

# **Functional Outcome after Decompression and Instrumented Arthrodesis in Degenerative Lumbar Spinal Stenosis: Factors Influencing Unsuccessful Outcome Change**

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**Objective:** To determine functional outcome after decompressive laminectomy and instrumented arthrodesis in patients with degenerative lumbar spinal stenosis and identify predictors of failed clinical outcome in these patients.

**Material and Method:** A retrospective cohort data were collected from January 1999 to February 2004. Degenerative lumbar spinal stenosis patients who had decompressive laminectomy and instrumented fusion with pedicular screw system and completed at least 2 years follow-up were enrolled in the present study. Outcomes included Oswestry Disability Index (ODI), Roland Morris score and patient satisfaction. Factors evaluated as outcome variables were age, gender, onset, patient income, associated diseases, smoking, diagnosis of spondylolisthesis or scoliosis, number of levels of instrumentation and presence of S1 fusion. Univariate analysis for factors influencing failed clinical outcome used Chi-square and Fisher exact test and multivariate analysis used the logistic regression.

**Results:** One-hundred and fifty-eight patients were included in the present study. Mean follow-up was 2.64 years (range, 2-5 years). The mean age of the patients at the time of surgery was 60.3 years (range, 34-87 years) and 129 cases (81.7%) were female. According to the US FDA, the criteria of significant successful clinical outcome change is reduction of ODI at least 15%, the proportion of patients reporting significant successful clinical outcome change was 63.9%. Multivariate analysis identified age > 65 years, onset > 24 months and number of levels of instrumentation > 4 as the factors of failed clinical outcome change ( $p < 0.05$ ).

**Conclusion:** Decompression and instrumented arthrodesis in degenerative lumbar spinal stenosis gained satisfactory functional outcome. Older age, prolonged onset and long level of instrumentation were the factors of failed clinical outcome change.

**Keywords:** Lumbar spinal stenosis, Surgery, Arthrodesis, Instrumentation, Outcome, Predictors

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Degenerative lumbar spinal stenosis is a major cause of low back pain and leg discomfort in the elderly<sup>(1)</sup>. Most of these patients can be treated by non-operative management, although a specific group of patients need to be operated upon. The choices of surgery include decompression alone, decompression and arthrodesis with or without instrumentation. The

indications of decompression surgery for patients with clinical symptoms of spinal stenosis and a confirmed imaging study are well defined. The clinical success rate of decompression is between 75-90%<sup>(2)</sup>. The indications for the addition of an arthrodesis with or without instrumentation following decompressive laminectomy remain controversial<sup>(2,3)</sup>.

The goals of instrumentation are to augment fusion, increase the rate and degree of fusion, correct deformities, provide initial stability to hasten recovery, and lead to less postoperative bracing and earlier return to activities<sup>(3,4)</sup>. Various systems for stabilization have been described using wire, hook and pedicle

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screw-based constructs. The pedicle screw fixation is the most popular system in instrumented arthrodesis in the lumbar spine. The relative indications for the addition of instrumentation following decompression of spinal stenosis and arthrodesis are deformity correction, multiple level fusion, recurrent stenosis with iatrogenic instability, degenerative spondylolisthesis, adjacent segment stenosis with instability, transitional motion  $> 4$  mm in flexion/extension and angular motion  $> 10$  mm compared with adjacent levels and revision for symptomatic pseudarthrosis<sup>(3,4)</sup>.

In the relevant literature, a few reports have been published on the results of instrumented arthrodesis in lumbar spinal stenosis patients. Usually they present on pain reduction, fusion rate or patient satisfaction, but the functional outcomes are less well-described, especially in the large number of cases<sup>(5)</sup>.

The present study aimed to analyze the outcomes in terms of functional results of instrumented arthrodesis and to identify the predictive factors that affect the functional outcomes.

## Material and Method

### *Patients*

All patients who entered into the present study had clinical and radiographic evidence of degenerative lumbar spinal stenosis and limitation of their functional activities. All patients had back, buttock and/or leg pain and radiographic documents of central or lateral canal stenosis on computed tomography scan, CT-myelography or magnetic resonance imaging. The data was collected from the patients who underwent decompressive laminectomy and instrumented arthrodesis at Ramathibodi Hospital from January 1999 until February 2004. In Ramathibodi Hospital, all cases of spinal arthrodesis have been augmented with instrumentation. The authors included only the patients that required arthrodesis in the present series. The indications of arthrodesis were based on two factors. Firstly, preoperative instability of the spine included translation  $> 4$  mm or  $> 10$  degrees of angular motion on lateral radiographs, degenerative spondylolisthesis. In degenerative scoliosis cases, fusion was required in painful, large, flexible or progressive curves, the patients who had sagittal imbalance or radicular symptoms in the concave side also needed the correction and fusion. The second consideration is the intraoperative spinal instability. The patients, who have undergone wide decompression that required multilevel laminectomy, excessive facet joint resection ( $> 50\%$  bilateral or

one-side total facetectomy) or pars removal for adequate decompression, needed the instrumented arthrodesis to stabilize the spine. The authors excluded the patients who had undergone previous spinal surgery and who could not answer the questionnaires because of cognitive impairment.

