Total disc replacement compared to lumbar fusion: a randomised controlled trial with 2-year follow-up

Svante Berg · Tycho Tullberg · Björn Branth ·
Claes Olerud · Hans Tropp

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Abstract The study design includes a prospective, randomised controlled study comparing total disc replacement (TDR) with posterior fusion. The main objective of this study is to compare TDR with lumbar spinal fusion, in terms of clinical outcome, in patients referred to a spine clinic for surgical evaluation. Fusion is effective for treating chronic low back pain (LBP), but has drawbacks, such as stiffness and possibly adjacent level degradation. Motion-preserving options have emerged, of which TDR is frequently used because of these drawbacks. How the results of TDR compare to fusion, however, is uncertain. One hundred and fifty-two patients with a mean age of 40 years (21–55) were included: 90 were women, and 80 underwent TDR. The patients had not responded to a conservative treatment programme and suffered from predominantly LBP, with varying degrees of leg pain. Diagnosis was based on clinical examination, radiographs, MRI, and in unclear cases, diagnostic injections. Outcome measures were global assessment (GA), VAS for back and leg pain, Oswestry Disability Index, SF36 and EQ5D at 1 and 2 years. Follow-up rate was 100%, at both 1 and 2 years. All outcome variables improved in both groups between preoperative and follow-up assessment. The primary outcome measure, GA, revealed that 30% in the TDR group and 15% in the fusion group were totally pain-free at 2 years ($P = 0.031$). TDR patients had reached maximum recovery in virtually all variables at 1 year, with significant

differences compared to the fusion group. The fusion patients continued to improve and at 2 years had results similar to TDR patients apart from numbers of pain-free. Complications and reoperations were similar in both groups, but pedicle screw removal as additive surgery, was frequent in the fusion group. One year after surgery, TDR was superior to spinal fusion in clinical outcome, but this difference had diminished by 2 years, apart from (VAS for back pain and) numbers of pain-free. The long-term benefits have yet to be examined.

Keywords Degenerative disc disease · Prospective randomised controlled trial · Total disc replacement · Spinal fusion · Patients global assessment of back pain

Introduction

The rationale for surgical treatment in lumbar degenerative disc disease (DDD) is to eliminate painful segmental motion [12]. The Swedish Spine Study [8] shows that fusion surgery decreases pain and disability in a selected group of patients with chronic low back pain (LBP) and DDD. Fusion has also been shown to have better results than conservative treatment [1, 18, 19]. However, fusion may have detrimental effects on the normal physiological and biomechanical function of the spine [12].

Decreased segmental mobility could lead to increased stress on the neighbouring spine, which increases degeneration at these levels, i.e. adjacent level disease [11, 13], and is the reason that different non-fusion techniques have been tried. Total disc replacement (TDR) is one such technique and was developed to avoid the negative effects of arthrodesis by preserving function of the motion segment. The theoretical mechanism of pain relief is based on

S. Berg (✉) · T. Tullberg · B. Branth · C. Olerud
Stockholm Spine Center, Löwenströmska Hospital,
19489 Upplands Väsby, Sweden
e-mail: svante.berg@spinecenter.se

H. Tropp
University Hospital, 581 85 Linköping, Sweden

a combination of complete excision of the painful disc and restoration or improvement of segmental load transfer, sagittal balance and motion [5, 14] hoping that this will improve both short- and long-term results. Reduced degeneration of the adjacent spine, as indicated by an in vitro study [6] may be an advantage, but still needs to be proven in prospective studies.

Prostheses are mainly used in the treatment of early DDD and the long-term effects on development of facet joint arthritis and spinal stenosis are unknown. Results from retrospective or prospective cohort studies on TDR with different devices have been presented [2, 3, 7, 15, 23, 26]; however, the long-term mechanical characteristics of the various prostheses have not been entirely studied.

The aim of the present study was to compare surgically treated DDD where preserved mobility is possible (TDR), with instrumented lumbar fusion causing stiffness, in terms of clinical outcome in a series of patients referred to a spine clinic for evaluation for surgical intervention.

