



**SWESPINE**  
**THE SWEDISH SPINE REGISTER**

**2012 REPORT**

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**SWEDISH SOCIETY OF SPINAL SURGEONS**

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## Introduction

This report was written in autumn 2012, as we celebrate the 20th anniversary of the inception of the spine register. Historically, it was introduced in 1992 at the state-of-the-art meeting, “The Degenerative Lumbar Spine” in Lund during an evaluation symposium led by Gunnar Andersson. At that time the register involved a short form completed by doctors, which was also presented in *Acta Orthopaedica Scandinavica* 1993 (Strömqvist & Jönsson 1993). Prospective data registration was not common then and was enthusiastically welcomed by the majority of spine surgeons in Sweden. However, only 4-6 departments actually began recording data in the early years during the mid-1990s. Consequently, Peter Fritzell, Olle Hägg, Bo Jönsson and Bjorn Strömqvist, who were all interested in establishing a register, formed a group to analyze the problems and suggest improvements. In the late 1990s, responsibility for the spine register was transferred to the Swedish Society of Spinal Surgeons, the current owner of what is now known as the Swedish Spine Register/Swespine. A largely patient-based online registration form was designed to address preoperative and postoperative variables. In addition, Carina Blom and Lena Oreby developed and provided support services over time; without their efforts there would be no register.

These modifications changed the scene and beginning in the late 1990s, the number of participating departments increased, varying over the past decade between 35 and 39 of 42-45 departments providing spinal surgery services in Sweden.

This year’s annual meeting of the Swedish Society of Spinal Surgeons focused on the spine register; data were presented that were published in international journals and had attracted considerable international attention. As Swedish spine surgeons we can be proud of this development.

This year’s report is the 13<sup>th</sup>, with 8890 patients—yet another increase compared with the previous year.

This year’s analysis focuses on disc replacement, see pages

Our goal is still to present expanded baseline data from other diagnostic groups, but we need larger quantities of data to make similar evaluations as for degenerative lumbar spine surgery. However, the number of cervical spine procedures is growing, with interesting results.

September 24, 2012

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## I. Preoperative and surgical data on lumbar spine procedures in 2011

A total of 7208 patients who had had lumbar spine surgery at a total of 43 departments were entered in the register in 2011. In 2010, 6992 patients from 38 departments were entered in the register.

The distribution of diagnoses for patients operated in 2011 was as follows: Disc herniation 28%, central spinal stenosis 45%, lateral spinal stenosis 7%, spondylolisthesis 4%, segmental pain/DDD (disc degenerative disorder) 8% and other 8%; see figure 1.

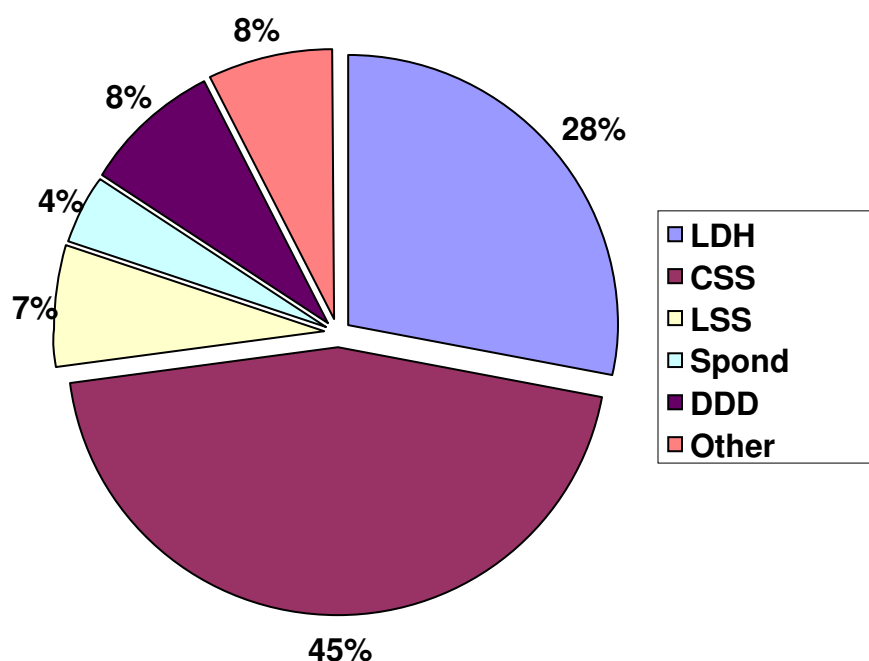


Fig. 1. Breakdown by diagnosis in the total material 2011, 7529 patients.

Diagnosis-related patient demographics and surgical data are presented below. For each variable a number are missing that are not included in the percent calculations

### Disc herniation

#### *Demographic data*

In 2011, 2118 disc herniation surgeries were registered. The patients included 55% men and 45% women. The proportion of smokers was 17%. Mean patient age was 45 (15–91) years and figure 2 shows the age distribution.

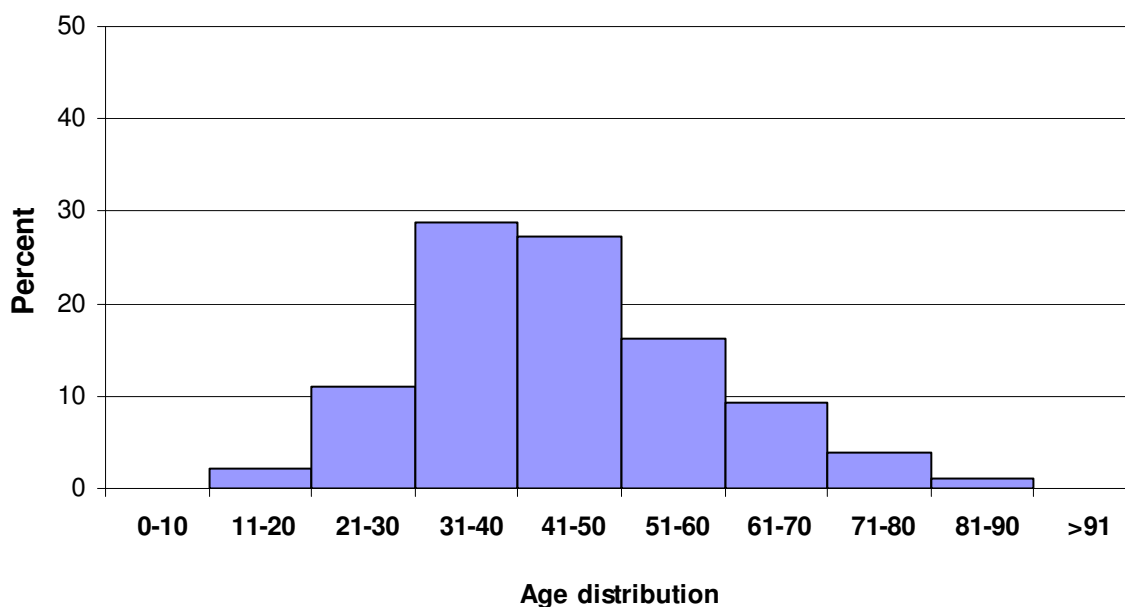


Fig 2. Distribution by age, disc herniation, n = 2118.

For 88% of patients this disc herniation operation was their first lumbar spine surgery, while 13% had been previously operated.

Preoperative duration of back pain was as follows: 6% had no back pain, 11% had a history of less than 3 months of back pain, 48% 3-12 months, 15% 1-2 years and 20% more than 2 years. Preoperative duration of leg pain/sciatica was as follows: 1% had no leg pain, 16% had leg pain for less than 3 months, 55% for 3-12 months, 16% for 1-2 years and 16% had pain for more than 2 years. Mean back pain on the visual analog scale (VAS) was 48 with a spread from 0–100, while mean leg pain/sciatica on the VAS was 67 with the same spread from 0–100. Distribution regarding both back and leg pain can be seen in figures 3 and 4.

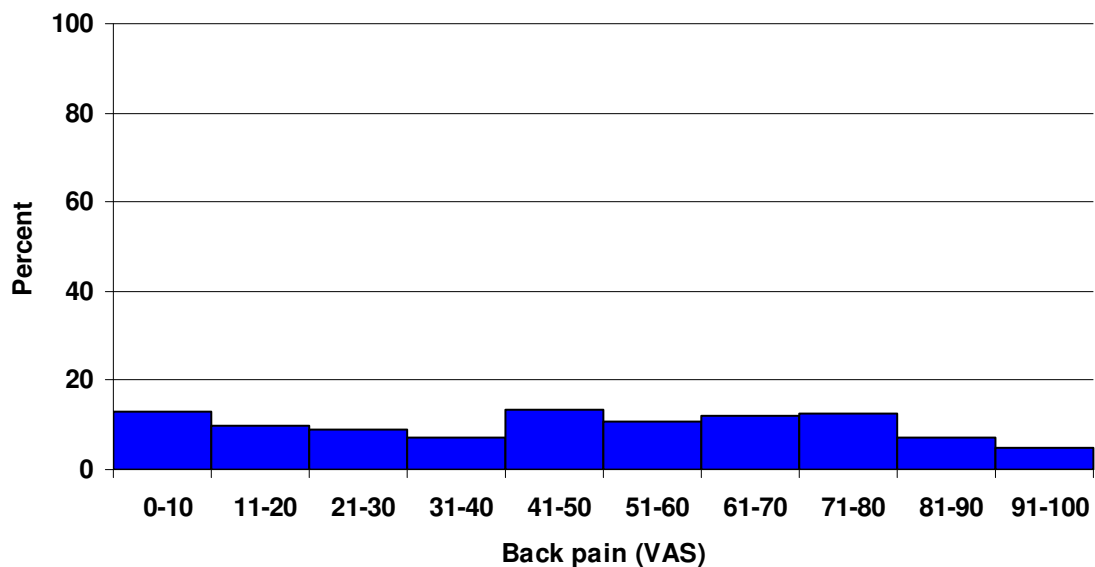


Fig 3. Back pain on the visual analog scale preoperatively in patients with disc herniation (%).

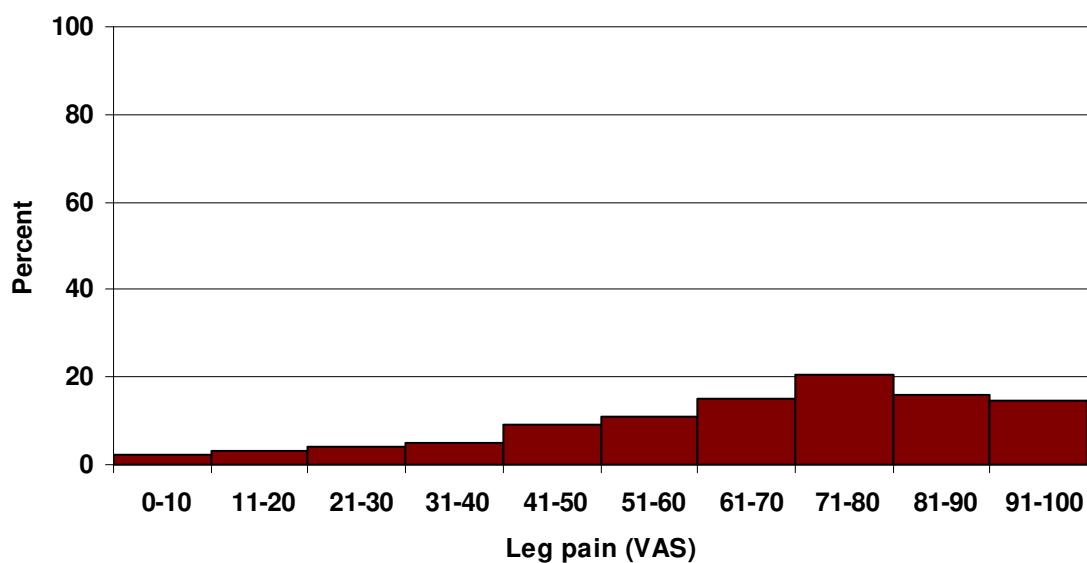


Fig 4. Leg pain on the visual analog scale preoperatively in patients with disc herniation (%).

Regular analgesic use was reported by 64% of patients, intermittent use by 26%, while 10% reported that they did not take any form of analgesics.

Walking distance was estimated at less than 100m by 31% of patients, 100–500m by 23% of patients, 500 m–1km for 15% of patients and more than 1 km by 31% of patients.

### *Surgical data*

Conventional disc surgery was carried out in 45% of cases and microscopic disc surgery in 41%. The remaining procedures consisted of various combinations mainly involving decompressive surgery for patients with disc herniation with spinal stenosis. Mean length of stay in days, i.e., time from admission through discharge, was 2.73 (0-22).

## **Central spinal stenosis**

### *Demographic data*

A total of 3367 patients were registered for operations for central spinal stenosis in 2011. The patients included 44% men and 56% women. Mean age was 68 (23–95) years. Figure 5 shows the age distribution.

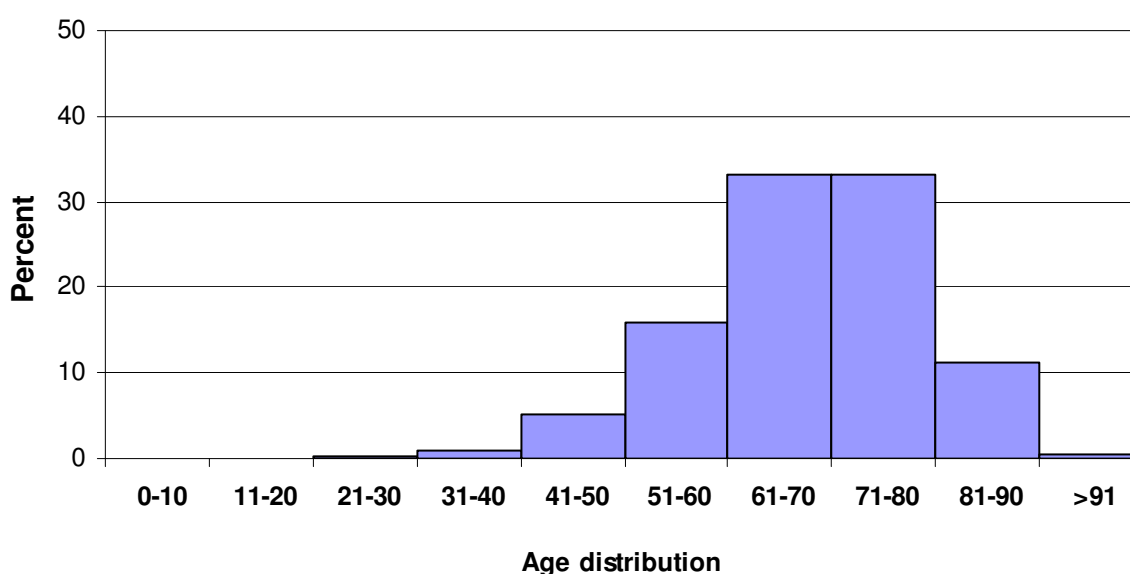


Fig 5. Distribution by age, central spinal stenosis, n = 3367 patients.

The proportion of smokers was 10%. For 79% of patients this operation was their first surgery, while 21% had been previously operated one to three times.

Preoperative duration of back pain was as follows: 5% had no back pain, 2% had a history of less than 3 months of back pain, 16% 3-12 months, 23% 1-2 years and 55% more than 2 years. Regarding leg pain, 4% of patients had no leg pain, 2% of patients with central spinal stenosis reported leg problems for less than 3 months, 24% for 3-12 months, 29% for 1-2 years and 41% reported problems for more than 2 years.

Mean back pain on the VAS in the group was 58 (0-100) and mean leg pain/sciatica (VAS) 63 (0–100). Figures 6 and 7 present the distribution of reported VAS.

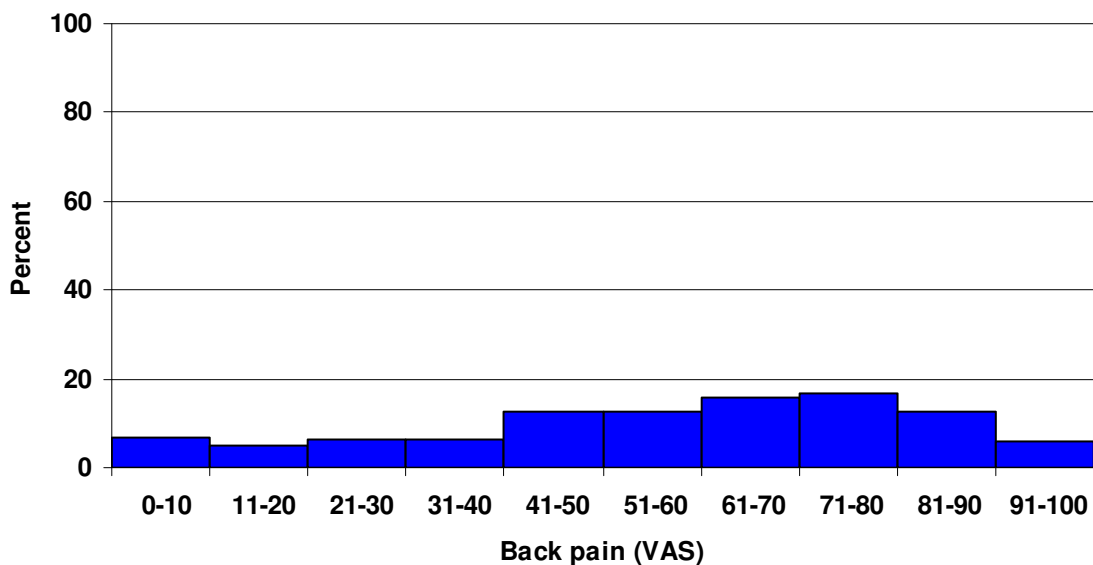


Fig 6. Back pain on the visual analog scale preoperatively in patients with central spinal stenosis (%).

