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Differences between 1- and 2-level cervical arthroplasty: more heterotopic ossification in 2-level disc replacement

Clinical article

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Object. The most currently accepted indication for cervical arthroplasty is 1- or 2-level degenerative disc disease (DDD) refractory to medical treatment. However, the randomized and controlled clinical trials by the US FDA investigational device exemption studies only compared cervical arthroplasty with anterior cervical discectomy and fusion for 1-level disease. Theoretically, 2-level cervical spondylosis usually implicates more advanced degeneration, whereas the 1-level DDD can be caused by merely a soft-disc herniation. This study aimed to investigate the differences between 1- and 2-level cervical arthroplasty.

Methods. The authors analyzed data obtained in 87 consecutive patients who underwent 1- or 2-level cervical arthroplasty with Bryan disc. The patients were divided into the 1-level and the 2-level treatment groups. Clinical outcomes were measured using the visual analog scale (VAS) for the neck and arm pain and the Neck Disability Index (NDI), with a minimum follow-up of 30 months. Radiographic outcomes were evaluated on both radiographs and CT scans.

Results. The study analyzed 98 levels of Bryan cervical arthroplasty in 70 patients (80.5%) who completed the evaluations in a mean follow-up period of 46.21 ± 9.85 months. There were 22 females (31.4%) and 48 males (68.6%), whose mean age was 46.57 ± 10.07 years at the time of surgery. The 1-level group had 42 patients (60.0%), while the 2-level group had 28 patients (40.0%). Patients in the 1-level group were younger than those in the 2-level group (mean 45.00 vs 48.93 years, p = 0.111 [not significant]). Proportional sex compositions and perioperative prescription of nonsteroidal antiinflammatory drugs were also similar in both groups (p = 0.227 and p = 1.000). The 2-level group had significantly greater EBL during surgery than the 1-level group (220.80 vs 111.89 ml, p = 0.024). Heterotopic ossification was identified more frequently in the 2-level group than the 1-level group (75.0% vs 40.5%, p = 0.009). Although most of the artificial discs remained mobile during the follow up, the 2-level group had fewer mobile discs (100% and 85.7%, p = 0.022) than the 1-level group. However, in both groups, the clinical outcomes measured by VAS for neck pain, VAS for arm pain, and NDI all significantly improved after surgery compared with that preoperatively, and there were no significant differences between the groups at any point of evaluation (that is, at 3, 6, 12, and 24 months after surgery).

Conclusions. Clinical outcomes of 1- and 2-level cervical arthroplasty were similar at 46 months after surgery, and patients in both groups had significantly improved compared with preoperative status. However, there was a significantly higher rate of heterotopic ossification formation and less mobility of the Bryan disc in patients who underwent 2-level arthroplasty. Although mobility to date has been maintained in the vast majority (94.3%) of patients, the long-term effects of heterotopic ossification warrant further investigation.
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Key Words • **heterotopic ossification** • **Bryan disc** • **cervical arthroplasty** • **degenerative disc disease**

Although anterior ACDF remains the gold standard for surgical management of DDD of the cervical spine,[5,10,13] cervical arthroplasty has emerged and become popular in the past decade.[6,11,21,23,24,26] Several artificial discs have been tested in large-scale, prospective, randomized, and controlled trials by the US FDA-IDE to compare with ACDF.[2,4,9,16,19] These studies, in which the minimum follow-up period was 2 years, have demonstrated that cervical arthroplasty is a safe and effective alternative to ACDF for 1-level cervical spondylosis or DDD.

The most currently accepted indication for cervical arthroplasty is 1- or 2-level DDD refractory to medical treatment.[3,17,18,28] However, the aforementioned FDA-IDE trials

Abbreviations used in this paper: ACDF = anterior cervical discectomy and fusion; DDD = degenerative disc disease; EBL = estimated blood loss; FDA-IDE = FDA investigational device exemption; HO = heterotopic ossification; NDI = Neck Disability Index; NSAID nonsteroidal antiinflammatory drug; VAS = visual analog scale.

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were all specifically designed to investigate the results of 1-level cervical arthroplasty. On the other hand, 2-level cervical spondylosis or DDD is also very commonly encountered during clinical practice.[25] Nevertheless, there is a lack of reports in the literature comparing the differences between 1- and 2-level cervical arthroplasty.

