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Clinical outcome after spinal fusion with a rigid versus a semi-rigid pedicle screw system

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Abstract Several biomechanical studies have evaluated the quality of fusion obtained with a rigid versus a semi-rigid pedicle screw implant. Some studies indicate that increased rigidity of the implant system results in an increased strength of the fusion mass. Other reports have underlined the risk of stress shielding due to rigid implant systems. Based on these findings some authors have recommended the use of a semi-rigid system. There are, however, few studies focusing on any possible difference in clinical outcome between the two different types of implant systems. Questionnaires were sent to 89 patients who had undergone primary spinal fusion with either a rigid or a semi-rigid pedicle-screw-based implant system. In every case the diagnosis was spondylolisthesis or degenerative lumbar disease. The questionnaires were analysed using forward stepwise logistic regression analysis. Eighty (90%) of the questionnaires were returned. There was

a mean follow-up of 4 years (range 2–8 years). It was not possible to demonstrate any difference in clinical outcome between patients undergoing lumbar fusion with a rigid implant system and those given a semi-rigid system. The overall patient satisfaction rate was 69%, with no difference between the two types of implant. No difference in clinical outcome between the two types of implant was found. Considering the fact that the primary goal of spinal fusion procedure is to obtain a solid fusion mass, biomechanical tests favour the use of a rigid pedicle screw system. This fact combined with the fact that early mobilisation is possible with rigid implants justifies the use of rigid implant systems, although no difference in clinical outcome could be demonstrated in this study.

Key words Outcome · Spinal fusion · Implant · Rigid · Semirigid

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Introduction

Over the years several pedicle screw implants have been developed. Biomechanically, the two main principles of pedicle-screw-based systems can be divided into semi-rigid and a rigid systems. In a semi-rigid system the pedicle screw is placed in an open-holed plate allowing some motion between the screw and the plate. This system was originally described by Roy-Camille [23, 24]. Later Steffee et al. [25, 26] proposed a system using a more rigid plate/screw fixation.

Several rigid systems have been developed [5, 8]. Compared to the semi-rigid systems, the general principle is that the longitudinal part of the implant is a rod rigidly connected to the pedicle screw. This should increase the rigidity of the instrumentation system as a whole, thereby in theory ensuring the fusion process [1]. This has been confirmed in several biomechanical studies showing that increased rigidity of the implant system resulted in increase rigidity of the fusion [7, 11, 16].

However, rigid implants may increase the risk of stress shielding, with a decrease in bone mineral density of the

involved vertebrae. Based on these findings some authors have recommended the use of a semi-rigid system [15, 16].

To our knowledge few studies have described the clinical outcome of spinal fusion procedures focusing on the rigidity of the implant system [28]. The aim of this study was to compare two series of patients undergoing lower lumbar spinal fusion on similar indications, but with two different principles of implant system, and to compare the rate of fusion and long-term clinical outcome.

Materials and methods

Two consecutive series of patients were operated on with lumbar fusion for spondylolisthesis or degenerative lumbar disease. None of the patients had operated on before. In every case the indication for surgery was prolonged pain not responding to conservative treatment, and/or neurological symptoms or back pain resulting in work incapacity. Forty-two patients underwent fusion with a Roy-Camille (semi-rigid) and 47 with a Cotrel-Dubousset (rigid) implant. None of the patients underwent anterior fusion. The characteristics of each series of patients is illustrated in Table 1. Only patients with grade I and II spondylolisthesis according to Meyerding [17] were included in this study, and all were fused in situ with no attempt at reduction. The exclusion of patients with reduction of spondylolisthesis was done because reduction is easier to obtain with the rigid implant system than the semi-rigid system. There was an average follow-up of 4 years (range 2–8 years). A questionnaire was sent to all patients describing medication, vocational status and patient satisfaction.

Fusion was evaluated on plain radiographs at a minimum of 12 months after the operation, classifying each patient as fused/not fused. Fusion was considered solid when bone could be identified between the involved transverse processes or when an oblique view showed fusion of the facet joints [12].

Statistical analysis

Statistical analysis was performed using forward stepwise logistic regression analysis. Outcome was assessed using patient satisfaction and return to work as dependent variables in turn. As inde-

pendent variables the following were used: implant (rigid vs semi-rigid), sex, age follow-up, fusion (fused vs not fused), reduced medication (reduced vs not reduced) and diagnosis (spondylolisthesis vs degenerative). Pain was assessed using the Visual Analogue Scale (VAS). The use of the result in the logistic regression analysis was done after classifying the results of the VAS scale into a rank ordinal scale. Assessment of any possible difference in reoperation rate between the two types of implant was done by defining the dependent variable for reoperation as "reoperated vs not reoperated", and selecting the previously mentioned independent variables.

A *P*-value < 0.05 was considered significant.

