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REPORTS OF ORIGINAL INVESTIGATIONS

Less leakage and dislodgement with a catheter-over-needle *versus* a catheter-through-needle approach for peripheral nerve block: an *ex vivo* study

Moins de fuites et de déplacements avec un cathéter par-dessus l'aiguille qu'avec un cathéter à travers l'aiguille pour un bloc nerveux périphérique: une étude *ex vivo*

Ban C. H. Tsui, MD · Jenkin Tsui

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Abstract

Purpose *The objective of this study was to compare the catheter-through-needle (CTN) and catheter-over-needle (CON) catheterization techniques ex vivo by measuring leak pressure around the catheter and the catheter's resistance to pulling force.*

Methods *Using an ex vivo porcine limb model, we compared the conventional CTN design with the CON design with respect to the ability to resist leakage at the catheter insertion site under high injection pressure and the force required to withdraw the catheter from tissue. One CON assembly (MultiSet, Pajunk) and three CTN assemblies (Contiplex, B.Braun; StimuCath, Arrow; Stimulong Sono, Pajunk) were studied. Ten porcine hind limbs were used to test leakage and another ten were used to measure withdrawal force. Catheters were placed at angles of 15° and 30° at depths of 3 cm and 5 cm. Leakage was assessed visually at the insertion site, and pressure was measured at the moment leakage occurred. Withdrawal force was measured by pulling the catheter from the tissue.*

Results *No evidence of leakage was detected at the CON catheter insertion site at the highest pressure applied (1,000 mmHg) (n = 40). The CON assembly withstood significantly higher injection pressure than the CTN catheters without causing leaks at the catheter insertion site [CON, mean (standard deviation) > 1,000 (0) mmHg; B.Braun, 596 (92) mmHg; Pajunk Stimulong, 615 (107) mmHg; and Arrow, 422 (104) mmHg; P < 0.001 CON vs CTN]. The force required to withdraw the catheter from the porcine limb was greater with CON catheters [3.8 (0.8) N] than with any of the CTN catheters [range, 0.4 (0.2) - 0.8 (0.2) N], depending on depth, angle, and manufacturer (P < 0.001 CON vs CTN).*

Conclusion *In the porcine leg model, CON catheterization provides greater resistance to leakage under high injection pressure and greater holding force in tissue than traditional CTN catheters.*

Résumé

Objectif *L'objectif de cette étude était de comparer deux techniques de cathétérisme ex vivo (cathéter à travers l'aiguille [CTN]et cathéter par-dessus l'aiguille [CON]) en mesurant la pression de fuite autour du cathéter et la résistance du cathéter à une force de traction.*

Méthodes *Nous avons comparé à l'aide d'un modèle ex vivo de patte de porc, le concept conventionnel CTN avec le concept CON pour ce qui concerne leur capacité à résister à des fuites au niveau du site d'insertion du cathéter sous une forte pression d'injection et la force nécessaire pour retirer le cathéter du tissu. Un montage CON (MultiSet, Pajunk) et trois montages CTN (Contiplex, B.Braun; StimuCath, Arrow; Stimulong Sono, Pajunk) ont été étudiés. Dix membres postérieurs de porcins ont été utilisés pour tester les fuites et dix autres ont été utilisés pour mesurer la force de retrait. Les cathéters ont été placés à des angles de 15° et 30° et à des profondeurs de*

Author contributions *Ban C.H. Tsui* and *Jenkin Tsui* were involved in the conception and design of this study. They participated in the acquisition, analysis, and interpretation of data as well as the drafting and critical revision of the article for important intellectual content.

B. C. H. Tsui, MD (✉) · J. Tsui
Department of Anesthesiology and Pain Medicine, University of Alberta, 8-120 Clinical Sciences Building, Edmonton, AB T6G 2G3, Canada
e-mail: btsui@ualberta.ca

3 cm et 5 cm. Les fuites ont été évaluées visuellement au site d'insertion et la pression a été mesurée au moment de survenue de la fuite. La force de retrait a été mesurée en tirant le cathéter hors des tissus.

