EDUCATION SESSION

Orthopedic Section

Regenerative Injections: Still Quackery?
PT Research and Rehab Pearls

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Disclosure

• No relevant financial relationship exists

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Learning Objectives

- Define regenerative injections for tendon and joint healing as well as elaborate upon the distinction between elements used in clinical practice
- Define terminology used within regenerative medicine to include prolotherapy, platelet rich plasms, (PRP), stem cell injection and others
- Identify the injectable elements used with prolotherapy with indications and contraindications associated with each
- Discuss the relevant outcome measures used in clinical practice to guide decision making with rehabilitation

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Medicine Today

- · Advanced care
- Manage symptoms or cure disease
- Short term effects and no long term solutions



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Regenerative Medicine

- Long term solutions
- Replace or regenerate human cells, tissues, or organs to restore or establish normal function

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Regenerative Medicine

- Degenerative
 - Heart, lungs, eyes, ears, bones, joints, metabolism.....
- · Regenerative
 - Assist body's potential to heal and repair



Clinical Application of Biologics

- "The first great advancement in sports medicine was arthroscopy; the second is going to be this!"
 - James R. Andrews, M.D.

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Musculoskeletal Medicine

- MSK injuries leading cause of disability and pain
- · Increasing prevalence
- Increase healthcare costs
- Decrease productivity and quality of life

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Scope of the Problem

- · MSK Pain
 - \$950 billion per year
 - >50% chronic conditions over 50 y.o.
- · TKR/THR in U.S.
 - 7 million current
 - 1 million per year
 - \$40,000-60,000 per surgery
 - Complications

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Acute Injuries and Healing



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Chronic Injuries

- Gradual process
- · Initially asymptomatic
- · Overuse injury
 - Tissue microtrauma and breakdown precedes pain
 - Creep and deformation occur without time to heal
- OA: Ineffective catabolic checks and balances

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Tendinosis vs. "-itis"

- Inadequate cycle of inflammation, scarring, hypoxia, neovessels, failed healing
- Jozsa and Kannus: 97% of spontaneously ruptured tendons exhibit degenerative changes

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Insufficient Healing

- Delayed Healing and Repair
 Age, protein deficiency, low vitamin C, smoking
 NSAID's, steroids
 Poor blood supply, excessive motion
- Connective tissue insufficiency Decrease tensile strength, increased laxity
 - Constant firing of mechanoreceptorsPain





Connective Tissue Healing

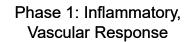
- · Sequential cascade, systematic process
- · Phases
 - Inflammation
 - Proliferation
 - Remodeling
- Regulation by various cells in different phases

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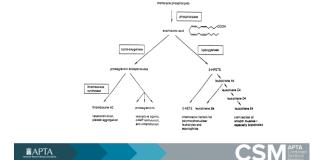
Inflammation is Necessary for



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Inflammatory Phase

- · Platelet aggregation
- Clot formation and platelets release signals to start repair
- Debris removed, circulation increases, new cells attracted
- 48-72 hours



Research and Rehab Pearls

Phase 2: Proliferative, Tissue Reconstruction, Repair

- Inflammatory cells attract new cell growth and blood vessels
- New collagen synthesis
 - 2 days to 6 weeks
 - Maturation begins by 3 weeks

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Phase 3: Remodeling, Functional Restoration

- Collagen
- Increase size and tensile strength
 - Reorganizes along lines of tension, crosslinks
- 3 weeks to 1-2 years

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Remodeling

- Ligament tensile strength 50% normal at 6 months
- Ligament tensile strength 100% after 1-3 yrs.

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Standard of Care ?? for Musculoskeletal Injuries

The Modern Definition (Hall v. Hilburn; McCourt v. Abernathy; Johnston v. St. Francis Medical Center)
That which a minimally competent physician in the same field would do under similar circumstances (2011)

- · NSAID's and corticosteroids
- Most frequent pharmacologic substance prescribed for tendinopathy
- · Inhibits inflammation



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Standard Treatment Options

Arthroscopy
Joint Injections
Physical therapy
Oral NSAID
Diet and Exercise
Activity Modification

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Injections Therapies

Stem cells + PRP
Stem cells
Platelet Rich Plasma
Viscosupplementation
Steroids
JOINT INJECTIONS

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Regenerative Medicine

- Prolotherapy
- · Platelet Rich Plasma
 - Growth factors
- · Stem cells
 - Cells for new tissue/organ growth





Why are we still debating if orthobiologics works?

