Computers in Biology and Medicine 54 (2014) 109–115

Contents lists available at ScienceDirect

Computers in Biology and Medicine

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

Computer-aided design of the human aortic root

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ARTICLE INFO

Article history:
Received 31 January 2014
Accepted 22 August 2014

Keywords:
Aortic root
Computed tomography
3D modeling
Echocardiography
Finite element analysis

ABSTRACT

The development of computer-based 3D models of the aortic root is one of the most important problems in constructing the prostheses for transcatheter aortic valve implantation. In the current study, we analyzed data from 117 patients with and without aortic valve disease and computed tomography data from 20 patients without aortic valvular diseases in order to estimate the average values of the diameter of the aortic annulus and other aortic root parameters. Based on these data, we developed a 3D model of human aortic root with unique geometry. Furthermore, in this study we show that by applying different material properties to the aortic annulus zone in our model, we can significantly improve the quality of the results of finite element analysis. To summarize, here we present four 3D models of human aortic root with unique geometry based on computational analysis of ECHO and CT data. We suggest that our models can be utilized for the development of better prostheses for transcatheter aortic valve implantation.

1. Introduction

Transcatheter aortic valve implantation (TAVI) is a common procedure used for the treatment of patients with severe symptomatic aortic stenosis (AS) who are not candidates for open chest surgery. During the last decade, more than 50,000 implants in over 40 countries around the world have been placed, demonstrating the reliability and quality of this technique. Despite the fact that TAVI is a preferable option for many groups of patients, its implementation can be associated with a number of complications caused by prosthesis design, namely, prosthesis migration [1], coronary ostias occlusion [2] induced by the disproportion between the frame and the recipient's aortic root (AR), paravalvular regurgitation [3], and atrioventricular block [4].

Novel approaches in the development of prostheses for TAVI, for example finite element analysis (FEA), involve generating accurate 3D models of the AR. Previous studies demonstrated that FEA can successfully predict biomechanical behavior of prosthesis and therefore can help to foresee potential complications and risks [5–7]. Hence, the use of FEA may greatly favor the optimization of prostheses for TAVI and similar procedures.

There are two commonly accepted approaches for the development of 3D models of the AR [8,9]. The first approach involves the development of one general model for all patients with a simplified geometry of AR elements. The main drawback of this model is that the standardised size may not fit well to all patients. Another important problem is that this model does not account for the dynamic data of the main AR elements, such as aortic annulus (AA) and sinotubular junction (STJ) systolic/diastolic dynamics. Another technique that has become increasingly popular in recent years is the "patient-specific" computer-based design of the AR [10–12], which is based on the computed tomography (CT) or magnetic resonance imaging (MRI) of the organ. In this model, the prosthesis is tailored to the individual according to the parameters of the AR elements. Despite good reliability and accuracy, this approach requires the *de novo* construction of the model, which increases calculation cost and time spent on prosthesis development.

Here we report a computer-aided approach for the development of 3D models of the AR for TAVI. Having calculated AR elements in a large cohort of patients, we constructed 4 models of the AR based on size, in accordance with the standard numbering of classic frame prostheses [13]. Furthermore, our model can be used for the numerical simulation of prosthesis–aortic root

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Abbreviations: AA, aortic annulus; AR, aortic root; AS, aortic stenosis; CT, computed tomography; ECHO, echocardiography; FEA, finite element analysis; STJ, sinotubular junction; TAVI, transcatheter aortic valve implantation; TEE, transesophageal echocardiography

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http://dx.doi.org/10.1016/j.compbiomed.2014.08.023
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interaction and also may predict possible risks and complications during the implantation.

2. Materials and methods

2.1. Echocardiography

We examined 117 patients aged 18–81 with and without aortic valve disease using the transthoracic ECHO method ($n=58$ and 59, respectively). We used this approach not only because of its safety, but also because it is recommended as an optimal method for the evaluation of the aortic rim diameter [14]. All patients with aortic valve disease had AS with various degrees of aortic valve regurgitation (mild, moderate, moderately severe, and severe). ECHO was conducted using the ultrasound diagnostic scanner Vivid 7 Dimension (“General Electric”, USA) with the M4S-RS transducer at 1.5–3.6 MHz frequency. The diameters of AA and STJ and the distance between AA and STJ were measured in longitudinal parasternal position Fig. 1.

