# Higher Levels of Postoperative Mobility and Activity as Measured by the AM-PAC 6 Clicks Instrument Are Associated with Improved Outcomes after Lumbar Fusion

Parimal Rana, Jane C. Brennan, Andrea H. Johnson, Justin J. Turcotte and Chad M. Patton

Luminis Health Orthopedics, Anne Arundel Medical Center, Annapolis, United States

#### Abstract:

**Introduction:** Previous studies have shown that early patient mobility and activity can improve patient outcomes after lumbar fusion procedures. This study aimed to explore the relationship between patient mobility and activity, measured by the Activity Measure for Post-acute Care (AM-PAC) "6-Clicks" assessment and postoperative outcomes in lumbar fusion patients.

**Methods:** A retrospective review of 306 lumbar fusions (105 with 6-Clicks mobility and 289 with 6-Clicks activity scores) was conducted. Statistical analyses were performed to evaluate the relationship between 6-Clicks scores and postoperative outcomes, such as prolonged length of stay (LOS), nonhome discharge, 30-day emergency department (ED) returns and readmissions, and minimal clinically important difference (MCID) achievement on the PROMIS-PF instrument at 3-12 months postoperatively.

**Results:** After controlling for age, body mass index, sex, race, number of levels, and preoperative PROMIS-PF, higher 6-Clicks mobility scores decreased the likelihood of 3+ day LOS (OR: 0.72; p=0.010), non-home discharge (OR: 0.68; p< 0.001), and 30-day ED return (OR: 0.78; p=0.022) and increased the likelihood of PROMIS MCID achievement (OR: 1.28; p=0.004). The odds of LOS 3+ days, non-home discharge, and ED return for each one-point increase in mobility scores all decreased by 28%, 32%, and 22%, respectively, while the odds of achieving PROMIS MCID for every one-point increase in mobility increased by 28%. After risk adjustment, higher 6-Clicks activity scores were protective against 3+ day LOS (OR: 0.78; p<0.001) and non-home discharge (OR: 0.69; p<0.001).

**Conclusions:** The AM-PAC 6-Clicks mobility and activity scores hold value as early indicators of prolonged LOS and nonhome discharge, while mobility scores may help identify patients who are at risk for ED returns and who fail to experience clinically significant improvement in physical function. These tools may be used to identify patients requiring additional resources and can inform discussions surrounding patient expectations.

## Keywords:

AM-PAC 6-Clicks, Lumbar fusion, Mobility, Activity, PROMIS-PF, Bundled-payment models

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# Introduction

Lumbar fusion surgery is a relatively common surgical procedure performed for various spine-related conditions that can improve quality of life for patients with spinal stenosis and associated instability<sup>1</sup>). However, clinical outcomes are variable, and efforts to enhance care are important to achieve maximum value from surgical intervention<sup>2</sup>). Early ambulation and mobility after spinal surgery are pivotal in enhancing functional outcomes and reducing compli-

cations<sup>3,4)</sup>. Limitations in mobility and daily activities not only affect patients' well-being but also significantly contribute to healthcare resource utilization and related costs<sup>5)</sup>. The median cost of hospitalization after spine surgery in the United States has been reported to exceed 14 thousand dollars, with expenses increasing for each additional day the patient occupies a hospital bed<sup>6)</sup>. Therefore, standardized measures of early mobility and activity are needed to identify patients requiring additional support to achieve optimal outcomes.

Corresponding author: Justin Turcotte, jturcotte@luminishealth.org

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The Activity Measure for Post-Acute Care (AM-PAC) "6-Clicks" inpatient daily activity and basic mobility short forms are standardized assessments of mobility and activity in the acute care setting that have been shown to be valid and reliable and have high inter-rater reliability<sup>7,8)</sup>. The 6-Clicks mobility score includes six questions evaluating a patient's level of difficulty turning in bed, sitting and standing from a chair, moving from lying to sitting on a bed, and the amount of help a patient needs moving from a bed to chair, walking in the hospital room, and climbing 3-5 steps with a railing. Each is scored from 1 (unable to do/total assistance required) to 4 (no difficulty/no assistance required) and scores are summed to yield a total score ranging from 6 (total functional impairment) to 24 (total absence of impairment)<sup>9)</sup>. The 6-Clicks activity score includes six questions evaluating the amount of assistance needed to put on and take off lower body clothing, bathe, toilet, put on and take off upper body clothing, groom, and eat meals<sup>10</sup>. Each question is scored on the same 1-4-point scale as the mobility assessment, and scores are summed to range from 6 to 24, again in the same fashion as described for the mobility score. Within spine surgery populations, the 6-Clicks measures have demonstrated utility for discharge planning and predicting hospital length of stay (LOS) in adult spinal deformity and anterior lumbar fusion patients9,11). However, the utility of these measures in evaluating mobility and activity across the broader spectrum of patients undergoing lumbar fusion remains unknown. Therefore, this study aims to assess the relationship between 6-Clicks mobility/activity scores and measures of perioperative and clinical outcomes after lumbar fusion.

