Two-Level Circumferential Lumbar Fusion Comparing Midline and Paraspinal Posterior Approach

5-Year Interim Outcomes of a Randomized, Blinded, Prospective Study

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Study Design: A prospective randomized and blinded comparative study of 2 patient groups with >5-year follow-up.

Objective: To compare the clinical outcomes and postoperative posterior muscle changes in patients with advanced degenerative disk disease undergoing 2-level circumferential spinal fusion using a posterior midline versus a paraspinal approach.

Summary of Background Data: Lumbar spinal fusion is often performed using a circumferential (anterior and posterior) technique. Paraspinal muscle alterations occur during the retraction of the muscles required for posterior instrumentation and fusion bed preparation, which may adversely affect outcomes.

Methods: Patients with advanced 2-level lumbar degenerative disk disease were randomized into 2 groups of 25 each for the approach to the posterior spine for their anterior-posterior fusion. A midline posterior skin incision was universal, but all patients were blinded to the fascial incision and exposure to the posterior spine. All had intertransverse and facet joint fusions with pedicle screw instrumentation. Outcomes (visual analog back and leg pain scale, pain drawing, Oswestry disability index, and self-assessment of procedure success) were assessed at various periods postoperatively. Preoperative and >1-year postoperative magnetic resonance images (MRI), including paraspinal muscles, were read by a radiologist who was blinded to the surgical approach and outcomes.

Results: No difference in operative time, blood loss, implant costs, or any other intraoperative parameter existed between the 2 patient groups. Although clinical improvement for all outcome scales was significant for both groups postoperatively, there was no difference between groups. Postoperative MRI T2 relaxation values were significantly increased at the operative levels and distally, but the changes were similar for both groups.

Conclusions: Midline and paraspinal approaches result in similar outcomes in 2-level spinal fusions. We were unable to demonstrate that a paraspinal muscle-splitting approach to 2-level fusion was superior to the muscle-stripping midline approach. However, the study has low statistical power.

Key Words: fusion, lumbar, minimally invasive, outcomes, pain, paraspinal muscles

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Residual low back pain after a technically successful lumbar fusion is not well understood but may be due in part to muscle injury related to the surgical approach.[1–4] Posterior lumbar surgery has been shown to affect the paraspinal muscles. Muscle abnormalities after lumbar decompressions were identified by electromyography (EMG) >30 years ago.[5] These EMG abnormalities and histologic changes may persist for many years after the posterior lumbar spine surgery.[3,6] The postoperative muscle abnormalities are believed to be related to retraction of the muscles during surgery.[7,8] A report using a rat model identified histologic and histochemical changes with muscle retraction and found that these changes were related to the pressure and duration of retraction.[9] This has been also shown in human subjects both histologically and by measurement of various serum markers for muscle injury and inflammation.[10–16]

Abnormalities in muscle may also be identified using magnetic resonance imaging (MRI) techniques with resulting increased T2 signal intensity ratio of the affected muscle relative to control muscle on axial cross-sections. Experimental animal MRI studies have identified denervation and myonecrosis.[17–19] MRI used to study the effect of retraction on the lumbar spine muscles in a rat model found signal changes in the muscles and suggested that these changes were related to the duration of retraction.[20]

Human MRI studies also have shown that muscle abnormalities may be due to denervation.[21] MRIs of human lumbar spines after posterior lumbar spine surgery have identified changes in the posterior spinal muscles and have been associated with greater retraction time.[4,22–24]

On the basis of the preceding information, one may conclude that paraspinal muscle retraction should be minimized during posterior lumbar surgery to avoid potential damage to the muscles. The rationale for a

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paraspinal muscle-splitting approach to lumbar spine fusion is that it parallels the trajectory required for pedicle screw instrumentation so that less muscle retraction is needed.[1] Recent studies have evaluated the use of a traditional midline posterior approach for lumbar spine surgery as compared with "minimally invasive" posterior surgery, which typically uses a paraspinal muscle-splitting approach.[14,24] However, these prior studies had confounding factors, such as varying techniques and types of instrumentation, which led to variable results and made interpretation of the results inconclusive.[25] Thus, further study is needed to support the hypothesis that the paraspinal approach results in superior outcomes.

The purpose of the present study was to assess and compare the clinical outcomes and postoperative posterior muscle changes in 2 groups of patients undergoing 2-level circumferential spinal fusion for degenerative disk disease (DDD). In 1 group of patients, the posterior procedure was performed using an open midline approach and, in the second group, the posterior procedure was performed using an open paraspinal muscle-splitting approach. The patients were randomized and blinded to the approach. The radiologist reading the postoperative MRIs for assessment of paraspinal muscle changes was also blinded to the approach.

METHODS

This study was designed as a single-center, randomized, parallel group study with a 1:1 ratio of participants. Fifty consecutive patients undergoing 2-level lumbar spinal fusion as treatment for low back pain due to DDD were enrolled in this study. Only patients with 2-level DDD were recruited, as this is the most common number of levels affected in the authors' community-based practice for surgical treatment of lumbar degenerative spinal conditions. Entry criteria were as follows: age between 18 and 65 years, <20 degrees of scoliosis, and axial low back pain greater than leg symptoms. Patients were eligible for the study if they had a previous discectomy but were excluded if they had recurrent disk herniation or stenosis that required additional decompression. Exclusion criteria included morbid obesity (>280 pounds), pregnancy, medical illness precluding surgery, or osteoporosis (DEXA score, <2.5 *T*-score). Patients underwent at least 9 months of nonoperative treatment, including physical therapy, pharmacological treatment, and spinal steroid injections. Discogenic pain was confirmed by independent discography. Owing to the strict criteria of the "pure" 2-level DDD diagnosis, enrollment occurred over a 5-year span (June 2002–June 2007) to reach the required number of subjects and establish a uniform patient population.

