

# Stockholm November 9-10, 2023

## Annual meeting Swedish society of spinal surgeons (4s)

### Swespine 25 years

- **How did it all start – development over time** Peter Fritzell
- **Some important findings** Olle Hägg
- **Where are we today and what about the future** Olle Hägg/Peter Fritzell

**Peter Fritzell**/Register manager of the Swedish national spine register, Swespine since 25 years. Associate professor in orthopedics Uppsala University, Sweden.  
Associated to Futurum Academy for Health and Care, Jönköping, Sweden. Stockholm Center for Spine Surgery (RKC), Stockholm Sweden.

**Olle Hägg**/ MD, PhD in orthopedics. Member of the Swespine steering group for 25 years.

**Welcome everyone – and we hope  
all technical Goods will be with us!**

**Peter Försth/president of the Swedish Society of Spinal Surgeons (4s)**

**Peter Fritzell/register manager Swespine – for the Steering group**

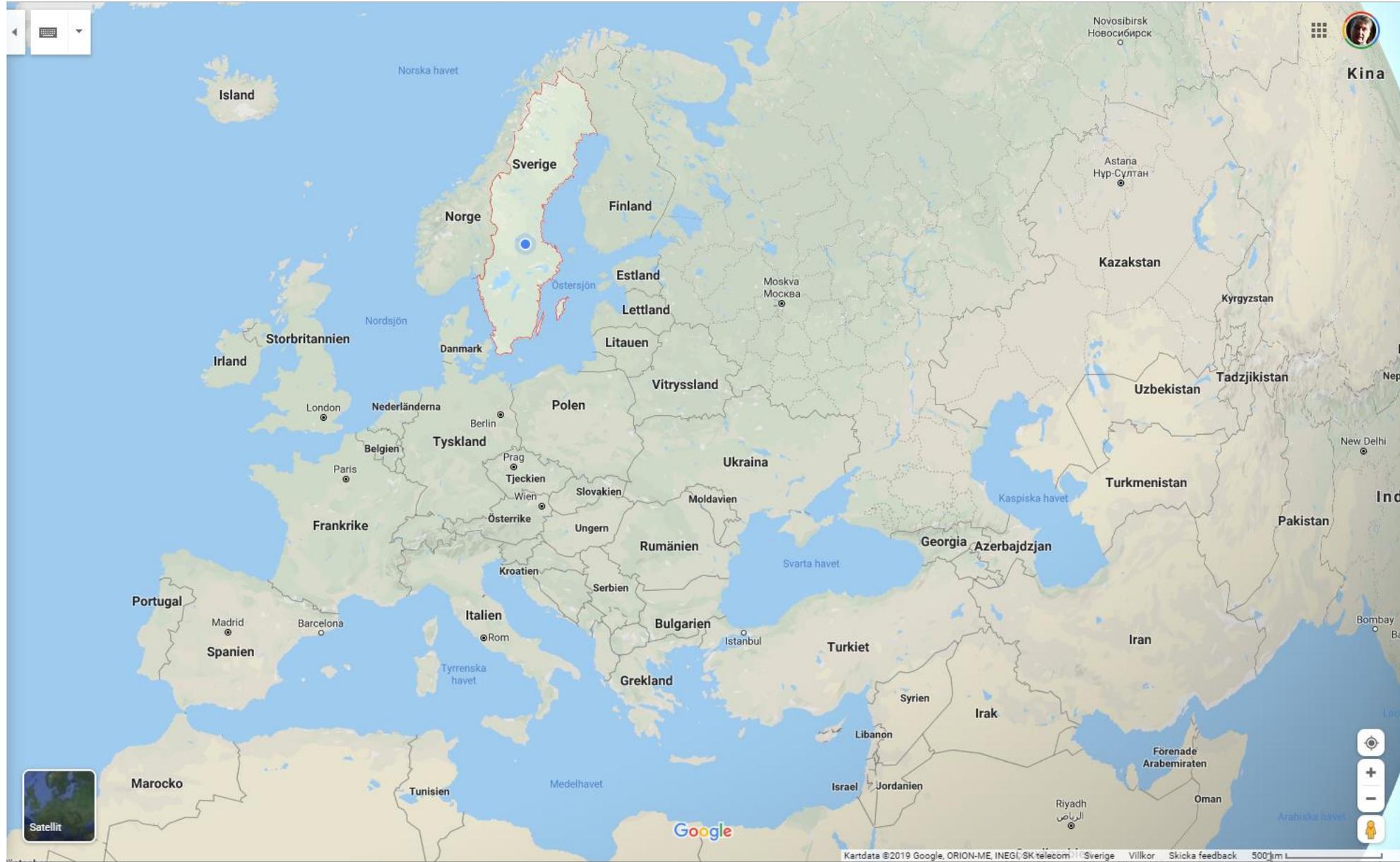
# Sweden and Europe

**Sweden;**  
appr. 10 milj. citizens

45-50 "spine clinics"

**Swespine;**  
a national spine register  
since 1998 – it started as a  
regional register in Lund  
1993

- Coverage >95%
- Completeness >85%
- Follow up 1 year >70%



# **Collection of data in health care – some perspectives**

- Historically - how did it all start**
- Development in Sweden - reflections**
- Important lessons learned**
- Future.... Validation and use in clinical practice/meeting with the patient**

# How did it all start?

**Florence Nightingale, Amory Codman\*, Archie Cochrane**

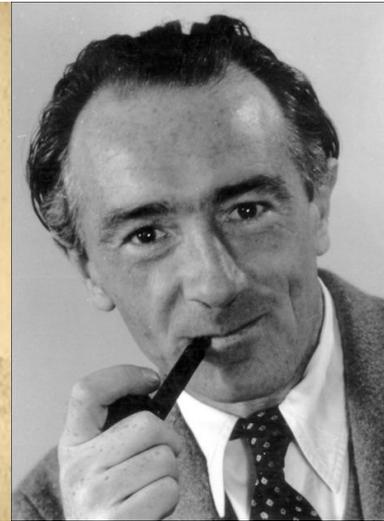
Where/when did they get their "inspiration"?



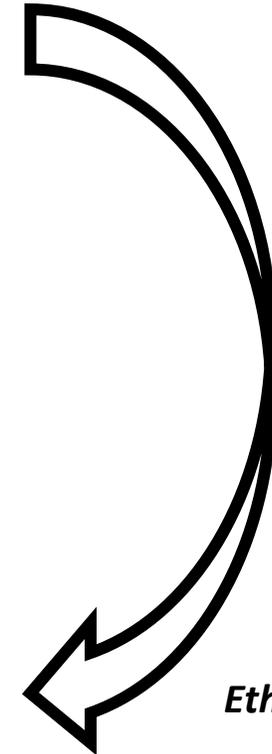
**1820-1910**  
Crimean war  
1853-56



**1869-1940**  
First world war  
1914-1919



**1906-1988**  
Second world war  
1939-1945



*Ethical approval....*

# The end result idea, 1914

**\*Ernest Amory Codman**  
**1869-1940**

*Clinical outcome*

"The Shoulder" 1934

Sarcoma register 1920



\*

**1917**

**"They consider me eccentric, but hospitals need to compare their results with others. *Such choices will not be eccentric in a few years.*"**

**Florence Nightingale**

**1820 – 1910**

**Crimean war 1853-1856**

*Mortality*



***We stand on her shoulders.....***



**\*1917**

**"I'm considered eccentric, because I say publicly that if hospitals want to be sure to improve, they need to find out what their results are. They need to analyze their results to find strong and weak points."**

***"They need to compare their results with others. Such views will not be eccentric in a few years."***

## **Today – 100 years later...Challenges**

**the fact that Codman's "few years" turned out to be a hundred years suggests that there are profound difficulties in realizing the ideas.**

**Many hospitals and healthcare organizations still lack systems that enable the follow-up of treatment results.**

**Together with Florence Nightingale, Codman laid the foundation for what we today call knowledge-based or *“Evidence-based care”***

**Many have placed their hope in the fact that more and more journal systems that become IT-based will be able to be used for performance measurement. However, the journals have been established for other purposes and are weighed down by traditions and regulations that are not readily compatible with evidence-based care work.**

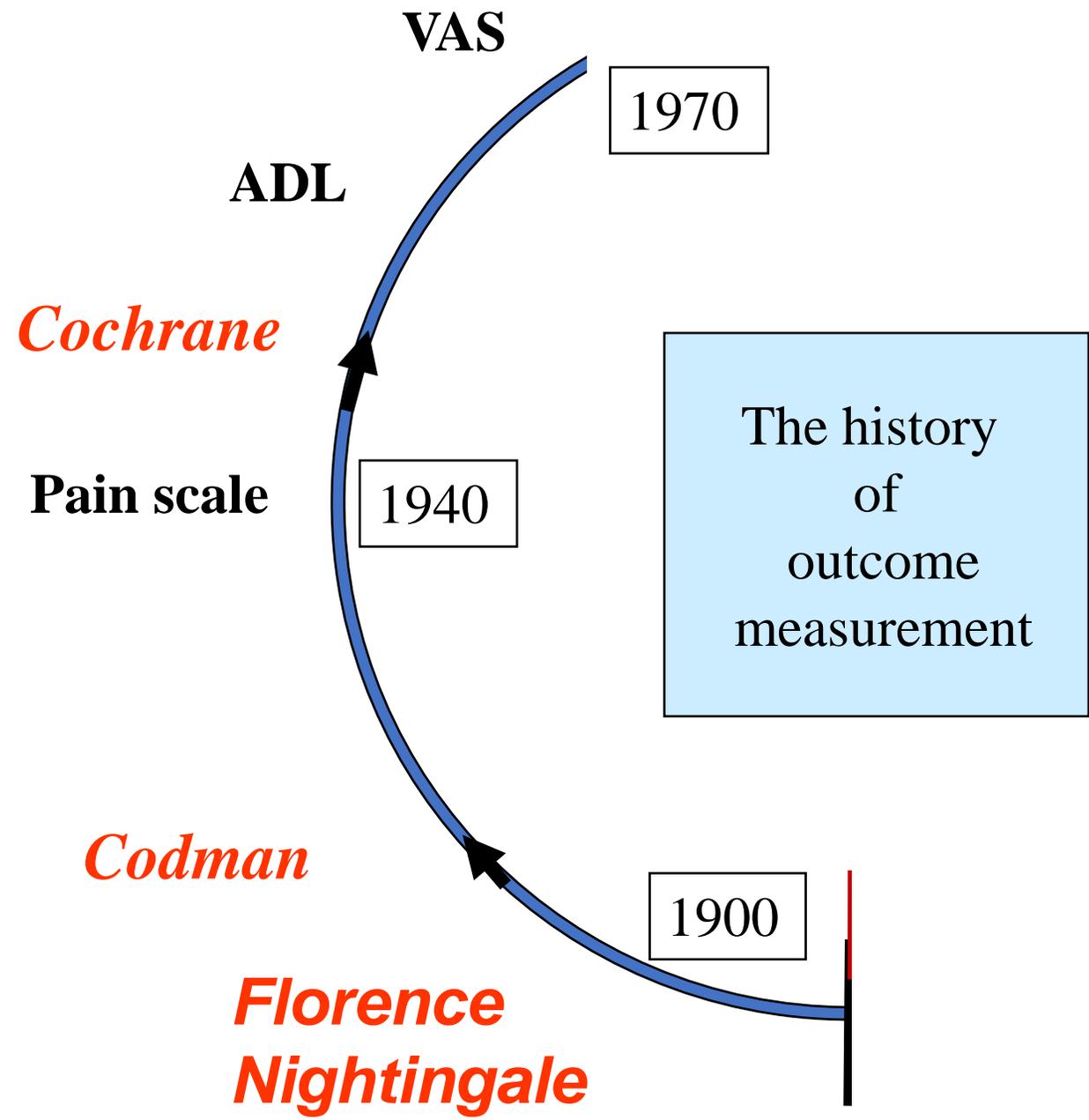
**Don Berwick, one of the US's and the world's leading authorities on evidence-based and quality work in health care, calls medical record systems "dinosaurs."**

**However, Codman's "End Result Idea" from 1917, has finally taken hold in Swedish healthcare, but there are many challenges ahead – not the least today's "battle" .....**

**“registries vs. medical journals”**

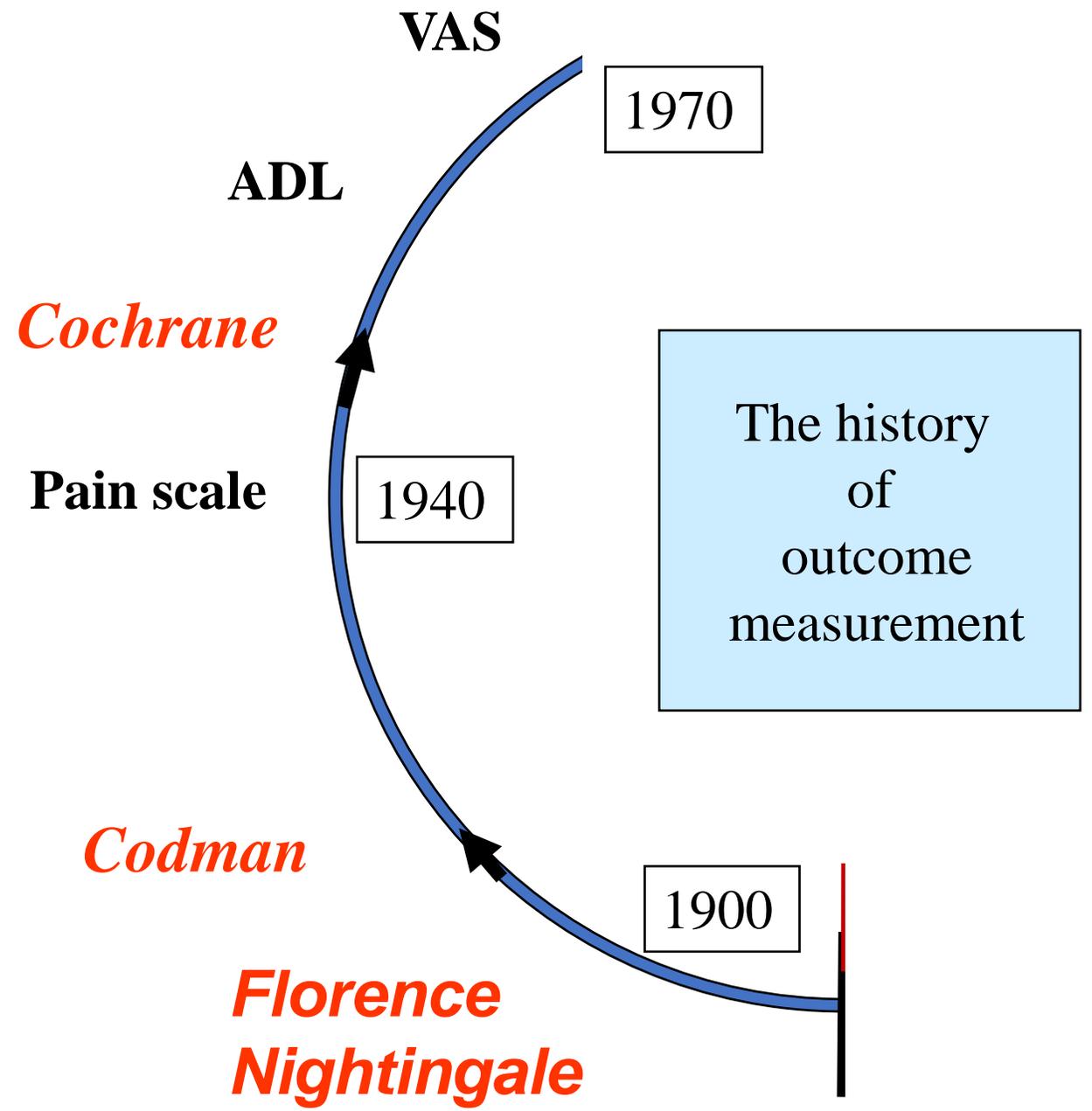
**Registering and FU during the last 100 years –  
outcome measuring in clinical practise.....**

**Physician rating**



**Physician rating**

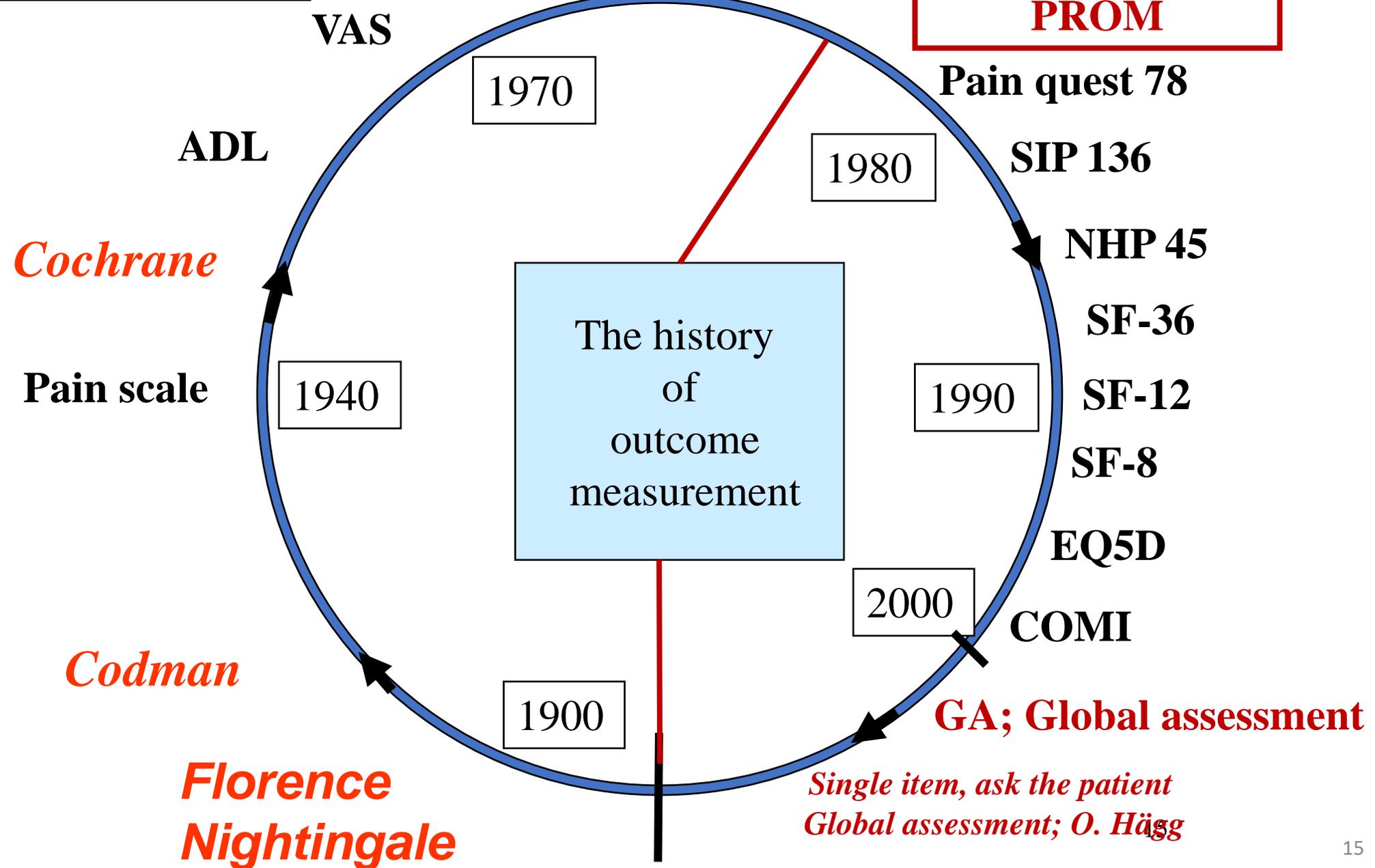
**"Independent" observer**



**Physician rating**

**"Independent" observer**

**Patient rating - PROM**



# So, what is a register?

**Prospective collection of data – and can therefore be used in an  
“observational study”**

The first (sic) “modern” register in Health care was Norwegian (sic),  
200 years ago - Lepra

Register have been used in other disciplines for thousands of years  
f ex in Astronomy

# Register study = Observational study vs. RCTs

**Can register data be trusted?**

**Yes - if validity is assured, and  
adequate statistical analyses are used;**

**STROBE** <https://www.strobe-statement.org/>

Special Articles

**A COMPARISON OF OBSERVATIONAL STUDIES AND RANDOMIZED,  
CONTROLLED TRIALS**

KJELL BENSON, B.A., AND ARTHUR J. HARTZ, M.D., PH.D.



## A COMPARISON OF OBSERVATIONAL STUDIES AND RANDOMIZED, CONTROLLED TRIALS

KJELL BENSON, B.A., AND ARTHUR J. HARTZ, M.D., PH.D. *N Engl J Med* 2000;342:1878-86

### ABSTRACT

#### **Background**

For many years it has been claimed that observational studies find stronger treatment effects than randomized, controlled trials. We compared the results of observational studies with those of randomized, controlled trials.

#### **Methods**

We searched the Abridged Index Medicus and Cochrane data bases to identify observational studies reported between 1985 and 1998 that compared two or more treatments or interventions for the same condition. We then searched the Medline and Cochrane data bases to identify all the randomized, controlled trials and observational studies comparing the same treatments for these conditions. For each treatment, the magnitudes of the effects in the various observational studies were combined by the Mantel–Haenszel or weighted analysis-of-variance procedure and then compared with the combined magnitude of the effects in the randomized, controlled trials that evaluated the same treatment.

#### **Results**

There were 136 reports about 19 diverse treatments, such as calcium-channel–blocker therapy for coronary artery disease, appendectomy, and interventions for subfertility. In most cases, the estimates of the treatment effects from observational studies and randomized, controlled trials were similar. In only 2 of the 19 analyses of treatment effects did the combined magnitude of the effect in observational studies lie outside the 95 percent confidence interval for the combined magnitude in the randomized, controlled trials.

#### **Conclusion**

We found little evidence that estimates of treatment effects in observational studies reported after 1984 are either consistently larger than or qualitatively different from those obtained in randomized, controlled trials.

# RCT ≈ Observational studies ≈ Register studies

1. [Benson K<sup>1</sup>](#), [Hartz AJ](#). A comparison of observational studies and randomized, controlled trials. [N Engl J Med](#). 2000 Jun 22;342(25):1878-86.

2. [Concato J](#), [Lawler EV](#), [Lew RA](#), [Gaziano JM](#), [Aslan M](#), [Huang GD](#). Observational methods in comparative effectiveness research. [Am J Med](#). 2010 Dec;123(12 Suppl 1)

3. [Concato J](#)<sup>1</sup>, [Shah N](#), [Horwitz RJ](#). Randomized, controlled trials, observational studies, and the hierarchy of research designs. [N Engl J Med](#). 2000 Jun 22;342(25):1887-92.

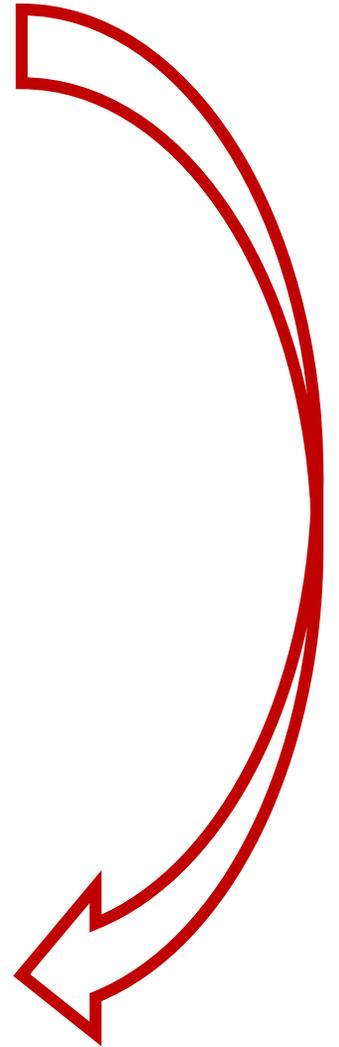
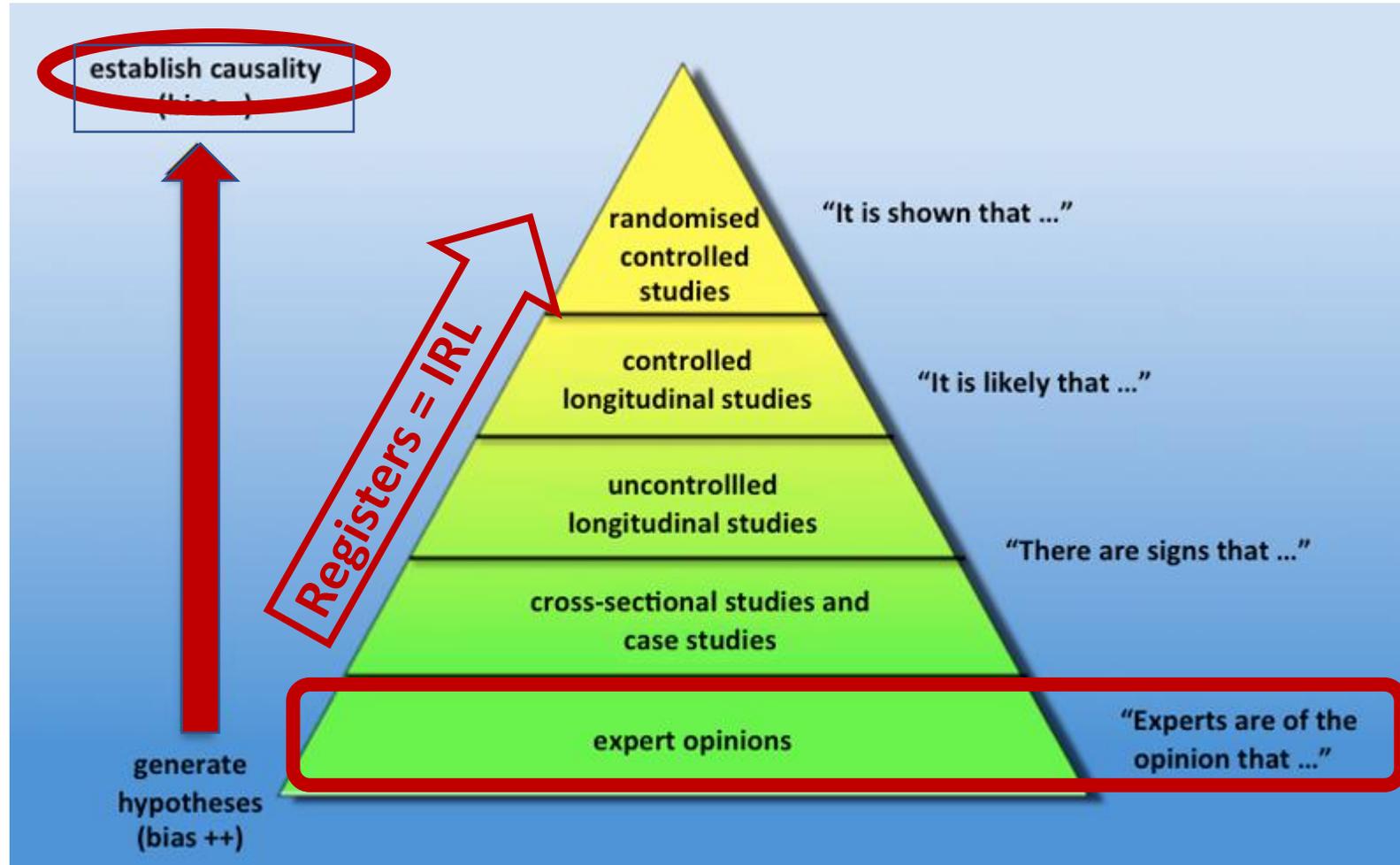
4. [Colditz GA](#). Overview of the epidemiology methods and applications: strengths and limitations of observational study designs. [Crit Rev Food Sci Nutr](#). 2010;50 Suppl 1:10-2.

5. [Jacobs WC](#) et al. Spine surgery research: on and beyond current strategies. [Spine J](#) 2012.

6. [Phillips et al](#). Lumbar spine fusion for chronic low back pain due to degenerative disc disease: a systematic review. [Spine](#) 2013.

- **Swespine - continuous annual reports : 1 year FU of patients operated on 2012;**  
<http://www.4s.nu/4s-f%C3%B6rening/%C3%A5rsrapporter-swespine-42017503>

# Level of evidence – today and in the Future



**Registers – in order to be useful;  
Psychology.....**

**”what’s in it for me/us!”**

# Who are “me”/us?

- **Therapists/Clinical situation**
- **The staff**
- **Administrators/Bureaucrats**
- **Secretaries**
- **Politicians**
- **Patients**
- **The public**
- **Scientists**
- **Risk capitalists.....**
- **.....**

# What makes a register useful?

## ADEQUATE;

1. aims
2. agreed upon variables
3. valid collection of valid data
4. coverage, completeness and FU
5. analyses
6. reporting
7. daily practice - willingness to change

# Ultimate keys

- **Simplicity**
- **Daily practice**
- **What's in it for me/us**
- **Consequence analyses**
- **Willingness to change practice**

# **SIMPLICITY = COMPLIANCE**

**a register is not a clinical study, although it can be used in such studies, which may increase compliance!**

# Registers in Sweden

**In 2022 > 100 registries funded by the government.  
That number is currently on the decline, and no new  
registers are being allowed to start**

# Boston Consulting Group 2011

- **“Sweden has the most cost-effective health care in the world, because of their use of national registers”**
- Health care authorities; appr. 30 million EUROS/year for 4 years to national quality registers, 2013-2016
- Currently; yearly reimbursement after application... less and less....

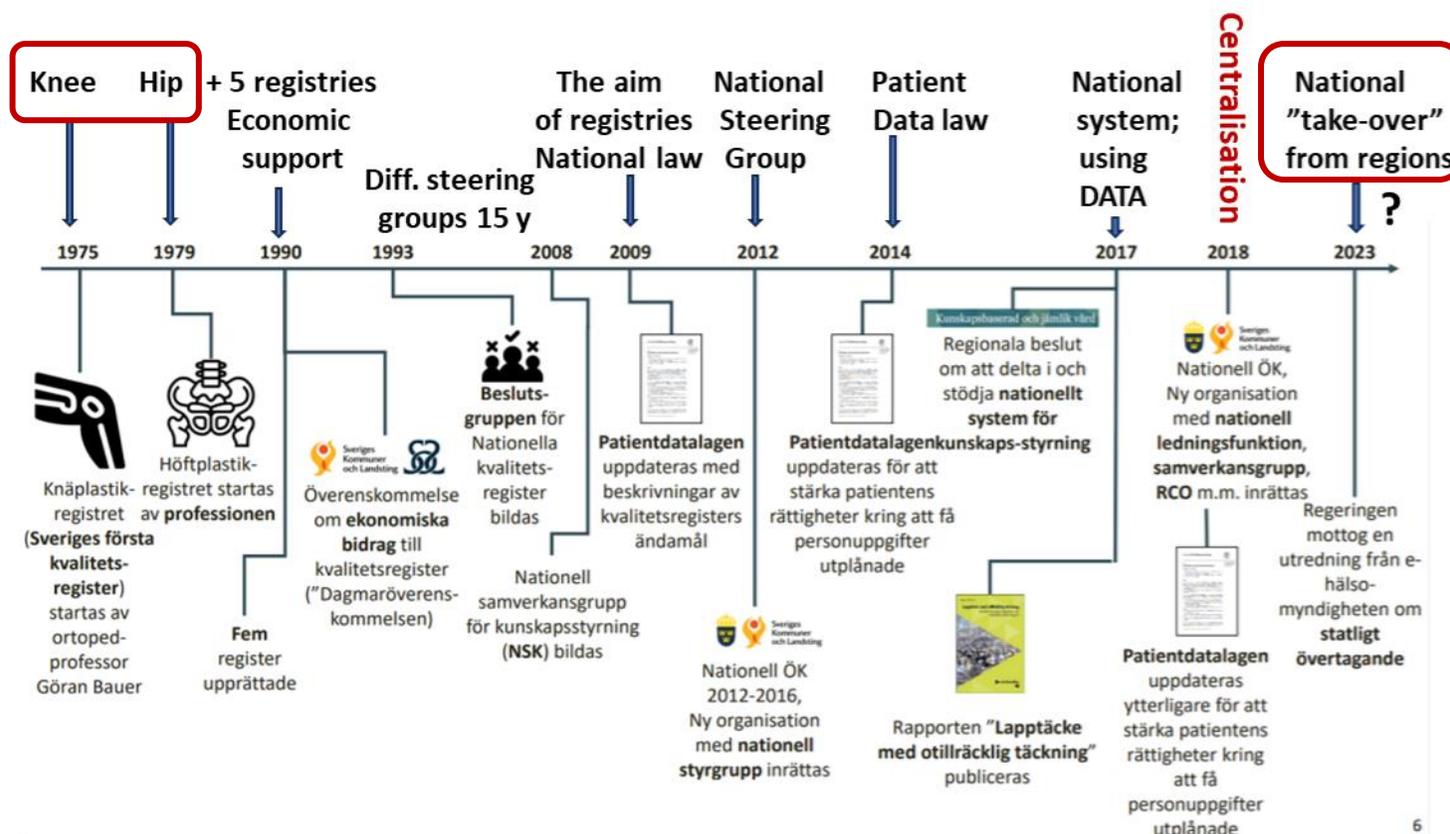
# History in Sweden since 1975

## National Quality registries in Sweden Organisation over time

The current tendency in Sweden is that the government is more active in how to monitor and storing/using register data.

