Michael Pfeiffer
Ralph Hildebrand
Michael Grande
Peter Griss

Evaluation of indication-based use of transpedicular instrumentations with different rigidity for lumbar spinal fusion: a prospective pilot study with 3 years of follow-up

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M. Pfeiffer (✉)
HELIOS Rosmann Klinik,
Zeppelinstrasse 37,
79206 Breisach, Germany
Tel.: +49-7667-84361,
Fax: +49-7667-84109,
e-mail:
michael.pfeiffer@med.uni-marburg.de

R. Hildebrand · M. Grande · P. Griss
Klinik für Orthopädie und Rheumatologie,
Philipps-Universität, Marburg, Germany

Abstract In a prospective cohort study in 94 patients with 3 years' follow-up the efficacy of rigid and semi-rigid transpedicular instrumentation for lumbar spine fusion was evaluated via three established scores. Patient groups were similar in respect of anthropometric data. The indication for using the semi-rigid technique was a fairly stable intraoperative situation; for the more common unstable situations, the rigid technique was chosen. Selecting implant rigidity on these criteria led to results with an improvement

rate well within the upper success range reported in the literature. Among people in employment, a lengthy preoperative sick leave was an important predictor for unsatisfactory outcome.

Keywords Spine · Fusion · Implant · Biomechanics · Flexible stabilization · Follow-up studies

Introduction

Hyper-rigid instrumentation for lumbar spinal fusion is said to promote adjacent segment instability, stress shielding, and retarded load transfer from the implant to the bony fusion mass [3, 5, 7, 10, 14, 19, 20, 22, 23, 35]. Adjacent segment instability is attributed to rigid instrumentation [38]. Conversely, overly flexible instrumentation, particularly of very unstable spines (e.g. high-grade spondylolisthesis), may lead to pseudarthrosis [16]. The rigidity of the instrumentation has rarely been the focus of clinical papers [1, 4, 12, 20, 25, 26, 36], and the question of whether an indication-based choice between different instrumentation rigidities would be beneficial needs to be clarified. Prospective factors for operative outcome should be established.

Materials and methods

Ninety-four consecutive patients (48 male, 46 female), with four different indications for spinal fusion underwent the following protocol between March 1995 and February 1998:

1. Preoperative protocol:
 - i. Detailed patient history and clinical examination with standardized protocols.
 - ii. Radiological examination including anteroposterior and lateral radiographs, and functional X-rays.
 - iii. Functional lumbar myelography with consecutive computerized tomography (CT) scans were performed in all patients with signs of spinal canal stenosis.
 - iv. Functional and pain assessment with three different scores.
2. Intraoperative protocol (i.e. after additional decompression, if necessary): Assignment to rigid or semi-rigid procedure. Rigid segments obtained the less rigid instrumentation, and vice versa.
3. Postoperative protocol:
 - i. Standard radiographs at discharge.
 - ii. Complete file documentation, including operative parameters and complications.
4. One year (maximum) follow-up protocol:
 - i. Clinical examination
 - ii. Standard radiographs; functional radiographs in case of persistent pain.
 - iii. If neurological deficits have developed or changed as compared with those prior to the operation, a neurological specialist examination was included.
5. Three-year (exact) follow-up protocol:
 - i. Patient history and functional/pain assessment with the scores as were used for the preoperative assessment.

Fig. 1 The implant system as used in the study (Dorsal Dynamic Spondylodesis, plus endoprosthesis): tapered slotted screws; one sacral screw without threadless neck; a sample of cable wire strand with end cap to prevent fraying; solid rod of the same diameter; one type of locking nut and three optional washers of different heights. The same screw type was used for all instrumentations

Orthopedic exclusion criteria were as follows: traumatic instability, active infection or tumor of the spine, rheumatoid disorders. On standard radiographs, visible osteoporosis did not, a priori, lead to exclusion, and was not quantified via quantitative computed tomography (Q-CT), Dual Energy X-ray Absorptiometry (DEXA) or sonography.

The implant consisted of self-tapping, full-titanium, tapered 6.5-mm top-loading screws connected with either 5-mm-diameter titanium rods or cables for rigid or semi-rigid transpedicular fixation respectively [27]. Rods or cables could be tilted within the slotted screw head (before final tightening of a locking nut at defined torque) by up to 30° in the sagittal plane using a half-ball-in-socket fixture for three-dimensional alignment (see Fig. 1).

