ProDisc Artificial Total Lumbar Disc Replacement: Introduction and Early Results From the United States Clinical Trial

Delamarter R, Fribourg D, Kanim L, Bae H.

SPINE 2003; 28:205, 5167 – 5175

Study Design. Multicenter prospective randomized study of artificial disc replacement (ProDisc) *versus* circumferential fusion (standard of care) for one- and two-level degenerative disc disease. This is an interim analysis on patients seen at the Spine Institute Saint John's Health Center, Santa Monica, California

Objectives. To evaluate early pain and functional outcomes of patients treated with disc rep0lacement or fusion and to assess the capacity of this intervertebral disc replacement for preserving motion in the lumbar spine.

Summary of Background Data. Disc replacement is intended to reduce pain *via* removal of the diseased disc while restoring physiologic motion and height at the affected level. The long-term physiologic advantage of disc replacement to fusion is that preservation of motion may prevent additional degeneration at adjacent levels.

Methods. Patients meeting inclusion criteria were consented for study. Randomization was performed using a 2 to 1 ratio of disc replacement procedure to a fusion procedure. Patients rated their pain on the visual Analogue Scale and completed the Oswestry Disability Index questionnaire. Radiographs were taken. Assessments were made before surgery and after surgery at 6 weeks, 3 months, 6 months, and 1 year (ongoing). Changes from preoperative pain, disability, or motion were separately evaluated as a function of treatment using repeated measures mixed design analysis of variance.

Results. This analysis includes data up to 6 months from the first 53 randomized patients. There were 35 patients who underwent disc replacements, and 18 patients had fusion procedures. Disc replacement patients had a significant reduction in pain and disability at earlier evaluations. By 6 months, the relative improvement on both the Visual analogue Scale and Oswestry (both, $P < 0.05$) were similar for disc replacement and fusion patients. Greater motion was found at L4-L5 for disc replacement patients ($P < 0.05$) than fusion patients. A similar trend was noted at L5-S1 (*P* was not significant).

Conclusions. Disc replacement patients reported significantly less pain (Visual Analogue Scale) and disability (Oswestry) in the early period following surgery compared to fusion patients. This difference disappeared by 6 months. When compared to fusion, the disc replacement allowed preservation of motion at L4-L5 with a similar trend at L5-S1.

Editor's Comments

This is a very timely article. There is increasing interest in the spine surgical community for the results of the U.S Pivotal Trial and the authors have taken the time to produce this assessment of their first 53 patients offered either ProDisc II or circumferential lumbar spine segmental fusion. The results, after many years of implanted ProDisc I, have been available including 11-year follow-ups with no reported mechanical implant failures.

This study does not report surgical complications though the authors report that the procedure is safe in experienced hands and they had not device-related complications requiring revision surgery. Interesting is the large number of smokers in the coterie. The "work comp" patients had fewer discoplasty procedures than fusions and this group may deserve further attention.

Spine surgeons are well aware of the many options available to sufferers of chronic low back pain with degenerative disc disease and the authors readily admit that this disease dilemma is endemic to our society. Surgical treatment options include many and amongst those, circumferential fusion which has not yielded anything more than mediocre results with long-term recovery, difficult postoperative courses, the known problems of adjacent level deterioration, wear particles, subsidence, implant failure (long-term), and longevity. Hence, an alternative to this mode of treatment would be welcomed.

The U.S. trial will eventually have 500 patients of which 300 had already been treated at the time of this report (January 2003); so, the study population has probably been treated at the time of this review. The patients have one or two-level lumbar degenerative disc disease with a predominance of back pain (The exact pathology is not described, i.e., disc protrusion, herniation, extrusions, documented instability, etc., but excluded from the study were those with spondylolisthesis and facet arthropathy / stenosis). They are studied with MRI and plain films and occasionally Discogram/CT. Ages range from 18 – 60 and they must have failed six months of conservative treatment (not delineated). Most patients had back pain for at least one year before surgery and all were blinded to the treatment, but told after surgery what had been done. The treatment was either ProDisc II placed via an anterior abdominal retroperitoneal approach or a circumferential spinal fusion including anterior fusion with a femoral allograft (one or two levels) followed by a posterior fusion with instrumentation and iliac crest autograft (assumed posterolateral fusion). The ProDisc II is modular and the UHMWPE insert snap-locks into the lower of the two metal plates anchored into the vertebrae., allowing motion of 13° of flexion, 7° of extension, 10° of lateral bending, and $\pm$ 3° of axial rotation.

The study uses known analysis instruments to allow readers comparison with other treatments and assessment is frequent between the groups, including VAS, Oswestry, and radiographs. Range of motion studies for the fusion group was not done until 6 months post-op. The authors do not describe any rehabilitation program for either group and spine patient treatment outcomes are affected by more than technique: psychological and motivational considerations, the type and compliance of rehabilitation, as well as response to treatment of complications. This study does not deal with that at all, but the follow-up trial report should. About half the patients were treated with two-level disc replacements and ten had two-level fusions.

The results are interesting: the disc replacement patients had “less of a surgery” and reported an early and significant reduction in pain and disability. By 6 months, both treatment groups reported significant improvement in symptoms from their pre-operative values, but the two groups did not differ much in either category. The disc replacement group had more prompt pain relief and functional ability. Disc replacement improved radiological range of motion at L4-L5. The L5-S1 segment was very hard to ascertain for range of motion, understandably. The authors chose to use an unaffected L3-L4 level for comparison of change in range of motion for both groups, trying to get some insight into prospective problems. The effect of intercurrent pain medications during range of motion studies was not considered in this report.

The authors are to be congratulated for breaking into their database and study to produce this interim report that is clearly encouraging to those considering disc arthroplasty to treat disc disease. They have shown that, to date, that the ProDisc II is mechanically sound and implantable and that pain and disability improvements are as least as good as spinal fusion. We will hear much on this technology in the next several years and be able to compare not just the concept but also the other similar devices on the market.

Kenneth P Burres MD ABNS
Montclair, California