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# Sentinel sign in standalone anterior cervical fusion: Outcomes and fusion rate

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ABSTRACT

*Background:* The authors aim to demonstrate the feasibility, outcomes and fusion rate of a standalone PEEK cage in the outpatient setting.
*Methods:* 48 consecutive patients undergoing standalone ACDF (S-ACDF) (Group 1) were compared to control group of 49 patients who had ACDF with ACP (Group 2).
*Results:* Analysis of follow-up at the one year period postoperative outcomes between groups 1 and 2 demonstrated no intergroup statistical significant difference in VAS neck, arm and NDI scores p = 0.414, 0.06 and p = 0.328 respectively.
*Conclusion:* We conclude that S-ACDF can be safely done in an ambulatory surgery center with satisfactory clinical and patient-reported outcomes.

## 1. Introduction

Degenerative disc disease of the cervical spine is a major factor leading to chronic neck pain.[1] Anterior cervical discectomy and fusion (ACDF) with the aid of fixation using anterior cervical plates (ACPs) has demonstrated value in the treatment of disc herniation and cervical spondylosis.[2–5] The use of ACPs has been a show to improve the overall fusion rate after ACDF by increasing the stability provided to the postoperative complex.[3,6]

Adjacent segment disease (ASD), however, remains a concern with ACDF with ACPs.[7–9] The advances in surgical techniques and medical device technologies have been demonstrated in cervical implants. The use of standalone devices offers the advantage of replacing the disc without having a rigid fixation as compared to ACDF with ACP.[10] Studies have demonstrated equivalent outcomes with a reduced risk of dysphagia and adjacent segment disease.[11–13]

The literature has demonstrated outcomes, safety and complications of ACDF with plates and without plates in the inpatient hospital setting.[11,12,14–16] The frequency of procedures performed in the outpatient setting has increased with numerous studies demonstrating the outcomes, safety, and trends of ACDF as an outpatient procedure.[17–22] The authors aim to demonstrate the feasibility, outcomes and fusion rate for patients who had standalone ACDF. In a study by Nathan et al. noted that if bone is seen bridging the interspace anterior to the cage on a lateral view, it is clear that healing has occurred and this fusion is termed sentinel sign.[23]

## 2. Materials and methods

This was a single-center, retrospective study of prospectively collected data with a total of 97 patients. We reviewed the charts of 48 patients who had single and two level standalone anterior cervical fusions (anterior cervical interbody fusion device A-CIFT Solofuse-P®, SpineFrontier Inc. Malden, MA, USA) in the outpatient setting and assigned them to Group 1 (S-ACDF). Our control group, Group 2 (ACDF-ACP) included 49 patients who underwent single and two level ACDF (Arena-C®, SpineFrontier Inc. Malden, MA, USA) in the outpatient setting; fusion was reinforced with an anterior cervical plate (ACP) (Inset®, SpineFrontier Inc., Malden, MA, USA). IRB approval was granted for patients involved in the study as part of a cohort of patients who had

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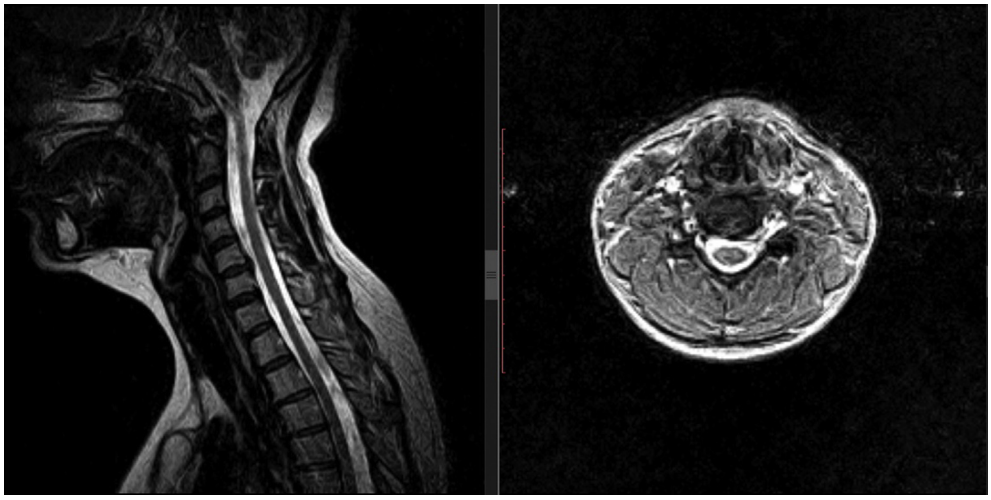