Materials and methods

The study was a randomised controlled trial (RCT) comparing TDR and instrumented lumbar fusion at Stockholm Spine Center, Stockholm, Sweden, and was approved by the Ethics Committee of the Karolinska Institute, Stockholm in 2003 (03-268). The patients had symptomatic DDD in one or two motion segments between L3 and S1, with LBP as a predominant symptom, although leg pain was not a contraindication. For inclusion in the study, back pain should be mechanical and discogenic in origin with interspinous tenderness on examination, disc narrowing on radiographs, and signs of disc degeneration on MRI. Low-grade facet joint arthritis at the index level, as well as low-grade degeneration at other levels, was accepted. Patients who fulfilled the inclusion criteria at the primary consultation but scored less on Oswestry Disability Index (ODI) and VAS at the time of surgery were included with their preoperative values as baseline. The inclusion and exclusion criteria are summarised in Table 1.

All patients fulfilling inclusion criteria were consecutively selected for the study, except, to avoid bias, patients with a strong belief that one treatment option was superior to the other. After inclusion, patients were randomised between fusion and TDR by means of a sealed envelope technique. The planning staff drew the envelope when the surgeon's inclusion form and the patient's informed consent had reached the planning office via internal mail. The surgeons were not informed of the result of randomisation until the patient arrived at the hospital for surgery. The patient was also informed at this time. No patient left the study when informed of his/her randomisation.

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Low back pain (LBP) with or without leg pain for more than 1 year. If leg pain occurred, then LBP should dominate	Spinal stenosis requiring decompression
Conservative treatment scheduled for more than 3 months had failed	Moderate or worse facet joint arthritis
Confirmation of disc degeneration on MRI	Three or more painful levels at clinical examination
Age 20–55 years	No obvious painful level, or levels, at diagnostic injection evaluation (if done)
Oswestry Disability Index over 30 or back pain (VAS) over 50/100 the week before inclusion	Isthmic spondylolysis/olisthesis
Signed informed consent	Degenerative spondylolisthesis >3 mm
Open mind to the two treatment options	Major deformity
	Manifest osteoporosis. If osteoporosis was suspected due to gender and age (females above 50), illness or medication, osteoporosis should be evaluated and excluded before inclusion
	Previous lumbar fusion or decompression with postoperative instability (e.g. facet joint damage or wide laminectomy)
	Compromised vertebral body
	Previous spinal infection or tumour
	Inability to understand information due to abuse, psychological or medical reasons
	Language difficulties with inability to understand follow-up instruments
	Pregnancy or other medical condition that would be a contraindication to surgery

TDR patients were randomised to one of three devices available in Sweden: Charité (Depuy Spine, Raynham, MA, USA), Prodisc (Synthes Spine, West Chester, PA, USA) or Maverick (Medtronic, Memphis, TE, USA), none has so far been shown to be superior or inferior to the others. We wanted to avoid a situation where our chosen prosthesis was withdrawn or not available for other reasons. The randomisation process was stratified for number of levels, one or two, to assure an equal proportion of one and two level

patients with each prosthesis design. The fusion technique was instrumented from a posterior approach. The surgeons active in the study were allowed to use their normally preferred method for posterior instrumented fusion—posterolateral fusion (PLF) or posterior lumbar interbody fusion (PLIF) (without complementary PLF). These two methods have been shown to give similar results [8]. No decompression was performed because none of the patients had a diagnosis of stenosis or root compression.

Demographics

Among the patients referred to the clinic, 152 consecutive patients were included in the study, 90 women and 62 men, with a mean age of 40 years (21–55 years). Forty-one patients, 27%, underwent preoperative diagnostic injection procedures, provocative discography and disc block. These were only used to identify pain-generating level/s when there was clinical uncertainty whether to treat one or two levels. Eighty patients were treated with TDR and 72 with instrumented fusion. Forty-four patients had PLF and 28 PLIF without posterior fusion. There were no differences between the treatment groups in age, gender, smoking status, baseline ODI, surgical levels, prior surgical treatment, or back pain and function. There was, however, a statistically significant difference after randomisation between the groups regarding leg pain ($P = 0.016$), Table 2. All smokers were encouraged to give up smoking before treatment, but 16 patients still smoked during the study.