- · Need to define what we are injecting
 - Platelet concentration
 - MSC concentration
 - Leukocyte count
 - RBC +/ RBC -
 - Autologous/ allogenic
 - Need to define the procedure

 - US guidance
 Needle tenotomy performed ?
 How many needle passes ?

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Why are we still debating if orthobiologics works?

- Rehabilitation methods
 - Need to be studied/ validated
 - Immobilization
 - Timing of eccentrics
- May need to separate out different body parts



Biologic Treatment Goals

- Tendinopathy
 - Degenerative tissue- ineffective healing cascade
- · Osteoarthritis
 - Increased catabolic activity, cartilage destruction
- · Pro- or anti-inflammatory or neither?





Indications for Regenerative Injections

- · Repair soft tissue/joint injuries or laxity
 - Acute, chronic
 - Any accessible ligament, tendon, joint including spine
- · Shorten rehabilitation time
- · Prevent surgery
- Enhance post-surgical healing

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Absolute Contraindications

- Acute infection or inflammatory
 disease
- · Active cancer site
- Acute non-reduced subluxations, dislocations, fractures
- · Allergies to injectants
- Prosthetic joint injection



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Absolute Contraindications

- Platelet dysfunction
- · Critical thrombocytopenia
- Hypofibrinogenemia,
- Hemodynamic instability
- · Septicemia
- Pregnancy (PRP, Stem cell)



Relative Contraindications

- NSAID < 48hr, corticosteroid < 2 wks
- · Recent fever or illness
- · Skin rash
- · Cancer (hemapoetic or bone)
- HgB <10g/dl, Platelets $<100,000 \mu L$
- Anticoagulated w/ high INR (>3)

Clin Rheum 2013 Dec; 32

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Risks of Injection Therapy

- Relatively safe procedure
 - Similar to risks of other injection procedures
 - Infection 1:50,000
 - Needle induced trauma (U/S guidance during procedure as needed
 - Allergic reactions (medication only)
- Post injection soreness

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Pre-Injection Preparation

- · No NSAID's or corticosteroids
- Tylenol or Rx pain medications prn
- · Consent forms
- · Supportive equipment prn
- · Transportation

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Post-Injection Protocols

- · Post-injection soreness
 - 2 to 5 days
- · Phases
- · Length of time
- · Restrictions
- Rehabilitation

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Prolotherapy Injections

- · Non-surgical
- Injection of substances into damaged tissue (muscle, ligament, tendon, cartilage)
 - stimulates proliferation and healing
 - decreases pain and improves function

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Prolotherapy Treatment

- Hyperosmolar Dextrose (12-25%)
 50% D, normal saline, 1% lidocaine
- Osmotic gradient initiates local injury and aseptic inflammatory response
- Multiple injections into enthesis, joints and damaged tissues to increase ligament/tendon strength

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Enthesis

- Zone of insertion of connective tissue to bone
 - Superficial fibers attach to periosteum
 - Deep fibers penetrate bone
 - "Weakness is in the weld" George S. Hackett, M.D.

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Prolotherapy Actions

- · Mechanisms
 - Inflammation stimulates fibroblast formation to repair connective tissue
 - Vascular: decrease neovessels
 - Neurologic function: Articular ligaments are rich in nerve endings.
 Weakness causes pain and alteration in motion, structure and function.
 - Reconstructing tensegrity

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Prolotherapy

- Photomicroscopy shows collagenous connective tissue
- Identical material and geometric alignment of collagen fibers of normal connective tissues





Effectiveness: Research

- · Evidence based publications about prolotherapy support the following:
 - Microscopic and macroscopic changes in local structures occur with prolotherapy injections supporting regeneration
 - Measurable mechanical improvement occurs in local structures
 - Decrease pain and increase function have been shown to occur in animal and human studies

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Rabago D., Patterson, JJ et al,

Dextrose prolotherapy for knee osteoarthritis: a randomized controlled trial. Ann Fam Med. 2013; 11(3):229-37 (ISSN: 1544-1717)

Rabago D; Patterson JJ; Mundt M; Kijowski R; Grettie J; Segal NA; Zgierska A

- · Decrease pain and disability
- Dextrose prolotherapy is statistically superior to blinded saline injections and at-home exercises for function at 24 and 52 weeks, and trends to superior pain relief at 52 weeks.

