

## A Newly Designed Flow-Regulating Device in Shunt Therapy of Hydrocephalus

Shigehiro Hashimoto and \*Nobuyuki Kawano  
Departments of Bioengineering and  
\*Neurosurgery, School of Medicine, Kitasato  
University, Sagamihara, Japan

**Abstract:** A new flow-regulating device for shunting in hydrocephalus was designed to limit an excess flow by a pressure-head between the cerebral ventricle and the abdominal cavity in a standing position. The device has two diaphragm valves connected to each other by two lines: one is a shunting line to transfer cerebrospinal fluid and the other is a control line filled with a control fluid with a higher density than cerebrospinal fluid. The performance of the model device with a natural rubber sheet diaphragm was tested in a mock system, using glycerol for the control fluid and water for the transfer fluid in vitro. Results show that device decreases the excess flow when the pressure-head between two valves exceeds 35 cm. **Key Words:** CSF Shunt—Flow-limiting valve—Hydrocephalus—Control-fluid—Diaphragm.

Due to its delicate structure, the brain is surrounded inside and out by circulating cerebrospinal fluid (CSF) within the intracranial cavity. In a brain with normal CSF circulation, the intracranial pressure is normal ( $\sim 15$  cm of  $H_2O$ ), and slightly higher

than venous pressure ( $\sim 8$  cm of  $H_2O$ ) regardless of one's posture. In hydrocephalus, the intracranial CSF pressure is higher than normal due either to increased resistance to CSF flow or to hyperproduction of CSF. The causes can be congenital or acquired (e.g., tumors). Hydrocephalus is treated with one-way shunts to drain CSF from the cerebral ventricle into the abdominal cavity and thereby restore intracranial pressure to normal. This CSF shunt works well when the patient lies down, but invites an excess flow when the patient stands. The excess flow is caused by a pressure-head between the cerebral ventricle and the abdominal cavity. This leads to a low intracranial pressure, which may produce headaches or cause development of subdural hematoma (1).

In order to limit the excess flow, devices called anti-siphon valves have been used clinically (2). One such device consists of a diaphragm valve which occludes the shunt pass with deformation of the diaphragm by a pressure difference between the outside and inside of the pass (1,3). When it is implanted, however, the antisiphon valve does not always function well, because its diaphragm can be deformed by the surrounding tissue (4).

In order to improve the performance of the valve, a flow-limiting valve was conceived of that could be operated directly by the pressure-head. This idea led to the development of a flow-regulating device with two diaphragm valves and its performance was tested in vitro.

## MATERIALS AND METHODS

### Principle of the flow-regulating device

The working principle of flow-regulating device is shown in Fig. 1. The device consists of two diaphragm valves connected to each other by two lines: a shunting line that transfers CSF (transfer fluid), and a control line that is filled with a fluid of higher density than the transfer fluid (control fluid). One of the diaphragm valves is implanted into or adjacent to the cerebral ventricle and the other into the abdominal cavity. The inlet and outlet lines are connected to the shunting line through each diaphragm valve and open into the cerebral ventricle and the abdominal cavity, respectively. In Fig. 1, a mock system for the performance test is shown employing two overflow-tanks with depths  $h_1$  and  $h_2$ , which represent pressures in the cerebral ventricle and the abdominal cavity, respectively. Two diaphragm valves are located adjacent to the respective overflow-tanks so that the pressure-head between the two valves is equal to that of the two tanks. Figure 1A illustrates the case with no pressure-head. In this case, the transfer fluid is trans-

Received: December 1987; revised February 1989.

Address correspondence and reprint requests to Shigehiro Hashimoto, at Department of Bioengineering, School of Medicine, Kitasato University, 15-1, Kitasato 1-chome, Sagamihara-shi, 228 Kanagawa, Japan.

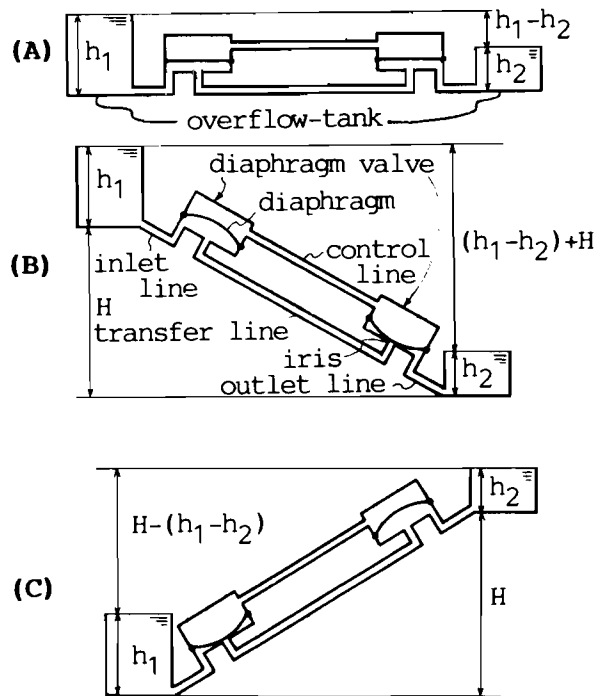


FIG. 1. Principle of flow-regulating device.

