Pedicle screw fixation in the spine

In August 1993, in the USA, an FDA advisory committee of experts reviewed the scientific data on pedicle screws and decided that not enough was known about the short-term problems or the long-term safety and effectiveness of these devices to allow their use to be approved. Manufacturers were therefore forbidden to promote the use of screws in the spine, and patients were warned that pedicle screws were experimental. Before discussing the significance of this decision it is appropriate to examine the history of the use of pedicle screws and their clinical indications.

Although surgeons had previously inserted screws into the pedicles to immobilise the facet joints in the performance of spinal fusion, the era of the pedicle screw began when Roy-Camille et al (1970, 1976) reported the use of a screw-plate device for the treatment of spinal fractures. The screw of the plate went down the pedicle and into the body of the vertebra, traversing all three columns of the spine (Denis 1984). Their results were first published in French and during the next few years several surgeons in France used their technique or modifications of it (Louis 1986). There were obvious mechanical advantages of this form of fixation over sublaminar wires or hooks attached to the posterior elements, and the fact that the spinal canal was not violated soon attracted surgeons in other countries to its use.

Manufacturers hastened to invent and market devices which used the pedicle screw principle, altering the design of the original Roy-Camille plate to deal with actual or perceived problems experienced during its use. The development of rod-screw systems made contouring easier, and encouraged the use of pedicle screws in the treatment of scoliosis. There are now many such systems on the market, but the rate at which they are modified and remodified suggests that the biomechanical input to their design may not always be adequate.

In the treatment of fractures of the spine, pedicle screws allow easy manipulation and reduction of displaced vertebrae, even if the posterior elements are fractured. Their use facilitates decompression of the neural elements by distraction, avoiding the need for laminectomy, and permits stabilisation of the segments without the requirement to extend fixation much beyond the injured area (Aebi et al 1987).

No pedicle system, however, can resist collapse, and eventual failure of the fixation is inevitable if there is much anterior bone crushing. Collapse may be prevented by an anterior operation to replace the crushed disc and vertebrae with bone graft, after posterior stabilisation with a pedicle system. Alternatively, the vertebra can be grafted through the pedicles (Daniaux et al 1991; Lindsey and Dick 1991) although with this technique there is always some recurrence of deformity due to disc collapse. Attempts to achieve interbody fusion by grafting through pedicles have usually failed. In cases in which the spinal canal is compromised from a burst fracture an anterior approach is best to achieve decompression, but combined with posterior fixation, it represents a formidable surgical onslaught; reduction and pedicle fixation alone may be a better option (Esses et al 1991).

Tumours of the spine, particularly metastases which destroy the vertebral body and threaten paraplegia, can be treated by anterior decompression and grafting with anterior fixation. These methods, sometimes combined with the use of cement, provide pain relief and adequate stability in patients with a poor prognosis. Vertebral resection and replacement with autologous bone are needed, however, in potentially curable patients, and it is then preferable to stabilise the spine from behind by pedicle fixation. In some cases reduction of the kyphosis can be achieved and maintained by pedicle fixation alone, without laminectomy or anterior surgery. Followed by appropriate radiotherapy this technique can achieve adequate decompression.

In the correction of severe scoliosis the use of pedicle screws, because of their firm hold in the three columns of the spine, allows accurate correction at each segment in all three planes. There is, however, a greater risk of serious neural injury when they are used in the thoracic spine and great caution is necessary. Alternatively, a combined system can be used, with sublaminar hooks and wires in the thoracic spine, and pedicle fixation in the lumbar spine. A contoured rod attached with screws and hooks allows excellent reduction and maintenance of correction (Webb, personal communication, 1994).

The rigid hold of the pedicle screws also simplifies the reduction of spondylolisthesis. Slip of 50% or less is not associated with significant cosmetic deformity and there is therefore no need for reduction. Indeed, if reduction is attempted a relatively stable situation may be converted into an unstable one. The maintenance of the reduction then depends upon the pedicle fixation until union of the bone graft occurs, and loss of correction is
almost invariable (Matsuzaki et al 1990). In major slips, especially those associated with a lumbar kyphosis, a case can be made for attempting reduction, or at least correcting the kyphotic deformity, but this necessitates both anterior and posterior surgery, and there is a risk of neurological injury. The only prospective trial comparing reduction and fusion with fusion in situ showed no advantage from the more major procedure (Poussa et al 1993).

The most contentious issue, however, is the use of pedicle screws in the treatment of degenerative lumbar disc disease. The results of lumbar fusion for low back pain are sufficiently unsatisfactory for there to be some dispute as to whether the operation is appropriate for this disorder. The reasons for the unsatisfactory results are many, but failure of fusion is the cause in some, and it has been presumed, although by no means proven, that providing a degree of rigidity during the healing process would increase the chance of fusion. Turner et al (1992) concluded, however, from a very comprehensive review of the English-language literature, that there was no evidence for this and that the use of internal fixation caused complications. In one series there were complications in 46% of the patients (Whitecloud et al 1989), many of them, such as root injury, infection and implant failure, related to the use of fixation.

