Measurement of the Infusion Flow Rate Produced by a Novel Non-electric-powered Infusion Pump

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Abstract

Intravenous (IV) fluid therapy is a common medical practice that is widespread worldwide, and the method has remained unchanged for more than a century. The IV bag is suspended from an IV stand or pole, and the pressure created by gravity is used to administer the drug. However, this method inevitably reduces the mobility of patients, and may cause accidents such as falls during movement. To solve these problems faced in home care, nursing home, and hospital settings, this study aims to develop a non-hanging, non-electric-powered IV infusion pump with reasonable portability and operability. In this study, instead of gravity, atmospheric pressure is used as the driving force. The infusion device developed is required to achieve a certain level of dosing stability and accuracy, in line with medical guidelines and ideally as comparable to the existing gravity method. We developed a number of prototypes based on different pressurization mechanisms using vacuum piston cylinders as the driving source in order to find an optimum mechanism capable to produce a stable flow rate comparable to the suspended drip system. Tests on performance in terms of discharged flow rate were conducted on three feasible prototypes based on three different pressurization mechanisms, using a gravimetric test bench built for this purpose. The tests show that the pressurization mechanism using an inflating air bag to compress a drip bag has the best performance in terms of flow rate stability.

1. Introduction

Intravenous (IV) fluid therapy is a common medical practice that is widespread worldwide, with 80-90% of hospitalized patients receiving IV therapy [1]. The method of administering gravity-feed IV therapy has remained unchanged for more than a century. The IV bag (drip bag) is suspended from an IV stand or pole, and the pressure created by gravity is used to administer the drug. However, as illustrated in Figures 1a-c, this method inevitably limits the mobility of patients [2, 3], and may cause accidental falls during movement [4]. To solve these problems faced in home care, nursing home, and hospital settings, this study aims to develop a non-hanging, non-electric-powered IV infusion pump with reasonable portability and operability that can potentially improve the quality of life of IV therapy patients (as illustrated in Figures 1d-f).

In this study, instead of gravity, atmospheric pressure is used as the driving force. We use a vacuum piston cylinder to derive the driving force from the pressure difference between a vacuum and the atmospheric pressure. As shown in Figure 2, a piston, with a cross-sectional area a separating a sealed vacuum chamber and an open chamber under atmospheric pressure, is driven towards the closed end of the cylinder. The larger the diameter d of the piston (cross-sectional area $a = \pi d^2 / 4$), the larger the magnitude of the driving force $F = p_{atm} a$ on the piston becomes. The length of the cylinder L determines the moving stroke of the piston.

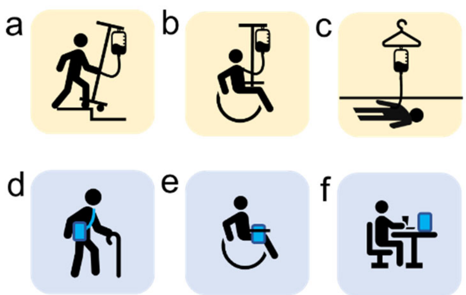

Figure 1: **a-c.** Various scenes of gravity-driven IV therapy under limitation of mobility and at risk of accidental fall. **d-f.** Various scenes of IV therapy using a portable infusion pump (shown as blue box) with improved mobility and reduced accidental risk.

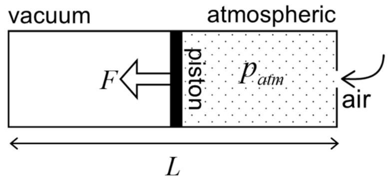

Figure 2: Vacuum piston cylinder.

The infusion device developed is required to achieve a certain level of dosing stability and accuracy, in line with medical guidelines [5, 6] and ideally as comparable to the existing gravity method. We developed various pressurization mechanisms using vacuum piston cylinders as the driving source in order to find an optimum mechanism capable to produce a stable flow rate comparable to the suspended drip system.

This paper discusses the problems and challenges faced in developing various pressurization mechanisms as well as the measurement of the discharged flow rates produced by the different pressurization mechanisms using a gravimetric test bench built for this purpose. Finally, a conclusion is made on the best pressurization mechanism with prospect on future works.

