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ORIGINAL ARTICLE

Value of single-level circumferential fusion: a 10-year prospective outcomes and cost-effectiveness analysis comparing posterior facet versus pedicle screw fixation

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Abstract

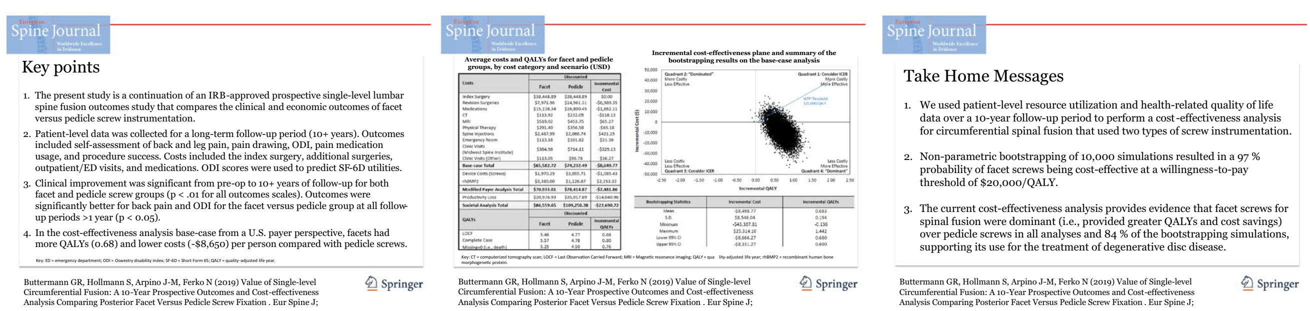
Purpose To compare the clinical and economic outcomes of facet versus pedicle screw instrumentation for single-level circumferential lumbar spinal fusion.

Methods Outcomes included self-assessment of back and leg pain, pain drawing, ODI, pain medication usage, and procedure success. The CEA was based on the 10-year data collected, and the base-case was from a US payer perspective. Costs included the index surgery, additional surgeries, outpatient/ED visits, and medications. To determine quality-adjusted life years (QALYs), ODI scores were used to predict SF-6D utilities. Sensitivity analyses were performed from a modified payer perspective including device costs and from a societal perspective including productivity loss. Discounted and undiscounted incremental costs and QALYs were calculated. Bootstrapping was performed to estimate the distribution of incremental costs and effects.

Results Clinical improvement was significant from pre-op to 10-year follow-up for both groups ($p < 0.01$ for all outcomes scales). Outcomes were significantly better for back pain and ODI for the facet versus pedicle group at all follow-up periods > 1 year ($p < 0.05$). In the CEA base-case, facets had more QALYs (0.68) and lower costs (−$8650) per person compared with pedicle screws. Therefore, facets were dominant (i.e., provided cost savings and greater QALYs) compared with pedicle screws. Facets had a 97% probability of being below a willingness-to-pay threshold of $20,000 per QALY gained and were estimated to be dominant over pedicle screws in 84% of the simulations.

Conclusion One-level circumferential spinal fusion using facet screws was clinically superior and provided cost savings compared with pedicle screw instrumentation in the USA.

Graphic abstract



Keywords Cost · Economic · Facet screws · Fusion · QALY · Lumbar spine

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Extended author information available on the last page of the article

Introduction

Single-level combined anterior (interbody)–posterior techniques have the advantage of providing the greatest and most reliable increase in disk height, indirect foraminal decompression, restoration of lordosis, and a large area in which to ensure interbody lumbar fusion [1, 2]. Posterior instrumentation using the facet screw technique, both transfacet and translaminar methods, is biomechanically sound and has gained increased clinical interest [3]. Biomechanical flexibility studies have demonstrated equivalent stability for facet and pedicle screws when combined with an interbody device regardless of anterior, lateral, or transforaminal approach for both single- and two-level fusion constructs [4–12]. Cyclic testing has shown mixed results implying a need for postoperative external immobilization [13, 14].

Although spinal disorders are common, the rate and cost of spine treatments are increasing, and it is unclear whether the value of spinal care is improving [15]. As healthcare spending continues to increase, there is a greater need for decision makers to assess treatments based on their evidence-based patient outcomes as well as their impact on resource use. Generating comparative effectiveness research including cost-effectiveness for different treatment options is becoming increasingly important as healthcare authorities are considering the findings in their coverage policies [16].

In a previous study of single-level circumferential lumbar fusion for degenerative disk disease (DDD), the authors demonstrated that posterior facet screws, compared to pedicle screw fixation, resulted in superior outcomes during a 5-year follow-up study period [17]. Additionally, the facet screw instrumentation group had reduced length of stay, was lower in charges/costs with regard to instrumentation and hospitalization, and had a lower rate of secondary surgery.

Although improvement in clinical outcomes has been demonstrated, the long-term value of spinal fusion is not well established compared to other treatments [18–20]. Rihn and colleagues also indicate that the value of spine care depends on patient-centered measures of outcomes and costs over a long-term follow-up [15]. While prior studies have aimed to predict long-term value by modeling and extrapolation of short-term outcomes and cost data [18, 21–23], the purpose of the present study was to assess the long-term outcomes of the previous study of single-level circumferential lumbar fusion using real-world data [17]. Specifically, the present continuation study compared the prospective outcomes of two patient cohorts with a minimum of 10-year follow-up and determined the cost-effectiveness of patients undergoing posterior fixation using low-profile facet screws versus pedicle screws.

