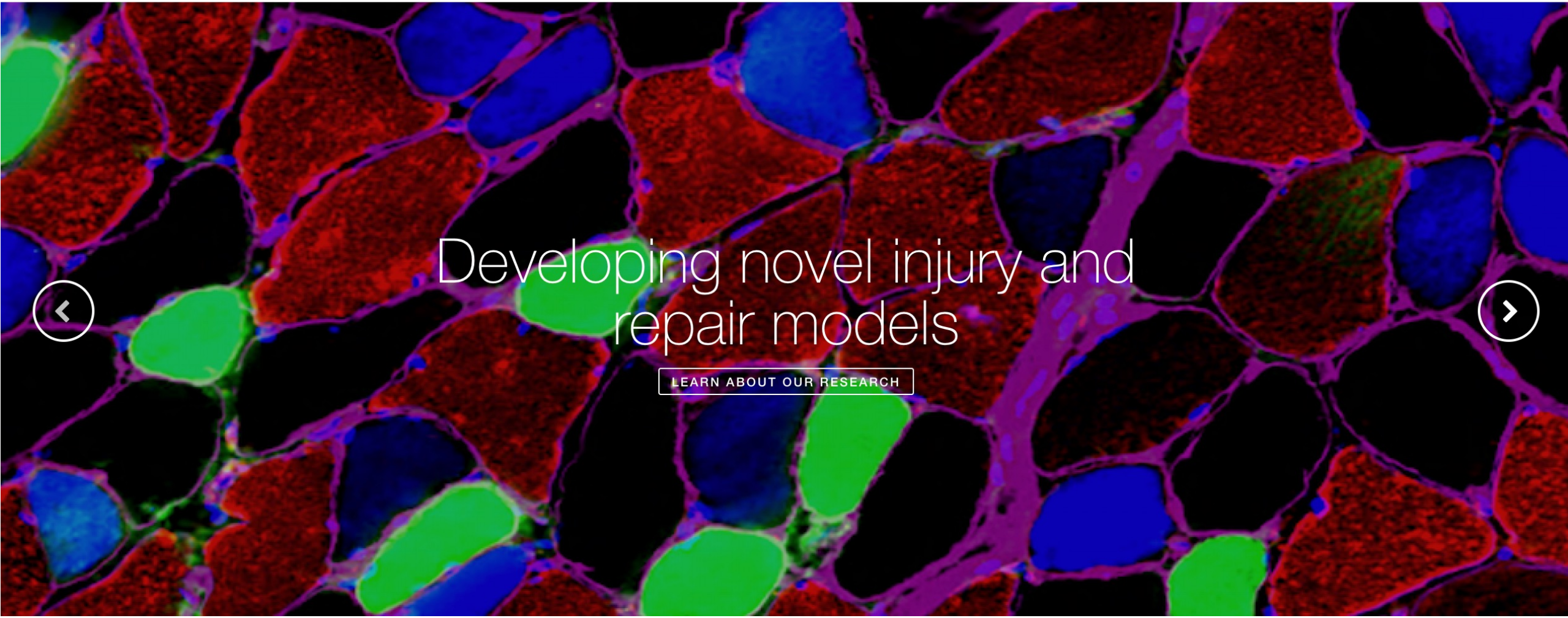
Biologic Treatments for MSK Conditions
PT/ATC Sports Conference
2021

Brian Feeley, MD
Chief, Sports Medicine and Shoulder Surgery

Disclosures

- Consultant—Bioniks, Kaliber
- Research—NIH, Orthofix,
- Editorial-JSES, CRMSM, JOR
- Advisory Boards—NFL SAB

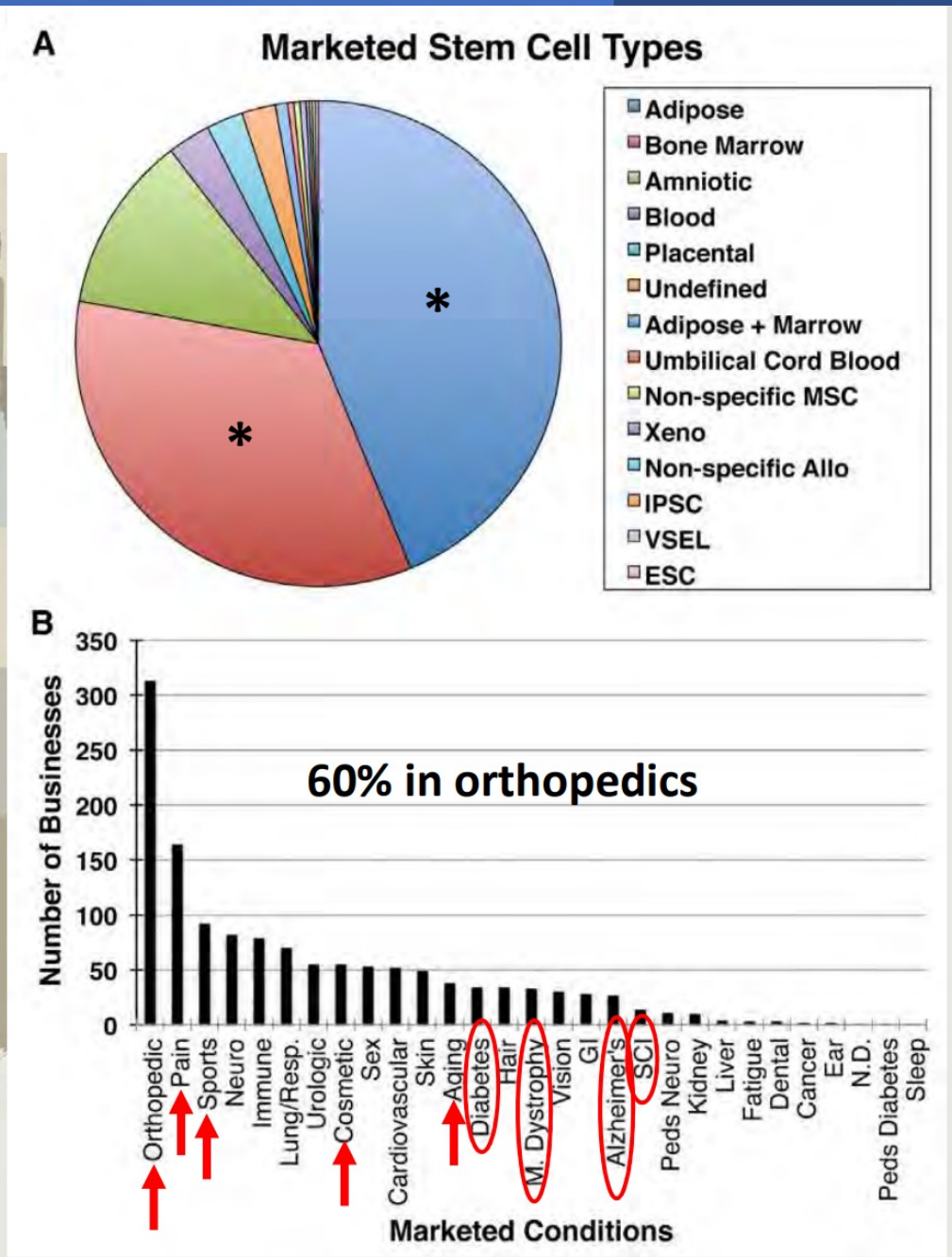

Developing novel injury and repair models
LEARN ABOUT OUR RESEARCH

Selling Stem Cells in the USA: Assessing the Direct-to-Consumer Industry

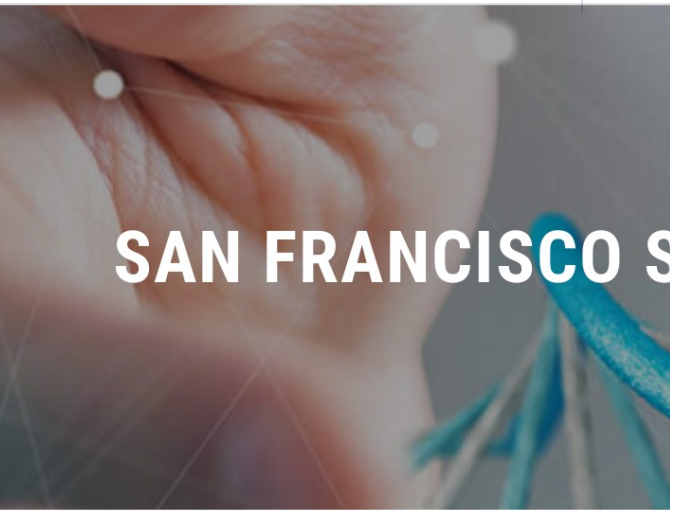
Leigh Turner[1,*] and Paul Knoepfler[2,3,*]

State	N
California	113
Florida	104
Texas	71
Colorado	37
Arizona	36
New York	21

Hotspot Cities	N
Beverley Hills	18
NYC	14
San Antonio	13
Los Angeles	12
Austin	11
Scottsdale	11
Phoenix	10



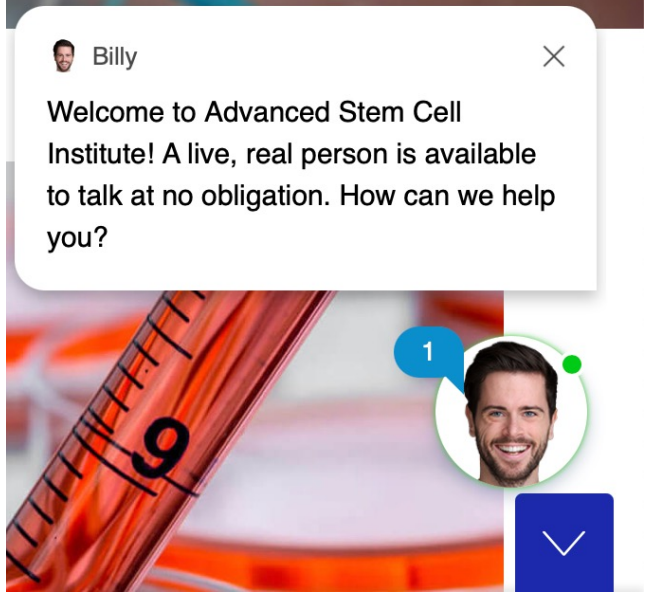
ADVANCED STEM CELL INSTITUTE



Stem Cell Injection Thera
California

Problems with the knees are so commo
arthroscopic knee surgery in the U.S. alc
is a surgical procedure in which a docto
while looking through an invasive instru
requires general or spinal anesthesia, ar

I am writing this review because I am excited. After 2 years and over 10 doctors, I can finally say my shoulder feels great. I was diagnosed with shoulder rotator cuff tear. I had cortisone shots, and therapy without significant improvement. My orthopedic surgeon insisted that surgery is my only option. Knowing some people who have done this surgery and their mediocre results I didn't feel comfortable with the idea of surgery. On researching the web I found that stem cells are helpful. I educated myself and consulted the doctors at Advamced Stem Cell Institute. The Dr spent a lot of time explaining my options, and show stem cells can help me avoid surgery. He reviewed my MRI and I scheduled he procedure. I have to say that their prices are very competitive, as I shopped around several other offices anywhere from $4,500-$. 6,500. I paid only $3,500 and it was the best investment. Now 4 months later I am playing baseball with my son again . If you were offered surgery, look into stem cells.

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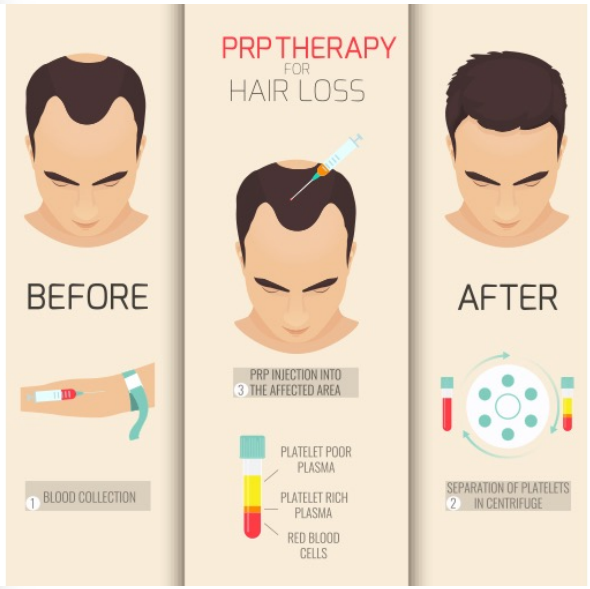
PRP-Platelet Rich Plasma
Stimulate Hair growth
Crinkling Skin around Eyes
Cheek & Mid face
Neck & Jawline
Back of hands & arms
Sports injury or chronic tendon
Chest & decolletage


PRP THERAPY
FOR
HAIR LOSS
BEFORE
AFTER
PRP INJECTION INTO THE AFFECTED AREA
3
BLOOD COLLECTION
1
SEPARATION OF PLATELETS IN CENTRIFUGE
2
PLATELET POOR PLASMA
PLATELET RICH PLASMA
RED BLOOD CELLS


Better Self-Image
WITH PLATELET-RICH PLASMA

The market will be **ACCELERATING** growing at a **CAGR** of nearly **11%**

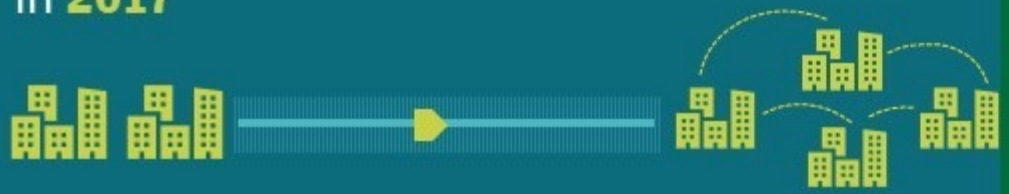
INCREMENTAL GROWTH

$820 mn

The year-over-year growth rate for **2018** is estimated at

10.50%

The **AUTOLOGOUS TRANSPLANTS SEGMENT** occupied **HIGHEST** market share in **2017**



53% of the growth will come from the **AMERICAS**

One of the **KEY DRIVERS** for this market will be the increase in awareness of stem cell therapy

READ THE REPORT:

