



The Spine Journal 10 (2010) 108-116

**Clinical Study** 

# Economic impact of improving outcomes of lumbar discectomy

John Sherman, MD<sup>a</sup>, Joseph Cauthen, MD<sup>b</sup>, Doug Schoenberg, MBA<sup>c</sup>, Matthew Burns, BME<sup>c</sup>, Nancy L. Reaven, MA<sup>d</sup>, Steven L. Griffith, PhD<sup>c,\*</sup>

<sup>a</sup>Twin Cities Orthopedics PA, 7373 France Ave. South, Suite 312, Edina, MN 55435, USA

<sup>b</sup>Neurosurgical and Spine Associates PA, 6510 NW 9th Blvd., Suite 1, Gainesville, FL 32605, USA

<sup>c</sup>Anulex Technologies, Inc, 5600 Rowland Road, Suite 280, Minnetonka, MN 55343, USA

<sup>d</sup>Strategic Health Resources, Inc, 4565 Indiana Ave., Suite 200, La Canada, CA 91011, USA

Received 7 January 2009; revised 14 July 2009; accepted 27 August 2009

#### Abstract

**BACKGROUND:** Lumbar discectomy is usually a successful operation with a relatively low cost. Potential adjunctive procedures, such as repairing the anulus fibrosus or nucleus replacements, necessitate a cost-benefit analysis.

**PURPOSE:** This economic analysis was performed to understand the potential value of advanced implantable technologies designed to improve outcomes after discectomy.

**STUDY DESIGN/SETTING:** Using an insurance claims–based database, the economics of lessthan-favorable outcomes after lumbar discectomy were studied. Estimates of improved clinical outcomes because of adjunctive surgical procedural items were modeled.

**PATIENT SAMPLE:** Using Current Procedural Terminology (CPT-4) codes and International Classification of Diseases, Clinical Modification procedure codes (ICD-9 CM), all lumbar discectomy patients were identified in a 6-month period from a large, 2002, commercially available claims-based data set representing 3.1 million insured lives.

**OUTCOME MEASURES:** Not applicable.

**METHODS:** Longitudinal data analysis from 3 years (2002–2004) of the database was performed for evidence of claims after the insured's discectomy (up to 18 months post) as a utilization estimate of surgical and medical treatment resultant of less-than-favorable outcomes. Incidence and cost of secondary operations, medical management, and complications were determined. Using these inputs, an economic model was generated to estimate the effect of improvement in discectomy outcomes.

**RESULTS:** Of the 494 patients who had a discectomy within a 6-month period, 137 (28%) had subsequent claims that suggested the outcome was less than favorable within 18 months. Patients whose insurance claims included codes for a second operation (n=52 patients with 56 operations; 11%) and patients being medically/nonsurgically managed (n=85, 17%) were studied. Average reimbursed charges incurred (2006 dollars) of repeated discectomy (80% of cases) was \$6,907 and for arthrodesis (20% of cases) was \$24,375. Average additional medical treatment cost to diagnose or manage poor outcome requiring another surgery was \$3,365. Procedure-related complications within 40 days of surgery were evident in 15% of the group; with additional average cost to manage of \$3,939.

**CONCLUSIONS:** Substantial cost associated with poor discectomy outcomes is often overlooked or underappreciated. Surgical technologies that can improve outcomes of discectomy by 50% to 70% thus improving patient quality of life can be overall cost-neutral between \$971 and \$1,655 additionally per patient. © 2010 Elsevier Inc. All rights reserved.

Keywords: Discectomy; Microdiscectomy; Cost-effectiveness; New technology

FDA device/drug status: none.

Author disclosures: JS (stock ownership, consulting fees, speaking arrangements, board of directors, scientific advisory board, Anulex Technologies, Inc); JC (stock ownership, scientific advisory board, Anulex Technologies, Inc); DS (stock ownership, other office in the company, Anulex Technologies, Inc); MB (stock ownership, board of directors, other office in the company, Anulex Technologies, Inc); NLR (other sponsorship, Anulex Technologies, Inc); SLG (stock ownership, other office in the company, Anulex Technologies, Inc). This study was supported by funding from Anulex Technologies, Inc., to Strategic Health Resources, Inc.

This study was presented at the 2007 AANS/CNS Joint Section Meeting, Phoenix, AZ (March 8, 2007); and the 2007 Spinal Arthroplasty Society Meeting, Berlin, Germany (May 1, 2007).

 Corresponding author. Anulex Technologies, Inc, 5600 Rowland Road, Suite 280, Minnetonka, MN, USA. Tel.: (612) 812-6301; fax: (952) 224-4040.
*E-mail address*: sgriffith@anulex.com (S.L. Griffith)

1529-9430/10/\$ – see front matter @ 2010 Elsevier Inc. All rights reserved. doi:10.1016/j.spinee.2009.08.453

### Introduction

Routine lumbar discectomy or microdiscectomy is generally perceived to be a successful operation [1] to relieve symptoms from a herniated intervertebral disc at a cost relatively lower than other spine surgeries such as cervical [2–4] or lumbar fusions [5–8]. Spine fusion procedures often require instrumentation or bone grafting alternatives such as bone morphogenetic proteins that can increase overall cost substantially [9]. More recently, artificial disc replacement has been suggested for some surgical cases that would have otherwise received a fusion; the cost-effectiveness of these devices is currently being challenged in spite of favorable analyses, reporting that the overall economic impact over a 2-year time horizon is likely to be significantly less than standard-of-care lumbar fusions [10].