**Fig. 1.** Preoperative MRI demonstrating herniated disc at C5-6.

**Table 1**
Cohort demographics with pathological levels and chief complaint.

| Variable | ACIFT ACDF | Arena C ACDF | P-value |
|---|---|---|---|
| (N) | 48 | 49 | |
| Age (years) | 47.8 ± 1.6 | 48.7 ± 1.4 | 0.691 |
| BMI (kg/m$^2$) | 29.7 ± 1 | 29.7 ± 1.1 | 0.947 |
| Male | 10 | 6 | 0.286 |
| Female | 38 | 43 | |
| Pathological Level | | | |
| C3-4 | 12 | 11 | |
| C4-5 | 13 | 12 | |
| C5-6 | 33 | 25 | |
| C6-7 | 15 | 15 | |
| C7-T1 | 2 | 1 | |
| Diagnosis | | | |
| Herniated disc | 15 | 14 | |
| Degenerative disc disease | 19 | 21 | |
| Spondylosis (chronic pain) | 3 | 7 | |
| Myelopathy | 7 | 5 | |
| Radiculopathy | 4 | 8 | |
| Levels (N) | | | |
| Single | 21 | 34 | 0.0191 |

anterior cervical surgery. All operations were performed by a single surgeon in an outpatient center and the decision for the location was made on outset with informed patient consent. Patients were only considered for surgery after failed conservative management for at least six weeks. Indications for ACDF surgery included symptomatic cervical spondylosis, stenosing herniated discs (Fig. 1), degenerative disc disease with instability, myelopathy, radiculopathy (Table 1) and facet arthritis, tropism or facetogenic pain. Exclusion criteria for this study and outpatient surgery included acute severe trauma, fractures, malignancy, infection, unstable chronic medical illnesses, patients requiring laminectomy, anterior corpectomy, prior anterior cervical fusions or total disc replacement and a BMI > 42,[24,25] a criterion for outpatient surgery used at this institute.[25] All patients were assessed preoperatively and were recommended to discontinue narcotics at least two weeks before surgery if the patient was on narcotics for greater than 6 months.[26] Patients with chronic but stable medical conditions, including hypertension, diabetes mellitus, asthma, hypercholesterolemia and heart disease were medically cleared by their family practitioner and/or cardiologist where applicable.

### 2.1. Surgical technique

Signed informed consent was obtained for the procedure. Under general anesthesia, patients were prepped and draped under sterile conditions. A modified approach to the standard Smith-Robinson operative technique was used.[27,28] Surgical exposure of the desired vertebral level was achieved through a midline anterior cervical incision. Subcutaneous dissection was performed to allow for adequate mobilization of the tissue through a 1.5-inch incision. Following discectomy with pituitary ronguers, curette and burr drill to remove the affected disc, the posterior longitudinal ligament was retained *in situ*.[29,30] The standalone cervical PEEK cage was inserted and two screws placed. Demineralized bone matrix (DBM) pure was placed within and anterior to the PEEK cage to aid with fusion. Once hemostasis was achieved and the wound was completely dry, a Penrose drain was placed above the implant, brought through the incision and secured with a sterile safety pin in all patients for wound drainage to prevent the development of a postoperative hematoma. A trained medical staff member removed the drain in the office after 24 h once there was no longer any active, visible drainage. Group 2 had a similar approach and localization of the operative level. ACDF was performed after discectomy; the appropriately sized PEEK cage with DBM was inserted. Supplemental fixation was then placed using an anterior cervical plate (ACP). The closure was performed in layers and a Penrose drain was left in-situ.