### *Surgical technique*

The surgery started with pedicular screw fixation at the levels to be fused. Then, wide decompression was done through a laminectomy, lateral recesses were decompressed by medial facetectomy and each nerve root was decompressed along its passage through the neural foramen. Decompression took place at those levels where the neural structures were compressed, as confirmed by radiography and symptoms. The pedicular plate systems were then placed to stabilize the spinal column and to correct the sagittal and coronal alignment of the lumbar spine. In Ramathibodi Hospital, the authors used the Ramathibodi Spinal System (RSS) which is the pedicular plate system that has been used for spinal stabilization in many spinal diseases for a long period of time. The efficacy of this system has been published in the literature<sup>(6-9)</sup>. In the cases where there was spondylolisthesis, the authors tried to reduce this as much as possible. Arthrodesis was completed through the placement of local bone grafts underneath the plate in all cases, in order to achieve posterolateral fusion.

### *Baseline characteristics*

Preoperative variables were obtained from a prospective database including age, sex, duration of symptoms, economic status, smoking, associated diseases, visual analog pain scores (VAS), walking capacity, working status, Oswestry Disability Index (ODI) and Roland Morris score. The diagnosis of spondylolisthesis and de novo/degenerative scoliosis was made when the slip and Cobb angle were more than 5 mm and 10 degrees, respectively. The number of levels of instrumentation was also recorded as one of the predictors.

### *Data collection*

Follow-up data was administrated by an interviewer or outcome assessor who was not involved in the patient's care and blinded to the outcome abstracted from medical records. The questionnaires included items on VAS, walking capacity, working status, Oswestry Disability Index

(ODI), Roland Morris score and patient satisfaction. The authors classified the patient satisfaction into 3 grades; good, fair and poor. The collection was obtained at the time of follow-up at 3 months, 6 months, 1 year and then annually afterward. In addition, any complications and required re-operation were also recorded.

### **Analyses**

The primary outcomes were the Oswestry Disability Index (ODI) and patient satisfaction after surgery. The authors used a reduction of ODI by at least 15% to indicate a successful clinical outcome change according to the criteria of the FDA US<sup>(10)</sup>. The patients who had a reduction of ODI less than 15% were indicated as a failed clinical outcome change.

Associations between potential predictors and dependent outcome were assessed. Univariate analysis for factors influencing failed clinical outcome change (reduction of ODI less than 15%) used Chi-square and Fisher exact test. Independent variables associated with outcomes at p-value < 0.15 were retained for multivariate analysis using the logistic regression. Analysis was performed with STATA 9.0 (Stata Corp. Texas).

### **Results**

Two hundred and forty patients underwent decompressive laminectomy and instrumented fusion during the period of the present study. Eighty-two patients were withdrawn from the present study because of loss of follow-up and incomplete data collection for analysis. One hundred and fifty-eight patients (66%) who were eligible to complete at least 2 years follow-up were enrolled in the present study. The mean follow-up was 2.64 years (range 2-5 years). The mean age of these patients at the time of surgery was 60.3 years (range 34-87 years) and 129 cases (81.7%) were female. Fifty-four patients (34.18%) had co-morbidities such as cardiovascular problems and arthritis of the lower extremity joints.

Mean preoperative and postoperative ODI and Roland-Morris scores are shown in Table 1. The proportion of patients reporting a significant successful clinical outcome change (using a reduction of ODI at least 15%) was 63.9%. Ninety-four percent of patients reported being "good" with the results of surgery, whereas 5.96% reported "fair or poor" results at the last follow-up.

Re-operation in the present study was observed in 5 cases at final follow-up. Two patients

developed junctional degeneration at the adjacent cranial level and were re-operated on with extended decompression and arthrodesis with instrumentation. Two cases had second surgery because of an implant related problem. One patient had symptomatic prominent instrumentation and 1 patient suffered from a painful broken plate. They underwent revision of the pedicle screw system and removal of the broken instrument, respectively. The last case had a deep wound infection that required open drainage and removal of instrumentation.

