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Simple and Effective Ultrasound Needle Guidance System

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Abstract—**In this paper, we describe our prototype of an ultrasound guidance system to address the need for an easy-to-use, cost-effective, and portable technology to improve ultrasound-guided procedures. The system consists of a lockable, articulating needle guide that attaches to an ultrasound probe and a user-interface that provides real-time visualization of the predicted needle trajectory overlaid on the ultrasound image. Our needle guide ensures proper needle alignment with the ultrasound imaging plane. Moreover, the calculated needle trajectory is superimposed on the real-time ultrasound image, eliminating the need for the practitioner to estimate the target trajectory, and thereby reducing injuries from needle readjustment. Finally, the guide is lockable to prevent needle deviation from the desired trajectory during insertion. This feature will also allow the practitioner to free one hand to complete simple tasks that usually require a second practitioner to perform. Overall, our system eliminates the experience required to develop the fine hand movement and dexterity needed for traditional ultrasound-guided procedures. The system has the potential to increase efficiency, safety, quality, and reduce costs for a wide range of ultrasound-guided procedures. Furthermore, in combination with portable ultrasound machines, this system will enable these procedures to be more easily performed by unskilled practitioners in non-ideal situations such as the battlefield and other disaster relief areas.**

I. Introduction

Ultrasound guided procedures are increasingly being used for the diagnosis and treatment of disease. In current guided needle procedures, the practitioner first identifies the region of interest using an ultrasound probe. Once the desired anatomy is in view, the practitioner estimates a needle trajectory and insertion point. The needle is then inserted and the practitioner adjusts the ultrasound probe to achieve visualization of the needle. A challenge with ultrasound-guided procedures is continuous visualization of the needle during the entire procedure. The full length of the needle must be completely maintained within the 1mm wide ultrasound beam. The inability to properly identify the needle tip, as depicted in Fig. 1, makes it dangerous to advance the needle. For example, improper needle placement has led to life threatening seizures, pneumothoraces, arterial dissections, and failed nerve blocks [1]. Once the practitioner achieves adequate needle visualization, he or she uses a "freehand" technique to complete the procedure. The term "freehand" is used to describe a technique where the practitioner has complete flexibility with insertion points and approach angles to avoid damaging important structures (such as arteries) and/or inject medication in different locations. Currently, many of these procedures are limited to more experienced practitioners mainly due to the fine motor skill needed to maintain needle imaging for safe placement [2].

Another issue is that these procedures commonly require two practitioners: one performing the procedure and the other assisting with ultrasound adjustments and injection of medication. The requirement of a second, trained practitioner to perform simple tasks adds to cost and limits efficiency. Making ultrasound-guided procedures easier to perform can help mid-level providers to offer cost effective care [3].

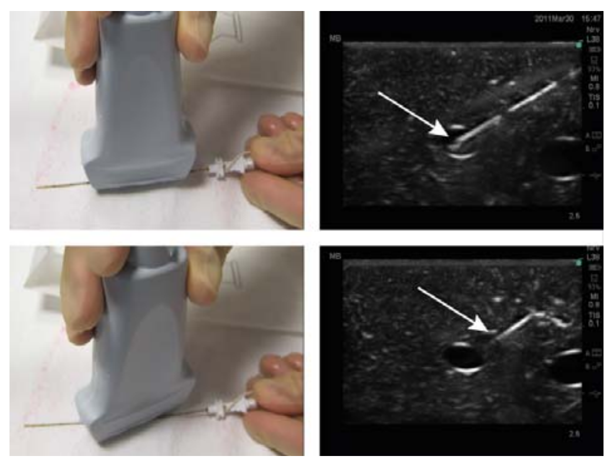

Fig. 1. Proper vs. improper needle alignment. Top: Needle aligned within imaging plane allows for full visualization including needle tip (arrow). Bottom: Ultrasound image reveals a "false" needle tip when not aligned.

A. Prior Art

A variety of needle guides have been suggested to improve ultrasound-guided procedures but none of them are both functional and cost-effective. The simplest needle guides restrict the user to one entry point and a fixed angle (Fig. 2A, [4]) or, at most, to predefined, discrete angles (Fig. 2B, [5]). These limitations do not preserve the "freehand" technique. In an attempt to emancipate such movements, two parallel plates (Fig. 2C, [6]) or rotational [7,8] and translational arms [9] have been suggested. Finally, Sonek [10] proposed a simple but functional design (Fig. 2D).

