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Fusion

Cost comparison of patients with 3-level artificial total lumbar disc replacements versus 360° fusion at 3 contiguous lumbar vertebral levels: an analysis of compassionate use at 1 site of the US investigational device exemption clinical trial

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Abstract

Background: We sought to evaluate the difference between hospital service costs of 2 treatment options for patients diagnosed with 3-level degenerative disc disease (DDD) in the lumbar spine. In this retrospective analysis, itemized billing records of hospital stay for patients with 3-level DDD treated with artificial disc replacement (ADR) were compared with those treated with circumferential fusion (standard of care).
Methods: Sequential 3-level DDD patients treated with either ADR (ProDisc-L; Synthes, West Chester, Pennsylvania) or circumferential fusion during the period from January 2004 to October 2005 were included. Surgeries were performed at the same hospital for all patients. The ADR-treated patients were participating in the investigational device exemption clinical trial as part of the compassionate-use arm. Patients treated with fusion at the same institution during this same time interval were evaluated. Itemized billing records were collected at least 1 year after the index surgery. Costs according to hospital service categories were compared between ADR-treated and fusion-treated patients by use of analysis of variance and multivariate statistical techniques.
Results: There were 43 consecutive patients treated for 3-level DDD between January 2004 and October 2005. Of these, 21 underwent 3-level ADR and 22 had a 3-level fusion procedure. There was a mean of 3 fewer hospital days for patients treated with ADR (4.77 ± 1.11 days) than for those treated with fusion (8.00 ± 1.82 days) ($P < .0001$). The cost of hospital services for ADR-treated patients was 49% less excluding instrumentation costs and 54% less when accounting for instrumentation. The pattern of cost was similar when workers' compensation patients were analyzed separately.
Conclusions: ADR-treated 3-level patients benefited from significantly lower costs from their in-hospital stay compared with those treated by fusion. Hospital service costs were 49% (54% when instrumentation was included in the costs) less for ADR patients than for fusion patients.

Keywords: Fusion; Artificial disc replacement (ADR); Cost

Healthcare costs must be economized in the United States today without sacrifice to quality of care (American Medical Association Code of Ethics, Section 2.09, Costs) and patient well-being. The cost associated with medical treatment of back pain is estimated at $26 billion annually, with an ever-increasing share of those costs directly from surgical care for treatments such as spinal fusion.[1,2] Further costs may be incurred from subsequent procedures for adjacent-level disease or fusion failure; however, these estimated costs are unknown. There are additional indirect or societal costs of another $25 billion for time lost from work and workers' compensation associated with duration of illness and healing. Estimates for the cost of the treatment of back pain vary, and no study has ever tried to formally include societal costs in the estimation.[3] Healthcare expenditures in 1998 for individuals with back pain were believed to be understated, at $91 billion.[2] The figure is high yet does not account for societal costs. In the United States, back pain is the fifth leading cause of admission to the hospital and the third most common indication for surgical procedures.[4] Discovery of less costly surgical procedures using competitive advanced technology, where the patient requires a shortened recovery time with minimized postsurgical morbidity, would benefit patients and conserve US healthcare dollars.

Generally, spinal fusion is the surgical standard of care for degenerative disc disease (DDD).[5] There are a variety of surgical techniques performed with the addition of screws,

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rods, bone grafts, or other materials to achieve a final result of bony union (fusion). The most effective of these techniques, circumferential fusion,[6–8] is also the most complicated and is also potentially the most costly. Statistical knowledge regarding cost patterns and cost-effectiveness for the various fusion techniques is limited. Instrumentation and grafting materials were identified as key components of differences in cost among the various spinal fusion procedures in a study completed by Soegaard et al.[9] This study also found that the circumferential fusion procedure was slightly more effective in terms of outcomes than other fusion procedures, but the evidence for the superior effect of one surgical technique over another was not convincing when correlated to incremental cost-effectiveness. In the study of Soegaard et al, there was no additional benefit gained from additional expenses.