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Conclusions

- Dextrose prolo is statistically superior to blinded saline injections and at-home exercises for function at 24 and 52 weeks, and trends to superior pain relief, at 52 weeks.
- Improvement exceeds minimal clinical improvement on the WOMAC for knee OA
- · Safe and satisfying to patients

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Prolotherapy for Tennis Elbow Scarpone M. et al, CJSM; 2008

- Pain relief for lateral epicondylosis with intratendinous injections of prolotherapy solutions
- Decreased pain, increased strength, increased function

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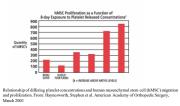
Platelet Rich Plasma

- >4x baseline concentrations
- · Autologous growth factors
 - Cell proliferation, tissue growth, angiogenesis
- Cytokines
 - Intercellular interactions
- · Chemokines
 - Attract stem cells and macrophages

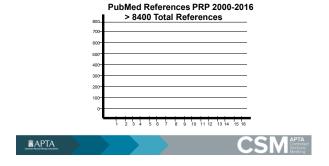
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Does PRP Work?

PubMed Article Search: 6,047

Peerbooms, AJSM 2010
Kon, KSSTA 2010
Radice, Arthroscopy 2010
Wang-Saegusa, AOTS
2011
Thanasas, AJSM 2011
Gosens, AJSM 2011

50 % ?

Silva, KSSTA 2009
DeVos, JAMA 2010
Creaney, BJSM 2010
DeJonge, AJSM 2011
Schepull, AJSM 2011

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PRP Research

- · Level 1 Evidence for PRP
 - Lateral epicondylosis
 - Patellar tendinopathy

 - ?Muscle regeneration
- · Overall safety of PRP demonstrated





PRP Research

- · Mishra AK, et al: Efficacy of platelet-rich plasma for chronic tennis elbow: A double-blind, prospective, multicenter, controlled trial of 230 patients. *Am J Sports Med* 2014;42(2):463-471.
- · Alsousou J, et al: Effect of platelet-rich plasma on healing tissues in acute ruptured Achilles tendon. Lancet 2015;385;S19.

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PRP Research

- PRP vs cortisone or HA
 - AJSM 2010-Gosens et al; PRP vs cortisone: Chronic lateral epicondylitis
 - Foot Ankle Int. 2014-Monto RR. PRP vs cortisone: Chronic plantar fasciitis
 - Arthroscopy 2011-Kon et al; PRP vs HA: Knee OA





PRP Research

- The Effectiveness of Platelet-Rich Plasma in the Treatment of Tendinopathy: A Meta-analysis of Randomized Controlled Clinical Trials.
- Fitzpatrick A, et al. Am J Sports Med. 2016 Jun 6
 Efficacy of Intra-articular Platelet-Rich Plasma Injections in Knee Osteoarthritis: A Systematic Review (Level 1)
 - Meheux C J, et al. Arthroscopy 2016 Mar; 32(3):494-505
- Platelet rich plasma versus corticosteroid injection for plantar
 - fasciitis: A comparative study.

 Jain K, et al. Foot 2015 Dec; 25(4): 235-7.
- Efficacy of Platelet-Rich Plasma versus Hyaluronic Acid for treatment of Knee Osteoarthritis: A systematic review and metaanalysis

 Hassan Niroomand S, et al. Am J Sports Med 2016 Jun6

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Specific Formulation per Indication

- Platelets
 - Growth factors
 - WBC's
 - RBC's
- Activation
- · Indications
- Tendinopathy
 - OA
 - Acute injuries

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Stem Cells

- · Stem cells
 - Cells for new tissue/organ growth
- Pluripotent
 - Embryonic
 - Induced (iPS)
- · Multipotent
 - Adult

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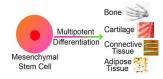
Adult Multipotent Stem Cells

- Allogenic
 - Placenta
 - Umbilical cord
- · Autologous
 - Bone marrow
 - Peripheral blood
 - Adipose



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Stem Cell Differentiation



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Bone Marrow

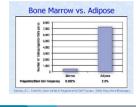
- Well established biotherapy
- · Painful to harvest
- · Donor site morbidities
- Reduced number and activity with age
- Less MSC yield
 - 30,000 NC/G of tissue

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Adipose Stem Cells (ASC)

- · Easy to harvest
- · Minimal donor site morbidity
- Less decrease in number and activity with age
- · Higher cell counts
 - 1,000,000 NC/G of tissue
 - 500x greater than BMAC
- Stromovascular fraction (SVF)
- · Abundant source

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Stem Cell Research 1964-2012



