# "Get Back Your Health With Amniotic Stem Cell Therapy"

#### EAST WEST HEALTH

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#### INTRODUCTION

Having had this therapy for my shoulder nearly 3 years ago, I can tell you that the outcomes we have seen have been nothing short of incredible at ending chronic and acute pain conditions. This report is meant to serve as a guide for you so that you can see if it may be the right approach for you. This is the medicine of the future and I honor you for looking beyond the conventional approaches of drugs and surgery to find out if this can help. Life is too short to live it in pain. Please share this report with friends and loved ones. STEM CELL THERAPY "Regenerative therapy"

Stem cell therapy is exploding in the medical field, and for good reason. Stem cells have the potential to regenerate into any type of body tissue. The amazing thing about stem cells is that when you inject them into the body, they know what kinds of cells your body needs – for example, meniscus cells or cartilage cells. It is a very exciting time for medicine, especially in the field of regenerative medicine.

Recent research conducted, "Transplanted mesenchymal stem cells with plateletrich fibrin glue scaffold stimulates full-thickness cartilage defects to heal."(8)

#### TIRED OF HEARING.....

- "You've got bone on bone, there's nothing that can be done.
- "Surgery is your only option from here."
- "We just don't know what else to do for you."
- "There's a new medication that might help."
- "Knee replacements work really well, why not just get it done?



#### WHERE DOES DEGENERATION AFFECT YOU?

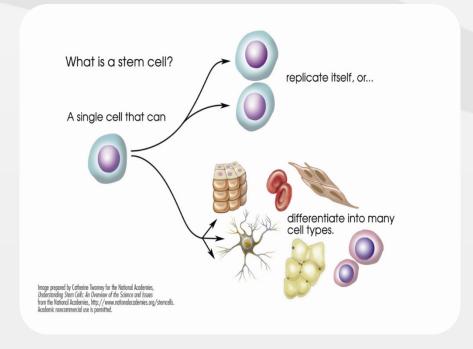
Shoulders, Knees, Lower Back and Neck conditions affect 85% of the population over the age of 65

#### Conditions can include

- Rotator Cuff Syndrome/Tears
- Tendinitis
- Frozen Shoulder
- Bursitis
- Knee Pain, Meniscus, ACL
- Degeneration, Bone Spurs
- Low Back Pain, Disc Problems
- Neck Pain, Disc Problems



Source: American academy of Orthopedic Surgeons http://www.aaos.org/news/aaosnow/jan11/cover1.asp





#### 1. REDUCE INFLAMMATION AND PAIN

Protein Growth Factors inherent in amniotic tissue have very powerful proven antiinflammatory properties. Elephin and SLP-1 are very effective growth factors for down regulating interleukin-1. Patients receiving a treatment often will experience a corresponding decrease in inflammation fairly soon after the injection. Over the next several weeks patients may continue to improve as the healing cascade initiated from the product takes effect.

#### 2. PROMOTE SOFT TISSUE RECONSTRUCTION

Growth Factors found in amniotic tissue such as PDGF, VEGF, EGF, FGF, promote cellular proliferation and new collagen formation. The mesenchymal stem cells attached to the amniotic tissue are at age 0. Their ability to proliferate and the robust nature of these neonatal cells make for a ongoing healing cascade that will last for many months after the initial injection.

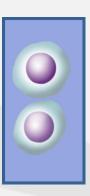
#### TYPES OF STEM CELLS

#### **ADULT**

- Your bone marrow or adipose (fat)
- Embryonic source
- Illegal in the United States

#### **AMNIOTIC**

- Tissue graft is taken from the placenta of a donor who is concerned with the welfare of others.
- Contains a high percentage of stem cells.
- From the uterus of legally performed C-section child births (not planned parenthood).

