RSI®

REGENERATIVE SPORTSCARE INSTITUTE

DiscHeal™

Gregory Lutz, M.D.

Chief Medical Officer| *Regenerative SportsCare Institute*
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Clinical Professor Of Rehabilitation Medicine |
Weill Medical College of Cornell University

Interventional Orthopedics Foundation

IOF MEMBER

Disclosures

HSS HOSPITAL FOR SPECIAL SURGERY

Weill Cornell Medical College

HSS educational activities are carried out in a manner that serves the educational component of our Mission. As faculty we are committed to providing transparency in any relevant external relationships prior to giving an academic presentation.

Gregory Lutz, MD

Orthobond Corporation
DiscHeal™

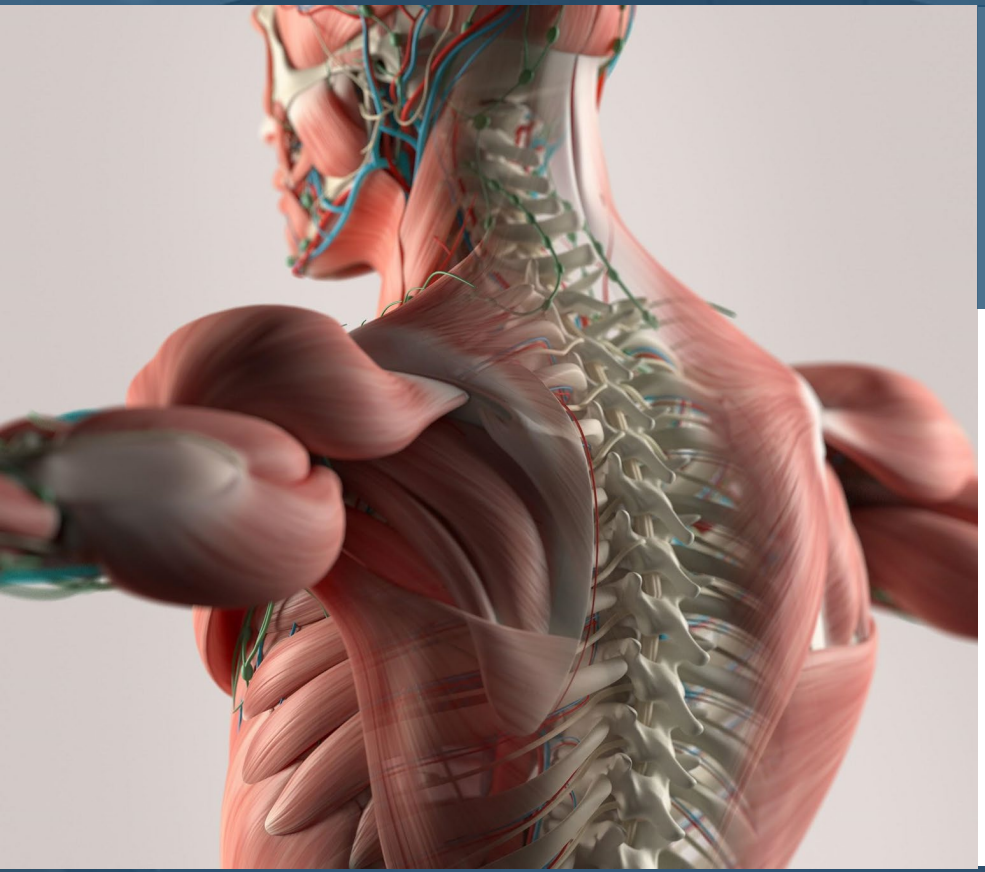
Regenerative SportsCare Institute

Executive Chairman

Chief Medical Officer

Inventor

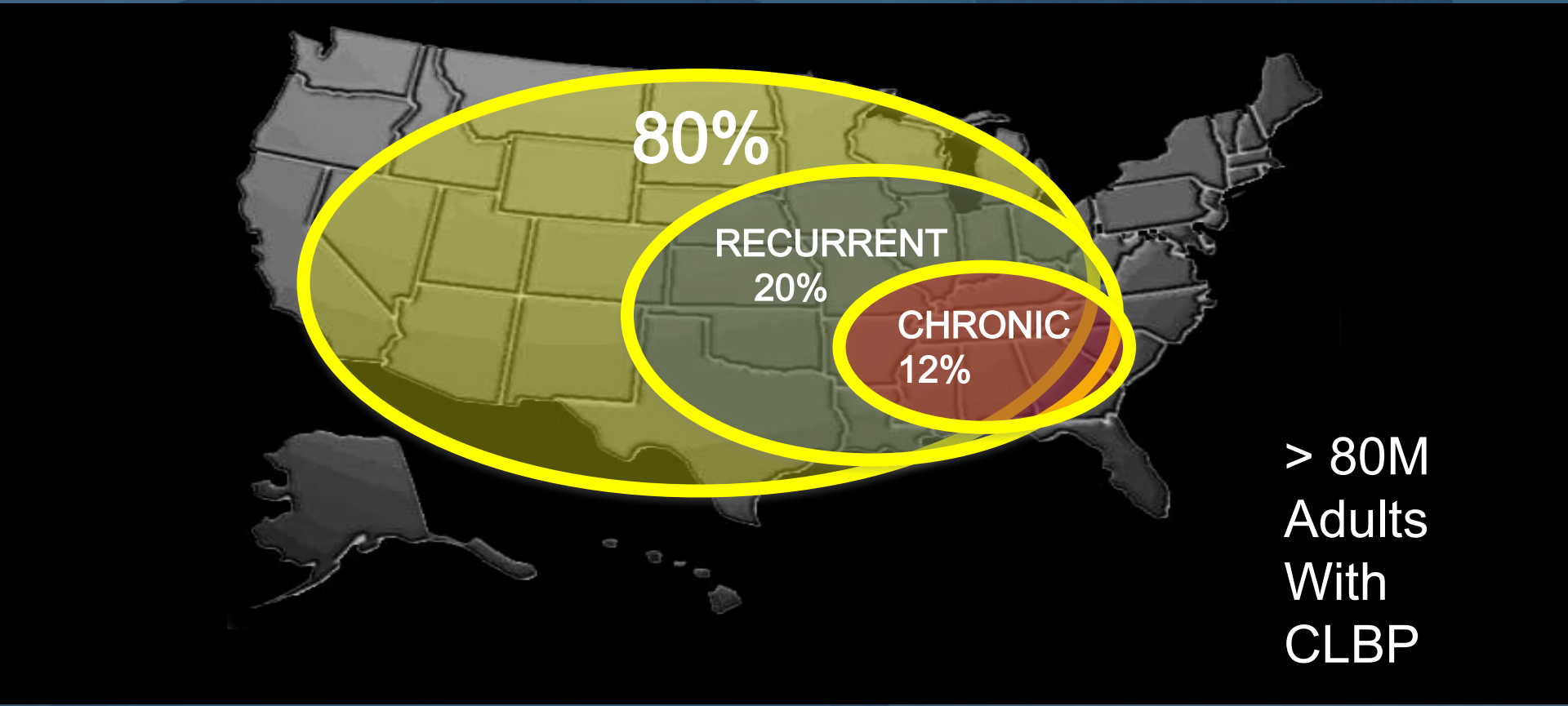
Overview



REINVENTING MUSCULOSKELETAL (MSK) HEALTHCARE

- THE LOW BACK PAIN PROBLEM
- THE NEED FOR A REGENERATIVE MEDICINE SOLUTION
- ARE WE KILLING TWO BIRDS WITH ONE STONE?
- RSI INNOVATION: *DiscHeal™*

CHRONIC LOW BACK PAIN (CLBP) IN THE US



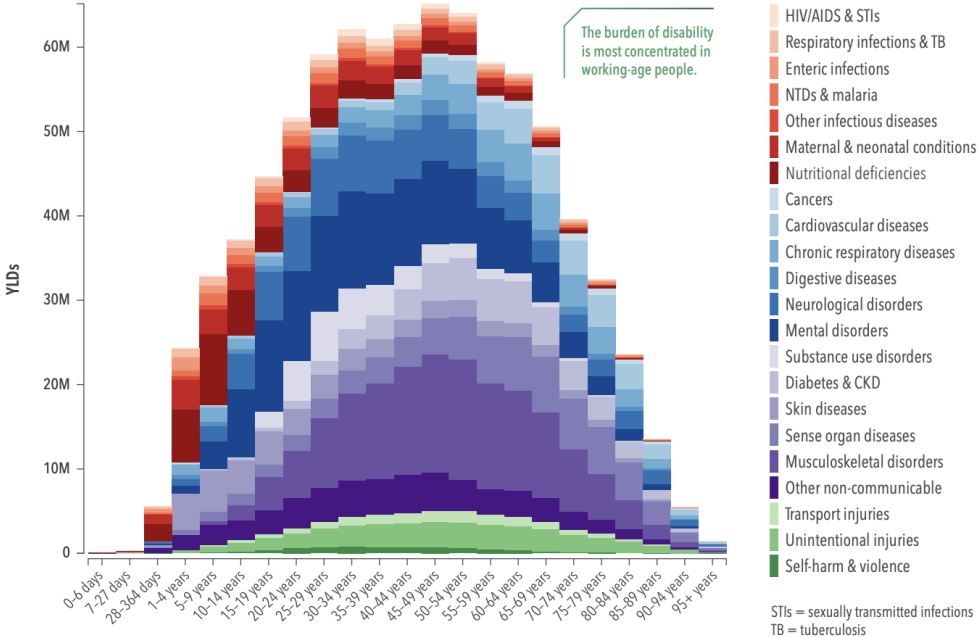
> 80M Adults With CLBP

GLOBAL BURDEN OF DISEASE STUDY
Bill & Melinda Gates Foundation

580 million people with CLBP globally

Years lived with disability (YLDs*), 2017

Number of total YLDs, global, both sexes, by age group and cause, 2017



STIs = sexually transmitted infections
TB = tuberculosis
NTDs = neglected tropical diseases
CKD = chronic kidney disease

YLDs represent time lived in less-than-ideal health. Nutritional deficiencies primarily include iron deficiency anemia; mental disorders are mainly composed of anxiety and depression; musculoskeletal disorders consist largely of back pain and neck pain; and sense organ diseases mostly include hearing loss and vision loss.

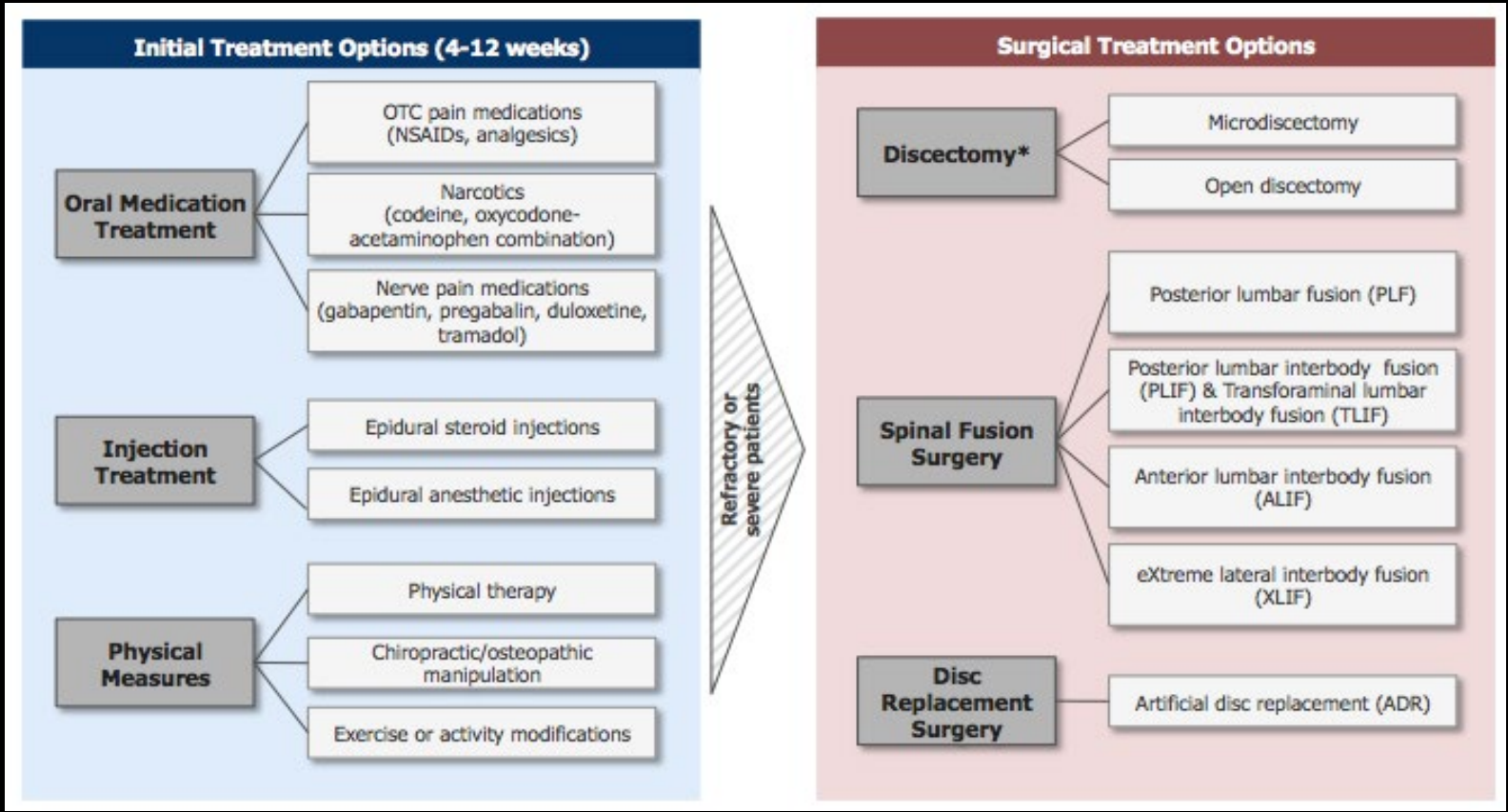
CLBP is the greatest cause of YLDs globally

CLBP IS THE MOST EXPENSIVE CONDITION

- $253 billion: Annual U.S. cost for treatment and lost wages due to back pain 2011 report
  - $150 billion: hospital cost to treat back pain
  - $103 billion: annual earnings loss for persons with back condition
- 291 million: lost workdays due to back and neck pain

Source: United States Bone and Joint Initiative: The Burden of Musculoskeletal Diseases in the United States (BMUS), Third Edition, 2014. Rosemont, IL. Available at http://www.boneandjointburden.org. Accessed October 10, 2017.