2. Pressurization mechanisms

We need to design an optimum pressurization mechanism acting on a drip bag to transform the driving force derived from the vacuum piston cylinder into fluid pressure inside the drip bag for fluid infusion. Feasible pressurization mechanisms can be generally categorized into three approaches: (i) pressing a rigid plate on a drip bag [7-10], (ii) squeezing a drip bag by one or multiple rollers [11] and (iii) compressing a drip bag by an inflating air bag [12-15]. But it is unknown whether these mechanisms have been evaluated in terms of the stability of infusion flow rate. Our attempt is novel in the way that we combine the vacuum piston cylinder with each of the three pressurization mechanisms mentioned above. Each prototype is discussed in the succeeding sections. At this early stage, design emphasis was placed more on prototype functionality rather than compactness and user-friendliness. Also do take note that the outlet of the drip bag is orientated upwards in most of the prototypes for easy air-bleeding of the drip bag.

2.1 Prototypes using a pressing rigid plate

A prototype (hereafter, V-PRESS) comprising a pressing plate orientated in a V-shape layout against the housing wall was fabricated (see Figure 3). The pressing mechanism is driven by a vacuum piston cylinder through a connecting structure. Theoretically, V-PRESS was designed to exert an increasing rotational momentum on the pressing plate as it moves towards the wall, with the aim of compensating the pressure (flow rate) drop during fluid infusion. However, measurements of the resulting fluid pressure from the drip bag did not turn out as expected, showing a significant pressure drop. The main reason for this is the change of contact surface area between the pressing plate and the drip bag as the mechanism moves. Placing an air bag between the pressing plate and the drip bag to improve the adherence of the contact surface did not solve the problem either.

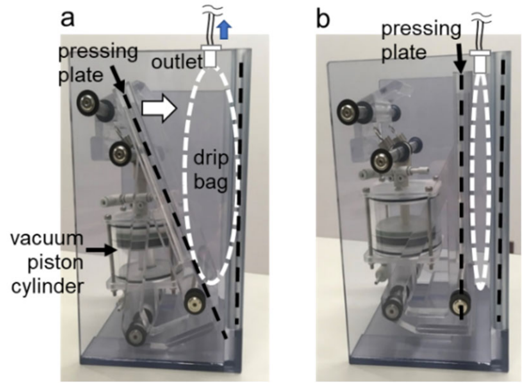

Figure 3: Prototype V-PRESS. **a.** Piston is at the starting position of cylinder. Pressing plate is at the standby position before moving towards the drip bag. **b.** Piston is at the end position of cylinder. Pressing plate fully compresses the drip bag.

Meanwhile we worked on another prototype as shown in Figure 4. This prototype (hereafter, UP-PRESS) works by elevating the pressing plate by two vacuum piston cylinders to exert pressure on a drip bag (see Figure 4a). This mechanism was thought to have the advantage of maintaining a more consistent contact area between the pressing plate and the drip bag.

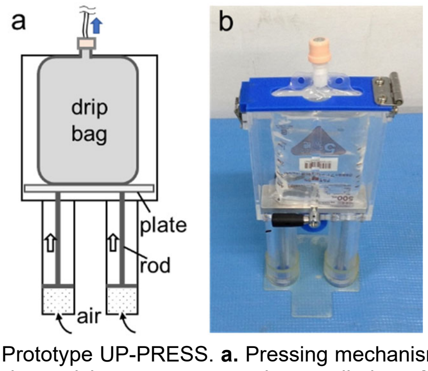

Figure 4: Prototype UP-PRESS. **a.** Pressing mechanism on the drip bag elevated by two vacuum piston cylinders. **b.** Actual fabrication of the prototype.

2.2 Prototypes using squeezing rollers

Another prototype (hereafter, MOVE-ROLLER) that works by squeezing the drip bag by a pair of rollers was also developed (see Figure 5). The rollers rotate itself and squeeze over a fixedly-mounted drip bag while being pulled down by vacuum piston cylinders (see Figures 5a&b). However, one problem arose in which the drip fluid escaped from the high-pressure side to the low-pressure side inside the drip bag, resulting in a leakage through the small gap between the rollers (see Figures 5c&d).