ferred from inlet to outlet according to the level difference of  $(h_1 - h_2)$ . Figure 1B illustrates the case with the pressure-head of  $H$ . In this case, the excess motive force generates and the transfer fluid would be transferred from inlet to outlet according to the level difference of  $[(h_1 - h_2) + H]$ . In this device, the excess flow by the excess motive force with the pressure-head of  $H$  is limited by the iris of the lower diaphragm valve. This performance is realized by the diaphragm deformation (in the lower valve) owing to the higher pressure in the control fluid. The higher pressure is generated by the higher

density. The extent of flow decrease is controlled by the volume or density of control fluid, or by the compliance of the diaphragm. Figure 1C illustrates the case with the counter-pressure-head of  $H$ . In this case, the transfer fluid would be transferred from outlet to inlet according to the level difference of  $[H - (h_1 - h_2)]$ . In this device, the counter flow is limited by the diaphragm deformation in the lower valve, as in the case of Fig. 1B.

#### Performance test in vitro

The performance of the manufactured model device (Fig. 2) was tested in the mock system; two diaphragm valves consist of a polymethylmethacrylate housing and a natural rubber sheet diaphragm (0.21 mm thick) and are connected by two polyethylene tube lines (1.5 mm inside diameter, 3.0 mm outside diameter, 100 cm length). A valve-iris is formed in the center part of housing of transfer flow-path side (Fig. 2B). The diameter of the opening port of the iris is 4.0 mm. The test was performed in this system with glycerol (1.26 g/cm<sup>3</sup> density at 20°C) for the control fluid and with water for the transfer fluid at 20°C. To link two overflow-tanks with the shunt system even in the case of no pressure-head between the two diaphragm valves (without function of flow-regulating device), 50-cm length polyethylene tube lines were connected for inlet and outlet flow paths. Thus, flow rate with function of the flow-regulating device was compared with that without function of the flow-regulating device in the way of controlling the level of difference between two diaphragm valves.

#### RESULTS

Figure 3 shows flow rates as a function of the pressure-head between inlet and outlet when the

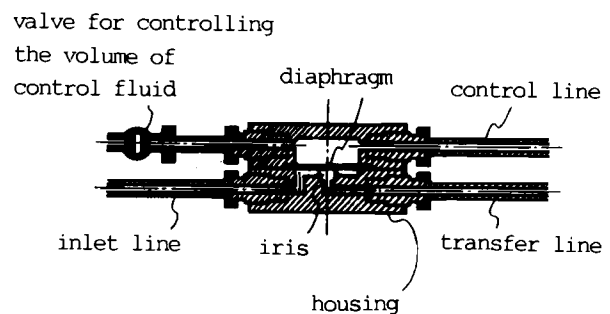
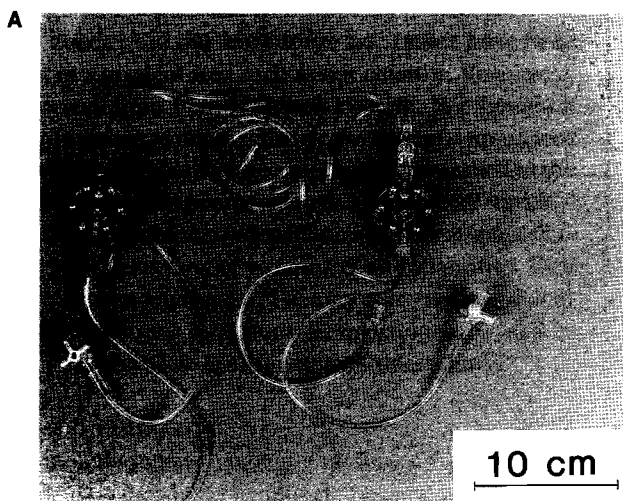
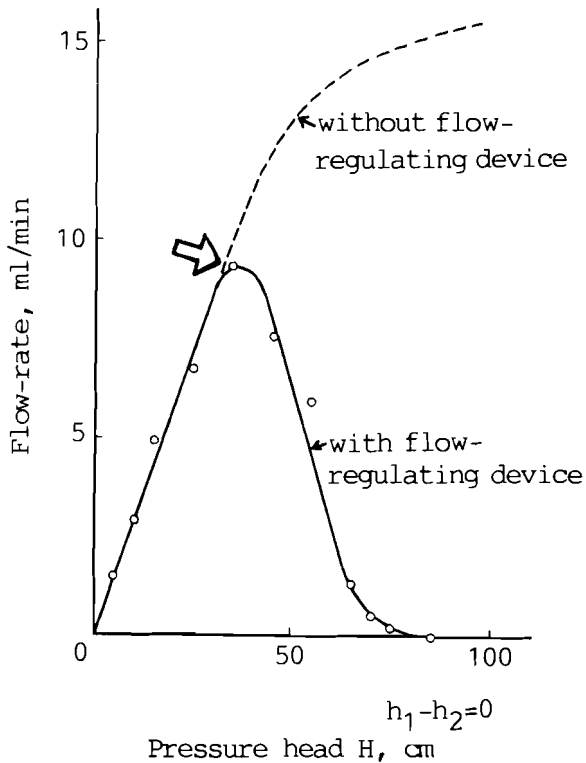


