ANESTHESIOLOGY

Suture-method *versus* Through-the-needle Catheters for Continuous Popliteal-sciatic Nerve Blocks

A Randomized Clinical Trial

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ABSTRACT

Background: The basic perineural catheter design has changed minimally since inception, with the catheter introduced through or over a straight needle. The U.S. Food and Drug Administration recently cleared a novel perineural catheter design comprising a catheter attached to the back of a suture-shaped needle that is inserted, advanced along the arc of its curvature pulling the catheter past the target nerve, and then exited through the skin in a second location. The authors hypothesized that analgesia would be noninferior using the new *versus* traditional catheter design in the first two days after painful foot/ankle surgery with a primary outcome of average pain measured with the Numeric Rating Scale.

Methods: Subjects undergoing painful foot or ankle surgery with a continuous supraparaneural popliteal-sciatic nerve block 5 cm proximal to the bifurcation were randomized to either a *suture-type* or *through-the-needle* catheter and subsequent 3-day 0.2% ropivacaine infusion (basal 6 ml/h, bolus 4 ml, lockout 30 min). Subjects received daily follow-up for the first four days after surgery, including assessment for evidence of malfunction or dislodgement of the catheters.

Results: During the first two postoperative days the mean ± SD average pain scores were lower in subjects with the *suture-catheter* (n = 35) compared with the *through-the-needle* (n = 35) group (2.7 ± 2.4 *vs.* 3.4 ± 2.4) and found to be statistically noninferior (95% CI, −1.9 to 0.6; $P < 0.001$). No suture-style catheter was completely dislodged (0%), whereas the tips of three (9%) traditional catheters were found outside of the skin before purposeful removal on postoperative day 3 ($P = 0.239$).

Conclusions: Suture-type perineural catheters provided noninferior analgesia compared with traditional catheters for continuous popliteal-sciatic blocks after painful foot and ankle surgery. The new catheter design appears to be a viable alternative to traditional designs used for the past seven decades.

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EDITOR'S PERSPECTIVE

What We Already Know about This Topic

- The fundamental design of perineural catheters has changed little since they were first introduced

What This Article Tells Us That Is New

- A novel catheter attached to the back of a suture-shaped needle can be inserted under ultrasound guidance to provide popliteal-sciatic nerve blockade
- In the first two days after foot and ankle surgery, analgesia provided using the suture-type catheters was found to be noninferior to that provided by conventional through-the-needle catheters

A peripheral nerve block can provide potent analgesia after surgery. However, to prolong the effects beyond the duration of a single injection of local anesthetic, a perineural catheter must be inserted to allow repeated or continuous local anesthetic administration.[1] The method of catheter insertion has remained relatively unchanged since the first catheter-based continuous peripheral nerve block report in 1951[2]: a straight, hollow-bore needle is inserted to the desired perineural location and a catheter is subsequently inserted either over or through the linear needle.[3] The needle is then removed, leaving the catheter which is secured at the single (entry) site.

However, the U.S. Food and Drug Administration recently cleared a novel perineural catheter design for use in the United States. The new system comprises a catheter attached to the back of a hollow, suture-shaped needle (fig. 1) that is inserted into the skin, passed adjacent to

Supplemental Digital Content is available for this article. Direct URL citations appear in the printed text and are available in both the HTML and PDF versions of this article. Links to the digital files are provided in the HTML text of this article on the Journal's Web site (www.anesthesiology.org). Interim analyses of the results of this study were presented in abstract form at the 44th Annual Regional Anesthesiology and Acute Pain Medicine Meeting in Las Vegas, Nevada, on April 12, 2019, and the 38th Annual European Society of Regional Anesthesia Congress in Bilbao, Spain, from September 11 to 14, 2019.

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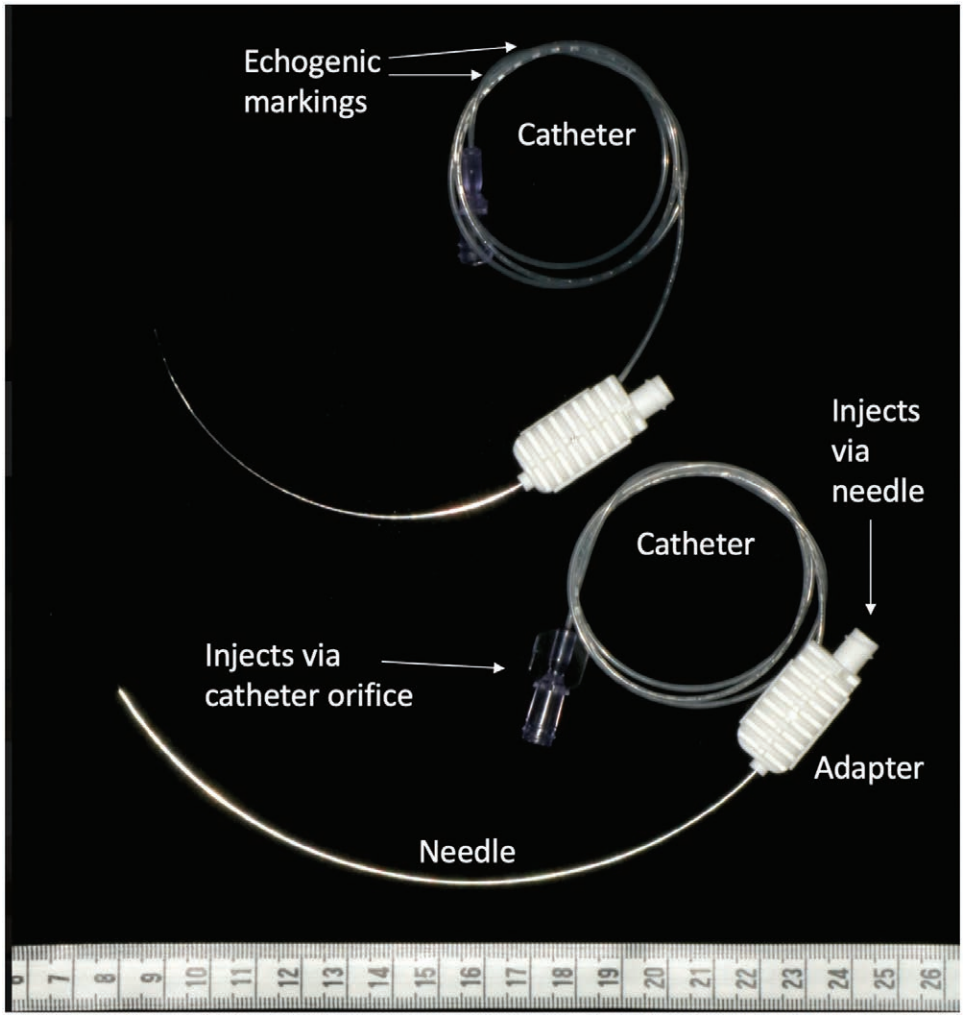

Fig. 1. Photograph of both the 100-mm (upper) and 160-mm (lower) suture-catheter assemblies. Note that the adapter contains a port for injecting fluid *via* the needle tip and the port on the catheter injects *via* the orifice.

the target nerve with ultrasound guidance, and then exits through skin in a second location (fig. 2).[4] As the needle is advanced along the arc of its curvature it pulls the catheter through the tissue and adjacent to the target nerve.[5] The needle is removed from the indwelling catheter and the catheter can then be pulled from either skin exit point to align its orifice immediately adjacent to the target nerve using ultrasound visualization (fig. 3).[6] Both ends of the catheter are secured and local anesthetic is administered through a port on the proximal end of the catheter (fig. 1).

