JACC Vol. 24, No. 3
September 1994:834-7

ACC POSITION STATEMENT

# Cardiac Angiography Without Cine Film: Erecting a "Tower of Babel" in the Cardiac Catheterization Laboratory

AMERICAN COLLEGE OF CARDIOLOGY CARDIAC CATHETERIZATION COMMITTEE

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Recent advances in computer storage technology have made feasible digital acquisition, processing and archival storage of angiographic images obtained during cardiac catheterization. These evolving technical developments have the potential to significantly enhance invasive cardiac procedures, providing major benefits for both the cardiovascular practitioner and patient. However, the promise of digital angiography is accompanied by significant problems that threaten to undermine current efforts to replace cineangiographic film. Each of the manufacturers of radiographic equipment is developing "cineless" digital archiving systems for the cardiac catheterization laboratory, but none of the proposed devices are mutually compatible. Thus, an angiographic study generated in the laboratory supplied by a particular vendor cannot be viewed by a cardiologist with equipment installed by an alternative manufacturer.

## The Problem: Lack of Compatibility

Today, all the proposed digital angiographic archiving systems lack the one critical advantage provided by 35-mm cine film—worldwide compatibility. The lack of compatibility between digital archiving systems threatens to erect a "Tower of Babel" in the cardiac catheterization laboratory. These dangers are reminiscent of the competition during the 1980s between the Betamax and VHS videotape cassette formats. In the case of videotape, the absence of an industry-wide standard cost consumers billions of dollars and exasperated a generation of echocardiographers who were forced to maintain the capability to review both formats.

Industry sources estimate that as many as 10% to 15% of cardiac catheterization laboratories under current installation will lack cine capability. In Europe the percent is higher. The cavalier conversion to cine-less laboratories creates significant problems for both the patient and practitioner. Cardiologists depend on the compatibility of cine film as a routine means to exchange images for both clinical care and research. Patients frequently have coronary angiography performed at one hospital and cardiac surgery at another facility. The ability of physicians at both institutions to review cineangiograms permits uncomplicated transfer of care and avoids unnecessary repetition of imaging studies. Similarly, many clinical research studies, particularly investigations of thrombolysis and angioplasty, depend on quantitative angiography performed by a single core laboratory. The widely accepted standard provided by 35-mm film makes possible this interchange of research data. The proliferation of alternative, noncompatible archival systems is already beginning to compromise clinical research studies.

## Background of Digital Cardiac Imaging

To understand the origins of archiving problems and potential solutions, it is useful to review the operational principles and history of digital cardiac imaging. Current digital imaging systems use a conventional television camera for

This Position Statement was approved by the Board of Trustees of the American College of Cardiology on March 12, 1994.

Address for reprints: ACCEL Department, American College of Cardiology, 9111 Old Georgetown Road, Bethesda, Maryland 20814-1699.



0735-1097/94/$7.00

image acquisition. The video image is typically acquired simultaneously during cineangiography using a semisilvered mirror that divides the light output of the image intensifier into two parallel pathways. Before the early 1980s, the video image was typically recorded on videotape for review during the procedure. Videotape recording of angiography provides limited image quality and is suitable only for ensuring that the framing and image content are adequate.

The first rudimentary digital imaging equipment was introduced to the cardiac catheterization laboratory in 1981 and 1982. The principles underlying digital recording of video-generated images are relatively simple. The video camera output consists of an analog signal in which the voltage level of the video signal is proportional to the brightness. For digital angiography, the voltage-modulated video signal is *digitalized* using an analog to digital converter consisting of a computer chip that samples the video signal and assigns a numerical value to the intensity (voltage). This operation consists of subdividing the image into a series of boxlike subdivisions known as picture elements, or *pixels*. The number of pixels used to form the image determines the resolution, and the number of binary digits (*bits*) assigned to each pixel determines the gray scale resolution.

Typical modern cardiac imaging systems use a matrix of 512 × 512 pixels with 8 bits (*1 byte*) assigned to each pixel, thus providing $2^8$ or 256 gray levels. This process of analog to digital conversion requires a staggering quantity of data to encode cardiac angiography. A single 512 × 512, 8-bit image consists of 256,000 bytes, or 256 kilobytes, of data. At 30 frames/s, cardiac angiography requires storage of >7.5 million bytes (or 7.5 megabytes), and a complete catheterization can occupy as much as 1 billion bytes, or 1 gigabyte. By 1985, the arrival of large and fast computer hard disk storage systems made possible temporary storage of all of the angiograms obtained during a single patient study. However, until recently the enormous quantity of data storage needed to record cardiac angiography precluded long-term storage and thus limited digital imaging primarily to applications that require only in-room viewing.