Materials and methods

The present study is a continuation of an IRB-approved prospective single-level lumbar spine fusion outcomes study of two cohorts based on type of posterior instrumentation. The pedicle screw group ($n = 27$) entailed all consecutive patients who fit the entry criteria treated between January 2002 and December 2004. The facet screw group ($n = 35$) entailed all consecutive patients who fit the entry criteria treated between December 2004 and December 2006 as previously defined [17]. The inclusion/exclusion criteria included age between 18 and 65 years, less than 20° of scoliosis, and axial low back greater than leg pain symptoms. Patients had single-level DDD and, however, could have adjacent level disk dehydration. They were eligible if they had had a previous discectomy but were excluded if they had recurrent disk herniation or stenosis that required additional open decompression. Patients underwent > 9 months of nonoperative treatment, including physical therapy, pharmacological treatment, and spinal steroid injections. All patients had preoperative lumbar radiographs including flexion/extension views and MRI. Patients were also excluded if they had greater than 4 mm spondylolisthesis. Technical surgical details include that both groups had a similar "mini" open anterior spinal fusion using femoral cortical ring allograft combined with bone graft material. All facet screw and 9 pedicle screw patients had bone morphogenic protein (BMP, 4.2-mg (small size) Infuse™, Medtronic, MN) placed within the femoral allograft cortical ring (FRA). BMP was not placed posterior to or peripheral to the cortical ring to avoid BMP-associated radiculitis [24]. The remaining patients had anterior iliac bone graft (IBG) placed within the cortical ring. Patients in the facet screw group had an anterior buttress screw and washer instrumentation placed or, if they were large (> 80 kg) or osteopenic/osteoporotic (DEXA scan T score < –1.5), they had supplementary anterior plate fixation. In the facet group, 16 patients had an anterior plate. Both groups had posterior iliac crest bone autograft harvested for the posterior fusion. BMP was not used posteriorly. Both groups had open posterior instrumentation to avoid subsidence/pseudarthrosis related to stand-alone FRA anterior lumbar interbody fusions [25].

Clinical outcomes

Clinical outcomes were assessed pre- and postoperatively with multiple outcome instruments: Visual Analogue Scale (VAS) for back and leg pain, pain drawing, Oswestry Disability Index (ODI), pain medication usage (nonsteroidal anti-inflammatory drugs and narcotics), and patient self-assessment of procedure success over a 10-year follow-up period. Outcomes data were tabulated in a blinded fashion to research staff and the treating surgeon.

Time horizon and perspective

The cost-effectiveness analysis (CEA) was based on individual patient-level data with a minimum of 10 years of follow-up. The base-case was conducted from a US payer (i.e., Medicare) perspective. A discount rate of 3% was applied to costs and effects.

Utilities

Quality-adjusted life years (QALYs) are recommended for assessing the value of interventions in health and medicine [26]. Therefore, QALYs were used as the effectiveness measure in the CEA. To determine QALYs, ODI scores, which reflect disease-specific quality of life, were used to predict Short-Form 65 (SF-6D) utilities, the preference-based scores that can be incorporated into CEAs. The SF-6D utilities were derived from the ODI values using the regression equation: SF-6D = 0.78275–0.00518 X ODI [27]. For patients with missing data, the last observation was carried forward for the base-case. QALYs were calculated for each patient at all follow-up intervals by multiplying the utility by the midpoint of each follow-up period (with the exception of the last visit, which was assumed to occur at 10 years), as not to bias the calculations based on follow-up date. QALYs were summed over the entire 10-year period for each patient, and the average total QALYs were determined for both the facet and pedicle groups.

Index procedures, additional surgeries, and resource use

The number of events and resources used was based on the individual patient-level data. The index surgical procedure (anterior–posterior fusion) was the same for all patients. Additional surgeries (e.g., fusion extension, adjacent segment fusion, pseudo-repair, decompression, spinal cord stimulator, and hardware removal) and resource use (e.g., pain medications, spinal injections, clinic and emergency room (ED) visits) varied by patient within the groups.

Unit costs

The cost of the index procedure and additional surgeries was based on 2018 DRG reimbursement amounts. For medical imaging, postoperative clinic visits, ED visits, spinal injections, and physical therapy, the costs were based on 2018 Medicare physician and facility amounts. Additionally, prescription medications were based on 2018 wholesale acquisition costs (WAC) [28]. The unit costs are presented in Table 1. Total costs for each patient were calculated over time, and the average costs were determined for the facet and pedicle groups.

Statistical analysis

Statistical comparisons were made between the groups using a two-tailed t test for all the continuous outcome scales. The p values were determined for the comparison between groups at each follow-up visit, as well as the overall comparison from pre-op to each follow-up visit. Differences in patient characteristics, additional surgeries, resource use, self-assessment of success, and recommending treatment to others were analyzed using the Fisher's exact test. Probability values of < 0.05 were considered statistically significant.

Cost-effectiveness analysis

Cost-effectiveness was determined by calculating the average incremental costs and the average incremental QALYs for each group over the 10-year period [30]. To evaluate the uncertainty, nonparametric bootstrapping was conducted using 10,000 simulations [31]. Bootstrapping results and net monetary benefit calculations were used to predict the probability of cost-effectiveness and confidence intervals against a willingness-to-pay threshold ranging from $0 to $200,000. A cost-effectiveness acceptability curve (CEAC) was generated based on these data.

Alternative scenario, subgroup, and sensitivity analyses

Several alternative costing scenario analyses were conducted over the 10-year time horizon. The first was a modified payer perspective which included all costs in the base-case plus (a) device costs (i.e., facet or pedicle screws, and rods/connectors) or (b) device costs plus biologics costs (i.e., bone morphogenetic protein [BMP]). Device utilization and costs were based on institutional records, and the BMP costs were estimated from the literature [32]. A second scenario analysis for a societal perspective included all costs in the base-case plus indirect costs associated with productivity loss. Total time off work following index and additional surgeries was obtained from patients' return to work data, and costs were assumed to reflect average wages in Minnesota.

Two subgroup analyses were conducted for only patients that received BMP, which included all facet screw patients ($n = 35$) and nine pedicle screw patients, as well as for only patients without hardware removal, which included all patients in the facet group ($n = 35$) and 13 patients in the pedicle group.