This new catheter design has been described in various case series.[5–7] However, it remains unknown how the new design compares with the traditional through-the-needle method. Therefore, we designed and executed a randomized, subject-masked, parallel-arm study comparing popliteal-sciatic catheters inserted using the new and traditional techniques. We hypothesized that pain would be noninferior using the new suture-type catheter compared with a through-the-needle perineural catheter in the first two days after painful foot/ankle surgery. The primary outcome measure was the average pain level during the first two postoperative days as measured on the Numeric Rating Scale. Secondary outcomes included pain levels at other time points, opioid consumption, opioid-related side effects, sleep disturbances, sensory and motor deficits, satisfaction with postoperative analgesia, fluid leakage, and complete catheter dislodgement.

Materials and Methods

This parallel group study adhered to Good Clinical Practice quality standards and ethical guidelines defined by the Declaration of Helsinki. Study protocol approval as well as data and safety oversight were conducted by the University of California San Diego Institutional Review

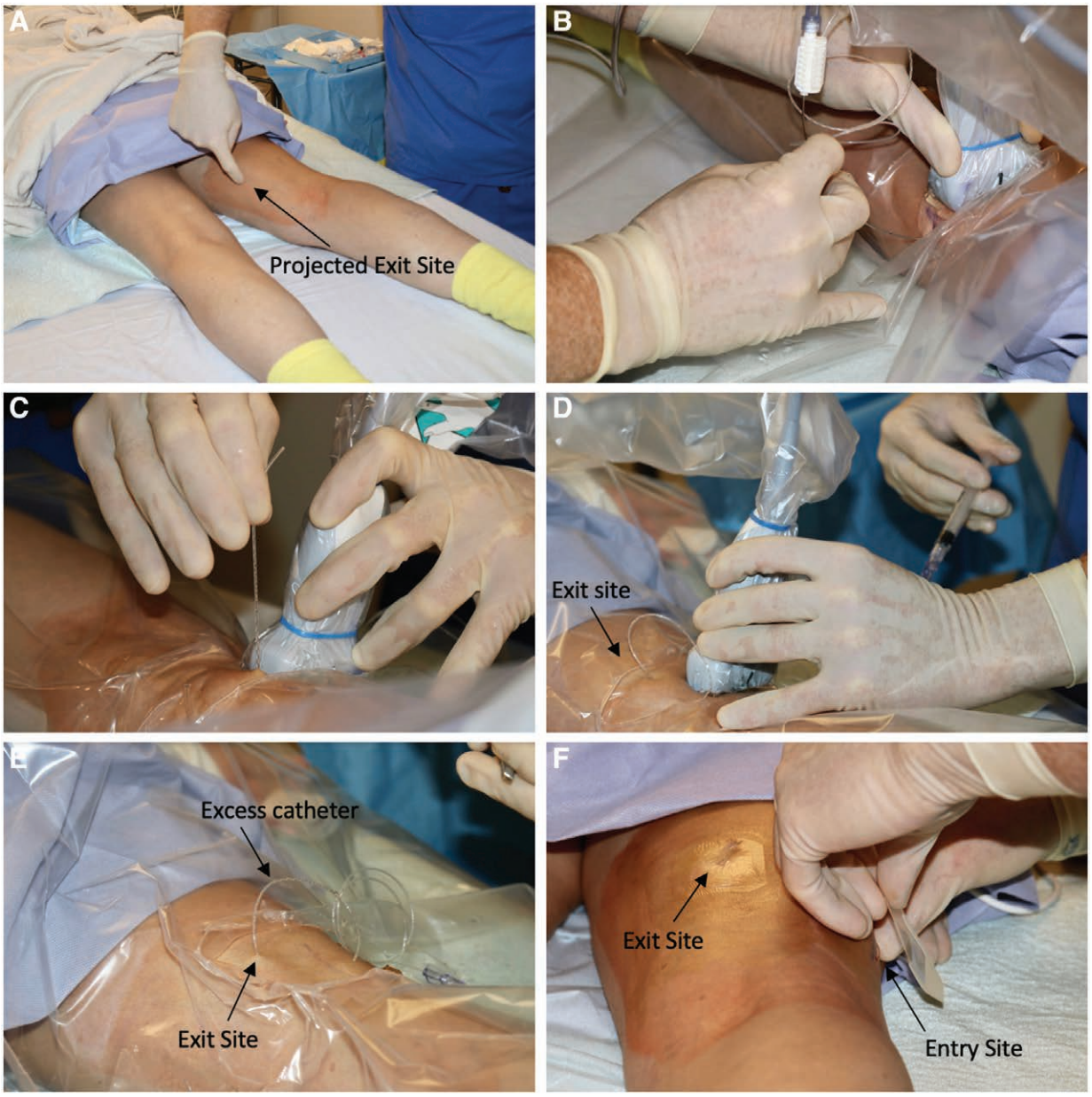

Fig. 2. (*A*) A wide sterile field is prepped, anticipating an exit site that is 6 to 8 cm medial to the needle entry site. (*B*) The suture-needle is inserted using in-plane ultrasound guidance. (*C*) After cutting the needle from the catheter, the catheter can be pulled in either direction to place the orifice directly adjacent to the target nerve. (*D*) Normal saline is injected *via* the catheter to confirm correct placement of the orifice. (*E*) Excess catheter at the exit site is clipped before securing the catheter. (*F*) The catheter is secured with clear, occlusive dressings at both the entry and exit sites.

Board (No. 170834; San Diego, California). Written, informed consent was obtained from all subjects participating in the trial. The trial was prospectively registered at clinicaltrials.gov (NCT03442036; Principal Investigator: Brian Ilfeld, M.D., M.S.; date of registration: February 22, 2018) before initiation of enrollment. The full protocol is available at clinicaltrials.gov.

Enrollment was offered to all adults who met study criteria undergoing painful unilateral ambulatory foot or ankle surgery with a planned popliteal-sciatic perineural catheter for postoperative analgesia at a single institution. Exclusion criteria included clinically-apparent neuropathy in the surgical extremity, chronic high-dose opioid use (defined as daily use for more than 4 weeks before surgery

