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A Novel End-Effector Design for Robotics in Image Guided Needle Procedures

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Abstract

Robotic end-effectors are being developed to facilitate image-guided minimally-invasive needle-based procedures such as tumor ablation, biopsy, thoracentesis, and blood sampling. A novel mechanical end-effector was designed to address the challenges associated with any major needle-based procedure, focusing on liver biopsy and ablation. In this end-effector embodiment, the distal end of a single articulating arm can grip needles and instruments and allow a fairly high number of degrees of freedom of movement during the complex motions associated with positioning and driving needles, as well as the periodic motions associated with breathing patterns. Tightening a cable that runs through the articulations fixes the arm in a rigid state, allowing insertion of the gripped needle. In its final form, we diagram a design that will require electro-mechanical stimulation and remote joystick control. Moreover, we discuss how cranial-caudal motion of soft tissue organs and the associated forces affect design constraints. A simulation protocol describes the use of tissue phantoms with mechanical properties in the range of hepatic tissue and the overlying abdominal wall. Finally, an in vivo protocol details the possible use of a robotic arm coupled with our end-effector in an image-guided interventional suite. Such a switchable and flexible mode for a robotic arm overcomes much of the current limitations for automated needle placements for mobile targets, subject to breathing or patient motion and the inherent risks thereof.

INTRODUCTION

Liver biopsies provide the level of specificity required to diagnose serious malignant hepatic ailments and their severity. A percutaneous liver biopsy is conducted through the skin into the liver. The categories of needles that are used in liver biopsies include: suction needles, cutting needles, and spring-loaded coring needles that have a triggering mechanism (Fig. 1). Bleeding incidents are related to the duration of needle placement in the liver and larger needle diameters (1). Sixty percent of complications follow approximately two hours post procedure and 96 percent follow within 24 hours post procedure (1). Continued, severe abdominal pain entails the possibility of a more serious complication, such as bleeding or peritonitis (inflammation of the membrane lining the walls of the abdominal cavity). Subclinical bleeding is present in up to 23% of cases, with hematomas visible on ultrasound within 24 hrs (2,3,4). The most serious bleeding complication of percutaneous liver biopsy is intraperitoneal hemorrhage (deep-seated abdominal bleeding outside organs). This usually becomes apparent within the first 2 to 3 hours after the procedure (1). The cranial-caudal motion of the liver during respiration is a likely instigator of bleeding and trauma to hepatic tissue, due to the additive periodic affect of the highly vascularized soft tissue organ interacting with the rigid shaft of a needle. Rigid needle end-effectors increase the risk of organ lacerations via a “stiff skewer effect.” The needle remains rigid during organ motion, subjecting the organ capsule to shear forces which may lacerate or traumatize the richly vascularized tissue.

Today, new robotics-based interventional strategies are being investigated and applied to liver biopsies and tumor ablations. The goal is not physician-intensive or robotics-intensive. Rather, it is physicians utilizing robots to promote accurate and efficient liver procedures. Because patients lie supine in nearly all CT imaging suites, where the CT modality is used to monitor the needle position in real time, robotic arms are likely to be mounted on the table or ceiling, or on a cranial-caudal moving stereo-tactical frame that may wrap around the body. These arms will possess articulations and ball and socket joints that allow bending and rotation in several different directions to accomplish tasks. Therefore, such arms will have multiple degrees of freedom.

NASA defines an end-effector as the gripping device that is located at the end of an arm and has an effect (such as grasping) on objects within its reach (5). For the abdomen, the object is the biopsy or ablation needle. In our view, the end-effector offers a chance to increase the overall degrees of freedom of the arm as a whole. Moreover, an end-effector with articulations and an ability to tense and relax could perhaps accommodate very well for motions of the liver associated with respiration. The actual gripper at the base of this extended end-effector will provide the means of grasping and releasing the biopsy needles, but the end-effector as a whole could be a part of a localized needle driving mechanism after gross approximate localization via alternate mechanism (remainder of arm). Ex vivo testing on bi-direction moving phantoms with tissue mimicking properties confirms the feasibility of our design. Future pre-clinical testing will involve CT image guided biopsies and ablations conducted on mechanically-ventilated pigs.

