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1-Year Post-Operative Radiographic and Patient-Reported Outcomes following Cervical Deformity Correction are not Affected by a Short-Term Unplanned Return to the OR

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Abstract

Study Design: Retrospective analysis of a prospectively-collected multi-center database.

Objective: Assess the radiographic and health-related quality of life (HRQoL) impact of a short term (< 1 year) return to the OR after adult cervical spine deformity (ACSD) surgery.

Summary of Background Data: Returns to the OR within a year of ACSD correction can be particularly devastating to these vulnerable hosts as they often involve compromise of the soft tissue envelope, neurologic deficits or hardware failure. This work sought to assess the impact of a short-term reoperation on 1-year radiographic and HRQoL outcomes.

Methods: Patients operated on from 1/1/2013 to 1/1/2019 with at least 1-year of follow-up were included. The primary outcome was a short-term return to the OR. Variables of interest included patient demographics, Charlson Comorbidity Index (CCI), HRQoL measured with the Modified Japanese Orthopaedic Association (mJOA), Neck Disability Index (NDI) and EuroQuol-5D visual analogue scale (EQ-5D VAS) and radiographic outcomes, including T1-slope (TS), C2-C7 sagittal cobb angle (CL), TS-CL and cervical sagittal vertical axis (cSVA). Comparisons between those who did vs. did not require a 1-year reoperation were performed using paired t-tests. A Kaplan Meier survival curve was used to estimate reoperation-free survival up to 2-years post-operatively.

Results: A total of 121 patients were included in this work (age 61.9 ± 10.1 years, BMI 28.4 ± 6.9, CCI 1.0 ± 1.4, 62.8% female). A 1-year unplanned return to the OR was required for 28 (23.1%) patients, of whom 19 followed-up for at least 1-year. Indications for a return to the OR were most commonly for neurologic complications (5%), infectious/wound complications (5.8%) and junctional failure (6.6%) No differences in demographics, comorbidities, pre-operative or 1-year post-operative HRQoL or radiographic outcomes were seen between operative groups.

Conclusion: Reoperation < 1 year after ACSD surgery did not influence 1-year radiographic outcomes or HRQoL.

1. ACSD correction led to sustained radiographic correction and health-related quality of life score improvement 1-year after surgery.
2. The unplanned short-term (< 1 year) return to OR rate was 23.1%. The most common indications for a short-term reoperation were neurologic deficits/myelopathy (5.0%), infection/wound complications (5.8%) and acute junctional failure (6.6%).
3. No differences in 1-year radiographic alignment or health-related quality of life scores were seen in patients who required a 1-year reoperation vs. those who did not.

Introduction

The year over year increase in posterior cervical fusions performed for deformity correction from 2000 to 2017 was 16.5%, which outpaced fusions performed for non-deformity cervical pathologies[1]. This increased demand has allowed for improved measurement strategies for quantifying adult cervical spine deformity (ACSD) in the context of both age[2] and deformity subtype[3] as well as a greater understanding of the broad quality of life benefits imparted by ACSD correction[4]. Goals of ACSD surgery are to improve the patient’s horizontal gaze, decompress the spinal cord and maintain alignment of the head over the pelvis, ultimately improving the patient’s health satisfaction and quality of life[5].

The benefits of ACSD correction in appropriately selected hosts, in particular those who match known fragility criteria[6], can be transformational. However, complications are common and represent significant morbidity to these vulnerable hosts. Smith et al.[7] in a retrospective analysis of prospectively collected data from 133 ACSD patients with minimum 1-year follow-up reported a 1-year complication rate of 56%, of which more than half were considered “major”. Horn et al.[8] in their assessment of 89 ACSD patients found that patients who required greater deformity correction, had osteoporosis, or presented with pre-operative neurologic deficits were more likely to have a poor outcome, which included the need for reoperation. These outcomes represent a higher rate of adverse events than those reported following thoracolumbar adult spinal deformity (ASD). Bortz et al.[9] in a National Surgical Quality Improvement Program (NSQIP) analysis reported an overall 30-day perioperative complication rate of 34.8% following surgery for ASD. Smith et al.[10] in their assessment of 120 patients with ASD in a prospectively collected multi-center database reported a 9.2% 1-year mortality rate, with mortality more likely in patients with a perioperative complication.

