We analysed the complications encountered in 102 consecutive patients who had posterolateral lumbosacral fusion performed with transpedicular screw and rod fixation for non-traumatic disorders after a minimum of two years. Of these, 40 had spondylolysis and spondylolisthesis, 42 a degenerative disorder, 14 instability after previous laminectomy and decompression, and six pain after nonunion of previous attempts at spinal fusion without internal fixation. There were 75 multilevel and 27 single-level fusions.

There were 76 individual complications in 48 patients, and none in the other 54. The complications seen were screw misplacement, coupling failure of the device, wound infection, nonunion, permanent neural injury, and loosening, bending and breakage of screws. Screw breakage or loosening was more common in patients with multilevel fusions (p < 0.001). Screws of 5 mm diameter should not be used for sacral fixation.

Forty-six patients had at least one further operation for one or several complications, including 20 fusion procedures for nonunion. The high incidence of complications is a disadvantage of this technically-demanding method.

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Although the concept of transpedicular fixation of the spine is not new, internal fixation devices based on transpedicular screw-fixation systems have evolved rapidly during the past two decades. Initially, various modifications of screws and plates were introduced, but recently pedicle screw and rod systems have gained popularity. The use of internal fixation is well established for the correction of scoliosis and stabilisation of spinal fractures, but because of the risk of complications related to the devices, augmentation of posterolateral lumbosacral fusion by transpedicular instrumentation is questionable if performed for non-traumatic disorders.

The number of lumbar spinal fusions undertaken has increased dramatically during the last few years, but only a limited number of studies on the use of new transpedicular devices for non-traumatic indications have been published, and there is little information available about the complications. We believe that before they are accepted for general extensive use, careful studies should be carried out on the incidence and nature of the problems associated with the devices.

PATIENTS AND METHODS

Between January 1989 and September 1993, we treated 102 consecutive patients, 41 men and 61 women, by posterolateral lumbosacral fusion with transpedicular instrumentation for non-traumatic disorders. Their mean age at the time of the operation was 45 years (16 to 75). The main indications for the fusion procedure were spondylolysis and spondylolisthesis (40), degenerative changes (42), post-laminectomy pain (14) and failed previous fusion (6) causing intractable lumbosacral pain, with or without sciatic-nerve symptoms, and resistant to non-operative treatment (Table I). Patients with previous traumatic or pathological fractures were excluded. Ninety-seven patients had some radiation of pain but five did not. Before operation, plain anteroposterior and lateral flexion-extension radiographs were obtained. Myelography and either contrast-medium-enhanced CT or MRI were used to detect herniated discs at the intended fusion levels or spinal stenosis at the level of the spondylolisthesis, and to exclude other causes of back pain and sciatica.

The patient was placed prone on bolsters on a radio-
for at least two years after the primary procedure. The associated with the implants had them removed.

Fatigue failure, loosening of the device or local back pain but later we became more liberal and only patients with one year or more after implantation regardless of symptoms, it was our policy to remove transpedicular fixation devices since they allowed use of a thicker pedicle screw. The choice between these two was the personal preference of the surgeon-in-charge. During the early years of our study the AO internal fixator often failed, and use of this device was therefore discontinued. We adopted the CD and PSF for multilevel fusions. Thirty-one patients with a stenosis using cancellous autogenous bone from the iliac crest and screws was confirmed radiologically in lateral, antero- posterior and orthogonal views.

Six surgeons performed the operations, four being residents. All the patients had a bilateral posterolateral fusion using cancellous autogenous bone from the iliac crest and transpedicular fixation. Thirty-one patients with a stenosis of the spinal canal at the level of the intended fusion had concomitant decompression laminectomy and eight with both stenosis and a herniated disc had decompression laminectomy and discectomy. An attempt at a reduction of the slip was carried out in 23 patients with spondylolisthesis. In the remaining 17 with a slip the vertebrae were fused in situ. Sixty fusions were performed between L4 and S1, 18 between L4 and L5, 11 from L3 to L5, six between L5 and S1, three from L3 to L4, two from L3 to S1 and two between L2 and L5. Thus, there were 75 multilevel fusions and 27 single-level fusions. In 98 cases the screws were placed in two vertebral and in four patients they were attached to three.