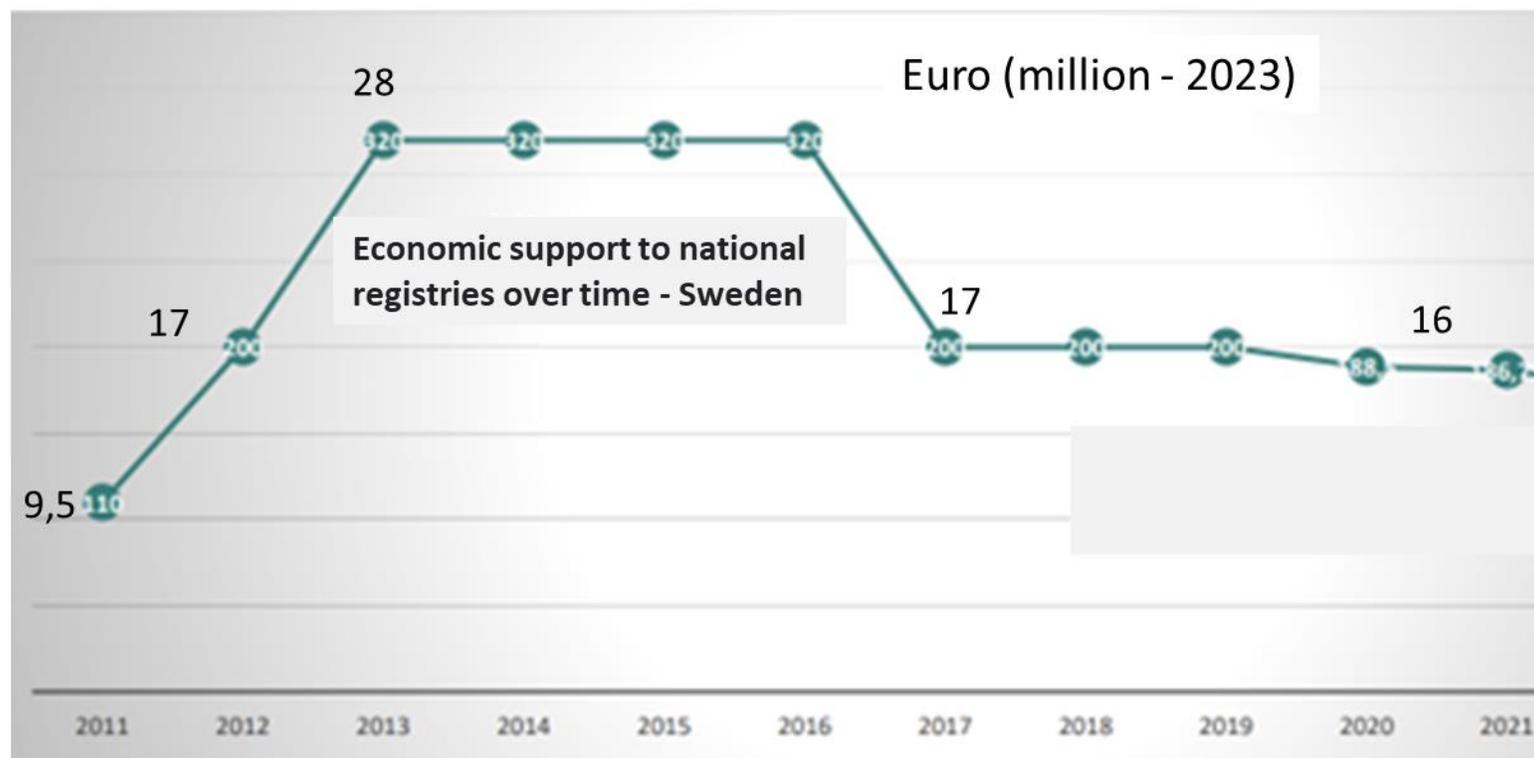
A lot of work is done by different work groups, aiming to simplify the registering of data, and to avoid "double registering" - in both registers and medical records

It could possibly be a threat to a well-functioning business, but the economy is crucial today



## History in Sweden since 2011

### National funding of quality registers in Sweden





## **Swespine in more detail - and in a national context**

## Sweden;

appr. 10 milj. citizens

45-50 "spine clinics"

## Swespine;

a national spine register since 1998.

- Coverage; 98%
- Completeness; >85%
- Follow up: 70%



## 5 diagnoses are included in Swespine;

*Fractures are registered in a separate national Fracture registry*

*\*Deg lumbar, Deg Cervical, Deformity, Infection, Metastases*

**Variables included in *\*Degenerative lumbar spinal disorders* (LDH, LSS, DDD)**

Diagnose

Type of clinic (University, County hospital, Private clinic)

Age

Gender

Work status

Sick pension

Retention pension

Smoking

Quality of life (EQ5D)

Walking distance

Pain duration LEG

Pain duration BACK

Preop pain LEG (NRS)

Preop pain BACK (NRS)

Function (ODI)How was your spine procedure financed?

Comorbidity

Are you active in sports?

What do you think of your possibilities to return to work?

How physical is your current workload?

Are you out of work?

Since how long have you been unable to work?

Type of previous spine procedure

Acute or Elective surgery

Type of procedure/Index operation

How many previous spine procedures?

Do you take pain killers for your back/leg pain?

Type of instrumentation

Type of implant

Type of bone transplant

Operated from the left/right

Antibiotic prophylaxis

Postop complications

Reoperation during Index stay

Type of reop procedure

Number of reop



**Swespine is a national quality register** that since 25 years is presenting outcome after surgical spinal procedures on both a departmental and a national level.

**The number of patients in Swespine** is today over 190 000, with appr. 10 000 added yearly.

**Opt-out** is used as patient approval. Detailed information is given in accordance with GDPR



Swespine is managed by a partly reimbursed **Steering group** with representatives from:

- **Spine surgeons: orthopaedic and neurosurgeons**
- **Indoor Care: nurse**
- **Primary care: physician**
- **Rehabilitaion: Physiotherapist/Naprapat**
- **Patients**
  
- **The Swedish Society of Spinal Surgeons (4s)**

Register data are owned by a regional gouvernement (Rjl)



**Swespine is using both digital means and paper in order to register Baseline/Therapies/FU**

- **Swespine is mainly relying on PROM for outcome**
- **70% of all patients are registered through digital means, 30% using paper**
- **Preop. patient data are filled in by the patient in connection with surgery – independently**
- **The only data included by the physician is the procedures/complications**
- **FU is currently performed after 1-2-5-10 years. By the patient alone at home – independently**

**Very few patients do not want to be part of the register (opt out is used).**



**Surgical data are registered, as**

- **Diagnosis/Procedure**
- **Complications and reoperations**
- **Implants**



**Swespine data are stored on a centrally approved register Platform/specific inlog**

- Data are freely available for each registering clinic - clinics own data**
- Data are on the whole only available for selected members in the steering group**
- Selected data are available for researchers after approval of an Ethics Board**
- Patients can disapprove of their data usage (Opt Out)**



**Swespine data are used in most clinical studies in Sweden today – appr. 10-20/year**

- 173 studies based on Swespine data have been published in international journals since 2000**
- 19 dissertations since 2000 are based on Swespine data**
- Swespine data have been validated against medical records throughout the years - sufficient**



**Missing values – does it affect treatment outcome (PROM)?**

**National registers; DaneSpine – NORspine – Swespine; "NO"**

**Up to 20% missing values** in the Nordic national registries did not overrate treatment success.

**Single Center register; Spine Tango; "YES"**

[Does loss to follow-up lead to an overestimation of treatment success? Findings from a spine surgery registry of over 15,000 patients.](#)

Mannion AF, Fekete TF, O'Riordan D, Loibl M, Kleinstück FS, Porchet F, Reitmeir R, Jeszenszky D, Haschtmann D. Eur Spine J. 2023 Mar;32(3):813-823.

**Why? Cultural differences? National data vs. data from selected clinics?**



## **The Industry**

**The government encourage Swedish national quality registers to cooperate with the industry.**

**However, there must be no profit – only reimbursement for hours spent – legal agreements must be signed**

**Swespine is currently cooperating with business companies – producing yearly reports; Implants/PROM**



## **Implant registration in Swespine is mandatory since 2006**

**Aggregated implant related outcome data are available for manufacturers according to contract.**

**During the last two years, we have for example supplied DePuy/J&J with such reports.**



Swespine Homepage, [www.swespine.se](http://www.swespine.se)

we present annual reports and case-mix adjusted outcome data,  
comparing f ex volume and outcome for all clinics to the public,  
For example LSS – also making clinical difference;

**Cost/Effectiveness!!**



**Swespine**  
**- an example of clinical impact**

# N. of Lumbar Spinal Stenosis + olisthesis >3mm – surgical procedure

Swespine data

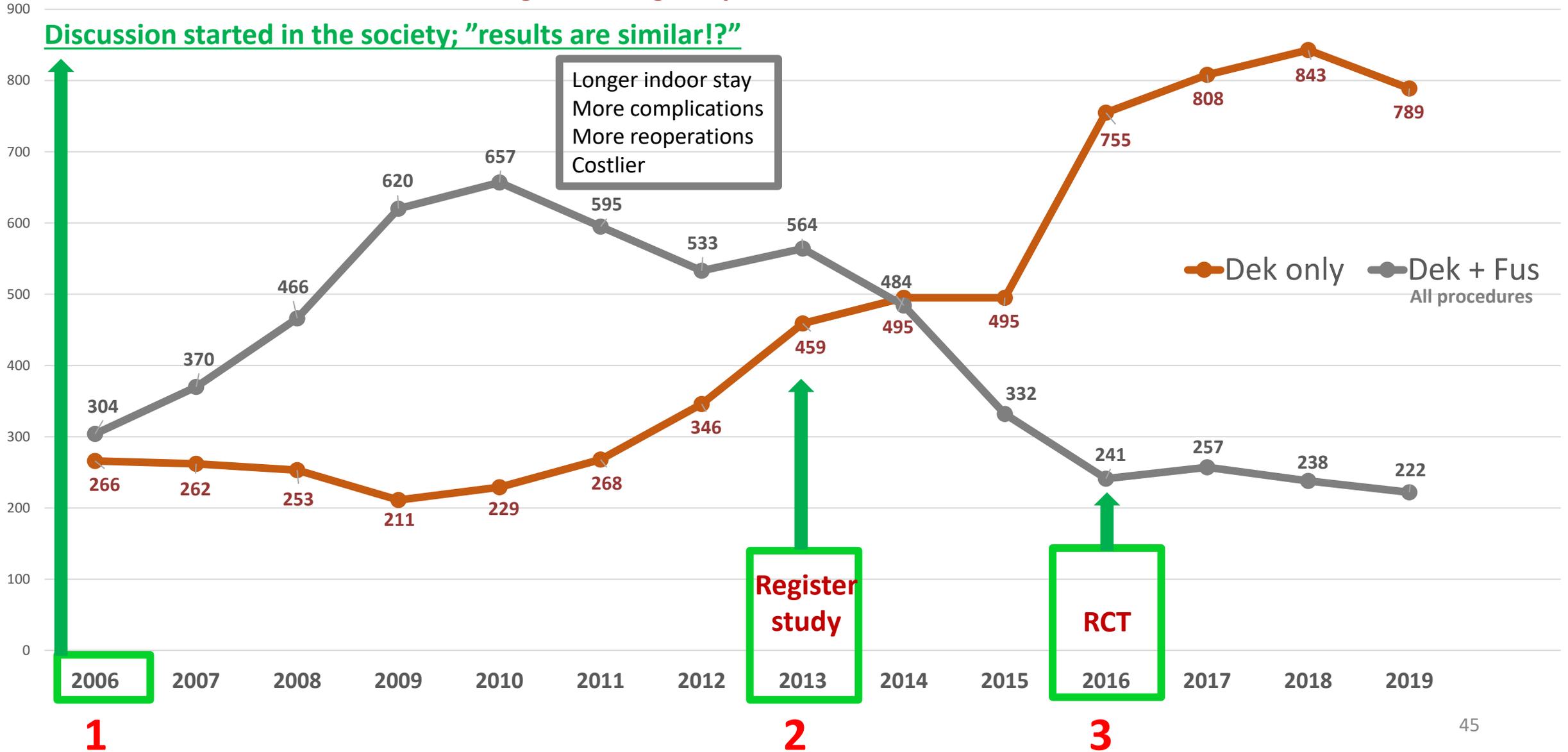
Changes in surgical practice in Sweden 2006-2019.....

N

Discussion started in the society; "results are similar!?"

Longer indoor stay  
More complications  
More reoperations  
Costlier

Dek only Dek + Fus  
All procedures





**Dig deep – and fly high!**



## Governmental initiatives; The Swedish Research Council; Vetenskapsrådet

The Swedish Research Council, established on 1 January 2001, is a Swedish government authority tasked by the Parliament to support and **promote Swedish basic research of the highest scientific quality in all scientific fields**



## **The Swedish Research Council – RUT = “Register Utilizer Tool”**

**Better overview of register contents, The metadata tool RUT provides a structured overview of what information is available in Swedish registers and biobank sample collections.**

**RUT describes the content of these data sources at a detailed level with metadata, i.e. data about data.**

**By searching and analyzing RUT's content, researchers can better understand the structure of a register and the significance of its content. With the help of RUT, researchers can therefore better assess which data could be used to answer a specific research question before they contact the authority or organization holding the records for further dialogue.**



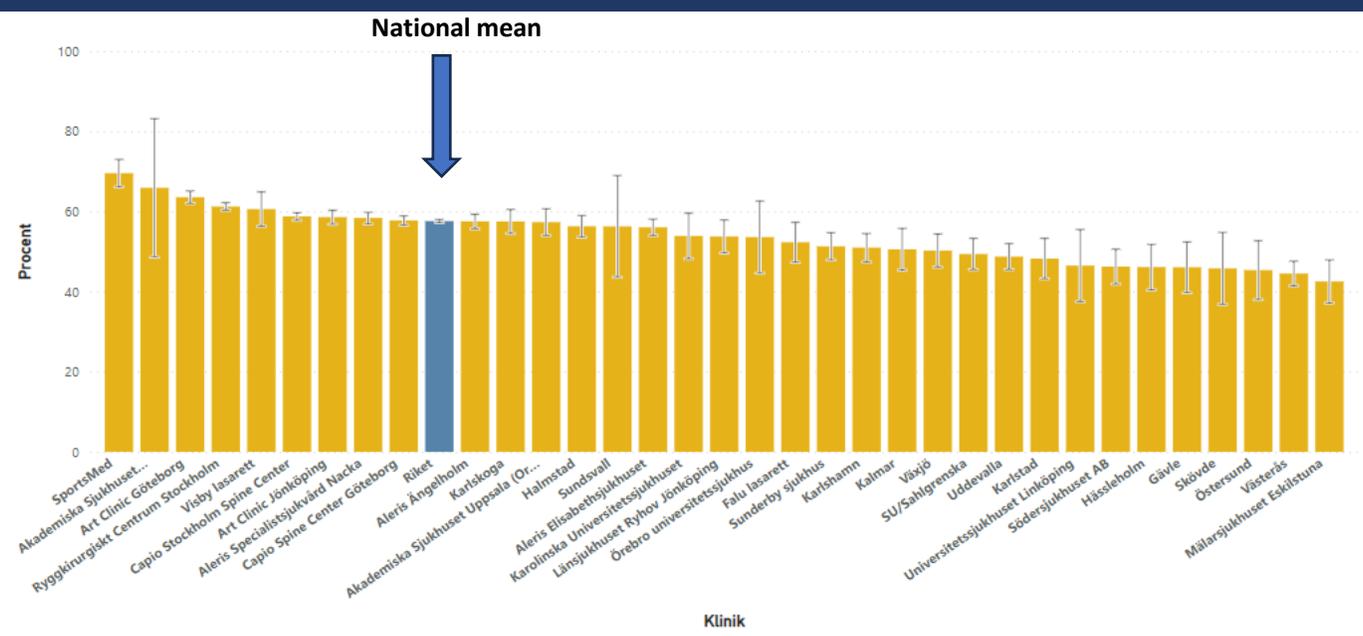
**Governmental initiatives; "Vården i siffror" – "Care in numbers"** <https://vardenisiffror.se/>

**Presenting comparative PROM-results per clinic and region in Sweden one year after surgery, with and without adjusting for case-mix (different populations are operated in different clinics)**

**For example;**

# Results leg pain LSS after 1 year – Pain free/much better adjusted for casemix = comparability

Results/clinic + CI



Kliniker med färre observationer än 10 st per år, redovisas ej i diagrammet.



[Om Swespine](#)

[Diagnoser](#)

[För patienter](#)

[Statistik](#)

[Länkar](#)

[Kontakt](#)

[Dialogstöd](#)

[Logga in](#)

n of patients behind comparative/clinics analyses usually between 5000-25000, depending on diagnosis

**Index procedures**

Nov 8, 2023

**190 538**

**Registering clinics**

**46/47**

**Follow Up 1 year**

**Appr. 70%**

Swespine administreras av [Svensk Ryggkirurgisk Förening](#).

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[Visa alla](#)

# **The importance of adjusting for “case-mix”**

- when comparing results from different clinics**

# Lumbar Disc Herniation. Improved leg pain – yearly results Swedish clinics

## *Not adjusted for "case-mix" – comparing results among clinics*

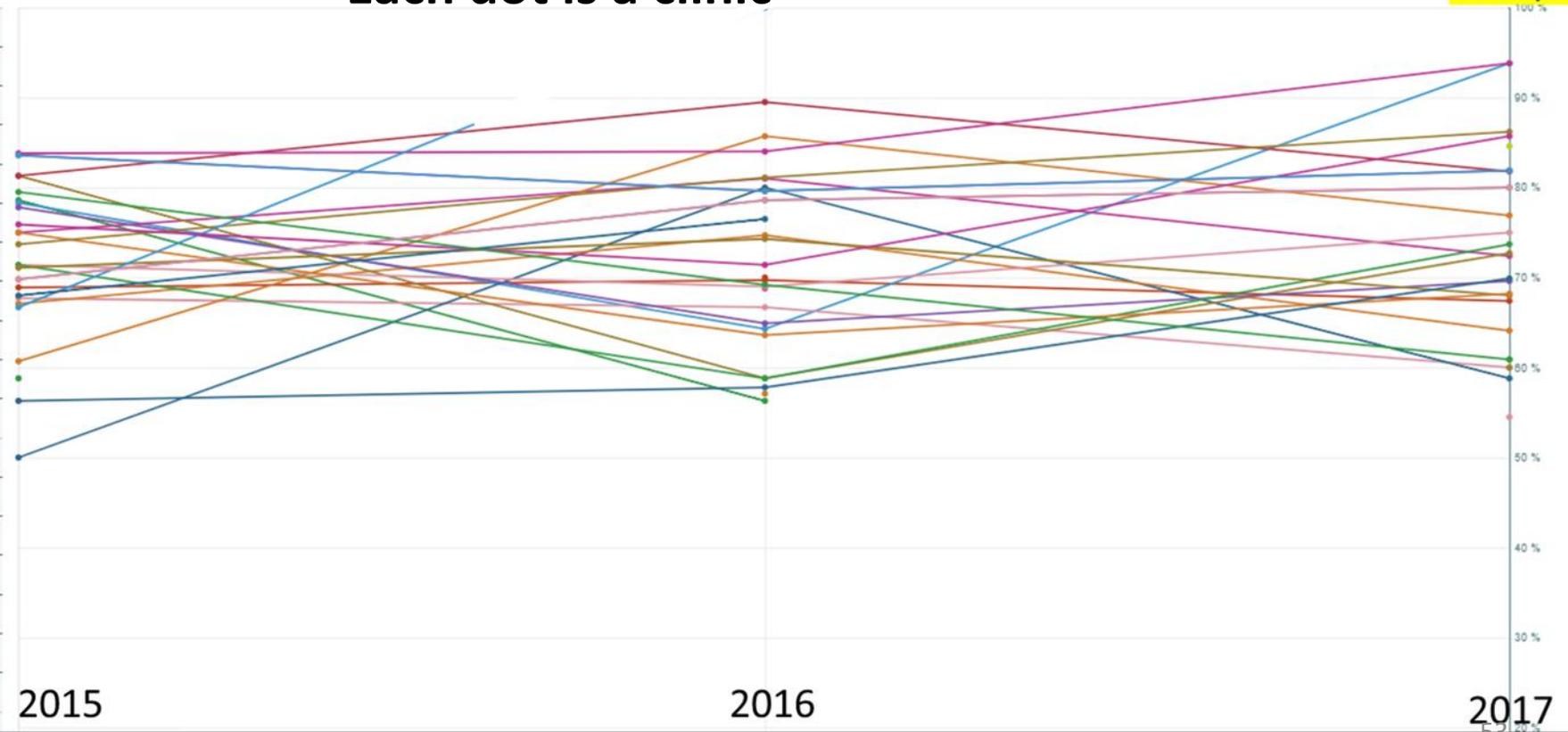
### Clinics

Senast Rapporterat Värde

×	SÖDRA ÄLVSBOGGS SJUKHUS	-
×	PRIMÄRVÅRD OCH NORRTÄLJE SJUKHUS	-
×	ALERIS SPECIALISTVÅRD SABBATSBERG	-
×	KALIX SJUKHUS	-
×	KIRUNA SJUKHUS	-
×	MÅLARSJUKHUSET ESKILSTUNA	MSK
×	NYKÖPINGS SJUKHUS	-
×	KULLBERGSKA SJUKHUSET KATRINEHOLM	-
×	HALLANDS SJUKHUS KUNGSBACKA	-
×	HALLANDS SJUKHUS VARBERG	-
×	SÖDERTÄLJE SJUKHUS AB	-
×	HELSINGBORGS LASARETT	-
×	SJUKHUSET ARVIKA	54,5 %
×	SJUKHUSET TORSBY	-
×	LJUNGBY LASARETT	-
×	CENTRALLASARETTET VÄXJÖ	MSK
×	ELISABETHSJUKHUSET	-
×	HALLANDS SJUKHUS HALMSTAD	67,4 %
×	VÄSTERVIKS SJUKHUS	MSK

Each dot is a clinic

% improved



# Lumbar Disc Herniation. Improved leg pain – yearly results Swedish clinics

## *Adjusted for "case-mix" – comparing results among clinics*

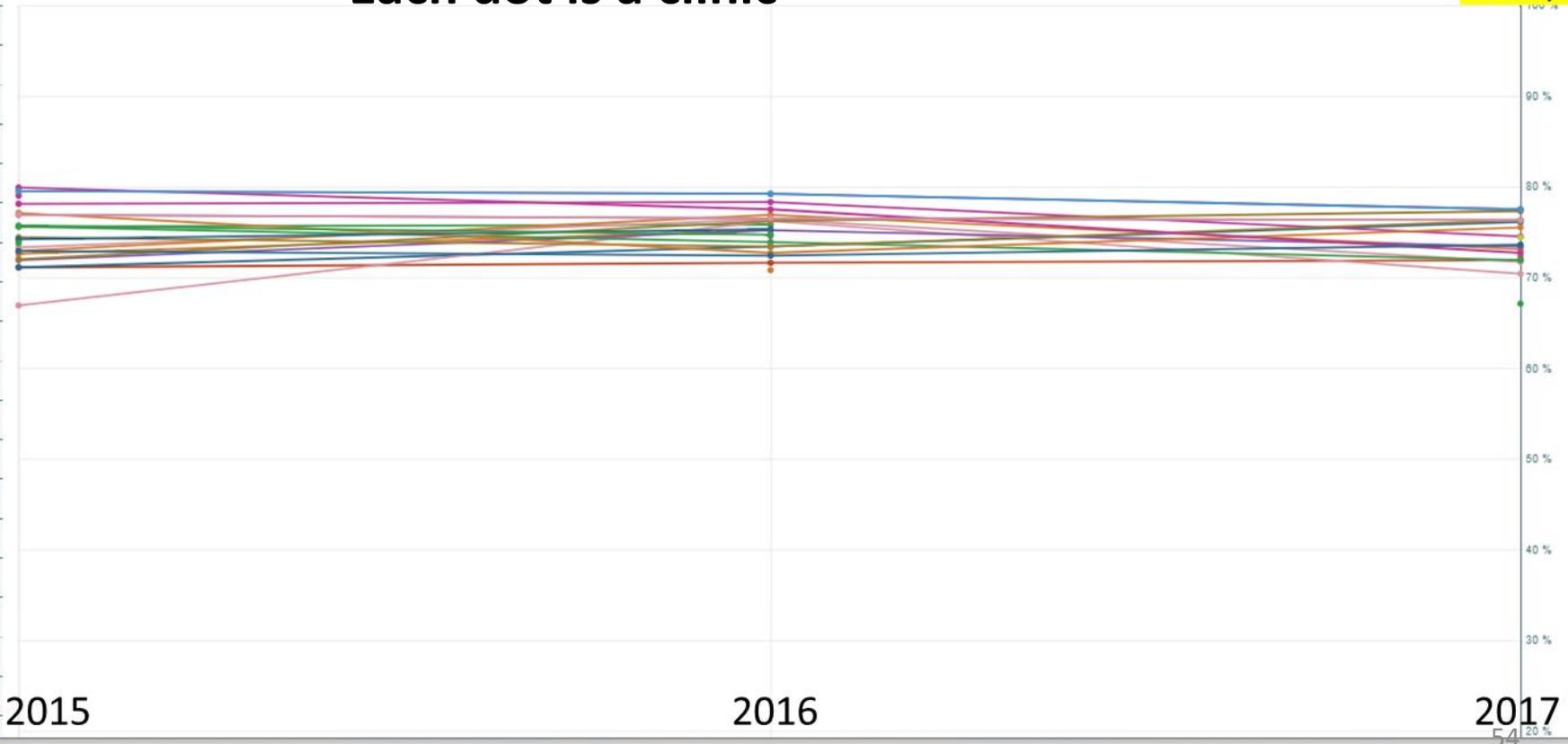
### Clinics

Senast Rapporterat Värde

✕	SÖDRA ÄLVSBOGGS SJUKHUS	-
✕	PRIMÄRVÅRD OCH NORRTÄLJE SJUKHUS	-
✕	ALERIS SPECIALISTVÅRD SABBATSBERG	-
✕	KALIX SJUKHUS	-
✕	KIRUNA SJUKHUS	-
✕	MÅLARSJUKHUSET ESKILSTUNA	MSK
✕	NYKÖPINGS SJUKHUS	-
✕	KULLBERGSKA SJUKHUSET KATRINEHOLM	-
✕	HALLANDS SJUKHUS KUNGSBACKA	-
✕	HALLANDS SJUKHUS VARBERG	-
✕	SÖDERTÄLJE SJUKHUS AB	-
✕	HELSINGBORGS LASARETT	-
✕	SJUKHUSET ARVIKA	MSK
✕	SJUKHUSET TORSBY	-
✕	LJUNGBY LASARETT	-
✕	CENTRALLASARETTET VÄXJÖ	MSK
✕	ELISABETHSJUKHUSET	-
✕	HALLANDS SJUKHUS HALMSTAD	71,9 %
✕	VÄSTERVIKS SJUKHUS	MSK

Each dot is a clinic

% improved



# The future – we lean on the past

## We rely on

Clinical experience  
Comparisons  
Trial and error  
Clinical expertise  
In my hands  
Observational studies  
Retrospective studies  
Prospective studies  
RCT  
Reviews  
Meta-analyses  
Registers  
Industry  
Validity of data  
Digitalization.....  
.....

## Problems/Possibilities

Subjective - bias - confounders  
Different baseline variables  
Different outcome variables  
Different populations  
Small population samples  
Different Diagnoses  
Different treatments  
Confounders  
Biases  
Industry  
Profit  
Medical records – registries: transfer  
Double registration  
Complexity of diagnoses/treatments  
Validity  
Coverage-Completeness-FU AND Compliance



- Digitalization – is a must  
- Economy – Cost/Effectiveness is a must  
.....

# Important findings using Swespine data

Olle Hägg

# ANNUAL REPORT 2023 SWESPINE 25 YEAR

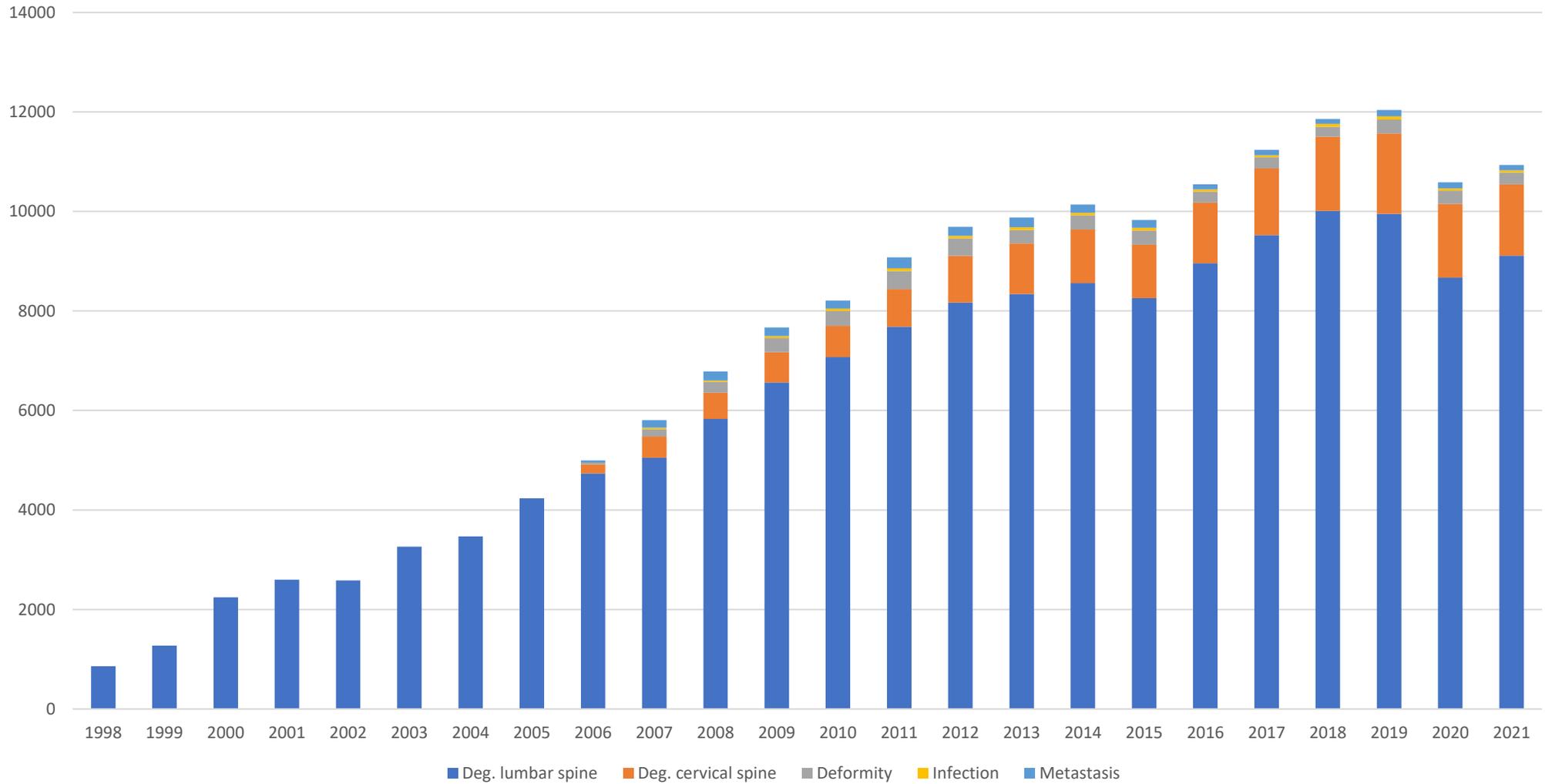


FOLLOW-UP OF  
SPINE SURGERY IN  
SWEDEN  
1998 - 2022

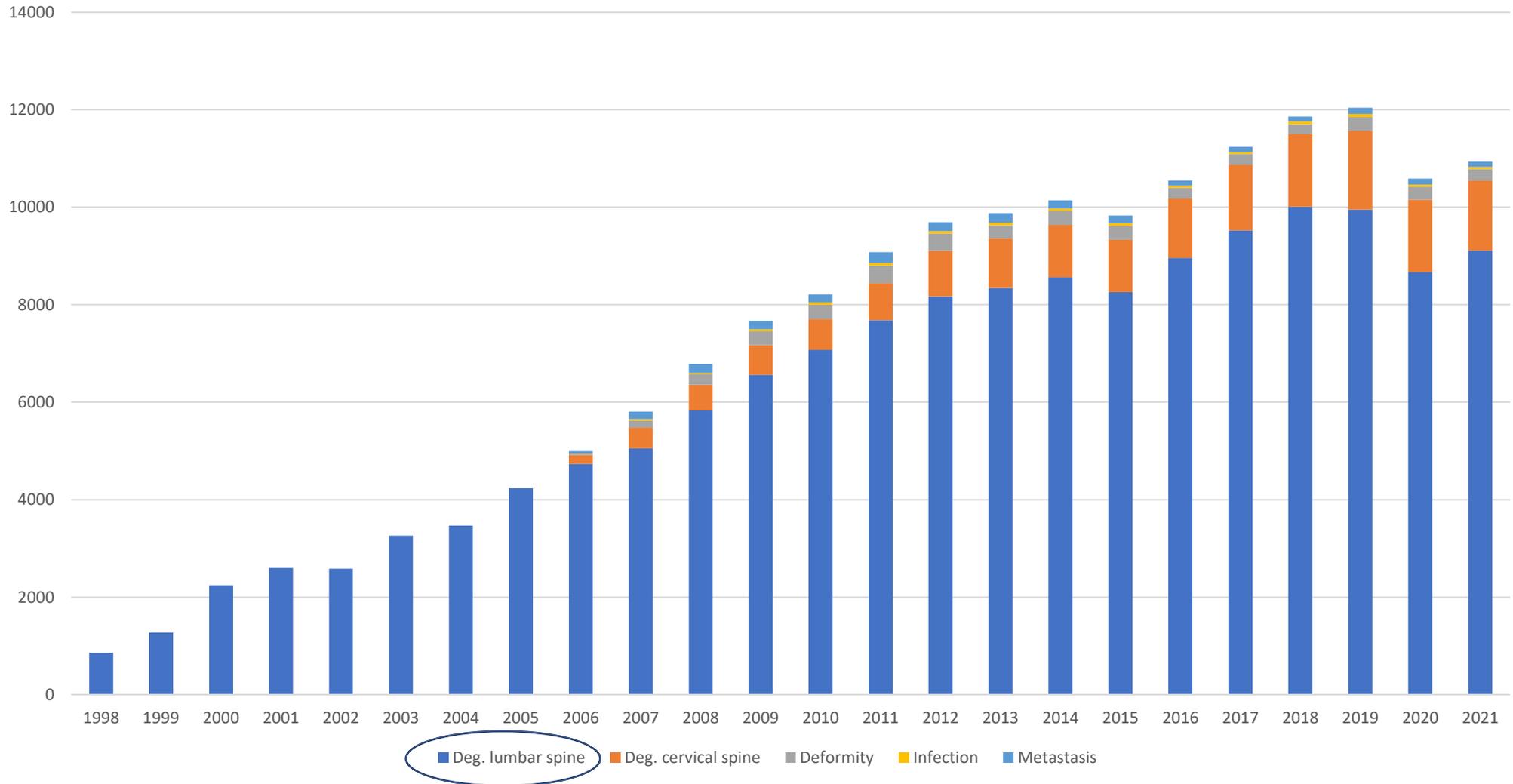
What have we achieved in 25 years?



