Peripherally Inserted Central Catheter Placement Using the Sonic Flashlight

Nikhil B. Amesur, MD, David C. Wang, MD, PhD, Wilson Chang, MD, PhD, David Weiser, BS, Roberta Klatzky, PhD, Gaurav Shukla, BS, and George D. Stetten, MD, PhD

The Sonic Flashlight is an ultrasound (US) device that projects real-time US images into patients with use of a semireflective/transparent mirror. The present study evaluated the feasibility of use of the Sonic Flashlight for clinical peripherally inserted central catheter placements, originally with the mirror located inside a sterile cover (n = 15), then with the mirror outside (n = 11). Successful access was obtained in all cases. Results show that this new design improved visibility, as judged subjectively firsthand and in photographs. The study demonstrated the feasibility of the Sonic Flashlight and the new design to help assure sterility without degrading visibility, allowing further clinical trials involving physicians and nurses.

J Vasc Interv Radiol 2009; 20:1380–1383

Abbreviation: PICC = peripherally inserted central catheter

PERIPHERALLY inserted central catheters (PICCs) are increasingly being used as a safe alternative to direct placement of central catheters, allowing longer dwell times compared with peripheral intravenous catheters. This makes PICCs the preferred access method for many uses, including long-term chemotherapy, hyperalimentation, repeated administration of blood products, and repeated venous sampling. As superficial antecubital and forearm veins become hard to access after multiple punctures, the upper arm becomes the optimal placement site for PICCs. Cannulation at this location requires ultrasound (US) guidance and is most reliably performed by experienced users. The recent trend in miniaturization of inexpensive US machines has prompted an increase in attempted PICC placement at the bedside, but the success rate remains variable, ranging from 67% to 92% according to three separate studies (1–3). Improving this success rate would help alleviate the bottleneck caused by PICC placement in the interventional radiology suite and reduce the risk posed by transporting patients.

Much of the difficulty in learning conventional US-guided procedures stems from the displaced sense of hand-eye coordination that occurs when the operator looks away from the operating field to see the US display, requiring mental computation of the relationship between the needle and the underlying anatomy. Eliminating this cognitive process could make it easier and faster to learn US-guided vascular access procedures, allowing more PICCs to be placed by bedside personnel instead of by experienced interventionalists in the interventional radiology suite.

To address this difficulty, some researchers have explored methods for viewing the US image, patient, instrument, and operator's hands in a single environment. Head-mounted display systems have been developed to superimpose the US image within the patient (4–7). These systems track the location of the US transducer relative to the head-mounted display, so the image can be computed and superimposed by the head-mounted display with the correct stereoscopic perspective and location. To the person wearing the head-mounted display, the US image appears within the patient at its actual physical location. Despite their promise, head-mounted display systems have yet to overcome significant obstacles, including lag time, low resolution, limited field of view, significant weight, and expense. In addition, if multiple observers are cooperating in a procedure, each observer requires a separate head-mounted display to see the same in situ US image.

The Sonic Flashlight (**Fig 1**) uses a novel means to display real-time US images inside the patient without positional tracking or a head-mounted display system (8,9). The Sonic Flashlight

From the Department of Radiology (N.B.A., G.D.S.), University of Pittsburgh Medical Center; Department of Bioengineering (D.C.W., W.C., D.W., G.S., G.D.S.), University of Pittsburgh; and Departments of Biomedical Engineering (D.C.W., W.C., G.S., G.D.S.) and Psychology (R.K.) and Human–Computer Interaction Institute (R.K.), Carnegie Mellon University, Pittsburgh, Pennsylvania. Received September 5, 2008; final revision received June 9, 2009; accepted July 7, 2009. **Address correspondence to** N.B.A., Department of Radiology, University of Pittsburgh Medical Center, 200 Lothrop St., CMT 3936, Pittsburgh, PA 15213; E-mail: amesurnb@upmc.edu

This research has resulted in an issued patent and several pending patents through the University of Pittsburgh, on which G.D.S., D.C.W., and D.W. are listed. None of the other authors have identified a conflict of interest. This study was funded by National Institutes of Health grants R01-HL074285 and R01-EB00860.