Clinical and radiographic outcome measurements

Preoperative baseline data included previous surgery, sick leave and work status information, pain was assessed using

VAS for back and leg separately, disease-specific function using ODI, quality of life using EQ5D and SF-36 was used to assess general health. Follow-up at 1 and 2 years included a question on patient satisfaction with their treatment and a global outcome score of pain: total relief, much better, better, unchanged, or worse [8], which also constituted the primary outcome variable at 2 years. ODI success was described as >25% improvement, as in some FDA studies on TDR [4, 10, 27]. Complications and reoperations, including patients scheduled for reoperation, were recorded as they occurred. The grading into minor and major complications used in “The Swedish Spine Study” was used [9]. Radiographs were acquired preoperatively, postoperatively and at the 1- and 2-year follow-ups. The radiographic examination was in the supine position and consisted of a standard AP-view and lateral views in flexion and extension. The radiographic results on disc prostheses positioning and motion, and fusion healing in the two groups, will be described in a separate article. All patients appeared at check-ups and answered questionnaires at both the 1- and 2-year follow-up, resulting in a 100% follow-up rate.

Power calculation and statistical analysis

The study was dimensioned to compare TDR and fusion with global assessment of back pain at 2 years as the primary outcome variable. “Total relief” was considered as the optimum result and “much better” was interpreted as essential improvement in contrast to “better”, “unchanged” and “worse”. The Lehr formula [16] was used to provide crude estimates of sample size. With 80% power at 5% significance level, the size of each group was estimated at 64 patients, which was increased to 72 to allow for potential dropout. Statistical analysis was made using

Table 2 Patient demographics and intraoperative data (mean values)

	TDR ($N = 80$)	Fusion ($N = 72$)	P	Total ($N = 152$)
Female gender	48 (60%)	42 (58%)	0.715	90
Age	40.2 $\pm$ 8.1	38.5 $\pm$ 7.8	0.229	39.4 $\pm$ 8.0
Smokers	8 (10%)	8 (11%)	0.824	16 (11%)
Previous spinal surgery	10 (12%)	8 (11%)	0.792	18 (12%)
Back pain VAS	62.3 $\pm$ 20.8	58.5 $\pm$ 21.7	0.218	60.5 $\pm$ 21.2
Leg pain VAS	32.8 $\pm$ 26.4	43.7 $\pm$ 28.2	0.016	37.9 $\pm$ 27.7
EQ5D	0.42 $\pm$ 0.31	0.36 $\pm$ 0.33	0.167	0.39 $\pm$ 0.32
ODI %	41.8 $\pm$ 11.8	41.2 $\pm$ 14.6	0.303	41.5 $\pm$ 13.1
LBP ≥ 2 years	79%	87%	0.147	83%
One level surgery	45 (56%)	33 (46%)	0.200	78 (51%)
Intraoperative blood loss (ml)	560 $\pm$ 400	444 $\pm$ 228	0.185	505 $\pm$ 335
Operating time (h)	2.3 $\pm$ 0.8	2.7 $\pm$ 0.6	0.0008	2.5 $\pm$ 0.7
Length of hospital stay(days)	4.4 $\pm$ 1.6	5.9 $\pm$ 1.2	0.0000	5.1 $\pm$ 1.6

VAS Visual Analogue Scale, EQ5D Euroqol, ODI Oswestry Disability Index questionnaire, LBP low back pain

Statistica version 7 (StatSoft Inc. Tulsa, OK, USA). Results are given as means, standard deviations and ranges. For comparison between the treatment groups, and for some sub-group analyses, two-tailed Mann–Whitney *U* test and Wilcoxon rank sum tests were used. For ordinal data, Student's *t* test was used, and for categorical data, e.g. global assessment, Spearman *R*, Fisher's exact and χ^2 tests were used. Multivariate statistics were used to analyse predictors. Statistical significance was defined as $P < 0.05$.

Surgical technique

TDR group

The patient was positioned supine with neutral lumbar flexion, on a radiolucent operating table with legs elevated in leg supports. Intra-operative AP and lateral fluoroscopy confirmed alignment. If only the lowest lumbar level was operated on and the patient was not obese, exposure was typically a transverse Pfannenstiel incision, otherwise, a longitudinal para-rectal incision was used. Dissection was extra-peritoneal and all access surgery for the procedure was performed by the same experienced vascular surgeon.

The disc was completely removed except for the outer lateral annulus, the disc space was distracted and the posterior longitudinal ligament released to ensure mobilisation of the segment. The cartilaginous endplates were carefully removed with curettes to maintain the integrity of the subchondral bony endplates. The final end plate preparation, the size of TDR, and the insertion procedure were according to respective manufacturer's recommendation.

