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ABSTRACT

Background

Previous reports of lumbar total disc replacement (TDR) have described significant complications. The US Food and Drug Administration (FDA) investigational device exemption (IDE) study of the Charité artificial disc represents the first level I data comparison of TDR to fusion.

Methods

In the prospective, randomized, multicenter IDE study, patients were randomized in a 2:1 ratio, with 205 patients in the Charité group and 99 patients in the control group (anterior lumbar interbody fusion [ALIF] with BAK cages). Inclusion criteria included confirmed single-level degenerative disc disease at L4-5 or L5-S1 and failure of nonoperative treatment for at least 6 months. Complications were reported throughout the study.

Results

The rate of approach-related complications was 9.8% in the investigational group and 10.1% in the control group. The rate of major neurological complications was similar between the 2 groups (investigational = 4.4%, control = 4.0%). There was a higher rate of superficial wound infection in the investigational group but no deep wound infections in either group. Pseudarthrosis occurred in 9.1% of control group patients. The rate of subsidence in the investigational group was 3.4%. The reoperation rate was 5.4% in the investigational group and 9.1% in the control group.

Conclusions

The incidence of perioperative and postoperative complications for lumbar TDR was similar to that of ALIF. Vigilance is necessary with respect to patient indications, training, and correct surgical technique to maintain TDR complications at the levels experienced in the IDE study.

Key Words lumbar spine, total disc replacement, artificial disc, complications, lumbar fusion, randomized study, IDE trial. ***SAS Journal.*** **Winter 2007; 1; 20–27.** DOI: SASJ-2006-0004-RR

INTRODUCTION

Total disc replacement (TDR) has been used to treat lumbar degenerative disc disease for 2 decades with varying success rates. As with any procedure in any surgical discipline, complications can and do occur. The Charité artificial disc (DePuy Spine, Raynham, Mass) was first made commercially available outside the United States in 1987. In October 2004, the device was approved by the US Food and Drug Administration (FDA) for the treatment of lumbar degenerative disc disease (DDD) at 1 level: L4-5 or L5-S1.

The literature contains multiple reports of the worldwide experience with lumbar TDR, almost all of which are retrospective case series or case reports that have been described previously in review articles.[1-4] Because the Charité artificial disc has the longest history of any TDR device, more complications have been reported in the literature for it than for other TDR devices. In 2003, van Ooij et al.[5] reported 27 complications of TDR with the Charité artificial disc. However, what was not reported, as described by McAfee,[6] was that these complications came from a series of 500 patients with widely varying patient indications, the use of early basic instrumentation, and, in some cases, inadequate sizing of the prosthesis.

Zeegers et al.[7] reported a retrospective series of 50 patients implanted with the Charité artificial disc with a complication

rate of 13%. In a series of 46 patients, Cinotti et al.[8] reported a reoperation rate of 19.5%. Other authors have reported similar or lower complication rates from TDR with the Charité artificial disc. Lemaire et al.[9] reported a total of 21 complications, both major and minor, in their series of 100 patients with minimum 10-year follow-up. David[10] reported a 14% complication rate in 197 patients followed for 10 years. All of these series were retrospective, involving the early experience of the authors with lumbar TDR. Since the time of these early implantations with the Charité artificial disc, patient selection criteria, surgical implantation instruments, and surgical technique have all evolved, in part as a response to the early failures reported. To date, an analysis of complications of lumbar TDR, using prospective, narrow, clinically defined indications and a standardized surgical technique with modern instrumentation have not been reported as part of a prospective, randomized, controlled trial.

