# Efficacy and Safety of Surgery for Mild Degenerative Cervical Myelopathy: Results of the AOSpine North America and International Prospective Multicenter Studies

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**OBJECTIVE:** To evaluate the degree of impairment in baseline quality of life as compared to population norms, as well as functional, disability, and quality of life outcomes following surgery in a prospective cohort of mild DCM patients undergoing surgical decompression. **METHODS:** We identified patients with mild DCM (modified Japanese Orthopaedic Association [mJOA] 15 to 17) enrolled in the prospective, multicenter AOSpine CSM-NA or CSM-I trials. Baseline quality of life Short Form-36 version 2 (SF-36v2) was compared to population norms by the standardized mean difference (SMD). Outcomes, including functional status (mJOA, Nurick grade), disability (NDI [Neck Disability Index]), and quality of life (SF-36v2), were evaluated at baseline and 6 mo, 1 yr, and 2 yr after surgery. Postoperative complications within 30 d of surgery were monitored.

**RESULTS:** One hundred ninety-three patients met eligibility criteria. Mean age was 52.4 yr. There were 67 females (34.7%). Patients had significant impairment in all domains of the SF-36v2 compared to population norms, greatest for Social Functioning (SMD –2.33), Physical Functioning (SMD –2.31), and Mental Health (SMD –2.30). A significant improvement in mean score from baseline to 2-yr follow-up was observed for all major outcome measures, including mJOA (0.87, P < .01), Nurick grade (–1.13, P < .01), NDI (–12.97, P < .01), and SF-36v2 Physical Component Summary (PCS) (5.75, P < .01) and Mental Component Summary (MCS) (6.93, P < .01). The rate of complication was low.

**CONCLUSION:** Mild DCM is associated with significant impairment in quality of life. Surgery results in significant gains in functional status, level of disability, and quality of life.

**KEY WORDS:** Cervical spondylotic myelopathy, Degenerative cervical myelopathy, Modified Japanese Orthopaedic Association score, Quality of life, Spine surgery, SF-36

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ABBREVIATIONS: 30MWT, 30-meter Walking Test; CI, confidence interval; DCM, degenerative cervical myelopathy; HLF, hypertrophy of the ligamentum flavum; MCS, Mental Component Summary; MCID, minimum clinically important difference; mJOA, modified Japanese Orthopaedic Association; NDI, Neck Disability Index; OPLL, ossification of the posterior longitudinal ligament; PCS, Physical Component Summary; SF-36v2, Short Form-36 version 2; SMD, standardized mean difference

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egenerative cervical myelopathy (DCM) is a progressive degenerative spinal condition, and the leading cause of spinal cord dysfunction among adults worldwide.<sup>1</sup> This clinicopathological entity encompasses osteoarthritic degeneration (ie, cervical spondylosis) and ligamentous aberrations (eg, ossification of the posterior longitudinal ligament (OPLL), hypertrophy of the ligamentum flavum [HLF]). Over 70% of individuals over 60 to 65 yr old demonstrate pathological or radiological evidence of cervical degeneration, and approximately one-quarter of these people become clinically symptomatic from mechanical neural compression.<sup>2-4</sup> The proportion of the United States population 65 yr or older is expected to nearly double from 13% in 2010 to 22% in 2050,<sup>5</sup> making optimal diagnosis and treatment of DCM a key public health priority.

