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Original Paper

Analysis of implantable catheter for draining malignant ascites

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Abstract: Among the symptoms of patients with terminal cancer, ascites accumulated in the abdominal cavity reduces quality of life. Ascites causes uncomfortable symptoms, and for this reason, drainage is necessary to expel ascites. Traditional drainage methods require a lot of time for the patient to expel the right amount of ascites. However, patients diagnosed with terminal cancer do not have a long time to live after diagnosis, so the time required for treatment can be a catastrophic loss of time for the patient. Considering that diagnosed patients want to spend time with their acquaintances, a new method of ascites drainage is needed to improve the patient's quality of life. We have devised two types of new implantable catheters. Afterwards, a laboratory apparatus was designed to test the performance of the catheter. The experiment was designed with two considerations: first, when abdominal pressure is higher than the bladder, malignant ascites should be allowed to move, and secondly, it is necessary to prevent reflux to prevent the movement of urine from the bladder to the peritoneum when the pressure in the bladder is higher than the abdominal cavity. As a result of the experiment, the catheter was activated under high abdominal pressure and drainage function was confirmed. However, in situations of high pressure in the bladder, the prevention of reflux did not work. When the pressure in the bladder is high, a sophisticated catheter must be designed to meet the second condition, which does not allow refluxes. Therefore, future research will be conducted to realize the idea of an implantable drainage catheter with a more sophisticated experimental setup and catheter.

Keywords: Ascites, Drainage, Implantable, Quality of life

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1. Introduction

Currently, most cancers are considered treatable diseases. This is because, in contrast to the poor outcomes associated with cancer treatment in the past, mortality rates are now gradually decreasing **[1][2]**. However, there are still many problems in the treatment process, and it is a time-limited disease **[3]**. Treatment for terminal cancer sometimes aims at complete recovery, but some patients voluntarily prepare for death by signing a no-resuscitation pledge, receiving hospice care, and relieving symptoms with the goal of improving quality of life **[4]-[6]**.

The factors influencing the quality of life of cancer patients can be divided into 5 factors: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression **[7][8]**. Currently, the accumulation of malignant ascites in the Abdominal Cavity (AC) is one of the cancer symptoms that affects the patient's daily life and quality of life due to pain/discomfort **[9]-[11]**. This symptom interferes with the patient's behavior and daily life, so the patient needs frequent visits to the hospital for drainage. The medical staff uses Paracentesis to drain the ascites, and the procedure can take from 30 minutes up to 24 hours **[12][13]**. It can be a catastrophic loss of time for patients who have been sentenced to a time limit **[14][15]**. In addition, ascites secretions can cause infection, intestinal perforation, and bleeding, which can threaten the patient.

To overcome this time loss and surgical complications, various methods and ascites drainage devices have been devised. Solbach *et al.* **[16]** focused on a catheter system that could be implanted in the abdominal and researched perforated catheter that could drain ascites anytime and anywhere when the patient had access to appropriate drainage. Stirnimann *et al.* and Fotopoulou *et al.* **[17][18]** studied a new type of ascites drainage method. It is a method of expelling ascites of AC through the bladder using an

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'alpha pump'. Their research observed positive results in puncture flow rate and procedure frequency, but the battery must be ready to operate these electrical devices.

We devised another implantable puncture method in a previous study in which an implantable catheter is inserted between the abdominal cavity and the bladder **[19]**. This Catheter is designed on the basis of the pigtail Catheter and has a silicone membrane and holes. It uses the pressure differential between BC and AC to aid the expulsion of ascites through the Bladder Cavity (BC) and urethra. Previous studies have controlled flow velocity and water level to observe changes in the flow rate of the catheter, activation pressure with rotation, and cycle time. As a result, it was found that the cycle time was affected by the flow rate, and the effect of the flow rate on the activation pressure was not identified. In contrast, the effect of cycle time on turns of the catheter has not been identified, and the effect of activation pressure on turns has been identified.

Based on the results of previous experiments, we designed and built an improved version of the implantable catheter. This version of the Catheter has reduced its size and standardized the holes in the silicone membrane. In addition, the diameter and turns of the catheter were varied to confirm the change in performance. Experiments were carried out to determine if the Catheter performed its drainage function normally while preventing backflow. Experiments were then conducted to measure the drainage performance of the Catheter under pressure.

