CAI, YI. Design, Analysis and Manufacturing of Compliant Needles for Vibratory Insertion in Medical Applications. (Under the direction of Dr. Yuan-Shin Lee.)

Needles are one of the most important medical devices in percutaneous intervention procedures. With the aim to reduce insertion force and thus improve needle insertion accuracy, a novel solid compliant needle is designed and manufactured for vibratory needle insertion in this paper, which is featured by its 4-bevel tip design and perpendicular micro slots on the needle shaft. The philosophy is to transfer the axial vibration at the needle base into both axial and transverse vibration at the needle tip.

To study the vibration motion at the needle tip, modal analysis and harmonic analysis based on finite element methods were used to simulate the axial and transverse vibration at the needle tip under working frequency. The relationship between the displacement amplitudes and the slot parameters including slot number, location, depth and width was investigated. An empirical method was developed to determine the slot locations which lead to peak or valley transverse needle tip displacement.

To overcome the manufacturing challenge of the proposed needle design due to its small dimensions and relatively intricate geometry, a fabrication method based on the micro-EDM and the tooling design was proposed. An analytical model was developed and validated for accurate calculation of slot depth and slot bottom profile based on the relative motions of foil electrode and needle. EDM control functions were tested to increase slot width with different motions after the initial cutting of the micro-slots.

To investigate and validate the capability of the proposed compliant needle design, insertion experiments with needle prototypes were conducted using ultrasonic actuators to provide the axial vibration at the needle base. Testing materials with different properties,
including candle gel, porcine skin and polyurethane sheet, were used. By relating the experiment results with material properties and needle tip vibration pattern, the practical guidelines for reducing insertion force in different insertion mediums were identified.

The experimental results show that the proposed method and compliant needle design is promising on reducing the insertion force and improving the needle placement accuracy. The proposed method, the new manufacturing technique, and the practical guidelines presented in this paper can be used for future development of new compliance surgical needles for engineering and bio-medical applications.
Design, Analysis and Manufacturing of Compliant Needles for Vibratory Insertion in Medical Applications

by
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DEDICATION

To my parents, Hanqi Cai and Bizhen Mai, who have worked very hard
to support me to achieve my goal.

To my beautiful wife, Min Qin, for everything she has done for me
during these wonderful years.
BIOGRAPHY

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CHAPTER 1 INTRODUCTION

This chapter gives a brief introduction to the critical problems of needle insertion accuracy in percutaneous procedures to be addressed, and the research motivation and objectives of the study to be presented.

1.1 Background

Needles are among the most widely used medical devices, and they serve in a wide variety of percutaneous procedures, from ordinary ones like blood sampling and regional anesthesia and drug delivery to advanced ones like tissue biopsy and brachytherapy [1]. The effectiveness of a treatment and the success or precision of a diagnosis is highly dependent on the accuracy of percutaneous insertion [2]. In procedures such as biopsy (for prostate, kidney, breast and liver), brachytherapy and anesthetic, placement accuracy of millimeters is required while in brain, fetus, eye and ear procedures placement accuracy of micro-millimeter is desirable. Furthermore, the target might be in the millimeter neighborhood of another organ, vessel or nerve. Therefore, extra caution is required to avoid any damage or spread of a disease which in turn may lead to subsequent complications. Although there is not a defined tolerance for the accuracy of needle insertion in clinical practice and in general, insertions with less needle misplacement result in more effective treatment or increase the precision of diagnosis.
Clinical studies have revealed that human errors [6], imaging limitations [1], target uncertainty [7], tissue deformation and needle deflection [4, 8] are a few known problems that contribute to needle misplacement in percutaneous procedures. Although the insertion accuracy may be improved using current tools such as real-time visualization and high precision imaging techniques [9], advanced surgical robots [10] and medical simulators [11], accurate needle placement for many applications still requires much more research and development.

1.2 Motivation and objectives

Whether a needle is solid or hollow, low insertion force is desirable, because it helps to reduce the tissue deformation and needle deflection and thus the placement accuracy of the needle can be improved [2, 12, 13]. Low insertion force also creates less pain, trauma and edema to the patients, and the insertion injury has the potential to recover better [5, 14]. To date, researchers have explored a variety of methods to reduce the insertion force, which include and are not limited to the modeling, optimization and innovation of needle geometries (rake angle, inclination angle, diameter, etc.) [15, 16], special treatments of needle surface [17, 18], and optimization of insertion process (velocity control and trajectory selection, etc.) [19-...
Among all these methods, vibratory needle insertion is a technique where minor high-frequency vibration is applied to a needle in addition to the main insertion motion. Although some researchers have demonstrated the capability of vibratory needle insertion in force reduction, the underlying mechanism between tissue and vibrating needle tip has not yet been fully understood, thus its potentials have not yet been fully explored. For example, the needles used in the experiments were of regular tip geometries in common insertion without vibration. Are there any new designs that can better take advantage of vibration? In a majority of the experiments, axial vibration was applied. Can transverse vibration help to further reduce the insertion force when used together with the axial one? If yes, on which types of tissue materials? Given the energy-absorbing property of tissue, how can transverse vibration be realized at needle tip in a predictable and controllable manner? Such questions still need to be answered.

As a result, the motivation of the presented research is to further explore force reduction using vibratory needle insertion especially in terms of new effective geometry and vibration mode. The objectives of this research include:

1. To design and fabricate a compliant needle with new geometry which can transfer axial vibration at needle base into both axial and transverse vibration at needle tip for vibratory insertion;

2. To investigate the effects of different geometry design variables and vibration
parameters on vibration pattern at the needle tip;

3. To investigate the effects of vibration pattern on insertion force for different tissue materials and identify optimized vibration pattern for different application scenarios.

Figure 1.1 A knowledge bridge across geometry design, vibration pattern and insertion performance.

The ultimate goal is to build up a knowledge bridge among needle geometry, vibration pattern and insertion performance, as shown in Figure 1.1. Through finite element simulation and in-field measurement, it is expected that the vibration pattern (e.g. amplitudes of axial and transverse vibration at tip) of a needle with specific design geometries can be obtained. On the other hand, the insertion performance of needles with different vibration patterns can be evaluated with analytical modeling of the insertion process and insertion experiments. The bridge among the three items will be of great value for improving the effectiveness of vibratory insertion processes and designing new vibratory needle insertion devices.
1.3 Organization of the report

The reminder of this paper is organized as follows:

Chapter 2 first gives a review of the factors affecting needle insertion accuracy, from which low insertion force is identified an important method for accuracy improvement. Research on modeling of tissue-needle interaction forces is then reviewed, followed by research efforts to reduce insertion force including optimization and innovation of needle geometries, special surface treatments, and optimization of insertion process. Vibratory needle insertion, as a method of process optimization, is highlighted and followed by the novelty and contributions of the reported research.

Chapter 3 introduces a unique design of solid compliant needle featured by its 4-bevel tip and shaft slots with the aim to further explore the potential of vibratory needle insertion. The design philosophy of the needle was introduced. To overcome the challenging issues faced in fabricating the designed needles, a non-traditional manufacturing process using electric discharging machining (EDM) for the tip and slots is presented, together with an analytical model for slot depth control and a method to increase the slot with after initial slot cutting. Needle prototypes of the proposed design were fabricated with different geometries and evaluated.

Chapter 4 presents two categories of experiments conducted using a piezoelectric
vibrator to investigate the capability of the proposed compliant needle design. In the first category, needles with different slot locations were inserted into tissue phantom, which mimicked soft tissues like muscles. In the second category, the needles were inserted into skin phantom, which aimed to study their penetration capability. After each category of experiment, the results of the needle performance are presented followed by discussions.

Chapter 5 presents the use of modal analysis and harmonic analysis based on finite element methods to study the vibration motion at the tip under working frequency. The relationship between the displacement amplitudes and the slot parameters including slot number, location, depth and width is investigated. An empirical method is developed to determine the slot locations which lead to peak or valley transverse displacement.

Chapter 6 presents insertion experiments with needle prototypes using ultrasonic actuators to provide the axial vibration at the needle base. Three common insertion materials with different properties, including candle gel, porcine skin and polyurethane sheet, are tested. Practical guidelines for reducing insertion force in different insertion mediums were identified by comparing the experiment results with material properties and needle tip vibration pattern.

Chapter 7 provides the concluding remarks and future research tasks. The limitations in current research are also highlighted, followed by future work with the aim to better explore the proposed new design.
CHAPTER 2 LITERATURE REVIEW

Given the importance of needle insertion accuracy, this chapter first gives a review of the factors affecting needle insertion accuracy, from which low insertion force is identified an important method for accuracy improvement. Research on modeling of tissue-needle interaction forces is then reviewed, followed by various research efforts to reduce insertion force. Vibratory needle insertion, as a method of process optimization, is highlighted with its advantages and current research limitations. This chapter concludes with the novelty and contributions of the proposed research.

2.1 Introduction

Percutaneous therapies are constrained procedures where target visibility, target access and tool maneuverability in addition to physiological changes to the target are key issues. During some conventional needle insertion procedures, the surgeon relies on kinesthetic feedback from the tool (needle or catheter) and his or her mental 3D visualization of the anatomical structure [2]. Real-time imaging techniques that are used in some procedures can improve target visibility. However, human errors [6], imaging limitations [1], target uncertainty [7], tissue deformation and needle deflection [4, 8] are a few known problems that contribute to needle misplacement in percutaneous procedures.
Human errors may be related to poor techniques and insufficient skills of a physician. Target uncertainty may be caused by patient motion, physiological or geometry related problems [7]. Despite the availability of different imaging modalities to improve visualization; there are several factors such as high cost, poor resolution, probe availability, X-ray exposure, material compatibility, reliable real-time image processing techniques, etc. that may limit application of imaging in some clinical and research studies [1]. A few examples of these limitations are: working with robots where MRI is the imaging modality (magnetic interference), using artificial phantoms when the imaging modality is ultrasound (acoustic properties), and using camera when performing ex vivo experiments (non-visibility of target).

Needle deflection is generally due to the bevel tip and diameter of the needle [22, 23]. The tissue, into which the needle is inserted, may also contribute to needle deflection. The factors that affect tissue deformation include mechanical properties of soft tissue, needle tip contact force, and frictional forces between the tissue and the needle shaft [24]. Other causes of inaccuracy in percutaneous therapies are physiological changes in the organ between the planning and treatment phases, glandular swelling during the operation, difference in tissue types involved in each procedure, differences in mechanical properties of healthy and diseased tissue, changes of mechanical properties when tissue is damaged and variability of soft tissue properties for the same organ in different patients [1].
Some of these factors such as tissue deformation and movement and needle bending are directly proportional to the forces experienced by the needle during the insertion procedure [18]. According to Han et al. [25], a practical approach to reduce needle placement errors is to reduce the insertion force.

2.2 Modeling of needle-tissue interaction forces

Knowledge of interactive forces during needle insertion plays an important role in precise needle insertion. This knowledge can help to identify and model different tissue types and it can also provide feedback for precise control of robot-assisted insertion while reducing tissue deformation and needle deflection. It also serves as the foundation for effectively reduce the insertion force. In general, an accurate model for insertion forces should be able to identify features such as the force peak, latency in the force changes, and separation of different forces. It is also desirable for the model to calculate the magnitude of the insertion force such that it matches the actual measurements.

Simone and Okamura [26] investigated modeling of needle insertion forces for bovine liver and considered puncture of the capsule as an event which divides the insertion to pre-puncture and post-puncture phases. In pre-puncture, the force increases steadily and a sharp drop in the amount of force identifies the puncture event. During post-puncture, the amount of
force is variable due to friction, cutting and collision with interior structures. The total force acting on the needle is the sum of stiffness force, cutting force and friction, where the stiffness force belongs to pre-puncture and the friction and cutting forces belong to post-puncture. Specifically, the stiffness force was modeled with a nonlinear spring model, the friction with a modified Karnopp model [14], and the cutting force a constant. A comparison was conducted between the above needle insertion model and two insertions in an excised bovine liver. The overall shape is similar, but there is a large discrepancy between their model and the actual data at the moment of puncture. They assumed that the discrepancy is due to the wide variations in liver geometry and its internal structure.

Using a specially developed seven-axis load cell for measuring and separating forces during needle insertion, Kataoka et al. [27] performed experiments using a needle with a triangular pyramid tip on an exposed prostate of a defrosted beagle cadaver. Three different forces acting on the needle were measured independently: the tip force, the friction force and the clamping force. The tip force acting on the needle tip in the axial direction was assumed to be primarily related to cutting. The shape of the needle tip affects the magnitude of this force. The friction force acting on the sidewall of the needle shaft in the axial direction was considered to be the summation of Coulomb and viscous friction. The clamping force acting on the sidewall of the needle shaft in the normal direction was taken to be the resistance force.
of the tissue due to its compression away from the needle path. The clamping force increases as the needle is inserted into the tissue. The magnitude is affected by the needle gauge and the incision shape. They presented that the total axial force is the summation of the tip force and the friction force. The clamping force affects the value of the friction force. They also found that the tip force decreases right after puncture to the constant value for the cutting force. This decrease occurs because the prostate capsule is harder than the inner tissue.

DiMaio and Salcudean [2, 28] explored the relationship between needle forces and 2D tissue deformation using a planar robot, a PVC tissue phantom and a CCD camera. The force distribution indicates the existence of two forces: a uniform axial friction force between the needle and the tissue along the shaft, and a force peak of cutting at the needle tip. They also showed that during penetration the shaft force increases with insertion velocity while the force peak appears to be somewhat independent of velocity. Their study is useful for preliminary simulations; however, needle insertion in such artificial tissue phantoms cannot help to realistically model interactive forces during needle insertion in inhomogeneous, viscoelastic tissue.

Besides the classic research works described above, new achievements have been made in recent years in modeling needle insertion force. Asadian et al. [29] presented a new approach to account for distributed friction in needle insertion in soft tissue. A distributed LuGre model
was adopted to characterize dynamic features of the complex nonlinear friction in various situations. Experimental results using an artificial phantom illustrated that the proposed method was capable of representing the main features of friction which is a major force component in needle-tissue interaction during percutaneous interventions. Tai et al. [30] presented a 3D finite element model (FEM) using cohesive zone (CZ) concept to simulate the hollow needle insertion and identify the change in cutting force. CZ is a FEM technique that integrates the fracture mechanics based on surface energy and has often used in analysis of crack propagation. Both experimental observation and modeling results showed higher cutting force for the lancet tip due to smaller rake angle along the cutting edge. Fracture mechanics based models have also been developed by incorporating the tissues fracture toughness, shear modulus, and friction force into understanding the total needle insertion force [31].

2.3 Reduction of insertion force

As the advancement in modeling and simulation provides deeper understanding of tissue-needle insertion forces, it is natural for researchers to make efforts to reduce the insertion force, because low insertion force is associated with less tissue deformation and needle deflection [2, 12, 13], which are important to improve needle insertion accuracy. To date, researchers have explored a variety of methods to reduce the insertion force, which include
and are not limited to the modeling, optimization and innovation of needle geometries, special
treatments of needle surface, and optimization of insertion process.

2.3.1 Optimization and innovation of needle geometries

According to Simone and Okamura [26], the insertion force is made of the stiffness
force before puncture and the cutting and friction forces after puncture. The stiffness force and
cutting force are largely affected by needle diameter and tip geometries. While it is intuitive
that a larger diameter results in larger values of these two forces, the effect of tip geometries is
difficult to tell at a glance.

Okamura et al. [32, 33] investigated the effect of needle diameter and tip type on
insertion forces. They found a significant effect of tip type on insertion forces. Insertion forces
increased as the needle tip type changed from triangular to bevel and bevel to cone but the
bevel angle did not affect the axial force significantly. They also found that for each of the tip
types, the increase of needle diameter increased the insertion force. Han et al. [34] developed
specific models for various tip geometries to investigate four types of needle tips including
one-plane, asymmetric three-plane, symmetric multi-plane, and symmetric three-curved-
surface needles. Their configurations were evaluated based on the included and inclination
angles of the cutting edges and their effects on cutting/insertion force. The proposed general
approach provided the foundation for designing medical needles with specific cutting edge properties. Moore et al. [35] derived the mathematical models of the inclination angle and the rake angle for plane needle cutting edges of hollow needles, and utilized a mechanistic approach based on the concept of elementary cutting tool was used to predict the initial peak needle insertion force [36]. Based on their works, Wang et al. proposed a method to find out the optimal design of two lancet needles with minimal insertion force and bevel length respectively [13].

Instead of optimizing the geometry variables of common existing needle tip types, some researchers developed new geometries. Moore et al. [15] developed a novel enhanced cutting edge for two-plane symmetric needle, which could reduce the insertion force while increasing biopsy sample length. The needle with lancet point (NLP), having three planes at the tip to generate a sharp lancet point, is the most common needle tip geometry. Wang et al. presented a five-plane lancet needle with two back bevels (FLN-B) and a five-plane lancet needle with two front bevels (FLN-F), to study the effect of two additional bevel planes on the reduction of soft tissue insertion force over that of the NLP. Compared to NLP, FLN-B and FLN-F have higher inclination and rake angles and can reduce the insertion forces by 9.1% and 8.3%, respectively in the PVC phantom tissue experiment.
2.3.2 Special treatments of needle surface

Friction along the needle shaft is another important force that contributes to the total insertion force. It increases proportionally to the insertion depth because of the increase of the contact surface between tissue and needle [37]. As the needle diameter increases, the more the tissue is displaced and compressed in the vicinity of the needle. This increases the forces normal to the surface of the needle, leading to higher friction forces. While it is not always possible to reduce the needle diameter due to specific application requirements, special treatments can be performed to the needle shaft to reduce the friction.

