mesoblast

Global Leader in Allogeneic Cellular Medicines for Inflammatory Diseases

Key Opinion Leader Event Series for Investors & Analysts

Chronic Low Back Pain due to Degenerative Disc Disease

June 2022

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This presentation includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. We make such forward- looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this presentation are forward-looking statements. Words such as, but not limited to, “believe,” “expect,” “anticipate,” “estimate,” “intend,” “plan,” “targets,” “likely,” “will,” “would,” “could,” and similar expressions or phrases identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and future events , recent changes in regulatory laws, and financial trends that we believe may affect our financial condition, results of operation, business strategy and financial needs. These statements may relate to, but are not limited to: expectations regarding the safety or efficacy of, or potential applications for, Mesoblast's adult stem cell technologies; expectations regarding the strength of Mesoblast's intellectual property, the timeline for Mesoblast's regulatory approval process, and the scalability and efficiency of manufacturing processes; expectations about Mesoblast's ability to grow its business and statements regarding its relationships with current and potential future business partners and future benefits of those relationships; statements concerning Mesoblast's share price or potential market capitalization; and statements concerning Mesoblast's capital requirements and ability to raise future capital, among others. Forward-looking statements should not be read as a guarantee of future performance or results, and actual results may differ from the results anticipated in these forward-looking statements, and the differences may be material and adverse. You should read this presentation together with our financial statements and the notes related thereto, as well as the risk factors, in our most recently filed reports with the SEC or on our website. Uncertainties and risks that may cause Mesoblast's actual results, performance or achievements to be materially different from those which may be expressed or implied by such statements, include, without limitation: risks inherent in the development and commercialization of potential products; uncertainty of clinical trial results or regulatory approvals or clearances; government regulation; the need for future capital; dependence upon collaborators; and protection of our intellectual property rights, among others. Accordingly, you should not place undue reliance on these forward-looking statements. We do not undertake any obligations to publicly update or revise any forward-looking statements, whether as a result of new information, future developments or otherwise.

Agenda – CLBP KOL Event

01 Introduction to Mesoblast – Tim McCarthy, LifeSci Advisors

02 CLBP Program Overview – Silviu Itescu

03 KOL Presentation – Dr. Douglas Beall

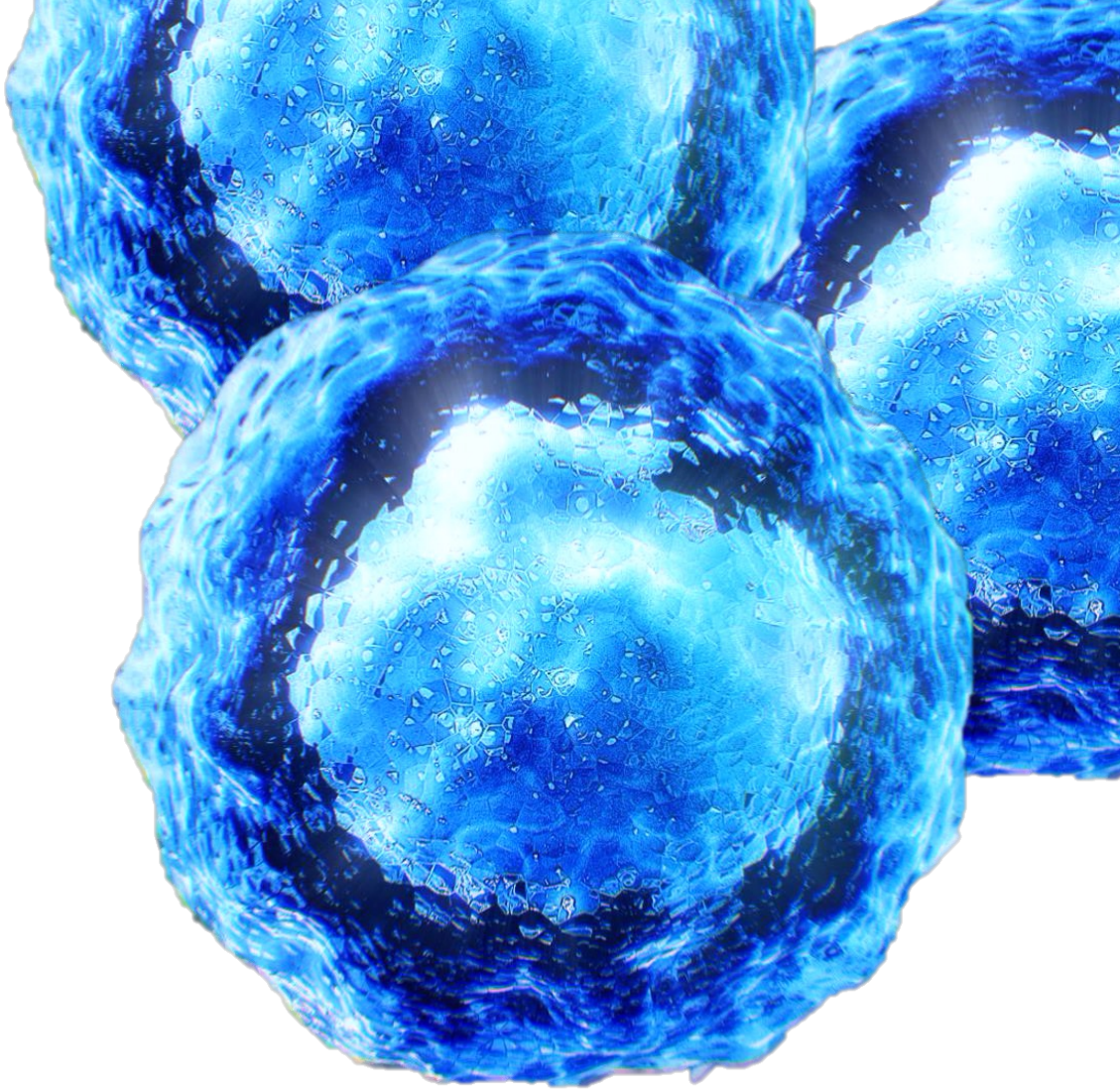
04 KOL Presentation – Dr. Hyun Bae

05 Q&A

mesoblast

Our Mission

Mesoblast is committed to bringing to market innovative cellular medicines to treat serious and life-threatening inflammatory diseases



Speaker Biographies - Douglas P. Beall, MD, FIPP, FSIR, DAAPM

Douglas P. Beall, MD, FIPP, FSIR, DAAPM attended medical school at Georgetown University School of Medicine in Washington, DC, and completed his residency at The Johns Hopkins Hospital in Baltimore, Maryland. Following residency, he was Chief of Interventional Services at Sheppard Air Force Base in Wichita Falls, Texas. He then completed a fellowship in Musculoskeletal Radiology at Mayo Clinic in Rochester, Minnesota, where he was trained in interventional spine techniques before returning to the US Air Force as Division Chief of Musculoskeletal Radiology. Following his service as a Major in the US Air Force Dr. Beall was chief of Musculoskeletal Radiology and Fellowship Director at the University of Oklahoma prior to entering private practice as the Chief of Services. In addition to his expertise in musculoskeletal imaging and interventional spine care, Dr. Beall is actively involved in teaching and research. He is board-certified in Diagnostic Radiology, has an added fellowship in Musculoskeletal Radiology, is a Diplomate of the American Academy of Pain Management and is a Fellow of the Society of Interventional Radiology and Interventional Pain Practice and board certified by the World Institute of Pain. He is currently in private practice focused on interventional pain management and orthopedic imaging.

Dr. Beall has published more than 250 articles in peer-reviewed journals, authored 6 textbooks and 75 textbook chapters, given more than 1000 invited lectures and scientific presentations and has participated in 55 clinical research trials. He is currently the Chief of Services for Comprehensive Specialty Care in Oklahoma City as well as the Division Head of Interventional Spine Care and Director of Pain Management Fellowship Programs at the Spine Fracture Institute and the Comprehensive Care Surgical Center.

Speaker Biographies - Hyun W. Bae, MD

Hyun W. Bae, MD is an orthopedic and spine fellowship trained board-certified orthopedic surgeon. Dr Bae joined the Spine-Center at Cedars-Sinai Medical Center in 2010. He is currently Professor of Surgery in the Department of Orthopedic Surgery Cedars-Sinai Medical Center, Director of Education and Fellowship program.

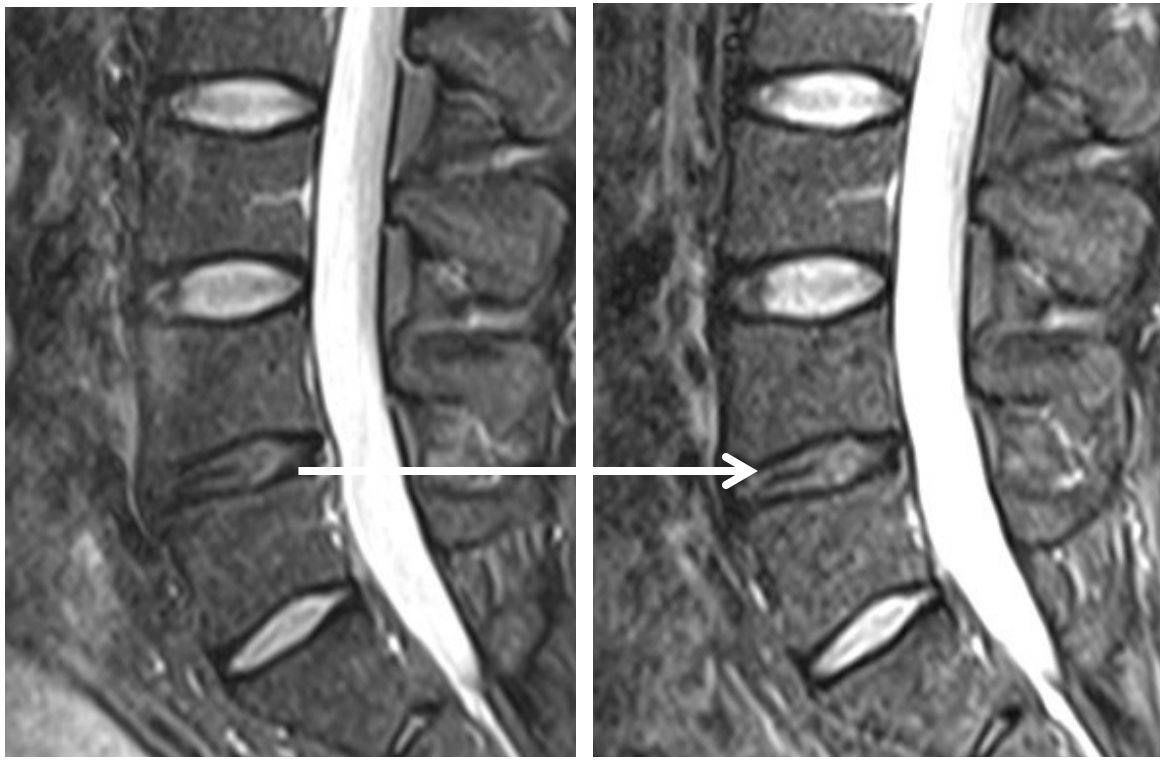
Dr. Bae began his medical studies at Columbia University School of Engineering and Applied Sciences where he graduated with a degree in biomechanics. He then went on to earn his medical degree, cum laude, at Yale University School of Medicine. Dr. Bae completed his surgical internship at North Shore University Hospital and his orthopedic surgical residency at the Hospital for Special Surgery in New York. He completed his spine fellowship at Case Western Hospital in Cleveland under the mentorship of late Henry H. Bohlman, MD. During 1993-1994 he performed research in Molecular and Cell Biology, NIH Howard Hughes Research Fellow Bethesda, MD. It was during that time, he caught the passion for musculoskeletal tissue engineering while working with scientists Guilak F, Setton LA, Soslowsky LJ, as an undergraduate in Dr. Van Mow's cartilage research laboratory.