DRUGS AND/OR SURGERY FALL SHORT



CLBP & The Opioid Epidemic In The US

- 20% of patients with CLBP remain on long-term opioids
- 63% of patients post lumbar fusion remain on long-term opioids
- >50% of global overdose deaths are in the US
- >100,000 drug overdose deaths in 2021
- ***Overuse of prescription opioids for CLBP is a major contributor to this public health crisis***

US HEALTHCARE EXPENSES PROJECTED TO BE 19.7% OF GDP BY 2028 (>4T USD)

COSTS & SPENDING

By Sean P. Keehan, Gigi A. Cuckler, John A. Poisal, Andrea M. Sisko, Sheila D. Smith, Andrew J. Madison, Kathryn E. Rennie, Jacqueline A. Fiore, and James C. Hardesty

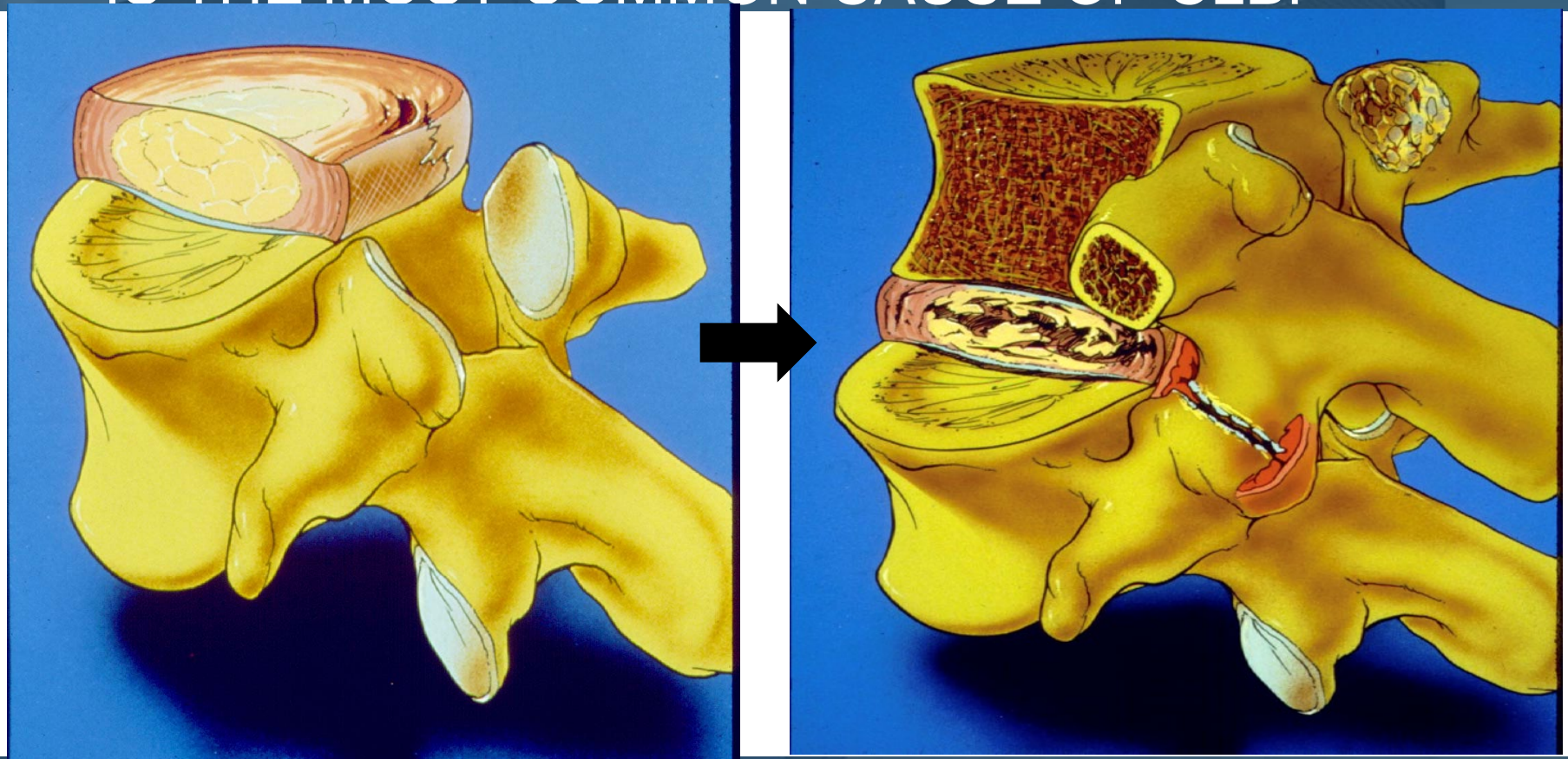
National Health Expenditure Projections, 2019–28: Expected Rebound In Prices Drives Rising Spending Growth

ABSTRACT **National health expenditures are projected to grow at an average annual rate of 5.4 percent for 2019–28 and to represent 19.7 percent of gross domestic product by the end of the period. Price growth for medical goods and services is projected to accelerate, averaging 2.4 percent per year for 2019–28, which partly reflects faster expected growth in health-sector wages. Among all major payers, Medicare is expected to experience the fastest spending growth (7.6 percent per year), largely as a result of having the highest projected enrollment growth. The insured share of the population is expected to fall from 90.6 percent in 2018 to 89.4 percent by 2028.**

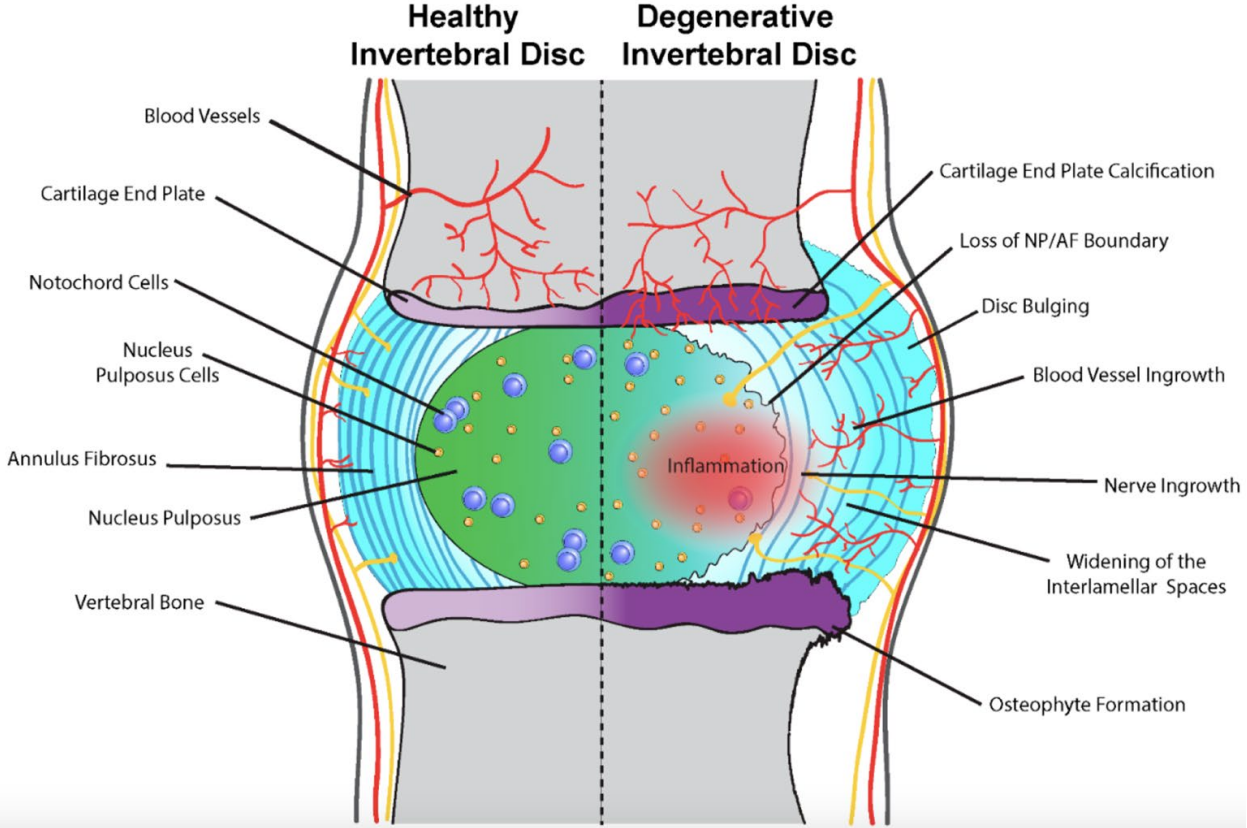
WE NEED A PARADIGM SHIFT

FROM VOLUME-BASED PALLIATIVE TREATMENTS (DRUGS & SURGERY) TO VALU BASED ROOT CAUSE TREATMENTS (REGENERATIVE MEDICINE)

