Review of the Needle Cutting Edge and Geometry

In Design and Manufacturing Course

2021/12/6

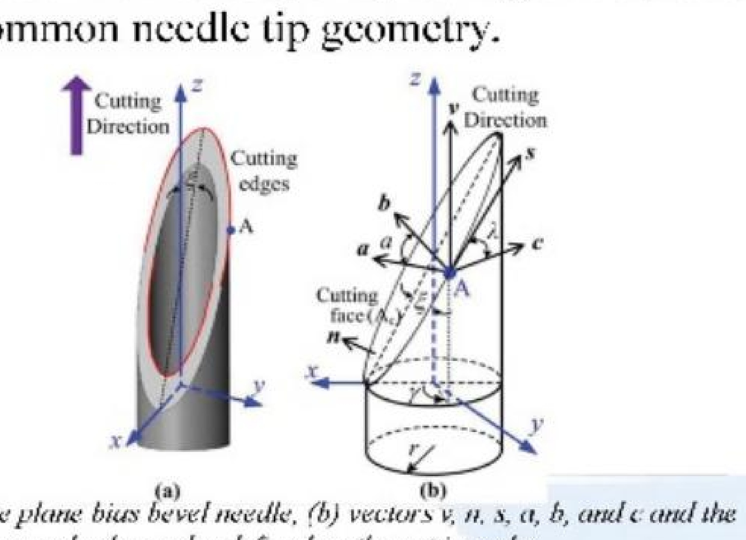
Introduction

- Needles are commonly utilized for minimally invasive intravascular or organ access to extract fluids or tissue samples for diagnosis delivery of drugs or placement of radioactive seeds for treatment.
- The understanding of tissue cutting mechanics enables better design. This research lays the foundation for developments of biomedical device and improvements of healthcare procedures.
- Mathematical models to calculate **the inclination and rake angles of the cutting edge of needles** will be introduced.
- **The relationship between the needle's tip geometry and insertion force** was established
- The cutting edge of the lancet needle can be optimally designed to **minimize insertion force or bevel length.**

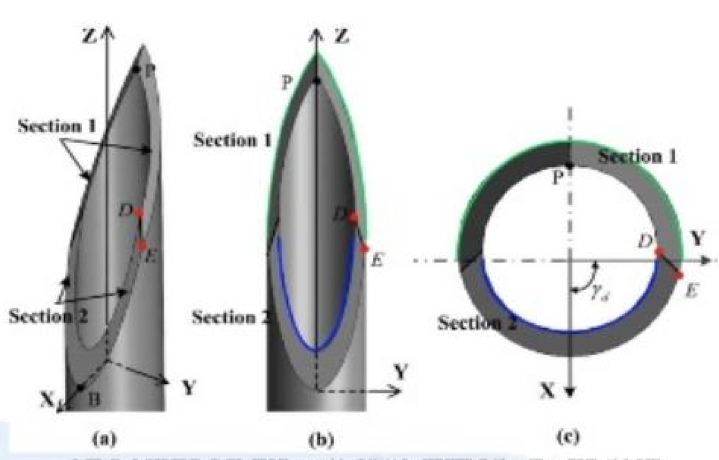
Needle Cutting Edge Geometry

➢ NLP

The needle with lancet point, having three planes at the tip to generate a sharp lancet point, is the most common needle tip geometry.



(a) Single plane bias bevel needle, (b) vectors v, n, s, a, b, and c and the inclination and rake angles defined on the cutting edge.



NLP NEEDLE TIP: (A) ISOMETRIC, (B) FRONT, AND (C) TOP VIEWS.

The inclination angle λ is defined as the angle between vectors **s** and **c**,

$$\lambda = \arccos\frac{\boldsymbol{s}\cdot\boldsymbol{c}}{|\boldsymbol{s}\cdot\boldsymbol{c}|} = \arccos\frac{1}{\sqrt{1+\cot^2\xi\sin^2\gamma}}$$

The rake angle α is defined as the angle between vectors **a** and **b**,

$$\alpha = \arccos\frac{\boldsymbol{s}\cdot\boldsymbol{c}}{|\boldsymbol{s}\cdot\boldsymbol{c}|} = \arccos\sqrt{\sin^2\xi\cos^2\gamma+\sin^2\gamma}$$

- $0 \le \lambda \le 90° - \xi, 0 \le \alpha \le 90° - \xi$
- $\lambda = 0°$, which is the worst cutting configuration for needle tissue cutting. Increasing λ at this point by grinding a sharp lancet point or using the multi-plane needle can improve tissue cutting efficiency.

