

THE RADIOLOGICAL OUTCOME OF LUMBAR SPINAL FUSION USING A SOUTH AFRICAN-DEVELOPED DYNAMIC SPINAL FIXATION SYSTEM

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Objectives. To investigate the radiological outcome of the use of a new Cape Town-developed spinal fixation system.

Design. One hundred and fifty-five patients underwent posterior lumbar spinal fusions with this fixation system and autogenous bone graft more than a year ago. Of these 121 were available for radiological follow-up.

Setting. Spinal pedicle fixation systems are in common use in spinal fusion surgery. Most systems use rigid screws with a high rate of implant failure.

In South Africa most spinal implants are imported and expensive, and this prompted the development of a locally manufactured dynamic spinal fixation system with the aim of producing a cheaper and more effective system with a lower risk of implant failure.

Outcome measures. A visual assessment of 1-year post-surgery radiographs by a qualified independent observer looking particularly at the rate of fusion and the incidence of implant failure.

Results. Bone fusion rates were comparable to all other pedicle fixation systems but implant failure rates were considerably less than in systems using rigid screws and more comparable to a similar dynamic spinal fixation system.

Conclusions. This spinal fixation system is safe and effective in aiding bone fusion. It has a low rate of implant failure and is currently cheaper than all imported spinal fixation systems. It has therefore achieved the objectives that prompted its inception.

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The efficacy of lumbar pedicle screw fixation as an adjunct particularly in long lumbar spinal fusions is now well accepted.¹ This success is reflected in the multitude of such devices developed over the last decade. Early plate and screw constructs were soon superseded by more versatile rod and screw systems. Initially all fixation systems employed rigid screws which necessitated very accurate rod contouring to accommodate sagittal coronal and torsional distortions of the spine. Failure to achieve a precise fit between the screw and the rod would result in preloading of the system with the risk of subsequent failure. Even where an adequate fit is obtained there is still a significant incidence of instrumentation failure²⁻¹⁷ such as screw breakage, rod breakage or failure at the bone-metal interface with loosening of the screws in bone (Table I).

Recognising the inherent defects in implant design von Stempel *et al.*¹⁸ developed a unique implant (segmental spinal correction system) whereby the head and shank of the screw are connected via a hinge to allow permanent uni-axial articulation — a so-called dynamic fixation system. At first glance this seems contradictory since the purpose of the implant is to achieve rigid fixation. Biomechanical testing in von Stempel's own laboratory² as well as in an independent laboratory¹⁹ showed that the dynamic system was as rigid *in vitro* as one utilising fixed screws.

A review of patients treated with this method of fixation showed that the bony fusion rate was as good as with any rigid system, and importantly that the instrumentation failure rate was considerably reduced.²⁰

This system has the further advantage that precise rod contouring to achieve a perfect fit between the rod and the screw head is largely eliminated by the perpetual mobility of the screw head which readily accommodates non-perpendicular angulation between the rod and the screw.

South African surgeons face a major cost problem with the use of spinal fixation devices. Most spinal implants are imported and costs have escalated enormously over the last few years. Many medical aid societies and medical insurance companies now impose a benefit limit on the cost of surgical implants, frequently well below the cost of a planned spinal surgical procedure. A cheaper but equally effective alternative was therefore sought.

In 1995 a Cape Town manufacturing company proposed that such a spinal fixation device could be manufactured to international standards in South Africa at considerable cost saving. It would also allow local surgeons to provide an input in the design of such implants. After a preliminary period of development and testing a proposal for the investigative and therapeutic use of this device was submitted to the Research Ethics Committee of the Faculty of Medicine of the University of Cape Town, and this study was formally approved by the Committee in June 1997.

