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Complications in lumbar fusion surgery for chronic low back pain: comparison of three surgical techniques used in a prospective randomized study. A report from the Swedish Lumbar Spine Study Group

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Abstract The reported complication rates after various surgical techniques used to create a lumbar fusion vary within wide ranges. In a previous paper, the Swedish Lumbar Spine Study Group have reported on the clinical outcome of lumbar spine fusion for chronic low back pain in a comparably homogeneous patient population where there were no significant differences between baseline sociodemographic, clinical and paraclinical characteristics. In this report we compared the complication rates of the surgical procedures used in that study and analyzed the association between complications and baseline variables, and between outcome results and complications. A multicenter randomized study was conducted where 211 patients aged 25–65 were treated with lumbar fusion according to three different surgical techniques: noninstrumented posterolateral fusion (PLF, $n=71$), instrumented posterolateral fusion (VSP, $n=68$), and in the third procedure we added an interbody fusion with solid autogenous bone grafts (“360”, $n=72$). We categorized complications as: early/late, major/minor. The association between complications and sociodemographic characteristics (age, gender, comorbidity, previous surgery, smoking), and technical variables (surgical technique, levels fused, hospital category) was analyzed. The association between outcome variables (patient

global assessment, pain, disability, depressive symptoms) and complications was analyzed. A literature review was conducted. There was no mortality. There was no significant difference in clinical outcome between the surgical groups after 2 years, although the power to detect such a difference was low. The total complication rate after 2 years in the PLF group was 12%, compared with 22% in the VSP group, and 40% in the “360” group ($P=0.0003$). After exclusion of complications, there was still no difference in outcome between the groups. The odds ratio (confidence intervals) of having a complication was 5.3 (2.2–12.7) when “360” was used compared with PLF, and 2.4 (1.1–5.3) for “360” compared with VSP. There was no association between clinical outcome and complications on a group level. The reintervention rate was 6% in the PLF group, 22% in the VSP, and 17% in the “360” group ($P=0.020$). The odds ratio (confidence intervals) of having a reintervention was 4.0 (1.3–11.9) when instrumentation was used compared with non-instrumented fusion. In this prospective randomized study comparing three lumbar fusion techniques in a comparably homogeneous patient population, complications increased significantly with increasing technicality of the surgical procedure. Even though we did not find a significant association between clinical outcome

and complications after 2 years, the increased morbidity inflicted on an individual patient was not negligible. In this light, and as no fusion technique produced superior clinical outcome irrespective of whether complications were included or excluded in the analyses, the patient and the

treating physician should carefully discuss the possible advantages and drawbacks of the different surgical options before making a decision. In order to make valid comparisons of both complication and reintervention rates after lumbar fusion, there is a need for a consensus in the spinal so-

ciety regarding the definition of these entities.

Keywords Chronic low back pain · Lumbar fusion · Surgical treatment · Complications · Reoperation

Introduction

Lumbar fusion is used increasingly often to treat different degenerative spine conditions, and a variety of surgical techniques have been performed during the last century. No particular technique has as yet been demonstrated to yield superior results [19, 23, 42, 55], and all techniques are associated with complications [2, 3, 5, 10, 12, 13, 21, 32, 36, 37, 38, 43, 44, 55, 60]. Added to the sometimes unsatisfactory clinical results when used in chronic low back pain (CLBP), this has created a debate over the surgical treatment of these conditions [3, 23, 41]. The possible clinical benefits of surgery must outweigh the

potential drawbacks of complications and reinterventions [22, 31, 38]. Many authors argue that the reported complication rates after instrumented lumbar fusion in chronic low back pain can be justified in light of the potential gains for these often severely disabled patients [4, 7, 16, 43, 47, 62], while others are more doubtful [13, 41, 44, 59].

In order to report on complications in a reproducible and comparable way, the concept needs to be defined. This has proven to be difficult, and the conditions that should be considered as complications often depend on the personal opinion of the physician, while the reported complication rates after lumbar fusion vary within wide ranges. A complication may be described as “any unin-

Table 1 Literature review of complications and reoperations associated with spinal surgery for comparable diagnoses causing lumbar pain (CLBP) [*RCT* randomized controlled trial, *SL(d)* de-

generative spondylolisthesis, *SL(i)* isthmic spondylolisthesis, *SS* spinal stenosis, *NO* no instrumentation, *I* instrumentation]

