

The attached reprints are inconsistent with indications for AxiaLIF® as cleared by FDA. The cleared indications are as follows:

INDICATIONS and INTENDED USE: TranS1 AxiaLIF® System is intended to provide anterior stabilization of the L5-S1 spinal segment as an adjunct to spinal fusion. The AxiaLIF® System is indicated for patients requiring fusion to treat pseudoarthrosis (unsuccessful previous fusion) spinal stenosis, spondylolisthesis (Grade 1 or 2), or degenerative disc disease as defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The AxiaLIF® System is also intended for minimally invasive access to the anterior portion of the lower spine for assisting in the treatment of degeneration of the lumbar disc, performing lumbar discectomy, or for assistance in the performance of L5-S1 interbody fusion. The AxiaLIF® System is not intended to treat severe scoliosis, severe spondylolisthesis (Grades 3 and 4), tumor, or trauma. Its usage is limited to anterior supplemental fixation of the lumbar spine at L5-S1 in conjunction with legally marketed facet screw or pedicle screw systems.

CONTRAINDICATIONS: Coagulopathy; Bowel disease (e.g. Crohn's, Ulcerative Colitis); Pregnancy; Severe scoliosis; Sacral agenesis; Severe spondylolisthesis (>grade 2); Tumor; Trauma; Do not use with facet screws when correction of spinal stenosis requires removal of significant portions of the lamina or any portion of the facets.

The information and data published in the attached publication(s) are the work and original thoughts of the named author(s) who do not represent TranS1® Inc. or any of its products. TranS1® Inc is not aware of any significant risks concerning the uncleared use discussed in the journal article(s) other than those in the cleared labeling and as discussed in this article(s).

The device described in the attached article(s) are manufactured by TranS1. The author, Dr. Neel Anand, acts in the capacity of a surgeon instructor and educator in the proper usage of minimally invasive spine surgery techniques which may include the TranS1® AxiaLIF® procedure. TranS1® has compensated Dr. Anand on a fee for service basis for surgeon instruction and education and has not funded the studies discussed in this publication(s).

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Mid-term to long-term clinical and functional outcomes of minimally invasive correction and fusion for adults with scoliosis

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Object. The goal of this study was to assess the operative outcomes of adult patients with scoliosis who were treated surgically with minimally invasive correction and fusion.

Methods. This was a retrospective study of 28 consecutive patients who underwent minimally invasive correction and fusion over 3 or more levels for adult scoliosis. Hospital and office charts were reviewed for clinical data. Functional outcome data were collected at each visit and at the last follow-up through self-administered questionnaires. All radiological measurements were obtained using standardized computer measuring tools.

Results. The mean age of the patients in the study was 67.7 years (range 22–81 years), with a mean follow-up time of 22 months (range 13–37 months). Estimated blood loss for anterior procedures (transpoas discectomy and interbody fusions) was 241 ml (range 20–2000 ml). Estimated blood loss for posterior procedures, including L5–S1 transsacral interbody fusion (and in some cases L4–5 and L5–S1 transsacral interbody fusion) and percutaneous screw fixation, was 231 ml (range 50–400 ml). The mean operating time, which was recorded from incision time to closure, was 232 minutes (range 104–448 minutes) for the anterior procedures, and for posterior procedures it was 248 minutes (range 141–370 minutes). The mean length of hospital stay was 10 days (range 3–20 days). The preoperative Cobb angle was 22° (range 15–62°), which corrected to 7° (range 0–22°). All patients maintained correction of their deformity and were noted to have solid arthrodesis on plain radiographs. This was further confirmed on CT scans in 21 patients. The mean preoperative visual analog scale and treatment intensity scale scores were 7.05 and 53.5; postoperatively these were 3.03 and 25.88, respectively. The mean preoperative 36-Item Short Form Health Survey and Oswestry Disability Index scores were 55.73 and 39.13; postoperatively they were 61.50 and 7, respectively. In terms of major complications, 2 patients had quadriceps palsies from which they recovered within 6 months, 1 sustained a retrocapsular renal hematoma, and 1 patient had an unrelated cerebellar hemorrhage.