2. Method

2.1 Experimental Theory

The apparatus was built using Bernoulli's law to test whether the catheter would operate above certain pressure conditions. Bernoulli's equation, which follows Bernoulli's law, follows the same formula as **Equations (1)**, **(2)**.

$$p + \rho g h + \frac{\rho v^2}{2} = constant \tag{1}$$

$$p_1 + \rho g h_1 + \frac{\rho {v_1}^2}{2} = p_2 + \rho g h_2 + \frac{\rho {v_2}^2}{2} \text{ [Pa]} \tag{2}$$

In this experiment, the cylinder and the outside of the catheter, which embodies the bladder and abdominal cavity, are all atmospheric pressure conditions, and the flow rate of the fluid is so small that it can be negligible and summarized as shown in **Equation (3)**.

$$p_1 + \rho g h_1 = p_2 + \rho g h_2 \text{ [Pa]} \tag{3}$$

Therefore, that equation is converted to an equation of the height of the fluid inside the cylinder as shown in **Equation (4)**.

$$\rho g (h_1 - h_2) = p_2 - p_1 \text{ [Pa]} \tag{4}$$

Here, the density (ρ) and the gravitational acceleration (g) are constant, so this formula is proportional as shown in **Equation (5)**.

$$h_1 - h_2 \text{(Water level Difference) [mm]} \quad \propto \quad p_2 - p_1 \text{(Pressure Difference) [Pa]} \tag{5}$$

$h_1$is considered to be the height of the ascites of intraperitoneal and is considered to h_2 be the height at which the entrance of the abdominal catheter is placed. h_1 as increases, the pressure acting on the catheter gradually increases, and it is expected that the fluid will pass through when the pressure difference inside and outside the catheter reaches a certain point. Therefore, we have created an experimental apparatus that can reflect these predictions.

2.2 Experimental Setup

2.2.1 Catheter Design

Catheter is designed with a total of 2 types. Both types of catheters are made of silicone. Each type is a form that complements the problems of the previous experiment.

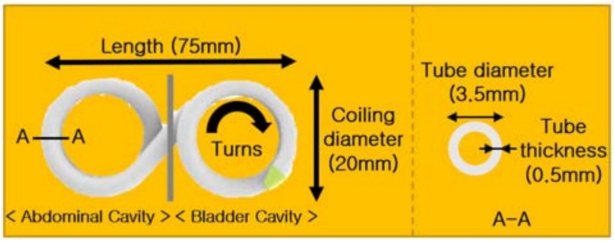

Figure 1: Definition of Dimension Designations for Catheters

For the Catheter of Type 1, the shape of the membrane was changed, and the size of the Catheter was reduced in order to improve the backflow prevention performance, which was a problem in previous studies. The diameter of the catheter is 2 cm, and the Turns are 1.5 revolutions on the abdominal side and 2 revolutions on the bladder side.

The membrane in **Figure 2**, was designed to wrap around the cavity of the catheter in the form of a semi-cylinder to prevent backflow, and in order to check the change in performance according to the diameter and Turns of the catheter, four samples were tested with a diameter of ±0.5 cm and a rotation ±speed of 0.5 from the standard size.