Clinical studies	Design	Diagnosis	Surgical technique	Complications % per technique	Reoperations % per technique	Follow-up (years) ^b
Bridwell et al. 1993 [6]	RCT	SL(d)	NO/I	20/17	10/4	4
Fischgrund et al. 1997 [16]	RCT	Various	NO/I	Very few	6/9	3
France et al. 1999 [17]	RCT	Various	NO/I	Very few	7/12	6
Greenough et al. 1998 [24]	Prospective	Various	I	13	16	2
Grob et al. 1995 [25]	RCT	SS	I	30	17	3
Katz et al. 1997 [33]	Prospective	SL(d)	NO/I	Not stated	10/11	2
Möller and Hedlund 2000 [40]	RCT	SL(i)	NO/I	3/14	0/11	2
Ohlin et al. 1994 [43]	Retrospective	Various	I	44	40	5
Okuyama et al. 1999 [44]	Retrospective	Various	I	51		6
Steffee and Brantigan 1993 [48]	Prospective	Various	I	27	24	2
Suk et al. 2000 [51]	Prospective	Various	I	12		2
Thomsen et al. 1997 [53]	RCT	Various	NO/I	6/22	5/11	2
Population studies		No. of patients				
Deyo et al. 1992 [10]	Cohort/1016	Various	NO/I	19		Early ^c
Deyo et al. 1993 [11]	Cohort/317	Various	NO/I	16	12	4
Malter et al. 1998 [38]	Cohort/347	Various	NO/I	18	18	Early ^c /5
Yuan et al. 1994 [62]	Cohort/2633	SL(d)	NO/I	1:2 ^a	15/18	2
Reviews		No. of papers				
Esses et al. 1993 [13]	Survey	Various	I	27	10	1
Mardjetko et al. 1994	15	SL(d)	NO/I	0/10		
Nachemson 1996 [41]	151	Various	I	20–25		
Turner et al. 1992 [55]	47	Various	NO/I	1–43	8	4–14

^a Approximate ratio NO:I

^b If a range was reported, we used the highest number

^c “Early” = hospitalization period after fusion

tentional development during or after a surgical procedure” [9], and although this broad definition has advantages and is simple and understandable, it means that a wide variety of even minor events that may not mean anything to the patient may be reported.

In the present study, we have chosen to define a complication as “any relevant unintentional development negatively interacting with the surgical procedure and/or the expected mobilization and rehabilitation of the patient after surgery”.

A literature review was undertaken. We included 12 studies from 1990 and onwards where we could assess the complications and/or reoperation rates in a reasonably comparable way. Four reviews and three cohort studies were included as well (see Table 1).

The main aims of this randomized study, conducted on a comparably homogeneous patient population with CLBP were:

- To report the total number of complications and specific complications in three lumbar fusion techniques
- To evaluate the association of complications in lumbar fusion surgery with baseline characteristics and with the technical aspects of surgery
- To evaluate the association of outcome results with complications
- To compare our results with other studies

Materials and methods

From 1992 through 1998, a total of 294 patients aged 25–65 and suffering from CLBP were assigned, using a computer-generated random list, to one nonsurgical group ($n=72$) and three surgical groups ($n=222$). The patients were referred by primary care physicians and other clinicians to 19 orthopedic departments participating in the Swedish Lumbar Spine Study [18, 19, 27].

There were 18 patients who did not comply with the randomization to surgery, and seven in the control group who insisted on surgery. Therefore, in this study, 211 surgically treated patients were analyzed for complications and reoperations. Group 1 ($n=71$) was treated with posterolateral fusion (PLF) without internal fixation [57], group 2 ($n=68$) with PLF + variable screw placement (VSP) [49], and group 3 ($n=72$) with PLF + VSP + interbody fusion, a circumferential fusion (“360”) [34] (see Fig. 1).

The ethics committees at all participating universities approved the study. All patients gave informed consent and all pretreatment questionnaires and protocols were completed prior to randomization.

Inclusion criteria

The criteria for inclusion in the study were:

- Patients between 25 and 65 with severe CLBP assessed by the treating surgeon as emanating from L4-L5 and/or L5-S1, and with no specific signs of nerve root compression.
- Pain duration of at least 2 years, and no obvious ongoing psychiatric illness.
- The patient must have been on sick leave (or have had equivalent pain and disability) for the last year and conservative treatment and life adjustments must have been tried unsuccessfully.
- Degenerative changes (spondylosis) on plain radiographs and/or computed tomography (CT), and/or magnetic resonance imaging (MRI).