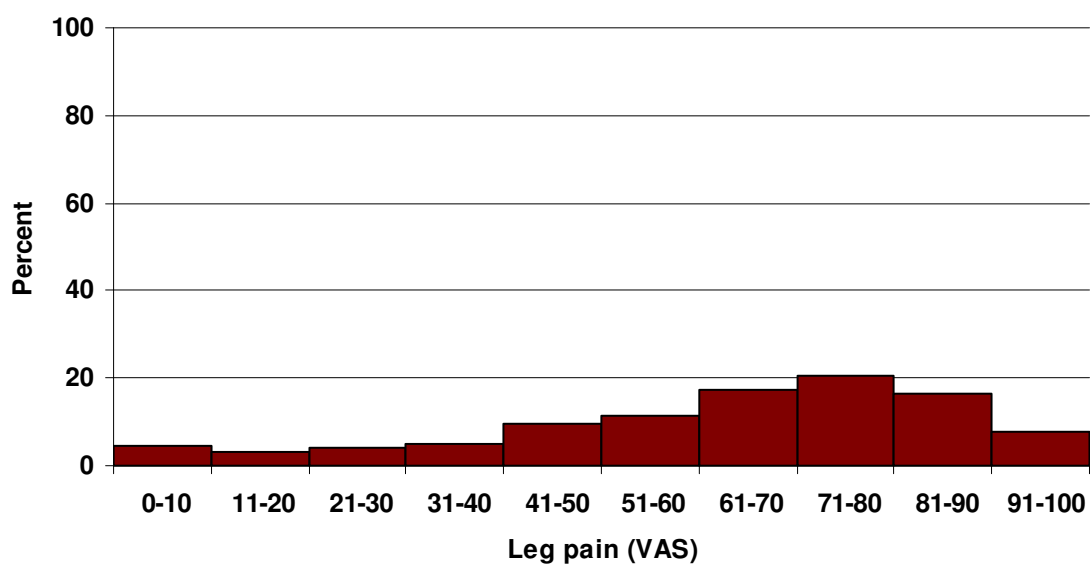


Fig 7. Leg pain on the visual analog scale preoperatively in patients with central spinal stenosis (%).

Among patients with central spinal stenosis, 55% reported regular use of analgesics, 29% reported intermittent use and 15% reported that they did not take any analgesic medication.

Walking distance was estimated at less than 100m by 40% of patients, 100–500m by 31% of patients, 500 m–1km for 15% of patients and more than 1 km by 14% of patients.



### *Surgical data*

In 72% of cases only decompressive surgery was carried out, in 52% conventional surgery and in 21% of cases microscopic surgery. Decompression combined with posterior instrumented fusion was carried out in 20% of cases, decompression + posterior non-instrumented fusion in 3%, Decompression + TLIF in 1% and other procedures in 4%.

Mean length of stay in days was 4.31 (0-29).

### **Lateral spinal stenosis**

#### *Demographic data*

During the year 532 patients were operated for lateral spinal stenosis. The patients included 52% men and 49% women. The group included 16% smokers.

Mean age was 61 (18–88) years and Figure 8 shows the age distribution.

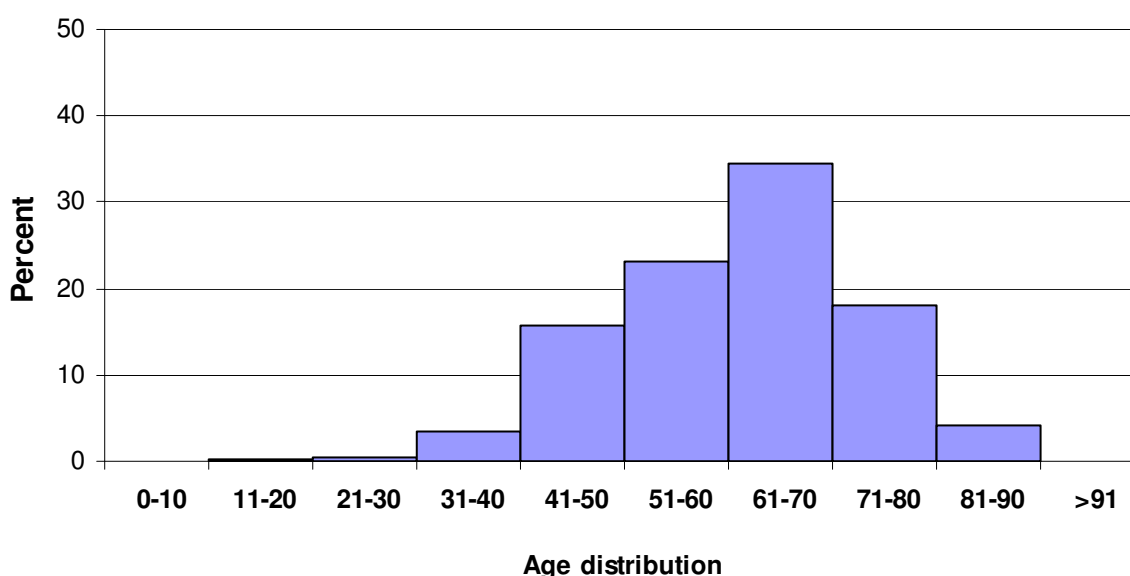


Fig 8. Distribution by age, lateral spinal stenosis, n = 532.

The majority of patients with lateral spinal stenosis, 75%, had had no previous spine surgery while 25% had been operated on one or more times before the current procedure.

Preoperative duration of back pain was as follows: 6% had no back pain, 2% had a history of less than 3 months of back pain, 19% 3-12 months, 18% 1-2 years and 54% more than 2 years. Regarding leg pain, 1% of patients with lateral spinal stenosis had no leg pain, 2% of patients reported leg problems for less than 3 months, 27% for 3-12 months, 29% for 1-2 years and 41% reported problems for more than 2 years. Mean back pain on the VAS in the group was 56 (0–100) and mean leg pain (VAS) 67 (0–100). Figures 9 and 10 present the distribution of reported VAS.

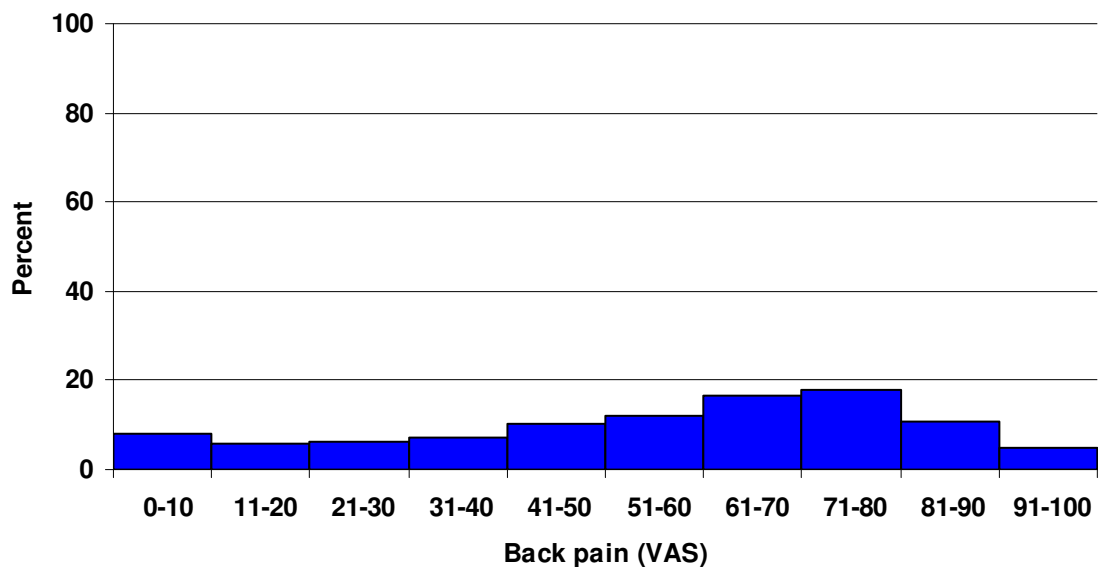


Fig 9. Back pain on the visual analog scale preoperatively in patients with lateral spinal stenosis (%).

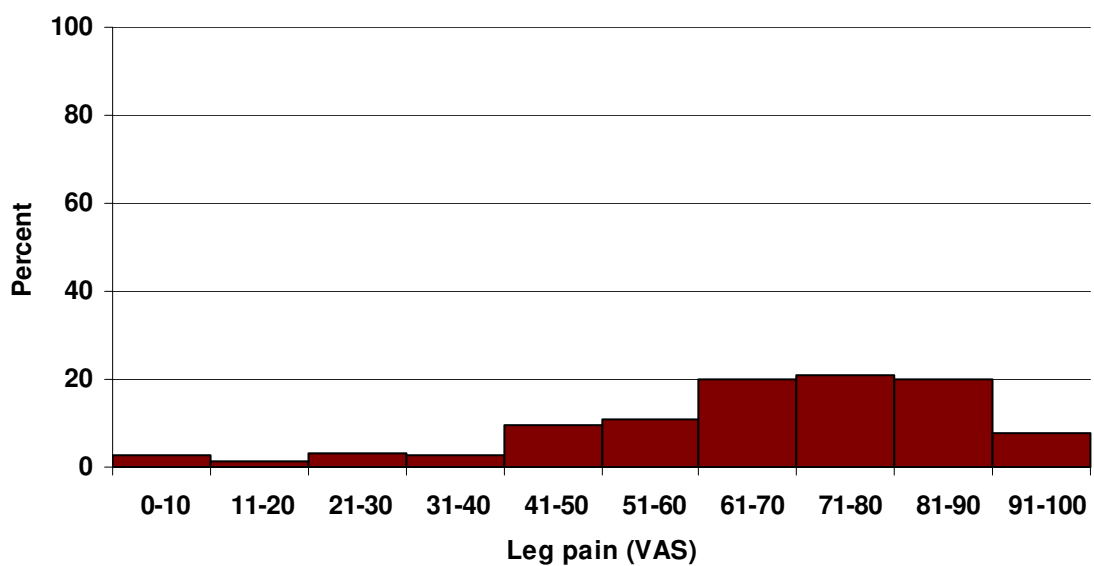


Fig 10. Leg pain on the visual analog scale preoperatively in patients with lateral spinal stenosis (%).

Regular analgesic use was reported by 60% of patients, intermittent use by 29%, and 12% reported they did not take any analgesics. The majority of patients reported limited walking ability, 28% reported they were able to walk less than 100m, 32% were able to walk 100–500m, 20% 500 m–1 km and 20% had a walking distance of more than 1 km.

### *Surgical data*

Decompression surgery was the type of procedure in the majority of cases, 72% including 49% conventional, 23% microscopic decompression, 18% had decompression + posterior instrumented fusion and 3% decompression + TLIF. Mean length of stay (total) was 3.5 (0-23).

## **Spondylolisthesis**

### *Demographic data*

A total of 323 patients, including 47% men and 53% women, were reported for 2011. This group included 12% smokers. Mean age was 50 (14–82) years and figure 11 shows the age distribution.

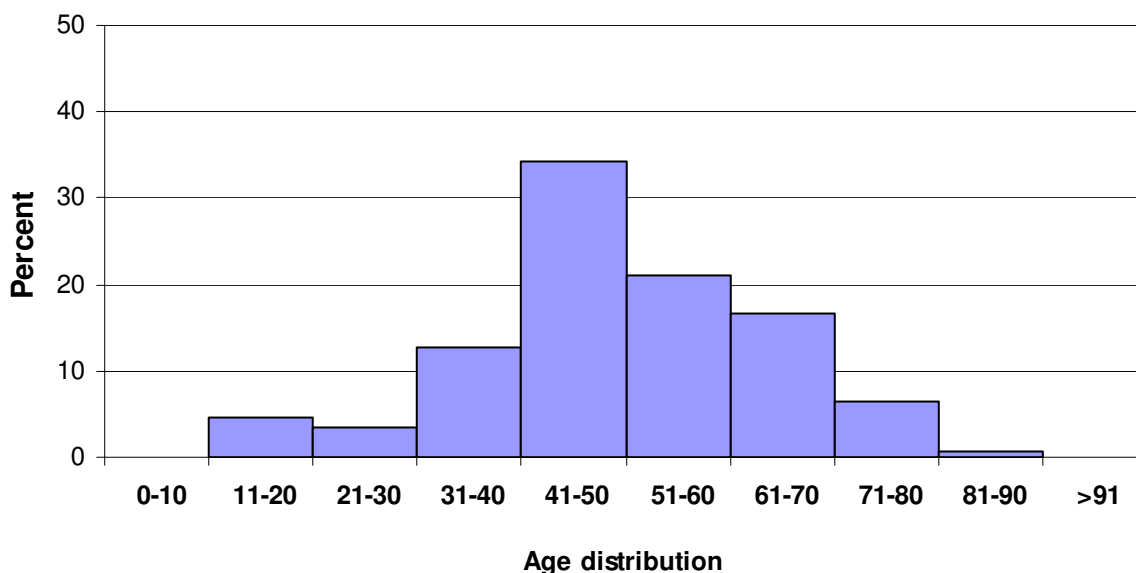


Fig 11. Distribution by age, spondylolisthesis, n = 323 patients.

For 89% of patients the current procedure was the first time they had surgery on the lumbar spine, while the remainder had one or two previous procedures.

Preoperative duration of back pain was as follows: 2% had no back pain, 1% had a history of less than 3 months of back pain, 11% 3-12 months, 19% 1-2 years and 66% more than 2 years. Regarding leg pain, 6% of patients with spondylolisthesis had no leg pain, 1% of patients with spondylolisthesis reported leg problems for less than 3 months, 18% 3-12 months, 29% 1-2 years and 47% reported problems for more than 2 years.

Preoperative lumbar pain on the VAS was 62 (0–100) and preoperative leg pain was 55 (0–99). Figures 12 and 13 present the distribution of pain on the VAS.

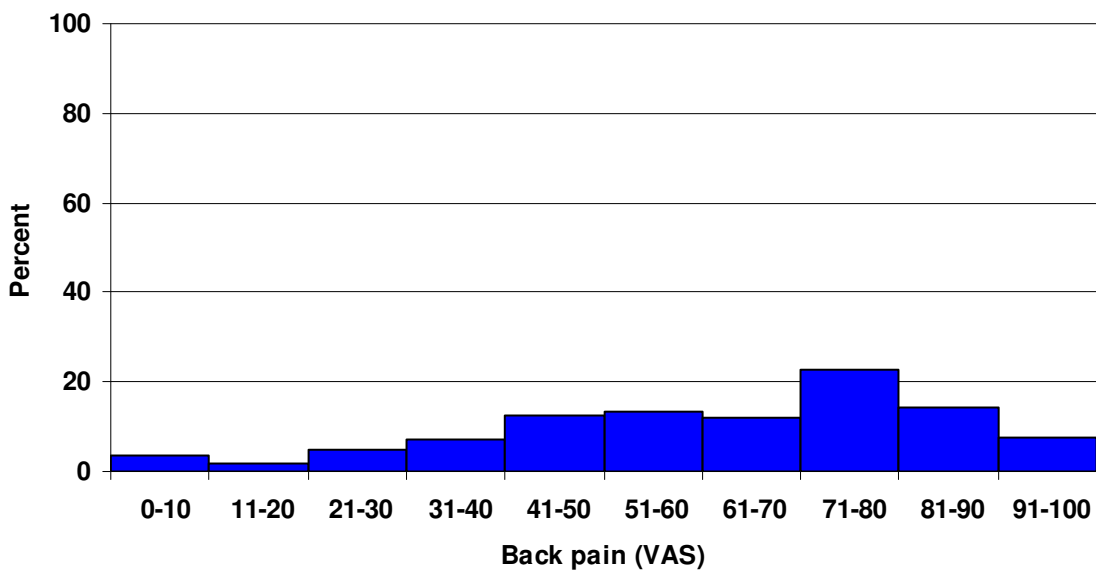


Fig 12. Back pain on the visual analog scale preoperatively in patients with spondylolisthesis (%).

