Numerous randomized trials have shown significant improvement with surgical intervention for lower-back pain. Unfortunately, a significant number of patients do not respond to surgical intervention. Multiple excellent FDA IDE randomized studies for arthroplasty have shown fairly consistent improvement with arthroplasty. The ProDisc-L (Synthes) IDE study demonstrated that 53.4% of patients who underwent arthroplasty improved based on the FDA’s definition of success. Only 40.8% of patients in the control 360° lumbar fusion group improved.11 Five-year results from the Charité prospective randomized study were similar with 57.8% of arthroplasty procedures defined as successful versus 51.2% of control anterior lumbar fusion procedures.7 The multicenter trials focus on mean ODI changes. Our analysis shows that patients do not have a graded improvement in outcome measures. A patient either responds to the surgery and has a dramatic improvement in the ODI or there is no change in outcome measures. Better patient selection for arthroplasty surgery will decrease the number of patients undergoing surgery with minimal improvement. The purpose of this study is to determine if the baseline ODI significantly predicts outcomes after lumbar arthroplasty.

Object. The goal of the study was to determine patient factors predictive of good outcome after lumbar disc arthroplasty. Specifically, the paper examines the relationship of the preoperative Oswestry Disability Index (ODI) to patient outcome at 1 year.

Methods. The study is a retrospective review of 20 patients undergoing a 1-level lumbar disc arthroplasty at the author’s institution between 2004 and 2008. All data were collected prospectively. Data included the ODI, visual analog scale scores, and patient demographics.

Results. All patients underwent a 1-level disc arthroplasty at L4–5 or L5–S1. The patients were divided into 2 groups based on their baseline ODI. Patients with an ODI between 38 and 59 demonstrated better outcomes with lumbar disc arthroplasty. Only 1 (20%) of 5 patients with a baseline ODI higher than 60 reported a good outcome. In contrast, 13 (87%) of 15 patients with an ODI between 38 and 59 showed a good outcome (p = 0.03). The negative predictive value of using ODI > 60 is 60% in patients who are determined to be candidates for lumbar arthroplasty.

Conclusions. Lumbar arthroplasty is very effective in some patients. Other patients do not improve after surgery. The baseline ODI results are predictive of outcome in patients selected for lumbar disc arthroplasty. A baseline ODI > 60 is predictive of poor outcome. A high ODI may be indicative of psychosocial overlay.

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Key Words • lumbar arthroplasty • outcome • back pain • Oswestry Disability Index • artificial disc

Methods

In this retrospective study, between 2004 and 2008 all patients underwent a single-level lumbar disc arthroplasty at L4–5 or L5–S1. All surgeries were done by one surgeon at a single institution. Devices used include the DePuy Charité artificial disc and the Aesculap Activ-L artificial lumbar disc. Twenty-four patients were identified, but 1-year follow-up was only available for 20 patients. Data including the ODI, VAS scores, and patient demographics were collected prospectively. Patients were selected for lumbar arthroplasty based on MR imaging findings including loss of disc height, low T2 signal intensity on MR images, endplate changes, and bulging disc (Fig. 1). Patients with spondylolisthesis, severe facet arthropathy, or multilevel degenerative changes were excluded from lumbar arthroplasty. All patients had symptoms lasting longer than 1 year, and all had undergone nonoperative treatment for more than 6 months. Baseline plain radiographs with flexion/extension views were obtained in all patients. Discography results were available for 4 of 20 patients.

Statistical Analysis

Patients were categorized as having a baseline ODI of either greater or less than 60. An ODI of 60 was selected as an approximately one standard deviation above the mean ODI of 52. Patients’ conditions were considered

Abbreviations used in this paper: IDE = investigational device exemption; ODI = Oswestry Disability Index; VAS = visual analog scale.
improved based on a reduction of 20 points in their ODI score at 1 year. The Fisher exact test was used to assess the significance of the $2 \times 2$ contingency table.