Résultats *Aucun signe de fuite n'a été détecté au site d'insertion du cathéter CON, à la plus forte pression appliquée (1000 mmHg) (n = 40). Le montage CON a supporté une pression d'injection significativement plus forte que les cathéters CTN sans provoquer de fuites au site d'insertion du cathéter (CON, moyenne [écart-type] > 1000 [0] mmHg; B.Braun, 596 [92] mmHg; Pajunk Stimulong, 615 [107] mmHg; et Arrow, 422 [104] mmHg; P < 0,001 CON contre CTN). La force requise pour retirer le cathéter du membre de porc a été plus importante pour les cathéters CON (3,8 [0,8] N), que pour n'importe lequel des cathéters CTN (valeurs de 0,4 [0,2] à 0,8 [0,2] N) en fonction de la profondeur, de l'angle et du fabricant (P < 0,001 CON contre CTN).*

Conclusion *Dans le modèle de membre porcin, le cathétérisme de type CON procure une plus grande résistance à la fuite sous une forte pression d'injection et une plus grande force de maintien dans les tissus que les cathéters traditionnels CTN.*

Continuous catheter regional anesthesia has been used successfully at a number of block sites[1] and provides effective pain relief with reduced incidence of side effects and an improved quality of life.[2,3] Accurate catheter placement is a major determinant of successful continuous peripheral nerve block (PNB), and incorrect positioning of catheters occurs in up to 40% of cases,[4,5] leading to an alarmingly high rate of secondary block failure. The recent introduction of stimulating catheters[6,7] and ultrasound[8,9] has improved the accuracy of catheter positioning; however, catheter dislodgement and leakage at the insertion site remain well-recognized but largely unresolved problems. Leakage from the catheter insertion site[10] presents a possibility of catheter dislodgement due to the loss of adhesion of material used to hold the catheter in place.

The design of typical catheter-through-needle (CTN) assemblies, in which a flexible microcatheter is threaded through a larger diameter needle, may be prone to leakage and dislodgement at the catheter insertion site. Various methods have been used in an attempt to overcome problems associated with CTN catheterization, including the application of adhesive glue[11,12] and tunnelling the catheter under the skin,[6] but these methods have drawbacks, including additional cumbersome steps and potential patient discomfort. We hypothesized that an alternative catheter-over-needle (CON) design, in which the catheter diameter is larger than that of the needle puncture hole, would be a potential solution to the problems of leakage and dislodgement. The objective of this study was to use an *ex vivo* porcine hind limb model to assess CON and CTN catheters for resistance to leakage under high injection pressure and to measure the holding force exerted by the surrounding tissue on these catheters.

Methods

Materials

Twenty *ex vivo* porcine hind limbs were acquired from a local abattoir. The limbs were freshly butchered and stored at room temperature for four hours to obtain a uniform tissue temperature prior to experimental use. The porcine limbs were maintained at room temperature during each experiment.

Three commonly used CTN assemblies were selected: an 18G Tuohy needle/20G StimuCath catheter assembly (Arrow International, Markham, ON, Canada); a Contiplex 18G Tuohy needle/20G catheter assembly (B.Braun, Melsungen, Germany); and an 18G Tuohy needle/20G Stimulong Sono catheter assembly (Pajunk, Geisingen, Germany). A Pajunk MultiSet assembly (Geisingen, Germany) featuring an 18G catheter over a 21G needle was selected to represent the CON group. The physical characteristics of these catheters are summarized in the Table.

