Lumbosacral arthrodesis using pedicular screws and ringed rods

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ABSTRACT

Sixty-one patients who had lumbar instability and chronic low back pain or deformity from non-traumatic lumbar pathologies were studied. In all of them a posterior lumbosacral fusion with CUN (Clinic of the University of Navarre) pedicle rod fixation was used. The mean follow-up period was 36 months (range 26-46 months). The consolidation rate was evaluated according to plain and functional radiographs, and a clinical evaluation was made using an analogue pain scale. The rate of fusion was 93.5%. Neurological complications occurred in 3.3%. The incidence of screw failure was 2.3% of all the screws. No other implant failure occurred. The patients rated their clinical results as “excellent” in 33.8% of the cases, “good” in 42.2%, “fair” in 16.9% and “poor” in 6.7%. CUN instrumentation is a versatile internal fixation system that has been shown to provide satisfactory stability. Furthermore, the clinical results are comparable to those reported in studies in which the most common hardwares were used.

KEY WORDS

Spinal instrumentation; Arthrodesis; Lumbar spine; Lumbosacral fusion; Low back pain

INTRODUCTION

In the last 10 years the efficacy of lumbosacral arthrodesis using pedicle screw plate and rod fixation has been widely evaluated both from the biomechanical [22, 28] and the clinical [17, 20, 24] point of view. In the United States and Europe, more than 30 years after the first description of a spinal fusion without instrumentation by Boucher [2], the most popular devices appear to be those designed by Roy-Camille [20], Louis [12], Cotrel and Dubousset [6], Steffee [24] and Dick [7]. At the present time the investigations seem to agree on two important points:

1. Arthrodesis rates have increased because of the better stability offered by pedicle fixation devices.
2. The incidence of complications can significantly increase during the period of the so called "learning curve", because of the technical difficulties in placing pedicle screws.

Since 1989 at the Clinic of the University of Navarre (CUN) we have been using pedicular screws and rods for lumbosacral arthrodesis. We analyse the results obtained in 61 patients with mechanical low back pain and instability secondary to a variety of non-traumatic pathologies, who underwent arthrodesis using the CUN instrumentation.

MATERIALS AND METHODS

We studied 61 patients with back pain secondary to non-traumatic conditions who underwent surgery at the CUN between June 1989 and February 1991. In 58 of them a lumbosacral arthrodesis using CUN devices was performed, 1 patient underwent an L4-L5 fusion and 2 patients had a long lumbosacral fusion using CUN instrumentation according to the Luque-Galveston technique. There were 41 male and 20 female patients with an age range of 11-80 years (average 43 years). The diagnosis included herniated lumbar disc with chronic back pain in 27 (44.3%), spondylosis in 9 (14.8%), degenerative lumbar stenosis in 7 (11.5%), spondylolysis or spondylolisthesis (Fig. 1) in 16 (26%) and lumbar metastatic lesions in 2 (3.3%). Eighteen patients (29.5%) had undergone previous lumbar operations. In the remaining 43, arthrodesis with CUN instrumentation represented their first operation. The arthrodeses were performed using autogenous bone graft in cases of short fusions and allograft from bone bank in the long ones. The L5-S1 levels were fused in 18 patients (29,5%), L4-S1 in 33 (54%), L3-S1 in 5 (8.1%), L2-S1 in 2 (3.2%) and L4-L5 in 1 (1.6%). The mean follow-up period was 36 months (range 26-46 months). Evaluation was based on conventional AP and lateral radiographs, and functional radiographs for assessment of instrumentation placement, mechanical failure and bone fusion. A fusion was considered solid in the absence of motion on flexion-extension radiographs and when bony trabeculae were clearly seen bridging the length of the fusion. When evaluating a spinal arthrodesis system, we try to weigh its capacity to achieve fusion against its complexity, cost, associated risks, morbidity and other technical aspects. In addition, at follow-up examination, 59 patients carried out a subjective evaluation of the result by recording on an analogue scale their levels of preoperative and postoperative pain and daily function. To summarize this subjective evaluation, patients defined their results as "excellent" or "good" if they were asymptomatic and had no (or minimal) limitations in their daily activities, including sports, "poor" if the operation did not give satisfactory improvement, and "fair" if their

condition had improved, but some degree of functional disability or pain persisted (Table 1) [25].

