The Development History of Pulsating Pumps and the Application for Perfusion Phantoms

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Abstract: There are several types of pumps for applying a pulsating flow to both simulated blood vessel phantoms and simulated organ phantoms. Our company provides pulsating flow phantom systems that use piston or gear pumps. The basic structure of the pump is the same as that of pumps generally, but we have independently developed and sold pumps that have the necessary functions for medical experimental use.
In this document, first of all, we show the history of the development of our pulsating pumps, their structures and advice for their particular usage. Finally, we talk about the perfusion phantoms as one of the applications of these pumps.
It would be our pleasure to help those who are experimenting with pulsating flow phantoms for the first time.

Keywords: Pulsating flow, Pump, Phantom, Hollow fiber, Perfusion

History of pulsating flow pump development

Along with the development of multi-slice CT, our company has started to develop a dynamic heart phantom — which consists of a simulated pulsating ventricle made of rubber— as a result of industry-academia collaboration

Full-scale production and sale of the product began around the time when the paper [1]
on the development of the first prototype was evaluated at the RSNA in 2000. After that, we decided to make a prototype of a dynamic heart phantom that can be used in MRI under new industry-academia collaboration. The purpose of the experiment was not only to measure the pulsation of the simulated ventricle but also measure it's flow velocity. This was achieved by attaching a simulated coronary artery tube to the simulated ventricle, and creating a pulsating flow there. We plan to measure the flow velocity in advance by using a flow wire outside the MRI room. We measure this flow velocity by the phase contrast method of MR and compare the data of both.

What was needed was a pulsating flow pump that could accurately simulate the flow of blood. We needed a function that could change both the heart and the flow rate, but such pumps were not commercially available in Japan. We believed that there were quite expensive products already on sale overseas. Originally, commercial pumps were premised on steady flow, and pumps with as little pulsation as possible were desirable, but there were no companies in Japan that would sell pumps designed for pulsation. Therefore, we decided to develop a pump with a so-called physiological flow.

A prototype pulsation pump of the piston type was designed and constructed. (Fig. 1).

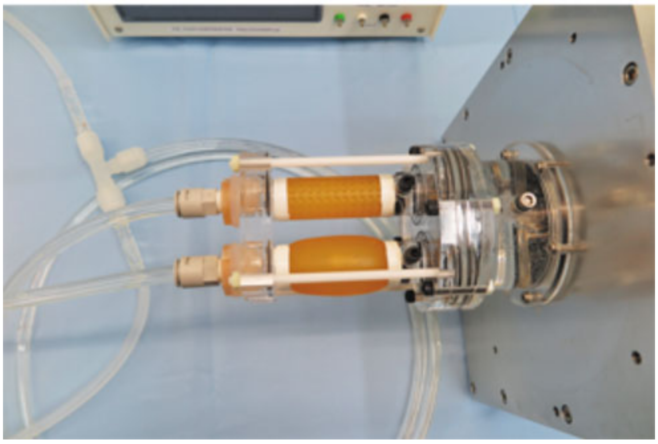


Fig. 1: A closed flow circuit type pulsating pump

This pump has two rubber tubes that are used to simulate real-life conditions in the flow circuit.
The function of these rubber tubes is to allow the flow of water in a closed circuit.
We explain the structure of the pumps in the following pages.

The prototype piston pump worked as successfully as we had expected. But, after consideration, in order to study the liquid flow under many different flow conditions, we needed a pump which could flow not only in a pulsating manner but also in a steady one. Therefore, the next pump system we developed was one which consisted of a gear-type pump and solenoid valves that moved at regular intervals. (Fig.2)

The merit of this pump system was that we could set a variety of conditions for pump movement and also produce a shock action for the pulsating flow.

On the other hand, there were several disadvantages such as the time taken to configure the flow parameters, because the setting procedure was of an analogue type. Other disadvantages were that, because of its mechanical characteristics, there was an upper limit of movement in the higher heartbeat area. Also, because of the nonlinearity of the flow valves, it needed operators trained in the skill of controlling the valve open rate.

Fig2: A pump system for both steaady flow and pulsating flow.

Afterwards, we eliminated these disadvantages and designed the outer dimensions of the pump to be smaller. We also added a brand new controlling system which gave us much better operability.

All operations of the pump are controlled by way of a tablet screen, and since this is connected to the main body of the pump, via a Bluetooth module, it can be operated freely, even from a distance. (Fig. 3).

Fig.3: Latest Pulsating Pumps

In addition, as standard, it comes with brand new GUI, such as a graphical pressure display of the flow path, a guideline display of the discharge amount, and so on.

Currently, this series of pumps is the most commonly used, but piston-type pumps are also used depending on the application. Operationally we have developed optional functions such as arrhythmia pattern, external synchronization, and continuous waveform output pattern.

Structure of Pulsating Pumps and their Characteristics.

We use piston pumps and gear pumps in order to provide a pulsating flow for both mock human blood vessels and organ phantoms.

There are many differences in the structure between piston pumps and gear pumps. These pumps in turn have their own merits and disadvantages. The basic structures of piston pumps and gear pumps and their pulsating patterns are described in Fig.4.

