Preoperative Disc Height as a Predictor of Success in Lumbar Total Disc Replacement

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BACKGROUND: For single-level lumbar degenerative disc disease (DDD), total disc replacement (TDR) is a viable alternative to spinal fusion. Severe spondylosis (loss of disc height) is thought to diminish the efficacy of TDR, as the preservation of motion may leave other pain generators, such as arthritic facet joints, intact. For these reasons, patients with severe spondylosis are not routinely considered candidates for TDR. However, the degree to which preoperative disc height may affect clinical outcomes following TDR remains uncertain. The purpose of this study is to determine whether preoperative disc height affects clinical outcomes following lumbar TDR for 1-level DDD.

METHODS: Two-hundred twelve patients underwent TDR as part of the FDA IDE trial comparing Pro-Disc-L to circumferential lumbar fusion. One-hundred sixty-five of these patients had adequate preoperative radiographic datasets and 24 month clinical follow-up. Preoperative anterior and posterior disc height measurements were obtained via third-party computerized radiographic analysis. The adjusted disc height ratio (ADHR) was defined as the ratio of the disc height at the operative level to that of the adjacent, superior level. Group 1 consisted of patients with an ADHR $<$ 0.5, and Group 2 of patients with an ADHR $\geq$ 0.5. Clinical outcome measures included Oswestry Disability Index (ODI), SF-36 physical (PCS) and mental (MCS) component scores, and Visual Analog Scale (VAS) pain and satisfaction scores. Changes in clinical outcome scores over the followup period were compared, and the statistical significance of the between-subjects effect of ADHR grouping was assessed by repeated measures ANOVA.

RESULTS: When grouped by anterior ADHR, patients in Group 1 (ADHR $<$ 0.5) showed a significantly greater improvement in VAS pain ($p=0.03$) and significantly greater VAS satisfaction ($p=0.04$) scores, as well as non-significant improvements in SF-36 outcomes when compared to those of patients in Group 2 (ADHR $\geq$ 0.5). Posterior ADHR grouping showed patients in Group 1 to have a trend toward significantly greater improvement in MCS ($p=0.05$) over those of patients in Group 2, and non-significant improvements in ODI, PCS, and VAS pain and VAS satisfaction.

CONCLUSIONS: Patients with single-level DDD undergoing lumbar TDR with more severe preoperative spondylosis had clinical outcomes that were no worse than those with less severe spondylosis. In fact, the group with severe spondylosis demonstrated superior VAS pain and VAS satisfaction at final followup. These findings suggest that TDR may be an appropriate treatment option for patients with single-level lumbar DDD even in the presence of severe spondylosis. This also contributes to the body of evidence suggesting that TDR may be efficacious in treating additional non-discogenic sources of pain that can coexist with DDD. Although the early clinical outcomes following TDR in patients with severe spondylosis are promising, additional long-term results are needed.

CONFLICT OF INTEREST: JDA (research support for staff and materials), RAB (consulting fees, equity ownership) - Synthes Spine, West Chester, PA

Introduction

The gold standard surgical intervention for lumbar degenerative disc disease (DDD) refractory to conservative treatment consists of anterior, posterior, or combined anterior/posterior spinal fusion.[1] Despite clinical success rates ranging from 65% to 93%,[2-4] lumbar fusion has the potential to create morbidity in the form of accelerated adjacent segment degeneration (ASD).[5-7] The rationale behind lumbar total disc replacement (TDR) is to preserve physiologic range of motion at the operative level, thereby preventing excessive biomechanical stresses at the proximal adjacent levels and, theoretically, ASD.[8]

While the indications for lumbar TDR are evolving as new evidence becomes available, one current contraindication to lumbar TDR is severe spondylosis, or loss of disc height.[9] It is postulated that with severe disc height loss, there is an increase in facet joint contact stresses and resultant arthrosis. In this situation, successful removal of the pain-generating intervertebral disc with replacement by a TDR prosthesis may still result in persistent back pain attributable to facet arthrosis. As such, patients with severe spondylosis are typically contraindicated for TDR. However, preliminary results from clinical and finite elemental model studies suggest that facet contact stresses are actually decreased with TDR, perhaps as a result of increased disc height which unloads the posterior elements, and in particular, the facet joints.[10-12] As a result, no consensus currently exists regarding the predictive value of preoperative disc height on clinical outcomes after lumbar TDR.

