

Functional outcomes of intensive rehabilitation versus fusion surgery among patients with low back pain from lumbar spine degenerative disease: a systematic review and meta-analysis

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Abstract

Objective: The aim of this study is to compare the functional outcomes of intensive rehabilitation and lumbar spine fusion surgery among patients with chronic low back pain from lumbar spine degenerative disease.

Methods: We did a systematic search of clinical trials on the topic followed by a meta-analysis using random effects model. The functional outcomes that were compared include Oswestry Disability Index score, improvement in low back pain and leg pain, as well as overall patient outcome.

Results: Five randomized controlled trials were included in the meta-analysis. There was a 7.25 improvement in change in Oswestry Disability Index (95% CI 1.22-13.17; $p=0.02$; $I^2=98\%$) favoring fusion surgery. All studies showed improvement in low back pain with a VAS score change of 11.49 favoring fusion surgery (95% CI 4.48-18.50; $p=0.001$; $I^2=96\%$). There was a VAS score change of 7.2 improvement in leg pain (95% CI -8.58-22.97; $p=0.37$; $I^2=98\%$) however the effect was not significant. There was no significant difference in terms of overall patient outcome (95% CI 0.23-1.08; $p=0.08$; $I^2=78\%$).

Conclusion: Among patients with chronic low back pain, lumbar spine fusion surgery showed improvement in functional outcomes of change in disability and low back pain when compared with intensive rehabilitation. However, the two treatment options showed no differences in terms of improvement of leg pain and overall patient outcome.

Introduction

Back pain is extremely common, with over 600 million individuals afflicted, and is the leading cause of years lived with disability worldwide.¹ Low back pain is the hallmark of lumbar degenerative disease; unfortunately, it is a nonspecific complaint when trying to determine which patients will benefit most from surgery.² Initial management is mostly non-operative, but lumbar spinal fusion has been used for nearly almost a century and has shown clinical efficacy in decreasing pain and disability scores as well as giving patients the ability to return to work.² The principle of spinal fusion is to provide a biomechanically lasting interbody union, which can be accomplished with the use of different surgical approaches, implants and grafts.³ However, fusion procedures have not been effective for all patients, and the alternative is physical therapy and rehabilitation.

Physical rehabilitation is the most common method used to apply non-operative treatment of symptoms of patient with chronic low back pain. Therapeutic protocols may include the use of modalities for pain relief, bracing, exercise, ultrasound, electrical stimulation, and activity modification. Physical rehabilitation is recommended to reduce pain, to restore range of motion and function, and to strengthen and stabilize the spine, and restore mobility of the neural tissue.^{4,5} In low- and middle-income countries where the costs of spinal implants could be prohibitive for the majority of patients with chronic low back pain, this study becomes relevant in determining whether intensive rehabilitation may become a reasonable option.

In randomized controlled trials (RCTs) by Brox and coworkers,⁶ Fairbank and coworkers,⁷ and Mannion and coworkers,⁴ there were no statistically significant differences between treatment groups randomized to either lumbar fusion surgery or cognitive intervention and exercises. In contrast, the RCTs by Moller and colleagues⁸ and Fritzel and colleagues⁹ showed that the patients who were randomized to the surgical group had better outcomes than their non-surgical counterparts. For clinicians who deliberate and ruminate on these two diverging treatment options, it becomes imperative to clarify the weights of evidences in a meta-analysis.

Materials And Methods

Search Strategy and Selection Criteria

We reviewed articles on the topic that were published between January 2000 and June 2020 in PubMed, the Cochrane Central Registry of Clinical Trials and EMBASE. The keywords used were "chronic low back pain," "lumbar spine," "degenerative disease," "spinal fusion," "lumbar fusion," "surgical stabilization," "physical therapy," and "rehabilitation." The search was limited to human subjects in a prospective, randomized controlled study design. An effort was made to search for grey literatures. RCTs comparing the outcome between groups of patients with chronic low back pain from degenerative disc disease or spondylosis with or without spondylolisthesis who were treated with fusion surgery or rehabilitation, and with random allocation between groups, were considered eligible for inclusion in this meta-analysis. We excluded trials that involved patients with low back pain due to fracture, metastasis, and inflammation. We also excluded trials that compared one form of surgery versus other types of operative intervention.