The main differences between the piston and the gear pumps are as follows;

1, Factors that determine the ejection volume.
2, The flow pattern in the pulsating flow.
3, The difference in ejection volume.
4, The ability to recreate a high heart rate flow.
5, Difference of ejection volume pattern.

Let's consider each these of differences.

1, One of these differences relates to factors that determine the ejection volume.

In the case of piston pumps, the ejection volume per minute is calculated by the number of piston movements per minute, the stroke length of the piston movement and the inner diameter of the cylinder. On the other hand, the ejection volume per minute of the gear pumps is calculated by the rotation of the gear unit per minute and the gear parameters.

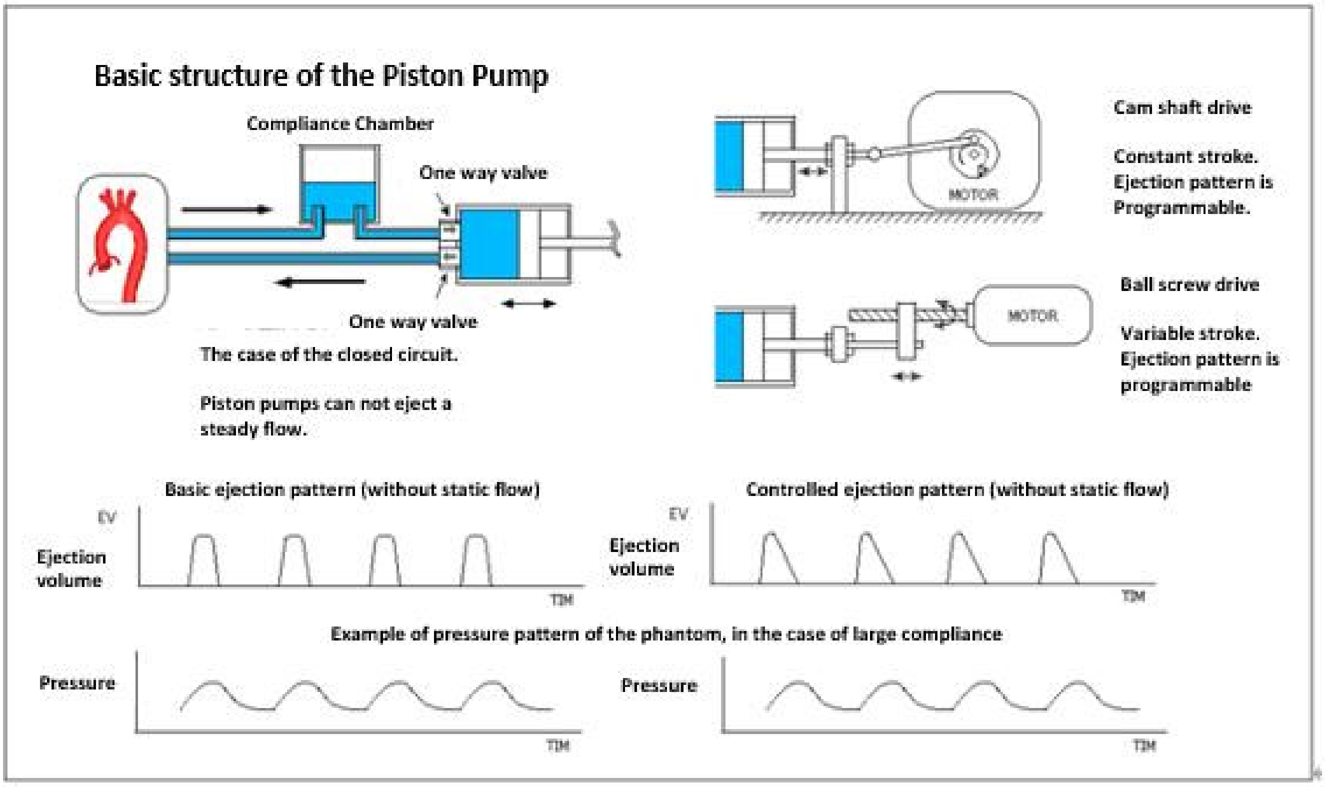
2, The difference in the flow pattern.

The piston pump can not produce a static flow by itself. In order to create a static flow with a piston pump, we have to add some form of compliance chamber or other equipment which can convert the pulsating flow into a static one

In the case of gear pumps, controlling the rotation speed of the gear unit can create both a static flow and a pulsating one continuously.

3, The second difference in the ejection volume:

A piston pump is more suitable for the simulation of the blood flow of the ascending aorta. This is because the piston pump ejects a large amount of liquid in a very short time. On the other hand, if we were to use a gear pump for this same simulation, we would have to use a very large gear pump and this approach is not realistic. For example, a piston pump the stroke of which is 100cc and moves at 60 bpm, ejects 100cc per 0.3sec (systolic period). If we were to make a gear pump which has the same ejection performance, we must make a gear pump which ejects 100/0.3*60=20000(ml/min), =20L/min. When the gear pump ejects 100cc within 0.3 second, the maximum ejection volume must be much larger than 20L/min. This is quite impractical.



