RESULTS AND COMPLICATIONS AFTER POSTERIOR LUMBAR SPONDYLODESIS WITH THE "VARIABLE SCREW PLACEMENT SPINAL FIXATION SYSTEM"

L. M. L. J. BOHNEN, J. SCHAAFSMA, A. J. TONINO

Between March 1988 and March 1990, 45 patients underwent a spondylodesis using transpedicular screws and plates of the "Variable Screw Placement Spinal Fixation System". The indications for operation were spondylolisthesis (13), spondylolisthesis plus discopathy at the adjacent level (4), degenerative discopathy (13), pseudarthrosis after interbody fusion (7), disc herniations (4) and disc herniations plus degenerative discopathy of the adjacent segment (4). In 1992, 43 patients were available for follow-up. The mean follow-up was 3.85 years. Side effects or complications of a more permanent character were seen 25 times in 43 patients. Eight patients had evidence of screw failure : loosening (5), fracture (2), and malposition (1). Complications, screw failure and reoperation all adversely affected clinical outcome. Overall only 60% of the patients reported a positive clinical outcome at follow-up.

In our opinion transpedicular instrumentation is a logical system to provide rigid stabilisation, but it has a high learning curve. The original V.S.P. system with its bulky plates and screws appears to be particularly prone to giving a high rate of unwanted side effects not offset by a high clinical success rate.

Keywords : lumbar spine ; spondylodesis ; instrumentation ; results ; complications.
Mots-clés : colonne lombaire ; rachisynthèse ; instrumentation ; résultats ; complications.

INTRODUCTION

High rates of nonunion have been reported after posterior fusions of the lumbar spine (5-55%) and are highly dependent on technique and assessment (1, 4, 18). Rigid spinal fixation techniques have been thought to reduce the rate of non-union by decreasing segmental mobility (2, 4, 5, 10, 14, 15, 16, 18), but the only valid comparative study by Bernhardt *et al.* (1) showed no significant difference in fusion rates between instrumented and noninstrumented methods of spondylodesis. Moreover, the instrumented method gave significantly more complications. The pedicle offers the strongest point of attachment to the spine, and most systems currently in development use some type of screw into the pedicle and vertebral body. Plates, wires or rods are attached to these screws to achieve intersegmental stability. One of these fixation techniques developed in order to obtain a higher fusion rate is the Variable Screw Placement Spinal Fixation System (V.S.P. system), designed by Steffee (figs. 1, 2). This is a report on our first experience with the V.S.P. System.

PATIENTS AND METHODS

Forty-five patients (22 males and 23 females) underwent a spondylodesis instrumented by the V.S.P. system between March 1988 and March 1990. The highest level of fusion was at the second lumbar vertebra, while the sacrum was involved 31 times (table I). Mean age was 46 years (range 19 to 75). The type of fusion was a posterior lateral fusion (P.L.F.) in 26 patients, a posterior lumbar interbody fusion (P.L.I.F.) in 13 patients

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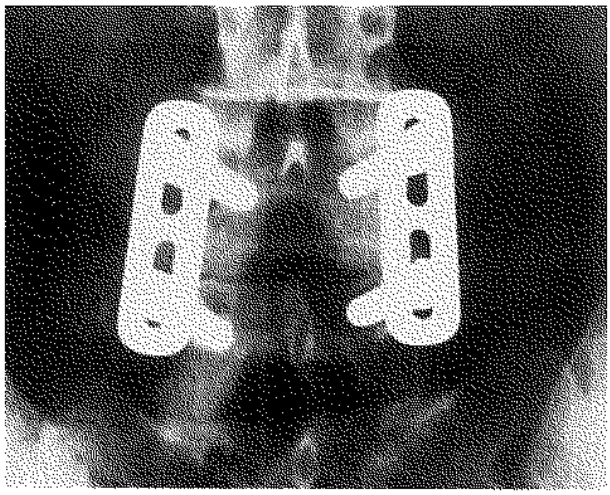

Fig. 1. — AP radiograph of a single level dorsal fusion (L_4-L_5), fixed by the "Variable Screw Placement Spinal Fixation System". The spondylodesis is rigidly fixed by a bilateral system of transpedicular screws and plates.