Results

Eighty patients returned the questionnaire after one reminder, giving a response rate of 90%. There was no difference in response rate between the two groups, and the non-responders did not deviate from the baseline characteristics of the other patients. The results of the questionnaires are shown in Tables 2 and 3 and Fig. 1. No statistical difference was found between the two types of implant.

The overall fusion rate was 80%, with no statistical difference between the two types of implant.

Eighteen patients were reoperated after an average period of 18 months (range 2–64 months). The indications for reoperation and the surgical findings at reoperation are shown in Table 4. Compared to patients without reoperation, there were no differences regarding primary indication, type of implant, patient satisfaction or follow-up.

Table 1 Patient characteristics (RC Roy-Camille, CD Cotrel-Dubousset)

	Total	Semi-rigid (RC)	Rigid (CD)
Age (years) at surgery (average, range)	44 (18–69)	41 (18–69)	46 (20–65)
Follow-up (years) (average, range)	4 (2–8)	6 (4–8)	3 (2–4)
Women:men	1:1.2	1:0.9	1:1.5
Spondylolisthesis	49	26	23
Degenerative lumbar disease	40	16	24
Fusion from L4 to S1	77	37	40
Fusion from L5 to S1	12	4	8

Table 2 Patients' evaluation of back/leg pain compared to preoperatively (seven patients did not answer this question)

	No. of patients	Semi-rigid	Rigid
Much better	42	19	23
Better	10	6	4
No change	11	5	6
Some worsening	5	3	2
Worsening	5	2	3
Total	73	35	38

Table 3 Reoperations

Indications	Surgical finding at reoperation
Continuing pain with suspected pseudoarthrosis (<i>n</i> = 14)	Pseudarthrosis (<i>n</i> = 4) Pedicle fracture (<i>n</i> = 1)
Severe implant discomfort (<i>n</i> = 2)	Proximal instability above primary fused level (<i>n</i> = 1)
L5 symptoms (<i>n</i> = 2)	Implant removal (<i>n</i> = 12)

Fig. 1 Pre- and postoperative status in 65 patients with complete information about work and sick leave. Arrows indicate the number of patients changing vocational status after the operation. The numbers in brackets show the distribution of implants in patients changing vocational status (RC Roy-Camille, CD Cotrel-Dubousset)

Discussion

In the present study 69% of the patients stated that they were satisfied with the outcome, and no differences in outcome was found between the two types of implant. Comparison of outcome with other studies is difficult, primarily because most studies include patients with primary fusions as well as patients who have had previous spinal procedures. Consequently, a variety of indications is present. This problem has been addressed by Turner et al. [27]. In their meta-analysis of 47 articles on spinal fusion, the indications for surgery included disc herniation, spondylolisthesis, spinal stenosis and segmental instability. Only few studies characterised a homogeneous patient population. An average of 68% of patients undergoing spinal fusion had a satisfactory outcome based on the surgeon's classification into excellent, good, fair and poor. According to Turner et al. [27], the outcome in most studies was classified by the surgeon. This makes it likely that an overall satisfaction rate of 68% is an overestimate. This was confirmed by the studies in which the patients classified the outcome. In these studies the average satisfaction rate was 61%.

To our knowledge only one study has compared the clinical outcome between semi-rigid and rigid pedicle screw systems. In a randomised study Zdeblick [28] compared lumbosacral fusion with no instrumentation, a semi-rigid pedicle screw/plate device and a rigid pedicle screw/rod system. There was no significant difference in clinical outcome between the three groups, but there was a tendency towards improved clinical outcome comparing the rigid and the semi-rigid system: 95% and 89% respectively. The criteria for the classification "excellent" were pain-free and return to previous occupation. The criteria for the classification "good" were mild backache, non-narcotic medication and return to full-time work. Therefore, these results cannot be compared directly with the results in the present study. Also, the follow-up in Zdeblick's study was relatively short, with an average follow-up period of 23 months. There was, however, a significantly improved fusion rate using rigid internal fixation, evaluated by radiographic appearance.

Some authors have described the use of flexion/extension, radiographs to assess the fusion [19, 20]. There are, however, several studies concluding that plain radiological assessment, including flexion/extension films, computed tomography and tomograms, is insufficient for determining whether a fusion mass is solid or pseudoarthrotic [3, 4, 12]. Also, a recent study by Pihlajamäki et al. [21] showed no correlation between radiologically evaluated fusion and clinical outcome. Johnsson et al. [9], using roentgen stereophotogrammetric analysis (RSA), showed that the fusion mass became rigid within 1 year after surgery, defined by intervertebral translation of less than 1mm. We therefore suggest that, if used, plain radiographic evaluation 12 months postoperatively is sufficient, since it is unlikely that intervertebral translation can be determined more accurately with plain radiographs than with RSA. In summary, spinal fusion judged by radiographic appearance is an insufficient parameter when comparing different fusion techniques. Until better methods, giving unbiased evaluation of the fusion mass, have been widely established, we find that outcome, reoperation rate and complication rate should be used when comparing different fusion techniques in clinical studies.