Biocompatible coatings are used in medical tools to improve biocompatibility, thermal stability, and dielectric properties. For example, parylene is a plastic coating currently used in many medical applications because of its environmental protection and electrical insulation. Another biocompatible coating is diamond-like carbon (DLC) whose carbon structure is between that of diamond and graphite. While DLC is mostly found in mechanical and electrical applications due to its low coefficient of friction, high hardness, chemical inertness, and high electrical resistivity, it can also be used in the body for orthopedic and cardiovascular applications [38]. It was found that the coatings of DLC and parylene reduced the frictional force between the needle and catheter by 24.2% and 34.9%, respectively compared to a regular uncoated needle [17].
Recently, laser surface texturing (LST) has been widely used in machining micro-features in a variety of materials because of its versatility, fast adaptability, high precision and cleanliness of environment. Various micro-features through LST have been applied to enhance the tribological properties of contact surfaces. Recently, Wang et al. [18] explored a method for creating micro-features with blended edges on echogenic needles and studied the friction behavior between textured echogenic needles and phantom tissue to identify blended texture patterns that would minimize the friction during needle insertion. Through needle extraction experiment, it was found that the blended textured needles with large fillet radii exhibit a much better friction behavior.

2.3.3 Optimization of insertion process

Needle insertion speed has great effects on the needle insertion forces. The soft tissue is considered to be viscoelastic, this means that the friction force increases as the relative velocity between needle and surrounding tissue increases [39]. Podder et al. [40] observed steady increase in main axial force (which was mainly the friction) on the needle as the insertion speed increased. However, according to Mahvash et al. [41], it was found that when the needle is inserted slowly, the tissue experienced substantial elastic loading prior to the onset of cutting. Once the critical cutting force was met, the stored potential energy was released and
the cut depth was observed to increase suddenly. When the needle velocity was increased, it could be seen that both the needle force and the displacement necessary to initiate cutting decreased. Moreover, Heverly et al. [42] showed with in-vitro test results on porcine heart samples that the force required to initiate cutting reduced with increasing needle velocity up to a critical speed, above which, the rate-independent cutting force of the underlying tissue became the limiting factor.

Generally, clinical needle insertion rates vary between 0.4 and 10 mm per second [43]. Dynamic needle insertion can be defined for situations when minor supplement motions are added to this main insertion motion. The purposes of dynamic insertion include reduction of insertion force, control of needle deflection and improvement of needle steering.

A typical dynamic insertion technique is to rotate the needle or cannula when it is being inserted. Badaan et al. [20] investigated the use of needle rotation in controlled in-vitro experiments performed with a specially developed revolving needle driver. The experiments showed that needle rotation could reduce axial insertion force, improve targeting and reduce errors by as much as 70%. Meltsner et al. [44] showed that rotating the needle as it was inserted might reduce frictional forces while increasing accuracy. However, needle rotation was observed to increase tissue damage due to the drilling nature of the insertion. After some investigation of rotating needles in gel, they suggested the rotate-cannula-only method of
conical needle insertion to minimize tissue damage while maintaining the benefits above. Han et al [37] proposed a force model based on the fracture mechanics approach to analyze the effect of needle rotation on the cutting forces in biopsy cannula. It was found that the cutting forces depend on the slice/push ratio given by $k = \text{speed parallel to the cutting edge}/\text{speed perpendicular to the cutting edge}$. Increasing the slice/push ratio reduced the cutting forces and a minimal slice/push ratio of 2 was recommended.

Some other researchers looked into the situations where the rotation was not performed continuously. Abolhassani et al. [8, 45] studied the effect of different trajectories on tissue indentation and friction force. They performed experiments on ex vivo turkey tissue with its skin intact using a 2-DOF robot. A needle with a bevel tip was used for the experiments with fixed bevel tip upward orientation. For each constant axial velocity, the effect of different rotational motions was compared. The following were considered: no rotation, continuous rotation with different speeds, bidirectional rotation with different rotational angles and speeds, and needle rotation based on forces orthogonal to the insertion direction. The result showed that having rotational motion can reduce the amount of tissue indentation as well as the friction force between the needle shaft and the tissue. It also showed that controlling the rotational motion by keeping as close to zero as possible the lateral forces acting on the needle gave the best result among different types of rotational motions. Podder et al. [40] investigated the
effects of modulation of insertion/linear velocity, rotational oscillation, and full rotation of 18G diamond tip needle (cannula plus trocar) commonly used for prostate brachytherapy procedures. The experimental results showed that needle rotation would decrease organ/tissue deformation/deflection as long as a high enough rotational speed could be obtained to counteract the deformation created by the higher insertion speeds. On the other hand, the rotational oscillation actually tended to increase the forces and thereby increases the target deflection, at least low frequency oscillation. Wood et al. [46] presented a nonlinear control law using a steering approach based on duty-cycled rotation during insertion with the aim to drive the bevel-tip needle to track a predetermined planar path. Duty-cycle was defined as the ratio of the rotation period to the sum of rotation and translation period. The control method was implemented into a variable curvature flexible needle steering system and validated with in vitro experiments. Minhas et al. [47] proposed a kinematic model for needle steering via duty-cycled spinning. They extended the original nonholonomic model [48] for bevel-tip needle steering by altering a term for rotation speed in the model to model the spinning behavior. Simulation results were validated with in vitro experiments of gelatin.

Albeit the benefits that it can bring in terms of insertion force reduction and needle deflection correction, needle spinning may induce tissue damage due to any minor defect in needle straightness, ofF-centric rotation or macro-structural defects at the needle tip as a result
of imperfect machining [49]. Also, continuous rotation could cause damage by hooking the tissue [4] or incurring whirling phenomenon [19]. Moreover, high-rate needle spinning requires removal of the force/torque sensor from the needle holder to avoid the wraparound of the sensor cable [5]. However, in many medical applications, the presence of a force/torque sensor in needle assembly could improve other aspects of insertion, such as detection of transition between tissue layers, parameter estimation and/or controlling tissue deformation [1].

2.4 Vibratory needle insertion

Another dynamic needle insertion technique is vibration. In the field of manufacturing, 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. In drilling, for example, studies have shown that ultrasonic vibrations in the feed direction could reduce burrs in drilling [50], create a better surface finish [51], and reduce the cutting force needed [52]. In our earlier research [53], vibration-assisted drilling was studied and an analytical modeling was developed for vibration-assisted drilling on bones and metals.
Figure 2.1 Medical needle insertion: (a) traditional and (b) proposed vibratory insertion.

In tissue cutting, increased insertion speed has been shown to reduce insertion force [42, 54] and improve insertion accuracy [41, 55], but higher insertion speed often results 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 [50]. Actually, vibration-assisted needle insertion has been shown to reduce insertion force in tissue cutting by several researchers. Shin-ei et al. [56] were among first to report a reduction in needle insertion force by applying mechanical vibration into a hypodermic needle. Multilayer piezoelectric elements were used to force the needle to vibrate laterally in the frequency range up to 10 kHz when it was inserted into swine muscle tissue. A maximum
reduction of 69% in interaction force was reported. However, it is unclear what vibration amplitude and insertion velocity were used in the experiments. Moreover, the transverse vibration was likely to dissipate as the insertion depth increased. Muralidharan [57] investigated the effect of axial vibration in terms of its amplitude and frequency on the penetration force through insertion experiments of soft tissue and tissue surrogate using a permanent magnet shaker. The results showed the penetration force could be reduced by 2 to 3 times when using a higher vibration amplitude and frequency. Huang et al. [58] studied the frequency response of Gauge 27 bevel needles using a vibratory insertion system, and showed that axial ultrasonic vibration (84 kHz) could reduce the insertion force by 28% in the experiment with porcine tissue. However, the 300V peak-peak voltage applied to the vibrator might have safety problems for clinical use. Kaiguo et al. [19] investigated two approaches in reducing the target movement physically. One was high frequency translational oscillation of the needle and the other was rotational drilling of the needle. The results showed that both methods could reduce the target movement effectively. Barnett et al. [59] 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%. The minimum insertion force was observed at lower maximum vibratory insertion speeds for needles with larger diameters. For micro
needles, a vibratory actuator operating in the kHz range was coupled with hollow needles hypodermic injection needles fabricated with a two-wafer polysilicon micro-molding process. Experiment results for insertion into excised animal tissues showed that the addition of axial vibration can reduce cutting force sometimes up to 70% [60]. The works reviewed above are basically experiment-based. From the viewpoint of physics, Khalaji et al. [49] 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. When the product of frequency and amplitude was much larger than the constant insertion velocity, the behavior of the medium could be driven from Coulomb/viscous friction into a pure linear viscous friction with a much lower friction coefficient.

In addition to insertion force, vibration has also been used to reduce the pain associated with needle insertion. According to the Gate Control Theory of Pain [61], when vibration and pain signals are combined in nerves, the “pain” pathway tends to be overwhelmed by the “tactile” pathway, so a patient only experiences vibration. Based on this theory, VibraJect [62] was developed as an battery-powered attachment to dental syringe for administration of anesthesia. Clinic trials received positive feedbacks from patients. GentleSharp [63] was a tool for blood sampling of small animals where low-frequency, oscillatory motion was added to the
needle during insertion. Experiments showed that less variable average corticosterone levels could be obtained during venipuncture in rodents.

2.5 Research opportunities

Dynamic needle insertion, as a relatively new insertion technique, has been demonstrated to have the capabilities of reducing insertion force, controlling needle deflection and tissue deformation, and improving the needle maneuverability. While rotation-based insertion methods tend to cause greater damage to the tissue, vibratory needle insertion seems to be a better option in terms of more tissue-friendly cutting and less-constrained system structure. However, the underlying insertion mechanism between the tissue and a vibrating needle has not yet been fully understood, especially at the needle tip. As reviewed above, most reported works are experiment-based, which focus on demonstrating the benefits of vibratory insertion and relating performance parameters (force, deflection or deformation) with various variables including vibration frequency, amplitude, type of needle tip, insertion speed, needle diameter, specimen type and even temperature. Although they are helpful for application guidance, the needle-tissue interaction at the needle tip, however, has not been systemically studied and modeled. One possible reason is that the rich modeling methodologies developed for insertion force, needle deflection and tissue deformation, which are quite useful when no
vibration is applied, cannot be directly applied here. As a consequence, the potentials have not yet been fully explored in terms of needle geometry and vibration mode. It still remains to be seen whether new needle design exists to better take advantage of vibration and whether transverse vibration at needle tip can further benefit. It is a common experience that it is easier to cut with a combined “pressing down and slicing sideways” action rather than “pressing down alone” [37]. However, given the energy-absorbing property of tissues, it could be a difficulty to transfer transverse vibration from the needle base to the tip.

2.6 Critical problems remaining to be answered

With the aim to further explore the potentials of vibratory needle insertion, this research sets up with three questions: (1) How to effectively generate predictable and controllable transverse vibration at needle tip (2) How does transverse vibration affect the performance especially the insertion force and (3) What is the underlying mechanism in which transverse vibration affect the performance?

In the study, we will focus our efforts in addressing the above-mentioned critical questions. For the first question, a novel design of solid compliant needle featured by its 4-bevel tip and shaft slots is proposed. Design details and an EDM-based fabrication method are presented in Chapter 3. Finite element methods are presented in Chapter 5 to provide
understanding the formation of transverse vibration at the needle tip. For the second question, insertion experiments with piezoelectric and ultrasonic vibrator on different tissue materials are presented in Chapters 4 and 6. By associating the experiment results with vibration pattern and material properties, insights into the third question are obtained.

2.7 Summary

Among the factors affecting needle insertion accuracy, needle deflection and tissue deformation are closely associated with the forces experienced by the needle during the insertion procedure. Based on the modeling and simulation of such tissue-needle interaction forces, various efforts have been made to reduce the insertion force through optimization/innovation of needle geometries, special surface treatments and optimization of insertion process. Although researchers have demonstrated the capability of vibratory needle insertion in force reduction, the underlying mechanism between tissue and vibrating needle tip has not yet been fully understood, thus its potentials have not yet been fully explored.

As a result, this paper proposed a new design of solid compliant needle for vibratory needle insertion. While it primarily aims to reduce the insertion force, it also helps to further explore the potentials of vibratory needle insertion. Details of the proposed methods are presented in the following chapters.
CHAPTER 3 DESIGN AND FABRICATION OF NEEDLES WITH SLOTS

This chapter presents the design and EDM-based fabrication method of the proposed needle. Two important parameters for needle cutting edges, the inclination angle and the included angle, are derived from fabrication variables. Needle prototypes of the proposed design were fabricated with different geometries and evaluated.

3.1 Introduction

As reviewed in Chapter 2, the needles currently used in vibratory insertion experiments are all with common tip types including beveled tip, diamond tip and conical tip, etc. While they are showing good results in insertion force reduction, it remains to be seen whether new needle design exists to better take advantage of vibration. After all, they were initially invented for conventional insertion without vibration. Moreover, these tip types are not able to generate transverse vibration at the needle tip, which lies further possibility for force reduction. As a result, a unique design of solid compliant needle featured by its 4-bevel tip and shaft slots is proposed with the aim to lower the insertion force and further explore the potentials of vibratory needle insertion.
3.2 Proposed design of compliant needles with intricate geometries

Figure 3.1(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 bevels are symmetrically distributed in a way that if they are cut by a reference plane perpendicular to the needle central axis, the intersection lines will form a diamond shape, as shown in Figure 3.1(b).

![Diagram of proposed needle design](image)

**Figure 3.1** The proposed needle design: (a) overview, (b) tip design, and (c) slot design.

In Figure 3.1(b), among the four edges formed by the four bevels, the two associated the sharp corners of the diamond shape are the main cutting edges during needle insertion, which are highlighted in the figure. The other two edges only push aside the tissue without
cutting. A coordinate system can be built with the Z axis coinciding with central axis of the needle and the X axis passing through the lowest point of the main cutting edges as shown in Figure 3.1(b). Actually, the geometry of the needle tip can be determined with only two variables: the bevel angle $\varphi$ and the interval angle $\beta$. Given CD is perpendicular to AB, $\varphi$ is defined as the angle between OC and CD, and $\beta$ is the angle between OD and OB. From an intuitive viewpoint, $\varphi$ determines the relationship between a bevel and the needle central axis, while $\beta$ determines the distribution relationship among the four bevels. Just like the bevel angles in commercial medical needles, the range of $\varphi$ can be set to be $10^\circ \leq \varphi \leq 30^\circ$. The range of $\beta$ is $0^\circ < \beta \leq 45^\circ$ in the coordinate system built above. These two variables are also useful in the fabrication process of the needle, which will be discussed in the next section.

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 along the X axis direction as shown in Figure 3.1(c), which enable the main cutting edges to vibrate more easily along the X direction to perform tissue cutting than along the Y direction under axial stimulation. This explains why a four-bevel design is used instead of the relatively simple tri-bevel needle commonly used in brachytherapy. When the tip of a tri-bevel needle vibrates along a specific direction perpendicular to the central axis,
only one cutting edge at maximum can perform tissue cutting, while the bevel between the other two cutting edges tends to hinder the vibration in that direction. By matching the location and depth of the slots to the amplitude and frequency of the vibration applied to the needle base in the Z axis direction, the main cutting edges can vibrate with high speed along both the Z and the X direction to perform micro tissue cutting, which will be beneficial to reduce the axial insertion force. An illustrative picture is shown in Figure 3.2. Although it is currently designed as a solid needle, the principles can be adapted for non-hollow needles in various medical applications. The design variables for the slots include the distance from the needle tip to the first slot, $D_1$, the distance between the two slots, $D_2$, and the depth of them, $H$. Their effects on insertion force will be demonstrated in the next two chapters.

![Figure 3.2 Illustration of insertion with the proposed needle design.](image)

3.3 Inclination angle and included angle of the designed compliant needle

For needles with curved cutting edges, two parameters, the inclination angle $\lambda$ and
rake angle $\alpha$, have been demonstrated to significantly affect the needle insertion force [36]. Although the main cutting edges are straight in the proposed compliant needle, these two parameters can still be used to characterize the cutting edge with minor adaptions. In the compliant needle, $\lambda$ is defined as the angle between a main cutting edge and the XY plane of the needle coordinate system for motions along Z axis. It indicates that sharpness of the needle tip. The rake angle $\alpha$ is represented by a new parameter, the included angle $\theta$, which is defined as the angle between the two bevel planes adjacent to the main cutting edge measured in a plane perpendicular to the cutting edge. In other words, $\theta$ is the angle between the two intersection lines of the two bevel planes and a perpendicular plane of the cutting edge. It indicates the thickness of the needle tip. Figure 3.3 illustrates $\lambda$ and $\theta$.

