Proceedings of the 2010 Design of Medical Devices Conference
DMD2010
April 13-15, 2010, Minneapolis, MN, USA

DMD2010-3913

MATERIAL SELECTION AND FORCE REQUIREMENTS FOR THE USE OF PRE-CURVED NEEDLES IN DISTAL TIP MANIPULATION MECHANISMS

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ABSTRACT

Pre-curved needles are used in a variety of medical applications for both passive and active control of instrument position. In one application, the deployment of a pre-curved stylet from a concentric outer cannula can be used to achieve lateral positioning of the distal tip of the stylet. This paper outlines how the material and geometry of the stylet can be chosen to ensure that it will not yield and thus repeatably return to its pre-curved shape when deployed from a cannula. Using this methodlogy we calculate the maximum strain for a range of stylet geometries and show that nitinol is required for the stylet material in order for then to not plastically deform. Then, sixteen stylets of varying diameter (0.508, 0.635, 0.838 and 0.990 mm) and radius of curvature (10, 20, 30 and 40 mm) were manufactured. Experiments were performed with four different diameter cannulas (20, 18, 16 and 14 gauge) to measure the forces required to deploy the stylets from and retract them back inside the cannulas. Retraction forces were measured between 0.3 and 13.9N, and deployment forces were measured between 0.2 and 7.0N. For a given cannula it was found that force increases as stylet diameter increases and bend radius decreases.

INTRODUCTION

In medicine, percutaneous needle insertion pertains to any medical procedure where the skin is punctured with a rigid needle or probe to access inner organs or tissue. As opposed to surgery, these procedures offer the advantages of reduced invasiveness and shorter recovery times for patients. Typically the procedures are performed under image-guidance such as computed tomography (CT), fluoroscopy, ultrasound or magnetic resonance imaging (MRI) that provide high resolution images of the patient anatomy. After a target is identified in the body a needle insertion point is chosen so as to avoid obstructing structures (such as ribs and blood vessels) and the needle is then manually inserted towards the target.

Once the needle has been placed, the radiologist will often desire to adjust the location of its distal tip. Reasons for this could be to correct for a targeting error due to instrument misalignment and deflection or to sample/treat multiple points adjacent to each other. However, reorientation of the needle once inside the body is difficult as there are forces from the tissue that resist the pivoting motion. Radiologists do attempt to reposition the distal tip of the instrument once it is inside the body by overcompensating when realigning the needle; however, these medical instruments are usually quite thin and easily bend. Thus, the radiologist is often forced to retract the needle and attempt to re-insert it along the correct trajectory. However, this approach leads to another needle insertion for the patient that can increase the risk of complications.

One approach that can be used to reposition the distal tip of a medical instrument is to deploy a pre-curved stylet from inside a concentric outer cannula as illustrated in Figure 1. Upon deployment of the stylet from the distal tip of the cannula, the stylet will then take its preformed shape and laterally deflect in the direction corresponding to the stylet curvature and the cannula angular position. Through rotation and translation of the outer cannula with respect to the patient and translation of the stylet relative to the cannula, the distal tip can be repositioned within a volume. Such a mechanism is thus useful for correcting for targeting errors, sampling/treating multiple adjacent points or for directing the needle tip around obstacles when a straight trajectory can not be taken.

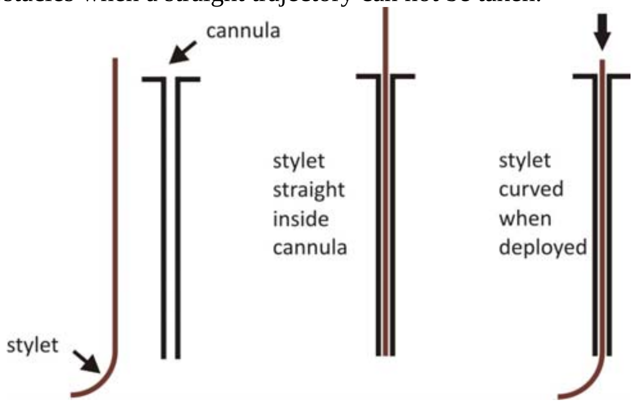

Figure 1 Illustration of the concept of achieving steering with a stylet with a pre-curved distal portion and a concentric outer cannula. When the stylet is inside the cannula it is substantially straightened but once it is deployed it will deflect laterally and assume its pre-curved shape.