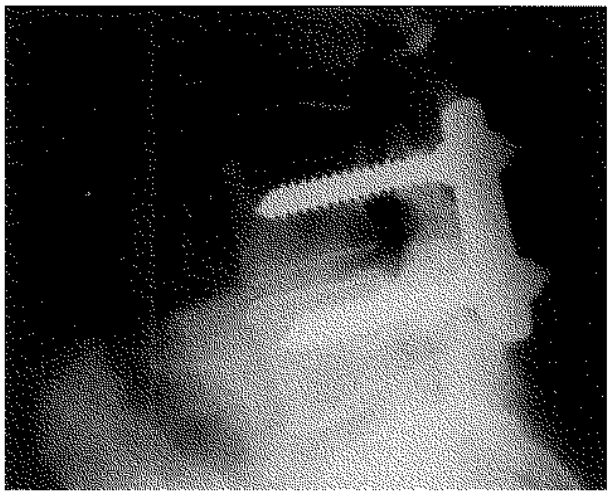

Fig. 2. — Lateral radiograph of a single level dorsal fusion (L_4-L_5), fixed by the "Variable Screw Placement Spinal Fixation System". The bone graft is located around and underneath the plate, in case of a posterior lateral fusion (P.L.F.).

Table I. — Levels of fusion (45 patients) :

1 segment :	L2-L3 :	1 patient
	L3-L4 :	1 patient
	L4-L5 :	11 patients
	L5-S1 :	18 patients
2 segments :	L3-L5 :	1 patient
	L4-S1 :	9 patients
3 segments :	L3-S1 :	4 patients

Table II. — Indications for operation (n = 45) :

Spondylolisthesis (Meyerding grade I-II)	13
Spondylolisthesis (grade I Meyerding) plus discopathy at adjacent level	4
Degenerative discopathy (discopathy after discectomy included)	13
Pseudarthrosis of interbody fusion	7
Herniations of the intervertebral disc	4
Disc herniations, plus discopathy of adjacent segment	4

and a combination of P.L.I.F. and P.L.F. in 6 patients. The mean duration of symptoms was 10 years, and 16 out of 45 already had failed back surgery. The indications for operation are listed in table II.

Surgical technique : The technique of spondylodesis with the V.S.P. system has been described extensively (12-14, 17, 18). Autografts from the operative field were used, supplemented by allografts. Bone blocks used for P.L.I.F. were carved to measure from an allograft.

More than half of the operations were performed in cooperation with a neurosurgeon. Twenty-four patients were referred by orthopedic surgeons, and 19 of them were submitted to a preoperative test by immobilization in a special brace, with a good response in 19 out of 21. Provocative discography elicited symptoms at the levels subsequently fused.

Postoperative regimen : Patients received preventive antiobiotics (Cefamandol) before and for 1 day after the operation. The average time of hospitalization was 11 days (6 to 30 days). For patient comfort we prescribed a temporary brace for mobilization in 34 out of 45 cases.

Forty-three patients were available for follow-up. One patient had moved to an unknown address, and one refused. The patients were evaluated for complaints, work conditions, physical activities and use of anal-

gesics, according to criteria derived from Stauffer and Coventry (11). The mean duration of follow-up was 3.85 years (range : 2.75 to 4.5 years). Evidence of fusion was assessed by standing anteroposterior and lateral flexion/extension xrays. Fusion was defined as absence of screw loosening or screw fracture with the bone mass confluent and no variation in position of the vertebrae on lateral dynamic xrays (1).

Complications and side effects : Complications were recorded, and side effects such as pain, muscle cramps, and subjective sensory disturbances were assessed postoperatively. In these 43 patients 23 complications and 26 side effects were recorded, but 24 of them were only transient (table III). Lower extremity sensory changes, were observed in 14 patients (permanent in 11). Postoperative leg weakness was seen in 5 patients ; it persisted in one patient (L_4-root lesion). Other permanent complications included screw problems (4) and progression of spondylolisthesis (1).

Table III. — Complications and side-effects in 43 patients :

	Temporary (24)	Permanent (25)
Complications :		
Paresis :	4	1
Decubitus :	1	–
Dural leakage :	1	–
Infection of initial operation wound :	2	–
Retroperitoneal haematoma :	1	–
Postoperative visceral dysfunction :	2	–
Urinary tract infection :	2	–
Progression of spondylolisthesis :	0	1
Technical problems :		
— malposition of screw :	0	1
— fracture of screw :	1	1
— loosening of screw :	3	2
Side-effects :		
Disturbance in sensibility :	6	11
Pain :	1	5
Muscle cramps :	0	1
Decrease of sexual potency :	0	1
Sore testis :	0	1

8 patients had a total of 14 screw problems :
5 patients had 9 episodes of loosening of a screw.
2 patients had early breakage of 4 screws.
1 patient had malpositioning of 1 screw.