![Diagram showing angles $\lambda$ and $\theta$.]

Figure 3.3 Inclination angle $\lambda$ and included angle $\theta$.

The relationship between the two process variables, the bevel angle $\varphi$ and the interval...
angle $\beta$, and $\lambda$ and $\theta$ can be determined as follows. As shown in Figure 3.3, the direction of the main cutting edge AB is the cross-product of $\mathbf{n}_1$ and $\mathbf{n}_2$, which are the normal vectors of its two adjacent bevel planes.

$$
\mathbf{n}_1 = (\cos \varphi \sin \beta, \cos \varphi \cos \beta, \sin \varphi) \quad (3.1)
$$

$$
\mathbf{n}_2 = (\cos \varphi \sin \beta, -\cos \varphi \cos \beta, \sin \varphi) \quad (3.2)
$$

$$
\mathbf{n}_1 \times \mathbf{n}_2 = (2 \sin \varphi \cos \varphi \cos \beta, 0, -2 \cos^2 \varphi \sin \beta \cos \beta) \quad (3.3)
$$

Based on Equation (3.3), in the XZ plane, the slope of edge AB can be expressed as:

$$
\tan \lambda = \frac{2 \cos^2 \varphi \sin \beta \cos \beta}{2 \sin \varphi \cos \varphi \cos \beta} = \frac{\sin \beta}{\tan \varphi} \quad (3.4)
$$

$$
\lambda = \tan^{-1} \frac{\sin \beta}{\tan \varphi} \quad (3.5)
$$

The $\theta$ is the supplementary angle of the angle between $\mathbf{n}_1$ and $\mathbf{n}_2$.

$$
\cos \theta = -\frac{\mathbf{n}_1 \cdot \mathbf{n}_2}{|\mathbf{n}_1||\mathbf{n}_2|} = 2 \cos^2 \varphi \cos^2 \beta - 1 \quad (3.6)
$$

$$
\theta = \cos^{-1}(2 \cos^2 \varphi \cos^2 \beta - 1) \quad (3.7)
$$

The correctness of Equation (3.5) and (3.7) is validated by building CAD models of the proposed needle with specified values of $\varphi$ and $\beta$ in SolidWorks and measuring the corresponding $\lambda$ and $\theta$. Generally speaking, a higher $\lambda$ and a lower $\theta$ will be beneficial in reducing the insertion force. With the range $10^\circ \leq \varphi \leq 30^\circ$ and $0^\circ < \beta \leq 45^\circ$ discussed in the previous section, Figure 3.3(a) gives the values of $\lambda$ and $\theta$ with varying $\varphi$ at $\beta = 20^\circ$ according to Equation (3.5) and (3.7). It can be seen that a lower $\varphi$ results in desirable higher
\( \lambda \) and lower \( \theta \). Actually, it can be mathematically proved based on Equation (3.5) and (3.7) that \( \lambda \) is a monotonic decreasing function of \( \varphi \) within the given range, while \( \theta \) is an increasing one. Figure 3.3(b) shows the values of \( \lambda \) and \( \theta \) with varying \( \beta \) at \( \varphi = 10^\circ \). It can be seen that a lower \( \beta \) result in both lower \( \lambda \) and \( \theta \), which results from the fact that both \( \lambda \) and \( \theta \) are monotonic increasing functions of \( \beta \) within the given range. This indicates an optimal value of \( \beta \) can be found to balance \( \lambda \) and \( \theta \).

![Figure 3.4](image)

**Figure 3.4** Inclination angle \( \lambda \) and included angle \( \theta \) with varying (a) bevel angle \( \varphi \) and (b) interval angle \( \beta \).
3.4 Fabrication of the designed compliant needle using EDM

The compliant needle shown in Figure 3.1 is challenging to manufacture due to its small dimensions and relatively intricate geometric design. Commercial needle tips are usually generated by a special burr-free grinding process. It can also be applied to fabricate the four bevels of the compliant needle. However, the two slots are difficult to process with traditional grinding due to their small dimensions, while the forceless electrical discharge machining (EDM) will be an economic feasible solution. Out of the consideration of process easiness, both the bevels and the slots are processed on an EDM machine in our method to avoid the alignment difficulty and inaccuracy caused by transferring the work piece between a grinding and an EDM machine.

3.4.1 Fabricating the bevels with EDM

The setup for the EDM of needle bevels is shown in Figure 3.5. The EDM was conducted in a Charmilles Roboform 3-axis CNC EDM machine. The work piece used was an AISI 304 stainless steel rod with a diameter \( D = 1.27 \text{ mm} \) and a length \( L = 300 \text{ mm} \). It was secured to a spin index with a resolution of 1 degree using a 5C collet. The spin index was fixed to a tilting table with bolts and nuts to form a composite structure, and the whole structure was fixed with the bottom of the tilting table clamped to the machine table. The rotation axis
of the tilting table was parallel to the Y axis of the EDM machine coordinate system, while the rotation axis of the spin index was perpendicular to that of the tilting table in space. With this setup, the bevel angle $\phi$ and the interval angle $\beta$ could be directly controlled by the rotation of the tilting table and the spin index respectively. The block electrode was made of a copper block milled to a standard rectangle shape.

Figure 3.5 Setup for EDM of needle bevels.

Figure 3.6 shows the four-step EDM procedure to generate the bevels on the needle tip. In Step 1, the tilting table was adjusted to bevel angle $\phi$, and the spin index was rotated to the $0^\circ$ position. The block electrode moved along the negative Z axis of the EDM machine to cut the first bevel needle tip at the end of the work piece. The final Z position of the bottom of the
electrode was below the center point at the end of the work piece. In Step 2, the spin indexed was rotated to the $2\beta$ position, and the block electrode moved to the same final Z position as in Step 1 to cut the second bevel. In Step 3, the spin indexed was rotated to the $180^\circ$ position, and the third bevel was cut with the electrode reaching the same final Z position. In Step 4, the spin indexed was rotated to the $180^\circ + 2\beta$ position, and the electrode completed the last bevel at the same final Z position. The block electrode was moved along the Y axis of the machine coordinate system after cutting a bevel to make sure each bevel was cut with an unworn section of the electrode. The needle remained secured to the collet after this step for the following processing of slots.

Figure 3.6 Four-step EDM procedure to generate tip bevels.
3.4.2 Cutting the slots with EDM

Figure 3.7 shows the setup for the EDM of the slots on the needle shaft. The block electrode was replaced with a foil electrode, which was prepared by using two rectangle copper blocks of a thickness of 8 \textit{mm} to compress a rectangle pre-flattened copper foil of a thickness of 50 \textit{μm}. One edge of the foil was extended outside the blocks with a suitable distance (3 \textit{mm} in this case) to form the cutting edge. The bottom edges of the copper blocks and the foil were parallel to the XY plane of the machine. Moreover, the tilting table was rotated to the horizontal position so that the rotation axis of the spin index was parallel to the X axis of the machine.

Figure 3.7 Setup for EDM of the slots on the needle shaft.

Figure 3.8 shows the two-step EDM procedure to generate the slots on the needle shaft under the setup above. In Step 1, the spin indexed was rotated to the $90^\circ + \beta$ position, and
the bottom of the foil electrode moved to a position with a distance of $D_1$ from the needle tip point to cut the first slot with a depth of $H$. In Step 2, the spin indexed was rotated to the $270^\circ + \beta$ position, and the foil electrode moved along the positive X axis by a distance of $D_2$ and cut the second slot with a depth of $H$. The foil electrode together with the two blocks were also moved along the Y axis of the machine coordinate system after cutting a slot to make sure each slot was cut with an unworn section of the foil.

![Figure 3.8 Two-step EDM procedure to generate the slots on the needle shaft.](image)

During the fabrication, the resultant $D_1$ was found to be relatively larger than the design value, which is probably due to the short-circuit method used on the EMD machine to determine the tip location by touching the needle tip with the foil electrode. After several trials, a distance of 0.1 $mm$ was determined to be subtracted from the length of $D_1$ in the EDM program as compensation.
3.5 Geometric analytical model and manufacturing control of micro-slot depth

During the EDM process of a slot, the sheet electrode moves along the negative direction of Z axis by a program depth of cut $L_0$. Due to the significant electrode wear of the thin sheet, however, the cylinder needle can hardly be cut with this depth. Because of the circular shape of the needle cross section, the obtained slot is not likely to be linearly related with $L_0$. It is desirable to find out the actual relation between $L_0$ and the final obtained slot width.

3.5.1 Experiment setup for micro-slot manufacturing

![Experiment setup](image)

Figure 3.9 Experiment setup: (a) work piece setup and (b) slot cutting.

For the micro-slot manufacturing, metal foil tools and the Electrical Discharge Machining (EDM) were set up at our laboratory for experiments. Figure 3.9 shows the
laboratory experiment setup to find out the relation and for the validation of our analytical modeling.

The EDM was conducted in a Charmilles Roboform 22 3-axis CNC EDM machine. The work piece used was an AISI 304 stainless steel rod with a diameter $D = 1.27$ mm. It was secured to a spin index with a resolution of 1 degree using a 5C collet. The spin index was fixed to a tilting table with bolts and nuts to form a composite structure, and the whole structure was fixed with the bottom of the tilting table clamped to the machine table. The rotation axis of the tilting table was parallel to the Y axis of the EDM machine coordinate system, while the rotation axis of the spin index was perpendicular to that of the tilting table in space. A sheet electrode was prepared by using two rectangle copper blocks of a thickness of 8 mm to compress a rectangle pre-flattened copper sheet of a thickness of 50 $\mu$m. One edge of the sheet was extended outside the blocks with a suitable distance (3 mm in this case) to form the cutting edge. The bottom edges of the copper blocks and the foil were parallel to the XY plane of the machine. Moreover, the tilting table was rotated to the horizontal position so that the rotation axis of the spin index was parallel to the X axis of the machine. After using the touch function of the EDM machine to locate the top of the stainless steel rod, the electrode moves along the -Z direction by a distance of $L_0$. 
After cutting a slot, the electrode offsets along -Y direction by a safety distance so that a new location of the electrode will cut the next slot. The conditions and parameters of the EDM machine are summarized in Table 3.1. A total of 10 values of $L_0$ were tested from $0.25D$ to $1.375D$ with an interval of $0.125D$. The corresponding values in micrometer are $317.5 \mu m$ to $1746.25 \mu m$ with an interval of $158.75 \mu m$.

Figure 3.10 shows the microscopic picture of the 10 fabricated slots taken from the side (parallel to the X-Z plane in Figure 3.9(a)) and the resultant worn sheet electrode. It can be observed the discharge between the electrode and inner surfaces of the slot leaves a dark region on the electrode, where the electrode is partially worn out, as shown in Figure 3.11(b). This is due to the EDM reaction area between the electrode and the needle surface. Figure 3.11 shows the plot of the measured slot depth from the side and $L_0$. When $L_0$ increases, part of the

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Work piece</td>
<td>AISI 304 steel</td>
</tr>
<tr>
<td>Tool electrode</td>
<td>Copper</td>
</tr>
<tr>
<td>Peak current</td>
<td>1 A</td>
</tr>
<tr>
<td>Pulse duration</td>
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<td>Pulse interval</td>
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<td>Dielectric fluid</td>
<td>IonoPlus</td>
</tr>
</tbody>
</table>

Table 3.1 EDM conditions and parameters
electrode is worn out, leaving a concave dent, as an example shown in Figure 3.10(b). The measured slot depth increases with $L_0$, and they can be well related with a polynomial curve with an order of 2. It can be noticed that even an $L_0$ greater than $D$ can’t cut the whole diameter of the rod due to electrode wear.

![Figure 3.10 Experiment results: (a) side view of the slots and (b) worn sheet electrode](image)

$y = -0.0002x^2 + 0.8764x - 10.916$

$R^2 = 0.9967$

![Figure 3.11 Measured slot depths from the side](image)
3.5.2 Analytic modeling of micro-slot depth control

In addition to the periphery polynomial fitting, the relation between the measured slot depth from the side and $L_0$ can be further identified with a closer observation of the relative movement and location of the electrode and rod. Two situations, namely $L_0 \geq D/2$ and $L_0 \leq D/2$, need to be discussed separately as below.

![Diagram](image)

Figure 3.12 A typical worn electrode when $L_0 \geq D/2$

Figure 3.12 shows a typical condition of the sheet electrode with $L_0 \geq D/2$ ($L_0 = 1500 \ \mu m$). A coordinate system is built where the X axis coincides with the electrode edge before worn out and Y axis is parallel to the electrode motion. Two areas can be clearly identified on the electrode, namely the discharge area on top in dark color and the worn area below. The intersection lines of these two areas consist of a flatter curve in the middle and a
steeper curve on both sides. These curves intersect at \( A(x_A, y_A) \) and \( B(x_B, y_B) \). The final position of the needle is marked as a red circle, which is determined by the program depth of cut.

In Figure 3.12, it can be observed that the circle also crosses Point A and Point B. To facilitate the presentation, three regions are defined based on Point A and Point B as shown in the figure. By investigating the relative movement between the needle and the electrode, it can be identified that if a line parallel Y direction is drawn in Region I or III which still intersects with the circle, \( L_1 \) will be the machined depth of the needle, which is the distance between the two intersections of the line and circle. Meanwhile, \( L_2 \), which is the distance between the X axis and the steep curve on the line, corresponds to the worn depth of the electrode. Note that \( L_1 \) is not connected directly with \( L_2 \) in Region I or III. In Region II, if a line parallel to Y direction is drawn, \( L_1 \) will be the machined depth of the needle, which is determined by the circle and the flatter curve. \( L_2 \) is the worn depth of the electrode and refers the distance between X axis and the flatter curve on the line. For all the three regions, a constant wear ratio can be defined as

\[
    r = \frac{L_2}{L_1}
\]  

(3.8)

To obtain the analytical model of the steeper curve, assume \( P(x_I, y_I) \) is on the steeper curve in Region I. We have
\[ L_1 = 2 \sqrt{\left( \frac{D}{2} \right)^2 - x^2_l} \quad \left( - \frac{D}{2} \leq x_l \leq x_A \right) \quad (3.9) \]

As a result,

\[ y_l = L_2 = rL_1 = 2r \sqrt{\left( \frac{D}{2} \right)^2 - x^2_l} \quad \left( - \frac{D}{2} \leq x_l \leq x_A \right) \quad (3.10) \]

For the flatter curve, assume \( P(x_{II}, y_{II}) \) is on the flatter curve in Region II. We have

\[ L_1 + L_2 = L_0 - \left( \frac{D}{2} - \sqrt{\left( \frac{D}{2} \right)^2 - x^2_{II}} \right) \quad (x_A \leq x_{II} \leq x_B) \quad (3.11) \]

Based on the definition of \( r = L_2/L_1 \), it can be obtained that

\[ \frac{y_{II}}{L_1 + L_2} = \frac{L_2}{L_1 + L_2} = \frac{r}{1 + r} \quad (3.12) \]

As a result,

\[ y_{II} = \frac{r}{1 + r} \left( L_0 - \left( \frac{D}{2} - \sqrt{\left( \frac{D}{2} \right)^2 - x^2_{II}} \right) \right) \quad (x_A \leq x_{II} \leq x_B) \quad (3.13) \]

To obtain the coordinate of Point A, we can set \( y_l = y_{II} \) and solve Equation (3.10) and (3.13) to get

\[ x_A = - \sqrt{\left( \frac{D}{2} \right)^2 - \left( \frac{L_0 - D}{1 + 2r} \right)^2} \quad (3.14) \]

\[ y_A = 2r \sqrt{\left( \frac{D}{2} \right)^2 - x^2_A} \quad (3.15) \]

Due to symmetry, the coordinate of Point B can be obtained immediately after Point A. The
theoretical slot depth measured from the side can therefore be calculated as

\[ H_{side} = L_0 - y_A \]  

(3.16)

The theoretical slot depth in the middle of the needle is

\[ H_{middle} = \frac{1}{1 + r} L_0 \]  

(3.17)

Figure 3.13 A typical worn electrode when \( L_0 \leq D/2 \)

Under the situation as shown in Figure 3.13 where \( L_0 \leq D/2 \) \( (L_0 = 500 \ \mu m) \), there is only the flatter curve between the discharge area and the worn area. Note that the discharge area is not yet fully darkened. Assume \( P(x,y) \) is a point on the curve, we have

\[ y = \frac{r}{1 + r} \left( L_0 - \left( \frac{D}{2} - \sqrt{\left( \frac{D}{2} \right)^2 - x^2} \right) \right) \quad (|x| \leq \sqrt{\left( \frac{D}{2} \right)^2 - \left( \frac{D}{2} - L_0 \right)^2}) \]  

(3.18)

In this case, the theoretical slot depth measured from the side can therefore be calculated as
\[ H_{\text{cal}} = L_0 \quad (3.19) \]

The theoretical slot depth in the middle of the needle is

\[ H_{\text{middle}} = \frac{1}{1 + r} L_0 \quad (3.20) \]

With the analytical model of the flatter curve, the area surrounded by the lower section of the red circle and the flatter curve can also be calculated. The accurate modeling of this cross section will be helpful for future finite element analysis for the future vibration analysis.

