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DEFORMITY

Stiffness After Pan-Lumbar Arthrodesis for Adult Spinal Deformity Does Not Significantly Impact Patient Functional Status or Satisfaction Irrespective of Proximal Endpoint

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Study Design. Prospective, multicenter.

Objective. To determine if stiffness significantly affects function or satisfaction after pan-lumbar arthrodesis.

Summary of Background Data. The Lumbar Stiffness Disability Index (LSDI) is a validated measure of the effect of lumbar stiffness on functional activities. Data suggests that patients undergoing fusion of the entire lumbar spine are at greatest risk of functional limitations from stiffness.

Methods. The LSDI, Short Form 36, Scoliosis Research Society-22, and Oswestry Disability Index were administered preoperatively and at 2-year minimum follow-up to 103 spinal deformity patients from 11 centers. Patients were separated according to the proximal arthrodesis level; upper thoracic (T2-5) to pelvis (UT-Pelvis) or thoraco-lumbar (T10-T12) to pelvis (TL-Pelvis). Outcome scores were compared using Student *t* test or Tukey–Kramer Honest Significant Difference Analysis of Variance. Regression analysis of final LSDI scores *versus* Scoliosis Research Society-22 Satisfaction scores was performed.

Results. Mean ages, baseline values, and final scores of all outcome parameters were statistically equivalent in the two groups. Final LSDI scores did not change significantly from baseline in the UT-Pelvis ($P = 0.478$) or TL-Pelvis ($P = 0.301$) groups. In contrast, highly significant improvements ($P \leq 0.0001$) from baseline were seen in both groups for other health-related QoL measures. The 2-year Satisfaction scores were statistically equivalent in the two groups, and the correlation between final LSDI and Satisfaction scores in the entire cohort was not significant ($R^2 = 0.013$, $P = 0.146$).

Conclusion. Patients undergoing pan-lumbar arthrodesis for adult spinal deformity did not experience substantial increases in disability due to stiffness of the low back, although they did report significant improvements in other health-related QoL measures. Further, LSDI scores did not correlate with patient satisfaction. There were no significant differences in perceived stiffness effects whether arthrodesis stopped in the thoracolumbar or upper thoracic regions. We hope these results will be useful to spine surgeons and patients during preoperative planning and discussions.

Key words: adult spinal deformity, clinical outcomes, collateral impacts, lumbar fusion, scoliosis.

Level of Evidence: 2

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Adult spinal deformity is a frequent cause of pain and disability, especially among older individuals. In cases of severe disability and substantial deformity, pan-lumbar spinal arthrodesis is increasingly chosen as a method of treatment in the United States.[1] In addition to the expected increase in patients undergoing fusions for *de novo*

adult deformity or untreated idiopathic scoliosis, large database reviews have shown that a number of patients undergo secondary surgeries for adjacent segment stenosis, pseudarthrosis, or spinal malalignment after shorter lumbar fusions.[2] Given these combined trends, a large number of patients are expected to undergo surgical arthrodesis of their entire lumbar spine in the coming decades.[3–11]

In recent years, a substantial volume of work has demonstrated significant improvements in pain and function after surgical treatment of degenerative scoliosis, untreated adolescent idiopathic scoliosis, and postoperative spinal deformity in properly selected adult patients.[12–21] Standardized self-reported outcomes instruments such as the Oswestry Disability Index (ODI), Short Form 36 (SF-36), or the Scoliosis Research Society-22 (SRS-22) are frequently used to document postoperative improvements in pain, function, and self-image.

Successful lumbar arthrodesis, by intention, results in decreased spinal motion. Given this, it is reasonable for patients to express concerns that the resulting loss of range of motion may cause limitations in overall function. Despite this, there are limited data measuring the functional effects of loss of lumbar mobility after arthrodesis. Especially among adult deformity patients indicated for pan-lumbar arthrodesis, there is a need to better understand the functional limitations that postoperative reduction of spinal mobility may create, and the effect these limitations have on patient satisfaction with surgery.

The LSDI (Figure 1) was developed and validated as a patient reported measure of the effect of stiffness on the performance of ADLs.[22–24] This 10-item questionnaire focuses on the effects of low back stiffness, independent of pain, on the performance of common ADLs. Previous reports have shown that LSDI scores track separately from ODI and SF-36 scores in adults with varying lengths of lumbar arthrodesis, suggesting that the LSDI may be more sensitive for functional limitations related to lumbar stiffness than other Health Related Quality of Life (HRQoL) instruments used in spine clinical research.[23,25]

The patients at greatest risk of functional impacts from stiffness would presumably be those undergoing pan-lumbar arthrodesis with no history of prior surgical fusion. To evaluate the functional effects of pan-lumbar arthrodesis to the sacropelvis, the LSDI was prospectively administered to a cohort of adult spinal deformity patients in a multicenter setting. We hypothesized that lumbar stiffness would not significantly affect overall functional status or patient satisfaction.

