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Coaxial Needle Insertion Assistant for Epidural Puncture*
Effect of Lateral Force on Needle

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Abstract— **We validated the effectiveness of a coaxial needle insertion assistant under the condition that the needles were laterally deformed. The coaxial needle insertion assistant separates the cutting force at the needle tip from shear friction on the needle shaft, and haptically display it to a user in order to assists her/his perception during epidural puncture. An outer needle covers the side of an inner needle, preventing the shear friction from acting on the inner needle. However when the needles are laterally deformed and make contact to each other, it is concerned that the effect of the separation is degraded. In this paper, the users punctured an artificial tissue with variable insertion angles, so that the needle is intentionally laterally deformed. The overshoot and user confidence in detecting puncture was examined.**

I. INTRODUCTION

Epidural anesthesia is a procedure to inject anesthetic drug into epidural space, and is popular, especially in obstetrics. For proper delivery of anesthetic drug and avoidance of accidental dural puncture, epidural needle has to advance far enough to penetrate ligamentum flavum, but stop before dura matter. Since the ligamentum flavum and dura matter are close to each other, steady and effective detection of epidural space is required for proper replacement of the needle [1, 2].

The sharp drop in cutting force that occurs at the moment of penetration of the ligamentum flavum is obfuscated by shear friction between the needle and surrounding tissue. This significantly complicates manual discrimination of the penetration. In a previous study, we used an instrumented coaxial needle to measure cutting force separately from shear friction force [3]. This instrumented coaxial needle operates as follow. The inner needle of the coaxial needle forms the front end of the needle, which cuts the tissue. The outer needle covers the side of the inner needle, preventing the shear friction between the tissue and needle from acting on the inner needle. A force sensor attached on the back end of the inner needle measures the drop in cutting force when the needle penetrates the tissue.

To display the cutting force to an operator, we have studied a robotic coaxial needle insertion assistant [4, 5]. In this method, the needles are pushed by both the operator and actuator. The actuator actively changes pushing force such that the operator resists a force equal or proportional to the cutting force. This allows the operator to intuitively perceive the cutting force by inserting the needle as is done in conventional procedure. We have studied a position-controlled and force-controlled assistant (the details will be described hereafter.). The effectiveness of the assistant was tested in an experiment in which users were asked to puncture artificial tissues with the assistant inactive and active. Results show that the ratio of successful to unsuccessful puncture detection was higher with the assistant than without. In addition, users were more confident that they could perceive the moment of puncture.

In conventional experiments, only forces along needle were considered. In clinical practice, a lateral force will be applied when the physician tries to change needle's trajectory and/or when the tissue is deformed in lateral direction (this will not often happen to epidural puncture). This might bend the needle and make a mechanical interference between the inner needle and outer needle. This might prevent the cutting force from being separated from shear friction, and degrade the effectiveness to facilitate the operator's perception of penetration.

In this paper, we have tested the effectiveness of the coaxial needle insertion assistant under the condition that the needle is deformed laterally. The contribution of this work is that the effectiveness of the coaxial needle insertion assistant was tested in adverse condition to establish its robust operation.

II. MATERIALS AND METHODS

The goal of the experiment was to compare user performance during a needle insertion task under the assistant active and inactive, and a lateral force on the needle applied and not applied.

The users were asked to insert a needle into artificial tissue, and to stop inserting as soon as they perceived the needle tip exiting the tissue. The overshoot of the needle past the exit point of the tissue was measured. Users were asked to rate their confidence in perceiving penetration after each trial. If the overshoot is smaller and the confidence is higher, the trial is rated positively.