Conclusions. Minimally invasive surgical correction of adult scoliosis results in mid- to long-term outcomes similar to traditional surgical approaches. Whereas operating times are comparable to those achieved with open approaches, blood loss and morbidity appear to be significantly lower in patients undergoing minimally invasive deformity correction. This approach may be particularly useful in the elderly. (DOI: 10.3171/2010.1.FOCUS09272)

KEY WORDS • minimally invasive spine surgery • adult deformity • transpoas approach

SCOLIOSIS has been estimated to occur in approximately 6% of the population older than 50 years of age.³² In adults, scoliosis may arise secondary to untreated adolescent idiopathic scoliosis, failed surgical or nonsurgical treatment, or de novo spinal deformity oc-

curing when the patient is an adult; for example, lumbar degenerative scoliosis.¹⁰ Adults with scoliosis typically present with back pain.¹⁰ Furthermore, 15% of the population with low-back pain and older than 60 years of age has been noted to have scoliosis.²⁸

Among the most common forms of adult scoliosis seen in the elderly is lumbar degenerative scoliosis. It has been postulated to develop because of asymmetrical degeneration of discs, osteoporosis, and vertebral body compression fractures.^{7,21} The treatment of adult scoliosis remains controversial. Although nonsurgical management is the mainstay of treatment for this condition, its efficacy is not well supported in the literature.³¹ When surgery is performed, little consensus exists for optimal

Abbreviations used in this paper: AxiaLIF = axial lumbar interbody fusion; DBM = demineralized bone matrix; DLIF = direct lateral interbody fusion; HRQOL = health-related quality of life; ODI = Oswestry Disability Index; PLIF = posterior lumbar interbody fusion; rhBMP-2 = recombinant human bone morphogenetic protein-2; SF-36 = 36-Item Short Form Health Survey; TIS = treatment intensity scale; VAS = visual analog scale; XLIF = extreme lateral interbody fusion.

management because of the heterogeneous presentation of the disorder, controversial surgical indications, numerous surgical options, and heterogeneous outcomes in reported series. Surgery is also associated with considerable complication rates, especially in the elderly.³¹

Minimally invasive spine surgery theoretically allows for less tissue damage and blood loss, and as a result less morbidity in the treatment of adult scoliosis.^{4,27} Earlier we reported the feasibility and technique of using 3 novel minimally invasive methods for circumferential deformity correction and fusion of scoliosis.⁴ In this paper we report on a consecutive series of patients with adult scoliosis in whom 3 or more levels were treated with instrumentation and fusion according to minimally invasive methods, and in whom more than 1 year of clinical and radiographic follow-up was available.

Methods

A research associate identified all patients who had undergone minimally invasive circumferential adult scoliosis deformity correction through a review of the database of surgical cases performed by the senior author (N.A.). Seventy-two consecutive patients were identified who had undergone minimally invasive percutaneous instrumentation and fusion for adult scoliosis. Only patients with fusions of 3 or more levels were included, and all had to have a minimum of 1 year of follow-up. Additionally, all had to have a minimum 15° Cobb angle to be included. Twenty-eight patients were identified who met the selection criteria. All patients had severe predominantly low- to middle-back pain, worsening over the day with any loading activity. Sitting was the worst position for pain, with stiffness in the morning being a ubiquitous symptom in all. Eighteen of these patients had associated radiculopathy; 10 had severe radiculopathy that worsened with standing and walking. These patients had central and lateral recess stenosis documented on MR imaging. The other 8 had intermittent radiculopathy and foraminal stenosis on MR imaging. There were 13 men and 15 women (mean age 67.7 years, range 22–81 years), and the mean follow-up time was 22 months (range 13–37 months). All patients had participated in extensive conservative therapies without adequate relief of their symptoms before being considered for surgery.

Data for this study were obtained through retrospective chart review with Internal Review Board approval. Outcome data were prospectively collected at each visit through self-administered patient questionnaires, with 100% follow-up. All surgery was performed by the senior spine surgeon at a single institution.

