Anterior cervical discectomy and fusion (ACDF) is the standard of care for symptomatic cervical degenerative disc disease and disc herniation in patients in whom conservative treatment has failed. Indications for ACDF include radiculopathy and myelopathy with or without neurological deficit, and the goal of treatment is to provide neural decompression and segmental stabilization.

Object. Anterior cervical plating decreases the risk of pseudarthrosis following anterior cervical discectomy and fusion (ACDF). Dysphagia is a common complication of ACDF, with the anterior plate implicated as a potential contributor. A zero-profile, stand-alone polyetheretherketone (PEEK) interbody spacer has been postulated to minimize soft-tissue irritation and postoperative dysphagia, but studies are limited. The object of the present study was to determine the clinical and radiological outcomes for patients who underwent ACDF using a zero-profile integrated plate and spacer device, with a focus on the course of postoperative prevertebral soft-tissue thickness and the incidence of dysphagia.

Methods. Using a surgical database, the authors conducted a retrospective analysis of all patients who had undergone ACDF between August 2008 and October 2011. All patients received a Zero-P implant (DePuy Synthes Spine). The Neck Disability Index (NDI) and visual analog scale (VAS) scores for arm and neck pain were documented. Dysphagia was determined using the Bazaz criteria. Prevertebral soft-tissue thickness, spinal alignment, and subsidence were assessed as well.

Results. Twenty-two male and 19 female consecutive patients, with a mean age of 58.4 ± 14.68, underwent ACDF (66 total operated levels) in the defined study period. The mean clinical follow-up in 36 patients was 18.6 ± 9.93 months. Radiological outcome in 37 patients was assessed at a mean follow-up of 9.76 months (range 7.2–19.7 months). There were significant improvements in neck and arm VAS scores and the NDI following surgery. The neck VAS score improved from a median of 6 (range 0–10) to 0 (range 0–8; p < 0.001). The arm VAS score improved from a median of 2 (range 0–10) to 0 (range 0–7; p = 0.006). Immediate postoperative dysphagia was experienced by 58.4% of all patients. Complete resolution was demonstrated in 87.8% of affected patients at the latest follow-up. The overall median Bazaz score decreased from 1 (range 0–3) immediately postoperatively to 0 (range 0–2; p < 0.001) at the latest follow-up. Prevertebral soft-tissue thickness significantly decreased across all levels from a mean of 15.8 ± 4.38 mm to 10.1 ± 2.93 mm. Postoperative lordosis was maintained at the latest follow-up. Mean subsidence from the immediate postoperative to the latest follow-up was 4.1 ± 4.7 mm (p < 0.001). Radiographic fusion was achieved in 92.6% of implants. No correlation was found between prevertebral soft-tissue thickness and Bazaz dysphagia score.

Conclusions. A zero-profile integrated plate and spacer device for ACDF surgery produces clinical and radiological outcomes that are comparable to those for nonintegrated plate and spacer constructs. Chronic dysphagia rates are comparable to or better than those for previously published case series.

KEY WORDS • anterior cervical discectomy and fusion • chronic dysphagia • prevertebral soft-tissue thickness

Abbreviations used in this paper: ACDF = anterior cervical discectomy and fusion; BMI = body mass index; NDI = Neck Disability Index; PEEK = polyetheretherketone; VAS = visual analog scale.
stability.\textsuperscript{8} Surgical outcomes have traditionally been favorable, and complication rates are low.\textsuperscript{24,29} An interbody spacer is used to increase disc space and neuroforaminal height and restore cervical lordosis. An anterior plate is commonly added to enhance construct stability and reduce the rate of pseudarthrosis; however, this addition may be complicated by postoperative dysphagia, soft-tissue injury, and hardware failure.\textsuperscript{2,4-6,19,26,32,34,39}

