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A Flexure-Based Steerable Needle: High Curvature With Reduced Tissue Damage

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Abstract

In the quest to design higher curvature bevel-steered needles, kinked bevel-tips have been one of the most successful approaches yet proposed. However, the price to be paid for enhancing steerability in this way has been increased tissue damage, since the prebent tip cuts a local helical path into tissue when axially rotated. This is problematic when closed-loop control is desired, because the controller will typically require the needle to rotate rapidly, and it is particularly problematic when duty cycling (i.e., continual needle spinning) is used to adjust curvature. In this paper, we propose a new flexure-based needle tip design that provides the enhanced steerability of kinked bevel-tip needles, while simultaneously minimizing tissue damage.

Index Terms

Duty cycling; flexure; image-guided surgery; medical robotics; needle design; steerable needle

I. Introduction

Needles are one of the least invasive tools available to reach sites requiring diagnoses or interventions in the human body. Many different procedures can be performed with needles including biopsy, thermal ablation (using either heat or cold), brachytherapy, and drug delivery, among others [1]. The efficacy of these needle-based procedures typically relies heavily upon the accuracy with which the needle tip reaches the desired location specified by the physician on medical images. However, there are numerous factors that contribute to needle placement inaccuracy, including tissue deformation, registration error, and (in the case of hand-held needles), the surgeon’s hand–eye coordination. There are also situations where a straight-line path to the surgical site is not possible because of anatomical constraints. Examples include deep brain stimulation, where certain targets can be obstructed by eloquent brain tissue [2], and transperineal prostate brachytherapy, where the

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pubic arch can sometimes obstruct a portion of the prostate [3]. It may also be desirable to reach multiple sites within the target area without full retraction of the needle [2].

Steerable needles have recently received a great deal of interest in the medical robotics community (see [1] and [4] for reviews), because they have the potential to address both accuracy enhancement and obstacle avoidance. In this paper, we consider only the subset of steerable needle research that addresses flexible needles that harness asymmetric tip forces (often combined with rotation of the needle shaft) to guide the needle through curved paths to reach a target. These needles, which typically feature a bevel tip, are able to enhance accuracy by enabling closed-loop control [5], [6], and can also enable the needle to steer around obstacles [2], [7] using preplanned trajectories.

While there has been a great deal of recent progress on needle modeling and control (see e.g. [4], [5], [8]–[11], among many others), comparatively little attention has been paid to needle design. One noteworthy design is a hand-held steering device that deflects a traditional biopsy needle through a curved path by varying the exposed length of a precurved stylet [12]. Another uses two interlocking shaft halves that can be extended relative to one another to steer the needle [13]. With bevel-tip needles, design studies have investigated the effects of bevel angles on curvature and bevel-tissue interaction parameters and needle curvature [8], [14]. The effects of kinked tips have been studied to enhance needle curvature [15], and tips that are larger than the needle shaft and are kinked [10] have also been used for this purpose.

Thus, much prior steerable needle work has considered a beveled or a kinked and beveled tip, with the latter enabling higher curvature and thus better steerability. An approach for adjusting the curvature of such a needle during insertion is duty cycling [10], which is achieved by interspersing short periods of rapid axial rotation with short periods of a fixed axial angle during insertion. Using a kinked bevel-tip needle with duty cycling yields high curvature capability with real-time curvature adjustment. However, a kinked bevel tip that is rapidly rotated during insertion cuts a helical path through the tissue larger than the needle's shaft, due to the rigid nature of the kinked tip.

To address this problem and enable high curvature while minimizing tissue damage, in this paper, we present a new bevel-tip needle design that incorporates a flexure. The flexure enables the needle to act like a kinked tip needle when inserted, while at the same time acting like a traditional bevel-tip needle when axially rotated. Thus, this new flexure-tip needle is able to provide high steerability with less tissue damage.

II. Flexure-Tip Needle Design

The flexure-tip needle consists of three parts: a flexible straight needle shaft, a beveled tip, and a flexure joint. During insertion into tissue, the bevel tip produces a transverse load which causes the needle to bend at the flexure [see Fig. 1(c)]. As will be shown shortly, during pure insertion, this causes the needle to behave like a kinked bevel-tip needle [the fact that it has the same shape can be seen in Fig. 1(c)]. However, during pure rotation, the flexure enables the needle to stay in place while spinning to reorient the bevel, without tearing through tissue.