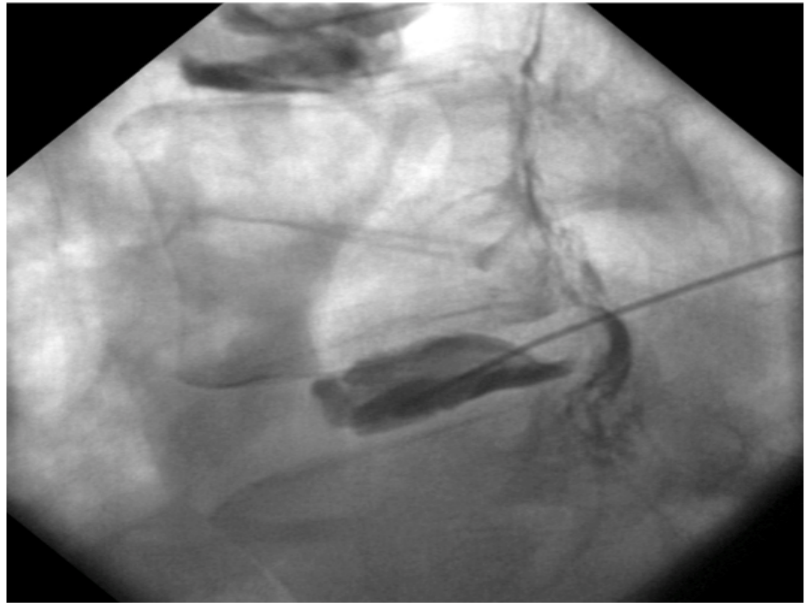
DEGENERATIVE DISC DISEASE (DDD) IS THE MOST COMMON CAUSE OF CLBP



BECAUSE THE DISC'S INHERENT CAPACITY TO HEAL IS POOR AFTER INJURY

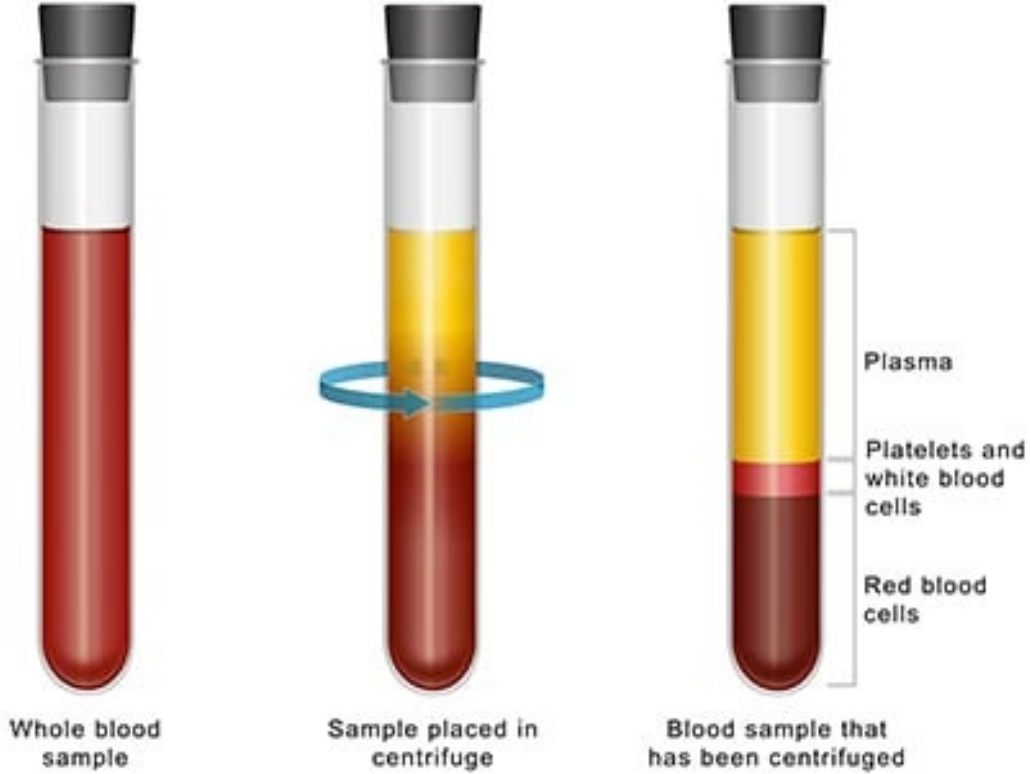


INTERVENTIONS THAT HEAL THE DISC ARE A ROOT CAUSE TREATMENT

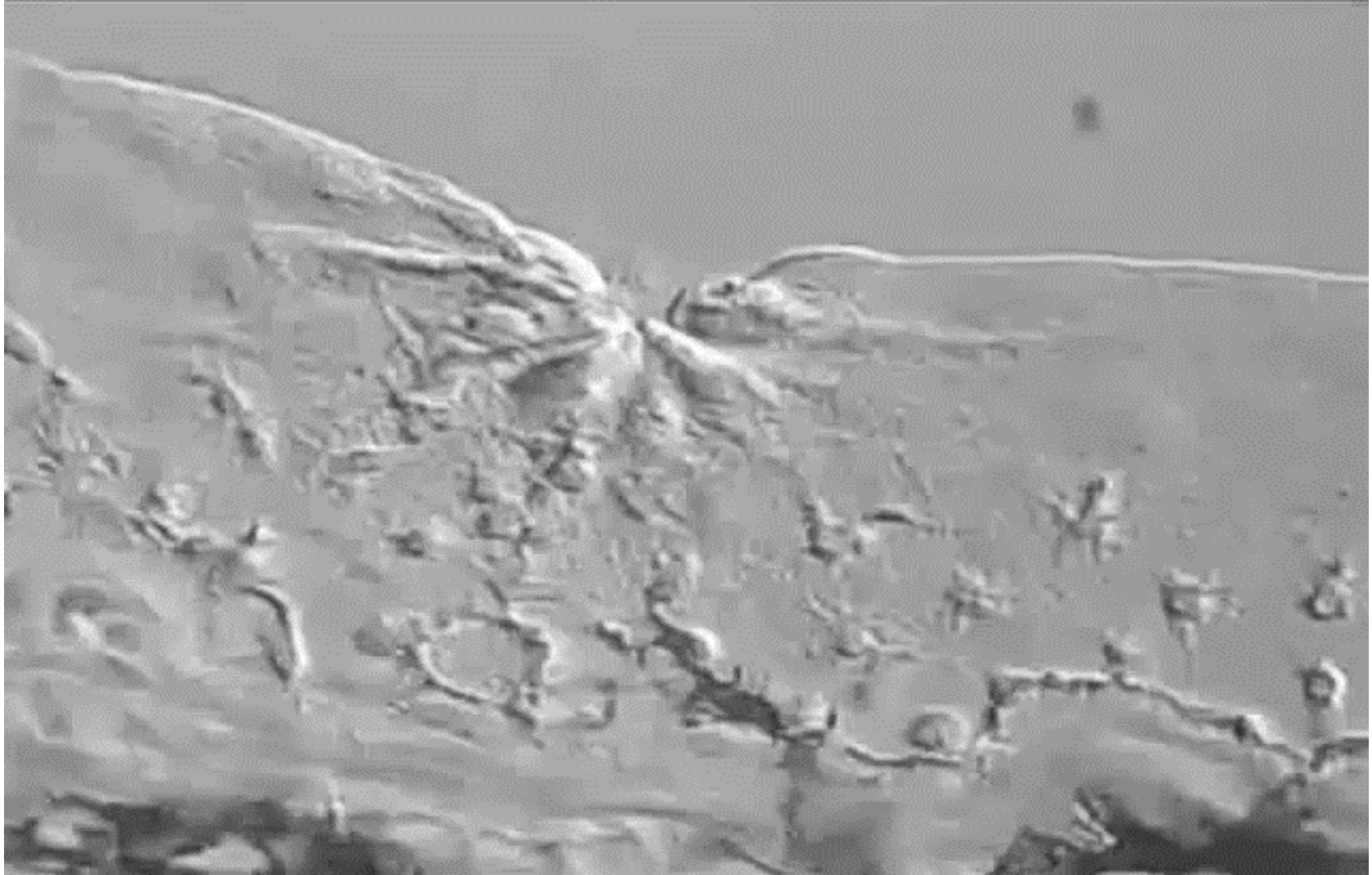


PLATELET RICH PLASMA (PRP)

PRP IS A POTENTIAL ROOT CAUSE TREATMENT FOR DDD



PRP HAS BEEN SHOWN TO STIMULATE THE DISC CELLS TO HEAL

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MRI LT. ANKLE

CLINICAL OUTCOME STUDY

PM R 8 (2016) 1-10

www.pmrjournal.org

Original Research—CME

Lumbar Intradiskal Platelet-Rich Plasma (PRP) Injections: A Prospective, Double-Blind, Randomized Controlled Study

Yetsa A. Tuakli-Wosornu, MD, MPH, Alon Terry, MD, Kwadwo Boachie-Adjei, BS, CPH, Julian R. Harrison, BS, Caitlin K. Gribbin, BA, Elizabeth E. LaSalle, BS, Joseph T. Nguyen, MPH, Jennifer L. Solomon, MD, Gregory E. Lutz, MD

LONG-TERM OUTCOME STUDY

Short Communication

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Regenerative Medicine

Treatment of symptomatic degenerative intervertebral discs with autologous platelet-rich plasma: follow-up at 5–9 years

Jennifer Cheng[1], Kristen A Santiago[1], Joseph T Nguyen[2], Jennifer L Solomon[1] & Gregory E Lutz*,[1]

[1]Department of Physiatry, Hospital for Special Surgery, 535 East 70th Street, New York, NY 10021, USA

[2]Healthcare Research Institute, Hospital for Special Surgery, 535 East 70th Street, New York, NY 10021, USA

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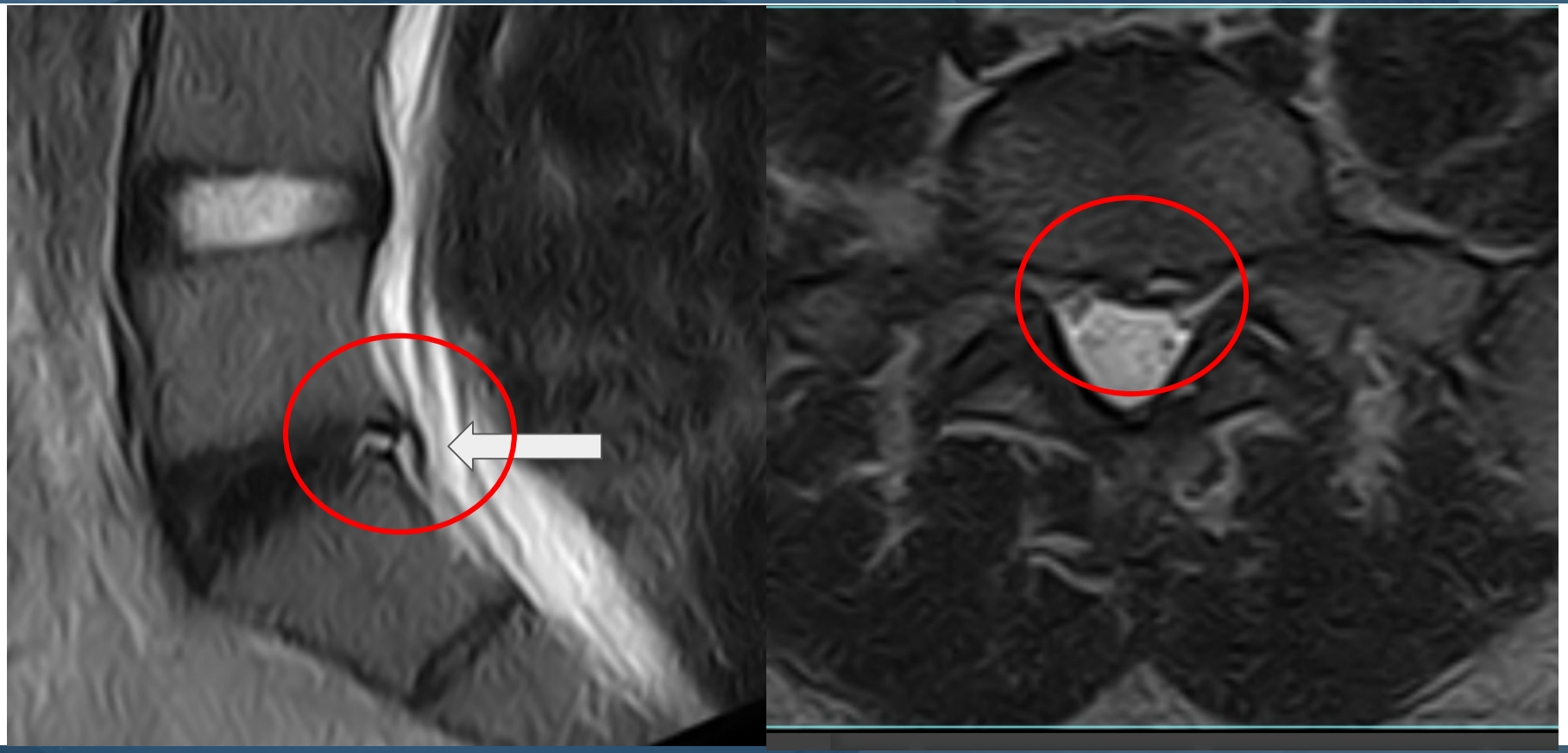
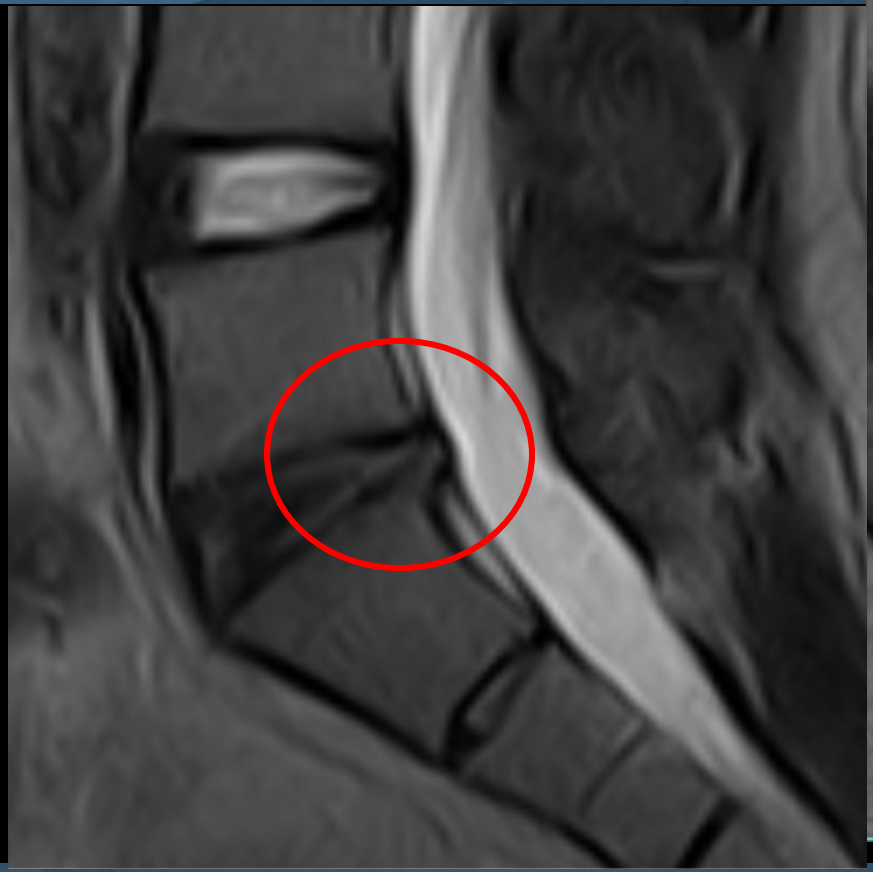
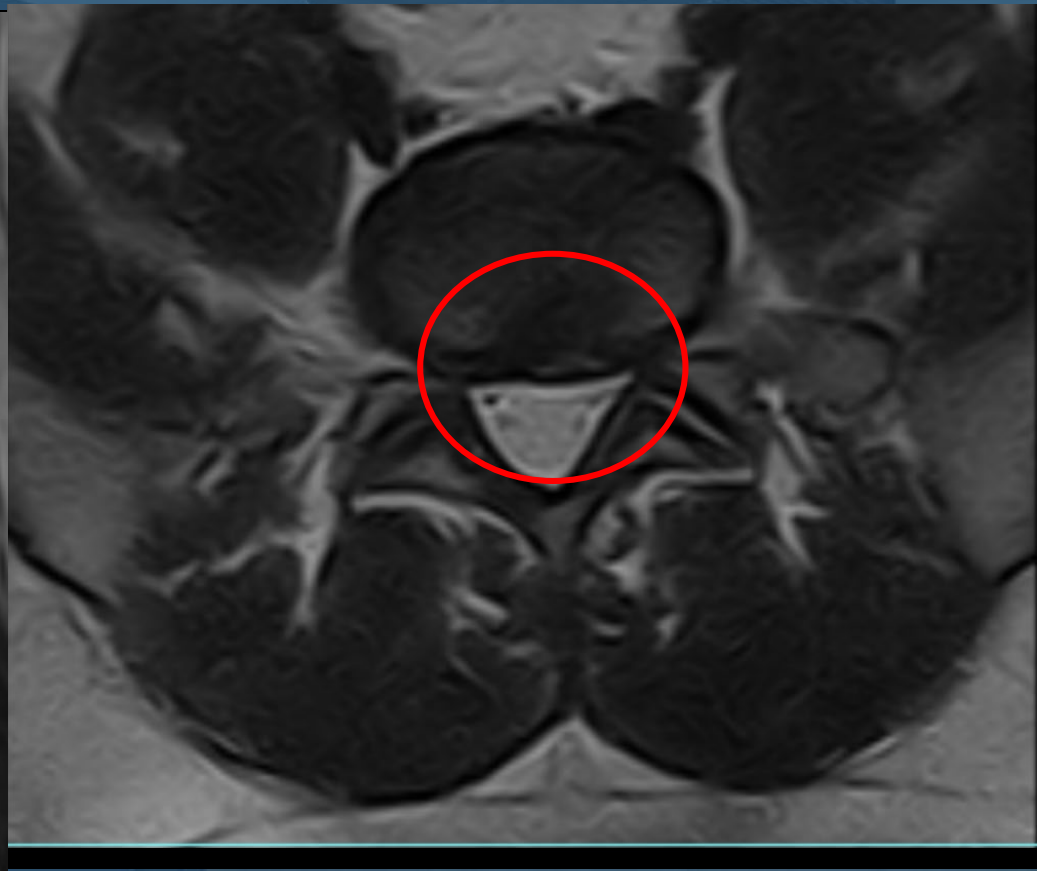
ARE WE CREATING STRUCTURAL CHANGES IN THE DISC?



