Vascular Access: Comparison of US Guidance with the Sonic Flashlight and Conventional US in Phantoms[1]

Wilson M. Chang, MD, PhD
Nikhil B. Amesur, MD
Roberta L. Klatzky, PhD
Albert B. Zajko, MD
George D. Stetten, MD, PhD

Purpose: To prospectively evaluate whether ultrasonography (US)-guided vascular access can be learned and performed faster with the sonic flashlight than with conventional US and to demonstrate sonic flashlight–guided vascular access in a cadaver.

Materials and Methods: Institutional review board approval and oral and written informed consent were obtained. The sonic flashlight replaces the standard US monitor with a real-time US image that appears to float beneath the skin and is displayed where it is scanned. In studies 1 and 2, participants performed sonic flashlight–guided needle insertion tasks in vascular phantoms. In study 1, 16 participants (nine women, seven men) with no US experience performed 60 simulated vascular access trials with sonic flashlight or conventional US guidance. With analysis of variance (ANOVA) and power-curve fitting, improvement with practice rate and mean differences between techniques and tasks were examined. In study 2, 14 female nurses (mean age, 50.1 years) proficient with conventional US performed simulated vascular access trials on three tasks with the sonic flashlight and conventional US. With random assignment, half the participants used the sonic flashlight first and half used conventional US first. Mean performance with each technique and that with each task were compared by using ANOVA. In study 3, feasibility of sonic flashlight guidance for access to internal jugular and basilic veins was demonstrated in a cadaver.

Results: For study 1, learning rates (ie, decrease in access time over trials) did not differ for vascular access with sonic flashlight and conventional US. Overall, participants achieved faster vascular access times with sonic flashlight guidance ($P < .007$). In study 2, participants performed procedures faster overall with the sonic flashlight ($P < .02$) and found the sonic flashlight easier to use. In study 3, sonic flashlight–guided vascular access was gained in the cadaver.

Conclusion: Learning and performance of vascular access were significantly faster with the sonic flashlight than with conventional US, and vascular access could be gained in a cadaver; the sonic flashlight is ready for clinical trials.

Supplemental material:
radiology.rsnajnls.org/cgi/content/full/241/3/771/DC1

[1] From the Department of Bioengineering, University of Pittsburgh, 749 Benedum Hall, Pittsburgh, PA 15261. From the 2004 RSNA Annual Meeting. Received September 27, 2005; revision requested November 14; revision received December 21; accepted January 24, 2006; final version accepted February 1. Supported by National Institutes of Health grants 1-R01-EB00860-1 and 1-R01-HL074285-01. **Address correspondence to** W.M.C. (e-mail: *wmchang@gmail.com*).

In most freehand ultrasonography (US)-guided interventional procedures, the US transducer is held in one hand, while the other hand guides a needle into the desired target. During the procedure, the operator's eyes are focused on the US image, which is displayed away from the operating field. Some of the difficulty in learning US-guided procedures stems from the displaced sense of hand-eye coordination, which occurs when the operator has to look away from the operating field to see the display.

To address this difficulty, some researchers have explored nonconventional methods for viewing the US image, patient, instrument, and operator's hands in one environment. Head-mounted display systems have been developed to display a US image as if within the patient (1–4). Despite their promise, head-mounted display systems have yet to overcome substantial obstacles, including lag time, low resolution, limited field of view, weight, and expense. Furthermore, if multiple observers are cooperating in a procedure or are involved in training, each observer requires a separate head-mounted display to observe the same in situ US image.

The sonic flashlight, a device in development at our institution, displays real-time US images inside the patient without the use of positional tracking or a head-mounted display system (5,6). The sonic flashlight fixes the relative geometry of the transducer, display, and a half-silvered mirror, which the operator looks through, to produce a virtual image of the US data inside the patient (Figs 1, 2). The US image appears to float beneath the surface of the skin. It is a *virtual* image in the exact optics sense of the word. For all intents and purposes, each pixel of the US image emanates from its correct anatomic location within the patient, as if being illuminated directly by the sonic flashlight (Fig 2).

The sonic flashlight is viewpoint independent, meaning that any or all users looking through the mirror from any vantage point will see the US image properly registered with the internal anatomy. The sonic flashlight merges the US image, the patient, the instrument, and the operator's hands into one visual environment and eliminates the need to look away from the operating field. This simplifies US-guided interventional procedures by allowing the user to aim directly for the US image (Fig 3). It should be noted that photographs cannot convey the very strong sense that the US image appears within the patient, as if emanating from its correct location.

We hypothesized that vascular access can be learned and performed faster with the sonic flashlight than with conventional US. Thus, the purpose of our study was to prospectively evaluate whether US-guided vascular access can be learned and performed faster with the sonic flashlight than with conventional US and to demonstrate sonic flashlight–guided vascular access in a cadaver.