Controversy in the treatment of DCM has stemmed by and large from mixed reports regarding the natural history of this condition. Although there is some variability, a large number of patients, ranging from 20% to 60%, will deteriorate neurologically over time when treated nonoperatively.<sup>6-8</sup> Traditionally, surgical decompression for DCM was performed to halt progression of neurological dysfunction and prevent further disability. However, more recent evidence indicates that surgical intervention for DCM is actually associated with improvement in function and quality of life.9,10 As a result, surgery is now becoming standard of care for patients with clearly symptomatic DCM. Nonetheless, controversy persists regarding the optimal management of patients with only mild symptomology. The latest clinical guidelines recommend surgery for patients with moderate and severe DCM, and nonoperative treatment with serial clinical follow-up for asymptomatic patients with imaging evidence of cervical spinal cord compression. For patients with mild DCM, the guidelines suggest that either surgery or a supervised trial of structured rehabilitation is reasonable initial management strategy; the less definitive nature of this suggestion likely reflects the paucity of clinical evidence surrounding the effectiveness of surgery for patients with mild DCM.<sup>11</sup> These patients present a conundrum to the surgeon. On one hand, if the disease is only causing mild symptoms, the risk-benefit scale may tip in favor of risk, with a lot to be lost, and little to be gained. The contrary view is that these patients stand to gain the most from intervention by halting progression of potentially irreversible neurological deficits early on in the course of the pathological process. Moreover, even "mild" DCM may be associated with a derangement in quality of life that patients consider unacceptable, and can perhaps be helped with operative intervention. To this end, the objectives of the present study were 2-fold: (1) to evaluate quality of life in mild DCM compared to population norms and (2) to evaluate the clinical outcomes of patients with mild DCM following surgical intervention. We hypothesized that (1) patients would have significant derangement in quality of life, despite having what is considered only "mild" DCM and (2) surgery in these patients would halt progression of symptoms, and in fact lead to improved functional status and quality of life.

# METHODS

#### Subjects

Over a 5-yr period, 193 patients with mild DCM, defined by a modified Japanese Orthopaedic Association (mJOA) score of 15, 16, or 17,<sup>12</sup> were enrolled in the AOSpine CSM North America (CSM-NA) or CSM International (CSM-I) trials. These were prospective, multi-

center cohort studies that aimed to evaluate the efficacy of surgical decompression in patients with DCM with regard to functional status, disability, and quality of life (QOL) outcomes. These larger studies separated patients into mild (mJOA 15-17), moderate (mJOA 12-14), and severe (mJOA < 12) disease categories based on the mJOA scale. This classification scheme was developed and adopted by the AOSpine investigators a priori and appropriately validated.<sup>12</sup> The rationale for this upfront was to permit substudies that would test the a priori hypothesis that the efficacy of surgical decompression for DCM varies with disease severity.

The AOSpine CSM-NA study recruited patients from 1 Canadian and 11 American sites from December 2005 to September 2007, and the AOSpine CSM-I study from 6 Asian, 5 European, 3 Latin American, and 2 North American sites between October 2007 and January 2011. Patients were enrolled if they provided written consent and met the following eligibility criteria: (1) age 18 yr or older; (2) symptomatic DCM with at least 1 clinical sign of myelopathy; (3) imaging evidence of cervical cord compression; and (4) no prior cervical spine surgery. Patients with asymptomatic DCM, active infection, neoplastic disease, rheumatoid arthritis, trauma, ankylosing spondylitis, or concomitant lumbar stenosis were excluded. Ethics approval was obtained from each site's internal review board.

#### **Surgical Techniques**

All patients underwent operative treatment, consisting of surgical decompression of the cervical spine, with or without an instrumented fusion procedure. Patients were treated anteriorly by cervical discectomy and/or corpectomy with fusion, or posteriorly by laminectomy with or without instrumented fusion or laminoplasty, or by a combined circumferential approach. The surgical approach, number of operated levels, and use and type of instrumentation were at the discretion of the treating spinal surgeon.

### **Data Collection**

Data pertaining to patient demographics (eg, age, sex, race, body mass index, education, work status, comorbidities, etc.), clinical presentation (eg, symptoms, signs, causative pathology, etc.), and surgical treatment (eg, approach, spinal levels operated, operative duration, etc.) were obtained. Functional status, disability, and quality of life were assessed at baseline and 6, 12, and 24 mo after surgery. Postoperative complications within 30 d of surgery were monitored.

#### **Quality Assurance**

External research monitors performed on- and off-site evaluations to ensure that the data were accurate, reliable, and complete, and that the study followed the protocol.

#### **Outcome Measures**

Patient outcomes were evaluated preoperatively at baseline and at 6 mo, 1 yr, and 2 yr after surgery. Functional status was assessed by the mJOA scale<sup>13</sup> and Nurick grade.<sup>1,14</sup> These are both investigatoradministered DCM-specific indices that score the severity of myelopathy with regard to neurological and functional impairment. Quality of life was evaluated by the Short Form-36 version 2 (SF-36v2)<sup>15</sup> and disability by the Neck Disability Index (NDI).<sup>16,17</sup> These are both patient self-reported measures, the SF-36 being a generic health-related quality of life instrument, and the NDI being specific to neck conditions. SF-6D utility scores were derived from SF-36 data.<sup>18</sup> Patients also completed the 30-meter Walking Test (30MWT),<sup>19</sup> which quantifies the degree of disability in DCM based on the length of time and number of steps taken to walk 15 m and back, starting from, and returning to, a seated position.