## **Materials and Methods**

## Study population

This study was approved by the institutional review board. A retrospective review of 306 lumbar fusions performed by two fellowship-trained orthopedic spine surgeons at a single institution was performed. All patients were cared for using a coordinated spine surgery pathway in a dedicated spine center from March 2020 to July 2023. Patients with Patient-Reported Outcomes Measurement Information System Physical Function (PROMIS PF) scores recorded preoperatively and at 3-12 months postoperatively and either a postoperative 6-Clicks basic mobility or a postoperative 6-Clicks daily activity score were included. The 6-Clicks mobility and activity scores were completed by physical and occupational therapists, respectively. The first score documented by the therapist after surgery was used in the study. On average, the first 6-Clicks mobility and activity score was documented 1.6 and 1.8 days after surgery, respectively (Table 1). Patient characteristics collected were age, body mass index (BMI), sex, race, American Society of Anesthesiologists (ASA) scores, and number of levels fused. All patients included in the study had complete data available for

 Table 1.
 Descriptive Statistics of the Whole Population.

|                                | All Fusions (n=306) |
|--------------------------------|---------------------|
| Patient Characteristics        |                     |
| Age                            | 66.6±10.6           |
| BMI                            | 30.9±5.8            |
| Sex                            |                     |
| Female                         | 188 (61.4)          |
| Male                           | 118 (38.6)          |
| Non-White Race                 | 54 (17.6)           |
| ASA 3+                         | 169 (55.2)          |
| Levels                         |                     |
| 1 or 2                         | 203 (66.3)          |
| 3+                             | 103 (33.7)          |
| Preoperative PROMIS PF         | 32.8±5.7            |
| Outcomes                       |                     |
| 6-Clicks Mobility Score        | 17.1±3.4            |
| 6-Clicks Activity Score        | 21.5±2.9            |
| Days Surgery to Mobility Score | 1.6±1.2             |
| Days Surgery to Activity Score | $1.8 \pm 1.8$       |
| LOS                            | 2.8±2.3             |
| Non-Home DC                    | 32 (10.5)           |
| 30-Day ED Return               | 24 (7.8)            |
| 30-Day Readmission             | 17 (5.6)            |
| Postoperative PROMIS PF        | 39.3±7.9            |
| Months to PROMIS PF            | 8.2±3.4             |
| PROMIS MCID                    | 157 (51.3)          |

all independent and outcome measures assessed.

#### **Outcomes**

The outcomes of interest are hospital LOS of 3 or more days (defined as hospital arrival date to discharge date), non-home discharge, 30-day emergency department (ED) return, 30-day readmission, and achievement of minimal clinical important difference (MCID) from preoperative to 3-12 months postoperatively on the PROMIS-PF measure. PROMIS MCID was defined as an increase of at least 5 points (1/2 standard deviation) from the baseline PROMIS-PF score, in alignment with prior studies<sup>14,15)</sup>. The PROMIS-PF instrument was selected for evaluation of functional status as it has been validated in multiple spine populations and has favorable psychometric properties in comparison to legacy outcome measures such as the Oswestry Disability Index (ODI)<sup>12-15)</sup>.

#### Statistical analysis

Descriptive statistics were used to show the patient characteristics, 6-Clicks mobility and activity scores, preoperative and postoperative PROMIS-PF scores, and outcomes of the entire population. A 6-Clicks basic mobility score was recorded in 105/306 (34.3%) patients, and a 6-Clicks daily activity score in 289/306 (94.4%) patients. Both 6-Clicks mobility and activity scores were recorded in 88/306 (28.8%) patients. At our institution, 6-Clicks mobility and activity assessments are performed by physical and occupa-