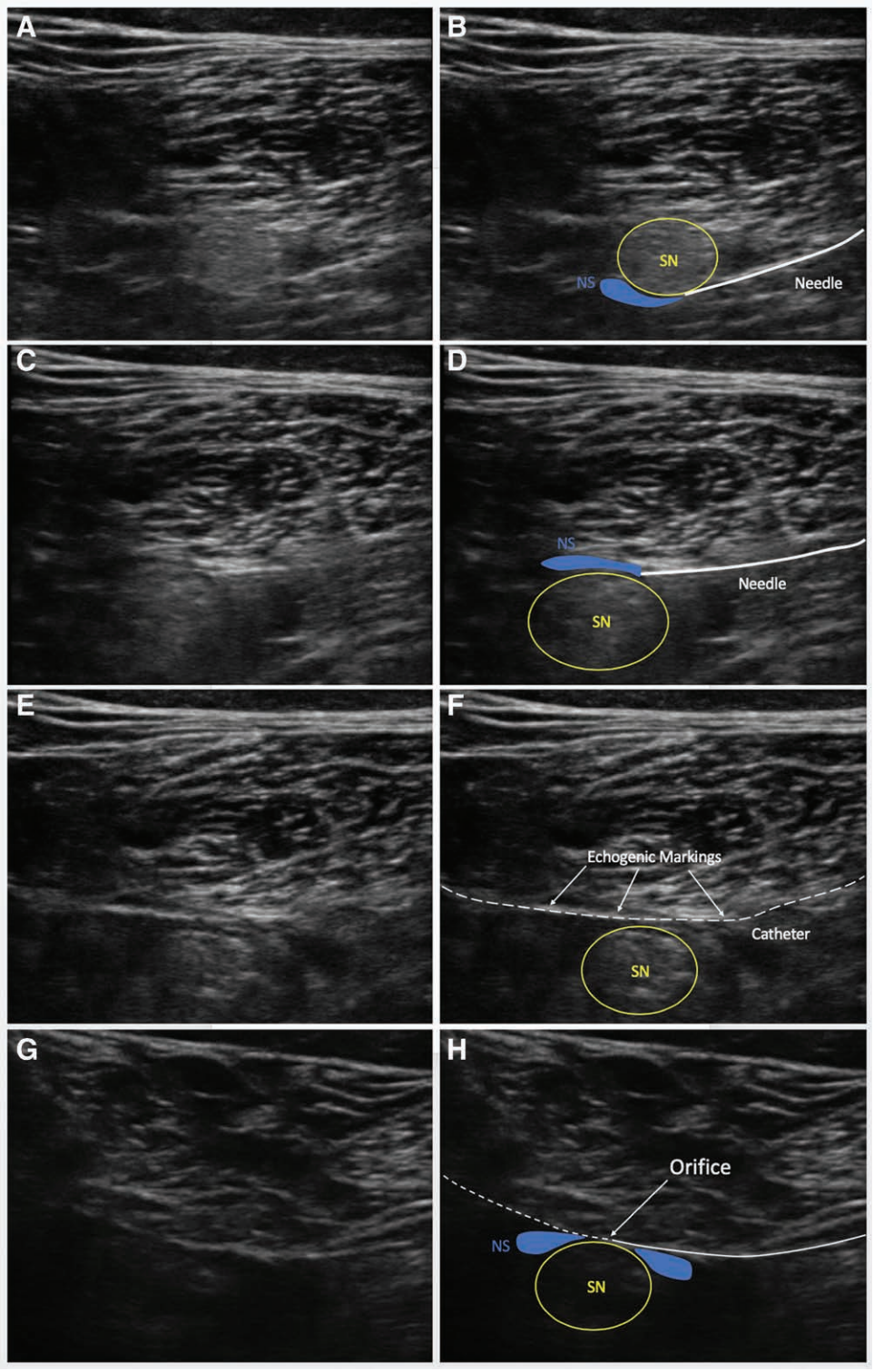

Fig. 3. (*A*) The suture-needle is advanced under the sciatic nerve (SN) and normal saline (NS) is used to hydrodissect between the nerve and the underlying fascia. (*B*) Needle, NS, and SN are diagramed. (*C*) After withdrawing the needle to the lateral border of the nerve, NS is then used to hydrodissect between the SN and the overlying fascia. (*D*) SN, NS, and needle are diagramed. (*E*) Echogenic markings on the catheter are used to properly position the orifice directly adjacent to the SN. (*F*) The catheter with its echogenic markings are diagramed. (*G*) After placing the orifice adjacent to the SN, NS is used to confirm location. (*H*) Orifice, NS, and SN are diagramed.

of at least the equivalent of 20 mg oxycodone), a history of opioid misuse, surgery outside of ipsilateral sciatic and saphenous nerve distributions (*e.g.*, iliac crest bone graft), patients with nerves deeper than 5 cm from the skin surface, pregnancy, an inability to communicate with the investigators and hospital staff, and incarceration. Patients eligible for the study were called the night before surgery by one of the investigators to offer enrollment. If not available by telephone, patients were offered enrollment in person by one of the investigators before block placement if there was sufficient time to fully discuss the study and answer all questions. Only one patient who was offered enrollment in the study declined.

Preoperative Procedures

After applying standard American Society of Anesthesiologists (ASA; Schaumburg, Illinois) monitors, oxygen by facemask, and positioning the patient prone, intravenous midazolam and fentanyl were titrated for patient comfort while ensuring patients remained responsive to verbal cues. A 13- to 6-MHz 38-mm linear array ultrasound transducer (Edge II; SonoSite, USA) was used to visualize the sciatic nerve 5 cm proximal to the bifurcation with a short-axis view. After confirming that this site was appropriate for catheter insertion, the subjects were randomized using a computer-generated list (prepared by an investigator not involved in enrollment or data collection) in opaque, sealed security envelopes to one of two treatments groups (1:1 ratio) in blocks of four: (1) through-the-needle (traditional group) or (2) suture-catheter (suture group). The catheter site was sterilely prepped, draped, and the needle entry site anesthetized with lidocaine 1% (3 ml).

Through-the-needle Insertion

A 17-guage Tuohy needle (FlexTip Plus; Teleflex Medical, USA) was inserted on the posterior aspect of the leg, from lateral to medial, using an in-plane, short-axis ultrasound-guided technique. Normal saline (5 to 10 ml) was used to hydrodissect around the sciatic nerve to facilitate catheter insertion. A 19-guage flexible, single-orifice perineural catheter was inserted under ultrasound guidance. Correct location of the tip was confirmed by injection of normal saline (1 to 2 ml) with visualization of spread adjacent to the nerve. The catheter was then secured with clear, occlusive dressings. To facilitate tourniquet placement in the operating room, the catheter was taped up the lateral thigh and secured on the lower abdomen.

Suture-catheter Insertion

A short-beveled 19-guage suture needle (75 mm radius, 160 mm length) joined to a 19-guage, single-orifice, nylon catheter (Certa Catheter, Ferrosan Medical Devices, Poland) was inserted on the posterior aspect of the leg, from lateral to medial, under ultrasound guidance using an in-plane technique. Normal saline (5 to 10 ml) injected through the hollow-bore needle was used to hydrodissect below (fig. 3, A and B) and then above (fig. 3, C and D) the sciatic nerve to facilitate spread of local anesthetic following catheter insertion. The suture needle was then advanced under ultrasound guidance to an exit point approximately 6 to 8 cm medial to the entry site. After anesthetizing the skin at the exit point with lidocaine 1% (1 to 2 ml), the needle was advanced through the skin and then removed (fig. 2E). The catheter was subsequently advanced under ultrasound visualization using the echogenic markings (fig. 3, E and F; Supplemental Digital Content 1, Echogenic Markings, http://links.lww.com/ALN/C180) to place the orifice directly adjacent to the sciatic nerve (Supplemental Digital Content 2, Markings to Orifice, http://links.lww.com/ALN/C181). Proper position of the catheter was confirmed by injection of normal saline (1 to 2 ml) through the catheter and visualizing spread adjacent to the nerve (fig. 3, G and H). The excess catheter was then cut, leaving a tail approximately 1 cm long at the exit site. The entry and exit sites were secured with clear, occlusive dressings (fig. 3F). To facilitate tourniquet placement in the operating room, the catheter was taped up the lateral thigh and secured on the lower abdomen.

If a postoperative neurologic exam was desired by the surgeon, no local anesthetic was administered preoperatively. In cases in which no postoperative exam was anticipated, 20 ml 2% lidocaine with 5 to 10 μg/ml epinephrine was injected *via* the catheter immediately after placement. This was done under ultrasound visualization to confirm that the injection produced circumferential spread of the local anesthetic around the sciatic nerve (Supplemental Digital Content 3, Infusion of Local Anesthetic, http://links.lww.com/ALN/C182). Successful block was defined as a decrease in temperature discrimination to ice after 30 min in the tibial nerve distribution (unless the foot was not accessible because of a splint) as compared with sensation in the contralateral foot. For cases in which the surgeon desired a postoperative exam before local anesthetic administration, a bolus with the same lidocaine–epinephrine volume/concentration was performed in the postanesthesia care unit.

