Lower Back Pain

Foundational Concepts

1. Needling of Tendons & Ligaments is NOT a Placebo: Puncture of Cell membrane With Inflammatory Lipid Release

In the treatment of low back pain there are four treatment comparison studies. The control group in all back studies involved needle contact with attachments of ligaments and tendons. By injecting ligaments and tendons, there is needle contact with cell membranes of connective tissue cells. Disrupting cell membranes releases lipids, which in turn cause signaling of fibroblasts.

Examples of Needling Effects

- 19% improvement (sustained 6 mo) in chronic low back pain (LBP) with saline injections with bone contact. (*Ongley MJ, Klein RG, Dorman TA, et al. A New Approach to the Treatment of Chronic Low Back Pain. Lancet 1987; 2: 143-146.)*
- 27% improvement (sustained 6 mo) in chronic LBP with anesthetic injection with bone contact. (*Klein RG, Bjorn CE, DeLong B, et al. A randomized double-blind trial of dextrose-glycerine-phenol injections for chronic low back pain. J Spinal Disord 1993; 6: 23-33.)*
- 36% improvement (sustained 1 yr) in chronic LBP with saline injection with bone contact. (*Yelland MJ, Glasziou PP, Bogduk N, et al. Prolotherapy Injections, Saline Injections, and Exercises for Chronic Low-Back Pain: A Randomized Trial. Spine 2004; 29(1): 9-16.*)

2. Needling of Tendons is NOT a Placebo: Microbleeding with Platelet Effects

In addition, microbleeding from needle contact is expected, and Edwards and colleagues have demonstrated the potential healing

effect of whole blood injection in patients with recalcitrant tennis elbow. (Edwards SG, Calandruccio JH: *Autologous blood injections for refractory lateral epicondylitis* J Hand Surg [Am] 28(2):272, 2003.)
The hope is that future studies on low back pain will include a near-placebo arm that avoids connective tissue contact or blood effects and that standard injection methods will be used. In the treatment of low back pain, standard treatment methods are now taught in cadaver courses offered by the American Academy of Orthopedic Medicine. An example of such a near-placebo would be needle insertion through skin without contacting bone or ligament.

Research Studies *(by year of publication)*

Ozone: Paoloni et al (2009). Intramuscular ozone therapy for acute low back pain.
Dr. Reeves' Notes: This study is included, even though it is on ACUTE back pain and not chronic, because it is still an example of injection to potentially stimulate healing of soft tissue. See the Ozone section on home page for a general summary. This appears to be a study on acute low back pain in patients, SOME of whom may have had a disc source of pain. It purports to be a study on back back from discal source but the only criteria was a disc bulge which does not clearly indicate a discal source of pain. The results were quite interesting with 61% pain free at 6 months post treatment in the treatment groups and 33% in the control group. There are issues about the effectiveness of blinding in this study. In communication with the primary author, his position is that post injection discomfort is minimal and that there is a heaviness sensation with injection that can be imitated by pressure from the treated physician in an attempt to blind the injection. Ozone naive

patients were also chosen that would not be aware of the actual sensation with ozone. The needle used was 40 mm which was said to be inserted into lumbar paravertebral muscles. Mention was not made of bone contact and a 40 mm is 1 and 3/4 inches and would clearly not touch the vertebral bodies to be able to infiltrate medial branch area. Dr. Paoloni confirmed that the infiltration of ozone was on each side in one spot only. A concern is that 12/24 in the control group were not followed up at the last two data points (3 and 6 months after treatment ended, leaving the last data point at 2 months from the start of the study). It is stated that 12/24 in the control group dropped out but less clear as to why they were not able to contacted to firm up their data. Costs of treatment will vary by practitioner and setting but the treatment course costs approximately $1,000 U.S. for the sessions described. Another issue of course is that acute low back pain prognosis is generally favorable anyway.

Treatment of Acute Back Pain With Lumbar Disc Herniation (2009)

Paoloni M; Di Sante L; Cacchio A; Apuzzo D; Marotta S; Razzano M; Franzini M; Santilli V Intramuscular oxygen-ozone therapy in the treatment of acute back pain with lumbar disc herniation: a multicenter, randomized, double-blind, clinical trial of active and simulated lumbar paravertebral injection Spine (United States), Jun 1 2009, 34(13) p1337-44. Physical Medicine and Rehabilitation Unit, Azienda Policlinico Umberto I, Rome, Italy. paolonim@tin.it

A copy of the abstract is available here, with a copy of the content below...

