NickRite: A Novel Design for a Specialized Seldinger Scalpel

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A Novel Design for a Specialized Seldinger Scalpel

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Abstract

The Seldinger technique for catheterization is the current clinical standard for establishing catheter access to blood vessels. Although this technique is widely used, it has several drawbacks that bring about risk of injury to both the operating physician and patient. Due to the fact that the Seldinger technique requires the operating physician to cut at a bleeding insertion point, risks of cutting away from the insertion point or too deeply are high. Additionally, systems that allow a scalpel blade to attach to the guidewire leave the physician vulnerable to injury when attaching the guidewire. Recently, the NickRite, a novel design for a specialized scalpel, was designed and tested, which has the potential to reduce the risks of physical injury to all parties during application of the Seldinger technique. By incorporating wire guidance systems, gear driven precision depth control, and a fully retractable blade, the NickRite prevents injuries to the physician before and after making a cut, and prevents injuries to the patient due to overly deep or laterally imprecise cuts. An early prototype of the NickRite was tested for lateral precision on a human simulation apparatus when compared against a standard disposable scalpel. While results were inconclusive, further testing under more controlled conditions and with a more precisely developed device are expected to show marked improvements over the standard scalpel.

Introduction

The Seldinger technique for catheterization is the current clinical standard for gaining catheter access to blood vessels during surgeries, in particular for angiography and inserting chest drains [1]. Developed in the early 1950's, the technique is a simple five step process (**Figure 1**) with low equipment costs, which has led to its dominance over the past 60 years as the preferred method for catheterization [2]. To begin, a hollow needle is inserted into the vessel of interest. After this, a guidewire is fed through the needle into the vessel, and the needle is removed. The catheter is then fed over the guidewire into the vessel, and the wire is removed, finishing catheterization. Although this technique is relatively simple, and has been used now for decades, there is significant risk posed to the patient and the physician in its application. Because the catheter is of a wider diameter than the hollow needle, the insertion point around the guidewire must be widened to allow for smooth insertion of the catheter. This additional cut is imperative, and usually performed using a standard disposable scalpel. The hazard in this step comes from the fact that once the hollow needle is removed, the insertion site around the guidewire begins to bleed, which obscures the insertion point from physician view and forces them to make a blind cut when widening the insertion point for the catheter. In making this cut by feel, the physician may miss the insertion point laterally, resulting in a skin bridge between the cut and the insertion point, and the need for either an additional cut or a new attempt at catheterization. In addition, the physician has more limited depth perception and control through the pooling blood, which poses a risk of lacerating the blood vessel and inducing the need for additional reparative surgery.

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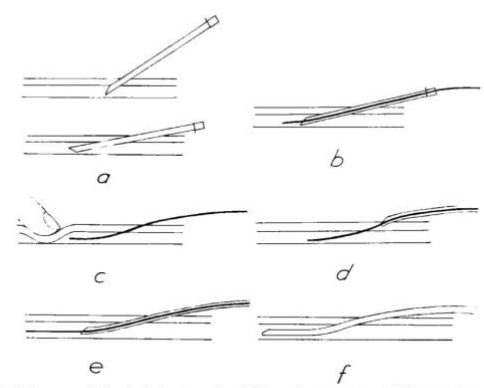

Fig. 2. Diagram of the technique used. a) The artery punctured. The needle pushe upwards. b) The leader inserted. c) The needle withdrawn and the artery compresse d) The catheter threaded on to the leader. e) The catheter inserted into the arter f) The leader withdrawn.

Figure 1: Diagram from original publication of the Seldinger technique, outlining the basic steps of the process. Widening of the insertion point occurs after step c. At this point, the catheter is too wide to fit smoothly into the puncture from the hollow needle, so a cut is made with a standard disposable scalpel. This step is unavoidable to the extent that scalpels are included with Seldinger technique kits.

Lastly, the lack of visibility endangers the physician, increasing the risk of cutting themselves without full view of the blade. This issue also poses a contamination risk should physicians should the blind cut result in accidental laceration of surgical gloves.

