Genlife
Regenerative Medicine

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GLRM Frequently Asked Questions

Q. How does each type of Regenerative Injection Treatment compare to each other?

A. I like my patients to think of these treatment options on a continuum of care spectrum, starting with the mildest, easiest, and cheapest at the low end to the most expensive, sophisticated, and strongest on the high end of the spectrum.
Prolotherapy is the safest, least expensive, and most effective place to start for milder disease. The younger the patient, the better it works. It still can help in more advanced disease, and in patients of advanced age, but the chance of significant improvement falls with severity and age. It can take three to six prolotherapy treatments to heal or manage most orthopedic conditions, with a range being one to ten treatments.
PRP is probably equal to two to three prolotherapy treatments, but it can cost two to three times more than a prolotherapy treatment. I generally prefer to use it for unstable ligament tears, larger tendon tears, more advanced cartilage lesions, and more advanced arthritis. Most orthopedic conditions that I treat take two to three treatments, with a range of one to five treatments to heal or manage.
Stem cells are reserved for severe tendon disease, ligament tears, cartilage lesions, and more advanced arthritis. In a more moderate case, it also can attain in one treatment what two to three PRP treatments can achieve. For someone with a limit to the amount of time they can commit to their healing schedule, it may be more cost effective to go right to a stem cell treatment plan. This is especially true for someone traveling a great distance for treatment. The other advantage is that the length of symptom relief a patient usually experiences from a stem cell treatment, particularly for a chronic incurable condition, such as degenerative arthritis, may be two to three times that of a series of PRP treatments.

Q. What are the out of pocket costs for the various treatment options?

A. As of 2016, treatment costs run as follows:
Prolotherapy costs a minimum of $200 for one ultrasound-guided injection. The more sites injected, the more time and materials it takes to complete the treatment, therefore, the more expensive it is. It costs $200-800 to treat any given area or region. This includes ultrasound guidance or x ray fluoroscopy in most scenarios. Actual costs will be determined after a full evaluation of a patient's problem including a medical history, physical examination, diagnostic ultrasound evaluation, and review of any pertinent diagnostic films and other test results.
PRP treatments cost $1,200 for most cases. This can include ultrasound examination each time a treatment is performed, ultrasound guidance, or x ray fluoroscopy, a PRP kit, preparation of the PRP, a platelet count, and injection of the PRP to all necessary sites to complete the treatment plan.
Stem cells from fat tissue costs range from $2,800 to $3,200 to perform the mini-liposuction, separate the fat from the blood and oil, and prepare the fat for implantation, as well as to perform the injection with or without ultrasound guidance.
Stem Cells from bone marrow, at this time, cost $2,800 for a single joint or region. This includes a bone marrow aspiration, preparing the bone marrow concentrate, and injecting the cells back into the joint or tendon.
Q. Are cellular medicine treatments covered by insurance, Medicare, Worker's Compensation, Auto Accident Insurance?
A. No, not at this time. Stem cell use is still experimental and third party payers have very well defined non-coverage information in their policies (usually called autologous blood based therapies, which covers PRP and stem cell injections). Prolotherapy is not covered as well. Policies all cite the same reason–there is not enough research evidence to show that these treatments work in large populations.

Q. What if I don't have a recent MRI?

A. If your MRI is more than one year old or if your condition has changed for the worse, we request you ask your treating physician or your primary care physician for an updated MRI order including a precertification, if required by your insurance plan. If I order an MRI for you, before you become an active patient in our practice, there is a probability that it will not be covered by your insurance and you may be responsible for the MRI bill.

Q. Do you offer a payment plan?

A. We do not offer payment plans at this time. Payment is expected at the time of treatment by credit card, check, or cash.

Q. Why not just get surgery to fix my problem?

A. Surgery is always an option for patients who suffer from severe arthritis, a cartilage tear, a severe ligament tear, or a complete tendon tear. Surgery is also the treatment of choice for badly torn cartilage and bone-on-bone arthritis. However, we all know friends and loved ones who didn't have the outcome they were hoping for after their surgery. Stem cell injections help many of my patients avoid surgery, but not all of them. Some are simply too far-gone and I tell them so when we discuss their case. Joint replacement surgery is 90% successful but only 70% of patients are satisfied with their outcomes. I see a lot of these 30% dissatisfied patients in my practice. They wonder what went wrong, and how I can help them now after their surgery. That's why I began to offer these experimental procedures to my patients. The risk of putting your cells into your orthopedic problem area is very low. If you can afford the treatment, understand your chances for a positive outcome, and are willing to accept the risks, complications, and benefits, then consider getting an autologous cellular medicine treatment. In patients younger than 60-years-old who are facing a joint replacement, or who have arthritis with a torn meniscus in their knee, the risk of having complications resulting in further surgery and chronic pain are significantly high.