STUDY DESIGN: Multicenter randomized, double-blind, simulated therapy-controlled trial in a cohort of patients with

acute low back pain (LBP) due to lumbar disc herniation (LDH).
OBJECTIVE: To assess the benefit of intramuscular-paravertebral injections of an oxygen-ozone (O2O3) mixture.
SUMMARY OF BACKGROUND DATA: Recent findings have shown that O2O3 therapy can be used to treat LDH that fails to respond to conservative management. However, these findings are based on intradiscal/intraforaminal O2O3 injection, whereas intramuscular-paravertebral injection is the technique used most in clinical practice in Italy and other Western countries.
METHODS: Sixty patients suffering from acute LBP caused by LDH was randomized to an intramuscular O2O3 or control group. Patients were observed up to assess pain intensity, LBP-related disability, and drug intake (15 [V2] and 30 [V3] days after treatment started, and 2 weeks [V4], and 3 [V5] and 6 [V6] months after treatment ended).
RESULTS: A significant difference between the 2 groups in the percentage of cases who had become pain-free (61% vs. 33%, $P < 0.05$) was observed at V6. Patients who received O2O3 had a lower mean pain score than patients who received simulated therapy throughout the observation period. A significant improvement was observed in LBP-related disability in the study group patients when compared with the control group patients. Active O2O3 therapy was followed by a significantly lower number of days on nonsteroidal anti-inflammatory drugs at V2 and V3 and by a lower number of days at V4. No adverse events were reported.
CONCLUSION: Treatment of LBP and sciatica is a major concern. Although the natural history of acute LBP is often self-limiting, conservative therapies are not always effective; in such cases, O2O3 intramuscular lumbar paravertebral injections, which are minimally invasive, seem to safely and effectively relieve pain, as well as reduce both disability and

the intake of analgesic drugs.

Phenol + Dextrose: Wilkinson (2005). Treatment of Patients Referred for Back Surgery, Usually With Prior Back Surgery

Wilkinson HA Injection therapy for enthesopathies causing axial spine pain and the "failed back syndrome": a single blinded, randomized and cross-over study.: Pain Physician (United States), Apr 2005, 8(2) p167-73

Dr. Reeves' Notes: Dr. Wilkinson, a neurosurgeon, performed a single blind study assigning patients with low back pain to either phenol/glycerine or anesthetic injection and demonstrated a better pain reduction with phenol/glycerine injection. The injection sites were not clearly described in his study and the patients required periodic injection. However they were patients with prior lumbar surgery (86%) and all had been referred for further back surgery. Only 4 out of 35 continued to pursue that option, with 29 out of 35 preferring periodic injections. Again, even though lidocaine is clearly not a control intervention, this study provides randomized and blinded assignment evidence that low back treatment with proliferant is better than with lidocaine alone.

The full study is available in PDF format here.

An abstract is available here, with a copy of the content below...

BACKGROUND: Enthesopathies are a common cause of axial pain that is amenable to "minimally invasive" therapy.

OBJECTIVE: To evaluate the effectiveness of injection therapy for enthesopathies.

DESIGN: Single blinded, randomized, and cross-over study.

METHODS: Thirty-five patients diagnosed as having painful enthesopathies as a major pain generator were studied. Of the patients studied, 86% of patients had undergone prior lumbar spine surgery and all were referred for neurosurgical evaluation for possible surgery. Patients were injected either with anesthetics alone or with

anesthetics combined with phenol-glycerol proliferant prolotherapy. Outcomes were analyzed both clinically at the time of regular follow-ups, and by a series of multipart questionnaires.

RESULTS: Patients received a total of 86 injections, 39 with local anesthetics, and 47 with prolotherapy. By clinical assessment patients obtained excellent to good relief of pain and tenderness after 80% of prolotherapy injections, but only 47% after anesthetics alone. By questionnaire, 66% reported excellent to good relief after prolotherapy vs. 34% after anesthetics alone. Patients reported improvement in work capacity and social functioning following both types of injections, but a greater reduction in focal pain intensity following prolotherapy injections. The mean and median durations of persistent relief were 2.4 and 1.75 months with prolotherapy vs. 1.8 and 0.75 months with anesthetics alone. Roughly 10% obtained greater than six months of relief from either injection. In the crossover portion of the study, patients reported that prolotherapy injections following initial anesthetic-only injections provided much better relief than that achieved after their anesthetic-only injections, and that anesthetic-only injections following initial prolotherapy injections failed to provide relief as good as that achieved after their prolotherapy. Subsequent to this study, only four of 35 patients required additional spine surgery, but 29 of the 35 patients requested additional injections.