In the present study we aimed to investigate the differences between 1- and 2-level cervical arthroplasty in which the Bryan artificial disc (Medtronic Spine and Biologics, Memphis, TN) was used. We compared demographic data, clinical outcomes, and the radiographic findings with specific analysis of the incidence of HO determined by CT. This is the first study to specifically address the diversity of 1- and 2-level/multiple-level cervical DDD treated by arthroplasty.

Methods

Inclusion and Exclusion Criteria

We reviewed data obtained in consecutive patients who underwent 1- and 2-level cervical arthroplasty with the Bryan disc between October 2006 and March 2009 at our institutions. The study was approved by the institutional ethics committee. Surgical indications included radiculopathy and/or myelopathy caused by 1- or 2-level cervical DDD. Loss of segmental mobility (resulting from severe spondylotic osteophytes or facet joint degeneration), target segmental instability (> 3 mm translational instability or > 15° angular motion), collapse of the intervertebral disc space by 50% of its normal height, incompetent facet joints, ossification of posterior longitudinal ligament, and diffuse idiopathic skeletal hyperostosis[27] were not considered candidates for cervical arthroplasty. Patients with osteoporosis (T score less than –2.5), malignancy, metabolic bone disease, infection or severe systemic diseases, and traumatic disc disease with ligament injury were also excluded.

Operative Techniques and Perioperative Management

We routinely performed generous decompression of neural elements (that is, resection of the bilateral uncovertebral joints, including the asymptomatic side, and the posterior longitudinal ligament) prior to insertion of the Bryan artificial disc. Also, we always applied copious irrigation with normal saline during the entire process of milling (that is, endplate preparation) and drilling. Aggressive hemostasis was also achieved intraoperatively with routine placement of a drainage catheter before the wound closure.

Perioperative nonsteroidal NSAIDs were routinely prescribed if not otherwise contraindicated by chronic renal insufficiency, acute gastritis, or a history of peptic ulcer. No neck collar therapy was suggested, and every patient was encouraged to undertake early postoperative ambulation. The surgical techniques and management policy were consistent with, and have been described in, our previously published report.[25]

Clinical and Radiographic Evaluations

All data were prospectively collected. Standard anteroposterior, lateral, and flexion-extension radiographs were taken within 5 days of surgery and at approximately 3, 6, 12, and 24 months postoperatively. Clinical outcome assessment was made during the same clinical visit by 2 special nursing assistants using the VAS and NDI under physicians' supervision. Segmental mobility at the index level was determined using the quantitative measurement analysis software, SmartIris (Taiwan Electronic Data Processing Co.).

Radiographic interpretations, including segmental mobility and HO formation, were made by independent radiologists and 2 neurosurgeons. Multidetector CT scans reconstructions of the cervical spine were acquired at follow-up after more than 12 months postoperatively to detect and grade the HO (Figs. 1–3). For any ambiguity or discrepancy, the CT scans were used for the final determination of HO. The grading of HO was defined by the classification proposed by McAfee et al.[14] Although the classification system was originally proposed for the lumbar artificial disc, it is the best currently available grading system for HO after spinal arthroplasty. The absence of a range of motion of greater than 3° on dynamic radiographs was defined as immobile or loss of arthroplasty function.

Statistical Analysis

All statistical analyses were performed using the SPSS software (SPSS Inc.). Independent t-tests and paired t-tests were used for continuous variables, and the Fisher exact test was applied for categorical data. A p value of 0.05 was considered statistically significant. In text and tables, the mean value is presented ± the SD.

Results

Overall Demographics

A total of 87 consecutive patients who underwent 1- or 2-level cervical arthroplasty with the Bryan disc were enrolled in the present study. Seventy patients (80.5%) had complete radiological evaluations (including CT scans) and clinical follow-up exceeding 2.5 years and were analyzed. Seventeen patients (19.5%) were lost to follow-up or had inadequate evaluations (including those who refused to undergo CT). Among the 70 patients, there were 22 females (31.4%) and 48 males (68.6%) whose mean age at the time of surgery was 46.57 ± 10.07 years.

There were 42 patients (60.0%) who underwent 1-level Bryan disc replacement and 28 (40.0%) who had 2-level Bryan disc replacement. The mean follow-up duration was 46.21 ± 9.85 months (Table 1).