GLOBAL STEM CELL THERAPY MARKET 2018-2022

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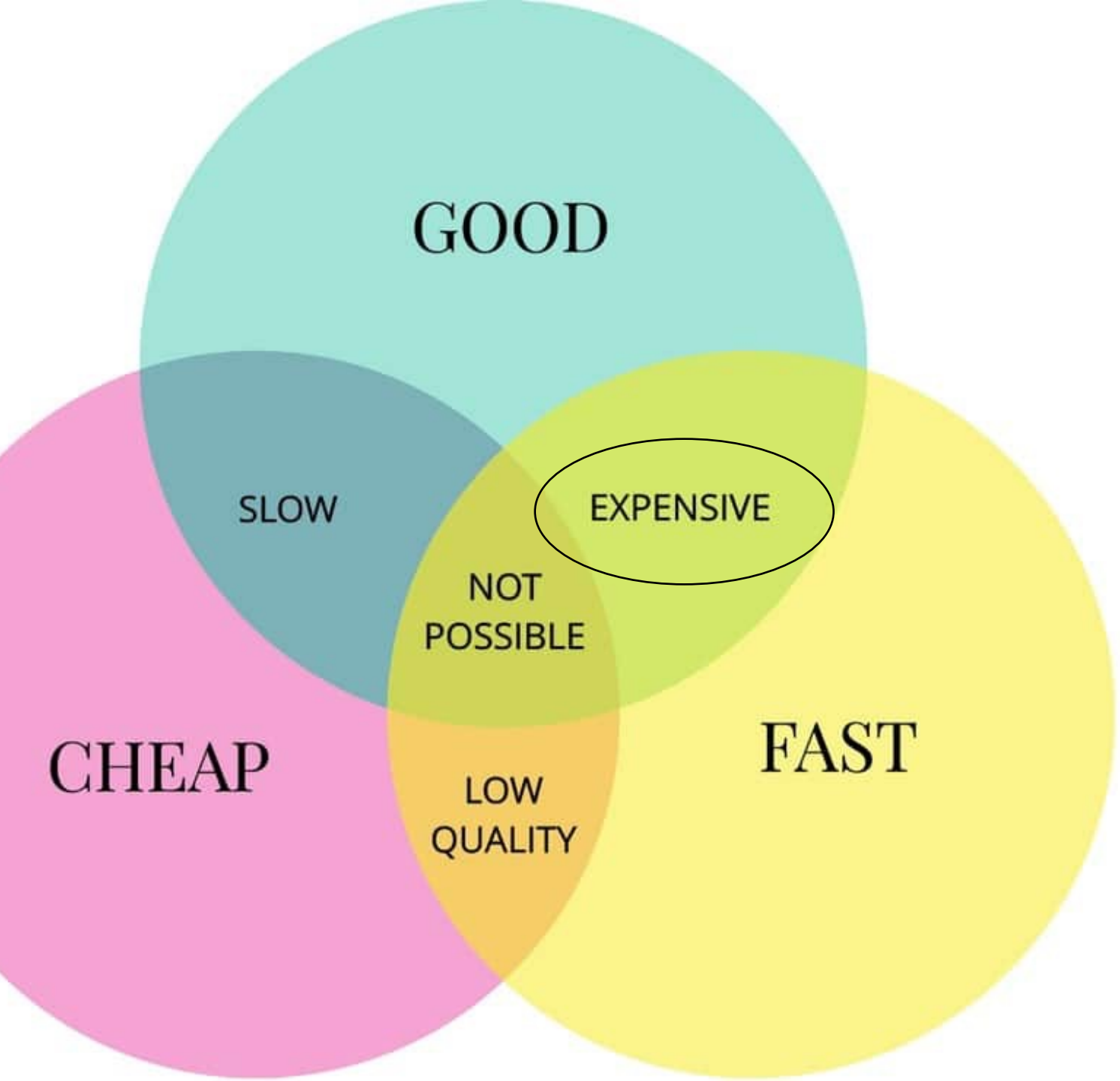


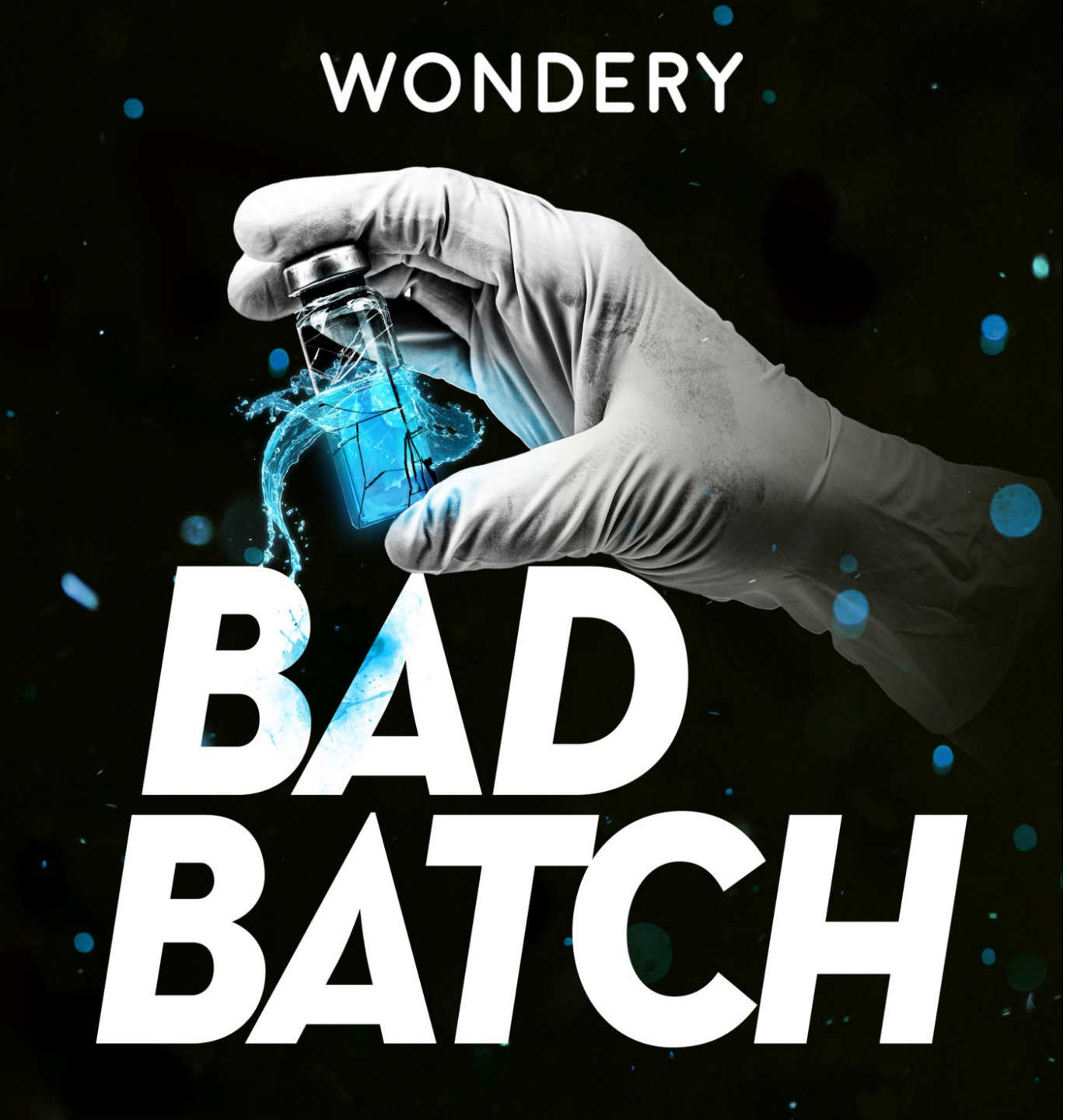
How Do You Figure Out What a Stem Cell Procedure Should Cost?

Regenexx

12 People Hospitalized With Infections From Stem Cell Shots

F.D.A. Moves to Stop Rogue Clinics From Using Unapproved Stem Cell Therapies

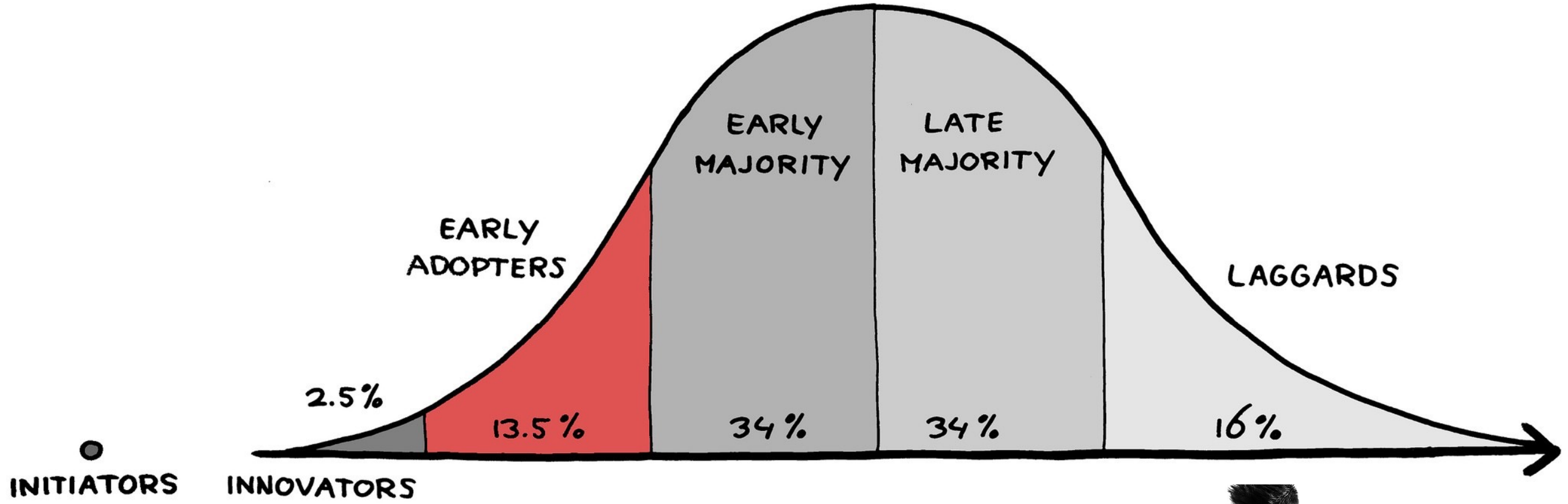
Dr. Mark Berman, of the Cell Surgical Network, in 2014 at his practice in Beverly Hills. Dr. Berman is a founder of the California Stem Cell Treatment Centers, where patients received an unapproved stem cell treatment made with the help of a smallpox vaccine and other ingredients. Raquel Maria Dillon/Associated Press

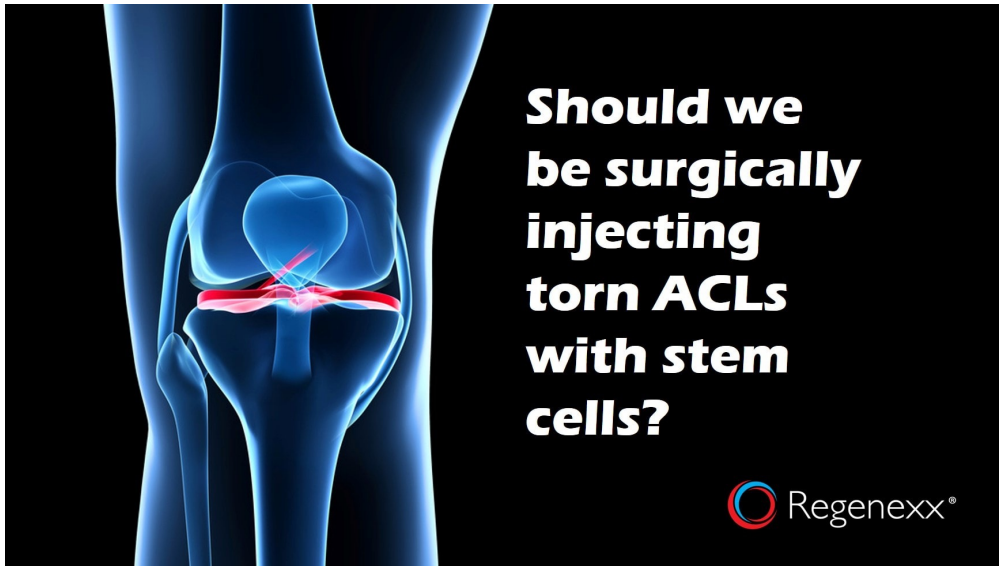


Harvard Calls for Retraction of Dozens of Studies by Noted Cardiac Researcher

Some 31 studies by Dr. Piero Anversa contain fabricated or falsified data, officials concluded. Dr. Anversa popularized the idea of stem cell treatment for damaged hearts.

Dr. Piero Anversa, affiliated with the Harvard Medical School, above, and Brigham and Women's Hospital in Boston, departed in 2015 following questions about his research.


EARLY MAJORITY
LATE MAJORITY
EARLY ADOPTERS
LAGGARDS
2.5%
13.5%
34%
34%
16%
INITIATORS
INNOVATORS


Should we be surgically injecting torn ACLs with stem cells?
Regenexx®


ALTERNATIVES TO SURGERY
Using Your Own Stem Cells to Heal Your Body
Regenexx®
Tampa Bay
The Orthopedic Stem Cell Experts

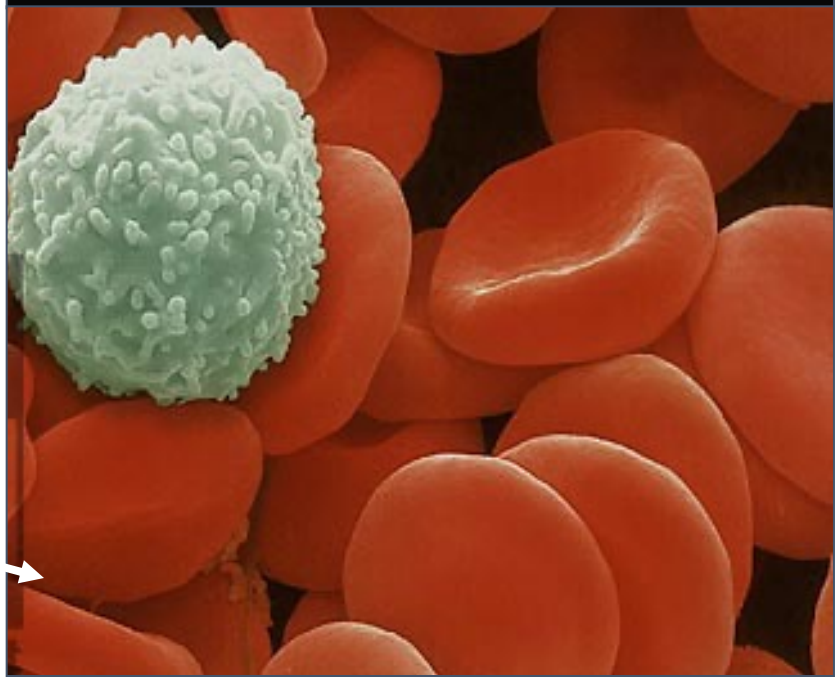
What would PRP or stem cells work for?

- **Cartilage regeneration**
  - *Knee osteoarthritis*
- **Tendonopathy/tendon to bone healing**
  - *Rotator cuff tears*
  - *Tennis elbow, achilles tendonopathy*
- **Bone healing**
  - *Spinal fusion*

What is PRP?

Platelet Rich Plasma: "Volume of plasma that has a platelet count above the baseline of whole blood."

Plasma and platelets



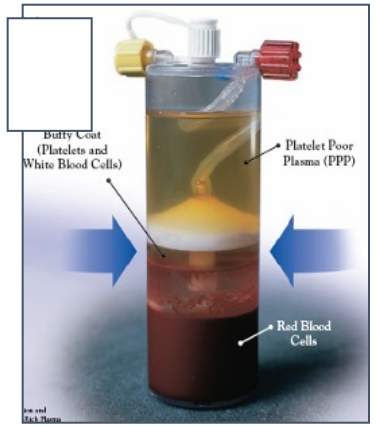
+/-WBC's

-RBC's

All PRPs are NOT the same!

