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Feasibility of Off-Pump ASD Closure Using Real-Time 3-D Echocardiography

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Stephen W. Downing, MD,[1] William R. Herzog, Jr., MD,[1] Michael C. McElroy, RDCS,[2] Timothy B. Gilbert, MD[1]

[1]University of Maryland School of Medicine, Baltimore, MD
[2]Volumetrics Corporation, Durham, NC

Dr. Downing

ABSTRACT

Background: If surgeons could "see" through blood and cardiac chamber walls, it would ultimately be unnecessary to open the heart or use cardiopulmonary bypass to perform procedures such as atrial septal defect (ASD) closure or mitral valve repair. Conventional echocardiography generates cross-sectional images that are not satisfactory as the only visualization for surgical procedures, and current 3-Dimensional (3-D) CT and echo systems take several minutes to compose and process a single still frame. Recently, however, the first system for real-time 3-D echocardiography has been developed. This study examines whether real-time 3-D echocardiography can provide images of sufficient anatomic definition, depth perception, and image resolution to substitute for optical visualization in performing ASD closures.

Methods: A prototype Volumetrics 3-D echocardiographic system was evaluated in a water bath on a complex-surfaced standard reference model to determine the image resolution and define the ideal imaging parameters. A static image and views of sutures being placed with an endoscopic needle driver and two commercial suture placement devices were evaluated at multiple angles and distances from the target. The resulting images were graded by a blinded reviewer. Once the best imaging parameters were determined, five porcine ASDs were closed with interrupted sutures, running sutures, or a pursestring suture using only echo visualization.

Results: The highest quality images were obtained with the probe at a distance of 4-6 cm and at angles perpendicular or 45 degrees forward to the target. Spatial and temporal resolutions were adequate to suture all ASDs closed under only echo guidance.

Conclusions: The evaluated real-time 3-D echo system provided adequate spatial and temporal information to act as a guide for surgical procedures.

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Address correspondence and reprint requests to: Stephen W. Downing, MD, Cardiac Surgery, Suite N4W94, University of Maryland Medical Center, 22 S. Greene Street, Baltimore, MD 21201 USA, Email: Sdowning@smail.umaryland.edu

BACKGROUND

The first major intra-cardiac operations such as atrial septal defect (ASD) closure and mitral commissurotomy were done without the aid of cardiopulmonary bypass (CPB) [Cutler 1924, Harken 1951, Gross 1952, Watkins 1952, Gross 1953, Watkins 1955]. The major shortcoming of these procedures was that they were performed blindly, often with the surgeon's finger as the only guide, and the accuracy was less than desired. The advent of CPB allowed surgeons an unimpeded view of their targets, and open procedures on CPB rapidly became the standard for heart surgery [Fedak 1998].

It is our hypothesis that if a surgeon could replace direct vision with a robust, high-resolution imaging technology, a number of intra-cardiac procedures such as mitral valve repair and ASD closures could be performed without CPB and its attendant morbidity [Downing 1992, Edmunds 1995, Brasil 1998].

Prior work by our laboratory has demonstrated that it is possible to suture the mitral valve in the beating heart using echocardiographic guidance alone [Downing 2001]. However, the difficulty of performing a complex procedure in three dimensions (3-D) while being able to see only a "slice" of the target area in two dimensions was obvious.

There are several systems currently available for generating 3-D echo images, but these generally require time-consuming off-line processing to generate each image. This delay renders these systems impractical for use as an active surgical guide. To overcome this obstacle, we evaluated a recently developed real-time 3-D echocardiographic system. We believed that this real-time 3-D echo system could generate images with sufficient spatial and temporal resolution to function as the sole guiding system for simulated ASD repair.

MATERIALS AND METHODS

A Volumetrics (Volumetrics, Durham, NC) 3-D echocardiographic imaging system with surface-rendering architecture was used. This system uses a unique echo probe with a 2.5 and 3.5 MHz matrix phased array design that collects a

Table 1. Scoring system for rating echo images.

Score	Description
1	Murky, can only make out general form
2	Less clear, some details visible
3	Clear, most details visible
4	Very clear, all details visible
5	Video quality

Table 2. Results of image quality score for task performance. The three highest scoring views are displayed. The scoring system is detailed in Table 1.

Distance from target	Orientation to target	Mean score	Standard deviation
4 cm	Perpendicular	2.38	0.79
4 cm	45° forward	2.43	0.87
6 cm	Perpendicular	2.87	0.46

volume of information (as opposed to a slice) with each scan (Figures 1, and 2,). This device samples 20 frames per second and generates on its monitor a B scan, a C scan, and a volume image (Figure 3,). The orientation of the target object on the screen is controlled by means of a rollerball.