Advances in Knowledge

- Operators without US experience who learned real-time US-guided vascular access gained access significantly faster ($P < .006$) throughout their learning with guidance from the sonic flashlight than with that from conventional US.
- Operators already proficient in conventional US guidance gained vascular access faster with the sonic flashlight, without prior experience, than they did with conventional US, and they found that the device was easier to use and could be used more intuitively.
- With guidance from the sonic flashlight, vascular access was possible in the internal jugular and basilic veins of a cadaver.

Materials and Methods

Institutional review board approval was obtained for studies involving human participants, and informed consent was obtained prior to enrollment in the studies. The cadaver was obtained and used in this study according to our institutional guidelines, and no special consent was otherwise required from the next of kin.

Sonic Flashlight Prototype

The sonic flashlight prototype is built around a Food and Drug Administration–approved commercially available 10-MHz US probe (Terason 2000; Teratech, Burlington, Mass), a small 44 × 33-mm flat-panel organic light-emitting display (AM550L; Kodak, Rochester, NY), and a 25 × 50 × 2-mm half-silvered mirror with 30% reflectance (Edmund Optics, Barrington, NJ) (Fig 1). Since the sonic flashlight can display US images up to only the size of the flat-panel display, the current prototype is limited to a region 44 mm deep and 33 mm wide. The US probe and the flat-panel display are fixed at 80° on opposite sides of the mirror by a rigid mount.

The US probe on which this version of the sonic flashlight is built is approximately 16 × 54 × 92 mm with a 14 × 54-mm scanning footprint. The sonic flashlight retains the same scanning footprint as that of the probe of 14 × 54 mm, and the size of the entire sonic flashlight is approximately 44 × 57 × 133 mm. The US data from the transducer are transmitted to a laptop computer (Latitude C840; Dell, Round Rock, Tex), which performs the rotation, scale, and translation necessary to display the US image at its correct size and position on the flat-panel display. The US system refresh rate is 22 frames per second, and the components of the sonic flashlight add no appreciable latency (<11

Published online
10.1148/radiol.2413051595

Radiology 2006; 241:771–779

Abbreviation:
ANOVA = analysis of variance

Author contributions:
Guarantors of integrity of entire study, W.M.C., N.B.A., G.D.S.; study concepts/study design or data acquisition or data analysis/interpretation, all authors; manuscript drafting or manuscript revision for important intellectual content, all authors; manuscript final version approval, all authors; literature research, W.M.C., R.L.K.; experimental studies, all authors; statistical analysis, W.M.C., R.L.K.; and manuscript editing, all authors

G.D.S. holds a patent on the sonic flashlight through the University of Pittsburgh, through which he would receive a percentage of any revenue. The patent has not been licensed at this time.

msec as measured with software). The digital US data contain 512 × 128 pixels, which are displayed on the flat-panel display with 521 × 218-pixel resolution, and no loss of display resolution occurs.

Vascular Phantom

We used a custom vascular phantom (Blue Phantom; Blue Phantom Division, Advanced Medical Technologies, Kirkland, Wash) that contained three vessels, which were labeled vessel 1, vessel 2, and vessel 3 (Fig 4). Vessel 1 is a bifurcating vessel that is 5 mm in diameter and is located 9 mm from the surface of the phantom. Directly beneath vessel 1 lies vessel 2, which is a 3-mm-diameter vessel that is 20 mm from the surface of the phantom. Vessel 2 also bifurcates but in the opposite direction from vessel 1. When viewed from above, the two vessels appear similar to a letter *Y* stacked on top of an upside down *Y*. In a separate region from vessels 1 and 2 lies vessel 3, which is a straight vessel that is 4 mm in diameter and is located 15 mm from the surface of the phantom.

Intravenous bags containing dyed saline were attached to each vessel, with green dye in vessels 2 and 3 and red dye in vessel 1. The intravenous bags were suspended approximately 6 inches above the phantom to provide positive pressure, which caused a "flash" of colored fluid in the needle hub when the needle was successfully placed in the vessel. Any penetration of an inappropriate vessel (ie, response error) could be detected according to the fluid color. The process involved in vascular access is reviewed in Movie E1 (*radiology.rsnajnls.org/cgi/content/full/241/3/771/DC1*).

Study 1: Learning and Statistical Analysis

Sixteen medical students with no US experience were randomized to either the sonic flashlight group or the conventional US group, with eight participants per group. The sonic flashlight group included three men and five women (mean age, 23.1 years; range, 21–25 years). The conventional US group included four men and four women (mean age, 24.3 years; range, 22–28 years). Participants attended standardized tutorials about how to use their respective device and how to perform the procedures before starting. The tutorials consisted of a description about how to use their respective device; what the US image represented; how to locate, aim, and guide a needle in a cross-sectional US scan of a vessel; and, last, a demonstration. Both tutorials included instruction about how to gauge depth and size of the target.

