Can segmental mobility be increased by cervical arthroplasty?

*Hsuan-Kan Chang, MD,1,2 Chih-Chang Chang, MD,1,2 Tsung-Hsi Tu, MD,1,2 Jau-Ching Wu, MD, PhD,1,2 Wen-Cheng Huang, MD, PhD,1,2 Li-Yu Fay, MD,1,3 Peng-Yuan Chang, MD,1,2 Ching-Lan Wu, MD,2,4 and Henrich Cheng, MD, PhD1–3

1Department of Neurosurgery, Neurological Institute, Taipei Veterans General Hospital; 2School of Medicine and 3Institute of Pharmacology, National Yang-Ming University; and 4Department of Radiology, Taipei Veterans General Hospital, Taipei, Taiwan

OBJECTIVE Many reports have successfully demonstrated that cervical disc arthroplasty (CDA) can preserve range of motion after 1- or 2-level discectomy. However, few studies have addressed the extent of changes in segmental mobility after CDA or their clinical correlations.

METHODS Data from consecutive patients who underwent 1-level CDA were retrospectively reviewed. Indications for surgery were medically intractable degenerative disc disease and spondylosis. Clinical outcomes, including visual analog scale (VAS)–measured neck and arm pain, Neck Disability Index (NDI), and Japanese Orthopaedic Association (JOA) scores, were analyzed. Radiographic outcomes, including C2–7 Cobb angle, the difference between pre- and postoperative C2–7 Cobb angle (ΔC2–7 Cobb angle), sagittal vertical axis (SVA), the difference between pre- and postoperative SVA (ΔSVA), segmental range of motion (ROM), and the difference between pre- and postoperative ROM (ΔROM), were assessed for their association with clinical outcomes. All patients underwent CT scanning, by which the presence and severity of heterotopic ossification (HO) were determined during the follow-up.

RESULTS A total of 50 patients (mean age 45.6 ± 9.33 years) underwent a 1-level CDA (Prestige LP disc) and were followed up for a mean duration of 27.7 ± 8.76 months. All clinical outcomes, including VAS, NDI, and JOA scores, improved significantly after surgery. Preoperative and postoperative ROM values were similar (mean 9.5° vs 9.0°, p > 0.05) at each indexed level. The mean changes in segmental mobility (ΔROM) were −0.5° ± 6.13°. Patients with increased segmental mobility after surgery (ΔROM > 0°) had a lower incidence of HO and HO that was less severe (p = 0.048) than those whose ΔROM was < 0°. Segmental mobility (ROM) was significantly lower in patients with higher HO grade (p = 0.012), but it did not affect the clinical outcomes. The preoperative and postoperative C2–7 Cobb angles and SVA remained similar. The postoperative C2–7 Cobb angles, SVA, ΔC2–7 Cobb angles, and ΔSVA were not correlated to clinical outcomes after CDA.

CONCLUSIONS Segmental mobility (as reflected by the mean ROM) and overall cervical alignment (i.e., mean SVA and C2–7 Cobb angle) had no significant impact on clinical outcomes after 1-level CDA. Patients with increased segmental mobility (ΔROM > 0°) had significantly less HO and similarly improved clinical outcomes than those with decreased segmental mobility (ΔROM < 0°).

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KEY WORDS cervical alignment; Cobb angle; sagittal vertical axis; range of motion; segmental mobility; cervical disc arthroplasty; heterotopic ossification

In the past decade cervical disc arthroplasty (CDA) has been considered an effective and safe alternative to anterior cervical discectomy and fusion (ACDF) in selected candidates for management of 1- or 2-level degenerative disc disease (DDD) or spondylosis.10,12,15,18,24,26,35 In addition to satisfactory clinical outcomes, successful preservation of segmental mobility after CDA has been demonstrated in several large-scale, prospective, randomized, controlled trials by the United States Food and Drug Administration (FDA).4,15,23,34,37 The averaged range of motion (ROM) pre-
served at each CDA-treated level was reported to be approximately $7^\circ$–$9^\circ$ during flexion and extension.\textsuperscript{9,10,17,24,25,34} Although the segmental mobility was preserved regardless of the brand of artificial disc that was tested, there are some variations in ROM. However, there are scarce data focusing on the extent of the post-CDA changes in segmental mobility or their clinical correlations.