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Stem Cell Research

- · BMAC w/ HA post meniscectomy
 - Randomized, double blind, control
 - Increase meniscal volume and decrease nain
 - JBJS, 2014 Vangness et al
- Stem cells for the treatment of musculoskeletal pain
 - Luminita L, et al. World L Stem Cells. 2015 Jan 26; 7(1):96-105

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Stem Cell Studies

- BMAC w/ HA post meniscectomy
 - Randomized, double blind, control
 - Increase meniscal volume and decrease pain
 - JBJS, 2014 Vangness et al
- Fat pad derived MSC s/p AKS
 - Decrease pain, increase cartilage growth
 - Arthroscopy, 2013 Koh et al

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PRP + MSC's

- PRP + ASC Synergy
 - Enhances stem cell and fibroblast proliferation
 - Inflammation
 - Anti-microbial
 - Angiogenic

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Research and Rehab Pearls

PRP + Stem Cells

- ADSC w/ PRP s/p AKS
 - 87% improved w/ 2nd look arthroscopy
 - Knee Surg Sport Trauma, 2013 Koh

et al

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PRP + Stem Cells

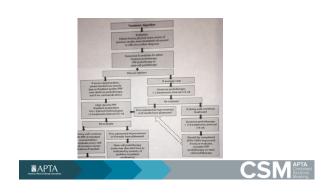
- · Disease modifying?
- · Optimal source and administration
- Optimal dose, frequency, timing, # of injections
- · Surgical correction of deformity in addition to MSC treatment

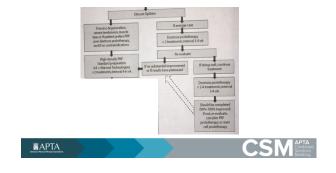
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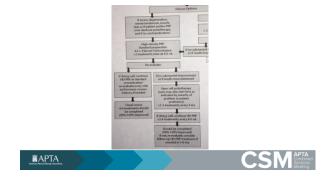
Treatment Course

- Prolotherapy
 - Average trial: 3-6 injections
 - Frequency: every 2-6 weeks
- Platelet Rich Plasma
 - Average trial: 1-3 injections
 - Frequency: every 6 weeks
- Stem Cells
 - Average trial: 1-2 injections
 Frequency: every 3 months

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Research and Rehab Pearls

Post-Injection Protocols

- Post-injection soreness
 - 2 to 5 days
- Phases
- Length of time
- · Restrictions
- Rehabilitation

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Rehabilitation Protocols Post-Injection

- Kaux, et al., 2014
- Peck, Mautner 2015
- Finoff et al., 2011
- M. van Ark et al., 2012
- UW Health, Sports Rehabilitation, 2014

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Rehabilitation Protocols Post-Injection

 Avoid NSAII period Early mobiliz

Similarities

Progressive e

program 12 weeks to u activities

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f cryotherapy

ng of eccentrics

ng of mobilization

itial weight bearing

Optimal Therapy Post Regenerative Injection

- Ice?
- NSAID?
- Immobilization?
- ROM?
- Stretching?
- Strengthening?
- · Full activities?

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Post Injection Rehabilitation

- Inflammatory phase (24-48 hrs)
 - No ice
 - No NSAID's (2-4 weeks)
- Proliferative phase (day 4-week 6)
 - ROM when painfree
 - Stretching (physiologic motion)
 - Strengthening (<3/10 level pain with PRE's)

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Post Injection Rehabilitation

- Strengthening (<3/10 level pain)
 - 2-4 weeks: Isometrics→Isotonics (concentrics)
 - 4-6 weeks: Concentrics → Eccentrics
 - 6+ weeks: Eccentrics→HSR
 - 6-12 weeks: CKC→Plyometrics
 →Sports specific training
 - 12 weeks: Return to full activities
 - Vary timeline to individual needs

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Basics of Joint Rehabilitation

- Phase 1 (protection/joint activation)
 - 0-7 days
 - Protective weight bearing status
 - − ↓pain/effusion
 - maintain normal ROM
 - avoid muscle atrophy

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Basics of Joint Rehabilitation

- Phase 2 (progress joint loading and functional restoration)
 - 7-21 days
 - Controlled stimulus to promote cartilage healing
 - Correct biomechanical deficits
 - Restore normal strength
 - Proprioceptive/balance activities (2 leg→1 leg)

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Basics of Joint Rehabilitation

- Phase 3 (activity restoration)
 - 21+ days
 - Progress aerobic activities per pain/swelling
 - Loading program varies with area of body and sport demand
 - Begin sport specific training

