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Predictors of Delayed Clinical Benefit Following Surgical Treatment for Low Grade Spondylolisthesis

Mladen Djurasovic MD[1], Leah Y. Carreon MD MSc[1], Erica F. Bisson MD, MPH[2], Andrew K. Chan MD[3], Mohamad Bydon MD[4], Praveen V. Mummaneni MD, MBA[5], Kevin T. Foley MD[6], Christopher I. Shaffrey MD[7], Eric A. Potts MD[8], Mark E. Shaffrey MD[9], Domagoj Coric MD[10], John J. Knightly MD[11], Paul Park MD[6], Michael Y. Wang MD[12], Kai-Ming Fu MD, PhD[13], Jonathan R. Slotkin MD[10], Anthony L. Asher MD[14], Michael S. Virk MD, PhD[13], Dean Chou MD[13], Regis W. Haid MD[10], Steven D. Glassman MD[1]

[1]Norton Leatherman Spine Center, 210 E. Gray St., Suite 900, Louisville, KY 40202

[2]University of Utah Health, Clinical Neurosciences Center, 175 N Medical Dr, Salt Lake City, UT 84132

[3]Department of Neurological Surgery, Columbia University Vagelos College of Physicians and Surgeons, 5141 Broadway 3FW—Room 18, New York, NY10034

[4]Department of Neurologic Surgery, Mayo Clinic College of Medicine and Science, 200 1st St SW, Rochester, MN 55905

[5]Department of Neurological Surgery, University of California, San Francisco, University of California, San Francisco Box 0112, 505 Parnassus Ave, Room M779, San Francisco, CA 94143

[6]Semmes-Murphey Neurologic and Spine Institute, University of Tennessee, 6325 Humphreys Blvd, Memphis, TN 38120

[7]Duke University Hospital, 40 Duke Medicine Circle Clinic 1b/1c, Durham, NC 27710

[8]Goodman Campbell Brain and Spine, 13345 Illinois St, Carmel, IN 46032

[9]Department of Neurosurgery, University of Virginia, 3rd Floor 415 Ray C. Hunt Drive Charlottesville, VA 22903

[10]Carolina Neurosurgery and Spine Associates, 225 Baldwin Ave, Charlotte, NC 28204

[11]Atlantic Neurosurgical Specialists and Altair Health, 197 Ridgedale Ave Ste 225 Cedar Knolls, NJ 07927

[12]Department of Neurological Surgery, University of Miami, 1295 NW 14th St, Miami, FL 33125

[13]Department of Neurosurgery, NewYork-Presbyterian Och Spine Hospital, 5141 Broadway, New York, NY 10034

[14]Geisinger Health, 100 North Academy Ave, Danville, PA 17822

[15]Atlanta Brain and Spine Care, 2001 Peachtree Road NE Suite 575, Atlanta, GA 30309

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Corresponding Author:

Leah Carreon, M.D., MSc
Norton Leatherman Spine Center, 210 East Gray Street, #900
Louisville, KY 40202
Phone: (502) 584-7525
Fax: (502) 589-0849
Email: leah.carreon@nortonhealthcare.org

ABSTRACT

Study Design: Retrospective review of prospectively collected data.

Objective: To investigate what factors predict delayed improvement after surgical treatment of low grade spondylolisthesis.

Summary of Background Data: Lumbar surgery leads to clinical improvement in the majority of patients with low grade spondylolisthesis. Most patients improve rapidly after surgery, but some patients demonstrate a delayed clinical course.

Methods: The Quality and Outcomes Database (QOD) was queried for grade 1 spondylolisthesis patients who underwent surgery who had patient reported outcome measures (PROMs) collected at baseline, 3-, 6- and 12-months, including back and leg pain numeric rating scale (NRS), Oswestry Disability Index (ODI), and EuroQol-5D (EQ-5D). Patients were stratified as "Early responders" reaching MCID at 3 months and maintaining improvement through 12 months and "Delayed responders" not reaching MCID at 3 months but ultimately reaching MCID at 12 months. These two groups were compared with respect to factors which predicted delayed improvement.