DOI: 10.1016/j.jvir.2009.07.002

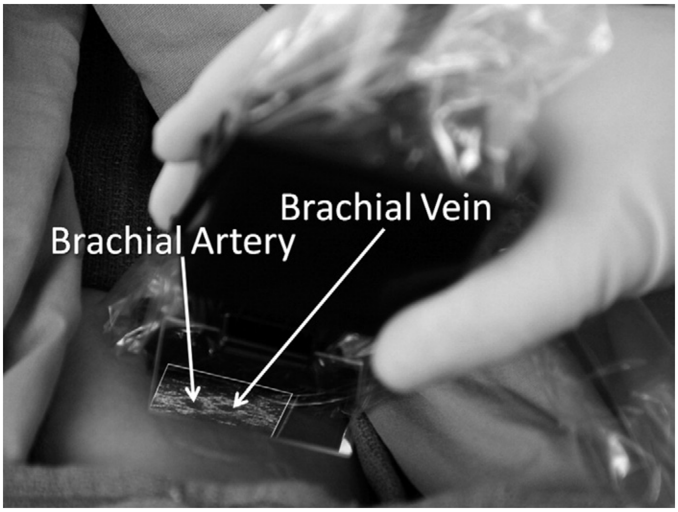

Figure 1. View of the brachial artery and vein through the half-silvered mirror of the Sonic Flashlight. The perceived location of the vessels is independent of viewpoint.

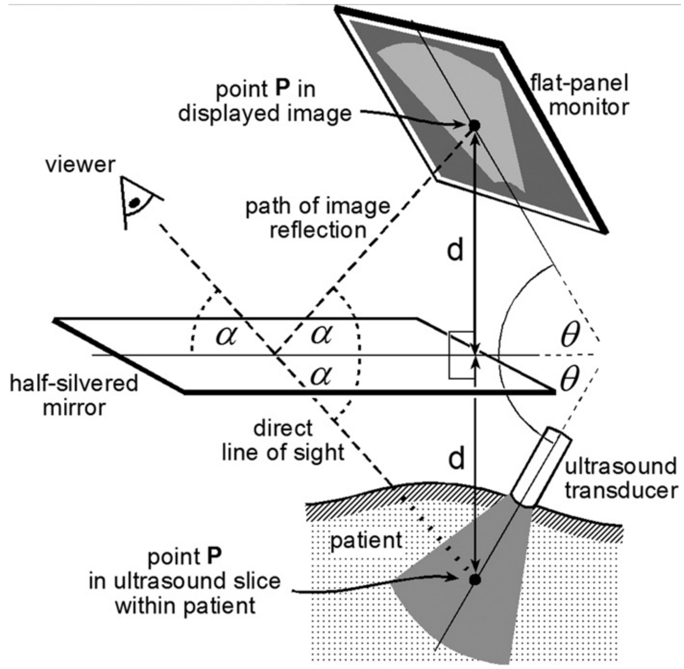

Figure 2. Geometric relationships for the Sonic Flashlight. The mirror bisects the angle between the display and the virtual image. By fundamental laws of optics, the virtual image will appear at its physical location, independent of viewer position.

fixes the relative geometry of the transducer, display, and a half-silvered mirror to produce a virtual image of the US display inside the patient (**Fig 2**). Looking through the half-silvered mirror, the US image appears to float within the patient, with each pixel of the scan seeming to emanate from its correct anatomic location within the patient. With the Sonic Flashlight, the US image, patient, instrument, and operator's hands are all merged into a single environment. This makes US-guided interventional procedures as simple as aiming for the US image itself. The Sonic Flashlight display is viewpoint-independent, meaning that users looking through the mirror from any vantage point will see the US image properly registered with the internal anatomy.

Unlike most conventional US displays, which are magnified to permit greater resolution of fine detail, the Sonic Flashlight display cannot be magnified. It is necessary for the Sonic Flashlight to display the US scan at its actual scale so the images of the underlying structures can appear at their correct locations. This lack of magnification can be a disadvantage for some applications involving very small structures. However, for PICC placement purposes, the true anatomic size is sufficient for identification of the underlying anatomy.

The Sonic Flashlight directly addresses many of the head-mounted display–related issues and has been proven effective in cadaveric retrobulbar injection of the eye (10) and cadaveric jugular vein access (11). It has been shown that, compared with conventional US, vascular access in phantoms with the Sonic Flashlight is faster and easier for experienced US users (12), as well as faster to learn for US novices (13). Precise psychophysical experiments have shown particular advantages in using the Sonic Flashlight versus conventional US by reducing errors in judging target location (14,15). The present study describes the first clinical trial in which an experienced interventional radiologist used the device to place PICCs in patients in the interventional radiology suite.