Patients with intraoperatively confirmed or created (e.g. extended facetectomy) overt high-grade instability obtained a rigid procedure with bilateral transpedicular rod instrumentation. Patients with low-grade instabilities, as tested manually, obtained a semi-rigid transpedicular instrumentation with bilateral cables or unilateral rod. If decompression was necessary on only one side, a unilateral rod instrumentation on the same side was favored. Unilateral cable instrumentation was never employed, due to biomechanical reasons (see below). Hence, the study design was not randomized but indication-based.

Bone grafting was always bilateral, in a modified Hibbs' technique without exposure of the transverse processes. The innovative

bilateral cable application could also well be termed "cable-controlled fusion".

The intraoperative manual assessment of stability by the four surgeons involved (one chief surgeon, three consultants) corresponded well with the diagnoses, as can be seen in Fig. 2. Patients with degenerative instabilities underwent rigid and semi-rigid procedures in almost equal proportions. In contrast, patients with proven spondylolysis, who were obviously more unstable, received rigid instrumentation in more than 90% of cases. Patients with spinal stenosis were, not unexpectedly, fairly stable after our decompression procedure, which generally avoids complete laminectomy; they were treated with semi-rigid techniques in more than 80% of cases. The "failed back" group was predominantly treated with a semi-rigid spondylodesis. In this diagnosis, we generally avoid extensive decompressive surgery and scar tissue revisions.

With an axial stiffness of 930 N/mm for bilateral rod use (ASTM Standard), the rod system rigidity was in the lower range of commercially available rigid implants. Additional anterior grafting would add little to the in-vitro stability of comparable constructs, especially in flexion-extension [24].

The results were evaluated via questionnaires, involving the Marburg Score (MS) [28], Aberdeen Score (AS) [34], and a 10-cm visual analog scale (VAS) [18, 33]. The statistical appropriateness of these methods as compared with the well-established Oswestry Score [9, 21] can be derived from Table 1 [30].

If items were not completed by the patient, the maximum possible score was corrected accordingly so that absolute values could be transformed into percentages.

The choice of statistical methods was based upon the results of a previous retrospective study of a series of patients with similar therapy selection criteria. In all the appropriately applied statistical procedures for data analysis, the significance level was generally set to $P < 0.05$, two-tailed. Power analyses were conducted using the GPOWER software [11].

Evaluation of the questionnaires and radiographs, and clinical and statistical assessment were generally carried out by researchers not involved in the operations and therapy assignment.

Results

Perioperative data

Ninety-four patients underwent instrumented fusions; 67 having a rigid and 27 a semi-rigid procedure. There were no significant differences between the two groups concerning the parameters age, body mass index, and postoperative inpatient treatment time, which are listed in Table 2. However, age was positively correlated with postoperative inpatient stay ($r = 0.334$, $P < 0.01$).

The average number of instrumented segments was 1.8; there were slightly more segments involved in the semi-rigid than in the rigid group.

Average operation time *per segment* was 124 min (SD 65.0 min). There were considerable differences between all bilateral (rod or cable) and the unilateral instrumentations ($P < 0.015$ – 0.001), the unilateral being faster.

The price of the implants for a one-segment fusion today amounts in our hospital (for an average screw length of 45 mm) to €1180.00 for bilateral rod, €872.00 for bilateral cable, and €590.00 for unilateral instrumentation. No transverse connectors were used.

Fig. 2 Post hoc assignment of diagnoses to the intraoperatively chosen type of instrumentation. The most unstable situation (cases of spondylolisthesis with spondylolysis) were usually treated with rigid instrumentation. Conversely, the more stable segments (cases of spinal stenosis—in our department patients with spinal stenosis rarely undergo wide laminectomy) received semi-rigid instrumentation

Table 1 Statistical parameters for the applied scores (Marburg score, Aberdeen score and visual analog scale) and for the Oswestry score (for comparison), as known from literature and our own calculations, justifying selection of all three for assessment of pain and functional results

	Marburg Score	Oswestry Score	Aberdeen Score	Visual analog scale
Internal consistency Cronbach's α	0.84	0.77	0.80	—
Validity ^a	n.a.	$r=0.53, P<0.001$	$r=0.71, P<0.001$	$r=0.79, P<0.001$
Test-retest reliability	$r=0.86$	$r=0.94$	$r=0.94$	—
Responsivity	0.88	0.78	0.63	—