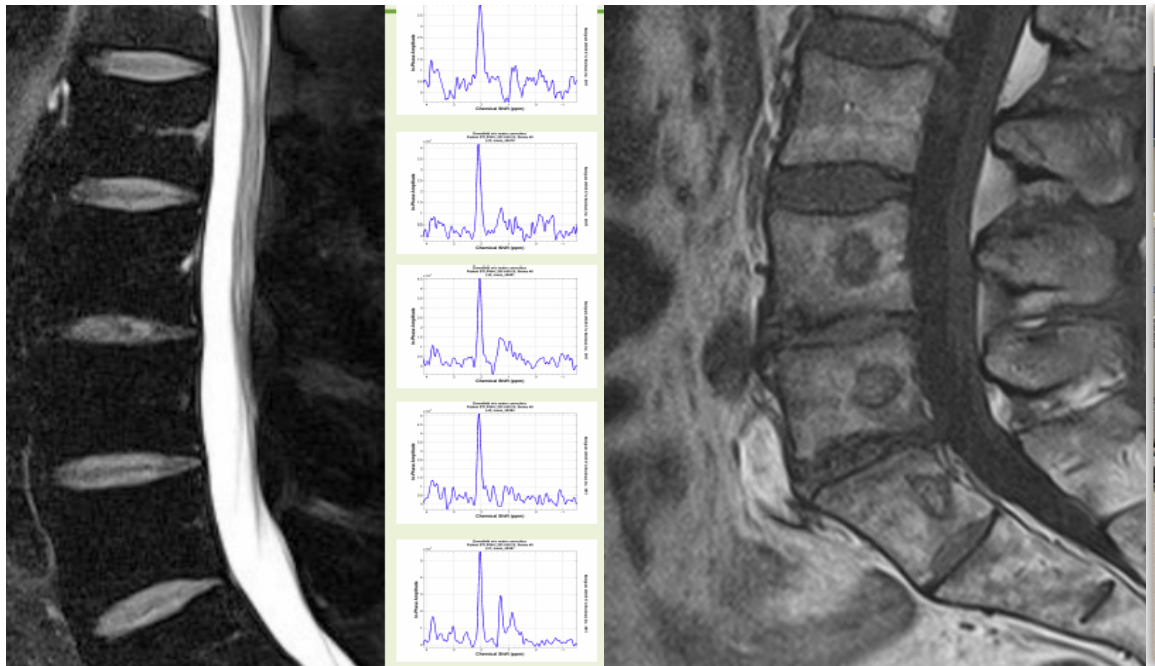
After spine surgery fellowship, He entered clinical practice, and developed a research program focusing on repair of IVD and evaluating instrumentation for spinal fusion, and grafting materials. Early translational studies were on chondrocytes expressing TGF-B1 to heal experimentally degenerated discs via needle puncture injury in rabbits (patents, cell technology with TissueGene Co.). Several disc repair treatment options were studied clinically for patients with less severe DDD with goals of preventing or delaying surgery. Other research areas include grafting with growth differentiation factors for fusion, variability in allografts, DBM-based allografts, and adult stem cells for the regeneration of intervertebral disc, and nervous system tissue after spinal cord injuries. He serves as the clinical partner of the basic science and translational Orthopedic Stem Cell and Tissue Engineering Laboratory. Dr. Bae is PI for 3-4 FDA-approved RCTs at any time with over 30 clinical studies completed throughout the last 20 years.

Dr. Bae has written or coauthored more than 70 published scientific paper, 5 review articles, and over 10 chapters. Has around 30 patents. A main area of research interest is targeted regeneration of the intervertebral disc. Hyun W. Bae, MD specializes in minimally invasive microsurgery, disc replacement surgery, degenerative spine, and surgical treatment of cervical and lumbar spinal diseases.

The Unmet Need in Treating Chronic Low Back Pain

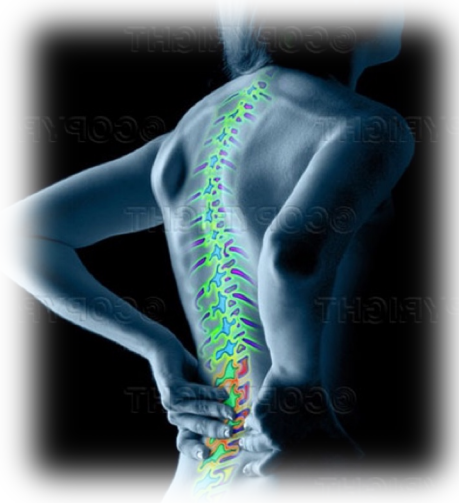
Douglas P. Beall, M.D., AAIPM, FIPP
Director of Clinical Research, Clinical Investigations
Oklahoma City, Oklahoma





Chronic Low Back Pain Impacts Society

LBP is the most common cause of job-related disability[1]



- Impacts 29% of the population[2]
- $150-200 billion in annual healthcare expenditures[3]
- 33 million people disabled[4]
- 102 million lost workdays annually[5]

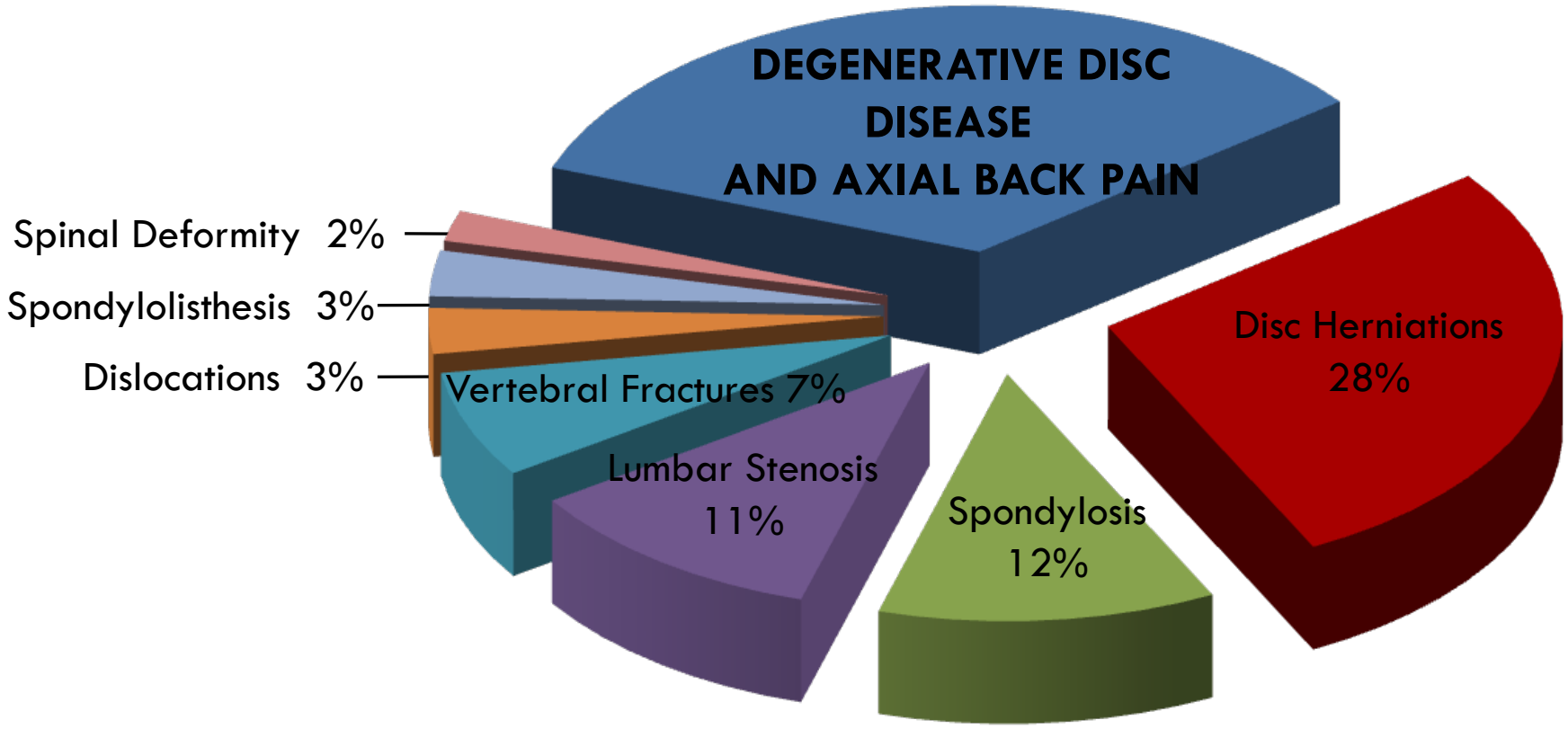
CHRONIC LOW BACK PAIN IS THE SINGLE GREATEST CAUSE OF YEARS LIVED WITH DISABILITY (YLDS) IN HUMANS, ON EARTH.

