Sharp turning steerable needle.

We propose a flexible steerable needle (a slender long flexible beam (or tube)) device that has the ability to create and follow a path through soft tissue that has multiple sharp curves. That is, as the needle is pushed into the tissue, an operator may steer the needle around obstacles and sensitive areas with high maneuverability. The invention utilizes the ability for the needle body to be stiff when straight and flexible when bent, such that the path of the needle may be controlled more precisely without significantly distorting the tissue.

BACKGROUND ON STEERABLE NEEDLES

The following is taken from US Patent 7822458 “Distal bevel-tip needle control device and algorithm” :

Accurate and precise needle insertion is an important aspect of many types of medical diagnoses and treatments. Accurate and precise needle placement is required in the treatment of afflictions including, for example, prostate cancer, liver cancer, and intracranial hemorrhage (ICH).

Needle biopsy for prostate cancer is performed on approximately 1.5 million men per year. A common treatment option is transperineal brachytherapy, which involves implanting thin needles to deposit radioactive seeds within the prostate. Precise placement of radioactive seeds is made difficult by organ deflection, dislocation and deformation. Further, significant seed placement error can occur if the needle is tangential to the prostate capsule wall upon penetration. This is generally due to the fact that the prostate's mechanical properties are considerably different from that of the surrounding tissue. According to the related art, needles for delivering radioactive seeds are substantially rigid. As such, accurate and precise needle insertion may be hampered by prostate deflection, dislocation, and deformation. The resulting inaccuracy may hinder optimal application of a radiation dose.

Hepatocellular (liver) cancer is one of the most common cancers in the world, and one of the deadliest. Liver tumors are often treated with thermal ablation administered at the tip of a needle inserted through the skin under the guidance of ultrasound imagery. Liver tumors often have very different mechanical properties than the surrounding tissue, similarly to the aforementioned difficulties in penetrating a prostate capsule. Accordingly, liver tumors are generally difficult to penetrate.

Thermal ablative treatment of liver cancer is further complicated by the typical need for multiple overlapping thermal treatments of a tumor. According to the related art, rigid thermal ablative needles must be removed and reinserted to penetrate the tumor from different angles.

Intracranial hemmorhage (ICH) occurs in roughly 10 to 20 persons out of 100,000. Untreated clot resolution generally takes two to three weeks, with a mortality rate of approximately 50-75%. Related art treatments involve introducing a needle (through a burr hole drilled in the skull) for injecting drugs. The burr hole is generally drilled by freehand. Depending on the surgeon's hand-eye coordination, the burr hole may be misplaced, thereby resulting in the needle path being off as much as 20-25 degrees. To compensate, the burr hole is generally made significantly larger than otherwise necessary, which can lead to technical and clinical complications. The larger burr hole is generally required because the needle is substantially rigid, and is not capable of being steered within the brain.

In all of the above cases, the needles are generally rigid and are typically inserted by hand. Any initial misplacement or misalignment of the needle requires that the needle be pushed through the tissue medium in such a way that the tissue medium is distorted. The mechanical properties of the tissue medium generally deflect the needle, complicating what is already an inaccurate and imprecise needle guiding approach. Further, any changes or anisotropy in tissue mechanical properties may deflect the needle in a manner that is unpredictable to the surgeon, exacerbating the problem of inaccurate and imprecise needle targeting.

Accordingly, there is a need for a steerable needle that may be used for diagnostic and treatment purposes, wherein the needle may be steered through tissues of varying mechanical properties substantially without distorting the tissue medium. In the exemplary case of prostate cancer treatment, there is a need for a needle that may be steered to an optimal prostate capsule penetration angle. In the exemplary case of liver cancer treatment, there is a need for a needle that can apply multiple overlapping thermal ablations to a tumor without having to remove and reinsert the needle. In the exemplary case of ICH treatment, there is a need for a needle that may be steered through brain tissue medium to accurately and precisely target a clot while compensating for inaccurate burr hole placement.