A hand-held digital force gauge meter (Digital Force Gauge HF-50, Shanghai, China) with a resolution 0.01 Newtons (N) and an accuracy of ± 0.5% was utilized to record peak tensile and compression measurements. Needle and catheter outer diameters (mm) were measured using an electronic caliper with digital display, a resolution of

Table Physical characteristics of catheters used to assess leakage and holding force

Catheter assembly	Catheter Size	Outer diameter (needle) (mm)	Outer diameter (catheter) (mm)	Catheter material	Tip shape	Location of ports	Tubing connection
B.Braun Contiplex (CTN)	20G	1.37	0.81	Polyamide	Closed	Lateral	Clamp style
Pajunk Stimulong Sono (CTN)	20G	1.39	0.81	Polyamide (wire-reinforced)	Open	End	Clamp style
Arrow StimuCath (CTN)	20G	1.35	0.80	Polyurethane (wire-reinforced)	Open	End	Clamp style
Pajunk MultiSet (CON)	18G	0.93	1.26	Fluorinated ethylene propylene	Open	End	Luer-lock

CTN = catheter-through-needle; CON = catheter-over-needle

0.01 mm, and an accuracy of 0.02 mm (Mastercraft, Toronto, ON, Canada).

Methodology

Two features of the CON and CTN catheter designs were measured: 1) resistance to leakage at the catheter insertion site from high injection pressure; and 2) holding force exerted by surrounding tissue. A set of measurements of leakage under high pressure injection was performed for each of the first ten porcine limb samples with sixteen needle/catheter insertions per limb. One CON and three CTN assemblies were inserted at 15° and 30° relative to the porcine skin at depths of 3 cm and 5 cm; each insertion was done in a fresh area (i.e., at least 1 cm away from the previous insertion) of the limb. Thus, insertions of 3 cm/15°, 5 cm/15°, 3 cm/30°, and 5 cm/30° were performed for each catheter assembly in each of the ten limb samples (i.e., 160 separate experiments to test leakage). After removing the needle, we used a normal saline infusion at a rate of 5 $mL\cdot min^{-1}$ to generate high pressure injection, and fluid pressure in the catheter was monitored. The infusion was continued until the first drops of fluid appeared on the surface of the pig skin at the catheter insertion site or until injection pressure reached 1,000 mmHg. Resistance to leakage was assessed by recording the injection fluid pressure value at this time—note: the maximum value of the instrument used to monitor fluid pressure was 1,000 mmHg. Ten individual infusions were performed for each catheter assembly. A schematic drawing of how leakage occurs with CTN catheters is shown in Fig. 1A, and the setup for the leakage experiment is shown in Fig. 1B.

Measurement of the holding force exerted by the surrounding tissue was performed using the other ten porcine limb samples. As before, insertions of each needle/catheter assembly were performed at 15° and 30° relative to the porcine skin at depths of 3 cm and 5 cm in each limb (i.e., 160 separate experiments to test holding force). We measured the force required to withdraw the catheter from the tissue (in Newtons) using a hand-held force gauge (i.e., the holding force that the skin exerted on the catheter). A schematic drawing of how CON catheters are held in place by the surrounding skin is shown in Fig. 2A, and the setup for the withdrawal force experiment is shown in Fig. 2B.

Statistical analysis

Mean and standard deviation values were calculated in Microsoft Excel, and the SPSS program (IBM, Armonk, NY, USA) was used to perform a one-way analysis of variance test to compare means between the CON assembly and the three CTN assemblies for each data set (holding force and fluid pressure). Comparisons were performed between the CON and CTN groups and also within the CTN group. The Bonferroni *post hoc* test was performed to adjust for six comparisons, between the CON and CTN groups and within the CTN group. Statistical significance was determined as $P < 0.05$.