Results: Of 608 patients enrolled, 436 (72%) met inclusion criteria for this study. Overall, 317 patients (72.7%) reached MCID for ODI at 12 months following surgery. Of these patients, 249 (78.5%) exhibited a rapid clinical improvement trajectory and had achieved ODI MCID threshold by the 3-month postop follow-up. 68 patients (21.4%) showed a delayed trajectory, and had not achieved ODI MCID threshold at 3 months, but did ultimately reach MCID at 12-month follow-up. Factors associated with delayed improvement included impaired preoperative ambulatory status, better baseline back and leg pain scores, and worse 3-month leg pain scores ($p<.01$).

Conclusions: The majority of patients undergoing surgery for low grade spondylolisthesis reach ODI MCID threshold rapidly, within the first three months after surgery. Factors associated with a delayed clinical course include impaired preoperative ambulation status, relatively better preoperative back and leg pain, and persistent leg pain at 3 months.

Key Words: Spondylolisthesis, lumbar fusion, recovery kinetics, outcomes, MCID.

KEYPOINTS

- In patients undergoing surgery for low grade spondylolisthesis, approximately 73% reach ODI MCID at one year after surgery.
- Most patients achieve ODI improvement rapidly after surgery, but about 21% have a delayed clinical course.
- Independent factors associated with delayed improvement include impaired preoperative ambulation status, relatively better preoperative back and leg pain, and persistent leg pain at three months.

INTRODUCTION

Degenerative spondylolisthesis with associated lumbar spinal stenosis is a common cause of pain and disability [1]. Patients will typically complain of mechanical back pain coupled with neurogenic claudication or radiculopathy. In patients who don't respond to typical conservative treatments, surgical treatment has been shown to lead to improved outcomes over further non-operative treatment with durable benefits demonstrated at intermediate and long term follow up [2,3]. Surgical treatment of degenerative spondylolisthesis has involved lumbar laminectomy with or without arthrodesis. Both laminectomy and fusion can be performed with traditional open techniques or with minimally invasive techniques such as the use of tubular retractors or percutaneous pedicle screws [1]. While controversy has emerged regarding the need for fusion versus decompression alone [4,5], decompression and fusion is a commonly performed procedure in the United States [6] and leads to substantial pain relief and improvement in function in well selected patients.

Recovery kinetics following spinal surgery has recently emerged as an area of investigation, following both cervical and lumbar procedures [7-9]. Several studies have examined recovery profiles in cervical and thoracolumbar deformity surgery, but relatively few have examined this phenomenon following lumbar degenerative surgeries [10-15]. Expectations about speed of recovery, trajectory of pain relief and recovery of function are important factors in setting expectations with patients in preoperative counseling and advising patients with respect to important functional milestones such as return to activities of daily living and return to work. The factors that predict which patients will have rapid improvement and which will have delayed improvement after lumbar fusion surgery remain incompletely understood.

The purpose of the current study is to identify factors associated with a rapid or delayed clinical improvement following surgery for low-grade spondylolisthesis. This information can help inform preoperative patient discussion about expectations for resuming activities of daily living and improvement of function. We analyzed a prospective, multicenter, multidisciplinary registry of patients undergoing surgery for grade 1 spondylolisthesis and compared patients who exhibited rapid versus delayed improvement after surgery. .

METHODS

The Quality Outcomes Database (QOD), formerly known as the National Neurosurgery Quality and Outcomes Database (N^2QOD), is a prospective multicenter quality assurance registry, with infrastructure to optimize data quality and integrity [16]. The structure and methodology of the QOD have been reported in previous publications [17]. This was a prospective study using an augmented dataset from the QOD Lumbar Module. Institutional review board approval (University of California, San Francisco IRB #16-20085) was obtained and patient consent was waived due to the study design.