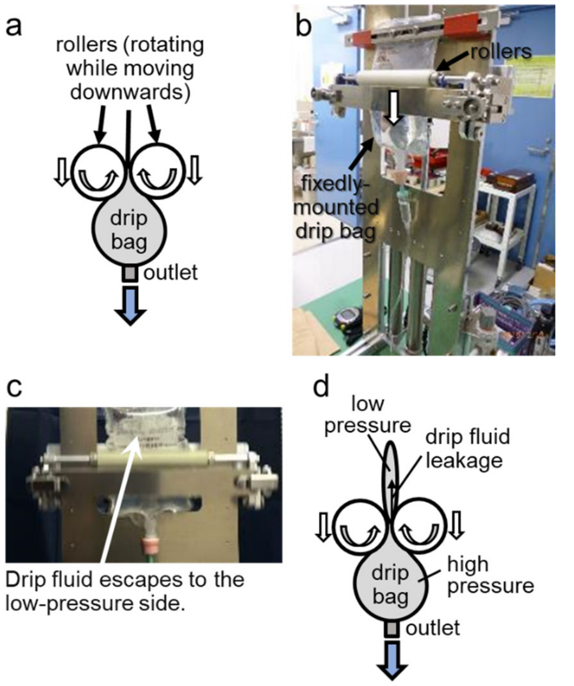

Figure 5: Prototype MOVE-ROLLER. **a.** Squeezing mechanism on the drip bag by a pair of rollers. **b.** Operational testing of the mechanism. **c.** Observation of drip fluid escape. **d.** Schematic explanation of the drip fluid leakage occurred inside the drip bag.

To solve the problem faced with the MOVE-ROLLER, we figured out a modified prototype (hereafter, FIX-ROLLER) as shown in Figure 6, in which a big roller was employed for the purpose of winding up emptied part of a drip bag, thus preventing the drip fluid escape encountered in MOVE-ROLLER. The opposite end of the drip bag outlet is attached to the big roller before operation. As shown in Figure 6a, a wire connected to a vacuum piston cylinder pulls and rotates the big roller, driving the whole mechanism. One should take note that, for simple representation, the movement of the piston (downwards) in Figure 6a differs from the actual one which is upwards in Figure 6c. Other new features in FIX-ROLLER include all rollers rotating at fixed positions and the outlet of the drip bag facing upwards.

2.3 Prototypes using inflated air bags

To see what shape of air bag performs best as a pressurization mechanism, we conducted a series of tests (Tests No. 1-3) as shown in Figure 7. Test No. 1 acts as an observatory test without using any air bag (see Figures 7a&b). Two parallel plates used for compression were loaded with dead weights to exert a constant force. A drip bag and air bags were filled with air. The air was released from the drip bag at a low flow rate controlled by a valve, while the air in the air bag was trapped by closing the valve. Both pressures in the drip bag and the air bag were measured at the same time.

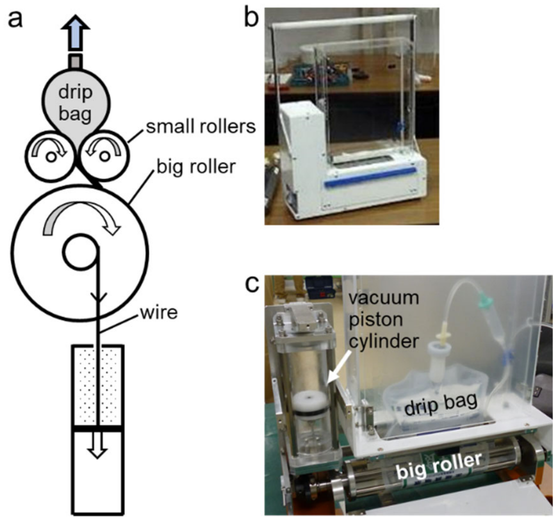

Figure 6: Prototype FIX-ROLLER. **a.** Squeezing mechanism combining two small rollers with a big roller. All rollers rotate at fixed positions. **b.** Exterior view of the prototype. **c.** Interior layout of the prototype.

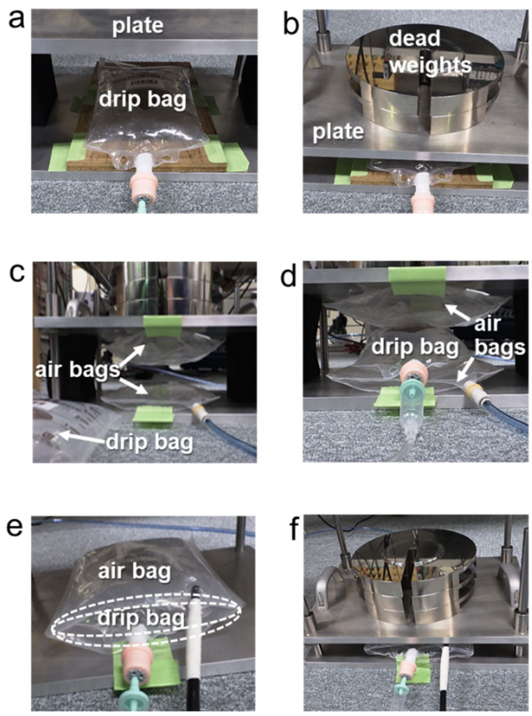

Figure 7:
a, b. Test No.1. A drip bag is placed between parallel plates with no air bag in **a**, and then loaded with dead weights in **b**.
c, d. Test No.2. Two pillow-shaped air bags are placed between the parallel plates in **c**, and then a drip bag is inserted in between the two air bags and the sandwiched drip bag is loaded with dead weights in **d**.
e, f. Test No.3. A drip bag is enwrapped in a sleeping-bag-shaped air bag in **e**, and then loaded with dead weights in **f**.

