IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Michelson
U.S. Patent No.: 8,251,997 Attorney Docket No.: 13958-0112IP1
Issue Date: August 28, 2012
Appl. Serial No.: 13/306,583
Filing Date: November 29, 2011
Title: METHOD FOR INSERTING AN ARTIFICIAL IMPLANT BETWEEN TWO ADJACENT VERTEBRAE ALONG A CORONAL PLANE

DECLARATION OF DR. PAUL McAFEE, M.D., M.B.A.

I, Dr. Paul McAfee, M.D., M.B.A., of Sparks Glencoe, Maryland, declare that:

QUALIFICATIONS

1. I am an orthopaedic surgeon board certified by the American Board of Orthopaedic Surgery and fellowship trained in spine surgery. I received my medical degree from the State University of New York at Upstate Medical Center, Syracuse, NY, in 1978. I performed an internship at the Department of General Surgery, University of Virginia, Charlottesville, VA, from 1978-1979, a residency in orthopaedic surgery at the State University of New York, Upstate Medical Center, Syracuse, NY, from 1979-1983, and a fellowship in spinal reconstructive surgery at the Case Western Reserve University / University Hospitals, in Cleveland, OH, from 1983-1984. I am currently the Chief of Spine Surgery, at Towson Orthopaedic Associates, P.A., in Baltimore, MD. I also currently have an academic appointment as Chief, Spinal Reconstructive Surgery, at University of Maryland St. Josephs Hospital, Towson, MD, a position I have held since 1989, and as Associate Professor, Department of Orthopaedic Surgery, The Johns Hopkins Hospital and Johns Hopkins University School of Medicine, a position I have held since 1988.

2. With specific regards to spinal surgical procedures using a lateral approach to the spine, I have the following experience. I have performed over 500 lateral approaches with discectomy, fusion, and instrumentation in the thoracolumbar spine. I have published over 150 peer-reviewed publications pertaining to spinal fusion. I have over 20 patents pertaining to the subject of spinal implants. I have participated in over 10 clinical studies registered with the United States Food and Drug Administration to

NUVASIVE 1001

investigate the clinical use of spinal implants. I have continuously maintained the clinical practice of spinal surgery caring for over 1000 outpatients per year for the last 28 years.

3. I am not an employee of NuVasive, Inc., but I have been a clinical and research consultant working with Nuvasive over the past 10 years. I am the inventor of the Porous Coated Motion (PCM) cervical disk replacement, and the intellectual property associated with that invention was held by a company named Cervitech Inc., which was acquired by NuVasive in 2009. I have been engaged in the present matter to provide my independent analysis of the issues raised in the above-mentioned *inter partes* review of U.S. Patent No. 8,251,997 ("the '997 patent"). I received no compensation for this declaration beyond my normal hourly compensation based on my time actually spent studying the matter, and I will not receive any added compensation based on the outcome of the above-mentioned reexamination of the '997 patent.

4. Based upon my knowledge and experience in this field, I am aware of the needs and the challenges orthopaedic surgeons face in performing spinal surgical procedures. I routinely perform and observe these spinal surgical procedures, and I am familiar with the various types of access systems that are used during spinal surgical procedures, including dilator instruments and retractor assemblies. I was a practicing spine surgeon prior to February 27, 1995 and I am familiar with the state of spinal surgery prior to February 27, 1995. I am also very familiar with what was considered acceptable in terms of lateral access to the spine before and after February 27, 1995. I have formulated my analysis on this matter based on this personal experience and what was considered standard by one skilled in the art prior to February 27, 1995.

5. I am familiar with the content of the '997 patent, and the prosecution history of the '997 patent. Additionally, I have reviewed the following documents: (1) U.S. Patent No. 4,545,374 to Jacobson ("Jacobson"); (2) Leu et al., "Percutaneous fusion of the lumbar spine," SPINE: State of the Art Reviews, Vol. 6, No. 3, Sep. 1992 ("Leu"); (3) U.S. Patent No. 5,192,327 to Brantigan ("Brantigan"); (4) U.S. Patent

No. 4,917,704 to Frey et al. ("Frey"); (5) U.S. Patent No. 5,015,247 to Michelson (Michelson '247); (6) European Patent Application No. 0 567 424 A1 to Alacreu ("Alacreu"); (7) "Baulot et al., "Spondylodese anterieure complementaire par thoracoscopie: Note technique a propos d'une observation," Lyon Chirurgical, Vol. 90, No. 5, pp. 347-51 (1994) ("Baulot"); (8) English translation of Balout; (9) Rosenthal et al., "Removal of a protruded thoracic disc using microsurgical endoscopy," SPINE, Vol. 19, No. 9, pp. 1087-1091 (1994) ("Rosenthal"); (10) U.S. Patent No. 4,573,448 to Kambin ("Kambin"); (11) Patent Cooperation Treaty (PCT) International Application Publication No. WO 94/28824 to Michelson ("Michelson PCT"); (12) U.S. Patent No. 5,772,661 to Michelson (Michelson '661); (13) U.S. Patent No. 6,241,770 to Michelson ("Michelson '770); (14) Crock, "Anterior Lumbar Interbody Fusion: Indications for its Use and Notes on the Surgical Technique," in Clinical Orthopaedics and Related Research, No. 165, pp. 157-63, May 1982 ("Crock") (attached as Exhibit A to this Declaration); (15) Affidavit of Dr. Henry Crock (attached as Exhibit B to this Declaration); (16) Berry et al., "A Morphometric Study of Human Lumbar and Selected Thoracic Vertebrae," Spine, Vol. 12, No. 4, pp. 362-67, at p. 364, Table 1 (1987) ("Berry") (attached as Exhibit C to this Declaration); (17) McAfee et al., "The value of computed tomography in thoracolumbar fractures: An analysis of one hundred consecutive cases and a new classification," The Journal of Bone and Joint Surgery, Vol. 65-A, No. 4, pp. 461-473, April 1983 (attached as Exhibit D to this Declaration). I also have reviewed additional references cited in this Declaration but not included in the list above.

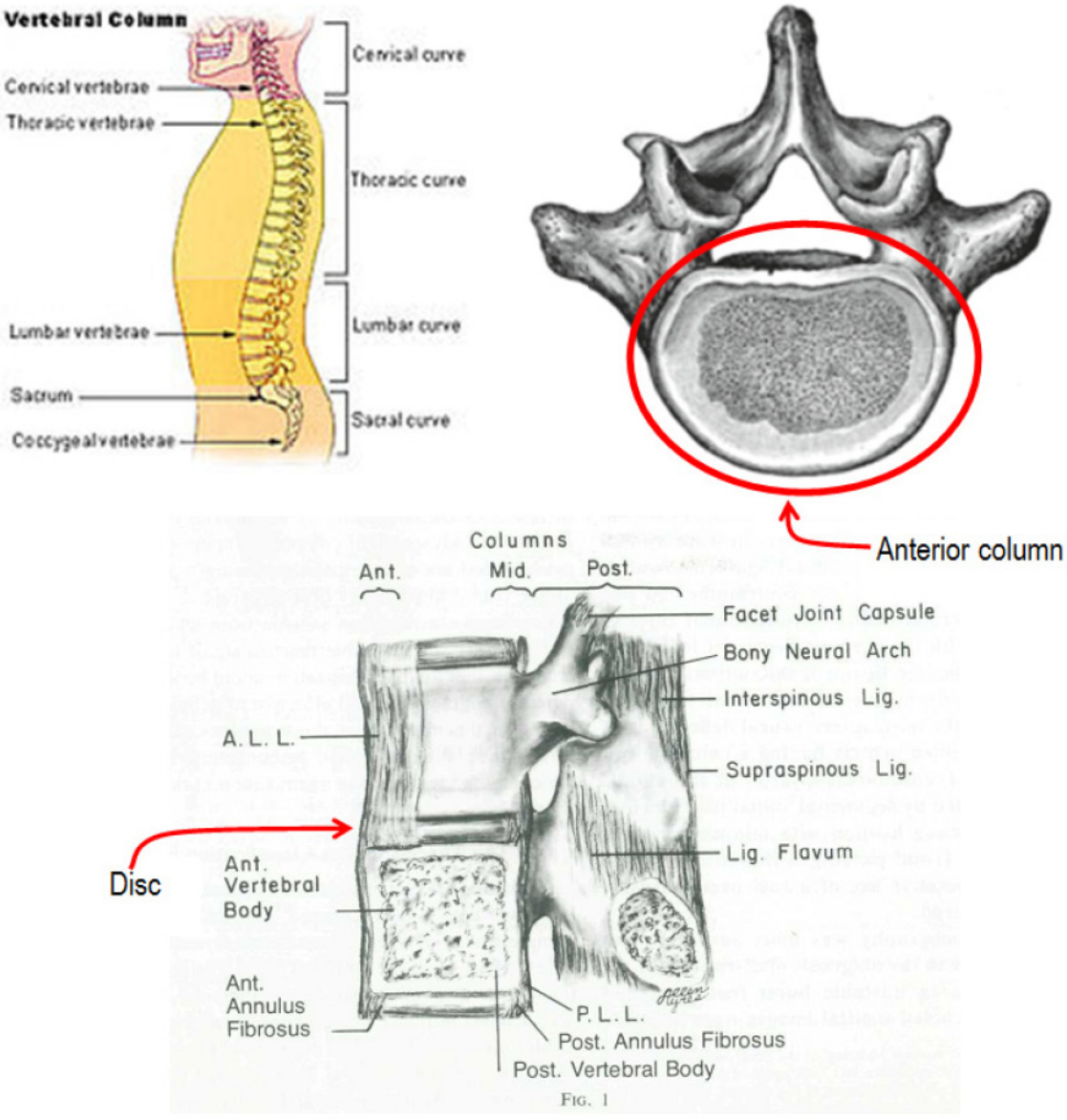
6. My findings, explained below, are based on my education, experience, and background in the fields discussed above.

BACKGROUND KNOWLEDGE ONE OF SKILL IN THE ART WOULD HAVE HAD PRIOR TO THE FILING OF THE '997 PATENT

7. The '997 patent is entitled "method for inserting an artificial implant between two adjacent vertebrae along a coronal plane." Specifically, the '997 patent discloses performing the method using an approach, or direction, to the spine that is generally lateral (that is, from the patient's side) or antero-lateral

(that is, obliquely from the front/side of the patient). *Id.*, col. 3, lines 36-37. The '997 patent describes the access tools for the surgery, or in other words, how the surgeon accesses the spine to perform the procedure, and in addition, discloses a particular procedure that is called "fusion." I am an expert in these areas of technologies and procedures, and was an expert in these areas prior to the filing of the '997 patent on February 27, 1995.

8. By way of background, the human spine (shown below) is made up of 33 vertebrae, including 24 articulating vertebrae and nine fused vertebrae of the sacrum and coccyx. The articulating vertebrae are divided into three groups, the cervical group in the neck region (seven vertebrae), the thoracic group in the middle (12 vertebrae), and the lumbar group in the lower back (five vertebrae). These articulating vertebrae articulate because they have discs positioned between adjacent vertebrae which allow the articulation. The patent claims of the '997 patent are directed to spinal fusion procedures in the thoracic and lumbar regions of the spine. Also as shown below, the spine is made up of an anterior (front) column, a middle column, and a posterior portion, with the spinal cord being enclosed between the latter two. In the anterior column, adjacent vertebrae are separated by an intervertebral disc. Each disc forms a joint that allows slight movement of the vertebrae, and acts as a ligament to hold the vertebrae together. The middle column is comprised by the posterior annulus fibrosis, posterior vertebral body, and posterior longitudinal ligament.



Upper-left figure, above – Wikipedia.org, [retrieved on March 20, 2013]

<http://en.wikipedia.org/wiki/File:Illu_vertebral_column.jpg>

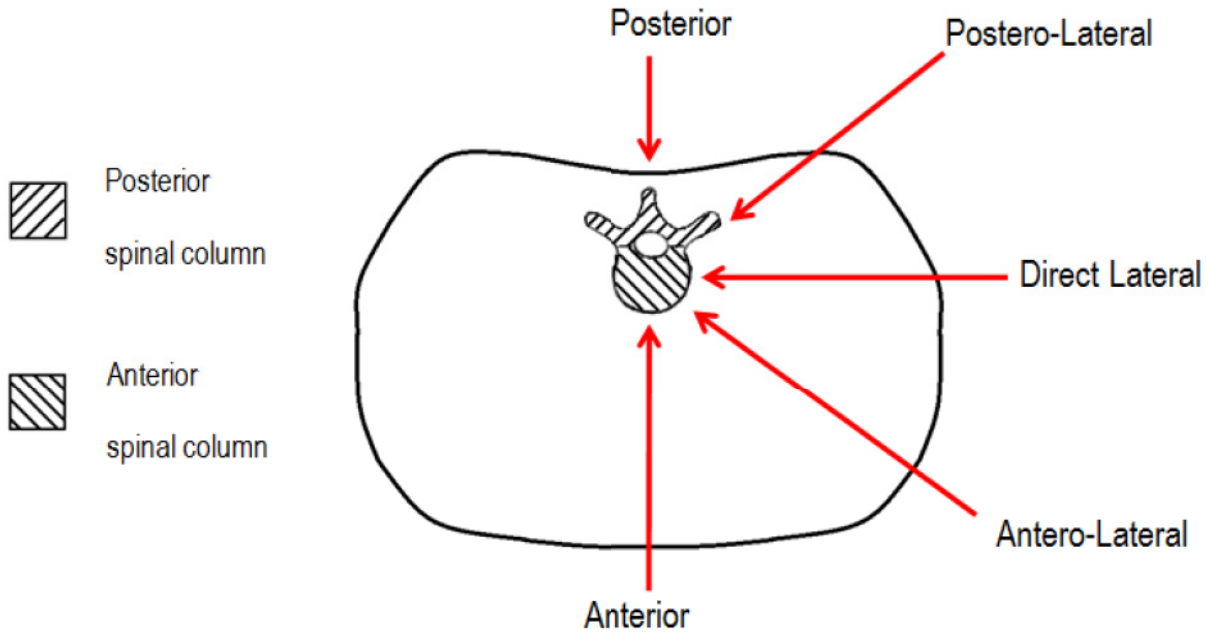
Upper-right figure, above – Wikipedia.org, [retrieved on March 20, 2013]

<http://en.wikipedia.org/wiki/File:Gray94.png>

Bottom figure, above – McAfee et al., "The value of computed tomography in thoracolumbar fractures: An analysis of one hundred consecutive cases and a new classification," The Journal of Bone and Joint Surgery, Vol. 65-A, No. 4, pp. 461-473, April 1983 (Exhibit D)

9. Spinal fusion is a surgical procedure, believed to be first reported in 1911, that fuses two or more parts of the vertebrae together. This is done in some cases to eliminate motion in the spine to decrease or eliminate back pain created by the motion, and in other cases to correct various spinal deformities. Fusion procedures may be performed in the spine's posterior portion or in its anterior column. Fusions in the anterior column in many cases involve removing all or a portion of an intervertebral disc, and implanting a fusion implant in the disc space to cause bone growth between two adjacent vertebrae. This may involve the fusion of two vertebrae across one disc space (single-level fusion), or three or more vertebrae across multiple disc spaces (multi-level fusion). A discectomy is another procedure that is sometimes performed in the anterior column of the spine. This is done in some cases to remove disc material that has been expelled from a ruptured intravertebral disc, and that is impinging on a nerve. A spinal fusion across a disc space also involves a discectomy, to remove a degenerated disc before implanting a fusion implant in the disc space where the removed disc had resided.

10. To perform a procedure in the anterior column of the spine – whether it be a fusion procedure, a discectomy or some other procedure – the spine is surgically accessed. This may be done from many different directions, or approaches, each approach having benefits and disadvantages or challenges. As illustrated in the diagram below, the various approaches that may be taken to the anterior column of the spine include posterior, postero-lateral, far or direct lateral, antero-lateral, and anterior. In posterior or postero-lateral approaches, the patient is typically positioned on his or her stomach (prone). In anterior and antero-lateral approaches, the patient is positioned on his or her back (supine). In a direct or far lateral approach, the patient is typically positioned in a so-called "lateral decubitus" position, which is on the patient's side. All of these approaches to the spine were known and used before the filing of the '997 patent.



11. The use of a direct or far lateral approach goes back at least to the early 1980's, as the approach is disclosed in a 1982 paper authored by the well-known and highly regarded spine surgeon, Dr. Henry Crock of Australia. Crock, "Anterior Lumbar Interbody Fusion: Indications for its Use and Notes on the Surgical Technique," in Clinical Orthopaedics and Related Research, No. 165, pp. 157-63, May 1982 (attached hereto as Exhibit A); *see also* Affidavit of Dr. Crock (attached hereto as Exhibit B). Dr. Crock describes that when a fusion procedure is to be performed in the upper lumbar region, the patient is placed in the lateral decubitus position (on the patient's side), and the anterior column of the upper lumbar spine is approached from a direct or far lateral direction. *Id.*, p. 158-59. Dr. Crock also illustrates two side-by-side openings having been formed in a lateral aspect (the side) of the intervertebral disc area, and describes that fusion-creating grafts in the form of cylindrical bone dowels are inserted into those laterally facing openings. *Id.*, p. 160-61. Also in the early 1980's, another publication of a direct or far lateral approach to the lumbar spine was provided in U.S. Patent No. 4,545,374 to Jacobson ("Jacobson"). Dr. Jacobson describes a less invasive "percutaneous" approach to the lumbar spine than the procedure described by Dr. Crock, but similarly Dr. Jacobson's access technique involves placing the patient in the lateral decubitus

position and advancing instruments to the anterior column of the spine along a direct or far lateral approach. *See, e.g.,* Jacobson, col. 2, line 31; col. 5, line 6; FIG. 3 et seq. Dr. Jacobson discloses that this direct lateral access technique may be used for discectomy procedures and fusion procedures, among others. *See id.*, col. 1, line 9; col. 6, lines 9-13. In the thoracic spine, direct or far lateral approaches were also known and used before the February 27, 1995 filing of the '997 patent.

INTERPRETATIONS OF THE '997 PATENT CLAIMS AT ISSUE

12. I understand that, for purposes of my analysis, the terms appearing in the patent claims should be interpreted according to their "broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b). I further understand that the words of the claims should be given their plain meaning unless that meaning is inconsistent with the patent specification or the patent's history of examination before the Patent Office. I also understand that the words of the claims should be interpreted as they would have been interpreted by a person of skill in the art at the time of the invention was made (not today); because I do not know what the date that the invention as claimed was made by Dr. Michelson, I have used the filing date of the claimed priority patent application to the '997 patent as the point in time for claim interpretation purposes, to the extent it matters. That date was February 27, 1995. I have been asked to provide my interpretation of the following terms and phrases of the '997 patent set forth below.

13. Claim 1 recites a "path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes" (col. 22, lines 60-63). First, the term "coronal plane" is illustrated in a diagram from TheFreeDictionary's medical dictionary that was provided by the patent applicant during the prosecution history, copied below:

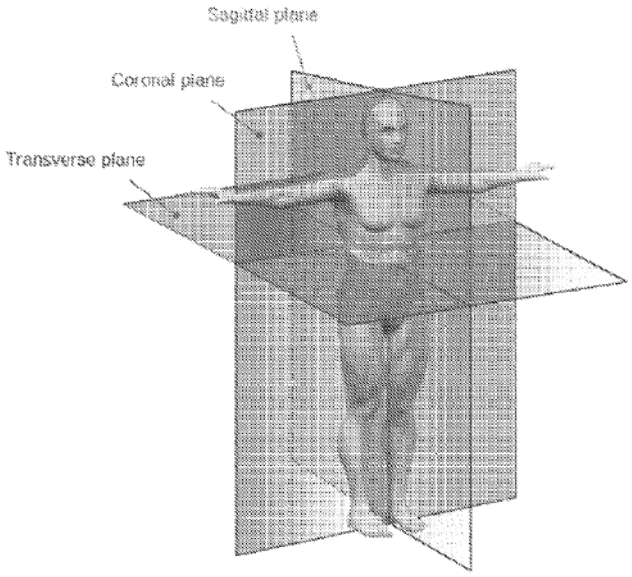


Figure A

'997 patent prosecution history, Reply to Office Action, March 20, 2012, p. 14. Claim 1 also defines that the "coronal plane" must "pass[] through a lateral aspect and a medial aspect of the two adjacent vertebrae." The phrase "lateral aspect" of vertebrae generally refers to each of the two sides – the left side and the right side – of the vertebrae. Given the curved nature of vertebrae, one of skill in the art would understand that there is no definitive starting point or ending point of a "lateral aspect" of a vertebra, but rather the lateral aspect is an approximate area. A "medial aspect" of two adjacent vertebrae is a phrase that would not be conventionally used by persons of skill in the art. In addition, I have not found that the phrase "medial aspect" is used or defined in the '997 patent specification. As such, and for purposes of my analysis in this matter only, I have assumed the term "medial aspect" to mean a mid-line of the vertebrae, extending anterior to posterior. Finally, I have assumed that the phrase "anterior to the transverse processes" defines the path, and thus it is the "path" that must be "anterior to the transverse processes." In addition, and although inconsistent with the plain language of the claim, I have also assumed that the clause does not require that the path be entirely anterior of the transverse processes (that is, directly in front of the transverse processes); indeed, if that were the case, then the path would not lie in a coronal

plane, but may lie in a sagittal plane. As such, I have assumed that the claim limitation requiring the "path" to be "anterior to the transverse processes" simply requires that the claimed "path" be anterior to a line extending through the right and left transverse processes, and extending to the sides of the transverse processes.

14. Claim 1 recites the step of "advancing a second surgical instrument … over at least a portion of the length of said first surgical instrument" (col. 23, lines 1-3). In accordance with the claim interpretation principles set forth above, I believe that a person of ordinary skill in the art would recognize the broadest reasonable interpretation of the above phrase in claim 1 to be as follows. The term "over," as used in this claim phrase, means external of an outside periphery of the claimed first surgical instrument, or in other words, surrounding it. In my opinion, this is consistent with the '997 patent specification, which shows an elongate bullet-nosed distractor 100 (with a central passageway 107 or lumen) being advanced "over" an elongate guide pin 30. *See* '997 patent, FIGS. 2 and 4.

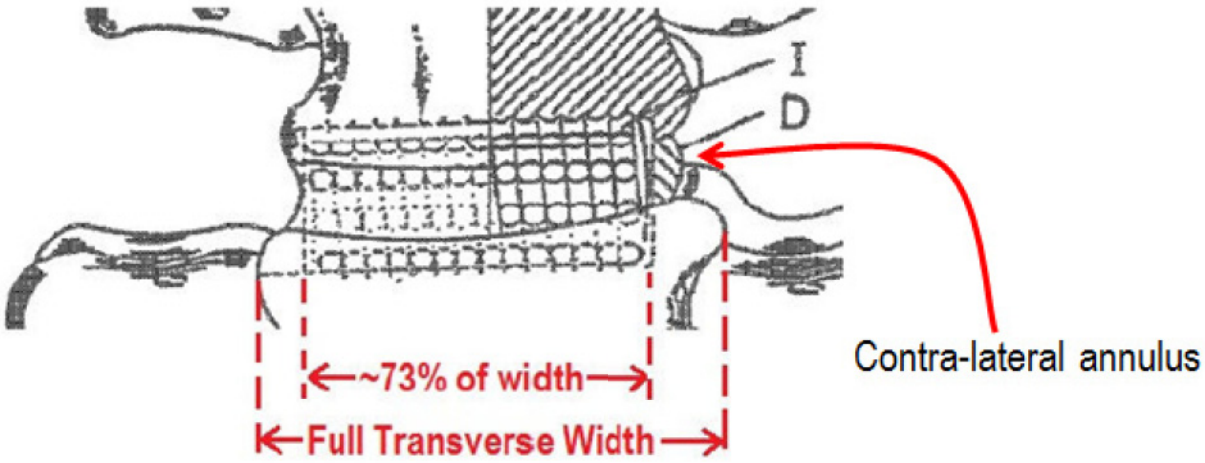
15. Claim 1 recites the step of "advancing a third surgical instrument … over at least a portion of the length of said second surgical instrument" (col. 23, lines 9-11). In accordance with the claim interpretation principles set forth above, I believe that a person of ordinary skill in the art would recognize the broadest reasonable interpretation of the above phrase in claim 1 to be as follows. The term "over," as used in this claim phrase and similarly to how it was used previously in the claim as discussed above, means external of an outside periphery of the claimed second surgical instrument, or in other words, surrounding it. In my opinion, this is consistent with the '997 patent specification, which shows a tubular "extended outer sleeve" 140 being advanced "over" the distractor 100. *See* '997 patent, FIGS. 6 and 7.

16. Claim 1 recites the phrase "non-bone interbody intraspinal implant" (col. 23, line 21). In accordance with the claim interpretation principles set forth above, I believe that a person of ordinary skill in the art would recognize the broadest reasonable interpretation of the above phrase in claim 1 to be as follows. The term "non-bone interbody intraspinal implant" means that at least part of the implant

comprises material that is not naturally occurring autograft (bone taken from the patient's body) or allograft (bone taken from a body other than the patient receiving the implant, such as a cadaver).

17. Claim 1 further recites the length of said implant "being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae" and "being greater than the depth of the disc space" (col. 23, lines 27-30). For purposes of my analysis, I have assumed the meaning of "sized to occupy substantially the full transverse width" includes within its scope lengths that are shorter than the full transverse width of the two adjacent vertebrae, because that is what the '997 patent discloses, as discussed in the next paragraph.

18. In particular, the '997 patent describes an implant that is shorter than the full transverse width of the vertebral bodies of the two adjacent vertebrae, and the '997 patent describes no implants that are equal to or greater than the full transverse width of the vertebral bodies. The fact that the implant is shorter than the full transverse width is illustrated not only in Figure 30 of the '997 patent, but also very clearly in Figure 23 of the '997 patent, which provides more anatomical detail than Figure 30. An annotated version of a portion of Figure 23 is copied below:



As shown in Figure 23 (above), the length of the implant (I) is less than (in fact, about 73% of) the full transverse width of the vertebral bodies of the two adjacent vertebrae. In addition, Figure 23 shows that

the portion of the annulus (the outer harder periphery of the disc) that is opposite of the side in which the implant was inserted (the so-called "contra-lateral annulus," which is on the right side of Figure 23 above) has been left in place. In order for the implant (I) to extend across the full transverse width of the adjacent vertebral bodies, the contra-lateral annulus would have to be "released," which means to cut through it, which would permit the implant to extend beyond the contra-lateral annulus. With the contra-lateral annulus shown left in place, one of skill in the art would understand that the length of the implant would be less than the full transverse width of the vertebral bodies of the two adjacent vertebrae. I understand that the reference letter "D" in Figure 23 is referenced in the '997 patent specification as being a "disc space," but I do not view that labeling as being contrary to my opinion that the contra-lateral annulus is shown in Figure 23 as having been left in place. There is in fact a disc space in Figure 23, as well as a contra-lateral annulus. In addition, the '997 patent does not describe removing the contra-lateral annulus, and does not describe an implant resting on the ring apophysus. One of skill in the art, in February 1995, would have understood that at that time it was most conventional to not drill through the opposite annulus when drilling a hole in a disc to implant a fusion implant. In addition, the '997 patent specification describes mechanisms for ensuring that the drilling of the hole for the implant does not extend too far (col. 13, lines 22-26), and states that the path of drilling is done to a "predetermined and limited depth" (col. 13, lines 60-61).

19. I also understand that the Patent Owner – in a reissue proceeding for U.S. Patent No. 5,772,661 to Michelson ('661 patent) that was eventually abandoned – relied on Figure 30 of the '661 patent (which is the same as Figure 30 of the '997 patent) in support of an argument that the specification discloses "positioning said implant to contact at least a portion of a cortical rim of at least one of the adjacent vertebrae with each of said ends of said implant." In connection with that, the Examiner rejected the Patent Owner's contention, and reasoned as follows:

> Fig. 30 of Applicant's disclosure is a two-dimensional representation of a three dimensional structure. The actual points of contact of the ends of the implant with each of the adjacent vertebrae are different due to the curvature of the implant in a sagittal plane. Since, the

> surface of an end of the implant curves away from the cortical rim due to the curvature of the implant in a sagittal plane, Applicant's argument that "The area of contact of the implant I with the vertebra L inherently includes the cortical rim thereof" is not persuasive.

U.S. Patent Application Serial No. 12/655,178, filed Dec. 23, 2009, Final Rejection, p. 13 (Aug. 11, 2011).