While the aforementioned Food and Drug Administration (FDA) trials successfully demonstrated preserved segmental mobility (as reflected by mean ROM) after CDA in hundreds of patients,\textsuperscript{3,4,10,11,17,24,25,28,34} these trials did not address individual differences in change of mobility after CDA—in other words, a patient whose segmental mobility might increase (e.g., preoperative flexion and extension ROM of $6^\circ$ at C5–6 increasing to $12^\circ$ after surgery) or decrease after CDA (e.g., preoperative ROM of $12^\circ$ decreasing to $6^\circ$ after surgery). These two patients would be summed up as representing preservation of segmental mobility at an average ROM of $9^\circ$. The reported radiographic measurement of mean ROM in the literature would not have picked up the differences between increased and decreased segmental mobility. In theory, increased postoperative ROM (a difference between pre- and postoperative AROM $> 0^\circ$) and decreased segmental mobility (AROM $< 0^\circ$) could imply substantial differences in CDA. Therefore, the current study focused on the changes in ROM (AROM during flexion and extension) after surgery.

The aim of this present study was to analyze the radiographic outcomes after CDA, particularly the changes in segmental mobility (ΔROM) and cervical alignment and establishing correlations between changes and clinical outcomes. The study cohort included consecutively treated patients who underwent a single-level CDA performed using the same kind of device that was approved by the FDA. To the authors’ knowledge, this is the first study to specifically address the changes in segmental mobility preoperatively and postoperatively and the influences on the outcomes.

**Methods**

**Inclusion and Exclusion of Patients**

Data obtained in patients in whom a 1-level subaxial (C3–7) CDA was performed using a Prestige LP disc (Medtronic) were retrospectively reviewed. The study’s inclusion criteria were medically intractable cervical radiculopathy, myelopathy, or both, caused by DDD and/or spondylosis at only a single level.\textsuperscript{17,24,25} Preoperative MR images and radiographs were reviewed for all patients for confirmation of diagnosis. Patients also underwent CT scanning for evaluation of extensive bone spur formation, calcified disc, or ossification of the posterior longitudinal ligament. In all cases medical treatment and physical therapy failed to resolve symptoms for at least 12 weeks prior to surgery. Exclusion criteria were as follows: 1) traumatic spinal cord injury or fracture; 2) evident segmental instability (i.e., $> 3.5$ mm translation or $20^\circ$ angular motion) at the index level; 3) segmental arthrodesis without mobility; 4) severely incompetent facet joints at the index level; 5) adjacent-segment disease after previous cervical fusion; 6) ossification of the posterior longitudinal ligament; 7) kyphosis at the index level or severe global kyphotic deformity; 8) discitis; or 9) long-term steroid use. Patients with chronic systemic diseases, including severe osteoporosis, malignancy, metabolic bone disease, autoimmune disease or spondyloarthropathy such as rheumatoid arthritis or ankylosing spondylitis, infection, or severe cerebrovascular disease such as stroke, were excluded from the current study as well.

**Surgical Technique**

All surgeries were performed by 3 experienced neurosurgeons and also the senior authors of the study (J.C. Wu, W.C. Huang, and H. Cheng). A consistent technique of anterior cervical discectomy was adopted, as described in previous studies.\textsuperscript{3–8} Generous decompression of the neural element and resection of bilateral uncovertebral joints and all the bone spurs were carefully performed. The posterior longitudinal ligament was routinely removed for direct visual confirmation of decompression in the spinal canal. We always aimed for decent technique, including meticulous endplate preparation and selection of the most appropriately sized artificial disc to minimize heterotopic ossification (HO) formation.\textsuperscript{21} Also, copious irrigation with normal saline to wash away the bone dust when drilling the osteophytes was applied in every case. After thorough decompression, a Prestige LP artificial disc was inserted in each patient in the current series. A closed-system drainage catheter was routinely placed, followed by layer-by-layer wound closure.

