

# Effects of side holes on blood removal characteristics based on measurement of the pressure distribution inside dialysis puncture needles

YAMAUCHI Shinobu <sup>1</sup>, MOTOHASHI Yuka <sup>1</sup>, SATO Toshio <sup>1,2</sup> and  
AGISHI Tetsuzo <sup>1</sup>

<sup>1)</sup> 桐蔭横浜大学医用工学部, <sup>2)</sup> 桐蔭横浜大学大学院工学研究科

(2016年3月28日 受理)

**Key Words** : Dialysis puncture needle, Pressure distribution, Guide wire, Side hole,  
Blood removal characteristics

## 1. Introduction

Indwelling hemodialysis needles with different characteristics are currently sold by various manufacturers. While the choice of indwelling needle is an important element in maintaining efficient dialysis <sup>1)</sup>, smaller diameter needles are desirable when considering factors such as alleviating pain during puncture, hemostasis, and shunt lifespan <sup>2)</sup>. Providing side holes are effective methods for preventing the decrease in the actual flow rate and the excessive negative pressure that occur in smaller diameter indwelling needles. However, very few studies offering a quantitative evaluation of the effect of this phenomenon on the blood removal properties of indwelling needles, and this effectively means that the number and placement of side holes in indwelling needles currently on sale have not been properly investigated. The aim of the pres-

ent study was to optimize the shape, number, and position of side holes in indwelling needles to develop a fine-gauge indwelling needle in which the actual flow rate is the same as the set flow rate and blood removal pressure is kept at a low level. To achieve this, we prepared indwelling needles with different numbers of side holes in different positions and clarified the effect of side holes on blood removed from the tip hole by measuring pressure distribution inside the needle tip using the guidewire fitted with a pressure sensor.

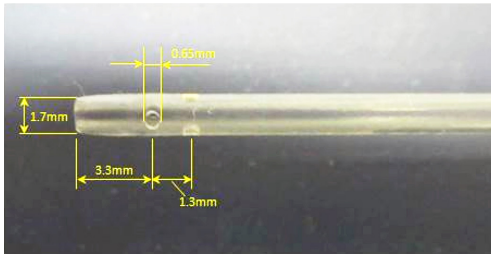
## 2. Methods

### 2-1. Measuring blood removal properties of modified indwelling needles

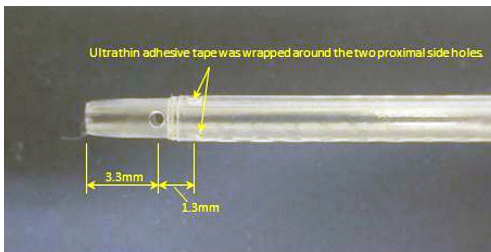
A Medicut™ Cannula with Clamping Tube two-step point type 16G needle (Nippon Covidien Inc.) with an effective length of 30 mm and

<sup>1)</sup> Faculty of Biomedical Engineering, Toin University of Yokohama

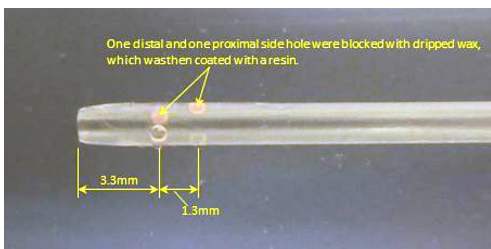
<sup>2)</sup> Graduate School of Engineering, Toin University of Yokohama  
1614 Kurogane-Cho, Aoba-ku Yokohama 225-8502, Japan.



**Fig. 1** A Medicut™ Cannula 16G needle with four side holes (1088M16SCE, 16G30mm+4)



**Fig. 2** Indwelling needle with two holes arranged concentrically (16G30mm+2\_concentric)



**Fig. 3** Indwelling needle with two holes arranged diagonally (16G30mm+2\_diagonal)

four side holes (1088M16SCE, needle external diameter 1.7 mm (16G); below, '16G30mm+4') was used as the indwelling needle. The four side holes were circular, 0.65 mm in diameter, and arranged so that two holes were opposite each other 3.3 mm from the tip, and the other two were 1.33 mm forward of the first two at right angles, as shown in **Fig. 1**. The blood removal properties of an indwelling needle with two holes arranged concentrically (16G30mm+2\_concentric) and an indwelling needle with two holes arranged diagonally (16G30mm+2\_diagonal) were measured. The needles were created by blocking different pairs of two of the four side holes in the 16G30mm+4 needle. For the

needle with two concentric side holes (**Fig. 2**), ultrathin adhesive tape was wrapped around the two proximal side holes, and for the needle with two diagonally arranged side holes (**Fig. 3**), one distal and one proximal side hole were blocked with dripped wax, which was then coated with a room temperature curable resin.