The prototype needle shaft used in experiments in the following sections is flexible [made from nitinol, see Fig. 1(b)] with an outer diameter (OD) of 0.91 mm and an inner diameter (ID) of 0.60 mm. The beveled tip section has the same OD as the shaft, is 4.0 mm long at its longest point, and features a 10° bevel angle. The flexure that connects the needle shaft and the tip section is made of three 0.125-mm diameter nitinol wires laid side by side in the middle of the needle, and oriented so that their least stiff direction is the one in which the bevel would naturally make the needle bend during tissue insertion [see Fig. 1(a)]. The gap between the tip section and the needle shaft is approximately 0.15 mm, which allows the tip to flex to a maximum angle of roughly 22°. To attach the wires to both the shaft and tip section, cold weld epoxy (J-B Weld, TX) was used.

The in-plane stiffness of the flexure joint [i.e., movement of the tip in the XZ plane in Fig. 1(a)] was determined experimentally by hanging weights from the beveled tip using a drop of glue and a hook (see Fig. 2) in 5-g increments. The resulting stiffness for the flexure was approximately 3.6 mN·m/rad. The out-of-plane stiffness was determined to be 16.5 mN·m/rad using the same experimental procedure.

III. Needle Characterization

To characterize our new flexure-tip needle, we began by determining whether we could achieve curvatures similar to the kinked bevel-tip design we seek to replace. We then investigated whether duty cycling was possible with the new needle, before lastly exploring tissue damage.

A. Curvature Comparison to Kinked Bevel-Tip Needle

We constructed a kinked bevel-tip needle using as the shaft the same nitinol tube used to make our kinked tip needle (0.91 mm OD × 0.6 mm ID).We constructed a kinked tip from a stainless steel wire with a 0.91-mm OD, a bevel angle of 15°, and a kink angle of approximately 25° at a point 4 mm from the tip. When inserted into a tissue phantom made from 10% by weight Knox Gelatin (Kraft Foods Global Inc., IL), the flexure-tip needle is able to achieve a comparable curvature to the kinked bevel-tip needle (see Fig. 3).

B. Feasibility of Duty-Cycling to Adjust Curvature

As proposed by Minhas *et al.* [10] duty cycling adjusts needle curvature by alternating between periods of insertion without rotation, and insertion while constantly spinning the needle. To explore whether our flexure-tip needle was capable of providing adjustable curvature via duty cycling, we performed the following experiment.

Two tissues were prepared: a 10% by weight Knox Gelatin tissue phantom, and *ex vivo* pork loin. The flexure-tip needle was inserted into these tissues with a constant insertion velocity of 0.5 cm/s, and constant rotational (during the periods of the duty-cycle when axial rotation occurs) of 4 rev/s. Insertions were performed with duty-cycle ratios of 0%, 20%, 33%, 50%, 66%, 80%, and 100% in phantom tissue, and 0%, 25%, 50%, 75%, and 100% in pork loin, with 0% indicating no axial rotation, and 100% indicating constant axial rotation. When not axially rotating, the bevel orientation was always the same, such that the needle paths were all in the same plane. Fig. 4 shows superimposed images of several flexure-tip needle insertions into both tissue types. The radius of curvature for each duty-cycle ratio was determined by visually fitting a circle to the needle paths. Fig. 4(c) shows the curvature with respect to the duty-cycle ratio in phantom tissue. The linear fit agrees with the results obtained in [10] using a kinked bevel-tip needle. The maximum nominal radius of curvature of the flexure-tip needle (0% duty cycle) was 12.1 cm in phantom tissue, and 17.6 cm in *ex vivo* pork loin.

C. Tissue Damage

While duty cycling is a good method for adjusting the curvature of a steerable needle during insertion, it can cause damage to the tissue surrounding the needle. For a qualitative assessment of tissue damage caused by needle insertion using duty cycling, we inserted the kinked bevel-tip needle, a clinical bevel-tip needle, and the flexure-tip needle (described in

Section III-B) into phantom tissue (10% by weight Knox gelatin). The clinical bevel-tip needle (Becton Dickinson and Co., NJ) was a 20 gauge spinal needle (OD 0.91 mm) with an 18° bevel angle. Each needle was inserted with a constant velocity of 0.5 cm/s, and constant axial velocity of 4 rev/s (that is, a duty cycle of 100%). After insertion, the needle was retracted using the same parameters with the intent of having its tip follow the same path as during insertion. Liquid dye was then injected into the insertion hole to visualize the needle path (see Fig. 5). As one can see in the figure, because of the spinning of the kinked bevel tip, the needle slices through the tissue in a local helical pattern during insertion. Note, however, that the flexure-tip needle's tissue damage under these conditions is comparable to the path created by the clinical bevel-tip needle.

