Less invasive surgery for treating adult spinal deformities: ceiling effects for deformity correction with 3 different techniques

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Object. Minimally invasive surgery (MIS) options for the treatment of adult spinal deformity (ASD) have advanced significantly over the past decade. However, a wide array of options have been described as being MIS or less invasive. In this study the authors investigated a multiinstitutional cohort of patients with ASD who were treated with less invasive methods to determine the extent of deformity correction achieved.

Methods. This study was a retrospective review of multicenter prospectively collected data in 85 consecutive patients with ASD undergoing MIS surgery. Inclusion criteria were as follows: age older than 45 years; minimum 20° coronal lumbar Cobb angle; and 1 year of follow-up. Procedures were classified as follows: 1) stand-alone (n = 7); 2) circumferential MIS (n = 43); or 3) hybrid (n = 35).

Results. An average of 4.2 discs (range 3–7) were fused, with a mean follow-up duration of 26.1 months in this study. For the stand-alone group the preoperative Cobb range was 22°–51°, with 57% greater than 30° and 28.6% greater than 50°. The mean Cobb angle improved from 35.7° to 30°. A ceiling effect of 23° for curve correction was observed, regardless of preoperative curve severity. For the circumferential MIS group the preoperative Cobb range was 19°–62°, with 44% greater than 30° and 5% greater than 50°. The mean Cobb angle improved from 32° to 12°. A ceiling effect of 34° for curve correction was observed. For the hybrid group the preoperative Cobb range was 23°–82°, with 74% greater than 30° and 23% greater than 50°. The mean Cobb angle improved from 43° to 15°. A ceiling effect of 55° for curve correction was observed.

Conclusions. Specific procedures for treating ASD have particular limitations for scoliotic curve correction. Less invasive techniques were associated with a reduced ability to straighten the spine, particularly with advanced curves. These data can guide preoperative technique selection when treating patients with ASD.

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Key Words • minimally invasive surgery • spinal deformity • scoliosis • interbody fusion • extreme lateral interbody fusion • kyphosis • percutaneous pedicle screw • Cobb angle

Surgery for adult spinal deformity (ASD) remains a challenging proposition. Several factors contribute to create a high likelihood of intraoperative and postoperative complication rates. Medical comorbidities, patient deconditioning due to pain and immobility, associated osteoporosis, a rigid skeletal deformity, and abnormal spinal anatomy all increase the likelihood of a complication from ASD surgery.6,9 Furthermore, the surgical enterprise needed to destabilize, realign, and fuse the spine over multiple segments is painful and debilitating, requiring prolonged anesthesia and lengthy hospital stays. It is therefore not surprising that even case series...
from centers specializing in these operations report a high rate of serious complications. In a series of 361 patients reported by Pateder et al.,10 the 30-day mortality rate was 2.4%. A more recent report by Smith et al.17 in which data from the Spinal Deformity Study Group were analyzed showed that 26.2% of 206 patients suffered a minor complication and 15.5% suffered a major complication.

Over the past decade spine surgeons have attempted to use the potential benefits of minimally invasive surgery (MIS) to address spinal deformities.11,12 For short-segment surgeries it appears that MIS techniques can result in less blood loss, lower infection rates, and quicker mobilization. If these principles could be applied to ASD surgery, then many of the problems associated with traditional open surgery could potentially be mitigated.12 Thus, a variety of techniques have evolved in an attempt to apply MIS methodologies to correct coronal spinal deformities.

To date, the plethora of techniques emerging to potentially reduce the morbidity of ASD surgery has only been described in reports focusing on single methods, without comparisons being made between the various techniques. In an effort to better understand the benefits and limitations of such approaches the International Spine Study Group (ISSG)3 formed a multiinstitutional effort to investigate MIS for ASD. The study group, composed of investigators from 9 academic medical centers, each with well-established expertise in MIS for ASD, assembled a retrospective cohort of patients to investigate the utility of MIS in the setting of ASD.

Methods

The MIS-ISSG Patient Selection Criteria

A total of 9 academic medical centers (Cedars Sinai, Northwestern University, University of California at San Diego, University of California at San Francisco [Neurosurgery], University of California at San Francisco [Orthopedics], University of Miami, University of Michigan, University of Pittsburgh, and University of South Florida) with well-established expertise in MIS for ASD were selected to participate in the MIS-ISSG. All centers obtained local institutional review board approval for participation in this study.