## Results

Demographics for the 20 patients are given in Table 1. Good outcome as defined by improvement of 20 points on the ODI score was noted in 14 patients (70%). The mean VAS outcome scores are shown in Table 2. Improvement was noted in back pain VAS score as well as right and left leg pain. The mean ODI score improved from 52.7 to 26 ($p < 0.01$). Individual ODI changes for all 20 patients are plotted in Fig. 1. Fifteen patients were categorized as having an ODI between 38 and 59. Of these 15 patients, 13 (87%) had a good outcome while only 1 (20%) of 5 patients with an ODI 60 and above demonstrated a good outcome (Fig. 2). Outcomes were statistically different between these groups ($p = 0.03$) (Fig. 3 and Table 3).

The mean operative time was 122 minutes. The mean length of hospital stay was 1.8 days. No serious complications related to surgery were noted. Transient lower-extremity paresthesias were noted in 3 (15%) of the 20 patients. One patient who did not improve following surgery underwent posterolateral arthrodesis 8 months after lumbar disc arthroplasty. Her condition failed to improve with the subsequent surgery.

## Discussion

Several FDA IDE studies provide Class I data showing that lumbar arthroplasty is effective in decreasing lower-back pain. The ProDisc-L IDE study demonstrated that 53.4% of patients undergoing arthroplasty improved based on the FDA’s definition of success.\(^\text{11}\) Only 40.8% of patients in the control lumbar fusion group improved.\(^\text{7}\) Five-year results from the Charité prospective randomized study were similar. Successful outcomes were seen in 57.8% of patients who underwent arthroplasty and 51.2% of the control patients who underwent anterior lumbar fusion. In the ProDisc study, 67.8% of patients demonstrated a greater than 15-point improvement in their ODI compared with 54.9% of control patients showing a similar improvement. The ODI improvement in the Charité and the ProDisc-L studies is comparable to ODI improvement noted in lumbar fusion surgeries for spondylolisthesis.\(^\text{4,6}\)

The ProDisc study reported the FDA and ProDisc ODI definitions of success. The FDA defined success as an ODI improvement of 15 points, and the ProDisc spon-

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**TABLE 1: Patient demographics**

<table>
<thead>
<tr>
<th>Variable</th>
<th>No. of Patients*</th>
</tr>
</thead>
<tbody>
<tr>
<td>no. of patients</td>
<td>20</td>
</tr>
<tr>
<td>mean age (yrs)</td>
<td>41</td>
</tr>
<tr>
<td>male/female</td>
<td>9:11</td>
</tr>
<tr>
<td>level</td>
<td></td>
</tr>
<tr>
<td>L4–5</td>
<td>7</td>
</tr>
<tr>
<td>L5–S1</td>
<td>13</td>
</tr>
<tr>
<td>hospital stay (days)</td>
<td>1.8</td>
</tr>
<tr>
<td>baseline VAS score</td>
<td></td>
</tr>
<tr>
<td>back pain</td>
<td>75.7</td>
</tr>
<tr>
<td>rt leg pain</td>
<td>28.5</td>
</tr>
<tr>
<td>lt leg pain</td>
<td>24.8</td>
</tr>
<tr>
<td>mean baseline ODI</td>
<td>52.7</td>
</tr>
</tbody>
</table>

*Unless indicated otherwise.

**TABLE 2: Patient outcomes**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline</th>
<th>1 Yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>ODI</td>
<td>52.7</td>
<td>26.6</td>
</tr>
<tr>
<td>VAS score</td>
<td></td>
<td></td>
</tr>
<tr>
<td>back pain</td>
<td>75.7</td>
<td>28.5</td>
</tr>
<tr>
<td>rt leg pain</td>
<td>28.5</td>
<td>17.2</td>
</tr>
<tr>
<td>lt leg pain</td>
<td>24.8</td>
<td>7.5</td>
</tr>
</tbody>
</table>