### 2.2. Discharge and follow up

All patients were discharged within 2–4 h of completing surgery after being deemed oriented and neurologically intact by the post-anesthesia care unit (PACU) team, anesthesiologist, and operating surgeon. A protocol developed by the outpatient center based on published literature was used as the discharge criteria.[31,32] Outpatient postoperative instructions were discussed with all patients and caregivers with written copies provided.[25] An assigned member of the outpatient team was responsible for educating all patients prior to consent on the risks and benefits of outpatient total disc replacement and ACDF, as well as potential complications such as transient to persistent dysphagia, postoperative hematoma, infection and soft tissue edema with possible airway compromise.[25] A team member called all patients postoperatively on the night of surgery as well as the following morning to ensure a normal and comfortable postoperative recovery period, as well as to identify any evolving complications, which may have required immediate hospital admission. In the event of a complication, a prearranged agreement with a nearby local hospital was established before surgery. A trained medical staff member removed the drain in the office after 24 h once there was no longer any active, visible drainage. Patient-reported outcomes included the 10-point Visual Analogue Scales (VAS) for neck pain and arm pain and Neck Disability Index (NDI). Follow up visits occurred within the first 6 weeks, 3 months, 6

months and 12 months postoperatively. Additional postoperative complications were also recorded. Fusion was defined as < 1 mm of motion on plain radiographs, including flexion and extension views.[33] Confirmation of the presence of continuous trabecular bone bridges on plain radiographs was also assessed in at least one of the following locations: anterior, within, or posterior to the cage.

### 2.3. Statistical analysis

Statistical analysis was performed using SPSS v22 (IBM Corporation, New York, USA). An independent sample student T-test was used to compare groups for continuous data and a chi-squared analysis was used for categorical data. Continuous data comparisons were expressed as means with standard error. Tests were considered significant if the $p < 0.05$. A power analysis was performed based on a previous study which demonstrated that an adequate sample size of 32 patients per group was adequate to verify a statistical difference with a power = 0.8 and alpha = 0.05.[11,34]

## 3. Results

Of the 48 patients in Group 1 (S-ACDF), 71% were female with the group's mean age being 47.8 ± 1.6 years and a mean BMI 29.7 ± 1.0 kg/m$^2$. Of the 49 patients in Group 2 (ACDF-ACP), 87% were female with the group's mean age being 48.7 ± 1.4 years and a mean BMI 29.7 ± 1.1 kg/m$^2$. No statistical differences in gender, age or BMI were found between groups, p = 0.286, 0.691 and 0.947 respectively. The demographics are summarized in Table 1, including pathological levels treated and chief complaints (indication for operation).

There was no significance between preoperative VAS neck, arm and NDI scores between Groups 1 and 2, p = 0.480, 0.818 and 0.390 respectively. Analysis of follow-up at the one year period demonstrated that Group 1 mean preoperative VAS neck scores improved from 8.2 ± 0.3 to 0.7 ± 0.1 at one-year follow-up, $p < 0.001$. Preoperative VAS arm scores improved from 5.7 ± 0.9 to 0.3 ± 0.7, $p < 0.001$. Preoperative mean NDI scores decreased from 28.6 ± 1.7 to 12.3 ± 0.3 at one-year follow-up, $p < 0.001$. Group 2 mean preoperative VAS neck scores improved from 8.0 ± 0.2 to 1.6 ± 0.3 at one-year follow-up, p = 0.001. Preoperative VAS arm scores improved from 5.0 ± 0.6 to 0.6 ± 0.2, $p < 0.001$. Preoperative mean NDI reduced from 27.8 ± 1.5 to 12.9 ± 0.6 at 1-year follow-up, p = 0.001. There is an overall improvement in VAS neck and arm and NDI scores shown in Figs. 2–4 respectively. Statistical comparison of postoperative outcomes between groups 1 and 2 demonstrated no intergroup statistical significant difference in VAS neck, arm and NDI scores p = 0.414, 0.058 and p = 0.328 respectively. The surgical operative time and estimated blood loss in Group 1 were 40 ± 8 min and 46 ± 9 mLs as compared to Group 2 which was 43 ± 6 min and 53 ± 7 mLs. There was no intergroup significance demonstrated, p = 0.315 and 0.15 respectively.