A fusion procedure is a widely accepted treatment for fractures and spondylolisthesis, whereas it is more controversial as a treatment for patients with complaints of low-back pain from degenerated discs.[1,10] Fusion is increasingly performed at a high cost in patients with complaints of only low-back pain.[11] The Agency for Healthcare Research and Quality found that the number of fusion surgeries increased 127% from 1997 to 2004 to more than 303,000. Although there is controversy in the treatment of back pain with spinal fusion, fusions continue to increase.

Fusion procedures are recognized as one of the more costly surgical procedures performed. These costs are multiplying because of the procedures' increasing incidence of use in treating low-back pain. In 1992 lumbar fusion represented 14% of total spending for back surgery, but in 2003 this number was 47%.[1] In the United States, from 1990 to 2001, the rate of fusions per 100,000 persons has increased by 220%.[12,13]

Biotechnology companies worldwide are developing many innovations that may be alternatives to fusion in treating DDD. However, there is still limited information available on costs. Is there a cost detriment or a cost benefit for innovation? Recently, a non-fusion procedure of artificial disc replacement (ADR) (using a Charité [DePuy Spine, Raynham, Massachusetts] or ProDisc-L device [Synthes, West Chester, Pennsylvania]) was Food and Drug Administration (FDA) approved for treatment of low-back pain due to DDD.[13] Suggested advantages of ADR procedures are that they allow for maintenance and restoration of motion may decrease adjacent-level degeneration, and the ProDisc-L randomized study showed overall superiority of the artificial disc procedure when compared with a 360° fusion.[14] Less has been mentioned about the associated decrease in hospital stay days as well as more rapid recovery after ADR surgery compared with fusion surgery. These factors may translate to a benefit of cost savings.

Today, ADR surgery, with either the ProDisc-L or the Charité device, is still untracked for cost-savings benefit by Medicare (it should be noted that ADR is still unsupported by the Medicare system, although it has been several years since its approval).[13,15] There are limited published cost comparisons between ADR and fusion based on a cost-to-efficacy benefit ratio. Recently in 2007 circumferential fusion was compared with single- and 2-level disc arthroplasty with the ProDisc. From the sample of 53 patients (36 ADR and 17 circumferential fusion), it was concluded that significant cost savings were achieved for the single-level ADR patients, but the difference was insignificant among the 2-level patients. If the use of ADR is shown to be cost-effective for the treatment of DDD, then both public and private insurance companies, as well as the US spine patient population, would sustain cost benefit from the covering of such procedures. Many researchers of spine surgery have discussed the importance of evaluating costs as well as clinical outcomes.[16] This study is important because it could provide surgeons, hospitals, and patients another way to evaluate surgical options and costs. Better medical care decisions may then be made, ensuring advanced technology and quality of care while limiting high costs of spine surgery.

There are no studies comparing the cost of 3-level ADR with 3-level fusion. This study compares the costs for patients who underwent treatment for sequential 3-level DDD with either ADR (ProDisc-L) or fusion.

Materials and Methods

Design

Patients with 3-level lumbar DDD were separately approved on a case-by-case basis for treatment by use of ADR (ProDisc-L) under the humanitarian device exemption for "compassionate-use" FDA-approved investigational device exemption study. Patients in this compassionate-use arm were followed up in the same manner as patients enrolled in the main randomized arm of the study. Sequential 3-level DDD patients treated with either ADR or circumferential fusion during the period from January 2004 to October 2005 were included. All surgeries were performed at the same hospital (St John's Health Center, Santa Monica, California). Itemized hospital billing records were collected at least 1 year after a patient's index surgery. Averages were computed separately by hospital service categories and compared between ADR-treated and fusion-treated patients by use of multivariate statistical techniques.

Device

The ProDisc is an artificial disc device composed of 3 components: 2 metal endplates made of cobalt chromium molybdenum alloy and a polyethylene convex bearing surface that fits into the inferior endplate. This device is easily implanted by a well-trained spinal surgeon and has been previously described.[14,17] The ProDisc-L was approved by the FDA in August 2006.