Rice ASC, Smith BH, Blyth FM
Pain and the global burden of disease. Pain. 2016;157(4):791-796. doi:10.1097/j.pain.0000000000000454

[1] National Institute of Neurological Disorders and Stroke (2014) *Back Pain Fact Sheet*
[2,3,4] The Burden of Musculoskeletal Diseases in the United States - Copyright 2011
[5] Back pain prevalence in US industry and estimates of lost workdays, Am J Public Health. 1999 July; 89(7): 1029–1035.

The Largest Population Segment

34% OF THE PATIENTS



Primary Spine Diagnosis, 2008

The problem is getting worse with time…

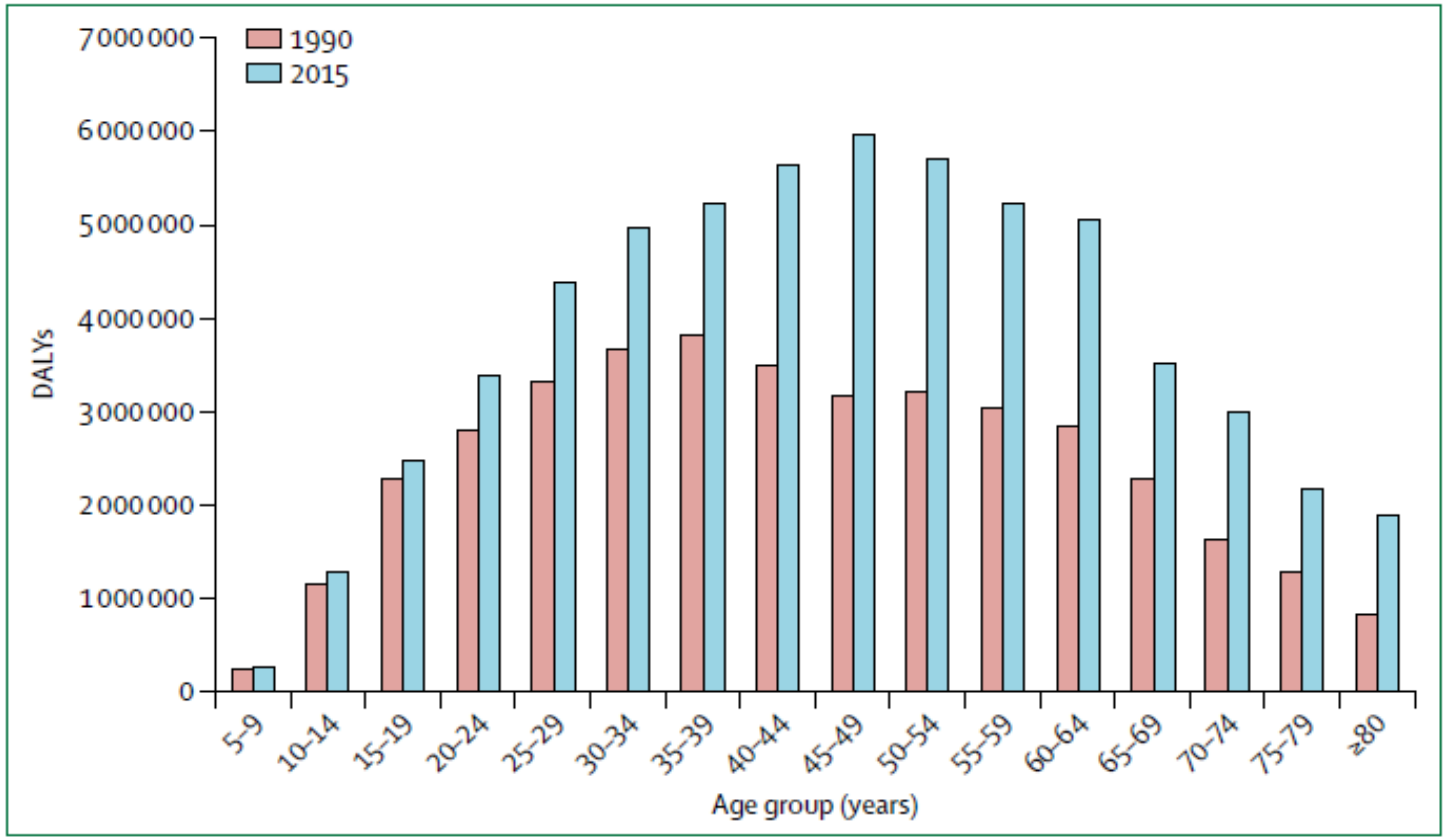


Figure 3: **Global burden of low back pain, in disability-adjusted life-years (DALYs), by age group, for 1990 and 2015**

Data are from the Global Health Data Exchange.

Identifying Discogenic LBP

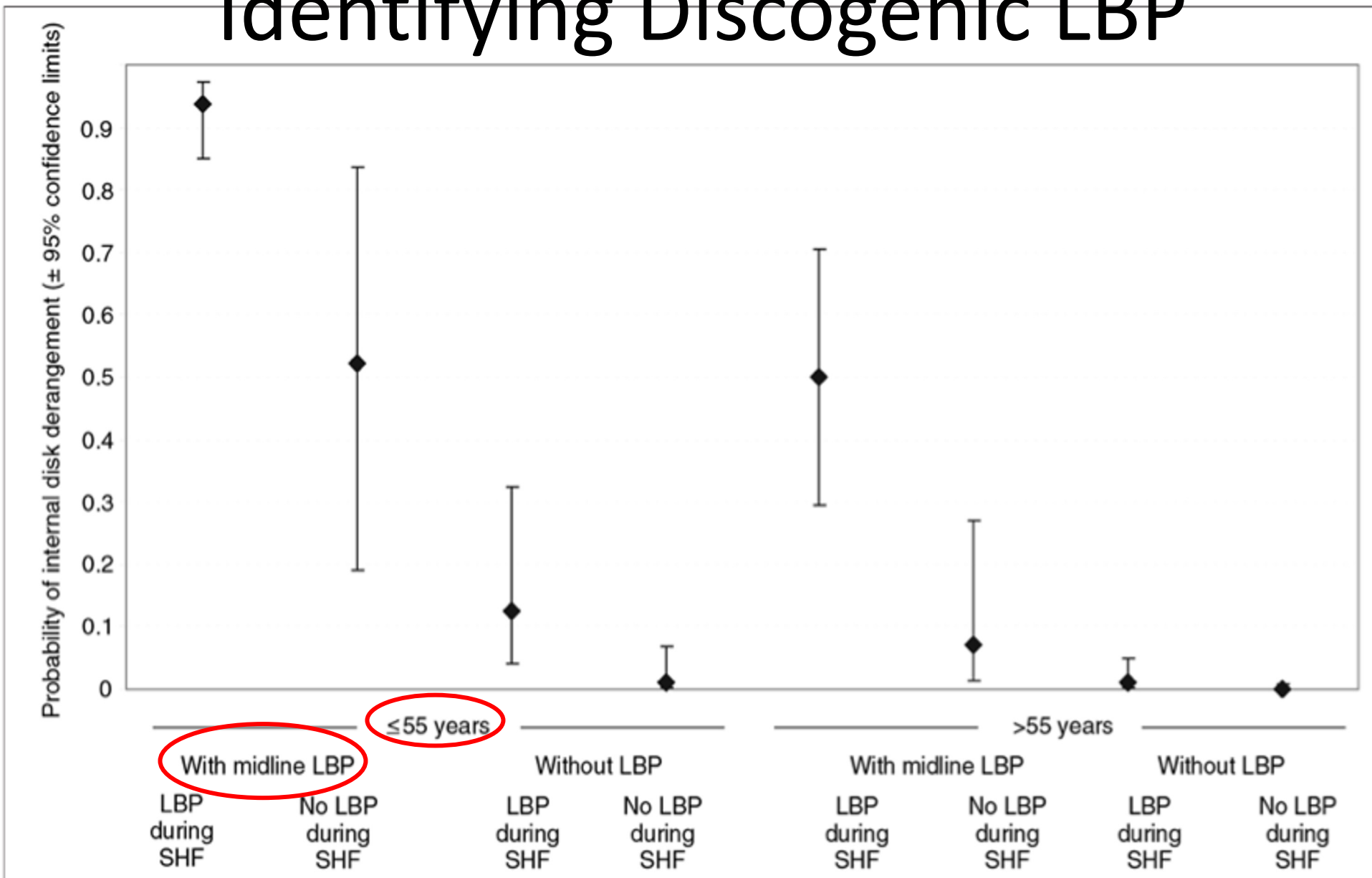
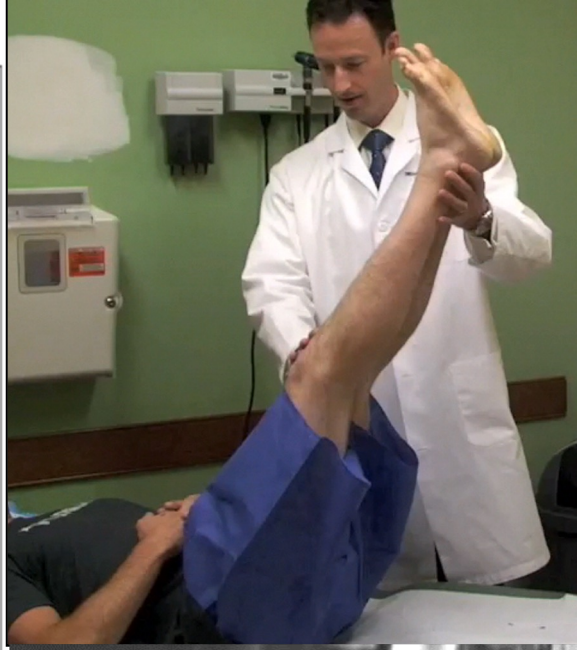
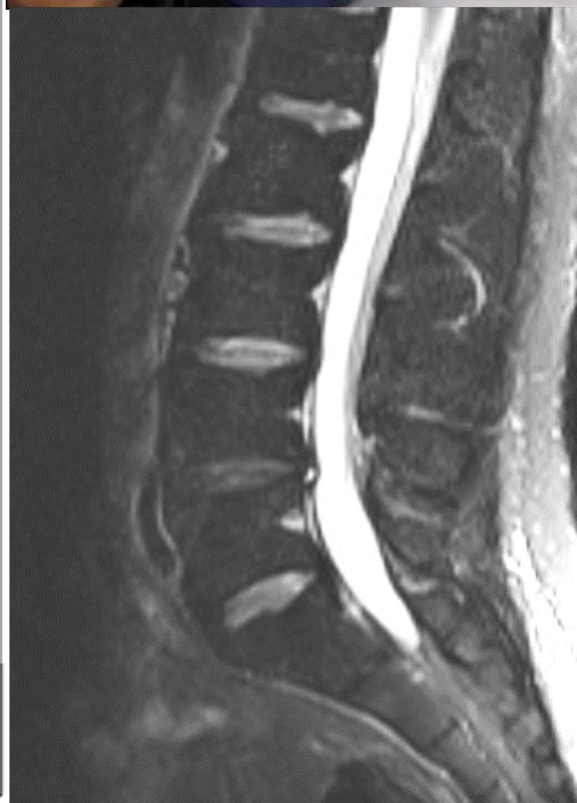


