Actuated, flexible and dynamically changeable surface textures for medical instruments

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INTRODUCTION

Certain medical devices such as deep brain stimulation (DBS) probes need to be implanted with high precision (few millimeters to um) relative to particular parts of an organ, nerves or blood vessel and, in addition, need to reside at a minute distinct position over a long period. Hence surface modifications of medical devices and implants are desirable which facilitate an increase of friction between device and tissue so that unintentional migration of the device can be reduced. However, for the positioning of the implant during operation, a smooth surface is needed so that it can easily be maneuvered through the tissue until it is in the correct position. Consequently a surgeon would like to have implants with surfaces which can be flexibly and dynamically changed by a simple actuation mechanism during operation. The challenge here is – in particular for minimally invasive surgery - that the actuators require small dimensions (µm-size) for various reasons: a) to fit on small implants, b) to create minimal damage to the surrounding tissue, and c) still to fulfill the purpose of reducing the implant's slippage when fully implanted. Our previous experiments [1] with fixed and static surface structures of a feature size in the range of 10µm to 500µm indicated already some reduction of probe migration in cadaverous pig brain which was subjected to a rotational motion for simulating a brain shift. Using a novel probe design, we demonstrate a dynamically changeable surface texture of similar flexible microstructures and present current results of tests conducted on artificial brain models.

MATERIALS AND METHODS

Test prototypes with actuated, flexible and dynamically changeable surface were fabricated onto platforms which emulates DBS electrode probes. The surface texture can undeniably also be applied to any other form of medical device such as cochlea implants in the inner ear.

The prototypes are intended for tests on artificial brain models (agar gel) to prove the concept that microactuators can alter surface properties and texture on demand so that slippage of the medical implants can be reduce and minimized when required.

A) Probe manufacturing with changeable surface A variety of novel test probes were built using different substrate materials such as silicon (Si), epoxy-base photoresist, or a medical grade silicone polydimethylsiloxane (PDMS). The flexible surface microstructures were fabricated from various layers of polyimide and metal. A Ti/Au metal layer was predominately used as stimulation electrode and for the electrical circuit to actuate the surface texture. A standard bi-layer lift-off process with LOR and JSR photo resist was applied for structuring these electrodes, which is a commonly used process in microelectronics or for fabrication of micro-electro-mechanical systems (MEMS) [2]. The surface texture and microactuators were structured by photolithography and dry etching techniques. For prototypes on Si, final probes were diced from the Si wafer in a shape of a needle (17.5 mm long, 9 mm or 1.3 mm wide, and 0.5 mm thick). The top end of each needle has a triangular tip with integrated stimulation electrodes; the bottom end of such needle is flat and contains contact pads for the electrical circuit of the actuators. Test probes based on epoxy-substrates or PDMS structures have similar dimensions and design apart from the thickness of the needle, which was approx. 0.25 mm. These types of probes do not need to be diced because their shape was defined for instance by photo- lithography and subsequently separated together with the surface texture from a Si wafer by wet chemical etching. A typical detail of a probe with texture on epoxy-based material is shown in Fig. 1. For testing purpose, prototype probes were glued to printed circuit boards (PCB) and the probe's contact pads were wire bonded to the PCB. A connector for a cable to a power supply and controller for the actuator was mounted on the opposite end of the PCB (Fig.2). The surface texture of the probe consists of microstructures, which protrude from the probe surface by up to 150 µm in default setting. When actuated, these structures retract and create a smooth surface. The length of actuators ranges from 200 µm to 400 µm and

typical actuator size of 200 µm was chosen. *B) Friction / gripping force measurement*

An experimental set-up with a variable inclined plane (Fig. 3) is used to test the friction between probes and

arrays of such structures are systematically distributed

across the surface of the probe. For initial tests on brain

models of agar gel, a textured probe on Si substrate with

agar gel while the texture of the probe is either protruding or flattened by the actuation mechanism. The inclination of the plane was increased so that the probe moves out of the agar gel under its own weight (15g). The rig was elevated using a mechanism of a linear bearing run by the DC motor with a slow angular velocity of 0.55 degree/s to avoid any vibration to the probe. The angle of elevation was recorded until the probe has fully slipped out of the agar gel and the required force was calculated from the degree of angulation and weight accordingly. Experiments were repeated several times and averaged. For calibration purpose, the slip angle was also recorded for the same sample which was not inserted into the agar gel.

RESULTS

The results obtained from a probe with 200μ m-long actuators showed that the sample was capable to hold on to the agar gel (tissue) up to a weight force equivalent of 2.34g and 4.70g for a flat and protruded surface texture, respectively. Hence a significant difference of friction was noticed between conditions with deployed texture and actuated flat surface (table 1). Similar but smaller differences were also observed for other samples.

Table 1: The summary results obtained from inclination test of probe with $200 - \mu m$ textured.

200μm Probe	Angle	SD	Force
	(°)	(°)	(gram force)
Calibration	18.43	0.68	4.74
Flat surface	28.15	3.78	2.34
Deployed surface	39.03	4.21	4.70

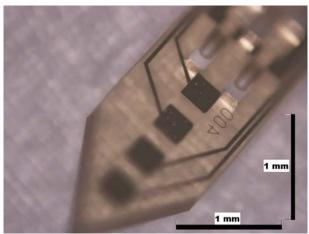


Fig. 1 Detail of test DBS probe on epoxy-based material with pointed top and 4 stimulation electrodes; surface actuators for changeable texture are visible behind those electrodes.

DISCUSSION

This experiment was designed to measure the required force to retract the sample from the brain model (agar gel). The results are promising and indicate that an anchoring effect to surrounding tissue is increased while the flexible texture of the probe is deployed. Because the elastic properties of agar gel are similar to brain tissue, we assume that the actuation mechanism and

flexible texture is suitable for DBS probes to reduce probe migration. A flatter texture creates less friction with tissue so that this is well suited for positioning the probe at target location during minimally invasive implantation. However, this assumption requires more repeatable experiments performed with different sizes and geometries of probe actuators and texture.

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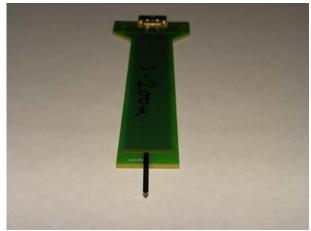


Fig. 2 Test DBS probe with dynamical changeable surface texture mounted onto a PCB with connector at the back.

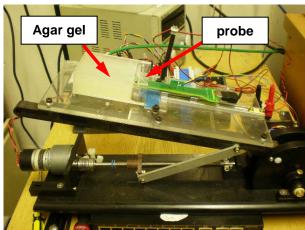


Fig. 3 Test set-up with variable 'inclined plane' using sample from Fig.2.