Comparing Surgical Treatments for Cervical Spondylotic Myelopathy—The CSM-S Trial

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**Background:** Cervical spondylotic myelopathy (CSM) is the most common cause of spinal cord dysfunction in the world. The optimal surgical approach for treating CSM is not known. For over 60 years, there has been active debate advocating either ventral or dorsal surgical approaches for treating CSM. Most agree that decompression of the spinal cord and fusion of the spinal column results in clinical improvement; however, clinical improvement does not occur in up to 30% of treated patients. Furthermore, complications of surgery are common and differ among the various surgical approaches. There is global variation in how cervical myelopathy is treated. From a clinical effectiveness and safety perspective, there is an urgent need to determine which procedure (ie, ventral or dorsal) is more effective and in which type of patient with cervical myelopathy.

**Objectives:** The Cervical Spondylotic Myelopathy–Surgical (CSM-S) trial was a randomized prospective study conducted to compare the effectiveness of a ventral vs dorsal approach to surgery for patients with multilevel CSM. Another goal of the study was to compare dorsal laminoplasty (DL) with ventral fusion (VF) and dorsal fusion (DF) strategies in a nonrandomized comparison. The trial consisted of 3 specific aims to test the following:

**Specific Aim 1**

1. Whether ventral surgery is associated with superior Physical Component Summary (PCS) scores of the Short-Form Health Survey-36 (SF-36) at 1-year follow-up compared with dorsal (DF or DL) surgery

1b. Compared with preoperative baseline status, whether both ventral and dorsal surgery for CSM improve symptoms of spinal cord dysfunction using the modified Japanese Orthopaedic Association (mJOA) score

**Specific Aim 2**

2. From a patient perspective, whether health resource use (out-of-pocket expenses and loss of productivity) for VF, DF, and DL surgery are different

**Specific Aim 3**

3. Whether cervical sagittal balance postoperatively is a significant predictor of SF-36 PCS score outcome

**Methods:** We conducted a multicenter prospective randomized controlled trial with patients aged 45 to 80 years with multilevel CSM. Patients were screened and enrolled over a 4-year period (2014-2018) from 16 sites. Patients were randomly assigned to ventral or dorsal surgery (2:3 randomization); the dorsal surgical approach (DF or DL) was at the discretion of surgeon and patient (ie, not randomly assigned). The primary outcome measure was the SF-36 PCS score. A clinically meaningful difference in SF-36 PCS scores is defined as 5 points. Secondary
outcome assessments (Neck Disability Index [NDI], mJOA, and EuroQol-5 Dimension [EQ-5D]), along with patient work status, were obtained preoperatively, 3 months, 6 months, and 1 year postoperatively. Complications were assessed by an independent study coordinator, who was blinded to other outcome data at 1 month and at 1 year postoperatively. Health resource use was measured using patient health diaries.

Results: A total of 16 sites randomly assigned 163 patients: 63 (38.7%) were randomly assigned to ventral surgery and 100 (61.3%) to dorsal. Average age was 62 years and 49% were male. Baseline characteristics were comparable between ventral and dorsal groups. After random assignment there was a 3.1% crossover rate. A total of 155 (95%) patients provided 1-year follow-up. There were 2.8 levels of spinal canal stenosis in patients enrolled in the study with no significant differences at baseline among the groups. Analysis as randomized demonstrated no difference in improvement in SF-36 PCS score at 1 year between ventral and dorsal surgery (5.90 ventral vs 6.22 dorsal; mean difference = 0.32; 95% CI, −2.62 to 3.26; \( P = .8372 \)). We conducted a planned analysis of patients as treated. Sixty-six patients ultimately underwent VF and 97 underwent dorsal surgery (69 DF and 28 DL). Regardless of strategy, patients demonstrated significant change from baseline in NDI (14.6 VF, 10.4 DF, 17.7 DL), mJOA (2.2 VF, 1.9 DF, 2.4 DL), and EQ-5D scores (0.14 VF, 0.12 DF, 0.19 DL) over a 1-year period postoperatively. DL had a superior primary outcome, the SF-36 PCS score (9.78), compared with VF (5.74; mean difference = 4.04; 95% CI, 0.13-7.95, \( P = .043 \)) and DF (4.99; mean difference = 4.78; 95% CI, 0.13-9.44; \( P = .044 \)). Patients undergoing VF and DF surgeries experienced a greater number of complications at 1 month postoperatively than did patients undergoing DL (42.4% VF vs 27.5% DF vs 10.7% DL; \( P = .007 \)). At 1 year, the proportion of patients working before surgery (68/163) who returned to work was similar among the 3 groups (85.2% VF vs 75.9% DF vs 90.9% DL).

Conclusions: Overall, patients with CSM randomly assigned to a ventral vs dorsal approach had similar 1-year outcomes. Compared with patients who had VF (n = 66) or DF (n = 69), the subgroup of patients, who at the discretion of the surgeon had DL (n = 28), experienced greater improvement in health-related quality of life, fewer complications, and less ongoing outpatient physical therapy and opioid usage at 1 year.

Limitations: The comparison of laminoplasty with DF or VF is limited by the potential for confounding by indication. Although baseline characteristics, including levels of spinal cord compression, were similar among all 3 surgical cohorts, there might have been anatomical features that influenced the choice of surgical approach (DF vs DL) that also influenced study outcomes independently of whether dorsal patients had laminoplasty or laminectomy with fusion (confounding by indication).
BACKGROUND

Cervical spondylotic myelopathy (CSM) is the most common cause of spinal cord dysfunction in the world. The condition presents insidiously and is defined in terms of its clinical symptoms (gait instability, bladder dysfunction, fine finger motor difficulties) and signs (hyperreflexia, weakness, alteration of joint position sense). CSM is caused by dynamic repeated compression of the spinal cord from degenerative arthritis of the cervical spine. Proposed mechanisms include axonal stretch-associated injury and spinal cord ischemia from compression of larger vessels and impaired microcirculation. Surgery to decompress and stabilize the spine is often advocated for severe or progressive symptoms, with mixed results. About two-thirds of patients improve with surgery, while 15% to 30% of cases do not have success with surgery. More than 112 400 cervical spine operations were performed in the United States for degenerative cervical spondylosis in the year 2000 (100% increase over the previous decade), with CSM accounting for nearly 20% of cervical spine operations in the United States. Annual hospital charges for CSM surgery exceeded $2 billion in 2000. CSM is also associated with substantial postsurgical outpatient expenses, such as physician visits, imaging, physical therapy (PT), and medications.

The optimal surgical approach for treating CSM is not known. The 3 surgical approaches that are currently used in contemporary US surgical practice include ventral decompression and fusion, dorsal decompression and fusion, and to a lesser extent dorsal laminoplasty (DL) (see Appendix A for a glossary of terms used in the report). In 2009, the Institute of Medicine (now the National Academy of Medicine) designated CSM as one of the top 100 national health research priorities for comparative effectiveness research. Our previous work suggested that most American cervical spine experts (both orthopedic and neurological surgeons) believe that there is sufficient clinical equipoise to support a comparative randomized controlled trial (RCT) if the study population is carefully defined. Several other important reasons justified a trial comparing surgical approaches for CSM. First, the complication rate for surgery for CSM is very high (cited as 17% in a prospective study), particularly for patients >74 years of age, a growing segment of the US population. Second, clinical outcomes are unsatisfactory in up to
30% of cases. Third, prior research suggests ventral surgery might be associated with significantly better health-related quality-of-life (QOL) outcomes compared with dorsal approaches. Finally, the adjusted 5-year reoperation rate for dorsal surgery (17.7%) has been reported to be significantly higher than for ventral surgery (12.1%, \( P < .001 \)) by members of our study team.

The objective was to conduct an RCT comparing ventral decompression with fusion (VF) vs dorsal decompression with fusion (DF) or DL for patients with multilevel CSM to test the following specific aims:

- **Specific Aim 1**
  
  1a. Whether ventral surgery is associated with superior Physical Component Summary (PCS) scores of the Short Form Health Survey (SF-36) at 1-year follow-up compared with dorsal (DF or DL) surgery

  1b. Compared with preoperative baseline status, whether both ventral and dorsal surgery for CSM improve symptoms of spinal cord dysfunction using the modified Japanese Orthopaedic Association (mJOA) score

- **Specific Aim 2**
  
  2. From a patient perspective, whether health resource use (out-of-pocket expenses and loss of productivity) for ventral fusion (VF), dorsal fusion (DF), and DL surgery are different

- **Specific Aim 3**
  
  3. Whether cervical sagittal balance postoperatively is a significant predictor of SF-36 PCS score outcome

The primary outcome measure was SF-36 PCS score. Secondary outcomes included mJOA score, Neck Disability Index (NDI), EuroQol-5 Dimension (EQ-5D), complication rates, patient-oriented health resource use (out-of-pocket expenses and loss of productivity), and cervical sagittal balance measurements. The goal was to randomly assign 159 patients with a minimum of 1-year follow-up. The overall goal was to define the optimal treatment for CSM. The study’s results should reduce harm from surgery for CSM, optimize patient-oriented health-
related QOL, and provide information about complications and loss of productivity following surgery that will empower patients to make more informed decisions about their own health care.
PARTICIPATION OF PATIENTS AND OTHER STAKEHOLDERS

During the preliminary phases of this project, we held a patient stakeholder meeting during which patients expressed their views on priorities associated with having surgery for CSM. We continued to speak with patients on a regular basis to solicit their input on the factors that are most important to them when considering various surgical options for CSM.