Study Selection and Reporting

All included articles were independently screened and assessed for validity and eligibility of studies. Appraisal was done to minimize bias using Cochrane Methodological risk assessment tool. The following data were extracted from each of the included trials: author, year of publication, type of population, study design, sample size, duration of study, intervention, comparator, study outcomes, location of population and study outcomes. Our report followed the generally accepted guideline that is the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).

Statistical Analysis

Data were extracted from tables and from the associated text describing the outcomes before and after treatment. The functional outcomes were pretreatment and posttreatment differences based on Oswestry Disability Index (ODI), low back pain or leg pain determined through the Visual Analog Scale (VAS) score, and overall patient outcome. The homogeneity of ORs was tested using Cochran's Q statistics. If homogeneity was rejected at the 0.1 level, then the ORs were treated using the random effects model, with the presumption that there were multiple potential sources of heterogeneity being present in the studies that were included. The overall odds ratio (OR) was computed using the Cochran-Mantel-Haenszel method. Meta-analysis results were presented as mean difference (MD) and standard deviations (SD), with 95% confidence intervals (CI), and graphically presented as forest plots. Inverse variance method was used to calculate estimates for continuous variables. Review Manager version 5.4 was the software used for the analyses.

Results

Search Results

The search revealed 220 articles from database search and 15 articles from bibliography search. After duplicates and non-RCTs have been excluded, 61 articles were screened and full-text articles were reviewed. Of the 11 screened-in articles, 6 were further excluded because they different outcome interest and similarity in patients involved. Five studies fulfilled eligibility criteria and were analyzed after full-text systematic review. *Figure 1* shows the flow of selection process while *Table 1* summarizes the characteristics of the included studies.

Study Characteristics

The 5 studies included were published from 2000-2020 involving 1288 patients. Studies took place in United Kingdom, Sweden and Norway. All of the studies involved patients with chronic low back pain. All studies had lumbar fusion as main surgical approach described as posterolateral fusion compared with rehabilitation and physical therapy. Nonsurgical approach which includes rehabilitation, physical therapy and exercises have different programs and routines across the studies. Follow-up ranged from 1 year to 11 years. Four of the studies has a follow up period of 2 years. All of the studies used the ODI for the changes in disability. Four studies used VAS to measure changes in pain. Most of the studies were single blinded. There were no significant differences in baseline characteristics of groups being compared and all studies reported randomization. Four studies had adequate follow-up. The study by Mannion and colleagues have 45% dropout on their long term follow up of 11 years. *Table 2* gives a summary of the risk of bias assessment for included studies.

Functional Outcomes

Oswestry Disability Index

The Forest plot (Figure 2) shows the mean difference in change in ODI between the Lumbar Spine Fusion Surgery and Rehabilitation groups. All studies showed improvement on change in ODI favoring surgery. There was a 7.25 improvement in change in ODI (95% CI 1.22-13.17; $p=0.02$; $I^2=98\%$)

The sensitivity analysis (Figure 2A) shows the mean difference in change in ODI between the Lumbar Spine Fusion Surgery and Rehabilitation groups in 2 years. Studies by Mannion and Brox have 11 years and 1 year follow-up respectively. All studies showed improvement in change in ODI after 2 years, favoring surgery. There was a 10.52 improvement in change in ODI (95% CI 2.45-18.58; $p=0.01$; $I^2=99\%$)

Low Back Pain

The subgroup analysis (Figure 3) shows the mean difference in improvement in low back pain between the Lumbar Spine Fusion Surgery and Rehabilitation groups. All studies showed improvement in low back pain favoring surgery. There was an 11.49 improvement in VAS score for low back pain (95% CI 4.48-18.50; $p 0.001$; $I^2=96\%$)

Leg Pain

The subgroup analysis (Figure 4) shows the mean difference in improvement in leg pain between the Lumbar Spine Fusion Surgery and Rehabilitation groups. There was a 7.2 improvement in VAS score for leg pain (95% CI -8.58-22.97; $p=0.37$; $I^2=98\%$); however, the effect was not significant.

Overall Patient Outcome

The subgroup analysis (Figure 5) shows the odds ratio in overall patient outcome between the Lumbar Spine Fusion Surgery and Rehabilitation groups. There was no significant difference in the overall patient outcome (95% CI 0.23-1.08; $p=0.08$; $I^2=78\%$).

