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Halid Ceylan[1] | **Ogan Karabaş**[2*] | **K. Süleyman Yiğit**[2]

[1]Department of Mechanical Engineering, Graduate School of Natural and Applied Sciences, Kocaeli University, 41000, Kocaeli, Türkiye.
[2]Department of Mechanical Engineering, Faculty of Engineering, Kocaeli University, 41000, Kocaeli, Türkiye.

Corresponding Author

Ogan Karabaş

E-mail: ogan.karabas@kocaeli.edu.tr Phone: +90 505 221 74 19
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Halid Ceylan[1] | Ogan Karabas[2*] | K. Süleyman Yigit[2]

[1]Department of Mechanical Engineering, Graduate School of Natural and Applied Sciences, Kocaeli University, 41000, Kocaeli, Türkiye.
[2]Department of Mechanical Engineering, Faculty of Engineering, Kocaeli University, 41000, Kocaeli, Türkiye.

Abstract

In this study, drop form flow examinations, which form the basis of IV applications used for therapeutic purposes, were performed. Fluid Intravenous (IV) is the practice of administering fluids into a vein. In IV applications, flow must be monitored in order to follow and control the treatment process. For this purpose, the fluid can be converted into drop form with a simple mechanism and the flow rate and volume data can be calculated by the drop counting method. Examining drop form flow processes and analyzing microdrops correctly increases the accuracy in calculating flow data and, most importantly, increases the quality of treatment in IV applications. In the scope of this study, the formation processes of microdrops and the affecting parameters were analyzed. Along with microdrop analysis, error evaluation of the drop counting method and evaluation of measurement techniques were carried out to ensure a healthy and accurate measurement process. System tests and verification were carried out with optical systems, one of the measurement techniques. As a result, this study was carried out on the importance of monitoring systems and measurement parameters in IV applications.

Keywords: Intravenous (IV) system, Gravity-Effected flow, Microdrip methodology, Drop counting, Optical sensing

INTRODUCTION

The technique of administering fluids into a vein through a needle or catheter is called infusion or fluid intravenous (IV). Fluid intravenous was developed following the need for resuscitation, that is, supportive treatment. The IV procedure is frequently used by doctors, nurses, anesthetists, and caregivers in areas such as the operating room, intensive care, interventional radiology, or assistive procedure practices [1].

Modern IV systems consist of 5 basic components. Our first component, the reservoir, is the component that contains the fluid required for the IV process. Reservoirs usually consist of plastic bags or glass bottles. Our second component, the drip chamber, structurally resembles a thick needle. The drip chamber consists of a pipe with a curved end to allow the flow to occur and a transparent chamber to monitor the flow. The flow occurs in drop formation or continuously, depending on the flow rate in the pipe section of the drip chamber. It enters the reservoir and acts as a pathway for flow. In Figure 2.A, microdrop formation can be seen at the pipe tip when the flow rate is low. Factors affecting the formation of microdroplets are the pipe diameter, the surface tension of the liquid and the density of the liquid [2]. In Figure 2.B, it is seen that continuous flow occurs from the pipe end when the flow rate is high. Our 3rd component, the throttle valve, is used to control the flow. Basically, it works by crushing the pipe in which the fluid flows, that is, by reducing the diameter of the pipe. Due to the decrease in pipe diameter, resistance to flow is created and the flow rate decreases. Our 4th component, the catheter, is the component through which fluid is administered into the vein. A catheter is a needle with a hole in it or a thin tube with a sharpened tip. Catheters can be of different diameters depending on the vessel to be entered. Our 5th component, the pipe, is the component that connects our other 3 components to each other and in which the flow takes place (The drip chamber enters the reservoir directly thanks to its needle structure).

In IV procedures, flow begins from the reservoir and ends in a catheter designed to be placed in peripheral veins or tissue vessels outside the heart or in a central vein.

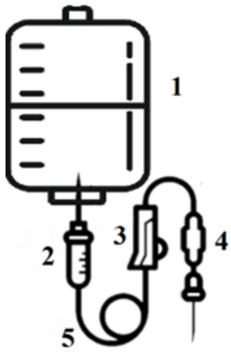

Figure 1 IV Set Components

Figure 2 A) Flow in Drop Form, B) Flow in Continious Form

In order for flow to occur, the reservoir pressure must be higher than the intravascular pressure. Reservoir pressure is affected by the pressure of the vessel to which the catheter is connected and gravity. In order for high pressure and flow due to this pressure to occur; the reservoir must be placed higher than the catheter connection point. Thus, gravity-based flow is achieved [3].