In my opinion, the Examiner was correct in this conclusion, for the following reasons. Figure 30 of the '997 patent does not illustrate the necessary detail to address the issue. In addition, the figure of the '997 patent that does provide the necessary detail – namely, Figure 23 copied and discussed above – shows that the implant (I) does not rest on the vertebral body cortical rim. In addition, the relative dimensions of depth and width of the fourth lumbar (L4) vertebra's end surface depicted in Figure 30 of the '997 patent is anatomically inaccurate. In particular, a typical depth-to-width ratio for the superior (upper) surface of the L4 vertebra is 49.6mm/33.9mm, or 1.46. *See* Berry et al., "A Morphometric Study of Human Lumbar and Selected Thoracic Vertebrae," Spine, Vol. 12, No. 4, pp. 362-67, at p. 364, Table 1 (1987) (attached hereto as Exhibit C). By contrast, the ratio of depth-to-width of the lumbar vertebra endplate depicted in Figure 30, as measured by me, is approximately 1.60. Given the anatomical inaccuracy of Figure 30, it would be inappropriate in my opinion to rely on it as depicting that the implant (I) is resting on the vertebra's cortical rim. Third, a later-filed patent of Dr. Michelson – U.S. Patent No. 6,241,770 ('770 patent) – explains, in its background section, that the implant (I) shown in the '997 patent (and thus in the '661 patent which has the same specification) "prevents the utilization of the apophyseal rim bone [labeled "AR" in FIG. 1 copied below], located at the perimeter of the vertebral body to support the implants at their trailing end." *See* '770 patent, col. 3, line 57 to col. 4, line 12. This is illustrated by Figures 1 and 11 of the '997 patent copied below:

FIG. 1

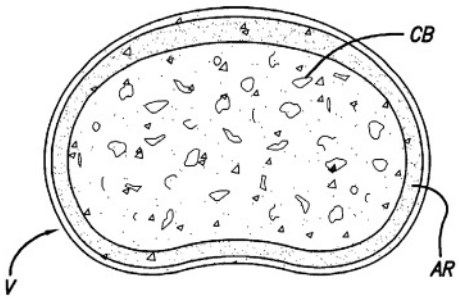
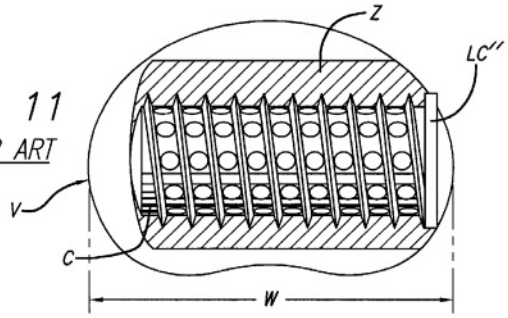


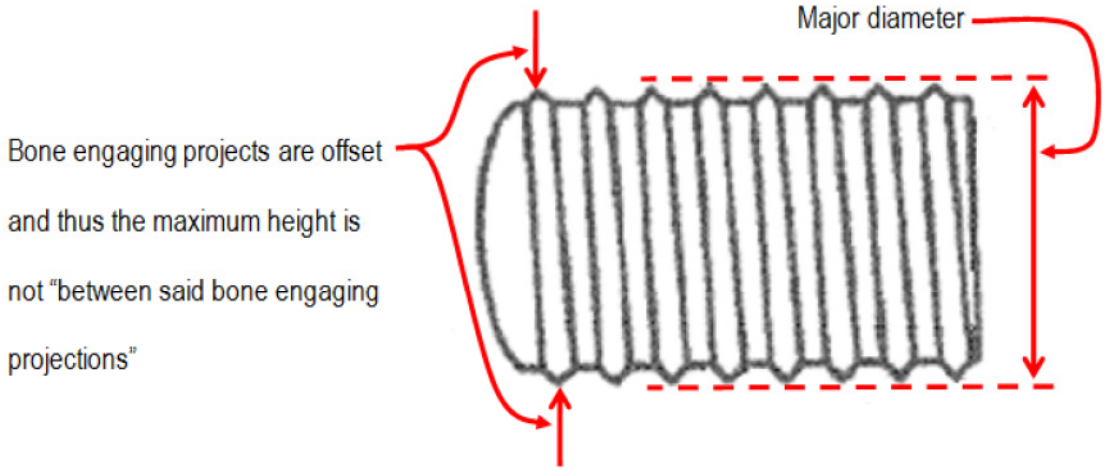
FIG. 11
PRIOR ART



As such, the characterization of the '661 patent (and hence the '997 patent) implant that Dr. Michelson made in his later '770 patent further illustrates that the Examiner was correct in assessing that the '661 and '997 patent specifications do not disclose "positioning said implant to contact at least a portion of a cortical rim of at least one of the adjacent vertebrae with each of said ends of said implant."

20. Claim 1 recites the phrase "said implant having a maximum height between said bone engaging projections of said opposed surfaces and perpendicular to the length of said implant, the length of said implant being greater than the maximum height of said implant" (col. 23, lines 35-39). In accordance with the claim interpretation principles set forth above, I believe that a person of ordinary skill in the art would recognize the broadest reasonable interpretation of the above phrase in claim 1 to be as follows. The definition in the claim of "maximum height" is unclear, because for the threaded cylindrical implant (I) described in the '997 patent, the "height between bone engaging projections of said opposed surfaces" is not "perpendicular to the length of said implant." This is shown with reference to the implant (I) as shown in Figure 30 of the '997 patent, as copied below (with annotations and modified to remove illustration of surrounding vertebrae):

21.



As illustrated above, a line perpendicular to the length of the implant would not extend between a bone engaging projection on the top of the implant and a bone engaging projection on the bottom of the implant. As such, for purposes of my analysis, I have assumed the claimed "height" to be a distance between a highest point of the implant and the lowest point of the implant, or in other words for a threaded, cylindrical implant, the outside thread diameter (or in other words, the major diameter).

JACOBSON IN VIEW OF LEU AND BRANTIGAN (CLAIMS 1 AND 8)

22. Jacobson discloses a spinal access technique that involves placing the patient in a lateral decubitus position, and advancing to a spinal disc space in the lumbar region via a direct lateral approach. *See* Jacobson, Figures 3 and 8; col. 2, lines 23-33; col. 5, lines 5-8. In Jacobson, the access technique involves the use of three instruments used in the establishment of an access cannula 11 (e.g., Figure 6), through which a spinal procedure is performed. Jacobson discloses that the access cannula may be used to perform a discectomy procedure (shown in Figures 7-8) and other types of surgical procedures in the spinal column lumbar region, including, among others, a "fusion" procedure (col. 6, lines 9-13).

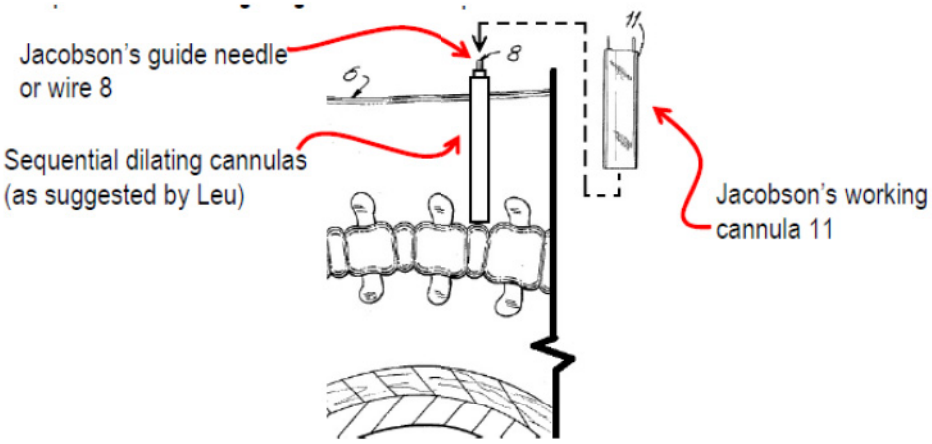
23. Based on my knowledge and experience in this field and my review of the Jacobson reference, I believe that a person having ordinary skill in the art would recognize that this direct lateral

approach to the spine, as disclosed in Jacobson, advances along a "path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse process," as recited in claim 1 of the '997 patent in accordance with its broadest reasonable interpretation. *See* Jacobson, Figures 3 and 8; col. 2, lines 23-33. Jacobson also discloses the claimed step of making a laterally-located incision through which the three claimed instruments are inserted. In particular, Jacobson describes the lateral insertion into the patient of a long spinal needle or guide wire 8 (Figure 3, and col. 5, lines 28-30 and lines 42-45), which one of skill in the art would understand to require the making of a skin incision (especially for the guide wire embodiment having a diameter of nearly "3-mm"). In addition, and after describing the insertion of the needle or guide wire 8, Jacobson then describes making a one centimeter long incision in the same area as the first, namely above the pelvic crest (col. 5, lines 45-46), which one of skill in the art would understand to be an increase in the incision already formed.

24. Jacobson discloses a cannulated second instrument in the form of a speculum 10, which may be advanced over the initial guide needle or wire 8 so as to widen the surgical access path for subsequent insertion of the final working cannula 11 within the speculum 10. Jacobson, col. 5, lines 48-54; FIGS. 4-5. Claim 1 requires, however, "advancing a second surgical instrument … over at least a portion of the length of the first surgical instrument," and "advancing a third surgical instrument … over at least a portion of the length of said second surgical instrument." In other words, claim 1 encompasses a conventional access technique known as sequential dilation, which is the advancement of successively larger tubes over one another to achieve a desired size of working cannula. By the early 1990s, surgeons commonly employed sequential dilators to widen a surgical access path from the width of an initial guide needle to a width that is sufficient for a working cannula of a desired size. *See, e.g.,* Leu at p. 596; U.S. Patent No. 4,449,532 to Storz (sequential dilator access system); U.S. Patent No. 4,573,448 to Kambin (sequential dilator access system for cannula access to a spinal disc space); U.S. Patent No. 4,969,888 to Scholten et al. (sequential dilation system for cannula access to vertebral body); U.S. Patent No. 5,015,255

to Kuslich, at col. 8, lines 29-32 (initial guide pin, sheath over guide pin, and locating cylinder 104 over sheath to access disc space to perform spinal fusion procedure); U.S. Patent No. 5,171,279 to Mathews, FIGS. 4A-4C (sequential dilator access system for cannula access to a spinal pedicle); U.S. Patent No. 5,472,426 to Bonati et al. (sequential dilator access system for cannula access to a spinal disc space).

25. An example of the use of sequential dilators in the access of a spinal disc space to perform a spinal fusion procedure is disclosed in Leu, which discloses a surgical method for accessing a lumbar disc space via a working cannula to deliver a spinal fusion implant. Leu, p. 594 (describing a technique of "percutaneous lumbar interbody fusion); p. 596 (describing "four cannulas" used for sequential dilation and a "working cannula"); p. 603 (suggesting the use of non-bone fusion implants ("composite grafts") through the working cannula). In such prior art surgical methods, Leu expressly teaches the general prior art practice in which sequential dilators (for example, "four cannulas of increasing diameter are stepwise overslipped, one upon the other") are advanced over a "central guide needle" to widen the surgical access path from the width of the initial guide needle to a width that is sufficient to introduce the final working cannula. *Id.* at p. 596. Based on my knowledge and experience in this field and my review of Jacobson and Leu, I believe that a person having ordinary skill in the art at the time (in the 1992 timeframe, and certainly before the filing of the '997 patent in February of 1995) would have considered it to be an obvious choice to replace Jacobson's second instrument (a speculum) with one or more of Leu's sequential dilators, so as to widen the surgical access path from the initial guide needle in a manner that reduces the trauma to the intervening tissue. One example of this obvious modification is illustrated below:



Jacobson, Figure 3 (modified according to Leu's suggestion to employ sequential dilating cannulas over Jacobson's guide wire). In addition, a person of ordinary skill in the art at the time (at least as early as 1992) would have considered the replacement of Jacobson's speculum with sequential dilators (as suggested by Leu) to be an application of a known technique (sequential dilation) to a known access system (one that starts with a guidewire and expands tissue to accommodate a working cannula) that would yield predictable results (access to the spinal disc space without undue tissue trauma). Here, a person of ordinary skill in the art at the time would have plainly understood that, even though Leu's specific surgical method employs four sequential dilators, Leu is exemplary of a more general prior art knowledge that surgeons could readily use any number of sequential dilators "[o]ver a central guide needle" prior to inserting the "working cannula." Leu, p. 596. In my opinion, it would have also been well within the skill of a skilled artisan (at least as early as 1992) to select a particular number of sequential dilators according to the desired size of the surgical access path for receiving the final working cannula (Jacobson's working cannula 11 or a predictably larger version thereof for purposes of Jacobson's suggested "fusion" surgery as described below) over the last sequential dilator. Thus, under the broadest reasonable interpretation standard described above, any one of the sequential dilators (as suggested by Leu) that are advanced over Jacobson's initial guide needle or wire 8 (the first instrument) along Jacobson's lateral approach path would provide the claimed second instrument. Namely, each sequential dilator would be advanced through the

incision and over a portion of Jacobson's initial guide needle or wire 8 using a central passageway of the sequential dilator.

26. Based on my knowledge and experience in this field and my review of Jacobson and Leu, I believe that the resulting surgical method of Jacobson in view of Leu (described above) would include the claimed step of "positioning said third surgical instrument such that said distal end of the third surgical instrument is proximate a lateral aspect of the vertebral bodies of the two adjacent vertebrae," as recited in claim 1. In particular, Jacobson expressly teaches that, in the lateral surgical approach, the working cannula 11 (the "third surgical instrument") should be positioned proximate to the lateral aspect of the vertebral bodies of the two adjacent vertebrae. *Id.* at FIGS. 6-8; col. 2, lines 25-30; col. 5, lines 1-4; col. 6, lines 9-13. Further, in accordance with Jacobson's express suggestion to employ his lateral access method for a "fusion" procedure (col. 6, line 13) and Leu's teaching of the general prior art knowledge that a working cannula for "fusion" procedures should be "larger than the types used for" procedures that merely remove some disc material (p. 596), a person of ordinary skill in the art at the time would readily understand that the resulting surgical method would predictably employ a larger working cannula size than what is illustrated in Jacobson's drawings. Accordingly, in the resulting surgical method of Jacobson in view of Leu, the working cannula 11 would be similarly positioned proximate to (and, predictably, in engagement with) the lateral aspect of the vertebral bodies (after advancing over sequential dilators as described above), thus achieving the benefits of a lateral surgical approach as taught by Jacobson.

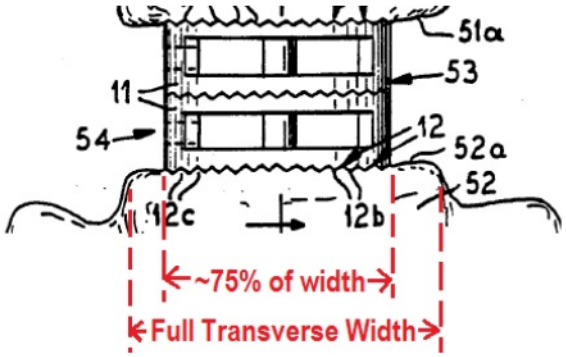
27. Regarding insertion of a non-bone spinal implant through the claimed third surgical instrument, Jacobson expressly discloses that the lateral access system may be used for performing a "fusion" procedure. *See* Jacobson, col. 6, lines 9-13. One of skill in the art at the time of Jacobson (and certainly by the early 1990s) would have understood that Jacobson's suggested fusion procedure would necessarily involve the implantation of a spinal implant. In addition, Leu expressly discloses the introduction of a non-bone, "composite graft" fusion implant structure through the working cannula (Leu, p.

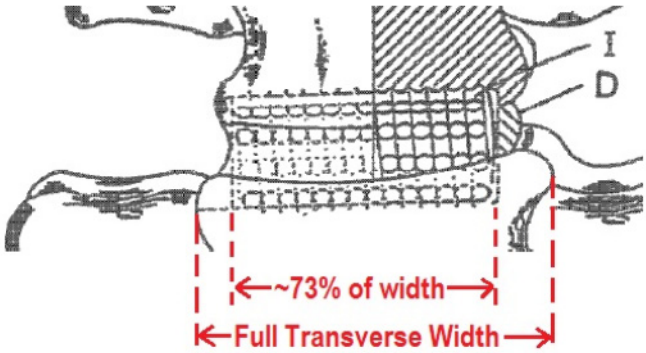
597), and discloses that such an implant is "promising" because it can reduce the time required for post-operative supplemental fixation of the vertebrae (Leu, p. 603). Thus, in the resulting surgical method of Jacobson in view of Leu, a person of ordinary skill in the art would have been prompted to employ the working cannula/third surgical instrument (Jacobson's cannula 11) to insert a non-bone interbody implant into a laterally facing opening in the lumbar spine for at least the widely known benefits described in Leu and in fusion cage disclosures. Indeed, by the early 1990's, non-bone "fusion cage" type spinal fusion implants had come on the scene, and numerous different designs were available. *See, e.g.,* U.S. Patent No. 4,501,269 to Bagby (disclosing in 1981 a cylindrical "basket" implant for spinal fusion that included bone chips inside and that included many apertures in the basket so that bone could grow through the implant and create the fusion); U.S. Patent No. 4,878,915 to Brantigan (disclosing in 1987 a rectangular shaped spinal fusion cage); U.S. Patent No. 5,015,247 to Michelson (disclosing in 1988 a threaded cylindrical spinal fusion cage similar in design to the implant later disclosed in the '997 patent); U.S. Patent No. 5,026,373 to Ray et al. (disclosing in 1988 a threaded cylindrical spinal fusion cage); U.S. Patent Nos. 5,489,307 and 5,489,308 (disclosing a threaded spinal implant and methods of implantation through a tubular cannula). Given this context, one of skill in the art as of the early 1990's would have readily known that the lateral access system including a cannula for performing a "fusion" procedure, as disclosed in Jacobson, would be employed to implant a non-bone fusion cage type spinal implant. Thus, in accordance with the resulting surgical method of Jacobson in view of Leu, one of skill in the art by the time of the early 1990's would have understood that the working cannula/third surgical instrument (Jacobson's cannula 11) would be well suited to receive a non-bone interbody implant (as suggested by Leu or as suggested by the numerous fusion cage teachings) for insertion into a laterally facing opening in the lumbar spine. One of skill in the art at the time would also have recognized that a size and dimension of working cannula may be selected to accommodate the selected implant, and doing so would be well within the knowledge of a person skilled in the art.

28. Jacobson and Leu do not disclose the specific dimensions of the interbody fusion implant as described in claim 1, but such implant structures were widely known in the prior art of spinal fusion cages of the early 1990's as discussed above. In one example, Brantigan (U.S. Patent No. 5,192,327) discloses various embodiments of non-bone spinal implants (fusion cages) for insertion from various approaches including "laterally" (like Jacobson's lateral path), and also discloses that these implants "are bottomed on the hard bone faces or end plates of adjacent vertebrae and are generally oval shaped to conform with the general outline perimeter of the vertebrae." Brantigan, col. 1, line 68 to col. 2, line 4; *see also* col. 2:64-66 and col. 6, lines 65-66 (describing that such an implant can be inserted "laterally"). With specific regard to the implant being introduced laterally, Brantigan illustrates a laterally inserted implant in Figure 10. Based on my knowledge and experience in this field and my review of Jacobson, Leu, and Brantigan, I believe that a person of ordinary skill in the art would recognize that Brantigan's Figure 10 shows implants 53 and 54 that have been inserted laterally into the disc space, given that the view in Figure 10 is anterior-to-posterior (that is, from the front of the spine), and the implants 53 and 54 have tool engagement mechanisms on their left sides (shown in hidden dashed lines). In addition, although Figure 10 shows two stacked fusion implants having been implanted, one of skill in the art would understand that Brantigan is disclosing the use of both singular and stacked implants, depending on the application and size needed.

29. In addition, Brantigan's implant 11 provides the claimed implant elements of: an insertion end, a trailing end, opposed surfaces having bone engaging projections, a maximum height between the bone engaging projections and perpendicular to the length of the implant, and the length of implant being greater than the maximum height of the implant. *Id.* at FIGS. 8, 10, 11. Brantigan also discloses the specifically claimed implant positioning vis-à-vis vertebrae dimensions, as set forth in claim 1, including the fact that the "length" of the implant is "sized to occupy substantially the full transverse width of the vertebral bodies" and "greater than the depth of the disc space." For example, in stating that the disclosed implants

"are bottomed on the hard bone faces or end plates of adjacent vertebrae," (Brantigan, col. 1, line 68 to col. 2, line 2), one of skill in the art would understand that Brantigan is disclosing that one option would be to position the implants such that they rest upon the hard bone faces of the vertebrae, or in other words, on the hard outer bone known as the ring of apophysis (which would be revealed after removal of the end plates that reside on the surface of the vertebrae adjacent the disc space). Following this teaching as well as Brantigan's teachings regarding inserting the implants laterally, one of skill in the art at time would have understood that a size of an implant would be selected to allow for a laterally placed implant to rest upon the hard bone faces of the vertebrae (namely, on the ring of apophysis). Doing so would yield an implant that would have a length that would "occupy substantially the full transverse width of the vertebral bodies." In addition, Brantigan's FIG. 10 illustrates a non-bone fusion implant having been inserted laterally into a disc space (note that the view of the spine in FIG. 10 is anterior, or from the front of the patient, and the insertion tool holes are on the left side of the implant in this figure) and occupying at least as much as the transverse width of vertebral bodies as the implant shown in the '997 patent (FIG. 23):





Compare Brantigan, FIG. 10, *with* '997 patent, FIG. 23. Based on my knowledge and experience in this field and my review of Jacobson, Leu, and Brantigan, I believe that a person of ordinary skill in the art would have been prompted (especially by the early 1990s) to employ an implant structure having a size/structure suggested by Brantigan in the resulting surgical method of Jacobson in view of Leu (described above) so that the implant extends longitudinally across nearly the full disc space and conforms

with the general outline perimeter of the vertebrae (as suggested by Brantigan), thereby providing the predictable result of reducing the chances of the implant collapsing into the soft cancellous bone in the central region of the vertebrae. In the resulting surgical method of Jacobson in view of Leu and Brantigan, the fusion implant (as suggested by Brantigan) would be indeed inserted into the disc space via a lateral approach (as suggested by Jacobson and Brantigan) so that the length of the implant is "sized to occupy substantially the full transverse width of the vertebral bodies" and is "greater than the depth of the disc space."

JACOBSON IN VIEW OF LEU, BRANTIGAN AND FREY (CLAIMS 2-7)

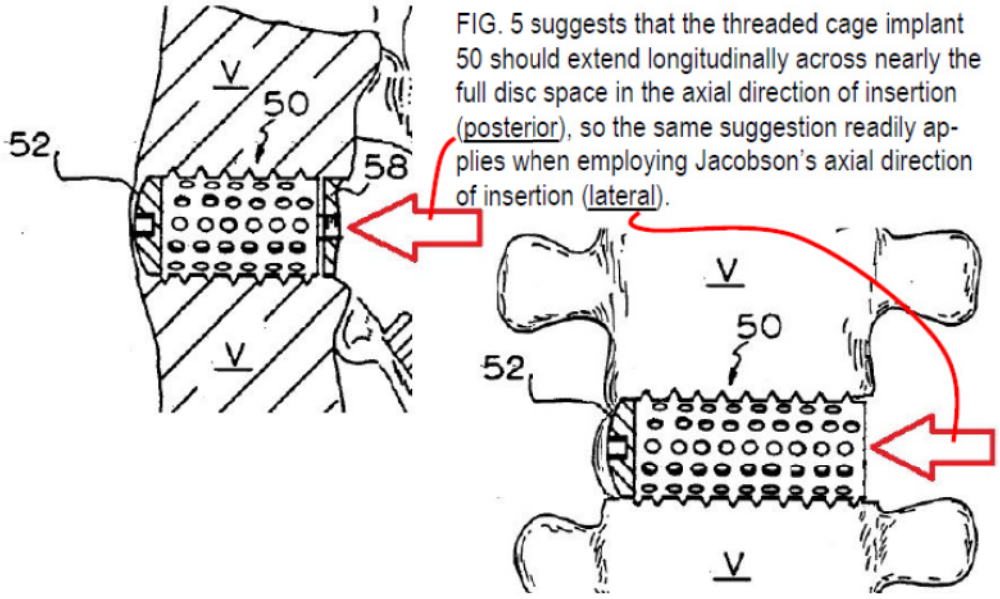
30. By the time of the 1990's, it had become well known that additional fixation of the vertebrae is sometimes warranted while the process of fusion is taking place. Indeed, the growing of bone between adjacent vertebrae to fuse two vertebrae together does not happen during the procedure; rather, the bone grows and fuses the vertebrae together after the procedure has occurred. Many different designs of fixation devices were known as of the early 1990's. For example, Frey discloses the traditional practice of engaging a spinal fixation plate 6 (FIG. 5) to the adjacent vertebrae after insertion of the intradiscal implant 1 so that the plate 6 covers the trailing end of the instradiscal implant 1. Frey, FIG. 5; col. 3, lines 14-23. According to Frey, the trailing end 5 of the implant 1 is "covered by" each plate 6, and each plate "is provided with a pair of openings 8 for the passage of bone screws in the adjacent vertebrae 9." *Id.* at col. 3, lines 14-23. A person of ordinary skill in the art at the time (at least as early as 1992) would have been prompted to modify the method of Jacobson in view of Leu and Brantigan (described above) to further include a step of coupling a spinal fixation plate to the implant and to the vertebrae immediately adjacent to the implant (as suggested by Frey) so as to predictably "improve a primary securement of the [implant] prior to ingrowth of bone tissue." *Id.* Furthermore, a person of ordinary skill in the art at that time would have been prompted to modify the method of Jacobson in view of Leu and Brantigan (described above) to further include a step of coupling a spinal fixation plate to the implant and to the vertebrae immediately adjacent to

the implant (as suggested by Frey) because to do so would have been, as of the early 1990's, nothing more than applying a widely known technique to an already conventional method to yield predictable results. In the resulting combination, the particular size and profile shape of the spinal fixation plate need not be identical to Frey's plate, but instead they would have been predictably selected by the person of ordinary skill according to the size of the surgical site and the access instruments.

JACOBSON IN VIEW OF LEU AND MICHELSON '247 (CLAIMS 1 AND 8)

31. The combined teachings of Jacobson and Leu have been described above. Based on my knowledge and experience in this field and my review of Jacobson, Leu, and Michelson '247, I believe that a person of ordinary skill in the art at the time (and, at least as early as 1992) would have recognized that a threaded cylindrical implant (as suggested by Michelson '247) would be effective for implantation using in the lateral access method resulting from Jacobson in view of Leu (described above). For example, Michelson '247 discloses a spinal fusion implant 50 (FIG. 5) having virtually the identical structure and function to the implant "I" disclosed in the '997 patent. Michelson '247, at FIGS. 4-5; col. 8, lines 36-51. As such, Michelson '247 teaches that the implant 50 provides the claimed implant elements of: an insertion end, a trailing end, opposed surfaces having bone engaging projections, a maximum height between the bone engaging projections and perpendicular to the length of the implant, and the length of implant being greater than the maximum height of the implant. *Id.* Michelson '247 does not expressly disclose that the implant 50 is inserted in a lateral approach, so it follows that the implant 50 does not expressly describe the claim limitation related to the "length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae, the length of said implant being greater than the depth of the disc space." A person of ordinary skill and creativity in the early 1990s would not have stopped there. Rather, Michelson '247 plainly suggests to a skilled artisan that the threaded cage implant 50 should extend longitudinally across the full disc space along the direction of insertion. *Id.* at FIG. 5 (shown below and depicting at the left side of the figure that the implant should be inserted such that the

axial length of the threaded cage should extend across the disc space along the direction of insertion). In the resulting surgical method of Jacobson in view of Leu (described above), the fusion implant would be inserted into the disc space via a lateral direction (described above), so a person of ordinary skill in the art would have recognized from the suggestion in Michelson '247 that the size of the threaded cage implant 50 should be selected to extend longitudinally across the full disc space in the axial direction of insertion (lateral insertion in this resulting method):



Id. at FIG. 5 (shown on the left, with a predictable modified version for lateral insertion shown on the right) *see also id.* at col. 10, line 10 (describing one example of a threaded implant that is "26 mm" length, which is known to skilled artisans to be more than sufficient in length to extend substantially the full transverse width of the vertebral bodies at particular levels of the spine and certainly for smaller patients). Based on my knowledge and experience in this field and my review of Jacobson, Leu, and Michelson '247, I believe that a person of ordinary skill in the art at the time (at least as early as 1992) would have been prompted to use a longer threaded fusion implant (as suggested by Michelson '247) for use in Jacobson's lateral insertion path so that the implant extends longitudinally across the full disc space in the lateral insertion direction and advantageously provides the improved mechanical support and reduces the likelihood of the

implant collapsing into the soft cancellous bone in the central region of the vertebrae. In the resulting surgical method of Jacobson in view of Leu and Michelson '247 (described above), the fusion implant would be inserted into the disc space via a lateral approach, so the relative dimensions of Michelson '247's implant 50 would have been predictably selected in accordance with the lateral insertion orientation, thereby providing a length of the implant that is "sized to occupy substantially the full transverse width of the vertebral bodies" and that is "greater than the depth of the disc space."

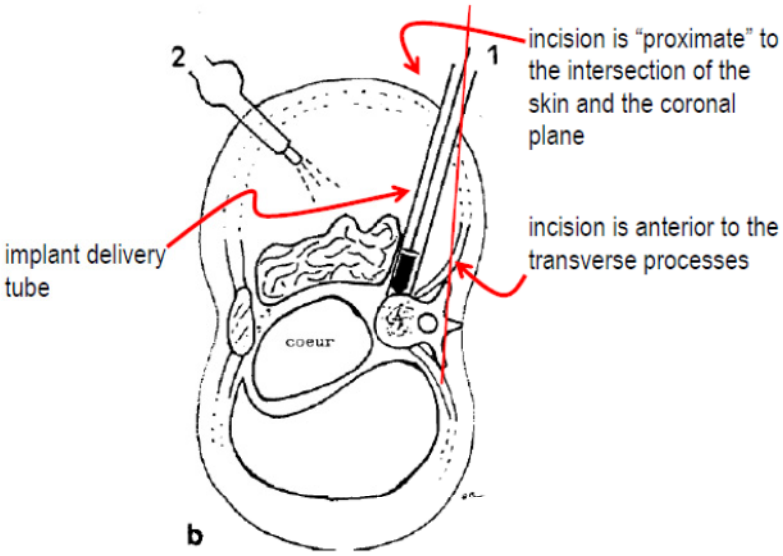
JACOBSON IN VIEW OF LEU, MICHELSON '247 AND ALACREU (CLAIMS 2-7)

32. As discussed previously, by the time of the 1990's, it had become well known that additional fixation of the vertebrae is sometimes warranted while the process of fusion is taking place. Indeed, the growing of bone between adjacent vertebrae to fuse two vertebrae together does not happen during the procedure; rather, the bone grows and fuses the vertebrae together after the procedure has occurred. Many different designs of fixation devices were known as of the early 1990's. For example, Alacreu discloses the traditional practice of engaging a spinal fixation plate 3 to a trailing end of a spinal implant (via a bolt 16) and to the vertebrae immediately contacting the spinal implant (via screws 14). Alacreu, col. 2, lines 6-11; col. 3, lines 34-39; FIG. 11. Alacreu explains that the spinal fixation plate 3 is "attached by screws laterally to the next above and the next below vertebras, contributing to stabilization by preventing . . . movements" of the spinal implant. *Id.* at col. 2:6-11. Based on my knowledge and experience in this field and my review of Jacobson, Leu, Michelson '247, and Alacreu, I believe that a person of ordinary skill in the art at the time (at least as early as 1992) would have been prompted to modify the method of Jacobson in view of Leu and Michelson '247 (described above) to further include a step of engaging a spinal fixation plate to the implant and to the vertebrae immediately adjacent to the implant (as suggested by Alacreu) so as to advantageously "contribute to the stabilization" of the spinal implant site and to prevent movements of the implant. *Id.* Furthermore, a person of ordinary skill in the art at the time would have been prompted to modify the method of Jacobson in view of Leu and Michelson

'247 (described above) to further include a step of engaging a spinal fixation plate to the implant and to the vertebrae immediately adjacent to the implant (as suggested by Alacreu) because to do so would be nothing more than applying a known technique to a known device (method, or product) to yield predictable results. In the resulting combination, the particular size and profile shape of the spinal fixation plate would have been selected by the person of ordinary skill according to the size of the surgical site and the access instruments.