The literature suggests that discectomy procedures are not always successful [11-16] when considering patient satisfaction or surgical outcomes despite advancements in operative techniques such as minimally invasive approaches or the use of adjunctive technologies, for example, anular repair products or nucleus replacements. In addition, these advancements tended to increase the base cost of the procedure. The cost-benefit ratio of proposed techniques such as chemonucleolysis [17], automated percutaneous discectomy [18], intradiscal electrothermal therapy [19], other perioperative items [20,21], or ancillary services [22–26] that may impact the overall cost of a discectomy have been studied in various ways with various historical outcomes. Many of these techniques were introduced with high expectations because many were perceived as less invasive and were purported to improve discectomy outcomes by changing clinical path decisions, decreasing morbidity, or reducing reoperation rates. Some eventually produced favorable clinical trial evidence, yet most of these have not become the standard of care that routine lumbar microdiscectomy surgery is today [27,28]. However, the impact of implantable materials and devices that could potentially be used during or after discectomy for herniated discs without significant degenerative collapse (ie, not requiring arthrodesis or total prosthetic replacement), such as anular repair devices [29-37] or nucleoplasty implant [38,39], has not yet been examined from an economic vantage point.

The purpose of this analysis was to understand the economic value to the US health care system of advanced implantable technologies designed to improve outcomes of lumbar discectomy. This study was based on an economic analysis of reimbursed charges from large claims-based data sets. Data from these large medical claims databases were analyzed with comparison to literature-based clinical outcome data after discectomy.

#### Methods

As a starting point, the overall annual volume of discectomy procedures in the United States was estimated from

# EVIDENCE SMETHODS

#### Context

Some proportion of patients undergoing surgery for lumbar disc herniation have continued or recurrent symptoms. Some have suggested that annular repair, reconstruction or nuclear augmentation may reduce the risk of postoperative problems or re-operation. This study attempts to estimate how effective a hypothetical surgical technology would need to reduce post-operative problems (and costs) to be cost-neutral to an insurance payor.

#### Contribution

With all the numerous assumptions inherent in this type of exercise, the authors calculated that a technology that improved outcomes in aggregate, by 50%, might be cost-neutral at approximately \$1,000 (USD).

#### Implication

This study provides an interesting glimpse of the complex set of assumptions needed to estimate a future cost-benefit effect for given technology. Still, it is unclear from this analysis how much improvement is potentially gained by even a perfect technology, given the multi-dimensional nature of low back pain illnesses.

—The Editors

three sources: 1) a 2002 research database (Reden & Anders Ltd, Minneapolis, MN, USA) that included over 3.1 million insured covered lives from a large national managed care plan; 2) the Nationwide Inpatient Sample distributed through the Healthcare Cost and Utilization Project (Agency for Healthcare Research and Quality), which is the largest all-payer inpatient care database in the United States containing all discharge data from 995 hospitals located in 35 states and approximating a 20% stratified sample of US community hospitals; and 3) a 5% sampling of 2002 Medicare data commercially available from the Centers for Medicare and Medicaid Services. Using Current Procedural Terminology (CPT-4) codes for professional claims and the International Classification of Diseases, Clinical Modification procedure codes for facility claims, the number of discectomy procedures was tabulated and categorized as either inpatient or outpatient claims. Table 1 describes the procedure codes that were used to identify claims used in this analysis. Secondary filters were applied to eliminate arthrodesis procedures and to isolate only lumbar procedures by cross-referencing lumbar-specific procedure codes with principal diagnostic codes (see Table 2); for example, because both the 63030 and 63047 codes can be used for complex decompressive procedures, by limiting the analysis to 63030 codes (ie, without the 63047 code and without fusion codes) resulted in a patient group that is most representative of primary lumbar

## Table 1

| Procedure codes used for analysis of number of primary discectomies |  |
|---|--|
| performed   |  |

|          | Description  |
|----------|--|
| ICD-9 CM |  |
| 80.51    | Excision of intervertebral disc                          |
| 80.59    | Other destruction of intervertebral disc                 |
| CPT-4    |  |
| 63030    | Laminotomy (hemilaminectomy), with decompression         |
|          | of nerve root(s), including partial facetectomy,         |
|          | foraminotomy, and/or excision of herniated intervertebra |
|          | disc; one interspace, lumbar (including open or          |
|          | endoscopically assisted approach)                        |
| 63035    | Each additional interspace                               |
| 63042    | Laminotomy (hemilaminectomy), with decompression of      |
|          | nerve root(s), including partial facetectomy,            |
|          | foraminotomy, and/or excision of herniated intervertebra |
|          | disc, reexploration, single interspace, lumbar           |
| 63044    | Each additional interspace                               |

CPT-4, Current Procedural Terminology; ICD-9 CM, International Classification of Diseases, Clinical Modification procedure codes.

discectomy only. Extrapolation to 2008 was accomplished by applying a conservative 5% year-over-year growth rate to the total number of procedures [40].

Specific additional claims data after discectomy were used to ascertain an estimate of the utilization of surgical and medical treatment as a result of less-than-favorable outcomes in the near-term (defined as within 2 years) postsurgery. A subset of data from two additional years (2003 and 2004) of the commercial claims research database was queried in the following manner. Patients in the first half of 2003 who met the following criteria were identified as the postsurgery economic outcome study group. Each patient's claim in this group was coded primarily for a nonarthrodesis discectomy in conjunction with selected codes:

Table 2

| Procedure codes used t | o limit analysis to | non-arthrodesis, | discectomy of | nly |
|------------------------|---------------------|------------------|---------------|-----|
|------------------------|---------------------|------------------|---------------|-----|

|          | Description   |
|----------|---|
| ICD-9 CM |   |
| 81.00    | Spinal fusion, not otherwise specified  |
| 81.05    | Dorsi and dorsolumbar fusion, lumbar approach   |
| 81.07    | Lumbar and lumbosacral fusion, lateral transverse<br>process technique  |
| 81.08    | Lumbar and lumbosacral fusion, posterior technique  |
| 81.37    | Refusion of lumbar and lumbosacral fusion, lateral<br>transverse process technique  |
| 81.38    | Refusion lumbar and lumbosacral fusion, posterior technique   |
| 81.61    | 360° spinal fusion, single-incision approach  |
| 81.62    | Fusion or refusion of 2-3 vertebrae   |
| 84.51    | Insertion of interbody spinal fusion device   |
| CPT-4    |   |
| 22630    | Arthrodesis, posterior interbody technique, including<br>laminectomy and/or discectomy to prepare interspace<br>(other than for decompression), single interspace, lumbar |
| 22632    | Each additional interspace  |
| 22840    | Posterior nonsegmental instrumentation  |

CPT-4, Current Procedural Terminology; ICD-9 CM, International Classification of Diseases, Clinical Modification procedure codes.

