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공학석사 학위논문

# A Disposable Peristaltic Pump Set for Wearable Artificial Kidney

# 휴대형 인공신장을 위한 교체형 연동식 펌프

**2018년 2월**

서울대학교 대학원
협동과정 바이오엔지니어링 전공

임 형 수

# 휴대형 인공신장을 위한 교체형 연동식 펌프

지도교수 이 정 찬

이 논문을 공학석사 학위논문으로 제출함

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서울대학교 대학원
협동과정 바이오엔지니어링 전공
임 형 수

임형수의 공학석사 학위논문을 인준함

**2018년 1월**

위 원 장 김 희 찬 (인)

부 위 원 장 이 정 찬 (인)

위 원 최 영 빈 (인)

MASTER THESIS

# A Disposable Peristaltic Pump Set for Wearable Artificial Kidney

BY

HYUNG SOO LIM

January 2018

INTERDICIPLINARY PROGRAM IN BIOENGINEERING

THE GRADUATE SCHOOL

SEOUL NATIONAL UNIVERSITY

# Abstract

# A Disposable Peristaltic Pump set for Wearable Artificial Kidney

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This dissertation focuses on development and evaluation of newly designed peristaltic pump which is integration of three pumps into one pump set. As need of wearable artificial kidney (WAK) emerged due to increasing population of end-stage renal disease (ESRD) patients and discomfort induced by dialysis treatment, pumps for dialysis treatment have been developed. Those pumps show good performance such as pressure and flow rate however, those are too heavy and big to mount in

WAK. Also, energy consumption and complication in exchange are limit. Therefore, this dissertation suggest newly designed pump set is made for WAK. Especially to meet specifications required for use in WAK, bevel gears were implemented to minimize size of the pump and housings are 3D printed with light material. Mass of the manufactured pump is 250g and volume is only 175cm$^3$. In order to evaluate performance of the pump, several tests were conducted. First, endurance test of tube for the pump was performed. The test was conducted for 12 hours. Flow rate gradually increased in first 3 hours, and then in interval of 9-12 hours the flow rate almost converged. Next, performance tests were proceeded changing types of motors with different gear ratio. Two motors which have relatively small torque with gear ratio of 1/128, 1/316 result in flow rates of 14.3 to 21ml/min and 5.11 to 10.21ml/min each. The other motor that has large torque with gear ratio of 1/157 achieved flow rate of 8.8 to 25.5ml/min. Lastly, the pump was set to circulate CRRT circuit in continuous veno-venous hemofiltration (CVVH) program and successfully circulated water as planned. Through those tests, potential of the pump for renal treatment is proved. Even though relatively low flow rates is its limitation, the size, weight, energy consumption and disposability make the pump suitable for WAK and further optimization will make the pump more powerful.

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**Keywords: peristaltic pump, dialysis, wearable artificial kidney, product design and development**

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# 1. Introduction

According to [1] the proportionate increase in the incidence of end stage renal disease (ESRD) of Republic of Korea was reported as 101% which is the fifth largest in the world and more than 80 % of the ESRD patients in Korea get in-center hemodialysis (HD) treatment, which consumes three to four hours for a session and is prescribed three times a week. Peritoneal dialysis (PD) takes more time due to dwelling time of infused dialysate while allows patients stay comfortable than HD. Nevertheless, since those treatments require frequent visit to hospital and some surgical procedures such as arteriovenous (AV) fistula and catheter insertion, life quality of the patients decreases. Another option is kidney transplantation of which rate is increasing gradually. Survivor rate of transplanted patients is higher than that of patients who get dialysis treatment. However, limited number of patients could get transplantation due to scarcity of donors and the patients need to take immunosuppressing medication continuously and might get complications after transplantation. Since population of chronic renal disease grows, expenditure related to chronic renal disease is increasing every year and it was reported as 170 billion won in 2016 [2] which also threaten life of patients. Studies about WAK have been conducted and some systems are proposed [3-6]. Kensinger et al. [5] devised implantable hemofilter with surface-modified silicon nanopore membrane and conducted in vivo test with dogs. Their device is driven with cardiac perfusion pressure so that it could operate without external pumps and power supply thus achieve small size and implantability. However, it got local failure due to its weak mechanical strength and since it only acquires pressure from cardiac output, filtration rate is too low to use for human renal replacement. Group of Victor Gura [4, 7, 8] has been developing wearable artificial kidney which consists of pumps,

hemodialyzer, filter, heparin, bags and solutions for compensate electrolytes in blood. Their device achieved stable blood urea nitrogen (BUN) level, good electrolyte homeostasis and ultrafiltration rate during 24-hour experiment for patients. Despite of its pros, generation of carbon dioxide due to urease and need of degasser which results in large and heavy system are pointed out as limitations. Also, dual-shuttle pump utilized in the system was vulnerable to resistance made by carbon dioxide.

Along the effort to WAK, importance of pumps for it emerged. Pumps are important in development of WAK for several points. First, general WAK is the extracorporeal circulation system that handles human blood or dialysate, characteristics of pumps such as flow rate, pressure and hemolysis rate are critical when designing the total system. Second, a WAK system requires at least three pumps, so the pumps take large portion of size and weight of the system thus development of compact pumps is required. In addition, constraints such as biocompatibility, precision, accuracy, energy consumption, weight and size are required for WAK pumps [9]. Several works considering those constraints and the use for WAK can be found in the literatures. Gura et al. [10] patented Dual-ventricle pump cartridge of use in a wearable continuous renal replacement therapy device and studied [8] and their wearable artificial kidney system measuring the flow rate and pressure at the inlet and outlet. The dual-ventricle pump alternatively transport solution into two chambers with alternating valves that induce pulsatile flow. Jane Kang [11] proposed finger-cam driven pump of which the fingers sequentially squeeze tube as the cam rotates and transport liquid. Markovic et al. [12] designed a blood pump actuated by magnetic force which can be connected in series and achieve required pressure for hemodialysis but consumes power about 1.17 W for each unit and at least three units are required to operate, thus inappropriate for wearable devices. Lee et al. [13] devised valveless pulsatile pump using a cam in order to prevent hemolysis during extracorporeal blood circulation. It shows good performance for in vivo test,

however the pump is significantly large and heavy. Recently, Longo et al. [14] studied flow dynamic and energetic aspect of commercial micro-pumps for artificial kidney including the comparison of diaphragm pumps and peristaltic pumps and found different power consumption aspects of each type of the pumps. Even though previously studied pumps showed great performance for dialysis, most of them are too large and heavy so that they increase total weight of portable renal replacement system which is carried by the weak patients. Also, due to their structure it is difficult to disassemble the parts of the pumps for sterilization or exchange to new parts in case of breakdown. In summary, to utilize a pump for WAK, following requirements must be met:

1. Portability − Considering that WAK is comprised of many components such as filter or dialysate regenerator, supplementary solution, electronic circuits for control, battery etc. lowering weight of each components is crucial task. Among the components, pumps take great portion of total weight so lightweight pump is a key to develop practically wearable renal replacement device. A device made by Gura et al. [15] contains one blood pump and two micropumps which weigh about 700 g and the mass of total device is 1.135 kg. Also, in [7], their device is made up of one blood pump and 4 micropumps which weigh about 1kg. Ronco and Fecondini[16] devised a device named ViWAK PD, and its total mass is 200 g including adsorption cartridges and a pump. Considering those studies, because pumps take great portion of total weight, a pump unit weight of less than 100 g would significantly reduce weight of WAK.
2. Flow rate − Most of the WAKs are designed to operate for 12 to 24 hours a day to achieve certain amount of clearance. According to Gotch[17],

clearance rate of urea during continuous flow peritoneal dialysis(CFPD), is dependent to molecular transport coefficient(MTC) which is related to the flow rate of dialysate. From this, minimally required flow rate can be calculated as shown in Figure 1.1. Urea clearance rate at dialysate flow rate of 25, 50 and 100 ml/min is 13.34, 22.98 and 36.09 ml/min each. Generally, CFPD is conducted for 8 hours at the flow rate of 100 ml/min, so about 17000 ml of urea is cleared from peritoneal cavity. To achieve this amount of clearance, WAK with flow rate of 25 and 50 ml/min need to operate for 21.5 hours and 12.5 hours each which is still in the range of required operation time. From this point, 25 ml/min can be the minimum flow rate for WAK.

3. Low power consumption – As mentioned above, to replace renal function WAK must continuously operate and for that, large battery is needed for the WAK system and it must be used efficiently. Since a main power consuming part is the pump, design it to consume less power is important. Once WAK starts to operate, it should work for at least 12 hours. Assuming a battery of 6 V, 10000mAh is mounted on the WAK. To operate 12 hours, power consumption of the system should be less than 5 W and usually three pumps are used, power consumption of a pump need to be smaller than 1.5 W.

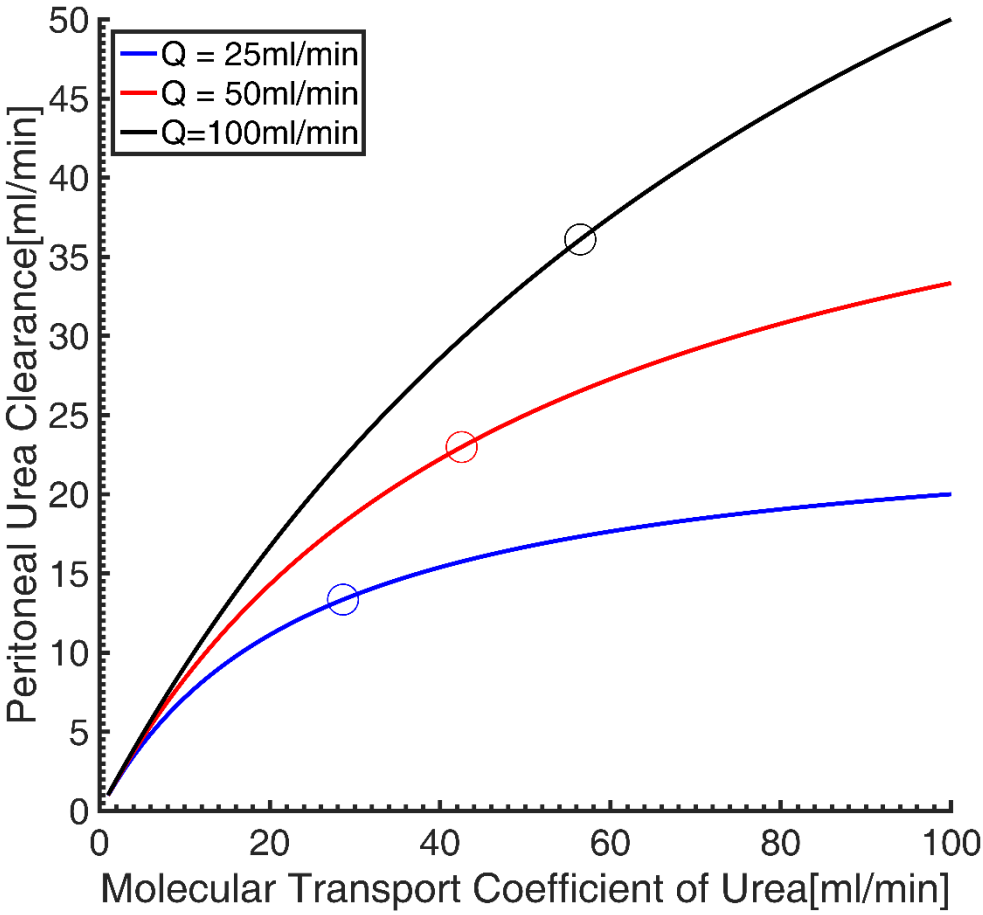


**Figure 1.1. Relationship between molecular transport coefficient(MTC) of urea and peritoneal urea clearance obtained from work of Gotch [17]. Hollow circles are points corresponding to MTC at the dialysate flow rate of 25, 50, 100 ml/min respectively. Corresponding urea clearance at each flow rate is 13.34, 22.98, 36.09 ml/min.**

Conceptually, WAK should continue to operate to get dialysis effect. But in case of system failure, quick inspection and self-repair of the components must be possible. In addition to the three requirements, disposability of pump component is needed to be considered..