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Table I. Reported fusion and instrumentation failure rates

Authors	Fixator	Fusion rate (%)	Complication rate
Anand and Tanna ²	VSP Copy	Not discussed	9.4% screw breakage rate affecting 17.8% of patients
Bailey <i>et al.</i> ³	BWM	94	2.6% screw breakage rate, 2.5% rod breakage rate
Davne and Myers ⁴	VSP	Undeterminable	1.1% screw breakage rate affecting 13.9% of patients 5.6% nut loosening
Esses <i>et al.</i> ⁵	VSP, Edwards, AO	Not assessed	2.9% screw breakage rate
France <i>et al.</i> ⁶	VSP	76	1 broken screw in 29 patients
Hall <i>et al.</i> ⁷	Isola	91	4 patients reoperated with broken/loose screws out of 120
Kucharzyk ⁸	Rogozinski	87	No comment on instrumentation failure
Marchesi <i>et al.</i> ⁹	AO	94	15% screw breakage or loosening rate
McAfee <i>et al.</i> ¹⁰	VSP, CD	96	4.2% screw failure rate affecting 10% of patients
Ohlin <i>et al.</i> ¹¹	Olerud, Zielke, BWM	Not discussed	6.0% screw breakage rate
Pihlajamaki <i>et al.</i> ¹²	AO, CD, Olerud	80	20 screws broken in 17 of 102 patients 18 screws loosening in 14 of 102 patients
Steffee and Brantigan ¹³	VSP	93	2.5% screw breakage rate affecting 13.9% of patients
Suk <i>et al.</i> ¹⁴	Moss Miami, VSP	97	5.0% metal failure rate
Temple <i>et al.</i> ¹⁵	VSP	92	6.6% screw failure rate affecting 17% of patients
von Strempel <i>et al.</i> ²⁰	SSCS dynamic screws SSCS rigid screws	93 91	0.5% screw breakage rate and 1.5% rod breakage rate 2.2% screw breakage rate
West <i>et al.</i> ¹⁶	VSP	Not discussed	2.3% screw breakage rate affecting 9.6% of patients
Yuan <i>et al.</i> ¹⁷	Various	89	2.6% screw and 0.7% rod or plate breakage rate
This study	Titamed	93	0.3% screw breakage rate (2 of 587 screws inserted) 0% rod breakage of 236 rods inserted

AO = Association of Osteosynthesis; CD = Cotrel Dubousset; SSCS = segmental spinal correction system; VSP = variable screw placement.

MATERIAL AND METHODS

A prospective multicentre study was started in July 1997. To date (March 2002) 439 patients have undergone spinal fusion surgery with the use of this device, utilising a total of 2 032 screws of which 1 615 were mobile and 417 rigid screws. Among these were 289 patients who had posterior lumbar spinal fusions with 587 mobile screws, mostly for degenerative disorders. Of these 155 had had their surgery more than 1 year ago and constitute the cohort for this study. The other operations utilising mobile screws include posterior scoliosis corrective procedures, posterior fixation of spinal fractures and anterior spinal fixation for scoliosis correction, spinal tumours and spinal tuberculosis.

The value of spinal fusion surgery as a valid and effective modality of treatment for low back disorders has been the subject of medical debate for decades and is not the purpose of this paper. Furthermore, the known non-implant-related complications associated with pedicle screw insertion are well recorded elsewhere and do not form part of the focus of this study. This study was in the first instance specifically designed to look at the technical aspects of the surgical outcome with use of this device.

In this controlled pilot study we wanted to establish whether this device was safe when used in a standard manner and at least as effective as existing pedicle fixation systems. Its

potential advantages over other systems appeared to be improved design with easier insertion and removal and the fact that it is considerably cheaper than competing imported products.

Table II. Reasons for non-availability for review

Reason	No. of patients
Deceased (unrelated to surgery)	4
Patient untraceable	17
Patient unavailable	7
Radiographs done too late for assessment	6
Total	34

This is a radiological review of 121 (of the 155) patients who underwent posterior lumbar spinal fusions with the Cape Town-developed dynamic spinal fixation system utilising autogenous iliac bone graft and who have been followed up for a minimum of 1 year postoperatively. Although every effort was made to locate all the patients for follow-up the social habits and geographical 'instability' of South Africans make this task impossible (Table II). A standard posterior pedicle fixation with the new dynamic screws and a posterolateral lumbar spinal fusion using autogenous bone graft was

performed on all the patients in this study. The surgery was performed by six surgeons in four separate locations.