Randomized to surgery

Postero Lateral Fusion (PLF)
PLF+VSP (internal fixation)
PLF+VSP+ALIF/PLIF (“360”)

Group changers

Patients actually operated on
(included in this study, $n=211$)

Early complications,
Hospitalization (approx 2 weeks)

Late complications,
Remaining time period till 2 years

Total complications after two years, 25%

Fig. 1 Complications in the Swedish Lumbar Spine Study

ing (MRI). No specific radiological findings such as isthmia spondylolisthesis, spinal stenosis, new or old fractures, infection, inflammatory process, or neoplasm. The presence of a disc herniation was allowed in the absence of clinical signs of nerve root compression.

- No previous spine surgery except for successful removal of a herniated disc more than 2 years before entering the study and with no persistent nerve root symptoms ($n=37$).
- A good understanding of the Swedish language.

Two spine surgeons had to agree independently on the eligibility and inclusion criteria for each patient.

There was no difference in baseline characteristics among the groups [19].

Surgical procedures

A total of 26 experienced spine surgeons from 19 orthopedic departments performed the different procedures. In 1992, all these surgeons routinely performed instrumented posterior fusions and the technical aspects of the different procedures were discussed thoroughly to ensure, as far as possible, that the same routines would be followed at the different centers. No patient was operated on by a surgeon who was unfamiliar with the technique. The patient was positioned according to local preferences in a prone position. Autologous bone harvested from the iliac crest (donor site front or back according to the procedure) was used in all cases. In the PLF group, bone was placed on decorticated transverse processes and facet joints bilaterally. In the VSP group and the “360” group, the fusion was supplemented with the VSP instrument, a device consisting of pedicle screws and open bendable plates (DePuy Acromed, Raynham, Mass.). Pedicle screw insertion was guided by imaging, and the plates were applied according to the technique of Steffee et al. [49]. The interbody procedure in the “360” group included either an anterior lumbar interbody fusion (ALIF) [28] ($n=54$), or a posterior lumbar interbody fusion (PLIF) [8] ($n=18$), according to the preferences of the surgeon. In

addition to the posterolateral fusion and VSP, as much disc material as possible was removed between the vertebral bodies both laterally and centrally, and the endplates were prepared using the VSP instruments to create an adequate subchondral support for the grafts. The tricortical bone blocks were inserted under slight distraction and then compressed during the instrument locking procedure. No spacer was used in any of the cases and patients in all groups were fused in situ with no intention of decompression. When the ALIF was used, the patient was operated on from the back and front as parts of the same procedure. After surgery the patients were ambulating within a couple of days. If no instrumentation was used the patients wore a rigid plastic corset, otherwise reinforced canvas, day and night for 5 months postoperatively.

Clinical outcome

The clinical outcome, reported in greater detail in a separate report [19], was assessed with questionnaires completed before surgery and after 2 years in 208/211 patients. Evaluations were made of back pain (VAS) [29], disability (Oswestry Disability Index, General Function Score) [14, 26], and depressive symptoms (Zung Depression Scale) [63]. We also included the patient global assessment of treatment result after 2 years, expressed as: “much better”, “better”, “unchanged” or “worse”. All surgical procedures significantly decreased pain and disability, with no significant difference between the groups. The patient assessed themselves as improved (“much better” or “better”) in 60% in the PLF group, 68% in the VSP group, and 60% in the “360” group. There were no significant differences in clinical outcome among the participating departments, nor were there any differences regarding results when the departments were categorized according to “University Hospital status” ($n=8$), and “County Hospital status” ($n=11$). There was no detectable learning curve in this series, as there was no significant difference in outcome for the first 100 patients (treated 1992–1994), compared with the last 100 patients (treated 1996–1998). The study protocol did not permit comparisons among surgeons.

In this study, radiographic “diagnoses” (broken screws, instrument loosening, dislocation of bone transplant, and pseudarthrosis) that did not cause a specific clinical action (for example a reoperation), or that were not correlated with specific clinical symptoms, were not reported as complications. Uncomplicated urinary tract infection and early-resolving bladder dysfunction were also not included. A “refusion” explicitly stated as caused by a pseudarthrosis was reported as both a complication and a reoperation. In this study, two more complications have been included compared with the study reporting on three surgical techniques [19], one refusion because of a pseudarthrosis in the PLF group, and one nerve root pain in the VSP group.

