Prognosis of patients post lumbar spinal fusion surgery: development of a risk stratification tool to stratify physiotherapy care

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Radboudumc

Low back pain:

- Reported lifetime incidences: 49 to 63%
- Point prevalences: 12 to 30%
- One-year prevalence of 44%
- Annual incidence: 19%

(Anderson 1999 and Cassidy et al 2005)

Diagnostic triage

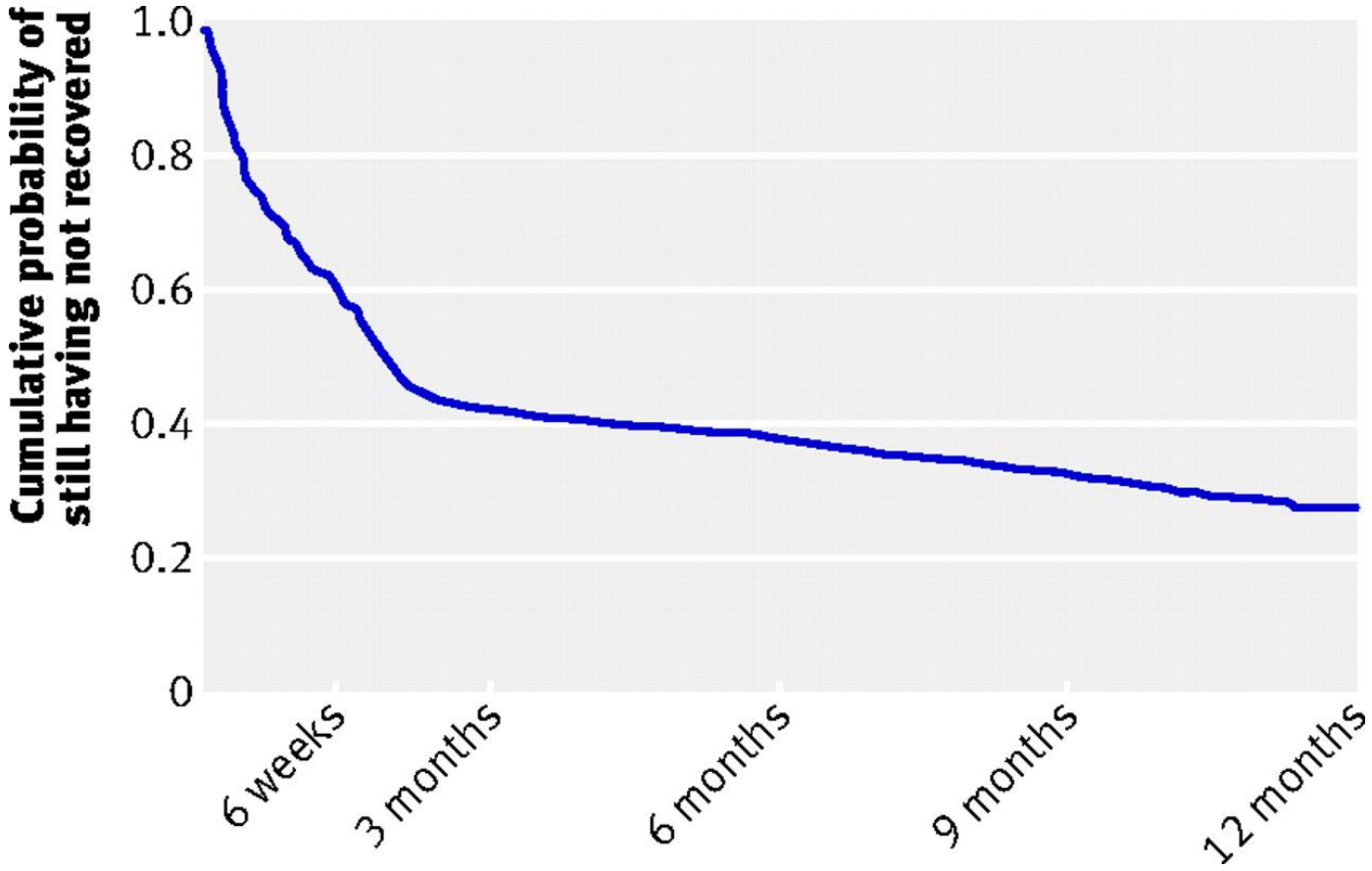
(Waddel. The back pain revolution 1998)

