https://doi.org/10.58256/rjmhs.v3i1.946

Research Article

Section: Health Sciences

Check for updates

Published by Royallite Global in the *Research Journal in Medical and Health Sciences*.

Volume 3, Issue 1, 2022

Article Information

Submitted: 17th October 2022

Accepted: 9th December 2022

Published: 18th December 2022

Additional information is available at the end of the article

To read the paper online, please scan this QR code

How to Cite:

Tummala, S., & Bowman, K. (2022). Evaluation of polytheretherketone (PEEK) cages in surgical treatment of multilevel cervical degenerative disease. *Research Journal in Medical and Health Sciences*, *3*(1). https://doi.org/10.58256/rjmhs.v3i1.946

Evaluation of polytheretherketone (PEEK) cages in surgical treatment of multilevel cervical degenerative disease

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Abstract:

Anterior Cervical Discectomy and Fusion (ACDF) with autograft spacer is a traditional surgical treatment option to correct cervical degenerative disc disease and maintain intradiscal height. There is not a clear consensus on what type of interbody spacer is the best treatment option for patients undergoing ACDFs, so this study seeks to mitigate the gap in available literature. The aim of this retrospective study is to evaluate the clinical findings and radiographic outcomes in ACDFs using polytheretherketone (PEEK) cages in the surgical treatment of multilevel cervical degenerative disease between C2 and T1. We examined 72 consecutive patients with degenerative cervical disorder from C2-T1 who underwent ACDFs with PEEK cages between 06/01/19 and 05/05/21. The collected measures were pain levels using the Visual Analog Scale (VAS), intraoperative and postoperative (post-op) complications, and radiographic outcomes. The average VAS score was 5.7 out of 10 preoperatively (pre-op), 3.5 out of 10 two weeks post-op, 2.4 out of 10 three months post-op, and 3.06 out of 10 six months post-op. Pre-op symptoms were resolved in 69 out of 72 patients (95.8%). Durotomies were observed in 4 out of 72 (5.6%) patients intraoperatively. Post-op complications included dysphagia (13.9%), wound healing (12.5%), cervical hematoma (0%), hoarseness (0%), cerebrospinal fluid leak (0%), infection (0%), and death (0%). Spinal fusions were seen in 65 out of 72 patients (90%) over a six-month period. While there were no abnormal instrumentations noted, malalignment was observed in 2 out of 72 patients (2.8%). None of the patients required revision spinal surgery. Most of the patients experienced an improvement of pain and relief of symptoms post-op. A majority of individuals achieved fusion with minimal complications. This study suggests that PEEK can be a viable interbody spacer in multilevel ACDFs for the treatment of individuals with degenerative cervical disorders. Additional evaluations of different interbody spacers can confirm these findings to identify the most effective spacer that will yield optimal patient outcomes.

Keywords: Anterior Cervical Discectomy and Fusion (ACDF), cervical vertebrae, spinal surgery

Background

ACDF was first introduced by Smith and Robinson in 1955 as a method to treat cervical disc herniation, bulging, and or degeneration[1]. Herniated discs or tear(s) in the annulus allow gel-filled nucleus material to leak and compress the spinal cord causing patients pain, numbness, and weakness[2]. Failure to correct herniated or degenerative disc disease can cause bone spur formation, leading to narrowing of the nerve root canal known as foraminal stenosis, leading to worsening symptoms. ACDF is an effective procedure in patients with surgical indications. Today, ACDF with plate fixation is used as a surgical treatment option for symptomatic individuals with radiculopathy and cervical myelopathy that are unresponsive to documented non-surgical treatment modalities such as pain control and anti-inflammatories, activity modifications, and physical therapy[3]. The surgery involves utilizing an anterior approach to remove the intervertebral disc and fuse the vertebral bodies[4]. The anterior approach to surgery allows for direct visualization and access to the disc(s) and less post-op pain than posterior cervical discectomy and fusion (PCDF)[5]. In comparison to PCDF, it was found that ACDF patients have shorter length of stays in the hospital and are more commonly performed at nonteaching hospitals[6]. The incidence of complications and mortality was 4.14% and 0.26% for ACDF patients and 15.35% and 1.44% for PCDF patients, respectively. Specific ACDF associated complications include post-op dysphagia, hematoma, and recurrent laryngeal nerve palsy[7]. Overall, ACDF has been associated with a significant improvement among patients with degenerative cervical disc disease[8].