Analyses performed in this study

Complications

- The treating surgeon reported both complications and reoperations at 6, 12, and 24 months after treatment start, and 23 relevant complications were exemplified in a study guide (see Table 2). In addition, medical records were retrospectively scrutinized for information. Four complication categories were defined:
- *Major*: potentially life threatening or cause of considerable suffering
- *Minor*: reversible relevant minor event/cause of minor suffering
- *Early*: intraoperative or initial hospitalization period following treatment start
- *Late*: time from end of initial hospitalization period

The number of patients with complications was used in the analyses, and not the actual number of complications.

Table 2 Study guide: complications

General	
1.	Mortality
2.	Thrombosis
3.	Hepatitis
4.	Gastrointestinal
5.	Urinary tract infection
6.	Pulmonary complication
7.	Skin problem
8.	Psychological problems
9.	Coping problems
Specific	
10.	Hematoma
11.	Infection superficial
12.	Infection deep
13.	Nerve root injury/pain
14.	Dural tear
15.	Cauda equina syndrome
16.	Injury to sympathetics
17.	Sex-related problems
18.	Retrograde ejaculation
19.	Donor site pain
20.	Miscellaneous
Technical	
21.	Screw placement
22.	Instrument related ^a
23.	Dislocation of transplant

^aBroken screw, instrument loosening

The associations of complications with baseline characteristics were analyzed, and also the associations of complications with technical characteristics. (Fig. 2).

The association between clinical outcome and complications was analyzed as well. We used patient global assessment dichotomized as: “much better – better” versus “unchanged – worse”, and also the change in pain (VAS), disability (Oswestry Disability Index, General Function Score), and depressive symptoms (Zung Depression Scale) Fig. 2.

Fig. 2 Associations between complications and baseline characteristics, and between outcome and complications

Other analyses

- Clinical outcomes among the three surgical groups were compared after complications had been excluded.
- Clinical outcomes within the combined surgical group, and within each of the three surgical groups, were compared between two subgroups: patients without a complication versus patients with a complication.
- Clinical outcomes were compared between relevant groups without a complication and subgroups with different specific complications.

Reinterventions

All reinterventions within 2 years were reported and associated with baseline, technical and outcome variables. In some patients the instrument (hardware) was removed before 2 years because of a suspicion of a pain-generating mechanism, or because the patient wanted it to be removed. These cases were reported as a reintervention, but not as a complication, since it was regarded as a part of the “instrumented fusion concept.”

Comparison with other studies

We compared our complication and reintervention rates with other studies. A restricted search on Medline was performed, and ade-

quate studies from 1990 onwards, where it was considered possible to make relevant comparisons, were included.

Statistical methods

Stepwise logistic regression analysis was used for testing the association between demographic, technical, and outcome variables with complications. The Chi-squared test was used when comparing the association between different categories of complications (early/late, major/minor) and the three surgical groups, and for comparing “improvement” between subgroups within the surgical groups. The Mann-Whitney U-Test and the Kruskal Wallis Test were used when appropriate for comparisons of subgroups within the surgical groups.

Results

There were 211 patients who had a lumbar fusion in this study. In all, 668 pedicle screws were inserted in 140 patients (86 one level and 54 two levels). In the “360” group, 54 patients were treated with an ALIF, and 18 patients with a PLIF. In the former group, there was an additional risk of an injury to the abdominal vessels and to

Table 3 Complications by surgical group (PLF postero-lateral fusion, VSP variable screw placement instrumented posterolateral fusion). The “360” procedure consisted of PLF+VSP+ALIF/PLIF circumferential interbody fusion

	PLF (n=71)			VSP (n=68)			“360” (n=72)			Total (%)	P-value*
	Major (n)	Minor (n)	All (%)	Major (n)	Minor (n)	All (%)	Major (n)	Minor (n)	All (%)		
Early	1	3	6	6	6	18	14	8	30	18	0.001
Late	3	1	6	2	1	4	0	7	10	7	0.414
Total %	6	6	12	12	10	22	19	21	40	25	0.003

*Chi-squared test

Table 4 Complications within 2 years in 211 surgically treated patients (RDS respiratory distress syndrome)

