An artificial intervertebral disc ought to have the same biomechanical properties as the body's own discs with regard to segmental height, the normal excursion of segmental motion, and the normal degree of lumbar lordosis (1).

Pathological movement properties must be corrected to optimize the function of the adjacent segments and to avoid unphysiological stresses. The prosthesis should be safely implantable as well as safely removable or replaceable. In addition, the following important requirements should be placed on any modern type of functional disc replacement (2):

- optimal mechanical durability of the biomaterials used
- biocompatibility of the materials used and of the particles that will be rubbed off of it by wear and tear
- the possibility of non-invasive postoperative imaging.

Methods

This narrative review article is based on the authors’ assessment of the current literature on lumbar disc prostheses, which can be found in the following databases: Embase, Cinahl, and PubMed. The time frame of the literature search was up to and including November 15, 2006.

The terms that were searched included “lumbar disc replacement”, "artificial disc", "lumbar disc", “intervertebral disc”, “randomized controlled trial”, "clinical trial", "cohort series", "retrospective study", and "prospective study." 42 relevant articles were identified on the basis of their titles and abstracts and classified according to their level of evidence, according to the classification scheme of the Centre for Evidence-Based Medicine, Oxford, U.K. (www.cebm.net).
The search revealed

- 2 randomized, controlled studies with 11 preliminary reports of results (1, 3-10, e1, e2) (evidence level I);
- 3 systematic reviews of the literature (11, e3, e4) (evidence level II/III);
- 7 prospective studies (12, 13, e5-e9) (evidence level II);
- 12 retrospective cohort studies (14-18, e10-e16) (evidence level III);
- 9 uncontrolled case series and expert opinions (2, 19, e17-e23) (evidence level IV-V).

Eysel’s review article (e24) entitled “The artificial disc” already appeared in the Deutsches Ärzteblatt in the year 2000. The current article is intended to provide an overview of the current status of lumbar disc prosthesis surgery.

**Indications and contraindications**

Symptomatic, monosegmental lumbar disc degeneration is described in the literature as the main indication for functional disc replacement surgery (3).
As in any type of elective, stabilizing spinal surgery, an operation should be considered only after the options for conservative therapy have been exhausted after at least 6 months of treatment (3). An important part of the diagnostic evaluation concerns the question whether the patient’s low back pain is truly of discogenic origin. Magnetic resonance imaging (MRI) is a suitable means of morphologically demonstrating the severity of disc degeneration as well as the degenerative changes in the adjacent upper and lower vertebral body endplates (2, e25).

One important diagnostic method involves the direct provocation of discogenic pain by discography to prove that the degenerated disc is the origin of the pain. The correct performance of the discographic technique is problematic, however, as is the interpretation of its results. The following factors lessen the diagnostic and predictive value of this method of objectifying discogenic pain (2, 10, e26):

- a high false-positive rate (e27);
- patients’ inability to distinguish “memory pain” (in which discographic stimulation of the disc exactly reproduces the pain of which the patient complains) from other, non-discogenic causes of the pain (e28);
- the still uncertain prognostic value of this test with regard to the long-term result of surgery (e29).

A further criterion of exclusion is the presence of pathological changes in the dorsal spinal elements, particularly the facet joints; diagnostic facet joint infiltration is necessary to verify that the joints are intact (1). Like discography, however, this type of diagnostic injection study is of limited predictive value, both because of the great latitude of interpretation of the findings and because of the potential for misuse so that surgery can be performed for incorrect indications.

The diagnostic studies (imaging studies and injection tests) should be correlated with the clinical finding of symptomatic, medically intractable lumbar disc degeneration, with a preoperative constant pain intensity of 40% or more on the Visual Analog Scale, and an Oswestry disability score of 30% or above (3) (box 1).

Bertagnoli and Kumar (12) postulated 4 criteria that together define the optimal patient profile for the implantation of a disc prosthesis:

- disc height > 4 mm
- no degenerative changes of the facet joints
- no degeneration of the adjacent segments
- intact posterior spinal elements without any pathological changes.

