A new method to gently place biopsy needles or treatment electrodes into tissues with high target precision

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1. Introduction

Currently, diagnosis of solid lesions, e.g. in the breast or prostate, is dependent on diagnostic tissue sampling procedures guaranteeing a representative cell- or tissue-sample. The most frequently used method is the core needle biopsy (CNB) technique with needles from approximately 1.2 mm to more than 3 mm outer diameter, equipped with a spring-loaded device to create inertia stabilization of the tissues during penetration. In order to get material which is representative of a specific lesion multiple shots are generally performed because the path and stop point cannot be exactly controlled at the substantial velocity used (in the order of 4–8 m/s). This highly traumatic multi-procedure results in a uniquely accurate and less traumatic procedure. Due to the risk of disseminating viable tumor cells the precision placement device can be combined with a computer controlled anti-seeding system, denaturing tumor cells detached during penetration of the biopsy needle or treatment electrode.

We present a new core needle biopsy and treatment electrode precision placement technique which, regardless of needle size, target lesion hardness and elasticity, makes it possible to precisely place an image guided device inside the abnormal tissue. Once inside the abnormal lesion, multiple tissue samples can be collected using a dedicated trocar and collecting system. Our unique “Fourier” driver substitutes the commonly used spring-loaded device or complements the jerky insertion technique used by experienced interventional physicians. It enables the physician to precisely and with extreme tactility maneuver even large diameter core needles or treatment-electrodes into the lesion using only a diminutive external force. This is achieved by applying supporting servo-controlled mechanical high-acceleration micro-pulses, proportional to the average vector directed by the physician. The Fourier-needle or Fourier-electrode stands completely non-moving when the system automatically goes into full idling. This means that the angle of attack successively and arbitrary can be aligned to hit the target, becoming successively symmetrically inserted into even small tumors to be treated as well as exactly hit any point outlined by real time ultrasound guiding. This kind of biopsy needle or treatment electrode placement results in a uniquely accurate and less traumatic procedure. Due to the risk of disseminating viable tumor cells the precision placement device can be combined with a computer controlled anti-seeding system, denaturing tumor cells detached during penetration of the biopsy needle or treatment electrode.

Abstract

We present a new core needle biopsy and treatment electrode precision placement technique which, regardless of needle size, target lesion hardness and elasticity, makes it possible to precisely place an image guided device inside the abnormal tissue. Once inside the abnormal lesion, multiple tissue samples can be collected using a dedicated trocar and collecting system. Our unique “Fourier” driver substitutes the commonly used spring-loaded device or complements the jerky insertion technique used by experienced interventional physicians. It enables the physician to precisely and with extreme tactility maneuver even large diameter core needles or treatment-electrodes into the lesion using only a diminutive external force. This is achieved by applying supporting servo-controlled mechanical high-acceleration micro-pulses, proportional to the average vector directed by the physician. The Fourier-needle or Fourier-electrode stands completely non-moving when the system automatically goes into full idling. This means that the angle of attack successively and arbitrary can be aligned to hit the target, becoming successively symmetrically inserted into even small tumors to be treated as well as exactly hit any point outlined by real time ultrasound guiding. This kind of biopsy needle or treatment electrode placement results in a uniquely accurate and less traumatic procedure. Due to the risk of disseminating viable tumor cells the precision placement device can be combined with a computer controlled anti-seeding system, denaturing tumor cells detached during penetration of the biopsy needle or treatment electrode.

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Currently, diagnosis of solid lesions, e.g. in the breast or prostate, is dependent on diagnostic tissue sampling procedures guaranteeing a representative cell- or tissue-sample. The most frequently used method is the core needle biopsy (CNB) technique with needles from approximately 1.2 mm to more than 3 mm outer diameter, equipped with a spring-loaded device to create inertia stabilization of the tissues during penetration. In order to get material which is representative of a specific lesion multiple shots are generally performed because the path and stop point cannot be exactly controlled at the substantial velocity used (in the order of 4–8 m/s). This highly traumatic multi-procedure - especially when using needles with more than 2 mm outer diameter is needed because of the lack of precise placement of the tissue sampling needle regarding each shot. The use of side-cut needles also forces the operator to penetrate smaller tumors all the way up to the rear side, which contribute to substantial cell displacement. The “Fourier” needle takes samples using a simple right-angled distal cut with no need of over-intercepting the tumor. Another important example of a serious medical problem is the exact placement of treatment electrodes used in palliative or curative radio frequency ablation treatment of metastatic (e.g. liver metastasis) or primary (e.g. breast cancer) malignancies. The general success rate of representative tissue sampling and RFA treatment is dependent on the possibility to place the tissue sampling needle or treatment electrode with supreme precision.

In the present paper we describe a new biopsy technique which can significantly improve lesion representative tissue sampling or local ablative treatment and at the same time reduce the extent of tissue destruction, inflammation and bleeding, in turn diminishing local and distant tumor cell dissemination. Initial results from studies in both experimental model devices and clinical applications
Preferential Radiofrequency Ablation (PRFA)

**Problem:** Some tumors are hard to penetrate with treatment electrode due to their fibrous structure

**Solution:** Power assisted insertion of electrode using *Fourier driver*

- *Fourier driver* enables for a power assisted insertion of the electrode when facing tumors that are hard to penetrate
- Tip design results in stable coupling between treatment electrode and *fourier driver*
- Tip on the back of the treatment electrode is long enough to stick out between sterile drapes

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**Fig. 1.** Demonstration of system precision on a melon seed.

