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Optimal needle design for minimal insertion force and bevel length

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ABSTRACT

This research presents a methodology for optimal design of the needle geometry to minimize the insertion force and bevel length based on mathematical models of cutting edge inclination and rake angles and the insertion force. In brachytherapy, the needle with lower insertion force typically is easier for guidance and has less deflection. In this study, the needle with lancet point (denoted as lancet needle) is applied to demonstrate the model-based optimization for needle design. Mathematical models to calculate the bevel length and inclination and rake angles for lancet needle are presented. A needle insertion force model is developed to predict the insertion force for lancet needle. The genetic algorithm is utilized to optimize the needle geometry for two cases. One is to minimize the needle insertion force. Using the geometry of a commercial lancet needle as the baseline, the optimized needle has 11% lower insertion force with the same bevel length. The other case is to minimize the bevel length under the same needle insertion force. The optimized design can reduce the bevel length by 46%. Both optimized needle designs were validated experimentally in ex vivo porcine liver needle insertion tests and demonstrated the methodology of the model-based optimal needle design.

1. Introduction

Needles are one of the most commonly used medical devices for a wide variety of medical procedures [1]. Currently, needle tips come in a wide variety of configurations for specific medical procedures [1,2]. The needle with lancet point (denoted as lancet needle), invented by Huber in 1946 [3], is the most commonly utilized needle tip for biopsy [4], vessel access [5], brachytherapy [6] and other procedures involved needle insertion. The lancet needle and other needles are usually tested and improved via trial-and-error in clinical practices. The needle insertion into soft tissue is a tissue cutting process. Effective cutting of soft tissue depends on the cutting edge geometry of needle tip [7–9]. To quantitatively predict the needle insertion force, we have developed mathematical models of needle cutting edge inclination and rake angles [10,11], studied their effects on needle insertion force into soft tissue [12] and the grinding procedures to generate lancet needle [13,14]. Based on this foundation, the model-based optimal needle design to minimize the insertion force or bevel length (the length of the bevel tip in the needle axis direction, as defined in [1]) is explored in this study.

The insertion force and bevel length are two key criteria to evaluate the performance of a needle tip. Lower insertion force generates less tissue deformation and needle deflection during needle insertion (e.g., in the prostate brachytherapy procedure [15]), and is more accurate in guidance for clinicians who perform the procedure and less painful [16] and traumatic for patients [17–19]. Also, shorter bevel length is preferred, especially in procedures for vessel access. Reducing the bevel angle will sharpen the lancet needle and reduce the insertion force; but it will also increase the bevel length and make the lancet needle more difficult to completely insert into the vessel. The optimal design of lancet needle can minimize the insertion force, bevel length, or the combination of both.

Along the needle cutting edge, the inclination angle λ and rake angle α have demonstrated to be important for the needle insertion force [10,11]. To define the λ and α on the lancet needle cutting edge (marked as the red line), as shown in Fig. 1(a). Four vectors $\boldsymbol{s}$, $\boldsymbol{v}$, $\boldsymbol{n}$, and $\boldsymbol{c}$, are defined at a point A on the needle cutting edge: $\boldsymbol{s}$ is tangent to the cutting edge, $\boldsymbol{v}$ is along the cutting direction, $\boldsymbol{n}$ is normal to the cutting face (A_γ), and $\boldsymbol{c}$ is the projection of vector $\boldsymbol{s}$ in plane P_r. Plane P_r is normal to the cutting direction and has a normal vector of $\boldsymbol{v}$. The λ is defined as the angle between vectors $\boldsymbol{s}$ and $\boldsymbol{c}$. The α is defined as the angle between two vectors $\boldsymbol{a}$ and $\boldsymbol{b}$, where $\boldsymbol{a}$ is the intersection between planes P_n and A_γ and $\boldsymbol{b}$ is the intersection

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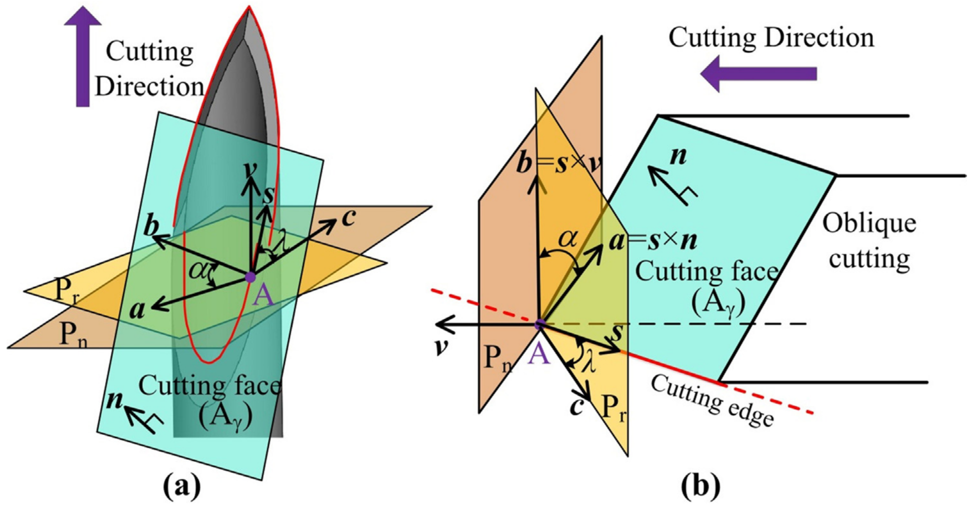