### **Power Calculation**

Based on power calculations, using a standard deviation for mJOA of 1.8,<sup>20</sup> a sample size of 193 patients with paired measures (repeated time points: baseline, follow-up) would have >99% power to detect an improvement of 1 mJOA grade.

## **Statistical Analysis**

Baseline descriptive statistics were calculated. Continuous variables were described using means and standard deviations, and categorical variables by frequencies and percentages. We calculated mean scores for each domain of the SF-36v2 in our cohort at baseline. These were compared to population normative data derived from a prospective survey of 9423 randomly selected Canadian men and women aged 25 yr or more living in the community.<sup>21</sup> The degree of derangement in quality of life of patients in our cohort compared to population norms was quantified by calculating the standardized mean difference (SMD; Cohen's *d*) and its associated 95% confidence interval (CI) for each domain. The magnitude of the SMD was interpreted using the thresholds proposed by Cohen: small (0.2), medium (0.5), or large (0.8).<sup>22</sup>

We performed pairwise comparison of means using the Tukey adjustment for multiple comparisons to evaluate how the outcomes of mJOA score, Nurick grade, 30MWT, each of the 8 domains and 2 composite scores of the SF-36v2, NDI, and SF-6D changed over time, from baseline to 6, 12, and 24 mo after surgery. We reported means and 95% CIs for each outcome at each time point, as well as the mean difference and associated 95% CI at 2 yr after surgery compared to preoperative status.

The threshold for accepting statistical significance was set a priori at  $\alpha = 0.05$ . Data were assumed to be missing at random, and these were omitted from the analysis. All statistical analyses were performed using Stata 14 (Stata Corp, College Station, Texas).

# RESULTS

A total of 193 patients with mild DCM (mJOA 15-17) were enrolled, 99 (51.3%) from sites in North America, 38 (19.7%) from sites in Asia-Pacific, 37 (19.2%) from European sites, and 19 (9.8%) from sites in Latin America. Baseline characteristics of the study cohort are summarized in Table 1. Mean age was 52.4 yr. There were 126 males (65.3%) and 67 females (34.7%). The majority of patients were Caucasian (140; 72.5%), followed by East Asian (38; 19.7%), African-American (8; 4.1%), and other (7; 3.6%). The causative pathology of DCM was disc herniation in most patients (144; 74.6%). Mean symptom duration was 26.7 mo. The greatest number of patients had an mJOA score of 15 (86; 44.6%) and Nurick grade of 2 (88; 45.6%). Mean baseline NDI was 31.3, SF-36v2 PCS 39.7, SF-36v2 MCS 42.7, and SF-6D (utility) 0.60. The most common presenting complaint was numb hands (156; 80.8%) and the most common exam finding was hyperreflexia (135; 69.9%; Table 2).

Baseline (preoperative) mean scores, population normative values, and calculated SMDs for each domain of the SF-36v2

Age (yr)	$52.42\pm10.1$
Female sex	67 (34.72%
Region	
North America	99 (51.30%
Asia-Pacific	38 (19.69%
Europe	37 (19.17%)
Latin America	19 (9.84%)
Race	
Caucasian	140 (72.54%
East Asian	38 (19.69%
African-American	8 (4.15%)
Other	7 (3.63%)
Current smoker	48 (24.87%
Diagnosis	
Disc herniation	144 (74.61%
Spondylosis	131 (67.88%
OPLL	40 (20.73%
HLF	34 (17.62%
Subluxation	7 (3.63%)
Congenital stenosis	4 (2.07%)
Symptom duration (mo)	$26.72 \pm 35.8$
mJOA	$15.76 \pm 0.7$
15	86 (44.56%
16	68 (35.23%
17	39 (20.21%
Nurick	$2.31 \pm 0.81$
0	3 (1.55%)
1	24 (12.44%
2	88 (45.60%
3	78 (40.41%
4	0
5	0
NDI (n = 158)	$31.34\pm17.3$
SF-36v2 (n = 185)	
PCS score	$39.74\pm8.8$
MCS score	42.72 ± 13.1
SF-6D (n = 182)	$0.60 \pm 0.11$