Complications that mandate a return to the OR < 1-year after surgery include wound complications/infections that risk the integrity of the soft tissue envelope, progressive neurologic deficits such as myelopathy and junctional failures that require extension of the fusion construct. While the short-term morbidity of these complications is implied, their longer-term impact on quality of life, pain and radiographic alignment are unclear. This work sought to characterize patients who required a short-term (< 1-year) revision surgery following ACSD correction and determine if this revision procedure predisposed to poor 1-year radiographic and patient-reported outcomes. We hypothesized that a short-term revision would not impact 1-year radiographic and patient-reported outcomes.

Methodology

This was an institutional review board-approved retrospective analysis of a prospectively collected, multi-center deformity database of patients operated upon from 1/1/2013 to 1/1/2019 at one of 16 tertiary referral spine care centers in the United States. Inclusion in the prospective registry as a whole were based on specific criteria that have been published elsewhere[3,11]. The additional inclusion criteria for this work were adult patients who were operated upon for ACSD as defined and classified by prior work with a minimum of 1-year of post-operative follow-up or a documented re-operation within 1-year. Acute traumatic ACSDs, ACSD due to a malignancy or infection and patients with a history of prior ACSD surgery (patients with prior non-deformity cervical surgeries were included) were excluded.

The primary outcome was survival without a short-term return to the OR, defined as any unplanned return to the OR within 1-year of ACSD surgery. Variables of interest included age, BMI, sex, comorbidities as measured with the Charlson Comorbidity Index[12], health-related quality of life scores as measured with the Modified Japanese Orthopaedic Association (mJOA) score[13], the Neck Disability Index (NDI)[14], the EuroQuol-5D visual analogue health scale (EQ-5D VAS)[15] and the numeric rating scale (NRS) of the back and neck, and sagittal alignment measurements including T1-slope (TS), C2-C7 sagittal cobb angle (CL), TS-CL, and cervical sagittal vertical axis (cSVA).

Statistical analysis was performed using SPSS 28.0.1 (IBM, Armonk, NY). Comparisons between patient demographics, intraoperative characteristics, and preoperative vs. 1-year post-operative sagittal alignment parameters and health-related quality of life scores were performed using paired t-tests. A Kaplan Meier survival curve was used to estimate the reoperation-free survival of patients with at least 1-year of follow-up after the initial deformity surgery. A p-value

< 0.05 was considered significant in all cases. Data are written as mean ± standard deviation (median) or percentages as indicated.

Results

A total of 168 patients met our inclusion criteria. Of these, 121 (72.0%) had follow-up data for at least 1-year. Mean follow-up was 33.3 ± 23.4 (median 25) months. Mean age was 61.9 ± 10.1 (median 62.0) years old, mean BMI was 28.4 ± 6.9 (median 27.3) and mean Charlson Comorbidity Index was 1.0 ± 1.4 (median 0.0, range 0-6, 24.8% with a score of 1, 24.8% with a score ≥ 2). Seventy-six patients were female (62.8%).

An unplanned return to the OR was required for 28 (23.1%) patients within a year of surgery. One-year follow-up data is available for 19 of these patients, two had 1-year mortalities unrelated to the surgical procedure (one accidental trauma and one > 90-day post-operative cardiac arrest) and the other 7 were lost to follow-up. Estimated survival rate at 30 days was 92.3 ± 2.3%, 60 days 86.9 ± 3.0%, 180 days 82.3 ± 3.3% and 1-year 78.4 ± 3.6% (Figure 1). Revision surgery indications are presented in Table 1. Operative complications within 1-year largely fell into four categories: neurologic complications (6 / 121, 5.0%), infection/wound complications (7 / 121, 5.8%), junctional complications (8 / 121, 6.6%), and hardware complications (2 / 121, 1.7%).