We learned from patients that risk of complications from surgery, such as difficulty with swallowing, new weakness, and pain, are very important. There is limited information available to patients on how to compare different surgical approaches in terms of understanding the differences in risks and complications. We designed the Cervical Spondylotic Myelopathy—Surgical (CSM-S) trial with these patient priorities in mind. Our data and safety monitoring board was charged with focusing on dysphagia and new neurological weakness following surgery. We included the NDI as a secondary outcome measure in the trial to capture disability caused by neck pain.

Patients are often confused by multiple surgical opinions on the optimal approach to treating CSM. We designed and implemented a unique surgical review of each case in the CSM-S trial. Patients enrolled in the CSM-S trial received the opinions (which they would not normally receive as part of standard of care) of at least 9 and up to 15 expert surgeons (at no additional cost) by entering the trial. A patient with CSM was featured in the Wall Street Journal article, “Help for spine patients sorting through surgery options,” published on March 18, 2014.42 In the article, the patient discussed his experiences in seeking treatment for his CSM. He received multiple different opinions from several surgeons. As a result of the article, patients all over the United States with similar experiences contacted our study team to express interest in participating in the study. The patients were redirected to study sites in their geographical area.

One of the goals during the CSM-S trial was to collaborate with payers to understand differences in health resource use between surgical approaches. We reached out to commercial payers who were, unfortunately, resistant to sharing data. We examined the health resource use captured in patient diaries and compared these data with data obtained from claims
databases within each center and found that approximately 40% of health care use pertaining to CMS is underreported by patients.

At the 34th Annual Meeting of the Congress of Neurological Surgeons Section on Disorders of the Spine and Peripheral Nerves in 2019, we held a meeting that was attended by neurosurgeons, orthopedic surgeons, payers, and other representatives who provided viewpoints on how to measure return to productivity, specifically following spine surgery. The participants were able to hear how patient-reported data would be useful from the perspectives of patients, payers, and employers. The discussion ultimately helped guide the analysis of the patient-reported data from the CSM-S trial. How best to measure productivity was discussed based on the use of data, meeting patient expectations, health care use, the role of the employer, and employer-based insurance.

In addition, one of our health economist stakeholders pointed out that health resource use might differ from the perspective of individual stakeholders. It was suggested that patient diaries might represent only 1 portion of the data. It was also suggested that capturing hospital data on usage is imperative to determine how health resource use looks from the perspective of a hospital or payer, compared with the patient’s health resource diary. This, along with each of the stakeholders who contributed meaningful suggestions at the round table discussion, will help formulate the analysis of return to productivity following surgery for CSM in the future.
METHODS

The CSM-S trial was a multicenter prospective RCT. Patients were screened and enrolled over a 4-year period (2014-2018). The objective was to conduct an RCT comparing ventral decompression with fusion vs dorsal decompression with fusion or DL for patients with multilevel CSM.

Participants

Inclusion Criteria

Inclusion criteria for the trial included patients aged 45 to 80 years at time of surgery for CSM. CSM was identified as ≥2 levels of spinal cord compression from C3 to C7 and confirmed by magnetic resonance imaging (MRI) or an equivalent study (Figure 1). Patients had to have 2 or more of the following symptoms or signs: clumsy hands, gait disturbance, hyperreflexia, up-going toes, bladder dysfunction, or ankle clonus. Patients were to be treated with ventral decompression with fusion, dorsal decompression with fusion, or DL. In addition, participants needed to be considered eligible for randomization based on majority review of the Spinal Expert Network (see the “Spinal Experts Network Review” section below).
**Figure 1. Cervical Spine MRI With Compression of the Spinal Cord That Would Be Expected to Cause Cervical Myelopathy**

Abbreviation: MRI, magnetic resonance imaging.

*Spinal cord compression is shaded red. Ventral decompression and fusion would typically involve removal of the disc that is compressing the spinal cord from the front of the neck (yellow arrow). Dorsal decompression would involve decompression of the spinal cord from the back of the neck (red arrow).

**Exclusion Criteria**

Patients with C2-C7 kyphosis >5° (measured on standing neutral cervical spine radiograph), a segmental kyphotic deformity defined as ≥3 disc-osteophytes that extend dorsal to a C2-C7 dorsal-caudal line measured on cervical spine computed tomography (CT) or MRI, structurally significant ossification of the posterior longitudinal ligament, previous cervical spine surgery, or significant active health-related comorbidity (anesthesia class IV or higher) were excluded from the study. The investigators in the trial reviewed imaging to evaluate each case for radiographic exclusion criteria.
Randomization

The randomization scheme was 2:3 ventral to dorsal. There was significant interest in obtaining outcomes data comparing dorsal laminectomy and fusion (a more commonly conducted procedure in the United States) with DL, the most commonly performed procedure for CSM worldwide. We determined that a 3-armed RCT was not feasible. The sample size estimate for a 3-armed RCT was 288 patients (96 patients per group). In contrast, the sample size estimate for a 2-armed trial was 159 patients, which we felt was more likely to be feasible given the volume assumption of 10 randomly assigned patients per site from 16 sites over 3 years. At the start of the trial, we did not know how many patients would undergo laminoplasty. We estimated that about 1 of every 3 patients randomly assigned to dorsal surgery would have laminoplasty. Therefore, we selected 2:3 randomization to generate roughly equal numbers of patients to compare as treated. We thought that it would be important to have more patients in the dorsal arm to allow for planned comparison of DL with VF and with dorsal laminectomy and fusion. Randomization assignment was preprogrammed with a block (2, 4, or 6 participants/block) scheme that was also stratified by a site-specific randomization scheme.

Spinal Experts Network Review

One of the most important barriers to performing high-quality RCTs in surgery is patient accrual. Participation in surgery RCTs often is limited by a lack of sufficient equipoise on the part of both the treating surgeon and the patient. We took several proactive and innovative steps to improve patient consent to randomization, including the development of a novel web-based Spinal Experts Network that was demonstrated to facilitate and increase patient enrollment and randomization. In this approach, each expert reviews the radiographic images of eligible patients and makes 2 assessments: whether or not to randomly assign the patient and then to characterize the preferred surgical approach as ventral or dorsal. Each surgeon was given a brief clinical vignette and 4 to 5 standardized clinical images to formulate an opinion regarding the preferred approach as well as whether or not the patient met criteria for equipoise.³⁶
For the CSM-S trial, once patients had been screened, identified as having CSM, and agreed to participate in the trial by signing consent, they underwent 2 reviews. The patient’s images were first reviewed by 2 surgeon investigators from the coordinating site to confirm eligibility. If the patient was deemed eligible, their images were then reviewed by the Spinal Experts Network. The patient’s images were uploaded onto the web-based platform, and an email was generated and sent to all 15 members (10 CSM surgeon investigators and 5 senior noninvestigator spine surgeons) of the Spinal Experts Network. Each surgeon was asked to vote: “randomize” or “do not randomize” and then to characterize his or her preferred surgical approach as ventral or dorsal for the specific case being considered. Each surgeon determined if each individual case met their threshold for clinical equipoise to recommend randomization. If after 72 hours, a majority (>50%) of the review network (with at least 9 votes for a quorum) favored randomization (equipoise) and <80% selected one procedure over another, then the patient was considered eligible for study randomization (Figure 2).

**Figure 2. Sample Enrollment Poll Response Sheet for Investigators to Share with Patients**

Abbreviation: CSM, cervical spondylotic myelopathy.

*Enrollment determination and approach preference were graphed to present the patient with multiple “second opinions.”*
The results of the voting (the number of votes for “randomize/do not randomize” and the number of ventral or dorsal votes) were available to patients both to increase their trust and confidence in the recommendation for randomization, as well as to protect patients from undergoing randomization when one approach (ventral or dorsal) might be superior for that patient. Patients were offered randomization if 2 conditions were met:

- Two study investigators confirmed that the images and clinical exam findings were consistent with CSM and that the patient met all eligibility criteria; and
- Spinal Experts Network confirmed clinical equipoise (>50% voted “randomize” and <80% selected one procedure over another) for randomization.

This provided scientific rigor to the definition of equipoise on an individual patient basis. We have published this approach to randomization in surgical trials.\(^1\)\(^4\) This approach with expert panel review also provided the patient with multiple “second opinions,” increasing the patient’s interest in participating in the RCT and trust in the appropriateness of randomization. Those patients who were ineligible for randomization were also enrolled and followed in a nonrandomized cohort. This report will only describe the results of the randomized cohort.

**Study Interventions**

Each of the 3 surgical options (ie, VF, DF, and DL) offered to the patients in this study were standard clinical care. Regardless of the approach, the goal of each surgical intervention was decompression of the spinal canal to a diameter of at least 13 mm with restoration of cerebrospinal fluid flow around the spinal cord. Surgical techniques were standardized across all sites for this study, as summarized below.

**Ventral Surgery**

Ventral decompression plus fusion\(^1\)\(^5\) was performed using a multilevel discectomy (including partial or single level corpectomy) with fusion and plating.\(^1\)\(^6\),\(^1\)\(^7\) Allograft was used at each disc space and all compressive osteophytes were removed using the operating microscope. Fixation was performed with rigid, semiconstrained, or dynamic titanium plates to optimize fusion and minimize complications.\(^1\)\(^8\),\(^1\)\(^9\)
Dorsal Surgery

Surgeons chose either dorsal laminectomy plus DF or DL.

Dorsal laminectomy plus DF. Dorsal decompression and fusion was performed using midline cervical laminectomy with the application of lateral mass screws and rods for rigid fixation.\textsuperscript{20} All surgeons used local bone and allograft as needed to perform a lateral mass fusion, which typically included 1 level rostral to the levels decompressed.