According to current scientific knowledge, there are a large number of contraindications to the implantation of prostheses for functional disc replacement. These can be divided into two large groups (16):

- painful changes in the spine that will not be corrected by the implantation of a disc prosthesis, including nerve compression due to spinal canal stenosis or recess stenosis, or disc protrusions or herniations producing radicular symptoms;
- degenerative changes of the posterior stabilizing elements of the spine, particularly of the facet joints; segmental instability due to spondylolisthesis or certain types of deformity such as scoliosis and kyphosis; impaired structural integrity of the vertebral body endplates due to osteoporosis, pseudarthrosis, infection.

### Table 1

<table>
<thead>
<tr>
<th>Study (evidence level)</th>
<th>Year</th>
<th>n</th>
<th>Follow-up (months)</th>
<th>Success rate</th>
<th>Prosthesis-specific complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Griffith et al. (e11) (III)</td>
<td>1994</td>
<td>139</td>
<td>12</td>
<td>65 %</td>
<td>4.3 %</td>
</tr>
<tr>
<td>Cinotti et al. (15) (III)</td>
<td>1996</td>
<td>56</td>
<td>38</td>
<td>63 %</td>
<td>26 %</td>
</tr>
<tr>
<td>Lemaire (17) (III)</td>
<td>1997</td>
<td>105</td>
<td>51</td>
<td>79 %</td>
<td>2.9 %</td>
</tr>
<tr>
<td>Büttner-Janz et al. (e10) (III)</td>
<td>1998</td>
<td>91</td>
<td>72</td>
<td>85 %</td>
<td>&lt; 10 %</td>
</tr>
<tr>
<td>Bertagnoli et al. (12) (II)</td>
<td>2002</td>
<td>108</td>
<td>3–48</td>
<td>90.8 %</td>
<td>none</td>
</tr>
</tbody>
</table>

As in any type of elective, stabilizing spinal surgery, an operation should be considered only after the options for conservative therapy have been exhausted after at least 6 months of treatment (3). An important part of the diagnostic evaluation concerns the question whether the patient’s low back pain is truly of discogenic origin. Magnetic resonance imaging (MRI) is a suitable means of morphologically demonstrating the severity of disc degeneration as well as the degenerative changes in the adjacent upper and lower vertebral body endplates (2, e25).

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Box 2 contains a list of the indications and contraindications for lumbar disc replacement surgery (3, 20) derived from the criteria accepted by the United States Food and Drug Administration (FDA) for the randomized, controlled studies that are currently in progress, employing various types of lumbar disc prosthesis.

**Properties of types of prostheses that are currently available on the market**

The first-ever disc prosthesis, described by Fernstrom in 1950, consisted of a stainless steel sphere that was implanted in the intervertebral space (e30). Since then, more than 100 types of mobility-preserving intervertebral implants have been described in the literature (e31).

Modern disc prostheses are firmly anchored in the upper and lower endplates of the vertebral bodies adjacent to the degenerated disc by metal plates and have a sliding central component made of ultra-high-molecular-weight polyethylene (1, 19). Such prostheses can be of either “semi-constrained” or “non-constrained” design. In prostheses of the former type, the inlay is fixed in the endplate of the lower vertebral body and therefore possesses a fixed center of rotation, around which only flexion/extension and lateral bending movements can take place. In contrast, the sliding central component of non-constrained prostheses can move freely; the center of rotation does not have a fixed location, and translational and rotational movements of the prosthesis remain possible (2).

