

# Curving Clinical Biopsy Needles: Can We Steer Needles and Still Obtain Core Biopsy Samples?

Patrick S Wellborn  
Philip J Swaney  
Robert J Webster III

Department of Mechanical Engineering, Vanderbilt  
University, Nashville, TN

## I. Background

Needle-based procedures such as biopsy, thermal ablation, brachytherapy, and drug delivery, provide a minimally invasive means for diagnosis or treatment. The success of the procedure relies on the needle reaching the physician's desired target (typically identified on a medical image) accurately. However, due to tissue deformation and the accuracy limits of human hand-eye coordination, the needle may go off course. To aid in targeting, steerable needles have been developed (see e.g. [5,6,8]). They offer the possibility of controllably deflecting the needle during insertion to enhance final tip accuracy, while also providing a means for obstacle avoidance (see [1] for a review).

Harnessing the bending forces that arise during insertion of a bevel tipped needle is one popular way to steer needles (see e.g. [2,5]). A fixed bend or "kinked tip" has also been employed to amplify steering [3,7]. While the kinked tip provides high curvature, when it is axially rotated (which must be done continuously to achieve a straight path), the tip cuts a locally helical track through tissue [4]. Recently, a new needle tip design that utilizes a flexure located between the needle shaft and bevel tip has been shown to provide high curvature with reduced tissue damage [4]. While the flexure-tip needle has been tested on the benchtop to evaluate curvature and tissue damage, it has yet to be incorporated into a device with either a diagnostic or interventional clinical payload. Indeed, nearly all bevel tip steerable needle research to date, regardless of tip design, has left the incorporation of diagnostic or interventional tooling to future work.

In this paper we describe a new device that incorporates flexure-tip steering into an FDA approved commercial core biopsy needle, the Quick-Core from Cook Medical, USA. In addition to the use of a flexure-tip, we investigate modification of the outer sheath of the biopsy needle to amplify steering. We show that the augmented Quick-Core can achieve appreciable curvature in tissue. We also show that the flexure-tip does not interfere with the needle's ability to collect core biopsy samples. This work illustrates the potential of the flexure-tip to augment current clinical needles, and demonstrates for the first time the delivery of a diagnostic payload in a hand-held bevel tipped steerable needle device.

## II. Methods

Our modified Quick-Core biopsy needle (Fig. 1) uses an outer sheath with a cutting edge on the tip of the sheath. An inner stylet with a cutout tray (shown in Fig. 4 with a biopsy

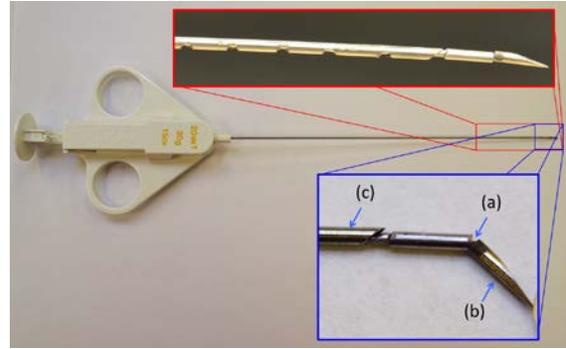


Fig. 1. Flexure-tip incorporated into the Quick-Core biopsy tool. The bottom right inset shows a close-up of the flexure-tip with (a) the flexure point, (b) the beveled tip, and (c) the nitinol sheath. The top right inset shows a close-up of the notched wall nitinol sheath designed for increased curvature within soft tissue.

sample in it) extends from this sheath when a core biopsy is to be taken, and the outer sheath uses a spring-based mechanism to fire rapidly over the stylet, cutting tissue and depositing it onto the tray in the process. We attached a flexure-tip to the end of the inner stylet and replaced the outer sheath with a superelastic nitinol sheath, decreasing the overall bending stiffness of the device. We further reduced the bending stiffness of the device by notching the nitinol sheath every 5-mm along its length (see Fig. 1). Both the solid wall and notched wall nitinol sheath designs were tested. The flexure needle tip design consists of three parts: (1) a beveled tip, (2) a flexure joint, and (3) the nitinol sheath. The beveled tip itself is 4 mm long and has approximately the same outer diameter of 0.91-mm as the stylet, and has a  $10^\circ$  bevel angle. The flexure joint, which connects the beveled tip section to the needle shaft, consists of three 0.125-mm nitinol wires lined up side by side and centered in the tip section (see [3] for additional details on the flexure-tip design). The gap between the beveled tip and the needle shaft is approximately 0.2-mm, allowing the flexure joint to bend to a maximum angle of  $47^\circ$ .

