



Development of an *in vitro* Compliance Tester for Vascular Grafts

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BACKGROUND

- Long-term success of synthetic vascular grafts depends largely on the host response.
- Radial compliance is one of the key factors for long-term graft success¹

$$C = \frac{\Delta D}{D \Delta P}, \text{ where } D \text{ is inner diameter and } P \text{ is internal pressure}$$

- Vascular prostheses should ideally mimic the compliance of healthy native arteries.
- Non-compliant (i.e. stiff) vascular grafts may lead to anastomotic intimal hyperplasia (AIH), the excessive thickening of intimal tissue in the peri-anastomotic region of vascular grafts.



Figure 1: Intimal tissue thickening as seen in anastomotic intimal hyperplasia

DESIGN OBJECTIVES

- Develop a system to replicate the physiological conditions within a patient's arteries, namely:

Blood pressure
Fluid viscosity
Temperature
Flow rate
Pulse frequency (heart rate)
Stroke volume
Host artery compliance

- Measure the graft compliance when subjected to the above conditions.
- Develop a static testing system to assess the dimensional changes of grafts under static internal pressurisation at incremental intervals.
- Develop a dynamic testing system to assess the dimensional changes of grafts with respect to dynamic internal pressure and flow profiles that vary with time. The pressure and flow profiles should follow closely the physiological profiles experienced by arteries at various locations in the body, and therefore require the design of a pulse duplicator system.

SYSTEM SPECIFICATIONS

	Physiological conditions	Compliance tester specifications
Compliance [%/100 mmHg]	< 8	0 - 15
Fluid pressure [mmHg]	80 - 120	0 - 250
Pulse frequency [bpm]	75 - 180	0 - 200
Flow rate [cm/s]	0 - 60	0 - 100
Temperature [°C]	37	37
Fluid viscosity [Ns/m ²]	0.0027 (blood)	0.0006 (water) - 0.0027 (glycerine saline solution)

MECHANICAL DESIGN

Drive system (Figure 2):

- Stepper motor [Ocean Controls FL865TH118-6004A, 48V, 8.7Nm]
- Variable crank to adjust crank radius, and hence stroke length and ejected volume
- Scotch Yoke linkage
- Piston pushrod

Flow system (Figure 3):

- Valve stage to facilitate uni-directional flow and bypass ejected fluid for optimal stroke length.
- Windkessel hydraulic compliance stage (not shown).
- Flow measurement stage.
- Graft adapter & mount for attachment & diameter matching of graft.
- Pretension stage to apply longitudinal tension to the graft specimen.
- Needle valves (x2) to control the pressure waveform in the graft and bypass volume.
- Heating element for temperature control.

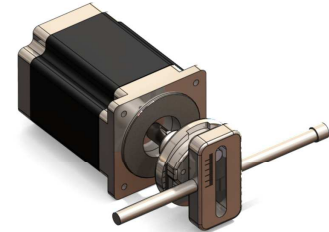


Figure 2: Variable crank and Scotch Yoke design

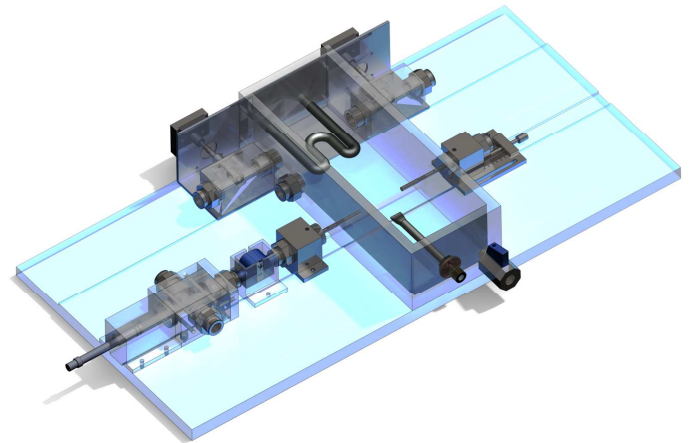


Figure 3: Flow system mechanical design

SOFTWARE SYSTEM DESIGN

[Software control and measurement: LabVIEW 8.20]

[Electro-mechanical interface: USB-6251 Data Acquisition Module from National Instruments]

Control system (Figure 4):

- The Programmable pulse-duplicator (with slider-based user interface) enables the user to define and programme custom flow / pressure waveforms.
- The custom flow waveforms are converted to stepper motor instructions for flow production.
- The custom pressure waveforms are converted to needle valve instructions to control the system back pressure.

Measurement system:

- The volume flow rate is measured using the Transonic T108 Volume Flow Meter.
- This flow rate is fed back to the control system to adjust the stepper motor profile accordingly.
- The fluid pressure is measured on either side of the graft using Biometrix DIPT disposable integrated blood-pressure transducers.
- The pressure is fed back to the control system to adjust the needle valve position accordingly.
- The graft internal diameter will be measured using B-mode ultrasound such that the graft compliance can be calculated.

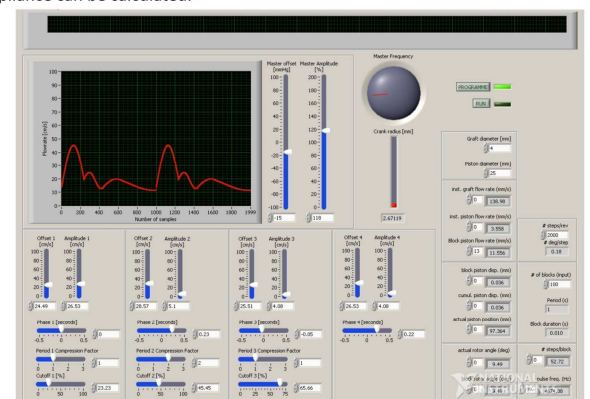


Figure 4: User interface for pulse duplicator and motor control system

¹ Seifalian, A.M., Giudiceandrea, A., Schmitz-Rixen, T., Hamilton, G., Noncompliance: The silent acceptance of a villain. In: Tissue Engineering of Vascular Grafts. Zilla, P., Greisler, H.P. (Eds.), RG Landes Co, Austin, Texas (1999) 47-58.