

4550 Investment Drive, #240 Troy Mi, 48098 Phone: (248) 792-9881 Fax: (248) 712-6365

www.JNPortho.com

# PalinGen Stem Cell (amniotic) Injections

## **How Does Amniotic Stem Cell Therapy Work?**

For many patients with debilitating knee osteoarthritis, treatment options are limited and include steroid injections, hyaluronic acid injections (viscosupplementation), physical therapy, and joint replacement surgery. Rotator cuff tendonitis is also a common problem and again, treatment is often limited to intermittent steroid injections, physical therapy and possibly surgery when conservative management fails. Steroid injections have frequently been met with either ineffectiveness, short-term pain relief and the risk of tendon atrophy and rupture. Currently, Dr. Jignesh Patel offers new cutting-edge treatment options like amniotic membrane stem cell injections which can be used to as an alternative to surgery to successfully treat patients with degenerative arthritis (knee and shoulder), rotator cuff tendonitis, lateral epicondylitis (tennis elbow) and other tendon and joint disorders.

Stem cell treatment takes advantage of the body's ability to repair itself. A stem cell is a type of cell the body uses to create new tissues and structures. Stem cells have the ability to differentiate into any kind of cell that the body might need: skin, bone, blood, cartilage, etc. They also remain stable for many years and have the ability to divide and regenerate.

With amniotic stem cell therapy, Dr. Patel injects stem cells from amniotic tissue into your affected area. This has been sterilely processed and converted into a flowable injectable form. For the knee, this is placed sterilely within the joint. For the shoulder it is either placed subacromially (above the rotator cuff) for tendonitis or into the joint under ultrasound if treating osteoarthritis. These stem cells have potent anti-inflammatory properties. Amniotic tissues are also a rich source of collagen, elastin, fibronectin, mesenchymal stem cells and growth factors that can support tissue repair and regeneration. This is the tissue that protects the baby in utero during pregnancy. While similar in concept to steroid injections, stem cell therapy is thought to have a longer and greater impact. At this stage we do not know if this will actually repair or restore damaged cartilage but preliminary data has been promising. A recent scientific paper published in January of 2014 out of University of Southern California showed a benefit in pain control and possibly in regeneration of meniscus tissue after knee arthroscopy for meniscus tears. Applications of this therapy are still being researched and implemented around the world.

While cortisone and other drugs only provide temporary pain relief, stem cells have the ability to restore degenerated tissue while providing pain relief. The growth factors in amniotic stem cells may replace damaged cells in your body. Additionally, stem cell injections contain hyaluronic acid, which lubricates joints and tendons, easing the pain and helping restore mobility. The hope and thought is that because of their regenerative capacity and stability, the impact and pain relief may be much longer than previously obtained with past treatments (steroid, viscosupplmentation, etc.).

### **Product information**

An advancement in regenerative medicine, the Amnio Technology line of products are made from human amniotic membrane and fluid. These amniotic tissues, or allografts, are transplanted to provide protection and support for native tissues in the body.

The amniotic membrane is the innermost layer of the placenta which nourishes and maintains an unborn child. Amniotic fluid is the liquid that surrounds the baby until delivery. Just as these tissues provide biologic and physiologic properties and act as a physical barrier to cover and protect the fetus during pregnancy, the Amnio Technology line of products provide a biological, physiological and physical overlay to support and protect an injury in the body.

Amniotic tissues contain a unique mix of bioactive substances such as collagen, cell adhesion molecules and growth factors recognized as important in the wound healing process<sup>1</sup>. Published studies on the benefits and efficacy of amniotic tissue in wounds date back over 100 years<sup>2</sup>. Amniotic tissue has reported anti-inflammatory, anti-bacterial and anti-fibrotic properties<sup>3</sup>. Amniotic tissues are also thought to have "immune privilege", reducing the risk of an adverse immune reaction. All of these characteristics make amniotic allografts an attractive wound biomaterial.

#### Where do the tissues come from?

Amnio Technology products do not require fetal sacrifice and recovery is performed with maternal consent during live birth. Placental tissues are collected at several facilities around the country, following strict guidelines and consistent with industry best practices.

Donors are healthy women between the ages of 18-45 years. A careful medical and social history is collected in advance to ensure mothers meet all eligibility requirements. Donors are thoroughly screened for communicable diseases. At the time of Cesarean delivery (also known as C-section), the baby is delivered and the placenta and fluid, which are typically discarded, are saved. All tissues are then tested to ensure viability and safety. Tissues are processed to the highest standards in a state-of-the-art American Association of Tissue Banks (AATB) accredited facility and allografts are subjected to stringent USP testing prior to release.

## What are the product risks?

PalinGen® products may not provide an improvement in your condition or injury. There is a possibility of an adverse immune reaction. This is not a complete list of risks. Discuss the potential risks and benefits of product use with your doctor or health professional.

Amniotic stem cell treatment has been used by ophthalmologists to aid with corneal surgery for over 20 years. It also has applications in plastic surgery assisting in burn patient healing. To date, more than 10,000 injections have been performed without a single reported adverse side effect. As with all treatment options, the biggest risk of a stem cell injection is that it does not alleviate all your pain but does afford one more option prior to surgical intervention.

- Amniotic stem cell therapy is a preferred type of stem cell therapy because the cells come from an immunoprivileged site (newborn babies). This means that patient-rejection is extremely rare.
- The use of amniotic stem cells is well researched, safe, and effective.
- All amniotic stem cell donors go through a rigorous screening process, as determined by the Food and Drug Administration (FDA) and American Association of Tissue Banks (AATB).

#### References:

- 1) Complements and the Wound Healing Cascade: An Updated Review. Hani Sinno and Satya Prakash. Plast Surg Int. 2013; 2013: 146764
- 2) The Grafting of Preserved Amniotic Membrane to Burned and Ulcerated Surfaces, Substituting Skin Grafts: A Preliminary Report. Maximilian Stern. JAMA. 1913; 60(13): 973-974
- 3) Amniotic Fluid: Not Just Fetal Urine Anymore. Mark A Underwood, William M Gilbert, Michael P Sherman. Journal of Perinatology. 2005; 25:341-348
- 4) Growth factors and cytokines in wound healing. Barrientos S, Stojadinovic O, Golinko MS, Brem H, Tomic-Canic M. Wound Repair Regen. 2008; 16(5): 585-601
- 5) Immunological characteristics of amniotic epithelium. Hori J, Wang M, Kamiya K, TakahashiH, Sakuragawa N. Cornea. 2006; 25(10): S53-58