	PLF n=71	VSP n=68	“360” n=72	Total ^d n (%)
Donor site pain (minor)	1	1	7 ^c	9/211 (4.3)
Dural tear (minor)			1	1/18 (5.6)
Injury to viliaca (major)			2	2/54 (3.7)
Gastrointestinal disorder (minor)	1	2		3/211 (1.4)
Infection deep back (major)		4 ^b	1 ^b	5/211 (2.4)
Infection superficial back (minor)	1 ^b	1 ^b		2/211 (0.9)
Injury to sympathetics (minor)			2	2/54 (3.7)
Miscellaneous ^a (major and minor)	1	1	5 (4 ^b)	7/211 (3.3)
New nerve root pain (major)		3 (1 ^b)	7 (2 ^b)	10/140 (7.1)
Pulmonary disorder/RDS (major)			2	2/211 (0.9)
Refusion due to pseudarthrosis (major)	3 ^b			3/211 (1.4)
Screw placement (minor)		1	1	2/140 (1.4)
Skin pressure wound postop (minor)		1	1	2/211 (0.9)
Thrombosis and/or pulmembolus (major)	1	1		2/211 (0.9)
Total number of complications	8	15	29	52/211

^a PLF: 1 winged scapula after surgery (minor); VSP: 1 pain in the arm after surgery (minor); “360”: 1 heart failure (major), 1 injured nerve over anterior iliac crest (major), 1 wrong level (major), 2 hematomas over donor site (minor)

^b Reintervention due to a complication within 2 years

^c All 7 were in the ALIF group where the anterior iliac crest was used (13%)

^d The percentage is calculated as relevant proportions. There were 18 patients in the PLIF group, 54 patients in the ALIF group, and 140 instrumented patients (VSP+“360”)

Table 5 Complications in patients operated with the circumferential “360° fusion” ($n=72$) subdivided into an anterior (ALIF) and a posterior (PLIF) interbody procedure (GI gastrointestinal)

	Major complications	Minor complications
ALIF ($n=54$)		
Early ^a	3 Postop. sensation of nerve root pain 2 Injury to v. iliaca during surgery 2 Nerve root hit by pedicle screw, cause of reoperation 1 Pulmonary edema 1 Aspiration-sepsis-RDS 1 Deep wound infection	2 Hematomas at the donor site 2 Injury to the sympathetics 1 Injured nervus cut. fem. lat. at the donor site 1 Laterally placed screw
Late	—	7 Donor site pain
PLIF ($n=18$)		
Early ^b	2 Postop. sensation of nerve root pain 1 Heart failure + GI bleeding 1 Patient operated at wrong level	1 Dural tear 1 Skin problem on the chin
Late	—	—

^a Early complication rate 16/54 (30%)

^b Early complication rate 6/19 (33%)

the sympathetics, and in the latter there was a risk of dural tear and compression to a nerve root through retraction.

Complications

A total of 52/211 patients encountered 56 complications. Early complications in the three surgical groups (PLF/VSP/“360”), were 6/18/31% respectively ($P=0.001$), and when late complications were included as well (PLF = three refusion and one donor site pain, VSP = two deep infection and one donor site pain, “360” = seven donor site pain), the complication rates were 12/22/40% ($P=0.0003$) (see Table 3). Specific complications for each surgical group are illustrated in Table 4 and Table 5.

Complications and associations with baseline characteristics and technical variables

In a stepwise logistic analysis, complications after 2 years were not found to be associated with baseline characteristics. Among the technical variables, complications were associated with the surgical procedure only. The odds ratio (confidence intervals) for suffering any complication when “360” was used instead of PLF was 5.3 (2.2–12.7), and it was 2.4 (1.1–5.3) when “360” was used instead of VSP (see Fig. 2 and Table 6).

Clinical outcome and associations with complications

There were no significant associations between clinical outcome (global assessment, pain, disability, depression) after 2 years, and complications. When “much better” was analyzed as a dependent variable, there was a tendency that patients with a complication were not in this group ($P=0.052$). A new sensation of nerve root pain was experienced by 10/140 patients in the instrumented groups

Table 6 Association between complications and baseline and technical variables using logistic regression analyses. Only surgical procedure was significantly associated with complications. The odds ratio (OR) for having more complications if one surgical procedure (listed first) was used compared with another are illustrated with confidence intervals (95% CI). Significant associations appear *in bold*

	OR	CI
Total complications		
“360” vs PLF	5.3	2.2–12.7
“360” vs VSP	2.4	1.1–5.3
VSP vs PLF	2.2	0.9–5.7
Early complications		
“360” vs PLF	7.4	2.2–22.7
“360” vs VSP	2.0	0.9–4.6
VSP vs PLF	3.6	1.1–11.7
Major complications		
“360” vs PLF	4.0	1.3–13.0
“360” vs VSP	2.0	0.7–5.8
VSP vs PLF	2.2	0.6–7.8
Early major complications		
“360” vs PLF	16.9	2.2–132.4
“360” vs VSP	2.5	0.8–7.6
VSP vs PLF	6.8	0.8–57.8

(7%), and six of these reported they were “much better” or “better” after 2 years.