Preoperatively, patients were informed by the surgeon that, for the posterior procedure, "…we either pull the muscles off the back of the spine or go through the muscles to get to the spine." On the day of surgery for the 2-level combined anterior-posterior spinal fusion, patients were computer randomized by a third party to 1 of the 2 posterior approaches: either an open midline approach or an open paraspinal muscle-splitting approach through a midline skin incision. The patients were blinded as to the approach for the posterior procedure. The rationale for an anterior-posterior approach relative to a posterior-only approach was that a uniform anterior fusion procedure with a large interbody fusion surface area decreases variability in obtaining a solid fusion, which may occur with posterior-only arthrodesis procedures. The anterior-posterior approach also reliably increases interbody height, restores lordosis, and stabilizes the anterior column while avoiding the potential posterior-approach asymmetry that may occur in posterior interbody techniques.[26,27] An additional rationale was that the author's experience with anterior-posterior "circumferential" fusion demonstrated improved outcomes relative to posterior fusions for the DDD diagnostic patient group.[28] The study was approved by the institutional review board, and patients also gave their consent to long-term outcomes assessment.

For anterior spinal fusion, a left retroperitoneal exposure was performed by an experienced access surgeon, after which the anterior spinal fusion was performed by the author, who began with a generous 2-level discectomy with cartilaginous endplate removal. Fusion was accomplished using a structural femoral cortical ring allograft combined with either morcellized left anterior iliac crest bone graft or with bone morphogenic protein (BMP) (15% in the midline and 18% of the paraspinal group) combined with local bone graft. Local bone graft was obtained from endplate shavings during endplate preparation for the anterior spinal fusion. Typically, if L5–S1 was included in the fusion, supplemental anterior buttress instrumentation was placed, encompassing a titanium 6.5 mm cancellous screw along with a spiked plastic washer.

Posterior spinal fusion was performed with the patient prone on a 4-poster frame. After the posterior spine was prepped and draped, the surgeon made a midline skin incision. Exposure of the posterolateral spine was as per the randomization protocol, either through an open midline approach or by elevating subcutaneous flaps bilaterally and then applying an open bilateral paraspinal muscle-splitting approach using a blunt technique. The supraspinous and interspinous process ligaments were maintained in patients in the midline group. In all patients, the facet joints were decorticated and fused and an intertransverse process fusion with iliac bone autograft was performed. No BMP was used posteriorly. The iliac crest bone graft was obtained using an intracortical technique. This entailed removing the 1–2 cm cap of the posterior superior iliac spine with an osteotome and then using variously sized curettes to obtain cancellous bone graft between the inner and outer table of the ilium. All bone graft sites were reconstructed to reduce donor site pain and also allow for bone graft reharvesting should a subsequent fusion become necessary.[29–31] Graft site reconstruction was accomplished using bone allograft

cubes, which were morselized, packed into the defect within the iliac crest, and backfilled using a tamp, after which the fascia over the posterior superior iliac spine was sutured closed. For both the paramedian and the midline groups, bilateral pedicle screw instrumentation was used by means of the tactile technique for pedicle screw hole placement. In both patient groups, handheld retractors were used for exposure and moved for each level exposed and static retractors were moved about with placement of each pedicle screw, never being maintained in a static position for >20 minutes, to avoid gross muscle injury. Although no fluoroscopy was performed during the procedure, plain radiographs were obtained during wound closure in all patients. Operative times, blood loss, implant costs, and hospitalization charges were recorded.

Preoperatively and postoperatively, multiple outcome measurements [the visual analog back and leg pain scale (VAS), pain drawing, the Oswestry disability index (ODI), and patient self-assessment of procedure success ("Do you consider your surgery to have been successful?"; "Would you undergo this treatment again under similar circumstances?"; "Would you recommend this procedure to others with similar symptoms and spine problems?")] were obtained to assess patient pain and function at numerous time points over a minimum 2-year follow-up period.[32] Outcome instrument results, to which the treating surgeon was blinded, were entered into computer spreadsheets by office personnel, who were not informed of the type of surgical approach. Postoperative follow-up evaluations were obtained at 2 weeks, 1–2 months, 3–7 months, 7–12 months, 1–2 years, and 2–4 years, and then every 2 years thereafter, with outcomes documented at follow-up visits beyond 6 months. Plain radiographs were obtained at all follow-up clinic visits. Additional surgeries were tracked over the minimum follow-up period and thereafter.

Postoperatively, in addition to outcomes assessment, a repeat lumbar MRI scan was obtained in patients to evaluate adjacent disk degeneration and paraspinal muscle signal changes. MRI scans were obtained at 1–2 years postoperatively. All lumbar MRI scans were read by a radiologist (with specialization in spine) who was blinded to the type of posterior approach used for the patients and to the time interval from the date of surgery to the postoperative MRI scan. MRI changes in the paraspinal muscles were assessed by measuring transverse relaxation time (T2) according to the method previously described.[4] Briefly, T2 measurements were obtained by placing a $100\,mm^2$ circular region of interest on axial MRIs in the central portions of each multifidus muscle at the L2–L3 to S1–S2 disk levels on preoperative and postoperative images and in each corresponding psoas muscle. The data were normalized by calculating the signal intensity ratio of multifidus to psoas muscle at each level.[33] Only 2 patients did not have a follow-up MRI; 1 from each group declined because they had moved far from the clinic. Additional MRIs were obtained as needed for clinical indications suggesting new lumbar spine derangements.