The tutorials for the two techniques differed only in where to look at the US image and how to aim at a target within the image. For both techniques, participants were instructed to orient the probe at a 90° angle to the surface of the phantom. The participants in the conventional US group were instructed to center the target horizontally within the scanning plane and to insert the needle out of plane at an approximately 45° angle relative to the scanning plane. They were shown that the needle entry point would thus be the same distance away from the scanning plane as the target depth. The participants in the sonic flashlight group were instructed to insert the needle out of plane at any entry angle. Both tutorials lasted approximately 5 minutes. All tutorials were conducted by one individual (W.M.C.,

Figure 1

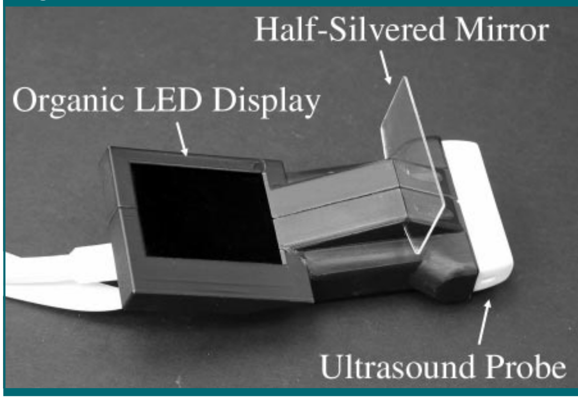

Figure 1: Sonic flashlight, which incorporates a 10-MHz linear probe, a 54.8-mm (diagonal) organic light-emitting display *(LED)*, and a 20 × 50-mm 30% reflective mirror.

Figure 2

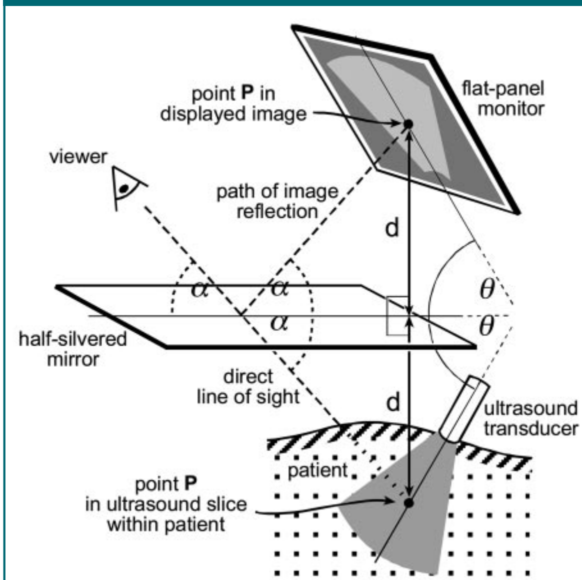

Figure 2: Diagram shows how the sonic flashlight functions. Half-silvered mirror bisects the angle between the US section within the patient and the flat-panel monitor. Angle θ is the angle between the flat-panel monitor and the half-silvered mirror, as well as the angle between the half-silvered mirror and the US section. Point *P* in the section and its corresponding location on the monitor are equidistant from the mirror along a line perpendicular to the mirror (distance = *d*). Because the angle of incidence equals the angle of reflectance (angle = α), the viewer (shown as an eye) sees each point in the reflection precisely at its corresponding physical three-dimensional location.

with 2 years of experience with the sonic flashlight and conventional US).

The conventional US machine used in this study was an unmodified unit with a 10-MHz probe, a probe that was identical to that used in the construction of the sonic flashlight. Participants were asked to perform three tasks: tasks A, B, and C (Fig 4). In task A, participants were asked to guide a needle between the bifurcation of vessel 1, without hitting vessel 1, and to access vessel 2. The operator was constrained to a region of the phantom with a gap of less than 23 mm between the bifurcations in vessel 1. In task B, the participants were asked to guide a needle into the right bifurcation branch of vessel 2. In task C, the participants were asked to guide a needle into vessel 3. Participants used a 21-gauge 7-cm-long needle (Boston Scientific, Natick, Mass) for all tasks. Task B was designed to be the most difficult, and task C was designed to be the easiest.

Total time from that when the probe first touched the phantom to a needle flash (ie, the correct colored fluid filled the needle hub) was recorded and included multiple attempts. If at any time the needle entered an incorrect vessel, the participant was asked to remove the needle completely from the phantom and reattempt guidance into the correct vessel. A trial was defined as the completion of one task, and time for completion was recorded from the time the probe touched the phantom until the needle flash occurred. In the course of two sessions, which were approximately 1 week (7–9 days) apart, participants were asked to perform 30 trials per session, for a total of 60 trials. Each session included a series of three-trial blocks, and each block contained one trial each of tasks A, B, and C performed in randomized order (eg, tasks B, A, and C; tasks C, B, and A; tasks A, C, and B, etc). Upon completion of the study, each participant had completed 20 successive blocks or 20 trials at each task.