Table 1 Costs

Inputs	Cost	Cost source
US payer perspective		
Index surgery (anterior–posterior fusion)	$38,448.89	2018 DRG Code #455
Revision surgeries		
Revision (fusion extension, adjacent segment fusion)	$38,448.89	2018 DRG Code #455
Revision (post-pseudo-repair, SI fusion)	$24,458.68	2018 DRG Code #460
Revision (decompression)	$6944.51	2018 DRG Code #520
Revision (hardware removal)	$11,767.56	2018 DRG Code #030
Spinal cord stimulator	$21,169.11	2018 DRG Code #029
Clinic visit (MSI or other)[a]	$74.16	2018 CPT/HCPCS Code #99213
Spine injections[a]	$793.94	2018 CPT/HCPCS Code #62323
Physical therapy[a]	$68.59	2018 CPT/HCPCS Code #98941
Medical imaging		
CT[b]	$297.70	2018 CPT/HCPCS Code #72131
MRI[b]	$461.63	2018 CPT/HCPCS Code #72148
Emergency room visit[b]	$475.05	2018 CPT/HCPCS Code #99284
Medications (dose per day):		
Ibuprofen (Advil) (600 mg TID)	$0.33	Red Book (NDC 53746-0140-10)
Aleve (440 mg BID)	$0.36	Red Book (NDC 00280-6000-10)
Aspirin (325 mg QID)	$0.05	Red Book (NDC 24385-0429-90)
Celebrex (100 mg BID)	$14.70	Red Book (NDC 00025-1520-51)
Darvocet (50:325 mg TID)	$1.41	Red Book (NDC 00002-0351-02)
Daypro (600 QD)	$7.84	Red Book (NDC 00025-1381-31)
Duragesic (25 mcg QD)	$43.16	Red Book (NDC 50458-0091-05)
Endocet (5 mg TID)	$0.71	Red Book (NDC 60951-0602-85)
Fentanyl transdermal system (25 mcg QD)	$4.57	Red Book (NDC 60505-7006-02)
Cyclobenzaprine HCl (25 mg QD)	$0.13	Red Book (NDC 52817-0330-50)
Indomethacin (50 mg TID)	$0.65	Red Book (NDC 31722-0543-05)
Methadone HCl (0.2 mg/kg QD)	$0.64	Red Book (NDC 00054-4570-25)
Morphine sulfate (15 mg BID)	$0.86	Red Book (NDC 00054-0235-25)
MS Contin (15 mg BID)	$7.94	Red Book (NDC 42858-0515-01)
Neurontin (300 mg TID)	$15.94	Red Book (NDC 00071-0805-24)
Norco (5 mg QID)	$11.83	Red Book (NDC 00023-6002-01)
Nortriptyline hydrochloride (50 mg QD)	$0.32	Red Book (NDC 51862-0017-05)
Percocet (5 mg TID)	$42.16	Red Book (NDC 63481-0623-85)
Oxycontin (5 mg QID)	$7.35	Red Book (NDC 59011-0410-10)
Nabumetone (1000 mg QD)	$1.95	Red Book (NDC 00115-1657-03)
Soma (250 mg BID)	$12.46	Red Book (NDC 00037-2250-10)
Tramadol HCl (50 mg BID)	$0.09	Red Book (NDC 33342-0201-44)
Tylenol (650 mg BID)	$0.36	Red Book (NDC 50580-0600-01)
Tylenol 3 (acetaminophen–codeine phosphate; 30 mg TID)	$0.34	Red Book (NDC 65162-0033-11)
Tylenol PM (500 mg TID)	$0.35	Red Book (NDC 50580-0244-80)
Ultram (50 mg BID)	$6.43	Red Book (NDC 50458-0659-60)
Vicodin (5 mg QID)	$6.59	Red Book (NDC 00074-3041-53)
Vioxx (50 mg BID)	$7.38	Red Book (NDC 00006-0114-74)
Voltaren (75 mg BID)	$2.60	Red Book (NDC 00028-0264-60)
Modified payer perspective:		
Facet screws	$1970.29	Author's private practice revenue cycle account
Pedicle screws and rods/connectors	$3055.71	Author's private practice revenue cycle account
rhBMP2 (4.2 mg, INFUSE Bone Graft; Medtronic)	$3380.00	Polly (2003) [17]

Table 1 (continued)

Inputs	Cost	Cost source
Societal perspective		
Monthly mean wage for all occupations (Minnesota)[c]	$4394.17	United States Bureau of Labor Statistics (May 2017)

CPT current procedural terminology; *CT* computerized tomography scan; *DRG* diagnosis-related group; *HCPCS* healthcare common procedure coding system; *MRI* magnetic resonance imaging; *NDC* national drug code; *rhBMP2* recombinant human bone morphogenetic protein

[a]Cost represents the sum of the CMS nonfacility physician payment price and the OPPS facility payment rate

[b]Cost represents the sum of the CMS facility physician payment price and the OPPS facility payment rate

[c]Potential productivity loss was estimated by multiplying the number of months off work by the United States Bureau of Labor Statistic's monthly mean wage in USD for all occupations in Minnesota for 2017 (U.S. Labor Bureau 2018). Where records on precise return to work dates were unavailable (for 2 patients in the facet cohort), months off work were estimated using a literature value of 3.6 months following lumbar spinal fusion [29]

Across all scenarios and subgroups, sensitivity analyses were conducted to assess the impact of missing utility data due to patients lost to follow-up, death, or declining to participate. One alternative was to evaluate only the complete cases. The second approach was to assume the missing data were equal to zero (i.e., data were missing due to death). This was considered the worst-case scenario. Finally, another sensitivity analysis was conducted assuming no cost of hardware removal for scenarios which included all patients.

Results

There was no significant difference in patient characteristics between the two groups (Table 2). Preoperative imaging found the most common characteristics related to DDD were Modic inflammatory endplate changes, prior laminectomy, central HNP, posterior annular tears, and up/down foraminal stenosis secondary to disk height collapse (none severe). In the facet screw group, there was one case with 3 mm retrolisthesis and no spondylolisthesis, and two patients had mild instability (< 3 mm) on flexion/extension lateral radiographs. In the pedicle screw group, there were three cases with 3 mm spondylolisthesis, of which one had mild instability on flexion/extension lateral radiographs. The mean postoperative follow-up period was 11.7 years. By the final follow-up of a minimum of 10 years, there were 3 (9%) facet patients lost to follow-up, and 2 pedicle patients lost to follow-up, one who declined to participate, and one deceased (total 15%). Thus, for the combined groups, a total of 7 (11%) patients were lost to follow-up or deceased.

