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ORIGINAL ARTICLE - SPINE - OTHER

Intermediate-term clinical and radiographic outcomes with less invasive adult spinal deformity surgery: patients with a minimum follow-up of 4 years

Michael Y. Wang[1] · Paul Park[2] · Stacie Tran[3] · Neel Anand[4] · Pierce Nunley[5] · Adam Kanter[6] · Richard Fessler[7] · Juan Uribe[8] · Robert Eastlack[9] · Christopher I. Shaffrey[10] · Shay Bess[11] · Gregory M. Mundis Jr[12] · G. Damian Brusko[1] · Praveen V. Mummaneni[13] · The MIS-ISSG Group

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Abstract

Background Little information exists regarding longer-term outcomes with minimally invasive spine surgery (MISS), particularly regarding long-segment and deformity procedures. We aimed to evaluate intermediate-term outcomes of MISS for adult spinal deformity (ASD).

Methods This retrospective review of a prospectively collected multicenter database examined outcomes at 4 or more years following circumferential MIS (cMIS) or hybrid (HYB) surgery for ASD. A total of 53 patients at 8 academic centers satisfied the following inclusion criteria: age $\geq$ 18 years and coronal Cobb $\geq$ 20°, pelvic incidence-lumbar lordosis (PI-LL) $\geq$ 10°, or sagittal vertical axis (SVA) > 5 cm.

Results Radiographic outcomes demonstrated improvements of PI-LL from 16.8° preoperatively to 10.8° and coronal Cobb angle from 38° preoperatively to 18.2° at 4 years. The incidence of complications over the follow-up period was 56.6%. A total of 21 (39.6%) patients underwent reoperation in the thoracolumbar spine, most commonly for adjacent level disease or proximal junctional kyphosis, which occurred in 11 (20.8%) patients. Mean Oswestry Disability Index (ODI) at baseline and years 1 through 4 were 49.9, 33.1, 30.2, 32.7, and 35.0, respectively. The percentage of patients meeting minimal clinically important difference (MCID) (defined as 12% or more from baseline) decreased over time, with leg pain reduction more durable than back pain reduction.

Conclusions Intermediate-term clinical and radiographic improvement following MISS for ASD is sustained, but extent of improvement lessens over time. Outcome variability exists within a subset of patients not meeting MCID, which increases over time after year two. Loss of improvement over time was more notable in back than leg pain. However, average ODI improvement meets MCID at 4 years after MIS ASD surgery.

Keywords Minimally invasive · Spinal deformity · Long-term follow-up · Patient reported outcomes measures (PROMs)

Abbreviations

ASD	Adult spinal deformity
ASA	American Society of Anesthesia
BMI	Body mass index
cMIS	Circumferential MIS
HYB	Hybrid techniques
IRB	Institutional Review Board
MCID	Minimal clinically important difference
MISS	Minimally invasive spine surgery
MIS-ISSG	Minimally Invasive Surgery-International Spine Study Group
NIH	National Institutes of Health
NPS	Numeric Pain Scores
ODI	Oswestry Disability Index
PROMs	Patient reported outcomes measures
PI-LL	Pelvic incidence-lumbar lordosis
PT	Pelvic tilt
PJK	Proximal junctional kyphosis
SVA	Sagittal vertical axis

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✉ Michael Y. Wang
MWang2@med.miami.edu

Extended author information available on the last page of the article

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SPORT Spine Patient Outcomes Research Trial
SD Standard deviation

Introduction

Patients undergoing a surgical intervention on the spine have to weigh the risks and benefits of the operation. While surgeons often discuss the immediate risks and benefits, there is a shortage of meaningful studies on the intermediate-term effects of these interventions [8, 10, 20]. There are numerous reasons for this, including the following: (1) difficulty in following large patient cohorts over extended periods of time [13, 15], (2) patients unwilling to return and see their healthcare providers [5, 12], (3) changes in healthcare coverage affecting follow-up [6, 9], (4) limitations in time and resources for the surgeon, and (5) lack of economic incentives to obtain this information.

However, this data is critical, particularly for operations that carry significant morbidity and cost. In the field of spinal surgery, the treatment of adult spinal deformity (ASD) ranks among the most risky and costly of interventions. If the benefits of surgery are significantly durable, then even a major surgical intervention can be warranted. While the long-term outcomes from open ASD surgery have been well studied and validated, newer minimally invasive spinal surgery (MISS) techniques have also been developed and are gaining in popularity. In this realm, there is a dearth of meaningful data on long-term results. Anand et al. have published their single center experience, with MIS ASD treatment, longitudinally over 5, 7, and 10 years showing the outcomes when patients are followed over long periods of time [2, 3].

