Effects of Pulse Duplicator Designs on Valve Behavior

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Effects of Pulse Duplicator Designs on Valve Behavior

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1 Motivation

- A perfect implantable valve that is satisfying both hemodynamic and durability requirements is still not found [1]
- This study is in the framework of developing a **fully-polymeric transcatheter heart valve** aiming to fulfill both requirements
- A pulse duplicator is needed to conduct the characterization of novel heart valve designs under physiological conditions

2 Methods of parametric study and evaluation

Objective

- Create an **accurate** simulator of the entire **cardiac cycle** for valve assessment and design optimization
- Valve exposure to physiological pressure differential (ΔP) & flow environment for all heart valves

Main challenge

- Pulse duplicator components can have a strong influence on pressure history & flow details

Parametric study: Effects of hemodynamic conditions and design

- Reference pulse duplicator with bioprosthetic valve in aortic and mitral position (Fig. 1)
- Physiological and pathological hemodynamic settings (Table 1)
- Components altered: compliance chamber (Ⓐ absence & Ⓑ air pressure), Ⓒ aortic resistance inducer, Ⓓ mechanical valve in mitral position, but also Ⓔ presence of endoscope apparatus

	Pressure condition [mmHg]	Heart rate [bpm]	Nominal cardiac output [l/min]
①	Normotensive (120/80)	70	5
②	Normotensive (120/80)	140	5
③	Normotensive (120/80)	140	10
④	Severe hypertensive (210/120)	70	5
⑤	Severe hypertensive (210/120)	140	10

Table 1: Five physiological and pathological hemodynamic settings

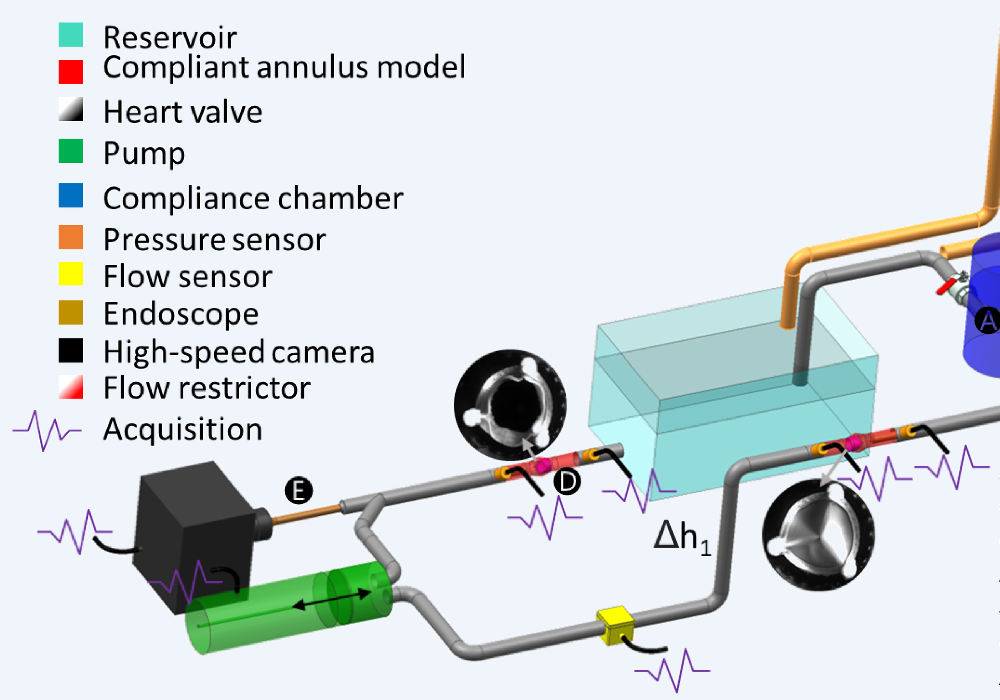

Figure 1: Reference pulse duplicator: piston pump actuated, equipped with two flexible annulus models, aortic compliance chamber & aortic resistance flow restrictor, reference pressure reservoir for left atrium, 4 high-resolution pressure sensors & 1 flow sensor, as well as imaging acquisition systems with 2 high-speed cameras and laparoscopic endoscopes. The experimented aortic resistance induction reservoir component is illustrated under an orange mask.