If the planned surgical procedure was anticipated to produce pain in the saphenous nerve distribution, a single-injection saphenous nerve block was performed with 20 ml 0.5% ropivacaine with 5 to 10 μg/ml epinephrine administered *via* a 17-guage Tuohy needle under direct ultrasound visualization.

Intraoperative Procedures

Surgical anesthesia was provided with either preoperative administration of local anesthesia as part of the nerve block combined with propofol sedation, or general anesthesia consisting of inhaled volatile anesthetic with or without nitrous oxide in oxygen with opioids provided, as needed.

Postoperative Procedures

Subjects received a 3-day perineural infusion *via* electronic pump (ambIT PreSet, Summit Medical Products, Inc., USA) of ropivacaine 0.2% (basal 6 ml/h; 4 ml demand bolus; 30-min lockout) initiated in the recovery room along with a prescription for oxycodone 5 mg tablets before discharge for supplementary analgesia. Subjects were contacted by telephone for 4 days after surgery to collect study outcome measures.

On the third postoperative day, subjects or their caretakers were instructed to remove the perineural catheter. Subjects were instructed to remove the occlusive dressing at the skin entry site and slowly pull out the catheter. Subjects in the suture-catheter group were specifically instructed to leave the distal dressing in place until the catheter was completely removed, thus ensuring that the small tail at the exit site was pulled through the skin before sterile dressing removal to avoid contamination of the catheter track.

Outcome Measures

The first four items of the Brief Pain Inventory were collected daily[8]: worst, average, least, and current surgical pain measured using the Numeric Rating Scale (provided verbally to the investigator with specificity to the 0.1 unit). The primary outcome measure was average pain score on the first two postoperative days. Additional outcomes included daily opioid use, sleep disturbances attributable to pain (binary), opioid and local anesthetic infusion (*e.g.*, perioral numbness) side effects (binary), local anesthetic leakage (binary), complete catheter dislodgement (binary), degree of sensory block (measured on a 0 to 10 scale with 0 = no deficits and 10 = completely insensate), satisfaction with postoperative analgesia (0 = very dissatisfied, 10 = completely satisfied), and the volume of local anesthetic consumed.

Statistical Methods

We assessed the balance of randomized groups on baseline and procedural characteristics using absolute standardized difference, defined as the absolute difference in means, mean ranks, or proportions divided by the pooled SD. Baseline variables with absolute standardized difference greater than 0.46 (*i.e.*, $1.96 \times\sqrt{[1/n1 + 1/n2]}$) were considered imbalanced and were adjusted for in all analyses, as appropriate.[9] All analyses used modified intention-to-treat such that all patients randomized and receiving at least some of the study intervention were included.

We tested noninferiority of the suture method to the through-the-needle perineural catheter method on the primary outcome of average pain score and other continuous secondary outcomes in the first two days after surgery using a one-tailed noninferiority *t* test at the 0.025 significance level. We used an *a priori* noninferiority delta of 1.25 for each pain score outcome and a ratio of means of 1.2 for the cumulative log-transformed opioid consumption. Noninferiority was claimed if the upper 95% confidence limit for the treatment effect (estimated from analyses described below) was less than the specified noninferiority delta. *P* values were obtained from a one-tailed *t* test using a test statistic defined as $T_{NI} = (\hat{\beta} - \delta) / SE\ (\hat{\beta})$, where (β) is the estimated treatment effect, $SE\ (\hat{\beta})$ is the estimated standard error of the treatment effect, and δ is the noninferiority delta. If noninferiority was found, superiority would be tested in the same direction.[10]

We assessed the effect of suture-method to the through-the-needle perineural catheter on each of four pain scores in the first two postoperative days using a repeated-measures linear mixed-effects model with an unstructured within-subject correlation structure adjusted for a variable's imbalances at baseline (age was the only imbalanced variable). The heterogeneity of the estimated treatment effect over time was assessed *via* the treatment-by-time interaction at a significance criterion of $P < 0.15$. A significant interaction suggested that the treatment effect varies over time, in which case we estimated the treatment effect individually for each of two time points at the 0.0125 significance level using Bonferroni correction (0.025/2). Treatment effect estimates from these regression models were used to assess noninferiority of the suture *versus* through-the-needle methods, as described in the preceding paragraph.

For cumulative opioid consumption during the first two days after surgery, we first estimated the treatment effect of the suture method *versus* the through-the-needle method on log-transformed opioid consumption using linear regression and adjusting for age. If a patient did not receive opioids (amount = 0), 0.5 mg was added to facilitate the log-transformation.

We originally planned to estimate the effect of the treatment on the side effect of complete catheter dislodgment as a secondary outcome for testing noninferiority. However, we observed no event in the suture method group. Therefore, we simply compared the groups using the Fisher exact test. We also compared the randomized groups on binary outcomes using chi-square or Fisher exact test, as appropriate.

Sample Size and Power Estimation

The study was designed to have 90% power at the 0.025 significance level to detect noninferiority of the suture method to the through-the-needle perineural catheter on mean average pain score on the first two days after foot or ankle surgery. Assuming a noninferiority delta of 1.25 points, a SD of 2.2,[11] and a true difference of 0.5 points in the pain score favoring the suture method, a total sample size of 70 patients (35 per group) was required. SAS statistical software (USA) was used for all analyses.

Results

Seventy subjects equally divided between the treatment groups were enrolled more than 12 months beginning in

April 2018 and were included in all analyses (fig. 4). Subjects were summarized and compared on potentially confounding baseline and procedural characteristics (table 1). All factors were balanced between two groups with the exception of age (suture group patients were more likely to be older) and surgical procedure (borderline imbalance). Age was adjusted for in all analyses. There were no missing data for any baseline variables or outcomes.

Primary Outcome

During the first two postoperative days the mean ± SD average pain scores were lower in subjects with the *suture-catheter* (n = 35) compared with the *through-the-needle* (n = 35) group (2.7 ± 2.4 *vs.* 3.4 ± 2.4) and found to be statistically noninferior (95% CI, −1.9 to 0.6; $P < 0.001$; table 2 and fig. 5). There was no evidence that the treatment effect varied over time, with $P = 0.908$ for the treatment-by-time interaction. We therefore assessed the overall treatment effect collapsing over time in the mixed effects model. Superiority was not found ($P = 0.282$). (Of importance, although the suture method resulted in, on average, just over a half-point improvement in average pain, the CI for this effect includes zero, and by the CI is consistent with a true effect ranging from about a 2-point benefit to 0.5-point harm. However, the primary analysis, determined *a priori*, was positive in that noninferiority was found.)