MATERIALS AND METHODS

Between May 2000 and April 2002, 304 patients underwent surgery in this prospective, randomized, nonblinded, FDA-approved study at 14 investigational sites across the United States. Before beginning patient enrollment, each site obtained local institutional review board approval for conducting the study. Complete inclusion and exclusion criteria were previously described by both Geisler et al.[11] and Blumenthal et al.[12] The primary inclusion criteria were single-level symptomatic DDD at L4-5 or L5-1 confirmed by provocative discography, back or leg pain without nerve root compression (radiculopathy) with a visual analog scale (VAS) score of ≥40 (range: 1–100) and an Oswestry Disability Index 2.0[13] score of ≥30 (range: 1–100), ability to tolerate an anterior abdominal approach, and failure to respond to nonoperative treatment for a period of at least 6 months. The primary exclusion criteria were multilevel symptomatic DDD, previous thoracic or lumbar fusion, current or previous lower lumbar fracture, osteoporosis, spondylolisthesis >3 mm, spondylosis, or scoliotic deformity greater than 11°.

Patients were randomly assigned in a 2:1 ratio to one of 2 groups. The investigational group received TDR with the Charité artificial disc. The control group received anterior lumbar interbody fusion (ALIF) with BAK threaded fusion cages (Zimmer Spine, Minneapolis, Minn) packed with iliac crest autograft. A total of 205 patients were enrolled in the investigational group, and 99 patients were enrolled in the control group. There was no significant difference between the groups with respect to all demographic variables with the exception of mean weight, which was slightly higher in the control group (Table 1).

A detailed surgical technique for implantation of the Charité artificial disc was previously described by Geisler.[14] Patients enrolled in the study were implanted with either the investigational device or the control device through an open (non–minimally invasive) anterior retroperitoneal approach. Clinical and radiographic outcomes were previously described by Blumenthal et al.[12] and McAfee et al.,[15] respectively. The follow-up rate at 24 months within the time window described by the protocol was 91.5% in the investigational group and 89.2% in the control group.

Adverse events were recorded throughout the study, both perioperatively and postoperatively, until the last enrolled patient reached the end of the 24-month follow-up period in April 2004. The reporting of adverse events followed adherence to strict FDA regulations concerning adverse event reporting in an investigational device exemption (IDE) study. All patient files and case report forms were monitored by a contract research organization to ensure that all adverse events were captured and reported to the FDA and local institutional review boards. Final adverse event data from the randomized arm of the study was verified as complete and submitted to the FDA in August 2004, before FDA approval of the investigational device in October 2004.

Adverse event data were reviewed by the authors. A large number of reported adverse events in an IDE study are often unrelated to the treatment. Examples include reported events such as dermatological events, psychological events, drug allergy, motor vehicle accidents, and coumadin overdoses. Some adverse events reported were secondary to another event, such as fever with infection and leg pain with a neurological event. Some reported adverse events are normal occurrences after spinal surgery, such as incision pain and musculoskeletal spasms. These adverse events, not related to the procedure or the approach, were excluded from this review to create a true account of the perioperative and postoperative complications associated with a TDR procedure in comparison to an ALIF procedure.

STATISTICAL METHODS

Fisher's exact test was used to test categorical variables between the 2 groups. Student's *t* test was used to test the difference between means.

RESULTS

The total number of subjects with reported adverse events was 155 (75.6%) in the investigational group (205) and 77 (77.8%) in the control group (99). This total includes all adverse events reported, including the ones excluded from this review. Therefore, approximately one quarter of all patients enrolled in the study had no reported adverse events.

Table 1

Patient Demographics: Food and Drug Administration Investigational Device Exemption Study of the Charité Artificial Disc