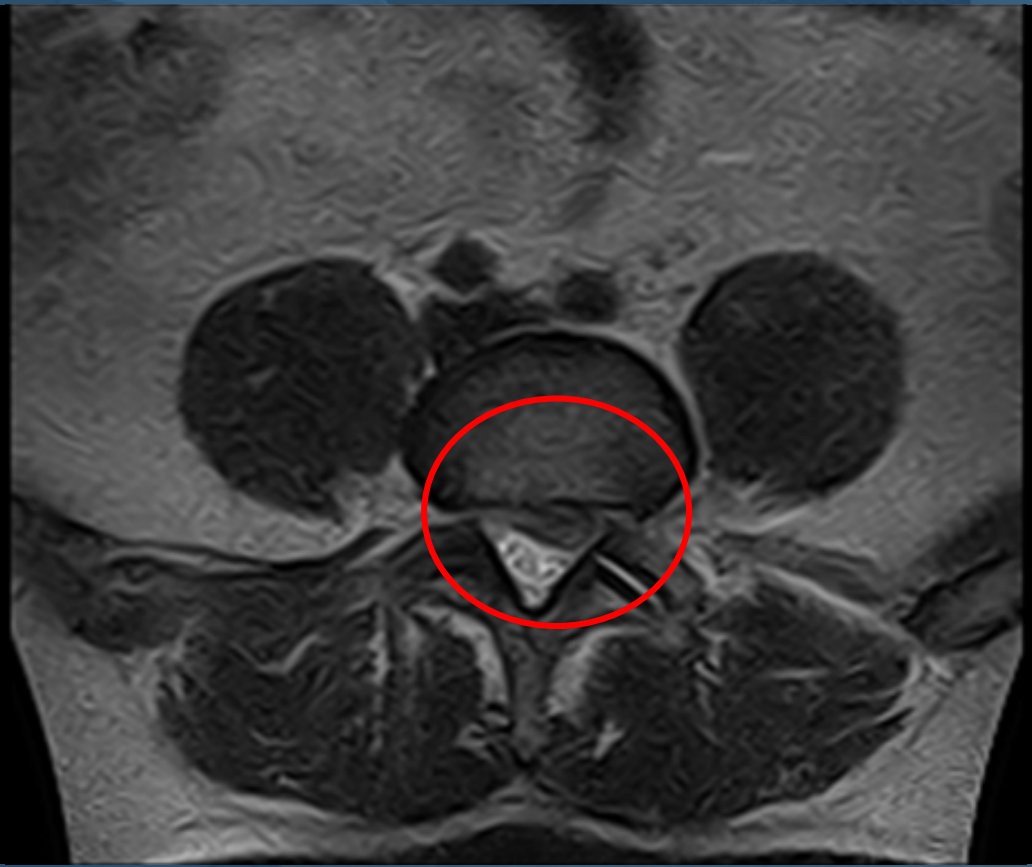
INTRADISCAL INJECTION OF PRP

3 MONTHS POST TREATMENT

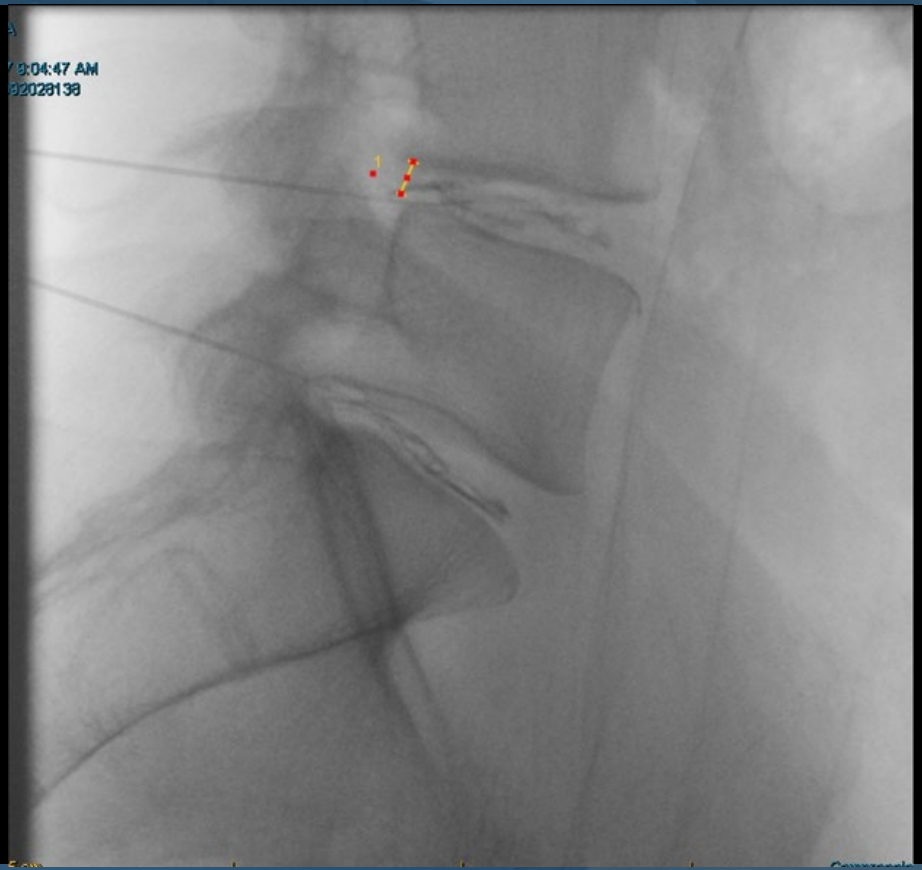




ARE WE CREATING STRUCTURAL CHANGES IN THE DISC?

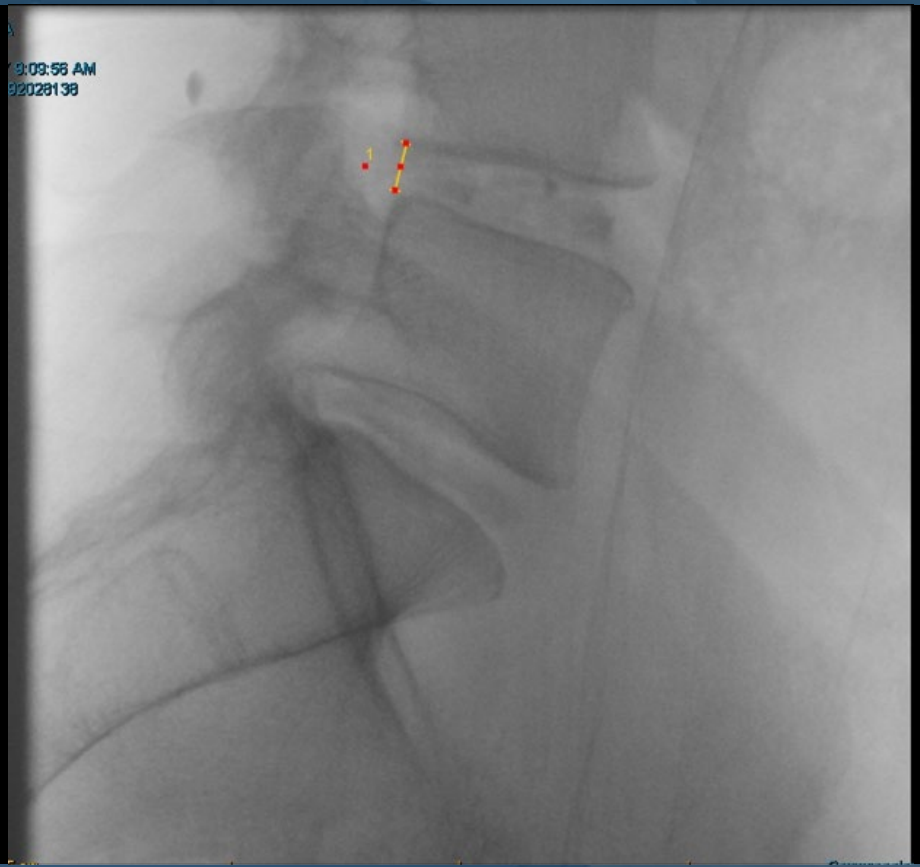


CAN WE HEAL A HERNIATED DISC?

