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FIRST OPERATION OF THE MEDICAL RESEARCH FACILITY AT THE NSLS FOR CORONARY ANGIOGRAPHY

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The Synchrotron Medical Research Facility (SMERF) at the National Synchrotron Light Source has been completed and is operational for human coronary angiography experiments. The imaging system and hardware have been brought to SMERF from the Stanford Synchrotron Radiation Laboratory where prior studies were carried out. SMERF consists of a suite of rooms at the end of the high field superconducting wiggler X17 beamline and is classified as an Ambulatory Health Care Facility. Since October of 1990 the coronary arteries of five patients have been imaged. Continuously improving image quality has shown that a large part of both the right coronary artery and the left anterior descending coronary artery can be imaged following a venous injection of contrast agent.

INTRODUCTION

The human coronary angiography project was started at Stanford University and the Stanford Synchrotron Radiation Laboratory (SSRL) in 1979. Beginning in 1986 and running through the spring of 1989, a total of 7 human studies at SSRL clearly demonstrated the feasibility of imaging the coronary arteries of humans following venous injection of contrast agent.[1-4] This method of serially imaging coronary arteries of patients using a safer technique in place of the conventional arterial injection promises to open up new areas of coronary artery disease research. Research groups in Germany, Japan, and the Soviet Union are also studying the use of synchrotron radiation for imaging coronary arteries.[5-7]

Early in the development of the project at Stanford, it was realized that the long term potential of the synchrotron based technique would depend on the creation of a clinical facility which would provide high flux, a large amount of dedicated beamtime, a medical suite for patient care, and local medical support. Those requirements gave rise in 1982 to the concept of the Synchrotron Medical Research Facility (SMERF) at the National Synchrotron Light Source (NSLS) at Brookhaven National Laboratory (BNL).[8] SMERF became operational for the coronary angiography project October 5, 1990 with the first human coronary artery images taken at the NSLS.[9]

I. THE NSLS FACILITY

The NSLS is located at Brookhaven National Laboratory. One of the attractive features of siting a medical research facility at the NSLS is the existence at BNL of the Clinical Research Center and Medical Research Department. Presently there are several human studies in progress at BNL. These include the PETT VI Positron Emission Transaxial Tomography facility and various nuclear medicine programs. The Medical Department is available for support of the patients during their stay at BNL.

From its inception, the NSLS x-ray ring has been scheduled to operate 24 hours a day, 7 days a week, for about 45 weeks a year. The x-ray ring routinely operates at 2.5 GeV with initial electron current fills of 230 mA. Lifetimes are now about 35 hours. Dedication of 25% of the beamtime to the SMERF facility on the X17 beamline has provided ample beamtime for the medical research programs.

The NSLS has developed the high field superconducting wiggler beamline, X17, to provide the necessary photons at the iodine K-absorption edge (33.169 keV) for the imaging system.[10] During the past year, the X17 wiggler has been commissioned to a field of 4.4 T with a maximum operating field of 5.2 T possible. The wiggler has seven superconducting poles (five at full field and two at one-half field) and a period of 17.4 cm. At 4.4 T the critical energy is 18.3 keV. The x-ray spectrum of the wiggler is shown in Fig. 1 in comparison with the flux available from a high intensity rotating x-ray generator source.

II. THE SMERF FACILITY

During the NSLS Phase II expansion project, new research laboratories were constructed to meet the medical research facility requirements. In addition all applicable health care facility codes were met for electric and plumbing, radiation shielding, access and egress, and infection control. The construction was completed in 1989.

In parallel with the conventional construction, work proceeded on the wiggler magnet installation, beamline construction and shielding, active interlock systems, and human safety systems. The Angiography Personnel Protection Interlock (APPI) was provided by SSRL and modified to meet the NSLS requirements.[11] The angiography beamline hardware was moved from SSRL to the NSLS and installed in SMERF in 1989.

