Affidavit of: Henry Vernon Crock, AO, MD, MS, FRCS, FRACS, FRCS Ed (Hon), D. Sc (Honoris causa) Melbourne.

Address: 13 Sargood Street

Toorak 3142

Victoria, Australia

Occupation: Retired Orthopaedic Spine Surgeon

Date:

11 September 2012

This is the exhibit marked 'HVC-5' referred to in the affidavit of Henry Vernon Crock sworn /

1

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

in Australia

ARIHISA FUJIMAKI, M.D.,* HENRY V. CROCK, M.D., M.S., F.R.C.S., F.R.A.C.S.,* AND SIR GEORGE M. BEDBROOK, M.D., M.S., F.R.C.S., F.R.A.C.S.**

The results presented in this paper are based on the studies of an independent observer (A.F.) carried out during his tenure of a postgraduate fellowship in Australia. Six months was spent interviewing 100 patients who had been operated on by one coauthor (H.V.C.) and a further 50 patients who had been operated on by the other coauthor (G.M.B.)

METHODS

Secretarial staff arranged all of the appointments without reference to the two surgeons who had performed the operations. In due course, each patient was interviewed independently by (A.F.) using a standard proforma. Physical examinations were carried out and pre- and postoperative roentgenograms were inspected, new films being obtained in most cases at the time of review.

PREOPERATIVE DIAGNOSIS

The indications for spinal fusion in this group of 150 patients are listed in Table 1. They are based on the acceptance and recognition of nonprolapsing disc disorders as an important cause of back and leg pain by the coauthors (G.M.B. and H.V.C.) The definitions of these pathologic entities have been published previously by Crock.³⁻⁵

Fusion had been attempted in 75 female and

Received: September 10, 1981.

75 male patients at 188 intervertebral disc spaces. The patients ranged in age from 19 to 62 years (average, 41.6 years). The frequency and number of fusions performed at different intervertebral levels are shown in Table 2.

The mechanism of injury in 69 patients was industrial; in 23 patients, a motor car accident; and in 16 patients, sports related. In 42 patients there was no history of injury. The data on these patients was gathered, considered, and classified into three groups: Group 1 (84 cases): those patients in whom their first and only spinal operation had been an interbody fusion; Group II (38 cases): those patients in whom interbody fusion had followed some other spinal operation; and Group III (28 cases): those patients in whom supplementary operations had been performed following lumbar interbody fusion operation. The rationale for these operations, to decompress the spinal canal and nerve root canals following anterior lumbar interbody fusions, has been described by Crock.⁶

The results, including information on occupation, time lost from work and on ultimate reemployment are listed for each group in Table 3.

In a recent publication on anterior fusion of the lumbar spine, Flynn and Hoque⁸ devoted considerable discussion to the radiologic evidence of fusion. We believe that the technique of involving the use of fibular bone is unacceptable. Using the method described previously by Crock,7 roentgenographic findings of fusion and nonunion were assessed, and the results are listed in Table 4.

COMPLICATIONS

When complications are discussed in relation to the use of interbody fusion operations, there was a striking difference in

0009-921X/82/0500/164 \$00.70 C J. B. Lippincott Co.

164



Find authenticated court documents without watermarks at docketalarm.com

^{*} Melbourne, Australia,

^{**} Perth, Western Australia.

Reprint requests to H. V. Crock, M.D., St. Vincent's

Hospital, Melbourne 3000, Australia.

surgical techniques that succeeded were really quite crude, aided by the use of antituberculous chemotherapy. Low back pain sufferers, on the other hand, present with a different mystique: their problems are not easily solved, diagnosis is difficult, and litigation among them abounds. The same surgical techniques which brought success in the management of spinal tuberculosis have fallen far short of satisfactory when applied to these various disorders; a nonunion rate of 37% was reported in a recently published series from Hong Kong.¹

Thus, with the use of a technique that allows repeated, reproducible accuracy, lumbar interbody fusions can be achieved in a high percentage of cases with a wide range of disorders of the lumbar spine.

Providing that the surgeon has had adequate training and experience in its use, the potential complications of large vessel damage, ureteric, dural sac, nerve root or cauda equina injury should not occur. Paralytic ileus is rarely seen with extraperitoneal approaches to the spine inasmuch as nothing is administered orally in the postoperative period until bowel sounds are audible or flatus has been passed. Furthermore, naso-gastric suction is used only when persistent abdominal distension occurs. Closed suction drainage of the retroperitoneal space and graft donor sites prevents blood accumulation, which might otherwise lead to the development of paralytic ileus.

Ureteric injury has not occurred in any of our cases; but, transient urine retention is relatively common during the first day after operation. Disturbances of ejaculation are rare. Deep vein thrombosis is still of major concern with an incidence, based on clinical grounds, of approximately 3%. Spu150

tum retention and its consequential problems can be prevented by the routine use of chest physiotherapy in the postoperative period.

Wound infections have been rare. One coauthor (H.V.C.) has had two cases of vertebral body infections in 20 years' experience, one of which required several drainage operations and chemotherapy for more than 12 months.