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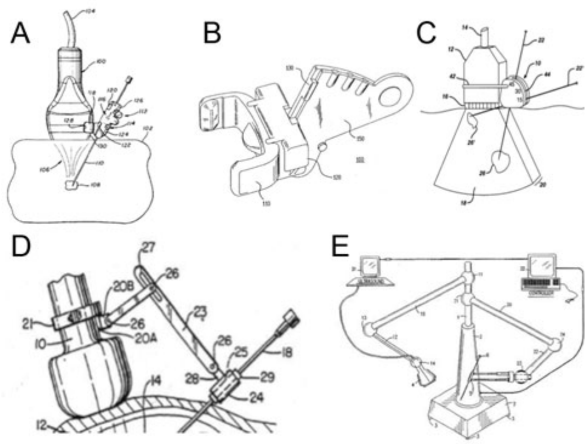

Fig. 2. Existing needle guides include small clamps attached to the ultrasound head (A, B, C), arms (D), and large, robot guided systems (E).

Furthermore, software ideas for full or semi-automation of the process have been suggested (Fig. 2E, [11]). Among these complex solutions, Ascension Technology and Ultrasonix's SonixGPS system as well as Philips PercuNav system use an electromagnetic (EM) sensor in the ultrasound probe and another one in the needle in order to map the needle to the ultrasound imaging coordinate system [12, 13]. EM tracking, however, is susceptible to external inferences (e.g. metal), and often requires a long calibration process. Obviously, these systems can only be used in well-defined conditions and not in difficult situations, such as disaster relief areas and battlefields.

While such devices have been commercialized, no system has seen full clinical adoption. To address this shortcoming, we present the design and fabrication of a novel, integrated hardware and software system that is easy-to-use, cost-effective, portable, and preserves the "freehand" technique.

II. Functional Requirements

The reasons for the limited clinical adoption of previous ultrasound guidance solutions are many fold. Based on the patent review, medical literature, conversations with practicing clinicians, and clinical observations, we identified the limitations in earlier approaches and compiled a list of primary and secondary requirements to improve needle guides. From among these, we selected the five functional requirements for our design, shown in Table 1.

Table 1. The five functional requirements for the needle guide.

1.	Needle is constrained to imaging plane, preserving the "freehand" technique within this plane.
2.	Visual feedback of the needle trajectory at real-time.
3.	Usable by a single person
4.	Lock the needle in position and orientation relative to the ultrasound probe, freeing one hand to perform other tasks.
5.	Accommodates different needle sizes (14-26 gauge)

III. System Description

A. System Overview

We designed an ultrasound guidance system consisting of: (1) a lockable, articulating needle guide that attaches to an ultrasound probe and (2) a user interface that provides visualization of the projected needle trajectory overlaid on the ultrasound image. A system overview is shown in Fig. 3.

Fig. 3. A depiction of the system workflow: the practitioner positions the needle with the needle guide attached to the ultrasound probe and reads the desired trajectory from the ultrasound monitor before inserting the needle.

B. Mechanical Modules

The needle guide is designed to mate specifically with the Sonosite Micromaxx portable imaging system but can easily be adapted for other systems. The hardware consists of six modules: (1) Attachment, (2) Arm, (3) Needle Holder, (4) Lock, (5) Sensors, and (6) Software as illustrated in Fig. 4A. The needle guide design maintains the "freehand" technique by constraining the needle's motion in only *one* translational dimension and *one* rotational dimension – the minimum required to keep the needle in plane. The practitioner is free to move the needle in the remaining dimensions – up/down, forward/backward, rotation about its axis, and rotation about the Needle Holder axis. The joints are low friction, thus maintaining the practitioner's haptic feedback from the needle-tissue interaction. The Arm is 10cm long when fully extended, with each joint 5cm long. The arm can be positioned into all configurations between a full extension and a complete retraction. Each of these configurations is lockable by engaging the lever. The mechanism uses friction locks that can be engaged at any position along a continuum rather than in discrete steps. Engaging the locking lever with a force F_1 results in normal braking forces F_2 given by:

$$F_1 = 3F_2\frac{d}{D} \qquad (1)$$

Where D is the total length of the lever and d is the length from the center of lever rotation to where it connects to the arm for each brake (Fig. 4B). We calculate that a force, F_1, of approximately $2N$ is needed to engage the lock.