There are two types of micropump which are suitable for medical use − peristaltic and diaphragm pumps. These types are suitable for minimizing while having enough output. Peristaltic pump is a type of positive displacement pump which transport a variety of fluids by compressing a tube pushing the fluids with rotor. Thanks to the use of tube, the fluids do not contact with inside surface of the pump and air thus avoid oxidation or contamination. As the pumps does not require additional components such as valves and seals, it is convenient to design and manufacture. In addition, the flow rate is independent to viscosity of the fluid [18]. Furthermore, multi-channel systems can be easily built. On the other hand, repetitive compression cause degradation and require periodic exchange. Due to deviation of tubing, the pump must be calibrated to get acceptable accuracy [18]. In addition, pulses are generated while the rotor rotates, thus incompatible for making smooth consistent flow. Diaphragm pump is an also positive displacement pump that makes pressure using a diaphragm and set a direction of flow with valves. This type of pumps can easily achieve good performance and can be applied to various fields. However, direct contact of fluid and the diaphragm limit the pumps' use in medical field. Difficult sterilization and corrosion of diaphragm, depending on the its material and kind of solutions, confines applications of the pump.

In this study, I suggest newly designed peristaltic pump for wearable artificial kidney and continuous renal replacement therapy which is lightweight, compact and has easily exchangeable pump head. Because it can be made to has several channels and is easy to sterilize and replace, the peristaltic pump was chosen. This study includes

three sections. First, concept design suggestion will be made. Integrated three-pump-head was designed and successfully manufactured. Second, performance tests that evaluates specification of the pumps in various situation − endurance test, simple open loop circuit, continuous renal replacement therapy (CRRT) circuit and in vitro test of WAK − were done. The results and analysis of the tests will be stated and the limitation of the pump will be discussed in the last section.

# 2. Material and Methods

## 2.1. Concept design

In addition to the constraints such as biocompatibility, precision etc., size and replaceability was specially considered for the design of pump. Most of the commercial peristaltic pumps consist of cassette, tube, rotor including roller, base and motor. Since the shaft of motor is directly connected to the rotor in same axis, size of the pumps is dominated by diameter of its pump head. Once the pump head or tubing need to be exchanged, the pump should be dissembled and the cassette, rotor and tubing should be replaced separately. As a solution for this problem, a set of bevel gears is introduced as shown in Figure 2.1. The pump was designed to divide into two parts - pump head and base. Since most of the wearable artificial kidney and renal replacement systems circulates many kinds of solution and medications, three pump heads are integrated into a set to transport three kinds of liquids for example, blood, dialysate and medication at once. The pump head set is locked in the base when it is in use. Button-release structured is introduced for easier assembly and exchange. The pump head set can be released from the base just by pushing the green buttons located at both ends of the base.

Important design parameters of peristaltic pump are inner radius of housing(***R***), tube wall thickness(***t***) and gap between rollers and housing(***d***). To securely maintain pressure to hold liquid inside of the tube, ***d*** must be smaller than two times of ***t***. However, if ***d*** is too small, force required to drive rotor would be significantly increase due to repulsion of squeezed tube. From several design modifications, ***d*** is determined to be 2 mm while using tube with wall thickness of 1 mm.

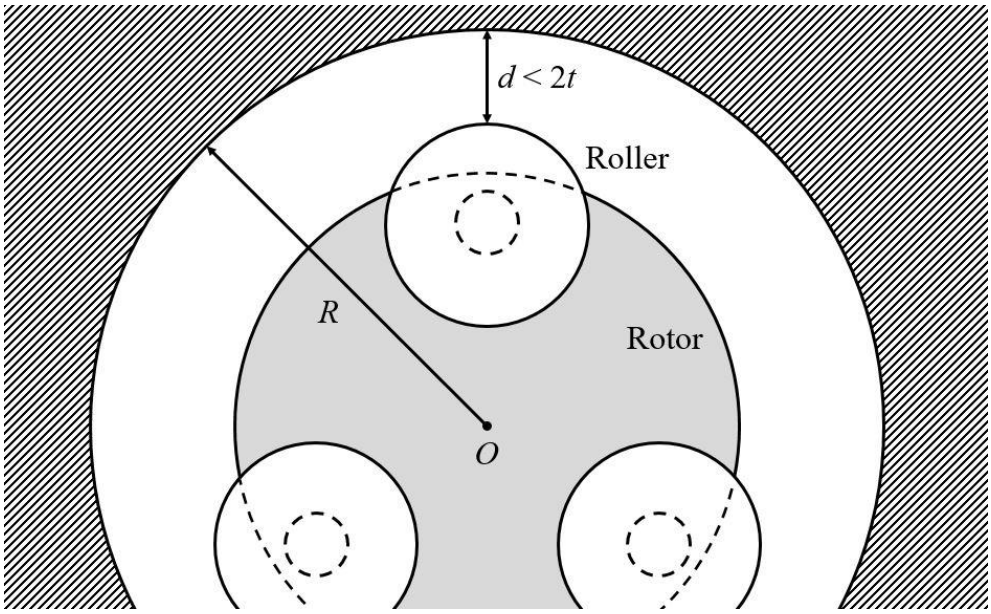


**Figure 2.1. Sketch of rotor and housing. *R* is inner radius of housing, *t* is wall thickness of tube, and *d* is gap between rollers and housing. Size of the pump head is dominated by R, and *d* should be less than two times of tube wall thickness *t*. However, if *d* is too small, load imposed on motor significantly increases thus overall efficiency would be dropped.**

## 2.2. Manufacturing

Housing parts were printed by EOS P396(EOS GmbH Electro Optical System, Munich, Germany) using PA2200GF as a printing material. Specification of the 3D printer is described in Table 2.1. Since printable layer thickness is around 0.1mm, good precision is expected. To achieve stability and endurability, PA2200GF which has good mechanical strength, was used. Rollers were made of acetal. Three types of geared motors are used as described in Table 2.3. to achieve large range of flow rate. Rest of the parts such as bearings, shafts, gears are commercially available mechanical components. 3D model and list of parts are shown in Figure 2.2 and table 2.2.

**Table 2.1. Specification of EOS P396**

| | |
|---|---|
| **Building volume** | 340 x 340 x 600 mm |
| **Laser type** | CO2, 70 W |
| **Building rate** | Up to 32 mm/h, up to 3.7 l/h |
| **Layer thickness (depending on materials)** | 0.06~0.18 mm |

**Table 2.2. List of components of a pump set**

| Parts | Quantity [EA] | Production Method |
|---|---|---|
| Housing front | 1 | 3D printing |
| Housing back | 1 | |
| Housing base | 1 | |
| Rotor plate | 6 | Machining |
| Rollers | 3 | |
| Bevel gear | 3 | |
| Shaft | 9 | Commercial mechanical components |
| Flange bearing | 6 | |
| Snap ring | 6 | |
| Bolt and Nut | M2.5 X 6 | |
| | M2 X 4 | |
| | No head M2 X 6 | |
| | M2 Nut X 2 | |

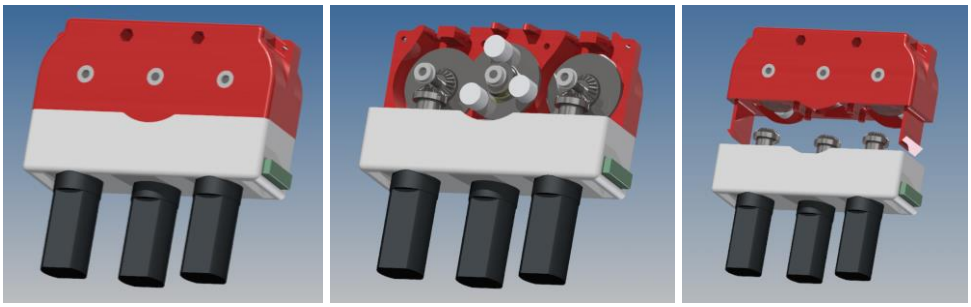

**Figure 2.2. 3D design model of pump. Rotors are designed to be located zig-zag to minimize dead space. By using bevel gears, depth of the pump can be smaller than normal peristaltic pumps. Pump head part containing rotors, shafts and tubes is locked when the pump is in use. It can be easily released from motor part just by pushing the green buttons in the figure.**

**Table 2.3. Specification of three types of motors**

| **Type** | IG-16GM **1/128** | IG-16GM **1/316** | A-max16 + **1/157** |
|---|---|---|---|
| **Rated RPM** | 51 | 20 | 29 |
| **Rated torque [N*m]** | 0.055 | 0.11 | 0.2 |
| **Voltage [V]** | 6 | 6 | 6 |
| **Rated current [mA]** | 160 | 160 | 408 |
| **Weight [g]** | 42 | 45 | 47 |

## 2.3.Tube endurance test

Repeated squeezing results in a change in the characteristics of the tube of the pump. This leads to change in flow rate. 12-hour test was proceeded to get rate of change of the flow rate. Test circuit was installed as Figure 2.3. The tube inside the pump head was silicon tube with outer diameter 5 mm and inner diameter 3 mm. IG-16GM 1/128 motor was used and the pump speed was set to maximum with Arduino control circuit using Pulse Width Modulation(PWM) technique. Pressure sensors(SC-210R, Sensys, Ansan, South Korea) and scale(EC-D, CAS, Seoul, South Korea) read and transfer data to PC via serial communication with Matlab(Mathworks, Natick MA USA) and NI LABVIEW (National Instruments Corporation, Austin, TX) each. Mass change rate acquired from the scale was calculated after finishing the test.