DISCUSSION

This paper reports on the results obtained following interview and examination of 150 patients without reference to the surgeons who had performed their operations (G.M.B. 50 cases, and H.V.C. 100 cases). All surgical techniques used were basically identical. It is clear from reviews in the literature that this valuable operation has failed to gain the acceptance it deserves for a number of reasons. Cloward² advocated a transspinal canal approach using cadaveric bone for interbody

TABLE 2. The Frequency and Number of Fusions Performed at Different ls

Intervertebral Leve	
---------------------	--

Single-Level Fusions		Double-Level Fusions	
Sites	Numbers	Sites	Numbers
L ₁₋₂	1	L ₂₋₃ 3-4	1
L ₂₋₃	1	L3-44-5	7 —
L ₃₋₄	4	L4-5-L5-51	30
L4-5	18		
L ₅ -S ₁	88		
	112		38

		84				
	Nonsedentary	23	24.0	14	6	3
2	Home duties	7	5.6	6	0	1
	Sedentary	8	6.5	7	0	1
		38				
	Nonsedentary	19	16.5	10	alest ali 3 milit densita	6
3	Home duties	5	11.5	a 3	1	1
	Sedentary	4	12.5	2	0	2
		28	t ti Leca x		- SL#L#L& -	4,00

fusion; but, few surgeons could match his technical skill. Wiltberger¹¹ advocated a dowel method of intervertebral body fusion to be performed through the spinal canal, and for similar reasons this operation failed to gain many proponents. Leaving aside the vexed question of indications, the safe and reliable performance of anterior interbody fusion demands the acquisition of skills that

TABLE 4.	Radio	logical	Assessment
----------	-------	---------	------------

Group	G.M.B.	<i>H.V.C.</i>
1. 84 Cases	26 cases	58 cases
Union	24	56
Nonunion	2	2
2. 38 Cases	16 cases	22 cases
Union	16	21
Nonunion	0	1
3. 28 Cases	8 cases	20 cases
Union	8	19
Nonunion	0	1
Total union	48 (96%)	96 (96%)

are not taught in most orthopedic centers techniques of far less sophistication than those used in everyday open heart operations. Furthermore, the reputation of the procedure has been damaged by the published results from the Mayo Clinic; Stauffer and Coventry¹⁰ reporting on 83 cases in eight years performed by seven surgeons. More recently Flynn and Hoque,⁸ also from the United States, reported on 52 patients treated by this operation in a 12 year period: thirtysix of these cases were performed by one surgeon and 16 by three other surgeons. The rate of operation averaged four cases per year.⁸

Neither of these papers stands up to scientific criticisms that could be leveled at the purely technical aspects of interbody fusion methods. The blood supply of the lumbar vertebral bodies is not disturbed in the anterior fusion techniques using dowel cutting instruments or osteotomes. Yet, one of the reasons for graft failure put forward by Stauffer and Coventry,¹⁰ was that the blood supply of the vertebral bodies was relatively poor. In the two major papers referred to the special instruments allows reproducible accuracy. There is no doubt, however, that a high level of proficiency has been reached involving the use of interbody fusion techniques with cutting of dowel cavities by hand using osteotomes. Freebody *et al.*⁹ have used this technique in the management of high grade vertebral slips in spondylolisthesis, with spectacular success.

SUMMARY

The work of two Australian surgeons using the same techniques for anterior lumbar interbody fusion operations in 150 patients has been analyzed by an independent observer (A.F.). Used as a primary procedure in 84 cases, only four patients failed to return to work. Time off work varied between 3.3 to 11.8 months, depending on the patients' occupations. Used as a salvage procedure in 38 cases, only five patients failed to return to work. Time off work varied between 24 and 5.6 months depending on the patients'

- A. C. B. C.: Anterior spinal fusion for deranged lumbar intervertebral disc. Spine 5:452, 1980.
- Cloward, R. B.: The treatment of ruptured lumbar intervertebral discs by vertebral body fusion. Neurosurgery 10:154, 1953.
- Crock, H. V.: A reappraisal of intervertebral disc lesions. Med. J. Aust. 1:983, 1970.
- 4. Crock, H. V.: Isolated lumbar disc resorption as a cause of nerve root canal stenosis. Clin. Orthop. 115:109, 1976.
- Crock, H. V.: Traumatic disc injury. *In* Vinken and Bruyn (eds.) Handbook of Clinical Neurology. Amsterdam, North-Holland Publishing Co., 1976, pp. 481-511.
- Crock, H. V.: Observations on the management of failed spinal operations. J. Bone Joint Surg. 58-B:193, 1976.
- 7. Crock, H. V.: Anterior lumbar interbody fusion, indications for its use and notes on surgical technique. Clin. Orthop. 165:1981.
- Flynn, J. C. and Hoque, M. A.: Anterior fusion of the lumbar spine. J. Bone Joint Surg. 61A:1143, 1979.
- Freebody, D., Bendall, R., and Taylor, R. D.: Anterior transperitoneal lumbar fusion. J. Bone Joint Surg. 53B:617, 1971.
- Stauffer, R. N., and Coventry, M. B.: Anterior interbody lumbar spine fusion. Analysis of Mayo Clinic Series. J. Bone Joint Surg. 54A:756, 1972.
- Wiltberger, B. R.: The dowel intervertebral body fusion as used in lumbar disc surgery. J. Bone Joint Surg. 39A:284, 1957.



Boyd0003621