The pathophysiological mechanism of postoperative dysphagia remains unknown, but proposed causes include soft-tissue edema, postoperative hematoma, recurrent laryngeal nerve palsy, esophageal injury, postoperative adhesions, and device migration.\textsuperscript{15} Some studies suggest patient age, sex, body mass index (BMI), blood loss, location of surgery, and number of operated levels as possible contributing factors to dysphagia.\textsuperscript{28} Lee et al. found a correlation between greater plate thickness and an increased incidence of dysphagia.\textsuperscript{23} During the early postoperative period, up to 67\% of patients may complain of difficulty swallowing.\textsuperscript{16,18,27,40,41} In most cases, the dysphagia resolves during the first 3 months after surgery;\textsuperscript{3,23} however, a subset of patients may continue to have chronic dysphagia after ACDF, with rates up to 35\%.\textsuperscript{46}

Anterior cervical plates represent a mass between the pharynx or esophagus and the cervical spine, similar to anterior osteophytes.\textsuperscript{10} Concerns about plate thickness as a possible cause of chronic dysphagia have led to the development of thinner profiles; however, such designs are still rather bulky and carry the risk of complications associated with anterior cervical plates and screws.\textsuperscript{6,23,34,37} A minimal-profile, polyetheretherketone (PEEK) integrated interbody spacer and plate implant (Zero-P, DePuy Synthes Spine; Fig. 1) was developed with the aim of reducing soft-tissue irritation since the device sits entirely within the intervertebral disc space. In this retrospective study, we describe the clinical and radiographic outcomes of a cohort of consecutive patients that underwent ACDF with a minimal-profile, PEEK integrated interbody spacer and plate implant. We also assessed postoperative prevertebral soft-tissue thickness as well as the incidence of early and late postoperative dysphagia.

Methods

We retrospectively reviewed a surgical database of consecutive patients who had undergone ACDF with the Zero-P implant between August 2008 and October 2011. All surgeries were performed by the senior author (R.H.). Institutional review board approval was obtained for this project.

In 2008 the Zero-P implant received US FDA approval for clinical use as an alternative to the traditional separate interbody spacer and plate device for ACDF. The entire implant is contained within the excised disc space and does not protrude outside the intervertebral disc space as anterior cervical plates do. The PEEK interbody spacer contains a radiopaque marker for visualization during fluoroscopy and lacks carbon fibers, thereby reducing the risk of systemic uptake. A small titanium plate, which is preassembled with the interbody spacer, provides an interface for anchorage. Four screws are placed within the plate at a 2.5° medial or lateral angle (Fig. 1) and a 40° cranial or caudal angle. Three different interbody spacer shapes are available for use: parallel, convex, and lordotic. The implant system contains three 3-mm-diameter screws of different lengths: 12, 14, and 16 mm. We typically used the 14- and 16-mm-long screws for our procedures.

Surgical Technique

We used a standard right-sided Smith-Robinson approach to reach the diseased cervical level.\textsuperscript{38} After plac-
Anterior cervical discectomy and fusion with a zero-profile implant

...ing distraction pins and incising the annulus, distraction is applied across the targeted level. Discectomies and, when appropriate, foraminotomies are performed using a high-speed drill, curettes, and Kerrison cervical rongeurs. Trial spacers are used under fluoroscopic guidance to determine the appropriate implant shape and size. The maximum implant size is used to optimize stability of the segment. We use a silicon-substituted calcium hydroxyapatite material (Actifuse, ApaTech) to pack the interbody spacer. Once the appropriate implant size is determined, an aiming device is used to introduce the implant into the intervertebral disc space as well as to direct the drill in creating the first pilot hole, which is caudally directed. The first locking screw is inserted, and the remaining pilot holes are drilled with the aid of the aiming device, followed by placement of the screws using torque limitation (1.2 Nm). The final implant position is then radiographically verified in the anteroposterior and lateral directions relative to the vertebral bodies. Patients are placed in a collar postoperatively only if they are smokers.

Clinical Evaluation

Demographic variables such as patient age, sex, BMI, and smoking habits were recorded. Clinical outcomes were collected at 2 weeks and 1, 3, 6, 12, and 24 months after ACDF. Dysphagia was recorded and graded according to the Bazaz scoring system. A numerical score ranging from 0 (no episodes of swallowing difficulty) to 3 (severe difficulty with the majority of food) was noted for each patient. Clinical outcomes were measured using the Neck Disability Index (NDI) and the visual analog scale (VAS). Intraoperative and postoperative complications were recorded.