TABLE 2. Presenting Symptoms and Signs.				
Symptoms				
Numb hands	156 (80.83%)			
Clumsy hands	104 (53.89%)			
Gait difficulty	93 (48.19%)			
Bilateral arm paresthesias	71 (36.79%)			
L'Hermitte's phenomenon	43 (22.28%)			
Weakness	126 (65.28%)			
Pain	84 (43.5%)			
Signs				
Corticospinal distribution motor deficits	91 (47.15%)			
Atrophy of hand intrinsic muscles	44 (22.80%)			
Hyperreflexia	135 (69.95%)			
Positive Hoffman sign	116 (60.10%)			
Upgoing plantar responses	47 (24.35%)			
Lower limb spasticity	59 (30.57%)			
Broad-based, unstable gait	58 (30.05%)			

Outcome	Preoperative	6 mo	12 mo	24 mo	Difference <sup>a</sup>	Р
Functional status						
mJOA	15.76 (15.53, 15.99)	16.40 (16.16, 16.65)	16.63 (16.38, 16.88)	16.63 (16.37, 16.89)	0.87 (0.42, 1.33)	< .01
Nurick	2.25 (2.09, 2.41)	1.26 (1.09, 1.43)	1.08 (0.92, 1.25)	1.12 (0.96, 1.28)	-1.13 (-1.42, -0.83)	< .01
30-meter Walk Test	26.50 (25.09, 27.90)	24.65 (23.11, 26.18)	24.03 (22.46, 25.61)	25.19 (23.60, 26.78)	–1.31 (–4.09, 1.48)	.62
Quality of life						
SF-36v2 Physical Functioning	39.98 (38.51, 41.46)	44.76 (43.19, 46.33)	45.45 (43.87, 47.04)	45.70 (44.08, 47.31)	5.71 (2.85, 8.58)	< .01
SF-36v2 Role Limitation Physical	35.92 (34.21, 37.62)	42.07 (40.25, 43.89)	43.89 (42.05, 45.73)	44.04 (42.17, 45.91)	8.12 (4.81, 11.44)	< .01
SF-36v2 Bodily Pain	37.92 (36.39, 39.44)	45.74 (44.11, 47.37)	46.92 (45.28, 48.56)	46.49 (44.82, 48.16)	8.57 (5.60, 11.54)	< .01
SF-36v2 General Health	45.61 (44.19, 47.02)	49.25 (47.73, 50.76)	49.28 (47.75, 50.81)	48.34 (46.79, 49.89)	2.73 (-0.02, 5.49)	.053
SF-36v2 Emotional Well-Being	42.47 (40.79, 44.15)	48.42 (46.62, 50.21)	49.76 (47.94, 51.58)	50.21 (48.36, 52.06)	7.74 (4.46, 11.01)	< .01
SF-36v2 Role Limitation Emotional	38.30 (36.36, 40.24)	44.22 (42.14, 46.29)	45.07 (42.97, 47.17)	45.18 (43.04, 47.31)	6.87 (3.09, 10.66)	< .01
SF-36v2 Social Functioning	40.37 (38.76, 41.98)	47.21 (45.49, 48.93)	47.45 (45.71, 49.19)	46.75 (44.98, 48.52)	6.38 (3.24, 9.52)	< .01
SF-36v2 Energy/Fatigue	44.96 (43.28, 46.63)	50.38 (48.59, 52.17)	51.56 (49.75, 53.37)	51.81 (49.97, 53.65)	6.85 (3.58, 10.12)	< .01
SF-36v2 Physical Component Summary	39.74 (38.37, 41.12)	44.94 (43.48, 46.40)	45.79 (44.32, 47.27)	45.49 (43.99, 46.99)	5.75 (3.08, 8.41)	< .01
SF-36v2 Mental Component Summary	42.72 (40.91, 44.53)	48.67 (46.74, 50.60)	49.55 (47.59, 51.50)	49.64 (47.66, 51.63)	6.93 (3.41, 10.45)	< .01
NDI	31.34 (28.67, 34.00)	21.05 (18.23, 23.87)	20.78 (17.88, 23.67)	18.36 (15.42, 21.31)	-12.97 (-18.18, -7.76)	< .01
SF-6D	0.60 (0.58, 0.62)	0.69 (0.67, 0.71)	0.72 (0.70, 0.74)	0.71 (0.69, 0.73)	0.11 (0.07, 0.14)	< .01