The instrumentation was developed from the one in use in our hospital for long arthrodeses since 1987 [1]. Basically, this instrumentation set is composed of ringed rods, tubular rings and pedicle screws (Figs. 2, 3). The rod material in the studied cases was stainless steel 316L (at the present time the system is also available in titanium). Its length varies in relation to the number of levels of spinal fusion, ranging from 30 to 500 mm (Fig. 2). The body surface of each rod has circumferential ringed prominences, 6.5 mm in external diameter, which are equally spaced (3 mm). In these 3 mm gaps between adjacent rings (rod diameter 5 mm) one blocking screw of the same diameter (3 mm) prevents an eventual displacement of the tubular ring along the rod (Fig. 4). The body surface of the rod (area between the rings) is not circumferential; it has a plane surface that must always face dorsally so it can be blocked by the 3-mm screws to avoid rotation (Fig. 4). The rod can be appropriately contoured in three dimensions. Ringed rods are coupled to pedicular screws through three types of tubular rings: cephalic, caudal and mid-type (Fig. 3). The latter is used when more than one level is fused, for fixing the intermediate vertebrae. The cephalic ring, which comes in a right and a left version, has an eccentric wing with a hole for insertion of the pedicle screw. Due to this eccentric configuration the proximal end of the ring does not lie over the inferior articular process of the superior vertebra. The caudal tubular ring, which also comes in separate right and left versions, has also an eccentric wing with two holes for sacral screws. The middle tubular ring can be used on either side, and its pedicular screw hole is central. Two 3-mm blocking screws (Fig. 3), which are perpendicular to the axial hole of the tubular ring, provide a rod blocking system that avoids displacement and minimizes rotational motion of the ringed rods. The self-tapping pedicular screw was stainless steel 316L (at the present time the system is also available in titanium). The length of the screw ranges from 30 mm to 50 mm. The diameter of the screw may be of 4.5 mm (adolescents) or 5.5 mm (adults) and its profile is in between the standard AO cortical and cancellous bone screws.

Initially we used only 4.5-mm screws but, because some ruptured, we decided to utilize a 5.5 mm screw for adults. In the two patients who underwent long fusion, CUN instrumentation with the Galveston technique was used combining a long fixation system with screw holders in order to make the fixation more stable. For the operative technique, the arthrodesis was prepared via a standard midline posterior approach. Self-tapping screws were inserted into the pedicle and their correct position was checked using AP and lateral views. A large decortication and removal of the spinous processes was performed. The appropriate rods were then contoured and the entire instrumentation was assembled.

During the first months (1989) the CUN device was designed to use only one sacral screw. Posteriorly, we preferred to use a second sacral screw in order to strengthen the sacral fixation points, so one screw was placed in the S1 pedicle and the other one into the sacral wing with a 45° lateral and caudal inclination.

Once the instrumentation was in place, the blocking screw heads were broken in order to achieve a more secure fixation. The amount of autogenous bone graft obtained from the arthrodesis bed was usually enough to cover the surface surrounding the instrumentation, especially the interapophyseal joints previously curetted. Weight

bearing was usually allowed during the 1st week, wearing a light orthosis limited to the lumbar area. Isometric exercises for abdominal and paraspinal muscles were prescribed 3 months after surgery. Until that time flexion-extension exercises as well as lifting of heavy weights and performing heavy work was prohibited. Sports were allowed 6 months after surgery.

RESULTS

The complications are summarized in Table 2. Overall, 392 pedicle screws were inserted. At follow-up we detected 9 screw failures, i.e. mobilization or breakage (2.3%). Six screws were broken, one of which had been inserted into the sacroiliac joint. Two broken screws in the same patient were associated with pseudarthrosis. The remaining three broken screws caused no complications. Loosening occurred twice, one in a pseudarthrosis case. One bent screw caused no complications. No broken rods were seen. There were 11 misplaced screws (2.8%). Three of these had been inserted partially outside the pedicle. One caused neurological deficit. The remaining eight misplaced screws were noted to cross the vertebral end plates and produced no symptoms. There were four pseudarthroses (6.5%), one with deep infection, one with screw loosening and one with two broken screws.

