

Clinical Studies

# Epidemiology of indications and contraindications to total disc replacement in an academic practice

Kingsley R. Chin, MD

Department of Orthopaedics, Spine Surgery Service, 2 Silverstein, 3400 Spruce Street, University of Pennsylvania, Philadelphia, PA 19104, USA

Received 3 April 2006; accepted 14 August 2006

## Abstract

**BACKGROUND CONTEXT:** Given the experience with anterior lumbar cages, the similar enthusiasm for total disc replacement (TDR) and the economic incentives driving use of this new technology, it is important to document reasonable expectations as to the incidence of patients with appropriate indications for this new technology.

**PURPOSE:** To document epidemiological data for the indications and contraindications to total disc replacement (TDR) to guide expectations for use of this new technology.

**STUDY DESIGN/SETTINGS:** Retrospective evaluation of contraindications and indications for lumbar TDR in consecutive symptomatic patients presenting to an academic spine practice.

**PATIENT SAMPLE:** Six hundred twenty-seven consecutive symptomatic patients presenting to an academic spine service.

**OUTCOME MEASURES:** Presence of contraindications to lumbar TDR based on Food and Drug Administration criteria.

**METHODS:** Over a year, 627 new patients were evaluated by the only orthopedic spine surgeon on faculty at a major university. 131 underwent lumbar surgeries. Surgical patients were divided into Group 1 (57 patients who had fusions) and Group 2 (74 patients who had nonfusion surgeries). The incidence (period prevalence) and prevalence (point prevalence) of indications for and contraindications to TDR were documented.

**RESULTS:** The incidence of indications for TDR was 0.5% (3/627). The prevalence of no contraindications to TDR in the fusion Group 1 was 5% (3/57). Overall, 9% (3 fusion and 9 nonfusion) had no contraindications to TDR and the same percentage satisfied indications for TDR. However, 96% (71/74) of Group 2 patients considered themselves satisfied with laminectomies and laminotomies. The combined average number of contraindications to TDR was 2 (SD, 1.33) (range, 0–6). For Group 1, it was 3 and 1 for Group 2 ( $p < .5$ ).

**CONCLUSIONS:** Despite early enthusiasm for TDR replacing fusion, there was only a 0.5% incidence of indications for TDR in the overall population and a 5% prevalence in the fusion patients, but the majority were in young patients who averaged about 38 years old. The absence of contraindications for TDR did not equate to indications for TDR because other nonfusion techniques exist. Based on the history of the introduction of other new spinal technologies and the fact that the current criteria for TDR seems to result in a relatively small number of eligible patients, there is risk of overuse of this new technology. © 2007 Elsevier Inc. All rights reserved.

## Keywords:

Disc Replacement; Lumbar; Prevalence; Incidence; Indication; Contraindication; Epidemiology

## Introduction

Spinal fusion was introduced in 1911 by Albee [1] and Hibbs [2] to immobilize the spine for the treatment of tuberculous spondylitis. During the ensuing years, the techniques and technologies have changed along with broadening of the indications such that there are currently over 450,000 lumbar and cervical spinal fusions performed annually in the United States [3,4]. However, because

FDA device/drug status: approved for this indication.  
Nothing of value received from a commercial entity related to this manuscript.  
Corresponding author. Department of Orthopaedics, Hospital of the University of Pennsylvania, 2 Silverstein, 3400 Spruce Street, Philadelphia, PA 19104. Tel.: (215) 349-8868; fax: (215) 349-5928.  
E-mail address: kingsleychin@hotmail.com (K.R. Chin)