Upon insertion into soft tissue, the bevel tip creates forces that act on the needle tip, producing a bend at the flexure joint. This enables the needle to curve through the tissue, and by controlling the axial angle of the bevel, the needle can be steered in a controllable manner. In order to determine whether we could achieve appreciable curvature, we inserted the new needle into a 10% by weight Knox Gelatin (Kraft Foods Global Inc., IL) phantom, which allowed us to observe the needle path (see Fig. 3). Finally, we replaced the gelatin phantom with ex vivo liver tissue to observe if we could attain a substantial needle curvature without interfering with core biopsy collection.

## III. Results

The addition of the flexure-tip and nitinol sheath to the Quick-Core biopsy device resulted in significant steering of the needle shaft when inserted into the gelatin phantom. Quantifying the needle curvature, the ratio of the width over the height of the needle path is 64.3% with the solid wall nitinol sheath and 109.9% with the notched wall nitinol sheath

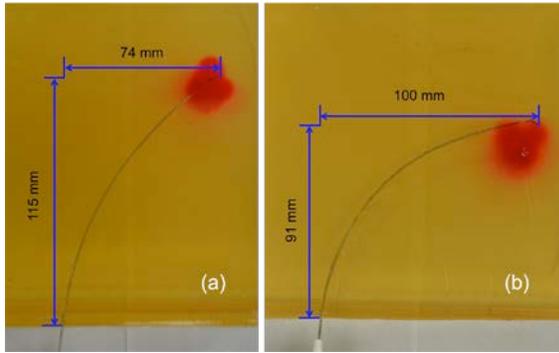


Fig. 2. Needle curvature achieved in gelatin with the core biopsy tool outfitted with a flexure tip and (a) a solid wall nitinol sheath and (b) a notched wall nitinol needle sheath. This steerability will enable physicians to steer the needle during insertion to correct for alignment errors and tissue deformation.

(see Fig. 2). This shows the steerability the needle can provide, which the physician can use to correct for targeting errors during insertion and/or to steer around critical structures. Note that the needle shaft returned to its normal straight shape after removal from the phantom and no plastic deformation was caused during insertion.

Next, to demonstrate that the flexure-tip does not interfere with biopsy collection, we performed an ex vivo bovine liver tissue experiment (Fig. 3). Again, more curvature was achieved by the combination of the flexure-tip and notched wall nitinol sheath (height to width ratio of needle path was 14.8% with the solid wall nitinol sheath compared to 20.5% with the notched wall nitinol sheath). Even while curved in the ex vivo liver tissue, we were still able to fire the core biopsy tool to obtain a core tissue sample (see Fig. 4).

#### IV. Interpretation

Our experiments in the gelatin phantom and liver tissue show that incorporation of the flexure-tip design and nitinol sheaths into an existing clinical biopsy needle enable steering without interfering with core biopsy sample collection. This device is the first bevel steered needle to incorporate a diagnostic payload.

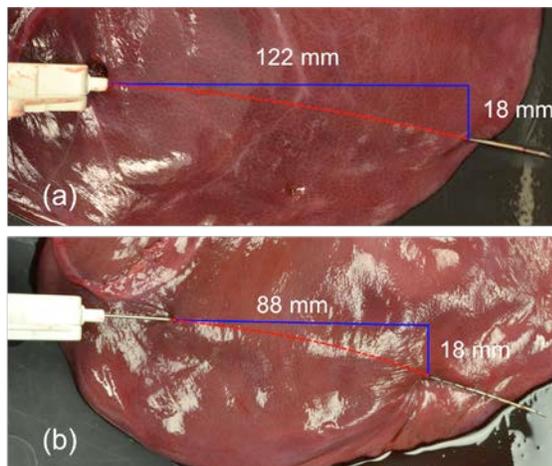


Fig. 3. Insertion into ex vivo bovine liver of core biopsy tool outfitted with a flexure tip and (a) a solid wall nitinol sheath and (b) a notched wall nitinol needle sheath (Fig. 1). We were able to collect the biopsy sample shown in Fig. 4 while the needle was curved.

In future work, we intend to characterize the maximum curvature which the needle can attain and still successfully collect tissue samples. Additionally, the flexure-tip itself provides multiple parameters that can be tuned to optimize



Fig. 4. The liver sample shown in the tray at the tip of the needle, with the sheath retracted. This illustrates that the needle can still perform a core biopsy when curved as illustrated in Fig 3.

steering. These include the bevel angle, the maximum flexure bend angle, and the distance behind the needle tip where the flexure is located.

Providing interventional radiologists with the ability to steer tools may ultimately lead to more accurate biopsies and enable less invasive biopsy paths, benefitting patients. The results described in this paper are a first step toward providing steering in a hand-held, low cost, disposable package.

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