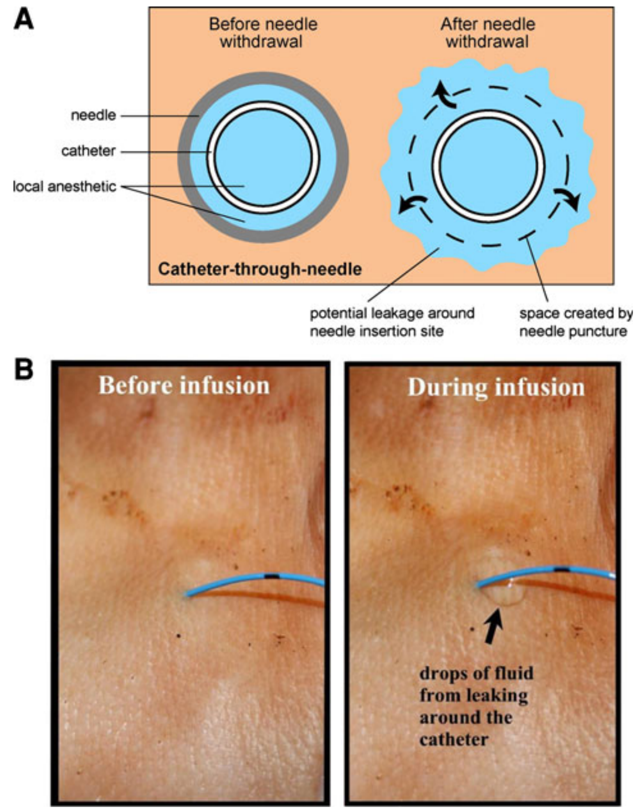


Fig. 1 (**A**) A possible mechanism to explain why the catheter-through-needle (CTN) design has a higher propensity for leakage from the catheter insertion site. The diameter of the needle puncture hole is larger than that of the catheter. (**B**) Experimental setup of fluid pressure measurement and leakage assessment using the Arrow CTN catheter. The catheter was inserted at a 15° angle relative to the skin surface at a depth of 3 cm, and a normal saline infusion at a rate of 5 $mL\cdot min^{-1}$ was connected to the catheter (*left panel*). Pressure values were recorded the moment saline leaked out from the catheter insertion site (*right panel*)

Results

As shown in Fig. 3, the CON assembly withstood significantly higher injection pressure than each of the CTN assemblies regardless of insertion angle or depth. During all trials, the CON catheter withstood injection pressures of > 1,000 mmHg, and we observed no evidence of leakage at CON catheter insertion sites. In contrast, we consistently observed leakage when infusing through the CTN catheters. Leakage occurred at pressures within an

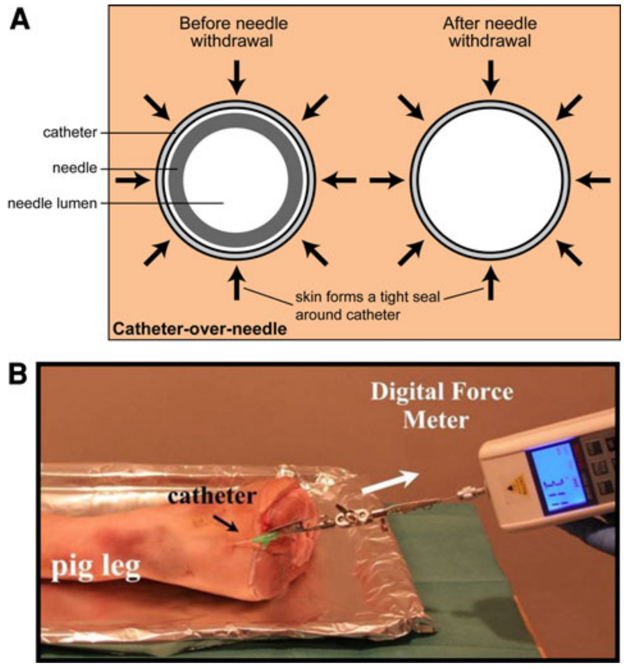


Fig. 2 (**A**) A possible mechanism to explain why the catheter-over-needle (CON) design has a lower propensity for dislodgement and leakage from the catheter insertion site. The catheter is held tightly by the surrounding skin (*arrows*) since the diameter of the catheter (light grey) is larger than that of the puncture hole left by the needle (dark grey). (**B**) Experimental setup of holding force measurement. The CON catheter was inserted at a 15° angle relative to the skin surface at a depth of 5 cm and connected to a digital force meter using alligator clips. The force required to extract the catheter from the skin was then recorded

