Steerable Needles: A Better Turning Radius with Less Tissue Damage

VANDERBILT UNIVERSITY CTTC Center for Technology Transfer & Commercialization

Summary

A team of Vanderbilt engineers and surgeons have developed a new steerable needle that can make needle based biopsy and therapy delivery more accurate. A novel flexure-based tip design provides enhanced steerability while simultaneously minimizing tissue damage. The present device is useful for almost any needle-based procedure including biopsy, thermal ablation, brachytherapy, and drug delivery.

Addressed Clinical Need

Millions of procedures are performed every year with needles that includes biopsy, thermal ablation, brachytherapy, and drug delivery, among others. As an example, it is estimated that annually there are 1.6 million breast biopsies in United States and 1 million prostate biopsies worldwide. Efficacy of these needle-based procedures is often compromised due to needle placement inaccuracy, tissue deformation, registration error, and (in the case of hand-held needles), the surgeon's hand-eye coordination. Additionally, there are instances where anatomical constraints prevent a straight-line path to the surgical site (e.g. deep brain stimulation, where certain targets can be obstructed by eloquent brain tissue and transperineal prostate brachytherapy, where the pubic arch can sometimes obstruct a portion of the prostate). The potential to address both accuracy enhancement and obstacle avoidance has lead to a growing interest in steerable needles in interventional medicine.

Challenges with Current Steerable Needle Designs

Current steerable needle designs with standard bevel tips achieve only small needle deflection. To address this, many today are using kinked bevel tips to achieve higher curvature and thus better steerability. This induces tissue damage (Figure 3), since real-time adjustment of the curvature during insertion requires interspersing short periods of rapid axial rotation with short periods of a fixed axial insertion (known as "duty cycling").

Technology Description

In this new design, a novel flexure-based needle tip provides the enhanced steerability characteristic of kinked bevel-tip needles, while simultaneously minimizing tissue damage by allowing the tip to straighten during axial rotation. This new flexure-tip needle is thus able to provide high steerability with less tissue damage. The flexure-tip needle consists of three parts: a flexible straight needle shaft, a beveled tip, and a flexure joint.

During insertion into Figure 1 tissue, the bevel tip produces a transverse load which causes the needle to bend at the flexure (as shown in Figure 1) and behave like a kinked beveltip needle. However, during pure rotation, the flexure enables the needle to stay in place while spinning to reorient the bevel, without tearing through tissue.

Figure 2 depicts C o m p a r a b l e Curvatures achieved by Flexure-tip needle and kinked bevel-tip needle.

In gelatin phantom experiments, a kinked tip needle cuts a helical path (indicating higher tissue damage) while

the flexure tip needle leads to a low damage path similar to a standard clinical needle. Figure 3 is an illustration of this comparison.

Development and Intellectual Property Status

- » Working prototypes have been built and are undergoing further testing and refinement.
- » Patent Application has been filed
- » Published paper <u>IEEE Transactions on Biomedical</u> <u>Engineering Vol. 60, No. 4, April 2013</u>
- » Lab home Page with list of publications and ongoing research portfolio: <u>http://research.vuse.vanderbilt.</u> <u>edu/MEDLab/index.htm</u>

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Link to Vanderbilt technologies

available for licensing

Flexure Tip