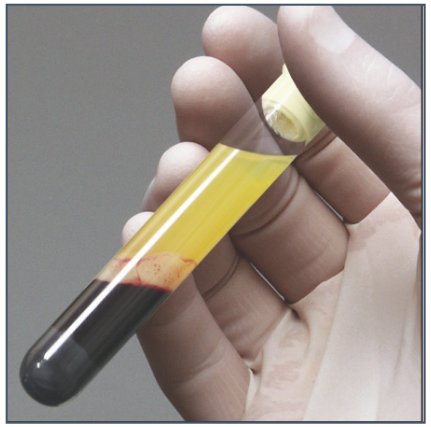
Magellan™ Medtronic

Caption™
Smith & Nephew

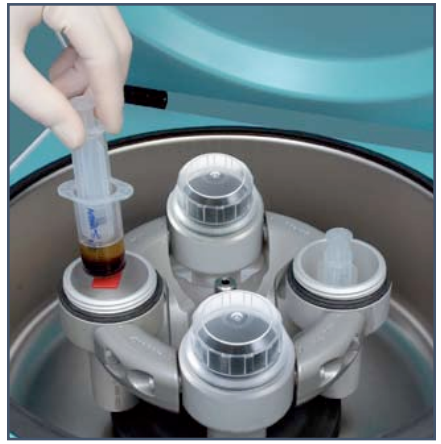


GPS®III Biomet

Symphony II™ DePuy

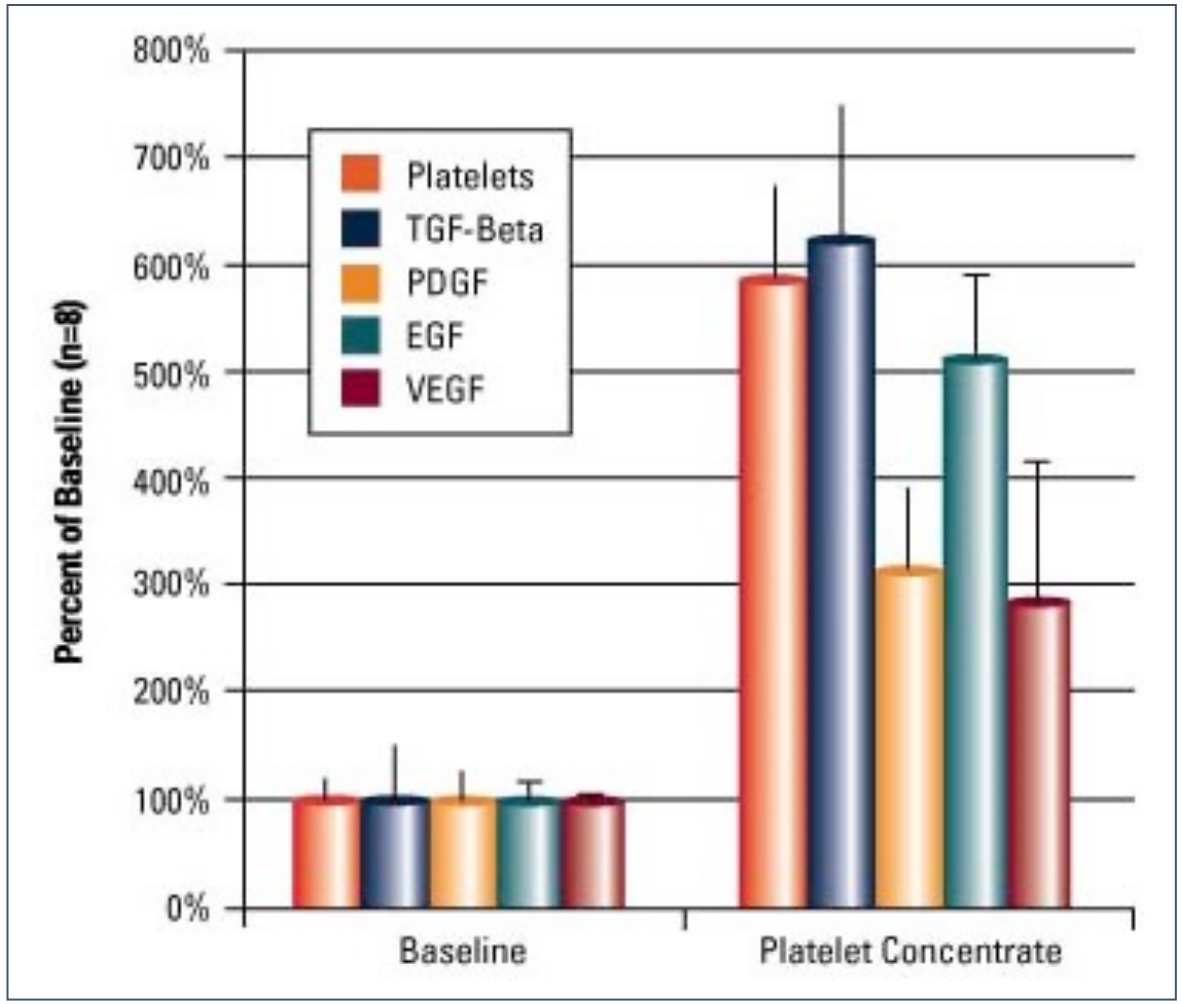


Cascade™ MTF



Arthrex ACP™

PRP releases potent growth factors



Platelet-membrane-based

- **1100 proteins**
- **The Good:**

TGF-B – Transforming growth factor
PDGF – Platelet derived growth factor
IGF – Insulin-like growth factor
FGF – Fibroblast growth factor
VEGF – Vascular endothelial growth factor
Cell-adhesion molecules – fibronectin, fibrin, vitronectin

Not so good
Growth factor inhibitors…they are there too

But the actual amount is not consistent…

Final platelet and growth factor concentration dependent upon:

- **Amount of whole blood used**
- **Efficacy of platelet recovery**
- **Final volume of plasma in which the platelets are suspended.**

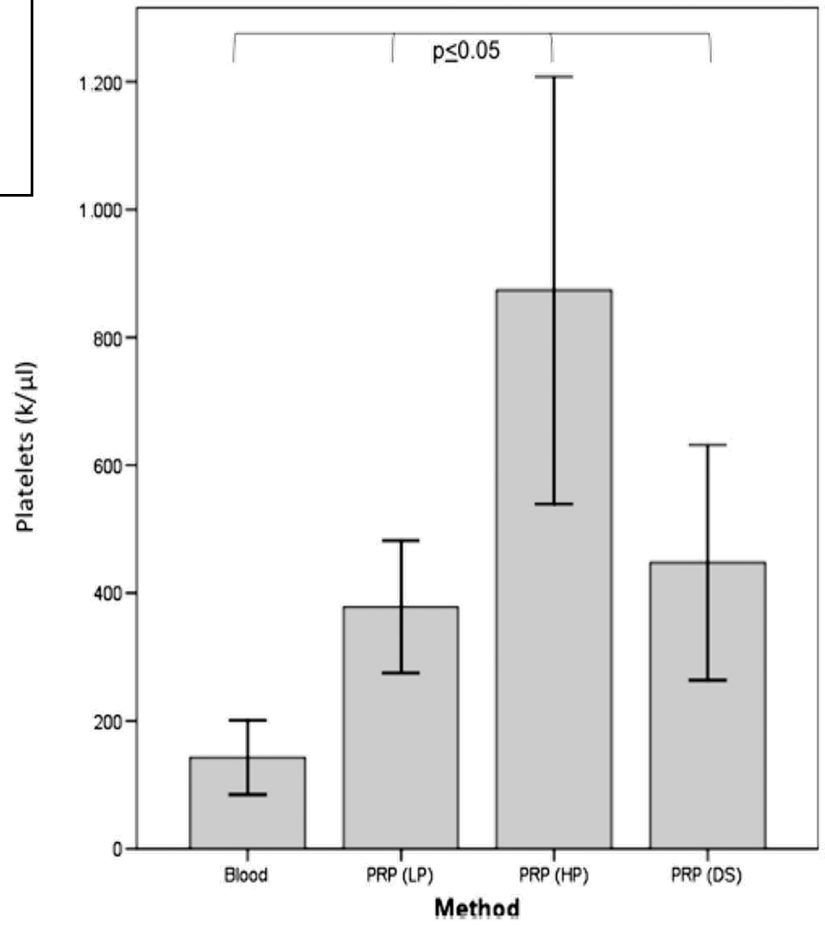
…and PRP can vary from day to day in the *same individual.*

Platelet-Rich Plasma Differs According to Preparation Method and Human Variability

Augustus D. Mazzocca, MS, MD, Mary Beth R. McCarthy, BS, David M. Chowaniec, BS, Mark P. Cote, DPT, Anthony A. Romeo, MD, James P. Bradley, MD, Robert A. Arciero, MD, and Knut Beitzel, MD

Investigation performed at the Department of Orthopaedic Surgery, University of Connecticut Health Center, Farmington, Connecticut

- 8 subjects
  - Mean age 31.6 years
  - 3 repetitive blood draws
- Conclusions
  - PRP > whole blood in plt conc
  - Single = Double spin techniques
  - High variability within systems



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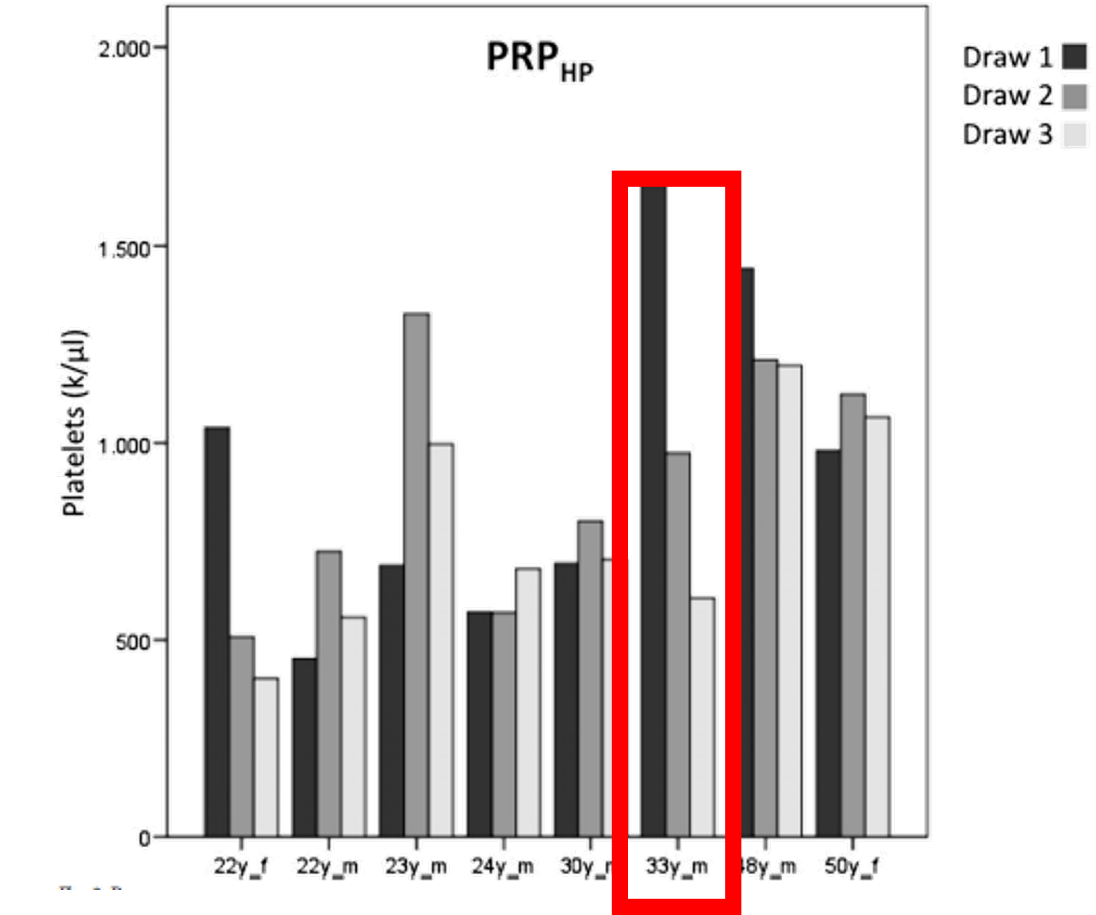

- Cell counts inconsistent day to day
- *Has implications since PRP is often given repetitively*
- *Biologic factors that may influence this variability unknown*

Hyaluronic Acid Versus Platelet-Rich Plasma

A Prospective, Double-Blind Randomized Controlled Trial Comparing Clinical Outcomes and Effects on Intra-articular Biology for the Treatment of Knee Osteoarthritis

Brian J. Cole,*†‡§||¶ MD, MBA, Vasili Karas,# MD, MS, Kristen Hussey,† MS, Kyle Pilz,†¶ MMS, PA-C, and Lisa A. Fortier,** DVM, PhD, DACVS
Investigation performed at the Rush University Medical Center, Chic

AJSM 2017

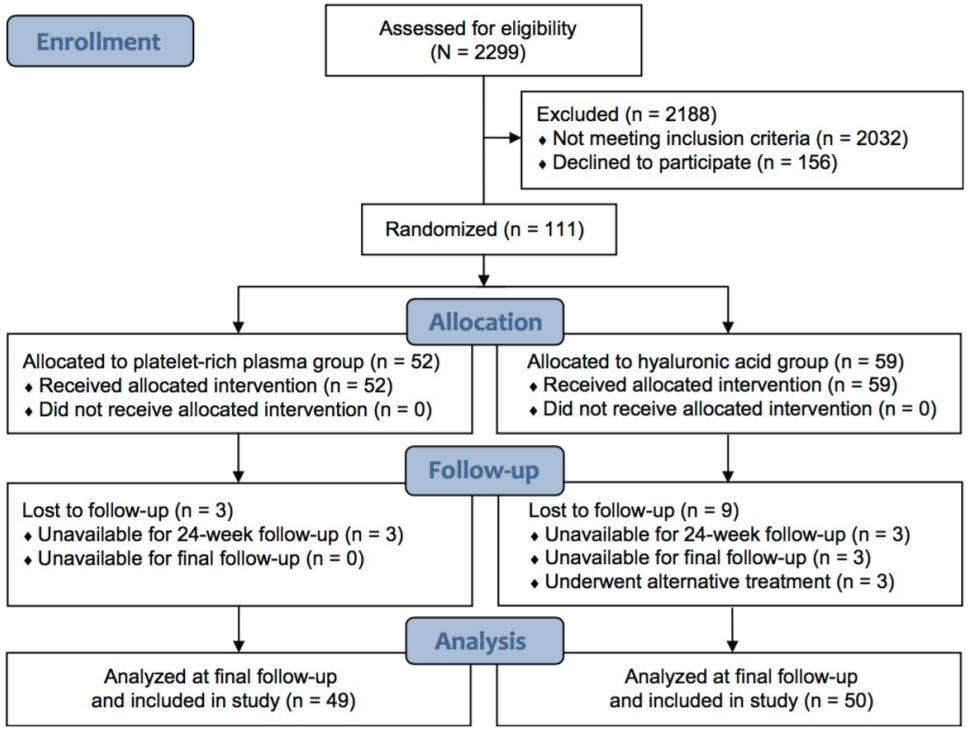

TABLE 3
WOMAC Pain Score at Study Time Points[a]

	PRP Group	HA Group
Before treatment	7.00 ± 0.53	7.52 ± 0.58
Treatment visit 2 (week 2)	6.15 ± 0.54	6.32 ± 0.55
Treatment visit 3 (week 3)	5.06 ± 0.48	5.53 ± 0.51
Follow-up		
6 weeks	4.57 ± 0.48	4.66 ± 0.47
12 weeks	3.98 ± 0.63	5.00 ± 0.60
24 weeks	4.11 ± 0.56	5.00 ± 0.50
52 weeks	3.02 ± 0.48	4.00 ± 0.60