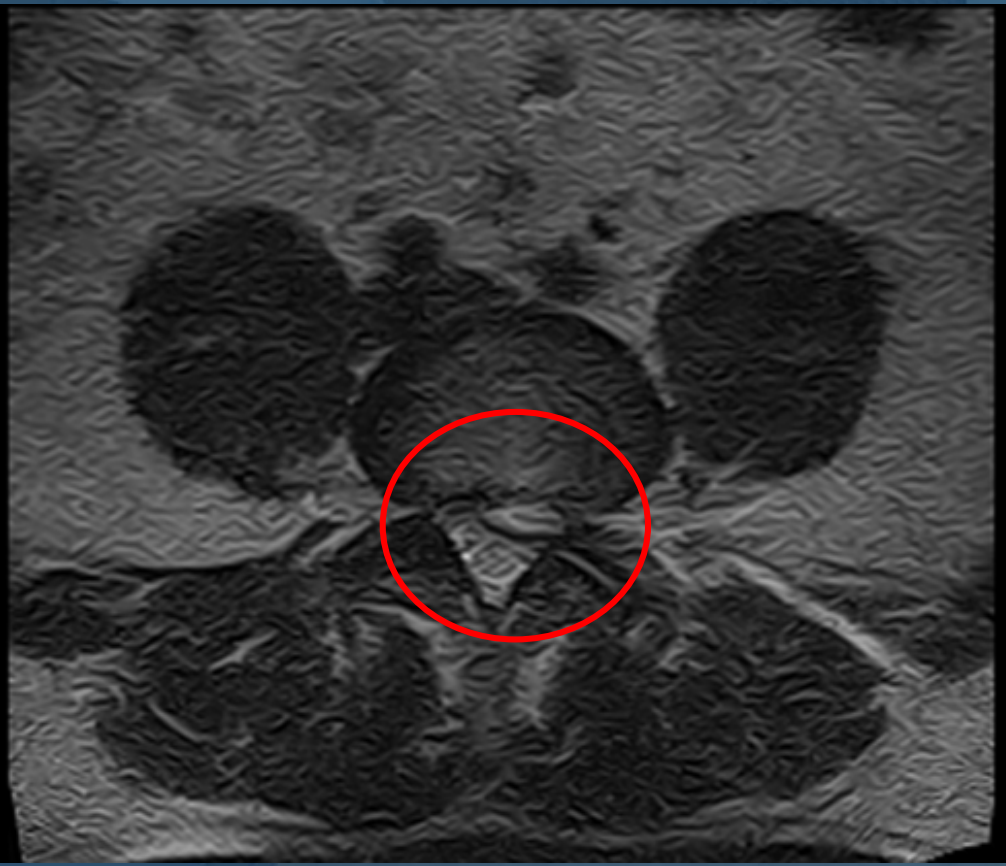


CAN WE HEAL A HERNIATED DISC?

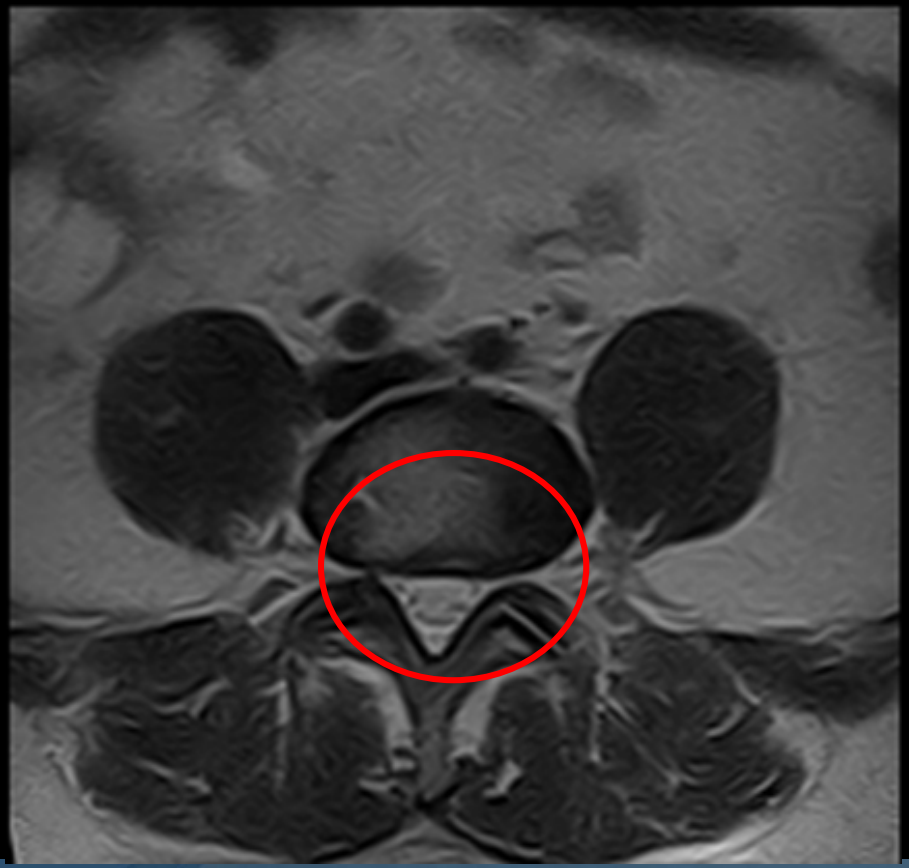
Post



ONE MONTH POST TREATMENT



TWO MONTHS POST TREATMENT



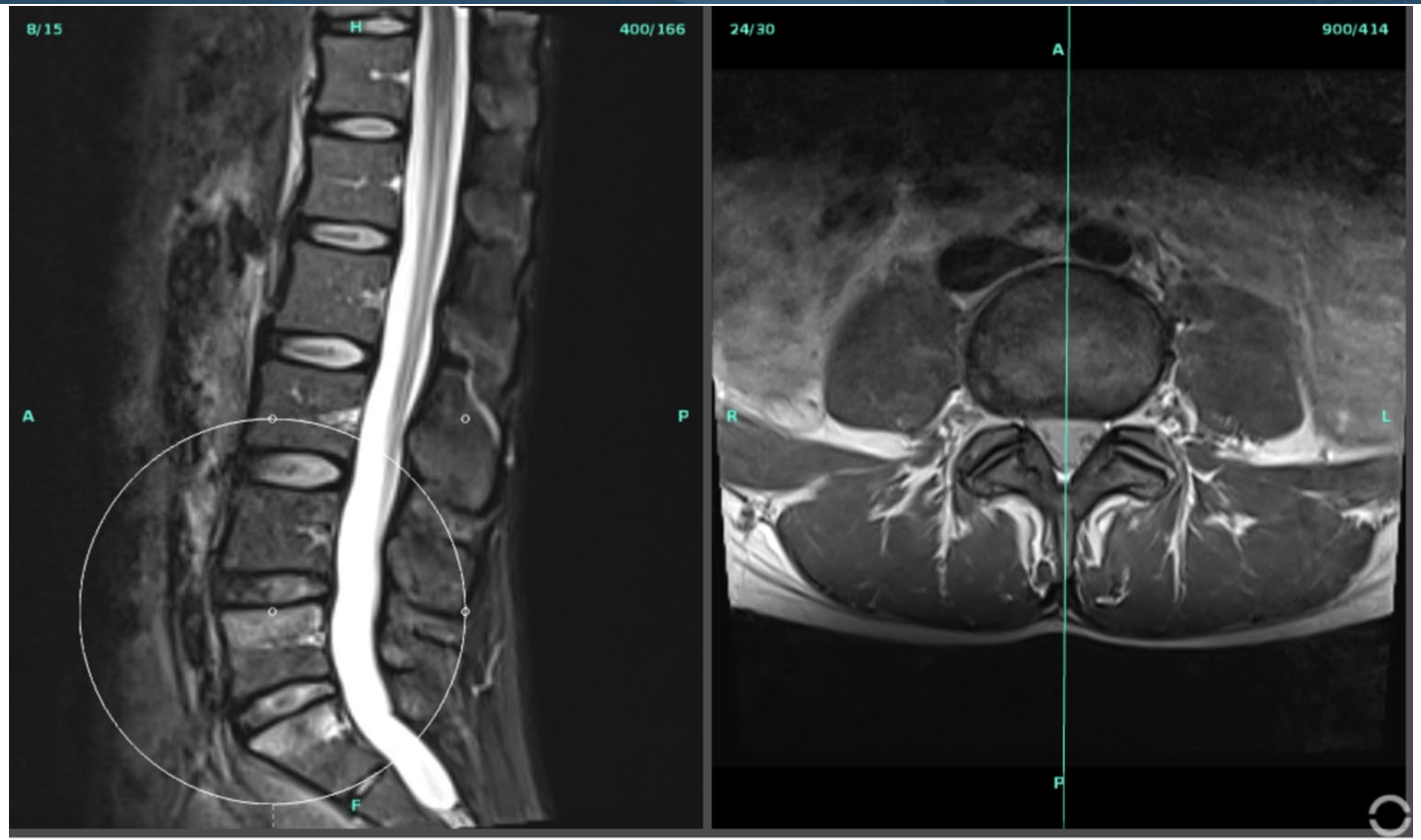
ARE WE CREATING LONGTERM HEALING?

2011 L4-5 & L5-S1
disc degeneration

2013 Static changes
historic treatments

2017 4 years after
intradiscal treatment

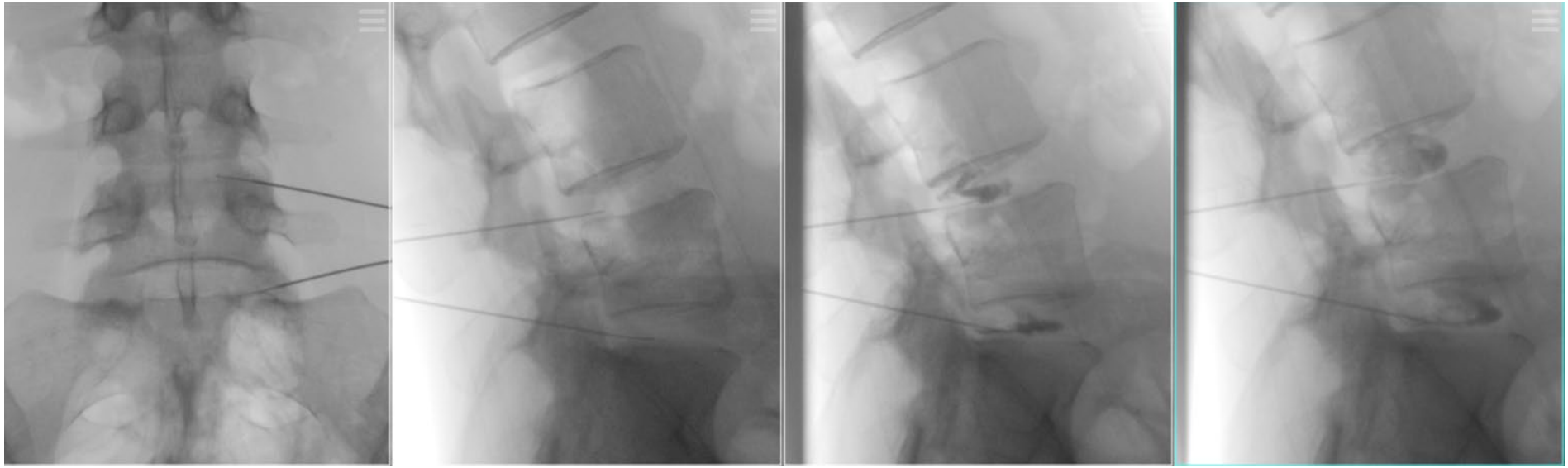
ARE WE KILLING TWO BIRDS WITH ONE STONE?



ARE MODIC TYPE I CHANGES AN OCCULT INFECTION?

Test Name	In Range	Out Of Range	Reference Range
SED RATE BY MODIFIED WESTERGREN	5		< OR = 20 mm/h
CBC (INCLUDES DIFF/PLT)			
WHITE BLOOD CELL COUNT	6.5		3.8-10.8 Thousand/uL
RED BLOOD CELL COUNT	4.43		3.80-5.10 Million/uL
HEMOGLOBIN	13.5		11.7-15.5 g/dL
HEMATOCRIT	40.7		35.0-45.0 %
MCV	91.9		80.0-100.0 fL
MCH	30.5		27.0-33.0 pg
MCHC	33.2		32.0-36.0 g/dL
RDW	11.9		11.0-15.0 %
PLATELET COUNT	223		140-400 Thousand/uL
MPV	11.3		7.5-12.5 fL
ABSOLUTE NEUTROPHILS	4128		1500-7800 cells/uL
ABSOLUTE LYMPHOCYTES	1684		850-3900 cells/uL
ABSOLUTE MONOCYTES	559		200-950 cells/uL
ABSOLUTE EOSINOPHILS	98		15-500 cells/uL
ABSOLUTE BASOPHILS	33		0-200 cells/uL
NEUTROPHILS	63.5		38-80 %
LYMPHOCYTES	25.9		15-49 %
MONOCYTES	8.6		0-13 %
EOSINOPHILS	1.5		0-8 %
BASOPHILS	0.5		0-2 %
C-REACTIVE PROTEIN	3.6		<8.0 mg/L

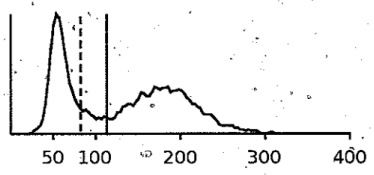
ARE WE KILLING TWO BIRDS WITH ONE STONE?



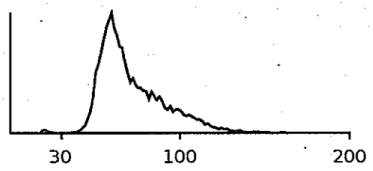
IS LR-PRP THE SAFEST?