The study found significant improvements across all outcome measures within both groups at all follow-up periods relative to the preoperative state (Table 3). The facet group demonstrated significantly greater improvements in lower back pain VAS scores than the pedicle group at the 1–2-year, 2–4-year, and 6–8-year follow-up periods. Also, the facet group demonstrated significantly greater improvements in ODI scores for all follow-up periods beyond one year. At 10 years, there were numerically greater patients in the facet group with minimal clinically important differences (MCID)

Table 2 Patient characteristics

Characteristics	Facet screws (*n* = 35)	Pedicle screws (*n* = 27)
Age (years, mean ± SD)	38.1 ± 10.4	42.4 ± 1
Female (%)	86	63
Height (cm, mean ± SD)	167 ± 7	169 ± 10
Weight (kg, mean ± SD)	71 ± 14	79 ± 20
BMI (mean)	25 ± 4	28 ± 6
Duration of symptoms (years, mean ± SD)	4.5 ± 3.9	4.1 ± 4.4
Smokers (%)	40	44
WC/litigation (%)	29	33
# Degenerated disks (mean, range)	1.6, 1–5	1.9, 1–5
Fusion levels		
L5–S1	26	19
L4–L5	6	8
L3–L4	3	0

Table 3 Average outcomes for facet versus pedicle groups over time

Outcome	Facet	Pedicle	*p* Value (between groups)	*p* Value (from pre-op; facet)	*p* Value (from pre-op; pedicle)
Lower back pain					
Pre-op	7.12	6.99	0.7702	–	–
V1 (7–12 months)	2.98	4.11	0.0937	**< 0.0001**	**< 0.0001**
V2 (1–2 years)	2.56	3.97	**0.0388**	**< 0.0001**	**< 0.0001**
V3 (2–4 years)	2.74	4.09	**0.0466**	**< 0.0001**	**< 0.0001**
V4 (4–6 years)	3.27	4.30	0.1748	**< 0.0001**	**< 0.0001**
V5 (6–8 years)	3.14	4.62	**0.0456**	**< 0.0001**	**< 0.0001**
V6 (8–10 years)	3.58	5.34	**0.0247**	**< 0.0001**	**0.0023**
V7 (10–12 years)	3.80	4.69	0.1812	**< 0.0001**	**< 0.0001**
Leg pain					
Pre-op	5.12	5.37	0.7563	–	–
V1 (7-12 months)	2.01	2.88	0.2204	**< 0.0001**	**0.0027**
V2 (1–2 years)	2.01	2.56	0.0931	**< 0.0001**	**0.0046**
V3 (2–4 years)	2.11	2.84	0.2577	**< 0.0001**	**0.0008**
V4 (4–6 years)	2.09	3.24	0.1421	**< 0.0001**	**0.0213**
V5 (6–8 years)	1.95	3.89	**0.0081**	**< 0.0001**	**0.0974**
V6 (8–10 years)	2.22	4.49	**0.0069**	**< 0.0001**	**0.2533**
V7 (10–12 years)	1.99	3.63	**0.0344**	**< 0.0001**	**0.0493**
Pain drawings (total)					
Pre-op	10.74	11.74	0.5542	–	–
V1 (7–12 months)	5.60	6.37	0.6060	**0.0002**	**0.0001**
V2 (1–2 years)	4.57	8.89	**0.0231**	**< 0.0001**	**0.0216**
V3 (2–4 years)	4.97	7.22	0.1447	**0.0001**	**< 0.0001**
V4 (4–6 years)	4.56	5.12	0.6809	**0.0001**	**0.0001**
V5 (6–8 years)	4.16	8.40	**0.0097**	**< 0.0001**	**0.0071**
V6 (8–10 years)	5.38	9.54	**0.0300**	**0.0005**	**0.0906**
V7 (10–12 years)	4.28	7.21	0.2254	**0.0002**	**0.0027**
ODI					
Pre-op	50.69	54.52	0.3017	–	–
V1 (7–12 months)	29.77	39.48	0.0775	**< 0.0001**	**< 0.0001**
V2 (1–2 years)	22.85	42.12	**0.0015**	**< 0.0001**	**0.0002**
V3 (2–4 years)	25.60	41.27	**0.0113**	**< 0.0001**	**0.0002**
V4 (4–6 years)	22.05	35.80	**0.0155**	**< 0.0001**	**< 0.0001**
V5 (6–8 years)	24.63	40.43	**0.0047**	**< 0.0001**	**0.0003**
V6 (8–10 years)	28.26	40.35	**0.0347**	**< 0.0001**	**0.0006**
V7 (10–12 years)	26.92	43.32	**0.0024**	**< 0.0001**	**0.0082**
SF-6D					
Pre-op	0.52	0.50	0.3017	–	–
V1 (7–12 months)	0.63	0.58	0.0775	**< 0.0001**	**< 0.0001**
V2 (1–2 years)	0.66	0.56	**0.0015**	**< 0.0001**	**0.0002**
V3 (2–4 years)	0.65	0.57	**0.0113**	**< 0.0001**	**0.0002**
V4 (4–6 years)	0.67	0.60	**0.0155**	**< 0.0001**	**< 0.0001**
V5 (6–8 years)	0.66	0.57	**0.0047**	**< 0.0001**	**0.0003**
V6 (8–10 years)	0.64	0.57	**0.0347**	**< 0.0001**	**0.0006**
V7 (10–12 years)	0.64	0.56	**0.0024**	**< 0.0001**	**0.0082**

Bold *p* values indicate statistical significance

ODI Oswestry Disability Index; *SF-6D* Short-Form Six-Dimension Health Index; *V* visit of ≥ 10.0 (75% vs. 48%; $p = 0.05$) as well as substantial clinical benefit of ≥ 18.8 (59% vs. 35%; $p = 0.10$) compared with the pedicle group [33]. Outcomes were reanalyzed using different imputation methods to evaluate the effect of the missing patient data. The results of the alternative scenarios were consistent with the base-case, therefore indicating that the missing observations had minimal impact on the findings.