➢ FLN-B

In section 2 and 3,

$$\lambda = \arccos\frac{1}{\sqrt{1+\cot^2\phi\sin^2(\gamma\pm\beta)}}$$

$$\alpha == \arccos\sqrt{\sin^2\phi\cos^2(\gamma\pm\beta)+\sin^2(\gamma\pm\beta)}$$

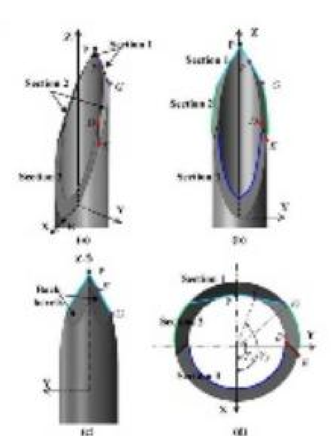
➢ FLN-F

In section 2 and 3,

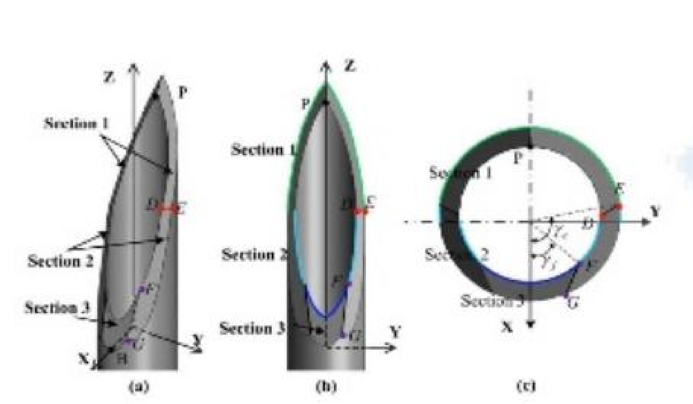
$$\lambda = \arccos\frac{1}{\sqrt{1+\cot^2\delta\sin^2(\gamma\pm\eta)}}$$

$$\alpha = \arccos\sqrt{\sin^2\xi\cos^2(\gamma\pm\eta+\pi)+\sin^2(\gamma\pm\eta+\pi)}$$

- Overall, FLN-B and FLN-F tips have **higher inclination and rake angles** than that of NLP.
- FLN-B and FLN-F needles have a much **lower initial peak needle insertion force** and **shorter deformation phase** to rupture the tissue bonds and initiate tissue cutting over regular lancet needles.



FLN-B NEEDLE TIP: (A) ISOMETRIC, (B) FRONT, (C) BACK, AND (D) TOP VIEWS.

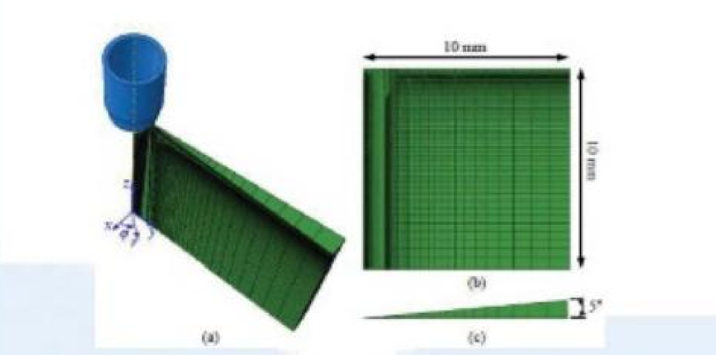


FLN-F NEEDLE TIP: (A) ISOMETRIC, (B) FRONT, AND (C) TOP VIEWS.

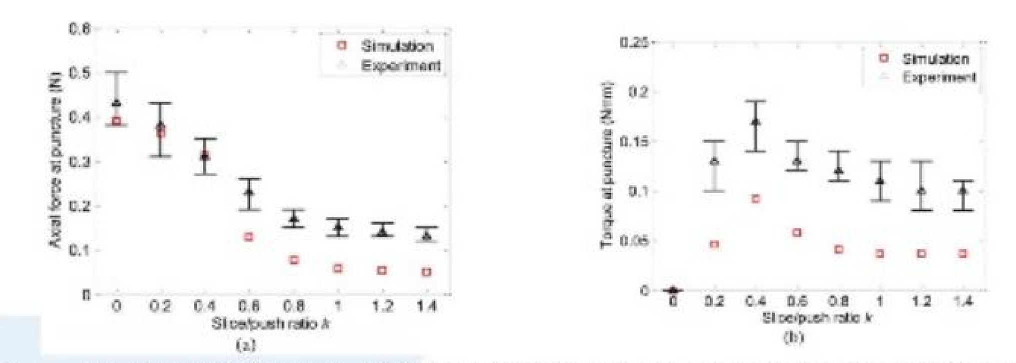
Needle insertion force

➢ The Slice/Push Ratio(k)

- **The slicing motion** significantly reduces the forces required to initiate cutting
- **The initial cutting forces depend on the slice/push ratio.**
- The effect of k is nonlinear.