According to Kim et al., there are many situations where you can cause errors in clothing-based infusion systems. Pressure and other effects on droplet formations outside of human components vary widely. Microinfusion and macroinfusion systems were compared. In this mixture, the distinctions between systems, the infusion system dead volume and its distribution over drug delivery are emphasized [1].

According to Flack et al., the most important factors of drop formation in the drip chamber are surface tension, density and the inner environment of the drip chamber tube where the drops form. When the flow rate is increased, the drop diameter decreases due to these factors [2].

According to Stoneham, if infusion systems are based on gravity, it is unnecessary to constantly adjust the bag height to control the pressure and adjust the drop size. By adding a pressure regulator to the system, the system pressure can be kept stable and the flow rate can remain constant [3].

According to Singh et al., the Poiseuille equation cannot adequately describe the relationships between system variables in a perfusion model. Subtle changes in IV set length or design can have unexpectedly significant effects on flow. Non-Newtonian fluids and shear in the flow were cited as the reasons why the equation did not hold in these flows [4].

According to Tolman et al., Gibbs thermodynamics is applied by the theory of capillarity, the effect of droplet tension on the surface tension in droplet formation is found by the tension radius. He considers the process to play a prominent role in surface tension, especially in the formation of small droplets. Even reductions of up to 30% in droplet radii are recorded, it becomes clear that the Gibbs atmosphere is unreliable for these processes. Instead, he found the interconnection of tight mechanics and the measure of forces exerted by individual molecules more satisfactorily [5].

According to La Cour, the structure of the drop tube affects drop formation and drop diameter. He determined the correlation and error rates between drop diameter change and drop tube diameter. The fineness of the drip tube linearity caused a 10% change in the drop size and that this error rate increased exponentially to 40% depending on the flow rate [6].

According to Hillman, the change in drop diameter is related to the structure of the drop tube, the structure of the glass and PVC bag used as a reservoir, and the different viscosity of the liquids. The change in drop diameter with the formation and break-up time of the drop in the tube and determined that the speed-dependent diameter change was more dominant than viscosity [7].

According to MurphY et al., it is necessary to add the length of the pipe through which the flow occurs and the resistances arising from the drop chamber to the flow calculations created using the Poiseuille equation. For flow to occur, not only the pressure created by the reservoir is important, but also it is related to the venous pressure to which the catheter is connected and the drip chamber outlet pressure [8].

According to Pierce et al., as volume requirements change in infusion applications, the flow of fluid changes significantly. In a gravity-powered infusion system, the drop diameter gradually decreases as the flow rate increases in the flow realized with the microdrop set. Although the flow rate depends on the reservoir height, it defines a function depending on the size of the IV drip chamber, the length of the tube through which the flow occurs, and the size of the IV catheter [9].

According to Ogawa et al., in infusion applications, drop lengths after drop fall and drop rate increase linearly from 50 drops/min. to 1000 drops/min. IV administrations must be monitored by drip counter systems because infusion pumps are sensitive but expensive. The best alternative in monitoring systems is to perform measurement with a sensor type that uses electrical impedance difference, since infrared systems cannot detect continuous flow [10].

According to Bhavasaar et al., it has studied IV monitoring system with load cell sensor and vibration sensor in IV treatments. The system creates flow and volume data by measuring the weight of the reservoir with the load cell. In addition, measurements are made with the vibration sensor against the possibility of embolism, that is, air entering the vein [11].

According to Arfan et al., stake-holder feedback on the major issues while using IV drip set gives the following statistics. As per their survey, there is 70.60% need to keep track of the IV fluid that is being administered; the accuracy of the drip rate is 44.10% whereas clotting at sight of administration is 55.90% and blood backflow is 38.30% [12].

According to Kamble et al., both drop counting and drop diameter can be measured with the optical systems used in IV monitoring systems. Thus, cost-effective flow control can be achieved with a small number of components [13].

According to Tanwar et al., a combination of IV monitoring systems, optical and ultrasonic systems should be created. In his study, he performed pressure and volume control with ultrasonic sensors. In addition, it tried to minimize the risk of embolism by controlling air bubbles with the optical system. Remote monitoring and control of the system was provided by data communication via Wi-Fi [14].

According to Cahyanurani et al., if optical tracking systems are operated based on drop time, error rates remain below 1%. It has been observed that drop stability gives more accurate results in flows provided by pumped systems [15].