fusion is associated with on average only around 76% clinical success, long recuperation period, risks of adjacent level degeneration, graft donor-site morbidity, and pedicle screw-related complications [4–9], there is increasing enthusiasm for nucleus replacement devices [10–27] as an alternative to spinal fusions with the hope of avoiding these complications as well as duplicating the favorable results seen with hip and knee arthroplasty [28]. On October 26, 2004, the Food and Drug Administration (FDA) approved the first lumbar total disc replacement (TDR) (Charité, Depuy Spine, Raynham, MA) in the United States, and current FDA clinical trials are nearing completion on other TDR devices. Early Level III to IV case series data from the European experience with the Charité prosthesis showed good to excellent clinical success of between 63% to 90%, whereas data from a FDA prospective randomized study showed 73.7%, which on average is equivalent to fusion but with faster recovery time and no need to harvest iliac crest graft [29–32]. As a result of the enthusiasm by venture capitalists and spine implant companies for total disc replacements, it is speculated that by 2010 70% of the spinal procedures performed in the United States may include some form of disc arthroplasty [3]. Recent estimate from internal data at Depuy Spine (Depuy Spine, Raynham, MA) report worldwide Charité implant of approximately 20,000 but only 7,000 in the USA since the FDA approval.

Similar enthusiasm had led to the implantation of 10,000 stand-alone BAK (Zimmer Spine, Minneapolis, MN) anterior interbody cages within 2 years after an expedited FDA approval on September 20, 1996, only to be followed by mixed outcomes [33,34]. Subsequently, the prevailing consensus regarding spinal fusions is that outcomes seem to be closely dependent on appropriate indications and patient selection [4–9].

The claim that TDR will replace spinal fusion led Huang et al. [35] to study the prevalence of contraindications to TDR in a cohort of 100 patients treated by one spine surgeon in a group of spinal surgeons at their institution. Despite biases in their methodology, they showed a 95% prevalence of contraindications and concluded that only 5% of patients had indications for TDR. Wong et al. [36] retrospectively reviewed 100 consecutive fusion patients and showed that 100% of fusion candidates had one or more contraindication for TDR with an average of 3.69 contraindications per patient. Given the experience with cages and the similar high level of enthusiasm for TDR coupled with the large economic incentives by the implant companies and vested surgeons to drive use of this technology, it is important to establish reasonable expectations as to the incidence of patients with appropriate indications for TDR. The purpose of this study was to document early epidemiological data for the indications and contraindications to TDR to guide expectations for use of this new technology. We hypothesized that majority of patients currently indicated for spinal surgery and fusions are not candidates

for TDR, and the absence of contraindications for TDR does not equate to indications for TDR.

## Methods

### *Patient population and data collection*

We performed a retrospective review of the medical records of 131 consecutive patients, mean age of 47.3 years (range, 20–88 years), who underwent lumbar surgery by one spine surgeon. The cohort of surgical patients was taken from patients directly referred to the same surgeon with either surgical indications or as new routinely scheduled patients in the spine clinic of the surgeon from July 10, 2003, to July 20, 2004, inclusive. Surgical patients were also included whose first evaluation was within this time period, although their surgeries were after July 20, 2004. Six hundred eighteen new patients were seen in the clinic during this period, and 9 were directly referred for surgery, for a total of 627 patients. The surgical patients were divided into fusion and nonfusion subgroups to determine the percentage of patients in either group who could have been candidates for a total disc replacement instead. Patients were divided into two surgical groups. Group 1 consisted of 57 patients, 21 men and 36 women, who had fusion and Group 2 consisted of 74 patients, 38 men and 36 women, who had nonfusion lumbar surgeries. The spine surgeon during this period did not have any inclusion or exclusion criteria for screening incoming patients nor had any established referral pattern since he had just joined the faculty from another state and was the only spine surgeon on the academic faculty in the department of orthopaedics at this major university. There were also no marketing efforts for patients. The surgeon documented patient diagnoses, radiographic findings, and procedures performed on all the patients. All 131 medical records and radiologic studies were available for further critical analysis by the surgeon for the purposes of this study.

### *Surgical indications*

All patients underwent appropriate preoperative evaluations by a multidisciplinary team that included the spine surgeon, before being considered for surgery. This included appropriate radiologic and laboratory studies and medical clearance. At a minimum, each patient underwent a physical examination and review of plain radiographs and MRI by the spine surgeon. Patients in Group 1 and 2 had minimum of 4 to 6 months of nonoperative therapy except Group 2 patients with acute herniated discs who had minimum 6 weeks of nonoperative therapy. These included physical therapy, medications, behavioral activity modifications, back school, lumbosacral stabilization therapy, orthotic management, spinal injections, acupuncture, and chiropractic manipulation.