No difference in WOMAC Pain

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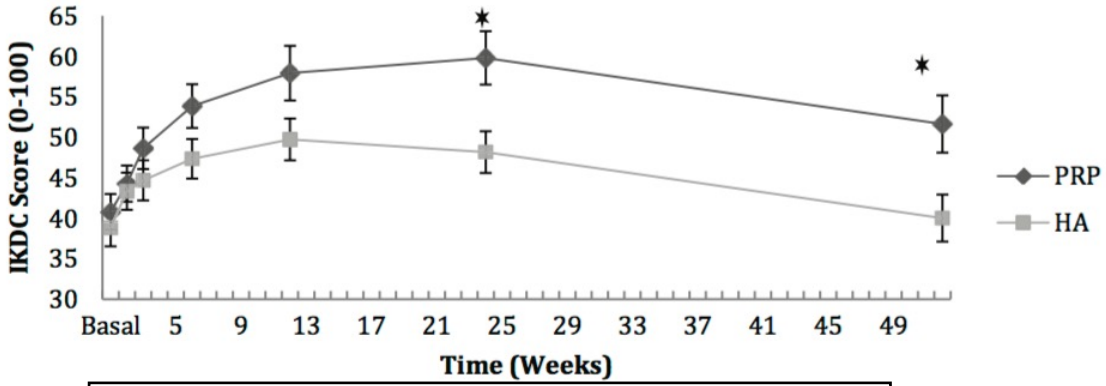
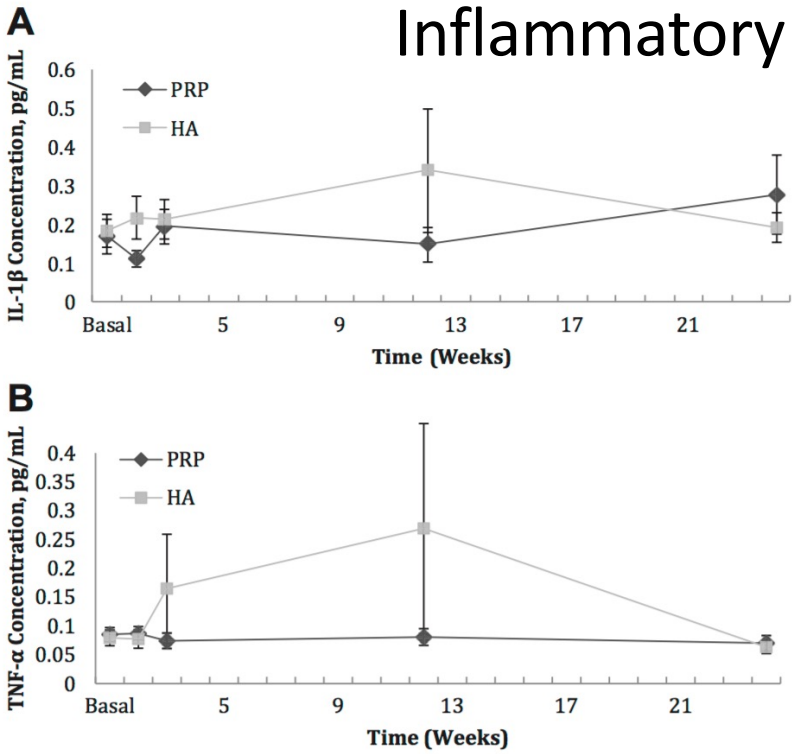


Improved IKDC Scores 6-12 Months with PRP

Inflammatory markers



Mild OA, lower BMI worked better
lowers pro-inflammatory cytokines.

Conclusion: “significant improvements were seen in other patient-reported outcome measures, with results favoring PRP over HA.”

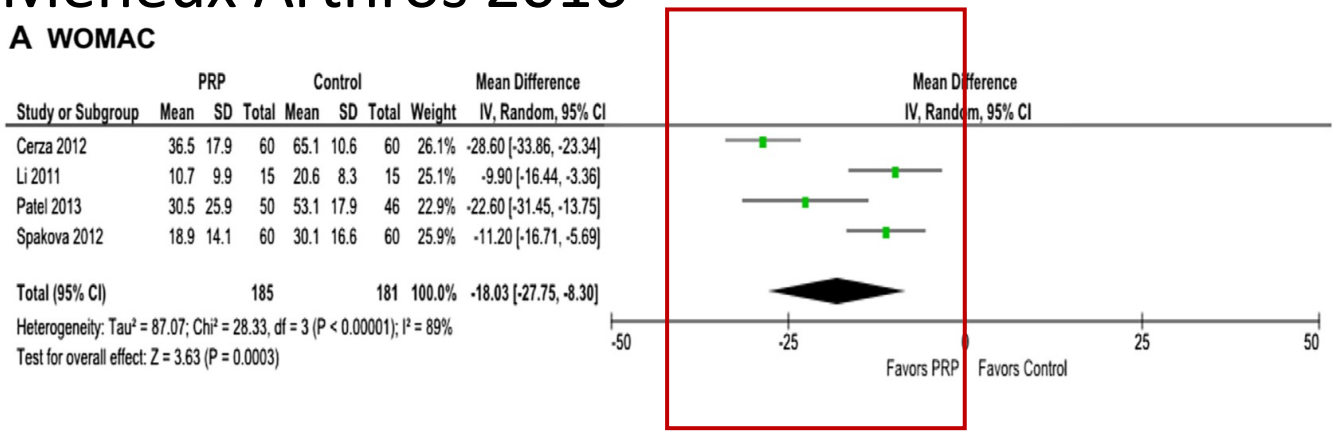
Systematic Reviews of Level 1 and Level 2 evidence

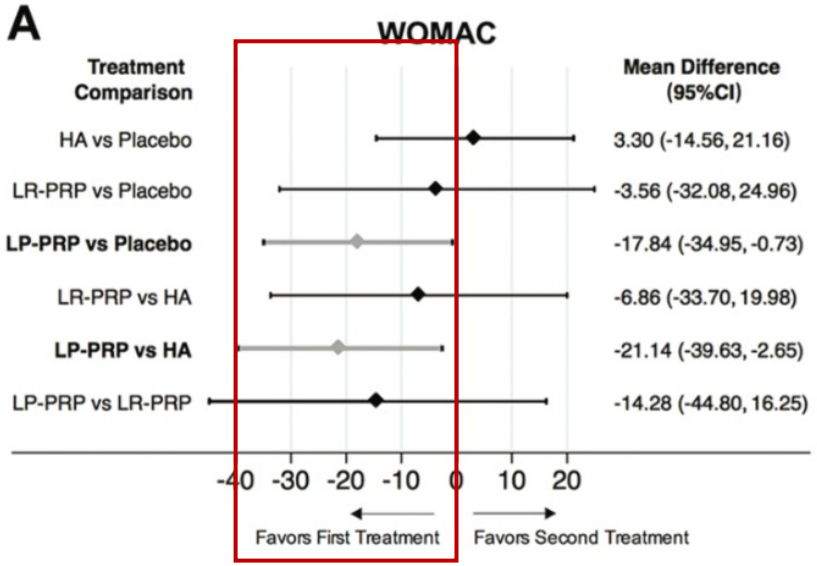
Khoshbin et al Arthrosc 2013

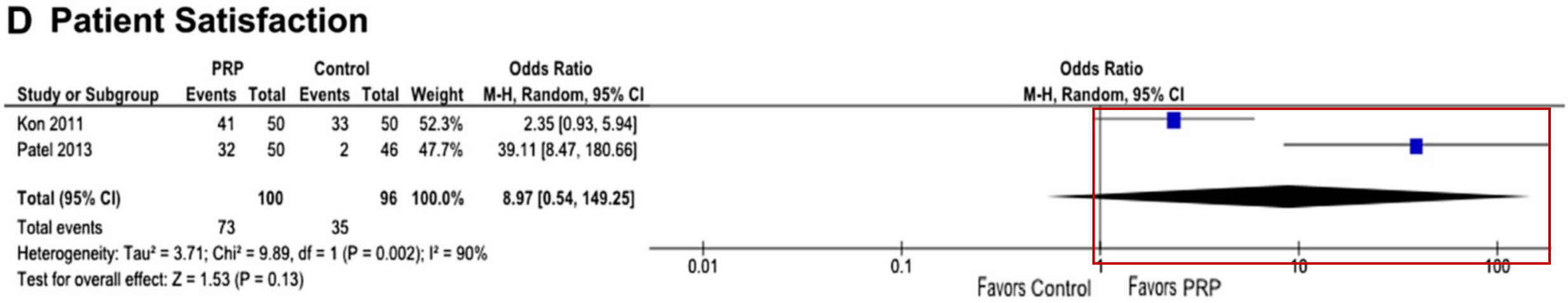
Chang et al APMR 2014

Riboh et al AJSM 2015

Meheux Arthros 2016







Randomized Controlled Trial > Am J Sports Med. 2021 Feb;49(2):487-496.
doi: 10.1177/0363546520986867.

Clinical Efficacy of Platelet-Rich Plasma Injection and Its Association With Growth Factors in the Treatment of Mild to Moderate Knee Osteoarthritis: A Randomized Double-Blind Controlled Clinical Trial As Compared With Hyaluronic Acid

Yong-Beom Park [1], Jun-Ho Kim [2], Chul-Won Ha [3 4 5], Dong-Hyun Lee [6]

Randomized controlled trial (Level 1 evidence)

--works for all areas of the knee equally well
--more patients reached MCID with PRP vs HA
--no statistical difference in clinical outcomes

…and PRP can vary from day to day in the *same individual.*

Platelet-Rich Plasma Differs According to Preparation Method and Human Variability

Augustus D. Mazzocca, MS, MD, Mary Beth R. McCarthy, BS, David M. Chowaniec, BS, Mark P. Cote, DPT, Anthony A. Romeo, MD, James P. Bradley, MD, Robert A. Arciero, MD, and Knut Beitzel, MD
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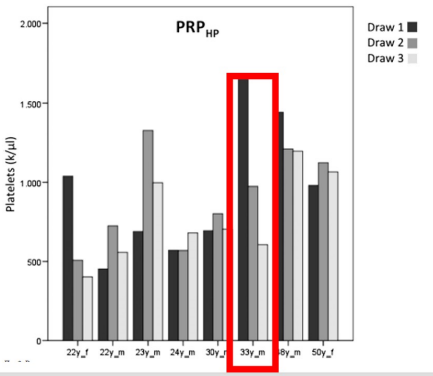
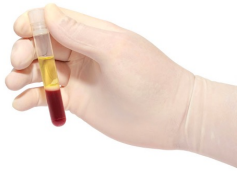




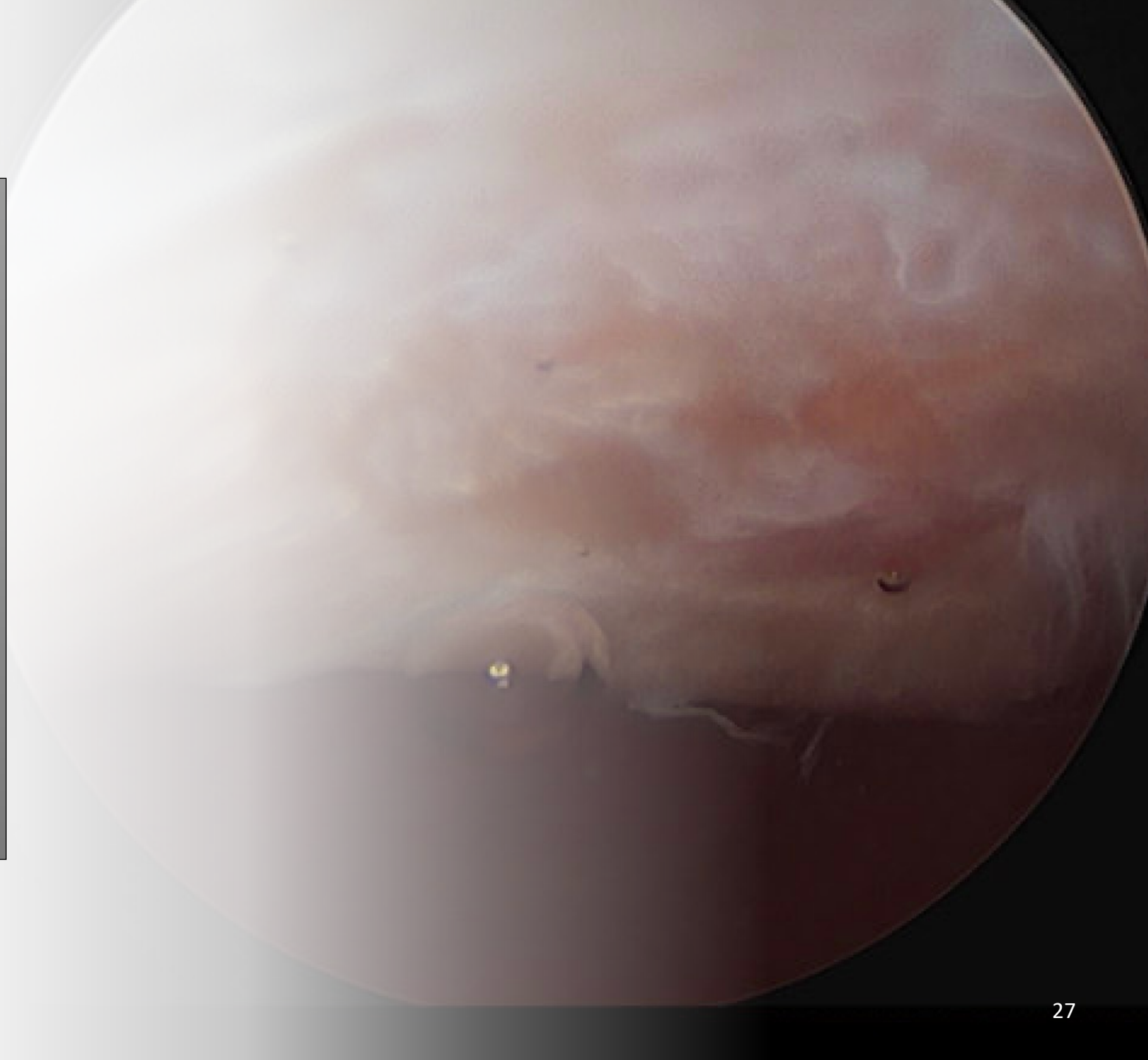
- Cell counts inconsistent day to day
- *Has implications since PRP is often given repetitively*
- *Biologic factors that may influence this variability unknown*

Within the PRP group, the concentrations of platelet-derived growth factors were high in patients with a score above the MCID for VAS at 6 months.