Removal of instrumentation was performed in cases with persistent postoperative complaints or complications, and on a systematic basis in patients under the age of 50 years to prevent stress-shielding osteoporosis (7).

RESULTS

Clinical results : Patients were scored as having a good, fair or poor clinical result according to Stauffer and Coventry's criteria (11). A positive clinical result was defined as either good or fair. Sixty percent (26 out of 43) showed a positive clinical result at an average follow-up of 3.85 years.

Improvement of low back pain and leg pain : of 32 patients with preoperative leg pain, 24 (75%) reported diminished pain at follow-up. The improvement of low back pain was more limited : only 46% (18/39) of all low back pain patients and 60% (15/25) of those with severe low back pain reported relief.

Daily activities of life : Thirty-five of 43 patients were severely disabled before the operation. At follow-up only 18 patients (42%) were still in this category.

Fifty-three percent (23/43) of the patients thought that the operation had contributed to an improvement in their working capacity. Only 26% (11/43) returned to their previous level of work.

Analgesics : Preoperatively 25 patients took analgesics on a daily basis. At follow-up this number fell to 12 (thus 52% became free from analgesic use).

Evaluation : Sixty-seven percent (29, N = 43) did not regret the operation. Patients who regretted the procedure mentioned a disappointing clinical outcome (9 cases), the severity of the operation and the long duration of convalescence (3 cases), and complications (2 cases).

Reoperation : Eighteen of 43 patients were reoperated, and the instrumentation was removed on one or both sides. Eleven of these were reoperated for complications or complaints : 4 patients with pseudarthrosis and/or loose screw underwent a new spondylodesis after removal of the hardware ; in 4 other patients the instrumentation was removed because of postoperative radicular pain. In all 4 the fusion was sound ; they underwent a radicular exploration, while an adjacent augmentation was also performed in 2 of them because of pathology at the adjacent level. Instrumentation was removed in 3 patients because of deep infection (one after reoperation, and one other also had an L_4 paresis). The hardware was

removed on a systematic basis in patients under 50 years to avoid the risk of bone resorption due to stress-shielding, especially when there were still some minor complaints without objective findings (7 patients). In all patients who were reoperated the fusion was checked intraoperatively by means of open manipulation. A solid fusion was noted in 14 of these 18 patients (78%). The patients with reoperations showed a negative clinical result in 67% (12 out of 18), whereas only 5 of the 25 patients without a reoperation had a negative result (25%).

Radiographic fusion: At follow-up all patients including those reoperated were assessed (table IV). Three patients could not be evaluated because of insufficient documentation. Twenty-two showed solid bone fusion, while in 17 patients this was radiographically not evident and they were assessed as having a doubtful fusion. Only one patient showed clear evidence of nonunion. There was no significant difference between the clinical outcomes of patients with definite radiological consolidation (65% with positive clinical results) and those with doubtful consolidation (57% with positive clinical results).

Technical assessment of the instrumentation: technical results were assessed as good, fair or poor, according to our own criteria (table V) on the basis of early postoperative standing AP and lateral xray views and from surgical notes (e.g. all screws tightly fixed or not before hardware removal). The position of the screws in the pedicle, the length of screws and plates, the stability of the instrumentation, and early technical complications (fracture of bone or screw, loose screw), were assessed by an unbiased resident. Out of 40 instrumentations, 17 were assessed as good, 13 as fair and 10 as poor. Poor instrumentation yielded a poor clinical result in 5 of 10 patients (50%), while good instrumentation yielded in 47% (8/17) a poor clinical outcome. Fair instrumentation however resulted in only 31% poor clinical results (4/13). This difference was not statistically significant (Chi-Square = 1.11).

DISCUSSION

Whitecloud *et al.* (18) stated that because of the technical difficulty of the operation, all transpedicular fixation systems are associated with high complication rates. Apart from objective complications, we also evaluated side effects (pain, disturbances of sensation, and muscle cramps). Therefore we reached a very high postoperative complication rate, with 25 permanent problems in 43 patients. Although West *et al.* (17) reported that most complications were incidental and not

Table V. — Criteria for assessment of technical result :

A good technical result :
- — Transpedicular position of the screws.
- — No evidence of damage to the pedicles.
- — Each screw grips at least 60% of the AP length of the vertebral body.
- — The plate does not extend above the margins of the vertebral body and does not impinge on facet joints.
- — The osteosynthesis is rigid.

A fair technical result :
- — The osteosynthesis is rigid, but one of the criteria for a technically good result is unsatisfactory without evidence of clinical consequences.

