The 2009 IEEE/RSJ International Conference on
Intelligent Robots and Systems
October 11-15, 2009 St. Louis, USA

Force-Based Needle Insertion for Medical Applications

Lonnie J. Love, *Member, IEEE*, John F. Jansen, *Member, IEEE*, and Peter D. Lloyd

Abstract—**Needle insertion is pervasive in almost all medical activities. The development of compact, lightweight automated tools for needle insertion with the reliability of an expert needle-inserting nurse could significantly reduce the risk to both civilian and military patients. Such tools could open the door to many advanced concepts for future medicine by being an "enabler" of one of the first actions in almost all procedures. The purpose of this paper is to discuss two force-based devices that address the needle insertion problem: a compliance-sensing system that mimics the nurse palpation to determine the best needle insertion point across a vein, and a needle insertion device that uses force-based profiles during insertion to achieve successful catheterization without puncturing the vein back wall. The methodologies and implementation approaches for the two enabling systems are described. Experimental data obtained with training pads and phantom arms are presented and discussed.**

I. Background

A. Needs and Benefits

Ninety percent of combat wound fatalities die on the battlefield before reaching a medical treatment facility [1]. Similarly, many civilian victims of accidents or trauma die while waiting for transport or being transported to a medical facility. Thus, improving the speed of intervention during "the golden hour," and possibly achieving the "golden minutes" following injury has the potential to save many lives. One of the first requirements before attempting to perform surgical or trauma care on a severely wounded person is the capability to administer pain relief, medication, anesthetics, or fluids through Intra Venous (IV) needles or catheters. Thus, automated systems capable of reliably inserting IV needles or catheters in an injured patient represent an enabling capability for the concepts of remote trauma or surgical cells [2].

In future operating rooms and hospital environments, these basic tube insertion technologies would also allow human resource optimization by freeing personnel from performing these functions, reduce training costs (from simple blood-drawing to IV emplacement for anesthesia, fluid delivery, etc) and would contribute significantly to more efficient, faster, and cheaper health care. The magnitude of the economical impact can be gauged "by the numbers." In the United States (U.S.) alone, an average of 300 "sticks" per day at each of the 30,000 hospitals, represents nearly a million "sticks" a day. The annual number of central venous catheter insertions in the U.S. is not known, but is estimated at "several million" for subclavian-vein catheters. The frequency of complications is quite variable, largely due to differences among selected venous insertion sites and the degree of prior clinician experience. In general, the rate of major and central venous catheter complications is between 0.5 and 10% [3].

The purpose of this paper is to discuss the work performed at Oak Ridge National Laboratory in the area of force-based needle insertion.

B. Challenges and State-of-the-Art

While successful insertion of a needle into a vein or artery requires a sensitive combination of visual and tactile stimulation and sensing, only tactile/force sensing will be discussed in this work. Soft tissue easily deforms and moves with the slightest application of forces. Subsequently, off-line or one-time identification of the location and orientation of a vein is insufficient for needle insertion. Movement of the syringe or associated structure can cause deformation of the soft tissue, which can result in movement of the vein during insertion. Clearly, there must be some level of real-time feedback of the vein location and needle insertion forces during the insertion process.

Clinicians, whose training and experience may vary greatly, use a combination of visual and tactile sensing to determine the location of a vein. Percutaneous insertions of central venous catheters are generally performed by "blind" techniques that rely on anatomical landmarks, palpable or visible structures with known relationships to the desired vein. Choosing the appropriate site is crucial for a successful venipuncture. The location, size and feel of the vein are important in selecting which vein to use. In the arm, the veins most often used for venipuncture are located in the antecubital area. The typical order of choice based on size and stability in vein selection is as follows: cubital, cephalic and basilica.

The required accuracy for vein location identification depends upon the application and vein size. For IV insertion, the cephalic and basilic veins in the forearm have the largest lumens, the best blood flow, are more durable, and are comfortable for the patient. Studies have shown variations in cephalic veins from 1.2 to 3.2 mm in

Manuscript received March 20, 2009. This work was supported in part by the U.S. Department of Energy (DOE) Laboratory Directed Research and Development Program and by the U.S. Department of Defense Advanced Research Projects Agency under Inter-Federal Agency Agreement No. 1868-HH00-X1 with the U.S. DOE.