Radiological Evaluation

Anteroposterior and lateral cervical radiological images were ideally obtained at 2 weeks and 3, 6, and 12 months after ACDF. At a minimum of 3 months, flexion and extension images were obtained as well. Preoperative, immediate postoperative, and latest follow-up radiographs were used to measure Cobb angles at the operated levels, subsidence, prevertebral soft-tissue thickness, and hardware failure or instability. Computed tomography scans were obtained at approximately 1 year to evaluate radiological fusion. Given that this was a retrospective cohort study, the imaging studies were used based on their availability in the system. Priority was given to CT scans as compared with radiographs. Cobb angle measurements were made to track changes in spinal alignment at the operated levels and were determined between the upper endplate of the vertebral body above the fusion and the lower endplate of the vertebral body below the fusion (Fig. 2 left). The height of the surgical motion segment was determined by measuring the distance from the upper endplate of the upper vertebral body to the lower endplate of the lower vertebral body from the anterior, middle, and posterior portions of the operated levels. Subsidence was calculated by subtracting the latest follow-up motion segment height from the immediate postoperative height. Subsidence was measured across the entire motion segment for both single and multilevel constructs and was defined as a loss of intervertebral height greater than 3 mm. Prevertebral soft-tissue thickness was determined by measuring the thickness of soft tissue from the anterior aspect of C3–7 vertebral bodies to the posterior aspect of the trachea. Magnification effects were corrected for by using the Zero-P implant as a standard reference. Radiographic fusion was defined by the presence of bony bridging across the intervertebral space on CT imaging or as less than 4° of motion on dynamic radiographs. Computed tomography was the preferred imaging modality for our fusion evaluation; however, in the cases in which CT studies were not available, dynamic flexion and extension radiographs were analyzed. Fusion was assessed at a minimum of 7 months of follow-up. A board-certified neuroradiologist (A.J.T.) independently evaluated postoperative CT images for bony fusion at the operated levels.

Statistical Analyses

Patient demographics and other continuous variables were expressed using descriptive statistics. The paired t-test was used for determining differences in clinical and radiological outcome scores between preoperation and the latest follow-up. The Pearson correlation coefficient was used to assess the relationship between prevertebral soft-tissue thickness and dysphagia. The chi-square or Fisher exact test was performed to evaluate the association between dysphagia and the number of fused vertebral levels. All statistical analyses were performed in PASW version 18.0 (SPSS Inc.), with p < 0.05 considered to be statistically significant. Adjusted p values from multiple tests were not considered.
of 1 day and ranged from 1 to 4 days.

The hospital stay was a median estimated blood loss per level was 50 ml with a range of 0–250 ml. The main indication for surgery was either cervical disc herniation associated with radiculopathy, or spinal stenosis and cord compression, which may or may not have been associated with radiculopathy. Neck pain was frequent in both groups, although it was not the sole indication for surgery. There were 20 monosegment, 17 bisegment, and 3 multisegment procedures. The median estimated blood loss per level was 50 ml with a range of 0–250 ml. The hospital stay was a median of 1 day and ranged from 1 to 4 days.

Clinical Results

The mean duration of clinical follow-up was 18.6 ± 9.93 months. Thirty-six patients underwent assessment of clinical and functional outcomes using the neck and arm VAS and NDI criteria. Preoperative or latest follow-up data were unavailable in 5 patients; therefore, they were excluded from this analysis. At the latest follow-up, there was a statistically significant reduction in the median VAS neck pain score from 6 to 0 (p < 0.001) and in the median VAS arm pain score from 2 to 0 (p = 0.006). The mean NDI score statistically improved from 43 ± 24.35 preoperatively to 21.7 ± 18.6 at the latest follow-up (p < 0.001; Table 3).