Please note: the LSDI is scored similarly to the Oswestry Disability Index (ODI) and that higher scores indicate increasing disability.

Choose the statement that best describes the effect of low-back stiffness on your ability to:

1. Bend to your feet to put on your underwear and pants while dressing independently
2. Bend through your waist to put on your socks and shoes
3. Drive a motor vehicle
4. Perform personal hygiene functions following toileting
5. Bend forward to pick up a small object off the floor
6. Get in and out of bed
7. Get in and out of a chair
8. Bathe the lower half of your body
9. Get in and out of an automobile
10. Engage in sexual intercourse

Response Options and Score for each item

0	No effect at all
1	Minor effect
2	Significant effect
3	Require assistance
4	Cannot do at all

Figure 1. Lumbar Spine Disability Index.

MATERIALS AND METHODS

A prospective, multicenter study was performed by 17 spine surgeons at 11 adult spinal deformity centers between October 2008 and October 2013. IRB approval was obtained at all centers. Inclusion criteria were adult patients undergoing arthrodesis from thoracic spine to sacrum for either scoliosis or kyphotic deformity. Deformity parameters for inclusion were a coronal curve of $\geq 20^{\circ}$, a sagittal vertical axis of ≥ 5 cm, or pelvic tilt of $>25^{\circ}$. Patients with deformity due to acute trauma, tumor, infection, or neuropathic diagnosis were excluded. In addition, all patients with a history of prior fusion in thoracic or lumbar spines were excluded.

After screening and providing informed consent, enrolled patients were administered baseline LSDI, ODI, SF-36 version 2, and SRS-22 questionnaires, and again at minimum 2-year follow-up. Patients undergoing revision fusion either for rod fracture/pseudarthrosis or proximal junctional failure during the first 2-years postoperatively were excluded. Final analysis was performed only on patients with complete 2-year radiographic and clinical follow-up.

Patients were categorized based on the proximal junction of their arthrodesis as either upper thoracic (UT; T2-5) or thoraco-lumbar (TL; T10-T12). All patients were fused to the sacrum, with or without pelvic fixation. Thus, two groups were comprised for comparison based on length of arthrodesis: (A) UT-Pelvis and (B) TL-Pelvis. The decision of whether to extend the fusion proximally to either the UT or the TL junction was made by the operating surgeon. Flexion/extension or side bending radiographs were not routinely obtained preoperatively. Figures 2A–D and 3A–D present case examples from each of the two cohorts.

Preoperative and 2-year outcome scores (LSDI, ODI, SF-36, and SRS-22) were compared between TL-Pelvis and UT-Pelvis groups using a Student *t* test. Change from baseline to 2-year follow-up for all HRQoL measures was also performed for TL-Pelvis and UT-Pelvis groups independently. Finally, correlation analyses were performed to examine the relationship between 2-year LSDI score and 2-year SRS-22 Satisfaction score, change in sagittal vertebral alignment,