Lonnie J. Love is with the Oak Ridge National Laboratory (ORNL), Oak Ridge, TN 37831-6305 USA (phone: 865-576-4630, fax: 865-574-4624, e-mail: lovelj@ornl.gov). ORNL is managed by UT-Battelle for the U.S. Department of Energy under contract DE-AC05-00OR22725.

J. F. Jansen is with the Oak Ridge National Laboratory, Oak Ridge, TN 37831-6305 USA (e-mail: jansenjf@ornl.gov).

P. D. Lloyd is with the Oak Ridge National Laboratory, Oak Ridge, TN 37831-6305 (e-mail: lloydpd@ornl.gov).

diameter [4]. Similar studies have been performed on the common femoral, proximal femoral, mid-femoral and distal femoral veins in the thigh and have likewise shown significant variations in diameter [5]. Automating this process is complicated by a number of fundamental issues. First, while there is contrast between the vein and skin, it is very light, complicating edge detection algorithms associated with vision-based sensory feedback. Second, insertion of a needle or catheter in a vein requires knowledge of both the vein location and its orientation. Third, as described previously, slight pressure changes on the skin can cause displacement of the vein. Subsequently, there must be real-time sensory feedback of the vein location, orientation and forces to ensure successful insertion.

Noteworthy systems that locate veins based on ultrasound (e.g., Site Rite, www.bardnordic.com) and infrared imaging (Vein Viewer from Luminetx, www.luminetx.com) already exist. The design goal of the force-based palpation tool is to have a low cost system that can fit into coat pocket.

The actual insertion of a needle or catheter into a vein is a problem that can be loosely compared to the problem of inserting a peg into a hole, for which Whitney, for example, described geometric and force equilibrium conditions sufficient for successfully mating the rigid parts [6] and requires careful regulation of both axial and transverse forces and torques. Compared with the case of rigid parts, the constraints are relaxed slightly due to the compliance of the skin. However, any misalignment of the needle with the vein or puncture will manifest itself as lateral forces, which must be minimized. Once the needle punctures the vein, not only must it be guided into the vein without straining or tearing the skin, requiring sensitive lateral force control, but care must also be given to ensure the needle does not puncture the far side of the vein. Zivanovic and Davies [7] describe the need for force measurement during needle insertion. Their experiments show a distinct force profile associated with a needle penetrating a vein, with axial force increasing steadily from 0 to approximately 1.5 N prior to penetration and dropping by approximately 0.5 N afterwards. Simone and Okamura report similar force profiles when inserting a needle through liver tissue.[8] Likewise, transverse forces during needle insertion play a critical role in determining if a needle or catheter is successfully inserted into a vein or artery. Furthermore, the use of these forces aids in aligning the needle with the vein or artery to reduce friction and ease insertion, which will reduce pain and increase reliability. This sensitivity to both axial and transverse forces suggests that the needle or catheter must be instrumented with a multi-axis force/torque sensor for automated control, which is the approach that we have successfully implemented in our proof-of-principle demonstration system. This paper will describe two basic components of the needle insertion problem. First the force-based palpation tool used to locate the most likely insertion point across the vein and the second is the force-guided needle insertion tool.

II. Force Based Tools

A. Description of Palpation Device

After a localized area has been selected (e.g., either by a medic or by means of a visual vein identification system) [9], the actual feel of the vein is key in the final determination of its location. With the tourniquet appropriately tied, a good vein should feel resilient or slightly bouncy when palpated slowly. Furthermore, the palpation process should provide detailed information about the location of the best insertion point along and across a vein, based on the local compliance and resilience felt. Additionally, for an automated system, palpation would provide detailed depth confirmation and registration between the venous imaging system and the force-guided needle insertion through a secondary measurement of the target needle insertion point, and a force-based estimate of the mechanical compliance of the vein, which can subsequently be used to accurately control the insertion. Thus, it became clear that force-based palpation provides a segue between the venous imaging and the force-guided insertion.