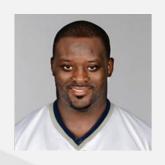




#### STEM CELL THERAPY IN THE NEWS

- Broncos Quarterback, Peyton Manning
- NE Patriots Lineman, Jarvis Green
- Texas Governor, Rick Perry
- Actor and Author, Suzanne Somers









# STEM CELL THERAPY WITH ATHLETES







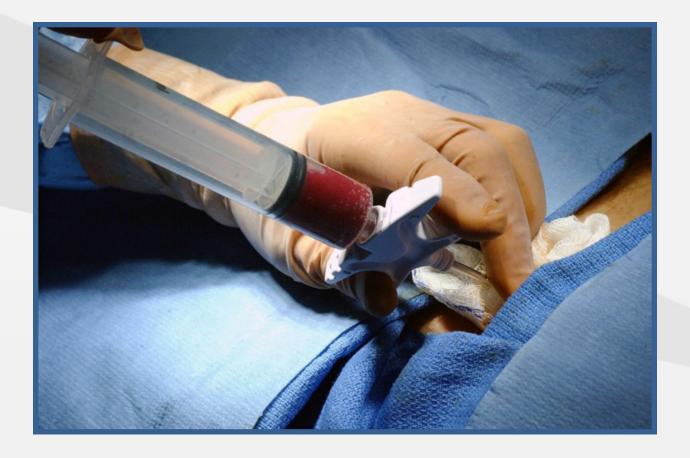


#### STEM CELL THERAPY COMPARISON

Three Different Types Of Stem Cells Available In The U.S.:

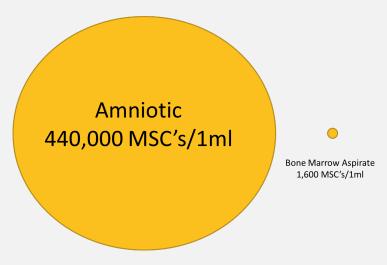
- 1. Stem Cells from Bone Marrow.
- 2. Stem Cells from Adipose tissue.
- 3. Placental Stem Cells from Amniotic tissue.

### **BONE MARROW ASPIRATE**



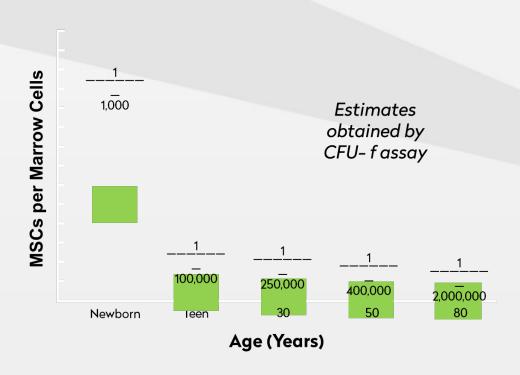


#### ALLOGRAFT STEM CELLS VS BMA: MSC COMPARISON



Jing Li et al: Chin J Cancer Res 23(1): 43-48, 2011

# **HUMAN MSCS DECLINE WITH AGE**



Adopted from: Al Caplan. J Pathol 2009; 217:318-314, 2008



Bone marrow MSCs decline with age. Bone marrow was obtained, dispersed, placed in a Percoll gradient and the light cell fraction seeded onto culture, After 7-10 days colonies can be visualized. The CFU-F assay is an incomplete and crude estimate of MSCs in marrow samples, but clearly we can see that the number of MSCs in marrow decreases with age.

#### **ADIPOSE HARVEST**



The quantity and quality of stem cells is suspect from adipose tissue.



#### HISTORY OF STEM CELL THERAPY

Prior to 2009 patients were going to Dominican Republic, Costa Rica, Panama, Mexico and China as well as other countries in Asia to receive stem cell therapy.



Many people for years have traveled outside the US for treatment but now it can be safely performed and is FDA approved for use.

#### WHY IS IT DIFFERENT IN AMERICA?

#### FDA Regulations for clinical use of stem cells:

- Minimally manipulated can't be changed.
- Can't be grown or cultured.
- Treatment must be performed on the same day.
- Stem cells are regulated with very strict guidelines.

#### CYTOKINES AND GROWTH FACTORS

#### Cytokines

These are like the FOREMAN that tell the stem cells and all the Growth factors below, exactly where to go, what to do and what to become.