Dural tear occurred intra-operatively in 2 patients. All were repaired with non-absorbable suture and no further complication was found. There were two cases of postoperative neurological deficit at ankle dorsi-flexors. One case had trivial recovery of the motor power but still needed the ankle-foot orthosis for better ambulation and 1 patient had nearly complete recovery of the weakness.

### **Predictors of outcome**

In univariate analysis, gender and economic status of the patients were not associated with the failed clinical outcome change. The older age (> 65 yrs) and longer instrumentation (> 4 levels) were associated with worse outcome ( $p = 0.049$  and  $p = 0.037$ , respectively). No statistically significant differences in outcome were noted among patients who had associated diseases or history of smoking or diagnosis of concomitant spondylolisthesis or degenerative scoliosis. The prolonged onset and independent status of patients tended to be associated with a worse outcome, but it was not statistically significant ( $p = 0.073$  and  $p = 0.063$  respectively). The presence of lumbosacral fusion was not associated with the worse outcome. The description of these factors is revealed in Table 2.

In multivariate analysis using logistic regression analysis, the associations of age at the time of surgery, onset of the disease and number of levels

**Table 1.** Mean ODI and Roland-Morris scores at pre-operation and postoperation

Functional outcome	Preoperative mean (SD)	Postoperative mean (SD)
ODI	54.59 (19.75)	25.93 (16.14)
Roland-Morris scores	16.25 (5.4)	9.17 (4.8)

ODI = Oswestry Disability Index

of instrumentation with the outcome had statistical significance. The odds ratios and 95% confidence intervals are shown in Table 3.

**Table 2.** Description of patients' characteristics in successful and failed clinical outcome change

Factors	Successful n = 101	Failed n (%)
Sex		
Male	15 (14.85)	14 (24.56)
Female	86 (85.15)	43 (75.44)
Age at time of surgery; year		
≤ 65	77 (76.24)	35 (61.40)
> 65	24 (23.76)	22 (38.60)
Onset of diseases; months		
≤ 24	61 (60.40)	25 (45.45)
> 24	40 (39.60)	30 (54.55)
Income; Baht		
0-5,000	84 (87.50)	44 (84.62)
5,001-10,000	6 (6.25)	4 (7.69)
10,001-50,000	5 (5.21)	1 (1.92)
> 50,000	1 (1.04)	3 (5.77)
Associated diseases		
Absent	68 (67.33)	36 (63.16)
Present	33 (32.67)	21 (36.84)
Smoking		
No	94 (93.07)	53 (92.98)
Yes	7 (6.93)	4 (7.02)
Work status		
Working	38 (38.0)	23 (40.35)
Household	10 (10.00)	5 (8.77)
Partially dependent	32 (32.0)	26 (45.61)
Totally dependent	20 (20.0)	3 (5.26)
Diagnosis		
Spinal stenosis	72 (71.29)	37 (64.91)
Spondylolisthesis	22 (21.78)	10 (17.54)
Degenerative scoliosis	7 (6.93)	10 (17.54)
No. of level of instrumentation		
1-4	80 (80.0)	37 (64.91)
> 4	20 (20.0)	20 (35.09)
S1 fusion		
No	86 (86.0)	50 (87.72)
Yes	14 (14.0)	7 (12.28)

## Discussion

Surgery for degenerative lumbar spinal stenosis is increasing because of more awareness and availability of advanced imaging tests in this condition. There are different possible forms of surgery that remain controversial. The choices mostly depend on the progress of the disease and experience of the surgeons. The operative procedures are based on decompression of the neural structures, which are mechanically compressed by degenerative tissues and stabilization of the spine in the case of deformity or instability using arthrodesis with or without instrumentation. The pedicular screw system in this surgery has been used widely for augmentation of the fusion procedures. However, the results of instrumented arthrodesis in this condition were less well defined in the large series. Most of the lumbar spinal stenosis patients in current literature show short and long term outcomes have been operated on with decompression alone or decompression with non-instrumented fusion<sup>[1,11-15]</sup>. The group of patients with a concomitant instrumented arthrodesis in lumbar spinal stenosis usually was small and was presented in the subgroup analysis of the studies. The authors reviewed the outcomes in those studies as shown in Table 4. It was difficult to compare the results between these studies because there were many differences among the enrolled population and outcome measures.

