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ORIGINAL RESEARCH

Evaluation of Healthcare Outcomes of Patients Treated with 3D-Printed-Titanium and PEEK Cages During Fusion Procedures in the Lumbar Spine

Katherine A Corso[1], Andreas A Teferra[1], Annalisa Michielli[2], Kristin Corrado[2], Amy Marcini[3], Mark Lotito[2], Caroline Smith[4], Michelle Costa[4], Jill Ruppenkamp[1], Anna Wallace[1]

[1]MedTech Epidemiology and Real-World Data Science, Johnson & Johnson, Raynham, Massachusetts & New Brunswick, New Jersey, USA; [2]Clinical Research, DePuy Synthes, MedTech, Johnson & Johnson, Raynham, Massachusetts, USA; [3]Medical Affairs, DePuy Synthes, MedTech, Johnson & Johnson, Raynham, Massachusetts, USA; [4]Franchise HEMA, DePuy Synthes, Medtech, Johnson & Johnson, Raynham, Massachusetts, USA

Correspondence: Katherine A Corso, MedTech Epidemiology and Real-world Data Science, Johnson & Johnson, 325 Paramount Drive, Raynham, MA, 02767, USA, Tel +1 857-523-0279, Email kcorso1@its.jnj.com

Purpose: The objective of this observational, real-world study was to describe reoperation, revision, index healthcare utilization and hospital costs among patients treated with PEEK (polyetheretherketone) or 3D-printed-titanium cages during lumbar/lumbosacral posterior fusion procedures, either TLIF (transforaminal lumbar interbody fusion) or PLIF (posterior lumbar interbody fusion). Statistical comparisons were not conducted.

Methods: This was a descriptive, retrospective, observational study. Patients with PEEK (OPAL™, DePuy Synthes, Raynham, MA) or 3D-printed-titanium (CONDUIT™ TLIF (transforaminal lumbar interbody fusion)/PLIF (posterior lumbar interbody fusion) Cage/EIT™ Cellular Titanium TLIF/PLIF Cage (DePuy Synthes, Raynham, MA)) spinal cages were identified in the Premier Healthcare Database between 1/1/2007 and 9/30/2022. Patients were required to have posterior approaches of the lumbar/lumbosacral spine and DDD, stenosis, back pain, instability, spondylolisthesis, or pseudarthrosis/failed prior surgery. Patient and procedure, healthcare utilization and hospital cost data were collected at the index surgery, and patients were followed up to 3 months for reoperation and 12 months for revision. All data were summarized descriptively, and no statistical comparisons were made between cage groups.

Results: A total of 5118 PEEK and 1189 3D-printed-titanium cage patients were included in this study. Among 3D-printed-titanium cages, 804 had PLIF and 345 had Curved TLIF cage types. Most PEEK cage patients were 18–64 years (61.9%), and 3D-printed-titanium was evenly distributed across age categories. The mean index hospital cost was ~$40,000, LOS was ~3 days, and discharge status to home/home health was ~85% for both; surgery time was 267 minutes for PEEK and 280 minutes for 3D-printed-titanium. The 0–3 month reoperation cumulative incidence was 1.0% for PEEK and 1.3% for 3D-printed-titanium. For revision, incidence within 0–3, 4–6, and 7–12 months was 1.2%, 0.6%, and 1.7% for PEEK and 1.6%, 0.5%, and 1.2% for 3D-printed-titanium. The mean costs per patient associated with reoperation and revision for the entire cohort were $220 and $1228 for PEEK and $290 and $1754 for 3D-printed-titanium.

Conclusion: This study provides real-world economic insights into an area where practice data are sparse, within hospital settings for PEEK and 3D-printed-titanium spinal cages. A key study limitation is the descriptive design in which potential confounding factors that may affect the outcome estimates are not addressed.

Keywords: spinal cage, 3D-printed, lumbar fusion, reoperation, revision rates, healthcare utilization, real-world data

Introduction

Interbody fusion is a commonly offered surgical technique for addressing degenerative disorders of the lumbar spine. Intervertebral body fusion devices, such as spinal cages and spacers, play a crucial role in realigning displaced vertebral bodies and correcting spinal instability.[1] Interbody cages should be strong enough to improve segmental alignment,

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alleviate pressure on discs, and facilitate bone fusion through stabilization post-discectomy.[2] The most frequently used materials in spinal interbody fusion surgeries are titanium (Ti) alloy and polyetheretherketone (PEEK). Titanium implants, utilized since the 1980s, are valued for their capacity to allow bone to be deposited (osteoconduction) at the surface of the cage. Furthermore, due to the development of a TiO2 surface layer, surface modifications and changes in cage porosity have been developed to improve osseointegration within and around the implant.[3] However, titanium's high elastic modulus of around 110 gigapascal can lead to issues such as stress shielding and implant subsidence.[3] PEEK implants, introduced in the 1990s, addressed these concerns by more closely matching the modulus of elasticity of bone, thereby enabling a load-sharing construct with surrounding bone and promoting biomechanical stability.[1,4] Additionally, PEEK cages offer the benefit of radiolucency, enabling better post-operative monitoring of fusion progress using radiographic methods.[1] However, PEEK cages have inferior osteoconductive properties compared to Ti/Ti alloy cages, potentially posing a risk of pseudarthrosis.[5] In recent years, advancements in three-dimensional (3D) printing technology offered the potential to create interbody implants that overcome the material limitations using additive manufacturing that enables osteointegration; in particular, these cages have porosity and surface roughness that aid in the osseointegration process.[2,6,7] Furthermore, these implants have enhanced radiolucency compared to Ti and thus can support a more accurate reading of spinal fusion and have been demonstrated to have a closer Young's modulus to bone compared to PEEK which can decrease the occurrence of cage subsidence.[2,6]

There are limited real-world data, that is healthcare data collected routinely from sources such as electronic healthcare records and medical claims, on the utilization and outcomes of established PEEK cage technology and newer 3D printed technology.

The aim of this study was to describe the real-world reoperation, revision, healthcare utilization and economic outcomes of patients with a DSD diagnosis treated with a PEEK or 3D-printed-titanium cage used for fusion procedures of the lumbar or lumbosacral spine. A descriptive study design was used because the goal of this research was to observe only and not compare the estimates of key index and postoperative outcomes of these two types of spinal cages with different material technology in a real-world hospital setting, an area of research where more data are needed to help providers, patients and payers understand the safety and utilization in healthcare settings common to where care is received.