Overview of Prior Art

Traditional scalpels are most commonly used currently for application of the Seldinger technique (**Figure 2**). These blades are cheap to purchase and are easily and often used by physicians, therefore they are most often included with Seldinger technique equipment kits. Although they are the current clinical standard, traditional disposable scalpels pose significant risks to patients and physicians in their inherent lateral and vertical imprecision when making a blind cut. While blades such as the Penblade, Guideblade, channel guided scalpel, and the design by a previous capstone team all include elements that increase safety during

Seldinger technique application, the NickRite design combines or improves on the attributes of each to create one optimized device to maximize patient and physician safety [3]–[5]. While the Penblade improves physician safety by allowing for full retraction of the blade into the scalpel when not in use, it does not improve on the lateral or depth imprecision of the blade when making a blind cut. Designs patented for a wire guidance system make improvements to the latter, but not the former. The Guideblade design mitigates all of the risks mentioned above, but the NickRite seeks to improve on the precision level of the depth control. Similarly, the design by a previous capstone team achieves the desired level of depth control, three-dimensional precision, and physician safety measures required, but was unintuitive for immediate use by physicians due to its unique shape and structure. This less intuitive design may pose more danger in the potential for its accidental misuse than even a standard scalpel. It is the goal of the NickRite scalpel to achieve lateral and vertical precision to the level of one millimeter and fully house the blade when not in use while maintaining a shape and structure similar enough to a traditional scalpel that no additional training hours are required before safe use.

NickRite Features

In order to achieve the goals of increased multidimensional precision and physician safety, the NickRite features several components geared towards these goals in a simple design reminiscent of a traditional scalpel. Among these, the NickRite features a rack and gear guided depth controller system which can be activated by the physician from a traditional scalpel grip. The gearing allows for millimeter-level blade extension control, and features a secure locking mechanism that can be activated with the scalpel holding hand to keep the blade from moving once a desired depth is selected. For lateral control, the design features a guidewire channel and single guidance ring. Lastly, for physician protection, the blade is fully retractable into the handle when not in use, or when inserting the guidewire into the guidance channel and ring.