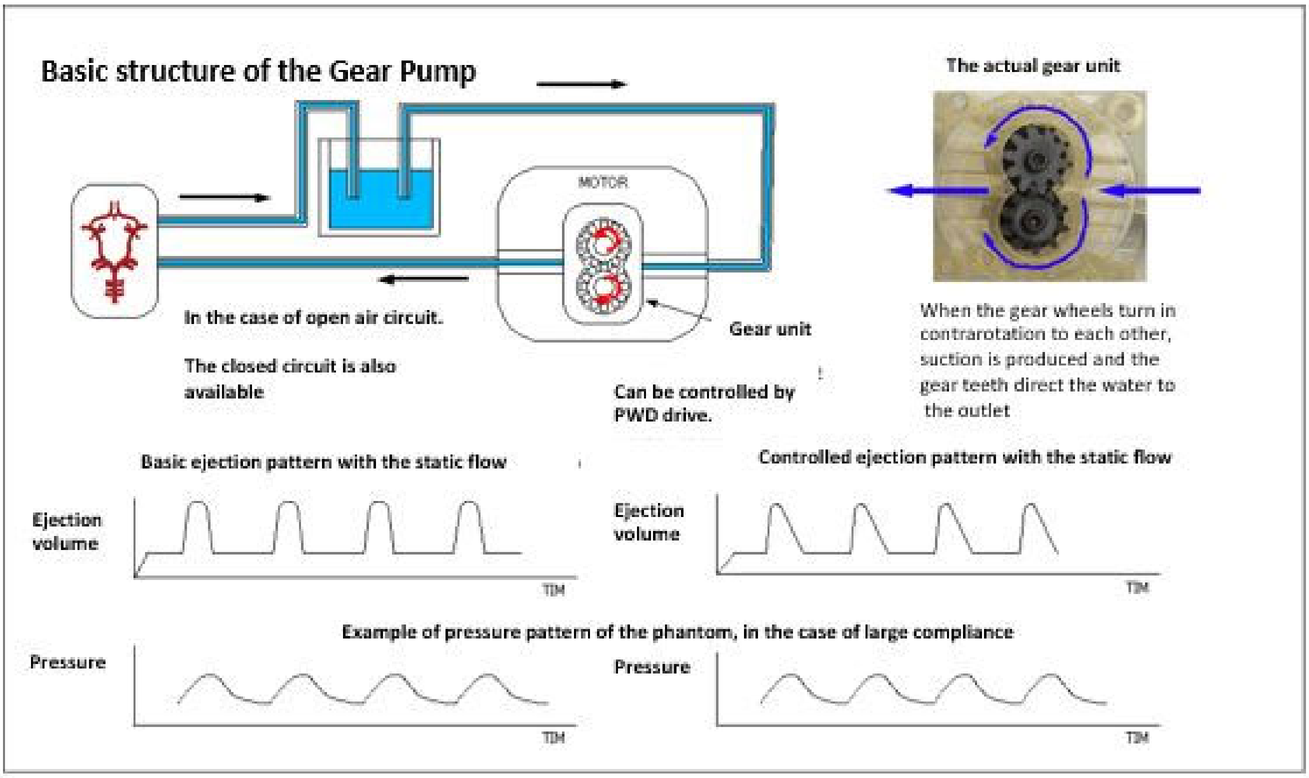


Fig:4 Basic structures of both pumps and examples of wave patterns

4, The ability to recreate a high heart flow.

When you use piston pumps in a high heart rate range, you have to take care of several factors. For example, the structure of the flow circuit, the power of the motor in the piston pump, the mechanical strength of the power unit, etc. If you flow high heart rate liquid into a narrow circuit, the power unit receives high pressure from the circuit and can possibly be damaged. In the case of using gear pumps in a high heart rate range, also you have to take care of the structure of the flow circuit and strength of the power unit. However, the effects of high heart rates for gear pumps are not as strong as compared to piston pumps. This is because the inertia of the gear pump drive is much less than that of a piston pump. Thus, gear pumps are relatively easier to use in a high heart rate range than piston pumps

5, The difference of ejection volume pattern.

The basic ejection volume pattern of piston and gear pumps is the same as the pulsating pattern described in Fig.4. The gear pumps can eject not only in a pulsating pattern but also in different patterns, however. This pulsating ejection pattern is almost the same as that of the human heart. It means that even a flow circuit which uses a piston pump can simulate flow patterns of the human body if the circuit has the same structure as the human body. If the volume of circuit compliance is large enough, even a static flow can be produced in the circuit.

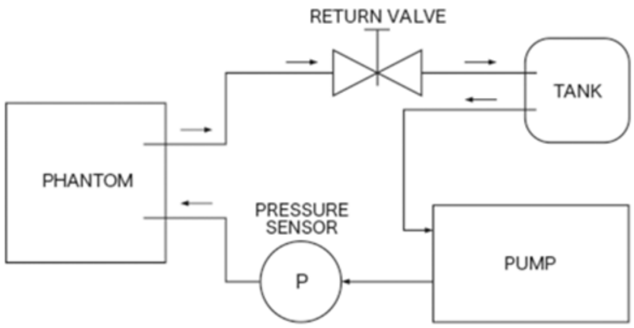
Important points in using the pumps.