<table>
<thead>
<tr>
<th>Complications</th>
<th>Disc prosthesis operations n = 295</th>
<th>Anterior interbody fusions n = 99</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Approach-specific (n [%])</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>venous injury</td>
<td>9 (4.4)</td>
<td>2 (2)</td>
</tr>
<tr>
<td>retrograde ejaculation</td>
<td>3 (3.3)</td>
<td>3 (5.5)</td>
</tr>
<tr>
<td>ileus</td>
<td>2 (1)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>perioperative venous thrombosis</td>
<td>2 (1)</td>
<td>0</td>
</tr>
<tr>
<td>blood loss &gt; 1500 mL</td>
<td>1 (0.5)</td>
<td>2 (2)</td>
</tr>
<tr>
<td>wound dehiscence</td>
<td>1 (0.5)</td>
<td>2 (2)</td>
</tr>
<tr>
<td>epidural hematoma</td>
<td>1 (0.5)</td>
<td>0</td>
</tr>
<tr>
<td>dural injury</td>
<td>1 (0.5)</td>
<td>0</td>
</tr>
<tr>
<td>deep venous thrombosis</td>
<td>0 (0)</td>
<td>0</td>
</tr>
<tr>
<td>arterial thrombosis</td>
<td>0 (0)</td>
<td>0</td>
</tr>
<tr>
<td><strong>Infection (n [%])</strong></td>
<td>26 (12.7)</td>
<td>8 (8.1)</td>
</tr>
<tr>
<td>among which:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>superficial wound infections</td>
<td>13 (6.3)</td>
<td>2 (2)</td>
</tr>
<tr>
<td><strong>Neurological (n [%])</strong></td>
<td>34 (16.6)</td>
<td>17 (17.2)</td>
</tr>
<tr>
<td>among which:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>burning pain/dysesthesia in the leg</td>
<td>5 (2.4)</td>
<td>3 (3.0)</td>
</tr>
<tr>
<td>motor deficit</td>
<td>4 (2)</td>
<td>1 (1.0)</td>
</tr>
<tr>
<td>nerve injury</td>
<td>1 (0.5)</td>
<td>0</td>
</tr>
<tr>
<td>sensory deficit</td>
<td>20 (9.8)</td>
<td>8 (8.1)</td>
</tr>
<tr>
<td><strong>Fusion-specific (n [%])</strong></td>
<td></td>
<td>27 (27.3)</td>
</tr>
<tr>
<td>pseudarthrosis</td>
<td>–</td>
<td>9 (9.1)</td>
</tr>
<tr>
<td><strong>Pain at bone graft removal site (n [%])</strong></td>
<td>–</td>
<td>18 (18.2)</td>
</tr>
<tr>
<td><strong>Prosthesis-specific (n [%])</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>sinking of prosthesis into adjacent vertebral body</td>
<td>7 (3.4)</td>
<td>–</td>
</tr>
<tr>
<td>implant dislocation</td>
<td>1 (0.5)</td>
<td>–</td>
</tr>
</tbody>
</table>
Though a number of types of prosthesis are already in routine clinical use in various countries, only 2 have been approved to date by the FDA for use in the USA (e32, e33).

**Results**

Most of the currently available middle- and long-term clinical results of lumbar disc prosthesis surgery are derived from uncontrolled clinical case series (2, 19, e17–23) and from an increasing number of retrospective (14–18, e10–e16) and prospective (12, 13, e5–e9) longitudinal follow-up studies. An overview of these results is provided in *table 1*.

After two years of follow-up, the clinical (3) and radiological (6) results of a prospective, controlled, randomized study performed under FDA supervision (evidence level I) on patients with painful, monosegmental L4/5 or L5/S1 disc degeneration revealed a 63.6% success rate of lumbar disc replacement in the study group and a somewhat lower success rate of 56.8% for anterior interbody monosegmental fusion (p=0.0004). The patients receiving disc replacements had a significantly shorter stay in the hospital (3.7 versus 4.2 days [p=0.0039]), but they did not differ from the control group in terms of the length of the operation (110.8 versus 114 minutes [p=0.6277]) or operative blood loss (205 versus 208.9 mL [0.8948]). When “success” was counted as an improvement in the Oswestry disability score by more than 25% 24 months after surgery, the success rates were 63.9% for disc replacement surgery and 50.5% for fusion (p=0.0338).

The problems reported in the two patient groups included both the general complications of the anterior approach to the lumbar discs (9.8% versus 10.1% [p = 0.7331]) and
prosthesis-specific complications (table 2). Overall, reoperations needed to be performed in 5.4% of patients in the study group and 9.1% in the control group (p = 0.4484).

A second randomized, controlled study overseen by the FDA and conducted in 18 centers in the USA was recently completed. Patients in the control group were treated with a 360° spondylodesis. Preliminary results of this study have been published to date in five separate articles (4, 5, 8, 9, 10). Ziegler et al. (10) reported 12 months of follow-up data on a group of 54 patients. At 6 months after surgery, the study group differed from the control group with respect to:

- significantly less intraoperative blood loss (103 versus 213 mL, p < 0.01),
- shorter operative time (90 versus 232 min), and
- a shorter stay in the hospital (2.24 versus 3.26 days).

