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EVALUATING THE EFFECT OF A DOUBLE-WALLED AORTIC STENT-GRAFT PROTOTYPE ON PULSE WAVE VELOCITY IN AN *IN VITRO* FLOW LOOP

Shannen B. Kizilski, Filippo Coletti, Rumi Faizer
University of Minnesota – Twin Cities
Minneapolis, MN

Victor H. Barocas[1]
University of Minnesota – Twin Cities
Minneapolis, MN

ABSTRACT

The effect of a double-walled stent-graft (DWSG) design on arterial compliance was evaluated using pulse wave velocity (PWV) measurements in an in vitro *mock arterial flow loop. The DWSG prototype was compared to a rigid stent-graft and to an unstented aorta model. The time delay between two pressure sensors a fixed distance apart was used to calculate PWV. Latex tubing simulated the compliant aorta, and a needle valve provided downstream resistance. A series of pulse rates and stroke volumes was applied to enable measurements at different mean pressures for the same system. PWV for the rigid stent-graft was higher than in the other two cases across all mean pressures. The DWSG exhibited behavior similar to the unstented model, demonstrating the capability of the DWSG to maintain aortic compliance in patients requiring an aortic stent-graft.*

Keywords: stent-graft design, arterial compliance, pulse wave velocity, endovascular aortic repair

NOMENCLATURE

PWV	pulse wave velocity
DWSG	double-walled stent-graft

1. INTRODUCTION

Aortic stent-grafts are wire-reinforced fabric tubes that are placed endovascularly in patients with aneurysm or dissection to restore vessel patency and protect the aortic wall from pressure-induced injury. Despite the growing popularity of stent-grafts over open surgical repair, many studies have warned about the long-term consequences of increased arterial stiffness and blood pressure as a result of these "rigid" implants [1–3]. In a healthy individual, the aorta is a highly elastic artery that helps to control the rate at which blood reaches the smaller, peripheral vessels. Increased aortic stiffness, or loss in elasticity, has been associated with increased risk of cardiovascular disease and all-cause mortality [4]. The aorta stiffens naturally with age, but this process can be exacerbated when a stiff stent-graft replaces a section of the native aorta.

Although the high radial stiffness of stent-grafts often draws criticism, this stiffness should be considered as a critical design feature. The radial stiffness of a stent-graft ensures that it remains anchored in its intended position and that it shields the damaged aortic wall from cyclic strains. Regardless of these benefits, long-term patient outcomes will suffer unless aortic compliance is restored after stent-graft placement.

To address the adverse effects of rigid stent-grafts, we have developed a new double-walled stent-graft (DWSG) design that leverages the compressibility of CO_2 gas to form a compliant layer within a rigid stent-graft [5]. Figure 1 shows one configuration of this design, where an inner wall is sealed against the outer wall at both ends, and gas fills the space between. The volume of the gas layer in the DWSG changes between cardiac systole and diastole, leading to an increase in apparent aortic compliance compared to a standard stent-graft.

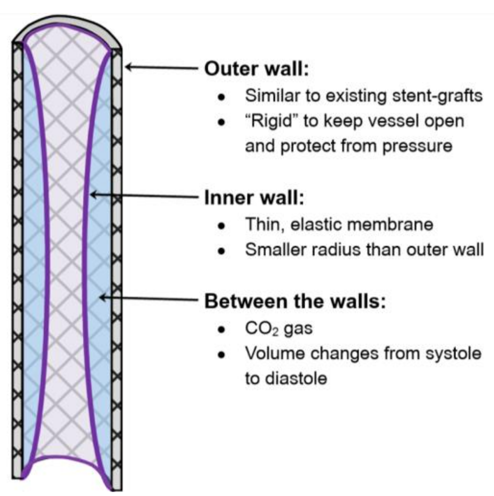

FIGURE 1: DIAGRAM OF DOUBLE-WALLED STENT-GRAFT (DWSG) DESIGN, SHOWING CROSS SECTION OF LAYERS

[1] Corresponding author: baroc001@umn.edu

In this work, the effect of the DWSG on aortic compliance is studied *in vitro* through measurement of pulse wave velocity (PWV) in a mock arterial flow loop. In clinical practice, PWV is a well-established surrogate for estimation of arterial compliance, measured by the time delay between pressure waveform measurements taken at two locations in the patient's vasculature [2, 6]. Lower PWV is associated with a more compliant arterial system. We hypothesize that the DWSG will lower PWV compared to a rigid stent-graft, though it may not be as low as in the unstented model.