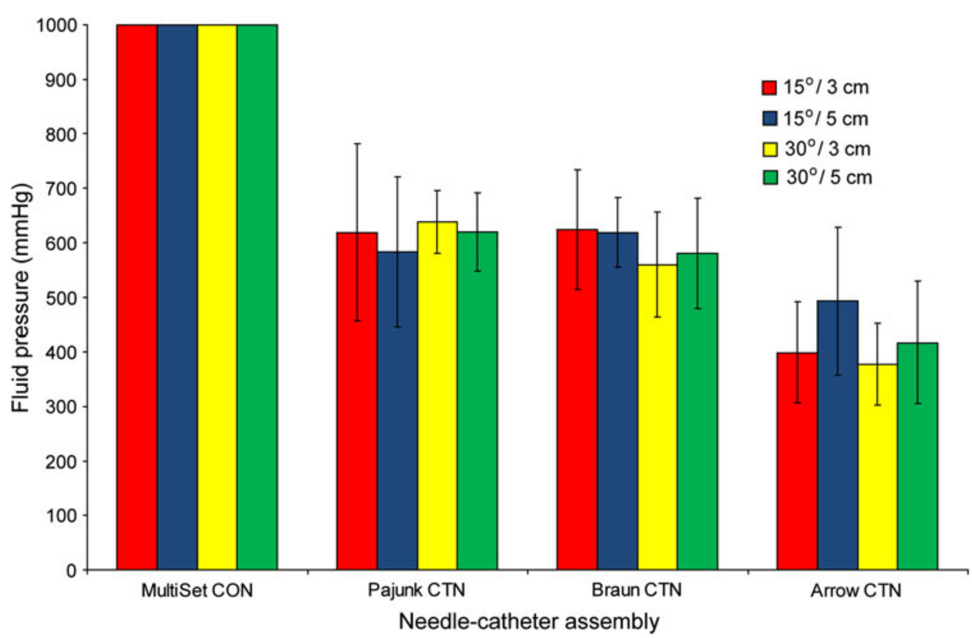
approximate range of 200-900 mmHg depending on the angle and depth of insertion and the catheter manufacturer.

Our results also show that the CON catheter is more resistant to withdrawal from tissue compared with the CTN catheters (Fig. 4). The mean force required to withdraw the CON catheter from the tissue (equivalent to the holding force exerted on the catheter by the surrounding tissue) was 3.9 (0.8) N, significantly higher than that of the Arrow [0.4 (0.2) N], B.Braun [0.5 (0.2) N], and Pajunk [0.8 (0.2) N] CTN catheters ($P < 0.001$ CON *vs* CTN). In general, it took approximately 6.5- sevenfold greater pulling force to withdraw the CON catheter from the tissue than to withdraw the CTN catheters.

Discussion

Our data clearly show that a CON catheter – represented here by the Pajunk MultiSet assembly – can withstand higher injection fluid pressure and is more resistant to withdrawal from the skin. These observations suggest that CON catheters can be more stable than CTN catheters and are less likely to be accidentally pulled out of the insertion site. These results have important implications for the delivery of local anesthetics during continuous PNB, since catheter stability is a major determinant of accurate catheter placement and efficient delivery of anesthetic solutions.

Fig. 3 Fluid injection pressure measurements (mmHg) for the catheter-over-needle (CON) and catheter-through-needle (CTN) catheters are shown at different insertion angles and depths ($P < 0.001$ CON *vs* CTN). Maximum pressure possible was 1,000 mmHg. Errors bars indicate standard deviation