Steerable needle technology has the potential to change the way many surgeries are performed. The post operative procedures after needle based surgery consists of simply applying a bandaid. Even “minimally invasive” laparoscopic surgeries with small ports still need to have the ports stitched closed. Currently straight needles are in common use to do this, but only in areas accessible by straight lines which limits them to places that are not blocked by important organs or bones. Fixed curved needles are also in use today, where a curved needle is used where simple geometry dictates its use (e.g. avoiding one sensitive region or obstacle). Steerable needles could drive around multiple sensitive areas and obstacles or be adjusted in real time as the operation proceeds.

In addition, there is the potential for a wider variety of capabilities. Since the needle is steerable, one could imagine catheter-like operations (e.g. transurethral resections of the prostate (TURP)) that include but the removal of tissue. The curvature based system has been exploring uses for brain clot reduction. [Burgner, 2013] and intracranial hemorrhage. One could also imagine tasks using multiple needles such as sewing operations, though this is further out.

Radio Frequency Ablation (RFA) is used to do a variety of things. One of them is the treatment of cancerous tumors including liver, kidney, adrenal gland, bone, lung and breast as well as soft tissue debulking and pain palliation [Friedman 2004]. RFA for cancerous tumors in the liver has been extensively used. Traditional methods are usually limited to tumors smaller than 5cm as more than that would require many (more than a dozen) needle insertions. There are several commercial devices which deploy an array of tines to ablate a larger spherical volume (5cm). The Boston Scientific RF 3000 deploys a set of about 10 tines that curve out like an umbrella. The RITA Medical system Starburst XL has 9 tines the fan out like a christmas tree. A needle that can achieve an arbitrary path can effect a volume of arbitrary shape and size by moving the RFA transducer along the path over time.

Steerable needles have been receiving a lot of attention from the research community due to the promises listed above. A search for “steerable needle” on Google Scholar returns over 500 papers since 2000. A patent search for “steerable needle” returns 244 since 1990. Some of the more promising work includes flexible needles with asymmetric (bevel-tip) devices [US 7822458]. They can create curving paths where the bevel tip causes the path of the needle to curve as it penetrates the tissue; and straight paths in tissue (by twisting while translating the bevel tip to form a helical path), but these paths are limited to those with large curvatures (typically many inches in minimum turning radius) that will vary in shape depending on the stiffness of the tissue. The record for tightest curve as of 2011 experimentally achieved was a radius of 1.5cm in artificial tissue and 3.4cm in liver [Majewicz 2010]. The proposed invention should be able to achieve an order of magnitude improvement.

The stiffness in the flexible needle needs to be strong enough to penetrate the tissue without buckling yet flexible enough and so it will curve in the tissue (ideally with small radius). In actual use, the flexible needle approaches (e.g. asymmetric (bevel-tip) devices) need to adjust a variety of properties to adjust for the tissue stiffness including the stiffness of the needle, the angle of any bevel, the angle of any prebend (kink or curve bias) [Swaney 2013]. This can be problematic as typically a needle must penetrate a variety of tissues which will often vary especially if it is a tumorous.

A survey paper [Reed 2011] summarizes many years of research in steerable needles using asymmetric-tip needles and concludes with four areas of development required to achieve application in the real world. They are:
1) mechanics-based modeling - understanding the needle / tissue interaction is important for asymmetric tip needles,
2) planning in 3D with uncertainty - though there are useful applications in 2D in-plane motion.
3) human in the loop control - surgeons prefer systems that they can control in real time and are typically better than automatically guided robotic systems
4) minimizing radius of curvature - for better control and wider variety of paths/obstacle avoidance

The first and last issues are a result of the stiffness trade-off. The needle must be strong enough to penetrate the tissue and maintain good control of where it goes, but must be flexible enough to have tight turning radius (item 4). In addition, a higher stiffness will distort the tissue as the needles path is traversed which requires a better needle/tissue model (item 1). The ideal needle will be very stiff when it needs to penetrate and very flexible when it needs to bend.