<sup>a</sup>Outcome at 24 mo vs preoperative status (baseline).

are presented in Table 3. Scores for all domains of quality of life were significantly lower in our cohort of mild DCM patients compared to population norms, with the difference being "large," as evaluated by Cohen's *d*. The greatest perturbation in quality of life was seen in the domains of Social Functioning (SMD – 2.33), Physical Functioning (SMD –2.31), and Mental Health (SMD –2.30).

Table 4 summarizes surgical treatment of the study cohort. The majority of patients were treated by an anterior approach (143; 74.1%). Of these, most involved a discectomy/fusion (140; 72.5%), and a smaller number underwent a corpectomy (29; 15.0%). A posterior approach was used in 46 patients (23.8%) and few patients (3; 1.55%) underwent a circumferential decompression. Considering posterior approaches, 1 patient (0.5%) underwent laminectomy alone, 14 (7.3%) laminoplasty, and 34 (17.6%) laminectomy plus instrumented fusion. In the majority of cases (145; 75.1%), a multilevel decompression was required.

Follow-up data were available for 180 patients (93.3%) at 24 mo. Table 3 presents measures of functional status and quality of life at preoperative status and 6, 12, and 24 mo after surgery. Overall, mJOA score and Nurick grade improved significantly from baseline to 2-yr follow-up (P < .01). Significant improvements in health-related QOL were found for the NDI, SF-6D, and 9 of the 10 components of the SF-36v2 (P < .01), with a trend toward improvement in the remaining general health component. No improvement was seen in scores on the 30MWT.

Table 5 presents surgical complications. The most common complication was worsening of myelopathy, seen in 13 patients (6.7%), followed by worsening of axial neck pain in 12 (6.2%), and dysphagia in 11 (5.7%). All patients who developed dysphagia had undergone an anterior approach surgery. Six patients (3.1%) developed a superficial wound infection, 6 (3.1%) had a malpositioned screw, and 4 (2.1%) developed

TABLE 4. Summary of Operative Management.			
Operative duration (min)	$169.07\pm69.59$		
Surgical approach			
Anterior	143 (74.09%)		
Posterior	46 (23.83%)		
Circumferential	3 (1.55%)		
Surgical technique			
Anterior discectomy/fusion	140 (72.54%)		
Anterior corpectomy	29 (15.03%)		
Anterior fixation	110 (56.99%)		
Laminectomy	1 (0.52%)		
Laminectomy/Instrumented fusion	34 (17.62%)		
Laminoplasty	14 (7.25%)		
Anterior grafting			
Autograft	21 (10.88%)		
Cage	38 (19.69%)		
Allograft	10 (5.18%)		
Synthetic	15 (7.77%)		
Posterior grafting			
Autograft	22 (11.40%)		
Allograft	1 (0.52%)		
Spinal level			
C1	0		
C2	7 (3.63%)		
C3	65 (33.68%)		
C4	118 (61.14%)		
C5	181 (93.78%)		
C6	176 (91.19%)		
C7	109 (56.48%)		
No. of levels			
1	48 (24.87%)		
2	70 (36.27%)		
3+	75 (38.86%)		

TABLE 5. List of Important Surgery-Related Complications.				
Progression of myelopathy	13 (6.74%)			
Worsening of axial neck pain	12 (6.22%)			
Dysphagia	11 (5.70%)			
Superficial infection	6 (3.11%)			
Screw malposition	6 (3.11%)			
Postoperative deformity	4 (2.07%)			
Hardware failure	3 (1.55%)			
Deep infection	3 (1.55%)			
New radiculopathy	3 (1.55%)			
C5 radiculopathy	2 (1.04%)			
Adjacent segment degeneration	2 (1.04%)			
Dural tear	2 (1.04%)			
Serious bleeding	2 (1.04%)			
Wound hematoma	2 (1.04%)			
Pseudoarthrosis	1 (0.52%)			
Cardiopulmonary event	1 (0.52%)			
$\geq$ 1 complication	59 (30.57%)			

a postoperative kyphotic deformity. At least 1 complication occurred in 59 patients (30.6%).