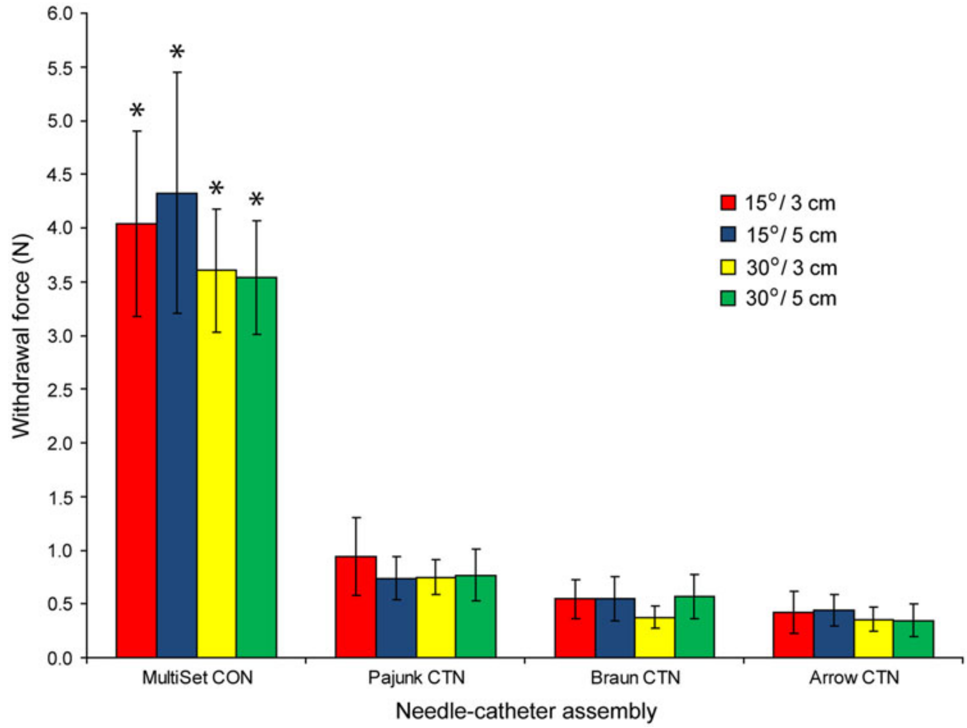


Fig. 4 Withdrawal force measurements (N) for the catheter-over-needle (CON) and catheter-through-needle (CTN) catheters are shown at different insertion angles and depths. Errors bars indicate standard deviation; asterisks (*) indicate $P < 0.001$ between the CON catheter and each of the CTN catheters

A CON catheter forms a tighter seal at the needle insertion site compared with CTN catheters, minimizing dislodgement and leakage. The diameter of the CTN catheter is smaller than the needle puncture hole, leaving it loose and susceptible to leakage around the insertion site (Fig. 1A). In contrast, the diameter of the CON catheter is larger than that of the needle, sealing the catheter in place and reducing the risk of leakage and dislodgement at the insertion site (Fig. 2A). As shown in Fig. 1, leakage is a recognized concern with the current continuous CTN technique. No leakage was observed when using the CON catheter, even at pressure levels of 1,000 mmHg, while leakage occurred during every single trial using the CTN catheters (Fig. 3). This result is important, as a recent study assessing thirty anesthesiologists' subjective evaluation of injection force showed that all participants injected fluid at pressures equivalent to or higher than 20 pounds per square inch or 1,034 mmHg,[13] suggesting that the incidence of leakage will likely be greater when using the CTN technique, particularly during bolus injection. With current CTN designs, leakage at the catheter insertion site is likely a result of the catheter diameter being smaller than the diameter of the puncture hole created by the needle. This is supported by electron microscopic observations showing that withdrawal of a CTN needle-catheter left a puncture hole with a smooth margin that remained open following removal of the catheter, whereas withdrawal of a CON needle-catheter left a smaller puncture hole with irregular margins that closed almost completely after withdrawal of the catheter.[14] The Spinocath system, which has a CON design, already takes advantage of this feature to minimize leakage of cerebrospinal fluid during continuous spinal anesthesia.[14] Together, these data suggest that the larger diameter of the CON catheter results in a more effective seal created by the surrounding skin, minimizing the chance of leakage at the insertion site.

