

Zero-profile Anchored Spacer Reduces Rate of Dysphagia Compared With ACDF With Anterior Plating

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Study Design: Retrospective cohort study.

Objective: To study clinical and radiologic outcomes after anterior cervical discectomy and fusion (ACDF) using a zero-profile anchored spacer compared with a standard interposition graft with anterior plating.

Summary of Background Data: Anterior plating increases fusion rates in ACDF but is associated with higher rates of postoperative dysphagia. Reduction of plate thickness or zero-profile fixation of the interposition graft have been suggested to decrease the incidence of postoperative dysphagia.

Methods: Retrospective cohort study of 70 consecutive patients of whom the first 35 patients underwent ACDF with anterior plating and the remaining patients received an LDR device. Patient demographics, operative details, neurological impairment, complications, and radiographic imaging were reviewed. Dysphagia occurring in the immediate postoperative period and lasting for > 3 months was recorded.

Results: Both the zero-profile anchored spacer and a standard interposition graft with anterior plating resulted in improvement of neurological outcome at a mean follow-up time of 13.9 months. Fusion rates were found to be similar between ACDF with anterior plating (96.0%) and LDR (95.2%). Evaluation of postoperative radiographs revealed significantly more swelling of the prevertebral space (20.4 ± 0.9 mm) after implantation of an anterior locking plate compared with a zero-profile device (15.6 ± 0.7 mm, $P < 0.001$). This difference remained significant at 6-month follow-up ($P = 0.035$). Seven patients (20%) with ACDF and plating complained about swallowing difficulties beyond 3 months compared with only 1 patient with the LDR device ($P = 0.027$). The severity of dysphagia was mild in all but 2 patients. Both patients with moderate and severe swallowing difficulties had undergone ACDF with anterior plating.

Conclusions: Zero-profile anchored spacers lead to similar clinical and radiographic outcomes compared with ACDF with plating and may carry a lower risk of postoperative dysphagia.

Key Words: cervical spine, spondylosis, ACDF, zero-profile spacer, dysphagia, LDR

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Cervical spondylosis constitutes a major cause for myelopathy and radiculopathy. If conservative therapy fails, patients frequently undergo anterior cervical discectomy and fusion (ACDF). Since the initial description of the procedure by Smith and Robinson as well as by Cloward,^{1,2} many technical modifications have been reported. Currently, the vast majority of surgeons use allograft, synthetic material, or metallic cages as interpositions grafts, whereas the use of autologous iliac bone graft has greatly diminished due to donor-site morbidity.^{3,4} Frequently interposition grafts are combined with anterior locking plates. Anterior plates enhance rigidity of fixation and decrease risk of nonunion, which may lead to kyphosis and pseudoarthrosis, particularly in multilevel cases.^{5–9} Moreover, anterior plating may also reduce the risk of graft extrusion.¹⁰ However, addition of an anterior plate to the construct is also associated with increased risk of complications such as screw or plate dislodgement, soft-tissue injury, and dysphagia.^{11,12} The reported rate of postoperative transient dysphagia after ACDF ranges from 2% to 67%.^{13–21} In the majority of cases dysphagia resolves within the first 3 months^{13,22}; however, in 12.5%–35.1% of patients dysphagia persists for > 3 months.^{13,22,23} Anterior plates may exacerbate postoperative dysphagia by greater esophageal retraction required for implantation of the device and by impingement of the esophagus once in place.²⁴ In order to avoid irritation of the esophagus, interposition grafts with zero-profile plates for fixation have been developed. A recent report indicates a low rate of dysphagia in a cohort of patients who underwent implantation of such a device.²⁵

The current study aims to compare clinical and radiographic outcome as well as complications of patients who underwent ACDF with anterior plating compared with patients who receive zero-profile anchored spacers (LDR).