# DISCUSSION

In a large prospective cohort of patients, we found mild DCM to be associated with significant impairment in quality of life compared to the general population. Surgery in these patients was associated with improved functional, disability, and quality of life outcomes, including mJOA score, Nurick grade, SF-36v2 score, NDI, and SF-6D utility scores. To be meaningful, these findings of course need to be taken into context of the natural history of mild DCM. While the available data would suggest most patients younger than 75 yr of age with this condition remain stable without intervention over a 3-yr period, patients rarely improve, and a long period of quiescence is considered the best case scenario.<sup>6,23,24</sup> Alternatively, many patients experience the typical slow, stepwise decline.<sup>6</sup> Our findings hence lead us to favor surgical intervention in mild DCM, because the degree of impairment in quality of life is significant, meaningful gains in function and quality of life can be achieved with an operation, and the alternative of nonoperative management offers only stability at best.

Indeed, it is interesting that although the patients in this study had only mild myelopathy, as rated by the mJOA scale, patients suffered from substantial impairment in health-related quality of life. The SF-6D is a useful and practical index because it provides a measure of preference for a given health state (ie, a utility score), allowing comparison between different health conditions. The mean SF-6D score of our cohort of mild DCM patients was 0.60. To shed perspective, the reported SF-6D utility score in patients with asthma is 0.76; cancer or malignancy, 0.72; epilepsy, 0.71; chronic bronchitis, 0.66; clinical depression, 0.64; stroke, 0.64; and congestive heart failure, 0.60.<sup>25</sup> This begs the question, why is patients' rating of their quality of life so poor, despite suffering from only mild DCM? The greatest alteration in quality of life was seen in the domains of Physical Functioning, Social Functioning, and Mental Health. The 3 most common presenting symptoms in our cohort were numb hands (81%), weakness (65%), and clumsy hands (54%). When we consider how much of our day-to-day life-work or leisure-depends on hand function, the apparent discordance between mJOA score and perceived quality of life becomes less surprising. Even minor disturbance in hand function likely significantly impairs physical function in day-to-day activities, and this extends to social functioning; for example, one's ability to partake in sports or other leisurely activities and hobbies. This would be expected to take a toll on one's mental health. Pain, which is known to have a significant negative association with physical health-related QOL,<sup>26</sup> was also an important symptom, present in 44% of our cohort. Further, improvement in pain has been shown to be an important factor in patient satisfaction following cervical decompression surgery,<sup>27</sup> and this is likely a key driver of the improvement in QOL observed following surgery in our study. With surgical intervention, at the 24-mo mark, the mean SF-6D score had improved to 0.72-nearly 4-fold the reported minimum clinically important difference (MCID) for the SF-6D of 0.03.<sup>28</sup> Similarly, gains in SF-36v2 PCS (5.75) and MCS (6.93) and NDI (-12.97) exceeded the MCID for these outcomes (5 points for SF-36v2 PCS and MCS scores<sup>29</sup>; 7.5 points for the NDI<sup>16,30</sup>). This would suggest that perhaps it is time we recalibrate the way we think about patient outcomes in DCM-clinical stability in DCM may not be a "good" or acceptable outcome.

