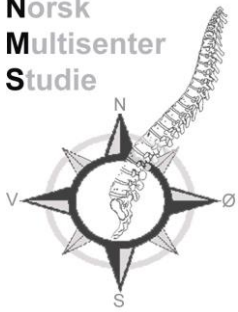


The Norwegian TDR Study

Lumbar total disc replacement

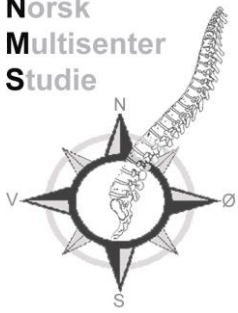
Predictors for long-term outcome



Background

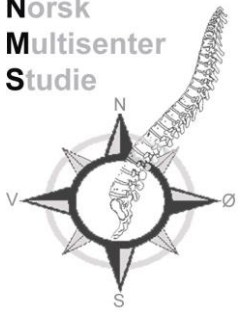


- Lumbar total disc replacement (TDR) is a surgical option for
 - selected patients with
 - chronic low back pain (LBP) and degenerative intervertebral discs
 - when non-operative treatment fails
- Data on predictors associated with favorable long-term outcome after TDR are warranted.



Purpose

- We aimed to identify predictors for favorable long-term outcomes after TDR that are easy for clinicians to assess prior to treatment.



Materials and methods

- A cohort of 82 patients with degenerative discs and chronic LBP were treated with TDR.
- The patients participated in a randomised trial comparing TDR and multidisciplinary rehabilitation eight years ago.

Inclusion criteria

- Age 25-55 years
- Low back pain as main symptom ≥ 1 year
- Conservative treatment ≥ 6 months without sufficient effect
- ODI ≥ 30
- Degenerative disc changes in L4/L5, L5/S1 or both

Main exclusion criteria

- Disc degeneration at ≥ 3 levels
- Nerve root involvement
- Generalised chronic pain
- Spondylosis, arthritis, deformity
- Former fracture in L1-S1
- Drug abuse
- Osteoporosis

173 patients

Potential predictors measured at baseline

Randomised

TDR (n=86)

- ProDisc II (Synthes Spine)

Rehabilitation (n=87)

77 received TDR

14 received TDR

Cross-over

6 lost to follow-up

- 3 lost contact
- 3 withdrew consent

3 lost to follow-up (lost contact)

71 included in analysis

- 9 had reoperation

11 included in analysis

Postoperative follow-up time: 8 years

Postoperative follow-up time: 6 (range 3.4-7.3) years

82 included in analysed cohort

Outcomes assessed at follow-up

Analysed baseline characteristics

Socioeconomic variables	Clinical variables	Psychological variables and pain	Radiological variables
Manual labour	Prior surgery	HSCL-25	Pelvic incidence
Education	Affected level	FABQ	Disc dehydration
Work status	Comorbidity	SF-36	Disc height
Duration of sick leave	ODI	Pain (VAS)	High Intensity zone
Smoking		Pain drawing	Modic changes (+/-)
Gender		Duration of back pain	Extent of Modic changes
Age		Consumption of narcotics	Facet joint degeneration

Statistics

1: Univariate binary logistic regression

... to test the association between baseline characteristics and outcome



2: Multiple logistic regression model

... to test the association between baseline characteristics that were significantly ($p < 0.05$) associated with outcome in the univariate model, and outcome



3: Prediction matrix

... based on data from the multiple model

Results



1: Patient characteristics associated with a clinically important improvement (≥ 15 ODI-points improvement from baseline):

- **Detectable Modic-changes ***
(type 1 and / or 2 vs. no Modic changes)
 - OR 5.0, 95% CI 1.4-18.2, $p=0.01$
- **Extent of Modic-changes ***
($> 50\%$ vs $< 50\%$ of vertebral height)
 - OR 3.8, 95% CI 1.3-11.5, $p=0.02$



* *The two variables were significantly associated with each other ($p=0.01$)*

Results



2: Patient characteristics associated with employment at follow-up:

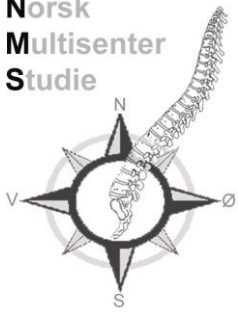
- **Duration of sick leave < 12 months**
 - OR 4.1, 95% CI 1.6-10.6, p=0.003
- **No comorbidity**
 - OR 4.4, 95% CI 1.4-13.8, p=0.01
- **ODI < 50 points**
 - OR 3.6, 95% CI 1.0-12.5, p=0.04
- **Education \geq 10 years**
 - OR 3.6, 95% CI 1.1-11.2, p=0.03

Prediction matrix

		Education < 10 years		Education ≥ 10 years	
		Comorbidity	No comorbidity	Comorbidity	No comorbidity
≥ 12 months sick leave	ODI ≥ 50	1 % (0-4)	9 % (3-15)	4 % (0-8)	24 % (15-33)
	ODI < 50	4 % (0-8)	25 % (16-35)	12 % (5-19)	52 % (41-63)
< 12 months sick leave	ODI ≥ 50	7 % (2-13)	38 % (28-49)	20 % (12-29)	67 % (56-77)
	ODI < 50	22 % (13-31)	68 % (58-78)	47 % (36-58)	87 % (80-94)

Probability of working (95 % CI) at eight-year follow-up after total disc replacement using a probability matrix model.

Educational level (< 10 years or ≥ 9 years, presence of comorbidity, duration of sick leave before treatment (< 12 months or ≥ 12 months) and Oswestry Disability Index (ODI, < 50 points or ≥ 50 points).



Conclusion

- Patients with Modic changes prior to the TDR surgery were more likely to report a clinically important functional improvement at long-term follow-up.
- Patients with lower ODI-score, no comorbidity, higher education and less time out of work prior to surgery were more likely to work at follow-up.
- These findings must be interpreted with caution since the size of the study population is limited (n=82).

Disclosures

Conflict of interest	Yes	No
Håvard Furunes, MD		X
Christian Hellum, MD, PhD		X
Helga Brøgger, MD		X
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Ansgar Espeland, MD, PhD		X
Kjersti Storheim, PT, PhD		X