Surgical technique

Surgical technique for 3-level ProDisc

The ProDisc was implanted by an anterior retroperitoneal approach, and the 3-level procedure is similar to the single-level procedure (previously well described). Intraoperative fluoroscopy is used throughout the surgery to verify the placement of the prosthesis. An anteroposterior view is used to confirm the levels and midline of the vertebral bodies. A complete discectomy is performed at each of the 3 target levels. For each level, the cartilaginous endplate is removed from the vertebra. If herniated disc material is present, this disc material is removed from the canal. If the posterior longitudinal ligament has contracted, the posterior longitudinal ligament is then released from the posterior vertebral body with a forward-angled curette. For each level, normal anatomic height is restored with distraction under fluoroscopy. A trial is placed to help select the proper disc size, angle, and height. A sagittal groove is cut in the vertebral endplates in the exact midline by use of a chisel placed over the trial. This groove receives the central keel of the implant. The trial is removed, and the final implant is gently impacted into place by use of an insertion tool. Gross inspection is done to ensure the ultrahigh–molecular weight polyethylene liner lies properly flush against the inferior endplate, and final fluoroscopic views are taken to confirm the correct position of the prosthesis. This same procedure is repeated for the other 2 levels.

Surgical technique for 3-level circumferential fusion

Two separate surgical incisions are used. The same anterior approach of the ADR procedure is used for the anterior discectomy and the anterior portion of the fusion procedure. The endplates are prepared in the same manner as for the ADR except that a femoral ring allograft (FRA Spacer; Synthes) is placed instead of the ADR prosthesis. The FRA spacer was filled with a recombinant human bone morphogenetic protein 2 sponge (INFUSE; Medtronic, Minneapolis, Minnesota). A standard approach technique is used for the posterior pedicle screw instrumentation. Laminectomy bone taken from the posterior decompression local bone was used in all cases and placed in the posterolateral gutters. Iliac crest graft was not harvested and was not used in any patient.

Hospital service costs

Itemized hospital billing records for the entire stay from surgery to discharge were obtained from hospital billing services (St John's Health Center, 2006) at least 1 year after the target surgery. Itemized data were retrospectively abstracted from these billing records. Costs were categorized into room and board, pharmacy, central supply, laboratory, radiology, implants, surgery, anesthesia, blood bank, physical therapy, and other consult costs. In addition, a total cost for each patient was computed across all categories excluding the implants. Because ADR patients participating in the FDA trial were not charged for the implant, these charges were left out of the total hospital service charges' dependent variable. A device is priced at $9,500 per artificial disc, 3 times per patient, for a total of $28,500. Charges including instrumentation were analyzed separately.

Room-and-board costs were standardized to the price of a semi-private room ($1,970) per day to avoid cost differences arising from patient room preferences. If a patient was transferred to the intensive care unit, the room and board costs for intensive care unit care were recorded (not adjusted).

Instrumentation costs

Instrumentation fees were figured at retail cost for the ADR patients. To eliminate device cost bias, numbers are provided with and without these charges.

Surgeons' fee

Because surgeons' fees vary so greatly, we excluded these altogether from these analyses.

Analysis

We used multivariate models for an evaluation of overall cost of services as a function of treatment (ADR vs fusion) controlling for age and workers' compensation. Actual hospital service costs were used without instrumentation or surgeon fees.

Results

Hospital stay characteristics by category of service

Inherent subject characteristics and those related to care were compared between the two treatment groups (Tables 1 and 2). The mean age of the patients in the fusion group was greater than that in the ADR group (53.12 ± 9.71 years vs 45.68 ± 9.16 years, $P < .01$). The percentage of patients receiving workers' compensation was higher in the fusion-treated group in comparison to the ADR patients (61.90% vs 18.18%, $P < .01$). When analyzed separately, differences in age and workers' compensation status between the two treatment groups had no significant confounding effect on cost differences between the two groups.