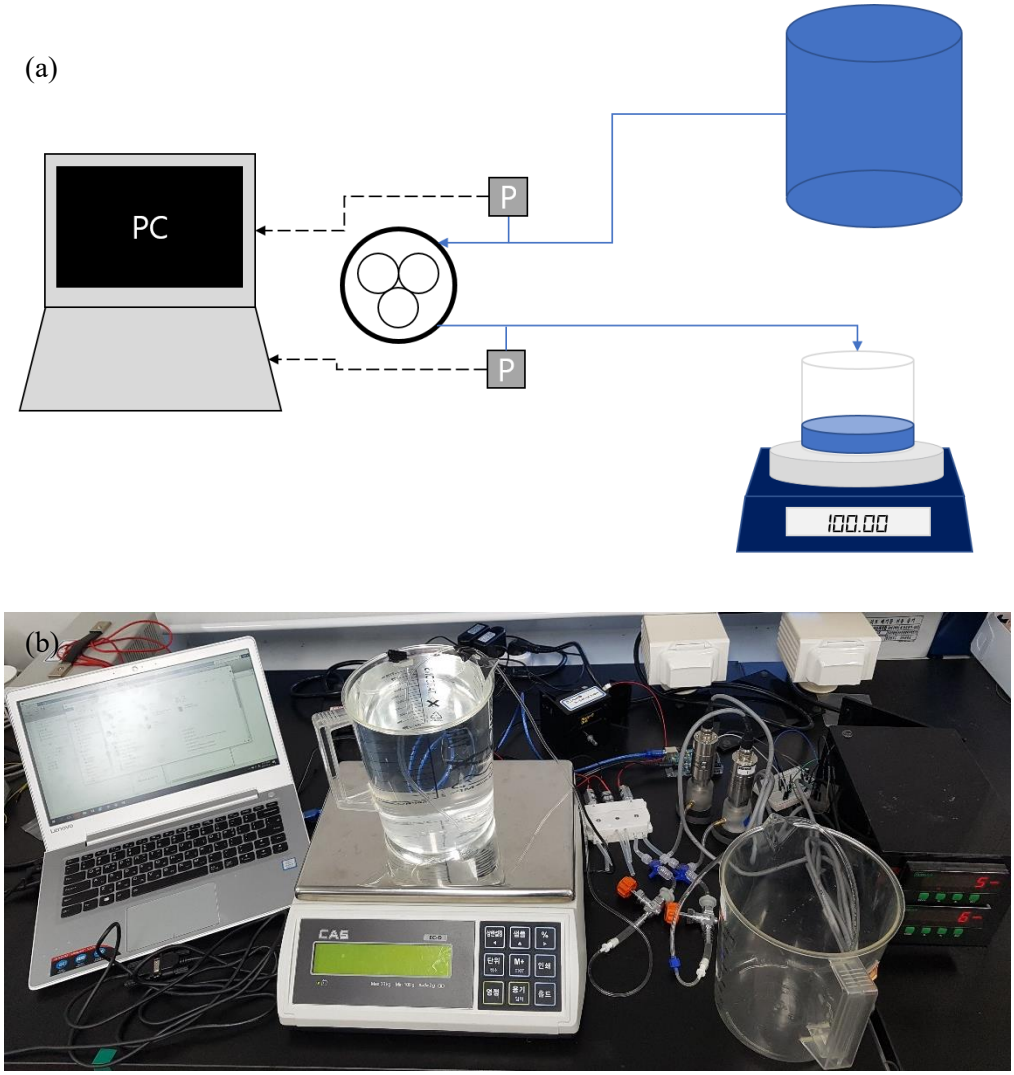


**Figure 2.3 (a) Diagram of tube endurance test, (b) photo of the test settings. Pressure and mass change data were collected using serial communication. Mass change rate along the time was calculated after finishing the test.**

## 2.4. Performance test

Flow rates and pressure difference were evaluated using circulation fluid as water. Simple test circuit(Figure 2.4) consists of two pressure sensors, two needle valves, tubes and two reservoirs was used for the assessment. Pressure sensors are located before inlet and after outlet each to measure pressure difference. Needle valves which are placed before inlet pressure sensor and after outlet pressure sensor each were used to control resistance. Each of the components were connected by Tygon tube. The tests were done by running each pumps changing resistance by controlling the valves. Resistance was changed from 20 mmHg(initial pressure difference of the pump) to 180 mmHg at 40 mmHg interval. All the tests were performed three times for each of pump units and for three kinds of geared motors and tube inside the pump head was silicon tube with outer diameter 5 mm and inner diameter 3 mm. To accurately measure the mass change rate, precision scale(EL-204 IC, METTLER TOLEDO, Greifensee, Switzerland) was used in this test.

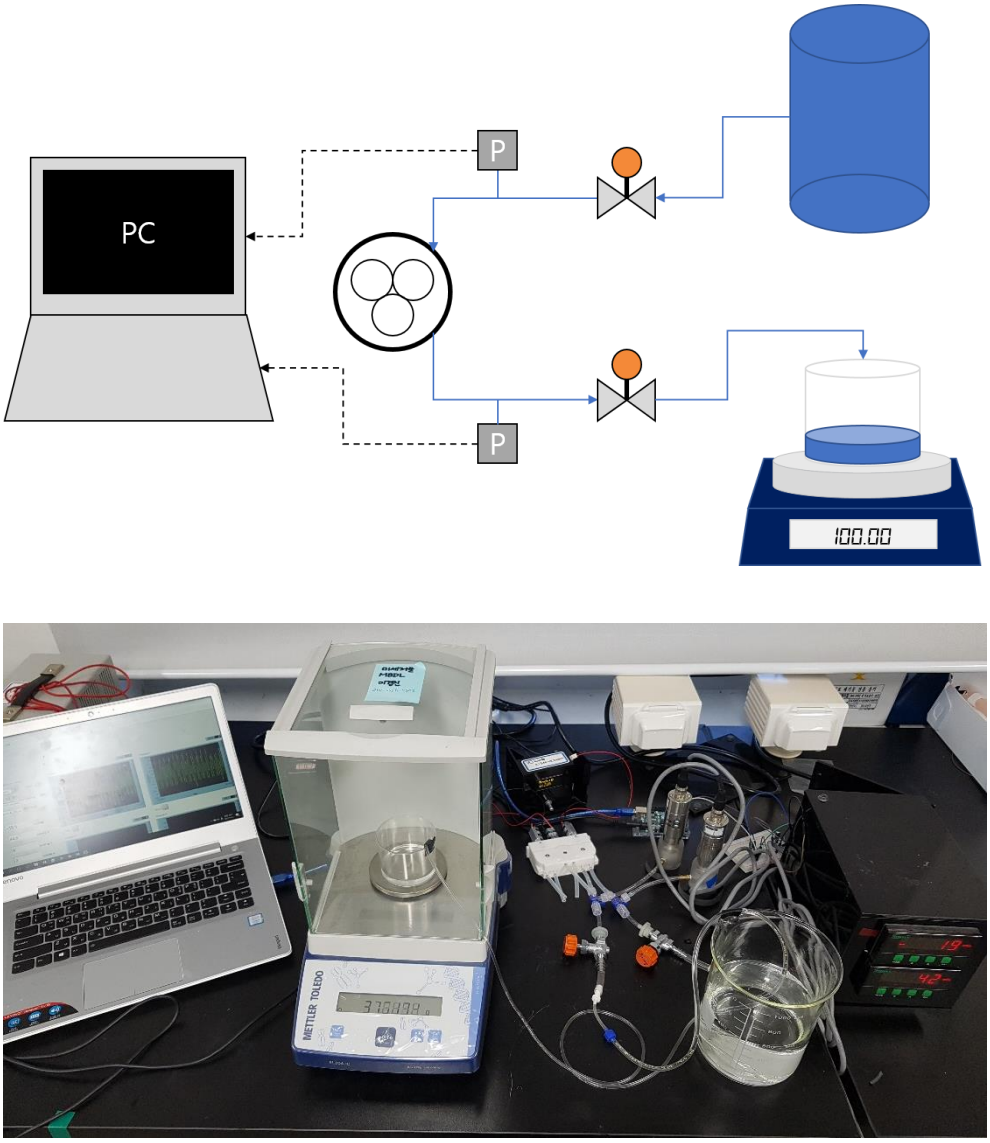


**Figure 2.4. (a) Diagram of performance test circuit. (b) photo of the test settings. Needle valves are used for controlling resistance from 20 mmHg(initial) to 180 mmHg in 40 mmHg interval. Mass flow rate at each pressure is calculated after finishing the test.**

## 2.5. Power consumption test

Power consumptions of the pumps were estimated. IG-16GM 1/316 and A-max16 1/157 motor were test. IG-16GM 1/128 was not tested since 1/128 showed unstable output and its flow range is not suitable. Test circuit is almost same as the performance test circuit but added a current sensor(ACS712, Allegro Microsystem, MA, USA) to collect current data via Arduino Uno. The test was performed controlling resistance pressure from 0 to 160 mmHg and relationship between pressure load and power consumption was investigated.

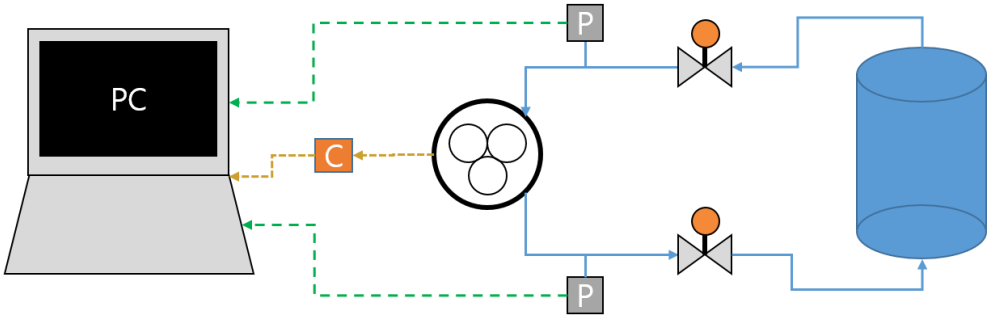


**Figure 2.5. Diagram of current consumption test circuit. Needle valves are used for controlling resistance from 20 mmHg(initial) to 180 mmHg in 40 mmHg interval. A current sensor was attached to measure current consumption of the pump. Power consumption is analyzed after finishing the test.**

## 2.6. Continuous renal replacement therapy(CRRT) circuit test

In order to assess the performance of newly designed pump, CRRT circuit(Prismaflex ST100 SET) was utilized(Figure 2.6 and 2.7). Following an instruction of the CRRT circuit, each pumps are connected to blood inlet port, blood outlet port and effluent outlet port to implement continuous veno-venous hemofiltration (CVVH) method that remove excessive fluid by effluent pump. The test was conducted in two ways – open loop and closed loop to check effect of hydrostatic pressure from reservoirs. Pressure sensors are connected as Figure 2.4 to measure pressure rise and drop through pumps and hemodialyzer. Flow rates of the pump before dialyzer, pump for effluent and pump for replacement fluid were set to 30, 9, 7 ml/min. Those flow rates can be regarded as treatment condition for 1/5 scale of 70-kg patient with middle level of high-intensity and low-intensity CRRT [19]. The test was conducted for an hour. By calculating difference between mass of water in blood reservoir at initial and return reservoir at last, ultrafiltration (UF) rate can be acquired.

To avoid difference in hydrostatic pressure between blood reservoir and return reservoir, closed-loop circuit was also tested. As shown in Figure 2.5, water in blood reservoir circulate through the circuit. In this test, flow rate of effluent is measured and calculated. Flow rates of blood, effluent and replacement fluid are 30, 12 and 10 ml/min each.

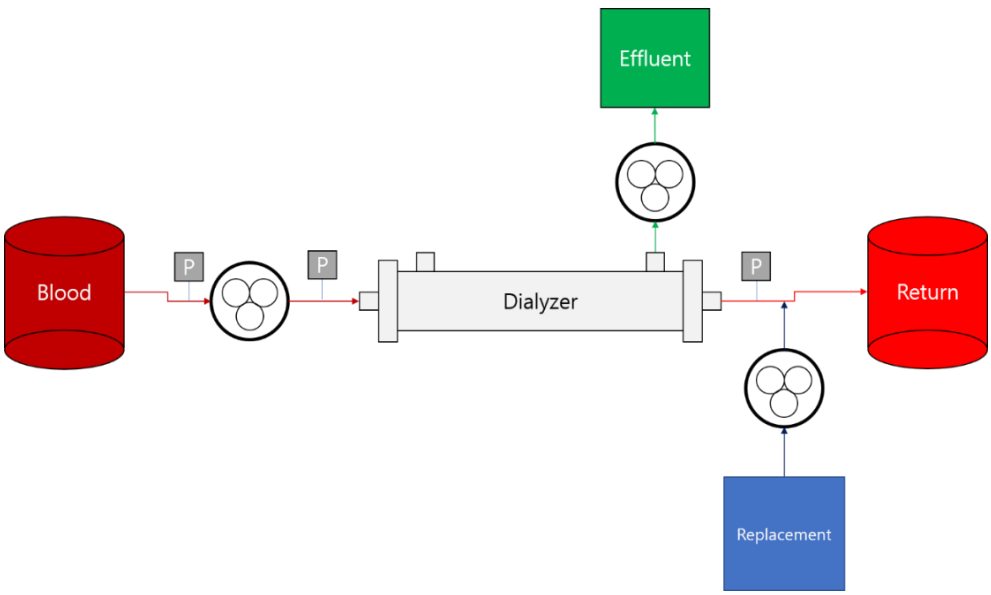


**Figure 2.6. Diagram of CRRT circuit test. The test is performed to realize CVVH method which remove excessive fluid in the body. Since we know flow rates of blood, effluent and replacement fluid, mass gradient of return reservoir gives ultrafiltration rate of the system. Flow rate of blood line, effluent line, and replacement fluid line was 30, 9, 7 ml/min each.**