PROPOSED INVENTION

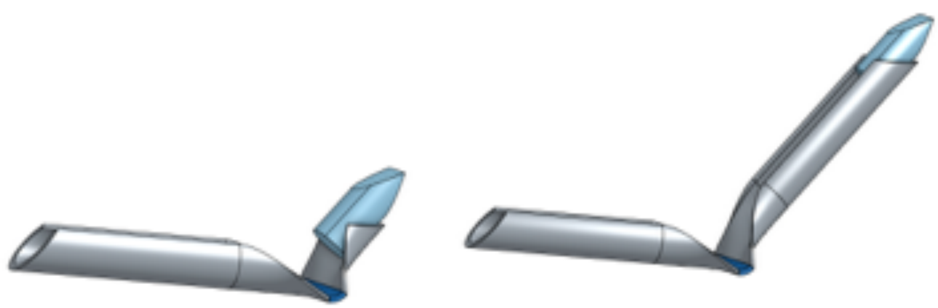
Our device can have sharp turns with a turning radius in the range of millimeters. This will enable paths not possible with previous methods which were highly constrained to simple large curves. In addition, the bends in the needle have negligible strain energy, so there is little stress put on the tissue to maintain the shape in the tissue (little tissue distortion) in contrast to the bevel-tip needles. Because of this, the device will have more precise control through tissues with varying stiffness (as one would find in actual surgeries) without strongly effecting the path of the needle. Whereas the other prior art ideally requires knowledge and modeling of the tissue stiffnesses to achieve similar precision (which not only could change between modeling and operation time, but as in muscles can be changed dynamically), this shape of the path of the proposed device will be less prone to errors making it more accurate in placement.

The primary innovation comes from using a curved spring form flattened beam (also known as a tape spring as commonly found in metal tape measures) as the shaft of the needle. This partial tube maintains axial stiffness when straight, but can controllably be buckled at the head of the needle. Nominally the beam is straight and acts as a straight needle would. However, when a bend is desired, the tip of the needle initiates a bend. Once a turn is initiated with a bend, that bend in the beam must traverse along the beam as the needle progresses into the tissue. Once a bend is in the band, it takes nearly zero energy to propagate that bend down the band. The strain energy required to bend a straight portion an incremental distance down the band is recovered in the strain energy of the curved part that is straightening.

Nominally the bends introduced in the band can only occur along one plane. That is the needle's curving path can only reach points on a 2D plane. For full 3D arbitrary positioning, we can rotate this 2D plane by adding a mechanism to introduce a screw-like twist in the head. In this manner the bending 2D plane can controllably rotate along the longitudinal axis of the needle allowing arbitrary 3D positioning. This twist rate will be relatively slow requiring some distance to rotate and this twist does create reaction forces in the tissue to maintain the twist shape.

The invention includes four parts, the needle shaft (comprised of a tape-spring), a steering head, a base and a transmission such as control wire(s). The needle shaft has been explained above and contains the primary mechanism by which the needle path can be stiff in straight portions and flexible in bent portions. The steering head leads the path (the distal portion of needle) and induces bends in the path and controls the direction of the needle as commanded by a user (e.g. a surgeon). The base is at the proximal portion of the needle outside the body and is the interface with the user (surgeon). The transmission transmits forces and torques from the base to the steering head.

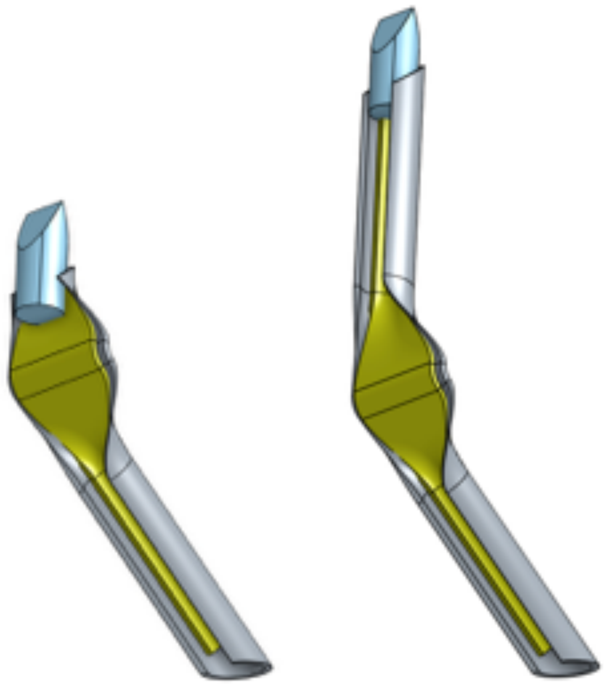
Figure 1: steering head on curved tape spring needle body with inner tape spring as control transmission.