- Non-specific low back pain (85-90%)
- Nerve root syndrome
- Possible serious pathology

  (tumor / metastasis, trauma, infection, cauda equina syndrome, ankylosing spondylitis etc.)
- Diagnostics in general: gold standard, sensitivity/specificity?

Natural history/course of low back pain

- Self-limiting and favorable
- Recurrent, episodic and intermittent
- Less than one third resolve annually, more than 20% recur within 6 months (Cassidy et al, 2005)



Henschke et al 2008

BMJ

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Why and when lumbar fusion?

- Not advocated in guidelines
- First conservative treatment (exercise, cognitive-behavioral treatment, multidisciplinary treatment)
- Final treatment option?

Why lumbar fusion?

ELSEVIER

CrossMark

THE SPINE JOURNAL

The Spine Journal 16 (2016) 588–590

Commentary

Consensus at last! Long-term results of all randomized controlled trials show that fusion is no better than non-operative care in improving pain and disability in chronic low back pain

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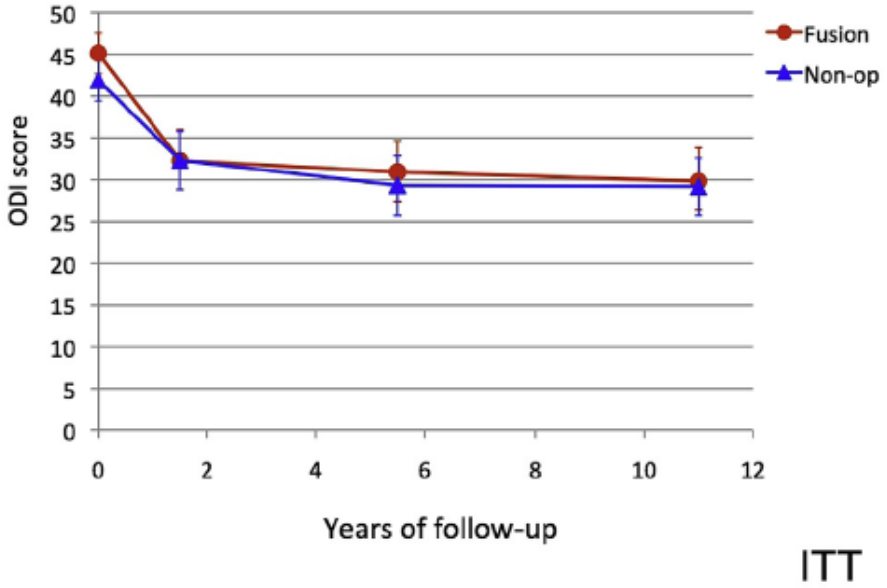
Why lumbar fusion?