The data analysis focused on three issues: First, is there a difference in the time to perform vascular access with the sonic flashlight compared with that with conventional US? Second, do users of the techniques become more proficient (ie, demonstrate learning) with time, and if so, is the rate of learning different for the two techniques? Third, are the first two questions moderated by the difficulty of the task being performed? For example, do the techniques differ most when the task is most difficult? These issues were addressed with analysis of variance (ANOVA), a method that allows the variability in a set of observations to be attributed to the manipulated variables in an experiment or, alternatively, to be attributed to noise. The test for a significant difference was applied to each variable and to interactions among variables.

We assessed effects of technique and learning by using a mixed ANOVA, which included factors of technique (guidance with the sonic flashlight vs guidance with conventional US, between-participant factor), trial (n = 20, within-participant factor), and task (n = 3, within-participant factor). In this analysis, the main effect of technique was used to test for mean differences in access time between the use of the sonic flashlight and that of conventional US. Learning, or the decrease in access time with practice, was indicated by an effect of trial, and variations in the rate of learning across techniques were indicated by the interaction between trial and technique. The interaction between task and technique indicates whether the effects of technique are comparable, given tasks of different difficulty, and the interaction between task and trial similarly indicates whether the learning rate varies with the difficulty of the task. For all ANOVAs, α was set at a significance level of .05.

To compare the techniques after performance had stabilized, we considered only the last five trials with each target. We compared guidance with the sonic flashlight and that with conventional US with a one-tailed t test, given our a priori hypothesis of an advantage for the sonic flashlight. For this comparison, α was set at a significance level of .05.

In our final analysis, we fit the access times as a function of trial number with a power function to describe the rate of learning. To quantify the learning rate, we fit a power function to the mean access time according to trial number for each technique. The function takes the following form: $T = a \cdot N^{-b}$, where T is access time, a is base-

Figure 3

Figure 3: Left: Overview of vascular access in phantom with sonic flashlight. Right: Operator's view through sonic flashlight. The operator sees the US image displayed exactly where it is being scanned, and the needle can be aimed directly at the vessel (arrow indicates needle within vessel lumen). Note that photographs cannot convey the very strong sense that the US image appears within the patient, as if emanating from its correct location.

line access time, N is trial number, and b is the learning rate.

If one considers the relationship between log performance time and log of trial number, the parameter a represents the baseline access time and b is a parameter that indicates the learning rate. An alternative to the power function would be an exponential function. Generally, however, human performance curves are approximated less well with an exponential function, which assumes a constant proportional decrease in access time over trials, than with a power function, which assumes that the returns from practice diminish over trials (7). Study 1 statistics were performed by using software (StatView, version 5.0.1, 1998; SAS Institute, Cary, NC).

Study 2: Proficient Conventional US Users and Statistical Analysis

In this study, we compared the use of the two techniques in a more skilled population. The study population consisted of 14 intravenous access team nurses (14 women; mean age, 50.1 years; range, 39–66 years) from our institution who were trained in US-guided peripherally inserted central catheter placement and placed these catheters in patients at the bedside on a daily basis. By using the same vascular phantoms and tasks as in study 1, participants (with exceptions noted later) performed 24 vascular access trials with the sonic flashlight and 24 with conventional US in two sets where the technique was held constant. Across participants, order of techniques was counterbalanced. Use of the second technique immediately followed use of the first technique, with no separation in time. The time of each trial was recorded. The trials included three-trial blocks, and each block consisted of the three tasks in random order in the same manner as was used in study 1.

For each participant, the first six trials (two trials with each task) were considered practice trials to familiarize the participants with the experimental procedures and equipment. Therefore, six trials per participant for each combination of task and technique were used in the data analysis. The first three participants only completed 18 trials per technique, and thus only four trials per task with each technique were available for data analysis. This was a result of a protocol change after the study began, and this change was implemented to increase the amount of data collected. The conventional US machine used in this study was an unmodified unit with a 10-MHz probe, a probe that was identical to that used in the construction of the sonic flashlight. Before use of each technique, the participants attended the same standardized tutorial about the use of the sonic flashlight and conventional US as those in study 1 attended. All tutorials were conducted by the same individual who conducted them in study 1.

ANOVA of the mean access time was performed with three factors: technique (sonic flashlight vs conventional US, within-participant factor), task (tasks A, B, and C; within-participant factor), and order of technique (sonic flashlight in first set vs conventional US in first set, between-participant factor). The value for α was set at a significance level of .05. The main effects in this analysis were used to test for differences between the techniques and the tasks, and the interaction between technique and task addresses whether the difference between guidance with conventional US and that with the sonic flashlight varies with the task. The further inclusion of order of technique as a factor addresses whether the outcomes were affected by which technique the participant used first, in which case interactions between other factors and order of technique would be found. Statistical analysis for study 2 was conducted by using the same software as was used for statistical analysis in study 1 and spreadsheet software (Excel, version 11.2, 2004; Microsoft, Redmond, Wash).