Utilizing a large retrospective, multi-institutional database, we examined the intermediate-term results following MISS ASD surgery. With this data, we have previously demonstrated both short- and medium-term improvements across numerous parameters of improvement [16–18]. Given the growing population of elderly patients harboring complex spinal pathologies, the intermediate-term outcomes following these interventions is of great economic and social importance.

Methods

MIS-ISSG patient selection criteria

This study was a retrospective review of an ASD database from eight institutions in the USA that utilized MISS procedures. The interventions included circumferential MIS (cMIS) and hybrid techniques (HYB) which were lateral interbody fusions with open posterior surgery. Each surgeon had the discretion to offer MIS or open surgery and there were no uniform criteria for approach selection. For inclusion in the database, patients had to be more than 18 years of age at the time of surgery. Their standing radiographs had to have either a coronal Cobb angle of greater than or equal to 20°, pelvic incidence-lumbar lordosis (PI-LL) $\geq$ 10°, or a sagittal vertical axis (SVA) greater than 5 cm. Patients had a minimum of 3 levels fused with a minimum of 4 years of follow-up after surgery.

Data Collection and Analysis

The database included information on the following: patient age, gender, body mass index (BMI), smoking status, previous spine surgeries, and American Society of Anesthesia (ASA) grade. Data on surgical parameters included as follows: total operative time, any staging of procedures, total blood loss, surgical methodology, number of levels treated, routes of approach, length of stay, any blood transfusions, and major/minor complications allocated by subtype.

Patient reported outcome measures (PROM's) included the Oswestry Disability Index (ODI), and separate Numeric Pain Scores (NPS) for leg and back pain. The NPS was conducted on a ten-point scale. For the purposes of this study, the minimally clinical important difference MCID defined as 12.8 point improvement in the ODI. PROM's were collected by a study coordinator and not the surgeon at each treatment center. Data was collected on an annual basis from 2008 to 2017 and audited by individual sites. All centers obtained local Institutional Review Board (IRB) approval for participation in this study which included a data-sharing agreement for centralized radiographic measurements, data analysis, and storage.

Results

A total of 53 patients in the database met follow-up criteria to be included. This was out of a total of 116 potential patients (patients enrolled in the MIS-ISSG early enough to allow for 4 potential years of follow-up and excluding centers that prematurely stopped MIS-ISSG participation). This represented 46% of potential study participants eligible for 4-year follow-up. The demographics of the patient population are shown in Table 1.

Clinical and radiographic outcomes

The NPS for leg and back pain is shown in Fig. 1. Maximal improvement in back pain was seen in year 1, and maximal improvement in leg pain was seen in year 2. The mean ODI at baseline and years 1 through 4 were 49.9, 33.1, 30.2, 32.7, and 35.0, respectively, as shown in Fig. 2. This reflected a 24.4% reduction in the gain between years 2 and 4. The percentage of patients meeting a MCID drop (defined as 12.8% or more

Table 1 Patient demographic data and surgical metrics

	Value ± SD (%)
Number of patients	53
Gender (M/F)	38/15
Age (yrs)	62 ± 6.45
ASA Grade	2 ± 0.80
BMI (kg/m2)	27 ± 4.40
History of spine surgery	20 (37.7)
Number of prior surgeries	1 ± 0.62
LOS (days)	10 ± 4.58
OR Time (min)	
First stage	326 ± 126.27
Second Stage	583 ± 117.66
EBL (cc)	
*First Stage**	654 ± 742.71
*Second Stage**	2019 ± 1899.66

ASA, American Society of Anesthesiologists; *BMI*, Body Mass Index; *EBL*, estimated blood loss; *LOS*, length of stay; *OR*, operating room

*First stage is typically anterior approach followed by a posterior approach for the second stage. May vary with surgeon preference and technique

from baseline) reduced over time. At year 1, 61% met MCID, whereas only 45% of patients met MCID at year 4.

The radiographic outcomes demonstrated an improvement of the PI-LL from 16.8° preoperatively to 10.8° at 4 years. The SVA reduced from 4.07 cm to 3.52 cm. The pelvic tilt (PT) was unchanged at 24°. An improvement of the coronal Cobb angle from 38° preoperatively to 18.2° at 4 ears. Radiographic data are shown in Table 2 and a case example is demonstrated in Fig. 3.