- Our Injections contain super-high numbers of <u>Cytokines</u>.
- Growth Factors all the factors needed for regeneration:
  - Collagen (key building block for joints & connective)
  - Growth factors (messenger RNA)
  - Amino acids (proteins)
  - Carbohydrates (for metabolism)
  - Electrolytes
  - Enzymes
  - These cells are <u>all</u> from the Amniotic Membrane (AM) and Amniotic
     Fluid
  - Totally pure. No synthetic or engineered material.

#### STEM CELL RETRIEVAL FDA APPROVED:

- ✓ The tissue is collected from human amniotic membrane & fluid.
- ✓ Chorionic membrane is on the mother's side of the placenta and is full of antigens. Using these cells is risky because, if put in your body, your immune system might create antibodies to it and there is a chance you will reject it.
- ✓ Amniotic membrane and fluid have <u>no antigens</u> and does not cause rejection when put into your body.
- ✓ Our tissue has been tested before and after processing to ensure it has ZERO Chorionic tissue and 100% Amnionic tissue.

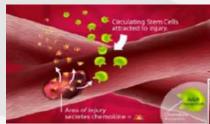
Over 350,000 injections have been done without 1 adverse reaction.



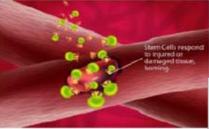
#### SAFE PROCESSING

- Processed at an AATB accredited facility, the tissue is processed and packaged in sterile containers and cryopreserved to protect cell viability.
- Processing is performed following the Food and Drug Administration's Tissue Reference Group (FDATRG) guidelines.
- Procedures have been implemented to meet or exceed all applicable industry standards for the use of human tissue products.

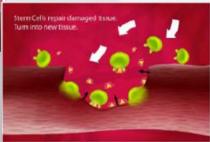
#### HOW DO THE STEM CELLS PRIORITIZE?



1. Injury secretes chemokines



2. Stem cells attracted to chemokines



 Stem cells secrete tissue growth factor, turn into new tissue



#### STEM CELL SIGNALING:

- Signaling occurs wherever there is inflammation, injury, deficiency, degeneration, or tissue in need of repair.
- The cells are actually DNA coded to send out a distress signal, asking for help when they need it.
- The signal attracts the stem cells and cytokines.
- Wherever the strongest signaling occurs, they go there first.
- As a possible example for a degenerated knee, the signaling order may be: Inflammation first, injured tissue next, cartilage next, then tendons, muscles, ligaments and bone spur.
- As a possible example for diabetes, the signaling sequence may be: Nerve cells first, circulation next, eyes cells next, kidneys next and then the pancreas cells.

#### CONDITIONS TREATED WITH STEM CELLS

- Achilles Tendonitis & Tears
- Ankle Sprains & Instability
- Arthritis Degenerative & Rheumatoid Bursitis
- Back Pain
- Cartilage Defects
- Degenerative Disc Disease
- Facet Joint Syndrome
- Failed Back Surgery
- Foot Pain
- Golfers Elbow
- Hip Pain Arthritis, Tendonitis
- Knee Pain Arthritis, Tendonitis
- Ligament Injuries
- Neck Pain
- Occipital Neuralgia
- Osteoarthritis All Joints



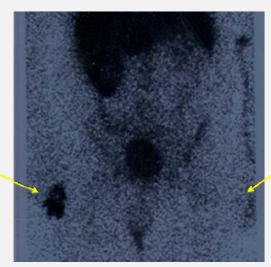
- Patellar Tendonitis
- Pes Anserine Bursitis
- Plantar Fasciitis
- Rheumatoid Arthritis
- Rotator Cuff Tendonitis/Tears
- Runners Knee
- Sacroiliac Joint Pain
- Scoliosis
- Shoulder Pain Arthritis/Tendon
- Spinal Arthritis
- Tarsal Tunnel Syndrome
- Tendonitis
- Tennis Elbow
- Trochanteric Bursitis
- Whiplash