Current Applications

Two manual instruments exist that are based on the concept illustrated in Figure 1 [1, 2]. The main application for these needles is in spinal based procedures such as vertebroplasty. Using these devices, materials (e.g. bone cement or ethanol) can be injected at multiples locations inside a vertebra by rotating and translating the stylet with respect to the cannula that is placed at the vertebra surface.

Pre-curved needles have also been employed in robots designed for actively steering needles as they are inserted [3, 4] and in continuum needle steering robots capable of highly dexterous motions [5, 6]. The system in [3], employing a pre-curved stylet and a concentric cannula, enables active needle steering by selectively exposing up to 2 cm of the pre-curved stylet from the tip of the cannula. In this application, the extended curve essentially acts as an adjustable bevel on the tip of the needle. The steering direction is selected by rotating the stylet and the steering rate is selected by extending the stylet and exposing the curve and motors provide actuation for the rotation and extension of the stylet with respect to the cannula. Our group is also currently developing a device based on the concept of a pre-curved stylet. It is for repositioning the distal tip of a medical instrument within a volume after a single needle insertion into the body and it will be described in detail in a future publication.

Contribution

Despite existing products and research projects that utilize a pre-curved stylet and a concentric straight cannula, limited analytical and empirical data exist to guide the design of new medical devices based on this concept. The important dimensions pertaining to the design of these systems are the stylet bend angle, stylet radius of curvature and diameters of the stylet and cannula. These dimensions determine the necessary material constraints, the forces necessary to move the stylet relative to the cannula, the stiffness of the stylet and the working volume that can be targeted.

This paper outlines how the material and geometry of the stylet can be chosen to ensure that the stylet material will not yield and thus repeatably return to its pre-curved shape when it is deployed from the cannula. Sixteen nitinol stylets were then prototyped and a set of experiments were performed with four different diameter cannulas, four different diameter stylets and four different stylet radii of curvature to measure the axial force required to move the stylet relative to the cannula as a function of these various geometric parameters.

MATERIAL AND GEOMETRY CONSIDERATIONS

From Figure 1 it is apparent that in being straightened the curved portion of the stylet will undergo significant longitudinal strains. For use as a medical instrument capable of accurately respositioning its distal tip, we wish that the stylet will take its initial pre-formed curvature every time it is deployed from the cannula. To accomplish this, the stylet material and geometry should be chosen such that the maximum strain in the stylet does not exceed the yield strain of the material. The first step in this process is to calculate the longitudinal strain in the stylet. Figure 2 illustrates the straightening of a beam from a neutral axis with initial curvature R_1 to a final curvature R_2 under the action of a pure bending moment.

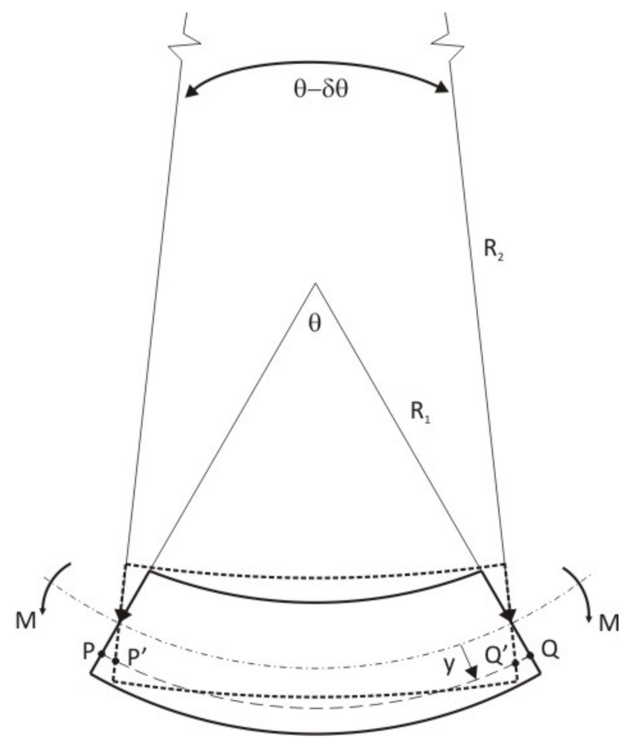

Figure 2 Changing of a curved beam from an initial radius R_1 to a final radius R_2.