| Measure                         | Patient Characteristic |                  | P-Value |
|---------------------------------|------------------------|------------------|---------|
| 6-Clicks Mobility Score (n=105) | <u>Age ≤70</u>         | Age Over 70      |         |
|                                 | 16.9±3.7               | 17.2±3.1         | 0.643   |
|                                 | <u>BMI ≤35</u>         | BMI Over 35      |         |
|                                 | 17.5±3.0               | $16.0 \pm 4.3$   | 0.099   |
|                                 | <u>Female</u>          | Male             |         |
|                                 | 17.3±3.0               | $16.5 \pm 4.4$   | 0.415   |
|                                 | <u>White</u>           | <u>Non-White</u> |         |
|                                 | 17.1±3.4               | 16.6±3.7         | 0.577   |
|                                 | <u>ASA &lt;3</u>       | <u>ASA 3+</u>    |         |
|                                 | 17.4±3.0               | $16.9 \pm 3.7$   | 0.462   |
|                                 | <u>1- or 2- Level</u>  | <u>3+ Levels</u> |         |
|                                 | 18.2±2.9               | 16.3±3.6         | 0.003   |
|                                 | <u>Age ≤70</u>         | Age Over 70      |         |
|                                 | 21.8±2.8               | 21.1±3.0         | 0.036   |
|                                 | <u>BMI ≤35</u>         | BMI Over 35      |         |
| 6-Clicks Activity Score (n=289) | 21.7±2.7               | 21.0±3.7         | 0.197   |
|                                 | <u>Female</u>          | Male             |         |
|                                 | 21.2±2.9               | 22.1±2.9         | 0.011   |
|                                 | <u>White</u>           | <u>Non-White</u> |         |
|                                 | 21.6±2.8               | 21.2±3.1         | 0.410   |
|                                 | <u>ASA &lt;3</u>       | <u>ASA 3+</u>    |         |
|                                 | 22.0±2.4               | 21.2±3.2         | 0.024   |
|                                 | 1- or 2 Level          | 3+ Levels        |         |
|                                 | 22.3±2.3               | $19.9 \pm 3.4$   | <0.001  |

**Table 2.** Univariate Comparison of Mobility and Activity Scores by De-mographics and Patient Characteristics.

tional therapists, respectively. Not all patients are evaluated postoperatively within the hospital by physical therapy prior to discharge, thereby resulting in the unequal sample sizes of patients with documented mobility and activity scores. Patient characteristics were categorized into binary groups: age ≤70, age 70+, BMI ≤35, BMI 35+, female, male, white race, nonwhite race, ASA <3, ASA 3+, one- or two-level fusion, and 3+ level fusion. Univariate comparisons of 6-Clicks mobility and activity scores between patient characteristics groups and outcomes using two-sided independent t-tests were conducted. Risk-adjusted multivariate logistic regression was conducted to assess mobility and activity as predictors of outcomes controlling for age, BMI, sex, race number of levels, and preoperative PROMIS PF. All statistical analyses were performed using R Studio (Version 4.2.2 ©2009-2023 RStudio, PBC). Statistical significance was set at p<0.05, indicating that if the null hypothesis is true, and all other assumptions made are valid, there is a 5% chance of obtaining a result at least as extreme as the one observed<sup>16)</sup>.

## Results

Table 1 shows the overall demographic characteristics and outcomes of the study population. There was no statistically significant difference in mobility score between age, BMI, sex, race, and ASA score groups. However, patients with a one- or two-level fusion had a significantly higher mobility score than those who had a 3+ level fusion (18.2 $\pm$ 2.9 vs. 16.3 $\pm$ 3.6; p=0.003) (Table 2). Patients who were 70 or younger had a higher activity score (21.8 $\pm$ 2.8 vs. 21.1 $\pm$ 3.0; p=0.036) than those who were older than 70. In addition, men had significantly higher activity scores (22.1 $\pm$ 2.9 vs. 21.2 $\pm$ 2.9; p=0.011) than women, patients with an ASA <3 had higher activity scores (22.0 $\pm$ 2.4 vs. 21.2 $\pm$ 3.2; p=0.024) than those who had an ASA of 3+, and those who had a one- or two-level fusion had higher activity scores (22.3 $\pm$ 2.3 vs. 19.9 $\pm$ 3.4; p<0.001) than those who had 3+ levels. There was no significant difference in activity scores between BMI and race (Table 2).

Patients with an LOS of 3+ days had significantly lower postoperative 6-Clicks mobility scores ( $16.2\pm3.2$  vs.  $19.2\pm2.9$ ; p<0.001) than those who had an LOS of less than 3 days. In addition, patients who were not discharged home had a lower mobility score ( $14.8\pm3.4$  vs.  $18.0\pm3.0$ ; p<0.001) than those who were discharged home. There were no significant differences in mobility scores between those who returned to the ED and those who did not and between those who were readmitted and those who were not. Finally, the mobility score was significantly higher in those who achieved PROMIS MCID ( $17.8\pm2.7$  vs.  $16.5\pm3.8$ ; p=0.049) than in those who did not (Table 3).