3 Results and Highlights

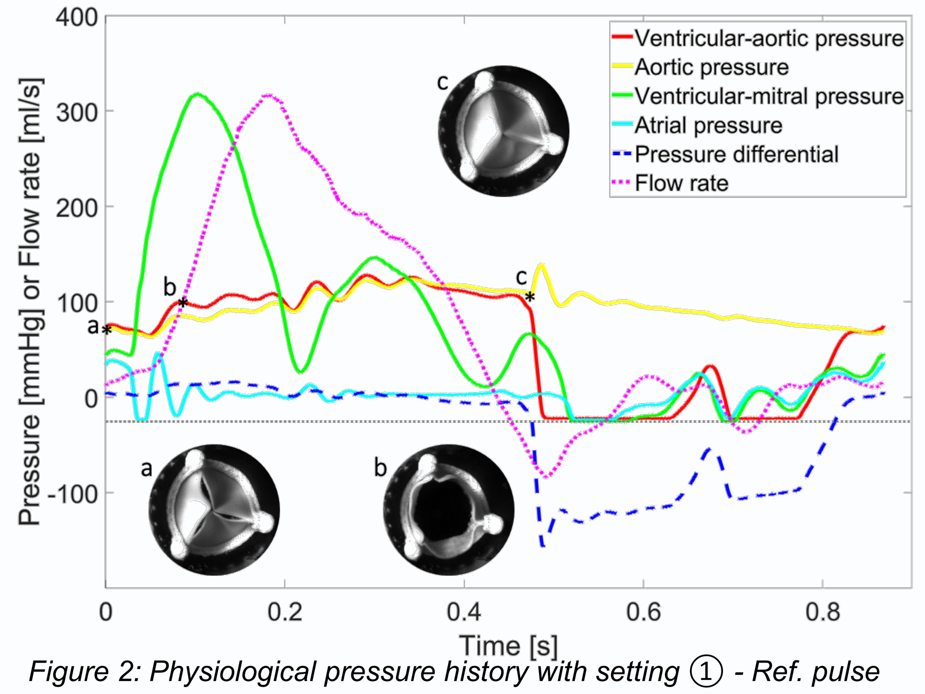

Figure 2: Physiological pressure history with setting ① - Ref. pulse duplicator

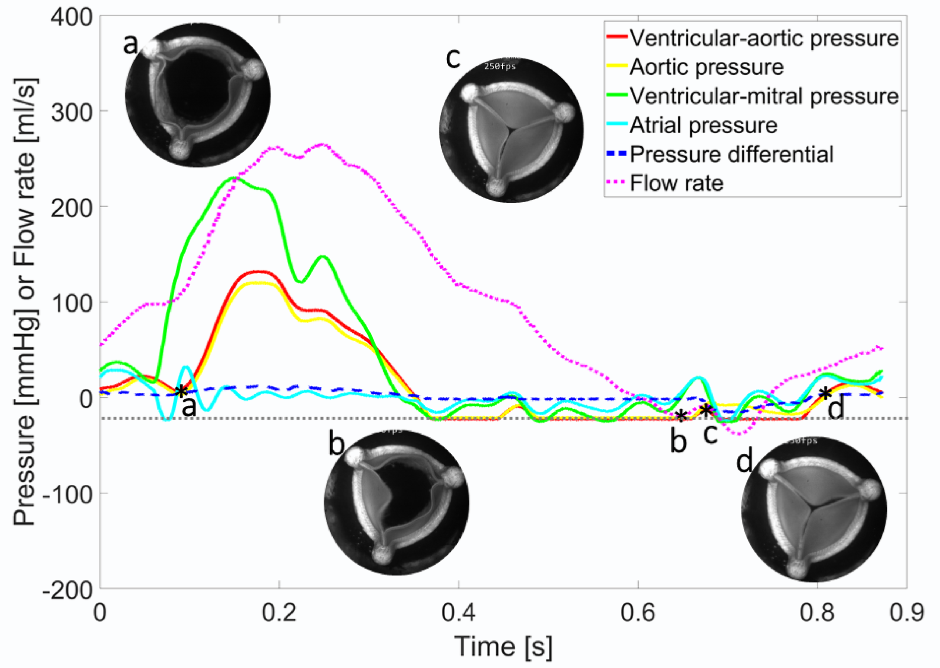

Figure 3: Pathological pressure history with setting ① - Ⓐ

- Absence of compliance chamber leads to
  - Aortic and ventricular-aortic pressure practically overlap. This can be attributed to the reduced flow resistance in the absence of the compliance chamber leading to lower ΔP.
  - A change in the wave propagation cannot be excluded
  - A lower regurgitation despite the increased cardiac output
- Late closing of mechanical valve leads to a very low actual cardiac output (same pump output), which is leading to a higher regurgitation & an apparent lower ΔP

