

EXHIBIT 1001



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(54) **METHOD AND APPARATUS FOR PERFORMING INTRA-OPERATIVE ANGIOGRAPHY**

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USPC 424/9.6; 600/431, 476
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,619,249 A 10/1986 Landry
4,995,396 A 2/1991 Inaba et al.

(Continued)

FOREIGN PATENT DOCUMENTS

CA 2212257 8/1996
CA 2413033 3/2000

(Continued)

OTHER PUBLICATIONS

Takayama et al. Intraoperative Coronary Angiography Using Fluorescein. *Ann Thorac Surg.* 51:140-143. 1991.*

(Continued)

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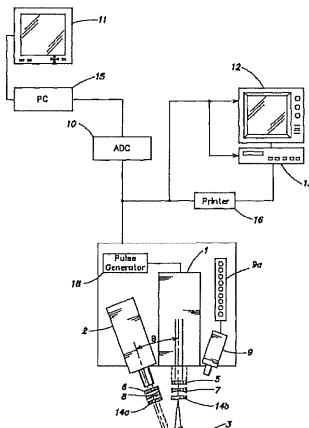
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ABSTRACT

Method for assessing the patency of a patient's blood vessel, advantageously during or after treatment of that vessel by an invasive procedure, comprising administering a fluorescent dye to the patient; obtaining at least one angiographic image of the vessel portion; and evaluating the at least one angiographic image to assess the patency of the vessel portion. Other related methods are contemplated, including methods for assessing perfusion in selected body tissue, methods for evaluating the potential of vessels for use in creation of AV fistulas, methods for determining the diameter of a vessel, and methods for locating a vessel located below the surface of a tissue.

3 Claims, 1 Drawing Sheet



(56)

References Cited

U.S. PATENT DOCUMENTS

4,995,398	A	2/1991	Turnidge	
5,115,137	A	5/1992	Andersson-Engels et al.	
5,279,298	A	1/1994	Flower	
5,318,869	A	6/1994	Hashimoto et al.	
5,375,603	A	12/1994	Feiler	
5,394,199	A	2/1995	Flower	
5,437,274	A	8/1995	Khoobehi et al.	
5,453,448	A	9/1995	Narciso, Jr.	
5,507,287	A	4/1996	Palcic et al.	
5,785,965	A	7/1998	Pratt et al.	
5,851,181	A	12/1998	Talmor	
5,927,284	A	7/1999	Borst et al.	
5,951,980	A	9/1999	Collen	
6,032,070	A	2/2000	Flock et al.	
6,081,612	A	6/2000	Gutkowicz-Krusin et al.	
6,122,042	A	9/2000	Wunderman et al.	
6,246,901	B1	6/2001	Benaron	
6,272,374	B1	8/2001	Flock et al.	
6,280,386	B1	8/2001	Alfano et al.	
6,293,911	B1	9/2001	Imaizumi et al.	
6,351,663	B1	2/2002	Flower et al.	
6,353,750	B1	3/2002	Kimura et al.	
6,447,443	B1	9/2002	Keogh et al.	
6,498,945	B1	12/2002	Alfheim et al.	
6,631,286	B2	10/2003	Pfeiffer et al.	
6,840,933	B1	1/2005	Pang et al.	
6,915,154	B1 *	7/2005	Docherty et al.	600/431
2005/0182434	A1 *	8/2005	Docherty et al.	606/170
2006/0239921	A1 *	10/2006	Mangat et al.	424/9.6
2009/0203993	A1 *	8/2009	Mangat et al.	600/431