Complications

The incidence of complications over the follow-up period was 56.6% (Table 3). Of the patients, 21 (39.6%) underwent a reoperation in the thoracolumbar spine. The most common cause was adjacent level disease or proximal junctional kyphosis, which occurred in 11 (20.8%) of patients. Regarding the cause for reoperation, they included radiographic findings (39%), implant-related (28%), infectious (14%), surgical site (7%), neurologic (7%), and gastrointestinal (4%) as shown in Table 4.

cMIS vs. HYB surgery

When comparing cMIS ($N = 31$) with HYB ($N = 22$) surgeries, there were differences identified. HYB surgeries were more extensive by number of levels treated ($P < 0.001$), involved more blood loss ($P < 0.001$), and involved more operative time $P < 0.001$) as shown in Table 2. However, these patients also had worse ODI scores ($P = 0.039$) and greater sagittal imbalance as measured by PI-LL ($P = 0.096$) and SVA ($P = 0.038$) as a baseline. Complications were also more common in the HYB group, particularly with neurological events ($P = 0.008$) as shown in Table 3.

Discussion

Durability of clinical benefits

This study demonstrates that MISS for ASD pathologies can have a meaningful and positive effect on PROM's. These effects were reproducible across sites and were in line with what has been scientifically demonstrated for traditional, open ASD surgery. If the basic surgical goals of neural decompression, stabilization of hypermobile segments, and sagittal/coronal realignment are achieved, then patients benefit clinically. In this study, patients improved more than 1.5 × MCID on average at the second year following an operation.

However, these salutary effects peaked at year two and slowly diminished with time. At 4 years following surgery, patients on average had lost 24% of the improvement in

