

A short bevel needle with a very thin tip improves vein puncture performance of peripheral intravenous catheters: An experimental study

The Journal of Vascular Access 2020, Vol. 21(6) 969–976 © The Author(s) 2020 Article reuse guidelines: sagepub.com/journals-permissions DOI: 10.1177/1129729820920108 journals.sagepub.com/home/jya



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Abstract

Background: Peripheral intravenous catheter placement is frequently unsuccessful at the first attempt. One suggested risk factor is a small vein size, because of the consequences of mechanical forces generated by the needle tip. We developed short bevel needles with a very thin tip and evaluated their puncture performance in two in vitro models.

Methods: Peripheral intravenous catheters with a new needle ground using the lancet method (experimental catheter (L)) or backcut method (experimental catheter (B)) were compared with a conventional peripheral intravenous catheter (Surshield Surflo[®]) in a penetration force test and a tube puncture test. Penetration forces were measured when peripheral intravenous catheters penetrated a polyethylene sheet. The tube puncture test was used to evaluate whether the peripheral intravenous catheters could puncture a polyvinyl chloride tube at two positions, at the center and at 0.5 mm from the center of the tube.

Results: Mean penetration forces at the needle tip produced by experimental catheters (L) (0.05 N) and (B) (0.04 N) were significantly lower than those produced by the conventional catheter (0.09 N) (p < 0.01). At the catheter tip, mean forces produced by experimental catheter (B) and the conventional catheter were 0.16 N and 0.26 N, respectively (p < 0.05). In the tube puncture test, the frequency at which the conventional catheter punctured the center-shifted site on the tube at an angle of 20° and speed of 50 mm/min was low (40%). In contrast, experimental catheters (L) and (B) were 100% successful at puncturing both the center and center-shifted sites at 20°.

Conclusion: Puncture performance was comparable between the lancet-ground and backcut-ground needles except for penetration forces at the catheter tip. The experimental catheters produced lower penetration forces and induced puncture without target displacement at smaller angles compared with the conventional catheter. Therefore, optimization of the needle can prevent vein deformation and movement, which may increase the first-attempt success rate.

Keywords

Backcut, double-wall puncture, first-attempt success rate, lancet, needle, penetration force, peripheral intravenous catheter, short bevel, small vein

Date received: 19 December 2019; accepted: 3 March 2020

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Introduction

Peripheral intravenous cannulation is a common procedure in clinical settings.^{1,2} Up to 70% of hospitalized adult patients require catheterization.³ However, this procedure is not easy, and many peripheral intravenous catheterizations are unsuccessful, with the first-attempt success rate being as low as 50%^{4,5} This can delay the initiation of prescribed therapy, but more importantly, it can be painful, uncomfortable, and stressful for patients because of the need for multiple attempts.⁶ In addition, multiple attempts to cannulate a peripheral vein are associated with adverse events such as nerve damage, paresthesia, hematoma, and arterial puncture.⁷ Moreover, repeated failures require increased time and additional medical equipment for correction. In fact, difficult venous access is estimated to cost the US health care system US\$4.7 billion annually.⁸ Accordingly, methods that can improve the first-attempt success rate are required from patient satisfaction, safety, and economic perspectives.

Various factors can affect peripheral intravenous cannulation. One risk factor of unsuccessful cannulation is small vein size.^{6,7,9–12} Multiple attempts are common in pediatric and elderly patients with small veins.¹³ In such cases, the trained clinician makes subtle adjustments to the needle insertion speed, angle, or orientation to avoid placement errors.¹⁴ Because this needle-steering process requires complex skills and clinical experience, ultrasound guidance has been proposed to improve peripheral intravenous catheter (PIVC) placement success rates in patients with difficult venous access.^{15–17} However, cannulation into smaller veins remains difficult even with the use of ultrasound-guided cannulation. In an observational study using ultrasound, the success rate was 56% (95% confidence interval (CI) = 40% to 71%) for a vein diameter < 0.3 cm and 92% (95% CI = 62% to 100%) for a diameter > 0.6 cm.¹⁰ Although this association between small vessel diameter and unsuccessful PIVC placement has not been explained, the needle insertion force can cause the target to collapse and move, resulting in placement error. Some studies using medical simulators have revealed that a soft tissue target is more likely to deform and displace during needle insertion.^{18,19} Therefore, attempts to insert a needle into a small vein can cause the vein to collapse or to move as a result of the needle insertion force, resulting in unsuccessful cannulation. This phenomenon suggests that a sharp needle may improve first-attempt success rates, given that minimizing the needle insertion force reduces deformation and displacement of the vein. Needle insertion force can be reduced with a smaller tip angle; however, a thin tip is typically used with longer bevel lengths. While a thin tip with a long bevel length generates lower insertion forces, complete insertion of the needle into the vein can be difficult. Needle design might therefore be optimized by the combination of both a thin tip and short bevel length, particularly in procedures for small vein access.