Figure 1 Graph showing the probability (± 95% confidence limits) of internal disk derangement by age group, presence of midline low back pain, and presence of low back pain during sustained hip flexion.





Huge Gap in Treatment Options

Non-Surgical Mgt

- **Non-steroid Anti-Inflammatory Drugs (NSAIDs), Narcotics,**
- **Injections: ESIs[1], nerve blocks**
- **Chiropractic, Physical Therapy, Acupuncture, etc**

Surgical Interventions

- **Fusion**
- **Disc arthroplasty**

1. Epidural steroid injections are not approved for treatment of CLBP

Effectiveness of Current Analgesic Therapies for Treating CLBP

Randomized controlled trials of currently approved analgesics show little to no difference in pain intensity when compared to placebo at short-term follow-up

- **Cochrane Systematic Review of Randomized Controlled Trials of NSAIDs from 9 to 112 Days Follow-up (Enthoven et al. 2016)**
  - Average mean difference in pain intensity between all NSAIDs and placebo treatment of -6.97 points (adjusted to a 0-100 VAS scale)
  - Risk ratio for adverse events of 1.04 favoring placebo over all NSAIDs
- **Systematic Review and Meta-Analysis of Randomized Controlled Trials of Strong Opioids from 4 to 15 weeks follow-up (Nurry et al. 2022)**
  - Examples of strong opioids (i.e. WHO-III) are morphine, buprenorphine, oxycodone, fentanyls and methadone
  - Average mean difference in pain intensity between opioids and placebo treatment of -9 points (adjusted to a 0-100 VAS scale)
- **Randomized Controlled Trial Comparing Opioid and Non-Opioid Medications in Patients with Chronic Back Pain or Hip or Knee Osteoarthritis Over 12 Months Follow-up (Krebs et al. 2018)**
  - Mean pain intensity change from baseline (adjusted to a 0-100 VAS scale) at 12 months showed a treatment difference of -5.0 favoring the non-opioid group ($p = 0.03$)
  - There was no significant difference between opioid and non-opioid groups for pain-related function ($p = 0.58$)
- **Phase 3 Randomized Controlled Trial of Duloxetine Compared to Placebo at 12 Weeks Follow-up (Skljarevski et al. 2010)**
  - LS mean change in pain intensity (adjusted to a 0-100 VAS scale) showed a treatment difference of -6.0 favoring duloxetine compared to placebo
- **Phase 3 Randomized Controlled Trial of Tanezumab 5 and 10 mg Compared to Tramadol and Placebo at 16 Weeks Follow-up (Markman et al. 2020)**
  - LS mean difference in pain intensity between Tramadol and placebo treatment of -1.2 points (adjusted to a 0-100 VAS scale)
  - LS mean difference in pain intensity between Tanezumab 10mg and tramadol treatment of -2.8 points (adjusted to a 0-100 VAS scale)

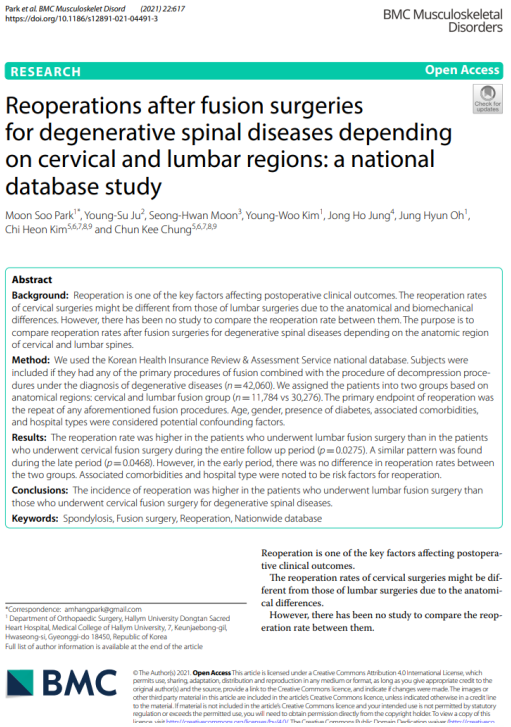
Adjacent Segment Disease

- The incidence of ASD in the Lumbar Spine ranges up to 14% per year
- Damage to the posterior ligamentous complex and sagittal imbalances are important risk factors

Harrop JS, Youssef JA, Maltenfort M, Vorwald P, Jabbour P, Bono CM, Goldfarb N, Vaccaro AR, Hilibrand AS. Spine (Phila Pa 1976). 2008 Jul 1; 33(15):1701-7.

2018 Study - 433 consec pts post LSF; mean f/u - 3.9 yrs; Reop rate @ 4 yrs – 19.3% (most common pathology – adj level degen); **1 in 5 pts have repeat sx in 4 yrs**

Irmola TM, Hakkinen A, Jarvenpaa S, Marttinen I, Vihtonen K, Neva M (2018) Reoperation rates following instrumented lumbar spine fusion. Spine 43:295–301. https://doi.org/10.1097/BRS.



Park et al. BMC Musculoskelet Disord (2021) 22:617
https://doi.org/10.1186/s12891-021-04491-3

BMC Musculoskeletal Disorders

RESEARCH Open Access

Reoperations after fusion surgeries for degenerative spinal diseases depending on cervical and lumbar regions: a national database study

Moon Soo Park[1*], Young-Su Ju[2], Seong-Hwan Moon[3], Young-Woo Kim[1], Jong Ho Jung[4], Jung Hyun Oh[1], Chi Heon Kim[5,6,7,8,9] and Chun Kee Chung[5,6,7,8,9]

Abstract

Background: Reoperation is one of the key factors affecting postoperative clinical outcomes. The reoperation rates of cervical surgeries might be different from those of lumbar surgeries due to the anatomical and biomechanical differences. However, there has been no study to compare the reoperation rate between them. The purpose is to compare reoperation rates after fusion surgeries for degenerative spinal diseases depending on the anatomic region of cervical and lumbar spines.

Method: We used the Korean Health Insurance Review & Assessment Service national database. Subjects were included if they had any of the primary procedures of fusion combined with the procedure of decompression procedures under the diagnosis of degenerative diseases ($n = 42,060$). We assigned the patients into two groups based on anatomical regions: cervical and lumbar fusion group ($n = 11,784$ vs 30,276). The primary endpoint of reoperation was the repeat of any aforementioned fusion procedures. Age, gender, presence of diabetes, associated comorbidities, and hospital types were considered potential confounding factors.

Results: The reoperation rate was higher in the patients who underwent lumbar fusion surgery than in the patients who underwent cervical fusion surgery during the entire follow up period ($p = 0.0275$). A similar pattern was found during the late period ($p = 0.0468$). However, in the early period, there was no difference in reoperation rates between the two groups. Associated comorbidities and hospital type were noted to be risk factors for reoperation.

Conclusions: The incidence of reoperation was higher in the patients who underwent lumbar fusion surgery than those who underwent cervical fusion surgery for degenerative spinal diseases.

Keywords: Spondylosis, Fusion surgery, Reoperation, Nationwide database

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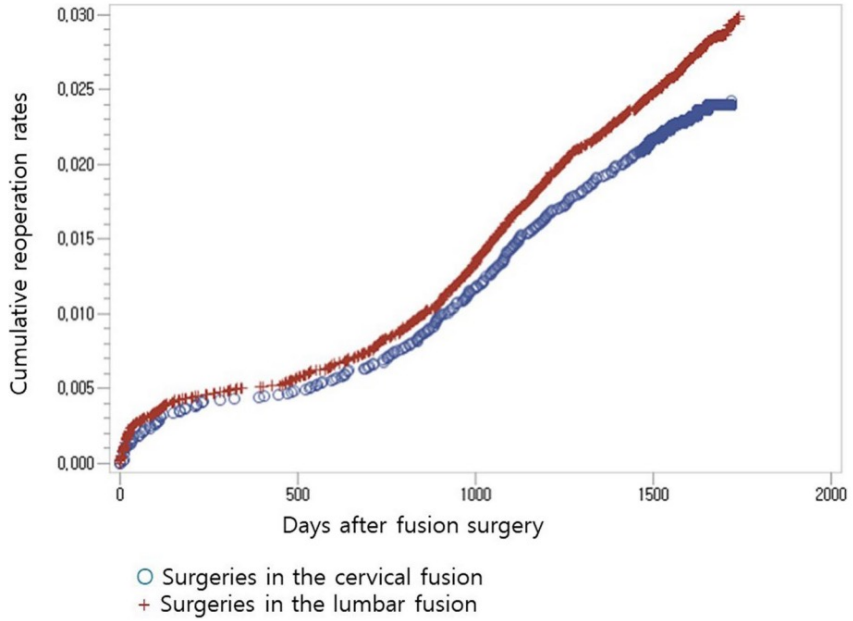
Reoperation is one of the key factors affecting postoperative clinical outcomes.