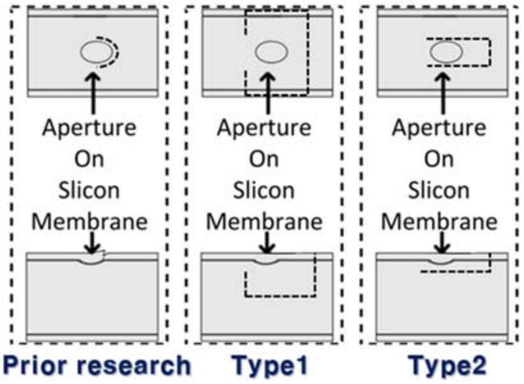

Figure 2: Changing the shape of the membrane

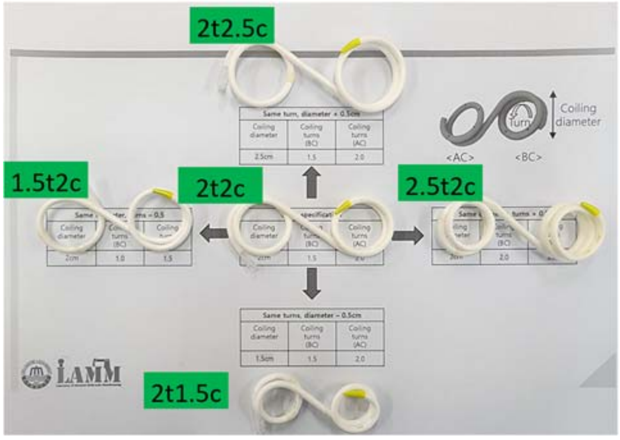

Figure 3: Catheter geometry and designation of Type1

The Catheter of Type2 has reduced the width of the membrane to a size that is approximately 1 mm larger than the hole in order to improve the fact that the normal drainage function of Type1 does not work well. Type2 is made in two types: A_n and B_n. A_n is silicon hardness 50 and Bn is 30. A_n and B_n have three samples each. To distinguish each sample, n is named 1 to 3.

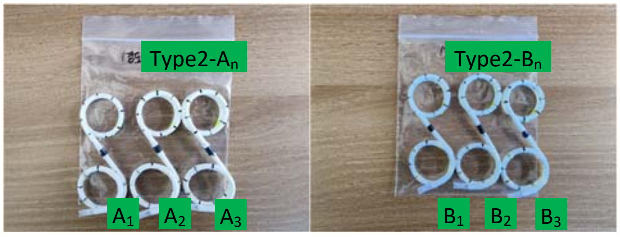

Figure 4: Catheter geometry in Type2

2.2.2 Experimental Equipment Setup

We designed an experimental apparatus to verify the performance of the catheter. First, fix the two cylinders as follows **Figure 5**. These two cylinders are connected so that they can share the water level in the lower part. A hole was made to measure the water level by installing a water level sensor in one cylinder and a catheter to be installed in the other cylinder. The water is supplied by a syringe pump connected to the bottom of the cylinder according to the action of the stepper motor.

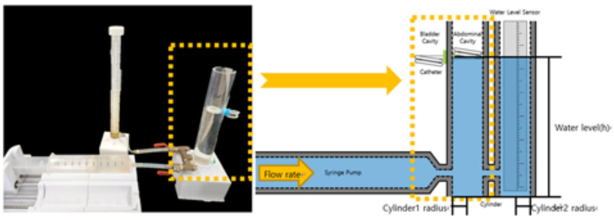

Figure 5: What a designed syringe pump looks like

We used the manufactured laboratory equipment to perform the experiment according to the following procedure. First, a water level sensor and catheter were installed on each cylinder. Then fill it with water to its initial position in **Figure 6**. Second, set the flow rate to be measured on the stepper motor. The final step is to rotate the stepper motor to observe the experimental data for 1 hour. Experimental data are recorded in seconds using a water level sensor and the amount of change is observed. The water level in the cylinder should be increased at a constant rate by the syringe pump, but when the catheter is activated, the rate of increase tends to decrease or, conversely, decrease. By analyzing this amount of change, the drainage performance of the catheter can be measured.

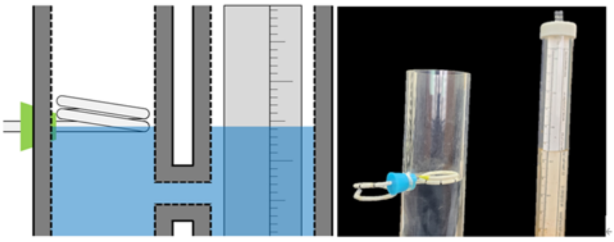

Figure 6: Placement of the Catheter and Initial Position of the Water Level

2.3 Setting the Conditions for the Experiment

2.3.1 Catheter Drainage Performance Experiments

The flow rate of the Catheter's drainage performance experiment is 200 mL/h. The experiment lasted 1 hour each. The inlet part of the catheter is placed on the inside of cylinder 1 to apply pressure (abdominal cavity) due to the water level, and the outlet part is placed on the outside of cylinder 1 to check drainage to the bladder. The change in water level with flow rate can be obtained by the relation of **Equation (6)**. The water level sensor is used to measure the amount of change in the water level and the data is used to check the drainage performance of the catheter.