DL. Laminoplasty was performed using an open-door approach with the application of plates and screws at each treated level. Ceramic or allograft laminar spacers (surgeon’s choice) were used with plates and screws to expand the canal diameter.\textsuperscript{21,22}

Study Outcomes

Primary Outcome Measure

The primary outcome measure was the PCS score of the SF-36. PCS scores are calculated using population-adjusted norms to generate normalized scores with a mean ± SD of 50 ± 10. Higher PCS scores represent better function. The SF-36 (version 2) was administered in the office by a study coordinator preoperatively, and at 3 months, 6 months and 1 year postoperatively. A clinically meaningful difference in SF-36 PCS scores is defined as 5 points.\textsuperscript{23-26}

Secondary Outcome Measures

Two validated disease-specific outcomes measures (mJOA\textsuperscript{27} and NDI\textsuperscript{28}) were measured preoperatively, and at 3 months, 6 months, and 1 year postoperatively. Preference-based health-related QOL measures reflecting US population values for calculation of quality-adjusted life-years were used. Preference-based outcome measures produce a single outcome score on an interval scale anchored at 0 (death) and 1 (perfect health). Preference-based QOL was assessed with the EQ-5D\textsuperscript{29} and Short Form 6-Dimension (SF-6D)\textsuperscript{32} at the same intervals as the primary outcome measure SF-36 PCS score, as were return to work status and disability benefits and payments.\textsuperscript{33} The SF-6D health state and utility scores are derived from 6 dimensions of the SF-36 questionnaire. Because both EQ-5D and SF-6D data are available at the
same time points, we will (in the near future) perform an analysis to compare these 2 measures of overall QOL. Appendix B contains the NDI, SF-36, mJOA, and EQ-5D questionnaires used in this study.

In addition to days missed from work due to medical treatments or evaluations, participants were asked to keep track of days missed from work and days unable to perform usual activities. Major adverse outcomes were recorded at 1 month and 1 year postoperatively. Health resource use information (including out-of-pocket expenses) was obtained using patient diaries, along with copies of all medical bills and receipts, at 1 month, 3 months, 6 months, and 12 months postoperatively for all patients. At 1 year postoperatively, full standing sagittal cervical–thoracic-lumbar-sacral radiographs were obtained to calculate cervical C2-C7 sagittal balance, overall spinal C7-sacral sagittal balance, and cervical C2-C7 kyphosis or lordosis. C2-C7 sagittal balance is defined as the distance between vertical lines placed at C2 and C7. Sagittal balance is a measurement of overall cervical alignment, which is thought to be relevant for QOL.

**Sample Size**

Sample size estimates were calculated based on analysis of covariance model with \( \alpha = .05 \) at 80% and 90% power using Power Analysis and Sample Size software (PASS 2008, NCSS, LLC). The primary end point was the SF-36 PCS score. This component of the SF-36 is derived from the sums of scores of 21 items and thus exhibits distributional behavior commensurate with assumptions for parametric analysis. Our preliminary observational data showed a 1-year SF-36 PCS difference score of 8.7 for ventral surgery compared with 4.0 for dorsal procedures, with SDs between 10 and 12 and correlations of baseline with 1 year SF-36 PCS score between 0.6 and 0.7 (Table 1). Table 2 describes the total sample size (2:3 ventral to dorsal randomization) required to detect a 5-point difference in SF-36 PCS score 1 year postoperatively for various combinations of power, standard deviation, and 1-year correlations under a fixed design.
Table 1. Preliminary Observational Data of Surgical Approach and the Correlation Between Preop and Postop SF-36 PCS Score Used to Determine Sample Size

<table>
<thead>
<tr>
<th>Surgery (n)</th>
<th>Preop</th>
<th>Postop</th>
<th>Correlation between preop and postop</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ventral (45)</td>
<td>35.5 ± 10.3</td>
<td>44.2 ± 11.7</td>
<td>0.64</td>
<td>+8.7 ± 8.2</td>
</tr>
<tr>
<td>Dorsal (70)</td>
<td>35.8 ± 11.3</td>
<td>39.8 ± 11.6</td>
<td>0.66</td>
<td>+4.0 ± 9.5</td>
</tr>
<tr>
<td>DF (42)</td>
<td>35.0 ± 11.7</td>
<td>39.6 ± 12.4</td>
<td>0.65</td>
<td>+4.6 ± 10.0</td>
</tr>
<tr>
<td>DL (28)</td>
<td>37.0 ± 10.9</td>
<td>40.1 ± 10.6</td>
<td>0.67</td>
<td>+3.1 ± 8.8</td>
</tr>
<tr>
<td>All patients (115)</td>
<td>35.7 ± 10.9</td>
<td>41.5 ± 11.8</td>
<td>0.64</td>
<td>+5.8 ± 9.7</td>
</tr>
</tbody>
</table>

Abbreviations: DF, dorsal fusion; DL, dorsal laminoplasty; PCS, Physical Component Summary; Postop/postop, postoperative; Preop/preop, preoperative; SF-36, Short-Form Health Survey-36.

Table 2. Sample Size, With a 2:3 Ventral to Dorsal Randomization, Required to Detect a 5-Point Difference in SF-36 PCS Score 1 Year Postoperatively Under a Fixed Design

<table>
<thead>
<tr>
<th>Difference, SD</th>
<th>Correlation</th>
<th>80% power/5% type I error (2 sided)</th>
<th>90% power/5% type I error (2 sided)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>n_Ventral</td>
<td>n_Dorsal</td>
</tr>
<tr>
<td>5, 10</td>
<td>0.60</td>
<td>38</td>
<td>56</td>
</tr>
<tr>
<td>5, 10</td>
<td>0.65</td>
<td>40</td>
<td>59</td>
</tr>
<tr>
<td>5, 10</td>
<td>0.70</td>
<td>42</td>
<td>62</td>
</tr>
</tbody>
</table>

Abbreviations: PCS, Physical Component Summary; SF-36, Short-Form Health Survey-36.

A minimum sample size assuming a 0.70 correlation of 137 patients across both study arms provides at least 90% power. The sample size was inflated by 5% to accommodate multiple significance testing for the primary outcome PCS score using an O’Brien-Fleming stopping boundary. Based on our preliminary data and pilot studies, we did not expect withdrawal and loss to follow-up to be high. The sample size was further inflated by 10% to accommodate attrition during the follow-up, leading to a sample size of 159 total patients to be recruited and randomly assigned. Based on our prior work in terms of both refusal rates and ineligible participants, we anticipated 91 patients would be ineligible to be randomly assigned but would consent to be enrolled in a nonrandomized cohort study.
Study Time Frame

Clinical Follow-Up (1 Year): End Point Assessment

Postoperative clinic visits (outcomes assessment) occurred at 1 month, 3 months, 6 months, and 1 year postoperatively. Timing of postoperative visits was agreed upon by the principal investigators before starting the study. The clinical site coordinator obtained clinical outcomes data at each planned clinical visit. Patients completed health resource use diaries at all time points. All complications were reported to the central project manager within 48 hours. The study coordinator recorded the following:

- **Thirty-day complications.** Death, myocardial infarction, pulmonary embolus, rehospitalization, recurrent laryngeal nerve injury, new hoarseness, new neurological deficit (eg, C5 palsy), infection, dysphagia at 30 days resulting in weight loss and/or formal swallow evaluation and therapy, esophageal perforation, and reoperation.

- **Delayed complications.** Reoperation, fusion complication, problems with instrumentation, deformity, and rehospitalization.

Postoperative Imaging Analysis (3 Months and 1 Year)

Available postoperative imaging from 78% of the randomly assigned patients (de-identified and on CD) was done by independent radiographic review at the central reading site. Postoperative cervical spine MRI was reviewed at 3 months to document satisfactory spinal cord decompression. Cervical spine flexion-extension radiographs were obtained 1 year postoperatively to assess cervical fusion and/or radiographic complications. Standing cervical-thoracic-lumbar-sacral films were obtained at 1 year to assess cervical as well as overall sagittal balance. Cervical spine CT scans were obtained at 1 year if the patient had an NDI score >30 or if plain films suggested instability.

Five-Year Extended Follow-Up

Long-term follow-up, scheduled to occur annually in years 2 through 5 postoperatively, includes the SF-36, NDI, and EQ-5D questionnaires, as well as a long-term follow-up phone questionnaire that addresses complications (including reoperations) and return to work status.
Since enrollment began in 2014, multiple patients have reached 5-year follow-up eligibility. Patients who are eligible for long-term follow-up are being contacted by the coordinators at each site. The overall potential follow-up rate at 5 years is 96% (Table 3). We recognize that follow-up becomes more difficult over time as patients have fewer reasons to connect with their treating surgeon, but the investigators are committed to reaching patients over the 5-year follow-up period. It is unlikely that follow-up at 5 years will actually approach 96%, but 157 of 163 patients are available for follow-up at this time. This portion of the study is not funded currently.

**Table 3. Long-Term Follow-up Projections**

<table>
<thead>
<tr>
<th>Follow-up time point</th>
<th>Current, No./total (%)</th>
<th>Potential/y, No./total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 y</td>
<td>109/137 (80)</td>
<td>132/163 (81)</td>
</tr>
<tr>
<td>3 y</td>
<td>68/84 (81)</td>
<td>139/163 (85)</td>
</tr>
<tr>
<td>4 y</td>
<td>35/52 (67)</td>
<td>151/163 (93)</td>
</tr>
<tr>
<td>5 y</td>
<td>5/13 (38)</td>
<td>157/163 (96)</td>
</tr>
</tbody>
</table>

**Data Collection and Sources**

Sixteen institutions were selected as enrolling sites for the CSM-S trial. All sites had a clinic volume that suggested that they would be able to randomly assign at least 10 patients to the CSM-S trial over 3 years. Also, all clinical sites demonstrated that all 3 clinical options for surgery were offered at that institution by experienced surgeons. Each site had at least 1 study coordinator and appropriate research infrastructure to participate in a clinical trial.