The distribution of the arthroplasty levels is summarized in Table 2. For 1-level surgery, C5–6 was the most frequent level (66.7%), whereas C4–6 accounted for the most frequently treated levels (60.7%) in 2-level arthroplasty.

One-Level Versus Two-Level Cervical Arthroplasty

Among the 70 patients in whom findings were analyzed, 42 (60.0%) were in the 1-level group and 28 (40.0%) were in the 2-level group. There were 98 overall levels treated with Bryan discs (42 one-level and 56 two-level, 42.9% and 57.1% per disc level, respectively) (Table 3).

The mean age of patients in the 1-level group (45.00

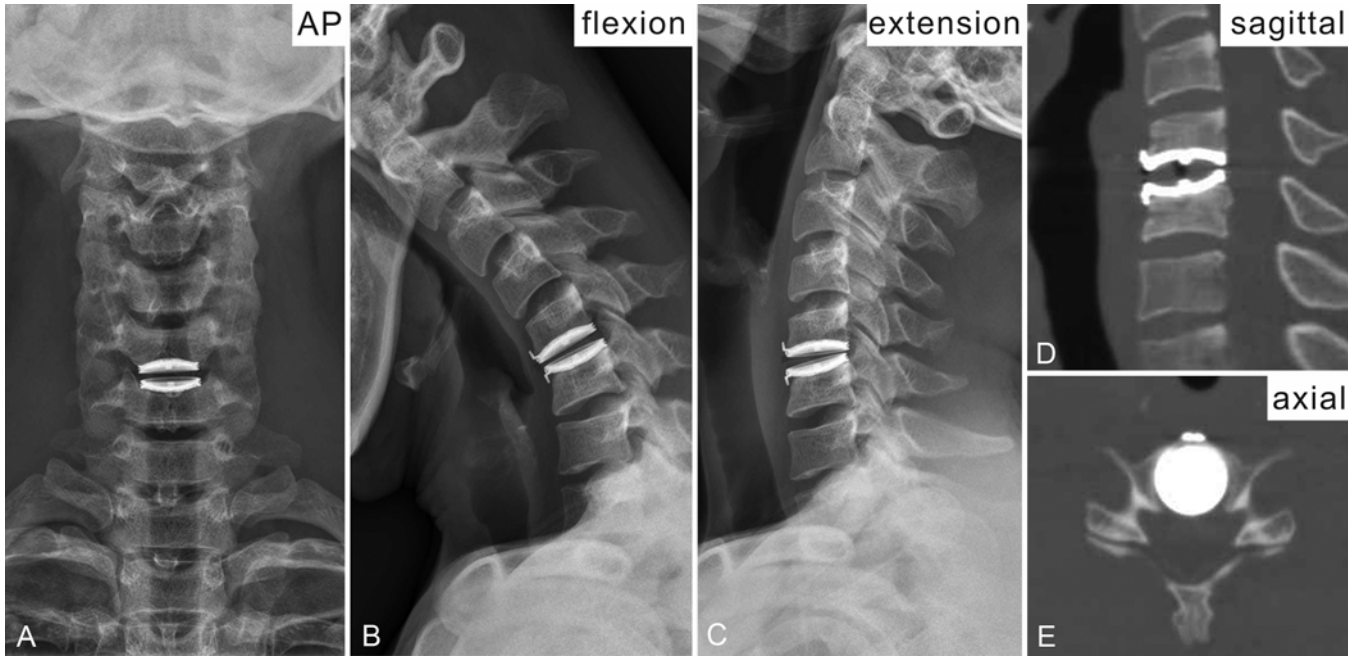

Fig. 1. Radiographs **(A–C)** and CT scans **(D and E)** obtained in a 23-year-old man who underwent Bryan arthroplasty at C5–6. There was no HO formation at 24 months postoperatively. AP = anteroposterior.

± 11.22 years) was lower than that in the 2-level group (48.93 ± 7.65 years) by almost 4 years, but this difference did not achieve statistical significance ($p = 0.111$). Proportional sex compositions in both groups were also not significantly different ($p = 0.227$). The perioperative prescription of NSAIDs was similar in both groups ($p = 1.000$).

