ELSEVIER

Seminars in
SPINE
SURGERY

Outcomes of CHARITE Lumbar Artificial Disk versus Fusion: 5-Year Data

Richard D. Guyer, MD,* Issada Thongtrangan, MD,† and Donna D. Ohnmeiss, DrMed†

Lumbar total disk replacement (TDR) has been used for the treatment of painful disk degeneration since the 1980s. Not until the Food and Drug Administration (FDA) regulated trials in the United States initiated in 2000 had there been formal prospective randomized trials evaluating the results of this technology compared with fusion, the traditional surgical treatment for disk degeneration. The purpose of this article was to provide a commentary on the results of the 5-year follow-up of CHARITÉ artificial disk (DePuy Spine, Raynham, MA) published by Guyer et al (Spine J 9:374-386, 2009) and to comment on this work in the context of other TDR literature. In the study, results of TDR using the CHARITÉ artificial disk, were compared with those of anterior lumbar interbody fusion (ALIF) with BAK cages and iliac crest autograft, for the treatment of single-level degenerative disk disease from L4 to S1. The results of the 5-year, prospective, randomized multicenter study were consistent with the 2-year outcomes. The TDR group had improved functional outcomes based on visual analog pain scales, Oswestry Disability Index, and the SF-36 Physical component scores. CHARITÉ patients reached a greater rate of part- and full-time employment and a statistically lower rate of long-term disability compared with ALIF patients. Radiographically, the range of motion at the index and adjacent levels was maintained. The incidence of adjacent level degeneration was lower for TDR than in the fusion group. The results of this study indicate that TDR with the CHARITE produced results similar or superior to ALIF at 5-year follow-up.

KEYWORDS total disc replacement, lumbar spine, randomized study, clinical outcome, anterior lumbar interbody fusion

Degenerative disk disease (DDD) is a major cause for chronic low back pain, with lumbar segmental instability in which surgical intervention is required when conservative treatment fails. Spinal fusion for DDD is the most common accepted treatment used to eliminate abnormal motion and instability at the symptomatic degenerated levels, and thereby reduce or eliminate low back pain. Artificial total disk replacement (TDR), as an alternative to spinal arthrodesis, is an option for surgically treating lumbar DDD. By performing lumbar TDR, it is postulated that the patient's intervertebral segment motion is restored and maintained, while the adjacent level is prevented from nonphysiologic loading, and thus the pain is relieved. The first described TDR was the Fernstrom steel ball endoprosthesis in the late 1950s. Since that time, multiple disk replacement prostheses have been designed for use in the lumbar spine. The first prosthesis designed to be commercially distributed as an artificial disk was initiated in 1982 by Schellnack and Buttner-Janz.[1] Currently, many different lumbar total disk prostheses are available and approved for the European and other markets. In the United States, Investigational Device Exemption (IDE) trials have led to Food and Drug Administration (FDA) approval for Charité and ProDisc-L prostheses. Since that time, several other articles demonstrated the promising outcomes of lumbar TDR. The purpose of this article was to provide a review and commentary on the safety and effectiveness at the 5-year follow-up of the CHARITÉ artificial disk, which was published by Guyer et al,[2] and to comment on this work in the context of other literature. This is the same cohort of the original 2-year follow-up FDA IDE trial, which was published earlier.[3,4]

*Texas Back Institute, Plano, TX.
†Texas Back Institute Research Foundation, Plano, TX.
Address reprint requests to Richard D. Guyer, MD, Texas Back Institute, 6020 W Parker Road Ste 200, Plano, TX 75093. E-mail: plane@texasback.com

Study Design

The Charite FDA IDE trial was initiated in 2000. The design was a multicenter, prospective, randomized trial using a 2:1 assign-

1040-7383/$-see front matter © 2012 Elsevier Inc. All rights reserved.
doi:10.1053/j.semss.2011.11.007

ment ratio. There were 304 patients, 205 in the TDR group and 99 in the control group, from 14 centers. The control group received anterior lumbar interbody fusion (ALIF) with BAK cages and iliac crest autograft. This control procedure was used rather than an anterior/posterior combined procedure to eliminate the possible confounder of the added posterior procedure. The original study protocol had a 2-year follow-up. After the 2-year follow-up was completed, based on a request from the FDA, a study was initiated to collect data for 3-, 4-, and 5-year follow-up periods. Six of the original 14 centers elected to not participate in the additional study.