IV. DISCUSSION AND CONCLUSION

The flexure-tip steerable needle introduced in this paper is a promising new design that provides good steering capabilities in terms of maximum nominal curvature while minimizing tissue damage, and it is capable of duty cycling. The mechanism that it appears to use to achieve both these things simultaneously is that the tissue forces appear to cause the flexure tip to bend back toward its initial straight configuration during axial rotation. If the needle is stopped within tissue and rotated, it appears to rotate in place, with the flexure bending in all necessary directions and the tip is reoriented.

In terms of future work on the flexure-tip design, this needle is similar to prior flexible steerable needles in that its parameters must be tuned (most notably flexure stiffness, but also shaft stiffness, bevel angle, etc.) to the tissue in which it is designed to work. Thus, future experiments and design adjustments will be needed to adapt this design to be intervention specific. To adapt this needle to carry specific interventional payloads (for e.g., biopsy, therapy delivery, brachytherapy, and others), similar to prior bevel-tip steerable needles, the flexure-tip needle can serve as a guide-wire to the region of interest, with a sheath advanced over the needle after the tip has reached the desired location.

While we note that although initial anecdotal phantom tissue histological images provided in this paper show little apparent tissue damage, more in-depth histological evaluations in living biological tissues are needed to quantitatively verify reduced tissue damage. It will also be useful to verify that the tissue damage incurred by any of these needle tip designs (including the kinked bevel-tip needle) is clinically significant. We suspect that it may not be, based on informal conversations with physicians experienced in needle insertion procedures. However, the natural inclination to wonder about tissue damage when presented with the kinked tip needle by some National Institutes of Health reviewers, Institutional Review Board officials and Food and Drug Administration employees may one day hinder the clinical translation of steerable needles into the operating room. We view our flexure-tip needle as providing an answer to such questions before they are asked, and hope that it may thus help to facilitate this clinical translation of flexible tip-steerable needles sooner rather than later.

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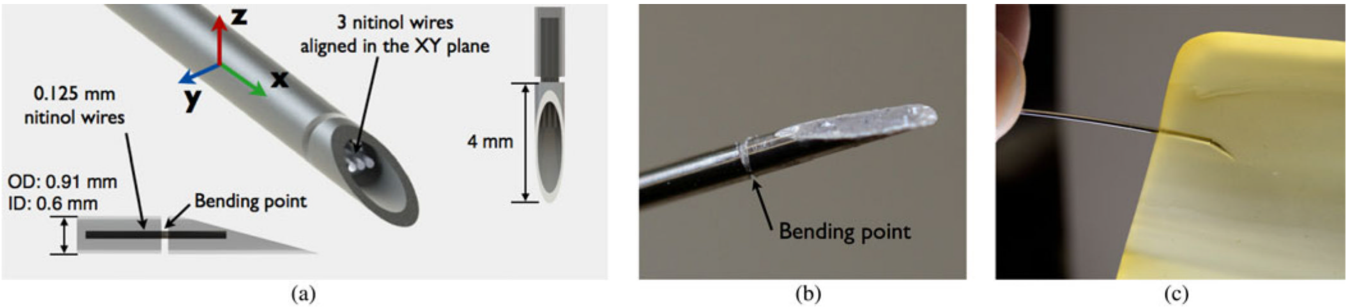


Fig. 1.

Flexure-tip needle design. The nitinol wires that comprise the flexure joint bend at the gap between the needle shaft and the tip as forces are applied to the bevel tip by tissue. (a) CAD drawing of the flexure-tip needle concept with dimensions shown. (b) Close-up of the flexure-tip prototype. The nitinol wires are held in place by a cold weld epoxy in both the bevel tip and the needle shaft, which begin as tubes. (c) Flexure-tip bends in the direction of the bevel when inserted into tissue due to reaction forces on the bevel that cause the nitinol wires to deflect, thus kinking the tip of the needle.

Fig. 2.

Experimental flexure stiffness test setup.