Surgical Technique

Fusion levels were based on the extent of degeneration and segmental instability. All degenerated discs in the Cobb angle were fused, and fusion extent was up to the first parallel normal disc on MR imaging. The techniques used for minimally invasive percutaneous correction and fusion for adult scoliosis have been described by us previously.⁴ In summary, the patients in this study underwent a single or a combination of the following

surgical interbody disc release and fusion procedures: 1) XLIF (NuVasive, Inc); 2) DLIF (Medtronic Sofamor Danek, Inc.); or 3) AxiaLIF for L5–S1 fusion, or in some cases L4–5 and L5–S1 fusion (TranS1, Inc.). Posteriorly, all patients underwent multilevel percutaneous pedicle screw instrumentation, for which the Medtronic CD Horizon Longitude system was used. If 3 or more levels were being treated, the surgeries were staged 2 to 3 days apart, with the lateral interbody discectomies and fusions being performed in the first stage, followed by the second stage, in which the axial interbody fusion and the posterior instrumentation and fusion were done.

The techniques of lateral lumbar interbody fusion procedures (XLIF and DLIF) have been well described.^{3,6,16,23,25,26} The technique was nearly identical for both the XLIF and DLIF procedures, with the exception of access to the disc space and use of different retractor systems. Proprietary instrumentation was used for disc space access, in addition to continuous neurophysiological monitoring, including free-running and triggered electromyography. In degenerative scoliosis, the side selected for access to the disc space was determined by the side where the L4–5 disc space was more readily accessible given the morphological features of the iliac crest. If L4–5 was not being fused, then access was always obtained on the side of the convexity. In adult idiopathic scoliosis, the MR imaging study was carefully reviewed with regard to the vascular anatomy, and access was obtained from the convex side. The disc was released all the way to the contralateral side to obtain maximal coronal correction at that segment. After endplate preparation, lordotic polyetheretherketone spacers supplemented with rhBMP-2/ACS (Infuse, Medtronic Sofamor Danek) and Grafton putty DBM (Osteotech) were then used to maintain the correction and perform fusion. A single large Infuse sponge (infused with 12 mg rhBMP-2) was equally divided among all the levels being fused, and placed within the polyetheretherketone cage in the DLIF procedure, augmented with Grafton putty DBM. This averaged to 3.5 mg of rhBMP-2 (range 2–4 mg/level) per disc space fused via the transpoas technique. The lowest level was always treated first, with sequential segmental discectomy and fusion being performed from a caudal to rostral direction.

The TranS1 AxiaLIF procedure was used as the percutaneous interbody fusion technique for L5–S1, and in some cases L4–5 and L5–S1 (when access to the L4–5 interspace via the transpoas approach was not feasible because the patient's iliac crest was relatively high). The general technique for this approach has also been described in detail elsewhere.²³ The AxiaLIF nondistracting screws were placed across the L5–S1 disc space (and in some cases also L4–5). Lordosis was obtained by positioning the patients' legs in extension, and by performance of discectomies. Fusion was obtained with local bone, Grafton putty DBM, and use of one-half of a small sponge of Infuse (from an additional kit) per level. This amounts to 2.1 mg of rhBMP-2 per disc space fused with this technique.

Posterior multilevel percutaneous pedicle screw stabilization was obtained using the Medtronic CD Horizon

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Longitude system. All screws were placed percutaneously with the aid of fluoroscopic guidance. Cannulated screws were placed over guide wires. All screws had extenders attached to them containing a slot to receive an unconstrained rod. Rods were shaped according to the sagittal contour desired, and then passed freehand through the slots under direct fluoroscopic control. After they were passed into all the screw extenders, the rods were reduced to seat them into the tulips of pedicle screw heads. Once reduced, a top locking nut was inserted to fix the rod to the screw, starting from the caudal screw and working proximally in a sequential manner. After all the nuts were placed in the screw heads, extenders were unseated and detached from the screws. Posterior fusion was then performed in long fusions at the levels that were not done anteriorly, and at all levels that underwent transsacral procedures. This was done through the same incision used for screw placements, via a Wiltse-style approach with an expandable tubular retractor. Facet joints and pars were identified, then decorticated with a high-speed bur and grafted with local bone augmented with Grafton putty DBM and rhBMP-2. Approximately 1.62 mg of rhBMP-2 was used per facet–pars complex fused with this technique. In patients in whom segments had already been treated with anterior lumbar fusion, pedicle screw instrumentation was used as a posterior tension band for increased stability and correction; there was no posterolateral fusion at these levels.⁴

Study Measures

Study measures included operative data consisting of blood loss and operating time. Length of hospital stay was noted, as were perioperative complications.