Other analyses

- There was no significant difference in outcome among the surgical groups when complications were excluded (see Table 7).
- There was no significant difference in outcome within the combined surgical group, or within the three surgical groups, between the two subgroups: patients without a complication and patients with a complication (see Table 8).

Table 9 Comparison of outcome after 2 years in subgroups of patients with and without complications (*n* indicates number of patients, *asterisk(s)* indicate number of comparisons). Due to small differences and small numbers (low power), there were no statisti-

cal differences between patients with and without complications. Only one complication per patient included in the table (no double counting) (*HW* hardware not removed, *HWR* hardware removed)

	NC all groups ^a (<i>n</i> =156)	Postop infection ^a (<i>n</i> =7)	Donor site pain ^a (<i>n</i> =9)	Other compl. ^a (<i>n</i> =26)	NC instru-mented ^b (<i>n</i> =93)	Nerve root pain postop ^b (<i>n</i> =10)	NC HW ^c (<i>n</i> =84)	NC HWR ^c (<i>n</i> =14)
Improved (%)	65	57	44	69	67	60	66	71
Back pain (VAS)	64–40	60–41	72–63	67–51	64–39	61–40	64–38	61–45
Leg pain (VAS)	36–27	23–25	50–50	27–30	37–28	38–26	36–26	45–36
Oswestry Disability Index	47–34	48–37	50–50	48–39	47–33	51–35	47–32	51–44
General Function Score	48–32	44–31	55–51	53–39	48–30	56–34	48–30	55–38
Zung Depression Scale	38–29	42–34	38–37	39–38	38–30	45–29	37–29	40–42

^{a,b,c} Groups with the same letter were compared with one another. The difference between the percentages “improved” was analyzed with the Chi-squared test; all other differences with the Mann-Whitney U-Test

Table 10 Reinterventions within 2 years

No. of patients (%)	PLF (<i>n</i> =71) <i>n</i> (%)	VSP (<i>n</i> =68) <i>n</i> (%)	“360” (<i>n</i> =72) <i>n</i> (%)	<i>P</i> - value*
All reinterventions	4 (6)	15 (22)	12 (17)	0.020
Hardware removal due to complication ^a		3 (4)	2 (3)	ns
Hardware removal not due to complication ^b		9 (13)	5 (7)	ns

*Chi-squared test

^a Three early screw extractions; two VSP extractions due to a late infection

^b “Hardware discomfort”, or patient wanted the device to be removed

Comparison with the literature

The complication rates reported in other studies vary within wide ranges and are presented in Table 1. The lack of agreement on definitions makes valid comparisons with the present study difficult, but our results are within the range presented in other studies.

Discussion

A major finding of this prospective randomized study was that the complication rates in lumbar fusion increased significantly with increasing surgical technicality in a comparably homogeneous patient group, where the baseline sociodemographic, clinical and paraclinical characteristics did not differ significantly among the groups. This indicates that the increased complication rate depended on the surgical procedure. Complications after 2 years were not found to be associated with any baseline sociodemographic characteristics (including smoking), but only with the surgical procedure, where the difference was explained mainly by the early complications.

Another finding was that outcome expressed as the patient global assessment, as well as reduction of pain, disability, and depression, was not significantly associated with complications or reinterventions (see Fig. 2). There was a tendency for patients who assessed themselves as “much better” to have fewer total complications than those who did not, but there was no such tendency when we analyzed major complications. As the risk of additional morbidity is a matter of concern when discussing different surgical treatment options, this finding was somewhat comforting, and may be important when discussing the indications for surgery. It is of course possible that either the outcome measures used, or the fact that they (with the exception of pain registering) were used only after 2 years, did not allow for capturing complication-related suffering encountered maybe several months earlier. Also, this was on a group level and some individual patients did suffer from longstanding morbidity due to iatrogenic injuries, or other complications inflicted through surgery.