- **PRP and Early OA**

- Level 1, 2 evidence
- **SAFE** for patients who want to use it

- Likely beneficial with LP-PRP
- Effect size relatively small
- No long term data on natural history
- No MRI findings showing cartilage preservation Or cartilage growth



Chronic Tendonopathies

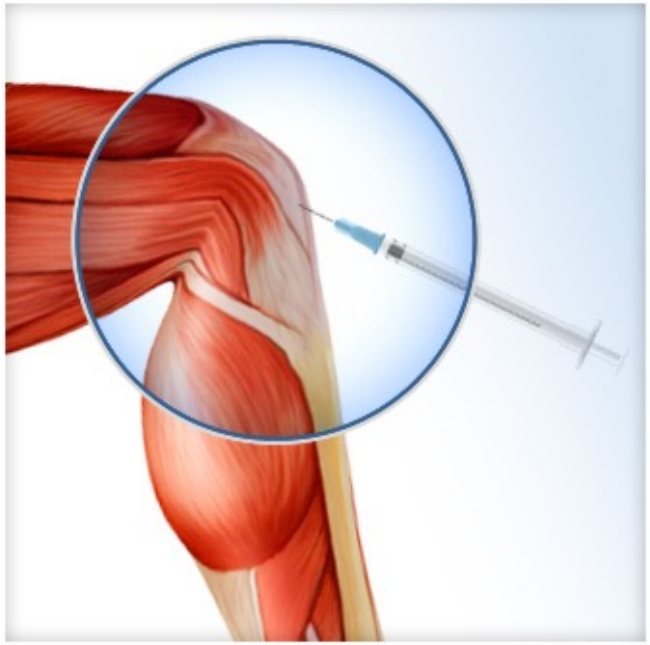
Elbow epicondylitis

Achilles tendinopathy

Jumper's knee

Conditions that have not done well historically with surgical treatment

- Increased growth factors in necrotic, degenerative tissue areas



Treatment of Chronic Elbow Tendinosis With Buffered Platelet-Rich Plasma

Allan Mishra,* MD, and Terri Pavelko, PAC, PT
From the Department of Orthopedic Surgery, Menlo Medical Clinic, Stanford University Medical Center, Menlo Park, California

AJSM 2006

- Level II evidence
- 20 patients with refractory epicondylar pain
  - PRP w **WBC** single injection vs. bupivicaine
- 6 month time point, PRP group with 81% improvement in VAS scores
- 25-month f/u – PRP group with 93% reduction in pain

Efficacy of Platelet-Rich Plasma for Chronic Tennis Elbow

A Double-Blind, Prospective, Multicenter, Randomized Controlled Trial of 230 Patients

Allan K. Mishra,*† MD, Nebojsa V. Skrepnik,‡ MD, PhD, Scott G. Edwards,§ MD, Grant L. Jones,|| MD, Steven Sampson,¶ DO, Doug A. Vermillion,# MD, Matthew L. Ramsey,** MD, David C. Karli,†† MD, MBA, and Arthur C. Rettig,‡‡ MD
Investigation performed at Department of Orthopaedic Surgery, Menlo Medical Clinic, Stanford University Medical Center, Menlo Park, California

AJSM 2014

- RCT, level II, double-blinded
- 230 pt, chronic lateral epicondylar tendinopathy 3 mo in duration
  - 116 in PRP, leukocyte-enriched
  - 114 in active control
- 12-week no difference
- 24-week significant improvement in pain and reduced tenderness

Summary for Lateral Epicondylitis

Decent level 1 evidence to support PRP over steroid to improve symptoms

Use LR-PRP for lateral epicondylitis

2019

The effects of regenerative injection therapy compared to corticosteroids for the treatment of lateral Epicondylitis: a systematic review and meta-analysis

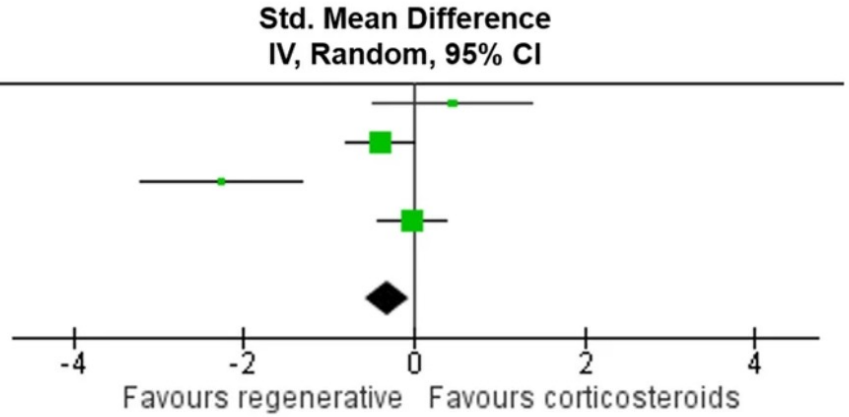
Julie Barnett ✉, Madison N. Bernacki, Jessica L. Kainer, Hannah N. Smith, Annette M. Zaharoff & Sandeep K. Subramanian

B

Six months

Study or Subgroup	Regenerative Injections Mean	SD	Total	Corticosteroids Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI	Year
Wolf et al 2011	20	16.3	9	13	12.8	9	7.5%	0.45 [-0.48, 1.39]	2011
Gosens et al 2012	27.8	24.7	51	37.6	23.1	49	42.4%	-0.41 [-0.80, -0.01]	2012
Gautam et al 2015	32	4.5	15	39.6	1	15	7.5%	-2.27 [-3.21, -1.32]	2015
Lebiedzinskie et al 2015	14.2	13.4	53	14.7	22	46	42.6%	-0.03 [-0.42, 0.37]	2015
Total (95% CI)			**128**			**119**	**100.0%**	**-0.32 [-0.58, -0.06]**	

Heterogeneity: Chi² = 21.26, df = 3 (P < 0.0001); I² = 86%
Test for overall effect: Z = 2.42 (P = 0.02)

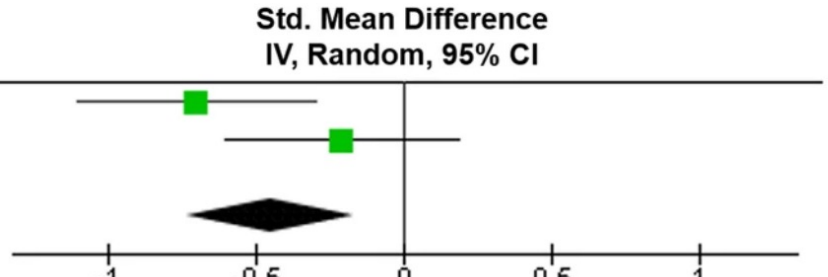


C

One year

Study or Subgroup	Regenerative Injections Mean	SD	Total	Corticosteroids Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI	Year
Gosens et al 2012	20	23.5	51	36.8	24	49	49.0%	-0.70 [-1.11, -0.30]	2012
Lebiedzinskie et al 2015	9.9	17.1	53	14.4	25.2	46	51.0%	-0.21 [-0.61, 0.19]	2015
Total (95% CI)			**104**			**95**	**100.0%**	**-0.45 [-0.73, -0.17]**	

Heterogeneity: Chi² = 2.90, df = 1 (P = 0.09); I² = 66%

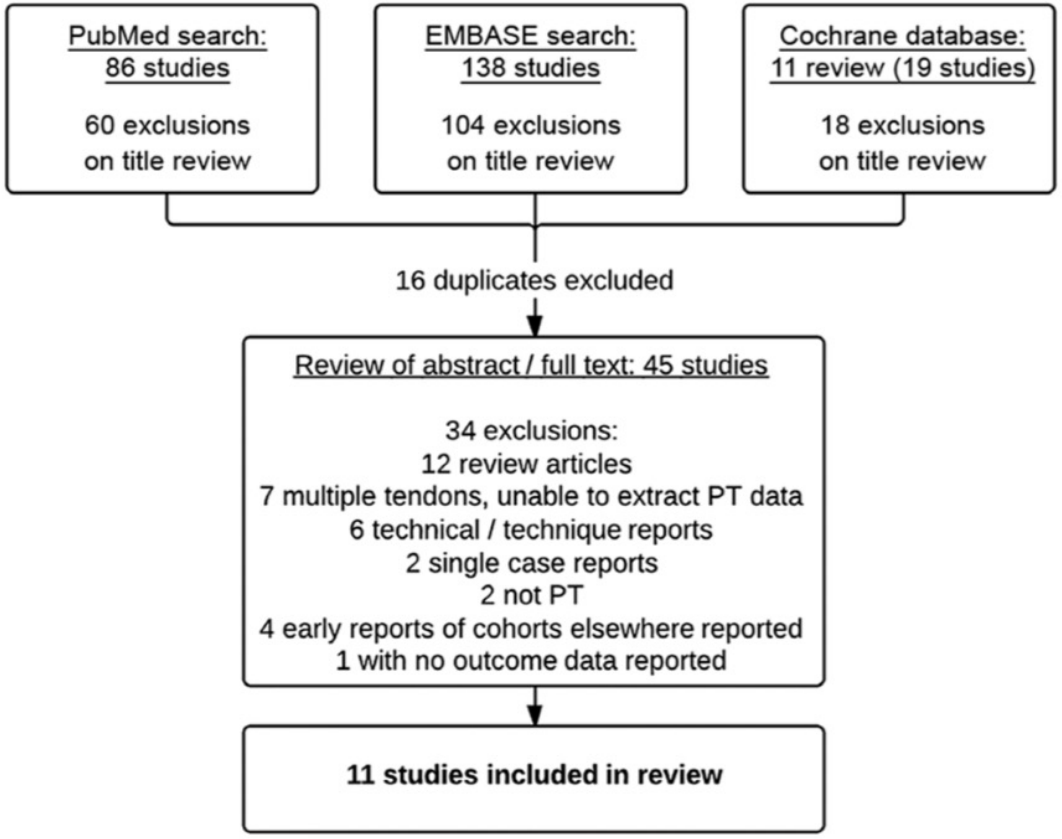


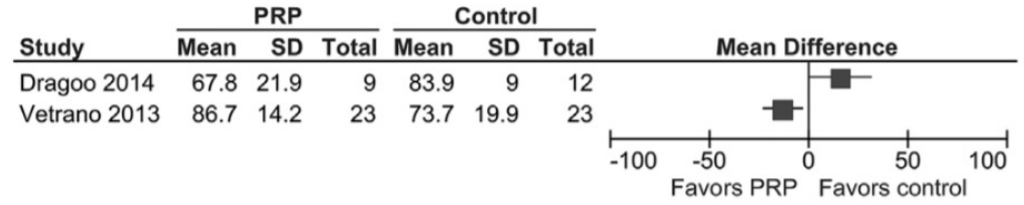
Platelet-Rich Plasma in the Treatment of Patellar Tendinopathy

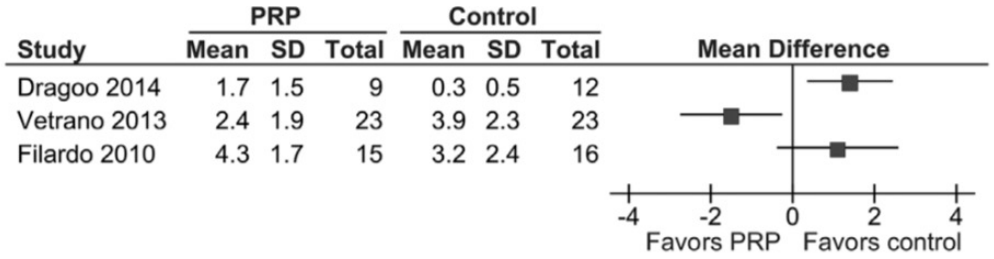
A Systematic Review

Alexander D. Liddle,* BSc, MRCS, and E. Carlos Rodríguez-Merchán,†‡ MD, PhD
Investigation performed at La Paz University Hospital, Madrid, Spain

AJSM 2015







Conclusions:
"Platelet-rich plasma is a safe and promising therapy in the treatment of recalcitrant PT. However, its superiority over other treatments such as physical therapy remains unproven."

What about PRP for tendonopathy/PTRCT?

Eur J Orthop Surg Traumatol. 2016 Aug 20. [Epub ahead of print]

Subacromial injection of autologous platelet-rich plasma versus corticosteroid for the treatment of symptomatic partial rotator cuff tears.

Shams A[1], El-Sayed M[2], Gamal O[1], Ewes W[3].

EJOST 2016

Randomized patients with partial tears to steroid vs PRP injection

Both groups got better

PRP slightly better than steroid at 12 weeks

No difference at 6 months

No difference in MRI findings at 6 months

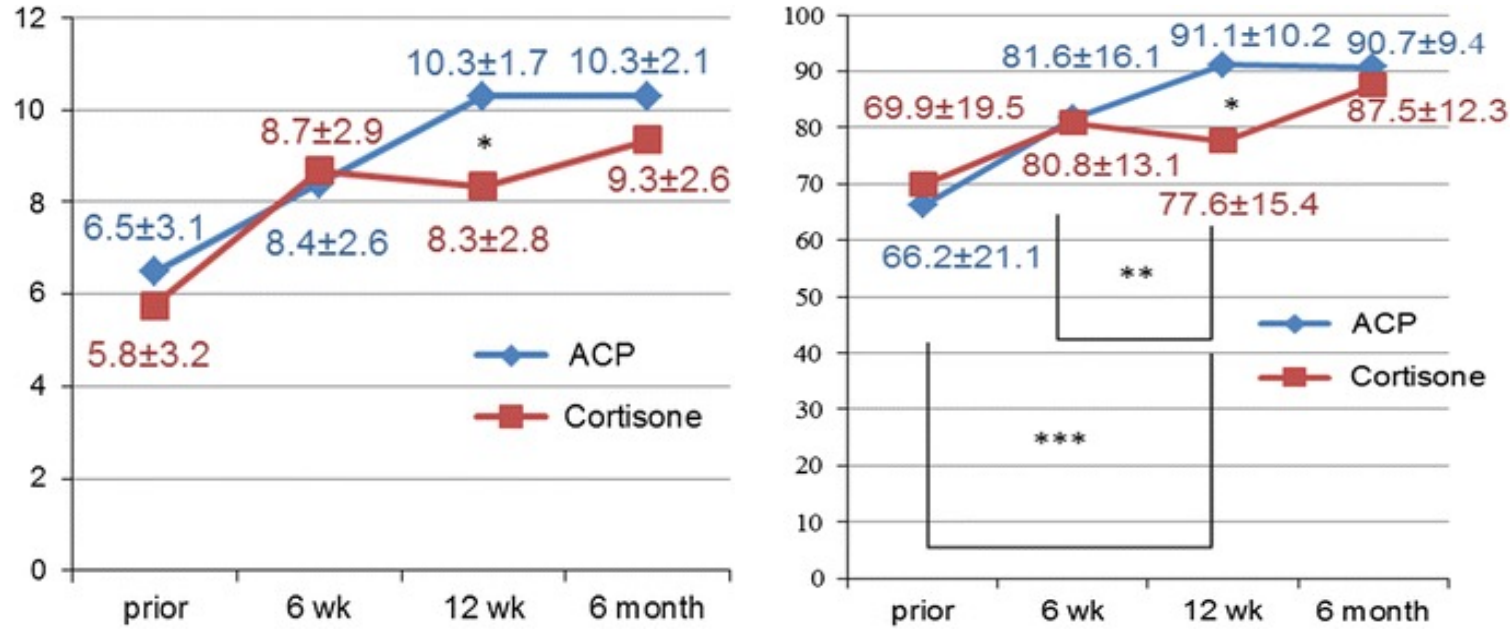
What about PRP for tendonopathy/PTRCT?

Knee Surg Sports Traumatol Arthrosc. 2015 May 28. [Epub ahead of print]

The effect of subacromial injections of autologous conditioned plasma versus cortisone for the treatment of symptomatic partial rotator cuff tears.

von Wehren L[1], Blanke F, Todorov A, Heisterbach P, Sailer J, Majewski M.

