessarily and unwisely supplant standard Prolotherapy in the treatment of the minimal to moderately severe ligament and tendon sprain injuries.

In a healthcare economy in which the United States spent \$1.6 trillion on healthcare in 2008, we need to abate the current burgeoning rate of total healthcare costs. If we continue our current rate of spending, we will have a healthcare economy by 2015 in which those costs will equal 20% of the GDP—or worse!⁷

Therefore, from the aspect of practical healthcare management aimed at practicing cost-effectiveness and common sense, PRP Therapy **should not** be considered

the panacea for treating **all** sprain injuries. Most minor to moderately severe sprain injuries of ligaments or tendons will respond to standard Prolotherapy just as quickly and at much less a healthcare cost—compared to the greater cost of PRP Therapy. In addition, PRP is a significantly more painful treatment than standard Prolotherapy.

Therefore, PRP Therapy should be reserved for the “too-hard” sprain injury cases for which standard Prolotherapy is less than adequate—especially the refractory tendinoses with significant tears. Continue to employ standard Prolotherapy for the minimal to moderately severe cases that are obviously responding. Just because it is an attractive “state-of-the-art” therapy does not mean that PRP Therapy need become an ever-pervasive “state-of-the-mind” option. “High-tech-Low-touch” often supplants “Low-tech-High-touch” therapies—often to the patient’s and the economy’s disadvantage. ■

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Errata: Correction regarding the first Literature Review article in JOP Volume I, Issue 2: For the sake of absolute accuracy, any reference to the Rabago, et. al, article as a ‘meta-analysis’ should, instead, have been as a ‘systematic review.’ A meta-analysis requires pooling of data. Since, Rabago, et al, could not pool their data, their report is a systematic review. This is a small but important distinction in describing their analytical statistical approach.

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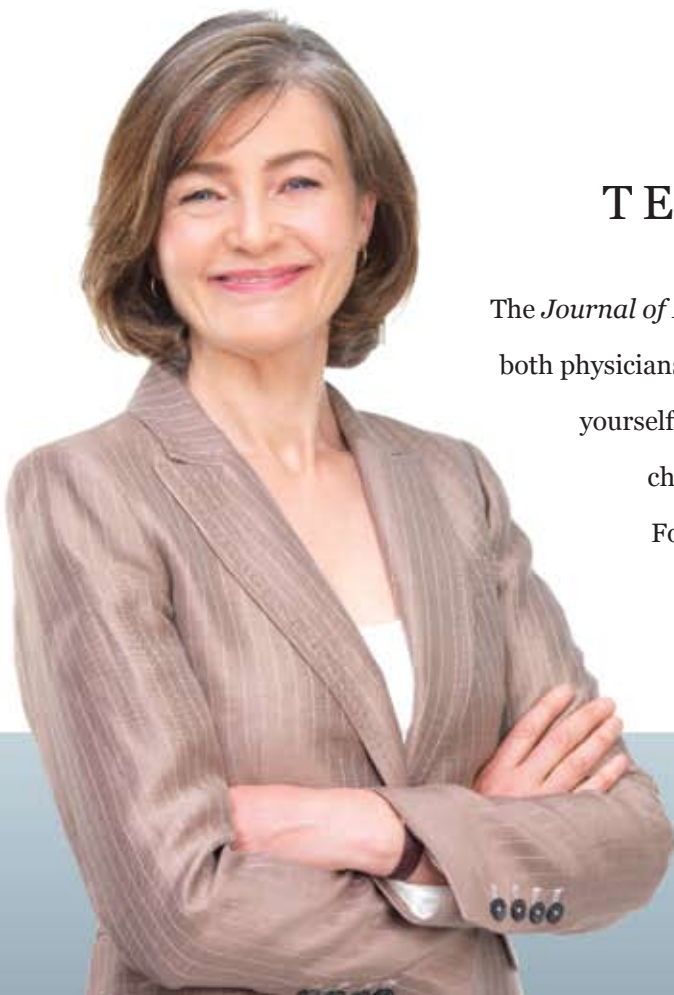


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