This augmented dataset represents coordination of 12 high-enrolling sites who combined their QOD Lumbar Module data and collected additional data points. Data was audited by a central team and by individual sites. The inclusion criteria of this augmented dataset (the QOD Lumbar Spondylolisthesis cohort) have been described previously [18]. We included adult patients of age >18 years, with (1) a surgical indication of grade 1 spondylolisthesis, confirmed at each site by preoperative imaging by the Meyerding classification, and (2) who underwent elective surgery between July 2014 and June 2016. Patients were included who underwent single segment surgery. The decision to perform a decompression only or a decompression and fusion

and surgical approach was made by the treating surgeon. Patients were excluded if they had grade 2 or higher spondylolisthesis, spinal infection, tumor, fracture, traumatic dislocation, deformity, or neurological paralysis due to preexisting spine disease or injury.

We identified patients who had minimum baseline and 12-month postoperative patient-reported outcomes data. Outcomes were collected at baseline, three months, six months and one year. Data included VAS back pain scores, VAS leg pain score, Oswestry Disability Index (ODI) [19] and EuroQOL-5D (EQ-5D) [20] scores as well as patient satisfaction. Proportions of patients reaching the minimum clinically important difference (MCID) were calculated [21]. MCID threshold values used were improvement of 12.8 points for the ODI, 1.2 points for back pain and 1.6 points for leg pain [21]

We divided these patients into two groups. “Early Responders” were identified who reached the MCID threshold for ODI at three months postop and maintained this level of improvement at 12 months. “Delayed Responders” were patients who had not reached MCID threshold at 3 months, but ultimately did reach MCID at 12 months. Primary comparisons were made comparing patient characteristics of these two groups.

Statistical analysis was by Statistical Package for the Social Sciences (SPSS v22.0) software (SPSS Inc., Chicago, IL). Independent sample t-tests were used to compare preoperative and one-year post-operative back pain, leg pain and ODI scores as well as changes with treatment. Categorical variables and proportions were compared with Fisher’s exact test or Chi-squared test. Binary logistic regression analysis was performed to identify variables associated with delayed ODI improvement including sex, age, body mass index, insurance status, smoking status, ambulatory status, arthrodesis performed, use of a minimally invasive approach, use of an interbody fusion, number of surgical levels, blood loss, operative time, VAS back pain

and VAS leg pain scores at baseline, three months and twelve month follow-up. Statistical significance was set at $p<0.05$.

RESULTS

Of 608 patietns enrolled, 436 had complete data for inclusion in this study. Overall, 317 (72.7%) patients reached the MCID threshold for ODI at 12 months following surgery. Of these patients, 249 (78.5%) exhibited a rapid clinical improvement trajectory (Early Responders) and had achieved ODI MCID threshold by the 3 month postop follow-up. 68 patients (21.5%) showed a delayed trajectory (Delayed Responders), and had not achieved ODI MCID threshold at 3 months but did ultimately reach the threshold at 12-month follow-up. The 119 (27.2%) who did not achieve ODI MCID at the 12-month post-op follow-up were not included in the analysis. The Early Responder and Delayed Responder groups were similar in terms of sex distribution (40% vs 32% males, p=0.324), age (63.26 years vs 61.55 years, p=0.292), body mass index (30.06kg/m2 vs 30.64 kg/mw, p=0.485), Insurance status and smoking status (12% vs 7%, p=0.432). There was smaller proportion of patients who were independent ambulators in the Delayed Responder group compared to the Early Responder Group (Table 1).

The surgical parameters were similar between the Early Responder and Delayed Responder groups (Table 2) in terms of arthrodesis performed (82% vs 76%, p=0.303), ASA grade (2.39 vs 2.42, p=0.708), estimated blood loss (187.87 mL vs 193.97 mL, p=0.811), operative time (188.65 min vs 178.89 min, p=0.437), length of stay (2.80 days vs 3.03 days, p=0.362) and revisions at 30 days (4% vs 4%, p=0.885). Patients in the Delayed Responder group had worse Back pain at 3 months (2.23 vs 3.94, p<0.001) and at 12 months (2.05 vs 2.77, p=0.036), worse Leg pain at 3 months (1.56 vs 2.75, p=0.003). They had better ODI scores at

baseline (50.47 vs 45.09, p=0.025) but worse ODI scores at 3 months (17.85 vs 40.79, p<0.001) and at 12 months (14.32 vs 20.43, p=0.009) (Table 3).