Study coordinators at each site were required to send all completed paper case report forms (CRFs) to the coordinating site and to enter the data directly into the study’s web-based platform (WBP). CRFs contained data points that could either be obtained from the surgeon or the health record. Patient-reported outcome questionnaires and health resource use diaries were completed by the patient either at the time of their clinical appointment, by phone, or by mail.
In addition to the CRFs, each site was also required to send the completed patient questionnaire forms to the coordinating site. The coordinating site was charged with scoring the questionnaire forms and entering the calculated scores directly into the WBP as well as a spreadsheet. The spreadsheet was used to facilitate interim data queries and to track individual patient progress through the course of the study, ensuring timely follow-up was completed.

The coordinating site remained in close contact with study coordinators at each participating site. Reminder emails communicating data that were due or soon to be due were sent to coordinators to maximize follow-up rates. Coordinators at each site would notify the main site if a patient withdrew or was deemed lost to follow-up. Patients were deemed lost to follow-up if there was no response after being contacted 3 times by phone and once by certified letter.

**Data Audit**

The data management team at the coordinating site planned an audit of CSM-S trial data before the close of the study. Data from the CRFs were directly entered into the WBP by the study coordinators. The patient-reported outcome scores were entered into the WBP by the coordinating site. The receipt of the CRFs and the questionnaires was also logged in a spreadsheet by the coordinating site. The audit process compared the source data (values written on CRF forms by sites) with the values entered into both the study spreadsheet (values entered by the coordinating site) and the WBP. In addition, all study patient-reported outcome questionnaires were rescored by the coordinating site (ie, source data verification) and the results were compared with the values entered into the spreadsheet and the WBP.

**Analytical and Statistical Approaches**

The statistical plan was to compare change in 1-year SF-36 PCS scores for patients as randomly assigned and as treated. An unadjusted analysis was planned if baseline characteristics were comparable in both groups. The randomization was weighted 2:3 to have roughly equal numbers of patients in the VF and DF groups for analysis based on preliminary data. We expected to have a smaller number of DL patients compared with the number of
patients treated with cervical laminectomy and fusion available for analysis. This analysis was also planned as an unadjusted comparison of change in 1-year SF-36 PCS scores if baseline characteristics were comparable. All continuous outcomes, including the change scores for SF-36 PCS, NDI, mJOA, and EQ-5D, were compared using independent group t tests for differences in means, which were reported along with 95% CIs. Categorical outcomes, including risk of complications, and health resource use, were compared using χ² tests, with 95% CIs for the difference in proportions. All testing was 2-sided with α = .05 for the primary outcome of PCS score. For secondary outcomes, P values should be interpreted more cautiously unless highly significant (eg, P < .005).

Changes to the Original Study Protocol

February 2014

Exclusion criteria and requirements for radiology assessments were amended. In addition, the randomization was changed from a 1:2 randomization to a 2:3 randomization. We designed the trial with a plan to include DL so that we could compare it with the other types of surgery for CSM. Initially, we started with a plan for 1:2 randomization. Preliminary data before the trial began suggested that a third of patients enrolled in the dorsal arm would be treated with laminoplasty. We therefore changed the randomization to 2:3 randomization to have roughly equal numbers of patients in the VF and DF groups for analysis. The number of patients in the DL group was expected to be smaller with this approach.

March 2016

The upper age limit of inclusion was increased from 75 to 80 years old. The study investigators noted that many eligible patients were being excluded from the study because they were between the ages of 75 to 80 years. All investigators agreed that we should be more inclusive and increase the age to 80 years because the results of the trial should be applicable to as many patients as possible.
Changes in Study Sites
The original list of enrolling sites specified in the grant application included the following:

- Lahey Hospital & Medical Center
- University of Medicine and Dentistry of New Jersey (now Rutgers School of Biomedical and Health Sciences), Newark
- University of Utah, Salt Lake City
- Cleveland Clinic Foundation, Cleveland, Ohio
- Thomas Jefferson University, Philadelphia, Pennsylvania
- Massachusetts General Hospital, Boston
- Greenwich Hospital, Greenwich, Connecticut
- Washington University School of Medicine, St. Louis, Missouri
- MetroHealth, Cleveland, Ohio
- Medical College of Wisconsin, Milwaukee

However, Massachusetts General Hospital and Greenwich Hospital ultimately did not join the study and did not enroll any patients. Initial accrual in the trial was slow. We therefore added the following sites that have a high volume of patients with cervical myelopathy to the study:

- University of Pittsburgh, Pittsburgh, Pennsylvania
- University of California San Francisco, San Francisco
- University Health Network, Toronto, Ontario, Canada
- Hospital for Special Surgery, New York, New York
- Kansas University Medical Center, Kansas City
- Columbia University, New York, New York
• Emory University, Atlanta, Georgia

• University of Wisconsin, Madison

All of these sites had appropriate research infrastructure for conducting clinical trials and demonstrated that they had expertise in performing all 3 types of surgery for CSM.
RESULTS

Patient Population

A total of 269 patients were enrolled into the CSM-S trial. Figure 3 depicts a flow chart for the enrollment, randomization, and follow-up for the trial; 163 patients were randomly assigned from 16 sites. Over 1 year of follow-up, a total of 6 patients (3 VF and 3 DF) were lost to follow-up and 2 died (1 DF and 1 DL). The 1-year follow-up rate was 95% overall in the randomized cohort. A total of 63 patients were randomly assigned to ventral surgery and 100 to dorsal. Of the 63 randomly assigned to ventral surgery, 1 crossed over to have a DF procedure, and, of the 100 patients randomly assigned to dorsal surgery, 4 crossed over to have ventral surgery. This resulted in a total of 5 crossover patients (3.1%). As a result (separating patients by treatment even though not as randomly assigned), 66 patients ultimately underwent VF, 69 DF, and 28 DL.
Figure 3. Patients Randomly Assigned to Either Ventral or Dorsal Surgery and Who Returned for Follow-Up at 3 Months, 6 Months, and 1 Year Postoperatively

The mean age was 62 years, with 51% being female study-wide. Baseline characteristics of patients, as treated, are shown in Table 4.
Table 4. Baseline Demographics of Patients Assigned to the 3 Surgical Approaches

<table>
<thead>
<tr>
<th></th>
<th>VF (n = 66)</th>
<th>DF (n = 69)</th>
<th>DL (n = 28)</th>
</tr>
</thead>
<tbody>
<tr>
<td>**Sex, female, No. (%)</td>
<td>36 (55)</td>
<td>32 (46)</td>
<td>15 (54)</td>
</tr>
<tr>
<td><strong>Race, No. (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>American Indian</td>
<td>2 (3)</td>
<td>2 (3)</td>
<td>0</td>
</tr>
<tr>
<td>Black</td>
<td>7 (11)</td>
<td>6 (9)</td>
<td>0</td>
</tr>
<tr>
<td>White</td>
<td>55 (83)</td>
<td>57 (83)</td>
<td>27 (96)</td>
</tr>
<tr>
<td>Asian</td>
<td>2 (3)</td>
<td>2 (3)</td>
<td>1 (4)</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>2 (3)</td>
<td>0</td>
</tr>
<tr>
<td><strong>Hispanic ethnicity, No. (%)</strong></td>
<td>2 (3)</td>
<td>3 (4)</td>
<td>1 (4)</td>
</tr>
<tr>
<td><strong>Age, mean (SD), y</strong></td>
<td>61.9 (7.4)</td>
<td>62.7 (8.7)</td>
<td>62.3 (8.9)</td>
</tr>
<tr>
<td><strong>Baseline work status, No. (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Working full time</td>
<td>19 (29)</td>
<td>26 (38)</td>
<td>12 (43)</td>
</tr>
<tr>
<td>Working part time</td>
<td>8 (12)</td>
<td>3 (4)</td>
<td>0</td>
</tr>
<tr>
<td>Not working but able to work</td>
<td>9 (14)</td>
<td>2 (3)</td>
<td>4 (14)</td>
</tr>
<tr>
<td>Not working, unable to work</td>
<td>16 (24)</td>
<td>14 (20)</td>
<td>5 (18)</td>
</tr>
<tr>
<td>Retired</td>
<td>14 (21)</td>
<td>22 (32)</td>
<td>7 (25)</td>
</tr>
<tr>
<td>Missing data</td>
<td>0</td>
<td>2 (3)</td>
<td>0</td>
</tr>
<tr>
<td><strong>ASA class, No. (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>0</td>
<td>1 (1.5)</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>32 (48.5)</td>
<td>33 (48)</td>
<td>12 (43)</td>
</tr>
<tr>
<td>3</td>
<td>32 (48.5)</td>
<td>34 (49)</td>
<td>15 (53.5)</td>
</tr>
<tr>
<td>Missing data</td>
<td>2 (3)</td>
<td>1 (1.5)</td>
<td>1 (3.5)</td>
</tr>
<tr>
<td><strong>No. of stenotic levels, mean (SD)</strong></td>
<td>2.7 (0.7)</td>
<td>2.9 (0.8)</td>
<td>2.8 (0.6)</td>
</tr>
<tr>
<td><strong>Measures, mean (SD)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NDI (0-100)a</td>
<td>37.3 (19.5)</td>
<td>37.3 (20.9)</td>
<td>33.0 (18.6)</td>
</tr>
<tr>
<td>SF-36 MCS score (0-100)b</td>
<td>45.3 (12.1)</td>
<td>46.0 (13.2)</td>
<td>48.8 (8.9)</td>
</tr>
<tr>
<td>SF-36 PCS score (0-100)b</td>
<td>37.8 (9.0)</td>
<td>37.1 (9.4)</td>
<td>36.7 (10.9)</td>
</tr>
<tr>
<td>mJOA score (0-18)c</td>
<td>12.3 (2.7)</td>
<td>11.9 (2.1)</td>
<td>12.5 (2.6)</td>
</tr>
<tr>
<td>EQ-5D score (0-1)d</td>
<td>0.63 (0.22)</td>
<td>0.60 (0.21)</td>
<td>0.64 (0.22)</td>
</tr>
<tr>
<td>EQ-5D Visual Analog Scale score (0-100)e</td>
<td>62.8 (20.1)</td>
<td>61.1 (22.7)</td>
<td>65.2 (21.0)</td>
</tr>
</tbody>
</table>