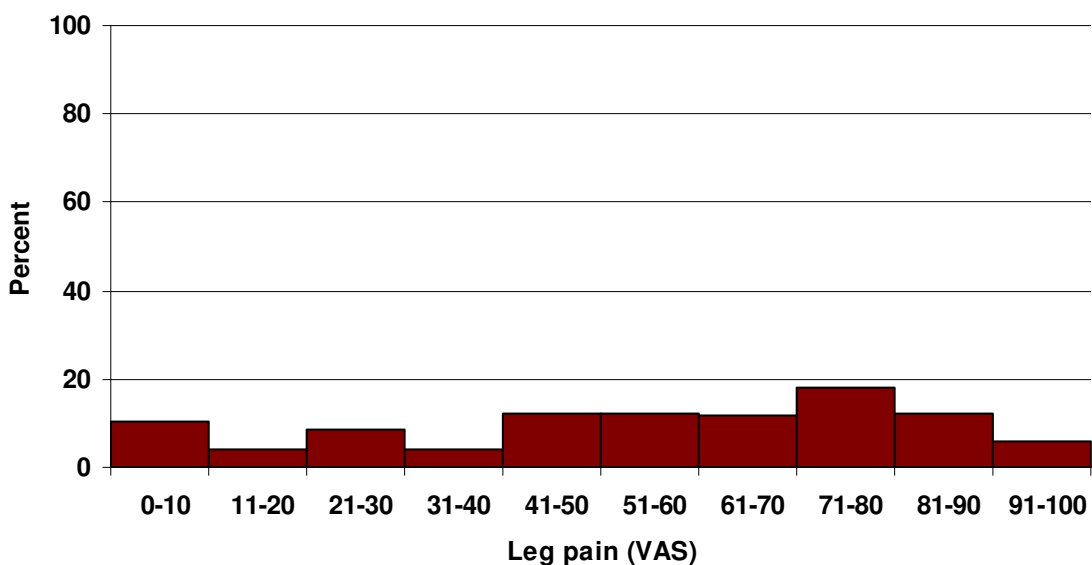


Fig 13. Leg pain on the visual analog scale in patients with spondylolisthesis (%).

Regular analgesic use was reported by 48% of patients, intermittent use by 37% of patients while 14% did not use analgesics.

Walking distance was estimated at less than 100m by 22% of patients, 100–500m by 24% of patients, 500 m–1km for 20% of patients and more than 1 km by 34% of patients.

#### *Surgical data*

Patients with spondylolisthesis had a variety of different procedures. They are presented in descending order of frequency: Decompression + instrumented fusion 53%, posterior instrumented fusion 15%, PLIF with or without foreign implant 14%, decompression + TLIF 4%, decompression + non-instrumented fusion 3%, decompression + PLIF 1%, posterior non-instrumented fusion 1% and decompressive interventions in remaining case.

Mean length of stay in days was 5.54 (1-27).

### **DDD (disc degenerative disorder)/segmental pain**

#### *Demographic data*

A total of 620 patients were registered for surgical intervention for DDD in 2011, including 43% men and 57% women. The proportion of smokers was 11%. Mean age was 47 (16–80) years and figure 14 shows the age distribution.

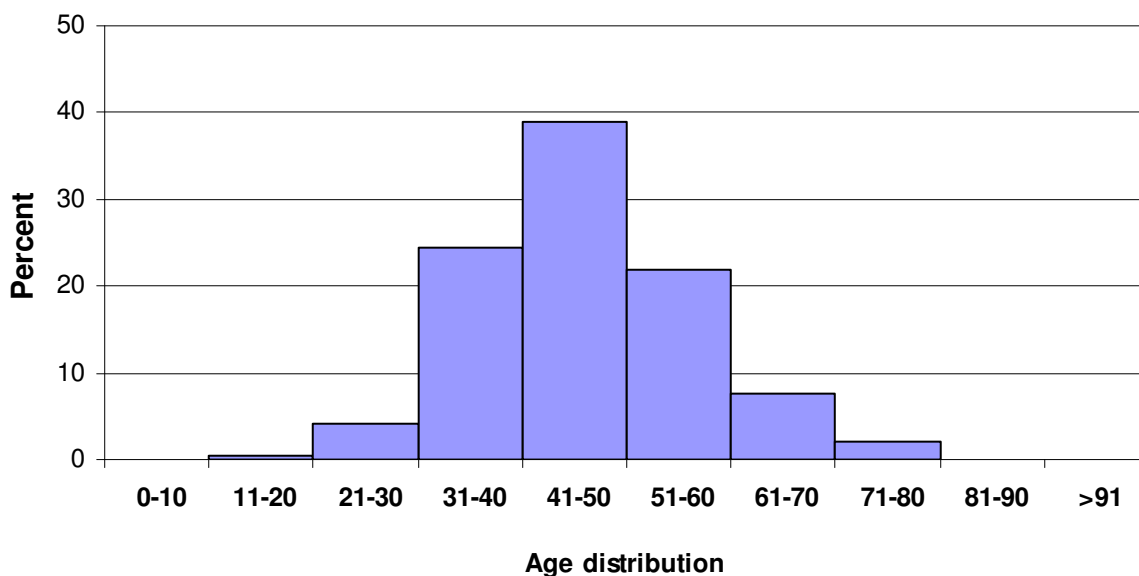


Fig 14. Distribution by age, DDD, N = 620 patients.

In this group of patients, 68% had surgery for the first time, while 32% had been operated one or more times previously.

Preoperative duration of back pain in patients with DDD was as follows: 0.4% had no back pain, 0.2% had a history of less than 3 months of back pain, 9% 3-12 months, 16% 1-2 years and 75% more than 2 years. Regarding leg pain, 18% of patients with DDD had no leg pain, 2% reported leg problems for less than 3 months, 16% 3-12 months, 18% 1-2 years and 47% reported problems for more than 2 years.

Estimation on the VAS scale for back pain showed a mean of 65 (0-100) and leg pain, 43 (0-100). Figures 15 and 16 present the distribution of pain on the VAS.

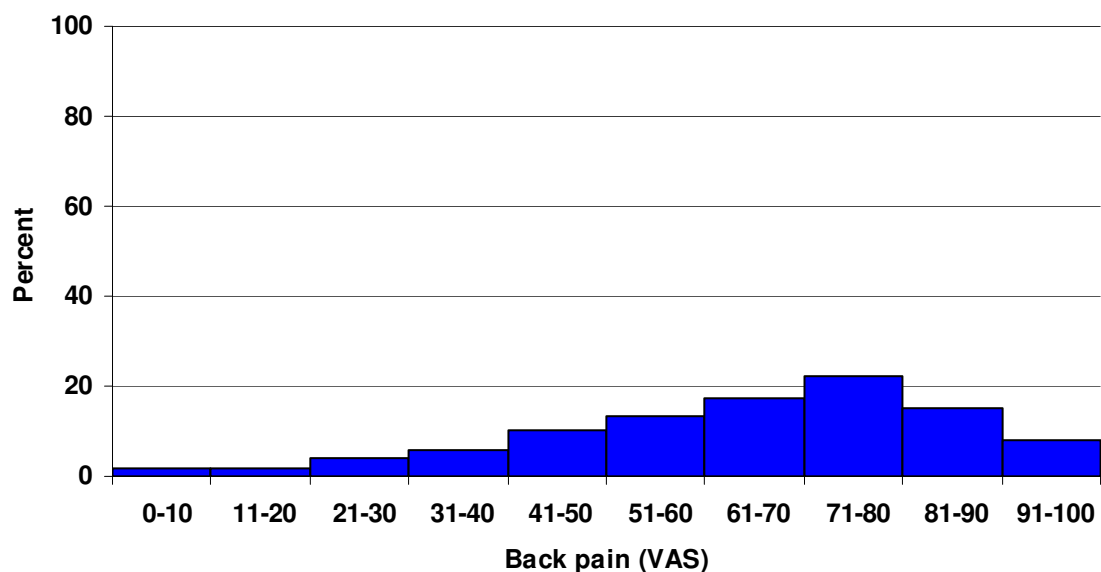


Fig 15. Back pain on the visual analog scale preoperatively in patients with DDD (%).

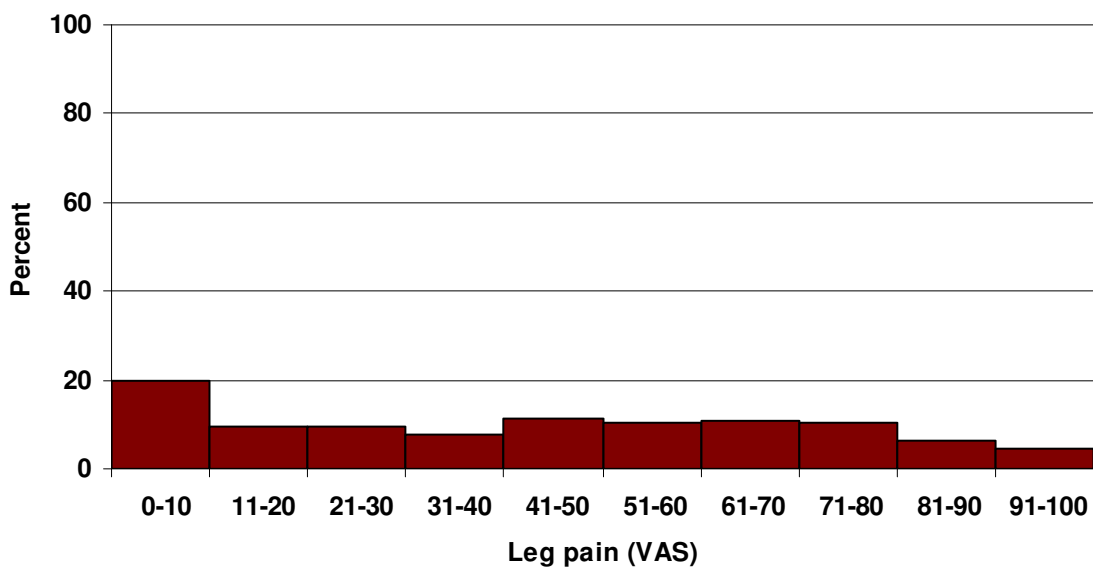


Fig 16. Leg pain on the visual analog scale preoperatively in patients with DDD (%).

Regular analgesic use was reported by 61% of patients, intermittent use by 31% while 8% never took analgesics.

Walking distance was estimated at less than 100m by 15% of patients, 100–500m by 21% of patients, 500 m–1km for 19% of patients and more than 1 km by 45% of patients.

*Surgical data*

A heterogenous surgical treatment spectrum was also seen for this diagnosis as follows: Posterior instrumented fusion 29%, PLIF 18%, disc replacement 18%, decompression + posterior instrumented fusion 14%, TLIF 5%, decompression + TLIF 5%, decompression + PLIF 4%, ALIF with instrument 2%, posterior non-instrumented fusion 1%, decompression + posterior non-instrumented fusion 1% and a smaller quantity other interventions. Mean length of stay was 5.08 (1-18).

## II. 1-year follow-up of lumbar spine procedures in Sweden in 2011

A total of 7051 patients were operated in 2010 and 5124 (73%) completed 1-year of follow-up. The distribution is as follows: disc herniation 1365, central spinal stenosis 2412, lateral spinal stenosis 399, spondylolisthesis 259 and DDD 530. Patients with “other operations” (159) are not presented in the following results.

### Disc herniation

Of 1365 patients who were operated for lumbar disc herniation and completed one year follow-up, 56% were men and 44% women, with a mean age of 44 (13–90) years.

Mean preoperative VAS for back pain was 46, compared with 26 postoperatively. The corresponding figures for leg pain were 67 preoperatively, and 22 postoperatively. Figures 17 and 18 show preoperative and postoperative VAS for back and leg pain, respectively.

Surgical interventions: 45% conventional herniated disc surgery, 44% microscopic disc surgery, 8% decompression surgery and 3% other procedures.

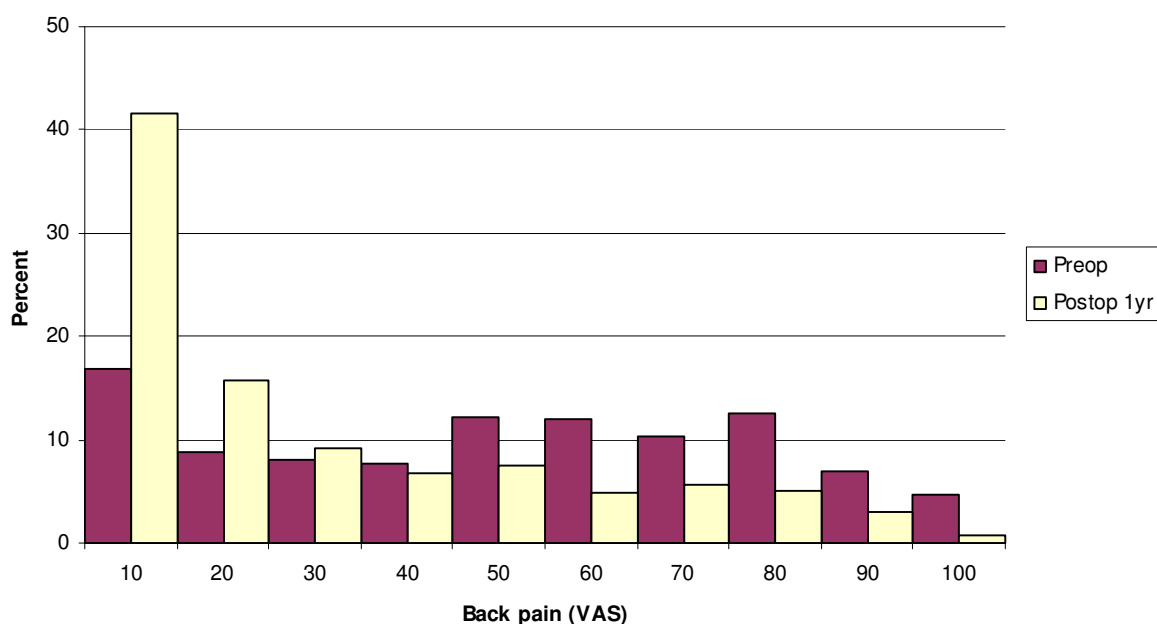


Fig 17. Back pain on the visual analog scale preoperatively and 1 year postoperatively in patients operated for lumbar disc herniation in 2010 (%).



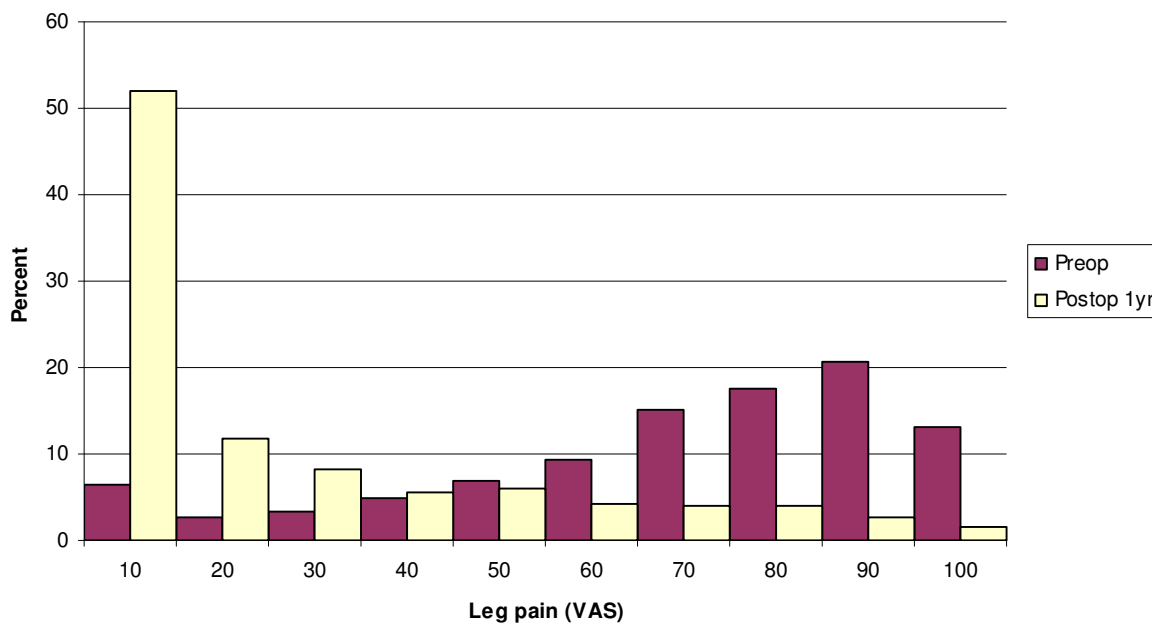


Fig 18. Leg pain on the visual analog scale preoperatively and 1 year postoperatively in patients operated for lumbar disc herniation in 2010 (%).

Perceived improvement relating to back pain: Completely pain-free 20%, significantly improved 45%, somewhat improved 17%, unchanged 6% and deteriorated 5%; 7% did not have preoperative back pain.

Perceived improvement relating to leg pain: Completely pain-free 35%, significantly improved 37%, somewhat improved 15%, unchanged 6% and deteriorated 5%; 2% had no preoperative leg pain.

Overall patient satisfaction with surgical outcome: 78% were satisfied, 15% uncertain and 7% dissatisfied.

Use of analgesics one year postoperatively: Regular 17%, intermittent 31%, none 52%.

Ability to walk one year postoperatively: < 100m 5%, 100-500m 8%, 500m-1 km 11%, >1 km 76%, a substantial improvement compared with preoperatively.

Figure 19 shows preoperative and one year postoperative status regarding health-related quality of life as measured with the SF-36. The improvement is significant in all domains except "General health".