MATERIALS AND METHODS

During 8 years of development, there have been multiple prototypes of the Sonic Flashlight. The first version ready for clinical use employed a 10-MHz US system (model 2000; Terason, Burlington, Massachusetts), the probe of which was fitted with a small flat-panel display (AM550L organic LED; Kodak, Rochester, New York) and a dedicated half-silvered mirror. A standard transparent disposable sterile probe cover (model 9001C0197; Bard Access Systems, Salt Lake City, Utah) was fitted over the Sonic Flashlight to eliminate cross-contamination between patients. For the first 15 patients, the mirror was attached directly to the Sonic Flashlight inside the sterile cover. For the remaining 11 patients, a subsequent design was employed that used a disposable mirror clipped on outside the sterile cover. To avoid variability between US systems, we used the same Terason US probe with its laptop-based display as the conventional US for comparison.

Under institutional review board approval, we recruited 26 subjects among those who had been referred to the interventional radiology department at our institution to have a PICC placed. After obtaining informed consent from each patient, an experienced interventional radiologist scanned the upper arm with both the Sonic Flashlight and

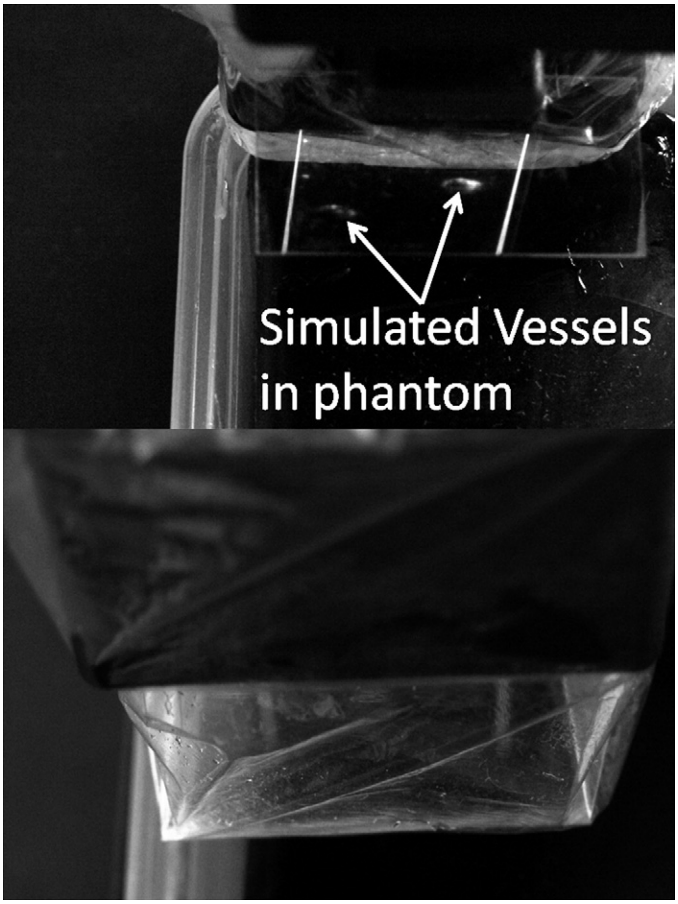

Figure 3. (Top) Initial version. Virtual image of two simulated vessels in a phantom seen through the half-silvered mirror with the plastic probe cover over the base only. (Bottom) The same virtual image seen through the half-silvered mirror with the plastic probe cover over the mirror. Note the degradation of image quality.