Cervical discectomies and fusions utilize various cages as bone substitutes to provide structural support. Previously, the gold standard for spinal fusions was the utilization of autogenous iliac bone grafts. Cancellous allografts have been used in orthopedic surgeries for many years and are traditionally used to fill bone defects caused by a fracture, tumor, or in joint revision surgeries. However, autogenous and allogenous bone graft users report high donor site morbidity, major complications such as deep wound infections, and chronic complications such as post-op pain at the donor site[9]. These concerns and material advancements have led to the use of interbody spacers instead of autografts. Ideal interbody spacers should allow for high fusion rates, post-op stability, sagittal alignment and disc height maintenance, and minimal graft breakdown that is historically seen with the autogenous or allogenous bone graft material[10]. It is important to select effective surgical cages to maximize decompression and fusion as well as contribute to a quick and safe recovery following surgery[11]. Numerous types of materials exist for cage development including titanium, carbon fiber, para-phenylene, and PEEK.

PEEK cages are synthetic thermoplastic polymers that are semi-crystalline in structure[12]. Composed of non-absorbable biopolymer similar to elastic modulus of native bone, PEEK minimizes the effect of stress shielding, but is more expensive than allografts[13]. The cage's application is limited by a biofilm layer around its surface that can impair fusion to cortical bone[14]. A study following 19 patients who underwent ACDF using PEEK cages filled with freeze-dried cancellous allograft bone found that 74% of patients reported excellent clinical outcomes and 100% interbody disc space was achieved at one year follow-up[15]. PEEK demonstrates the absence of cytotoxicity and mutagenicity in in-vitro studies, is biocompatible, non-absorbable, and corrosion resistant making it an optimal material for interbody spacers. The material is radiolucent and does not create artifacts on CT scans or radiographs, allowing for better visualization and evaluation of fusion on films and post-op metrics. This retrospective study aims to illustrate the outcomes of ACDF surgeries that utilized PEEK cages.

Methods

Following TCU Institutional Review Board approval (2021-103), a retrospective study of consecutive patients undergoing ACDFs with PEEK cages was administered. The study was conducted at a small, single privately-owned suburban neurosurgical clinic in Texas. Inclusion criteria included patients with degenerative cervical disorders from levels C2 to T1 between June 1, 2019 and May 5, 2021. All surgeries were performed by a single surgeon and informed consent was ascertained. Seventy-two patients were

selected and included in the study population. Clinical measures comprised of pain levels utilizing the VAS, intraoperative and post-op complications, and radiographic outcomes. All statistical analyses were performed using Excel.

Results

A total of 72 patients underwent ACDFs with PEEK cages in this study. The average reported VAS scores on a scale of 0 to 10 were 5.7 immediately pre-op, 3.5 at 2 weeks post-op, 2.4 at 3 months post-op, and 3.06 at 6 months post-op (*Table 1*).

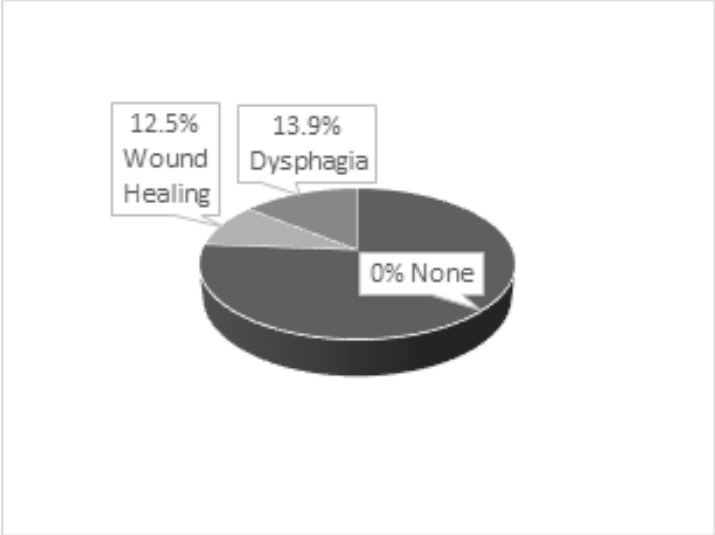
Table 1. Average VAS Scores

Post-operative Timing	**VAS Score (0-10)**
Immediately	5.7
2 Weeks	3.5
3 Months	2.4
6 Months	3.06

95.8% of patients reported that their symptoms resolved after surgery. 4 out of 72 patients (5.6%) had durotomies intraoperatively. No patients underwent revision spinal surgery six months following their initial ACDF.