Both groups demonstrated substantial reduction in their use of pain medication (Table 4). The facet group used significantly fewer narcotics than the pedicle group in the early 7- to 12-month follow-up period (34% vs. 63%, $p < 0.05$). The facet group still had numerically lower narcotic use than pedicle group at 10 years (22% vs. 48%; $p = 0.08$). Patients' self-assessment of overall success, their willingness to undergo the surgery under similar conditions, and their openness to recommend the treatment to others were similar ($p > 0.05$) when asked again at the 10-year follow-up visit.

There were more additional surgeries in the pedicle screw group, primarily owing to irritation and pain caused by the more prominent and bulky instrumentation. For the 13 patients in the pedicle group from whom instrumentation was removed, removal was performed, on average, 23 ± 16 months after the index fusion procedure. It is notable that for both groups, postoperative MRI and/or CT scans were obtained in all patients. This confirmed proper positioning of screw instrumentation; there were no instrumentation removals for malpositioned screws. Over the 10-year follow-up, the rate of revision surgeries for pseudarthrosis repair and for extension of the fusion adjacent to the index levels, as well as spinal cord stimulator implants, was not statistically different between the groups (Table 4). Regarding pseudarthrosis repair, this occurred in two patients that had IBG and was indeterminate in one who had BMP used. There were no specific complications related to IBG donor sites or BMP use. The average time to return to work was significantly shorter for the facet group compared with the pedicle group (6.9 ± 7.3 vs. 11.4 ± 6.8 months, $p = 0.028$).

The CEA base-case demonstrated the average cost per patient over 10 years was lower for facets versus pedicle screws (Table 5). The average total discounted cost per patient associated with facet screw fixation was $8650 less than pedicle screws. Results from the modified payer perspective demonstrated that facet screw fixation was $9735 less than pedicle screws when accounting for the device costs, and facet screws still cost $7482 less than pedicle screws after accounting for device costs and BMP costs. From a societal perspective including productivity loss, the facet group was associated with even greater cost savings ($22,691 less than pedicle screws). The undiscounted average cost per patient over 10 years aligned with the

Table 4 Additional surgeries and resource use by group

Additional surgeries and medication use	Facet ($n = 35$)	Pedicle ($n = 27$)	p Value (difference between groups; Fisher's test)
Revision surgeries (patients over 10 years)			
Fusion extension, adjacent segment fusion	6	3	0.719
Post-pseudo-repair, SI fusion	2	4	0.390
Decompression	2	1	1.000
Hardware removal	0	13	**< 0.0001**
Spinal cord stimulator	1	2	0.575
Medication use at 10 years (number of patients):			
Narcotics	7	11	0.079
NSAIDs	18	9	0.277
None	11	8	1.000
Resource use	**Facet ($n = 35$)**	**Pedicle ($n = 27$)**	**p Value (difference between groups; t test)**
Spine injections (number)	116	81	0.776
Physical therapy (number)	149	141	0.222
Medical imaging (number)			
CT	14	22	**0.018**
MRI	43	29	0.549
Emergency room visit (number)	9	6	0.624

Bold p values indicate statistical significance

CT computerized tomography scan; *MRI* magnetic resonance imaging; *NSAIDs* nonsteroidal anti-inflammatory drugs

Table 5 Average discounted and undiscounted costs and QALYs for facet and pedicle groups, all patients, by cost category and QALY scenario. All cost values are shown in USD

Costs	Discounted			Undiscounted		
	Facet (*n* = 35)	Pedicle (*n* = 27)	Incremental cost	Facet (*n* = 35)	Pedicle (*n* = 27)	Incremental cost
Index surgery	$38,448.89	$38,448.89	$0.00	$38,448.89	$38,448.89	$0.00
Revision surgeries	$7971.96	$14,961.31	– $6989.35	$8990.54	$16,170.80	– $7180.26
Medications	$15,138.34	$16,800.45	– $1662.11	$18,081.81	$19,760.41	– $1678.60
CT	$113.92	$232.05	– $118.13	$119.08	$242.57	– $123.49
MRI	$519.02	$453.75	$65.27	$567.15	$495.82	$71.32
Physical therapy	$291.40	$356.58	– $65.18	$292.00	$358.19	– $66.19
Spine injections	$2487.99	$2066.74	$421.25	$2631.34	$2381.82	$249.52
Emergency room	$113.18	$101.82	$11.36	$122.16	$105.57	$16.59
Clinic visits (Midwest Spine Institute)	$384.98	$714.11	– $329.13	$471.41	$807.52	– $390.11
Clinic visits (other)	$113.05	$96.78	$16.27	$118.66	$101.63	$17.03
Base-case total	$65,582.72	$74,232.49	– $8649.77	$69,789.03	$78,873.22	– $9084.18
Device costs (screws and rods)	$1970.29	$3055.71	– $1085.43	$1970.29	$3055.71	– $1085.43
Modified payer analysis (device costs without rhBMP2) total	$67,553.01	$77,288.20	– $9735.20	$71,759.32	$81,928.93	– $10,169.61
rhBMP2	$3380.00	$1126.67	$2253.33	$3380.00	$1126.67	$2253.33
Modified payer analysis (device costs plus rhBMP2) total	$70,933.01	$78,414.87	– $7481.86	$75,139.32	$83,055.60	– $7916.28
Productivity loss	$20,976.93	$35,017.89	– $14,040.96	$21,549.00	$35,591.09	– $14,042.08
Societal analysis total	$86,559.65	$109,250.38	– $22,690.72	$91,338.04	$114,464.30	– $23,126.27
QALYs	Discounted			Undiscounted		
	Facet	Pedicle	Incremental QALYs	Facet	Pedicle	Incremental QALYs
LOCF	5.46	4.77	0.68	6.45	5.64	0.81
Complete case	5.57	4.78	0.80	6.59	5.64	0.94
Missing = 0 (i.e., death)	5.25	4.50	0.76	6.19	5.29	0.90

CT computerized tomography scan; *LOCF* last observation carried forward; *MRI* magnetic resonance imaging; *QALY* quality-adjusted life year; *rhBMP2* recombinant human bone morphogenetic protein

discounted results for all scenarios (Table 5). When the cost of hardware removal was considered zero, the average discounted and undiscounted costs of facet screws were still lower than pedicle screws, but to a less extent (results not showed).