Health-related quality of life scores and sagittal alignment measurements pre-operatively vs. at 1-year follow-up for the full cohort are shown in Table 2. Patients reported significant improvements in their neck discomfort (NRS Neck) and NDI. The difference between pre-operative (47.2 ± 17.8, median 48.0) and max follow-up (36.5 ± 21.1, median 38.0) median NDI scores was 10, which exceeded the previously established MCID for the NDI in ACSD patients of 7.0[16]. However, mJOA scores and overall health status as measured with EQ5D VAS were equivalent. Back discomfort as measured with the NRS Back was also unchanged after surgery. Significant improvements in TS (32.3 ± 17.9, median 27.5° pre-op vs. 36.6 ± 14.5, median 35.0° at 1-year; p = 0.04), CL (-5.9 ± 20.7, median -5.0° pre-op vs. 8.0 ± 14.4, median 7.0° at 1-year; p < 0.0001), TS-CL (38.2 ± 20.1, median 32.0° pre-op vs. 28.7 ± 12.4, median 27.5° at 1-year; p < 0.0001) and cSVA (38.7 ± 20.5, median 38.0 mm pre-op vs. 33.7 ± 15.0, median 33.0 mm at 1-year) were noted 1-year after surgery.

The pre- and intra-operative characteristics of patients who did vs. did not have a 1-year reoperation were equivalent (Table 3). No differences in any demographic, HRQOL or radiographic outcome were observed when a 1-year reoperation was required (Table 4).

Discussion

An unplanned return to the OR can represent significant morbidity and risk to the vulnerable patient with cervical spine deformity. In a retrospective analysis of 121 patients with ACSD and minimum 1-year follow-up from a multi-center prospective database, 23.1% required a subsequent surgery within 1-year of their initial deformity correction. The predominant indications for an unplanned return to the OR were wound complication/infection, junctional deformity and a neurologic complication (radiculopathy or myelopathy).

Our choice to focus on early unplanned re-operations following ACSD correction was due to the potential avoidability of these adverse events. While our operative infection rate of 5.8% in the present work is slightly deflated due to the exclusion of superficial infections that did not require intervention, it is less than half that of 12.8 and 18.9% reported by Shillingford et al.[17] in their query of adult kyphosis and scoliosis procedures recorded in the Scoliosis Research Society

Morbidity & Mortality database, respectively. We consider most infections following cervical spine surgery to be preventable, an assertion supported by the insurance database recall by Begier et al.[18] that showed a 0.5-2.0% incidence of SSI after posterior cervical fusion. While some surgical site infections (SSI) may be traced to wound contamination due to poor sterility during surgery, we cannot solely blame perioperative strategies such as draping, drain placement and prophylactic topical and intravenous antibiotics for these events. Multiple systematic reviews have failed to identify conclusive intraoperative strategies, such as drain placement, longer prophylactic antibiotics or dressing selection, that reduce SSI[19–21], although all lament the lack of high-quality trials to this end. The use of vancomycin powder was shown to reduce the incidence of SSI after instrumented spine surgery in adults and pediatrics in single-institution retrospective works[22,23]. However, a larger multicenter propensity score matched-analysis by Horii et al.[24] only found a significant change in culture speciation with the use of vancomycin powder. Surgical efficiency has been shown to impact SSI, and Puffer et al.[25] found a relationship between longer total anesthetic and operative times and SSI, particularly in patients with higher BMIs. However, our work did not find an association between operative time, EBL or hospital length of stay with a < 1 year return to the OR. We largely attribute our surgical infection rate to patient selection and host vulnerability. Metabolic syndrome and diabetes in particular may predispose to SSI after ACSD. Patel et al.[26] in their retrospective review of 264 posterior cervical fusions associated postoperative glycemic lability with an increased incidence of SSI and re-admissions. Obesity (BMI ≥ 30) has also been associated with a 4-times greater risk of infection after ASD surgery[27] and a 2.5-times greater risk after cervical deformity surgery[28]. Given the known influence of obesity and diabetes on bone quality[29] and the association between osteoporosis and complications, re-operation and cost following ASD surgery[30], weight and glycemic optimization are strongly encouraged when considering a patient's candidacy for ACSD correction. Thoughtful nutritional and weight loss interventions can also improve surgical cost utility, an increasingly important factor given the growing emphasis on value-based medicine[31,32]. Finally, Passias et al.[33] associated neuromuscular disease with an increased likelihood of post-operative DJK following ACSD correction. Pre-operative neurology consultation and electromyography should be considered in patients suspected of having concurrent neuromuscular pathology, especially in patients with a history of neurologic injury such as stroke or in the setting of a severe sweeping cervicothoracic kyphosis.