Design Methodology

An affective end-effector design is able to compensate with the cyclical nature of the forces associated with respiration. The forces that are exerted throughout the respiratory cycle cause shape alterations in soft tissues in the thorax and abdominal regions. Cranial-caudal shortening greater than 1 cm in length has been observed between CT models extracted from scans during breathing hold at exhale and at inhale states (6). For the initial design speculations, the liver is assumed to undergo small linear and elastic deformations in the cranial-caudal direction. The assumption is made that complex organ shift geometries and deformations are negligible.

Design Goals

Two different states of device activity are essential to the design analysis. The first state of activation details a rigid end-effector that drives a needle into a patient's liver. If the patient can hold their breath during the needle driving portion of the procedure; a simple algorithm would permit the physician to maneuver the needle to the point of entry via a coordinate grid. The needle would then enter the liver via a straight line trajectory from the surface entry point. This rigid state of activation must deal with a patient that cannot hold their breath. An algorithm which takes into account the sinusoidal nature of the respiratory cycle would then need to be devised. For our calculations, we assume 12 breaths per minute (or 0.20 breaths per second) and an amplitude of motion in the cranial-caudal direction as 10 mm (4). Assuming that no phase shift occurs and that the region of interest is displaced from a coordinate grid centered on the cranial-caudal axis, the following sinusoidal function would form the basis for an algorithm to drive a needle in a breathing patient:

$$y = 10 \sin [2\pi(0.20t)] \quad (\text{Equation 1})$$

where y is the distance along the cranial-caudal axis in millimeters and t is the time in seconds. The second state of activation is when the end-effector becomes flaccid, post-needle insertion. In the simplified bi-directional cranial-caudal model, two degrees of freedom are all that is required. However, the reality of the situation demands many more degrees of freedom. Better estimates of the number of degrees that are sufficient can be made by examining heavy

breathing scenarios. During heavy breathing, extra force is generated via contraction of abdominal muscles, which pushes the abdominal contents upward against the bottom of the diaphragm. Another method of expanding the lungs is to raise the rib cage. In their natural resting position, the ribs slant downward. The ribs project almost directly forward during elevation (9). Because of the complexities that have just been detailed, overcompensating by maximizing the numbers of degrees of freedom is recommended.

The muscles that dominate inspiration are the *external intercostals*. Conversely, the muscles that dominate expiration include the *abdominal recti* and the *internal intercostals*. The forces that are generated by these muscles have been gleaned from the linear envelopes of EMG signals. As seen in figure 2, the maximum amount of force that is generated by the *external intercostals* is approximately 100 N, and the maximum amount of force that is generated by the *abdominal recti* is approximately 40 N (8).

As seen in figure 3, in the flaccid state of activation, angular acceleration occurs because the torque (τ) applied by the forces associated with breathing (F_{BR}), in Newtons, on a needle of length (r), in meters, overcomes the torque associated with the tension of the end-effector's articulating arm. The latter torque is exerted in opposition to the former torque, and the pivot point is considered to lie at the center of the needle along the axis of the shaft. Each of the moment arms associated with the individual forces is then $r/2$. Therefore, the tension force exhibited in the flaccid state cannot produce a torque that exceeds or equals the torque that accompanies F_{BR} . The target tension range in the flaccid state is then, at most, 75% of the tension that would establish static equilibrium.

On the other hand, when rigidity is desired to hold the needle completely still, static equilibrium must be maintained and enough tension force must be generated in the articulating arm to counter the torque effects of F_{BR} . Once again, the pivot point is assumed to be at the center of the long axis of the needle. Allowing F_{BR} to equal 100 N permits an estimated target tension associated torque of $100 (r/2)$ N to be incorporated into the design goals (Fig. 4).

Activating the end-effector's rigid state could potentially result in tearing of hepatic tissue. An elastic modulus equivalent to 10 KPa was selected based on values used in previous studies of liver tissue properties (6). The associated ultimate tensile strength and shear strength for liver tissue are 24 KPa and 2200 KPa, respectively (9). In order to avoid permanent damage to liver tissue surrounding the needle, a feedback mechanism in the end-effector must guard against pressures in the cranial caudal direction exceeding 10 KPa. Control mechanisms that maintain a tension in the articulating portion of the end-effector would help to set a safe maximum tension during rigid mode operation.

