Newly Designed, Self-Coiling Catheters for Regional Anesthesia—An Imaging Study

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Background and Objectives: A major concern with the use of continuous peripheral nerve block is the difficulty encountered in placing the catheters close enough to the nerves to accomplish effective analgesia. The aim of this study was to investigate if a self-coiling catheter would remain close to the sciatic nerve once introduced through needles placed under ultrasound guidance and if contrast dye injected through the pigtail catheter made direct contact to the nerves.

Methods: First, Tuohy needles were placed anterior to the sciatic nerves under ultrasound guidance (needle-in-plane/nerve in short-axis approach). Next, the self-coiling catheters were blindly introduced through the needles. A total of 40 catheters were placed; 2 per sciatic nerve in the right and left legs of 10 human cadavers. To detect the exact catheter location, computer tomographic imaging of the legs was performed. Finally, the spread of injected contrast dye in relation to the nerves was assessed by magnetic resonance imaging.

Results: There was direct contact of the coil with the nerve in 37 cases. In the remaining cases, the shortest distances from the coil to the nerves were 5, 6, and 7 mm. In all but 1 case, the contrast dye was directly in contact with the nerves. The median circumferential covering of the nerve by contrast dye was 50% (25-interquartile range of 40%).

Conclusions: By using self-coiling catheters, it is possible to blindly introduce the catheter through needles placed under ultrasound guidance with a low risk of catheter misplacement away from the targeted nerves.

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Orthopedic surgery of the lower limb is known to be painful, requiring safe and efficient postoperative analgesia. McGrath et al[1] reported that 40% of patients experienced moderate to severe pain (numeral rating pain score >3 of maximal 10) 24 hrs after surgery, despite a single-injection nerve block having been used. Routine use of both the perineural femoral or popliteal catheter techniques for orthopedic knee or foot surgery has made a significant advance in providing sustained analgesia while potentially minimizing the need for opioid analgesics throughout the postoperative course.[2–4] Continuous peripheral nerve blocks have become increasingly popular because they provide better pain relief than opioids and similar analgesia with fewer adverse effects than epidural block.[5] A major concern with the use of continuous peripheral nerve block is the placement of the catheter close enough to the nerve. This allows effective analgesia with small amounts of diluted local anesthetic solutions for the "secondary analgesic block" after the initial primary anesthetic block has resolved.

The advantage of ultrasound guidance to precisely place the needle adjacent to nerves is undisputed.[6–8] Block performance (success rate, number of unintentional vessel punctures, block placement time) can be improved by using ultrasound guidance for single-shot peripheral nerve blocks compared with nerve stimulator guidance. Similar results can be obtained for catheter placement with ultrasound.[9,10] Concerning the secondary block failure rates, however, the superiority of ultrasound guidance compared with the nerve stimulator guidance for catheter placement has not yet been demonstrated.[11] Despite having the possibility to visualize the needle, it remains difficult to track catheters with ultrasound, because catheters are frequently located distant from the initial needle-tip position. One explanation might be the catheter material; catheters are often stiff and designed to avoid kinking. This stiffness that should allow catheters to be advanced along the course of the nerves could be a disadvantage when the nerves are approached in a perpendicular plane.[4] When using ultrasound guidance, nerves are often visualized in short axis, while the needle is advanced in-plane and thus perpendicular to the nerve course. This method allows accurate placement of the needle tip, but has the immanent risk of potentially inaccurate catheter placement beyond the nerve. We therefore designed and developed an alternative catheter, which coils up as soon as it is advanced beyond the needle tip. This allows the catheter tip to remain close to the initial needle-tip position, even when a perpendicular approach to the nerve has been chosen.

With this imaging cadaver study, we tested our new catheter by focusing on 2 main questions:

(1) Does the blindly introduced, newly developed self-coiling catheter remain close to the sciatic nerve after the needle tip is placed directly behind the nerve using ultrasound guidance?
(2) Does the contrast dye injected through the catheters reach the nerves in all cases?