### Data analysis and statistics

The surgical procedures performed in each group were documented and compared (Table 1). Because there are theoretical benefits to TDR as a nonfusion option, we wanted to determine if patients in Group 2 who had current nonfusion techniques were satisfied. We elected not to compare satisfaction levels with Group 1 fusion patients given the many shortcomings of lumbar fusion and the multiple treatment and outcome variables that determine satisfaction in fusion patients.

The patients in Group 2 were asked if they were satisfied with their outcome and if they felt the surgery was beneficial. The number of contraindications for total disc replacement in each group were documented and compared between each group (Table 2). Because degenerative disc disease is an existing condition, versus a new occurrence of a disease, at the time of evaluation, period prevalence and point prevalence may be considered more appropriate terms, but from the perspective of the surgeons these were new patients presenting to the spine clinic, and therefore incidence and prevalence were used in this report interchangeably with period prevalence and point prevalence, respectively. The incidence was defined as the number of existing cases during the study period divided by the total number of patients at risk (627). The prevalence was defined as the number of existing case at a given time among the lumbar surgical patients (131). The incidence and prevalence of indications for and contraindications to total disc replacement were calculated for each subgroup and for the entire population. The mean, standard deviation, and range of the number of indications and contraindications present in patients from each group was also calculated. The data was analyzed by using Microsoft Excel 2002 (Microsoft Inc., Redmond, WA). Statistical comparisons were made by using a Student *t* test with statistical significance defined as  $p < .05$ . Where applicable, data are presented along with standard deviations.

### Selection for TDR

There is controversy regarding the selection criteria for TDR. We used indications and contraindications used in the FDA trial for the Charité total disc replacement and

Table 1  
Surgical procedures performed

Procedure	Fusion group (%) (n=57)	Nonfusion group (%) (n=74)
Decompressive laminectomy	42 (74)	34 (50)
Decompressive laminotomy	0	42 (57)
Discectomy	31 (54)	53 (72)
Fusion	57 (100)	0
Removal of hardware	1 (2)	2 (3)

Values are actual numbers and percent of patients in fusion and nonfusion groups who underwent various procedures rounded to nearest whole number.

Table 2  
Prevalence of contraindications to TDR in fusion and nonfusion groups

Contraindications	Fusion group (%) (n=57)	Nonfusion group (%) (n=74)
Central or lateral recess stenosis	42 (74)	19 (26)
Facet arthrosis	32 (56)	5 (7)
HNP with neural compression	4 (7)	53 (72)
Spondylolisthesis	25 (44)	0
Spondylolysis	8 (14)	0
Scoliosis	10 (17)	2 (3)
Osteopenia	15 (26)	3 (4)
Postsurgical deficiency of posterior elements	11 (19)	3 (4)
Interbody pseudoarthrosis	6 (10)	0
Age <18	0	0
Age >60	20 (35)	6 (8)
Any contraindication	49 (86)	65 (88)

inclusive of those used in the comparative study by Huang et al. for the purposes of comparisons [10–27,35–41] (Tables 2 and 3).

### Contraindications to total disc replacement

Because TDR is intended mainly for correcting pain pathology of the disc, like Huang et al. [35], we considered contraindications under two broad categories that included painful conditions not caused by the disc and conditions that may compromise the long-term stability of the disc. In the first category were conditions that related to neural compression or facet pathology such as, central and lateral recess stenosis, facet arthrosis, facet cyst, or herniated disc causing radiculopathy. In the second category were conditions such as spondylolisthesis, spondylolysis, deficiency of posterior elements, deformity, or deficiency of endplate structural integrity (osteopenia, osteoporosis, and interbody pseudoarthrosis).

