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Clinical Characteristics and Post-surgical Outcomes in Patients with ACIS™ -Anterior Cervical Interbody Spacer (ACIS) Placement in Anterior Cervical Discectomy and Fusion Surgery

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Abstract

Introduction: The ACIS™ -Anterior Cervical Interbody Spacer (ACIS, Johnson & Johnson MedTech, Raynham, MA) is a polyetheretherketone (PEEK) cervical cage and is intended for use as intervertebral body fusion device in skeletally mature patients with degenerative disease of the cervical spine (C2–C7). Supplemental fixation is recommended in multi-segmental fusions. Narrowing of the intervertebral height (IH) is an important pathological change in degenerative spinal disease. This study aims to study clinical characteristics, surgical measures and adverse events in patients that received ACIS and VECTRA anterior cervical plate (VECTRA, Johnson & Johnson MedTech, Raynham, MA). It also aims to provide a better understanding of the role that IH plays in clinical outcomes following anterior cervical discectomy and fusion (ACDF).

Methods: In this retrospective cohort study, patients with degenerative disease of the cervical spine were obtained from the hospital electronic medical records of Carilion Medical Center between 2016 to 2020. Patients that received treatment with ACIS and VECTRA and allograft bone grafting were selected. Information on patient demographics, clinical characteristics, and surgical characteristics was collected. Plain film radiographs were reviewed to evaluate changes in anterior and posterior IH at pre-operative, immediate post-operative, 6-month follow-up visit, and 12-month follow-up visit. A two-tailed T-test was used to identify if there was a statically significant difference in preoperative IH compared to post-operative IH. Radiographic assessment to look for bridging bone was done in order to confirm successful fusion.

Results: This study included 106 patients. There are 55 males and 51 females. The mean age is 54.4 years and median age is 53 years-old ranging from 26 to 84 years-old . The average body mass index of the population is 31 (95% confidence interval of 18-45). Thirty-one patients never smoked, 35 patients quit over 3 months ago, and 40 patients were current smokers (28%, 32%, and 37%, respectively). Overall, the mean anterior and posterior IH at each post-op visit was significantly greater than pre-op mean anterior and posterior IH ($P<0.05$). After surgery, a few patients had persistent symptoms of neck pain and swallowing difficulties. In general, the number of patients with swallowing difficulties improved with time; however, the number of patients experiencing neck pain remained constant (Figure 2). Five patients underwent a reoperation procedure, four of which were revision procedures in which supplemental posterior fixation was added to the index vertebral levels. One patient underwent reoperation adjacent to the index levels for treatment of adjacent level disease. Fifty-

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two of the 56 patients were fused by the 6 month post-op visit and the remaining four patients were fused by the 12 month post-op visit.

Conclusion: This single center, retrospective cohort study is the first study to look at clinical and surgical factors in patients with degenerative spine disease that were surgically treated with ACIS and VECTRA in single and multilevel ACDF procedures. This study showed that patients received satisfactory fusion as exemplified by radiographic imaging. This study revealed that IH significantly increased post-operatively. Additionally, this difference was sustained throughout all follow-up visits for at least 1 year after surgery.

Keywords: Anterior cervical discectomy and fusion; anterior cervical interbody spacer; PEEK; Intervertebral Height

Introduction

Degenerative cervical spine conditions are a leading cause of pain and disability worldwide, often necessitating surgical intervention. [1] Intervertebral disc space height loss is a hallmark of degenerative cervical spine disorders, often resulting from the natural aging process. As discs dehydrate and shrink, the space between vertebrae diminishes, leading to potential nerve compression and associated symptoms such as neck pain, radiculopathy, and myelopathy. [2] This reduction in disc height can also cause abnormal motion between vertebrae, contributing to further degeneration and instability. [3]

Anterior cervical discectomy and fusion (ACDF) has become the standard of care for patients with cervical spondylosis, herniated discs , or radiculopathy refractory to conservative treatment. [4] The procedure involves the insertion of an interbody spacer or cage into the disc space, which serves to re-establish the normal disc height and maintain proper alignment of the cervical spine. Central to the success of ACDF is the restoration of intervertebral height (IH) and the achievement of solid bony fusion. [5]

Some studies suggest that while ACDF effectively increases disc height postoperatively, the long-term maintenance of this height and its correlation with clinical outcomes remain uncertain. For instance, Aboudouaini et al found that postoperative intervertebral height changes did not significantly impact clinical outcomes, indicating that factors other than disc height restoration may play a role in patient recovery. [6] Conversely, other research emphasizes the importance of disc height restoration. Peng et al highlighted that inadequate restoration of disc height during ACDF could lead to suboptimal neural foramen decompression and persistent symptoms. [7] This underscores the necessity of achieving appropriate disc height to ensure effective nerve root decompression and favorable clinical outcomes.