Methods

Study Design

This was a descriptive, retrospective, observational cohort study without comparative statistical analysis. The descriptive and observational aspect of this study allowed for understanding of outcomes in a real-world setting for a cage brand with established material technology, OPAL™ Spacer System (DePuy Synthes, Raynham, MA), a PEEK cage, and a cage brand with newer material technology, CONDUIT™ Curved TLIF (transforaminal lumbar interbody fusion)/PLIF (posterior lumbar interbody fusion) Cage/EIT™ Cellular Titanium TLIF/PLIF Cage (DePuy Synthes, Raynham, MA), 3D-printed-titanium cage. Throughout this manuscript, these devices are referred to as PEEK or 3D-printed-titanium cage. This study estimated the cumulative incidences of reoperation within 0–90 days and revision within 0–90 days, 91–180 days, and 181–365 days following index surgery/fusion procedure. The study also describes primary and secondary diagnoses of interest at the time of index surgery and at the time of revision and reoperation for patients with these outcomes. Diagnoses of interest included DSD of the lumbar or lumbosacral spine, based on the intended use and indications according to the indications for use (IFU) for both cage types.

Patients

Patients were eligible for inclusion in this study if they met the following criteria: 1) had a billing charge for the brand name of each cage between January 1, 2007, and September 30, 2022; 2) had a primary or secondary procedure code for posterior approaches of the lumbar or lumbosacral spine, according to the International Classification of Diseases, 9th and 10th revisions (ICD-9 and 10), or Current Procedural Terminology (CPT) procedure codes (See Supplemental File, Table S1 for Codes and Code Definitions); 3) had a primary or secondary diagnosis code for DSD, including DDD,

stenosis, back pain, instability, spondylolisthesis, or pseudarthrosis/failed prior surgery of the lumbar or lumbosacral spine (see Supplemental File, Tables S2 through S7).

Patients under 18 years of age, those with a billing charge indicating the use of a CONDUIT™ALIF or LLIF cage, with missing age or sex information, active systemic or local spine infection indicated by a primary diagnosis of infection or secondary diagnosis of infection that was present on admission (See Supplemental File, Table S8), and patients from hospitals with less than 90 days of continuous participation in the database after the index surgery were excluded from this study.

Data Source

This study used inpatient and outpatient hospital billing records contained in the Premier Healthcare Database (PHD). The PHD contains complete clinical coding, hospital cost, and patient billing data from more than 1000 hospitals throughout the United States (US). PHD represents 1 in 4 inpatient hospital stays in the US, and it includes a wide variety of regions and most healthcare insurances in the US. Premier collects data from participating hospitals in its health care alliance. The Premier Alliance was formed to improve the quality of care. Participation in the Premier Alliance is voluntary by hospitals. Although the database excludes federally funded hospitals (eg, Veterans Affairs), the hospitals included are nationally representative. The use of this data source was determined to be exempt from Institutional Review Board (IRB) approval by the New England IRB because the PHD consists of de-identified healthcare records. In the US, retrospective analyses of the PHD data are considered exempt from informed consent and institutional review board (IRB) approval as dictated by Title 45 Code of Federal Regulations, Part 46.

Variables

The cohorts of interest were the PEEK and 3D-printed-titanium cages. 3D-printed-titanium cages were also stratified by implant shape into two categories: 1) PLIF (straight implant, may be placed using PLIF or TLIF approach) and 2) Curved TLIF (curved implant, placed using TLIF approach).

Outcome variables included 1) Reoperation – defined as a new surgical procedure (excluding fusion, decompression, or device removal) within 0–90 days following the index procedure for surgeries in the lumbar or lumbosacral spine and with a wound complication (seroma and hematoma), infection, or dural tear diagnosis (for clinical codes that comprise this definition, see Supplemental File, Tables S9 to S10). The rationale for this definition is that reoperation for conditions such as infections or dural tear pathologies typically involve non-fusion surgical procedures. 2) Cumulative cost of 0–90 days reoperation, in United States Dollars (USD). 3) Revision – defined as a new surgical procedure in the lumbar or lumbosacral spine within 0–90 days, 91–180 days, and 181–365 days following the index procedure for fusion, decompression, or device removal, and with a diagnosis indicating the presence of unresolved spinal pathology, nerve injury, nonunion/pseudarthrosis, or device-related complications (for clinical codes that comprise this definition, see Supplemental File, Tables S11 to S12). The rationale for this definition is that revisions to address failure of the index surgery or device typically involve the same or similar type of surgical approach as the index surgery. 4) Cumulative cost of 0–365 days revision, in USD. 5) Time to first reoperation – days from index surgical procedure to first reoperation procedure within 0–90 days. 6) Time to first revision – days from index surgical procedure to first revision procedure within 0–365 days. 7) Primary and secondary diagnoses of interest at the time of the index procedure for the overall cohort and of those with reoperation or revision (see Supplemental File, Tables S2 through S7), as well as at the time of the first reoperation and first revision (see Supplemental File, Tables S10 and S12). 8) Length of stay (LOS) of the index procedure, in days. 9) Operation room time (ORT) of the index procedure, in minutes. 10) Discharge status after the index procedure. 11) Cost of the index procedure, in USD.

Patient demographics collected at index in this study were age, gender, race, marital status, insurance payer, smoking status, setting of care (inpatient or outpatient) and admission type (elective or nonelective).

Clinical characteristics collected at index included preoperative pathologies: degenerative disc disease (DDD), stenosis, back pain, instability, spondylolisthesis, and pseudarthrosis/failed prior surgery. Other patient clinical characteristics collected included the presence of osteoporosis (see Supplemental File, Table S13), mortality status at the time of discharge and the Elixhauser Comorbidity Index (ECI), Functional Comorbidity Index (FCI), All patient refined (APR)-Diagnostic

related groups (DRG) Severity, APR-DRG Mortality, and Medicare Severity (MS)-DRG Code and Description. The ECI and FCI were identified using the ICD codes assigned at index designated as present on admission. Both indices are used to adjust for comorbidity in observational studies. The ECI is a summary measure of the Elixhauser comorbidity system which is a set of 31 chronic comorbidity indicators. The FCI is a summary measure of the Functional comorbidity system, which is a set of 18 comorbidity indicators that affect physical function. The Medicare Severity Diagnostic Related Groups (MS-DRG) is a classification system used to group patients by their health status at the time of surgery and facilitates billing for patients' visits. The APR-DRG Severity and Mortality are assigned at discharge to further classify postoperatively the severity of patients' clinical diagnosis(es) and the risk of mortality and supports billing for the patients' visit. The assignment of the APR-DRG classifications depends on patients' diagnoses amount and type.