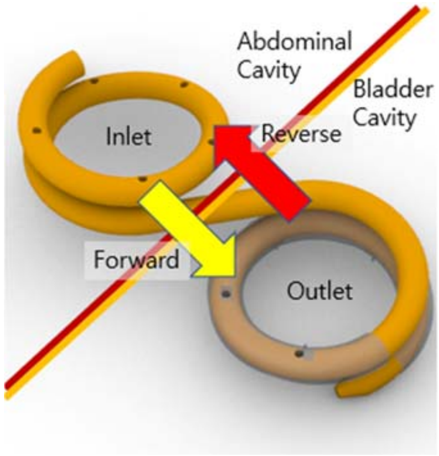

Figure 7: Drainage direction of the catheter

$$\text{Flow rate} = \text{Total floor area of cylinder} \times \text{Water level} \quad (6)$$

2.3.2 Backflow Inhibition Ability Experiment

Couple the Catheter to cylinder 1 in the opposite direction. At this time, the outlet part was located inside the cylinder to exert pressure (bladder pressure) due to the water level, and the inlet part was placed on the outside of cylinder 1 to inhibit the reflux into the abdominal cavity.

3. Experimental Results

3.1 Catheter Drainage Performance Experiments

3.1.1 Results of Type1 Forward Orientation

Table 1: Type2 Forward Water Level Change Data

category	Initial Water Level (mm)	Water level after 1H(mm)	Water level difference(mm)	Total Drainage (ml)
2t2c	31.3	78.4	47.1	107.6
2t1.5c	26.1	27.9	1.8	196.5
2t2.5c	27.8	19.4	-8.4	216.5
1.5t2c	35.0	35.6	0.6	198.8
2.5t2c	22.7	30.2	7.5	185.3

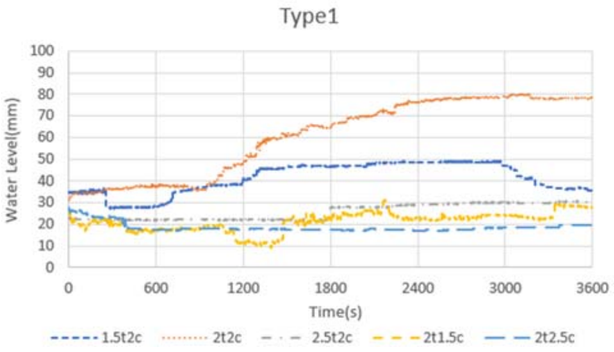

Figure 8: Type1 Forward Water Level Change Graph

Figure 8 as shown in, the forward drainage showed good performance with about 100~ 200ml. In terms of drainage performance, Catheter-2t2c was the lowest at 101.8ml, and Catheter-2t2.5c was the highest at 200ml. Changes in drainage performance with changes in the coiling diameter and rotation speed of the catheter did not show a similar relationship.

3.1.2 Results of Type2 Forward Orientation

Table 2: Type2 Forward Water Level Change Data

category	Initial Water Level (mm)	Water level after 1H(mm)	Water level difference(mm)	Total Drainage (ml)
Type2-A$_1$	168.8	213.6	44.8	112.1
Type2-A$_2$	161.7	163.8	2.1	195.9
Type2-A$_3$	155.6	160.5	4.9	190.4
Type2-B$_1$	163.5	234.8	71.3	60.1
Type2-B$_2$	181.3	269.7	88.4	26.5
Type2-B$_3$	176.0	265.8	89.8	23.8