On average, fusion patients spent an additional 3.23 days in the hospital compared with ADR patients. In the operating room, fusion patients were under anesthesia a mean of 164.59 minutes longer than ADR patients (384.32 ± 88.95 minutes vs 219.73 ± 68.52 minutes, $P < .0001$), and their surgical time was 202.88 minutes longer (359.2 ± 72.14 minutes vs 156.32 ± 58.28 minutes, $P < .0001$). For fusion patients, increased procedure time was correlated with increased blood loss ($r = 0.50$, $P < .02$). Fusion patients lost a mean of 1,634.34 mL more blood than ADR patients (2,085.7 ± 845.01 mL vs 451.36 ± 291.54 mL, $P < .0001$) (Table 3).

Fusion patients intraoperatively received a mean of 1,102.56 mL more blood return. Blood return was accom-

Table 1
Subject characteristics related to hospital care/treatment

Subject characteristics	ADR (n = 22)	Fusion (n = 21)	Significance
Mean age (range) (y)	40.30 (19–59)	42.19 (26–59)	
Workers' compensation	50,865.56	107,022.10	$P < .002$
Non–workers' compensation	55,306.50	107,313.86	
Vertebral levels treated (3-level surgeries)	66/22	63/21	$P < .0001$
L2-5	(0/22) 0%	(7/21) 32%	
L3-L5,S1	(22/22) 100%	(14/21) 68%	
In-hospital physical therapy visits			$P < .05$
1	(1/22) 4%	(0/21) 0%	
3	(5/22) 23%	(0/21) 0%	
4	(7/22) 32%	(1/21) 5%	
5	(2/22) 9%	(5/21) 24%	
6	(3/22) 14%	(5/21) 24%	
7	(3/22) 14%	(3/21) 14%	
8	(1/22) 4%	(3/21) 14%	
9	(0/22) 0%	(4/21) 19%	
Days before ambulation			$P < .05$
1	(17/22) 77%	(5/21) 24%	
2	(4/22) 18%	(7/21) 33%	
3	(1/22) 4%	(5/24) 24%	
5	(0/22) 0%	(1/21) 5%	
Unknown	(0/22) 0%	(3/21) 14%	

plished by 3 methods: cell saver, banked blood, or autologous transfusion. The differences in blood return for each were 644.7 mL, 125.37 mL, and 329.48 mL more for the fusion group, respectively. Postoperative blood loss collected by the Hemovac (Davol Inc., Warwick, Rhode Island) was greater in the fusion patients than the ADR patients (224 ± 380.06 mL vs 9.53 ± 43.65 mL, $P < .05$) (Table 3). The fusion patients averaged 6.66 hospital physical therapy visits before discharge compared with 4.60 visits ($P < .05$) for the ADR patients (Table 1).

Of 18 fusion patients, 12 took up to 2 days before ambulation began (12 of 18 [67%]); it was unknown when 3 of the fusion patients began ambulation. After 1 day, 17 of 22 ADR patients (77%) were ambulating. The difference in days before ambulation was found to be significant ($P < .05$) (Table 1).

Hospital stay costs by vertebral levels operated

There were differences in the levels operated on for the fusion and ADR patients. All 22 ADR patients were treated from L3 to S1, whereas 14 of the 21 fusion patients were treated from L3 to S1 (Table 1). The other 7 fusion patients were treated from L2-5. Statistical tests were done to compare the variations in levels operated. The test comparing costs for the L3-S1 patients confirms the previous result that treatment type leads to cost differences. The average L3-S1 fusion patient spent $100,722 ± $16,490 ($174,010.35 ± $23,961.19 with implant accounted for), whereas the average L3-S1 ADR patient (all 22) spent $54,499 ± $15,402 (with implant retail price of $81,499.05 ± $15,401.73). The 7 fusion patients who were treated from L2-5 spent a mean of $119,955 ± $22,826. The cost difference between the two sets of levels among fusion patients was found to be significant ($P < .05$).

Summary of hospital costs

Throughout the hospital stay, significantly fewer costs for a variety of hospital services were enjoyed by the ADR patients when compared with the fusion patients. On average, the total cost (excluding implant costs) for the fusion patient was 49% more than the cost incurred by the ADR patient ($107,133 ± $20,479 vs $54,499 ± $15,402.00, $P < .0001$). These data are presented in Fig. 1 (instrumentation-biased data) and Fig. 2 (unbiased data).