The reoperation rates of cervical surgeries might be different from those of lumbar surgeries due to the anatomical differences.

However, there has been no study to compare the reoperation rate between them.

BMC



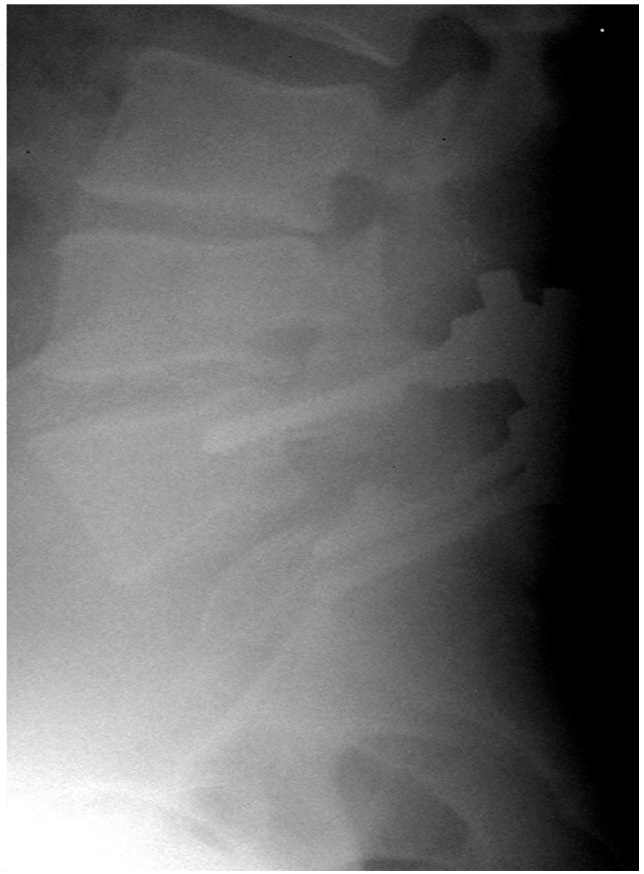
Cumulative reoperation rates of fusion surgeries according to anatomical regions for the entire follow-up period

What about Surgical Treatment for LBP: Even in "Positive" Studies Results are Mixed

Fritzell – Swedish Spine Study, 2001

"RESULTS: Lumbar fusion in pts with severe CLBP can ↓ pain & ↓ disability more efficiently than nonsurgical treatment."

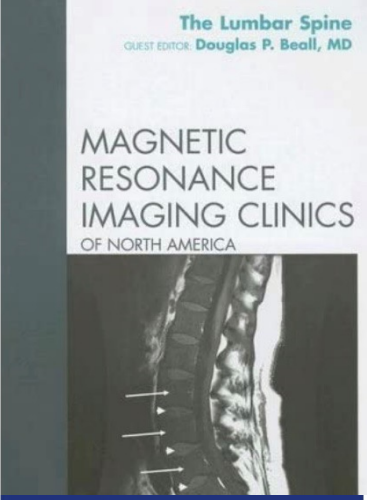
- In surgical group **only 63%** rated themselves as "better"/"much better"
- Back pain was ↓ in the surgical group by **only 33%**

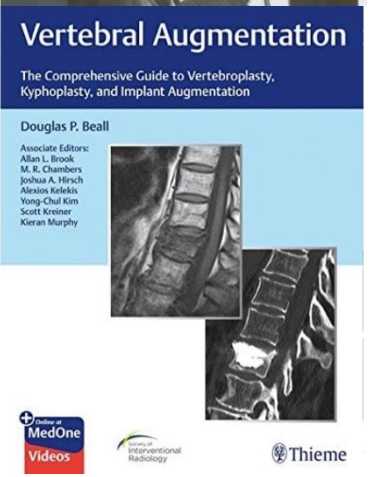


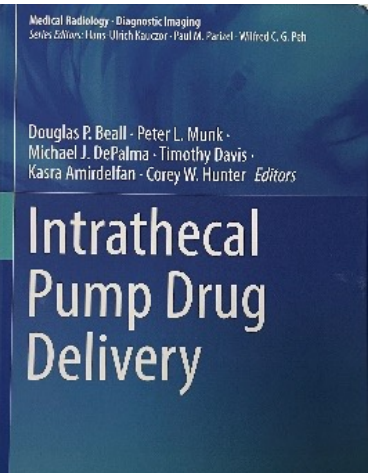
Peter Fritzell, et al: *2001 Volvo Award Winner in Clinical Studies: Lumbar Fusion Versus Nonsurgical Treatment for Chronic Low Back Pain - A Multicenter Randomized Controlled Trial from the Swedish Lumbar Spine Study Group*, Spine 2001, Vol 26, No 23, pp2521–2534

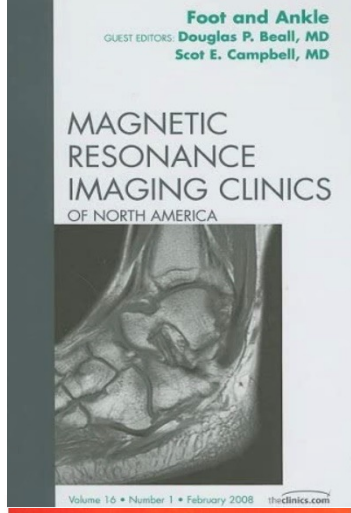
Conclusions

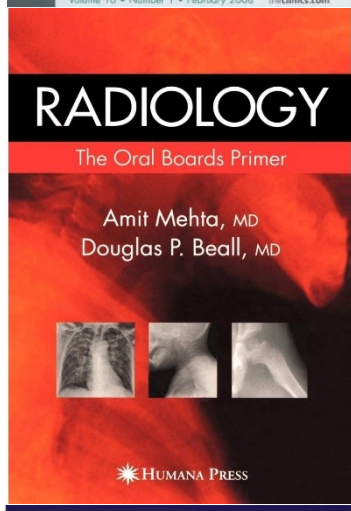
- Discogenic CLBP is a serious condition that results in significant disability, reduced quality of life and suffering for patients
- Direct and indirect costs associated with CLBP are significant
- Patients who do not improve with conservative therapy have limited options for treatment other than invasive surgical procedures that have mixed results and have the potential to cause future problems
- New minimally invasive treatments that are effective for treating CLBP improving function and quality of life are needed to help alleviate the unmet need for these suffering patients

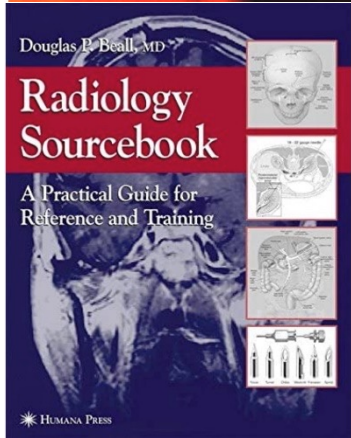












Thank You for Your Attention

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THE SPINE FRACTURE INSTITUTE

Mesoblast KOL Webinar

Dr. Hyun Bae
Professor of Orthopaedic Surgery
Department of Orthopaedic Surgery
Co-Medical Director Cedars Spine Center
Director of Education Cedars Spine Center
Cedars Sinai Medical Center

Disclaimer

Rexlemestrocel-L is an investigational therapy that has not been approved for commercial use by any Health Authority.

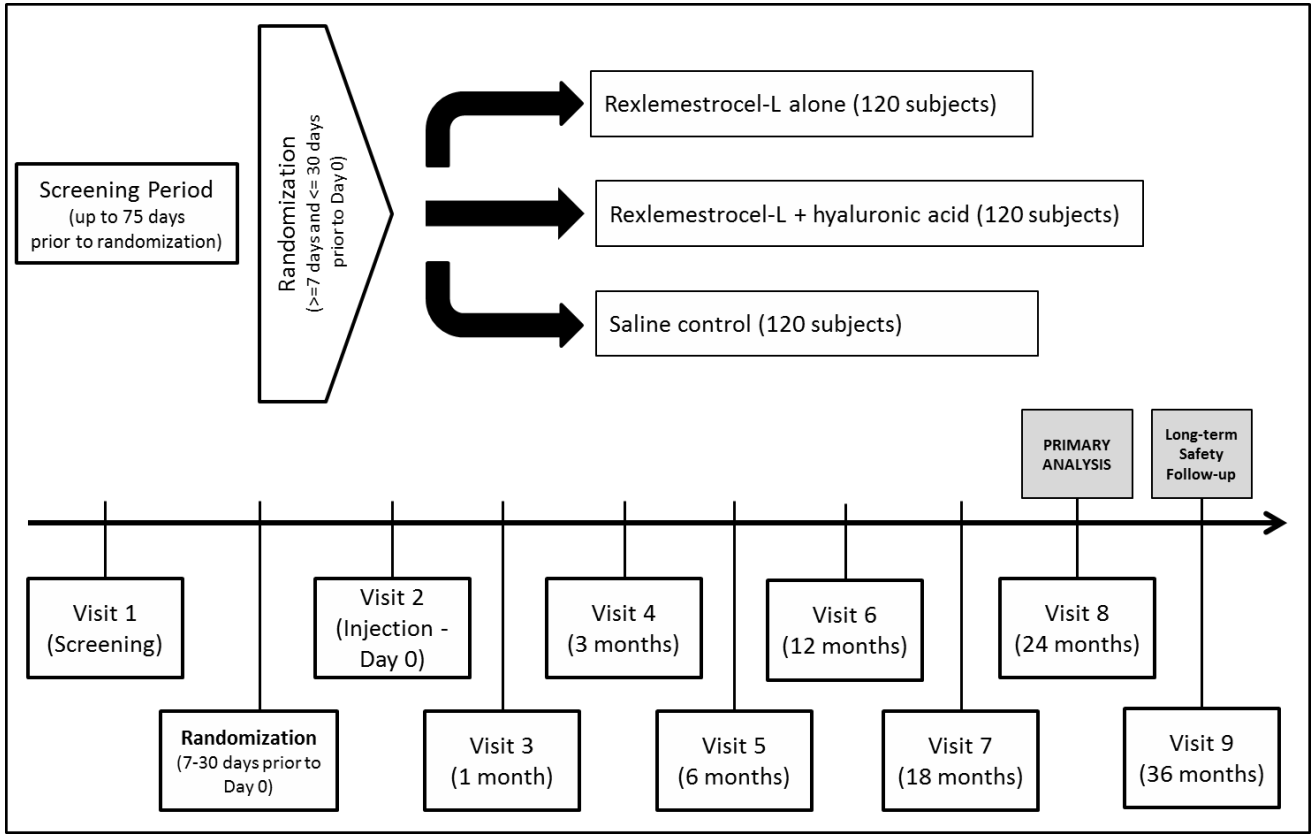
Conclusions concerning its safety or efficacy should not be made.