In liquid intravenous (IV) infusion applications, the flow rate is calculated by the drop counting method if the system is not connected to an electromechanical system. IV set manufacturers indicate how many mL one drop equals in the drip chambers they produce. Sets of 20 drops/mL are mainly used in the market. Additionally, sets up to 60 drops/mL are also available. In the drop counting method, for a set of 20 calculations, the time during which 20 drops have passed is counted. The ratio of the found time to hours gives us the approximate flow rate in mL that will pass in 1 hour. In this way, the practitioner performs the flow rate calculation at certain intervals depending on the suitability and criticality of the treatment. If deemed necessary, it adjusts with the throttle valve. Another reason for these controls is that situations such as stopping of intravenous flow and arm closure, which we describe as other factors, prevent the flow, and also the necessity of monitoring whether the fluid is administered properly.

In this study, we examined the effects and results of pressure changes on infusion sets as the main flow rate factor, excluding other factors. Unlike other studies in the literature, an electronic monitoring system that works with the drop counting method was created. In the system, based on optical principles, photodiodes, which are semiconductor elements that change the current flowing through them depending on the intensity of the light falling on them, were used as sensors. Functions were defined depending on the reduction in drop diameter in gradual flow rate ranges (Stage-1: 0-100 mL/h, Stage-2: 100-1000 mL/h). In the system where drop counting was performed with photodiodes, functions were processed depending on the flow rate and error correction was provided.

MATERIAL AND METHODS

Poiseuille equation; describes the relationship between fluid viscosity, pressure, pipe diameter, and flow. Flow rate (Q) passing through a pipe according to Equation (1).

$$Q = \frac{\Delta \mathrm{P}\pi \mathrm{r}4}{8\mu \mathrm{L}}\ (\mathrm{m}^3/s) \qquad (1)$$

It is inversely proportional to the pipe length (L) and fluid viscosity (μ), and directly proportional to the pressure drop along the pipe (ΔP) and pipe radius (r).

Poiseuille's equations are valid for non-turbulent flow and non-slip boundary ranges. The flow chart of Newtonian fluids independently satisfies the Poiseuille equations. It was stated that the Poiseuille equation, the research at the University of Wisconsin (UW), caused errors in flow rate programming in IV treatments. The reason for this is that in non-Newtonian fluids, negative effects occur due to changes in pipe diameter, liquid viscosity, drop chamber size and bag pressure in the system [4].

In non-Newtonian fluids, the diameter of liquid droplets is not constant. Droplet sizes; According to Equation (2), in these types of fluids, the surface tension changes depending on the molecular properties of the additives and especially the temperature [1].

$$r = \sqrt[3]{\frac{3\gamma d_t}{4\rho g}}\ (m) \qquad (2)$$

In IV applications, the drop counting method works by simplifying the system. In the drop counting method, negative effects may be observed in the treatment due to the accuracy of the linearity in the flow and volume graphs. In order to eliminate these negative effects, it is necessary to switch to electromechanical or purely electronic systems.

Monitoring systems are used for flow monitoring in electromechanical systems or electronic systems. Flow monitoring systems mainly control the flow status in electromechanical systems. Flow monitoring system is used to create flow and volume data in electronic systems. Although there are different systems such as obtaining data with weight difference by using load cells as sensors in flow monitoring systems or obtaining data with drop detection based on electromagnetic field change, systems built on optical foundations are mostly used. Photodiodes are preferred as sensors in optical systems due to their fast response times and stable operation. Photodiodes are sensors that allow current to flow depending on the intensity of light. The current flowing can be detected with the help of an added resistor in photodiode circuits. Depending on the value of the resistor, the system sensitivity can be adjusted. Light intensity can be determined using microprocessors from the voltage difference caused by the current flowing through the resistor. Figure 3 shows the optical detection device. In the device, an electromagnetic source, that is, an LED as a light source, is placed around the transparent chamber of the drop chamber, facing the photodiode. Thus, the lens effect of the drop passing through the chamber was also utilized. Due to this effect, droplets could be counted with varying light intensity.