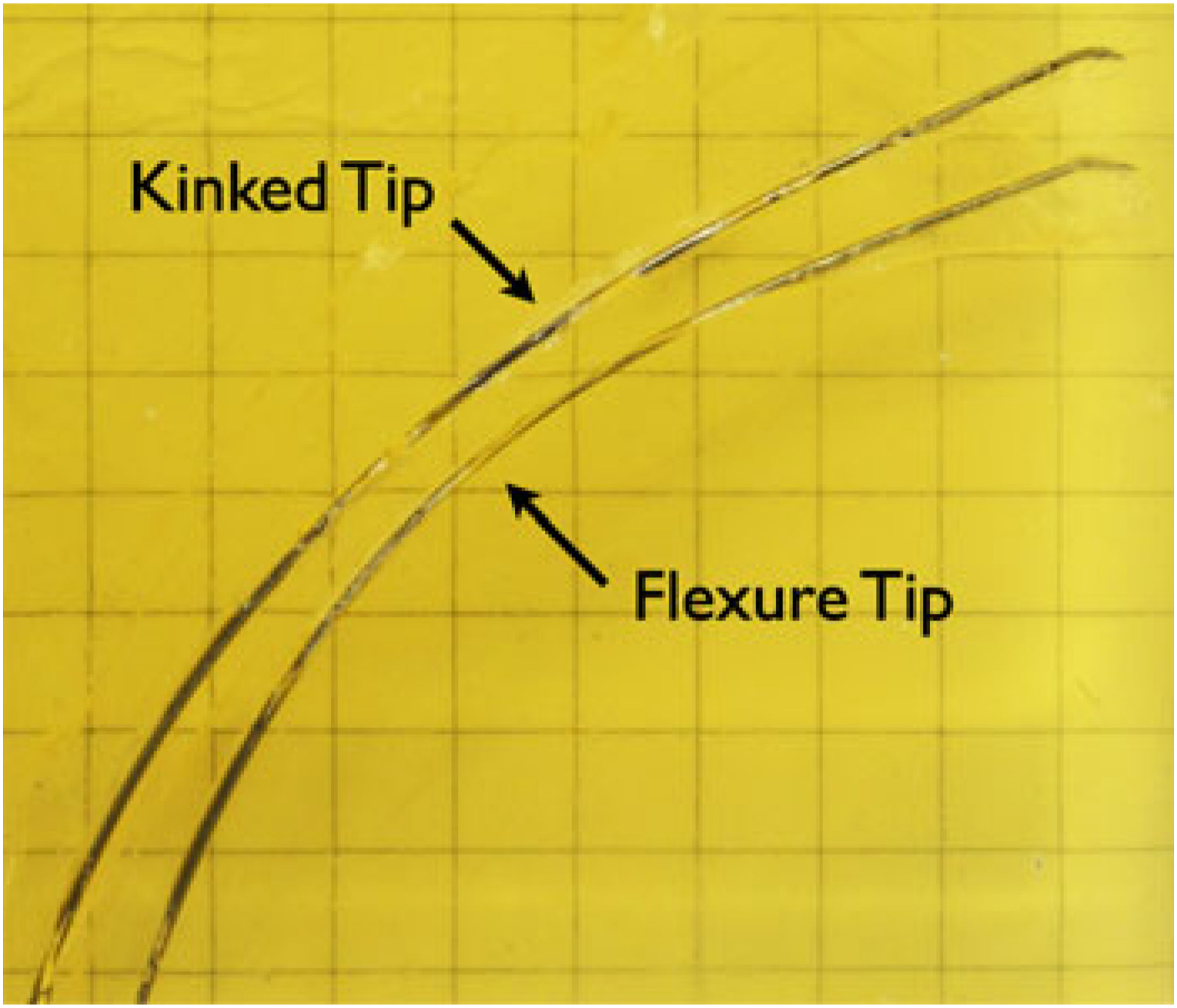
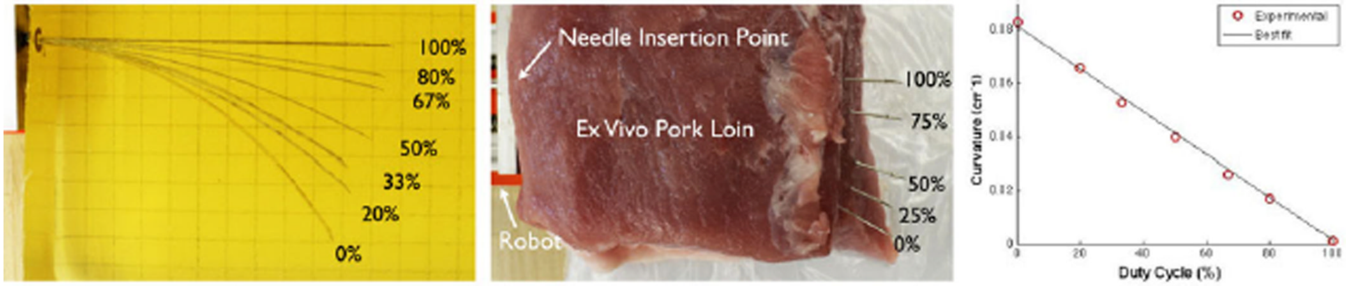


Fig. 3.