"Important for clinical translation is the fact that Human Stem Cells maintain the immunosuppressive activity observed in vitro after their infusion in vivo. Thus, Human Stem Cells provided highly effective therapy for Arthritis by strikingly reducing the 2 deleterious components of the disease, the Th1/Th17-mediated autoimmune and inflammatory responses. As a consequence, Human Stem Cells were shown to reduce the frequency of arthritis, ameliorate arthritis symptoms, and prevent joint damage". (8)



### **CLINICAL EVIDENCE**

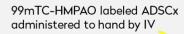
#### Stem cells home on arthritic hand



No stem cells in other hand

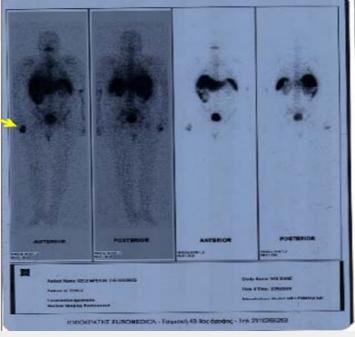
# **CLINICAL EVIDENCE**

#### FDA-Approved 99mTC Radio Tagging



Dark area: stem cells

that were tagged





#### THE HEALING CHARACTERISTICS OF AMNIOTIC TISSUE

Human amniotic fluid cells can differentiate into multiple cell lineages and thus have a great potential to become a cell source for clinical applications. Human amniotic tissue has been proven to contain unique forms of cells that can differentiate into many cell types. Amniotic tissue also contains collagen substrates, the full range of growth factors, amino acids, carbohydrates, cytokines, hyaluronic acid, fibroblasts, epithelial cells, extra cellular matrix, micronized amniotic membrane and other cells. The amniotic membrane is rich with the basic components necessary for tissue healing providing an anti-microbial environment, as described in several peer reviewed articles, and anti-inflammatory characteristics with anti-adhesion/antifibrotic capabilities, as noted in several studies. [2],[3],[4],[5],[6] To remove the risk of graft host reaction, the chorion, which has been shown to contain maternal antigens, has been removed. This maximizes the potential benefits of amniotic membrane in a variety of medical and surgical specialties. Additionally, the immunologically privileged nature of amniotic membrane has been shown in a multitude of research papers. With these capabilities and characteristics, this allograft may be used in a variety of clinical applications.

- 1., DeCoppi, P et al.' Isolation of Amniotic Stem Cell Lines With Potential for Therapy. Nature Biotechnology 2007; Vol 24, No. 1:1274 1280
- 2.,3. Toda, A, et al. The Potential of Amniotic Membrane/Amnion Derived Cells for Regeneration of Various Tissues. Journal of Pharmacological Sciences 2007; 105:215228
- 4. Huiren, T, et al., Implantation of amniotic Membrane to Reduce Post Laminectomy Epidural Adhesions. Eur Spine Journal, DOI10,1007/s00586-009-1013
- 5. Huiren, T, et al., Implantation of amniotic Membrane to Reduce Post Laminectomy Epidural Adhesions. Eur Spine Journal, DOI10,1007/s00586-009-1013
- 6. Young, R. Birth Tissue/Ankle Tendon Repair Study Released, Orthopedics This Week Extremities, Wed, Sep 12th, 2012



#### TREATMENT FOR BURN SCARRING



6-month non-healing wound from laser treatment



6 weeks after treatment



8 weeks after treatment

### STEM CELL CASE STUDY: HAIR REGROWTH FOR ALOPECIA















After



# TREATMENT FOR BURN SCARRING

Before



After



# **ANTI-AGING TREATMENT**

70 year old woman



Before After



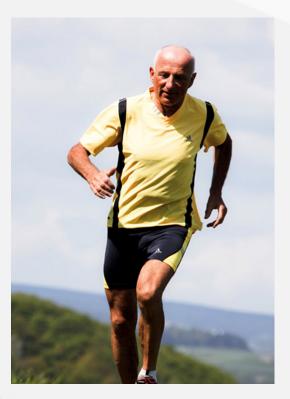
#### AMNIOTIC STEM CELL FUNCTION

Amniotic stem cell rich treatments have been proven effective for difficult wounds, such as in diabetics.

