

Research Article

Comparison of Early and Late Complications after Circumferential Minimally Invasive and Hybrid Surgery for Adult Spinal Deformity

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Abstract

Background: Current treatment strategies for the correction of adult spinal deformity (ASD) include the options of circumferential minimally invasive surgery (CMIS), open surgery, and hybrid correction. This study compares outcomes and complications of CMIS and hybrid surgery for the management of ASD.

Methods: This is a retrospective analysis of a multicenter database using prospectively collected data on patients with ASD. Patients were evaluated for early and late complications following treatment with CMIS or hybrid techniques.

Results: Of the 190 patients in the study, 104 were in the CMIS group and 86 were in the hybrid group. Compared to the hybrid group, CMIS patients reported less blood loss, shorter operative time, fewer posterior levels fused, and lower follow-up ODI ($p < .05$). Radiographic parameters were similar between the two groups; however, the mean of 4.7 levels fused in the CMIS group was significantly less ($p < 0.001$) than the mean of 8.2 levels fused in the hybrid group.

There was a significantly lower rate of early major ($p < 0.01$) and minor ($p < 0.001$) complications in the CMIS group (Major: 13.5%; Minor: 9.6%) compared to the hybrid group (Major: 29.1%; Minor: 36.0%). However, there was no statistically significant difference in the rate of late complications between the two groups. Patients who had an early major or early minor complication had a higher 2-year ODI compared with those that did not.

Conclusion: Both CMIS and hybrid techniques are effective in the treatment of ASD. The greatest advantage of CMIS techniques may be in reducing the early morbidity associated with these surgeries. In the late period, both the CMIS and hybrid techniques fare similarly well as evidenced by an equivalent late complication rate. Hybrid deformity surgery was associated with a higher reoperation rate than circumferential minimally invasive surgery.

INTRODUCTION

Correction of adult spinal deformity (ASD) is frequently done with open surgery, but there remain many challenging issues. Chief among them is the high intraoperative and postoperative complication rates along with a measurable risk of mortality [1-5]. This has stimulated the development of potentially safer approaches in the ever-expanding field of ASD correction [4]. Circumferential minimally invasive surgical (CMIS) and hybrid methods have emerged as efficacious and less invasive alternatives to traditional open surgical interventions.

CMIS correction offers several benefits in comparison to open surgery. These include shorter hospital stay, decreased pain, less blood loss, lower transfusion rates, and quicker recovery [6-15]. However, minimally invasive surgery (MIS) is not without limitations including technical difficulty and a steep learning curve. Furthermore, reports suggest that the limited exposure inherent to these less invasive approaches does not offer the same radiologic correction attainable through open surgery - particularly in the sagittal plane [1,2,5,16-18]. Consequently, surgeons tend to reserve CMIS correction for the less complex ASD cases that do not require significant sagittal realignment and choose hybrid approaches in the hope of obtaining greater sagittal correction.

Hence along with CMIS and open surgery, the hybrid approach has developed as a blend of these contrasting surgical philosophies. Hybrid correction involves MIS arthrodesis through lateral interbody fusion followed by open posterior osteotomies and pedicle screw fixation. Theoretically, this strategy capitalizes on the sagittal correction attainable in open surgery while attempting to benefit from the lower morbidity rates of an MIS approach. Early studies validate the ability of hybrid surgery to achieve superior sagittal balance compared to CMIS correction [1,2,5,18]. However, its benefits on morbidity and complication rates are not clear.

The aim of this study is to compare CMIS and hybrid approaches both in terms of early and late complications. This pool of patients has been used in prior studies but not for this purpose. Our investigation may allow surgeons to better gauge whether the benefits in alignment using a more invasive approach outweigh its inherent risks. In a broader sense, we may strengthen our understanding of the spectrum of MIS techniques and how they can evolve in the future.

MATERIALS AND METHODS

Patient population

This was a retrospective, multicenter study from 8 participating institutions utilizing data from October 2009 to October 2012. Institutional review board approval was obtained at each of the institutions. Eleven surgeons participated, each with experience in minimally invasive spine surgery. Each institution contributed patients to the database who underwent CMIS and hybrid correction of ASD (Cobb angle > 20 degrees or SVA > 50 mm or PI/LL mismatch > 10). Indications for surgery included symptomatic back and/or leg pain attributed to ASD that was unresponsive to conservative measures.

All patients were 18 years of age or older. Patients who did not undergo CMIS or hybrid approaches were excluded. 427 patients met inclusion criteria. 190 of these patients had at least 2-year follow-up data, including 36-inch standing radiographs, and were included in our final analysis.