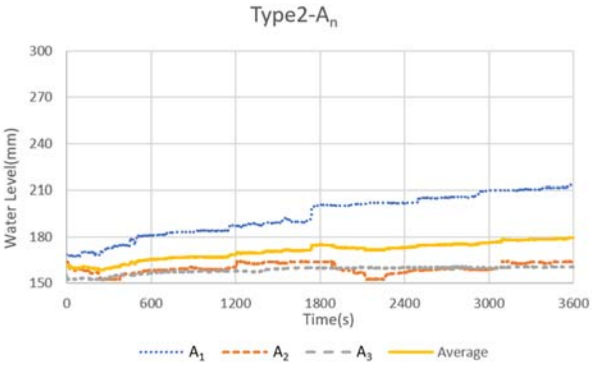

Figure 9: Type2-A$_n$ Forward Water Level Change Graph

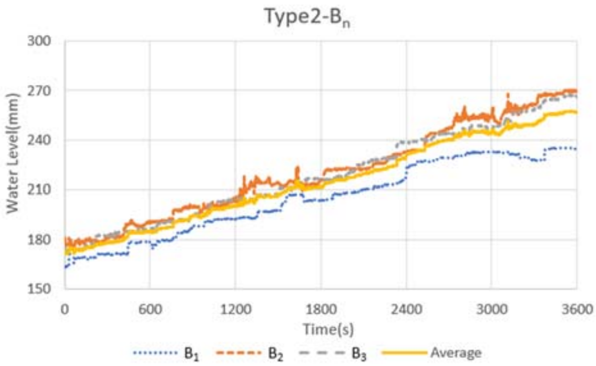

Figure 10: Type2-B_n Forward Water Level Change Graph

Table 2 as shown in, the drainage in the forward direction showed a large deviation of about 24 ~ 196ml. The drainage performance was 166.1ml on average for Type2-A_n and 36.8ml for Type2-B_n, which was about 129.3ml higher for Type2-A_n than for Type2-B_n.

3.2 Backflow Inhibition Ability Experiment

3.1.1 Results of Type1 Backflow Inhibition Ability

In the case of Type1, the results were excellent in the experiment on the ability to suppress backflow. Despite changes in the coiling diameter and turns of the catheter, water was successfully injected up to 280 mm, which is the maximum cylinder height of the experimental device, to prevent backflow.

3.1.2 Results of Type2 Backflow Inhibition Ability

In the case of Type2, the ability to suppress backflow began to be drained from the initial position in both A and B as a result of the experiment. Being drained means that reflux is not controlled.

4. Discussion and Conclusion

This study studied an implantable catheter that can improve patients' quality of life by directly linking AC and BC to eliminate ascites in terminal cancer patients, thereby reducing the time spent on hospital visits and punctures. The main objective of this catheter is to allow flow when the pressure in the peritoneal cavity is higher than the bladder and vice versa. The results of the experiment showed that ascites was well drained when the pressure in the abdominal cavity was high, but the reflux was successfully prevented by Type1 when the pressure of the bladder was high, but the reflux was not suppressed by Type2. If we look at the causes of Type2, as the Catheter rotated, the hole twisted, and the membrane was too narrow to completely block the hole, resulting in an error in **Figure 11**. These results mean that the designed Catheter can control the forward flow but not the other way around, and it also requires further refinement to compensate for the experimental conditions.

Figure 11: Mispositioning of Type2-B membrane and hole

The method of implanting this catheter was studied by corresponding author, Prof. Il-Hwan Kim. He is a specialist at Haeundae Paik Hospital. Prof. Kim developed a procedure device that is inserted through the urethra. The shape is shown in **Figure 12 [22]**.

Figure 12: Internal drainage tube procedure delivery device

In the previous study, experiments were conducted in a big size to experiments the applicability of check valves, but in this study, experiments were conducted in a size suitable for implantation in the human body. And previous catheter was activated when a certain pressure was reached, and a large amount of water was drained at once. In addition, in the backflow prevention experiment, it was activated under a pressure greater than the forward activation pressure to allow backflow. On the other hand, when activated, the catheter in this study continuously drained a small amount of water rather than previous study, and Type 1 successfully prevented backflow. In the previous study, catheters drained large amounts at once, which can lead to sudden urination. Therefore, new implantable catheters are considered to be more advantageous in daily life. In addition, since reflux of urine through catheters can cause complications, it is judged that clear improvement has been achieved in previous studies.

In this study, we designed two types of implantable catheters and checked the performance of the stents with dedicated laboratory equipment, confirming the feasibility of the newly revised ascites drainage method, which is considered a more time-efficient method than the traditional method. As a result, while the main idea of implantable catheter for ascites drainage remains a challenge, the experiment suggested that catheter design and experimental setup should be improved to validate new types of ascites drains. Therefore, in order to compensate for the shortcomings of this experiment, additional research will be conducted, Future research will validate the idea of an implantable catheter for malignant ascites.

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Author Contributions

Conceptualization, I. Kim, H. Kim, I. Kim, and J. Ko; Methodology, I. Kim and H. Kim; Software, I. Kim; Validation, I. Kim and J. Ko; Formal Analysis, I. Kim and J. Ko; Investigation, I. Kim and H. Kim; Resources, I. Kim, H. Kim, and J. Ko; Data Curation, I. Kim; Writing - Preparation of the Original Draft, I. Kim; Writing - Reviewing and Editing, I. Kim and J. Ko; Visualization, I. Kim; Supervision, I. Kim and J. Ko; Project Management, I. Kim and J. Ko; Funding, J. Ko.

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