Amniotic membranes have been used extensively in through IV to enhance immune function, balance autoimmune diseases like heart disease and diabetes.

Amniotic derived stem cell rich treatments have been successfully used to treat COPD, Asthma, tremors and MS.

Our findings also indicate that Human Stem Cells migrate (when given systemically) to inflamed joints and strongly reduce joint inflammation by down-regulating the production of a wide range of mediators involved in the pathogenic inflammatory response that causes joint damage". (8)



#### RHEUMATOLOGY RESEARCH

#### Application to bone and cartilage repair.

Expert Opin Biol Ther. 2008 Mar; 8(3): 255-68. Role of mesenchymal stem cells in regenerative medicine: application to bone and cartilage repair.

<u>Granero-Molto F, Weis JA, Longobardi L, Spagnoli A.</u>

University of North Carolina at Chapel Hill, Division of Endocrinology, Department of Pediatrics, 3341 Medical Biomolecular Research Building, 103 Mason Farm Road Campus Box: 7039, Chapel Hill North Carolina 27599-7239, USA.

**BACKGROUND:** Mesenchymal stem cells (MSC) are multipotent cells with the ability to differentiate into mesenchyme-derived cells including osteoblasts and chondrocytes.



**OBJECTIVE:** To provide an overview and expert opinion on the ability of MSC to home into tissues, their regenerative properties and potential applications for cell-based therapies to treat bone and cartilage disorders.

**METHODS**: Data sources including the PubMed database, abstract booklets and conference proceedings were searched for publications pertinent to MSC and their properties with emphasis on the in vivo studies and clinical use in cartilage and bone regeneration and repair. The search included the most current information possible.

**CONCLUSION:** MSC can migrate to injured tissues and some of their reparative properties are mediated by paracrine mechanisms including their immunomodulatory actions. MSC possess a critical potential in regenerative medicine for the treatment of skeletal diseases, such as osteoarthritis or fracture healing failure, where treatments are partially effective or palliative.

PMID: 18294098

# HUMAN AMNION TISSUE INJECTED MESENCHYMAL STEM CELLS REPAIRS DAMAGED SCIATIC NERVES IN RATS

- Dehua Li1, Changhui Wang2, Wei Shan1, Ruixia Zeng1, Yan Fang1, Pan Wang1
   Neural Regeneration Research Volume 7, Issue 23, August 2012
- "Mesenchymal stem cells do not cause a host response in animal experiments[16], thus provide a suitable source for neural (Nerve) regeneration."

#### SPINAL SURGERY OUTCOMES

- Researchers reviewed records from 1,450 patients in the Ohio Bureau of Workers' Compensation database who had diagnoses of disc degeneration, disc herniation or radiculopathy.
- Half of the patients had surgery to fuse two or more vertebrae in hopes of curing low back pain. The other half had no surgery, even though they had comparable diagnoses.



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#### RESEARCH

• Stem cells have become an increasingly feasible option for the future treatment of spinal disorders. Recent scientific advances have allowed researchers and spinal surgeons alike to investigate the potential of stem cells in the regeneration of degenerated disks, healing spinal cord injury and helping bone growth in spinal fusion. World J Stem Cells. 2015 Jan 26; 7(1): 186–194.

#### **NEW LIFE FOR YOUR BACK**



Stem cell therapy is a repair process that takes weeks or months to complete.

Generally, the repair process takes two to three months to complete, but in most cases improvement can be noticed before then. About four to six weeks after the stem cell injection, the patient receives a platelet-rich plasma injection on the afflicted area; this is followed by another injection four to six weeks afterward. These injections enable the stem cells to continue growth and multiply into cartilage tissue(6).