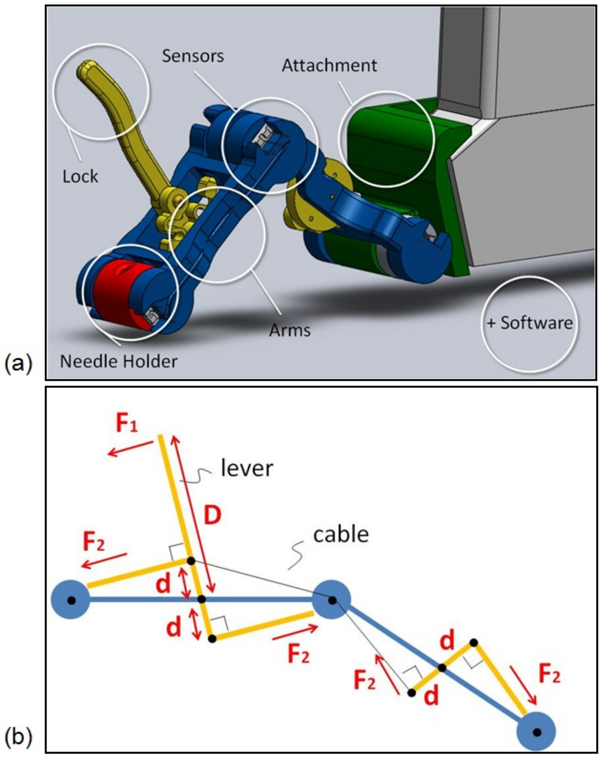

Fig. 4. **(a)** The needle guide attaches to an ultrasound probe (grey). It consists of five modules: (1) Attachment, (2) Arm, (3) Needle Holder, (4) Lock, (5) Sensors, and (6) Software. **(b)** The force diagram for the lock module. A force F_1 is applied to the lever resulting in a normal force F_2 at each of the three joints.

The guide is attached to the ultrasound probe using principles of exact constraint design so that it can be accurately and repeatedly positioned. This is required since a fixed coordinate transformation between the needle guide and the imaging system is required to predict the needle path. Potentiometers are mounted on each of the three joints of the articulating arms to measure the rotation angles. A needle holder attached to the end of the articulating arms provides the guide for the needle. This needle holder can be easily adapted to accommodate the various needle sizes required for different procedures.

C. *Software and User Interface*

The software interface provides a live feed of the ultrasound image with the predicted needle trajectory superimposed on top, as shown in Fig. 5A. The trajectory prediction algorithm is based on readings from the three rotation sensors – two in the arm joints and one connecting the arm and needle holder. They measure the angles between every two adjacent linkages of the guide. Our software is currently implemented in MATLAB on a portable computer. In the future, it will be integrated into an ultrasound machine to allow for greater ease-of-use.

Fig. 5B illustrates the forward kinematic model with the base frame chosen at the first joint, and the subsequent frames at each of the other two joints. The forward kinematics specifies the Cartesian position and orientation of the local frame attached to the needle guide relative to the base frame which is the origin of the ultrasound image. It is derived by multiplying a series of matrices parameterized by joint angles and translational offsets. Homogenous transformation matrices (HTM) are used in this case.

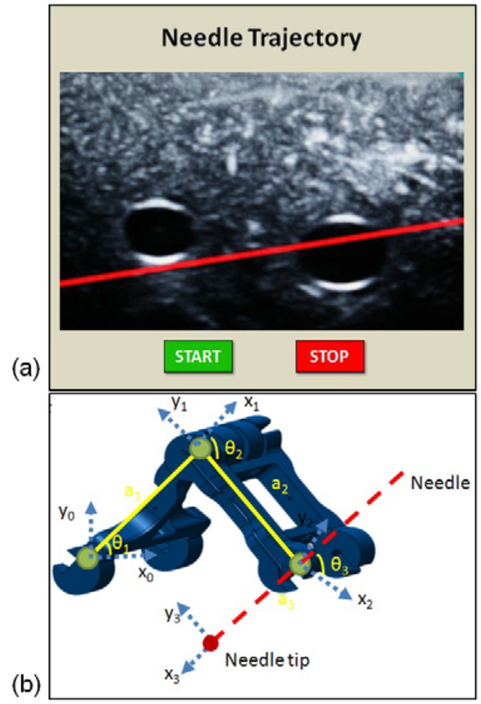

Fig. 5. **(a)** The user interface shows the needle trajectory (red line). **(b)** Schematic overlay of the forward kinematic model onto the Arms

Using a series of coordinate transformations, we arrive at a single transformation matrix that is the HTM of the needle tip in the image coordinates:

$$\begin{bmatrix} c_{12}c_3 - s_{12}s_3 & -c_{12}s_3 - s_{12}c_3 & 0 & a_1c_1 + a_2c_{12} + a_3c_{123} + t_x \\ c_{12}s_3 + s_{12}c_3 & c_{12}c_3 - s_{12}s_3 & 0 & a_1s_1 + a_2s_{12} + a_3s_{123} + t_y \\ 0 & 0 & 1 & 0 \\ 0 & 0 & 0 & 1 \end{bmatrix}$$

In this notation, a_i is the length of each link, while c_i is the shorthand notation for $\cos(\theta_i)$ and s_i for $\sin(\theta_i)$. Multiple subscripts, c_{123} and s_{123}, denote $\cos(\theta_1+\theta_2+\theta_3)$ and $\sin(\theta_1+\theta_2+\theta_3)$, respectively (Fig. 5B). t_x and t_y are the respective x and y offsets of the x_0y_0 frame to the origin of the image frame. They are known based on relative mounting location of the needle guide to the ultrasound probe.