Q. How many stem cell treatments and other cellular medicine treatments have you performed?

A. I perform approximately one to two stem cell cases a week and ten to twenty PRP cases a week. I also do ten to twenty prolotherapy cases a week. I perform approximately five to ten interventional spine injection cases a week. I've been performing stem cell treatments, PRP, spine injections, and prolotherapy all through Latin America and train and teach other Orthopedists and Pain Specialists throughout the world.

Injections are either guided with C-Arm fluoroscopy or with high-resolution ultrasound technology or both if needed.

Q. What kind of problems can be treated?

A. Stem cell injections can treat degenerative arthritis of the shoulder, elbow, wrist and hand, as well as the hip, spine, knee, ankle, and foot. They are also used for most types of ligament sprains, tendon tears without significant retraction, certain types of meniscal and labral tears, and certain size chondral lesions (surface cartilage holes). They are also helpful to treat avascular necrosis of the end of the bones in joints, as well as certain bones in the foot and wrist. Stem cell injections are also used for certain types of non-union fractures. They are also helpful in treating certain types and severity of spinal disc injuries and degenerated discs that cause pain and disability.

Q. Can non-musculoskeletal medical conditions be treated with stem cells?

A. We do not offer stem cell treatments for non-musculoskeletal medical conditions at this time. This includes spinal cord injury or disease.

Q. How many treatments are required to give me the best outcome attainable for my problem?

A. First of all, ideally, a stem cell treatment consists of three separate treatments:

Pre-treatment consists of a hypertonic dextrose solution or a platelet lysate injected in the joint to calm it down and prepare it for the stem cell injection the following week. It is much more advantageous for the stem cells to be injected into a joint that is not so inflamed. Any unstable ligaments are pre-treated as well to provide the joint with a more stable support system to prepare the joint for the stem cell injections. This treatment, including your initial consultation, takes one to one-and-a-half hours to complete.

Stem Cell Day occurs one week after the pre-treatment. During this treatment, you return for the bone marrow aspiration. If needed, we will also perform a mini-liposuction to prepare a fat graft preparation. In addition, your blood is drawn to prepare a stem cell plasma preparation. Then, depending on your clinical problem, the cells are injected into the joint and cartilage lesions inside the joint, and also into the supporting ligaments and tendons if needed. This treatment takes two to two-and-a-half hours to complete.

Post-treatment injection is performed with a stem cell plasma treatment into the joint, or any place the stem cells were injected, to help them stay on site. This keeps them working a little longer before they die off. This treatment takes up to an hour to complete.

The more severe the orthopedic problem, the greater the chance of needing more than one treatment to attain the pain relief and healing we are hoping you will achieve.

What constitutes a treatment failure? The patient exhibits no clinical improvement by 3-4 months after treatment.

Q. What are the risks, complications, and side effects of a cellular medicine treatment?

A. Anytime a needle is placed into the human body there is a chance of bleeding, bruising, pain, infection, and nerve injury. Patients generally experience some bruising after a treatment. This usually clears up in a week or two even after liposuction and bone marrow aspirations.

The pain involved is related to the needle procedure and then, after the procedure, by the initial inflammation produced in the injected tissue by the treatment. When possible, the pain is minimized during the procedure with superficial injections of lidocaine. Sometimes the anesthesia can be injected closer to the target tissue to minimize the effect of the procedure pain. We also employ regional anesthesia blocks to help the patient feel minimal pain when their joint is being treated. The pain after treatment may be treated with narcotic pain medication for a few days to a few weeks depending on what area was treated and the patient's tolerance to pain.

Although my patients have not experienced an infection, the chance of suffering an infection from a needle-based procedure is 1 in 50,000 for a joint injection. We take meticulous care in our skin preparation and follow all proper injection guidelines. Nerve injury is a rare occurrence in injection work, especially when performed with guidance. It is not normal or expected to hit a nerve during regenerative injection work. If you ever feel an electric shock going down the limb or pins and needles during an injection, you should let your doctor know immediately so the needle can be redirected. Even if the nerve is touched and injected with cells or dextrose, nerves usually recover very quickly and completely. The risk of permanent injury to nerves when inadvertently injected by anesthesiologists performing regional anesthesia in the operating room setting is 1 in 90,000.