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The objective of our study is to compare the clinical outcomes of patients with and without severe spondylosis undergoing lumbar TDR. We hypothesize that lumbar TDR in patients with severe spondylosis, as represented radiographically by narrowing of the intervertebral disc space, will result in equivalent clinical outcomes to those of patients with less severe spondylosis.

Materials and Methods

Study Participants

Two-hundred twelve patients underwent TDR as participants in a multicenter, randomized, prospective Food and Drug Administration study comparing the efficacy of the ProDisc-L (Synthes Spine, West Chester, PA) to circumferential fusion. All patients had a diagnosis of degenerative disc disease refractory to conservative therapy. Of these, 47 were excluded due to radiographic data that were not adequate for quantitative analysis. The remaining 165 patients had a mean age of 38.9±8.0 years, 88 (53%) were male and 77 (47%) female. All patients received intervention at a single operative level: 4 (2.4%) at L3-4, 51 (30.9%) at L4-5, and 110 (66.7%) at L5-S1.

Outcome Measures

Clinical outcome measures consisted of Oswestry Disability Index (ODI), SF-36 physical (PCS) and mental (MCS) component scores, and Visual Analog Scale (VAS) pain and satisfaction scores. All postoperative outcome data were assessed at 24 months.

Classification Criteria

Radiographic measurements of anterior and posterior disc height at operative and adjacent levels were obtained via third-party quantitative analysis (Medical Metrics, Inc., Houston, TX).[13] For both anterior and posterior disc height measurements, a separate Adjusted Disc Height Ratio (ADHR) was calculated by dividing the disc height at the operative level by the corresponding disc height at the proximal, superior, non-degenerative level. The ADHR was used in order to compensate for inter-individual and inter-level variability in absolute disc height, and to provide an objective approximation of the severity of spondylosis and degenerative changes at the operative level. Group 1 consisted of patients with an ADHR < 0.5, which was considered to be representative of severe spondylosis, and Group 2 of patients with less-severe spondylosis (ADHR ≥ 0.5). Demographic data for each of the subgroups under the anterior and posterior ADHR classification schemes are summarized in Table 1.

Statistical Analysis

Participants were classified for independent analyses on the basis of both anterior ADHR and posterior ADHR in order to

Table 1. Patient demographic characteristics:*
Baseline characteristics are compared between groupings based on anterior ADHR and posterior ADHR.

Anterior ADHR	Group 1 (ADHR < 0.5)	Group 2 (ADHR ≥ 0.5)
no. (% of total)	18 (11)	147 (89)
Age (yrs.)	36.4 ± 8.5	39.2 ± 7.9
Male (% of group)	12 (67)	76 (52)
Female (% of group)	6 (33)	71 (48)
L3-L4 operative level (% of group)	0 (0)	4 (3)
L4-L5 operative level (% of group)	4 (22)	47 (32)
L5-S1 operative level (% of group)	14 (78)	96 (65)

Posterior ADHR	Group 1 (ADHR < 0.5)	Group 2 (ADHR ≥ 0.5)
no. (% of total)	39 (24)	126 (76)
Age (yrs.)	39.4 ± 8.3	38.8 ± 7.9
Male (% of group)	23 (59)	65 (52)
Female (% of group)	16 (41)	80 (63)
L3-L4 operative level (% of group)	0 (0)	4 (3)
L4-L5 operative level (% of group)	6 (15)	45 (36)
L5-S1 operative level (% of group)	33 (85)	77 (61)

ADHR, adjusted disc-height ratio; TDR, total disc replacement.

* Plus-minus values are means±SD.