2.2. Computed tomography

In addition, we also used CT to measure AR elements. CT allowed us to reveal the sinuses of Valsalva, as their visualization is restricted by 2D ECHO [3]. We collected the data from 20 patients aged 60–65 years without aortic valvular diseases who underwent coronary CT. The analysis was performed using the Siemens Sensation SOMATOM 64 CT scanner (“Siemens”, Germany). Scan direction was craniocaudal, and CT characteristics were the following: field of view 200 mm, pitch 0.7 mm, tube voltage 120 kV, electrocardiogram sync 1 mm and section thickness 1 mm. The contrast agent Ultravist at iodine concentration of 370 mg/mL was used for intravenous injection at a dose rate of 1–1.5 mL/kg of body weight. The analysis of sections was performed in coronal, sagittal and axial planes. The sections were reconstructed at the Leonardo workstation (“Siemens”, Germany). 3D-reconstruction of the sections was made in MPR-mode with the maximum slice thickness of 1–3 mm and also using the VRT software (“Siemens”, Germany). CT images were analyzed according to the following criteria: the major and minor diameters of AA (Fig. 2A), the STJ diameter, the distance between AA and STJ, the height of coronary ostia (Fig. 2B), the depth of sinuses of Valsalva (Fig. 2C), and the ascending aorta flaring angle (right and left) (Fig. 2D). Considering the complexity of AR geometry, parameters such as AA–STJ distance and depth of sinuses were measured referring to all three valve leaflets. The height of coronary arteries was measured between AA and lower edge of their ostias for both vessels. The aorta flaring angles were measured in the 3D representation of CT data referred to the coronal plane for both sides of the aorta.

2.3. Statistical and computational analyses

Statistical analysis was performed utilizing the STATISTICA 8.0 for Windows software package (“StatSoft”, USA). The differences were tested using Student's *t* test for normally distributed continuous variables and Mann–Whitney *U* test for categorical variables. Means, standard deviations, and medians with quartiles were calculated to describe the characteristics of subjects involved in the study. Kruskal–Wallis test was performed when comparing three or more groups. The correlation between parameters was assessed with Spearman's rank correlation coefficient. Regression analysis was performed to evaluate the dynamic changes between systolic and diastolic parameters. P values less than 0.05 were considered as statistically significant.

All the parameters required for the design of 3D models were determined at peaks of systole and diastole. 3D models were created using the computer-assisted UGS NX 7.0 design software (“Siemens”, Germany). The modeling was based on the supporting elements (points, lines) in planes and sections, corresponding to the data obtained from ECHO and CT. Final 3D models were built by the consecutive connection of the supporting elements with second-order surfaces.

FEA validation of the developed aortic root models was performed using different parameters of material models obtained from literature [15,16]. ABAQUS 6.12-1 CAE software (“Dassault systemes”, France) was used for numerical simulation. For the determination of the optimal element size we performed the sensitivity analysis on the AR model “No. 19”. The starting mesh element size $0.1 \times 0.1\ \text{mm}^2$ was increased by the factor of 4 times, 9 times, 16 times and 25 times. During the analysis, the three parameters were measured: maximum von Mises stress, radial displacement, and calculation time. Calculation time was normalized to the one obtained with the initial mesh size. The analysis showed that the mesh size of $0.2 \times 0.2\ \text{mm}^2$ had a good agreement with the reference (deviation on stress and displacement did not exceed 5%) and acceptable calculation time (Fig. 3).

Based on the results of the sensitivity analysis, the model “No. 19” was meshed with 21 504 shell elements (S3 and S4 type). The artificial thickness of the shell elements was 0.8 mm for the AA zone, 1.3 mm for the sinuses of Valsalva, and 1.8 mm for the STJ [17]. To simulate the biological tissue behavior the following isotropic linear materials were used: the model with the Young's modulus (E) of 1.3 MPa and Poisson's ratio (ν) of 0.49 for the whole 3D AR (Fig. 4A) [16]; and the separate material description for the

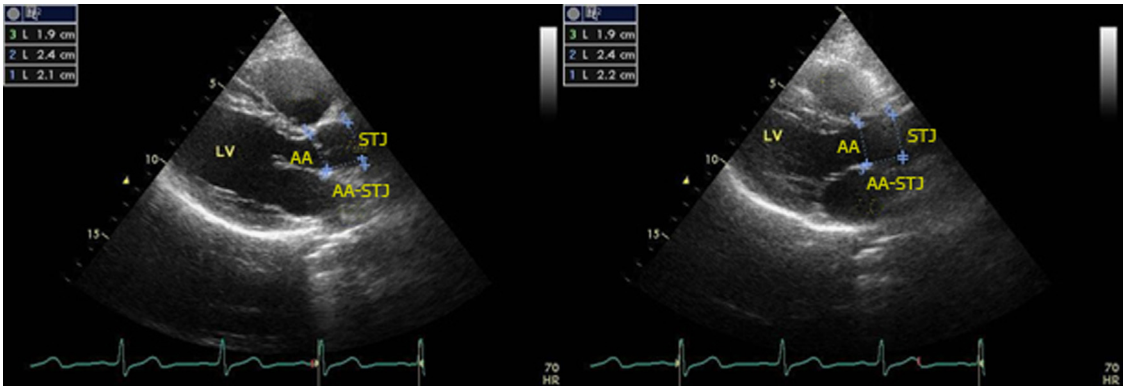

Fig. 1. The parameters measured by ECHO in diastole (left) and systole (right): AA diameter, STJ diameter, and AA–STJ distance. LV – left ventricle.