Clinical and functional outcome was evaluated using the VAS, the ODI and TIS questionnaires, and the SF-36 health survey. These were collected prospectively preoperatively and at 6-week, 3-month, 6-month, 1-year, 2-year, and 3-year intervals. The TIS questionnaire⁵ was administered to document objectively the amount of treatment for pain that patients received postsurgery. It consists of 5 questions with 6 choices each. The questionnaire is scored 0 to 100, and it objectively quantifies the basic postoperative treatment received by each patient, and assigns a score at follow-up.⁵ The self-administered questionnaires and radiographic data were scored and tabulated in a database. Patients were asked to rate the surgery as excellent, good, fair, or poor, and to state whether they would recommend the surgery to another patient or friend.

Results

The demographic data of the patients in the cohort are listed in Table 1, along with the levels treated and the number of anterior and posterior levels fused. Seventeen patients underwent a TranS1 AxialLIF procedure at L5–S1 or at L4–5 and L5–S1.

Surgical and Clinical Data

Surgical data are shown in Table 2. For anterior procedures (transpsoas discectomy and interbody fusions),

the estimated blood loss was 241 ml (range 20–2000 ml). A single patient incurred a 2000-ml blood loss subsequent to retrocapsular renal bleeding, which tamponaded off without any sequelae. Estimated blood loss for posterior procedures, including L5–S1 transsacral interbody fusion and percutaneous screw fixation, was 231 ml (range 50–400 ml). The mean operating time, which was recorded from time of incision to closure, was 232 minutes (range 104–448 minutes) for the anterior procedures, and for posterior procedures it was 248 minutes (range 141–370 minutes). The mean length of stay was 10 days (range 3–20 days).

All patients had a solid arthrodesis documented at 1 year. This was confirmed on plain radiographs, and further documented on CT scans in 21 patients. The mean Cobb angle preoperatively was 22.3° (range 15–62°), and postoperatively it was 7.47° (range 0.6–22°) ($p < 0.0001$; see Figs. 1 and 2).

Clinical results were all found to be statistically significant, and are shown in Table 3. The mean preoperative VAS and TIS scores were 7.05 and 53.5; postoperatively these were 3.03 and 25.88, respectively. The mean preoperative SF-36 and ODI scores were 55.73 and 39.13; postoperatively these were 61.50 and 7, respectively.

Postoperative Complications

Seventeen patients were noted to have immediate postoperative thigh dysesthesias, which resolved within 6 weeks. Transient hip flexor weakness and pain was also noted in several patients, which completely resolved again within 6 weeks of surgery. All patients showed fusion on imaging studies, with no evidence of pseudarthrosis. One patient required removal of the proximal screw at T-12 once fusion was confirmed on CT scans; the screw had to be removed because of its prominence. Another patient had an asymptomatic proximal screw fracture at L-2, with solid fusion confirmed on imaging studies. Two patients developed quadriceps palsy with weakness of the vastus medialis, and these patients went on to achieve complete recovery by 6 months. There were no vascular or permanent neurological issues. One patient had an intraoperative retrocapsular renal hematoma, which tamponaded off and needed no further intervention. She did lose 2000 ml of blood, and received appropriate transfusions, with no untoward sequelae. Another patient had an unrelated cerebellar hemorrhage that presented as lethargy 2 days postoperatively. The patient required emergency craniectomy, clot evacuation, and ventriculostomy placement. She recovered well without long-term sequelae: she has no dysarthria, dysmetria, ataxia, or other cerebellar signs and symptoms. No durotomy occurred during surgery, and the extensive cardiac and neuroimaging workup was negative for an embolic, ischemic, or aneurysmal/vascular malformation source (Table 4).