Table 2. Preoperative baseline and 24 month postoperative followup scores of patients by ADHR grouping: Clinical outcome scores are compared for the anterior and posterior ADHR groups to determine the predictive value of the ADHR classification.*

	Preoperative		24 months		
Anterior ADHR	**Group 1 (ADHR < 0.5)**	**Group 2 (ADHR ≥ 0.5)**	**Group 1 (ADHR < 0.5)**	**Group 2 (ADHR ≥ 0.5)**	**P value**
no. (%)	18 (11)	147 (89)	18 (11)	147 (89)	
Oswestry	61.9 ± 13.3	63.1 ± 12.4	22.3 ± 18.4	33.5 ± 24.3	0.10 †
PCS	31.6 ± 7.5	31.3 ± 6.4	46.3 ± 8.9	43.0 ± 11.1	0.30 †
MCS	43.6 ± 11.5	39.7 ± 13.4	48.9 ± 12.0	47.4 ± 13.4	0.33 †
VAS Pain	70.8 ± 15.5	74.8 ± 17.1	19.5 ± 19.0	35.0 ± 29.7	0.03 †
VAS Satisfaction			87.3 ± 19.9	75.4 ± 30.7	0.04 §

	Preoperative		24 months		
Posterior ADHR	**Group 1 (ADHR < 0.5)**	**Group 2 (ADHR ≥ 0.5)**	**Group 1 (ADHR < 0.5)**	**Group 2 (ADHR ≥ 0.5)**	**P value**
no. (%)	39 (24)	126 (76)	39 (24)	126 (76)	
Oswestry	63.1 ± 13.6	63.0 ± 12.1	30.2 ± 22.2	33.0 ± 24.5	0.64 †
PCS	31.2 ± 6.8	31.4 ± 6.4	43.9 ± 9.4	43.3 ± 11.4	0.87 †
MCS	43.3 ± 13.4	39.1 ± 13.1	50.6 ± 11.7	46.6 ± 13.5	0.05 †
VAS Pain	71.5 ± 18.2	75.2 ± 16.6	29.9 ± 27.1	34.4 ± 29.6	0.21 †
VAS Satisfaction			76.1 ± 30.7	76.9 ± 29.7	0.88 §

ADHR, adjusted disc-height ratio; PCS, physical component score; MCS, mental component score; VAS, visual analog scale.

* Plus-minus values are means±SD.

† P value represents signficance of the between-subjects effect of adjusted disc height ratio (ADHR) grouping as calculated by repeated measures ANOVA.

§ P value calculated by the t-test.

determine the predictive value of each classification scheme. Paired preoperative baseline and 24 month postoperative data were available for four of the clinical outcome measures (ODI, PCS, MCS, VAS pain). The significance of the between-subjects effect of ADHR grouping (Group 1 versus Group 2) on changes in these variables over the followup period was assessed by repeated measures analysis of variance (ANOVA). The fifth clinical outcome measure (VAS satisfaction) did not contain a preoperative component, and thus these 24 month scores were compared using the t-test. All statistical analysis was performed using Statistical Package for the Social Sciences (SPSS), version 16.0. P-values less than 0.05 were considered significant for all tests.