Categorically, the major hospital services contributing to the total cost difference were surgery, implant, room and board, and blood bank charges. When compared with the ADR patients, fusion patients endured charges totaling 194%, 160%, 102%, and 212% more, respectively, for these services. Costs for the hospital services grouped under laboratory ($3,279.60 ± $1,254.60 vs $2,467 ± $2,136.90), radiology ($4,044.90 ± $2,244.10 vs $5,220.80 ± $4,035.90), and other consults ($2,167.80 ± $1,741.90 vs $2,353.20 ± $2,430.40) were not different for fusion versus ADR patients (P = not significant). Central supply costs ($9,067.30 ± $1,868.60 vs $6,118.90 ± $2,518.40), anesthesia costs ($9,738 ± $1,804.70 vs $4,980.70 ± $1,275.50), in-hospital physical therapy costs ($1,318 ±

Table 2
Subject characteristics

Continuous	ADR	Fusion	Significance
Age (mean ± SD) (y)	45.98 ± 9.16	53.12 ± 9.71	$P < .01$
Body mass index (mean ± SD)	28.28 ± 4.85	29.32 ± 8.00	NS
Currently smoking [n (%)]	5/22 (22.73%)	2/21 (9.52%)	NS
Workers' compensation [n (%)]	4/22 (18.18%)	13/21 (61.90%)	$P < .01$
Male [n (%)]	15/22 (68.18%)	15/21 (71.43%)	NS
Previous lumbar surgery [n (%)]	4/22 (18.18%)	4/21 (19.05%)	NS
Previous chronic condition [n (%)]	18/22 (81.82%)	16/21 (76.19%)	NS
Previous surgery—non-orthopaedic [n (%)]	2/22 (9.09%)	3/21 (14.29%)	NS
Previous surgery—spine [n (%)]	5/22 (22.73%)	4/21 (19.05%)	NS
Previous surgery—other orthopaedic [n (%)]	4/22 (18.18%)	2/21 (9.52%)	NS

Abbreviation: NS, not significant.

Table 3
Operative results

	ADR (n = 22) (mean ± SD)	Fusion (n = 21) (mean ± SD)	Significance
Length of surgery (min)	156.32 ± 58.282	359.2 ± 72.136	$P < .0001$
Length of anesthesia (min)	219.73 ± 68.523	384.32 ± 88.947	$P < .0001$
Days in hospital	4.77 ± 1.11	8.00 ± 1.82	$P < .0001$
Estimated blood loss (mL)	451.36 ± 291.54	2,085.7 ± 845.01	$P < .0001$
Postoperative Hemovac blood (mL)	9.53 ± 43.65	224 ± 380.26	$P < .05$
Cell saver return (mL)	138.86 ± 224.83	783.57 ± 366.26	$P < .0001$
Banked blood return (mL)	22.73 ± 106.60	148.1 ± 287.71	NS
Autologous blood return (mL)	34.09 ± 116.89	363.57 ± 345.32	$P < .01$

Abbreviation: NS, not significant.

$270.25 vs $875.79 ± $1,180.5), and pharmacy costs ($17,464 ± 5,343 vs $9,440.20 ± 3,828.20) also added to the marked increase in total cost the fusion patients were billed compared with the ADR patients (Fig. 3 and Table 4).

Postoperative severe adverse events and discharge transfers

Postoperatively, 5 fusion patients (24%) and 2 ADR patients (9%) had significant adverse events. Two fusion patients had deep vein thrombosis postoperatively. Two fusion patients and one ADR patient had ileus and abdominal distension postoperatively.

After the hospital course, 4 patients who underwent fusion (18%) ($P < .05$) were discharged to rehabilitation facilities. None of the ADR patients were discharged to rehabilitation facilities.