Phase 3 Trial: Regulatory Background

FDA provided substantial guidance regarding the design of the Phase 3 clinical trial to evaluate the safety and potential benefits of MPCs for the treatment of CLBP associated with moderate DDD

- Phase 2 study demonstrated that 6-million MPCs with HA carrier was the lowest effective dose for improvement in pain and function, and HA alone was not significantly different from the saline control
- MSB proposed use of the mean change in pain intensity at 12 months as the primary endpoint for the Phase 3 study similar to the endpoint used for evaluation of analgesic products.
- FDA indicated that the Phase 3 study design should be based on spinal implant guidance (e.g. spine fusion and artificial disc replacement), which requires a two-year composite responder endpoint demonstrating significant improvement in both pain and function
- Therefore, MSB followed FDA's guidance regarding the primary efficacy endpoint for the Phase 3 trial, but also explored endpoints consistent with FDA's evaluation of analgesics (e.g mean change in pain intensity)
- In accordance with the combination product rule, MPCs with and without HA would be evaluated in the Phase 3 study to determine if HA enhanced any observed benefit of MPCs

Phase 3 Trial: Study Design



- **A single 2mL intra-discal treatment injection**
  - **Rexlemestrocel-L+HA:** 6-million Mesenchymal Precursor Cells (MPC) mixed 1:1 by volume with HA
  - **Rexlemestrocel-L:** 6-million Mesenchymal Precursor Cells (MPC) mixed 1:1 by volume with saline
  - **Saline Control**
- **Double Blinded Study**
  - All subjects, site personnel dealing with patient care after the treatment injection and efficacy/safety evaluators blinded through 36-month follow-up
  - Sponsor and personnel involved in the 24-month primary endpoint blinded through 24-months and did not interact with patients or blinded site personnel prior to completion of the 36-month follow-up
- **45 investigational centers**
  - 44 centers in the USA and 1 center in Australia
- **Subject Enrollment**
  - 404 subjects enrolled
  - 398 subjects received treatment

Phase 3 Trial: Safety Outcomes

Summary of Adverse Events Through 36 Months

Category of TEAE	Rexlemestrocel-L N=140 n (%)	Rexlemestrocel-L + HA N=128 n (%)	Placebo N=130 n (%)
Subjects with any AE	111 (79.3%)	100 (78.1%)	102 (78.5%)
Subjects with any AE by Maximum Severity			
Mild	31 (22.1%)	26 (20.3%)	34 (26.2%)
Moderate	54 (38.6%)	54 (42.2%)	51 (39.2%)
Severe	26 (18.6%)	20 (15.6%)	17 (13.1%)
Subjects with any AE Leading to Discontinuation	1 (0.7%)	0	2 (1.5%)
Subjects with any Serious AE (SAE)	17 (12.1%)	15 (11.7%)	10 (7.7%)
Subjects with any AE Leading to Death	0	1 (0.8%)	0
Percentages are based on the number of subjects (N) in the safety analysis set within each treatment group. HA = hyaluronic acid; SAE = serious adverse event; AE = adverse event;			

- Similar percentage of subjects with any AE across treatment groups
- Most common AEs (≥5% of all subjects): **Back pain** (36.4, 43.8, 40.0%); **Pain in extremity** (13.6, 13.3, 14.6%); **Arthralgia** (9.3, 12.5, 10.0%); **Hypoaesthesia** (7.1, 6.3, 9.2%); M**uscle spasms** (7.1, 5.5, 7.7%): **Paraesthesia** (7.9, 3.9, 3.1%).
- No SAE was considered related to treatment or injection procedure

Phase 3 Trial: Primary Efficacy Endpoint

Overall Treatment Success Composite at both 12 and 24 months:

- At least 50% reduction from baseline in average LBP at both 12- & 24-months post-treatment; **AND**
- At least a 15-point decrease from baseline in Oswestry Disability Index (ODI) score at both 12- & 24-months post-treatment; **AND**
- No post-treatment interventions affecting the treated disc through 24 months
- Study powered for $p<0.025$ to assess superiority of either MPC arm vs placebo and required a posterior probability of superiority >0.9875

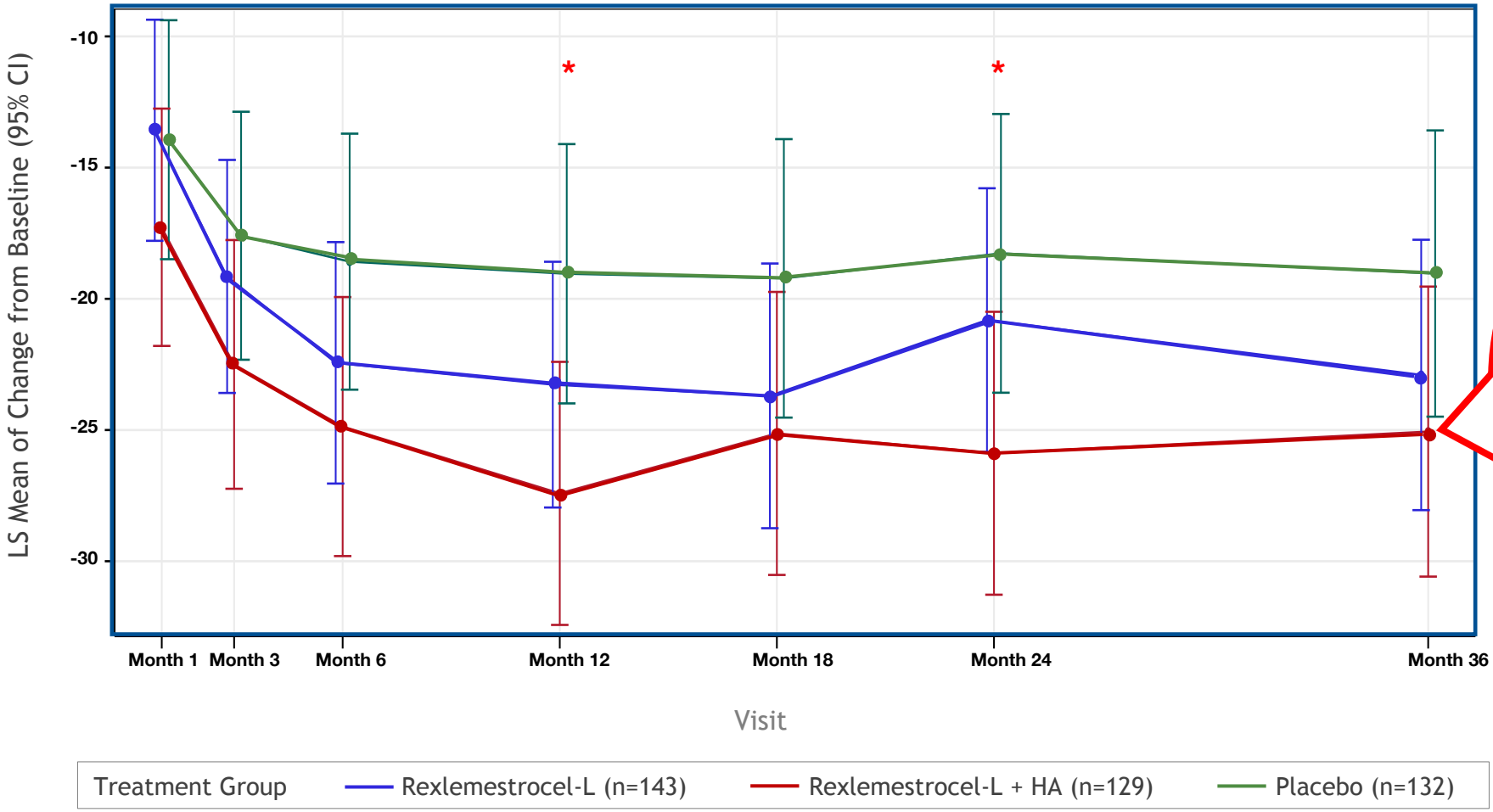
Response Rate Estimate			Probability of Superiority	
MPC	MPC+HA	Saline	MPC	MPC+HA
0.267	0.335	0.313	0.2072	0.6427

- FDA specified use of a 24 month composite endpoint typically used for evaluation of permanent implantable spinal devices such as spine fusion and artificial discs in patients with end stage DDD for the first Phase 3 study
- Analgesics evaluated in earlier stage patients with CLBP typically use a primary endpoint of mean change in pain
- FDA has agreed that the second phase 3 study focusing on earlier stage patients can use a primary endpoint of mean change in pain at 12 months

Pre-Specified Exploratory Efficacy Outcome

LS Mean Change in Low Back Pain from Baseline - Entire Study (n=404)

Rexlemestrocel-L reduces pain durably through 36 months, addition of HA enhances the effect