Secondary Analyses

We also found the suture method to be noninferior to the through-the-needle method on least pain in the first two postoperative days, with an estimated mean (95% CI) Numeric Rating Scale difference of −0.4 (−0.9 to 0.2), $P < 0.001$, and on current pain with an estimated mean difference of −0.1 (−1.3 to 1.0), $P = 0.009$ (fig. 5). Superiority was not found on least (mean difference [95% CI] of −0.4 [−0.9 to 0.2]; $P = 0.222$) or current pain (mean difference [95% CI] of −0.1 [−1.3 to 1.0]; $P = 0.824$). Although the actual mean scores for worst pain were slightly lower for the suture group (fig. 4), we could not conclude noninferiority given the upper limit of the CI (estimated mean difference [95% CI] of 0.0 [−1.5 to 1.5]) was above the predetermined noninferiority delta ($P = 0.046$). Of note, the inability to find the suture method noninferior for worst pain is not a finding that it was inferior to through-the-needle. The best estimate of the true effect is given by the estimated CI for the difference. The treatment effect of the two treatments on

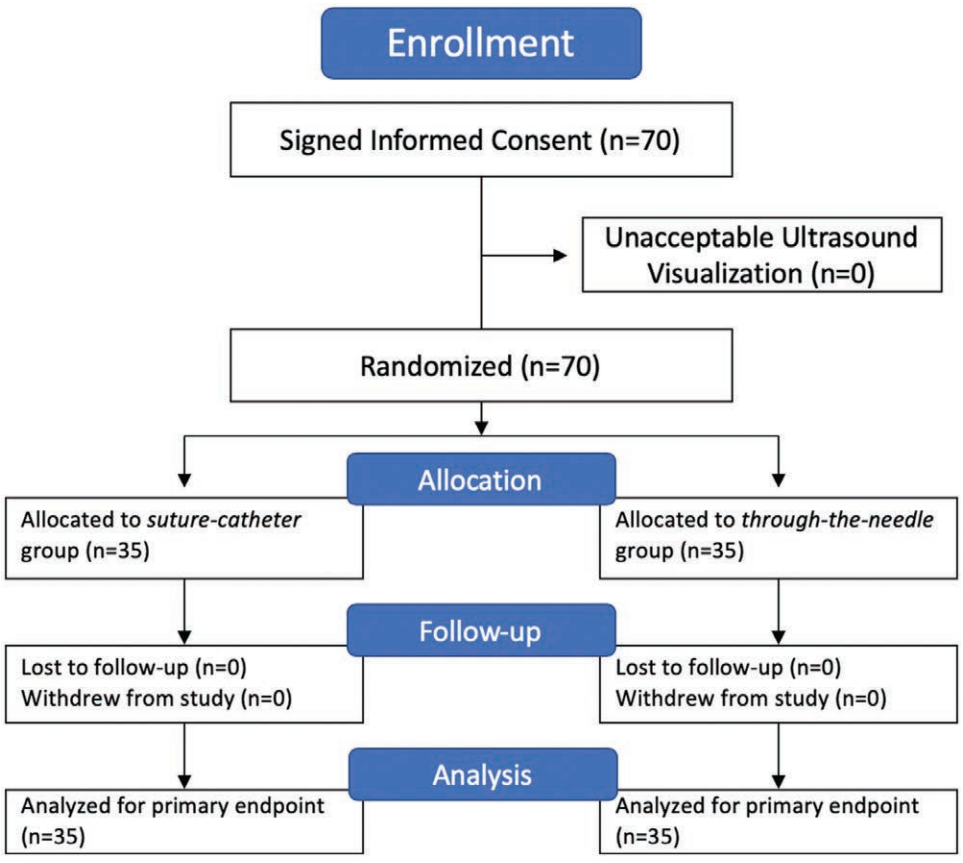

Fig. 4. Consolidated Standards of Reporting Trials diagram displaying the flow of participants through the study.

Table 1. Demographics and Surgical Factors

Factor	Suture-catheter (N = 35)	Through-the-needle (N = 35)	Absolute Standard Differences*
Age, yr	53 ± 17	38 ± 13	1.01
Female, no. (%)	14 (40)	14 (40)	0.00
BMI, kg/m^2	29.4 ± 5.8	27.6 ± 6.1	0.30
Procedure time, min	5 ± 3	5 ± 3	0.05
Local administration postop, no. (%)	3 (9)	2 (6)	0.11
Saphenous blocked, no. (%)	26 (74)	30 (86)	0.28
Surgical duration, min	103 ± 48	98 ± 49	0.09
Surgical procedure			
Ankle open reduction internal fixation	13	21	0.47†
Midfoot arthrodesis	6	4	
Ankle fusion	6	1	
Hallux deformity correction	3	2	
Midfoot open reduction internal fixation	3	2	
Exostosis excision	2	1	
Calcaneus open reduction internal fixation	1	1	
Anterior talofibular ligament repair	1	1	
Achilles tendon repair	0	2	

Values are reported as mean ± SD or percentage of treatment group, as appropriate. BMI, body mass index.

*Absolute standard difference (ASD): The absolute difference in means mean ranks, or proportions divided by the pooled SD, with a criteria ASD ≥ 0.46 considered as imbalanced .

†Comparing the first category (ankle open reduction internal fixation) with all others because of small counts.

Table 2. Noninferiority Comparisons of the Suture Method *versus* Through-the-needle on Primary and Secondary Outcomes

Primary Outcome	Suture-catheter (N = 35)	Through-the-needle (N = 35)	Mean Difference* (95% CI)	Noninferiority Delta	Noninferiority *P* Value†	Superiority *P* Value
Average pain score[a]	2.7 ± 2.4	3.4 ± 2.4	–0.7 (–1.9 to 0.6)	1.25	0.001‡	0.282
POD 1	2.6 ± 2.6	3.3 ± 2.4				
POD 2	2.7 ± 2.3	3.5 ± 2.4				
Secondary outcomes						
Worse pain[b]	5.5 ± 3.4	5.7 ± 3.2	0.0 (–1.5 to 1.5)	1.25	0.046	NA
POD 1	5.4 ± 3.8	5.8 ± 3.4				
POD 2	5.6 ± 2.9	5.6 ± 3.1				
Least pain[c]	0.8 ± 1.7	1.1 ± 1.4	–0.4 (–0.9 to 0.2)	1.25	< 0.001‡	0.222
POD 1	0.3 ± 1.1	0.7 ± 1.3				
POD 2	1.3 ± 2.0	1.5 ± 1.5				
Current pain[d]	2.3 ± 2.6	2.5 ± 2.4	–0.1 (–1.3 to 1.0)	1.25	0.009‡	0.824
POD 1	2.6 ± 2.7	2.9 ± 2.6				
POD 2	2.0 ± 2.5	2.2 ± 2.2				
			Ratio of geometric means (95% CI)§			
Cumulative opioid consumption, mg in POD 1 and 2	15 [0, 35]	25 [5, 45]	0.6 (0.2 to 1.8)	1.20	0.108	NA
POD 1	5 [0, 15]	10 [0, 20]				
POD 2	10 [0, 20]	10 [0, 20]				

Values are reported as mean ± SD or median [interquartile range], as appropriate. POD, postoperative of day.

*Estimated from a linear mixed-effects regression model with an unstructured correlation structure. This model adjusted for age and used a noninferiority delta of 1.25 (*i.e.*, the mean for the suture treatment can be no more than 1.25 points worse than the through-the-needle method to claim noninferiority). Noninferiority also claimed if upper limit of the 95% CI was less than 1.25.

†Noninferiority *P* value obtained from a one-tailed *t* test using a test statistic defined as $T_{NI} = \frac{\hat{\beta}_1 - \delta}{SE_{\beta_1}}$, where $\hat{\beta}_1$ is the estimated treatment effect, SE_{β_1} is the standard error of the treatment effect, and is the noninferiority delta; noninferiority was claimed if $P < 0.025$.

‡Statistically significant ($P < 0.025$).

§Estimated from a linear regression adjusted for age. [a, b, c, d]Treatment by time interaction $P = 0.908$, 0.609, 0.630, and 0.895, respectively, suggesting no evidence of treatment effect heterogeneity over time on any of the four pain scores.

each of the secondary pain scores was not found to change over the first two days (all treatment-by-time interaction *P* values > 0.15).