A poor technical result :
- — All other situations.
- — Breaking or loosening of a screw.
- — Necessity of revision or removal of implant before bony consolidation is achieved.

Table IV. — Radiographic consolidation at follow-up (N = 43) :

Consolidation :	Definite	Doubtful/ partial	None	Unknown
P.L.I.F. (N = 11) :	5	4	–	2
P.L.F. (N = 26) :	14	11	–	1
Combination (N = 6) :	3	2	1	–

related to the device, most complications in our study appeared to be related in some way to the instrumentation : problems with screws, disturbance in sensation, paresis and postoperative pain. Most of these can be explained by contusion of nerve roots during screw insertion or by a change in the position of the vertebrae.

Patients with spondylolisthesis were found to have more sensorimotor complaints [65% (11/17)] compared to other patients [19% (5/26)]. This likely results from the reduction and the deeper location of the slipped vertebra resulting in more contusion of spinal roots. The P.L.F. technique also showed substantially more complications or side-effects (60%, 15/25) compared to the P.L.I.F. technique (25%, 3/12). This likely reflects the wider exposure and better visualization of the nerve roots with the P.L.I.F., resulting in less contusion of these roots.

Instrumentation of 1 level showed in 9 of 29 cases (31%) disturbance in sensibility and/or paresis, and for a 2-level fusion this problem was seen in 7 of 10 patients (70%). It appears that the more screws inserted, the higher is the chance of damage to a nerve root.

In this series mechanical screw problems (2 patients with a total of 4 broken screws, and 5 patients with a total of 9 loosened screws) were not seen more often than one might expect from the literature. Whitecloud *et al.* (18) found 7 fractured screws in 7 of 40 patients, while Zuchermann *et al.* (19) reported a screw fracture in 19 of 77 patients. If we compare the mechanical screw problems to the type of surgery, 7 of 25 patients with a P.L.F. (28%) versus 2 out of 12 with a P.L.I.F. (17%) showed screw problems. It is very likely that this results from the wider exposure in the P.L.I.F. technique. A one-level fusion showed technical screw problems in 14% (4/29), while for a two-level fusion this was 20% (2/10). Statistically, the more levels that are fused with more screws inserted, the higher is the chance of technical screw problems. In assessing the technical result we also have to point out the problem of too large a plate in 6 patients. This can result in direct pressure on the adjacent facet joint, causing pain or limiting local mobility. In 3 patients the instrumentation was removed later because of complaints, and this resulted in relief of pain in two. We believe that the new instrumentation systems using rods (instead of plates) that can be cut to the appropriate lengths, can be a solution to this problem.

The rate of infection after the initial operation was 4% (2/45) which is similar to previous studies (1, 14, 17, 19). The size of the implant as well as the longer duration of the operation because of the instrumentation may contribute to an increased risk of infection (18). One male patient with spinal stenosis and L_5-S_1 spondylolisthesis experienced erectile difficulties after an L_4-S_1 P.L.F. Johnson *et al.* (3) described the anatomic nerve supply of the urogenital system : because erection is related more closely to the parasympathetic innervation which is located inside the pelvis, and since in our case there was no perforation of the anterior cortex of the vertebrae, we cannot propose an anatomical explanation for this complication.

In the literature on spondylodesis autologous bone graft is often preferred because it reportedly yields better fusion rates (6, 8, 9). However, harvesting enough autologous bone for the spondylodesis may be a problem, while excision of large autografts from the ilium causes an increased risk of morbidity, prolongs the operation time, and increases blood loss (6). Therefore, we chose allograft bone from the hospital bone bank. Lorenz *et al.* (5) and Steffee and Brantigan (14) found a significant improvement in the fusion rate by V.S.P. as compared with previous literature reports. From this point of view, our patients with pseudarthrosis and/ or failed instrumentation raise the question whether these problems could have been reduced if we had used autologous bone grafts only. Reliable radiographic assessment of bony fusion of the lower back is very difficult, especially when a bulky implant covers most of the bone grafts. Our rate of definite fusion at follow-up is significantly less (55%) than reported in the literature : 78% versus 98% (1, 14, 16, 18). One reason may be that we assessed „bony consolidation" only if there was full evidence of bony continuity without mobility, instead of assessing only the absence of a pseudarthrosis. Other-

wise we would have had a very high fusion rate (reoperations included), as there was only one case of nonunion out of 40 at follow-up (table IV).

The overall success rate of 60% positive clinical results is fair compared to the range of 80 to 94% reported by other authors (1, 14, 18, 19). As our patients with a negative clinical result had very few other lumbar discopathies, we think that missed degenerative discs did not play a significant role in our clinical results.