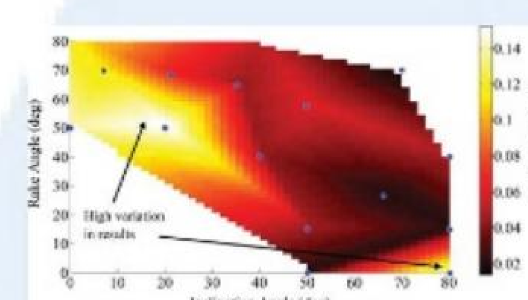


(a) FEM modeling of needle insertion, (b) mesh in the r-z plane and (c) mesh in the r-ϕ plane

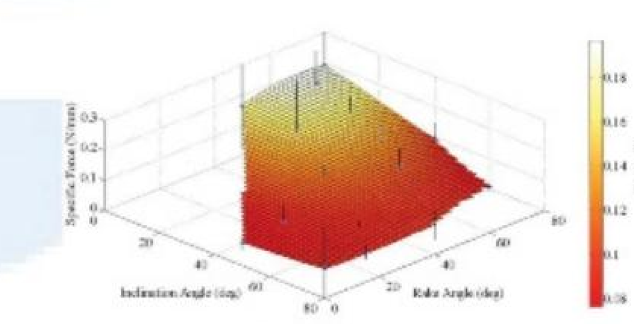


Initial cutting forces as a function of slice/push ratio: (a) axial force and (b) torque at puncture (friction coefficient = 0.3)

➢ Initial cutting - The inclination angle effect



Specific force f (λ,α) model based on blade cutting results



Standard deviation of the specific force

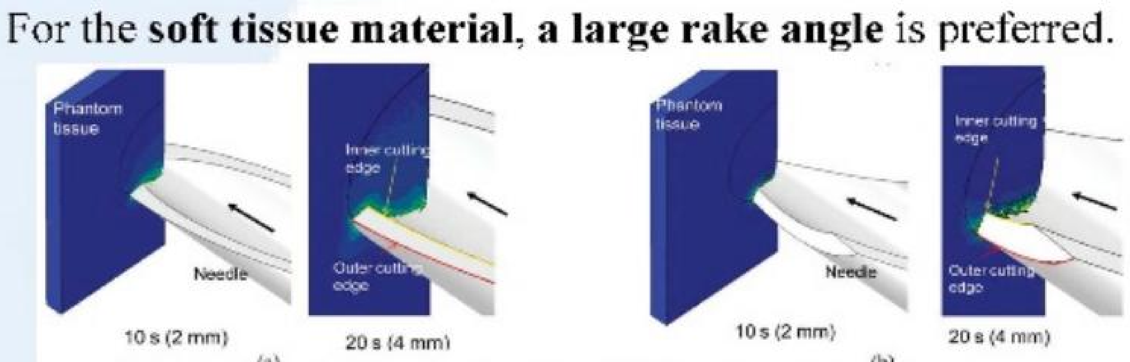
A 3rd-order multivariable (λ and α) best fit polynomial of the data from the blade cutting results:

$$f = -0.042+0.296\lambda+0.298\alpha-0.255\lambda^2-0.408\lambda\alpha-0.011\alpha^2+0.083\lambda^3+0.118\lambda^2\alpha+0.080\lambda\alpha^2-0.059\alpha^3$$

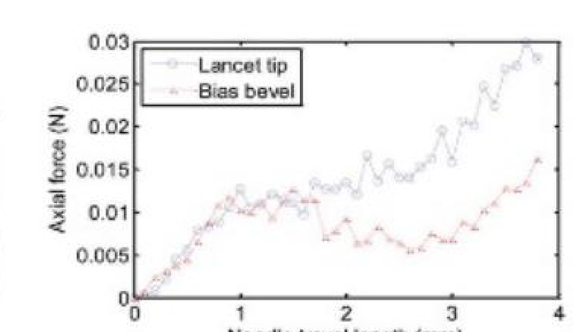
- **High λ could lower the needle insertion force.**

➢ Steady-state cutting—The rake angle effect

- For the **continuous cutting phase, the rake angle is hypothesized to be more important than the inclination angle** on the cutting force.
- **A large rake angle yields smaller cutting forces** (sharp and easier to cut), while a small or negative rake angle generates larger cutting forces.
- For the **soft tissue material**, **a large rake angle** is preferred.