The SMERF area (see Fig.2) is a 180 m^2 complex of rooms. Located at the end of the X17B wiggler beamline, it forms the separate X17B2 experimental station. Entry into SMERF is via doors opening to a hallway off the main experimental floor.

A set of stairs and an elevator lead one flight up from the hallway to a double door entrance through which patients and physicians enter. SMERF consists of the Reception Room for use by the patients and attending staff; the Fluoroscopy Room where venous catheterization occurs with the assistance of an x-ray fluoroscopy unit; the Angiography Room where the coronary angiography imaging procedure takes place and in which the patient chair and imaging detector are located; the Physician's Room where the Responsible Physician monitors and controls the imaging sequence; the Data & Control Room containing equipment for safety systems as well as imaging computers and monitors; and the Monochromator Room where the dual-beam monochromator and patient safety shutters are located. This experimental station can operate only when the upstream X17B1 materials science station is inactive and a transport pipe has been installed in the B1 hutch to bring beam back to the B2 Monochromator Room.

SMERF is classified as an Ambulatory Health Care Facility and meets the specified standard and emergency electrical and lighting requirements. The review process for facility approval has been extensive.[12] The protocols for human research in venous coronary angiography were reviewed and approved by the BNL Human Studies Review Committee as well as by the Institutional Review Boards of North Shore University Hospital and Stanford University.

Facility radiation shielding requirements focus on the two rooms through which white and monochromatic synchrotron radiation pass, the Monochromator and Angiography Rooms. The PHOTON program[13] was used to calculate the shielding requirements of the facility walls, windows, doors and beamline components. Bremmstrahlung shielding is placed in line with the white beam in the Monochromator Room. In addition to the above, the fluoroscope in the Fluoroscopy Room is an x-ray source. This room is also shielded with lead sheet.

Whereas access to and operation of the fluoroscope is under the administrative direction of the Responsible Physician, access to the Angiography and Monochromator Rooms is controlled by well defined electromechanical safety systems. The Monochromator Room is classified as a white beam hutch and operates using a standard NSLS Kirk key interlock system.[14] The Angiography Room operates in set-up and

patient modes, and access is allowed only by closure of the Monochromator Room fast-acting safety and photon shutters. Set-up mode is similar to standard NSLS monochromatic beam mode and, as such, the Kirk key interlocks are used. During patient mode the safety system is controlled by the APPI. In this case, Kirk keys are not used, but door switches are active. The Responsible Physician initiates the patient imaging sequence from a console in the Physician's Room. The purpose of the APPI is to protect the patient from excessive radiation dose due to malfunctioning imaging equipment or human error. Should a problem be detected, a fault is registered by the APPI and the fast-acting safety shutters close in less than 50 msec.

As an Ambulatory Health Care Facility, SMERF has medical equipment necessary for research and patient safety. In addition to an x-ray fluoroscope, monitor, and catheterization supplies, the facility has an ECG/Defibrillator unit and a crash cart. These pieces of equipment as well as standard medical supplies are stocked and maintained by BNL Medical Department personnel. Should a patient emergency occur, the research medical staff has prime responsibility for patient stabilization. Emergency response is provided by cardiologists as well as nurses who have had cardiac intensive care unit training and are advanced cardiac life support certified. To assist them, a fully equipped BNL ambulance and EMT staff may be called.

III. ANGIOGRAPHY IMAGING RESULTS

The angiography imaging system is essentially the same as the one used at SSRL.[1-4] Details of this system have been extensively described elsewhere. A schematic of the system is shown in Fig. 3. Two monochromatized fan x-ray beams, 120 mm wide and 0.5 mm high, are produced by a pair of asymmetrically cut Si(111) crystals. The energy difference of the two beams which bracket the iodine K-edge is about 150 eV and the energy width of each beam is about 75 eV. The beams converge and cross at the patient, then separate and are incident on a dual-beam Si(Li) detector. Each beam enters a linear array of 300 detector elements, 0.5 mm center to center and with a separation of 0.1 mm. The patient is translated vertically

through the fixed beams at 12 cm/sec while the detector is gated to collect a dual energy line image every 4 msec. The acquisition of a two dimensional image, constructed of 256 line images, takes about 1 sec. Motion artifacts are essentially eliminated by the 4 msec exposure of each line. The patient's ECG signal is recorded and correlated with the image phase.