### Indications to total disc replacement

The typical patient had low back pain with or without nonradicular leg pain, no contraindication to TDR, and had discogram-positive disc degeneration at only single

Table 3  
FDA Indications for TDR

Single-level degenerative disc disease between L4–S1 confirmed by myelogram/CT or MRI followed by discogram
Discogenic low back pain at the operative level with concordant pain upon provocative discogram
Back and/or leg pain (usually above the knees) without nerve root compression
18 < age < 60
Oswestry Disability Index (ODI) score $\geq 30$
Pain on visual analog score $\geq 40$
Failed $\geq 6$ months of conservative therapy
No contraindications

or two intervertebral levels at L3–4, L4–5, or L5–S1 [39]. Because foraminal stenosis alone may be corrected with restoration of disc height by a TDR, it was not considered a contraindication by itself [22,39]. In the absence of other contraindications listed earlier, intervertebral disc height of at least 4 mm, with or without scarring, and thickening of annulus fibrosis with osteophytes indicating osteoarthritis were considered indications for TDR [39].

## Results

The incidence of lumbar spine surgery was 20.9% (131/627). The incidence of indications for TDR in the overall population was 0.5% (3/627).

### *Contraindications*

In the fusion Group 1, 5% (3 of 57) of patients had no contraindications to TDR. In the nonfusion Group 2, 12% (9/74) of patients had no contraindications to TDR. Overall, 9% (12/131) had no contraindications to TDR. The mean age of the patients with no contraindications to TDR was 38 (range, 36–42 years) in the fusion Group 1 and 45.1 (SD, 6.8; range, 37–59 years) in the nonfusion Group 2. Overall, the patients in Group 1 were significantly older than those in Group 2 with an average age of 57.2 years (SD, 14; range, 23–82 years) in Group 1 compared with 41.9 years (SD, 14; range, 20–88 years) in Group 2. If two-level degenerative disc between L4–S1 was not a contraindication then in the fusion Group 1, 14% (8/57) patients would have no contraindications to TDR.

### *Indications*

#### *Group 1 (fusion)*

In the fusion group, all three patients with no contraindication to TDR were also indicated for TDR and all three underwent interbody fusion. Therefore, the prevalence of indications for TDR remained the same at 5% (3/57) in the fusion group.

#### *Group 2 (nonfusion)*

In the nonfusion group, 12% (9/74) had indications for TDR, which was equal to the number of patients with no contraindications. However, only 4% (3/74) of the nonfusion patients were not satisfied and therefore had the potential to have had better outcome if they had chosen a TDR. The combined prevalence of indications for TDR in the lumbar surgery group was 9% (12/131). The patients who would have possibly benefited from a TDR were the 3 fusion and 3 dissatisfied nonfusion patients (4.6% [6/131]). Although all the patients with herniated discs had primarily leg pain, each had some low back and buttock complaints. If these patients with herniated discs and low back complaints were considered candidates for TDR, the prevalence

of indications for TDR would increase to 66% (49/74) in the nonfusion group and 37.4% overall.

The overall average number of contraindications to TDR was 2 (SD, 1.33) (range, 0–6). The average number of contraindications to TDR in the fusion subgroup was 3 (SD, 1.46) (range, 0–6) and 1 (SD, 0.57) (range, 0–4) in the nonfusion group.

## Discussion

The current climate of enthusiasm for TDR is reminiscent of that seen during the “cage rage” era after the FDA approved the anterior interbody cage. However, the mistakes and lessons learned from that experience should compel us to seek ways to establish strict criteria for selecting patients with appropriate indications and to establish epidemiological data to guide expectations with this new technology. Huang et al. [35] initiated the first epidemiologic study to assess prevalence of contraindications to TDR in a group of 100 patients with degenerative spine conditions referred to one surgeon. They found that 95% of patients had one or more contraindications to TDR. Although it was an important study for initiating interest in the epidemiology of TDR, it was criticized for having many shortcomings. The study was biased by the referral pattern of the surgeon who already had an established practice that rarely included patients with isolated degenerative disc disease without neural compression. Proponents of TDR would argue that such patients would be ideal candidates for TDR, and hence the prevalence should be higher. In contrast, the lack of contraindications to TDR does not mean a TDR was indicated, and thus the 5% prevalence of indications for TDR inferred from their study may be inflated. In addition, the surgeon had been enrolled for 1 year in a FDA trial of the ProDisc (Synthes, Paoli, PA) and therefore may have a higher number of referrals for patients likely to have indications for TDR. The short period of time that it took to perform 100 fusions suggested a highly selective referral pattern. Finally, the study did not address incidence of indications for TDR that would have been a useful benchmark for comparison among other centers.