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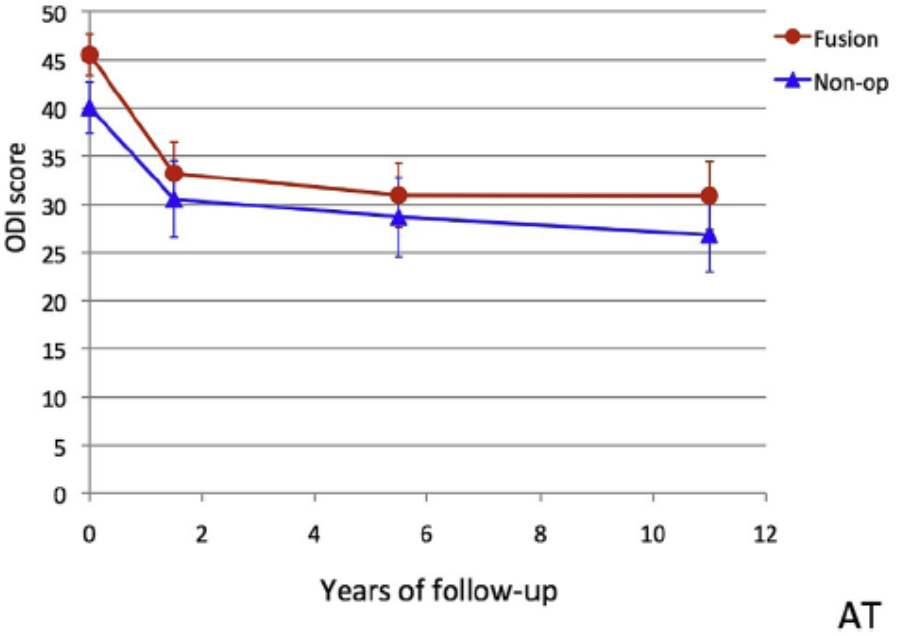


AT

Mannion et al (Spine J 2013)

Why lumbar fusion?

Clinical Study

Spinal fusion for chronic low back pain: systematic review on the accuracy of tests for patient selection

Paul C. Willems, MD, PhD[a,*], J. Bart Staal, PT, PhD[b], Geert H.I.M. Walenkamp, MD, PhD[a], Rob A. de Bie, PT, PhD[c]

	LR $^{+}$ (median, range)	LR $^{-}$ (median, range)
TLSO (n=3)	**1.10 (0.94 - 1.13)**	**0.92 (0.39 - 1.12)**
Provocative Discography (n=4)	**1.18 (0.70 - 1.71)**	**0.74 (0.24 - 1.40)**
TETF (n=3)	**1.22 (1.02 - 1.74)**	**0.58 (0.15 - 0.94)**