In a personal review of 65 papers published in English in the last five years concerning pedicle screws, I found more than 30 which dealt specifically with the complications and biomechanical problems encountered. The one prospective study which compared uninstrumented and instrumented lumbar fusion reported a 65% fusion rate in the first group and a 95% rate in the second. The study was flawed, however, as the patients were not independently reviewed (Zdeblick 1993). The only comparative study which was independently reviewed showed no benefit from instrumentation (Bernhardt et al 1992). The insertion of pedicle screws was described by one experienced surgeon as "a formidable procedure with a significant complication rate" (West, Ogilvie and Bradford 1991) and the results of their use seem not to have improved the clinical results of lumbar fusion. For example, in the series reported by Thalgott et al (1989) there was only a 59% overall clinical success rate, with pseudoarthrosis in 25%. Despite these results the authors strongly supported the use of fixation to encourage fusion.

The North American Spine Society has responded robustly to the FDA embargo. Their newsletter (October 1993) asks "Are there no medical control boundaries to the FDA?", and it refers to "tens of thousands of patients" in whom pedicle screws have been used "to encourage grafted bone to grow into solid fusions". A survey of its active members (414 out of 731 responding) showed that they overwhelmingly supported the view that pedicle screw fixation is the 'state-of-the-art' technique for some disorders of the lumbar spine. The American Academy of Orthopaedic Surgeons has made a more measured response, emphasising the value of pedicle screws in spinal fractures, and suggesting that the FDA, the specialist societies and the manufacturers should collaborate to collect and analyse the data and to clarify standards for the use of screws in the spine.

In 1995 the use of implants in the United Kingdom will be controlled by the Medical Devices Directorate, which will function much as the FDA does in the USA. The confrontation in America is of relevance to surgeons not only in the UK but throughout the European Union where similar controls will be introduced. Under these provisions all devices will need to acquire a certificate of compliance with 'the essential requirements', which are that the device is safe and performs as the manufacturer claims. Whether these requirements will go beyond the mechanical performance of implants, to include the clinical consequences of their use is not yet clear. It would seem that in the case of pedicle screws it is because of their unproven clinical value rather than their mechanical defects that the FDA has acted. In the treatment of spinal fractures and tumours, and perhaps in some types of spondylolisthesis, the usefulness of pedicle screws seems evident, but they are most widely utilised in the treatment of degenerative low back pain, in which their value has not been established, despite what most spinal surgeons seem to believe.

Perhaps this confrontation will be of benefit by encouraging manufacturers to support, and clinicians to organise prospective studies of the value of newly developed devices before they are widely marketed. If they do not then they may find themselves, from 1995 onwards, confronting not only the FDA but an array of licensing authorities in the rest of the world.

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Can ‘favouring’ one leg damage the other?

Lay people, and many doctors as well, believe that pain or disability in one leg can stress the other and produce symptoms in it. In a recent four-year period, 13 such appeals were heard by the Workers’ Compensation Appeals Tribunal of Ontario and 11 of them were allowed. In each case, the panel concluded that the compensatable injury to one leg caused the patient to ‘favour’ it and that this in turn unduly stressed the other normal leg causing or accelerating arthritis in one of its joints (usually the knee). ‘Favouring’ was thought to have resulted from limping, the need to use crutches or, in one case, from a leg-length discrepancy of 1.25 cm.

We believe that there is no scientific basis for such reasoning. The mechanics of limping are poorly documented in the orthopaedic literature and we have found few references to the effect of a limp on the other leg. To clarify the position for lay adjudicators and the physicians who advise them we reviewed the mechanics of the two basic limbs; paralytic and antalgic. In the former the muscles of the weak leg are not strong enough to balance body-weight and the patient walks with a characteristic lurching gait. The trunk, head and arm are displaced towards the affected side, moving the body’s centre of gravity directly over the weak leg and thereby reducing the muscle force required to balance the body-weight (Maquet 1976). In the antalgic gait the patient shortens the stance phase by adopting a similar Trendelenburg lurch.

It may seem logical that manoeuvres designed to lessen the load on one leg must increase that on the other, but there is no evidence to support this. Gait studies on patients who had a paralytic and short-leg limp from old poliomyelitis confirmed that the force transmitted in the affected leg was reduced, but that in the opposite leg it was the same as in normal individuals (Harrington 1976, 1992). The findings were similar in patients with an antalgic gait resulting from arthritis (Harrington 1983, 1992).

Paul (1969, 1970) showed that the magnitude of hip force in normal individuals varies with body-weight, stride length and walking speed and Harrington (1983) reported similar findings in patients with a limp. A person with a weak or painful leg is likely to walk less briskly than he would if he had normal limbs and the forces in the unaffected limb are therefore likely to be less than those that occur in a normal person. Morrison (1968) offered theoretical reasons why knee loads should be less in elderly or infirm people than in more vigorous individuals.

About 5% of otherwise normal people have some leg-length discrepancy (up to 4 cm) which causes no symptoms. A discrepancy of more than 4 cm produces a dip on the shorter side during the stance phase but the rhythm of gait is unchanged. Theoretically, a large discrepancy could increase the hip force on the side of the longer leg because of tilting of the pelvis away from the short side at the moment of heel strike but there is no experimental evidence to support this theory.

During treatment of an injured limb the patient often needs to use crutches or a cane and it is widely believed that this may stress the normal leg. When crutches are used, however, there is little change in the rhythm of gait and the force transmitted by the normal leg is increased only by the weight of the crutches. From an engineering point of view the effect of using crutches is similar to standing on one leg, a circumstance in which the forces at the hip and knee are significantly less than those during normal walking. Using a cane may also reduce the force in the normal leg because cane users walk more slowly.

Patients sometimes complain that walking with a plaster cast on one leg brings on symptoms in the other