	Investigational Group (N = 205)	Control Group (N = 99)	*P*
Gender, no. (%)			
Men	113 (55.1)	44 (44.4)	.088
Women	92 (44.9)	55 (55.6)	
Age, y			
Mean (SD)	39.6 (8.16)	39.6 (9.07)	.946
Median	40.0	39.0	
Range	19–60	20–60	
>45, no. (%)	47 (22.9)	30 (30.3)	.205
≤45, no. (%)	158 (77.1)	69 (69.7)	
Race, no. (%)			
White	188 (91.7)	87 (87.9)	.540
African American	8 (3.9)	5 (5.0)	
Other	9 (4.4)	7 (7.1)	
Height, cm			
Mean (SD)	172.3	173.6	.249
Median	170.2	172.7	
Range	150–201	155–196	
Weight, kg			
Mean (SD)	77.5 (15.67)	81.7 (16.46)	.035
Median	77.1	79.4	
Range	46–120	51–122	
Body mass index[a]			
Mean (SD)	26.0 (4.23)	27.0 (4.76)	.056
Median	26.0	26.9	
Range	17–39	18–40	
Previous spinal surgery, no. (%)			
Yes	70 (34.1)	33 (33.3)	.999
No	135 (65.9)	66 (66.7)	
Normal activity level before experiencing back pain, no. (%)			
Active	188 (91.7)	86 (86.9)	.284
Moderate	15 (7.3)	11 (11.1)	
Light	1 (0.5)	2 (2.0)	
Minimal	1 (0.5)	0	
Activity level at enrollment, no. (%)			
Active	9 (4.4)	1 (1.0)	.064
Moderate	26 (12.7)	5 (5.0)	
Light	54 (26.3)	27 (27.3)	
Minimal	116 (56.6)	66 (66.7)	
Preoperative work status, no. (% working)	109 (53.2)	57 (57.6)	.470

Note. Fisher's exact test was used to test categorical variables. Student's *t* test was used to test means.

[a]Weight (in kg) divided by height (in m)2.

Approach-Related Events

The rate of approach-related complications in all 304 patients was 9.9% (30/304) and was similar between the 2 groups, with 9.8% (20/205) in the investigational group and 10.1% (10/99) in the control group (Table 2). The rate of venous injury in the investigational group (4.4%) was twice that of the rate in the control group (2.0%). The overall rate of retrograde ejaculation in men was 4.1% (6/147), and it was slightly higher in the control group (5.5%, 3/92) compared with the investigational group (3.3%, 3/55). Of these 6 cases of retrograde ejaculation in both groups, 1 resolved spontaneously 17 months after onset, 3 continued at the latest follow-up, and the prognosis for the last 2 cases of retrograde ejaculation is unknown. There were no cases of either arterial thrombosis or deep vein thrombosis in either group. There was no significant difference with respect to incidence of approach-related complications in the TDR group at L4-5 versus L5-S1 ($P = .145$, Fisher's exact test).

Table 2

Approach-Related Complications: Food and Drug Administration Investigational Device Exemption Study of the Charité Artificial Disc

	Investigational Group (N = 205)	Control Group (N = 99)	*P*
All approach related, no. (%)	20 (9.8)	10 (10.1)	.925
Venous injury, no. (%)	9 (4.4)	2 (2.0)	
Retrograde ejaculation, no. (%)[a]	3 (3.3)	3 (5.5)	.515
Ileus, no. (%)	2 (1.0)	1 (1.0)	
Perioperative vein thrombosis, no. (%)	2 (1.0)	0	
Clinically significant blood loss >1500 mL, no. (%)	1 (0.5)	2 (2.0)	
Incisional hernia, no. (%)	1 (0.5)	2 (2.0)	
Epidural hematoma, no. (%)	1 (0.5)	0	
Dural tear, no. (%)	1 (0.5)	0	
Deep vein thrombosis, no. (%)	0	0	
Arterial thrombosis, no. (%)	0	0	

Note. Fisher's exact test was used to test categorical variables.
[a]Of 92 men in the investigational group and 55 men in the control group.

Infection

The rate of all infections was higher in the investigational group (12.7%) compared with the control group (8.1%) (Table 3). The rate of superficial wound infection was 3 times higher in the investigational group (6.3%) compared with the control group (2.0%), but there was no significant difference between the groups ($P = .103$). Deep wound infections requiring irrigation and debridement or intravenous antibiotics did not occur in either group. There were 3 (3.0%) cases of iliac crest donor site infection in the control group.

