Title:
Novel Surgical Needle Design and Manufacturing for Vibratory-assisted Insertion in Medical Applications

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Keywords:
Design and manufacturing, Vibratory needle insertion, Modal analysis, Biomedical applications.

DOI: 10.14733/cadconfP.2016.352-356

Introduction:

Needles are among the most widely used medical devices, and they serve in a wide variety of medical procedures, from ordinary ones like blood sampling and drug delivery to advanced ones like tissue biopsy and brachytherapy [1]. Depending on the specific procedure, a medical needle may come in a solid or a hollow configuration, and sometimes hollow and solid needles are used together as cannula and stylet. Whatever the configuration is, low insertion force is desirable because it helps to reduce tissue deflection and needle bending, so that the placement accuracy of the needle can be improved and the insertion injury has the potential to recover better [3]. Low insertion force also reduces the pain sensed by patients, which is very important when anesthesia is not applicable [4]. A good example to illustrate the importance of low insertion force is in brachytherapy, where radioactive seeds are placed systematically in a diseased organ to kill cancer cells. Accurate seed placement is critical to ensure the seeds are within the cancer areas requiring treatment and far away enough from healthy cells. However, insertion force not only causes the needle to deflect and bend, but also pushes the target area away from its original location, which will result in incorrect placement and even medical complication. Low insertion force is desirable to minimize such deflection and displacement.

Vibration-assisted cutting has been used in advanced manufacturing processes, where a high frequency vibration with small amplitude is added to the main feed motion of the cutting tool, as shown in Fig. 1. In drilling, for example, studies have shown that ultrasonic vibrations in the feed direction could reduce burrs in drilling [12], create a better surface finish [9], and reduce the cutting force needed [11]. In our earlier research [8], vibration assisted drilling was studied and an analytical modeling was developed for vibration assisted drilling on bones and metals. In tissue cutting, increased insertion speed has been shown to reduce both insertion force [5] and tissue deflection [10], but higher insertion speed often result in more difficulty in control. Vibration, however, offers a method to increase the maximum local insertion speed of the needle tip while maintaining a slow and controllable average insertion rate [12]. Actually, vibration-assisted cutting has been shown to reduce insertion force in tissue cutting by several researchers. Huang et al. [6] studied the frequency response of Gauge 27 bevel needles and showed that ultrasonic vibration could reduce the insertion force. Barnett et al. [2] tested the effectiveness of axial vibration in reducing the insertion force into porcine skin across a range of frequencies, amplitudes and needle sizes, and found that the addition of the vibration was able to reduce the insertion force by up to 35%. For micro needles, results have shown that the addition of axial vibration can reduce cutting force sometimes up to 70% [13]. From the viewpoint of physics, Khalaji et al. [7] extended the LuGre friction model with high-frequency vibration for translational friction, and demonstrated that it could be reduced with the introduction of low-amplitude vibratory motion onto a regular insertion profile.

This paper presents a novel design of solid surgical needle featured by its 4-bevel tip and shaft slots with the aim to further explore the potential of vibratory needle insertion. Details of the proposed design and manufacturing processes along with the experimental results are presented in the following sections.

Design of the Proposed Novel Surgical Needle:

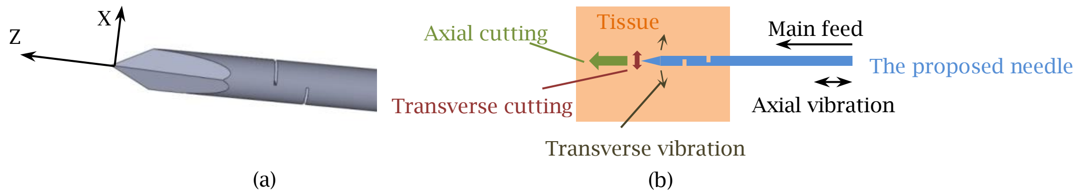


Fig. 1: (a) The new design and (b) illustration of insertion with the new design.

Fig. 1(a) shows the design of the proposed medical needle for vibration-assisted insertion. The needle tip is featured by the four bevels forming the needle tip and the two slots on the shaft. The two slots on the opposite sides of the needle shaft, where lies the major novelty of the proposed design, aim at modifying the stiffness of the needle, and thus the frequency response. The slots are cut perpendicular to the shaft center line, which enable the main cutting edges to vibrate more easily along the X direction to perform tissue cutting than along the Y direction under stimulation. By matching the amplitude and frequency of the vibration applied to the needle in the Z axis direction with the location and depth of the slots, the main cutting edges can vibrate with high speed along the Z and X directions to perform micro tissue cutting, which will be beneficial to reduce the insertion force. An illustrative picture is shown in Fig. 1(b).