CPT code 63030 or CPT code 62287, or International Classification of Diseases, Clinical Modification procedure codes 80.51 or 80.59 and any one or more of the following International Classification of Diseases (ICD-9) diagnostic codes listed in Table 3. Further claims of this group of patients were then longitudinally evaluated in the subsequent 18 months of their continuous insurance eligibility. The number, incidence, and cost of secondary operations; complications; and medical management during this 18-month period after their primary discectomy were determined. Both repeat discectomy and spinal fusion procedures subsequent to the primary discectomy were considered. The incidence and average hospital treatment costs for procedure-related complications associated with both discectomy reoperations and fusions were examined. Complications listed in Table 4 were identified according to ICD-9 diagnostic codes. The use of magnetic resonance imaging (MRI), myelograms, or epidural injections in the 18 months after discectomy but without a second surgery were considered to be indicative of less-than-favorable outcomes and were accounted for in the subsequent economic model. Furthermore, the use of prescription pain medications and antidepressant medications for the period 30 days to 18 months after the primary discectomy was also identified.

Costs associated with the utilization of these medical treatments were determined from paid insurance claims, and thus overall benefit or neutrality was modeled from the commercial payer's perspective based solely on direct costs [41,42]. The following health care cost inflation factors were used to extrapolate to 2006 dollars: 4.5% for 2003 to 2004, 5% for 2004 to 2005, and 5% for 2005 to 2006 [43]. It is important to note that there are many other indirect costs associated with medical outcomes, particularly in a population of middle-aged wage earners.

Finally, an economic model was developed that included the cost of an implant or technology applied to the primary

Table 3

Diagnostic codes used for subset analysis of repeat surgery after discectomy

| ICD-9 CM | Description  |
|----------|--|
| 722.1    | Displacement of thoracic or lumbar intervertebral disc without myelopathy  |
| 722.10   | Displacement of thoracic or lumbar intervertebral disc without myelopathy  |
| 722.2    | Displacement of intervertebral disc, site unspecified, without myelopathy  |
| 722.52   | Degeneration of lumbar or lumbosacral intervertebral disc; degeneration of intervertebral disc, site unspecified |
| 724.3    | Sciatica   |
| 724.4    | Thoracic or lumbosacral neuritis or radiculitis, unspecified   |
| 724.9    | Other unspecified displacement of thoracic or lumbar intervertebral disc without myelopathy                      |

CPT-4, Current Procedural Terminology; ICD-9 CM, International Classification of Diseases, Clinical Modification procedure codes.

To be included in the analysis, these codes had to be represented in conjunction with CPT code 63030 or CPT code 62287 or ICD-9 procedure code 80.51 or ICD-9 procedure code 80.59.

Table 4

| Complications identified by ICD-9 diagnostic codes during secondary |  |
|---|--|
| discectomy or fusion  |  |

Complications

| Complications  |
|--|
| Abdominal wound  |
| Wound dehiscence   |
| Arterial and bowel injuries  |
| Cellulitis   |
| Cerebrospinal fluid fistulae   |
| Deep vein thrombosis   |
| Dural tear or perforation of iliac vessels                             |
| Femoral nerve palsy  |
| Graft extrusion and implant  |
| Ileus  |
| Lumbar spondylodiscitis  |
| Nausea   |
| Delirium   |
| Neuritis of ulnar nerve  |
| Drug dermatitis  |
| Iatrogenic hypotension   |
| Pneumonitis  |
| Renal failure  |
| Shock  |
| Skin symptoms  |
| Sudden death   |
| Systemic responses   |
| Urticaria  |
| Peroneal palsy   |
| Postoperative adhesions or excessive keloids                           |
| Pseudomeningocele  |
| Pulmonary atelectasis  |
| Pulmonary atelectasis  |
| Pulmonary infarct  |
| Renal calculus   |
| Secondary hemorrhage   |
| Serum hepatitis  |
| Superficial and deep infection   |
| Thrombophlebitis   |
| Urinary retention  |
| Other-acute respiratory (ie, hypoxemia, respiratory arrest)            |
| Other-chest symptoms (ie, dyspnea, hyperventilation, orthopnea, apnea, |
| chest pain, etc)   |
| Other-mental status (ie, altered consciousness, coma, syncope,         |
| convulsions, etc)  |
| Other-nervous system   |
| Other-postoperative (ie, shock, retained foreign body, emphysema,      |
| nonhealing wound, etc)   |
| Other-pulmonary (ie, edema, acute and/or chronic respiratory failure,  |
| pulmonary insufficiency, etc)  |
| Other-reactions (ie, air embolism, anaphylactic shock, serum           |
| reaction, etc)   |

ICD-9, International Classification of Diseases.

discectomy that could ultimately reflect a benefit by reducing overall utilization of medical services after surgery. The model did not account for indirect costs such as time off work, disability income, or litigation costs; these are important societal considerations, but the model was formulated only on the basis of direct costs as paid by the insurer. The economic model ultimately yielded a threshold cost that depended on the anticipated outcome improvement that could be deemed cost-neutral from the payers' perspective to the overall care of an insured, herniated, lumbar disc patient.