As can be seen from the figure, the strain in an element at a distance *y* from the neutral axis is given by

$$\varepsilon_\theta = \frac{P'Q' - PQ}{PQ} = \frac{(R_2 + y)(\theta - \delta\theta) - (R_1 + y)\theta}{(R_1 + y)\theta} \quad (1)$$

This can be simplified to

$$\varepsilon_\theta = \frac{R_2(\theta - \delta\theta) - R_1\theta - y\delta\theta}{(R_1 + y)\theta} = \frac{-y\delta\theta}{(R_1 + y)\theta} \quad (2)$$

Assuming that there is no longitudinal extension of the beam, the length of the neutral axis should remain constant, i.e.

$$R_2(\theta - \delta\theta) = R_1\theta \quad (3)$$

Then if we consider only cases where R_1 is much larger than y, i.e. the radius of curvature is significantly larger than the diameter of the wire, and noting from equation (3) that

$$\delta\theta = \left(\frac{R_2 - R_1}{R_2}\right)\theta \quad (4)$$

Then the longitudinal strain can be approximated by

$$\varepsilon_\theta = y\left(\frac{1}{R_2} - \frac{1}{R_1}\right) \quad (5)$$

For a beam that is straightened, R_2 will be infinite and thus the maximum strain to straighten a curved beam is given by

$$\varepsilon_\theta = -\frac{d}{2}\left(\frac{1}{R_1}\right) \quad (6)$$

From this we see that the longitudinal strains in the stylet are inversely proportional to the initial radius of curvature and proportional to the diameter of the wire. A review of medical procedures and input from physicians provided rough specifications on the stylet size so that it could fit inside standard medical cannulas. Then the maximum longitudinal strain was calculated and plotted for a subset of stylet diameters (range, 0.5 – 1.0 mm) as shown in Figure 3. From the figure it is clear that as the radius of curvature is reduced the strain in the stylet increases rapidly.

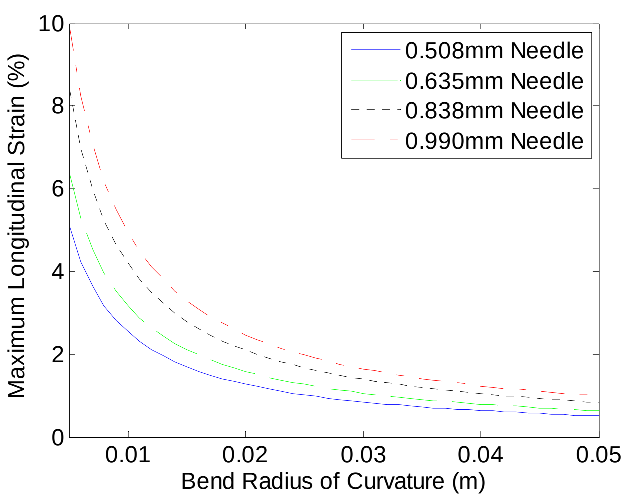

Figure 3 Predicted Wire Strain for Pre-Bent Wire Drawn into Straight Cannula

Stainless steel is commonly used for medical instruments and is biocompatible. However, from Figure 3, it can be seen that for all of the cases the yield strain of stainless steel (0.2%) is exceeded and so it would not be suitable for this application. Nitinol is another material that is widely used in medical devices for its superelastic and shape memory properties. Specifically, superelastic nitinol can withstand strains of up to 6-10% with little to no yielding in conditions around the alloy's active austenite finishing temperature. At high stress, austenitic nitinol is induced into a deformed martensitic crystal structure, allowing it to elongate with relatively constant stress applied to it. The nitinol will revert back to the austenite phase (and its original shape) once the stress is relieved. Based on the previous analysis, we decided to manufacture a number of stylets of varying diameter (0.508, 0.635, 0.838 and 0.990 mm) and radius of curvature (10, 20, 30 and 40 mm) from Nitinol.

MANUFACTURING OF NITINOL STYLETS

Nitinol was obtained in straight wire form (Forte Wayne Metals, IN, USA). In general, a bend in a piece of nitinol wire may be achieved through plastic deformation or through a heat treating process. Heat treatment was chosen for these stylets to maintain homogenous material composition throughout the stylet and avoid the residual stresses caused by cold working. The process for heat setting nitinol has been previously reported [7] and involves evenly heating the material to an annealing temperature of 550˚C where it is maintained for 3 to 15 minutes until internal stresses have been relieved, followed by a rapid quenching operation to maintain the material in the desired austenitic phase (A_f) [8].