The transpedicular fixation devices used were an AO internal fixator (AO) in 63, Cotrel-Dubousset instrumentation (CD) in 30 and a posterior segmental fixator (PSF) in nine patients. No cross-link system was used between the rods. It became obvious that the 5 mm diameter screws of the AO internal fixator often failed, and use of this device was therefore discontinued. We adopted the CD and PSF devices since they allowed use of a thicker pedicle screw. The choice between these two was the personal preference of the surgeon-in-charge. During the early years of our study it was our policy to remove transpedicular fixation devices one year or more after implantation regardless of symptoms, but later we became more liberal and only patients with fatigue failure, loosening of the device or local back pain associated with the implants had them removed.

All patients were followed clinically and radiologically for at least two years after the primary procedure. The follow-up averaged 40 months (24 to 81). During the first postoperative day the position of the transpedicular fixation device was confirmed by plain radiography and if there was any doubt, by CT. After discharge from hospital, at about nine days (4 to 30) after surgery, clinical and radiological assessment was done at six weeks and at three, six and nine months and one year. After one year we followed regularly only those patients who still complained of severe back or leg pain. We invited all the patients to attend once again for a follow-up examination. We have previously reported the detailed clinical outcome in 63 of the 102 patients.

At the final examination, in addition to routine antero-posterior and lateral views, lateral flexion-extension radiographs and an antero-posterior view with a 20° caudocranial tilt were taken. CT scans through the lumbar fusion were obtained, and sagittal reconstruction images produced to visualise the whole length of the fusion. If the fusion mass seen on two-dimensional CT images was difficult to interpret, we also obtained oblique posterolateral CT images by reconstruction. The criteria for fusion were continuous bony bridging verified at all intended sites, and no movement in the flexion-extension radiographs. Any discontinuities in bony bridging observed on plain films, axial CT, two-dimensional parasagittal or three-dimensional oblique postero-lateral images, or any movement in the flexion-extension radiographs were termed nonunion. Screw loosening was defined by a continuous lucency at the screw-bone interface 1 mm or more wide and surrounded by a thin sclerotic zone. Loosening was verified at surgery in the cases of subsequent implant removal.

For statistical analysis the chi-squared test was used with p ≤ 0.05 regarded as significant.

RESULTS

Overall results. Of the 74 patients who were employed before surgery 38 returned to work and the remainder retired on a disability pension. The overall number of individual complications was 76, seen in 48 patients. Of the 38 patients who returned to work, 17 had one or more complications, and in 21 of the 36 who retired one or more complications was detected during the follow-up. The difference was

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**Table I.** Data on the complications/reoperations* after posterolateral lumbosacral fusion with transpedicular screw-rod fixation for a non-traumatic disorder in 102 patients

<table>
<thead>
<tr>
<th>Complication</th>
<th>Spondylolysis/-Listhesis (n = 40)</th>
<th>Degeneration only (n = 42)</th>
<th>Pain postlaminectomy (n = 14)</th>
<th>Failed previous fusion (n = 6)</th>
<th>Total (n = 102)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screw misplacement</td>
<td>3/2</td>
<td>3/2</td>
<td>3/2</td>
<td>-/-</td>
<td>9/6</td>
</tr>
<tr>
<td>Coupling failure</td>
<td>1/1</td>
<td>-/-</td>
<td>-/-</td>
<td>1/1</td>
<td>2/2</td>
</tr>
<tr>
<td>Superficial wound infection</td>
<td>-/-</td>
<td>-/-</td>
<td>-/-</td>
<td>-/-</td>
<td>1/-</td>
</tr>
<tr>
<td>Deep wound infection</td>
<td>1/1</td>
<td>1/1</td>
<td>-/-</td>
<td>-/-</td>
<td>2/2</td>
</tr>
<tr>
<td>Nonunion</td>
<td>9/9</td>
<td>4/4</td>
<td>5/5</td>
<td>2/2</td>
<td>20/20</td>
</tr>
<tr>
<td>Permanent neural injury</td>
<td>1/1</td>
<td>1/1</td>
<td>1/1</td>
<td>-/-</td>
<td>3/3</td>
</tr>
<tr>
<td>Screw loosening</td>
<td>9/8</td>
<td>4/3</td>
<td>5/3</td>
<td>-/-</td>
<td>18/14</td>
</tr>
<tr>
<td>Screw bending</td>
<td>-/-</td>
<td>1/1</td>
<td>-/-</td>
<td>-/-</td>
<td>1/1</td>
</tr>
<tr>
<td>Screw breakage</td>
<td>9/9</td>
<td>11/8</td>
<td>-/-</td>
<td>-/-</td>
<td>20/17</td>
</tr>
<tr>
<td>Total</td>
<td>33/31</td>
<td>26/20</td>
<td>14/11</td>
<td>3/3</td>
<td>76/65</td>
</tr>
</tbody>
</table>