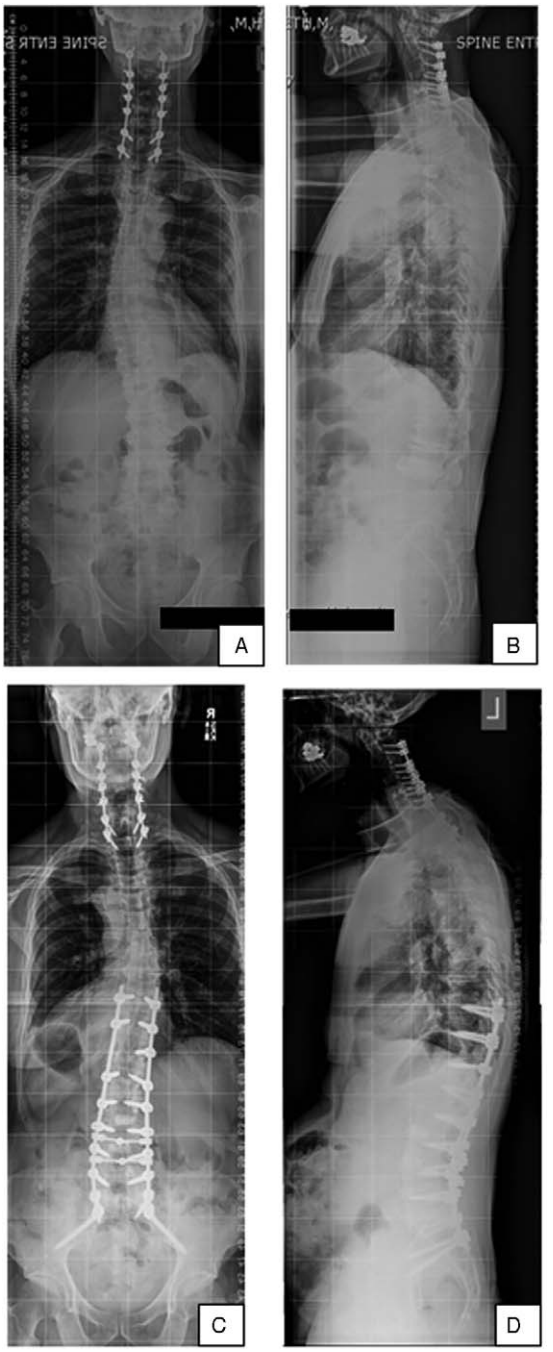

Figure 2. AP (A) and lateral (B) radiographs of a 64-year-old man. He was 5-years status post-L1-L5 laminectomy for lumbar stenosis but had developed disabling recurrent radiculopathy and sagittal imbalance due to lumbar kyphosis. SVA was −0.22 cm and PI-LL was 27.5°. Preoperative LSDI was 36, ODI was 50, PCS was 29, and SRS-22 was 2.36. AP (C) and lateral (D) radiographs taken 2 years status poststaged posterior arthrodesis from T10 to pelvis, followed by anterior diskectomy and fusion from L2-S1. SVA was −0.8 cm and PI-LL was 4.6°. LSDI was 39, ODI was 38, PCS was 34, and SRS-22 4.05. SRS-22 Satisfaction score was 5 (very satisfied and would elect same treatment again).