Postoperative utility scores improved significantly compared to preoperative scores for both groups. There were significantly greater improvements in SF-6D for the facet group compared with the pedicle group at most follow-up intervals, including the 10-year time point (SF-6D: 0.64 vs. 0.56 $p = 0.0024$; Table 3). Similarly, the average total QALYs were significantly higher for facets than pedicle screws (Table 5). This remained true when only complete cases were analyzed or when missing data were assumed to equal zero. Both subgroup analyses resulted in similar conclusions (Tables 6, 7).

The incremental cost-effectiveness plane illustrates the results of the bootstrapped incremental costs and QALYs (Fig. 1). Most (84%) of the simulated data points fell within the dominant quadrant, indicating facet screws were less costly and provided greater QALYs. The CEAC showed a 94% probability of facets being cost-effective at a willingness-to-pay of $10,000/QALY and 97% probability of being cost-effective at a willingness-to-pay of $20,000/QALY (Fig. 2). The summary bootstrapping statistics are also shown in Fig. 1.

Table 6 Average discounted and undiscounted costs and QALYs for facet and pedicle groups, for the subgroup analysis of only patients that used BMP, by cost category and QALY scenario. All cost values are shown in USD

Costs	Discounted			Undiscounted		
	Facet ($n=35$)	Pedicle ($n=9$)	Incremental cost	Facet ($n=35$)	Pedicle ($n=9$)	Incremental cost
Index surgery	$38,448.89	$38,448.89	$0.00	$38,448.89	$38,448.89	$0.00
Revision surgeries	$7971.96	$12,886.34	– $4914.38	$8990.54	$13,527.26	– $4536.73
Medications	$15,138.34	$17,417.92	– $2279.59	$18,081.81	$20,821.24	– $2739.42
CT	$113.92	$221.50	– $107.59	$119.08	$231.54	– $112.46
MRI	$519.02	$281.64	$237.38	$567.15	$307.75	$259.39
Physical therapy	$291.40	$348.73	– $57.34	$292.00	$350.57	– $58.57
Spine injections	$2487.99	$1335.89	$1152.10	$2631.34	$1499.66	$1131.68
Emergency room	$113.18	$103.28	$9.90	$122.16	$105.57	$16.59
Clinic visits (Midwest Spine Institute)	$384.98	$549.49	– $164.51	$417.41	$609.76	– $192.35
Clinic visits (other)	$113.05	$92.34	$20.71	$118.66	$98.88	$19.78
Base-case total	$65,582.72	$71,686.02	– $6103.30	$69,789.03	$76,001.13	– $6212.10
Device costs (screws and rods)	$1970.29	$3055.71	– $1085.43	$1970.29	$3055.71	– $1085.43
rhBMP2	$3380.00	$3380.00	$0.00	$3380.00	$3380.00	$0.00
Modified payer analysis total	$70,933.01	$78,121.74	– $7188.73	$75,139.32	$82,436.84	– $7297.52
Productivity loss	$18,809.89	$28,166.63	– $9356.73	$19,322.87	$28,422.79	– $9099.93
Societal analysis total	$84,392.61	$99,852.65	– $15,460.04	$89,111.90	$104,423.92	– $15,312.02
QALYs	Discounted			Undiscounted		
	Facet	Pedicle	Incremental QALYs	Facet	Pedicle	Incremental QALYs
LOCF	5.46	5.02	0.44	6.45	5.93	0.52
Complete case	5.57	5.02	0.56	6.59	5.93	0.66
Missing = 0 (i.e., death)	5.25	4.49	0.76	6.19	5.27	0.93

CT computerized tomography scan; *LOCF* last observation carried forward; *MRI* magnetic resonance imaging; *QALY* quality-adjusted life year; *rhBMP2* recombinant human bone morphogenetic protein

Discussion

The present study compared single-level circumferential spinal fusion operations that used two types of posterior instrumentation. Both groups achieved significant improvement in pain and disability outcomes and were within the range of previous reports [34, 35]. Additionally, both groups achieved substantial clinical improvements, with changes in VAS and ODI exceeding the MCID [33, 36, 37]. Fusion rates were high in both groups; presumably, this was enhanced equally by both groups having interbody fusions.

To the author's knowledge, this is the first study to evaluate the cost-effectiveness of facet versus pedicle screw fixation for circumferential spinal fusion. Based on patient-level resource utilization and health-related quality of life data, the analysis demonstrated that facet screws were dominant (i.e., provided more QALYs and lower total costs) over pedicle screws over a 10-year postoperative interval from a US payer perspective. Furthermore, alternate scenario analyses confirmed that facet screws remained dominant when considering device costs or productivity loss. The lower costs in the facet group were driven by lower device costs, fewer additional surgeries (after the index procedure), lower postoperative care and pain medication utilized, and less time off work.

Cost-effectiveness thresholds have been described, such as the £20,000 to £30,000 considered by the National Institute for Health and Clinical Excellence (NICE) in the UK [38]. For medical devices, it is particularly useful to compare the incremental cost-effectiveness ratios (ICERs) within the therapeutic area. Previous studies demonstrated that instrumented spinal fusion surgery is cost-effective versus noninstrumented spinal surgery, with ICERs ranging from $30,053/QALY to $69,403/QALY [18, 21, 22]. In comparison, 97% of our bootstrapping simulations of facets versus pedicle screws were at or below $20,000/QALY (and 84% of the simulations were dominant). Therefore, facet instrumentation was associated with clinical and economic value, particularly in the context of other CEAs of various spine treatments including single-level instrumented lumbar fusion and fusion for degenerative spondylolisthesis [18, 21, 22].