Results

Demographic Characteristics

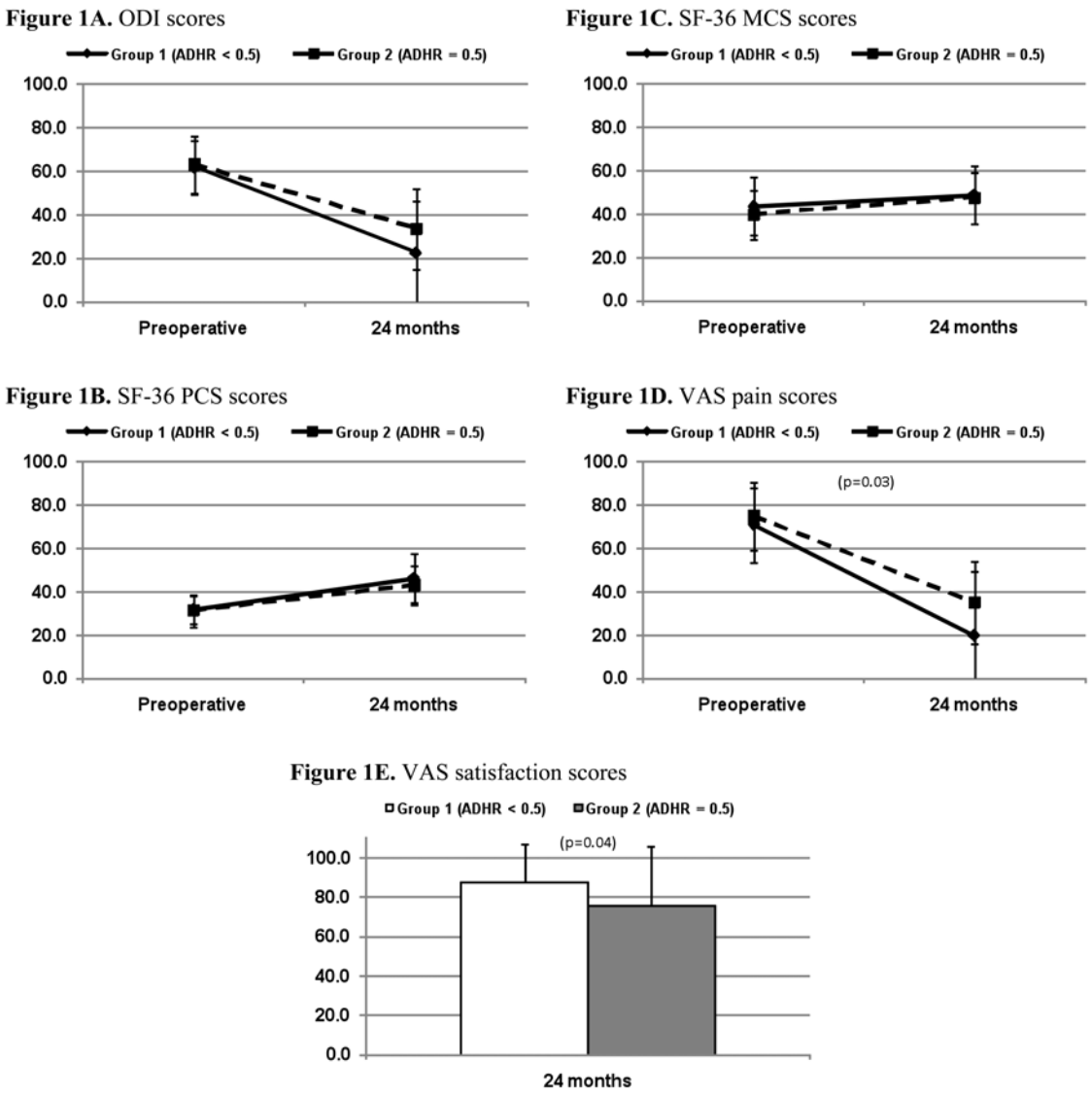
Retrospective evaluation of baseline demographic data reveals comparable profiles of age, gender composition, and operative level despite non-randomized reclassification by either anterior or posterior ADHR (Table 1). These data are also consistent with the demographic data reported for the overall cohort in the IDE trial.

Anterior ADHR Classification

From preoperative baseline to followup at 24 months, subjects in Group 1 (anterior ADHR < 0.5) showed significantly greater improvements in VAS pain (70.8±15.5 to 19.5±19.0 versus 74.8±17.1 to 35.0±29.7, p=0.03) than subjects in Group 2 (anterior ADHR ≥ 0.5). Subjects in Group 1 also reported significantly higher VAS satisfaction with the procedure at 24 months than did subjects in Group 2 (87.3±19.9 versus 75.4±30.7, p=0.04). Differences in ODI, PCS and MCS between the two anterior ADHR groups from preoperative baseline to 24-month followup were non-significant. (Table 2, Figures 1A-E)

Posterior ADHR Classification

Subjects in Group 1 (posterior ADHR < 0.05) showed a trend toward significantly greater improvements in MCS (43.3±13.4 to 50.6±11.7 versus 39.1±13.1 to 46.6±13.5,



Figures 1 (A-E). Clinical outcome scores by anterior ADHR grouping Changes in clinical outcome scores over the followup period for ODI, PCS, MCS and VAS pain are presented, along with VAS satisfaction scores at 24 months, on the basis of anterior ADHR grouping.

p=0.05) over the followup period compared to those of subjects in Group 2 (posterior ADHR $\geq$ 0.5). Differences between the two posterior ADHR groups with respect to change in ODI, PCS, and VAS pain from preoperative baseline to followup at 24-months were non-significant, as were differences in VAS satisfaction at 24 months. (Table 2, Figures 2A-E)

Discussion

By employing radiographic disc height as a quantitative surrogate measure of severity of spondylosis, we have shown that patients with more severe spondylosis, who have traditionally been considered poor candidates for TDR, may achieve long-term clinical outcomes equivalent to those of patients with less severe spondylosis. In fact, the group with more severe spondylosis displayed significantly greater improvements in certain clinical outcome measures over the followup period.