Discussion

Adult scoliosis remains a challenge for the spine surgeon. Given the patients' age and the often-associated medical comorbidities in this population, surgical treatment can be particularly challenging.¹⁴ In their series of

TABLE 1: Demographic characteristics, surgical data, and follow-up time in 28 patients with adult scoliosis*

Indication	Levels Treated	No. of Procedures			LOS (days)	FU (mos)	EBL (ml)		OR Time (min)	
		Transposas Lat Interbody Fusion	Pst Perc Screws & Rods	Axia-LIF			Stage 1	Stage 2	Stage 1	Stage 2
DLS	L2-5	3	3		17	37				
DLS	L2-5	3	3		6	33	100		167	276
DLS	L1-S1	4	5	1	11	32	100	50	366	208
DLS	L1-S1	3	3		3	31	100		156	
DLS	T12-S1	5	6	1	10	30	150	350	425	267
DLS	T10-S1	3	8	1	11	29	20	150	225	336
DLS	L1-S1	4	5	1	5	29	500		448	
DLS	L2-S1	3	4	1	6	28	100	100	124	263
AIS	T12-S1	5	6	1	7	26	300	300	225	227
DLS	L2-S1	3	4	1	10	26	150	150	137	261
DLS	L1-5	3	3		6	26	100	300	208	270
DLS	L2-5	3	3		6	24	300	200	248	186
postlami	T12-S1	1	6		4	23	300		250	
AIS	T12-S1	5	6	1	7	21	100	300	257	310
DLS	L1-S1	4	5	1	9	21	100	150	206	178
AIS	L1-S1	4	5	1	4	20	300	200	255	308
DLS	T12-S1	4	6	2	9	18	100	300	193	296
DLS	L2-5	3	3		15	18	250		313	
AIS	L2-S1	2	4		7	17	150	100	104	191
AIS	T12-S1	4	6	2	10	17	100	400	150	221
AIS	T12-S1	4	6	2	20	16	200	300	169	370
AIS	L1-5	3	3		9	16	150	200	139	141
DLS	L2-S1	2	4	2	9	16	100	300	114	192
postlami	T10-S1	5	8	1	9	16	250	200	197	354
DLS	L3-S1	2	3	1	17	15	200		296	
DLS	L1-S1	4	6		8	15	100	150	431	165
AIS	T12-L5	5	5		16	14	2000	400	255	153
AIS	T12-S1	5	6	1	17	13	200	250	196	276

* AIS = adult idiopathic scoliosis; DLS = degenerative lumbar scoliosis; EBL = estimated blood loss; FU = follow-up; LOS = length of stay; OR = operating room; Perc = percutaneous; postlami = after laminectomy; Pst = posterior.

28 patients undergoing surgery for adult scoliosis, Ali et al.² noted that 18% of patients experienced a perioperative complication. The average blood loss was reported as 1600 ml, with patients receiving a transfusion of 2.4 U on average. Similarly, Shapiro et al.³⁰ reported outcomes in 16 patients undergoing circumferential deformity correction for adult scoliosis with concurrent low-back pain and spinal stenosis. In patients undergoing combined surgery as an index procedure, they noted a mean blood loss of 3665.7 ml, and they reported a complication rate of 75%. Daubs et al.¹⁵ reported complications in 46 patients with arthrodesis of 5 or more levels undergoing adult deformity correction surgery. Among these patients, 28 (60%) had the diagnosis of lumbar degenerative scoliosis or adult idiopathic scoliosis. These authors noted a mean blood loss of 2056 ml, and an average transfusion of 5 U packed red blood cells per patient. They noted an overall

complication rate of 37%, with 20% of patients sustaining a major complication.