METHODS

Patient Population

Retrospective analysis of a prospectively collected database including 70 consecutive patients who underwent

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ACDF between October 2007 and April 2011 at Weill Cornell Medical College, New York Presbyterian Hospital, New York, NY. The patient cohort had a mean age of 54.1 years (range, 29–82) and was comprised of 34 males and 36 females (Table 1). The average body mass index was 28.1 (range, 18.1–59.4). Procedures were most commonly performed at the level of C5/6 and C6/7. Thirty-five patients who received an LDR biomechanical device between June 2009 and April 2011 were compared with 35 patients who received a conventional intervertebral spacer with anterior plating between October 2007 and June 2009.

Epidemiological data, location of pathology, levels of fixation, surgery time, estimated blood loss, length of hospital stay, complications, and follow-up data were collected. Preoperative and postoperative neurological impairment was assessed using the Nurick²⁶ and the modified Japanese Orthopaedic Association score (JOA).^{27,28} The presence of dysphagia was evaluated at postoperative follow-up of 2 weeks and 3–6 months after the procedure. Severity of dysphagia was graded as none, mild, moderate, or severe (Table 2).^{13,23} The null hypothesis of the current study was that there is no difference between radiographic and clinical parameters of patients who received either the LDR device or an interposition graft with anterior plating.

Operative Procedure

Patients were intubated using general endotracheal techniques. The patient remained supine on the operating room table. Patients received antibiotics within 1 hour of incision. Lateral fluoroscopy was used for localization of the appropriate cervical level and during placement of instrumentation. A horizontal curvilinear incision was

TABLE 1. Patient Characteristics

Characteristics	Total	LDR	Non-LDR	P
Total no. patients	70	35 (50.0%)	35 (50.0%)	NS
Sex				
Male	34 (48.6%)	16 (45.7%)	18 (51.4%)	NS
Female	36 (51.4%)	19 (54.3%)	17 (48.6%)	
Age (y)	54.1 ± 1.3	56.8 ± 1.6	51.5 ± 2.0	0.043*
BMI	28.1 ± 1.0	28.0 ± 1.3	28.2 ± 1.4	NS
Level of pathology				
C3–C4	2	2	0	NS
C3–C5	5	2	3	
C3–C6	2	1	1	
C4–C5	6	4	2	
C4–C6	15	9	6	
C4–C7	1	1	0	
C5–C6	12	4	8	
C5–C7	14	6	8	
C6–C7	10	4	6	
C6–T1	1	1	0	
C7–T1	2	1	1	
Hospital stay (d)	1.2 ± 0.1	1.2 ± 0.2	1.2 ± 0.2	NS
Follow-up time (mo)	13.9 ± 1.3	13.0 ± 1.6	14.8 ± 2.1	NS

Continuous variables are shown as mean ± SEMs and categorical variables as total number (percentages).

*Assessed by the Student *t* test.

BMI indicates body mass index; NS, not significant.

TABLE 2. Dysphagia Score

Severity	Symptoms	
	Liquid	Solid
None	None	None
Mild	None	Rare
Moderate	None or rare	Occasionally (only with specific food)
Severe	None or rare	Frequent (majority of solids)

made in a skin crease from the midline to the anterior border of the sternocleidomastoid muscle. After careful soft tissue dissection, the carotid artery was retracted laterally and the esophagus and trachea were mobilized medially. Once the prevertebral space was entered, the medial aspect of the longus coli muscles were dissected off the vertebral bodies using a guarded tip bovie and self-retaining retractors were placed. Distraction pins were placed under fluoroscopic guidance into the target cervical vertebrae. Distraction was applied across the interspace. Discectomy and removal of osteophytes were performed using the operating room microscope. Briefly, an 11-blade was used to perform an annulotomy. Discectomy was done using straight curettes and pituitary rongeurs. Osteophyctomy was accomplished using a high-speed drill. The posterior longitudinal ligament was resected using Kerrison rongeurs. Before insertion of interposition grafts, vertebral endplates were prepared using the high-speed drill. In the current series, half of the patients received an LDR biomechanical cervical spacer, which was anchored in the cephalad and caudal vertebral body by curved blades. The other half received a DePuy carbon-fiber cage (BENGAL, DePuy Synthes) combined with an anterior plate (SKYLINE, DePuy Synthes). The wound was irrigated and closed in the standard manner. Patients received standard postoperative care including postoperative antibiotics for 24 hours, appropriate analgesic medication, as well as gastric ulcer and deep venous thrombosis prophylaxis.