Coding classification systems like the ICD-9-CM have been used to estimate complication rates by researchers such as Deyo et al. and Malter et al., who investigated the complication and reoperation rates in lumbar spine surgery using observational hospital databases in cohort studies. They found a complication rate after various lumbar fusion procedures of 16–19% in three study populations of approximately 300 to 1000 patients [10, 11, 38]. However, the use of this classification system did not allow for assessing the severity of symptoms or assessing patient baseline characteristics, symptom relief or functional status. It is quite probable that patients differed in relation to their suffering, and that the treating surgeon identified differences in clinical picture that they believed justified a fusion procedure. Although the authors tried to correct for these shortcomings by multivariate analyses and stratification, they end their paper reporting on the 5-year follow-up: “Because of the limitations inherent in analyzing administrative and observational data, random-

ized trials should be conducted to compare the complications, reoperation rates, and other outcomes associated with fusion and non-fusion lumbar surgery in homogeneous groups of patients.” [38]. This was done in the present study and we found comparable early complication rates: 18% compared with 19% (Table 1, Table 3).

In the literature, definitions of a complication range from nerve root injuries and postoperative infection to increased costs and steep learning curves for certain procedures [31]. The lack of agreement of definitions makes statistical comparisons difficult, and one reason for maybe not reporting on all complications may be due to this lack of agreement. We believe that to be meaningful to clinical practice and hence promote adequate registration, a definition must fulfil the criteria of being “relevant” to all involved actors.

The definition used in the present study meant that the physician must decide on the relevancy of an unintended event before it was labelled as a complication, and we find that this is in line with the concept of “meaningfulness”. Using this definition, there was no significant difference in outcome between the surgical groups after 2 years, independently of whether complications were included [19] or excluded from the analysis (Table 7). This rather contradicts the hypothesis that if complications can be eliminated, the technically advanced procedures would yield superior results in this patient category. It should be remembered though that, due to a combination of small differences in outcome between patients without complications and patients with a complication and the fact that there were relatively few patients in the analyses, the power to demonstrate differences as significant was low. We proceeded all the same with comparisons between the patients without complications and subgroups with specific complications (infection, donor site pain, postoperative nerve root pain, and other complications). We believe that it may be interesting to reflect over the outcome in these subgroups expressed as “improvement”, as well as over the preoperative and “2-year values” for pain, disability and depression (see Table 9). These figures should, however, be regarded only as hypothesis generating.

The reported number of complications in this study may be an underestimate according to the opinion of others, as we have kept “relevant complications” in mind. For example, some patients had a urinary tract infection and some had an early-resolving bladder dysfunction in connection with the surgical episode, but none of these were considered as relevant to the patient in the circumstances. We also did not record any obvious sex-related complications, although such have been reported after anterior lumbar spine surgery in particular [54, 56], and this complication may warrant a separate approach to be analyzed.

Donor site problems were reported in nine cases, seven of these in the ALIF group ($n=54$) where the anterior iliac crest was used for bone harvesting (13%) and only 2/139

where the posterior iliac crest was used. Several authors have reported that both the posterior iliac crest [15] and the anterior crest [52] may be a source of “post-harvesting morbidity”, while others consider this problem as minor [46]. However, the problem is recognized, and more or less successful attempts to minimize this inconvenience have been proposed [50, 58]. In the present study, reported donor site pain after 2 years was associated with more back pain both before and after fusion, and 4/9 patients with this complication (44%) reported they were improved after 2 years (see Table 9). The finding should be viewed in the light that few patients with donor site pain were recorded. Probably, donor site discomfort in several patients was regarded as “not relevant”, and had these minor problems been included, the reported outcome (“improved”) would have been better in this subgroup. There is a possibility, however, that a patient with more severe preoperative pain is more vulnerable to suffering from this complication.

A new sensation of nerve root pain was experienced in 10/140 patients in the instrumented group (7%). Although six of these patients were in the improved group (“much better” or “better”) after 2 years, the possibility of inflicting a nerve root injury when using instrumentation or when entering the spinal canal has to be considered when discussing indications for surgery and deciding on surgical technique.

The patients in the study received prophylactic antibiotics. All the same, the infection rate was 7/211 (3.3%), which is comparable to other series [1, 45]. Two infections were “early superficial” (one in the PLF group and one in the VSP group), and three were “early deep” infections (two in the VSP group and one in the “360” group). They were all treated with debridement and healed successfully without removal of any hardware. Others have described this strategy [45], and we found it defensible providing an early and aggressive debridement is performed. Two “late deep” infections (at between 1 and 2 years) in connection with the device occurred in the VSP group, and the instruments were removed with subsequent healing. One of these patients reported being “improved” at the 2-year follow-up.

