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A compliant aortic model for *in vitro* simulations: Design and manufacturing process

Stefania Marconi[a,*], Ettore Lanzarone[b], Guido H.W. van Bogerijen[c], Michele Conti[a], Francesco Secchi[e], Santi Trimarchi[c,d], Ferdinando Auricchio[a]

[a] Department of Civil Engineering and Architecture, University of Pavia, Pavia, Italy
[b] Institute for Applied Mathematics and Information Technologies, Consiglio Nazionale delle Ricerche (CNR), Milan, Italy
[c] Thoracic Aortic Research Center, IRCCS Policlinico San Donato, San Donato Milanese, Italy
[d] Department of Scienze Biomediche per la Salute, University of Milan, Milan, Italy
[e] Unit of Radiology, IRCCS Policlinico San Donato, San Donato Milanese, Italy

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ABSTRACT

We design and manufacture a silicone model of the human aorta, able to mimic both the geometrical and the mechanical properties of physiological individuals, with a specific focus on reproducing the compliance. In fact, while the models available in the literature exhibit an unrealistic compliant behavior, though they are detailed from the geometrical viewpoint, here the goal is to provide an accurate compliant tool for *in vitro* testing the devices that interface with the vascular system. A parametric design of the aortic model is obtained based on the available literature data, and the model is manufactured with a specific silicone mixture using rapid prototyping and molding techniques. The manufactured prototype has been tested by means of computed tomography scans for evaluating the matching of the mechanical properties with the desired ones. Results show a high degree of adherence between the imposed and the measured compliance values for each main aortic section. Thus, our work proves the feasibility of the approach, and the possibility to manufacture compliant models that reproduce the mechanical behavior of the aorta for *in vitro* studies.

1. Introduction

The pathophysiological behavior of the vascular system can be analyzed by means of different approaches, e.g., mathematical and numerical methods, *in vivo* analyses and *in vitro* tests. Among them, *in vitro* investigations of physiological/pathological fluid dynamic conditions help physiologists and clinicians in understanding the behavior of the vascular system and the impact of specific pathologies. Moreover, *in vitro* analyses support the design of prostheses and devices, and the pre-operative planning. The fluid dynamic behavior of prostheses and other devices meant to interface with the human vascular system, e.g., valves, vascular prostheses and stents, is commonly tested *in vitro* prior to *in vivo* for both ethical (limiting the number of animal experiments) and practical (*in vitro* experiments are cheaper than animal testing and allow for testing multiple experimental conditions in an easy and repeatable way) reasons [5,11,13,15,28,29,37]. As for pre-operative planning, *in vitro* investigations allow simulating surgical interventions and prosthesis deployments before the actual intervention on the patient, to compare different alternatives and find out the most suitable procedure [4,10,24,34].

Finally, we underline that several medical specialties have started to benefit from rapid prototyping in the last few years, especially for preoperative planning purposes, as clinicians prefer to deal with a physical object [26,30]. Moreover, the educational value of in vitro tools to train new surgeons is also recognized [22].

In all these cases, a proper reproduction of the pathophysiological conditions is crucial for the significance of the experiment; otherwise, the results obtained *in vitro* are not significant for the description of the target pathophysiological behavior. Two aspects must be accurately taken into account for a good reproduction: the generation of realistic pressure/flow characteristics inside the vessel and the accuracy of mechanical and geometrical features of the vessel wall.

Concerning the reproduction of the vessel mechanical and geometrical properties, two different approaches can be followed: a patient-specific or a general approach. Ideally, in the

* Corresponding author.
E-mail address: stefania.marconi@unipv.it (S. Marconi).

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patient-specific approach, geometries and mechanical properties are directly acquired from the patient by means of accurate imaging techniques or, more roughly, from clinical information. For example, the aortic stiffness can be estimated considering several Computed Tomography (CT) images acquired during the cardiac cycle [1], or through a regression method based on available clinical data [2]. Then, the experimental layout is built up to evaluate the peculiarities of the specific patient. This approach is useful for planning unconventional treatments on patients with uncommon or rare pathologies On the contrary, to derive general knowledge and to analyze the physiological behavior or the impact of common pathologies, working on general mechanical and geometrical configurations is the most effective approach. In this case, a faithful reproduction of the vessel properties requires including all possible information from the literature in order to design an *average* model that respects the general physiological features.