#### Results

The total estimate of commercially insured inpatient discectomy procedures (Healthcare Cost and Utilization Project discharge data) in 2002 was 131,398 and outpatient discectomy procedures totaled 120,276. The total number of discectomies covered by Medicare was 35,448, and these procedures were heavily skewed toward inpatient procedures (86%) versus outpatient procedures (14%) [44]. Therefore, the total number of discectomies performed in 2002 was 287,122. Furthermore, CPT coding modifiers for inclusion of more than one spinal disc level (ie, 63035 and 63044) suggested an overall average of 1.25 operative levels per procedure, and therefore, a total number of lumbar spine levels operated on for herniated disc numbered 358,902. Applying a conservative compounded annual growth reflective of other spine surgery demographics of 5% [45,46] suggests that the overall number of discectomy operative levels in 2008 would extrapolate to be greater than 480,000.

The postsurgery economic outcome study group consisted of 494 patients identified within a 6-month period who had a discectomy and who had continued insurance coverage over the analysis time frame, that is, could be reliably tracked within the database over the course of 18 months post surgery. One hundred thirty-seven (n=137) of these patients (28% of the sample) were identified with claims that suggested that their primary discectomy was less than favorable or had a "bad" outcome. This determination included not only patients whose insurance claims included codes for a second operation (11%) but also patients who were being medically managed as evidenced by claims for MRI, computed tomography (CT) with or without myelograms, or epidural injections (17%).

In the 18 months after their primary discectomy, 52 patients had evidence of 56 reoperations (38% of the lessthan-favorable outcome group). Repeat surgery procedures included 17 disc procedures coded with CPT 63030 or 62287, 28 procedures coded as disc reoperations (CPT 63042), and 11 procedures coded as arthrodesis (CPT 22558–22840). Therefore, the ratio of repeat discectomy versus fusion after discectomy was 80:20 in this sample. The average cost (in 2006 dollars) of a repeated discectomy was \$6,907, and the average cost for lumbar fusion was \$24,375. The overall average additional medical treatment cost for a poor outcome requiring reoperation workup, irrespective of the type of surgery performed, was \$3,365 (in 2006 dollars) inclusive of costs associated with imaging studies. All patients with another operation had at least one other MRI performed (average-1.3/patient) with an average reimbursed cost of \$812 per MRI (\$931 in 2006 dollars). Myelograms (with or without CT) were used in 15% of the patients before their second surgery at a rate of 1.8 procedures per patient and at an average cost of \$943 (\$1,081 in 2006 dollars).

Seventy-four patients (15% of the total study population) experienced at least one procedure-related complication

with either the primary discectomy or the secondary discectomy or fusion. These complications resulted in 14 inpatient readmissions for treatment of complications with an average length of stay of 6.8 days. The average cost to manage these complications was \$11,571 per admission. Procedure-related complications also resulted in 23 additional outpatient visits in this group with an associated average treatment cost of \$417 per visit. Furthermore, there were 48 inpatient admissions for back surgery procedures in which complication ICD-9 diagnostic codes were reported adding an average of 0.7 days to the length of stay at an additional cost of \$2,802. In summary, at least one procedure-related complication within 40 days of the primary discectomy was experienced in 15% of the group at additional average cost of approximately \$3,435, which adjusted for inflation is \$3,939 in 2006 dollars.

The management of complications was only one of the areas identified that can add to the overall economic cost of lumbar discectomy. The nonsurgical medical management of the unsatisfied patients was also noted and accounted for. For example, 48 of the 137 patients (35%) in the poor outcome group had at least one epidural injection 6 months after their initial surgery. The large majority of this unsatisfied less-than-favorable subgroup did not progress to a secondary surgery (n=85 of the 137 patients) during the period studied, but the medical services used during this time suggest that many of these patients were being managed or worked up for a potential second surgery. For instance, the average number of epidural injections for the group without subsequent surgery was 6.1 per patient, whereas those with a second surgery received an average of 6.6 injections at a cost of \$82 (\$323 in 2006 dollars). Sixty-six of the 85 patients (78%) without a second surgery had at least one MRI during the 18-month postsurgery study period (compared with 100% of those patients receiving a second surgery), and therefore, it might be presumed that longer follow-up might reveal that these patients may have indeed eventually required another operation. Fiveand 10-year outcomes after discectomy have suggested a reoperation rate between 15% and 25% [12–16].

The use of pharmaceutical medications was seen in both the good and bad outcome groups. Patients with a good outcome consumed painkillers and related medications averaging \$242 per patient, the one to 18 months post discectomy. These medications included analgesics, corticosteroids, Cox-II inhibitors, muscle relaxors, narcotic pain relievers, and antidepressives. (Serotonin reuptake inhibitors such as Prozac (Eli Lilly & Co, Indianapolis, IN) were not included in the analysis.) In contrast, for the less-thanfavorable outcome group without a second surgery, the average cost of medications was \$461, which reflects an additional \$219 per patient. And in the less-than-favorable group with reoperation, patients consumed an additional \$1,245 per patient (adjusted to 2006 dollars).

An economic model was used to calculate the overall cost and benefit of improving lumbar discectomy.

Utilization rates and costs identified in this study were used in the algorithm described in the Figure. Key assumptions were put into this model in two ways: 1) using percentages gleaned from the primary data from this short-term (eg, 2 years) economic study and 2) using percentages from a synthesis of a literature review with a longer (eg. 5-10 years) time horizon. In each case, the average additional cost per patient that could be incurred and still be cost-neutral was calculated as a function of the anticipated improvement in overall outcomes. Table 5 describes each scenario and ultimately the cost and benefit for improving lumbar discectomy given each set of assumptions. For example, the primary data suggest a per patient cost-benefit neutral point of \$971 if discectomy outcomes in aggregate could be improved by 50%. Considering a longer time horizon, a cost-benefit neutral point of \$1,655 is suggested if discectomy outcomes are improved by 70%.