The procedure for manufacturing pre-curved stylets began with preparing straight annealed superelastic nitinol for quenching. Four pieces of each diameter wire were cut to 45 cm lengths and a 30° conical tip was ground into one end. The reason for this was so that the stylets would have sharp symmetric tips suitable for being inserted into ballistics gel and tissue. To grind the wires, each was inserted through a cannula so its tip was exposed at the other end. The wire was angled 15° off the face of a diamond grinding wheel and was rotated while being pushed against the wheel.

A fixture was designed (Figure 4) that could maintain the nitinol wire in its final desired shape through heating and quenching while providing minimal thermal resistance to ensure rapid cooling. The fixture could be used to batch manufacture four stylets at a time. The outline plate had four 1 mm wide channels cut in it to accept wire diameter ranging from 0.5-1 mm. Each of the channels had a curved portion corresponding to one of the desired radii. The lower and upper vent plates sandwiched the outline plate so as to constrain the wire and provide access for the water to contact the nitinol wire during the quenching procedure. The upper and lower stiffening frames were designed to be 2.5-4X the thickness of the other plates so as to provide sufficient stiffness to stop them from buckling due to the high temperature gradients during the quenching operation. Finally, the straight ends of the wires were secured with the wire locating clamp.

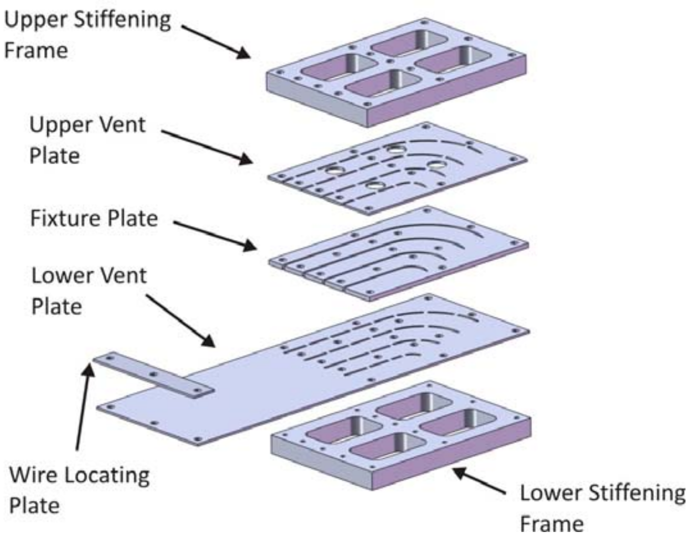

Figure 4 Nitinol quench fixture design.

With sharpened tips at the end of each stylet, sets of four wires were placed in the nitinol quench fixture as shown in Figure 5. All of the components of the quench fixture were manufactured from steel using a waterjet cutter. The steel had a rated melting temperature of approximately 1350°C, well above the 550°C required for heat treating the nitinol.

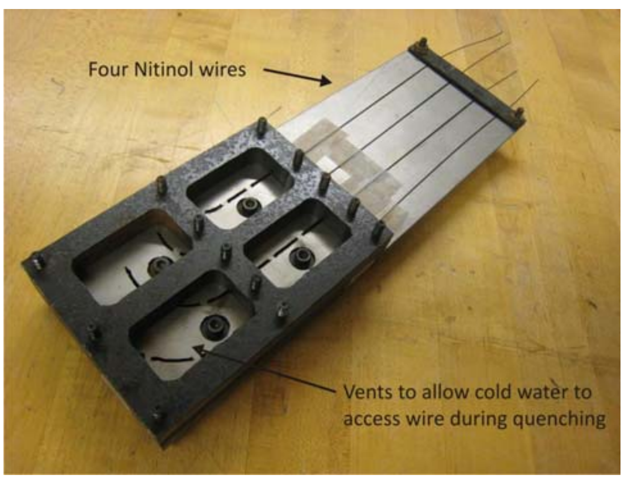

Figure 5 Nitinol Quench Fixture with straight nitinol wire assembled

An annealing oven (www.lindbergmph.com) was then pre-heated to 550°C, and a 5-gallon water bucket was filled with tap water (Temperature = 20-25°C). When the furnace reached 550°C, the assembled fixture was placed in the furnace and a 15 minute timer was started when the oven returned to 550°C. After 15 minutes, the fixture was removed with heavy tongs and dunked into the bucket of water and stirred vigorously. Moments after quenching, the fixture was cool enough to touch, and it was disassembled and the finished stylets were removed. The now warm water was replaced with cold water and four different diameter straight wires were located in the fixture for the same heat treatment. The sixteen different stylets are shown in Figure 6 along with a Sharpie marker for scale.