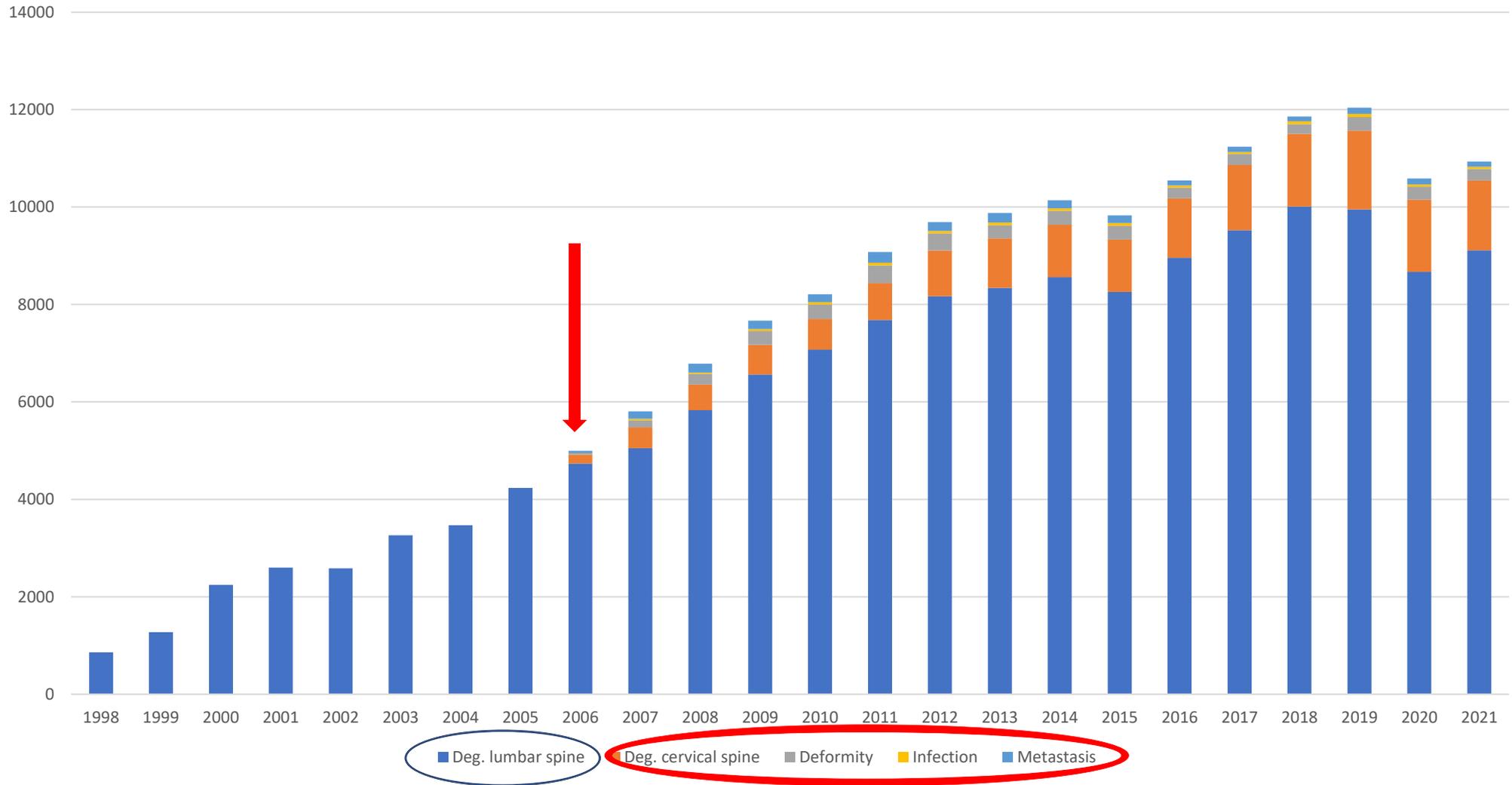
Total amount of registered procedures



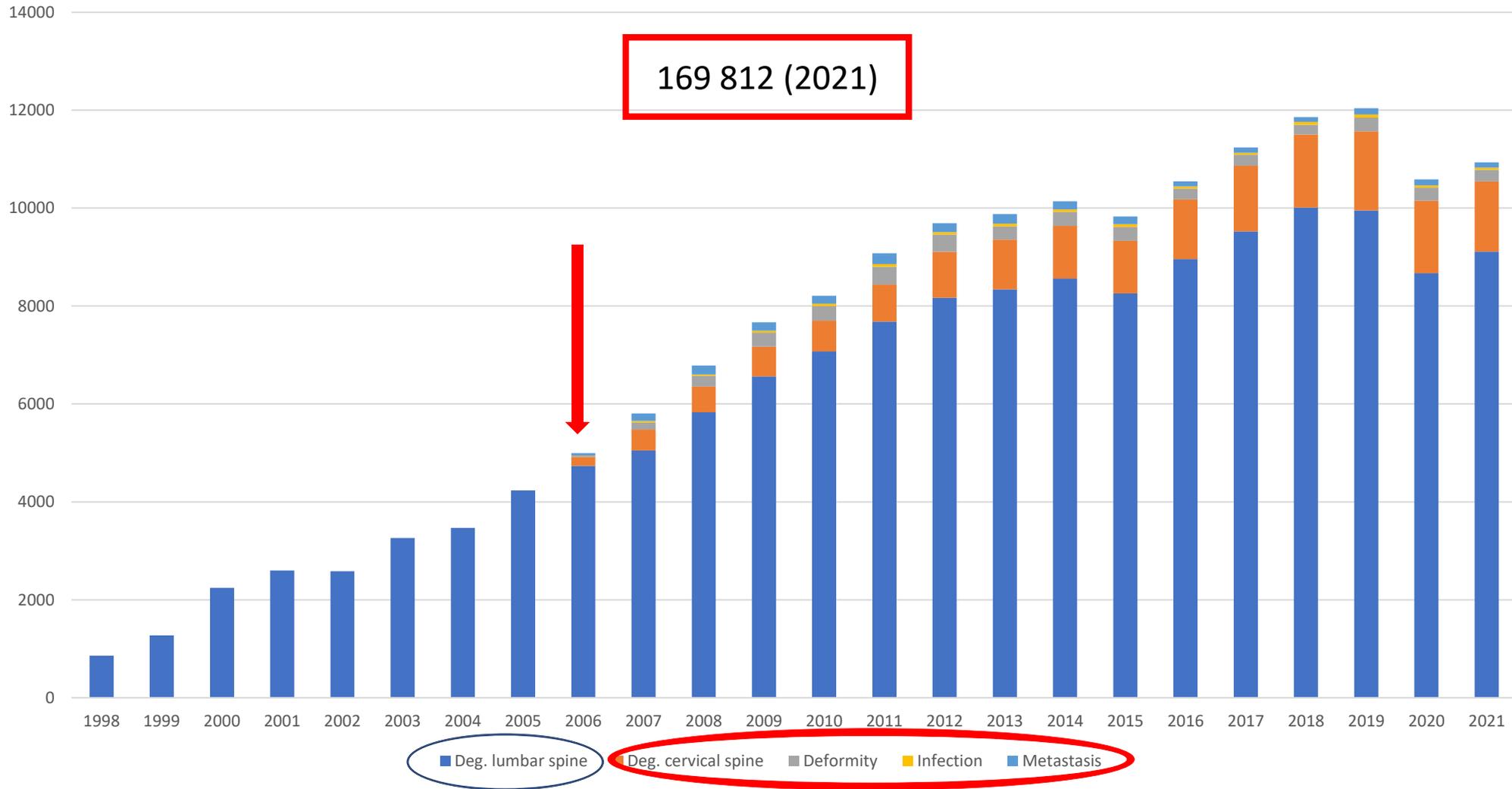
Total amount of registered procedures

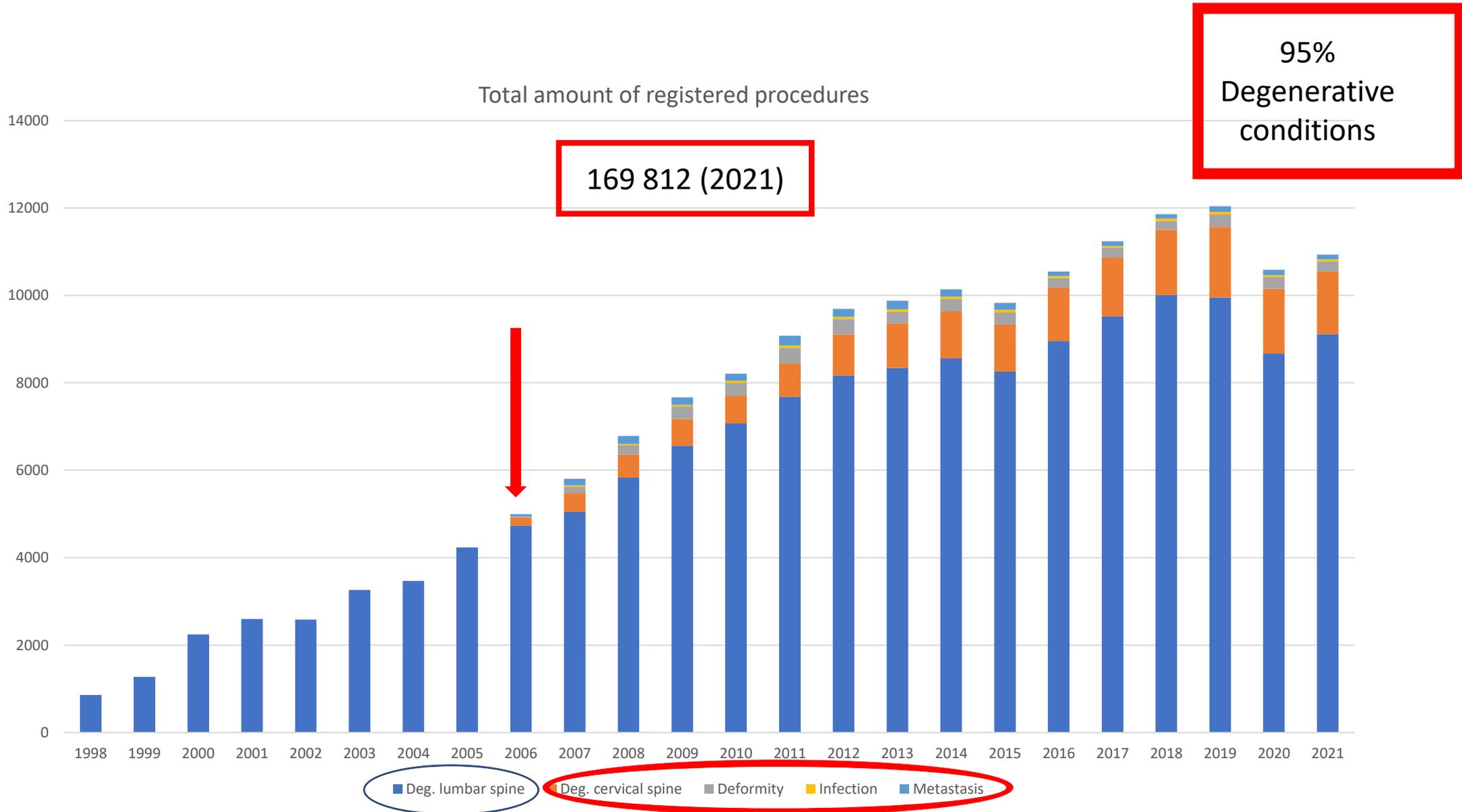


Total amount of registered procedures

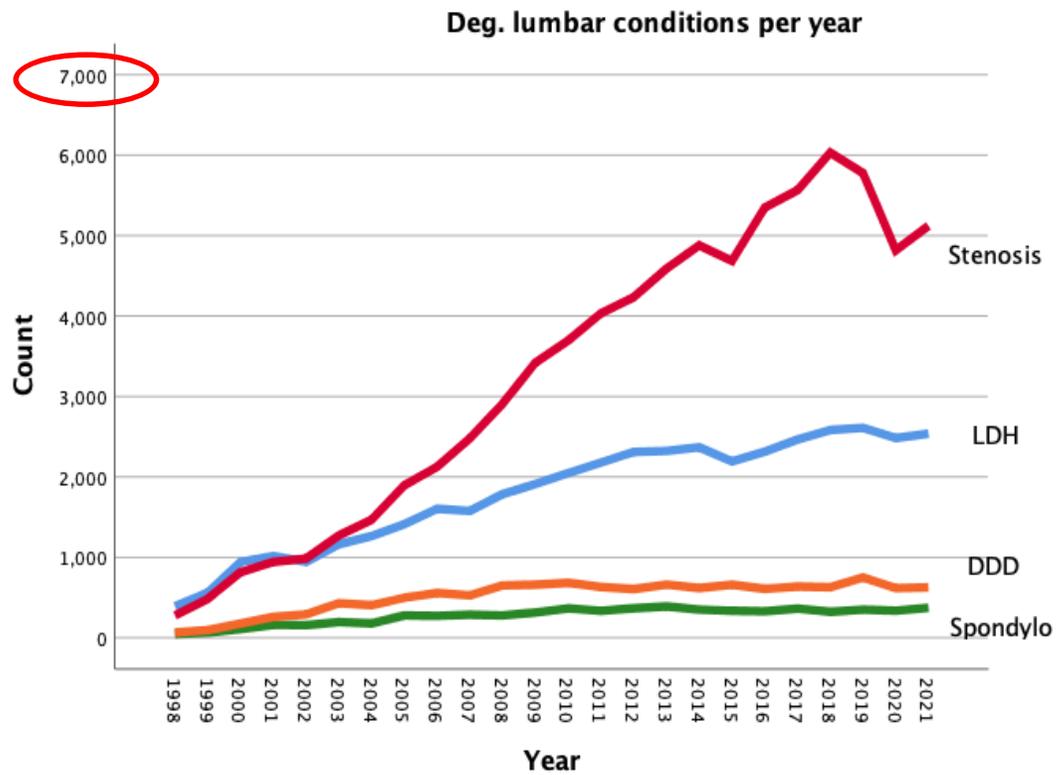


Total amount of registered procedures

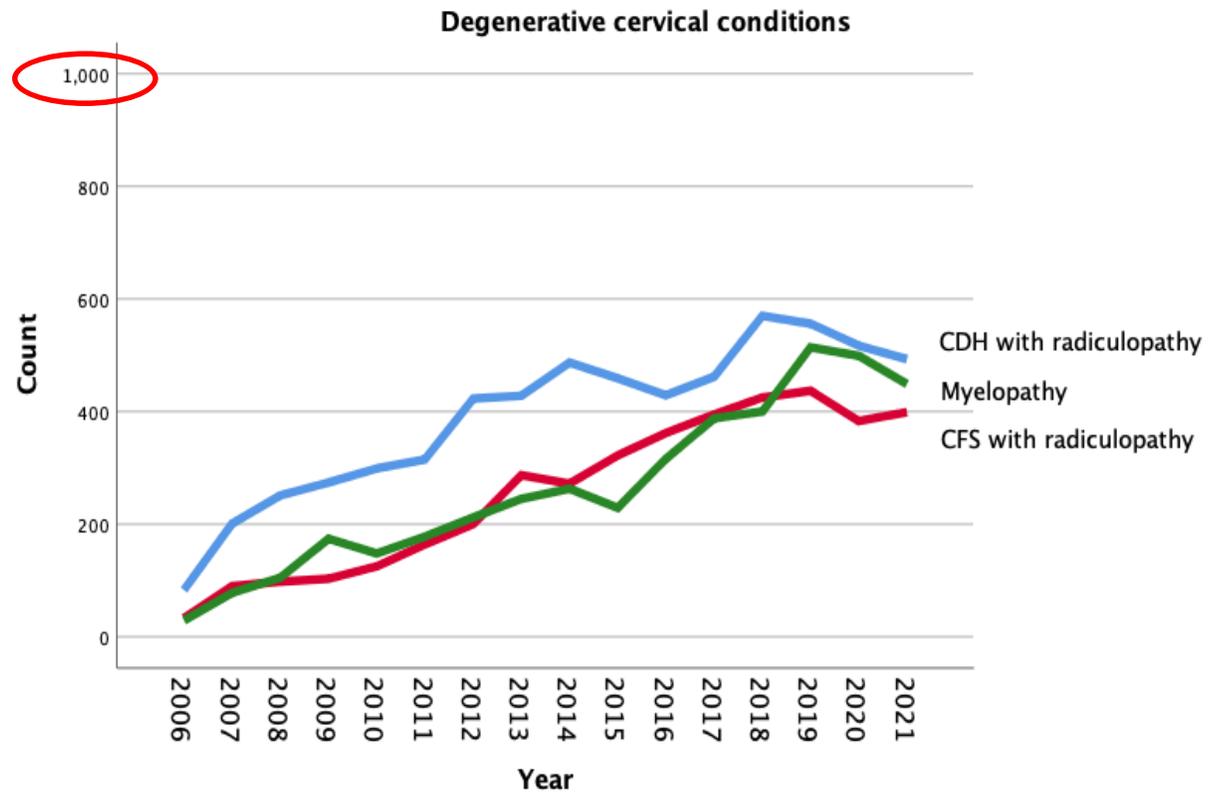
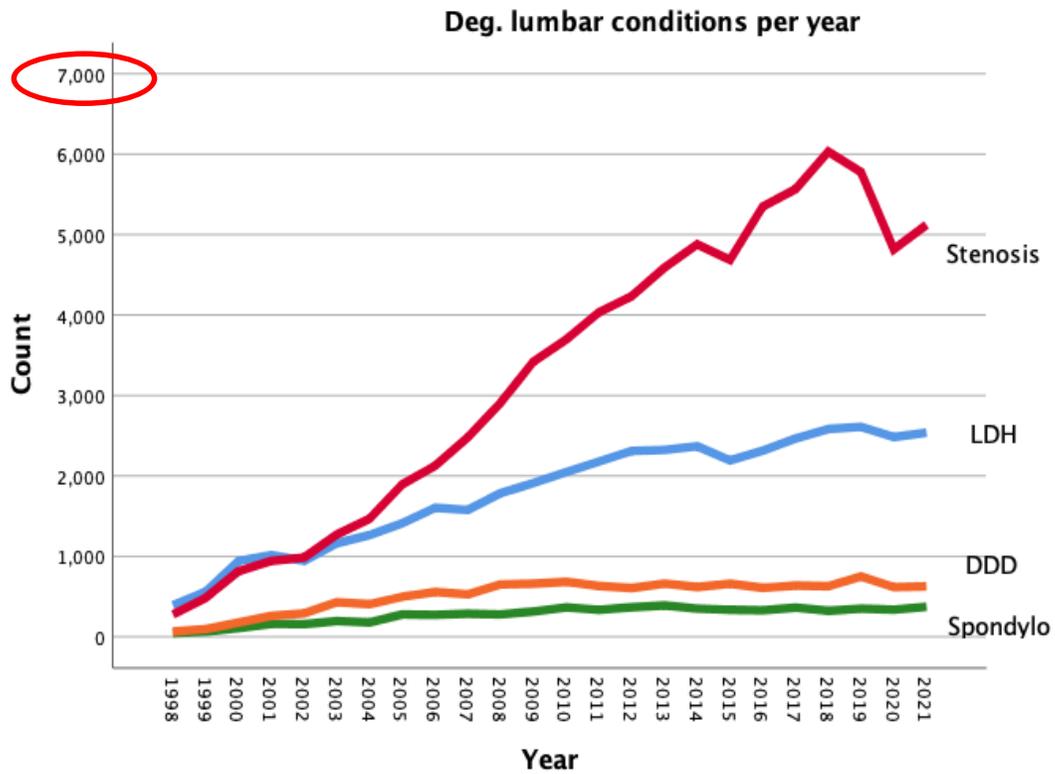




The increase is mainly lumbar spinal stenosis



# The increase is mainly lumbar spinal stenosis



**The registry contains unique data not present in any available medical record system (at least not in Sweden)**

**These data are critical for assessing the patient value of spine surgery**

**AND**

**It is a gold mine for clinical research**

# Important aspects of a registry

# Important aspects of a registry

## *The strength:*

Real everyday life data

No distorting study bias

**Promotes external validity**

***Limitations (as in planned studies):***

- Surgical data delivered by surgeon
- Baseline and Outcome data reported by patient

## ***Limitations (as in planned studies):***

- Surgical data delivered by surgeon
- Baseline and Outcome data reported by patient



Data quality subject to  
incompleteness (baseline, surgery, follow up)  
errors (mistakes by patient, surgeon or data recorder)

## ***Limitations (as in planned studies):***

- Surgical data delivered by surgeon
- Baseline and Outcome data reported by patient



Data quality subject to  
incompleteness (baseline, surgery, follow up)  
errors (mistakes by patient, surgeon or data recorder)

**Constrains external validity**

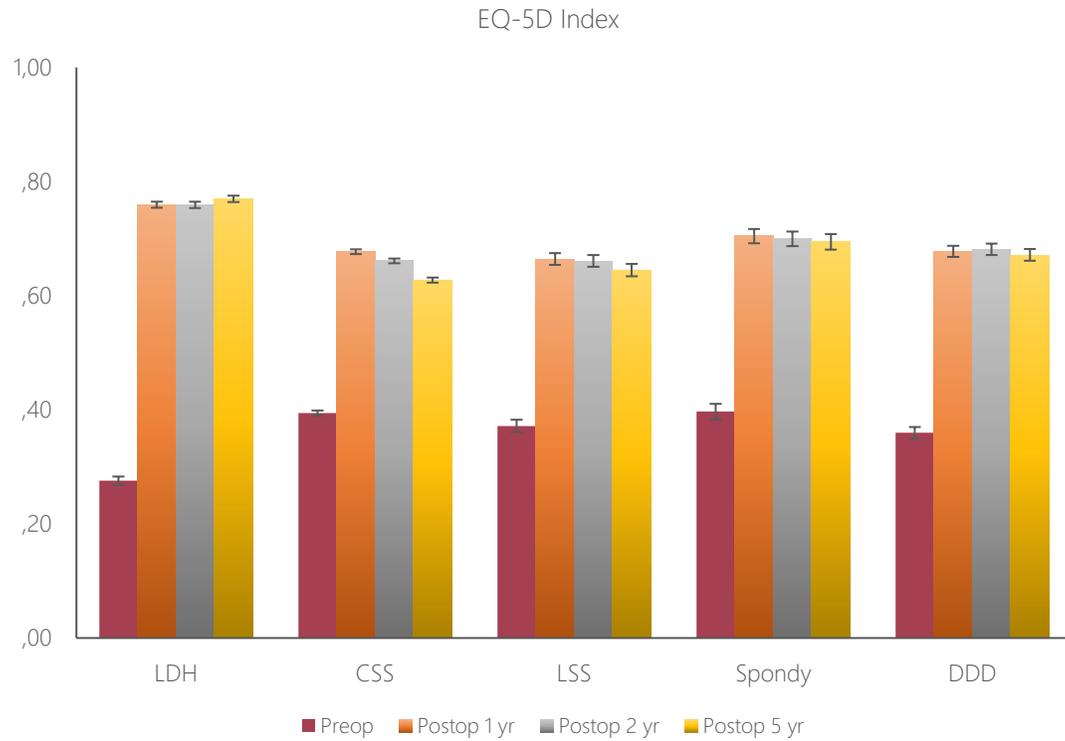


**Interpretation of data with precaution**

# Outcome overview (EQ-5D)

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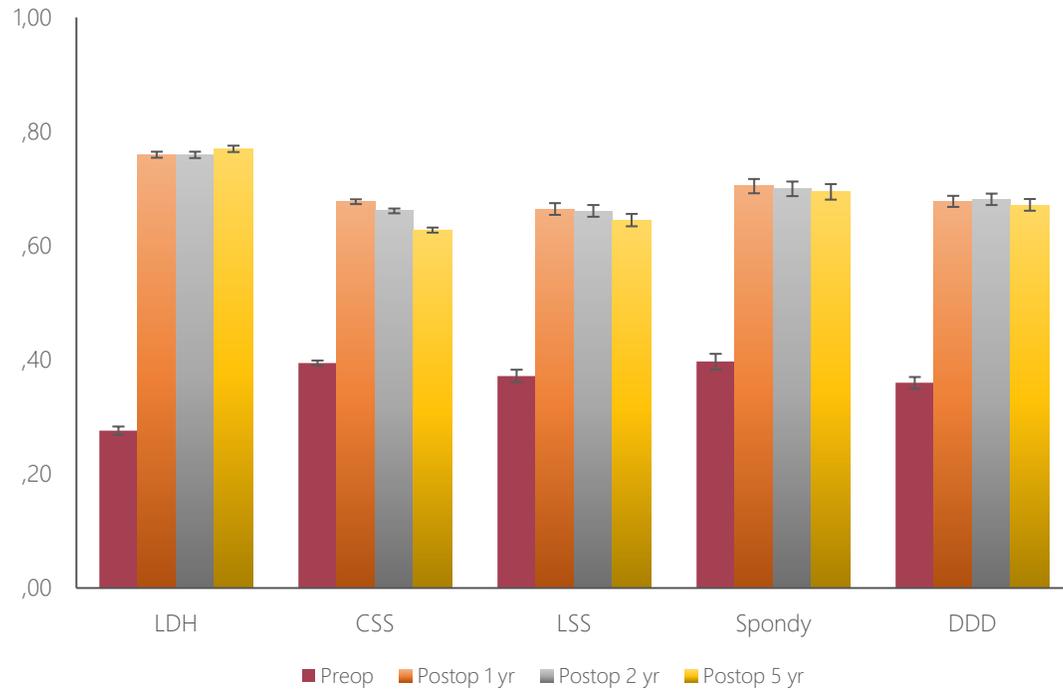
## Deg. lumbar spine



# Outcome overview (EQ-5D)

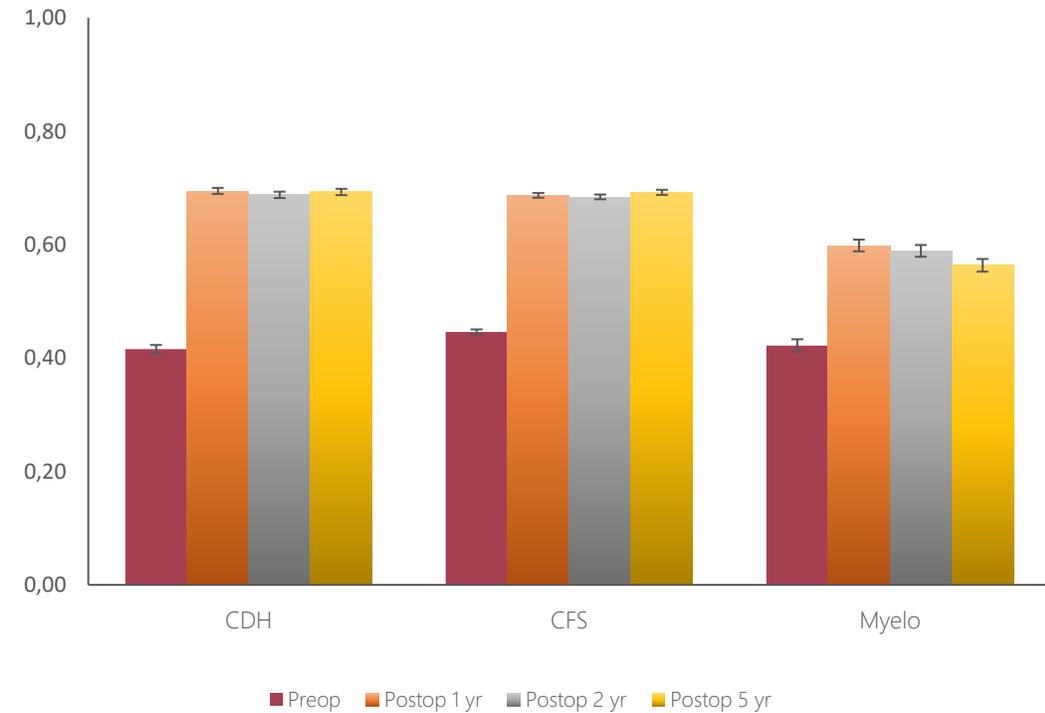
## Deg. lumbar spine

EQ-5D Index



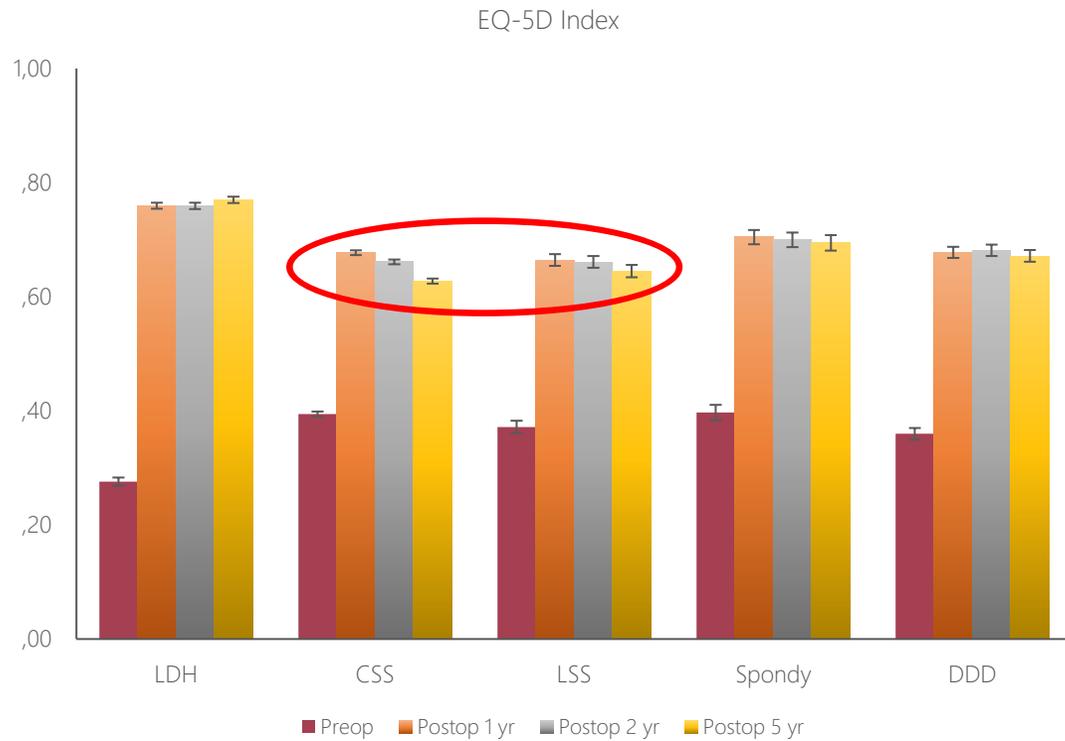
## Deg. cervical spine

EQ-5D Index

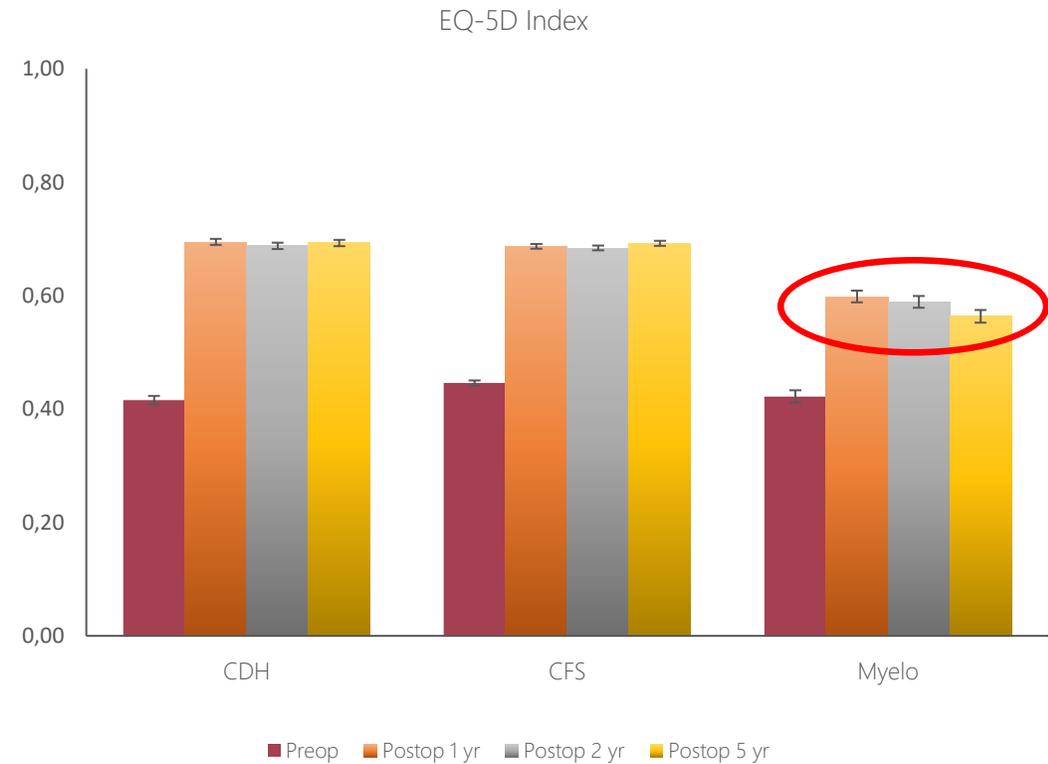


# Outcome overview (EQ-5D)

## Deg. lumbar spine



## Deg. cervical spine

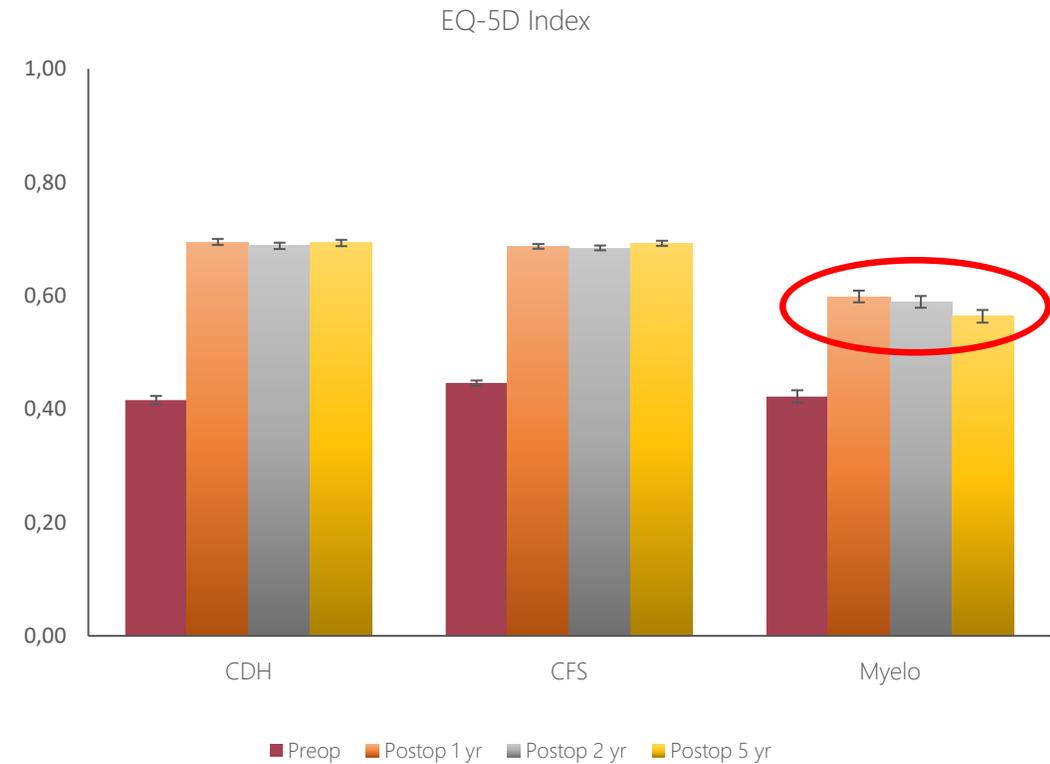


# Outcome overview (EQ-5D)

## Deg. lumbar spine



## Deg. cervical spine



Outcome is less favorable in spinal stenosis

# What have we learned in 25 years?

- A few examples from the current annual report
- More is to be found through the link:

<https://www.swespine.se/page.aspx?id=12&lang=1>

# Primary outcome measure for clinical routine

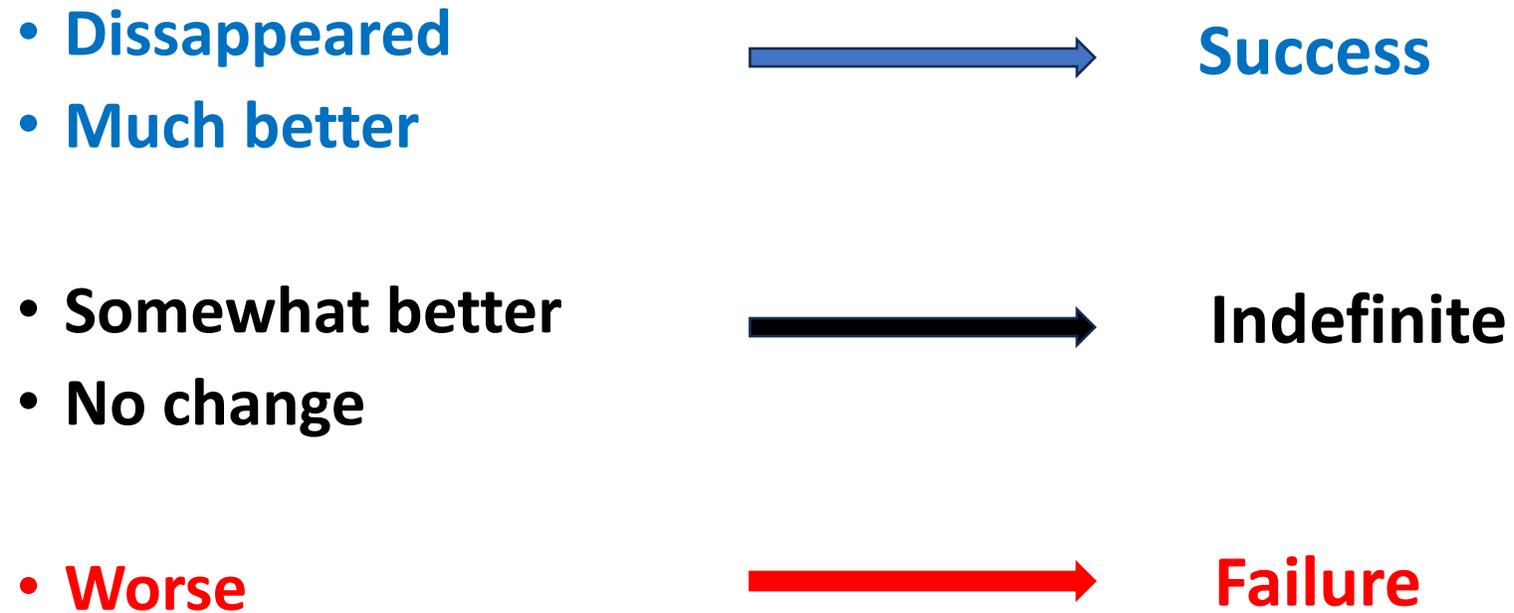
***Global assessment*** (single item, retrospective)

**”How is your leg/back/arm/neck pain today compared to before the operation?”**

- I had no leg/back/arm/neck pain before the operation
- Dissapeared
- Much better
- Somewhat better
- Unchanged
- Worse

# Primary outcome measure for clinical routine

## *Interpretation*



# Primary outcome measure for clinical routine

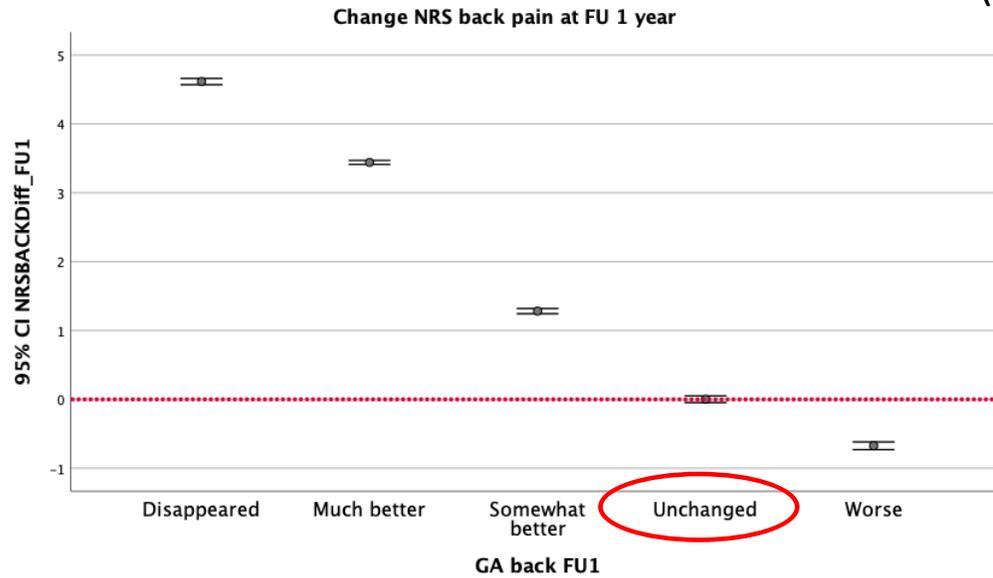
## *Application*

- Lumbar spinal stenosis - leg pain
- Lumbar disc herniation - leg pain
- Lumbar DDD - back pain
- Cervical disc herniation - arm pain

# How valid is Global Assessment?

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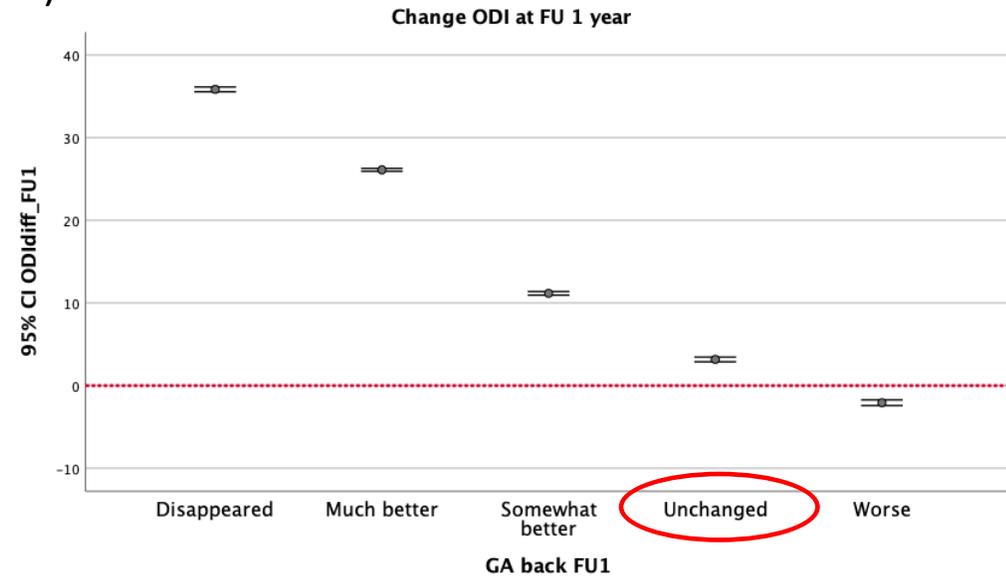
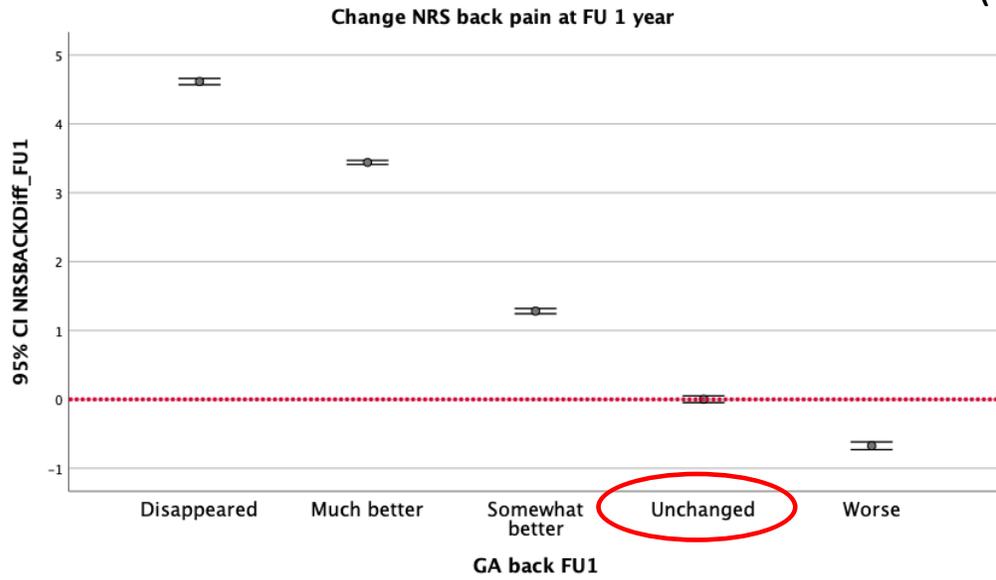
(N = Swespine)



Parai C, et al. The value of patient global assessment in lumbar spine surgery: an evaluation based on more than 90,000 patients. *Eur Spine J.* 2018 Mar;27(3):554-563

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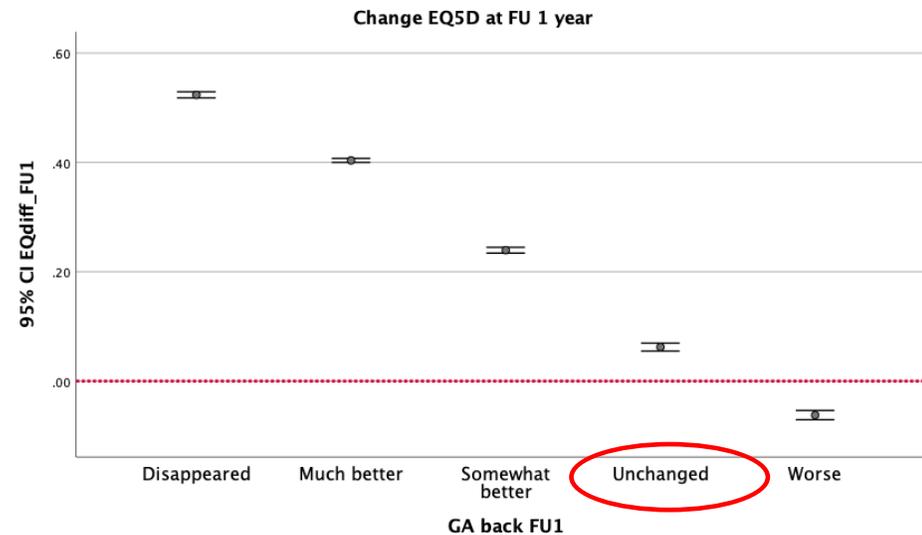
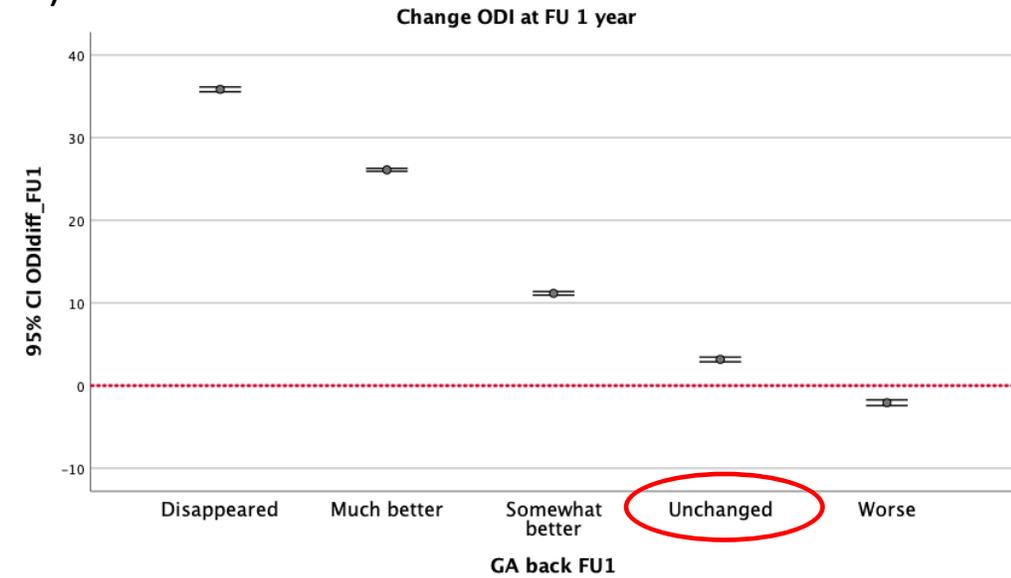
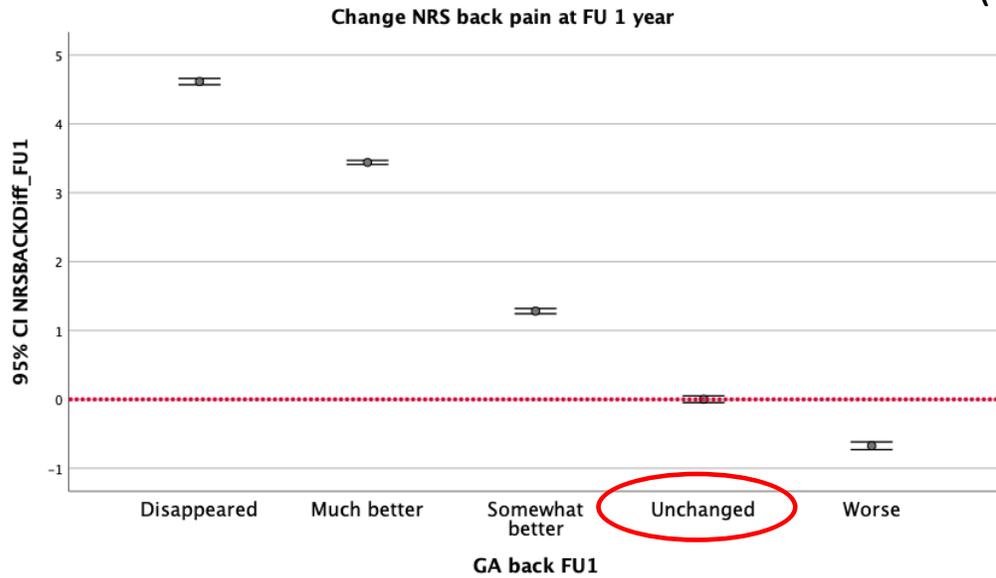
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(N = Swespine)



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***Example 1:***

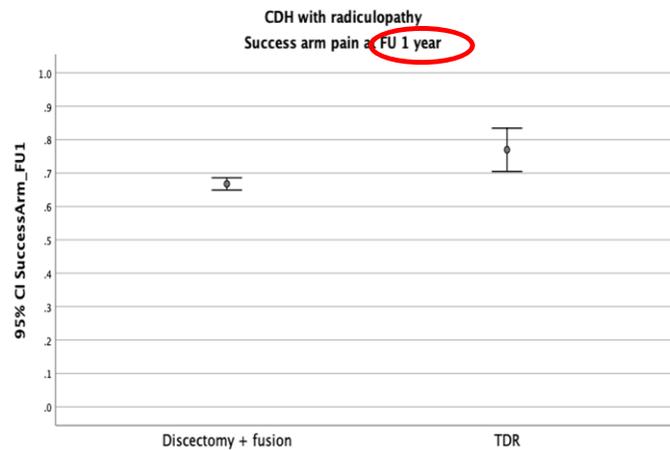
Is the outcome with disc prosthesis better than fusion in CDH with radiculopathy?

# Example 1:

Is the outcome with disc prosthesis better than fusion in CDH with radiculopathy?

**N = TDR 372, ACIF 5 811**

**Success rate arm pain (GA)**

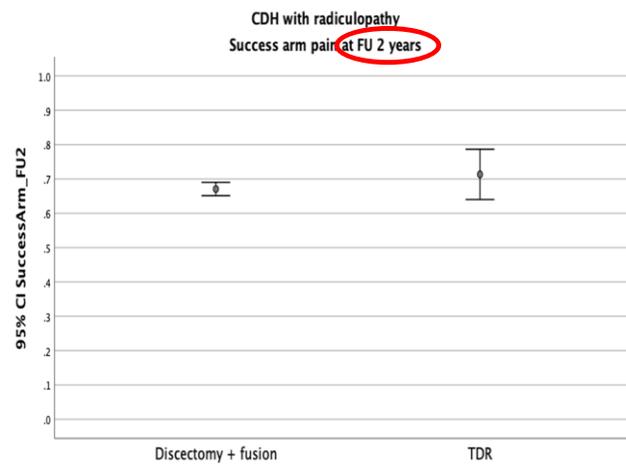
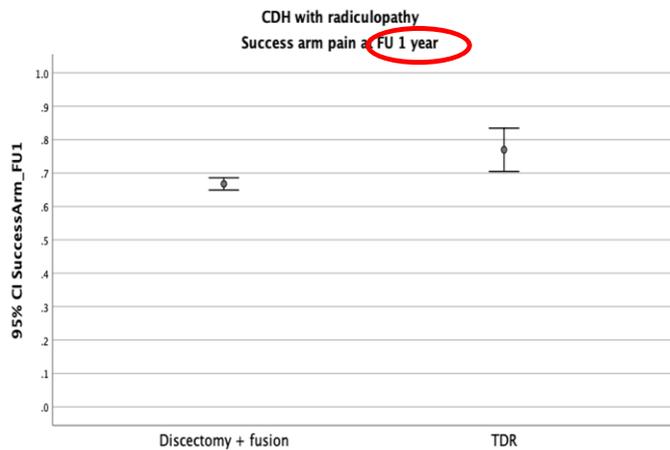


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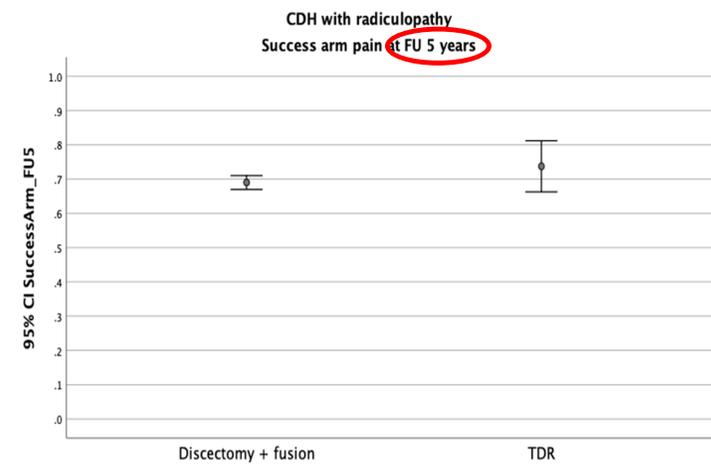
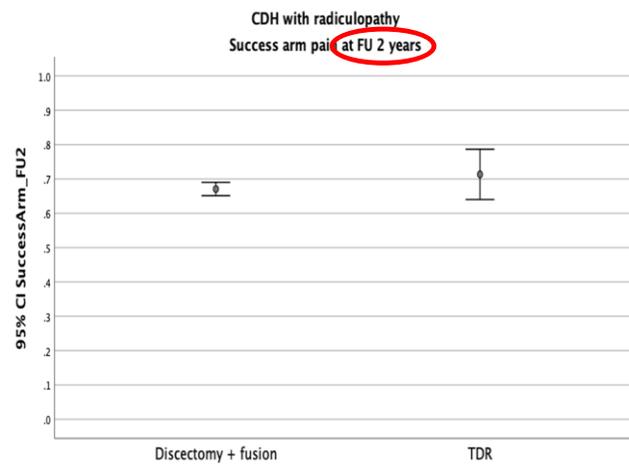
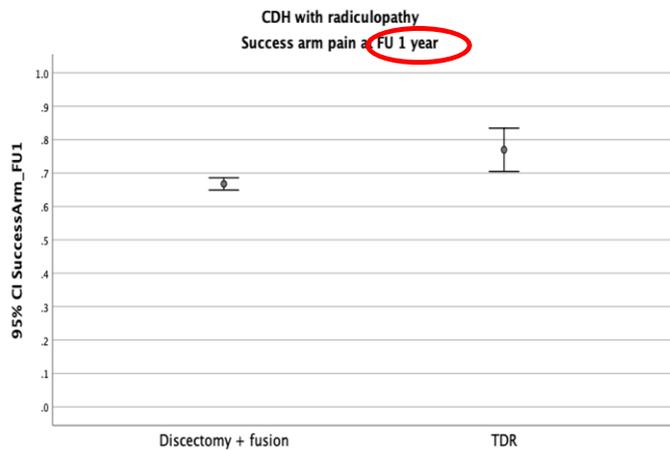


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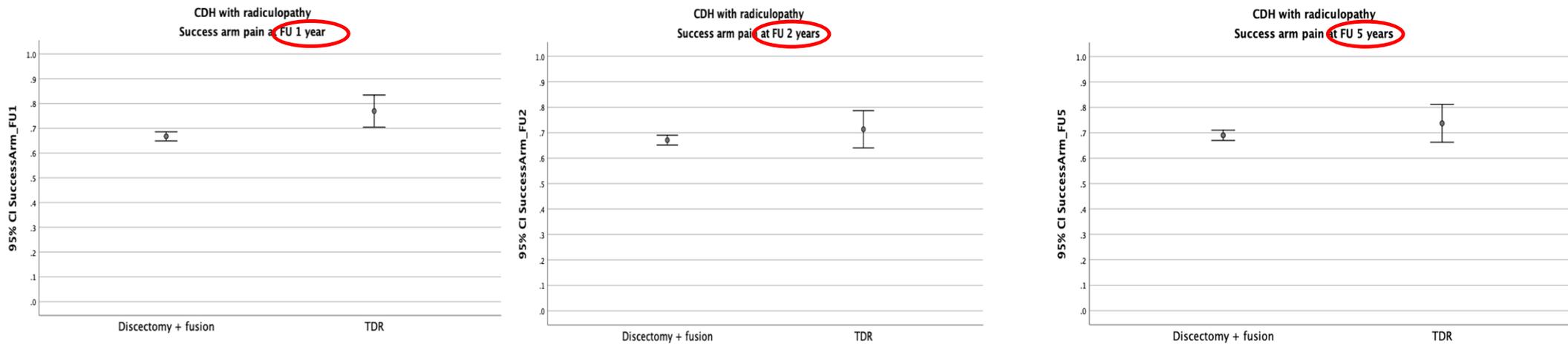


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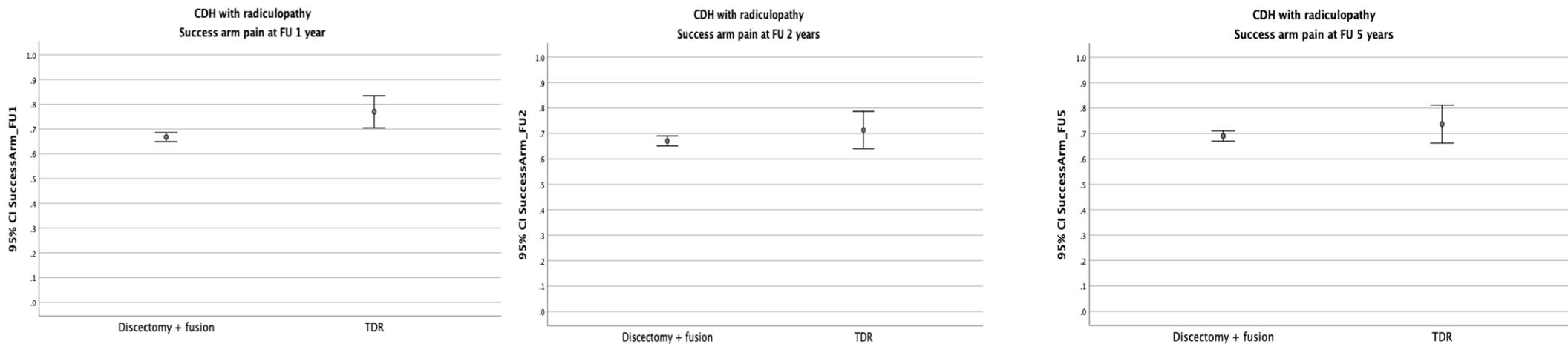
Reinterventions within 1 year: TDR 4,8% - ACIF 1,2%

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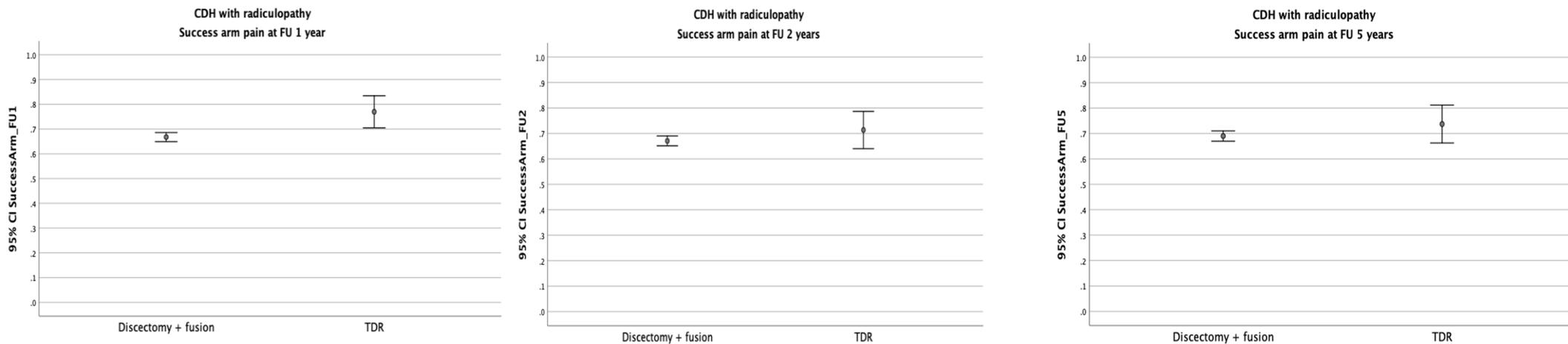
Answer: Outcome is not better with TDR

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Swespine data equivalent to Swedish RCT with FU 2 and 5 years:

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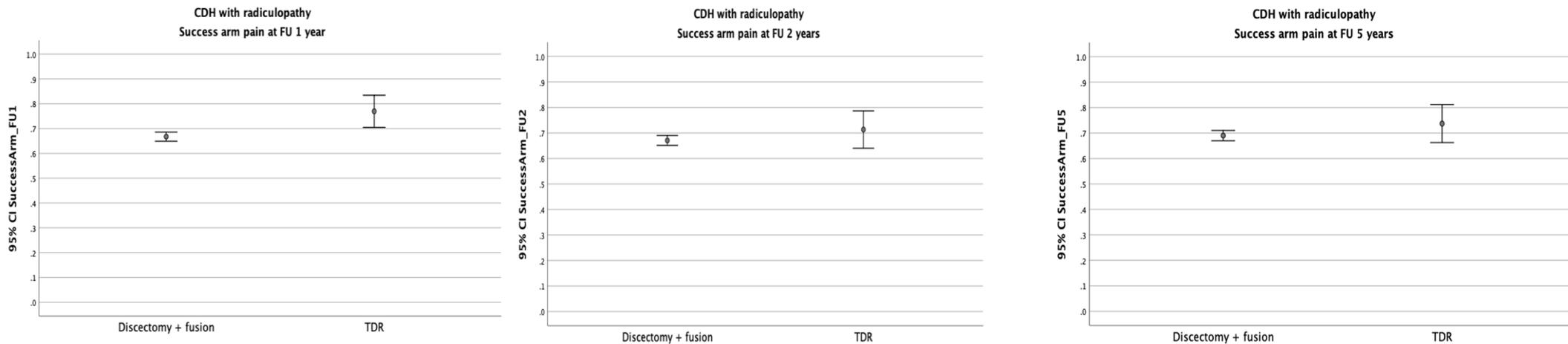
MacDowall A, et al. Artificial disc replacement versus fusion in patients with cervical degenerative disc disease with radiculopathy: 5-year outcomes from the National Swedish Spine Register. *J Neurosurg Spine.* 2018 Nov 2;30(2):159-167. doi: 10.3171/2018.7.SPINE18657. PMID: 30485205.