Analyser Alarms
Analysis Alarms G1, G2

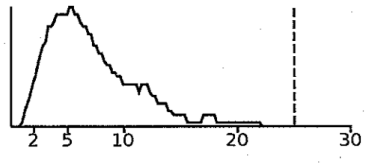
				Normal range	
WBC	3.7	L	10³/mm³	4.1	10.5
LYM%	37.7		%	16.0	43.3
MON%	7.3		%	2.8	10.2
GRA%	55.0		%	48.5	80.3
LYM#	1.30		10³/mm³	1.00	3.10
MON#	0.20		10³/mm³	0.10	0.70
GRA#	2.20	L	10³/mm³	2.30	7.70



RBC	2.54	L	10⁶/mm³	4.30	5.80
HGB	7.7	L	g/dl	13.1	16.7
HCT	22.2	L	%	39.9	51.0
MCV	87		µm³	83	98
MCH	30.5		pg	27.0	32.2
MCHC	34.9	H	g/dl	31.8	33.7
RDW-CV	13.9		%	11.9	14.8



PLT	134	L	10³/mm³	150	399
MPV	7.3		µm³	6.8	10.1



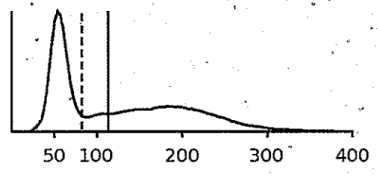
14X

12X

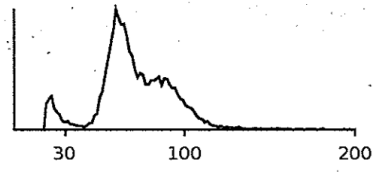
19X

Analyser Alarms
Analysis Alarms SCH, G1, G2

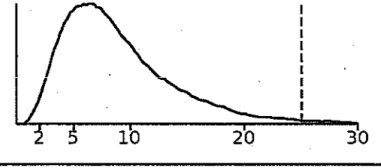
				Normal range	
WBC	52.2	H	10³/mm³	4.1	10.5
LYM%	44.2	H	%	16.0	43.3
MON%	7.3		%	2.8	10.2
GRA%	48.5		%	48.5	80.3
LYM#	23.00	H	10³/mm³	1.00	3.10
MON#	3.80	H	10³/mm³	0.10	0.70
GRA#	25.40	H	10³/mm³	2.30	7.70



RBC	2.96	L	10⁶/mm³	4.30	5.80
HGB	8.6	L	g/dl	13.1	16.7
HCT	25.5	L	%	39.9	51.0
MCV	86		µm³	83	98
MCH	28.9		pg	27.0	32.2
MCHC	33.6		g/dl	31.8	33.7
RDW-CV	17.4	H	%	11.9	14.8



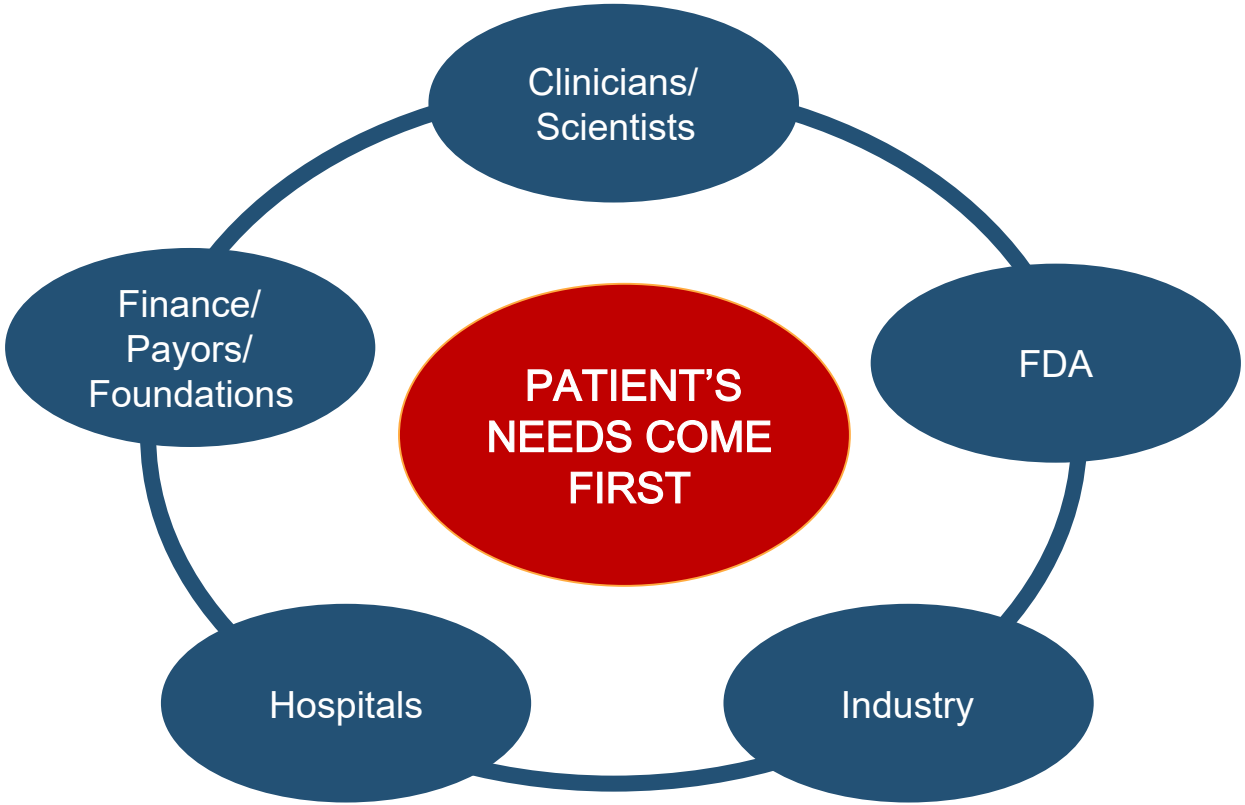
PLT	2512	D	10³/mm³	150	399
MPV	8.3	D	µm³	6.8	10.1



REGENERATIVE MEDICINE CHALLENGES

1. WIDE VARIABILITY BETWEEN PATIENTS IN CELLS
2. WIDE VARIABILITY IN COMMERCIAL SYSTEMS
3. POOR QUALITY CONTROL
4. UNSOPHISTICATED DELIVERY METHODS
5. LIMITED CLINICAL OUTCOMES DATA
6. NOT WITHOUT RISK
7. FDA REGULATIONS
8. REIMBURSEMENT ISSUES

RSI'S Philosophy: Collaborate To Innovate



WHAT IS THE SAFEST BIOLOGIC?

Research Article

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Regenerative Medicine

Optimizing the safety of intradiscal platelet-rich plasma: an *in vitro* study with *Cutibacterium acnes*

Meredith H Prysak*,[1], Cole G Lutz[2], Tyler A Zukofsky[1], Jordan M Katz[1], Peter A Everts[3] & Gregory E Lutz[2]

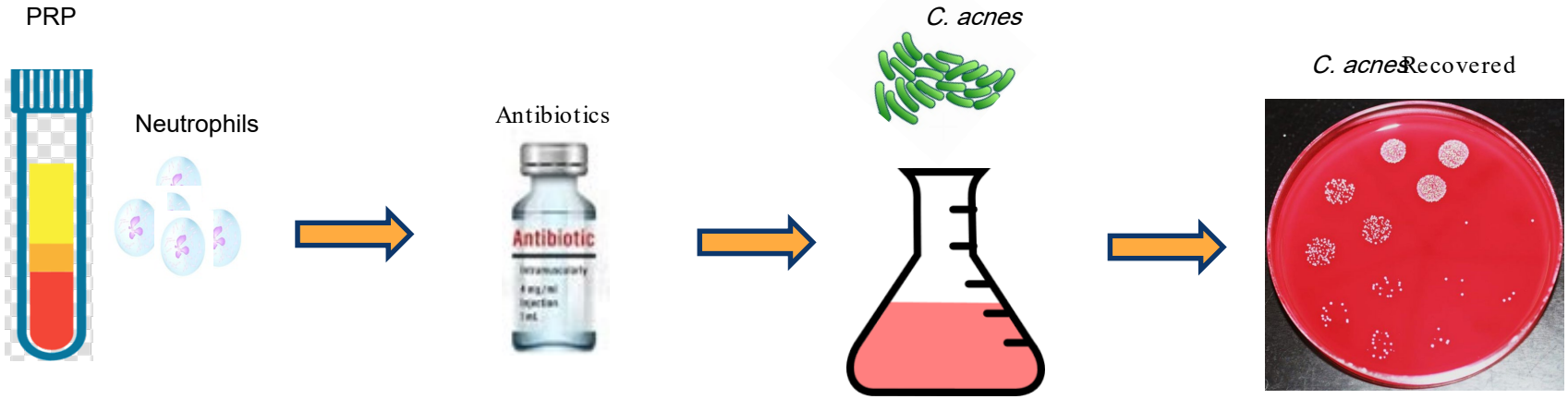
[1]Orthobond Corporation, 671 Suite B, US 1 North, North Brunswick, NJ 08902, USA

[2]Regenerative SportsCare Institute, 62 East 88th Street, New York, NY 10128, USA

[3]Gulf Coast Biologics, 4331 Veronica S Shoemaker Blvd. #4 Fort Myers, FL 33916, USA

*Author for correspondence: Tel.: +1 732 729 6235; Ext.: 14; prysakm@orthobond.com

Can The Type Of PRP Used Inhibit C Acnes Growth?



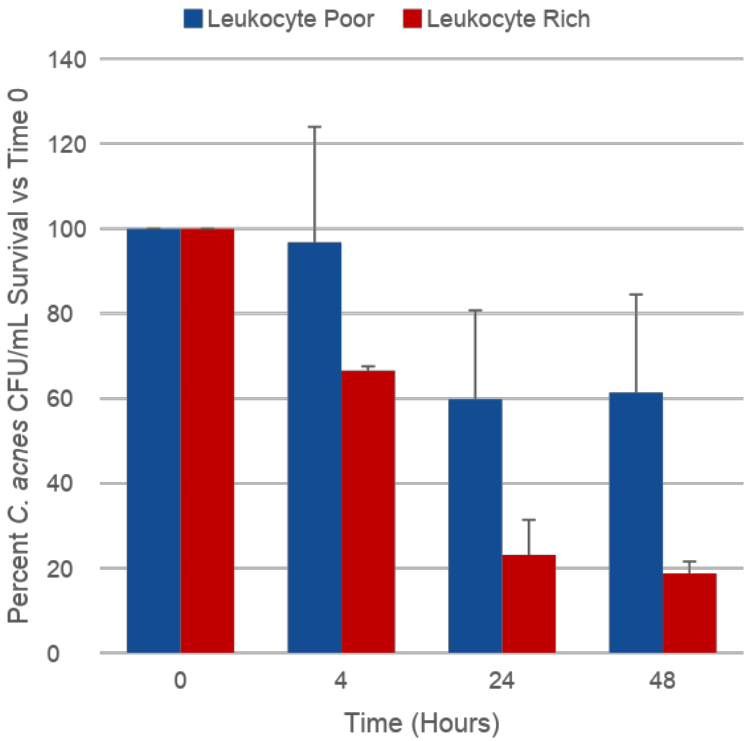
- PRP obtained from healthy volunteers
- Processed to be either leukocyte-rich (LR) or–poor (LP)
- Levels of platelets also modulated (PRP to 20X)

- PRP was split into antibiotic-free or antibiotic arms
- Samples were also taken for growth factor analysis

- 1 – 4 million *C. acnes* per mL added to different PRP preparations and incubated together
- At 4, 24, and 48 hours, samples were taken to measure bacterial recovery

- Bacterial recovery was enumerated and compared to initial values to measure antibacterial efficacy

Leukocyte-Poor Versus Leukocyte-Rich PRP



Prysak *et al.* Regen. Med. (2019) 14(10), 955–967

- Pooled data
- Leukocyte-rich preparations associated with a greater drop in bacteria recovery
- Neutrophil counts directly correlated with drop in bacteria recovery
- Effect of platelets on bacteria viability varied between preparation methods (kit)

Neutrophils are capable of lowering contaminating *C. acnes* counts in PRP *in vitro*