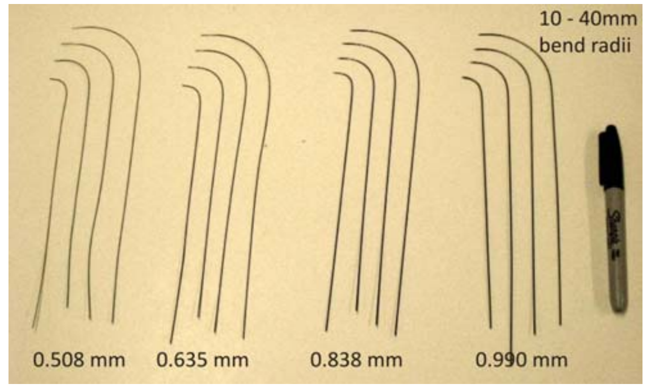

Figure 6 Pre-bent nitinol Needles manufactured with the heat treatment process described above.

As mentioned previously, the fixture for setting the curves into the nitinol wire was designed so that it could be used for wire ranging from 0.5-1 mm. While this provided versatility, it also provided some variability in how the straight wire settled into the channels. Thus, to determine the actual radii of curvature of the stylets, they were scanned, points along their curves were digitized and a circle equation was fit to the data. The values are shown in Table 1. It should be noted that these values were obtained after the following deployment/retraction experiments were performed.

Table 1 Actual radii of curvature that were set into the four different diameter nitinol wires.

Wire (mm)	Diameter (mm)			
0.508	11.0	21.4	31.5	41.1
0.635	13.1	21.5	30.6	42.2
0.838	11.2	21.4	31.1	40.3
0.990	12.3	21.6	31.1	41.6

FORCE TO STRAIGHTEN THE NEEDLE

Previously we discussed various uses of pre-curved needles in passive and active medical devices. In our group we are designing a lightweight device that can rotate and translate the cannula with respect to the patient and translate the stylet relative to the cannula. For all devices a force is required (from either the user or an actuator) to move the stylet relative to the cannula. In the passive devices, knowledge of the magnitude of the force would be useful from an ergonomics point of view to know if it could be readily applied by a physician. For the active devices, it would provide specifications when sizing the actuators and transmission.

Experimental Setup

An experimental rig was developed that enabled these stylets to be deployed from and withdrawn into standard medical cannulas (Figure 7).

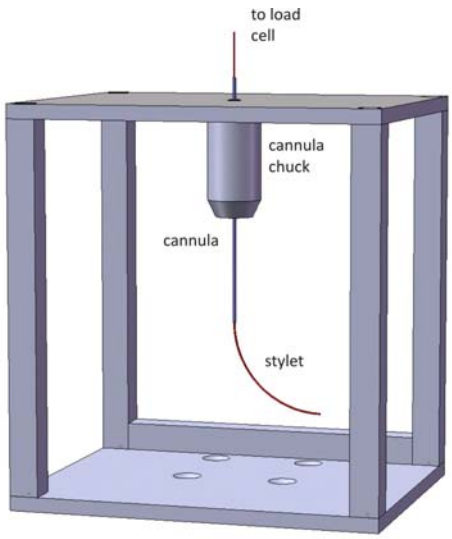

Figure 7 Test fixture for moving a stylet relative to a cannula.

The fixture was designed to (1) bolt to an ADMET universal testing machine, (2) hold a cannula rigidly and vertically, and (3) provide sufficient space for ballistics gel samples to be held under the cannula for future experiments. Four different cannulas were obtained. They had sizes 20 Gauge (OD = 0.91 mm, ID = 0.6 mm), 18 Gauge (OD = 1.3 mm, ID = 0.84 mm), 16 Gauge (OD = 1.6 mm, ID = 1.2 mm) and 14 Gauge (2.1 mm, ID = 1.6 mm). For each experiment, a cannula was held in a pin vice attached to the rig and a matching pin vice screwed into the load cell above the test fixture held the stylet. The test rig is shown mounted to the ADMET universal testing machine in Figure 8.

