

# Fellowship Award Recipient

## Gaseous Emboli Generation By a Pulsatile Assist Device

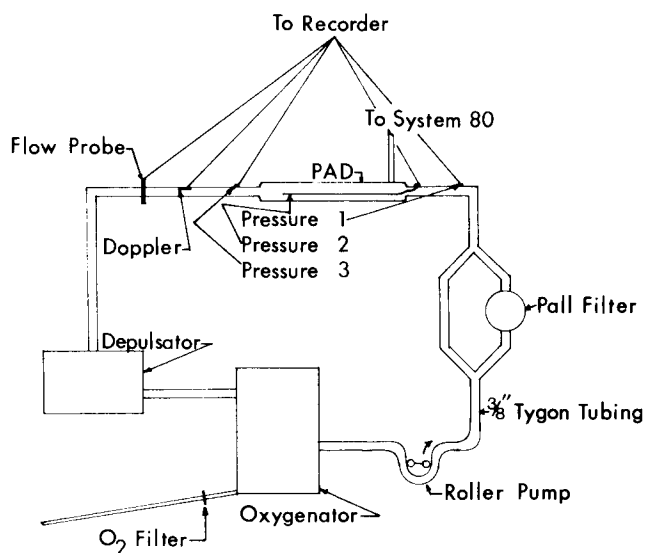
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### INTRODUCTION

In 1976 a balloon-like device incorporated into the arterial line of an extracorporeal circuit to create pulsatile flow was made available for clinical use (1). Since a vacuum is applied to the device, the possibility exists that gas could be drawn out of plasma. The resulting bubble formation would then be extremely hazardous because of the close proximity to the patient's arterial system. Consequently, a study was designed to measure the pressures within a representative device of one of the three currently manufactured types of pulsatile assist devices and to detect any possible gaseous emboli production. Thus, the safety of this device could also be evaluated.

### MATERIALS AND METHODS

An extracorporeal circuit was set up and primed with 3 L of either Lactated Ringer's or hemodiluted, filtered human blood and maintained at 37°C (Fig. 1).



**FIGURE 1**  
*The extracorporeal test circuit*

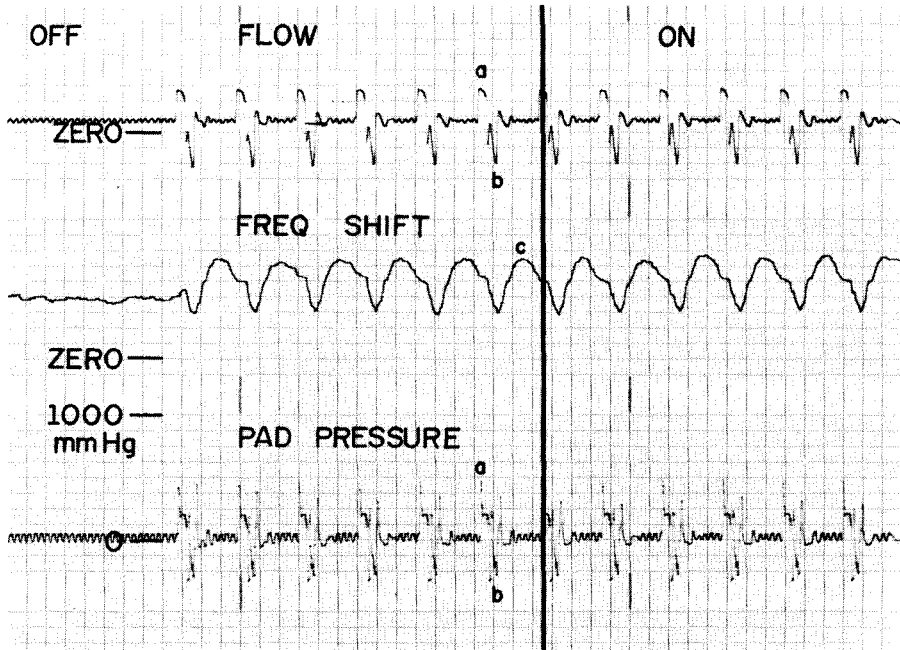


FIGURE 2. This tracing was recorded when the PAD was either operating (ON) or not operating (OFF). The top channel is flow, the middle channel frequency shift changes, and the lower channel pressure in the PAD. The vertical line, which was drawn to assist in the interpretation of the tracings, occurs during the compression of the PAD balloon (a). When the balloon re-expands due to application of vacuum (b), gas emboli come out of solution and are propelled by roller pump flow past the doppler probe (c).