The selection criteria for surgery were surgeon-dependent. All patients presented with back pain with or without leg pain. The indications for surgery are presented in Table III. All patients were carefully documented prospectively. Radiographs were obtained preoperatively, in the immediate postoperative phase and again at 3, 12 and 24 months postoperatively.

Table III. Indications for surgery

Pathology	No. of patients	%
Degenerative disc disease	47	39
Spondylolisthesis	47	39
Post-discectomy	4	3
Pseudarthrosis	6	5
Extension of fusion	17	14
Total	121	100

The radiographs were reviewed and the results recorded by each operating surgeon. The 12-month (or greater) radiographs were then further (independently) reviewed by an orthopaedic surgeon knowledgeable in the interpretation of post-spinal fusion radiographs.

The fusion status was assessed (Table IV) using the criteria described by Jorgenson *et al.*:²¹ (i) solid fusion: continuous trabecular pattern of bone formation; (ii) not sure: continuous bone formation but amorphous and not clearly trabecular; and (iii) not solid: amorphous and non-continuous bone formation.

The following instrument-related complications were recorded: screw breakage, rod breakage, screw-rod interface loosening and screw-bone interface loosening (Table V).

Table IV. Fusion rate

Fusion status	No. of patients	%
Solid fusion	113	93.4
Not sure	5	4.1
Not fused	3	2.5
Total	121	100

Table V. Implant failures

Complication	Number	%
Screw breakage	2 of 587	0.3
Rod breakage	0 of 236	0.0
Screw-bone loosening	6 of 587	1.0
Screw-rod loosening	0 of 587	0.0

The implants used in this study were manufactured from surgical-grade titanium and have the following design features. The standard pedicle screws are 6 mm in diameter and have a unique uni-axial permanently articulating junction between the screw head and the shank (Fig. 1). The screws are all toploading and a smooth 5.5 mm rod is secured in the screw head by a single cap with a buttress thread (to prevent loosening) and an integral outer ring to prevent splaying of the screw head when the cap is tightened. The screw head and securing cap are cylindrical to allow easier rotation in a restricted operative field and more particularly to allow easier removal when the instrumentation is surrounded by well-consolidated bone graft.

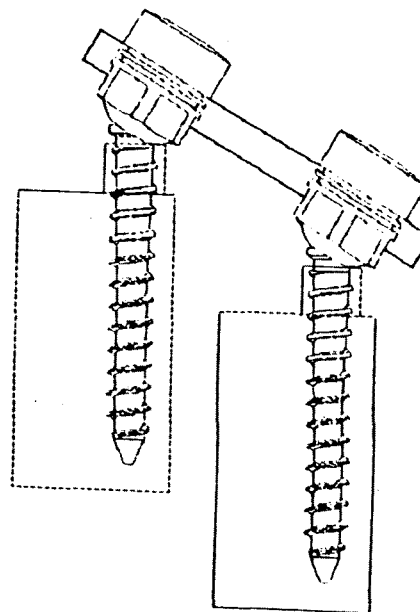


Fig. 1. Articulating screw heads accommodate the insertion of the rod non-perpendicular to the screw shanks.

In the evolution of this instrumentation system various design modifications were made (including the availability of 4.5 mm and 7 mm articulating and rigid screws and hooks) to suit particular operative circumstances such as fracture and scoliosis surgery. This does not form part of this paper and will not be discussed further at this time.

A parallel clinical outcome study of these patients is in progress and is being conducted by members of the Occupational Therapy Department of the University of Cape Town.

RESULTS

There were 74 women with an average age of 57.2 years (range 30 - 81 years) and 47 men with an average age of 51.6 years (range 27 - 80 years).

Table VI shows the breakdown of instrumented levels .