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**Recommendation: Do not replace – Fuse!**

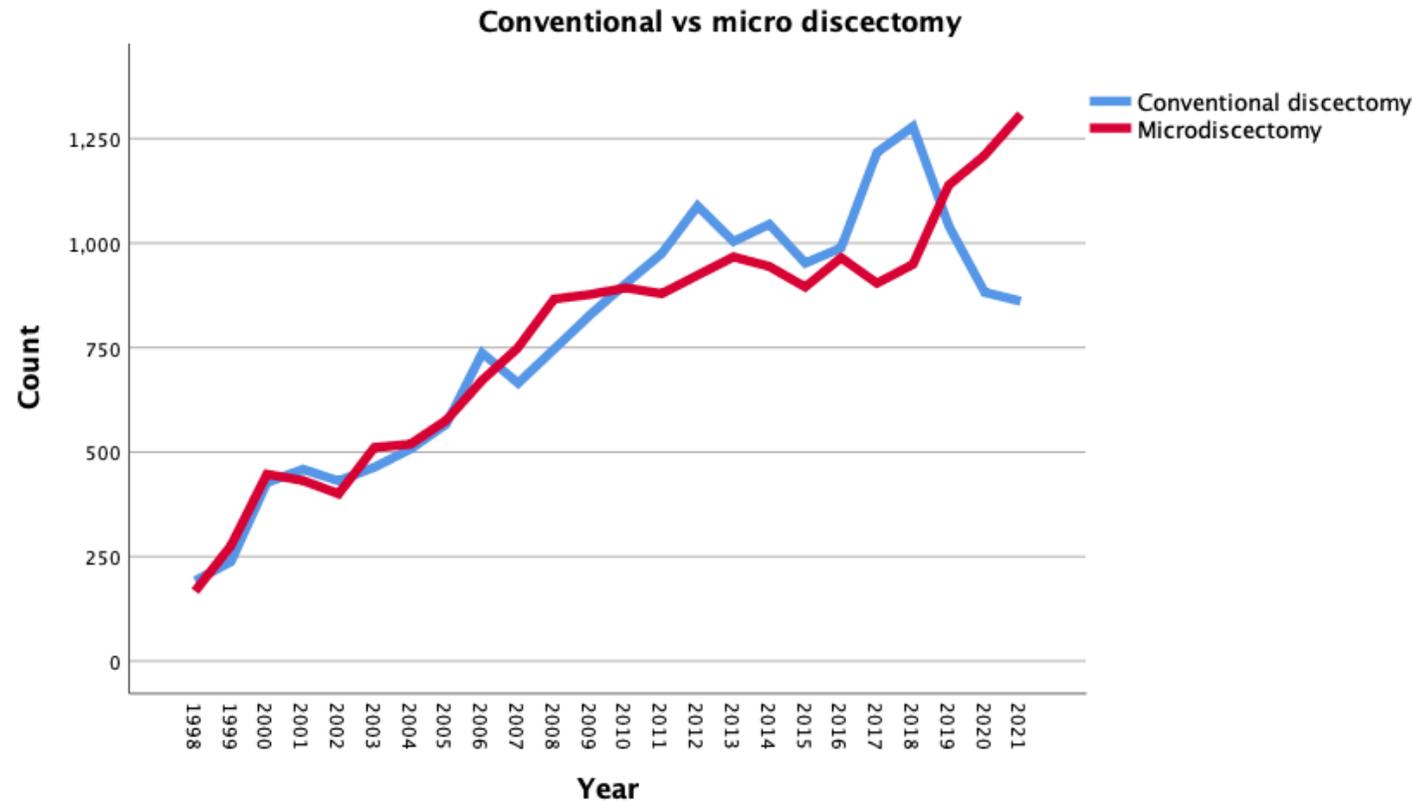
## **Example 2:**

Does microdiscectomy lead to better outcome than conventional discectomy?

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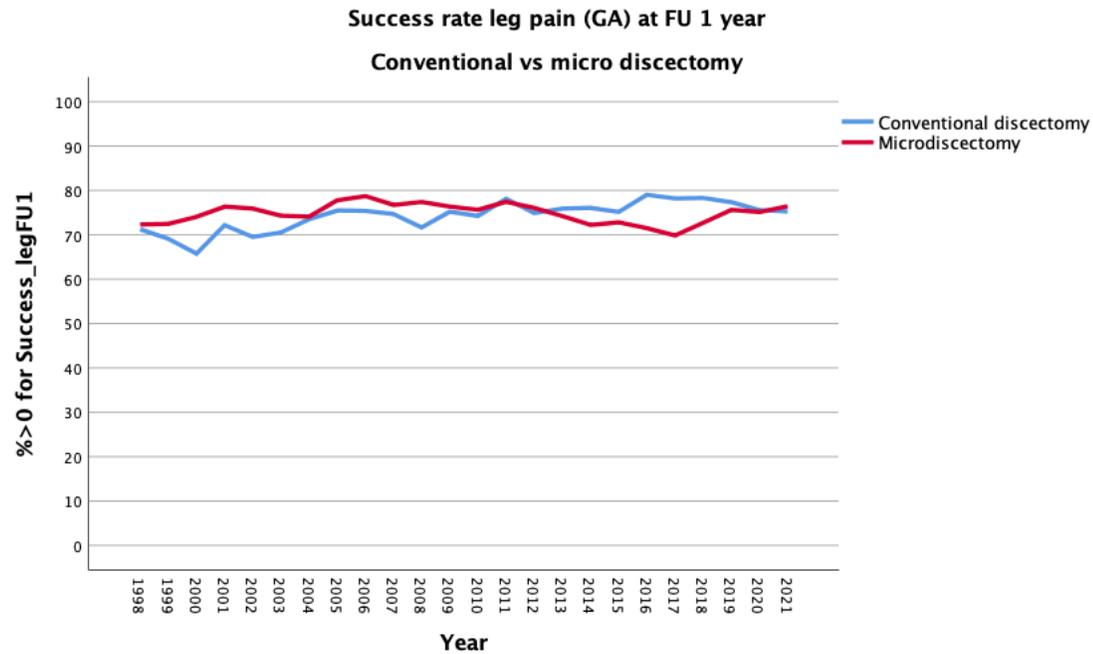
N = 42 979



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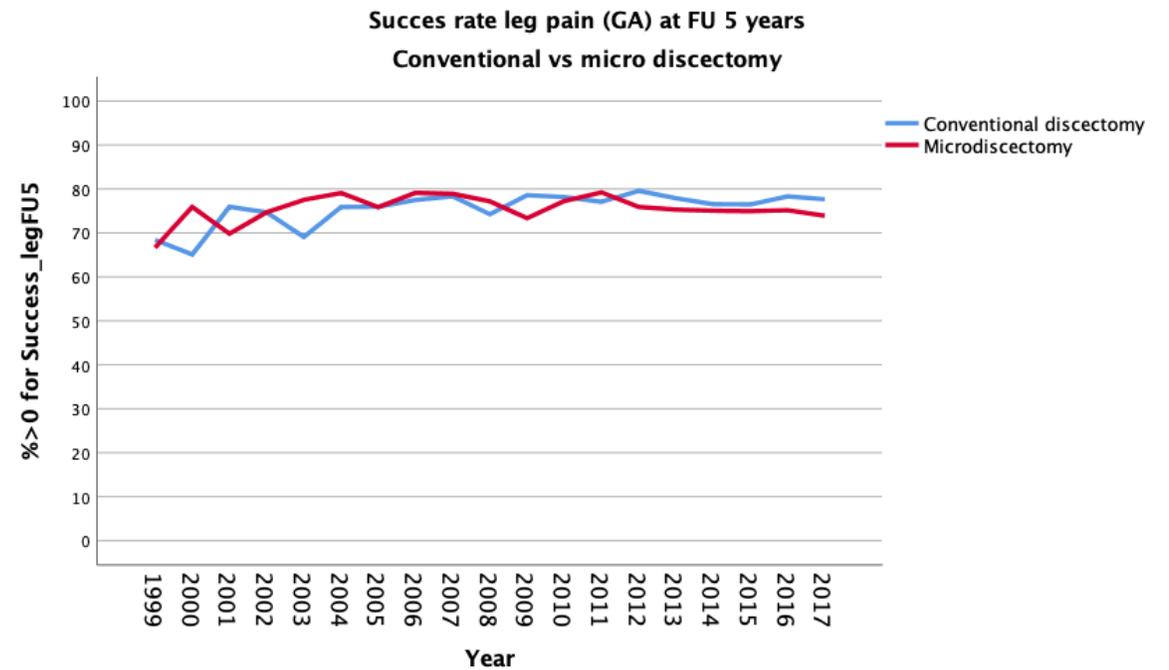
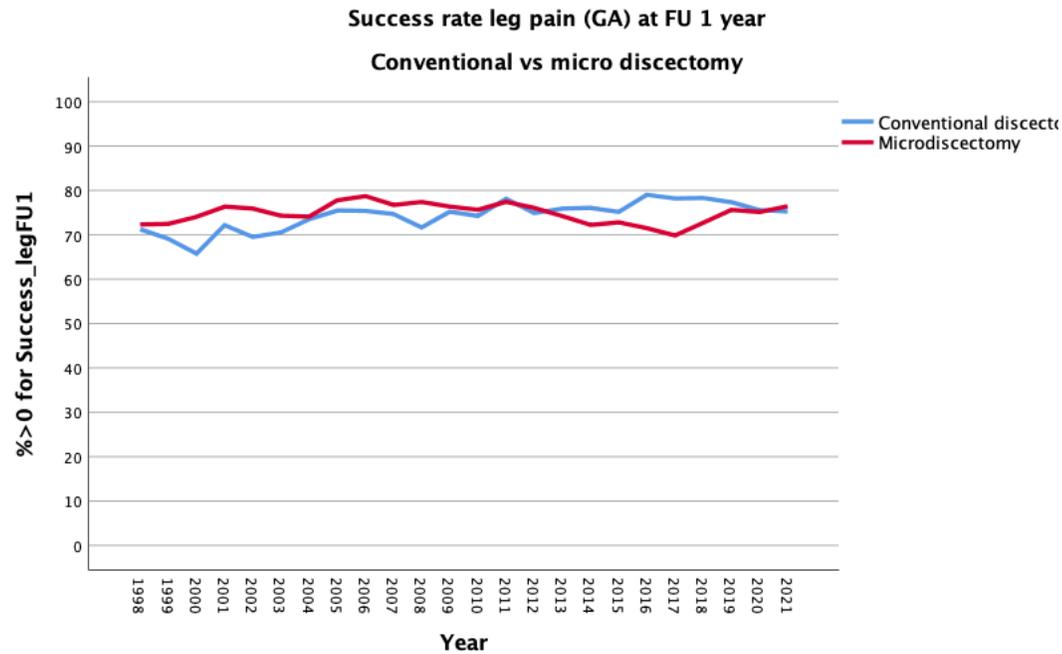
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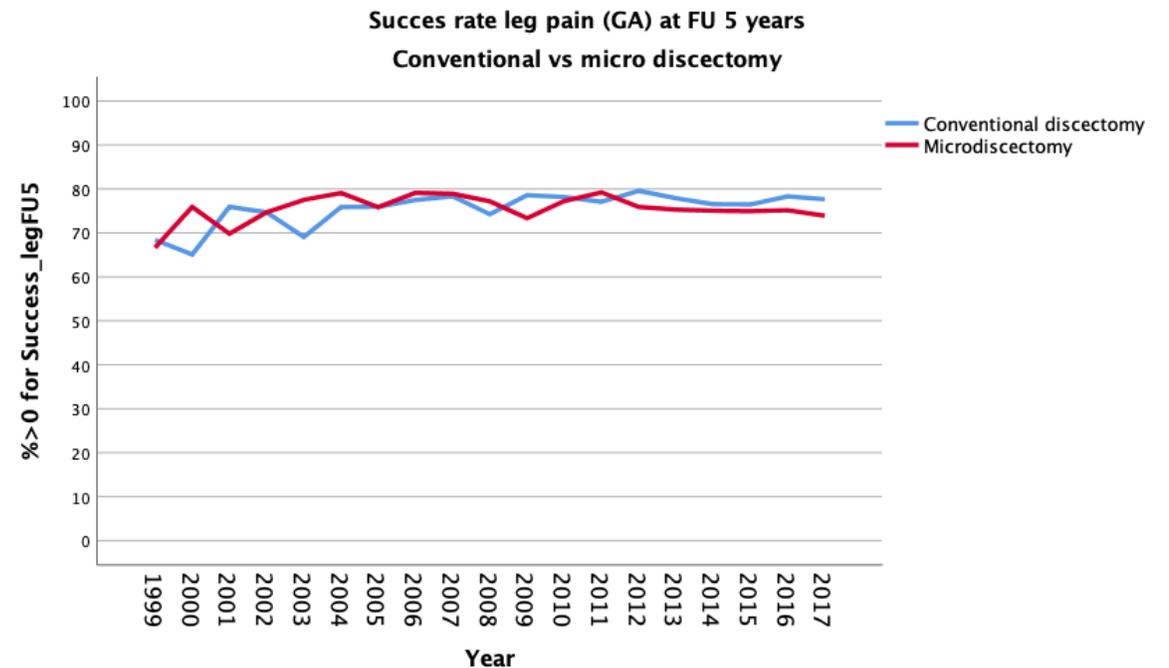
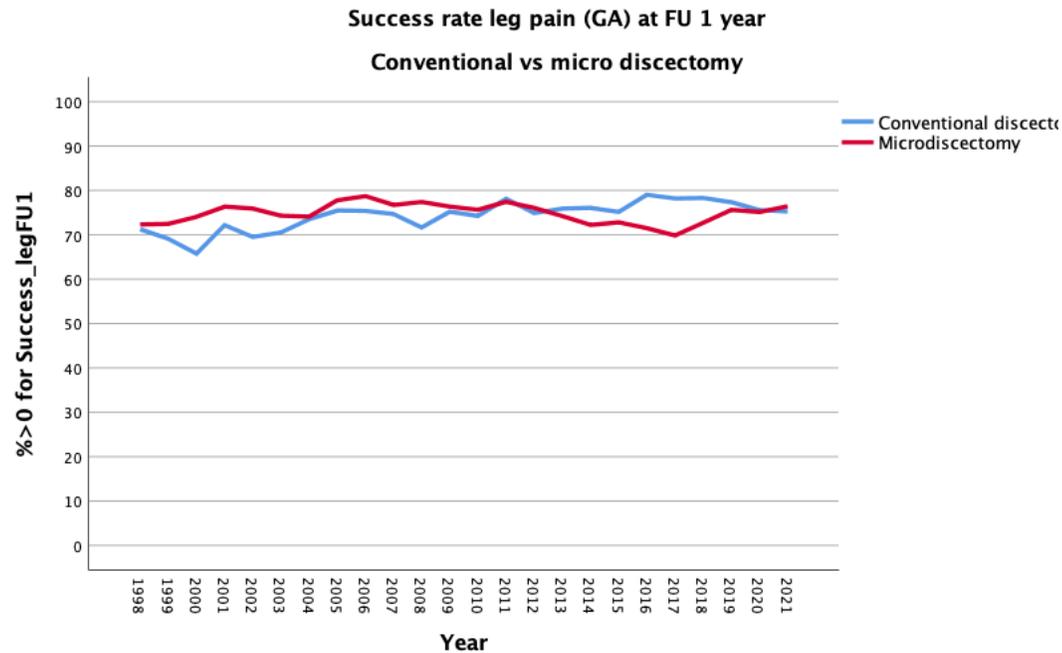
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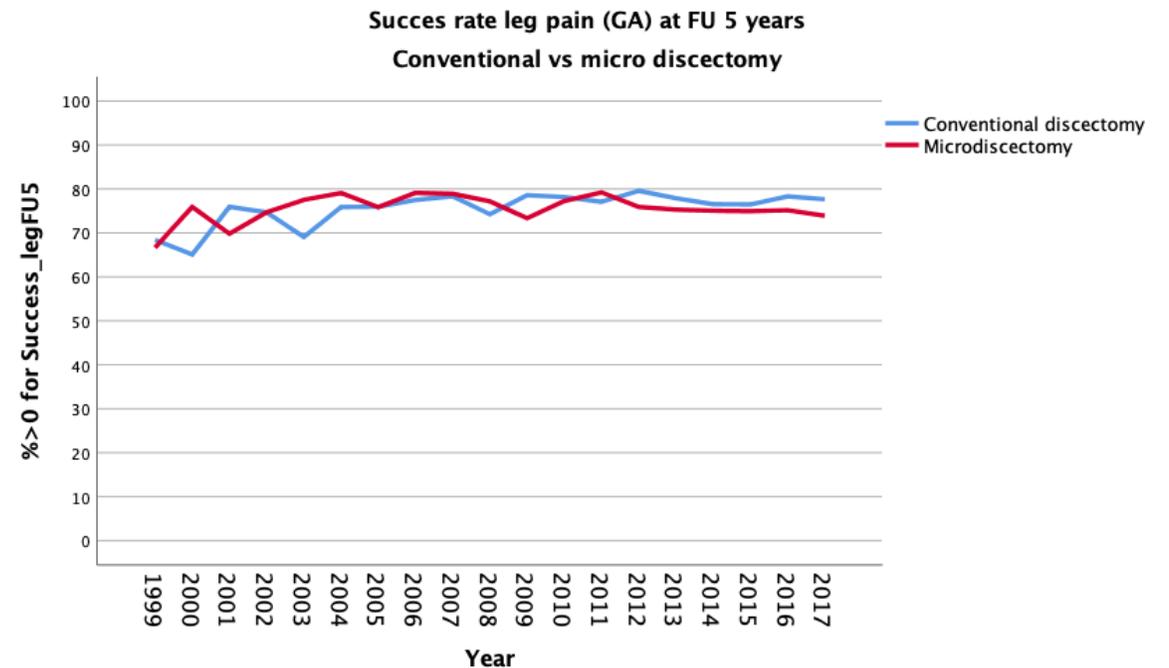
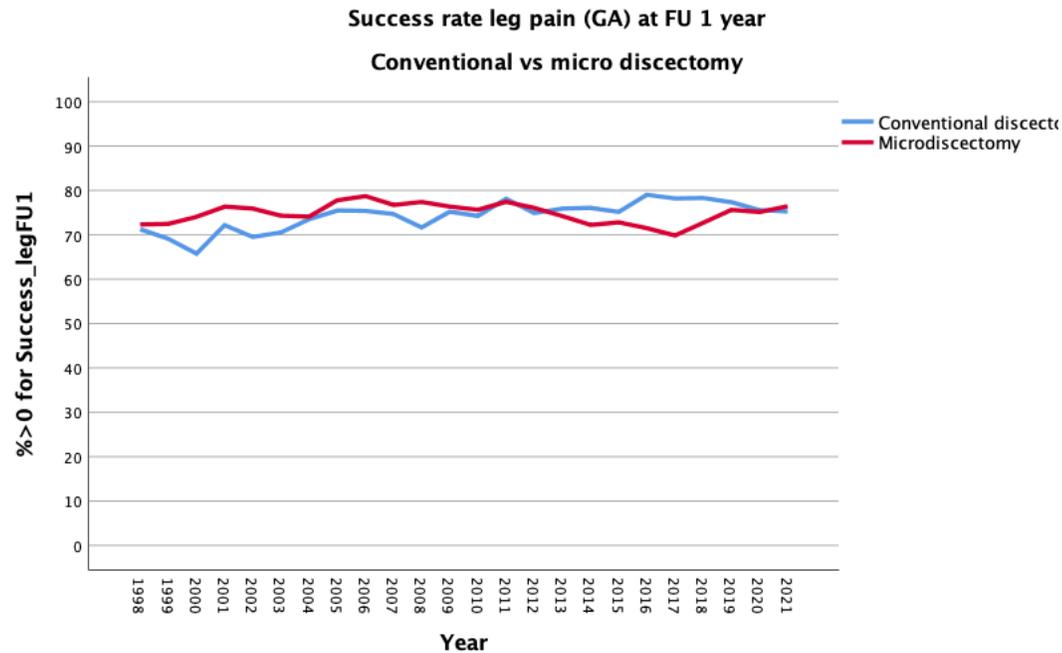


Reintervention: Conv = 4,2% Micro = 4,1%

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Outcome is not better after microdiscectomy

### **Example 3:**

What has happened with the outcome of surgery for Degenerative Disc Disease (DDD) in the lumbar spine ?

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N = 12 339

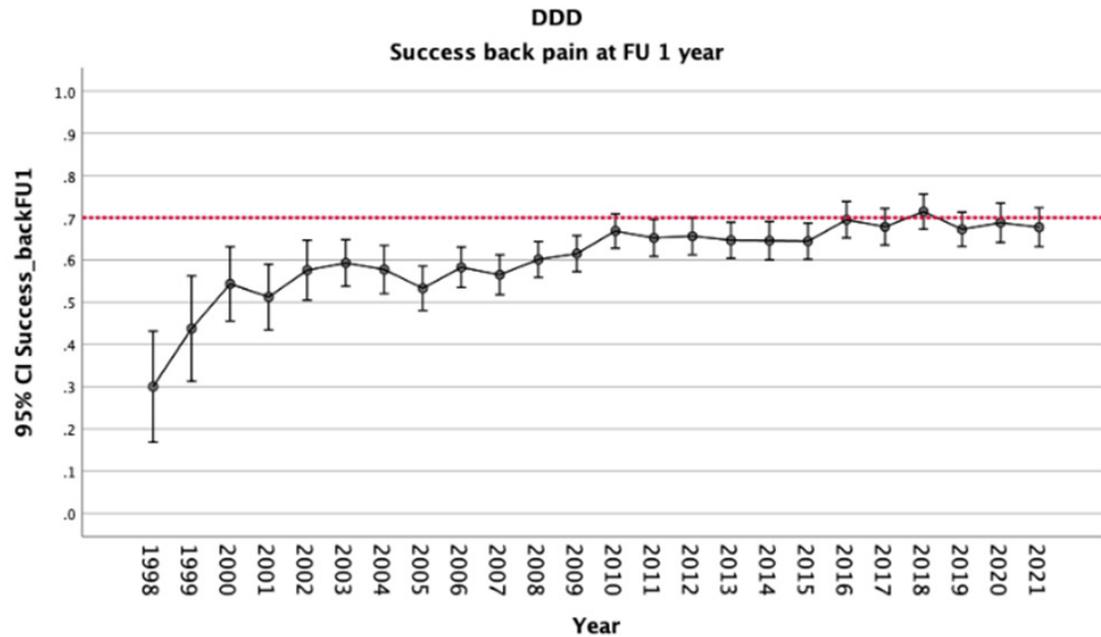
**Success rate back pain**

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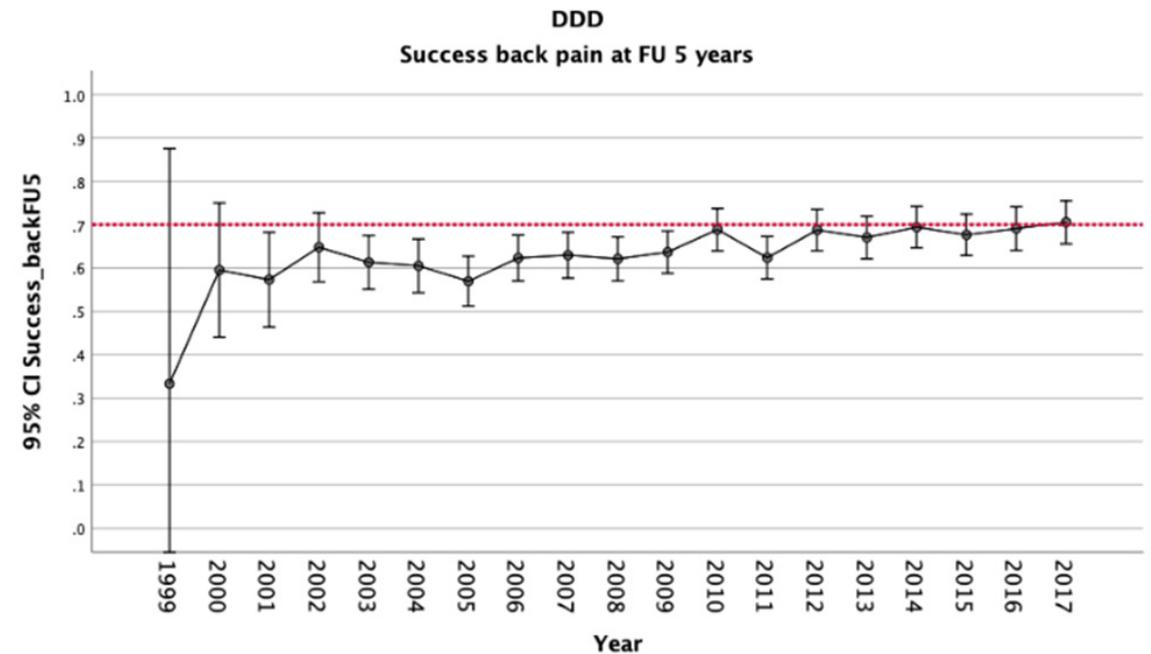
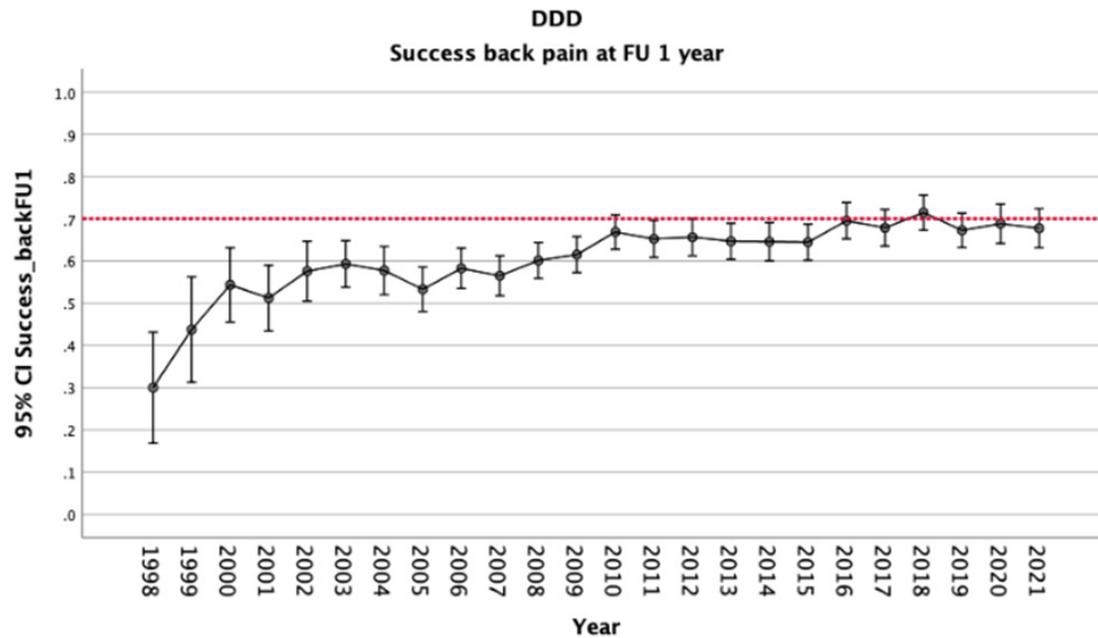


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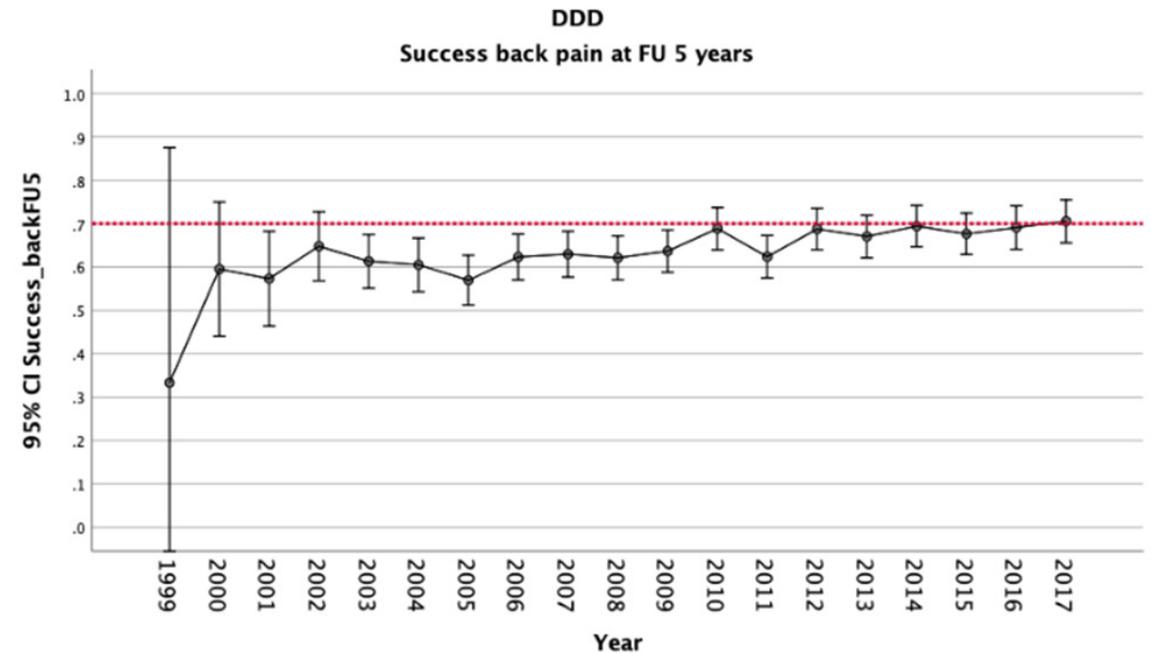
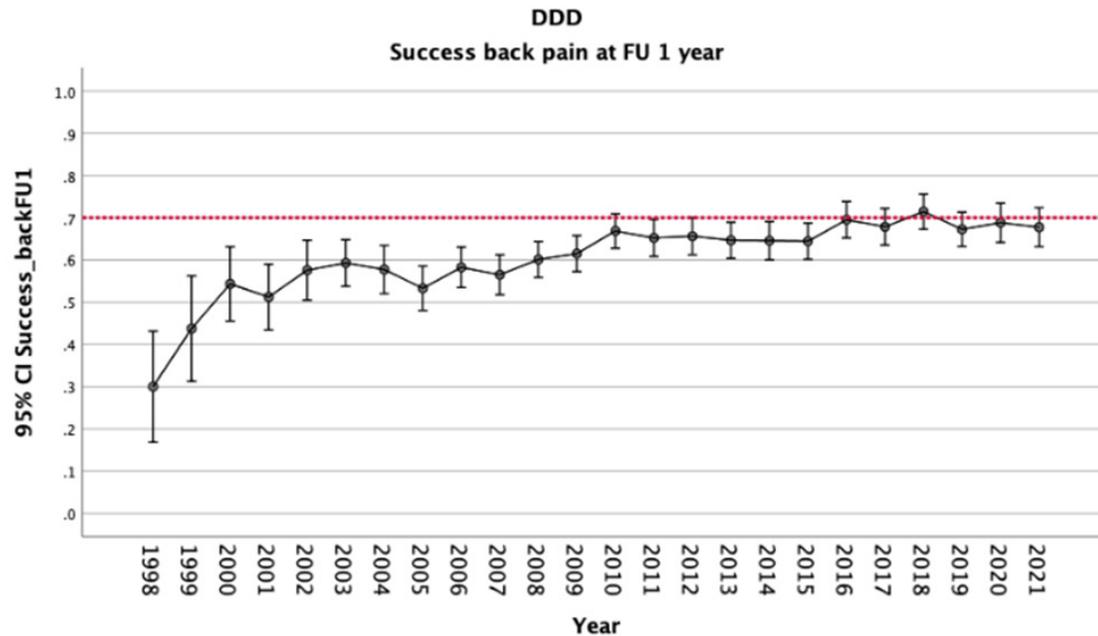


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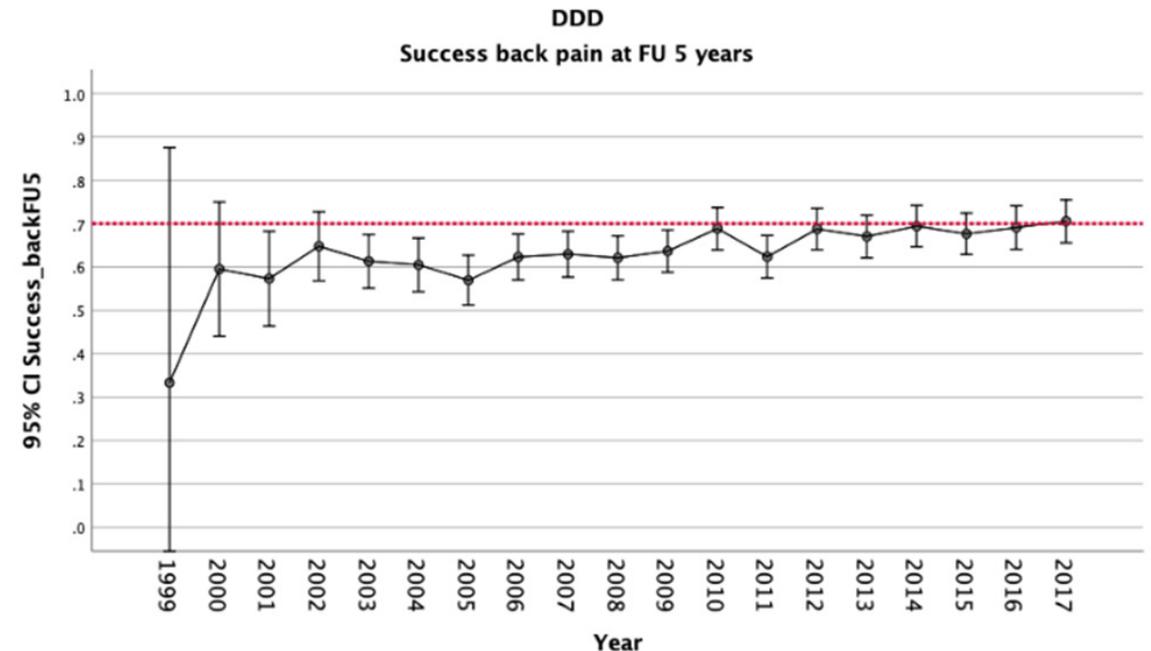
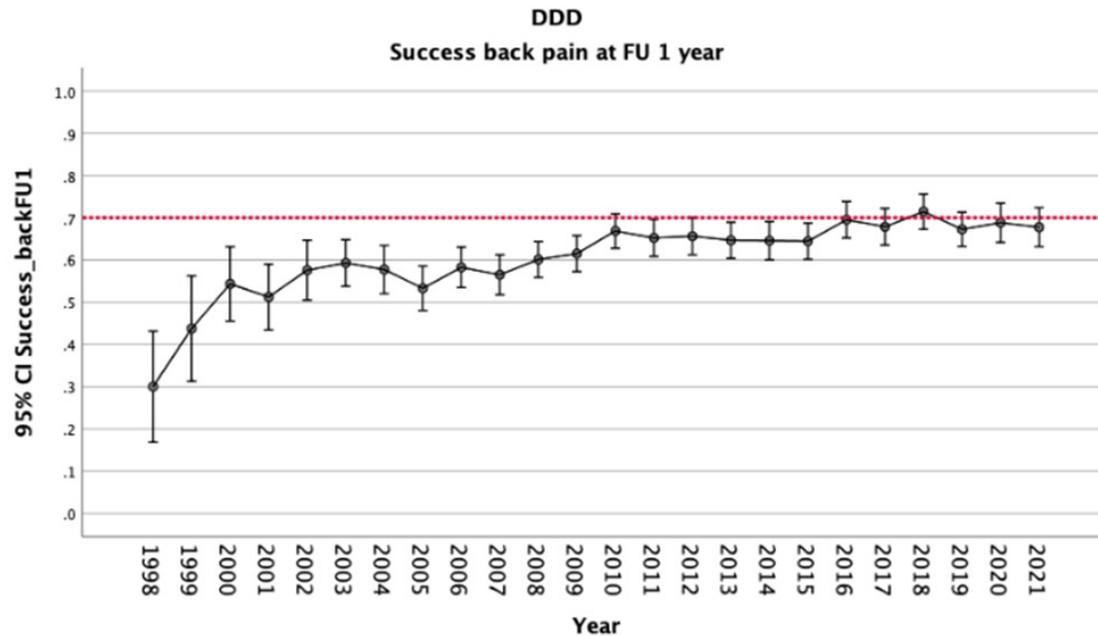
! Outcome has improved  
Approaching the outcome  
of surgery for LDH

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N = 12 339

#### Success rate back pain



! Outcome has improved.  
Approaching the outcome  
of surgery for LDH

WHY?