a b

Figure 2: needle body buckled inward (transmission not shown) a) initiated bend. b) bend translated down needle body as needle insertion progresses

For 2D planar motions, a steering head can be a symmetric stylet as seen in Figure 1. When inserted into tissue, the steering head in the nominal position will lead to straight paths. Pulling on a control wire relative to the tape spring will cause a moment at the steering head bending the tape spring locally as in Figure 2a. As the needle continues its insertion, the currently bent portion will straighten leaving that bend in the path (Figure 2b). Note the work required to induce this bend is input from a user (e.g. surgeon) outside the tissue and transmitted to the head. Advantageously, the supplied forces to apply this moment can be arbitrarily large - where as the bevel tip methods rely on tissue interaction forces for turns. The proposed control mechanism is similar to US20120136381A1, and the Morrison Steerable Needle from AprioMed. Similarly, pushing a stiff control wire can cause a moment in the opposite sense to induce a bend in the tape spring in the other direction (Figure 3). The wires could be replaced with flexible tube, rod or a second tape spring (Fig 3a-b) that could be stiff enough to push on as well as have the same buckling attributes.



a b

Figure 3: needle body bucked out with 2nd inner a) initiated, b) translated down.

If stiff wires rods or tubes are not viable for pushing, a bias in the tape spring can be included in the needle shaft so that the nominal rest-position of the spring is bent away from the cable. Then only pulling on the control wire with different magnitudes is required to obtain straight paths or turning in either direction.

Yet another method is to use a transmission that does not create axial tension/ compression (pushing or pulling) and instead transmits forces/torques by twisting. An example of this is to incorporate a threaded shaft interface at the steering head where the transmission twists axially to rotate the threaded shaft (without inducing twist in the needle body). The threaded shaft translation then induces similar bending at the steering head.

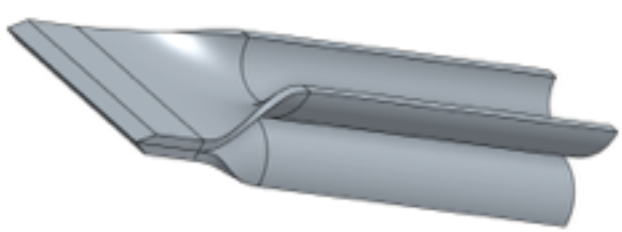
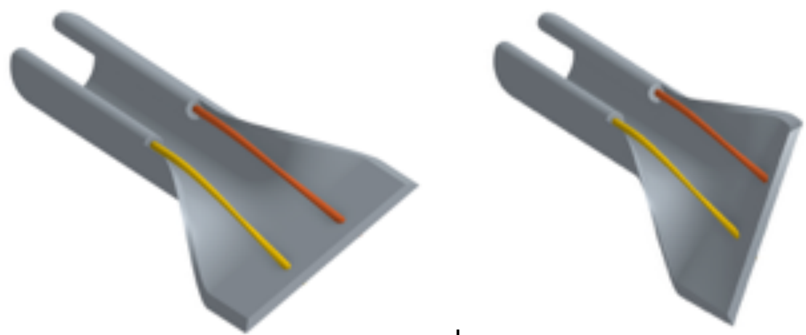


Figure 4: Two tape spring elements back to back attached together only at the tip.