Procedural characteristics were procedure year, number of spinal levels fused and type of surgical approach used (Minimally Invasive Surgery (MIS) or Open). Spinal levels fused and approach were assigned using ICD-10 codes.

Hospital characteristics were hospital type, geography, bed size, and urban setting.

Provider characteristics considered the procedure physician specialty (orthopedic vs neurosurgeon vs other).

Analysis

No statistical comparisons were made in this study. Descriptive analyses were performed for all patient demographic, clinical, procedural, and hospital characteristics for cohorts overall (PEEK and 3D-printed-titanium, which included PLIF, Curved TLIF and cages where the type could not be identified). Stratified analysis was conducted for the 3D-printed-titanium subgroups (PLIF and Curved TLIF only; unidentified cages were not included in the stratified analysis). Continuous variables were summarized as mean, standard deviation, upper and lower 95% confidence levels, median, and range. Categorical variables were summarized as frequency and percent. Standard mean differences (SMDs) between PEEK and 3D-printed-titanium groups were generated for patient demographic, clinical, procedural, hospital and provider characteristics as an indicator of differences between the two unmatched device groups; a SMD ≤ 0.10 is typically used as a cut-off to identify adequate differences between groups for conducting matched analyses using the propensity score approach.[8] Deceased patients were removed from any analyses involving postoperative variables.

Outliers or extreme observations were not excluded from analysis.

Results

The study included a total of 6307 patients, with 5118 (81.2%) receiving the PEEK and 1189 (18.8%) receiving 3D-printed-titanium cages. Among the 1189 3D-printed-titanium cages, 804 patients received PLIF (67.6%) and 345 patients received Curved TLIF (29.0%) cages.

Patient Characteristics

Table 1 presents the patient demographics for the spinal cage cohorts as well as the PLIF and Curved TLIF subgroups within the 3D-printed-titanium cohort. The majority of patients were aged between 18 and 64 years in the PEEK cohort (61.9%) and the majority were aged 65+ in the 3D-printed-titanium cohort (50.2%). Patients aged 65 and above had a higher representation in the 3D-printed-titanium cohort overall and for PLIF and Curved TLIF (50.2%) subgroups than in the PEEK cohort (38.1%). There was a slightly higher proportion of females in both cohorts, comprising 56.5% of the overall cohort, with similar distributions observed between the PEEK and 3D-printed-titanium cohorts. Patients identifying as White constituted the largest racial group in both cohorts (PEEK, 79.4%; 3D-printed-titanium, 86.0%); however, there were variations in racial distribution between the PEEK and 3D-printed-titanium cohorts. The majority of patients were married in both cohorts (around ~60%), and single individuals comprised ~35.0% of both cohorts. Medicare was the most common payer type (46.1%) across both cohorts, 3D-printed-titanium cohort overall was 53.4%, and by subgroup was 51.3% and 54.6%; PEEK cohort was 44.4% Medicare. Regarding spine diagnoses at index, among both cohorts, Degenerative Disc Disease (DDD), Stenosis and Spondylolisthesis were the most prevalent diagnoses at index. For the PEEK cohort, DDD was the most common diagnosis (68.1%), followed by Spondylolisthesis (54.8%) and Stenosis (54.1%). In the 3D-printed-titanium cohort, Stenosis was the most common diagnosis (82.3%), followed by DDD (79.9%) and Spondylolisthesis (70%). Osteoporosis was present in a small percentage of patients (4% to 5%).

Table 1 Patient and Provider Characteristics of Patients with PEEK and 3D-Printed-Titanium Cages

Variables	PEEK Cage		3D-printed-titanium Cage, All (PLIF/ Curved TLIF)		SMD	Subgroup: PLIF		Subgroup: Curved TLIF	
	N	%	N	%		N	%	N	%
All	**5,118**	**100.0%**	**1,189**	**100.0%**		**804**	**100.0%**	**345**	**100.0%**
Age category									
18–64	3,166	61.9%	592	49.8%	0.25	395	49.1%	173	50.1%
65+	1,952	38.1%	597	50.2%		409	50.9%	172	49.9%
Sex									
Female	2,882	56.3%	682	57.4%	0.02	467	58.1%	193	55.9%
Male	2,236	43.7%	507	42.6%		337	41.9%	152	44.1%
Race category									
White	4,062	79.4%	1,022	86.0%	0.22	717	89.2%	283	82.0%
African American	418	8.2%	79	6.6%		46	5.7%	25	7.2%
Other	623	12.2%	78	6.6%		37	4.6%	31	9.0%
Unknown	15	0.3%	10	0.8%		4	0.5%	6	1.7%
Marital Status									
Married	3,040	59.4%	739	62.2%	0.17	502	62.4%	218	63.2%
Other	290	5.7%	29	2.4%		17	2.1%	10	2.9%
Single	1,788	34.9%	421	35.4%		285	35.4%	117	33.9%
Payer type									
Commercial	1,990	38.9%	403	33.9%	0.27	267	33.2%	123	35.7%
Medicaid	337	6.6%	98	8.2%		58	7.2%	34	9.9%
Medicare	2,274	44.4%	635	53.4%		439	54.6%	177	51.3%
Other	517	10.1%	53	4.5%		40	5.0%	11	3.2%
Spine Diagnoses at Index*									
Degenerative Disc Disease	3,487	68.1%	950	79.9%	0.27	641	79.7%	282	81.7%
Stenosis	2,770	54.1%	978	82.3%	0.63	674	83.8%	269	78.0%
Back Pain	189	3.7%	43	3.6%	0.00	33	4.1%	9	2.6%
Instability	154	3.0%	163	13.7%	0.39	94	11.7%	67	19.4%
Spondylolisthesis	2,803	54.8%	832	70.0%	0.32	597	74.3%	211	61.2%
Pseudarthrosis	323	6.3%	89	7.5%	0.05	64	8.0%	22	6.4%
Osteoporosis	206	4.0%	60	5.0%	0.05	43	5.3%	16	4.6%
Smoking status (Yes)	1,975	38.6%	530	44.6%	0.12	380	47.3%	136	39.4%

(*Continued*)

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Table 1 (Continued).