The heart is imaged in several views and a single positioning frame is taken in each view to establish alignment of the patient. After the patient is positioned an imaging sequence of 4 to 6 frames is recorded, with the frames timed to correspond to the passage of the iodine bolus through the central circulation. The total radiation dose to a patient for a single imaging sequence is limited to 35 rads by the CRC protocol and to date has been far less than this amount.

As an example of a recent image, Fig. 4 is a left anterior oblique (LAO 45°) view of the right coronary artery (RCA) of a 44-year-old male taken in February 1991 at SMERF. During this run, the wiggler field was 4.4 T and the electron current was 180 mA. An increase in flux of about 40% was available for this run compared to previous runs because of new Si(111) crystals cut at a higher asymmetry angle. The angle was increased from 0.9 to 2.6 degrees. The catheter was inserted into the brachial vein and positioned with its tip in the high portion of the right atrium. The injection volume of contrast agent (Angiovist 370; Berlex) was 36 ml at 15 ml/sec. The radiation dose for this image was 0.7 rad. The patient received a total of 16 rads for the entire study, including the fluorsocopy during the venous catheterization.

The patient whose image is shown in Fig. 4 was known to have a totally occluded RCA based on a conventional angiogram done in October 1990. This venous synchrotron image clearly shows the occlusion distal to an acute marginal branch. A comparison of this image with images from previous patients shows a significant improvement in image quality. Details of the arteries as small as 0.7 mm (as quantified on the conventional angiogram) are now clearly defined. The additional flux and detailed alignment of the beamline optics led to the improvements.

IV. CONCLUSIONS

The SMERF facility is fully operational for coronary angiography. Future experimental runs will continue the evaluation of the optimal parameters for the imaging such as flux, contrast agent types and injection parameters, patient positions, chair and data acquisiton speeds, wiggler fields to control harmonic contamination of the images,[15] detector response functions and catheter position. The computer system is being upgraded to allow faster processing for real time imaging, direct data transfer to work-station-based processing, and larger memory. A new monochromator, currently under construction, is expected to significantly increase the monochromatic flux.[16]

Present plans for coronary research at SMERF are to continue the validation of the visualization of clinically relevant segments of the coronary circulation. Research programs are being planned to study the response of atherosclerotic disease in selected patient populations being treated with various drugs.

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Fig. 1. The x-ray spectrum generated by the X17 superconducting wiggler compared to a tungsten rotating anode x-ray tube.

Fig. 2. The floor plan for the SMERF facility.

Fig. 3. A schematic view of the arrangement of the imaging hardware installed in SMERF.

Fig. 4. Coronary angiogram of a human patient taken in a left anterior oblique view (LAO 45°) following venous injection of contrast agent. The right coronary artery (RCA), aorta (AO), venous catheter (CATH), and right ventricle (RV) are identified. The complete blockage of the patient's RCA is indicated by the arrow.