The specific challenge associated with the force-based palpation was the sensitivity required for identifying a vein. Figure 1 shows a cross section view of the proof-of-principle palpation tool developed for this feasibility investigation and Fig. 2 shows the actual hand-held system developed. Mechanical compliance estimation is based on controlling the force (bias and dither) and measuring the resulting displacement. A voice coil with a parallelogram flexure structure provides the actuation force. A load cell, specifically designed for this application, provides the primary feedback of the palpation force to the force controller. A linear variable-differential transformer provides a measurement of the tissue deformation. By feeding back the probe force, the palpation tool carefully regulates the applied force and dither force. The combination of dither amplitude and frequency enables a real-time estimate of the tissue/vein compliance. Human hand tremors are mitigated and the tool can be either hand-held or rigidly attached to a secondary structure. Salient features of this approach include integrated active force control, low friction and active tremor reduction. The system provides an effective nurse mimetic sense of touch when probing for a vein or needle insertion point.

Test results for the system successfully achieved identification accuracies of the order of 0.1 mm. Tests were performed on a venous training pad (see Fig. 3). As an example, Fig. 4 shows the resulting position-dependent compliance for the 5-mm diameter tube with a 1-mm depth on the venous training aid. Clearly, there is a significant dip in the compliance at the center of the vein, which can be estimated with accuracies approaching 0.1 mm.

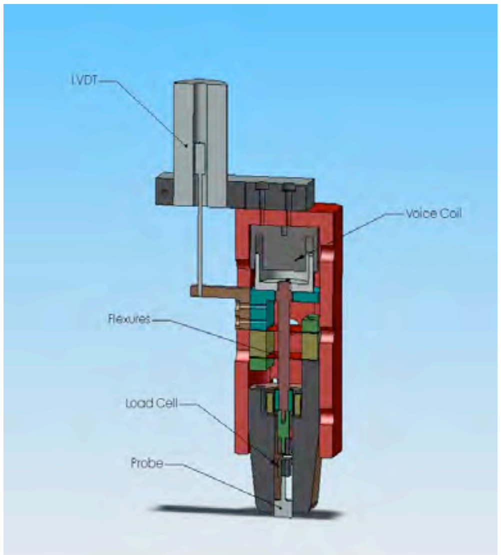

Fig. 1. Cross-section of palpation tool.

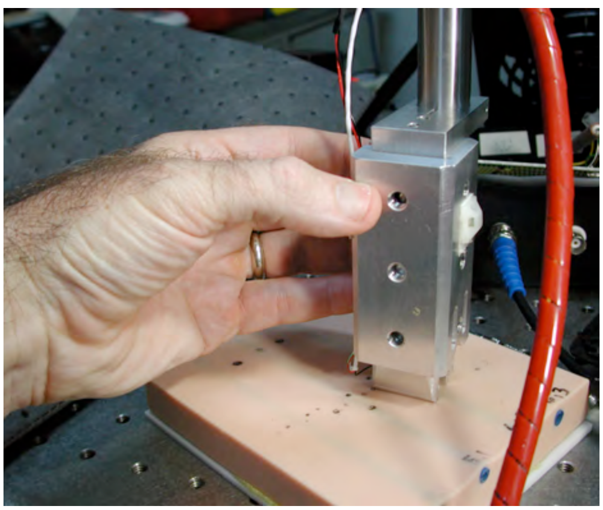

Fig. 2. Palpation tool on training pad.

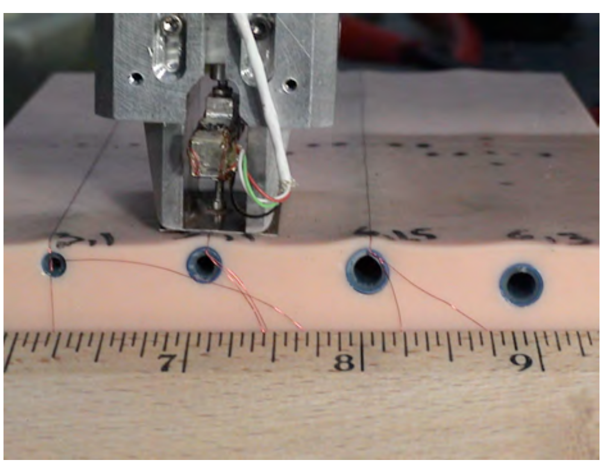

Fig. 3. Cross section of palpation and training pad.