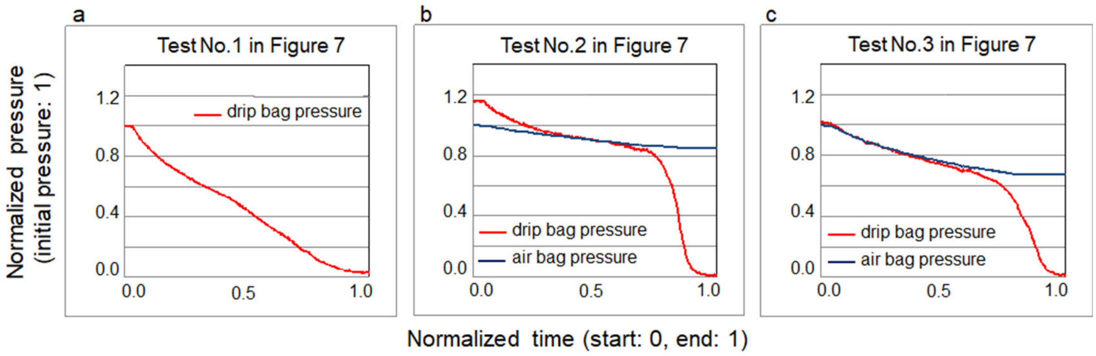

Figure 8: Pressure measurement results of the tests shown in Figure 7. **a.** Test No. 1. A drip bag only (see Figures 7a&b). **b.** Test No. 2. A drip bag sandwiched by two pillow-shaped air bags (see Figures 7c&d). **c.** Test No. 3. A drip bag enwrapped in a sleeping-bag-shaped air bag (Figures 7e&f).

Test No. 1 shows the steady decreasing of the drip bag pressure that is normalized by the initial drip bag pressure, though under a constant force from the dead weights (see Figure 8a). This may be due to the change of contact surface area between the plate and the drip bag as the drip bag deflated. The pressure value in the ordinate in Figures 8b&c is normalized by the initial air bag pressure. At the starting point in Test No.2, the drip bag pressure is higher than that of the air bag pressure (see Figure 8b). This may be attributed to the surface tension occurred at both the curving (arc-like) side-surfaces of the drip bag which were not in contact with the air bags [16]. However, this did not happen in Test No.3 in which the side-surfaces of the enwrapped drip bag were in contact with the sleeping-bag-shaped air bag (see Figure 8c). In both Tests No.2 and No.3, it can be observed that the air bag pressure decreases slightly due to the change of contact surface area with the plates as the air bags compress the drip bag. Seeing that the pressures of both drip bag and air bag show the best unison in Test No.3 (see Figure 8c), we came to conclude that the sleeping-bag-shaped air bag (see Figure 7e) is the best inflating mechanism to pressurize the drip bag.

A prototype (hereafter, AIR-BAG) using the sleeping-bag-shaped air bag as the pressurizing mechanism was developed (see Figure 9). As shown in Figure 9a, a small piston with a cross-sectional area of a_S in a vacuum piston cylinder (upper cylinder) pushes a large piston with a cross-sectional area of a_L through a connecting rod in an air piston cylinder (bottom cylinder), resulting in compressed air being supplied to an inflating air bag enwrapping a drip bag. The pressure of the compressed air p_c (gauge pressure) can be approximately estimated as $p_c \approx p_{atm}(a_S/a_L)$ where p_{atm} is the atmospheric pressure. Figure 9b shows the actual fabrication of the prototype with a transparent interior view.