A PVC tube with an internal diameter of 12 mm was used as a mock blood vessel, and water was circulated through the mock vessel at 700 mL/min using the roller pump (Multiflow, Stockrt Instr.) from a heart and lung machine. The mock vessel was punctured at an angle of about 25° because the Guidelines of Vascular Access Construction and Repair for Chronic Hemodialysis recommend an AVF puncture angle of about 25°<sup>3)</sup>, and the four indwelling needles (16G indwelling needle with an effective length of 30 mm and no side holes (1088M16SCE, 16G30mm+0), 16G30mm+2\_concentric, 16G30mm+2\_diagonal, 16G30mm+4) were each arranged against the flow of water in the mock vessel, with the needle tip in the centre of the mock vessel. The needle's connector was connected to the arterial access part of a dialysis blood circuit (NV-Y030P, Nikkiso), and the venous access part was placed inside a 500 mL graduated cylinder. The blood removal rate from the indwelling needle was increased from 50 mL/min to 500 mL/min in 50 mL/min increments using the roller pump of a multipatient dialysis system (DCS-73, Nikkiso). The actual flow rate per minute for each set flow rate was measured 10 times using the graduated cylinder, and the mean actual flow rate was calculated for each set flow rate.

## 2-2. Measuring pressure distribution in modified indwelling needles

To measure the pressure distribution in the tips of the indwelling needles (16G30mm+0, 16G30mm+2\_concentric, 16G30mm+2\_diag-

onal, 16G30mm+4) described in section 2-1, a pressure-sensor guidewire with a piezoresistive sensor 3 cm from the tip, housing a Wheatstone bridge circuit for converting changes in vascular pressure into electrical resistance<sup>4)</sup> (Certus™, St. Jude Medical), was used. The guidewire has an outer diameter of 0.36 mm (0.014 in) and is mainly used for determining, from the pressure data, the fractional flow reserve (FFR)<sup>5)</sup>, which serves as a physiological indicator of coronary artery stenosis. The nominal operating pressure range was -30 to 300 mmHg, and when the guidewire was used in conjunction with the dedicated SJM blood vessel pressure measurement system (RadiAnalyzer, St. Jude Medical), measurement precision was 'measured value  $\pm 1$  mmHg  $\pm 1\%$ ' at measured values of -30 to 50 mmHg, and 'measured value  $\pm 3\%$ ' at measured values of 50 to 300 mmHg. Before using the guidewire to measure the pressure distribution in the needle tip, its performance was evaluated at negative pressures in excess of -30 mmHg, which is the upper limit of the nominal operating range at negative pressure. The test confirmed that pressures could be measured up to -60 mmHg with the same precision as a handy manometer ( $\pm 0.5\%$ F.S.  $\pm 2$  digits)<sup>6)</sup>.

An indwelling needle marked at 5-mm intervals from the needle tip (0 mm) towards the root was placed inside the mock vessel described in section 2-1, and the connector was connected to the arterial access part of the dialysis blood circuit. Another indwelling needle for guidewire insertion was placed in a position facing the first needle, as shown in Fig. 4, and the pressure-sensor guidewire was inserted into the second needle. The guidewire was advanced as far as the root (30 mm) of the needle containing the needle whose tip pressure distribution