- Benchmarking?
- Improved diagnostics?
- Improved surgical technique?
- More restrictive attitude to surgery?

## **Example 4:**

Is TDR better than fusion for lumbar DDD?

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Is TDR better than fusion for lumbar DDD?

Public debate 3 years ago

TDR stopped

What does registry data show?

## Example 4:

Is TDR better than fusion for lumbar DDD?

TDR = 1 591 Fusion = 10 748

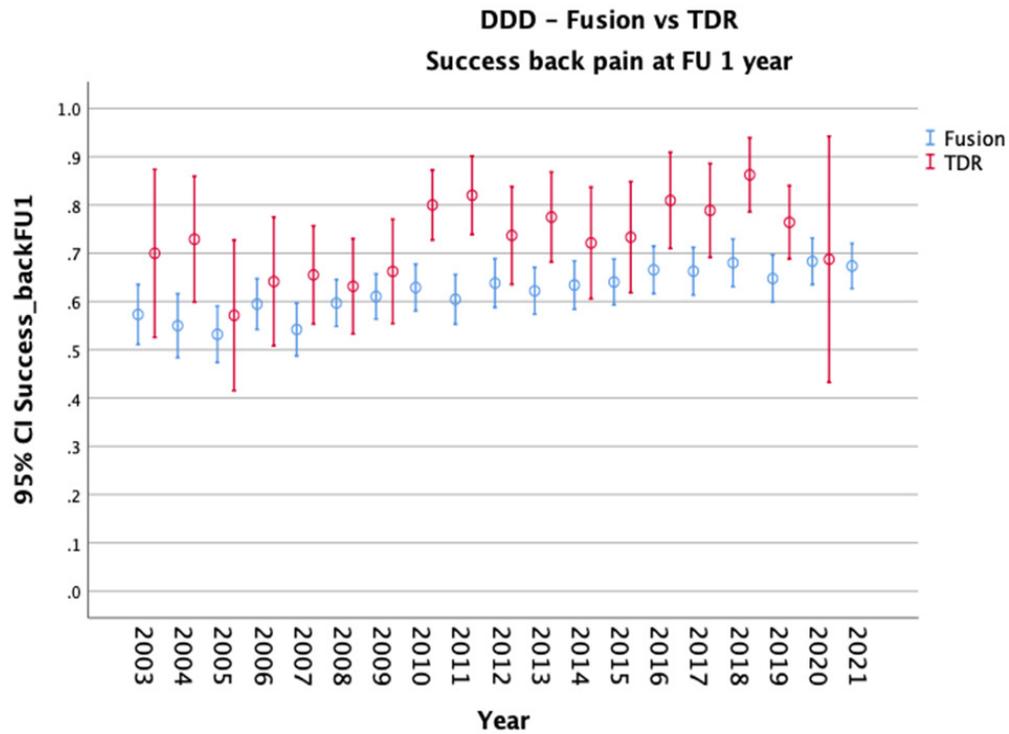
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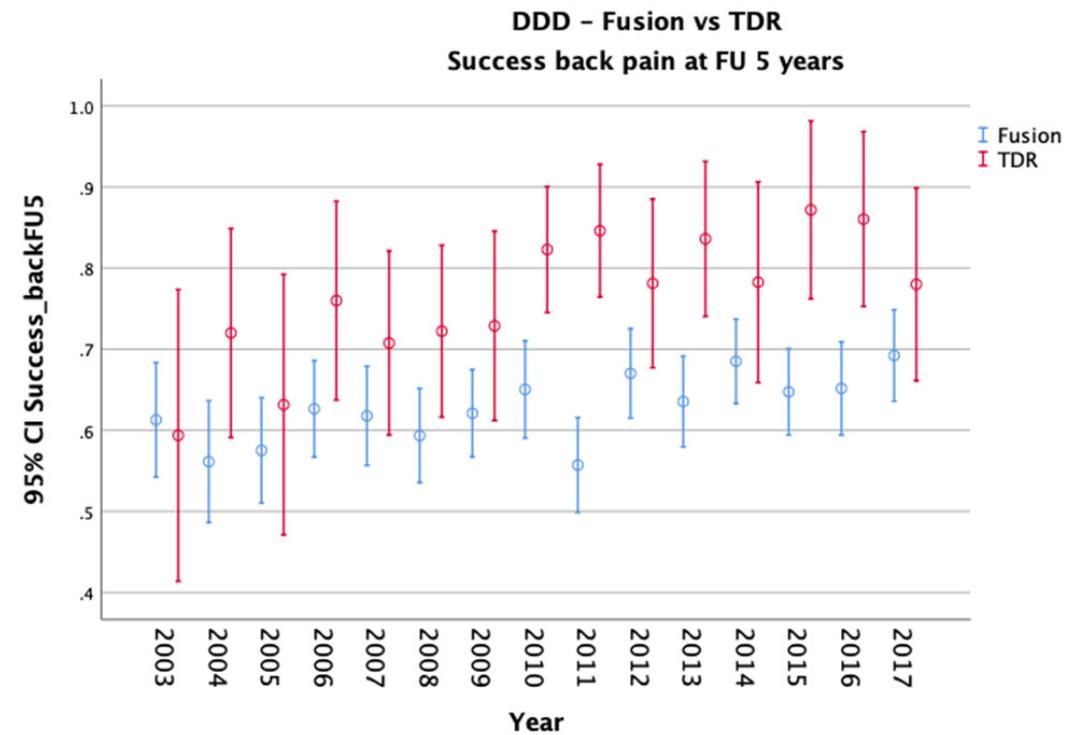
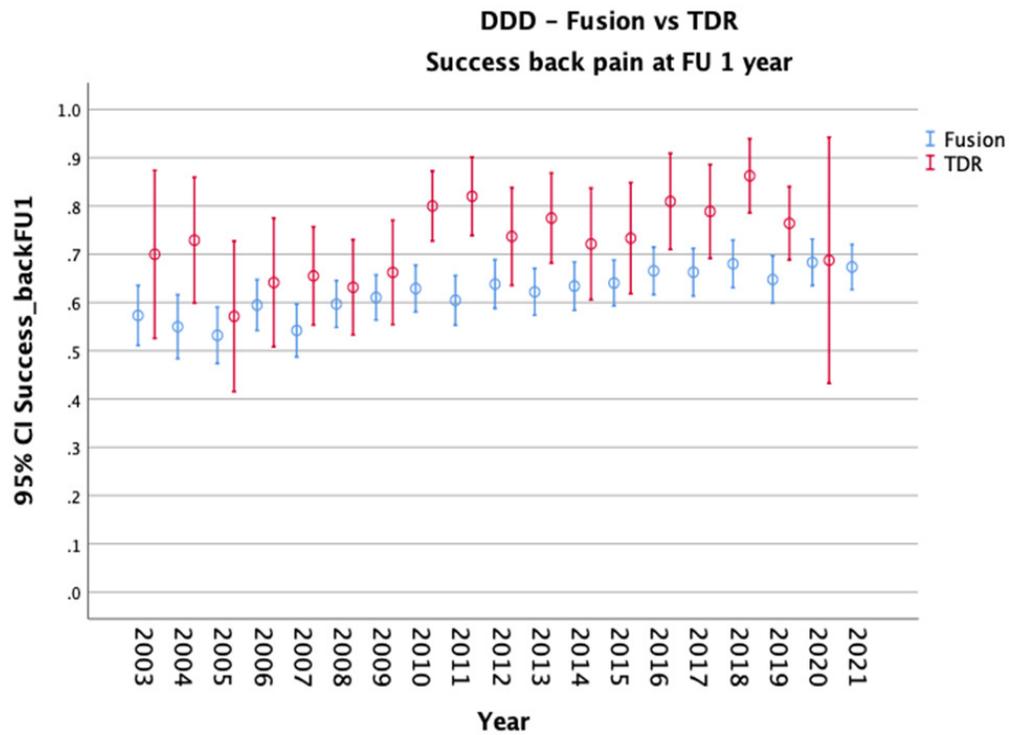


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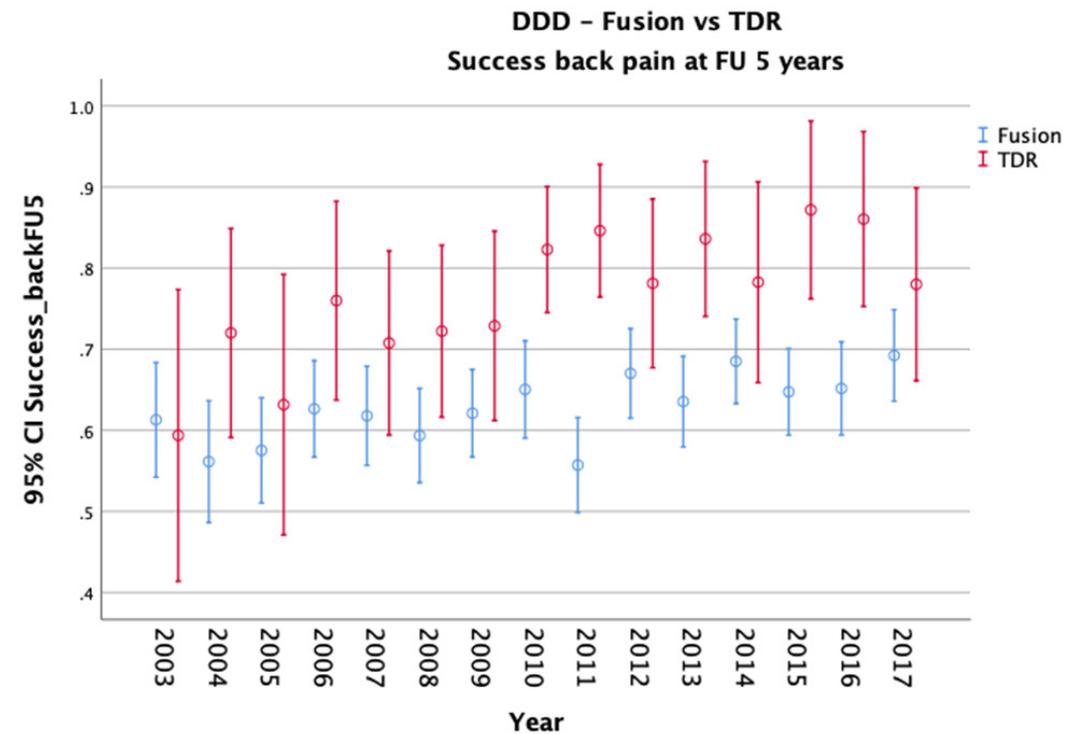
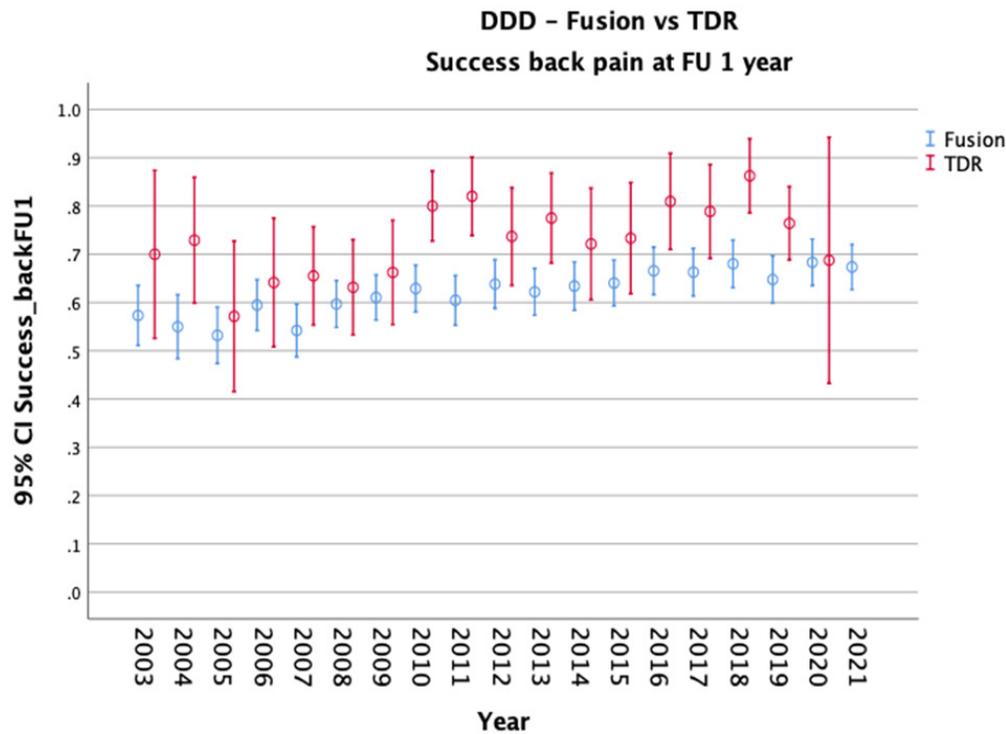


# Example 4:

## Is TDR better than fusion for lumbar DDD?

TDR = 1 591 Fusion = 10 748

Success rate back pain



TDR: at least as good as fusion

RCT with FU 1, 2 and 5 years = equivalent outcome

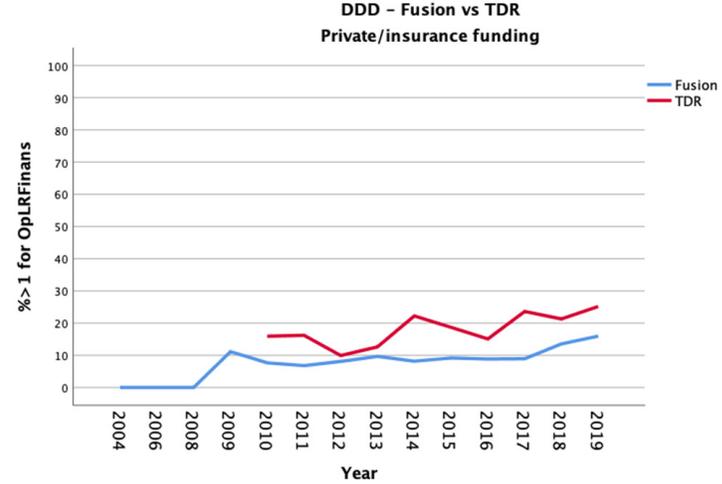
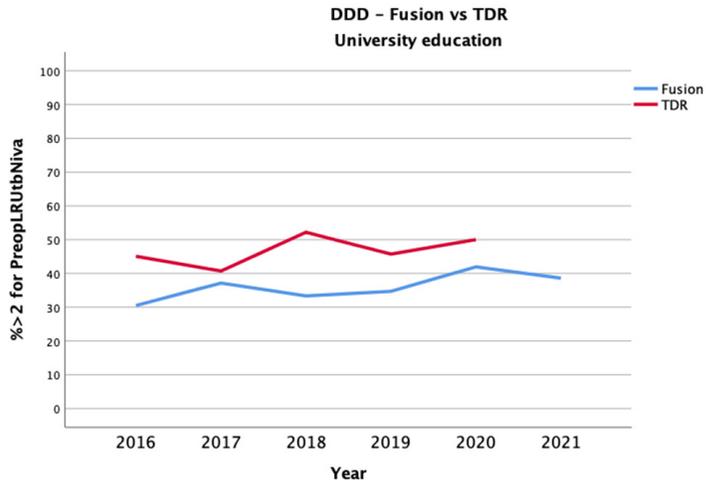
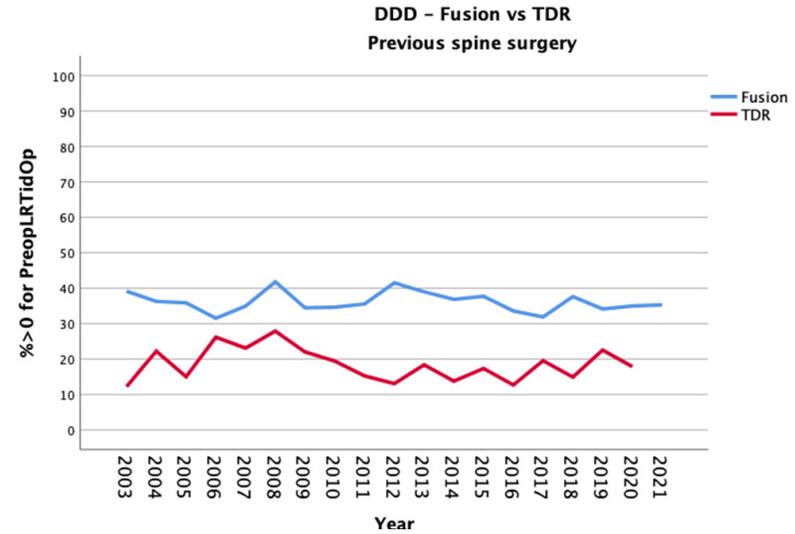
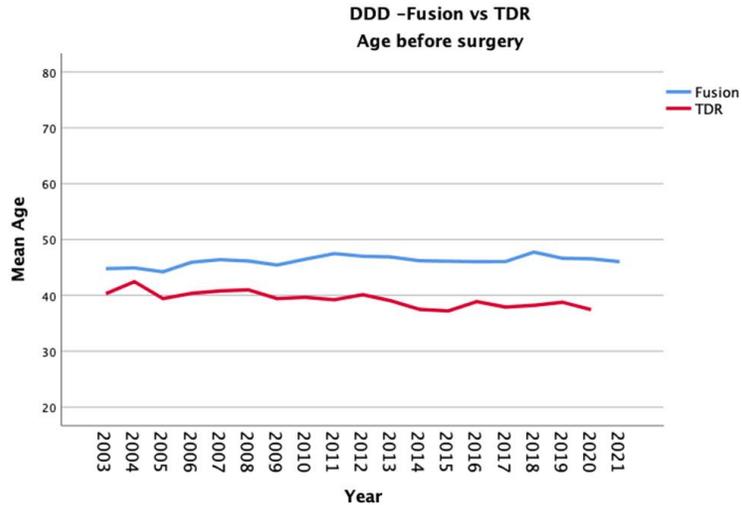
Berg S, et al. Total disc replacement compared to lumbar fusion: a randomised controlled trial with 2-year follow-up. *Eur Spine J.* 2009 Oct;18(10):1512-9. doi: 10.1007/s00586-009-1047-0. Epub 2009 Jun 9. PMID: 19506919; PMCID: PMC2899375.

Sköld C, et al. Five-year follow-up of total disc replacement compared to fusion: a randomized controlled trial. *Eur Spine J.* 2013 Oct;22(10):2288-95. doi: 10.1007/s00586-013-2926-y. Epub 2013 Jul 29. PMID: 23893083; PMCID: PMC3804684.

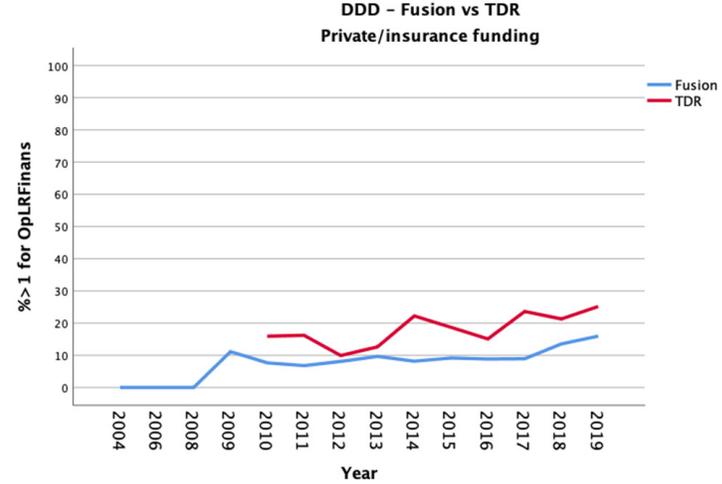
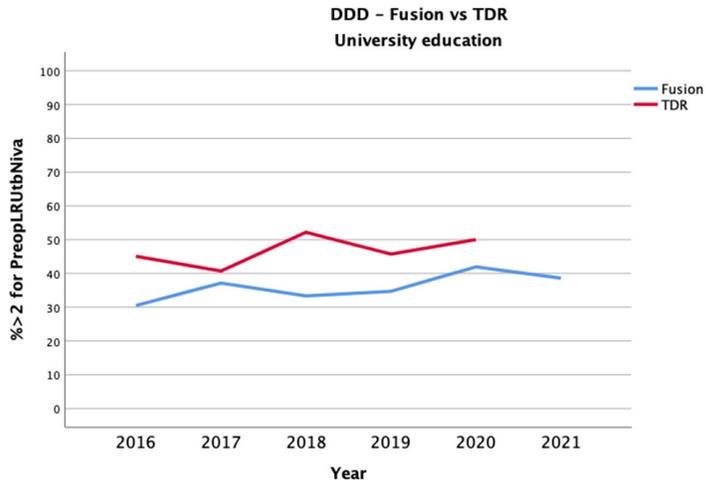
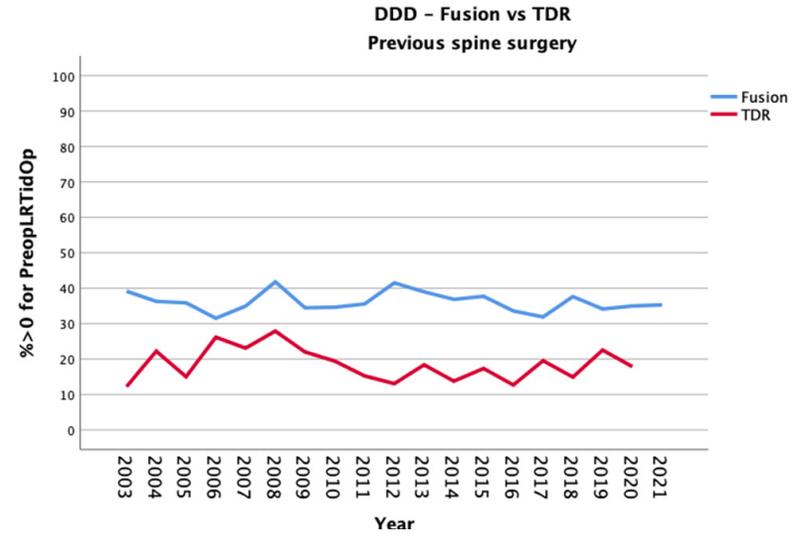
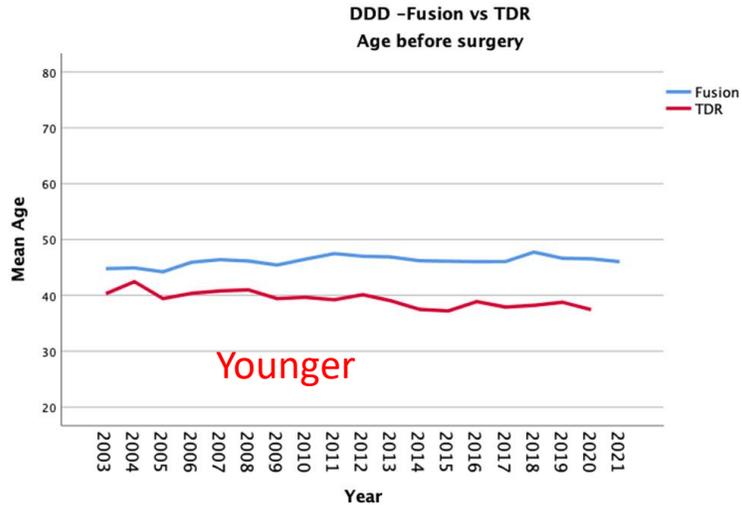
# But

- Difference of outcome is small
- TDR and Fusion are different populations

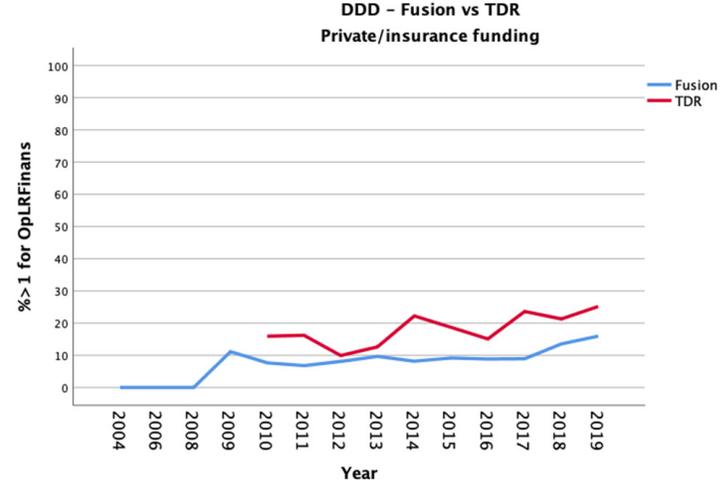
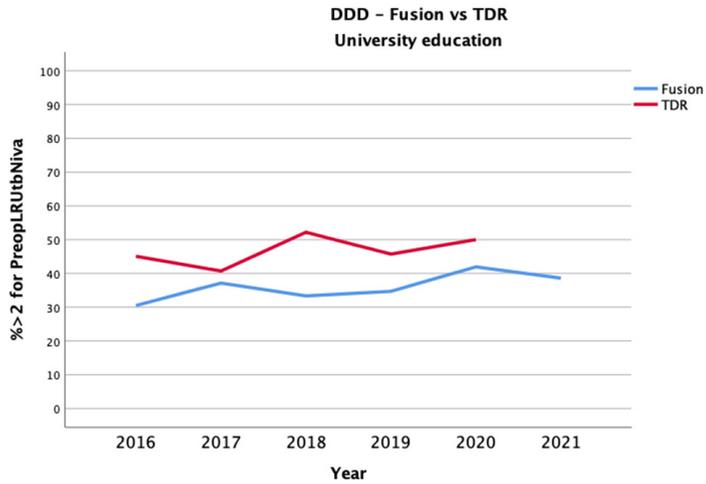
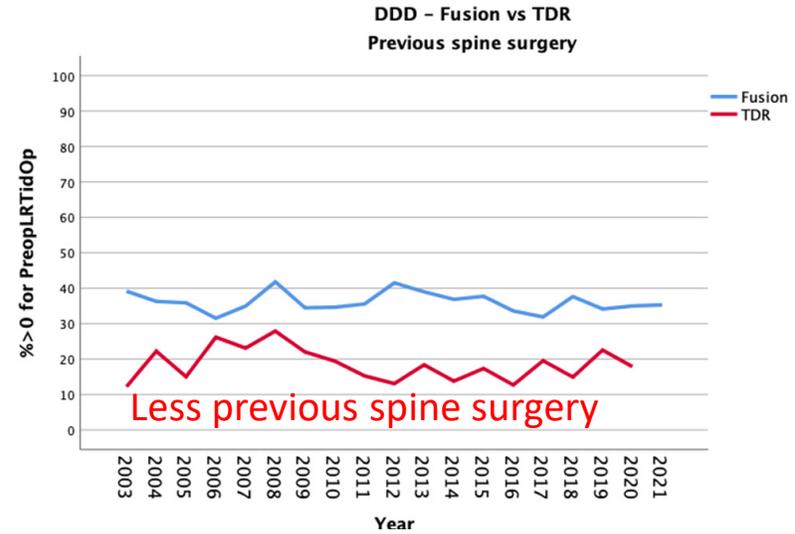
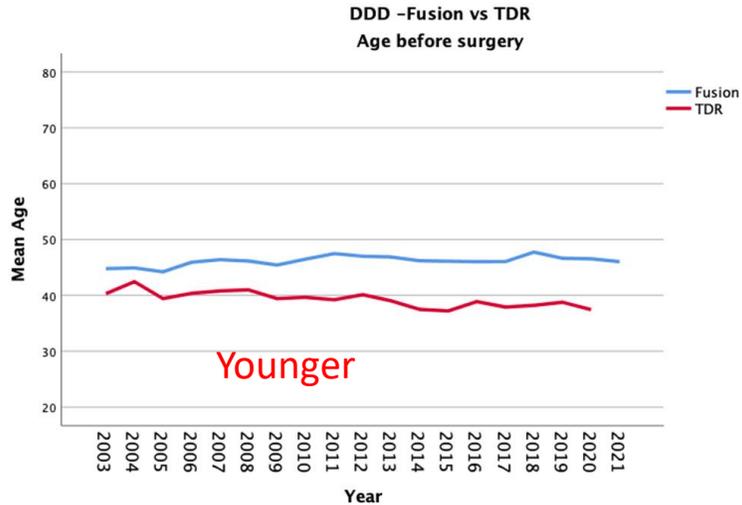
## Preoperative demographics TDR