CONCLUSIONS: Injection therapy of painful enthesopathies can provide significant relief of axial pain and tenderness combined with functional improvement, even in "failed back syndrome" patients. Phenol-glycerol prolotherapy provides better and longer lasting relief than injection with anesthetics alone. Prolotherapy provides over six months of relief for some patients but generally provides relief for only a few months. However, most patients described good to excellent relief, felt that the injections had been beneficial, and

requested additional injections for recurrent or residual focal pain. 5 Rockridge Rd. Wellesley Hills, MA 02481-1432, USA. hrldawlknsn@aol.com

Chronic LBP DEX: Hooper et al (2004)

Hooper RA; Ding M Retrospective case series on patients with chronic spinal pain treated with dextrose prolotherapy J Altern Complement Med (United States), Aug 2004, 10(4) p670-4

Dr. Reeves' Notes: 177 consecutive patients with chronic spinal pain were injected with dextrose 20% in facet capsule at affected levels as determined by palpation. (cervical, thoracic, lumbar) Iliolumbar and SI ligaments injected in those with low back pain. Weekly injection up to 3 within a 1 month period. Outcome measures included levels of pain, ADL and work ability on a 5 point scale each. 91% had reduced pain, 84% had improvement in work ability and 85% could do self care more easily.
An abstract of the study is available here.

Chronic LBP DEX: Yelland et al (2004)

Yelland MJ, Glasziou PP, Bogduk N, et al: Prolotherapy injections, saline injections, and exercises for chronic low-back pain: A randomized trial. Spine 29(1):9, 2004.

Dr. Reeves' Notes: The fourth RCT in chronic low back pain was reported in 2004 and designed by an experienced physician in Brisbane. This study, like the previous studies, had no placebo arm, but compared needling of ligament attachments to bone to doing the same thing but with dextrose 20% included in the solution. Substantial and sustainable important improvements in pain and function were demonstrated by both injection groups. Highlighted by this study is the importance of the beneficial effect

of needling alone and that needling is not a placebo intervention.
A PDF version of the complete study is available here.
An abstract of the study is available here.

Chronic LBP PDG: (Phenol Dextrose Glycerine) Dechow et al (1999)

Dechow E, Davies RK, Carr AJ, et al: A randomized, double-blind, placebo-controlled trial of sclerosing injections in patients with chronic low back pain. Rheumatology 39:1255, 1999.

Dr. Reeves' Notes: Incorrect injection sites along with failure to examine lead to worse rather than better outcomes. The third study on chronic low back pain was led by a chief investigator (rheumatologist) who had a mandate to "prove or disprove prolotherapy", was armed with a complete lack of knowledge of prolotherapy technique or referral patterns for ligament or tendon, and brilliantly, but probably unwittingly, designed the study to fail. Failure was ensured by:

1. Accepting patients with axial (back) pain only and excluding patients with leg pain referral.
2. Finding a physician who was conversant with prolotherapy but preventing him from examining the patients for areas to inject. Rather the physician was forced to inject only specified areas.
3. Allowing treatment only on ligaments that would cause leg pain and not any ligaments that would treat axial (back) pain, *and* ...
4. Injecting inflammatory (phenol-based) proliferant in these incorrect areas.

As a consequence of injecting inflammatory solution in completely wrong areas, this study is recorded as a prolotherapy study in which the active group did worse than the control. This study is worthy of inclusion in a discussion of back pain studies because of what it says about study design in musculoskeletal medicine; ie, it trumpets the importance of knowing anatomy, and referral patterns in connective tissue, and of hands-on examination.

Dextrose-Glycerine-Phenol Injections For Chronic Low Back Pain (1993)

Chronic LBP PDG: Klein et al 1993 Near significant (P = .056) evidence for superior effect of the inflammatory proliferant solution anesthetic needling (Klein et al) in chronic low back pain. Klein RG, Bjorn CE, DeLong B, et al: A randomized double-blind trial of dextrose-glycerine-phenol injections for chronic low back pain. J Spinal Disord 6:23, 1993.

Chronic LBP PDG: Ongley et al (1987) Significant evidence for superior effect of the inflammatory proliferant solution over saline needling in chronic low back pain.

Ongley MJ, Klein RG, Dorman TA, et al: A new approach to the treatment of chronic low back pain. Lancet 2:143, 1987.

Dr. Reeves' Notes: Despite better-than-placebo improvement in the control group, the first two blinded studies of chronic low back pain (using phenol/dextrose/glycerin as active solution) demonstrated significant (P < .001) Ongley MJ, Klein RG, Dorman TA, et al: A new approach to the treatment of chronic low back pain. Lancet 2:143, 1987. and near significant (P = .056) Klein RG, Bjorn CE, DeLong B, et al: A randomized double-blind trial of dextrose-glycerine-phenol injections for chronic low back pain. J Spinal Disord 6:23, 1993. evidence for superior effect of the inflammatory proliferant solution over saline needling (Ongley et al) and anesthetic needling (Klein et al). These two studies were weakened somewhat by multiple simultaneous treatments, although the injection solution was the only significant difference between the two groups.