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This is the exhibit marked 'HVC-3' referred to in the affidavit of Henry Vernon Crock sworn /

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affirmed at Toorak in Victoria on 11 September 2012.

Before me:

ROBYNNE SANDERS DLA Piper Australia 140 William Street, Melbourne An Australian Legal Practitioner within the meaning of the Legal Profession Act 2004

NUVASIVE NuVasive, Inc. v. Warsaw Orthopedic IPR2013-0

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made should help to prevent many failures.

Patients with serious spinal problems are often given dire warnings about surgical operations, not only from non-medical sources but even from some specialist surgeons. In a review article on intervertebral disc prolapse, Taylor and Akeson (1971) wrote: "Surgery has long since been shown to be far from the ideal solution". Reviews of various types of spinal operations usually refer to a hard core of up to 20 per cent of poor results. In some specific instances such as Stauffer and Coventry's (1972) review of anterior lumbar fusion operations carried out at the Mayo Clinic, results may be so poor that any useful role for a particular operation is placed in serious doubt.

Against such a background, problems in the management of failed spinal operations present a sobering spectacle. The aim of this paper is to present a rational approach to them and so to sound a note of confidence and hope which may help to dispel the gloom that so often confounds the unfortunate patient and depresses his physician. This can be a rewarding field of surgery because many patients will be found to have readily correctable lesions even after prolonged periods of disability.

THE PSYCHOLOGY OF FAILURES

With rare exceptions psychological disturbances will be found in these patients. The surgeon should remember that chronic pain adversely affects a patient's mental state, rendering him in varying degrees depressed, anxious and aggressive—features of behaviour which are reversible if the cause of pain can be discovered and corrected. Drug addiction sometimes causes added difficulties, though it may not contra-indicate further operation. A few patients will insist on operation after operation, often seeking many opinions and submitting to multiple procedures at the hands of different surgeons. They form a rare and tragic group for whom further operation may only lead to suicide, though many survive to end in financial ruin.

Psychological assessment along the lines suggested by Wiltse and Rocchio (1975) has been found useful, and in the present context such testing assumes even greater importance. Formal psychiatric treatment may also be required.

The analysis of individual cases of failed spinal

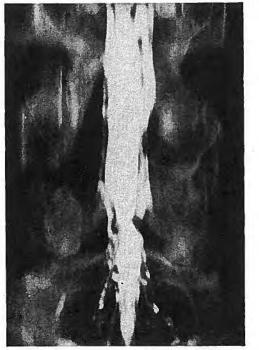


FIG. 1

Antero-posterior tomograph of the lower lumbar spine in a patient aged 37 years, said to have undergone laminectomy for removal of left lumbo-sacral disc prolapse. Part of the upper margin of the lamina of the fourth lumbar vertebra has been removed, so that the space between the third and fourth vertebrae was probably explored. The outline of the myodil shows that there is bilateral stenosis of root canals at the L.4-5 level.

operations may be facilitated by using the following classification: 1) *Outright failure*: This group comprises patients who show no improvement or who become worse after the first operation. 2) *Temporary relief*: These patients may be free of symptoms for months or years.

Paper read at the 108th Anniversary Meeting of the Texas Medical Association, San Antonio, Texas, United States of America, in May 1975.

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outcome can be predicted. Such special circumstances excluded, patients in this group can usually be identified soon after operation. They complain of pain which is more severe than is normally to be expected. Those with infections will have elevated temperatures and altered blood counts.

The questions to be determined are simply these: Is the failure due to an unrecognised condition? Is it due to wrong diagnosis of the spinal lesion? Or finally, is it due to technical failure?

Unrecognised conditions

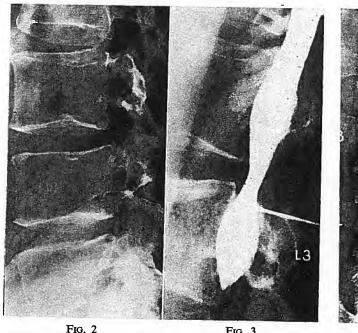
Investigations should begin as soon as possible, but several months may elapse before the diagnosis can be established. For example, a carcinoma involving the apex of the lung may be the cause of neck pain and brachial neuralgia persisting after anterior cervical fusion. Operation for lumbar spondylolisthesis may fail because the true cause of pain is a secondary prostatic carcinoma.

Rarely, infection after operation may be caused by tuberculosis or gonorrhoea.

Primary tumours in the spinal canal are relatively rare. They are usually diagnosed before operation by has been confirmed at operation. If a considerable amount of fragmented and desiccated disc material has been removed, it is likely that a further fragment has been displaced beneath the root sleeve after operation, or that a migrating sequestrated fragment has not been removed.

If a pre-operative diagnosis of disc prolapse was made but no disc prolapse was found at the time of operation, it is likely that the intervertebral space at the wrong level has been explored (Fig. 1).

