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Abstract: Motivated by the need for a simulator for varying degrees of vascular stenosis and different stenosis geometries, a pneumatic actuator was conceived and developed using additive manufacturing.

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# I. Introduction

The aim of this paper is to investigate a 3D-printed adaptive stenosis actuator in order to simulate different degrees of superficial femoral artery (SFA) stenosis.

Figure 1: CAD rendering of the pneumatic actuator shown without lid, allowing view of the air chamber. The compressible inner actuator component is opaque; the outer actuator component is transparent.

Lower extremity peripheral arterial disease (PAD) is the third leading cause of atherosclerotic cardiovascular morbidity, following coronary arterial disease and stroke. An estimated 200 million people suffer from peripheral arterial disease, making PAD a global issue [1]. The most frequently afflicted vessel is the SFA, which is why it is the vessel of primary interest for this actuator [2].

Due to the prevalence of vascular disease, vascular phantoms are an essential part of medical research and stenosis phantoms present a feasible way to test interventional devices and procedures [8]. Thus, the actuator described here has a variety of applications, especially considering its small size and simple construction and mechanism. Another benefit is the lack of artifact-causing metals in the construction, allowing the actuator to easily be used in MRI, CT or MPI applications, especially for quantitative research. Constructing such an

actuator digitally and manufacturing it via 3D-printing has the benefit of easily allowing the construction to be altered. Hence, the resulting actuator can be produced swiftly with the desired dimensions for specific applications.

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# **II. Materials and methods**

## **II.I. Construction**

The actuator is comprised of three central parts: a lid, the hard outer actuator component, and the either completely or partially soft, compressible inner actuator component. All parts were constructed using SolidWorks.

Both the vessel and the adaptive pneumatic actuator were printed with the Stratasys J850 (Stratasys Ltd., Minnesota, USA), a multi-material polyjet printer. The vessel phantoms are comprised of Stratasys Agilus30 White, a soft, flexible 3D-printed material with a Shore hardness of 30A. They measure 10 cm in length with a lumen diameter of 5 mm and a wall thickness of 0.5 mm. This geometry aims to approximate that of a superficial femoral artery [3,4]. The outer actuator component is comprised of Stratasys VeroClear, a hard 3D-printed material. There are two variants of inner actuator components: one is comprised of Agilus30 White and the other is a combination of both VeroClear and Agilus30 White. In Fig. 2, the inner actuator component, comprised primarily of VeroClear with an Agilus30 White patch, is shown. The purely Agilus30 White variant allows for a two-sided stenosis and the combination variant allows for a one-sided stenosis [5].

Luer adapters are printed using Formlabs Form 3B using model resin. Luer connections allow for use with various standardized and universal Luer syringes and tubing, thus allowing easy connection of the pneumatic compressor. The lid, shown in magenta in Fig. 3, is comprised of a blend of different Vero materials and has a thin layer of Agilus30 to guarantee that the air chamber is sealed.



Figure 2: Inner actuator component comprised of VeroClear (clear, firm) and Agilus30 White (white, flexible) to allow simulation of one-sided stenoses.

## II.II. Pneumatic Mechanism

Inspired by the pneumatic simulator by Maréchal et al. (2017) [6], the pneumatic mechanism of this actuator is created by air pressure entering the air chamber. This is realized via the syringe shown in Fig. 3. The lid attached securely using M3 screws. The Agilus30 White coating on the lid allows for airtightness. Once the actuator is rendered completely airtight, air pressure can be administered using a syringe. Once the pressure rises in the air chamber, the soft components of the inner actuator component yield to the pressure and are displaced inwards. This creates an artificial stenosis.



Figure 3: Fully assembled actuator with a 10 ml syringe connected to the pneumatic actuator via Luer lock adapter. Vessel phantoms can be threaded through the hole in the magenta lid.

When a vessel phantom—a flexible test vessel with anatomical dimensions as described above— is threaded through the hole in the lid and through the center of the inner actuator component, it can then be compressed and stenoses of varying degrees can be simulated by changing the air pressure via the syringe.

## **III. Results and discussion**

The pneumatic actuator generally simulates varying degrees of vascular occlusion and different stenosis geometries. However, a correlation between pressure in the air chamber and inner diameter of the compressed vessel are still needed in order to quantify the degree of stenosis. Using the different inner actuator components, different geometries are successfully simulated—a two-sided and a single-sided stenosis. Many more geometries are possible and can easily be included by (CAD) constructing and additively manufacturing different actuator components.

As described by Vaalma et al., Magnetic Particle Imaging (MPI) is very accurate tool for stenosis quantification [9].

Furthermore, MPI can quantify the lumina of endovascular stents without the influence of material induced artifacts [7]. A pneumatic actuator, such as the one described in this work, would be very beneficial for a wide range of in vitro experiments regarding cardiovascular applications of MPI as well as studies using MRI or CT. The exceptional benefits of small size, simple construction, and lack of metal artifacts would be rather helpful in such studies. Due to the progressive characteristic of vascular stenoses, the actuator offers the possibility for instrument testing, as well as hemodynamic studies regarding different degrees of stenoses. Concerning construction, additive manufacturing allows for quick alteration of such an actuator - different vessel sizes and different air chamber dimensions, for example, could quickly be achieved. Little adjustment would be necessary to allow application with other vessels, as they are similar in size to the superficial femoral artery for which this actuator was constructed.

## **IV.** Conclusion

An adaptive 3D-printed actuator using a pneumatic mechanism to simulate different stenosis geometries and degrees of stenosis can be used in a wide variety of clinical research applications. The speed, design freedom, and variety of materials now available in additive manufacturing allow realistic simulation of vascular pathologies and make adaptive mechanisms, as shown here, possible. The elastic 3D-printed material, used for both vessel and actuator, paves the way for new simulation studies and many applications in the field of cardiovascular research.

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#### **AUTHOR'S STATEMENT**

Authors state no conflict of interest.

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