Unplanned returns to the OR due to radiculopathy and/or myelopathy within 1 year of ACSD surgery (seen in 5.0% of the patients in the present work) may be more the result of pre-operative deformity and construct selection than the consequence of adjacent segment disease. While logic dictates that residual kyphosis may not fully relieve the cord tension contributing to myelopathy, evidence that improved sagittal alignment prevents the occurrence or recurrence of cervical myelopathy is sparse. Tang et al.[34] associate a pre-operative cSVA > 40mm with worse outcomes following ACSD correction, as measured with NDI and Short Form-36 (SF-36) scores. Roguski et al.[35] report that patients with a post-operative cSVA > 40 mm did not improve following treatment for myelopathy. Passias et al.[36] in the largest work to this end report that the quality of life scores of over half of 70 patients with cervical deformity and myelopathy did not improve, and an improved cSVA was associated with improved quality of life scores. However, the authors do not address whether patients required a reoperation for recurrent myelopathy or radiculopathy. It may be possible that the early recurrence of myelopathy symptoms represent a distinct complication subset, and that early neurologic deficits are associated with reduced quality of life scores at final follow-up. Four of the 19 (21.1%) patients who were indicated for reoperation within 1-year of surgery and 6 / 28 (21.4%) from the full cohort co-presented with myelopathy. Further evaluation of this distinct cohort will be the subject of subsequent analyses.

Indications for reoperation due to early junctional kyphosis were fracture adjacent to the fusion construct, hardware loosening, rapid loss of deformity correction and advanced local degenerative disease. Adjacent level fracture, or acute proximal junctional failure, has been associated with severe pre-operative sagittal imbalance, age and poor bone quality[37]. Unfortunately, the present work lacked the granularity and power to evaluate acute radiographic changes following ACSD correction. However, prior work has identified several contributors to early and late junctional complications. Passias et al.[38] in a retrospective study of 101 patients who underwent a mean 7 level cervical deformity correction reported a 23.8% incidence of DJK within 1 year of CD correction, and found that cervical kyphosis > 12°, thoracic kyphosis > 50.6°, cSVA > 56.3 mm, a combined anterior/posterior cervical surgical approach and Smith-Petersen osteotomies were predictors of early DJK. Further, in a separate text Passias et al.[33] warn that ACSD constructs that cross the cervicothoracic junction must adhere to the age-adjusted targets for lumbar lordosis – thoracic kyphosis set forth by Lafage et al.[39] to minimize the risk of severe symptomatic DJK. It is unclear if the rate of acute < 1-year junctional failure due to DJK (n = 7, 5.8%) is higher than expected, or reflective of the severe deformity criteria required for inclusion in the multicenter database. Such a small sample also does not permit a reliable focused analysis and comparison of these patients. Improved understanding of acute DJK requiring a return to the OR is likely only to be possible with a larger multicenter study with a larger sample size.

This work has several limitations beyond those intrinsic to a retrospective analysis. Most prominent is its limited follow-up period. While the majority of reoperations appeared to occur within 1 year of surgery, our follow-up rate > 2 years following the index procedure was only 60.7%, precluding analysis. It is likely that a mid-term analysis would reveal a higher reoperation rate on patients with post-operative deformities. Second, while an advantage of a prospective multi-center database is the ability to follow a larger number of patients recruited over a shorter time-period, our revision sample size was still modest and did not permit more granular analyses of factors such as levels operated upon and levels decompressed vs. corrected. It is also likely underpowered to detect secondary effects and interactions, as evidenced by some of the wide standard deviations reported in our radiographic and patient-reported outcomes measurements. This underpowering is likely to be present for other variables as well. Third, while follow-up protocols were standardized between sites, surgical indications for revision procedures for recurrent deformity may vary regionally and by operating surgeon. While this makes mid- and long-term reoperation studies important to furthering our understanding of the natural history of ACSD correction, we believe that acute and subacute complications are more likely to be preventable than long term deformity recurrence, justifying their emphasis in the present work. Fourth, the limited event rate cited in this work permits only bivariate comparisons. There is no capacity for adjusting to confounders. Fifth, given the study design, there is potential for selection, indication and expertise bias. The surgeons whose patients were included in this prospective multicenter analysis were also high-volume surgeons, whose experience and outcomes may not translate to all other clinical settings. Finally, given our study design and approach, the results of the present work should be viewed as hypothesis generating only based on the retrospective clinical experience of a multi-center clinical registry. It cannot be considered definitive or prescriptive.

