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Sapphire Smart Scalpel

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Abstract—A new type of surgical instruments—sapphire scalpel with an opportunity of simultaneous resection and fluorescent diagnostics of a resected tissue state close to the cutting edge, allowing the surgeon to differ between the cancerous and normal tissues during operation—has been developed.

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Success of operation is conditioned on the one hand by surgeon's skills and, on the other hand, by the instrumentation capabilities. Currently the studies aimed at searching for new materials for scalpel and optimizing its cutting edge and on expansion of scalpel functional capabilities that can provide additional information on the state of dissected tissue are under way.

One of the most promising materials for fiber surgical scalpels is sapphire because of its unique combination of optical and mechanical properties. Sapphire has a wide optical transmission band, high melting temperature, good thermal conductivity, strength, chemical inertness, and bio-compatibility [1]. Sapphire scalpels substantially exceed those made of special medical steels. High sapphire hardness provides a scalpel cutting edge with a rounding radius of 25 nm (for comparison: the rounding radius of metal scalpel edge is 500 nm), which substantially decreases the tissue damage at resection and reduces the post-operation rehabilitation period [2]. Sapphire edges have a higher stable cutting edge, longer service life, and low friction coefficient; they can also sustain repeated sterilization of any type without risk of changing edge geometry. Sapphire scalpels have also a number of advantages in comparison with nonmetal instruments. They are much less expensive than diamond scalpels [3] and are not limited in size to be used only in microsurgery. As compared to ceramic ones [4, 5], sapphire scalpels have a cutting edge rounding of smaller radius and optically transparent edge. The edge transparency makes it possible to supply laser radiation directly to the resection zone not only to enlighten it and improve visualization of blood vessels and other structures [6] but also to affect in various ways the tissues during operation [7].

The work on expansion of scalpel functional capabilities is carried out in two ways: to ensure capability of detecting possible deviations of biotissue "mechanical" parameters by miniature (temperature, pressure, etc.) sensors built in the edge [8–10] and to develop optical diagnostics systems. In particular, to determine the degree of tissue malignancy, a system using a semiconductor laser has been developed; blood microsamples taken from the dissection area are introduced into the space between its mirrors [11]. The principle of its operation is based on the analysis of the eigenfrequency shift for a cavity with a test and change in the amplitude of radiation from the cavity; such an analysis allows one to estimate the protein content in the test, which differs in healthy and cancerous cells. One of the main disadvantages of this diagnostic system is the extremely low operation speed: it processes an area of 1 cm^2 for 1 h.

We propose here a radically new type of surgical instruments: scalpels with an opportunity of simultaneous resection, laser photodynamic impact on the biotissues adjacent to the edge, and fluorescent diagnostics of the dissected tissue state near the cutting edge directly during surgical operation on resection of malignant tumor. The principle of fluorescent diagnostics is based on the capacity of dyes (photosensitizers selectively accumulated in malignant tissue) introduced into the body to effectively absorb laser radiation in a certain spectral range and emit some part of absorbed energy (fluoresce) [12]. Measuring the parameters of this radiation, one can carry out spectral fluorescent diagnostics and draw conclusions about the presence of cancerous cells in the tissue.

The principle of the new diagnostic system is based on the use of sapphire edge with isolated channels, whose end faces are in the immediate vicinity of the scalpel cutting edge (Fig. 1). The channels contain optical quartz fibers, one of which is for supplying fluorescence exciting radiation or coagulation radiation to the tissue dissection region, while the other fiber (or fibers if there are more than two channels) are for transmitting fluorescence radiation from the dissection region to the spectrometer for fluorescent diagnostics in this region.

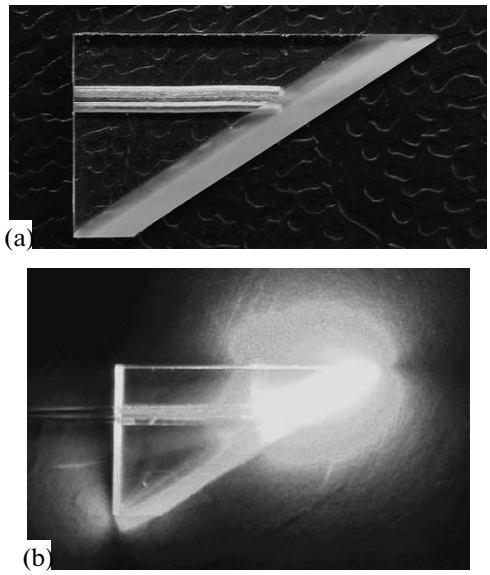

Fig. 1. (a) Appearance of the edge of the laser-spectroscopic scalpel made of sapphire ribbon with capillary channels with an internal diameter of 0.5 mm and (b) the formation of maximum laser radiation density in the resection zone.