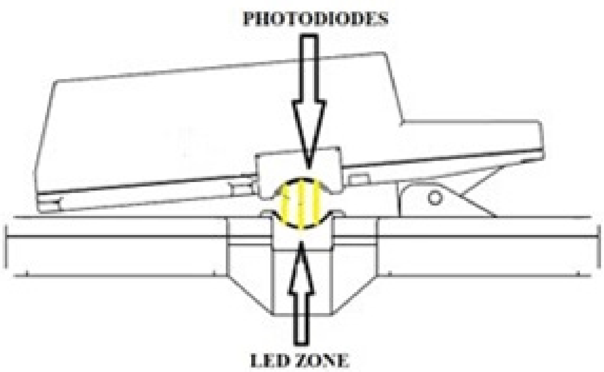

Figure 3 Optical Detection Device

Figure 4.A shows that there are 2 photodiodes in the device. During the drop passage in the system, a delay time occurs regardless of the time between the photodiodes placed on the vertical axis (Figure 4.B). While the drop counting process is carried out with these delays, the system's internal verification process is also carried out with its 2 sensors structure.

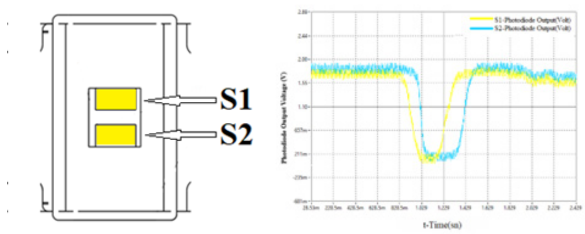

Figure 4 A) Photodiodes B) Flow to Vertical Axis Photodiodes Output Signals

With the drop counting process, volume data can be obtained regardless of time. The drip chamber has a capacity of 1/20 mL/drop. The volume of each drop was accepted as 1/20 mL. The derivative of the obtained volume data with respect to

time creates flow data. A syringe pump was used to obtain gravity-induced pressure in the system. The purpose of this is to provide pressure change without changing the height of the reservoir. Syringe pumps are sensitive devices that can provide constant flow rate. In our system, liquid flow was provided to the infusion set at different speeds with the HARVARD APPARATUS brand 70200 model syringe pump.
The fluid limitation device of the IV set on the fluid path in the system was opened completely and the device was rendered dysfunctional. In the system, fluid was transferred from the pump to the set via a 3-way valve. The sets used in the system are 20 drops/mL sets and different sets from different manufacturers were used.

With this study, differences in flow rate due to these changes caused by in-pipe shifts in droplet formation in the serum set were observed.

Flow at a constant flow rate and a certain volume was obtained with the syringe pump shown in Figure 5.A, which was used to obtain flow in the experiments. Reference Flow Rate (mL/h) and Reference Volume (mL) specified in Table 1 and Table 2 are the data of the syringe pump. The flow was transmitted to the drop chamber to which the measuring device in Figure 5.B was connected, using the standard drop counting method, with the help of pipes, thus the drops formed in the chamber were counted with the measuring device and flow rate and passing volume data were obtained with the system in Figure 6.

Figure 5 A) Syringe Pump B) Placement of the Measuring Device in the Drop Chamber

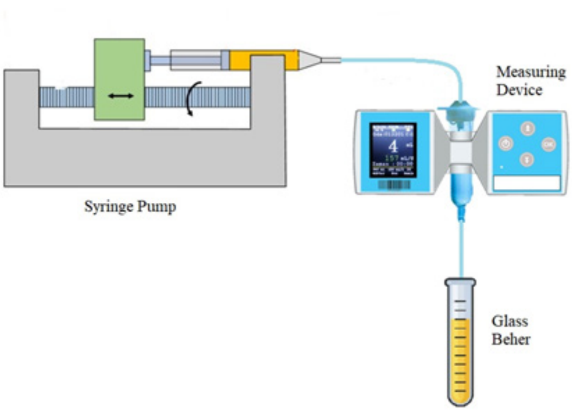

Figure 6 Schematic experimental setup

RESULTS AND DISCUSSION

In IV treatments, the speed of the fluid and the passing volume, directly affect the treatment. In the tests performed, changes in the diameter of the micro drops were detected depending on the increase or decrease in the flow rate. It has been observed that there are differences in flow rate and passing volume caused by these changes.

As seen in Table 1, resistances due to shear stresses occurring on the flow can be examined at 2 different flow rates. Since the flow rate is low in flows up to 0-100mL/h, results are produced in accordance with the Poiseuille equations. The reason for this is that due to the low flow rate, shear stress resistance remains low and its effect on the system remains low. At speeds above 100mL/h, reductions in drop diameter begin to appear significantly. In this flow rate range, the resistance due to shear stress reveals a linear graph. This linearity continues up to 100-1000mL/h flow rate.