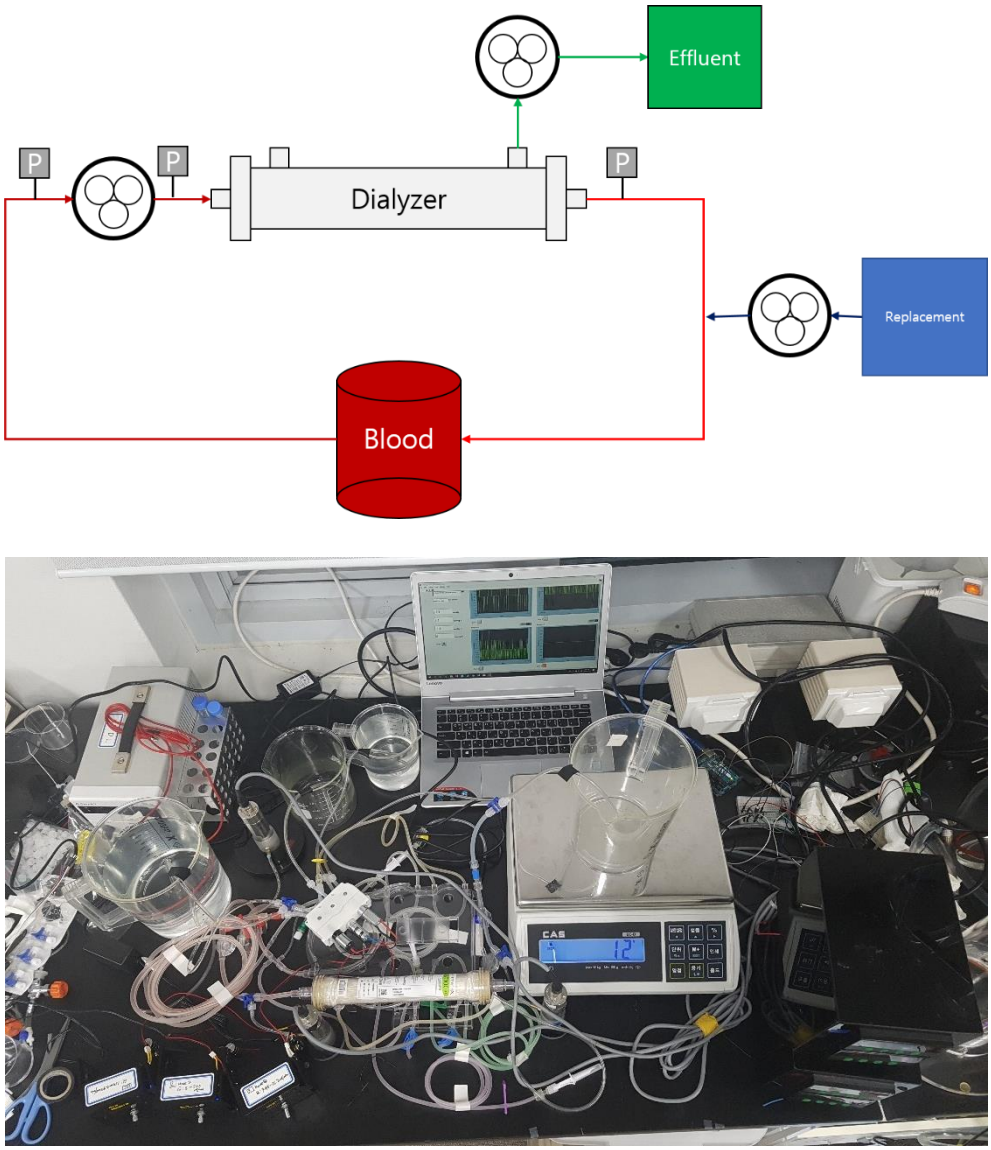


**Figure 2.7. (a) Diagram of closed-loop CRRT circuit test, (b) photo of the test settings. Flow rates of blood line, effluent line and replacement fluid line was 30, 12, 10 ml/min each. Flow rate of effluent was measured and calculated.**

## 2.7. In vitro test

To check validity of a WAK system including the pump, dialysate regenerating system and infusion pumps, in vitro test was performed. As shown in Figure 2.7, my pump set circulates main fluids – used dialysate, purified dialysate and buffer solution. Once a pump pull out used dialysate and transport to the dialysate regeneration system, the other pump transport purified dialysate to used dialysate chamber. The buffer solution was only injected into the regeneration system by a pump and recirculate to the buffer solution chamber. Flow rates of all three pumps were set to 10 ml/min with IG—16GM 1/316 motors each. Infusion pumps are used to model ultrafiltration into peritoneal cavity(fluid replenishment), effluent(removed water) and ion supplement(supplementary solution) .The test was performed for 12 hours and pressure data were collected throughout the test and analyzed after finishing the test.

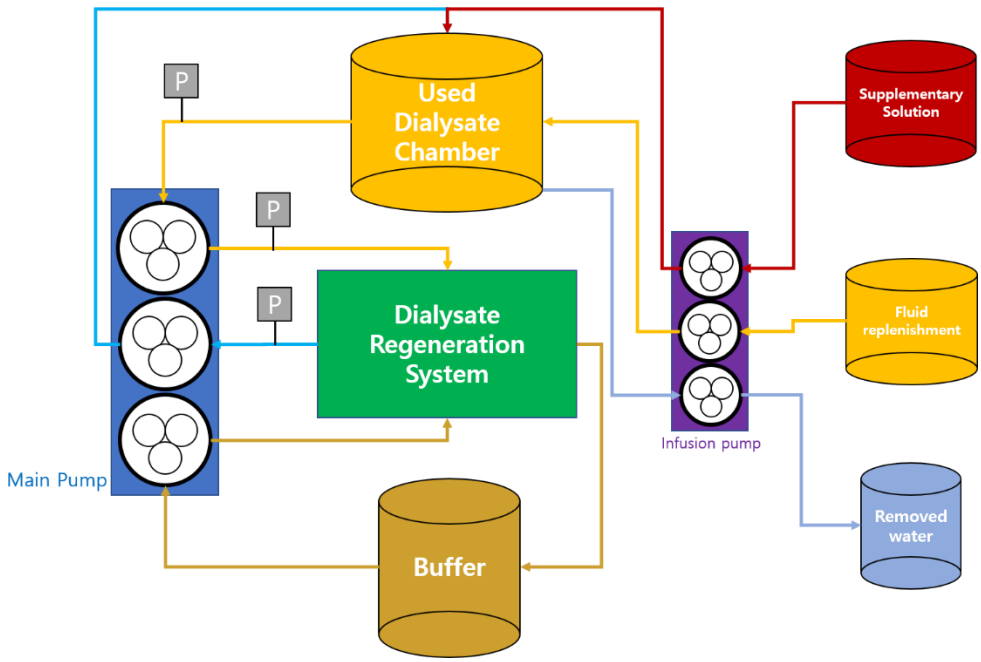


**Figure 2.8. Diagram of in vitro test of WAK system. The pumps circulate used dialysate, purified dialysate and buffer solution with flow rate of 10 ml/min. Used dialysate recirculates through dialysate regeneration system by two pumps. Buffer solution circulates by a pump. The test was performed for 12 hours and pressure data were collected throughout the test.**

# 3. Results

## 3.1. Pump design and manufacturing

As described in previous section, the housing of the pump was 3D designed and was made with EOS P396 3D printer. Figure 3.1 to 3.4 are drawings of the housing. Mass of the housing itself is 65.3 g. For rotating parts, commercial mechanical components and machined components are used. Bevel gears, shafts and bearings are commercial goods made of stainless steel. Rotor plates and rollers are machined with stainless steel and acetal respectively. All the parts are assembled using standard bolts and nuts. Detail of size and weight according to the type of motors will be discussed later.