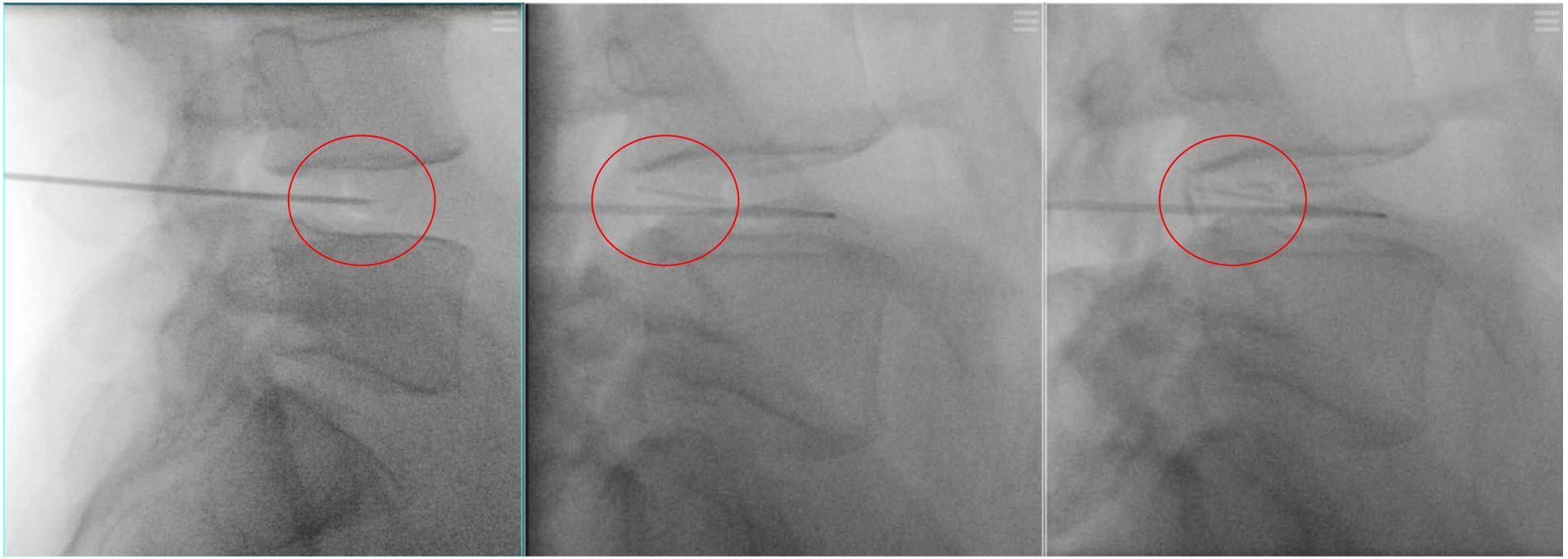
DiscHeal™

INTRODUCER NEEDLE INSERTED INTO DISC

DiscCath™ INSERTED THROUGH INTRODUCER NEEDLE

DiscCath™ PRECISELY INTO REGION OF TEAR

DiscHeal™



INTRODUCER NEEDLE INSERTED INTO DISC

DiscCath™ INSERTED PRECISELY INTO REGION OF TEAR

PRP DELIVERED PRECISELY INTO TEAR

DiscHeal™ PRP

Analyser Alarms
Analysis Alarms G1, G2

				Normal range	
WBC	3.7	L	10³/mm³	4.1	10.5
LYM%	37.7		%	16.0	43.3
MON%	7.3		%	2.8	10.2
GRA%	55.0		%	48.5	80.3
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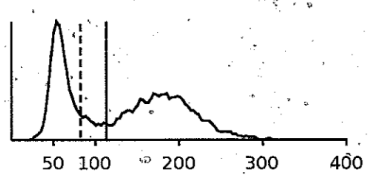
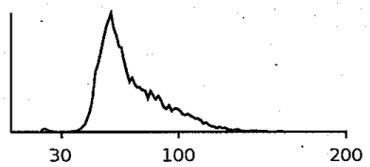
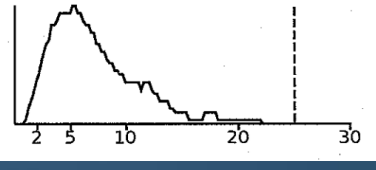
GRA#	2.20	L	10³/mm³	2.30	7.70



RBC	2.54	L	10⁶/mm³	4.30	5.80
HGB	7.7	L	g/dl	13.1	16.7
HCT	22.2	L	%	39.9	51.0
MCV	87		µm³	83	98
MCH	30.5		pg	27.0	32.2
MCHC	34.9	H	g/dl	31.8	33.7
RDW-CV	13.9		%	11.9	14.8



PLT	134	L	10³/mm³	150	399
MPV	7.3		µm³	6.8	10.1



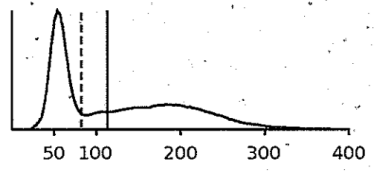
14X

12X

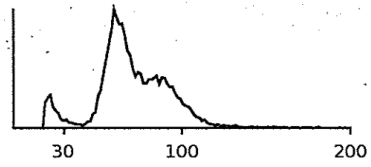
19X

Analyser Alarms
Analysis Alarms SCH, G1, G2

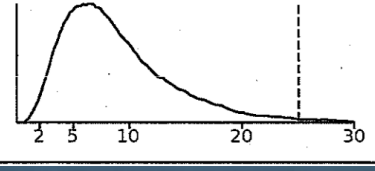
				Normal range	
WBC	52.2	H	10³/mm³	4.1	10.5
LYM%	44.2	H	%	16.0	43.3
MON%	7.3		%	2.8	10.2
GRA%	48.5		%	48.5	80.3
LYM#	23.00	H	10³/mm³	1.00	3.10
MON#	3.80	H	10³/mm³	0.10	0.70
GRA#	25.40	H	10³/mm³	2.30	7.70



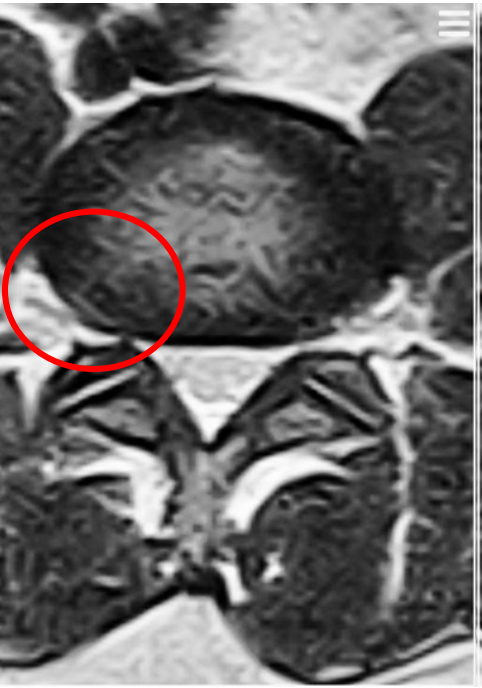
RBC	2.96	L	10⁶/mm³	4.30	5.80
HGB	8.6	L	g/dl	13.1	16.7
HCT	25.5	L	%	39.9	51.0
MCV	86		µm³	83	98
MCH	28.9		pg	27.0	32.2
MCHC	33.6		g/dl	31.8	33.7
RDW-CV	17.4	H	%	11.9	14.8



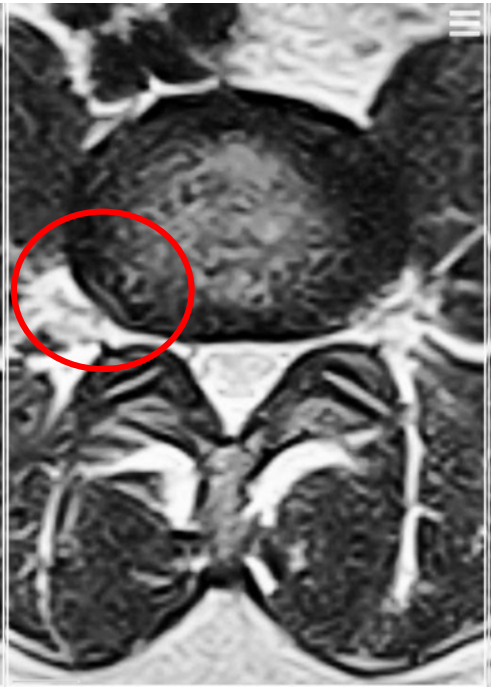
PLT	2512	D	10³/mm³	150	399
MPV	8.3	D	µm³	6.8	10.1



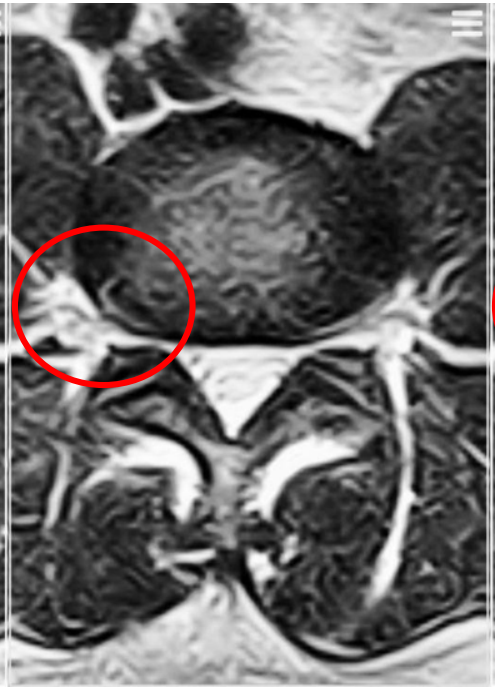
DiscHeal™



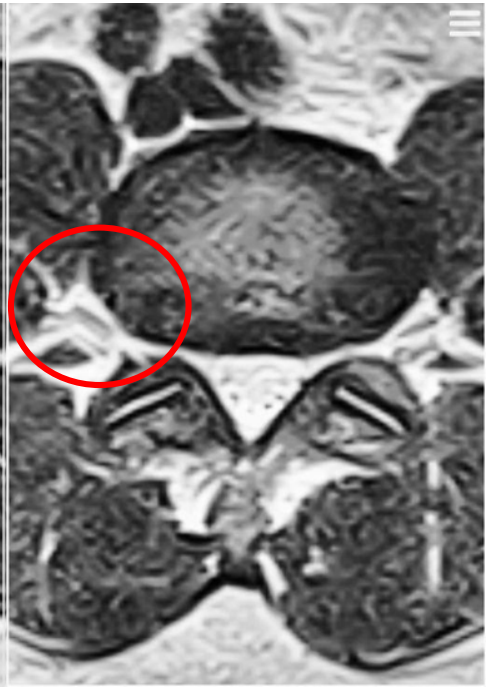
CHRONIC UNHEALED TEAR FOR 8 YEARS



1 MONTH POST HEALING



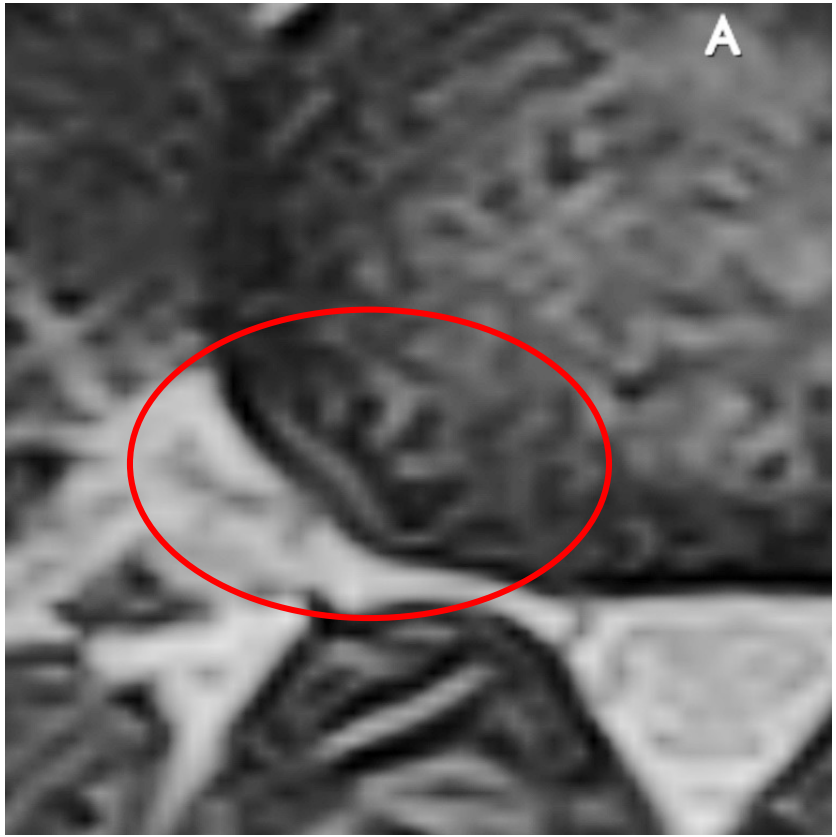
2 MONTHS POST HEALING



3 MONTHS POST HEALED

DiscHeal™

PAIN RELIEF ALONE IS PALLIATIVE



STRUCTURAL CHANGES IN TISSUE CAN BE CURATIVE

HIGHER CONCENTRATION PRP
> 80% SUCCESS RATE

International Orthopaedics
https://doi.org/10.1007/s00264-022-05389-y

ORIGINAL PAPER

Check for updates

Clinical outcomes following intradiscal injections of higher-concentration platelet-rich plasma in patients with chronic lumbar discogenic pain

Cole Lutz[1] · Jennifer Cheng[2] · Meredith Prysak[3] · Tyler Zukofsky[3] · Rachel Rothman[2] · Gregory Lutz[1,2]

Received: 31 January 2022 / Accepted: 23 March 2022

Abstract

Purpose This study aimed to assess clinical outcomes following intradiscal injections of higher-concentration (> 10×) platelet-rich plasma (PRP) in patients with chronic lumbar discogenic pain and to compare outcomes with a historical cohort.