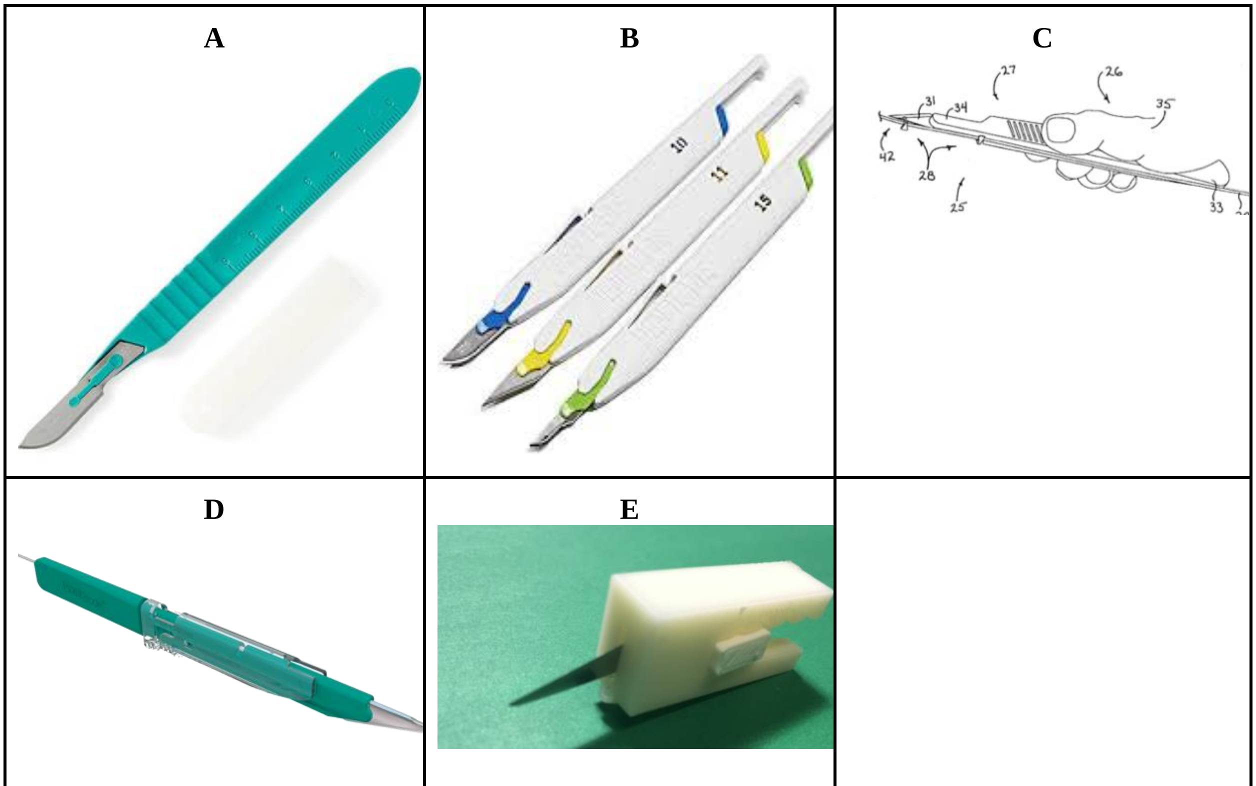

Figure 2: An outline of scalpel designs and design components available for use with the Seldinger technique. **A)** A traditional disposable scalpel. These blades are the current standard for use in catheterization, but also pose the greatest risk to patients and physicians. **B)** The Penblade is a scalpel design developed for physician safety. This blade can be fully retracted into the handle when not in active use for cutting. **C)** A patent was awarded for a scalpel design involving attachment directly to a guidewire system. This design theoretically decreases the likelihood of missing the insertion point by increasing lateral precision, but still leaves depth control to the physician. **D)** The Guideblade was recently developed specifically for the Seldinger technique. This scalpel design features guidewire guidance similar to C, in addition to some level of depth control using the sliding blade guard (the clear component in the figure). The Guideblade also features physician safety measures in the full extension of the blade guard to fully cover the blade when not in use, or when inserting the guidewire into the guidance channel. **E)** A previous University of Virginia undergraduate capstone project team developed a minimalist scalpel design which features wire guidance and depth control using a slider attached to the blade. Although this design reduces the outlined risks of the Seldinger technique, the design was too dissimilar from a standard scalpel, making the device less intuitive to use, and bringing about the need for additional training before safe use.

Results

Components of Finalized Design

After a series of iterations, a finalized design was selected for prototyping and testing using a simulated human apparatus. The design consists of two major components, a handle (also called the housing), and a blade holder (also called the insert). For depth control, it was decided at the onset of the design phase that the mechanism for extending and retracting the blade should be a gear and rack, where the gear is locked in the housing and pushes or pulls the insert along a track. This gearing maintains single millimeter precision while allowing the user to adjust the extension of the blade by manipulating the gear with a single finger from the scalpel holding hand (**Figure 3**). In order to stop the gear from turning and the blade from changing depth