Table 7 Average discounted and undiscounted costs and QALYs for facet and pedicle groups, for the subgroup analysis of only patients that did not have hardware removal, by cost category and QALY scenario. All cost values are shown in USD

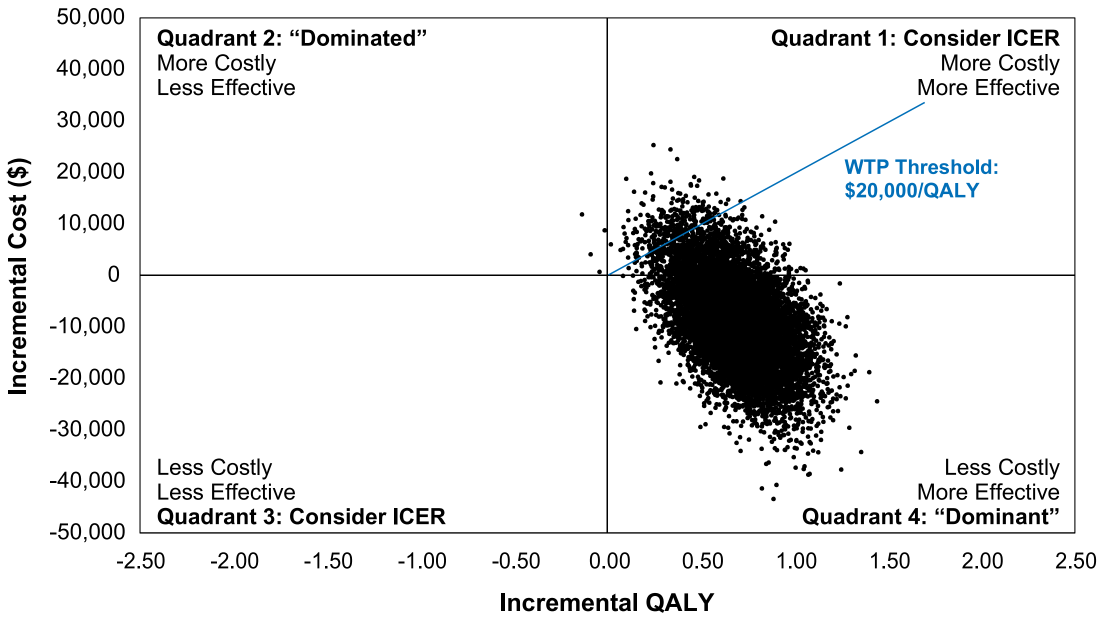
Costs	Discounted			Undiscounted		
	Facet ($n=35$)	Pedicle ($n=13$)	Incremental cost	Facet ($n=35$)	Pedicle ($n=13$)	Incremental cost
Index surgery	$38,448.89	$38,448.89	$0.00	$38,448.89	$38,448.89	$0.00
Revision surgeries	$7971.96	$13,130.60	−$5158.63	$8990.54	$14,563.27	−$5572.73
Medications	$15,138.34	$24,031.56	−$8893.22	$18,081.81	$28,459.32	−$10,377.51
CT	$113.92	$175.25	−$61.34	$119.08	$183.20	−$64.12
MRI	$519.02	$357.46	$161.55	$567.15	$390.61	$176.54
Physical therapy	$291.40	$304.40	−$13.00	$292.00	$306.02	−$14.02
Spine injections	$2487.99	$1212.55	$1275.44	$2631.34	$1404.66	$1226.68
Emergency room	$113.18	$73.08	$40.09	$122.16	$73.08	$49.07
Clinic visits (Midwest Spine Institute)	$384.98	$540.61	−$155.64	$417.41	$604.69	−$187.27
Clinic visits (other)	$113.05	$95.48	$17.58	$118.66	$96.98	$21.68
Base-case total	$65,582.72	$78,369.89	−$12,787.17	$69,789.03	$84,530.72	−$14,741.69
Device costs (screws and rods)	$1970.29	$3055.71	−$1085.43	$1970.29	$3055.71	−$1085.43
rhBMP2	$3380.00	$1040.00	$2340.00	$3380.00	$1040.00	$2340.00
Base-case total	$70,933.01	$82,465.60	−$11,532.60	$75,139.32	$88,626.44	−$13,487.12
Productivity loss	$19,089.80	$25,407.72	−$6317.92	$19,610.41	$25,909.41	−$6299.00
Societal analysis total	$84,672.52	$103,777.61	−$19,105.09	$89,399.44	$110,440.13	−$21,040.69
QALYs	Discounted			Undiscounted		
	Facet	Pedicle	Incremental QALYs	Facet	Pedicle	Incremental QALYs
LOCF	5.46	4.75	0.71	6.45	5.60	0.85
Complete case	5.57	4.80	0.77	6.59	5.65	0.93
Missing = 0 (i.e., death)	5.25	4.54	0.72	6.19	5.33	0.86

CT computerized tomography scan; *LOCF* last observation carried forward; *MRI* magnetic resonance imaging; *QALY* quality-adjusted life year; *rhBMP2* recombinant human bone morphogenetic protein

Data from Glassman and colleagues indicate that QALY gains may be lower when estimated from SF-6D instead of the EQ-5D value [21]. Therefore, the results of our CEA may be conservative. SF-6D was used in our analysis because it has been commonly used in recent CEAs of various spine treatments and there is evidence ODI may be used to estimate SF-6D more accurately than EQ-5D [27, 39, 40]. Of note, conversion of standard spine outcomes using instruments such as ODI to utilities such as SF-6D, as described by Carreon and Glassman, has made it possible to use clinical research with only disease-specific health measures in CEAs [27]. This is important, as it allows health economic evaluation and comparison of current, past, and future research.

The value of facet screw instrumentation during spinal fusion was consistently demonstrated in all analyses, including all costing scenarios, sensitivity analyses, and subgroup analyses including only patients that received BMP or only those that did not have hardware removal. The multiple scenario and sensitivity analyses are the strength of our CEA. Overall, the methods we employed were consistent with other studies that considered similar cost categories [18, 21, 22]. However, our analysis had a longer time horizon (10 years) than some other analyses of spinal fusion [21, 22].