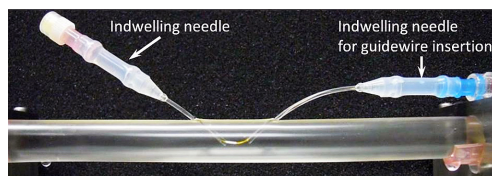


Fig. 4 Guide wire insertion

was to be measured. At this stage, the pressure sensor was calibrated to zero before beginning blood removal through the needle. The set flow rate was increased from 50 to 500 mL/min in 50 mL/min increments using the roller pump of a multipatient dialysis system (DCS-73, Nikkiso), and at each flow rate, the pressure was measured at points 5 mm apart as the guidewire was withdrawn. At this stage, the pressure at each measurement point was measured continuously for 15 seconds, and the mean value was calculated, in order to exclude the influence of pulsatile pressure fluctuations in blood removal caused by the roller pump and to ensure reproducibility.

### 3 Results

#### 3-1. Measurements of blood removal properties of modified indwelling needles

Fig. 5 shows the measurements of blood removal properties of the commercial 16G30mm+4 and 16G30mm+0 indwelling needles, the 16G30mm+2\_concentric needle (with two concentrically arranged holes), and the

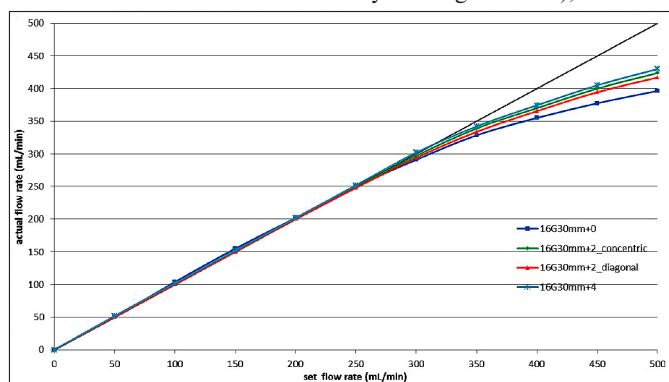
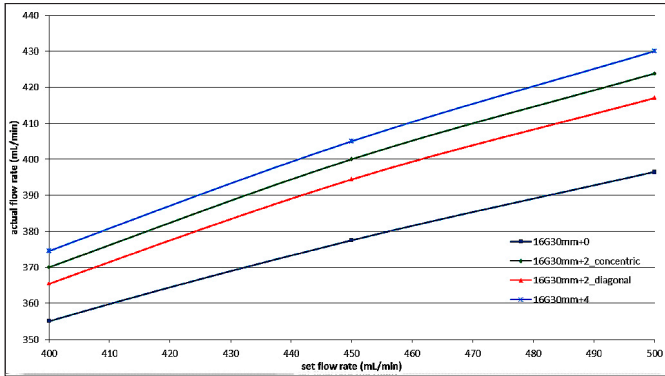


Fig. 5 Measurements of blood removal properties



**Fig. 6** Measurements of blood removal properties (enlarged from 400mL/min)

16G30mm+2\_diagonal needle (with two diagonally arranged holes). There were no significant differences (0.01 level) in the blood removal properties of the 16G30mm+0, 16G30mm+4, 16G30mm+2\_concentric, and 16G30mm+2\_diagonal needles when  $Q_0 \leq 250$  mL/min. However, significant differences (0.01 level) appeared at flow rates over  $Q_0 = 300$  mL/min. Beyond  $Q_0 = 400$  mL/min (**Fig. 6**), the achievable actual flow rate increased in order from 16G30mm+0, 16G30mm+2\_diagonal, 16G30mm+2\_concentric, and 16G30mm+4, but at  $Q_0 = 500$  mL/min, the highest achievable flow rate,  $Q$  was  $430.0 \pm 2.8$  mL/min in 16G30mm+4, compared to  $Q = 423.8 \pm 3.3$  mL/min (a difference of  $-1.4\%$ ) in 16G30mm+2\_concentric, and  $Q = 417.0 \pm 4.1$  mL/min (a difference of  $-3.0\%$ ) in 16G30mm+2\_diagonal. These small differences demonstrate that the actual flow rate achieved with two side holes was very close to the actual flow rate with four side holes.