For the first two postoperative days, the median [interquartile] cumulative opioid consumption was 15 [0, 35] mg in the Suture group and 25 [5, 45] in the traditional

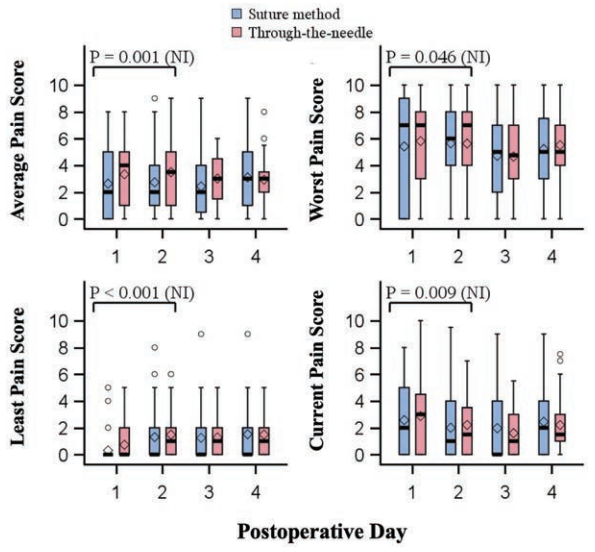

Fig. 5. Effects of the suture *versus* through-the-needle catheter on postoperative pain score over time. Data are expressed as mean (*diamond*) and median (*horizontal bar*) with 25th through 75th (*box*); *whiskers* extend to the most extreme observations within 1.5 times the interquartile range of the first and third quartiles, respectively; *circles* represent outliers. At the 0.025 significance level, using a noninferiority delta of 1.25 points, the suture method was found noninferior to the through-the-needle method for average pain score, least pain, and current pain on the first two postoperative days, but not on worst pain.

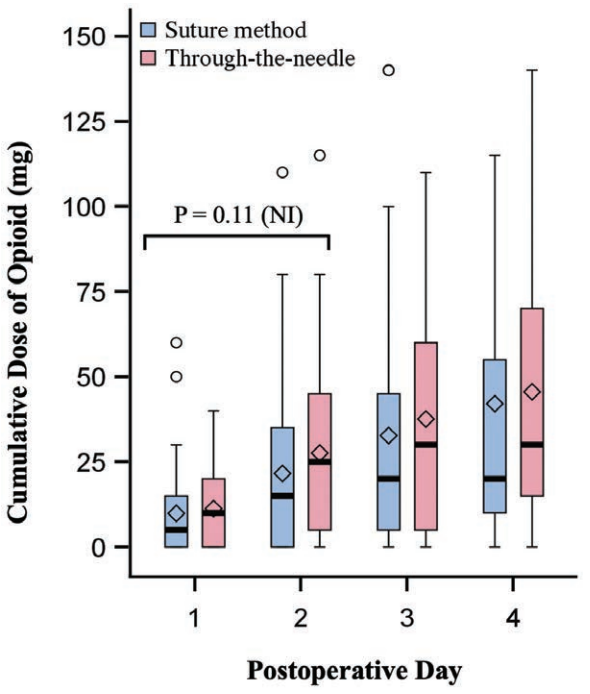

Fig. 6. Effects of the suture *versus* through-the-needle catheter on postoperative opioid consumption over time. Data are expressed as mean (*diamond*) and median (*horizontal bar*) with 25th through 75th (*box*); *whiskers* extend to the most extreme observations within 1.5 times the interquartile range of the first and third quartiles, respectively; *circles* represent outliers.

group (fig. 6). The estimated ratio of geometric means of the suture group compared with the traditional group on opioid consumption through the first two days was 0.6 (95% CI, 0.2 to 1.8), adjusting for age. Noninferiority was not found on cumulative opioid consumption because the upper limit for the CI was above the noninferiority delta of 1.2 ($P = 0.108$).

Whereas the suture method had a lower risk of leaking fluid (6% *vs.* 31%) compared with the through-the-needle method ($P = 0.006$), no differences were found between the treatment groups for any of the other secondary outcomes (table 3). No suture-style catheter was completely dislodged (0%), whereas the tips of three (9%) traditional catheters were found outside of the skin before purposeful removal on postoperative day 3 ($P = 0.239$). Neither group experienced any local anesthetic side effects.

Adverse Events

One patient in the suture group who had undergone an open reduction, internal fixation of a pilon-type ankle fracture was readmitted approximately 10 h after discharge complaining of severe pain and swelling in the operative leg, chest pain, and shortness of breath. He was diagnosed with a deep vein thrombosis in the operative leg and a pulmonary embolus. With appropriate anticoagulation therapy, his symptoms resolved over the following 12 h and he was discharged the following day. No falls, catheter-related infections, or nerve injuries were observed in either group.

Discussion

Described in 1946, the first continuous peripheral nerve block comprised a needle fixed adjacent to the brachial plexus using a cork secured with tape, permitting local anesthetic readministration throughout the surgical procedure lasting multiple hours.[12] However, to administer local anesthetic for multiple days, a catheter is required and was first described in 1951 to treat intractable hiccups.[2] In this report, a straight, hollow-bore needle was percutaneously inserted to lie adjacent to the phrenic nerve, after which a polyethylene catheter was placed through the needle, the needle was removed over the catheter, and the catheter was then secured in place using cutaneous collodion. Although various design revisions such as the stimulating catheter were developed,[13] the basic technique of inserting a catheter either through or over a straight, hollow-bore needle has remained unchanged since the first report. However, in 2015, a suture-shaped needle and trailing catheter were

Table 3. Comparisons of the Suture Method *versus* Through-the-needle on Tertiary Outcomes

Tertiary Outcomes	Suture-catheter (N = 35)	Through-the-needle (N = 35)	*P* Value*
Catheter dislodgement	0 (0)	3 (9)	0.239
POD 1	0	1	
POD 2	0	1	
POD 3	0	1	
Sleep disturbances	20 (57)	26 (74)	0.131
POD 1	13	18	
POD 2	8	21	
POD3	6	5	
POD4	4	9	
Opioid side effects	13 (37)	14 (40)	0.806
POD 1	5	7	
POD 2	7	6	
POD 3	5	7	
POD 4	3	3	
Local anesthetic side effects	0 (0)	0 (0)	NA
POD 1	0	0	
POD 2	0	0	
POD 3	0	0	
Leakage at site	2 (6)	11 (31)	0.006
POD 1	0	7	
POD 2	0	7	
POD 3	2	4	

Values are reported as number of events (%). NA, not available; POD, postoperative day.