Postoperative radiographs were used to assess interbody graft subsidence, which was determined by measuring intradiscal height immediately postoperatively and 6 months postoperatively and determining the difference between these 2 measurements. Fusion assessment was accomplished by high-resolution computed tomography scanning (total of 37 patients), fusion mass exploration at the time of instrumentation removal, or both.

Statistical analysis included within-group changes versus preoperative values. Changes between the 2 groups also were evaluated. The study size was based on interim analysis of a concurrent study by the authors of single-level fusion in which different posterior techniques were compared and statistically significant differences were found with n = 25 in each group.[34] Midline versus paraspinal group comparisons included *t* tests and repeated-measures regression analysis to investigate whether differences between the groups occurred over time with the change in these parameters from preoperative values. Additional analyses included a repeat-measures regression model used to compare the T2 MRI relaxation values between surgical approaches, spinal level, and right to left sides. In addition, differences between surgical approach groups by level were evaluated using 2-sample *t* tests.

RESULTS

Preoperative patient characteristics of the 2 study groups were similar and, where differences existed, none were significant (Table 1). In the midline group, the mean number of degenerated lumbar disks on MRI was 2.6 (range, 2–4) per patient; 21 patients had preoperative discography with testing of a mean of 3.6 disks, of which a mean of 2.1 disks produced concordant pain on provocation. In the paraspinal approach group, the mean number of degenerated lumbar disks on MRI was 2.5 (range, 2–5) per patient; 23 patients had preoperative discography with testing of a mean of 3.4 disks, of which a mean of 2.0 disks produced concordant pain on provocation.

TABLE 1. Patient Characteristics

	Midline (n = 25)	Paraspinal (n = 25)
Age (mean ± SD) (y)	45.8 ± 12.6	44.0 ± 10.6
Female (%)	68	68
BMI (mean ± SD)	28.1 ± 3.6	27.8 ± 6.1
Duration of symptoms (mean ± SD) (y)	4.9 ± 5.4	7.7 ± 6.8
Smokers (%)	40	60
WC/litigation (%)	52	44
Prior discectomy (%)	28	32
Fusion levels		
L4–S1	21	20
L3–L5	2	4
L2–L4	2	1

BMI indicates body mass index; WC, work compensation case.

A comparison of operative and hospitalization parameters between the groups found no significant differences. Blood loss, length of stay, and operative time for the anterior and posterior portions of the procedure were all similar, as was the turnover time between the anterior and posterior portions of the procedure (Table 2). Hospitalization implant costs and hospitalization charges (which included implant charges) were similar for both groups as well.

Postoperatively, outcomes for both groups over time were assessed and compared with the preoperative measurements and between groups. For all periods up to 4 years, follow-up data were available for 100% of patients and, at the 4- to 6-year follow-up period, follow-up data were available for 88% of patients. It is noteworthy that the mean preoperative VAS leg pain in these DDD patients without significant stenosis was 5.7, in which the buttock and posterior thigh were most commonly indicated on the preoperative pain drawings. The authors presumed this to indicate referred pain. Intention-to-treat analysis found that all postoperative outcomes—including VAS for back pain and leg pain, pain distribution as measured by the pain diagram, and disability related to pain as measured by the ODI—improved significantly relative to preoperative values in both groups (all $P < 0.001$ except drawing scores at the 2–4 y follow-up, which were $P = 0.02$; Figs 1–4). Statistical analysis between the groups did not find any difference in the preoperative or follow-up scores, or for change in scores, for any of the outcome measures listed (Table 3). In addition, subgroup analysis found no difference at any outcome period between workers' compensation (WC) patients and non-WC patients when comparing the change from preoperative condition at each follow-up period.

Nonsteroidal anti-inflammatory medication, NSAID, and narcotic usage for treatment of pain were compared between groups and, though narcotic pain medication usage was reduced in both groups, there was no significant difference between the groups in the degree of reduction of pain medication usage. Specifically, preoperative use of NSAID was 14/25 and 12/25 patients in the midline and paraspinal groups, respectively. The preoperative use of narcotics was 16/25 and 19/25 patients in the midline and paraspinal groups, respectively. Only 1 midline and only 2 paraspinal patients took no pain medication preoperatively. Postoperatively, NSAID use remained relatively stable varying between 28% and 48% for the various follow-up periods for both groups. Narcotic use decreased postoperatively for both groups: the use of narcotics was 9/25 and 13/25 patients in the midline and paraspinal groups, respectively, at the 7- to

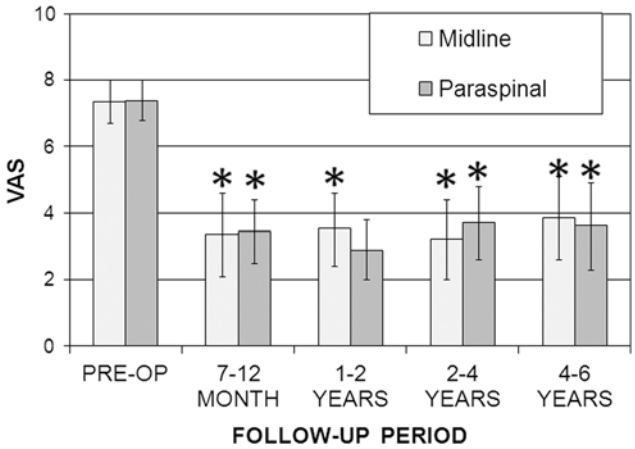

FIGURE 1. Low back pain severity over follow-up periods for midline versus paraspinal approach groups (pain visual analog scale, mean ± 95% upper and lower confidence limits). *Significant in-group difference from preoperative value.