### 3-2. Measurements of pressure distributions of modified indwelling needles

Pressure distribution measurements in the tips of the commercial 16G30mm+4 needle and the 16G30mm+2\_concentric and 16G30mm+2\_diagonal needles are shown **Fig. 7, 8, 9**. The results for 16G30mm+4 (**Fig. 7**) show that at each set flow rate, the negative

pressure increased steadily from the needle tip (0 mm) towards the root (30 mm), whereas at the tip hole (0 mm), the negative pressure was only  $-0.5$  mmHg, almost zero.

The results for 16G30mm+2\_concentric (**Fig. 8**) show that the negative pressure increased steadily from the needle tip (0 mm) towards the root (30 mm), following the same pattern as for 16G30mm+4. However, at  $Q_0 = 500$  mL/min, the negative pressure at

the tip hole (0 mm) was  $-12.6$  mmHg, rather than zero, as seen in 16G30mm+4. A similar result was seen in 16G30mm+2\_diagonal (**Fig. 9**). In 16G30mm+2\_concentric, the negative pressure at the side hole 3.3 mm from the tip hole was the same as at the 5 mm point. In 16G30mm+2\_diagonal, the negative pressure at the first side hole 3.3 mm from the tip hole was much lower than at 5 mm and was close to the value at the tip hole (0 mm). In contrast, the negative pressure at the second side hole 4.6 mm from the tip was greater than at 5 mm, and about the same as the value at 10 mm. The second side hole therefore accounted for a greater proportion of blood removal in 16G30mm+2\_diagonal than in 16G30mm+2\_concentric.

## 4. Discussion

The results in **Fig. 5** show that the actual flow rates achieved in the 16G30mm+2\_concentric and 16G30mm+2\_diagonal needles with two side holes were very similar to that of the commercial 16G30mm+4 needle with four side holes. We attribute this to the fact that the suction pressure at the tip hole in 16G30mm+4 was almost zero (**Fig. 7**), whereas the suction pressure at the tip hole in 16G30mm+2\_concentric and 16G30mm+2\_diagonal (**Fig. 8, 9**) was  $-13$

mmHg to -14 mmHg at  $Q_0=500$  mL/min, demonstrating that the tip hole in these needles also contributed to suction. A pressure level of almost zero means that there was almost no suction from the tip hole. The tip hole has the largest opening area, but despite having four side holes, 16G30mm+4 had substantially no suction from the tip hole and was only able to achieve the same actual flow rate as the 16G30mm+2\_concentric and 16G30mm+2\_diagonal, both of which have two side holes and a functioning tip hole. Side holes in indwelling needles are effective during dialysis when blood circulation is impeded in the arterial circuit by vessel walls and valves, and they are also effective in removing blood in the venous circuit<sup>7)</sup>. However, side holes have also been found to greatly increase resistance in arterial circuits during blood removal<sup>7)</sup>, and it is suggested that this might result from blood flowing from the side holes colliding with blood flowing from near the needle tip and creating turbulence inside the needle. Providing side holes to increase the opening area in the indwelling needle as a whole is an effective way of increasing the actual flow rate, but from the results of the present study, it is clear that simply increasing the number of side holes without taking account of interior flow in the region of the needle tip will not lead to efficient functioning. The results of the present study were obtained with water, which has a lower viscosity  $\eta$  than normal blood, and it

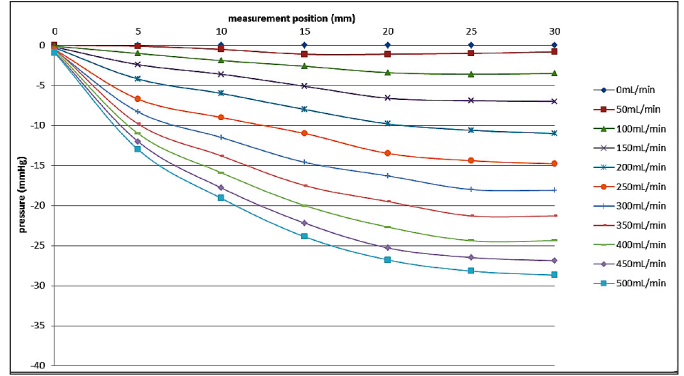


Fig. 7 Pressure distribution inside needle (16G30mm+4)