The ideal operating parameters for using this system (best transducer position and best transducer angle to target) were unknown. To define these parameters, a water bath model was examined. A standard reference object—a complex 3-D object with several distinct surface features of known size and shape—was submerged in the water bath (Figure 4,). Video clips were recorded during a repeated series of standard maneuvers and were later reviewed and scored for both surgical utility and visual clarity. The maneuvers consisted of grasping the object with an endoscopic grasper (Genzyme, Boston, MA) in the operator's left hand, then manipulating the target's "eyes" and "ears" with a separate grasper in the operator's right hand (Movie 1,). Next, a suture was placed through the target's "ear" with an endoscopic suturing device (Figure 5,) (Autosuture, US Surgical Corp., Norwalk, CT). The operator was blind to the target and operated only under echo guidance.

The transducer was evaluated in positions that were 2, 4, 6 and 8 cm from the target, at angles perpendicular to the target, 45° forward, 45° backward, and 45° lateral to the target. The images were scored by three blinded reviewers who were experienced in conventional cardiac ultrasonography. Scoring was on an arbitrary 1-5 scale (see Table 1,) for surgical utility and temporal resolution. Spatial resolution (fine features on the model surface) was scored separately.

After determining the best operating parameters, 15 model ASD defects of 2 x 5 cm were created in Teflon felt sheets (Movie 2,). These defects were sutured closed using only the echo for guidance. Sutures were placed in a multiple interrupted fashion (Movie 3,) (n = 5), a running continuous fashion (n = 5), or as a pursestring (Movie 4,) (n = 5) (see Figure 6,). Each suture was tied with an endoscopic knot pusher.

In addition, the intra-atrial septa from five slaughterhouse pig hearts were mounted in the water bath and the septum secundum regions were excised to create an ASD. These were then closed using interrupted or pursestring sutures.

RESULTS

The best images were obtained at distances of 4-6 cm from the target with the probe either perpendicular to the object or angled 45° forward from it. The results for the best views are summarized in Table 2 (). The mean score was approximately 2.5 (between "Clear, most details visible" and "Less clear, some details visible"). The resolution of the smaller model details is displayed in Table 3 () and Figure 2 (). Details down to 1 mm were reasonably well seen. All 15 felt defects were successfully closed by the three suture methods. The five porcine ASDs were closed with either interrupted (n = 3) or purestring (n = 2) sutures. Representative images are shown in Figures 7A and 7B .

DISCUSSION

The idea of using image guidance to perform intra-cardiac surgical procedures is not a new one. Both Graham and Wilson in the 1920s independently described the use of a cardioscope inserted into the atrium to guide diagnostic and therapeutic procedures [Allen 1922, Wilson 1930]. Catheter-based ASD closures and balloon mitral commissurotomies, as well as atrial and ventricular arrhythmia ablations, are commonly performed in the cardiac catheterization laboratory under echocardiographic and fluoroscopic guidance [Cohen 1993, Olgin 1997, Chiang 1998, Tardif 1999]. However, the imaging modalities do not provide enough information to replace a surgeon's vision as the sole guide for operating.

If a robust imaging technology could be identified and developed that would allow a surgeon to "see" through the blood and cardiac chamber walls, a number of traditionally open, on-bypass procedures could be performed on the beating heart without cardiopulmonary bypass. Access to the heart could be obtained through a valved port placed in the atrium via a lateral mini-thoracotomy or possibly by thoracoscopic techniques.

Work from our laboratory in a pig model of mitral valve surgery has shown that safe access to the interior of the heart can be obtained through a cardiac port placed in the left atrium. However, conventional echo imaging functions only

Table 3. Results of image detail resolution testing. Scores for the three best probe positions are displayed for features of 1, 4, 10 and 15 mm. The scoring system is detailed in Table 1.

Distance from target	Orientation to target	1 mm linear	4 mm round	10 mm thick	15 mm tall
4 cm	Perpendicular	3	2	4	3
4 cm	45° forward	3	3	4	3
6 cm	Perpendicular	3	3	4	3

adequately as a surgical guide. Although standard echo images are obtained and displayed in real-time, they are only 2-dimensional. Most surgical maneuvers require instantaneous information in three dimensions for their completion.

Among the imaging systems that could provide real-time 3-D imaging are echocardiography, CT scanning, and MRI. Real-time CT scanning has been used to guide lung biopsies and bronchoscopies, but a true real-time 3-D system has not yet been developed. CT also has the drawbacks of high cost and exposure to ionizing radiation, as well as requiring a large scanning ring around the patient to obtain images. Theoretically, MRI has the most potential to generate real-time 3-D images. MRI scans can be performed in milliseconds, and instantaneous volumes of information of very high resolution can be obtained. The three major disadvantages of MRI are its high cost, the bulkiness of the equipment, and the strong magnetic fields it generates, which would interfere with most traditional operative instruments and monitoring systems.