TABLE 2. Hospitalization

	Midline (n = 25)	Paraspinal (n = 25)
EBL (mL; mean ± SD)	515 ± 319	482 ± 279
OR time total (mean, h:min)	4:58 ± 0:36	5:09 ± 0:39
OR time ASF (mean, h:min)	1:44 ± 0:21	1:45 ± 0:23
OR time turnover (mean, h:min)	0:17 ± 0:04	0:17 ± 0:05
OR time PSF (mean, h:min)	2:56 ± 0:25	3:06 ± 0:26
Length of stay (d)	3.7 ± 1.1	3.3 ± 1.0
Implant costs ($; mean ± SD)	13,214 ± 1789	12,915 ± 1588
Hospital charges ($; mean ± SD)	68,526 ± 18,297	72,017 ± 14,777
Additional surgery [n (%)]		
Instrumentation removal	13 (52)	16 (64)
Pseudo repair	1 (4)	0
Adjacent segment fusion	3 (12)	3 (12)
Other (adjacent decompression, SCS)	2 (8)	2 (8)

ASF indicates anterior spinal fusion; EBL, estimated blood loss; OR, operating room; PSF, posterior spinal fusion; SCS, spinal cord stimulator.

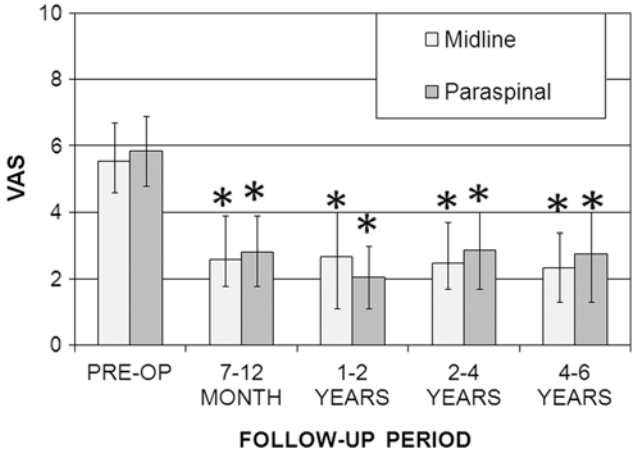

FIGURE 2. Leg pain severity over follow-up periods for midline versus paraspinal approach groups (pain visual analog scale, mean ± 95% upper and lower confidence limits). *Significant in-group difference from preoperative value.

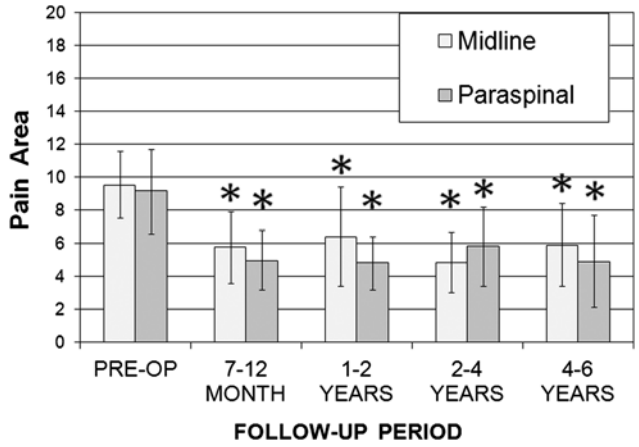

FIGURE 3. Low back and leg pain area over follow-up periods for midline versus paraspinal approach groups (pain drawing, mean ± 95% upper and lower confidence limits). *Significant in-group difference from preoperative value.

12-month follow-up period; was 9/25 and 5/25 patients in the midline and paraspinal groups, respectively, at the 1- to 2-year follow-up period; was 8/25 in both groups at the 2- to 4-year follow-up period; and was 5/25 and 6/25 patients in the midline and paraspinal groups, respectively, at the 4- to 6-year follow-up period. The number of patients who took no pain medication postoperatively increased from 20% to 44% for the various follow-up periods for both groups.

Patients' self-assessment for success of the procedure, whether they would repeat the procedure under similar conditions, and whether they would recommend the procedure to others with the same condition were also evaluated (Table 4), and found not to differ significantly between groups.

Radiographic assessment for the follow-up period identified only 1 patient, from the midline group, with a pseudoarthrosis. Postoperative radiographs also identified subsidence. Radiographic review found interbody graft subsidence to be 1.1 ± 1.6 mm at the proximal fusion level and 0.6 ± 0.8 mm at the distal fusion level in the midline group, which was not significantly different from 1.8 ± 2.6 mm at the proximal and 0.9 ± 1.5 mm at the distal level in the paraspinal group.

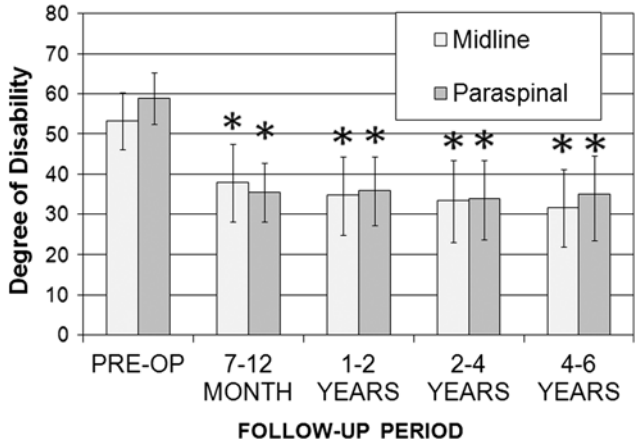

FIGURE 4. Disability severity over follow-up periods for midline versus paraspinal approach groups (Oswestry Disability Index, mean ± 95% upper and lower confidence limits). *Significant in-group difference from preoperative value.