Flux Curves

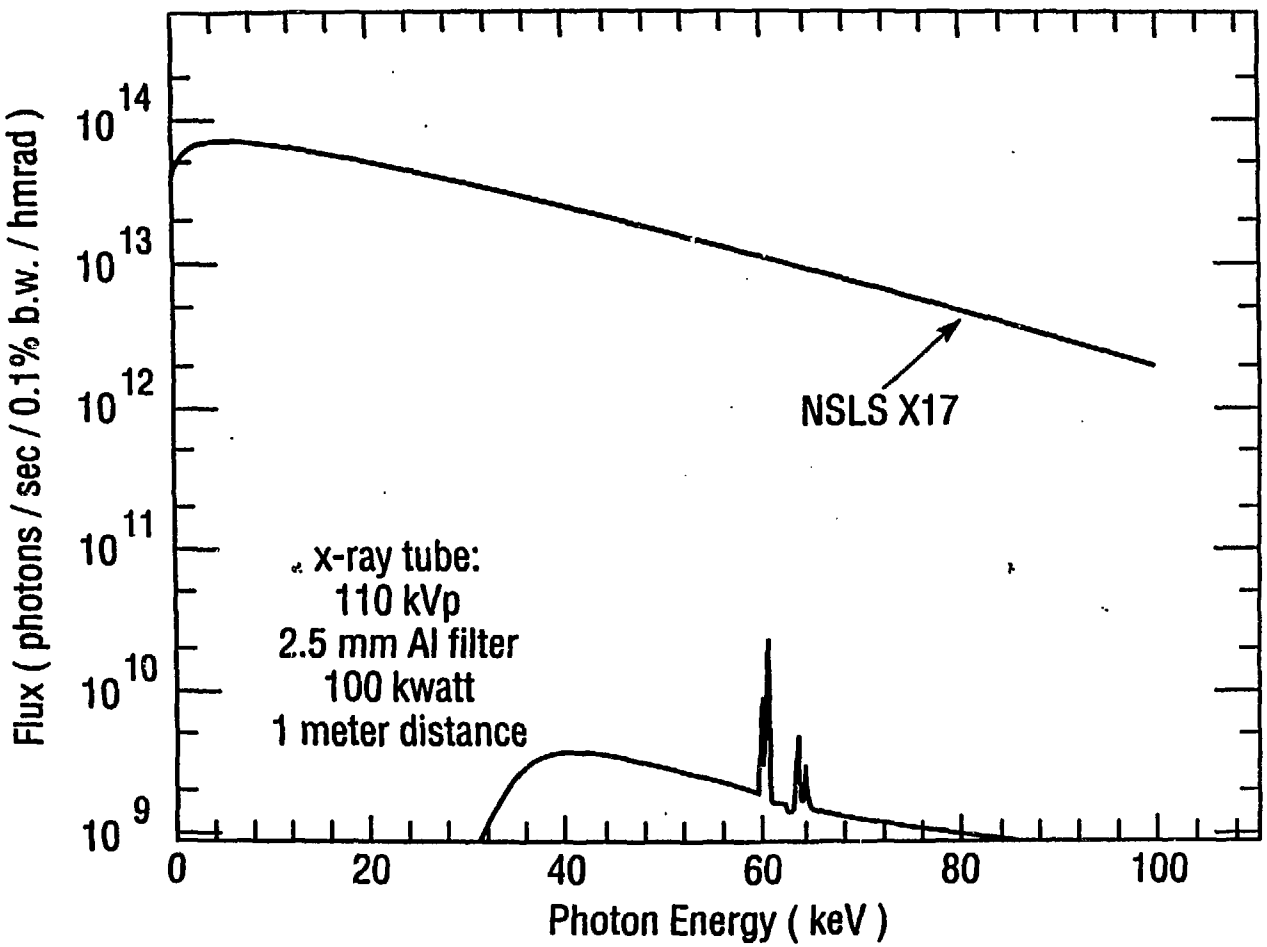


Fig. 1

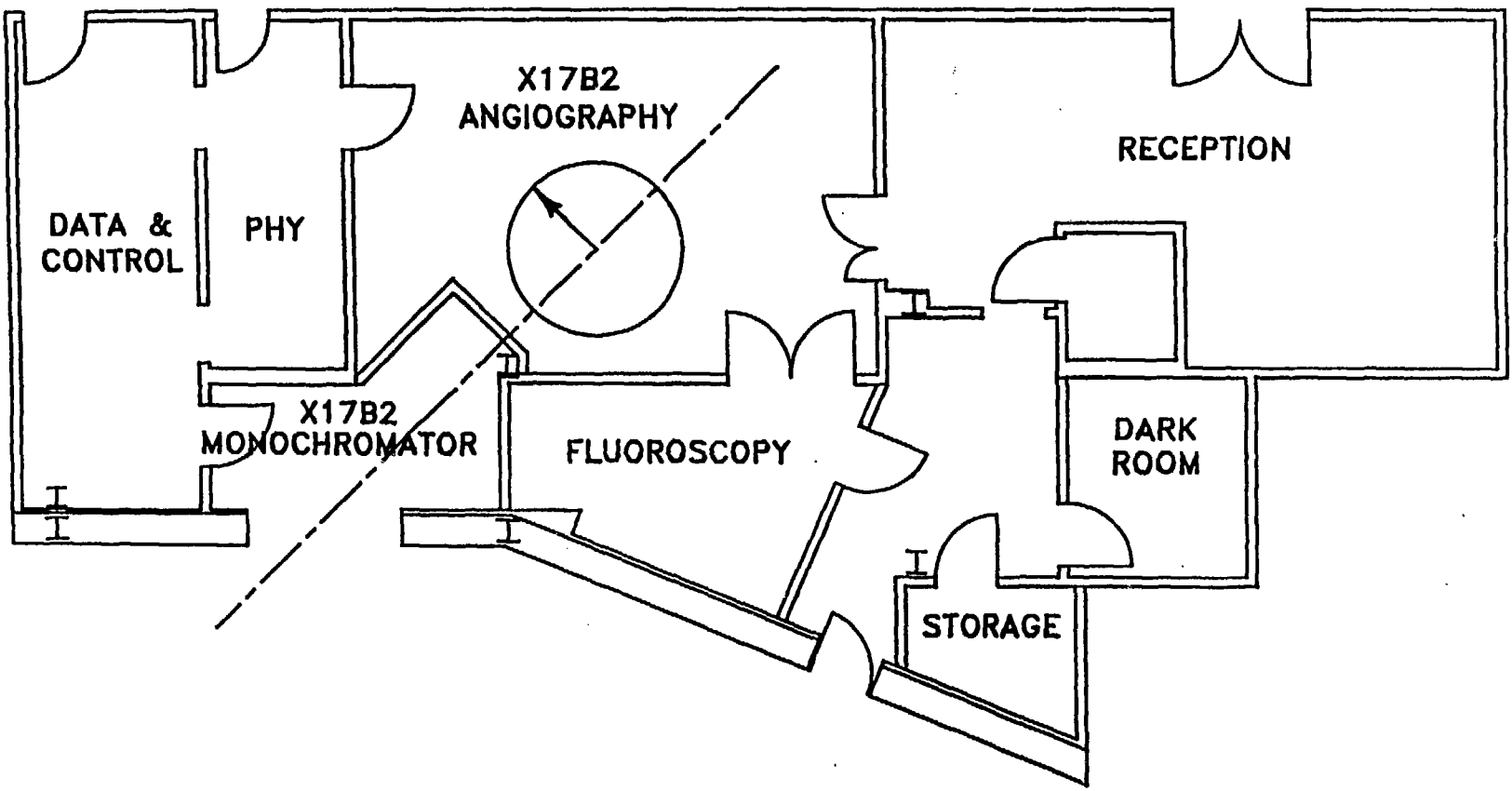