METHODS

The newly developed self-coiling catheter (Fig. 1) with an outer diameter of 1.0 mm consists of soft, radiopaque material. After the catheter emerges out of the needle tip, a coil forms due to a memory effect of the material. The coil tip is closed,

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Pajunk GmbH in Geisingen Germany will manufacture a catheter according to the prototype catheter described in this present study. To date, neither funding nor patent licensing arrangements have been signed or discussed between the authors of the study and Pajunk GmbH. However, a nondisclosure agreement between Dr Luyet and Pajunk GmbH has recently been formalized.

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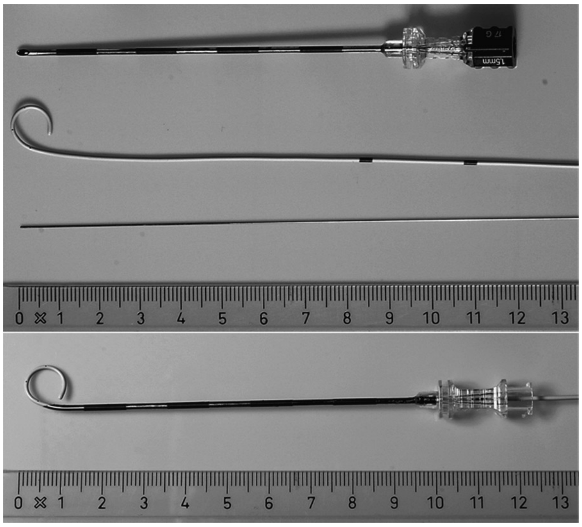

FIGURE 1. This figure depicts the catheter set, containing the 17-gauge Tuohy needle, guidewire, and the catheter with markings—the distal marking indicates the catheter tip is at the needle orifice; the proximal marking indicates the mandatory introduction depth to achieve a complete coil.

and there are 3 side-holes located on both sides of the catheter coil. The catheter was designed and tested by the authors of this study but is not yet approved for clinical use.

Ten cadavers in legal custody of the Institute of Anatomy, University of Bern, Switzerland, were studied with institutional approval for this procedure. The study was performed according to the ethical guidelines of the Swiss Academy of Medical Sciences for investigations using human cadavers.[12] The cadavers were embalmed using the method described by Thiel.[13] With this special embalming procedure, the tissue of the cadavers corresponds well to live humans, and therefore, these cadavers are well suited for sonographic examination, as demonstrated in previous studies.[14–16]

The cadavers were placed in the prone position on the computed tomography (CT) table. The sciatic nerves of both legs were tracked and visualized with ultrasound by scanning the leg from the infragluteal region to the popliteal groove. The ultrasound used was a portable ultrasound machine (M-Turbo; Sonosite, Bothell, Wash) with a 2- to 5-MHz curved array transducer for nerves lying deeper than 4 cm underneath the skin, or with a 5- to 10 MHz linear array transducer for nerves lying more superficially. A clear identification of the separation of the nerve into the tibial and peroneal nerve branches was mandatory to confirm the correct identification of the sciatic nerve. Thereafter, a 17-gauge Tuohy needle was placed behind (ie, anterior to) the sciatic nerves. Two needles were placed in each leg—one in the midfemoral region and the second was 10 cm distal from the first needle (and if possible, at least 1 cm cranial to the physical separation of the sciatic nerve into the tibial and peroneal nerve branches). Thus, in each cadaver, 4 needles and catheters were placed adjacent to the sciatic nerves (2 per sciatic nerve). As visualized in Figure 2, the needles were advanced in plane to the transducer with the nerve visualized in short axis. All needles were placed by the same operator (C.L.) experienced in ultrasound-guided regional anesthesia.

