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Fiber photo-catheters for laser treatment of atrial fibrillation

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Abstract

A fiber photo-catheter has been developed for surgical treatment of atrial fibrillation with laser radiation. Atrial fibrillation (AF) is a heart rhythm abnormality that involves irregular and rapid heartbeats. Recent studies demonstrate the superiority of treating AF disease with optical radiation of the near infrared region. To produce long continuous transmural lesions, solid-state lasers and laser diodes, along with end-emitting fiber catheters, have been used experimentally. The absence of side-emitting flexible catheters with the ability to produce long continuous lesions limits the further development of this technology. In this research, a prototype of an optical catheter, consisting of a flexible 10-cm fiber diffuser has been used to make continuous photocoagulation lesions for effective maze procedure treatments. The system also includes: a flexible optical reflector; a series of openings for rapid self-attachment to the tissue; and an optional closed-loop irrigating chamber with circulating saline to cool the optical diffuser and irrigate the tissue.

Keywords

Atrial Fibrillation Treatment; Fiber Diffuser; Photo-Catheter; Laser Surgery

1. Introduction

In recent years, laser and optical fiber technologies have grown to become increasingly important in the medical instrumentation market. Procedures such as cancer treatments, cosmetology, skin treatment, laser acupuncture, and surgery have benefited greatly from the use of red, near IR and middle IR radiation. Optical fiber technologies can be used for power delivery, to act as sensors, and as multifunctional devices, controlling the laser's radiation and the transfer and processing of data. Unfortunately, the currently available optical energy delivery devices are limited in their effectiveness because their inherently large illumination areas can cause tissue damage outside the desired treatment area. Also, the large bend radii of

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currently available devices prevent them from being used in some endoscopic and cardiovascular applications [1]. The solution to this is to create a miniature, flexible probe of relatively long length, which can precisely deliver a narrow strip of light and can be operated with different light sources. Such a device would have a wide range of uses, including therapeutic applications such as irradiation of the brain [2] or the liver [3].

In this paper, we present a novel catheter based on a flexible side-emitting optical fiber that can be used for making continuous photocoagulation lesions for effective maze procedure treatments. This innovative, side-emitting, fiber optic, high-energy delivery platform uniformly emits optical energy over its entire 10-cm length. Long Period Gratings (LPGs) imprinted in the multimode optical fiber provide the basis for the technology behind this proposed catheter.

LPGs are induced periodic changes in the refractive index of optical fibers. The period of these induced changes is many times higher than the wavelength of the light in the fiber [4,5]. These gratings couple light effectively from the core mode to the cladding modes. The general view of the mode envelope and exact spectral positions of the mode lines depend on the parameters of the fiber and the LPG. LPGs have applications as strain, bend, temperature, and refractive index change sensors [6–8]; light diffusers for medical applications [9]; and chemical sensors [10,11]. Hence, a fiber with an LPG may be used to monitor a patient's temperature and pulse, and could potentially be used to analyze the patient's blood chemical content levels. Therefore this technology has the potential to be a “universal” multifunctional catheter that can be used both as a surgical instrument, and as a patient monitoring device.

2. Atrial Fibrillation Problem

During atrial fibrillation (AF), rapid and irregular electrical impulses cause erratic and incomplete activation of the atria, which in turn leads to the loss of normal sinus rhythm. Over time this condition can contribute significantly to the likelihood of cardiovascular disorders and even death. Each year, a considerable amount of money is spent on the diagnosis and treatment of this disorder. The surgical maze procedure was the first treatment that offered a permanent solution for maintaining a normal sinus rhythm in patients with AF [12,13]. This procedure involves the creation of a maze-like series of incisions in the left atrium, resulting in isolation of the pulmonary vein and removal of the left atrial appendage. The scarring resulting from the incisions permanently blocks the path of the erratic electrical impulses, thereby eradicating the arrhythmia.

To simplify the procedure, make it less time-consuming, and in some cases to make it less invasive by eliminating the need for cardiopulmonary bypass, a so-called partial maze procedure has been developed [13]. Further improvements have been achieved by replacing the traditional scalpel-performed incisions with thermoablative, cryoablative lesions formed by alternative energy sources such as radiofrequency, cryotherapy, microwave, and ultrasound.

In current practice, a radio frequency probe or cryoprobe is used to create rings of scar tissue around each of the four pulmonary veins: around the left atrial appendage, around the mitral valve annulus, along the route of the coronary sinus (which carries blood back to the heart from the cardiac veins), and along a line connecting the pulmonary veins and the mitral valve annulus. This effectively isolates the sources of the chaotic electrical signals.