The 2-level group had significantly greater EBL during arthroplasty than the 1-level group (220.80 ± 218.95 vs 111.89 ± 77.63 ml, respectively; $p = 0.024$). The average increase in EBL for the 2-level surgery was almost twice that for the 1-level surgery, as one would expect. Both thin-cut CT scans and radiographs were combined for detection of HO formation. Overall, HO was found in 38 patients (54.3%). The 1-level group had 17 patients (40.5%) in whom HO was identified around the arthroplasty device. Moreover, it must be noted that the incidence of HO was significantly higher in the 2-level group

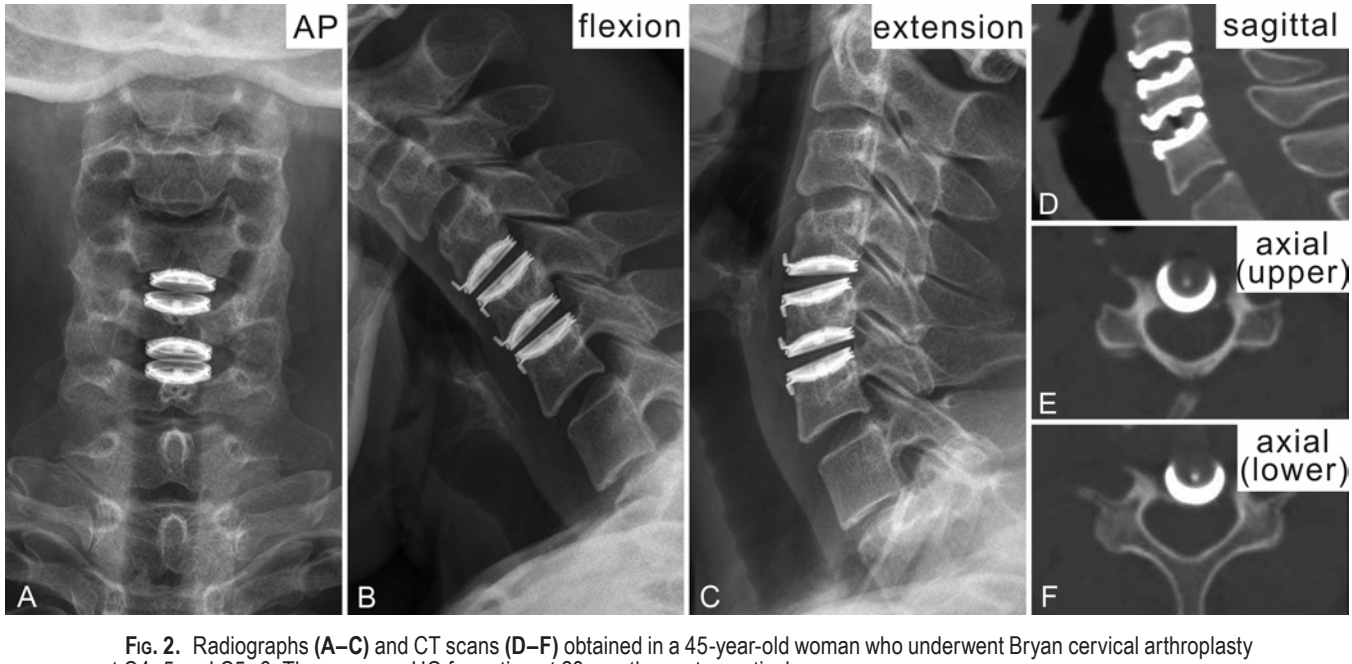

Fig. 2. Radiographs **(A–C)** and CT scans **(D–F)** obtained in a 45-year-old woman who underwent Bryan cervical arthroplasty at C4–5 and C5–6. There was no HO formation at 23 months postoperatively.