There are many important points to consider when we set up and use the pulsating flow phantom systems. For example, the flow volume of the liquid, the flow velocity of the liquid, the compliance of the circuit, leakage in any of the connecting parts, the reproducibility of the experiment and so on. But, the most significant point is not to cause damage or destruction to the phantom in the flow circuit or the pump itself. The possible causes of such damage or destruction are as follows:

1, Excess-pressure

2, The residue of the contrast agent or flow liquid which contains particles.

Let's consider the cause of excess-pressure. Figure 5 shows the simple pulsating flow phantom system.



Fig,5 Pulsating Flow Phantom System

In Fig.5, "PUMP" represents a piston pump or a gear pump.

"RETURN VALVE" adjusts the total pressure of the circuit without a change in pump ejection volume.

Here, we are mostly concerned about damage or destruction to the phantom. This is because, in many cases, the phantoms have less mechanical strength than the pumps.

Case 1, When the ejection volume increases more than the specified volume through user error.

When the operators are inexperienced in handling the pulsating flow phantom system, they sometimes increase the flow volume without due consideration for the specified flow volume. Maybe, this is owing to their enthusiasm for the experiment!

In other situations, someone might change the settings of the pump during the experiment. If this escapes the operator's notice, and the pump is started again, this would lead to the development of excess pressure. If the flow velocity becomes two times faster, the pressure will be four times stronger. Thus, this influence of the flow speed on the circuit pressure is very significant. So, when we use a phantom which is made of very thin skin we must exercise caution.

Case 2. When the flow resistance of the circuit 'downstream' of the phantom increases without any change to pump ejection volume.

If the RETURN VALVE in Fig..5 is closed too much, the pressure in the circuit 'upstream' of the RETURN VALVE would become excessive and the phantom could be damaged.

If the tube 'downstream' of the PHANTOM is kinked or compressed in any way the PHANTOM might become broken due to the build-up of back-pressure that this trouble point in the circuit would cause.

For example, when you do your experiment, you may put your phantom on the cradle of the CT or MRI scanner or Angiography device in order to place it onto the ISO centre of these modalities.

During the in/out motion of the phantom, the flow circuit tube could become kinked accidentally by something around this cradle.

In this scenario, the pressure in the circuit would become very high and the phantom could be damaged or broken.

So, care must be taken with regard to the system setup.

Next, we explain cases in which pumps are broken.

For example, when the circuit flow stops, the RETURN VALVE is either fully closed or the tube is kinked, and in this case, the pump could become damaged. If the pump is a gear pump, the gear unit could be broken, and if the pump is a piston pump, the tie rod of the link unit could be broken because the mechanical strength of these pumps may not be sufficient.

Even if the mechanical strength of these pumps is adequate, the drive unit may be locked and the drive unit motor could be burned out.

If the cross-sectional area of the flow circuit is too narrow, the piston pump might become damaged.

For example, in the case of the outlet, the inner diameter of the piston pump may be 20mm and the connecting tube's inner diameter, 10mm. If you keep driving the pump in a higher output range, the linkage part of the piston pump could experience metal fatigue and break down. In such a case, this faulty arrangement might not be noticeable because initially, the pump appears to move naturally. However, the only clue would be that the pump may be noisier than usual. Therefore, care should be taken to operate the pump according to the instructions given in the pump's operating manual.

When the fluid contains a contrast agent or particles, care must be taken not to allow the liquid to dry up in the pump. This is because the residue of the contrast agent or particles might clog the gears of the gear pump or piston in the case of a piston pump. In this situation, you might be able to dilute the residue with lukewarm water and fix the problem. But, in the worst case, the pump, or parts of the pump may need to be changed. If you install a pressure sensor in the flow circuit, similar care must also be taken as regards residue. Any residue in the pressure sensor may distort the accuracy of the sensor readings and, if such is the case, the pressure sensor cannot be used.

Thus, whenever the pump is used, care should be taken to check the condition of the flow circuit in order to prevent an unexpected excess of pressure.

Examples of the application of the Pulsating Pumps

Our pulsating pumps are used in conjunction with diagnostic imaging equipment like CT, MRI, RI, Angiography, US and other simulators. Furthermore, our pumps can be used in many fields, for example, in the application of photosensors or pressure-sensitive devices alongside other medical equipment, supporting the transplantation of living tissue, the developmental study of new types of electric cells, and the reconstruction of the vessels of a donor body. In each case above, pulsating flow pumps are used instead of steady flow ones because a pulsating flow seems more effective for this purpose.

Now, we explain the example of how we apply the use of a pulsating pump with regard to a perfusion phantom.

Almost all the perfusion phantoms that we made were originally for the MRI. However, they may also be used in conjunction with CT scanners. This is because all the materials that comprise our perfusion phantoms consist of non-metallic materials and this is what allows them to be suitable for CTs. Our perfusion phantoms can also be used in Angiography. The basic structure of perfusion phantoms is such that fluid being sent from the tube simulates arterial flow to organs such as the brain or heart and likewise, this fluid, in returning to the tube, will simulate venous flow.