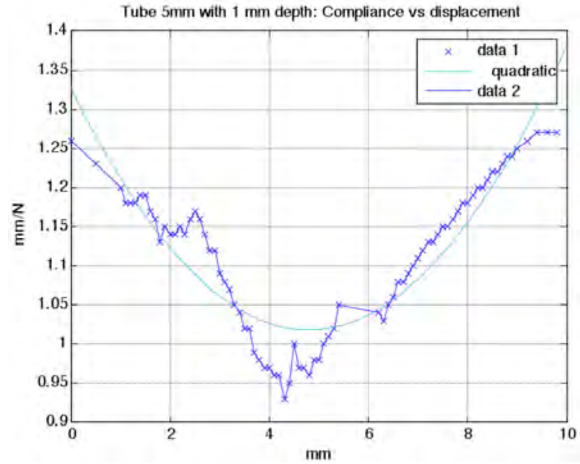

Fig. 4. Compliance vs. displacement on training pad.

B. *Description of Force-Guided Needle Insertion*

As stated previously, there is little information regarding the magnitude and nature of forces experienced during needle insertion. Most data has focused primarily on axial forces. The magnitude of these forces is generally less than 2 N [10]. The primary assumption, based on discussions with nursing personnel, was that force/tactile feedback plays a critical role in successfully inserting a needle or catheter in a vein. Many clinicians describe the feeling of a distinct 'pop' when the needle penetrates a vein. In order to better understand the nature and magnitude of these needle insertion forces, we developed an instrumented syringe that provided high-resolution, real-time measurement of all forces and moments exerted on a needle (see Figs. 5 and 6). A sample profile of the needle insertion forces and torques measured during a successful vein puncture test is displayed in Figs. 7 and 8. The primary results of this study suggested that there is a distinct force signature associated with the puncture of the vein wall by the needle, clearly shown on the F_z force profile. This signature, which can be measured and detected in real-time, provided the enabling information for our investigation on preventing puncture of the back wall (i.e., avoiding going through the entire vein) during force-guided needle insertion. Forces in the orthogonal directions and torques are due to misalignment during insertion. These orthogonal forces can be regulated and provide guidance in terms of alignment during insertion.

Figure 9 shows the test apparatus that was designed and fabricated for the proof-of-feasibility demonstration of force-guided needle insertion without puncture of the back wall. This proof-of-principle test-bed served two purposes. The first objective was to provide fine control over the needle insertion speed and direction during test insertions. Removal of the human from the insertion tests clarified the relationship between needle displacement, speed and force as a function of vein puncture, which then provides insight into potential solutions for detecting vein penetration. The basic system includes an electric motor with a low-friction lead screw to provide linear motion. Feedback on the mechanism included an linear variable displacement transducer for needle position feedback, a tachometer for needle insertion speed, and a six-axis force/torque sensor to provide feedback of needle insertion forces and torques. Repeated tests on the phantom arm suggested a discernable, and measurable, force discontinuity when the needle first penetrated the vein (see Fig. 10). Furthermore, it was clear in tests that this force was not present when the needle missed the vein. These simple tests provided insight into both the magnitude of forces to expect during needle insertion and the basic force signature associated with a successful needle insertion. When the needle pops through the vein, there is a distinct signature, which is visible on the force profile.

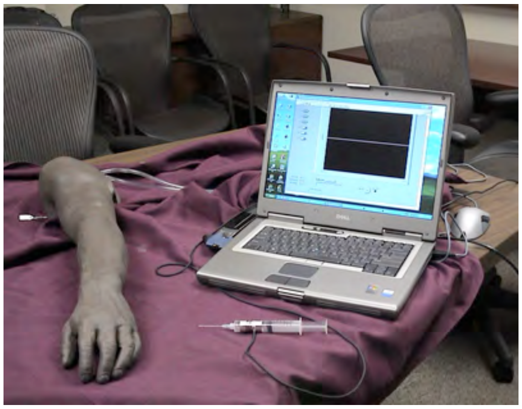

Fig. 5. Instrumented syringe.