No statistically significant LRs

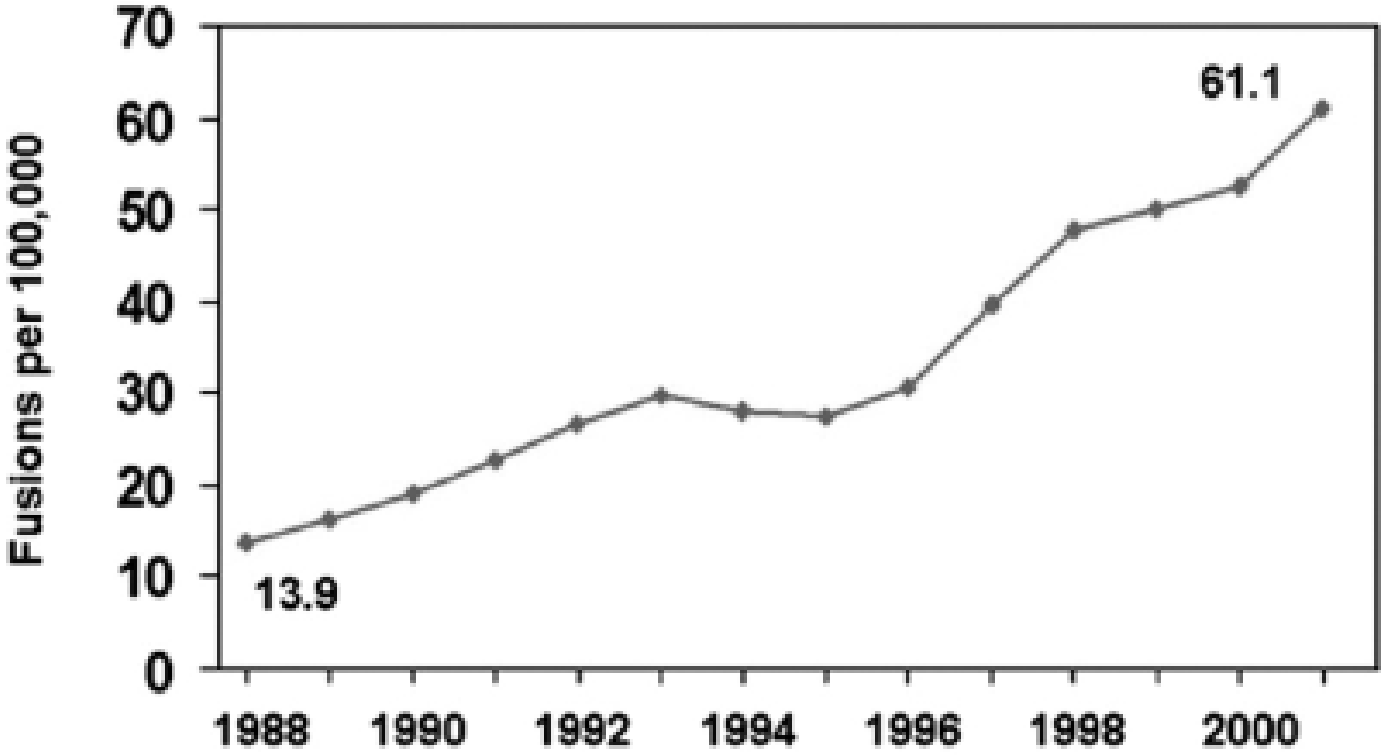


Figure 1. The rise of spinal fusion procedures for degenerative conditions in the USA between 1988 and 2001. Note the rapid increase after 1996, when fusion cages were approved. (Courtesy from Mr Richard A Deyo, J Am Board Fam Med 2009;22:62-68, reproduced with permission).

(Willems, PhD thesis 2013)

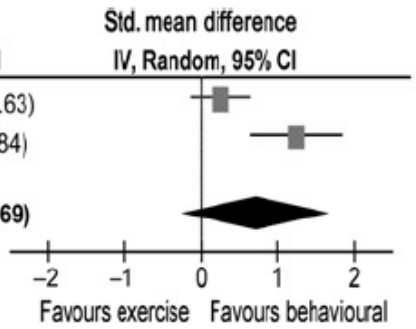
How to improve recovery after fusion surgery?

- Wait and see-policy? Do they need an intervention?
- Minimal physiotherapy intervention
- Extensive rehabilitation (for subgroups)?

Evidence?

Study or subgroup	Exercise Mean	SD	Total	Behavioural Mean	SD	Total	Weight	Std. mean difference IV, Random, 95% CI
Abbott *et al*, 2010[33]	−29.4	25.4	54	−35.9	26.1	53	52.8%	0.25 (−0.13 to 0.63)
Christensen *et al*, 2003[13]	4	1.67	26	2	1.5	26	47.2%	1.24 (0.64 to 1.84)
Total (95% CI)			**80**			**79**	**100.0%**	**0.72 (−0.25 to 1.69)**

Heterogeneity: τ^2=0.43; χ^2= 7.51, df = 1 (p=0.006); I^2 = 87%
Test for overall effect: Z =1.45 (p=0.15)



Rushton A, Eveleigh G, Petherick E-J, *et al*. *BMJ Open* 2012;**2**:e000829. doi:10.1136/bmjopen-2012-000829

exercises.[33] Behavioural interventions included psychomotor therapy using cognitive behavioural principles in addition to exercise[33] and a back-cafe using physiotherapist and group support to continue exercises. Timing of interventions ranged from 1 day to 9 weeks, starting between 1 day and 3 months post-surgery.

Evidence- Rushton et al 2012

- Comparison behavioral versus exercise
- Wide CI: potentially beneficial or harmful
- Substantial risk of bias

Evidence - Rushton et al 2012

Some thoughts:

- Why not exercise or behavioral interventions versus no intervention (usual care)?
- Please do not conduct PITO trials (comparisons or interventions not likely to be replicated)
- Either replicate or start something complete new after carefull development

TIDieR
Template for Intervention Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.		
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.		
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).		
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.		
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.		
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.		
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.		