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Future Solutions

- Preparation
 - Centrifuge, Cells, Activation, Anticoagulants
- Growth factor quantities
- Injury environment
- Pain and injury biomarkers
- · Combined treatments
- Genomics/Exposome

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Conclusions

- Regenerative injections may offer effective long term, non-surgical treatment options for MSK injuries, when indicated
- Cost effective with *effective* outcomes vs. surgery
- Great potential in MSK medicine

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Progression of Scientific Truth

- Initially it is *ridiculed*
- Next, it is violently opposed
- Then finally, it is accepted as self evident

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Regenerative Injections: Still Quackery? PT Research and Rehab Pearls

February 18, 2017



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EDUCATION SESSION

Orthopedic Section

Regenerative Injections: Still Quackery? PT Research and Rehab Pearls

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Learning Objectives

- Define regenerative injections for tendon and joint healing as well as elaborate upon the distinction between elements used in clinical practice
- Define terminology used within regenerative medicine to include prolotherapy, platelet rich plasms, (PRP), stem cell injection and others
- Identify the injectable elements used with prolotherapy with indications and contra-indications associated with each
- Discuss the relevant outcome measures used in clinical practice to guide decision making with rehabilitation

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- Include a course outline, address the major points of the presentation.
- Include diagrams or graphic images (in black and white) or guiding questions, as appropriate. If the presentation includes more than one speaker, summarize each speaker's presentation points.
- speaker, summarze each speaker is presentation points.

 Electronic files of articles may be included if you are the author and they have been published by APTA; otherwise, you are responsible for obtaining copyright permission. Identify copyrighted materials by using a reference number within the body of the text or providing information directly under a chart or diagram.
- Include time for learning assessment (discussion, polling, small group work, etc...)

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Decision Making Algorithm

- · Which injection?
 - _ Prolotherapy
 - _ Platelet Rich Plasma (PRP)
 - _ Adipose Stem Cell

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Orthopedic Injection Options:

- Corticosteroid injections
- Hyaluronic Acid injection (HA)
- Regenerative injection therapy (RIT)



Orthopedic Injections

Corticosteroid +'s:

- · Fast acting
- · Analgesic/pain relief
- · Anti-inflammatory
- · 1-2 months duration typical
- · Can repeat 3x/year
- Covered by insurance Corticosteroid -'s:

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	'	Effects	wear	off	with	time	typical	ll'	y
--	---	---------	------	-----	------	------	---------	-----	---

- · Can damage connective tissue
- Sleep disturbances
- Weight gain
- Irritability

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Orthopedic Injections

Hyaluronic Acid_'s:

• Effects wear off with time

· Not curative/reparative

Hyaluronic Acid +'s:

- · Fast acting
- · Lubricant to joint
- · Pain relief
- · Aprx 6 month duration
- Can repeat 3x (18 months)
- · Covered by insurance

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Orthopedic Injections

Regenerative +'s:

- Analgesic pain relief
- Regenerative goal for connective tissues
- Can repeat monthly for 3-6 months
- Cash based service for facility

Regenerative_'s:

- · Cost to patient
- Slow acting: 1-3 months max per injection so can take 6+ months maximum outcome results
- Multiple injections and can be painful

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Expectations with Regenerative Injections

• Alternative option if patient is <u>not</u> a safe medical candidate for	
 Surgery Age, smoker, diabetic, multiple co-morbidities, lack of family support before/during/after a surgical procedure 	
Alternative option to exhaust non-surgical options for patients	
 not wanting to undergo surgical procedure Time off work, expense, lack of family support before/during/after a surgical procedure 	
 Safe option to strengthen natural tissue in conjunction with prescriptive rehabilitation guidelines 	
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Expectations with Regenerative Injections	
• Decrease pain • Increase function: retest with	
outcome instrument • Decrease use of assistive	
device • Normalization of ROM • Progression	
of prescription exercise program	
02/18/2017	
Dec December the Injection Theorem	
Pre Regenerative Injection Therapy	
• Establish outcomes measures:	
 Evaluation standards: Visual Analogue Scale (VAS), ROM, MMT, palpation, subjective data, SF-36 	
Pre Regenerative Injection Therapy (RIT)	
Deticut advantion about diamonic/come of the	
 Patient education about diagnosis/care of the environment 	
• Supportive Equipment: tape, shoes, braces,	
ergonomics until patient has independence	
Assistive Devices: assessment of current/short	
term future need	
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Socialist Mediting testing	