Curvature comparison of kinked bevel-tip needle and flexure-tip needle.



(a) (b) (c)

Fig. 4.

Achievable needle curvatures in phantom and biological tissue. (a) Superimposed insertions into phantom tissue. (b) Superimposed insertions into *ex vivo* pork loin. (c) Curvatures achieved for varying duty-cycle ratios in phantom tissue.

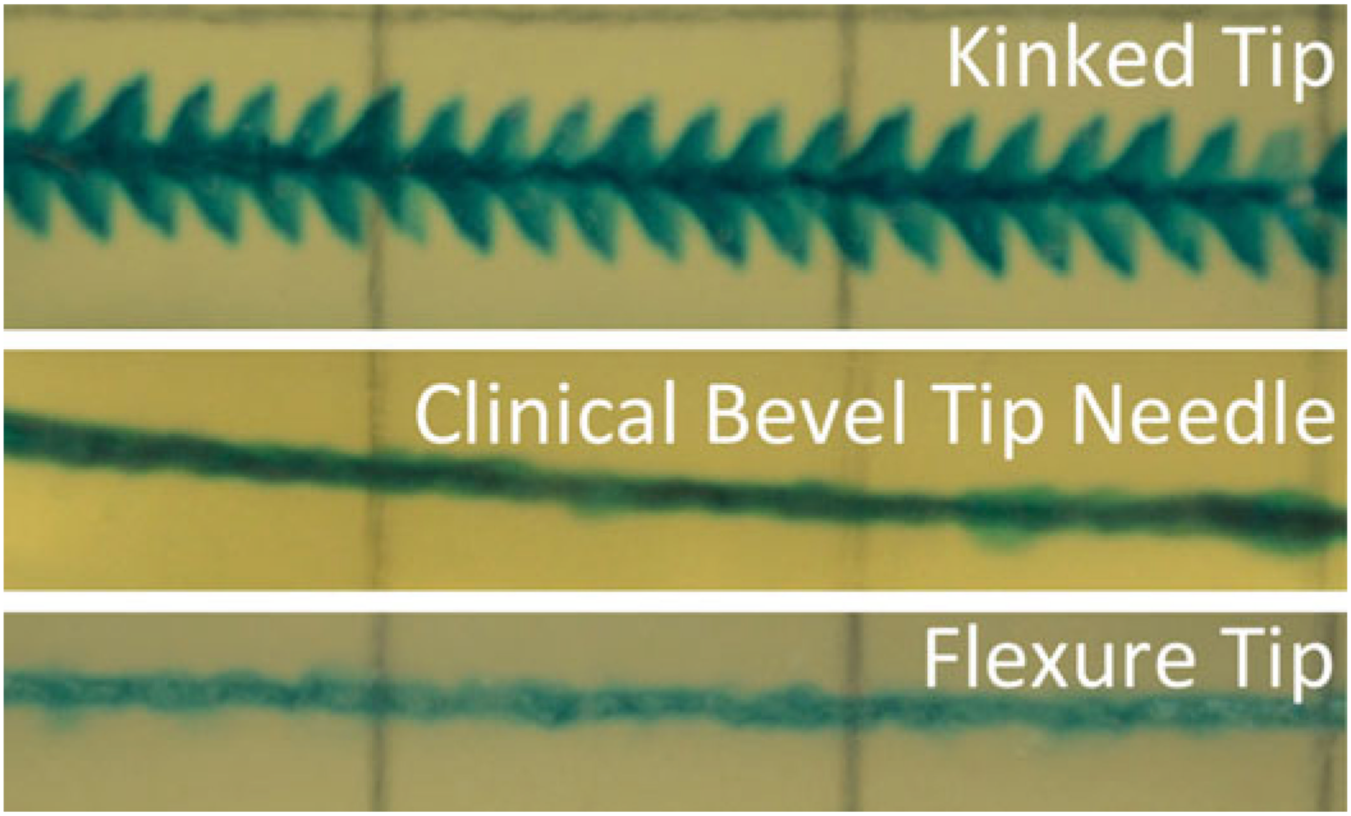


Fig. 5.

Tissue damage comparison of kinked bevel-tip needle, clinical bevel-tip needle, and flexure-tip needle.