End-Effector Design

The design is a robotic end-effector for driving needles during image guided biopsy procedures, in which a single articulating arm, with a needle gripper on its distal tip, tenses and relaxes based on electronic signals conveyed to it via operator instructions. The arm will be mounted on a stereo-tactic frame (Fig. 5). Fixing the arm is accomplished through tensioning of a single cable that runs through the articulations. The articulating arm on the end-effector is comprised of a series of ball and socket links. The links contain a hemispherical protrusion on their proximal ends, and hemispherical indentations on their distal ends. The shapes of the links are identical to promote smooth rotation against one another. The cable passes through the center of all the links and is connected between the tightening mechanism in the robotic arm and the needle gripper on the distal tip. Rotation of a triggering mechanism in the arm tightens the cable and forces the links to hold against one another in place.

The articulating arm portion will adapt to interface with a variety of grippers, and will not be designed at this point to interface with one specific gripper. However, solely for the purpose of constructing the prototype detailed here, the needle gripper segment of the end-effector was provided by Mondo-tronics Inc. This particular gripper includes rugged molded components and HS-300 servo motor for gripper open/close (Fig. 6). The gripper arms spread up to 3.3 cm (1.3 in). An operator can control the gripper via Mini SSC servo controller. Associated circuitry lets you control up to eight R/C servos via one serial line. Input at 2400 or 9600 baud from any PC, Mac, Stamp, et al is possible. Serial Motor Interfaces exists for compatible drivers that can be used for DC motors boards (10). The *Animatronics* software program allows easy writing, editing, and playback moves for up to 64 R/C servos. This is ideal for running any robot or system via a serial port and Mini SSCs. The software reads and writes "Access" data files so motion recording is limited only by hard disk space, or up to 2 billion moves (10).

At this juncture in treatment planning, CT guidance to locate the region of interest and place a needle coupled with ultrasound for real-time monitoring of a needle's location is common. As a result, materials that avoid introducing streak artifacts during CT scanning are preferred. Moreover, MR compatibility of materials would permit a greater range of operating environments. The articulations might then be produced from rigid plastics that can be laced with glass fiber or carbon re-enforcement to offer a material stiffness that compares with that of metal. Preferably, the cable running through the links should be made out of bundled stranded, or braided Kevlar™.

Standard, 6-axis stepper drive electronics are suggested as the means to automate a mechanical prototype for proof of concept testing (Fig. 7). The motor connections in this system use standard 9-conductor d-sub cables. Using stepper drive electronics makes low RFI/EMI stepper driver circuitry and linear power supplies available to controlling systems, and eliminates PWM circuitry scenarios. The interface to a PC occurs through measurement computing PCI-DIO24 & 37-conductor cable. Other power speculations include 110-120 or 220-240 VAC at 50-60Hz. Front panel switches for motor control allow manual control mechanisms access when PC based automation fails. A "disable" switch for emergency stopping facilitates safety control. The maximum speed of the system is approximately 1200 steps/second (11).

Angular positioning elements spread throughout the articulating joints would greatly aid preserving the degrees of freedom that are inherent in the mechanical design once electrical stimulation is introduced. Angular positioning elements would also be instituted within the joints of the robotic arm itself and at the interface between the end-effector and the robotic arm. Mechanical motion resolution of the desired angular positioning elements includes: a stepper motor driven, resolution of 7200 steps/revolution, or 20 steps/degree. Motion transmission occurs through toothed belts. Manual positioning can be accomplished via hand cranks and graduated dials for manual positioning. Motor system connections are made by 9-conductor d-sub cables (11).

Needle driving could be accomplished post-positioning either by the end-effector acting to drive the needle, or by the remainder of the arm driving the rigid end-effector gripping the needle to its target location. One way to develop the former approach would be to imbed an additional flexible mechanism inside the end-effector that would protrude via servo motors to drive the needle along the trajectory line toward the target point as close to the center of the target as possible. Three-dimensional sensing elements could be located on the tips of the cable and the driving mechanism to ascertain the needle position in real-time. Another driving solution is to use a linear actuator that utilizes a corkscrew motor. The screw is embedded inside an actuator that extends or contracts the needle based on the turning motion of the motor. Most likely, this mechanism would be a part of the gripper.

METHODOLOGY

In Vitro Protocol

An *in vitro* protocol must test the ability of the end-effector to adjust to cranial-caudal motion and not tear soft tissue. This objective can be accomplished with the mechanical prototype detailed in this paper. Also required are a motion simulator and a tissue phantom.