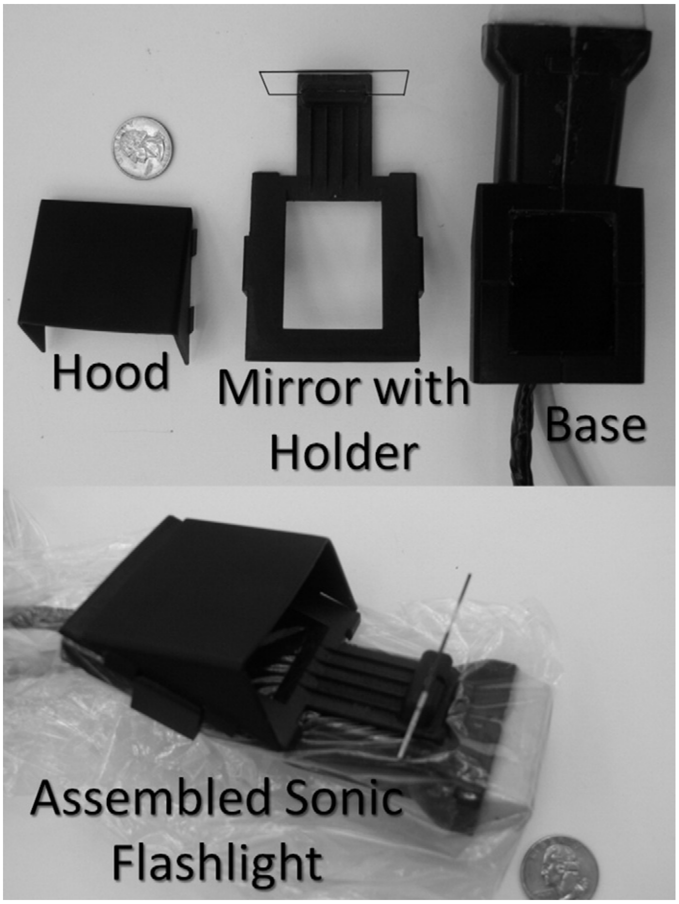

Figure 4. (Top) Revised version. The Sonic Flashlight, separated into three pieces, from left to right: hood, mirror with holder, and base. (Bottom) The assembled Sonic Flashlight with the plastic probe cover enveloping only the base.

conventional US. The same radiologist performed the procedures on all subjects. Identification of the basilic vein, brachial veins, and brachial artery were compared and recorded with each modality. If the identifications by both modalities agreed, it was considered a successful identification. If the basilic vein was visualized with the Sonic Flashlight, the Sonic Flashlight was used to guide a needle (21 gauge, 7 cm) into the basilic vein. The basilic vein was favored as it typically is more superficial and does not present with an accompanying artery, reducing the risk of complications related to arterial puncture. If the basilic vein was determined to be an inappropriate target—eg, it was thrombosed—the brachial vein was used instead. If vascular access was unsuccessful after three attempts with the Sonic Flashlight, the radiologist was to revert to the use of conventional US for the procedure (however, this never occurred in the present study). If successful access was gained in the selected vein, the procedure continued as in a standard PICC procedure.

RESULTS

Our first set of clinical trials involved 15 of the 26 patients (16). The vessels were visualized in situ with the Sonic Flashlight. The identities of the vessels were confirmed by comparison with conventional US. The needle was easily aimed and inserted into the basilic or brachial vein in all cases, and the needle tip was visualized at its expected location. Successful access was obtained in all 15 subjects: 13 on the first attempt and two on the second attempt. Therefore, no case had to be converted to conventional US guidance. However, a problem was noted with probe cover, which enveloped the entire Sonic Flashlight device, including the mirror, to ensure sterility. Commercial probe covers currently marketed as "transparent" are not actually designed to prevent all distortion of visible light. Resulting image blurriness was noted as inconvenient during three procedures, even though it did not affect outcome (**Fig 3**, bottom).

In reviewing the initial trial, it was decided that a redesign of the Sonic Flashlight was required to solve this problem. Accordingly, we created a separate mirror holder that snapped onto the flat-panel display, holding the plastic probe cover flat over the organic LED display. This greatly reduced the diffusive effect of the probe cover on the display (Fig 4). In the process, the mirror was moved entirely outside the cover, eliminating any effect of the cover on the direct line of sight. An optional darkened hood was also added that could be snapped onto the entire apparatus to reduce reflection form ambient light.

The resulting image (Fig 3, top) shows little or no light-distorting effect. As the mirror and hood are now unprotected by the probe cover, they must be sterilized for each patient. We chose to make them disposable to eliminate any risk of cross-patient contamination.

With this new model, successful access was obtained in the remaining 11 subjects: eight on the first attempt, two on the second, and one on the third. The vessels were visualized in situ with substantially greater clarity, as judged by the radiologist, than in the first set of clinical trials. The identities of the vessels were again confirmed by comparison with conventional US. The needle was easily aimed and inserted into the basilic or brachial vein as before, and the needle tip was clearly visualized inside the vessels.

DISCUSSION

The present two-stage study validated our basic design for the Sonic Flashlight and the improvements made to it with the disposable sterile mirror assembly. It showed that the basilic and brachial veins can be safely accessed with use of the Sonic Flashlight for guidance. Although there are insufficient patient numbers to show a statistically significant difference between the previous and current designs, we believe the improved visualization can only aid cannulation. The overall success rate on first puncture attempted by our interventional radiologist was 78%, which is within the 67%–92% range referred to earlier for conventional US guidance. A larger trial would be required for a more accurate comparison.