Preoperative and follow-up MRI scans were used to assess the development of adjacent disk deterioration and paraspinal muscle changes. Follow-up MRI scans (mean, 17 ± 8 mo after index fusion surgery) identified new or progressive adjacent-segment disk degeneration in 21% of the midline patients and 25% of the paraspinal muscle patients. 24 of 25 patients in each group had follow-up MRI available for the assessment of the adjacent disk, however, assessment of the paraspinal muscle changes was more limited. Of a total of 98 preoperative and postoperative MRI scans, 8 MRI scans in the midline group and 5 in the paraspinal group were not usable for measurement of the T2 muscle changes. Most of the unusable MRIs were unavailable in a digital format or were not viable for some other technical reason. Of the usable follow-up MRIs, increased T2 signal within the posterior paraspinal musculature was greatest at the distal L5–S1 and S1–S2 levels (Fig. 5). The increase in T2 signal from L2–L3 to S1–S2 was significant between each level for both preoperative and postoperative scans (Fig. 6, $P < 0.0001$). There was no significant difference in T2 signal between midline and paraspinal approaches at any level for both preoperative and postoperative MRIs. At all levels, the increase in T2 MRI signal from preoperative to postoperative scans was significant ($P < 0.03$) except in the midline group at L2–L3. A comparison of right and left sides revealed an overall small but significantly greater T2 signal for the left side for both preoperative and postoperative scans ($P = 0.001$). The correlation between MRI T2 values of the posterior spinal muscles and VAS or ODI scores at 1 year was not significant.

Postoperative adverse events included 1 patient each in the midline approach group with nausea and tachycardia, transient meralgia paresthetica over the bone graft donor site, superficial wound infection treated with oral antibiotics, and septic shoulder 1 month postoperatively (thought to be unrelated), and 2 patients had pneumonia. The paraspinal group included 1 patient each with an ileus, pneumonia, delirium, deep venous thrombosis, and a seroma treated with aspiration. Additional surgeries included instrumentation removal from more than half the patients in each of the midline and paraspinal muscle groups at 20 ± 9 months after the index procedure, and all were after follow-up MRIs. Additional surgeries also included pseudarthrosis repair for 1 patient in the midline group, adjacent-level decompression at 6 years in a midline patient and in 2 paraspinal patients, a misplaced pedicle screw revision in 1 patient in the midline group, spinal cord stimulator implantation in 1 midline patient, and fusion extension with or without decompression for 3 patients each in both groups (2 patients at 3 y and 1 each at 4, 4.5, 5.5, and 8 y after the index fusion).

TABLE 3. Change in Outcomes

Approach	Follow-up Period	Mean	SD	Lower 95% CL	Upper 95% CL
(*A*) *Within Group*					
Change in back pain VAS					
Midline	7–12 mo	−4	2.8	−5.1	−2.8
	1–2 y	−3.8	2.5	−4.8	−2.8
	2–4 y	−4.1	2.6	−5.2	−3
	4–6 y	−3.5	2.9	−4.7	−2.2
Paraspinal	7–12 mo	−3.9	2.6	−5	−2.9
	1–2 y	−4.5	2.6	−5.6	−3.4
	2–4 y	−3.7	3.1	−5	−2.4
	4–6 y	−3.8	3.7	−5.4	−2.1
Change in leg pain VAS					
Midline	7–12 mo	−2.9	3.3	−4.3	−1.6
	1–2 y	−2.9	3.6	−4.4	−1.3
	2–4 y	−3	3.2	−4.4	−1.7
	4–6 y	−3.1	3	−4.4	−1.8
Paraspinal	7–12 mo	−3	3.3	−4.4	−1.7
	1–2 y	−3.8	2.9	−5	−2.6
	2–4 y	−3	3.8	−4.5	−1.4
	4–6 y	−3.2	3.7	−4.9	−1.5
Change in pain drawing					
Midline	7–12 mo	−3.8	6.4	−6.4	−1.1
	1–2 y	−3.1	6.6	−5.9	−0.4
	2–4 y	−4.7	4.9	−6.7	−2.6
	4–6 y	−3.6	7.6	−6.8	−0.4
Paraspinal	7–12 mo	−4.2	6.8	−7	−1.4
	1–2 y	−4.4	6.9	−7.2	−1.5
	2–4 y	−3.4	9.6	−7.3	0.6
	4–6 y	−5	9.1	−9.1	−0.8
Change in Oswestry Disability Index					
Midline	7–12 mo	−15.4	19.5	−23.5	−7.4
	1–2 y	−18.6	18.6	−26.3	−10.9
	2–4 y	−19.9	21.1	−28.6	−11.2
	4–6 y	−21.1	24.1	−31.3	−10.9
Paraspinal	7–12 mo	−23.5	19.8	−31.6	−15.3
	1–2 y	−23.1	20.4	−31.5	−14.7
	2–4 y	−25.1	22	−34.2	−16.1
	4–6 y	−23.3	24.6	−34.5	−12.1