**Measurement of Radiological Parameters and Clinical Outcomes**

Preoperative MR images, CT scans, and radiographs were reviewed for surgical indication. Our follow-up protocol involves patient-reported scores and radiographs (standing anteroposterior, lateral, and lateral dynamic flexion and extension views) at each specific follow-up time point after surgery. Patient-reported scores, including visual analog scale (VAS) of the neck and arm, Neck Disability Index (NDI) scores, and Japanese Orthopaedic Association (JOA) scores, were collected by two physician assistants under the physicians’ supervision during clinic visits. The detection and grading of HO were established by careful review of postoperative radiographs and CT scans, and by application of McAfee’s classification (Grade 0–4).\textsuperscript{21} We found that the 3D reconstructed CT scans were particularly useful for final assessment of HO if there was any ambiguity or discrepancy during the assessment.

Radiographic measurements included segmental ROM and overall cervical alignment. The segmental ROM of the index level was measured on standing dynamic lateral flexion/extension radiographs, obtained at 24-month follow-up examinations, using the Cobb angle method, which was the same as that previously reported on in the US FDA trials.\textsuperscript{24} The change of segmental mobility (ΔROM) was defined as the differences between preoperative and postoperative segmental ROM (24-month postoperative value minus the preoperative value). Cervical alignment was assessed by using the C2–7 Cobb angle and C2–7
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sagittal vertical axis (SVA), which were measured on the standard lateral radiographs at the 24-month follow-up visit, as described previously in the literature30 (Fig. 1). Lordosis was defined as positive values of the C2–7 Cobb angle, while kyphosis was defined as negative values of the C2–7 Cobb angle. The changes in C2–7 Cobb angles and SVAs after surgery were also evaluated and yielded ΔC2–7 Cobb angle and ΔSVA, defined as the differences between pre- and postoperative values (postoperative minus preoperative Cobb angle and SVA values). The current series did not measure T-1 slope because the T-1 vertebral body was frequently obscured by soft-tissue shadow on lateral radiographs and could not be consistently evaluated. Radiological assessments and measurements were conducted by a radiologist and 2 neurosurgeons independently using picture archiving and communication system (PACS) software, SmartIris (Taiwan Electronic Data Processing Co.) on a medical-use screen in our institute.

Statistical Analysis

For analysis of continuous variables, we used t-tests, 1-way ANOVA tests, and correlation coefficients. Pearson’s chi-square test was used for categorical variables analysis. All statistical analysis was performed using the SPSS software. Statistical significance was set at p < 0.05.

Results

Demographics and Patient-Reported Clinical Outcomes

As demonstrated in Table 1, a total of 50 patients who underwent 1-level CDA were analyzed in the current study. The Prestige LP device was implanted in all 50 patients. The mean age of the population was 45.6 ± 9.33 years. There was a slight female predominance (male/female ratio 21:29). The mean follow-up period was 27.7 ± 8.76 months. The C5–6 level was the level most commonly treated (n = 36, 72%). The pre- and postoperative patient-reported clinical outcomes, including neck and arm VAS, NDI, and JOA scores, are also summarized in Table 1. There was significant improvement in each of the outcome measurements at 24 months after surgery (p = 0.001, 0.000, 0.000, and 0.000 for VAS neck, VAS arm, NDI, and JOA score, respectively).