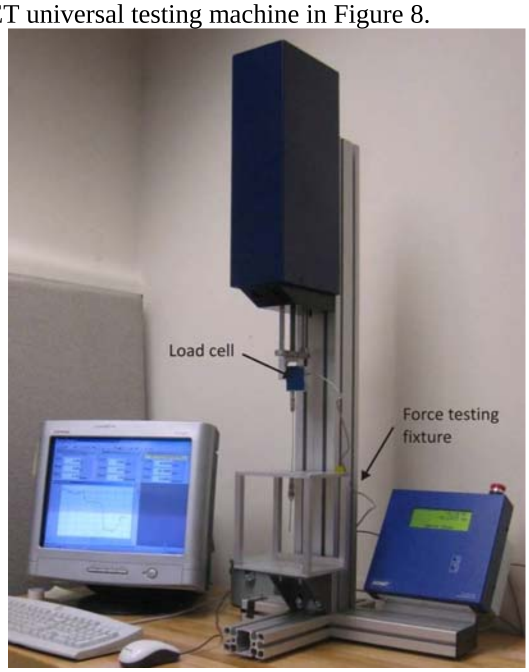

Figure 8 Experimental setup showing the rig for holding the cannula mounted to the ADMET universal testing machine. The proximal end of a stylet is secured in a pin vice that was modified so that it could be screwed into the load cell.

Before each set of experiments, the cannula and stylet were cleaned with Isopropyl alcohol and let dry and the distal tip of the stylet was located 5-10 mm inside the cannula. Using the ADMET software, the force required to move the stylet was recorded while the stylet was deployed from and retracted back into the cannula at a speed of 7.5 mm/s. Data were recorded for 48 permutations of cannula diameter, wire diameter, and bend radius to identify trends across all three dimensions.

Deployment/Retraction Experiments

Figure 9 illustrates the force-time data for a 0.508 mm stylet with a 30 mm bend radius inside a 14 gauge cannula. Five different data sets were recorded and are plotted in different colors. The large internal diameter of the cannula and the small diameter of the stylet resulted in relatively low deployment and retraction forces for this particular data set.

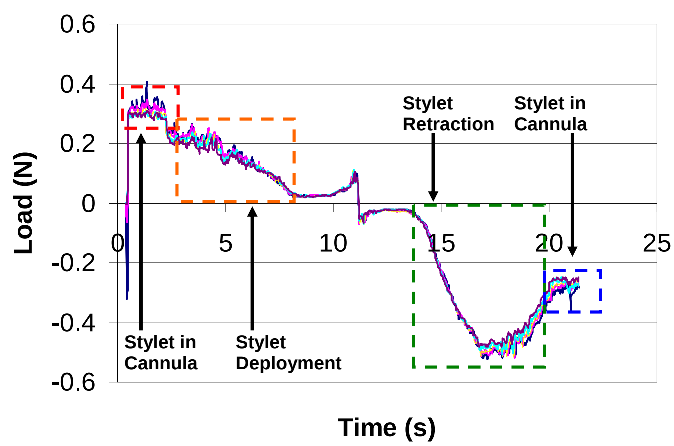

Figure 9 Load vs. Time plot for 5 runs of .508mm stylet with 30mm bend radius deployed through a 14G cannula at 7.5mm/s

The four different phases of the data can be described as follows. Starting from the left of the time axis, motion of the stylet while it was completely within the cannula produced a nearly constant force as measured with the load cell (phase 1 – stylet in cannula). As the stylet was deployed from the cannula the force was observed to decrease until it reached a level close to zero when the curved portion of the stylet was completely deployed (phase 2 – stylet deployment). Some small force was still observed due to slight misalignment between the cannula and stylet. The stylet motion was then reversed using the ADMET software (hence the sign change for the force). As the stylet was pulled back inside the cannula, the force gradually increased before gradually reducing (phase 3 – stylet retraction). Finally, when the stylet was fully inside the cannula once again, the force settled back to a steady state value close to that observed just before the stylet was deployed from the cannula (phase 4 – stylet in cannula).