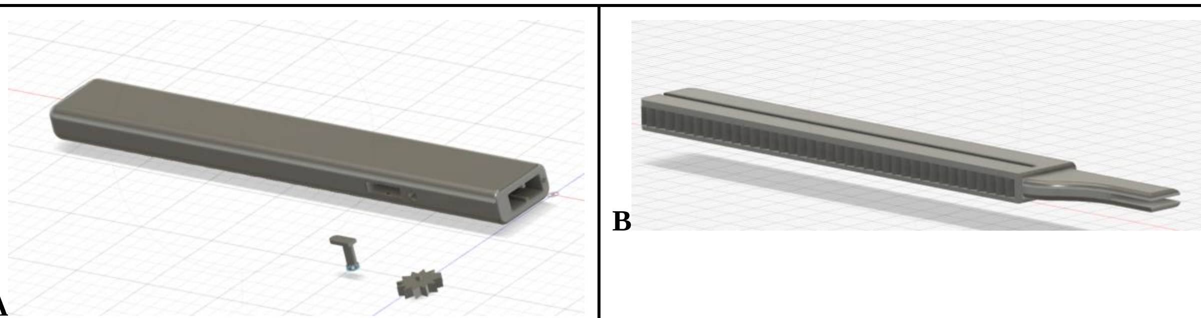

Figure 3: CAD designs for the NickRite. **A)** The housing or handle, with gear and locking swivel. The gear is locked into the housing at the opening along the long face of the handle, so that the gear rotates by manipulation with a finger, pushing the insert (**B**) with attached rack along the tracks in the opening of the handle. The handle also includes a locking swivel, which is inserted just ahead of the gear towards the blade end, so that by turning the swivel the lever arm moves between open gear teeth and prevents further motion of the gear. The blade slides into the end of the insert and is held in place firmly by friction, but it is the intent of the design team that this should be revised in the future to hold custom blades in place by use of an insert into a cutout in the blade, as is the case with a standard scalpel blade.

once a depth is selected, a swivel locking mechanism is included just ahead of the gear towards the blade end of the scalpel, so that when the lock is rotated around a vertical pin, its horizontal arm moves between teeth of the gear, preventing gear rotation forward or backward. To increase lateral precision, the device uses a similar guidance system to the prior art outlined above, where a circular channel runs lengthwise down the blade on the face opposite from the gear. This channel is angled such that when the guide wire is inserted, it is contained within the channel for at least one centimeter for stability, and enters the handle towards the blade end to intersect with the point of a scalpel blade when extended two millimeters from the end of the handle. This guidance system generates the highest lateral precision, directly connecting the blade with the wire, and thereby with the cutting site, while still providing some length of guidewire beyond the exit hole towards the hand end of the handle for use in further stabilizing the apparatus by the operating physician. For physician protection when the blade is not in use, particularly when inserting the guidewire into the housing from the blade end, the blade insert is fully retractable into the handle. In order to make the device highly intuitive, the ratios of dimensions of the handle were kept similar to a traditional scalpel, and the device was designed for use with standard scalpel blades.

Testing Results

To test the effectiveness of the finalized design at improving lateral precision over a traditional disposable scalpel, the design was tested on an apparatus simulating the human operation environment (**Figure 4**). This design consists of a rectangular chamber open on the top face, with four pointed cylinders at the bottom of the chamber which are used to secure model human skin at the four corners during the operation. There is a narrow channel running along the bottom of the chamber which allows for insertion of the needle and guide wire during application of the initial steps of the Seldinger technique. The chamber can be filled above the level of the skin with model human blood to simulate the blind cut environment. For testing an early prototype of the finalized Seldinger scalpel design, a model of this ideal testing apparatus was constructed using model human skin and copper wire. To test the lateral precision of the 3-D printed prototype of the NickRite, a