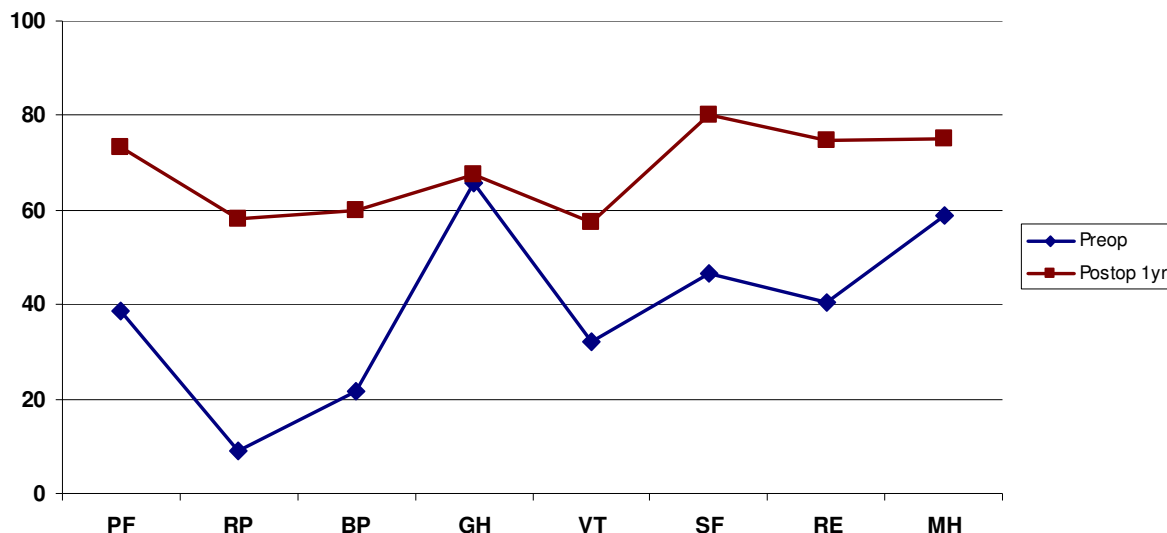


Fig 19. SF-36 preoperatively and 1 year postoperatively for patients operated for lumbar disc herniation in 2010.

The results from the EQ-5D-analysis are presented both as EQ-5D 5, i.e. the answers of the 5 questions included in the questionnaire, and also on the VAS scale, EQ-VAS. The results for lumbar disc herniation are as follows: Mean figure for EQ-5D 5 preoperatively: 0.26, 1 year postoperatively 0.71. Mean VAS preoperatively (max 100): 46, 1 year postoperatively 72.

### Central spinal stenosis

This group includes 2412 patients with a mean age of 68 (18–95) years.

Gender distribution: 45% men, 55% women.

Surgical intervention: Decompression alone 67%, decompression + posterior instrumented fusion 24%, decompression + posterior non-instrumented fusion 3%, decompression + PLIF 1%, decompression + TLIF 1% and other interventions 3%.

Mean preoperative VAS for back pain was 56, compared with 35 one year postoperatively. The corresponding figures for leg pain were 63 and 34 respectively. Figures 20 and 21 show pre- and postoperative VAS for back and leg pain, respectively.

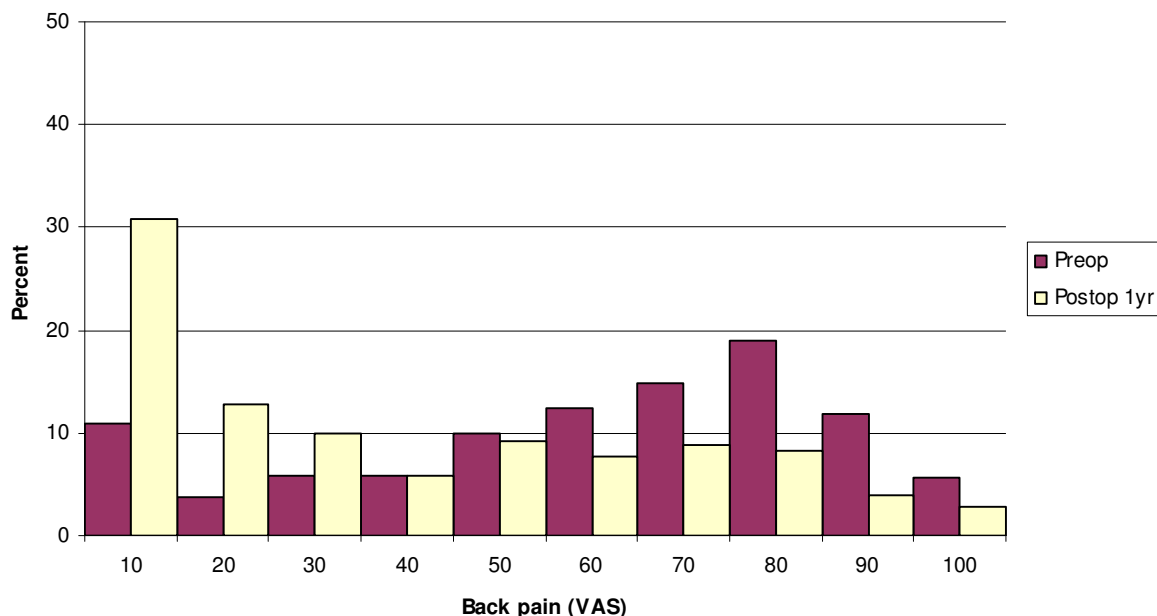


Fig 20. Back pain on the visual analog scale preoperatively and 1 year postoperatively in patients operated for lumbar central spinal stenosis in 2010 (%).

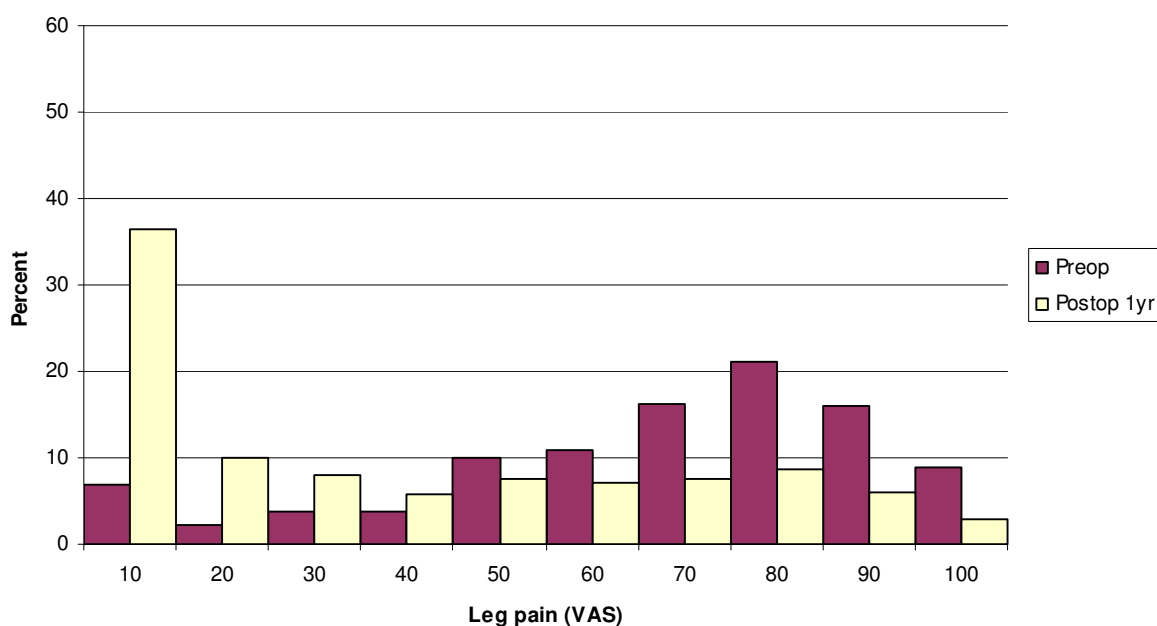


Fig 21. Leg pain on the visual analog scale preoperatively and 1 year postoperatively in patients operated for lumbar central spinal stenosis in 2010 (%).

One year postoperatively, 16% of patients felt they were completely pain-free, 36% significantly improved, 18% somewhat improved, 13% unchanged and 9% deteriorated with regard to back pain. 8% had no preoperative back pain. The corresponding figures for leg pain were 24% completely pain-free, 29% significantly improved, 18% somewhat improved, 12% unchanged and 11% deteriorated; 7% reported no preoperative leg pain.

Overall patient satisfaction with the procedure was as follows: 64% were satisfied, 22% uncertain and 13% dissatisfied with the surgical outcome.

Analgesic use one year postoperatively: Regular 31%, intermittent 33%, none 36%.

Ability to walk one year postoperatively: < 100m 20%, 100-500m 21%, 500m-1 km 17%, >1 km 42%, a substantial improvement compared with preoperatively.

In addition, one year postoperatively patients in the central spinal stenosis category demonstrated improvement of SF-36 score on all points except “General health”. The improvement was less pronounced than in disc herniation, but was probably similar when adjusted for age; see figure 22.

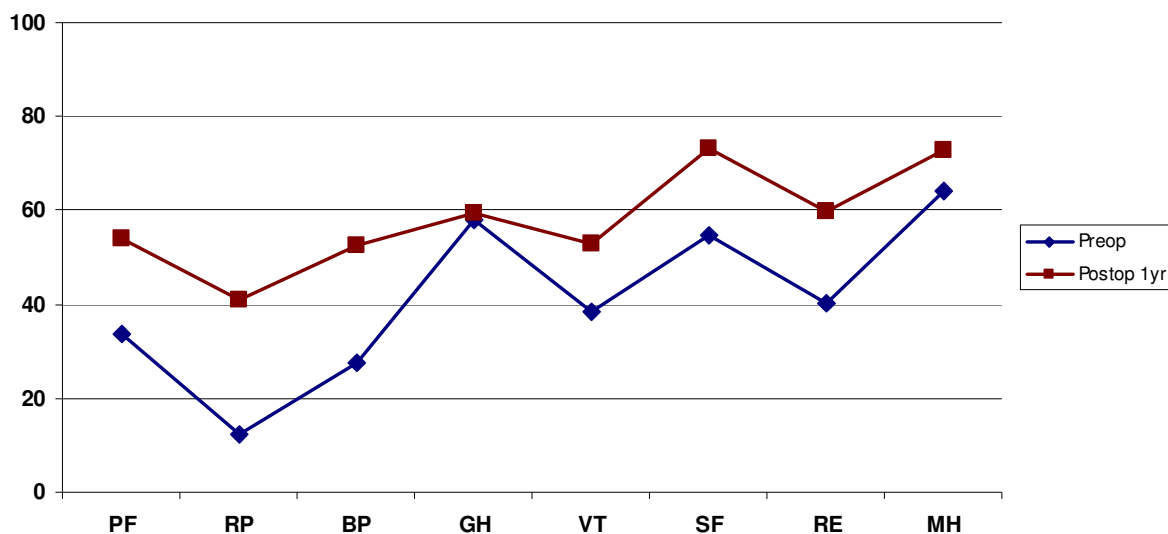


Fig 22. SF-36 preoperatively and 1 year postoperatively for patients operated for lumbar central spinal stenosis 2010.

Mean figure for EQ-5D 5 preoperatively: 0.35, 1 year postoperatively 0.63. Mean VAS preoperatively (max 100): 48, 1 year postoperatively 64.

### Lateral spinal stenosis

This patient group included 335 patients with a mean age of 61 (26–88) years. Gender distribution was 50% men and 50% women. Decompression alone was used in 69% of cases, decompression + posterior fusion in 18% (17% instrumented and 1% non-instrumented), decompression + PLIF 3% and other procedures 10%.

Mean preoperative VAS for back pain was 53, compared with 33 one year postoperatively. The corresponding figures for leg pain were 65 and 34 respectively. Figures 23 and 24 show the distribution of pre- and postoperative VAS for back and leg pain.

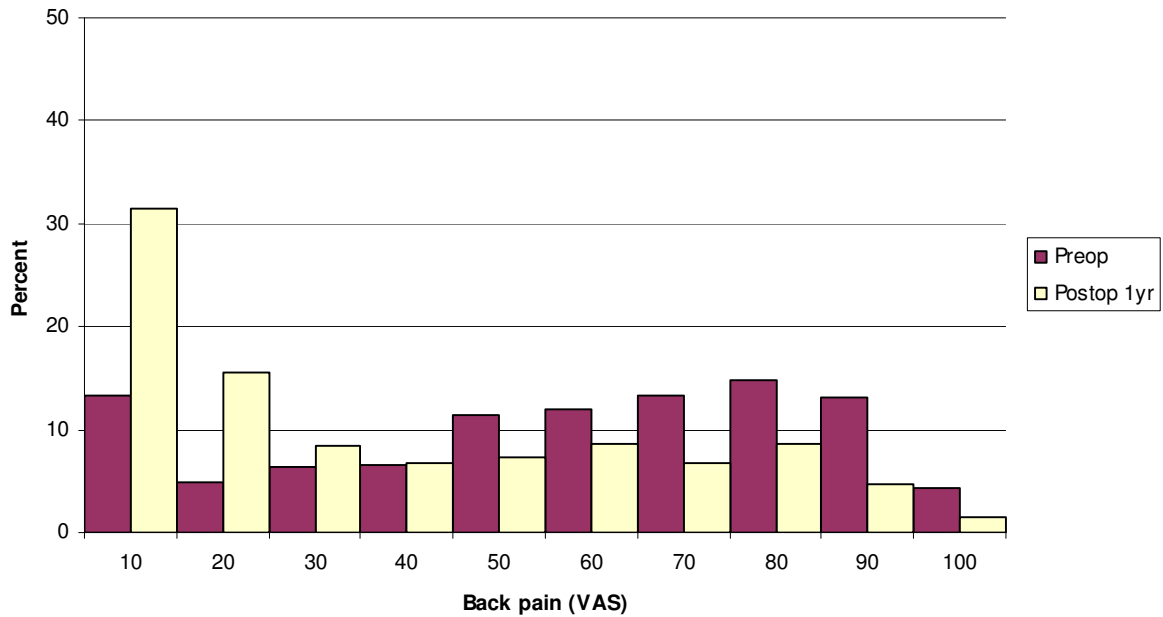


Fig 23. Back pain on the visual analog scale preoperatively and 1 year postoperatively in patients operated for lumbar lateral spinal stenosis in 2010 (%).

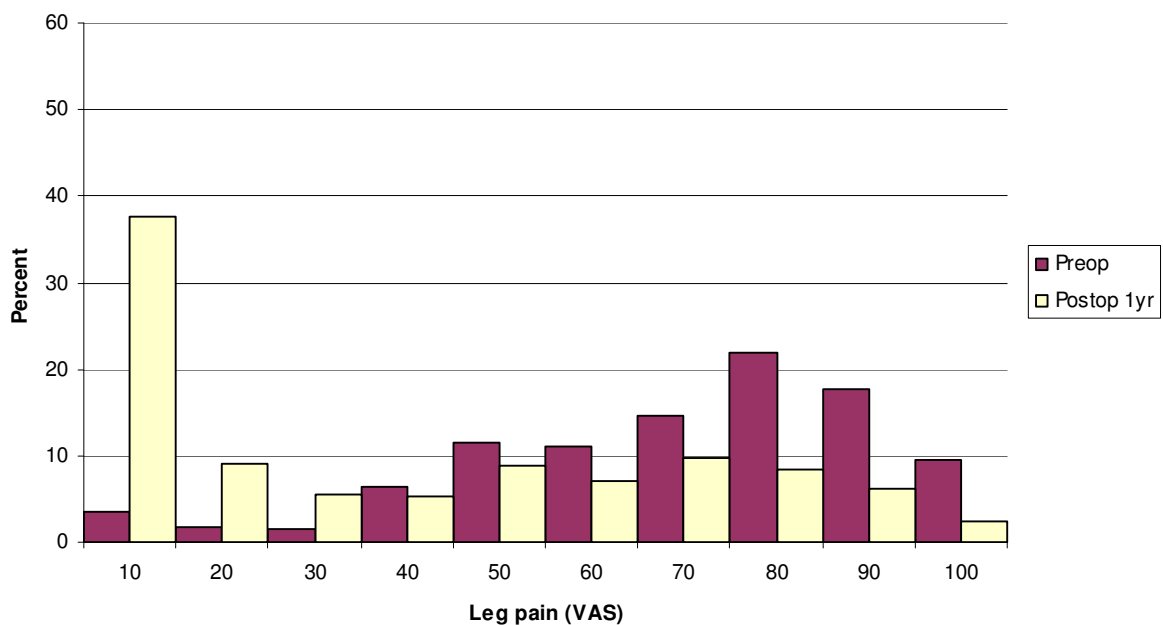


Fig 24. Leg pain on the visual analog scale preoperatively and 1 year postoperatively in patients operated for lumbar lateral spinal stenosis in 2010 (%).

One year postoperatively 14% of patients were completely pain-free, 33% significantly improved, 22% somewhat improved, 13% unchanged and 11% deteriorated with regard to back pain. 8% had no preoperative back pain. The corresponding figures for leg pain were 24% completely pain-free, 30% significantly improved, 21% somewhat improved, 13% unchanged and 9% deteriorated; 3% had no previous leg pain.

Patient satisfaction with surgical outcome: 62% satisfied, 25% uncertain and 14% dissatisfied.

Medication use 1 year postoperatively: 30% regularly, 33% intermittently and 38% took no medication.

Ability to walk one year postoperatively: < 100m 15%, 100–500 m 19%, 500 m–1 km 17% and >1 km 49%.

The patient group operated for lateral spinal stenosis also showed improvement in SF-36 scores, though somewhat less pronounced; see figure 25.