In order to simulate a tissue we use such materials as plastic sponges, acrylic beads, dialyzers and so on. In the case of a plastic sponge, we can use plastic sponge filters. There are several kinds of mesh filters. (Fig.6) The mesh of plastic sponge filters is uniform in size and consists of cells made of continuous air pockets.

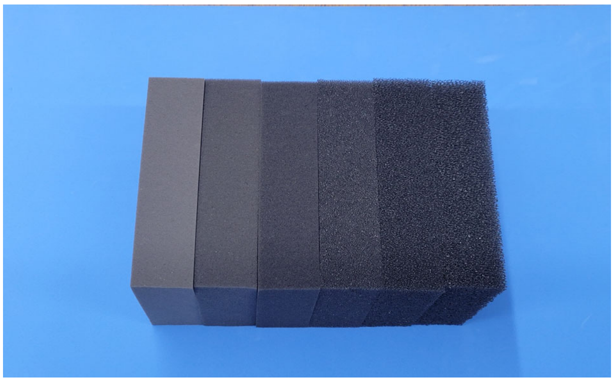


Fig.6: The different meshed-sized plastic sponges.
Product name INOAC MOLT FILTE
From the right side:CFH-13,20,30,40,50. CF-S

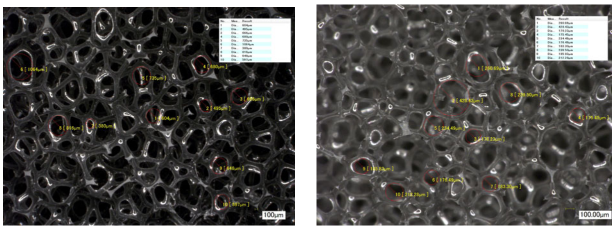


Fig.7: Comparison of the mesh. Left CH-13 Right CH-502

Fig.8 shows one example of using a plastic sponge for the tissue. You can cut the plastic sponge and fix it into the plastic case which is made with a 3D printer as shown in Fig.8. Then, liquid may be passed through this tube which contains many small holes thereby simulating an artery.

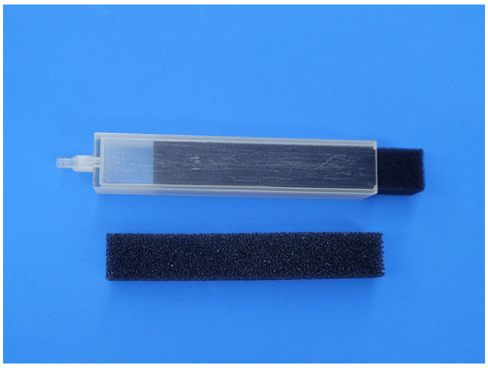


Fig.8: Cut plastic sponge and case with tube made with 3D printer.

When we use a plastic sponge as simulating tissue, in order to use it correctly within the pump's range of abilities, we must prepare a sample of it and try using it with some water flow. Then we can specify the dimensions and mesh size of the plastic sponge.

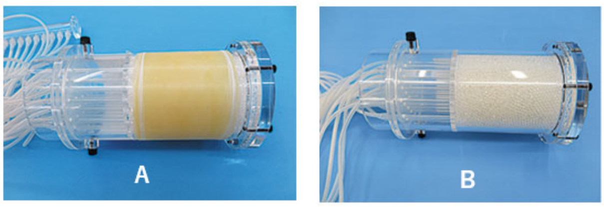


Fig 9: Perfusion phantoms using acrylic beads as simulating tissue.

A: With rubber type B: Non-rubber type

Fig 9 shows examples of a perfusion phantom using acrylic beads as a simulating tissue. φ3mm acrylic beads are enclosed in the acrylic case. The tubes with φ0.4mm holes are attached inside the acrylic case. 12 tubes equivalent to arteries and 12 tubes equivalent to veins are placed, in a staggered arrangement, to form fluid inflow and outflow routes. It has been discovered that if we add a pressure buffer to the perfusion phantom by making φ3mm holes in the acrylic case, and covering these holes with rubber, the resulting measurement of fluid flow simulates that which is found in the human brain. Papers [2][3]. If we add compliance in other kinds of phantoms, the same results regarding fluid flow can be expected.

In the case of using perfusion phantoms with multimodality, the material of the simulating tissue can present problems. We have found a paper on the study of multimodality perfusion phantoms. In the paper, a mixture of activated carbon and silica granules was used for the MRI, and a plastic sponge was used for the CT. [4]

If we use a plastic sponge instead of acrylic beads, we can use the phantom in Fig. 9 for CT.