Conclusion

The 1-year reoperation rate after ACSD correction was 23.1%. Significant indications for revision surgery were wound/infectious complications, myelopathy/radiculopathy and junctional deformity. While an early return to the OR did not impact 1-year HRQOL and radiographic outcomes, longer-term outcomes are necessary to fully understand the lasting impact of these early reoperations.

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Figure 1: Return to OR survival curve up to 2 years after ACSD surgery

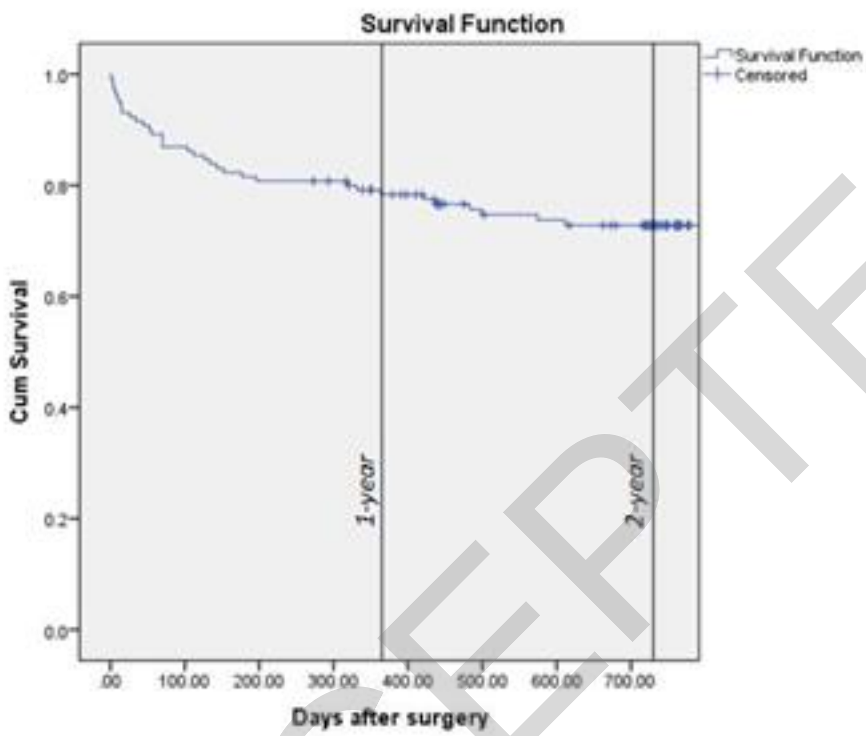

Table 1: Unplanned Returns to the OR following Cervical Deformity Correction

RETURN TO OR WITHIN 1 YEAR OF SURGERY	**N = 28 (23.1%)**
N = 6	Neurologic (Radiculopathy/Myelopathy)
N = 2	Trauma
N = 7	Infection / Wound Complication
N = 8	Junctional Complication (7 DJK, 1 PJK)
N = 2	Hardware Complication
N = 1	Airway Edema
N = 1	Unplanned staged procedure
N = 1	Unknown
RETURN TO OR 1-2 YEARS AFTER SURGERY	**N = 9 (7.4%)**
N = 2	Junctional Complication (2 DJK)
N = 1	Wound Complication
N = 1	Pseudoarthrosis
N = 2	Neurologic
N = 2	Hardware Complication
N = 1	Other (poor outcome improvement)
RETURN TO OR WITHIN 2-YEARS	**n = 37 (30.6%)**

Table 2: Cohort X-ray and quality of life scores pre-op vs. 1-year post-operative (n = 121)