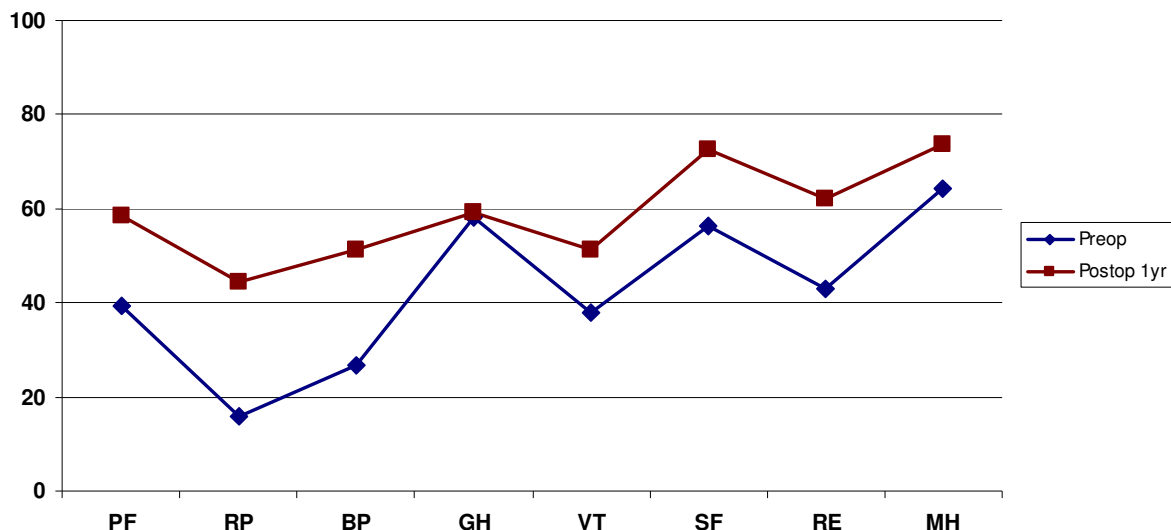


Fig 25. SF-36 preoperatively and 1 year postoperatively for patients operated for lumbar lateral spinal stenosis in 2010.

Mean figure for EQ-5D 5 preoperatively: 0.35, 1 year postoperatively 0.62. Mean VAS preoperatively (max 100): 47, 1 year postoperatively 65.

### Spondylolisthesis

In all, 247 patients operated during the period for spondylolisthesis completed 1-year follow-up. Mean age was 50 (11–83) years; gender distribution 45% men and 55% women.

Among the patients with spondylolisthesis, 56% were operated with decompression and posterior instrumented fusion, 17% with posterior instrumented fusion alone, 10% with PLIF, 4% with decompression + PLIF, 5% with decompression + TLIF, 3% with decompression + posterior non-instrumented fusion, 1% with posterior non-instrumented fusion, 2% with decompression alone, 1% 360° instrumented/global fusion and 1% other procedures.

Mean preoperative VAS for back pain was 60, compared with 29 one year postoperatively. The corresponding figures for leg pain were 52 and 23 respectively. Figures 26 and 27 show preoperative and postoperative VAS relating to back and legs.

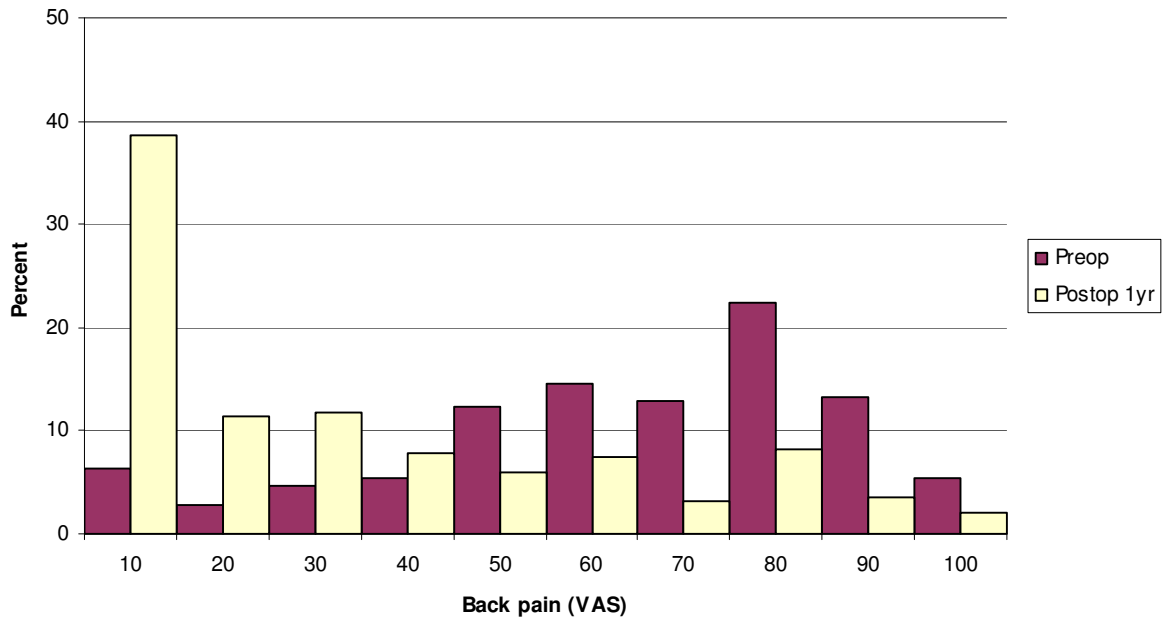


Fig 26. Back pain on the visual analog scale preoperatively and 1 year postoperatively in patients operated for spondylolisthesis in 2010 (%).

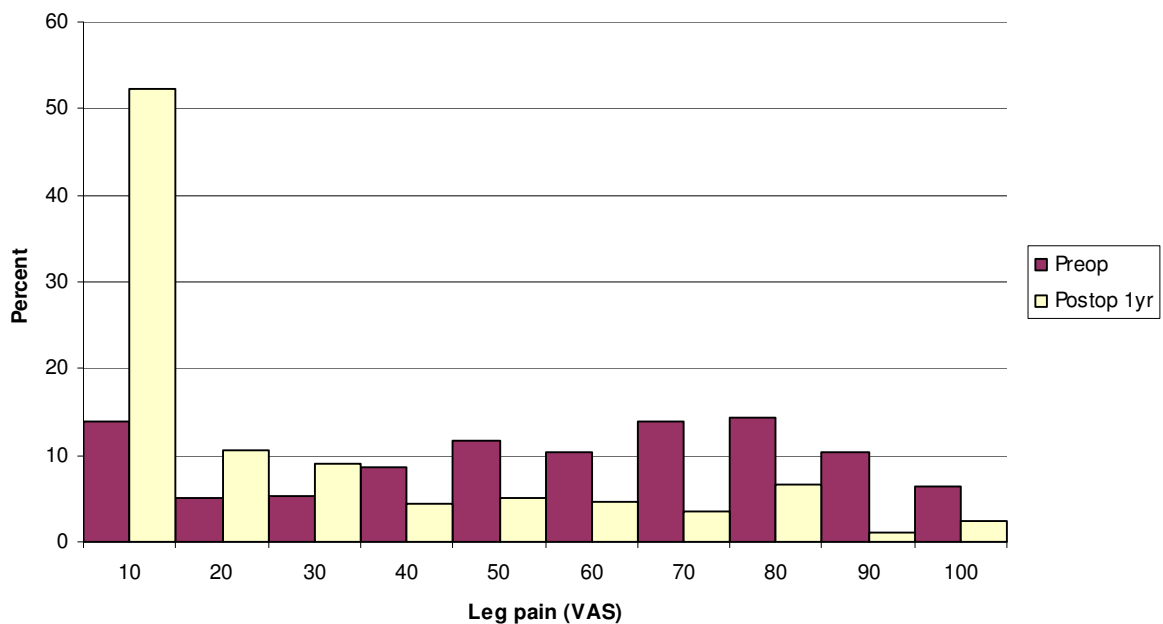


Fig 27. Leg pain on the visual analog scale preoperatively and 1 year postoperatively in patients operated for spondylolisthesis in 2010 (%).

At the 1-year follow-up, 15% of patients felt they were completely pain-free, 47% significantly improved, 18% somewhat improved, 9% unchanged and 7% deteriorated with regard to back pain; 4% did not have back pain previously. The corresponding figures for leg pain were 27% completely pain-free, 39% significantly improved, 13% somewhat improved, 7% unchanged and 6% deteriorated; 9% reported no preoperative leg pain.

Overall patient satisfaction with the operation: 73% satisfied, 16% uncertain and 11% dissatisfied.

Regular intake of analgesics one year postoperatively was reported by 23%, intermittent use by 32% and no intake of analgesics at all by 45%.

Ability to walk one year postoperatively: < 100m 7%, 100-500m 11%, 500m-1 km 13%, >1 km 70%, a substantial improvement compared with preoperatively.

Spondylolisthesis patients showed good improvement in their SF-36 scores one year postoperatively compared with preoperatively; see figure 28.

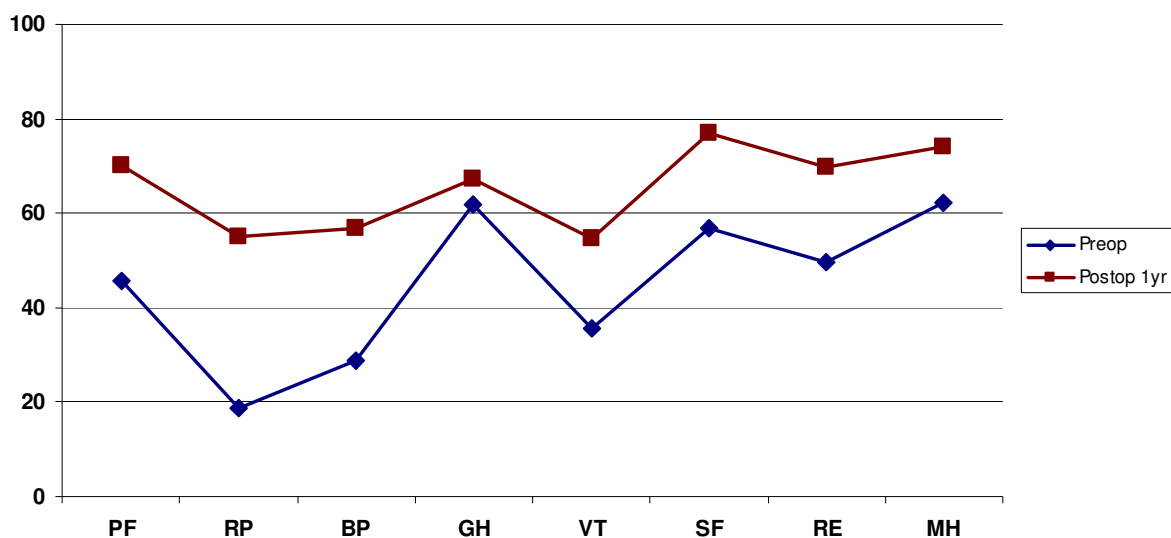


Fig 28. SF-36 preoperatively and 1 year postoperatively for patients operated for spondylolisthesis in 2010.

Mean value for EQ-5D preoperatively: 0.37, 1 year postoperatively 0.69. Mean VAS preoperatively (max 100): 48, 1 year postoperatively 68.

### DDD (disc degenerative disorder)/segmental pain

In all, 1-year follow-up was completed by 518 patients operated during the period. Mean age was 45 (18–80) years, gender distribution 48% men and 52% women.

In 26% of cases patients with DDD were operated with posterior instrumented fusion, in 19% with PLIF, in 22% with disc replacement, in 11% with decompression + posterior instrumented fusion, in 6% with decompression + TLIF, in 6% with TLIF, in 5% with decompression + PLIF, in 1% with posterior non-instrumented fusion and in 4% with other procedures.

Mean preoperative VAS for back pain was 62, compared with 30 one year postoperatively. The corresponding figures for leg pain were 42 and 23 respectively. Figures 29 and 30 show pre- and postoperative VAS for back and leg pain.



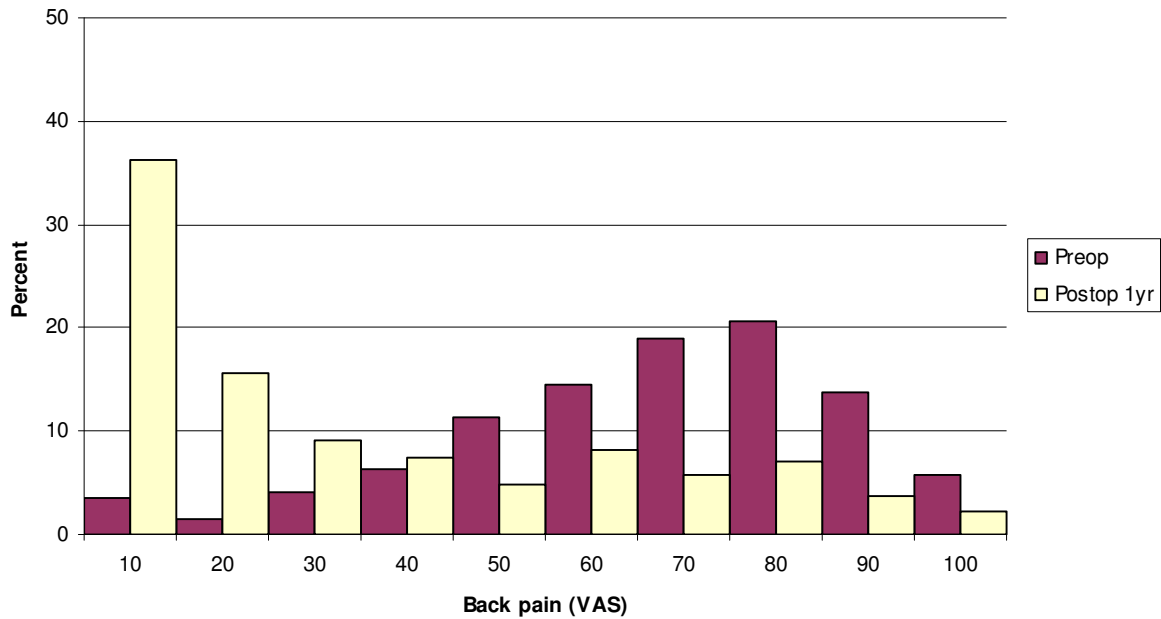


Fig 29. Back pain on the visual analog scale preoperatively and 1 year postoperatively in patients operated for DDD in 2010 (%).

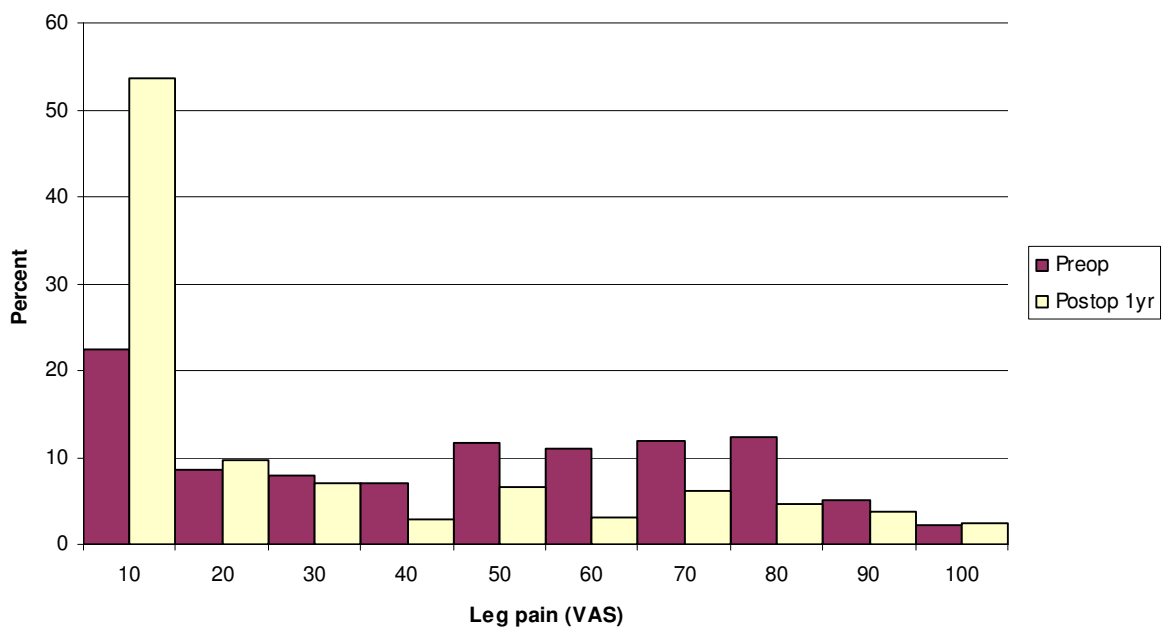


Fig 30. Leg pain on the visual analog scale preoperatively and 1 year postoperatively in patients operated for DDD in 2010 (%).

One year postoperatively, patients operated for DDD perceived back pain as follows: Completely pain-free 20%, significantly improved 47%, somewhat improved 17%, unchanged 7% and deteriorated 8%; 1% did not have back pain previously.

Corresponding figures for leg pain: Completely pain-free 26%, significantly improved 28%, somewhat improved 15%, unchanged 7% and deteriorated 9%; 14% reported no preoperative leg pain.

Regarding patient satisfaction with the operation, 74% were satisfied, 14% uncertain and 12% dissatisfied.

Among these patients, 26% took analgesics regularly one year postoperatively, 30% did so intermittently and 44% reported that they did not use any analgesics.

Ability to walk one year postoperatively: < 100m 6%, 100-500m 9%, 500m-1 km 13%, >1 km 73%, a substantial improvement compared with preoperatively.