A previous study manufactured an 11-gauge (outer diameter: 3.0 mm) regular lancet needle with a very thin tip (bevel angle: 12°) and evaluated its initial peak insertion force using porcine liver tissue.²⁰ The force produced by the needle was 11% lower than that produced by a conventional needle. However, the needle cannot be used with intravenous catheters because its bevel is not sufficiently short and a gauge of 11 is too large. Furthermore, the study did not measure the needle's penetration forces. In the measurement of the insertion force, the bevel face did not fully penetrate the tissue; only part of the needle's cut edge made contact with the soft tissue. In addition, the needle design appears to include a spiny projection at the back of the bevel face, which can substantially increase the penetration force. Thus, intravenous catheters require a small-diameter needle tube and smooth bevel face, and penetration forces should be measured.

We developed short bevel needles with a very thin tip for patients with small veins that are prone to collapse or movement. The new needles are 24-gauge (outer diameter: 0.55 mm) needles without any projections on the bevel face. The aim of this study was to compare the venous puncture performance of PIVCs with and without the sharp needles in two in vitro models. In the first model, we measured penetration forces to evaluate the needle's ability to prevent vein collapse. In the second model, we evaluated the needle's ability to prevent target movement during PIVC placement.

Methods

PIVCs with and without the new needles were tested in two in vitro models to measure penetration forces and to evaluate target displacement. Because needles for vascular access are divided into two main groups, lancet-ground needles and backcut-ground needles, we developed two new needles according to these groups. Three types of PIVC were compared: a Surshield Surflo[®](Terumo Corporation, Tokyo, Japan) used as a control (conventional) catheter and two PIVCs in which the needle was replaced with a new short bevel needle with a very thin tip ground using the lancet method (experimental catheter (L)) or backcut method (experimental catheter (B)). All catheters were 22 gauge (length: 25 mm) and made of polyurethane and were identical except for the needle.

The study did not involve any living entity, and accordingly no ethical statement is required.

Needle design

Photographs of the needles and their sizes are shown in Figure 1. A needle for a PIVC is composed of a tip, an angled bevel, and a main needle tube. Needle tips for the conventional catheter and experimental catheter (L) were ground using the lancet method. The backcut method was used to produce the needle for experimental catheter (B),

Sample name	Geometric design of the needles	Grinding method	Bevel length, mm	Bevel angle, degrees
Conventional catheter	Bevel length Bevel angle	Lancet	2.0	30
Experimental catheter (L)	Bevel length Bevel angle	Lancet	2.0	20
Experimental catheter (B)	Bevel length Bevel angle	Backcut	2.0	20

Figure 1. Comparison of needle tip designs among experimental catheters (L) and (B) and the conventional catheter.

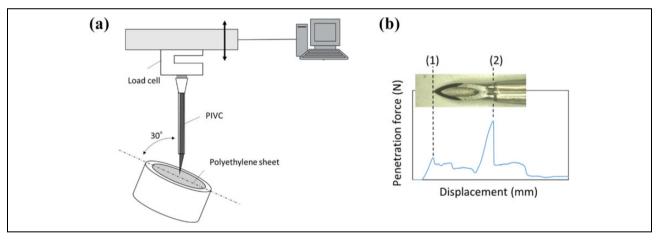


Figure 2. Measurement of penetration forces. (a) Schematic diagram of the experimental apparatus. (b) An example of a typical penetration force versus displacement graph. Peaks indicate penetration by the needle tip (1) and catheter tip (2).

which had an edge behind the bevel. The tips of the bevels of the needles on experimental catheters (L) and (B) were acutely angled (20°). Bevel length of both was equivalent to that of conventional needles. All needles had an outer diameter of 0.55 mm.

