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Biomechanical evaluation of a personalized external aortic root support applied in the Ross procedure

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ABSTRACT

A commonly heard concern in the Ross procedure, where a diseased aortic valve is replaced by the patient's own pulmonary valve, is the possibility of pulmonary autograft dilatation. We performed a biomechanical investigation of the use of a personalized external aortic root support or exostent as a possibility for supporting the autograft.

In ten sheep a short length of pulmonary artery was interposed in the descending aorta, serving as a simplified version of the Ross procedure. In seven of these cases, the autograft was supported by an external mesh or so-called exostent. Three sheep served as control, of which one was excluded from the mechanical testing. The sheep were sacrificed six months after the procedure. Samples of the relevant tissues were obtained for subsequent mechanical testing: normal aorta, normal pulmonary artery, aorta with exostent, pulmonary artery with exostent, and pulmonary artery in aortic position for six months. After mechanical testing, the material parameters of the Gasser-Ogden-Holzapfel model were determined for the different tissue types.

Stress-strain curves of the different tissue types show significantly different mechanical behavior. At baseline, stress-strain curves of the pulmonary artery are lower than aortic stress-strain curves, but at the strain levels at which the collagen fibers are recruited, the pulmonary artery behaves stiffer than the aorta. After being in aortic position for six months, the pulmonary artery tends towards aorta-like behavior, indicating that growth and remodeling processes have taken place. When adding an exostent around the pulmonary autograft, the mechanical behavior of the composite artery (exostent + artery) differs from the artery alone, the non-linearity being more evident in the former.

1. Introduction

Patients suffering from aortic valve disease can be treated by replacing their aortic valve with their own pulmonary valve, i.e. a pulmonary autograft. This procedure, known as the Ross procedure, has several advantages compared to replacement with a mechanical valve, such as better hemodynamic performance, no need for lifelong anticoagulant therapy, and the natural increase of autograft size in children (Takkenberg et al., 2009). Despite these advantages, possible dilatation of the autograft limits the use of this treatment (Ungerleider et al., 2010). Freedom from autograft reoperation in the German-Dutch Ross registry was 89.6% after ten years (Charitos et al., 2009).

Schoof et al. demonstrated the growth and dilatation of the pulmonary autograft in growing pigs, when replacing a length of the ascending aorta with an interposition pulmonary artery. They found that the increase in size of the pulmonary autograft is partly caused by normal growth and partly by dilatation. The authors believe that the main dilatation of the pulmonary autograft occurs at the moment the pulmonary autograft is loaded with aortic pressure. Despite the growth and dilatation, the pulmonary autograft wall still showed pulmonary characteristics both micro- and macroscopically after implantation in aortic position (Schoof et al., 1998).

However, in another study by the same authors on the histological evaluation of human pulmonary autograft explants, they discovered that the autograft wall showed an increase in collagen content and a reduction and fragmentation of elastin, corresponding to severe aneurysmal degeneration (Schoof et al., 2006).

Carr-White et al. compared human pulmonary artery wall to the normal aortic wall, noticing that the aorta is both stiffer and stronger. Additionally, they evaluated a pulmonary autograft that had been

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implanted for four months in a 14 year old patient, and described an increase in stiffness for this autograft, compared to pulmonary tissue (Carr-White et al., 2000).

When comparing the mechanical behavior of non-diseased human pulmonary and aortic roots, Azadani et al. found that the pulmonary artery is significantly stiffer than the aorta at systemic pressures (Azadani et al., 2012).

Mookhoek et al. had the opportunity to mechanically evaluate dilated pulmonary autografts of 10 patients who underwent the Ross operation and discovered that the autografts were significantly more compliant than the native aortic roots (Mookhoek et al.,). In a subsequent paper by the same authors, they also noticed that pulmonary autografts are less stiff than the normal pulmonary roots (Mookhoek et al., 2016).

To avoid dilatation of the pulmonary autograft when subjecting the pulmonary artery wall to systemic pressures, several types of reinforcements are suggested.

Ungerleider et al. described a technique in which they place the pulmonary autograft in a Dacron graft prior to implantation in aortic position (Ungerleider et al., 2010). Both Carrel et al. and Gebauer et al. proposed a similar technique, but instead of a Dacron graft, they used the sinus of the Valsalva graft (Carrel and Kadner, 2016; Gebauer and Cerny, 2009). A case study by Kollar et al. reports the use of a Gore-Tex wrapping around the pulmonary autograft (Kollar et al., 2009). However, all these reinforcements are significantly stiffer than the native aorta and do not provide sufficient vascular compliance. Therefore, Nappi et al. proposed a resorbable reinforcement to strengthen the pulmonary autograft, which they evaluated in an ovine model (Nappi et al., 2014, 2015a, 2015b, 2016a, 2016b).