#### Discussion

Costs associated with new technology introduced within a surgery that has already been deemed overall cost-effective is often a matter of heated debate from many different perspectives. Hospital administration is concerned about rising

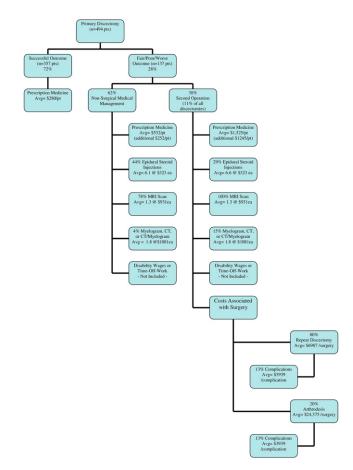


Figure. Utilization rates and costs.

| Table | 5 |
|-------|---|
|-------|---|

Economic model calculation for improving lumbar discectomy outcomes in the 480,000 cases performed annually

| Key assumption   | Primary data | Literature review [11–16]         |
|--|--------------|-----------------------------------|
| Overall poor outcome post discectomy   | 28%          | 25%                               |
| With reoperation0 (fusion:discectomy)  | 1% (20:80)   | 5% (25:75)                        |
| Without reoperation  | 17%          | 10%                               |
| Percentage with procedure-related complications  | 13%          | 15%                               |
| Anticipated improvement in outcomes Additional surgery cost that maintains overall cost-neutrality |              | maintains overall cost-neutrality |
| Moderate improvement—50%   | \$971        | \$1,189                           |
| Moderate to high improvement—60%   | \$1,165      | \$1,427                           |
| High improvement—70%   | \$1,360      | \$1,655                           |

costs that make it difficult to continue or add to the variety of services it is accustomed to offering because of reductions in reimbursements from third-party insurance companies and the US Federal government's Medicare system. Yet physicians and surgeons are striving to offer patients what they believe to be the best possible technical solutions, sometimes with limited regard to the technology's cost. Ultimately, new and effective medical procedures and products do not come without a price [40,47]. The medical economic balance is precarious and often misunderstood.

The overall cost-effectiveness of primary lumbar discectomy for the treatment of herniated disc was studied over 10 years ago [48-50]. In contrast to an earlier study by Shvartzman et al. [50], lumbar discectomy surgery compared with nonsurgical medical treatment was shown to provide substantial benefit with reasonable cost-effectiveness for carefully selected patients in a study conducted by Malter et al. [48] and Malter and Weinstein [49] and recently confirmed by a cost-effectiveness analysis of the Spine Patient Outcomes Research Trial [51]. The temporal effects in the analyses suggested a temporary short-term improvement in quality of life as a result of the procedure. This surgery's incremental benefit was greatest in the 2 to 4 years after the operation, but this effect diminished over time as the quality of life associated with medical management improved. A classic study by Weber [52] and more recently the Spine Patient Outcomes Research Trial results [53,54] have also confirmed the near-term benefits of herniated disc operations. In contrast to these more classical cost-effectiveness study designs, the present study attempted to examine the cost-benefit balance by analyzing the post-primary surgery impact of new techniques, implants, or materials that are perceived to add an additional initial layer of direct cost at surgery.

Attempts to limit utilization of these new innovative surgical technologies include questioning whether or not there is scientific evidence in support of their cost-effectiveness compared with existing technologies or other procedures [55,56]. This tactic is particularly true when proposed procedures or products compete directly with established standard practice or are competing for reimbursement from the same pool of dollars. But when a paradigm shift is proposed that attempts to introduce a new layer of perceived cost rather than a simpler cost shift from current standard of care in a particular procedure, it is even more difficult to overcome uninformed objections. This study extends the earlier studies of the cost-effectiveness of lumbar discectomy to include additional adjunctive products or procedures.

The current analysis did not undertake the classical costeffectiveness approach because this has been previously published by others [40,42,51,57,58]. In the classical sense, the first step in the analysis is to estimate the intervention's benefit relative to a standard therapy; this part of the analysis is often calculated in health quality-adjusted life years. Second, the classical approach estimates overall cost associated with the intervention. Finally, cost-effectiveness is arithmetically calculated as the ratio of the incremental cost versus the incremental effective benefit. This effectiveness calculation is then compared in a somewhat arbitrary manner with other life-saving or life-improving medical procedures to judge its favorability or nonacceptability. The costs associated with adding adjunctive technologies within the surgery's direct costs that may improve outcomes are not well examined in the context of this classical approach.

Discectomy surgery for the treatment of herniated lumbar disc is one of the more gratifying spine surgeries with rapid clinical improvement perceived to be the outcome in a large majority of cases. Patients both understand the surgical procedure and preferentially choose to trust that the surgery will result in the documented early positive outcomes [53,54]. But there is a substantial and costly failure rate of many discectomy procedures. This study confirms much of the published literature with respect to poor outcomes that are often overlooked or underappreciated. Asch et al. [11] have suggested that more than 20% of discectomy patients have a fair or poor outcome measured by their ability to return to normal activities or work or their overall satisfaction with the result. The data from the present study dichotomized patients into acceptable favorable outcomes versus less-than-favorable outcomes on the basis of a secondary surgery (11% of the group) or utilization of additional medical services such as imaging modalities (17% of the group) within 18 months of their surgery. This study's finding that 28% of patients had evidence of a bad outcome is similar to the generalized 20% to 25% suggested by Abramovitz and Neff [59] and later confirmed by Asch et al. [11], but our study also examined the cost expenditures necessary to manage these outcomes.

Reoperations occurred in approximately 40% of the poor outcomes.