Radiographic Evaluation

Plain lateral postoperative cervical x-rays were used to evaluate cervical prevertebral soft tissue immediately postoperatively and at 6 months after the procedure. X-rays were obtained in a “near-neutral” position of the neck. The cervical prevertebral soft tissue was measured in the midportion of the fusion construct. Measurements were recorded to the nearest half millimeter. The occurrence of bony fusion was assessed on anteroposterior (AP) and lateral cervical spine x-rays 6 months after surgery. Trabecular bridging across the bone-graft interface and absence of radiolucent gaps between graft and vertebral endplate were radiographic criteria for fusion.

Statistical Analysis

Continuous variables in the result section as well as in Tables 2–4 are shown as mean ± SEMs. Differences between 2 treatment groups were assessed utilizing the Student *t* test. Repeated measurements were compared with a paired sample *t* test. For comparisons of mean

TABLE 3. Operative Details

Details	Total	LDR	Non-LDR	P
EBL (mL)	78.9 ± 11.8	53.8 ± 4.3	103.3 ± 22.3	0.035*
Operative time (min)	108.3 ± 3.7	107.1 ± 4.5	109.4 ± 5.7	NS
Levels of fusion				
1	34 (48.6%)	17 (48.6%)	17 (48.6%)	NS
2	33 (47.1%)	15 (45.7%)	17 (48.6%)	
3	3 (4.3%)	2 (5.7%)	1 (2.9%)	

Continuous variables are shown as mean ± SEMs and categorical variables as total number (percentages).

*Assessed by the Student *t* test.

EBL indicates estimated blood loss; NS, not significant.

values mean differences and 95% confidence intervals (CIs) are given. Categorical variables of interest are depicted as total numbers and percentages (in parentheses). Differences of categorical variables were assessed using the χ^2 test. Statistical significance levels were designated * $P < 0.05$, ** $P < 0.01$, and *** $P < 0.001$. All analyses were carried out using appropriate statistical software (SPSS version 19.0.0.2; SPSS Inc., Chicago, IL).

RESULTS

Treatment Groups

Our patient cohort consisted of 2 treatment groups: one group received a zero-profile LDR implant and the other group underwent ACDF with anterior plating. Patient characteristics were very similar among the 2 treatment groups (Table 1) except for higher mean age of patients receiving LDR implants. Severity of preoperative neurological impairment was similar in both groups (Fig. 1). Thus, the preoperative Nurick score was 0.7 (range, 0–3) in patients receiving LDR and 0.5 (range, 0–2) in patients undergoing ACDF with anterior plating. Likewise, JOA scores were comparable in both groups (LDR: 13.5; range, 9–16 and ACDF with anterior plating: 13.8; range, 12–16).

Surgical Details

The vast majority of patients (95.7%) underwent either 1-level or 2-level ACDF (Table 3), whereas only 3 (4.3%) patients underwent 3-level procedures. Average blood loss was low in our patient cohort (mean 79.4 mL; range, 20–500). Blood loss was slightly less in patients who received LDR implants compared with patients with ACDF with

anterior plating ($P = 0.037$; mean difference 49.6 mL; 95% CI, 3.4–95.7 mL). Operative times were similar between the 2 surgical groups. As expected, multi-level procedures lasted longer compared with single-level procedures (3-level: 144.0 ± 23 min, 2-level 121.1 ± 5.5 min, and single-level 93.6 ± 3.7 min). There were no intraoperative complications. Patients left the hospital after an average stay of 1.2 days (range, 0–7).