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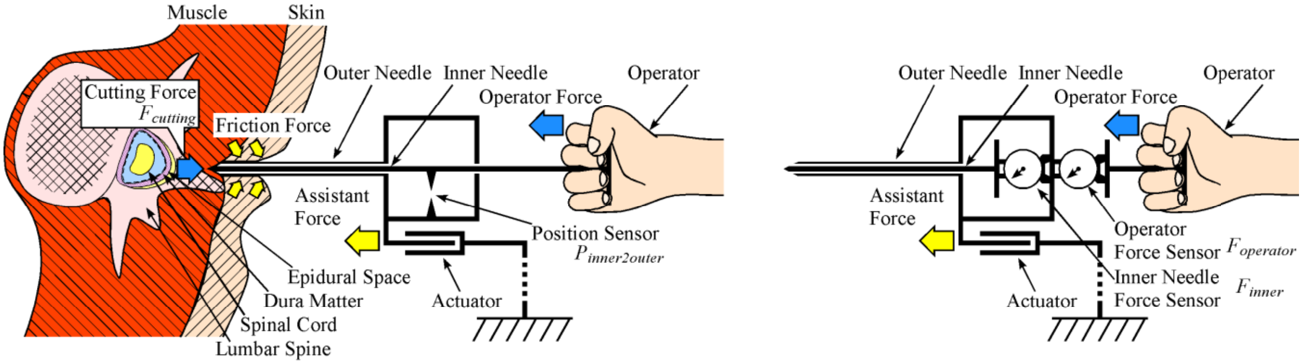


(A) Position-Controlled Assistant (B) Force-Controlled Assistant

Figure 1. Overview of the coaxial needle insertion assistant. (A) In the position-controlled case, the user controls the motion of the inner needle, and the motion of the outer needle is controlled by a motor. (B) In the force-controlled case, force sensors are used to sense the force applied by the operator and the force applied by the inner needle to the tissue (at the tip). An actuator controls the motion of the outer and inner needle together such that the operator receives force feedback that is a scaled version of the force applied to the tissue.

A. *Coaxial Needle Insertion Assistant*

The details of the coaxial needle insertion assistant were reported in [4] and [5], and the summary of the mechanism is introduced here. Fig. 1(A) shows a coaxial needle inserted into the lumbar region of the spine with the position-controlled coaxial needle assistant. Fig. 1(B) shows the force-controlled coaxial needle insertion assistant.

The front end of the inner needle cuts the tissue. The outer needle covers the side of inner needle and prevents the shear friction from acting on the inner needle, while still allowing the inner needle to perform the cutting at the tip. This configuration allows the operator or a force sensor to detect the cutting force by pushing back end of the inner needle.

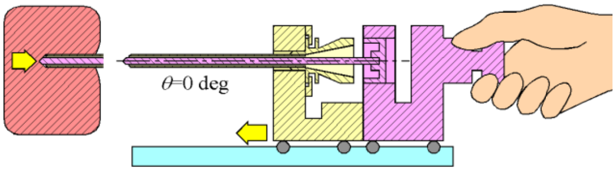
In case of the position-controlled assistant (Fig. 1(A)), the inner needle and outer needle are pushed by the operator and an actuator, respectively. The actuator is position-controlled in an attempt to make the relative position between the inner needle and outer needle constant. The operator inserts only the inner needle, which is mechanically isolated from the outer needle, so that the position-controlled assistant presents only cutting force to the operator.

In the case of the force-controlled assistant (Fig. 1(B)), the inner and outer needles are jointed at the back end and inserted by the operator and actuator collectively. The actuator is force-controlled [6] in an attempt to make the operator force 1.5 times as much as the cutting force measured by the inner needle.

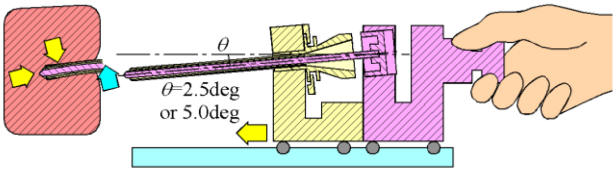
In the case of non-assistant, the inner and outer needles are jointed at the back end and inserted by the operator. The actuator is mechanically isolated in this mode.