Both groups of patients, the study group and the control group, had a marked improvement in their Visual Analog Scores and Oswestry Disability Index. There was a trend toward greater patient satisfaction in the study group, but this did not reach statistical significance (p = 0.08). The final results from all of the 18 participating centers have not yet been reported.

**Discussion**

Lumbar disc prosthesis surgery is an alternative to interbody fusion that marks the start of a new era in spinal surgery, but its proper role in treatment cannot yet be definitively evaluated.

There are still no well-founded scientific data to support the hypothesis that maintenance of a physiological range of movement by the implantation of a functional disc prosthesis reduces stress on the adjacent segments, not only in the early postoperative period, but also over the long term. The facet joints in the operated segment take on increasing clinical relevance, however, because the functional disc prosthesis – as compared to complete stabilization of the segment by a fusion procedure – creates a new dynamic situation for the posterior spinal elements. Thus, any existing damage to the facet joints should be considered a contraindication to disc replacement surgery (16). Likewise, the degree of stress reduction on the posterior spinal elements seems to depend crucially on precise performance of the implantation technique, as well as on the type of prosthesis used – semi- versus non-constrained, fixed versus migrating center of rotation (11, 14, 21, 22).

A normal lumbar motion segment has a migrating center of rotation, but semi-constrained implants allow only flexion/extension movements and lateral bending about a fixed center of rotation (2). The postoperative range of motion is largely a function of the position of the fixed center of motion within the intervertebral space; thus, even small deviations from the optimal position in the sagittal plane can have major effects on the range of motion and the pattern of stress on the dorsal spinal elements (21). Semi-constrained implants, if they are optimally implanted, protect the facet joints from injury and afford the motion segment greater stability, but they place greater demands on the bone-prosthesis interface. On the other hand, non-constrained implants, in which the mobile polyethylene central element is designed to imitate the natural biomechanical properties of a normal nucleus pulposus, seem to be less sensitive to suboptimal positioning, because their center of rotation migrates in any case. Nonetheless, their greater postoperative range of motion places a greater stress on the dorsal spinal elements, especially the facet joints (13, 15, 17). The long-term consequences of a fixed versus a migrating center of rotation, as well as the possible consequences of accelerated facet joint degeneration, and the potential effects of these phenomena on the durability and long-term clinical results of functional disc prostheses, remain unknown to date and need to be studied further (2).

Because the range of motion of a lumbar segment is much smaller than that of the knee or hip, the rubbing off of small particles from an implanted prosthesis by wear and tear is considered to be less of a problem in the lumbar spine than it is for hip and knee prostheses. Tests have shown that the volume of such particles is about 10% of what is found in artificial knee and hip joints under comparable testing conditions (e34). The extent to which this problem might affect the long-term durability of disc prostheses is currently unknown (2). Longitudinal clinical studies with up to 17 years of follow-up have not revealed any clinically significant loosening of disc prostheses by the rubbing off of particulate matter (13, 15, 17, 22); the few cases that have been described to date remain exceptional (18).

The purpose of a functional disc prosthesis is to maintain segmental mobility while avoiding any non-physiological stress on the adjacent motion segments. Heterotopic
heterotopic ossification or even spontaneous fusion can markedly lessen segmental mobility. The reported rates of heterotopic ossification, ranging from 1.4% to 15.2% (2), and the reported 60% rate of spontaneous fusion after 17 years of follow-up – with a significantly higher rate of patient satisfaction associated with motion segments that have been immobilized by fusion (22) – are both good reasons to question the entire concept of disc prosthesis surgery.

One disadvantage of all kinds of disc prostheses that are currently available on the market has to do with postoperative imaging of the affected motion segment. MRI studies of the operated area are currently considered inadvisable (25), because metal artefact generally renders the MRI scan difficult to interpret, and because prosthesis manufacturers currently do not supply any in vitro data about possible side effects, such as heat generation or implant migration. Thus, any further diagnostic studies that must be done on the patient will have to be performed with "second-line" techniques such as CT, myelography, or post-myelographic CT. Three-dimensional CT reconstructions at least provide some information as to the position of the implant (figure) (2).