* if two or more concomitant complications existed, the reoperation was classified according to the main indication for surgery; many patients were reoperated twice or more for their complications (see text)
The individual complications seen were screw misplacement, coupling failure of the device, wound infection, nonunion, permanent neural injury, and loosening, bending and breakage of screws (Table I). Altogether, 108 reoperations were performed on 83 patients during the follow-up time. Only 19 patients did not undergo further surgery after the primary fusion. Eightytwo patients had removal of the transpedicular fixation device without reapplication or a refusion procedure; in 17 the only indication for this was our former policy of routine removal. In 26 patients the implants were removed because of local discomfort or radiating pain and in the remaining 39 cases because of another complication. Altogether 65 reoperations were performed for one or several other complications (Table I). In six patients after removal of the implant the transpedicular fixation device was reapplied. There were 20 attempts at refusion following nonunion. Reoperation for one or several postoperative complications caused a prolonged hospital stay for 46 patients.

**Screw misplacement or coupling failure.** In nine patients inaccurate screw positioning was observed postoperatively on radiographs (Table I). Eight had another operation. In eight patients one or two screws had been placed totally or partially outside the pedicle (Fig. 1) and in one a sacral screw had perforated the anterior wall of the vertebra (Fig. 2). One screw became loose and backed out because of malposition (Fig. 3). In one patient two screws had perforated the upper endplate (Fig. 4). In two patients with screw misplacement outside the pedicle, a lesion of the fifth lumbar nerve root caused permanent paralysis. Coupling failure of the device due to inadequate nut tightening statistically insignificant ($p = 0.24$).
resulted in a screw disengaging from the clamp elements of the rod in two cases (Table I, Fig. 5).

**Nerve-root injuries.** Three patients developed permanent foot drop (Table I), probably caused by an iatrogenic lesion of the fifth lumbar nerve root during the fusion, due, in one case, to the reduction manoeuvre for spondylolisthesis performed with the transpedicular device. In two other patients with foot drop misplacement of an upper screw was observed radiographically. At reoperation the nerve root was found to be injured in one due to screw misplacement, but in the other the lesion was probably caused by the distraction manoeuvre performed with the transpedicular device. The paralysis remained permanent in these patients. No transient postoperative paralysis was seen.

**Implant failure.** In 21 cases there was fatigue failure of one or two screws (Table I), 19 of which were in the sacrum (Fig. 6). In one patient only an upper screw was broken, and in another a sacral screw was bent. In five patients both sacral screws were broken. In one, in addition to the sacral screw, the upper screw on the opposite side attached to the fourth lumbar vertebra was broken. In the 27 single-level fusions, only one screw breakage occurred whereas in the 75 multilevel fusions there were 19. There were four patients with multilevel fusions in whom the intermediate vertebra was also fixed with transpedicular screws. In these patients no fatigue implant failures were seen. The time of radiological detection of the screw breakage was at six weeks in one, three months in five, six months in 12, and at the one-year examination in three. All the screws which broke during the first six postoperative months were of the AO type. No rods had fatigue failure. In nine of the cases of fatigue failure of a screw subsequent posterolateral refusion was performed for nonunion. The association was statistically significant (p < 0.01). The transpedicular fixation devices used in the cases of screw breakage were the AO in 17, the CD in one and the PSF in two patients. The patient with screw bending had a PSF device.

