



THE CENTER FOR REGENERATIVE ORTHOPEDICS

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Informed Consent Form

Treatment Overview

This is an informed-consent document that has been prepared to help inform you concerning the below treatment, condition and delivery method, as well as its risks, and alternative treatments.

Treatment: Adipose Derived Regenerative Cells (ADRC), Bone Marrow Aspirate Cells (BMAC) and Platelet Rich Plasma

Delivery Method: Direct injection into Joint, tendon, ligament or muscle

It is important that you read this information carefully and completely. Sign the consent for the procedure as proposed by your physician.

Procedure Overview

Before the procedure, the areas from where the fat is being removed may be injected with fluid / local anesthetic to minimized bruising and discomfort. The adipose tissue (fat) will be removed from the body by a narrow surgical instrument (cannula) through a small incision. Once approximately 60 ccs (around 4 table spoons) of fat has been obtained, the fat undergoes a process to isolate the cells within the tissue. This process includes centrifugation (spinning) of the fat.

If you lack the amount of body fat needed to do Adipose Derived Regenerative Cells, we can utilize Bone Marrow Aspirate Cells. This process will utilize Bone Marrow that we will harvest from your Iliac Crest (top of the hip bone). The Bone marrow will be harvested with a narrow surgical instrument that will be inserted into the bone marrow and a small amount of bone marrow will be removed. The Bone Marrow will then be centrifuged.

The blood will undergo processing to isolate the Platelet Rich Plasma (PRP). At this point, the Adipose or Bone Marrow tissue will be suspended in the proper volume of PRP and injected directly into the effected area. The entire process takes around 2-4 hours.

ALTERNATE TREATMENTS

- Acetaminophen
- Nonsteroidal anti-inflammatory drugs (NSAIDS)
- Narcotics
- Physical Therapy
- Occupational Therapy
- Braces or shoe inserts
- Cortisone shots
- Lubrication Injections
- Realigning bones
- Joint replacements
- Acupuncture
- Glucosamine and Chondroitin

Financial Responsibilities

The total cost of the procedure includes fees charged by your doctor, the number of sites injected, the cost of surgical supplies, stem cell processing and facility fee. Additional costs may occur should complications from the procedure.

By initialing below I confirm to have read and fully understand what is contained on this informed consent form.
Sign: _____ Date: _____

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Risks of Fat or Bone Marrow Extraction Procedures

Any procedure involves a certain amount of risk, and it is important that you understand the risks involved. An individual's choice to undergo a procedure is based on the comparison of the risk to its potential benefit. Although the majority of patients do not experience these complications, you should discuss each of them with your physician to make sure you understand the risks, potential complications, and consequences of the procedure.

Bleeding: It is possible, though unusual, to experience a bleeding episode during or after this procedure. Should bleeding occur, it may require emergency treatment to drain accumulated blood (hematoma). Do not take any blood thinning medications, aspirin, or nonsteroidal anti-inflammatory medications (acetaminophen is acceptable) for 7 days before and after this procedure, as these may contribute to a greater risk of bleeding or significant bruising. Tell your physician if you are on any of these medications before stopping them.

Seroma: Although unlikely, a collection of fluid may appear at the site where fat was removed. This is usually treated by draining the fluid with a needle. Wearing the abdominal binder reduces the chances of this occurring.

Infection: Infection is unusual after this procedure. Should an infection occur, additional treatment including antibiotics or surgery may be necessary.

Scarring: All invasive procedures leave scars, some more visible than others. Although good wound healing after a procedure is expected, abnormal scars may occur both within the skin and in the deeper tissues. Scars may be unattractive and of different color than the surrounding skin. Scars may also limit mobility and function.

Asymmetry: Asymmetric body appearance may result from fat extraction procedure. Factors such as skin tone, fatty deposits, bony prominence, and muscle tone may contribute to normal asymmetry in body features.

Long term effects: Subsequent changes in the shape or appearance of the area where the fat was removed or placed may occur as the result of aging, weight loss or gain, or other circumstances not related to the fat or bone marrow extraction procedure.

Pain: Chronic pain is rare, but may occur after fat removal or transfer.

Unsatisfactory result: There is the possibility of an unsatisfactory result from the procedure, resulting in unacceptable visible deformities, loss of function, wound disruption, skin death, or loss of sensation. You may be disappointed with the results of the procedure.