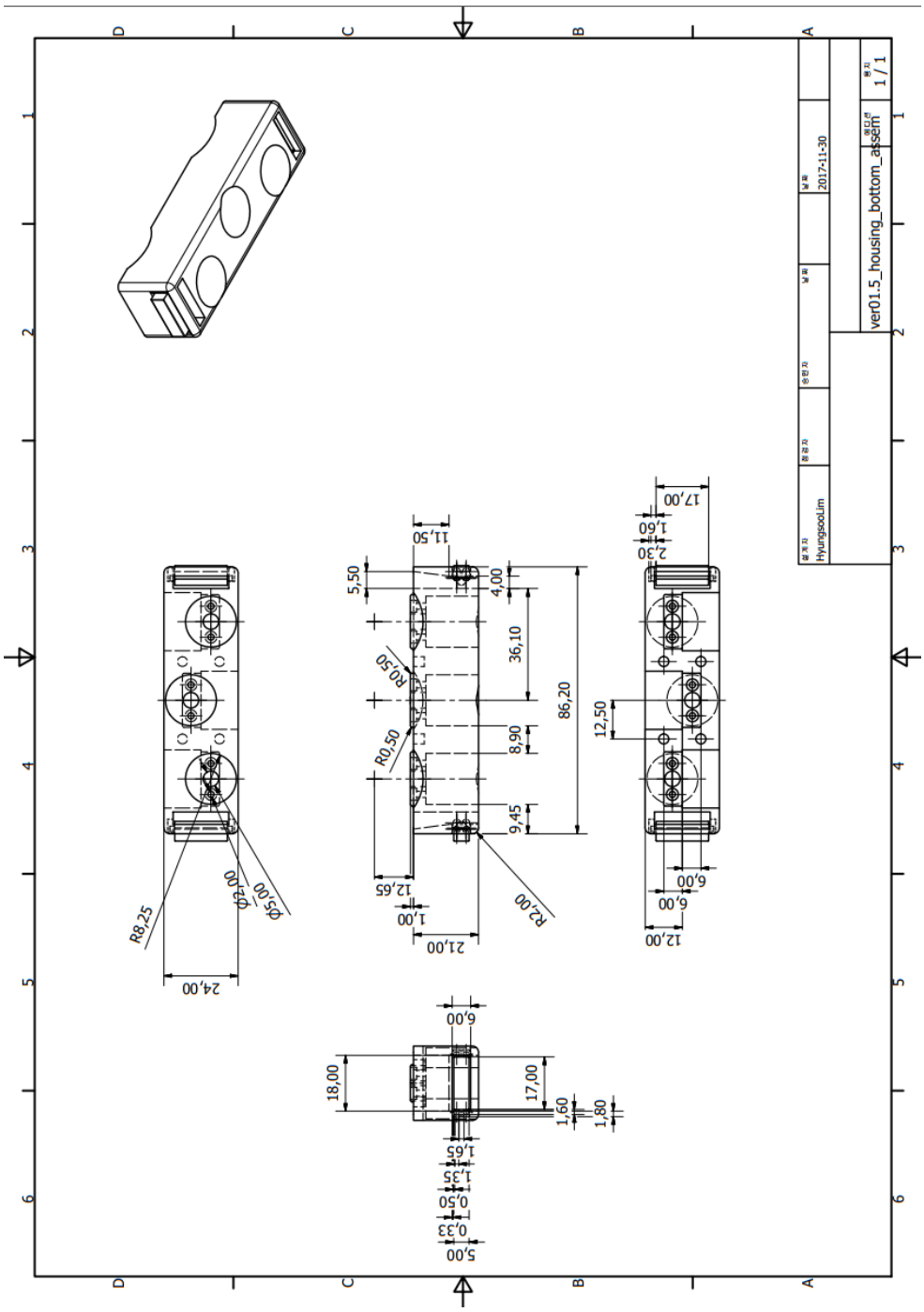


**Figure 3.1. Drawing of housing - bottom part**

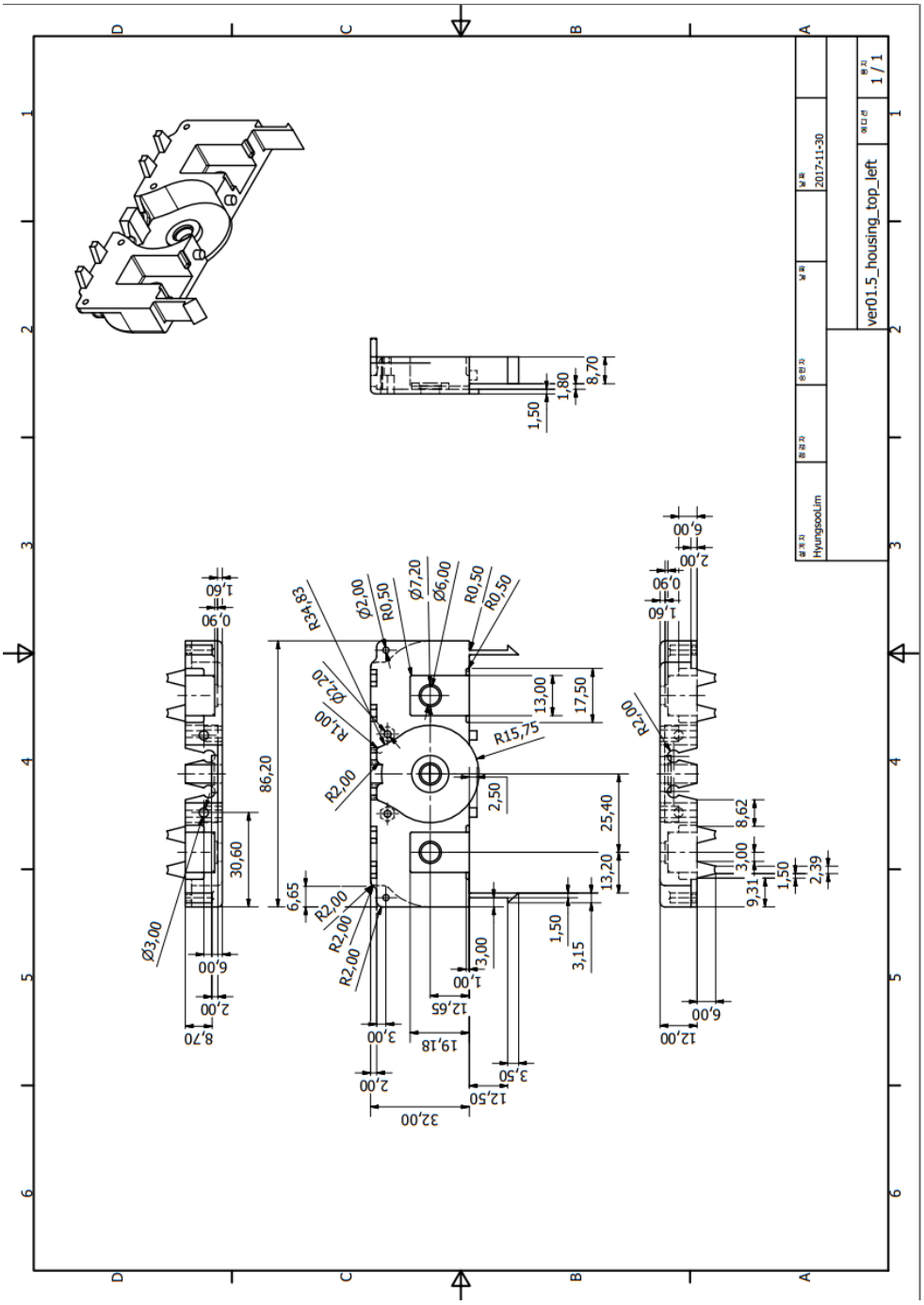


**Figure 3.2. Drawing of housing - top left part**

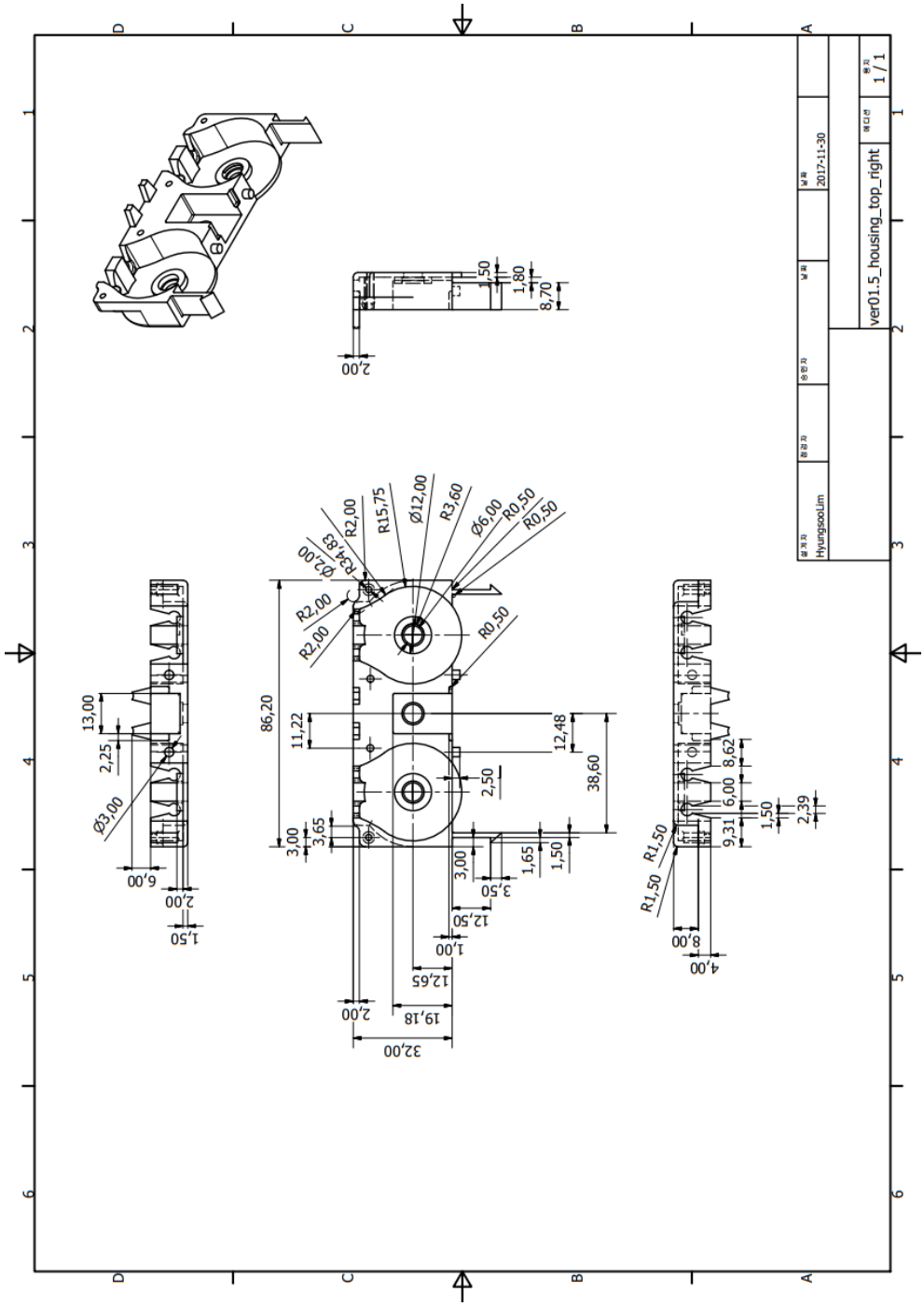


**Figure 3.3. Drawing of housing - top right part**

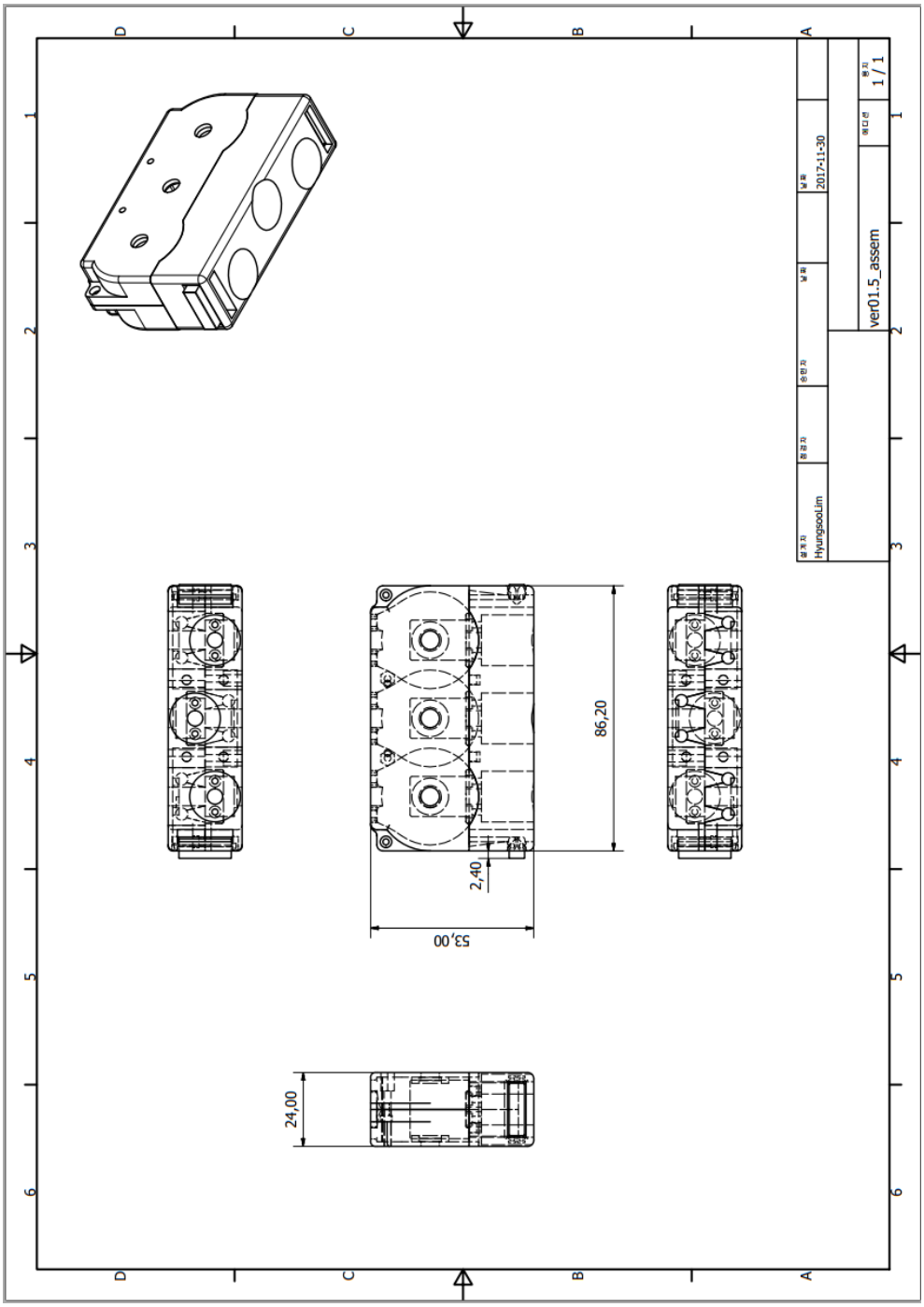


**Figure 3.4. Drawing of housing - assembled parts**

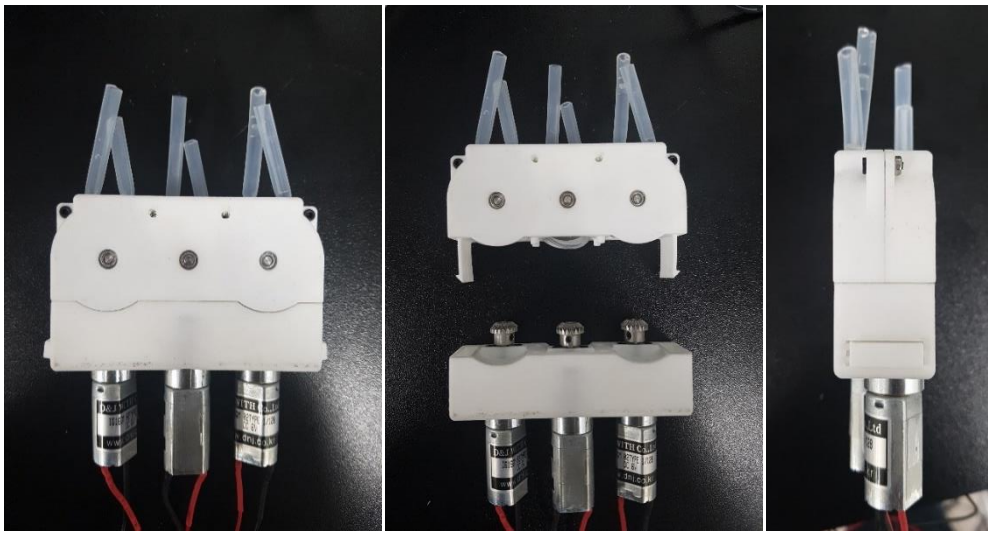

**Figure 3.5. Assembled pump set with IG-16GM 1/128. Housing parts were 3D printed, and gears, bearings and shafts are commercial mechanical components which are made of stainless steel. Rotor plate and rollers are machined.**

## 3.2. Tube Endurance test

After a 12-hour tube endurance test, mean mass flow rate and average RPM at each time interval (3 hours) were calculated. For first three hours, the mean mass flow rate was 16.85 ml/min. However, in next interval, the flow rate increased by 15.13%. At interval of 6-9 and 9-12 hours, flow rate increased only a bit and it seems to be converged to about 20ml/min.

**Table 3.1. Results of tube endurance test.**

| **Hours interval [hr]** | **Mean flow rate [ml/min]** | **Incremental rate [%]** |
|---|---|---|
| 0-3 | 16.85 | - |
| 3-6 | 19.4 | 15.13 |
| 6-9 | 19.78 | 1.96 |
| 9-12 | 19.89 | 0.556 |

## 3.3. Performance test

Performance tests were conducted changing types of motor described in Table 2.1. Flow rate − Pressure difference curves of IG-16GM 1/316 is shown in Figure 3.6. Although there are deviations among each pump head, average flow rate ranges from about 5 ml/min to 10 ml/min at initial pressure difference for all units. As higher the pressure, larger the deviations are especially at low PWM step and