Alternatively, Figure 4 shows two similar tape spring elements lined up back to back attached at the steering tip. The steering head consists of the two ends flattened and joined at a sharpened tip. Steering occurs by pushing differentially on the two halves. As one skilled in the art can appreciate, one of the two halves could be flipped the other direction resulting in a closed tube with two split halves attached only at the tip through a steering head.



a b

Figure 5: a) two cable transmission also b) enabling screw-like twist

For straight paths, pulling or pushing on the transmission can occur even if the needle shaft is an open beam (not a closed tube). However, if the path has curves in it, pulling on the transmission with an open beam needle shaft may cause the transmission to separate from the needle shaft (e.g. a control wire at a bend will cut the corner) this will result in loss of control at the steering head and more damage to the tissue. There are several ways to mitigate this. One is to use a flattened tube as the beam and have the transmission contained inside the tube. Another is to add edge features to the beam that constrain the transmission geometry in a curved path which can be achieved with a transmission that is constrained upon and rides upon the edge feature as in Figure 5. Note this is different than the bevel-tip which is twisted at the base and those flexible needles are torsionally stiff. In this case, the needle shaft is not torsionally stiff. The torsional stiffness affects how far the needle must travel for the bending plane to twist a given amount.

Advantageously, the base can be hand held and controlled by a user (e.g. surgeon) as the control can be made intuitive (as in the Morrison Steerable Needle and unlike the bevel-tip devices). This does not preclude the use of robotic motorized control of the device either.

For various applications, a flexible tube may ride in the middle of the needle shaft to deliver medications, or radioactive seeds, or to remove material, such as liquids or for biopsies or other applications. The transfer of material to or from the base and the end can be considered a payload. This payload can be carried at or near the tip of the needle or can be transferred there after the needle has reached a target site by another medium guided by the needle path or can use the path through the tissue created by the needle (after the needle has been removed). The needle can have a hollow portion as part of the band through which the payload may be delivered.

Prior art:

This section on prior art is primarily a published article that is used as a “sample prior art review” that happens to cover many of the basic topics of this invention. The focus of the search is on steerable needles, though their invention was with respect to haptic feedback control. Those elements have been omitted but the rest is included.

Steerable medical devices can be broken down into two categories: steerable needles and steerable catheters (e.g. urethrascope). In medicine, percutaneous pertains to any medical procedure where access to inner organs or other tissue is done via a needle-puncture of the skin as opposed to an approach where surgery is performed to expose the inner organs or tissue. Percutaneous procedures can be further divided into two categories

1. Rigid needle insertion – where a “rigid” needle is inserted through the skin and subcutaneous soft tissue to a location inside the body.

2. Catheter procedures – where a wire is placed into a blood vessel that is used as a channel to guide a tool on the tip of the catheter to a point inside the body.

As can be seen from the table below, there is a clear distinction between percutaneous catheter and needle based procedures. In particular, catheters are generally an order of magnitude larger in size than the needles. Further, catheters are typically inserted into either fluid or open space inside the body and thus their distal tip can be manipulated with minimal resistance. Needles inserted percutaneously are typically used to target lesions in soft-tissue for biopsy or ablation. Current needles are designed to be inserted directly to a target and redirection when inside the body is limited due to the resistance of the tissue.

Table I – Catheter and Needle based procedures

	Catheters	Needles
Scale/Size	3 - 10 mm in diameter	0.5 – 3.0 mm in diameter
Length	50 – 200 cm	5 – 10 cm
Medium	Fluid/air	Soft-tissue/bone
Applications	Vascular examination, cardiac, urinary etc.	Lung/Kidney/Liver biopsy/ ablations
Design	Flexible segments that can be steered with cables attached to tip	Single metal cylinder or rod
Guidance	Fluoroscopy, ultrasound	CT, fluoroscopy, ultrasound
Steering	YES	NO

While both are capable of distal tip steering, catheter pass through channels within the body, and therefore are designed to steer in free space or fluid-filled conduits. Steerable needles, on the other hand, are designed to maneuver through tissue. To alter direction, steerable elements must be pre-curved when retracted and deployed along a curved path into tissue or an organ or else use the reaction forces at the tip of the needle for steering.

Another difference between steerable needles and catheter besides size is the attainable radius of curvature. Although cannula have much larger diameters, mechanisms can be more sophisticated that enable sharper curvatures (e.g. 1cm) where as steerable needles have limited flexibility. In order to maintain enough stiffness to move into the flesh in a controlled fashion, the needles must maintain a minimum stiffness.