Radiological Results

The mean radiological follow-up was 9.76 months with a range spanning from 7.2 to 19.7 months. Thirty-seven patients were evaluated for changes in spinal alignment as well as for changes in prevertebral soft-tissue thickness. Preoperative or latest follow-up data were missing in 4 patients, making radiographic comparison impossible in these patients. Postoperative lordosis was achieved in all patients, with a median angle of 5.5° (range –14° to 18°) immediately postoperation. Lordosis was maintained at the latest radiological follow-up, with a median of 2.4° (range –9.8° to 26.3°; p = 0.012). The most common device size was 7 mm (range 6–9 mm), which was implanted in 65% of levels. Average height of the surgical segment immediately after surgery was 41 ± 11.50 mm, and this decreased at the latest follow-up to 37 ± 9.96 mm. Subsidence was observed in 22.7% (15 of 66 operated levels) of the implanted devices at the latest follow-up. No correlations were found between the size of the implant and the amount of subsidence. The radiographic fusion rate at the latest follow-up was 92.6% of the implants (50 of 54 levels) in the 33 evaluated patients with available CT or dynamic radiographs. Subsidence did not show any correlation with clinical outcome; neither did it correlate with the fusion rate. No evidence of screw or implant migration was observed. No long-term adjacent-level degeneration was noted in any of our patients.

Immediately postoperative soft-tissue thickness was significantly greater than the preoperative prevertebral value across all vertebral levels (p < 0.001), and the latest follow-up prevertebral soft-tissue thickness was significantly smaller than the immediately postoperative values (p < 0.001; Table 4). However, there was no statistically significant difference in soft-tissue thickness between the preoperative and the latest follow-up (Fig. 3). Dysphagia was experienced immediately after surgery by 58.4% of patients, and 12.2% of patients experienced mild dysphagia at the latest follow-up. The overall median Bazaz score significantly decreased from 1.0 (range 0–3) immediately postoperation to 0 (range 0–2) at the latest follow-up (p < 0.001; Table 3).

There was no correlation immediately postoperation

### TABLE 1: Summary of characteristics in 41 patients who underwent ACDF

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>mean age at surgery in yrs*</td>
<td>58.4 ± 14.68</td>
</tr>
<tr>
<td>sex</td>
<td>M 22 (53.7)</td>
</tr>
<tr>
<td>F 19 (46.3)</td>
<td></td>
</tr>
<tr>
<td>mean BMI in kg/m²*</td>
<td>28.4 ± 5.67</td>
</tr>
<tr>
<td>diabetes</td>
<td>yes 6 (14.6)</td>
</tr>
<tr>
<td>no 35 (85.4)</td>
<td></td>
</tr>
<tr>
<td>smoking</td>
<td>yes 3 (7.3)</td>
</tr>
<tr>
<td>no 38 (92.7)</td>
<td></td>
</tr>
</tbody>
</table>

* Values expressed as the mean ± standard deviation.

### TABLE 2: Summary of surgical details and operated level(s) in 41 patients who underwent ACDF

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>median EBL/level in ml (range)</td>
<td>50 (0–250)</td>
</tr>
<tr>
<td>median hospital stay in days (range)</td>
<td>1 (1–4)</td>
</tr>
<tr>
<td>no. of surgical levels/patient (%)†</td>
<td>1 20 (48.8)</td>
</tr>
<tr>
<td>2 17 (41.5)</td>
<td></td>
</tr>
<tr>
<td>3 4 (9.8)</td>
<td></td>
</tr>
<tr>
<td>surgical level (%)</td>
<td>C3–4 10 (15.1)</td>
</tr>
<tr>
<td>C4–5 13 (19.7)</td>
<td></td>
</tr>
<tr>
<td>C5–6 24 (36.4)</td>
<td></td>
</tr>
<tr>
<td>C6–7 18 (27.3)</td>
<td></td>
</tr>
<tr>
<td>C7–T1 1 (1.5)</td>
<td></td>
</tr>
</tbody>
</table>

* Twenty-six (63.4%) of 41 patients were discharged on postoperative Day 1. EBL = estimated blood loss.
† Total of 66 operated levels.
Anterior cervical discectomy and fusion with a zero-profile implant

TABLE 3: Summary of clinical measures in 36 patients who underwent ACDF*

<table>
<thead>
<tr>
<th>Measure</th>
<th>Preop</th>
<th>Latest FU</th>
<th>p Value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>mean NDI in % (± SD)</td>
<td>43 ± 24.35</td>
<td>21.7 ± 18.62</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>median VAS neck pain (range)</td>
<td>6 (0–10)</td>
<td>0 (0–8)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>median VAS arm pain (range)</td>
<td>2 (0–10)</td>
<td>0 (0–7)</td>
<td>0.006</td>
</tr>
<tr>
<td>median Bazaz score (range)‡</td>
<td>1 (0–3)</td>
<td>0 (0–2)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

* The mean follow-up was 18.6 ± 9.93 months. FU = follow-up.
† p < 0.05 is statistically significant.
‡ Bazaz score was taken immediately postoperatively.