^a Validity as measured against the change in Marburg score, measured by linear regression

Table 2 Age, body mass index (BMI) and postoperative inpatient treatment period for all patients enrolled in the study. The average patient was relatively old, indicating a high number of cases of spinal stenosis. There were only a few patients of normal weight included in the study

	Minimum	Maximum	Mean	SD
Age (yrs)	15	82	53.2	13.6
BMI	17	42	26.9	4.2
Postoperative stay (days)	8	37	16.1	5.5

Gender ($\chi^2=0.04$, n.s.) and grafting ($\chi^2=0.38$, n.s.) did not differ between the two groups. All patients obtained bone chips, 80 of them autologous, the others either homologous or mixed grafts.

There was also no difference between the two groups concerning postoperative bracing ($\chi^2=0.61$, n.s.). A total of 85 patients were administered a postoperative orthosis, with an average wearing period of 5 months.

Clinical results

There was a drop-out of 13 patients (16%) in total, the reasons for which are analyzed in detail below. Seventy-nine patients delivered complete forms for calculation of AS changes, 81 patients for MS changes, and 75 for VAS changes.

Whereas preoperatively, 42% of patients were under daily medication with painkillers, at follow-up only 25% took analgesics on a daily basis, while the percentage of patients without any pain medication increased from 28% to 46%. There was no difference in the medication figures between the two different rigidity groups (Fig. 3).

The number of patients with virtually unlimited pain-free walking distance increased from a 5% to 35%, and while prior to operation 56% of the patients had a walking distance of less than 500 m, at follow-up 22% gave this figure in their questionnaire.

The number of patients with strong and permanent back pain was reduced from 53% to 15%. The number of patients

Fig. 3 A marked reduction of analgesics intake towards follow-up in the rigid group is paralleled in the semi-rigid group. (Patients with “on demand” medication are omitted. The percentage of patients they account for can be calculated as follows: 100 minus sum of bars with same style and number)

Fig. 4 There was a strong reduction of back pain in both groups, as can be seen from the shift between the extremes of the pain spectrum. Patients with moderate pain strength and frequency are not depicted, for clarity. Their number can be derived as described in the legend to Fig. 3

either without, or with mild and rare, back pain increased from 9% prior to operation (those who were operated for radicular pain + instability) to 47%. Figure 4 displays the same improvement in this respect for both rigidity groups.

Leg pain was virtually absent in 17% of the patients prior to operation, and in 47% at follow-up. (These percentages were calculated relative to the total number of individual answers obtained for the mentioned items. It

Table 3 High intercorrelations between the applied scores show that pain, which is the only factor measured by the visual analog scale, is also dominant in the two other more function-oriented scores. The negative correlation coefficients between the Marburg Score and the other two scores results from the fact that the latter rate pain and/or disability while the former rates absence of pain and patient performance

	Marburg score change	Visual analog scale change	Aberdeen score change
Marburg score change	n.a. n.a.	$r=-0.705$ $P<0.001$	$r=-0.786$ $P<0.001$
Visual analog scale change	$r=-0.705$ $P<0.001$	n.a. n.a.	$r=0.775$ $P<0.001$
Aberdeen score change	$r=-0.786$ $P<0.001$	$r=0.775$ $P<0.001$	n.a. n.a.

should be borne in mind that some patients did not answer all questions, as explained in the Materials and methods section.)

Sixteen of the 50 patients who had formerly been gainfully employed received payments from pension funds within 3 years of follow-up. Yet only two of the seven women who were compensated were younger than 55 years and only five of the nine compensated men were younger than 60 years, which in Germany is the age limit for early retirement (in case of severe certified disabilities even without reduced pension). Thus, roughly one-seventh of them were pensioned off for disability reasons without having reached the pensionable age limit. Additionally, five patients lost or changed their previous job. At follow-up, two of the latter remained unemployed.

The preoperative MS in the group instrumented with the rigid technique was on average 38.7%, and in the semi-rigid group it was 35.4% of the total possible score. The values at follow-up were 61.3% and 60.4% respectively, showing an improvement in both groups. (The MS, unlike the AS and VAS, is an "ability-based" score, giving an increasing score for better patient performance.)