Historically, complication rates ranging from 20 to 80% have been reported in the treatment of lumbar degenerative scoliosis.^{1,12,29,36} Recent series have reported similar complication rates. Cho et al.¹³ reviewed their experience with 47 patients undergoing PLIF with instrumentation for lumbar degenerative scoliosis. They noted an overall complication rate of 68%, with 30% of patients having early perioperative complications and 38% having late complications. These authors concluded that abundant blood loss was a significant risk factor for early perioperative complications. They noted a mean blood loss per patient of 2.1 ± 1 L, with an average hospital stay of 20.7 ± 9.6 days. They further noted that patients with degenerative lumbar scoliosis often require long-segment fusion, which may increase the risk of complications re-

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TABLE 2: Surgical data in 28 patients with adult scoliosis

Parameter	Anterior Procedures*	Posterior Procedures†
EBL	241 ml (range 20–2000 ml)	231 ml (range 50–400 ml)
op times (time in OR to time out)	232 min (range 104–448 min)	248 min (range 141–370 min)

* Transposas discectomy and interbody fusion.

† Percutaneous pedicle screw and rod placement; possible transsacral L5–S1 interbody fusion.

lated to instrumentation. An overall pseudarthrosis rate of 4.3% was noted.

The surgical environment of degenerative lumbar scoliosis remains challenging for patients, especially given the hypolordosis associated with this condition, osteoporosis, and the advanced patient age. Thus, interbody

fusion has been suggested for achieving a higher fusion rate and theoretically achieving better alignment than posterolateral instrumented fusion alone.³⁵ Wu et al.³⁵ reported on 29 consecutive patients with degenerative scoliosis who underwent a PLIF procedure. They noted a mean blood loss of $1.7 \text{ L} \pm 129 \text{ ml}$, with an average hospital stay of 11.7 ± 8.3 days. They noted no major medical complications, except for 1 patient who had a superficial infection. The ODI scores were noted to improve from 58 ± 11.5 preoperatively to 25.8 ± 19 postoperatively. Lumbar scoliosis improved considerably with this technique, with a preoperative Cobb angle measuring $16.5 \pm 5.7^\circ$ and postoperatively measuring $7.4 \pm 3.4^\circ$. The authors concluded that PLIF, performed after laminectomy in patients with degenerative lumbar scoliosis, is a safe and effective procedure.

Bono and Lee⁹ pooled 78 articles regarding spinal fusion for lumbar degenerative disc disorders, and they