Prognosis of patients post-fusion

- Heterogeneous group of patients: different in suffering from pain, expectations, coping style etc.
- (Very) resistent to conservative treatment (that's why they were operated).
- Susceptible to iatrogenic effects?

Prognosis of patients post-fusion

- International study proposal:

A. Rushton, P. Goodwin, N. Heneghan (UK)
B. Staal, P. Willems, T. Hoogeboom (NL)
M. Verra, L. Benneker, G. Luder, B. Winteler (CH)

Development of a risk stratification tool.

Example STarT backtool

Key objectives STarT backtool-project:

1) to identify patients with potentially treatment modifiable prognostic indicators using a brief, user-friendly tool, and

2) to validate cut-off scores for subgrouping patients into 1 of 3 a priori initial treatment options in primary care

(Hill et al 2008)

STarT backtool: ‘clinically driven’

low risk subgroup:
few negative prognostic indicators, suitable for primary care management according to best-practice guidelines

medium risk subgroup:
unfavorable prognosis with high levels of physical prognostic indicators, appropriate for physiotherapy

high risk subgroup:
very unfavorable prognosis, high levels psychosocial prognostic indicators, appropriate for management by a combination of physical and cognitive– behavioral approaches

(Hill et al 2008)

Steps undertaken

1) selecting items for inclusion

2) validating psychometric properties and identifying cut-off scores for subgroup allocation

3) Independent external validation

STarT backtool: step 1 selecting items

Literature search for selecting modifiable prognostic indicators

Secondary analyses of RCT and cohort study to select significant indicators using logistic regression

Expert panel

Brevity was important, therefore best performing individual items were selected from full questionnaires

STarT backtool: step 2, psychometrics

Development sample: cross-sectional study, survey among primary care patients

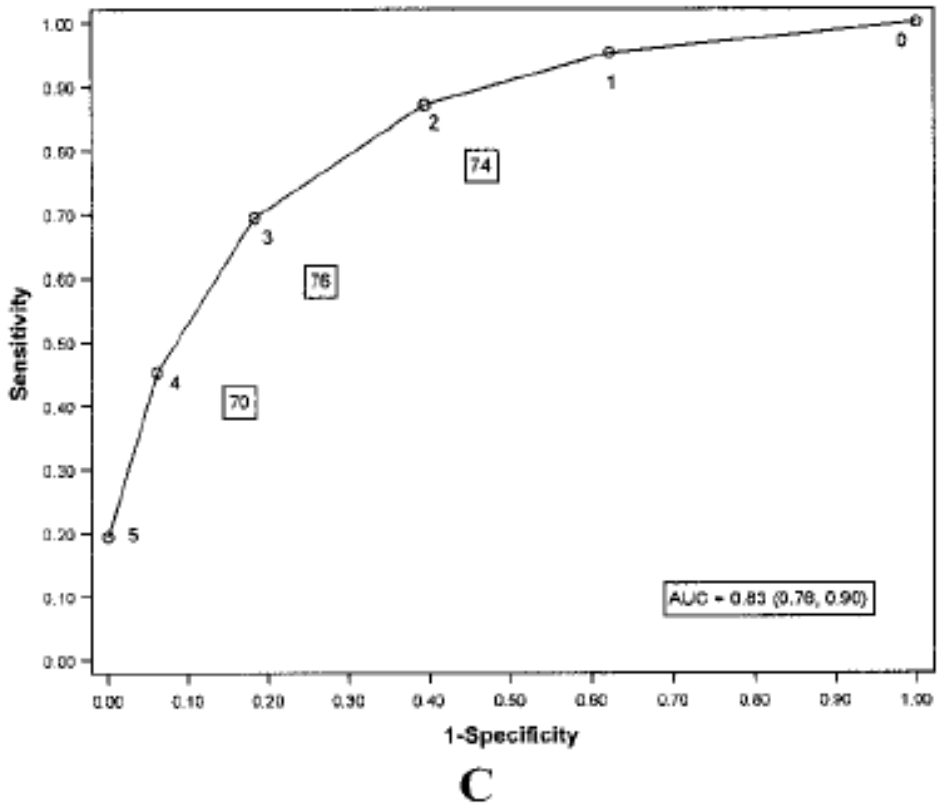
Psychometric properties of the tool:
Discriminant validity, internal consistency and repeatability

