GENESISCS REGENERATIVE MATRIX GRAFT TREATMENT DESIGN

This design process is implemented when the GenesisCS Component Concentrating System is employed for patient application. It is encouraged that all protocol steps be followed to attain the best performance outcomes.

Regulatory Requirements

1. Obtain informed patient consent
2. Facility blood management protocols must be upheld when handling and drawing blood products.

The Blood Draw

The health care professional responsible for blood collection should be trained in the practice of veni-puncture and the inherent risks. Aseptic technique, proper skin preparation and continued protection of the veni-puncture site are essential. Use the intravenous butterfly catheter provided in the blood draw kit of the GenesisCS Concentrating System. Prepare the syringe with 5 mL of citrate anticoagulant then prime the needle with citrate anticoagulant. Apply the tourniquet to identify the venipuncture site and then release the tourniquet. Scrub the area covering 2 cm from the access point for 30 seconds with alcohol or other facility approved disinfectant. Perform the veni-puncture and clamp the access catheter. Secure the catheter to the skin. Attach the syringe with 5 mL citrate anticoagulant and draw 55 mL of blood, filling the syringe to 60 mL. Gently draw blood from the patient. Excessive force may activate the platelets and potentially hemolyze red blood cells. Invert the syringe several times during the blood draw to insure adequate mixing of the blood and anticoagulant. When completed, clamp the butterfly catheter and apply pressure while removing the needle from the puncture site. Hold pressure until bleeding stops.

The Bone Marrow Aspiration

Expose the area for aspiration and locate posterior superior iliac crest. A towel roll or small pillow placed under the hips may allow easier location of the iliac crest. If necessary, a staff member can help secure the patient's position. Using aseptic technique, swab the aspiration site with povidone-iodine swab stick, applying some friction and working in a circular motion beginning in the center and moving outward. Repeat x 2 with new swabs. Allow povidone-iodine to dry. Apply the sterile drape and using a 3 mL syringe and 22 gauge 1" needle, draw up 2-3 mL lidocaine 1% from a vial held by an assistant. Locate the exact point for aspiration and perpendicularly inject the lidocaine subcutaneously and into periosteum. Avoid injecting too much because it may obscure the landmarks. Prepare the bone marrow needle by priming with Heparin 1000 U/mL and making sure the stylet moves freely. Prepare (2) 60 mL vac-lock syringes by pre-priming each with 9 mL of Heparin 1000 U/mL. Stretch skin taunt over puncture site, keeping crest between thumb and index finger of one hand. Holding the bone marrow needle with stylet in place, puncture the skin and advance through the subcutaneous tissue, periosteum and into the marrow cavity using steady and controlled pressure with a twisting motion. When the needle is firmly in place and a slight give in pressure is felt, the cavity has been entered. Penetrate up to 3 cm

into the crest. Remove the stylet and quickly attach the 60 mL vac-lock syringe with heparin. Apply strong, quick suction utilizing the syringe locking mechanism. Obtain approximately 51 mL of marrow aspirate per syringe, filling each syringe to 60 mL. Aspirate then ¼ turn the needle and aspirate again. Repeat the ¼ turn step until the necessary amount of aspirate is attained. Remove the needle and maintain pressure over site for approximately 2 minutes until bleeding has stopped. Meanwhile, remove the sterile drape and cleanse the povidone-iodine from skin with alcohol swab.

Patient Considerations

Patients are identified by two forms of ID or according to facility protocol. Patients that had taken aspirin one week prior to blood donation or NSAIDS three days prior to donation should be excluded from treatment.

Blood Sample Considerations

Fifty five (55) mL of blood is collected from the patient into a pre-loaded syringe containing 5mL of citrate anticoagulant. Ten (10) mL of blood is collected from the patient into a pre-loaded syringe with 1mL of CPD is collected from the patient to serve as baseline whole blood control. The blood draw should be performed using a 16-19GA needle and all samples should be kept at room temperature from the time of draw through processing and analysis. During the blood draw, the syringe is rocked back and forth to mix in the citrate anticoagulant. This prevents clotting or premature activation during the blood draw. Blood samples from each donor are processed according to the instructions provided in the GenesisCS Component Concentrating kit. The EmCyte Executive Series Centrifuge is preferred because it has full swinging bucket capabilities which optimizes platelet separation.

Sample Testing Considerations

Platelet counts are measured in the Beckman Coulter Counter, or any approved blood analyzer that has the capability of counting up to three (3) million platelets without dilution. Test samples must be placed in an empty red top tube (no anticoagulant inside the tube) and preferably plastic tube. Glass tubes can activate platelets prior to performing a count. The samples should be tested immediately after final collection. Prior to testing, the sample should be kept at room temperature and continuously rocked back and forth to prevent clumping or activation.

Chronic Open Wound

Studies show that the use of platelet growth factors can support the rapid closure of chronic non-healing wounds of various causes. When preparing a patient for treatment there are standard considerations. At the first visit each patient should provide a complete history and must have a physical examination that will include wound ulcer area, depth, presence of infection and presence of necrosis. A clinical work-up consisting of CBC, chemistry and blood cultures should be completed prior to treatment. If there is infection, the patient should be treated with antibiotics until the infection is minimized or completely gone. At each visit, if indicated, the wound should be sharply debrided of all necrotic tissue prior to the application of the regenerative matrix graft. The regenerative matrix graft is prepared using the GenesisCS Concentrating Systems. Follow the system protocol as indicated for the graft type and volume. When preparing the

wound bed prior to application, it is good to thoroughly irrigate with isotonic normal saline solution to softly debride. Once this is completed the site should be dried with sterile gauze. The GenesisCS regenerative graft is then applied to the wound bed. It can be sprayed on or it can be made into a tissue graft for complete wound coverage. A XEROFORM Petrolatum Gauze is then applied over the graft which helps to keep the graft intact and wound bed moist. 4 X 4 dry gauzes are then placed over the Petrolatum Gauze and then finally wrapped with KERLIX bandages. This dressing must be kept dry and intact for 3-5 days. After the 5th day, the dressing is removed and the wound cleaned. A wet to dry dressing should be applied until the next regenerative matrix graft treatment. The regenerative matrix graft applications should be done every two to three weeks.

Injection Therapy

Intraarticular injection therapy using regenerative matrix grafting has shown amazing promise for patients with various joint disorders. When preparing a patient for this treatment there are standard considerations. Patients selected for regenerative matrix grafting generally fit a criteria of symptoms or conditions. These would include damage to the articular cartilage, connective tissue or bone within the joint. This is generally seen during arthroscopy or on weight bearing radiography. Patients usually exhibit an analog pain score (VAS) of 60 on a 100-mm scale. The pain is usually refractory or unresponsive to steroid injections, non-steroidal anti-inflammatory (NSAIDS) drugs, and other conventional therapies. These patients are encouraged to discontinue the NSAIDS at least one week prior to the injection therapy. The injection is usually performed under local anesthesia. Guided fluoroscopy or ultrasound is used to locate the injury site. The regenerative matrix graft material is attained according to facility protocol and is prepared using the GenesisCS Concentrating System. The graft is then injected into the injury site under guidance. Patients can be given acetaminophen and hydrocodone for pain. Patients must limit mobility in the injected site for at least 24 hrs after the injection. Patients are then instructed to return to normal daily activities. This is an outpatient procedure and can be repeated according to facility protocol.