Once the needles were placed with a cranial orientation of the needle orifice, 10 mL of water was injected through the needles to dilate the perineural space. The catheters were then blindly introduced through the needles as follows: First, the catheters where threaded through the needle with the guidewire placed into the catheter until the tip reached the orifice of the needle. This position is achieved when the first marking on the catheter is located at the needle hub. At this position, the guidewire was withdrawn at least 3 cm to allow the catheter tip to form the coil, and the catheter was introduced 2.5 cm further until the second marking was at the needle hub. After placement of the catheter, the needle was withdrawn cautiously, and the catheters were taped to the skin, to prevent displacement of the catheter. The contents of the preassembled catheter set are shown in Figure 1. To exactly localize the radiopaque catheters, a CT scan of the legs was performed. Thereafter, 5 mL of magnetic resonance imaging (MRI) contrast dye was injected through the catheters, and the spread of contrast dye was assessed by MRI. A viscous solution of hydrophilic contrast was used (PEG-200; Schärer&Schläpfer AG, Rothrist, Switzerland) as contrast dye. This contrast solution is routinely used for forensic angiographic imaging purposes. The MRI has been chosen because of the superior differentiation of the neurovascular bundle from the adjacent structures (like fat and muscle).

Imaging was performed under the direction of a forensic radiologist (S.R.). Computed tomography imaging was performed on a 6-row multislice CT scanner (Somaton Emotion 6; Siemens Medical Solutions, München, Germany). Raw data acquisition was performed with the following settings: 130 kV, 150 mAs, collimation 6 × 1 mm. Image reconstruction was carried out with a slice thickness of 1.25 mm and an increment of half the slice thickness, in soft tissue and bone weighted reconstruction kernels. Magnetic resonance imaging was performed on a 1.5-T TIM (Total Imaging Matrix, Siemens Magnetom/Symphony; Siemens) with the following settings: VIBE T1 fat-saturation isotropic mode with a 0.9-mm slice thickness, which allows for 3-dimensional image reconstruction. For final evaluation of the radiological images, a picture archiving and communication system workstation (IDS5; Sectra AB, Linköping, Sweden) was used. All analyses were performed after termination of data acquisition. All images of the catheters were assessed by an independent forensic radiologist who was not involved during

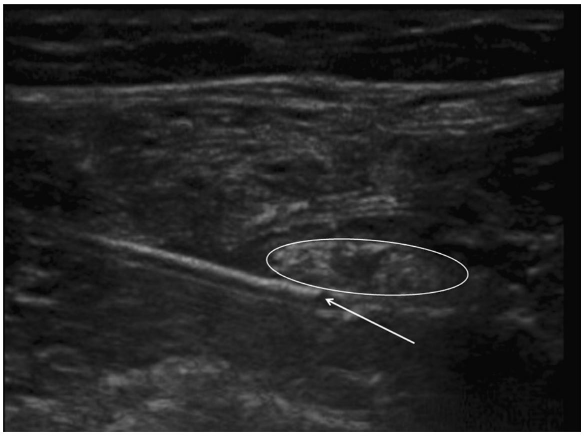

FIGURE 2. This transverse ultrasound image displays the sciatic nerve (encircled) 1 cm superior to the clear separation of the nerve into tibial and peroneal nerves, in the left leg, after injection of water to dilate the perineural space. Left is lateral; right is medial. The needle has been advanced until the opening (arrow) lies adjacent to the center mass of the nerve. In this example, the tibial and peroneal bundles are distinguishable, but not yet branching.

data acquisition (G.H.) as follows: (*a*) coil formation: complete coiling, partial coiling, and no coiling; (*b*) coil position in relation to the nerves; parallel to the nerves, deviation of the coil plane to the nerve plane in degrees; (*c*) minimal distance from the coil to the nerve in millimeters; (*d*) distance from the catheter tip to the sciatic nerve in millimeters. Contrast dye distribution around the nerves was assessed as follows: (*e*) degree of circumferential spread around the nerves; 0% to 100%; (*f*) craniocaudal spread of contrast dye along the nerves in centimeters; and (*g*) presence of intraneural or intramuscular contrast dye.