Table 3

Infection Complications: Food and Drug Administration Investigational Device Exemption Study of the Charité Artificial Disc

	Investigational Group (N = 205)	Control Group (N = 99)	*P*
All infection complications, no. (%)	26 (12.7)	8 (8.1)	.233
Superficial wound with incision site pain, no. (%)	13 (6.3)	2 (2.0)	.103
Other non–wound related, no. (%)	5 (2.4)	1 (1.0)	
Urinary tract infection, no. (%)	5 (2.4)	1 (1.0)	
Wound swelling, no. (%)	2 (1.0)	0	
Pulmonary complication, no. (%)	1 (0.5)	0	
Peritonitis, no. (%)	0	1 (1.0)	
Iliac crest donor site, no. (%)	0	3 (3.0)	

Note. Fisher's exact test was used to test categorical variables.

Neurological Events

As previously reported and as described in detail by Geisler et al., the overall rate of neurological complications was equivalent between the 2 groups (Table 4). Geisler divided the neurological complications into categories of major, minor, and other. The rate of major neurological adverse events, which included burning or dysthetic pain, motor deficit, or nerve root injury, was 4.4% in the investigational group and 4.0% in the control group ($P = .887$). The rate of minor neurological events, which included numbness, was 9.8% in the investigational group and 8.1% in the control group.

Table 4

Neurological Complications: Food and Drug Administration Investigational Device Exemption Study of the Charité Artificial Disc

	Investigational Group (N = 205)	Control Group (N = 99)	*P*
All neurological complications, no. (%)	33 (16.1)	17 (17.2)	.813
Major, no. (%)	9 (4.4)	4 (4.0)	.888
Burning or dysthetic pain	5 (2.4)	3 (3.0)	
Motor deficit—index level related	3 (1.5)	1 (1.0)	
Nerve root injury	1 (0.5)	0	
Minor, no. (%)	20 (9.8)	8 (8.1)	
Numbness—index level related	20 (9.8)	7 (7.1)	
Numbness lower sacral root distribution	0	1 (1.0)	
Other, no. (%)	8 (3.9)	8 (8.1)	
Numbness—non–index level-related	5 (2.4)	4 (4.0)	
Reflex change	2 (1.0)	2 (2.0)	
Positive Waddell signs	1 (0.5)	1 (1.0)	
Mechanical signs (SLR)	0	1 (1.0)	

Note. SLR = straight leg raise. Fisher's exact test was used to test categorical variables.

Fusion Treatment–Related and Prosthesis-Related Complications

The rate of pseudarthrosis in the control group was 9.1% (9/99) (Table 5). There were 8 (3.9%) prosthesis-related complications in the investigational group, which included 7 cases of subsidence of the prosthesis endplate into the vertebral endplate (≥2 mm) and 1 cases of implant displacement >3 mm. There were no catastrophic device failures and no cases of osteolysis in the investigational group. A total of 18 (18.2%) patients in the control group reported bone graft donor site pain. All reports of donor site pain arose within 42 days after surgery.

Table 5

Fusion Treatment–Related Events, Device-Related Events, and Reoperation Index Level: Food and Drug Administration Investigational Device Exemption Study of the Charité Artificial Disc

	Investigational Group (N = 205)	Control Group (N = 99)	*P*
Fusion treatment related, no. (%)	0	27 (27.3)	
Nonunion/pseudarthrosis	0	9 (9.1)	
Bone graft donor site pain	0	18 (18.2)	
Prosthesis related, no. (%)	8 (3.9)	1 (1.0)	.163
Collapse or subsidence of implant into adjacent vertebrae	7 (3.4)	1 (1.0)	
Implant displacement	1 (0.5)	0	
Additional surgery index level, no. (%)	11 (5.4)	9 (9.1)	.127
Revision	5 (2.4)	0	
Reoperation	4 (2.0)	8 (8.1)	
Removal	2 (1.0)	1 (1.0)	

Note. Fisher's exact test was used to test categorical variables.