There are several commercially available 3-D echo systems, such as that made by TomTec (TomTec Imaging Systems GMBH, Unterschleissheim Germany), that generate 3-D images off-line using multiple 2-D images obtained from a transesophageal echocardiograph (TEE) probe or similar device. A volume of image data is obtained by moving the probe at a known speed across the target area. These views can take several seconds to generate, and thus are not practical as a real-time guide. (By comparison, in surgical robotics, millisecond delays are not acceptable for real-time work).

The Volumetrics prototype we used operates on a different principle. On the echo transducer head, there is a matrix of crystals (as opposed to a simple linear array), which enables the system to obtain 20 volumes of information per second (down to a depth of 16 cm). Although the acquisition rate is only one-third the rate of a standard 2-D echo system, the volume of data contains a significantly larger amount of spatial information and allows the generation of real-time 3-D surface or volume renderings.

The Volumetrics system obtained its best images at distances that were 4-6 cm from the target, with the transducer perpendicular to the object or angled 45 degrees forward from it. This distance represented the best compromise between image quality and view of the entire field. The echo system obtains a "pyramid" of data. The farther away from the transducer a particular object is located, the farther spaced the imaging nodes are; thus, the resolution will decrease as the distance from the probe increases (apart from any signal degradation due to interference and reflection). The image clarity is highest when there is maximal reflection of the ultrasound waves back to the transducer from the target. This generally occurs when the transducer is directly perpendicular to the target.

The image seen on the video screen can be manipulated by the use of a trackball that allows the operator to view the target from any angle without moving the image transducer. This is a significant advantage over conventional optical 2-D systems because it allows the surgeon to see "under an object." For example, the waterbath model was designed to mimic a transducer position on the right atrial appendage, with a view of the ASD from the right atrium. When the suturing device obscured the view of the target, the image could be rotated to a left atrial or lateral view to allow the operator to see the target from the side or from underneath. The most accurate positioning of the instruments often occurred when using multiple views.

The temporal resolution, while only one-third the speed of conventional video images, was more than adequate. The surface renderings occasionally have a slightly choppy appearance, but not to an extent that would interfere with the procedure. The temporal resolution may be more of an issue when operating on a target that is moving rapidly, such as a valve leaflet.

The detail resolution of this first generation system was acceptable, with details down to 1 mm being scored in a range between "clear, most details visible" and "less clear, some details visible." This image resolution was more than adequate for guiding the closure of all 20 ASDs in the water bath model. Operating under 3-D guidance is clearly superior to operating under 2-D guidance, even with allowance made for the decreased resolution of currently available 3-D systems. Although the Volumetrics system proved adequate as an image guidance technology overall, improved detail resolution will be needed to advance from simulation into a clinical setting.

The prototype imaging system we tested is not commercially available at the present time. In addition to the Volumetrics system, real-time 3-D echo systems are currently under development at other corporations (personal communication: Mary Bianchi, Phillips Medical). Several companies are likely to have commercially available systems within the next year. As this technology continues to advance, high quality real-time 3-D images will become commonplace in the operating room.

Among the three suturing methods tested, the interrupted suture technique was the most familiar and the simplest. However, with multiple sutures in the field, there was occasionally some tangling and hooking on the previously placed sutures, as the sutures are hard to see on echo. This problem was completely avoided by the use of a pursestring technique. However, a pursestring approach would most likely be useful only for smaller defects.

We view this model primarily as a first step in the development of the methods and equipment necessary to perform an array of intracardiac procedures on the beating heart. These procedures would include mitral valve repair and replacement, atrial arrhythmia surgery, and septal defect closure.

Among the currently available procedures for ASD closure, both surgical [Kappert 1999] and catheter-based approaches have excellent results and low complication rates. However, if a surgical approach could be accomplished with an incision size close to that of catheter-based techniques, and the patient could avoid the risks of an implanted device (embolization, infection, malposition, late erosion, fracture, and migration) [Chan 1999, Cooke 1999, Berdat 2000], a minimally-invasive, off-pump surgical approach would offer significant advantages.

CONCLUSIONS

The Volumetrics 3-D echo probe generated real-time 3-D images of adequate spatial and temporal resolution to guide a number of surgical maneuvers. Complex manual maneuvers, such as grasping and suturing and ASD closure, were possible using 3-D imaging alone in a simulation setting. As a surgical guide, 3-D imaging is clearly superior to 2-D imaging. Upcoming developments in instrumentation, imaging systems, and techniques will likely allow the performance of multiple types of beating heart intracardiac surgery in the near future.

Disclosure

Michael McElroy is an employee of Volumetrics Corporation, who provided technical guidance.

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