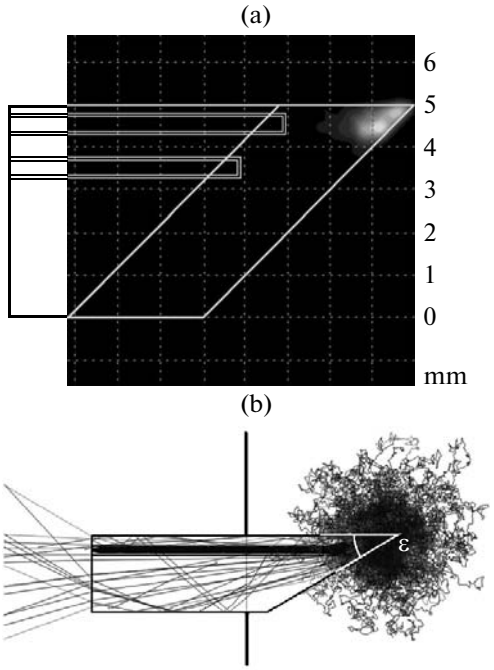

Fig. 2. (a) Calculated light distribution on the inclined edge face near the cutting edge and (b) modeled ray paths in a tissue with optical characteristics of liver (edge height 5 mm, distance between capillary channels 2 mm).

To obtain a diagnostic scalpel of minimum thickness, sapphire ribbons with capillary channels 500 μm in diameter (this value permits location of standard quartz fibers 400 μm in diameter in the channels) were grown. The formation and maintenance of channels of such diameter (close in size to the melt meniscus height) in the sapphire ribbon requires, first of all, to prevent channels from collapsing during growth due to the increase in the Laplace pressure in the meniscus with a decrease in the average curvature radius of the meniscus surface (decrease in the channel diameter) and with an increase in the meniscus height, which excludes supercooling at the crystallization front and, consequently, yields a high-quality ribbon.

The problem was solved by not only optimizing the growth rates and temperature modes in the crystallization zone but also using new approaches to the shaper design and the system controlling the crystallization front state. Various shaper versions have been developed to provide optimal temperature distribution in the crystallization zone area due to the difference in the relative heights of shaper working end face in the zone of capillary channel and ribbon perimeter. Extra opportunities (change in the pressure above the shaper channel-forming hole) were also used to form and maintain the channel size, which made it possible to control the channel collapse and repeated formation in the ribbon bulk.

Sapphire ribbons with capillary channels 500 μm in diameter (spaced by a distance of 500 μm) were grown by the EFG (edge-defined film-fed growth) Stepanov method in an induction heating facility with weight sensor control. Figure 1a shows the edge obtained by mechanical treatment of this ribbon.

A conical light beam with a divergence angle of 10°–30° emerges from the optical fiber located in the sapphire edge channel and is incident on the channel end surface, completely (except for the Fresnel loss) passing through the interface. When passing through sapphire, all rays are incident on the oblique edge planes. Then the edge operates as an optical wedge. In other words, after several complete internal reflections at the sapphire–biotissue interface, the angle of incidence of each ray becomes less than the critical angle for these two materials (sapphire and biotissue) and each subswquent rereflection increases the energy emerging from the crystal edge. Thus, two zones of high radiation density are formed at both oblique edge faces near the cutting edge, which is proved by modeling the optical ray pass (Fig. 2a). All rays supplied by optical fiber directly to the cutting edge region are involved in the formation of these zones.

The distal ends of optical fibers are located near the cutting edge; this arrangement makes it possible to capture the fluorescence from adjacent tissues by the detecting fiber in amounts sufficient for spectral diagnostics with photosensitizers.

The radiation density used for fluorescent diagnostics varies from several units to 30 mW/cm^2. For most soft tissues this energy is dissipated mainly within a tissue volume of 2 mm^3 of biological. Therefore, infor-

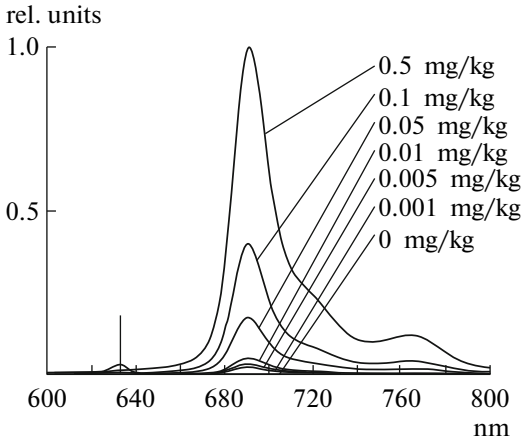

Fig. 3. Fluorescence spectra obtained with a sapphire scalpel for different photosensitizer concentrations in gel.