Statistics

A convenience sample of 10 cadavers has been chosen for the investigation. Normally distributed data are presented as mean and SD; non–normally distributed data are presented as median with 25% interquartile ranges. Normality distribution

TABLE 1. Detailed Results of the CT and MRI Analysis: Coil Position and Contrast Dye Spread

Number	Coiling	Coil Distance to Nerve, mm	Tip Distance to Nerve, mm	Circumferential Spread Around Nerve, %	Craniocaudal Contrast Spread, cm
1	Complete	0	0	50	5.5
2	Complete	0	2	75	8
3	Complete	0	0	50	6
4	Complete	0	2.5	40	6.5
5	Complete	0	0	50	7.5
6	Complete	0	6.5	50	7.5
7	Partial	0	2	50	5.5
8	Partial	0	6	50	7.5
9	Complete	5	0	40	7.5
10	Complete	0	6	0	NA
11	Complete	0	0	50	5*
12	Complete	0	2.5	95	5*
13	Complete	0	3	50	4.5
14	Partial	0	7	60	4.5
15	Complete	0	3	50	4
16	Complete	0	0	35	5.5
17	Complete	0	9	50	7
18	No coiling	0	15	65	7.5
19	Complete	0	0	30	7.5
20	Complete	0	5	30	6.5
21	Complete	0	0	50	4.5
22	Complete	0	0	50	4
23	Complete	0	3	100	5.5
24	Complete	0	0	100	5
25	Complete	0	0	50	5
26	Complete	0	2	50	3.5
27	Complete	0	0	40	4
28	Complete	0	6	50	6
29	Partial	0	0	30	5
30	Complete	0	0	40	3
31	Complete	0	0	30	4.5
32	Complete	0	3	40	6
33	Complete	7	10	50	6.5
34	Partial	0	2	50	8
35	Complete	0	0	75	10
36	Complete	0	4	50	6
37	Partial	0	0	50	4.5
38	Complete	0	0	80	5.5
39	Complete	6	6	50	5.5
40	Partial	0	2	75	5

All but 1 catheter (number 18) formed a coil. Except for catheters 9, 33, and 39, all coils were in direct contact to the nerve.

*There was a confluence between contrast dye of 2 neighboring catheters (11 and 12), which made clear evaluation of craniocaudal contrast dye spread impossible for these 2 catheters. The measured value (5 cm) entered for each catheter reflects half of the total contrast spread from both injections. Contrast dye spread through catheter 10 was extensive but not in direct contact to the nerve.

NA indicates not applicable.

was tested by using the Kolmogorov-Smirnov test. Spread of contrast dye was calculated as percentage of the circumferential spread around the nerve.

RESULTS

We performed a total of 40 catheter placements in 10 cadavers (placing 2 catheters per sciatic nerve in each leg). The visualization and identification of the sciatic nerves by ultrasound as well as the ultrasound-guided placement of the needles adjacent to the nerves were easily accomplished in all cases. The ultrasound image in Figure 2 displays a typical appearance of a sciatic nerve with the approaching needle, using an in-plane technique. All 40 punctures were documented and recorded by an ultrasound image. The catheter insertion was possible without problems in all cases. All catheters could be placed at the first attempt without need to replace any of the needle tips, and there was no need to inject a second bolus of water to further dilate the space around the nerves. The results of the CT and MRI analysis are detailed in Table 1. There was direct coil contact to the nerve in 37 of 40 cases. One example of a catheter coil in direct contact to the nerve is illustrated in Figure 3. For the 3 catheters without direct coil contact to the nerves, the shortest coil-nerve distances were 5, 6, and 7 mm. Half of the catheter coils (20/40 catheters) were placed parallel to the nerves as visualized in the segmented, 3-dimensional volume-rendered image in Figure 4. The deviation of the virtual plane of the coil from the plane of the nerves of the other catheters ranged between 10 and 90 degrees. The coils of 4 of 6 catheters with a deviation of 90 degrees were hooking the nerves (ie, placed partially around the nerve). The evaluation of the magnetic resonance images after contrast dye injection revealed that contrast dye was in contact to all but 1 nerve. In this case, there was a small layer of fat tissue between the contrast dye and the nerve. The circumferential coverage of the nerves (evaluation of the cross section of the nerves in axial images) by contrast dye in all 39 other cases ranged from 40% to 100% with a median coverage of 50% (25-interquartile range of 40%). An example magnetic resonance image to show contrast dye spread is shown in Figure 5. The craniocaudal spread of contrast dye along the nerves ranged from 3 to 10 cm, with a mean spread of 5.8 (SD, 2.5) cm. No intramuscular or intraneural contrast dye could be detected.