#### STEM CELLS FOR DISK

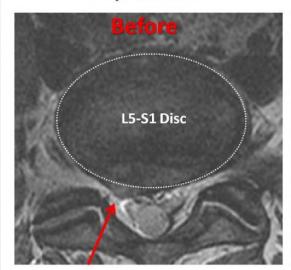




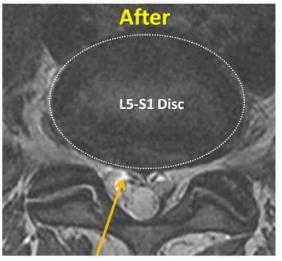
Axial views of LM-continued from prior slide. Note the right sided (red arrow to the left of the disc in this inverted image) disc bulge that extends beyond the margin of the disc (white dashed circle). In the after image, the yellow arrow points to the area where the bulge past the disc margin (white dashed circle) is not longer present. GE 3.0 T MRI: Ax FRFSE T2 images. Before at ET:16, TR: 5350.0, TE: 99.6 After image at ET: 16, TR: 5083.3, TE: 102.6.

#### Pre-procedure

#### **4 Weeks Post Procedure**







**Reduction in Disc Protrusion** 



#### **SHOULDER PAIN**



### **SURGERY?**

• February 8, 2012 — <u>Large rotator cuff repairs re-tore at a rate of 57% in a series of 500 patients</u>, researchers reported at the American Academy of Orthopedic Surgeons 2012 Annual Meeting.



# OR STEM CELL THERAPY?





6 months after therapy

# **KNEES NOT WORKING?**







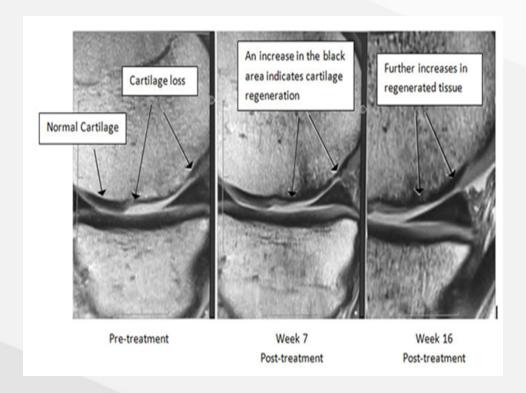
## RISKS OF SURGERY

- Pain. 3-6 months of healing and rehabilitation time.
- No guarantee of result.
- High percentage of failure and complications.
- 50% or more will need additional surgery.
- Total Average Cost for Uncomplicated Case
   \$55,000.00. Much comes out of deductible.
- What's the cost of your lost time, function, pain and suffering?









#### STEM CELL INJECTION RESULTS

Pre-Injection MRI: 7.29.2008 Post-Injection MRI: 2.25.2011





#### \*\* IMPRESSION \*\*:

1. Improved appearance of the known complex tear of the posterior horn medial meniscus. Lateral meniscus and remainder of the tendons/ligamentous structures are unremarkable.



# MESENCHYMAL STEM CELLS (MSCS) REPARATIVE PROMISE IN KNEES

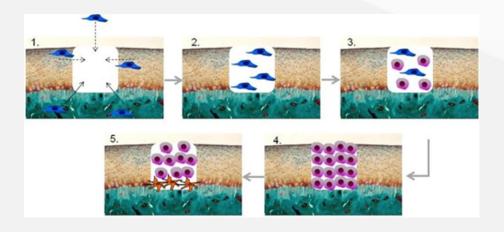
- Current MSC treatments for OA include BMA derived autogenous stem cells that are immediately injected into the knee
- Andrews Institute believes it controls swelling and inflammation and eases pain in knee OA
- Results in a pilot study of 31 NFL
   players, at 10 months, showed efficacy
- Reported decreased pain up to 45%
- Knee scores improved by 50% from baseline at 6 months



#### STEM CELLS: REPARATIVE PROMISE IN WORN KNEES

- Meniscal Regeneration:
  - Increased meniscal volume in post-menisectomy patients who received adult MSC (stem cells) injections into the knee
- Restore Cartilage:
  - MSC injected for knee OA showed improved activity levels and cartilage regeneration
  - MSC surgical treatment for large full thickness chondral defects showed improvement and significant cartilage fill





# STEM CELL OUTCOMES





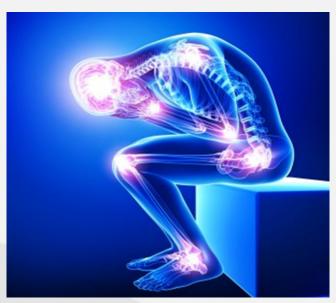
Before

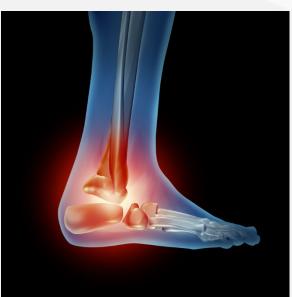
After

Weight-bearing X-Ray demonstrates increased bone separation from cartilage regeneration.