BAULOT IN VIEW OF ROSENTHAL AND KAMBIN (CLAIMS 1 AND 8)

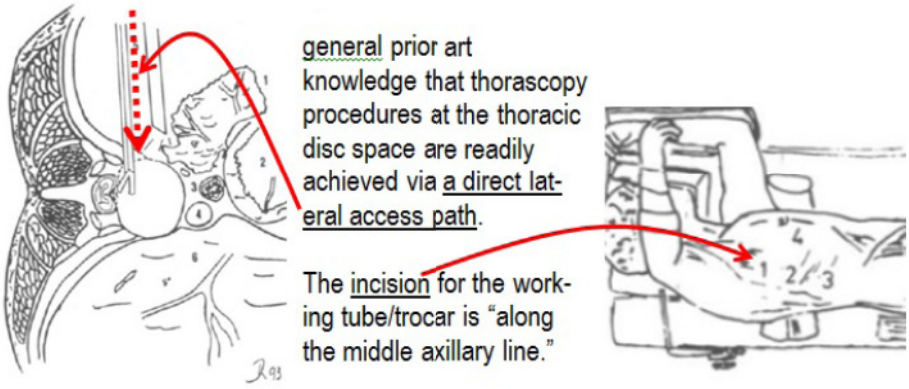
33. Baulot discloses a spinal fusion method performed on a patient in January 1994, which involved the implantation of a hydroxyapatite graft (a non-bone implant) through a tube into a thoracic disc space. Baulot, FIG. 2(b); Baulot translation, p. 4. Baulot discloses (under a broadest reasonable interpretation of "proximate") that the incision is proximate an intersection of the skin and a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes:



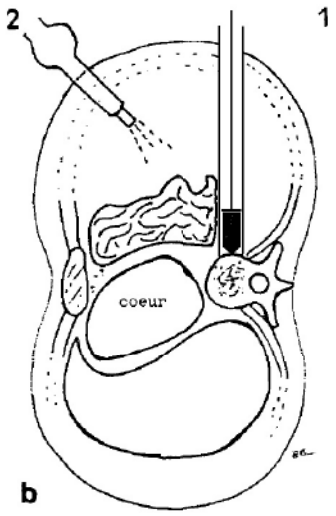
Baulot, FIG. 2(b).

34. Assuming claim 1 is interpreted to require an exactly direct lateral approach, the prior art plainly discloses that such an approach path to the thoracic disc space could be shifted slightly to a more

direct lateral approach. For example, Rosenthal discloses a similar spinal surgical method in the thoracic region that uses thorascopy and a trocar tube providing a direct lateral access path to the thoracic disc space for the surgical instruments:



Rosenthal, FIGS. 3 and 1; p. 1087 (describing the access paths, including the working path for the surgical instruments, inserted along the "middle axillary line"). Here, a person of ordinary skill in the art (at least as early as the filing of the '997 patent) would have been prompted to modify Baulot's surgical method to orient the working corridor at a slightly more lateral position (e.g., a more direct lateral access path as suggested by Rosenthal) so as to provide "a wide exposure of the thoracic spine by changing only the insertion site of the trocars." *Id.* at p. 1090. One predictable example is illustrated below:



See Balot, FIG. 2(b) (modified to show the predictable modification in view of Rosenthal). In addition, a person of ordinary skill in the art at the time would have been prompted to modify Baulot's surgical method to orient the working corridor at a slightly more lateral position (as suggested by Rosenthal) because to do so would be nothing more than applying a known technique to a known device (method, or product) to yield predictable results.

35. Baulot teaches that the implant delivery tube (e.g., the "third surgical instrument" in claim 1) is advanced to the thoracic disc space (Fig. 2(b)), but Baulot does not expressly describe the precursor first and second instruments that provide for the insertion path for Baulot's implant delivery tube. Numerous prior art references, however, explain the conventional prior art knowledge at the time (in the early 1990's) that such larger working tubes for accessing the spine were typically advanced to the spine after a set of guidance instruments (e.g., a guide wire and at least one cannulated dilator/trocar) established the insertion path. For example, Kambin provides a typical example of this commonly used prior art method. Kambin discloses a surgical access method to a targeted spinal disc that, similar to Baulot, uses a larger working cannula 32 for insertion of the surgical instruments. Kambin, at FIG. 10 (showing the working cannula 32). Kambin teaches the general prior art knowledge that such a working cannula (Kambin's cannula 32 or Baulot's implant delivery tube) should be advanced to the targeted disc space after a first instrument (e.g., a guide wire 18) initially defines the insertion path and a second instrument (e.g., a cannulated trocar/dilator 20) dilates the path to a size sufficient to receive the working cannula. Kambin, col. 4, lines 33-44; col. 3, lines 16-46; FIGS. 3, 4, and 6. Based on my knowledge and experience in this field and my review of Baulot, Rosenthal and Kambin, I believe that a person of ordinary skill in the art at the time would have been prompted to modify the surgical method of Baulot alone or alternatively Baulot in view of Rosenthal (as described above) to include a guide wire and a cannulated trocar (as suggested by Kambin) for defining the insertion path of Baulot's working tube so that the larger working tube can reach the targeted disc space in a procedure that provides reduced trauma to the

intervening tissues and "low post-operative morbidity." *Id.* at col. 1, line 58 to col. 2, line 2; col. 5, lines 16-21 ("post-operative back pain was minimal"). In addition, a person of ordinary skill in the art would prompted to modify the surgical method of Baulot alone or alternatively Baulot in view of Rosenthal (described above) to include a guide wire and cannulated trocar (as suggested by Kambin) for defining the insertion path of Baulot's working tube because to do so would be nothing more than applying a known technique to a known device (method, or product) to yield predictable results.

36. The resulting surgical method of Baulot in view of Rosenthal and Kambin would provide the claimed step of "inserting" a non-bone interbody intraspinal implant through the third surgical instrument, as recited in claim 1. First, Baulot express teaches that the non-bone fusion implant ("hydroxyapatite graft[]" or "a block of porous apatite") is inserted through Baulot's implant delivery tube (the "third surgical instrument"). Baulot translation, pp. 4, 6; FIG. 2(b). Also, in the resulting surgical method (described above), Baulot's implant delivery tube would be advanced in a direct lateral path (an example is illustrated above), and Baulot's implant would be inserted through "a hole in the external face of the disc." *Id.* at p. 4. Thus, in accordance with the resulting surgical method of Baulot in view of Rosenthal and Kambin, the non-bone implant would be inserted through the third working instrument and into a laterally facing opening in the thoracic spine.

37. Baulot describes the spinal fusion implant as "a block of porous apatite" and illustrates the structure in FIGS. 2(b), 3(e)-(f), and 5. Baulot translation, p. 6. From this disclosure, Baulot teaches the claimed implant elements of: an insertion end, a trailing end, opposed surfaces having bone engaging projections (resulting from the upper and lower "porous" surfaces), a maximum height between the bone engaging projections and perpendicular to the length of the implant, and the length of implant being greater than the maximum height of the implant. *Id.* at FIGS. 2(b), 3(e)-(f), and 5; p. 4 (teaching that the porous block is "35 mm in length" for insertion into the thoracic disc space). Based on my knowledge and experience in this field and my review of Baulot in view of Rosenthal and Kambin, I believe that a person of

ordinary skill in the art would have understood that the roughened surface of the "porous block" provides frictional projections for engaging the opposing vertebrae. In addition, Baulot's FIG. 5 clearly illustrates that the fusion implant has a length that is "sized to occupy substantially the full transverse width of the vertebral bodies" and that is "greater than the depth of the disc space." *Id.* at FIG. 5; *see also* FIG. 2(b).

38. With respect to claim 8, the resulting surgical method of Baulot in view of Rosenthal and Kambin would provide the claimed fusion implant that is provided in combination with fusion promoting substances. Indeed, Baulot expressly discloses that the fusion implant includes a "hydroxyapatite graft[]," which was known to be a fusion promoting substance in that it supports bone ingrowth and ongrowth, and is known to absorb over time. Balout translation, at 4.

BAULOT IN VIEW OF ROSENTHAL, KAMBIN AND FREY (CLAIMS 2-7)

39. As discussed previously, by the time of the 1990's it had become well known that additional fixation of the vertebrae is sometimes warranted while the process of fusion is taking place. Indeed, the growing of bone between adjacent vertebrae to fuse two vertebrae together does not happen during the procedure; rather, the bone grows and fuses the vertebrae together after the procedure has occurred. Many different designs of fixation devices were known as of the early 1990's. For example, Frey discloses the traditional practice of engaging a spinal fixation plate 6 (FIG. 5) to the adjacent vertebrae after insertion of the intradiscal implant 1 so that the plate 6 covers the trailing end of the instradiscal implant 1. Frey, FIG. 5; col. 3, lines 14-23. According to Frey, the trailing end 5 of the implant 1 is "covered by" each plate 6, and each plate "is provided with a pair of openings 8 for the passage of bone screws in the adjacent vertebrae 9." *Id.* at col. 3, lines 14-23. A person of ordinary skill in the art at the time would have been prompted to modify the method of Baulot in view of Rosenthal and Kambin (described above) to further include a step of coupling a spinal fixation plate to the implant and to the vertebrae immediately adjacent to the implant (as suggested by Frey) so as to advantageously "improve a primary securement of the [implant] prior to ingrowth of bone tissue." *Id.* Furthermore, a person of ordinary skill in the art at that

time would have been prompted to modify the method of Baulot in view of Rosenthal and Kambin (described above) to further include a step of coupling a spinal fixation plate to the implant and to the vertebrae immediately adjacent to the implant (as suggested by Frey) because to do so would have been, at the time, nothing more than applying a known technique to a known device (method, or product) to yield predictable results. In the resulting combination, the particular size and profile shape of the spinal fixation plate would have been selected by the person of ordinary skill according to the size of the surgical site and the access instruments.

MICHELSON PCT IN VIEW OF JACOBSON AND BRANTIGAN (CLAIMS 1 AND 8)

40. Michelson PCT (International patent application under the "Patent Cooperation Treaty") discloses a spinal fusion surgical procedure at a disc space between two adjacent vertebrae located within a portion of one of a human thoracic or lumbar spine. Michelson PCT, at FIGS. 1, 6, 11B, and 17; pp. 1-2 (describing a "method of inserting the implant within the interverbral space left after the removal of the disc material"); p. 9 (disclosing that the method "can be utilized in the cervical, thoracic, and lumbar spine"). Michelson PCT does not expressly disclose that the skin incision is located proximate to a path having an axis lying in a coronal plane, but instead discloses "posterior" or "anterior" approaches to the spine. *Id.* at p. 65 (disclosing the "posterior" and "anterior" approaches, and furthermore explaining that "the method for installation of a large, singular midline graft will become obvious"). However, the claimed location of the skin incision was commonly employed in other surgical methods for similarly accessing the spine through an outer tubular sleeve. For example, Jacobson, as discussed above, expressly describes a "lateral" approach for accessing a disc space between two adjacent vertebrae for purposes of performing a discectomy and, optionally, a vertebral fusion procedure. Jacobson, at FIGS. 3 and 8; col. 2: 23-33; col. 2: 40-43; col. 6:13 (describing a "fusion" procedure that necessarily includes an interbody implant). As previously described in the analysis of Jacobson above, Jacobson plainly discloses the insertion of a guide needle or wire 8, which includes the claimed skin incision location (especially for the guide wire having a

diameter of nearly "3 mm"). Based on my knowledge and experience in this field and my review of Michelson PCT and Jacobson, I believe that a person of ordinary skill in the art at the time (at least as early as the publication of the Michelson PCT) would have been prompted to modify the surgical method of the Michelson PCT so as to employ Jacobson's "lateral approach" path for accessing the disc space so as to avoid "major back support muscles" that "would otherwise have to be cut or retracted" and for the additional reasons described below. *See id.* at col. 2:31-33. In the resulting surgical method, the skin incision (as indicated in both Michelson PCT and Jacobson) would be employed, but the location of the skin incision and the path of initial guide wire would be proximate to a path having an axis lying in a coronal plane (as suggested in Jacobson). Additionally, a person of ordinary skill in the art would have been prompted to modify the surgical method of Michelson PCT so as to employ Jacobson's "lateral approach" path for accessing the disc space because the resulting surgical method would eliminate the "need to cut spinal laminae" that is customary in the posterior approach of Michelson PCT and because the patient "may be released from the hospital on the same day." *Id.* at col. 2:52-53 and 62-63. Finally, a person of ordinary skill in the art would have been prompted to modify the surgical method of Michelson PCT so as to employ Jacobson's "lateral approach" path for accessing the disc space because to do so would be nothing more than applying a known technique to a known device (method, or product) ready for improvement to yield predictable results.

41. As taught by Jacobson, during the lateral approach, an initial guide needle or wire 8 extends in the lateral path until proximate to the targeted spinal disc and thereafter serves "as a guide member" for a second instrument that is subsequently advanced. Jacobson, at col. 5:39-41; FIG. 3. Accordingly, one of skill in the art at the time would have understood that the initial guide needle or wire 8 may be similarly used in the resulting surgical method of Michelson PCT in view of Jacobson so as to provide the same guidance benefits to the subsequent instruments. Regarding the claimed "second instrument," Michelson PCT discloses a distractor 100 that is virtually the identical structure of the claimed

"second surgical instrument" (e.g., distractor 100 in FIG. 2) of the '997 patent. Michelson PCT, at FIGS. 1 and 4. Indeed, the distractor 100 of Michelson PCT has the same outer shape and serves a similar purpose as the distractor/second surgical instrument of the '997 patent. *Id.* at p. 22 (describing the distractor 100 as being "self-orienting" and "self-centralizing between opposed vertebral surfaces"); p. 47. As previously described, Jacobson expressly teaches that, in the lateral surgical approach, the guide needle or wire 8 should "act[] as a guide member" for the second instrument, and furthermore teaches that the second instrument should be cannulated or otherwise equipped with a guide bore. Jacobson, at col. 5:39-41; col. 3:2-6 (teaching that the "guide means may be a bore"); col. 9:11-13 (teaching again that the guide means of the second instrument "is a tube 25" for sliding over the guide needle or wire 8). Thus, in the resulting surgical method of Michelson PCT in view of Jacobson (described above), the distractor 100 of Michelson PCT serves as the second instrument which is advanced over the initial guide needle or wire, and therefore this second instrument would be cannulated (as suggested by Jacobson) so as to provide a passageway configured to receive the initial guide needle or wire therein. Jacobson, at col. 5:39-41; col. 3:2-6 (teaching that the "guide means may be a bore"); col. 9:11-13. Additionally, a person of ordinary skill in the art at the time would have been prompted to modify the distractor 100 of Michelson PCT so as to include a bore to receive the guide needle or wire (as suggested by Jacobson) because to do so would be nothing more than combining prior art elements according to known methods to yield predictable results.

42. Regarding the claimed "third instrument," a person of ordinary skill in the art would have recognized that the surgical method of Michelson PCT in view of Jacobson (described above) results in the claimed step of advancing a third surgical instrument as recited in claim 1. Indeed, Michelson PCT discloses an outer sleeve 140 that is structurally similar to the claimed "third surgical instrument" (e.g., outer sleeve 140 in FIG. 7) of the '997 patent. NUVA 1014 at FIG. 6. Much like the claimed "third surgical instrument" (e.g., outer sleeve 140 in FIG. 7) of the '997 patent, Michelson PCT's sleeve 140 serves as a working cannula for the surgical instruments and purportedly "places all of the delicate soft tissue

structures, nerves, blood vessels, and organs outside of the path." *Id.* at p. 19. Also, Michelson PCT's sleeve 140 has "teeth for engaging the two adjacent vertebrae." *Id.* at p. 29; FIG. 6; *see also* FIG. 7 (suggesting prongs at the distal end). Michelson PCT also expressly teaches that the sleeve 140 is advanced into the body of the patient over at least a portion of the length of the second surgical instrument (the distractor 100). *Id.* at FIG. 6; p. 47 (teaching that the distal end of the sleeve 140 is "fitted over" the distractor to engage the vertebrae).

43. Based on my knowledge and experience in this field and my review of Michelson PCT and Jacobson, I believe that a person of ordinary skill in the art would recognize that the resulting surgical method of Michelson PCT in view of Jacobson provides the claimed step of positioning the third surgical instrument as recited in claim 1. In particular, Jacobson expressly teaches that, in the lateral surgical approach, the working cannula should be positioned to engage the lateral aspect of the vertebral bodies of the two adjacent vertebrae. NUVA 1004 at FIGS. 6-8; col. 2:25-30; col. 5:1-4; col. 6:9-13. Accordingly, in accordance with the resulting surgical method of Michelson PCT in view of Jacobson, the working cannula/third surgical instrument (Michelson PCT's outer sleeve 140) would be similarly positioned to engage the lateral aspect of the vertebral bodies of the two adjacent vertebrae so as to achieve the aforementioned benefits of the lateral surgical approach.

44. Based on my knowledge and experience in this field and my review of Michelson PCT and Jacobson, I believe that a person of ordinary skill in the art would recognize that the resulting surgical method of Michelson PCT in view of Jacobson provides the claimed step of "inserting" a non-bone interbody intraspinal implant through the third surgical instrument, as recited in claim 1. First, Jacobson expressly teaches that, in the lateral surgical approach, the working cannula can be the conduit through which a laterally facing opening is created in the lumbar spine. Jacobson, at FIGS. 6-8. Also, Jacobson then explains that, in the lateral surgical approach, the working cannula can also serve as the conduit for a "fusion" procedure (col: 6:13), which necessarily includes the insertion of an implant into the disc space

(Michelson PCT expressly states that the fusion implant is "necessary" for a fusion procedure at pp. 1-2). Lastly, Michelson PCT teaches that a non-bone implant should be inserted through the outer sleeve 140 (third instrument) and into the disc space so as to induce bony fusion between the adjacent vertebrae. Michelson PCT, at pp. 34 and 37; FIG. 17. Accordingly, in accordance with the resulting surgical method of Michelson PCT in view of Jacobson, the working cannula/third surgical instrument (Michelson PCT's outer sleeve 140) would be similarly positioned to receive the non-bone interbody implant from the position anterior to the transverse processes and for insertion into a laterally facing opening in the lumbar spine.

45. Based on my knowledge and experience in this field and my review of Michelson PCT and Jacobson, I believe that a person of ordinary skill in the art would recognize that the resulting surgical method of Michelson PCT in view of Jacobson provides the claimed step of "inserting" a non-bone interbody intraspinal implant through the third surgical instrument, as recited in claim 1. First, Jacobson expressly teaches that, in the lateral surgical approach, the working cannula can be the conduit through which a laterally facing opening is created in the lumbar spine. Jacobson, at FIGS. 6-8. Also, Jacobson then explains that, in the lateral surgical approach, the working cannula can also serve as the conduit for a "fusion" procedure (col: 6:13), which necessarily includes the insertion of an implant into the disc space (Michelson PCT expressly states that the fusion implant is "necessary" for a fusion procedure at pp. 1-2). Finally, Michelson PCT teaches that a non-bone implant should be inserted through the outer sleeve 140 (third instrument) and into the disc space so as to induce bony fusion between the adjacent vertebrae. Michelson PCT, at pp. 34 and 37; FIG. 17. Accordingly, in accordance with the resulting surgical method of Michelson PCT in view of Jacobson, the working cannula/third surgical instrument (Michelson PCT's outer sleeve 140) would be similarly positioned to receive the non-bone interbody implant from the position anterior to the transverse processes and for insertion into a laterally facing opening in the lumbar spine.

46. Michelson PCT discloses a fusion implant "I" in the form of a threaded titanium cage that is virtually identical to the structure of the implant "I" in FIG. 19 of the '997 patent. Michelson PCT, at FIG. 17.

For example, Michelson PCT's implant "I" provides the claimed implant elements of: an insertion end, a trailing end, opposed surfaces having bone engaging projections, a maximum height between the bone engaging projections and perpendicular to the length of the implant, and the length of implant being greater than the maximum height of the implant. *Id.* at FIGS. 16-17. However, because the Michelson PCT does not expressly disclose the insertion of the implant "I" along a lateral approach, the Michelson PCT does not disclose an implant being positioned such that the length of the implant "occup[ies] substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae." However, in the resulting surgical method of Michelson PCT in view of Jacobson (described above), a fusion implant is inserted into the disc space via a lateral approach, and so a person of ordinary skill in the art at the time would have predictably selected an implant sized appropriately given its eventual lateral orientation in the disc space for the reasons described in detail above.

47. In addition, and as discussed previously, Brantigan also explicitly discloses an implant being positioned and sized such that it "occup[ies] substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae." Based on my knowledge and experience in this field and my review of Michelson PCT in view of Jacobson and Brantigan, I believe that a person of ordinary skill in the art would have been prompted (especially by the early 1990s) to employ an implant structure having a size/structure suggested by Brantigan in the resulting surgical method of Michelson PCT in view of Jacobson (described above) so that the implant extends longitudinally across nearly the full disc space and conforms with the general outline perimeter of the vertebrae (as suggested by Brantigan), thereby providing the predictable result of reducing the chances of the implant collapsing into the soft cancellous bone in the central region of the vertebrae. Furthermore, a person of ordinary skill in the art would have been prompted (especially by the early 1990s) to employ an implant structure having a size/structure suggested by Brantigan in the resulting surgical method of Michelson PCT in view of Jacobson (described above) because doing so would be merely a substitution of a known device (Brantigan's implant) in a known

method (lateral approach via a working cannula) to achieve a predictable result. In addition, it would have been obvious to one of skill in the art at the time to have modified the size and shape of the working cannula to accommodate such an implant, and that doing so would have been well within the knowledge of those skilled in the art at the time.

MICHELSON PCT IN VIEW OF JACOBSON, BRANTIGAN AND ALACREU (CLAIMS 2-7)

48. As discussed previously, a "spinal fixation device" that is engaged to the adjacent vertebrae as part of a spinal fusion procedure were commonly employed in the prior art, with Alacreu being one example. A person of ordinary skill in the art at the time would have been prompted to modify the method of Michelson PCT in view of Jacobson and Brantigan (described above) to further include a step of engaging a spinal fixation plate to the implant and to the vertebrae immediately adjacent to the implant (as suggested by Alacreu) so as to advantageously "contribute to the stabilization" of the spinal implant site and to prevent movements of the implant. *Id.* Furthermore, a person of ordinary skill in the art would have been prompted to modify the method of Michelson PCT in view of Jacobson and Brantigan (described above) to further include a step of engaging a spinal fixation plate to the implant and to the vertebrae immediately adjacent to the implant (as suggested by Alacreu) because to do so would be nothing more than applying a known technique to a known device (method, or product) ready for improvement to yield predictable results. In the resulting combination, the particular size and profile shape of the spinal fixation plate would have been selected by the person of ordinary skill according to the size of the surgical site and the access instruments. Indeed, given that the implant in the resulting method is smaller than the implant in Alacreu, it follows that the spinal fixation plate would likewise be significantly smaller than that illustrated in Alacreu. Nevertheless, Alacreu's more general suggestion to engage a spinal fixation plate after insertion of the spinal implant is readily and predictably applicable to the resulting method as described above.

LEGAL PRINCIPLES

Anticipation

49. I have been informed that a patent claim is invalid as anticipated under 35 U.S.C. § 102 if each and every element of a claim, as properly construed, is found either explicitly or inherently in a single prior art reference. Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes the claimed limitations, it anticipates.

50. I have been informed that a claim is invalid under 35 U.S.C. § 102(a) if the claimed invention was known or used by others in the U.S., or was patented or published anywhere, before the applicant's invention. I further have been informed that a claim is invalid under 35 U.S.C. § 102(b) if the invention was patented or published anywhere, or was in public use, on sale, or offered for sale in this country, more than one year prior to the filing date of the patent application (critical date). And a claim is invalid, as I have been informed, under 35 U.S.C. § 102(e), if an invention described by that claim was described in a U.S. patent granted on an application for a patent by another that was filed in the U.S. before the date of invention for such a claim. A claim is also invalid, as I have been informed, under 35 U.S.C. § 102(f) if the invention was invented by another.

Obviousness

51. I have been informed that a patent claim is invalid as "obvious" under 35 U.S.C. § 103 in light of one or more prior art references if it would have been obvious to a person of ordinary skill in the art at the time the invention was made, taking into account (1) the scope and content of the prior art, (2) the differences between the prior art and the claims, (3) the level of ordinary skill in the art, and (4) any so called "secondary considerations" of non-obviousness, which include: (i) "long felt need" for the claimed invention, (ii) commercial success attributable to the claimed invention, (iii) unexpected results of the claimed invention, and (iv) "copying" of the claimed invention by others. For purposes of my analysis above, unless otherwise stated I have applied a date of February 27, 1995, as the date of invention, in my obviousness analyses, although in many cases the same analysis would hold true even at an earlier time than February 27, 1995. I have assumed the date of February 27, 1995 because I do not know what the

date that the invention as claimed was made by Dr. Michelson, and therefore have used the filing date of the claimed priority patent application to the '997 patent as the point in time for claim interpretation purposes, to the extent it matters. That date was February 27, 1995.

52. I have been informed that a claim can be obvious in light of a single prior art reference or multiple prior art references. To be obvious in light of a single prior art reference or multiple prior art references, there must be a reason to modify the single prior art reference, or combine two or more references, in order to achieve the claimed invention. This reason may come from a teaching, suggestion, or motivation to combine, or may come from the reference or references themselves, the knowledge or "common sense" of one skilled in the art, or from the nature of the problem to be solved, and may be explicit or implicit from the prior art as a whole. I have been informed that the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. I also understand it is improper to rely on hindsight in making the obviousness determination.

53. I have been informed that a patent claim composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. I have been further informed that it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.

ADDITIONAL REMARKS

54. I currently hold the opinions set expressed in this declaration. But my analysis may continue. If and as my study of the investigation continues, I may acquire additional information and/or attain supplemental insights that result in added observations.

55. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or

imprisonment, or both, under Section 1001 of the Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Dated: March 21, 2013

By: _____ 3/21/13

Dr. Paul McAfee, M.D.

Appendices to McAfee Declaration

APPENDIX A: Crock, "Anterior Lumbar Interbody Fusion: Indications for its Use and Notes on the Surgical Technique," in Clinical Orthopaedics and Related Research, No. 165, pp. 157-63, May 1982

APPENDIX B: Affidavit of Dr. Henry Crock

APPENDIX C: Berry et al., "A Morphometric Study of Human Lumbar and Selected Thoracic Vertebrae," Spine, Vol. 12, No. 4, pp. 362-67, at p. 364, Table 1 (1987)

APPENDIX D: McAfee et al., "The value of computed tomography in thoracolumbar fractures: An analysis of one hundred consecutive cases and a new classification," The Journal of Bone and Joint Surgery, Vol. 65-A, No. 4, pp. 461-473, April 1983

Appendix A to McAfee Declaration

Crock, “Anterior Lumbar Interbody Fusion: Indications for its Use and Notes on the Surgical Technique,” in Clinical Orthopaedics and Related Research, No. 165, pp. 157-63, May 1982

Clinical Orthopaedics and Related Research

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Operative Arthroscopy

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SECTION II

GENERAL ORTHOPAEDICS

Anterior Lumbar Interbody Fusion

Indications for its Use and Notes on Surgical Technique

H. V. CROCK, M.D., M.S., F.R.C.S., F.R.A.C.S.

Looking back on the major surgical achievements of the 1970s, the technical feats of cardiovascular surgeons and the range of application of microsurgical techniques in plastic, reconstructive, and neurosurgery are impressive. Moreover in orthopedic surgery, remarkable improvements occurred in operations for joint replacements. However, in the surgery of spinal disorders technological improvements have been confined largely to procedures for the correction of deformities, as introduced by Harrington[10] in the United States and by Dwyer *et al.*[6] in Australia.

While knowledge of problems caused by spinal stenosis increased dramatically during this period, reflecting the wider use of water soluble myelography and computerized tomography, spinal surgery *per se* has failed to reach the heights of achievement as seen in the other special fields.

The purpose of this paper and the one following by Fujimaki *et al.*[9] is to draw attention to anterior lumbar interbody fusion as a major operation in spinal surgery. It deserves to be included in the range of surgical procedures that *any surgeon who regularly operates on the spine* offers to his patients. This article describes the indications for its use and the techniques that have proved safe and effective with 20 years of use.

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Received: September 10, 1980.

INDICATIONS FOR ANTERIOR LUMBAR INTERBODY FUSION

The operation of spinal fusion was introduced first by Albee[1] for the treatment of spinal tuberculosis. Its use was then extended by the application of anterior interbody fusion methods, as popularized in Hong Kong by Hodgson and Stock (1956).[11] In selected cases with spinal tuberculosis, anterior interbody fusion still enjoys an undisputed and favored place in treatment.

The role of spinal fusion in the treatment of disorders of the lumbar spine has remained vexed and confused. Apart from a general agreement on the possible application of spinal fusion in the treatment of spondylolisthesis, there are no published or clear-cut statements for the use of spinal fusion techniques. Wtih the decline in the use of fusion operations for major joints in the limbs, there has been a corresponding fall in the number of these procedures as applied

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to spinal problems. In particular, a number of the degenerative disorders of the lumbar spine now can be more effectively treated by some form of spinal canal or spinal nerve root canal decompression.

In the author's opinion, the present indications for the use of anterior lumbar interbody fusion operations are as follows: (1) for the treatment of other failed spinal operations; (2) for the treatment of certain disc lesions;[4] (3) in the management of selected cases of spondylolisthesis; (4) for the treatment of certain spinal infections; (5) following some vertebral fractures; (6) for the correction of selected spinal deformities; and (7) for the treatment of rare miscellaneous cases, *e.g.*, vertebral body tumors and nucleus pulposus calcification.