X17B2
ANGIOGRAPHY
RECEPTION
DATA &
CONTROL
PHY
X17B2
MONOCHROMATOR
FLUOROSCOPY
DARK
ROOM
STORAGE

Fig. 2

NSLS ANGIOGRAPHY BEAMLINE

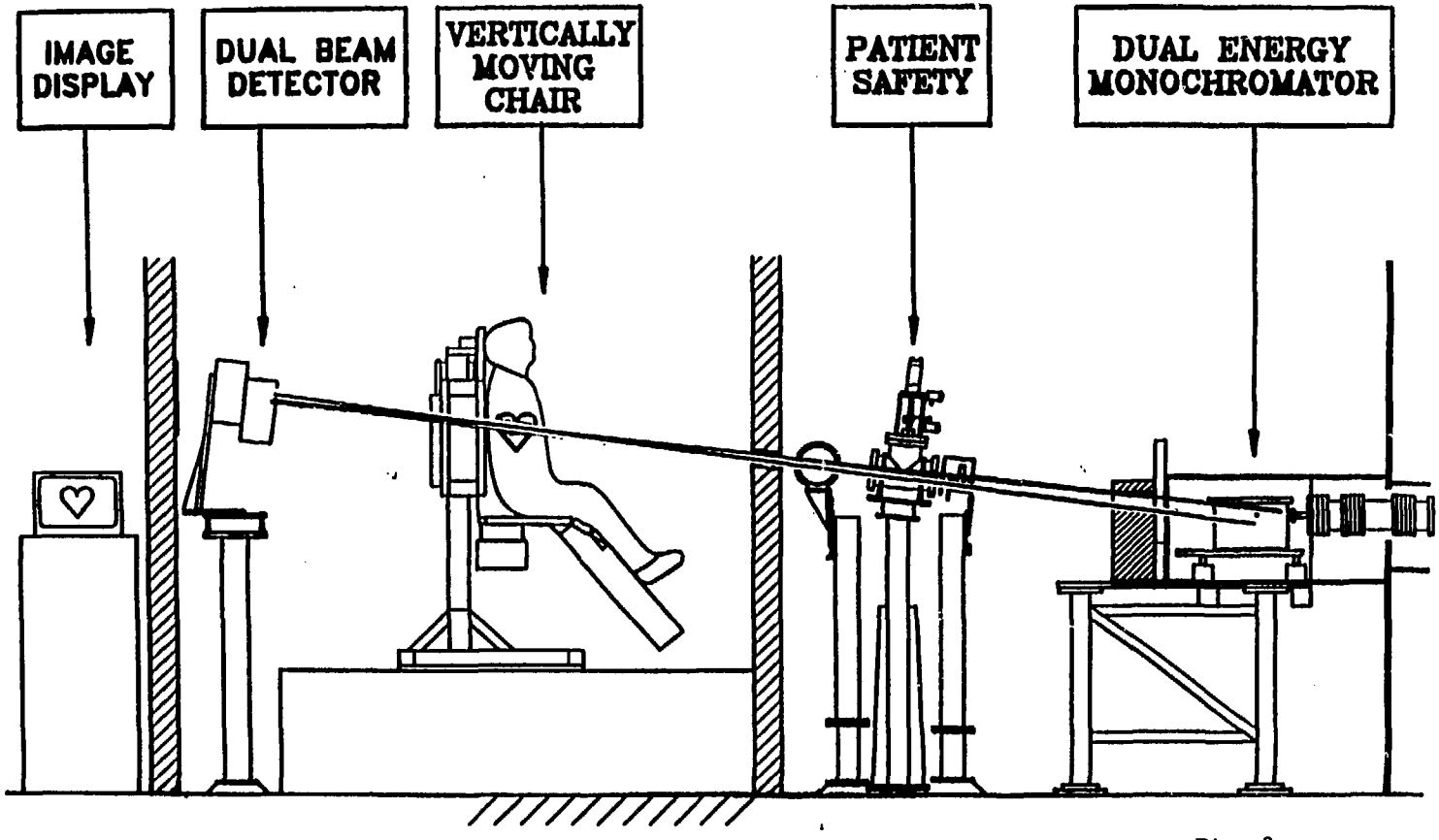