ROCs were used to establish cut-off scores

(Hill et al 2008)

STarT backtool: step 3, external validation

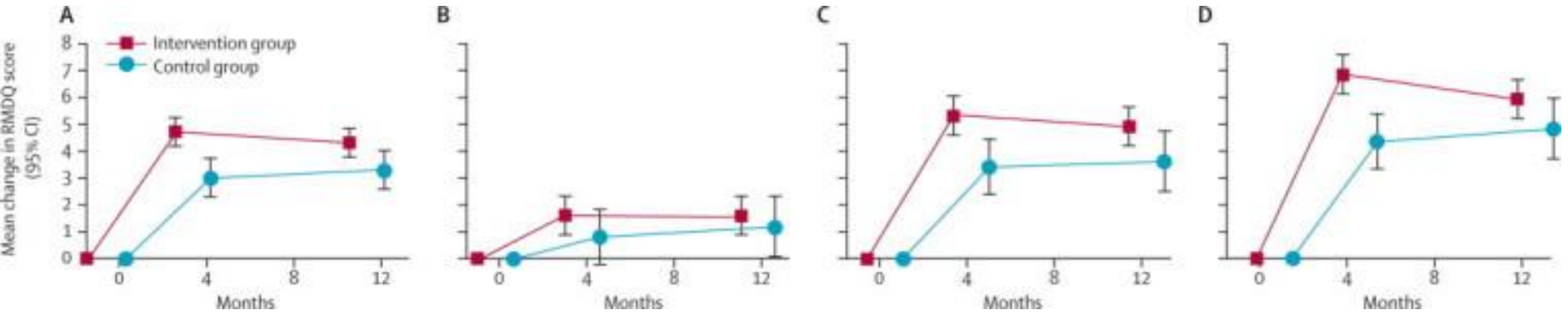
Prospective cohort study in primary care



Example development study: Reference case Pain catastrophizing scale

(Hill et al 2008)

Stratified care (STarT Back tool)



Hill et al. Lancet 2011

Pros and Cons STarT backtool

- It works but ….. small effects
- Simple brief tool – easy to use
- Development:
  Scientific rigour combined with clinically driven approach
- Many arbitrary choices: e.g. why 3 groups?

Prognosis of patients post-fusion

- Disadvantage of a brief tool:

  ‘oversimplification of the decision making process, impact on professional reputations and professional development, patient satisfaction and threats to patient centred care (Woods and Gaskell 2014)

- Not a panacee!

Prognosis of patients post-fusion

Starting point for our research group:

- We don’t know if they need physiotherapy, if so
- We don’t know what they need, and
- We don’t know who needs something

Our working plan

Systematic review natural history

Koenders *et al. Systematic Reviews* (2016) 5:72
DOI 10.1186/s13643-016-0252-2

Systematic Reviews

PROTOCOL Open Access

Pain and disability following first-time lumbar fusion surgery for degenerative disorders: a systematic review protocol

Niek Koenders[1*], Alison Rushton[2], Nicola Heneghan[2], Martin L. Verra[3], Paul Willems[4], Thomas Hoogeboom[5] and J Bart Staal[5,6]