Factors associated with delayed ODI improvement included pre-op ambulatory status (OR=6.09, p<0.001), baseline back pain (OR=0.80, p=0.018), and baseline leg pain (OR=0.82, p=0.032) and 3 month leg pain (OR=1.46, p<0.001).

DISCUSSION

This study demonstrates that the majority of patients undergoing surgery for low-grade spondylolisthesis improve rapidly, but a significant minority demonstrate a more delayed clinical course. Overall, we found that 73% of patients in the QOD database who underwent single-level fusion for grade 1 spondylolisthesis, reached the threshold for minimally clinically important difference (MCID) for ODI improvement at one year. Approximately 79% of patients who did reach ODI MCID at one year, did so within the first three months after surgery, demonstrating a rapid clinical improvement. However, about 21% of patients who ultimately achieved ODI MCID at one year demonstrated a more delayed response and had not reached ODI MCID at 3 months. Using multivariate statistical methods, we found that independent factors associated with a more delayed clinical course included impaired preoperative ambulation status (use of a walker or a cane), better preoperative back and leg pain scores, and persistent leg pain at 3-month follow-up. These findings suggest that patients should be counseled to expect more gradual improvement after surgery if they have relatively low levels of pain, or if their ability to walk independently has been impaired.

The study of recovery kinetics following spine surgery is a relatively new area of investigation. Many of recently published studies have focused on patients undergoing adult

deformity surgery, particularly cervical deformity. Studies from the International Spine Study Group (ISSG) have delineated multiple predictors for recovery kinetics following cervical deformity surgeries, including negative effects of neurologic complications [22], and the finding that patients with higher degree of frailty experienced greater improvement in overall health state [23], as they have more "room" for improvement postoperatively. They have created a predictive model using both baseline patient factors as well as radiographic measures, which can accurately predict postoperative recovery kinetics [8]. Studies of thoracolumbar deformity have demonstrated that implant-related complications requiring revision surgery definitely adversely affect recovery kinetics in the two year window following surgery [24].

Studies which examine recovery kinetics following more limited lumbar degenerative surgeries, have also been published recently, with many examining whether baseline patient reported outcomes can predict speed and likelihood of recovery. Some studies have focused on patients undergoing decompression only surgery. Nie and coauthors reviewed their single center database for patients undergoing laminectomy or discectomy at 1-3 levels [11]. They found that patients with worse preoperative Pain Interference (PI) scores had a higher likelihood of reaching MCID in PI, pain and disability outcomes. An additional finding in this study was that worse VAS pain scores and ODI predicted greater improvement at early time points (6 weeks and 3 months). Similarly, Rubery and coauthors found that combining baseline PROMIS physical function and pain interference scores with clinical factors (e.g. straight leg raising, leg pain predominance) was strongly predictive of early improvement after lumbar discectomy [15].

A limited number of studies have recently focused on recovery kinetics in patients undergoing fusion. Snavely and coworkers studied whether baseline PROMIS scores could predict postoperative outcomes in a mixed group of decompression and fusion patients [25].

Again, worse preoperative scores correlated with greater improvement postoperatively. In two separate reports from Rush University, Patel found that worse preoperative PROM values predicted early achievement of MCID for legacy outcome measures (i.e. VAS leg pain, back pain and ODI), with a mixed group of interbody fusion patients (TLIF, ALIF and LLIF) [12]. Jenkins found a similar pattern in their minimally invasive TLIF patients, with worse preoperative PROMIS physical function scores predicting higher likelihood of MCID at 6 weeks and 3 months, with disappearance of this effect by 6 months [10]. Finally, Shaikh and coworkers examined whether preoperative PROMIS scores could predict early versus late improvement with single level fusion. Overall, they found that only 40-50% reached MCID by 6 months after surgery. Preoperative PROMIS symptomatology did correlate with higher probability of MCID at final follow-up but was not predictive of early improvement by 6 months [13].