We did not observe an improvement in 30MWT times following surgery. This is perhaps not surprising given a study population of mild DCM patients. A minority of patients (48%) reported gait difficulty as a symptom, and an even smaller proportion (30%) had a broad-based, unstable gait on examination. Moreover, considering this was a cohort with a baseline mJOA score of 15, 16, or 17, any gait impairment is likely to have been mild, and a simple walk test is unlikely to have detected an improvement in such. Testing of the psychometric properties of the 30MWT has found it to be responsive to change only in patients with more severe myelopathy.<sup>31</sup>

In our cohort of patients, 30.6% of patients experienced at least 1 complication. This included a mix of intraoperative and acute inpatient events (eg, dural tear, cardiopulmonary event) and also long-term complications (eg, postoperative deformity, pseudoarthrosis). Although this rate of complication appears high, this is consistent with the contemporary literature, with reported complication rates ranging from 16% to 41% depending on surgical approach.<sup>32</sup> Further, studies have demonstrated the complication rate varies significantly with age, with elderly age being associated with significantly greater complication risk.<sup>32,33</sup> Although we had no mortalities in our cohort, postoperative complications in the setting of DCM have previously been shown to increase length of stay, mortality rate, and hospitalization costs.<sup>34</sup>

Compared to the general AOSpine CSM-I study population,<sup>10</sup> our cohort of mild DCM patients was on average younger (52.4 vs 56.4 yr). In many cases, this may have been due to earlier presentation prior to progression to moderate or severe myelopathy. However, the pattern of degenerative cervical changes also appeared to be different between the 2 populations. In our cohort, disc herniation was the most common causative pathology, occurring in 75% of patients. Spondylosis (68% vs 76%), OPLL (21% vs 28%), hypertrophy of the ligamentum flavum (18% vs 25%), and subluxation (4% vs 6%) were relatively less frequent. Most patients (61%) had either 1 or 2 levels of disease. Considering a cohort of DCM patients with mostly focal anterior compressive disease, it follows that anterior approaches (74% vs 58%) were far more commonly employed than posterior approaches (24% vs 40%), as compared to AOSpine CSM-I. Of course, it is important to note that a significant proportion of our cohort (59%) was derived from the AOSpine CSM-I study.

As described in a recent systematic review of the literature, most patients in clinical series related to the surgical management of DCM have moderate to severe neurological impairment; few studies to date have focused on patients with mild DCM, as defined by an mJOA of 15 or greater.<sup>35</sup> Hence, the key knowledge gap in DCM relates to a high-quality prospective comparison of outcomes of operative vs nonoperative management of patients with mild DCM. To our knowledge, this is the largest study to evaluate surgical outcomes of mild DCM. This study draws on a cohort of patients from diverse cultural backgrounds prospectively enrolled at multiple centers across several continents, making the results generalizable across a wide range of practice settings. Moreover, we evaluated a comprehensive battery of validated functional outcome measures and quality of life indices, including the mJOA score, Nurick grade, NDI, SF-36v2, and SF-6D. There were minimal losses to follow-up (6.7%).

#### Limitations

Our study does have several limitations. Perhaps the most notable is the lack of a nonsurgical control group. The AOSpine CSM-NA and CSM-I studies, which enrolled patients of mild, moderate, or severe DCM, did not include a conservative treatment group, due to concern over the ethical implications of denying treatment to symptomatic patients who are at risk of progressive neurological deterioration. We are hence left to draw comparisons to studies of nonoperative cohorts of patientsie, natural history studies. Furthermore, although spinal cord decompression was achieved in all cases, a standardized surgical protocol was not employed, and the surgical approach, number of operated levels, and use and type of instrumentation were at the discretion of the treating spinal surgeon. It is important to recognize that some of the outcomes used, including the mJOA and NDI, have ceiling and floor effects.<sup>36</sup> By virtue of having mild DCM, many patients fell at one extreme end of these scales, where it is difficult to detect change. Hence, it is possible these patients are experiencing even more improvement than we are

able to capture. Another notable issue relates to the generalizability of our results. Every attempt was made to maintain consecutive enrollment at all participating sites. Nonetheless, given that treatment was at the discretion of treating physicians, all of whom were spinal surgeons with significant experience in managing DCM, and a total of 193 patients were enrolled over a 5-yr period, there may have been at least some degree of selection bias. Further, any clinical research study is biased toward academic centers with the resources and infrastructure to undertake highquality prospective research. Still, it is recognized that the number of patients enrolled in AOSpine CSM-NA and CSM-I is larger than previous studies, and these are 2 of the very few studies to use validated outcome measures.<sup>37</sup> This latter point-the paucity of other large studies of DCM using the mJOA, Nurick scale, NDI, SF-36, and 30MWT-limits our ability to compare our results to those obtained in other practice settings in order to assess the external validity of our findings.