For the AS, the rigid group scored 43.3% and the semi-rigid group 46.0% preoperatively. At follow-up the values improved to 26.2% and 28.9%.

The 10-cm VAS scores were 8.3 cm (rigid) and 8.2 cm (semi-rigid) prior to the operation. Follow-up values improved to 4.7 cm and 4.9 cm respectively.

All three scores on average showed the same lack of significant between-group differences, and a significant

improvement in the preoperative score towards 3-year follow-up: $P<0.001$. Since all the scores were significantly intercorrelated (Table 3), the AS percentage change (as related to its preoperative value) is presented here *paris pro toto*.

The average AS change as related to the preoperative values amounted to 36.5%, indicating strong improvement. All the values were normally distributed. In 81% of the cases the AS follow-up scores were better than the preoperative ones.

No significant difference between the two differently rigid groups could be detected (Table 4).

Since avoiding a type II error (falsely assuming there was no difference between the groups) was particularly crucial in this design, a compromise power analysis according to Erdfelder [8] was carried out for the small effect size observed here, using the definition $q=\beta/\alpha=0.5$. This yielded a sufficient test power ($1-\beta$) of 0.81.

The search for perioperative predictors via explorative statistics (pilot study, assessment of necessary sample sizes for future studies) yielded the following results.

There was a significant correlation between the duration of preoperative sick leave in employed people and the score improvement at follow-up ($r=-0.32$, $P<0.035$). An attempt was made to confirm the negative predictive value of preoperative sick leave using a linear regression analysis model with an ability to show the observed medium-size effect ($f^2=0.11$) at $1-\beta=0.75$. Unfortunately, due to the small sample size (not all patients had been on preoperative sick leave), an overly high α resulted ($P=0.25$).

We were also unable to predict the outcome from behavioral parameters such as intake of painkillers, preoperative wearing of braces, self-assessment of daily physical workload, and retrospective self-assessment of preoperative pain history. Linear regression analysis also failed to show predictors among four preoperative job situations (unchanged compared to before onset of spine disease, job with reduced workload, loss of job, retirement due to disease).

We also looked for any correlation between change in pain/function scores and the duration of postoperative inpatient treatment in rehabilitation facilities. Improvement in the VAS over time was found to be negatively correlated with the length of stay ($r=-0.27$, $P<0.03$). However, although the trend was similar, correlation with the other scores failed to be significant.

Table 4 A comparison of Aberdeen score changes over the 3-year follow-up period between the rigid and semi-rigid groups shows no significant difference

	<i>P</i>	Mean difference	Standard error of difference	95% confidence interval of difference	
				Lower	Upper
Aberdeen score difference	<0.31	10.68	10.34	-9.91	31.28

Complications

Revisions

A total of four revisions were carried out within the first weeks postoperatively, with a further nine revisions within the following 3 years in a total of 13 patients. The first revisions were all due to soft tissue problems (no infections) and healed uneventfully after debridement. Not every subsequent revision was due to complications of the first operation. Two patients demanded material removal for personal reasons. Four patients developed symptomatic instability of adjacent segments, which was countered by transpedicular fusion of these segments. One patient obtained material removal due to a symptomatic misplacement of one screw. One patient had pseudarthrosis and was treated by non-instrumented fusion. The remaining patient, after loss of deformity correction, underwent circumferential re-operation in another hospital and refused to show up for follow-up (see analysis of drop-outs).

Radiologically detectable complications

Material failure occurred in six cases: three screw breakages, one rod breakage and two loosening of a screw cap, all in the rigid group. These patients did not need revision, because they were asymptomatic. All but one of the above-mentioned nine patients with delayed revision surgery had their complications detected on functional radiographs and/or CT scans. The pseudarthrosis was discovered during material removal, but not on functional radiographs. There was a screw backing out in one patient, and two patients had marked loss of correction (osteoporosis), one of whom (see above) was re-operated for aseptic vertebral body necrosis (M. Kümmell-Verneuil). Retrospectively, it is clear that the patient should have been rejected due to their poor bone stock. The diagnosis of all above-mentioned adjacent segment instabilities was based upon functional radiographs or functional myelographies. A further two adjacent segment instabilities detected in this way have not been treated with further surgery so far. Adjacent segment instabilities occurred in both rigidity groups.