2. MATERIALS AND METHODS

An experimental model of the arterial system was created using a pulsatile flow pump (EnvivoPC) to provide controlled flow profiles, latex 2.54 cm (1") diameter penrose drains to represent the compliant aorta, and a needle valve to represent the high-resistance peripheral vasculature. Two penrose tubes were layered to more closely match the stiffness of the aorta (~100kPa), and the tubing was prestretched by 20% in the flow loop to mimic axial aortic prestretch [7]. After axial stretch, the penrose tubing spanned 40.6 cm (16"). Two pressure transducers (Validyne) were connected to the system directly upstream and downstream of the penrose tubing.

A prototype of the DWSG was created using thin, 2.54 cm (1") diameter polypropylene tubing for the outer wall, with a wire coil adhered to the outside for additional structural support. Standard bubble wrap was used for the gas layer and inner wall by adhering a sheet to the inside of the outer tubing. The rigid stent-graft was subsequently modeled by removing the bubble wrap layer from the polypropylene tubing. Both stent-graft models were deployed into the proximal penrose tubing by manually collapsing and then re-expanding when in position.

Each case (no stent-graft, rigid stent-graft, and DWSG) was tested at five different flow rates in order to collect data at different mean pressures without changing the system setup. Mean pressure was expected to affect PWV due to the nonlinear behavior of the materials. The time delay between pressure waves was found by manually marking the foot of each cycle and taking the average delay over all cycles. PWV was calculated as the distance between the pressure sensors divided by the time delay.

3. RESULTS AND DISCUSSION

Figure 2 shows PWV as a function of mean pressure for each of the stent-graft cases. Measurements ranged between 7-18 m/s, which is within normal limits established for human PWV [3, 8]. The no-stent and DWSG cases followed nearly identical trends, though the mean pressure in the DWSG was always 2-5 mmHg higher for the flow rates tested. This increase in pressure can be explained by the higher flow resistance posed by the narrowed DWSG lumen compared to the unstented tube.

The rigid stent-graft maintained higher PWV than the other two conditions for all pressures. Two different trends emerged within the three cases, with the rigid stent-graft showing a monotonic decrease in PWV as pressure increased, while the no-stent and DWSG cases exhibited a maximum PWV of approximately 10.7 m/s at 60 mmHg mean pressure. An interplay between the nonlinearity of the material stiffness and the needle valve may have caused the nonmonotonic behavior in these cases, but this theory requires further investigation. In addition to PWV analyses, we shown that although the DWSG increases flow resistance due to a narrowed lumen, peak and pulse pressures in an *in vitro* system were decreased compared to a rigid stent-graft due to the increased compliance. Next we will expand testing to an *ex vivo* porcine model for further concept validation.

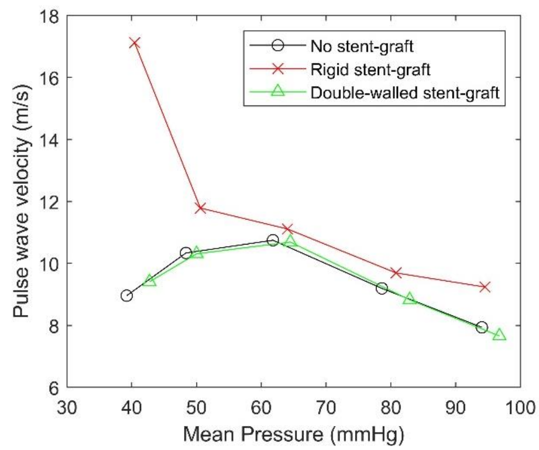

FIGURE 2: PULSE WAVE VELOCITY IN FLOW LOOP MODEL WITH DIFFERENT STENT-GRAFT CONDITIONS

4. CONCLUSION

This study showed that a DWSG design more closely matched the compliance of an unstented vessel compared to a standard, rigid stent-graft. Arterial stiffness is a critical factor predictive of cardiovascular morbidity, so minimizing stiffness should be considered a necessary stent-graft attribute.

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