For this retrospective study each center collected data on a minimum of 10 and a maximum of 20 patients who had been consecutively treated with MIS techniques for ASD. The primary surgical procedure of interest had to have been performed after November 2009, and patients had to have a minimum of 12 months of clinical and radiographic follow-up. In addition, the following data were obtained in all patients at baseline (preoperative) and last follow-up: 36-in anteroposterior and lateral standing scoliosis radiographs, Oswestry Disability Index (ODI) score,2 and separate Numeric Pain Scores (NPSs) for leg and back pain. The NPS was assessed on a 10-point scale. In addition, the database included patient demographic data (age, sex, body mass index, smoking status, previous spine surgeries, and American Society of Anesthesiologists grade); data for surgical parameters (total operating time, any staging of procedures, total blood loss, surgical methodology, number of levels treated, and routes of approach); and clinical outcomes (length of hospital stay, any blood transfusions, and major/minor complications allocated by subtype).

For inclusion in the database patients had to be more than 45 years old at the time of surgery. Their standing radiographs had to have either a coronal Cobb angle of greater than or equal to 20° or a sagittal vertical axis (SVA) greater than 5 cm. The coronal Cobb angle was determined by measuring the maximal coronal angulation between the 2 most angulated upper vertebral endplates on 36-in standing radiographs.

Lumbar lordosis was measured between the upper endplates of L-1 and S-1 in the standing lateral position with 36-in radiographs. The SVA was measured by dropping a plumb line from the anterior inferior aspect of the C-7 vertebra. The minimum distance from this line to the posterior superior endplate of S-1 was the SVA measured in centimeters. Data from all centers were combined in Excel, and data analysis was performed using SPSS software.

Surgical Techniques: MIS for ASD

Due to the diversity of specific techniques used to treat complex and varied pathological conditions in ASD, consensus was needed on how to classify the surgical procedures. Based on MIS-ISSG consensus meetings the procedures were categorized into 1 of 3 types (Fig. 1).

Patients undergoing a stand-alone operation had an MIS lateral procedure. This technique, first described as an extreme lateral interbody fusion (L. Pimenta, presented at the Brazilian Spine Society Meeting, 2001), involved the use of a tubular retractor to access the intervertebral disc via a lateral approach through or in front of the psoas muscle. The technique later became even more popular as a direct lateral interbody fusion or MIS lateral interbody fusion. Patients who underwent a stand-alone procedure did not have any posterior surgery, transpedicular screws, or laminectomy. The surgery did involve intervertebral cages, often with an osteobiological fusion material, and possibly with anterior screws to hold the cages in place. In patients in this category surgery was performed at multiple levels in the lumbar spine under a single anesthetic.

For the circumferential MIS group, patients underwent any possible combination of 2 types of minimally invasive fusion. In essence, at any single level of the spine this was either an MIS lateral interbody fusion supplemented with percutaneous pedicle screws at that level or an MIS transforaminal lumbar interbody fusion (TLIF). Typical circumferential MIS procedures would include the following: 1) lumbar lateral interbody fusion supplemented with percutaneous pedicle screws; 2) lateral interbody fusion at multiple levels, with MIS TLIF at levels that are not easily or safely accessible via the lateral approach (L4/5 or L5/S1) and supplemented by percutaneous pedicle screws; 3) multilevel MIS TLIF such as L2– S1; or 4) any of the first 3 surgeries, with extension into the low thoracic spine with percutaneous pedicle screws and MIS facet fusions.

The hybrid group included those patients who had undergone an MIS lateral interbody fusion that was supplemented with an open posterior procedure. The poste-
Ceiling effects for MIS deformity correction

The MIS-ISSG database included 85 patients who met the inclusion criteria. With regard to surgery type, 7 had a stand-alone procedure, 43 underwent circumferential MIS, and 35 had hybrid surgery. The demographic data for the group are shown in Table 1. For the group as a whole, an average of 4.2 discs (range 3–7) were fused. The mean follow-up was 26.1 months with a minimum of 12 months.