**Fig. 2.** Preliminary method to connect micro-pulse driver to treatment electrode.

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application strongly indicate that this new biopsy and electrode treatment method, the so-called “Fourier method”, has the potential to revolutionize both CNB tissue sampling and electrode cancer treatment due to exact placement (see Figs. 1–3).

2. Method

Our work to test the addition of external mechanical and electrical energy to moving parts during in vivo insertions started with development, prototype production, ethical approval and clinical use of the CytoTest system. CytoTest used fine needle aspiration biopsy (FNAB) technique and a sinusoidal vibration in order to boost the penetration phase and to increase tissue harvesting. Clinical studies were successfully performed in 443 patients [8]. The transient and stationary frequency of the oscillation is of great importance for both penetration and sampling, using sinusoidal, i.e. in principal a single spectral-line in the frequency plane. For core biopsy needles and electrode insertions design conditions become more focused on the type of the moving device spectrum, where a fast-shifting square-wave basically adds up with inertia stabilization, i.e. not tending to push the tumor away, even if very calcified, fibrous and extremely elastically anchored, due to the high acceleration during consecutive short iterative limited distances, with a final speed in the order of 8 m/s. The impulse-like fast movement and the relatively long iterative variable a pause combines to make a near-ideal needle movement. Only some 50 mJ per stroke are needed to penetrate even the hardest tumor. Saw-tooth shape gives boosted penetration to the needle or electrode when passing them into tissues (however not through skin where a scalpel is used for an initial entrance due to the extreme elasticity of the skin). The treatment electrode or biopsy needle might be slowly-pushed through normal tissues to the level of a tumor. It is further possible to invert the wave-shape to become ramp-shaped, so the retraction phases instead become facilitated. Initially we developed a test system that could easily drill a hole into a walnut or objects with similar structure, even when a spherically rounded tip was used (diameter for instance 4 mm) and transport the nut all along the needle length, driven by the interchange from interacting static friction and acceleration pulses. By inverting the wave-shape, the nut would be transported back to the tip again. By further lowering the bound rise-time even high viscous silicon rubber spheres or even a soft wood-piece could be manipulated in the same way. In dry materials accumulated friction-heat might rise due to almost no cooling. Initially we generated the wave-shape or vibration by using three excenter-wheels journaled on bearings mounted on a pivot-bar in turn connected to the needle. The wheels were driven with identical rotation speed, but having different diameters, i.e. frequencies. We know from computer-simulations on trigonometric series type (saw-tooth): $2\sin(x/1) - \sin(2x/2) + \sin(3x/3) \ldots \sin(nx/n)$, that even when a considerable amount of Gibbs phenomenon (a ripple) will be present when series were not infinite. A contribution number as low as 3 gave a well usable result. Later the driver was exchanged to a computer controlled light-weight pneumatic system made insensitive to the direction of the gravitation field and accelerations due to handpiece movements. We also applied a simple servo system that made both the amplitude and the pause time functions controlled by the operators applied average inserting-force. The minimum movement was adjusted to give a diminutive but non-reversible tissue effect, however movements completely stopped when force zeroed. Typical total energy distribution during electrode placement is in the order of 25 kJ, where the precision insertion takes some 5%, anti-seeding 15% and the tumor destruction 80%.

3. Discussion

Using square-wave like pulses means that inertia stabilization will act on both insertion and retraction, while saw-tooth shape will act only on insertion as will ramp-shape on retraction. For minor invasive procedures as CNB tissue sampling or heat treatment...
electrode positioning, the herein described Fourier technique is probably the most lenient and patient friendly procedure. Because of the fact that precision placement of the core biopsy needle or the treatment electrode requires only one single insertion, the extent of tissue trauma and thus tumor cell dissemination is significantly reduced. Using Fourier-biopsy needles or Fourier-electrodes equipped with our anti-seeding device [8] makes it possible to further increase patient safety by denaturizing detached tumor cells in the tissue penetrance channel braking both local and distant cancer cell spread. It is important to design a system so there will be only a low amount of transversal oscillations in the needle. The acoustic propagation velocity in steel is approx. 5000 m/s but even longitudinal speed in thin steel tubes will be many times lower. Due to the needle or electrode type used the system computer can match selected driver responses to avoid resonances. Also patient tissue will significantly load system and damp oscillation tendencies as soon as the needle tip or electrode has started to penetrate. It is important to monitor needle signatures in order to safely protect against metal fatigue fractures or electrode overload including internal electrode parts such as thermo-couples. Even elastography has been proposed and might be valuable using the needle to excite tissues including tumor structure and ultrasound scanner for detection and analysis. In case of non-linear carbonizing tendencies during high-power RFA procedures electrode vibration pulses might increase possible current density and maximize lesion size, homogeneity and quality.

4. Conclusion

Precision placement of biopsy needles or treatment electrodes is decisive for sampling of representative tissue and for successful heat treatment of tumors. The herein described Fourier technique for the first time makes it possible to guarantee this indispensability.

Clinical approvals

Swedish Medical Product Agency has not found impediment for this clinical activity, Dnr: 461:2010/503820. Human ethical approval; Anti-Seeding 446/04, 1280-31/1, 03-416 PRFA-treatment 03-389, 1280-31/1, 685-23, 1372-32, 1512-32, 03-416.

Conflict of interest statement

The authors in this study are also interested in bringing the heat treatment into clinical routine use.

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References