Discussion

This meta-analysis of five RCTs showed significant improvement in the change in disability index scores and low back pain among patients who underwent surgery compared to those who underwent intensive rehabilitation. However, there were no significant differences in the improvement of leg pain and overall patient outcome.

The Forest plot on change in the disability score (Figure 2) shows the rather high heterogeneity of $I^2=98\%$. An important factor that may be considered is the duration of evaluation. Duration of follow-up may confound the assessment for disability and pain. A sensitivity analysis was done to include only the studies that followed up the patients after 2 years. A high heterogeneity is noted after sensitivity analysis wherein other factors may be considered such as the differences on the plan for rehabilitation and surgical technique. Studies of this kind of treatment wherein it is difficult to blind the patients and the caregiver were prone to performance bias.

Pain is subjective hence a validated tool to quantify pain was used in the included studies. There was significant improvement in pain scores for low back pain following surgery. For leg pain however, there was no significant improvement in the pain scores. The overall patient outcome measured in the study is equivalent to the patient's subjective perception of improvement. There was no statistical difference between lumbar spine fusion surgery and rehabilitation in terms of overall patient outcome.

The results of our meta-analysis corroborate that of Chou and colleagues¹⁰ wherein surgery was found to be equivalent to an intense rehabilitation program for patients with low-back pain and lumbar spondylolisthesis. The argument for fusion surgery is stronger in patients with lumbar degenerative disease presenting mostly as stenosis with evidence of instability. The landmark Spine Patient Outcomes Research Trial (SPORT) with randomized ($n = 304$) and observational ($n = 303$) patients who have lumbar spondylolisthesis, it was concluded after as-treated analysis that surgery was better in each outcome measure at 2-, 4-, and 8-year follow-up.¹¹⁻¹³

Given the overall findings, lumbar spine fusion surgery can somehow provide more benefit in lowering disability and low back pain among patients with chronic low back pain from degenerative causes like spondylolisthesis. Intensive rehabilitation presents as a respectable alternative for patients who does not want to undergo surgery because it appears equivalent to lumbar spinal fusion surgery when it comes to improving leg pain and overall patient outcome. Considering costs and accessibility, intensive rehabilitation can also be offered to patients who refuse to undergo surgery and who have comorbid illnesses for which general anesthesia and surgery are contraindicated.

Conclusion

Among patients with chronic low back pain, lumbar spine fusion surgery showed improvement in functional outcomes of change in disability and low back pain when compared with intensive rehabilitation. However, the two treatment options showed no differences in terms of improvement of leg pain and overall patient outcome.

Declarations

Conflict of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Tables

Table 1

Study	Randomised patients (surgery/rehabilitation or physical therapy)	Inter-vention	Follow-up interval	Inclusion criteria	Setting	Tool	Endpoints
Fairbank 2005	176/173	Intensive rehabilitation/ Spinal Fusion surgery	2 years	Aged between 18 and 55, with more than a 12 month history of chronic low back pain (with or without referred pain) and irrespective of whether they had had previous root decompression or discectomy	United Kingdom	Oswestry disability index and the shuttle walking test, SF-36 questionnaire	No difference
Fritzell 2001	72/222	3 Spinal Fusion Surgery (Posterolateral Fusion, Variable Screw Placement, Add Interbody Bone Graft/Physical Therapy (Nonsurgical)	6 months, 12 months, 2 years	Aged 25–65 years and of both sexes with severe CLBP may have Previous spine surgery except for successful removal of a herniated disc more than 2 years before entering the study and with no persistent nerve root symptoms	Sweden	Oswestry disability index, VAS, GFS and Zung Depression Scale	Decrease in disability, pain, depression and overall result was significantly greater in the surgical group
Mannion 2013	242/231	Spinal Fusion Surgery/ multidisciplinary cognitive-behavioral and exercise rehabilitation	2 years, 11 years	Aged 18–55years (UK), 25–60 y (Norway); LBP duration of at least 1 year	United Kingdom and Norway	Oswestry disability index score	no statistically or clinically significant differences between treatment groups for ODI scores
Brox 2003	35/26	Lumbar Fusion Surgery/ Cognitive Intervention and Exercises	1 year	Age 25–60 years. Low back pain duration for at least 1 year	Norway	Oswestry disability index score	equal improvement in patients with chronic low back pain and disc degeneration randomized to cognitive intervention and exercises, or lumbar fusion
Moller 2000	77/34	Spinal Fusion Surgery/Exercise Program	1 and 2 years	lumbar isthmic spondylolisthesis of any grade, at least 1 year of low back pain or sciatica, and a severely restricted functional ability in individuals 18 to 55 years of age	Sweden	Disability Rating Index (DRI)	Surgical management of adult isthmic spondylolisthesis improves function and relieves pain more efficiently than an exercise program