Our pragmatic approach included the examination of costs associated not with the initial lumbar discectomy but those medical and surgical costs associated up to 18 months later in patients with less-than-favorable outcome. Repeat discectomy added an estimated \$6,900 each in health plan expenses for direct physician and hospital care, and when a fusion procedure was required, costs increase 350%. In addition, associated complications in 13% of repeat surgeries added an average of over \$11,571 in hospital costs each time they occurred.

Moreover, failed discectomies treated nonsurgically were also not without additional costs because of further medical services utilization such as CT, MRI, injections, etc. Health plans paid additional costs of approximately \$2,200 per patient in specific diagnostics, injections, and drugs over the first 18 months after the initial discectomy. In all, each failed discectomy added over \$8,000 to commercial health plan medical costs. Further longitudinal analysis may indeed demonstrate that many of these patients ultimately chose to undergo another surgical procedure.

These cost data along with other assumptions then were used to calculate the potential, overall, incremental direct cost savings or neutrality to the health care system if positive effectiveness could be demonstrated by adjunctive technologies to lumbar discectomy. Assuming the percentages found in this study can be applied to the total number of lumbar discectomies in the United States, any product or technique that shows a benefit to patient outcomes of the magnitudes described would be justified at an additional cost to the primary surgery component (goods and services) of between \$971 and \$1,655 per patient. With these assumptions, the overall cost to the health care system would be cost-neutral to the payers while hospitals continue to be able to provide quality care without additional cost to their internal systems. And probably most importantly, surgeons are not precluded from offering the very best care to their patients because of concerns about overall cost.

There are obvious technical flaws inherent in analyzing data from claims-based databases rather than prospective clinical data collection or retrospective chart review. Namely, assumptions are made that the repeat surgery or the less-than-favorable outcome is indeed a result of pathology at the same spinal level or even the same side. Without specific patient follow-up or chart review, there is the possibility that some of the pathology is at a different location that would most likely not be affected by the addition of adjunctive technologies that are applied to a particular spinal level. Nevertheless, given these limitations, it remains reasonable to provide such estimates.

The data analyzed in this study do not allow the delineation of which technologies might improve postdiscectomy outcomes to the extent required to achieve costneutrality. Rather, the emphasis of this study was to set the framework for the cost evaluation of these technologies that may require clinical trials or case series that demonstrate incrementally better outcomes to the current standard of care. For example, there are commercially available devices and others in development being used to repair the anulus fibrosus after lumbar discectomy. In recently reported clinical series [36,60], it has been suggested that using these devices can reduce the overall rate of reherniation and reoperation when compared with the current practice of leaving the anulus unrepaired. In a limited series of 20 patients by Vilendecic et al. [60], they reported no reherniations in their implant group compared with a 10% reherniation rate in the patient group that did not receive an anular repair implant. Hartman et al. [36], likewise, reported a single-surgeon clinical series of 124 patients evaluating the subsequent need for a second surgery after discectomy with or without anular repair implants. They reported a reduction in this reoperation rate of nearly 50% in the 12 months after the primary surgery. It is these types of studies describing technology advances that should be examined in light of the economic vantage point described in the present study.

One of the obvious limitations of this study is that it focused on the perspective of the payer and the hospital because the direct costs were the only consideration in the analysis. To better understand the overall societal impact, it is worthwhile to consider the indirect cost component resultant from less-than-favorable outcomes after discectomy that may or may not require another surgery. These indirect costs are defined by work absenteeism, permanent or temporary disability, low work productivity, and lost wages; the need for other personal caregivers during this period is often included. These costs are not insignificant and have been estimated by other studies using the more traditional cost-effectiveness analyses comparing the outcome of surgery versus nonsurgery treatment [51,57,58]. In these studies, the indirect cost component up to 2 years is estimated to be approximately 50% of the direct costs related to discectomy surgery [51]. Although inclusion or exclusion of these indirect costs (ie, \$5,000-\$7,000) in the aforementioned study [51] had no impact on the conclusion that there is a positive economic value of discectomy surgery, others [57,58] have suggested that the inclusion of indirect costs estimated to be substantially greater than the direct costs can result in an overall cost savings from a societal viewpoint even though direct surgery costs incurred early are high. The addition of an indirect cost component in our model would most likely increase the relative value of adjunctive technologies substantially while still maintaining cost-neutrality.

Optimistically, medical and health costs could be saved if technologies were developed that improved discectomy outcome but were at still a lower cost. Alternatively, it is intuitive that if greater beneficial aspects could be realized such as even further reduction in postoperative morbidity, reduced reoperations, faster return to work, and so on, then a net savings to the health care system could be appreciated. In either situation, either cost-neutral or cost savings, improvement to the current outcome of lumbar discectomy is a worthwhile and cost-beneficial goal. Future studies defining the relative benefit of adjunctive products in discectomy surgery can be evaluated using this cost algorithm.