Table VI. Breakdown of levels instrumented

Fusion area	No. of patients
One-level fusion	
L1 - L2	1
L2 - L3	5
L3 - L4	8
L4 - L5	16
L5 - S1	14
Subtotal	44
Skipped-level fusions	
L2 - L4	1
L3 - L5	1
L4 - S1	35
Subtotal	37
Multilevel fusions	
L1 - L4	2
L1 - L5	2
L1 - S1	3
L2 - L4	3
L2 - L5	1
L2 - S1	1
L3 - L5	3
L3 - S1	4
L4 - S1	21
Subtotal	40
Total	121

One hundred and thirteen of the 121 patients (93.4%) had a radiologically solid fusion at 1-year follow-up (Table IV).

A total of 587 articulating screws and 236 rods were used. There were only two screw breakages.

The implant-related complication rate is presented in Table V.

DISCUSSION

These results are comparable to those achieved by von Stempel *et al.*²⁰ using a similar dynamic uni-axial permanently articulating system. This study supports the assertion that permanently articulating screws achieve fixation and fusion rates equal to or better than those of rigid screw systems, but lead to lower screw breakage rates.

The use of a toploading cylindrical screw head and a smooth rod has considerably eased both the insertion and removal of this device.

This fixation system has proved to be effective when used as

an internal spinal fixator in the intact (usually degenerate) spine. Dynamic (mobile) screws should, however, not be used in a single-level fusion where there is a risk of anteroposterior translation such as a spine fracture with anteroposterior instability (e.g. fracture dislocation) or an unstable spondylolisthesis. A single mobile screw above and below can move in parallel (Fig. 1) and in such circumstances possibly result in anteroposterior translational displacement. Fixation under these conditions is achieved better with rigid screws or adding a third articulating screw above or below if articulating screws have been used.

Table I illustrates the pedicle fixation instrumentation failure rates and fusion rates reported in the literature in the past decade. From this it is clear that an unacceptably high failure rate has occurred where rigid screw systems were used.

The use of permanently articulating screws has significantly reduced this rate of failure with an equal or better rate of fusion. No major complications have occurred as a consequence of using this device.

The manufacturer of this spinal fixation system recently achieved the stringent International Standards Organisation (ISO) 9001:2000 certification (an international quality and business management system that promotes delivery of improved products and service). Furthermore, the implants were awarded the CE mark (a mark of international quality acceptance). The local manufacture of this device in South Africa has resulted in considerable saving in medical implant costs.

CONCLUSION

This dynamic (permanently mobile) pedicle fixation system has proved to be safe (when properly inserted) and effective in achieving spinal stabilisation to allow fusion and has a remarkably low rate of implant failure. Its design features facilitate easier insertion and removal than other similar fixation systems.

A substantial part of the South African health budget goes towards the cost of medical implants. With the continuing decline in the value of our currency a reality which surgeons in this country will soon face²² will be the inability of not only the public sector but also the private sector to afford expensive imported medical implants. The alternatives would be to accept a progressive decline in the standard of medical care because of inaffordability, or to become self-sufficient through local manufacture. The expertise undoubtedly exists locally and it merely needs to be harnessed to produce products of international standard.

In a developing country with strained financial resources the obvious non-medical economic benefit of such an implant system is local manufacture which provides employment for

South Africans, the potential for export and savings on foreign exchange. It allows local surgeons an opportunity to provide input into the design and development of this and similar products and even customisation of products in selective cases.