Radiographic Outcome

All patients underwent AP and lateral cervical spine x-rays either on the day of surgery or the day after. Postoperative imaging confirmed appropriate placement of the instrumentation in all patients. Radiographic analysis of the prevertebral space was performed using lateral cervical spine x-rays. On postoperative radiographs, there was significantly less prevertebral space swelling in patients who received the zero-profile LDR device compared with patients who underwent ACDF with anterior plating. Thus, the prevertebral space was on average 15.6 ± 0.7 mm in patients who received the LDR device compared with 20.4 ± 0.9 mm in patients with ACDF and plating ($P < 0.001$; mean difference 5.0 mm; 95% CI, 2.8–7.2 mm). For further analysis, prevertebral space measurements were stratified according to the level of instrumentation (Fig. 2). The most pronounced differences of prevertebral space swelling were seen in constructs that spanned C5/6 and C6/7, whereas the differences in upper cervical levels did not reach statistical significance. Six months after the procedure, swelling of the prevertebral space decreased in both surgical groups. The prevertebral space was on average 11.8 ± 0.6 mm in patients with LDR compared with 13.7 ± 0.7 mm in patients who underwent ACDF with anterior plating ($P = 0.035$; mean difference 1.9 mm; 95% CI, 0.14–3.7 mm). Bony fusion rates were similar in both groups (LDR: 95.2%; ACDF with anterior plating: 96.0%).

Clinical Outcome and Complications

ACDF were generally well tolerated. Both, patient groups reported partial relief of preoperative symptoms. Patients who underwent implantation of the LDR device experienced significant improvement of the Nurick score ($P = 0.023$; mean difference 0.14; 95% CI, 0.02–0.26) and JOA score ($P < 0.001$; mean difference 2.1; 95% CI, 1.7–2.6) compared with preoperative values (Fig. 1).

TABLE 4. Complications

Complications	Total	LDR	Non-LDR	P
Swallowing difficulties (< 3 mo)	25 (35.7%)	11 (31.4%)	14 (40.0%)	NS
Swallowing difficulties (> 3 mo)	9 (12.9%)	1 (2.9%)	7 (20.0%)	0.027*
CSF leak	2 (2.8%)	1 (2.9%)	1 (2.9%)	NS
New neurological deficit	1 (1.4%)	0 (0.0%)	1 (2.9%)	NS
Paraspinal abscess	1 (1.4%)	1 (2.9%)	0 (0.0%)	NS
Adjacent level disease	2 (2.8%)	2 (5.8%)	0 (0.0%)	NS

Categorical variables are shown as total number (percentages).

*Assessed by the χ^2 test.

CSF indicates cerebrospinal fluid; NS, not significant.

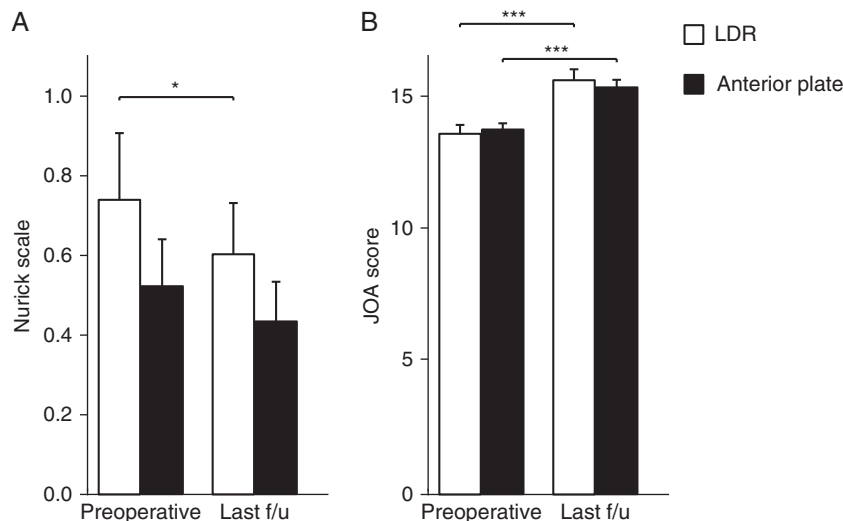


FIGURE 1. Bar graphs depict Nurick (A) and JOA scores (B) before surgery and at the time of last follow-up in patients who underwent implantation of LDR or ACDF with anterior plating. Repeated measurements were compared with a paired sample *t* test and levels of significance are designated with asterisks (* $P < 0.05$ and *** $P < 0.001$). ACDF indicates anterior cervical discectomy and fusion; JOA, Japanese Orthopaedic Association; f/u, follow-up.