Penetration force test

Given that peripheral venous insertion is usually performed at a penetration angle of about 30° or less,²¹ penetration forces were measured when the PIVCs penetrated a polyethylene sheet (thickness 50 μ m) at 30° and a speed of 30 mm/min using a compression testing machine (EZ-SX; Shimadzu Corporation, Kyoto, Japan). The PIVCs and polyethylene sheet were attached to the machine (Figure 2), and real-time changes in penetration force were recorded from initiation of penetration at the tip of the needle until catheter penetration. Each group of PIVCs was allocated 10 experimental or conventional catheter samples, and each catheter was tested once. We

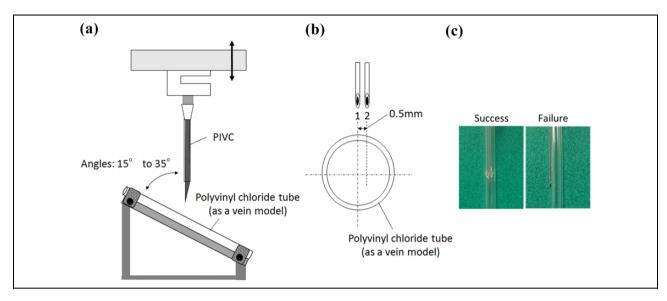


Figure 3. Measurement of target displacement. (a) Schematic diagram of the experimental apparatus. (b) Two puncture sites were tested: I, the center of the tube; 2, 0.5 mm from the center. (c) Criterion for successful cannulation into the tube.

measured the maximum load when the needle tip and catheter passed through the sheet.

Tube puncture test

The tube puncture test was used to evaluate whether the PIVC was capable of puncturing a polyvinyl chloride tube (as a vein model) at angles from 15° to 35° (at 5° increments) using a compression testing machine (AGS-1kNX; Shimadzu Corporation, Kyoto, Japan). Because insertion speed may be an important parameter during puncture, we set two puncture speeds, at 50 (slow) and 300 mm/min (fast). The PIVC and the tube were attached to the machine (Figure 3(a)). Both ends of the tube (outer diameter: 3.3 mm, inner diameter: 2.1 mm) were fixed at a distance of 90 mm. Needle puncture was tested at two sites on the tube, at the center of the tube and 0.5 mm from the center (Figure 3(b)). Each group of PIVCs was allocated 5 samples for each angle and position, and each catheter was tested once. We recorded the number of successful punctures of the tube without tube deflection (Figure 3(c)).

Data analysis

Statistical analyses were performed to determine differences in performance among experimental catheters (L) and (B) and the conventional catheter in the two in vitro models. Penetration force data were analyzed for statistical significance using the unpaired t-test. Values of p < 0.05were considered statistically significant. All statistical analyses were performed using SPSS, version 25 (IBM, New York, USA).

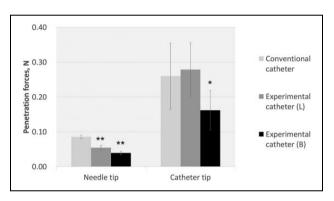


Figure 4. Experimental measured average and standard deviation of peak loads at the needle tip and catheter tip when penetrating the polyethylene sheet (N = 10; *p < 0.05, **p < 0.01, statistically significant compared with the conventional catheter).

Results

Penetration forces

Figure 4 shows the mean penetration forces of the three catheter types. Penetration forces at the needle tip and catheter tip are shown. Mean penetration forces at the needle tip of the experimental catheters (L) and (B) were significantly lower (0.05 N and 0.04 N, respectively) (p < 0.01) than that of the conventional catheter (0.09 N). The point of maximum load was at the catheter tip for all catheters tested. At the catheter tip, mean forces produced by experimental catheter (B) and the conventional catheter were 0.16 N and 0.26 N, respectively (p < 0.05).

Tube puncture performance

Table 1 shows success rates in the tube puncture test. When the puncture site was at the center of the tube, experimental

	Conventional catheter, n (%)		Experimental catheter (L), n (%)		Experimental catheter (B), n (%)	
Speed (mm/min)	Slow 50	Fast 300	Slow 50	Fast 300	Slow 50	Fast 300
(a) Center of the tube	2.					
۲ 15 °	3/5 (60%)	5/5 (100%)	5/5 (100%)	5/5 (100%)	0/5 (0%)	0/5 (0%)
20 °	5/5 (100%)	5/5 (100%)	5/5 (100%)	5/5 (100%)	5/5 (100%)	5/5 (100%)
25°	5/5 (100%)	5/5 (100%)	5/5 (100%)	5/5 (100%)	5/5 (100%)	5/5 (100%)
30 °	5/5 (100%)	5/5 (100%)	5/5 (100%)	5/5 (100%)	5/5 (100%)	5/5 (100%)
35°	5/5 (100%)	5/5 (100%)	5/5 (100%)	5/5 (100%)	5/5 (100%)	5/5 (100%)
(b) 0.5 mm from the	center.	. ,	, , ,	. ,	. ,	, ,
۲. 15°	0/5 (0%)	1/5 (20%)	3/5 (60%)	4/5 (80%)	0/5 (0%)	0/5 (0%)
20 °	2/5 (40%)	3/5 (60%)	5/5 (100%)	5/5 (100%)	5/5 (100%)	5/5 (100%)
25°	3/5 (60%)	5/5 (100%)	5/5 (100%)	5/5 (100%)	5/5 (100%)	5/5 (100%)
30°	4/5 (80%)	5/5 (100%)	5/5 (100%)	5/5 (100%)	5/5 (100%)	5/5 (100%)
35°	5/5 (100%)	5/5 (100%)	5/5 (100%)	5/5 (100%)	5/5 (100%)	5/5 (100%)