After completion of all the trials with both techniques, participants were asked to complete a questionnaire containing six subjective questions that were used to compare guidance from the sonic flashlight with that from conventional US. The questions included a set of responses that could be chosen for assessment and addressed the following: *(question a)* ease of procedural performance (assessed with a response scale of 1–5, where 1 signified "much easier" and 5 signified "much harder"), *(question b)* ease of US interpretation (assessed with the same response scale as was used for question *a*), *(question c)* degree to which the mirror impeded the procedure as a result of blocking the view (assessed with a response scale of 1–5 where 1 signified "disagree strongly" and 5 signified "agree strongly"), *(question d)* degree to which sighting through the mirror increased the difficulty of the procedure (assessed with the same response scale as was used for question *c*), *(question e)* effect of the smaller image from the sonic flashlight on interpretation of the US image relative to the conventional US image (assessed with a response scale of 1–5 where 1 signified "much easier" and 5 signified "much harder"), and *(question f)* whether the image with the sonic flashlight helped or hindered aim and guidance for needle placement (assessed with a response scale of 1–3, where 1 signified "helped" and 3 signified "hindered").

Figure 4

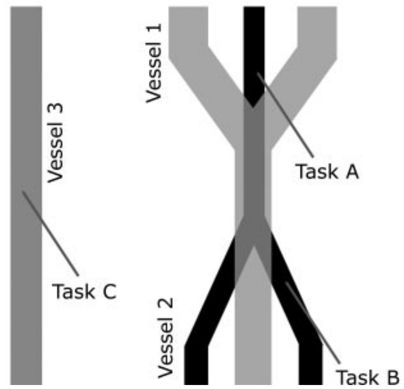

Figure 4: Diagrammatic representation of custom vascular access phantom used in studies 1 and 2. Vessel 1 was 5 mm in diameter and 9 mm deep, bifurcating; vessel 2, 3 mm in diameter and 20 mm deep, bifurcating; and vessel 3, 4 mm in diameter and 15 mm deep, straight. Task A was to access vessel 2 between the bifurcation of vessel 1, without penetrating vessel 1; task B, to access vessel 2 after the bifurcation; and task C, to access vessel 3.

Study 3: Cadaveric Vascular Access

The goal of this study was to perform vascular access in a cadaver to validate the use of the sonic flashlight in the human. In contrast to the first two studies, this study was not performed to attempt to establish statistically reliable efficacy but rather was simply undertaken to demonstrate feasibility. The cadaver was a woman of unrevealed age and cause of death who had received heparin in the course of her treatment prior to death. The neck and right upper arm were scanned by using the sonic flashlight to identify the internal structures, and a 21-gauge 7-cm-long needle was aimed and inserted into the internal jugular vein and basilic vein, sites that would normally be used for a central catheter and a peripherally inserted central catheter, respectively. At each location (neck, arm), there were three needle insertions, and no artifacts were noted from the introduction of air. Successful entry into the lumen was determined by a needle flash in the needle hub. Vascular access was obtained by a practicing interventional radiologist with more than 10 years of experience (N.B.A.).

Results

Study 1: Learning

Figure 5 shows the mean access time and standard error for each technique and task according to trial number. Results of ANOVA indicated a main effect of technique ($F = 10.32$; $df = 1, 14$; $P = .006$); performance was faster overall for the sonic flashlight than for conventional US (mean, 9.63 vs 12.07 seconds, respectively). These results indicate that, with conventional US, access time increases relative to the sonic flashlight by a factor of 1⅓. There was also an effect of task ($F = 39.18$; $df = 2, 28$; $P < .001$); performance of task C was fastest and that of task B was slowest for both techniques. The analysis of interaction between task and technique revealed that the advantage of the sonic flashlight varied with the task ($F = 6.43$; $df = 2, 28$; $P = .005$). Finally, there was a main effect of trial ($F = 25.54$; $df = 19, 266$; $P < .001$) and an interaction between trial and task ($F = 4.13$; $df = 38, 532$; $P < .001$), and these results indicated that there was a decrease in performance time across trials (ie, learning) that varied with the target vessel. Note that there were no significant interactions involving trial and technique, which indicated that the rate of decrease in access time with practice did not significantly differ between the techniques: For interaction between trial and technique, the values were $F = 0.93$, $df = 19$ and 266, and $P = .542$. For interaction among trial, technique, and task, the values were $F = 1.09$, $df = 38$ and 532, and $P = .334$.

To evaluate the variations across task, we conducted ANOVA of the interaction between trial and technique for each task separately. There was a significant effect of trial for tasks A, B, and C in that $F = 23.00$, 11.05, and 7.36, respectively, with $df = 19$ and 266 and $P < .001$ for all tasks. None of the tasks showed an interaction between trial and technique, and this finding supports the implication of the overall results of ANOVA that the practice effect did not differ between conventional US and the sonic flashlight. Specifically, for tasks A, B, and C, the values for interaction between trial and technique were $F = 1.12$, 0.95, and 1.207 and $P = .335$, .522, and .251, respectively, with $df =$ 19 and 266. The effect of technique was significant for tasks B and C, with $F =$ 11.34, $df = 1$ and 14, and $P < .005$ and $F = 5.15$, $df = 1$ and 14, and $P < .04$, respectively; the effect of technique only approached significance for task A, with $F = 3.38$, $df = 1$ and 14, and $P = .088$. This marginal effect appears to reflect high levels of variability in early trials with task A, as the curves can clearly be seen to separate later.