Similar neurological improvements were recorded in patients who underwent ACDF with anterior plating. These patients had a trend toward a better Nurick score ($P = 0.083$; mean difference 0.86; 95% CI, -0.12 to 1.83) and significantly improved JOA score ($P < 0.001$; mean difference 1.6; 95% CI, 1.20–2.06) at the time of last follow-up compared with preoperative values. Although recovery of neurological function was similar in both surgical groups, we found a marked difference in postoperative dysphagia. Transient postoperative dysphagia (< 3 mo) was found in 31.4% of patients with LDR and 40% of patients with ACDF with anterior plating. Although complaints of dysphagia persisted beyond 3 months in only 1 patient who received the LDR device, they were recorded in 7 patients (20%) who underwent ACDF with anterior plating. Thus, dysphagia was significantly more frequent in patients with ACDF and anterior plating compared with patients who receive the LDR device ($P = 0.027$). The severity of dysphagia lasting > 3 months was in the vast majority of patients mild. One patient with an LDR graft experienced rare events of swallowing difficulties. Five patients who underwent ACDF with anterior plating experienced mild dysphagia lasting > 3 months after the surgery. Another patient had moderate dysphagia with difficulties swallowing liquid. One patient with ACDF and anterior plating suffered from severe dysphagia with frequent swallowing difficulties eating solid food. He underwent a swallow evaluation that revealed partial aspiration of food. We encountered 2 cases of intraoperative cerebrospinal fluid leak in our current series. Both of these leaks were successfully repaired with small muscle grafts obtained from the longus colli muscle followed by dura seal. One patient experienced severe right upper and lower extremity weakness after a C5–C7 ACDF with anterior plating.

This patient required acute rehabilitation and eventually recovered almost fully. Ten months after the procedure, he ambulated with a cane and experienced minimal residual weakness in his right lower extremity. One patient who received an LDR suffered from a postoperative paraspinal abscess in the operative field. He was treated with antibiotics and the infection resolved. Two patients with LDR required repeat surgical interventions for adjacent level disease. One patient who received a 3-level LDR (C3–C6) suffered from a C6/7 symptomatic disk herniation 1 month after the initial procedure, requiring repeat surgical intervention. Another patient who initially underwent a C4–C6 LDR procedure developed C6/7 adjacent level disease and received a C6/7 LDR device 1 year after the initial procedure. The only LDR device-related radiographic complication was seen in a patient who underwent a 2-level C5–C7 procedure. On immediate postoperative radiographs, interposition grafts and anchoring blades were in appropriate position (Fig. 3). At 6-month follow-up, the cephalad blade of the LDR device in the C6/7 interspace was noted to have migrated out. Given the minimal prominence of the blade and that the patient was clinically doing well, we elected to closely monitor the patient with serial x-rays. The blade remained in stable position and 12 months after the procedure bridging bone and lack on motion on flexion and extension x-rays indicated bony fusion.

DISCUSSION

In the current study, we demonstrate that a zero-profile LDR device allows for similar clinical and radiographic outcomes compared with ACDF with anterior plating. Importantly, omission of an anterior plate may reduce the rate of postoperative dysphagia.