(*B*) *Between Groups*

Follow-up Period	Difference in Mean Change	SD	SE	95% CI Difference	*P*
Difference in mean change in LBP VAS from preoperative by group (midline-paraspinal)					
7–12 mo	−0.02	2.69	0.76	−1.56, 1.51	0.98
1–2 y	0.69	2.52	0.71	−0.75, 2.12	0.34
2–4 y	−0.42	2.84	0.80	−2.04, 1.20	0.60
4–6 y	0.31	3.29	0.98	−1.67, 2.30	0.75
Difference in mean change in leg VAS from preoperative by group (midline-paraspinal)					
7–12 mo	0.07	3.26	0.92	−1.78, 1.92	0.94
1–2 y	0.92	3.32	0.94	−0.96, 2.81	0.33
2–4 y	−0.07	3.50	0.99	−2.07, 1.92	0.94
4–6 y	0.09	3.36	1.00	−1.93, 2.12	0.93
Difference in mean change in pain drawing from preoperative by group (midline-paraspinal)					
7–12 mo	0.44	6.62	1.87	−3.33, 4.21	0.82
1–2 y	1.24	6.76	1.91	−2.60, 5.08	0.52
2–4 y	−1.32	7.64	2.16	−5.70, 3.06	0.55
4–6 y	1.37	8.33	2.49	−3.65, 6.39	0.60
Difference in mean change in Oswestry from preoperative by group (midline-paraspinal)					
7–12 mo	8.01	19.65	5.56	−3.17, 19.18	0.16
1–2 y	4.51	19.53	5.52	−6.60, 15.61	0.42
2–4 y	5.24	21.55	6.09	−7.01, 17.50	0.39
4–6 y	2.20	24.31	7.27	−12.45, 16.85	0.76

DISCUSSION

The present study sought to determine whether the type of posterior approach during spinal fusion surgery had an effect on the posterior musculature and subsequent patient outcomes. As many factors as possible in the clinical setting were controlled so as to reduce the variability that is common to clinical studies. Comparison of preoperative and >1-year follow-up MRI scans as-

TABLE 4. Patient-reported Self-Assessment of Success (%)

	n/N (%)	
	Midline	**Paraspinal**
Overall, do you consider your surgery to have been successful?		
7- to 12-mo follow-up	18/25 (72)	19/25 (76)
1- to 2-y follow-up	20/25 (80)	19/25 (76)
2- to 4-y follow-up	20/25 (80)	19/25 (76)
4- to 6-y follow-up	19/24 (79)	17/22 (77)
Would you undergo this treatment again under similar circumstances?		
7- to 12-mo follow-up	17/25 (68)	19/25 (76)
1- to 2-y follow-up	19/25 (76)	19/25 (76)
2- to 4-y follow-up	17/25 (68)	21/25 (84)
4- to 6-y follow-up	16/24 (67)	17/22 (77)
Would you recommend this procedure to others with similar symptoms and spine problems?		
7- to 12-mo follow-up	17/25 (68)	20/25 (80)
1- to 2-y follow-up	22/25 (88)	20/25 (80)
2- to 4-y follow-up	16/25 (64)	21/25 (84)
4- to 6-y follow-up	17/24 (71)	18/22 (82)

sessed posterior spinal muscle and adjacent disk changes, and multiple outcome instruments were used to evaluate outcomes.

The results of the present study seem to be valid; the values for the VAS and ODI improvement over time being similar to or better than previously published 1-level and 2-level spinal fusion outcome studies.[35–38] In the present study, both groups had substantial improvements in outcomes, with VAS and ODI changes not only greater than the minimally clinical important difference but also at the level considered to be substantially clinically improved.[39–43] That said, few patients considered themselves to be pain free.

To assure uniformly high fusion rates and thus decrease potential adverse outcomes related to nonunion, a combined anterior-posterior fusion procedure was performed. Postoperative imaging found high fusion rates and also interbody graft subsidence similar to a prior report of interbody fusion.[44] One patient in the midline group developed a pseudarthrosis. Despite the technically high success rate of obtaining a solid fusion, many patients had some degree of residual pain. Postoperatively, many patients had additional physical therapy or intervention such as adjacent-level spinal steroid injections or sacroiliac or trigger point injections. Numerous patients had tenderness over the pedicle screw instrumentation on follow-up examination. Many patients desired instrumentation removal, which also allowed for a fusion exploration.

Instrumentation removal was unexpectedly common in this study but is controversial among spine surgeons and thus warrants additional discussion. Within the author's region, some spine surgeons never remove instrumentation, whereas other do so routinely. The protocol used in this study was as follows: in 16 patients with thin body habitus, if there was tenderness to direct palpation over the pedicle screwheads, then a radiograph with a radiopaque marker at the site of maximal tenderness was obtained. If this marker was directly over the pedicle screwhead, then the patient was offered instrumentation removal (along with fusion mass exploration). In another 15 patients, they were referred to an interventional anesthesiologist who performed a selective diagnostic and therapeutic injection under fluoroscopy. This entailed injecting 2–3 mL 4% lidocaine and Omnipaque 300, along with Depomedrol (80 mg/mL) directly adjacent to each pedicle screwhead. In this study of 2-level fusion patients, the injection most commonly was made at L5 and S1 but, in a few patients, up to 6 pedicle screwheads were injected. A limitation of this protocol is that the medial branches of the posterior rami for the adjacent facet joint could be affected by proximal screwhead injections, as could the adjacent muscles. Three patients did not improve with the diagnostic portion of the injection, and their instrumentation was retained. Five patients had sustained decrease in pain (> 6 mo duration), and 3 had no further surgery. Twelve patients had only temporary pain improvement and, based on this protocol, desired removal of their pedicle screw instrumentation. A concern related to secondary surgery is the increased cost associated with the procedure. The actual costs for instrumentation removal were not assessed in this study; however, an estimate can be made based on the Medicare reimbursement for the author's region, which is $7021.00 for hospitalization and $620.00 for surgeon payments. Alternative types of posterior instrumentation may reduce secondary surgery rates and improve outcomes.[34]

