Computerized Medical Imaging and Graphics 50 (2016) 24–30

Contents lists available at ScienceDirect

Computerized Medical Imaging and Graphics

journal homepage: www.elsevier.com/locate/compmedimag

Phantom study of an ultrasound guidance system for transcatheter aortic valve implantation

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ARTICLE INFO

Article history:
Received 13 May 2014
Received in revised form
28 September 2014
Accepted 2 December 2014

Keywords:
Transcatheter aortic valve implantation
Transapical
Mixed reality
Image guidance
Fluoroscopy
Echocardiography

ABSTRACT

A guidance system using transesophageal echocardiography and magnetic tracking is presented which avoids the use of nephrotoxic contrast agents and ionizing radiation required for traditional fluoroscopically guided procedures. The aortic valve is identified in tracked biplane transesophageal echocardiography and used to guide stent deployment in a mixed reality environment. Additionally, a transapical delivery tool with intracardiac echocardiography capable of monitoring stent deployment was created. This system resulted in a deployment depth error of 3.4 mm in a phantom. This was further improved to 2.3 mm with the custom-made delivery tool. In comparison, the variability in deployment depth for traditional fluoroscopic guidance was estimated at 3.4 mm.

1. Introduction

Transcatheter aortic valve implantation (TAVI) is a safe and effective treatment for aortic stenosis in patients unsuitable for conventional surgery [1]. As a result, this stent-based technique for delivery of a bioprosthetic valve has been used in over 40,000 patients worldwide [2]. This minimally invasive technique relies largely on single-plane fluoroscopy, with only gross structures visible [3]. In addition, the contrast agents injected into the aortic root during fluoroscopic guidance are nephrotoxic and can increase a patient's risk of acute kidney injury [4–7]. This is a major concern as many TAVI patients have underlying renal dysfunction and are more vulnerable to acute kidney injury. Furthermore, fluoroscopic imaging exposes both the patient and physicians to ionizing radiation. While the radiation dose for a single procedure is low, the cumulative radiation exposure of health care professionals at centers with a high throughput of TAVI is a concern [8].

There have been several proposed alternatives to single plane fluoroscopy that aim to improve stent placement and reduce or eliminate the use of nephrotoxic contrast and ionizing radiation, including rotational angiography, magnetic resonance imaging (MRI), and transesophageal echocardiography (TEE) guidance. In rotational angiography, an intraoperative cone beam computer tomography (CT) volume is acquired by rotating a C-arm around the patient. This volume can be used to generate models of the aortic root which are overlaid on the fluoroscopy images to provide more anatomical context and can also be used to select the ideal fluoroscopy imaging plane [9]. This technique requires contrast and ionizing radiation to acquire the intraoperative CT volume and for fluoroscopy throughout the procedure. Alternatively, intraoperative MRI has been used to guide placement of the valve stent, resulting in successful implantation in animal studies [10]. Although this technique eliminates contrast and radiation exposure, intraoperative MRI is expensive and not widely available [11].

Intraoperative ultrasound provides a more attractive modality for image guidance since it does not require nephrotoxic contrast agents or ionizing radiation in addition to being inexpensive and easily integrated into surgical workflow. TEE is frequently used during TAVI procedures for assessing valve function after the stent is deployed. Intraoperative guidance using only TEE [12] and TEE with fluoroscopy (without contrast agents) [13] has been previously

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http://dx.doi.org/10.1016/j.compmedimag.2014.12.001
0895-6111/

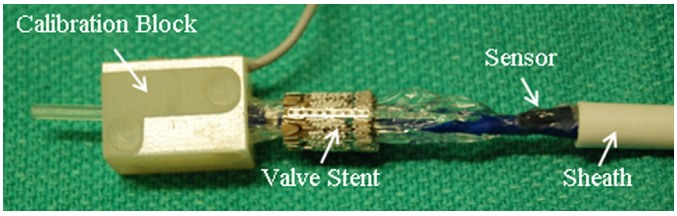

Fig. 1. Magnetically tracked catheter with crimped valve and calibration block. The sensor was affixed to the catheter tip just below the balloon as shown. The outer sheath can be moved up to completely cover the sensor. A ledge inside the calibration block allows the crimped valve to be held in a specific configuration so that the transformation between the catheter sensor and the prosthetic valve can be defined.