There were two neurological complications. One patient suffered postoperative irritative S1 neuropathy attributed to penetration of the screw through the wall of the pedicle, which was subsequently removed. The other one suffered a dural tear that had occurred during decompression, and was subsequently sutured. Both patients recovered without sequelae. Infection occurred in three patients (4.9%). All the cultures were positive for Staphylococcus aureus. In one patient removal of the instrumentation was required. The remaining two recovered with antibiotic therapy. Four patients (6.5%) required reoperation. The first developed a deep wound infection that was initially treated with antibiotics unsuccessfully. Three months after surgery, removal of the instrumentation, wound irrigation and debridement was performed. The second patient, who had undergone L4-S1 arthrodesis, developed L5 radiculopathy 3 months later. An L4-L5 herniated disc was observed, so an L4-L5 discectomy and fusion using a Louis plate was performed. This case was considered to represent a delayed union. The third patient requiring reoperation underwent removal of the instrumentation 11 months after surgery, due to persistent severe back pain with pseudarthrosis. The treatment was continued with a corset and rehabilitation. The fourth patient needed a removal of one sacral screw, 1 week after surgery, due to radiculopathy.

Fifty-nine patients completed the questionnaire (Table 3). The remaining two patients had metastatic lesions and died within 15 months after surgery. Twenty patients (33.8%) rated their result as excellent, 25 (42.3%) as good, 10 (16.9%) as fair and 4 (6.7%) as poor. Only the four patients with poor results believed that the operation had not been worthwhile.

Regarding lumbar pain, the average improvement was 7.5 points out of 10. The mean preoperative function level was 3.8 points out of 5 (where 1 represents no disability), while at follow-up it was 2.1. Regarding the evaluation of pain, the average preoperative level was 8.2 points (where 1 represents no pain), while at follow-up it was 2.6. Patients were asked to define their work as heavy, moderate or light. It was noted that 54.5% of

patients who were involved in heavy work rated their result as excellent or good, while 79.4% of patients who defined their work as moderate rated their result as excellent or good. One hundred percent of those who defined their work as light reported excellent or good results.

DISCUSSION

Lumbosacral arthrodesis has undergone a fast evolution characterized by controversial results [4, 5, 11, 13, 15, 16, 21, 24, 25] as witnessed by various and complex problems not yet classified. Arthrodesis without instrumentation [19, 23, 27], Harrington rods [9] and Luque segmental wire fixation [14] represented different solutions to the same problem: chronic lumbar pain and instability. Pedicle plate and rod fixation appears to be an improvement on all its predecessors and the incidence of pseud-arthrosis has decreased. With pedicle instrumentation only the vertebrae immediately adjacent to the lesion need to be included in the fusion. Furthermore, because it provides immediate stability, early mobilization and rehabilitation is possible [24]. Although a solid arthrodesis is not always synonymous with a good clinical outcome, the incidence of fusion remains the most important criterion for evaluation of the effectiveness of a given arthrodesis technique. With a 6.5% nonunion rate, our data further strengthen the positive results reported in the literature regarding the high rate of fusion achieved with pedicle instrumentation [4, 5, 11, 13, 15, 16, 21, 24, 25].

The biomechanical advantages of pedicle screw instrumentation are stability and rigid fixation. Our system is a semi-rigid one, in which fixation is sufficiently stable to achieve fusion, in spite of micromotion between the screws and tubular rings. Questions of what influence device rigidity may exert on bone formation and fusion as well as on materials fatigue remain controversial. We observed a 2.3% incidence of instrumentation failure at the screws (4.5 mm diameter). Since 1991 we have been using screws with a larger diameter (5.5 mm), in order to obtain not only a greater resistance to breakage, but also a greater pull-out strength, as shown by Skinner et al. [22]. McAfee et al. [18], analysing the life-span of pedicle spinal instrumentation, observed a 4.1% rate of problem screws and concluded that pedicle screws are more prone to break or bend in association with a solid fusion than with a conventional hook-based instrumentation system. Furthermore, hardware breakage in the absence of spinal pseudarthrosis was not associated with unfavourable results. In our experience of nine problematic screws, two were associated with pseudarthrosis. The remaining problem screws were noted in solid fusions without clinical complications. An effective pedicular screw fixation system should withstand the breakage and loosening throughout the time needed to obtain a solid fusion. In cases of nonunion, 316L stainless steel material will not withstand breakage under a concentrated load, especially in the lumbosacral area, where a three-column fixation is associated with posterior column arthrodesis.