The magnitude of the surgical events was more substantial in the hybrid group and least invasive in the stand-alone group, with the circumferential MIS group being intermediate. Blood loss and the probability of having the procedures staged into several anesthetic events were also found to be different between the 3 groups (Table 1). Total surgical time was 355, 479, and 748 minutes in the stand-alone, circumferential MIS, and hybrid groups, respectively.

Clinical Outcomes

Clinical improvement as measured by the NPS and ODI was seen in all 3 groups, as shown in Table 2. Improvements in axial back pain were similar between groups, with 3.0, 3.5, and 4.4 points of improvement seen in the stand-alone, circumferential MIS, and hybrid groups, respectively (p > 0.05). Improvement in leg pain was 4.8, 2.3, and 2.4 points of improvement seen in the

Fig. 1. Radiographs obtained in case examples of the 3 surgical constructs. Preoperative (A and B) and postoperative (C and D) hybrid constructs. Preoperative (E and F) and postoperative (G and H) circumferential MIS constructs. Preoperative (I and J) and postoperative (K and L) stand-alone constructs.
Improvement in ODI was similar between groups, with 23.1, 19.5, and 17.7 points of improvement seen in the stand-alone, circumferential MIS, and hybrid groups, respectively (p > 0.05). Major complications were 29%, 14%, and 40% in the stand-alone, circumferential MIS, and hybrid groups, respectively (p = 0.03). There were no cases of death, myocardial infarction, or blindness seen in any of the 85 patients. Three (7%) of patients who underwent circumferential MIS and 5 (14%) of the patients with hybrid procedures had a return to the operating room.

**Radiographic Outcomes (Coronal Plane)**

For the stand-alone group the preoperative Cobb angle ranged from 22° to 51°, with 57% of patients having a curve greater than 30°, and 28.6% greater than 50°. The mean Cobb angle improved from 35.73° to 30.0° (p = 0.001). A ceiling effect of 23° for curve correction was observed, regardless of preoperative curve severity or the number of levels treated, as shown in Fig. 2. Cobb angle correction was determined as the difference between the preoperative and last follow-up measurements on 36-in standing radiographs. For the circumferential MIS group the preoperative Cobb angle ranged from 19° to 62°, with 44% greater than 30° and 5% greater than 50°. The mean Cobb angle improved from 32° to 12° (p < 0.001). A ceiling effect of 34° for curve correction was observed. For the hybrid group the range for the preoperative Cobb angle was 23°–82°, with 74% greater than 30° and 23% greater than 50°. The mean Cobb angle improved from 43° to 15°. A ceiling effect of 55° for curve correction was observed (p < 0.001).

**Radiographic Outcomes (Sagittal Plane)**

In the sagittal plane for the stand-alone group the

### TABLE 1: Demographic data and surgical parameters in 85 patients with ASD*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Stand-Alone</th>
<th>cMIS</th>
<th>Hybrid</th>
</tr>
</thead>
<tbody>
<tr>
<td>no. of patients</td>
<td>7</td>
<td>43</td>
<td>35</td>
</tr>
<tr>
<td>mean age in yrs</td>
<td>65</td>
<td>64</td>
<td>65</td>
</tr>
<tr>
<td>sex (% female)</td>
<td>100%</td>
<td>77%</td>
<td>89%</td>
</tr>
<tr>
<td>mean no. of comorbidities</td>
<td>4</td>
<td>1.72</td>
<td>2.91</td>
</tr>
<tr>
<td>mean ASA grade</td>
<td>2.9†</td>
<td>2.0‡</td>
<td>2.2</td>
</tr>
<tr>
<td>% w/ prior spine op§</td>
<td>57%</td>
<td>14%</td>
<td>26%</td>
</tr>
<tr>
<td>mean BMI</td>
<td>30.8</td>
<td>25.6</td>
<td>28.4</td>
</tr>
<tr>
<td>% smokers</td>
<td>0%</td>
<td>21%</td>
<td>6%</td>
</tr>
<tr>
<td>mean no. of levels fused</td>
<td>3.7</td>
<td>4.3</td>
<td>4.2</td>
</tr>
<tr>
<td>range of levels fused</td>
<td>3–5</td>
<td>3–7</td>
<td>3–6</td>
</tr>
<tr>
<td>mean total op time (mins)</td>
<td>355</td>
<td>479</td>
<td>746‡</td>
</tr>
<tr>
<td>mean total surgical blood loss (ml)</td>
<td>95</td>
<td>585</td>
<td>1743**</td>
</tr>
<tr>
<td>% w/ staged op§</td>
<td>0%</td>
<td>58%</td>
<td>89%</td>
</tr>
<tr>
<td>% w/ major complications§</td>
<td>29%</td>
<td>14%</td>
<td>40%</td>
</tr>
<tr>
<td>% w/ minor complications§</td>
<td>29%</td>
<td>7%</td>
<td>29%</td>
</tr>
</tbody>
</table>