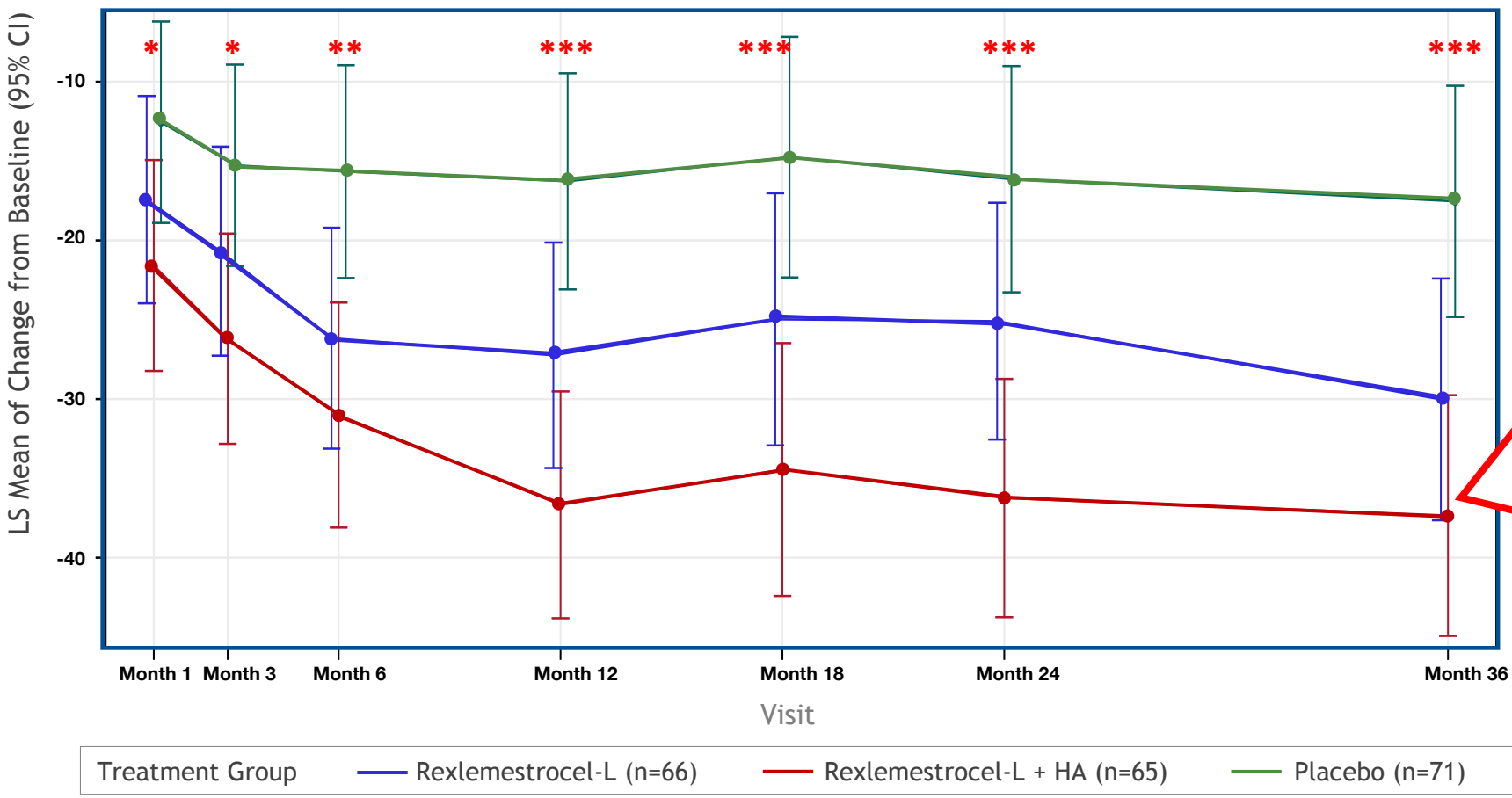
All Subjects
Rexlemestrocel-L+HA demonstrated reductions in pain at 12 and 24 months across entire study population

Nominal p-value (not adjusted for multiplicity) * = < **0.05** MPC+HA vs. Placebo

Pre-Specified Exploratory Efficacy Outcome

LS Mean VAS Change in Low Back Pain from Baseline – Pre-specified Subgroup of Subjects (n=202) with Duration CLBP < Median (68 months)

Effects of Rexlemestrocel-L are maximal in subjects with shorter duration of low back pain, addition of HA enhances the effect



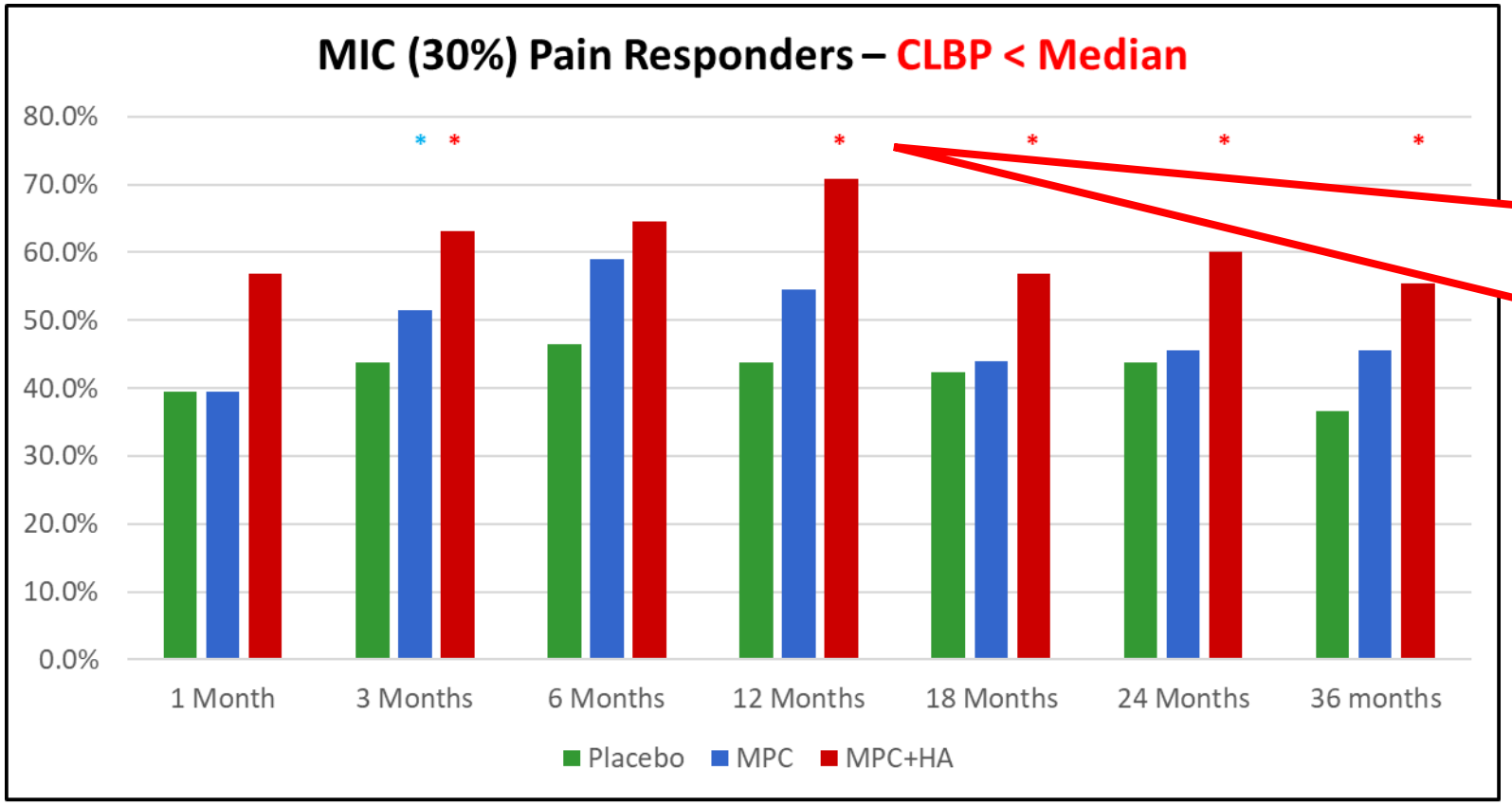
- **LS mean difference between Rex+HA and control of -20.4 at 12 months**
- ***FDA has agreed to this as the primary endpoint for the second Phase 3 trial***
- ***FDA has agreed to this enriched patient population for second Phase 3 trial***

Nominal p-values (not adjusted for multiplicity) * = p < 0.05; ** = p < 0.01; *** = p < 0.001 MPC+HA vs. Placebo

Pre-Specified Exploratory Efficacy Outcome: 30% Reduction Pain Responders

Pre-specified Subgroup of Subjects (n=202) with Duration CLBP < Median (68 months)

Rexlemestrocel-L effects durable through 12 months, addition of HA enhances the effect and extends durability through 36 months