(correlation = −0.23, p = 0.20) or at the latest follow-up (correlation = −0.23, p = 0.20) between the degree of prevertebral soft-tissue thickness and early dysphagia (Fig. 4). Interestingly, we noted no significant correlation between dysphagia immediately after surgery and the number of operated vertebral levels; that is, there was no statistically significant increase in dysphagia as the number of operated levels increased immediately postoperatively (p = 0.168; Fig. 5).

Complications

One patient, a 71-year-old female with a history of hypertension, diabetes mellitus, and cardiac disease, underwent an uneventful C3–4 ACDF for myelopathy. She was discharged to home on postoperative Day 3 without any complaints. She died from an unknown cause 4 days after surgery. At the request of the family, no autopsy was performed. There was one instance of nonunion in which the patient experienced persistent left arm pain with transient left deltoid muscle weakening. No further intervention was undertaken, as the patient refused additional surgery. Hoarseness occurred after surgery in 5 patients but had completely resolved by the 3-month follow-up visit. There were no occurrences of postoperative CSF leakage, wound infection, or deep venous thrombosis.

Discussion

Anterior cervical disectomy and fusion is the standard surgical treatment for symptomatic cervical degenerative disc disease after conservative medical management fails. The addition of an anterior cervical plate with an interbody spacer during an ACDF is associated with improved fusion rates compared with the rates in ACDFs without plating.17 However, anterior cervical plates and screws are associated with both immediate and delayed hardware complications such as screw or plate migration and breakage.5,26,32,39,43 Despite improvements in anterior cervical instrumentation, such as improved screw-locking mechanisms, complications persist.14,15,25 Moreover, anterior cervical instrumentation is believed to contribute to the chronic postoperative dysphagia that can occur after ACDF.

Radiological Outcome

Our 92.6% radiological fusion rate after a relatively short follow-up is comparable to standard fusion rates using anterior plates.27 The fusion rate in the ACDF group in a randomized controlled clinical trial comparing cervical disc arthroplasty to standard ACDF with anterior plating in 221 patients was 94.3% at an average follow-up of more than 3 years.28 Similarly, in another randomized prospective clinical study evaluating total disc replacement and anterior discectomy and fusion, Coric et al. noted a 97% fusion rate in their ACDF cohort12 at an average follow-up of 6 years. Overall, our fusion rate is within the range previously reported in the literature for ACDF with anterior plating.21,30

In the present study, we defined subsidence as a decrease in vertical motion segment height greater than 3 mm. Measurements were taken on lateral radiological images, and intra-individual variations in magnification were corrected for by using the size of the Zero-P implant as reference. Despite our 92.6% fusion rate, subsidence was observed in 22.7% (15 of 66 operated levels) of the implanted devices at the latest follow-up. Overall subsidence did not appear to affect other radiographic or clinical outcome parameters. In Gercel et al.’s study on stand-alone titanium cervical cages, the authors noted subsidence in 5 (55.6%) of 9 patients but found no correlation between subsidence and clinical outcome.20 Subsidence may in part be attributed to poor bony quality in the patients. Our subsidence rate at an average follow-up of 10 months was 22.7%, which is within the range previously reported by other authors (Table 5).7,9,20,44,45

Dysphagia and Soft-Tissue Thickness

Chronic dysphagia is a well-documented phenomenon following ACDF, with rates ranging from 10% to

TABLE 4: Summary of radiographic outcomes in 37 patients who underwent ACDF*

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Preop</th>
<th>Immediately Postop</th>
<th>Latest FU</th>
<th>p Value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>median segmental sagittal lordosis (range)</td>
<td>NR</td>
<td>5.5° (−14° to 18°)</td>
<td>2.4° (−9.8° to 26.3°)</td>
<td>0.012</td>
</tr>
<tr>
<td>mean tissue swelling in mm (mean ± SD)</td>
<td>7.8 ± 2.48</td>
<td>15.8 ± 5.34</td>
<td>10.1 ± 2.93</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

* The mean radiographic follow-up was 9.76 ± 5.79 months. NR = not reported.
† p < 0.05 is statistically significant.