MATERIALS AND METHODS

The lumbar interbody fusion operation cannot be performed safely without the aid of two competent assistants. Until the orthopedic surgeon is thoroughly familiar with every aspect of the procedure, he would be wise to work with a senior general surgeon who has special competence in vascular surgery.

When Sir John Charnley[2] first introduced his operation of total hip joint replacement in the early 1960s, he provoked an angry response from many surgeons by refusing to allow them to buy the recommended instruments until they had been specially instructed in their use. The wisdom of his early caution doubtlessly served a good purpose inasmuch as total hip joint replacement operations, as performed by otherwise untrained surgeons, can maim. But when anterior lumbar interbody fusion is attempted by surgeons who are not specially trained the results can be far higher; the patient may lose his life.

Preliminary Preparations

Patients arrive at the operating room with an intravenous set pre-inserted. Two or three liters of compatible blood should be available for use during the operation; blood loss at the time of surgery is usually about 300–500 ml, varying with single or double level fusions.

The patient's X-rays, including lumbar discograms when appropriate, should be clearly displayed. Facilities should be available for taking control X-rays on the theater table when fusions above the lumbosacral junction are to be performed; the quality of such films is often clear. Good quality films of the patient's spine must be available in the theater for comparison with those taken at the time of surgery.

Positioning

For approaches to the lower three lumbar intervertebral discs, patients are placed supine on the operating table. For rarer upper lumbar fusions, they are placed in the lateral position with the left loin uppermost. The surgeon should pay particular attention to the placing of restraining devices and arm supports, ensuring that the patient's trunk is held in a stable position and that undue pressure is not exerted on the peripheral nerves or veins in the legs. Electric calf stimulators are applied.

Abdominal Incisions

In the lower lumbar region, oblique, left-sided incisions are made, commencing at the midline between the umbilicus and symphysis pubis and extending upwards and laterally, parallel to the level of the iliac crest. The anterior rectus sheath is divided in the line of the skin incision, extending out into the fibers of the external oblique muscle and over the length of the skin incision. At the lateral border of the rectus abdominus muscle, the internal oblique muscle and transversalis fascia are divided to identify the extraperitoneal space. The peritoneum is separated from the inner aspect of the abdominal wall, and these two muscles are further divided laterally in the line of the main incision. In obese patients, it is wise to retract the lateral border of the left rectus abdominus muscle, to identify the inferior epigastric vessels. These should be divided between ligatures and the rectus abdominus muscle then divided across transversely to the level of the midline; such an incision will allow wide extraperitoneal approach to the lower lumbar spine.

The skin incision should be placed nearer the umbilicus if the L_{3-4} disc is to be approached. Midline transperitoneal approaches may be indicated for operations at the L_5–S_1 level in some cases of spondylolisthesis or in very obese patients with high Ferguson angle measurements at the lumbosacral junction.[7]

When the abdominal wall incision has been completed, the peritoneum is separated from the posterior abdominal wall and the psoas major muscle. A small raytec pack is inserted into the paracolic gutter and pushed upwards for some distance. The ureter can be seen lying adherent

to the peritoneum. It is carried forward when a large modified Deever type retractor is inserted, resting on the anterior surface of the lumbosacral disc or on the anterolateral edge of the L_{4-5} or L_{3-4} discs at the anterior edge of the left psoas major muscle, depending on the level to be fused.

Vessel Ligation

The techniques of vessel ligation are vital to the success of exposing the disc spaces at various levels in the lumbar spine and essential for the safe performance of these operations.

Vascular sutures, including 5/0 suture material on atraumatic needles, are required. In addition, long handled instruments and right angled artery forceps must be available for use.

When the median sacral vessels have been ligated and divided, small gall bladder dissecting swabs mounted on long-handled forceps are used to clear the loose tissues from the front of the disc space; thus, clearly exposing the anterior longitudinal ligament. In retroperitoneal approaches to the L_5–S_1 disc space, the filaments of the presacral sympathetic plexus are rarely seen (the danger of damaging these nerves in the male has been exaggerated by opponents of this method of spinal fusion[8]). The thin, anterior, longitudinal ligament is then divided transversely across the middle of the disc space and the ends are swept upwards and downwards to expose the junction of the vertebral end-plate and the disc, on either side of the disc space. The cuff of tissue formed by its rolled ledges helps to protect the wall of the great veins at the side of the disc space.

To expose the disc between the L_4 and L_5 vertebral bodies it may be necessary to ligate and divide the left ascending lumbar vein. The sympathetic trunk is first identified where it lies along the anterior margin of the psoas major muscle, on the side of the vertebral body. The fibers of the fibrous arcade, which attach the psoas muscle to the superior and inferior vertebral margins at the disc space, are divided and the psoas muscle is retracted laterally.

The ascending lumbar vein is often quite large, with a diameter at its entry point into the lateral wall of the left common iliac vein of between 3 and 5 mm. The techniques for the safe handling, dissection and ligation of this vessel are among the most critical maneuvers to be performed in the whole of this operation. Whether or not ligation is required depends on the length of the vessel and its site of entry into the left common iliac vein. This vein is usually surrounded by fatty tissues from which it must be dissected free. This can be done by using a blunt probe and a smooth ended fine sucker.

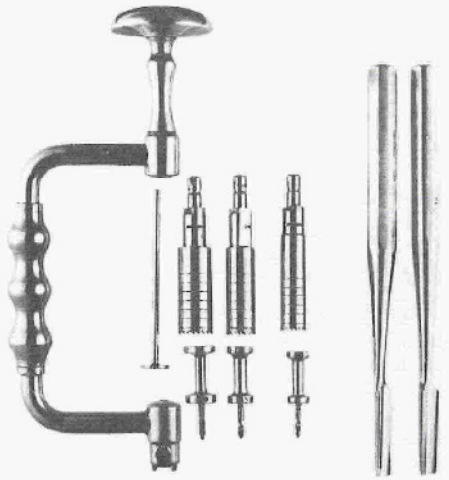


FIG. 1. A photograph showing a modified Hudson brace and three dowel cutting instruments, with the starter center pieces and one graft ejector. On the right side, note the special gouges which are used with the cutters (Trewavis Surgical Melbourne Pty. Ltd., Nunawading, Victoria).

The vessel is ligated with sutures of 3/0 black silk, just beyond its entry point into the left common iliac vein and again, further along its course, deep to the psoas muscle. It is essential to lock these black silk sutures onto the wall of the ascending lumbar vein with 5/0 sutures, transfixing its wall and encircling the vessel adjacent to each suture. The vessel is then divided between these locking sutures with a fine scalpel blade, mounted on a long handle. With these precise maneuvers safely completed, the great vessels may then be retracted towards the midline from the anterolateral surface of the L_{4-5} disc space.

Exposure of the L_{3-4} disc space can often be achieved satisfactorily without division of any significant vessels; although, on occasions the lumbar vessels lying on the side of the body of L_4 may need to be separately ligated near the anterior margin of the psoas major muscle before the great vessels can be safely retracted from the anterolateral surface of this disc.

Exposure of upper lumbar discs is best done with the patient in the lateral position on the operating table and with the incision running through the bed of the twelfth rib to allow extraperitoneal exposure of the upper lumbar vertebral column.

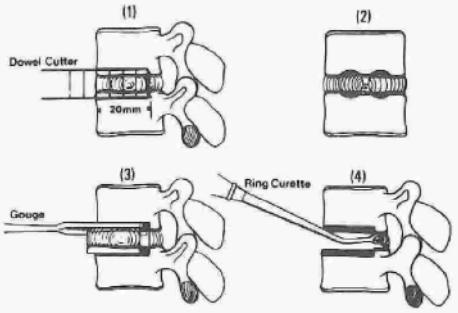


FIG. 2. Lower lumbar dowel cavities. (1) The use of a dowel cutting instrument in the lumbar spine. (2) The anteroposterior orientation of two dowel cavities in the lower lumbar area. (3) The use of the special gouge to displace the disc and adjacent fragments of the vertebral bodies. (4) The use of the ring curette for the removal of vertebral end plate and disc tissue remnants from the interbody space.

PREPARATION OF THE INTERSPACE FOR GRAFT INSERTION

The preparation of dowel cavities in the intervertebral space is carried out with the use of special cutters supplied in six sizes for use at any vertebral level. Each cutting cylinder has circumferential markings clearly visible on its external surface. These rings are separated from each other by 5 mm (Fig. 1). Dowel cavities are cut across the vertebral interspace with a cutting cylinder of appropriate size (Figs. 2 and 3).

In due course, *grafts are cut using the cutting cylinder that is one size larger than that used to cut the intervertebral dowel cavities*. When the cutting instruments are in use in the disc spaces, the surgeon must at all times have the undivided attention of his two assistants, to ensure that the great vessels are protected from injury. Specially modified Deever's retractors, (Trewavis Surgical Melbourne Pty. Ltd., Nunawading, Victoria)

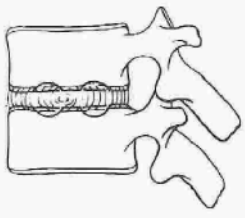


FIG. 3. A lateral illustration of the orientation of dowel cavities transversely in the intervertebral space suitable for interbody grafting in the upper lumbar area.

which have smooth excavated ends, are held in place with loose raytec swabs positioned beneath them to prevent herniating the edge of the great vessels or adjacent soft tissues from herniating beneath them.

The surgeon must be thoroughly familiar with the measurements of the intervertebral space in each patient when preparing the dowel cavities.

Measurements of the vertical height of the disc space and the anteroposterior depth should be available from preoperative roentgenograms. In addition it is to be noted that the anteroposterior measurements vary, being greatest in the midline and smallest laterally because the shape of the disc bearing surface of the vertebral body is oval, not rectangular.

When the parallel plugs of the adjacent vertebral body fragments and the intervening intervertebral disc have been displaced from the interspace using a gouge specially tooled to match the size of the cutter (Fig. 1), the disc remnants are then removed from the interspace with rongeurs. In addition, vertebral end-plate remnants should be removed with ring curettes. Aided by the use of a vertebral spreader, it is possible to remove the bulk of disc tissue and vertebral endplates from the interspaces. However, during these maneuvers the surgeon must avoid penetrating the spinal canal or damaging the great vessels, which may have slipped out from beneath the retractors.

The graft beds prepared by this method are well vascularized. Indeed one of the great advantages of this operation is that the blood supply of the vertebral bodies is not disturbed; thus, vascularization of appropriately placed grafts is assured.[5]

GRAFT PREPARATION

The use of autogenous bone grafts is strongly recommended. The left iliac crest is exposed by retracting the inferolateral edge of the abdominal incision. A supplementary incision is then made running along its upper border. *Dowel cutting instruments of one size larger than those used to prepare the dowel cavities in the intervertebral space, are then used to cut grafts from the iliac crest*, passing vertically downwards to the required depth. Grafts of 2.5 cm to 2.8 cm in depth are of satisfactory size in most patients. On occasion, cancellous chips may be cut from the bony fragments of vertebral bodies obtained from the dowel cavities. These fragments may be used to supplement the iliac crest grafts in larger patients.

The iliac crest grafts have three cortical faces

and two "tooled" cancellous faces. They are designed to be impacted parallel to each other with the cortical faces orientated laterally in the disc space and the cancellous surfaces facing the vertebral bodies. Purely cancellous grafts inserted into the intervertebral disc space have been shown by Crock[3] to be liable to invasion by disc remnants; thus, predisposing to nonunion. This complication has been largely obviated by the use of grafts cut from the anterior iliac crest in the manner just described (Fig. 4).

Graft Impaction

In the last phase of this operation the intervertebral disc space is again carefully exposed by the assistants. A vertebral spreader is inserted into one of the dowel cavities and opened to allow for a final inspection of the interspace. The depth of the dowel cavity is checked with a depth gauge and ruler and the first graft then impacted. This is a potentially dangerous maneuver as the edge of a great vessel may become trapped between the graft and the wall of the intervertebral space dowel cavity. Successful retraction at this critical stage of the operation calls for strict attention to detail.

Following impaction of the first graft, the vertebral spreader is removed from the second dowel cavity and the second graft is impacted. Some hemorrhage will occur from the site; but, this is never severe and usually ceases in two or three minutes (Figs. 5, 6, 7A and 7B).

Attention is finally focused on the donor site. If two grafts have been cut from the iliac crest then the bony defect is filled with orthopedic bone cement before the wounds are closed in layers with suction drainage.

DISCUSSION

The method of operation described in this paper has been used by the author at St. Vincent's Hospital, Melbourne, since 1961. Of approximately 1000 operations performed in 20 years, three patients have died. Two of these died in the postoperative period of acute coronary occlusion; the third committed suicide four months postoperation.

No significant urologic complications have been encountered with this method of spinal fusion. Retention of urine occurs in some patients, but its management only rarely involves the use of a catheter for one or two days. In most cases bladder function is restored after the use of one or two doses of Urecholine (Merck Sharp & Dohme).

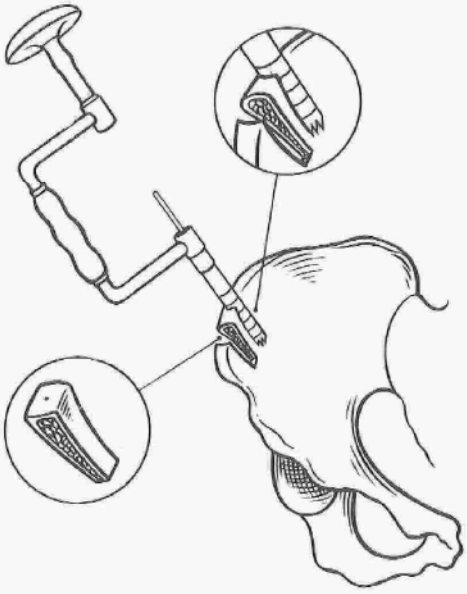


FIG. 4. Method of cutting grafts from the anterior third of the iliac crest. The graft has "tooled" cancellous surfaces and stout cortical faces on three sides. Reprinted with permission from: Crock, H. V.: Observation on the management of failed spinal operations. J. Bone Joint Surg. 58B:193, 1976.

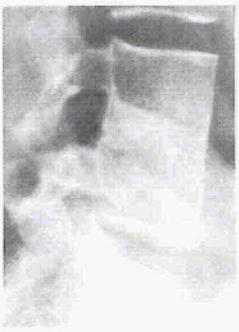


FIG. 5. A lateral view roentgenogram showing L_{4-5} interbody fusion in a 46-year-old woman, ten years after operation.

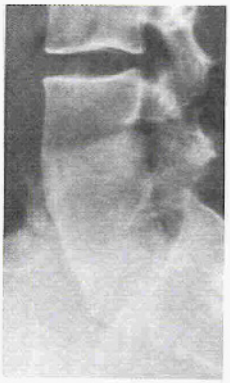


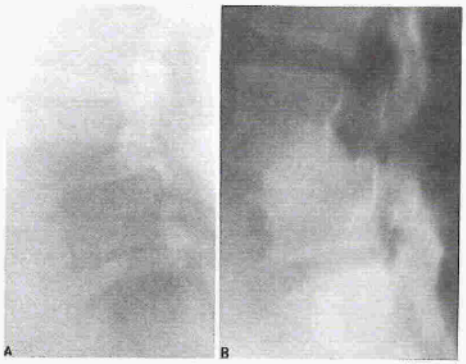
FIG. 6. A lateral view roentgenogram showing L_{4-5} and L_5–S_1 interbody fusions in a 48-year-old man, five years after operation.

In exposing the lumbosacral intervertebral disc space in the male, the use of diathermy in the presacral area has been avoided. The author is aware of complaints of sterility in only two patients, both of whom were psychiatrically disturbed and both of whom had complained of impotence before operation.

POSTOPERATIVE CARE

Patients are nursed supine with one or two pillows, and rolled from side to side several times a day with a pillow placed between their legs. We recommend the use of beds which can be tilted vertically to allow patients to stand and to get out of bed with little assistance from the nursing staff. Intravenous therapy is continued until bowel sounds are heard or flatus has been passed. Urine retention is not a common problem after this operation.

Prophylactic anticoagulant therapy with subcutaneous calciparine (Heparin, Difrex Australian Laboratories Pty. Ltd., Glebe, N.S.W.) is administered until patients have become fully mobile. Spinal supports are fitted within a few days of operation and worn for three or four months afterwards.



FIGS. 7A AND 7B. (A) Lateral view roentgenogram of the lumbar spine in a 45-year-old man, showing Grade 2 spondylolisthesis at L_{4-5}. (B) Interbody grafts have been inserted transversely (one year after operation).

SUMMARY

A technique using dowel cutting instruments for anterior lumbar interbody fusion operations is recommended for the treatment of other failed spinal operations; certain disc lesions; in the management of selected cases of spondylolisthesis; certain spinal infections; following some vertebral fractures; correction of selected spinal deformities and in the treatment of rare miscellaneous cases, *e.g.*, vertebral body tumors and nucleus pulposus calcification. Extra peritoneal approaches to the lumbar vertebral column are recommended. Dowel cavities are cut to predetermined depths with specially designed cutters of appropriate size. The greater bulk of disc tissues and vertebral end plate cartilages are then removed using ring curettes and pituitary rongeurs. Autogenous grafts are cut from the iliac crest using a cutter one size larger than that used to prepare the intervertebral dowel cavities. With the depths of the dowel cavities having been checked with a depth gauge, the grafts are duly impacted after careful retraction of all adjacent structures away from the cavities.

ACKNOWLEDGMENTS

The author wishes to thank sincerely the Trustees of the William Angliss Foundation and of the William Buckland Foundation for their financial support.

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Appendix B to McAfee Declaration

Affidavit of Dr. Henry Crock

Affidavit

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

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8	**Exhibit HVC-7** being a copy of Crock, A Short Practice of Spinal Surgery, Springer-Verlag Wein New York, Revised 2nd Edition, 1993	16	

I, Henry Vernon Crock, of 13 Sargood Street, Toorak 3142, Victoria, Australia, retired orthopaedic spine surgeon, say on oath:

1 I have been engaged by NuVasive, Inc. to review and provide comment on a number of publications in the field of spinal surgery. I have been advised that the disclosures and teachings in these publications have been put into issue in a patent lawsuit pending in the United States between NuVasive, Inc. and a subsidiary of Medtronic, Inc., namely, Warsaw Orthopedic, Inc. I have also been engaged to provide comment on certain testimony and contentions arising in connection to this lawsuit.

2 I am being compensated for my time actually spent in working on this matter at my customary rate for consulting matters, and have received no compensation for this declaration from NuVasive, Inc., its representatives, or otherwise beyond that. In addition, I will not receive any added compensation based on the outcome of any proceedings in which my prior work is at issue. Finally, I am not, and never have been, an employee of NuVasive, Inc.

3 I have been provided with a copy of the Federal Court of Australia Practice Note CM7 entitled "Expert Witnesses in Proceedings in the Federal Court of Australia" by a representative of NuVasive, Inc. Now shown to me and marked **Exhibit HVC-1** is a copy of Practice Note CM7. In considering the matters put to me and making this affidavit, I have complied with Practice Note CM7.

Experience and Qualifications

4 I have been asked me to provide details of my background and experience, particularly in relation to spinal interbody fusion procedures, in other words, surgical procedures

wherein disc material between adjacent vertebral bodies is removed and replaced with one or more fusion-promoting implants for the purpose of forming a bone bridge between the adjacent vertebral bodies to immobilize that spinal segment.

5 I practiced spinal surgery from 1961 until my retirement in 2001. I practiced first at St. Vincent's Hospital in Melbourne, Australia from 1961 until 1986 and held various titles including Senior Orthopaedic Surgeon. In 1986, I moved to London, England and practiced spinal surgery at various hospitals and held various appointments including Honorary Senior Lecturer and Consultant Spinal Surgeon in the Department of Orthopaedic Surgery at the Royal Postgraduate Medical School, Hammersmith Hospital, and Director of the Spinal Disorders Unit at Cromwell Hospital. I retired in 2001 and moved back to Melbourne.

6 I obtained a Doctor of Medicine and Doctor of Surgery (M.B.B.S.) from the University of Melbourne in 1953, a Medical Doctorate (M.D.) from the University of Melbourne in 1967, and a Masters of Surgery (M.S.) from the University of Melbourne in 1977.

7 In terms of specialised training in surgery, I was made a Fellow of the Royal College of Surgeons in London in 1957 and a Fellow of the Royal Australasian College of Surgeons in 1961.

8 I have received numerous awards and honours during my career, including Officer of the Order of Australia (A.O.) in 1984 for services to medicine, especially in the field of orthopaedic surgery, Corresponding Fellow of the Japanese Orthopaedic Association in 1990, Honorary Fellow of the Royal College of Surgeons, Edinburgh in 1997, Honorary Member Spine Society of Australia in 2006, and Honorary Doctorate of Science from the University of Melbourne in 2009, the highest honorary award given by a university. In addition, I was elected President of the International Society for the Study of the Lumbar Spine in 1985, and have been awarded the LO Betts Medal by the

Australian Orthopaedic Association, the Sir Alan Newton Prize by the Royal Australasian College of Surgeons and the Wood Jones Medal by the College of Surgeons of England.

9 I have lectured extensively on spinal surgery, including at least 66 guest lectures in at least 17 countries between the years of 1985 and 2001 alone, and extended lecture tours once or twice a year from 1966 until my retirement in 2001 visiting Europe, Russia, Scandinavia, Canada, Japan, USA, Peoples' Republic of China, Hong Kong, India, Singapore, Indonesia, the Philippines, India, Great Britain, and Saudi Arabia.

10 I pride myself on being a teacher. Following my appointment at St. Vincent's Hospital, Melbourne in 1961, I became actively involved in undergraduate and post-graduate teaching of orthopaedic surgery and, in particular, spinal surgery. I continued training post-graduate fellows in spine surgery after moving to London in 1986. I have trained at least 26 post-graduate fellows from countries ranging from Indonesia, India, Canada, USA, Japan, Scotland, and Pakistan. In terms of teaching positions, I was also Lecturer in Orthopaedic Surgery at Oxford University from 1959-1961, Professorial Associate at St. Vincent's Hospital, Melbourne from 1961-1986, Visiting Lecturer in the Department of Anatomy at the Royal College of Surgeons of England, Senior Lecturer in the Department of Orthopaedics at the Royal Postgraduate Medical School at Hammersmith Hospital, and Director of Spinal Disorders Unit at Cromwell Hospital.

11 I have written a multitude of publications regarding spine surgery and served on the editorial boards of the British Journal of Bone and Joint Surgery, The European Spine Society Journal, Neuro-Orthopaedics (now ceased), and The Journal of Orthopaedic Science from the Japanese Orthopaedic Association. Among my publications include 6 books, 26 book chapters, and at least 35 papers, all of which were peer-reviewed. My book "An Atlas of Vascular Anatomy of the Skeleton and Spinal Cord" won the British

Medical Association prize for Basic Science and Clinical Medicine in 1996. My paper "A Reappraisal of Intervertebral Disc Lesions" originally published in the Medical Journal of Australia in 1970 was in 2005 cited in The Spine Journal of North America as a seminal paper on spinal surgery in the 20th Century.

12 Now shown to me and marked **Exhibit HVC-2** is a copy of my curriculum vitae setting out my experience and publications.

13 I was born on Sept 14, 1929 and am currently 82 years of age. I am of sound mind and able to understand completely and fully the contents of the materials I have reviewed and the statements I am making below. Although I am retired, I continue to receive and read various medical journals in my field of expertise, and attend medical conferences and collaborate with others in the field of spinal orthopaedics. For example, I still receive and regularly read publications including the Journal of Orthopaedic Science from the Japanese Orthopaedic Association, the Journal of the British Orthopaedic Association, the Australia and New Zealand Journal of Surgery, and the Journal of the Royal College of Surgeons of Edinburgh. I am also still a member of a variety of spine surgery associations, including the Australia Orthopaedic Association, the British Orthopaedic Association, the Japanese Orthopaedic Association, and am currently President of DISCS – The Diagnostic Investigation of Spine Conditions and Sciatica in London – a charitable trust established in 1993.

14 Currently, my physical health is such that I am not able to handle undue stress, and I am not able to travel long distances to the United States to participate in legal proceedings.

15 I have voluntarily agreed to provide this Affidavit and the evidence contained therein of my own free will. The information contained in this Affidavit comes from my own recollection or from the documents that I identify as having consulted.

Consideration of documents

16 I have been asked to review and comment on five documents, which are now shown to me and marked as follows:

(a) **Exhibit HVC-3**, being a copy of Crock, "Observations on the management of failed spinal operations," in The Journal of Bone and Joint Surgery, Vol. 58-B, No. 2, pp. 193-199, May 1976 (hereinafter referred to as "**my 1976 paper**");

(b) **Exhibit HVC-4**, being a copy of Crock, "Anterior Lumbar Interbody Fusion – Indications for its Use and Notes on Surgical Technique," in Clinical Orthopaedics and Related Research, No. 165, May 1982 (hereinafter referred to as "**my 1982 paper**");

(c) **Exhibit HVC-5** being a copy of Fujimaki, et. Al. "The Results of 150 Anterior Lumbar Interbody Fusion Operations Performed by Two Surgeons in Australia," in Clinical Orthopaedics and Related Research, No. 165, May 1982 (hereinafter referred to as the "**Fujimaki et al. paper**");

(d) **Exhibit HVC-6** being a copy of Crock, A Practice of Spinal Surgery, Springer-Verlag Wein New York, Revised 1st Edition, 1983 (hereinafter referred to as "**my 1983 book**");

(e) **Exhibit HVC-7** being a copy of Crock, A Short Practice of Spinal Surgery, Springer-Verlag Wein New York, Revised 2nd Edition, 1993 (hereinafter referred to as "**my 1993 book**").

17 I was asked to review the publications above and any other materials I deemed necessary and proper in order to render the recollections about my prior publications set forth below. Specifically, I was asked to provide statements on factual matters within my knowledge. I was given ample time to review the documents.

Witness Statement

18 To my best recollection, I learned of a spinal access technique that uses a direct lateral approach to the spine (90 degrees off of midline) during a visit to a group of spinal surgeons in Hong Kong, which occurred in about 1968. The group in Hong Kong included Dr. Hogsdon of the University of Hong Kong, who is one of the authors of the 1956 article, entitled "Anterior spinal fusion: A preliminary communication on the radical treatment on Pott's disease and Pott's paraplegia," in The British Journal of Surgery, Vol. 44, pp. 266-75 (1956).

19 I have a specific recollection of the first spinal fusion surgery in which I used a direct lateral approach to the spine, and that was in a surgery performed in 1970. This direct lateral procedure was performed at the L2/L3 level of the patient, at the site of tuberculosis abscess formation (both in the disc space and in the L2 and L3 vertebral bodies). For this procedure, given it involved access at the L2/L3 region, I used a 12th rib incision for access, as discussed in my 1982 paper. This spinal fusion procedure addressed a condition known as "Pott's Disease," namely the resection of an abcess formation due to tuberculosis. The procedure involved partial resection of the L2 and L3 vertebral bodies, as well as partial removal of the L2/L3 disc, and implantation of one or more rib grafts harvested from the patient to create a bone bridge from the L2 vertebral body, through the L2/L3 disc space, to the L3 vertebral body. Based on the fusion which occurred at the L2/L3 disc space, it can be said that this procedure involved interbody fusion. The resulting fusion is shown in Figure 8.10 a,b of my 1983 book, and the patient is also shown in this book in Figure 8.11. The patient was a nun from New Guinea, and she is still alive today and is in her 90's. I remain in contact with this patient, as she has written me every year for the last 40 years, and she informs me how she is doing. I know the patient's name, but I am not revealing her name in

this Affidavit because it is my understanding that under Australian law that is confidential information I am not at liberty to disclose.

20 Although I do not specifically recall the first time I performed a spinal interbody fusion procedure other than for Pott's Disease (that is, focusing solely on interbody fusion and not involving partial resection of adjacent vertebral bodies – which I refer to hereinafter simply as "interbody fusion") using a direct lateral approach and do not recall the specific patient on which I performed this procedure, I know that the first time I performed a spinal interbody fusion procedure using a direct lateral approach was in the early-to-mid-1970's. In particular, I know that the first spinal interbody fusion procedure using a direct lateral approach occurred after I performed the direct lateral spinal fusion surgery for Pott's Disease on the patient discussed in the immediately preceding paragraph, and I know that it was before the publication of my 1976 paper in which I reported details of two lateral interbody fusion procedures.

21 At the time I did my first spinal interbody fusion procedure using a direct lateral approach in the 1970's, I was not aware of anyone else having done such a procedure before. Still today, I am not aware of anyone else having done such a procedure before I did it in the 1970's.

22 During the 1980's and 1990's, I trained many other spinal orthopaedic surgeons in the spinal fusion techniques described in my 1982 paper and in my 1983 and 1993 books.

23 I am the author of my 1976 paper. This paper was read at the 108th Anniversary Meeting of the Texas Medical Association, San Antonio, Texas, in May 1975. At the time I authored the paper, I was Senior Orthopaedic Surgeon at St. Vincent's Hospital, University of Melbourne, Australia.

24 I am the author of my 1982 paper. I submitted this paper for publication in September of 1980. At the time I authored the paper, I was Senior Orthopedic Surgeon at St. Vincent's Hospital, University of Melbourne, Australia

25 I am co-author with Arihisa Fujimaki, M.D. and Sir George Bedbrook, M.D. of the Fujimaki et al. paper. This paper reports on 150 surgeries performed by my colleague, Dr. Bedbrook, and me, with 100 of those surgeries having been performed by me.

26 I am the author of my 1983 book, and I am also the author of my 1993 book, which is a second edition of my 1983 book.

My 1982 Paper

27 My 1982 paper describes spinal fusion procedures that my colleague, Dr. Bedbrook, and I had performed over an 18-year period from 1961 until 1980, when I wrote my 1982 paper. As reported in my 1982 paper, by 1980 I had performed approximately 1000 operations over the preceding 20 years. *See* my 1982 paper, at p. 161. As reported in my 1993 book, by the time of the writing of my 1993 book I had performed over 1500 of the described procedures over the preceding 30 years, and had experienced no patient mortality during operation. *See* my 1993 book, at p. 94.