3.5.3 Analytical model validation

To validate the model presented above, the curves between the discharge area and the worn area are calculated and examples are shown in Figure 3.14. In Figure 3.14, the electrodes used in calculation are based on the electrodes specifications mentioned earlier in Figures 3.12 and 3.13. For the example electrodes, the program depth of cut \( L_0 \) is 1500 \( \mu m \) mentioned earlier in Figure 3.12 and it is 500 \( \mu m \) of the electrode mentioned in Figure 3.13. Figure 9 shows the comparison results. The value of \( r \) is set be 1.0 based on the measurement of \( L_1 \) and \( L_2 \) in Figure 3.12. It falls within the tool wear rate provided by the manual of the EDM machine used, and it is not uncommon for the electrode wear rate to be 1.0 for situations with positive electrode and short pulse duration [64]. In Figure 3.14, the blue semi-circle is the calculated final position of the needle. It is used to overlap with the top half of the red circle.
so that the calculated curve and the electrode have a consistent scale. In Figure 3.14, the calculated intersection curves are marked in yellow. It can be seen that they are very accurate in both conditions.

![Calculated curves overlapped on worn electrodes](image)

Figure 3.14 Calculated curves overlapped on worn electrodes

With the model presented above, it is also able to calculate the theoretical slot depth. Figure 3.15 shows the calculated and the measured slot depth on the side relative to the needle diameter $D$. It can be seen that the calculated values are very consistent with the measured values. The minor variations may result from measurement and fabrication uncertainty. Although the model is also able to predict the slot depth in the middle of the flatter curve, it is difficult to measure this depth on a fabricated needle without damaging it. As a result, the comparison of slot depth in the needle is temporarily not reported in this paper at this point.
3.6 Micro-slot width accuracy with control of electrode movements

As a single layer of sheet electrode sets the baseline of slot width, it seems likely that stacking multiple sheet electrodes can result in slot width which is multiple times greater. However, experiments showed that this was not the case. Since the multiple sheets are of the
same polarity and not always absolutely flat, they tend to separate during the cutting and result in the structure shown in Figure 3.16. Moreover, multiple sheets can’t achieve slot widths which are not integral times of the baseline, while a required slot width can’t find an available sheet with suitable thickness. As a result, electrode movement is investigated in this study to control slot width.

Figure 3.17: Increasing slot width using (a) VECT and (b) EXPAN function

To increase the slot width with a sheet electrode of a specific thickness, two functions commonly found in EDM machine can be used, as shown in Figure 3.17. The first one enables the translational movement of electrode in the 3 axis, separately or simultaneously, as shown in Figure 3.17(a). The second one enable the electrode to move translationally following a spiral path in the X-Y plane until it reaches a radius of R, during which the orientation of the electrode remains unchanged, as shown in Figure 3.17(b). For the EDM machine used in this research, these two functions are “VECT” and “EXPAN” respectively. These functions are applied right after the electrode reaches the program depth without retracting the electrode.
This is primarily due to the reason that it is difficult to reposition a new electrode at the same narrow slot due to actual limitation in flatness of thin foil sheet electrode during EDM machining.

Figure 3.18 shows the microscopic picture of 7 slots fabricated using “VECT” function and the resultant worn sheet electrode. $L_0$ was set to be $1.375D$ for all the slots. The baseline slot width was $90 \, \mu m$ without post movement, and a translational distance of $45 \, \mu m$ was added accumulatively for each subsequent slot in the X axis. It can be seen that the slot width increased with VECT distance. As the VECT distance reached $270 \, \mu m$ at the seventh slot, the electrode almost wore out after fabrication. The results of slot width are shown in Figure 3.19. Since some slots are not uniform in width along the cutting direction and the width in the
needle center was difficult to measure due to distortion, the width at the red middle line on the needle surface was used. The width and the VECT distance had a relation close to linear. However, as the VECT distance increased, the slot began to distort and was no longer perpendicular to the needle axis. This is not desirable in terms of vibration stability and stress concentration.

![Graph showing the relationship between slot width and VECT distance.](image)

Figure 3.19 Relation between slot width and VECT distance

Figure 3.20 shows the microscopic picture of 8 slots fabricated using “EXPAN” function and the resultant worn sheet electrode. \( L_0 \) was set to be 1.375\( D \) for all the slots. The baseline slot width was 90 \( \mu m \) without post movement, and an expansion radius of 22.5 \( \mu m \) was added accumulatively for each subsequent slot to match the previous 45 \( \mu m \) VECT distance. It can be seen that the slot width increased with EXPAN distance. As the
EXPAN radius reached 90 μm at the fifth slot, the electrode almost wore out after fabrication. Chamfers could be clearly observed for the fifth and subsequent slots, which resulted from the relative movement of the electrode and needle in the X-Y plane. These chamfers were beneficial in terms of reducing the chance of hooking tissues and stress concentration, and they were difficult to be generated by other manufacturing processes in such a cost-effective way.

![Figure 3.20 Slots fabricated with EXPAN function](image)

As discussed later in Section 5.4, the tip vibration displacement is not sensitive to slot width, so the “EXPAN” function can be safely applied to get the beneficial chamfers without significantly altering the tip motion. The slots were much more uniform in width along the cutting direction. Two types of slot width could therefore be measured at the red middle line.
on the needle: one with chamfer and the other without. The results of slot widths are shown in Figure 3.21. The slot width including chamfer and the EXPAN radius have a relation close to linear. The slot width (not including chamfer) remains at around 145 \( \mu m \) for EXPAN radius greater than 90 \( \mu m \) because the electrode was already worn out.

![Figure 3.21 Relation between slot width and EXPAN radius](image)

\[ y = 1.5181x + 73.065 \]
\[ R^2 = 0.9813 \]

3.7 Evaluation of needle prototypes

Figure 3.22(a) shows a prototype of the compliant needle model shown in Figure 3.22(b) with design variables as \( \varphi = 10^\circ, \beta = 20^\circ, D_1 = 5\text{mm}, D_2 = 1\text{mm}, H = 0.75D, \) and \( W = 100\mu m \). Overall, the geometries are sufficiently accurate for following experiment purpose. The slots of such a width should not trap any tissue during insertion, which would otherwise hinder needle movement and cause further damage to the surrounding tissue.
Figure 3.22 A prototype of the needle design: (a) overview of tip, (b) the corresponding CAD model and (b) close view of slots.

Figure 3.23 shows the microscopic pictures of the bevel of a compliant needle created by EDM. Micro craters can be observed on the bevel surface, which are typical for EDM. The diameter of the craters is at the level of around 20 \( \mu m \), and the depth should be less than half of this value. According to the parameter manual of the EDM machine and the figure, the
estimated surface roughness $R_a$ is between $3.2 \ \mu m$ and $6.4 \ \mu m$. This was not superb when compared with commercial medical needles, which usually had an $R_a = 1.6 \ \mu m$ or lower, but it was sufficient for the prototypes to serve the experiments in the following chapters.

Figure 3.23 Microscopic pictures of needle tip: (a) 200 X and (b) 350 X.

3.8 Summary

This chapter presented the design of a novel solid compliant needle for vibratory insertion. Two slots were located on the shaft so that the two main cutting edges formed by the four bevels at the tip can perform both axial and transverse cutting under axial base excitation. Such two-direction movement held the potential to reduce insertion force. Two important parameters for needle cutting edges, the inclination angle and the included angle, were derived from the two fabrication variables of the bevel angle and the interval angle.
The fabrication procedures of the bevels and slots using EDM were elaborated. An analytical model was presented for accurate calculation of slot depth based on the relative motions of electrode and needle. The model was validated by overlapping the calculated worn electrode edge on actual pictures and by comparison of measured and calculated slot depth. The EDM EXPAN function was found to result in relatively uniform slots with beneficial chamfers along the slot edges. Needle prototypes were fabricated with these procedures. They demonstrated the feasibility of the EDM-based method in that they had accurate dimensions as designed and surface roughness comparable to commercial medical needles.

To investigate and validate the proposed compliance needle design, insertion experiments were conducted. Details of the experimental study are presented in the next chapter.
CHAPTER 4 INSERTION EXPERIMENTS WITH PIEZOELECTRIC VIBRATOR

This chapter presents two categories of experiments conducted using a piezoelectric vibrator to investigate and validate the capability of the proposed compliant needle design. In the first category, needles with different slot locations were inserted into tissue phantom, while in the second, the needles were inserted into skin phantom. The results of the needle performance are presented in the following sections, followed by a discussion.

4.1 Introduction

Needle insertion experiment plays an important role in understanding the interaction between tissue and needle, and in validating models for needle deflection, tissue deformation and needle steering. The insertion medium can be prepared with either artificial materials or biological tissues. Typical artificial materials include silicon rubber, polyurethane, and some other polymers, while biological tissues may come from porcine, bovine or poultry organs. Artificial tissue offers many practical advantages over biological tissue, in terms of reproducibility, availability, visibility, etc. [65]. As a result, two categories of experiments are conducted using artificial materials. In the first category, needles with different slot locations were inserted into tissue phantom, which mimicked the working condition in soft tissues like muscles. In the second category, the needles were inserted into skin phantom, which aimed to
study their penetration capability.

4.2 Insertion experiment for tissue phantom

4.2.1 Experiment setup

Figure 4.1 Experiment setup for tissue phantom insertion.

Figure 4.1 shows the setup for the tissue phantom experiment. A linear motor (Dunkermotoren) was utilized to insert the needle into tissue phantom at a constant rate. A piezoelectric actuator (Physik Instrumente (PI) P-840.60) with a maximum travel amplitude of 90μm was mounted to the slide on the linear motor to provide vibration during the tests. A six-axis force sensor (ATI GAMMA IP65) was used to measure the force during insertion, and it was attached to a manual thread guide fixed on an adjacent table for vibration isolation. A
data acquisition system (National Instruments, PXIe-6361) and LabVIEW software were used to record the force data and to control the linear motor and the piezoelectric actuator.

The tissue phantom used in the experiment was a PVC-based plastisol (MF Manufacturing) with 10% volume of mineral oil as lubricant. It was molded into a container made from acrylic boards with an inner dimension of $50mm \times 50mm \times 200mm$. A rectangle hole was opened on two parallel walls of the container, so that a needle can pass through the whole width of the phantom. After each insertion trial, the container was moved manually by a horizontal distance along with the manual slide to avoid duplicate insertions at the same location. To ensure that the needles can be inserted deep enough through the phantom, the length of the needles were set to be $250mm$. A grid template with arrays of holes was installed between the phantom and the linear motor to prevent a needle from bending downwards and better control the insertion location.

4.2.2 Experiment design

Four needle prototypes of the proposed design, together with a control needle without slots, were fabricated with the dimensions shown in Table 4.1.
Table 4.1 Dimensions of the needles used in the experiment.

<table>
<thead>
<tr>
<th>Needle</th>
<th>$\varphi$</th>
<th>$\beta$</th>
<th>$D$</th>
<th>$D_1$</th>
<th>$D_2$</th>
<th>$H$</th>
</tr>
</thead>
<tbody>
<tr>
<td>No(Control)</td>
<td>10°</td>
<td>20°</td>
<td>1.27mm</td>
<td>No slots</td>
<td>0.75D</td>
<td></td>
</tr>
<tr>
<td>N1</td>
<td></td>
<td></td>
<td>5mm</td>
<td>0.5mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N2</td>
<td></td>
<td></td>
<td>5mm</td>
<td>1mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N3</td>
<td></td>
<td></td>
<td>10mm</td>
<td>0.5mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N4</td>
<td></td>
<td></td>
<td>10mm</td>
<td>1mm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Based on the capacity of the piezoelectric actuator, three frequency-amplitude combinations (250Hz-5\( \mu \)m, 250Hz-45\( \mu \)m and 1500Hz-5\( \mu \)m) were used to represent the low frequency – low amplitude, the low frequency – high amplitude, and the high frequency – low amplitude situation respectively [59]. They could provide preliminary insight into the performance of the needle under typical vibration conditions, and more interpolating frequency-amplitude combinations can be tested in the future. The needles were also inserted with no vibration as a control to investigate the effects of utilizing vibration on insertion performance. Five trials were conducted for each frequency – amplitude combination.
The average velocity of insertion was set to a constant of $2 \text{mm/s}$ for all the trials. Force and position data were collected for each trial with a sampling rate of four times the vibration frequency to accurately measure the force. An example force-position plot is shown in Figure 4.2, where two phases can be identified during the insertion process. In the first phase, the needle tip gets touch with the tissue phantom and passes through it. The insertion force consists of the cutting force at the needle tip and the friction force between the needle shaft and the tissue phantom. As the insertion depth increases, the force increases in a linear manner. In the second phase, the needle tip exits from the back of the tissue phantom, and no cutting force is needed at the tip. Theoretically, the insertion force, which is now mainly made of friction force, should remain constant because the contact area between the needle shaft and the tissue phantom experiment.
phantom does not change. However, the contact face of the phantom gradually wears out due to friction, so a slight linear drop of insertion force can be observed. To compare the performance of different needles, the friction slope was measured, which was defined as the slope of the data between 0.1N and the maximum insertion force in the first phase of force-position plot. It began at 0.1N to avoid the noise in data before the needle actually contacts the tissue phantom. This parameter indicates how fast the friction force increases as the needle inserts into the tissue phantom, and a lower value of it means the friction force accumulates more slowly, which is beneficial.

4.2.3 Results and discussion

Figure 4.3 shows the results of friction slope for the five needles under different frequency-amplitude combinations with the standard deviation, which have been published in [66]. For each combination of a needle, the friction slopes of the five trials were derived individually and averaged. It can be seen that variations exist among the friction slopes calculated for each frequency-amplitude combination of a needle. The average standard deviation was 4.16%, 3.91%, 4.58%, 4.85% and 2.85% respectively for the five needles. It is acceptable for experiments involving soft tissue cutting to have variability as high as 25% [67].
From Figure 4.3, it can be noticed that when no vibration is applied, the friction slopes for the needles with slots are lower than that of control except N4, while theoretically the friction slopes for all needles should be the same. Although this may result from the minor tip geometry difference occurring during the fabrication process, it may be also because the slots reduced the contact area between the needle shaft and the tissue phantom. Moreover, the different friction slopes of the needles with slots indicate the location of the slots may also matter. In the future, duplicate needles of the same tip geometry should be fabricated and tested to avoid inaccurate results caused by fabrication uncertainty.

Given the friction slopes are quite different when vibration is not applied, a one-way analysis of variance (ANOVA) $F$-test is conducted for each needle where vibration frequency-amplitude combination is the only factor. In other words, we focus on the self-comparison of...
each needle under different frequency-amplitude combination. The $p$-values of N0 to N4 are 0.014, 0.001, 0.001, 0.001 and 0.001 respectively, which indicate different combinations result in significant difference in friction slope for each of the needles. When vibration is applied, the friction slope increases for all the five needles under each of the three vibration conditions, while the only exception is N3 under the 1500Hz-5\(\mu m\) condition. This indicates that vibration is not always beneficial in reducing the friction between needle and tissue. It is also interesting to notice that four of the five needles reach their individual largest value of friction slope at 250Hz-45\(\mu m\), the low frequency – high amplitude condition, and then the slope drops. The only exception is N1, which has the largest slope at 250Hz-5\(\mu m\). This suggests the location of the slots do affect the performance of a needle.

A possible reason for the increase in friction slope is the relatively long length (250 mm) of the needles used in the experiment, which resulted in slight buckling of the needles during insertion. The tissue contacting the needle shaft was compressed harder, so the friction increased with the compressive force. Moreover, the 5\(\mu m\) axial vibration amplitude seems be too small to perform axial puncturing or to generate effective transverse vibration, given the long needle length and the energy-absorbing property of tissue phantom. Since the friction slope begins to drop for most of the needles at the high frequency – low amplitude condition, more frequency-amplitude combinations should be tested, especially those with higher
frequencies. Based on these more comprehensive results, the relationship between slot locations and friction under different frequency-amplitude combinations may be numerically modeled, which will be of great value to optimize needle performance.

4.3 Insertion experiment for skin phantom

4.3.1 Experiment setup

Figure 4.4 shows the setup for the skin phantom experiment. The previous tissue phantom container was replaced by a rotational structure where the testing medium was clamped by two plates with screws. A polyurethane sheet (MF Manufacturing) with a Shore Hardness of 40A and a thickness of 1.588 mm was used here as an analog to human skin. The plates had 12 aligned holes in them. By rotating the plates together with the phantom, a needle can pass through the phantom at 12 different locations without causing any tension to the skin. Since the skin phantom was tougher than the previous tissue phantom, the needles were cut to the length of 100 mm to avoid buckling, and the grid template was removed.
4.3.2 Experiment design

The needles used in this experiment were N0, N1 and N3 in Table 4.1, while the frequency-amplitude combinations tested were the same as those in the tissue phantom experiment. As before, five trials were conducted for each frequency – amplitude combination, and force and position data were collected with a sampling rate of four times of the vibration frequency. The average velocity of insertion was set to a constant of 1\text{mm/s} for all the trials.