As with any study, there is always a challenge with patients who are lost to follow-up. Generally, the longer the study duration, the more patients will be lost. The authors performed multiple analyses to investigate any potential impact on results due to the 6 centers opting to not participate in the post-24-month follow-up as well as the potential impact of patients lost to follow-up during the 5 years. In the additional analyses, in the BAK group, there was no significant difference in the preoperative visual analog scale (VAS) and Oswestry Disability Index (ODI) scores when comparing those completing 5-year follow-up with those who were either lost to follow-up or who were treated at a center that opted out of the extended follow-up study. In the TDR group, the patients who competed the 5-year follow-up had significantly lower preoperative scores than those who were either lost to follow-up or from a center not participating in the long-term follow-up. However, in the fusion and TDR groups, there was no difference in the 2-year outcomes for the 5-year completers and those who were lost to follow-up or those treated at a site that opted out of the 5-year follow-up.

There were 133 randomized cases (90 TDR and 43 ALIF with BAK cages and iliac crest autograft patients). There was no significant difference between the 2 groups (CHARITE and BAK fusion) with respect to gender, age, race, height, body mass index, incidence of prior spinal surgery, activity level before the onset of symptoms, activity level at the time of enrollment, or preoperative working status.

Outcome Measures

Overall Success Rate

It has become common for FDA trials to now have a primary outcome measure of a success rate. There is not such a validated or commonly used success criteria for spine surgery. The criteria used incorporated a combination of the ODI score as a measure of patient function and several measures related to safety. The overall success score was based on 4 components. A patient had to meet each of the criteria to be considered as having a successful outcome:

- Improvement of at least 15 points on ODI from the baseline value.
- No device failure requiring additional surgery (defined as requiring revision, reoperation, or removal).
- Absence of major complications (defined as major vessel injury, neurological damage, nerve root injury, or death).
- Maintenance or improvement of neurological status.

Table 1 Both Groups Maintained Significant Improvement With No Significant Change in the Oswestry or VAS Scores From 2 to 5 Years After Surgery

Outcome Assessment	TDR	Fusion
Oswestry		
Preoperative	47.7	50.0
24 month	23.2	25.6
5 years	25.4	21.7
VAS		
Preoperative	69.7	70.4
2 years	27.2	32.8
5 years	31.1	29.8

Secondary Outcome Measures

Secondary outcome measures included the ODI, VAS assessing pain intensity, SF-36, work status, patient satisfaction, reoperations, and radiographic data, including range of motion (ROM) and adjacent segment degeneration. The minimal clinically important difference (MCID) for ODI scores has been reported to be 10 with a 95% confidence interval that ranged to 13.[5] For the current study, the value of a 15-point improvement was used. The MCID value for VAS has been estimated to be between an 18- and 19-point improvement from the preoperative scores.[5] For the current study, the percentage of patients who experienced at least a 20-point improvement was calculated.

Clinical Outcomes

Overall Success

At 5-year follow-up, the overall clinical success criteria were met in 57.8% of the TDR group and 51.2% of the ALIF group. At the 2-year follow-up, these figures were 65.2% and 60.6%, respectively. This primary outcome measure provided a high degree of confidence that the CHARITÉ group was noninferior to the BAK group based on a Blackwelder's analysis as defined in the original protocol for the 2-year study.

Oswestry Disability Index

ODI values significantly improved at all postoperative time points compared with baseline in both treatment groups. There was no statistical difference between the groups in terms of ODI scores, at the 2- and 5-year postoperative time points (Table 1). The percentage of patients who reached the MCID-based criteria of at least a 15-point improvement in ODI was similar at the 5-year follow-up (Table 1).

VAS Pain Scores

The mean VAS scores improved significantly in both groups from preoperative to 2- and 5-year follow-up (Table 1). There were no statistically significant differences between the groups at any of these periods, including the percentage of patients with at least a 20-point improvement at the 5-year follow-up (Table 1).