Allergic reaction: in rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions, which are more serious, may result from drugs used during the procedure or prescription medicines. Allergic reactions may require additional treatment.

Serious Complications: Although serious complications have been reported to be associated with fat extraction procedures, these are very rare. Such conditions include, but are not limited to: Fat embolism (a piece of fat may find its way into the blood stream and result in a serious or life threatening condition) stroke, meningitis (inflammation of the brain), serious infection, blindness or loss of vision, or death

By initialing below I confirm to have read and fully understand what is contained on this informed consent form.

Sign: _____ Date: _____

Informed Consent Form

Risks of Homologous Adipose Tissue Transfer and Bone Marrow Aspirate:

Any procedure involves a certain amount of risk, and it is important that you understand the risks involved. An individual's choice to undergo a procedure is based on the comparison of the risk to its potential benefit. Although the majority of patients do not experience these complications, you should discuss each of them with your physician to make sure you understand the risks, potential complications, and consequences of the procedure.

- Pain / Stiffness at the injection site
- Bruising
- Infection
- Nausea / Vomiting
- Allergic reaction
- Nerve or muscle injury
- Tendon, ligament, or joint injury
- Dizziness or fainting
- Bleeding

Disclosure Statement

Informed consent documents are used to communicate information about the proposed treatment of a disease or condition along with disclosure of risks and alternative forms of treatments. The informed consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances. However, informed consent documents should not be considered all inclusive in defining other methods of care and risks encountered. Your physician may provide you with additional or different information that is based on all the facts in your particular case and the state of medical knowledge.

Informed consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve. It is important that you read the above information carefully and have all of your questions answered before signing the consent. Homologous Adipose Tissue Transfer and Bone Marrow Aspirate is within the scope of Practice in Medicine but not necessarily the "standard of care", the following important disclosures are made:

- The treatment described on our list have not been evaluated nor have yet been approved by the FDA
- Although Homologous Adipose Tissue Transfer and Bone Marrow Aspirate is not necessarily the "standard of care", it is under the scope of practice of medicine
- The science of Adipose Derived Regenerative Cells and Bone Marrow Aspirate is in its early stage and for most diseases or medical conditions no prospective, randomized clinical trails nor long-term studies have yet been completed; therefore no guarantee of safety or effectiveness is made or implied
- Treatments by licensed medical doctors and / or medical practitioners will be performed after the patient understands and agrees to this disclosure and signs a standard informed consent.
- The results of testimonials of people mentioned on our website who have undergone these treatments may not be necessarily typical.

Consent For Procedure or Treatment

1. I hereby authorize Dr. Doug Frye and assistants to perform the following procedure or treatment: Homologous Adipose Tissue Transfer or Bone Marrow Aspirate.
2. I have been advised and consulted about the extraction and injection technique of the treatment
3. I have been informed that even though this is not an FDA approved procedure, this procedure has been used safely and successfully on other patients.
4. I have been advised that the technique requires the re-injection of tissue derived from my own adipose tissue according to standard fat harvesting and injection techniques. The site of injection is within a specific area to treat. I have been advised that the procedure may not completely eradicate my symptoms.
5. I recognize that during the course of the procedure and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgement necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
6. I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
7. I consent to the disposal of any tissue, medical devices or body parts which may be removed and not needed after the isolation of Adipose or Bone Marrow tissue.
8. For purposes of advancing medical education, I consent to the admittance of observers to the operating room. (I will be made aware of this prior to the procedure)
9. I have been informed that not having the procedure is an option.
10. I have been informed of the risks and complications Homologous Adipose Tissue Transfer and Bone Marrow Aspirate.
11. I understand that this procedure is not covered by insurance and I am responsible for the total charges of all services rendered.
12. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
13. I certify that I understand all the information above in its entirety, have received answers for all my questions, and that I understand the potential side effects.
14. It has been explained to me and I understand:
 - The above treatment or procedure to be undertaken
 - There may be alternative procedures or methods of treatment
 - There are risks to the procedure, treatment, or injection proposed
 - I consent to the treatment or procedure and the above listed items (1-14) and I am satisfied with the explanation

By signing below I confirm to have read and fully understand what is contained on this informed consent form.

Print: _____

Signature: _____

Date: _____