Currently, physicians attempt to steer standard needles by bending the part of the needle that is partially or fully outside the body so that it takes a curved trajectory when inserted. They also exploit the asymmetric bevel tip to cause the needle to deflect to one side. Patents US 5938635 and US 2004/0133168 highlight ways of steering within tissue using concentric pre-bent needles and "airfoil" needle shapes. These designs make use of specialized cutting surfaces to direct the orientation of a medical device. The mechanisms in US 2007/0167868 and US 5318528 show two strategies for changing the orientation and curvature of tissue harvesting and surgical devices in free space. The mechanisms in US 5792110, US 6,592,559B1, US 6,572,593 show devices that use concentric compliant cylinders to change the orientation of the tip of a needle.

Distal tip manipulation is achieved with a variety of strategies: bending the cannula with a pre-bent stylet, deploying a pre-bent stylet from a straight rigid cannula, and bending a stylet with a feature in the cannula lumen. Samples of three steerable needles in use on the market today are the COOK Pakter Curved Needle Set & the COOK Osteo-Site Bone Access Products, US 6,592,559 B1 and the PneumRx

Seeker Biopsy Needle US 2006/0167416. The Pakter and Osteo-Site products both employ pre- bent needles in concentric rigid cannulae. The Pakter and Osteo-Site products implement distal-tip needle steering to access the center of damaged vertebrae and spinal disks. The Seeker needle mechanism US 2006/0167416 A1 consists of a pivoting handle on the proximal end of the needle that is attached to its distal tip via four small steel bands. The radiologist can cause the needle to take a curved shape by manipulating the handle or joystick with his/her thumb. However, this device lacks accurate controllability; in particular, when it is already partially inserted into the body. Further, there is no locking mechanism to hold a particular curvature.

[…]

Salcudean et al. US 2004/0133168 developed a robotic device that enables multiple needle curvatures to be achieved by employing a stylet that is longer than the cannula so that up to 2 cm of the stylet tip (with a mild curve) can be selectively exposed. The extended curve essentially acts as an adjustable bevel on the tip of the needle. Motors provide actuation for the rotation and extension of the stylet with respect to the cannula. The steering direction is selected by rotating the stylet and the steering rate is selected by extending the stylet and exposing the curve. By withdrawing the stylet, the stiffer cannula straightens out the curve and the needle becomes approximately straight. A miniature two-axis analog joystick is mounted on the shaft of the device facing opposite the insertion direction so that the physician can firmly hold the device in his or their palm and manipulate the joystick with the thumb. This system also requires a thin flexible needle that can bend so that the entire shaft can follow behind the steering tip and although the hand held device improves the controllability, it would be difficult for a physician to hold for a long period of time.

There are fundamental problems with the needle steering strategies that have been developed to date; in particular, relying on knowledge of the material properties has obvious limitations. Material properties will be inhomogeneous, vary with patients as well as across tissue layers. Many of the research projects offer the potential for steering around anatomic structures; however, a major problem is that once the needle tip is placed at the desired point, it cannot be easily repositioned to a near by point. Instead of steering the entire needle length, another approach is to insert the needle along a straight trajectory and then have a mechanism for repositioning the distal tip of the needle. Such a mechanism would be useful for targeting multiple points in a volume or for directing the needle tip around obstacles when a straight line trajectory can not be taken.

US5938635 - Biopsy needle with flared tip

An apparatus and method for performing percutaneous needle biopsies under direct visualization by medical imaging technologies is provided. The apparatus is a biopsy needle comprised of a shaft, a tip which is flared in dimension with respect to the diameter of the shaft, and a longitudinal bevel which is imposed on the tip. The *flared tip of the needle causes it to travel naturally in an arc as the needle is pushed through tissue. This feature is advantageous because obstacles can be avoided and errors in positioning between the needle and the needle's target can be easily corrected by appropriate choice of arcs. The method for advancing the needle into a target or around an obstacle is comprised of combinations of both linear and arcing trajectories. Linear trajectories are obtained either by continuous rotation of the needle about its long axis or by stepwise rotations of the needle about its long axis as it is advanced into tissue. An arcing trajectory is obtained by rotating the shaft of the needle, and hence the bevel, into an appropriate angular position, holding fixed this angular displacement, and then advancing the needle into tissue.*

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