Costs from treatment failures

Two patients (one ADR and one fusion) required rehospitalization (Figs. 4 and 5). One of the patients treated with ADR L3-S1 had to undergo surgery again 2 weeks after the initial procedure to reposition her artificial disc at L5-S1. There was slight anterior listhesis of L5 on S1 due to initial malpositioning. The repositioning procedure was successful, and the patient recovered well. The patient had stopped taking medications after 1 month and returned to work at 3 months. The additional cost for this corrective procedure was $36,149.16.

One of the patients treated with a 3-level fusion procedure at L2-5 underwent an additional surgical procedure for continuing pain. The procedure entailed evaluation of the fusion mass and removal of the instrumentation (there was no pseudarthrosis at the level suspected). The hospital services cost for this procedure was $33,538.51.

Discussion

The cost of care of new treatments for DDD at multiple levels is an important consideration after safety and efficacy have been shown. The current surgical standard of care for a patient with low-back pain due to disease at 3 segmental levels in the lumbar spine is circumferential fusion, but treatment with a fusion procedure demands high direct costs

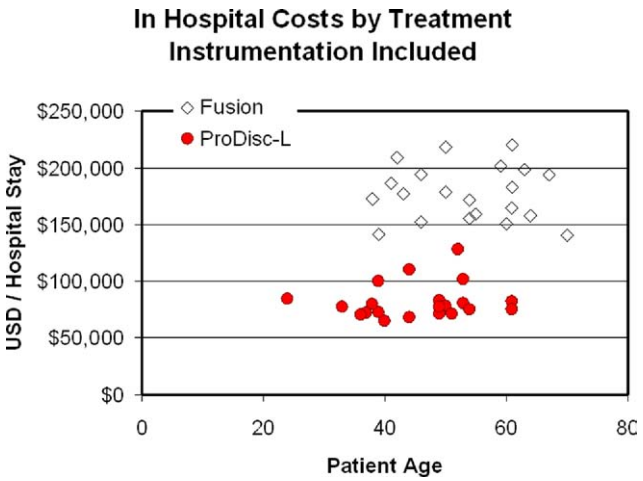

Fig. 1. Scatter plot comparing in-hospital costs in US dollars (USD) for fusion and ADR treatment groups including instrumentation costs. The total cost for fusion-treated patients was statistically higher than that for ADR patients ($P < .0001$).

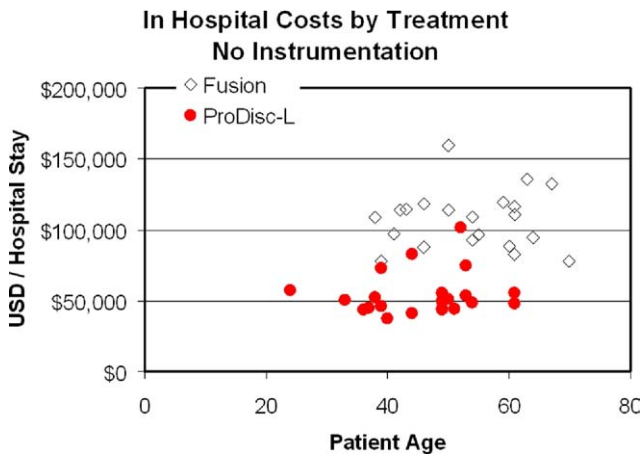

Fig. 2. Scatter plot comparing in-hospital costs in US dollars (USD) for fusion and ADR treatment groups excluding instrumentation costs. The total cost for fusion-treated patients was statistically higher than that for ADR patients ($P < .0001$).

