

# A prospective randomized study of surgical treatment for degenerative spondylolisthesis

Tokyo Medical and Dental University

Department of Orthopaedic Surgery

Hiroyuki Inose, Tsuyoshi Kato, Atsushi Okawa

# Surgical methods for degenerative spondylolisthesis



Decompression



Fusion (PLF)



Stabilization (Graf system)

In early surgical practice, only the decompression of neural structures was performed. Spinal instrumentation using pedicle screws have been shown to improve surgical outcomes.

Herkowitz et al, J Bone Joint Surg Am 1991

More recently, posterior pedicle-based dynamic stabilization was developed to prevent instability from joint degeneration and decompression procedure and to combat post-operative adjacent segmental stenosis.

Konno et al. Spine 2000

However to date, the selection of a surgical procedure for lumbar spinal stenosis due to degenerative spondylolisthesis is still under debate, especially **in terms of the addition of instrumentation because of the few prospective, randomized studies.**

# Purpose

- Furthermore, no prospective studies have compared the clinical outcome of **these three procedures**.
- Thus, **to establish a consensus regarding whether it is better to fuse, to stabilize, or not to fuse nor stabilize**, the purpose of this study was to prospectively assess the clinical results of decompression alone, decompression plus fusion, and decompression plus stabilization for degenerative spondylolisthesis.

# Patients and Methods

## Inclusion criteria

One level lumbar spinal stenosis with degenerative spondylolisthesis at the L4/5 level

Age  $\leq 75$

Degenerative spondylosis was defined as

the presence of a slip  $>3\text{mm}$  of the L4 vertebra on a plain lateral radiograph