In all, 2/54 patients were reported to have sympathetic dysfunction in the ALIF group. Both patients improved with time, although both claimed to have some residual problems at the 2-year follow-up. This specific complication was reported by Viswanathan in 6/60 patients treated with non-instrumented ALIF, and the authors suggested that this complication may be underestimated and a cause of persistent discomfort after anterior lumbar fusion surgery [56]. They also reported an overall complication rate of 40%, but suggested that this may be due to strict definition criteria, and that most complications were minor and resolved over time without long-term sequelae. This line of argument accords with other authors who have reported high complication rates [43, 44].

A pseudarthrosis is difficult to assess on radiographic imaging [30], and furthermore seems to be poorly associated with clinical outcome [23]. Therefore we considered a pseudarthrosis to be an “unintended event” which must be expected in a certain percentage of fusion procedures, and a complication only when it was used as the cause of a refusal. The mean outcome for the three patients who were refused (all three in the non-instrumented PLF group) was not worse compared with patients without complications after 2 years.

In all, there were 668 pedicle screws inserted in 140 patients (86 at one level and 54 at two levels). There were five radiographically detected and also reported misplaced screws (0.7%). Three screws seen to penetrate the medial pedical cortex were removed because of a new nerve root pain, and these patients reported an outcome after 2 years in line with mean values. Two screws penetrating the lateral pedicle cortex were left in place as they were assessed as being of no clinical relevance. Probably the number of misplaced screws is an underestimation, as others have reported higher numbers using different radiographic imaging than used in the present study [61], and the risk of inflicting nerve root injury when using pedicle screws has led to the development of computer-guided imaging. Laine et al. reported a risk of 13.4% of pedicle perforation without guidance, and 4.6% with the help of an optoelectronic navigation system. Pedicle perforation greater than 4 mm was found in 4/277 patients where no guidance was used (1.4%) [35]. However, it must be emphasized that the present study was not designed to detect specific technical unintended events not considered relevant to the clinical outcome.

In the present study there were approximately three times as many complications in the instrumented group compared with the non-instrumented fusion. Similar results have been reported in the literature, and according to a careful interpretation of the studies included in the review, there were at least twice as many complications when instrumentation was used compared with non-instrumented fusion (see Table 1). A similarly careful estimation by one of the authors (P.F., using medical records), indicated that about 20 patients (9%) could have been experiencing persisting inconvenience at the time of the 2-year follow-up, or had had major inconvenience over a considerable time during the 2-year period following treatment start, which could be related to a complication: five deep infections, five new and persisting nerve root pain, four donor site pain, three pseudarthroses that were reoperated, one winged scapula, one patient operated on wrong level, one injury to nervus cutaneus femoris lateralis. A possible “hardware discomfort” ($n=14$), which

caused removal of the instrument, was not included as a complication as the association between the hardware and pain seems doubtful.

However, most complications in the present study did not seem to be associated with persistent relevant problems after 2 years, and it is important that these drawbacks are viewed in light of both the potential and the real clinical benefit these suffering patients may encounter. Each patient and the treating physician should discuss the potential risks and benefits of a lumbar fusion on an individual basis, as the importance of possible benefits and unintended effects may differ among individuals.

Different perspectives can be applied to the concept of complications. In this study, from the perspective of the patients as a group, there was no significant association between the long-term clinical outcome and any form of complication, whereas complications could cause major morbidity in individual patients. From the perspective of the physician, all three techniques were considered adequate, and most complications, both technical and clinical, were handled without major sequelae for the patient. However, the more advanced procedures included potentially dangerous technical complications, which could increase operation time and cause reinterventions. From the perspectives of health care and society, a complication may increase the burden on the healthcare system and increase costs [20].

Conclusion

In this prospective randomized study comparing three lumbar fusion techniques in a comparably homogeneous patient population, complications increased significantly with increasing technicality of the surgical procedure. Even though we did not find a significant association between clinical outcome and complications after 2 years, the increased morbidity inflicted on an individual patient was not negligible. In this light, and as no fusion technique produced superior clinical outcome irrespective of whether complications were included or excluded in the analyses, the patient and the treating physician should carefully discuss the possible advantages and drawbacks of the different surgical options before making a decision.

In order to make valid comparisons of both complication and reintervention rates after lumbar fusion, there is a need for a consensus in the spinal society regarding the definition of these entities.

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