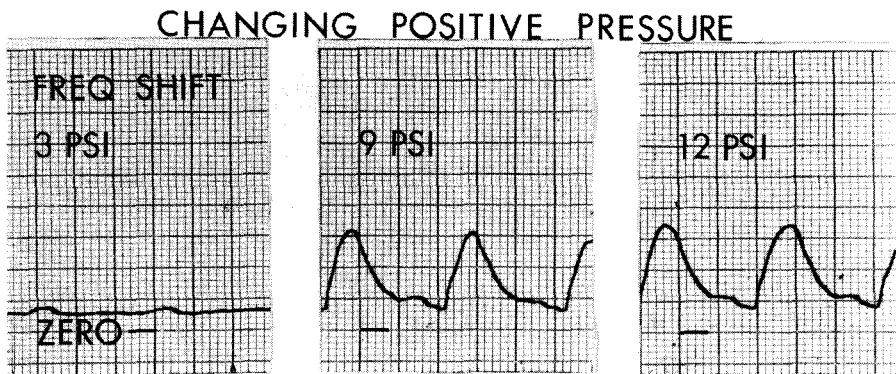


FIGURE 3. Increasing frequency shifts, as a result of increasing emboli production, are recorded when balloon compression was increased from 3 to 9 to 12 p.s.i.

Clamps controlled the direction of flow either through a 40 $\mu$  filter or the filter bypass. Gas flow through the oxygenator was 2 L/min or filtered 100% medical grade oxygen.

Pressures were monitored proximally, distally, and within a Datascope Pulsatile Assist Device (PAD). A Datascope System 80 intra-aortic balloon system was used to drive the PAD. A doppler ultrasonic probe and an electromagnetic flow probe were placed distal to the PAD. A Parks 806 Directional Doppler was used to monitor frequency shifts caused by gaseous emboli. Since the doppler is flow dependent, a Biotronix 610 flow module was used to measure changes in flow caused by the pulsating PAD. An 8-channel monitoring and recording system was used to record all parameters.

Embolic activity, as monitored by changes in frequency shifts, was recorded under the following conditions:

1. at 1, 3, and 6 L/min roller pump flow
2. with and without an arterial line filter to the circuit
3. at different arterial line pressures, which were changed by adjusting a distally located Hoffmann clamp
4. at balloon driving pressures of 3, 9, and 12 p.s.i.

These conditions were tested while following the manufacturer's recommended drive system settings; namely, pressure exhaust mode, 300 msec delay, 300 msec primary interval, and 140 msec fill time.

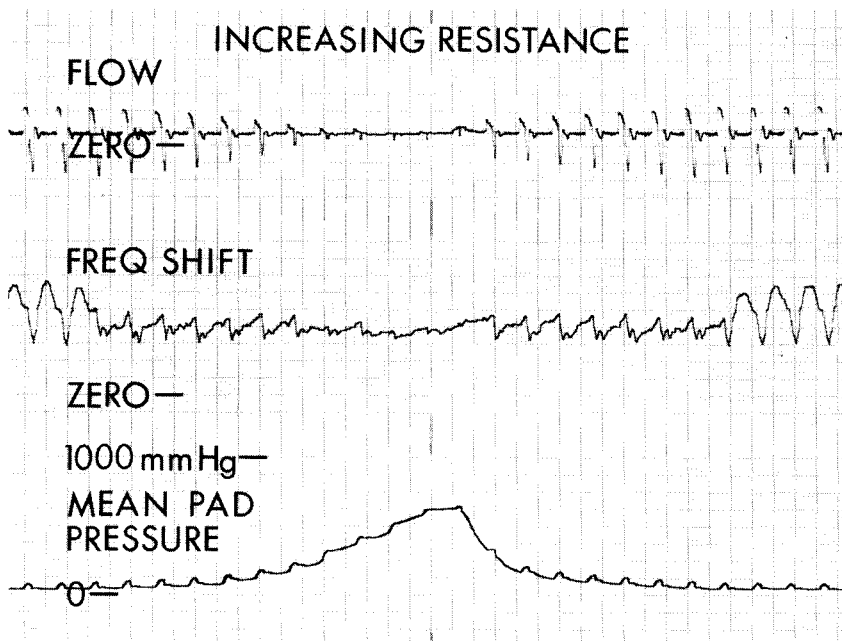
The PAD operation was also photographed by a 16 mm high speed movie camera.