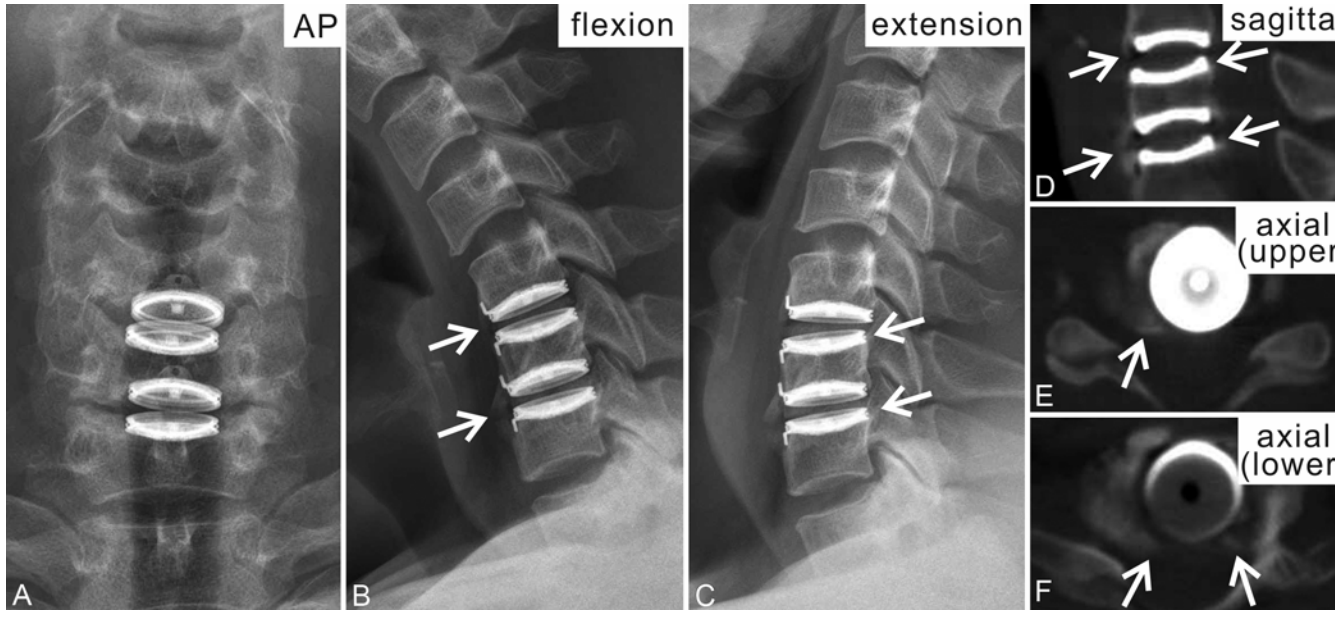

Fig. 3. Radiographs **(A–C)** and CT scans **(D–F)** acquired in a 34-year-old man who underwent Bryan cervical arthroplasty at C5–6 and C6–7. The *arrows* indicate the formation of HOs at 24 months postoperatively.

(21 patients) than in the 1-level group (75.0% vs 40.5%, respectively; p = 0.009).

Despite HO formation in many of these patients, most (94.3%) of the artificial discs in this series remained mobile. Significantly more mobile artificial discs were found in the 1-level group than the 2-level group (100% vs 85.7%, p = 0.022) (Table 3).

The clinical outcomes measured by VAS for neck pain, VAS for arm pain, and NDI significantly improved after surgery in both treatment groups. There were also no significant differences between the 1-level and 2-level groups at each time point of evaluation (that is, preoperatively, at 3, 6, 12, and 24 months postoperatively) (Fig. 4). Furthermore, these clinical outcomes were not affected by the development of HO at each follow-up evaluation (Fig. 5). The formation of HO had no adverse impact, at least for the 2-year follow-up period.

TABLE 1: Clinical and demographic characteristics in 70 patients who underwent cervical arthroplasty

Characteristic	Value (%)
sex	
male	48 (68.6)
female	22 (31.4)
mean age (years)	46.57 ± 10.07
mean follow-up (mos)	46.21 ± 9.85
mean EBL (ml)	155.81 ± 159.12
operated level	
1-level	42 (60.0)
2-level	28 (40.0)
NSAID prescription	
yes	55 (78.6)
no	15 (21.4)

To date, no secondary surgery (for example, revision, removal, fusion, or reoperation) has been performed in the current series. One patient had postoperative hoarseness that resolved 6 months after surgery, and another patient, in whom a cerebrospinal fluid leak occurred intraoperatively, was free of clinical symptoms or wound complications. No other complications (for example, instrument failure, wound infection, or worsened neurological symptoms) were found in the present series. Also, there have been no symptomatic adjacent-segment diseases identified to date (the longest follow-up duration was > 5 years).