Methods This retrospective study included 37 patients who received intradiscal injections of higher-concentration (> 10×) PRP and had post-procedure outcomes data (visual numerical scale pain score, Functional Rating Index [FRI], and NASS Patient Satisfaction Index). Outcomes were compared to a historical cohort of 29 patients who received intradiscal injections of < 5X PRP.

Results Pain and FRI scores significantly improved by 3.4 ± 2.5 and 46.4 ± 27.6, respectively, at 18.3 ± 13.3 months following intradiscal injections of > 10 × PRP ($p < 0.001$). These improvements were greater than those reported by the historical cohort (1.7 ± 1.6 and 33.7 ± 12.3; $p = 0.004$ and 0.016, respectively). Additionally, the satisfaction rate was higher in patients receiving > 10 × PRP compared to those receiving < 5 × PRP (81% vs. 55%; $p = 0.032$).

Conclusions Findings from this study suggest that clinical outcomes can be optimized by using PRP preparations that contain a higher concentration of platelets. Further research is needed to continue to optimize the composition of PRP used to treat patients with lumbar disc disease.

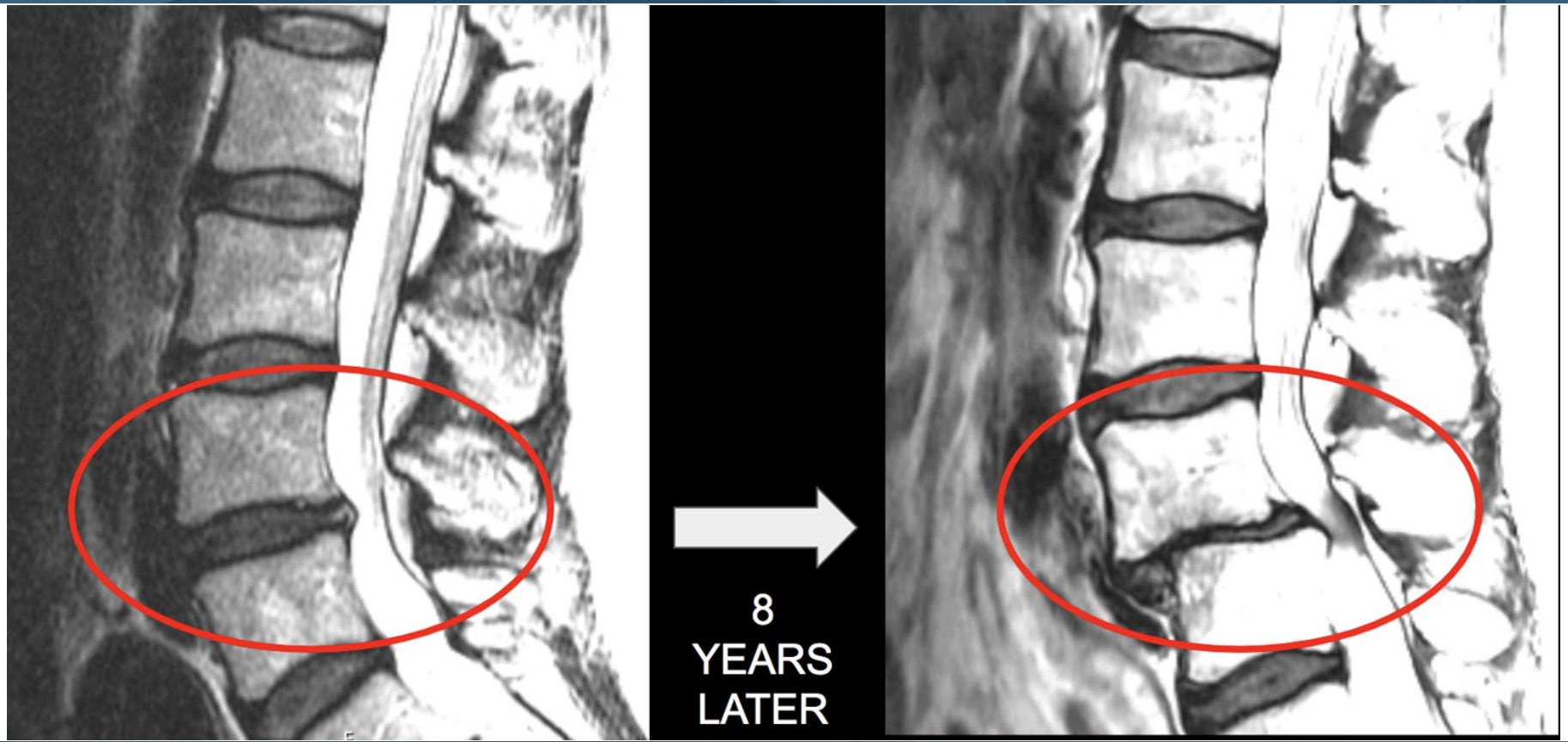
Lumbar Fusion vs DiscHeal ™

	Fusion	DiscHeal ™
Infection Rate	5% reported	< 0.1%
Nerve Injury	9% reported	< 0.1%
Chronic Opioid Use	60% reported	< 0.1%
Success Rate	<60% reported	>80%
Time Off From Work	Months	Days
Cost (Average)	$100K -150K	$10K-15K
Insurance Coverage	YES	NO

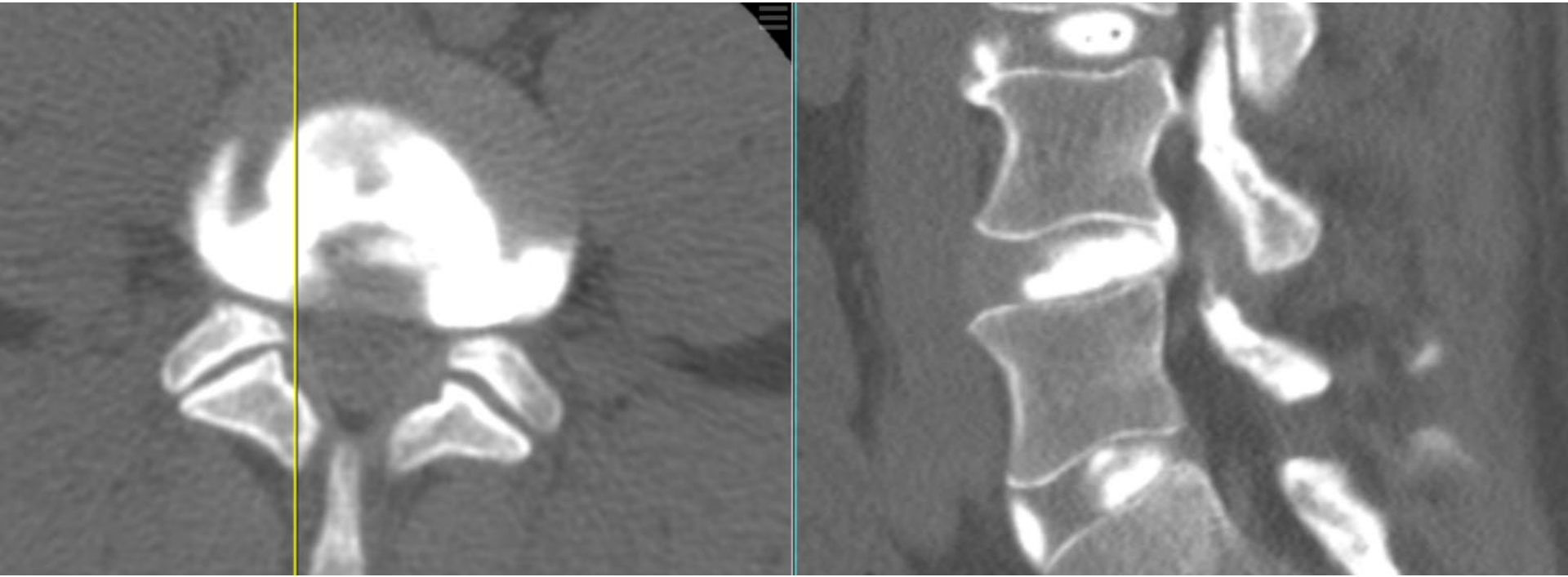
DiscHeal™

- *A simple opioid -sparing solution to a complex problem.*
- *Target market = 280 million patients worldwide suffering from DDD.*
- *Contains DiscCath ™ plus an optimized LR -PRP kit.*
- *Both are 510(k) approved devices for commercial use in the US.*

CAN WE PREVENT THE DISC FROM DEGENERATING?



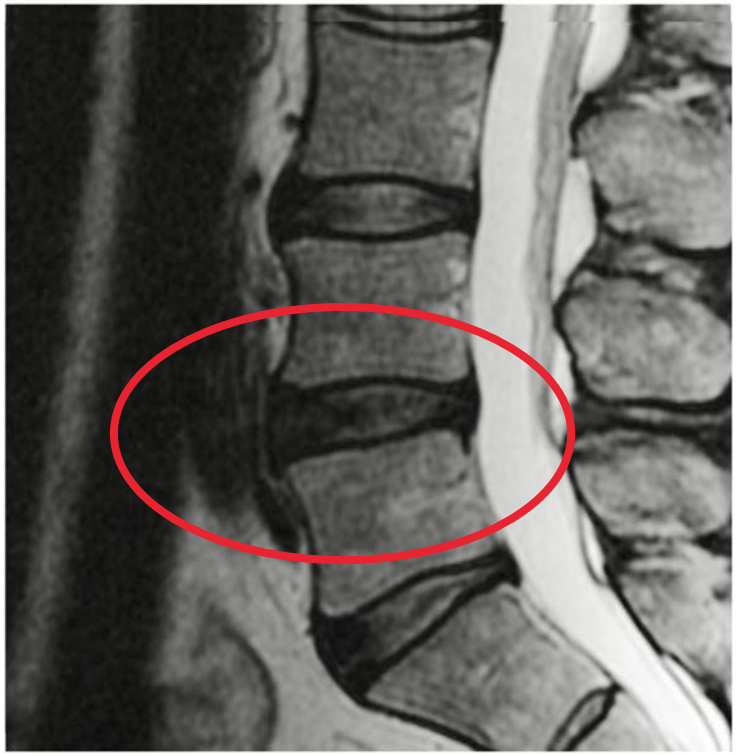
CAN WE PREVENT THE DISC FROM DEGENERATING?



CT DISCOGRAM AT L4-5 REVEALED SIGNIFICANT ANNULAR DISRUPTION IN 2010

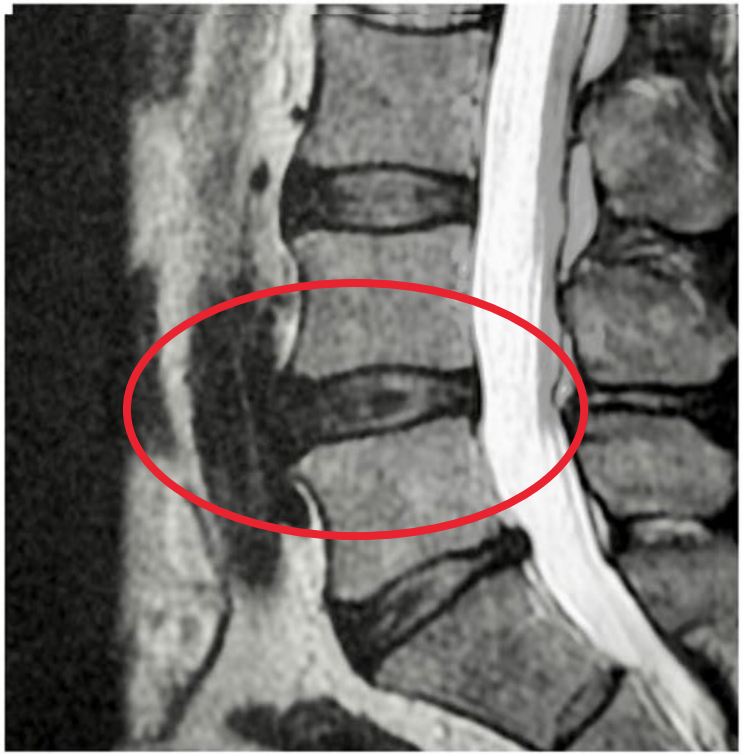
CAN WE PREVENT THE DISC FROM DEGENERATING?

2010



11 YEARS POST
INTRADISCAL
LR-PRP AT L4-5

2021



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