Historically, the development of digital cardiac angiography has been gradual, characterized by a series of rapid developments interspersed with periods of relative quiescence. The history reflects both the evolution of the technology and the capacity of the cardiologist to understand and use this new imaging modality. Initially, digital angiographic equipment was quite limited in capability and considered too slow and cumbersome for most clinical imaging tasks. The pioneering investigators of this evolving technology concentrated their efforts on *digital subtraction*, a process whereby an image acquired before contrast injection is mathematically subtracted from all subsequent frames to remove non-contrast-containing background structures. Theoretically, this process, known as *mask mode subtraction*, could increase the visual detectability of contrast-containing structures, enabling development of unique applications such as intravenous ventriculography.

The clinical application of digital subtraction angiography was highly problematic. Intravenous ventriculography was unattractive as a means to quantify ventricular function in an era of rapid development of noninvasive imaging techniques, such as echocardiography and nuclear ventriculography. Digital subtraction coronary angiography was hampered by a particularly troublesome problem known as *misregistration artifact*, produced by patient motion during the interval between acquisition of the mask and contrast-containing frames. However, digital angiography (without subtraction) discovered many new advocates in the mid-1980s during evolution of percutaneous transluminal coronary angioplasty.

## Advantages of Digital Imaging

In the coronary angioplasty era, the advantages of digital angiography are manifold. The image quality provided by digital angiography is significantly better than any videotape format. Improvements in computer speed and processing capability enable virtually instant replay of high quality images with random access to any injection sequence within a few seconds. During angioplasty, the instant imaging capability of digital angiography enables evaluation of the results of each balloon inflation before proceeding with the next. Complications such as intraluminal thrombus and dissection can be rapidly identified and appropriate action initiated. Injection sequences can be reviewed in a continuous *cine loop* at virtually any replay speed. Digital angiography permits close examination of a magnified portion of the image to study the structural details (*zoom*). Although digital subtraction proved impractical, most current digital angiography systems use some form of image enhancement (*filtration*) to improve image quality.

In many laboratories, the availability of high quality imaging during catheterization permits diagnostic and therapeutic catheterization to consist of a single procedure, a capability with significant implications for the cost of interventional procedures. Industry sources now estimate that >75% of laboratories under current installation are equipped with digital imaging capability. Cardiologists have become so comfortable with digital imaging that it seems natural for many practitioners to desire the elimination of cine film.

## The Standardization Problem

However, in the rush to replace cine film, both practicing cardiologists and manufacturers have overlooked the standardization problem—an oversight that now threatens the future of digital imaging. In some cases, the conversion to cine-less catheterization has resulted in irrational and insupportable archiving strategies. For example, some laboratories have elected to store digital angiographic studies on analog Super-VHS videocassette tape. Unfortunately, virtually all analog videocassette tape formats result in significant image degradation, offering at best only about one-half the resolution of the original digital image. Analog videocassette tape angiograms are inadequate for clinical decision making and unacceptable to most core laboratories for quantitative angiography. Other

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vendors have adapted digital videotape for long-term archiving of catheterization studies. Although image quality is much better than analog videotape, not all digital videotape devices incorporate a computer interface—a shortcoming that could impair facile interchange of angiographic studies between centers. Other proposed systems use data compression to enable storage of complete studies on limited-capability media. However, high levels of data compression may produce measurable image degradation with an uncertain clinical impact. Thus, none of the currently available analog or digital archiving systems meet all of the requirements for cine replacement.

There is little doubt that some form of digital storage will soon replace cineangiography. The advantages of this conversion are numerous and reflect the fundamental advantages of digital archiving methods over cine film. Computer storage will enable duplication of digital studies, with each copy retaining quality identical to the original. Advanced networking and communications technologies will permit immediate viewing of angiograms from anywhere within a hospital or clinic. Eventually, rapid long-distance communications will permit remote review and consultation. Digital archiving also provides an opportunity to reduce the cost of cardiac catheterization. Current estimates indicate that 35-mm film, processing and storage cost an average of ~$100/patient. Eventually, the expense of digital storage of data required for cardiac catheterization (~1 gigabyte) will decline to a few dollars, perhaps even a few cents. Many authorities in the field of digital storage technology confidently predict that an entire angiographic study will be stored on a credit card-sized medium carried in the patient's wallet.