CUN instrumentation is versatile and easily assembled without altering its intrinsic stability. Because of its eccentric position, the screw holder does not impinge on the inferior articular process of the superior vertebra. Rods are easily contoured to adapt and stabilize physiological lumbar lordosis in all three planes, in contrast to place systems. Furthermore, while not having a fixed centre hole, the CUN set offers more freedom when choosing the most appropriate point to insert the screw. The versatility of the

implant was demonstrated in one patient who had spondylosis with a significant lumbosacral scoliotic deformity. It was only possible to insert the pedicle screw instrumentation by contouring the rods and placing the contralateral screw holder on one side (Fig. 4).

The CUN system has been used in combination with other instrumentations appropriate for degenerative conditions of the lumbar spine in cases of tumor and paralytic scoliosis. In these conditions, in which bone quality decreases and multiple levels are commonly involved, a stable fixation is needed in order to avoid implant failure and loss of correction [1]. This series included two patients with metastatic lesions (Fig. 6) in whom CUN instrumentation with Galveston-Luque technique was used. There were no implant failures or pseudarthroses. The main reason for using pedicle screws is to strengthen the fixation in the lumbar and lumbosacral region, avoiding the placement of rods at the sacroiliac joint.

Recent data have highlighted the importance of the “learning curve”, with a relationship being noted between the operative time, the incidence of complications and the surgeon's experience. We noted a 3.3% incidence of neurological complications and a 4.9% incidence of infections. West et al. [26], reporting on the complications of this technique, observed a 2.4% incidence of infection and 6% incidence of neurological complications. In 1987 the authors, using Louis plates, observed a 3.5% incidence of neurological complication and a 5.8% incidence of infection [5].

According to the clinical questionnaire, we noted a 76% rate of excellent and good results. Of the patients interviewed (95%), all except four, believed that the operation had been worthwhile. These data, which are comparable to those reported in the literature, need some consideration. We agree with West et al. [25] that this operation is not indicated for patients who wish to return to strenuous work, judging by the relatively low incidence of excellent and good results among the heavy work group. Regarding the four patients with pseudarthrosis, one rated their result as poor, two as fair and one as excellent. As for the four patients who rated their results as poor (the operation wasn't worthwhile), we were unable to find an explanation for their persisting low back pain, except in the patient who underwent removal of instrumentation for a symptomatic pseudarthrosis. The remaining patients with poor results had a solid fusion. This is comparable to the proportion of solid fusions (7 out of 10) among spinal instrumentation patients with persisting pain reported by Flatey [8]. These perplexing figures point to two possibilities:

1. Different types of pseudarthrosis may predispose to more or less pain [10]
2. A more appropriate choice of candidates for lumbosacral arthrodesis may reduce the number of patients with psychosocial problems who are treated surgically. Possibly a multidisciplinary evaluation and adequate physical rehabilitation programme would facilitate this.

CONCLUSIONS

This study indicates that our procedure for spinal arthrodesis is safe and effective. In our series there were no serious complications and, in addition, almost all patients (93.2%) felt that their pain was significantly relieved and that they had benefited from surgery. Pedicle screw fixation affords a high incidence of fusion (93.5%).

The CUN system is versatile: it can be used in association with the Luque-Galveston technique and it can also be easily assembled in different configurations, providing an immediate and acceptably rigid fixation by a relatively simple operative technique.

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Table 1. Subjective evaluation of back pain and daily function

Patient name:

Date of interview:

The following questions are in relation to the arthrodesis operation:

I. Comparing your pain now with the pain that you experienced preoperatively, how much has the pain improved over the preoperative period?