28 My 1982 paper describes two different approaches or trajectories to be taken to the spinal column for lumbar interbody fusion, namely: (a) an anterior or anterolateral approach or trajectory, which is used in most cases of the lower lumbar region (that is, for intervertebral discs at L4/L5 and L5/S1), and (b) a direct lateral approach or trajectory (that is, 90 degrees from the midline), which is used in the upper lumbar region (that is, for intervertebral discs at L1/L2, L2/L3, and L3/L4) and, if permitted by the anatomy, also in some cases of the lower lumbar region.

29 In entitling my 1982 book "anterior lumber interbody fusion," I used that phrase in a manner that was conventional at the time, and that was to use the phrase "anterior

lumbar interbody fusion" to refer to any fusion procedure that made an approach that did not traverse the posterior portion of the spine. In other words, if the approach was anterior of the posterior portions of the spine, it would be considered anterior lumbar spinal fusion. As such, I considered all of the procedures in my 1982 book to be anterior lumbar interbody fusion procedures, regardless of whether the approach was directly anterior, anterolateral, or directly lateral.

Anterior and Anterolateral Approaches Described in my 1982 Paper

30 My 1982 book describes that, for those procedures where an anterior or anterolateral approach is used (for example, in the lower lumbar fusions), the patient is placed supine on the operating table. *See* my 1982 paper, at p. 158. My 1982 paper describes that, using this anterior or anterolateral approach to the disc space, two parallel cavities would be formed in the disc space, each cavity extending from the anterior aspect of the disc space toward the posterior aspect of the disc space, or in other words, each of these cavities lies in an "anteroposterior" orientation, as illustrated in Figure 2 of my paper, copied below:

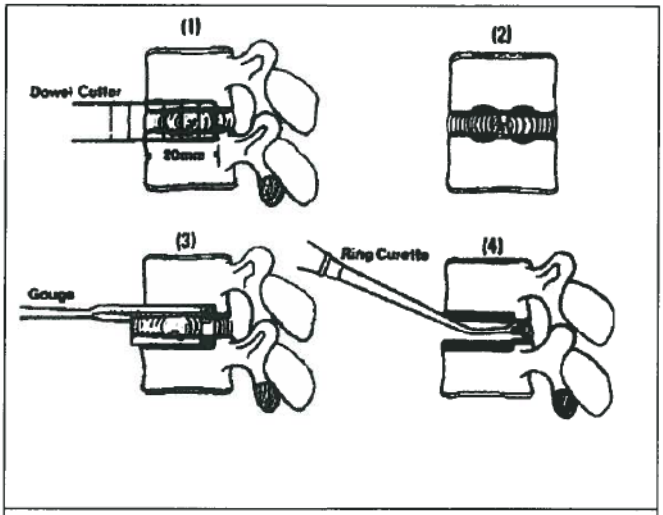

Figure 2

31 My 1982 paper then describes that the two parallel cavities may be filled with autogenous bone grafts or "dowels" obtained from the patient's iliac crest. My 1982 paper states that the dowels from the iliac crest were cut to be one size larger than the dowel cavities to ensure a proper fit. *See* my 1982 paper, at p. 160. My 1982 paper further describes the use of iliac crest grafts with three cortical faces, as illustrated in Figure 4, and also describes the use of purely cancellous grafts. *See* my 1982 paper, at pp. 160-61. In the case of purely cancellous bone grafts, these too would be harvested from the patient's iliac crest, albeit from a location more posterior than the location shown in Figure 4. My 1982 paper notes that the purely cancellous grafts are liable to invasion by disc remnants, thus predisposing to non-union. *See* my 1982, at p. 161.

32 My 1982 paper also describes, specifically with respect to fusions in the L4/L5 disc space, that the great vessels may be retracted towards the midline from the anterolateral surface of the L4/L5 disc space. *See* my paper, at p. 169. This is done because the typical location of the great vessels (running down the midline) makes a directly anterior placement of the two parallel cavities difficult or impossible. *See* my 1983 book, at p. 79, Fig. 2.44a (illustrating the great vessels running down the anterior midline of the spinal column at the L4/L5 disc space). As such, for the L4/L5 disc space, the two grafts would be introduced into the disc space from a location that is offset from the anterior midline, toward the anterolateral surface of the disc space. *See* my 1983 book, at p. 80, Fig. 2.46a and b; *see also* my 1993 book, at p. 73, Fig. 2.25:

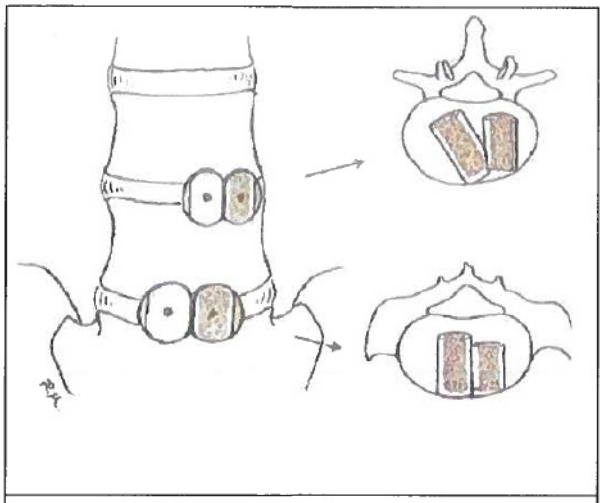

Figure 2.25

33 Again, the reason for the different positioning as shown in Figure 2.25 of my 1993 book for the L4/L5 disc space (top) as compared to the L5/S1 disc space (bottom), is due to the location of the great vessels. *See* my 1993 book, at page 95, Figure 2.50a. In particular, the bifurcation of the great vessels above the L5/S1 disc space enables a more central, or midline, anterior introduction of the implants in the L5/S1 location (as shown in Fig. 2.25 of my 1993 book copied above), whereas the central anterior location of the vessels above L5/S1 requires a more oblique, or anterolateral, trajectory to the disc space (as is also shown in Fig. 2.25 of my 1993 book copied above).

Direct Lateral Approaches Described in My 1982 Paper

34 I used direct lateral approaches for lumbar interbody fusion as described in my 1982 paper, where possible, because the use of a lateral approach in the upper lumbar region was preferred given it avoids contact with the great vessels. I also used direct lateral approaches for interbody fusion in the lower lumbar region where it was not possible to perform the procedure using an anterior approach, for example, in patients with Grade 2 spondylolisthesis, as shown in Figures 7A and 7B of my 1982 paper.

35 My 1982 paper describes, for those procedures where a direct lateral approach is used (for example, the rarer upper lumbar fusions), that the patient is placed in the lateral decubitus position on the operating table with the left loin uppermost. *See* my 1982 paper, at pp. 158, 159. For the lateral approaches to the L1/L2 or L2/L3 disc space, I would form an "incision running through the bed of the twelfth rib to allow extra-peritoneal exposure of the upper lumbar vertebral column." *See* my 1982 paper, at p. 159; *see also* my 1983 book, at p. 74; my 1993 book, at p. 88. This twelfth rib incision is one that is known in other fields of surgery, for example to access the kidney, and the incision runs straight along the twelfth rib, from anterior of a direct lateral position to posterior of a direct lateral position. As such, the twelfth rib incision allows a direct lateral trajectory to the spine. For the lateral approaches to the L3/L4 disc space, my 1982 paper describes that the incision would be similar to the incision used for the L4/L5 and L5/S1 access, namely, an oblique incision on the left side of the patient, commencing at the midline between the umbilicus and symphysis pubis (although nearer to the umbilicus for the L3/L4 approach) and extending upwards and laterally parallel to the level of the iliac crest. *See* my 1982 paper, at p. 158. As such, this incision allows a direct lateral trajectory to the L3/L4 disc space.

36 My 1982 paper also describes that, after direct lateral access to the disc space is made, two parallel dowel cavities would be cut into the disc space, and those cavities are oriented "transversely." By "transversely," I meant lying in the transverse plane, and as such, by saying that the cavities are oriented transversely, that meant that they are oriented laterally, from side-to-side in the disc space, and not anterior-to-posterior. I would typically use a smaller-diameter, cervical-sized dowel cutting instrument for cutting the cavities in the lateral face of the disc space in the upper lumbar region. *See* my 1982 paper, at p. 159, Fig. 1 (showing the three dowel cutter sizes, with the smaller one on the left being the cervical-sized dowel cutter). Figure 3 of my 1982 paper (p.

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160) shows the lateral faces of adjacent vertebrae into which two parallel cavities have been formed:

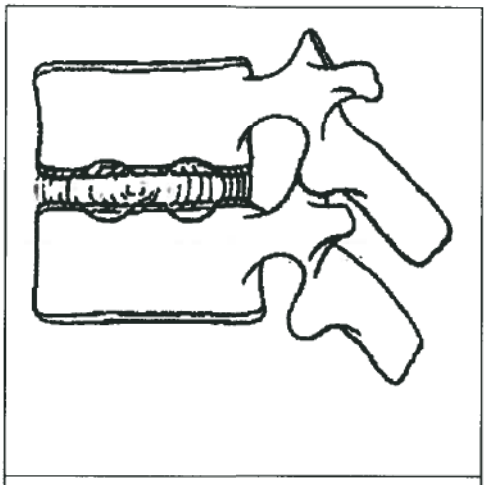

Figure 3

37 Figure 3 of my 1982 paper was drawn by an artist, Mr. Dale Howat, who I engaged to prepare many of the illustrations used in my publications. It was my normal practice at the time to have Mr. Howat prepare figures such as this in my presence, and we would work together to ensure that the figures illustrated what I intended them to illustrate. Figure 3 accurately makes a diagrammatic representation of what I intended Figure 3 to illustrate, namely, two cavities having been formed in the lateral face of the disc space. The purpose of Figure 3 was not to convey exact dimensions for a particular vertebra, although the dimensions of Figure 3 are generally accurate for typical vertebrae.

38 Figure 3 of my 1982 paper was not included in my 1983 book or in my 1993 book. Although I do not have a specific recollection today as to why Figure 3 was not included in my 1983 and 1993 books, I know for certain that its omission was not because I or anyone else deemed the figure to be inaccurate. Indeed, I never have considered Figure 3 of my 1982 paper to be inaccurate, and do not consider Figure 3 to

be inaccurate today. Until now, I have never had the accuracy of my drawings called into question.

39 As discussed above, my 1982 paper describes that the two parallel cavities are filled with autogenous bone grafts or "dowels" including both cortical bone and cancellous bone, or alternatively, with purely cancellous bone grafts obtained from the patient's iliac crest. *See* my 1982 paper, at pp. 160-61 and Figure 4. Such implants were effective, in my view, because the implants had cancellous bone in contact with the cancellous bone of the vertebrae. This enabled blood flow from the exposed cancellous bone of the vertebral bodies into the cancellous bone of the grafts, thereby facilitating bone growth and effective fusion. Vascular anatomy is one of my specialties and this biological view (vs. mechanical) of fusion is an outcropping of and consistent with my early work in this area. *See,* e.g., Crock et al., "*The Blood Supply of the Vertebral Column and Spinal Cord in Man,*" Springer-Verlag New York, 1977.

40 In terms of sizing the implants, my 1982 paper describes that the dowels were typically cut from the iliac crest to be one size larger in diameter than the dowel cavities to ensure a proper fit. *See* my 1982 paper, at p. 160. My 1982 paper describes that the length of a dowel cavity is checked with a depth gauge and ruler. *See* 1982 paper, at p. 161. The depths of the cavities are measured to make sure the grafts are long enough to fit the depth of the cavity. *See also* my 1993 book, at p. 97, Figure 2.51a, b (illustrating implants extending across the length of the cavity into which the implant is inserted). In the case of the lateral implants extending transversely, they were sized to occupy substantially the full transverse width of the two adjacent vertebrae.

41 My 1982 paper states that grafts of 2.5 cm to 2.8 cm in depth are of satisfactory size in most patients. *See* 1982 paper, at p. 160. My experience was that this was typically true for the upper lumbar applications in which lateral implants were used. In some cases (for example, larger patients), grafts greater than 2.8 cm could be obtained from

the iliac crest. In addition, given the shape of the iliac crest, while the longer dowels may include thinner distal portions of the iliac crest graft, I found these implants to be sufficiently strong to be safe and effective intervertebral implants and did not witness any post-operative subsidence of those dowels in those patients who received them via my direct lateral interbody fusion technique.

42 Although my 1982 paper indicates my strong recommendation that autogenous bone grafts be used as the implant, I noted in my 1993 book that non-bone implants such as porous ceramic and titanium implants had by that time also been used by others as substitutes for autogenous interbody grafts. *See* my 1993 book, at p. 74.

1982 Paper, Figures 7A and 7B: Lateral Approach Example

43 Figures 7A and 7B of my 1982 paper (copied below) shows a roentgenogram of a specific case of an interbody implant that has been inserted "transversely," using a direct lateral approach, such that the implant extends substantially the full transverse width of the two adjacent vertebrae. The 1982 paper notes that the patient here had Grade 2 spondylolisthesis at L4/L5 (lower lumbar), which means that the L4 vertebral body was "slipped" forward above the L5 vertebral body by approximately 50%. In this case (Grade 2 spondylolisthesis) I would have only used one graft, and the notation in the caption of the figure to "grafts" would seem to be incorrect. Also, given the Grade 2 spondylolisthesis condition, it would not have been possible to have inserted the implant using an anterior approach due to the degree of the "slip," which was not corrected before the lateral graft was implanted. I therefore would have not used the anterior or anterolateral approach typically used at this level, but rather would have used a direct lateral approach. As such, the notation in the caption for Figures 7A and 7B of "transversely" (that is, insertion in a transverse plane, or laterally from one side to the other in the disc space) is correct. Figures 7A and 7B of my 1982 paper definitively depict the result of a direct lateral interbody fusion procedure.

FIGS. 7A AND 7B. (A) Lateral view roentgenogram of the lumbar spine in a 45-year-old man, showing Grade 2 spondylolisthesis at L_{4-5}. (B) Interbody grafts have been inserted transversely (one year after operation).

Figures 7A and 7B

1993 Book, Figures 2.48a-c: Lateral Approach Example

44 Figures 2.48a-c on page 93 of my 1993 book (also shown in my 1976 paper and in Figures 2.47a-b on page 81 of my 1983 book) disclose another example of a spinal fusion technique using a direct lateral approach, this one having been done in the L2/L3 disc space. I specifically recall this patient (a Russian female residing in Australia), and specifically recall that I performed the procedure using a direct lateral approach, and placed the implant directly across substantially the full transverse width of the two adjacent vertebrae. This patient, unfortunately, had a complication called discitis due to a previous procedure at a different spinal level than where the lateral interbody fusion was done. The discitis was the result of a diagnostic procedure called a discography, which unfortunately created over-pressurization in an otherwise healthy disc that over time caused erosion of the disc into the adjacent vertebrae resulting in great pain. She committed suicide.

45 Post mortem histological investigation identified, not only the complication at a different disc level, but also showed that complete fusion in the L2/L3 disc space had not occurred as it should have. Through this investigation it became apparent that the incomplete union of the laterally placed cancellous graft was caused by the infiltration of disc remnants into the cancellous bone graft, which prevented the necessary blood flow into the graft to achieve fusion. The incomplete union was not determined to be the result of the use of the cancellous bone graft in and of itself, and it is not the case that insufficient strength of the cancellous bone graft resulted in fusion not being successfully achieved in this case. In other instances, the use of cancellous grafts placed laterally into the lumbar spine resulted in full fusion, which I suspect was due to more complete disc removal before the insertion of the cancellous grafts such that the vascular flow between the cancellous bone of the vertebral bodies and the cancellous bone of the graft was sufficient to enable the fusion process as desired.

1993 Book, Figures 2.58a-b: Lateral Approach Example

46 Figures 2.58a-b on page 103 of my 1993 book (and also in my 1976 paper and in Figures 2.58a-b on page 92 of my 1983 book) disclose another example of a spinal fusion technique using a direct lateral approach, this one having been done in the L3/L4 disc space. In this case, one instead of two parallel grafts was used, given the size of the disc space. This graft collapsed for the same reason that the graft discussed above and shown in Figures 2.48a-c of my 1993 book collapsed, namely, because of disc remnants having been left in the disc space, which prevented the necessary blood flow to achieve fusion. Again, the incomplete union and subsequent collapse in this case was not the result of the use of a cancellous bone graft in and of itself, and it is not the case that insufficient strength of the cancellous bone graft resulted in fusion not being successfully achieved in this case.

Surgical Records

47 It is possible that surgical records may exist, but no such records are in my custody or control, and I have not attempted to obtain them. I did not feel it necessary to review any surgical records in order to provide my factual recollections set forth above, which were qualified in cases where my recollections were not clear. If any such surgical records exist, they may exist with the St. Vincent Hospital in Melbourne, Australia, or with certain other hospitals where I performed surgeries, including Hammersmith Hospital and Cromwell Hospital in London.

Responses to Specific Statements About My Work And Publications

48 I understand that various opinions and statements have been made about lateral fusion techniques generally and about my publications in particular. Some of these opinions and statements are copied below. I will address each one in turn.

49 I understand that the following testimony was given by Dr. Barton Sachs in a trial proceeding in the United States:

50 Q. NOW DR. SACHS, IS IT THE CASE UNTIL 1995, NO SURGEON DID ANY SORT OF SPINAL FUSION PROCEDURE FROM A LATERAL APPROACH?

A. I WOULD AGREE WITH THAT.

51 I disagree with the statement in ¶50 above made by Dr. Sachs because I performed spinal fusion procedures, including spinal interbody fusion procedures, from a lateral approach before 1995, and in fact did so as early as the 1970's. Such procedures are documented in my 1982 paper, as well as my 1976 paper and my 1983 and 1993 books.

52 I understand that U.S. Patent No. 5,860,973 to Dr. Gary Michelson (the '973 patent) makes the following statement: "In the past [prior to the filing of the patent, on June 7, 1995], spinal fusion implants have been inserted only from either an anterior or posterior direction, from the front or the back of the patient," and Dr. Barton Sachs stated that it was his opinion that this was true. This statement is not true.

53 Long before June 7, 1995, and in fact in the 1970's, I had on multiple occasions inserted spinal fusion implants using a direct lateral approach and into the lateral aspect of the disc space, and I made such laterally inserted implants public in my 1982 paper and other publications.

54 I understand that it has been contended that my 1982 paper does not disclose insertion of a spinal implant from the lateral aspect of the spine. This statement is incorrect.

55 My 1982 paper, as well as my 1983 book and my 1993 book, all disclose insertion of a spinal implant into the disc space through the lateral aspect of the spine.

56 Figure 3 of my 1982 paper is not inaccurate, and conveys what I intended it to convey, namely, that two parallel cavities can be formed in the lateral aspect of the disc space from a lateral approach, so that two interbody fusion dowels may be inserted into to those laterally facing cavities.

57 I understand the following testimony was given by Dr. Barton Sachs relating to Figure 3 from my 1982 paper.

58 Q. DR. SACHS, YOU TESTIFIED YESTERDAY AND AGAIN TODAY THAT YOU BELIEVE FIGURE THREE WAS INAPPROPRIATELY DRAWN, THOSE WERE YOUR WORDS. COULD YOU PLEASE EXPLAIN FURTHER?

A. WELL AS I WAS SAYING YESTERDAY AND I WAS ALLUDING TO BEFORE, I BELIEVE THAT THE LENGTHENING OF THAT BODY, OF THAT PICTURE THAT SHOWS THE VERTEBRAL BODY AND A SIDE VIEW IS MISREPRESENTED. IT'S TOO LONG. AND IT'S SHOWING THERE ARE TWO IMPLANTS BEING PLACED IN A LONG VERTEBRAL BODY WHERE IN ACTUALLY LOOKING AT THE UPPER LUMBAR SPINE FROM THE SIDE, IT IS GOING TO BE MUCH SHORTER AND THAT WAS MY IMPRESSION FROM READING THIS. I THOUGHT THERE MIGHT BE A MISTAKE. SO LOOKING

AND LOOKING AT THE NEXT TREATISE THAT DR. CROCK CREATED, WHICH ALSO TALKED ABOUT THE SAME TOPIC OF ANTERIOR LUMBER FUSIONS, HE ACTUALLY USED THE SAME CHAPTER, EVERY OTHER DRAWING WAS THE SAME, HE ADDED SOME MORE INFORMATION, HE TOOK THAT DRAWING OUT AND HE REPLACED IT WITH A MORE APPROPRIATE DRAWING WHICH SHOWED THE IMPLANTS COMING IN LATERAL TO THE ANTERIOR MIDLINE.

59 I disagree with the statement in ¶58 above. Figure 3 is not drawn inappropriately, and it is not drawn anatomically incorrectly. Figure 3 is a diagrammatic representation, designed as a guide for surgeons in performing the lateral fusion techniques described in my 1982 paper. Further, it was not a mistake to publish Figure 3. While it is true it was not included in my later publications, it most certainly wasn't "withdrawn" as suggested by Dr. Sachs.

60 I understand the following is testimony of Dr. Barton Sachs, referring to Figure 3 from my 1982 paper.

61 Q. ALL RIGHT. I WANT TO GO BACK TO THE FUNDAMENTAL QUESTION ON THE CROCK ARTICLE AS TO WHETHER FIGURE 3, WHETHER WE HAVE AN INTERPRETATION DISPUTE OR WHETHER YOU'RE SAYING THAT THIS FIGURE IS WRONG.

OKAY. YOU TESTIFIED TO THE JURY THAT THIS FIGURE WAS DRAWN INAPPROPRIATELY; DO YOU RECALL THAT?

A. YES, SIR, I DO.

Q. YOU SAID IT WAS MISREPRESENTED. DO YOU RECALL THAT?

A. YES, I DO.

Q. YOU SAID IT WAS A MISTAKE, RIGHT?

A. YES, THAT'S WHAT I SAID.

Q. YOU SAID IT WAS ANATOMICALLY INCORRECT, RIGHT?

A. YES, SIR.

Q. EVEN THOUGH YOU'RE NOT GOING TO DISPUTE THAT IT'S PUBLISHED IN A PEER REVIEW JOURNAL, RIGHT?

A. I'M NOT GOING TO DISPUTE THAT IT WAS PUBLISHED IN A PEER REVIEW JOURNAL. WE KNOW THAT A LOT OF THINGS THAT GET PUBLISHED ARE MISTAKES. THE FACT THAT FOR SOMEBODY TO SAY THAT MISTAKES ARE NOT MADE IN PUBLICATIONS I THINK IS NOT SENSIBLE, AND I BELIEVE THAT, AS I'VE SAID BEFORE, THAT THIS IS AN ILLUSTRATION, ALBEIT A POOR ILLUSTRATION, OF WHAT THE AUTHOR IS TRYING TO REPRESENT IN HIS ARTICLE, SO MUCH SO THAT IT NEVER SHOWED THE LIGHT OF DAY AND APPEARED IN ANY OF HIS FURTHER TREATISES. ACTUALLY, IT WAS WITHDRAWN FROM HIS TEXT CHAPTERS. WITHIN 12 MONTHS, IT DISAPPEARED. IF IT WAS SO REPRESENTATIVE, I BELIEVE HE WOULD HAVE KEPT IT AND USED IT AGAIN.

62 I disagree with the statements made by Dr. Sachs in ¶61 above. Again, Figure 3 is not drawn inappropriately, and it is not drawn anatomically incorrectly. Figure 3 is a diagrammatic representation, designed as a guide for surgeons in performing the lateral fusion techniques described in my 1982 paper.

63 I understand the following testimony was given by Dr. Barton Sachs, referring to Figure 2.25 from my 1993 textbook as it relates to Figure 3 from my 1982 paper.

64 Q. DR. SACHS, DID YOU PREPARE A DEMONSTRATIVE TO SHOW THE JURY WHAT THE FIGURE WAS CHANGED TO?

A. YES.

Q. CAN WE PUT UP SAR 32 [showing Fig. 2.25 of my 1993 book, copied below], THIS IS AN EXCERPT OF DDX 58[8]3 [this being an exhibit of my 1993 book]?

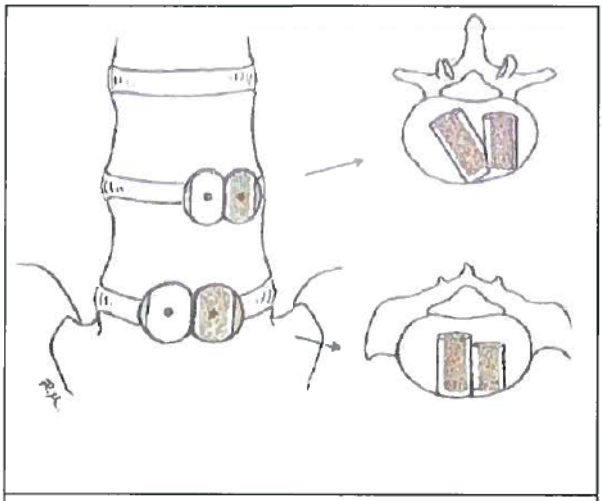

Figure 2.25

A. THIS IS THE DRAWING THAT WAS REPLACED, THAT REPLACED THE OTHER ONE WE SAW AND WE CAN SEE THAT AT ONE LEVEL, HE SHOWS DIRECT ANTERIOR APPROACH AT L FIVE, S-1, THAT'S THE BOTTOM HERE AND AT THE LEVEL UP HERE, HE SHOWS THESE IMPLANTS ARE COMING UP MORE LATERAL TO THE MIDLINE AND WE CAN SEE HOW THE IMPLANTS FIT IN HERE AND HOW THE IMPLANTS FIT IN HERE. SO AGAIN, WE'RE TALKING ABOUT AN ANTERIOR APPROACH JUST OFF MIDLINE HERE. I THINK AS THE SPINE WOULD BE ROLLED SLIGHTLY, DR. CROCK REALIZED IT WAS MISREPRESENTING WHAT HE WAS TRYING TO PORTRAY AND HE CORRECTED THAT IN THE NEXT TREATISE.

65 I disagree with the statement in ¶64 above. Figure 2.25 in my 1993 book is not a replacement for Figure 3, and it was not included in my 1993 book because Figure 3 of my 1982 paper had an error in it (which it did not). In particular, Figure 2.25 addresses a particular procedure in the lower lumber region, and in particular, at disc spaces L4/L5 (anterolateral approach) and L5/S1 (direct anterior approach), whereas Figure 3 of my 1982 paper addresses a different procedure in the upper lumbar region (lateral approach). These different procedures have different anatomical considerations, and in particular, the illustration of the implants at L4/L5 in Figure 2.25 is depicting an anterolateral approach instead of a direct lateral approach, given the midline location of the great vessels at the L4/L5 disc space.

66 I understand the following testimony was given by Dr. Barton Sachs, referring to my 1982 paper.

67 Q. JUNE 7, 1995. WAS IT A TRUE STATEMENT THAT ALL SPINAL FUSION IMPLANTS HAD ONLY BEEN INSERTED FROM EITHER ANTERIOR OR POSTERIOR DIRECTION?

A. YES. I WOULD AGREE WITH THAT.

Q. OKAY. CAN I HAVE DDX 2060 [my 1982 paper]. OUR FREUND [SIC] DR. CROCK, THIS IS A 1982 ARTICLE, RIGHT?

A. YES, IT IS.

Q. AND I THINK WE ALREADY DISCUSSED YESTERDAY, HE PUBLISHED SUBSTANTIALLY THE SAME DESCRIPTION IN 1973 DIDN'T HE?

A. HE DID.

Q. AND AGAIN IN 1983, RIGHT?

A. YES? AND AGAIN IN 1993.

Q. FOURTH TIMES, RIGHT?

A. WELL, I KNOW OF AT LEAST TWO OF THEM. WE HAVE REFERENCED THE 1970'S, SURE.

Q. ALL OF THEM WELL BEFORE JUNE 7, 1995?

A. YES.

Q. ALL OF THEM SHOWING IMPLANTS PLACED LATERALLY TRANSVERSELY IN THE INTERVERTEBRAL SPACE, RIGHT?

A. NO. WRONG. WE ADDRESSED THIS YESTERDAY AND I WAS TRYING TO EXPLAIN AND I BELIEVE THAT THERE'S A MISCONCEPTION, MISREPRESENTATION IN THAT DRAWING AND ACTUALLY, IF WE DID TURN TO DR. CROCK'S NEXT TREATISE, WHERE HE USED THIS SAME CHAPTER AND PUBLISHED IT IN HIS BOOK IN 1993, HE CORRECTED THAT DRAWING. HE HAS EVERYTHING ELSE THAT IS EXACTLY THE SAME AS THE CHAPTER IN 1983. HE SHOWS THE PICTURES BEFORE AND THE PICTURES AFTER, THE HARVESTING OF THE BONE GRAFT AND HE WAS TAKES THIS PICTURE OUT HE ROTATES IT AND SHOWS THE IMPLANTS COMING IN ANTEROLATERAL, LATERAL TO THE MIDLINE. AND IF WE LOOK AT THE TOPIC OF THIS ARTICLE, THIS ARTICLE, EVERYTHING IN THIS ARTICLE SAYS ANTERIOR LUMBAR INTERBODY FUSION. IT'S A TECHNIQUE FOR BONE GRAFTING. IT'S INDICATIONS. THERE'S NOTHING THAT TALKS ABOUT THE LATERAL

68 I disagree with many of the statements made by Dr. Sachs in ¶67 above. It is not correct that as of June 7, 1995 implants had only been inserted from either an anterior or posterior direction because I had inserted them directly laterally. It is not correct that Figure 3 of my 1982 paper is a misrepresentation, rather that figure accurately

depicts what I intended it to show. It is not correct that I corrected Figure 3 in any later treatise; rather, I do not believe there is anything that requires correcting. It is also is not correct that there is nothing about lateral in my publications; in fact, each of my 1982 paper, as well as my 1983 and 1993 books describe the direct lateral insertion of bone dowel implants for interbody fusion.

69 I understand the following testimony was given by Dr. Barton Sachs, referring to Figure 2.58A from my 1993 book.

70 Q. BUT THERE ISN'T ANY DOUBT THAT IN THIS BOOK IN 1992, WE HAVE GOT AN X-RAY OF A PERSON WITH A TRANSVERSELY PLACED CIRCULAR CANCELLOUS GRAFT, RIGHT?

A. WE HAVE A TRANSVERSE GRAFT WHICH IS NOT LATERAL. THAT'S NOT A DIRECT LATERAL APPROACH TO THE SPINE, AND IT DOESN'T SHOW A DIRECT LATERAL APPROACH.