The ACIS™ Anterior Cervical Interbody Spacer (ACIS, Johnson & Johnson MedTech, Raynham, MA)is a polyetheretherketone (PEEK) device designed to address these needs. With a modulus of elasticity closely matching that of bone, ACIS minimizes stress shielding while providing a stable construct to support bone fusion. [18] This is the first study to evaluate clinical characteristics in patients that underwent ACDF surgery with placement of ACIS system. It aims to explore patient characteristics and evaluate radiographic and clinical outcomes within this population. This single-center retrospective cohort study is the first to evaluate clinical and surgical outcomes in patients with degenerative cervical spine disease who underwent single- or multi-level ACDF procedures using the ACIS and VECTRA systems.

Methods

Study Design

This retrospective cohort study was conducted at Carilion Roanoke Memorial Hospital. An IRB-approved retrospective chart review was conducted to assess fusion outcomes in patients who underwent ACDF with ACIS between 2016 and 2020. The primary outcome measure was changes in anterior and posterior IH over time. Secondary outcomes included rates of post-operative complications (neck pain, dysphagia), hardware subsidence and radiographic evidence of bridging bone.

Patient Characteristics

Inclusion criteria included adult patients (≥18 years) undergoing ACDF with ACIS and VECTRA plating. Patients were excluded if they had prior cervical fusion, significant trauma, or malignancy involving the cervical spine. Patient age, BMI, smoking status, number of levels fused, and specific levels that were fused were recorded. Radiographic assessments of anterior and posterior IH were performed preoperatively, immediately postoperatively, and at 6 and 12 months. Clinical fusion status and any complications, including neck pain, dysphagia, and hardware-related issues, were documented at each timepoint.

Statistical Analysis

Descriptive statistics were used to summarize baseline characteristics. One analysis looked at differences between 1-level, 2-level, 3-level and 4-level ACDF on anterior and posterior IH. Another analysis looked at differences on anterior and posterior IH based on patient's smoking status: never smoked, quit smoking for over 3 months, current smoker. Repeated measures ANOVA and two-tailed T-tests compared outcomes across groups. A p-value <0.05 was considered significant.

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Results

Demographics and Baseline Characteristics

The study cohort included 106 patients (55 males and 51 females) with a mean age of 54.4 years (SD 11.9) and a mean BMI of 31.3 (SD 6.7). There were 23 patients that received 1-level ACDF, 34 patients that received 2-level ACDF, 24 patients that received 3-level ACDF, and 12 patients that received 4-level ACDF. Among the patients in this cohort, 31 were non-smokers, 35 were ex-smokers, and 40 were current smokers. There were no significant differences in age, BMI, or comorbidity burden between smokers, ex-smokers, and non-smokers.

Radiographic Outcomes

In general, post-operatively there was a statistically significant increase in anterior and posterior IH in patients irrespective of the number of levels being operated on ($P<0.05$). This is illustrated well in Figure 1. Not only was the post-operative anterior and posterior IH increased compared to preoperative values, but also, they were sustained throughout follow-up ($P<0.05$). It is also evident that the anterior and posterior IH do decrease with time post-operatively.

Postoperative increases in anterior and posterior IH were also seen to be statistically significant across all patients within the smoking status cohorts ($p<0.05$). However, smokers and ex-smokers demonstrated greater increases in anterior IH at 6 and 12 months compared to non-smokers ($p=0.02$ and $p=0.03$, respectively). Posterior IH did not differ significantly among groups, suggesting uniform improvements in posterior stability. This trend is described in Table 1 and illustrated in Figure 2.