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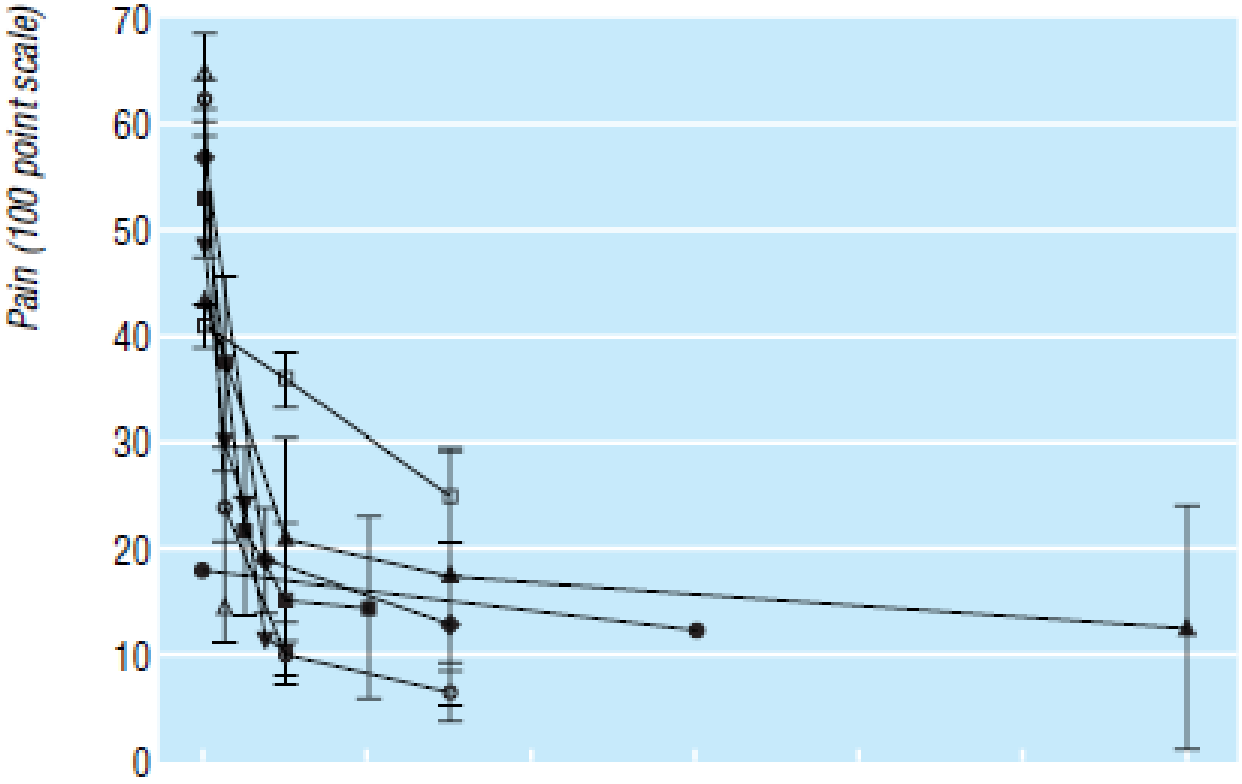
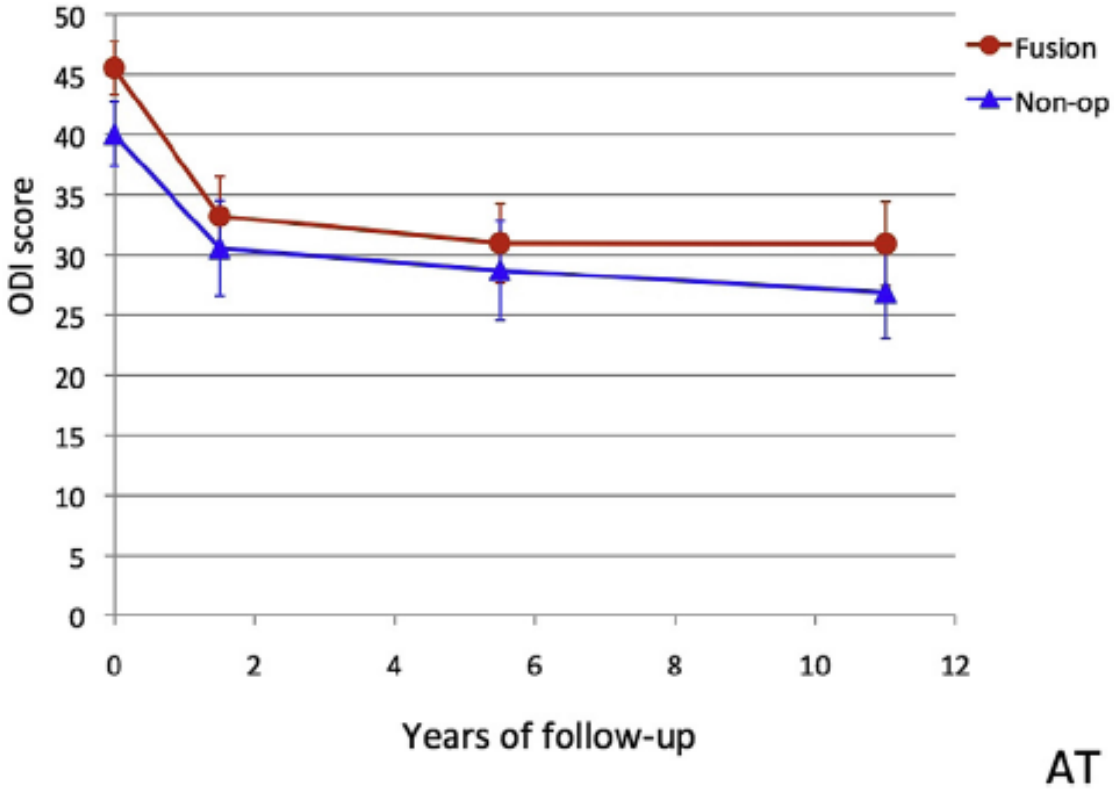
Prognosis of patients post-fusion