<table>
<thead>
<tr>
<th>TABLE 1. Demographic data</th>
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<tr>
<td><strong>Variable</strong></td>
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<td>Age (yrs)</td>
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<td>Male/female ratio</td>
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<tr>
<td>Device</td>
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<td>Follow-up (mos)</td>
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<td>C3–4</td>
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<td>C5–6</td>
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<td>C6–7</td>
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<td>Segmental ROM (°)</td>
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<td>Postop 24 mos</td>
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<td>C2–7 Cobb angle (°)</td>
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<td>Preop</td>
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<tr>
<td>Postop 24 mos</td>
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<td>C2–7 SVA (cm)</td>
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<td>Preop</td>
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<tr>
<td>Postop 24 mos</td>
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<tr>
<td>VAS neck score</td>
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<tr>
<td>Preop</td>
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<td>Postop 24 mos</td>
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<tr>
<td>VAS arm score</td>
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<tr>
<td>Preop</td>
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<tr>
<td>Postop 24 mos</td>
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<tr>
<td>NDI score</td>
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<tr>
<td>Preop</td>
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<tr>
<td>Postop 24 mos</td>
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<tr>
<td>JOA score</td>
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<tr>
<td>Preop</td>
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<tr>
<td>Postop 24 mos</td>
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</table>

Boldface indicates statistical significance.
* Values are presented as the number (%) or as the mean ± SD.
Segmental ROM and HO

The segmental ROM at the index level was well maintained at 24 months after surgery compared with that of the same level before surgery (9.0° ± 5.81° vs 9.5° ± 4.28°, p = 0.596, Table 1). The postoperative reduction in segmental mobility (ROM) was significantly correlated (p = 0.012) with formation of HO (Fig. 2). Patients in whom greater segmental ROM was achieved after CDA had a lower-grade HO at the index level. Once changes of ROM (ΔROM) were determined postoperatively, patients were then divided into two groups accordingly: those with increased segmental mobility (ΔROM > 0°) and those with decreased or unchanged segmental mobility (ΔROM < 0°). All the clinical outcomes in the two groups were compared. The overall mean ΔROM was −0.5° ± 6.13° in the current series, and there were no significant differences in segmental mobility after CDA. Patients in whom segmental mobility increased (ΔROM > 0°) had significantly less HO and less severe HO (Figs. 3 and 4). In contrast, patients who had signs of decreased segmental mobility postoperatively (i.e., ΔROM < 0°) had significantly higher grades of HO. (p = 0.048, Figs. 3 and 5). The clinical outcomes of these two groups of patients were similar during the follow-up. The changes in segmental mobility (ΔROM) after CDA did not affect clinical outcomes in the current series of patients.

Cervical Alignment and HO

The mean postoperative C2–7 Cobb angle did not change significantly from the mean preoperative angle (12.0° ± 11.19° vs 10.8° ± 12.22°, respectively; p = 0.386). The mean postoperative C2–7 SVA also did not change significantly (1.7 cm ± 1.18 cm [postoperative] vs 1.8 cm ± 1.40 cm [preoperative], p = 0.733). Overall cervical alignment, including both C2–7 Cobb angle and SVA, did not demonstrate significant changes after 1-level CDA (Table 1).

The postoperative cervical alignment, including both C2–7 Cobb angle and SVA, did not correlate with the severity of HO formation or the clinical outcomes (i.e., neck and arm pain VAS, NDI, and JOA scores) (Tables 2 and 3). The changes in cervical alignments, including both ΔC2–7 Cobb angle and ΔSVA, also did not correlate with the severity of HO formation or the clinical outcomes. There was no statistical significance between cervical alignment parameters (C2–7 Cobb angle, C2–7 SVA, ΔC2–7 Cobb angle, and ΔSVA) and degree of HO formation (Table 2) or between cervical alignment parameters and patient-reported outcomes (i.e., neck and arm VAS, NDI, and JOA scores [Table 3]). These alignment parameters had no association with postoperative neck pain, arm pain, neck disability, or myelopathy.