Clinical Outcomes

All of the patients in our cohort showed successful fusion by their 12-month follow-up appointments. There were only 5 patients that required reoperation surgery (3%). Among these patients, 4 of the patients required revision procedures in which supplemental posterior fixation was added to the index vertebral levels. There were no reported incidents of hardware failure.

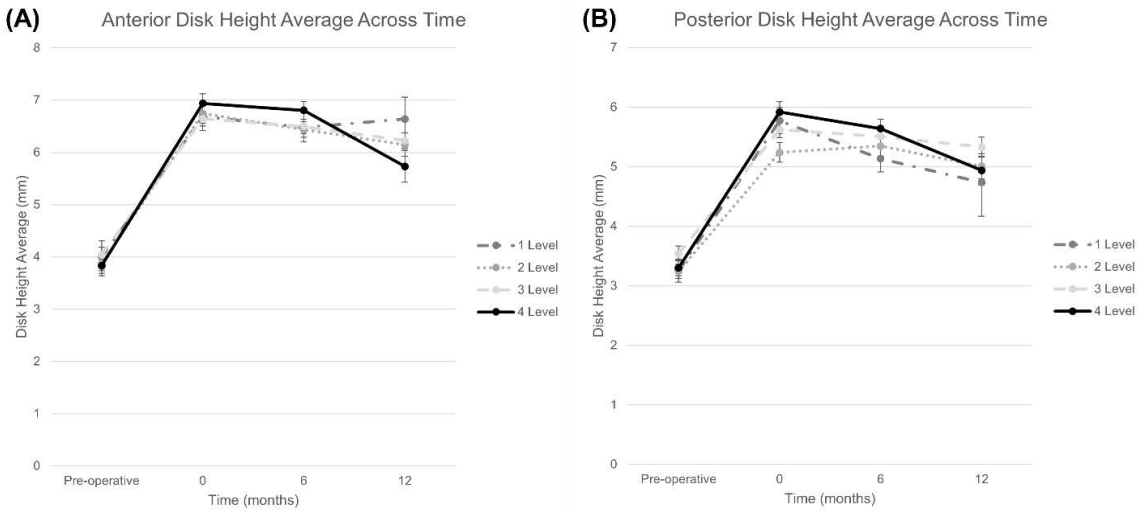

Figure 1: Average anterior (A) and posterior (B) intervertebral height (IH) before surgery, immediately after surgery, 6-months after surgery, and 12-months after surgery separated by number of levels operated on during the ACDF procedure.

Table 1: Average and standard error of anterior (A) and posterior (B) intervertebral height (IH) before surgery, immediately after surgery, 6-months after surgery, and 12-months after surgery separated by smoking status: nonsmoker, quit smoking > 3 months, and current smokers. P-values were calculated using ANOVA: single factor.

		Nonsmoker (n=31)		Quit > 3m (n=35)		Smoker (n=40)		ANOVA:single factor
Location	Timepoint	AVG	STE	AVG	STE	AVG	STE	P-Value
Anterior	Pre-operative	4.068966	0.185959	3.860256	0.143413	3.92069	0.125233	0.410735
	0	6.5125	0.18082	6.864634	0.149981	6.775556	0.146582	0.301143
	6	6.1	0.16461	6.669565	0.148483	6.606667	0.12916	**0.019536**
	12	5.688372	0.20764	6.336957	0.201093	6.301818	0.166677	**0.03411**
Posterior	Pre-operative	3.368966	0.153211	3.314103	0.114409	3.416092	0.103208	0.819294
	0	5.214063	0.175182	5.592683	0.144348	5.621111	0.125555	0.115715
	6	4.986538	0.178945	5.450725	0.135929	5.468	0.140323	0.055112
	12	4.702326	0.261872	5.126087	0.187365	5.207273	0.169964	0.170887