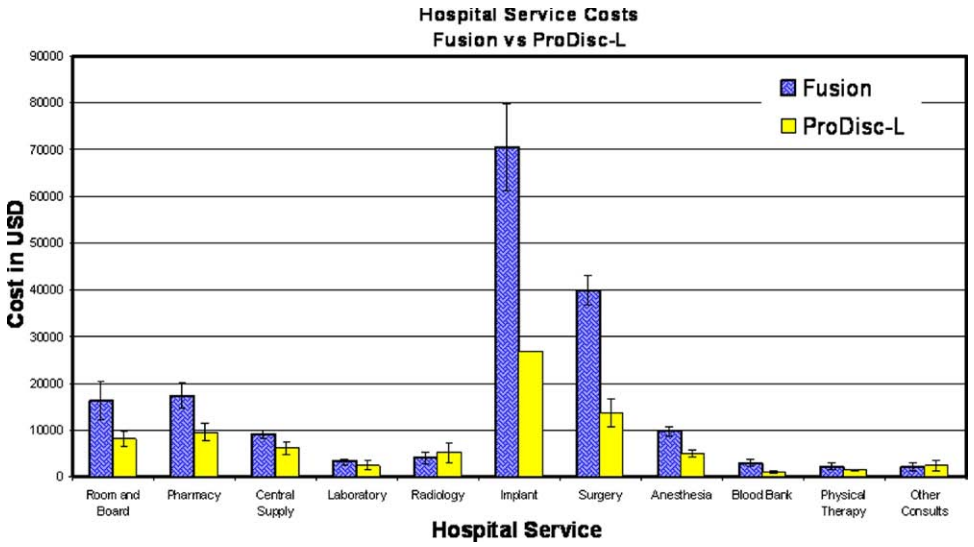

Fig. 3. Comparison of hospital service costs in US dollars (USD) between fusion and ADR treatment groups.

(healthcare dollars) as well as possible high indirect costs in terms of long recovery.[2,4]

A detailed analysis was presented on the direct costs of surgical procedure, length of hospitalization, and course during the hospitalization for patients treated by ADR or fusion. Instrumentation costs were figured separately because they differ according to contracts arranged by various hospitals and payers, even though all the records studied herein were from the same hospital. These results show that mean direct costs were significantly lower for patients treated at 3 levels with an ADR procedure than with a fusion procedure; this finding was similar for both analyses—hospitalization plus surgical procedure both including and excluding the cost of instrumentation for fusion (screws, rods, and femoral ring plus growth factor [recombinant human bone morphogenetic protein 2])–treated or ADR (disc)–treated patients. Treatment during the perioperative period and the hospital stay account for the significantly increased costs because of medical care and services for fusion-treated patients. There are additional costs, indirect costs, resulting from a slower recovery and return to activity not accounted for in this study. Furthermore, the longer-term implications of these indirect costs result in greater costs for workers' compensation coverage, for health insurance for employers and workers, for insurance companies, and most basically, in terms of the financial security of families.

Optimizing outcomes to direct cost of treatment is fundamental to the preservation of US healthcare dollars. Thus post-approval evaluations would serve well to also include measures of costs in addition to standard outcomes.[16] Estimated healthcare direct costs typically include cost to per-

Table 4
Comparison of ADR patient versus fusion patient hospital service costs from surgery through discharge

	ADR (USD) (mean ± SD)	Fusion (USD) (mean ± SD)	Significance
Surgical			
*Implant costs	27,000 ± 000.00	70,460.00 ± 18,663.00	$P < .0001$
Surgery costs	13,618 ± 5,947.60	39,995 ± 6,030.80	$P < .0001$
Anesthesia costs	4,980.70 ± 1,275.50	9,738.00 ± 1,804.70	$P < .0001$
Radiology costs	5,220.80 ± 4,035.90	4,044.90 ± 2,244.10	NS
Blood bank costs	944.17 ± 325.22	2,946.3 ± 1,661.90	$P < .0001$
Hospital stay			
Room and board	8,038.60 ± 3,306.80	16,237.00 ± 8,324.40	$P < .01$
Pharmacy	9,440.20 ± 3,828.20	17,464.00 ± 5,343.00	$P < .0001$
Central supply	6,118.90 ± 2,518.40	9067.30 ± 1,868.60	$P < .0001$
Laboratory costs	2,467.00 ± 2,136.90	3,279.60 ± 1,254.60	NS
In-hospital physical therapy costs	875.79 ± 1,180.50	1,318.00 ± 270.25	$P < .05$
Other consult costs	2,353.20 ± 2,430.40	2,167.80 ± 1,741.90	NS
Total surgical and hospital costs without implant	54,499.00 ± 15,402.00	107,133.00 ± 20,479	$P < .0001$
Total surgical and hospital costs with implant (estimated ADR)	81,499.00 ± 15,402.00	177,593.00 ± 24,145.00	$P < .0001$