This initial trial lays the groundwork for an expanded clinical trial comparing bedside personnel's ability to place PICCs using the Sonic Flashlight versus conventional US. Although the Sonic Flashlight does not solve subsequent catheter placement problems such as the inability to advance a PICC centrally, we believe it will help with the initial needle access to the vessel. The Sonic Flashlight permits direct freehand aiming at structures without a needle guide. We hope to show the utility of the Sonic Flashlight in facilitating the use of US guidance by nonradiologists, with the goal of reducing the number of patients who need to be transported to the interventional radiology suite for PICC placement. We also hope to show the utility of the Sonic Flashlight in helping interventional radiologists place catheters in the jugular, subclavian, and femoral veins.

Acknowledgment: The authors thank the staff in the interventional radiology suite, especially Thomas Killcrece, RT, at the University of Pittsburgh Medical Center Presbyterian Hospital for their support in this project.

References

1. Keyes LE, Frazee BW, Snoey ER, Simon BC, Christy D. Ultrasound-guided brachial and basilic vein cannulation in emergency department patients with difficult intravenous access. Ann Emerg Med 1999; 34:711–714.
2. Costantino TG, Fojtik JP. Success rate of peripheral IV catheter insertion by emergency physicians using ultrasound guidance. Acad Emerg Med 2003; 10:487–491.
3. Chinnock BF, Thornton S, Hendey GW. Nurse-performed ultrasound-guided upper extremity venous cannulation in emergency department patients with difficult venous access (abstr.). Acad Emerg Med 2005; 12(suppl):S35.
4. Fuchs H, State A, Pisano ED, et al. Towards performing ultrasound-guided needle biopsies from within a head-mounted display. Presented at Visualization in Biomedical Computing; September 22–25, 1996; Hamburg, Germany.
5. Rosenthal MS, Lee J, Hirota G, et al. Augmented reality guidance for needle biopsies: an initial randomized, controlled trial in phantoms. Med Image Anal 2002; 6:313–320.
6. Sauer F, Khamene A, Bascle B, et al. System description, calibration, and features. Presented at the 4th International Symposium on Augmented Reality; October 29–30, 2001; New York, NY.
7. State A, Livingston MA, Garret WF, et al. Realizing ultrasound-guided needle biopsies. Presented at SIGGRAPH 96, 23rd International Conference on Computer Graphics and Interactive Techniques; August 4–9, 1996; New Orleans, LA.
8. Chang WM, Stetten GD, Lobes LL Jr, Sheldon DM, Tamburo RJ. Guidance of retrobulbar injection with real time tomographic reflection. J Ultrasound Med 2002; 21:1131–1135.
9. Stetten GD, Chib V. Overlaying ultrasound images on direct vision. J Ultrasound Med 2001; 20:235–240.
10. Chang W, Stetten GD, Lobes L, Shelton D. Guidance of retrobulbar injection with real time tomographic reflection. J Ultrasound Med 2002; 21:1131–1135.
11. Chang W, Amesur N, Zajko A, Stetten GD. Cadaveric central venous access using the Sonic Flashlight, a novel ultrasound display system. Presented at the 2004 Meeting of the Radiological Society of North America; November 28 through December 3, 2004; Chicago, IL.
12. Chang W, Amesur N, Zajko A, Stetten GD. The Sonic Flashlight is faster to learn and use compared to conventional ultrasound guidance for vascular access. Presented at the 105th Annual Meeting of the American Roentgen Ray Society; May 15–20, 2005; New Orleans, LA.
13. Chang W, Amesur N, Zajko A, Stetten GD. Sonic Flashlight: a new ultrasound display system that makes vascular access easier (abstr.). J Vasc Interv Radiol 2004; 15(suppl):S166.
14. Wu B, Klatzky R, Shelton D, Stetten GD. Psychophysical evaluation of in-situ ultrasound visualization. special issue on haptics, virtual and augmented reality. IEEE Trans Vis Comput Graph 2005; 6:684–693.
15. Klatzky R, Wu B, Shelton D, Stetten GD. Learning to perform actions in near space under perceptual vs. cognitive control. ACM Trans Appl Percept 2008; 1:1–23.
16. Chang W, Amesur N, Wang D, Zajko A, Stetten GD. First clinical trial of the Sonic Flashlight—guiding placement of peripherally inserted central catheters. Presented at the 2005 Meeting of the Radiological Society of North America; November 27 through December 2, 2005; Chicago, IL.