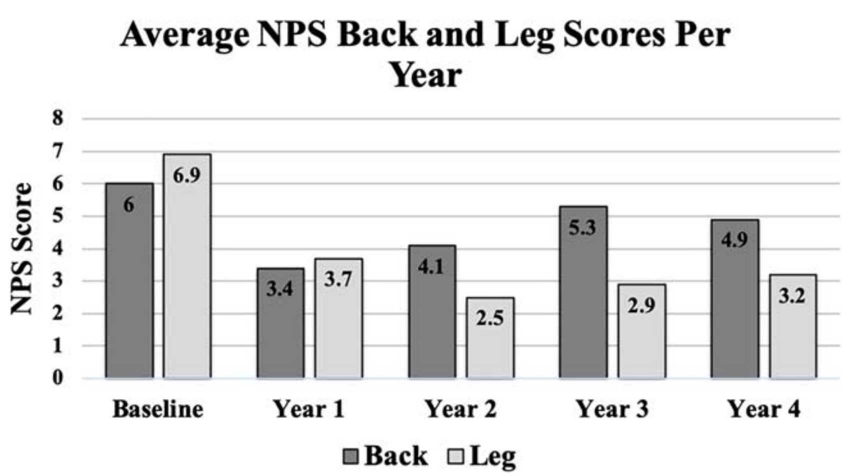

Fig. 1 Numeric Pain Scale (NPS) for back and leg pain over time

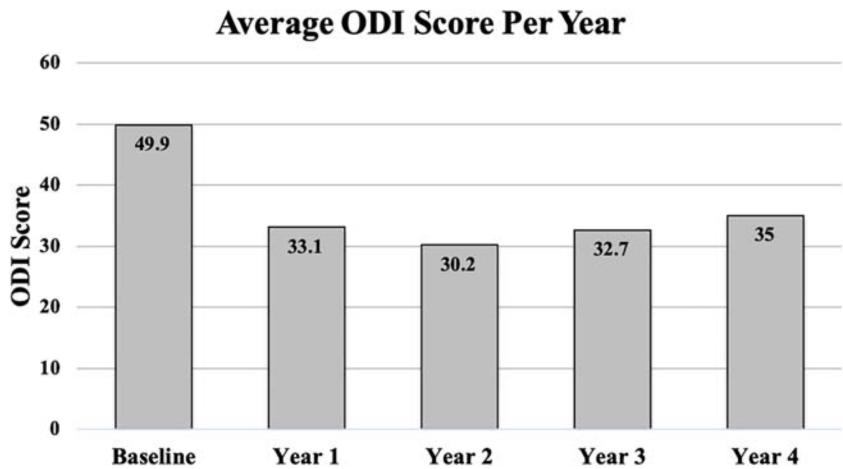

Fig. 2 Oswestry Disability Index (ODI) scores over time

Table 2 Radiographic outcomes. Values reported as Mean ± SD

	Composite	HYB	cMIS	*P* value
N	53 ± 31	22	31	
Age (yrs)	62.1 ± 11.3	60.6 ± 9.8	63.2 ± 12.3	0.999
BMI (kg/m^2)	27.7 ± 5.6	26.6 ± 4.8	28.4 ± 6.1	0.539
Follow-up (mos)	61.8 ± 9.1	65.0 ± 10.7	59.5 ± 7.2	0.063
Staged	31 (58.5%)	15 (68.2%)	16 (51.6%)	0.228
Levels instrumented	6.5 ± 3.6	9.0 ± 4.1	4.8 ± 1.8	**< 0.001**
IBF levels	3.7 ± 1.5	3.4 ± 1.3	3.9 ± 1.6	0.149
Total OR time (min)	586.8 ± 288.3	763.2 ± 281.7	463.3 ± 224.1	< 0.001
Total EBL (cc)	1031.6 ± 1252.1	1932.3 ± 1490.1	392.4 ± 382.1	< 0.001
Total LOS (days)	8.9 ± 4.9	10.3 ± 4.7	8.0 ± 5.0	0.045
Preop back pain	6.9 ± 1.8	7.3 ± 1.9	6.6 ± 1.7	0.072
Postop back pain	4.8 ± 6.7	6.0 ± 10.1	4.0 ± 2.9	0.823
Preop leg pain	6.0 ± 2.7	6.1 ± 2.9	5.9 ± 2.5	0.678
Postop leg pain	2.78 ± 3.1	4.1 ± 3.4	2.0 ± 2.7	0.031
Preop ODI	49.9 ± 17.1	56.1 ± 15.7	45.5 ± 16.9	**0.039**
Postop ODI	33.9 ± 17.5	37.2 ± 15.6	31.3 ± 18.7	0.23
Preop max Cobb (°)	37.9 ± 19.4	42.7 ± 22.0	34.6 ± 17.0	0.2
Postop max Cobb	18.3 ± 14.5	16.7 ± 14.0	19.3 ± 15.0	0.464
Preop SS (°)	29.7 ± 12.1	28.9 ± 15.4	30.4 ± 9.3	0.795
Postop SS	29.1 ± 10.6	30.0 ± 12.8	28.6 ± 9.0	0.464
Preop PT (°)	24.3 ± 9.8	25.7 ± 9.1	23.3 ± 10.3	0.236
Postop PT	24.4 ± 9.25	24.1 ± 9.3	23.9 ± 9.3	0.692
Preop PI (°)	54.0 ± 11.9	54.5 ± 12.1	53.7 ± 11.9	0.711
Postop PI	53.5 ± 12.0	55.1 ± 12.3	52.5 ± 11.9	0.464
Preop LL (°)	37.1 ± 19.8	31.7 ± 25.1	41.1 ± 14.1	0.247
Postop LL	42.7 ± 15.7	45.1 ± 17.6	41.2 ± 14.5	0.285
Preop PI-LL (°)	16.9 ± 18.2	22.8 ± 18.0	12.6 ± 17.4	0.096
Postop PI-LL	10.8 ± 14.9	10.0 ± 16.1	11.3 ± 14.3	0.968
Preop SVA (cm)	40.7 ± 59.4	57.7 ± 51.4	29.0 ± 62.5	**0.038**
Postop SVA	35.2 ± 44.4	33.9 ± 38.9	36.0 ± 48.5	0.839

BMI, Body Mass Index; *cMIS*, circumferential MIS; *EBL*, estimated blood loss; *HYB*, hybrid; *IBF*, interbody fusion; *LL*, lumbar lordosis; *LOS*, length of stay; *N*, total number of patients; *NPS*, Numeric Pain Score; *ODI*, Oswestry Disability Index; *OR*, operating room; *PI*, pelvic incidence; *PT*, pelvic tilt; *SS*, sacral slope; *SVA*, sagittal vertical axis

Fig. 3 Case example of a patient followed for 7 years after surgery. Pre-and post-operative imaging with spinopelvic parameters provided

ODI scores. This also impacted the percentage of patients meeting MCID by year 5 suggesting that particular subsets of patients may be experiencing new health issues that would impact the ODI. Our findings corroborate those seen with open deformity spinal surgery. In a study of 111 patients by Odogwa et al., patients undergoing major thoracolumbar deformity correction were followed for 5 or more years. They were able to demonstrate meaningful improvements with surgery, but PROM's in all dimensions maximized at 2-year follow-up and were reduced by the 5-year time point [1].