* ASA = American Society of Anesthesiologists; BMI = body mass index; cMIS = circumferential MIS.† The mean number of comorbidities was significantly lower in the cMIS group compared to the others.‡ The mean ASA grade was significantly lower in the cMIS versus the stand-alone group.§ The percent with prior spine surgery was significantly different among the groups (we performed a chi-square test with 3 groups, but did not do multiple comparisons). The same comment applies to percent with staged surgery, major complications, and minor complications.¶ The mean operating time was significantly longer in the hybrid group compared to the others.** The mean blood loss during surgery was significantly higher in the hybrid group compared to the others.

### TABLE 2: Clinical outcomes in 85 patients with ASD*

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Op Type</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Stand-Alone</td>
</tr>
<tr>
<td>NPS back pain</td>
<td>6.8</td>
</tr>
<tr>
<td>baseline</td>
<td>3.8</td>
</tr>
<tr>
<td>1 yr</td>
<td>3.0</td>
</tr>
<tr>
<td>mean decrease</td>
<td>7.8</td>
</tr>
<tr>
<td>leg pain</td>
<td>4.8</td>
</tr>
<tr>
<td>baseline</td>
<td>48.8</td>
</tr>
<tr>
<td>1 yr</td>
<td>25.7</td>
</tr>
<tr>
<td>mean decrease</td>
<td>23.1</td>
</tr>
</tbody>
</table>

* No statistically significant differences were found between groups.
Ceiling effects for MIS deformity correction

Preoperative lumbar lordosis averaged 34.7° ± 9.0°, and improved after surgery to an average of 39.7° ± 8.7°. This reflected a mean improvement of 5° (p = 0.43). The preoperative pelvic tilt averaged 33.8° ± 8.2° and increased after surgery to an average of 36.4° ± 9.5°. This reflected a mean increase of 2.6° (p = 0.033). The preoperative pelvic tilt ranged from 16.3° to 42°, and the range at 1-year follow-up was 20°–45°. The preoperative SVA averaged 37.6 ± 64.8 mm, and after surgery it averaged 37.8 ± 43.7 mm, reflecting a mean improvement of 20 mm (p = 0.9). The preoperative SVA ranged from -8 mm to 149 mm, and the range at 1-year follow-up was -2 to 109 mm (Figs. 3 and 4).

In the sagittal plane for the circumferential MIS group the preoperative lumbar lordosis averaged 34.0° ± 10.9°, and improved after surgery to an average of 39.6° ± 12.1°. This reflected a mean improvement of 5.7° (p = 0.001). The preoperative pelvic tilt averaged 26.4° ± 11.5° and changed minimally after surgery to an average of 25.1° ± 9.1°. This reflected a mean decrease of 1.27° (p = 0.41). The preoperative SVA averaged 29 ± 41.4 mm and after surgery averaged 29.7 ± 44.6 mm, reflecting a mean increase of 0.8 mm (p = 0.889).

In the sagittal plane for the hybrid group the preoperative lumbar lordosis averaged 31.9° ± 16.1°, and improved after surgery to an average of 48.5° ± 13.8°. This reflected a mean improvement of 16.6° (p < 0.001). The preoperative pelvic tilt averaged 34.4° ± 13.7° and increased after surgery to an average of 34.3° ± 13.7°. This reflected a mean increase of 0.16° (p = 0.94). The preoperative SVA averaged 62.9 ± 52.2 mm, and after surgery it averaged 28.7 ± 24 mm, reflecting a mean improvement of 34.1 mm (p < 0.001).