Figure 31 shows the pre- and postoperative SF-36 profiles for patients operated for DDD; the profiles are similar to the other diagnoses. Both the physical and mental domains show improvement.

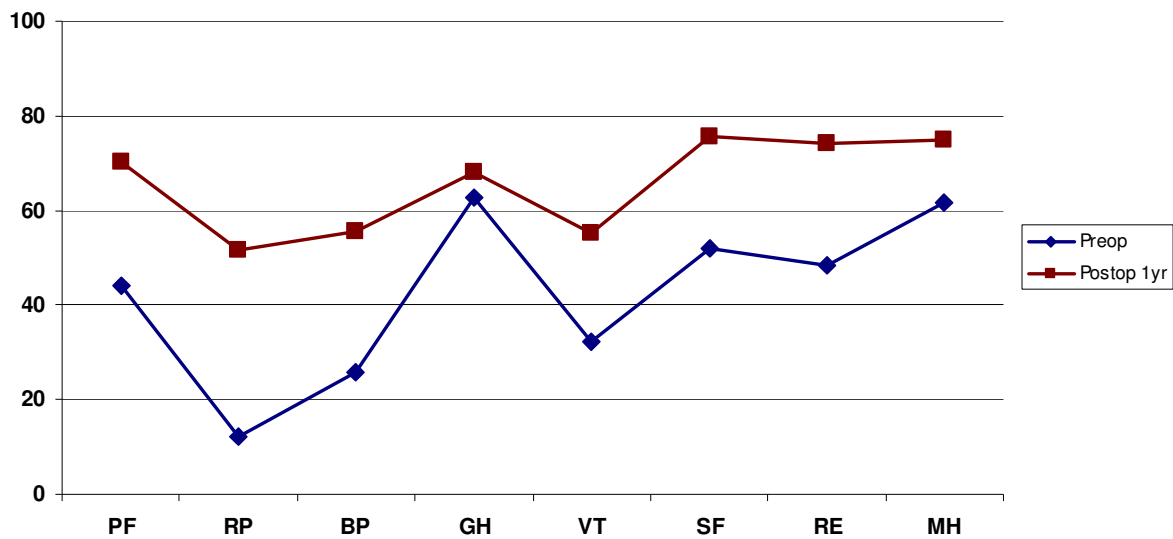


Fig 31. SF-36 preoperatively and 1 year postoperatively for patients operated for DDD in 2010.

Mean figure for EQ-5D 5 preoperatively: 0.33, 1 year postoperatively 0.65. Mean value on the scale preoperatively (max 100): 44, 1 year postoperatively 68.

### Oswestry Disability index, ODI, before and 1 year after surgery for all diagnoses

Below is a comparison of pre- and postoperative “disability” as measured by the Oswestry index. All diagnoses show a significant reduction in measured functional limitation; most pronounced is disc herniation; see figure 32. A score of 0-20 is regarded as no or little “disability”.

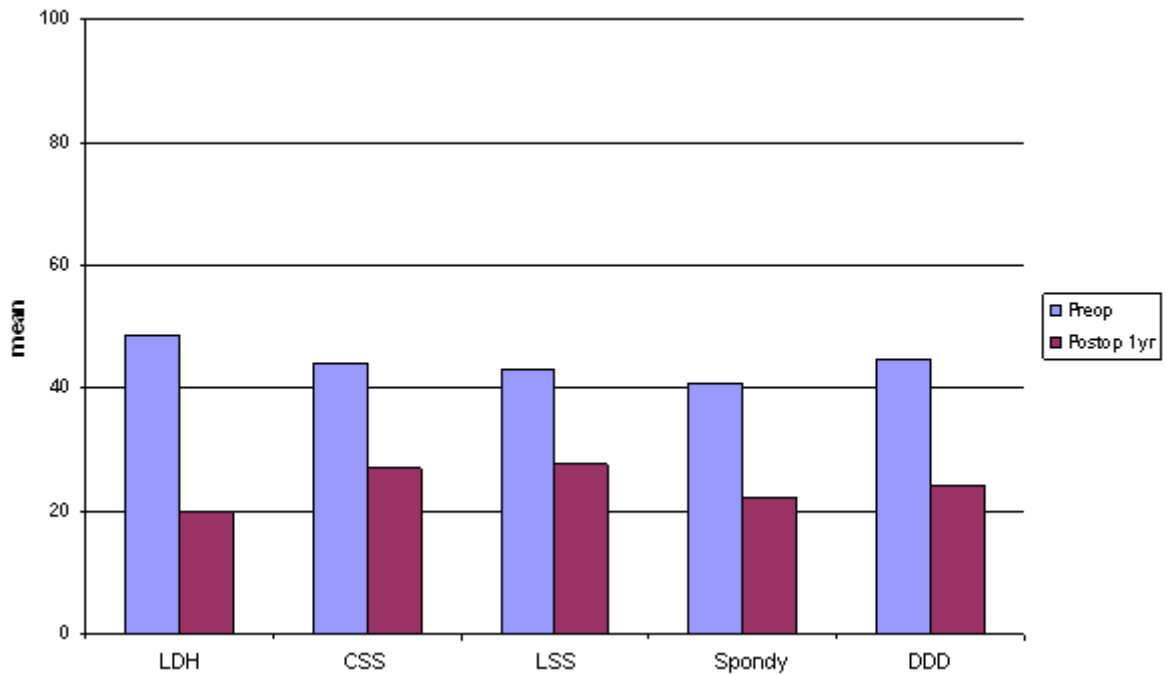


Fig 32. ODI score before and one year after lumbar spine surgery, related to diagnosis, for patients operated in 2010.

### III. 2-year follow-up of lumbar spine procedures in Sweden in 2011

A total of 3912 patients operated on in 2009 have completed preoperative, 1-year and 2-year follow-up postoperative protocols. The most common diagnoses are disc herniation, 1035 and central spinal stenosis, 1907 patients. In all, 249 patients had been operated for lateral spinal stenosis, 1202 for spondylolisthesis and 391 for DDD. The remaining 102 had other diagnoses. Below is a comparison of several parameters assessed at 1-year and 2-year follow-up. Only patients who responded on all 3 occasions are included.

Table 1 presents pain on the VAS, diagnosis-related, over time.

Table 1. Pain on the VAS (mean), diagnosis-related.

	Back			Leg		
	Preop	1 year	2 year	Preop	1 year	2 year
Disc herniation	46	22	25	66	19	22
Central stenosis	55	31	35	61	31	35
Lateral stenosis	51	31	31	62	34	32
Spondylolisthesis	59	27	29	52	26	25
DDD	62	29	32	42	22	25

Tables 2-6 present walking distance after the different procedures preoperatively as well as 1 and 2 years postoperatively.

Table 2. Walking distance, disc herniation (%)

	Preoperatively	1 year	2 year
< 100m	32	4	4
100m–500m	20	8	7
500m–1 km	16	11	11
>1 km	32	77	78

Table 3. Walking distance, central spinal stenosis (%)

	Preoperatively	1 year	2 year
< 100m	41	18	21
100m–500m	30	20	20
500m–1 km	14	17	15
>1 km	16	45	44

Table 4. Walking distance, lateral spinal stenosis (%)

	<b>Preoperatively</b>	<b>1 year postop</b>	<b>2 years postop</b>
< 100m	29	17	16
100m–500m	32	16	19
500m–1 km	11	16	11
>1 km	28	51	54

Table 5. Walking distance, spondylolisthesis (%)

	<b>Preoperatively</b>	<b>1 year postop</b>	<b>2 years postop</b>
< 100m	17	5	9
100m–500m	28	13	12
500m–1 km	13	13	15
>1 km	42	69	64

Table 6. Walking distance, DDD (%)

	<b>Preoperatively</b>	<b>1 year postop</b>	<b>2 years postop</b>
< 100m	11	4	5
100m–500m	19	9	7
500m–1 km	24	16	15
>1 km	41	71	73

Tables 7-11 show consumption of analgesics preoperatively and 1 and 2 years postoperatively, related to diagnosis for surgery.

Table 7. Consumption of analgesics, disc herniation, preoperatively, 1 and 2 years postoperatively (%).

	<b>Preoperatively</b>	<b>1 year postop</b>	<b>2 years postop</b>
Regular	62	15	17
Intermittent	28	32	30
None	10	53	53

Table 8. Consumption of analgesics, central spinal stenosis preoperatively, 1 and 2 years postop (%).

	<b>Preoperatively</b>	<b>1 year postop</b>	<b>2 years postop</b>
Regular	53	28	31
Intermittent	31	33	32
None	16	40	37

Table 9. Consumption of analgesics, lateral spinal stenosis preoperatively, 1 and 2 years postop (%).

	<b>Preoperatively</b>	<b>1 year postop</b>	<b>2 years postop</b>
Regular	55	30	31
Intermittent	28	31	30
None	17	39	39

Table 10. Consumption of analgesics, spondylolisthesis preoperatively, 1 and 2 years postop (%).

	<b>Preoperatively</b>	<b>1 year postop</b>	<b>2 years postop</b>
Regular	44	23	25
Intermittent	28	30	28
None	28	48	47

Table 11. Consumption of analgesics DDD preoperatively, 1 and 2 years postop (%).

	<b>Preoperatively</b>	<b>1 year postop</b>	<b>2 years postop</b>
Regular	57	24	29
Intermittent	34	39	32
None	9	37	39

Table 12 presents patient-assessed satisfaction with surgical outcome after 1 and 2 years.

Table 12. Attitude toward surgical outcome 1 and 2 years postop, diagnosis-related.

	<b>1 year postop</b>			<b>2 years postop</b>		
	<b>Satisfied</b>	<b>Uncertain</b>	<b>Dissatisfied</b>	<b>Satisfied</b>	<b>Uncertain</b>	<b>Dissatisfied</b>
Disc herniation	81	14	6	81	13	6
Central stenosis	66	24	10	64	22	13
Lateral stenosis	61	26	13	64	24	12
Spondylolisthesis	72	19	9	72	18	10
DDD	75	16	10	75	15	10

Tables 13-14 and figure 33 present quality of life as measured by EQ-5D and by VAS. All patient groups experience a significant improvement in quality of life postoperatively.

Table 13. EQ-5D means preoperatively, 1 year and 2 years postop, diagnosis-related.

	<b>Preop</b>	<b>1 year postop</b>	<b>2 years postop</b>
Disc herniation	0.29	0.73	0.73
Central spinal stenosis	0.37	0.64	0.62
Lateral spinal stenosis	0.36	0.63	0.64
Spondylolisthesis	0.40	0.71	0.68
DDD	0.33	0.65	0.66

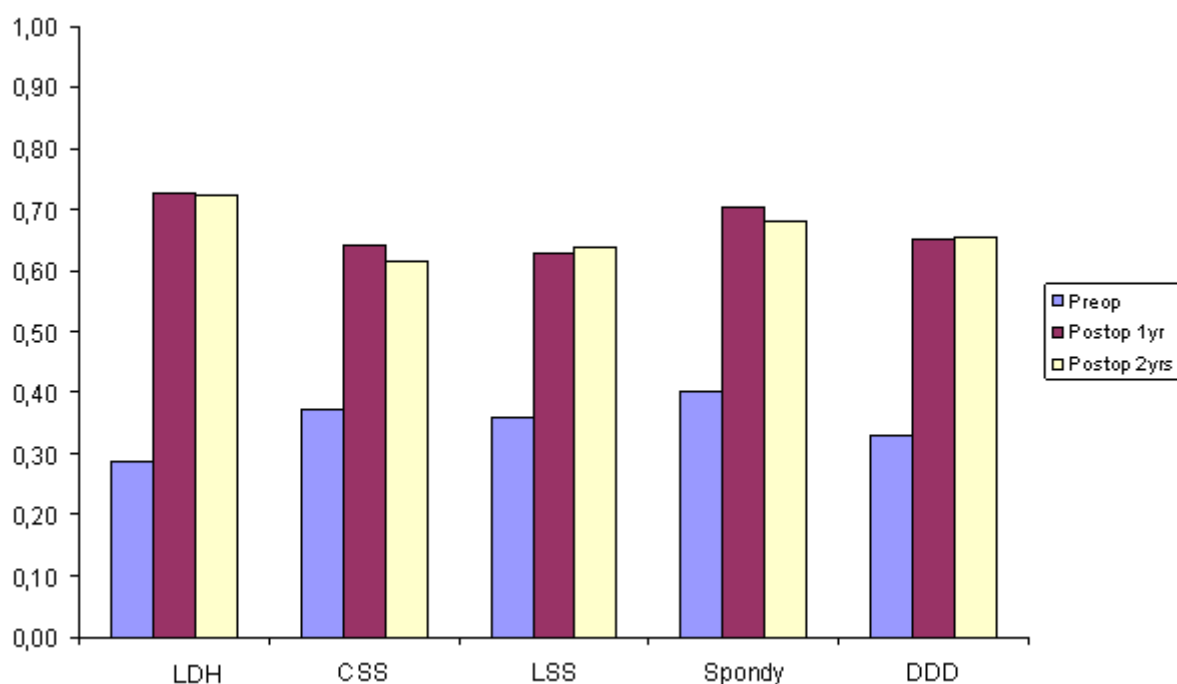


Fig 33. Quality of life preoperatively, 1 and 2 years postoperatively, as measured by EQ-5D.

Table 14. EQ-5D health assessment according to the VAS, means.

	<b>Preop</b>	<b>1 year postop</b>	<b>2 years postop</b>
Disc herniation	46	73	73
Central spinal stenosis	48	65	63
Lateral spinal stenosis	50	65	66
Spondylolisthesis	52	72	72
DDD	42	67	66

**Oswestry Disability index, ODI, preoperatively, 1 and 2 years post-operatively for all diagnoses**

Table 15. ODI results preoperatively, 1 and 2 years after lumbar spine surgery, diagnosis-related.

	<b>Preoperatively</b>	<b>1 year postop</b>	<b>2 years postop</b>
Disc herniation	48	18	18
Central spinal stenosis	43	26	28
Lateral spinal stenosis	42	26	25
Spondylolisthesis	41	22	22
DDD	45	25	25



#### IV. 5-year follow-up of lumbar spine procedures in Sweden in 2011

A total of 1840 patients completed 1, 2 and 5-year follow-up after having undergone lumbar spine surgery in 2006. The most common diagnoses are disc herniation, 581 and central spinal stenosis, 706 patients. In all, 140 patients had been operated for lateral spinal stenosis, 130 for spondylolisthesis and 230 for segmental pain (DDD). The remaining 53 had other diagnoses. Below is a comparison of several parameters at 1, 2 and 5-year follow-up. Only patients who responded on all 4 occasions are included.

Table 16 presents pain on the VAS, diagnosis-related, over time.

Table 16. Pain on the VAS (mean), diagnosis-related.

	Back				Leg			
	Preop	1 year	2 year	5 years	Preop	1 year	2 year	5 years
Disc herniation	42	21	22	22	63	19	20	20
Central stenosis	53	28	29	34	61	29	30	35
Lateral stenosis	53	28	28	31	62	31	29	33
Spondylolisthesis	56	25	26	28	52	24	24	24
DDD	62	31	29	30	45	22	22	22

Tables 17-21 present walking distance after the different procedures preoperatively as well as 1, 2 and 5 years postoperatively.

Table 17. Walking distance, disc herniation (%)

	Preoperatively	1 year	2 year	5 years
< 100m	32	4	5	5
100m–500m	22	7	7	5
500m–1 km	17	8	9	9
>1 km	29	81	79	81

Table 18. Walking distance, central spinal stenosis (%)

	Preoperatively	1 year	2 year	5 years
< 100m	40	16	17	22
100m–500m	33	17	17	17
500m–1 km	13	16	15	16
>1 km	15	51	52	44

Table 19. Walking distance, lateral spinal stenosis (%)

	<b>Preoperatively</b>	<b>1 year</b>	<b>2 year</b>	<b>5 years</b>
< 100m	22	7	10	16
100m–500m	33	11	10	10
500m–1 km	16	20	18	18
>1 km	29	62	62	57

Table 20. Walking distance, spondylolisthesis (%)

	<b>Preoperatively</b>	<b>1 year</b>	<b>2 year</b>	<b>5 years</b>
< 100m	16	4	5	6
100m–500m	24	19	11	11
500m–1 km	20	12	12	12
>1 km	40	76	71	72

Table 21. Walking distance, DDD (%)

	<b>Preoperatively</b>	<b>1 year</b>	<b>2 year</b>	<b>5 years</b>
< 100m	9	5	6	5
100m–500m	23	10	8	9
500m–1 km	26	14	12	9
>1 km	42	72	74	77

Tables 22-26 show consumption of analgesics preoperatively and 1, 2 and 5 years postoperatively, related to diagnosis for surgery.

Table 22. Consumption of analgesics, disc herniation, preoperatively, 1, 2 and 5 years postoperatively (%).

	<b>Preoperatively</b>	<b>1 year</b>	<b>2 year</b>	<b>5 years</b>
Regular	59	16	17	15
Intermittent	29	28	29	33
None	13	56	54	52

Table 23. Consumption of analgesics, central spinal stenosis preoperatively, 1, 2 and 5 years postop (%).

	<b>Preoperatively</b>	<b>1 year</b>	<b>2 year</b>	<b>5 years</b>
Regular	48	23	26	29
Intermittent	33	33	34	32
None	19	45	40	39

Table 24. Consumption of analgesics, lateral spinal stenosis preoperatively, 1, 2 and 5 years postop (%).