FOREIGN PATENT DOCUMENTS

CN	1049781	3/1991
CN	1200174	11/1998
EP	0091805	10/1983
EP	0 826 335 A1	3/1998
JP	5969721	4/1984
JP	59070903	4/1984
JP	02-200237	8/1990
JP	04-297236	10/1992
JP	06-335451	12/1994
JP	07-065154	3/1995
JP	07-079955	3/1995
JP	07-222712	8/1995
JP	08-024227	1/1996
JP	09308609	2/1997
JP	09120033	6/1997
JP	10085222	8/1997
JP	09309845	12/1997
JP	10201707	4/1998
JP	10506550	6/1998
JP	11137517	5/1999
JP	11509748	8/1999
JP	3115958	11/2005
JP	05264232	8/2013
WO	9412092	6/1994
WO	9609792	4/1996
WO	9669792	4/1996
WO	9618415	6/1996
WO	9623524	8/1996
WO	9639925	12/1996
WO	9708538	3/1997
WO	9830144	7/1998
WO	9900053	1/1999
WO	WO 99/47940	9/1999
WO	0117561	3/2001
WO	0122870	4/2001

OTHER PUBLICATIONS

Torok, B. et al. "[Simultaneous digital indocyanine green and fluorescein angiography]" *Klinische Monatsblätter für Augenheilkunde*,

Jagoe, J.R. et al. "Quantification of retinal damage during cardiopulmonary bypass," *Third International Conference on Image Processing and its Applications (Conf. Publ. No. 307)*, IEE, 1989, pp. 319-323.

Murphy, Douglas B. *Fundamentals of light microscopy and electronic imaging*. John Wiley and Sons. 2001. pp. i-xi, 259-281.

Nakamura, T. et al., *Use of Novel Dyes, Commassie Blue, and Indocyanine Green in Dye Dilution Methods*, *Internal Medicine* vol. 14, No. 7, Dec. 1964, pp. 1361-1366.

Ooyama, Masa, "The 8^{supth} Congress of International YAG Laser Symposium," *The 15th Annual Meeting of Japan Society for Laser Medicine*, Sun Royal Hotel, Oct. 12, 1994.

Sakatani, *Noninvasive Optical Imaging of the Subarchnoid Space and Cerebrospinal Fluid Pathways Based on Near Infrared Fluorescence*, *J. Neurosurg.* 87:738-745 (1997).

Takayama, T., *Intraoperative Coronary Angiography Using Fluorescein*, *Ann. Thoracic Surgery*, 51:140-3 (1991).

Takayama T., *Intraoperative Coronary Angiography Using Fluorescein: Basic Studies and Clinical Application*, presented at the 37^{sup}th Annual Meeting, American College of Angiology, Atlanta, Georgia, Oct. 1990.

Benson et al., *Fluorescence Properties of Indocyanine Green as Related to Angiography*, *Phys. Med. Biol.*, 23(1):159-163, (1978).

Boer et al., "Effect of ventilation on first-pass pulmonary retention of alfentanil and sufentanil in patients undergoing coronary artery surgery," *British Journal of Anaesthesia*, 73:458-463, (1994).

Boldt et al., "Does the technique of cardiopulmonary bypass affect lung water content?," *Eur J Cardio-thorac Surg*, 5:22-26, (1991).

Boldt et al., "Lung management during cardiopulmonary bypass: influence on extravascular lung water," *J. Cardiothorac Anesth*, 4(1):73-79, (1990).

DeGrand et al., "An Operational Near-Infrared Fluorescence Imaging System Prototype for Large Animal Surgery," *Technology in Cancer Research & Treatment*, 2(6):1-10, (2003).

Desai et al., *Improving the Quality of Coronary Bypass Surgery with Intraoperative Angiography*, *Cardiac Surgery*, 46(8):1521-1525, (2005).

Flower, "Choroidal Angiography Today and Tomorrow," *Retina*, 12(3):189-190, (1992).

Flower, "Does Preinjection Binding of Indocyanine Green to Serum Actually Improve Angiograms," *Arch Ophthalmol*, 112:1137-1139, (1994).

Flower, *Effects of free and liposome-encapsulated hemoglobin on choroidal vascular plexus blood flow, using the rabbit eye as a model system*, *European Journal of Ophthalmology*, 9(2):103-114, (1999).