Long-term results after lumbosacral fusion with a semi-rigid implant system have been reported by Roy-Camille et al. [22]. In a 10-year follow-up of 43 patients

Table 4 Results of questionnaires

Question	Total	Semi-rigid	Rigid
Satisfied with the result of the operation	69% (55/80)	72% (28/39)	66% (27/41)
Reduced medication	66% (53/80)	64% (25/39)	68% (28/41)
Working	46% (37/80)	46% (18/39)	46% (19/41)
On sick leave	19% (15/80)	21% (8/39)	17% (7/41)
Change in vocational status	56% (45/80)	56% (22/39)	56% (23/41)
Improved vocational status	23% (18/80)	23% (9/39)	22% (9/41)
Worsened vocational status	31% (25/80)	36% (14/39)	27% (11/41)

undergoing lumbosacral fusion with either two plates and screw or unilateral instrumentation with articular screws, 15 patients out of 35 who were working prior to surgery were able to return to their previous work. There was no difference in outcome between the two types of instrumentation. This corresponds to our findings shown in Fig. 1. This Figure also shows that, of 34 patients on sick leave before surgery, 14 returned to work, with no difference between the two types of implant. Of the 31 patients who were working pre-operatively, 16 were on sick leave at the time of follow-up. Again no difference was found between the two types of implant. In other words, no overall improvement in working status was found. This is in contradiction to the number of patients reporting satisfaction with the outcome and reduced medication. Previous studies have shown a similar discrepancy between patient evaluation of pain relief and return to work [14, 19]. Recently Pihlajamäki et al. [21] reported the outcome 4 years after lumbosacral fusion. In accordance with our results, the patient satisfaction rate was 68%. However, of 40 patients who were employed, but on sick leave pre-operatively, 21 returned to employment and 19 received disability pension. All of these findings support the concept that return to employment may be a confounder instead of an outcome parameter in the evaluation of the clinical results after spinal fusion [6]. As pointed out by Keller et al. [13], work status depends on several factors such as motivation and the general socio-economic conditions affecting the availability of work. Therefore, return to work should not be the primary parameter in studies evaluating the outcome after spinal fusion procedure. Also, improved work status should not be the only factor that determines whether the surgical procedure is justified.

Several studies have paid attention to the possibility of vertebral osteoporosis caused by the stiffness of the implant. Some studies have shown that increased stiffness of the implant may lead to increased osteoporosis of the involved vertebral segments due to stress shielding [7, 10]. Another experimental study, however, has led to the conclusion that the osteoporosis induced after instrumented fusions primarily is caused by the stiffer fusion mass compared to fusion obtained with non-instrumented fusion [16]. This has been confirmed by Johnston et al. [11]. In an experimental study it was shown that increased stiffness of the implant resulted in a stiffer fusion mass with no biomechanical signs of osteoporosis. Lipscomb et al. [15] studied the spinal bone density in 25 patients undergoing compression rod instrumentation. They found a tendency toward and increase in the density of the fusion

mass and fused vertebrae, following a cyclic pattern that could be caused by cycling remodelling. The same pattern was found in the vertebrae above the fusion mass. In every case there was an immediate loss in bone density above the fusion mass averaging 16%. However, in the following period the density increased, and after 1 year 60% of the patients had bone mineral densities above the preoperative level. No study has demonstrated any correlation between clinical outcome and osteoporosis caused by the spinal instrumentation, and the theory that stiffer implants should result in spinal osteoporosis, reflected in the clinical outcome, is not supported by the results of the present study.

Although the present study is retrospective, we find that it fulfils most of the recommendations for such studies regarding follow-up period, patient selection, number of patients included and number of patients followed [2, 18]. It could be argued that the follow-up period in the two series is different. We find that a minimum follow-up of 2 years makes a comparison justified, and as long as no randomised, clinical trials are available, results from consecutive series of patients are an acceptable alternative. Furthermore the follow-up period was entered as a variable in the logistic regression analysis.

A study of the present nature, with relatively few patients in each group, holds limited statistical power, i.e. a relatively high risk of falsely accepting the null hypothesis that there is no difference between the clinical outcome with the two types of implant systems. It is important to recognise, however, that we are comparing two methods with the same potential complications. Both surgical techniques are based on inserting screws into the pedicles using the same surgical approach, and in principle implying the same risks. In other words, we do not withhold a risk-free treatment from the patient if we falsely conclude that the two methods are equal.

In conclusion, the present study did not demonstrate any differences in clinical outcome between the two types of implant. Biomechanical studies, however, have clearly favoured the rigid implant system with regard to fusion rate and stiffness of the fusion mass. Combined with the fact that early mobilisation without a brace is possible with rigid implants, and the fact that rigid implant systems imply the same potential complications as semi-rigid systems, the use of rigid implant systems is justified in patients undergoing lumbar fusion procedures for degenerative disc disease or spondylolisthesis.

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