Fabrication Method of the Proposed Needle:
To fabricate he intricate geometry of the proposed needle both the bevels and the slots are processed on an EDM machine to avoid the alignment difficulty and inaccuracy caused by transferring the work piece between a grinding and an EDM machine. Fig. 2(a) shows the four-step EDM procedure to generate the bevels on the needle tip, and Fig. 2(b) shows the two-step EDM procedure to generate the slots on the needle shaft. Fig. 3 shows a prototype of the proposed needle design.

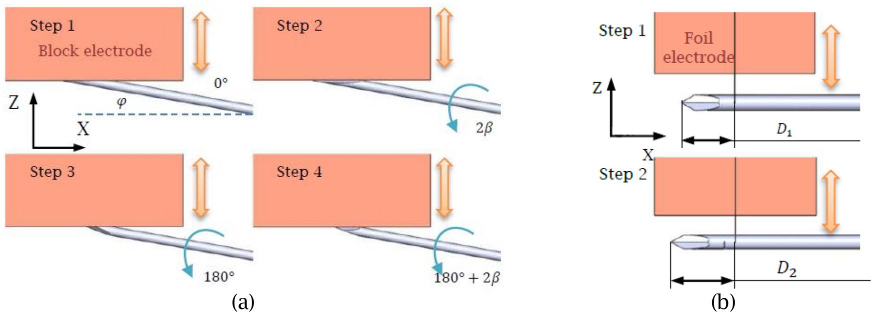
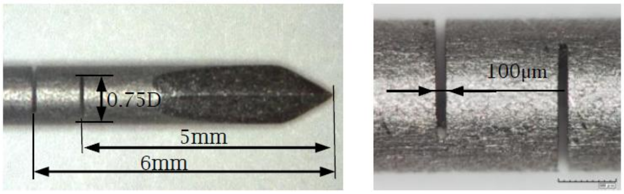


Fig. 2: EDM-based fabrication of the (a) bevels and (b) slots.

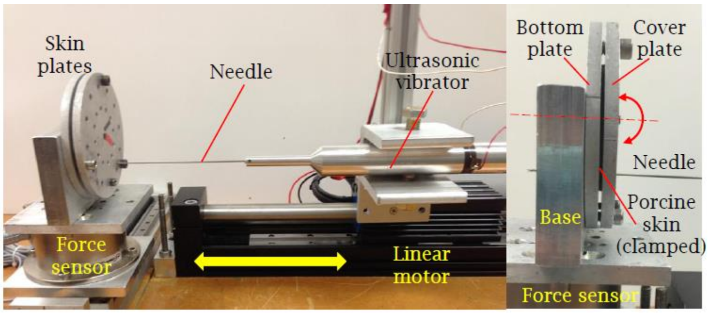
Insertion Experiment with Porcine Skin:
To investigate and validate the performance of the proposed needle design, insertion experiment with porcine skin was conducted using the setup in Fig. 4. For this study, an ultrasonic piezoelectric transducer (Honda Electronics, Toyohashi, Japan) with a resonance frequency of 20 kHz was applied to provide vibration to a needle in the axial direction. The average velocity of insertion was set to a constant of 1mm/s for all the trials. To study the effects of needle geometry parameters on insertion performance,

two sets of needle prototypes with different slot locations were fabricated with the methods presented above. The needle length was calculated as 123.7 mm. Five trials were conducted for the vibration and the non-vibration condition of each needle respectively. Puncture force and depth were chosen as the performance indicators.



(a) (b)

Fig. 3: A fabricated needle prototype: (a) overview of tip and (b) close view of slots.



(a) (b)

Fig. 4: Experiment setup for needle insertion: (a) overview and (b) the skin plates.

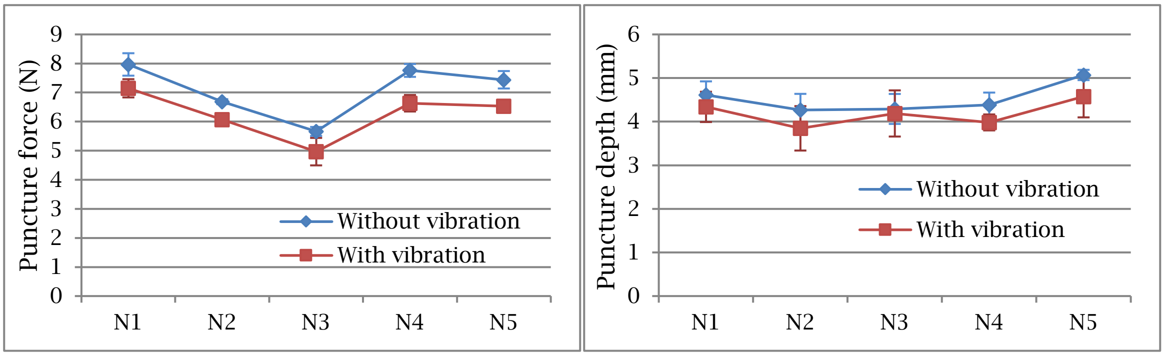
Modal Analysis and Vibration Simulation:

To determine the motion of the needle tip in air, a modal analysis study was conducted using the Simulation Add-in in SolidWorks (Concord, MA) software. The CAD models of the needle sets were meshed with a global size of 0.5 mm and a tolerance of 0.025 mm. An axial excitement with amplitude of 50 μm was applied at the bottom of the needle between the frequencies of 19 kHz and 21 kHz for harmonic analysis. For all the needles, the Z (axial) and X (transverse) direction displacement of the needle tip were recorded.

Results and Discussion:

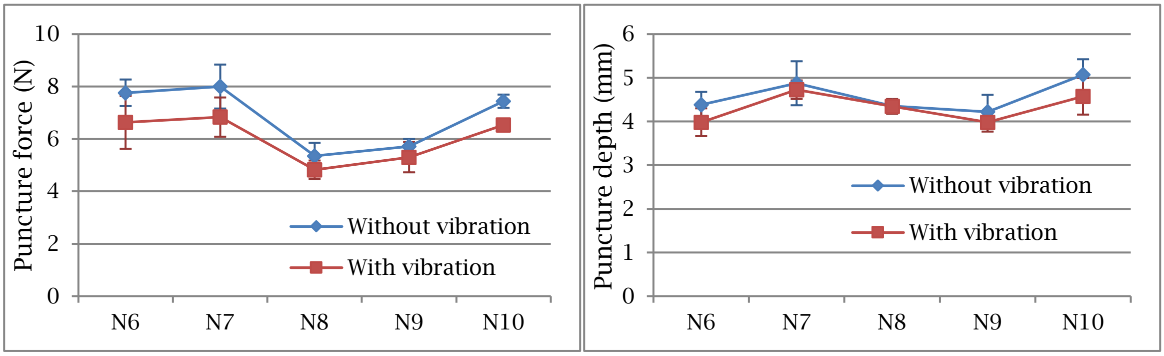
For each needle in the first set, applying vibration resulted in the reduction in puncture force and depth as shown in Fig. 5. N3 had the smallest values of puncture force for both conditions with and without vibration. The puncture depth also decreased, although it was not significant for N3. According to the relative decrease of puncture force, while N5 as control could reduce the puncture force by 12.2% after applying vibration, N1 to N4 can reduce by 10.3%, 11.5%, 12.3% and 14.5%, respectively. In other words, the proposed novel design of surgical needle can result in greater reduction in puncture force with proper selection of slot locations. By referring to the results of simulated Z and X displacement, it can be seen that a larger Z displacement resulted in greater reduction in puncture force, so the difference in the puncture force of this needle set seemed to be mainly determined by Z displacement.

For each needle in the second set, applying vibration resulted in the reduction in both puncture force and depth as shown in Fig. 6, although the depth reduction for N8 was not significant. N8 had the smallest values of puncture force for both vibration conditions. While N10 as control could reduce the puncture force by 12.2% after applying vibration, N6 to N9 can reduce by 14.5%, 14.6%, 10.0% and 7.1%, respectively. For this needle set, the design of N6 and N7 can result in greater reduction in puncture force. The reduction of puncture force didn't show much similarity with the simulated Z or X displacement. However, if the X and Z displacement were combined like two perpendicular vectors, the new displacement matched the reduction of puncture force. In other words, a larger combined amplitude of X and Z vibration would result in greater reduction of puncture force.



(a) (b)

Fig. 5: Experiment results for the first needle set: (a) puncture force and (b) puncture depth.



(a) (b)

Fig. 6: Experiment results for the second needle set: (a) puncture force and (b) puncture depth.

Conclusions:

This paper presents a novel design of solid surgical needle featured by its 4-bevel tip and shaft slots with the aim to further explore the potential of vibratory needle insertion for medical applications. The design philosophy was discussed, and the EDM processes for fabricating the needle were introduced. Prototypes of the needle design with different geometry parameters were fabricated and used for insertion into porcine skin with ultrasonic vibration. The results showed that the needle design could reduce the puncture force by 14.5% at maximum than the 12.2% of control. The reduction of puncture force was determined by the Z displacement and/or the combined X and Z displacement. From the design point of view, changing D_1 will be more effective in increasing transverse displacement than D_2 for the presented range.

Acknowledgement:

This work was partially supported by the National Science Foundation (NSF) Grants (CMMI-1125872, CMMI-1404916 and CMMI-1547105) to North Carolina State University and the National Science Foundation (NSF) Grants (CMMI-1404916) to The Penn State University. Their support is greatly appreciated.

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