No improvement 1 - 5 - 10 Completely relieved

II. How disabled were you preoperatively?

1. Not disabled at all; worked full time
2. Was able to work full time but at less than normal level
3. Was able to work only part time but at usual level
4. Was able to work only part time and at a lower level
5. Was not able to work at all

III. How disabled are you now? Use scale in II above 1-2-3-4-5-

IV. Describe your level of low back pain before the operation

No pain 1 - 5 - 10 Pain extremely severe, intolerable

V. Describe your level of low back pain at the present time

No pain 1 - 5 - 10 Pain extremely severe, intolerable

VI. At the present time, how would you rate the results of the operation?

Excellent - Good Fair - Poor -

VII. Do you feel that the operation was worthwhile? Yes - No –

Table 2. Complications and reoperations

Neurological deficit (3.3%)	
Dural tear	1
Radiculopaty	1
Infection (4.9%)	
Screw failure (2.3% of all screws)	
Breakage	6
Loosening	2
Bending	1
Misplaced screw (2.8% of all inserted screws)	
Partially out of the pedicle	3
Crossing the disc	8
Pseudarthrosis (6.5%)	
With screw failure	2
With infection	1
Delayed union	1
Reoperation (6.2%)	
Removal of screw	1
Infection, pseudarthrosis, removal of instrumentation	1
Pseudarthrosis, removal of instrumentation	1
Hemiated disc, delayed union, discectomy and fusion	1

Table 3B. Subjective results by work category		
Work category	**Results**	
	Excellent-Good	**Fair-Poor**
Heavy	54,5%	45,4%
Moderate	79,4%	20,5%
Light	100%	—

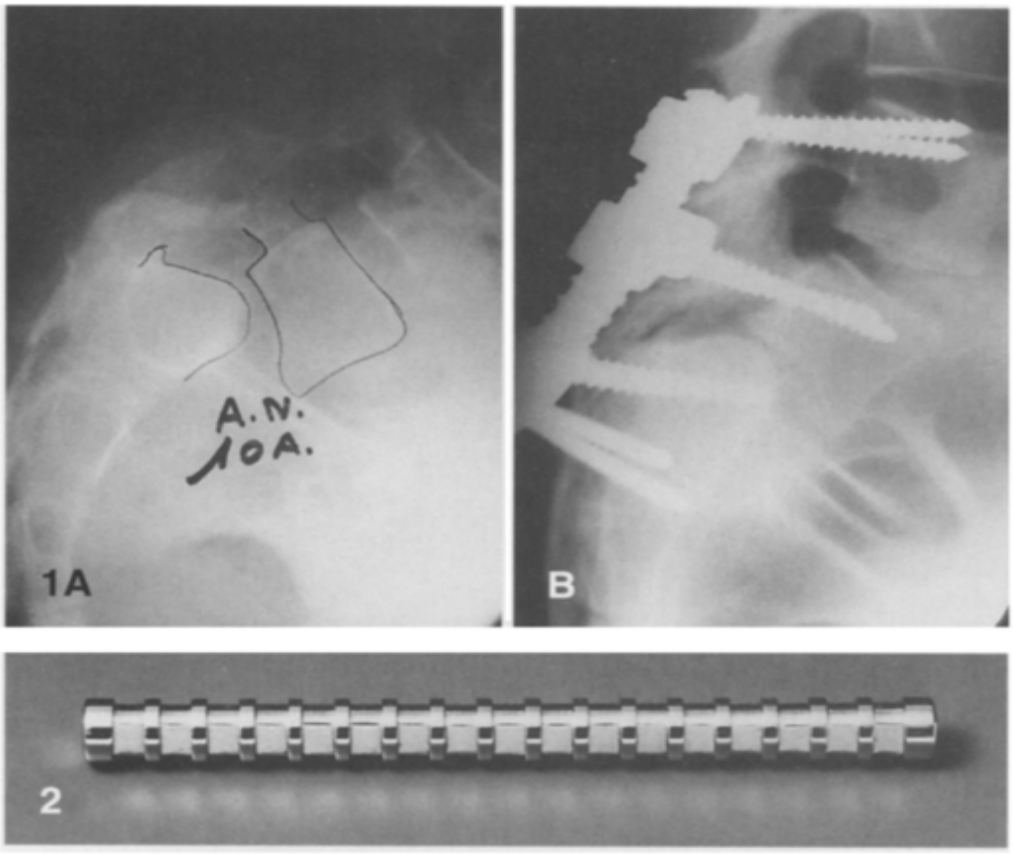

Figure 1. A. Spondylolysis and spondylolisthesis at the L5-S1 level: preoperative roentgenogram. **B.** Postoperative plain radiograph showing L4-S 1 arthrodesis with CUN instrumentation. The L4 level was included in the arthrodesis to achieve a more rigid fixation.

Figure 2. Stainless steel 316 rod showing the plane surface of its body with a series of l-mm rings 3 mm apart.

