SPINE Volume 31, Number 19, pp 2270–2276

Evaluation of Surgical Volume and the Early Experience With Lumbar Total Disc Replacement as Part of the Investigational Device Exemption Study of the Charité Artificial Disc

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Study Design. A prospective, randomized, multicenter, Food and Drug Administration regulated Investigational Device Exemption (IDE) clinical trial.

Objectives. To discern whether there is a correlation between surgical volume and clinical outcomes, as well as the complication rate and perioperative data points, for lumbar total disc replacement. To examine the early experience for lumbar total disc replacement as part of an IDE study.

Summary of Background Data. To our knowledge, an analysis of the effect of surgical volume has not been performed for any spine surgical procedure. Prior reports of the early experience with lumbar total disc replacement consist of retrospective reviews with nonspecific indications.

Methods. An analysis was performed of the Food and Drug Administration IDE Study of the Charité Artificial Disc (DePuy Spine, Inc., Raynham, MA). Patients enrolled in the control group were omitted from the analysis. Up to 5 nonrandomized cases (representing the early experience) were performed at each site before beginning the randomized arm of the study. There were 3 comparisons performed: nonrandomized cases (71) *versus* randomized cases (205); randomized cases performed by high-enrolling surgeons *versus* low-enrolling surgeons; and randomized cases at high-volume institutions *versus* low-volume institutions.

Results. The high-enrolling groups had a significantly lower mean hospital stay and operating time compared to the low-enrolling groups ($P < 0.05$). High-enrolling surgeons and institutions showed significantly shorter operating times, length of hospital stay, and complication rates. High-enrolling surgeons had significantly fewer device failures and cases of neurologic deterioration. Mean operating time and hospital stay were significantly lower in the randomized group ($P < 0.05$) compared to the nonrandomized group. Blood loss and approach-related complications were similar between the 2 groups. Device failure requiring removal was 4.2% in the nonrandomized group and 1.5% in the randomized group.

Conclusions. Surgeons and institutions with a high volume of lumbar total disc replacement cases have a reduction in key perioperative and postoperative parameters that provide a clinical and/or economic benefit. Surgeons may expect longer hospital stays, higher blood loss, and a higher rate of certain complications in their early experience with total disc replacement procedures, but there was no effect on clinical outcomes.

Key words: lumbar spine, total disc replacement, artificial disc, surgical volume, randomized study, Investigational Device Exemption trial. **Spine 2006;31:2270–2276**

High-surgical volume is associated with better clinical outcomes across a wide range of procedures and conditions. This has been an intense area of research for insurers, purchasers, and health care consumer groups. Birkmeyer *et al*[1,2] used Medicare claims databases to derive the "evidence based hospital referral" standards of the Leap-Frog Group, a coalition of more than 145 Fortune 500 companies representing 34 million health plan enrollees. Surgeon volume had a significant impact on the clinical results of 10 operative procedures (coronary artery bypass graft, aortic valve replacement, aortic abdominal aneurysm repair, esophagectomy, pancreatic resection, etc.). The investigators stated, "The volume of individual surgeons had more of an impact on outcomes than a hospital's total volume."

The only orthopedic surgical procedures included in these analyses were total hip replacement and total knee replacement, each of which had lower dislocation rates, infections, and complications with high surgical volume. Katz *et al*[3] recently confirmed the data reported for total knee replacement. The investigators published lower rates of complications and a lower risk of adverse outcome in patients who had total knee replacement performed by surgeons who did ≥50 total knee replacement procedures annually. Halm *et al*[4] performed a literature review of case volume for a wide array of treatments and procedures. The investigators reported that 69% of the studies they reviewed showed a statistically significant correlation between physician case volume and clinical

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Acknowledgment date: May 6, 2005. First revision date: September 8, 2005. Second revision date: October 28, 2005. Third revision date: November 18, 2005. Fourth revision date: November 30, 2005. Acceptance date: December 2, 2005.

The device(s)/drug(s) is/are FDA-approved or approved by corresponding national agency for this indication.

Corporate/Industry funds were received in support of this work. One or more of the author(s) has/have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this manuscript: e.g., honoraria, gifts, consultancies, royalties, stocks, stock options, decision making position.

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