Accordingly, to compare the techniques after performance had stabilized, we considered only the last five trials with each target and compared the sonic flashlight and conventional US with a t test (one-tailed, given our a priori hypothesis of an advantage for the sonic flashlight). All tasks showed a significant advantage for the sonic flashlight of, on average, 1.3, 3.6, and 1.7 seconds with $P = .024$, .005, and .002, for tasks A, B, and C, respectively.

To quantify the learning rate, we fit a power function to the mean access time according to trial number for each

Figure 5

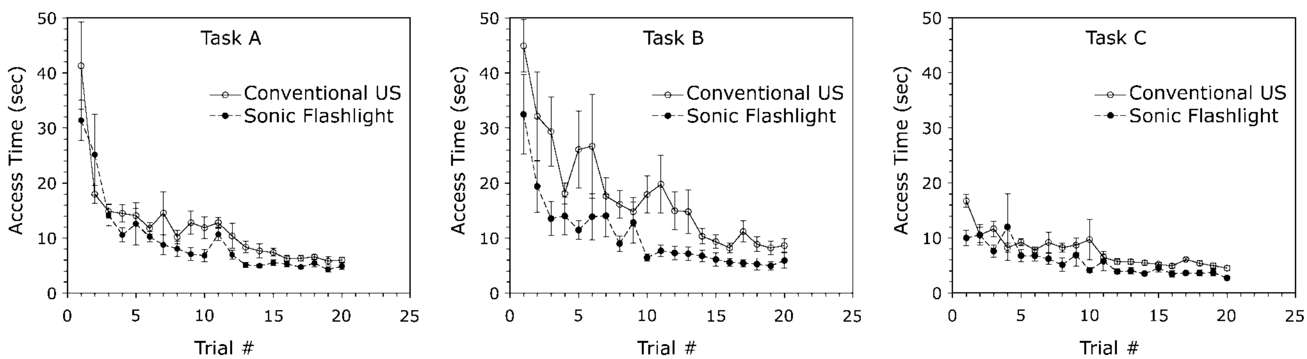

Figure 5: Study 1. Graphs depict mean vascular access time to perform tasks A (left), B (middle), and C (right) as a function of the number of trials with the sonic flashlight versus conventional US for US novices. With all tasks, the sonic flashlight showed an advantage, whereas learning rates were statistically equivalent. Error bars = 1 standard error of the mean.

Parameters of Power Function Fit and R^2 according to Task and Technique

Value*	Task A		Task B		Task C	
	Sonic Flashlight	Conventional US	Sonic Flashlight	Conventional US	Sonic Flashlight	Conventional US
Parameter *a*	32.46	34.13	32.15	52.41	13.92	16.58
Parameter *b*	−0.65	−0.55	−0.60	−0.57	−0.46	−0.39
R^2	0.93	0.88	0.90	0.84	0.80	0.84

* Parameter *a* is the coefficient, parameter *b* is the exponent, and R^2 is the variance accounted for by the power function.

technique. The functions accounted for between 80% and 93% of the variance (R^2) in performance time with trials (Table). Although, for all three tasks, the learning rate parameter, parameter *b*, fit to the sonic flashlight data was greater than that fit to the conventional US data, these differences were not significant with *t* tests (two-tailed) for each task for which we used the standard error of estimation from the power regression: For tasks A, B, and C, respectively, t = 1.59, 0.42, and 1.03 and P = .112, .674, and .303, with df = 38.

Study 2: Proficient Conventional US Users

Mean trial times were compared between techniques across tasks by using ANOVA. None of the effects involving technique order were significant: For order main effect, $F = 1.89$, df = 1 and 12, and P = .195. For interaction between order and task, $F = 2.27$, df = 2 and 24, and P = .125. For interaction between order and technique, $F = 1.57$, df = 1 and 12, and P = .234. For the three-way interaction among order, task, and technique, $F = 0.640$, df = 2 and 24, and P = .536. In Figure 6, the data are combined for technique order to show the access times for task and technique. Most important, there was a main effect of technique, with $F = 7.27$, df = 1 and 12, and $P < .02$; performance with the sonic flashlight was faster than that with conventional US (6.7 vs 9.2 seconds). As in study 1, this finding indicates that access time is increased with conventional US relative to the sonic flashlight by a factor of approximately 1⅓. There was a significant effect of task, with $F = 3.82$, df = 2 and 24, and $P < .037$. The access times were greater for task B (mean, 9.1 seconds) than for tasks A and C (mean, 7.2 and 7.5 seconds, respectively). The interaction between technique and task, which would indicate that the advantage for the sonic flashlight varied with the task, was not significant. We note, however, that the interaction approached significance, with $F = 2.90$, df = 2 and 24, and P = .074; this finding reflects the fact that the advantage of the sonic flashlight was greatest for the slowest task, task B.