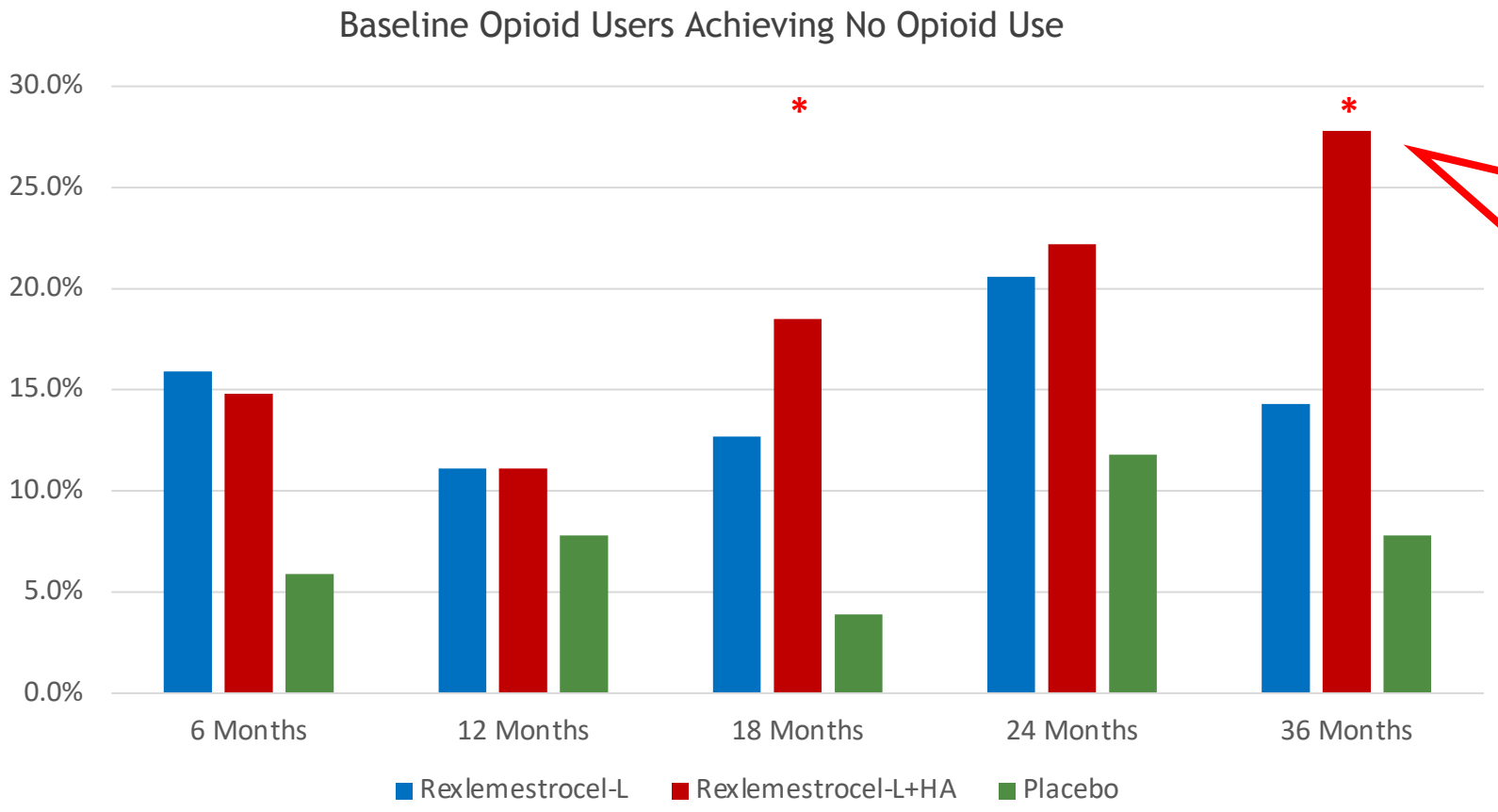


- **70.8% of MPC+HA subjects compared to 43.7% of placebo control subjects achieved at least a 30% reduction in pain at 12 months**
- ***FDA has agreed to this enriched patient population for second Phase 3 trial***

Nominal p-value (not adjusted for multiplicity) * = < **0.05** MPC+HA vs. Placebo

Pre-Specified Exploratory Efficacy Outcome - Cessation of Opioid Use

Rexlemestrocel-L + HA Associated with Greater Proportions of Subjects Ceasing Opioid Use Through 36 Months



Baseline Opioid Users

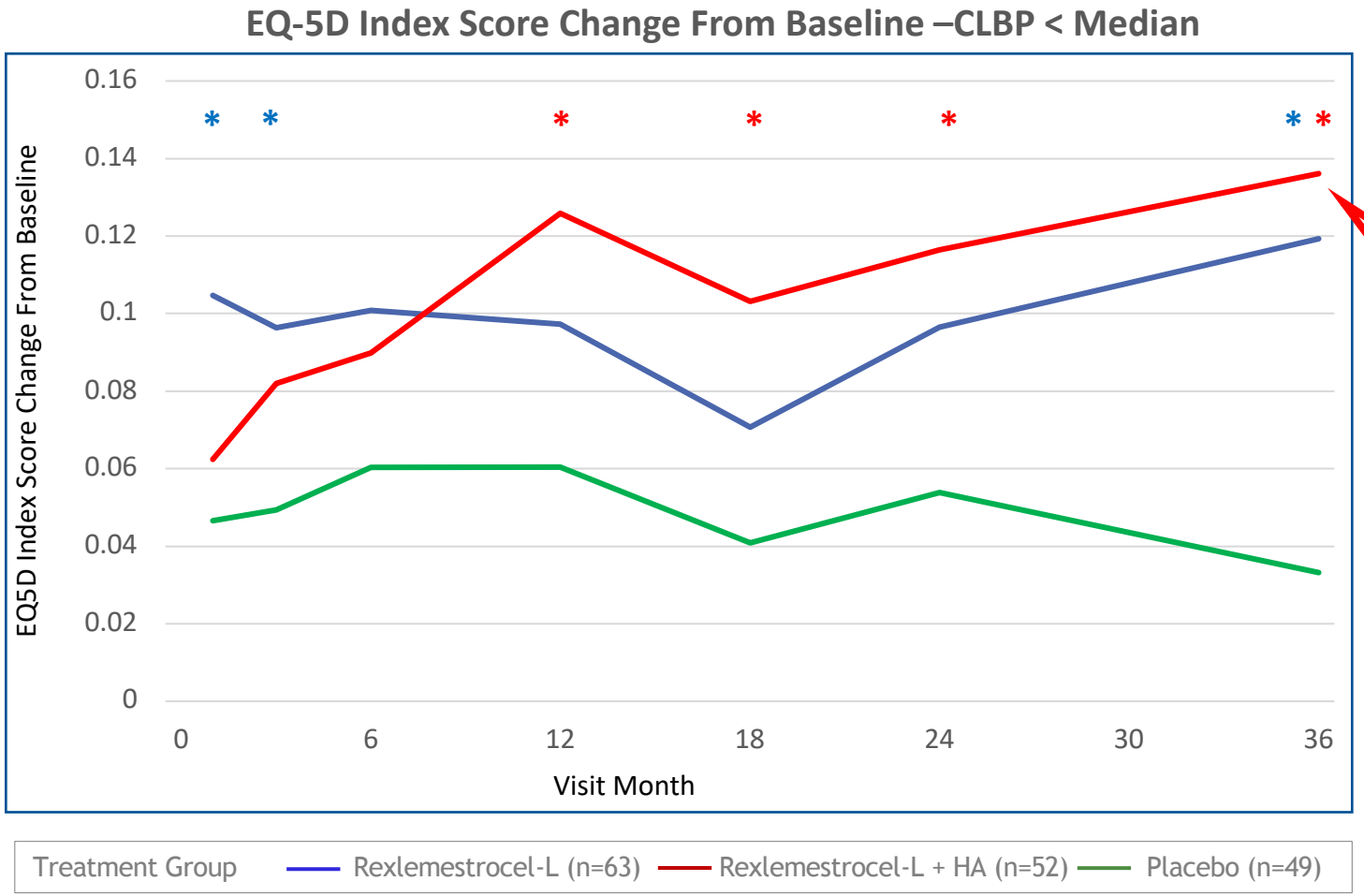
- **Subjects were instructed not to change their pain medication usage during the study**
- **However, Rexlemestrocel-L+HA resulted in a greater proportion of baseline opioid users ceasing opioid use at 18 and 36 months compared with controls**
- **At 36 months, 27.8% of Rexlemestrocel-L+HA baseline opioid users were no longer using opioids compared to 7.8% of placebo control subjects**

Nominal p-value (not adjusted for multiplicity) * = < **0.05** MPC+HA vs. Placebo

Pre-Specified Exploratory Efficacy Outcome on Quality Life Limitations Associated with DDD

LS Mean Change in Quality of Life (EQ-5D) from Baseline – Pre-specified Subgroup of Subjects (n=202) with Duration CLBP < Median (68 **months**)

Rexlemestrocel-L effects durable through 36 months, addition of HA enhances the effect



EQ-5D Index score assesses a subject's quality of life, including mobility, self-care, usual activities (e.g. work, study, housework, family or leisure activities), pain/discomfort and anxiety/depressions

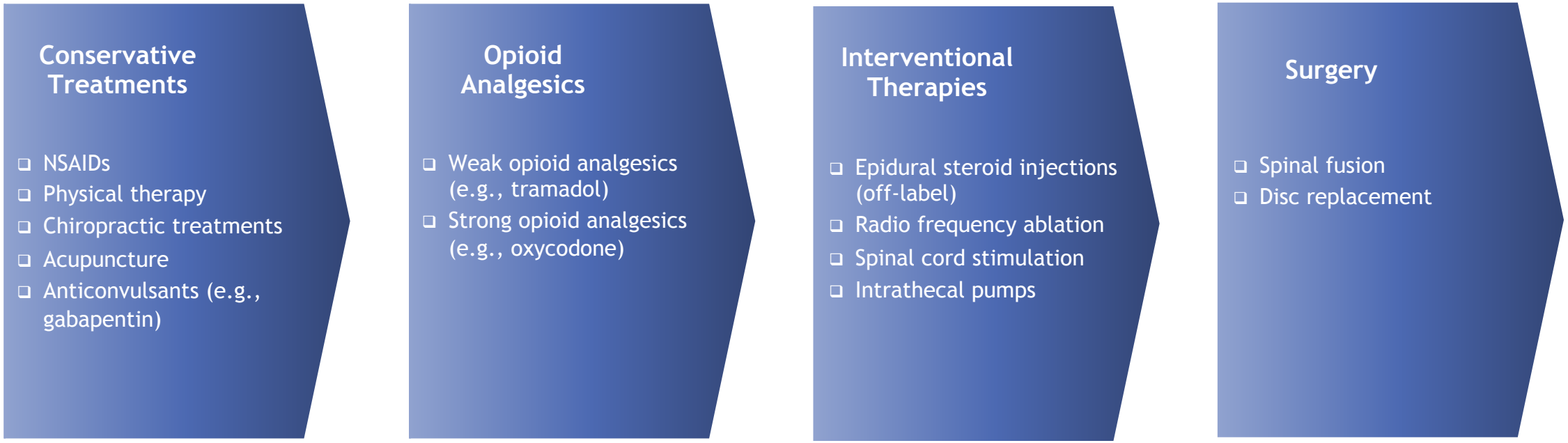
- **Rexlemestrocel-L+HA demonstrated 2 to 3 times the improvement in quality of life assessment, measured by EQ-5D Index score, compared to control at 12, 18, 24 and 36 months**
- ***FDA has agreed to this enriched patient population for second Phase 3 trial***

Nominal p-value (not adjusted for multiplicity) * = < **0.05** MPC+HA vs. Placebo; * = < **0.05** MPC vs. Placebo

The Patient Treatment Journey

Rexlemestrocel-L has Potential to be First-Line in Choice for Treatment of Discogenic CLBP Refractory to Conservative Treatment

Rexlemestrocel-L targeting moderate-to-severe CLBP



Questions