Discussion

The development of new techniques for MIS to treat ASD has been inherently appealing. If spinal MIS procedures can achieve neural decompression, curve correction, and intervertebral fusion with less blood loss and tissue trauma, then these methods may improve patient outcomes by reducing the rate of complications. However, MIS methods are also likely to pose limitations when compared with traditional open surgery. This is expected given that MIS is typically performed over fewer motion segments, and the limited exposures will reduce a surgeon’s ability to decompress neural elements, perform osteotomies, manipulate the spinal segments, and fuse exposed dorsal bony surfaces.

To date, most methods have focused on using the MIS lateral transpsoas interbody procedure to assist with correcting the coronal deformity and providing the access for an interbody cage and fusion. This technique, applied with much enthusiasm, has proven to be excellent for treating local degenerative arthritis, restoring foraminal height, achieving indirect neural decompression, and correcting coronal deformity.1,2,4,8,15 A role for MIS and open TLIF has also been seen when performed over multiple motion segments for correcting spinal deformities.7,14

Cobb Angle Correction

However, the ideal application of both MIS TLIF and lateral interbody fusion in the setting of ASD remains unclear. This study was conducted to identify the efficacy of multilevel MIS interbody fusion techniques to correct spinal deformities and achieve clinical improvement. The 3 types of surgery in this study, stand-alone, circumferential MIS, and hybrid procedures, were associated with increasing surgical invasiveness. As expected,
with increasing invasiveness we saw improvements in the ability to manage more severe scoliotic curves, as well as an improved ability to obtain a good correction. In this study we found a “ceiling effect” with each of the surgical procedures. This was found to be 23°, 34°, and 55° for stand-alone, circumferential MIS, and hybrid techniques, respectively.

Because the stand-alone procedures relied solely on interbody distraction for curve correction and did not involve the use of pedicle screw fixation, it is anticipated that the surgeons used less corrective force and had more difficulty maintaining any curve correction and that patients were susceptible to intervertebral settling. This was reflected in the less robust ability to manage more serious spinal deformities.

However, with increasing invasiveness we also saw an increased amount of blood loss and surgical complications. For example, in the hybrid group, much of the posterior surgery could be considered to be quite similar to an open procedure. This is highlighted by the fact that 14 patients (40%) in the hybrid group had a Type 3 osteotomy (pedicle subtraction osteotomy) and an associated mean blood loss of 1743 ml. These findings highlight the complex decision making and technical maneuvers needed to effect correction of more severe curves, such as those greater than 50° in the coronal plane.

**Sagittal Plane Correction**

The limitations of MIS for deformity were even more apparent when examining spinal deformities in the sagittal plane. In this series the effects of primary interbody surgery (stand-alone and circumferential MIS groups) introduced a minimal amount of lordosis. The average amount of lordosis added at 1 year was 5° and 5.7°, respectively. The maximal addition of only 22° of lordosis reveals that these techniques are likely to be of limited long-term benefit for patients with positive sagittal balance as their primary complaint. The hybrid surgeries were able to effect greater improvements in lumbar lordosis, with a maximal addition of 58°. Although the reduction of pain and disability due to neural entrapment, claudication, and disc/facet joint arthritis can be seen when using the less invasive techniques in patients with ASD, these findings should be considered when planning the surgical treatment of patients with a thoracolumbar kyphosis.
Clinical Benefits of Surgery

Any surgical intervention for degenerative spinal disease must consider the entire picture of the individual patient. This includes not only the radiographic findings but also the clinical complaint(s), medical comorbidities, patient expectations, socioeconomic factors, and life expectancy of the patient. In this multicenter clinical study we found that clinical outcomes showed acceptable levels of improvement in all groups, with a mean ODI reduction of 20 points. Although some of the MIS techniques may have been less robust for treating severe deformities, many of the patients in this series did not require a major correction of sagittal or coronal plane abnormalities, as was reflected in their spinal and spinopelvic parameters. Thus, in this series treatments were tailored to the individual patients’ needs, with attention paid to avoiding more invasive surgeries if possible. However, the potential implications of undercorrecting a spinal deformity over the longer term is yet another consideration that is beyond the scope of this study.

Complications in MIS

This study was undertaken by a group of surgeons with specific expertise in minimally invasive spinal surgery. However, in this cohort we still found a significant complication rate. Major complications were seen in 29%, 14%, and 40% of patients in the stand-alone, circumferential MIS, and hybrid groups, respectively (p = 0.03). Although there were no cases of death, myocardial infarction, or blindness this complication rate remains high, and is similar to those seen with open spinal deformity surgery. In addition, the operating times involved in these interventions was significant, particularly with multistage operations. Thus, surgeons contemplating adoption of these methods should do so with a full understanding of these limitations.