Q. What if I have a torn labrum or torn meniscus or a chondral lesion in my joint?

A. If the lesion is very large and unstable, we probably cannot help you without surgical repair or removal. However, most of the time, the lesions are not that big. For example, if the lesion is an unstable, herniated knee meniscus tear, there is a treatment protocol aimed at stabilizing the meniscus and healing the tear after the cells are injected on site. The joint may then be braced for six to twelve weeks to help the meniscus heal in the right position. According to my colleague Dr Shiple, "the most exciting results I have seen are on focal chondral lesions in younger adult and adolescent athletes". We are seeing excellent filling in of these smaller cartilage lesions and the avoidance of microfracture surgery. In his opinion, if faced with a decision to undergo stem cell injections or have surgery, surgery should always be a treatment of last resort.

Q. What about stem cells for bone fractures?

A. Stem cells in bone fractures already have an important role in orthopedics. Non-unions can finally heal if concentrated bone marrow stem cells are injected directly into the fracture site and stabilized with another period of immobilization. Also well established is the role of concentrated bone marrow injections into bones that have suffered avascular necrosis or osteonecrosis, otherwise known as death of the bone. AVN of the hip, knee and ankle are areas where we are seeing a successful alternative to surgical drilling to try to re-establish blood flow and healing in the dying bone. Patients with Stage 1 and 2 AVN in the hip can expect about a 90% success rates with this stem cell procedure and patients with grade 3 AVN of the hip, 70-80% success range while grade 4 AVN is only 60 plus % successful. (Successful AVN treatment outcomes in the orthopedic literature are defined as preventing an early total joint replacement.)

Q. Will stem cells help my spine condition?

Stem cells and PRP are being used in spine conditions with good results in some select cases, but it is still very experimental. The evidence that cellular medicine treatments in the spinal disc work for a large population is still at the case series and case report stages. There are no high level controlled studies yet showing this form of treatment works for the multitude of chronic pain patients with damage to their intervertebral disc. Several promising presentations at cellular medicine conferences have shown such good evidence that I am offering several different treatment options for my disc patients as a last resort prior to a surgical option. The evidence seems to point to a stepwise approach based on the results of a preliminary diagnostic discogram that will help establish which disc needs treatment. The severity of the disc condition will dictate what the discs need to give pain relief and help the disc heal. For instance, mild injuries can be effectively treated with PRP into the disc, stem cells for more advanced disc injuries, and stem cells with a matrix (such as the patient's own fibrin glue) for the most severely injured discs.

We do have some options for patients with arthritis in a facet joint and nerves that are irritated by a herniated disc. Traditionally, pain doctors inject high dose steroids around the nerve or into the joints. These only have a temporary effect. Putting PRP into arthritic or injured facet joints and sacral-iliac joints with C-Arm fluoroscopic guidance is helping many of my patients avoid radio frequency ablation, where the nerves to the painful joint have to be burned with high energy every year or so to help them attain pain relief. We can also inject a platelet lysate with a very, very low dose of steroid to help calm the

inflamed nerve near a damaged disc with as much pain relief as a high dose steroid shot without the risk of the patient getting too many steroid injections in a calendar year. Early research appears to show a platelet lysate treatment provides the patient with a high dose of the patient's own growth factors along with a micro dose of steroid that acts as an anti-inflammatory growth factor to help the patient's painful injured disc or spinal nerve calm down and recover after one to several treatments.
We have nothing yet to offer our end stage spinal stenosis patients other than standard interventional spine treatments and a trial of prolotherapy, which works well for milder disease.
Using cellular medicine injection techniques for spinal conditions is an exciting new frontier in interventional spine medicine that will hopefully make spinal fusion surgery a rare event in medicine.

Q. If I have less severe arthritis, are my chances to experience a good outcome with stem cell injections improved?
A. Yes, definitely. We see better results that last longer if we can intervene at an earlier stage in the degenerative process. 80% of patients are happy at the end of their treatment (without fat grafting), and report that they would undergo the treatment again and recommend it to friends and family.

Q. What are my chances of getting good pain relief if I have bone-on-bone arthritis of the knee or hip?
A. About 60% of patients with advanced arthritis get to the point where they experience at least 50% pain relief. This is the clinical criteria for a good outcome in most orthopedic surgery research. Anecdotally, the addition of a fat graft to the bone marrow treatment seems to increase the odds of getting good pain relief up to about 80%.

Q. Can a stem cell injection grow your cartilage back in your bone-on-bone degenerative arthritic joint?
A. Probably not, though we have a few cases that have shown regeneration of some surface cartilage. At least one patient who has had four stem cell treatments in the last three years has definitely shown significant regeneration of her surface cartilage on repeat MRI imaging. It may be that with repeated stem cell injections, we can expect to see more and more cartilage regeneration. This is a topic for future research.

