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Does 360° lumbar spinal fusion improve long-term clinical outcomes after failure of conservative treatment in patients with functionally disabling single-level degenerative lumbar disc disease? Results of 5-year follow-up in 75 postoperative patients

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Abstract

Background: Surgical treatment of patients with mechanical degenerative disc disease has been controversial, but improvements in clinical outcomes have been shown in properly selected patients with disease-specific diagnoses, with fusion arguably now becoming the "gold standard" for surgical management of these patients. No published study thus far has been designed for prospective enrollment of patients with specific inclusion/exclusion criteria in whom at least 6 months of conservative therapy has failed and who are then offered a standardized surgical procedure and are followed up for 5 years.

Methods: The study group was composed of the patients in the prospective, randomized Food and Drug Administration Investigational Device Exemption trial comparing ProDisc-L (Synthes Spine, West Chester, Pennsylvania) with 360° fusion for the treatment of single-level symptomatic disc degeneration. Of 80 patients randomized to 360° fusion after failure of nonoperative care, 75 were treated on protocol with single-level fusions. Follow-up of this treatment cohort was 97% at 2 years and 75% at 5 years and serves as the basis for this report. Patients in the trial were required to have failure of at least 6 months of nonoperative care and in fact had failure of an average of 9 months of nonoperative treatment. The mean Oswestry Disability Index score indicated greater than 60% impairment. The mean entry-level pain score on a visual analog scale was greater than 8 of 10.

Results: After fusion, not only did patients have significant improvements in measurable clinical outcomes such as the Oswestry Disability Index score and pain score on a visual analog scale but there were also substantial improvements in their functional status and quality of life. Specifically, over 80% of patients in this study had improvements in recreational status that was maintained 5 years after index surgery, indicating substantial improvements in life quality that were not afforded by months of conservative care. The percentage of patients using narcotics at the 5-year follow-up visit was less than half the percentage of patients who had used narcotics as part of their prior conservative treatment.

Conclusions: The 5-year results of this post hoc analysis of 75 patients involved in a multicenter, multi-surgeon trial support 360° fusion surgery as a predictable and lasting treatment option to improve pain and function in properly selected patients with mechanical degenerative disc disease. These improvements occurred dramatically immediately after surgery and have been maintained through the scope of this follow-up period, with 98% follow-up at 2 years and 75% of patients available at 5 years.

Keywords: Degenerative disc disease; Lumbar spine; 360° fusion; 5-Year follow-up

Low-back pain is a fairly ubiquitous condition that remains one of the leading causes for medical treatment in the United States each year. Most acute episodes are due to musculoligamentous strains and are self-limited. Even conditions such as herniated discs and flare-ups in patients with underlying degenerative conditions (eg, spondylolisthesis) will frequently respond to rest, medication, and conditioning.

However, there is a small subset of patients who have axial low-back pain due to intrinsic damage to the intervertebral disc. With initial structural damage from mechanical

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overload, biochemical and microstructural changes to water content and proteoglycan content can lead to macrostructural changes such as loss of disc height, annular fissuring, ligamentous laxity, instability, and osteophyte formation. Both chemical and physiological stimuli can trigger secondary muscle spasm and cause inflammatory changes in supporting structures, resulting in pain syndromes that become either constant or increasingly frequent sources of functional disability.

Within the described subset of patients are some who do not improve with standard therapies. They become increasingly disabled and are unable to perform activities that are important to their lifestyles. They also become increasingly reliant on medical therapy (nonsteroidal anti-inflammatory drugs, muscle relaxers, non-narcotic and/or opioid analgesics) and seek progressive levels of conservative care management (chiropractic, physical therapy, pain management injection therapies).

Some of these patients plateau at an unacceptable level, will not or cannot tolerate narcotic analgesic medication as their definitive treatment option, and do not improve. They frequently seek a surgical solution. If single-segment disease can be diagnosed by imaging (radiographic changes of degenerative disc disease [DDD] or instability, magnetic resonance imaging changes in disc quality with or without Modic changes) or by invasive testing (diagnostic blocks, provocative discography), fusion of the affected segment has been the traditional surgical recommendation.