#### References

- Schoeggl A, Reddy M, Matula C. Functional and economic outcome following microdiscectomy for lumbar disc herniation in 672 patients. J Spinal Disord 2003;16:150–5.
- [2] Angevine PD, Zivin JG, McCormick PC. Cost-effectiveness of single-level anterior cervical discectomy and fusion for cervical spondylosis. Spine 2005;30:1989–97.
- [3] Castro FP Jr, Holt RT, Majd M, Whitecloud TS. A cost analysis of two anterior cervical fusion procedures. J Spinal Disord 2000;13: 511–4.
- [4] McLaughlin MR, Purighalla V, Pizzi FJ. Cost advantages of two-level anterior cervical fusion with rigid internal fixation for radiculopathy and degenerative disease. Surg Neurol 1997;48:560–5.
- [5] Katz JN. Lumbar spine fusion—surgical rates, costs, and complications. Spine 1995;20:78S–83S.
- [6] Katz JN, Lipson SJ, Lew RA, et al. Lumbar laminectomy alone or with instrumented or noninstrumented arthrodesis in degenerative lumbar spinal stenosis—patient selection, costs, and surgical outcomes. Spine 1997;22:1123–31.
- [7] Tunturi T, Niemela P, Laurinkari J, et al. Cost-benefit analysis of posterior fusion of the lumbosacral spine. Acta Orthop Scand 1979;50:427–32.
- [8] Kuntz KM, Snider RK, Weinstein JN, et al. Cost-effectiveness of fusion with and without instrumentation for patients with degenerative spondylolisthesis and spinal stenosis. Spine 2000;25:1132–9.
- [9] Mendenhall S. Higher costs with spinal 'fusion helpers'. OR Manager 2006;22:12–3.
- [10] Guyer RD, Tromanhauser SG, Toselli R. An economic analysis of lumbar total disc replacement vs fusion. Paper presented at the, 5th Global Symposium on Motion Preservation Technology, May 7, 2005; New York, NY.
- [11] Asch HL, Lewis PJ, Moreland DB, et al. Prospective multiple outcomes study of outpatient lumbar microdiscectomy: should 75 to 80% success rates be the norm? J Neurosurg 2002;96(1 Suppl):34–44.
- [12] Atlas SJ, Keller RB, Chang Y, et al. Surgical and nonsurgical management of sciatica secondary to lumbar disc herniation: five-year outcomes from the Maine Lumbar Spine Study. Spine 2001;26: 1179–87.
- [13] Yorimitsu E, Chiba K, Toyama Y, Keskimaki I. Long-term outcomes of standard discectomy for lumbar disc herniation. Spine 2001;26: 652–7.
- [14] Malter AD, McNeney B, Loeser JR, Deyo RA. Five-year reoperation rates after different types of lumbar surgery. Spine 2001;23:814–20.
- [15] Hu RW, Jaglal S, Axcell T, Anderson G. A population based study of reoperations after back surgery. Spine 1997;22:2265–71.
- [16] Osterman H, Sund R, Seitsalo S, Hirabayashi K. Risk of multiple reoperations after lumbar discectomy: a population-based study. Spine 2003;28:621–7.
- [17] Bradbury N, Wilson LF, Mulholland RC. Adolescent disc protrusions: a long-term follow-up of surgery compared to chymopapain. Spine 1996;21:372–7.
- [18] Stevenson RC, McCabe CJ, Findlay AM. An economic evaluation of a clinical trial to compare automated percutaneous lumbar discetomy with microdiscectomy in the treatment of contained lumbar disc herniation. Spine 1995;20:739–42.
- [19] Webster BS, Verma S, Pransky GS. Outcomes of workers' compensation claimants with low back pain undergoing intradiscal electrothermal therapy. Spine 2004;29:435–41.
- [20] Reitman CA, Watters WC III, Sassard WR. The Cell Saver in adult lumbar fusion surgery: a cost-benefit outcomes study. Spine

2004;29:1580-3.

- [21] Erstad BL. What is the evidence for using hemostatic agents in surgery? Eur Spine J 2004;13(Suppl 1):S28–33.
- [22] Reddy P, Williams R, Willis B, Nanda A. Pathological evaluation of intervertebral disc tissue specimens after routine cervical and lumbar decompression—a cost-benefit analysis retrospective study. Surg Neurol 2001;56:252–5.
- [23] Miller P, Kendrick D, Bentley E, Fielding K. Cost-effectiveness of lumbar spine radiography in primary care patients with low back pain. Spine 2002;27:2291–7.
- [24] Ostelo RWJG, Goosens MEJB, deVet HCW, van den Brandt PA. Economic evaluation of a behavioral-graded activity program compared to physical therapy for patients following lumbar disc surgery. Spine 2004;29:615–22.
- [25] Mayer T, McMahon MJ, Gatchel RJ, et al. Socioeconomic outcomes of combined spine surgery and functional restoration in workers' compensation spinal disorders with matched controls. Spine 1998;23:598–606.
- [26] Lurie JD, Birkmeyer NJ, Weinstein JN. Rates of advanced spinal imaging and spine surgery. Spine 2003;28:616–20.
- [27] Anderson GBJ, Brown MD, Dvorak J, et al. Consensus summary on the diagnosis and treatment of lumbar disc herniation. Spine 1996;21: 75S–8S.
- [28] Maroon JC. Current concepts in minimally invasive discectomy. Neurosurgery 2002;51(5 Suppl):S137–45.
- [29] Kamaric E, Yeh O, Velagic A, et al. Restoration of disc competency by increasing disc height using an annular closure device. In: Proceedings of the Fifth Global Symposium on Motion Preservation Technology. New York, NY: Spine Arthroplasty Society (SAS), 2005.
- [30] Einhorn J, Yeh O, Kamaric E, et al. Stability of a mechanical barrier used to seal annular defects. In: Proceedings of the Fifth Global Symposium on Motion Preservation Technology. New York, NY: Spine Arthroplasty Society (SAS), 2005.
- [31] Yeh O, Chow S, Small M, et al. Novel approach to closing anular defects: a biomechanical study. In: Proceedings of the Fifth Global Symposium on Motion Preservation Technology. New York, NY: Spine Arthroplasty Society (SAS), 2005.
- [32] Peppelman WC, Davis R, Sherman J, et al. Feasibility results of a novel anular repair device in a goat model. Proceedings of World-Spine III; 2005; Rio de Janeiro, Brazil.
- [33] Bajares G, Perez-Olivia A. A pilot study evaluating a novel device for anular repair following spinal discectomy. In: Proceedings of the Fifth Global Symposium on Motion Preservation Technology. New York, NY: Spine Arthroplasty Society (SAS), 2005.
- [34] Yonemura K, Sherman J, Peppelman W, et al. Improving the outcome of discectomy with specific attention to the annulus fibrosus. In: Lewandrowski KU, Yaszemski MJ, Kalfas IH, et al, eds. Spinal reconstruction—clinical examples of applied basic science, biomechanics, and engineering. New York, NY: Informa Healthcare USA Inc., 2007:59–79.
- [35] Cauthen JC, Sherman JE, Davis RJ, et al. Repair of the anulus fibrosus (anuloplasty) after lumbar discectomy. In: Maxwell JH, Grifith SL, Welch WC, eds. Nonfusion techniques for the spine: motion preservation and balance. St Louis, MO: Quality Medical Publishing, 2006:269–82.
- [36] Hartman L, Griffith S, Melone B, Melone D. Surgical outcome of lumbar microdiscectomy with emphasis on the benefit of anular repair techniques. Proceedings of the 2009 Annual Meeting of the Congress of Neurological Surgeons (CNS); New Orleans, LA.
- [37] Griffith SL, Davis RJ, Hutton WC. Repair of the anulus fibrosus of the lumbar disc. In: Davis RJ, Girardi FP, Cammisa FP, eds. Nucleus arthoplasty technology in spinal care, volume II: biomechanics and development. Bloomington, MN: Raymedica Inc, 2007:41–8. Available at: http://www.raymedica.com. Accessed November 21, 2008.
- [38] Di Martino A, Vaccaro AR, Lee JY, et al. Nucleus pulposus replacement: basic science and indications for clinical use. Spine 2005;30(16)