The pattern of early functional improvement, followed by maximal benefit and then slight declination, is a pattern seen in many interventions for degenerative pathologies [8, 14]. In the 8-year follow-up study from the Spine Patient Outcomes Research Trial (SPORT), the initial improvements following treatments for lumbar stenosis maximized at the 12-month follow-up period. Thereafter, a declination was seen in all measures of pain and function leading to a significant loss of effect, but never a return to baseline [8].

These effects might be generalizable to musculoskeletal surgeries. In a study by Singh et al., 2667 patients undergoing hip arthroplasty were followed longitudinally to validate the Harris Hip Score [14]. That study identified not only a decline in PROM's between years 2 and 5 but also showed that declining year 2 scores could predict the need for early revision. These findings were important given the lifespan of hip prostheses as well as the very focal anatomical area of treatment. For spinal deformities, it is still unclear whether early loss of benefit can predict a revision surgery, as the accepted PROM's are not purely anatomically specific.

Table 3 Complications. Values reported as *n* patients (%)

	Composite	HYB	cMIS	*P value*
N	53	22	31	
Complication	30 (56.6)	15 (68.2)	15 (48.4)	0.125
Reop	21 (39.6)	11 (50.0)	10 (32.3)	0.155
Major	21 (39.6)	11 (50.0)	10 (32.3)	0.155
Minor	25 (47.2)	12 (54.5)	13 (41.9)	0.265
Infection	6 (11.3)	4 (18.2)	2 (6.5)	0.187
Implant	11 (20.8)	6 (27.3)	5 (16.1)	0.259
Radiographic	14 (26.4)	5 (22.7)	9 (29.0)	0.426
Surgical Site	3 (5.7)	2 (9.1)	1 (3.2)	0.371
Neurologic	10 (18.9)	8 (36.4)	2 (6.5)	**0.008**
Cardio	4 (7.5)	3 (13.6)	1 (3.2)	0.188
Gastro	3 (5.7)	2 (9.1)	1 (3.2)	0.371
Operative	3 (5.7)	3 (13.6)	0 (0.0)	0.066

cMIS, circumferential MIS; *HYB*, hybrid

Causes of lost durability

There have been numerous etiologies proposed for the erosion in benefit from spinal deformity surgery. These include new

Table 4 Reoperation indication. Values reported as *n* patients

	Composite	HYB	MIS
Infection	4	3	1
Implant	6	2	4
Radiographic	11	4	7
Surgical site	2	1	1
Neurologic	2	1	1
Gastro	1	1	0
Operative	2	2	0

health conditions, progression of arthritic conditions outside of the spinal column, cervical degeneration, and traumatic events. In addition, the effect of loss to follow-up has been studied extensively. Both patients experiencing poor and excellent outcomes are more likely to be lost to follow-up in longer term studies, but study design can be bias toward one or the other.

Patients presenting with degenerative spinal deformities often harbor concomitant osteoarthritic conditions in other joints. In this study, a proportion of the reduction in ODI scores was likely due to progression of painful arthritis in the knees, shoulder, and hip. Sacroiliac (SI) joint pain is also a well-known problem following ASD surgery and may be exacerbated by increased mechanical stress placed on those articulations.

There are also clear spinal structural reasons why ASD patients may lose surgical benefit over time. These include adjacent level disease (ASD), symptomatic nonunion, instrumentation failure, loss of mobility due to long-segment fusion, and proximal junctional kyphosis (PJK) [11]. This was seen in our series as well. These conditions were the most common cause for a revision spinal operation (21%) in this series, similar to our previously published series comparing reoperation rates between MIS and open approaches [7].

Implications for value analysis

Value is defined as the longitudinal improvement in health measures derived from an intervention over cost. The more sustained a health improvement is, the more valuable and cost-effective an intervention will be. Since ASD surgery is a very costly endeavor, one of the assumptions of spine surgery advocates is that there will be durability to the positive effect of an operation. Since we have identified a declination in improvement over time, this could have an impact on cost-value analysis. However, surgery for ASD has been shown to reduce both mortality and respiratory dysfunction over time [4]. Thus, longer duration studies are critical in exploring the value analysis of ASD surgeries.

Study limitations

This study has several limitations. Like most retrospective studies, this one is limited by potential under reporting of complications. As an uncontrolled and non-consecutive patient series, there are also many patients at the eight treating centers who likely qualified for inclusion but underwent traditional open surgery. Thus, this report did not attempt to compare the results of MIS with open operations. Furthermore, a preoperative selection bias likely exists in regard to the types of patients offered MIS approaches.