An example force-position plot is shown in Figure 4.5, where three phases can be identified during the insertion process. In the first phase, the needle tip touches the skin phantom but no cutting or penetration occurs. The force is mainly caused by the elastic deformation of the skin phantom. In the second phase, the needle tip cuts and punctures through the skin phantom, which is featured by a significant drop in the force. In the third phase, the
needle tip has exited the phantom skin. The force is mainly caused by the friction between the needle shaft and the inner surface of puncture hole. Two parameters can be measured as the indicator of the performance of a needle. The first parameter is the puncture force, which is the peak value of insertion force before it suddenly drops. It is the maximum force the phantom endures before penetration begins. The second parameter is the puncture depth, which is defined as the insertion distance between 0.1N and the puncture force. It is related to the maximum deformation of the phantom during insertion. Both parameters are of great importance in evaluating the needle performance in practice, and keeping them low is usually preferred.

Figure 4.5 An example force-position plot in the skin phantom experiment.
4.3.3 Results and discussion

Figure 4.6 The results of puncture force and depth in the skin phantom experiment.

Figure 4.6 shows the results of puncture force and depth for the three needles under different frequency-amplitude combinations together with the corresponding standard deviations, which have been published in [66]. For each combination of a needle, the puncture forces and depths of the four trials were derived individually and averaged. The average
standard deviation of puncture force was 4.21%, 2.89%, and 2.73% respectively for the three needles, while that of puncture depth was 5.79%, 4.31%, and 4.42% respectively.

From the figure, it can be noticed that the puncture force and the puncture depth share similar shapes in the two sets of plotting for all of the three needles, which indicates they are related. This is reasonable because the insertion force before puncture is caused by the elastic deformation of the testing medium. As the deformation increases, the insertion force also rises.

When no vibration is applied, the control has both lower puncture force and depth than the other two needles do, which is opposite from the observation of friction slopes in the previous tissue phantom experiment. This may be due to the fact that the slots reduce the stiffness of the needle along the axial direction, so a greater displacement of the needle is needed to reach the required amount of force to puncture the testing medium. Moreover, the front section of the needles with slots is likely to bend (buckle) slightly under force, so the tip is not interacting with the testing medium with its best perpendicular orientation. Another possibility is the minor geometry difference at the tips of the three needles caused during fabrication. However, given the needles used in the two experiments are exactly the same ones, this possibility is relatively low, because a needle with tip geometry defects is likely to perform worse under all the circumstances.

Just as in the previous tissue phantom experiment, a one-way ANOVA F-test where
frequency-amplitude combination is the only factor is conducted for the puncture force to focus on the self-comparison of each needle. The $p$-values of the three needles are 0.060, 0.097 and 0.127 respectively, which indicate different combinations result in insignificant difference in puncture force for each of these needles. In other words, the vibration does not improve the insertion performance in terms of puncture force for each needle. Nevertheless, the mean values can still be used to infer the possible effects of vibration. For the control and N3, applying vibration does not reduce the puncture force or depth under the three vibration conditions. Instead, an increase in these two parameters can be observed, especially under the 250Hz-45$\mu m$ condition. For N1, however, the 250Hz-45$\mu m$ condition results in an obvious drop in the puncture force and depth to the lowest values under all conditions, while the 1500Hz-5$\mu m$ condition also reduces these two parameters by a smaller amount. Such different performance patterns among needles may be explained by the different locations where the slots lie. It may be evidence that the puncture force and depth can be reduced under certain vibration conditions, and more experiments are needed to find out the real reasons. Overall, the puncture force and depth of the control are lower than those of the other two needles under every frequency-amplitude combination. This could also be explained by the decrease in shaft stiffness and the bending of front section mentioned above.

With the data from the two experiments above, the proposed design can be evaluated
from the view point of strength. The yield strength of stainless steel 304 is 275 MPa. The area of the cross section with $H = 0.75D$ is 0.248 mm$^2$. The yield force is calculated as 68.1 N. Since the forces measured across the whole experiment were below 10N, there should be no danger of tip break. This complied with the observation that no needle broke during the experiments. Nevertheless, finite element analysis should be conducted in the future for dynamic situations in addition to this static analysis.

4.4 Summary

This chapter presented two categories of insertion experiments with the aim to investigate and demonstrate the capability of the compliant needle design. In the experiment with tissue phantom, it was found that the maximum value of friction slope tends to occur at the low frequency – high amplitude condition. While vibration didn’t reduce the friction slop within most of the tested frequency-amplitude combinations, there lied a possibility for higher frequencies. In the experiment with skin phantom, the low frequency – high amplitude vibration condition also tends to be active. For some needles, it resulted in the maximum value of puncture force and depth, while for other needles, it led to the minimum value which was even lower than that without vibration. The slots are likely to result in the performance difference between the control and the other needles when no vibration is applied, while the
uncontrollable needle fabrication repeatability may also be a reason for such difference.

Overall, the expected advantages of vibratory needle insertion were not significant in this chapter, and the feasibility and effectiveness of the proposed compliant needle design was not yet well demonstrated. Several issues need to be properly addressed. The length of the needles needs to be optimized to make better use of the vibration. At least, it cannot be too long, which increases the chance of buckling, or too short, which is impractical for clinical use. The amplitude of the axial vibration at the needle base needs to be large enough to generate effective axial and transverse vibration at the needle tip. Last but not least, the highest vibration frequency used in the experiments was only 1500 Hz, which is actually quite low for engineering applications using vibration. Khalaji et al. [49] demonstrated through mathematical derivation and ex-vivo experiments that vibration could significantly reduce the static force required to Coulomb friction when \( aw \gg |v_0| \), where \( a \) was the vibration amplitude, \( w \) the vibration angular frequency, and \( v_0 \) the insertion velocity of main feed. As a result, ultrasonic vibration with frequency over 20 kHz will be analyzed in the next chapter to further explore the potential of the proposed compliant needle design.
CHAPTER 5 DESIGN ANALYSIS WITH FINITE ELEMENT METHODS

This chapter presents the analytical modeling and harmonic analysis of needle designs based on the finite element methods for simulating the axial and transverse vibration at the tip under the ultrasonic working frequency. The relationship between the displacement amplitudes and the micro slot geometric parameters including slot number, location, depth and width is investigated. Based on the observation of the simulation results, an empirical formulation is developed to determine the slot locations which lead to the peak or valley transverse displacement.

5.1 Introduction

For a homogeneous rod subjected to free vibration, the system is considered as continuous system in which the beam mass is considered as distributed along with the stiffness of the shaft. The equation of longitudinal motion can be written as [68]

\[- \frac{d}{dx} \left[ EA(x) \frac{dU(x)}{dx} \right] = \omega_a^2 \rho A(x) U(x)\]  

where \( E \) is the Young’s modulus of the material, \( A(x) \) is the cross-sectional area of the needle at a given position \( x \) from the base, \( \rho \) is the density of the needle material, \( \omega_a \) is the axial resonant frequency of the needle, and \( U(x) \) is the axial displacement of the needle at a given position \( x \). Figure 5.1 shows the setup of the ultrasonic vibration-assisted insertion device,
which is adapted from typical ultrasonic welding machines. The boundary conditions of the needle are modeled as free–free where each end of the needle is free to move. Other researchers have also used free–free boundary conditions in modeling ultrasonic machining tools [69]. This is appropriate because the back of the needle is free to move with the horn attached. The corresponding boundary conditions for Equation (5.1) are \( U'(0) = 0 \) and \( U'(L) = 0 \), where \( L \) is the length of needle. Assuming the needle is a rod with constant cross section, the frequency equation is given as

\[
f_{a(i)} = \frac{i}{2L} \sqrt{\frac{E}{\rho}} \quad (i = 0, 1, 2, \ldots)
\]  

(5.2)

![Figure 5.1 Amplitude chain of axial vibration in ultrasonic insertion device.](image)

The situation of \( i = 0 \) refer to the translational movement of the whole needle body. For
the situation where the excitation frequency has been determined by the device, the needle length can be calculated as

\[ L = \frac{i}{2f_{\text{excitation}}} \sqrt{\frac{E}{\rho}} \quad (i = 1, 2, \ldots) \]  
(5.3)

Figure 5.1 refers to the situation \( i = 1 \), where the needle length equals half of the wavelength of wave propagation in the needle. This mode shape generates the maximum amplitude of axial vibration at the ends of the needle, as shown in Figure 5.1. With a Young’s Module \( E = 190 \text{ GPa} \) and a density of \( \rho = 8000 \text{ kg/m}^3 \), \( L \) was calculated as 121.8 mm for an excitation frequency of \( f_{\text{excitation}} = 20 \text{ kHz} \). Theoretically, the needle length can be multiple times of the half of wavelength to achieve suitable working length, but a longer length is more likely to subject to buckling.

For a cantilever beam subjected to free vibration, the equation of transverse motion can be written as [68]

\[ \frac{d^2}{dx^2} \left[ EI(x) \frac{d^2 Y(x)}{dx^2} \right] = \omega_t^2 \rho A(x) Y(x) \]  
(5.4)

where \( E \) is the Young’s modulus of the material, \( I(x) \) is the area moment of inertia of the needle cross section at a given position \( x \), \( A(x) \) is the cross-sectional area of the needle at a given position \( x \), \( \rho \) is the density of the needle material, \( \omega_t \) is the transverse resonant frequency of the needle, and \( Y(x) \) is the transverse displacement of the needle at a given position \( x \). \( I(x) \) is given as \( \pi d^4 / 64 \), where \( d \) is the diameter of the needle. With the setup shown in Figure 6.1,
since the diameter of the horn is significantly larger than that of the needle, the needle can be considered fixed at the base and free to move at the end like a cantilever beam. The corresponding fixed-free boundary conditions for Equation (5.4) are \( Y(0) = 0, \ Y'(0) = 0, \ Y''(L) = 0 \) and \( Y'''(L) = 0 \). Assuming the needle is a beam with constant cross section, the frequency equation is given as

\[
\cos \beta L \cosh \beta L + 1 = 0
\]

(5.5)

By solving this equation numerically, the transverse resonant frequencies are given as

\[
f_{\text{fixed-free}(i)} = \frac{(\beta_i L)^2}{2\pi} \sqrt{\frac{EI}{\rho S L^4}}
\]

\[
\left( \beta_1 L = 1.875, \beta_2 L = 4.694, \beta_3 L = 7.855, \beta_i L = \frac{2i - 1}{2} \pi, i \geq 4 \right)
\]

(5.6)

If a needle is free to move at both ends, the corresponding free-free boundary conditions for Equation (5.4) are \( Y(0) = 0, \ Y'(0) = 0, \ Y(L) = 0 \) and \( Y'(L) = 0 \). The transverse resonant frequencies are given as

\[
f_{\text{free-free}(i)} = \frac{(\beta_i L)^2}{2\pi} \sqrt{\frac{EI}{\rho S L^4}}
\]

\[
\left( \beta_1 L = 4.730, \beta_2 L = 4.853, \beta_3 L = 10.996, \ldots \right)
\]

(5.7)

If a needle is fixed at one end and connected to a hinge at the other end, the corresponding fixed-hinge boundary conditions for Equation (5.4) are \( Y(0) = 0, \ Y'(0) = 0, \ Y(L) = 0 \) and \( Y''(L) = 0 \). The transverse resonant frequencies are given as
\[ f_{\text{fixed-hinge}}^{(i)} = \frac{(\beta_i L)^2}{2\pi} \sqrt{\frac{EI}{\rho SL^4}} \]

\[
(\beta_1 L = 3.927, \beta_2 L = 7.069, \beta_3 L = 10.210, \ldots ) \quad (5.8)
\]

Since the cross-section changes at the needle tip, modal analysis was conducted to validate the results from Equation (5.3) and (5.6) using the Simulation Add-in in SolidWorks 2016 Education Edition (Concord, MA) software. The goal of modal analysis in structural mechanics is to determine the natural mode shapes and frequencies of an object or structure during free vibration.

![Figure 5.2 Meshing of needle with no slots in SolidWorks](image)

Total nodes: 23719
Total elements: 13610

A CAD model of the needle without any micro-slot was built and meshed as shown in Figure 5.2, and the material was set to be AISI 304 stainless steel. Two solid element options
are provided in the software. A linear tetrahedral element is defined by four corner nodes connected by six straight edges, while a parabolic tetrahedral element is defined by four corner nodes, six mid-side nodes, and six edges. In general, for the same mesh density (number of elements), parabolic elements yield better results than linear elements because they represent curved boundaries more accurately, and they produce better mathematical approximations. As a result, although they require greater computational resources than linear elements, parabolic elements were used. Additionally, the curvature based mesher which creates more elements in higher-curvature areas automatically was activated. The maximum element size was set to be 0.5 mm, the minimum was 0.05 mm. The minimum number of elements in a circle was 8, and the element size growth ratio was 1.5. For the resultant meshed model, the maximum aspect ratio of the elements was 4.73, and 99.4% of the elements had an aspect ratio lower than 3. Normally an aspect ratio below 10 is acceptable. The resultant meshed model had a maximum Jacobian Ratio of 2.51, while it is generally seen that a ratio of 40 or less is acceptable based on stochastic studies. The boundary conditions were set according to Equation (5.3) and (5.6).
Figure 5.3 The 1\textsuperscript{st} longitudinal mode shape of needle with no slots under free-free boundary conditions.

Figure 5.3 shows the 1\textsuperscript{st} longitudinal mode shape at the frequency of 20015 Hz, which corresponds to the situation when $i = 1$ in Equation (5.3). The mass-normalized Z displacements at the needle tip and the needle base are very close in magnitude but opposite in signs, indicating the wave takes half-wavelength in the needle. Figure 5.4 shows the 11\textsuperscript{th} and 12\textsuperscript{th} transverse mode shapes at the frequency of 18268 Hz and 21844 Hz, which corresponds to the situation when $i = 11$ and 12 in Equation (5.6). These two frequencies are monitored because of their affinity to the 1\textsuperscript{st} longitudinal resonant frequency and influence of the mode shape at that frequency. Table 5.1 shows the comparison between the calculated and simulated values of the above three frequencies. It is found that the simulated frequencies tend to be slightly higher than the calculated values. Actually, the simulated frequencies are very close to the ones calculated with theoretical equations, indicating the effect of needle tip is not
significant.

Figure 5.4 The 11th and 12th bending mode shapes of needle with no slots under fixed-free boundary conditions.

Table 5.1 Results of calculated and simulated resonant frequencies

<table>
<thead>
<tr>
<th></th>
<th>1st axial resonant frequency (free-free)</th>
<th>11th transverse resonant frequency (fixed-free)</th>
<th>12th transverse resonant frequency (fixed-free)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Theoretical value</td>
<td>20000 Hz</td>
<td>18003 Hz</td>
<td>21596 Hz</td>
</tr>
<tr>
<td>Simulated value</td>
<td>20015 Hz</td>
<td>18268 Hz</td>
<td>21844 Hz</td>
</tr>
<tr>
<td>Relative error</td>
<td>0.075%</td>
<td>1.47%</td>
<td>1.14%</td>
</tr>
</tbody>
</table>

While modal analysis gives the resonant frequencies and the corresponding mode
shapes, it is desirable to know the actual vibration amplitude of the needle under a specific excitation, so harmonic analysis was also conducted in SolidWorks. A harmonic analysis is used to determine the response of a structure under a steady-state sinusoidal (harmonic) loading at a given frequency. Typical output of a harmonic analysis includes the displacement and stress at the points of interest on the structure. An axial excitement with a peak-peak amplitude of 25 \( \mu m \) was applied at the bottom of the needle between the frequencies of 17 kHz and 23 kHz to cover the three frequencies in Table 5.1. This amplitude was based on the capability of the available vibration device. Figure 5.5 shows the response of transverse (X) and axial (Z) amplitudes of the needle over the frequency range. It can be seen that the axial amplitude reaches its peak at about 20 kHz, which corresponds to the 1\(^{st}\) axial resonant frequency. The peak of transverse amplitude occurs not only at the 20 kHz frequency related to longitudinal resonance, but also at 18268 Hz and 21644 Hz due to transverse resonance. Since there was no micro slots on the needle shaft, the transverse vibration amplitude was only within the magnitude of \(10^{-1}\) micron.
5.2 Study of one-slot situation

To study the effects of shaft slots on vibration modes, we began with the situation of one slot. The CAD models of 23 needles, namely N4 to N26, with one slot were built where the distance between the tip and the slot changed from 4 mm to 26 mm with an interval of 1 mm. The results of needles with larger slot-tip distances were not listed because the maximum stress in the harmonic analysis exceeded the yield strength of AISI 304 stainless steel when
then distance was greater than 26 mm. The results might be not accurate in this case, and the needle was likely to break in practice. Moreover, the vibration was supposed to occur mainly at the front section of the needle near the tip. The slot width $W$ was 100 $\mu m$, and the slot depth was $0.6D$, where $D$ was the needle diameter. For meshing of CAD models, the maximum element size was set to be 0.5 mm, the minimum was 0.05 mm. The minimum number of elements in a circle was 8, and the element size growth ratio was 1.5. The resultant number of nodes was 33593, and the number of elements was 20089. The maximum Jacobian Ratio was 3.47, the maximum aspect ratio of the elements was 7.46, and 99.3% of the elements had an aspect ratio lower than 3. All these parameters were under suitable ranges.