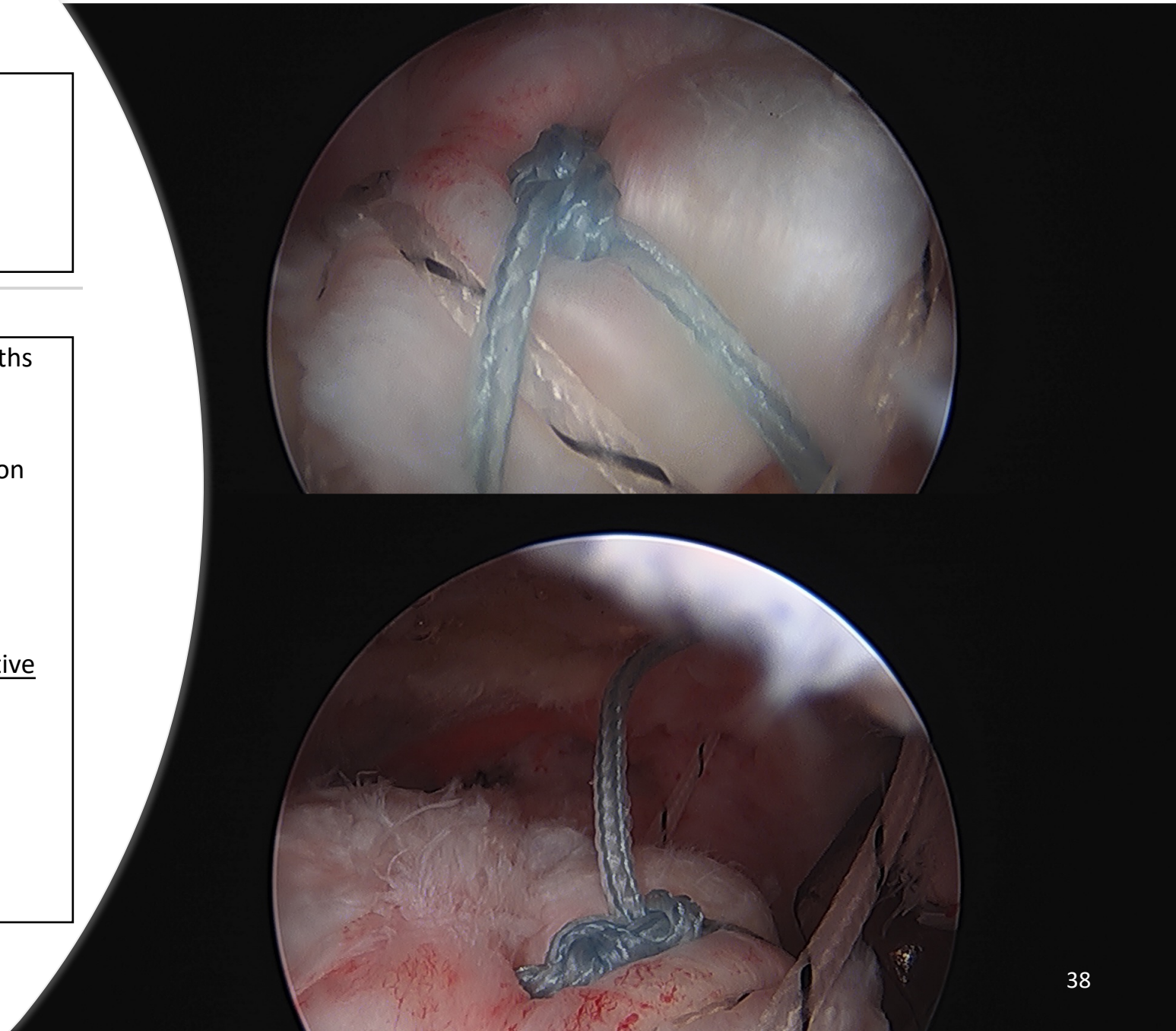
KSSTA 2015



Slight improvement with PRP at 3 months, no difference at 6 months

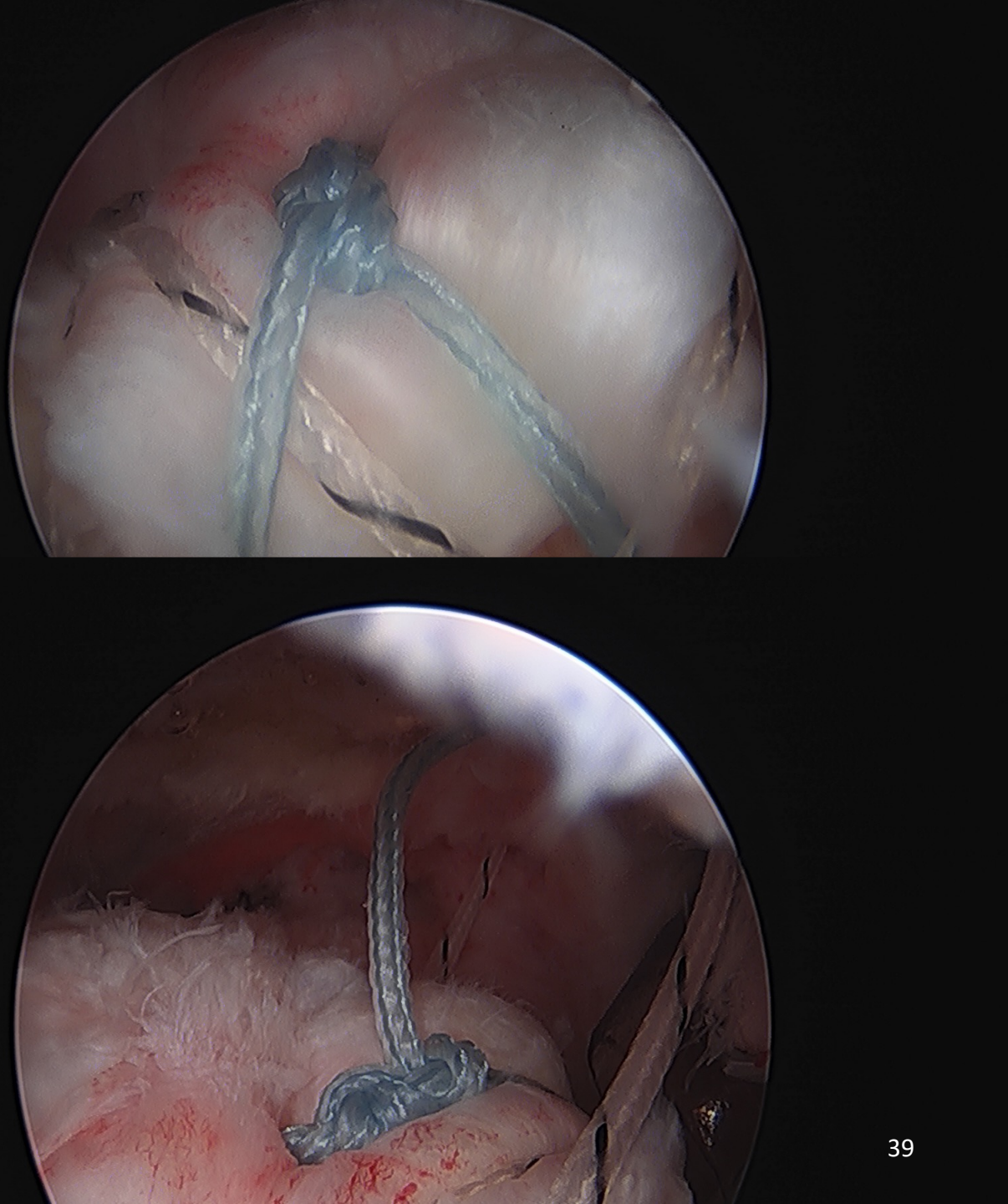
Rotator Cuff Repair Studies
PRP doesn't work!

- No difference in UCLA scores outcomes at 6, 12, 24 months
  - ***Randelli et al JSES 2011***
- No significant difference in Constant and tendon scores on MRI
  - ***Castricini et al AJSM 2011***
  - ***Wang et al AJSM 2015***
- No difference in clinical scores at 1-yr f/u, possible negative effect on healing
  - ***Jo et al AJSM 2011***
  - ***Rodeo et al AJSM 2012***
  - ***Weber et al AJSM 2015***



Rotator Cuff Repair Studies
PRP might work?

- Early pain reduction, no difference in healing
  - ***D'Ambroisi MSK Surg 2016***
  - ***Holtby AJSM 2016***
- Improved healing in large tears (SR only)
  - ***Pandey JSES 2016***
  - ***Jo et al AJSM 2015***
    - *(3% PRP vs 20% Control)*

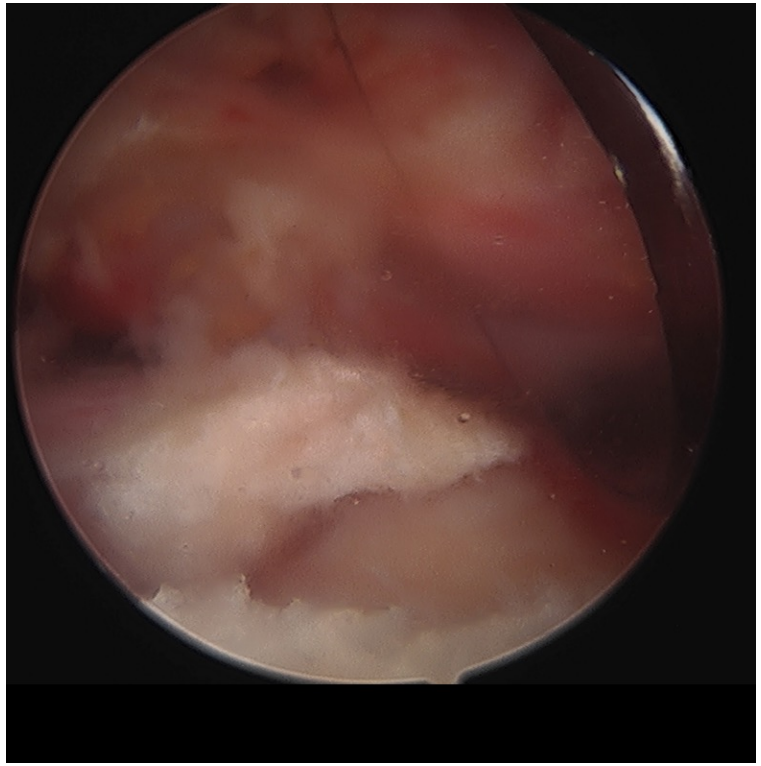


Am J Sports Med. 2018 Nov;46(13):3134-3141. doi: 10.1177/0363546518795895. Epub 2018 Sep 20.

Clinical and Structural Evaluations of Rotator Cuff Repair With and Without Added Platelet-Rich Plasma at 5-Year Follow-up: A Prospective Randomized Study.

Malavolta EA[1], Gracitelli MEC[1], Assunção JH[1], Ferreira Neto AA[1], Bordalo-Rodrigues M[1], de Camargo OP[1].

- Prospective RCT of 54 patients at 5 years after RC repair of small to medium tears
  - No difference in clinical outcomes
  - No difference in retear rates
  - **“PRP did not enhance healing rates or clinical outcomes at 5 years”**



Platelet-Rich Product Supplementation in Rotator Cuff Repair Reduces Retear Rates and Improves Clinical Outcomes: A Meta-Analysis of Randomized Controlled Trials

Arthroscopy 2021

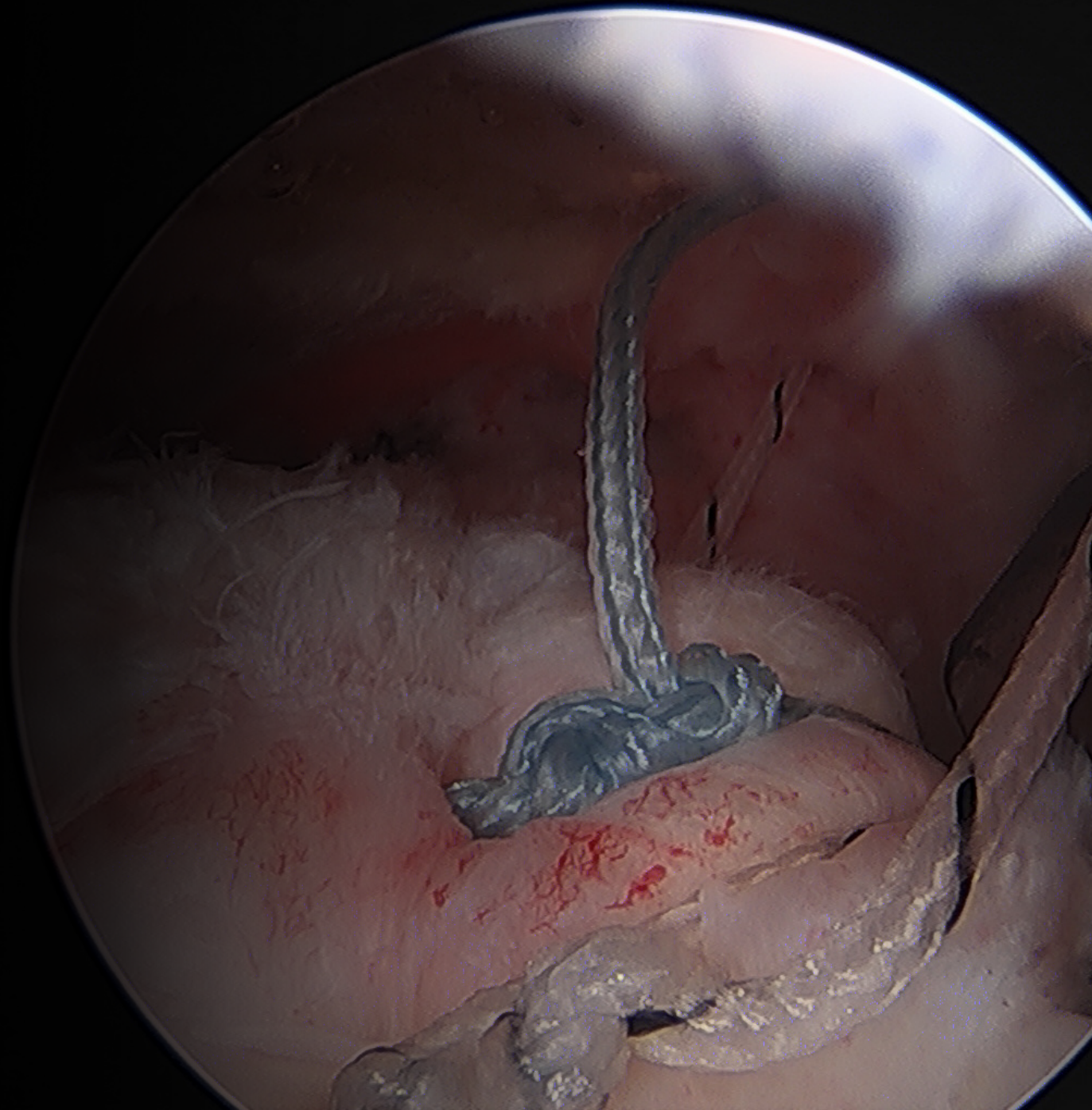
James Ryan [1], Casey Imbergamo [2], Suleiman Sudah [3], Greg Kirchner [4], Patricia Greenberg [2], James Monica [2], Charles Gatt [2]

Compared different types of PRP---only ‘pure’ PRP seemed to make a difference

Retear rates were lower--19% vs 25%
Constant score better—did not meet MCID
ASES, UCLA score no different

Summary for rotator cuff

- Not beneficial for partial tears
- May add some benefit to decrease retear rates
- Other options (scaffolds, augments) may be better



PRP and injections for spine disorders

- Discogenic back pain
  - *Goal of successful treatment and avoid surgery*
- Spine fusion
  - *Improve fusion rates*
  - *Decrease need for autograft harvest*

Int Orthop. 2016 Jun;40(6):1321-8. doi: 10.1007/s00264-016-3178-3. Epub 2016 Apr 12.

Intradiscal platelet-rich plasma (PRP) injections for discogenic low back pain: an update.

Monfett M[1], Harrison J[1], Boachie-Adjei K[1], Lutz G[2].

"Intradiscal PRP is a safe and a possibly effective treatment for discogenic low back pain."

Pain Med. 2016 Jun;17(6):1010-22. doi: 10.1093/pm/pnv053. Epub 2015 Dec 26.

Intradiscal Platelet-Rich Plasma Injection for Chronic Discogenic Low Back Pain: Preliminary Results from a Prospective Trial.

Levi D[1], Horn S[2], Tyszko S[2], Levin J[3], Hecht-Leavitt C[4], Walko E[2].

"This trial demonstrates encouraging preliminary 6 month findings, using strict categorical success criteria, for intradiscal PRP as a treatment for presumed discogenic low back pain."