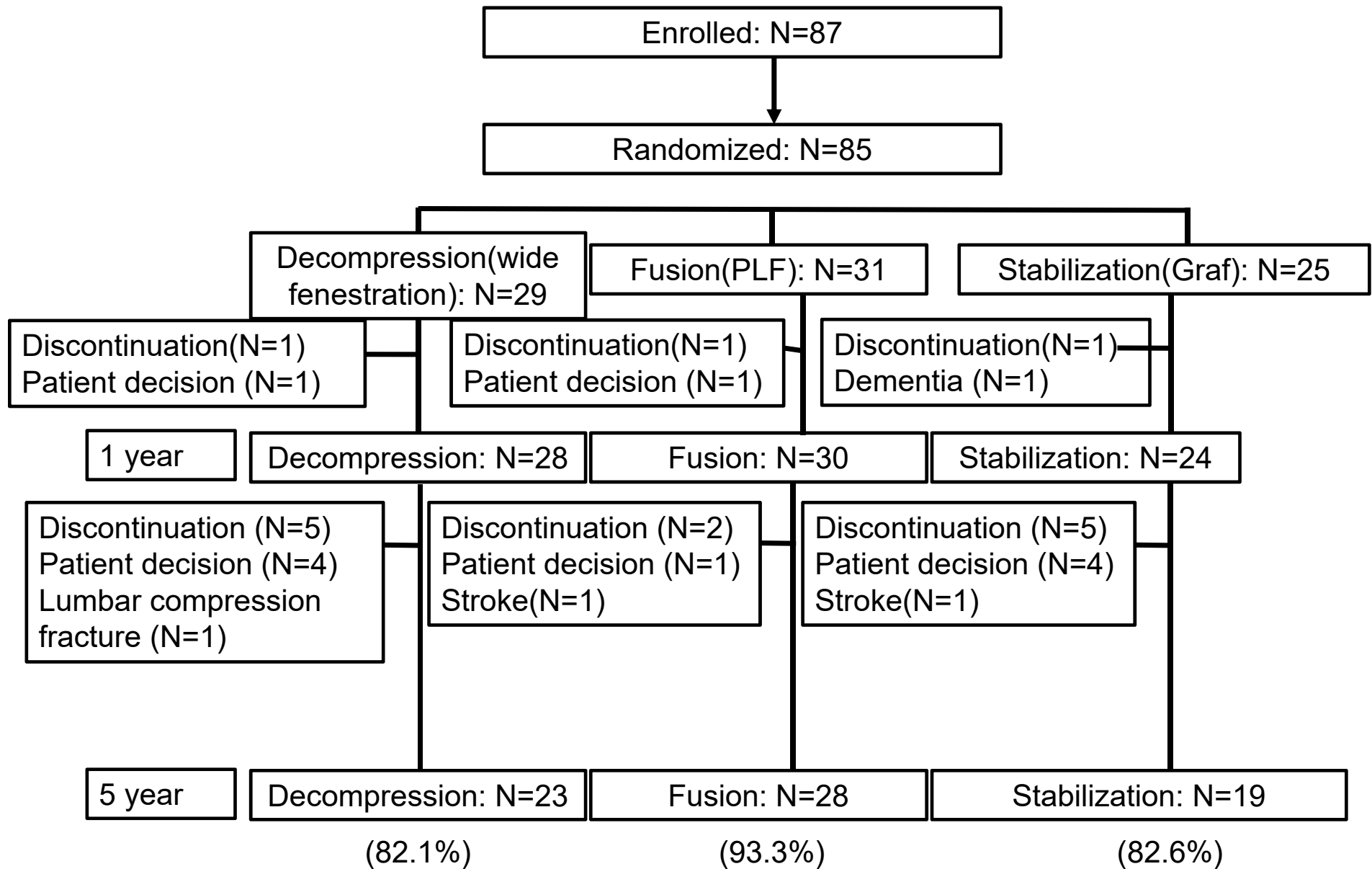
## Exclusion criteria

Previous history of lumbar spinal operation

Multilevel stenosis

Foraminal stenosis

Randomization : according to the computer generated random number tables



# Results

	Decompression Group (N=29)	Fusion Group (N=31)	Stabilization Group (N=25)	P value (P <sub>D-F/D-S</sub> /P <sub>F-S</sub> )
Age (yr)	63.4±8.6	61.2±6.7	65.9±5.7	p=0.93/ p=0.71/ p=0.47 <sup>a</sup>
Female sex (no.(%))	12(41)	20(65)	17(68)	p=0.36/ p=0.18/ p>0.99 <sup>b</sup>
Degree of vertebral slip (mm)	6.5±2.2	8.1±3.8	6.5±2.5	p=0.98/ p=0.98/ p=0.96 <sup>a</sup>
Dynamic instability (no.(%))	12(41)	13(42)	10(40)	p>0.99 <sup>b</sup> / p>0.99 <sup>b</sup> / p>0.99 <sup>b</sup>