*From chi-square or Fisher exact test, as appropriate.

introduced by Rothe *et al.*,[4,5] offering an alternative perineural catheter introduction method for the first time in more than six decades.[1]

Multiple potential benefits were proposed by the original investigators. Because the catheter remains within a two-dimensional plane, the initial placement of the local anesthetic-distributing orifice may be clearly viewed by ultrasound and therefore located precisely adjacent to the target nerve, unlike through-the-needle catheters that rarely remain in plane. Subsequent orifice readjustment is also possible using ultrasound visualization.[6,7] Another theoretical benefit of the suture-catheter design is that there is less likelihood of catheter dislodgement because it is secured at two sites (entry and exit).[14] However, the risk of internal dislocation might actually be increased because there is no slack between the orifice and anchoring locations therefore, the orifice might be pulled away from the nerve, possibly decreasing accurate local anesthetic deposition and thus compromising analgesia. In contrast, through-the-needle catheters usually have a variable amount of slack inserted between the catheter tip/orifice(s) and the skin anchor, allowing for a good deal of catheter retraction/withdrawal before the catheter tip location is altered relative to the nerve.[15] In fact, a recent case series involving suture-type adductor canal catheters in volunteers reported a 100% success rate for initial in-plane, short-axis insertions, whereas 20% (3 of 15) were found to be displaced internally when rechecked the following day.[7]

Therefore, the findings of the current randomized, subject-masked, parallel-arm clinical trial are reassuring in that the new suture-type perineural catheters provided noninferior analgesia compared with traditional catheters for continuous popliteal-sciatic blocks after painful foot and ankle surgery. In these ambulatory subjects, the degree to which each type of catheter dislodged internally remains unknown. However, considering that the primary goal of clinicians (and patients) is achieving adequate analgesia—whereas the degree of any internal dislodgement is a surrogate endpoint—we believe that our findings remain highly relevant. The greater incidence of leakage in the traditional group may be an indication of a higher degree of internal orifice dislodgement compared with the suture-type catheters. Alternatively, the decreased leakage may be attributable to the fact that the needle and catheter diameters are equivalent, unlike through-the-needle techniques in which the needle must be larger than the catheter passing internally, leaving a larger hole in the skin relative to the remaining catheter after needle withdrawal.[16]

Relatedly, it is notable that three (9%) through-the-needle catheters were completely dislodged *versus* none in the suture group, although this difference did not reach statistical significance ($P = 0.239$), and the study was not powered to detect a difference in dislodgement rate. Popliteal-sciatic catheters, located behind a highly mobile joint in a location with significant perspiration, are theoretically prone to dislodgement, with traditional catheters secured solely at the insertion site having dislodgement rates reportedly as high as 40%.[17] Many methods of securing catheters to decrease dislodgement have been proposed, including the use of pig-tail shaped catheters, adhesives such as 2-octyl cyanoacrylate glue or other liquid adhesives at the insertion site,[18,19] tunneling,[20] inserting the catheter past the needle tip,[15] securing the catheter to the skin with suture,[21] and various taping/dressing strategies. However, all of these methods have in common the potential disadvantage that they secure a catheter at the level of the skin solely at the entry point, whereas the tip of the (usually flexible) catheter remains unanchored.[17]

Hypothetical increased risks of the new suture-type catheter design must be considered in addition to the theoretical benefits. One possible risk is an increased incidence of infection with two skin penetration sites rather than the single site associated with traditional perineural catheters (no infections occurred in either treatment group of our study).[22] Previous reports of suture-type catheter placement have left a longer tail at the exit site, possibly to increase the ease of subsequently repositioning a displaced catheter.[6,7] However, in ambulatory patients such as those of the current investigation, leaving a long tail at the catheter exit site and asking the patients to sterilize and trim this tail before catheter removal was deemed to be too difficult and unacceptably increase the infection risk for patients or their caregivers to accomplish at home without direct medical supervision. Therefore, a tail of only approximately 1 cm was left at the catheter exit site. To

prevent contamination of this tail during catheter extraction, the patients were specifically instructed to remove the dressing over the entry (proximal) site, withdraw the catheter with gentle traction, and only then remove the exit (distal) site dressing, thus ensuring a contaminated distal catheter end was not withdrawn through the entire catheter track during removal. Risk to the provider should also be considered, and anesthesiologists who choose to use suture-type perineural catheters should be mindful of the risk of needle stick when advancing the needle through the exit site.

Additionally, the curvature of the suture-type needle both limits the possible target nerve depth and adds a level of complexity that requires experience to overcome.[23] The radius of the needle—of which there are currently three available (50, 75, and 120 mm)—combined with the needle length (100 *vs.* 160 mm available) and depth of the target nerve all determine the optimal entry (and exit) points. Perhaps helping to balance this increase in technical challenge, our subjective experience suggests that the curved needle is easier to visualize using ultrasound than linear counterparts.[24] Importantly, at the current time within the United States, there is only one brand of suture-type catheter available and it is cleared for use solely in the lower extremity.

It should be noted that the saphenous nerve block with 20 ml 0.5% ropivacaine with 5 to 10 μg/ml epinephrine was of intermediate duration and likely resolved before the first follow-up telephone call in most or all cases. For this reason, pain scores at all follow-up points were not zero in most subjects and there was likely variability in the contribution of saphenous distribution pain among subjects.

Study Limitations

Although the subjects of this investigation were masked to treatment group assignment, investigators were aware of the randomization results. In addition, the results apply only to the specific local anesthetic type, concentration, volume, and rate of the current study. Similarly, different anatomic locations,[6,7] linear needle catheter brands and designs,[16] suture-type catheter orifice design (a multi-orifice catheter is available), ultrasound approaches (*e.g.*, out-of-plane or long-axis visualization),[6,7,23] and catheter securement techniques (*e.g.*, surgical glue, additional adhesive, tunneling, alternative taping strategies)[18–20] would probably alter the results. The location for the catheter orifice—5 cm proximal to the bifurcation of the sciatic nerve and outside the paraneural sheath—was chosen based on a recent study demonstrating similar analgesic efficacy between this location and a distal, subparaneural placement for popliteal sciatic perineural catheters.[25] However, other recent studies involving single-injection blocks have found evidence for the use of the distal, subparaneural location as the optimal target of popliteal sciatic nerve blocks.[26–28] The results of the present study, therefore, may be more relevant to anesthesiologists who choose a proximal, supraparaneural location for their catheter orifice when performing a popliteal sciatic nerve block. An additional limitation is the imbalance observed for age (absolute standard difference = 1.01), which occurred as a result of chance. To correct for this imbalance, age was adjusted for in all analyses. Finally, although the catheter insertion was considered successful with a decrease in temperature discrimination in the tibial nerve distribution, complete surgical-block success was not assessed.[29]

In conclusion, suture-type perineural catheters provided noninferior analgesia compared with traditional catheters for continuous popliteal-sciatic blocks after painful foot and ankle surgery. Therefore, the new catheter design appears to be a viable alternative to the traditional designs used for nearly 70 yr. However, further study is needed to thoroughly evaluate the risks and benefits of suture-type relative to traditional through- or over-the-needle catheters. Considering the potential benefits of decreased dislodgement and leakage, improved ability to precisely control the placement of the catheter orifice, and the option of adjusting a previously placed catheter under ultrasound visualization, this new catheter design may have the potential to revolutionize perineural catheter placement.

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Ferrosan Medical Devices (Søborg, Denmark) provided an unrestricted research grant and suture-type perineural catheters used in this study. This company was given the opportunity to review the protocol (minor revisions were suggested), but the investigators retained full control of the investigation, including study design, protocol implementation, data collection, data analysis, results interpretation, and manuscript preparation.

Competing Interests

Drs. Finneran, Swisher, Gabriel, Said, Abramson, and Ilfeld: The University of California has received funding and product for other research projects from cryoneurolysis device manufacturers Myoscience (Fremont, California) and Epimed (Farmers Branch, Texas); infusion pump manufacturer Infutronics (Natick, Massachusetts); and a manufacturer of a peripheral nerve stimulation device, SPR Therapeutics (Cleveland, Ohio). In addition, Dr. Ilfeld's institution has received funding for a different research project from a manufacturer of a long-acting bupivacaine formulation, Heron Therapeutics (San Diego, California). Dr. Dalstrom reports being a paid consultant for Wright Medical (Memphis, Tennessee) and Arthrex (Naples, Florida). Dr. Schwartz reports being a paid speaker for DePuy Sythes (Raynham, Massachusetts) and consultant for Globus Medical (Audubon, Pennsylvania), and her husband is an employee of Zimmer (Warsaw, Indiana). The remaining authors declare no competing interests.