71 I disagree with the statement made by Dr. Sachs in ¶70 above. Figure 2.58A from my 1993 book shows a graft positioned laterally within the disc space, which by definition means it is a transverse graft. It also describes the insertion of an implant using a direct lateral approach to the spine. The lateral tomogram, i.e., taken along the sagittal plane, shows a round cross-section. Had the implant been inserted obliquely, the cross-section would appear oblong. I believe a competent spine surgeon looking at Figure 2.58A from my 1993 book would recognize that it could only show a directly laterally placed implant, and that because of the shape of the cross-section, i.e., perfectly round, Figure 2.58A does not show an obliquely placed implant.

72 I understand the following question and answer refers to Figure 7A and 7B of my 1982 paper.

73 Q. LET'S GO BACK TO FIGURE 7. SO DR. SACHS, I JUST WANT TO SUM THIS UP. SO IN FIGURE A, FIGURE 7A, WE'RE LOOKING AT THE DISEASE, THE DISEASED DISC, RIGHT; YOU HAVE THE DOWNWARD SHIFT IN THE FRONT OF THE VERTEBRAL BODY, RIGHT?

A. YES, MA'AM.

Q. AND IN FIGURE B, IT'S CORRECTED. SO IF I UNDERSTAND WHAT YOU'RE SAYING, THE ONLY WAY YOU CAN DO THAT IS IF YOU WERE TO GO IN ANTERIORLY?

A. YES.

74 I disagree with the statement made by Dr. Sachs in ¶73 above in many respects. First, the "downward shift," or Grade 2 spondylolisthesis, in the front of the vertebral bodies was not corrected. Rather, the two vertebrae were fused in that position. In addition, if what Dr. Sachs was saying is that the fusion in Figure 7 could have only been done using an anterior approach, then I disagree with that statement. To the contrary, it would not have been safe to have attempted it from the front (using an anterior approach), because of the slip in the discs. It should be noted that correction of the sponydylolisthesis wasn't performed in this case because I didn't use posterior fixation at that time. That is why I performed a direct lateral approach and a transversely oriented implant to fuse the two vertebrae.

75 I understand the following question and answer refer to my 1982 paper.

76 Q. DR. SACHS, DO YOU SEE THE SECOND TO THE LAST SENTENCE READS, "GRAFTS OF 2.5 CENTIMETERS TO 2.8 CENTIMETERS IN DEPTH ARE OF SATISFACTORY SIZE IN MOST PATIENTS." AND IT CONTINUES, "ON OCCASION CANCELLOUS CHIPS MAY BE CUT FROM THE BONY FRAGMENTS OF THE VERTEBRAL BODIES OBTAINED FROM DOWEL

CAVITIES. THESE FRAGMENTS MAY BE USED TO SUPPLEMENT THE ILIAC CREST GRAFTS IN LARGER PATIENTS."

DR. SACHS, REFERENCING THIS PORTION OF CROCK, IS IT POSSIBLE TO HARVEST A PIECE OF BONE THAT'S LONGER THAN 28 MILLIMETERS?

A. NO, IT'S NOT. THE REASON DR. CROCK WAS TELLING US THAT WAS BASED ON WHAT THE TRUE ANATOMY OF THE ILIAC CREST LOOKS LIKE. IT'S VERY THICK AT THE TOP AND AS ONE STARTS TO WORK ON THE ANATOMY AND GET FURTHER AND FURTHER DOWN, IT GETS VERY PAPER THIN AND ACTUALLY WILL JUST BREAK OFF. SO THAT'S WHY HE PARTICULARLY DESCRIBED GRAFTS IN THE RANGE OF 25 TO 28 MILLIMETERS IN LENGTH, WOULD BE ABOUT THE MAXIMUM. HE WAS ALSO SAYING THAT IF WE NEEDED SOMETHING LONGER THAN THAT, JUST TAKE SOME OTHER CHIBBLES AND PASS THEM IN.

77 I disagree with the statements made by Dr. Sachs in ¶76 above. It is possible to harvest grafts longer than 28 millimetres from the iliac crest, and when such grafts are harvested, they are not paper thin. The maximum possible size of an iliac crest implant depends on the size of the patient. In addition, the tools for obtaining grafts – namely, the dowel cutters shown in Figure 1 of my 1982 paper, and in particular the cervical dowel cutter that I used for lateral procedures involving two parallel dowels – were capable of obtaining grafts as long as 40 millimetres in length (the length of the bore of the cervical dowel cutter).

78 I understand the following testimony was given by Dr. Barton Sachs, and relates to my 1982 paper.

79 Q. NOW DR. SACHS, IS THERE ANYTHING IN THE CROCK REFERENCE ITSELF THAT INDICATES TO YOU THAT IT WAS ONLY AN ANTERIOR LUMBAR INTERBODY FUSION?

A. THERE ARE MULTIPLE POINTS IN THIS ARTICLE. IN THE ARTICLE IN PARTICULAR, IT TALKS ABOUT TECHNIQUES FOR ANTERIOR LUMBAR INTERBODY FUSION. IT TALKS ABOUT INDICATIONS FOR ANTERIOR LUMBAR INTERBODY FUSION. IT ALSO TALKS ABOUT HAVING A VASCULAR SURGEON HELP WITH THE ACCESS FOR ANTERIOR LUMBER INTERBODY FUSIONS AND IN PARTICULAR, MOST SPINE SURGEONS, MOST, DO USE A VASCULAR SURGEON WHEN THEY'RE APPROACHING FROM THE FRONT OF THE SPINE ANTERIORLY IF THEY'RE APPROACHING LATERALLY, THEY DON'T USE A VASCULAR SURGEON

80 I disagree with the statements made by Dr. Sachs in ¶79 above in many respects. First, my references to "anterior lumbar interbody fusion" refer to both anterior approaches and lateral approaches. Both are entirely in an anterior region (forward of the transverse processes), and not in a posterior region (posterior of the transverse processes). The indications and techniques for anterior interbody fusion are not limited to cases that use an anterior or anterolateral approach, but include cases where the lateral approach techniques described in my 1982 paper may be used. Further, with respect to my comments about general (access) surgeon participation in the procedure, I would draw no distinction between lateral approaches and anterior approaches with respect to when the participation of a general surgeon may be appropriate. As described in my 1982 paper, it is only until the orthopaedic surgeon is thoroughly familiar with the procedure that I said it would be wise to involve a general surgeon. That would be the case whether the procedure use a lateral approach or an anterior approach.

81 I understand that the following statement is made in U.S. Patent No. 5,484,437 to Dr. Gary Michelson (the "'437 patent") at column 6, line 61 to column 7, line 2: Crock (Crock, H. V., "Anterior Lumbar Interbody Fusion-Indications for its Use and notes on Surgical Technique," Clinical Orthopaedics, Volume 165, pg. 157-163, 1981) described his technique and instrumentation for Anterior Interbody Fusion of the lumbar spine, wherein he drilled two large holes side by side across the disc space from anterior to posterior essentially unprotected and then pounded in two at least partially cylindrical grafts larger than the holes prepared."

82 The statement in ¶81 is inaccurate. In particular, it is inaccurate where he states that I drilled two large holes side by side across the disc space "essentially unprotected," and then I "pounded" in at least two partially cylindrical grafts. No one who has seen me perform the fusion procedures described in my 1982 paper would describe it as that way, and my 1982 paper certainly does not describe my procedures in those terms. As I explain in my 1982 paper, great care is taken in making precise measurements to properly cut the cavities into which the grafts are inserted. It cannot be said that these cavities are "essentially unprotected." In addition, I have never "pounded" in grafts. Rather, I used a spreader to widen the space into which the graft is inserted, and then I tapped the implant in. Finally, although the discussion of my 1982 paper in the '437 patent above describes the anteroposterior orientation of implants, it does not mention the lateral approach nor the orientation of lateral implants in the disc space.

83 In preparing this affidavit, I have made all the inquiries which I believe are desirable and appropriate and no matters of significance which I regard as relevant have, to my knowledge, been withheld.

Sworn by the Deponent)
at Toorak)
in Victoria)
on 11 September 2012)
Before me:)

Signature of deponent

Signature of witness

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

Appendix C to McAfee Declaration

Berry et al., "A Morphometric Study of Human Lumbar and Selected Thoracic Vertebrae," Spine, Vol. 12, No. 4, pp. 362-67, at p. 364, Table 1 (1987)

A Morphometric Study of Human Lumbar and Selected Thoracic Vertebrae

JAMES L. BERRY, MS, JAMES M. MORAN, DEng, WILLIAM S. BERG, BS, and ARTHUR D. STEFFEE, MD

The results of a morphometric study of selected human vertebrae undertaken to provide data for implant design are presented in this report. Twenty-seven dimensions were measured from thoracic (T2, T7, T12) and lumbar (L1–L5) vertebrae using prepared spinal columns from 30 skeletons belonging to the Hamann-Todd Osteological Collection. Maximum and minimum pedicle dimensions indicated that the pedicles are less symmetric cephalad than they are caudal. Vertebral body height increases caudally except posteriorly where, after an initial increase, it decreases in the lower lumbar region. Major and minor body diameters and the major spinal canal diameter slightly increase caudally, whereas minor spinal canal diameter exhibits little or no change. [Key words: vertebral morphometry, pedicle dimensions, implant design]

ACCURATE ANATOMIC DESCRIPTIONS of vertebral shape are necessary for the development of implantable devices and spinal instrumentation. The authors' interest in spinal implants and fixation devices resulted in a need for more detailed morphologic and anthropometric data on the vertebrae than could be found in the existing literature.

Several previous studies have investigated the morphometry of the vertebrae but through differing experimental techniques such as direct measurements, roentgenography with plain films, and CT scans.[2,3,5,7,8,10,11,14] The studies also varied with regard to the anatomic structure of interest. Whereas some were strictly concerned with the morphometry of the vertebral body,[2,3,7,8,10,11] others concentrated on the dimensions of the spinal canal,[1–3,5,8,11] transverse process,[14] and pedicle.[6,9,12,14,16] Additional measurements receiving scrutiny include interpedicular distance[4,11] and the angle between the facet joints and lamina.[15] Nissan et al performed a multifaceted analysis which, in addition to body shape, described vertebral length, the spinous process, disc size, and the distance between spinal processes in the intact spine.[10] All of the above-mentioned studies examined lumbar vertebrae, and some studied selected cervical[1,4,5,7,10,14] and thoracic[6,9,12,13,16] vertebrae as well.

The current study was undertaken due to a lack of information needed for design projects involving instrumentation for the lumbar and thoracic vertebrae. Direct measurements were made of 27 vertebral dimensions from prepared skeletal components. Radiographs of cadaver specimens were also used to determine the cross-sectional dimensions of the pedicles. Even though some of the measurements duplicate previous studies, they are included for comparative purposes, inasmuch as experimental techniques vary between investigators. Additionally, a wide variability has been reported between demographic groups.[11]

MATERIALS AND METHODS

Direct dimensional measurements were obtained from contemporary human skeletons belonging to one of the most extensive skeletal collections in the world, the Hamann-Todd Osteological Collection at the Cleveland Museum of Natural History in Cleveland, Ohio, which houses more than 3,000 skeletons with accompanying autopsy reports. In some instances medical histories are also available.

Vernier and outside dimension calipers were used to measure the bone geometry (precision: .1 mm). Angular measurements were taken with a goniometer (precision: 1°). For the sake of consistency, all measurements were taken by the same observer. The lumbar (L1–L5) and three thoracic (T2, T7, T12) vertebrae of randomly selected normal Caucasian male and female skeletons were studied. The sample population consisted of five men and five women from each of the fifth through seventh decades of life for a total of 30 skeletons, or 240 vertebrae. Skeletons having gross evidence of congenital or acquired vertebral pathology and/or written documentation (autopsy report) of bone abnormalities such as tumors, fractures, or arthritis were excluded from this study.

With present and future applications in mind, virtually the entire geometry of the vertebrae was quantified by recording a total of 27 measurements per vertebra. Complete descriptions of the measured parameters are presented in Figures 1–3. Three of these measurements (the angle between the pedicle and the body, the cross-sectional dimensions of the pedicle, and the distance through the pedicle and body) primarily pertain to pedicle screw fixation and are reported in greater detail elsewhere.[9]

From the Cleveland Research Institute at St. Vincent Charity Hospital and Health Center, Cleveland, Ohio.

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The authors thank Eileen Morgan, for technical assistance, Mary Hank, for typing the manuscript, and Bruce Latimer, of the Cleveland Museum of Natural History, who graciously provided access to the Hamann-Todd collection.

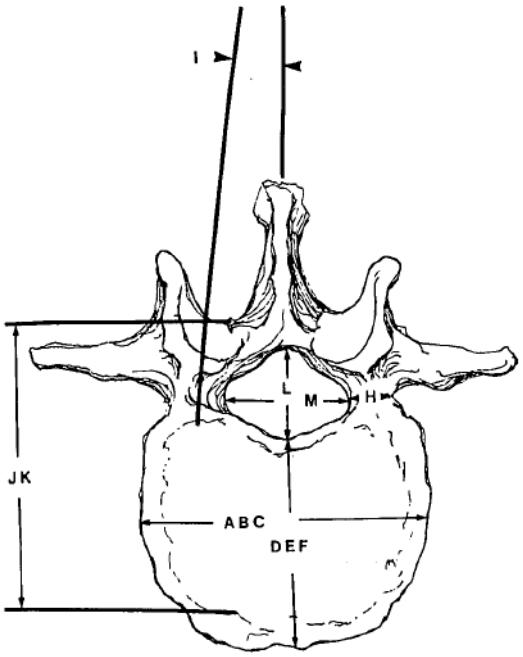

Fig 1. Description of vertebral measurements taken from the superior–inferior aspect. Major body diameter was measured along a frontal line bisecting the vertebral body and spinous process, (A) at the most superior level, (B) at the midline, and (C) at the most inferior level. Minor body diameter was measured along the midsagittal plane, (D) at the most superior level, (E) at the midline, and (F) at the most inferior level. Minor (H) dimensions of the right and left pedicles were measured regardless of orientation. Pedicle angle (I) was defined as the angle formed between the midsagittal plane and the plane bisecting the pedicle. Pedicular screw path lengths through the pedicle's center into the body to a point at the anterior border of the body's center were measured by two different approaches: (J) a straight path parallel to the midline bisector of the pedicle and (K) an oblique path representing the largest permissible deviation from this line. Minor spinal canal diameter (L) was measured along the midsagittal plane. Major spinal canal diameter (M) was measured along the frontal plane passing through the canal's midpoint.

RESULTS

The means and standard deviations of the dimensional data for all 240 vertebrae are presented in Table 1. To narrow the scope of the article, and simplify presentation of the results, the data for the males and females at all ages have been combined. Note that even with this simplification the data remain consistent, with the coefficients of variation being generally less than 10%.

The average maximum and minimum pedicle dimensions for the entire population are presented in Figure 4. Maximum and minimum dimensions were obtained for two pedicles per body, thus the data in Figure 4 represent both the right and left pedicle for each vertebra. The relative differences between the maximum and minimum dimensions demonstrate that the pedicles are less symmetric cephalad and become more so caudad. The minimum dimensions correlate well with those reported in other recent studies.[13,16]

A consistent trend is seen between vertebral body height and level (Figure 5). Three of four dimensions (anterior, posterior, right, and left height) increase progressively from T2 to L5. The posterior measurement levels off and then slightly decreases in the lumbar region. This is probably due in part to the lumbar curvature between L4 and S1. The data are in agreement with Nissan et al.[10] However, Postacchini et al[11] reported a single height measurement which did not reflect the decrease.

Major and minor body diameters were also plotted as a function of level (Figure 6). With the exception of the major diameter at T7, both dimensions exhibit slight increases caudally. Several other authors have reported similar findings[2,3,8,11,14] although only lumbar vertebrae were measured.

The dimensions of the spinal canal were also correlated to vertebral level (Figure 7). As with body height, the major spinal canal diameter increased caudally, with the exception of T7. Minor diameter showed little or no change between T2 and L5. Postacchini et al[11] and Eisenstein et al[2] reported similar data.

The anterior, posterior, right, and left body heights of all the vertebrae were averaged, and the total for each spinal column was plotted against the body height measured at autopsy. No correlation was found (r^2=.006). No attempt was made to relate weight to

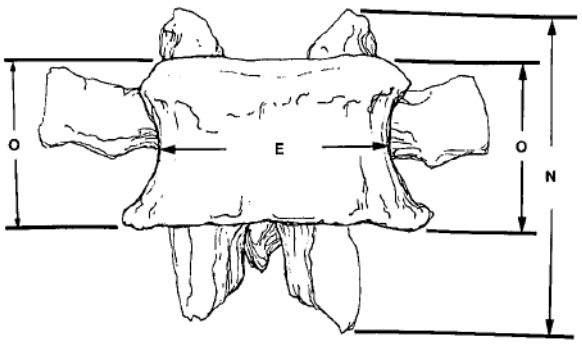

Fig 2. Description of vertebral measurements taken from the posterior–anterior view of the vertebrae. Height of the vertebrae was measured from the most superior aspect of the superior articular process to the most inferior aspect of the inferior articular process (N). Body height was measured along the frontal plane through the widest part of the body at the left and right lateral borders (O). The midline (E) major body diameter was measured along the frontal plane.

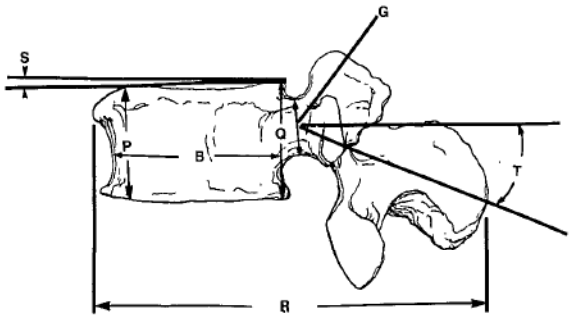

Fig 3. Description of vertebral measurements taken from the sagittal view of the vertebrae. Body height was measured along the midsagittal plane, (P) anteriorly and (Q) posteriorly. Length of the vertebrae was measured from the most anterior aspect of the body to the most posterior aspect of the spinous process (R). Body descent angle was defined as the angle between the superior surface of the body and a plane parallel to the inferior surface (S). Angle of declination of the spinous process was defined as the angle between the plane bisecting the spinous process and the plane parallel to the body's inferior surface (T). Major dimensions (G) of the right and left pedicles were measured regardless of orientation. The midline (B) minor body diameter was measured a sagittal line bisecting the vertebral body and spinous process.

Table 1. Mean and Standard Deviations for a Total of 240 Vertebrae, 30 at Each Level

Measurement	T2	T7	T12	L1	L2	L3	L4	L5
A	29.8 ± 2.4	31. ± 2.8	43.8 ± 3.3	45.2 ± 4.6	47.7 ± 4.7	49.6 ± 3.2	51.2 ± 5.6	53.4 ± 4.4
B	28.1 ± 2.5	28.0 ± 2.9	37.6 ± 3.2	39.5 ± 3.8	44.8 ± 3.1	42.3 ± 3.5	40.8 ± 3.2	46.1 ± 4.5
C	33.5 ± 2.9	33.2 ± 3.2	46.8 ± 3.8	49.1 ± 3.7	54.8 ± 4.8	53.8 ± 3.7	50.9 ± 4.6	52.7 ± 4.3
D	18.1 ± 1.5	27.0 ± 3.3	31.7 ± 4.4	31.9 ± 3.7	33.3 ± 3.7	33.9 ± 3.3	34.9 ± 3.4	35.1 ± 2.8
E	17.5 ± 1.7	26.1 ± 3.2	29.2 ± 3.4	28.9 ± 3.5	29.9 ± 3.3	31.6 ± 3.3	32.5 ± 2.9	32.4 ± 2.8
F	19.0 ± 1.6	28.0 ± 3.6	31.2 ± 3.9	32.3 ± 3.5	33.4 ± 3.4	34.2 ± 3.3	35.6 ± 3.1	34.5 ± 3.0
G								
Right	11.7 ± 1.2	12.1 ± 1.0	17.2 ± 1.6	15.6 ± 1.4	15.4 ± 1.0	14.6 ± 1.2	13.0 ± 1.3	13.8 ± 2.5
Left	11.9 ± 1.3	11.9 ± 1.0	17.0 ± 1.3	15.6 ± 1.5	15.2 ± 1.0	14.3 ± 1.0	13.2 ± 1.4	13.6 ± 2.8
H								
Right	6.1 ± 1.2	5.1 ± 1.4	7.7 ± 2.1	7.0 ± 1.9	7.4 ± 1.6	9.2 ± 1.3	10.3 ± 1.6	10.9 ± 3.4
Left	6.3 ± 1.0	4.8 ± 1.4	7.6 ± 1.5	6.9 ± 1.7	7.5 ± 1.5	9.1 ± 1.6	10.4 ± 1.6	10.5 ± 2.9
I								
Right	23 ± 6	8 ± 4	−5 ± 8	6 ± 8	11 ± 3	14 ± 4	20 ± 5	32 ± 5
Left	23 ± 6	7 ± 5	−1 ± 10	9 ± 7	12 ± 3	14 ± 4	20 ± 4	31 ± 5
J								
Right	26.4 ± 2.4	36.2 ± 3.2	38.8 ± 3.8	42.1 ± 3.8	45.2 ± 3.8	45.0 ± 3.3	44.0 ± 2.9	40.8 ± 3.2
Left	27.1 ± 2.0	36.3 ± 4.2	38.8 ± 3.8	40.2 ± 3.4	46.5 ± 3.5	45.7 ± 3.7	45.6 ± 3.9	40.3 ± 4.0
K								
Right	30.3 ± 2.3	40.7 ± 3.2	44.0 ± 5.0	47.5 ± 4.4	50.5 ± 4.0	49.0 ± 3.5	49.5 ± 3.2	47.8 ± 3.5
Left	32.1 ± 2.0	42.0 ± 4.0	46.9 ± 4.9	49.8 ± 3.7	53.1 ± 3.8	52.0 ± 3.5	53.2 ± 3.8	50.9 ± 4.3
L	15.0 ± 1.3	16.6 ± 5.0	17.2 ± 1.9	17.2 ± 1.3	16.0 ± 2.6	16.2 ± 2.6	16.1 ± 1.5	17.3 ± 2.9
M	18.3 ± 1.5	17.1 ± 5.1	20.2 ± 2.3	22.1 ± 2.3	23.0 ± 2.3	22.7 ± 1.7	22.0 ± 1.8	26.0 ± 2.5
N								
Right	31.6 ± 2.0	34.0 ± 5.1	45.5 ± 2.8	47.6 ± 3.7	45.2 ± 3.6	48.0 ± 3.2	48.5 ± 2.7	41.5 ± 4.4
Left	31.7 ± 2.0	33.0 ± 5.6	45.2 ± 2.9	47.3 ± 3.7	44.8 ± 4.6	48.6 ± 3.3	49.1 ± 3.5	42.2 ± 3.7
O								
Right	17.9 ± 1.4	19.9 ± 1.8	24.2 ± 1.7	25.6 ± 1.6	27.3 ± 1.5	26.5 ± 1.7	25.7 ± 1.3	27.0 ± 1.8
Left	17.7 ± 1.2	20.2 ± 3.5	23.9 ± 1.5	24.9 ± 1.6	27.7 ± 1.8	26.5 ± 1.7	25.7 ± 1.3	27.0 ± 1.7
P	17.6 ± 1.2	18.7 ± 2.8	23.4 ± 2.0	25.0 ± 2.9	27.9 ± 1.9	27.4 ± 1.7	26.7 ± 1.5	28.7 ± 1.9
Q	16.5 ± 1.2	19.1 ± 1.8	24.8 ± 1.8	25.8 ± 2.1	25.2 ± 2.2	26.0 ± 1.6	26.4 ± 1.7	23.1 ± 1.5
R	64.1 ± 4.6	63.9 ± 8.6	73.4 ± 11.0	79.9 ± 6.3	85.0 ± 5.8	85.6 ± 6.0	83.4 ± 5.5	74.1 ± 15.3
S	136 ± 21	110 ± 30	20 ± 7	21 ± 19	14 ± 3	17 ± 5	14 ± 4	20 ± 6
T	137 ± 21	110 ± 31	20 ± 7	18 ± 6	14 ± 4	17 ± 5	14 ± 3	20 ± 6

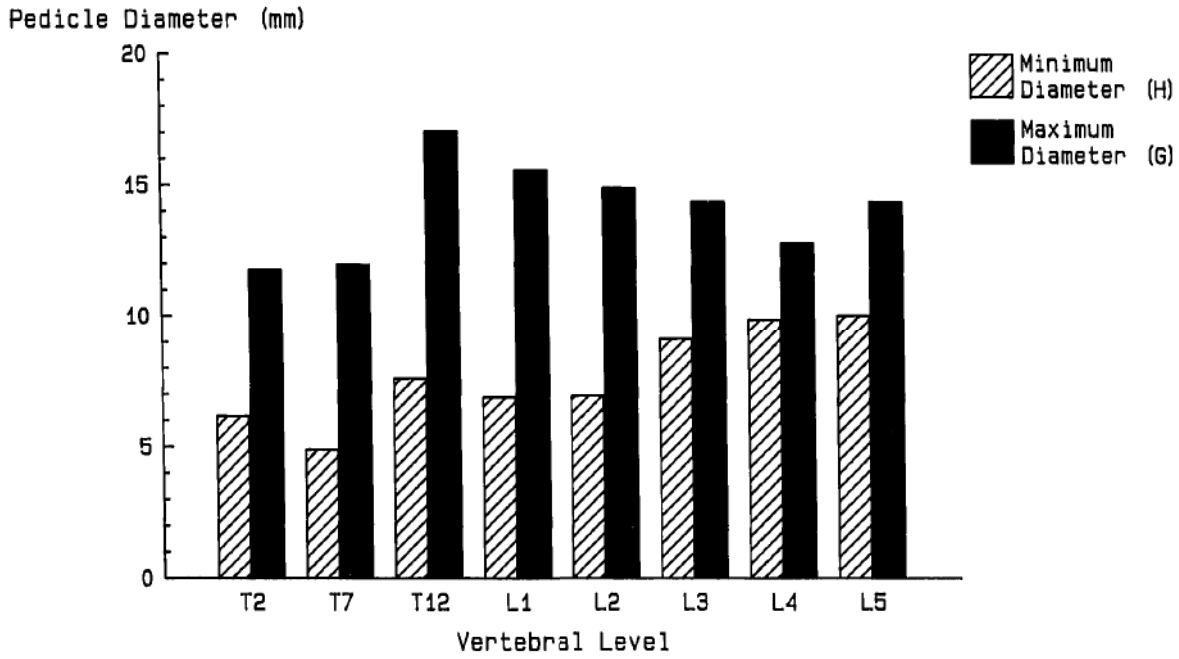

Fig 4. Minor (H) and major (G) pedicle diameters, means of 15 each males and females, fifth through seventh decades.

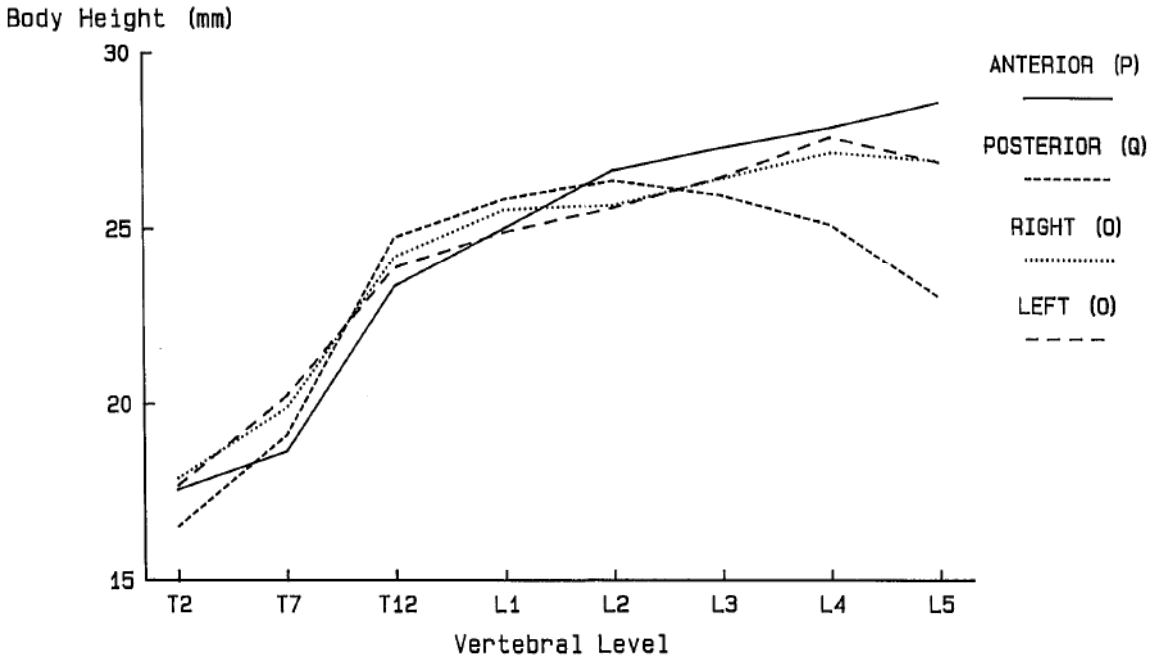

Fig 5. Body height (O,P,Q) versus vertebral level, combined data for all specimens studies.