Most failures occur when no frank prolapse is found. The diagnosis of internal disruption of the disc should have been established by discography before operation. **Failure after operation for internal disruption of the disc**— If this diagnosis has been established by discography and disc excision and interbody fusion have been done, early failure may indicate that the operation was at the wrong level. In the neck particularly, levels should be identified by radiographs taken during operation. The injection of methylene blue at the time of discography is an unreliable method of identifying the level of an affected disc. Even in the lumbar spine, levels may be wrongly identified, especially if there are anomalies such as sacralisation.



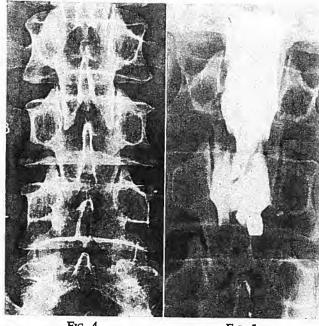
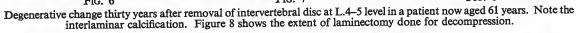


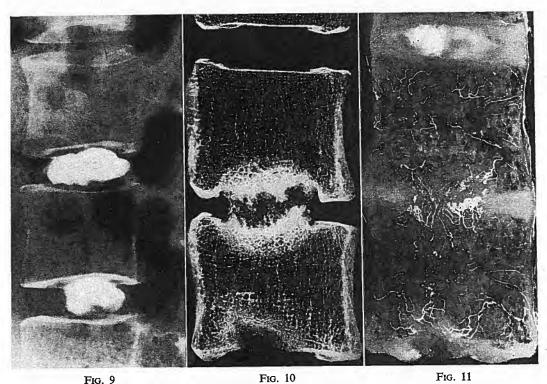
FIG. 2 Spinal stenosis in a man aged 54. Note the short pedicles (Fig. 2) and the spindling of the myodil column (Fig. 3).

FIG. 4 FIG. 5 Spinal stenosis. Note the facet orientation and decreased interlaminal space (Fig. 4), and the obstruction at L.3-4 (Fig. 5).

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Chemical discitis in a woman aged 32. Figure 9—Discograph shows posterior disruption at the level L.2–3, with normal disc at level L.3–4. The patient killed herself six months after anterior intervertebral fusion. Figure 10— Photograph of thin sagittal section of the lumbar spine taken at necropsy. At the level L.2–3 union of the graft is incomplete. There is erosion of the lower end-plate of the body of the third vertebra with reactive changes in an excavated area of the body, from chemical discitis. Figure 11—Section of the same specimen after arterial injection. Note the disc remnants infiltrating the grafted area at L.2–3 in the centre of the picture. On the right tufted vessels abut against invading disc tissue. Centrally the graft is vascularised. Note the reactive changes around the lesion in the lower part of the third vertebra.

If there is any doubt about identification, radiological examination should be done before anaesthesia is discontinued.

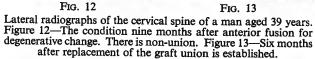
Other causes of failure

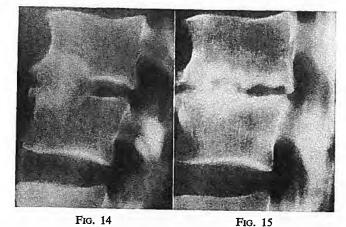
Stenosis of the spinal canal or of a nerve root canal must be excluded as an underlying cause of failure. The possibility that the symptoms are those of "claudication." of the cauda equina must be borne in mind. Under such circumstances myelography is essential. Figures 2 to 5 show spinal stenosis in the case of a man previously operated upon at the lumbo-sacral level for suspected disc prolapse. Myelography was not done before operation. Although the plain radiographs indicate that the

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Lateral tomographs of the upper lumbar spine of a man aged 46 years. Figure 14—Three months after operation. A circular cancellous graft has been inserted transversely at the L.3-4 level. Figure 15—One year later. There is collapse of the graft and established non-union.

of disabling pain. The largest number of cases fall into this category.

Failure after operation for disc prolapse—Recurrence is usually caused by recurrent prolapse at the level operated

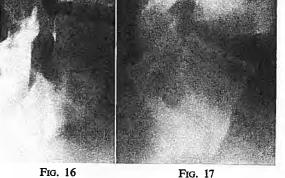
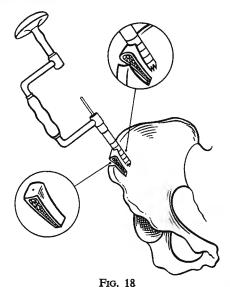


Figure 16—A lateral tomograph of the lumbo-sacral junction in a woman aged 32 years taken four months after interbody fusion showing graft incorporation with preservation of disc height and intervertebral foramen dimensions. Figure 17—A lateral radiograph of the lumbo-sacral junction in a man aged 46 years taken eighteen months after interbody fusion. The graft has incorporated but secondary disc space collapse has occurred with resulting nerve root canal and intervertebral foramen stenosis.



Method of cutting grafts from the anterior third of the iliac crest. The graft has "tooled" cancellous surfaces and stout cortical faces on either side.

fresh prolapse of disc material or by stenosis of the nerve root canal following deformation due to the reduction in intervertebral disc height.

The commonest cause of late recurrence of symptoms after initial successful excision of a disc prolapse is stenosis of the spinal and root canals secondary to de-

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