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The Spine Journal 9 (2009) 360–365

THE SPINE JOURNAL

Relationship between the length of time off work preoperatively and clinical outcome at 24-month follow-up in patients undergoing total disc replacement or fusion

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Received 17 January 2008; accepted 20 July 2008

Abstract

BACKGROUND CONTEXT: A recent study involving interbody fusion patients found that preoperative work status was significantly related to clinical outcome. In another study comparing the best and worst outcomes of total disc replacement, among a battery of variables analyzed, the only one that differentiated the best and worst outcome groups was the length of time off work before total disc replacement.

PURPOSE: The purpose of this study was to determine if there was a relationship between the length of time off work and treatment outcome at 24-month follow-up. If such a relationship existed, a secondary study objective would be to determine if a duration of work could be identified beyond which would be associated with compromised clinical outcome.

STUDY DESIGN AND SETTING: Data were collected prospectively from randomized clinical trials comparing total disc replacement with lumbar fusion conducted at a single site.

PATIENT SAMPLE: A database of 232 patients enrolled in one of two Food and Drug Administration-regulated trials comparing total disc replacement with fusion for the treatment of symptomatic disc degeneration was the basis of the study group. Only patients who had reached 24-month follow-up were included. The 28 patients who were not employed by choice preoperatively were not included in the analysis.

OUTCOME MEASURES: Primary outcome measures used were visual analog scales (VAS) assessing pain and Oswestry disability index.

METHODS: The length of time off work before surgery was recorded in weeks. The mean percentage improvement between preoperative and 24-month follow-up scores were analyzed.

RESULTS: There was a significant relationship between duration off work preoperatively and clinical outcome ($p<.05$). The length of time off work preoperatively was more strongly related to outcome than was surgery type, insurance type, job demand, or preoperative VAS and Oswestry scores. Further analysis of the data identified a window of approximately 0 to 13 weeks off work preoperatively that was related to significantly greater improvements on visual analog scales (VAS) and Oswestry scores after surgery compared with patients who were off work for more than 13 weeks preoperatively. Although the subgroup off work for more than 13 weeks improved

FDA device/drug status: approved for this indication (Prodisc-L, Charite Artificial Disc).

Author disclosures: DDO (employee of a foundation that received support to conduct IDE trial and also received educational/research support from Synthes Spine and DePuy Spine); RDG (co-director of fellowship program that receives support from Synthes Spine and DePuy Spine, receives royalties from DePuy Spine and consultant); JEZ (co-director of fellowship program that receives support from Synthes Spine and DePuy Spine, receives travel support for lecturing from Synthes Spine and consultant and speaker); SLB (Receives royalties from DePuy Spine; Faculty for fellowship program that receives education/research support from DePuy Spine and Synthes Spine and Speaker (DePuy Spine)); SHH (Faculty for fellowship program that receives education/research support from DePuy Spine and Synthes Spine and consultant (DePuy Spine)); BLS (Faculty for fellowship program that receives education and research support from DePuy Spine and Synthes Spine and speaker (Synthes Spine)); RFR (Consultant and Faculty for fellowship program that receives education and research support from DePuy Spine and Synthes).

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1529-9430/09/$ – see front matter
doi:10.1016/j.spinee.2008.07.004

significantly from their preoperative status, the improvement was not as great as in the subgroup off work for a shorter duration.

CONCLUSIONS: The results of this study found that patients off work for a longer duration before surgery improved significantly postoperatively, but had less favorable clinical outcomes than patients off work for a lesser duration. This study suggests a window of approximately 13 weeks off work before surgery after which clinical improvement is reduced. Implications of this finding may be that once a patient becomes unable to work for an extended period, more rigorous psychological screening may be in order as well as perhaps engaging in more rigorous rehabilitation after surgery. Further investigation is needed to determine if the 13 weeks identified in this study is applicable to other populations.

Keywords: Surgical outcome; Time off work; Total disc replacement; Fusion; Lumbar spine

Introduction

Lumbar intervertebral disc degeneration is a major cause of disability in adults [1]. Intervertebral arthrodesis has been the mainstay of surgical treatment for this disorder. Long-term follow-up reveals complications at the levels above and below an intervertebral fusion. Disc degeneration, facet arthrosis, dynamic instability, and spinal stenosis have all been seen at adjacent levels [2,3]. Revision surgery is frequently performed to address these problems [4].

Lumbar disc arthroplasty was developed to relieve pain and prevent adjacent level deterioration. In carefully selected patients, lumbar disc arthroplasty and arthrodesis have been effective at relieving discogenic low back pain that fails to respond to prolonged nonoperative treatment [5,6]. Both short-term [7,8] and long-term [9,10] results indicate lumbar disc arthroplasty to be clinically successful in 63% to 90% of cases.

There is much interest in studying patient selection criteria to improve clinical outcome. Psychological screening has been shown to be effective in predicting poor outcome in lumbar spine surgery [11–15]. Other patient factors such as osteoporosis, spinal stenosis, spondylolisthesis, facet arthrosis, severe disc space narrowing, and off work status have been shown to have a negative effect on lumbar disc arthroplasty and fusion [16–19].

In a recent study of one center's Food and Drug Administration Investigational Device Exemption (FDA IDE) trials for two separate lumbar disc arthroplasty devices, the patients with the best and worst outcomes based on VAS assessing pain and the Oswestry Disability Index were studied. Among the battery of demographic, surgical, and radiographic variables analyzed, the only one that was statistically significantly related to the best/worst outcome classification was preoperative time off work [20]. In another recent study, Anderson et al. reported that preoperative work status was not only related to postoperative work status but also the changes in clinical outcome assessed by VAS and the Roland-Morris questionnaire [19]. The purpose of this study was to build on these earlier reports. The first objective of the current study was to determine if there was a relationship between the length of time off work and treatment outcome at 24-month follow-up. If such a relationship existed, a secondary study objective would be pursued to determine if a duration off work time point could be identified and associated with compromised clinical outcome.

Methods

A database of 232 patients enrolled in one of two FDA-regulated trials comparing total disc replacement to fusion was the basis of the study group. All patients were treated for symptomatic disc degeneration unresponsive to at least six months of nonoperative care. Only patients with 24-month follow-up were included. Most of the data were collected prospectively as part of the FDA IDE protocol. The length of time off work before surgery was not included in the IDE study protocols and this variable was collected retrospectively by a spine surgery fellow blinded to the clinical outcome. Data available for analysis included demographic information such as age, gender, operative level, and worker's compensation status. The length of time off of work before surgical intervention was recorded in weeks. Primary outcome measures included VAS assessing pain and the Oswestry Disability Index assessing function.

Of 232 patients, 28 were not working by choice before surgery (homemaker, student, retired, and others) and were therefore excluded from analysis. Among the remaining 204 patients, 52 received a Charité, 111 received a ProDisc, 27 underwent a combined anterior/posterior instrumented fusion, and 14 underwent anterior lumbar interbody fusion with Bagby and Kuslich cages packed with autogenous iliac crest bone graft. The mean patient height was 68 in and mean weight was 181 lb, giving a mean body mass index (BMI) of 27.14 kg/m^2. There were 120 males and 84 females with a mean age of 41 years (21–60 years). Surgery was limited to one level for 136 patients at L3–L4 for six patients, L4–L5 for 26 patients, and L5–S1 for 104 patients. Sixty-seven patients had surgery at two levels with 61 patients having L4–L5 and L5–S1 and six patients having surgery at L3–L4 and L4–L5. There was one patient with three-level surgery at L3–L4, L4–L5, and L5–S1.