Our study overall found that about 73% of patients undergoing surgery for low grade spondylolisthesis demonstrate meaningful improvement at one year, a finding which is consistent with prior studies which have suggested a high rate of success for surgery in the diagnostic setting of spondylolisthesis [26]. Independent factors associated with delayed improvement in our study included impaired preoperative ambulation status, relatively better preoperative back and leg pain, as well as persistent leg pain at 3 months after surgery. Impaired preoperative ambulation status, such as the use of a cane or walker, likely reflects more long-standing disability and may also reflect other non-spinal impairments to overall quality of life (e.g. concomitant lower extremity arthritis, comorbid medical conditions). In such cases a more slow, gradual clinical improvement is somewhat expected. Our findings that lower preoperative back and leg pain were associated with a delayed clinical course are consistent with findings of previous studies of recovery kinetics following lumbar fusion, which showed less disability

measured by preoperative PROMIS scores correlated with lower likelihood of MCID at early time points [10,12]. This finding is somewhat intuitive. Patients with a greater levels of pain preoperatively, both radicular leg pain and mechanical back pain related to instability, will likely respond rapidly when neural compression is relieved and instability is fixed. These patients have "more room" to improve and are likely to follow a more rapid clinical course.

Finally patients with persistent leg pain at 3 months are less likely to meet criteria for ODI MCID and thus will follow a more delayed course. In some ways, persistent leg pain at 3 months is as much a definition of delayed improvement as a risk factor. But this finding does seem to identify a subset of patients who demonstrate delayed improvement of radiculopathy who will ultimately reach meaningful overall improvement at one year.

The reason for delayed improvement in the subset of patients identified in our study appears multi-factorial. The finding that patients with lower levels of pain and disability were more likely to experience delayed recovery may indicate that those patients were relatively less disabled prior to surgery and may have underestimated the invasiveness of the surgery. This may also represent ceiling effects in the amount of improvement that can be obtained in these patients. Finally, in many patients following spondylolisthesis surgery, relief of leg pain is often immediate secondary to the relief of mechanical pressure on nerve roots following laminectomy. In contrast, improvement in instability related mechanical back pain is a much slower process which depends on healing of the arthrodesis. In our study, early responders demonstrate a trend towards higher levels of leg pain preoperatively and this rapid relief of radiculopathy symptoms may have caused them to be "early responders".

These findings have practical implications for patient care, including preoperative counseling and the design of individual treatment plans for patients. Preoperatively, patients will

often inquire about specific recovery milestones, such as return to work, return to basic activities of daily living and return to recreational activities and sports. Patients also will often inquire at early postoperative checks whether they can expect further improvement or whether they should expect to chronically live with their level of symptoms. Based on the findings of this study, patients with relatively low levels of preoperative disability can be counseled to expect further improvement beyond their 6 week or three month postoperative visity and to be patient with respect to their expectations. Similarly, patients using a cane or walker preoperatively should expect a slower improvement and likely they should be prescribed a longer course of postoperative physical therapy and rehabilitation given the expected prolonged recovery kinetics found in our study. An improved understanding of recovery kinetics can help guide surgeons in setting proper and realistic expectations for patients throughout the entire length of their postoperative recovery.

Our study has several limitations. The retrospective study design does introduce potential for bias. However the use of a prospectively collected registry is also a strength of the study, since recovery kinetics are best examined in "real-world" practice settings which are better captured in a registry than in randomized experimental designs with strict inclusion and exclusion criteria. Indications for surgery, surgical techniques and postoperative rehabilitation protocols were not standardized and varied across centers. This heterogeneity of surgical techniques and postoperative care is a limitation of the study, but again mirrors standard clinical care practiced throughout the country. The absence of granularity with respect to surgical indications is also an inherent limitation of database studies. Future analysis of large-scale national registry data, such as the American Spine Registry [27] which includes surgeon specified indications may help to address this deficiency. The majority of patients in this study

underwent decompression and fusion, which may limit the generalizability of findings to patients who had decompression only. Finally, unknown confounding variables which were not included in the multivariate analysis may impact recovery kinetics. Multivariate analyses can only control for potential confounding variables which are included in the analysis.