Variables	PEEK Cage		3D-printed-titanium Cage, All (PLIF/ Curved TLIF)		SMD	Subgroup: PLIF		Subgroup: Curved TLIF	
	N	%	N	%		N	%	N	%
Elixhauser score category									
0	1,081	21.1%	163	13.7%	0.27	84	10.5%	71	20.6%
1–2	2,450	47.9%	525	44.2%		354	44.0%	152	44.1%
3–4	1,242	24.3%	384	32.3%		276	34.3%	97	28.1%
5 +	345	6.7%	117	9.8%		90	11.2%	25	7.3%
Functional score category									
0	104	2.0%	10	0.8%	0.28	5	0.6%	5	1.4%
1–2	1,429	27.9%	446	37.5%		334	41.5%	104	30.1%
3–4	1,568	30.6%	244	20.5%		132	16.4%	98	28.4%
5 +	2,017	39.4%	489	41.1%		333	41.4%	138	40.0%
APR-DRG Severity									
No Information	95	1.9%	150	12.6%	0.43	101	12.6%	48	13.9%
Mild	2,415	47.2%	535	45.0%		329	40.9%	191	55.4%
Moderate	2,186	42.7%	420	35.3%		316	39.3%	82	23.8%
Severe	374	7.3%	75	6.3%		50	6.2%	23	6.7%
Extreme	48	0.9%	9	0.8%		8	1.0%	1	0.3%
APR-DRG Mortality									
No Information	95	1.9%	150	12.6%	0.43	101	12.6%	48	13.9%
Mild	4,157	81.2%	837	70.4%		544	67.7%	260	75.4%
Moderate	670	13.1%	154	13.0%		121	15.0%	28	8.1%
Severe	155	3.0%	39	3.3%		31	3.9%	7	2.0%
Extreme	41	0.8%	9	0.8%		7	0.9%	2	0.6%
MS-DRG Code & Description									
Spinal Fusion except cervical without MCC	3,918	76.6%	209	17.6%	1.61	128	15.9%	72	20.9%
Combined Anterior or Posterior fusion with CC	373	7.3%	416	35.0%		309	38.4%	88	25.5%
Combined Anterior or Posterior fusion without CC/MCC	425	8.3%	348	29.3%		217	27.0%	123	35.7%
Outpatient	95	1.9%	150	12.6%		101	12.6%	48	13.9%
Other	307	6.0%	66	5.6%		49	6.1%	14	4.1%

(*Continued*)

Table 1 (Continued).

Variables	PEEK Cage		3D-printed-titanium Cage, All (PLIF/ Curved TLIF)		SMD	Subgroup: PLIF		Subgroup: Curved TLIF	
	N	%	N	%		N	%	N	%
Surgery year									
2007 to 2018	4,371	85.4%	0.0	0.0%	2.51	0	0.0%	0	0.0%
2019	403	7.9%	58	4.9%		35	4.4%	23	6.7%
2020	185	3.6%	209	17.6%		87	10.8%	110	31.9%
2021	116	2.3%	544	45.8%		387	48.1%	140	40.6%
2022	43	0.8%	378	31.8%		295	36.7%	72	20.9%
Admission Type – Elective	4,855	94.9%	1,139	95.8%	0.04	775	96.4%	324	93.9%
Setting of Care									
Inpatient	4,996	97.6%	1,028	86.5%	0.44	692	86.1%	297	86.1%
Outpatient	122	2.4%	161	13.5%		112	13.9%	48	13.9%
Number of Spinal Levels									
1	1,729	33.8%	740	62.2%	1.00	486	60.4%	233	67.5%
2+	604	11.8%	303	25.5%		221	27.5%	64	18.6%
N/A	2,785	54.4%	146	12.3%		97	12.1%	48	13.9%
Surgical Approach									
MIS	11	0.2%	5	0.4%	1.00	5	0.6%	0	0.0%
Open	2,323	45.4%	1,038	87.3%		702	87.3%	297	86.1%
N/A	2,784	54.4%	146	12.3%		97	12.1%	48	13.9%

Note: *Categories are not mutually exclusive: patients may have more than 1 diagnosis.
Abbreviations: SMD, Standard mean difference; MCC, major complication or comorbidity; CC, complication or comorbidity; MIS, Minimally Invasive Surgery.

Current or past smoking behavior was 44.6% in the overall 3D-printed-titanium cohort and was 39.6% in the PEEK cohort. Patients with Elixhauser scores within the range of 3 to 4 or 5+ were ~42% for 3D-printed-titanium and ~31% for PEEK patients; by 3D-printed-titanium subgroup, PLIF also had the majority of scores within these categories (~45%), while Curved TLIF (~35%) did not. Of the Functional comorbidity score category, the highest proportions were observed in patients with functional scores of 5 and above in both the 3D-printed-titanium overall (41.1%) and subgroup (range of scores: 40.0% to 45.0%) and the PEEK (39.4%) cohorts. In terms of MS-DRG code and description, spinal fusion except cervical without major complication or comorbidity (MCC) was the most common procedure in the PEEK cohort, accounting for 76.6% of cases. In the 3D-printed-titanium cohort overall, the most common MS-DRGs were combined anterior or posterior fusion with complication or comorbidity (CC), representing 35.0%, and combined anterior or posterior fusion without MCC/CC, representing 29.3%; Curved TLIF had more cases without MCC/CC (35.7%) than PLIF (27%). APR-DRG severity and mortality showed comparable distributions between the two cohorts across all severity levels.

The Supplemental File, Tables S1R to S5R, reports additional descriptive demographic and clinical data on each cohort including individual Elixhauser and Functional comorbidities.

The standard mean differences of the demographic and clinical characteristics of the PEEK cohort and 3D-printed-titanium cohort ranged from <0.01 to 1.61. Characteristics that were below a threshold of SMD ≤ 0.10 were gender, back pain, pseudarthrosis, and osteoporosis.