In conclusion, our findings show that a solid fusion is no guarantee for a good clinical result. This illustrates the fact that the underlying disease process is often multifactorial. This was reflected not only by the long-standing history (average 10 years), but also by the fact that a high percentage (37%, 16 out of 43) of the patients had previously undergone failed low back surgery. Our findings also show that there is no straightforward relationship between good or bad instrumentation and a good or a poor clinical result. Therefore we conclude that this technique is worthwhile only for patients with severe symptoms, provided that they are relieved by a test brace, the provocative discogram is typical and conservative treatment has failed. In cases with long-standing isolated low back pain not fulfilling these criteria, our indications have become very restrictive, because of the low success rate.

There may be a need for rigid stabilization in cases of lumbar fractures, after reduction of spondylolisthesis, and in patients with spinal instability, especially when there is also a root impingement. The V.S.P. instrumentation may also be a solution for selected patients in poor condition who require early mobilization or who are not candidates for external bracing. However, in our hands the disadvantages of bulky and rigid V.S.P. instrumentation (high complication and reoperation rates, low clinical success rates, extra costs and extra operation time) did not balance its presumed advantages. More refined instrumentation techniques with rods and screws could be the answer.

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SAMENVATTING

L. M. L. J. BOHNEN, J. SCHAAFSMA EN A. J. TONINO. De resultaten en complicaties van dorsale lumbale spondylodeses met het „Variable Screw Placement Spinal Fixation System".

Van maart 1988 tot maart 1990 ondergingen 45 patiënten een dorsale spondylodese met een transpediculaire schroef-/plaatfixatie volgens het „Variable Screw Placement Spinal Fixation System". De indicaties hiervoor waren spondylolisthesis (13), spondylolisthesis met een aangrenzende discopathie (4), degeneratieve discopathie (13), pseudarthrose na een intercorporele fusie (7), discusherniatie (4), discusherniatie met een aangrenzende degeneratieve discopathie (4). In 1992 konden 43 patienten voor na-onderzoek bereikt worden. De gemiddelde follow-up duur was 3,85 jaar (2,75-4,5). Complicaties of bijwerkingen van een meer permanent karakter werden 25 maal gezien bij 43 patiënten.
8 patiënten hadden schroefproblemen : 5 × loslating, 2 × breuk, en 1 × een malpositie. Een slecht technisch resultaat (schroefproblemen), complicaties en re-operaties hadden allen een negatieve invloed op het klinische resultaat. In totaal toonden slechts 60% van de patienten een positief klinisch resultaat bij de follow-up. Naar onze mening is transpediculaire fixatie een logisch systeem om een rigide stabilisatie te verkrijgen, maar het heeft een lange leercurve. Speciaal het originele V.S.P. systeem met haar forse platen en schroeven lijken te neigen tot een hogere complicatieratio alsmede ongewilde nevenwerkingen, die niet opwegen tegen het klinische succes.

RÉSUMÉ

L. M. L. J. BOHNEN, J. SCHAAFSMA EN A. J. TONINO. Résultats et complications après arthrodèse dorso-lombaire avec le système de fixation rachidienne à positionnement variable de vis.

Entre mars 1988 et mars 1990, 45 patients ont subi une arthrodèse dorso-lombaire par plaque vissée du système de fixation rachidienne à placement variable des vis (Steffee). Les indications d'arthrodèse étaient un spondylolisthésis (13), un spondylolisthésis avec discopathie au niveau adjacent (4), une discopathie dégénérative (13), une pseudarthrose après arthrodèse intersomatique (7), des hernies discales (4) et des hernies discales avec discopathie dégénérative du segment adjacent (4). En 1992, 43 patients ont été revus. Le suivi moyen était de 3,85 années. Des effets secondaires ou des complications de caractère plus permanent ont été notés chez 25 des 43 patients. Un problème en rapport avec les vis a été noté chez 8 patients : déchaussements (5), fractures (2), et malposition (1). Les complications, les problèmes de vis et les réinterventions ont affecté de façon négative le résultat clinique. Dans l'ensemble, 60% seulement des patients ont fait état d'un résultat clinique favorable lorsqu'ils ont été revus.

A notre avis, l'instrumentation transpédiculaire est un système logique pour assurer une stabilisation rigide, mais la courbe d'apprentissage est difficile. Le système VSP original avec ses plaques volumineuses et ses vis nous semble exposer à un risque d'effets secondaires indésirables disproportionné par rapport à la qualité du résultat clinique.