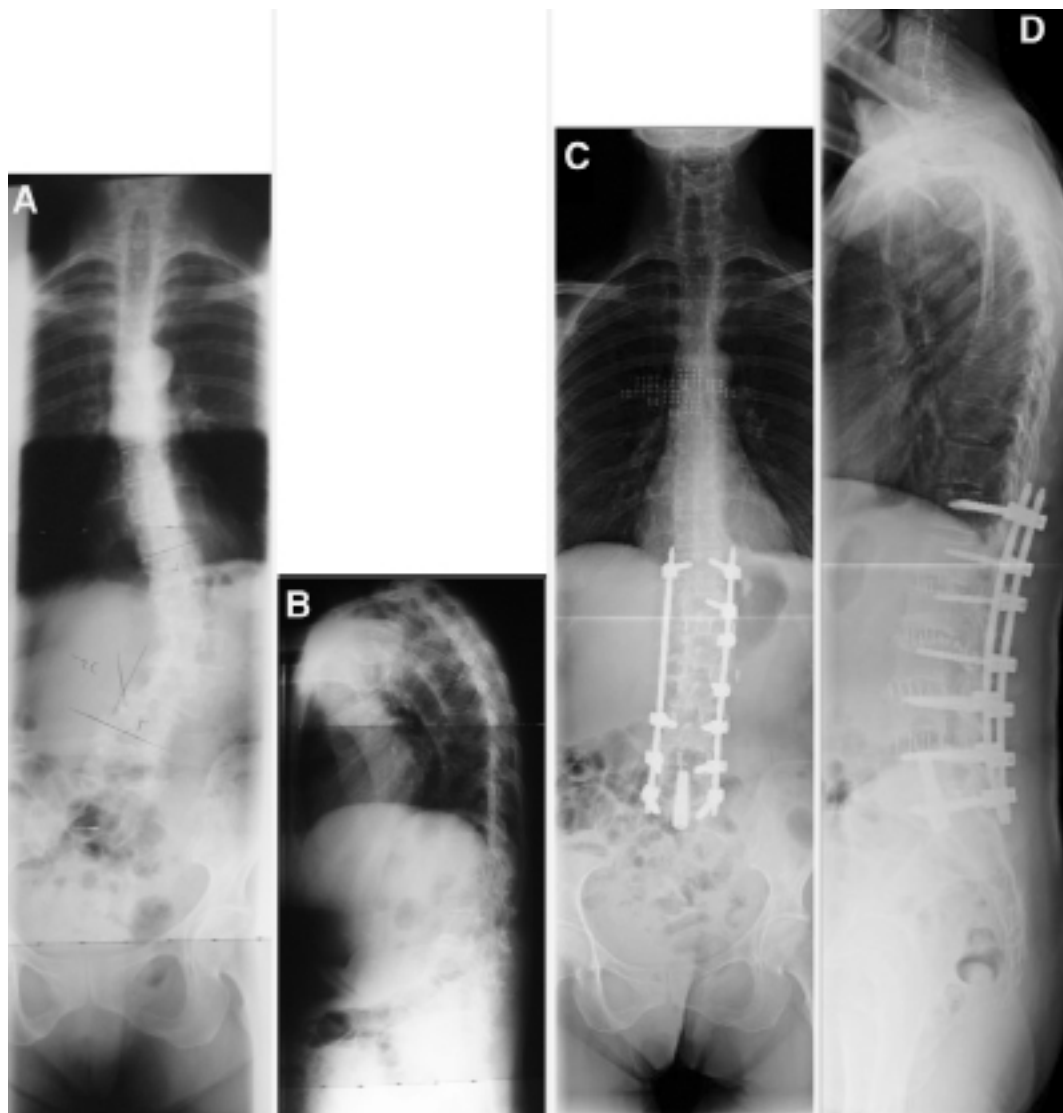


Fig. 1. **A and B:** Preoperative anteroposterior and lateral long-cassette standing radiographs demonstrating $\sim 35^\circ$ adult lumbar scoliosis, with the apex to the left, in a 61-year-old woman. **C and D:** The 1-year postoperative anteroposterior and lateral radiographs reveal excellent correction (Cobb angle of 4°), with good sagittal balance.



Fig. 2. Postoperative CT scans, sagittal (A and B) and coronal (C) reconstruction images, demonstrating a solid arthrodesis.

reported the pooled outcomes for lumbar decompression and fusion for degenerative scoliosis. They reported an overall good-to-excellent outcome in 82% of patients; the fusion rate was reported at 87%. Nevertheless, complication rates for scoliosis based on the pooled data were 55%. Clearly, surgery for a subset of patients with lumbar degenerative scoliosis appears to be of benefit, but perioperative complications remain a major problem. Blood loss is a major concern. Given that the average blood loss for adult deformity correction has been reported as 1.5 L, and has been reported to range from 360 ml to 7 L for instrumented fusion, such operative interventions may be considered very risky in elderly patients, given their increased risk for cardiovascular morbidity.^{21,24} Weidenbaum³⁴ recommended consideration of focal surgical intervention rather than long-segment deformity correction within this patient population.

Our operative results are particularly attractive when comparing complications and blood loss to historical controls. Clearly, the total blood loss for circumferential procedures averages < 500 ml, which is considerably less than any of the abovementioned series for treatment of similar patients. Additionally, operating times were comparable to those for open procedures, and the length of stay was considerably shorter than those reported by the above-named authors. The clinical outcomes, in terms of both VAS and TIS scores, which are measures of patient narcotic use and pain intervention requirements,⁵ demonstrate excellent results for these procedures.