Table 2

Cochrane Methodological Quality Assessment					
Randomization sequence generation	Low	Low	Low	Low	Low
Allocation concealment	Low	Low	High	Low	Low
Blinding	High	High	High	High	High
Incomplete data	Low	Low	High	Low	Low
Selective reporting	Low	Low	Low	Low	Low
Overall RoB	Low	Low	Low	Low	Low
Remarks	High risk for Performance bias	High risk for Performance Bias	High risk for Selection, Performanc and Attrition Bias >Risk for Reporting bias	High risk for Performance Bias	High risk for detection and performance bias

Figures

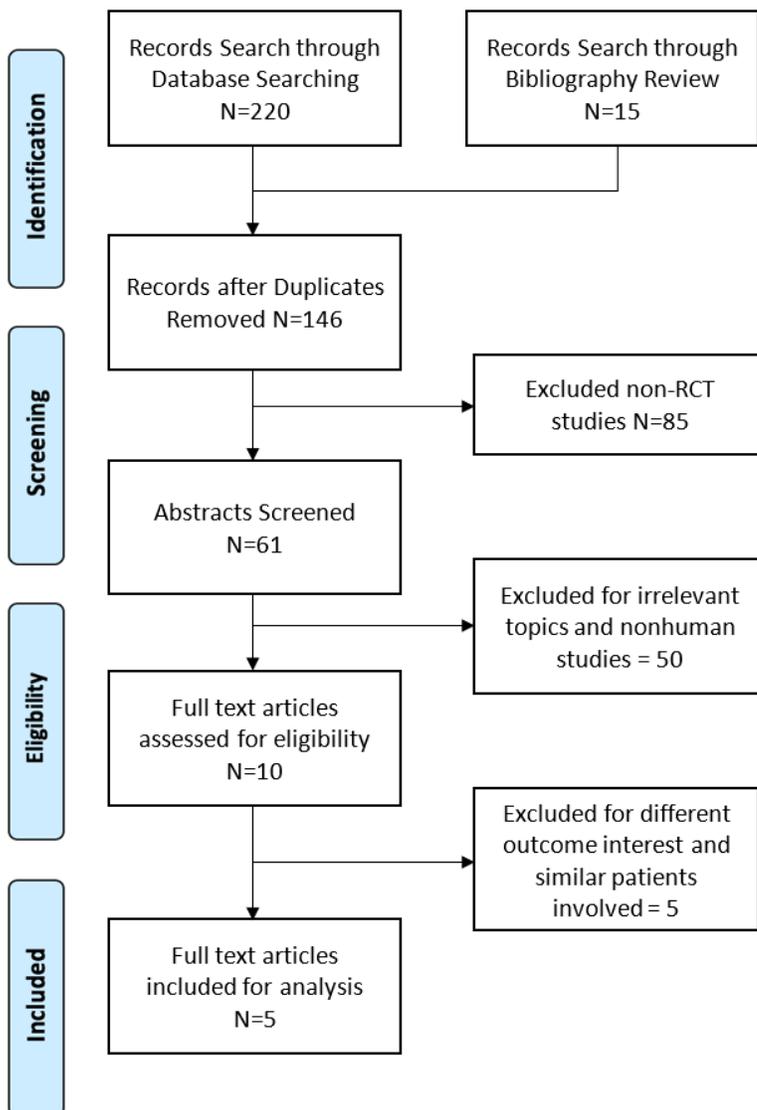


Figure 1

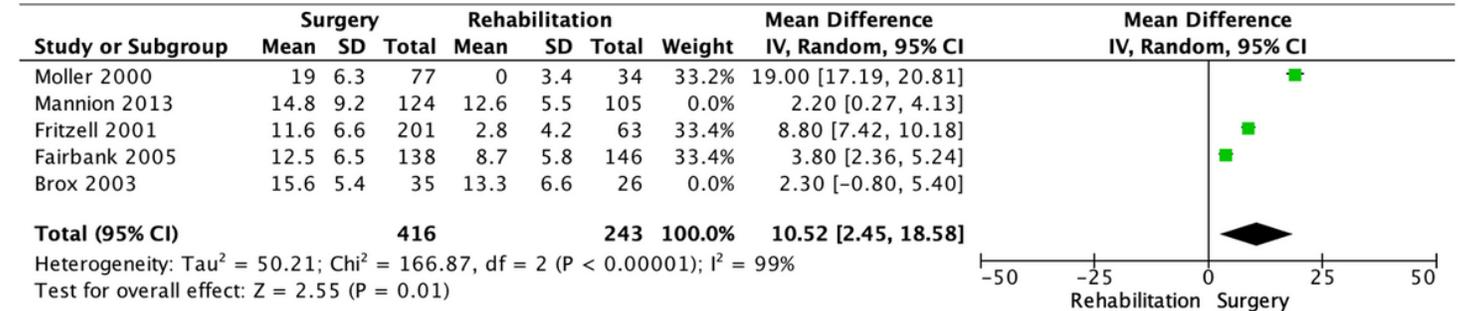
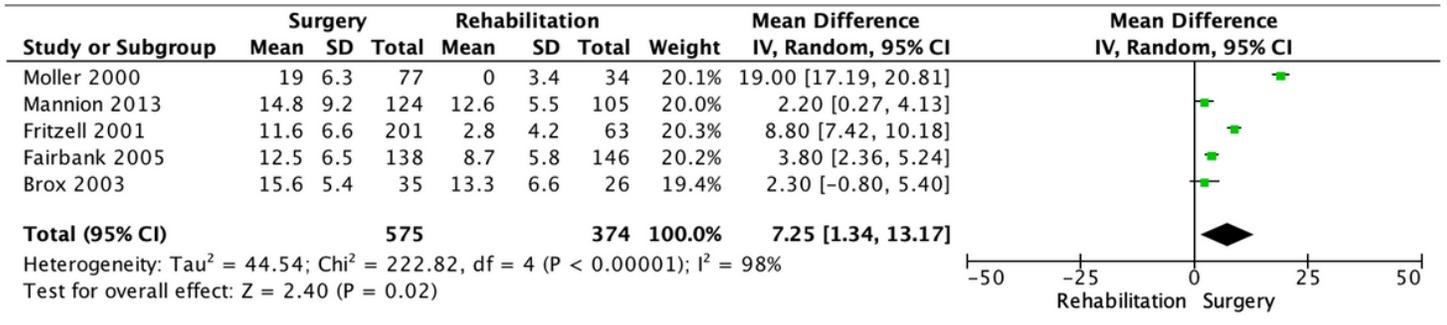


Figure 2

Constructed Forest Plot among patients with Chronic Low Back Pain using Random Effects Model Comparator 01: Lumbar Spine Fusion Surgery and Rehabilitation Outcome 01: change in Oswestry Disability Index A. Sensitivity analysis among patients with Chronic Low Back Pain using Random Effects Model Comparator 01: Lumbar Spine Fusion Surgery and Rehabilitation Outcome 01: change in Oswestry Disability Index in 2 years