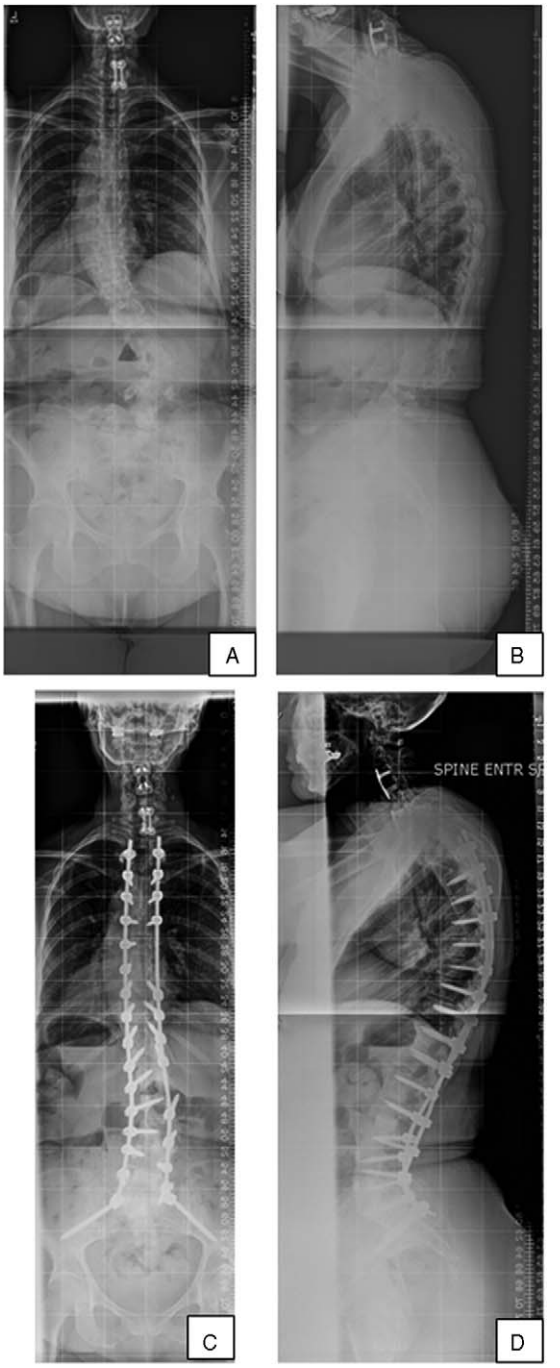

Figure 3. AP (A) and lateral (B) radiographs of a 69-year-old woman 2 years status postlaminectomies with bilateral complete facetectomies of L2/3-L5/S1. Small preoperative degenerative scoliosis had rapidly progressed producing recurrent radiculopathy, sagittal imbalance, and early satiety. Preoperative SVA was −2.5 cm and PI-LL was 18.3°. LSDI was 62.5, ODI was 64.4, PCS was 13.0, and SRS-22 was 2.91. AP (C) and lateral (D) radiographs taken 2 years status poststaged posterior arthrodesis from T4 to pelvis, followed by anterior diskectomy and fusion from L2-S1. SVA was −3.0 cm and PI-LL was −9.4°. Final LSDI was 70, ODI was 40, PCS was 27.4, and SRS-22 was 4.15. SRS-22 Satisfaction score was also 5 (very satisfied and would elect same treatment again).

lordosis, and baseline pelvic incidence. Minimal Clinically Important Difference (MCID) values used were 12.8 for ODI,[26] 4.9 for SF-36 physical component score,[26] and 0.4 for SRS total score.[27] An analysis of the impact of upper *versus* lower thoracic endpoint on reaching MCID was performed. All statistical analyses were performed with JMP 8.0.2 (SAS Foundation, Cary, NC).

TABLE 1. Mean Baseline Values (Range)			
	UT-Pelvis = 50	**TL-Pelvis = 53**	***P* Value**
Age	60.7 (37.9–84.3)	63.1 (29.9–80.2)	$P = 0.604$
LSDI	32.7 (0–70)	33.6 (0–66.7)	$P = 0.993$
ODI	44.0 (8–88)	44.3 (10–72)	$P = 1.000$
SRS-22 Total	2.8 (1.1–4.1)	2.7 (1.6–4.1)	$P = 0.705$
SF-36 PCS	31.6 (13.1–56.0)	30.0 (10.0–53.5)	$P = 0.826$

LSDI indicates lumbar stiffness disability index; ODI, Oswestry Disability Index; SF-36, Short Form-36 health survey; SRS-22, Scoliosis Research Society-22 questionnaire; TL, thoraco-lumbar; UT, upper thoracic.

RESULTS

One hundred twelve patients did meet inclusion criteria and did not undergo revision fusion surgery during the study period. Over the enrollment period, 40 patients were fused to the pelvis but were ineligible because they had previous thoracic or lumbar fusions. An additional 48 patients were ineligible because their fusion did not extend to the pelvis. Of the 112 eligible patients, 103 (92%) completed radiographic and clinical outcome assessments at final follow-up. Mean ages of the UT-Pelvis and TL-Pelvis groups were statistically similar with the numbers available (60.7 *vs.* 63.1, respectively). In addition, baseline values of all outcome parameters (LSDI, ODI, SRS-22 Total, SF-36 PCS) were statistically similar in the two groups (Table 1).

Final 2-year clinical outcome scores for the two study cohorts are shown in Table 2. LSDI, ODI, SRS-22 Total, and SF-36 PCS values were all statistically equivalent between the UT-Pelvis and TL-Pelvis groups at 2-years postoperatively. Although final LSDI scores were higher among UT-Pelvis as opposed to the TL-Pelvis cohorts, this did not reach statistical significance with the numbers available (35.4 *vs.* 30.0, $P = 0.500$).

More importantly, LSDI scores from pre- to 2-years postoperatively in both UT-Pelvis and TL-Pelvis groups did not change significantly from baseline ($P = 0.478$ and $P = 0.301$, respectively). In contrast, highly significant improvements ($P \leq 0.0001$) from baseline were seen in all other HRQoL measures, including ODI, SRS-22 Total, and SF-36 PCS. These data are summarized in Table 3.

Final SRS-22 Satisfaction scores were statistically equivalent in the two groups with the numbers available (UT-Pelvis = 4.4 *vs.* TL-Pelvis = 4.3, $P = 0.835$). The correlation between LSDI and SRS-22 Satisfaction scores in the combined UT-Pelvis and TL-Pelvis cohorts did not reach statistical significance ($R^2 = 0.013$, $P = 0.146$). Figure 4 shows a scatter plot of the regression analysis.

There was no effect of fusion length on the percent of patients reaching MCID for the ODI, PCS, or SRS-22 Total scores ($P > 0.53$ for all) (Table 4). We examined the correlation between the change in LSDI and the baseline pelvic incidence, as well as the correlations between the change in LSDI and the change in sagittal vertebral alignment and lumbar lordosis. None showed a significant correlation (Table 5), although the correlation with change in lordosis was nearly significant ($P = 0.051$).