Flower, "Quantification of Indicator Dye Concentration in Ocular Blood Vessels," *Exp. Eye Res.*, 25:103-111, (1977).

Goldstein et al., "Intraoperative Angiography to Assess Graft Patency After Minimally Invasive Coronary Bypass," *Ann Thorac Surg*, 66:1978-1982, (1998).

Green, et al., "Burn Depth Estimation Using Indocyanine Green Fluorescence", *Arch Dermatol*, 128:43-49, (1992).

Hayashi, et al., "Transadventitial localisation of atheromatous plaques by fluorescence emission spectrum analysis of mono-L-aspartyl-chlorin e6," *Cardiovascular Research*, 27:1943-1947, (1993).

International Search Report for International Application No. PCT/US00/22088, dated Oct. 18, 2000.

Keon et al., "Coronary endarterectomy: An adjunct to coronary artery bypass grafting," *Surgery*, 86(6):859-867, (1979).

Kitai et al., "Fluorescence Navigation with Indocyanine Green for Detecting Sentinel Lymph Nodes in Breast Cancer," *Breast Cancer*, 12(3):211-215, (2005).

Laub et al., "Experimental use of Fluorescein for Visualization of Coronary Arteries," *Vascular Surgery*, 23(6):454-457, (1989).

Lee et al., "A new method for assessment of changes in retinal blood flow," *Medical Eng. Physics*, 19(2):125-130, (1997).

Lund et al., "Video fluorescein imaging of the skin: description of an over-viewing technique for functional evaluation of regional cutaneous blood perfusion in occlusive arterial disease of the limbs," *Clinical Physiology*, 17(6):619-633, (1997).

May, "Photonic Approaches to Burn Diagnostics", *Biophotonics*

(56)