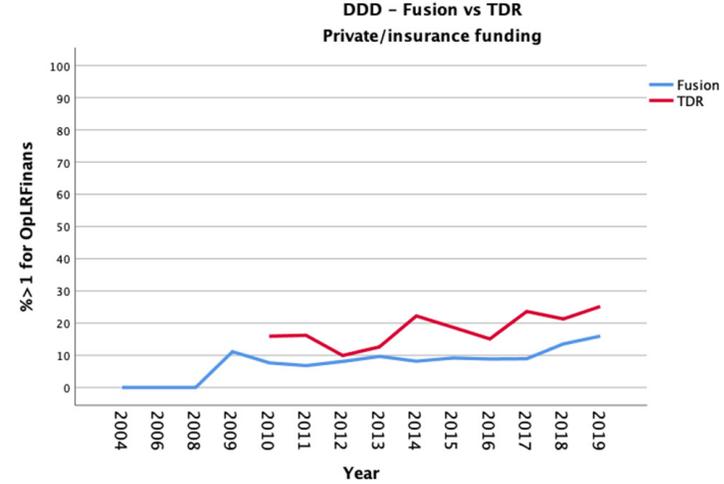
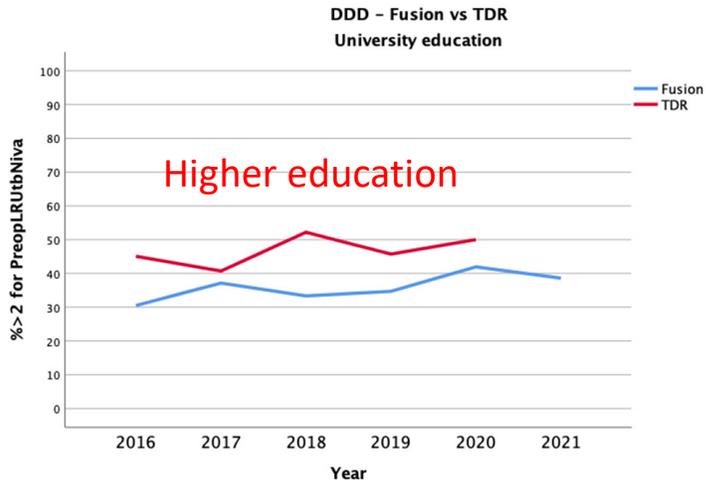
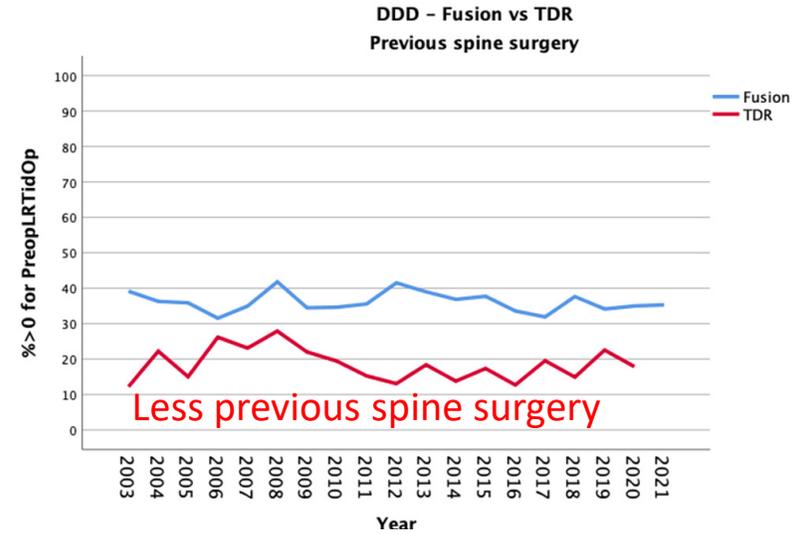
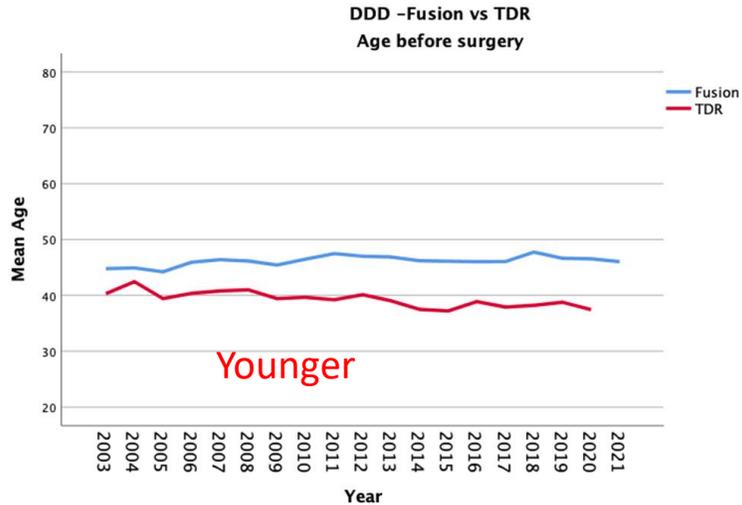
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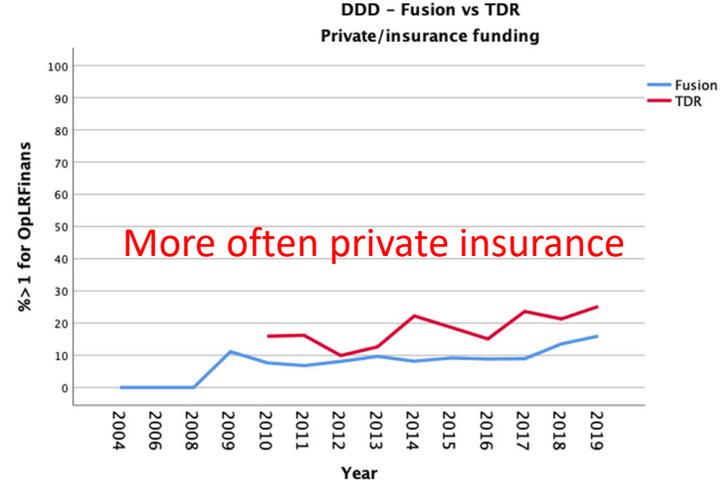
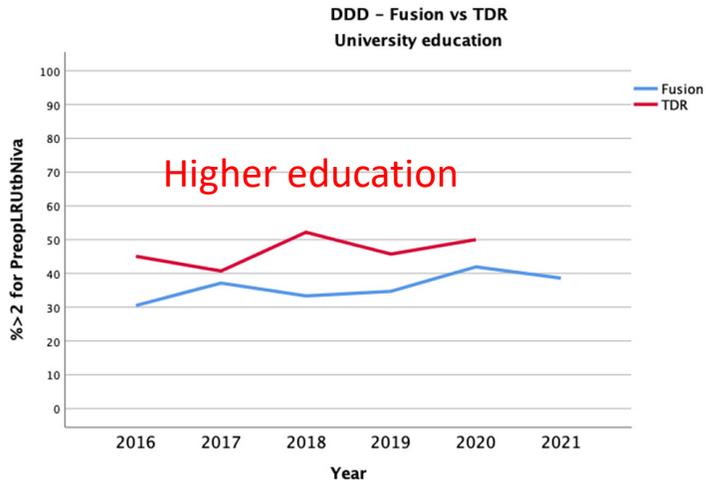
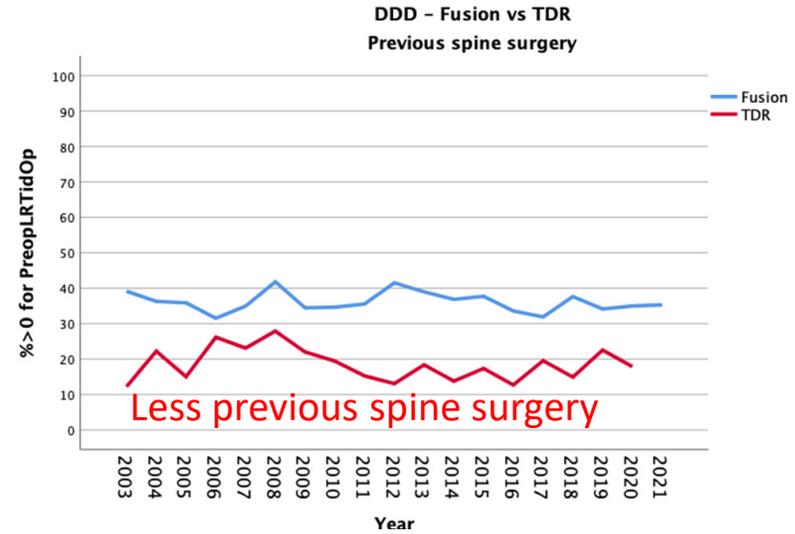
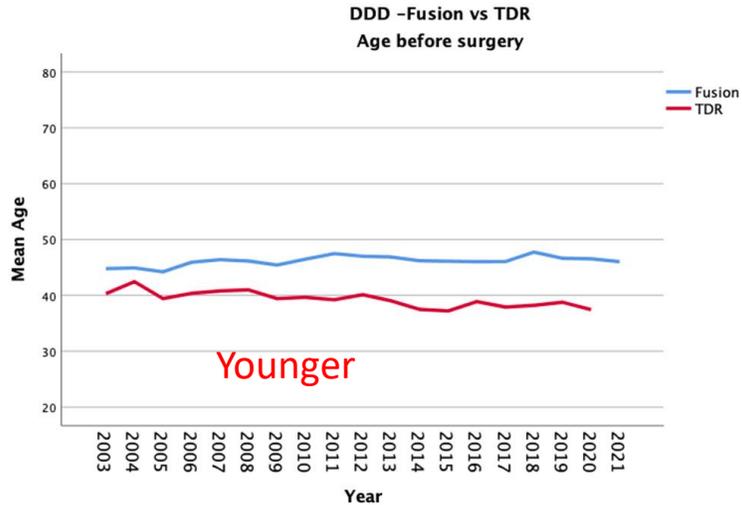
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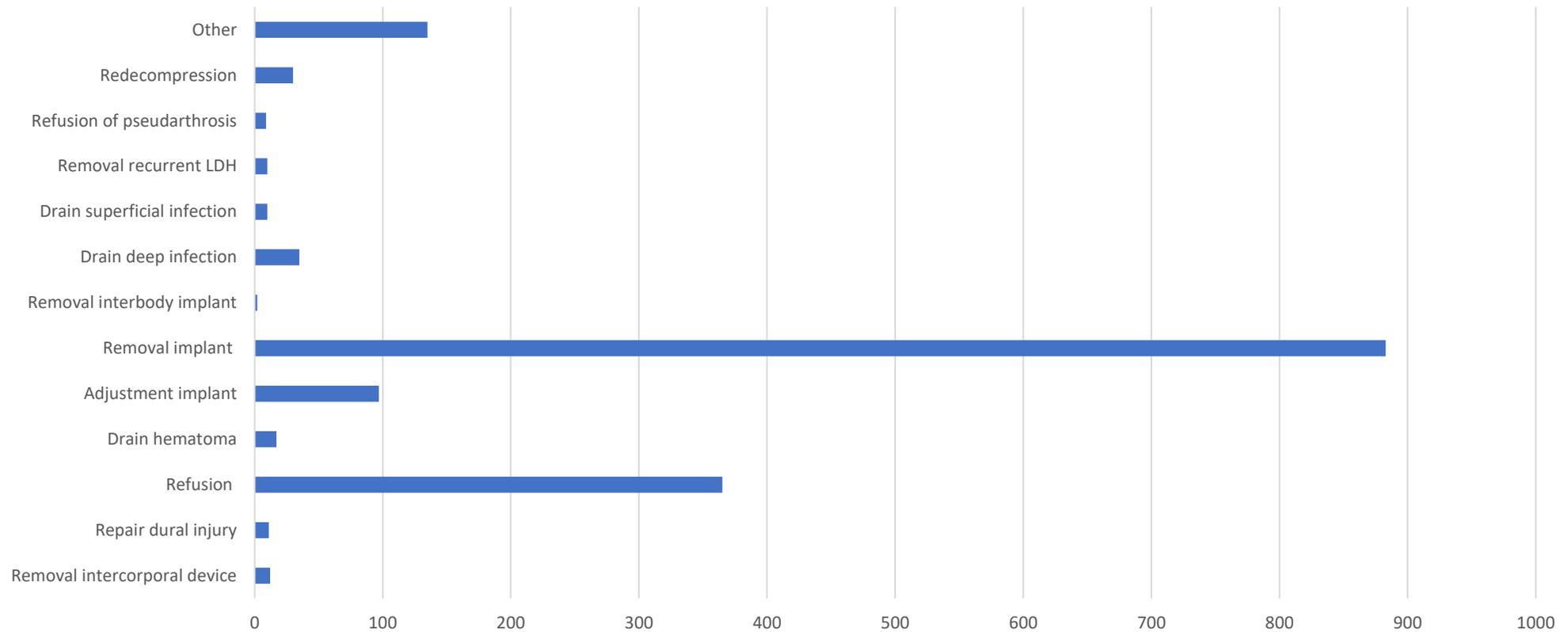
Reinterventions: Fusion 15,1% - TDR 5,2%

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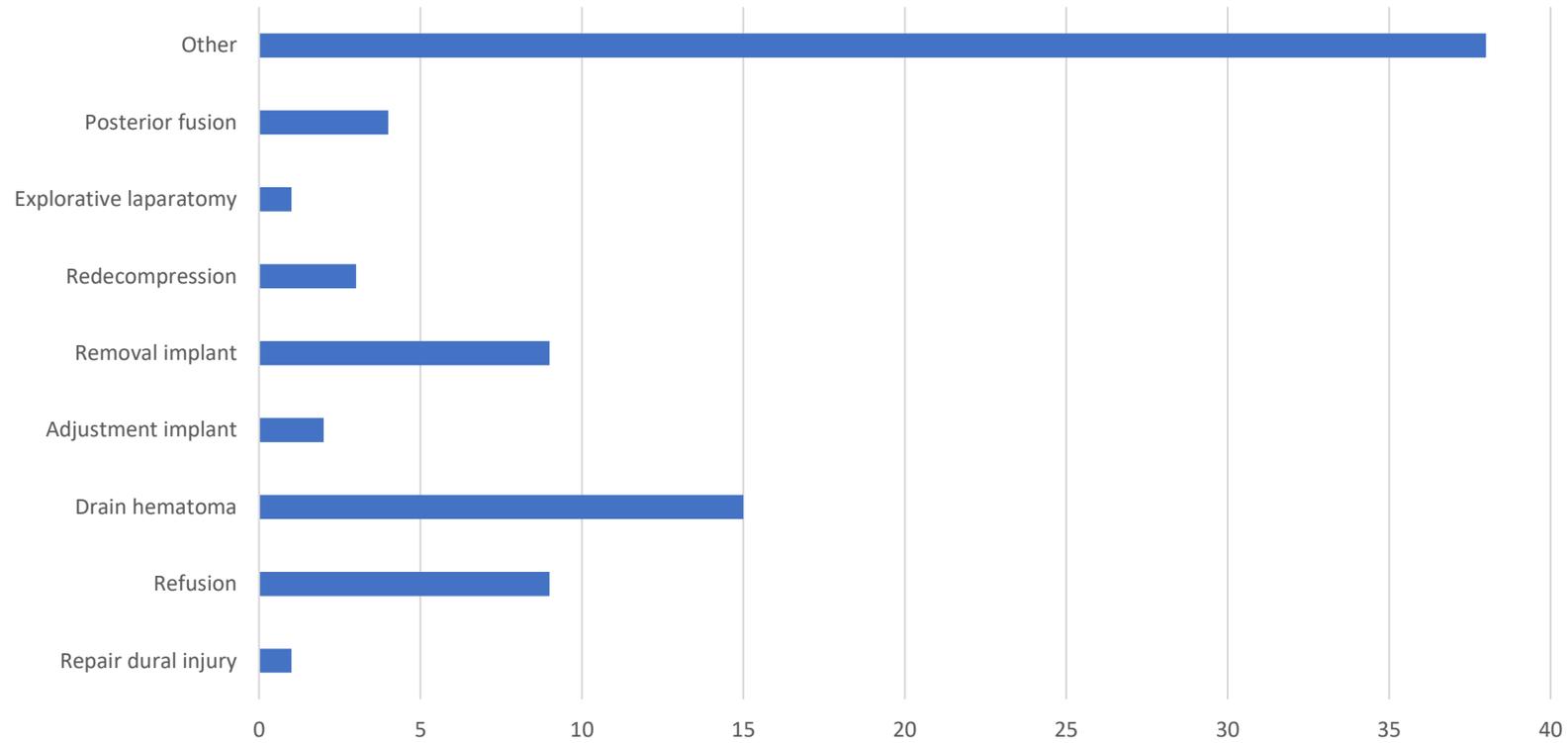
But

- Repeat anterior lumbar surgery is high risk
- Registry data on complications are not detailed

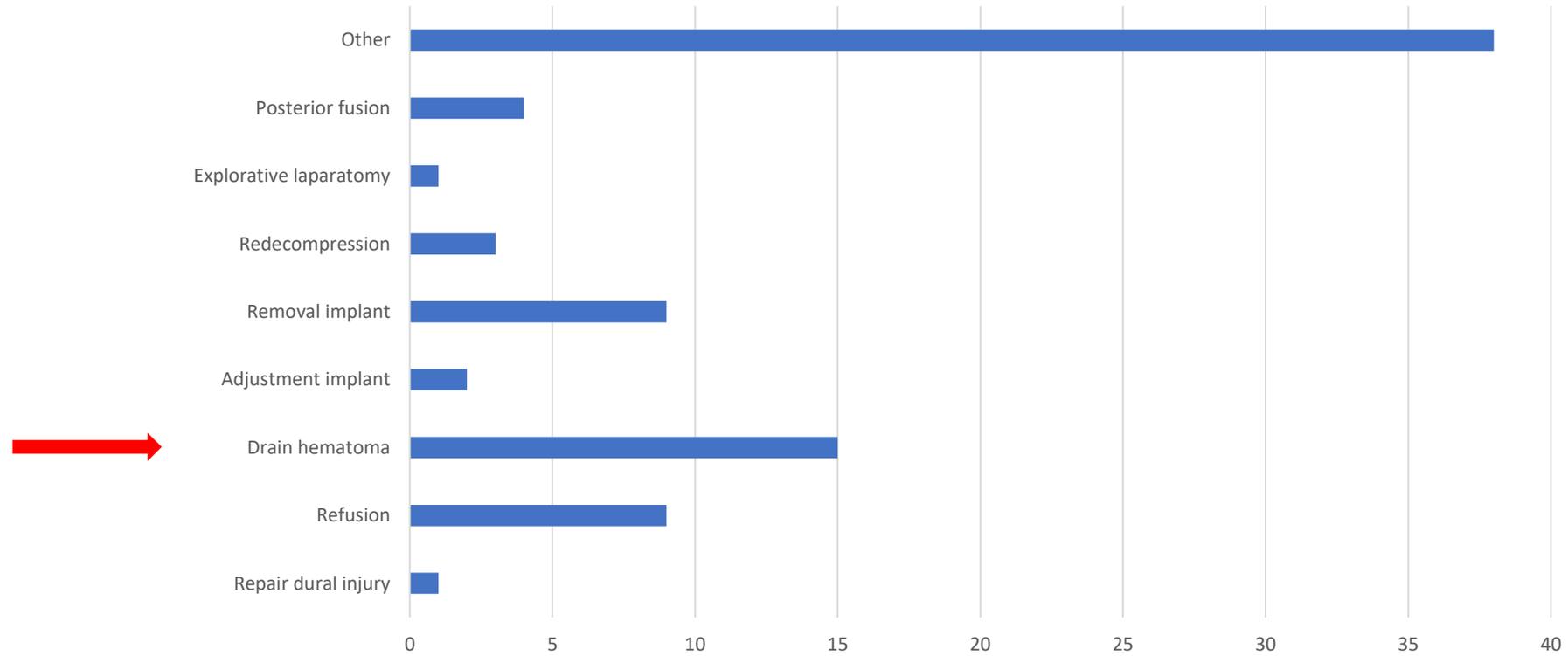
# Reintervention fusion, N = 1616



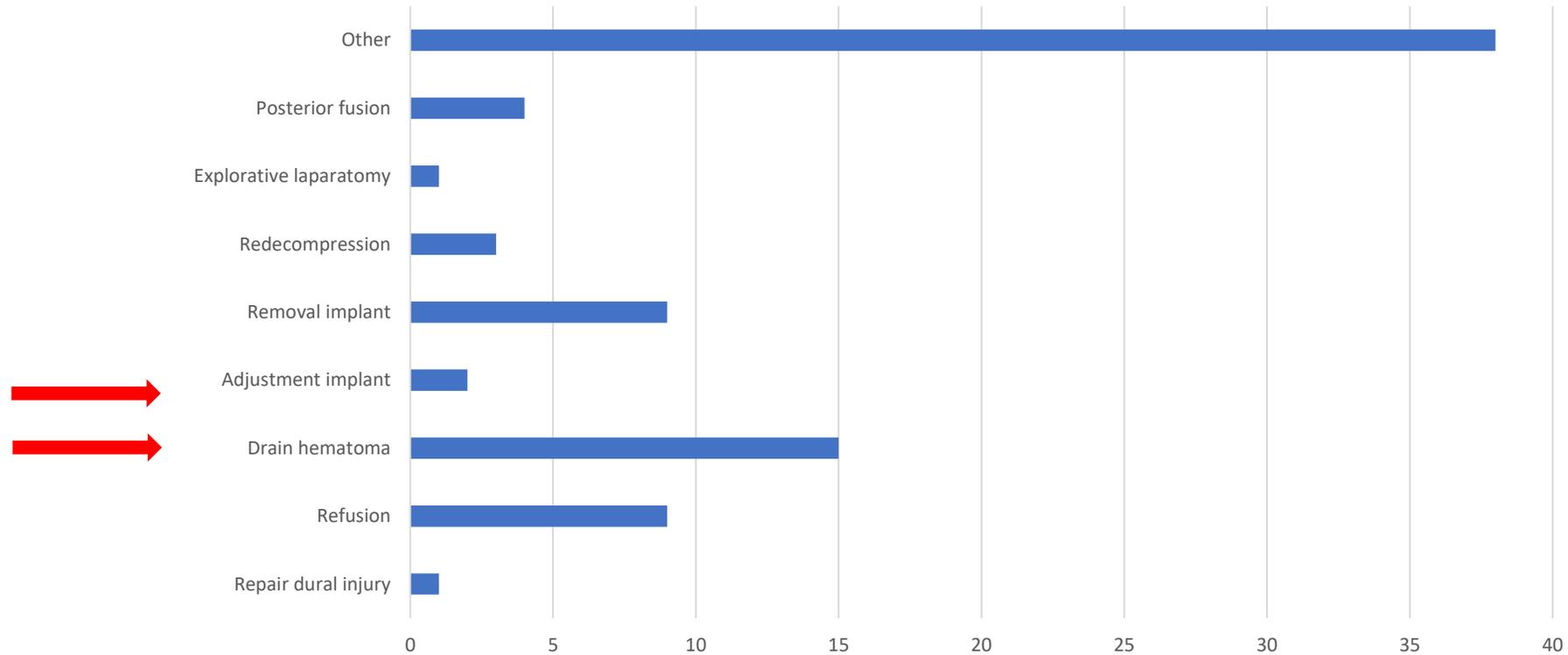
# Reintervention TDR, N = 82



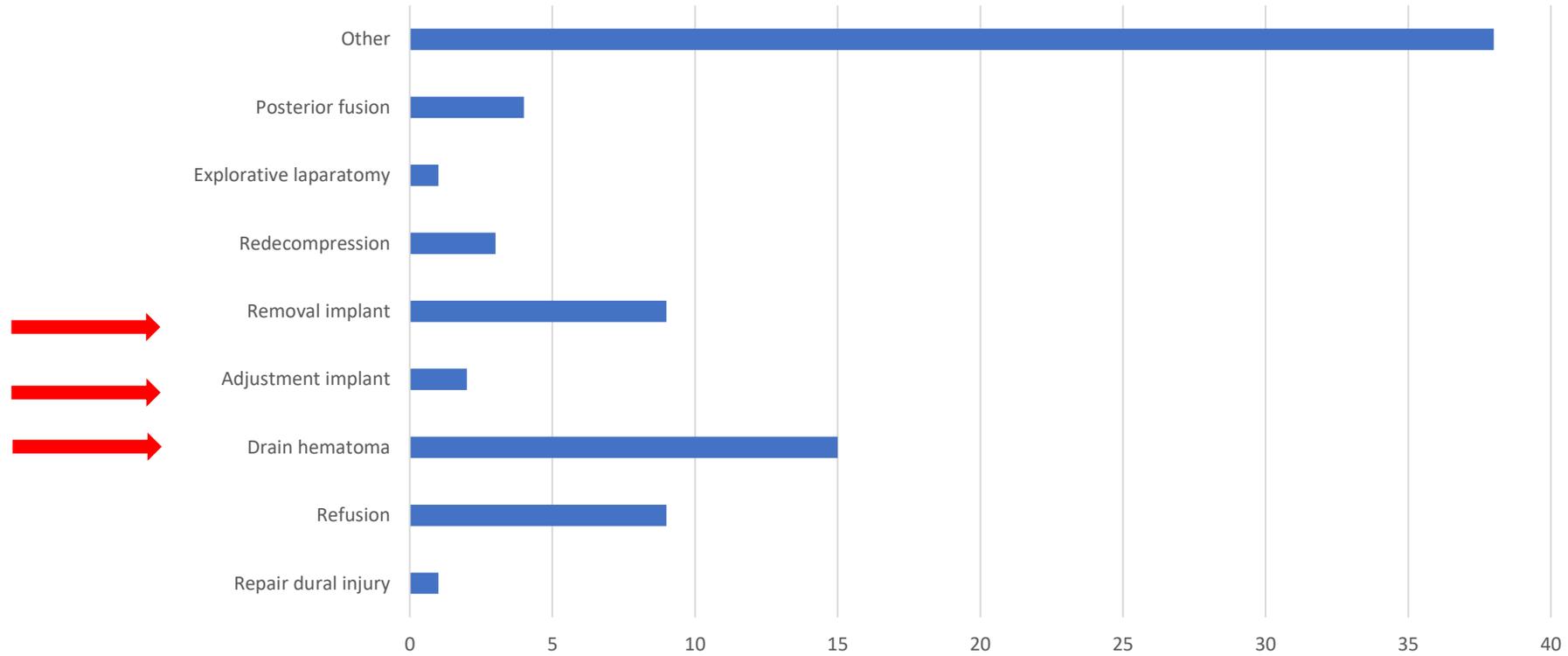
# Reintervention TDR, N = 82



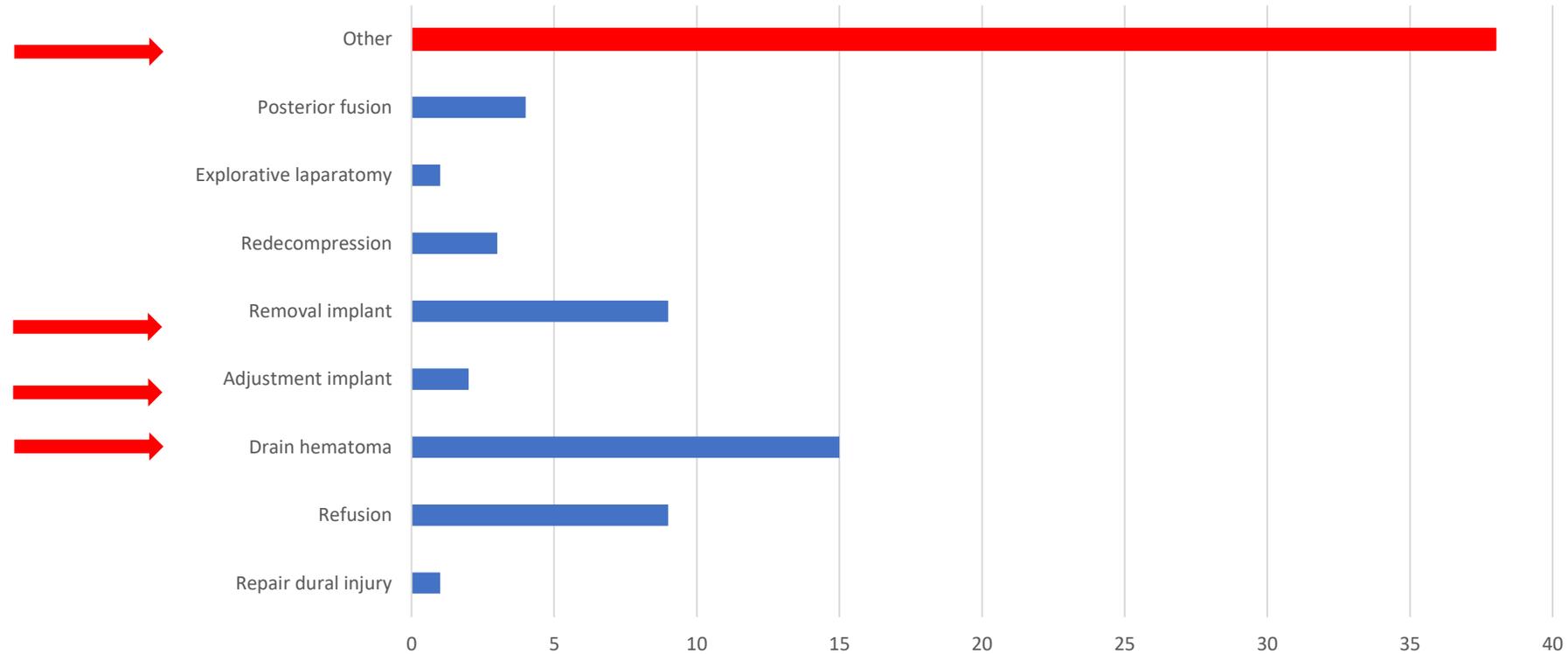
# Reintervention TDR, N = 82



# Reintervention TDR, N = 82



# Reintervention TDR, N = 82



# Interpretation

Registry data are not detailed enough for conclusive discussion

# Suggestion

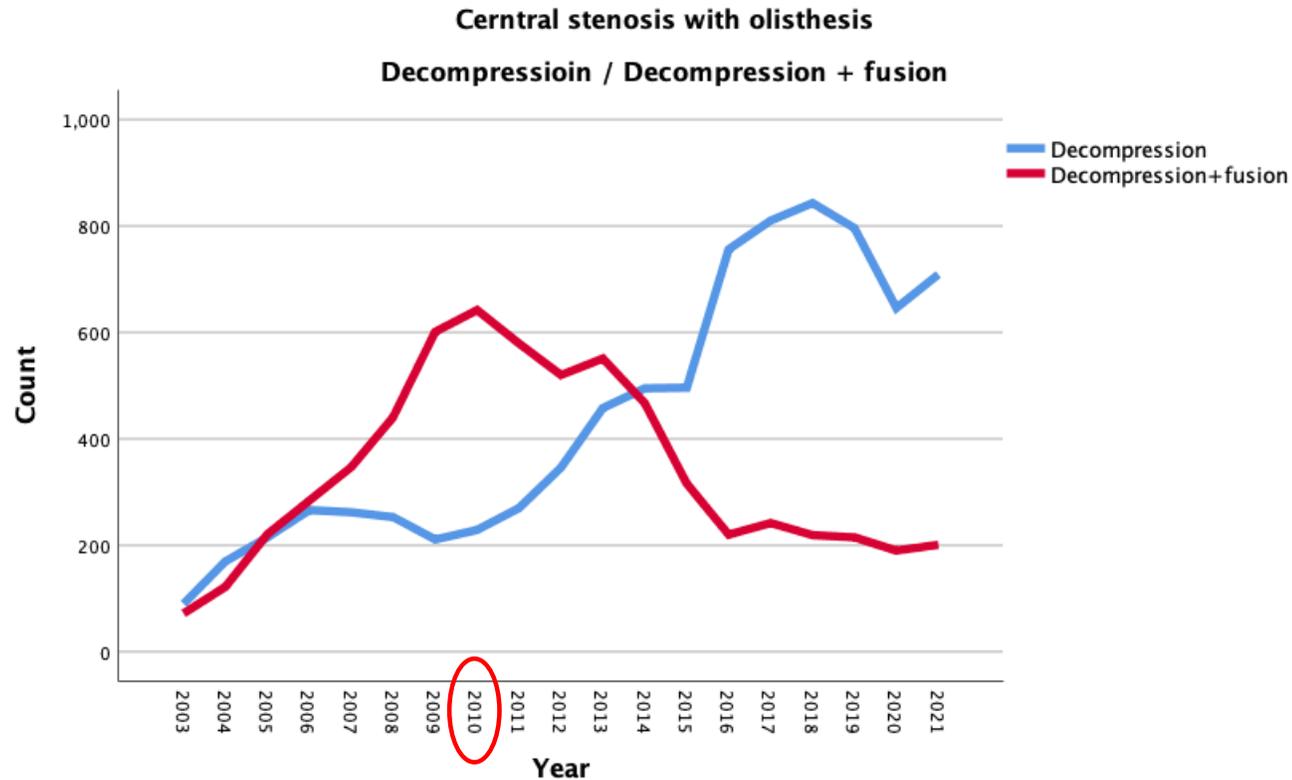
Thorough analysis of all TDRs including scrutiny of medical records and available radiology

## **Example 5:**

Has outcome after decompression of lumbar stenosis changed since we abandoned routine fusion in cases with spondylolisthesis?