Our study attempted to address the criticisms of that study as well as be the first to report the incidence of indications for TDR in an academic referral practice before TDR becomes widespread and the opportunity to limit referral biases is lost. We examined a larger cohort of patients without any established referral pattern or any screening criteria for spinal complaints. All patients referred to orthopedics were scheduled to see one surgeon, and there was no marketing information to contaminate our data.

We considered contraindications under two broad categories that included painful conditions not caused by the disc and conditions that may compromise the long-term stability of the disc. TDR has been shown to be unable to correct central and lateral recess stenosis [18–22]. Facet

arthrosis is widely accepted as a contraindication because a TDR does not address the pathology and over time will likely lead to worsening pain likely because of facet innervation or facet hypertrophy leading to lateral and subarticular stenosis [8–23,27]. These findings have been reported by several authors who have performed TDR in patients with mild facet arthrosis [20,23,37]. Conditions that may lead to unstable forces on the TDR and subsequent mechanical failure such as spinal deformity and instability are considered contraindications [13,18–22,42]. Factors affecting the endplates such as osteoporosis risks subsidence of the implant with time and subsequent failure [13,18–22,40]. Intervertebral pseudoarthrosis also risks endplate integrity and has been considered a contraindication to TDR [21].

Although we along with other authors considered herniated nucleus pulposus with neural compression as a contraindication [19,20,35], Zigler et al. [21] listed this condition as an indication, although they did not comment specifically on nerve root compression. According to Zigler et al. [21], the anterior discectomy can be extended back past the annulus fibrosus, where most surgeons would stop, to the posterior longitudinal ligament to remove herniated disc material. It is unknown whether even this aggressive of an anterior discectomy will consistently address all herniated discs and especially extruded and sequestered fragments. Tropiano et al. [16] listed sequestered herniated disc that could not be decompressed from the front as a contraindication in their series but did not mention other exclusion criteria for herniated discs.

The study by Huang et al. [35] did not include obesity and old age as contraindications, and we did the same in this study. According to their argument, weight has not been statistically correlated to radiographic [41] outcomes after TDR, and there are also no supportive clinical studies. Their argument also stated that age in the absence of other contraindications need not be a limiting factor [38]. However, others have considered obesity and old age as contraindications [18,19,39]. McAfee [39] listed age 18 to 60 years, optimally below 50 years as indications suggesting that those outside this age range are contraindicated. Without supportive data for these criteria, we listed the occurrences of age less than 18 and greater than 60 in our table of contraindications for completeness but only considered age <18 as a contraindication for TDR.

Our data showed a 0.5% incidence of indications for TDR in this population. Using similar criteria for contraindications as those reported by Huang et al. [35], the prevalence of no contraindications to TDR in the fusion group was 5% (equal to the 5% reported by Huang et al. [35]), 12% in the nonfusion group, and 9% in the combined lumbar surgery patients. The overall prevalence result in the lumbar surgery patients is substantially higher than the 5% found by Huang et al. [35], but the incidence and prevalence results are still low and suggested that unlike joint arthroplasty TDR may not replace all spinal fusion surgeries. In addition, the number of contraindications to TDR

also rose with age thus TDR may become a technique for young patients in whom TDR has to compete with established motion-sparing techniques such as laminotomies and laminectomies. Furthermore, other motion-sparing technologies are entering the market that will also compete with TDR among younger patients [43–45].

We found that 96% (71/74) of the patients undergoing current nonfusion surgeries such as laminectomies and laminotomies considered themselves satisfied despite a 12% (9/74) prevalence of no contraindication to TDR. Only 4% (3/74) of nonfusion patients felt dissatisfied who had no contraindications to TDR and probably could have benefited from a TDR. One went on to a fusion. A TDR may have produced similar or 100% success rate in the nine nonfusion patients with no contraindication to TDR, but the six satisfied patients would have had an unnecessary TDR in place of safer and more established motion sparing surgeries. It is noteworthy that the nonfusion patients did not satisfy the FDA criteria for TDR. This result confirmed that the absence of contraindications to TDR does not equate to an indication for TDR over other motion-sparing techniques and thus limiting the selection to patients who will be best treated with a TDR over other methods may decrease the rate of use of TDR.