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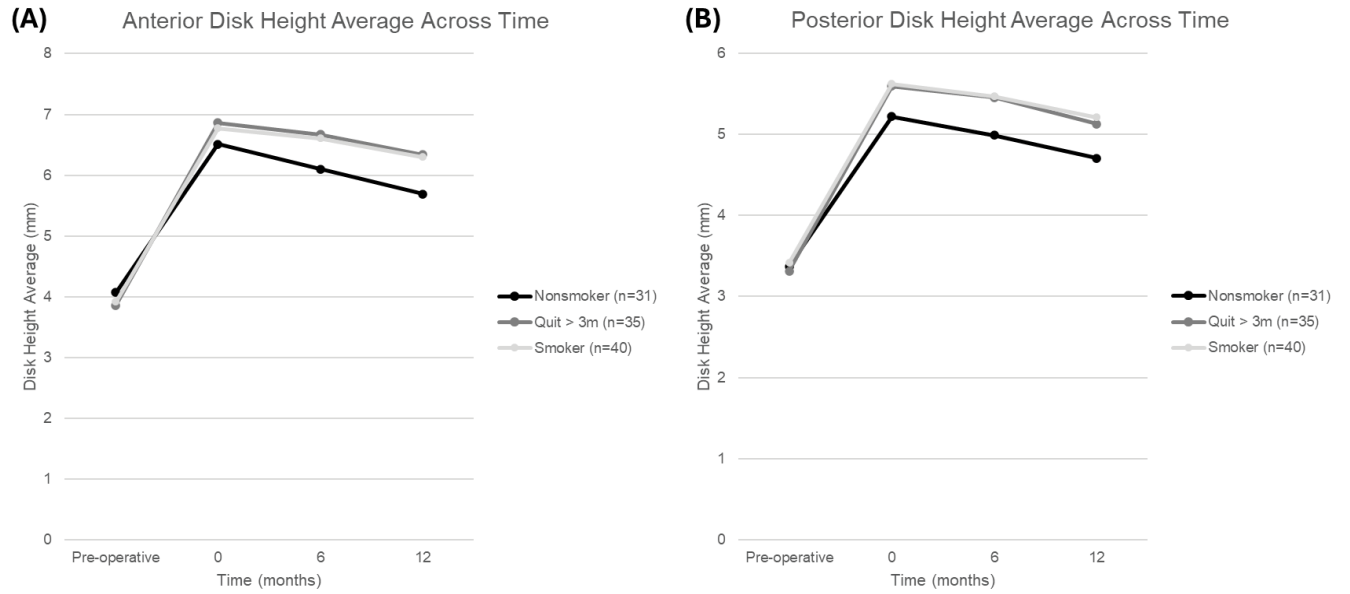

Figure 2: Average anterior (A) and posterior (B) intervertebral height (IH) before surgery, immediately after surgery, 6-months after surgery, and 12-months after surgery separated by smoking status: nonsmoker, quit smoking > 3 months, and current smokers.

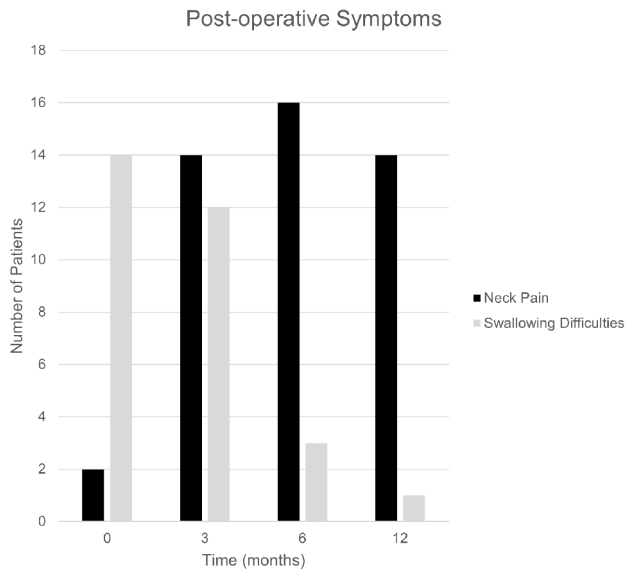

Figure 3: Symptoms of neck pain and swallowing in patients immediately after surgery, 3 months after surgery, 6-months after surgery and 12-months after surgery.

There were a few patients who complained of post-operative symptoms during their subsequent follow-up appointments. These commonly included neck pain and dysphagia (Figure 3). Interestingly, dysphagia improved over time, with resolution in most patients by 12 months (n=1; <1%). However, neck pain persisted in a subset of patients (n=14; 13%). Our current follow-up was only 1 year out, it would be interesting to continue follow-up to see if neck pain diminished in this subset of patients. These complications did not correlate with smoking status.