FIG. 2. Manufactured model device of flow-regulating device. A: External appearance of the entire device. B: Cross-sectional view of diaphragm valve.

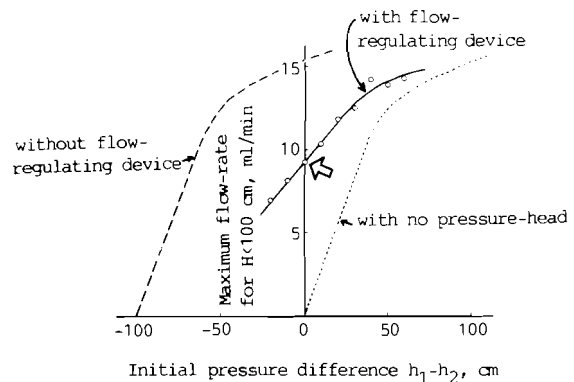


**FIG. 3.** Flow rate as a function of pressure-head without initial pressure difference. The arrow shows the maximum flow rate (with flow-regulating device). This value corresponds to the datum point (with the arrow in Fig. 4) of which the abscissa equals zero in Fig. 4.

initial pressure difference between them is zero ( $h_1 - h_2 = 0$ ). In this case, the ideal flow rates are zero to balance the pressures of inlet and outlet, because  $h_1$  equals  $h_2$ . When the flow-regulating device did not function, however, the excess flows according to the pressure-head occurred as indicated by the broken line in Fig. 3. The excess flow rates decreased with the flow-regulating device in the range of pressure-head  $>35$  cm, as indicated by the solid line in Fig. 3. The similar functions were measured for variable initial pressure differences:  $-20 \text{ cm} < h_1 - h_2 < 60 \text{ cm}$ . The maximum flow rate for each initial pressure difference was determined from each function curve and is indicated by the open circles in Fig. 4. Without function of the flow-regulating device, the maximum flow rates were the values on the broken line for the pressure-heads  $<100$  cm. These excess flow rates again decreased to the solid line level and approached those without pressure-head (the dotted line in Fig. 4).

**DISCUSSION**

Some devices have been clinically applied to shunt therapies of hydrocephalus in order to limit an excess flow by a pressure-head between a cere-



**FIG. 4.** The maximum flow rate in the range of pressure-head  $<100$  cm as a function of initial pressure difference between inlet and outlet.

bral ventricle and an abdominal cavity in a standing position (2). They are called antisiphon devices and may be constructed in several ways, with a diaphragm valve operated by the pressure difference between atmosphere and intrashunt path (1,3), a ball valve with a spring of which deformation controls the intrashunt pressure, a series of valves of variable opening pressure, or a ball valve operated by gravitational force. When any of these devices are implanted, however, they do not always function well. This is because the diaphragm is not deformed by the atmospheric pressure but rather is pressed by the surrounding tissue, because the pressure difference between the upper and lower sides of the valve does not correlate with that between the inlet and outlet of shunt, and because the pressure-head does not reflect on the direction of gravitational force.

The flow-regulating device described in the present study is operated directly by the pressure-head (between two diaphragm valves) amplified by the density difference. Its working principle ensures the same performance in vivo as in vitro. Thus, this study suggests that the flow-regulating device would limit the excess flow by the pressure-head between the cerebral ventricle and the abdominal cavity in the standing position in shunt therapies of hydrocephalus.

**REFERENCES**

1. Portnoy HD, Schulte RR, Fox JL, Croissant PD, Tripp L. Anti-siphon and reversible occlusion valves for shunting in hydrocephalus and preventing post-shunt subdural hematomas. *J Neurosurg* 1973;38:729-738.
2. Mori K, ed. *CSF shunt systems*. Tokyo: Excerpta Medica, 1986.
3. Gruber R, Jenny P, Herzog B. Experiences with the anti-siphon device (ASD) in shunt therapy of pediatric hydrocephalus. *J Neurosurg* 1984;61:156-162.
4. Portnoy HD. Shunt selection and operative technic. *Mod Techniques Surg Neurosurg* 1983;27:1-10.