
*Accelerate GF™*

Natural Regenerative Medicine Treatments

# Treatment Protocols

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**About Us:**

Science has recently shown that the body has enormous potential to heal itself. Regenerative medicine is an exciting area in medicine that is evolving very rapidly and PlasmaGenix is proud to be at the forefront of developing new therapeutics to treat a wide variety of chronic conditions. We can now deliver products to accelerate the body's own natural healing mechanisms and enrich the body's inherent ability to repair and regenerate.

The culmination of over 3 decades of clinical experience and research gave birth to PlasmaGenix which is poised to be a leader in the field of regenerative medicine. To date, PlasmaGenix has successfully treated over 10,000 patients for various neurologic conditions, chronic non-healing wounds, sports related injures as well as muscular sclerosis and Charcot-Marie Tooth disease.

**Mission:**

Our mission is to develop regenerative therapeutics
derived from the patients own blood, commercialize them and facilitate access to those that suffer from chronic pain, non healing wounds and debilitating neurologic conditions.

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## Treatment Modalities

### *Platelet Rich Plasma: Indications*

As with any musculoskeletal complaint, a thorough history and examination is required to reach a differential diagnosis. Additional diagnostic studies may be warranted and review of the prior “failed” treatments. PRP is generally considered an elective treatment for subacute and chronic conditions. Generally, healing slows or stops 6-12 weeks after an acute injury. If a patient has had no improvement for over six weeks, it is possible their healing phase has arrested. In overuse or repetitive conditions, it can be more challenging to isolate the transition from an acute phase.
We present some of the common orthopedic indications for which PRP is used along with a partial-not circumspect-review of current evidence for each indication. We believe that evidence based medicine is a helpful tool, but a great deal of the art of treating a patient with concurrent modalities is very difficult to quantify in the RDBCT trial.

### *Tendinopathies*

Tendinopathy refers to a degenerative condition of tendons marked by the chronic loss of collagen, tissue integrity, stability and strength. Tendinopathy is not an inflammatory condition, as histologic specimens lack inflammatory cells. Causes are multifactorial, but natural aging, injury, repetitive stress, neural, vascular and hormonal inputs all likely contribute. Whereas tendinopathy is nearly ubiquitous as we age, pain and dysfunction generally occur only when sufficient stresses are applied to the degenerated tendon.
Basic science and animal studies are supportive for the use of PRP in tendinopathy. Lab studies have shown improved tenocyte proliferation, collagen deposition and endogenous growth factors. Animal models with surgically induced lesions are common and show good results.
We encourage further research on technique, number of injections, spacing of injections, number of platelets, concentration of platelets over baseline, with or without leukocytes in the injection, exogenous activation of injected platelets, use of common and validated outcome measures (i.e. VISA scores) in studies and patient selection.

***Ligament Sprains***

Most ligament studies on humans to date have been in combination with surgical anterior cruciate ligament reconstruction. Overall, the evidence suggests improved pain, healing and graft quality. The sports medicine literature with regard to non-surgical care is lacking at this point in time. Anecdotal evidence from expert sources indicate improved time of healing, reduced pain and reduced time to return to sport. We encourage more research in this area.

***Muscle Strains***

Muscle strains are a very common source of pain in dysfunction, particularly in the athlete. Muscles are rich in blood supply and generally heal with usual care, approximately 8 times faster than ligaments. If a subacute or chronic condition developed, consideration for PRP treatment would be acceptable. In rare situations, the delivery to an acute injury in an attempt to facilitate function could be considered, but there is insufficient evidence to endorse this currently. A study by Sanchez has shown faster recovery of acute muscle tears with PRP injection. If applicable to larger scale human use, it is unknown if this is relevant clinically, functionally or for return to sport. Treatment of myositis ossificans with barbotage, aspiration and PRP injection is an area of specific interest to consider.