*Fig. 1. Left: Preoperative MR image showing a loss of disc height at L5–S1, diffuse disc bulging, and endplate changes. Other discs are unremarkable. Right: Postoperative radiograph showing an artificial lumbar disc in place at L5–S1.*

*Fig. 2. Plot of the ODI change from baseline to 1 year.*
Predictive value of ODI in lumbar arthroplasty

The 15-point ODI improvement was more rigorous than the 15% criteria (67.8% of patients improved vs 77.2% of patients). The overall success reported in the FDA study was lower (53.4% of patients) because it included additional success criteria such as radiographic measures and 36-Item Short Form Health Survey results. In this study, because other outcome measures were not assessed, a higher (20-point) ODI improvement was selected as a measure of success. Additionally, improvement in all patients was not ambiguous; patients showed either a dramatic improvement or minimal change. Analysis of the mean ODI change often fails to appreciate the bimodal results distribution. In many patients, lumbar arthroplasty is highly effective. In our experience, some patients have a dramatic clinical improvement with surgery while other patients have no improvement. This fact is verified visually by reviewing Fig. 2 where individual patient ODI changes are plotted.

The results after lumbar disc arthroplasty are good, but approximately one-third of patients do not respond to surgical intervention. Patient selection in the ProDisc-L study was based on radiographic findings, symptoms lasting longer than 6 months, and an ODI greater than 40. Unfortunately, no better selection criteria exist. Tests such as discograms or newer functional discograms have failed to demonstrate a significant increased specificity in selecting patients for surgical intervention. The failure of one-third of patients to respond to surgery could be viewed as a limitation of surgery and disc arthroplasty. The fact that surgery fails in about one-third of patients undergoing fusion and in one-third of patients undergoing various disc implants argues against the failure being device related. Geisler et al. reported on patients who underwent fusion after they had unsuccessfully undergone arthroplasty. In the Charité IDE study, 7.1% of patients undergoing arthroplasty also underwent supplemental instrumentation for fusion because of poor clinical outcome with arthroplasty. The patients all had poor outcome. Geisler and colleagues concluded that failure to respond to surgery was not a limitation of the surgery but indicated an underlying problem in patients who were not amenable to surgical correction. These authors characterized the failure as an “imprecision in preoperative evaluation.”

The author reports no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

An explanation for the inconsistent results with lumbar arthroplasty is that the population of patients with lower-back pain is not homogeneous. While about two-thirds of patients with lower-back pain and appropriate radiographic findings have true discogenic pain, the remaining one-third have other pathological conditions that are not amenable to current surgical intervention. Significant psychosocial overlay is a possibility. Studies by Carragee et al., in which the authors used discography extensively demonstrated the overlap between psychosocial variables and lower-back pain. These authors reported that about one-third of patients with chronic pain had a positive discography result without a history of significant lower-back problems.

In the present study, worse outcomes were observed in patients with a very high ODI (> 60) after lumbar arthroplasty. A low ODI has been associated with better outcomes. Siepe et al. also examined outcomes after lumbar arthroplasty, and they observed that patient improvement was predicted by a lower baseline ODI. The relationship of ODI to psychosocial issues has not been well documented, although Slover et al. noted that psychosocial issues affect ODI. The information that a high ODI is associated with poor outcome will allow for better informed decisions and expectations by surgeons and patients regarding the appropriateness of surgical intervention for chronic lower-back pain. A high ODI by itself does not exclude a patient from consideration for lumbar arthroplasty.

**Conclusions**

Lumbar disc arthroplasty is highly successful in reducing lower-back pain in about two-thirds of patients. A significant one-third of patients do not respond to surgery. The ability to adequately exclude patients who respond poorly to surgery can improve arthroplasty surgery outcome. This paper shows that patients with very high ODI scores have relatively poor outcomes with lumbar disc arthroplasty.

**Disclosure**

The author reports no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

**Acknowledgment**

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**References**

1. Carragee EJ, Alamin TF, Carragee JM: Low-pressure positive