Across all experiments, retraction and deployment forces ranged from 0.3-13.9 N and 0.2-7.0 N respectively. The standard deviations between runs of the same stylet/cannula combination ranged from 2-19% for retraction forces and 1-10% for deployment forces. Values for certain combinations of stylet and cannula geometry were not obtained when the forces fell out of the measurement bounds of the experiment load cell, or the stylet was unable to fit into the cannula.

The deployment and retraction forces with a 14 gauge cannula are plotted as a function of the stylet bend radius and diameter in Figure 10. Maximum and minimum values from each of the five runs were averaged and the error bars represent the standard deviation between five experimental runs at each data point. For a given cannula diameter, the deployment and retraction force increased as stylet diameter increased and bend radius decreased. The values were higher for the reaction force (Figure 10) as we would expect since energy is required to straighten the naturally curved beam.

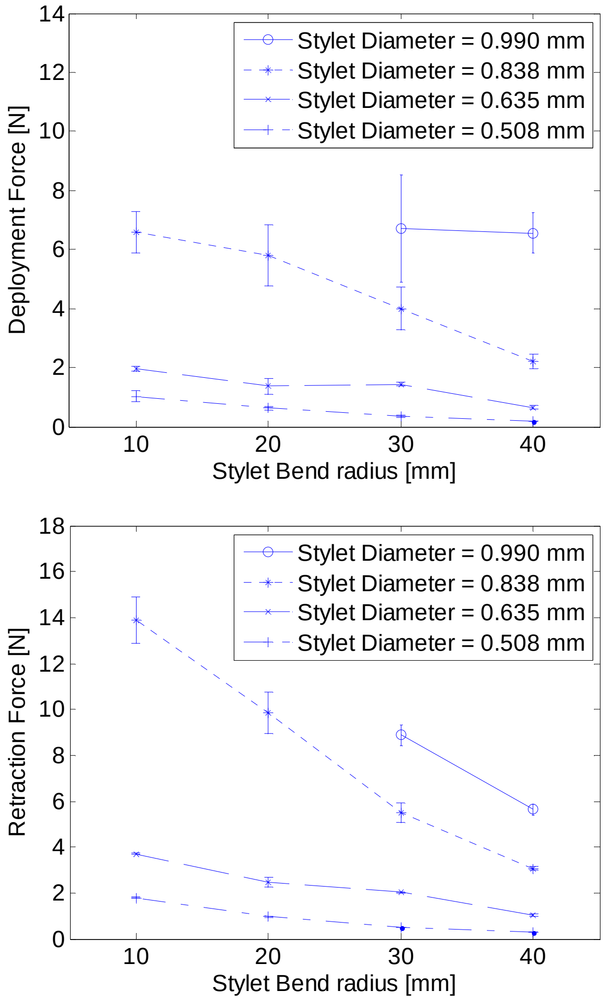

Figure 10 Deployment and retraction forces as a function of bend radius for 0.508 mm-.990 mm stylets with 10 mm-40 mm bend radii deployed through a 14G cannula at 7.5 mm/s.

Figure 11 shows that the retraction and deployment force generally increase with increasing cannula gauge (decreasing cannula inner diameter) but that this is not necessarily always the case. In these experiments we found that stylets drawn through the 16 gauge cannula consistently had the lowest deployment and retraction forces recorded. We are currently investigating what other local effects, such as surface finish or friction coefficient variations, could have caused this.