After controlling for age, BMI, sex, race, number of levels, and preoperative PROMIS-PF, 6-Clicks mobility was

| Measure                         | Patient Characteristic |                    | P-Value |
|---------------------------------|------------------------|--------------------|---------|
| 6-Clicks Mobility Score (n=105) | LOS <3                 | LOS 3+             |         |
|                                 | 19.2±2.9               | 16.2±3.2           | <0.001  |
|                                 | Home DC                | Non-Home DC        |         |
|                                 | 18.0±3.0               | 14.8±3.4           | <0.001  |
|                                 | <u>No ED Return</u>    | ED Return          |         |
|                                 | 17.3±3.3               | 15.3±3.7           | 0.084   |
|                                 | No Readmission         | <b>Readmission</b> |         |
|                                 | 17.1±3.4               | 16.8±4.2           | 0.889   |
|                                 | No PROMIS PF MCID      | PROMIS PF MCID     |         |
|                                 | 16.5±3.8               | 17.8±2.7           | 0.049   |
|                                 | LOS <3                 | LOS 3+             |         |
|                                 | 22.6±2.1               | 20.1±3.2           | <0.001  |
| 6-Clicks Activity Score (n=289) | Home DC                | Non-Home DC        |         |
|                                 | 22.0±2.5               | 17.4±3.1           | < 0.001 |
|                                 | <u>No ED Return</u>    | ED Return          |         |
|                                 | 21.6±2.8               | 20.6±3.7           | 0.216   |
|                                 | No Readmission         | <b>Readmission</b> |         |
|                                 | 21.6±2.8               | 20.1±4.5           | 0.194   |
|                                 | No PROMIS PF MCID      | PROMIS PF MCID     |         |
|                                 | 21.2±3.1               | 21.9±2.7           | 0.039   |

**Table 3.** Univariate Comparison of Mobility and Activity Scores by Outcomes.

**Table 4.** Risk-adjusted Logistic Regression, Mobility asPredictor of Outcomes.

|                | Odds Ratio | 95% CI    | P-Value |
|----------------|------------|-----------|---------|
| LOS 3+         | 0.72       | 0.54-0.91 | 0.010   |
| Non-Home DC    | 0.68       | 0.53-0.82 | <0.001  |
| ED Return      | 0.78       | 0.63-0.96 | 0.022   |
| Readmission    | 1.21       | 0.83-1.87 | 0.334   |
| PROMIS PF MCID | 1.28       | 1.09–1.53 | 0.004   |

Controlling for age, BMI, sex, race, number of levels, and preoperative PROMIS PF.

predictive of LOS 3+ days (OR: 0.72, 95% CI: 054-0.91; p= 0.010), non-home discharge (OR: 0.68, 95% CI: 0.53-0.82; p<0.001), 30-day ED return (OR: 0.78, 95% CI: 0.63-0.96; p=0.022), and PROMIS MCID (OR: 1.28, 95% CI: 1.09-1.53; p=0.004). The odds of LOS 3+ days, non-home discharge, and ED return for each one-point increase in mobility scores all decreased by 28%, 32%, and 22%, respectively, while the odds of achieving PROMIS MCID for every one-point increase in mobility increased by 28% (Table 4).

The activity score was significantly lower in patients who had an LOS of 3+ days (20.1 $\pm$ 3.2 vs. 22.6 $\pm$ 2.1; p<0.001) than in those who stayed less than 3 days. In addition, the activity score was significantly lower in patients who were not discharged home (17.4 $\pm$ 3.1 vs. 22.0 $\pm$ 2.5; p<0.001) than in those who were. However, the activity score was significantly higher in patients who achieved a PROMIS MCID (21.9 $\pm$ 2.7 vs. 21.2 $\pm$ 3.1; p=0.039) than in those who did not. There was no significant difference in activity scores between ED return and readmission (Table 3).

