Stem Cell Biologics in Practice

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Overview

- Orthobiologics?
- Procedure
- Challenges
- Cases
- Finances

Orthobiologics Questions?

- Is it legal?
- Is it safe?
- Does it work?

Everyone is doing it

- FDA- "Minimally Manipulated"
- The NFL considers it a medical treatment rather than a performance-enhancing substance.
Stem Cell

- Embryonic- from embryos that are 3-5 days old
- Adult Stem cells
  - Bone Marrow BMAC
  - Adipose Derived
  - +/- PRP
- Duke Experience
  - 34 Cases
  - 12 for OA
  - Operative Cases

PRP

Particular Autologous Conditioned Plasma Injections Provide Safe and Efficacious Treatment of Osteoarthritis: An FDA-Sanctioned, Randomized, Double-blind, Placebo-controlled Clinical Trial

Patrick A. Smith

DOI: 10.1177/0363546515586767

This is safe and provides quantifiable benefits for pain relief and functional improvement with regard to knee OA.

After 1 year, WOMAC scores for the ACP subjects had improved by 78% from their baseline score.

Scores for the placebo control group had improved by only 7%.

Ultrasound-Guided Injection of Platelet-Rich Plasma and Hyaluronic Acid, Separately and in Combination, for Hip Osteoarthritis: A Randomized Controlled Study

Dante Dellanì, Cesare Stagni, Nicola Rani, Giacomo Sabbioni, Patrizia Pelotti, Paola Torricelli, Matilde Tschon and Gianluca Giavaresi

DOI: 10.1177/0363546515620383

PRP injections significant improvement of WOMAC scores in hip OA.

Benefit still seen at 12 months.

The addition of HA to PRP or HA alone did not lead to a significant improvement in pain symptoms.
Fat Harvesting

Donor Site Preparation

• 1) Sterilize and drape donor site.
• 2) Anesthetize area of aspiration (25G needle).
• 3) Create skin puncture (18G needle #11 blade).

Collection of Adipose Tissue

• 1) Tumesce with infiltrator cannula.
• 2) Harvest with harvester cannula.
• 3) Decant for at least 1 minute and express infranatant.

Processing of Adipose Tissue

• 1) Transfer adipose sample to Process Disposable using Fem/Fem connectors.
• 2) Remove syringe handle by sliding off laterally and place green tip cap on.
Processing of Adipose Tissue

- 3) Process disposable on SMP2; stop when display reads “10” (4 minute run).
- 4) Expel infranatant fluid and transfer to treatment syringe.

What is in the Fat?

- Adipocytes and pre-adipocytes (20% of cells, but 80% of volume due to size); mesenchymal cells; pericyte-endothelial-adventitial cells.
- Small percentage of miscellaneous cells: macrophages, RBC/WBC, lymphocytes, hemangioblasts, platelets, etc.

Challenges in the Elite Athlete

Clinical Cases
Case 1: Partial Pec Major Tear at Musculotendinous Junction

Injecting tumesce into gluteus fat for harvest

After injection of PRP/Adiprep into Pec Maj Tear
Case 1: Partial Pec Tear

10 days later

Case 2: Partial UCL Tear in a Pitcher

Case 2, Partial Pec Tear: Returned to Play
Case 2: Partial UCL Tear in Baseball Pitcher

- 17 y/o rising junior with right partial UCL.
- High School pitcher being recruited by Division 1 schools.
- Did not want surgery for partial tear which would end his junior year.

Stem Cell + PRP- UCL Tear

Partial UCL tear of proximal deep fibers

Partial UCL tear, 4 weeks post injection
Case 3: Grade III MCL in Football Player

Grade III Distal MCL Tear

- 21yr old Football Receiver
- Valgus “clipping” Injury mechanism
- 10mm opening in Flexion
- 4mm opening in Extension

Grade III MCL Tear in Football Player

- Notice the distal fibers lifted off the medial tibia
MCL Follow Up 6 weeks

- No complaints
- No fibers lifted of the tibia

Partial Pec Tear

Partial Pec Tear: 10 days later
Partial Pec Tear: Returned to Play

Case 4: ACL tear, Grade II MCL Tear, Vertical Tear of PHMM, Radial Tear of LM

Arthroscopy

Findings:
- Complete ACL tear.
- Healed medial meniscus meniscocapsular injury.
- Displaced radial lateral meniscus tear, 10% of body.
- Grade II CM LFC where displaced flap impinged.

Procedures Performed:
- ACLR using BTB Autograft.
- Lateral meniscus debridement back to stable base.
- Injection of 7cc AdiPrep/PRP mixture around ACL insertions.
- Injection of remaining 3cc AdiPrep/PRP mixture subcutaneously at proximal MCL origin.
Stem Cell Harvest

Injection of PRP/Stem Cells to graft docking sites
**Other Indications**

Partial UCL in a Javelin thrower  
Peripheral Meniscal Tear in Men’s LCX player  
Chronic Hamstring in a Women’s LCX player  
Chronic Biceps in a Women’s Tennis player  
Strain in Achilles repair in Quarterback

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**Results**

1. No major adverse events related to the treatment or to the cell harvest have been reported.

2. A clinical benefit of using MSCs therapies has been reported in most of the studies, regardless of cell source, indication, or administration method. This effectiveness has been reflected by clinical improvements and also positive MRI and macroscopic findings, whereas histologic features gave more controversial results among different studies.

3. Young age, lower BMI, smaller lesion size for focal lesions, and earlier stages of OA joints have been shown to correlate with better outcomes, even though the available data strength does not allow to define clear cutoff values.

4. Definite trends can be observed with regard to the delivery method: currently cultured cells are mostly being administered by i.a. injection, while one-step surgical implantation is preferred for cell concentrates.

5. While promising results have been shown, the potential of these treatments should be confirmed by reliable clinical data through double-blind, controlled, prospective and multicenter studies with longer follow-up, and specific studies should be designed to identify the best cell sources, manipulation, and delivery techniques, as well as pathology and disease phase indications.
Human Amniotic/Chorionic Membrane

Amniotic membrane has collagen, fibronectin, and HA, growth factors, cytokines, and anti-inflammatory proteins such as IL-1 receptor antagonist. Thought to have anti-inflammatory, anti-fibroblastic, and antimicrobial properties. Cryopreserved has amniotic derived fluid cells.

Australasian College of Sports Physicians members must inform all patients receiving MSC therapy that:
- They are part of a research trial, or are receiving innovative therapy.
- Mesenchymal stem cells are experimental and have not yet been proven to be safe or effective for clinical use.
- Any conflicts of interest held by the researcher or clinician providing innovative therapy will be declared.
- The full cost of the procedure, including a full breakdown will be provided to the patient. Costs involved in MSC interventions used within research will not be passed onto participants.
- Informed consent to the procedure will be obtained in writing.

Research is ongoing.
No certification process.
Insurance does not cover this- Pay Cash.
Cost vary from $9,000 to $2,500 per injections.
Some advocate adipose, bone marrow, PRP, prolo any combination.