Significantly, successful continuous PNB does not seem to be affected by the distance the catheter is threaded beyond the needle tip,[15-17] but catheters threaded a shorter distance (0-1 cm) tend to dislodge more frequently,[17] suggesting that a balance must be achieved between accurate catheter placement and catheter stability. Our results show that a more than sixfold greater holding force was exerted on CON catheters, which is a significant difference (Fig. 4). A greater holding force implies that CON catheters will be less likely to dislodge, particularly when the catheter is secured by only tape or adhesive. This is another direct result of the catheter diameter being larger than that of the needle puncture hole, whereby a tighter seal is created by the skin at the insertion site. Another common problem with CTN catheter placement is the physical inability to hold the catheter and maintain its position as the needle is being withdrawn. Conveniently, the CON design allows the clinician to hold the catheter directly in place while simultaneously withdrawing the needle. The fact that the skin at the insertion site holds CON catheters tightly also means that the clinician can withdraw the needle with one hand while ensuring that the catheter does not move forward or backward relative to the point where it enters the skin.

The four needle-catheter assemblies used here were chosen because they all produce the same diameter puncture hole in the skin. This feature allowed us to maintain some consistency throughout the experiments despite the MultiSet assembly possessing a catheter with a larger diameter than that of the three CTN catheters (Table). Furthermore, the ratio between the inner object (catheter in the case of CTN and needle in the case of CON) and the outer object is similar between the four assemblies. These features minimize the effect of the relative catheter sizes on insertion and percutaneous placement of the needle-catheter assemblies and amplify the effect of the underlying design properties on catheter stability and propensity for leakage. These aspects serve to show the advantage of the larger diameter of the CON catheter in helping reduce the incidence of leakage and dislodgement.

Our study has limitations. In particular, due to a maximum limit of 1,000 mmHg, our fluid pressure gauge did not allow us to measure injection pressures accurately when using the CON catheter. Another obvious limitation is our *ex vivo* experimental model. Significant differences exist between the physical properties of *ex vivo* porcine tissue and human tissue, which may limit our ability to extrapolate data for clinical situations. We also acknowledge that the experiments described here may not completely assess the true physical properties of the tissue into which the catheter is inserted. Rather than using tissue at a live body temperature of 37°, the porcine limb was maintained at room temperature. Due to the extended length of time required to perform multiple insertions, we found it more practical and consistent to keep the samples at room temperature. This method also avoids testing on and sacrificing a live animal. Regardless, it is our view that the data generated should provide us with valuable information, similar to other human cadaver studies that are generally performed with the tissue at room temperature.

The CON design is not a new concept, although it was not practical for continuous PNB until recently due to uncertainty regarding both the depth of target nerves and the accurate placement of CON catheters of fixed length. However, the use of ultrasound has made it possible to predict target distance and visualize the positioning of catheters in real time,[18,19] suggesting the feasibility of preselecting a CON catheter assembly of appropriate length in order to place the catheter tip in proximity to a target nerve with accuracy. In designing future clinical studies, other factors, such as the materials used to make the catheter, should also be considered since most CON catheters used in the past were known to kink easily. Most CON catheters, such as the one used in our study, are constructed from fluorinated ethylene propylene (Teflon) polymer. These catheters are stiff enough to allow smooth penetration through the skin, but they are more prone to kinking than most CTN catheters, which are made from more flexible and soft material. The Contiplex B.Braun and Pajunk Stimulong Sono catheters studied here are made from polyamide, while the Arrow catheter is made from polyurethane. Additionally, the StimuCath Arrow and Stimulong Sono catheters are reinforced with an internal helical coil. Thus, a new generation of CON smooth-tapered tip assemblies made from kink-free material may need to be developed for future clinical use.

In conclusion, it is our view that the data presented here serve as sufficient confirmation to suggest the superiority of the CON technique over the CTN technique with regard to catheter stability. This concept remains to be proven in humans, but our results represent a suitable starting point to assess the two methods in the clinical setting.

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Competing interests None declared.

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