There were only two studies in which all the enrolled patients were operated on with decompression and instrumented fusion. Hansraj KK et al<sup>[23]</sup> reported 54 complex lumbar spinal stenosis patients (defined as associated previous surgery with evidence of radiographic instability, junctional stenosis, radiographic evidence of instability, degenerative spondylolisthesis greater than grade I with instability and degenerative scoliosis with a curve greater than 20°). This study did not include any functional scores to measure the outcomes. They used the validated questionnaire and the results revealed improvement in pain, physical function and 96% of patients were very or somewhat satisfied with the

**Table 3.** Factors influenced failed clinical outcome change: multivariate analysis used logistic regression

Factors	Odds ratio	SE	p-value	95% CI
No. of level of instrumentation > 4 levels	2.207	0.87	0.043	1.02-4.76
Age > 65 years	2.161	0.83	0.043	1.02-4.57
Onset > 24 months	2.026	0.72	0.048	1.01-4.08

**Table 4.** The literatures reported the results of surgery in degenerative lumbar spinal stenosis. The group of patients with a concomitant instrumented arthrodesis usually was small and presented in the subgroup analysis of the studies

Literatures	Year published	Study design	No. of cases	No. of instrumented fusion	Years follow-up mean (SD)	Outcome measures	Results of instrumented fusion group
Katz JN et al <sup>(19)</sup>	1997	Prospective multi-center observational study	272	41	2 yrs	Health status, Walking capacity, Back and leg pain	No report the number of significant relief of symptom
Cornefjord M et al <sup>(20)</sup>	2000	Retrospective review	96	37	7.1 yrs (4-12.2 yrs)	Satisfaction with surgery Satisfaction Constant or daily leg and back pain	62% satisfaction
Rompe JD et al <sup>(21)</sup>	1999	Observational study	117	27	8 yrs (5-10yrs)	Walking capacity Low back pain outcome scale (Greenough and Fraser, Turner) Walking capacity	Score good to excellent = 23.8% Significant reduction in pain Significant increase walking capacity
Niggemeyer O et al <sup>(22)</sup>	1997	Meta-analysis	1,668	198 (pedicle systems)	4.7 yrs	Residual pain, Satisfaction Author's own definition rating criteria (good, fair and poor)	Unsatisfied 33.3% Good results 67% in leg/back pain
Malmivaara A et al <sup>(16)</sup>	2007	Randomized controlled trial	94	10	2 yrs	72% in neurological symptoms 69% in ability to work	ODI improved in both treatment groups (non-operative and surgical groups)
Fokter SK et al <sup>(17)</sup>	2006	Retrospective	58	20	27 months (12-54)	Walking ability Zurich Claudication Questionnaire (ZCQ) - Symptom severity - Physical function - Patient satisfaction at least 2 = Overall success	75% clinical success
Katz JN et al <sup>(18)</sup>	1999	Prospective observational study	199	30	2 yrs	Walking capacity Symptom severity Satisfaction	Not reported 75% satisfaction

operation. In a prospective clinical study of 41 multi-level lumbar spinal stenosis patients with 4 revision cases operated on by decompression and fusion using transpedicular instrumentation system and bone graft, Panagiotis ZE et al<sup>(24)</sup> found statistically significant improvement on the ODI and VAS compared to preoperative values, but they did not define the criteria of clinical significant change. Thirty-nine of 41 patients were satisfied with the outcome in this study. The present study did not enroll the re-operation cases and the number of instrumented fusion cases was larger than the other studies. The presented results found 63.9% successful clinical outcome change on the ODI according to the criteria of the FDA U.S. and 94% of patients satisfied with the surgery, which were comparable to 2 previous referred studies.

The predictors influencing the outcomes after surgery for spinal stenosis were extensively analysed in many studies, but the results were widely varied. Many authors reported many factors affecting the outcomes such as: gender, age, presence of co-morbidities or associated diseases, severity and duration of symptoms, patient self-rated health, compensation and litigation issues, prior back surgery and the number of decompressed or surgical levels<sup>(1,11-13,18,23,25,26)</sup>. The results of predisposing factors in these reports were inconsistent. The authors think that the causes were the variation of the entered population, different surgical procedures or techniques and outcome measures between each study. In almost all of these reports, the surgical techniques were decompression alone with the small number of fusion procedures. The aim of the present report was to find the predictors in patients who received decompression and instrumented fusion. In multivariate analysis, the authors found statistically significant worse results in older age, prolonged onset and patients who had more levels of instrumentation. This finding has important implications. Surgeons should discuss with the patients the prognosis and patients' expectation and the selection of number of levels to be fused should be considered before surgery.

The strength of the present study, was that the authors used a cohort data collection and evaluated the patients clinically at the time of follow-up by an interviewer who was uninformed in the treatment to avoid observer bias. Another advantage, compared to most other studies was that the authors included a relatively large sample of instrumented arthrodesis patients, so the authors could assess the predictors of outcome properly.