Fig. 6. Close up of instrumented syringe.

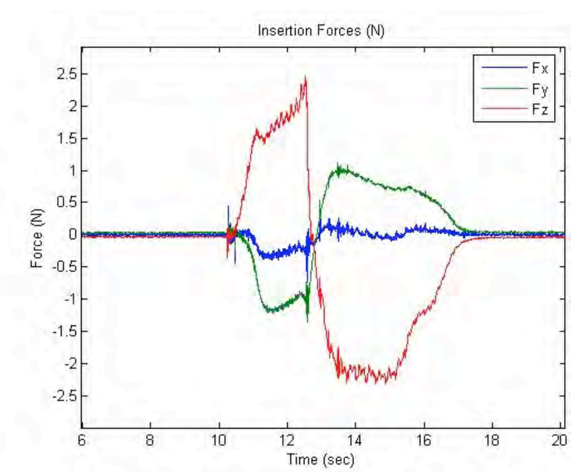

Fig. 7. Insertion forces.

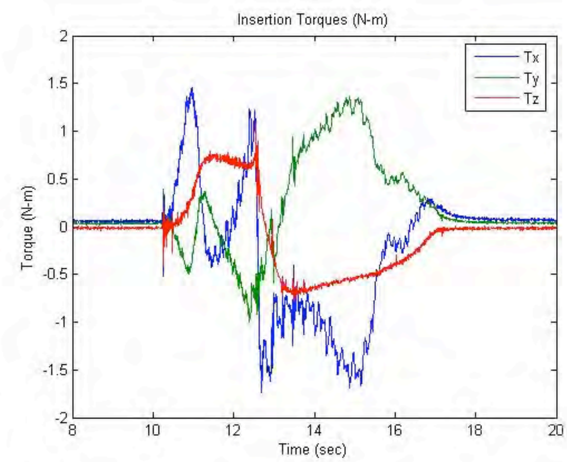

Fig. 8. Insertion torques.

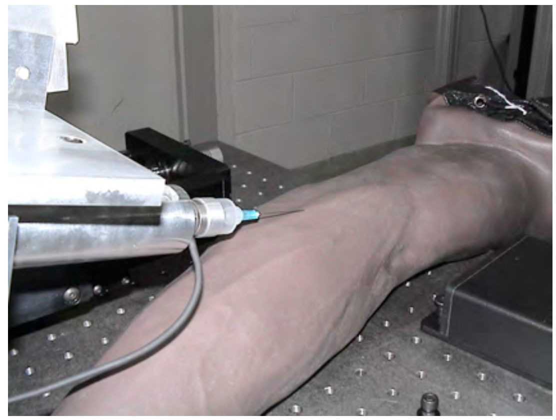

Fig. 9. Needle insertion tool with phantom arm.

In order to detect this characteristic in real time, we developed a nonlinear identification algorithm that decomposes the force profile into linear and quadratic components. Figure 10 shows the force profile measured during a controlled experiment (constant speed) utilizing a phantom like that shown in Fig. 9. While the needle is inserted into the arm, the force rises initially until the pop, shown in terms of a drop in the force in Fig. 10. Determination of penetration is based on observing a negative quadratic term while the forward velocity is constant. This triggers a flag, shown as the penetration flag, in Fig. 11. The red star on the force profile in Fig. 10 corresponds to the flag changing from 0 to 1. This flag is then used as a signal to the needle insertion tool to stop forward motion. The basic control methodology uses speed control during the needle insertion. While the needle is in motion, the system monitors the needle insertion force. The real time nonlinear identification algorithm detects the distinct characteristic of the puncture force and sends a stimulus to the controller for further actions that might include, for example, the start of fluid flow, the validation of blood flash back to further verify venous puncture, extraction of a sample of fluid, and/or the insertion of a catheter. If the system does not detect a venous puncture within a specified needle displacement, the system retracts and signifies a failed needle insertion.