Based on the history of the introduction of other new spinal technologies and the fact that the current criteria for TDR seems to result in a relatively small number of eligible patients, there is risk of overuse of this new technology. For instance, aggressive marketing by a practice for TDR candidates could affect the incidence of indications above that found in our study because we did not market TDR surgery to our patients or referring physicians. The 0.5% incidence may therefore represent a baseline estimate and could have been higher especially with changes in the list of contraindications. For example, broadening the indications such as to include patients with herniated disc with low back pain may represent the largest pool of patients currently not indicated for TDR that could increase the prevalence of TDR patients. There are reasons to believe that this may already be the case [16,18]. For instance, if herniated discs with low back pain were not contraindications, the prevalence would increase to 66% (49/74) in the nonfusion group and 37.4% overall.

Our contraindications excluded postsurgical patients who had laminectomies and radiographic evidence of facet arthritis. However, there are no randomized clinical trials on which to base this decision. Furthermore, changes in the technology such as in the amount of constraint may eliminate these contraindications. For instance, if future designs were developed to be protective of the facets, they could potentially slow disease progression or reverse hypertrophic changes. Additionally, the degree of constraint may allow for the treatment of instability. TDR with ball-and-socket designs will have greater resistance to shear forces [41,42] and may be able to maintain stability after laminectomies and in patients with spondylolisthesis or

spondylolysis. Coupling TDR with posterior dynamic stabilization devices has theoretical benefits and has not been tested to date but has the potential to broaden the indications to include instability [43–45]. These are areas for future biomechanical studies and could possibly increase the pool of patients indicated for TDR.

In summary, although it is improbable to control for all biases in an epidemiological study to look at indications and contraindications for TDR, we improved on the shortcomings of the only prior study to address epidemiological data for TDR [35]. All three hypotheses were proven to be true. The majority of patients undergoing spinal surgeries and fusions were not candidates for TDR, and patients with no contraindications to TDR were not necessarily indicated for TDR.

Although it was anticipated by industry and venture capitalists that TDR will replace spinal fusion for discogenic low back pain, it is unlikely that other disorders currently treated with spinal fusion will be replaced by TDR especially in patients older than 65 years. It is more likely that practices have to proactively seek methods to increase the rate of TDR surgeries. However, we risk increasing the number of complications and poor outcomes and as such, patients, the FDA, and lawyers will ultimately determine the frequency of TDR surgeries similar to what occurred with early pedicle screw fixation [12,17,27,38]. Already we see insurance companies denying payments for TDR surgeries, and this has had a chilling effect on the rate of adoption of this treatment. Furthermore, the claim that TDR may be equivalent or even better than fusion has not been substantiated by long-term follow-up [32]. It is hoped that the data in this study will provide some guide as to the expectations for the pool of patients indicated for TDR surgery and that there will be greater emphasis on indications and patient selection more so than on technique and economics.