Abbreviations: USD, United States dollars; NS, not significant.
* Estimated, not commercially available at time of surgery.

form the surgical procedure, cost of the instrumentation or technology, length of hospitalization, and length-of-stay days in the hospital. Also of interest are the indirect costs to payers that may include production losses such as the length of recumbency and time off work. The literature shows that estimates for low-back pain health-related costs, including societal costs, exceed $100 billion, and many of these costs are indirect from lost wages and productivity.[11] Seventy-five percent of that $100 billion is a result of the worst 5% of patients with lower-back pain.[11] These costs can be attributed to those undergoing fusion procedures and especially those undergoing additional or multiple procedures.

Cost data are germane because a strategy for treatment is often presented to a patient via the surgeon's decision and must have hospital support of the technology, as well as willingness to pay by payers. Currently, hospitals can restrict physician and surgeon selection of devices in an effort to limit costs, which leads to a reduction in price competition among instrumentation companies and also leads to the selection of inferior devices.[18]

This study's ADR procedure fulfills a pressing goal of providing state-of-the-art healthcare technology at reduced direct costs. Further evaluation is needed to determine whether treatment with ADR maintains spinal biomechanics enough to also reduce costs by preventing the need for additional surgery (ie, at adjacent levels). One of the goals of surgical treatment for DDD at multiple levels in the lumbar spine is that the treatment is cost-effective within the larger context of the US healthcare system. Ultimately, direct cost issues determine whether a treatment such as ADR can actually be offered to patients with support of US healthcare dollars. The more cost-effective a novel treatment showing good outcomes is, the more likely the treatment may be available to patients.

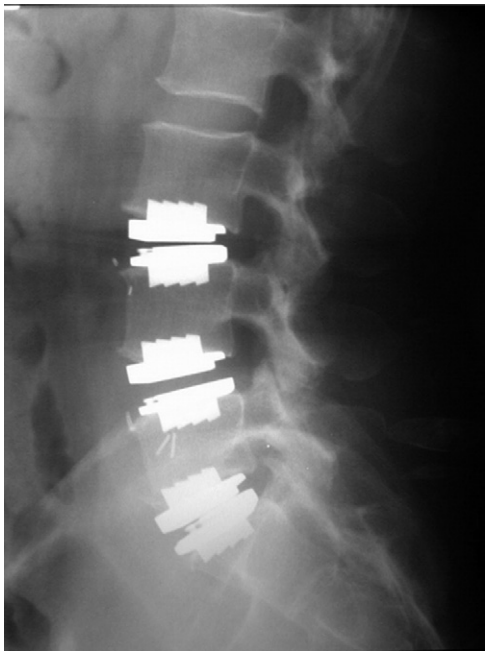

Fig. 4. One-year postoperative lateral radiograph of 3-level ADR.

Fig. 5. One-year postoperative lateral radiograph of 3-level circumferential fusion via described operative technique.

Conclusions

There are high costs associated with surgical treatment of multiple levels of DDD. Of the fusion procedures, circumferential fusion at multiple levels is associated with the highest success rate yet also with required long-term recovery including significant postoperative morbidity and the possibility of future degeneration at the adjacent levels. Patients with disease at 3 levels treated with an ADR required less recovery time and incurred lower overall costs compared with those patients treated with a fusion procedure. Disc replacement is a promising alternative to fusion especially for patients with disease at 3 levels.

Disc replacement requires a shorter recovery period than does fusion. After a 360° fusion procedure, there are issues of 2 incisions and consolidation of the actual bone that needs to heal. The more important benefit of protection of adjacent levels by ADR can only be assessed with completion of the multicenter study and long-term follow-up.

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