**Table 5.** Risk-adjusted Logistic Regression, Activity asPredictor of Outcomes.

|                | Odds Ratio | 95% CI    | P-Value |
|----------------|------------|-----------|---------|
| LOS 3+         | 0.78       | 0.68-0.88 | <0.001  |
| Non-Home DC    | 0.69       | 0.58-0.80 | <0.001  |
| ED Return      | 0.91       | 0.79-1.06 | 0.217   |
| Readmission    | 0.96       | 0.81-1.15 | 0.621   |
| PROMIS PF MCID | 1.10       | 1.00-1.22 | 0.066   |

Controlling for age, BMI, sex, race, number of levels, and preoperative PROMIS PF.

After controlling for age, BMI, sex, race, number of levels, and preoperative PROMIS-PF, 6-Clicks activity was predictive of LOS 3+ (OR: 0.78, 95% CI: 0.68-0.88; p<0.001) and non-home discharge (OR: 0.69, 95% CI: 0.58-0.80; p< 0.001). The odds of LOS 3+ and non-home discharge for every one-point increase in activity scores decreased by 22% and 31%, respectively (Table 5).

## Discussion

The results of this study demonstrate that early mobilization and activity are associated with improved postoperative outcomes after lumbar fusion. After risk adjustment, increased mobility scores were independently associated with decreased odds of prolonged LOS  $\geq$ 3 days, non-home discharge, and ED returns. Furthermore, the odds of achieving clinically significant improvement in physical function at 3-12 months postoperatively for each one-point improvement in mobility scores improved by 28%. Although not prognostic of ED returns, readmissions, or patient-reported outcomes improvement, higher 6-Clicks activity scores were associated with decreased odds of prolonged hospitalization and non-home discharge.

The relationship between early mobility, LOS, and discharge disposition observed in this study is largely in alignment with the findings of prior studies showing the relationship between early mobilization and improved outcomes after surgery<sup>11)</sup>. The utility of 6-Clicks scores for discharge planning has also been established by studies establishing its ability to accurately distinguish between patients discharged home and skilled nursing facilities, and showing a mobility threshold of  $\leq 15$  may help prepare for non-home discharge<sup>9,17)</sup>. Although we did not formally assess a threshold mobility score for predicting discharge disposition, 15 of the 24 patients (65%) with mobility scores  $\leq 15$  in our population were discharged to skilled nursing facilities, demonstrating that this cutoff may be useful in clinical practice.

To our knowledge, this study is one of the few to evaluate the relationship between 6-Clicks activity scores and outcomes of lumbar fusion patients. Patients in our study who reported lower postoperative levels of daily activity, such as difficulties in dressing or bathing independently, also exhibited prolonged hospitalization and nonhome discharges. In a previous study including 238 lumbar fusion patients, the odds of home discharge for each one-point increase in activity scores during hospitalization increased by 92%<sup>17)</sup>. A notable finding from this study was the lack of association between 6-Clicks activity scores and ED returns, readmissions, or clinically significant improvement in PROMIS-PF scores in the risk-adjusted model. Based on the items assessed by the activity score-dressing, bathing, toileting, grooming, and eating-this finding is logical. While the ability to perform these activities directly influences the need for continued hospitalization and ability to discharge home, it is unlikely that differing ability to complete these functions would translate to the need for re-hospitalization or decreased physical improvement, except for in the most severely impaired patients. Given that average 6-Clicks activity scores were 21.5 out of a possible 24 points, it appears that most of the lumbar fusion patients are able to complete activities of daily living with relatively little impairment.

This study contributes significantly to the limited literature regarding assessing the relationship between early AM-PAC 6-Clicks scores and long-term patient-reported functional outcomes. In this study, there were statistically, but likely not clinically, significant differences in 6-Clicks activity scores between patients who did and did not achieve PROMIS-PF MCID; however, these differences dissipated after risk adjustment. Conversely, 6-Clicks mobility scores were independently associated with an increased likelihood of achieving MCID on the PROMIS-PF instrument. The finding that the odds of MCID achievement for each onepoint increase in the initial 6-Clicks mobility score improved by 28% appears to be a clinically significant one in the context of the relatively wide dispersion in mobility scores, which had a standard deviation of 3.4 points. These findings suggest that early assessment of 6-Clicks mobility scores may be useful in clinical practice to identify patients that may benefit from interventions aimed at enhancing their long-term postoperative functional status.