	Pre-Operative (n=121)	*1-Year Follow-Up (n=121)*	*1-Year p-Value*
NSR Back	5.1 ± 3.1 (median 5.0)	4.5 ± 2.9 (median 5.0)	0.1
NSR Neck	6.6 ± 2.5 (median 7.0)	4.2 ± 2.9 (median 4.0)	**< 0.0001**
NDI	47.2 ± 17.8 (median 48.0)	36.5 ± 21.1 (median 38.0)	**< 0.0001**
mJOA	13.5 ± 2.7 (median 14.0)	14.1 ± 3.0 (median 14.0)	0.1
EQ5D VAS	68.1 ± 89.6 (median 65.0)	72.4 ± 83.8 (median 70.0)	0.7
T1 Slope (deg)	32.3 ± 17.9 (median 27.5)	36.6 ± 14.5 (median 35.0)	**0.04**
C2-C7 Cervical Lordosis (deg)	-5.9 ± 20.7 (median -5.0)	8.0 ± 14.4 (median 7.0)	< **0.0001**
T1S – Cervical Lordosis (deg)	38.2 ± 20.1 (median 32.0)	28.7 ± 12.4 (median 27.5)	< **0.0001**
Cervical SVA (mm)	38.7 ± 20.5 (median 38.0)	33.7 ± 15.0 (median 33.0)	**0.03**

Table 3: Pre- and Peri-Operative Characteristics of Patients with vs. without a < 1-Year Reoperation

	Re-Operation (n = 28)	*No Re-Operation (n = 102)*	*p-Value*
Age	60.9 ± 10.3	61.9 ± 10.0	0.7
BMI	28.3 ± 6.4	28.4 ± 7.1	1.0
Charlson Comorbidity Score	0.6 ± 0.8	1.1 ± 1.5	0.1
Sex (% Female)	17 / 28 (60.7%)	59 / 93 (63.4%)	0.8
Hx of Cervical Spine Surgery	37 / 93 (39.8%)	11 / 28 (39.3%)	0.9
NSR Back	5.4 ± 3.5	5.0 ± 3.0	0.6
NSR Neck	6.3 ± 2.8	6.8 ± 2.5	0.4
NDI	45.1 ± 18.5	47.9 ± 17.7	0.5
mJOA	13.7 ± 2.7	13.5 ± 2.7	0.7
EQ5D VAS	64.6 ± 21.0	69.2 ± 101.7	0.8
T1 Slope (deg)	35.0 ± 18.0	31.5 ± 17.8	0.4
C2-C7 Cervical Lordosis (deg)	-8.0 ± 23.4	-5.3 ± 19.9	0.6
T1S – Cervical Lordosis (deg)	42.9 ± 25.6	36.8 ± 18.2	0.2
Cervical SVA (mm)	44.0 ± 22.4	37.1 ± 19.8	0.1
Perioperative Data			
Estimated Blood Loss (cc)	932.5 ± 1093.6	899.5 ± 1561.5	1.0
Operative Time (mins)	393.9 ± 233.0	398.0 ± 236.6	0.9
Length of Stay (days)	7.5 ± 7.1	6.8 ± 8.1	0.5
Combined Front/Back Approach	7 / 28 (25.0%)	36 / 93 (38.7%)	0.3
3-Column Osteotomy	13 / 28 (46.4%)	49 / 93 (49.5%)	0.6

Table 4: 1-Year Post-operative HRQOL and Radiographic Outcomes of Patients with vs. without Early Reoperation

	< 1 Yr OR (n = 19)	*No Re-Operation (n = 102)*	*p-Value*
NSR Back	5.5 ± 3.4	4.3 ± 2.9	0.1
NSR Neck	4.5 ± 3.3	4.1 ± 2.8	0.2
NDI	39.2 ± 23.7	35.7 ± 20.4	0.2
mJOA	14.5 ± 3.1	14.0 ± 2.9	0.8
EQ5D VAS	64.6 ± 21.9	74.8 ± 95.1	0.6
T1 Slope (deg)	38.4 ± 14.8	36.1 ± 14.4	0.4
C2-C7 Cervical Lordosis (deg)	6.5 ± 13.0	8.5 ± 14.7	0.8
T1S – Cervical Lordosis (deg)	31.9 ± 15.3	27.7 ± 11.4	0.6
Cervical SVA (mm)	36.0 ± 16.8	33.0 ± 14.5	0.9