Study Limitations

This study has several limitations. The first is the classification of all 85 operations into only 3 subtypes. Although there are clear differences between surgeries in the different categories, there is also significant heterogeneity within each of the 3 groups. For example, the circumferential MIS group contained patients who underwent lateral interbody fusion with percutaneous screws, multilevel MIS TLIF, and combination surgeries. Similarly, many patients with hybrid surgery did not have a Level 3 osteotomy, significantly changing the expected blood loss of the dorsal procedure.

Like most retrospective studies, this one is limited by potential underreporting of complications. In addition, with a mean follow-up duration of 26.1 months, this study does not have the ability to ascertain rates of delayed loss of correction, adjacent-level problems, and screw/rod fracture. These are all problems that are well known to occur in a delayed fashion in patients with open ASD.

We enrolled patients at 9 centers with a track record of proficiency in MIS for ASD. However, specific arenas of technical expertise were probably different between sites, and a study of this size would not allow for a meaningful analysis of center effects. Similarly, the selection process for the surgical procedure was uncontrolled. Factors such as a scoliotic curve’s flexibility in the coronal plane were not assessed in this study, and this probably has a significant impact on the surgeon’s choice of approach. Thus, the ability to correct a patient’s Cobb angle is the result of multiple factors, only one of which is the surgical approach taken.
Finally, the number of cases in the stand-alone group was limited to only 7 patients. This does limit our ability to draw definitive conclusions as to the utility of this surgical procedure.

Conclusions

This study is the first to our knowledge to compare a multitude of MIS methods for ASD to assess their efficacy. Although there are numerous study limitations, it does appear that the choice of surgical approach can impose specific limitations on the surgeon’s ability to correct a spinal deformity. Furthermore, as expected, the less invasive approaches were associated with a more limited ability to correct severe curves, whereas more invasive strategies were able to achieve results comparable to open surgery. Proper clinical decision making resulted in acceptable clinical outcomes in all groups.

Disclosure

Dr. Wang is a consultant for and also holds a patent from DePuy Spine. Dr. Mummaneni has received honoraria from Globus; royalties from DePuy Spine, quality Medical Publishers, and Thieme; and owns stock in Spinicity. Dr. Fu is a consultant for Medtronic and has received an honorarium from DePuy Spine. Dr. Anand is a patent holder with Medtronic and is also a consultant for that company and for Baxano Surgical. Dr. Okonkwo receives royalties from Lanz. Dr. Kanter receives royalties from Lanz, and from NuVasive he has received support of non–study-related clinical or research effort that he oversaw. Dr. La Marca is a consultant for Globus and for Biomet. Dr. Fessler owns In Queue Innovations and is a consultant for DePuy Synthes. Dr. Uribe is a consultant for NuVasive and Orthofix. Dr. Shaffrey is a consultant for the following companies: Biomet, Globus, Medtronic, NuVasive, and Stryker. He also is a patent holder with and receives royalties from Biomet and Medtronic. Dr. Deviren is a consultant for NuVasive, Guidepoint, and Stryker. Dr. Mundis is a consultant for K2M and NuVasive. He received support from NuVasive for a non–study-related clinical or research effort that he oversaw, and he also received research support from JSSGF, as well as fellowship support from NuVasive, Pioneer, and the Orthopaedic Research and Education Foundation (OREF).

Author contributions to the study and manuscript preparation include the following. Conception and design: Wang, Mummaneni, Uribe. Acquisition of data: Wang, Mummaneni, Anand, Okonkwo, Kanter, La Marca, Fessler, Haque, Deviren, Mundis. Analysis and interpretation of data: Wang, Fu, Uribe, Lafage. Drafting the article: Wang, Mummaneni, Mundis. Critically revising the article: Wang, Okonkwo, La Marca, Shaffrey, Mundis. Reviewed submitted version of manuscript: Wang, Mummaneni. Approved the final version of the manuscript on behalf of all authors: Wang. Statistical analysis: Wang, Lafage. Administrative/technical/material support: Wang. Study supervision: Wang, Shaffrey.

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