A PEDICLE SCREW MODIFICATION FOR THE HARTSHILL SYSTEM : BIOMECHANICAL AND CLINICAL RESULTS

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The Ilartshill Rectangle with sublaminar wiring has become widely accepted in the management of a variety of spinal disorders. However, in certain circumstances in the lumbar spine, in particular in the presence of a spondylolysis or previous wide laminectomies, pedicle fixation undoubtedly has much to offer. We therefore designed a bridge device to link a rectangle to pedicle scerews. Thorough mechanical testing has been carried out. These test have shown that the pedicle screw system is mechanically satisfactory and has superior stiffness compared to the standard kwired rectangle.

A prospective trial of all patients in whom the device was implanted was carried out. We have implanted 64 bridges in 50 patients, the longest for two years. The early results are excellent, with only one mechanical failure to date. 'There have been no serious clinical complications. 'The major advantages of the system to be ease of use, reliability, increased security of fixation in difficult cases, and the ability to minimize the number of levels fused, which is particularly important in the lumbar spine.

Key Words : Back pain, sublaminar wires, pedicle screws.

The standard Hartshill Rectangle with sublaminar wiring is the usual method in Stoke-on-Trent for the posterior internal fixation of the spine and has become widely accepted internationally in the management of the variety of spinal disorders, including deformity, fractures, tumours and low back pain. (1) In certain circumstances, the sublaminar wiring technique is not possible, usually because the laminae arc absent or not suitable for fixation. For example, in spondylolysis, the posterior elements do not provide secure fixation for sublaminar wires. A patient who has had **a** laminectomy likewise has no posterior elements onto which a rectangle can be wired. In these cases, it is necessary to extend the fixation above and below the level of the defect. This is undesirable, particularly in the lumbar spine, where the number of fused levels should be kept to a minimum. We felt that some alternative fixation was required.

Transpcdicular screw fixation was originally described by Ro-Camille, (2) and a number of designs of pedicle screws and fixation devices have been described. (3,6) The general technique of screw placement is easily learned (3). Biomcchanically, transpedicular fixation gives sound fixation. (3,7,18) We therefore concluded that transpcdicular fixation undoubtedly had much to offer.

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MATERIALS AND METHODS

Development

In the initial stages, we simply wired a rectangle to Dwycr screws - the Hartshill - Dwyer technique, which has been described by Mchdian ct al. (9) Biomcchanically, we found this method to be unsatisfactory. The next development was a unilateral device which clamped a specially machined screw onto the rectangle. Initial biomechanical tests and subsequent clinical experience revealed that this was also unsatisfactory. Our final design was a bridge device which linked a rectangle to two pedicle screws. It consists of **a** central bridge shaped component and two side clips fixed to the rectangle, with standard AO canccllous screws in the pedicles. We make the device in four sizes, to accomodatc the variation in intepedicular distance.

We use standard AO 6.5 mm fully threaded cancellous screws of 35 mm length with the bridge, as a previous study has shown that there is no difference between AO and other screws in pull-out strength (7). We therefore elected to use the cheap and readily available AO screw. The aim is to achieve secure fixation within the pedicles only, and not to penetrate the weak canccllous bone of the vertebral body any further than necessary. Deep penetration may result in perforation of the anterior cortex of the vertebral body, with risk to the great vessels and other anterior structures.

Biomechanical testing

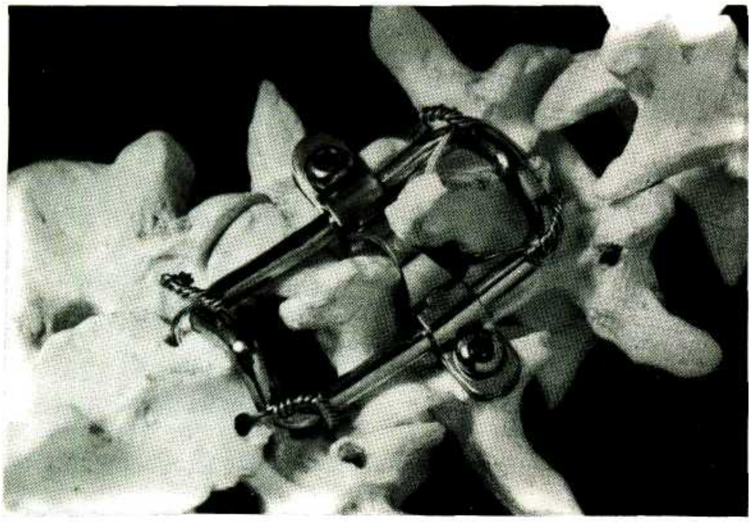
We carried out a thorough programme of biomechanical testing on the pedicle bridge, including simple pull to failure, cyclical fatique, and wet endurance tests. Full details of the testing techniques and detailed results have been published elsewhere (10).