Study design

Patients were separated into 2 groups, CMIS and hybrid. CMIS was defined as patients who had circumferential MIS techniques with a combination of MIS Lateral Lumbar Interbody Fusion (LLIF), MIS TLIF/ALIF/AxiaLIF at L5-S1 and MIS percutaneous posterior pedicle instrumentation. A minority of patients underwent stand-alone lateral fusion (10 patients), and 10 patients had posterior MIS screws with TLIF. These patients were included in the CMIS group. Hybrid surgery was defined as initial LLIF followed by open posterior spinal instrumentation. Demographics, operative parameters, clinical outcomes, radiographic markers, and complication rates were collected. Clinical outcome was quantified using standard health related quality of life (HRQOL) forms including the Oswestry Disability Index (ODI) and Visual Analogue Scale (VAS) at baseline and at fixed post-operative intervals. Complications were classified as major based on consensus from prior studies [3,19]. Moreover, complications requiring reoperations were categorized as major. We chose a 30-day post-operative cut-off to distinguish between early and late complications. Radiographic deformity was assessed using full-length 36-inch radiographs at the time of enrollment and at latest follow-up. Fusion was graded at a central site using 1 or 2 year follow-up radiographs.

In a separate analysis, the total patient pool was compared based on the incidence of complications. 2-year follow-up ODI scores were calculated and compared between those patients who had suffered complications and those patients who had not.

Statistical methods

Patient groups were compared using T-testing and chi-squared analysis for continuous and categorical variables, respectively. Statistical analyses were 2-sided and $p < 0.05$ was considered statistically significant. All statistical analysis was conducted using SPSS (Version 22).

RESULTS

For the 190 patients analyzed, the mean age was 61.2. Of this total, 144 were females and 46 were males. The mean number of levels fused posteriorly was 6.2 (4.1, 0-17). Demographic data for hybrid and CMIS groups is summarized in Table (1).

Our results comparing CMIS and hybrid patients are summarized in Table (2-5). Compared to the hybrid group, the CMIS group reported less blood loss, shorter operative time, fewer posterior levels fused, and lower follow-up ODI ($p < .05$). In terms of complications, CMIS patients suffered less early major and early minor complications than the hybrid group ($p < .05$). The major early complication rate for hybrid and CMIS patients was 29.1% and 13.5%, respectively. The minor early complication rate for hybrid and CMIS patients was 36.0% and 9.6%, respectively. Moreover, CMIS patients required fewer re-operations than hybrid patients ($p < .05$). There was no statistically significant difference in late complication rates

Table 1: Patient Demographics.

| | Hybrid | CMIS | p-value |
|-------------------------------------|------------------|------------------|---------|
| Number of patients | 89 | 104 | |
| Age | 60.4 | 61.9 | 0.398 |
| Gender-Females | 64 (74.4%) | 80 (76.9%) | 0.408 |
| Mean BMI | 26.9 (16.8-43.8) | 27.3 (16.8-45.7) | 0.66 |
| Mean ASA | 2.2 (1-4) | 2.4 (1-3) | 0.244 |
| Mean No of Levels Fused Posteriorly | 8.2 (0-17) | 4.7 (0-14) | <0.001* |

*Statistically significant result if p < 0.05

Table 2: Intraoperative Parameters.

| | Hybrid | CMIS | p-value |
|--|--------|-------|---------|
| Total Estimated Blood Loss (milliliters) | 1584.2 | 481.3 | <0.001* |
| Total Operative Time (minutes) | 682.6 | 427.5 | <0.001* |
| Posterior Levels Fused | 8.2 | 4.7 | <0.001* |

*Statistically significant result if p < 0.05

Table 3: Radiographic Markers.

| | Hybrid | CMIS | p-value |
|-----------------|--------|------|---------|
| Pre Op | | | |
| Cobb (Degrees) | 44.2 | 36.5 | 0004* |
| PT (Degrees) | 24 | 24.2 | 0.879 |
| PI-LL (Degrees) | 18.2 | 13.4 | 0.082 |
| SVA (mm) | 52.2 | 36 | 0.061 |
| LL (Degrees) | 38.2 | 40.1 | 0.466 |
| Post Op | | | |
| Cobb (Degrees) | 17.7 | 20.4 | 0.175 |
| PT (Degrees) | 23.4 | 24.3 | 0.616 |
| PI-LL (Degrees) | 10.2 | 11.2 | 0.678 |
| SVA (mm) | 48.2 | 34.2 | 0.158 |
| LL (Degrees) | 47 | 42.9 | 0.073 |
| Delta | | | |
| Cobb (Degrees) | -26.5 | 15.8 | <0.001* |
| PT (Degrees) | -0.7 | -0.2 | 0.664 |
| PI-LL (Degrees) | -7.4 | -3.1 | -0.043* |
| SVA (mm) | -3.4 | 1.1 | -0.582 |
| LL (Degrees) | 7.9 | 3.3 | 0.03* |