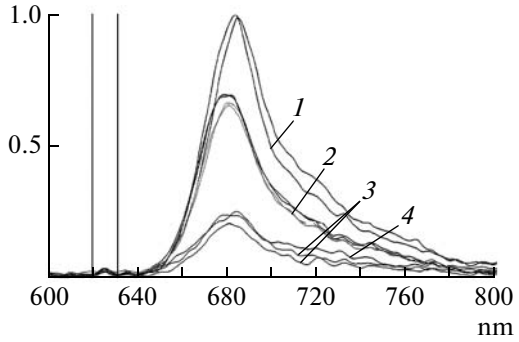

Fig. 4. Fluorescence spectra obtained at mouse tumor resection by the new sapphire scalpel with spectral diagnostics control by the Photosense photosensitizer with the edge position (*1*) outside and (*2*) inside the tumor (the tumor is under the skin), (*3*) in the healthy muscle, and (*4*) the control measurement for human arm (tissue norm).

mation on the photosensitizer concentration in tissue can be obtained for this volume.

Modeling and statistic calculation (by the Monte Carlo method) of the optical system showed that, due to the high degree of radiation dissipation by tissues, the light field form in the tissue is independent of the angle between the fiber axis and the edge (edge inclination angle); it is close to spherical and is formed on the fiber axis continuation in the tissue $\omega = 90°$), shifting with a decrease in the edge inclination angle ω by several tenths of a millimeter upward from the edge: up to 0.6 mm at $\omega = 30°$ (Fig. 2b). An increase of the distance between the fibers leads to a decrease in the number of signal photons entering the diagnostic fiber, which negatively affects the sensitivity of the system.

The edge channel for the irradiating fiber should be located so as to form the light field from the irradiating fiber primarily in the vicinity of the inserted part of the edge. The channels for the irradiating and diagnostic fibers must be parallel and located spaced by a minimum distance.

We experimentally tested the sapphire smart scalpel based on the sapphire edge with an inclination angle of 30° and a small distance between the channel axes: 0.8 mm (Fig. 1). The smart scalpel sensitivity to the concentration of trisulfophthalocyanine hydroxyaluminum photosensitizer ("Photosens") in the model medium was evaluated. To this end, a weakly scattering gel with a photosensitizer concentration compatible with therapeutical (5 mg/kg of aluminum phthalocyanine) or lower was prepared. The data obtained were processed using laser fiber spectroanalyzer (LECA-01-Biospek).

The data obtained with the sapphire smart scalpel on gel samples were compared with the data of video fluorescent diagnostic system (Biospek) for the same samples. The sensitivity of the system based on the sapphire scalpel allows one to measure Photosense concentrations of about 0.001 mg/kg, which is smaller by a factor of 5000 than the average therapeutical doze (Fig. 3). Such a sensitivity cannot be obtained with a video fluorescent diagnostic system (Biospek).

The scalpels developed were tested in experiments on mice with interwoven intramuscular tumor (Erlich carcinoma). A day prior to the operation Photosense photosensitizer was injected to each mouse in a dose of 5 mg/kg. A cw 50 mW semiconductor laser with a wavelength of 633 nm was used. The fluorescence spectra obtained during scalpel resection show that the maximum fluorescence intensity captured by the edge in the malignant tumor exceeds the maximum fluorescence intensity for a healthy tissue by a factor of more than 3 (Fig. 4). Such measurements, processing, and analysis of real-time data (continuous monitoring) allow a surgeon to distinguish between cancerous and healthy tissues directly during surgical operation on malignant tumor resection.

CONCLUSIONS

Based on the technique for growing sapphire ribbons with capillary channels, a radically new type of surgical instruments has been developed: scalpels for simultaneous resection and fluorescent diagnostics of dissected tissue state near the cutting edge, which allows a surgeon to differ between cancerous and normal tissues directly during operation. The system based on the sapphire edge with integrated optical fibers, irradiating and diagnostic ones, has demonstrated a high spectrometric sensitivity in experiments with models (gels); this parameter is well compared with the fluorescent diagnostics systems for malignant diseases. The cutting edge with a small rounding radius, whose faces form an optical wedge, serves also to efficiently accumulate light energy from the emitting fiber in the edge channel in the local area of pri-

mary (initial) tissue dissection for photodynamic impact or coagulation.

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