47% success at 6 months

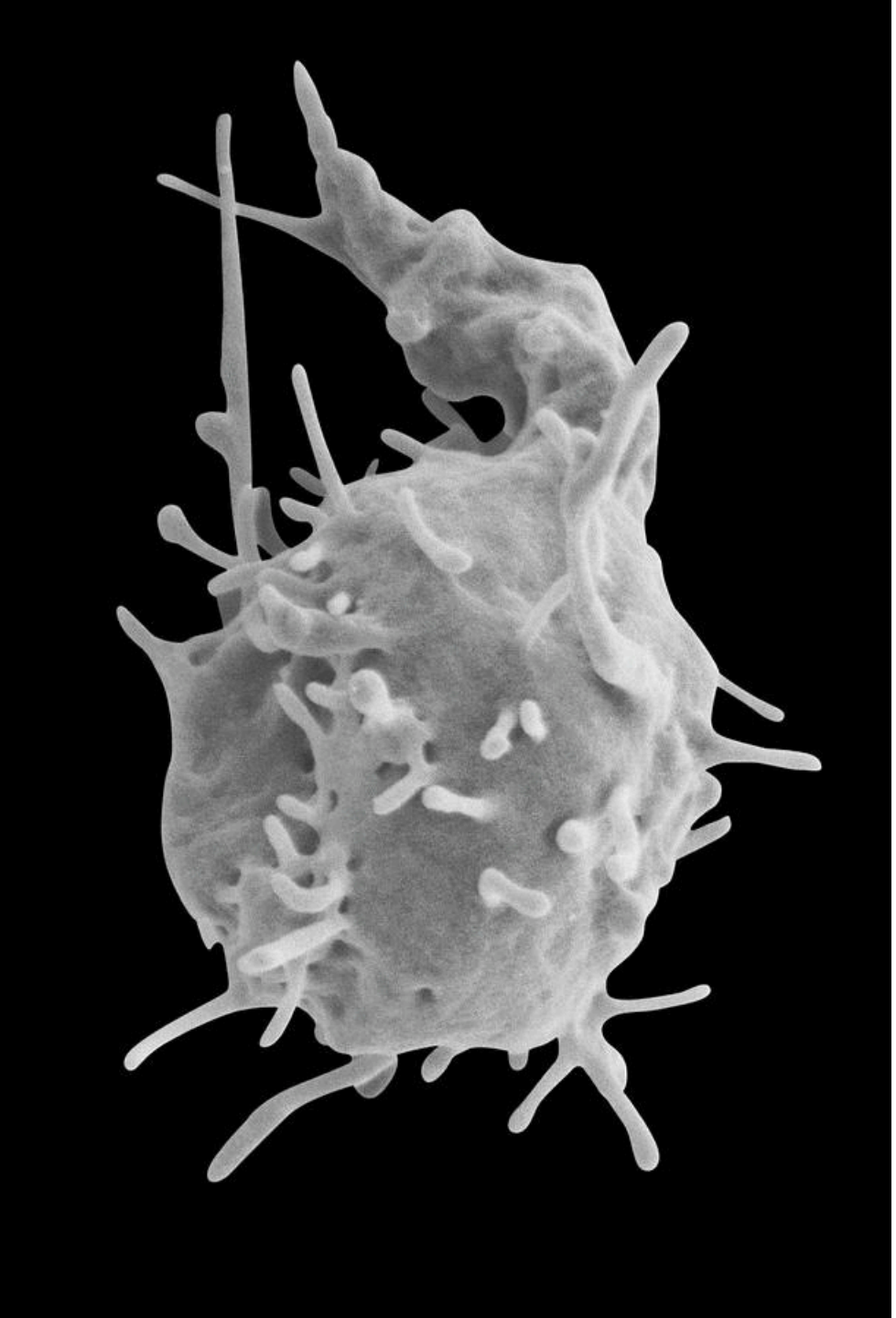
PRP and the Spine, Clinical Studies

> Global Spine J. 2021 Jan 21;219256822098827 8. doi: 10.1177/219256822098827 8.
Online ahead of print.

Is Platelet-Rich Plasma Effective in Enhancing Spinal Fusion? Systematic Overview of Overlapping Meta-Analyses

Sathish Muthu [1], Madhan Jeyaraman [1], Parvez Ahmad Ganie [1], Manish Khanna [1]

The current best evidence showed that utilization of PRP **was not associated** with significant improvement in patient-reported outcomes such as Visual Analog Score for pain compared to the. Moreover, **PRP was found to be associated with lower fusion rates.**



What I tell patients about PRP

- PRP is overall **SAFE**
- **Probably will make some conditions better**
- Not all formulations are the same
  - Daily concentrations of platelets and growth factors are actually different
- Clinical effects are going to be **variable**—and that's why the studies are so all over the place!

Stem cell treatments

I. INTRODUCTION

Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use

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Guidance for Industry and Food and Drug Administration Staff

Definition of Stem Cells

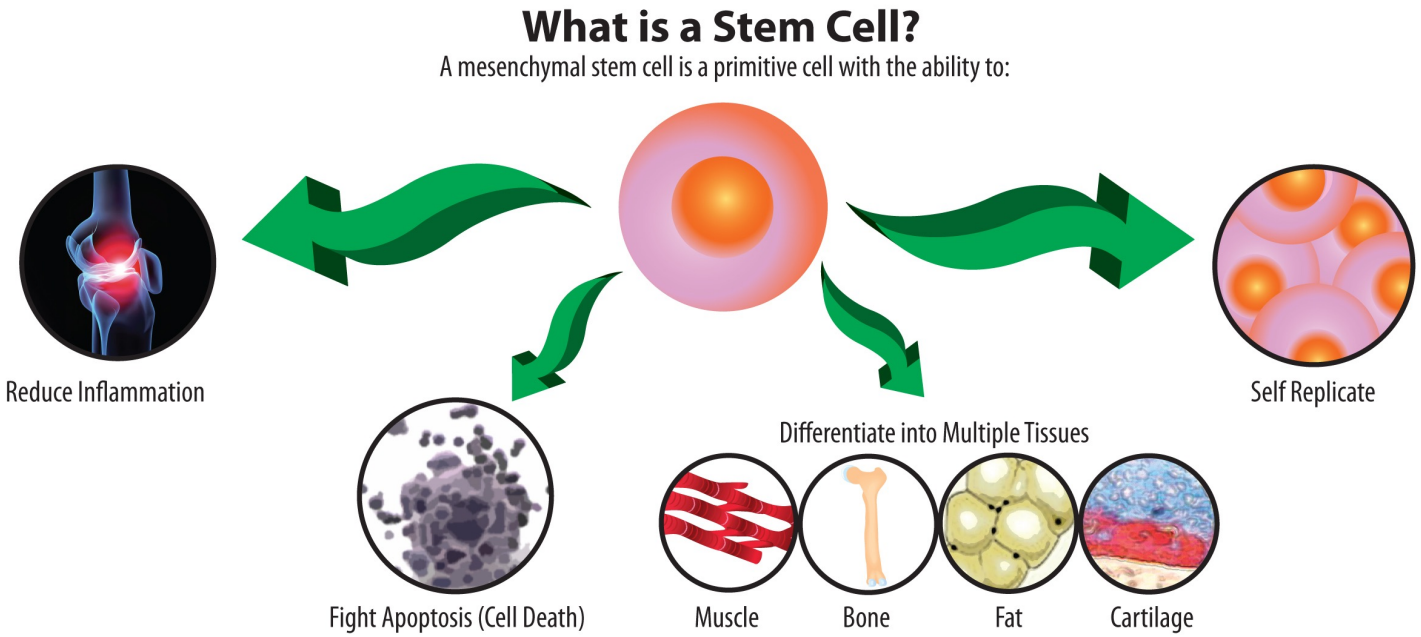
3 Key Characteristics

- Unspecialized cells
- Capable of self renewal
- Induced into specialized tissue with the right signals

Defined by their cell surface markers

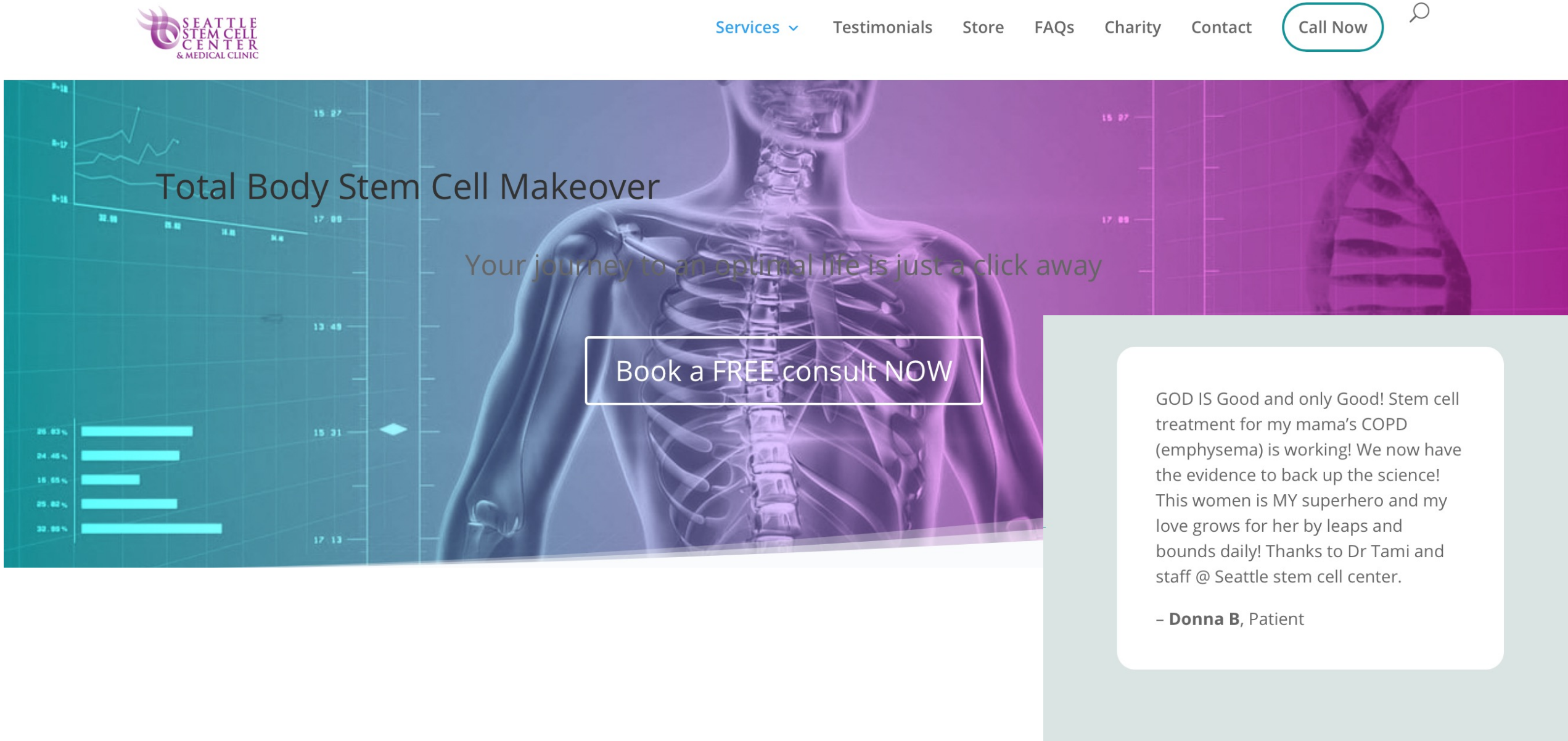
- MSCs CD117+,CD34-
- ESCs CD134, CD31-

Stem Cells



- **Adult** and Embryonic Stem Cells
  - **Mesenchymal**, hematopoietic, juvenile
    - Stromal Vascular Fraction (Fat)
  - Induced pluropotent stem cells (iPSC)
  - Amniotic Membrane

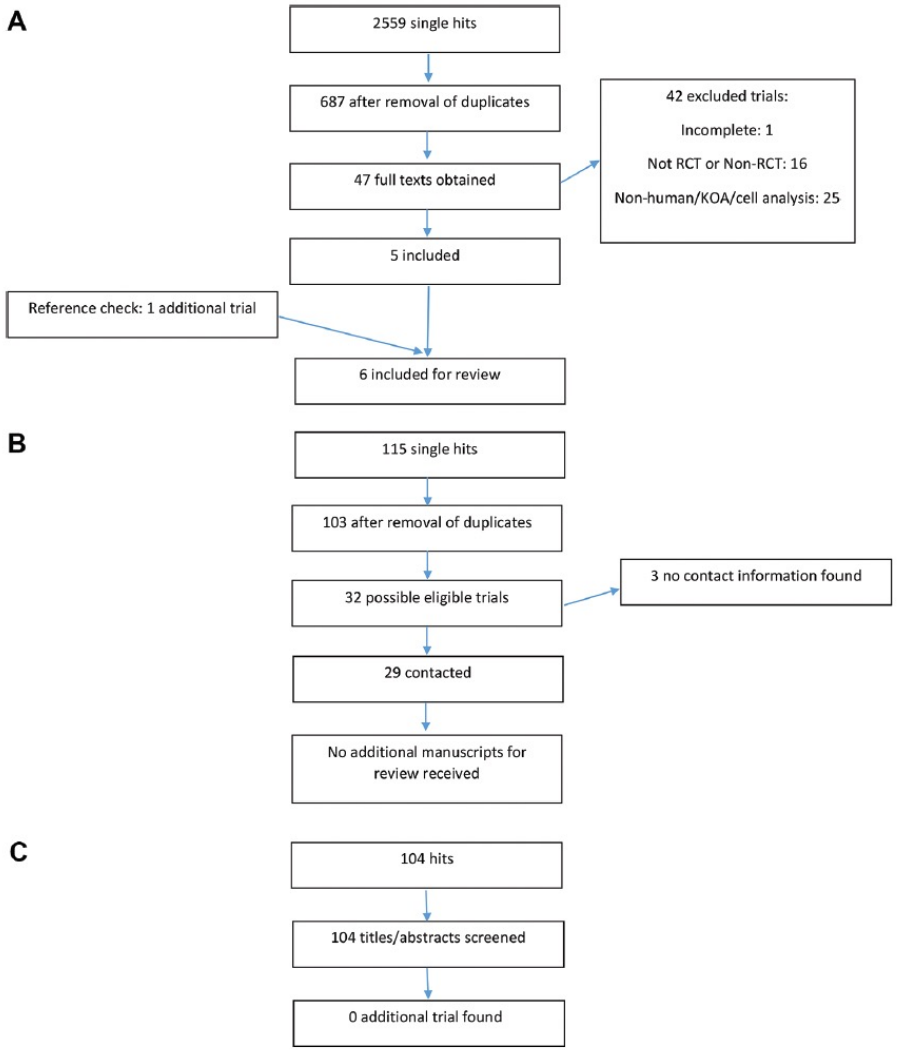
How do Stem Cells Work? (does it matter?)



Br J Sports Med. 2017 Mar 3. pii: bjsports-2016-096793. doi: 10.1136/bjsports-2016-096793. [Epub ahead of print]

Stem cell injections in knee osteoarthritis: a systematic review of the literature.

Pas HI[1,2,3], Winters M[4], Haisma HJ[5], Koenis MJ[6], Tol JL[7,3,8], Moen MH[7,9,10].



"There is level-3 or level-4 evidence for the use of stem cell injection of different types in the treatment of KOA when evaluating PROMs, pain and radiographic, arthroscopic and histological outcomes. It should be noted that all treatments **were additional to surgery, HA or PRP injections.** All studies were found to be at high risk of bias. Therefore, we do not recommend to use stem cell therapy for patients with KOA"

Concentrated Bone Marrow Aspirate for the Treatment of Chondral Injuries and Osteoarthritis of the Knee

A Systematic Review of Outcomes

Jorge Chahla,* MD, Chase S. Dean,* MD, Gilbert Moatshe,*† MD, Cecilia Pascual-Garrido,‡ MD, Raphael Serra Cruz,*§ MD, and Robert F. LaPrade,*||¶ MD, PhD

Investigation performed at Steadman Philippon Research Institute, Vail, Colorado, USA

Orthop J Sports Med. 2016 Jan 13;4(1):2325967115625481.