The arm is attached to a stereotactic frame that surrounds the motion simulator and allows access to the tissue phantom or bovine liver that is mounted on the simulator. The phantom could be produced from an agarose gel that is manipulated to simulate the mechanical properties of hepatic tissue, primarily Young's modulus and sheer modulus. The acoustic transparency of the gel will make it an ideal medium to observe any needle drag marks that disturb the matrix. The presence of ridges and imperfections that will be formed by the drag marks will reflect the ultrasound beam and show up on the image scans.

The motion of the simulator, and thus the phantom, will proceed according to equation 1 in a sinusoidal fashion. A target point will be chosen in the phantom, and various biopsy needles will be driven toward this point. An accuracy error measurement can be calculated based on the difference in distance from the target location and the actual needle location.

Another setup will involve driving the needle and then releasing the tension cable to induce the relaxed state. The motion simulator will then simulate respiration for a period of up to 30 minutes. The gel phantom will be monitored every 5 minutes visually and with ultrasound to determine if tearing caused by needle movement has occurred.

A third leg of the *in vitro* protocol will assess the degree to which artifacts plague CT scans that are produced when the end-effector is used in the scanning zone. A CT-compatible phantom with a tissue gel insert will be used to design a setup that mirrors the previous two *in vitro* setups that were detailed above. At this stage, the end-effector should be past the prototype stage and be made from the materials detailed in the design section of this investigation.

RESULTS (PRELIMINARY IN VITRO TESTS)

In a series of needle grips in both rigid and flexible modes, the end-effector grasped an 18 gauge, 15 cm long Chiba Biopsy needle inserted into a bovine liver that was moved in 10 mm increments in one direction (Figure 7). The needle was inserted so that approximately 6.3 cm remained between the surface of the liver and the gripped end. An axis of motion was setup on a platform that locked in place the frame to which the mechanical arm was attached. The position of the needle insertion point was marked as the origin on the axis of motion prior to any manual movement. Because the bovine hepatic tissue exhibited mechanical birefringence, the direction of motion that exhibited less resistance to motion of the needle barrel was chosen. If tearing did not occur in this direction along the liver's anatomy, then the results might be applicable in the other, more resistant, direction as well.

During operation in flexible mode (Figure 8a), the liver was moved in a single direction as far as 100 mm. The flaccid end-effector allowed the needle to move freely with the liver without exhibiting noticeable stretching on the liver surface as much as 40 mm along the axis. However, at 40 mm there was no visual evidence of tissue tearing at the surface. Monitoring the liver surface was a more effective indicator of the end-effector performance because the torque on the needle barrel was greater closer to the tip than at the surface. There was more resistance to motion along the needle barrel closer to the liver surface. Stretch marks perpendicular to the axis of motion became more pronounced as the liver was pushed closer to an endpoint of 100

mm (Figure 8b). There was still no evidence of tissue tearing at the endpoint. When the liver was returned to the origin, and the needle was removed, the surface dimpled slightly, indicating that the needle was slowly rising out of the liver as the distance from the origin increased (Figure 8c).

The end-effector was triggered to its rigid mode and the same procedure was conducted as in flaccid mode, but in this step the distance between the surface of the liver and the gripped end was carefully monitored to assess the magnitude of needle protrusion (Figure 8d). Operating during the rigid mode simulated current rigid end-effector designs that do not adjust for cranial-caudal motion of the liver during respiration. The endpoint was set at 40 mm. Stretch marks on the liver surface became evident when the liver was moved 20 mm. The magnitude of stretching was greater at points along the axis of motion during the rigid mode of operation relative to the flaccid mode (Figure 8e). When the liver was returned to the origin, 0.5 cm of tearing was observed on the liver's surface (Figure 8f). The needle barrel had also drifted outward approximately 20 mm as the liver was moved from the origin to the 40 mm endpoint confirming the dimpling phenomenon seen on the liver surface in step 1 was due to the needle being slowly pulled out of the liver tissue. The inherent tension provided by the end-effector itself is the likely cause of this drifting.