## RESULTS

The PAD produced macro- and microemboli when operated at the manufacturer's recommended settings. These emboli were visually observed as well as detected by the doppler at all flows tested and at varying positive pressures. Figure 2 shows a typical recording that was taken when the PAD was both in operation and still in the circuit but not in operation. A line drawn through the tracing helps illustrate the greater frequency shifts occurring as a result of macro- and microemboli rather than increases in flow caused by the compressed PAD balloon (a, Fig. 2). The greater frequency shifts were visually observed to occur simultaneously with showers of emboli passing the doppler probe (c). The cause of the emboli was the preceding negative pressures generated within the PAD when vacuum was applied to the device (b). A time delay exists between the negative pressure peaks and the detection of emboli by the doppler. This is caused by the transit time required of the roller pump to propel fluid from the PAD to the doppler probe. A reverse flow was also observed when the balloon re-expanded (b).

The only difference in the pre, post, and intra PAD pressures was a small pressure drop across the PAD.

Figure 3 demonstrates that the magnitude of the frequency shifts appeared to be proportional to the amount of positive drive pressure applied to the PAD balloon. Thus, the more the balloon is collapsed (greater drive pressure), the greater number of emboli are produced when the vacuum is reapplied during the next cycle.



**FIGURE 4.** *PAD pulse amplitude and emboli production are negated when the resistance distal to PAD is increased. The resistance was increased by slowly tightening an adjustable clamp located distal to the PAD.*

Figure 4 shows the result of increasing the resistance distal to the PAD. By adjusting the distal Hoffmann clamp, the distal resistance increased; thus, the arterial line pressure increased up to 615 mmHg. This resistance then negated the PAD produced pulse amplitude and flow, and, consequently, decreased emboli production.

Baseline levels of microemboli were lower when flow was filtered as opposed to unfiltered. Thus, emboli produced by the oxygenator and pumphead were greatly reduced before entering PAD.

There were no noticeable changes in data recorded from systems that were primed with either Lactated Ringer's or hemodiluted blood.

## DISCUSSION

Applied negative pressures in the arterial lines of extracorporeal circuits have been shown to produce gaseous emboli.<sup>234</sup> The PAD appears to be another extracorporeal source of gaseous emboli as a result of application of vacuum to the balloon. The amount of emboli that was produced by PAD appeared to be directly proportional to the degree of balloon collapse; that is, the greater the collapse of the balloon, the more negative the pressure applied, and the more gaseous emboli produced.

There are four variances with which the PAD operator should be concerned when controlling the degree of balloon collapse:

- a. arterial line pressure magnitude
- b. fill time
- c. positive pressure applied to the balloon
- d. and, negative pressure applied to the balloon

For instance, if the arterial line pressure increases and the fill time and positive pressure remain constant, the balloon loses its ability to produce a pulse. On the other hand, if the arterial line pressure decreases and the fill time and positive pressure remain constant, the balloon has more potential to collapse. Thus, the possibility exists for greater emboli production. Furthermore, if the fill time increases and the other parameters remain constant, balloon collapse is greater, resulting in greater emboli production. Finally, the degree and duration of vacuum to blood will also determine the volume of gas drawn out of solution.

Although the doppler used in this study obtained qualitative information rather than specific numbers and sizes of emboli, the results clearly indicate a causal relationship between negative pressure and subsequent gaseous emboli production. Moreover, the sensitivity of ultrasound at detecting and quantifying embolic activity in extracorporeal circuits has been demonstrated with the use of microspheres.<sup>5</sup>

Inclusion of a micropore filter distal to PAD to remove the emboli would probably greatly diminish the magnitude of the pulse amplitude. Therefore, filtration would not be an appropriate solution to reduce the gaseous microemboli hazard created by the PAD.

Based on this preliminary study, the authors propose the following recommendations:

1. The operator should be cognizant of the hazards of gaseous emboli production when negative pressures are applied to extracorporeal components situated in the arterial line, such as in a pulse producing device. Moreover, the manufacturers should advise the operator of this hazard in writing.
2. The physician and operator should consider the benefit of pulse producing devices exposed to negative pressures and located in the arterial line against the possible hazards of gaseous emboli production.
3. Manufacturers of pulse producing devices incorporated in the arterial line should thoroughly investigate the potential hazards of emboli production. Thus, this study should be repeated by the manufacturers with a device which can quantitate the number, size, and volume of gaseous microemboli.

#### REFERENCES

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