Procedural Characteristics

Most PEEK surgeries were performed starting in 2007 to 2018 (85.4%), which aligns with the cage's earlier Food and Drug Agency (FDA) clearance date, and of the 3D-printed-titanium surgeries, a substantial proportion was conducted in 2021 (45.8%). The majority of admissions were elective (95.0%), with similar distributions observed in both cohorts and across subgroups. Most surgeries for both cohorts were in the inpatient setting PEEK: 97.6%, 3D-printed-titanium: 86.5%. Among the patients for which spinal level data were collected, 3D-printed-titanium cohort overall and across subgroups had mostly single (62.2%; PLIF, 60.4%; Curved TLIF, 67.5%) level fusions, and one-third of patient in PEEK cohort had single-level fusion (33.8%); however, 12.3% and 54.4% of patients with 3D-printed-titanium and PEEK did not have spinal level data available. The majority of surgeries were performed using an open approach (53.3%), with 87.3% in 3D-printed-titanium cohort and 45.4% in PEEK cohort; similar to spinal level data, 12.3% and 54.4% of patients in 3D-printed-titanium and PEEK, respectively, did not have approach data available.

The SMDs of the procedure characteristics of the PEEK cohort and 3D-printed-titanium overall cohort ranged from 0.04 to 2.51. Elective surgery was the single characteristic that was below a threshold of SMD ≤ 0.10.

Index Healthcare Utilization and Costs

The mean length of stay (LOS) varied across the cohorts, with the PEEK cohort having a mean LOS of 3.4 days (SD = 2.3), and the 3D-printed-titanium cohort overall with a mean of 2.9 days (SD = 2.7) and by subgroup (PLIF, 2.9 (SD = 2.7); Curved TLIF, 2.7 (SD = 2.6)) (Table 2).

The PEEK cohort had a mean surgery time of 266.7 minutes (SD = 160.2), and the 3D-printed-titanium cohort had a mean time of 280.4 minutes (SD = 132.2) and by subgroup was PLIF, 262.9 (SD = 134.9) and Curved TLIF, 309.5 (SD = 117.5) (Table 2).

The majority of patients across all cohorts (~85%) were discharged to home or home healthcare (Table 2).

PEEK cohort had a mean index hospital cost of $39,877 (SD = $21,036), and 3D-printed-titanium cohort had a mean hospital cost of $40,672 (SD = $22,307); within the 3D-printed-titanium subgroups, the mean index hospital cost was PLIF, $39,368 (SD = $22,092) and Curved TLIF, $41,439 (SD = $22,900) (Table 2).

Reoperation

The cumulative incidence of reoperation within 0–3 months post-index was estimated at 1.0% (95% CI: 0.8–1.3%) in the PEEK cohort (Table 3). For the PEEK cohort, the mean time to first reoperation within 0–3 months was 0.8 months (SD:

Table 2 Index Healthcare Utilization and Costs of Patients with PEEK and 3D-Printed-Titanium Cages

		PEEK Cage	3D-printed-titanium Cage, All (PLIF/Curved TLIF)	Subgroup: PLIF	Subgroup: Curved TLIF
	N	5,118	1,189	804	345
Length of Stay	Mean (SD)	3.4 (2.3)	2.9 (2.7)	2.9 (2.7)	2.7 (2.6)
Surgery Time	Mean (SD)	266.7 (160.2)	280.4 (132.2)	262.9 (134.9)	309.5 (117.5)
Discharge status to home or home health	N (%)	4,341 (84.8%)	1,017 (85.5%)	680 (84.6%)	299 (86.7%)
Index hospital cost	N*	4,866	785	410	338
	Mean (SD)	$39,877 ($21,036)	$40,672 ($22,307)	$39,368 ($22,092)	$41,439 ($22,900)

Note: *This analysis was performed only for patients with cost validated data at time of index in PHD.
Abbreviation: SD, Standard Deviation.

Table 3 Reoperation and Revision Risks of Patients with PEEK and 3D-Printed-Titanium Cages (NA = Not Applicable)

	PEEK Cage			3D-Printed-Titanium Cage, All (PLIF/Curved TLIF)			Subgroup: PLIF			Subgroup: Curved TLIF		
	Patients at Risk*	N	Estimate (95% CI)	Patients at Risk*	N	Estimate (95% CI)	Patients at risk*	N	Estimate (95% CI)	Patients at Risk*	N	Estimate (95% CI)
Reoperation												
0–3 months post-index	5,113	51	1.0% (0.8% - 1.3%)	1,187	15	1.3% (0.8% - 2.1%)	802	11	1.4% (0.8% - 2.4%)	345	3	0.9% (0.3% - 2.5%)
Revision												
0–3 months post-index	5,113	60	1.2% (0.9% - 1.5%)	1,187	19	1.6% (1.0% - 2.5%)	802	10	1.2% (0.7% - 2.3%)	345	6	1.7% (0.7% - 3.7%)
4–6 months post-index	4,975	32	0.6% (0.5% - 0.9%)	1,020	5	0.5% (0.2% - 1.1%)	676	2	0.3% (0.1% - 1.1%)	314	3	1.0% (0.3% - 2.8%)
7–12 months post-index	4,761	80	1.7% (1.4% - 2.1%)	741	9	1.2% (0.6% - 2.3%)	469	3	0.6% (0.2% - 1.9%)	247	5	2.0% (0.8% - 4.7%)

Notes: *Deceased patients are not included in the patients at risk denominators. Patients were considered at risk for revision within 4–6 months if they were from hospitals that participated in the PHD for 6 months after index surgery and they had not yet had a revision within 0–3 months following index date. Patients were considered at risk for revision within 7–12 months if they were from hospitals that participated in the PHD for 12 months after index surgery and they had not yet had a revision within 0–3 months or 4–6 months following index date.

Abbreviations: CI, Confidence Interval; NA, Not applicable.

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Table 4 Time to First Reoperation and Revision for Patients with PEEK and 3D-Printed-Titanium Cages

		PEEK Cage	3D-Printed-Titanium Cage, All (PLIF/Curved TLIF)	Subgroup: PLIF	Subgroup: Curved TLIF
Time to Reoperation (within 0–3 months)*	N	51	15	11	3
	Mean	0.8	1.4	1.5	1.0
	SD	1.0	0.5	0.5	0.0
	Lower CI	0.6	1.1	1.2	1.0
	Upper CI	1.1	1.7	1.9	1.0
	Median	1	1	2	1
	Min	0	1	1	1
	Max	3	2	2	1
Time to Revision (within 0–12 Months)*	N	172	33	15	14
	Mean	5.9	4.1	3.9	4.6
	SD	4.0	3.7	3.4	3.5
	Lower CI	5.3	2.8	2.0	2.6
	Upper CI	6.5	5.4	5.8	6.7
	Median	6	2	2	5.5
	Min	0	0	1	0
	Max	12	12	11	9

Note: *0 months indicates that the outcome occurred in the same calendar month as the index surgery.
Abbreviations: SD, Standard Deviation; CI, Confidence Interval; Min, Minimum; Max, Maximum.