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200 West Arbor Drive MC 8770, San Diego, California 92103-8770. jfinneran@ucsd.edu. Information on purchasing reprints may be found at www.anesthesiology.org or on the masthead page at the beginning of this issue. Anesthesiology's articles are made freely accessible to all readers, for personal use only, 6 months from the cover date of the issue.

References

1. Ilfeld BM: Continuous peripheral nerve blocks: An update of the published evidence and comparison with novel, alternative analgesic modalities. Anesth Analg 2017; 124:308–35
2. Sarnoff SJ, Sarnoff LC: Prolonged peripheral nerve block by means of indwelling plastic catheter; treatment of hiccup; note on the electrical localization of peripheral nerve. Anesthesiology 1951; 12:270–5
3. Ilfeld BM: Continuous peripheral nerve blocks: A review of the published evidence. Anesth Analg 2011; 113:904–25
4. Rothe C, Steen-Hansen C, Madsen MH, Lundstrøm LH, Heimburger R, Jensen KE, Lange KH: A novel suture method to place and adjust peripheral nerve catheters. Anaesthesia 2015; 70:791–6
5. Rothe C, Steen-Hansen C, Madsen MH, Lange KH: A novel concept for continuous peripheral nerve blocks. Presentation of a new ultrasound-guided device. Acta Anaesthesiol Scand 2015; 59:232–7
6. Jordahn ZM, Lyngeraa TS, Grevstad U, Rothe C, Lundstrøm LH, Lange KHW: Ultrasound guided repositioning of a new suture-method catheter for adductor canal block: A randomized pilot study in healthy volunteers. BMC Anesthesiol 2018; 18:150
7. Lyngeraa TS, Rothe C, Grevstad U, Lundstrøm LH, Lange KHW: Adductor canal block with a suture-method catheter: A parallel or perpendicular approach? Acta Anaesthesiol Scand 2019; 63:523–30
8. Mendoza TR, Chen C, Brugger A, Hubbard R, Snabes M, Palmer SN, Zhang Q, Cleeland CS: The utility and validity of the modified brief pain inventory in a multiple-dose postoperative analgesic trial. Clin J Pain 2004; 20:357–62
9. Austin PC: Type I error rates, coverage of confidence intervals, and variance estimation in propensity-score matched analyses. Int J Biostat 2009; 5:Article 13
10. Mascha EJ, Sessler DI: Equivalence and noninferiority testing in regression models and repeated-measures designs. Anesth Analg 2011; 112:678–87
11. Monahan AM, Madison SJ, Loland VJ, Sztain JF, Bishop ML, Sandhu NS, Bellars RH, Khatibi B, Schwartz AK, Ahmed SS, Donohue MC, Nomura ST, Wen CH, Ilfeld BM: Continuous popliteal sciatic blocks: Does varying perineural catheter location relative to the sciatic bifurcation influence block effects? A dual-center, randomized, subject-masked, controlled clinical trial. Anesth Analg 2016; 122:1689–95
12. Ansbro FP: A method of continuous brachial plexus block. Am J Surg 1946; 71:716–22
13. Boezaart AP, de Beer JF, du Toit C, van Rooyen K: A new technique of continuous interscalene nerve block. Can J Anaesth 1999; 46:275–81
14. Finneran JJ IV, Gabriel RA, Swisher MW, Said E, Doan CN, Hamilton JR, Ilfeld BM: Suture catheter for rescue perineural catheter placement when unable to position a conventional through-the-needle catheter: A case report. A A Pract 2019; 13:338–41
15. Ilfeld BM, Sandhu NS, Loland VJ, Madison SJ, Suresh PJ, Mariano ER, Bishop ML, Schwartz AK, Lee DK: Ultrasound-guided (needle-in-plane) perineural catheter insertion: The effect of catheter-insertion distance on postoperative analgesia. Reg Anesth Pain Med 2011; 36:261–5
16. Ip VH, Rockley MC, Tsui BC: The catheter-over-needle assembly offers greater stability and less leakage compared with the traditional counterpart in continuous interscalene nerve blocks: A randomized patient-blinded study. Can J Anaesth 2013; 60:1272–3
17. Hauritz RW, Pedersen EM, Linde FS, Kibak K, Børglum J, Bjoern S, Bendtsen TF: Displacement of popliteal sciatic nerve catheters after major foot and ankle surgery: A randomized controlled double-blinded magnetic resonance imaging study. Br J Anaesth 2016; 117:220–7
18. Klein SM, Nielsen KC, Buckenmaier CC III, Kamal AS, Rubin Y, Steele SM: 2-octyl cyanoacrylate glue for the fixation of continuous peripheral nerve catheters. Anesthesiology 2003; 98:590–1
19. Auyong DB, Cantor DA, Green C, Hanson NA: The effect of fixation technique on continuous interscalene nerve block catheter success: A randomized, double-blind trial. Anesth Analg 2017; 124:959–65
20. Ekatodramis G, Borgeat A: Subcutaneous tunneling of the interscalene catheter. Can J Anaesth 2000; 47:716–7
21. Klein SM, Greengrass RA, Gleason DH, Nunley JA, Steele SM: Major ambulatory surgery with continuous regional anesthesia and a disposable infusion pump. Anesthesiology 1999; 91:563–5
22. Nicolotti D, Iotti E, Fanelli G, Compagnone C: Perineural catheter infection: A systematic review of the literature. J Clin Anesth 2016; 35:123–8
23. Fredrickson M: Promoting the use of peripheral nerve catheters: Better catheter accuracy or more user-friendliness? Anaesthesia 2017; 72:939–43
24. Ilfeld BM, Fredrickson MJ, Mariano ER: Ultrasound-guided perineural catheter insertion: Three approaches but few illuminating data. Reg Anesth Pain Med 2010; 35:123–6
25. Sztain JF, Finneran JJ IV, Monahan AM, Khatibi B, Nguyen PL, Madison SJ, Bellars RH, Gabriel RA, Ahmed SS, Schwartz AK, Kent WT, Donohue MC,

Padwal JA, Ilfeld BM: Continuous popliteal-sciatic blocks for postoperative analgesia: Traditional proximal catheter insertion superficial to the paraneural sheath *versus* a new distal insertion site deep to the paraneural sheath. Anesth Analg 2019; 128:e104–8

26. Tran DQ, Dugani S, Pham K, Al-Shaafi A, Finlayson RJ: A randomized comparison between subepineural and conventional ultrasound-guided popliteal sciatic nerve block. Reg Anesth Pain Med 2011; 36:548–52
27. Perlas A, Wong P, Abdallah F, Hazrati LN, Tse C, Chan V: Ultrasound-guided popliteal block through a common paraneural sheath *versus* conventional injection: A prospective, randomized, double-blind study. Reg Anesth Pain Med 2013; 38:218–25
28. Choquet O, Noble GB, Abbal B, Morau D, Bringuier S, Capdevila X: Subparaneural *versus* circumferential extraneural injection at the bifurcation level in ultrasound-guided popliteal sciatic nerve blocks: A prospective, randomized, double-blind study. Reg Anesth Pain Med 2014; 39:306–11
29. Christiansen CB, Madsen MH, Rothe C, Andreasen AM, Lundstrøm LH, Lange KHW: Volume of ropivacaine 0.2% and common peroneal nerve block duration: A randomised, double-blind cohort trial in healthy volunteers. Anaesthesia 2018; 73:1361–7