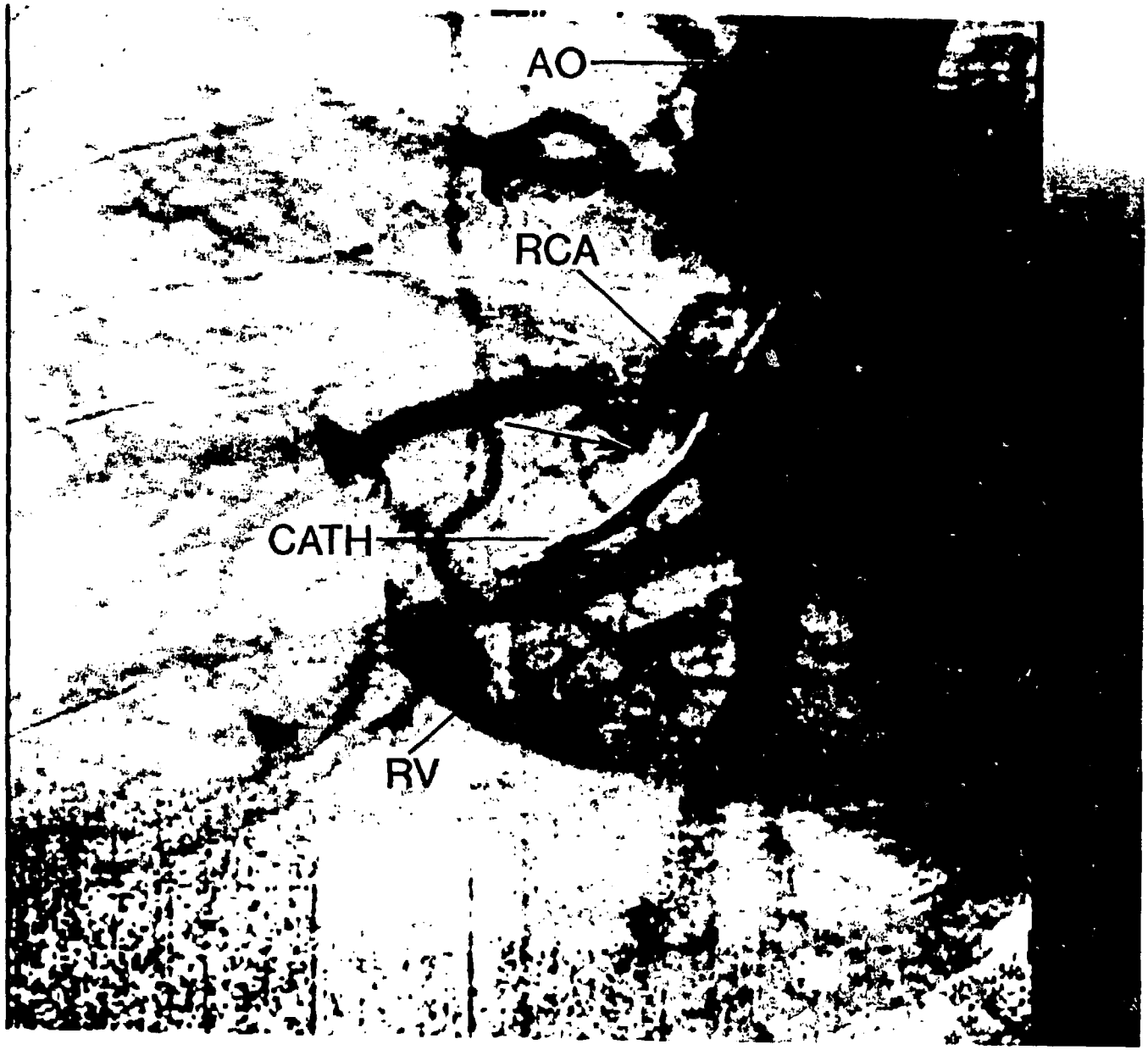


Fig. 3


AO
RCA
CATH
RV