	<b>Preoperatively</b>	<b>1 year</b>	<b>2 year</b>	<b>5 years</b>
Regular	49	23	27	27
Intermittent	26	33	32	29
None	25	44	41	44

Table 25. Consumption of analgesics, spondylolisthesis preoperatively, 1, 2 and 5 years postop (%).

	<b>Preoperatively</b>	<b>1 year</b>	<b>2 year</b>	<b>5 years</b>
Regular	40	20	23	24
Intermittent	39	33	33	29
None	21	47	44	48

Table 26. Consumption of analgesics DDD preoperative, 1, 2 and 5 years postop (%).

	<b>Preoperatively</b>	<b>1 year</b>	<b>2 year</b>	<b>5 years</b>
Regular	51	25	24	26
Intermittent	36	36	38	35
None	14	40	38	39

Table 27 presents patient-assessed satisfaction with surgical outcome after 1, 2 and 5 years.

Table 27. Attitude toward surgical outcome 1, 2 and 5 years postop, diagnosis-related.

	<b>1 year postop</b>			<b>2 years postop</b>			<b>5 years postop</b>		
	<b>Satis fied</b>	<b>Uncer tain</b>	<b>Dissati sfied</b>	<b>Satis fied</b>	<b>Uncer tain</b>	<b>Dissati sfied</b>	<b>Satis fied</b>	<b>Uncer tain</b>	<b>Dissati sfied</b>
Disc herniation	80	16	5	81	14	5	83	11	6
Central stenosis	70	21	10	68	20	12	66	21	13
Lateral stenosis	73	18	7	70	20	11	69	21	10
Spondylolisthesis	80	16	5	82	12	6	83	6	11
DDD	76	17	7	75	17	8	77	14	9

Tables 28-29 and figure 34 present quality of life as measured by EQ-5D and by VAS. All patient groups experience a significant improvement in quality of life postoperatively.

Table 28. EQ-5D means preoperatively, 1, 2 and 5 years postop, diagnosis-related.

	<b>Preoperatively</b>	<b>1 year postop</b>	<b>2 years postop</b>	<b>5 years postop</b>
Disc herniation	30	75	75	76
Central stenosis	39	66	66	62
Lateral stenosis	41	70	68	65
Spondylolisthesis	43	67	69	69
DDD	34	65	66	66

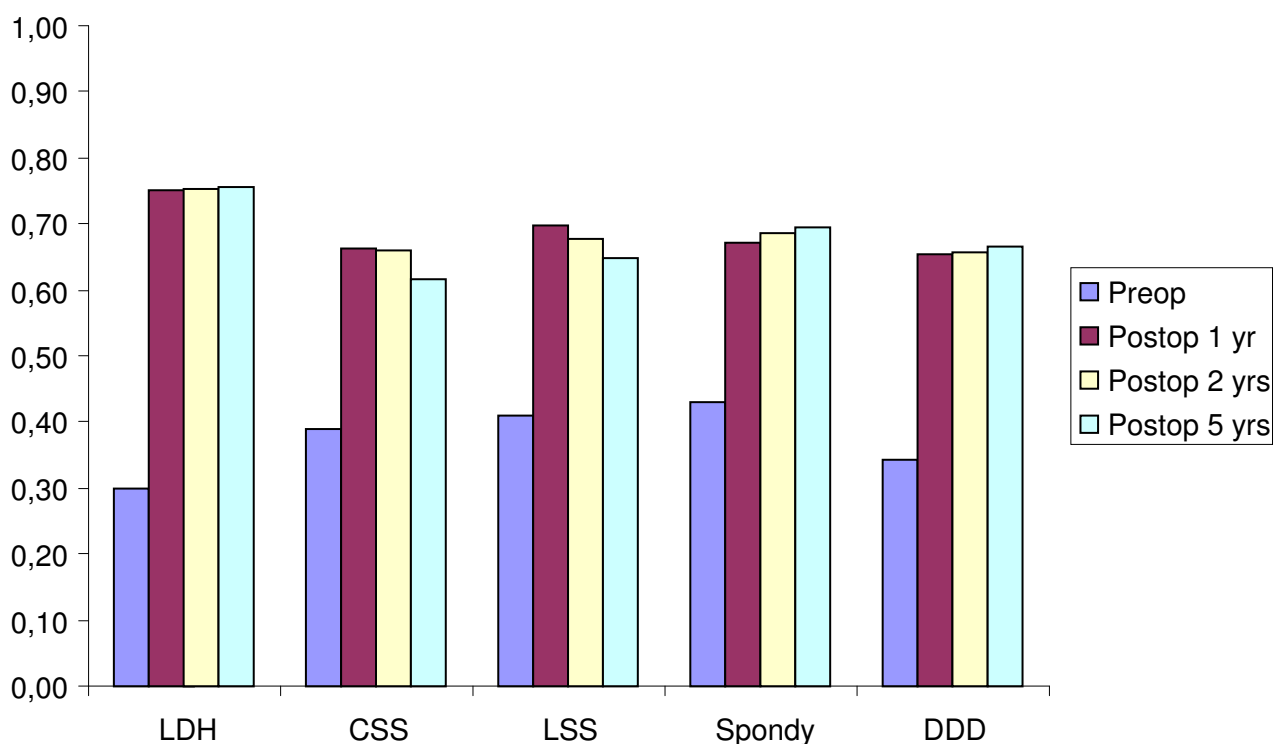


Fig 34. Quality of life preoperatively, 1, 2 and 5 years postoperatively, as measured by EQ-5D.

Table 29. EQ-5D health assessment according to the VAS, means.

	<b>Preoperatively</b>	<b>1 year postop</b>	<b>2 years postop</b>	<b>5 years postop</b>
Disc herniation	47	74	74	74
Central stenosis	52	67	65	62
Lateral stenosis	52	70	70	66
Spondylolisthesis	52	70	70	71
DDD	48	65	67	66

## V. Surgery for degenerative cervical spine disease

In 2011, 698 patients were operated for degenerative cervical spine disease, including 53% men and 47% women. In all, 20% of the patients were smokers and 10% had previously had cervical spine surgery.

Preoperative duration of pain was as follows: <3 months 2%, 3-12 months 24%, 1-2 years 20% and more than 2 years 45%, while 9% denied any neck pain. Patients experienced radiation of pain to the arm(s) as follows: 4% of patients for <3 months, 32% for 3-12 months, 24% for 1-2 years and 33% for more than 2 years, while 7% denied any arm pain.

Regular consumption of analgesics was confirmed by 53% of patients, intermittent by 30% and none by the remaining 17%.

Estimated walking distance was reported by 13% of patients to be <100m, 12% 100-500m, 16% 500 m – 1 km and 59% >1 km. In all, 75% reported subjective deterioration of fine motor function in their hands.

Co-morbidity was reported in the form of heart disease 2%, neurological disease 3%, cancer 0%, other disease affecting ability to walk 9%, or other disease causing pain 13%, while 72% denied co-morbidity.

Mean neck pain on the VAS was 55 with a spread from 0-100. The corresponding figures for arm pain were 53 with a spread from 0-100.

Mean EQ-5D was 0.38 for patients, while the results of the Neck Disability Index (NDI) were as follows: mean 62.6. Distribution on the European myelopathy score was 15.11.

### *Data on the procedure*

In all, 44% of patients were operated for cervical disc herniation, 26% for cervical spinal stenosis, 23% for cervical foraminal stenosis, 1.48% for segmental neck pain, 1.9% for rheumatoid arthritis, and 0.1% for ankylosing spondylitis; 3.2% were operated for some other diagnosis.

With respect to the neurological clinical picture, 12% of patients had no neurological findings, 59% radicular involvement, 23% medullary involvement and the remaining 6% combined radicular and medullary involvement. On the Ranawat score, patients were distributed as follows: I: 29%, II: 48%, IIIa: 21% and III: 2% .. Neurological deficit according to the Frankel Classification system was distributed as follows: A 0%, B 2%, C 13%, D 54%, E 31%.

Horizontal instability between C1-C2 was seen in 1.6% of cases, vertical between C0 and C2 in 0.1% of cases and subaxial between C2 and Th1 in 2.7% of cases. Combined instability was assessed to be present in 0.6% of cases.

Surgical interventions were as follows:

Disk removal without fusion 0.3%,

Disc removal with fusion without plate 2.1%,

Disc removal with fusion with plate 9.4%,

Disc removal with fusion cage without plate 20.2%,  
Disc removal with fusion cage with plate 35.3%,  
Corpectomy 6.8%,  
Disc replacement 5.0%,  
Transoral decompression 0%,  
Laminectomy without fixation 3.8%,  
Laminectomy with fixation 5.5%,  
SKIP laminectomy 0%,  
Laminoplasty 0.3%,  
Foraminotomy 5.6%,  
Combination laminectomy/foraminotomy 1.5%,  
Posterior fixation without decompression 2.4%,  
Other procedure without implant 0.4% and  
Other procedure with implant 1.5%.

Anterior implant was used in 80% of cases and posterior in 10% of cases.

#### *Results after follow-up*

About 76% of the 620 patients operated in 2010 also had 1-year follow-up.

Average preoperative NDI in Sweden was 63 and postoperative 47.

Rhizopathy/arm pain improved from an average of 48 preoperatively to an average of 26 postoperatively.

Corresponding subjective scoring of change in arm pain one year postoperatively: Greatly improved 53%, somewhat improved 18%, unchanged 23% and 7% perceived worsening.

Patient assessment of change in walking distance one year postoperatively: >100m 9%, 100-500m 12%, 0.5-1 km 14%, >1 km 64%.

Quality of life as measured by EQ-5D improved from 0.39 preoperatively to 0.64 postop at one year.

## VI. Spine fracture surgery

In 2011, 423 surgeries were registered for spinal column fractures. Without any compensation for population age distribution, surgery for fracture was most common in the age group 60-69 years, and 65% were male. In all, 22% of patients operated had some degree of neurological damage, while 92% of the procedures registered were carried out at university hospitals. According to AO classification, 31% of the fractures were type A, 46% type B and 23% type C (table 30).

Table 30. Fracture types according to AO classification (%).

Class A	Class B	Class C
31	46	23

The single largest group of fractures in the register involved Th11 – L2 fractures. Of the fractures registered to date, 86% were operated with posterior fusion with or without decompression and 4% with vertebroplasty. Even here, the most common age group was 60-69 years, but these fractures also have a clear peak at age 20-29 years. These fractures include both high-energy injuries in younger and middle-aged patients and osteoporotic fractures in older patients.

Neurological involvement in the form rhizopathy was seen in 20% of cases and in the form myelopathy in 21% of cases with the following distribution according to the Frankel Scale: A 28%, B 9%, C 19%, D 24% and E 20% (table 31).

Table 31. Neurological function according to the Frankel Classification system (percent)

Classification	Percent
A	28
B	9
C	19
D	24
E	20

Two years after surgery, 72% of patients were satisfied with the procedure, 21% uncertain and 6% dissatisfied. However, many of the patients probably had no or very moderate back pain before the fracture and have difficulty assessing what the status would have been without surgery. Of those who worked before the fracture, 38% returned to work full-time and 15% had returned to work part-time. In all, 29% of patients took analgesics regularly and 33% occasionally. EQ-5D was 0.66 two years after the procedure.

## VII. Surgery for spinal metastases

In all, 211 patients are registered for spinal metastasis surgery; 8% were smokers. Indications for surgery are as follows: Neurological involvement 53%, back/leg pain 14.5%, progressive deformity 1.4%, neurological involvement + back/leg pain 18.8%, neurological involvement + progressive deformity 2.2%, back + progressive deformity 3.6%, neurological involvement + back + progressive deformity 6.5%; no indication for surgery was recorded for 34.6%.

The primary tumor was known in 72% of cases and unknown in 28%. Among known primary tumors, the following were most common: prostate 41%, breast 9.8%, kidney 3.9%, thyroid 1%, lung 10.8%, blood-forming organs 12.7%, GI tract 2.9%, Other 17.6% (table 32).

Table 32. Primary tumor at spinal metastasis (percent)

Primary tumor	Percent
Prostate	41
Lung	11
Breast	10
Kidney	4
GI tract	3
Blood-forming organs	13
Thyroid	1
Other known primary tumor	18
Unknown primary tumor	28

In 41.8% of cases a pathologic fracture was seen. Neurological involvement was distributed as follows on the Frankel Scale: A 6%, B 6.7%, C 32.8%, D 31.3%, E 23.1%. Preoperative analgesic consumption was as follows: 81.9% morphine analgesics, 13.4% non-morphine analgesics and 4.7% no analgesic consumption.

Surgical procedures included posterior and anterior decompression as well as possible fusion. In all, 90.8% had posterior decompression, at the following levels: cervical, thoracic and lumbar levels, while 9.9% had anterior decompression at the following levels: cervical, thoracic and lumbar. Fusion was carried out in 38.6% of cases.

Resection of tumor was carried out in 84.3% of cases; in 4.5% of cases as wide excision, 18.8% marginal excision, 76.7% intralesional excision and in 0% RF ablation.



## VIII. Disc replacement surgery of the lumbar spine

### *Introduction*

Total disc replacement (TDR) of the lumbar spine has been carried out quite extensively abroad since the late 1980s, especially in Europe. The first disc prosthesis used in clinical practice was designed in the former East Germany and has been used implanted in several European countries.

TDR was developed because fusion of the lumbar spine is associated with some risk of overload and future degeneration, with new surgery required, in adjacent segments. The hypothesis underlying the disc replacement procedure is that preserved mobility will reduce the risk of future degeneration in adjacent non-operated segments.

A few such procedures were carried out in Sweden in the 1990s, but they are not included in the register. TDR has been performed more routinely and systematically in Sweden since 2003. Little scientific documentation is available. Two randomized FDA studies in the US have been published. However, their results have been strongly disputed and it is doubtful whether these results can be applied to Swedish conditions.

TDR in Sweden has been evaluated in a randomized study published in a thesis in 2010 with 2-year follow-up (S. Berg).

### *Material*

A total of 879 disc replacements in the lumbar spine have been registered in our database through the end of September 2012. Figure 35 shows the number of procedures performed annually.

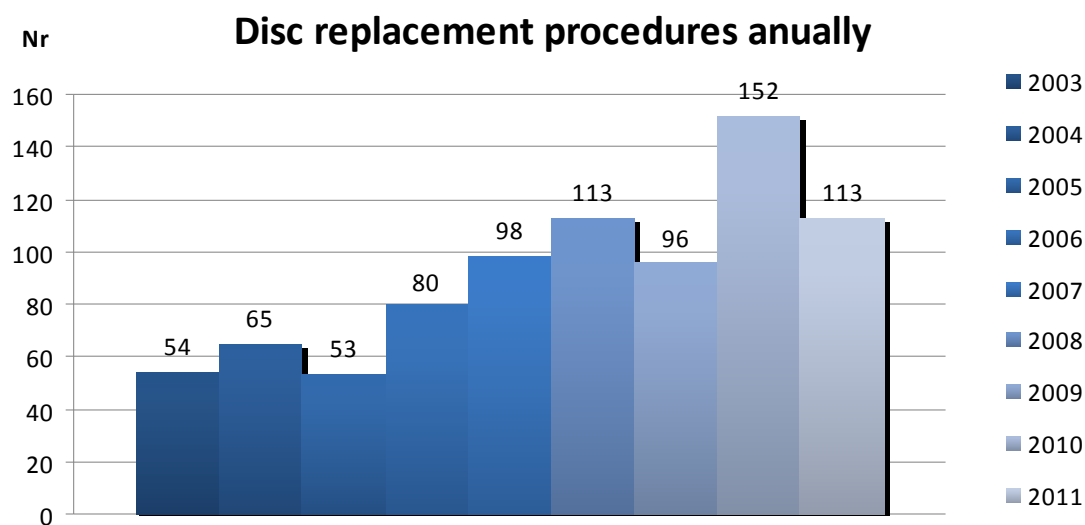


Fig 35. Number of disc replacement procedures annually, 2003-2011.

The diagnoses entered in the register are as follows: Segmental pain 834, paramedian disc herniation 17, central disc herniation 11, postoperative instability 8, central spinal stenosis 3, isthmic spondylolisthesis 2, other diagnosis 2, and no information about diagnosis in 2 cases.

The procedures were largely carried out at the Stockholm Spine Center, 773. Spine Center Göteborg carried out 29, Ängelholm 20, Sahlgrenska University Hospital 18, Ryhov 12 and Falun 6 disc replacements.

This analysis compares the 879 disc replacements with 3066 fusions carried out during the same time period. Follow-up data for at least 1 year were available for 670 disc replacements

and 2517 fusions. Table 33 presents follow-up rate at 1 year (FU1), 2 years (FU2) and 5 years (FU5).

Table 33: Follow-up rate FU 1 year, FU2 years & FU 5 years (%)						
Time	Fusion (n=2517)			Disc replacement (n=670)		
	Followed up	Missing	FU%	Followed up	Missing	FU%
FU1	1914	603	76	561	109	84
FU2	1399	745	65	388	133	74
FU3	603	502	56	165	56	75

The follow-up rate is consistently higher for TDR, probably due to the previously mentioned dissertation project carried out during the period. Clearly, a higher follow-up rate can be achieved with greater effort.

Table 34 shows baseline data. Significant differences between disc replacement and fusion patients can be seen in several regards.