References Cited

OTHER PUBLICATIONS

- Nakamura et al., "Use of Novel Dyes, Coomassie Blue and Indocyanine Green in Dye Dilution Method," Tohoka University, Nakamura Internal Department, The Tuberculosis Prevention Society, Tuberculosis Research Laboratory, 17(2):1361-1366, (1964).
- Ogata et al., "Novel Lymphography Using Indocyanine Green Dye for Near-Infrared Fluorescence Labeling," *Annals of Plastic Surgery*, 58(6):652-656, (2007).
- Ooyama, Masa, "The 8th Congress of International YAG Laser Symposium," The 15th Annual Meeting of Japan Society for Laser Medicine, Sun Royal Hotel, Oct. 12, 1994.
- Reuthebuch et al., "Novadaq SPY: Intraoperative Quality Assessment in Off-Pump Coronary Artery Bypass Grafting," *Chest*, 125(2):418-424, (2004).
- Rubben et al., "Infrared Videoangiography of the Skin with Indocyanine Green-Rat Random Cutaneous Flap Model and Results in Man," *Microvascular Research*, 47:240-251, (1994).
- Rubens et al., "A new and Simplified Method for Coronary and Graft Imaging During CABG," *The Heart Surgery Forum*, 5(2):141-144, (2002).
- Sakatani et al., "Noninvasive optical imaging of the subarachnoid space and cerebrospinal fluid pathways based on near-infrared fluorescence," *J. Neurosurg*, 87:738-745, (1997).
- Salmon et al., "High Resolution Multimode Digital Imaging System for Mitosis Studies In Vivo and In Vitro," *Biol. Bull*, 187:231-232, (1994).
- Siemers et al., "The acoustic advantage of hunting at low heights above water: behavioural experiments on the European 'trawling' bats *Myotis capaccinii*, *M. dasycneme* and *M. daubentonii*," *Journal of Experimental Biology*, 204:3843-3854, (2001).
- Skalidis et al., "Regional Coronary Flow and Contractile Reserve in Patients with Idiopathic Dilated Cardiomyopathy," *Journal of the American College of Cardiology*, 44(10):2027-2032, (2004).
- Still et al., "Evaluation of the Circulation of the Reconstructive Flaps Using Laser-Induced Fluorescence of Indocyanine Green," *Annals of Plastic Surgery*, 42(3):266-274, (1999).
- Suma et al., "Coronary Artery Bypass Grafting Without Cardiopulmonary Bypass," *Cardiol*, 36(2):85-90ac, (2000).
- Taichman et al., "The Use of Cardio-Green for Intraoperative Visualization of the Coronary Circulation: Evaluation of Myocardial Toxicity," *Tex Heart Inst. J.*, 14(2):133-138, (1987).
- Takahashi et al., "SPY.TM: an innovative intra-operative imaging system to evaluate graft patency during off-pump coronary artery bypass grafting," *Interactive Cardiovascular and Thoracic Surgery*, 3:479-483, (2004).
- Takayama et al., "Intraoperative Coronary Angiography Using Fluorescein," *The Society of Thoracic Surgeons*, 51:140-143, (1991).
- Takayama et al., "Intraoperative Coronary Angiography Using Fluorescein: Basic Studies and Clinical Application," *Vascular Surgery*, 26(3):193-199, (1992).
- Taylor Kenneth M., "Brain Damage During Cardiopulmonary Bypass," *Annals of Thoracic Surgery*, 65:S20-S26, (1998).
- Unno et al., "Indocyanine Green Fluorescence Angiography for Intraoperative Assessment of Blood Flow: A Feasibility Study," *Eur J Vasc Endovasc Surg*, 1-3 (2007).
- Wachi et al., "Characteristics of cerebrospinal fluid circulation in infants as detected with MR velocity imaging," *Child's Nerv Syst*, 11:227-230, (1995).
- Woitzik et al., "Intraoperative control of extracranial-intracranial bypass patency by near-infrared indocyanine green videoangiography," *J. Neurosurg*, 102:692-698, (2005).
- Wollert et al., "Intraoperative Visualization of Coronary Artery Fistula using Medical Dye," *The Thoracic and Cardiovascular Surgeon*, 46:382-383, (1998).
- Yada et al., "In vivo Observation of Subendocardial Microvessels of the Beating Porcine Heart using a Needle-probe Videomicroscope with a CCD camera," *Circulation Research*, 72(5):939-946, (1993).
- Yoneva et al., "Binding Properties of Indocyanine Green in Human Yoneya et al., "Improved Visualization of the Choroidal Circulation with Indocyanine Green Angiography," *Arch Ophthalmol*, 111:1165-1166, (1993).
- European Patent Office Opposition Division, Application No./Patent No. 00 955 472.6-1269/1143852, Decision revoking the European Patent (Art. 101(3)(b) EPC), Jun. 10, 2010.
- Sato, et al., "Development of a Visualization Method for the Microcirculation of Deep Viscera using an Infrared Intravital Microscope System", Suzuken Memorial Foundation, Dec. 20, 1991.