Fusion group

The fusions were either PLFs or PLIFs, according to each surgeon's habit, and were all instrumented by pedicle screw technique, with either Steffee plates or Monarch instrumentation (DePuy Spine). Autologous bone graft, either locally or from the posterior iliac crest, was utilised. Only in PLF cases were the facet joints destroyed at index level, and bone graft was positioned in the joint spaces and on the transverse processes after thorough decortication. In PLIF cases, the discs were evacuated, the cartilage removed from the end plates, and two carbon fibre cages (Brantigan, DePuy Spine) were placed at each level, with bone graft between and lateral to the cages.

Postoperatively, patients in both groups increased their activities as quickly as they could tolerate and were instructed to be as mobile as possible without restriction. A soft lumbar orthosis, as recommended by some TDR suppliers, was used for 6 weeks in patients in the TDR group. As soon as the patient could take care of him/herself, they were discharged from hospital. This was often determined

by the patient's ability to transfer and ambulate independently with oral pain management only.

For both groups, walking, together with a small programme to activate back and trunk muscles, was recommended. No sport was allowed for 6 weeks and no heavy lifting for 3 months. All patients were referred to outpatient physiotherapy.

Results

Perioperative data

There was no difference in blood loss between the two treatment groups, most fusion but no TDR patients had a drain: blood loss in the drain was not measured. Median bleeding in the TDR group was 450 ml (50–1,900 ml), and in the fusion group 400 ml (150–1,200 ml). In the TDR group, there were some outliers with major haemorrhage. Both operation time and hospital stay were shorter in the TDR group than in the fusion group (Table 2). All patients were admitted to hospital the day before surgery: this was counted as Day 1.

Outcome

All clinical outcome parameters improved for both groups between baseline and 1 and 2 years. There was no difference in outcome between one or two-level surgery, or between different TDR devices, nor the two different fusion techniques (PLF and PLIF).

Global assessment

At both 1 and 2 years, the primary outcome parameter differed between the two groups. In the TDR group, 30% were pain-free at 1- and 2-year follow-up. In the fusion group, 10% were pain-free at 1 year and 15% at 2 years (Table 3).

Back and leg pain

The TDR group made greater improvement than the fusion group regarding back pain VAS at 1 and 2 years, but there were no differences in improvement in leg pain VAS. There was no change in this parameter between 1 and 2 years. The TDR group had a lower VAS back at both 1 and 2 years (Fig. 1).

ODI

The absolute ODI improvement in the TDR group remained constant between 1 and 2 years, and was better for TDR after 1 year but not after 2 years.

Table 3 Outcome of “Global assessment of pain” and other parameters

Global assessment of back pain	Preoperative			1 year			2 years		
	TDR	Fusion	<i>P</i> value between groups	TDR	Fusion	<i>P</i> value between groups	TDR	Fusion	<i>P</i> value between groups
Totally pain-free	–	–	–	23 (29%)	7 (10%)	0.003	24 (30%)	11 (15%)	0.031
Much better	–	–	–	35 (44%)	38 (53%)	n.s.	32 (40%)	35 (49%)	n.s.
Better	–	–	–	12 (15%)	15 (21%)	n.s.	14 (18%)	16 (22%)	n.s.
Unchanged	–	–	–	7 (9%)	7 (10%)	n.s.	5 (6%)	7 (10%)	n.s.
Worse	–	–	–	3 (4%)	5 (7%)	n.s.	5 (6%)	3 (4%)	n.s.
VAS back pain	62.3 ± 20.8	58.5 ± 21.7	0.218	25.5 ± 26.5	33.4 ± 26.8	0.030	25.4 ± 29.8	29.2 ± 24.6	0.048
Difference pre-postop	–	–	–	36.8 ± 30.0	25.1 ± 34.2	0.027	36.9 ± 31.0	29.3 ± 31.6	n.s.
VAS leg pain	32.8 ± 26.4	43.7 ± 28.2	0.016	13.2 ± 21.9	20.6 ± 25.1	0.007	16.4 ± 24.5	20.7 ± 24.3	0.037
Difference pre-postop	–	–	–	19.6 ± 32.1	23.1 ± 32.7	n.s.	21.0 ± 26.4	23.2 ± 28.1	n.s.
EQ5D	0.42 ± 0.31	0.36 ± 0.33	0.167	0.71 ± 0.28	0.63 ± 0.27	0.046	0.67 ± 0.33	0.69 ± 0.25	n.s.
Difference pre-postop	–	–	–	0.25 ± 0.36	0.33 ± 0.38	0.057	0.25 ± 0.36	0.33 ± 0.38	n.s.
ODI %	41.8 ± 11.8	41.2 ± 14.6	0.303	19.5 ± 18.7	24.9 ± 16.1	0.023	20.0 ± 19.6	23.0 ± 17.0	n.s.
Difference pre-postop	–	–	–	22.4 ± 17.8	16.3 ± 18.4	0.036	21.9 ± 18.9	0.33 ± 0.38	n.s.
ODI success	–	–	–	44%	49%	n.s.	31%	39%	n.s.