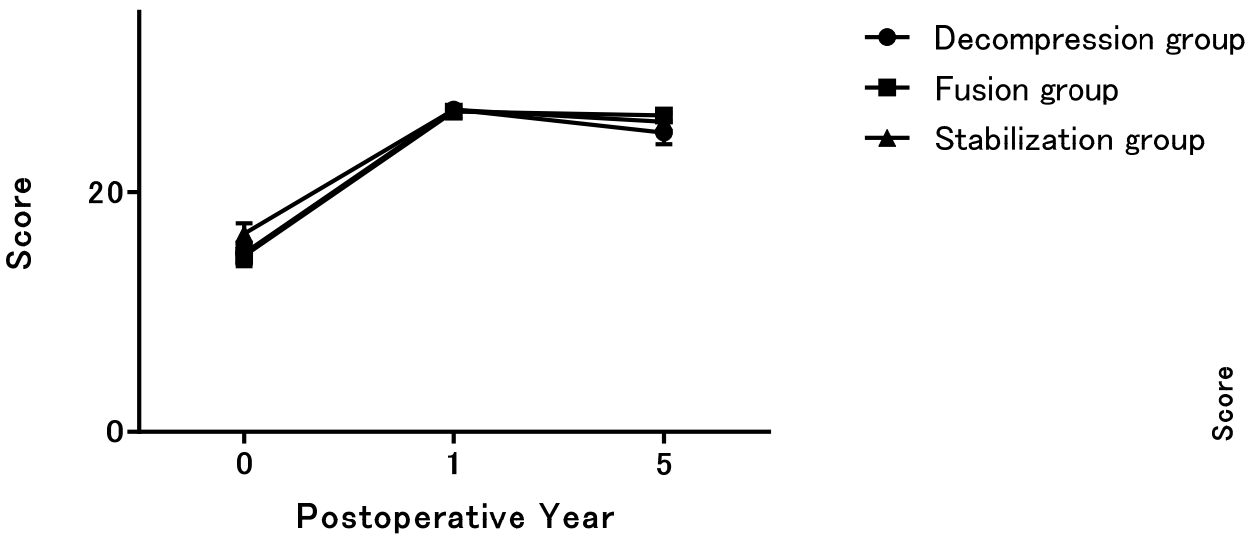
There were no significant differences among the three groups in any of the preoperative variables.

Dynamic instability; >10 degrees angulation or >4 mm translation

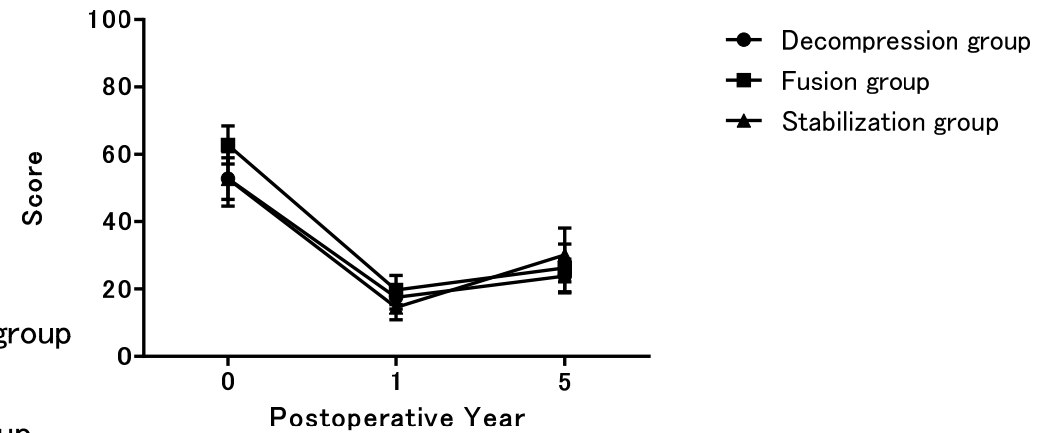
	Decompression Group (N=29)	Fusion Group (N=31)	Stabilization Group (N=25)	p-value (P <sub>D-F</sub> /P <sub>D-S</sub> /P <sub>F-S</sub> )
Estimated blood loss	80.3±62.5	334.8±206.3	209.8±111.8	p<0.001 <sup>(c)</sup> / p<0.001 <sup>(c)</sup> / p=0.013 <sup>(c)</sup> a
Operation time	148±46	244±50	205±39	p<0.001 <sup>(c)</sup> / p<0.001 <sup>(c)</sup> / p=0.016 <sup>(c)</sup> a
Duration of hospital stay after surgery	11.6±2.5	14.1±3.6	13.9±6.5	p=0.007 <sup>(c)</sup> / p=0.16 / p=0.74 <sup>a</sup>
Postoperative slip progression (%)	26.1	0	26.3	p=0.02 <sup>(c)</sup> / p>0.99 / p=0.02 <sup>(c)</sup> b
Complications				
Any	1	8	5	p=0.08 / p=0.26 / p>0.99
Dural tear	0	2	0	
Delusion	0	0	1	
Hematoma	1	0	1	
Meralgia	0	5	1	
Pulmonary embolism	0	1	1	
Misplacement of pedicle screw	0	0	1	