Figure 5.6 Simulated deformation of N7 in X, Y and Z direction at 20 kHz.
Harmonic analysis was conducted to individual needle with an axial excitement with a peak-peak amplitude of 25 \( \mu m \) applied at the bottom of each needle between the frequencies of 17 kHz and 23 kHz. As illustration, the deformation results of N7 as its displacements in the three directions at 20 kHz can be seen in Figure 5.6. It clearly demonstrates that transverse vibration can be generated at the tip with the axial vibration applied at the needle base.

![Graph showing simulated X and Z displacement of N5.](image)

Figure 5.7 Simulated X and Z displacement of N5.

For all the 23 needles, the X (transverse) and Z (axial) direction displacement of the
needle tip were recorded. The displacement in the Y direction was at the magnitude of $10^{-1} \mu m$ and thus not recorded. As an example, Figure 5.7 gives the plots of X and Z displacement of N5 between the frequencies of 17 kHz and 23 kHz. The axial amplitude reached its peak at about 20 kHz, which corresponds to the 1st axial resonant frequency under free-free boundary conditions. The peak of transverse amplitude occurred not only at the 20 kHz frequency related to longitudinal resonance, but also near the 11th and 12th transverse resonant frequencies as in Figure 5.5. The peak transverse amplitudes were much greater than those in Figure 5.5 due to the micro slot.

Figure 5.8 shows the results of X and Z displacement at the needle tip of N4 to N26 at 20 kHz.
20 kHz. The Z displacements stay around 25 \( \mu m \) among all the needles, which is the amplitude of excitation. It is interesting to notice that the X displacement changes in a period-like manner as the slot changed from 4 \( mm \) to 26 \( mm \). It reaches the peak values in N7 and N18, and valley values in N10 and N21. The peak value in N18 is greater than that in N7, and it is anticipated that another peak will appear after N26. It should be noticed that the peak value does not occur in the exact middle of two valleys, i.e. somewhere near N15.

To find out how the X displacement changes along with the slot location, the mode shape of N7 at 20 kHz is presented in Figure 5.9, where the first peak value occurs. It is found that the needle can be divided into two sections in this mode shape. The section between the needle tip and the slot is in the rigid body mode which does not deform, while the section between the needle base and the slot is close to the 11\(^{th}\) transverse bending mode under fixed-free boundary condition. By making \( f_{\text{excitation}} = 20 \) kHz and \( i = 11 \) in Equation (5.6), it is
found the corresponding needle length at resonance is 115.7 mm. This matches the distance between the needle base and the slot in N7, which is 114.8 mm. The peak value in N7 can be considered to mainly result from the large deformation at the end of the base section under fixed-free transverse vibration resonance. Similarly, by making $f_{\text{excitation}} = 20$ kHz and $i = 10$ in Equation (5.6), it is found the corresponding needle length at resonance is 104.7 mm. This matches the distance between the needle base and the slot in N18, which is 103.8 mm. Figure 5.10 shows the mode shape of N18 at 20 kHz. The base section in the 10th transverse bending mode under free-free boundary condition as predicted, while the tip section is under the 1st transverse bending mode under free-free boundary condition. By putting $f_{\text{excitation}} = 20$ kHz and $i = 1$ in Equation (5.7), it is found the corresponding needle length at resonance is 17.1 mm. This length matches the distance from needle tip to slot which is 18 mm. The peak value in N18 can be considered to mainly result from the large deformation at the end of the base section under fixed-free transverse vibration resonance and the tip section under free-free transverse vibration resonance.
To find out when valley values occur, the mode shape of N10 at 20 kHz is presented in Figure 5.11. It is found that the needle can also be divided into two sections in this mode shape. The section between the needle tip and the slot is in the rigid body mode which does not deform, while the section between the needle base and the slot is close to the 10th transverse bending mode under fixed-hinge boundary condition. By making $f_{excitation} = 20$ kHz and $i = 10$ in Equation (5.8), it is found the corresponding needle length at resonance is 112.7 mm. This matches the distance between the needle base and the slot in N10, which is 111.8 mm. The valley value in N10 can be considered to mainly result from the small deformation at the end
of the base section under fixed-hinge transverse vibration resonance. Similarly, by making $f_{\text{excitation}} = 20 \text{ kHz}$ and $i = 9$ in Equation (5.8), it is found the corresponding needle length at resonance is 101.8 mm. This matches the distance between the needle base and the slot in N21, which is 100.8 mm. Figure 5.12 shows the mode shape of N21 at 20 kHz. The base section is close to the 9th transverse bending mode under fixed-hinge boundary condition as predicted.

Figure 5.12 Mode shape of N21 at 20 kHz.

![Mode shape](image)

Figure 5.13 Results of simulated X and Z displacement for N4 to N16 at 40 kHz.

![Displacement results](image)
To test the capability of the method presented above, situations were also simulated when the slot width $W = 0.5D$ and $0.7D$. The slot locations of peak and valley displacements were not found to significantly change under these two slot widths, and the proposed method was still applicable. The situation of 40 kHz excitation was also studied, which corresponded to another available ultrasonic transducer in the lab. By using Equation (5.3), the needle length is calculated as 60.9 mm. The CAD models of 13 needles, namely N4 to N16, with one slot were built where the distance between the tip and the slot changed from 4 mm to 16 mm with an interval of 1 mm. Needles with larger slot-tip distances were not considered because the concentrated stress near the slot tended to exceed yield strength of material in that case, as mentioned in the above analysis in the 20 kHz case. Figure 5.13 shows the harmonic analysis results of X and Z displacement at the needle tip of N4 to N16 at 40 kHz excitation with a peak-peak amplitude of 12.5 $\mu$m, which is half of that in the previous 20 kHz situation. The peak value occurs in N12, while the valley values in N6 and N14. By making $f_{\text{excitation}} = 40$ kHz and $i = 7$ in Equation (5.6), it is found the corresponding needle length at resonance is 50.7 mm. This matches the distance between the needle base and the slot in N12, which is 48.9 mm. In terms of the valley values, by making $f_{\text{excitation}} = 40$ kHz and $i = 7$ in Equation (5.8), it is found the corresponding needle length at resonance is 56.5 mm. This matches the distance
between the needle base and the slot in N6, which is 54.9 mm. By making $f_{\text{excitation}} = 40$ kHz and $i = 6$ in Equation (5.8), it is found the corresponding needle length at resonance is 48.6 mm. This matches the distance between the needle base and the slot in N14, which is 46.9 mm. They method also demonstrated substantial accuracy for the 40 kHz situation.

The above method can be implemented more conveniently with Figure 5.1, which shows the relationship between resonant length and resonant frequency under free-free axial vibration and fixed-free transverse vibration. The red dotted curve on the upper right is based on Equation (5.3) when $i = 1$, while other continuous curves are based on Equation (5.6) when
i changes from 1 to 12. For example, if the working frequency is 20 kHz, by drawing a horizontal line and make it intersect with the red dotted curve, the needle length can be obtained as 121.8 mm (Point A). The same horizontal line also intersects with the 11th transverse curve at the length of 115.7 mm (Point B). According to the proposed empirical method, the first peak in X displacement will occur when the distance between the needle tip and slot is around 6.1 mm by subtracting 115.7 mm from 121.8 mm. This distance corresponds to somewhere between N6 and N7.

Table 5.2 Summary of the calculated and simulated slot-base distance at peaks and valleys

<table>
<thead>
<tr>
<th>Location</th>
<th>20 kHz</th>
<th>40 kHz</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needle length</td>
<td>121.8 mm</td>
<td>60.9 mm</td>
</tr>
<tr>
<td>Calculated slot-base distance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st peak</td>
<td>115.7 mm</td>
<td>56.5 mm</td>
</tr>
<tr>
<td>1st valley</td>
<td>112.7 mm</td>
<td>50.7 mm</td>
</tr>
<tr>
<td>2nd peak</td>
<td>104.7 mm</td>
<td>48.6 mm</td>
</tr>
<tr>
<td>2nd valley</td>
<td>101.8 mm</td>
<td></td>
</tr>
</tbody>
</table>

| Simulated slot-base distance |        |        |
| 1st peak       | 114.8 mm | 54.9 mm |
| 1st valley     | 111.8 mm | 48.9 mm |
| 2nd peak       | 103.8 mm |        |
| 2nd valley     | 100.8 mm | 46.9 mm |

| Relative error | 0.78% | 0.81% | 0.87% | 0.99% | 2.91% | 3.68% | 3.62% |

The empirical method presented above provides a convenient way to estimate the corresponding distance between the needle base and the slot when peak and valley X
displacements occur. Table 5.2 summaries the results for both 20 kHz and 40 kHz situations. It can be seen that as the needle length in 40 kHz becomes only half of that in 20 kHz, the relative error increases as a shorter needle tends to be more sensitive to the location of the slot. The minor difference between the calculated and simulated values result from the fact that the equations are developed for rods with constant cross-section while the needle tip is not. This makes the calculated distances always greater than the simulated ones. Another source of inaccuracy comes from the approximation of the status at the slot location. When calculating the distance for peak X displacements, the slot was approximated as a free end, while for valley X displacements, it was as a hinge end. Actually, due to the front section of the needle, the slot location can’t be entirely free or rotate without displacement like a hinge. The accuracy of the method will be further validated and evaluated in Chapter 6 with microscopic measurement of vibration amplitude for needle prototypes used in insertion experiments.

5.3 Study of two-slot situation

While the one-slot needle design is relatively easy to fabricate, it tends to have limited amplitude of X displacement, so two-slot needle design as shown earlier in Figure 3.1(a) is also investigated. The CAD models of a total of 72 needles with two slots on opposite sides were built. The distance between the tip and the first slot, $D_1$, changed from 4 mm to 15 mm
with an interval of 1 mm. The distance between the two slots, $D_2$, changed from 1 mm to 13 mm with an interval of 2 mm. The needle length was 121.8 mm, slot width $W$ was 100 μm, and the slot depth was 0.6$D$, where $D$ was the needle diameter. Figure 5.15 shows the harmonic analysis results of X displacement at the needle tip under a 20 kHz excitation with a peak-peak amplitude of 25 μm.

Figure 5.15 Simulated X displacement for needles with two slots at 20 kHz.
While the X displacement was limited to below 20 $\mu m$ under the situation of only one slot, the X displacement can be much larger, reaching even above 100 $\mu m$. It can be observed that the results of the two-slot design are closely related to the single-slot design. In other words, the locations where peak and valley X displacement values occur in two-slot design can be predicted with the results of single-slot design. For example, the peak value of X displacement occurs when $D_1$ is about 7 $mm$ and $D_2$ is about 16 $mm$. Meanwhile in the single-slot design, the distance between needle tip and slot is about 7 $mm$ for the 1$^{st}$ peak X displacement and about 18 $mm$ for the 2$^{nd}$ peak. For a specific $D_1$, the peak value is likely to occur when $D_1 + D_2$ is around 16 $mm$ as the $D_2$ changes. On the other hand, the valley value of X displacement occurs when $D_1$ is about 10 $mm$ and $D_2$ is about 21 $mm$. Meanwhile in the single-slot design, the distance between needle tip and slot is about 10 $mm$ for the 1$^{st}$ valley X displacement and about 21 $mm$ for the 2$^{nd}$ valley. For a specific $D_1$, the valley value is likely to occur when $D_1 + D_2$ is around 10 $mm$ or 21 $mm$ as the $D_2$ changes.

To test whether the observations above also applied to the situation of 40 kHz excitation, harmonic analysis was conducted for the above 72 needles under a 40 kHz excitation with a peak-peak amplitude of 12.5 $\mu m$. The location, width and depth of the needles are the same with those in the previous 20 kHz simulation, while the length was changed to 60.9 $mm$. Figure 5.16 shows the results of X displacement at the needle tip. A peak value of X displacement
occurs when $D_1$ is about 13 mm and $D_1 + D_2$ is about 18 mm. Meanwhile in the single-slot design, the distance between needle tip and slot is about 12 mm for the 1st peak X displacement and about 19 mm for the 2nd peak. For a specific $D_1$, the peak value is likely to occur when $D_1 + D_2$ is around 18 mm as the $D_2$ changes. An interesting observation is that another peak value of X displacement occurs when $D_1$ is about 5 mm and $D_1 + D_2$ is about 11 mm. Meanwhile in the single-slot design, the distance between needle tip and slot is about 6 mm for the 1st valley X displacement and about 12 mm for the 1st peak. On the other hand, the valley value of X displacement occurs when $D_1$ is about 6 mm and $D_1 + D_2$ is about 14 mm. Meanwhile in the single-slot design, the distance between needle tip and slot is about 6 mm for the 1st valley X displacement and about 14 mm for the 2nd valley. Similar to the single-slot situation, a shorter needle tends to induce more errors in the estimated slot locations for peak and valley X displacement.
5.4 Study of the effects of slot width and depth

In addition to the number and locations for the slots, the effects of slot width $W$ and depth $H$ were also studied using harmonic analysis with the 72 needles above. $W$ was set to be 100 $\mu m$, 200 $\mu m$ and 300 $\mu m$, and $H$ was $0.25D$, $0.5D$ and $0.6D$. For illustration, Figure 5.17 shows the combinations of $W$ and $H$ for the needle with $D_1 = 5 \ mm$ and $D_2 = 1 \ mm$. Figure 5.18 shows the harmonic analysis results of this needle, where the frequency was 20
kHz and the excitation peak-peak amplitude was $25 \, \mu m$. The remaining needles have similar trends with and are thus not shown.

For each slot depth, both Z and X displacement only increased slightly along with the increase of slot width, which indicated the tip vibration motion was not very sensitive to slot width. This also reduces the requirement of small sheet electrode thickness in the manufacturing process. On the other hand, slot depth has a more phenomenal influence on the displacements. For all the three tested slot widths, the displacement increase from $H = 0.5D$ to $H = 0.6D$ is much higher than that from $H = 0.25D$ to $H = 0.5D$. In other words, the tip vibration motion was relatively sensitive to slot depth. Actually, when $H$ was greater than
0.6\(D\), the stress in the needle began to be comparable with the yield point of material, and thus the results might not be reliable.

![Bar chart showing X displacement amplitude for different slot widths and depths.](image)

**Figure 5.18** Effects of slot width and depth on X displacement amplitude.

From an intuitive point of view, increasing \(H\) or \(W\) reduces the overall strength of the needle, so that it can swing with a larger amplitude under the same excitation. From the view
point of manufacturing, among the four variables of the slots, $D_1$ and $D_2$ can be easily achieved using the EDM machine axis servo, while $H$ and $W$ are relatively difficult to control accurately due to electrode wear. Given the influence of $H$ and $W$ on vibration pattern discussed above, $H$ can be used to determine the overall tip vibration pattern in practice, while $W$ can be used to fine tune the vibration motion.

### 5.5 Summary

This chapter presented the use of modal analysis and harmonic analysis based on finite element methods to study the motion at the needle tip with a focus on the axial and transverse displacement amplitude at the tip under working frequency. The relationship between the displacement amplitudes and the slot parameters including slot number, location, depth and width is investigated. It was found that in the single-slot situation, the peak and valley values of transverse vibration amplitude occur in a period-like manner. Based on the observation of mode shapes associated with peak and valley transverse displacement values in the single-slot situation, an empirical method was developed to identify the slot locations that lead to peak or valley displacement values. The method was tested at both 20 kHz and 40 kHz, and can be adapted to the two-slot situation. The two-slot situation can result in much larger transverse displacement than in the single-slot situation, and a greater slot width or depth can increase the
displacement. The effect of slot depth is much greater than that of width. The simulation results together with the empirical method provides guidelines for designing and fabricating needle prototypes with desirable axial and transverse vibration amplitude.
CHAPTER 6 INSERTION EXPERIMENTS WITH ULTRASONIC VIBRATORS

This chapter presents the experimental designs of needle insertion testing conducted using lab-built ultrasonic vibrator to investigate and to validate the capability of the proposed compliant needle design. Three types of common testing materials with different material properties, namely candle gel, polyurethane sheet and porcine skin, were tested. The experiment results are presented and discussed with material properties and needle tip vibration pattern obtained from harmonic analysis.

6.1 Insertion experiments for tissue phantom with 40 kHz ultrasonic vibrator

6.1.1 Experiment setup

Figure 6.1 shows the setup for the tissue phantom experiment. A linear motion guide was utilized to insert the needle into tissue phantom at a constant rate. It was controlled by an Arduino Mega 2560 microcontroller and a TB6600 stepper motor driver. A 50W 40 kHz ultrasonic transducer together with a horn was mounted to the slide on the linear motor to provide vibration during the tests. The displacement amplitude at the working surface, \( A \), can be calculated as

\[
A = \sqrt{\frac{2I}{\rho c \omega^2}}
\]

(6.1)

where \( I \) is the sound density at surface and is calculated by dividing the power by surface area,
\( \rho \) is the material density of transducer front end, \( c \) is the velocity of longitudinal sound propagation of transducer front end, \( \omega \) is the angular velocity. In the case of aluminum, \( \rho \) equals 2700 kg/m\(^3\) and \( c \) equals 5051.59 m/s. With working frequency of 40 kHz, \( A \) is calculated to be 270.15 nm. According to modal analysis, the amplitude gain of the horn was 4.52. A maximum vibration amplitude at the output end of the horn is therefore estimated to be 2.44 \( \mu \)m. Due to energy efficiency and loss, the actual amplitude will be smaller than this value. The actual amplitude will be measured later this Chapter.