In this context, the liabilities of the current rush to digital conversion can be fully appreciated. Digital interchange standards must provide for the ability to review images generated in any laboratory, regardless of manufacturer. Nothing less is acceptable. Laboratories that adopt nonstandard digital archiving technologies will compromise the retrievability of patient records or confront major expenses to translate archives into a standard format. It is likely that any hospital embarking on this course of action will invest in costly technology that will require replacement within a few years. In a worst case scenario, legal problems may complicate the inability to retrieve unique patient records.

## Standardization Effort

The Cardiac Catheterization Committee of the American College of Cardiology (ACC) is coordinating efforts to develop and promote a standard for archival storage and exchange of digital cardiac angiography. The Committee has joined in this common cause with an industry organization, the National Electrical Manufacturers Association (NEMA), and representatives of the American College of Radiology (ACR). The ACR and NEMA have worked together for many years to promote exchange of radiologic images and have recently released an interim standard known as Digital Imaging and Communications in Medicine (DICOM Version 3.0). This alliance maintains the opportunity for cardiac imaging workstations to review studies generated by other imaging modalities, including general radiography, computed tomography and magnetic resonance imaging. Parallel efforts have been initiated by the European Society of Cardiology (ESC) and the American Society of Echocardiography (ASE). The ASE is focusing on development of appropriate standards for cardiac ultrasound. The closest possible liaison between these organizations will be required to achieve a common standard.

The initial efforts of the ACC-NEMA committee have focused on the adoption of a file format and physical medium for interchange of digital angiographic studies. An interchange medium would permit transfer of angiographic studies between centers with digital systems manufactured by different vendors. Thus, a proprietary archiving system could be used internally within a medical center while maintaining compatibility for external data interchange. When the need arises to transfer images between medical centers, a DICOM-compatible file would be generated by the sender for review by the receiver. However, if proprietary archiving devices are involved, two transformations of the digital data would be required: conversion from the sending system to the interchange medium and reconversion from the interchange medium to the digital system at the receiving end.

Some ACC representatives believe that it would be preferable for a single common medium to serve as both the interchange and final storage archive, an approach analogous to 35-mm cineangiographic film. However, vendors are reluctant to abandon proprietary archiving technologies, and none of the current storage media meet all of the necessary criteria for both the interchange and archival storage of images. In addition, not all authorities agree that a single common medium for archiving and storage is desirable. Thus, the final structure of the future digital archiving standard remains controversial. Accordingly, the ACC-NEMA committee has focused on the selection of an interchange format and medium as the necessary first step in the standardization effort. A demonstration of the evolving interchange standard will be conducted at the ACC Scientific Sessions, March 1995, in New Orleans, Louisiana.

## Requirements for Cine Replacement

For the ultimate replacement of film by digital angiography, the ACC Cardiac Catheterization Committee has outlined the clinical and research requirements for replacement of cineangiography. These include image quality no less than currently provided by cine film and the capability of 30 frames/s acquisitions. The Committee has also stipulated that all imaging data should be stored and not a clinically "edited" subset. The special needs of pediatric cardiac catheterization (e.g., biplane) are being addressed by appropriate ACC representatives. The Committee has emphasized the need for a single-unit patient record and the importance of high speed *random access* to imaging sequences from a low cost cardiac workstation. Although, cine film currently provides only serial access to images, the Committee believes that future cine-less archiving systems should offer the improved ergonomic features provided by random access viewing.

## Recommendations

Many potential strategies for achieving these goals are feasible, including both digital tape and disk-based archiving devices. Direct viewing of digital tapes typically provides only serial access to angiograms, although transfer ("uploading") of images to a high speed disk system can partially ameliorate this deficiency. Currently available disk-based storage devices are either too slow for 30 frames/s review or lack adequate storage capacity. Thus, the ideal film replacement strategy awaits further maturation of the digital storage technology. None of the currently offered proprietary archival systems meets all of the needs of the cardiovascular practitioner and patient. More important, no current system provides the worldwide compatibility of 35-mm film. Although the standardization process may slow down the transition to digital catheterization, the resulting uniformity and reduced cost will be worth the wait. In the long term, patience now will ensure the development of powerful future capabilities that will improve the quality and efficiency of cardiac angiography.