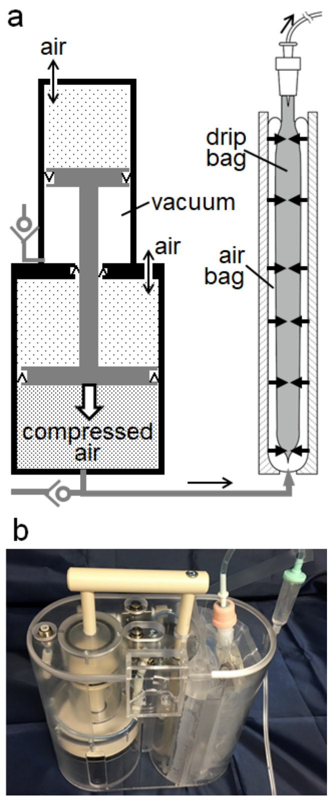

Figure 9: Prototype AIR-BAG. **a.** Pressurizing mechanism acting on a drip bag comprises a vacuum-piston-cylinder built together with an air-piston-cylinder, and a sleeping-bag-shaped air bag in a separate compartment. **b.** Actual fabrication of the prototype.

3. Evaluation of flow performance

As one of the criteria to be a possible alternative to the gravity-driven infusion method, the pressure-driven method needs to achieve a dosing stability level comparable to the gravity method. Medical guidelines [5, 6] also recommend that the flow rate accuracy for non-electrically driven infusion devices to be within ± 20 % of the nominal flow rate. To conduct measurements of the discharged flow rate from the prototypes, we built a gravimetric test bench which is discussed in the following section.

3.1 Gravimetric test bench

As shown in Figure 10a, a gravimetric (weighing) test bench is enclosed in a wind shield to avoid any wind effect. A pneumatically liftable stage supports a weighing balance at a variable height for flow rate measurement at different head pressures. Figure 10b shows a specially designed weighing vessel sitting on a weighing plate. The weighing range of the weighing balance is up to 6 kg with a resolution of 0.01 g.

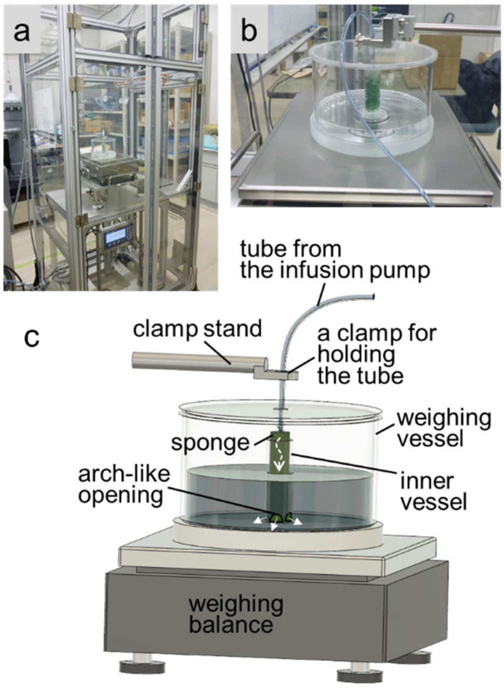

Figure 10: Gravimetric test bench for flow rate measurement. **a.** A weighing balance sits on a liftable stage in a wind shield enclosure. **b.** A specially designed weighing vessel sits on a weighing plate. **c.** Features of the weighing vessel.

As shown in Figure 10c, the weighing vessel has a special feature in which an inner vessel stands on the bottom surface of the weighing vessel. To avoid liquid dropping from the tube into the weighing vessel, one method is to immerse the tube into the liquid, but this will create immersion effects such as buoyancy effect of immersed tube beneath the rising liquid level. To maintain a constant immersed depth of the tube, many studies adopted an overflowing inner vessel where a tube or a needle is immersed into an overflowed inner vessel [17-20]. Another method is to maintain a constant liquid bridge or stream connecting the tube outlet and a liquid-absorbing material such as glass filter or foam mounted inside a weighing vessel [21]. For liquid collection in this study, we combined the two methods mentioned above by not overflowing the inner vessel but filling it with liquid-absorbing spongy material so that liquid stream from the tube outlet is absorbed. Liquid then weaves through the sponge down the inner vessel and flows out from the openings at the bottom of the inner vessel (see Figure 10c).

