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Prospective, Randomized, Multicenter FDA IDE Study of CHARITÉ Artificial Disc versus Lumbar Fusion: Effect at 5-year Follow-up of Prior Surgery and Prior Discectomy on Clinical Outcomes Following Lumbar Arthroplasty

Fred H. Geisler, MD, PhD,[a] Paul C. McAfee, MD,[b] Robert J. Banco, MD,[c] Scott L. Blumenthal, MD,[d] Richard D. Guyer, MD,[d] Richard T. Holt, MD,[e] Mohamed E. Majd, MD[e]

ABSTRACT

Background

Candidates for spinal arthrodesis or arthroplasty often present with a history of prior surgery such as laminectomy, laminotomy or discectomy. In this study, lumbar arthroplasty patients with prior surgery, and in particular patients with prior discectomy, were evaluated for their clinical outcomes at the 5-year time point.

Methods

Randomized patients from the 5-year CHARITÉ investigational device exemption (IDE) study were divided as follows: 1) fusion prior surgery (excluding prior decompression with fusion) group (FSG); 2) fusion prior discectomy group (FDG); 3) fusion no prior surgery group (FNG); 4) arthroplasty prior surgery group (ASG); 5) arthroplasty prior discectomy group (ADG); and 6) arthroplasty no prior surgery group (ANG). The 5-year clinical outcomes included visual analog scale (VAS), Oswestry Disability Index 2.0 (ODI), patient satisfaction, and work status.

Results

In the arthroplasty group, all subgroups had statistically significant VAS improvements from baseline (VAS change from baseline: ASG = -36.6 ± 29.6, $P < 0.0001$; ADG = -40.2 ± 30.9, $P = 0.0002$; ANG = -36.5 ± 34.6, $P < 0.0001$). There was no statistical difference between subgroups ($P = 0.5587$). In the fusion group, VAS changes from baseline were statistically significant for the FNG and FSG subgroups, but not for the FDG patients (FNG = -46.3 ± 28.8, $P < 0.0001$; FSG = -24.2 ± 36.4, $P = 0.0444$; FDG = -26.7 ± 38.7, $P = 0.2188$). A trend of decreased VAS improvements was observed for FSG versus FNG ($P = 0.0703$) subgroups. Similar findings and trends were observed in ODI scores (Changes in ODI from baseline: ASG = -20.4 ± 23.8, $P < 0.0001$; ANG = -26.6±21.1, $P < 0.0001$; ADG= -17.6 ± 28.6, $P = 0.0116$; FSG = -14.5 ± 21.2, $P = 0.0303$; FNG= -32.5 ± 22.6, $P < 0.0001$; FDG = -10.7 ± 9.4, $P = 0.0938$). The greatest improvement in work status from preoperative to postoperative was seen in the ADG subgroup (28% increase in part- and full-time employment), while the FDG subgroup showed the greatest reduction in work status (17% decrease).

Conclusions

Arthroplasty patients with prior surgery or prior discectomy had similar clinical outcomes as arthroplasty patients without prior surgery, while fusion patients with prior surgery or prior discectomy showed trends of lowered clinical outcomes compared to fusion patients without prior surgery or discectomy.

Key Words: arthrodesis; arthroplasty; lumbar; clinical trial; 5-year follow-up; prior surgery. ***SAS Journal.*** March 2009;3:16–24. DOI: SASJ-2008-0019-RR

[a]Illinois Neuro-Spine Center, 2020 Ogden Avenue, Suite 335, Aurora, IL 60504 [b]Spine and Scoliosis Center, Towson, MD 21204 [c]Boston Spine Group, Boston, MA 02120 [d]Texas Back Institute, Plano, TX 75093 [e]Spine Surgery, Louisville, KY 40202

Address correspondence to Dr. Fred H. Geisler, Illinois Neuro-Spine Center, 2020 Ogden Avenue, Suite 335, Aurora, IL 60504 (e-mail: fgeisler@gmail.com)

Fred Geisler, PhD, MD, consults for DePuy Spine, Inc., Aesculap, Inc., Abbott Spine, K2M, and Spinal Motion; receives royalties from DePuy and Aesculap; and owns stock in Disc Motion and Impliant, Inc. Paul McAfee, MD, owns stock in, consults for, and has received research support from DePuy Spine, Inc., Cervitech, Inc., and Globus Medical, Inc. Robert Banco, MD, is a consultant for DePuy Spine, Inc., Stryker Corporation, Medtronic, Inc., and Impliant, Inc. Scott Blumenthal, MD, is a consultant to DePuy Spine, Inc. Richard Guyer, MD, is a consultant to and receives royalties from DePuy Spine, Inc. Mohamed E. Majd, MD is a member of the faculty with Stryker Corporation, Alphatec Spine, Inc., and DePuy Spine, Inc.

IRB approval was obtained at each of the participating study sites.