Many studies have extensively investigated the use of lasers for cardiac ablation and have shown them to be a promising alternative to RF and microwave energy sources for creating deep, continuous transmural lesions. However, in the majority of these studies, the optical fiber was oriented normal to the tissue's surface, and the radiation was delivered through the fiber's tip. This configuration produces high irradiance near the output end of the fiber, which increases

the probability of tissue vaporization, creates a char layer that decreases the probe's depth of penetration, and can even result in fiber damage.

Furthermore, to produce a continuous linear lesion, such a probe must be drawn along the tissue's surface, which is highly undesirable in a transcatheter ablation procedure. To avoid these problems, it is necessary to develop a light source that will create a deep homogeneous, electrophysiologically inactive scar with a controllable lesion size, and a clear-cut lesion border in a single application. In this paper, we describe the development of such a catheter able to complete the aforementioned tasks.

3. Long Period Grating Technology

In general the problem may be summarized as: It is necessary to create a flexible, thin, up to 10 cm long, light source. It should provide constant intensity along the source and be focused onto the tissue with up to 1W/cm linear light power density. All tasks were successfully resolved:

- A 10-cm long diffuser was fabricated in a multimode fiber, using a fiber Long Period Grating (LPG) technology;
- The fiber catheter body was cast from high-temperature rubber silicone, and was then gold-coated to form a reflector;
- The fiber catheter end had a cooler-reflector that dissipated excess heat, kept the fiber mechanically sound, and improved the optical homogeneity of radiation near the fiber end.

Fig.1 shows an outline of the catheter design, and Fig.2 shows a 3D image of the catheter. A photograph of the first prototype is shown in Fig.3. As the development of the catheter proceeds, the most challenging part, the fabrication of the 10-cm long side-emitting diffuser, has been completed. Our technical approach, and the optical characteristics of this design are discussed in the following sections.

Our application is based on LPG technology [4,14]. The gratings were written into the multimode optical fibers. These gratings produce a refractive-index modulation at the fiber core-cladding interface that disrupts the total internal reflection in the fiber core, and enables the light traveling the fiber to be scattered sideways. Typically the LPGs have a period many times higher than the light wavelength in the fiber [14]. These gratings are very effective at coupling light from the core mode to the cladding and out modes. For the single-mode fiber, the wavelengths of the coupled modes are primarily determined by the period of the refractive index modulations. As the period increases, the resonant wavelengths also increase, as does the spacing between them. In a multimode fiber, the overlapping of several grating spectra results in continuous, cladding mode spectra. Moreover, for fibers with a high numerical aperture, multiple reflections on the grating quickly result in an increase of the propagation angle to a value higher than the critical angle, and radiation leaves the diffuser. Non-resonant LPG technology is used to create scattering centers within the fiber. By varying the refractive index modulation value, density, and period of the gratings, it is possible to control the energy scattered along the entire length of the fiber.

For constant longitudinal radiant emission, the remaining power inside the fiber core decreases linearly with a corresponding increase in the strength of scattering as a function of the length of the grating. The local transmittance of each diffuser segment falls exponentially, reaching a minimum at the diffuser's end. The minimal local transmittance dictates diffuser parameters such as the minimal length of a uniform diffuser, and uniformity of the longitudinal emittance. An example of the theoretical distribution of the transmittance "density" along the

diffuser is shown in Fig.4. To rapidly terminate the radiation near the fiber end, a large increase in diffuser efficiency is necessary. Some transmittance variations may be introduced at the end if certain residual power is provided at the output fiber end.

Two obstacles are in the way of successful diffuser recording. Firstly, as for any optical material, fused silica has a limited range of possible changes of the refractive index under UV irradiation. For a long diffuser it might not be enough to provide the same scattering strength along the whole diffuser. Secondly, refractive index changes are nonlinear versus the exposure dose of radiation. With relatively high laser pulse intensity instability, it is practically impossible to predict an advance protocol of exposure variations, providing a smooth and desirable profile of scattering along the diffuser.