Example prognosis acute low back pain, Pengel et al, BMJ 2003

Natural history review



Mannion et al, 2014

But we prefer cohort studies, no RCTs

Systematic review of prognostic factors for recovery

- Identification of factors related to the outcome
- Outcomes: Pain, disability, quality of life, RTW
- Preferrably modifiable factors to inform future physiotherapy interventions

Qualitative study

In-depth **semi-structured interviews (n=40)** following discharge and at 12-months post surgery:

- pre and post-operative experiences,
- underlying attitudes and beliefs
- facilitators and barriers to recovery
- adherence to advice and physiotherapy
- experiences of rehabilitation, and return to normal function/activity/work

Selection of candidate predictors

- Informed by systematic review of prognostic factors and qualitative study
- What is currently registered in UK, Netherlands and Switzerland
- No planning of new cohort studies, but using data from existing spine registries.

Study design of cohort studies

- Agreement on time points

- Priority time points:

  * Pre-surgery (baseline)

  6-8 weeks post surgery (to separate out initial impact of surgery) (need approval in NL)

  * 12 months post surgery

  2 years post surgery

Selection of candidate predictors

- Shortlist modifiable factors collected from patient:

Smoking status, ODI, VAS back pain, VAS leg pain ,
Distribution of pain (How?), HADS, EQ5D-5L
Current work status / days post surgery when returned to work / normal function
Self reported physical activity IPAQ-S7S
Pain self-efficacy questionnaire
Coping strategies questionnaire
Pain catastrophizing scale
Preparedness for surgery (expectancy?)

Selection of candidate predictors

Non-modifiable factors collected from patient:

Age
Gender
Height
Education (individualized to each country and dichotomise)
Pre-operative walking capacity
Duration of symptoms prior to surgery

Selection of candidate predictors

Non-modifiable factors collected from surgeon:

Indication for surgery
Positive SLR pre operatively
No of levels fused
Surgical approach
Surgical complications

Prognostic models

- Focus on modifiable factors
- Development of prediction model in UK
- External validation in NL and Switzerland

Final steps of this project

systematic reviews →

qualitative studies →

prediction models →

↓

Research team will develop risk stratification tool → future RCT?

Risk stratification tool to stratify post-fusion care

- Questions?

- Suggestions for improvement?