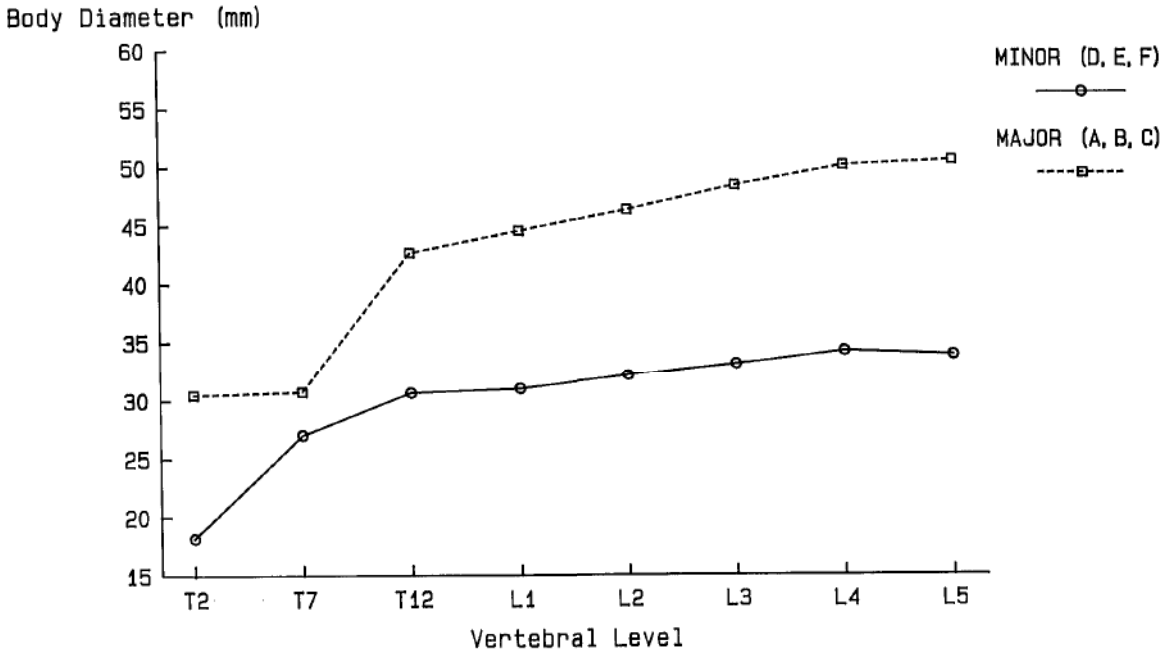

Fig 6. Body diameter versus vertebral level. Points represent means of superior (A,D), midline (B,E) and inferior (C,F) measurements for all specimens studied.

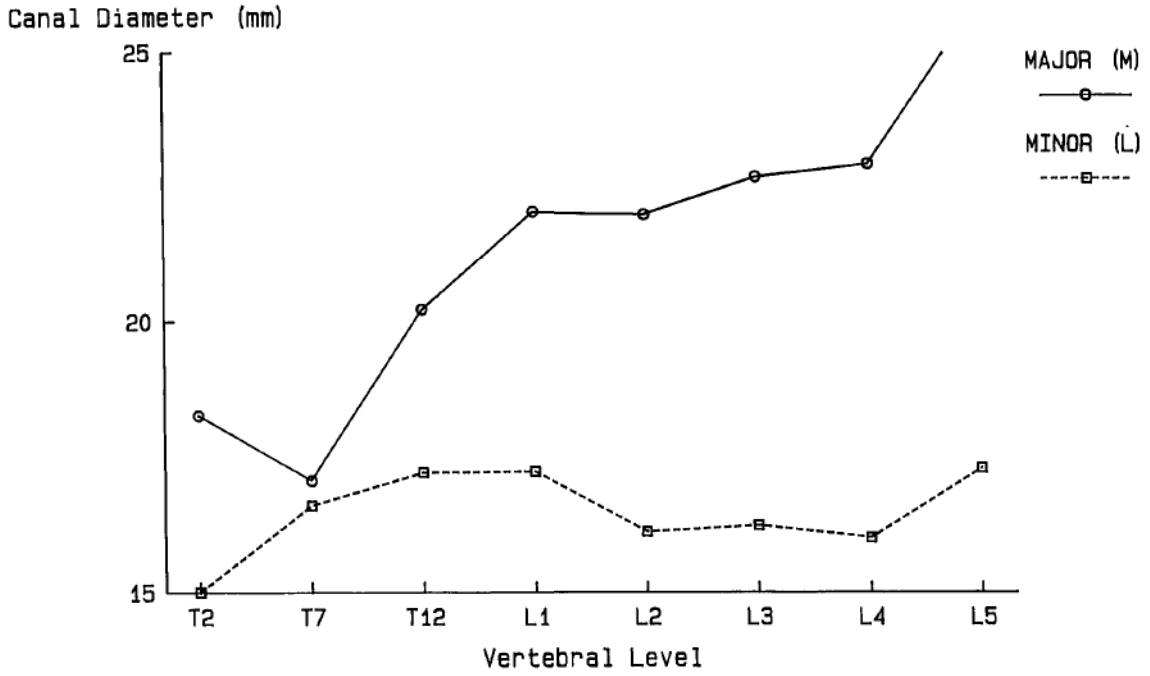

Fig 7. Major (M) and minor (L) spinal canal diameters versus vertebral level, combined data for all specimens studied.

cross-sectional dimensions, since many of the weights at autopsy appeared low relative to the height. This was possibly indicative of dehydration or decomposition of the cadaver or perhaps malnutrition during life.

DISCUSSION

The overall goal of this study was to generate information that would be useful for geometric modeling of the vertebrae. Such information has numerous potential applications. Biomechanical and ergonomic analyses of the spine frequently have need of spinal dimensions as input. Although specific requirements vary, it is hoped that these data on spinal morphometry are general enough to be useful to a variety of studies.

The authors' immediate need was in the design of spinal instrumentation. The application to pedicle screw fixation is outlined elsewhere,[9] and a total vertebra replacement has also been designed. For the one total vertebra that has been implanted, the data were used only to double check dimensions scaled from computed tomography (CT) scans. Agreement between the patient's CT data, average skeletal data, and one skeleton whose living dimensions closely matched the patient's own size, was extremely good. The artificial vertebra could thus be made to duplicate the geometry of the replaced vertebra. In instances where destruction of the vertebra is more extensive, due to trauma or gross invasion by a tumor, the data will be necessary for sizing the replacement and reconstructing normal alignment.

Through comparison of the results with other studies of spine geometry that have used CT scanning, and our own CT work for vertebral replacement, it is apparent that CT scanning can be a useful tool for evaluating spinal geometry *in vivo*. However, proper care must be exercised in regard to factors such as slice thickness, scan diameter, calibration standards, and orientation of the scanning plane relative to the anatomic structure of interest. The current data might also be applied to the detection of anatomic abnormalities by comparison of CT scans with the population averages.

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Appendix D to McAfee Declaration

McAfee et al., "The value of computed tomography in thoracolumbar fractures: An analysis of one hundred consecutive cases and a new classification," The Journal of Bone and Joint Surgery, Vol. 65-A, No. 4, pp. 461-473, April 1983

The Value of Computed Tomography in Thoracolumbar Fractures

An Analysis of One Hundred Consecutive Cases and a New Classification*

BY PAUL C. McAFEE, M.D.†, HANSEN A. YUAN, M.D.†, BRUCE E. FREDRICKSON, M.D.†, AND JOHN P. LUBICKY, M.D.†, SYRACUSE, NEW YORK

From the Department of Orthopedic Surgery, Upstate Medical Center, Syracuse

ABSTRACT: **We studied 100 consecutive patients with potentially unstable fractures and fracture-dislocations by multiplane computed tomography. The mechanism of failure of the middle osteoligamentous complex of the spine (posterior longitudinal ligament, posterior part of the vertebral body, and posterior annulus fibrosus) was determined by three-dimensional analysis. Three modes of middle-column failure were used to classify the injuries: axial compression (seventy-three patients), axial distraction (fifteen patients), and translation within the transverse plane (twelve patients). Fifty of eighty-six patients who were evaluated in the acute phase of injury underwent operative stabilization, and the mechanism of middle-column disruption determined the type of instrumentation that was used. Compression and distraction injuries of the middle complex could be appropriately treated by Harrington distraction and compression instrumentation, respectively. However, in translational injuries (torn posterior longitudinal ligament) routine Harrington instrumentation was contraindicated due to the risk of overdistraction. Translational injuries were associated with the greatest degree of instability and often had complete ligament discontinuity at the level of the affected vertebrae. Patients with a translational injury had the most severe neural deficits (six of eleven patients studied acutely having a complete spinal cord lesion). Translational injuries of the middle column were treated by segmental spinal instrumentation to provide strong fixation with minimum risk of neural sequelae from passing sublaminar wires. Moreover, postoperative use of a cast over insensate skin was not required.**

Computed tomography was more sensitive than any other modality in the diagnosis of disruption of the posterior elements in unstable burst fractures, and computer-reconstructed sagittal images were accurate in evaluating the nature of facet-joint failure in distraction injuries. Computed tomography with metrizamide proved superior to either conventional tomography or myelography alone in localizing the site of neural canal compromise in acute thoracolumbar injuries.

The mode of failure of the middle osteoligamentous complex as visualized by computed tomography determined the pattern of spinal injury, the severity of the neural deficit, the degree of instability, and the type of instrumentation required.

Formerly thoracolumbar fractures and fracture-dislocations were evaluated mainly by plain radiographs, and tomograms if indicated, but because computed tomography visualizes bone and soft tissues three-dimensionally we tried to compare its value with that of plain radiographs in 100 consecutive potentially unstable thoracolumbar injuries. One advantage of computed tomography is that the patient need not change position during the examination, unlike lateral tomography or myelography. We developed a simplified classification scheme from which the degree of instability, the probable mechanism of injury, and the indicated method of stabilization could be derived. Computed tomography proved effective in defining the type of injury in the majority of these patients. This paper describes the classification and the comparative usefulness of the computed tomography examination in the 100 patients whose cases we studied.

The Three-Column Classification System

Traditional classifications of spinal injuries, such as Holdsworth's[29], differentiated between stable injuries (simple wedge fractures, burst fractures, and extension injuries) and unstable injuries (dislocations, rotational fracture-dislocations, and shear fractures). The risk of neural damage in the acute phase of management of unstable injuries was emphasized but the potential for instability of a certain group of fractures, the burst fractures, was ignored. Whitesides[70] and Kelly and Whitesides[34] recognized that unstable burst fractures are "the most common cause of neural injury in the thoracolumbar region"[70], and they developed a classification system based

* Read in part at the Annual Meeting of the Scoliosis Research Society, Denver, Colorado, September 24, 1982, and in part as the Keim Foundation Spinal Research Award Paper at the Annual Meeting of the Eastern Orthopaedic Association, Southampton, Bermuda, October 15, 1982.

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on a two-column structure — an anterior weight-bearing column of vertebral bodies and a posterior column of neural arches resisting tension. Injuries that presented with late instability could be incorporated into their scheme. Denis[13] described a third middle column — the osteoligamentous complex (Fig. 1) — but unfortunately his system of classification is too complex for routine use because it contains more than twenty divisions. He subclassified burst fractures into five subtypes, but because the treatment of each is the same the complex subdivision has little value.

White and Panjabi[68] used a biomechanical analysis of the motion of the contiguous spinal segments, including the affected vertebra, as the basis for a classification of injuries. It did not require placement of any given fracture into a rigidly defined subgroup, so that any fracture or fracture-dislocation could be defined in terms of the forces acting on the involved vertebrae with reference to the x, y, and z axes. Their concept presupposed six degrees of freedom in spinal motion (Fig. 2-A). Compression-distraction and rotation occur in the y axis; flexion-extension and lateral translation, in the x axis; and lateral flexion and anteroposterior translation, in the z axis. This three-dimensional description of forces is aptly translated to the three-dimensional anatomical alterations visualized directly by multiplanar computed tomography (Fig. 2-B). Their classification also is somewhat complex, however, and is difficult to use.

Combining some of the individual merits of the two classifications, we developed a simplified system based on three forces as they act to injure the middle column: *axial compression, axial distraction,* and *translation within the transverse plane*. After using this classification in 100 cases we found that there was minimum overlap of the three categories, because axial compression and axial distraction forces cannot coexist, and if either one occurs in combination with translation then translation usually determines the amount of instability. There are six kinds of injuries.

A *wedge-compression fracture* is an injury causing isolated failure of the anterior column. This fracture results from forward flexion and is rarely associated with neural loss except when it occurs in multiple adjacent vertebral levels. The vertebral body or bodies usually are wedge-shaped.

A *stable burst fracture* is one in which the anterior and middle columns fail because of a compressive load, with no loss of integrity of the posterior elements.

An *unstable burst fracture* is one in which the anterior and middle columns fail in compression and the posterior column is disrupted. The posterior column can fail in compression, lateral flexion, or rotation, but because of the instability there is a tendency for post-traumatic kyphosis and progressive neural symptoms to develop[3,39,70]. Because the anterior and middle columns fail in compression, the posterior column cannot fail in distraction.

A *Chance fracture*[10] is a horizontal avulsion injury of the vertebral body as a result of flexion about an axis anterior to the anterior longitudinal ligament, so that the entire expanse of the vertebra is pulled apart by strong tensile forces.

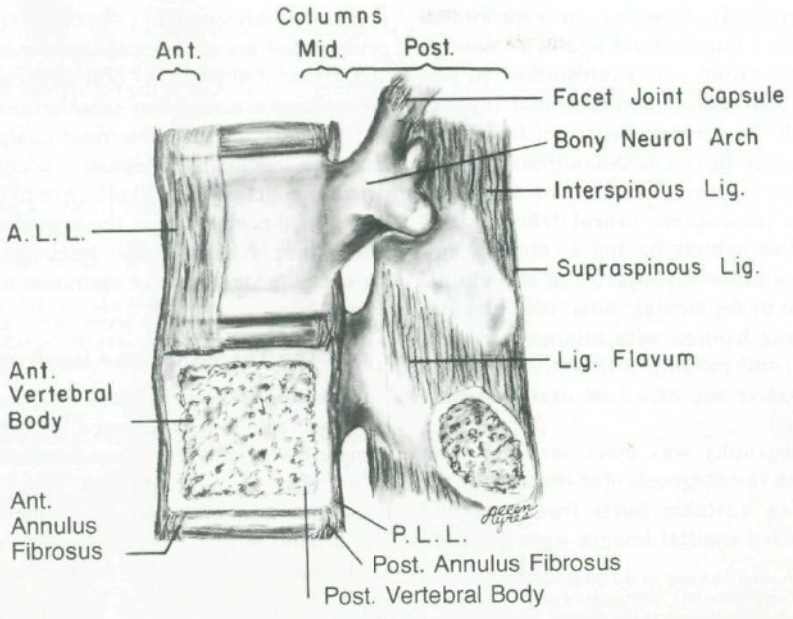

FIG. 1

The anatomical structures comprising the three longitudinal columns of stability in the thoracolumbar spine. Anterior column — anterior two-thirds of the vertebral body, anterior part of the annulus fibrosus, and anterior longitudinal ligament. Middle column — posterior one-third of the vertebral body, posterior part of the annulus fibrosus, and posterior longitudinal ligament. Posterior column — facet-joint capsules, ligamentum flavum, osseous neural arch, supraspinous ligament, interspinous ligament, and articular processes.

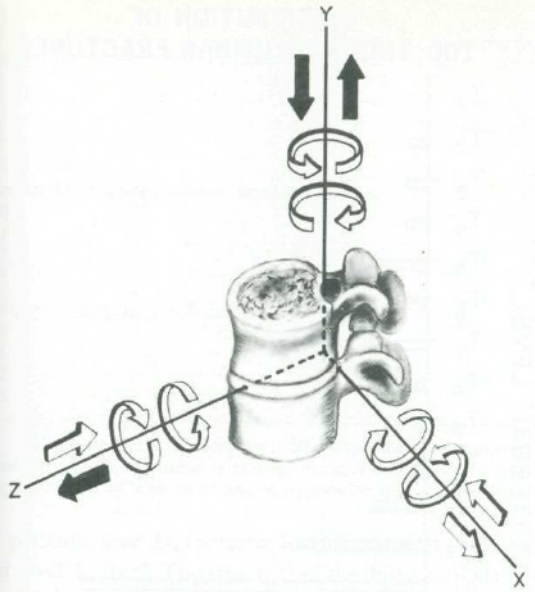

FIG. 2-A

The individual components of a complex spinal injury can be analyzed with reference to the x, y, and z axes. In the x axis there are three mechanisms of injury: flexion, extension, and left and right lateral translation. In the y axis there are axial compression, axial distraction, and clockwise and counterclockwise rotation. In the z axis there are lateral flexion to either side and anterior or posterior translation. Axial compression, axial distraction, and translation are of prognostic significance and correlate with specific patterns of injury. (Adapted by permission from: White, A. A., and Panjabi, M. M.: Clinical Biomechanics of the Spine, p. 38. Philadelphia, J. B. Lippincott, 1978.)

A *flexion-distraction injury*[33] is one in which the flexion axis is posterior to the anterior longitudinal ligament. There is compressive failure of the anterior column while the middle and posterior columns fail in tension. Tensile failure of the middle column results in a tear or attenuation of the posterior longitudinal ligament. If the zygoapophyseal joint capsules are disrupted there may be subluxation or dislocation of the facet joints, or fracture of the facets can occur. Most varieties of this injury are potentially unstable because the ligamentum flavum, interspinous ligament, and supraspinous ligament usually are torn.

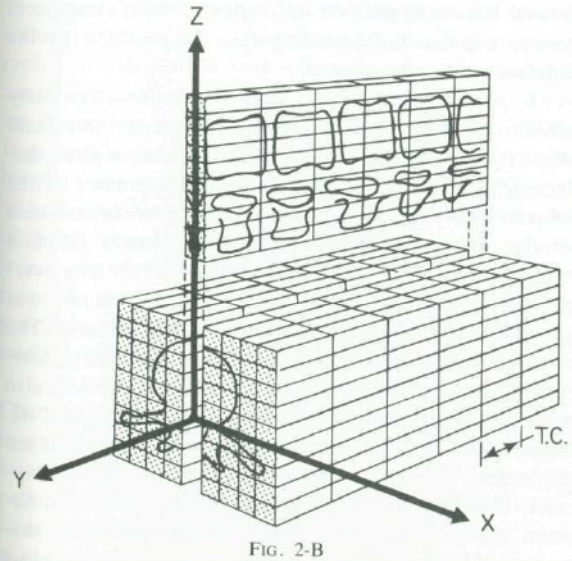

FIG. 2-B

Three-dimensional coordinate system of multiplane computed tomography. A sagittal reconstructed image through the middle column has been derived from a series of transaxial cuts (T.C.).

Translational injuries are those in which the alignment of the neural canal has been disrupted. At the affected level one part of the spinal column has been displaced in the transverse plane. Usually all three columns have failed in shear. This category of injury includes Holdsworth's so-called slice fractures[29] as well as rotational fracture-dislocations and pure dislocations.

Materials and Methods

In our department more than 1,000 computed tomographic examinations of the spine have been performed for all types of lesions since November 1975, using techniques that have been reported previously[7,38-40,50,63-65]. Transaxial images, three to seven millimeters in thickness, were employed in thoracolumbar fractures. Until 1979 the examinations were done with an Ohio Nuclear Deltascan 50 FS unit, and thereafter with either a Technicare Deltascan 2020, a Pfizer 0450, or a General Electric 8800 unit. The latter proved superior for demonstrating fragments of herniated nucleus pulposus or bone, or both, displaced into the lateral recesses or neural foramina. Sagittal, coronal, and oblique reconstruction images were obtained routinely during the last four years, with standard computer programs. In approximately 20 per cent of patients better visualization of the dural sac was necessary, so the computed tomography was performed after metrizamide had been introduced through a lateral subarachnoid puncture between the first and second cervical vertebrae with the patient supine[4,7,43,52,53].

The criteria that were used to select the patients for computed tomographic examination after spinal trauma were as follows. After a thorough examination of plain radiographs of good quality, computed tomography was used for any patient with any of the following presentations: (1) thoracolumbar injury with neural deficit, (2) thoracolumbar injury with possible or definite disruption of all three columns as assessed on plain radiographs, or (3) severe deformity, particularly with fractures at multiple levels, notably adjacent wedge-compression fractures of the upper part of the thoracic spine with acute kyphosis. We also included any patient who was being evaluated for neural decompression or operative stabilization and any patient with an injury that previously had warranted anteroposterior and lateral tomographic evaluation. Similarly, an injury that traditionally required myelography was studied by the intrathecal metrizamide or iopamidole computed-tomography technique.

Our computer retrieval identified exactly 100 examinations from 1975 to 1982 that had been performed for thoracolumbar trauma (excluding pathological fractures). The cases of all orthopaedic surgical patients who had spi-

nal decompression or internal stabilization performed at the Upstate Medical Center over the same time-interval also were reviewed, and we found that every one had been studied preoperatively by computed tomography.

Eighty-six patients were examined within the first ten days after injury. Their average age was 27.8 years. Fifty of them underwent spinal decompression, instrumentation, or fusion, or a combination of these. Their postoperative follow-up averaged thirty-one months (range, twelve to sixty months). The remaining fourteen patients had originally been treated elsewhere and had the initial computed-tomography studies for late complications of the fracture — increasing neural deficit, pseudarthrosis, post-traumatic deformity, or localized mechanical back pain. Their average age was 32.2 years. Eleven of the fourteen had an operation on the spine, and their post-surgical follow-up averaged 32.1 months (range, twelve to sixty months). Of the 100 patients who form the basis for this study, sixteen also had postoperative computed tomography to assess the adequacy of the spinal decompression.

Results

The most common vertebral level of injury was thoracolumbar (Fig. 3).

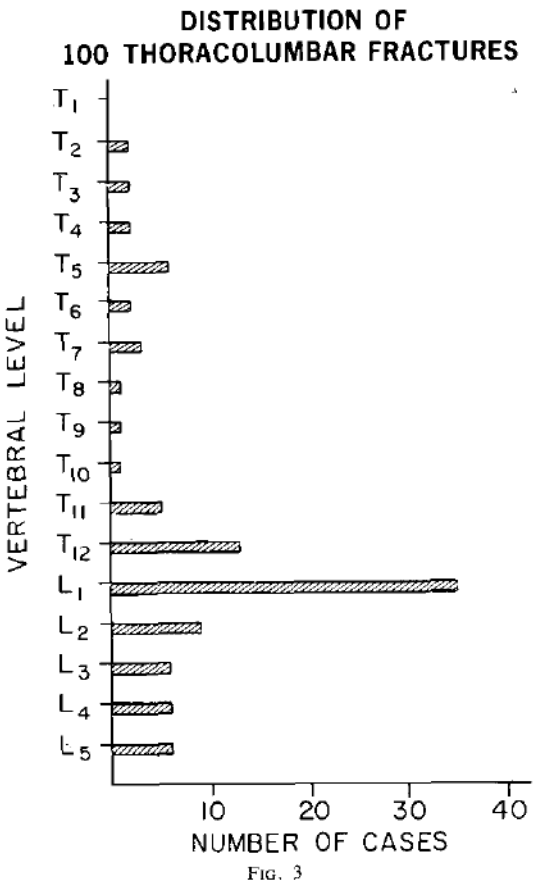

FIG. 3

The thoracolumbar junction was the most common area of injury.

Patients Seen within Ten Days

The value of computed tomography with and without metrizamide is compared for the six types of spinal injuries in Table I.

Wedge-compression fracture: These occurred in twelve patients, ten with Frankel functional-level E and two with level D*. These fourteen wedge-compression fractures were studied by computed tomography for one of two reasons: (1) there was more than a 50 per cent collapse of the vertebral body by plain radiographic assessment, and it was therefore necessary to exclude middle as well as posterior column disruption, or (2) there were multiple adjacent wedge-compression fractures. Each of the two patients with a neural deficit had multiple wedge-compression fractures (first to third thoracic vertebra and fourth to seventh thoracic vertebra) and a severe kyphosis, measuring 68 and 70 degrees, respectively. These deformities may have developed due to late plastic deformation of the posterior longitudinal ligaments; both patients required operations and the neural deficits improved with correction of the kyphosis. The remaining ten patients with wedge-compression fractures were treated non-operatively (body cast, thoracolumbosacral orthosis[66], or extension brace). In all twelve patients the computed tomography examination confirmed that the middle and posterior columns were intact and that there were no bone fragments within the spinal canal.

Stable burst fracture: These occurred in eighteen patients (Frankel functional-level E in fourteen and Frankel level D in four). These patients were also treated by a body cast or orthosis. The computed tomography examination showed the comminution of vertebral body fragments more clearly than did the radiographs and revealed that the posterior column was intact.

Unstable burst fracture: This was diagnosed in thirty patients, as shown by subluxation of one or more facet joints, fracture of one or more neural arches, or gross displacement of the neural elements. Measurements of the diameter of the spinal canal were made for the first sixteen unstable burst fractures at the thoracolumbar junction (tenth thoracic to second lumbar vertebra)[39,65]. The average mid-sagittal diameter at the level of the fracture was 8.4 millimeters (range, six to fourteen millimeters). The lower limit of normal at the first lumbar vertebra is fourteen millimeters. In ten of these sixteen patients who also had a computed tomography examination after spinal decompression, the diameter invariably was more than ten millimeters. In general these measurements were of interest, but because there was no reliable correlation between the measurement and the neural deficit, we dispensed with making this measurement. Unstable burst fractures, as one compression injury, produced the most severe neural deficits in the present series (Frankel level E,

* The neural level of function of the patients was assessed by the criteria of Frankel et al.[22]: E — neurally intact, D — motor function useful, C — motor function present but useless, B — sensation present but no motor function, and A — complete spinal-cord deficit.

TABLE I

PATIENTS SEEN WITHIN TEN DAYS

	Wedge Compression Fracture	Burst Fracture		Chance Fracture	Flexion-Distraction Injury	Translation Injury
		Stable	Unstable			
No. of cases	12	18	30	4	11	11
Computed tomography without intrathecal contrast*	11	14	23	4	8	5
0				1		
1	9	2		1	3	
2	1	3	2	2	4	2
3	1	9	21		1	3
Computed tomography with intrathecal contrast*	1	4	7	0	3	6
0						
1						
2		1	1		2	1
3	1	3	6		1	5

* 0 = computed tomography provided misleading information, 1 = computed tomography provided confirmatory information only, 2 = computed tomography was useful in making operative decisions or in assessing stability, and 3 = computed tomography was the most definite preoperative diagnostic study or it provided unique information that was confirmed at surgical exploration.

six patients; level D, fourteen; level C, three; level B, two; and level A, five). Twenty-eight of the thirty patients were treated surgically, twenty-two with a fracture at the thoracolumbar junction having a one-stage modified posterolateral decompression and Harrington distraction-rod stabilization[3,8,11,18,21,39]. The transaxial image on the computed tomography examination showed the proper side from which the approach should be selected so as to decompress the conus medullaris when decompression was needed. Three patients with a lower lumbar fracture had nerve-root decompression and two-level posterior fusion. Two patients with an unstable burst fracture died from associated cardiovascular injuries before stabilization procedures could be performed. Aside from three patients who were not candidates for instrumentation, Harrington distraction instrumentation was required in twenty-four of twenty-five patients with an unstable burst fracture shown by computed tomography. After having examined the first sixteen unstable burst fractures with computed tomography, we dispensed with conventional tomograms because computed tomography proved so reliable in detecting disruption of the posterior elements. Often small bone fragments in the canal or neuroforamina that were not seen by plain radiography, myelography, or tomography were visualized on the transaxial image (Fig. 4-A). Eleven cases of displacement of the thecal sac and its neural contents were diagnosed by computed tomography with metrizamide myelography (Fig. 4-B). The presence or absence of congruity of the facet articulations was most accurately assessed by computed tomography (Fig. 4-C).

Chance fracture: There were four patients with a Chance fracture, all secondary to a motor-vehicle accident in which sudden deceleration of the car caused a passenger wearing a lap seatbelt to be thrown forward[59]. All of the patients remained neurally intact. These horizontal fractures, parallel to the plane of the transaxial image, were hard to detect by computed tomography, but sagittal reconstructions were diagnostic and revealed the extent of distraction of the posterior elements (Figs. 5-A and 5-B). Three patients were managed successfully by a body cast applied in extension, which reduced the fracture. Only one of the four lesions was visualized well by computed tomography without sagittal reconstruction. It was a displaced fracture requiring open reduction and internal fixation. Of all the types of fractures in the classification scheme, computed tomography was least helpful in the Chance fractures.

Flexion-distraction injury: Four of the eleven patients who had this ominous unstable fracture[33] had a neural deficit (Frankel level D) and surgical reduction was done in ten. The majority of patients had extreme kyphosis, particularly if the injury was mid-thoracic. Usually it could be reduced with two Harrington compression rods, with two hooks engaged above and two hooks engaged below the fracture site on each side. The only patient of the ten who had failure of fixation had a flexion-distraction injury between the twelfth thoracic and first lumbar vertebrae that was treated with bilateral distraction rods and not in compression. The rods dislodged postoperatively. If the zygoapophyseal joints were subluxated or dislocated tomograms revealed the displacement best, even though computed tomography showed a characteristic so-called naked-facet sign[59]. Because of an acute gibbus at the fracture site, the spinal cord and roots tended to bowstring anteriorly and to be injured in tension. This was particularly well shown with metrizamide computed tomography as a loss of subarachnoid space anterior to the spinal cord (Figs. 6-A, 6-B, and 6-C). The conus was often visualized at a higher level than normal secondary to the acute kyphosis.

Translational injury: Of eleven patients, all but two were treated operatively and the spinal discontinuity often was nearly complete at the level of injury. The computed tomography reconstruction characteristically showed the malalignment. There were two vertebral-body outlines on one level, referred to as the double-margin sign[38] (Figs. 7 and 8-A). Oblique reconstructions were needed to visualize the longitudinal extent of the injury to the spinal

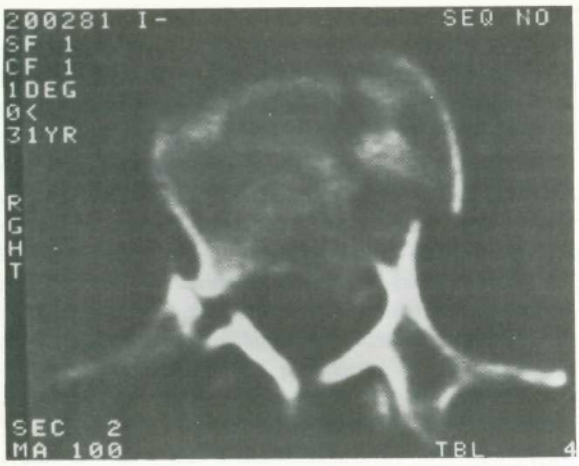

FIG. 4-A

Figs. 4-A through 4-E: Five different cases illustrate information unique to computed tomography in the evaluation of unstable burst fractures.