INTRODUCTION

The development of new spinal arthroplasty devices has prompted multiple level I randomized controlled trials to evaluate the clinical impact of arthroplasty versus fusion in controlled patient populations.[1-4] While these studies are creating a wealth of information on the safety and effectiveness of various devices for the treatment of degenerative disc disease (DDD), their indication

is usually restricted to a very narrowly defined patient population and, as such, they provide only limited information on the critical issue of patient selection for either fusion or arthroplasty.

A prior CHARITÉ (DePuy Spine, Raynham, Massachusetts) investigational device exemption (IDE) study, which was designed to evaluate the Artificial Disc versus BAK (Zimmer Spine, Minneapolis, Minnesota) interbody fusion with iliac crest autograft for the treatment of degenerative disc disease at 1 level from L4 to S1, also included strict inclusion and exclusion criteria that ensured a homogeneous patient population.[1,3] However, the study design allowed inclusion of patients with prior laminectomies, foraminotomies or discectomies. At the 2-year time point, all the patients were analyzed and it was found that those who had undergone a prior surgery experienced similar benefits from their spinal surgery as those who had not had a prior surgery.[5] No information exists, however, on the long-term benefits of fusion and arthroplasty on this specific (prior surgery) patient population.

The long-term clinical benefits of spinal fusion have been discussed in multiple reports.[6,7] Long-term arthroplasty results have also been the subject of several publications[8,9]; however, the information included in these reports represents level IV data as none of the studies were based on multicenter, randomized controlled cases. Recently, the 5-year results from the artificial disc versus interbody fusion study were compiled, providing long-term efficacy data—for both fusion and arthroplasty—from a multicenter, randomized controlled trial. Our study of the 5-year results provides a unique opportunity to understand the long-term impact of both fusion and arthroplasty on specific patient populations, such as patients with prior surgery as well as patients with prior discectomy.

In this study, both the arthroplasty and fusion patient populations were subdivided based on the patients' history of prior surgery or prior discectomy. The prior surgery patient subgroups were compared to the subgroups without prior surgery or discectomy.

MATERIALS AND METHODS

Study Design and Surgical Technique

Between May 2000 and April 2002, 375 patients were randomized for treatment by either anterior lumbar fusion with the interbody fusion system and iliac crest autograft or total disc replacement with the artificial disc as part of a prospective, randomized, non-blinded, FDA-approved IDE study conducted at 14 investigational sites across the United States. At the completion of the 2-year study, a new investigation was initiated to further collect data from this study, up to the 5-year time point. All 14 sites were invited to participate; however, 6 sites declined continuation, reducing the number of available patients by 90. A total of 160 patients presented for their 5-year follow-up: 43 interbody fusion patients, 90 randomized arthroplasty cases, and 27 non-randomized (training) arthroplasty cases. Randomized cases only are included in this analysis. Patients were subdivided by prior surgery history as shown in Table 1. Prior surgery was not an exclusion criterion for the IDE study, as long as it was defined as prior decompressions via discectomy or laminotomy/foraminotomy without fusion. Prior decompression with fusion, on the other hand, was listed as an exclusion criterion. Patients in this study, therefore, do not include cases with prior fusion surgery. Of the 90 arthroplasty patients, 37 had prior surgery of which 21 had prior discectomy. Of the 43 fusion patients, 12 had prior surgery of which 6 had prior discectomy. The groups are defined as arthroplasty prior surgery group (ASG) and fusion prior surgery (excluding prior fusion) group (FSG); arthroplasty prior discectomy group (ADG) and fusion prior discectomy group (FDG); and arthroplasty no prior surgery group (ANG) and fusion no prior surgery group (FNG).

Clinical Outcome Measurements

Comparisons of clinical outcomes between patients with prior surgery, prior discectomy or no prior surgery were performed using VAS (0–100) and ODI scores preoperatively, at 6 weeks, and at 3-, 6-, 12-, 24- and 60-months postoperative. At 12-, 24- and 60-months postoperative, additional analyses were conducted to compare patient satisfaction and return to work status between groups.

Statistical Methods

Data were analyzed using the SAS v8.2 statistical software package (SAS Institute, Cary, North Carolina). For categorical variables, P values were generated using Fisher's exact test. A t test was used to test means.

RESULTS

Demographics

Demographic information was compiled and compared for all groups, as shown in Table 1. No statistical difference was observed between groups. In the arthroplasty group, a majority of females had prior surgery or prior discectomy. This trend was not observed in the fusion group. Average age, height, weight, and BMI were also not statistically different between groups. A majority of patients were treated at L5-S1 in all groups except the FDG, where the same number of procedures was performed at both L4-L5 and L5-S1.

Surgical Data

Surgical times, blood loss and hospitalization days are shown in Table 2. There were no statistical differences for these variables between the prior surgery/prior