*Statistically significant result if p < 0.05; PT = Pelvic Tilt; PI-LL = Pelvic Incidence-Lumbar Lordosis; SVA = Sagittal Vertical Axis; LL indicates Lumbar Lordosis

Table 4: Clinical Outcomes Based on HRQOL Questionnaires.

| | Hybrid | CMIS | p-value |
|----------|--------|------|---------|
| Pre Op | | | |
| ODI | 51.7 | 47.5 | 0.11 |
| VAS Back | 6.8 | 6.6 | 0.499 |
| VAS Leg | 5.6 | 5.9 | 0.449 |
| Post Op | | | |
| ODI | 36 | 29.3 | 0.025* |
| VAS Back | 3.7 | 3.2 | 0.166 |
| VAS Leg | 3 | 2.7 | 5.04 |
| Delta | | | |
| ODI | -16.1 | -18 | 0.525 |
| VAS Back | -3 | -3.5 | 0.33 |
| VAS Leg | -2.5 | -3.1 | 0.316 |

*Statistically significant result if p < 0.05; ODI = Oswestry Disability Index; VAS = Visual Analog Scale

Table 5: Complications and Reoperations.

| | Hybrid | CMIS | p-value |
|--------------|------------|------------|---------|
| Major Early | 25 (29.1%) | 14 (13.5%) | 0.007* |
| Minor Early | 31 (36.0%) | 10 (9.6%) | <0.001* |
| Major Late | 13 (15.1%) | 10 (9.6%) | 0.175 |
| Minor Late | 6 (9.3%) | 5 (4.8%) | 0.175 |
| Reoperations | 23 (26.7%) | 15 (14.4%) | 0.035* |

*Statistically significant result if p < 0.05

between the two groups. Specific complications noted in each group are included in Table (6).

Pre Op Cobb angle was higher in the hybrid group (p < .05) while all other radiographic markers, including pelvic tilt (PT), pelvic incidence-lumbar lordosis (PI-LL) mismatch, SVA, and lumbar lordosis (LL) at baseline and follow-up, were similar between the two groups. Delta values (Post Op - Pre Op) for Cobb angle, PI-LL, and LL, were higher in the hybrid group (p < .05).

Our results comparing the incidence of complications on follow-up disability are summarized in Table (7). Patients who suffered early complications had a statically significant increase in 2-year follow-up ODI compared to those who had not. This was true for both major and minor complications (p < .05). Those who suffered late complications had no statistically significant difference in 2-year follow-up ODI compared to those who had not.

DISCUSSION

Approaches to ASD correction have slowly evolved into a spectrum of decreasingly invasive philosophies. Open, hybrid and MIS approaches have emerged, each with specific benefits and risks. As a general principal, early results suggest that more invasive strategies achieve greater sagittal and coronal correction but carry an added risk of complications. By quantifying outcomes for each operative method, the benefits of MIS correction and the risk of adverse outcomes following more invasive techniques can better be realized. Our study reports lower early complication rates and improved disability using CMIS correction when compared to more invasive hybrid approaches to ASD.

Complication rates following open correction of ASD range from 10-75% with mortality rates as high as 3% [2,3,19-25]. Glassman et al., demonstrated a relationship between post-operative morbidity and adverse clinical outcomes, as quantified by HRQOL questionnaires [19]. Potential alternatives, including CMIS and hybrid approaches, could presumably reduce morbidity associated with ASD correction and lead to better clinical results. Anand et al., showed that multiple level corrections could be performed using MIS techniques with less morbidity and blood loss than open procedures [11].