Discussion

In this study we analyzed 98 Bryan artificial discs in 70 (of 87 consecutive) patients with symptomatic cervical DDD who underwent 1- or 2-level arthroplasty. The mean clinical follow-up was 46.21 ± 9.85 months, with a follow-up rate of 80.5%. The 1-level group was composed of 42 patients, whereas the 2-level group was composed of 28 patients. Patients in the 1-level group were a mean of 3.93 years younger than those in the 2-level group, but the difference was not statistically significant. Other demograph-

TABLE 2: Level distributions

Arthroplasty Span	Level	No. of Patients (%)
1-level	C3–4	6 (14.3)
	C4–5	6 (14.3)
	C5–6	28 (66.7)
	C6–7	2 (4.7)
2-level	C3–4, C5–6	1 (3.6)
	C3–5	1 (3.6)
	C4–6	17 (60.7)
	C5–7	9 (32.1)

TABLE 3: Comparison of variables between the 1- and 2-level groups

Variable	Total (%)	Group (%)		p Value
		1-Level	2-Level	
no. of patients	70	42	28	
age (years)	46.57 ± 10.07	45.00 ± 11.22	48.93 ± 7.65	0.111
sex				0.227
male	48 (68.6)	26 (54.2)	22 (45.8)	
female	22 (31.4)	16 (72.7)	6 (27.3)	
EBL (ml)	155.81 ± 159.12	111.89 ± 77.63	220.80 ± 218.95	0.024*
NSAIDs				1.000
yes	55 (78.6)	33 (78.6)	22 (78.6)	
no	15 (21.4)	9 (21.4)	6 (21.4)	
HO formation				0.009*
yes	38 (54.3)	17 (40.5)	21 (75.0)	
no	32 (45.7)	25 (59.5)	7 (25.0)	
mobility†				0.022*
yes	66 (94.3)	42 (100)	24 (85.7)	
no	4 (5.7)	0 (0)	4 (14.3)	

* Statistically significant at $p < 0.05$.

† Mobility was defined as range of motion at the index level of Bryan disc greater than 3° on dynamic lateral radiographs.

ic features, such as sex composition and perioperative prescription of NSAIDs, were similar in both groups. As expected, the 2-level group had significantly greater EBL during surgery than the 1-level group. The VAS neck pain scores, VAS arm scores, and NDI values were significantly improved after surgery compared with preoperatively in both groups. Moreover, there were no significant intergroup differences at each time point of evaluation (that is, preoperatively, at 3, 6, 12, and 24 months postoperatively) regarding the treated levels or the formation of HO (Figs. 4 and 5). However, the incidence of HO was significantly higher in the 2-level group than that the 1-level group (75.0% vs 40.5%, $p = 0.009$), and significantly more mobile Bryan discs were found in the 1-level group than the 2-level group (100% vs 85.7%, $p = 0.022$).

In the present series, the midterm clinical outcomes (mean follow-up duration 46 months) in 1- and 2-level groups were very similar. Despite the significantly more frequent formation of HOs in patients with 2-level disease, clinical correlation was still vague. However, 2-level cervical DDD requiring surgical treatment usually implies substantially spondylotic changes of the cervical spine. It is reasonable to infer that 2-level cervical spondylosis was in a more advanced degenerative stage than the 1-level cases. More importantly, the higher incidence of HO in the 2-level group may also suggest that the degeneration continued even after cervical arthroplasty. Thus, the implanted 2-level arthroplasty devices might be more vulnerable to adverse events related to continuous degeneration. Further investigation with a longer-term follow-up is required to clarify this issue.

The best candidates for cervical arthroplasty are young patients with a 1-level herniated disc causing cervical radiculopathy and no facet joint abnormality. The FDA-IDE trials have successfully demonstrated the efficacy and safety of 1-level cervical arthroplasty compared