Our study was limited due to its nonrandomized nature. Another limitation is that health state values were not measured directly using a preference-based instrument such as the SF-6D. Instead, data were collected using the ODI, a low back pain-specific instrument, and a regression equation was used to predict SF-6D utility scores. However, a previous study demonstrated the regression model was sufficiently robust, with strong correlation coefficients between the two measures (Pearson = 0.83, Spearman = 0.82) [27]. Further, the authors validated their results using an independent cohort ($N = 2174$) and found there were no statistically significant differences between the actual and the estimated SF-6D values. Our study may also be limited by the



Bootstrapping Statistics	Incremental Cost	Incremental QALYs
Mean	-$8,498.77	0.683
S.D.	$8,546.04	0.194
Minimum	-$43,387.81	-0.136
Maximum	$25,314.10	1.442
Lower 95% CI	-$8,666.27	0.680
Upper 95% CI	-$8,331.27	0.690

Fig. 1 Incremental cost-effectiveness plane and summary of the bootstrapping results on the base-case analysis. The graph presents the results of the nonparametric bootstrapping replication of facet versus pedicle screw fixation over a 10-year horizon. The data points represent the 10,000 iterations. Incremental costs are on the y-axis and incremental QALYs on the x-axis. Facet screws are predicted to be dominant in 84% of the simulations. The table below the graph presents a summary of the bootstrapping results. Note that CEA comparisons in quadrants 2 and 4 represent interventions that are easy to reject or accept, respectively. Incremental cost-effectiveness ratios (ICERs) for CEA comparisons that fall in quadrants 1 and 3 represent the added cost per unit of added gain and estimate the cost-effectiveness of treatments that fall into those categories, which can be evaluated compared to the willingness-to-pay (WTP) threshold

small sample size; however, a bootstrapping analysis was conducted to estimate the distribution of incremental costs and effects, with most of the simulations resulting in facets dominating pedicle screws. Further, the US payer perspective was based on Medicare costs and may not represent all US payers for which costs may differ. However, it is expected that differences in costs would impact both groups. Lastly, our CEA may be limited by the incomplete 10-year follow-up for 5 patients. However, when conducting a sensitivity analysis using only complete cases or even assuming the missing entries were equal to zero (i.e., death), results were consistent with base-case analysis.

In conclusion, this study demonstrated a sustained improvement in outcomes for more than 10 years after single-level circumferential lumbar fusion with both facet and pedicle screws. The study also showed that, similar to our 5-year outcomes, patients undergoing fusion with minimally invasive low-profile facet posterior instrumentation had superior outcomes compared to larger-profile pedicle

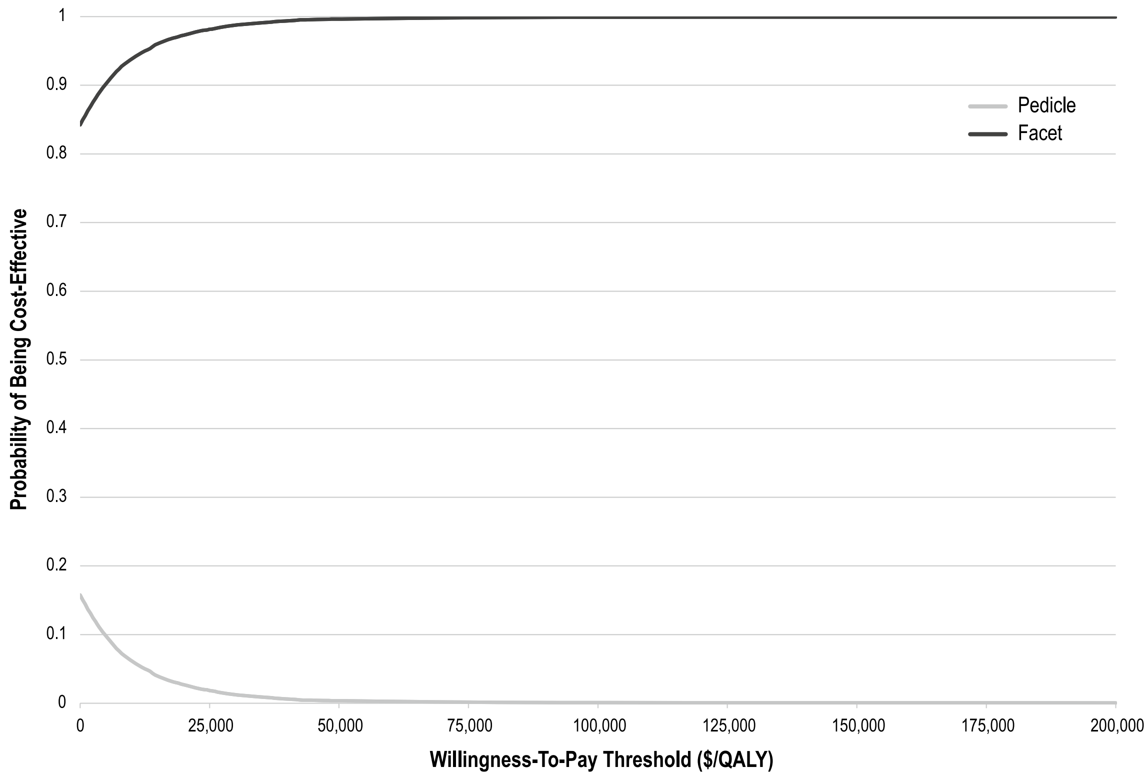


Fig. 2 Cost-effectiveness acceptability curve based on cost ($) per QALY thresholds for facet compared to pedicle screw fixation. The curve plots the probability that facets are cost-effective compared with pedicle screws against a range of willingness-to-pay thresholds. At a willingness-to-pay threshold of $20,000/QALY, there is a 97% probability that facets will be cost-effective compared with pedicle screws

screws. CEAs are becoming increasingly important to healthcare reform initiatives for spinal disorders, as there is a push toward value-based healthcare. The current CEA provides evidence that use of facet screws for spinal fusion was dominant (i.e., provided greater QALYs and cost savings) when compared with pedicle screws in all analyses and 84% of the bootstrapping simulations. Overall, this study supports the use of facet screws for the treatment of patients with advanced DDD.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no confict ofinterest.

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