Abbreviations: ASA, American Society of Anesthesiologists; DF, dorsal fusion; DL, dorsal laminoplasty; EQ-5D, EuroQol-5 Dimension; MCS, Mental Component Summary; mJOA, modified Japanese Orthopaedic Association; NDI, Neck Disability Index; PCS, Physical Component Summary; SF-36, Short-Form Health Survey-36; VF, ventral fusion.

aFor NDI, a lower score represents less disability.
bFor SF-36 MCS and PCS scores, mean population score is 50 with higher scores representing better QOL.
cFor mJOA, a higher score represents less dysfunction from myelopathy.
dFor EQ-5D, 0 refers to death and 1 represents perfect health state.
eFor the EQ-5D Visual Analog Scale, patients represented their health state on a scale from 0 to 1, with higher scores representing greater health state.
Specific Aim 1: Primary Outcome Measure (1-Year Change in SF-36 PCS Score)

At 1 year following surgery, there was no significant difference in improvement in SF-36 PCS score between ventral and dorsal patients as randomly assigned (5.90 vs 6.22 points, respectively; mean difference = 0.32; 95% CI, −2.62 to 3.26; P = .8372) (Table 5). There were no significant differences in baseline characteristics, and therefore an unadjusted analysis comparing 1-year change in SF-36 PCS scores was performed. Independent group t tests or χ² tests were used as described in the Methods section. We had planned to evaluate patients who had DL separately when the trial was designed. This was accomplished with a secondary analysis that was limited by breaking the randomization (placing crossovers into their actual treatment cohort) and by nonrandom treatment assignment (in the dorsal arm, laminoplasty vs laminectomy plus fusion was selected by the treating surgeon). In order to accomplish this task, we examined the patients as treated and compared 1-year change in SF-36 PCS scores between individual treatment groups. We first examined DL vs DF and DL vs VF separately. DL had superior outcomes in the primary outcome measure (SF-36 PCS score) compared with DF (Figure 4). Improvement in SF-36 PCS score for DL patients was higher at 1 year than for DF patients (9.78 vs 4.99 points; mean difference = 4.78; 95% CI, 0.13-9.44; P = .0442), and change in 1-year SF-36 PCS score was greater for DL patients than for VF patients (9.78 vs 5.74 points; mean difference = 4.04; 95% CI, 0.13-7.95; P = .0428) as well (Table 6).
Figure 4. Improvement in SF-36 PCS Score Between VF, DF, and DL From Baseline to 3-Month, 6-Month, and 1-Year Follow-Up

<table>
<thead>
<tr>
<th>Ventral (n = 60), mean (SD)</th>
<th>Dorsal (n = 95), mean (SD)</th>
<th>Mean difference (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.90 (8.2)</td>
<td>6.22 (10.2)</td>
<td>0.32 (−2.62 to 3.26)</td>
<td>.8372</td>
</tr>
</tbody>
</table>

Table 5. Primary Analysis: ITT Comparison of Mean Change in SF-36 PCS Score

Abbreviations: ITT, intention to treat; PCS, Physical Component Summary; SF-36, Short-Form Health Survey-36.

Table 6. Secondary Analysis: As-Treated Comparison of Mean (SD) Change in SF-36 PCS Score

<table>
<thead>
<tr>
<th>VF (n = 63)</th>
<th>DF (n = 66)</th>
<th>DL (n = 26)</th>
<th>Mean difference (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.74 (8.04)</td>
<td>4.99 (10.4)</td>
<td>9.78 (9.33)</td>
<td>0.74 (−2.49 to 3.98)</td>
<td>.6494</td>
</tr>
<tr>
<td>5.74 (8.04)</td>
<td>4.99 (10.4)</td>
<td>9.78 (9.33)</td>
<td>4.04 (0.13-7.95)</td>
<td>.0428</td>
</tr>
<tr>
<td>4.99 (10.4)</td>
<td>9.78 (9.33)</td>
<td>4.78 (0.13-9.44)</td>
<td>.0442</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: DF, dorsal fusion; DL, dorsal laminoplasty; PCS, Physical Component Summary; SF-36, Short-Form Health Survey-36; VF, ventral fusion.

Secondary analysis breaks randomization with assignment of crossovers to how they were actually treated and by including DL as a separate cohort that was not randomized (DL vs laminectomy and fusion was selected by surgeon).
Secondary Outcomes

Secondary Patient-Reported Outcomes

Regardless of the type of surgery, patients demonstrated improvements (change) in NDI (−14.6 VF, −10.4 DF, −17.7 DL; Figure 5A and Table 7A), mJOA (2.2 VF, 1.9 DF, 2.4 DL; Figure 5B and Table 7B), and EQ-5D (0.14 VF, 0.12 DF, 0.19 DL; Figure 5C and Table 7C) scores over a 1-year period postoperatively.

Figure 5A. Improvement in NDI Score Between VF, DF, and DL From Baseline to 3-Month, 6-Month, and 1-Year Follow-Up

Table 7A. Improvement in NDI Score Between VF, DF, and DL at 1-Year Follow-Up

<table>
<thead>
<tr>
<th></th>
<th>VF (n = 63)</th>
<th>DF (n = 66)</th>
<th>DL (n = 26)</th>
<th>Mean difference (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>VF</td>
<td>−14.6 (16.3)</td>
<td>−10.4 (18.0)</td>
<td></td>
<td>4.3 (−1.7 to 10.3)</td>
<td>.1630</td>
</tr>
<tr>
<td>DF</td>
<td>−14.6 (16.3)</td>
<td></td>
<td>−17.7 (17.5)</td>
<td>−3.0 (−10.7 to 4.7)</td>
<td>.4362</td>
</tr>
<tr>
<td>DL</td>
<td>−10.4 (18.0)</td>
<td>−17.7 (17.5)</td>
<td></td>
<td>−7.29 (−15.5 to 0.94)</td>
<td>.0817</td>
</tr>
</tbody>
</table>

Abbreviation: DF, dorsal fusion; DL, dorsal laminoplasty; NDI, Neck Disability Index; VF, ventral fusion.

*A negative score represents a reduction in neck disability. Lower NDI scores are better.
**Figure 5B. Improvement in mJOA Score Between VF, DF, and DL From Baseline to 3-Month, 6-Month, and 1-Year Follow-Up**

Abbreviations: DF, dorsal fusion; DL, dorsal laminoplasty; mJOA, modified Japanese Orthopaedic Association; VF, ventral fusion.

**Table 7B. Improvement in mJOA Score Between VF, DF, and DL at 1-Year Follow-Up**

<table>
<thead>
<tr>
<th>VF (n = 63)</th>
<th>DF (n = 66)</th>
<th>DL (n = 26)</th>
<th>Mean difference (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.22 (2.86)</td>
<td>1.92 (3.04)</td>
<td>--</td>
<td>~0.30 (~1.35 to 0.74)</td>
<td>.5676</td>
</tr>
<tr>
<td>2.22 (2.86)</td>
<td>2.42 (2.72)</td>
<td>0.20 (~1.11 to 1.51)</td>
<td>.7609</td>
<td></td>
</tr>
<tr>
<td>1.92 (3.04)</td>
<td>2.42 (2.72)</td>
<td>0.50 (~0.86 to 1.87)</td>
<td>.4670</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: DF, dorsal fusion; DL, dorsal laminoplasty; mJOA, modified Japanese Orthopaedic Association; VF, ventral fusion.
Figure 5C. Improvement in EQ-5D Score Between VF, DF, and DL From Baseline to 3-Month, 6-Month, and 1-Year Follow-Up

Table 7C. Improvement in EQ-5D Score Between VF, DF, and DL at 1-Year Follow-Up

<table>
<thead>
<tr>
<th>VF (n = 63)</th>
<th>DF (n = 66)</th>
<th>DL (n = 26)</th>
<th>Mean difference (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.14 (0.212)</td>
<td>0.124 (0.192)</td>
<td></td>
<td>−0.016 (−0.087 to 0.054)</td>
<td>.6483</td>
</tr>
<tr>
<td>0.14 (0.212)</td>
<td>0.194 (0.218)</td>
<td>0.054 (−0.046 to 0.153)</td>
<td>.2852</td>
<td></td>
</tr>
<tr>
<td>0.124 (0.192)</td>
<td>0.194 (0.218)</td>
<td>0.07 (−0.022 to 0.162)</td>
<td>.1327</td>
<td></td>
</tr>
</tbody>
</table>

Complications

Analysis of complications was performed as randomly assigned and as treated. Complications were categorized as minor or major (Table 8) by the principal investigators, who were blinded to other outcomes data and to surgical treatment. Analysis first focused on patients as randomly assigned. In the ventral cohort, there were significantly more complications (42.9%) vs 23% in the dorsal cohort (P = .012). However, there was no difference in major complications (~16%) in both groups (P = .9828). When examined as treated, patients undergoing VF and DF surgeries experienced a greater number of overall complications than did patients undergoing DL (P = .007). The overall major complication rate was 16% and did not
differ among the groups. Ventral surgery had significantly greater minor complications, of which dysphagia was more prevalent ($P < .001$).