B. *User Experiment*

Fig. 2 shows a method to cause a lateral deformation on the needle. When no lateral deformation is expected, the needle is inserted in parallel with its axis. When the lateral deformation is expected, the needle is inserted at the angle with its axis. Because the direction of the needle and direction of movement disagree, the needle is laterally deformed to minimize the disagreement. Without any additional actuation, the lateral force occurs to the coaxial needles naturally by the insertion configuration. The insertion angle θ was set to 0.0 degree (no lateral deformation), 2.5 degrees (small lateral deformation), and 5.0 degrees (large lateral deformation), that made sufficiently large deformation but avoided a plastic deformation of the needles.



(A) No Lateral force is applied to needle



(B) Lateral force is applied to needle

Figure 2. A method to cause lateral deformation on the needle during puncturing. (A) When no lateral deformation is expected, the needle is inserted in parallel with its axis (θ = 0 deg). (B) When a lateral deformation is expected, the needle is inserted at angle with its axis (θ= 5 deg or 2.5 deg).

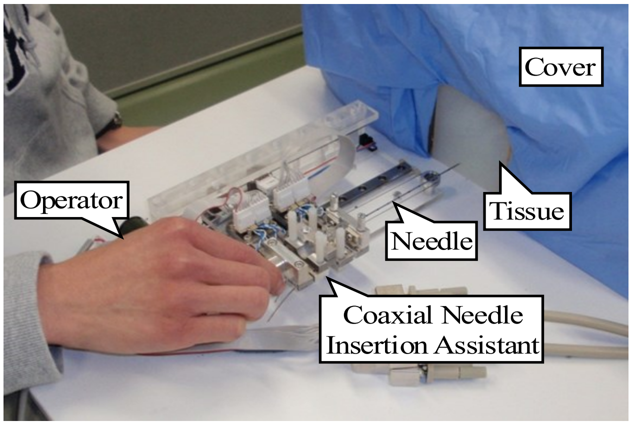


Figure 3. Experiment setup. A subject punctured a tissue with and without coaxial needle insertion assistant. The subject advance a needle into the tissue and stop as soon as he/she perceives the tip of the needle exiting from the other side of the tissue. Overshoots f penetration and confidences of perception in each condition are compared as performance indices

Artificial tissues were made of silicone rubber with two different hardness values (Ecoflex H10 and H30, Smooth-on, where the H-number represents the rubber hardness on the Shore 00 scale). The artificial tissues were cured in two different thicknesses: 30mm and 40mm. The artificial tissues were supported behind by an acrylic plate with a Ø25mm hole to allow the needle to pass through. One steel coaxial needle was used (C2016B, Bard: 19G- diameters of outer needle and inner needle were 1.11mm and 0.93mm, respectively).

Ten right-handed, neurologically healthy, non-medical-professional users participated in this study. This study was approved by the National Institute of Advanced Industrial Science and Technology (AIST), Institutional Review Board (Human 2011-317).

Fig. 3 shows the experiment setup. The users were seated in front of the experimental setup. Holding the handle with the right hand, they punctured the artificial tissues with coaxial needles. The speed of insertion was voluntarily decided by each user. The tissue was covered except for the entry point of the needles, so that the users could not observe the back of the tissue where the needle exited. Each user performed one needle insertion under each combination of three assistant types (position-controlled assistant, force-controlled assistant, and non-assistant), one needle sizes (19G), four tissue types (combinations of two hardnesses and two thicknesses), and 3 insertion angles (0.0, 2.5, and 5.0 degrees). Thus, the total number of insertions performed by each user was 36.

The experiment was designed to evaluate the immediate impact of different assistant types and insertion angle (lateral deformation of the needle), but not to measure the learning aspect of needle insertion. To equalize user adaptability to needle insertion, the order of insertion was sequenced as randomly as possible, given the experimental setup. Four artificial tissues were punctured in pseudo-random order after a certain assistant type and insertion angle were selected. The order of assistant types was changed randomly between users and that of insertion angles was changed randomly within assistant type. Before the actual session, the users practiced puncturing tissue approximately three times in each condition. The practice session was also sequenced pseudo-randomly.