high pressure. Flow rate dropped about 20% at 180 mmHg than 20 mmHg and it was 4.4 to 9 ml/min. Figure 3.7. shows result of IG-16GM 1/128. Since the motors are changed with higher RPM, maximum flow rate increased. However, due to relatively low torque, flow rate range is narrower. Also, flow rate drops along increasing pressure are much larger than that of 1/316, which is also due to lack of driving torque. Resultant flow rate is 11 to 15.4 ml/min at zero resistance pressure and 11.9 to 13.2 ml/min at 180mmHg. Result of A-max16 with 1/157 gear box is shown in Figure 3.8. High torque of the motors results in wide range of flow rate and drop in flow rate along increasing resistance pressure was less than 10%. With no load, flow rate is 12.2 to 27.6 ml/min and at pressure of 180 mmHg, it was 10 to 23.7 ml/min. Figures are plotted with IBM SPSS program.

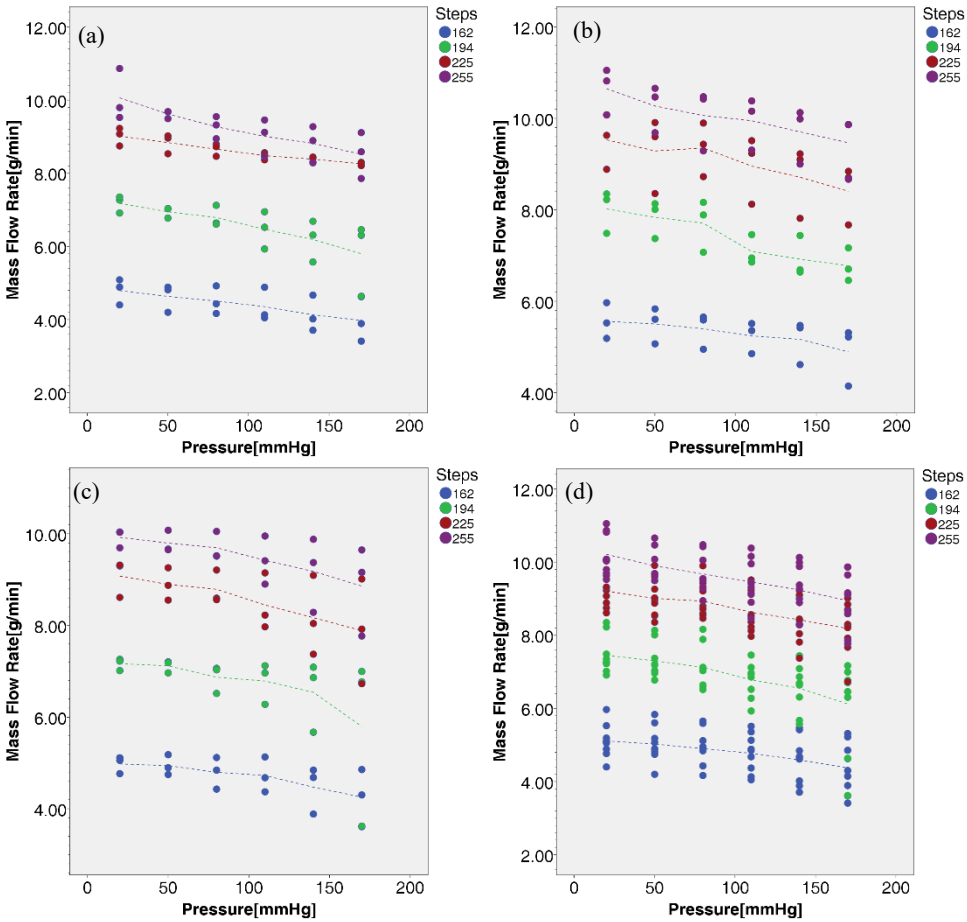


**Figure 3.6. Flow rate - Pressure difference curve of the pump with 1/316 geared motor, (a) result of left pump head unit, (b) result of middle pump head unit, (c) result of right pump head unit, (d) total result of the pump head. Flow rate ranges from 5.1 to 10.2 ml/min at zero resistance pressure and 4.4 to 9 ml/min at 160 mmHg.**

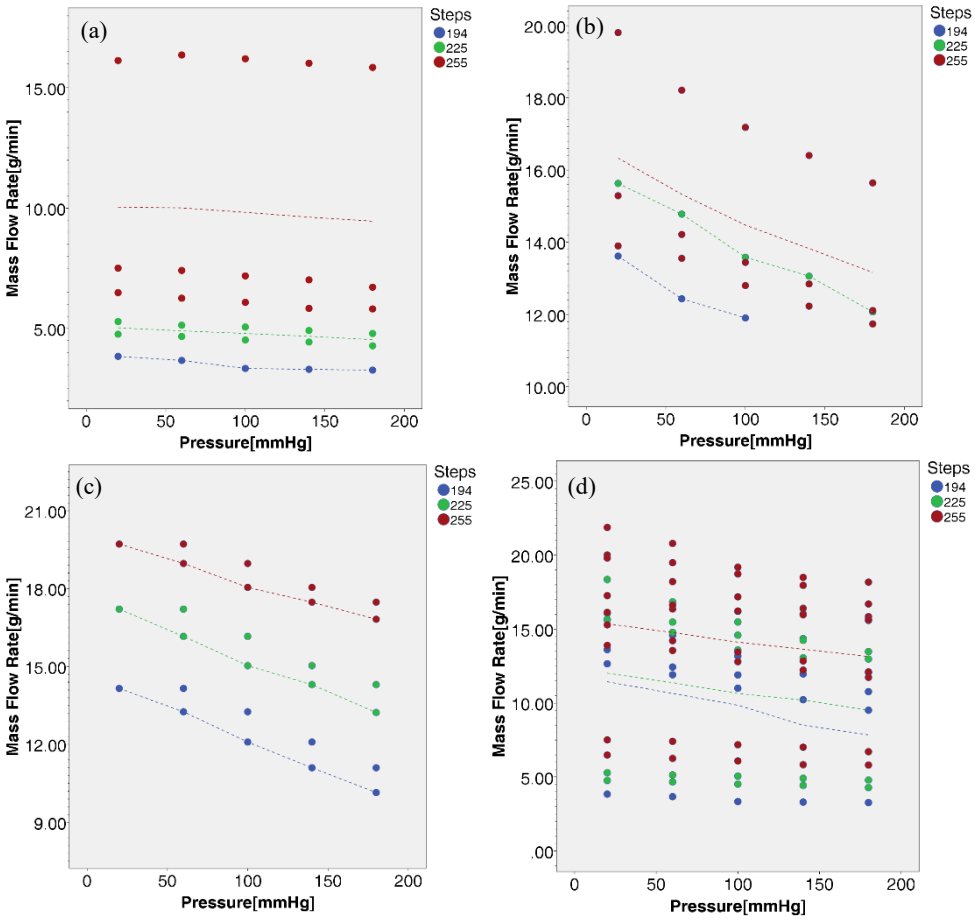


**Figure 3.7. Flow rate - Pressure difference curve of the pump with 1/128 geared motor, (a) result of left pump head unit, (b) result of middle pump head unit – at step of 194, pump stopped to operate when the resistance is higher than 100 mmHg, (c) result of right pump head unit, (d) total result of the pump head. Flow rate ranges from 11 to 15.4 ml/min at zero resistance pressure and 11.9 to 13.2 ml/min at 160 mmHg.**