1.0, 95% CI: 0.6–1.1), with a median of 1 month and a range from 0 to 3 months (Table 4). Common diagnoses at index for patients with PEEK that had reoperation were DDD (80.4%), Spondylolisthesis (49.0%) and Stenosis (35.3%) (see Supplemental File, Table S6R). Of the diagnosis collected at reoperation for this study, infection was the most common (74.5%) (see Supplemental File, Table S7R).

Within the 3D-printed-titanium cohort, the cumulative incidence of reoperation was 1.3% (95% CI: 0.8–2.1%) and by subgroups, the cumulative incidence varied from Curved TLIF, 0.9% (95% CI: 0.3–2.5%) to PLIF, 1.4% (0.8–2.4%) (Table 3). The mean time to first reoperation was 1.4 months (SD: 0.5, 95% CI: 1.1–1.7), with a median of 1 month and a range from 1 to 2 months. Within the 3D-printed-titanium subgroups, the mean time to reoperation was 1.0 month (SD = <0.05) for Curved TLIF and 1.5 months (SD = 0.5) for 3D-printed-titanium PLIF (Table 4). Spondylolisthesis (86.7%), DDD (80.0%), and Stenosis (80.0%) were the most frequent diagnoses at index for patients, with 3D-printed-titanium overall having reoperation (Supplemental File, Table S6R); these diagnoses were most frequent in the subgroups (range from 72.7% to 100%). At the time of reoperation, infection (80.0%) was most frequent overall and across subgroups (range 66.7% to 100%) (Supplemental File, Table S7R).

Revision

The cumulative incidence of revision within 0–3 months post-index was estimated at 1.2% (95% CI: 0.9–1.5%) in the PEEK cohort, and in the 3D-printed-titanium cohort, it was 1.6% (95% CI: 1.0–2.5%). Within the 3D-printed-titanium subgroups, revision ranged from PLIF, 1.2% (95% CI: 0.7–2.3%) to Curved TLIF, 1.7% (0.7–3.7%) (Table 3).

At 4–6 months post-index, the cumulative incidence of revision was 0.6% (95% CI: 0.5–0.9%) in the PEEK cohort and 0.5% (95% CI: 0.2–1.1%) in the 3D-printed-titanium cohort. Among the 3D-printed-titanium subgroups, the lowest

cumulative incidence of revision was observed for PLIF (0.3%, 95% CI: (0.1–1.1%)), while the highest was seen in the Curved TLIF (1.0%, 95% CI: 0.3–2.8%) (Table 3).

The cumulative incidence of revision at 7–12 months post-index slightly increased compared to earlier time points for the PEEK cohort, reaching 1.7% (95% CI: 1.4–2.1%). In the 3D-printed-titanium cohort, it was 1.2% (95% CI: 0.6–2.3%), with occurrence ranging from PLIF, 0.6% (95% CI: 0.2–1.9%) to Curved TLIF, 2.0% (0.8–4.7%) (Table 3).

Time to first revision within 0–12 months among the PEEK cohort was 5.9 months (SD: 4.0, 95% CI: 5.3–6.5), with a median of 6 months and a range from 0 to 12 months. Patients with 3D-printed-titanium had a mean time to first revision of 4.1 months (SD: 3.7, 95% CI: 2.8–5.4), with a median of 2 months and a range from 0 to 12 months. Within the 3D-printed-titanium subgroups, the mean time to revision ranged from PLIF, 3.9 months (SD = 3.4) to Curved TLIF, 4.6 months (SD = 3.5) (Table 4).

Common diagnosis codes assigned at index for patients with PEEK having revision within 12 months was DDD (70.9%), Spondylolisthesis (50.0%), and Stenosis (49.4%) (Supplemental File, Table S8R). For 3D-printed-titanium, DDD and Stenosis diagnosis codes were assigned at the same frequency (84.8%) and Spondylolisthesis was also commonly assigned (63.6%) at index for patients that had revision; these diagnosis codes were also most frequently assigned across the subgroups (Supplemental File, Table S8R). Of the diagnosis codes assigned at revision, device-related complication occurred the most frequently for PEEK (41.9%), and radiculopathy was most frequently assigned for 3D-printed-titanium overall (57.6%); across subgroups, both complication diagnosis codes were assigned in equal frequency for PLIF (46.7%), radiculopathy was assigned most commonly for Curved TLIF (71.4%) (Supplemental File, Table S9R).

The ICD codes that represent the index and reoperation or revision diagnoses of patients that had reoperation or revision can be viewed in the Supplemental File for both cohorts, Tables S10R to S14R.

Reoperation and Revision Costs

For the PEEK cohort, the mean cost of three-month reoperation and twelve-month revision was $220 (SD: $2667) and $1228 (SD: $8139), respectively. In the 3D-printed-titanium cohort, the mean cost of reoperation and revision for the overall cohort was $290 (SD: $3145) and $1754 (SD: $9489), respectively. Within the 3D-printed-titanium subgroups, the mean reoperation costs for the subgroups ranged from $242 (SD: $2690) in the PLIF subgroup to $282 (SD = $3337) in the Curved TLIF subgroup, and the mean revision costs ranged from $821 (SD: $5297) in the PLIF subgroup to $2125 ($10,884) in the Curved TLIF subgroup (Table 5).