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In Bazaz et al.'s prospective study involving 249 patients, the incidence of dysphagia was 50%, 32%, 17%, and 12% at 1, 2, 5, and 12 months, respectively. Causes of dysphagia are believed to be multifactorial. Lee et al. suggest that plate design may play a role in chronic dysphagia. In their nonrandomized prospective study, a cohort undergoing ACDF with 2.5-mm-thick plates was compared with a cohort that underwent surgery with 1.6-mm-thick plates. Thicker cervical plates are associated with higher chronic dysphagia rates than the rates associated with thinner plates. The Zero-P implant, with its integrated plate and spacer profile, sits completely within the intervertebral disc space, eliminates ongoing contact with the prevertebral soft tissue, and minimizes soft-tissue irritation, which may lower the incidence of dysphagia. A study by Scholz et al. investigated the short-term clinical outcomes of patients who had undergone ACDF with the Zero-P implant. Patients in that study showed statistically significant reductions in VAS scores and significant improvements in functional outcomes, which were sustained for up to 6 months after surgery. The short-term dysphagia rate was 62% and decreased to 2.9% at 6 months. Postoperative radiographic fusion and postoperative prevertebral soft-tissue thickness data were not presented.

Biomechanically, the Zero-P implant performs similarly to traditional plate and spacer devices. A cadaveric study comparing the stand-alone device with the

![Fig. 3. Prevertebral soft-tissue thickness as a function of dysphagia.](image)

![Fig. 4. Prevertebral soft-tissue thickness as a function of dysphagia.](image)

![Fig. 5. Dysphagia as a function of the number of operated levels.](image)
Anterior cervical discectomy and fusion with a zero-profile implant

TABLE 5: Subsidence rates reported in the current literature

<table>
<thead>
<tr>
<th>Authors &amp; Year</th>
<th>Definition of Subsidence (mm loss of surgical segment height)</th>
<th>Interval Btwn Op &amp; Subsidence Evaluation (mos)</th>
<th>Type of Implant</th>
<th>Subsidence Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chen et al., 2013</td>
<td>&gt;3</td>
<td>99.7</td>
<td>titanium &amp; PEEK cages alone</td>
<td>34.50% &amp; 5.40%, respectively</td>
</tr>
<tr>
<td>Wang et al., 2013</td>
<td>&gt;3</td>
<td>43.6</td>
<td>PEEK cage alone</td>
<td>9.38%</td>
</tr>
<tr>
<td>Chiang et al., 2008</td>
<td>NS</td>
<td>53</td>
<td>PEEK cage w/ bovine xenograft</td>
<td>14.30%</td>
</tr>
<tr>
<td>Wu et al., 2012</td>
<td>&gt;2</td>
<td>3</td>
<td>titanium cage alone</td>
<td>19.10%</td>
</tr>
<tr>
<td>present study</td>
<td>&gt;3</td>
<td>9.76</td>
<td>zero-profile PEEK</td>
<td>22.70%</td>
</tr>
<tr>
<td>Gercek et al., 2003</td>
<td>&gt;3</td>
<td>15</td>
<td>titanium cage alone</td>
<td>55.6%</td>
</tr>
</tbody>
</table>

* NS = not specified.

traditional interbody spacer and locking plate apparatus showed that the Zero-P device decreased range of motion in all tests and did not demonstrate any significant difference in stability as compared with that offered by the cage plus anterior plate construct. Likewise, another biomechanical cadaveric study done by Clavenna et al. showed that treatment with an integrated plate and spacer allows for a shorter operative time with fewer surgical steps as well as similar device stability as compared with the traditional plate and spacer.