IV. Preliminary Prototype Testing

As a first evaluation, we conducted qualitative tests to ensure the needle guide meets the functional requirements in Table 1. The tests ensured that (a) the "freehand" technique is preserved, and (B) that the locking mechanism functions.

A. *Preserving the "Freehand" Technique*

For these experiments, the practitioner first inserted the needle, then withdrew it and reinserted it at a different angle. Upon each reinsertion there was a risk of applying lateral forces that could push the needle out of plane. In our trials, illustrated in Fig. 6, the needle remained in-plane after each reinsertion. This indicates that the practitioner was able to adjust the needle's angle while the needle guide kept it aligned with the imaging plane.

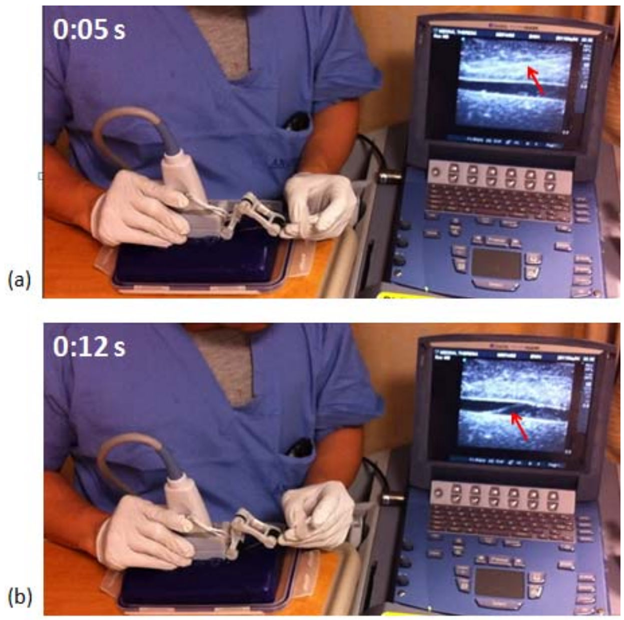

Fig. 6**. (a)** The practitioner inserted a needle into a phantom using the needle guide. The needle readily entered in-plane and was visible on the monitor (red arrow). **(b)** The practitioner then pulled the needle out of the phantom and reinserted it into a different spot. It remained visible on the screen.

B. Needle Guide Lock

The objective of this test was to verify that the needle stays upright when the lock was engaged. In Fig. 7A the practitioner engaged the lock, and in Fig. 7B the needle remained supported by the guide, demonstrating the functionality.

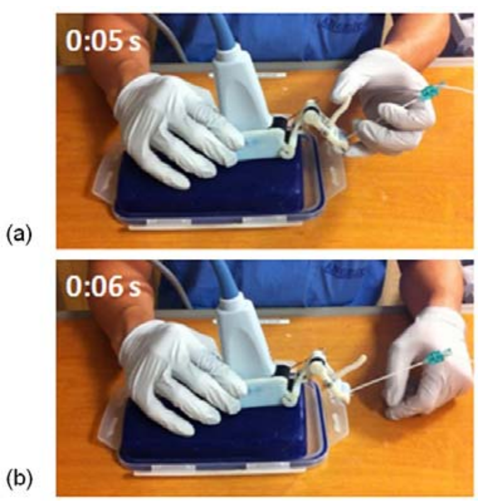

Fig. 7. A demonstration of our needle guide being locked. **(a)** The practitioner engaged the manual lock by pulling on the lever. **(b)** The lock is engaged and the needle remains supported after the practitioner let go.

V. CONCLUSIONS AND FUTURE WORK

This paper presents the design of a probe-mounted ultrasound guidance system that provides increased functionality compared to existing passive needle guides and is an order of magnitude less expensive than commercial navigation systems. The guide consists of instrumented links and a software system that calculated the predicted needle trajectory and overlaid it on the ultrasound image. The system has the potential to increase efficiency, safety, quality, and reduce costs for ultrasound-guided procedures such as central line placements, peripheral nerve blocks and image-guided tumor ablation. Furthermore, with the advent of portable ultrasound imaging systems, the needle guide will enable these procedures to be more easily performed by less skilled practitioners in settings such as hospitals in the developing world, battlefields and other disaster relief areas.

We plan to conduct a study comparing the time to perform a complex clinical task tests in phantoms and mannequins, such as a central line placement, with and without the device. Feedback from this study will be used to modify the design so that the system will be ready for clinical testing.

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