Questions *a* and *b* of the questionnaire indicated that 93% (13 of 14) of participants found the procedure much easier or somewhat easier to perform with the sonic flashlight, and 64% (nine of 14) found the results with the sonic flashlight much easier or somewhat easier to interpret. Responses to question *c* were evenly split between whether the mirror did or did not block performance; 50% (seven of 14) of respondents strongly agreed or somewhat agreed, and 50% (seven of 14) of respondents strongly disagreed or somewhat disagreed. Responses to question *d*, which considered the negative effect of the mirror on sighting the image, showed that 79% (11 of 14) of respondents disagreed strongly or disagreed somewhat. With respect to reading the smaller image with the sonic flashlight (question *e*), 57% (eight of 14) of respondents thought that the sonic flashlight image made interpretation much easier or somewhat easier, whereas 14% (two of 14) indicated that interpretation was somewhat harder (none indicated a strong negative effect). In regard to question *f*, 93% (13 of 14) of the participants responded that having the US image inside of the phantom helped in aim and guidance, and none responded that having it there hindered the procedure.

Figure 6

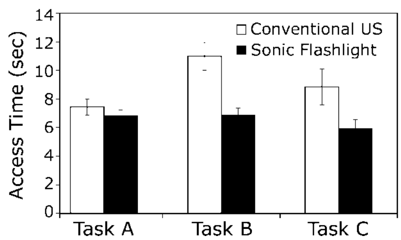

Figure 6: Study 2. Graph depicts mean vascular access time to perform tasks A, B, and C with the sonic flashlight versus conventional US for nurses proficient with conventional US. Performance was significantly faster with guidance from the sonic flashlight than from conventional US ($P < .036$). Error bars = 1 standard error of the mean.

Study 3: Cadaveric Vascular Access

The internal anatomy was visualized in situ by using the sonic flashlight, with the carotid artery and internal jugular vein identified in the neck and the basilic vein identified in the arm. The needle was aimed and inserted into the internal jugular vein and the basilic vein at the first attempts, and the needle tip was visualized at the expected location (Figs 7, 8). When the needle entered the veins, blood freely flowed out of the needle hub (Fig 8).

Discussion

US is increasingly used to guide venous access procedures because it has been shown to increase accuracy, safety, and patient comfort (8–12). Even though US has been shown to be a safer alternative to traditional venous access methods, there is a steep learning curve associated with effective use of it for freehand needle guidance. Vascular access, along with drainage catheter placement and biopsy, is a clinical application in which use of the sonic flashlight may be particularly well suited. We have previously shown that the sonic flashlight can be used in areas of medicine in which real-time US guidance is not traditionally used, and these areas are retrobulbar injection guidance (5), joint injection and drainage, and intraoperative neurosurgical tumor biopsy (13). The present work represents the first direct comparison between the sonic flashlight and conventional US for guidance.

In study 1, we compared the effects of practice and initially hypothesized that the sonic flashlight group would show faster learning and have a faster vascular access time once they achieved proficiency. Results of this study support the general conclusion that the sonic flashlight leads to overall faster performance than does conventional US. Although the learning rate was not shown to be significantly different, the advantage of the sonic flashlight is initially present and remains essentially constant with practice ($P < .006$). Results in study 2 showed that proficient conventional US users performed vascular access significantly faster with the sonic flashlight ($P < .02$), despite that they had no prior training with the device, and that participants almost unanimously judged the procedures easier to perform with the sonic flashlight. These results strongly suggest that performance with the sonic flashlight is easier and faster than with conventional US, at least in phantoms. Findings in our feasibility study in a cadaver support this suggestion.

Our choice of a through-plane insertion of the needle reflects the approach used by our particular clinical colleagues in placing peripherally inserted central catheters and other central catheters. Venous access and other US-guided procedures often are performed by constraining the needle to the plane of the scan, with or without a needle guide, and showing the complete path of the needle to avoid hitting critical structures. The sonic flashlight also can be used to perform in-plane procedures, without the constraint of a needle guide. Furthermore, for through-plane procedures, the operator can sweep the sonic flashlight through the path of the needle to avoid critical structures and provide an in situ three-dimensional sense of the anatomy.

Our positive conclusions about the promise of the sonic flashlight should be tempered by examining the limitations of this study. The measurement used in studies 1 and 2 to compare the sonic flashlight and conventional US was the time to successful vascular access, with all trials ending in successful access. A better metric in the clinical setting would be successful versus failed access, since these are the actual outcomes with clinical importance. Failure to achieve access by the nurse at the bedside usually leads to referral to the interventional radiologist. The selection of time as the measurement for comparison was necessitated by the limitations of the current vascular phantoms. No phantom currently available, to our knowledge, can simulate the difficulty of vascular access in real tissues (eg, vessels "rolling" away from the needle and heterogeneous tissue types). Therefore, it was unlikely for a participant to fail in an access attempt.