Nevertheless, the utility of such an approach needs to be analyzed by studying clinical outcomes data. The

HRQOL measures such as the SF-36, the ODI, and VAS scores allow the clinician to achieve better understanding of the degree of patient improvement for any given intervention, and have become standard instruments for studying outcome for lumbar degenerative conditions.^{18,19} In our study, the mean ODI improvement was 32.13 points at 1 year, the mean SF-36 improvement was 5.77, and the mean VAS improvement was 4.02 points. This compares quite favorably to the data reported by Glassman et al.¹⁸ in a study in which they assessed patients who had undergone posterolateral instrumented lumbar fusion. In their

TABLE 3: Clinical and radiological outcomes at 1 year in 28 patients with adult scoliosis*

Outcome	Preop	Postop	Average Change	p Value†
clinical				
VAS	7.05	3.03	-4.02	<0.0001
TIS	53.5	25.88	-27.62	0.02
SF-36	55.73	61.50	5.77	0.014
ODI	39.13	7.00	-32.13	0.02
radiological				
Cobb angle (range)	22.3° (15–62°)	7.47° (0.6–22°)	-14.9°	<0.0001

* All values are presented as means unless otherwise indicated. All patients had fusion confirmed on plain and flexion-extension radiographs; 21 patients had confirmed solid arthrodesis on CT scans.

† According to paired t-tests.

Minimally invasive scoliosis correction: outcomes in adults

TABLE 4: Surgery-related complications in 23 patients with adult scoliosis

Complication	No. of Patients
minor	
transient dysesthesia	17 (recovered w/in 6 wks)
major	
quadriceps palsy	2 (recovered w/in 6 mos)
retrocapsular renal hematoma	1
cerebellar hemorrhage	1
miscellaneous	
screw prominence	1
asymptomatic proximal screw fracture	1

series, 17 patients with degenerative scoliosis were noted to have a 1-year improvement in ODI scores of 21.2, and an improvement in the SF-36 physical component score of 6.8. These results are consistent with achieving a minimally and clinically important difference for each outcome measure, where a value change of 10 points for the ODI and 5.42 points for the SF-36 physical component score are considered an important difference.^{17,33} In the same series, Glassman et al. noted an overall complication rate of 41.2% for patients undergoing surgery for degenerative scoliosis.

In our series, all patients had a solid arthrodesis on plain radiographs, which was further confirmed on CT scans in 21 patients at 1 year. In terms of dosing of rhBMP-2, we used between 2 and 4 mg per interbody level fused, and approximately 1.62 mg per facet–pars complex (3.24 mg per posterolateral level) fused. In terms of interbody fusion technique, these doses were considerably lower than the 12–18 mg per level used in 3 different clinical trials in which rhBMP-2 was used with anterior lumbar interbody fusion.¹¹ Similarly, much less rhBMP-2 was used posteriorly than the 10–40 mg per level reported by other groups performing instrumented posterolateral fusions.^{8,22} Given the successful fusion achieved in our series with much lower dosing of rhBMP-2 per level, further studies are probably warranted to determine the minimum effective dose of rhBMP-2 necessary to achieve a successful arthrodesis.

There was only 1 case noted of screw fracture, and another with screw prominence due to inadequate contouring of the rod. Longer-term follow-up will determine whether there are long-term problems. Although not reported in this series, sagittal balance correction achieved via this technique was excellent. Additionally, no pseudoarthrosis at L5–S1 was seen, and no sacral stress fractures or sacral screw loosening were noted. Patients did not receive instrumentation to the ilium. Longer-term follow-up will address the issue of whether techniques such as the ones described by us may obviate the need for iliac bolts.

Conclusions

Circumferential minimally invasive correction and fusion for adult scoliosis represents a newer method of

achieving long-term outcomes similar to those obtained with open methodologies in terms of clinical improvement, but has considerably lower morbidity and complication rates. Blood loss and hospital stays are significantly lower than those reported in earlier literature. The HRQOL measures revealed that clinical outcomes achieved with these techniques at > 1 year of follow-up were comparable to those of historical open controls. Recently, Glassman et al.²⁰ noted that HRQOL parameters stabilized at 1 year postoperatively: they noted no statistically significant differences when comparing 1- and 2-year outcomes in 283 adult patients with deformity who underwent surgery. Given all this, minimally invasive circumferential deformity correction remains attractive, especially in elderly patients and in patients with medical comorbidities who are being considered for deformity correction, decompression, and fusion.

Disclosure

Dr. Anand serves as a consultant for NuVasive, TranS1, and Medtronic; owns stock in TranS1; and receives royalties from Medtronic. Dr. Baron is a member of the Speakers Bureau for TranS1.

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