Considering the findings of this study, surgeons and therapists face the new challenge of determining how to incorporate early 6-Clicks mobility and activity scores into practice. At a minimum, we suggest that our findings highlight that incorporating 6-Clicks into the assessment of lumbar fusion patients provides a valid and reliable way of communicating early postoperative functional status across members of the care team. In addition, both measures may improve surgeons' ability to set patient expectations during the early recovery period, as establishing realistic expectations has been demonstrated to improve functional outcomes in lumbar fusion patients<sup>18</sup>. Furthermore, as both the 6-Clicks mobility and activity scores were independent predictors of increased LOS and non-home discharge, these measures may be used to identify patients that may require additional inpatient resources to reduce LOS and discharge home safely. When low levels of mobility or activity are identified, these patients may benefit from receiving additional inpatient therapy services to improve their functional status. In addition, surgeons may consider adjusting pain management modalities in an attempt to enable these patients to mobilize and complete activities within the hospital. However, given the multitude of factors influencing LOS and discharge destination decisions, we do not advise that 6-Clicks scores be used in isolation as a basis for discharge decisions. Beyond the initial hospitalization, low initial 6-Clicks mobility scores may be used to identify patients who are at risk for ED returns and who fail to achieve clinically significant improvement over 3-12 months postoperatively. To address the former, surgeons may consider assigning nurse navigator resources to check in with these patients soon after discharge or modifying follow-up protocols to include earlier in-clinic assessment, in an attempt to reduce ED utilization. In an effort to improve longer-term function, patients with low initial mobility scores may be triaged to more aggressive outpatient therapy regimens or followed more closely by their surgeon over the first postoperative year. Further research is required to evaluate whether each of these interventions improves outcomes for patients with impaired mobility and activity levels after surgery.

The results of this study must be considered in the context of its limitations. Inherently, the retrospective nature of the study and its single institution design reduce its generalizability. In addition, we did not directly study the association between specific symptoms, such as pain and stiffness, which have been shown to influence early mobility and activity levels. Furthermore, not all participants completed both AM-PAC assessments, creating a possible selection bias. Similarly, only patients who completed baseline and follow-up PROMIS-PF surveys were included, again introducing potential selection bias. In addition, our assessment of clinically significant improvement in physical function

was evaluated using a wide window of 3-12 months postoperatively, potentially resulting in lower rates of MCID achievement in patients with shorter follow-up duration. However, there was no significant difference between 6-Clicks mobility or activity scores and time to PROMIS-PF completion, suggesting that similar follow-up patterns existed across the population and thus potentially mitigating the impact of this source of bias. Another limitation of the study is that it presents only a cross-sectional view of patients' activity and mobility levels after surgery. Therefore, we were unable to assess whether changes in 6-Clicks scores during hospitalization affected outcomes and which inpatient physical and occupational therapy interventions yielded the greatest improvement in early mobility and activity. This presents an opportunity for further research to improve early postoperative protocols. Finally, although we controlled for multiple factors known to influence outcomes of lumbar fusions, it is possible that unmeasured factors confounded our results. Therefore, we are unable to assess whether there is a truly causal relationship between initial mobility and activity levels and postoperative outcomes. A multitude of unmeasured factors such as social support, mental health status, and disease-specific characteristics influence the outcomes assessed, and we were unable to assess the specific reasons for the observed outcomes in this study. These limitations should be considered when interpreting the results.

## Conclusion

The AM-PAC 6-Clicks mobility and activity scores hold value as early indicators of prolonged LOS and nonhome discharge. Mobility scores may help identify patients who are at risk for ED returns and who fail to experience clinically significant improvement in physical function. These tools may be used to identify patients requiring additional resources and can inform discussions surrounding patient expectations. Early mobilization and activity of lumbar fusion patients should be the focus of care teams in order to optimize patient outcomes.

**Conflicts of Interest:** The authors declare that there are no relevant conflicts of interest.

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Author Contributions: Conceptualization: Justin J. Turcotte, Andrea H. Johnson, and Chad M. Patton

Formal analysis: Jane C. Brennan, Parimal Rana, and Justin J. Turcotte

Investigation: Parimal Rana, Jane C. Brennan, and Justin J. Turcotte

Methodology: Justin J. Turcotte, Jane C. Brennan, and Chad M. Patton

Project administration: Justin J. Turcotte

Writing - original draft: Parimal Rana

Writing - review and editing: Parimal Rana, Andrea H. Johnson, Justin J. Turcotte, and Chad M. Patton

**Ethical Approval:** Approved as exempt research by Western Institutional Review Board (WIRB) (IRB # 1993664). Ethical approval was waived by the ethics committee due to the retrospective study design and exclusion of patient identifiers.

**Informed Consent:** Consent was waived by the ethics committee due to the retrospective study design. A review of patient records was necessary for the study; however, patient identifiers were excluded.

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