Fig. 4-A: A transaxial image demonstrates comminution of the vertebral body and severe disruption of the osseous neural arch — bilateral pedicle, laminar, and unilateral transverse-process fractures.

cord (Frankel level E in one, level D in three, level B in one, and level A in six patients). Seven patients in this category had segmental spinal instrumentation.

Perhaps the true value of analyzing the middle-column disruption by computed tomography in this series of eighty-six consecutive patients can be shown from the results of instrumentation. Twenty-four of thirty patients with a compression injury who were operative candidates underwent Harrington distraction instrumentation, seven of eleven patients with a distraction injury had compression instrumentation, and seven of nine patients with translational failure had segmental spinal instrumentation. After an average follow-up of thirty-one months (range, twelve to sixty months), only one patient had a loss of stability or fixation pursuant to this recommended scheme of management. That patient had an extensive translational injury treated with segmental spinal instrumentation. Asymmetrical collapse developed nine months postoperatively due to a lumbosacral pseudarthrosis and unilateral facet-joint comminution. In general, posterior fusion utilizing iliac-bone graft was performed along the length of the instrumentation in all types of injuries[15,21,31,72].

Patients Seen Late

All fourteen patients who were referred from other institutions for complications of a thoracolumbar fracture had either radiculopathy or displacement of the fixation apparatus. Two had a wedge-compression fracture, eleven had an unstable burst fracture, and one had a fracture-dislocation. All but one had been neurally intact at the time of initial examination, and nine patients had been treated by conservative methods. They were seen between four and thirty-two months after injury. The radiculopathy had developed due to bone displacement, progressive kyphosis, or collapse of a vertebra at the fracture site[2]. Seven patients had deteriorated to Frankel level D and three patients, to Frankel level C. The remaining four patients had subjective paresthesias, although objectively they were at Frankel level E.

Nine patients had post-traumatic spinal stenosis with evidence on computed tomography of displaced fragments of bone, most commonly in the lateral recesses. Computed tomography sagittal reconstruction in two patients also showed neuroforaminal encroachment. A thirty-eight-year-old woman had a computed tomography examination eleven months after injury that showed fibrous inter-

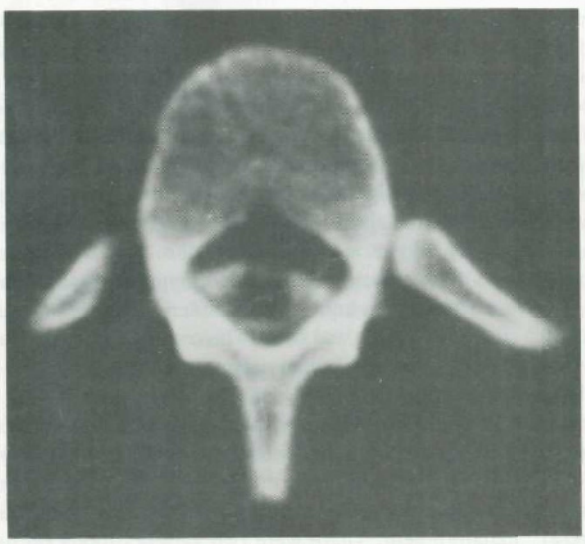

FIG. 4-B

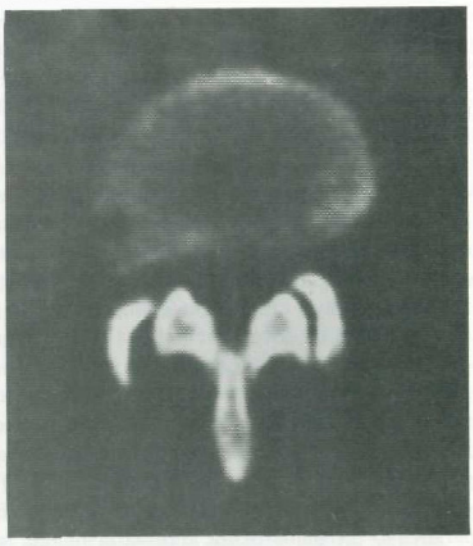

FIG. 4-C

Fig. 4-B: A metrizamide computed-tomography scan at the level of the twelfth thoracic vertebral body in a patient with an unstable burst fracture of the first lumbar vertebra. The degree of posterior displacement of the conus medullaris and thecal sac can be appreciated.

Fig. 4-C: Unilateral subluxation of the facet joints indicates disruption of the facet-joint capsule and instability of the posterior elements.

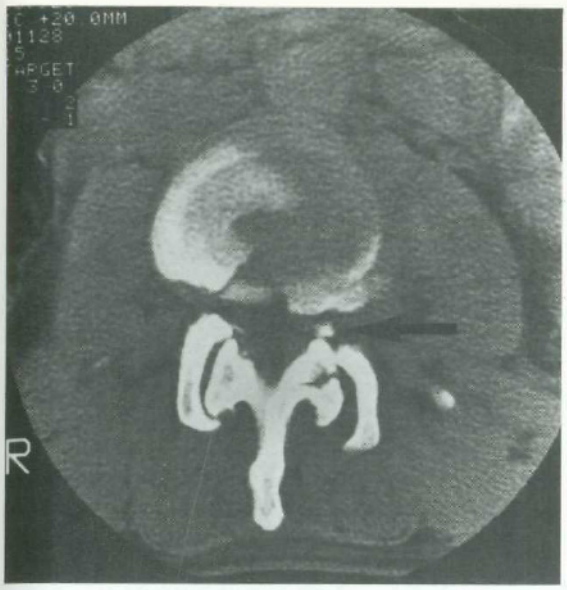

FIG. 4-D

This man, thirty-five years old, had an unstable burst fracture of the fourth lumbar vertebra with localized paresthesias along the lateral aspect of the left thigh (third lumbar dermatome). Computed tomography shows a corresponding bone fragment in the neuroforamen between the third and fourth lumbar vertebrae on the left and a non-displaced fracture of the left inferior articular process of the third lumbar vertebra. The radiculopathy resolved after decompression and foraminotomy.

vertebral-disc material retropulsed into the canal and neuroforamen. This was confirmed at surgery and the patient's symptoms abated after late decompression.

Of the five patients who had initial operative treatment at other medical centers, one had displacement of a Harrington hook; computed tomography showed the change in position of the hook but did not indicate the surrounding bursa and inflammation that was encountered at surgical exploration. One patient had undergone an inadequate costotransversectomy decompression, and computed tomography showed a large bone fragment in the central canal. Two patients had complete failure of Harrington distraction fixation and progressive neurological findings (Frankel level E to D). The computed tomography examination was useful in planning the removal of the loose devices and the decompression through the previous fusion mass. The remaining patient was a fifty-year-old woman with a fracture-dislocation who was originally treated with a three-level bilateral decompression laminectomy. Although she had improved in the immediate postoperative period, she was seen at our institution eight years after injury with paraparesis and neurogenic bladder dysfunction (Frankel level C). Computed tomography examination showed a first and second lumbar retrolisthesis that increased with extension of the spine. This patient was the only one in the series for whom computed tomography was performed in the lateral position; she had paresthesias when lying supine. Sagittal reconstruction showed a 70-degree gibbus deformity from the eleventh thoracic to the second lumbar vertebra. The chief value of computed tomography was the identification of the anterior spinal compression at the first lumbar level, which necessitated a transthoracoabdominal approach for decompression. The gibbus was corrected in two stages by anterior rib-strut grafting and posterior segmentally-wired Harrington distraction rods. During the posterior spinal instrumentation the area of the laminectomy scar was avoided, as the computed tomography scan had shown no lamina, facets, or posterior element remnants that were of adequate integrity

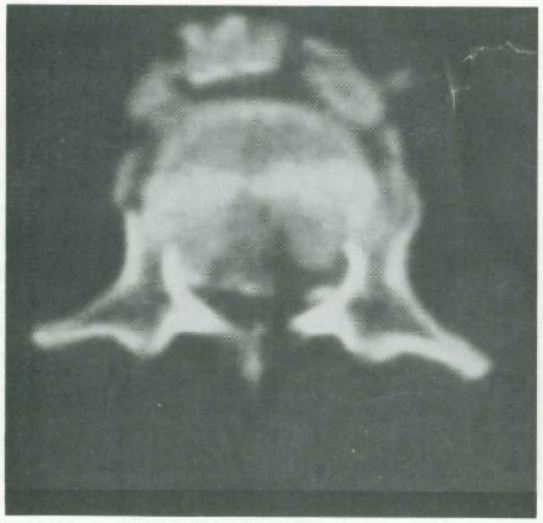

FIG. 4-E

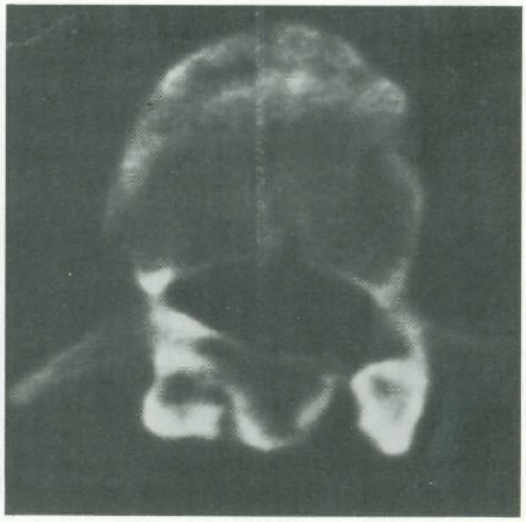

FIG. 4-F

Fig. 4-E: A preoperative axial scan of this unstable burst fracture shows severe retropulsion of bone fragments into the canal, which corresponds to the patient's Frankel level-C neural deficit. The patient underwent a one-stage modified posterolateral decompression with Harrington distraction-rod instrumentation and had a complete neural recovery.

Fig. 4-F: Thirty months after operation (one year after removal of the Harrington rods), there is marked improvement in the anterior-posterior diameter of the spinal canal and no residual neural compression.

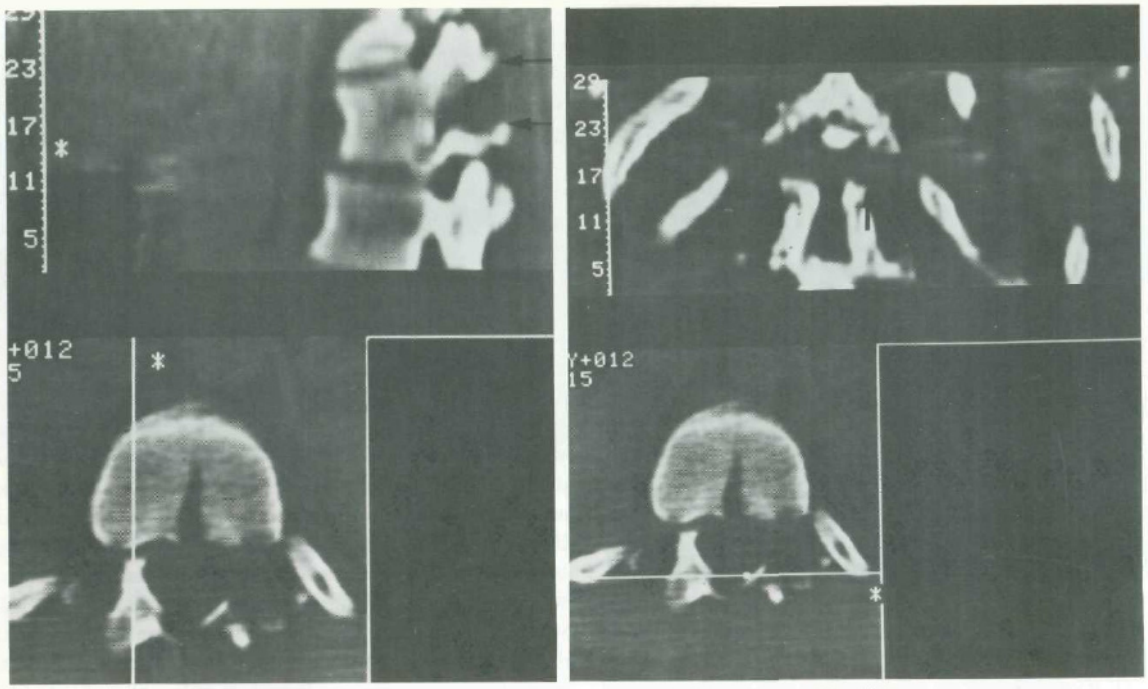

FIG. 5-A

FIG. 5-B

Sagittal and coronal reconstructions demonstrate a displaced Chance fracture of the first lumbar vertebra.

to provide attachment of segmental wires from the eleventh thoracic to the second lumbar vertebra. This information allowed us to avoid a meticulous and difficult operative dissection adjacent to the dura at the level of injury.

Discussion

The value of computed tomography in the full spectrum of spinal injuries has been well documented[9,19,23-25,27,28,30,48,62,69]. However, most previous studies have consisted of comparisons of computed tomography with plain radiographs, tomograms, and plain myelograms. It was the purpose of our study of a consecutive series to focus on the particular diagnostic contribution of computed tomography in the assessment of spinal stability from the perspective of operative stabilization. In compression injuries, the important determination is the integrity of the posterior elements. The stability of burst fractures is largely dependent on whether the neural arches and facet articulations are intact[9,29,46,55,60]. The osseous ring surrounding the spinal canal is in the same plane as transaxial computed tomography; therefore, the neural arch is optimally evaluated by this method. The degree of compromise of the spinal canal from retropulsion of the annulus fibrosus or vertebral body can also be demonstrated[44,49,71]. In distraction injuries, on the other hand, transaxial images can miss horizontal fractures entirely. Here, sagittal and coronal reconstructed images are necessary to show the mode of failure of the zygoapophyseal joint complex. Although its presence can only be deduced rather than visualized directly in the computed tomography examination, posterior deformation of the annulus fibrosus is an important anatomical finding to appreciate before attempting an open reduction of a flexion-distraction injury. As the vertebral bodies are compressed together with compression instrumentation, the annulus fibrosus can be retropulsed posteriorly into the spinal canal as the disc space is forcibly narrowed. We recommend removal of any displaced or redundant soft tissue within the spinal canal that is visualized preoperatively by computed tomography.

The considerations in translational injuries are complex. The spinal canal is discontinuous from one level to the next. Computed tomography is an effective way to detect the degree of vertebral comminution. If comminution is extensive, progressive settling can occur if segmental spinal instrumentation is applied. In the one patient with loss of position of instrumentation in our series, computed tomography, in retrospect, accurately showed a unilateral comminuted fracture of a lumbar facet joint. Within nine months postoperatively the spine collapsed asymmetrically and the patient had a list toward the fractured side. Two new instrumentation techniques are being developed that have particular application to translational injuries with vertebral comminution in patients with preservation of neural function[32,47].

Computed tomography with metrizamide myelography should be performed if: (1) a dural tear is suspected, (2) soft-tissue stenosis is likely, or (3) the patient has increasing neural symptoms or signs out of proportion to the degree of osseous injury. The defect may be localized to a

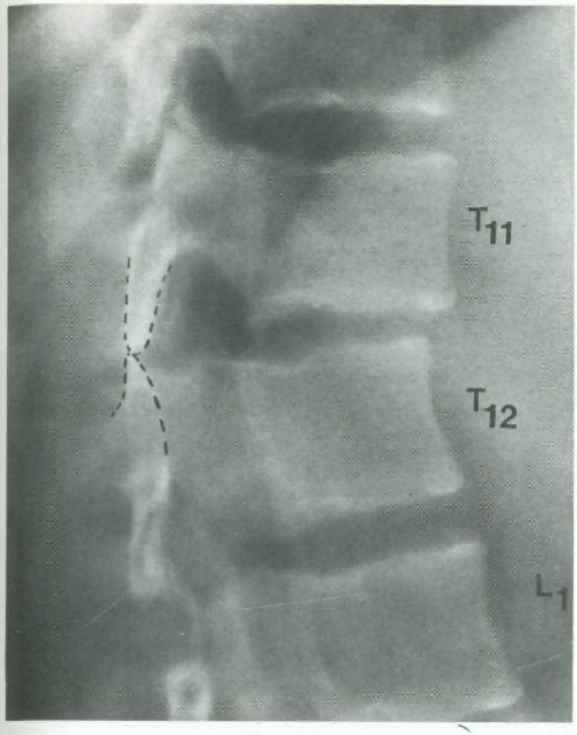

FIG. 6-A

Figs. 6-A, 6-B, and 6-C: Flexion-distraction injury at the eleventh and twelfth thoracic vertebrae.

Fig. 6-A: The inferior articular processes of the eleventh thoracic vertebra are perched on the superior articular processes of the twelfth thoracic vertebra.

spinal level different from that of the osseous injury, or may defy explanation using the information provided by conventional radiographic modalities.

Computed tomography may also be helpful in distinguishing lesions that require only conservative treatment. Frankel et al.[22], Burke and Murray[6], Guttmann[26], Bedbrook[1], and more recently Davies et al.[12] have recommended non-surgical management of some unstable injuries, including some with neural damage. If manipulation is required, the method of manipulation or spinal reduction will depend on the mechanism of injury, and the choice of method can be aided by computed tomography. Davies et al.[12] advocated early surgical intervention and instrumentation in several instances: "(1) an unsuccessful reduction of vertebral-body displacement by conservative means, such that the neural canal is narrowed by 50 per cent or more; (2) dislocation with locked and unfractured facets; (3) irritable, restless patients who cannot be controlled, and risk movement at the fracture site and aggravation of existing spinal cord damage; and (4) separation of the vertebral bodies to such a degree that soft-tissue interposition and non-union is likely". Three of these conditions should be identifiable by computed tomography.

Our proposed simplified classification of thoracolumbar fractures and fracture-dislocations into six groups, based on the type of failure of the middle column, utilizes the mechanism as well as the morphology of injury. The structural column of vertebral bodies resists compressive force, whereas the posterior elements have a stabilizing function and resist tensile forces[45,51,57,58,70]. The transition between these structural columns is the middle osteoligamentous complex — the key anatomical determinant of the surgical method of stabilization. If the middle column has not failed, operative fixation is rarely indicated. The single exception to that generalization is multiple-level wedge-compression fractures associated

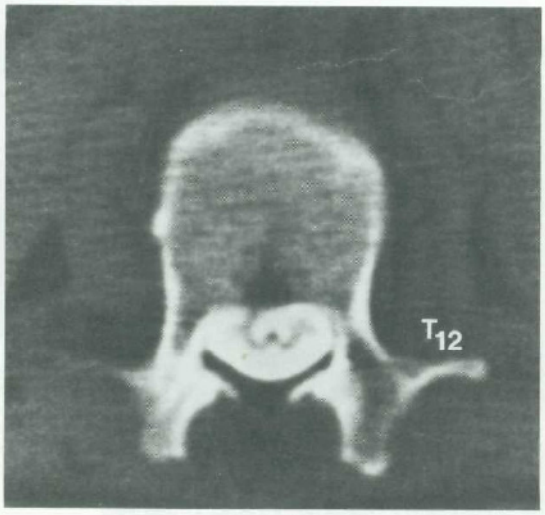

FIG. 6-B

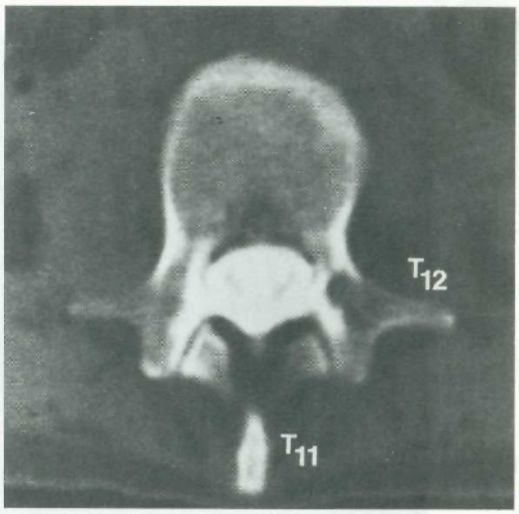

FIG. 6-C

Fig. 6-B: The so-called naked-facet sign. The posterior elements of the eleventh thoracic vertebra, which should be visualized at the level of the transverse processes of the twelfth thoracic vertebra, are absent. The neural structures are bowstrung anteriorly against the posterior aspect of the twelfth thoracic vertebral body. Note the radiolucent empty space between the lamina and the posterior aspect of the thecal sac, indicating anterior displacement.

Fig. 6-C: For comparison, this scan shows the normal amount of the spinous process of the eleventh thoracic vertebra and lamina visualized at the level of the transverse processes of the twelfth thoracic vertebra. There is no empty space in the spinal canal posterior to the thecal sac.

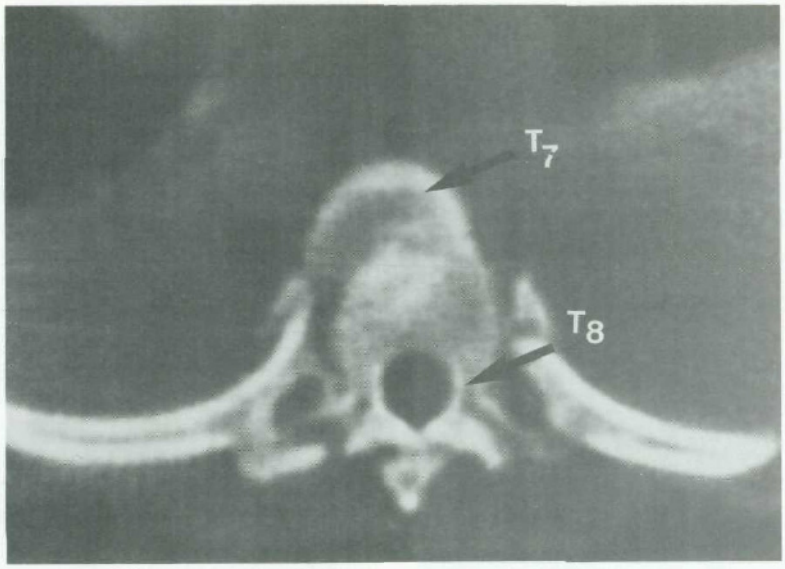

FIG. 7

Translational injury at the seventh and eighth thoracic vertebrae. There is marked discontinuity of the spinal canal.

with a progressive neural deficit. The middle column may fail in three ways: *compression, tension,* and *translation*. It fails rarely, if ever, in the two other mechanisms of injury — extension and rotation. In contrast to the common extension injury to the cervical spine, extension injuries of the thoracolumbar spine are extremely rare. In several large series of fracture-dislocations[5,15,21,26,29,31,33,56,72], the highest incidence of extension injuries was 2.5 per cent[5]. Bedbrook[1] reported only one case in a personal experience of 200 fractures and dislocations of the thoracolumbar spine. There was one extension injury in our eighty-six patients: the first lumbar vertebra was forced posteriorly on the second in a shearing manner. Thus, most extension injuries of the thoracolumbar spine can be appropriately considered posterior translational injuries[5,14,46,68].

Rotational forces usually are secondary to other forces producing the injury. The main structure in the thoracolumbar spine resisting rotational forces is the facet-joint complex[36,46,60,68]. If the facets are subluxated or fractured from a compression-rotation force, an unstable burst fracture results. If the facet-joint capsules are avulsed in tension, then usually a flexion-distraction injury is responsible. In our series we did not encounter a pure rotational injury in the absence of malalignment of the

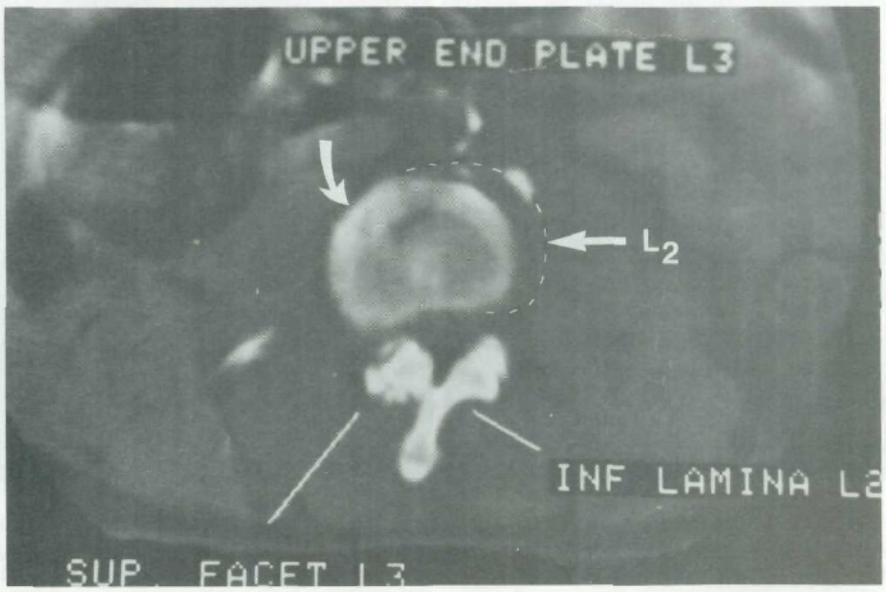

FIG. 8-A

An axial scan of a translational injury at the second and third lumbar vertebrae (Frankel level E).

neural canal (which would be considered a translational injury).

Whether to use compression or distraction rods in fixation of the fracture can be partially solved by the computed tomography evaluation of whether the middle column is intact. If the middle column fails in compression, then computed tomography shows either comminuted bone fragments from the vertebral body in the spinal canal or elsewhere, or the sagittal reconstructions show an unattached fragment of bone potentially displaceable into the canal. In this type of injury, Harrington compression rods are absolutely contraindicated[3,15,31,35,42,72] (as are Knodt compression rods[70], Weiss springs[61], the Wisconsin compression system[16], and similar devices). On the other hand, compression rods are indicated in cases of middle column failure by tensile forces (distraction injuries), because the middle column acts as the principal stabilizer of the spinal cord. The height of the vertebral canal will be maintained while a corrective compressive force is applied to the middle column through the rods, as applied to the lamina.

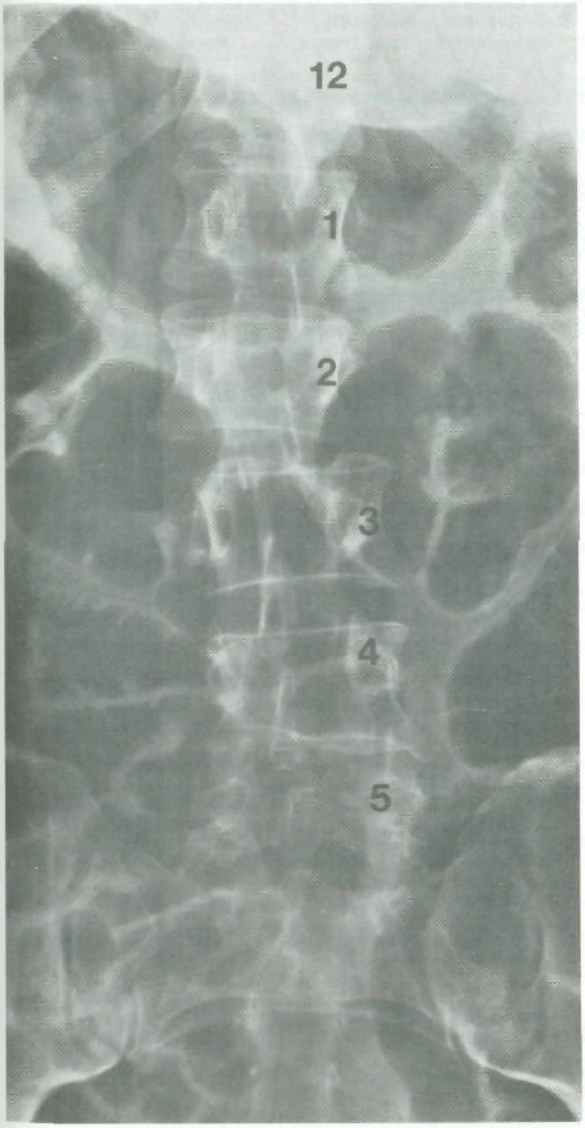

FIG. 8-B

The second lumbar vertebra has been displaced to the left of the third lumbar vertebra. Surgical exploration revealed complete ligament discontinuity of the second and third lumbar vertebrae with disruption extending inferiorly to the ligamentum flavum of the fourth and fifth lumbar vertebrae. Segmental spinal instrumentation successfully obtained adequate reduction of this highly unstable lesion.

Extensive clinical experience with unstable fractures of the spine has been reported with treatment by Harrington distraction and Harrington compression instrumentation[3,15,17,18,21,31,39,54,60,68,70,72]. The role of the Luque segmental spinal-instrumentation system is still under investigation[20,37]. Because Luque rods do not counteract axial compressive or tensile forces, they would not seem to be useful for fixation of unstable burst fractures or displaced flexion-distraction injuries. In patients with pure translational injuries, however, there is no requirement for compressive or tensile forces to maintain stability. Because the Luque system is the strongest[67] of the three instrumentation systems in general use, it might be useful for patients with translational spinal injuries that are unstable, but one of its shortcomings is the danger of iatrogenic neural sequelae[20].

Conclusions

In many thoracolumbar fractures and fracture-dislocations, visualizing the middle column of the spine by computed tomography may contribute importantly to the treatment of the patient. In compression injuries of the middle column, computed tomography will allow assessment of the degree of retropulsion of vertebral body fragments or of the posterior aspect of the annulus fibrosus, or both.

Computed tomography is usually a reliable method of identifying unstable burst fractures by illustrating facet-joint subluxation or disruption of the neural arch. Burst fractures that are associated with incomplete or progressive neural deficits or with progressive vertebral collapse or angulation should be subjected to computed tomography examination because it can show the sites of neural compression preoperatively and can indicate the approach for spinal decompression, either transthoracoabdominal or posterolateral. It can also help one to predict whether Harrington-rod stabilization is feasible.

Computed tomography can provide useful information in displaced Chance fractures and flexion-distraction injuries provided sagittal and coronal reconstructions are utilized. It can reveal facet-joint dislocations or subluxations and facet fractures, all three of which can be important causes for loss of stability.

Translational injuries are the most unstable of all spinal injuries. Surgical exploration in such patients often demonstrates complete ligament discontinuity of the in-

volved vertebra, information that can be derived preoperatively from computed tomographic studies.

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