Figure 6.1 Experimental design and setup for tissue phantom with 40 kHz ultrasonic vibrator.

A strain gauge load cell (Lotooclub) of a capacity of 30 N was used to measure the force
along the insertion direction, and it was attached to a support structure fixed on an adjacent table for vibration isolation. A 9V DC voltage was supplied to the strain gauge load cell, and an INA 125 instrumentation amplifier was used to amplify the gauge output with a gain of 604. A data acquisition system (National Instruments, USB-6002) and LabVIEW software were used to record the force data.

The tissue phantom used in the experiment was candle wax (Gelly Candle Wax), which was used in the literature as tissue phantom for needle insertion experiments [70-72]. It was molded into a metal cylinder container with a diameter of 80 mm and a depth of 40 mm. The container was aligned and connected to a round acrylic plate whose center was able to rotate around a short shaft fixed on the strain gauge. After each insertion trial, the plate together with the container was rotated manually by 30 degree using a pin to avoid duplicate insertions at the same location. In other words, a mold of tissue phantom could be used for a maximum of 12 insertion trials.

6.1.2 Experiment design

To study the effects of needle geometry parameters on insertion performance, four needle prototypes with one slot, together with a control needle without slots, were fabricated with the dimensions shown in Table 6.1. The four needles with slot were chosen based on
Figure 5.12, where the X displacement at the needle tip increases from N6 to N12 and then decreases in N14 under 40 kHz excitation. They not only serve the purpose of insertion experiments, but also help to validate and evaluate the results of finite element analysis presented earlier in Chapter 5.

<table>
<thead>
<tr>
<th>Needle</th>
<th>Length</th>
<th>$\varphi$</th>
<th>$\beta$</th>
<th>$D$</th>
<th>Slot-tip distance</th>
<th>$H$</th>
</tr>
</thead>
<tbody>
<tr>
<td>N0(Control)</td>
<td>60.9 mm</td>
<td>10°</td>
<td>20°</td>
<td>1.27mm</td>
<td>No slots</td>
<td></td>
</tr>
<tr>
<td>N6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6 mm</td>
<td>0.6D</td>
</tr>
<tr>
<td>N9</td>
<td>60.9 mm</td>
<td></td>
<td></td>
<td></td>
<td>9 mm</td>
<td></td>
</tr>
<tr>
<td>N12</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>12 mm</td>
<td></td>
</tr>
<tr>
<td>N14</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>14 mm</td>
<td></td>
</tr>
</tbody>
</table>

To mitigate the effects of property variations among different molds of tissue phantom, each needle was inserted into the same sample twice, once with vibration and once without. As a result, only 10 holes were created in a mold of phantom. Another option was not chosen where the insertion trials of a specific needle were all conducted on the same mold of phantom. In that case, a needle would have been inserted into a harder sample, while another into a softer one, so the results would be biased and not accurate. During the insertion, each needle
was inserted into the tissue phantom by 25 mm with a constant average velocity of 2 mm/s and then retracted with a velocity of 5 mm/s. Five trials in total were conducted for the vibration and the non-vibration condition of each needle respectively, and the force data were collected for each trial with a sampling rate of 1000Hz.

For all the needles, when no vibration was applied, an example force-position plot was as shown in Figure 6.2. At the beginning, as the needle tip gets touch with the tissue phantom and passes through it, the force increases in a linear-like manner as the insertion depth increases. The insertion force consists of the cutting force at the needle tip and the friction/dragging force between the needle shaft and the tissue phantom. When the insertion depth reaches some point, the dragging force between needle and tissue is partially released, which is identified as a bump.
in the force-position plot followed by a temporary decrease of insertion force. The insertion then begins to increase again. When vibration was applied, however, the bump is not easily observed, and the insertion force increases continuously as the insertion depth increases. To compare the performance of different needles, the insertion force in the center of the bump, $F_{\text{bump}}$, was measured when vibration was not applied, and the insertion force corresponding to the depth when the bump center occurs, $F_{\text{depth}}$, was also measured when vibration was applied. For example, if the bump occurs when the insertion depth is 10 $\text{mm}$ under non-vibration condition, the insertion force with an insertion depth of 10 $\text{mm}$ under vibration condition was measured.

6.1.3 Experiment results and discussion

To determine the effects of the compliant geometry on the motion of the needles and to validate the results of harmonic analysis in Chapter 5, the displacements of the tips were measured using a Hirox KH-7700 Advanced 3D Digital Microscope. Images were captured for each needle with and without vibration applied. The motion of the tip was determined by the ghost image in the capture, as shown in Figs. 6.3(b). Figures 6.3(a) and 6.3(b) show the needle tip of N12 with and without vibration applied. The motion can be tracked by measuring the displacement of the reflected spots caused by surface textures shown in Figure 6.3(b). The
exposure time for the images was 8 ms. At 40 kHz frequency, this allowed for 320 cycles to be captured in each image, ensuring the capture of the full range of motion.

Figure 6.3 Microscopic images of needle tip without and with applied vibration.

(a) No applied vibration

(b) With applied vibration

Figure 6.3 Microscopic images of needle tip without and with applied vibration.
Figure 6.4 Measured and simulated X displacement amplitudes for tested needles.

The motion was recorded for the output end of the horn and each of the five needles used in this study, and the results are shown in Figure 6.4 together with the simulated results from harmonic analysis extracted from earlier Figure 5.13. The motion amplitude at the end of the horn was 1.47 μm, which is consistent with the calculation using Equation (6.1), given the issue of transition efficiency and energy loss. Ideally, the control needle N0 should only have motion in the axial direction of the vibration. However, minor transverse vibration motion was still observed, which may be due to needle fabrication asymmetry and environment disturbance. The needles with slot had motion in both the axial direction and the transverse direction. As the distance between the tip and slot increases from N6 to N12, the transverse displacement also increases, followed by a drop in N14. This follows the overall trend of the results of harmonic analysis in Figure 5.13. It should be pointed out that the excitation amplitude in the
harmonic analysis was 12.5 μm, while the actual horn provided only 1.47 μm. This may be due to the fact that tetrahedron meshing during the harmonic analysis tended to give too stiff of results, as mentioned in the literature [73-75]. Other meshing elements such as hexahedron should be considered in the future.

Figure 6.5 shows the results of $F_{\text{bump}}$ and $F_{\text{depth}}$ for the five needles shown in Table 6.1. When vibration was not applied, $F_{\text{bump}}$ increased as the distance between needle tip and slot increased. This indicated that the slot changed the contact between the needle shaft and the tissue phantom, so the dragging force was released earlier in a needle with a shorter tip-slot distance. It can be found in the literature that researchers tried to add micro laser-carved patterns on the needle shaft to reduce the friction/dragging force [18, 25]. Since the $F_{\text{bump}}$ tended to occur at different depths for each needle, the $F_{\text{depth}}$ of the five needles can’t be compared directly to evaluate the performance of each needle given its definition. Instead, we focus on the self-comparison of each needle for conditions without and with vibration. For N0, $F_{\text{depth}}$ was 5.31% lower than $F_{\text{bump}}$. This relative reduction rate is 8.32%, 8.43%, 10.60% and 7.43% for N6, N9, N12 and N14 respectively. The ANOVA $F$-test $p$-values of N0 to N14 are 0.125, 0.051, 0.037, 0.027 and 0.035, respectively, which indicate vibration resulted in significant reduction of insertion force for all the needles except N0. Since N0 had mainly axial vibration, transverse vibration was found to be more helpful in reducing the insertion force.
when cutting soft tissue phantom in this study.

![Figure 6.5 Experiment results of $F_{\text{bump}}$ and $F_{\text{depth}}$ for the tested needles.](image)

By comparing the relative force reduction rate and the transverse vibration shown in Figure 6.4, it seemed that a larger transverse displacement resulted in more force reduction as in the case of N12. This should be because the needle tip with a larger transverse displacement is able to create a larger incision opening in the soft tissue phantom used in the study, so the needle is not pushed that hard by the phantom and the resultant friction will be lower. This analysis can be supported by Figure 6.6, which shows the insertion paths of N6, N9, N12 and N14. While the difference of the path widths of N6, N9 and N14 are not easy to tell at a glance, the width of N12 is visually greater than others. This actually matches the highest relative
reduction rate of N12 and the comparable rates among N6, N9 and N14, as presented in the last paragraph. Since the paths are in a non-transparent metal container, it is not possible to measure the exact width of each path for the side. Transparent container with flat surfaces should be considered in the future to facilitate such measurement.

![Figure 6.6: Insertion paths of needles in the tissue phantom.](image)

6.2 Insertion experiments for skin phantom with 40 kHz ultrasonic vibrator

6.2.1 Experiment setup

Figure 6.7 shows the setup for the skin phantom needle piercing experiment. The previous tissue phantom container was replaced by a rotational structure where the testing
medium was clamped by two plates with screws. A polyurethane sheet (M-F Manufacturing) with a Shore Hardness of 40A and a thickness of 1.588 mm was used here as an analog to human skin. The plates had 12 aligned holes in them. By rotating the plates together with the phantom, a needle can pass through the phantom at 12 different locations without causing any tension to the skin.

![Figure 6.7 Experimental design and setup for skin phantom with 40 kHz ultrasonic vibrator.](image)

**6.2.2 Experiment design**

The five needles in Table 6.1 used in the previous tissue phantom experiments were also used in this study. The control needle N0 was inserted with and without applied vibration,
while each of the other four needles with slots was inserted with an applied axial ultrasonic vibration of 40 kHz, resulting in six needle-vibration combinations. Five trials were conducted for each combination. The average velocity of insertion was set to a constant of 2 mm/s for all the trials, and the force data were collected for each trial with a sampling rate of 1000Hz. An example force-position plot is shown in Figure 6.8, where three phases can be identified during the insertion process. In the first phase, the needle tip touches the skin phantom but no cutting or penetration occurs. The force is mainly caused by the elastic deformation of the skin phantom. In the second phase, the needle tip quickly cuts and punctures through the skin phantom, which is featured by a significant drop in the force. Since the deformation happened in a short time, the force fluctuates due to the elastic property of the load cell. In the third phase, the needle tip has exited the phantom skin. The force is mainly caused by the friction between the needle shaft and the inner surface of puncture hole. Two parameters can be measured as the indicator of the performance of a needle. The first parameter is the puncture force, which is the peak value of insertion force before it suddenly drops. It is the maximum force the phantom endures before penetration begins. The second parameter is the friction force in the third phase. Both parameters are of great importance in evaluating the needle performance in practice, and keeping them low is usually preferred.
6.2.3 Experiment results and discussion

The puncture force and friction force were recorded for the control needle N0 with and without applied vibration and also for the other four needles with vibration. The results are shown in Figure 6.9 and Figure 6.10, respectively. Compared to the control insertion with no vibration, the puncture force was reduced with applied vibration by 4.98% for the control needle N0, and by 7.21% and 16.75% for N6 to N14, respectively. The ANOVA $F$-test $p$-values were 0.001, 0.001 and 0.001 respectively. On the other hand, the puncture force was increased by 4.36% and 8.09% for N9 and N12, respectively. The ANOVA $F$-test $p$-values were 0.013 and 0.010, respectively. N14 had the lowest mean value of puncture force, and it was tested to be significantly lower than the puncture forces of other needles. The friction force was reduced
with applied vibration by 2.16%, 17.83%, 27.43% and 25.29% for N0, N9, N12 to N14, respectively. The ANOVA F-test p-values were 0.778, 0.060, 0.001 and 0.005, respectively. On the other hand, the friction force was increased by 8.58% for N6 with the ANOVA F-test p-value of 0.123. Although N12 had the lowest mean value of friction force, it was not significantly lower than that of N9 and N14 with ANOVA F-test p-values of 0.234 and 0.728, respectively.

Figure 6.9 Puncture force results of the tested needles.
By relating Figure 6.9 and Figure 6.4, it seems that a small amplitude of transverse vibration was helpful to further reduce the puncture force. As the amplitude increased, since the polyurethane film was relatively tough, the cutting edges of the needle were not able to cut a larger incision opening directly as expected with just a few microns of transverse vibration. Instead, the increased transverse motion increased the transverse compressive force applied on the needle tip area, resulting higher resistant force. Moreover, the needle tip was not interacting with the testing medium with its best perpendicular orientation. Both of these would increase the puncture force, so some needles like N9 and N12 even had larger puncture force with applied vibration than N0 without applied vibration. As the polyurethane film was finally penetrated with a larger puncture force, a larger area around the needle tip was affected and a
larger incision opening was formed. This explained why the needles with larger puncture forces tended to have lower friction forces, just like the four needles with slots.

Figure 6.11 Cracks formed by needles on the polyurethane sheet.

The above analysis can be supported by measuring the incision openings (cracks) on the polyurethane sheet after the insertion experiment using microscopic camera. Figure 6.11
shows two examples of the cracks, which were formed by N9 and N12, respectively. Figure 6.12 shows the results of crack length of the needles. As predicted, a larger crack is associated with larger puncture force and lower friction force. It is also noticed that the standard deviation of N12 is much greater than other needles, indicating the formation of large cracks may be unstable and unpredictable.

![Figure 6.12 Crack lengths of the needles on the polyurethane sheet.](image)

The results above are consistent with the results in [76], where crack lengths after penetration were also measured to explain the reduced friction force.

### 6.3 Insertion experiments for porcine skin with 20 kHz ultrasonic vibrator

Based on the observations in the previous two sets of insertion experiments, it was
found that the vibration amplitude provided by the 40 kHz ultrasonic vibrator was too limited, failing to creating substantial vibration at the needle tip, especially in the axial direction. Moreover, the polyurethane sheet seemed to be too tough for the needle tip to tear apart transversely given the relatively small vibration amplitude. As a result, a 20 kHz ultrasonic vibrator is used in the following insertion experiments together with porcine skin as the testing material.

6.3.1 Experiment setup

Figure 6.13 shows the setup for the porcine skin experiment. A porcine skin sample was clamped by two plates using screws on a rotational structure. The plates had 12 aligned holes in them. By rotating the plates together with the skin sample around the central axis, a needle can pass through the skin at 12 different locations without causing any tension to the skin. A linear motor (Dunkermotoren) was utilized to insert the needle into tissue phantom at a constant rate. A six-axis force sensor (ATI) was used to measure the force during insertion, and it was attached to a manual thread guild fixed on an adjacent table for vibration isolation. A data acquisition system (National Instruments, PXIe-6361) and LabVIEW software were used to record the force data and to control the linear motor.
Table 6.2 Amplitude of the ultrasonic vibrator under different voltages.

<table>
<thead>
<tr>
<th>Voltage (V)</th>
<th>5</th>
<th>25</th>
<th>50</th>
<th>75</th>
<th>100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amplitude (μm)</td>
<td>5.93</td>
<td>19.44</td>
<td>32.47</td>
<td>44.93</td>
<td>55.53</td>
</tr>
</tbody>
</table>

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. Since the actuation amplitude of the piezoelectric ceramics alone was small, a stepped horn made of 6061 aluminum was used to increase the amplitude. A short conical section was added in between the steps to reduce the stress in the horn. A needle could be inserted into the hole at the end of the horn and fixed with screw. A fiber-optic probe (MTI Instruments, Albany, NY) was used to measure the peak-to-peak amplitude at the end side of

Figure 6.13 Experiment setup for needle insertion: (a) overview and (b) the skin plates.
the horn, and the results for different actuation voltages were summarized in Table 6.2. Although a higher actuation voltage resulted in larger amplitude, which might be beneficial for reducing insertion force, 25V was used in the experiment for safety considerations.

6.3.2 Experiment design

To study the effects of needle geometry parameters on insertion performance, two sets of needle prototypes were fabricated with the methods presented in Chapter 3. They all had a $\varphi$ of 10°, an $\beta$ of 20° and a $D$ of 1.27 mm (Gauge 18). For four needles in the first set, $D_1$ was set to be a constant of 5 mm, while $D_1 + D_2$ changed from 10 mm to 25 mm with an interval of 5 mm. For four needles in the second set, $D_1 + D_2$ was set to be a constant of 25 mm, while $D_1$ changed from 5 mm to 20 mm with an interval of 5 mm. The slot width was set to 100 $\mu$m, and the slot depth $H$ was set to a constant of 0.6$D$. For each needle set, an additional needle was made as control (N5 and N10), which didn’t have the two slots on the needle shaft. Their performance serves as the baseline for subsequent comparison. A summary of the needles in the two sets is shown in Table 6.3. Given that a needle can be approximated to be a homogeneous rod, the length of the needle $L$ was calculated to be 121.8 mm using Equation (5.3).
Table 6.3 A summary of the two needle sets in the experiment.