Building on this point, recent studies have assessed outcomes of hybrid and MIS approaches as alternatives to open correction. Deukmedjian et al., reported low complication rates on 27 patients that underwent CMIS or hybrid approaches. Hybrid surgery was reserved for the 2 most severe cases based on radiographic markers of which 1 suffered transient thigh numbness. Of the remaining 25 patients who were treated using CMIS techniques,

Table 6: Complication Frequencies Categorizes by Major and Minor.

| Major | Hybrid | CMIS | Minor | Hybrid | CMIS |
|-----------------|-----------|----------|------------------|----------|----------|
| Death | 0 (0.0%) | 0 (0.0%) | Infection | 7 (8.1%) | 3 (2.9%) |
| Blind | 0 (0.0%) | 0 (0.0%) | Implant | 2 (2.3%) | 2 (1.9%) |
| Cardiopulmonary | 2 (2.3%) | 1 (1.0%) | Radiographic | 6 (7.0%) | 0 (0.0%) |
| DVT | 4 (4.7%) | 0 (0.0%) | Neuropathy | 3 (3.5%) | 1 (1.0%) |
| PE | 6 (7.0%) | 0 (0.0%) | Radiculopathy | 4 (4.7%) | 9 (8.7%) |
| Implant Fail | 8 (9.3%) | 2 (1.9%) | Nerve Palsy | 2 (2.3%) | 0 (0.0%) |
| Neurologic | 8 (9.3%) | 2 (1.9%) | Delirium | 3 (3.5%) | 2 (1.9%) |
| Infection | 8 (9.3%) | 3 (2.9%) | Cardiopulmonary | 5 (5.9%) | 3 (2.9%) |
| Sepsis | 2 (2.3%) | 1 (1.0%) | Vascular | 0 (0.0%) | 0 (0.0%) |
| Stroke | 1 (1.2%) | 0 (0.0%) | Gastrointestinal | 4 (4.7%) | 1 (1.0%) |
| Vascular | 1 (1.2%) | 1 (1.0%) | Renal | 0 (0.0%) | 1 (1.0%) |
| Visceral | 0 (0.0%) | 1 (1.0%) | Operative | 7 (8.1%) | 1 (1.0%) |
| Dehiscence | 1 (1.2%) | 2 (1.9%) | Dehiscence | 3 (3.5%) | 0 (0.0%) |
| Pseudoarthrosis | 4 (4.7%) | 6 (5.8%) | | | |
| Hematoma | 0 (0.0) | 0 (0.0%) | | | |
| PJF | 7 (8.1%) | 3 (2.9%) | | | |
| Other | 9 (10.5%) | 1 (1.0%) | | | |

Table 7: 2-year Follow-Up ODI Stratified by the Presence of Early and Late Complications.

| | Presence of Complication | | |
|-------------|--------------------------|------|---------|
| | Yes | No | p-value |
| Major Early | 39.1 | 30.5 | 0031* |
| Minor Early | 39 | 30.4 | 0020* |
| Major Late | 38.8 | 31.3 | 0.076 |
| Minor Late | 34.1 | 32.1 | 0.576 |

*Statistically significant result if $p < 0.05$

3 patients experienced complications including wound infection, transient thigh numbness and groin pain [18]. In a retrospective review of 184 patients, Haque et al., reported major complication rates in MIS, hybrid, and open surgeries at 14%, 14%, and 45%, respectively. When compared to hybrid patients, MIS patients had shorter operative times, less blood loss, lower transfusion rates, less coronal curve correction, less sagittal curve correction, and less change in PI-LL mismatch. Follow-up ODI and VAS scores were the same between the two groups [1].

A multicenter study of 60 patients by Uribe et al., reported intraoperative complication rates of MIS, hybrid, and open surgeries at 0.0%, 5.3%, 25.0%, respectively. When compared to hybrid patients, MIS patients had shorter operative times and less blood loss. No statistically significant changes were noted between radiologic parameters when comparing hybrid and MIS groups and all patients had improved pain scores at follow-up [2]. In a retrospective review of 85 patients, Wang et al., reported major complication rates of MIS, hybrid, and open surgeries at 14%, 29%, and 40%. When compared to hybrid patients, MIS patients had shorter operative times, less blood loss, less coronal curve correction and less sagittal curve correction. The study found favorable clinical outcome measures in all groups [5].