A dialyzer（Fig.10） is a device which is used in dialysis. The inner structure of a dialyzer consists of a band of hollow fibers. This hollow fiber contains lots of micro-holes. Examples of the perfusion phantom using a dialyzer can be found in papers - [5][6]

Fig10: Dialyzer AEF-13

We will now explain the development of perfusion phantoms using hollow fibers. From our investigations on the web, we found that almost all papers involving perfusion phantoms, which used a dialyzer as a simulating tissue, used the dialyzer without any modification whatsoever. But, we did find a unique paper about perfusion phantoms using dialyzers issued by Dr. Eiji Okaniwa et al. [5] According to this paper, there were dry-type dialyzers and wet-type dialyzers. They used a dry-type dialyzer that added air pressure in order to prevent the contrast agent from flying out of the hollow fiber. The reason why the wet-type dialyzer was not used was that the hollow fiber allowed contrast agent to fly out through its pores. This meant that the hollow fibers didn't simulate the function of the BBB (Blood-brain barrier). So, air pressure was added into the dry-type dialyzer lumen in order to prevent the flowing out of contrast agent.

Another result of this study was that, because of the heavy specific gravity of the iodinated contrast agent, its flow in the dialyzer was concentrated more in the under part of the latter than in the center of it. Generally, the inner diameter of the dialyzer enclosure is 35mm or more even if it is of a narrow type. So, it is an understandable phenomenon that the contrast agent, which flows into the dialyzer, will concentrate more in the under part of the latter than at its center. We realized that we must be careful about this phenomenon when we make a hollow fiber perfusion phantom. Therefore, we planned to make a perfusion phantom without a dialyzer enclosure when using hollow fibers. Another reason is that hollow fibers can be difficult to procure.

We assumed that the contrast agent that flowed out from a hollow fiber would return to the latter. It has already been stated that contrast agents would flow out from the hollow fiber in the wet-type dialyzer. Next, we needed to confirm whether or not the water could flow through the dialyzer reversibly using a pulsating pump and different types of dialyzers. (Fig 10,11)

Fig 11: The dialyzers used in the experiment to confirm flow reversibility.

We used the flow circuit as depicted in Fig 12 for this experiment. Fig 13 and Fig 14 show the results.

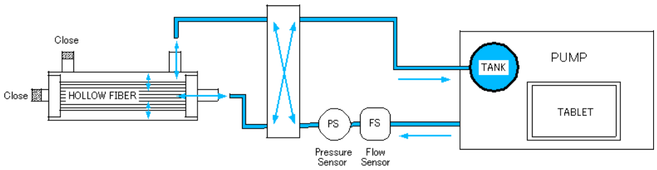


Fig 12: The flow circuit for confirming reversibility.

EC-2 setting

1st	2nd	Duration	BPM
30	1	100	60

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		AEF-13		UT-15S		PUT-15		AUT-15	
Forward	Pressure	173/168	mmHg	194/188	mmHg	77/74	mmHg	222/215	mmHg
	Flow rate	522	ml/min	504	ml/min	531	ml/min	496	ml/min
Backward	Pressure	202/196	mmHg	228/223	mmHg	103/98	mmHg	105/100	mmHg
	Flow rate	504	ml/min	469	ml/min	531	ml/min	531	ml/min
				According to the AUT-15 result we retried UT-15S				Because of many bubbles we retried the forward flow	
		Forward	Pressure	202/197	mmHg			76/72	mmHg
			Flow rate	504	ml/min			541	ml/min

Fig 13: Data from the first experiment.

EC-2 setting

1st	2nd	Duration	BPM
30	1	100	60

2023/5/10

		AEF-13		UT-15S		PUT-15		AUT-15	
Forward	Pressure	199/191	mmHg	223/214	mmHg	122/115	mmHg	224/216	mmHg
	Flow rate	550	ml/min	530	ml/min	609	ml/min	545	ml/min
Backward	Pressure	202/194	mmHg	220/212	mmHg	141/135	mmHg	103/100	mmHg
	Flow rate	550	ml/min	540	ml/min	592	ml/min	636	ml/min

. Fig 14: Data from the second experiment.

The results of the first experiment are as follows:

1, We could make water flow through the hollow fiber reversibly.

2, The flow resistance of each dialyzer was different from that of the others.

3, The resistance to the standard flow (the blood flow direction the dialyzer uses in clinical applications) was smaller than that in the opposite direction.

Accordingly, we made an experimental chamber - shown in Fig. 15 - and used a pulsating pump for the water flow. To this water, we added red food coloring in order to confirm the flow direction.

The results of this experiment confirmed our expectations. We confirmed that the colored water flows out into the chamber lumen from the first hollow fiber and then is sucked into the second hollow fiber and then flows out from the chamber. But when, about 10 months later, we tried to use the chamber, the flow resistance of the set-up was so high that we couldn't repeat the same experiment. It appeared that the hollow fibers had become clogged within 10 months. It may have been that the storage conditions of the chamber were not suitable.

Therefore, we repeated the initial experiment. Fig 14 shows the results of this second experiment. We found that the flow- resistance in the second experiment seemed to be higher than that in the first experiment. Because of the fact that the storage conditions of the dialyzers were better than that of the chamber, there was a seeming increase in the flow resistance ratio between the dialyzer and the chamber. According to these results, it would appear that the holes of hollow fibers are so small that they get clogged too easily.