Reoperations

Of these 9 patients in the control group with a pseudarthrosis, 8 had supplemental transpedicular fixation after the index surgery for the treatment of their pseudarthrosis. One patient in the control group underwent removal of the BAK cages as a result of misplacement, for a total of 9 reoperations (9.1%). The cages were replaced with an alternative ALIF cage/graft composite and concomitant posterior instrumented fusion. A total of 11 (5.4%) patients in the investigational group had a reoperation at the index level ($P = .127$). Of these, 5 were revisions to a new Charité prosthesis, usually with a smaller footprint; 4 were supplemental posterior fusions with transpedicular fixation; and 2 were removals with conversion to an ALIF and concomitant instrumented posterior fusion (Table 5).

Other Complications

Other reported complications are shown in Table 6.

Table 6

Other Complications: Food and Drug Administration Investigational Device Exemption Study of the Charité Artificial Disc

	Investigational Group (N = 205)	Control Group (N = 99)
All other complications, no. (%)	9 (4.4)	4 (4.0)
Adjacent level DDD	2 (1.0)	1 (1.0)
HNP adjacent level	2 (1.0)	1 (1.0)
Spondylolisthesis	1 (0.5)	1 (1.0)
Spinal stenosis	1 (0.5)	0
Annulus ossification	1 (0.5)	0
Calcification resulting in bridging trabecular bone	1 (0.5)	0
Other lumbar degenerative	1 (0.5)	0
Facet joint degeneration	0	1
Death narcotic related	1 (0.5)	0

Note. DDD = degenerative disc disease; HNP = herniated nucleus pulposus.

Pain

An adverse event related to postoperative pain was reported for 52.7% (108/205) of patients in the investigational group and for 52.5% (52/99) of patients in the control group. Many patients had multiple reports of pain-related adverse events. Individual adverse event reports for back pain totaled 59 (28.8%) in the investigational group and 32 (32.3%) in the control group. For lower extremity pain alone, the rate was 30.7% (63) in the investigational group and 25.3% (25) in the control group. The rate for a report of both back and lower extremity pain at the same time was 11.7% (24) in the investigational group and 14.1% (14) in the control group.

DISCUSSION

A key point that is often lost in the literature is that the majority of complications related to TDR procedures, particularly complications necessitating revision or removal of a prosthesis, are unrelated to a specific device. In addition, the literature contains just a small subsection of the total worldwide experience with lumbar TDR. A wider experience describing complications and revision strategies for the Charité artificial disc and other lumbar prostheses, including important revision approach considerations, has been previously described by McAfee et al.[16] This is a significant educational resource on the topic of complications resulting from lumbar TDR procedures.

In this study, the rate of perioperative venous injury was twice as high in the investigational group compared with the control group. This is most likely because of issues with retraction of the great vessels at L4-5 to implant the investigational device. The prosthesis must be placed in the exact center of the disc space, but complete vessel retraction to the right at L4-5 is sometimes difficult to achieve, depending on the patient's vascular anatomy. One other possible cause of the venous injuries in the investigational group may have been the use of first-generation instrumentation throughout the randomized phase of the study. For example, the original endplate inserter had a 30° offset, which forced the instrument laterally onto the patient's left abdomen while inserting the prosthesis endplates. This has since been corrected to a 0° offset with the introduction of new instrumentation (Centreline TDR, DePuy Spine, Raynham, Mass).

Because the Charité prosthesis incorporates sharp teeth for vertebral fixation, great care must be taken to avoid a vessel laceration when implanting the prosthesis endplates. Of the 11 perioperative venous injuries, only 1 resulted in blood loss of more than 1500 mL. The overall rate of venous injury in all 304 patients enrolled in the study was 3.6%. This is 2.5 times higher than the rate of venous injury reported by Brau et al.[17] in 1315 consecutive ALIF procedures (1.4%). However, the patients in the Brau series may have benefited from the ability to place fusion devices or femoral rings anterolaterally when vessel retraction was insufficient. This was not possible in the IDE study.