Discussion

With the growing utilization of lumbar/lumbosacral surgeries, diverse interbody fusion implants have emerged, highlighting the need to understand the clinical outcomes and utilization of each implant in real-world settings. The findings of this study contributed to our comprehension of reoperation, revision, costs and healthcare utilization associated with

Table 5 Cost of Reoperation and Revision per Patient for PEEK and 3D-Printed-Titanium Cages

		PEEK cage	3D-Printed-Titanium Cage, All (PLIF/Curved TLIF)	Subgroup: PLIF	Subgroup: Curved TLIF
Cost of three-month Reoperation	N*	4,866	785	410	338
	Mean (SD)	$220 ($2,667)	$290 ($3,145)	$242 ($2,690)	$282 (3,337)
Cost of twelve-month revision	N^	4,624	554	261	265
	Mean (SD)	$1,228 ($8,139)	$1,754 ($9,489)	$821 ($5,297)	$2,125 ($10,884)

Notes: *This analysis was performed only for patients with cost validated data in PHD and with 3-month hospital enrollment. ^This analysis was performed only for patients with cost validated data in PHD and with 12-month hospital enrollment.
Abbreviation: SD, Standard Deviation.

the use of PEEK or 3D-printed-titanium cages for lumbar/lumbosacral spine fusion surgeries in patients diagnosed with DSD using real-world data.

In this current study, real-world data was used to measure reoperation and revision occurrence within specific time frames for both PEEK and 3D-printed-titanium cages. The cumulative incidence of reoperation within 0–3 months post-index was estimated at 1.0% for PEEK and 1.3% for 3D-printed-titanium overall. For revision, the incidence within 0–3, 4–6, and 7–12 months was 1.2%, 0.6%, and 1.7% for PEEK and 1.6%, 0.5%, and 1.2% for 3D-printed-titanium.

Existing literature reports a range of reoperation/revision occurrences across various study designs and follow-up periods for patients treated with the PEEK and 3D-printed-titanium cages evaluated in this study.

For OPAL™, retrospective, single-center studies with mixed cohorts reported revision occurrences from 0.6% to 11.4%, with follow-up durations ranging from 18 to 96 months.[9–11] A randomized controlled trial comparing the OPAL™ cage (non-banana-shaped) with a banana-shaped cage assessed fusion rates within 12 months. The authors stated that no revisions occurred and did not report on the reoperation occurrence; results from the trial suggested favorable outcomes for the OPAL™ cage group, with a fusion rate of 96.6% vs 95.2% compared to the banana-shaped cage.[12]

For CONDUIT™, there was one previous hospital database study, using the same data source as this study (PHD) that assessed six-month revision and reoperation rates among 93 patients implanted with CONDUIT™ and 93 implanted with PEEK cages. This study reported no cases of device-related revision and only one case (1.1%) of non-device-related reoperation within the CONDUIT™ group within six-month follow-up.[13] Kang et al used CONDUIT™ to evaluate two different TLIF surgical techniques in a prospective case series study (n = 79) with an average of 15 months follow-up and found patients experiencing complications such as hematoma and dural tear but did not report revision or reoperation occurrence. The fusion rate within one year was 87% and 88% in the two surgical groups.[14]

Furthermore, studies have reported outcomes on the class of PEEK and/or 3D-printed spinal cage implants. A retrospective single-center study of patients treated with 3D-printed titanium (n = 40) or PEEK (n = 43) cages during single-level MIS-TLIF found low occurrence of complications (1 screw loosening in the PEEK group), reported no reoperation occurred and did not state if there was revision occurrence for both groups after one-year follow-up. The overall fusion rate was similar between both groups at six months (95.0% for 3D and 93.0% for PEEK, p = 0.705) and at one year (96.4% for 3D, and 96.7% for PEEK, p = 0.737).[15]

A prospective study comparing patients that received 3D-printed cages (n = 40) or PEEK cages during TLIF (n = 40) demonstrated excellent clinical outcomes for both groups. Patients were followed for six months postoperatively. The authors stated that no revisions or complications occurred and did not report on reoperation occurrence. In summary, the 3D-printed cage group exhibited advantages in fusion quality, subsidence severity, and bone-cage interface contact. In particular, fusion rates at three and six months postoperative were 84.6% and 58.3% (p = 0.08), 92.3% and 75% (p = 0.132), respectively, 3D and PEEK.[16]

In a single-center case series of patients (n = 129) receiving only 3D printed cages for MIS TLIF, including the 3D-printed-titanium cage from this current study and other brands, after a follow-up of an average of 27 months, six reoperations occurred (4.7%). The fusion rate was not reported in this study.[17]

Due to the varied study designs, follow-up times and definitions for reoperation or revision in the past research, it is challenging to compare the estimates in this current study to these prior publications.[9–15,17,18] This current study adds to this body of evidence on reoperation and revision for PEEK and 3D printed cages by reporting occurrence for brand-specific spinal cages within consistent time frames for all patients, 3-month reoperation and 0 to 3/4 to 6/7 to 12-month revision. Furthermore, this study provides a unique perspective in that it uses a US-wide hospital-based data source to capture outcomes in patients that had lumbar fusion with specific degenerative conditions. This current study identifies the economic and healthcare utilization of the cages. The index utilization was similar in both groups. The mean index hospital cost was roughly $40,000, LOS was about 3 days, and discharge status to home or home health was about 85% for both; surgery time was 267 minutes (PEEK) and 280 minutes (3D-printed-titanium cage). Postoperatively, the mean costs, accounting for all patients per device group regardless of occurrence, associated with three-month reoperation and twelve-month revision were PEEK, $220 and $1228, and 3D-printed-titanium $290 and $1754.

To our knowledge, there is little evidence available on economic and healthcare utilization endpoints for spinal cages, but several studies have generated these outcomes for lumbar fusion procedures. A real-world data study conducted by Huang et al[19] reported the cost of healthcare from the payer perspective using the MarketScan database containing a population of patients receiving commercial, Medicare supplemental or Medicaid insurance. The total mean cost of PLIF surgery (n = 7460 patients) for payers amounted to $42,400 (SD = $42,700) solely during the initial hospitalization period and the mean total cost of two-year postoperative healthcare was $36,200 (SD = $56,200). In another study, index hospital costs were estimated for both MIS and Open one and two level TLIF/PLIF procedures by Wang et al (n = 6106 patients) using the same database as this study, PHD. This study reported cost ranged from as low as $29,187 for one-level MIS to $35,984 for two-level open surgery.[20] Prior studies have estimated postoperative cost after MIS or open PLIF/TLIF procedures as reported in a systematic literature review by Goldstein et al;[21] however, these studies reported postoperative costs within and outside the hospital, unlike this current research we report. Of the two publications that provided postoperative costs, only Parker et al[22] provided data from a US perspective in their prospective study; they reported two-year total healthcare costs in USD for PLIF/TLIF procedures, including index, amounted to $38,563 (MIS) and $47,858 (Open) for the 50 patients per group. Our study, in contrast, provides an alternative data point on cost not reported to our knowledge: the cost burden of reoperation or revision on a cohort level for two different types of spinal cages. These are data points that can be of potential value of payers and providers who may want an understanding of the cost burden of these outcomes specific to a PEEK or 3D-printed spinal cage on a patient group basis. However, these results must be interpreted with caution because the analyses performed here are presented separately for each cohort and are not compared directly and adjusted for confounding factors; furthermore, no current benchmarks exist in the literature to our knowledge to understand how these costs compare to other populations.