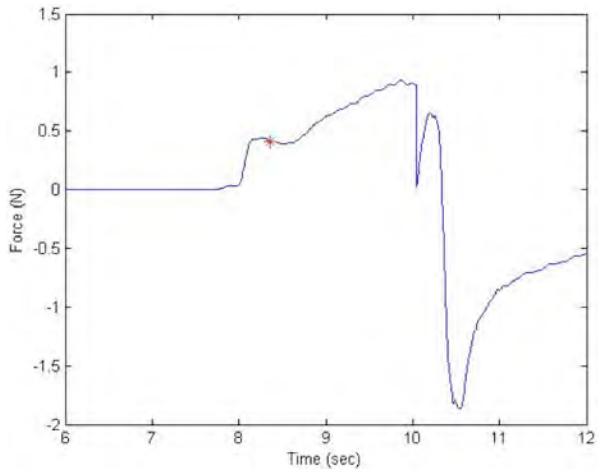

Fig. 10. Controlled force during insertion.

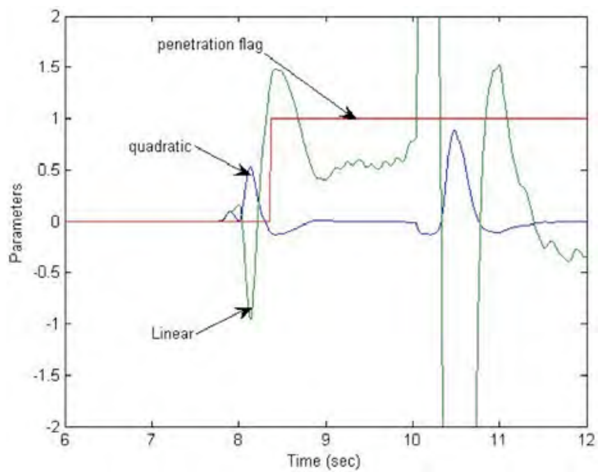

Fig. 11. Force profile components.

Using the phantom shown in Fig. 14, two example tests are shown in Figs. 12, 13, 16, and 17. The first series of figures (Figs. 12 and 13) show a successful needle insertion. The system was set up such that the needle was aligned with one of the simulated veins in Fig. 14. Figure 12 displays the force profile during insertion and Fig. 13 shows the resulting needle displacement. When triggered to start the insertion process, the system extends at a constant velocity while monitoring the force. When a venous puncture is established, the controller triggers a puncture vein stimulus after which the system pauses for a preset time (5 seconds in this test). After the pause the system retracts. Figure 14 shows a close-up of the needle during the above successful insertion. It is clear that the needle entered the vein, with no prior knowledge of the vein diameter or depth, without puncturing the far wall of the vein. These tests were successfully demonstrated on all four of the veins (of varying diameter and depths) on the training pad as well as various veins on the arm and hand of the phantom training arm in Fig. 15.

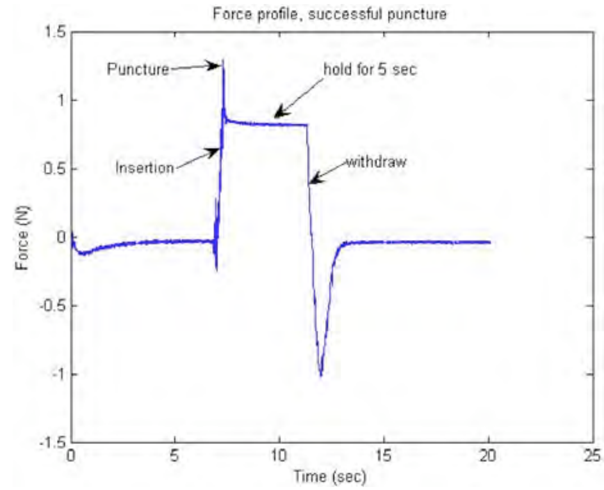

Fig. 12. Force during successful insertion.