The higher rate of superficial wound infection in the investigational group may be attributable to the investigational group being more active preoperatively (and postoperatively) compared with the control group. As reported in the clinical results article by Blumenthal et al.,[12] although the difference between the groups was not significant, the investigational group had a higher rate of active or moderately active patients preoperatively compared with the control group.

The rate of retrograde ejaculation in male patients enrolled in the study was 4.1%. This rate was higher than the rate of 0.3% reported by Brau[18] in a study of 17 spine surgeons performing 686 ALIF procedures through a minilaparotomy approach. There is no obvious reason for the disparity between the rate experienced in the IDE trial and the experience of Brau. Sasso et al.[19] reported a retrograde ejaculation rate of 1.7% in 116 consecutive cases of ALIF via a retroperitoneal approach and a rate of 13.3% in 30 consecutive cases of ALIF using a transperitoneal approach. Sasso et al.[19] recommend avoidance of the transperitoneal approach, except in cases of revision at L5-S1, to reduce the incidence of retrograde ejaculation in male patients. Early identification of the sympathetic plexus and avoiding the use of monocautery also will reduce the incidence of retrograde ejaculation in male patients undergoing a retroperitoneal approach to the lumbar spine.

As previously described by Geisler et al.,[11] the rate of major neurological complications was small in both groups, and the overall rate of neurological adverse events was equivalent between both groups. Therefore, it can be expected that the

incidence of neurological complications as a result of TDR with the Charité artificial disc will be no greater than for ALIF procedures.

Subsidence occurred in 7 patients enrolled in the investigational group. We believe that these cases were technique related. It is important to perform a complete discectomy before prosthesis insertion. However, as with an ALIF procedure, removal of the bony vertebral endplate in the central part of the vertebral body will result in exposure of soft cancellous bone, which is unable to biomechanically support the prosthesis under normal loading, causing subsidence. We believe that the discectomy may have been too aggressive in these 7 cases, and we caution against removing the bony endplate during the discectomy phase of the procedure. Further, it is important to size the prosthesis correctly and maximize the surface area so that the footprint of the device covers as much of the vertebral rim of cortical bone as possible. Since FDA approval, 2 additional footprint sizes have been added to assist in matching up the footprint size to the patient's vertebral anatomy.

The rate of confirmed nonunion in the control group (9%) further validates the study performed by Kuslich et al.[20] using BAK cages for standalone interbody fusion in narrowly indicated patients. In the 7 cases of revision to a new prosthesis (5) or removal and replacement with interbody fusion (2), all of the devices were placed too anteriorly, which led to migration or displacement of the prosthesis. Placement of the prosthesis too anteriorly can lead to migration or core displacement because adequate posterior disc space height is not achieved. Therefore, it is imperative that the prosthesis be placed in the ideal position in the sagittal plane, 2 mm dorsal to the exact center of the disc space, with particular attention to fluoroscopic landmarks to avoid parallax-related positioning errors. Revisions and reoperations in the randomized arm of the study, as well as the training and continued access arms, are described in greater detail by McAfee et al.[21]

It is unclear whether many of the complications classified as "other" were a result of the surgical intervention, or whether they were not realized preoperatively. This may be the case for reported events such as postoperative spondylolisthesis and spinal stenosis in both groups. As described by McAfee et al.,[21] 2 pars fractures in the investigational group were evident retrospectively on preoperative radiographs that were not diagnosed until after the index surgery. Inclusion of these patients in the study was a protocol deviation, and because the fractures were present preoperatively and not caused by the device or the procedure, they are not classified as adverse events or complications. The rate of adjacent-level disc disease is exceedingly low out to 24 months. However, we believe this topic needs to be studied with long-term data because adjacent-level disc disease does not normally present itself in such a short timeframe.