High rates of loss to follow-up were also seen, as is typical for a longitudinal series of this duration. However, this is not uncommon for long-term studies. In the 4-year SPORT study, the number of enrollees providing data was only 440 of 654 (67%) of patients, and that was in the setting of an NIH funded clinical trial [19]. It is unclear if the losses in our study could have led to overestimation or underestimation of the benefits from MIS ASD surgical interventions. However, it is common for most patients seeking care in a tertiary care center to continue with follow-up if they have new or persistent symptoms. Thus, it is likely in long-term studies to see a selection bias for patients losing durability over time.

Conclusions

In select patients, the intermediate-term clinical and radiographic improvement following MISS for ASD is sustained, but the extent of improvement lessens over time. There is variability in outcome with a subset of patients not meeting MCID which increases over time after the second year. Loss of improvement over time was more notable in back than leg pain. However, the average ODI improvement meets MCID at 4 years after MIS ASD surgery, despite a high complication rate. However, complications more frequently occurred in patients undergoing HYB procedures compared with cMIS.

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Compliance with ethical standards

Conflict of interest Dr. Wang reports royalties from DePuy-Synthes Spine, Inc., Children's Hospital of Los Angeles, Springer Publishing, and Quality Medical Publishing; grants from the Department of Defense; personal fees from DePuy-Synthes Spine, Inc., Stryker Spine, K2M, and Spineology; advisory board member from Vallum; and stock from Spinicity and Innovative Surgical Devices, outside the submitted work. Dr. Park reports personal fees from Globus, NuVasive, and AlloSource, grants from Pfizer and Vertex, and personal fees from Medtronic, outside the submitted work. Dr. Tran has nothing to disclose. Dr. Anand reports personal fees, royalties, and stocks from Medtronic, royalties and stock from Globus Medical, and stock options from GYS Tech, Paradigm Spine, and TheraCell, and royalties from Elsevier, outside the submitted work. Dr. Nunley reports stock from Amedica Corporation; royalties, speakers bureau, consultant from Zimmer Biomet, and K2M; stock from Paradigm; speakers bureau, consultant, and stock from Spineology; consultant from Vertiflex; royalties, speakers bureau, consultant, and stock from Camber Spine; royalties, consultant from Integrity; consultant from Centinel Spine, outside the submitted work and patents with royalties paid to K2M, and a patent with royalties paid to LDR Medical. Dr. Kanter reports consulting and royalties from

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Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. For this type of study, formal consent is not required. This article does not contain any studies with animals performed by any of the authors.

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Affiliations

Michael Y. Wang[1] · Paul Park[2] · Stacie Tran[3] · Neel Anand[4] · Pierce Nunley[5] · Adam Kanter[6] · Richard Fessler[7] · Juan Uribe[8] · Robert Eastlack[9] · Christopher I. Shaffrey[10] · Shay Bess[11] · Gregory M. Mundis Jr[12] · G. Damian Brusko[1] · Praveen V. Mummaneni[13] · The MIS-ISSG Group

[1] Department of Neurological Surgery, Lois Pope Life Center, University of Miami Miller School of Medicine, 1095 NW 14th Terrace, Miami, FL, USA

[2] Department of Neurological Surgery, University of Michigan, Ann Arbor, MI, USA

[3] Department of Orthopedic Surgery, San Diego Center for Spinal Disorders, La Jolla, CA, USA

[4] Department of Orthopedic Surgery, Cedars Sinai Hospital, Los Angeles, CA, USA

[5] Department of Orthopedic Surgery, Spine Institute of Louisiana, Shreveport, LA, USA

[6] Department of Neurological Surgery, University of Pittsburgh Medical Center, Pittsburgh, PA, USA

[7] Department of Neurosurgery, Rush University, Chicago, IL, USA

[8] Department of Neurosurgery, Barrow Neurological Institute, Phoenix, AZ, USA

[9] Department of Neurological Surgery, Scripps Clinic Torrey Pines, La Jolla, CA, USA

[10] Department of Neurological Surgery, Duke University, Durham, NC, USA

[11] Department of Orthopedic Surgery, Denver International Spine Center, Denver, CO, USA

[12] Department of Orthopedic Surgery, Scripps Clinic Torrey Pines, La Jolla, CA, USA

[13] Department of Neurological Surgery, University of California, San Francisco, CA, USA>