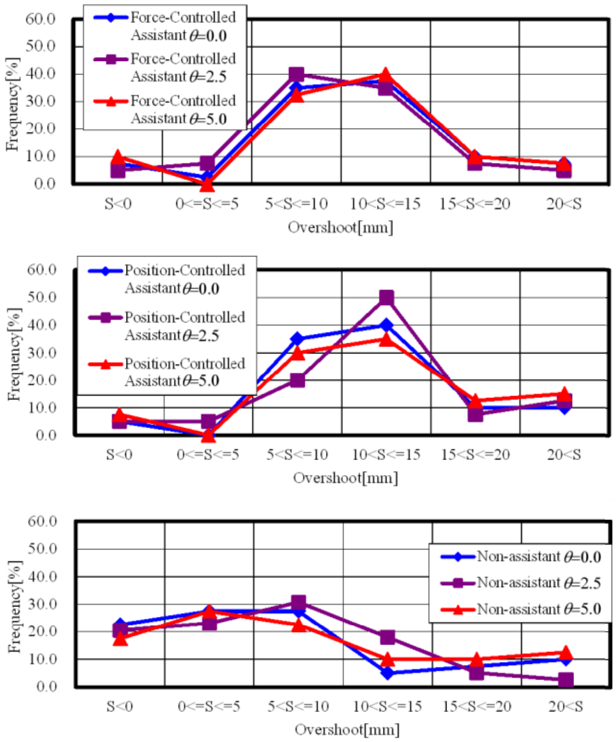


Figure 4. Frequency of needle's overshoot, for 3 insertion angles q of 0.0 degree (no lateral deformation), 2.5 degrees (small lateral deformation), and 5.0 degrees (large lateral deformation), in case of position-controlled assistant, force-controlled assistant, and non-assistant.

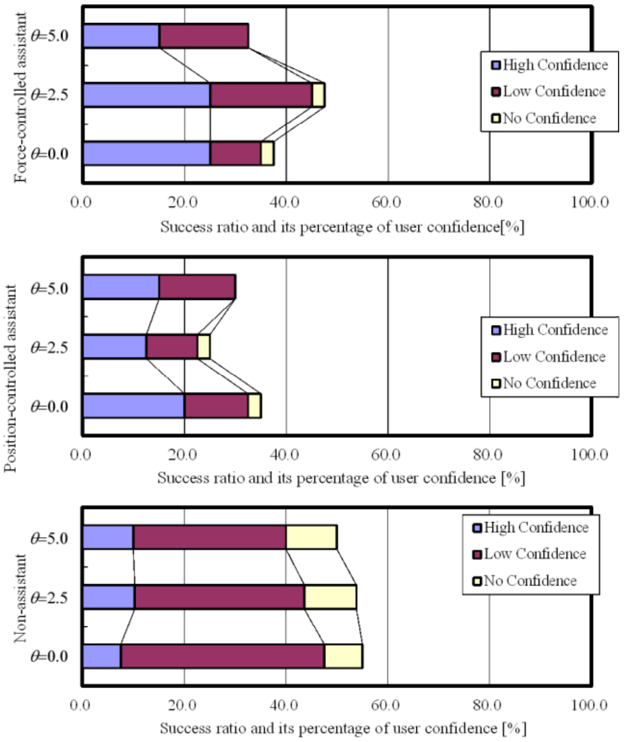


Figure 5. User confidence in successful insertions, for 3 insertion angles θ of 0.0 degree (no lateral deformation), 2.5 degrees (small lateral deformation), and 5.0 degrees (large lateral deformation), in case of position-controlled assistant, force-controlled assistant, and non-assistant. For each successful insertion, users were asked to rate their confidence that they felt the moment of penetration.