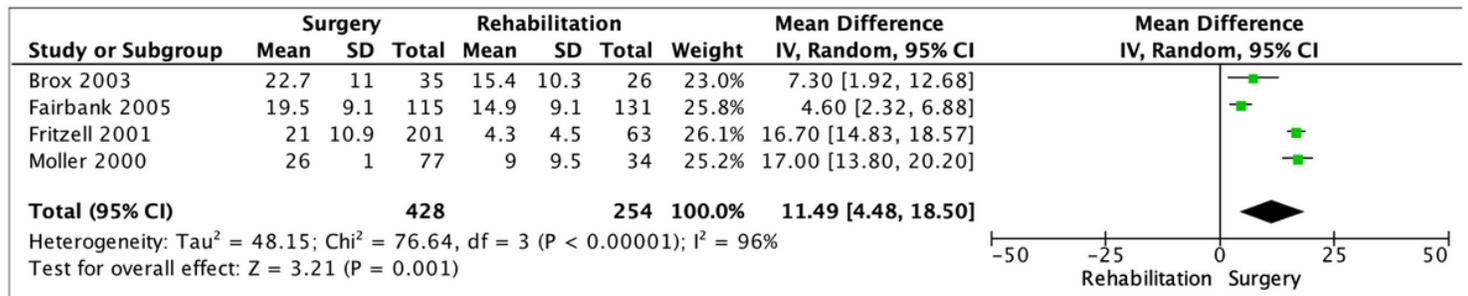


Figure 3

Subgroup analysis of Improvement in Low Back Pain using Random Effects Model between Lumbar Spine Fusion Surgery and Rehabilitation Comparator 01: Lumbar Spine Fusion Surgery and Rehabilitation Outcome 02: Improvement in Low Back Pain

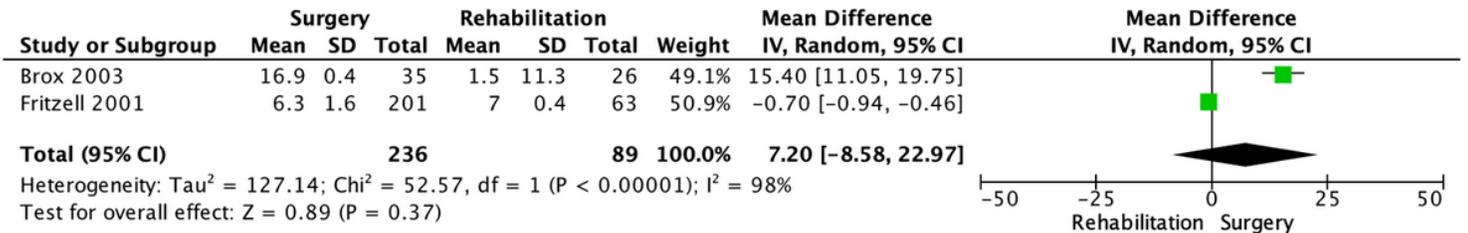


Figure 4

Subgroup analysis of Improvement in Leg Pain using Random Effects Model between Lumbar Spine Fusion Surgery and Rehabilitation Comparator 01: Lumbar Spine Fusion Surgery and Rehabilitation Outcome 03: Improvement in Leg Pain

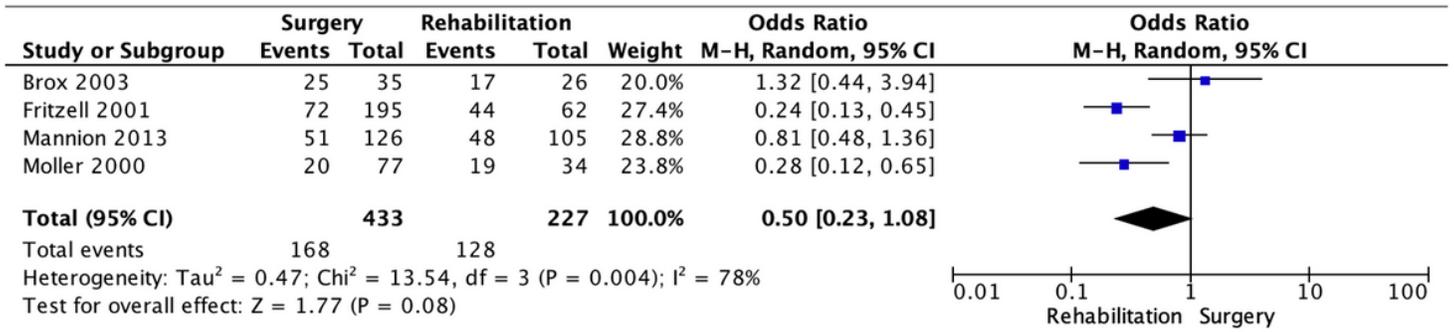


Figure 5

Subgroup analysis of Overall Patient Outcome using Random Effects Model between Lumbar Spine Fusion Surgery and Rehabilitation
 Comparator 01: Lumbar Spine Fusion Surgery and Rehabilitation Outcome 04: Overall Patient Outcome