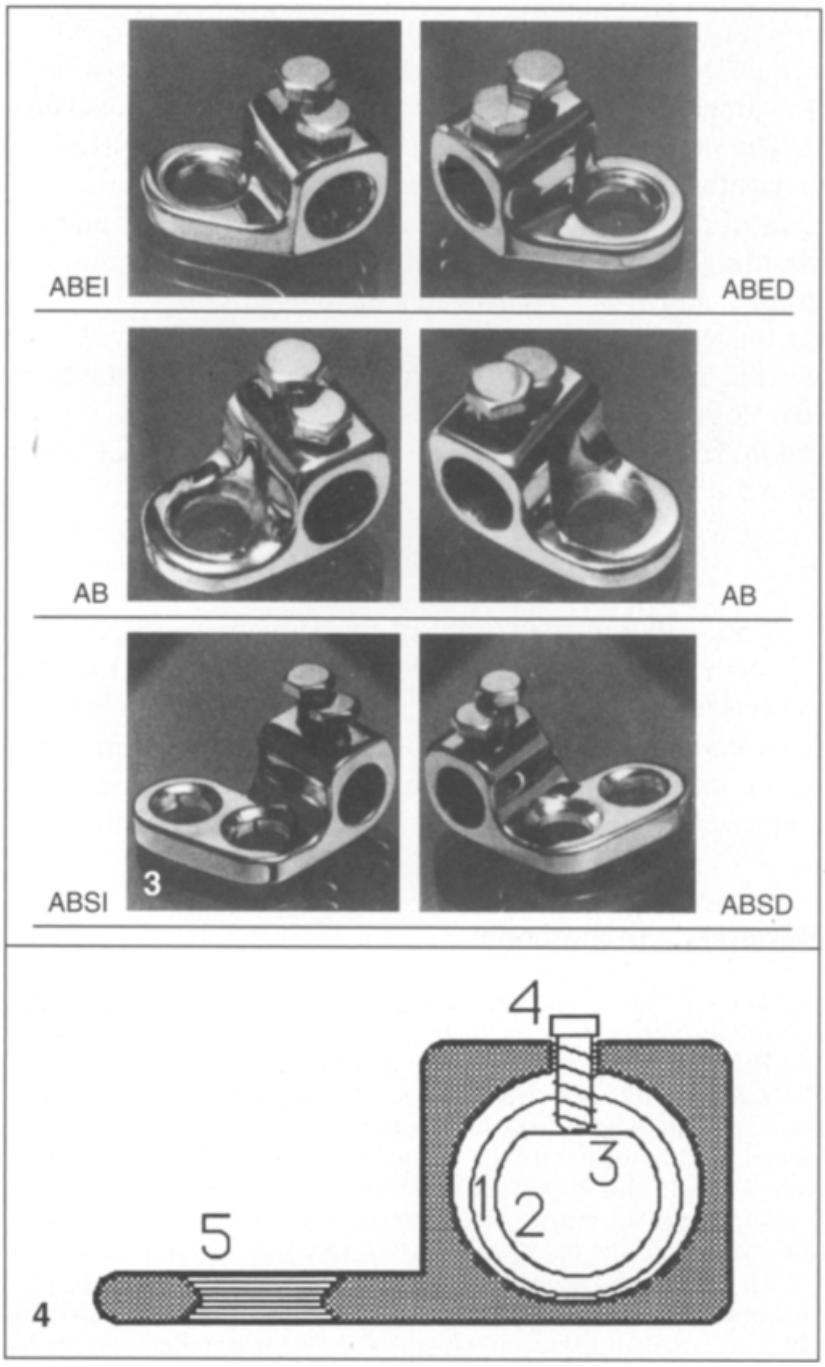

Figure 3. Cephalic (ABEI, ABED), middle (AB) and caudal (ABSI, ABSD) tubular rings, each with two 3-mm blocking screws

Figure 4. Axial view of a tubular ring (in black) showing how the ringed rod can be fixed with a screw against its flat surface (3). Rotation is prevented by the 3-mm screw (4) placed against the rod in its inner portion (2) between two consecutive rings (1). This flat surface has always to face dorsally. The location of the hole for the pedicular screw is marked 5