For each insertion, the overshoot length (S) out of the tissue sample was measured using a scale. If the user stopped at the moment of puncture, the overshoot would be small. The users rated their confidence in perceiving the needle tip exiting the tissue on a scale of "No", "Low", and "High".

III. RESULTS AND DISCUSSION

In Fig. 4, the frequency distributions of needle overshoot for the different needle insertion angles: $\theta = 0$ (no lateral deformation), $\theta = 2.5$ (small lateral deformation), and $\theta = 5.0$ (large lateral deformation) were shown under the different types of controllers: non-assistant, position-controlled assistant, and force-controlled assistant, respectively. The other conditions (thickness of tissue and hardness of tissue) are summed for each condition. Each trial was classified depending on the level of overshoot (S), with the width of a class defined as 5 mm. Two special cases, failure to penetrate (S<0) and failure to perceive any penetration (20<S), were also defined as classes.

Overall, the results indicated that the insertion angles did not influence the frequency distribution of needle overshoot as much as the type of assistant did. Even though the needle was not deformed laterally, users failed to penetrate with a higher frequency under the non-assistant. Even though the needle was deformed laterally, users failed to penetrate with a lower frequency under the position-controlled assistant and force-controlled assistant.

As for non-assistant condition, it should be noticed that the results reported in this study and those reported in [4] were different. In previous experiment, the users failed to perceive the penetration (the users inserted the needle too much) more frequently than they failed to penetration. In this experiment, the users failed to penetrate the tissue (the users inserted the needle too little) more frequently than they failed to perceive the penetration. This might happen because the participants in previous experiment (mainly students in Johns Hopkins University, USA) were confident and the participants in this experiment (mainly students in Toyo University, Japan) were cautious [7]. Whatever the users' background was, under the position-controlled assistance and force-controlled assistance, the users succeeded in penetration and perception of penetration more frequently than they did under non-assistant condition.

In Fig. 5, percentages of the confidence that users had in performing a successful insertion for the different needle insertion angles were shown under the different types of controllers. Here, successful insertion was defined as an insertion whose overshoot was less than 10 mm ($0<S<=10$). This threshold is larger than the actual epidural space (approximately 5 mm). Considering the discrepancies between our experimental setup and clinical epidural needle insertion (in particular, needle types, tissues, supporting condition of tissue, and user expertise), the threshold was defined independently of a clinically relevant value in order to best illustrate differences between the conditions.

As the insertion angle increase, the successful ratio and the confidence of users tend to decrease, but the tendency was minor. This indicated that the friction between the inner needle and outer needle is sufficiently small in comparison with cutting force and shear friction of needle insertion.

As for successful ratio for all types of assistant, it should be also noticed that the results reported in this study and those reported in [4] were different. In previous experiment [4], the ratio of successful insertion and ratio of high confidence with force-controlled assistant were the highest among all types of assistant. In this study the ratio of high confidence with force-controlled assistant was the highest, but the ratio of successful insertion with non-assistant was the highest. In both experiments, the overshoots of successful insertion in the position-controlled and force-controlled assistant conditions were larger than those in the non-assistant condition. This occurs because a user cannot react sufficiently quickly to the rapid drop in the cutting force and thus inserted the needle deeper before stopping. The population of users in this experiment was less experienced in haptic devices, the users reacted less quickly. This situation can be improved by changing the control parameters. Optimizing the control parameters is urgent issue in this study.

IV. CONCLUSION AND FUTURE WORKS

In this paper, we have tested user performance during a needle insertion task with the assistant active and inactive under the condition that a lateral force is applied and not applied on the coaxial needle. This condition is clinically practice in needle insertion. The results indicated that the influence of lateral force on the needle was minor.

In this study, it was confirmed that the assistant facilitated user's perception of tissue penetration, whether the users insert the needle too little or too much. However, it was also confirmed that the assistant tend to increase the overshoot of needle. The control parameters should be optimized in an attempt to minimize the overshoot of needle. Since the overshoot is influenced by hardness and friction of a tissue [4], the optimization should be tested in clinically relevant condition.

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