OSTEOARTHRITIS AND MSK CONDITIONS

PRELIMINARIES

Osteoarthritis (OA) is a condition associated with failure of the joint. It is not a disease of only the cartilage but instead the synovial joint in which all the tissues are affected including: subchondral bone, synovium, meniscus, ligaments, and cartilage. OA is the most common joint disease in humans.

Causes of Orthopedic (OA & Injuries): OA and other orthopedic injuries caused by some kind of trauma, synovitis, capsulitis, articular cartilage and bone fracture, ligament tears, muscle tears.
Presently, stem cells have shown much promise in their use for many orthopedic conditions. Umbilical Cord Blood (UCB) is a rich source of adult stem cells that have shown therapeutic potential (Lee et al., 2010).

It is well understood that stem cells work in a paracrine fashion by enhancing the body's own endogenous repair mechanisms through release of growth factors, cytokines and chemokines.

TREATMENT OPTIONS:

Conservative management, including non-steroidal pain medicine, prescription opioids, steroid injections and radiofrequency. Steroid injections are commonly used to treat articular pain, although it has been found to be more beneficial in providing short term relief of symptoms rather than long lasting effects. There is a need to address the disease process itself, and current research is aimed at altering the biological healing in which stem cells may offer an alternative.

MONONUCLEAR LAYER CORD BLOOD PRODUCT TREATMENT OPTION:

Concentrated human stem cell product comprised of donated cord blood, that has been processed to remove excess plasma, red blood cells, vascular material and tissue solids leaving stem cells and other celular components, which are then concentrated and banked through a validated process.

a. Objective:

Mononuclear cell layer cord blood injection utilizes cells that express immuno-modulatory and anti-inflammatory properties There is an abundance of evidence that describes the role of the growth factors released by stem cells in healing and repair. For example, bFGF is a strong mitogen that may aid in cartilage repair (Ribatti et al., 2007; Lee et al., 2013) while IL1ra may help control the inflammatory response (Perrier 2006). VEGF is considered one of the key growth factors that help increase vasculature which aids in host endogenous repair and may play a role in cartilage repair (Palmer 2014; Gerber et al., 1999).

b. Patient management:

- ***Initial patient evaluation:*** Reviews the medical information, lab work, and diagnostic imaging provided by the patient in order to determine the stage of the medical condition and any other secondary conditions

- ***Patient consultation:*** Informed consent is obtained from all patients physical exam, most up-to-date lab results and imaging studies. MRI highly recommended. Standardized questionnaires are to be administered to patient to obtain a baseline. Visual analog scale.

- WOMAC for knee or hip
- WOOS for shoulder
- AAOS for ankle

- Treatment day:

    - Premedication infusion protocol is started one hour before product application.
    - Benadryl 25mg IM, Zantac 200mg IV, Solumedrol 125mg IV. Single Dose.
    - Attach certificate of analysis to patient's chart.
    - Place the bottle in the palm of your hand until product is in a complete liquid form which can take about 3-5 min.
    - Swab the outside of the vial with alcohol, then remove the sterile cover and draw the contents into a syringe using aseptic technique.
    - Injection will performed using sterile technique, per specific protocol consistent with the condition to be treated. Sample should be injected within 2 hours of thawing.
    - ***Procedure for application of intra articular/ ligament/ muscle/ tendon:*** Using aseptic technique, a 3 cc syringe, and a 25 1/2 G needle administer cell mixture to affected areas. Radiological guidance is paramount. Take good care not to apply extra pressure to the syringe when administering the injection.
    - Product should not be mixed with any other biologic compound.

c. Risks:

There are possibilities for unwanted effects related to the injection of stem cells. Even with the most established protocol, adequate technique, and careful administration; a medical team may encounter uncontrollable events. Although there is no guarantee of perfect results, excellent results can be attained. The risks of complications with the administration of cord blood products are very low.

Possible risks include but are not limited to:

- Pain at site of injections
- Malaise
- Fever
- Allergic reaction

d. Outcomes :

Clinical response showing improvement in biomechanical function, decrease of pain level, enhanced functional recovery, return to previous level of activity. Changes in MRI in terms of tissue growth and control defect filling and overall improvement in the questionnaire scores.

e. Follow Up Plan:

- 3 month after injection: Patients will be seen by physician for evaluation including review of Medical History, complete physical exam,Visual Analog Scale, Patient questionnaire.

- 6 months after injection: Patients will be seen by physician for evaluation including medication history complete physical exam, visual Analog Scale, Patient questionnaire. Repeat Imaging evaluation.

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

Name _____ Date of Birth _____ Today's Date_____

Height _____ ft _____ inc Weight_____lbs

Instructions: Please rate the activities in each category according to the following scale of difficulty: 0 =

None, 1 = Slight, 2 = Moderate, 3 = Very, 4 = Extremely Circle one number for each activity

Pain	1. Walking	1	2	3	4
	2. Stair Climbing	1	2	3	4
	3. Nocturnal	1	2	3	4
	4. Rest	1	2	3	4
	5. Weight bearing	1	2	3	4
Stiffness	1. Morning stiffness	1	2	3	4
	2. Stiffness occurring later in the day	1	2	3	4
Physical Function	1. Descending stairs	1	2	3	4
	2. Ascending stairs	1	2	3	4
	3. Rising from sitting	1	2	3	4
	4. Standing	1	2	3	4
	5. Bending to floor	1	2	3	4
	6. Walking on flat surface	1	2	3	4
	7. Getting in / out of car	1	2	3	4
	8. Going shopping	1	2	3	4
	9. Putting on socks	1	2	3	4
	10. Lying in bed	1	2	3	4
	11. Taking off socks	1	2	3	4
	12. Rising from bed	1	2	3	4
	13. Getting in/out of bath	1	2	3	4
	14. Sitting	1	2	3	4
	15. Getting on/off toilet	1	2	3	4
	16. Heavy domestic duties	1	2	3	4
	17. Light domestic duties	1	2	3	4

Total Score: _____ / 96 = _____%
Comments / Interpretation (to be completed by therapist only):

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