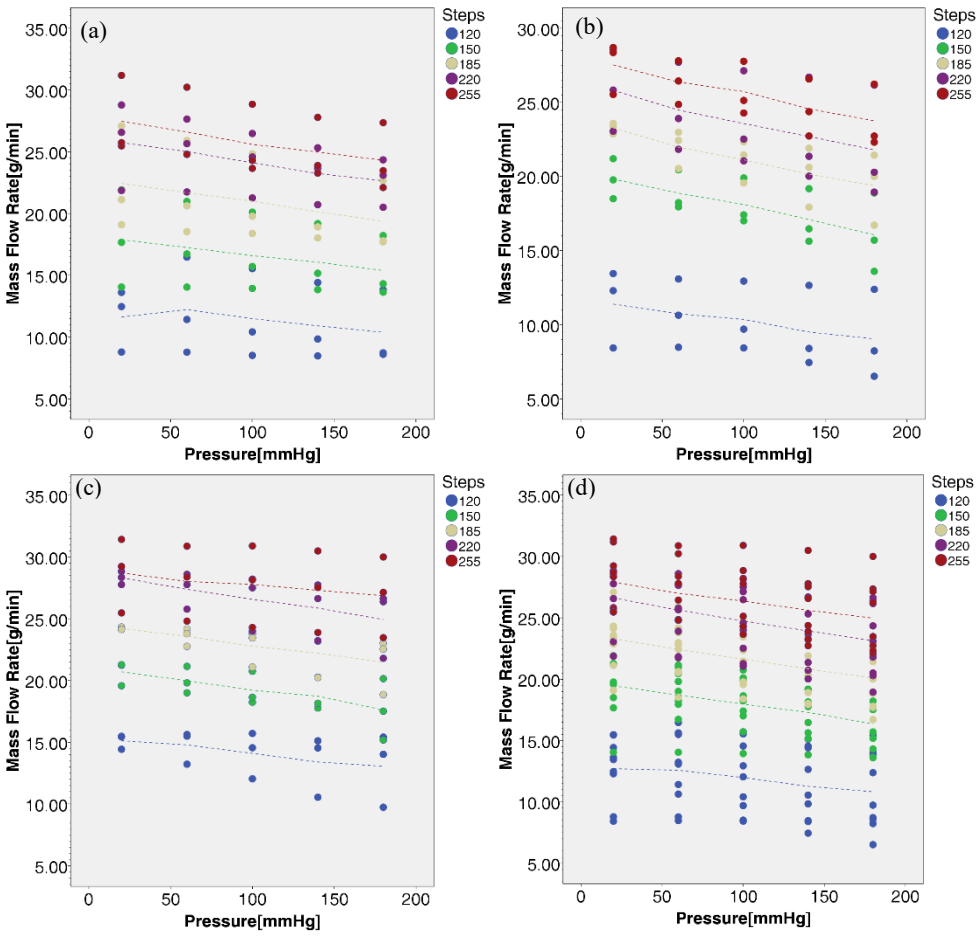


**Figure 3.8. Flow rate - Pressure difference curve of the pump with A-max 1/157 geared motor, (a) result of left pump head unit, (b) result of middle pump head unit (c) result of right. Flow rate ranges from 12.2 to 27.6 ml/min at zero resistance pressure and 10 to 23.7 ml/min at 160 mmHg.**

## 3.4. Current consumption test

Current consumption of the pump was estimated using current sensor. As shown in Figure 3.9, two types of motors were tested. When using IG-16GM 1/316, current ranged 0.135 ~ 0.15 A. Also using A-max16 1/157, current was 0.173 ~ 0.18 4A. Both motors were driven at 6 V. Since rated current of A-max16 is higher than IG-16GM, current of A-max16 turned out to be higher than that of IG-16GM. However, current seems to be independent to pressure and power consumption is less than 1.2 W.

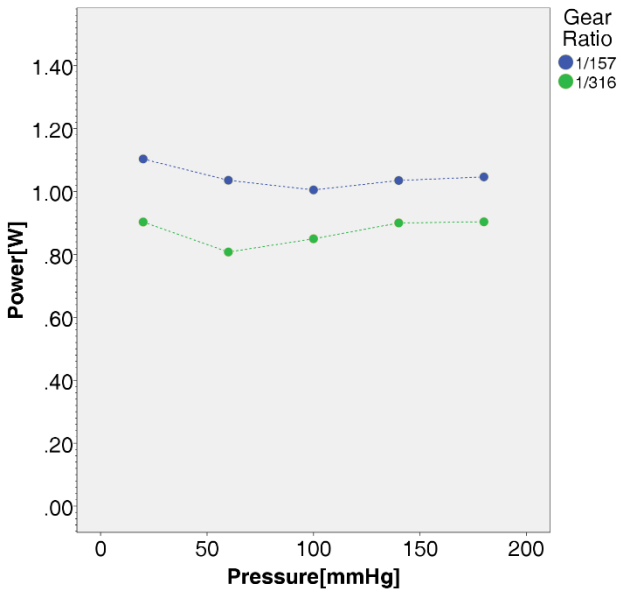


**Figure 3.9. Current - Pressure difference curve of the pump with IG-16GM 1/316 and A-max16 1/157. Even though current consumption of A-max16 is larger than that of IG-16GM, both power consumptions are small enough(less than 1.2 W) to use in WAK.**

## 3.5. Pump specification

Based on conducted experiments, resultant pump specification can be summarized as Table 3.2. Total mass of the pump set is around 250 g, which is made up with three pumps, so only 83 g per a pump. With IG-16GM series, the pump set consumes 0.6~1.0 A and with A-max 16 motors, the pump set consumes 0.45 - 0.75 A. The input voltage was 6v, so the resultant power consumption is about 3.6 - 6.0 W and 2.7 - 4.5 W.

Although IG-16GM series motors are slightly lighter than A-max16 with 1/157 gearbox, A-max 16 motor shows much better performance than IG-16M series.

Comparison with commercial peristaltic pumps and previously studied pumps are summarized in Table 3.3. Note that my pump is composed of three units, it is smaller than all the pumps except Markovic's and lighter than other pumps except Welco WPM. Power consumption of my pump is also the smallest among the pumps. It only takes 1.14 W. However, flow rate of the pump is only up to 27.6 ml/min which is much smaller than that of other pumps.

**Table 3.2. Specification of the pump**

| **Type of Motor** | IG-16GM 1/128 | IG-16GM 1/316 | A-max16 1/157 |
|---|---|---|---|
| **Size and Weight** | 86 * 24 * 87.7 mm, 230 g | 86 * 24 * 90.8 mm, 239 g | 86 * 24 * 85 mm, 245 g |
| **Operating Voltage** | 6 V | | |
| **Current Consumption** | 0.2 – 0.3 A | | 0.15 – 0.25 A |
| **Mass flow rate** | 11.0 – 15.4 ml/min @ 20 mmHg<br>11.9 – 13.2 ml/min @ 180 mmHg | 5.1 – 10.2 @ 20 mmHg<br>4.4 – 9.0 @ 180 mmHg | 12.2 – 27.6 ml/min @ 20 mmHg<br>10.0 – 23.7 ml/min @ 180 mmHg |
| **Operating Pressure** | 0 - 180 mmHg | | |

**Table 3.3. Comparison with commercial pumps and previous studies**

| Type of pump | Flow rate [ml/min] | Size and volume [mm, $cm^3$] | Weight [g] | Power [W] |
|---|---|---|---|---|
| My pump (three unit) | 12.2 - 27.6 | 86 x 24 x 85 / 167.28 | 245 | 3.42 |
| My pump (one unit average) | 12.2 - 27.6 | 29 x 24 x 85 / 59.16 | 82 | 1.14 |
| Welco WPX | 25 - 110[14] | 49 x 46 x 102 / 229.91 | 200 | - |
| Welco WPM | 30 - 70[14] | 38 x 38 x 68 / 98.19 | 68 | 5 |
| Markovic [12] (one unit) | - 150 | - / 34.7 | 104 | 1.17 |
| Kang [11] | 45 - 150 | 44 x 49 x 41 / 105.7 | - | 1.3 |
| Gura [8] | - 95 | 100 x 70 x 50 / 350 | 380 | 3 |

## 3.6. CRRT circuit test

Two IG-16GM 1/316 motors and one A-max16 1/157 motor were assembled to the housing to circulate fluid through CRRT circuit. Flow rates of pump units were set to 29 ml/min, 9 ml/min and 7 ml/min. Because of maximum flow rate limitation, 1/5 scale CRRT model was tested. Since flow rate of effluent was 9 ml/min and that of replacement fluid was 7 ml/min, ultrafiltration rate must be 2 ml/min. This can be proved by calculating mass gradient of return reservoir. As input flow rate was 30 ml/min, return flow rate should be 28 ml/min. From the tests, mean mass flow rate of return is calculated as 28.2 ml/min which shows good concordance with theoretical flow rate. Pressure drop through dialyzer was about 7 mmHg. As the experiment proceeded, negative pressure from the inlet gradually decreased (absolute value increased) and outlet pressure increased. Due to decreasing height of water in blood reservoir, larger negative pressure is induced. Increasing outlet pressure came from increasing hydrostatic pressure of return reservoir. To avoid difference in hydrostatic pressure between blood reservoir and return reservoir, closed-loop circuit was tested. As shown in Figure 3.10, inlet pressure and outlet pressure are almost rarely changed. Also in this test, flow rate of effluent is calculated. Flow rates of blood, effluent and replacement fluid are 30, 12 and 10 ml/min each. Calculated flow rate of effluent was 11.97 ml/min which is almost same as set flow rate.

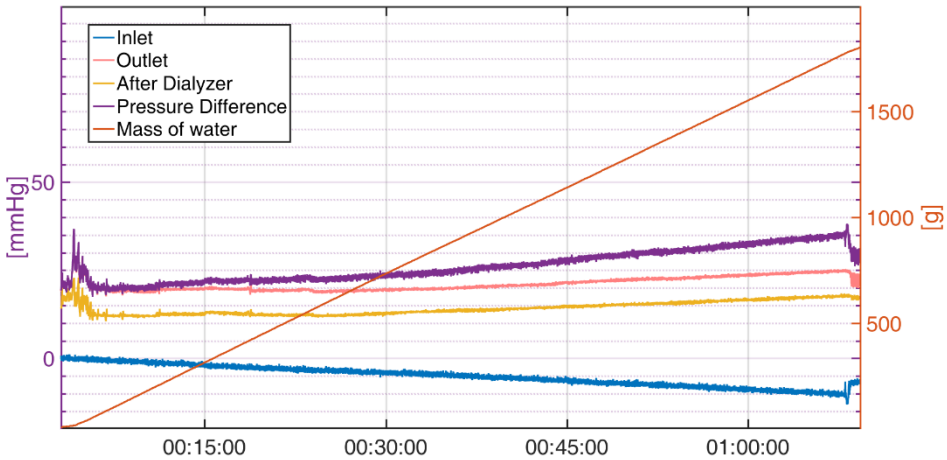


**Figure 3.10. Pressure and mass curve during an hour from CRRT circuit. Blue line: inlet pressure of the pump, orange line: outlet pressure of the pump, yellow line: outlet pressure of dialyzer, purple line: pressure difference across the pump. UF rate is approximately 1.8 ml/min which have concordance with difference of effluent and replacement fluid**

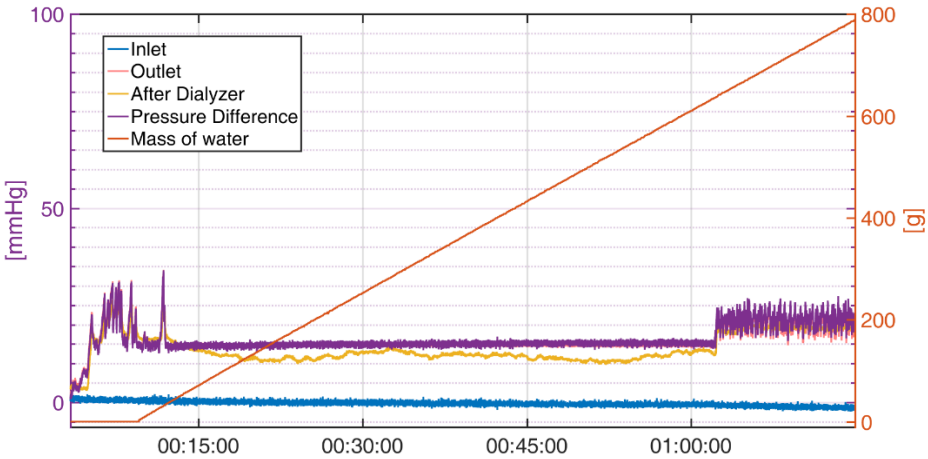


**Figure 3.11. Pressure and mass curve during an hour from CRRT circuit. Blue line: inlet pressure of the pump, orange line: outlet pressure of the pump, yellow line: outlet pressure of dialyzer, purple line: pressure difference across the pump. UF rate is approximately 11.97 ml/min which have concordance with flow rate setting of effluent pump.**

## 3.7. In vitro test

After the in vitro test for 12 hours, pressure data collected during the test were analyzed as Figure 3.11. Drastic pressure drop intervals were pauses of the test due to water leakage at dialysate regeneration system. Mean pressure difference between inlet and outlet pressure excluding pausing periods was 98.82 mmHg which only decrease no-load flow rate less than 10%. Average pressure drop through dialysate regeneration system was 25.75 mmHg that is larger than that of dialyzer in CRRT circuit. Nevertheless, the pump overcame those resistances and circulated fluids without any problem.