## CONCLUSION

The present prospective multicenter analysis found significant impairment in quality of life in patients with mild DCM. Surgical decompression in these patients resulted in significant gains in functional status, level of disability, and quality of life. Future studies should be directed at evaluating predictors of clinical improvement in mild DCM patients undergoing surgery, as there is variability in the degree of improvement, and some patients are likely to not improve or even worsen. Moreover, cost-utility and economic analyses of surgery for mild DCM are needed to guide decision-making, as optimization of healthcare resource expenditure is becoming an increasingly important priority for policy maker

#### Disclosures

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# COMMENTS

The authors are to be commended for an excellent prospective, nonrandomized, non-controlled, multi-center study on the surgical treatment of "mild" degenerative cervical myelopathy (DCM). They define "mild DCM" as JOA 15–17. The number of 193 patients entered is substantial, although a larger cohort with more data points (such as alignment) would be beneficial in the future. This group seems to comprise a younger cohort (mean age 52.4) with more hand function complaints, as opposed to ambulation issues. It also seems to be more short segment disease, localized mainly to the C5-6 cord level, which is expected for loss of hand dexterity.

Two points worth noting: Even with "mild" cervical spondylotic myelopathy, patients report lower quality of life (QOL) issues than a similar cohort. In other words, this dysfunction is NOT "mild" to them.

The second point is that surgical intervention not only slows down or stops the myelopathy deterioration, but there is significant functional improvement across the board.

Thus, a positive Babinski is not the issue of myelopathy, but the importance of the neurologic dysfunction that is interfering with the patients' lives. It is my experience that hand "clumsiness," or "hands feel like wood... stiff... swollen....arthritic" is a very important aspect of the diagnostic evaluation. The simple question of any difficulty with buttoning a button, putting on jewelry, or hand dexterity is often the earliest and most subtle of the symptoms; with the levels often being at the C5-6-7 spinal cord level.

Several aspects of this database would be worth exploring or including in future studies. Is dysphagia (5.7%) dependent upon levels, number of levels, duration of surgery? Does axial neck pain worsening (6.2%) correspond to lack of alignment? lack of fusion? abnormal motion on post-op follow-up radiographs?

Although it is difficult to assess whether surgical approach matters, if larger numbers were acquired in a registry, would we be enabled to select a preferable management schema?

The role of spinal alignment is not addressed, via cervical-sagital vertical axis and other parameters. I would posit that this would influence certain aspects of outcomes, both neurologic and axial neck pain.

## Regis Haid

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This paper presents the results of a retrospective, multicenter, noncomparative, nonrandomized study of a cohort of patients drawn from 2 larger studies. These patients were diagnosed with mildly symptomatic cervical spondylotic myelopathy (CSM), defined as a modified Japanese Orthopedic Association (mJOA) score of 15 to 17, inclusive, and underwent surgery. The mean 2-year postoperative outcomes are compared to the mean baseline preoperative scores on several patient-reported outcomes measures. Statistically significant differences, defined as a P value less than .05, were found for most comparisons. While the magnitude of the mean

differences on the general QOL scores (SF-36, SF-6D) exceeded minimally clinically important difference (MCID) thresholds, it is not clear if the mean changes in the Nurick or mJOA scores did so.

This study provides some interesting information regarding the postoperative changes in QOL scores of a specific subgroup of patients. If patient enrollment was uniformly distributed geographically and temporally, which is unlikely, a mean of 1.5 patients were enrolled per site per year. This low number may indicate that this is a very select group of patients or that not all eligible patients were enrolled, or both. Furthermore, this was a young cohort (mean age 52 years) with predominantly disc-related pathology limited in a majority of patients to 1 or 2 levels. Almost half of the patients had pain, which was not further characterized, in addition to myelopathic signs or symptoms. To the extent that these results may be generalizable to other centers they should be assumed to apply only to patients with similar characteristics.

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*Dancers in Pink*, Edgar Degas [Public domain], 1880-1885, oil on canvas, Hill-Stead Museum, Farmington, Connecticut (https://www.flickr.com/photos/ gandalfsgallery/25395494803/ in/photostream/, Public Domain, https://commons. wikimedia.org/w/index.php? curid=53236417)