The majority of patients (73.6%) did not have any complications following surgery. Post-op complications included dysphagia (13.9%), wound healing (12.5%), cervical hematoma (0%), hoarseness (0%), cerebrospinal fluid leak (0%), infection (0%), and death (0%) (*Figure 1*).

Figure 1. Post-op Complications Following ACDF with PEEK



Fusions were noted on operative spinal levels in 65 out of 72 patients (90%) within a six-month period. Radiograph findings did not reveal any abnormal instrumentation. However, malignment was observed in 2 out of 72 patients (2.8%).

Discussion

Our study results indicate that almost every single patient reported a resolution of symptoms post-op compared to prior to surgery. After suffering from pain for months or even years, patients initially present to neurosurgeons for evaluation of possible degenerative disc disease after not receiving relief from their discomfort from less invasive measures such as physical therapy and spinal injections. As a result, patients likely seek reduced pain as their primary outcome in receiving ACDFs. In identifying an effective interbody spacer, it is important to consider pain relief, which can be reflected in VAS scores, as a quality-of-life measure. While the trend in VAS scores was not a linear downward trend, the average VAS score 6 months post-op was lower than pre-op. Accordingly, the lower VAS scores contribute to maximizing patient outcomes in our study.

A majority of individuals achieved fusion within a six-month period with only minimal complications. While most patients did not have any complications following their ACDFs, the most common post-op complication was dysphagia. ACDF complications can be minimized by avoiding prolonged and forceful retraction to prevent injury to the esophagus, recurrent laryngeal nerve, and carotid arteries[16]. Even though incidental durotomy is a common complication for PCDFs[17], there were four durotomies seen intraoperatively.

Given the nature of spinal fusion procedures, the likelihood that a patient needs a revision procedure several years later is high. An ineffective interbody spacer could further lessen the timeframe required between an initial ACDF and a revision fusion procedure. This would unfortunately translate into greater medical costs for the patient and the healthcare system. The average cost for ACDF inpatient ACDF costs up to $74,667 whereas outpatient costs around $33,362[18]. A study including 85 patients who underwent revision of cervical spine surgery for adjacent segment disease found an average direct cost of $27,702[19]. However, when an effective interbody spacer with greater fusion rates is implanted in a patient during initial ACDF procedures, patients will likely not require a revision procedure due to spacer concerns, which is supported by our patients who did not undergo a revision within six months post-op. This could decrease the number of medical visits that patients make to the surgeon, and this could reduce the number of ACDF revision procedures conducted, which can reduce the cost to the healthcare system.

There are several limitations to this study. Comorbidities such as smoking, diabetes mellitus, frailty, and steroid use are potential confounding variables that could have altered our analysis of post-op complications[17,20]. Similarly, dysphagia can be affected by several confounding variables such as operating on C4 or C5, anesthetic times, and intubation tube sizes[21]. Since the study participants were all patients at a single suburban Texas neurosurgical clinic, the data of these patients undergoing post-op appointments at another clinic or hospital was not collected. While these factors can potentially limit the application of the data to larger populations of individuals undergoing ACDFs with PEEK cages, the work nonetheless provides insight into the benefits of the PEEK interbody spacer.

In conclusion, our study suggests that the PEEK interbody spacer is an effective interbody spacer in ACDF procedures. Examining fusion rates and complication rates in individuals undergoing ACDF with other popular interbody spacers such as titanium and silicon spacers would be insightful. Conducting longer term studies with at least a five-year post-op period would allow for a more accurate exploration of post-op revision rates. These proposed future studies can be compared with one another to not only confirm our findings but also help identify the most cost-efficient and top-quality spacer that will result in optimal patient outcomes

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