**Screw loosening.** Screw loosening was observed radiologically in 18 patients. Both sacral screws were loose in eight, one sacral screw in six, both upper screws in two and both upper and sacral screws in two patients (Fig. 7). In one of the patients, in addition to a loose screw, breakage of another also occurred. The 27 single-level fusions showed only one screw loose, whereas the 75 patients with multi-level fusions had 17 loosenings. Of the 18 patients with loose screws five underwent reoperation for obvious nonunion. Patients with multilevel fusions were over-represented among those sustaining screw breakage or loosening (p < 0.001).

**Infections.** Three patients developed wound infection (Table I), one of which was superficial. Of the two deep...
wound infections one was caused by *Staphylococcus aureus* and necessitated early removal of the device four months after primary fusion; the other healed.

**Nonunion.** During the follow-up period posterolateral refusion for nonunion was performed in 20 cases (Table I). By the criteria presented above solid bony union had been achieved in the remaining 82 (Fig. 8).

**Hospitalisation for complications.** A total of 46 patients had a further operation for one or several complications, two during the first postoperative day, which prolonged their primary hospitalisation. During the follow-up period only one further procedure was performed for a complication in 30 patients. Thirteen patients had two reoperations and in three, three were needed. Readmission for complications caused an average increase in hospital stay of 8 days (3 to 30) per patient.

**DISCUSSION**

The advantages of transpedicular screw and rod fixation over previous methods of fixation in the treatment of thoracolumbar fractures are well established. They include locking of only a short length of the spine, the achievement of reduction and fixation with the same instrumentation and the stability of fixation which allows early mobilisation of the patient without external support. Our study showed a high incidence of complications related to their use as an augmentation to posterolateral lumbosacral fusion for non-traumatic disorders. Nearly one-half of the patients had a complication which required a further procedure. The duration of additional hospitalisation and the need for lengthy reoperation indicate that about one-third of the complications were major.

The high number of intraoperative complications indicates that pedicle screw placement is a technically-demanding procedure. Pedicle fracture and vessel injury, which have already been previously described, did not occur in our patients. Intraoperative complications such as screw misplacement and coupling failure may have been the result of lack of experience of the method in some of the surgeons. To avoid such errors this procedure should be performed only by well-trained spinal surgeons who undertake these operations regularly.

Problems were also encountered with the implants after operation. Fatigue failure and loosening of a pedicle screw indicate micromovement at the region of the screw and rod. We believe that there is an association between nonunion and implant failure. One of the factors influencing loosening of a screw may be osteoporosis, as many of the patients were in the older age range. Most breakages occurred with 5 mm diameter AO sacral screws. These seemed to break more easily than the upper screws, and multilevel fusions...
patients who underwent spinal fusion for degenerative conditions with the Texas Scottish Rite Hospital pedicle screw-rod fixation system\(^{30}\) one linkage loosening and three screw misplacements were the only complications detected.

Nonunion cannot be regarded only as a device-related complication. The radiological assessment of fusion is imperfect and no uniform method of diagnosing nonunion exists.\(^{34}\) While there is no reliable method of establishing fusion achieved after these operations the clinical consequences of nonunion remain unresolved. In previous studies on lumbar fusions no correlation between solid bony healing and clinical outcome was observed.\(^{12,35,36}\) In contrast to some previous studies dealing with spinal fusions with instrumentation\(^{28,37}\) infection was not a cause for concern in our series.

Our study has shown that the high incidence of intraoperative complications and fatigue failures of the transpedicular screw-rod devices is a serious drawback in this technically-demanding method. Considerable problems exist with the mechanical properties of the implants and the standardisation and accuracy of the operative techniques used.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

REFERENCES