DISCUSSION

After placement of a block needle close to the target nerve, the use of ultrasound to precisely place catheters remains challenging. In a recent editorial, Ilfeld and colleagues[17] nicely highlighted the problems associated with the precise placement of catheters for continuous perineural infusions. When a perineural catheter is inserted past the needle tip, the likelihood of being misplaced away from the nerve might be important. This question has been addressed in the recently published study by Mariano et al,[11] and the surprising result was that the pure ultrasound-guided catheter placement technique had a higher secondary block failure rate compared with the stimulating catheter technique. In contrast to the correct placement of needle tips near the target under direct visualization, the catheters are more difficult to be visualized and correctly placed by ultrasound. Skilled operators may be able to track the catheter during the insertion either directly or indirectly by tissue movement, but the only possibility to change the position would be to withdraw and replace the catheter until it is in the desired position. Even if the field is rapidly evolving and the generation of echogenic catheters as well as further improvement of the ultrasound technology will allow better visualization of the catheters, the main issue with catheters is not only to visualize them, but more importantly also to bring them toward the desired

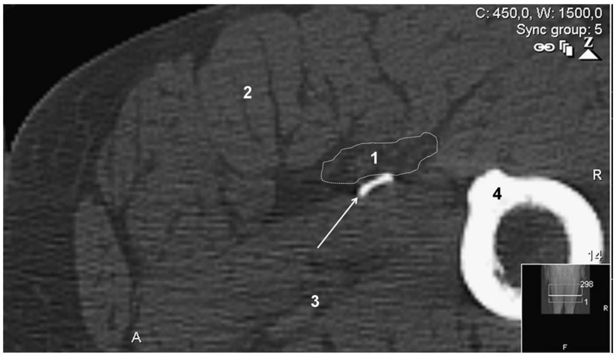

FIGURE 3. This axial CT image shows parts of the radiopaque catheter coil (arrow) in direct contact with the sciatic nerve (dashed line). 1 = sciatic nerve, 2 = hamstring muscles, 3 = adductor muscle group, 4 = femoral cortex.

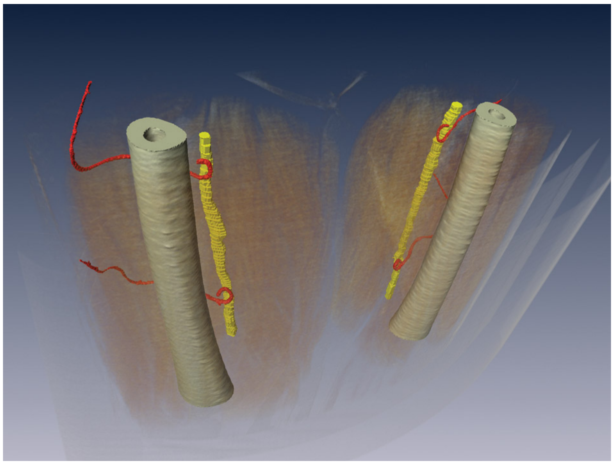

FIGURE 4. This segmented, 3-dimensional volume-rendered image from one of the cadavers shows catheter position in relation to the course of the nerves (view is from anterior, looking slightly inferiorly and to the cadaver's left). The catheter coils in red are lying parallel to the sciatic nerves in yellow. In this case, the femoral bones are colored in brown.