In the present study, postoperative MRI found the T2 signal intensity ratio of the multifidus muscles to psoas control muscle to be substantially increased relative to the preoperative ratio. The present study found an approximately 50% increase at the L4–L5 level and approximately a 3-fold increase at the L5–S1 level. The greater increase in MRI changes at the distal levels has been previously described, but the magnitude of the changes in the present study were substantial as compared with a prior study that found only a 23%–34% increase in ratios.[23,24] It is speculated that the slightly greater values for the left relative to the right side are attributable to the fact that the left side was typically instrumented first. Postoperative MRIs in prior studies performed elsewhere and comparing patients undergoing a minimally invasive paraspinal muscle approach to those undergoing an open midline approach for 1-level fusion procedures revealed less signal change in muscles of the paraspinal approach group.[45,46] However, it is difficult to draw a conclusion as both of these prior studies involved very few participants (14 patients combined) in each group. The similar MRI findings between the 2 groups of the present study suggest that the duration of retraction is not the only major cause of muscle changes. That is, the retraction for the paraspinal group was less, as only 1 side was retracted at a time, which allowed the opposite side to relax. The notion that factors other than retraction affect the posterior musculature is supported by a previous animal study of lumbar fusion compared with a sham operation (same exposure and duration of retraction), in which EMG and histologic findings suggested that fusion had an effect

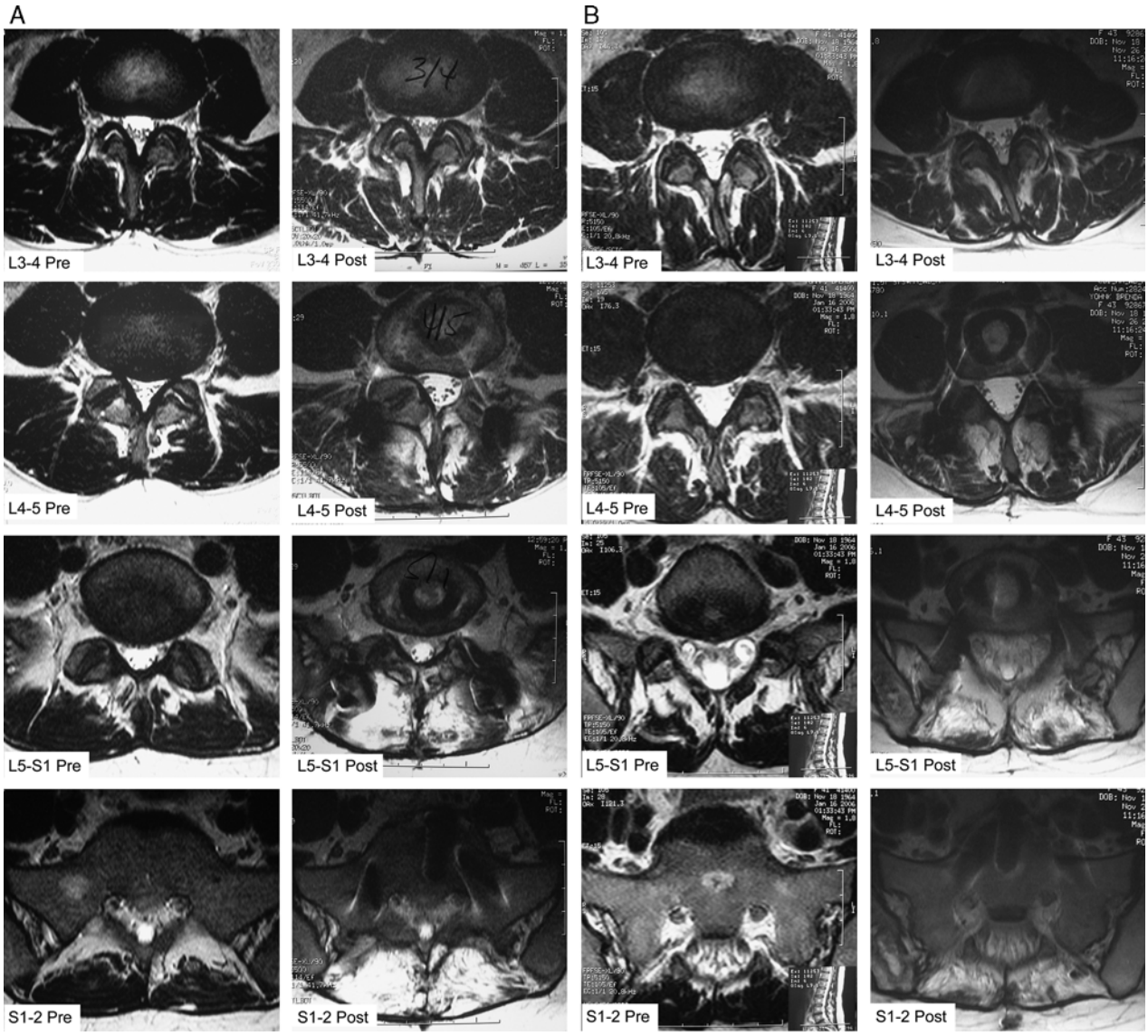

FIGURE 5. Examples of lumbar MRI axial images from proximal to distal levels (L3–L4, L4–L5, L5–S1, and S1–S2) with increased region of T2 posterior muscle signal intensity on postoperative images (right). A, Representative images for a midline approach patient (42 y old female). B, Representative images for a paraspinal approach patient (42 y old female).