- English Translation of Sato, et al., "Development of a Visualization Method for the Microcirculation of Deep Viscera using an Infrared Intravital Microscope System", Suzuken Memorial Foundation, Dec. 20, 1991.
- Report on Observation by C2400-75i and ARGUS20 Under Low illumination conditions, Jan. 17, 2008.
- Supplementary European Search Report (Jun. 22, 2004).
- Emery, et al., "Revascularization Using Angioplasty and Minimally Invasive Techniques Documented by Thermal Imaging", *The Society of Thoracic Surgeons*, No. 62, Elsevier Science Inc., 1996, pp. 591-593.
- Roberts, et al., "Laparoscopic Infrared Imaging", *Technique*, No. 11, *Surgical Endoscopy*, 1997, pp. 1221-1223.
- Van Son, et al., "Thermal Coronary Angiography for Intraoperative Testing of Coronary Patency in Congenital Heart Defects", *The Society of Thoracic Surgeons*, No. 64, Elsevier Science Inc., 1997, pp. 1499-1500.
- Mohr, et al., "Thermal Coronary Angiography: A Method for Assessing Graft Patency and Coronary Anatomy in Coronary Bypass Surgery", *The Society of Thoracic Surgeons*, No. 63, Elsevier Science Inc., 1997, pp. 1506-1507.
- International Searching Authority, "International Preliminary Examination Report from PCT/USOO/22088 (N0001/7000WO)", Aug. 11, 2000, Patent Cooperation Treaty.
- Phillips R. P., et al., "Quantification of Diabetic Maculopathy of Digital Imaging of the Fundus", *Eye*, 5(1): 1991, pp. 130-137.
- Partial European Search Report for EP 10 18 6218, mailed Dec. 16, 2010.
- Barton, J.K. et al. "Simultaneous irradiation and imaging of blood vessels during pulsed laser delivery." *Lasers in Surgery and Medicine* 1999, vol. 24, No. 3, 1999, pp. 236-243.
- Torok, B. et al. Abstract of "[Simultaneous digital indocyanine green and fluorescein angiography]" *Klinische Monatsblätter für Augenheilkunde*, May 1996, vol. 208, No. 5, May 1996, pp. 333-336.
- Jagoe, J.R. et al. Abstract of "Quantification of retinal damage during cardiopulmonary bypass," *Third International Conference on Image Processing and its Applications (Conf. Publ. No. 307)*, IEE, 1989, pp. 319-323.
- Ott, "Hepatic Elimination of Indocyanine Green with Special Reference to Distribution Kinetics and the Influence of Plasma Protein Binding," Thesis. 1998.
- Unno et al., "Indocyanine Green Fluorescence Angiography for Intraoperative Assessment of Blood Flow: A Feasibility Study," *Eur J Vase Endovasc Surg*, 1-3 (2007).
- Wachi et al., "Characteristics of cerebrospinal fluid circulation in infants as detected with MR velocity imaging," *Child's Nerv Syst*, 11:227-230, (1995).
- Argus-50/CA, Inter-cellular CA2+ (calcium ion) Image Analysis System, Observation and 2-dimensional analysis of Ca2+ concentration distribution. Fura-2 and Indo-1 compatible. Ca2+ concentrations are calculated from the fluorescence ratio, Feb. 1992, pp. 1-10.
- Balacumaraswami et al. Does off-pump total arterial grafting increase the incidence of intraoperative graft failure? *Cardiopulmonary Support and Physiology, The Journal of Thoracic and Cardiovascular Surgery*, Aug. 2004, pp. 238-244.
- C2741, Compact High-Performance Video Camera for Industrial Applications with Built-in Contrast Enhancement Circuit, Jun. 1998.
- Tsutsumi et al. "Moisture Detection of Road Surface using Infrared Camera," *Reports of the Hokkaido Industrial Research Institute (No. 297)*, Issued on Nov. 30, 1998.
- Reuthebuch et al. "Graft Occlusion After Deployment of the Symmetry Bypass System." *Clinic for Cardiovascular Surgery, University*

(56)

References Cited

OTHER PUBLICATIONS

Taggart et al. "Preliminary Experience with a Novel Intraoperative Fluorescence Imaging Technique to Evaluate the Patency of Bypass Grafts in Total Arterial Revascularization," Department of Cardiothoracic Surgery, John Radcliffe Hospital, Oxford, United Kingdom, pp. 870-875, 2003.

Wise et al. "Simultaneous Measurement of Blood and Myocardial Velocity in the Rat Heart by Phase Contrast MRI Using Sparse q-Space Sampling" *Journal of Magnetic Resonance Imaging*, 2005, 22, pp. 614-627.

Young et al. "Depth-of-Focus in Microscopy", SCIA '93, Proc. Of the 8th Scandinavian Conference on Image Analysis, Tromso, Norway, 1993, pp. 493-498.

* cited by examiner

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