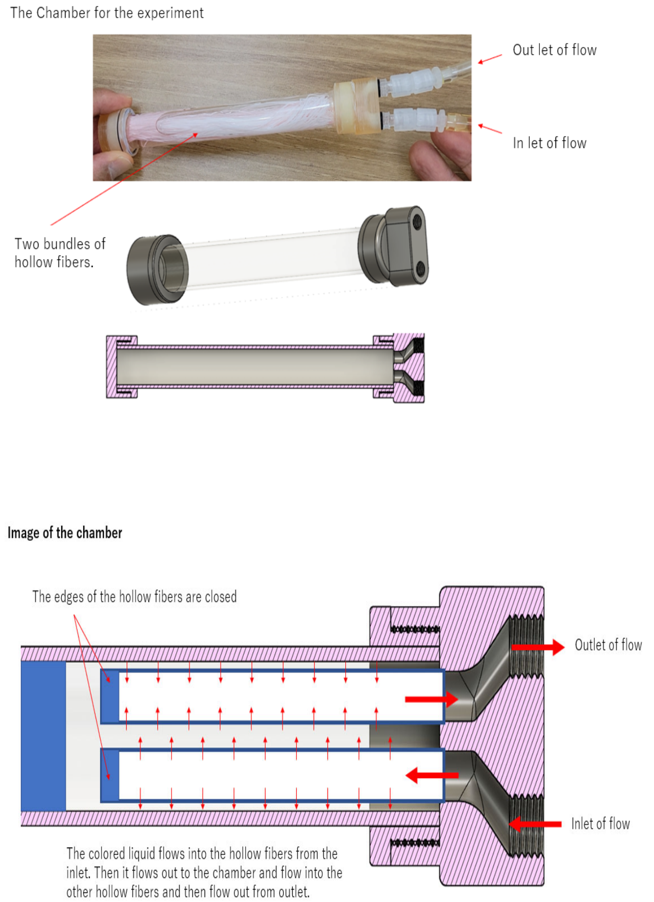

Fig 15: The prototype experimental chamber and diagram of the water flow.

The diameters of the holes are generally 0.01 microns to 0.2 microns — according to the data from [7].

We asked the manufacturer of the dialyzer about the dimensions of the holes in their hollow fibers, but they did not publish this data because of its confidentiality.

On the other hand, we assumed that the increased flow resistance might be caused by the connection between the hollow fibers and the chamber. This is because the diameter of each hollow fiber is very small and the thickness of the sidewall of the latter is very thin. So, we began to review the method of how to bind the hollow fibers that are connected to the chamber. Fig 16 shows a prototype. We disassembled the dialyzer and took out the hollow fibers. Then, we bound the hollow fibers and inserted them into a plastic tube using adhesive to fix them together. The surface of the edge was then cut and polished.

Fig16: A prototype. A bundle of hollow fibers fixed in a plastic tube.

Fig 17 shows the enlarged view of Fig 16. It can be seen that almost all the hollow fibers are crowded and crushed.

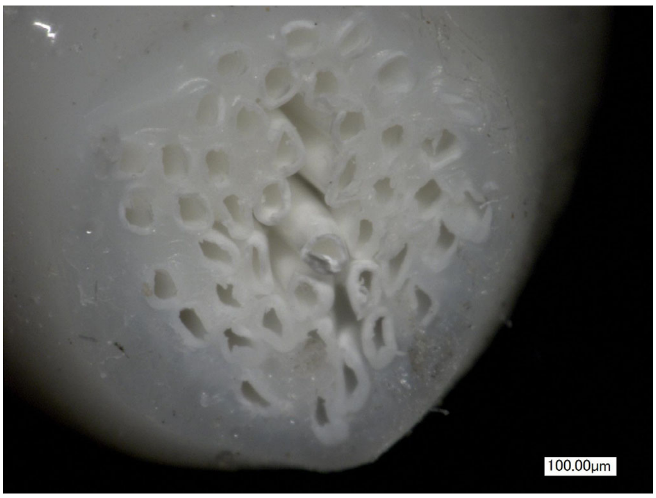

Fig 17: A cross-sectional view of the bound hollow fibers.

On the other hand, Fig 18 shows an enlarged view of the edge of a disassembled dialyzer. In this view, almost all hollow fibers are circular in shape, and not deformed. Some of the hollow fibers seem to be clogged with a white material. This white material is a scratch of resin resulting from the method used to disassemble the dialyzer. A larger amount of white material was seen in another cross-section of the dialyzer's edge. There also was another characteristic observed in the hollow fibers within the dialyzer.

This was due to the fact that the density of the hollow fibers was much smaller than that of our sample. When we assembled the sample, we tried to bind the hollow fibers as tight as possible. This then, caused a crushing of the hollow fibers which also caused the increase of the flow resistance.