Fig. 1 TDR showed less low back pain at 1-year follow-up ($P = 0.030$) and at 2 years ($P = 0.048$)

There were no differences in ODI success between groups at 1 and 2 years, but the frequency of ODI success improved in the fusion group between 1 and 2 years ($P = 0.027$) (Table 3).

EQ5D

At 1 year, the TDR group was better than the fusion group, but due to continuous improvement ($P = 0.011$) in the fusion group during the second year the difference was not seen at 2 years.

SF36

At 1 year, TDR had improved more in domains RP, BP and SF, but this was not seen at 2 years.

Patient satisfaction

At 1 year, 77% in the TDR group were satisfied with the treatment and 64% in the fusion group ($P = 0.072$). After 2 years, 71% of the TDR group and 67% in the fusion group were satisfied with their treatment ($P = 0.586$).

Work status

The percentage on sick leave prior to surgery was 69% for both groups.

After less than 3 months 30% of the total TDR group (24/80) and 18% of the total fusion group (13/72) had returned to work ($P = 0.102$). After 1 year, 71% of the TDR group and 68% of the fusion group were back at work (full or part-time: $P = 0.776$). At 2 years, 76% of the TDR group and 72% of the fusion group were back at work (full or part-time $P = 0.750$).

Complications and reoperations

The treating surgeon reported both complications and reoperations at 1 and 2 years after treatment start. In addition, medical records were retrospectively scrutinised for information. Complications were equally common in both groups (Table 4). The grading of complications from

“The Swedish Spine Study” was used, and there were two major complications in the TDR group and six in the fusion group. There were 12 minor complications in the TDR group and 9 in the fusion group.

Reoperations, performed (or planned), within 2 years was 10% for the fusion group (excluding patients complaining of supposed screw/instrument irritation) and 10% for TDR group. Reoperation did not alter outcome after 1 and 2 years, but most reoperations were performed close to the 2-year follow-up. The effect of reoperations can be evaluated at the 5-year follow-up. The most common cause of reoperation in the fusion group was operation at an adjacent level (7%). In the TDR group, the most common cause of re-operation was to fuse index level that was believed to cause persistent or recurrent pain (5%), then evacuation of haematoma (2%). Twenty-two TDR patients underwent postoperative facet block, two of them also had discography, due to remaining pain. Nine fusion patients underwent postoperative discography due to suspected adjacent level disease, and one of them had facet block.

Table 4 Complications and re-operations

	TDR (80)	Fusion (72)	Total (152)
No complication	66	57	103
Infection	0	4	4
Haematoma	2	1	3
Facet joint problem	6	0	6
Pseudarthrosis	0	2	2
Wound hernia	1	0	1
Nerve entrapment	1	0	1
Donor site pain	0	1	1
Adjacent	1	6	7
Dural tear	1	1	2
Meralgia paresthetica	1	0	1
Subsidence/re-operation	1	0	1
Total complications	14	15	48
No reoperation	72	65	117
Decompression	1	0	1
Decompression together with extraction of pedicular screws	0	1	1
Fusion at TDR level	4	0	4
TDR above fusion	0	5	5
Haematoma removal	2	0	2
Hernia repair	1	0	1
Repair of dural tear	0	1	1
Total re-operations	8	7	35
Extraction of pedicular screws	0	20	20

The complications documented in both groups were equal, in the fusion group (21%) and in the TDR group (18%, $P = 0.747$). In both groups there were 10% of reoperations. The types of operations are listed. Bold figures show major complications

Twenty fusion patients had their instrumentation removed, due to persistent or recurrent pain.