# **MULTIPLE JOINT PAIN?**





# HIP DETERIORATING?



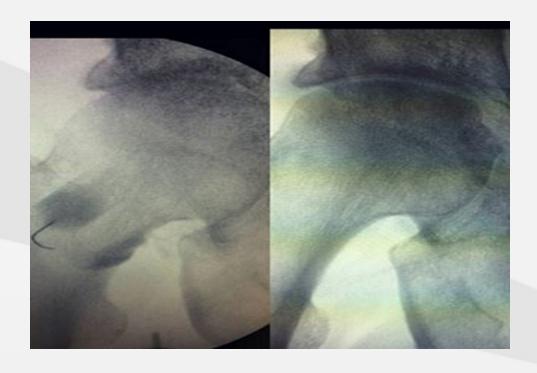


#### T.H.R.

"By 2030, the demand for hip replacements is projected to more than double." S. Kim, "Changes in Surgical Loads and Economic Burden of Hip and Knee Replacements in the U.S."

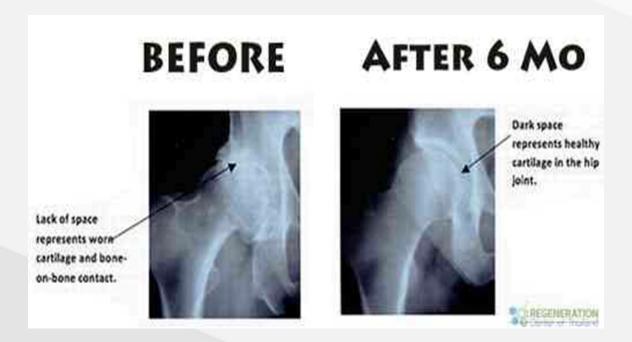
Cost \$40,000 to \$70,000 Wikipedia, 2015

# BEFORE AND AFTER STEM CELL





#### STEM CELL OUTCOMES



## **RISKS OF SURGERY**

- Bleeding Problems During Surgery
- Blood Clots Caused by Surgery
- Difficulty Breathing After Surgery
- Infections After Surgery: 4 in 100
- Deaths: 1 in 400 deaths in 30 days following TKP
- Increased use of narcotics, NSAIDS, and muscle relaxers.
  - -Journal of Orthopedic Medicine



#### ANTI-INFLAMMATORY MEDICINE

"There's an epidemic of adverse drug reactions to NSAIDs. The Food and Drug Administration believes anywhere from 10,000 to 20,000 deaths each year are the result of severe bleeding caused by NSAIDs. It's a big problem."-Dr. James F. Fries, Stanford University School of Medicine





#### **CORTISONE INJECTIONS**

Cortisone injections are a powerful antiinflammatory drug that may reduce swelling.

#### Side Effects:

- Osteoporosis- up to 8% loss of bone in 4 months
- Low doses for 1 year can cause cataracts
- Elevated blood sugar
- Suppressed ability to fight infection





# AMNIOTIC TISSUE STEM CELLS ARE THE IDEAL INJECTABLE BIOLOGIC:

Safe: Amniotic tissue has been used in a variety of clinical settings since the early 1900s with No Reported adverse events.

Easy to Use: Simply inject. No additional equipment or reagents needed. Pain relief in 24-48 hrs.