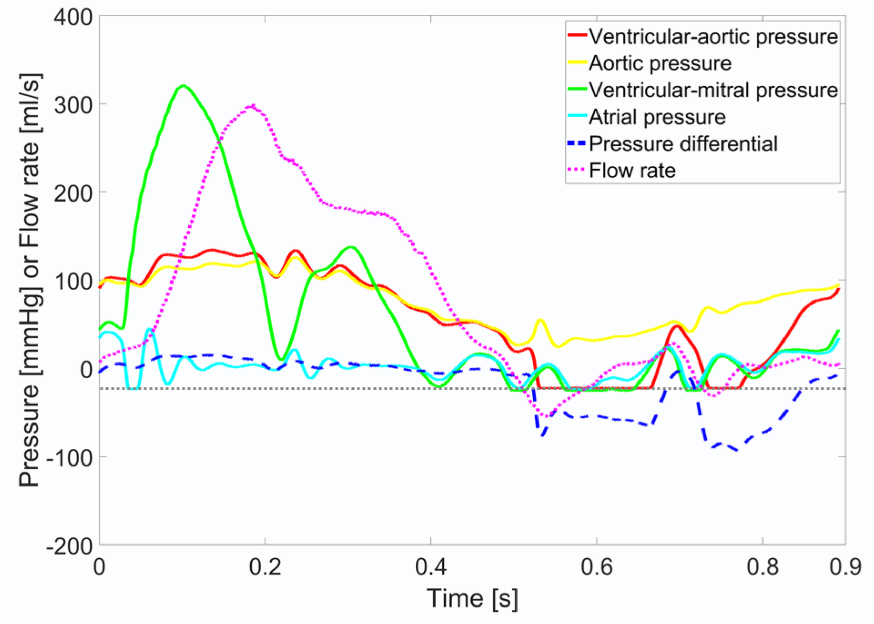

Figure 4: Physiological pressure history with setting ① - Ⓑ

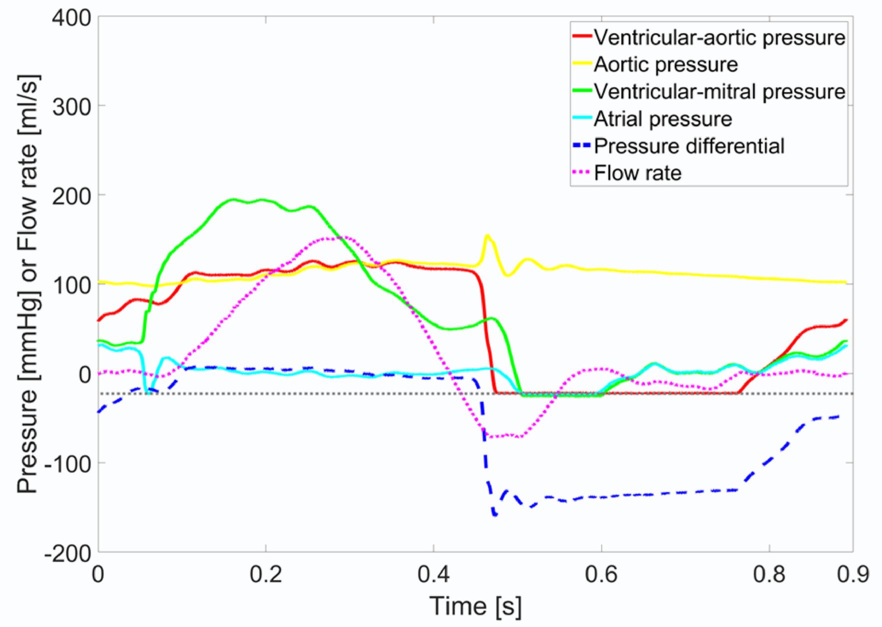

Figure 5: Physiological pressure history with setting ① - Ⓓ

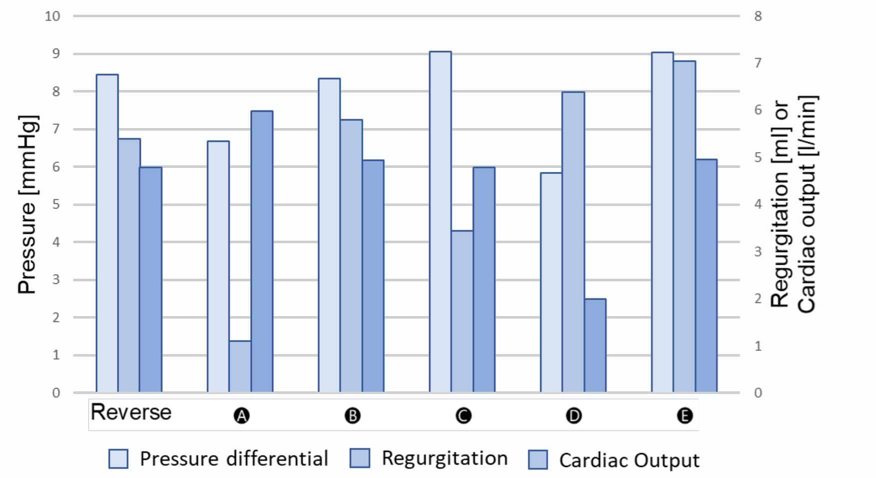

Figure 6: Pressure, regurgitation, and cardiac output with setting ① for each variation

Note that:
1. Nominal cardiac output is based on Ref. pulse duplicator, where true cardiac output was measured with the flow sensor
2. All history data are averaged over 10 cycles according to the ISO5840-3 [2]
3. The gray dashed line in the Figures 2 – 5 show the negative pressure limit that can be acquired with the pressure sensors
4. Pressure differential often referred as pressure gradient

4 Remarks

- High acquisition rate (~ 3.5 kHz) is needed to capture the phenomena [3,4]
- Fully-synchronized pressure, flow, and image acquisition is essential [5]

5 Conclusion

- Optimized set-up replicates a physiological and pathological valve environment in a robust manner
- Of paramount importance are: 1. compliance chamber, 2. flow restrictor as circulation pressure resistance. These are essential to maintain aortic and narrow pulse pressure. The less flow-disturbing pressure induction via reservoir is not sufficient to maintain the above characteristics, while the positive effect on the flow is minimal.
- Above mentioned characteristics can vary with valve type

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