It is unknown how many reports of postoperative pain are true complications in this study, related to either the device or procedure in either group. The protocol did not specify the reporting threshold for postoperative pain. General guidelines to the investigative sites recommended that pain be reported as an adverse event if the pain is (1) (a) possibly, (b) probably, or (c) definitely related to the device or the intervention; (2) more severe than the patient experienced before the intervention; or (3) represented in a new area where the patient did not have pain before the intervention. These guidelines were not adequately communicated to the investigators in the study, so it is not known how many of these adverse event reports fit the definition described previously mentioned.

Pain after lumbar surgery is often expected. With respect to point 1a above, almost all patients experience pain related to the procedure in the immediate postoperative timeframe and for several weeks after surgery. At 24 months of follow-up, the mean VAS score was 31.2 in the investigational group and 37.5 in the control group. This represents a significant improvement in pain compared with baseline levels, but clearly some patients in both groups were not pain free. Is postoperative pain a complication of a lumbar TDR procedure or a lumbar fusion procedure? If so, when? In terms of classifying pain as a complication, we should be more concerned with instances of pain fitting the definition of points 2 and 3; pain more severe than before the intervention, and pain in a new area. Perhaps point 2 should be expanded to include the same amount of pain as before the intervention, because certainly "breaking even" on a patient's pain is not a good result for the patient. Unfortunately, because of the reporting of pain-related adverse events in this study, it is not possible to adequately address the true rate of pain-related complications.

Complications occur with every surgical procedure in every surgical discipline. However, specific steps can be taken to minimize perioperative and postoperative surgical complications, particularly with respect to lumbar TDR procedures. The first of these steps is correct patient indications. Clinical and radiographic results previously described, as well as the complications reported here, are directly related to the narrow patient indications used in this IDE study. Use of the Charité artificial disc, or any spine surgery device, in nonindicated patients may not yield the same results and may lead to unintended, avoidable complications.

Both training and experience are important in terms of minimizing complications. Each of the investigators in this IDE study had extensive experience with ALIF procedures and the retroperitoneal approach to the lumbar spine before enrolling patients in the study. It is imperative that surgeons wishing to

add lumbar TDR procedures to their armamentarium attend a company-sponsored training course on the procedure and perform the procedure without shortcuts. This holds true for other TDR prostheses as well, because each prosthesis has its own surgical technique and instrumentation. It is recommended that after training, surgeons observe at least 1 case in the operating room before attempting the procedure. Further, for those surgeons who have performed few or no ALIF procedures, it is recommended that they first become comfortable with ALIF before including TDR procedures in their practice.

The senior author prefers to perform his own approaches. However, the coauthors believe an approach surgeon is a valuable addition to the surgical team, to assist with mitigating perioperative complications, as well as for prescreening patients who have had previous abdominal surgery for potential problems during the approach. In our opinion, major neurological complications may be minimized by taking care not to overdistract the disc space. The goal of TDR (as with interbody fusion) is to restore the original disc height relative to the heights of adjacent discs. The goal is not to increase disc height to the maximum possible.

TDR procedures differ from interbody fusion procedures because exact placement of the prosthesis is required for the best results. This is not necessarily true for all interbody fusion procedures. Particular attention should be paid to device placement in the ideal position, as described by McAfee et al.[15]: 2 mm dorsal to the midpoint of the disc space in the sagittal plane and in the exact center in the coronal plane. If the prosthesis is placed too anteriorly, migration or displacement are more likely to occur. If initial placement of the prosthesis is too anterior on fluoroscopy, we recommend repositioning of the prosthesis before closing the wound. Revision anterior lumbar surgery is often difficult because of scarring in between and around the vessels; therefore, repositioning the prosthesis during the index surgery may eliminate the need for a potentially life-threatening revision surgery in the future.

Incidence of perioperative and postoperative complications for lumbar TDR was similar that of ALIF. Vigilance is necessary with respect to patient indications, training, and correct surgical technique to maintain TDR complications at the levels experienced in the IDE study.

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Institutional review board approval was obtained at the 14 hospital sites that participated in the original IDE study, in accordance with FDA regulations.

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