***Joints***

Osteoarthrosis (OA) is a chronic degenerative condition of hyaline cartilage. OA accounts for profound morbidity, pain and health care expenses. The consequences to the individual and to the population as a whole are very significant, particularly with our aging population. There are few validated interventions that improve the clinical condition of a patient once the degenerative process becomes symptomatic. Given the lack of response of the body's healing mechanisms to degenerative conditions generally, injection of growth factors and cytokines is sensible. Lab and animal models exist for using PRP in OA with generally favorable results. It is unknown whether PRP acts by local paracrine factors to alter pain, by new hyaline or fibrocartilage formation or a combination of both or neither. We encourage further high quality studies, pre/post imaging and joint fluid analysis to help elucidate the effects. Animal models describe improved healing in meniscus, glenohumeral labrum and OCD with induced defects, but human studies are currently lacking in these areas.

***Intervertebral Discs***

Animal models using various preparations and matrices show encouraging results, however, no human studies exist. Placing PRP in a disc will necessitate damage to the disc, which has been shown to be potentially permanent after discography. Due to the close proximity of critical neurologic structures to the posterior annulus, CT or fluoroscopic guidance would be the preferred methods of regenerative factor placement in discs.

***Nerves***

Entrapment neuropathies that have failed “conservative management” have traditionally been treated with surgical release/decompression (neurolysis). With the advancement of musculoskeletal ultrasound, peripheral nerves and their adjacent structures can now be clearly visualized. There is growing experience in performing percutaneous release of nerves using different solutions (termed hydrodissection or hydroneurolysis). There is insufficient information to endorse PRP treatment for this use, however, in cases of ischemic damage to a nerve due to scar tissue banding, there is theoretically a role for PRP during percutaneous procedures and we encourage further investigation.

***Fracture Non-Union***

Fracture non-union is a debilitating, albeit fortunately rare complication in the care of fractures. PRP has been shown to be inferior to recombinant BMP-7 to speed non-union healing in one randomized human study. The role in acute fractures in humans has not been well evaluated and seems impractical given the rate of successful healing without intervention. PRP has been used in spinal and joint fusion surgeries with success. Further study of fracture non-unions would be of value to the literature base and may hold significant benefit for patients if extended courses of healing or bone stimulator use could be avoided.

**Platelet Rich Plasma: Contraindications Absolute Contraindications:**

- Platelet dysfunction syndrome
- Critical thrombocytopenia
- Hemodynamic instability
- Septicemia
- Local infection at the site of the procedure
- Patient unwilling to accept risks

**Relative Contraindications:**

- Consistent use of NSAIDs within 48 hours of procedure
- Corticosteroid injection at treatment site within 1 month
- Systemic use of coriticosteroids within 2 weeks
- Tobacco use
- Recent fever or illness
- Cancer- especially hematopoetic or of bone
- HGB < 10 g/dl
- Platelet count < 105/ul

Platelet Rich Plasma: Protocols, Technique and Safety Recommendations

***Protocol/Technique***

Generally speaking, the procedure only requires the physician and an assistant to aid in preparation of a PRP graft, maintenance of aseptic technique and saving images on ultrasound (if applicable).
*Pre-procedure Considerations*

1) There should be a specific indication correlated with physical exam and confirmed with imaging studies such as x-ray, ultrasound, MRI, or CT scan prior to treatment.

2) Appropriate patient education and discussion has occurred with an informed consent signed prior to the initiation of the procedure.

3) Contraindications to the procedure are reviewed prior to initiation (see above).

4) Analgesics (no NSAIDs) or anxiolytics have been administered, if applicable

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***Graft Preparation***

1) The patient is placed in a comfortable seated or recumbent position.

2) Sterile single use needles and syringes should be used with appropriate handling and disposal.