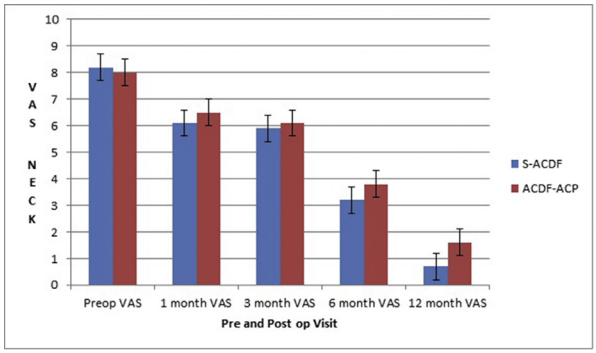


**Fig. 2.** Bar chart demonstrating VAS neck pain scores.

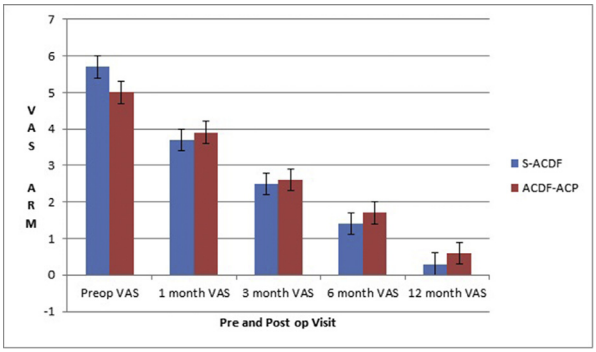


**Fig. 3.** Bar chart demonstrating VAS arm pain scores.

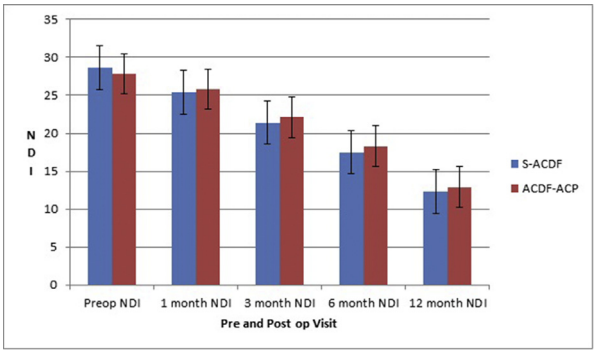


**Fig. 4.** Bar chart demonstrating NDI pain scores.

**Table 2**
Demonstrating complications after outpatient surgery in each group.

| Complication | S-ACDF | ACDF |
|---|---|---|
| Dysphagia | 3 | 4 |
| Visited ER (not admitted)* | 2 | 2 |
| • Pain not relieved by TTH medications | 1 | 2 |
| • Dressing completely soaked | 1 | 0 |
| Revision for ASD | 0 | 1 |

ASD: Adjacent segment disease.

**Table 3**
Bazaz-Yoo dysphagia severity scale.

| Dysphagia severity | | |
|---|---|---|
| Severity | 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) |

During the study period, enrollments began from January 2016 to September 2016 and continued to completion of the final one-year follow-up in all patients during September 2017; there were no unplanned postoperative admissions for pain, nausea or any other complaints. All complications are listed in Table 2; the main complaint of postoperative dysphagia was defined as any discomfort or difficulty with swallowing which was not historically present prior to surgery. The severity was assessed using the Bazaz-Yoo dysphagia severity scale of mild, moderate and severe, over the initial 3-month postoperative period, Table 3[35] This occurred in both groups which were mild in severity and transient lasting for the longest period of 6 weeks, with 3 patients in the S-ACDF group and 4 in the Arena-C ACDF. There was no intergroup significance, p = 0.678.