Yaszay *et al* also employed data from the ProDisc-L IDE trial to determine which groups on the basis of preoperative disc height realized the greatest postoperative range of motion, and whether motion preservation was associated with improved clinical outcome scores.[14] A cohort of 42 patients undergoing single-level TDR was analyzed. Disc height and range of motion were measured using identical radiographic analysis software, with disc height values recorded in millimeters as opposed to the relative values used in our study. Anterior and posterior disc heights were examined for the presence of possible threshold values of disc height necessary to maximize postoperative range of motion. TDR was found to produce a significant mean increase in both anterior and posterior disc height in the overall cohort; however, no correlation between preoperative disc height and postoperative range of motion was found. Instead, a tendency toward normalization of range of motion was observed, as patients above or below preoperative disc height threshold values (anterior: 9mm, posterior: 6mm)

Figure 2A. ODI scores

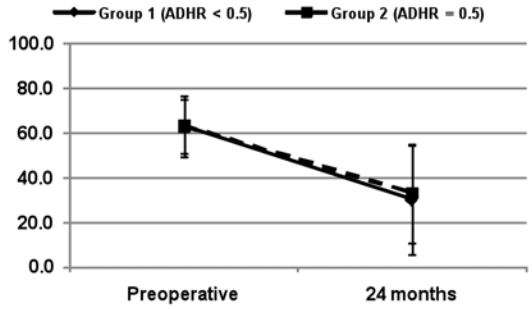


Figure 2C. SF-36 MCS scores

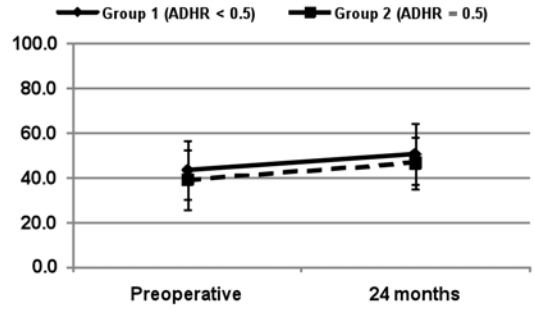


Figure 2B. SF-36 PCS scores

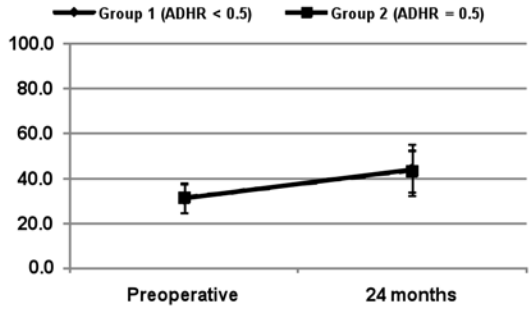


Figure 2D. VAS pain scores

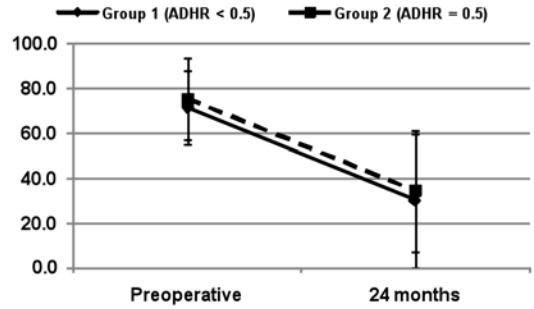
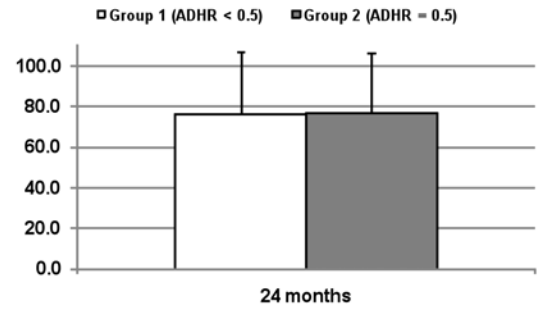