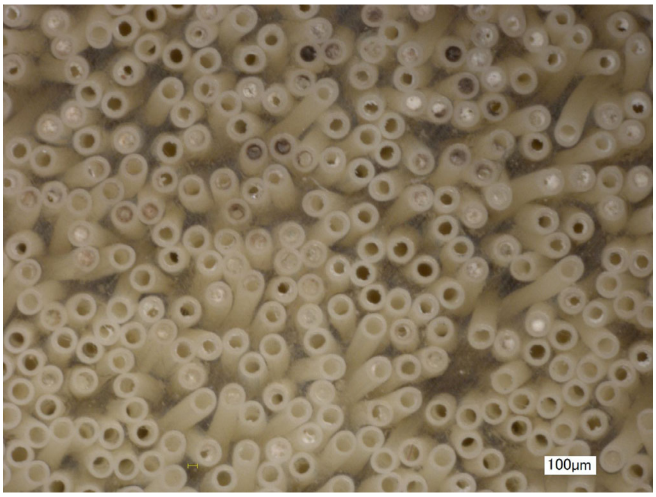

Fig 18: Across-sectional view of the dialyzer

We have selected a new perfusion phantom, partly made up of hollow fibers, as one example of a pulsating pump. Unfortunately, we can't show you a completed perfusion phantom as yet, because of ongoing improvements. We are at present developing a unit part, which is made of a sufficient bundle of hollow fibers, and which will be possible to attach to any of our phantoms. When we successfully complete the development of this unit part we will fix it to the phantom as shown in Fig19, Fig20, and Fig21. If you have any interest in this development, please feel free to contact us.

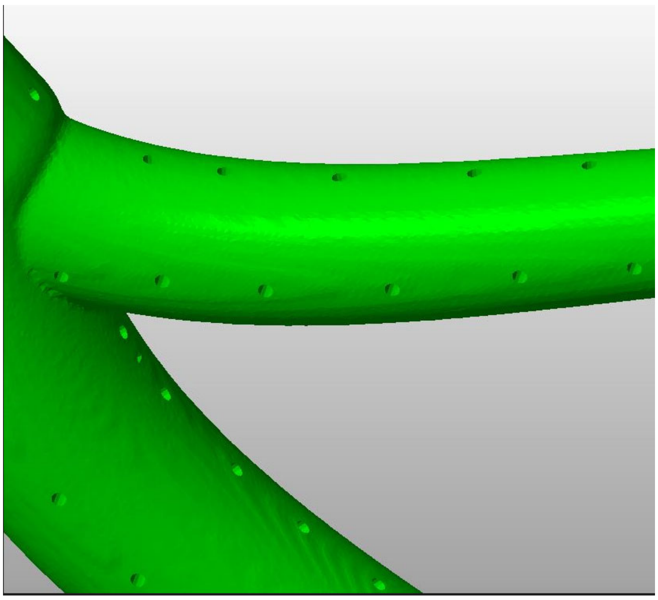

Fig19: The 0.3mm holes fixed to a mock coronary artery.

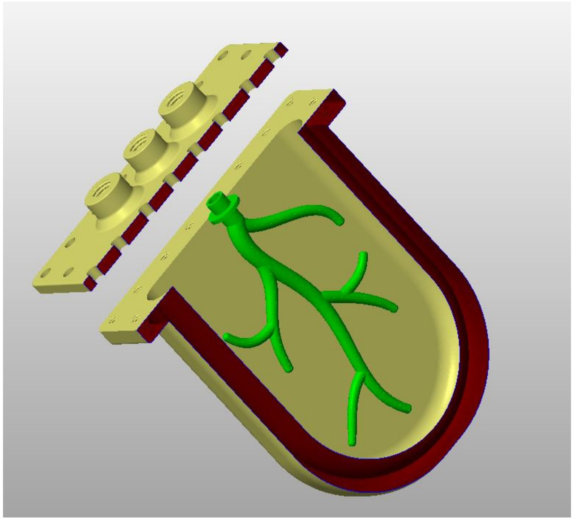

Fig20: A conceptual drawing of mock myocardial perfusion phantom.

The unit part under development will be fixed to this phantom.

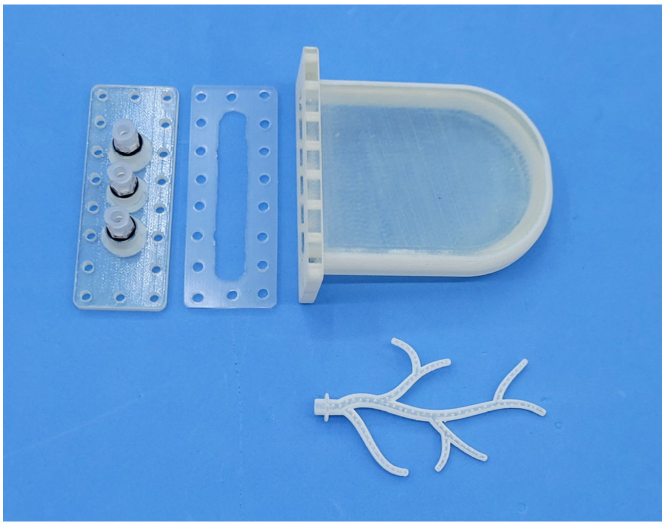

Fig21: The parts of the mock myocardial perfusion phantom.

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