Table 8. Complication Rates Defined as Minor and Major Between VF, DF, and DL

<table>
<thead>
<tr>
<th>Complication</th>
<th>VF (n = 66), n (%)</th>
<th>DF (n = 69), n (%)</th>
<th>DL (n = 28), n (%)</th>
<th>$P$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor$^a$</td>
<td>18 (27.3)</td>
<td>5 (7.3)</td>
<td>1 (3.6)</td>
<td>.009 ($\chi^2$) .0011 (exact)</td>
</tr>
<tr>
<td>Major$^b$</td>
<td>10 (15.2)</td>
<td>14 (20.3)</td>
<td>2 (7.1)</td>
<td>.2697 ($\chi^2$) .2845 (exact)</td>
</tr>
<tr>
<td>Total</td>
<td>28 (42.4)</td>
<td>19 (27.5)</td>
<td>3 (10.7)</td>
<td>.0073 ($\chi^2$) .0068 (exact)</td>
</tr>
</tbody>
</table>

Abbreviations: DF, dorsal fusion; DL, dorsal laminoplasty; VF, ventral fusion.

$^a$Minor complications resolved within 3 months and included dysphagia (18 cases), infection (4 cases), or C5 paresis (2 cases).

$^b$Major complications included deep venous thrombosis/pulmonary embolism (1 case), new postoperative neurological deficit (2 cases), hospital readmission within 30 days (6 cases), and other complications that did not resolve within 3 months, including dysphagia (9 cases), infection (1 case), and C5 paresis (7 cases).

Specific Aim 2: Health Resource Use

We summarized outpatient health resource use among the groups by focusing on diagnostic testing (MRI, CT, and x-ray), outpatient visits (visits to physician’s office, PT, etc), and medication use. These data were collected at 1 month, 3 months, 6 months, and 1 year postoperatively. In Table 9, we summarize the cumulative health resource use over a 1-year period based on patient diaries. Overall, 141 of 163 (86.5%) patients completed health resource diaries with >80% follow-up within each of the 3 cohorts. Overall, health resource use was comparable across groups. At 1 year, health resource use, particularly the number of patients who were still enrolled in PT and were prescribed ongoing opioids for pain management, differed between the 3 surgical strategies (Table 10). Of particular interest, none of the patients treated with DL were using opioids at 1 year.
Table 9. Cumulative Health Resource Use Over 1 Year Varied by Surgical Strategy

<table>
<thead>
<tr>
<th>All data</th>
<th>VF (n = 66), n (%)</th>
<th>DF (n = 69), n (%)</th>
<th>DL (n = 28), n (%)</th>
<th>χ² P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostic testing (any)</td>
<td>52 (79)</td>
<td>60 (87)</td>
<td>17 (60)</td>
<td>.0156</td>
</tr>
<tr>
<td>MRI</td>
<td>28 (42)</td>
<td>32 (46)</td>
<td>11 (39)</td>
<td>.7924</td>
</tr>
<tr>
<td>CT</td>
<td>12 (18)</td>
<td>11 (16)</td>
<td>4 (14)</td>
<td>.8827</td>
</tr>
<tr>
<td>X-ray</td>
<td>50 (76)</td>
<td>51 (74)</td>
<td>13 (46)</td>
<td>.0114</td>
</tr>
<tr>
<td>PT (No. of visits)</td>
<td>34 (51.5)</td>
<td>39 (56.5)</td>
<td>13 (46)</td>
<td>.6430</td>
</tr>
<tr>
<td>Pain medications</td>
<td>53 (80)</td>
<td>60 (87)</td>
<td>20 (71)</td>
<td>.1900</td>
</tr>
<tr>
<td>Opioids</td>
<td>30 (45)</td>
<td>45 (65)</td>
<td>11 (39)</td>
<td>.0208</td>
</tr>
<tr>
<td>Physician appointments</td>
<td>16 (24)</td>
<td>26 (38)</td>
<td>6 (11)</td>
<td>.1368</td>
</tr>
</tbody>
</table>

Abbreviations: CT, computed tomography; DF, dorsal fusion; DL, dorsal laminoplasty; MRI, magnetic resonance imaging; PT, physical therapy; VF, ventral fusion.

Table 10. Differences in Health Resource Use Between VF, DF, and DL at 1-Year Follow-Up

<table>
<thead>
<tr>
<th>Health resource use</th>
<th>VF (n = 66), n (%)</th>
<th>DF (n = 69), n (%)</th>
<th>DL (n = 28), n (%)</th>
<th>χ² P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing PT</td>
<td>11 (17)</td>
<td>15 (22)</td>
<td>0</td>
<td>.0293</td>
</tr>
<tr>
<td>Ongoing opioids</td>
<td>6 (9)</td>
<td>11 (16)</td>
<td>0</td>
<td>.0599</td>
</tr>
</tbody>
</table>

Abbreviations: DF, dorsal fusion; DL, dorsal laminoplasty; PT, physical therapy; VF, ventral fusion.

*aThere was a trend suggesting less ongoing opioid use among DL patients at 1 year.

Return to Work

At 1 year, the proportion of patients who were working preoperatively and who returned to work was similar among the 3 groups (85.2% VF vs 75.9% DF vs 90.9% DL).

Specific Aim 3: Cervical Sagittal Alignments

To assess postoperative cervical C2-C7 sagittal alignment, we obtained neutral plain cervical radiographs at 1 year and reviewed them. The cervical C2-C7 sagittal vertical axis (SVA) in millimeters was calculated by drawing a plumb line from the center of C2 and from the dorsal caudal aspect of C7 and measuring the distance as described. In Table 11, we show the mean postoperative C2-C7 SVA for all 3 groups of patients as well as the percentage of patients with SVA ≥40 mm in each group.
Table 11. Postoperative Cervical Alignment for VF, DF, and DL

<table>
<thead>
<tr>
<th>Postoperative cervical alignment</th>
<th>VF (n = 51)</th>
<th>DF (n = 51)</th>
<th>DL (n = 19)</th>
<th>$\chi^2$ P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>C2-C7 SVA</td>
<td>23.5</td>
<td>28.4</td>
<td>24.4</td>
<td>.144</td>
</tr>
<tr>
<td>% patient SVA ≥40 mm</td>
<td>9.8</td>
<td>21.6</td>
<td>15.8</td>
<td>.175</td>
</tr>
</tbody>
</table>

Abbreviations: DF, dorsal fusion; DL, dorsal laminoplasty; SVA, sagittal vertical axis; VF, ventral fusion.

Preliminary data from our pilot study suggested that postoperative SVA ≥40 mm was associated with poorer health-related outcomes.\textsuperscript{35} We examined postoperative SVA in this study and also found that increased SVA was negatively associated with overall SF-36 PCS scores ($P = .001$). This is consistent with other literature showing that postoperative C2-C7 SVA is an important consideration when contemplating surgical approach to the cervical spine.\textsuperscript{34,35} Many surgeons feel that correction of abnormal C2-C7 SVA should be a priority when treating patients with CSM and that posterior cervical fusion without osteotomies might limit the ability to achieve optimal postoperative SVA.

**CSM-S Trial Audit**

A data quality review for the CSM-S trial was implemented in 2017 about a year before the trial closed to enrollment. The audit involved all primary and secondary outcomes deemed critical to the final analysis of the study. We performed an audit of 100% of these data points for all randomly assigned patients. We discovered a low overall error rate of 4.1%, with the majority of these errors being transcription-related (ie, transferring a scored questionnaire value and mismatch between CRF and WBP data entry) (Figure 6).
Figure 6. Audit of Primary and Secondary Outcomes Deemed Critical to the CSM-S Trial Analysis

<table>
<thead>
<tr>
<th>Case Report Forms</th>
<th>Mismatch</th>
<th>Missing</th>
<th>Invalid</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>6.04%</td>
<td>1.40%</td>
<td>0.45%</td>
</tr>
</tbody>
</table>

<p>| Scoring of Patient Questionnaires |</p>
<table>
<thead>
<tr>
<th>Scoring</th>
<th>Transcription</th>
<th>Missing</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>0.33%</td>
<td>1.59%</td>
</tr>
</tbody>
</table>

Abbreviation: CSM-S, Cervical Spondylotic Myelopathy–Surgical.
DISCUSSION

The CSM-S trial used a unique clinical equipoise panel that successfully randomized 163 patients to either ventral or dorsal surgery for CSM. For patients randomly assigned to DF, surgeons then selected laminoplasty vs laminectomy. This decision was largely driven by surgeon usual practice or preference. Because laminoplasty was expected to differ from DL with fusion, we decided to randomly assign more patients (2:3 randomization ventral to dorsal) to the dorsal surgery arm of the study to permit comparison of these 2 approaches. We found no difference in the change in SF-36 PCS scores at 1 year between ventral and dorsal surgery. When examining the groups as treated, we separated the laminoplasty cases to permit a more meaningful clinical comparison. Laminoplasty was associated with greater improvement in QOL as measured by change in SF-36 PCS score at 1 year compared with dorsal laminectomy and fusion as well as ventral decompression and fusion. These better outcomes reported for laminoplasty should be considered with caution because patients who underwent dorsal surgery were not randomly assigned to receive laminoplasty. Laminoplasty was at the discretion of the treating surgeon and might therefore represent a selection bias that could influence clinical outcomes (ie, patients selected for laminoplasty might have had better predicted outcomes based on presurgical factors).