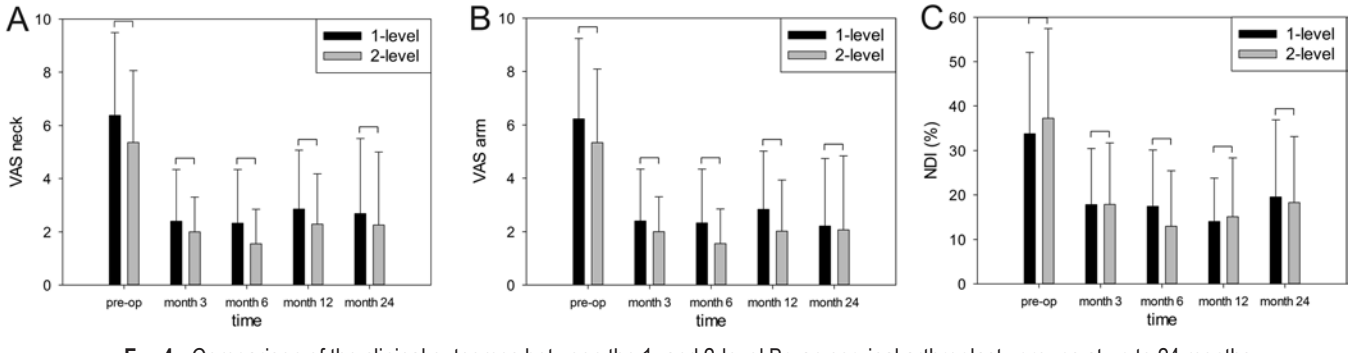

Fig. 4. Comparison of the clinical outcomes between the 1- and 2-level Bryan cervical arthroplasty groups at up to 24 months postoperatively. In both groups the VAS neck pain, VAS arm pain, and NDI scores all significantly improved after surgery compared with preoperative scores. Moreover, there were no significant intergroup differences at each time point of evaluation (that is, preoperatively, at 3, 6, 12, and 24 months postoperatively).

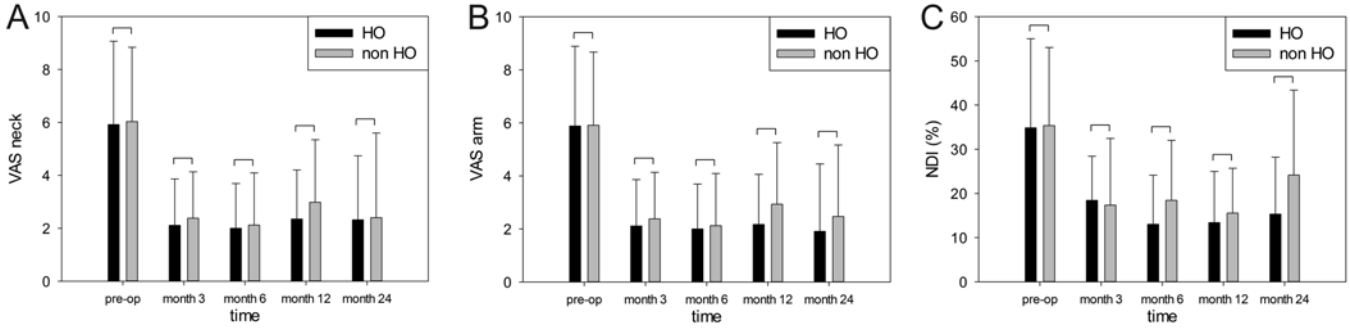

Fig. 5. Comparison of the clinical outcomes between the patients with and without the formation of HOs after Bryan cervical arthroplasty. In both groups the VAS neck pain, VAS arm pain, and NDI scores were significantly improved after surgery compared with preoperative scores. Moreover, there were no significant intergroup differences at each time point of evaluation (that is, preoperatively, at 3, 6, 12, and 24 months postoperatively).

with ACDF.[2,3,7,9,16,19] There is no doubt that not all patients are candidates for arthroplasty, but nevertheless there is this option for patients with 1-level cervical disc disease and competent facets to undergo arthroplasty. Given the successful experiences with 1-level diseases, 2-level arthroplasty makes intuitive sense and appears to be very appealing in the management of cervical DDD, especially with preservation of segmental spinal motion. However, due to the lack of large-scale, randomized, and controlled trials, the extension of this option of cervical arthroplasty to treat 2-level or more levels of cervical DDD should be considered with caution. Although the HO reported is often asymptomatic, the long-term effects of this unwanted bony growth are unknown.