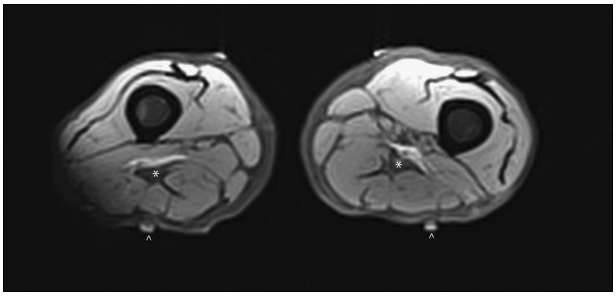

FIGURE 5. The axial MR image shows the contrast dye spread on both sciatic nerves of 1 cadaver. The dye mainly reaches both nerves on their anterior aspects. The neurovascular bundle appears as dark structure (asterisk), whereas the contrast dye is white, and the muscles gray. The white spots (arrowhead) at the posterior part of the legs are nitroglycerin capsules, which are marking the level where the catheter has been placed and thus the area of interest for the magnetic resonance scanning.

position. As hypothesized with this study for the sciatic nerve, the use of a self-coiling shaped catheter might be the solution to this problem: The catheter tip should remain in vicinity of the block needle, which can be properly placed and guided because of its rigidity and echogenicity.

The needle-in-plane/nerve in short-axis approach was used for 2 different reasons. First, this technique allows an easier identification and differentiation of the nerve from the surrounding tissues, and the needle can be seen all the way to the target point.[18] Second, when a conventional catheter is inserted past the needle tip, it might have the tendency to bypass the nerve, given the perpendicular orientation of the block needle to the target nerve.[19] Thus, by combining this approach with the use of a self-coiling catheter (which should remain in the region of the needle tip), the preconceived advantage of the new catheter could best be tested.

In this present investigation, not all coils could be placed parallel to the nerves as intended. Because the orifices for injection in our catheter are located at the level of the coil, compared with the distal opening in standard catheters, the plane of the coils seems to be of less importance as was shown by the favorable contrast dye distribution in our subjects. It is sufficient to place at least a part of the catheter coil in vicinity to the nerves to achieve contact of the injected drug with the targeted nerves. Spread of contrast dye reached a median circumferential covering of the sciatic nerve of 50%. It is unknown what exact percentage of the nerve surface needs to be bathed in anesthetic fluid to produce an effective block. Therefore, we cannot definitely conclude that the median circumferential coverage of the sciatic nerve of 50% found in our study would block the nerve and provide sufficient analgesia. To properly address this question, further evaluation in clinical studies is necessary. Nevertheless, Morau et al[20] showed in their recently published study that circumferential spread is not mandatory to achieve a complete sensory block in patients, and Latzke et al[21] found that circumferential spread was not mandatory to lose pinprick sensation in the studied volunteers. There might be concerns about the risk of coiled catheters: During the development of the catheters, the decision was made to use only 1 coil to avoid wrapping or knotting of the catheters around nerves. Even in the 4 catheters hooking the nerves, no resistance was felt during withdrawal of the soft catheters.

Despite the fact that hydrodissection is somewhat controversial, we dilated the perineural space by injecting a volume of 10 mL of water to facilitate the coiling of the catheter. Whether the coil forms reliably even if the catheter is introduced "dry" has to be the subject of subsequent studies.

One might further argue that the necessity to use larger needles for introducing this catheter could be a disadvantage. Larger needles are potentially more harmful than smaller needles; an unintended vascular puncture would be more problematic with a larger-gauge needle. On the other hand, the larger-bore needle could also be an advantage because the larger the needle is, the better its visibility with ultrasound will be.[22] This leads to the benefit of requiring fewer needle passes, given the relative ease of keeping a rigid, larger-gauge needle in plane. With larger needles, there is less risk of misinterpretation of the needle shaft for the needle tip. Of course, the use of large needles might be more painful, but this can be resolved by providing adequate skin or needle track anesthesia by first injecting local anesthetic via a small-gauge needle.[9,19]

We can conclude that our newly developed self-coiling catheter can easily be introduced blindly through a needle placed under ultrasound guidance with a low risk of catheter misplacement away from the targeted nerves. These results should be interpreted with caution, because they are confined to the sciatic nerve and to the study settings with cadavers. These findings have to be tested in further studies before introducing the new catheter in clinical practice. Even more importantly, the self-coiling catheter has to be tested and compared with other catheters in a clinical study. This feasibility and proof-of-concept study, however, was mandatory for the further development and for the approval for the clinical use of such a catheter.

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