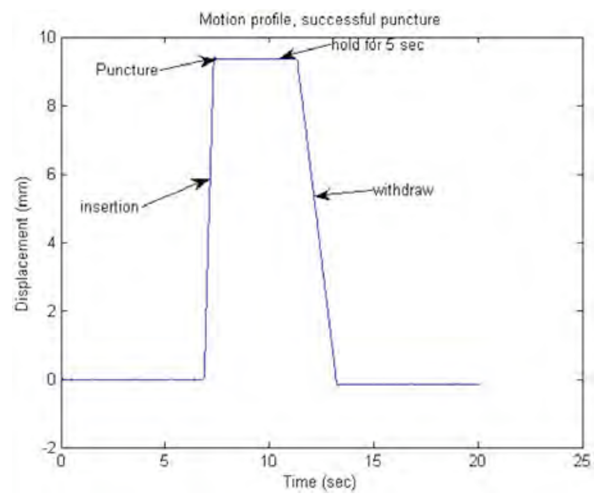

Fig. 13. Motion during successful insertion.

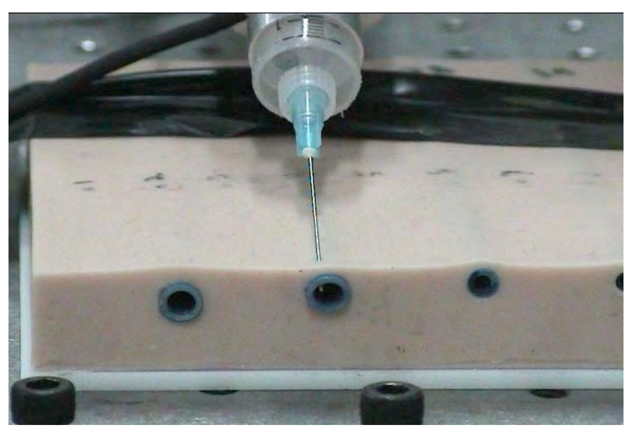

Fig. 14. Close-up of successful penetration.

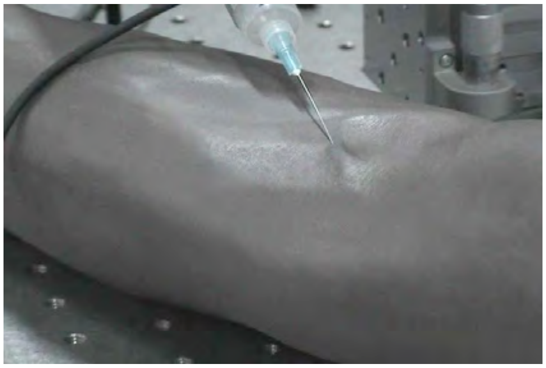

Fig. 15. Success on Phantom.

The feasibility of detecting a failed attempt was also demonstrated. In tests, the venous training aid was displaced to ensure that the needle would not hit the vein. Figures 16 and 17 illustrate the resultant force and displacement. Clearly, the force ramps up to a pre-specified threshold. If the needle has not penetrated a vein, as would be detected by the quadratic analysis system, it immediately triggers a "too-far" stimulus and retracts.

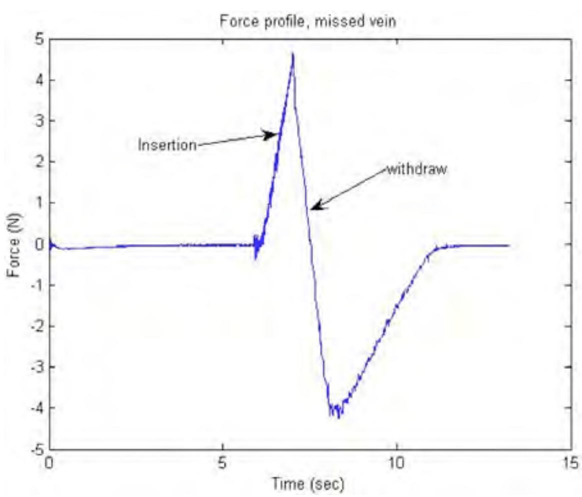

Fig. 16. Force during failed insertion.