In the present series, 1 (2%) of the 50 patients had intraoperative CSF leakage, which did not cause problems and required no further management. One patient (2%) had transient C-5 palsy, which was self-limited and resolved after 3 weeks. Overall, there was no need for secondary surgery (i.e., reoperation, revision, removal of implant, or conversion of arthroplasty to fusion) and no other major surgical complications such as nerve injury, permanent dysphagia or hoarseness, wound infection, or postoperative hematoma. However, a longer time is required to follow up for complications.

Discussion

Although many FDA trials have proven the effectiveness of preserving segmental mobility after CDA at approximately 7°–9° during flexion and extension for each
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level of disc replaced, it is still not clear if the extent of changes in segmental mobility affects clinical outcomes. Given the fact that the postoperative ROM averaged approximately 9° in the present study, there were variations among patients’ segmental mobility after CDA. It is possible that CDA increased ROM in some patients while reducing ROM in others, and it might affect clinical outcomes. The present study aimed to investigate the differences between the patients whose segmental mobility was increased (ΔROM > 0°) and those whose segmental mobility decreased (ΔROM < 0°). Thus, the present series analyzed 50 consecutively treated patients who underwent 1-level CDA between C-3 and C-7. This was a single-institute experience that uniformly chose an FDA-approved device, the Prestige LP artificial disc and followed up these patients for more than 24 months. The surgical indications were 1-level symptomatic and medically intractable DDD and/or spondylosis. All imaging parameters, including segmental mobility (ROM), cervical alignment (C2–7 Cobb angle), and sagittal balance (C2–7 SVA) were assessed. Additionally, the postoperative changes in these parameters, including ΔROM, ΔC2–7 Cobb angle, and ΔC2–7 SVA, were calculated and correlated with clinical outcomes, including VAS neck pain, VAS arm pain, NDI, and JOA scores.

In the present study, 2 years after CDA, the segmental mobility was well preserved at the index level (mean 9.0° ± 5.81°), and cervical alignment exhibited little change. All...
TABLE 2. Relationship between HO grade and cervical alignment parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>HO Grade</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postop C2–7 Cobb angle (°)</td>
<td></td>
<td>13.9 ± 15.94</td>
<td>9.9 ± 9.87</td>
<td>8.7 ± 10.07</td>
<td>17.3 ± 13.17</td>
<td>15.1 ± 10.27</td>
<td>0.453</td>
</tr>
<tr>
<td>ΔC2–7 Cobb angle (°)*</td>
<td></td>
<td>−2.0 ± 10.88</td>
<td>1.7 ± 8.47</td>
<td>0.9 ± 11.47</td>
<td>−1.0 ± 11.51</td>
<td>1.9 ± 7.11</td>
<td>0.918</td>
</tr>
<tr>
<td>Postop SVA (cm)</td>
<td></td>
<td>2.4 ± 0.40</td>
<td>1.4 ± 1.10</td>
<td>1.9 ± 1.24</td>
<td>1.3 ± 1.24</td>
<td>2.2 ± 1.40</td>
<td>0.255</td>
</tr>
<tr>
<td>ΔSVA (cm)*</td>
<td></td>
<td>0.6 ± 0.67</td>
<td>−0.1 ± 1.15</td>
<td>0.2 ± 0.64</td>
<td>−0.1 ± 0.89</td>
<td>−0.3 ± 1.61</td>
<td>0.490</td>
</tr>
</tbody>
</table>

Values are presented as the mean ± SD.
* ΔC2–7 Cobb angle = postoperative C2–7 Cobb angle minus preoperative C2–7 Cobb angle.
† ΔSVA = postoperative SVA minus preoperative SVA.
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and ΔSVA were not statistically significant in terms of patients’ outcome, including VAS, NDI, and JOA scores, after 1-level CDA.