## References

- [1] Albee FH. Transplantation of a portion of the tibia in to the spine for Pott's disease. *JAMA* 1911;57:885–6.
- [2] Hibbs RA. An operation for progressive spinal deformities. *N Y Med J* 1911;93:1012–6.
- [3] Weinstein M, Denhoy R, Krishnan A. Disruptive medical technologies. The next big thing in spine. *JP Morgan. North America Equity Research* 2003.
- [4] Bono C, Lee C. Critical analysis of trends in fusion for degenerative disc disease over the last twenty years: influence of technique on fusion and clinical outcome. *Spine* 2004;29:455–63.
- [5] Turner JA, Ersek M, Herron L, Haselkorn J, Kent D, Ciol MA, Deyo R. Patient outcomes after lumbar spinal fusions. *JAMA* 1992;268:907–11.
- [6] Deyo RA, Nachemson A, Mirza SK. Spinal-fusion surgery—the case for restraint. *N Engl J Med* 2004;350:722–6.
- [7] Ivar Brox J, Sorenson R, Friis A, et al. Randomized clinical trial of lumbar instrumented fusion and cognitive intervention and exercise in patients with chronic low back pain and disc degeneration. *Spine* 2003;28:1913–21.
- [8] Fritzell P, Hagg O, Wessberg P, et al. Chronic low back pain and fusion: a comparison of three surgical techniques. A prospective multicenter randomized study from the Swedish Lumbar Spine Study Group. *Spine* 2002;27:1131–41.
- [9] Fritzell P, Hagg O, Wessberg P, Nordwall A. Swedish Lumbar Spine Study Group. Lumbar fusion versus nonsurgical treatment for chronic low back pain: a multicenter randomized controlled trial from the Swedish Lumbar Spine Study Group. *Spine* 2001;26:2521–34.
- [10] Szpalski M, Gunzburg R, Mayer M. Spine arthroplasty. A historical review. *Eur Spine J* 2002;11(Suppl 2):S65–84.
- [11] Bao QB, Yuan HA. Prosthetic disc replacement: the future? *Clin Orthop* 2002;342:139–45.
- [12] Singh K, Vaccaro AR, Albert TJ. Assessing the potential impact of total disc arthroplasty on surgeon practice patterns in North America. *Spine J* 2004;4:195S–201S.
- [13] Lemaire JP, Skalli W, Lavaste F, templier A, Mendes F, Diop A, Sauty V, Laloux E. Intervertebral disc prosthesis: results and prospects for the year 2000. *Clin Orthop* 1997;337:64–76.
- [14] Guyer RD, Ohnmeiss DD. Intervertebral disc prosthesis. *Spine* 2003;28(Suppl):15–23.
- [15] Bao QB, Huan YA. New technologies in spine: nucleus replacement. *Spine* 2002;27:1245–7.
- [16] Tropiano P, Huang RC, Girardi FP, Cammissa FP, Marnay T. Lumbar total disc replacement: seven to eleven-year follow-up. *J Bone Joint Surg Am* 2005;87A:490–6.
- [17] Pointillart V. Cervical disc prosthesis in humans: first failure. *Spine* 2001;26:E90–2.
- [18] Zigler JE, Burd TA, Vialle EN, et al. Lumbar spine arthroplasty. Early results using the ProDisc II: a prospective randomized trial of arthroplasty versus fusion. *J Spinal Disord Tech* 2003;16:352–61.
- [19] Hochschuler SH, Ohnmeiss DD, Guyer RD, et al. Artificial disc: preliminary results of a prospective study in the United States. *Eur Spine J* 2002;11(Suppl 2):106–10.
- [20] Zeegers WS, Bohnen LM, Laaper M, Verhaegen MJ. Artificial disc replacement with the modular type SB Charite III: 2-year results in 50 prospectively studied patients. *Eur Spine J* 1999;8:210–7.
- [21] Mayer HM, Wiechert K, Korge A, et al. Minimally invasive total disc replacement: surgical technique and preliminary clinical results. *Eur Spine J* 2002;11(Suppl 2):124–30.
- [22] Tropiano P, Huang RC, Girardi FP, et al. Lumbar disc replacement: preliminary results with ProDisc II after a minimum follow-up period of 1 year. *J Spinal Disord Tech* 2003;16:362–8.
- [23] Cinotti G, David T, Postacchini F. Results of disc prosthesis after a minimum follow-up period of 2 years. *Spine* 1996;21:995–1000.
- [24] Griffith SL, Shelokov AP, Buttner-Janz K, LeMaire JP, Zeegers WS. A multicenter retrospective study of the clinical results of the LINK SB Charite intervertebral prosthesis. The initial European experience. *Spine* 1994;19:1842–9.
- [25] Delamarter RB, Fribourg DM, Kanim LE, et al. ProDisc artificial total lumbar disc replacement: introduction and early results from the United States clinical trial. *Spine* 2003;20(Suppl):S167–75.
- [26] McAfee PC, Fedder IL, Saredy S, et al. Experimental design of total disc replacement. Experience with a prospective randomized study of the Sb Charite. *Spine* 2003;20(Suppl):S153–62.
- [27] Wigfield CC, Gill SS, Nelson RJ, Metcalf NH, Robertson JT. The new Frenchay artificial cervical joint: results from a two-year pilot study. *Spine* 2002;27:2446–52.
- [28] Mahomed NN, Barrett JA, Katz JN, et al. Rates and outcomes of primary and revision total hip replacement in the United States medicare population. *J Bone Joint Surg Am* 2003;85A:27–32.
- [29] Blumenthal S, McAfee PC, Guyer RD, et al. A prospective, randomized, multicenter Food and Drug Administration investigational device exemptions study of lumbar total disc replacement with the CHARITE artificial disc versus lumbar fusion: part I: evaluation of clinical outcomes. *Spine* 2005;30:1565–75.