reported. However, TEE does not provide satisfactory imaging of the catheter or surrounding tissue due to the highly reflective surface of the catheter and resulting shadowing artifacts. For this reason, TEE has been proposed as a bridging modality allowing preoperative models to be registered into the intraoperative environment. Lang et al. [14], proposed using TEE to register preoperative CT models to fluoroscopy to improve image guidance without requiring rotational angiography. Luo et al. [8] proposed a system using magnetic tracking of the TEE and catheter to eliminate the need for fluoroscopy entirely. In this system, a preoperative model of the aortic root was registered to the tracked ultrasound. The tracked catheter could then be visualized in relation to the aortic model so that the stent could be deployed at the desired depth. One challenge of these techniques is that the registration between ultrasound and preoperative CT is difficult resulting in a target registration error of 5.9±3.2 mm and 3.3±1.6 mm respectively. In addition, both these works used a manual segmentation of the aorta from preoperative CT which is time consuming and difficult to integrate into clinical workflow. Previous work with mitral valve repair has found that simply defining the valve annuli from tracked TEE is sufficient for image guidance and eliminates the need for complex preoperative models and registrations with associated errors [15]. Here, a simplified guidance system using TEE and magnetic tracking is developed and validated against fluoroscopic guidance in a phantom environment. A preliminary version of this guidance system was presented in McLeod et al. [16]. In our current paper we extend the guidance system to make use of biplane ultrasound, develop a novel delivery tool and validate our methods against fluoroscopy in a phantom environment.

2. Methods

2.1. Image guidance system

The proposed guidance system consists of a mixed reality environment displaying real-time ultrasound along with the location of the tracked valve stent and the intraoperatively defined anatomy. In order to display the TEE images and catheter in a common frame of reference, both of these tools were magnetically tracked using the Aurora tabletop tracking system (NDI, Waterloo, Ontario). A 6 degree of freedom (DOF) magnetic tracking sensor was affixed to the Ascendra TAVI catheter (Edwards Life Sciences, Irvine, California) just below the balloon with the cable running inside the outer sheath of the catheter. The iE33 ultrasound system with an X7-2t TEE probe (Philips Healthcare, Andover, MA) was used and is capable of providing 2D, biplane and live 3D imaging. A second 6 DOF sensor was integrated into a custom-made cap that attaches to the TEE probe and calibrated using a Z-bar phantom. Once the valve was crimped onto the catheter, it was calibrated by inserting it into a tracked calibration block designed to hold the catheter shaft and valve in a precise configuration with the leading edge of the valve resting against a ledge inside the calibration block (Fig. 1).

The aortic valve can be defined intraoperatively by selecting points on the aortic valve in the tracked biplane ultrasound. These points, along with a tubular spline outlining the valve, are displayed in the guidance system and a targeting plane is then created at the ideal deployment depth. The remaining distance from the catheter to this plane is displayed numerically and the targeting plane changes color to indicate when the ideal deployment depth is reached (Fig. 2). When visible in the echo image, other pertinent anatomy including the coronary ostia can also be displayed in the guidance system.

2.2. Delivery tool with integrated ICE

One limitation of relying on mixed reality guidance is the lack of adequate imaging during deployment. In conventional procedures, live fluoroscopy video provides feedback to monitor deployment and fine tuning the position of the stent as the balloon is inflated. The image quality of TEE is very poor once the catheter and stent have entered the aortic valve, limiting its usefulness at this stage of the procedure. To overcome these issues a custom-made stent delivery tool with integrated ultrasound imaging was created for transapical procedures. The delivery tool contains a channel through which an intracardiac echocardiography probe can be inserted. The ICE probe acquires images through an acoustic window in the shaft of the tool. The prosthetic valve is positioned so that it partially covers the ICE transducer. This ensures that the leading edge of the stent will be visible in the ultrasound image. Calibration is performed using a similar method to the one used for the tracked catheter. The delivery tool is placed inside a calibration block with the leading edge of the valve resting against a ledge in the block. However, this calibration block is half open to accommodate the delivery tool and a tracked needle is used to locate the tip of the delivery tool so that both the tool and the valve may be tracked and visualized in the guidance system (Fig. 3).

The tool itself was manufactured through rapid prototyping, using VeroWhite material on an Objet30Pro printer (Stratasys, Eden Prairie, MN), and contained a channel for an AcuNav10F ICE catheter (Siemens, Erlangen, Germany). The outer diameter of the shaft was 14 mm to accommodate the fragility of the rapid prototyping material. In comparison, the TAVI introducer used in conventional transapical procedures is 10 mm in diameter and other transapical tools are of similar sizes. For instance, the Neochord (Neochord, Eden Prairie, MN) is a rigid tool being used successfully for mitral valve repair and is approximately 9 mm diameter. The diameter of the delivery tool could easily be reduced to under 10 mm if machined from stronger material. While the size and rigidity of the tool are unlikely to pose a problem for transapical procedures, it would be very difficult to create a similar system for transfemoral procedures as a small and flexible catheter is required for this approach.

2.3. Phantom

The phantom used in this experiment is a modified version of a custom-made system designed to simulate functional mitral and aortic valves. The phantom consists of a left ventricle, atrial reservoir, valve sheet containing mitral and aortic valves, and an actuator system. The ventricle has an apical access port to simulate interventions such as TAVI. In this instance, the phantom was made of a soft silicone (Shore A 30 durometer) while water was used to simulate blood. The inner diameter across the aortic valve was 23 mm at the commissures. To facilitate fluoroscopic imaging for this study, the aortic valve annulus was placed approximately 30 mm beyond the mitral valve plane, relative to the apical entry point. Experiments were performed in a static model to simulate rapid pacing, but a raised tower was attached beyond the aortic root to increase