The dynamic weighing method is adopted for the test bench in which the increasing liquid mass collected inside the weighing vessel is measured by the weighing balance as a function of time to ultimately give the mass flow rate. The flow rate is determined by taking a simple ratio of the differences in mass and time over a time interval. Though fitting methods such as linear fit over a time window will give a smoother curve with reduced noise, we consider that the noise is not so significant in the gravimetric system and the present calculation method is good enough to see the flow performance of the infusion pump prototypes. Taking into consideration uncertainty factors such as liquid evaporation, resolution of weighing balance, buoyancy effect and so on, we performed a preliminary uncertainty analysis of the test bench, obtaining an expanded uncertainty of about 3.3 % for the smallest flow rate of 3.0 g/min. The dominant uncertainty factor in the flow rate determination is the resolution of the weighing balance. Nevertheless, the amplitude order of the measurement uncertainty (3.3 %) is considered sufficient in the context of the present study, seeing that the flow rate accuracy requirement for non-electrically driven infusion pumps is ± 20 %.

3.2 Tests of flow performance

Using the test bench described in Section 3.1, tests of flow performance were conducted on three feasible prototypes, namely a. UP-PRESS, b. FIX-ROLLER and c. AIR-BAG of which the measurement results are shown in Figure 11. The left ordinate corresponds to the discharged flow rate whereas the right ordinate corresponds to the amount of discharged liquid. In the performance test, liquid was discharged from the drip bags with 500 mL content over a time period of about 2 to 3 hours at a flow rate adjusted between 3 to 4 g/min. Apparently, prototype AIR-BAG (see Figure 11c) shows a relatively high flow stability as compared to prototypes UP-PRESS and FIX-ROLLER (see Figures 11a&b). In terms of flow variation, UP-PRESS shows a relatively large up-and-down while FIX-ROLLER demonstrates small zigzagging of flow fluctuation. In a general sense, the unstable contact surface interaction between the pressurization mechanism and the drip bag in the two prototypes can be accounted for these flow behaviours.

4. Conclusion

As a potential alternative to the gravity-driven infusion method, three prototypes based on three different pressurization mechanisms driven by the vacuum-piston-cylinder were designed and fabricated. Performance of each prototype in terms of flow rate stability was tested using a gravimetric test bench. Prototype AIR-BAG shows the most promising result in terms of flow stability compared to prototypes UP-PRESS and FIX-ROLLER. We will work further on AIR-BAG to enhance its performance.

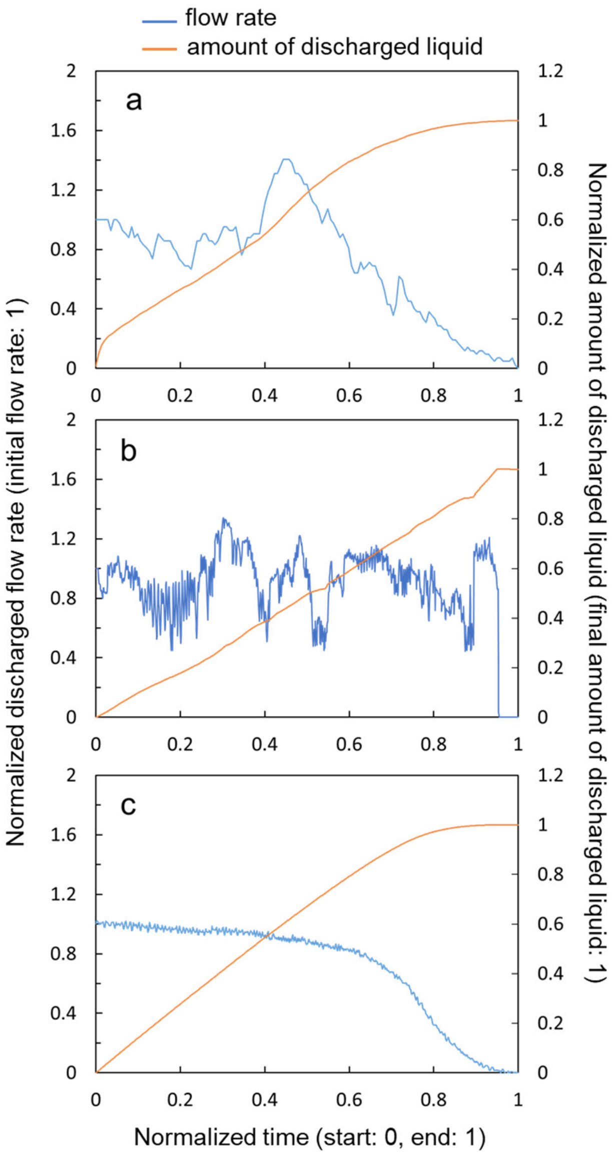

Figure 11: Flow rate measurement results of the prototypes. **a.** Prototype UP-PRESS. **b.** Prototype FIX-ROLLER. **c.** Prototype AIR-BAG.

Acknowledgement

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