However, the limitations of the present study should be noted as relative short-term follow-up, no assessment in radiographs of the patients and the authors did not evaluate perception of the patients' health and psychological aspect of patients to be possible factors affecting the outcome. Thus, a comprehensive, prospective long-term study of instrumented arthrodesis in lumbar spinal stenosis may be needed in the future.

## Conclusion

The posterior decompression and pedicular screw instrumented fusion in lumbar spinal stenosis surgery gained satisfied outcomes with the accepted complication. Older age, prolonged onset and long level of instrumentation were the factors of worse outcome.

## Potential conflicts of interest

None.

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## การศึกษาผลการรักษาในและการกลับไปใช้ชีวิตหลังการผ่าตัดขยายช่องไขสันหลัง และเชื่อมกระดูกสันหลังด้วยโลหะตาม ในผู้ป่วยกระดูกสันหลังส่วนเอวตีบจากภาวะกระดูกสันหลังเสื่อม: รวมทั้งหาปัจจัยที่มีผลต่อความไม่สำเร็จของการรักษา

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**วัตถุประสงค์:** เพื่อศึกษาผลการรักษาในและการกลับไปใช้ชีวิต (functional outcome) หลังผ่าตัดขยายช่องไขสันหลัง และเชื่อมกระดูกสันหลังโดยใช้โลหะตาม ในผู้ป่วยกระดูกสันหลังส่วนเอวตีบจากภาวะกระดูกสันหลังเสื่อม และเพื่อหาปัจจัยที่มีผลทำให้ผลการรักษาไม่ดี

**วัสดุและวิธีการ:** ศึกษาคนไข้มูลที่มีการเก็บไปข้างหน้า ตั้งแต่เดือนมกราคม พ.ศ. 2542 ถึงเดือนกุมภาพันธ์ พ.ศ. 2547 ในผู้ป่วยไขสันหลังตีบจากภาวะกระดูกสันหลังเสื่อมที่ได้รับการผ่าตัดขยายช่องไขสันหลัง และเชื่อมกระดูกสันหลังด้วยโลหะตาม ที่ได้รับการติดตามการรักษาอย่างน้อย 2 ปี ผลการรักษาใช้แบบสอบถาม Oswestry Disability Index (ODI), Roland Morris score และความพึงพอใจของผู้ป่วย ปัจจัยที่อาจมีผลต่อการรักษาได้แก่ อายุ, เพศ, ระยะเวลาที่เริ่มเป็นโรค, รายได้, โรคประจำตัวอื่น ๆ, การสูบบุหรี่, การมีภาวะกระดูกสันหลังเคลื่อนหรือกระดูกสันหลังคุดร่วมด้วย, จำนวนระดับของกระดูกสันหลังที่ได้รับการผ่าตัด และการเชื่อมกระดูกลงไประดูก sacrum ศึกษาหาปัจจัยที่มีผลทำให้ผลการรักษาไม่ดี Univariate analysis ใช้ Chi-square และ Fisher exact test และใน Multivariate analysis ใช้ logistic regression

**ผลการวิจัย:** ผู้ป่วยจำนวน 158 ราย ได้รับการติดตามการรักษาเฉลี่ย 2.64 ปี มีอายุเฉลี่ยขณะได้รับการผ่าตัด 60.3 ปี เป็นผู้ป่วยหญิงอยู่ 81.7 โดยอ้างตาม FDA อเมริกา ค่าของ ODI ที่ลดลงอย่างน้อยร้อยละ 15 บ่งบอกถึงความสำเร็จของผลการรักษาในและการกลับไปใช้ชีวิต (functional outcome) พบได้ในสัดสวนผู้ป่วยร้อยละ 63.9 เมื่อใช้ Multivariate analysis พบปัจจัยที่มีผลให้การรักษาไม่สำเร็จ ได้แก่ อายุมากกว่า 65 ปี, ระยะเวลาที่เริ่มเป็นโรคนานกว่า 24 เดือน และจำนวนระดับของกระดูกสันหลังที่ได้รับการผ่าตัดมากกว่า 4 ระดับ ( $p < 0.05$ )

**สรุป:** การผ่าตัดขยายช่องไขสันหลังและเชื่อมกระดูกสันหลังด้วยโลหะตาม ในผู้ป่วยกระดูกสันหลังส่วนเอวตีบจากภาวะกระดูกสันหลังเสื่อม ได้รับผลการรักษาในและการกลับไปใช้ชีวิต (functional outcome) เป็นที่น่าพอใจ อย่างมาก, ระยะเวลาที่เริ่มเป็นโรคนาน และการได้รับการกระดูกสันหลังที่ยาวหลายระดับเป็นปัจจัยที่ทำให้ผลการรักษาไม่สำเร็จ

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