Other complications

There was one patient with a postoperative single nerve root lesion, the reason for which remained unclear. There were no pulmonary embolisms or fatalities.

Analysis of drop-outs and non-responders

Thirteen of 94 patients did not finish the study. Three of them died due to reasons unrelated to the operation. Five

patients could no longer be reached in spite of serious efforts to do so. The remaining five patients were contacted by phone. Three of the five considered their result unsatisfactory, two among them even being involved in malpractice law suits or filing litigation claims. The other two patients were repeatedly summoned, and gave assurances that they would attend for follow-up. However, they proved to be unreliable in this respect. They themselves, however, considered their result satisfactory.

Discussion

Clinical results

A major problem with spine scores is that measuring their difference over time does not in itself reveal whether a given result can be considered sufficient. So they are often broken down into categories such as “good”, “satisfactory”, and “poor”. This assignment is generally done arbitrarily. Classification of results based only on the final score bears the risk of neglecting floor and ceiling effects. Thus, relating the score changes over time to the preoperative values seems the best way to go [21]. We may reasonably assume that a value ≤ 0 on this measurement indicates a treatment failure (no improvement).

At the time of launching the study, the full complement of statistical parameters required for sufficient statistical soundness of the study – encompassing validity, test-retest reliability, responsivity, and internal consistency – were available only for the AS and MS. However, since these scores are less popular, it is difficult to compare the values with other published reports. The more common Oswestry score, on the other hand, has the drawback of not including the socio-economic capacities of the patient [32] and failing to discriminate between leg and back pain.

In a previous (retrospective) study of anterior and posterior fusions [31] and a study comparing prospective with retrospective results in patients treated with pedicle screws [30], the average value for the MS difference over time, and its range, was nearly exactly the same as in this prospective study. In all studies the value differences were normally distributed. Clinical treatment failures as defined above always ranged around 20%. This corresponds well with the often-quoted failure rates of around 30% in spinal fusion operations [37]. The influence of the mostly minor complications (see Results section) could not be quantified in our study design.

In 267 retrospectively analyzed patients with spinal fusions, linear regression analysis revealed that preoperative loss of workplace and long duration of symptoms had some (but not significant) tendency towards poor results at an average of 4 years' follow-up [31]. In the prospective study presented here, the only preoperative predictor for a less favorable clinical outcome was a lengthy period of preoperative sick leave. This accords very well with clinical experience.

At first sight, it was somewhat surprising that being overweight did not statistically correlate with the results. However, only around one-quarter of the patients were not overweight, and 30% of the others were severely obese, with a body mass index greater than 30, the latter being over-represented in this study. This clearly indicates that being overweight may well contribute to the *development* of diseases and/or the *indication* for surgery in the lumbar spine, if not detectably to the outcome of treatment. The number of patients with normal weight in this study was too small for a statistically valid interpretation. Nevertheless, a tendency towards longer duration of post-operative inpatient treatment and operation time among patients who were overweight was noted, plus the fact that the group of patients with more than three segments (average: 1.8) fused had a mean body mass index of almost 30.

The perioperative predictors showed a trend to indicate that a long inpatient rehabilitation correlates with inferior results. This type of rehabilitation is usually administered for corset weaning (several weeks after the operation), or in case of protracted recovery of the patient. Care must be taken not to blame the rehabilitation itself for this effect. It is a well-known phenomenon that patients with jeopardized work ability in our country receive more and longer rehabilitation programs than others. If, after 2 or 3 weeks time, these programs seem to fail, they are usually extended. So the statistical trend may well reflect the predictive value of a long preoperative sick leave in terms of socio-economic secondary gain (compensation claims etc.).

It is noteworthy that the results in the semi-rigid group were no worse than in the rigid group, despite the fact that the former patients had more segments instrumented on average. The potential disadvantage this might have posed for the semi-rigid group was obviously overcome by the choice of implant.

Biomechanics

The influence of implant rigidity on the clinical results in our study was negligible. While this has been shown before prospectively for one-segment [1, 20] and multi-segment [36] unilateral versus bilateral instrumentation, this is the first time it has been proved for semi-rigid *bilateral* instrumentation. Note that the implant in use must not be confused with mere "tension-band" augmentation [6, 15]. The biomechanical characteristics of semi-rigid implants for lumbar *fusion* purposes currently available on the market have occasionally featured at least as a partial aspect of clinical papers [4, 12, 13, 17, 25, 27] and, thus, should briefly be reiterated.