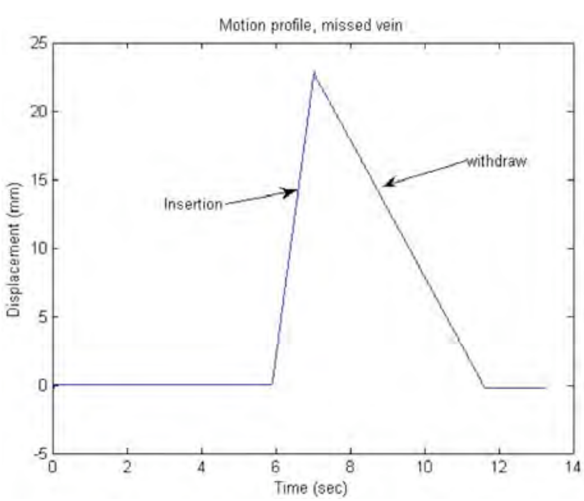

Fig. 17. Motion during failed insertion.

III. Conclusion

Needle insertion is pervasive in almost all medical activities. The development of compact, lightweight automated tools for needle insertion, with the reliability of an expert needle-inserting nurse, could significantly reduce the risk to both civilian and military patient and combat medics and have significant impact on the health of the country. Furthermore, it represents an "enabler" of one of the first actions in almost all procedures and opens the door to many advanced concepts for future medicine including remote testing, treatment or trauma care in rural or battlefield conditions or first responders vehicles. The purpose of this paper was to discuss a force-based needle insertion device. The feasibility of force-based palpation and needle insertion has been demonstrated on phantom devices and initial results are encouraging. Additional effort is needed to increase the sensitivity of the palpation device while ruggedizing and miniaturizing the hardware. Obviously, human subject testing would have to follow.

References

[1] R. Ballamy, "The causes of death in conventional land warfare: implications for combat casualty care research," *Mil. Med*. 1984; 149:55-62.

[2] R. M. Satava, "The operating room of the future: observations and commentary," *Surgical Innovation*, vol. 10, no. 3, 99-105, 2003.

[3] http://www.injuryboard.com/view.cfm/Article=668

[4] R. Mendes, M. Farber, W. Marston, L. Dinwiddie, B. Keagy, and S. Burnham, "Prediction of wrist anteiovenous fistula maturation with preoperative vein mapping with ultrasonography," *J. Vascular Surgery*, vol. 36, no. 3, pp. 460-463, 2002.

[5] S. Cunha, S. Shuman, and H. Beebe, "Planning endovascular vein valve implantation: significance of vein size variability," *J. Vascular Surgery*, vol. 37, no. 5, pp. 984-990, 2003.

[6] D. Whitney, "Quasi-static assembly of compliantly supported rigid parts," *J. Dynamic Systems, Measurement and Control*, vol. 104, pp.65-77, 1982.

[7] A. Zivanovic, and B. Davies, "A robotic system for blood sampling," *IEEE Trans. on Information Technology in Biomedicine,* vol. 4, no. 1, pp. 8-14, March 2000.

[8] C. Simone, and A. Okamura, "Modeling of needle insertion forces for robot-assisted percutaneous therapy," in *Proc. IEEE Int. Conf. on Robotics and Automation,* pp. 2085-2091, May 2002.

[9] T. L. Ferrell, F. G. Pin, L. J. Love, J. F. Jansen, K. W. Tobin, R. Farahi, J. R. Price, V. Paquit, D. Hedden, F. Meriaudeau, and R. Seulin, "Intelli-cath: toward automated needle-insertion systems and intelligent catheters," in *Proc. 13th Annual Medicine Meets Virtual Reality (MMVR) Conference*, Long Beach, Calif., January 26-29, 2005.

[10] C. Simone and A. Okamura, "Modeling of needle insertion forces for robot-assisted percutaneous therapy," in *Proc. IEEE Int. Conf. on Robotics and Automation,* pp. 2085-2091, May 2002.