FEM results for (a) bias bevel needle and (b) lancet tip needle at 2mm and 4mm(close-up view) insertion depth



FEM cutting forces for lancet tip and bias bevel needle

➢ Oblique cutting flow angle for tissue

- Differs from **Stabler's rule.**
- In soft tissue cutting, the overall needle geometry, which includes **both inclination and rake angles**, rather than only the inclination angle, dictates the tissue **flow direction** that is along the needle face and in the plane of the needle direction.

Application——Optimal lancet needle design and manufacturing

➢ Needle design optimization

The objective function is

$$\min_{x=\xi,\phi,\text{and}\beta} O(x) = C_F F + C_h h$$

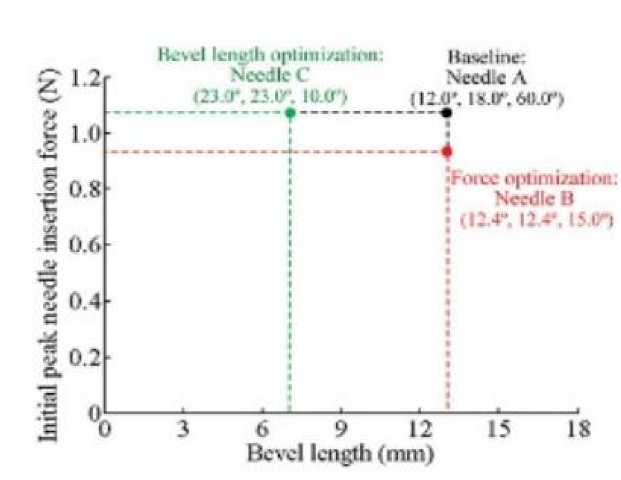
The optimization was conducted using the exhaustive search method and genetic algorithm (GA) in MATLAB Toolbox.

➢ Initial needle insertion force vs. bevel length

- **Lower insertion force generates less tissue deformation and needle deflection**
- **short bevel length is preferred especially in procedures for vessel access.**

➢ Future work

Using the experimental validation to determine **the initial peak needle insertion force corresponds exactly where in the needle** (either the tip point or the transition between the lancet to bias bevel cutting edge) during needle insertion will be conducted in the future work.



Optimized and baseline NLPs Initial needle insertion force vs. bevel length

Needles		Angles	Bevel length (mm)	Model-predicted needle insertion force (N)*
Needle A		$\xi = 12.0°$ $\varphi = 18.0°$ $\beta = 60.0°$	13.30	1.06
Needle B		$\xi = 12.4°$ $\varphi = 12.4°$ $\beta = 15.0°$	13.30	0.94
Needle C		$\xi = 23.0°$ $\varphi = 23.0°$ $\beta = 10.0°$	7.17	1.06

*Assuming $\theta = 360°$.

(a)

Needles		Angles	Bevel length (mm)	Angle of contact area, θ	Initial peak insertion force, F_N		
					Measured (N)	Predicted (N)	Discrepancy
Needle A		$\xi = 12°$ $\varphi = 18°$ $\beta = 60°$	13.30	287.9°	0.94	0.89	5.6%
Needle B		$\xi = 12°$ $\varphi = 12°$ $\beta = 15°$	14.29	216.2°	0.81	0.78	3.7%
Needle C		$\xi = 23°$ $\varphi = 23°$ $\beta = 10°$	7.17	360.0°	1.02	1.06	3.9%

(b)

Optimal designed and manufactured lancet needles: (a) optimized and (b) manufactured lancet needles

References

[1] Wang, Y. , Chen, R. K. , Tai, B. L. , & Shih, A. J. . (2014). Advanced Five-Plane Lancet Needle Design, Grinding, and Tissue Insertion. ASME 2014 International Manufacturing Science and Engineering Conference collocated with the JSME 2014 International Conference on Materials and Processing and the 42nd North American Manufacturing Research Conference.

[2] [1] Wang, Y. , Li, W. , Han, P. , Giovannini, M. , Ehmann, K. , & Shih, A. J. . (2016). Contributions in medical needle technologies—geometry, mechanics, design, and manufacturing. Machining Science & Technology, 20(1), 1-43.

[3] Wang, Y. , Chen, R. K. , Tai, B. L. , Mclaughlin, P. W. , & Shih, A. J. . (2014). Optimal needle design for minimal insertion force and bevel length. Medical Engineering & Physics, 36(9), 1093-1100.