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References

1. Boos N, Webb JK. Pedicle screw fixation in spinal disorders: a European view. *Eur Spine J* 1997; 8: 2-18.
2. Anand N, Tanna DD. Unconventional pedicle spinal instrumentation. *Spine* 1994; 19: 2150-2158.
3. Bailey SI, Bartolozzi P, Bertagnoli R, et al. The BWM spinal fixator system. A preliminary report of a 2 year prospective, international multicenter study in a range of indications requiring surgical intervention for bone grafting and pedicle screw fixation. *Spine* 1996; 21: 2006-2015.
4. Davne SH, Myers DL. Complications of lumbar spinal fusion with transpedicular instrumentation. *Spine* 1992; 17: suppl 65, 185-189.
5. Esses SI, Sachs BL, Dreyzin V. Complications associated with the technique of pedicle screw fixation. A selected survey of ABS members. *Spine* 1993; 18: 2231-2239.
6. France C, Yaszanski MJ, Lauerman WC, et al. A randomized prospective study of posterolateral lumbar fusion outcome with and without pedicle screw instrumentation. *Spine* 1999; 24: 553-560.
7. Hall BB, Asher MA, Zang RH, Quin LM. The safety and efficacy of the Isola spinal implant system for the surgical treatment of degenerative disc disease. A prospective study. *Spine* 1996; 21: 982-994.
8. Kucharzyk DW. A controlled prospective outcome study of implantable electrical stimulation with spinal instrumentation in a high-risk spinal fusion population. *Spine* 1999; 24: 465-469.
9. Marchesi DG, Thalgott JS, Aebi M. Application and results of the AO internal fixation system in nontraumatic indications. *Spine* 1991; 16: suppl 35, 162-169.
10. McAfee PC, Weiland DJ, Carlow JJ. Survivorship analysis of pedicle spinal instrumentation. *Spine* 1991; 16: suppl 85, 422-427.
11. Ohlin A, Karlsson M, Duppe H, Hasserijs R, Redlund-Johnell I. Complications after transpedicular stabilization of the spine. A survivorship analysis of 163 cases. *Spine* 1994; 19: 2774-2779.
12. Pihlajamaki H, Myllynen P, Bostman O. Complications of transpedicular lumbosacral fixation for non-traumatic disorders. *J Bone Joint Surg Br* 1997; 79-B: 183-189.
13. Steffee AD, Brantigan JW. The variable screw placement spinal fixation system. Report of a prospective study of 250 patients enrolled in food and drug administration clinical trials. *Spine* 1993; 18: 1160-1172.
14. Suk KS, Lee HM, Kim NH, Ha JW. Unilateral versus bilateral pedicle screw fixation in lumbar spinal fusion. *Spine* 2000; 25: 1843-1847.
15. Temple HT, Kruse RW, van Dam BE. Lumbar and lumbosacral fusion using Steffee instrumentation. *Spine* 1994; 19: 537-541.
16. West JL III, Ogilvie JW, Bradford DS. Complications of the variable screw plate pedicle screw fixation. *Spine* 1991; 16: 576-579.
17. Yuan HA, Garfin SR, Dickman CA, Mardjetko SM. A historical cohort study of pedicle screw fixation in thoracic, lumbar, and sacral spinal fusions. *Spine* 1994; 19: suppl 205, 2279-2296.
18. von Stempel AH, Kronauer I, Morlock M, Schneider E. Stability of the instrumented spine: dynamic versus rigid instrumentation. In: Hafer TR, Merola AA, eds. *Spine: State of the Art Reviews*. Philadelphia: Hanley and Belfus, 1996; 397-408.
19. Scifert JL, Sairyo K, Goel VK, et al. Stability analysis of an enhanced load sharing posterior fixation device and its equivalent conventional device in a calf spine model. *Spine* 1999; 24: 2206-2213.
20. von Stempel AH, Neckrütz A, de Muelenaere P, du Toit G. Dynamic versus rigid implants. In: Gunzburg R, Szpalski M, eds. *Lumbar Spinal Stenosis*. Philadelphia: Lippincott Williams and Wilkins, 2000; 275-285.
21. Jorgenson SS, Lowe TG, France J, Sabin J. A prospective analysis of autograft versus allograft in posterolateral lumbar fusion in the same patient. A minimum of 1-year follow-up in 144 patients. *Spine* 1994; 19: 2048-2053.
22. Wessels V. Private healthcare at breaking point. Business Report. *Cape Times* 30 January 2002: 5.

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