4. Diffuser Experimental Parameters

Diffusers with an effective length of 50–100 mm were produced, enabling the irradiation of long tissue structures [15]. Uncoated fibers show periodic scattering centers, from which light is coupled out of the core, mostly into the cladding. A germanium-doped 200- μm core fiber with a 20- μm cladding and a polyamide buffer, and a 400- μm core fiber with a 40- μm cladding and Tefzel buffer silica-silica, both with a numerical aperture (NA) of 0.37 (Ceramoptec GmbH, Siemens str. 44, 52121, Bonn, Germany) were used in these experiments. Before recording the grating, 2.5-m sections of the fiber were prepared and placed into a chamber filled with 100% hydrogen at 100-atm pressure for several days. Following hydrogen loading, the fibers were stored (for less than 2 weeks) at -60°C until use. Before exposure, the buffer was chemically or mechanically removed for a length of 1 cm greater than the intended diffuser length. A periodic scattering structure was written into the fiber using 10-ns pulses from a KrF excimer laser, emitting at 248 nm. The fiber was irradiated through an amplitude mask, and the radiant exposure on the fiber during the pulse was as high as $8.5 \text{ J}\cdot\text{cm}^{-2}$. To monitor the transmission losses of the fiber on line during grating writing, we coupled a pilot laser into the fiber and used a photodiode at its distal end to monitor the transmission [1]. Transmission monitoring was used to achieve a predetermined longitudinal emission. After writing the long-period grating we applied a protective acrylic-polyurethane coating (Dymax Corporation, Torrington, CT) containing TiO_2 (5% by volume; Sigma Aldrich, St. Louis, MO) to obtain a final outer diameter of 250 μm . Curing was achieved over 15 min with a NovaCure UV light source.

Fig.5 shows an example of the longitudinal emission of a fiber with a 10-cm length and 400- μm -core diameter. For the 200- μm core fiber, there were no peculiarities in the longitudinal distribution of the scattered light intensity. A goniometer [1] was used to test the polar (circumferential) and azimuth radiance emission of the diffusers. As anticipated for a Lambertian emitter, the emission was angular independent. Further randomization of the light emission was achieved via the second mechanism of light scattering (i.e., the titanium dioxide (TiO_2) contained within the coating). This second light scattering provided for Lambertian emission, and since the TiO_2 particles are small enough to act as a Rayleigh scatterer, the directional randomization by multiple scatterings was sufficient over the entire wavelength range of interest (600–1064 nm) for the intended clinical applications [16].

5. Problem of the “End Hat”

When an optical diffuser is used as a photo-catheter, serious problems appear. The residual radiation at the output fiber end may cause the vaporization of, or damage to, adjacent tissue. If the output power achieves ~5% of the input power, which is around 80W, and the diffuser core diameter is 200 μm , the output radiation density is $\sim 12.7 \text{ kW}/\text{cm}^2$. One well-known method for producing radiation reflection inside the fiber involves the creation of Bragg gratings in the fiber core. This method can only be applied effectively to single-mode fibers. Reflecting the

optical power back into the diffuser remains a practical option, provided that the effects on the longitudinal radiance emission are considered when the desired emission profile is calculated. Fig.5 illustrates that placing a distal mirror on the longitudinal emission of a cylindrical diffuser results in increased emission intensity at the distal end. Conversely, this increased emission intensity can be exploited to achieve higher emission, without the need to go to low elementary transparency at the distal end of the diffuser.

From a simple design point of view, the simplest and best technology for providing beam retro-reflection is to place a dielectric multi-layer deposition on the polished end of the optical fiber. Since the deposited surface is very small, the long term stability and optical strength of the layers is questionable. Dielectric film deposition is, however, quite appropriate for mass production. Besides the previously mentioned coatings, retro-reflection could be achieved by using a Right Angle Prism, a Corner Cube Retro-reflector, or a Right Angle Conical End (Fig. 6). According to our analysis, the Right Angle Prism can provide less than 50% of the power retro-reflection. Manufacturing the fiber tip in the shape of a right angle cone, or using a right angle cone joined to the fiber end, does not solve this problem. Indeed, a right angle cone operates like a Right Angle Prism as long as the rays propagate along a plane that contains the height of the cone, and any diameter of the cone base. Other rays do not meet the conditions of constant 180° deviation. Moreover, even for rays that may be retro-reflected, the total internal reflection is fulfilled if the cone refractive index exceeds 1.82 (at $NA=0.37$ and the core refractive index ≈ 1.5) (Fig.7). These arguments are valid for exact beam focusing on the fiber end along the joint axis of the focusing system and the fiber.

Undesirable radiation flow from the fiber end may be eliminated by shaping the distal end of the fiber. Using a horn shape of some length provides a significant decrease in the power density because of the high divergence ($\pm 21^\circ$) of the beam in free space. The exiting power may also be absorbed, and then dissipated by a radiator (see Fig.2). Using an appropriate radiator in combination with a metal-coated fiber tip may also be useful. The specific design for reducing the undesirable action of the outcoming radiation depends on parameters such as the laser's average output power, and the exposure duration.