In the literature, to the best of our knowledge, there are no *in vitro* models of the whole aorta that consider the reproduction of both the geometrical and mechanical properties of each segment, even though this is a promising research direction [4]. There are only works that deal with specific segments of the aorta, e.g., the aortic root [15] or other districts [17], and works based on very specific cases, e.g., the replication of a patient-specific aortic arch aneurysm [33]. Recent works rely on the 3D printing technology; however, they consider the same compliance in each district [3]. Doyle and co-workers [7–9] used a mold composed by two outer shells and an inner one to produce a deformable abdominal aorta with constant wall thickness of 2 mm. Finally, Cloonan et al. [6] developed a direct 3D printing approach with two commercially available materials and compared it to the molding technique adopted in [9].

Thus, the goal of this paper is to fill this gap by proposing a design and manufacturing process to create a model of the entire aorta that reproduce the desired geometrical and mechanical properties, to get a reliable fluid dynamic and compliant behavior. We provide thorough guidelines to build a general *in vitro* aortic model, made up of silicone. Moreover, to validate the feasibility of the approach, we have built a real aortic model, considering an *average* healthy aorta based on mechanical and geometrical properties taken from the literature.

The design is based on a parametric model, which is in terms of a Computer-Aided Design (CAD) file. The physical model is made of transparent silicone, to provide an instrument that can be used where transparency is a crucial feature to visually inspect and follow the procedure performed inside the vessel, e.g., for benchmarking vascular prostheses and pre-operative planning or training.

2. Methods

To build an *average* aorta, we consider mean values representative of the entire population, by retrieving the most exhaustive number of literature parameters from the geometrical and mechanical viewpoints. Parameters include lengths, diameters, angulations of the aortic arch and the branches, as well as compliances.

2.1. Specifications

We consider the aorta from the root to the proximal part of the iliac arteries. Briefly, this includes the ascending aorta, the aortic arch and the descending aorta, which is further divided in thoracic and abdominal aorta; the abdominal aorta then branches into the two common iliac arteries that provide blood to the pelvis. Moreover, we include in the model the main aortic branches with a relevant flow that affects hemodynamics:

- The coronary arteries, which originate in the ascending aorta from the left and right aortic sinus, respectively.
- The brachiocephalic trunk or innominate artery, the left common carotid artery (LCCA), and the left subclavian artery (LSA), which originate from the aortic arch. The brachiocephalic trunk then splits into right subclavian artery (RSA) and right common carotid artery (RCCA).
- The celiac trunk, i.e., the major branch of the abdominal aorta, which arises at the T12 vertebra level.
- The superior mesenteric artery, which arises at the L1 vertebra level.
- The two renal arteries, which arise between the L1 and L2 vertebrae.

Other minor branches, e.g., vertebral arteries, are not considered.

The main features to reproduce are the decreasing aortic diameter and the decreasing compliance, with higher values in the ascending aorta compared to the aortic arch, and higher values in the arch compared to the descending aorta. See the works by Kälsch et al. [16] and Rengier et al. [27] with respect to diameter; and those by Mohiaddin et al.[23] and Stergiopulos et al. [31] with respect to compliance.

We have derived the set of parameters that define the *average* aortic model. Most of the parameters are collected from the literature, while other values are not available, e.g., some lengths and angulations. To retrieve the missing data, we have retrospectively evaluated images of patients that underwent CT for clinical reasons. In particular, we considered ten patients[1] who underwent imaging before treatment with thoracic endovascular aortic repair (TEVAR) for different thoracic aortic pathologies (6 cases of thoracic aortic aneurysm; 4 cases of penetrating aortic ulcer). We have created a 3D model of the aorta with central lumen line using a 3Surgery workstation (3Mensio Medical Imaging B.V., Bilthoven, The Netherlands), and we have measured the length of the central lumen line of the different aorta segments not affected by the pathology.

The set of parameters, the considered values, and the reference for the values taken from the literature are reported in Tables I–III of the *Supplementary material*.

2.2. Design of the aortic model

The aorta does not lie in a single plane, while it changes its osculatory plane along with the length; thus, we have defined the following planes in the three dimensional space: *(i)* the inclination of the ascending aorta in the sagittal and coronal plane with respect to the vertical plane; *(ii)* the inclination of the descending aorta in the sagittal and coronal plane with respect to the vertical plane; *(iii)* the orientation of the aortic arch.

There is no widely adopted way of measuring the angulation of the aortic arch; only Malkawi et al. [21] developed a method to measure the arch angulation at the level of the left LSA, which is a marking point for endovascular therapy. However, this method is not suitable for our approach, because of the dependence between the involved parameters, which could cause problems to the CAD consistency. Thus, we get the arch angulation from the distance of 5 reference points along the arch from the pivot point in the aortic root.

Our goal is to reproduce the behavior of the aorta at the blood-wall interface: consequently, the internal geometry of the vessel and its compliance must be faithfully reproduced, while there are no constraints related to the external geometry and the wall

[1] See ethical approval in the acknowledgments.