The classification of the implants as "semi-rigid" and "rigid" was based upon the biomechanical two-segment *in vitro* tests for posterior instrumentation after discectomy and partial facetectomy, partly described elsewhere [2, 29].

The rigid bilateral rods stabilized an L3–4 transfixed segment in the primary movement planes, providing 87.3% stability compared to the intact spine in flexion-extension, 86.3% in lateral bending, and 76.8% in axial rotation. The semi-rigid bilateral cable achieved 79.6% stability in flexion-extension, 82.7% in lateral bending, and 51.7% in axial rotation. The semi-rigid unilateral rod gave 59.6% of intact stability in flexion-extension, 64.7% in lateral bending, and 49.6% in axial rotation.

Thus, the cable acts as a tension-band in flexion, but it is also stable in retroflexion due to its inherent buckling resistance. The residual motion after this flexible stabilization is always well below the range of an intact spine.

Some semi-rigid implants cannot be recommended as stand-alone posterior devices due to implant failure (e.g. thin-threaded rods) [17]. This is obviously no problem with the cable system used here.

Semi-rigid implants are not suitable for unilateral instrumentation. A unilateral cable implant would not provide enough rotational stability to the functional spinal segment. This is the reason why all the work on unilateral applications deals with more rigid implants. Yet, when a rigid system is used unilaterally, a semi-rigid segment-implant complex ensues.

However, one may ask: When there is no difference in outcome between unilateral instrumentation with an "ordinary" pedicle screw system and a bilateral semi-rigid system, why take the risk and cost of bilateral instrumentation? The answer is that, unlike unilateral instrumentation, bilateral instrumentation with thick cables allows reconstruction of the sagittal profile, if necessary. It also facilitates coronal re-alignment via tensioning of the convex side of the scoliosis. The cable itself can even withstand possible buckling loads due to its mechanical characteristics. Since pre-bending is not necessary, no stress-risers are created on its surface and insertion is quick and easy. Unlike rods or plates with inserted dynamic elements, it has a narrow profile and allows ample bone grafting. It is highly suitable for *in situ* fusions, and lordosis can be amplified if desired to restore a physiological sagittal profile. This does not have to be done by pulling tight the cables but by approximating the screws, not unlike the way it is done on a rod. In hyperlordosis and high-grade slip, rod instrumentation should be preferred.

The study also shows that semi-rigid implants do not prevent the (rare) occurrence of adjacent segment instability. Obviously, after fusion, implant rigidity does not matter any more in this respect.

Material failure has been more common in the rigid group, begging the question of whether the use of cable implants prevents screw loosening or breakage at the cost of (masked) pseudarthrosis. Our material failure rate was much lower than the one recently reported by Suk et al. in their study of unilateral versus bilateral instrumentation [36]. However, we detected no more pseudarthroses on functional radiographs in the semi-rigid than in the rigid

group. The validity of functional radiographs for detecting residual instability is often discussed. One pseudarthrosis was detected only during revision and not by functional radiography. However, we did not see a general necessity for CT scans in symptom-free patients.

Some argue that residual instability may be a problem that can only be avoided by circumferential fusion [17]. Semi-rigid implants do not preclude additional anterior fusion. However, the usefulness of this procedure was not the focus of this study.

There was not enough material failure in our cohort to allow statistically significant statements about the correlation between radiologically detectable material failure and clinical success.

Conclusions

The results of this prospective study indicate that indication-based semi-rigid instrumentation can achieve clinical

and radiological results equivalent to rigid techniques, while resulting in reduced operating time (in the case of unilateral application) and being cheaper to employ. This may lead to a recommendation for semi-rigid instrumentations for patients with single- and multi-level instabilities without severe spondylolisthesis or loss of anterior column support. Osteoporosis should be an exclusion criterion, at least for rigid instrumentation, in further studies.

For future studies about general success predictors on the basis of linear regression analysis, larger series of patients are necessary, if small effect sizes are targeted.

General considerations about secondary gain and preoperative social situation remain unaffected by the choice of the implant. It is essential to take them into account for successful lumbar spine fusion surgery.

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