Q. Why do patients report they are doing so well if they are not growing their cartilage back?
A. We don't know exactly. We are probably changing the cellular and chemical composition of the joint for an extended time period. We know the arthritic joint is a hostile environment for the continued survival of already degenerating cartilage. We know that injecting good growth factors in an arthritic joint improves this chemical environment for a while. How long is a while? The Filardo PRP study showed clinical improvement in arthritis of the knee with a series of three PRP injections over nine to twelve months. According to other data, with same-day stem cell procedure, patients average eighteen months of relief with one to two series of these treatments. For arthritis of the knee and hip, the pain relief ranges from six months to five years for one to two series of stem cell injections.

Q. Does the bone marrow draw hurt?
A. Despite common belief, it is actually much less painful than most people think. In a recent survey, 83% of patients reported that the bone marrow draw was much less painful than they anticipated and they would return for a repeat treatment without hesitation.

Q. What about the risk of stem cells causing tumors to form where they are injected?
A. There is no report of a tumor growing in an area where the patient's own cells were injected into an orthopedically treated area. This is a possibility, however, in two circumstances:
Embryonic stem cell work where the genetic make up of another human being is injected into your body. The genetic influence and triggers that may cause the stem cells to mutate or form a tumor in the future is a real risk one assumes when receiving embryonic or any autogenic stem cells from another human being.
Culture expanded stem cells have the risk of being grown too long or of being put through too many passages in culture. The risk here is the more passages a stem cell is passed through, the more chances the stem cell can mutate into a tumor cell that could go unrecognized and be implanted into the host patient, thus putting them at risk of developing a tumor. It is illegal to culture expand stem cells in the United States.

Q. How soon can I schedule a stem cell procedure?

A. It usually takes about 2-4 weeks to get on the schedule, although sometimes we can get you in sooner. This also gives patients adequate time to prepare for their treatment. Preparation involves dietary changes, the use of supplements, changes in medication, and starting an exercise program to help change the patient's ability to produce an optimal stem cell sample that is critical to achieving the best outcome possible.

Q. Are stem cell injections approved by the FDA to treat orthopedic conditions we routinely treat?

A. The answer is no, they are not. But, the FDA does not approve treatments of disease. They approve medicines and devices used to treat patients. They are charged to protect the public from the harmful use of devices–such as surgical instruments– from ever reaching the doctor's office or hospital where patients are treated. They are also charged to make sure the medicine supply doctors use to treat their patients is safe and is transported safely across state lines.

Q. Are stem cell injections legal?

A. Yes. The use of your own tissue to treat a medical problem in your body is legal if doctors follow certain rules and regulations developed by the FDA. As long as the procedure is performed on the same day in the same clinic where the cells were harvested and we do not over-manipulate them, we are operating within the guidelines and rules specified by the FDA.

Q. Why does the FDA have legal jurisdiction over my cells?

A. If a stem cell, or any tissue for that matter, was altered enough in preparation so that it was technically no longer that person's cell, the FDA considers it to be a drug. As such, the FDA has control over these altered cells to make sure no harm can occur to the patient being treated by their own tissue, or drug, depending on your viewpoint.

Q. What's the future for stem cell treatments in orthopedics?

A. We are starting to figure out more sophisticated ways to deal with our patients' orthopedic problems that will change the specialty of orthopedics. Just like interventional cardiology was developed after cardiothoracic surgery to create minimally invasive catheter procedures to avoid open-heart surgery (placing a cardiac stent, for instance), we are developing interventional orthopedics, which are office-based, minimally invasive needle procedures to replace orthopedic surgery procedures commonly done in the hospital.

Q. How do I prepare for a stem cell treatment?

A. There are supplements we recommend that may help prepare stem cells for your treatment. If you talk to a dozen doctors who perform stem cell treatments, you will get a dozen different answers on what you can and should be doing to prepare for a stem cell treatment. There really is only scant data on what if anything we can do to most effectively help prepare for a stem cell treatment. Most of this is theory at this point, or data that has been collected from university animal studies and extrapolated to humans. With that said, vitamin D3 helps stem cells grow, much like adding Miracle Grow to tomato plants. Vitamin C and E are important too as is Calcium and Magnesium. We also ask our patients to take Neo-40 to help build up Nitric Oxide and Stem XCell, to optimize their ultimate result.

It turns out that strength training can also help our stem cell numbers. For example, exercising in the pool to try to get some muscular development helps our stem cell numbers increase. This may be impossible for some patients, but any increase in strength can only help you prepare for your treatment. In our practice, patients receive the "Yellow Folder" once they schedule their treatment outlining all of these topics to try to help them achieve the best outcome with their treatment.

Dr Mahl wishes to thank his colleague Dr Brian Shiple for the information contained in this brochure.