Discussion

This study demonstrates the effectiveness of ACIS in restoring IH and achieving bony fusion in ACDF. Across the cohort, patients demonstrated substantial postoperative increases in both anterior and posterior IH, which were sustained over the 12-month follow-up period. Notably, these outcomes were achieved irrespective of the number of cervical levels treated, underscoring the versatility and robustness of the ACIS system in both single-level and multi-level fusion procedures. The ability of ACIS to maintain structural integrity and facilitate fusion across varying levels of complexity is a testament to its biomechanical design, which closely mimics the modulus of elasticity of bone. This feature likely minimizes stress shielding while allowing for a stable construct to facilitate bone ingrowth for long-term stability. Furthermore, the consistent fusion rates observed in this study reflect the reliability of the system in providing a stable environment for bony union, even in high-risk patient populations such as smokers or those with suboptimal bone quality. These findings emphasize the utility of ACIS as a dependable interbody device for ACDF, capable of delivering successful outcomes in a wide range of clinical scenarios. Its performance in both single- and multi-level procedures highlights its adaptability and supports its use as a preferred choice for surgeons aiming to restore spinal alignment, preserve motion, and achieve fusion in patients with degenerative cervical spine disease.

Interestingly, this study showed favorable outcomes across smoking groups. The sustained improvements in IH suggest that the ACIS system provides robust structural support, even in high-risk populations such as smokers. While numerous

studies have validated the effectiveness of ACDF, the impact of patient-specific factors, such as smoking, on outcomes with the ACIS system remains underexplored. Smoking is well-documented to impair bone healing, delay fusion, and increase the risk of adjacent segment disease. [8 9 10 11 12 13] However, the extent to which these effects manifest in patients undergoing ACDF with ACIS™ is unclear. The greater anterior IH observed in smokers and ex-smokers likely reflects compromised bone quality, as smoking is known to reduce bone mineral density and vascularity. [8 11 14 15] Despite these concerns, the lack of significant differences in subsidence or complications suggests that the ACIS system yields comparable outcomes in higher-risk populations; however, further research is needed to determine its role in mitigating risks associated with compromised bone quality and durability of ACIS system.

The findings in this study underscore the effectiveness of the ACIS system in achieving favorable surgical outcomes across diverse patient populations, including those with risk factors like smoking. Nonetheless, optimizing bone health prior to surgery—through interventions such as smoking cessation or pharmacologic therapies targeting bone density—could potentially improve fusion rates and overall outcomes.

Recent insurance policies have increasingly restricted the use of interbody cages, favoring cortical allograft spacers instead. However, synthetic and alloy cages, such as those made from polyetheretherketone (PEEK) or titanium, have demonstrated superior biomechanical stability in maintaining cervical lordosis and disc height. Studies have shown that PEEK cages, for instance, are associated with higher fusion rates and lower subsidence compared to titanium cages. [16] Additionally, the design evolution of interbody cages has focused on improving lordotic alignment and increasing disc height, contributing to better clinical outcomes. [17] Given these advantages, the implications of insurance-driven restrictions on long-term surgical outcomes warrant further investigation.

This study's limitations include its retrospective design and the single-center setting, which may limit the generalizability of the results to broader populations. Furthermore, the relatively short follow-up period restricts the ability to assess longer-term outcomes, including the development of adjacent segment disease or the durability of intervertebral height restoration. Future studies with multi-center designs and extended follow-up are needed to validate these findings and explore long-term implications.

To build upon the findings of this study, prospective, multi-center research with extended follow-up periods is essential. Such studies would provide a broader and more diverse patient population, enhancing the generalizability of the results and addressing limitations inherent in single-center, retrospective designs. By incorporating long-term follow-up, future research could evaluate the durability of the ACIS system in maintaining intervertebral height and achieving sustained fusion, particularly in high-risk populations such as smokers and patients with compromised bone health. Additionally, these studies could investigate potential late-onset complications, including adjacent segment disease and implant-related issues, to determine the true longevity and safety of the ACIS system. Insights gained from these investigations would help refine surgical protocols, improve patient selection criteria, and optimize preoperative and postoperative management strategies for diverse patient populations.

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