In the present study, we noted significant improvements in postoperative dysphagia over time, which is consistent with the findings reported by Scholz et al. The chronic dysphagia rate in our cohort was 12.2%, which is slightly higher than that reported by Scholz and colleagues but comparable or slightly lower than the rates reported in larger patient series (Table 6). A well-established trend in the use of the traditional plate and spacer is the increase in dysphagia rates as the number of fusion levels increases. With the integrated device, however, we noticed no significant difference with an increasing number of fusion levels. This may prove beneficial as it indicates that patients undergoing multilevel fusion with this device do not have any greater risk for postoperative dysphagia than those undergoing single-level procedures. The duration of our long-term follow-up (mean of 18.6 months) was greater than that reported by Scholz et al. Consequently, we were able to track radiological outcomes, such as spinal alignment and radiological fusion, and noted maintained lordosis in all our patients at the latest follow-up as well as a 92.6% fusion rate on CT scans or dynamic imaging, which is comparable to the fusion rate of 94.3% in the Heller et al. study.

Another parameter measured in this study was postoperative prevertebral soft-tissue thickness. Edema of the prevertebral soft tissue is routinely observed after ACDF. A study by Suk et al. identified the natural course of prevertebral soft-tissue swelling in the immediate postoperative period, with peak swelling noted at postoperative Day 2 or 3 and a gradual decrease starting at postoperative Day 4. A retrospective study of 100 patients who underwent ACDF compared prevertebral soft-tissue measurements from preoperation, 2 weeks postoperation, and 6 weeks postoperation. It was found that the majority of prevertebral swelling resolves by 6 weeks after surgery. Given the incidence and course of postoperative prevertebral soft-tissue swelling, it has been hypothesized that it contributes to dysphagia following ACDF. Interestingly, when we investigated the relationship between degree of postoperative prevertebral soft-tissue thickness and dysphagia at both early and later time points after surgery in our cohort, we did not find any significant correlation. This finding suggests that prevertebral soft-tissue thickness may not be related to dysphagia and highlights the fact that the etiology of dysphagia after ACDF is not completely understood. Furthermore, prevertebral thick-
ness may not be an appropriate radiological surrogate for dysphagia. In the postoperative period, other factors may contribute to dysphagia, such as esophageal irritation or ischemia, recurrent laryngeal nerve palsy, adhesions, and screw or plate migration in a small fraction of cases. Thus, other modifications in ACDF surgery, such as refinements to retractors, which would minimize retraction pressure on adjacent key soft-tissue structures, may be important in reducing postoperative dysphagia.31 A limitation of our analysis is the lack of preoperative lumbar lordosis measurements. Nevertheless, although we did not focus on the amount of lumbar lordosis post-operatively as compared with that before surgery, the data showed that lordosis was maintained from the postoperative to the latest follow-up time point. Additional limitations of this study include the lack of a control group, the small cohort size, and the relatively short follow-up for radiological fusion. A randomized controlled study with a larger cohort would better define the potential advantages of the minimal-profile integrated plate and spacer implant over the standard plate and spacer construct as well as the predictors and nonpredictors of dysphagia. Although no adjacent-level disease was observed in this study, a longer follow-up is needed to investigate any differences in adjacent-level degeneration with this integrated plate and spacer implant as compared with standard plate and spacer constructs.

Conclusions

The Zero-P implant, a minimal-profile integrated interbody spacer and plate device for ACDF, is associated with pain outcomes, functional outcomes, and radiographic fusion rates that are comparable with those for standard ACDF plate and spacer implants. The chronic dysphagia rate following the use of this implant is comparable or decreased as compared with rates reported in the literature. The relationship between prevertebral soft-tissue thickness and dysphagia after ACDF surgery may not be directly correlative. Thus, further study of the pathophysiology of dysphagia is needed, and additional refinements should focus on techniques or instruments that address other causes of dysphagia following ACDF.

Acknowledgments

We thank our statistician, Yang Liu, Department of Biostatistics, for performing and verifying our statistical analysis and Ms. Tatianna Saleh for her help in collecting patient information.

Disclosure

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