Taken as a whole, the evidence from prior studies indicates that MIS surgery results in less blood loss, shorter operative times, and lower transfusion rates compared to hybrid approaches. We substantiate these findings, demonstrating significantly less blood loss and operative time in the MIS cohort. It should be noted that the hybrid group in our study operated on a greater average number of levels, nearly 2-times greater than the CMIS group, which presumably added to the increased OR time. Nonetheless, additional exposure of open instrumentation and possible posterior column osteotomies, likely contributes to operative time. Moreover, it should be noted that blood loss, compared to the number of levels operated on, was disproportionately higher in the hybrid group at nearly 4-times the CMIS group. Such a dramatic increase in the blood loss may be due to the more invasive posterior technique, not simply a greater number of levels fused. The added morbidity of blood loss and operative stress may outweigh the benefit of surgical intervention in certain populations - namely, elderly patients who are more prone to adverse events [3,25-27]. Such cases highlight the potential utility of MIS correction in providing less potential exposure-related morbidity. Considering our progressively aging population, finding strategies that reduce blood loss and complication rates may prove a meaningful endeavor.

The MIS group demonstrated relatively low early major and minor complication rates of 13.5% and 9.6% and late major and minor complications rates of 9.6 and 4.8%. These values are more favorable than published literature for more invasive hybrid and open procedures [1,2,5,16,18]. Those selected for the MIS group had fewer posterior levels fused and more favorable pre-op sagittal and coronal alignment. It could be argued that a lesser deformity correction presumably risks fewer early complications; nonetheless, the reduced surgical footprint inherent in MIS techniques should not be overlooked. Short-term complications are largely the consequence of intraoperative and

immediate post-operative insults such as bleeding, infection, and transient inflammation. Increased tissue destruction and greater blood loss of more invasive approaches may lend themselves to these processes.

Anand et al., showed that reducing the intra and perioperative complication rates may be the mainstay for reducing the 30 day unplanned readmission and reoperation rate. This metric is gaining increasing importance to third party payers and the authors further showed that long term disability was higher in patients with early complications [28].

When compared to the reported literature on the open approach, both CMIS and hybrid groups experienced relatively low late complication rates [3,4]. However, when compared to each other, we report no statistically significant difference in the late complication rate between MIS and hybrid corrections. Uribe et al., had similar findings, noting no disparity between MIS and hybrid patients in terms of late complications including implant failure and proximal junctional kyphosis (PJK) [2]. Presumably, advances in the learning curve have played a role in mitigating late complications. We can better anticipate morbidity and manage injurious events, limiting progression to the short-term. Additionally, it must be considered that certain late complications, such as non-union, are likely related to the critical fusion step. Both hybrid and MIS techniques achieve arthrodesis through MIS lateral interbody fusion as the first phase. It is plausible that these identical approaches would confer a similar risk for late morbidity. Nonetheless, hybrid patients did trend towards a higher late complication rate. Moreover, the reoperation rate for hybrid surgery was higher and statistically significant compared to CMIS correction. It seems CMIS correction is at least comparable to its hybrid counterpart with respect to late term morbidity.

In terms of radiologic outcomes, we report no significant differences between MIS and hybrid patients. Amongst the contributing surgeons to this study it appears that hybrid approaches were chosen when greater preoperative spinal misalignment was noted. Hybrid patients had more coronal deformity and a higher trend in baseline SVA as compared to CMIS patients. Moreover, hybrid surgery resulted in greater delta values for Cobb angle, PI-LL, and LL. Recent innovations such as hyperlordotic cages, anterior longitudinal ligament (ALL) release, aggressive rod contouring and reduction techniques, may improve the sagittal gains attainable using CMIS correction. Subsequent studies incorporating the above alignment techniques may show a preference for CMIS correction as compared to hybrid techniques even when larger spinal alignment is needed. Looking to the future, it is vital we maintain these radiological benchmarks in MIS patients if CMIS correction is to be embraced alongside hybrid and open approaches.

As mentioned, there may have been a bias towards hybrid correction for treating more severe deformity as the hybrid group, on average, had almost 2-times more levels fused. It is possible that perceived improvements in complication rates for CMIS correction are confounded by patient selection - namely less severe deformity translating to a lower number of levels operated on. Moreover, our data was somewhat limited by our ability to match based on certain patient factors. In our retrospective

review, information such as medical co morbidities, smoking history, psychosocial factors, were not sufficient for powerful analysis.

CMIS and hybrid approaches show great promise as alternatives to traditional open surgical correction of ASD [1,2,30]. When compared to the more invasive hybrid approach, CMIS correction has less blood loss and less short-term complications, both major and minor. We also report a lower reoperation rate and comparable late morbidity with CMIS correction. Overall, 2-year follow-up ODI was improved in CMIS patients compared to hybrid surgery. With careful patient selection and by capitalizing on the reduced complication rate of CMIS correction, we can achieve comparable if not superior results using less invasive approaches for adult spinal deformity.

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