Our testing has shown this pedicle screw system to be more rigid then standard wiring. On a single test to failure, the pedicle bridge is significantly superior to a standartd wired rectangle. Initial stiffness in torsion and lateral bending is also superior to the wired rectangle. Cyclical testing of the current pedicle screw bridge has shown no failure after loading at SOON for over three million cycles. Wet endurance testing in buffered saline at 37°C showed no evidence of crevice corrosion or accelarated fatique.

Surgical Method

The implantation technique is simple. The pedicles are identified under direct vision in most cases, or by the method described by Stcffce. We use a long awl rather than a drill, preferring to "feel" our way down the pedicles. The hole is tapped, and a marker pin inserted. This is repeated on the contralatcral pedicle. The appropriate size of bridge is placed over the markers, wires inserted as required, and the assembly completed. (Figure) The procedure requires a minimum of instrumentation.

Patients



Caption for illustration : Model showing L4-S1 fixation with a pedicle bridge at L4.

A prospective trial of all patients in whom the device was implanted was performed, to assess the suitability and reliability of the device in clinical practice.

Full details were kept on each patient and the information was entered onto a computer database for subsequent analysis. We looked particularly at the reasons for using pedicle screws rather than wires, any problems with the technique, any complications attributable to the implant, and any evidence of implant failure.

Between June 1988 and September 1989 we implanted 64 bridges in 50 patients. Average age of the patients was 46, with a range of 16 to 77 years. 15 patients had spondylolysis / spondylolisthcsis, 13 degenerative disc disease, 7 posl-lamincctomy instability, 3 facet arthritis, 4 spinal stenosis, 4 fractures, and 3 tumours. It shoul be noted that 19 out of these 50 cases were revision cases, having had one or more failed previous operations of various descriptions. Our patients stayed in hospital an average of 12 days, and post-operative external support was not used routinely, Follow-up on these first 50 patients is currently 6 to 18 months.

RESULTS

The results to date arc excellent. We have had no mechanical implant failures, and only one failure of fixation, due to a screw cutting out of a pedicle. On the post-operative radiographs, 5 screws have been found to be incorrectly placed , which compares favourably with the incidence of misplaced screws reported by Roy-Camille (11). In all cases the screw was superior or lateral to the pedicle. There was no case where the screw was inferior or medial. There have been no serious clinical complications related to the implant. We have had a few technical difficulties, often related to the previous surgery. All 7 dural tears were sutured, with no further problems. The wound infections settled, with no signs of deep infection. Althougn difficulty in screw placement was noted in two cases, there were no sequelae from this. Post operative problems were few. One of the cases with persisting leg pain required a further operation to release continuing root compression. He is now improving. The drop foot persists at 9 months follow-up. The burning leg pain has settled. We can finding no evidence that the fixation device was responsible for any of these difficulties.

Technical problems

Dural tear	7
Superficial wound infection	3
Difficulty placing screws	2
Tight spinal canal	2

Post-operative problems

Persisting leg pain	2
Dof foot	1
Increased low back pain	1
Burning leg pain	1

DISCUSSION

The value of a rectangular construct in posterior internal fixation of the spine is, well established (12,13). The Hartshill system was introduced in 1984 and is now widely used, but we have fount that, in a number of patients, particularly where there has been previous surgery, satisfactory fixation cannot be achieved in the lumbar spine with sublaminar wires alone. Many papers have been published on the use of pedicle scerws, and this method of fixation is becoming more popular. (2, 6, 11). In addition, some surgeons have expressed reservations about the use of sublaminar wires and the possibility of late complications, (14, 15) although this remains unproven. In view of the above, we designed a suitable pedicle screw attachment for the Hartshill system. This was subjected to thorough biomechanical testing, reported in detail elsewhere, before proceeding to a clinical trial. We have had no mechanical failures of the device in our first fifty patients, followed up for up to 18 months. There have been no serious clinical complications, and no complications attributable directly to the new implant. Long term follow up continues.

We have found the pedicle bridge device to be invaluable in many cases. For example, in spondylolysis, and even in the very difficult, multiply operated case, with major deficiency of the posterior elements, it has been possible to achieve good secure fixation which would not have been feasible with the traditional Hartshill system.

For midlumbar fractures, it is possible to achieve secure fixation taking only one level above and below. Additionally, passing sublaminar wires through a possibly already compromised epidural space can now be avoided. For example, one of our patients was a young girl with a burst fracture of L3. Using a rectangle and wires, we would have had to fix from LI to L5, which would be very disabling. The security of the pedicle screw system allowed us to fix L2 to L4 only, saving two levels in the lumbar spine.

We emphasise that our technique docs not claim to be the answer for all back pain. Surgery for back pain remains controversial, (16) and the clinical result of fusion is dependent on many factors, particularly patients selection and accurate identification of the painful lesion.

In conclusion, we feel that the pedicle bridge is a useful addition to the Hartshill system and allows increased adaptability in the lumbar spine. It gives the surgeon the option of using pedicle screws, or sublaminar wires, or a combination of both. The bridge also allows the surgeon to minimise the number of levels fused, which is of particular importance in the lumbar spine.

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