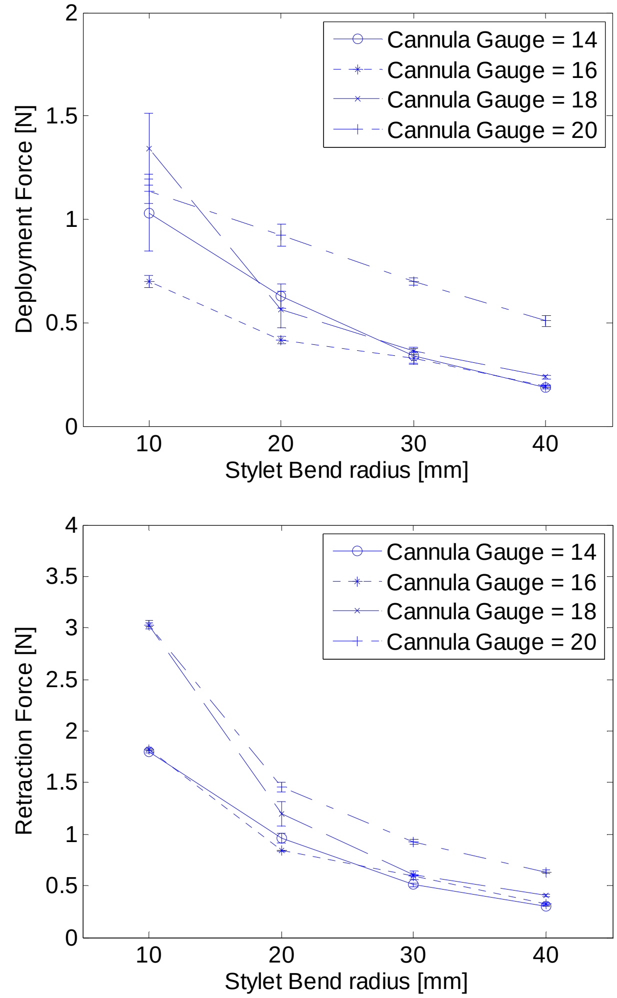

Figure 11 Deployment and retraction forces 14 – 20 gauge cannulas and 10 mm-40 mm bend radii for a 0.508 mm diameter stylet.

DISCUSSION

The results of this paper are intended to provide analytical and experimental tools to assist in the design and prototyping of devices using pre-curved needles. The dimensions of the stylets that were prototyped were based on the dimensions of current medical instruments and needle steering robots. However, the analysis and experimental protocol could easily be adapted to needles of other dimensions.

While the experimental setup provided a means for recording deployment and retraction loading, certain factors during the procedure were observed that we believe contributed to variability in the measurements. The needle test rig had to be aligned with the load cell by hand to allow the stylet to slide through the cannula. This may have lead to the stylet and cannula not being perfectly concentrically aligned. For retraction and deployment loads above 10N, slipping between the stylet and the pin vice in the load cell was occasionally observed. When observed during experiments, the operator tightened the pin vice with pliers and marked the stylet to prevent slipping but some small slippage may have gone unobserved. Due to the pin vice not being perfectly normal to the top plate of the test fixture, the cannula was sometimes observed pointing a few degrees off vertical. This angle would have resulted in a slight increase in the friction forces during the experiments. A stronger, more precise mechanism for gripping cannulas and stylets combined with a modified test fixture that automatically locates it relative to the load cell could improve experiment reliability.

The nitinol wire manufacturing process proved capable of forming the stylets to approximately the correct dimensions. The clearance between the profiled slots on the outline plate and the wire meant that there was a slight difference between the desired and actual radii of curvature. In future experiments we will also measure the radii before and after the deployment/retraction experiments to see if there was any non-recovered strain during the experiments. No tests were done to examine and compare the material properties between batches of stylets and heat treated vs. annealed material because insufficient lengths of annealed and heat treated nitinol was available to conduct tensile tests. However, in the future we plan to perform tensile tests before and after heat treating.

When a straight cannula has a pre-curved needle placed inside it, it will take a shape that is a function of the ratio of the area moment of inertia of the cannula and stylet and their material properties. For the cases when there is little difference between the stylet outside and cannula inside diameter, significant curvature of the cannula will occur and was observed during the deployment/retraction experiments. The result of the deflection was that the stylet was never perfectly straightened (i.e. the cannula was never perfectly rigid). Furthermore, for a larger amount of clearance between the cannula and stylet diameters the stylet would have a smaller curvature when inside the cannula. Ultimately, these additional factors would affect the maximum deployment and retraction forces.

Previously, various groups have built image-guided medical robots for instrument alignment and insertion [9-11]. As was described earlier, groups are also developing systems that can actively steer needles inside the body using pre-curved needles [3-6] and our group has built another device based on this principal. The work in this paper will provide designers with tools for developing devices that utilize pre-curved needles as part of their design.

ACKNOWLEDGMENTS

The authors wish to express their sincere appreciation to Pierce Hayward for providing access to the oven for the heat treating and to Julio Guerrero for his feedback on the experimental testing protocol. Conor Walsh was supported by a Whitaker Health Sciences Fund Fellowship provided by MIT.

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