In regard to healthcare utilization measures, both case series that evaluated the 3D-printed-titanium cage evaluated in this study alone in two surgery groups (Kang et al 2021) or in a mix cohort (Thayaparan et al 2019) reported mean LOS of 13/15 days and 4 days and surgery times of 135/170 minutes and 153 minutes, respectively; however, these studies were performed outside the US.[14,17] In US-based studies of patients receiving lumbar fusion, Wang et al 2012 reported estimates similar to this study, LOS ranging from 3.4 days to 4.0 days and reported discharge status to home ranging from 87% to 90% for MIS and Open one- to two-level surgeries.[20] Parker et al 2014 reported mean surgery times of 274 minutes to 229 minutes for MIS and Open, respectively, also similar to the estimates provided in this study.[22]

In regard to implication on clinical practice, this study may assist providers with understanding trends of the patient populations receiving each cage type, which in turn may support individualized decision-making on cage selection. For example, in this study, we observed 68.1% of patients with PEEK cage had a diagnosis of DDD and 82.3% of patients with the 3D-printed cage had stenosis and that 6.7% of patients with PEEK and 9.8% of patients with the 3D-printed cage had comorbidity scores of 5+. These data could support a surgeon in cage selection based on the results we have provided for each separate patient cohort.

Furthermore, it is important to be aware of the design of each cage and how this may relate to the outcomes observed here. Given the material design of the newer generation of cage, 3D-printed cages may increase the spine's ability to fuse (increased fusion rate) and thus result in less reoperation or revision over time compared to other cage designs. By the end of the follow-up time in this current study, 3D-printed cages had a 0–3-month reoperation and 7–12-month revision incidence of 1.3% and 1.2%. PEEK, which is made of a material that has low osteoconductive properties, had a 0–3-month reoperation and 7–12-month revision incidence of 1.0% and 1.7%. Because potential confounding factors of the outcome data were not controlled for in this analysis, this may have impacted the reoperation and revision occurrence for both cages, and these results must be interpreted with caution. Despite these limitations, this study gives important baseline understanding of these outcomes for different cage designs, so providers have an awareness of occurrence that could potentially be observed in population of patients receiving lumbar fusion surgery.

Currently, there is limited evidence about the clinical, healthcare utilization and economic outcomes in patients receiving brand-specific spinal cages for lumbar/lumbosacral spine surgery. This study comprehensively evaluated these outcomes for both a PEEK cage and a 3D-printed cage which represents a cage design that mimics the properties of bone.[23] Furthermore, unlike previous research,[13] this study also analyzed outcomes based on 3D-printed cage type (PLIF and Curved TLIF) revealing variations observed within each subgroup. Another strength of this study is the utilization of

data from a nationally representative database (PHD), allowing for the collection of different patient-level data, such as details on the specific implant type or cage subgroup, which may not be accessible in other databases. Furthermore, this database study benefits from its large sample size, allowing for the observation of outcomes within a broader patient population compared to past studies of these spinal cages. It offers a more comprehensive understanding of real-world outcomes and allows for the exploration of subgroup analyses and rare outcomes.

The study has several limitations. Firstly, the study is limited by its descriptive study design where comparative statistical testing was not performed and thus this study is not equipped to inform how different implant types or cage subgroups compare. This limits the ability to draw definitive conclusions about the outcomes of PEEK or 3D-printed-titanium cages compared to each other. Additionally, the retrospective nature of the study design introduces inherent biases and limitations associated with data collection and analysis. The use of large administrative databases, such as PHD, may introduce issues such as inaccuracies in coding and missing codes affecting the quality of the study's collected data. Collection of study outcomes was also limited because outcomes that require radiographic confirmation or measurement such as fusion are not available in this data source, unlike the prior published work on PEEK and 3D cages. Finally, the use of PHD limited the study's focus to one-year outcomes because it is an episode-level hospital database where patients cannot be tracked to other hospitals and thus the ability to track patients past one year to the same hospital is less certain. Study of only one-year outcomes overlooks important long-term effects that can occur past the one-year time frame, such as delayed revision occurrence.

Conclusion

Because of the design of this study, no conclusions on inference of superiority between PEEK or 3D-print cages can be made from these data. Additionally, the outcome estimates per device group must be considered with caution given they are not adjusted for confounding factors. The objective of this study was to provide outcome estimates separately for two types of spine cages made of different materials. To this goal, this study provided valuable findings about the revision, reoperation, economic and healthcare utilization outcomes related to the utilization of PEEK or 3D-printed-titanium cages used in lumbar spine fusion surgeries for patients with DSD. Furthermore, the economic and healthcare utilization analysis gives important evidence on these outcomes for PEEK and 3D-printed-titanium cages that, to our knowledge, have not been reported elsewhere.

Abbreviations

ALIF, Anterior lumbar interbody fusion; APR-DRG, All Patient Refined Diagnostic Related Groups; CPT, Current Procedural Terminology; DDD, Degenerative disc disease; DSD, Degenerative spinal disorders; ECI, Elixhauser Comorbidity Index; FCI, Functional Comorbidity Index; FDA, Food and Drug Agency; ICD, International Classification of Diseases; IFU, Indications for Use; IRB, Institutional Review Board; LOS, Length of hospital stay; MCC, Major Complication or Comorbidity; MIS, Minimally Invasive Surgery; MS-DRG, Medicare Severity Diagnostic Related Groups; ORT, Operation room time; PEEK, Polyetheretherketone; PHD, Premier Healthcare Database; PLIF, Posterior lumbar interbody fusion; SMD, Standard Mean Difference; Ti, Ti (titanium); TLIF, transforaminal lumbar interbody fusion; USD, United States Dollars.

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