Suppl):S16-22.

- [39] Goins ML, Wimberley DW, Yuan PS, et al. Nucleus pulposus replacement: an emerging technology. Spine J 2005;5(6 Suppl):317S–24S.
- [40] Lieberman IH. Disc bulge bubble: spine economics 101. Spine J 2004;4:609–13.
- [41] Eisenberg JM. Clinical economics: a guide to the economic analysis of clinical practices. JAMA 1989;262:2879–86.
- [42] Weinstein MC, Statson WB. Foundations of cost-effectiveness analysis for health and medical practices. N Engl J Med 1977;296:716–21.
- [43] Reden & Anders: Tourville LF. Medical expense trends: update on recent trend drivers and future expectations. Paper presented at: the Society of Actuaries 2006 Annual Meeting; October 6, 2006.
- [44] CMS-1478-1FC, 4/29/05; Medicare Programs: Update of Ambulatory Surgical Center List of Covered Procedures. Center for Medicare & Medicaid Services.
- [45] 2000 Spinal Surgery Update. Orthopaedic Network News October 2000;11(4). Available at: http://www.orthopedicnetworknews.com. Accessed November 21, 2008.
- [46] NASS Preview—Now This is Spinal Tap. Merrill Lynch Global Securities Research and Economics Group, October 2003.
- [47] Bodenheimer T. High and rising health care costs. Part 2: technologic innovation. Ann Intern Med 2005;142:932–7.
- [48] Malter AD, Larson EB, Larson EB, et al. Cost-effectiveness of lumbar discectomy for the treatment of herniated intervertebral disc. Spine 1996;21:1048–55.
- [49] Malter AD, Weinstein J. Cost-effectiveness of lumbar discectomy. Spine 1996;21:69S–74S.
- [50] Shvartzman L, Weingarten E, Sherry H, et al. Cost-effectiveness analysis of extended conservative therapy versus surgical intervention in the management of herniated lumbar intervertebral disc. Spine 1992;17:176–82.
- [51] Tosteson ANA, Skinner JS, Tosteson TD, et al. The cost effectiveness of surgical versus nonoperative treatment for lumbar disc herniation

over two years: evidence from the Spine Patient Outcomes Research Trial (SPORT). Spine 2008;33:2108–15.

- [52] Weber H. Lumbar disc herniation: a controlled, prospective study with ten years of observation. Spine 1983;8:131–40.
- [53] Weinstein JN, Tosteson TD, Lurie JD, et al. Surgical vs nonoperative treatment for lumbar disk herniation—the Spine Patient Outcomes Research Trial (SPORT): a randomized trial. JAMA 2006;296: 2441–50.
- [54] Weinstein JN, Lurie JD, Tosteson TD, et al. Surgical vs nonoperative treatment for lumbar disk herniation—the Spine Patient Outcomes Research Trial (SPORT) observational cohort. JAMA 2006;296:2451–9.
- [55] Laupacis A, Feeny D, Detsky AS, Tugwell PX. How attractive does a new technology have to be to warrant adoption and utilization? Tentative guidelines for using clinical and economic evaluations. CMAJ 1992;146:473–81.
- [56] Haentjens P, Annemans L. Health economics and the orthopedic surgeon. J Bone Surg Br 2003;85:1093–9.
- [57] Hansson E, Hansson T. The cost-utility of lumbar disc herniation surgery. Eur Spine J 2007;16:329–37.
- [58] van den Hout WB, Peul WC, Koes BW, et al. for the Leiden—The Hague Spine Intervention Prognostic Study Group. Prolonged conservative care versus early surgery in patients with sciatica from lumbar disc herniation: cost utility analysis alongside a randomized controlled trial. BMJ 2008;336:1351–4.
- [59] Abramovitz JN, Neff SR. Lumbar disc surgery: results of the prospective lumbar discectomy study of the Joint Section on Disorders of the Spine and Peripheral Nerves of the American Association of Neurological Surgeons and the Congress of Neurological Surgeons. Neurosurgery 1991;29:301–7.
- [60] Vilendecic M, Ledic D, Eustacchio S, et al. Treatment of lumbar disc herniations: a prospective study. Proceedings of the 2009 Annual Meeting of the International Society for the Advancement of Spine Surgery (SAS); London, United Kingdom.