Recently, a new technique was developed to reinforce the dilating aortic root in Marfan patients, i.e. a personalized external aortic root support (PEARS), as an alternative for the total root replacement or valve-sparing root replacement therapy. The PEARS is an external wrapping, which is tailored to the patient-specific geometry of the aortic root. Based on a CT or MRI of the aortic root of the patient, a replica of the patient's geometry is made by additive manufacturing. A polyethylene terephtalate mesh with a pore size of 0.7 mm is then crimped around this replica. Next, this PEARS is surgically placed around the patient's dilated aortic root (Pepper et al., 2010, 2015; Treasure et al., 2014). The initial results of this less invasive treatment option for Marfan patients are promising (Pepper et al., 2010; Treasure et al., 2014). The inventors claim that this method, as opposed to wrapping of aneurysms with rigid woven grafts, results in the incorporation of the soft pliant mesh in the outer layer of the aorta (Treasure et al., 2014). This claim was confirmed after an autopsy on a patient, deceased 4.5 years after he received a PEARS due to unrelated circumstances, where the incorporation of the mesh was histologically shown. Moreover, the aortic root of this Marfan patient showed normal histology, instead of the expected cardiovascular manifestations (medial degeneration with fragmentation of elastic fibers and smooth muscle cell nuclei loss) (Pepper et al., 2015).

The mechanical performance of the PEARS mesh was studied in sheep, of which the common carotid artery was enclosed in a mesh, made of the same material as the PEARS. Four to six months after implantation, the sheep were sacrificed and both meshed and normal portions of the carotid artery were analyzed mechanically and histologically. Again, incorporation of the mesh in the outer arterial wall was confirmed, and the histological architecture of the arterial wall preserved. Based on uniaxial tensile tests, a significant increase in both stiffness and tensile strength of the supported segments with respect to the normal carotid artery was reported (Verbrugghe et al., 2013).

In a more recent paper, Van Hoof et al. histologically evaluated the PEARS material, after it had been placed around the abdominal aorta of three sheep for a year, and compared it to the fabric used in the common vascular graft Gelweave. The PEARS material caused less disturbance to the native aortic wall compared to the material of the common vascular graft (Van Hoof et al.,).

The above studies strongly suggest PEARS to be a promising method to reinforce the pulmonary autograft in the Ross procedure. To evaluate this hypothesis, this paper investigates the use of PEARS material in a simplified version of the Ross procedure in sheep. In the next sections, the surgical procedure and the mechanical characterization methodology are presented, after which the obtained results are described and discussed.

2. Materials and methods

2.1. Surgical procedure

A simplified version of the Ross procedure was performed on thirteen Lovenaar sheep: part of the thoracic aorta descendens was replaced by part of the truncus pulmonalis. In ten sheep an exostent was positioned around the pulmonary autograft. The exostent, made of a polyethylene terephtalate mesh with a pore size of 0.7 mm, was loosely fitted around the pulmonary autograft during surgery. The three remaining sheep served as control sheep. The sheep were sacrificed after an average of 28.4 weeks. Three sheep with the exostent died during surgery and were excluded. One of the control sheep did not have sufficient tissue harvested for mechanical testing and was excluded from mechanical testing. However, slices of the different tissues of this control sheep were obtained and examined microscopically. Before sacrifice, the diameter of the pulmonary artery, and the diameter of the aorta were measured on a CT scan. After sacrifice, the following types of tissues were harvested: normal aorta (A), reinforced aorta (AW), and reinforced pulmonary artery in aortic position (PW). In the control sheep, normal aorta (A^c), normal pulmonary artery (P^c), and pulmonary tissue in aortic position (P^c_A) were harvested. An overview of the harvested tissue types is shown in Fig. 1. Table 1 summarizes the details of all sheep. After removing the different tissue types, the tissues were frozen either in a physiological PBS solution or in a physiological NaCl solution, and stored at − 80 °C.

All experiments were approved by the Animal Ethics Committee of the KU Leuven (P053/2013).

2.2. Experimental protocol

First, the tissue obtained from the surgical procedure was divided into different samples. Next, sample preparation was performed including thickness measurements and marker attachment. Subsequently, the sample was mounted in a biaxial tensile testing device and mechanically loaded. The different steps are summarized in Fig. 2 and detailed below.

2.2.1. Sample preparation

Overnight, the tissues were thawed in a refrigerator at 4 °C. After thawing, the tissue was divided into square samples of 8 mm × 8 mm for planar biaxial tests. The samples' edges were aligned with the circumferential and longitudinal direction of the vessel.

The thickness of each sample was obtained from an image in which the sample was placed between two metal plates of known thickness.

Small fragments of surgical suture wire served as markers. They were glued in the center region of the sample, where the stresses and strains are considered to be most homogeneous (Sacks, 2000). Four markers were placed at the corners of a square, and a fifth marker was placed in the center of this square.

2.2.2. Planar biaxial tensile test

The samples were mounted in a BioTester device (CellScale, Waterloo, Canada) by means of four BioRakes. Each BioRake consists of 5 pins spaced by 1 mm, with a diameter of 300 μm and a puncture length of 3 mm. The BioTester has four actuators, which can be actuated independently, and two 23 N loadcells (with an accuracy of 0.2%