Table 34: Baseline - data			
	Fusion	Disc replacement	
	%	%	Chi <sup>2</sup> -test
Woman	53	50	ns
Smokers	16	12	<0.01
Previous back surgery	37	21	<0.001
Full-time sick leave	43	37	0.002
Duration of symptoms < 6 months	23	30	0.002
Duration of symptoms <12 mos	78	79	ns
Other disease	21	15	ns
Pt believes in return to employment	53	75	<0.001
	Unit	Unit	Mann-Whitney /T-test
VAS back pain	64	61	<0.01
EQ5D	0.3	0.4	<0.001
ODI	46	41	<0.001
Age	46	40	<0.001
BMI	26	25	<0.01

## Results

The results are presented in five different ways:

1. Global assessment, which means that the patient answers the question “How is your back pain today compared with before surgery?” and we have calculated the proportion of patients who state they are “pain-free or significantly improved”.
2. Full-time sick leave after surgery.
3. Patient satisfaction with the surgical outcome by asking the question “What is your opinion of the surgical outcome?,” with response options “Satisfied, uncertain, dissatisfied”.
4. Change in quality of life as measured by EQ-5D.

5. Changes in back pain as measured by visual analog scale (VAS).

Tables 35-39 present the results. A significant difference, in favor of disc replacement surgery, was found in all measurements using the Global assessment and the VAS for back pain. No significant difference was found at 5-year follow-up regarding satisfaction with results, nor was any significant difference found in any of the measurements concerning changes in quality of life.

**Table 35: Improvement of back pain as measured by Global Assessment**

Time	Fusion	TDR	Chi <sup>2</sup> -test
FU1	58	68	<0.001
FU2	59	71	<0.001
FU3	58	69	<0.001

**Table 36: Full-time sick leave after**

Time	Fusion	TDR	Chi <sup>2</sup> -test
FU1	20	7	<0.001
FU2	15	7	<0.001
FU3	8	8	ns

**Table 37: Percentage of patients (%) "satisfied with the surgical outcome"**

Time	Fusion	TDR	Chi <sup>2</sup> -test
FU1	69	77	<0.001
FU2	71	78	<0.001
FU3	69	75	ns

**Table 38: Change in quality of life (a) as measured by EQ-5D after surgery**

Time	Fusion	TDR	Mann-Whitney T-test
FU1	0.28	0.31	ns
FU2	0.29	0.3	ns
FU3	0.28	0.31	ns

**Table 39: Change in back pain (a) as measured by visual analog (VAS)**

Time	Fusion	TDR	Mann-Whitney T-test
FU1	-29	-35	<0.001
FU2	-29	-33	<0.01
FU3	-28	-34	<0.04

Figure 36 measures the rate of the responses "Pain-free/Significantly improved" on an annual basis at 1-year follow-up to ascertain whether any change in outcome occurred over time. No

clear trends regarding changes were found when comparing fusion and disc replacement surgery.

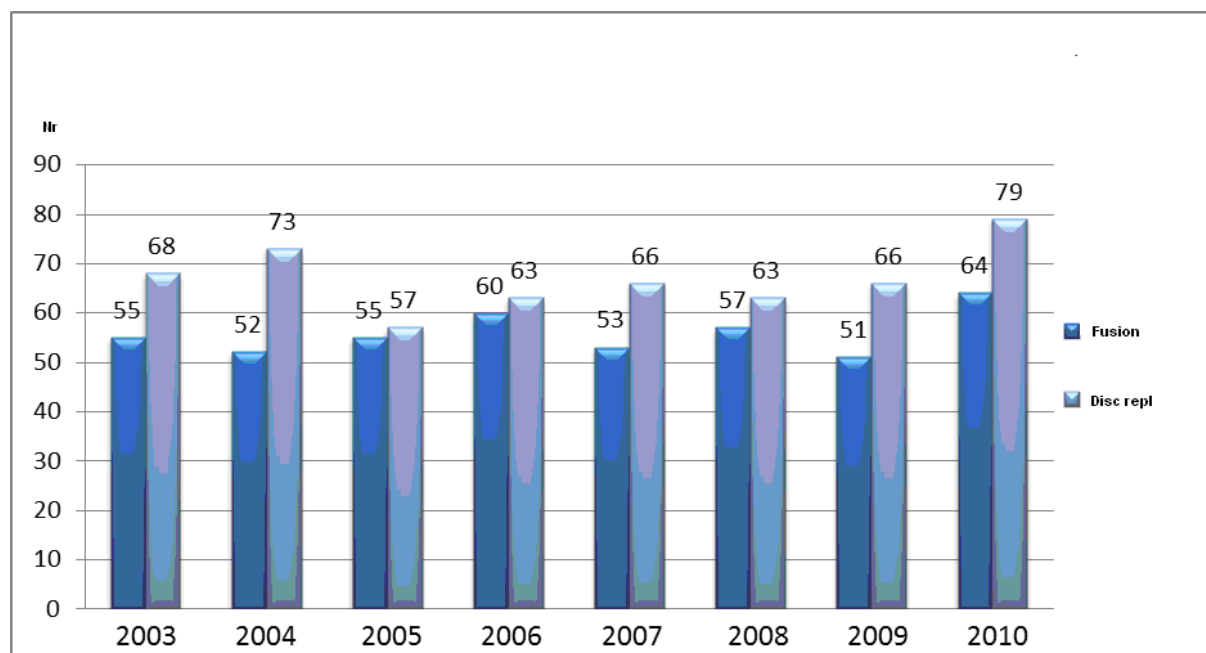


Fig 36. Improvement of back pain as measured by Global Assessment.

Table 40 compares the two surgical methods regarding the proportion of patients who state that they are worse at 1-year and 2-year follow-up than they were prior to surgery. The comparison shows a trend toward fewer patients who rate their status as worse after disc replacement surgery than after fusion.

Surgery year	Fusion		Disc replacement	
	FU1year	FU2years	FU1year	FU2years
2003	6	5	2	0
2004	8	5	2	4
2005	8	8	9	6
2006	7	7	0	1
2007	8	6	3	2
2008	8	6	5	5
2009	5	5	4	3
2010	6	3	3	0

### *New index operation and reoperation*

The term “new index operation” refers to a new operation carried out to address a new diagnosis in a different segment from prior surgery. Reoperation refers to a repeat procedure in the previously operated segment. In the fusion group, 457 of 3066 (15%) patients underwent a new fusion procedure in an adjacent segment. A new disc replacement procedure was carried out in 79 of 879 cases (9%).

Tables 41 and 42 present data about reoperation after disc replacement surgery. The type of operation carried out in the group “Other procedure” cannot be ascertained from the register,

but in the majority of cases likely refers to posterior surgical fusion. A total of 28 reoperations (3%) were carried out. In the fusion group, 427 reoperations (14%) were carried out, including 226 surgeries with removal of implant. If these are excluded, the remaining 177 (6%) reoperations were carried out because of complications.

Table 41: Reoperation after primary disc repl	
Reason	Number
Repositioning of prosthesis	4
Removal of prosthesis	1
Reoperation of dural damage	1
Other procedure	22

Tabel 42: Reoperation because of complication		
	Number of reop	%
Fusion, reop total	427	14%
Fusion, implant removal	226	7.4%
Fusion, other reop	201	6.6%
Disc replacement	28	3%

In tables 43 and 44, baseline data suspected of influencing surgical outcome were assessed at all 3 follow-ups using a multivariate regression analysis, both in relation to Global Assessment and in relation to satisfaction with surgical outcome. Surgical procedure (disc replacement or fusion) was entered as an independent variable. Several of the variables correlated significantly at several follow-ups, but surgical procedure showed no significant correlation at any of the follow-ups. Previous back surgery, ODI and the patient's own belief in the possibility of returning to work postoperatively correlated significantly with the results at all 3 follow-ups.

Table 43: Multivariate regression analysis of factors with possible influence on surgical outcome. Dependent variable = Global Assessment (0 = pain-free/significantly improved, 1 = not pain-free/significantly improved)						
	FU1		FU2		FU5	
	OR	p	OR	p	OR	p
Men	0.74	0.001	-	ns	-	ns
Smokers	-	ns	-	ns	2	0.002
Previous back surgery	1.8	<0.001	1.6	<0.001	1.6	0.006
Duration of symptoms	1.3	<0.001	1.4	<0.001	1.6	0.02
Age	-	ns	-	ns	-	ns
Does not expect to return to work	1.2	<0.001	1.3	<0.001	1.2	0.002
Surgical technique	-	ns	-	ns	-	ns
ODI	1.02	<0.001	1.02	<0.001	1.03	<0.001

Follow-up Fusion: FU1year: 1725, FU2years: 1285, FU5years: 545  
Follow-up Disc Replacement: FU1year: 575, FU2years: 424, FU5years: 197

**Table 44: Multivariate regression analysis of factors with possible influence on surgical outcome.**  
 Dependent variable = "Satisfied with surgical outcome" (0=Yes, 1=No)

	FU1		FU2		FU5	
	OR	p	OR	p	OR	p
<b>Men</b>	0.7	<0.001	0.7	0.004	-	ns
<b>Smokers</b>	-	ns	1.4	0.03	-	ns
<b>Previous back surgery</b>	1.8	<0.001	1.4	0.005	1.8	0.001
<b>Duration of symptoms</b>	1.3	0.006	1.4	0.002	-	ns
<b>Age</b>	-	ns	-	ns	-	ns
<b>Does not expect to return to work</b>	1.1	<0.001	1.2	<0.001	-	ns
<b>Surgical technique</b>	-	ns	-	ns	-	ns
<b>ODI</b>	1.02	<0.001	1.02	<0.001	1.03	<0.001
<i>Follow-up Fusion: FU1year: 1698, FU2years: 1276, FU5years: 540</i>						
<i>Follow-up Disc Replacement: FU1year: 572, FU2years: 421, FU5years: 195</i>						

### Discussion

The documentation and follow-up rate are good for the results reported at 1-year and 2-year follow-up, while the statistical base is smaller for the 5-year follow-up, which is why the interpretation of 5-year results is much more uncertain. However, the results at 1 and 2 years for patients who undergo disc replacement are significantly better in many respects than for patients who undergo fusion surgery. The finding that there was no difference in change (improvement) of quality of life may be explained by the fact that disc replacement patients begin at a higher level and therefore end at a higher level of quality of life. Also in regard to incapacity to work, disc replacement patients fare better than fusion patients.

The multivariate analysis also shows that surgical procedure seems to be less important than several individual-dependent factors. Nevertheless, surgical method should not be construed as irrelevant. However, it does express the differences in case mix between the two surgical groups. Patients who are candidates for disc replacement are a subgroup among those diagnosed with segmental pain with other prognostic factors than patients who are candidates for fusion and in our register study, there is a selection process before surgery which most likely influences the outcome in favour of TDR.

The results support the conclusion that TDR works as well as fusion in patients with lumbar pain due to degenerative disc disease. However, it must be underscored that patient selection appears to be more important than surgical method, and that TDR candidates have a better initial status than fusion patients as a group. This assessment applies to one-year follow-up. Data from subsequent follow-ups are still insufficient. Problems with reoperations in the aftermath of surgical procedures for DDD, regardless of method, can still be seen and have not yet been resolved. It should also be noted that most TDR surgeries were performed at one clinic by the same surgeon, which is why the generalizability of these results must be questioned..

TDR may be a viable alternative to fusion in a small group of patients with chronic low back pain who meet strict selection criteria; however, the final comparison cannot be based solely on registry data, but also requires prospective randomized studies.

## IX. Number of registered operations and follow-up rate

The number of patients entered in the surgery register for degenerative lumbar disorders has steadily increased in recent years, as illustrated in Figure 37.

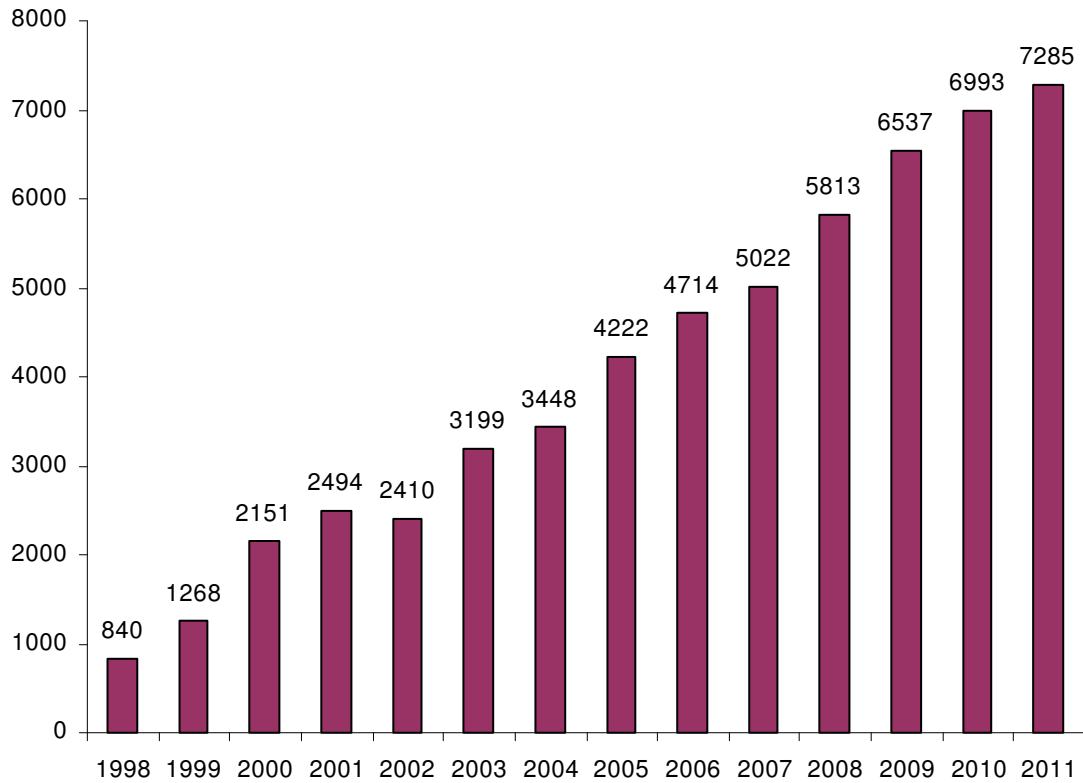


Fig 37. Number of patients entered in the register for degenerative disorders of the lumbar spine 1999-2011.

Figure 38 below shows the follow-up rate at 1 and 2 years for patients operated in 2009.

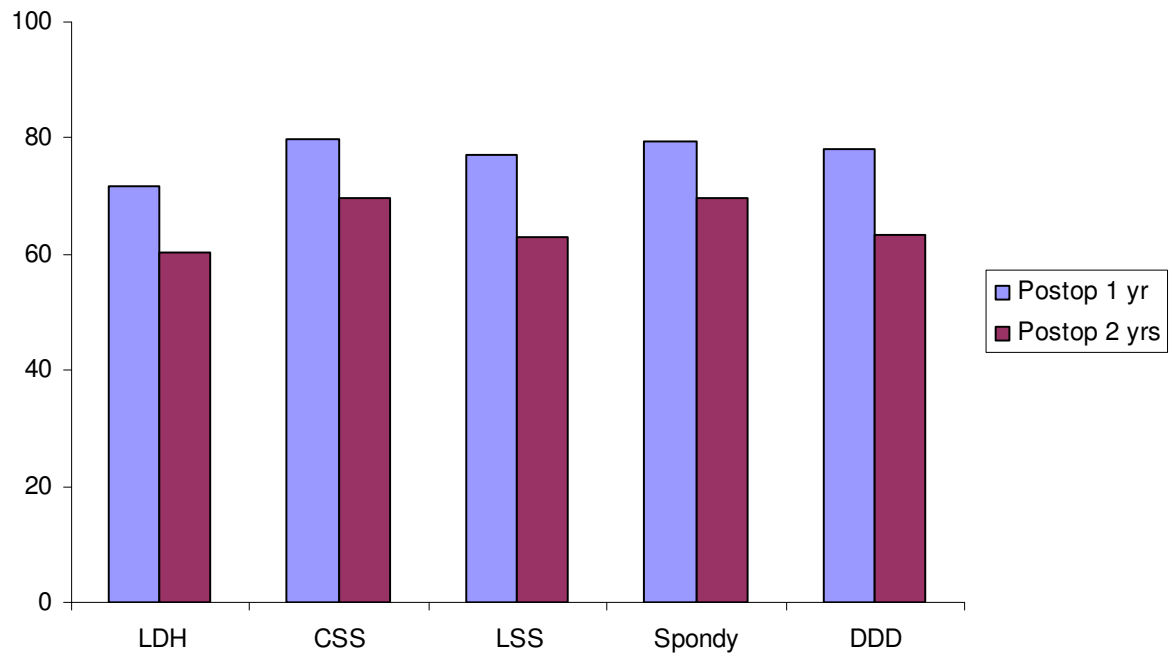


Fig 38. Current follow-up rate.



## **X. Conclusion**

Once again the mega effort by register doctors, secretaries and patients has resulted in a comprehensive annual report from Swespine. The disc replacement analysis answers some questions, while raising others and we will return to this subject in the future. As the quantity of data from other diagnoses grows, their contribution will make the Swespine spine surgery register even more interesting in the future.

Once again, the number of procedures entered in the register has set a new record in 2011, while the follow-up rate remains largely unchanged. Through the newly launched Register Center, which will assist with collection and entry of follow-up data, it is our top priority to further improve the rate of follow-up.

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