 Spine: Oswestry, Neck Disability Index UE: Disabilities of the Arm, Shoulder, Hand (DASH), quick DASH LE: WOMAC, Timed Up & Go (TUG), BERG, Tinetti, walking speed, 6 min walk test 	
MAPTA CSM APTA General Meleng	
Pre Regenerative Injection Therapy (RIT) • Stretches: prescriptive for diagnosis • Strengthening: phases I, II, III for load to connective tissue – UE: Shoulder joint by side to progression to overhead as improvements tracked – LE: open kinetic chain to progression to closed kinetic chain as improvements tracked	
Rehab Goals AFTER Regenerative Injections Rehabilitation team: understand structural cell biology and time frames for rebuilding NSAID: do not use for prescriptive time to allow inflammatory cells to assist in healing	
Pre Regenerative Injection Therapy • Cardio: low impact even in LE for 13 months; walk not jog • Sport/higher work demands: progressive resistive exercise per VAS and outcome measures	
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 Ice vs heat indications/discussion: Activity limitation: short term Assistive Devices: short term for LE 	
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Same day-2 weeks post RIT #1 NSAID: none. Tylenol is allowed for prn pain Ice • Assistive device prn 1-2 weeks; DC asap Stretching: per rehab protocol • Strengthening: none • Cardio: none	
 4-6 weeks post RIT Follow up with physician • Decide on sequential injection or • Progression of rehab protocol with increased graduated load 	
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RIT #2 - #3 etc	
 Must follow same protocol to protect the tissue 1st-2nd weeks of controlled tissue load 3rd-4th weeks of graduated rehab protocol load added 	
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After RIT #1: Proceed with RIT #2 No further RIT · Progress rehab • Resume protocol of RIT #1 - Stretches: continue - NSAID: none Strengthening: progress 10 -- Tylenol if needed for pain _ Cardio: increase low impact Assistive Device if needed _ Stretches only _ Follow protocol as before RIT completed · After all RIT completed · # injections could be from 1-6 injections and could be 1-6 months + • Rehabilitation protocol is progressed incrementally at each injection phase if symptoms are improving Rehab after RIT completed · Stretches: per protocol and safe for diagnosis • Strengthening: progressed - Repetitions increased to 50-60 total per exercise - Add 1-2 lb. light weights with same repetitions - Increase therabands from yellow to red or blue with same repetitions Rehab after RIT completed • Cardio: establish 20 - 30 min of low impact base • Walk/Jog protocol: 20 min duration only _ 4 min walk/1 min jog: repeat 4 sets (20 min)

_ 3 min walk/2 min jog _ 2 min walk/3 min jog _ 1 min walk/4 min jog

- After 20 min jog then increase in 2' increments weekly - Do not increase speed or hills during this time

10-20%

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- Advance controlled closed chain exercises RESEARCH • Tendons: Achilles and forearm • Cartilage: knee osteoarthritis • Spine: ligaments primarily; disc not as successful	
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RESEARCH • FOREARM:	
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Case Review: Platelet Rich Plasma (PRP) for Chronic Lateral Epicondyllitis SCIENCE CENTER The Base of	
Activate As a meta-information and an administration of the second of t	
American Journal of Sports Medicine 2010 CSM APTA AP	

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Abstract Cone of some law independent for being and processing the some processing to the s	
open segment lighter of open and part of PSP years and part of PSP years are seen as the part of PSP years a	
The state of the s	
Conclusions Tremendous potential for "biologic augmentation" to	
 improve healing and regeneration of cartilage, meniscus, and tendon Learn from embryologic development 	
 Overall goal: recapitulation of molecular signals that can lead to tissue regeneration 	
 <u>Tissue regeneration</u> will provide new approaches for tissue replacement and <u>may ultimately improve management of common</u> orthopedic injuries 	
ormopeut injures	
Level V Evidence	
Personal Observation/Anecdotal	-
 My 2nd plantar plate cartilage tear in foot Left foot: 2006 	
Rehab + tendon transfer with limitationsRight foot: 2016	
 Rehab + 1 prolotherapy: no pain/no limitations 	-
®APTA CSM APTA	
Meeting	

Future

- · Regenerative Medicine is transforming all of areas medicine - not just orthopedics. • Future conferences will be divided by specializations
- Further research needed before drinking the Kool-Aid



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- 1 Comparison of Growth Factors and Platelet Concentrates from Commercial PRP Systems
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