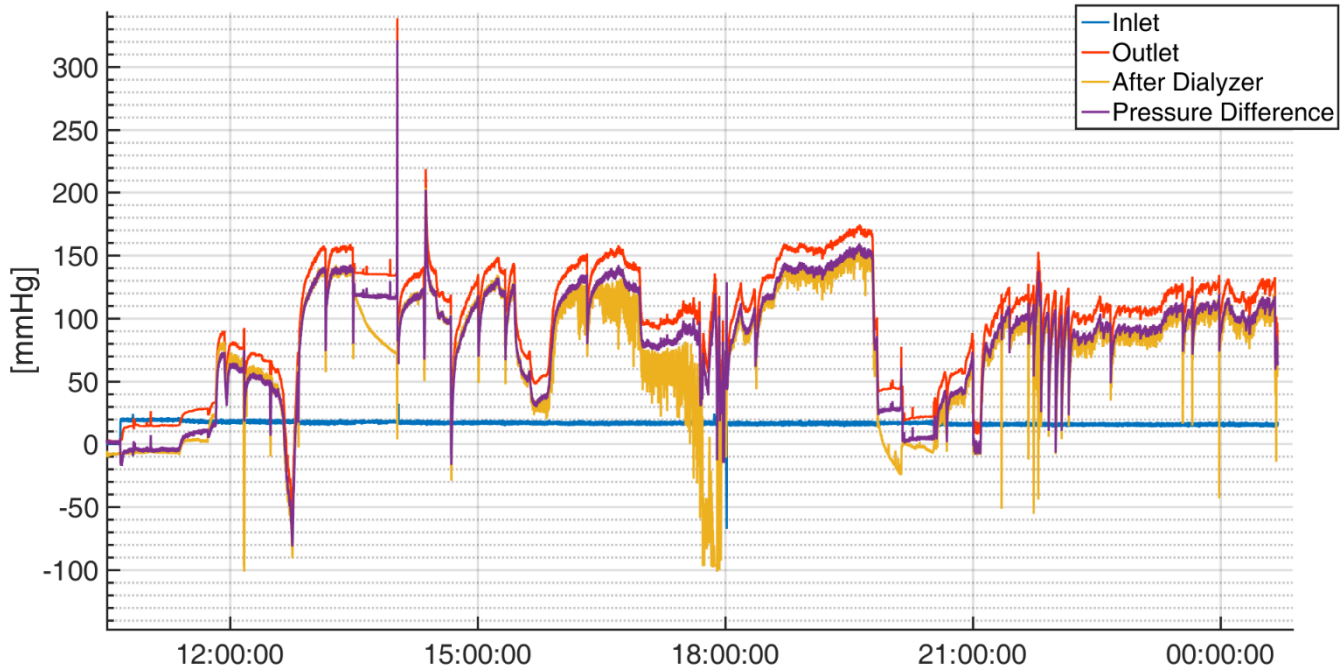


**Figure 3.12. Pressure data of 12-hours in vitro test. Mean pressure difference between inlet and outlet was 98.82 mmHg and mean pressure drop through dialysate regeneration system was 25.75 mmHg. My pump overcame resistance of the circuit and operated well throughout the test.**

# 4. Discussion

## 4.1. 3D printed housing

Thanks to the good resolution of the printer, dimensions of the housing were almost same as designed. In addition to that, material properties of the printing material are good enough to be kept solid during use. The material properties are shown in Table 4.1. Mechanical strength of PA220GF is similar to general ABS which is widely used in industry and 3D printing. On top of that, density of PA2200GF is smaller so it has advantage when making a product lighter. Thanks to these properties, no crack or deformation occurred during this study. Also, the potential of using 3D printed products not only as prototype but also finished product is confirmed.

**Table 4.1. Material properties of PA2200GF and general ABS**

| Properties | PA2200GF | General ABS[20] |
|---|---|---|
| **Density [g/cm3]** | 0.93 | 1.03 - 1.11 |
| **Tensile Modulus [MPa]** | 1700 | 1700 - 2800 |
| **Tensile Strength [MPa]** | 50 | 34 - 51 |
| **Strain at break [%]** | 20 | 8.8 - 36% |
| **Charpy impact strength [kJ/m$^2$]** | 53 | 5.67 - 29.4 |
| **Flexural modulus [MPa]** | 1500 | 1500 - 2900 |

## 4.2. Performance evaluation

Performance of the pump is evaluated in several ways. First, tube endurance test was performed. Flow rate changed along time for 12 hours. This flow rate change comes from deformation of tube. Repeating compression-release makes wall thickness of the tube thinner, and then inner diameter of the tube elongates. Due to enlarged inner cross-sectional area of the tube, more fluid got into the tube. Also, as thinner the wall thickness, smaller the load applied to the motor. This lead to higher RPM at same applied voltage. Considering this, calibration along time or pre-operation before use are needed. Rest of the tests in this study were performed after pre-operation of at least 3 hours.

Next, flow rates at various pressure loads are tested. Except the case of IG-16GM 1/128 motor, the pump functioned well even though flow rate decreased about 10% at 180 mmHg. From unstable operation of IG-16GM 1/128 case, minimum torque required to rotate the rotor of the pump can be figured out.

In power consumption test, currents of two cases turned out to be smaller than 0.2 A so that the power consumption of one pump unit is also smaller than 1.2 W which satisfy the requirement for WAK.

Summarizing overall performance tests, A-max 16 motor with 1/157 or 1/29 gear boxes seems to be suitable for getting the performance for WAK. Considering weight, size, flow rate and power consumption, this newly designed pump would be suitable for being mounted on WAK.

When comparing the pump with commercial pumps and pumps in other studies, it has advantages in size, weight and power consumption. However, the flow rate is much smaller than other pumps which is inappropriate for HD. Even though the pump met the minimum flow rate criteria(25 ml/min), to get better dialysis effect and reduce operating time of WAK, higher flow rate must be achieved in future work.

## 4.3. Renal treatment circuit tests

In addition to the performance tests, CRRT circuit test and in vitro test of WAK are proceeded. In CRRT test, the pump functioned well and achieved ultrafiltration rate as programmed in both open loop and closed loop situations. Regardless of change in hydrostatic pressure of reservoirs. In actual clinical situations, not only hydrostatic pressure affects ultrafiltration, but also concentration of solutes affects, so the UF rate might change. Nevertheless, hydrostatic pressure is dominant, this result shows potential of using the pump as renal treatment.

The pump showed good performance during 12-hour in vitro test too. Even though resistance of the dialysate regeneration system is much larger than normal dialyzer, the pump flowed the dialysate properly and worked well without any breakdown for 12 hours. From this test long-term stability, which is crucial for WAK, was proved.

# 5. Conclusion

Specially designed peristaltic pump for wearable artificial kidney is presented in this study. Most of peristaltic pumps are for general use so that those are not optimized for medical use. Our pump was designed to fulfill the requirement for operating and fitting into wearable artificial kidney. Size of the disposable pump head is smaller than three commercial pump head in series. When a wearable artificial kidney needs maintenance or repair, lock – release structure of the pump can help user exchange the pump head much easier than any commercially available pumps. As the housings are 3D printed, parts for replacement could be rapidly produced. Besides of that, flow rate of pump can be selected using different geared motor. The pump drove CRRT circuit as planned and shows good performance. During in vitro test of WAK system, the pump circulated all the fluids properly and was stable throughout 12 hours that proving potential of the pump.

However, due to small roller size and high gear ratio, range of the flow rate of each geared motor is bit small compared to commercial peristaltic pumps. This could be improved by optimizing the design of the roller plate or using special machined bevel gear which is integrated with the roller plate that can make the rollers bigger and changing gear box to lower gear ratio. Considering use for WAK, flow rate achieved in this study(29 ml/min) is still enough because a patient would wear the system at least 12 hours so that compensate clearance rate of normal peritoneal dialysis. The deviations in each pump head unit could be reduced through precision manufacturing. Noise induced from squeezing and releasing of tube is also one of the limitations of this pump. Using a tube with wall thickness of smaller than 1mm would be helpful for attenuating the noise.

Even though those limitations exist, this pump is suitable for wearable artificial

kidney thanks to its size, performance and disposable feature. In vivo test with WAK circuit for verifying the performance of the pump should be performed in future. With smaller motors and molded parts, the pump will occupy only a small space in a wearable artificial kidney and other dialysis systems and help their downsizing which eventually would shorten the way to commercialization of portable renal replacement devices.

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# 8. Abstract in Korean

## 국문 초록

이 논문은 하나의 펌프 세트에 3 개의 펌프가 통합된 형태로 새롭게 설계된 연동 펌프의 개발 및 평가를 다룬다. 말기 신장 질환 환자의 증가 및 투석으로 인한 불편함을 해결하기 위해 휴대형 인공신장에 대한 요구가 높아졌고, 투석 치료를 위한 펌프가 개발되었다. 개발된 펌프들은 압력 및 유량과 같은 부분에서 우수한 성능을 나타내지만 휴대형 인공신장에 탑재하기에는 너무 크고 무겁다는 문제가 있다. 또한, 그러한 펌프의 에너지 소비 문제와 교환의 복잡성이 한계점으로 지적된다. 이에 따라 이 연구에서는 혈액 투석, 복막 투석 및 지속적 신대체요법 (continuous renal replacement therapy, CRRT)와 같은 다양한 신부전 치료법을 운용할 수 있는 펌프세트를 개발했다. 휴대형 인공신장에 탑재하기 위한 크기 및 무게 조건을 만족시키기 위하여, 베벨 기어를 사용했고, 펌프의 하우징은 가벼운 재질을 사용해 3D 프린터로 출력했다. 제작한 펌프의 무게는 250g이고 부피는 175cm$^3$에 불과하다. 펌프의 성능을 평가하기 위해 몇 가지 테스트가 수행되었다. 먼저, 펌프에 사용되는 튜브의 내구성 시험을 수행했다. 시험은 12 시간 동안 수행되었는데, 유속이 처음 3 시간 동안 점진적으로 증가하고, 그 후 9-12 시간 간격에서 거의 수렴하는 것을 확인했다. 다음으로는 각기 다른 감속비의 모터를 사용하여 성능 테스트를 진행했다. 2개의 모터는 비교적 작은 토크를 가지며, 기어비는 각각 1/128, 1/316이었으며 유량은 14.3 ~ 21 ml/min, 5.11 ~

10.21 ml/min 로 측정됐다. 다른 하나의 모터는 비교적 큰 토크를 가지며 1/157의 기어비로 8.8 ~ 25.5 ml/min의 유량을 달성했다. 마지막으로 펌프를 이용해 지속적 정맥-정맥 혈액 여과(continuous veno-venous hemofiltraion, CVVH) 프로그램으로 지속적 신대체요법 회로를 순환시키고 설정한 유량에 맞춰 물을 순환시켰다. 이러한 실험들을 통해 개발된 펌프를 신장치료에 사용할 수 있는 가능성이 입증되었다. 상용 펌프에 비해 비교적 유량이 작지만 펌프의 크기, 무게, 에너지 소비 및 교체 용이성 측면에서 인공신장에 적합하며 추가 최적화를 통해 더욱 뛰어난 성능을 가질 수 있을 것이다.

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**주요어: 연동식 펌프, 투석, 휴대형 인공신장, 제품 설계 및 개발**

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