* varying degrees of beneficial results with the use of BMAC

TABLE 3
Knee Osteoarthritis Studies[a]

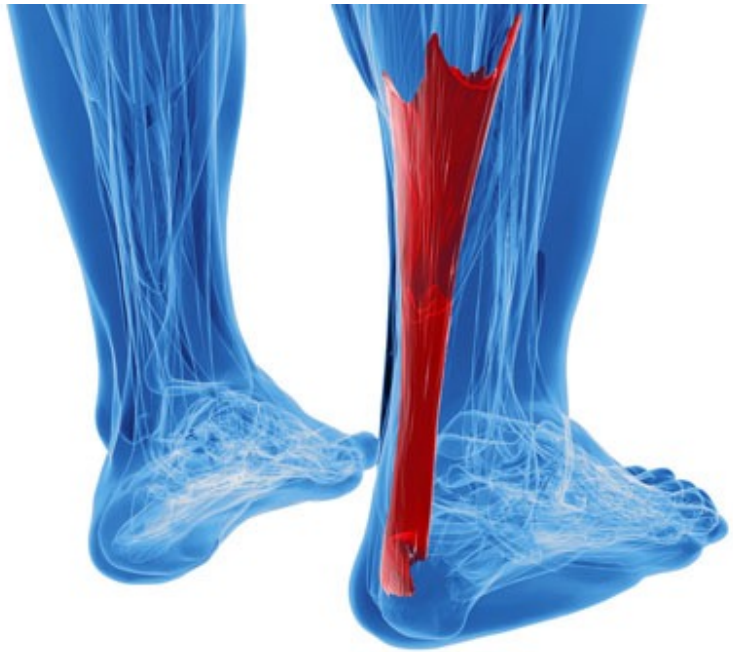
Study	Study Type (N)	Age, y, Mean (Range)	Follow-up, mo (Range)	Pathology	Treatment	Additional Factors	Results	Conclusion	Complications

Conclusion: “there still remains a paucity of high-quality studies……..Studies reviewed reported varying degrees of beneficial results with the use of BMAC with and without an additional procedure for the treatment of chondral defects and early OA. Most articles present the use of BMAC as a safe procedure and report good results”

Br J Sports Med. 2017 Jan 11. pii: bjsports-2016-096794. doi: 10.1136/bjsports-2016-096794. [Epub ahead of print]

No evidence for the use of stem cell therapy for tendon disorders: a systematic review.

Pas HI[1,2], Moen MH[1,3,4], Haisma HJ[5], Winters M[6].



What are the findings?

- The current level of evidence for stem cell use in tendon disorders is extremely poor.
- Only case reports or poorly designed trials are available.
- The results from the identified trials are at high risk of bias.

How might it impact on clinical practice in the future?

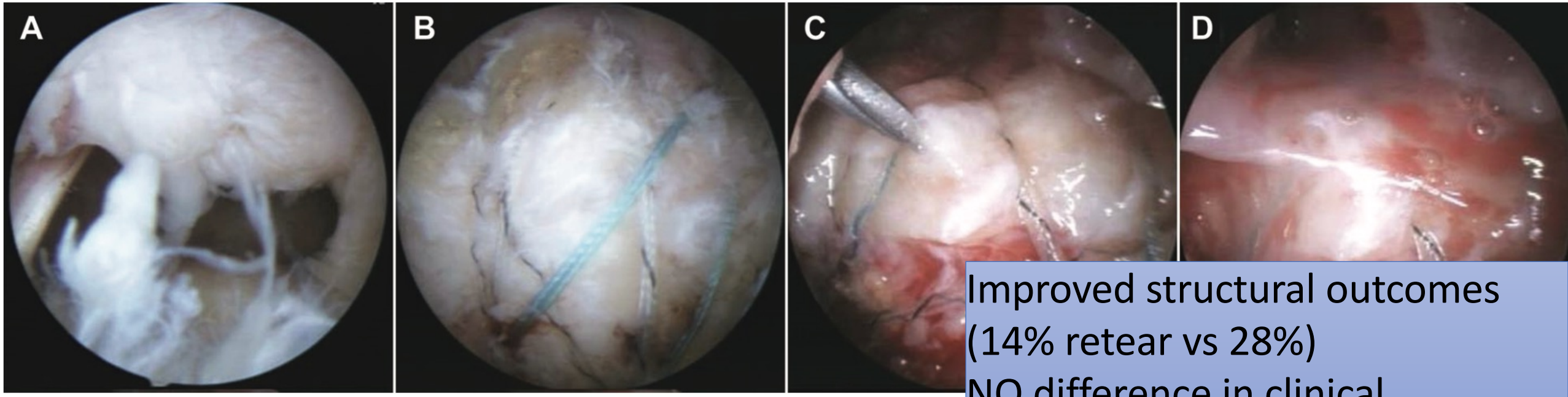
- The use of stem cell therapy for tendon disorders in clinical practice is not suitable outside of an appropriate ethics approved clinical trial.
- Patients seeking stem cell treatment for their tendon disorders can now be made aware of the lack of evidence and potential dangers.
- In cases where stem cells are used, safety must be monitored and reported by the investigator.

Evidence that Stem Cell Therapy Works for Musculoskeletal Conditions

Am J Sports Med. 2017 Apr 1:363546517702863. doi: 10.1177/0363546517702863. [Epub ahead of print]

Does an Injection of Adipose-Derived Mesenchymal Stem Cells Loaded in Fibrin Glue Influence Rotator Cuff Repair Outcomes? A Clinical and Magnetic Resonance Imaging Study.

Kim YS[1], Sung CH[1], Chung SH[1], Kwak SJ[2], Koh YG[1].



Improved structural outcomes (14% retear vs 28%)
NO difference in clinical outcomes

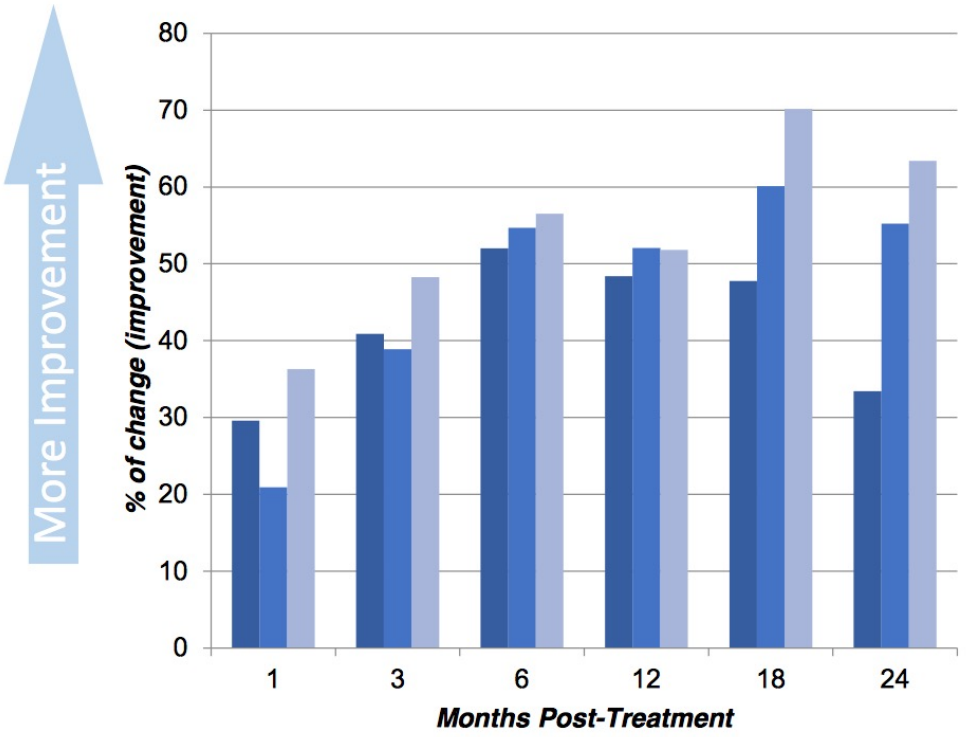
Shoulder Arthritis and Rotator Cuff Tears

N=199 Patients

Collected from 14 Clinics

2014 Registry Data

Caution-This is registry data collected as patients are treated, which is not the same as a randomized controlled trial typically used for FDA approval. In addition, later time points in this graph have more patients who did not answer questionnaires.



What's important?

This graph shows pain scores, function as measured by the DASH questionnaire, and the % improvement rating as determined by the patient at various points after the procedure. All of these are reported in terms of percentage improvement to make them easier to interpret. The outcome information shows robust improvement in both pain and function as well as high marks reported by patients when asked to rate their percentage improvement from 0-100% (% Improvement Rating). The patients represented here are a mix of rotator cuff tear only patients and patients who also had shoulder arthritis.

Details?

Mean age is 56.9 years old. BMI is 26.5. There were 56 women and 143 men. N is 199 at pre-treatment, 73 at 1 month, 83 at 3 months, 59 at 6 months, 21 at 12 months, 22 at 18 months, 15 at 24 months.

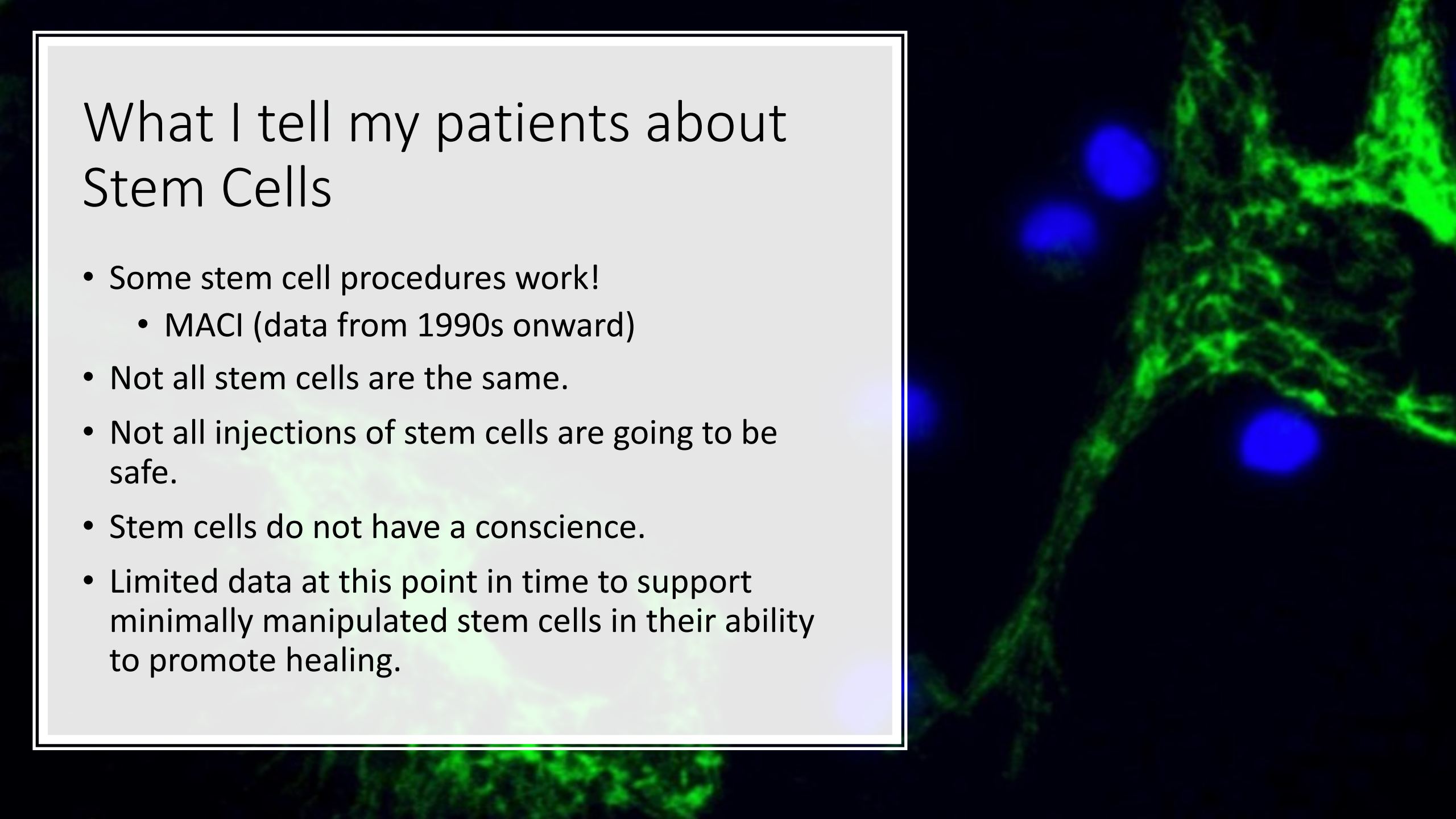
Regenexx®

Same Day Stem Cell Procedure

This procedure involves taking bone marrow stem cells from the back of the hip and re-injecting them under precise imaging guidance into the hip joint and associated structures like labrum.

What I tell my patients about Stem Cells

- Some stem cell procedures work!
  - MACI (data from 1990s onward)
- Not all stem cells are the same.
- Not all injections of stem cells are going to be safe.
- Stem cells do not have a conscience.
- Limited data at this point in time to support minimally manipulated stem cells in their ability to promote healing.



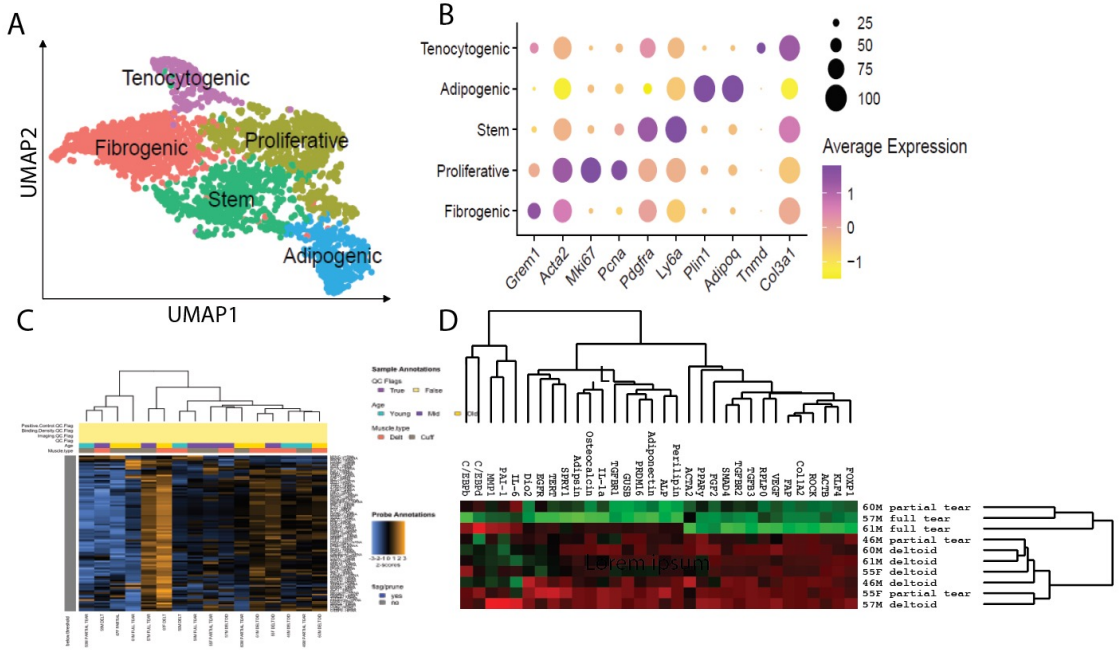
What's on the horizon?

- Regulation of stem cell/aging clinics
- Harnessing endogenous cells, patient specific treatments?
- Better studies, lack of financial incentive in studies
  - Would better study design lead to successful biologic strategies or do we need a different strategy?
- What do we do at UCSF?
  - Orthopedic Regenerative Center
  - Starting August/September 2021
  - Email me brian.feeley@ucsf.edu

How to Legally Offer Anti-Aging Treatments at Your Medical Spa

*Posted By **Administration**, Tuesday, May 7, 2019*

NO!!!!



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Regenerative Medicine
Consultation Service


Thank you