- [30] Cinott G, David T, Postacchini F. Results of disc prosthesis after a minimum follow-up period of 2 years. *Spine* 1996;21:995–1000.
- [31] Lemaire JP, Carrier H, Ali-el HS, Skalli W, Lavaste F. Clinical and radiological outcomes with the Charite trademark artificial disc: a 10-year minimum follow-up. *J Spinal Disord Tech* 2005;18:353–9.
- [32] Putzier M, Funk JF, Schneider SV, Gross C, Tohtz SW, Khodadadyan-Klostermann C, Perka C, Kandziora F. Charite total disc replacement—clinical and radiographical results after an average follow-up of 17 years. *Eur Spine J* 2006;15:183–95.
- [33] Heim SE, Arbitol JJ. Complications and strategies for salvage of intervertebral fixation devices. *Orthop Clin North Am* 2002;3392:393–402.
- [34] Lonstein JE. Re: four-year follow-up results of lumbar spine arthrodesis using Bagby and Kuslich lumbar fusion cage. *Spine* 2001;26:1506–8.
- [35] Huang RC, Lim MR, Girardi FP, Cammissa FP. The prevalence of contraindications to total disc replacement in a cohort of lumbar surgical patients. *Spine* 2004;29:2538–41.
- [36] Wong DA, Annesser B, Birney TJ, Kumar A, Lamond R, Johnson SD, Jatana S, Ghiselli G. Contraindications to total disc arthroplasty in fusion patients including analysis of facet arthrosis. Paper #112. Paper presented at: the AAOS 73rd Annual Meeting; March 22–26, 2006; Chicago, IL.
- [37] Bertagnoli R, Kumar S. Indications for full prosthetic disc arthroplasty: a correlation of clinical outcome against a variety of indication. *Eur Spine J* 2002;11(Suppl 2):131–6.
- [38] Sott AH, Harrison DJ. Increasing age does not affect good outcome after lumbar disc replacement. *Int Orthop* 2000;24:50–3.
- [39] McAfee PC. The indications for lumbar and cervical disc replacement. *Spine J* 2004;4:177S–81S.
- [40] Van Ooij A, Oner FC, Verbout AJ. Complications of artificial disc replacement: a report of 27 patients with the SB Charite disc. *J Spinal Disord Tech* 2003;16:369–83.
- [41] Huang RC, Girardi FP, Cammissa FP, Tropiano P, Marnay T. Long-term flexion-extension range of motion of the ProDisc total disc replacement. *J Spinal Disord Tech* 2003;16:435–40.
- [42] Huang RC, Girardi FP, Cammissa FP Jr, Wright TM. The implications of constraint in lumbar total disc replacement. *J Spinal Disord Tech* 2003;16:412–7.
- [43] Gardner A, Pande KC. Graf ligamentoplasty. A 7-year follow-up. *Eur Spine* 2002;11(suppl):157S–63S.
- [44] Stoll T, Dubois G, Schwarzenbach O. The dynamic neutralization system for the spine: a multicenter study of a novel non-fusion system. *Eur Spine* 2002;11(Suppl):170S–8S.
- [45] Senegas J. Mechanical supplementation by non-rigid fixation in degenerative intervertebral lumbar segments: The Wallis system. *Eur Spine* 2002;11(Suppl):164S–9S.