DISCUSSION

This study demonstrates that patients undergoing pan-lumbar arthrodesis for adult spinal deformity do not experience substantial increases in disability due to perceived stiffness of the low back. This is the first study to examine this question in a prospective fashion among this patient population. We hope that these results will provide a better ability to inform patients preoperatively regarding the expected impact from loss of lumbar motion after their procedure.

This study expands on prior work demonstrating the validity and utility of the LSDI in assessing stiffness impacts among lumbar arthrodesis patients.[22–25,28,29] While the LSDI has been successfully used in these single-center studies,[22–24] this is the first attempt to utilize the LSDI in a prospective, multicenter cohort. This study also focuses on a single diagnostic and surgical treatment category, *i.e.*, adult spinal deformity patients undergoing pan-lumbar arthrodesis. By restricting our cohort only to patients with no prior lumbar arthrodesis, we are able to isolate the impact of the studied effect from a single surgical event. Given the limited increased impact due to stiffness reported among this group of patients undergoing arthrodesis of their entire lumbar spine, concerns that surgical arthrodesis will inevitably lead to substantial functional limitations due to loss of motion do not appear to be born out, at least for most patients.

Our results demonstrate that perception of the effects of stiffness and pain are incompletely correlated. Our patients

TABLE 2. Mean 2-Year Values (Range)			
	UT-Pelvis = 50	**TL-Pelvis = 53**	***P* Value**
LSDI	35.4 (0–80.0)	30.0 (0–83.0)	$P = 0.500$
ODI	27.3 (0–82.2)	26.0 (0–74.0)	$P = 0.988$
SRS-22 Total	3.8 (2.1–4.8)	3.7 (2.1–4.9)	$P = 0.993$
SF-36 PCS	42.3 (22.3–60.1)	40.2 (13.0–59.4)	$P = 0.803$

TABLE 3. Mean Change in Values at 2-Years Postoperative				
	UT-Pelvis = 50	*P* value	TL-Pelvis = 53	*P* Value
LSDI	32.7–35.4; Δ = 2.4	$P = 0.4780$	33.6–30.0; Δ = −3.9	$P = 0.3010$
ODI	44.0–27.3; Δ = −17.3	$P = 0.0001$	44.3–26.0; Δ = −19.8	$P < 0.0001$
SRS-22 Total	2.8–3.8; Δ = 0.9	$P < 0.0001$	2.7–3.7; Δ = 1.1	$P < 0.0001$
SF-36 PCS	31.6–42.3; Δ = 8.4	$P < 0.0001$	30.0–40.2; Δ = 10.9	$P < 0.0001$

reported less pain and greater function postoperatively, but no significant change in stiffness-related functional impacts. It may be that pain-related stiffness preoperatively is replaced by fusion-related stiffness postoperatively. It thus appears that while patients with substantial low back pain may also experience substantial stiffness, there are others for whom stiffness is not a result of low back pain.

The limited reported impacts may appear unexpected, and the reasons for this are open to conjecture. One possible explanation is the fairly advanced age and high level of disability among our patients at baseline. While adult spinal deformity patients have been shown to experience disability due to reasons including back and leg pain, as well as sagittal imbalance, some patients may also develop marked stiffness of the spine as a result of degeneration or ankylosing conditions. Another potential effect of degenerative disease is pain with activity, which may prevent patients from active use of their available range of motion. On the other hand, surgical improvements in alignment and reduction in pain levels may offer patients an opportunity for less restricted activity despite the surgical tradeoff of reduced spinal motion. It seems likely that all of these issues may be limiting factors in usable lumbar spine flexibility preoperatively.

While patients fused to the upper thoracic spine reported higher mean LSDI scores than patients with thoracolumbar stopping points, this did not reach statistical significance. In addition, neither group reported significant increases in stiffness-related disability from baseline. Finally, both groups did report significant improvements in ODI, SRS-22, and SF-36 PCS scores, and likelihood of reaching MCID level improvements was not different between UT and TL endpoints. Taken as a whole, these results suggest that the postoperative function of patients fused to upper thoracic proximal endpoints is similar to those with a thoracolumbar upper instrumented vertebra. While there may be structural or radiographic aspects of patients' preoperative deformity which lead their surgeon to choose upper thoracic *versus* thoracolumbar endpoints, we are unable to assess this question in the current analysis.