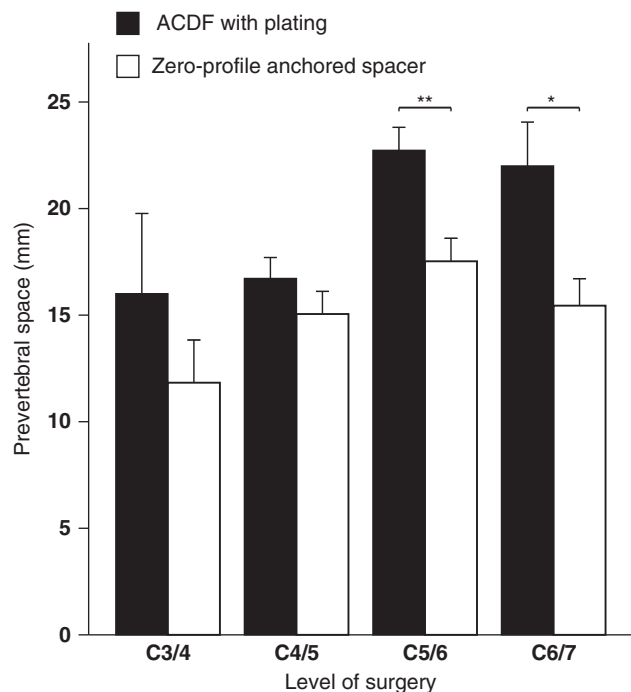


FIGURE 2. Postoperative measurements of prevertebral soft tissue stratified for the level of surgery. In the upper cervical spine, ACDF with anterior plating is associated with a trend toward increased prevertebral swelling compared with the LDR device. The difference between the 2 groups is more pronounced in the lower cervical spine. Thus, in constructs centered at C5/6 and C6/7, addition of an anterior plate is associated with a significant increase of prevertebral swelling. Each bar depicts the mean prevertebral soft tissue \pm SEM measured at the center of the construct either at the indicated disk level or at the midportion of the lower vertebral body. Measurements were statistically analyzed using a Student *t* test. Levels of significance are designated with as: **P* < 0.05 and ***P* < 0.01. ACDF indicates anterior cervical discectomy and fusion.

Solid bony fusion constitutes a goal of ACDF, because nonunion has been linked to poor outcomes.⁷ Only stable bony fusion prevents delayed kyphotic deformity with

concomitant foraminal stenosis causing root compression and neck pain.^{29–31} Increased rates of bony fusion have been reported in ACDF enhanced with anterior plating compared with ACDF without plate.^{10,32–34} Thus, fusion rates of ACDF with cervical plating have been estimated to be 97.1% for single-level and 94.6 for 2-level procedures.³³ A similar rate of bony fusion was detected in our patients who underwent ACDF with anterior plating (96.0%). Importantly, we found that an anchored spacer was associated with a comparable rate of bony fusion (95.2%).

Dysphagia (> 3 mo) rates after ACDF with anterior plating have been estimated to range between 12.5% and 35.1%.^{13,22,23} We found a similar rate of dysphagia in our patients who underwent ACDF with anterior plating (20.0%). Although the causes of dysphagia after ACDF procedures are not well understood, several physiological mechanisms have been proposed.²⁴ The anterior cervical locking plate is placed directly posterior to the esophagus and may impinge or irritate the esophagus.^{10,13,22,25,35} It has been demonstrated that design and thickness of anterior locking plates correlate with postoperative dysphagia.²² Lee and colleagues showed that reduction of plate thickness from 2.5 to 1.6 mm combined with a smoother surface design led to decrease of dysphagia from 22.5% to 14% at 6-month follow-up and from 14% to 0% at 24-month follow-up. Moreover, there are several studies that suggest that addition of anterior locking plates is associated with a higher rate of postoperative dysphagia.^{10,13,22,25} Mobbs and colleagues analyzed 242 cases with ACDF. They found a significantly higher rate of dysphagia in patients who received an anterior locking plate (4.5%, 5/112 patients) compared with constructs without anterior plating (0.8%, 1/130 patients). Bazaz et al.¹³ studied 249 consecutive patients undergoing anterior cervical spine surgery and observed a similar trend toward a lower rate of dysphagia (14.1%) in patients without anterior plating compared with a 21.1% of dysphagia in patients who received a construct including an anterior locking plate. However, this study did not distinguish between patients who underwent cervical discectomy or corpectomy. Similarly, low rates of dysphagia (2.9%) have been reported 3–6 months after implantation