The currently available middle- and long-term results of lumbar disc prosthesis surgery are mostly derived from retrospective series, case reports, and expert opinions (evidence levels III–V) and thus do not meet the requirements of evidence-based medicine. The data from many studies lacking a control group treated with conventional interbody fusion can be evaluated only in comparison with previously published (long-term) results of the conventional techniques. There are as yet no long-term results from controlled, prospective, and randomized studies (evidence level I) that might provide important information about the potential long-term complications of lumbar disc prosthesis surgery, which, the longer these prostheses remain in place, can be expected to necessitate an increasing number of reoperations, with the attendant risk of still further complications. Because of the lack of adequate experience with the removal or replacement of lumbar disc prostheses, and the major risk of vascular injury during such procedures (7), most of the reoperations that are currently performed involve a dorsal fusion rather than a repositioning of the prosthesis (7, 19).

The results, after 2 years of follow-up, of the FDA-supervised, prospective, randomized and controlled study (3, 6) open up encouraging perspectives for the operative treatment of degenerative spinal diseases. Nonetheless, the comparison of lumbar disc prosthesis surgery with anterior interbody fusion as the procedure performed on the control group must be regarded critically. This type of purely ventral fusion through an anterior approach, without any dorsal spondylodesis employing "cages," is not currently performed as state of the art in Europe. The results of the second FDA-supervised, prospective, randomized and controlled multicenter study (16), in which disc prostheses are compared with the gold standard of 360° spondylodesis (transpedicular fusion and interbody "cage" placement or bone grafting) are likely to be decisive.

Nor is there any international consensus at present on the indications and contraindications for lumbar disc prosthesis surgery. The criteria accepted by the FDA include, alongside an extensive list of contraindications, a number of "good" indications (3), but there are no clear-cut "hard" indications, as there are, for example, for lumbar discectomy. Monosegmental symptomatic disc degeneration, which the proponents of disc prosthesis surgery hold out as the main indication for the procedure, is no more than a "soft" indication and is, as such, highly controversial. Depending on the particular specialist responsible for determining the indication, an operation might be deemed to be indicated, according to this criterion, at a time when another spine specialist might consider further conservative therapy to be preferable. It is clear, therefore, that no well-defined standards exist either for diagnosis or for treatment. The operating surgeon bears the responsibility of weighing the generally favorable spontaneous course, without surgery, of patients possessing this "soft" indication against the surgical risks, which are considerable, particularly if a reoperation should need to be performed at some point in the future. Though the FDA recommends that such operations should be restricted to persons aged 18 to 60 (3), it would seem that their performance in persons under age 30 should be reserved for rare, exceptional cases, in view of these patients' long life expectancy, the limited functional expectancy of the implants, and their as yet unknown late complications, with the possible need for dangerous reoperative procedures. In view of these considerations, further scientific studies need to be performed to enable an evidence-based analysis of the indications and contraindications for lumbar disc prosthesis surgery and a comparison of the results with the alternative gold standard of 360° fusion.
Regardless of pressure from the medical instruments industry, and despite the expectant attitude of our patients, we should still await reports of clinical success rates and complication rates from controlled longitudinal studies before recommending functional disc prosthesis surgery as standard treatment.

Summary and conclusions

The manufacturers and proponents of lumbar disc prostheses predict a great future for this new technology. Spinal surgeons will soon face enormous pressure, both from industry and from their patients, to perform disc prosthesis surgery. Nonetheless, in view of the discrepancy between the small number of evidence-based studies and the existing plethora of uncontrolled reports, operating surgeons ought to maintain a constructively critical attitude. Future evidence-based studies must be aimed at hardening the indications for functional disc replacement surgery and at standardizing the diagnostic criteria to be used. We must still wait and see whether the types of prostheses that are currently on the market, or their further elaborations, will truly be up to the task posed by the complex movements of the lumbar motion segment, so that they can fulfill the high therapeutic expectations that have already been placed on them.

Conflict of Interest Statement

The authors state that they have no conflict of interest as defined by the guidelines of the International Committee of Medical Journal Editors.

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REFERENCES

For e-references please refer to the additional references listed below.


ADDITIONAL REFERENCES


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