The true cause of HO after cervical arthroplasty remains unclear. Previously published papers have suggested that the risk factors for HO may include old age, male sex, surgical indications, techniques, and multilevel arthroplasty.[12,15,18,22,25] In the literature, there is also quite a disparity in the reported incidence rates of HO after cervical arthroplasty. The formation of HO has been reported from none to more than two-thirds in various series of cervical artificial discs. In studies of ProDisc-C arthroplasty high rates have been reported of HO: 68% in 60 levels and 66.2% in 77 levels.[15,22] The authors of a report on Mobi-C arthroplasty indicated a rate of 67.1% in 76 treated levels.[1] For Bryan disc placement, the reported HO rates have included 48.1% in 52 levels, 29% in 59 levels, and 17.8% in 90 levels.[8,12,25] Nevertheless, in the 4 largest multicenter, prospective, randomized, and controlled trials by the US FDA-IDE for PRESTIGE ST, Bryan, ProDisc-C, and Kineflex-C, the incidence rate of HO with osseous fusion was 1 of 276, 0 of 242, 3 of 103, and approximately 1% of 136 patients, respectively.[2,4,9,16,19] This huge discrepancy in the reported incidences can be attributed to differences in management protocols (that is, perioperative use of NSAIDs, selection of patients, or techniques of insertion), method of HO determination (CT is certainly more sensitive than plain radiography), and device related (that is, biomechanics and composite materials).[20]

Plain radiography is the most common imaging modality for arthroplasty follow-up, but it may not be sufficiently sensitive to pick up small HOs around the neural foramen. In our previous study, we described concordance and discrepancy between CT scans and radiographs for determining HO.[25] It is not ideal to grade HO after cervical arthroplasty using the McAfee classification[14] because it was originally designed for lumbar arthroplasty. A specifically tailored classification system for HO in cervical arthroplasty would be helpful to reduce the discrepancies in its identification. Also, a CT scan is perhaps necessary for detection of those tiny HOs that might be overlapped by the metallic opacity on plain radiographs.

There are several limitations of this study. The relatively small sample size and short follow-up period may be insufficient to detect the clinical outcome differences in the 2 groups. However, the results of these standardized outcome measurements were comparable with other published reports. A larger sample size and longer follow-up duration are necessary to determine whether the clinical improvement in the 2-level group would remain as good as the 1-level group. Also, in the present study the heterogeneity between the two levels in the 2-level group could have been overlooked. This disparity, again, could be better addressed by having a larger sample size. Moreover, there is a gray zone between 1- and 2-level DDD requiring surgical treatments. In some scenarios, inclusion of an adjacent-level disc disease into the operation is surgeon dependent and can be arbitrary. This ambiguity might be even more prominent in arthroplasty than in fusion surgery.

There are several characteristics of this study that merit notice. First, CT scans were used for the determination of HO in every patient. Unlike other studies based on plain radiographs only, the HO in all 70 of our patients was graded on CT scan. Thus, the HO was analyzed with significantly higher sensitivity and specificity. Second, this is the first study focusing on a comparison of 1- and 2-level Bryan cervical arthroplasty with an average follow-up of almost 4 years. The findings may shed light on our understanding of the effects of arthroplasty in multilevel cervical spondylosis. Third, a uniform type of arthroplasty device (Bryan) was implanted using the same technique by the 2 senior surgeons (W.H. and H.C.) with similar perioperative management. The confounding covariates in clinical practice were thus reduced. However, there is no doubt that further investigations are necessary to corroborate the findings and improve the understanding of arthroplasty as a treatment for multilevel cervical DDD.

Conclusions

Clinical outcomes after 1- and 2-level cervical arthroplasty were similar at 46 months after surgery. However, there was a significantly higher rate of HO formation and less Bryan disc mobility in patients who underwent 2-level arthroplasty. Although the vast majority (94.3%) of arthroplasty-treated patients have maintained their disc mobility to date, the long-term effects of HO warrant further investigation.

Disclosure

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 to the study and manuscript preparation include the following. Conception and design: Ko, JC Wu. Acquisition of data: Huang, Tsai, Fay, Tu, CL Wu. Analysis and interpretation of data: Ko, Tsai, Tu, CL Wu. Drafting the article: JC Wu, Huang, Tsai, Fay, Tu, CL Wu. Critically revising the article: all authors. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Ko. Statistical analysis: Ko, Tsai. Administrative/technical/material support: JC Wu, Huang, Cheng. Study supervision: Huang, Cheng.

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