3) Using aseptic technique (see below), an appropriate amount of venous blood is obtained for the
given procedure.

a. Single-stick draws are preferred to decrease chances of activation.

b. If a vein is passed through completely, blood flow is not smooth, needle comes out of vein
or multiple attempts at a single site occur, consideration of a second site should be given. c. If the patient is a difficult draw, consider using ultrasound

4) Using sterile technique, the venous blood is transferred to the centrifuge. PRP should be obtained using a separating device designed for autologous blood. Preference is given to a closed system that prevents exposure of the blood and cellular components to the open air in the room and allows for minimal manipulation of the tissue.

5) If multiple patient grafts are prepared concurrently, proper labeling of each graft should be completed to ensure no cross contamination or the graft being used on the wrong patient.

***Image Guidance***

1) Real-time image guidance using CT, fluoroscopy or ultrasound should be used when injecting PRP.

2) If ultrasound is used, the following considerations should be decided upon in advance:

Sterile gel. We recommend this for longer procedures, intra-articular injections, and any injections around the spine. Universal use has not been shown to improve infection rates, and in the setting of simple soft tissue injections, judicious use of aseptic technique is sufficient.

Sterile probe covers. We recommend probe cover use with longer procedures (percutaneous needle tenotomy, etc). Cleansing of the probe before and after procedures and adherence to aseptic technique is sufficient. Covering the probe with sterile wound products (tegaderm) or using sterile gloves are other options that have been used in the community with success.

Scout images and indelible markings of the site of probe position and needle entry should be made prior to final cleansing of the skin.

***PRP Injection***

1) The patient is placed in an appropriate and comfortable position that allows for sterility and access to the site of injection.

2) All necessary materials for the injection (PRP, additives, 4X4s, needles, US gel) should have been planned and placed on a sterile table adjacent and easily accessible to the physician.

3) The patient's skin is cleansed appropriately and towels or drapes may be used to create an aseptic field.

4) If local anesthetic will be used, it is to be applied with aseptic technique. See above discussion on anesthetic effects on PRP; consider infiltrating only the local subcutaneous area with anesthetic. Consider nerve block for larger/ longer procedures (tenotomies).



5) If ultrasound is used, apply gel consistent with markings made previously.

6) Complete the injection with real-time recording of images.

7) Apply a dressing or appropriate bandage to protect the needle entry site.

***Post-Injection***

1) Monitor for post-procedure complications (vaso-vagal most common)

2) Patients should be given post-procedure instructions, precautions, and emergency contact information.

3) Protocols for immobilization and post-procedure activity allowed/ encouraged vary widely. Future recommendations will be forthcoming once protocols are more widely accepted +/- studied.

4) Post procedure analgesic prescription should be dispensed. Avoid NSAIDs until the patient has healed, is pain free, has full function or has reached a plateau.

5) Contaminated areas should be disinfected in between patients per OSHA guidelines.

*6)* The procedure should be recorded in detail with a procedure note including: date, pre/post-
procedure diagnosis, procedure title, performing physician w/wo assistants, anesthesia, brief indication of procedure, description of graft preparation, description of procedure including guidance and instruments.

***Follow-up***

1) Patients are generally re-examined 2-4 weeks after the procedure to follow pain, function, injection site and to discuss concerns and future course.

2) Patient response should be recorded using validated outcome measures such Nirschl, VISA, etc.

3) Complications, response and all other pertinent data should be entered in the patient tracking data file.

4) Consideration for re-injection should be a patient centered decision and made based on functional outcome. We do not endorse a specific number of injections at any site.

***Safety**:*

1) Universal precautions at all times during the procedure and immediately following the procedure.

2) Infection: PRP is antimicrobial and effective against most bacteria classes except Klebsiella, Enterococcus and Pseudomonas. Standard skin disinfection should be used before injection.

3) This is entirely an autologous graft making eliminating the concern for disease transmission unless the graft were contaminated.

4) Risks to patient from the procedure:

a. Infection
b. Bleeding
c. Nerve damage
d. Pain
e. Lack of result
f. Loss of limb and death are very rare but possible.

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