<table>
<thead>
<tr>
<th>Set</th>
<th>Needle</th>
<th>$D_1$</th>
<th>$D_1 + D_2$</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>N1</td>
<td>5 mm</td>
<td>10 mm</td>
</tr>
<tr>
<td></td>
<td>N2</td>
<td></td>
<td>15 mm</td>
</tr>
<tr>
<td></td>
<td>N3</td>
<td>20 mm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>N4</td>
<td>25 mm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>N5</td>
<td>No slots</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Set</th>
<th>Needle</th>
<th>$D_1$</th>
<th>$D_1 + D_2$</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>N6</td>
<td>5 mm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>N7</td>
<td>10 mm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>N8</td>
<td>15 mm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>N9</td>
<td>20 mm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>N10</td>
<td>No slots</td>
<td></td>
</tr>
</tbody>
</table>

The control needle in each needle set was inserted with and without applied vibration, while each of the other four needles with slots was inserted with an applied axial ultrasonic vibration of 20 kHz, resulting in six needle-vibration combinations for each set of needle. Five trials were conducted for each needle-vibration combination. To mitigate the effects of property variations of different porcine skin samples, each needle in a needle set was inserted through the holes on the plates into the same sample. Accordingly, the 12 holes on the plates could support 2 insertion trials for each of the above needle-vibration combination. Another option was not chosen where the insertion trials of a specific needle were all conducted on the same skin sample. In that case, a needle would have been inserted into a tougher skin sample, while another into a softer one, so the results would be biased and not accurate. The current option also mimicked the insertion situations of different skins, which could reflect the capability of a needle in a more comprehensive way. The average velocity of insertion was set to a constant of $1 \text{ mm/s}$ for all the trials, and the force and position data were collected for each
trial with a sampling rate of 1000Hz. The averaged values of insertion force and depth were used as the results.

An example force-position plot is shown in Figure 6.14, where three phases can be identified during the insertion process just like in the skin phantom experiment in Section 6.2. The only difference worth mentioning is that the second phase lasts for longer, which can be explained by the properties of porcine skin that are different from skin phantom and the larger thickness of porcine skin. As a result, the puncture force and the puncture depth were used as the indicators for needle performance. Low values of these two parameters were preferred.

![Force-position plot in porcine skin experiment](image)

Figure 6.14 An example force-position plot in the porcine skin experiment.
6.3.3 Experiment results and discussion

Figure 6.15 shows the results of puncture force and depth for the first needle set with the aforementioned needle-vibration combinations. Compared to the control insertion of N5...
with no vibration, the puncture force was reduced with applied vibration by 8.76% for the control needle N5, and by 12.0%, 25.3%, 38.8% and 8.3% for N1 to N4, respectively. The ANOVA F-test p-values for N1 to N5 were 0.001, 0.001, 0.001, 0.006 and 0.001, respectively. N3 had the lowest mean value of puncture force, and it was tested to be significantly lower than the puncture forces of other needles in this set.

Usually, a larger force is associated with larger deformation. However, the puncture depths of all the needle-vibration combinations in this needle set did not follow the same trend as puncture force. The observation here in the experiment may be due to possible weakening or reduction of elastic modulus of the porcine skin samples under vibration, where a smaller amount of force was required for the skin to deform to the same extend. Another possibility was the material property variation among the porcine skin samples, although careful experiment design was conducted as presented in Section 6.3.2. Moreover, the standard deviations for insertions with applied vibration tended to be greater than insertion without vibration, indicating the penetration was not as stable with applied vibration.
Figure 6.16 Simulated (a) X and (b) Z displacement of the first needle set at 20 kHz.

Figure 6.16 showed the simulated X and Z displacement of the needle tip with a base excitation of 10 \( \mu m \) at 20 kHz for the first needle set. As can be expected, the X displacement of N5 is basically zero. For N1 to N4, the X displacement changes between 14.1 \( \mu m \) and 121.2 \( \mu m \), while the Z displacement changes between 9.7 \( \mu m \) and 12.8 \( \mu m \), close to the excitation amplitude of 10 \( \mu m \).
By relating Figure 6.15 and Figure 6.16, it seems that a moderate amplitude of transverse vibration was helpful to further reduce the puncture force, as in the case of N2 and N3. The transverse displacement in N1 was relatively small than other needles with slots, so the resultant force reduction outcome was comparable to applying vibration directly to the control needle N5. This may be because the small amplitude couldn’t create an incision opening effectively in the porcine skin. While the transverse displacement was too larger, as in the case of N4, the increased transverse motion increased the transverse compressive force applied on the needle tip area, resulting higher resistant force. Moreover, the needle tip was not interacting with the porcine skin with its best perpendicular orientation. Both of these would increase the puncture force. For N2 and N3, their transverse displacements were 72.1 \( \mu m \) and 42.7 \( \mu m \), which laid between N1 and N2. Meanwhile, the axial vibration amplitude of N3 was more than 20% higher than that of N2, so its puncture force was the lowest in the needle set.
Figure 6.17 shows the results of puncture force and depth for the second needle set with the aforementioned needle-vibration combinations. Compared to the control insertion of N10 with no vibration, the puncture force was reduced with applied vibration by 12.2% for the control needle N10, and by 10.9%, 14.9%, 35.2% and 29.8% for N6 to N9, respectively. The ANOVA $F$-test $p$-values for N6 to N10 were 0.06, 0.15, 0.001, 0.001 and 0.001 respectively.
N8 had the lowest mean value of puncture force, and it was tested to be significantly lower than the puncture forces of other needles in this set except for N9, where the ANOVA F-test $p$-value was 0.19. As in the first needle set, the puncture depths of all the needle-vibration combinations in this needle set did not follow the same trend as puncture force.

Figure 6.18 Simulated (a) X and (b) Z displacement of the second needle set at 20 kHz.
Figure 6.18 shows the simulated X and Z direction displacement of the needle tip calculated in SolidWorks for the second needle set. Just as N5 in the first needle set, N10 has an X displacement or near zero and a Z displacement close to the excitation amplitude. For N6 to N9, the X displacement changes between 20.1 \( \mu m \) and 121.2 \( \mu m \), while the Z displacement changes between 7.3 \( \mu m \) and 11.7 \( \mu m \).

By comparing Figure 6.17 and 6.18, it can be found that the large transverse amplitude of N6 made its puncture force to be the largest among the needles with slots, even though its axial displacement was only smaller than that of N8. This is similar to the situation of N4 in the first needle set. For N7 and N9, their transverse displacements were 41.9 \( \mu m \) and 35.8 \( \mu m \), respectively, which were comparable. In this case, the larger axial amplitude enabled N9 to reduce the puncture force further. For the case of N8, its relatively small axial displacement of 22.1 \( \mu m \) was compensated by its axial amplitude of 11.7 \( \mu m \), which was much larger than that of N7 and N9. As a result, this needle had the smallest puncture force.

Based on the above analysis of the two needle sets, it seemed the transverse displacement had a decisive effect on the puncture force. A small transverse displacement could not generate effective transverse cutting, while an overly large transverse displacement would result in larger resistant force. When the transverse displacement amplitude was within a moderate range, e.g. 30 \( \mu m \) – 50 \( \mu m \) with an axial base excitation amplitude of 10 \( \mu m \) in
the porcine skin experiment, the puncture force was mainly affected by the axial displacement amplitude at the needle tip. A larger axial displacement would help in this case.

The experiment and harmonic analysis results above in Section 6.3 have been published in [77].

6.4 Summary

This chapter presented three sets of insertion experiments involving different testing materials and working frequencies.

In the candle gel experiment using a 40 kHz ultrasonic vibrator, $F_{\text{bump}}$ and $F_{\text{depth}}$ were used as the evaluation parameter for situation without and with applied vibration respectively. It was found that the slot could help to release the dragging force between needle and tissue, and a larger transverse vibration resulted in greater percentage of force reduction at the depth of $F_{\text{bump}}$.

In the polyurethane sheet experiment using a 40 kHz ultrasonic vibrator, the puncture force and friction force were used as the evaluation parameters. It was found that a larger transverse displacement tended to increase the resistance to penetration, resulting in a larger puncture force. After the sheet was finally penetrated, a larger puncture force was likely to leave a larger incision crack, resulting in lower friction force between tissue and needle shaft.
In the porcine skin experiment using a 20 kHz ultrasonic vibrator, the puncture force and depth were used as the evaluation parameters. The results showed significant reduction in puncture force after vibration was applied for all the needles, while the effects of vibration on puncture depth were not significant. Furthermore, some needle prototypes of the proposed design resulted in greater percentage of reduction than the control needle without slots. With the results from harmonic analysis, it was revealed that the transverse displacement seemed to have a decisive effect on the outcome of reduction, while the axial displacement was also important. A moderate transverse displacement range of 30 $\mu m$ – 50 $\mu m$ was found to result in lowest puncture force in the porcine skin experiment with an axial base excitation amplitude of 10 $\mu m$ at 20 kHz.

With the results obtained in this chapter, the expected advantages of vibratory needle insertion were validated. And, the feasibility and effectiveness of the proposed compliant needle design was clearly demonstrated.
CHAPTER 7 CONCLUSIONS, LIMITATIONS AND FUTURE WORKS

7.1 Conclusions

With the aim to reduce insertion force and improve insertion accuracy, a novel solid compliant needle has been proposed in this paper for vibratory needle insertion. The needle has a 4-bevel tip design, and two micro-slots perpendicular to the needle shaft are located on opposite of the shaft. These slots serve the purpose of transferring the axial vibration at the needle base into both axial and transverse vibration at the needle tip. As a result, the cutting edges can perform micro cutting in both axial and transverse direction, which is beneficial in reducing the axial insertion force.

To overcome the manufacturing challenge of the proposed needle design due to its small dimensions and relatively intricate geometry, a method has been proposed based on micro-EDM. A four-step procedure is used to process the four bevels using a block electrode, while a subsequent two-step procedure is carried out to process the two micro-slots with a foil electrode. An analytical model has been developed and validated for accurate calculation of slot depth and slot bottom profile based on the relative motions of foil electrode and needle. The EXPAN EDM control function after initial slot cutting has been found to result in relatively uniform slots with beneficial chamfers along the slot edges. The capability of the EDM-based method has been validated with fabricated needle prototypes with controlled geometric
parameters.

To investigate and validate the capability of the proposed compliant needle design, needle prototypes have been used to carry out insertion experiments with two types of actuators providing the axial vibration at the needle base. In the experiments with piezoelectric vibrator using tissue and skin phantom, three frequency-amplitude combinations were used to represent the low frequency – low amplitude, the low frequency – high amplitude, and the high frequency – low amplitude situation respectively. Friction slope was chosen as the evaluation parameter for the tissue phantom, while puncture force and depth were for the skin phantom. The results showed that the low frequency – high amplitude combination tended to result in the largest friction slope. This combination was also active in the skin phantom experiment as it led to either the largest or the lowest puncture force and depth for the needles. Overall, however, vibration didn’t seem to improve the parameters above in the experiments, and the needle prototypes didn’t seem to perform better than the control without slots.

In the insertion experiments using an ultrasonic vibrator, a total of three types of materials and two ultrasonic frequencies have been tested. In the candle gel experiment at 40 kHz, $F_{\text{bump}}$ and $F_{\text{depth}}$ were used as the evaluation parameter for situation without and with applied vibration respectively. It was found that the slot could help to release the dragging force between needle and tissue, and a larger transverse vibration resulted in greater percentage
of force reduction at the depth of $F_{\text{bump}}$. In the polyurethane sheet experiment at 40 kHz, the puncture force and friction force were used as the evaluation parameters. It was found that a larger transverse displacement tended to increase the resistance to penetration, resulting in a larger puncture force. After the sheet was finally penetrated, a larger puncture force was likely to leave a larger incision crack, resulting in lower friction force between tissue and needle shaft.

In the porcine skin experiment at 20 kHz, the puncture force and depth were used as the evaluation parameters. The results showed significant reduction in puncture force after vibration was applied for all the needles, while the effects of vibration on puncture depth were not significant. Furthermore, some needle prototypes of the proposed design resulted in greater percentage of reduction than the control needle without slots. With the results from harmonic analysis, it was revealed that the transverse displacement seemed to have a decisive effect on the outcome of reduction, while the axial displacement was also important. A moderate transverse displacement range of 30 $\mu m$ – 50 $\mu m$ was found to result in lowest puncture force in the porcine skin experiment with an axial base excitation amplitude of 10 $\mu m$ at 20 kHz.

While the expected advantages of vibratory needle insertion have been well presented, the capability of the proposed needle design has also been demonstrated. The proposed method, the new manufacturing technique, and the practical guidelines can be used for future
development of new compliance surgical needles for engineering and bio-medical applications.

7.2 Limitations

Despite of the capability of the proposed compliant needle design demonstrated in experiments, some limitations regarding this research are worth mentioning as follows.

1. As mentioned in Chapter 3, the needles were currently fabricated solely using EDM for ease of slot alignment after the bevels were cut, while the bevels in commercial needles are usually fabricated using burr-free grinding. This is limited by the machines and equipment we have.

![Fabrication uncertainty of needle tip](image)

**Figure 7.1.** Fabrication uncertainty of needle tip: (a) a blunt tip and (b) a sharp tip.

An observed drawback in the EDM was that repeatability was not always dependable, especially for the bevel tip. Figure 7.1 shows the microscopic pictures of the needle tips of two
needles with identical EDM variables. It is clear that the needle on the left had a much larger tip radius than the right one. Although needles with over-sized radius were discarded from experiments, such fabrication inconsistency may account for the diverse puncture force results of different needles when inserted without vibration. Grinding is planned to be used to process the bevels by developing adequate equipment to transfer the needles from a grinding machine to an EDM machine in the future.

2. The modal analysis and harmonic analysis in Chapter 5 estimated the vibration displacements of the needle in the air. It may still be accurate enough for insertion into thin tissues like porcine skin. As the needle advances deep into the tissue and the damping effect increases, the vibration pattern could be totally different. This calls for a more comprehensive stepwise simulation for both in-air and in-tissue situation.

7.3 Future works

To better explore the potential of proposed needle design, efforts will be spent on the following aspects.

1. Needle tip cutting modeling. As reviewed in Chapter 2, the underlying insertion mechanism between the tissue and a vibrating needle has not yet been fully understood. It would be of great value to know how a vibrating needle tip punctures in the axial direction and
cuts in the transverse direction. This can begin with the modeling on the motions of needle tip in the axial and transverse direction, based on which the cutting rate of tissue and average cutting velocity can be calculated. Ref. [49] and [37] will be helpful on such modeling. Additionally, material properties, such as Young’s modulus, fracture toughness and shear module, should be considered, which will be helpful for identifying optimized needle design for different insertion applications.

![Curved path](image)

Figure 7.2. Asymmetrical transverse vibration.

2. Needle deflection during insertion. At the current stage, we only focused on the puncture force and depth of the proposed needle design. Given the slots are not symmetrical along the needle shaft, the transverse vibration of the needle tip is not likely to be equal on both sides. As a result, the transverse tissue cutting will be more significant on one side than the other, which may force the needle to deflect during insertion to the side with more tissue cutting. While this sounds to be undesirable, it can be taken advantage for needle steering. By adjusting the vibration frequency and amplitude, the ratio of tissue cutting on both sides can
be changed. The curvature of needle deflection may therefore be controlled. For validation purpose, a simplified needle with only one slot will be tested as the first step as shown in Figure 7.2. Currently, a maximum of two slots are considered. It remains to be seen whether more slots ($\geq 3$) can result in better performance. Asymmetrical distribution of different numbers of slots on opposite sides of the needle shaft is also worth trying.

3. Optimization of cutting angels for better insertion. In Chapter 3, the inclination angle and included angle of a main cutting edge were calculated along the insertion direction with the EDM variables (bevel angle $\varphi$ and interval angle $\beta$). It should be noticed that the equations presented were for the axial cutting, and these angles are different for transverse cutting. Actually, there is a trade-off for these angles in the axial and the transverse direction. For example, a larger inclination angle in the axial direction will result in a smaller transverse one. It will be beneficial to model the cutting in both directions to determine suitable EDM variables. Meanwhile, the ratio of axial and transverse vibration can be altered by changing $D_1$ and $D_2$, as presented in Chapter 5. These two steps together will open up the opportunity to optimize the needle performance.

4. Other possible new needle geometric design. The two slots on the needle shaft aim to partially transfer the translational vibration into transverse vibration, and they are currently at least 5 mm away from the tip. In other words, they don’t intersect with the four bevels or the
cutting edges. While this design worked quite well in the porcine skin experiment, it may not work as well when inserted deep into tissues. The circle needle shaft surface can’t perform cutting, so the transverse vibration of the needle section between the tip and slots are likely to be dissipated by the tissue on both sides. A modified design is to move the slots to the main cutting edges as shown in Figure 7.3. The edges should be better at cutting than the shaft itself. However, this design imposes a greater challenge for the fabrication process. Moreover, whether the mass of the new transverse vibration section is sufficient for effective cutting needs to be tested with experiments.

Figure 7.3 Modified design with slots on the cutting edges.
YI CAI’s PUBLICATIONS

Referred journal papers:

Referred conference proceedings:

REFERENCES


[74] E. Li, Z. C. He, and X. Xu, "An edge-based smoothed tetrahedron finite element method (ES-