Fig. 1. Definitions λ and α at a point A on a (a) oblique cutting edge and (b) lancet needle cutting edge. (For interpretation of the references to color in text, the reader is referred to the web version of the article.)

of planes P_n and P_r. Plane P_n is normal to the cutting edge and has a normal vector of $\boldsymbol{s}$. Each cutting point on the lancet needle cutting edge can be considered as an oblique cutting configuration, as shown in Fig. 1(b).

Mathematical models of λ and α for lancet needle have been derived [13,14]. To predict the initial peak needle insertion force based on λ and α, Moore et al. [20,21] utilized the mechanistic approach based on the concept of elementary cutting tool (ECT). In this model, the insertion force per unit width, called the specific insertion force, on an ECT is determined using the ECT's λ and α and a specific cutting force database, which is based on the insertion force measured using 16 blades with various λ and α [21]. The initial peak needle insertion force is the sum of the insertion force of all ECTs along the needle cutting and leading edges. This study utilizes this model as the foundation to develop a more accurate force model for lancet needle and its optimal design.

In this paper, the geometrical definition and mathematical models of λ and α, bevel length, and needle insertion force model for lancet needle are presented. The design parameters, constraints, and objective functions for optimization are defined. The optimal design of two lancet needles, one with the minimal insertion force and another with the minimal bevel length, are conducted. Effects of lancet needle design parameters on insertion force and bevel length and the optimization results and experimental validation are discussed.

2. Lancet needle geometry

As shown in Fig. 2(a), the geometry of a lancet needle is determined by six parameters: bevel angle (ξ), secondary bevel angle (φ), angle of rotation (β), grinding wheel offset distance (l), and needle tube outer and inner radius (r_o and r_i) [13,14]. The lancet needle tip is fabricated using the four-step grinding procedure, as summarized in Appendix A. The ξ, φ, and β are three parameters in lancet needle grinding and define the lancet needle cutting edge geometry, and also utilized in the optimization of needle performance. The lancets divide the lancet needle tip into two sections. Section 1 includes two lancets (with normal vectors marked as $\boldsymbol{n_1}$ and $\boldsymbol{n_2}$ in Fig. 2(a)) in the needle tip. Section 2 is the remaining bias bevel plane. The cutting edges on Sections 1 and 2 are marked by green and blue lines in Fig. 2, respectively.

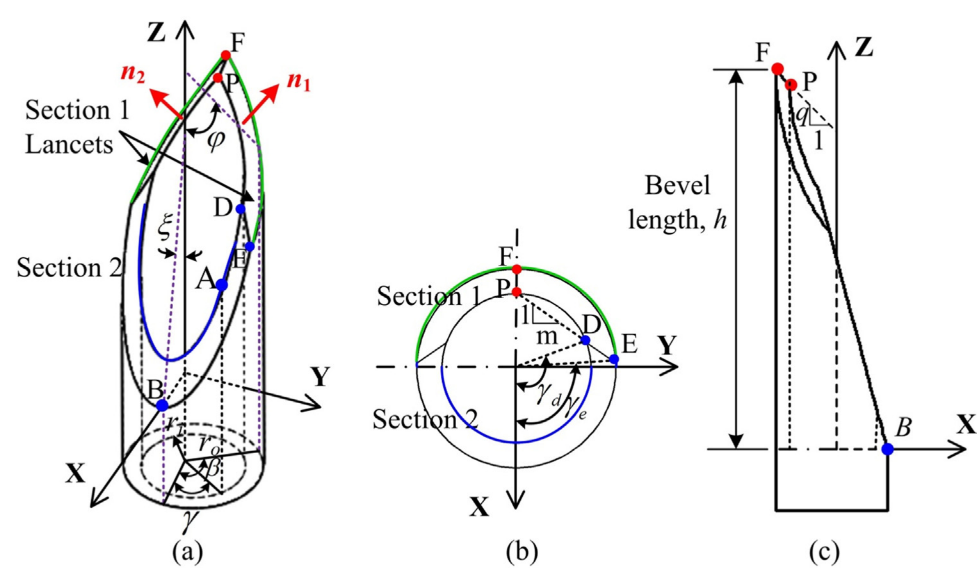

Fig. 2. Lancet needle tip and key parameters to define the geometry: (a) side view, (b) top view, and (c) left view. (For interpretation of the references to color in text, the reader is referred to the web version of the article.)