Table I. Success rates in the tube puncture test: (a) puncture site at the center of the tube diameter and (b) puncture site at 0.5 mm from the center of the tube diameter.

Shading in the tables indicates < 100% success rate.

catheter (B) and the conventional catheter succeeded at puncturing the tube at angles of 20° and greater. At angles of 15° and greater, in contrast, only the experimental catheter (L) successfully punctured the tube at both slow (50 mm/min) and fast puncture speeds (300 mm/min). When the puncture site was 0.5 mm from the center, the minimum angle at which puncture was successful for all catheters in each group (100%, 5/5) at the speed of 50 mm/min was 20° , 20° , and 35° for experimental catheters (L) and (B) and the conventional catheter, respectively. Respective values at the speed of 300 mm/min were 20° , 20° , and 25° .

Discussion

This is the first study to manufacture short bevel needles with a very thin tip for PIVCs and evaluate their vein puncture performance. We made two types of needle, the first one ground using the lancet method (L) and the second one ground using the backcut method (B), and compared the puncture performance of PIVCs with the new needles in two in vitro models. Penetration forces at the needle tip of experimental catheters (L) and (B) were significantly lower than those of the control. Penetration forces at the catheter tip of experimental catheter (B) were also significantly lower than those of the control. While tube puncture performance among the three catheter types was closely similar when the puncture site was at the center of the tube, the results differed when the site was shifted 0.5 mm from the center; in these cases, both experimental catheters (L) and (B) successfully punctured the tube at a similarly small angle to that at which they were successful at the center site.

The new needles had a very thin tip with a bevel angle of 20° , which can contribute to reducing penetration forces at the needle tip. Needles used in clinical settings are

divided into two main groups, those with a regular bevel and those with a short bevel. The regular bevel needle has a small bevel angle (approximately 20°) and generates lower penetration forces but is associated with increased risk of inadvertent tissue trauma due to its long bevel length. In contrast, the short bevel needle is associated with decreased risk of inadvertent tissue trauma but generates higher penetration forces due to its large bevel angle (typically over 30°). Generally, short bevel needles are used for vascular access so that the whole bevel length is easily inserted into the vein. Therefore, penetration forces generated by short bevel needles are relatively large compared with those produced by regular bevel needles. The needles we developed had a short bevel and a small bevel angle of 20° and therefore possessed the merits of regular bevel and short bevel needles, including reduced penetration forces and possible risk of inadvertent tissue trauma. Although manufacturing a bevel angle smaller than 20° was technically possible, we designed the angle to match that of a regular bevel. A bevel angle that is too small has a risk of bending when puncturing patients with hard skin. Thus, 20° may be both a minimum and an appropriate angle for intravascular needles. In addition, we found that penetration forces at the catheter tip of experimental catheter (B) were significantly lower than those of the conventional catheter. A previous study that compared the shapes and sizes of holes created by needle punctures on a polyethylene film between lancet-ground needles and backcutground needles showed that the backcut-ground needle created a Y-shaped hole and that this triangular area was larger than holes created by the lancet-ground needle.²¹ The needle of experimental catheter (B) was ground using the backcut method, suggesting that the Y-shaped hole generated during puncture may have allowed for smooth insertion of the catheter tip. The standard deviation of forces at the catheter tip was relatively large compared

with that at the needle tip. This may be because the processing precision to form a catheter tip is lower than that for needle tips. Differences in variability in the dimensions of catheter tips would have affected the magnitude of the standard deviation. Given this result, the test method used in this study appears to be appropriate for clarifying differences in the geometry of needles with high sensitivity. In addition, a considerably slower speed is needed to detect small changes in resistance forces produced by a needle. Indeed, our company (Terumo Corporation) has used a speed of 30 mm/min in its quality control of manufactured needles for more than 20 years and considers it suitable for the detection of minor changes in needles.