6. Flexible Reflector

The diffusion end is embedded in a flexible reflector. The reflector is fabricated from silicon rubber. A gold coating is applied to the rubber base. The major concerns are the flexibility and the adhesive properties of the material. To find an optimal configuration (i.e., one that is small and able to provide a well-focused linear beam), the distribution of light intensity (on the target) for different shapes of reflector cross-sections was simulated using the ASAP-8 program. Fig. 8 shows the variation in the normalized power flux as a function of the space between the back surface of the cylindrical reflector and the fiber. The curve demonstrates a relatively strong dependence on this spacing. For this particular reflector, the maximum intensity is achieved at a distance of 3.9 mm. This means that for AF operations, we can use a laser whose output power is eight times lower (10W instead of 80W) than demonstrated in recent studies related to side-emitting diffusers [17,18].

A cylindrical cross-section of the reflector is the simplest shape for manufacturing but it is not optimal in focusing. It is well known that if the light source is placed in one focus of the elliptical reflector, the whole radiation is focused into the second one. If the tissue surface is placed close to the second focus, the width of the light strip may be around 0.3–0.5 mm. In other words, one achieves, in effect, a “light knife” to provide delicate surgery on the heart tissue.

Fig.9 demonstrates an elliptical diffuser cross-section and a numerical simulation of the laser light intensity distribution on the tissue plane. Evidently, the irradiated area is quite sharp, which will surely provide fast action of the photo-catheter. Initial experiments show that to

achieve 1W/cm linear density with an ordinary 10-cm diffuser it should be coupled to the fiber over 100 W of laser optical power. However, with well-focused radiation, a 10W power level is quite sufficient for successful operation of the catheter.

7. Discussion

During the experimental sessions two types of fibers were tested: 400- μ m core and 200- μ m core of 5-cm and 10-cm length. First one (with larger core) can accept four times more optical power, which is an advantage in the sense of shortening the operation time. However, the 200- μ m core fiber is more flexible and easily follows the tissue surface's relief. In principle, with the development of a precisely reflecting/focusing system we can even plan to use a 50- μ m core fiber/diffuser. Attempts to achieve homogeneous emission from the 10-cm long, 400- μ m core fiber resulted in the appearance of cracks near the output end of the diffuser. Strong intensity spikes were generated near the end of this diffuser. The intensity distribution was monitored directly on the diffuser surface. On a plane several mm from the surface, the radiation is mixed well, and is much more homogeneous than the radiation on the diffuser surface.

Clinical tests will demonstrate what combination of parameters is the most appropriate in order to achieve the effect with minimal surgery time and minimal diode output power. According to preliminary estimations in consultations with medical specialists, the general surgery time may be decreased to 10–12 minutes.

8. Conclusions

A prototype energy delivery and control system that can be located in a catheter has been demonstrated. The key element of the proposed system is a flexible reflector, containing a 10-cm fiber diffuser that can be used for making continuous photocoagulation lesions in maze procedure treatments. The emission performance compares well with that of commercially available diffusing-tip fibers, and provides a smaller cross-section, increased diffuser length, and improved mechanical properties. This permits transcatheter, intravascular, and novel interstitial applications, and hence increases the range of clinical applications.

In total, the system includes: a 10-cm long, 200- μ m-core fiber diffuser; a 50-W laser diode; flexible elliptical or cylindrical reflector; an end fiber cooler; a series of openings for rapid self-attachment to the tissue (vacuum holder – gripper); and a closed-loop irrigating chamber with circulating coolant to cool the optical diffuser. It is planned to include a distributed temperature sensor array for monitoring the temperature in the surrounding tissue. The development of a light source/catheter system that will create deep homogeneous, electrophysiologically inactive scars with a controllable lesion size and a clear-cut lesion border in a single application, creates a significantly useful tool for AF treatment.

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Fig.1.
Top and side view of tentative design

Fig.2.
3D image of the catheter with a diffuser and pumping laser diode

Fig.3.
Photograph of the catheter prototype

Fig.4.
Computer evaluation of the local transmittance of the diffuser versus the length

Fig.5.

Experimental local emittance of the 100-mm diffuser with and without end mirror

Fig.6.
Conical fiber end reflector with examples of ray tracings

Fig.7.
Critical and incident angles versus refractive index of the Right Angle Prism material

Fig.8.

Relative intensity on the tissue surface versus space between cylindrical reflector and diffuser

Fig.9.
On tissue light intensity distribution (transverse cross-section) for different types of reflectors