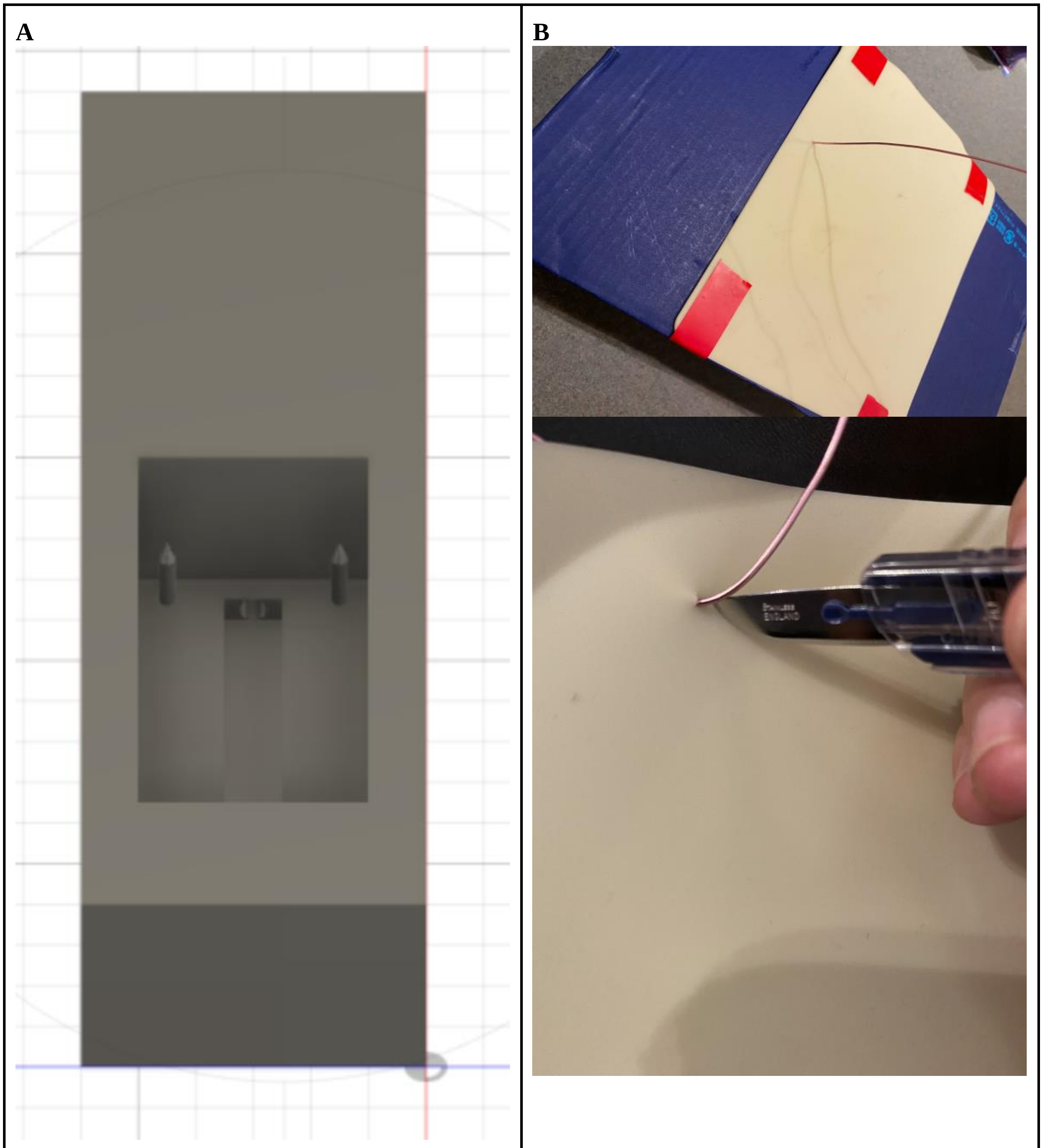

Figure 4: A) Initial model for a human simulation apparatus. This design consists of an open chamber which can be filled with simulated human blood in order to model the blind cut made in the application of the Seldinger technique. There are four points at the bottom of the chamber in the corners where model human skin can be attached by pushing through the spikes. At the bottom, a second open chamber runs lengthwise down the model so that the initial steps of the Seldinger technique can be applied. **B)** Model of the ideal design apparatus, using copper wire and practice tattoo skin. This design was used for testing when manufacturing resources became limited. This model of the testing apparatus was used to test the increase in lateral precision of the NickRite compared to a traditional disposable scalpel.

volunteer unfamiliar with the Seldinger technique was given a brief overview of the process and asked to perform five cuts with each of a traditional scalpel and the NickRite in an unblinded testing scenario. Then, the cutting site was obscured using simulated human blood and the five trials were repeated in this blind cut environment (**Table 1**). After making each cut, the distance from the closest point on the cut to the insertion point where the wire enters the vessel was measured to millimeter exactness. Average distances for the unblinded tests showed the traditional scalpel slightly outperformed compared to the NickRite. The volunteer noted that the NickRite design reduced their freedom of movement in attaching the scalpel to the guidewire, which may have contributed to difficulty making a closer cut when the insertion point is visible. For blinded tests, the NickRite average distance is much lower on average than the traditional scalpel, however the variance in distances in all test results makes these findings inconclusive due to lack of statistical significance. The volunteer also noted that moving along the guidewire was worth the limited mobility in the blinded trials, as getting near to the insertion point was guaranteed due to the physical attachment of the handle to the guide.

