

Consent for Prolotherapy

I, _____, have been advised and consulted regarding the injection technique of Prolotherapy, as follows.

I am the patient____.

I am a person with authority of consent for _____.

BASIS OF PROLOTHERAPY: I understand Prolotherapy is an established technique for shortening and healing stretched/torn ligaments and tendon attachments. The technique requires the injection of a proliferant solution into the ligament or tendon. This solution may consist of various combinations of local anesthetic, glucose, phenol, Vitamin B₁₂, and/or other proliferative agents. The exact composition is determined for each patient on a case-by-case basis, aimed at producing the least inflammatory reaction with the best proliferative (regenerative) effectiveness. The proliferant solution is injected at the site of the injury where the ligament or tendon attaches to the bone.

APPLICABLE DIAGNOSES: Prolotherapy is an appropriate therapy for treating ligament or tendon sprain injury resulting in joint laxity, instability, dysfunction, and pain. In regard to back pain, (lumbar, thoracic, or cervical) the differential diagnosis must include the possibility of spinal stenosis or other causes of nerve compression or impingement. The symptoms and signs of ligament or tendon sprain injury may mask coincidental nerve involvement.

PROCEDURE: I understand that the Prolotherapy technique requires delivering a small volume of proliferant solution to the injured ligament, as follows:

1. The patient may receive a preparatory skin test for allergy to Procaine and other constituents of the proliferant solution.
2. The patient may receive a pre-therapeutic dose of a non-anti-inflammatory analgesic.
3. The physician will position the patient, examine, and demarcate the injured ligament.
4. The physician will inject the proliferant solution into the injured tissue. This is likely to elicit some pain since the ligaments are injured and already tender.

FREQUENCY AND TOTAL NUMBER OF TREATMENT SESSIONS: The frequency of treatment sessions depends on the nature and severity of the patient's sprain injury. The usual frequency of repeated treatment sessions is every two to six weeks. The total number of treatment sessions is entirely dependent on the severity of the injury, the patient's state of health and findings on follow-up physical examination. Most commonly patients require between 3 and 6 sessions.

RISKS OF NO PROLOTHERAPY: I understand that the possible RISKS of NO Prolotherapy are:

- No relief of the pain.
- Progressively worsened pain.
- Continued or progressively worsened joint dysfunction, such as decreased range of motion.
- Continued or progressively worsened degeneration of the joints involved with the ligament laxity.

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ALTERNATIVES TO PROLOTHERAPY: I understand that possible ALTERNATIVES to

- Prolotherapy are:
- Doing nothing.
- Osteopathic or chiropractic manipulation.
- Physical therapy
- Sacral belt and other temporary splints and braces
- Steroid injections, which may reduce the pain but not give lasting results—may even be injurious.
- Surgical intervention.

I understand that my physician will discuss with me appropriate adjunctive therapies while I am receiving prolotherapy (i.e. massage therapy, physiotherapy, chiropractic, etc.).

RISKS OR COMPLICATIONS OF PROLOTHERAPY:

I understand that the potential RISKS or COMPLICATIONS of Prolotherapy are:

- No effect from the treatment
- Immediate pain at the injection site, lasting up to 100 hours (3-4 days) or more
- Bruising of the general treatment area
- Bleeding at the injection site
- Infection at the injection site
- Fainting or dizziness
- Post-therapeutic tendonosis pain flare
- Post-therapeutic muscle spasm
- Similar to risk of surgical intervention, temporary (transient) or permanent injury to cutaneous nerves or muscles at the injection site, including local
 - autonomic nervous system-related skin and sensory changes
 - sensory numbness or pain, aching, or burning sensations, or
 - motor paralysis
- Spinal cord injury during back injections
- Pneumothorax (air on the outside of the lung) during chest injections
- Allergic reaction to one of the components of the proliferant solution,

I. **PATIENT PRECAUTIONS:** I understand that important PRECAUTIONS are:

ALLERGY TESTING: If the patient has a significant allergy history—skin or serum testing for specific allergy may be required before therapy. I do not have any specific history of allergic reaction to the Procaine family of local anesthetics, phenol, or corn from which glucose and glycerin are synthesized. In the event of skin rash, respiratory distress, or other medical complications related to the Prolotherapy or pain control medication, contact the nearest emergency room or dial 911 for assistance. Call the clinic for additional help at 480-341-9400. Patient's Initial _____

SMOKING: I have been informed that tobacco and other nicotine sources significantly impedes the effectiveness of Prolotherapy. Subsequently, if I use nicotine and I choose to pursue a series of Prolotherapy sessions, I understand that I run the risk of experiencing either delayed healing (requiring

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more than the statistical average number of sessions), incomplete healing or no healing at all.
_____(initial)

NUTRITION: During the course of Prolotherapy treatment sessions, it would be helpful to take supplemental Vitamin C to take advantage of its facilitating the laying down of new collagen and healing the connective tissue injury. 2-4 grams of Vitamin C orally per day is recommended, in divided doses (i.e. 500mg every 2 hours is ideal). Some diarrhea may occur on initiating the supplementation, which is usually easily controlled by reducing the dosage.