Discussion

In this study, both groups improved after the operation, confirming that surgery was a successful remedy for LBP in carefully selected patients. However, the primary aim of this study was to compare clinical outcome after fusion or TDR. The primary outcome measure, “Global Assessment”, showed that a higher proportion of TDR patients than fusion patients were totally pain-free. At 2 years, twice as many TDR patients still reported total absence of LBP. In the secondary outcome measures, a slightly different pattern emerged. There were better results after TDR at 1 year, but the difference disappeared at 2 years and was due to the fusion group improving during the second year. The TDR group appeared to reach maximum improvement at 1 year indicating that the TDR group improved more rapidly than the fusion group (Fig. 1), which is in accordance with the findings of others [22]. Whether this difference is a positive effect of preserved motion in the segment, the total excision of the pain source (disc), or a negative effect of the surgical approach in the fusion group remains unclear. The differences in hospital stay and return to work could well be an effect of the surgical approach rather than TDR or fusion. If anterior fusion (ALIF) had been performed, the results may have been the same for both groups. Radiological mobility analysis compared to clinical outcome may provide further clarification in this matter. In contrast to “the Swedish Spine Study”, the fusion patients showed further improvement during the second year concerning EQ5D and ODI, and a trend towards less back pain (VAS), the reason for this being unclear [8].

In the fusion group 20 patients had instrumentation removed. This may be a true frequency of “screw irritation” associated with posterior surgery, but “technique bias” cannot be discounted. If a fusion patient complains of residual discomfort, he/she may be offered removal of implant as a last alternative: an option that is not available for TDR patients. The effect of this intervention will be recorded at the 5-year follow-up. Nevertheless, a high frequency of reoperations was undertaken in both groups, although it is too early to evaluate whether this altered the outcome. There is a possibility that the re-operated patients should not have been treated surgically for their LBP.

At the time this study commenced (2003), there were no published RCTs comparing the results of TDR and fusion. Subsequently, three “IDE” trials were designed and undertaken comparing different TDR techniques to fusion in order to reach FDA approval in the USA [4, 10, 27].

These studies were on highly selected cases and without equal randomisation to compare the effect of TDR with fusion.

Many studies dealing with TDR [4, 10, 15, 23, 26, 27] include patients with only one symptomatic level causing pain and dysfunction due to DDD, being discography-positive and without spondylosis or facet joint arthritis, the patients sampled thus representing a subgroup of all patients with painful motion segments. Based on these studies, TDR cannot be recommended for a wide group of patients with degenerative problems.

The posterior approach is usual for fusion [25], and is standard at the Stockholm Spine Center. All fusion patients were thus operated with this approach.

All patients had ODI > 30 or VAS back > 50 at the time of inclusion. However, as symptoms fluctuated with time, five in the TDR group and eight in the fusion group reported better values at the time of surgery. This was interpreted as a “deviation towards the mean” and the patients were not excluded.

Relation to other studies

Both treatment groups benefited from surgery with better overall results than in “The Swedish Spine Study” [8] where 29% reported “pain free” or “much better” compared to 67% in the present series ($P = 0.000$). The total improvement of pain in the FDA trials [4, 10, 27] was larger than in this study and the difference could be the effect of a different case mix in our series.

No differences between levels operated or if one or two levels were treated were seen. This is in contrast to a previous report [24]. No published studies compare TDR to physiotherapy or intense rehabilitation [12], although one study is being conducted.

Further questions

There are still a substantial number of patients in both treatment groups with poor results. This raises the question: is there a subgroup suited for TDR and another for fusion? The degenerative process may start in the disc, but will eventually involve the entire motion segment. As TDR can only be effective against discogenic pain, symptomatic facet joint arthritis is considered a contraindication by many. However, the degree of arthritis that is acceptable and how to distinguish between the different sources of LBP need to be clarified. There is a subgroup of TDR patients with excellent early results, but who develop new LBP later with positive facet joint block [21]. This could be a matter of patient selection, or an opportunity to prevent secondary facet joint degradation [20]. Whether or not

TDR reduces the frequency of adjacent level disease remains uncertain.

The most demanding task in this patient group is to select the right cases for surgery, and to choose the best technique. The solution is still unclear, and we could not identify any consistent predictor of clinical outcome to clarify this, nor could we confirm previously reported predictors of poor outcome [17]. There is a possibility that patients who do not improve after this type of surgery have another mechanism for their pain, which is why the treatment rational does not work.

Conclusion

In this prospective randomised study comparing TDR to fusion in a carefully selected population, we found a better outcome for TDR in most parameters at 1-year follow-up. The fusion group improved during the second year. However, the TDR group had a larger number of pain-free patients at both 1 and 2 years.

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