It may seem paradoxical that the mean LSDI scores for patients fused from the thoracolumbar junction to the pelvis actually decreased from preoperative levels, indicating a reduction in their perceived stiffness (33.6–36.0). However, this was not a statistically significant change, and it may well be within the level of measurement error of the LSDI. We are unable, with our current data, to establish a MCID for the LSDI. In addition, the LSDI has not been validated as a measure of thoracic or thoracolumbar stiffness. This trend, if a true difference, may also represent a positive change in perceived stiffness as a result of reduced pain and improved spinal alignment, as discussed above. Regardless of its clinical validity, however, it does support our contention that perceived stiffness is not markedly increased after surgical fusion in this patient population.

It is important to recognize that there may be functional domains affected by lumbar stiffness that are not evaluated within the 10 questions of the LSDI. In addition, the limited changes in mean LSDI scores may mask more substantial changes in a smaller group of the domains queried. Recently, Kimura *et al*[30] published data within a Japanese surgical population using an expanded version of the LSDI. Their results appear very similar to our prior report of stiffness effects with lower numbers of fused segments, despite the addition of several further ADLs.[25] It thus seems likely that the 10-question version of LSDI contains sufficient breadth of content for the purpose of its design.

One limitation of our study is that we have not made measurements of our patients' actual lumbar range of motion to establish a true "gold standard." However, prior

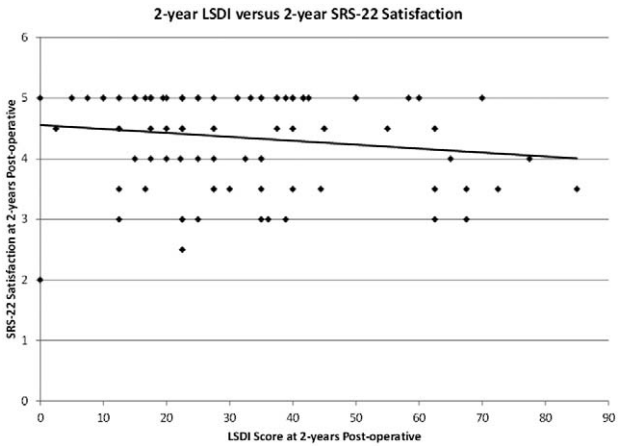

Figure 4. Scatter plot representing correlation between 2-year post-operative LSDI score and 2-year postoperative SRS-22 Satisfaction score ($R^2 = 0.013$; $P = 0.15$).

TABLE 4. Percent of Patients Reaching MCID for the Respective Questionnaires Between UT-Pelvis and TL-Pelvis			
	UT-Pelvis	TL-Pelvis	*P* Value
MCID ODI (%)	62.8	63.0	0.9803
MCID PCS (%)	63.6	66.7	0.7811
MCID SRS-22 total (%)	74.4	80.0	0.5323

TABLE 5. Change in LSDI Score *Versus* Radiographic Parameters

	R^2	*P* Value
Baseline pelvic incidence	0.0056	0.3338
Change in sagittal vertebral alignment	0.0001	0.8821
Change in lordosis	0.0232	0.0514

Regression analysis of change in coronal and sagittal alignment and lordosis with respect to change in LSDI from baseline to 2-year follow-up.

work has established that the LSDI does indeed correlate to radiographic measurements of lumbar mobility.[22] In addition, the use of a self-reported questionnaire directed at questions regarding perceived impacts of lumbar stiffness does assess patients' own perceptions of their disability level, which may be different than true lumbar flexibility. In general, clinical success is better gauged by patients' self-reported assessments than by radiographic results.

Despite these concerns, this data does provide reassurance to surgeons and patients considering extended thoracolumbar fusion for adult spinal deformity. We hope that these results will be useful in the informed consent process to answer patient concerns regarding the expected effect of a pan-lumbar arthrodesis and resulting loss of lumbar range of motion on daily activities.

➢ Key Points

- ❑ Adult spinal deformity patients did not experience substantial increases in disability due to perceived stiffness of the low back following pan-lumbar arthrodesis.
- ❑ Patients' satisfaction with their surgical result showed no correlation with their perceived stiffness.
- ❑ There was no significant difference in perceived stiffness or clinical outcome whether arthrodesis stopped at the upper thoracic or thoracolumbar junction.
- ❑ These results may be useful in the informed consent process to answer patient concerns regarding the expected effect of a pan-lumbar arthrodesis and resulting loss of lumbar range of motion on daily activities.

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