The choice of surgical strategy for patients with CSM is thought to be based on both patient anatomical factors as well as surgeon preference regarding procedure. In order to create a study population with clinical equipoise, we used a novel spine expert review process (ie, the Spinal Expert Network). The overall results suggest that the spinal expert review was successful. Of 269 eligible patients from 16 sites, we were able to randomly assign 163 (60%) eligible patients. There are specific anatomical factors that were not considered in this trial. The study population was not large enough to examine specific anatomical patterns in subgroup analysis. This study found that laminoplasty is associated with superior outcomes, although it is certainly possible that specific anatomical features were being used by surgeons to select patients for laminoplasty once they were randomly assigned to a dorsal approach and that
these features predict better outcomes irrespective of the type of procedure performed. Only another randomized study could eliminate this type of bias.

One of the observations from having patient stakeholders involved in this process is that patients were very interested in the reduction of complications. The overall 16% major complication rate observed in the CSM-S trial is comparable with that published by multiple other prospective studies; however, our study identified a higher rate of complications in the ventral cohort compared with previous studies, which have generally found a higher rate of complication among patients treated with a dorsal approach.\textsuperscript{37,38} In our study, there were fewer complications observed in the DL cohort, while the VF cohort had significantly more minor complications. These differences could be related to the procedure or to patient-specific clinical factors. Most of the complications observed in the ventral cohort in this study were related to dysphagia that resolved within 3 months (a minor complication). It is likely that other studies have not reported transient dysphagia as a complication.

Another factor of great importance to patients is the degree of postoperative pain and the ability to return to activities, including work. This analysis shows that there was a trend toward greater pain in the DF cohort. On the other hand, all 3 cohorts had impressive return to work rates, suggesting that all 3 types of surgery are effective in restoring physical function.

Subpopulation Considerations

One of the key strengths of the study was the use of an expert panel to establish clinical equipoise in real time. It is likely that this approach made it feasible to conduct and complete enrollment in this randomized surgical trial. However, some patients within the randomized cohort might have had specific anatomic features that would lead to different outcomes among the surgical procedures examined. Future analyses will focus on patients with more rostral stenosis to determine whether they have more dysphagia after ventral surgery. We are also in the process of examining follow-up radiographic studies to identify specific categories of patients who might have different results among the surgical options. For example, previous work has suggested that poor sagittal alignment is more common after dorsal laminectomy with fusion.\textsuperscript{37} Our analysis of these data also show that suboptimal postoperative sagittal
alignment is associated with poorer SF-36 PCS score outcomes. Further studies will be necessary to understand how to optimize postoperative sagittal alignment among the surgical options for CSM. Moreover, a separate analysis of patients who did not reach meaningful clinical improvement might yield useful information for patients and their treating physicians.

**Study Limitations**

The study has some limitations. Although every effort was taken to include all eligible patients with CSM, we recognize that 85% of the CSM-S patient population was White and that the results of the study might not apply to patients of other races. CSM is a condition that affects all races and future studies should work to include these populations more than the CSM-S trial was able to accomplish. We also recognize that patients who participated in the CSM-S trial represented only a subset of eligible patients at each site and therefore, the group of patients in the trial may represent an inclusion bias. Furthermore, the accuracy of patient diaries for reporting health resource use was not verified against claims data. Future studies could address this limitation. Finally, although baseline characteristics were comparable between DL, DF, and VF cohorts, we recognize that patient and surgeon bias could have affected the choice of DL in the dorsal cohort. Future studies should include randomization between laminoplasty and dorsal decompression and fusion. Finally, the number of patients treated in this randomized study was appropriate for the analysis of the primary outcome measure, but a larger registry study with robust radiographic data collection would permit useful subgroup analyses of patients with specific anatomical features such as differences in T1 slope or cervical SVA. A larger registry study would be more likely to generate data that would be generalizable to the rest of the US population given the relatively small sample size of patients included in the CSM-S trial.

One of the key conclusions of this study is that fusion may not be necessary when treating many patients with CSM. The results of the study, however, should be interpreted with caution because the patients treated with laminoplasty were not randomly assigned to this treatment option, which was at the discretion of the treating surgeon when patients were randomly assigned to a dorsal strategy. Laminoplasty is the dominant form of treatment for this
condition in many parts of the world. Adoption of laminoplasty in the United States has been relatively slower, perhaps because of concerns about reimbursement from payers. Although laminoplasty was first described in 1982, there was no CPT code for it until 2005 in the United States, meaning that it was not possible for US surgeons to be reimbursed reliably for this procedure. It is possible that dissemination of the CSM-S trial results will increase interest in the use of laminoplasty in the United States. The results underscore a need for future RCTs aimed at randomly assigning patients to laminoplasty vs other surgical alternatives for treating CSM.
CONCLUSIONS

Surgical treatment for CSM is associated with improvement in symptoms of myelopathy and in restoring function that allows patients to return to work. Patients randomly assigned to ventral vs dorsal surgery did not differ in 1-year primary outcome (ie, SF-36 PCS scores). In a secondary as-treated analysis, DL was associated with fewer complications and superior outcomes compared with ventral or dorsal decompression and fusion. In addition, DL might be associated with less need for ongoing PT and less opioid usage 1 year postoperatively. The findings observed among patients treated with DL should be confirmed with a future RCT. The results of the CSM-S trial should be interpreted with caution because the patients treated with laminoplasty were not randomly assigned to this treatment option. Patients treated with laminoplasty were selected by the treating surgeon among patients randomly assigned to the dorsal arm of the trial.
REFERENCES


24. Copay AG, Glassman SD, Subach BR, Berven S, Schuler TC, Carreon LY. Minimum clinically important difference in lumbar spine surgery patients: a choice of methods


RELATED PUBLICATIONS


ACKNOWLEDGMENTS

We would like to acknowledge Jill Curran, MS, and Susan Christopher, RN, for their many contributions to this research effort, including the management of the overall database. We would also like to acknowledge Norma Terrin, PhD, and Janis Breeze, MPH, who performed the statistical analysis on the data. Zoher Ghogawala would also like to acknowledge Dr Karen Freund, Dr Fred Barker, and Dr Edward Benzel for their mentorship and support of this effort over many years.
Appendix A. Glossary of Terms

**CSM** - Cervical Spondylotic Myelopathy

**Compression** - Pressure on the spinal cord

**Decompression** – Removal of pressure on the spinal cord

**Laminectomy** – Removal of bone from the cervical spine to decompress the spinal cord

**Laminoplasty** – A motion preserving technique to decompress the spinal cord by enlarging the diameter of the spinal canal at individual spinal levels of the neck.

**Dorsal** – Posterior approach from back of the neck

**Equipoise** – A state of genuine uncertainty amongst clinical investigators regarding the comparative effectiveness of one medical option versus another. In general, clinical equipoise must exist between two clinical options in order to ethically randomize patients in a clinical trial.

**Ventral** – Anterior approach from front of the neck

**Hyperreflexia** – Abnormally brisk deep tendon reflexes that imply spinal cord dysfunction or pressure

**Ankle clonus** – Rhythmic movements of the ankle that imply pressure on the spinal cord

**Kyphosis** – Abnormal forward bend to the spinal column

**Ossification of the posterior longitudinal ligament** – calcification (hardening) of the ligament behind the spinal column that can result in spinal cord compression.

**Allograft** – cadaver bone that is used for bony fusion of the spinal column
Appendix B. Patient-Reported Outcome Measures Questionnaires
36-Item Short Form (SF-36) Health Survey (Version 2)

The physical component summary (PCS) score, derived from the 36-Item Short Form (SF-36) Health Survey (Version 2) was the primary outcome. The range of the SF-36 PCS is between 0 and 100, where higher scores represent better physical functioning.
Your Health and Well-Being

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Thank you for completing this survey!

For each of the following questions, please mark an □ in the one box that best describes your answer.

1. In general, would you say your health is:

<table>
<thead>
<tr>
<th>Excellent</th>
<th>Very good</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
<tr>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
</tbody>
</table>

2. Compared to one year ago, how would you rate your health in general now?

<table>
<thead>
<tr>
<th>Much better now than one year ago</th>
<th>Somewhat better now than one year ago</th>
<th>About the same as one year ago</th>
<th>Somewhat worse now than one year ago</th>
<th>Much worse now than one year ago</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
<tr>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
</tbody>
</table>
3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

<table>
<thead>
<tr>
<th></th>
<th>Yes, limited a lot</th>
<th>Yes, limited a little</th>
<th>No, not limited at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>a Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports</td>
<td>☐ 1 ☐ 2 ☐ 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf</td>
<td>☐ 1 ☐ 2 ☐ 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c Lifting or carrying groceries</td>
<td>☐ 1 ☐ 2 ☐ 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d Climbing several flights of stairs</td>
<td>☐ 1 ☐ 2 ☐ 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>e Climbing one flight of stairs</td>
<td>☐ 1 ☐ 2 ☐ 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>f Bending, kneeling, or stooping</td>
<td>☐ 1 ☐ 2 ☐ 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>g Walking more than a mile</td>
<td>☐ 1 ☐ 2 ☐ 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>h Walking several hundred yards</td>
<td>☐ 1 ☐ 2 ☐ 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>i Walking one hundred yards</td>
<td>☐ 1 ☐ 2 ☐ 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>j Bathing or dressing yourself</td>
<td>☐ 1 ☐ 2 ☐ 3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4. **During the past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>a Cut down on the amount of time you spent on work or other activities</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
<tr>
<td>b Accomplished less than you would like</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
<tr>
<td>c Were limited in the kind of work or other activities</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
<tr>
<td>d Had difficulty performing the work or other activities (for example, it took extra effort)</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
</tbody>
</table>