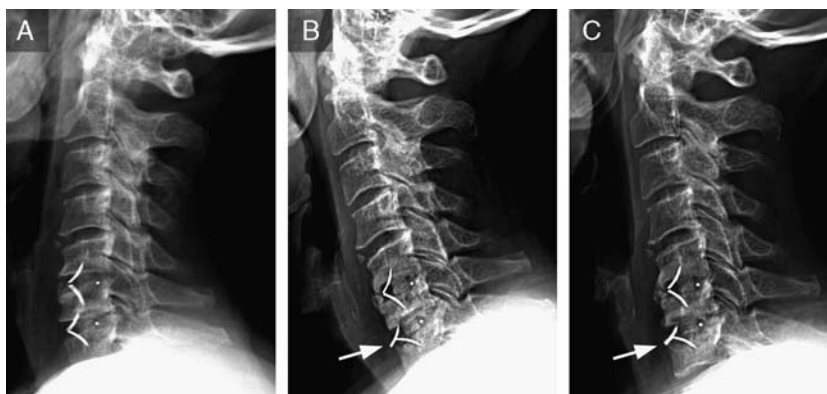


FIGURE 3. Postoperative lateral cervical spine radiograph depicts satisfactory placement of 2-level C5–C7 instrumentation using LDR (A). At 6-month follow-up, the cephalad blade of the LDR device in the C6/7 interspace (arrow) has migrated out (B). The blade remains in stable position (arrow) 12 months after the procedure (C).

of a zero-profile implant.²⁵ The rate of dysphagia is comparable with the current study (2.9% of LDR cases). Another possible mechanism for postoperative dysphagia after ACDF with anterior plating may be additional traction required to place an anterior locking plate. Increased pressure on the esophagus during implantation of an anterior plate has also been suggested to contribute to dysphagia in patients who undergo ACDF with anterior plating.²⁴

The current study has several limitations. First, the design of the study is a retrospective cohort study of 70 consecutive patients. We compared patients who received the LDR device with historical controls who underwent ACDF with plating. The use of historical controls is problematic as differences between treatment group and control group may be due to differences in patient selection and alteration of the hospital environment during the time of the study. Thus, studies with historical controls tend to exaggerate the value of a novel treatment modality. However, thorough analysis of our patient cohorts revealed that patient populations in both groups were very similar except for a slightly higher average age of patients who received the LDR device. This would have, however, favored the control group, as higher age has been proposed to be associated with increased risk of dysphagia after anterior cervical procedures.¹⁹ Moreover, no major changes were made to our operative or postoperative patient care during the extent of our study. Thus, the functional outcomes of patients in both groups were very similar, whereas we detected a difference in the rate of postoperative dysphagia. Randomized controlled trials with blinded assessment would be required to definitely link anterior plating to postoperative dysphagia. Another shortcoming of the current study and the gross majority of studies assessing cervical interbody fusion is the use of plain AP and lateral x-rays to assess bony fusion.³³ Although computed tomography is generally considered a more accurate means to assess for radiographic fusion, the correlation of radiographic and bony fusion is controversial. Studies have shown that radiographic assessment of bony fusion correlates poorly with mechanical stiffness, long-term durability, and actual bony fusion mass.³⁶ Blumenthal and Gill³⁷ report a mere 69% agreement between radiographic and operative findings in 49 explored surgical fusion sites. In addition, a significant proportion of pseudoarthroses and failures of cervical instrumentation occur >2 years after implantation.¹² Therefore, we plan to continue to follow our patient cohort in order to obtain an accurate assessment of the long-term durability of LDR-based fusion constructs.

In conclusion, ACDF using an LDR device results in similar clinical and radiographic outcomes compared with traditional interposition grafts combined with anterior plating. Omission of the anterior locking plate may decrease the incidence of postoperative dysphagia.

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