Product	Source	Anti-Infl.	Anti- microbial	Growth Factors	Toxicity	Pluripotency
Amniotic Allograft	Amniotic Tissue	Yes	Yes	Yes	None	Yes
PRP	Platelets	No	No	Yes	None	No
Steroid	Synthetic	Yes	No	No	Yes	No
НА	Synthetic	No	No	No	None	No
Adipose Derived Stem Cells	Bone Marrow	No	No	Yes	None	Yes

#### MENISCAL TEARS RESPOND TO CELL INJECTIONS

Biloine W. Young Orthopedics This Week • Tue, Feb 14th, 2012

"Vangsness reported that a few patients in the low-dose MSC group also showed evidence of meniscal regeneration in MRI scans taken after one year."



#### TENDON REGENERATION AND REPAIR WITH STEM CELLS

S. MacLean, 1W. S. Khan, 2A. A. Malik, 2M. Snow, 3 and S. Anand 1 Stem Cells International Volume 2012, Article ID 316281, 6 pages

"With stem cells or genetically modified stem cells have been shown to contribute to tendon healing in numerous animal studies"

# LOCAL ADHERENT TECHNIQUE FOR TRANSPLANTING MESENCHYMAL STEM CELLS AS A POTENTIAL TREATMENT OF CARTILAGE DEFECT

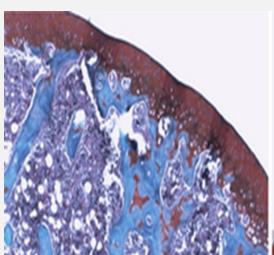
Hideyuki Koga1, Masayuki Shimaya1, Takeshi Muneta1,2, Akimoto Nimura1, Toshiyuki Morito1, Masaya Hayashi1, Shiro Suzuki1, Young-Jin Ju1, Tomoyuki Mochizuki3 and Ichiro Sekiya3 Therapy Vol 10 No 4 Koga et al.

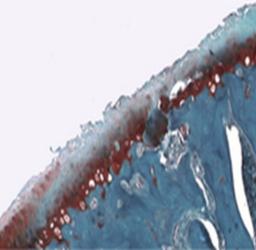
"We developed a novel implantation procedure with synovial MSCs for cartilage regeneration. The technique could achieve successful cartilage regeneration with low invasion, without periosteal coverage, and without a scaffold."





#### 21 DAYS AFTER INJECTION





#### REDUCE INFLAMMATION AND PAIN

Protein Growth Factors inherent in amniotic tissue have very powerful proven antiinflammatory properties. Elephin and SLP-1 are very effective growth factors for down regulating interleukin-1. Patients receiving a Restore treatment often will experience a corresponding decrease in inflammation fairly soon after the injection. Over the next several weeks patients may continue to improve as the healing cascade initiated from the product takes effect.

#### PROMOTE SOFT TISSUE RECONSTRUCTION

Growth Factors found in amniotic tissue such as PDGF, VEGF, EGF, FGF, promote cellular proliferation and new collagen formation. The mesenchymal stem cells attached to the amniotic tissue are at age 0. Their ability to proliferate and the robust nature of these neonatal cells make for a ongoing healing cascade that will last for many months after the initial injection.





#### 1. REDUCE INFLAMMATION AND PAIN

Protein Growth Factors inherent in amniotic tissue have very powerful proven antiinflammatory properties. Elephin and SLP-1 are very effective growth factors for down regulating interleukin-1. Patients receiving a Restore treatment often will experience a corresponding decrease in inflammation fairly soon after the injection. Over the next several weeks patients may continue to improve as the healing cascade initiated from the product takes effect.

#### 2. PROMOTE SOFT TISSUE RECONSTRUCTION

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#### WHAT'S NEXT?



#### YOUR HEALING STARTS WITH A SINGLE DECISION

- The most successful action taken by people who get out of pain is the decision to change.
- The time is now to see if we can help you.
- You're worth investing in.



## 3 REASONS TO DO STEM CELL NOW:

- 1. Stem Cells only work if you GET THEM.
- 2. You're best chance of improvement is right now. Things get worse over time.
- 3. There is nothing more important than your health. Not your car, not your house, not anything. It's no longer necessary to be in pain and unhealthy. Think of how happy you're loved ones will be when you feel better.