beyond that of the fusion bed exposure.[47] In addition, a recent clinical study found posterior muscle MRI changes even in patients who underwent an anterior-only lumbar fusion.[48] Furthermore, even unoperated patients with lumbar disk herniation may have MRI changes.[49]

The results of muscle changes, particularly at the more distal levels of the spine, regardless of approach, suggest that further study is needed to determine the cause of the muscle changes, such as denervation, devascularization, and disuse atrophy (fusion disease). Denervation particularly deserves further study because, in both groups of the present study, the medial and lateral branches of the posterior rami were at risk of injury during the fusion bed preparation, which entailed decortication of the adjacent transverse processes, the cranial articular process, and the pars interarticularis between them.[50]

This study had numerous advantages, including the prospective and randomized design, blinding of patients and those performing analysis, and performance of all procedures in a similar manner by a single surgeon. However, there are also limitations, including those related to the surgery and those related to data analysis. Among the surgical limitations is the variable use of BMP during the anterior procedure. The authors contend that this is unlikely to alter our conclusions, as the fusion rates were similar between the 2 groups. Another limitation is that retraction pressure and duration was not measured during surgery. Retractors were also repeatedly repositioned during surgery, but this frequency was not meas-

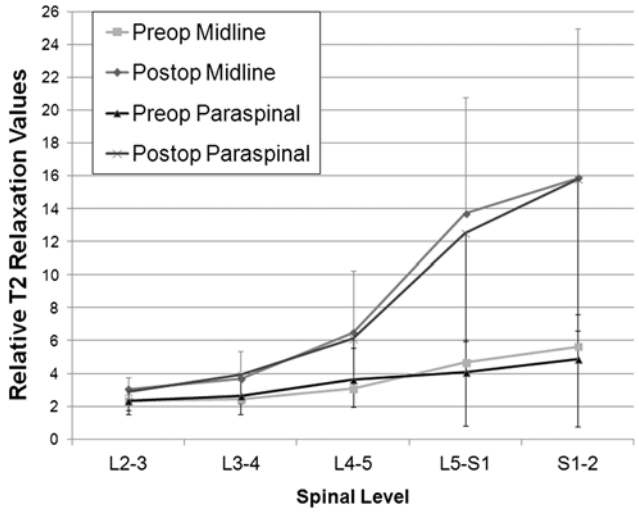

FIGURE 6. Graph of MRI T2 signal intensity for midline and paraspinal approach groups with preoperative and postoperative ratios at each spinal disk level.

ured. Analysis limitations include a possible β-error in the statistical analysis. Although prior studies of similar sample size were able to detect significant differences in outcomes between 2 types of posterior fusion technique, the present study did not.[34,51] A post hoc power analysis was performed to determine the number of patients that would have to be studied to show a difference in VAS low back pain and ODI. This power analysis was based on our results at 2- to 4-year follow-up, targeted a clinically meaningful difference of 1.5 for the VAS and 10 for the ODI, and assumed a desired power of 0.8 and *P*-value of 0.05.[43] On the basis of these inputs, a minimum sample size of 96 patients per group is needed. The present study is underpowered to detect a true outcomes difference between groups, and thus it is possible that this study's conclusion represents a false negative; also, not all MRIs could be analyzed for muscle T2 relaxation values. In addition, a limitation related to determining the rate of adjacent-segment degeneration was due to the variable number of MRIs obtained for patients after the initial 1-year postoperative MRI scan: Because repeat MRIs after 1 year were obtained only if clinically indicated, typically for new or increased pain, there may be some patients with adjacent-segment degeneration but minimal symptoms who did not undergo another repeat MRI. In this case, the actual rate of adjacent disk degeneration would be greater than that reported in this study. The applicability of this study's results is a relative limitation owing to the ever-changing techniques to achieve spinal fusion. That is, before long-term results, or even mid-term results, for a particular technique are published, many surgeons evolve to use newer techniques, including low-profile instrumentation or "minimally invasive" spinal surgery.

The paraspinal approach used in the 1 study group was an open approach and should not be interchanged for the paraspinal approach used in minimally invasive spinal surgery. It is emphasized that this study evaluated 2 types of open posterior approach and does not predict fusion outcomes performed through smaller skin incisions and percutaneous "tubes" or other minimally invasive techniques.[45,52,53] If future studies confirm improved clinical outcomes with minimally invasive posterior fusion techniques, the improved outcomes are unlikely to be attributable to midline versus paraspinal approach but rather to other factors such as the degree of muscle injury, type of instrumentation, and length of retraction.

In summary, 2-level circumferential fusion patients who were randomized as to the type of posterior approach experienced similar clinical improvement as assessed by multiple measures relative to their preoperative measurements. Not only was there no difference in outcomes, but there was no difference in the 1-year postoperative MRI appearance of the posterior spinal muscle changes between approach groups. Both types of approach were found to change the T2 intensity of the posterior muscle, with significantly greater effects found at the more distal levels. In conclusion, we were unable to support the hypothesis that an open paraspinal muscle-splitting approach for 2-level spinal fusion was superior to the muscle-stripping midline approach. The study is underpowered statistically, and surgeon readers need to consider this before a change in their surgical techniques.

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