5. **During the past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>a Cut down on the amount of time you spent on work or other activities</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
<tr>
<td>b Accomplished less than you would like</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
<tr>
<td>c Did work or other activities less carefully than usual</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
</tbody>
</table>
6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

<table>
<thead>
<tr>
<th>Not at all</th>
<th>Slightly</th>
<th>Moderately</th>
<th>Quite a bit</th>
<th>Extremely</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
</tbody>
</table>

7. How much bodily pain have you had during the past 4 weeks?

<table>
<thead>
<tr>
<th>None</th>
<th>Very mild</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Very severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
<td>□ 6</td>
</tr>
</tbody>
</table>

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

<table>
<thead>
<tr>
<th>Not at all</th>
<th>A little bit</th>
<th>Moderately</th>
<th>Quite a bit</th>
<th>Extremely</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
</tbody>
</table>
9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

<table>
<thead>
<tr>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
</tbody>
</table>

a. Did you feel full of life? ..................................................□ 1 ..............□ 2 ..............□ 3 ..............□ 4 ..............□ 5

b. Have you been very nervous? ..................................................□ 1 ..............□ 2 ..............□ 3 ..............□ 4 ..............□ 5

c. Have you felt so down in the dumps that nothing could cheer you up? ..................................................□ 1 ..............□ 2 ..............□ 3 ..............□ 4 ..............□ 5

d. Have you felt calm and peaceful? ..................................................□ 1 ..............□ 2 ..............□ 3 ..............□ 4 ..............□ 5

e. Did you have a lot of energy? ..................................................□ 1 ..............□ 2 ..............□ 3 ..............□ 4 ..............□ 5

f. Have you felt downhearted and depressed? ..................................................□ 1 ..............□ 2 ..............□ 3 ..............□ 4 ..............□ 5

g. Did you feel worn out? ..................................................□ 1 ..............□ 2 ..............□ 3 ..............□ 4 ..............□ 5

h. Have you been happy? ..................................................□ 1 ..............□ 2 ..............□ 3 ..............□ 4 ..............□ 5

i. Did you feel tired? ..................................................□ 1 ..............□ 2 ..............□ 3 ..............□ 4 ..............□ 5

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

<table>
<thead>
<tr>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
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<tr>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
</tbody>
</table>
11. How TRUE or FALSE is each of the following statements for you?

<table>
<thead>
<tr>
<th>Definitely true</th>
<th>Mostly true</th>
<th>Don’t know</th>
<th>Mostly false</th>
<th>Definitely false</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
</tbody>
</table>

a. I seem to get sick a little easier than other people .................. □ 1 .......... □ 2 .......... □ 3 .......... □ 4 .......... □ 5

b. I am as healthy as anybody I know ........................................ □ 1 .......... □ 2 .......... □ 3 .......... □ 4 .......... □ 5

c. I expect my health to get worse ............................................. □ 1 .......... □ 2 .......... □ 3 .......... □ 4 .......... □ 5

d. My health is excellent ......................................................... □ 1 .......... □ 2 .......... □ 3 .......... □ 4 .......... □ 5

Thank you for completing these questions!
Neck Disability Index (NDI)

The Neck Disability Index (NDI) measures how neck pain affects the patients’ ability to manage in everyday life. Each section is scored on a scale of 0 to 5, where 0 = “no pain” and 5 = “worst imaginable pain.” The summed total range is between 0 and 100, with a lower score representing less disability.
Please Read: This questionnaire is designed to enable us to understand how much your neck pain has affected your ability to manage everyday activities. Please answer each Section by circling the ONE CHOICE that most applies to you. We realize that you may feel that more than one statement may relate to you, but Please Just circle the one choice which closely describes your problem right now.

### SECTION 1 -- Pain Intensity
- A. I have no pain at the moment
- B. The pain is mild at the moment.
- C. The pain comes and goes and is moderate.
- D. The pain is moderate and does not vary much.
- E. The pain is severe but comes and goes.
- F. The pain is severe and does not vary much.

### SECTION 2 -- Personal Care (Washing, Dressing etc.)
- A. I can look after myself without causing extra pain.
- B. I can look after myself normally but it causes extra pain.
- C. It is painful to look after myself and I am slow and careful.
- D. I need some help, but manage most of my personal care.
- E. I need help every day in most aspects of self-care.
- F. I do not get dressed, I wash with difficulty and stay in bed.

### SECTION 3 -- Lifting
- A. I can lift heavy weights without extra pain.
- B. I can lift heavy weights, but it causes extra pain.
- C. Pain prevents me from lifting heavy weights off the floor but I can if they are conveniently positioned, for example on a table.
- D. Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned.
- E. I can lift very light weights.
- F. I cannot lift or carry anything at all.

### SECTION 4 -- Reading
- A. I can read as much as I want to with no pain in my neck.
- B. I can read as much as I want with slight pain in my neck.
- C. I can read as much as I want with moderate pain in my neck.
- D. I cannot read as much as I want because of moderate pain in my neck.
- E. I cannot read as much as I want because of severe pain in my neck.
- F. I cannot read at all.

### SECTION 5 -- Headache
- A. I have no headaches at all.
- B. I have slight headaches which come infrequently.
- C. I have moderate headaches which come infrequently.
- D. I have moderate headaches which come frequently.
- E. I have severe headaches which come frequently.
- F. I have headaches almost all the time.

### SECTION 6 -- Concentration
- A. I can concentrate fully when I want to with no difficulty.
- B. I can concentrate fully when I want to with slight difficulty.
- C. I have a fair degree of difficulty in concentrating when I want to.
- D. I have a lot of difficulty in concentrating when I want to.
- E. I have a great deal of difficulty in concentrating when I want to.
- F. I cannot concentrate at all.

### SECTION 7 -- Work
- A. I can do as much work as I want to.
- B. I can only do my usual work, but no more.
- C. I can do most of my usual work, but no more.
- D. I cannot do my usual work.
- E. I can hardly do any work at all.
- F. I cannot do any work at all.

### SECTION 8 -- Driving
- A. I can drive my car without neck pain.
- B. I can drive my car as long as I want with slight pain in my neck.
- C. I can drive my car as long as I want with moderate pain in my neck.
- D. I cannot drive my car as long as I want because of moderate pain in my neck.
- E. I can hardly drive my car at all because of severe pain in my neck.
- F. I cannot drive my car at all.

### SECTION 9 -- Sleeping
- A. I have no trouble sleeping.
- B. My sleep is slightly disturbed (less than 1 hour sleepless).
- C. My sleep is mildly disturbed (1-2 hours sleepless).
- D. My sleep is moderately disturbed (2-3 hours sleepless).
- E. My sleep is greatly disturbed (3-5 hours sleepless).
- F. My sleep is completely disturbed (5-7 hours sleepless).

### SECTION 10 -- Recreation
- A. I am able engage in all recreational activities with no pain in my neck at all.
- B. I am able engage in all recreational activities with some pain in my neck.
- C. I am able engage in most, but not all recreational activities because of pain in my neck.
- D. I am able engage in a few of my usual recreational activities because of pain in my neck.
- E. I can hardly do any recreational activities because of pain in my neck.
- F. I cannot do any recreational activities all all.

Subject ID: ___________ Visit: __________

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DISABILITY INDEX SCORE:  %
Modified Japanese Orthopedic Association (mJOA)

The modified Japanese Orthopedic Association (mJOA) score is used to evaluate the functional status of patients with degenerative cervical myelopathy. Each section is summed to obtain a score (range = 0-17), with a higher score representing less dysfunction from myelopathy. A typical patient with moderate cervical myelopathy has a mJOA score between 12 and 14. Many other surgical studies show that patients with cervical myelopathy have mJOA scores in this range.
mJOA Scale

mJOA: ____________ (0-17)

Motor, arms
0  Unable to feed oneself
1  Unable to use a knife and fork, able to eat with spoon
2  Able to use knife and fork with much difficulty
3  Able to use knife and fork with slight difficulty
4  No deficit

Motor, legs
0  Unable to walk
1  Can walk on flat floor with a walking aid
2  Can walk up or down stairs with a handrail
3  Lack of stability and smooth gait
4  No deficit

Sensation, arms
0  Severe sensory loss or pain
1  Mild sensory loss
2  No deficit

Sensation, legs
0  Severe sensory loss or pain
1  Mild sensory loss
2  No deficit

Sensation, trunk
0  Severe sensory loss or pain
1  Mild sensory loss
2  No deficit

Bladder function
0  Unable to void
1  Marked difficulty with micturation (retention)
2  Difficulty in micturation (frequency, hesitation)
3  No deficit
**EuroQol 5-Dimensions (EQ-5D)**

The 3-level version of the EuroQol-5 Dimensions (EQ-5D) comprises of five discrete aspects of quality-of-life that taken together, sum into one number (between 0 and 1), where the higher score denotes greater quality-of-life. The second aspect of the EQ-5D is a visual analogue scale (VAS) to assess the patients’ current health between the best state (100) and worst state imaginable (0).
Health Questionnaire

(English version for the US)
By placing a checkmark in one box in each group below, please indicate which statements best describe your own health state today.

**Mobility**
- I have no problems in walking about
- I have some problems in walking about
- I am confined to bed

**Self-Care**
- I have no problems with self-care
- I have some problems washing or dressing myself
- I am unable to wash or dress myself

**Usual Activities (e.g. work, study, housework, family or leisure activities)**
- I have no problems with performing my usual activities
- I have some problems with performing my usual activities
- I am unable to perform my usual activities

**Pain/Discomfort**
- I have no pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

**Anxiety/Depression**
- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed
To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.
Disclaimer:
The [views, statements, opinions] presented in this report are solely the responsibility of the author(s) and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute® (PCORI®), its Board of Governors or Methodology Committee.

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