Figure 2E. VAS satisfaction scores



Figures 2 (A-E). Clinical outcome scores by posterior ADHR grouping Changes in clinical outcome scores over the followup period for ODI, PCS, MCS and VAS pain are presented, along with VAS satisfaction scores at 24 months, on the basis of posterior ADHR grouping.

tended toward decreases or increases their segmental range of motion, respectively. While mean improvements in ODI and VAS scores in the overall cohort were highly significant, no correlation was found between these scores and either disc height or range of motion. Of note, this normalization of range of motion, as well as a lack of direct correlation with clinical outcomes, has been similarly observed in cervical TDR with the ProDisc-C.[15] These findings suggest that patients with severe disc space narrowing may be in a position to realize the greatest gains from TDR biomechanically, and also shows that they may expect outcomes equivalent to those with less severe spondylosis.

Siepe *et al* reported early results from the ProDisc-II IDE trial to address the question of preoperative disc height and its effect on clinical outcomes after lumbar TDR.[16] Their analysis included 62 patients, with followup ranging from 24.2 to 77.6 months. As in Yaszay *et al*, absolute disc height was measured in millimeters. In this study, postoperative range of motion at the operative level did display a significant positive correlation with preoperative disc height ($r=0.45$, $p=0.002$), yet maximal VAS satisfaction was observed in the cohort of patients with the greatest preoperative disc space collapse (disc height less than 4.5mm). This observation highlights the potential for discordance between biomechanical findings and clinical outcomes in assessing the long-term results of TDR. Preservation of range of motion may remain essential to prevent ASD and ensure the durability of positive results, but other factors, such as severity of preoperative spondylosis, may be more predictive of near-term patient satisfaction. Despite their differing analytic techniques, the finding of higher satisfaction in the cohort with disc spaces less than 4.5mm is consistent with our results, and further supports the notion that TDR may address other potential pain generators in addition to the degenerative disc.

Microdiscectomy is a well-established treatment for disc herniation refractory to conservative measures, yet it may result

in accelerated disc degeneration, particularly in patients with preexisting DDD.[17-19] Leahy *et al* examined the ProDisc-L IDE data for patients who had undergone a prior microdiscectomy, or laminectomy with discectomy, to determine how outcomes after lumbar TDR in this cohort differed from those in patients with no prior lumbar spinal procedures.[20] Even in this series of 20 patients with severe post-discectomy spondylosis, clinical outcomes at each postoperative timepoint out to 24 months were statistically equivalent to those of the control group. These results undermine the limitation of TDR to patients with relatively preserved disc spaces, and further support the potential use of TDR in the setting of severe spondylosis.

There are several important limitations to this study. First, while the data were collected as part of a prospective, randomized trial, our analysis is retrospective in nature and therefore potentially subject to sampling bias. This effect is minimized by the use of an objective classification scheme based on the ADHR, and does not appear to have resulted in relevant baseline group differences (Table 1). Second, many patients had preoperative radiographic studies that were not conducive to quantitative analysis and therefore were unable to be included in this study. These additional patients would have improved the power of our analysis. Third, the calculation of the ADHR is not a previously established technique to facilitate pooling of data from different operative levels. This method was considered a logical approximation within the confines of the lumbar spine for the purposes of quantifying the decrease in disc height relative to an individual's normal disc, and thus creating an objective classification of spondylosis severity. We determined that any potential inaccuracies of this classification were outweighed by the absence of inter-rater variability that would inevitably accompany a subjective rating scale of spondylosis severity that relied upon individual review of the radiographic studies. However, there exists no published data validating the correlation between loss of disc height and progression of symptoms in spondylosis.

Conclusions

The variability of clinical outcomes following spinal fusion for lumbar DDD propels the search for improved treatment modalities, and more importantly, for preoperative factors that will predict success in the patient selection process. Our data shows that patients with severe spondylosis fared equivalently or better at 24 months postoperatively than patients with less severe spondylosis, and calls into question whether or not severe spondylosis should be considered an exclusion criterion for TDR. While the complete segmental immobilization occurring with fusion is thought to represent definitive treatment of patients with combined discogenic and non-discogenic pain, it appears as though TDR may be effective in certain members of this group as well. Additional long-term followup data is needed, however, before these results can be incorporated into recommendations for clinical practice.

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