Other measurements were considered but were deemed unreasonable or impractical to measure. For example, although the number of attempts, or sticks, per successful access might seem like a logical measurement, it is difficult to clearly define one attempt: What if the needle is only partially withdrawn from the phantom and the trajectory is

Figures 7, 8

Figure 7: Study 3. Access of the left internal jugular vein in the cadaver. Arrow indicates needle tip within the vessel lumen.

Figure 8: Study 3. Access of the right basilic vein in the cadaver. A flash in the needle hub indicated successful access. Arrow indicates needle tip within the vessel lumen.

re-aimed, with the needle tip remaining within the phantom? Time to success was the only consistently measurable variable. We plan to compare guidance with the sonic flashlight and conventional US in the clinical setting by performing a randomized controlled trial by using guidance with these techniques in human patients and measuring actual success and failure rates in addition to mean access times. Before this large-scale study can be performed, a small-scale safety and feasibility study will first be conducted.

In summary, we demonstrated the first comparison between the sonic flashlight and conventional US. First, novices who are learning US-guided vascular access perform consistently faster with the sonic flashlight than with conventional US throughout their learning to proficiency. Second, performance in users already proficient in conventional US guidance is faster with use of the sonic flashlight, despite no prior experience with the device, and these users find the sonic flashlight subjectively easier to use. With more experience in the use of the sonic flashlight, we would expect the differences in access times and ease of use to further increase. Third, we showed that vascular access is possible in the cadaver. Therefore, we believe that the sonic flashlight is ready for initial clinical trials.

Practical application: Performance with the sonic flashlight is faster even early in the course of learning, and this finding suggests that the device may be particularly well suited for use in areas of medicine where use of US has not been widespread. These areas include emergency medicine, critical care medicine, and anesthesiology. Although this work focused on vascular access, the sonic flashlight could be used in other applications currently performed by using conventional US guidance, and these applications include biopsy and drainage catheter placement.

References

1. Fuchs H, State A, Pisano ED, et al. Towards performing ultrasound-guided needle biopsies from within a head-mounted display. In: Lecture notes in computer science. Vol 1131, Visualization in biomedical computing. Hamburg, Germany: Springer, 1996; 591–600.
2. Sauer F, Khamene A, Bascle B, Schimmang L, Wenzel F, Vogt S. Augmented reality visualization of ultrasound images: system description, calibration, and features. In: Fourth International Symposium on Augmented Reality—ISAR. New York, NY: IEEE, Association for Computing Machinery, 2001; 30–39.
3. State A, Livingston MA, Garrett WF, et al. Technologies for augmented reality systems: realizing ultrasound-guided needle biopsies. In: SIGGRAPH. New Orleans, La: ACM, 1996; 429–446.
4. Rosenthal M, State A, Lee J, et al. Augmented reality guidance for needle biopsies: an initial randomized, controlled trial in phantoms. Med Image Anal 2002;6:313–320.
5. Chang WM, Stetten GD, Lobes LL Jr, Shelton DM, Tamburo RJ. Guidance of retrobulbar injection with real time tomographic reflection. J Ultrasound Med 2002;21:1131–1135.
6. Stetten GD, Chib V. Overlaying ultrasound images on direct vision. J Ultrasound Med 2001;20:235–240.
7. Newell A, Rosenbloom PS. Mechanisms of skill acquisition and law of practice. In: Anderson JR, ed. Cognitive skills and their acquisition. Hillsdale, NJ: Erlbaum Associates, 1981; 1–53.
8. Yonei A, Nonoue T, Sari A. Real-time ultrasonic guidance for percutaneous puncture of the internal jugular vein. Anesthesiology 1986;64:830–831.
9. Miller AH, Roth BA, Mills TJ, Woody JR, Longmoor CE, Foster B. Ultrasound guidance versus the landmark technique for the placement of central venous catheters in the emergency department. Acad Emerg Med 2002;9:800–805.
10. Tseng M, Sadler D, Wong J, et al. Radiologic placement of central venous catheters: rates of success and immediate complications in 3412 cases. Can Assoc Radiol J 2001;52: 379–384.
11. Sofocleous CT, Schur I, Cooper SG, Quintas JC, Brody L, Shelin R. Sonographically guided placement of peripherally inserted central venous catheters: review of 355 procedures. AJR Am J Roentgenol 1998;170: 1613–1616.
12. Keenan SP. Use of ultrasound to place central lines. J Crit Care 2002;17:126–137.
13. Chang WM, Horowitz MB, Stetten GD. Intuitive intraoperative ultrasound guidance using the Sonic Flashlight: a novel ultrasound display system. Neurosurgery 2005;56:434–437.