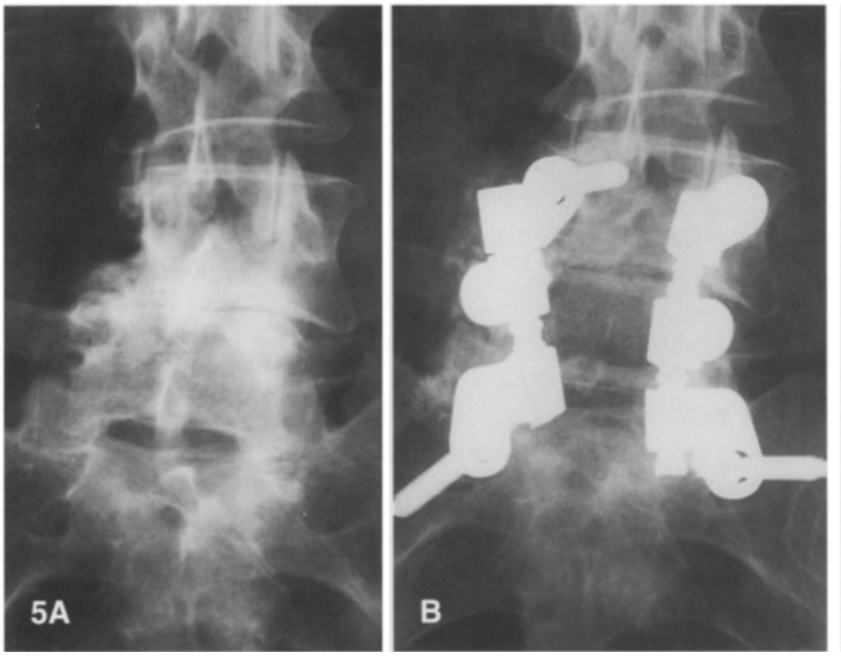

Figure 5. A. Preoperative AP roentgenogram in a case of degenerative lumbar stenosis in which an L4-S1 fusion was performed. **B.** Postoperative AP view. It was only possible to place the instrumentation by contouring the rods and placing on one side the contralateral cephalic tubular ring.

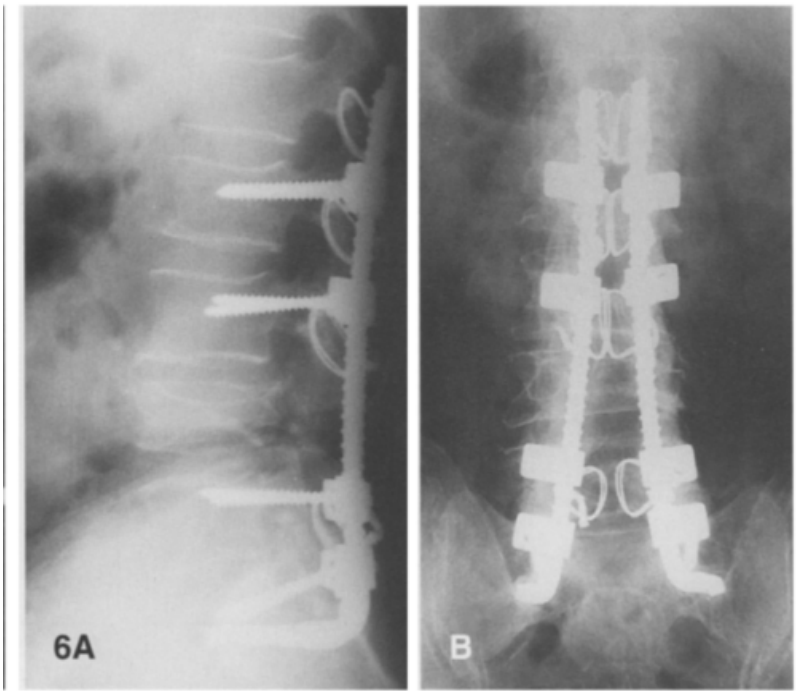

Figure 6. A. Lateral view showing a pathologic L4 fracture treated by using L-shaped, long, ringed rods (similar to the Galveston technique) fixed by transpedicular screws. Sublaminar wiring can be added in cases of poor bone quality and/or extensive bone resection, as in this tumoral case, in order to improve the strength of the fixation. **B.** AP view.