Recent prospective randomized studies of fusion versus nonoperative care have been criticized for various reasons, including their inclusion of patients with a mixed bag of diagnoses, a mixed bag of surgical techniques, and a lack of long-term follow-up.[1–4] No published study thus far has been designed for prospective enrollment of patients with specific inclusion/exclusion criteria in whom at least 6 months of conservative therapy has failed and who are then offered a standardized surgical procedure and are then followed up scrupulously for 5 years.

Post hoc evaluation of patient outcome data from the ProDisc-L (Synthes Spine, West Chester, Pennsylvania) Food and Drug Administration (FDA) Investigational Device Exemption (IDE) study[5] offers a unique opportunity to remedy this gap in our literature. Although that study was ostensibly a comparison between ProDisc-L and fusion, it was actually a 3-armed study. To meet eligibility for inclusion in the study, patients had to have a minimum of 6 months of failed conservative care and an Oswestry Disability Index (ODI) of greater than 40%. The study thus eliminated from consideration the greater pool of patients who improved with conservative care, and it only considered those with failure of a minimum time requirement of treatment while also meeting baseline criteria for impairment as measured by the ODI.

By using 2 of the study arms (failed conservative treatment and 360° fusion) for a post hoc analysis rather than starting a de novo study, we have essentially been able to make use of the prospectively collected information to jump ahead in time to evaluate these data now. The average patient enrolled in the ProDisc-L versus fusion single-level IDE study had failure of 9 months of conservative care and had an ODI indicating greater than 60% impairment (>50% more impaired for 50% longer than the minimums required for inclusion). The entry-level pain score on a visual analog scale (VAS) for these patients was greater than 8 of 10. Of 80 patients randomized to 360° fusion after failure of nonoperative care, 75 were treated on protocol with single-level fusions. Follow-up of this treatment cohort was 97% at 2 years and 75% at 5 years and serves as the basis for this report.

In a prospective study of a large group of patients receiving conservative care, such care would be expected to relieve symptoms in a majority of those enrolled. We acknowledge this, and the percent responding to conservative care, who were never considered for inclusion in this study, is not the issue of this report. Rather, this analysis begins its evaluation at the next branch point in the algorithm, asking the following question: Among those in whom nonoperative treatment fails, is surgical treatment a better option than accepting their level of disability on a continuing conservative care management program? We believe that this study provides the data to answer this question. We can show the immediate postoperative improvement compared with the baseline of 9 months of failed conservative care and can document maintenance of those clinical outcome improvements out to 5 years.

Methods

Patients with symptomatic single-level DDD were treated in this randomized, controlled, multicenter FDA clinical trial that evaluated total disc replacement (TDR) (ProDisc-L) compared with circumferential fusion. The major inclusion criteria were as follows: skeletally mature individuals with functionally disabling radiographically proven DDD at 1 vertebral level between L3 and S1 (by plain radiographs, magnetic resonance imaging scan, computed tomography scan, or discography), in whom conservative treatment for a minimum of 6 months had failed, who had back and/or leg (radicular) pain, and who had a minimum ODI score of 40% impairment or greater. The main exclusion criteria were as follows: patients with greater than grade I spondylolisthesis, previous lumbar fusion, T score on dual-energy x-ray absorptiometry scan worse than −1.0, or clinically relevant facet joint degenerative disease.

Seventeen sites participated in the study. The average patient enrolled in this study had a VAS pain score greater than 8 of 10, had an ODI of 63%, and was symptomatic for 9 months. Patients at each site were randomized in a 2:1 ratio of TDR to circumferential fusion. Separate randomization schedules were generated for each of the 17 sites using a fixed block size of 6. The randomization was held by the sponsor and disclosed to the site only after individual