# Clinical outcome

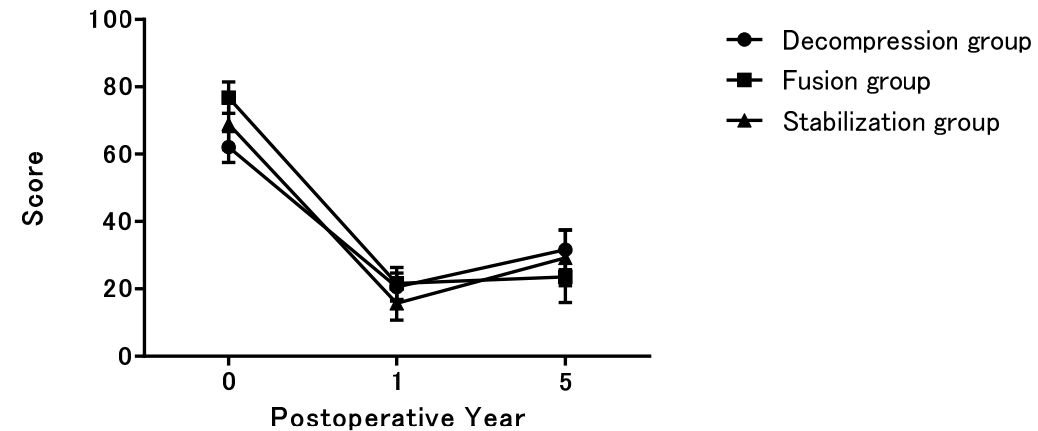
L-JOA score



VAS score for lower back pain



VAS score for leg pain



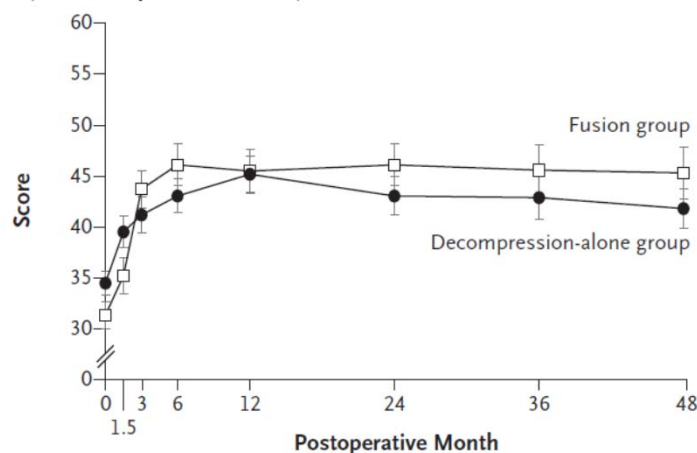
No statistical significant difference was observed among the groups at 1 year and 5 years postoperatively.