A few studies have investigated the association between alignment and clinical outcomes after cervical fusion surgery. One prospective, randomized, double-blinded clinical study compared cervical sagittal alignment and clinical outcomes using a lordotic or parallel cage for fusion.36 The authors of that study concluded that there were no statistically significant differences in clinical outcome scores between the lordotic and parallel cage groups. Another study demonstrated that patients with cervical myelopathy treated by anterior corpectomy and fusion would develop more chronic neck pain if there was postoperative kyphosis present.2 A paper on posterior fusion surgery written on behalf of an international spine study group also demonstrated significant correlations between C2–7 SVA and SF-36 scores and NDI scores, but it identified no correlations between alignment and VAS scores.81 The existing evidence on whether cervical alignment affects patient outcomes is conflicting, and there is no consensus on cutoff values for these radiological parameters suggested for patients’ outcomes. Nevertheless, only selected patients (i.e., only those with disc diseases rather than facet arthropathy or deformity) among the fusion candidates should undergo CDA. For example, a patient with negative C2–7 Cobb angle should undergo ACDF even if the DDD is limited to merely 1 or 2 levels anteriorly; and since SVAs were strongly correlated with C2–7 Cobb angle,14 patients with large SVAs should also avoid CDA. The mean SVA in the present series was 1.7 ± 1.18 cm, whereas that reported by Tang et al. was 3.62 ± 1.59 cm.31 This indicates that the cervical alignment of arthroplasty-treated patients fell in a more narrow and specific range than in those patients who underwent fusion.

There were limitations to this study. It was a retrospective analysis of 50 patients who underwent 1-level CDA with Prestige LP disc. The 50 arthroplasty-treated levels were distributed unequally from C-3 to C-7; thus, the radiographic measurements could not represent every disc level or any other brand of CDA device. The changes in segmental mobility (ΔROM), for which significance was demonstrated, might be caused by the surgical techniques applied during insertion and thus might vary in different hands. Also, the imaging parameters (ROM, C2–7 Cobb angles, and SVAs) could be subject to changes, as cervical spine degeneration continues to occur during longer follow-up periods. However, this study merits analysis of consecutive single-level arthroplasty with the same inclusion and exclusion criteria used in the FDA trials. The differences in changes in mobility separated the CDA patients by the degree of degeneration, which might yield disparities in the propensity for HO development. The relatively short follow-up period, averaging 27 months, was not long enough to yield differences in other clinical outcomes. Furthermore, the T-1 slope, another common radiographic parameter for evaluation of cervical alignment, was not measured in the present series because the lateral radiographs were frequently inadequate for visualization of the entire T-1 vertebra. Future investigations of a larger number of patients, longer follow-up, and optimized radiological images are required for further corroboration of the results.

Conclusions

Segmental mobility (mean ROM) and overall cervical alignment (SVA and C2–7 Cobb angle) had no significant impact on clinical outcome after 1-level CDA. Patients with increased segmental mobility (AROM > 0°) had significantly less HO and similarly improved clinical outcomes as patients with decreased segmental mobility (AROM < 0°).

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Disclosures
The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author Contributions
Conception and design: JC Wu, HK Chang, CC Chang, Tu, Huang, Fay, PY Chang, CL Wu. Acquisition of data: JC Wu, HK Chang, CC Chang, Tu, Huang. Analysis and interpretation of data: JC Wu, HK Chang, CC Chang, Tu, Huang. Drafting the article: JC Wu, HK Chang, CC Chang, Tu, Huang, Fay, PY Chang, CL Wu. Critically revising the article: JC Wu, HK Chang, Huang, Cheng.

Reviewed submitted version of manuscript: JC Wu, HK Chang, Huang, Fay, PY Chang, CL Wu, Cheng. Approved the final version of the manuscript on behalf of all authors: JC Wu. Statistical analysis: HK Chang. Administrative/technical/material support: JC Wu, CC Chang, Tu, Huang, Fay, PY Chang, CL Wu, Cheng. Study supervision: JC Wu, Huang, Cheng.

Correspondence
Jau-Ching Wu, Department of Neurosurgery, Neurological Institute, Taipei Veterans General Hospital, Rm. 525, 17F, No. 201, Shih-Pai Rd., Sec. 2, Beitou District, Taipei 11217, Taiwan. email: jauching@gmail.com.