CONCLUSION

A needle-driving end-effector has been designed to interface with various robotics systems that will aid in automating liver biopsy and ablation procedures, or any needle based procedure like cryotherapy, brachytherapy, microwave ablation, or radiofrequency ablation. The end-effector apparatus will not only grip and drive the needles, but it will also permit two activation states, rigid mode and relaxed mode, to be used throughout the duration of the procedure. Actual needle driving and gripping will utilize the rigid activation state, where the articulating arm of the end-effector is locked to inhibit non-controlled movement. In the relaxed mode, the articulations along the length of the end-effector facilitate concurrent movement of the engaged needle with the liver along the cranial-caudal axis and many other axes that the liver travels on during respiration. Any shear tearing of the liver and other soft tissue due to the needle barrel will be eliminated because the end-effector will adjust its position in accordance with respiratory induced liver motion. Stepper motors and angular positioning elements will convert PC automated electrical signals to the desired mechanical motion. Physicians will benefit from end-effector facilitated advances because robotic elements will enhance procedure efficiency and overcome some of the bottlenecks and risks incumbent to current liver procedures. Such an end-effector could be interfaced with almost any needle driver whose needle might be subject to the risk of patient or organ motion. The end result should be safer, more efficient, and more comfortable procedure with better outcomes for patients.

A series of tests with a bovine liver sample indicate that the flaccid mode of operation can accommodate amplitudes of motion as great as 10 cm without any serious damage to the hepatic tissue. During rigid mode, the end-effector become taut enough to tear the hepatic tissue at a magnitude of motion of 40 mm, and may induce tearing at slightly smaller magnitudes. When the performances during the flaccid and rigid modes are compared, the effectiveness of the design's ability to accommodate soft tissue organ motion in a single direction indicates that the flexibility offered by the flaccid state of the end-effector effectively eliminates the tearing that could occur if a rigid needle-driving end-effector was used instead.

RECOMMENDATIONS

In Vivo Protocol

Once the *in vitro* protocols have enabled the investigators to optimize the efficiency of the design, testing on porcine models in a CT suite will follow. Because tumor tissue differs in its mechanical properties, hepatic tumor targets will be simulated. This will also establish geographic targets that can be visualized throughout the needle driving process.

Initial in vivo testing will image the pig with continuous CT to follow the exact needle path in time during insertion and breathing. The next phase will incorporate electromagnetic tracking for needle navigation and monitoring. Magnetically tracked needles coupled with ultrasound and CT guidance will allow precise needle location monitoring throughout active and relaxed end-effector device states. If magnetic tracking is utilized, two sensors will be embedded in the needle barrel; the first would rest in the tip, and the other, at the surface point of entry. This will control for torque effects manipulating the needle barrel farther from the tip with greater ease. Throughout the procedure, two parameters must be monitored: the ability of the end-effector to target and drive accurately and the amount of tearing (or absence of tearing) that occurs when the end-effector arm is relaxed. The coordinate-based information that is made available via the magnetically tracked needle and the pre-procedural and intra-procedural CT scans can be coupled with the visual feedback from the ultrasound images to assess the two parameters.

As robotics become more integrated into image guided therapies, there will emerge the need for engineering solutions to the rigid needle driver problem so that the sheer stress upon organ capsules is minimized for patient safety. We present one such solution that could be adapted to various robotic end effectors for patient safety.

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Figure 1.
Assorted Biopsy Needles (Left to Right) Coaxial core biopsy gun, Chiba cutting biopsy needle,
Lung biopsy set

Figure 2.
Force Generated by External Intercostal Muscles During Inspiration and Expiration (8).

Figure 3.
Analysis During Flaccid/Relaxed State of Activation to Allow Free Motion of Inserted Needle

Figure 4.
Analysis During Rigid State of Activation for Driving Needles or Holding them Steady

Figure 5.
Robotic Needle Driver with End-Effector on Stereotactic Frame

Figure 6.
Complete End-Effector Including Articulating Arm and Gripper

Figure 7.
Standard 3-Axis Stepper Driver Electronics (11)

Figure 8.

a (Upper Left): End-effector flaccid state, biopsy needle insertion at axis origin. **Figure 8b (Upper Middle):** Stretch marks appear across tissue field, perpendicular to motion axis at 50 mm from origin during flaccid state operation. **Figure 8c (Upper Right):** Dimpling on tissue surface due to needle barrel extrusion while liver is moved along axis of motion. **Figure 8d (Lower Left):** Rigid state, biopsy needle insertion at axis origin. **Figure 8e (Lower Middle):** Prominent Stretch marks appear as early as 20 mm from the origin during rigid state. **Figure 8f (Lower Right):** One-half centimeter hepatic tissue tearing apparent on liver surface during rigid state activation.

Figure 7.
In Vitro protocol setup using bovine liver and manual motion simulation. Amplitude is measured via tape.