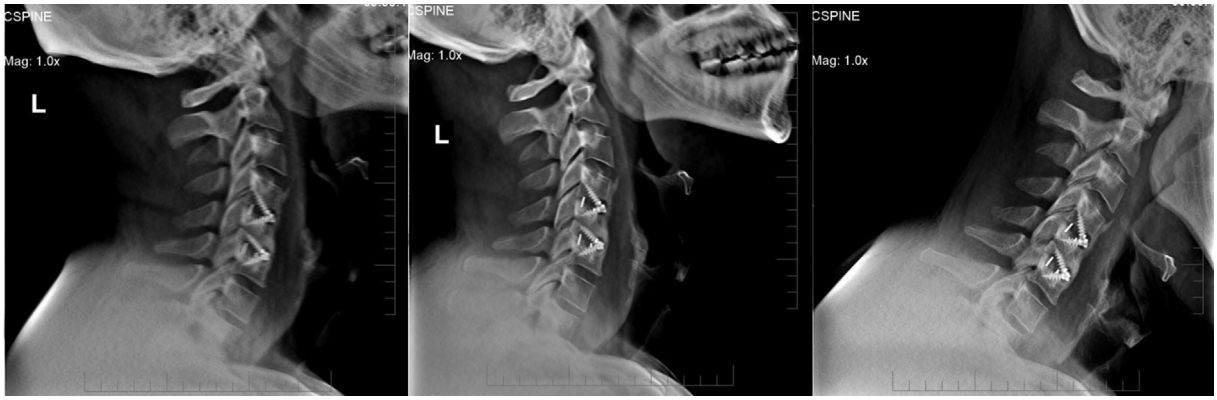


**Fig. 5.** Plain radiograph in extension, neutral and flexion showing sentinel sign of fusion anterior the cage.

### 3.1. Follow-up

One patient in Group 2 had a second surgery within the one-year follow up for ASD. Neutral and flexion-extension spinal radiographs were evaluated for graft subsidence, implant failure, and the status of fusion at 1-year follow-up. Fusion was defined as < 1 mm of motion on plain radiographs, including flexion and extension views (Fig. 5). Sentinel sign is also noted in Fig. 5 with bridging bone anterior to the interbody cage. No evidence of implant failure or signs of nonunion in the groups were noted at the 1-year follow-up period.

## 4. Discussion

The authors aimed to assess the outcomes of standalone anterior cervical fusion in the outpatient setting. This study showed significant improvement in postoperative outcomes in both groups; however, no intergroup significance was noted. Of note, one patient in ACDF with ACP group required revision for ASD.

The literature continues to grow in support of anterior cervical discectomy and fusion as the gold standard treatment for the failed conservative management of numerous cervical pathologies.[36–38] The benefit of ACDF as an outpatient procedure has also been supported by several studies with the healthcare industry seeing an increasing trend for outpatient procedures.[22,39,40]

The use of plating anterior to the cage is associated with various complications [11,41-43]. The stand-alone anchored cage offers a theoretical advantage of favorable clinical and radiological outcomes. Several studies have described that this type of new stand-alone cage achieved similar clinical and radiological outcomes with lower dysphasia, compared to using a cage with plating.[11,41–43]

In a retrospective study by Scholz et al.[11] with 38 patients, they demonstrated that solid fusion and decreased post-operative pain were associated with a low rate of dysphasia. Miao et al. [41]. reported similar favorable outcomes in a prospective study comparing the application of Zero-P with the use of a PEEK cage with plating. They concluded that clinical and radiographic efficacies were similar to those of ACDF using a plate, with a lower incidence of dysphasia.

However, in a recent study by Alonso et al.,[44] they reported implant failure in 10 (4.74%) patients and pseudarthrosis in 7 patients out of a cohort of 211 patients who had standalone cervical fusion. This large retrospective review had several differences noted compared to our study. First: our study was a single surgeon study with a standardized operative technique based on pathology. Second: the study involved only single and two level cases with a total of 139 levels performed. Patients who required corpectomy or posterior laminectomy did not get standalone fusion. Third: fusion was aided by adding DBM both within and anterior to the cage, increasing the chances of bony fusion post-operatively.

We found two prospective, randomized, controlled studies supporting standalone fusion.[42,43] Nemato et al.[42] reported on a two-year follow-up of 50 participants with 46 patients completing the final follow-up at two years. This study concluded comparable clinical and radiological outcomes with a significantly lower rate of adjacent level ossification. Panchal et al.[43] reported on a cohort of 54 patients demonstrating similar clinical and radiologic outcomes as compared with plate and spacers with the possibility to minimize dysphonia.

The authors do acknowledge the limitations of this study: its retrospective nature and a single center study. Most of our patients were female, and their average age was noticeably lower than that of those reported in other studies. This may not be representative of the general patient population. Our follow up was only 12 months and this was due to the start date of use of the implant. Further study will be needed to evaluate if clinical and radiological findings vary by age or by sex. The authors also did not perform the comparative study between the ACIFT implant with any other type of standalone PEEK cage. However, despite these limitations, we conclude that standalone cervical fusion is safe in the outpatient setting with good clinical and radiologic outcomes with fusion seen as early as 9–12 months.

## Conflicts of interest and sources of funding

We did not seek or receive any funding from the National Institutes of Health, Wellcome Trust, Howard Hughes Medical Institute, or others for this work. KRC is a shareholder in and receives other benefits from SpineFrontier Inc. None of the other authors (FJRP, LSM, MSM, AB and JAS) or any member of his or her immediate family has funding or commercial associations (e.g., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article.

## Appendix A. Supplementary data

Supplementary data related to this chapter can be found at https://doi.org/10.1016/j.jor.2018.08.027.

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