In conclusion, our study showed that the majority of patients who undergo surgery for low grade spondylolisthesis achieve meaningful improvement in symptoms at one year. Most of these patients improve rapidly and show meaningful improvement within 3 months while a minority exhibit a more delayed clinical course. Consistent with other studies of recovery kinetics for degenerative lumbar conditions, we found that patients who are more disabled preoperatively, as reflected by high levels of back and leg pain, tend to exhibit more rapid improvement after surgery. Patients with relatively milder back and leg pain at baseline are more likely to follow a delayed clinical course. In addition, impaired preoperative ambulation and persistent leg pain also put patients at risk for a more delayed clinical course. These finding can help surgeons counsel patients on recovery milestones following surgery, such as pain medication use, return to activities of daily living and return to work after surgery. Future studies should focus on the most effective ways to improve recovery kinetics. These studies could compare the use of physical therapy and different standardized postoperative rehabilitation protocols to identify the optimal clinical pathway to best restore all patients to their maximal clinical improvement as quickly as possible.

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Table 1. Summary of Demographic Data			
	Early Responder	Delayed Responder	p-value
Total	249	68	
Males, N (%)	99 (40%)	22 (32%)	0.324
Age, years, Mean (SD)	63.26 (11.12)	61.55 (11.97)	0.292
BMI, kg/m^2, Mean (SD)	30.06 (5.79)	30.64 (7.63)	0.564
Osteoporotic, N (%)	21 (8%)	3 (4%)	0.436
Diabetic, N (%)	43 (17%)	12 (18%)	0.942
Insurance, N (%)			0.485
Uninsured	1 (<1%)	0	
Medicare	96 (39%)	27 (40%)	
Medicaid	10 (4%)	6 (9%)	
VA	8 (3%)	1 (1%)	
Private	134 (54%)	34 (50%)	
Smoker, N (%)	31 (12%)	5 (7%)	0.432
Ambulation, N (%)			0.018
Independent	225 (90%)	56 (82%)	
Assistive Device	23 (9%)	9 (13%)	
Wheelchair bound	1 (<1%)	3 (4%)	

Table 2. Summary of Surgical Parameters			
	Early Responder	Delayed Responder	p-value
Total	249	68	
ASA Grade, Mean (SD)	2.39 (0.57)	2.42 (0.56)	0.708
Arthrodesis performed, N (%)	204 (82%)	52 (76%)	0.303
Pedicle Screws, N (%)	198 (97%)	50 (96%)	
Cortical Screws, N (%)	6 (3%)	2 (4%)	
Minimally Invasive Approach, N (%)	99 (40%)	26 (38%)	0.889
Interbody Fusion, N (%)	68 (27%)	23 (34%)	0.294
Surgical Levels, N (%)			0.666
One	198 (80%)	51 (75%)	
Two	51 (20%)	17 (25%)	
Estimated Blood Loss, mL, Mean (SD)	187.87 (175.29)	193.97 (187.16)	0.811
Operative time, min, Mean (SD)	188.65 (87.67)	178.89 (89.86)	0.437
Length of Stay, days, Mean (SD)	2.8 (1.71)	3.03 (1.83)	0.362
Revision at 30days, N (%)	10 (4%)	3 (4%)	0.885

Table 3. Summary of Patient Reported Outcomes			
	Early Responders	Delayed Responder	p-value
Back Pain, (0-10), Mean (SD)			
Baseline	6.84 (2.66)	6.11 (2.98)	0.087
3-months	2.23 (2.24)	3.94 (2.41)	<.001
12 months	2.05 (2.38)	2.77 (2.42)	0.036
Leg Pain, (0-10), Mean (SD)			
Baseline	6.95 (2.65)	6.37 (2.65)	0.111
3-months	1.56 (2.39)	2.75 (3.01)	0.003
12 months	1.6 (2.54)	2 (2.68)	0.281
Oswestry Disability Index			
Baseline	50.47 (14.28)	45.09 (17.92)	0.025
3-months	17.85 (14.09)	40.78 (19.29)	<.001
12 months	14.32 (14.08)	20.43 (17.44)	0.009