Measured Flow Rate (Q_o) calculated according to Equation 3 and Measured Volume (V_o) calculated according to Equation 4 are the data obtained by the standard drop counting method. Measured Flow Rate (Q_o) was found by dividing the time 20 drops passed to 1 hour according to Equation (3), finding $\Delta q_{(drop/h)}$ and dividing it to the serum set constant $C_{(drop/mL)}$. Measured Volume (V_o) was found by counting the total passing drop $\Delta q_{(OD)}$ according to Equation (4) and proportioning it to the serum set constant $C_{(drop/mL)}$.

$$C_{drop/mL} = 20\ (drop/mL) \quad (3)$$

$$Q_O = \frac{\Delta q_{drop/h}}{C_{drop/mL}}\ (mL/h) \quad (4)$$

Isotonic solution, electrolyte solution and dye added solution were used as fluid in the experiments. Isotonic solutions are solutions in which salt is dissolved in certain percentages. Their properties are equal to osmotic pressure and they are the most used liquid in the healthcare system. The isotonic solutions used contain 0.45% and 0.9% sodium chloride. Electrolyte solution can also be referred to as sugar serum. It is a solution administered intravenously and used to meet calorie needs, especially in cases of nutritional problems. The electrolyte solutions used contained 5%, 10% and 20% dextrose in the content stream. Dye solutions, chemotherapy solutions used in infusion treatments, solutions containing amino acids, etc. For solutions, it is the solution obtained by mixing baticon (povidone-iodine) in isotonic solution. The study of situations where the lens effect of the drop does not occur through dye solutions has been examined.

Table 1 Flow Rates Results

Reference Flow Rates (mL/h)	Measured Flow Rates (mL/h)	Error Rate (%)
25	26	4,0
50	51	2,0
100	101	1,0
200	193	3,6
250	244	2,4
500	474	5,4
750	694	8,0
1000	878	13,8
1250	1110	12,6

When we look at the volume comparisons in the results in Table 2, the same results are obtained depending on the flow rate. The change in volume is as noticeable as the change in flow rate. According to these results, the error rate in non-Newtonian liquids confirmed the inaccuracy of the single function method in the drop counting method.

Table 2 Measured Volume Results

Reference Flow Rates (mL/h)	Reference Volume (mL)	Measured Volume (mL)	Error Rates (%)
25	50	51	2,0
50	50	50	0
100	50	50	0
200	50	48	4,1
250	50	47	6,3
500	50	45	11,1
750	50	43	16,2
1000	50	41	21,9
1250	50	39	28,2

In optically constructed systems, even though the most accurate method is to create flow rate and volume data starting from drop volume measurement, as in KAMBLE et al.'s study, by specifying the gradual flow range (Stage-1: 0-100 mL/h, Stage-2: 100-1000 mL/h), flow and volume data can be measured with high accuracy by the 2-function drop counting method.

CONCLUSION

In this study, it is seen that measurements should be made with mechanical pump systems or electronically controlled volume measurement systems. Especially in low-flow applications, critical situations may occur as a result of people consciously or unconsciously tampering with the serum speed. In order to prevent these situations, it is important that the system is monitored correctly and the measurement is accurate. As seen in the Table 3, it is necessary to think about the advantages and disadvantages of the systems and to use the right system at the right time.

Table 3 Infusion Types Comparison Charts [1]

	Gratity-Based Flow	Peristaltik/Casette Type Pump- Syringe Pump
Infusion Category	Macroinfusion	Macroinfusion/ Microinfusion- Microinfusion
Ease of Use	Basic Set/ No External Components	Use of External Components is Mandatory / Having to Adjust at Every Startup
Costing	Low Cost	High Cost- Mid Cost
Flow Sensitivity	Low	High- Very High
Volume Sensitivity	Low	High- Very High

Gravity-based flow infusion systems are the simplest systems in terms of ease of use and accessibility. Using gravity-based infusion systems configured to increase sensitivity will be suitable for both the patient and the administering team. Although there are many alternatives for configuration, optical monitoring systems are cost-effective and accessible due to their non-contact measurement ability and reusable feature. Thus, a technology that can be used by everyone who needs treatment is created.

In IV applications, adding RF (WiFi, SubGhz, etc.) communication systems to the architecture for data transfer and recording of the transferred data in systems aimed at monitoring the operations performed with optical or other types of detection, both for verifying the information by the patient and for detecting negative situations on the practitioner's side, results in more functional products. Thanks to this method, both patient rights and practitioner rights will be protected legally.

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