ANTI-INFLAMMATORY MEDICATIONS: For the relief of post-therapeutic pain, DO NOT use any steroidal or nonsteroidal anti-inflammatory drugs (see list below)—neither prescribed, over-the-counter, oral, or injection—for two weeks prior to prolotherapy treatment and for four weeks following prolotherapy treatment.

Anti-inflammatory drugs to avoid include:

- steroidal drugs such as cortisone and prednisone and
- nonsteroidal drugs such as Advil, Alka Seltzer, Anaprox, Arrotec, Aspirin (acetylsalicylic acid), Bristel, Cataflam, Celebrex, Clinoril, Ecotrin, Excedrin, Feldene, Indocine, Lodine, Motrin (ibuprofen), Naprosyn, Percodan, Vioxx, any Cox-2 inhibitors, or white willow bark derivatives.

For pain relief the only acceptable analgesic drugs are those that are NOT anti-inflammatory.

These include:

- over-the-counter drugs such as Tylenol (acetaminophen) or
- prescribed Class II medications, such as codeine (e.g., Tylenol 3) or hydrocodone (e.g., Lorcet or Vicodin) or oxycodone (e.g., Percocet).

You are to follow the dosage directions as prescribed. Do not use additional dosages or medications without Dr.'s personal permission.

If you experience any collapse, difficulty breathing, shortness of breath, chest discomfort, gastrointestinal discomfort, rash, or any other kind of acute-onset medical emergency, obtain immediate transportation to an emergency room or dial 911 for emergency medical assistance.

- DO NOT APPLY ICE, which is anti-inflammatory, at any time during the course of Prolotherapy.
- APPLICATION OF LOCAL HEAT (e.g., heating pad) or diffuse, intense heat (e.g., sauna, hot tub) can be applied to the treated area during the first three days following Prolotherapy—a hot shower or bath is also no problem – but only for short periods of less than 10 minutes. After the third day, the patient may use local or diffuse heat if it provides comfort as needed.

POST-THERAPEUTIC ACTIVITY: In the case of Prolotherapy, non-painful normal activity movement, stretching, and exercise are important for the laying down of normal collagen in the healing of ligaments or tendons. Therefore, use common sense in your daily, exercise, or sports activity.

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DO NOT IMMOBILIZE any treated joint with a sling or restrictive bandage. A sacroiliac belt may be appropriate.

Move and exercise the treated joint as much as possible throughout the post-prolotherapy healing phase, including normal/routine daily activity movements. However, limit the degree of range of motion and strength exercising to that which is tolerated BEFORE it becomes painful. Let pain limit your movement or degree of stretching. Do not participate in aggressive exercise training or sports activities until you have received endorsement from the Doctor who is treating the injury.

Contact the clinic if you need help in determining what degree of exercise is appropriate or if there is excessive limitation of movement due to pain. Additional assistance through other treatment modalities (e.g. Pilates) may be necessary.

Healing of ligaments and tendons is a slow process, and requires time and patience. Most ligaments and tendons heal within a period of 3 months; however, the majority of healing after a prolotherapy session occurs in the first two weeks. The first 4 days post prolotherapy are the most important and you should avoid stressing the joint or you may cause the treatment to be undone. The next 10 days should be a gradual return to 60-75% activity levels using pain as your indication to pull back.

POST-THERAPEUTIC REHABILITATION: Prolotherapy is a treatment for stabilizing joint instability due to ligament sprain injury or muscle tendon sprain injury. Following joint stabilization, I recommend

- Yoga or Pilates;
- Walking

as rehabilitative therapies to help resolve residual compensatory myofascial restriction and core muscular weakness problems (e.g., core weakness, short leg abduction weakness, scoliosis).

EMERGENCIES: Following treatment and after leaving the clinic, if you experience any collapse, difficulty breathing, shortness of breath, chest discomfort, rash, or any other kind of acute-onset medical emergency, obtain immediate transportation to an emergency room or dial 911 for emergency medical assistance. After receiving emergency treatment, call this clinic — 480-341-9400— as soon as possible.

Signature of Patient or Person with Authority of Consent

Date

Signature of Witness

Date

Copy of Original Informed Consent: I am in receipt of a copy of this informed consent: _____