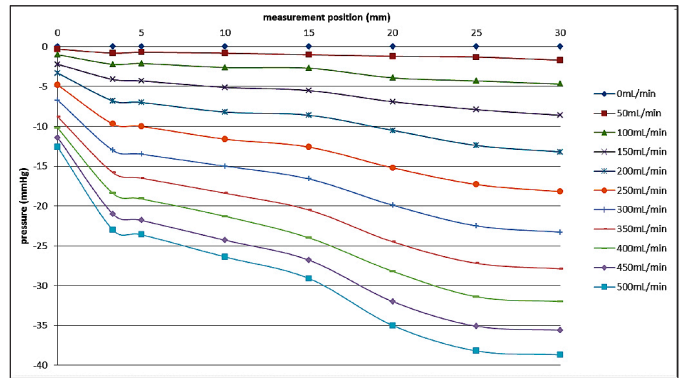


Fig. 8 Pressure distribution inside needle (16G30mm+2\_concentric)

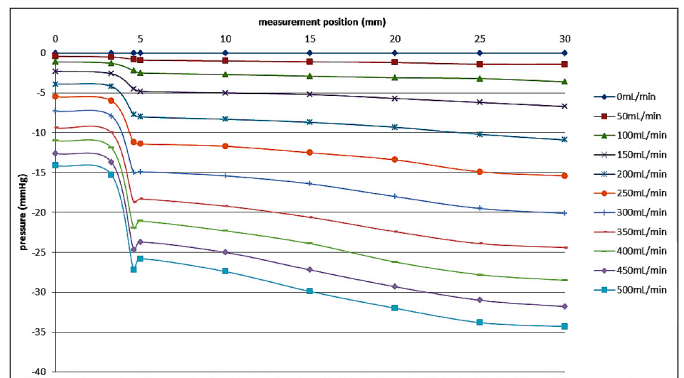


Fig. 9 Pressure distribution inside needle (16G30mm+2\_diagonal)

is therefore possible that different results would be obtained with a solution with the viscosity of blood.

## 5. Conclusions

The provision of side holes is effective in overcoming the problems of the decrease in ac-

tual flow rate and the excessive negative pressure that occur in smaller gauge indwelling needles. This study showed that blood removal from the tip of an indwelling needle with four side holes was actually impeded by the provision of these side holes, and, consequently, the same actual flow rate could be achieved in an indwelling needle with two side holes. This suggests that even higher actual flow rates could be achieved simply by suitably arranging the holes in a needle with four side holes. Furthermore, the optimum arrangement of side holes will also be an important element in the design of even finer 17G and 18G indwelling needles, which exhibit an even greater discrepancy between set and actual flow rates.

## References

- 1) T.Shoji, C.Hagiwara A.Saito, T.Maeba, T.Kakuta (2005) : Shunt maintenance and puncture technique, pp.92–94, MEDICUS SHUPPAN
- 2) S.Osawa, H.Yamamoto, T.Saito, Y.Kohan, S.Kushima (2004) : Study of penetration force of dialysis fistula needle (AVF needle), Kidney and dialysis, Separate volume Access 2004 , pp112–117
- 3) The Japanese Society for Dialysis Therapy (2011) : Guidelines of Vascular Access Construction and Repair for Chronic Hemodialysis, Journal of The Japanese Society for Dialysis Therapy, 44(9), pp855–937
- 4) St. Jude Medical Japan (2013) : Package insert of SJM Pressurewire Certus, pp1–3
- 5) N.Tanaka, N.Endo, H.Tanaka, D.Chikamori, T.Hida, Y.Kohori (2007) : FFR Practical Guide, pp2–49, Nakayama Shoten
- 6) S.Yamauchi, Y.Motohashi, T.Sato, T.Agishi (2016) : Measurement of pressure distribution inside the dialysis indwelling needle by using guide-wire fitted with a pressure sensor, Journal of Therapeutic & Engineering, 28(1) (It will be published)
- 7) H.Inagaki, T.Hamazaki, H.Kuroda, S.Yano, T.Ohashi (1991) : Characteristics of commercially available and newly developed needles for hemodialysis, Journal of The Japanese Society for Dialysis Therapy, 24(8), pp1161–1165