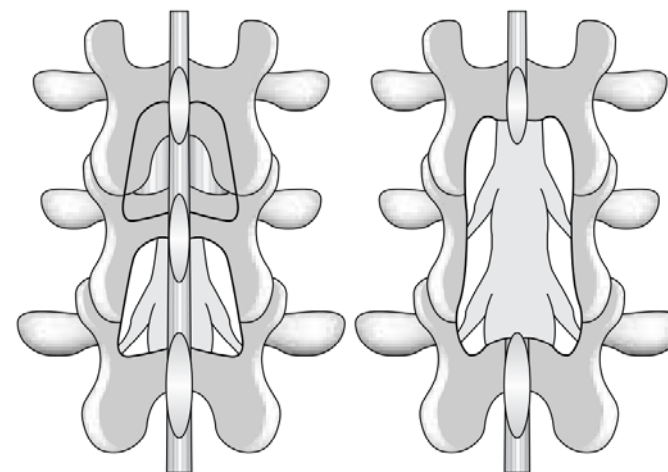
# Discussion

The difference between our trial and NEJM trial

A SF-36 Physical-Component Summary



Ghogawala et al, NEJM 2016



This study

Ghogawala's study

Operative procedure

This study; wide fenestration

Ghogawala; complete laminectomy

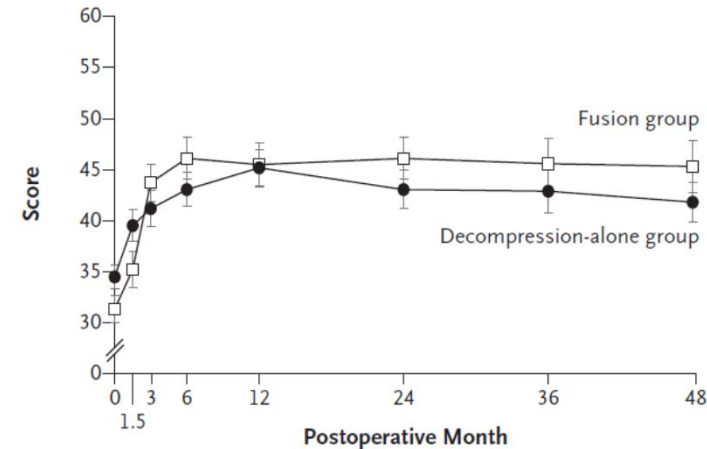
Thus, postoperative instability caused by the decompression procedure may be less in our study

# The difference between our trial and NEJM trial

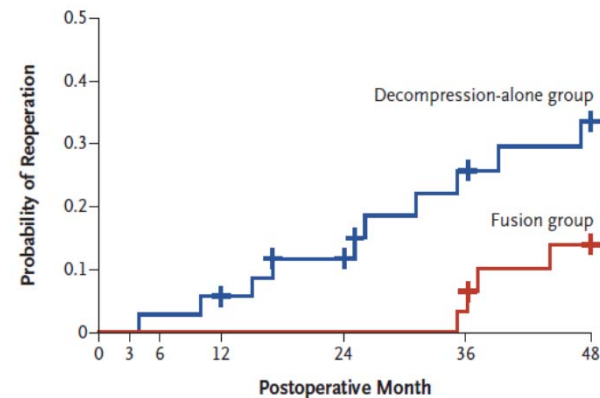
Reoperation rate  
Ghogawala's study  
Decompression 34%  
Fusion 14%

Our study  
Decompression 0%  
Fusion 3%  
Stabilization 3%

A SF-36 Physical-Component Summary



Cumulative Risk of Reoperation over Time



Ghogawala et al, NEJM 2016

Reoperation is a risk factor for poor surgical results

Schnee et al, J Neurosurg. 1997

# To stabilize, or to fuse?

- Within the instrumentation group, while the addition of fusion effectively inhibited the postoperative slip progression, the addition of stabilization could not inhibit postoperative slip.
- Thus, **the addition of fusion, not the stabilization**, might be considered for the patients with high grade slip (>30%) and/or high risk for postoperative slip progression.

## Limitations of this study

1. Most of the patients involved in this study had a low grade slip (<30%)
2. the operative procedures involved in this study did not contain recently developed less invasive procedures (MEL, LIF etc)
3. the sample sizes in the groups were small and the possibility of a type II error cannot be excluded.

# Conclusion

Decompression plus fusion or stabilization did not result in superior results to decompression alone at 1 year and 5 years after surgery in this prospective randomized study for lumbar spinal stenosis with low grade (<30%) degenerative spondylolisthesis.

**EUROSPINE 2018**

**Disclosure of Conflict of Interest**

*Name of first author: HIROYUKI INOSE*

I have no COI  
with regard to this presentation.