	Unblinded Distance Average (n=5)	Blinded Distance Average (n=5)
Standard	0.6 +/- 0.8 mm	2.4 +/- 0.74 mm
NickRite	0.8 +/- 1.7 mm	1.2 +/- 1.5 mm

Table 1: A prototype of the NickRite was tested using a model of the ideal human simulation apparatus. Five cuts were performed by a volunteer using each blade in both blinded and unblinded testing environments.

Discussion

Although the testing results were quantitatively inconclusive, it is expected that more testing using a more precisely machined prototype would show clear advantage in using the NickRite design over a traditional scalpel. Due to manufacturing limitations associated with COVID-19, the testing was performed using a first print of the finalized design, which did not have working depth control or gearing due to the limited precision of 3-D printers used. Additionally, the model testing apparatus was less secure than the ideal design, and copper wire was used rather than the more flexible guidewire typically used in the Seldinger technique. It was expected that these elements may limit the conclusiveness of the experiment. In the initial ideal timeline, the design iteration phase includes rapid prototyping using 3-D printing to generate proof of concept prototypes with functional components made to scale. After printing of a finalized working prototype was complete, it was expected that the design would move to high precision machining to produce exact prototypes at experimental scale using sterile materials. These machined prototypes were then expected to be used for testing in the printed human simulation apparatus, then eventually tested on animal models. Testing was expected to include depth and lateral movement control as well as testing of safety features. This testing was also expected to compare several blade types, including a traditional scalpel and the Guideblade. It is predicted that if this ideal protocol is followed in the future, clear improvement over prior art will be measured.

Limitations, challenges, and areas for future work

Although the NickRite Seldinger scalpel design is expected to greatly improve the safety of the Seldinger technique for catheterization, there are several limitations and manufacturing challenges that must be addressed before the NickRite can be expected to compete with disposable scalpels. To start, the NickRite design is significantly more complex than a traditional scalpel, with moving parts that must be machined at extremely high precision. The gearing must be custom manufactured due to its unique design for manipulation by the human finger. This custom production may raise manufacturing costs, and make the Seldinger scalpel less desirable than cheaper traditional blades. For the NickRite to overcome this obstacle, the production must be simplified, price reduced, or the increase in safety must be so significant that using a traditional scalpel could be deemed a hazardous choice over the NickRite. It was also noted in testing that the attachment of the guidewire to the handle may limit the degrees of freedom of the scalpel movement, which may reduce a physician’s ability to make a clean and precise cut. It should be noted that this conclusion may be due partly due to the wire type used in the model testing apparatus, which is markedly stiffer than that used in the Seldinger technique. Future work with this design could include following the ideal process outlined above, with precise machining and testing of working prototypes. Additionally, alternate designs may be worth exploring, including alternate depth controllers using spring loaded mechanisms or sliders, and non-traditional scalpel design such as that produced by a previous capstone group may still be viable if it can be made intuitive without decreasing precision. Lastly an alternate method for improving the safety of the Seldinger technique may lie in methods for removing blood from the incision site, and thereby preventing the necessity of a blind cut.

Materials and Methods

Prototype design was conducted using Autodesk Fusion 360 CAD software. Prototypes were 3-D printed using a Stratasys F170 printer, and assembled by hand. For testing, the 3-D printed prototype was glued together and a blade was removed from a traditional scalpel and attached to the device insert. Ideal manufacturing would be performed by computer numerical control (CNC) machining of stainless steel to form a two-piece handle that can be assembled with three machine screws into the body, and a single piece blade insert. Testing was performed using a layer of practice tattoo skin taped to a shoe box using electrical tape, with copper wire inserted at several points to simulate the guidewire used during application of the technique. The assembled early prototype was attached to the copper wire and tested for lateral exactness over five blinded and five unblinded trials, and compared to the results from a traditional scalpel. Ideal testing would include full execution of the Seldinger technique, including insertion of a hollow needle and actual guidewire from a current Seldinger catheterization kit.

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