Experimental catheters (L) and (B) and the conventional catheter successfully punctured the tube at insertion angles of 20° and greater at the center site. In contrast, when the insertion site was shifted 0.5 mm from the center of the tube, the experimental catheters (L) and (B) were equally able to penetrate the tube at similarly small angles (from 20°), whereas the conventional catheter did so less frequently (50 mm/min: 40%, 300 mm/min: 60%). This is because the low penetration forces of the new needle tip can contribute to preventing target displacement. In clinical settings, a needle needs to be able to successfully puncture a vein even if the insertion point is off-center because it can be difficult for health-care professionals to accurately puncture the very center of the vein. Given that the curvature (1/r) of a vein decreases as the radius (r) decreases, small veins may be particularly difficult to puncture because they are more prone to movement. Therefore, preventing target displacement can be effective for increasing the success rate of inserting PIVC into small veins. Experimental catheter (L) successfully punctured the tube at the minimum angle (15°) only at the center site. The low penetration forces induced by the sharp tip and grinding methods contributed to these results. A lancetground needle can pierce a target at smaller angles because the cutting edge is located laterally on the needle compared with backcut-ground needles. The slower the test speed, the lower the success rate of the conventional catheter tended to be. When puncture speed is slow, the tube might be moved aside by the needle before the needle successfully punctures it. The experimental catheters can be particularly helpful for patients who require a deliberate puncture speed, such as those with small and fragile veins. A previous study showed that needle velocity during PIVC operations is typically around 2 \pm 1 mm/sec (120 + 60 mm/min).²² Although test results will change with changes in puncture speed, our results likely reflect actual success rates given that the test speeds we used (50 and 300 mm/min) cover a wide range of insertion speeds (120 \pm 60 mm/min).

The two types of needles manufactured in this study had comparable puncture performance. One major difference between them was that catheter (L) produced greater penetration forces at the catheter tip. Thus, the merits of experimental catheter (L) versus (B) may vary in accordance with clinician preference. Some health-care professionals may prefer to use experimental catheter (B) because high penetration forces at a catheter tip may prevent a smooth insertion procedure. In contrast, others who use the force as a sign of successful cannulation into the vein may prefer experimental catheter (L). User preference should be confirmed before using a needle in clinical settings.

The short bevel needle with a very thin tip developed in this study may contribute to improving the first-puncture success rate for patients with small veins. The success of PIVC may strongly depend on not only the vein itself but also on the accuracy of percutaneous insertion. Accuracy can be impaired by the movement of tissue, including the skin, and needle deflection before the vein is reached. The success of PIVC might critically depend on needles which create a lower insertion force and smaller tissue movement or needle deflection. In addition, the needle may prevent complications associated with needle puncture. Doublewall puncture caused by the unintentional passing of a needle through both walls of a vein is associated with complications such as hematoma and inadvertent puncture of an artery.^{23,24} This sharp needle can prevent double-wall puncture because the lower insertion forces can lead to a more patent vessel lumen during insertion. Therefore, the needle may also be effective for patients with low blood pressure and hypovolemic veins because these veins are less likely to be patent. Furthermore, a study showed that a lower penetration force can lead to less pain in patients.²⁵ An animal study revealed that the level of pain was correlated with the force required for a needle to penetrate the skin.²⁶ Therefore, this new needle may reduce pain experienced by patients.

This study, which used two in vitro models, suggests that PIVC with a short bevel needle and very thin tip may be useful for intravenous cannulation. While the results of the penetration force test may not be directly translatable to humans, polyethylene is a commonly used and accepted substitute material for human skin and veins in evaluating puncture performance in intravascular catheter research.²⁷ In addition, the minimum angle for successful insertion may not be 15° or 20° in humans as it was in our study; however, the magnitude of the angle is expected to be similar. Nevertheless, further studies are needed to examine the efficacy of these needles in clinical settings.

Conclusion

It is clear from this study that penetration forces and target displacement generated during PIVC placement differ according to needle tip configuration. A PIVC with a short bevel needle with a very thin tip produced significantly lower resistance forces at the needle tip and achieved successful puncture at smaller angles than a conventional catheter, even when the insertion site was off-center. Puncture performance was comparable between lancet-ground and backcut-ground needles except for penetration forces at the catheter tip. Our results suggest that this new needle may be effective in improving first-puncture success rates in patients with small veins by preventing vein collapse and movement. Further studies are required to demonstrate the effectiveness of this needle in clinical settings.

Declaration of conflicting interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Hidenori Tanabe, Manami Kawasaki, Takehiko Ueda, Takayuki Yokota, and Yasunobu Zushi are employees of Terumo Corporation. Ryoko Murayama and Mari Abe-Doi are employees of a laboratory supported by Terumo Corporation.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This study was a joint research venture between Terumo Corporation and The University of Tokyo and was funded by Terumo Corporation.

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