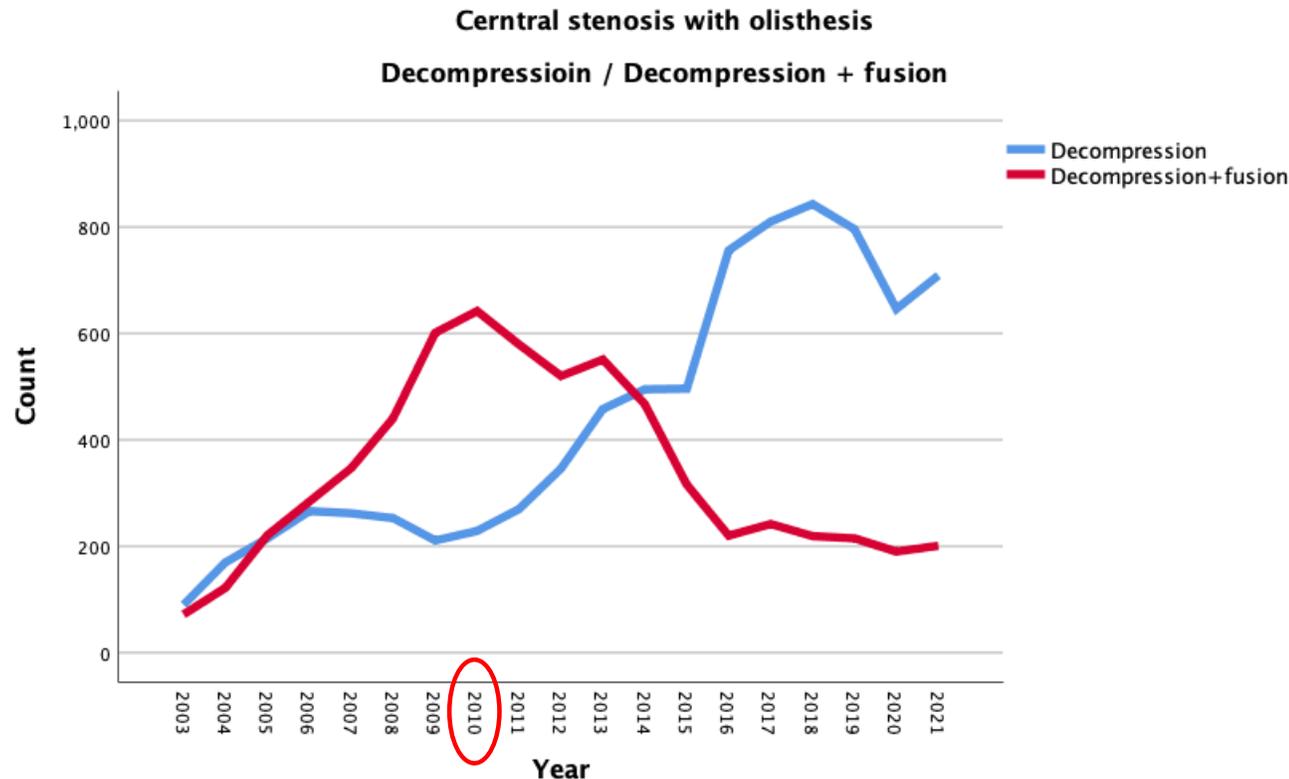
## Example 5:

Has outcome after decompression of lumbar stenosis changed since we abandoned routine fusion in cases with spondylolisthesis?



## Example 5:

Has outcome after decompression of lumbar stenosis changed after we abandoned routine fusion in cases with spondylolisthesis?



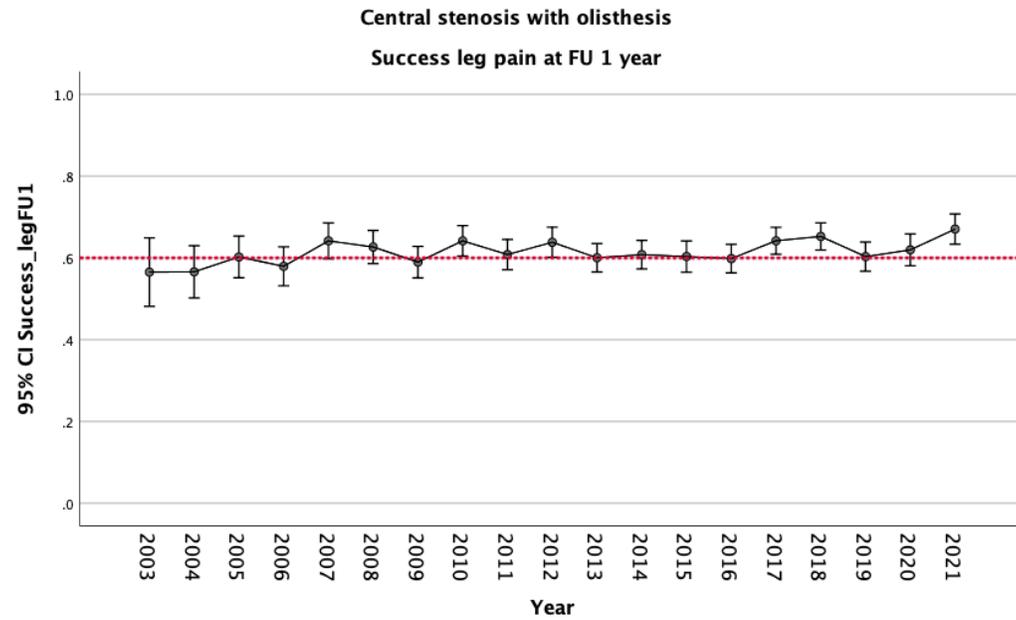
Registry study 2013

Försth P, et al. Does fusion improve the outcome after decompressive surgery for lumbar spinal stenosis?: A two-year follow-up study involving 5390 patients. Bone Joint J. 2013 Jul;95-B(7):960-5. doi: 10.1302/0301-620X.95B7.30776. PMID: 23814250.

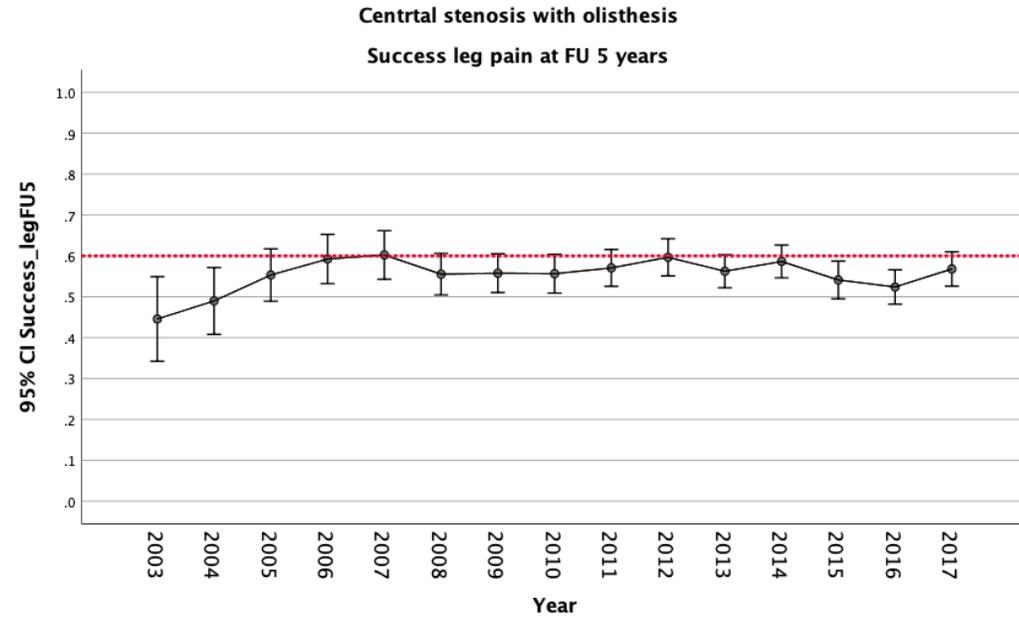
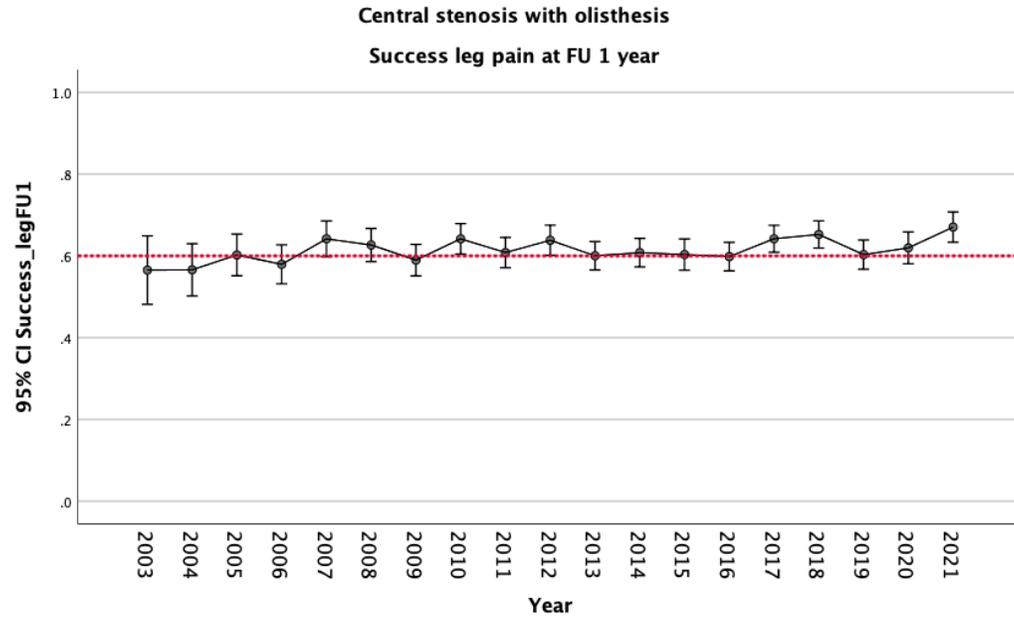
RCT 2016

Försth P, et al. A Randomized, Controlled Trial of Fusion Surgery for Lumbar Spinal Stenosis. N Engl J Med. 2016 Apr 14;374(15):1413-23. doi: 10.1056/NEJMoa1513721. PMID: 27074066.

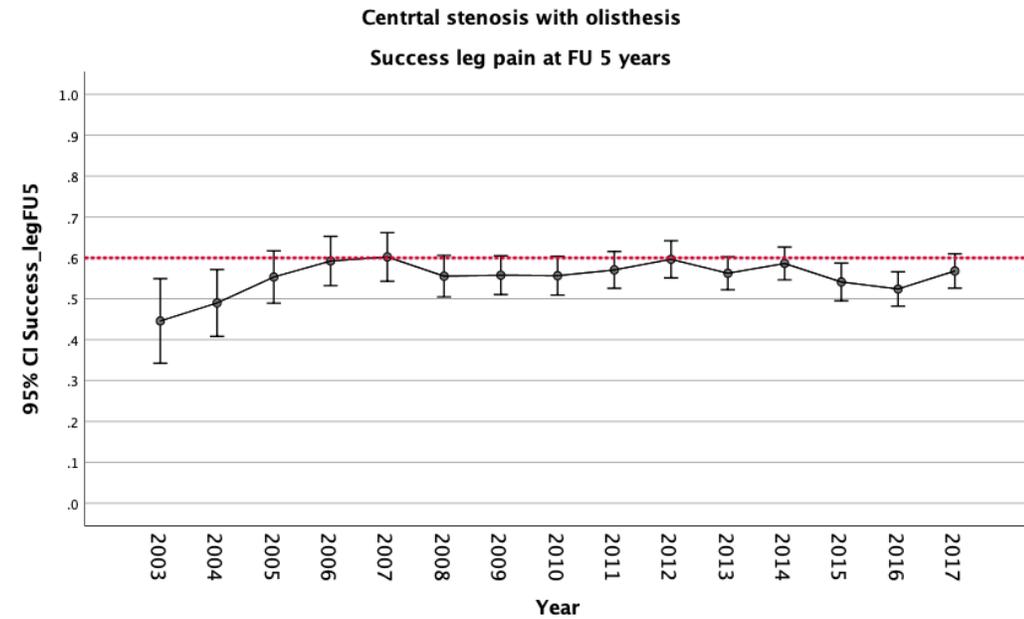
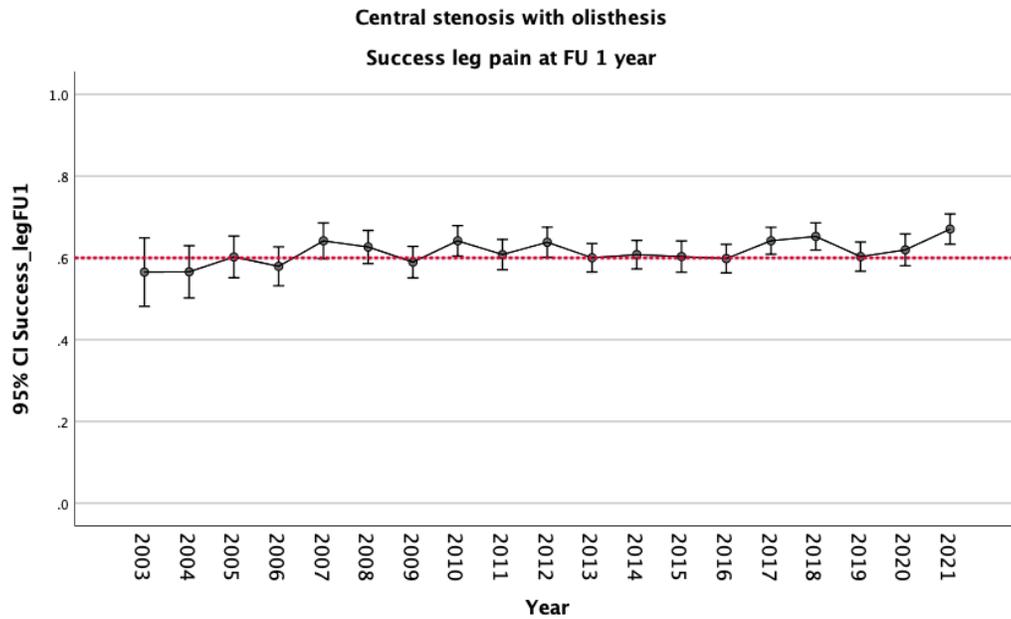
# Outcome remains on the same level



# Outcome remains on the same level

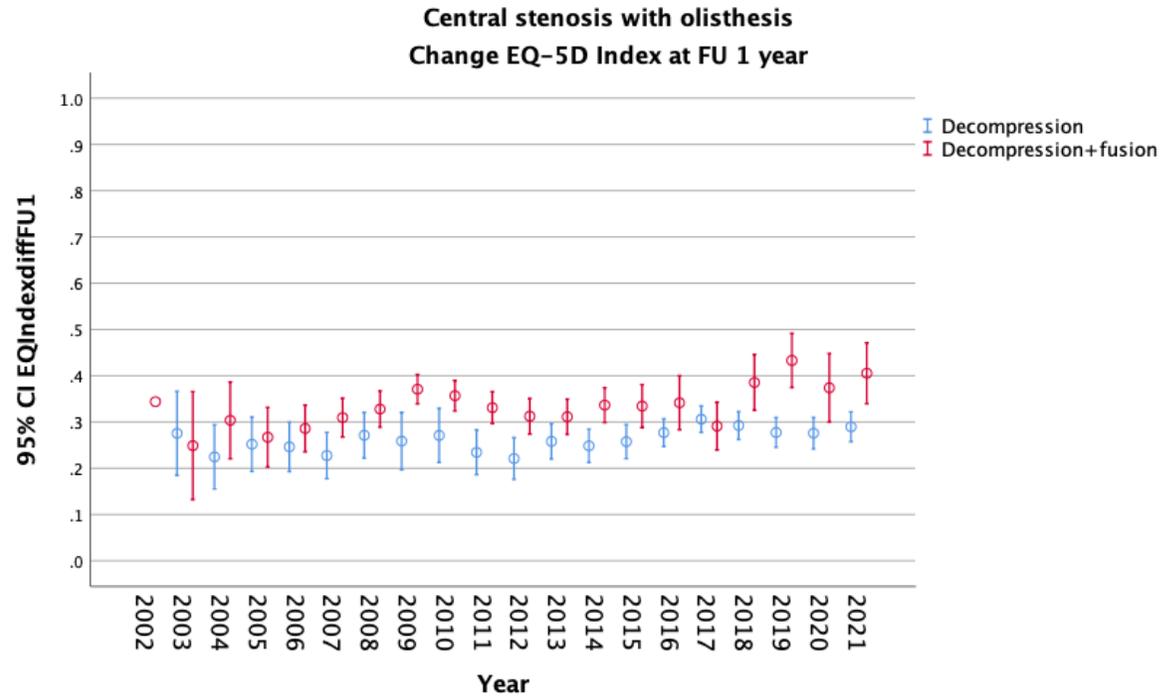


# Outcome remains on the same level

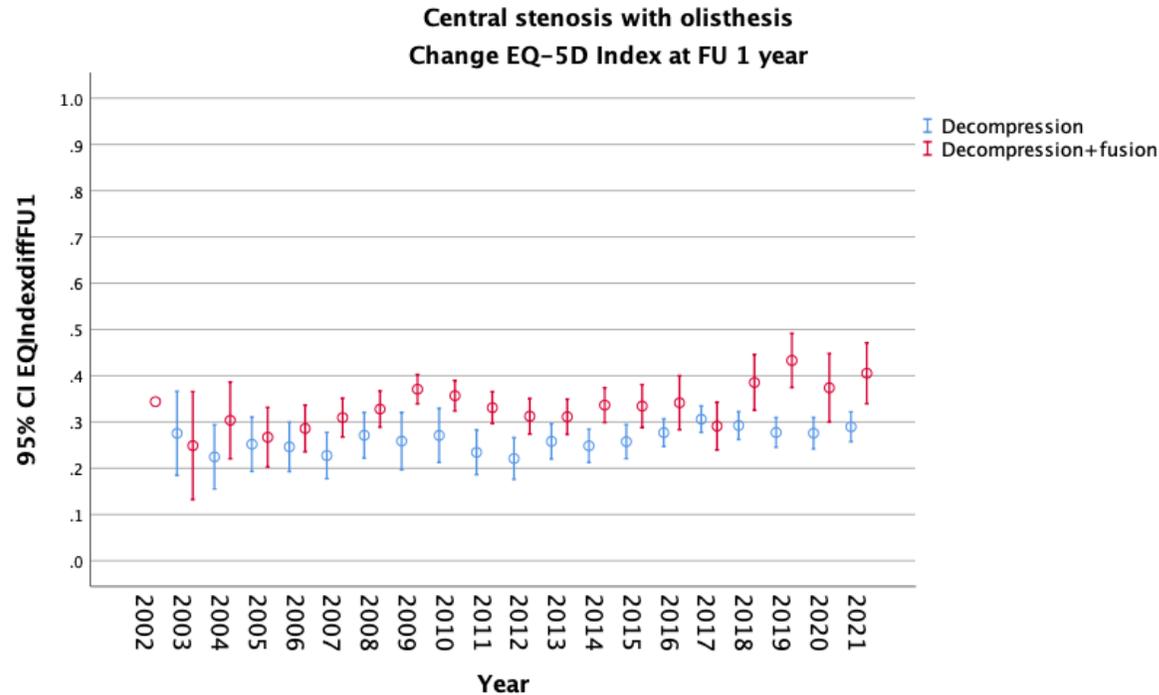


**Conclusion:** Sole decompression is sufficient in the majority of cases with olisthesis

**But:** outcome seems better after fusion and may increase in later years

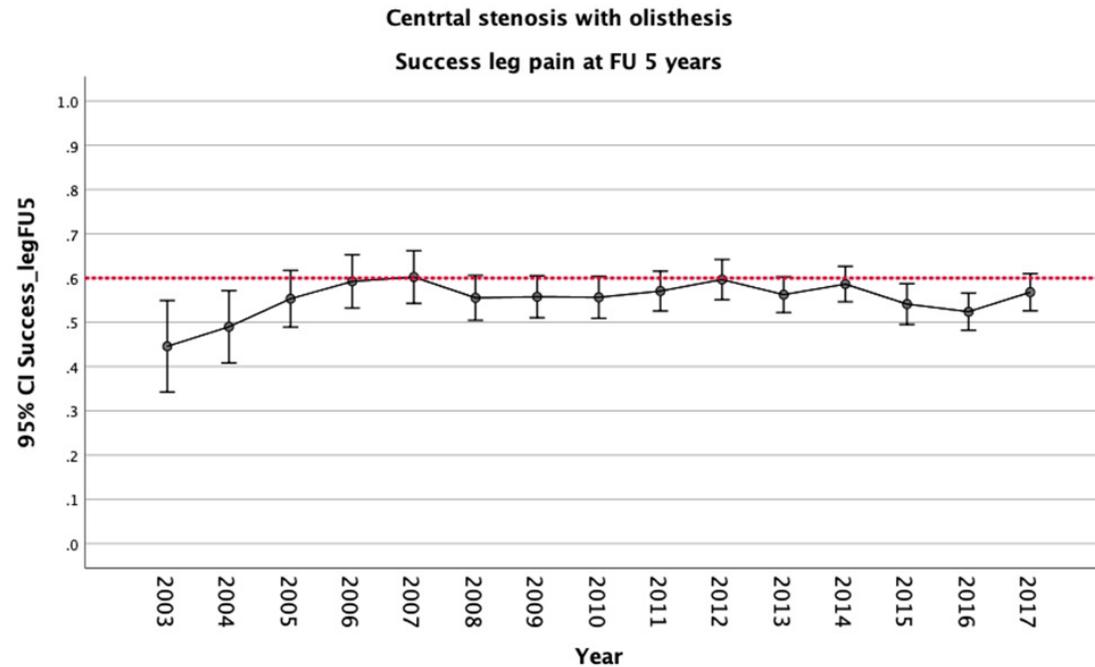


**But:** outcome seems better after fusion and may increase in later years

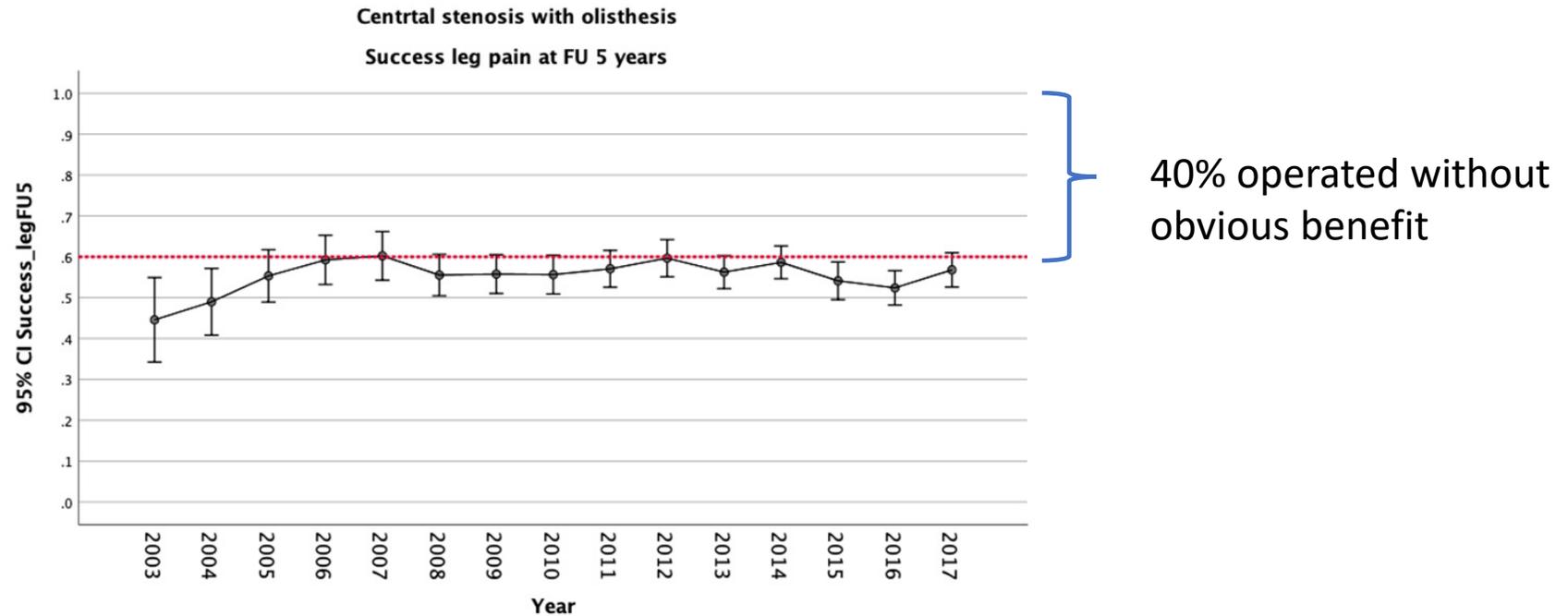


**Hypothesis:** There is probably a subgroup of patients who benefit from added fusion

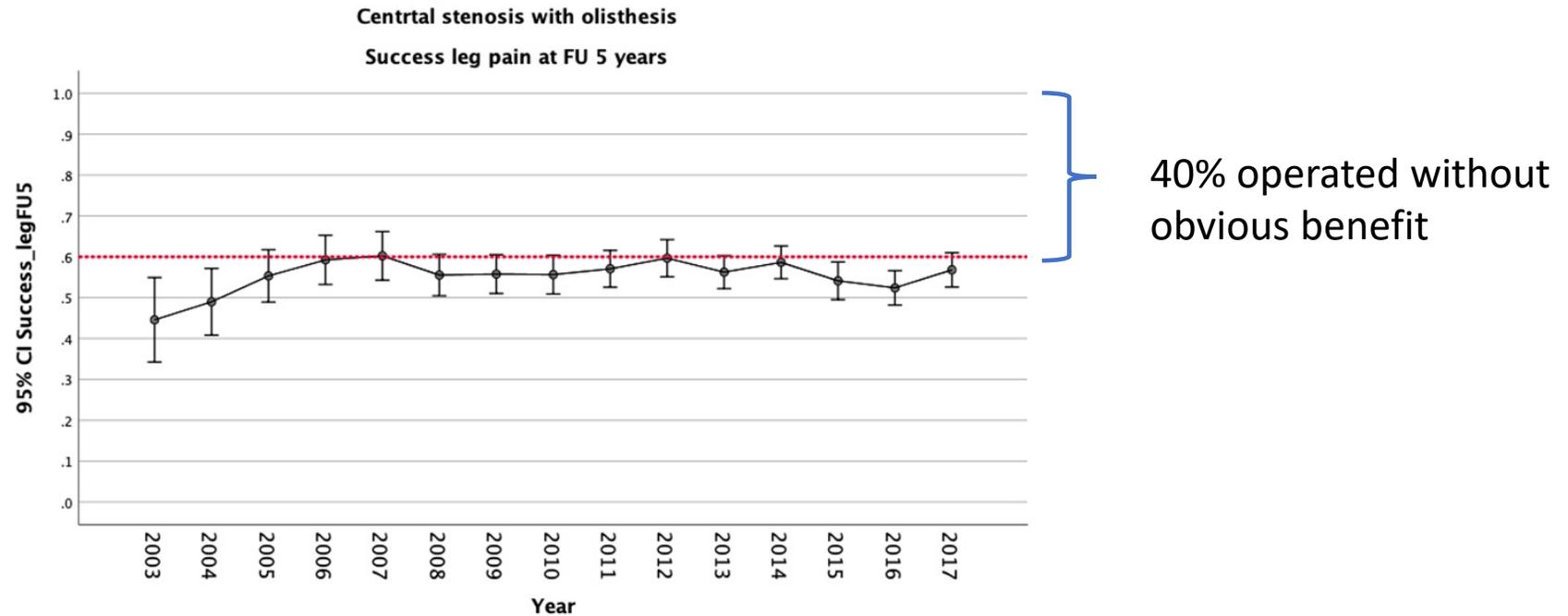
**And also:** Despite >10 Swespine based publications on prognostic factors, outcome remains less favorable



**And also:** Despite >10 Swespine based publications on prognostic factors, outcome remains less favorable



**And also:** Despite >10 Swespine based publications on prognostic factors, outcome remains less favorable



**Problem:** Indications for surgery may be too wide and diagnostics need better precision

# Suggestions

- Define the subgroup of patients who benefit from fusion
- Examine diagnostics, including radiology, as indications of surgery

# ANNUAL REPORT 2023 SWESPINE 25 YEAR



FOLLOW-UP OF  
SPINE SURGERY IN  
SWEDEN  
1998 - 2022

<https://www.swespine.se/page.aspx?id=12&lang=1>

# Spine surgery – meeting the patient

## The “Dialogue support”

[www.eurospine.org](http://www.eurospine.org)

A prediction tool based on data from  
the Swedish national quality spine register;

**Swespine**

Peter Fritzell/register manager Swespine

**The "Dialogue support", is based on national Swespine data in a  
"ten year window" - upgraded each year**

**each prediction is based on appr. 2-20 000 patients depending on the individual's profile at baseline**



# EUROSPINE

Your all-in-one destination for everything spine.

**Advancing Spine Healthcare: Discover EUROSPINE's Comprehensive Offerings**



**Shaping the Future of Spine Care**  
at the EUROSPINE Annual Meetings



**Advancing Treatment through Education**  
with innovative learning opportunities for all career stages



**Improving Patient Care through Quality Assurance**  
starts with collecting reliable data on spine healthcare practices.

Who are we?

# The Dialogue Support (Swespine)

The Dialogue Support is predicting outcome 1 year after surgery for spinal disorders. The underlying prediction models used have been trained on a sizable body of data throughout Sweden during a 10-year period and is updated every year. The data quantity thus always includes outcomes no more than 1 year old.



[Visit the website](#)

https://swestudy.se/SweSpine/Dialogstod.aspx

Undergrupp

**Diagnose** Diskbräck

**Type of clinic** Universitet

Sociodemografi

**Age** 0 45 110

**Gender** Kvinna

**Work status**

**Sick pension** Nej

**Age pension** Nej

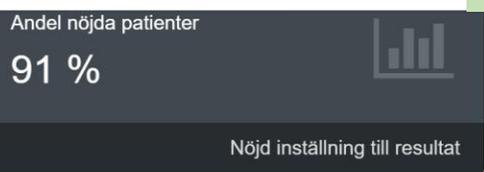
Hälsoprofil

**Smoking**

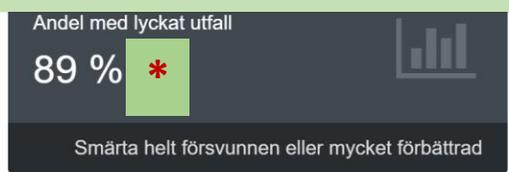
**Previous spine surgery**

**QOL** -0.59 0.3 1

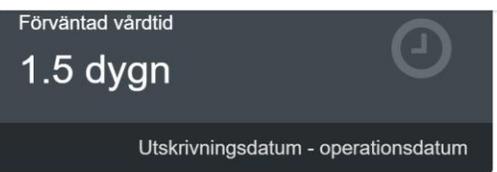
### Satisfied patients



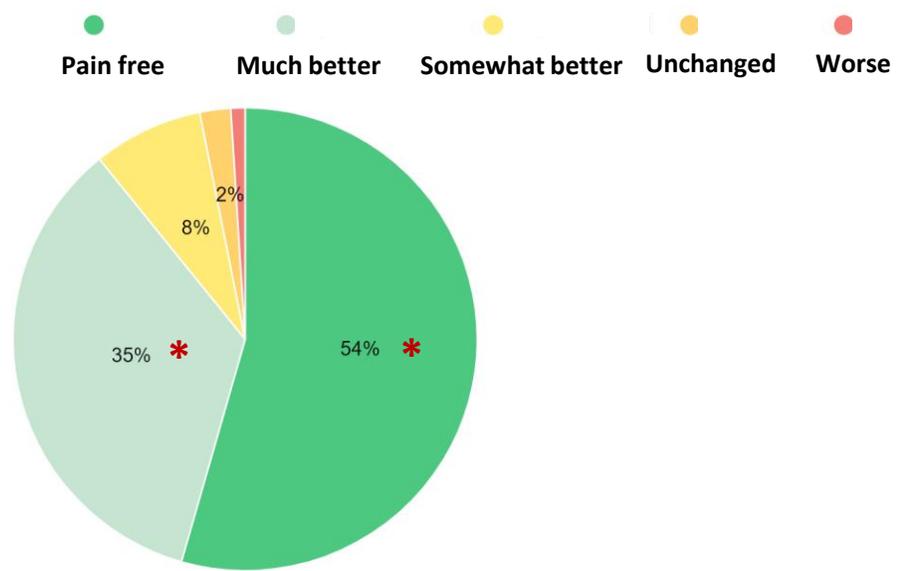
### \* Improved patients = Pain free+Much better



### Indoor stay



Improved patients (Pain free+Much better) after 1 year = dark + light green.



# The "Dialogue support"

**We want to acknowledge the Board of Eurospine Society, especially Everard Munting for the foresight of making register data available in the clinical situation - and to make this available on one of the biggest spine Home pages in the world; [www.eurospine.org](http://www.eurospine.org)**

***This should be an important part for the compliance of registering***

## Theme 3 Variables included in a spine register

**1600-1605 ICHOM** *Peter Fritzell*

<https://www.ichom.org/patient-centered-outcome-measures/#Musculoskeletal>



# Low Back Pain

Completed

The ICHOM Set of Patient-Centered Outcome Measures for Low Back Pain is the result of hard work by a group of leading physicians, measurement experts and patients. It is our recommendation of the outcomes that matter most to patients with low back pain. We urge all providers around the world to start measuring these outcomes to better understand how to improve the lives of their patients.

1. Includes operative mortality, nerve root injury including cauda equina, deep wound infection, pulmonary embolus, wrong site procedure, vascular injury, dural tear, other, and need for rehospitalisation.
2. Tracked via the Oswestry Disability Index (ODI)
3. Tracked via the Numeric Pain Rating Scale (NPRS)
4. Tracked via the EuroQol-5D (EQ-5D)

[Request Implementation Support](#)



## Implementation Resources

You will need a Connect account to access the following documents:

Low Back Pain Reference Guide [Login](#)

Low Back Pain Data Dictionary [Login](#)

You can access the following documents without:

Low Back Pain Flyer [Download](#)

Low Back Pain Manuscript [Download](#)

You can join [here](#). If you are already a member, please login [here](#).

All of the basic information you need to implement ICHOM Sets is available in the links above.

## Team that developed this set

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Richard Kahler | BrizBrain and Spine

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Wilco Jacobs | Leiden University Medical Center  
Wilco Peul | Leiden University Medical Center

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Isador Lieberman | Texas Back Institute  
Kevin Foley | University of Tennessee Health Science Center  
Neil Shonnard | Rainier Orthopedic Institute  
Safdar Kahn | Ohio State University  
Carter Clement | University of North Carolina at Chapel Hill

\* Patient representative



