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Intravascular low-power laser illumination through special fiber diffusers

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Abstract. This paper presents the method of intravascular endothelial cell illumination with low-power laser radiation. Some special instruments were prepared, including designed fiber diffusers. The technical parameters of the set-up and the results of arterial system treatment with illumination instruments are presented.

Key words: coronary angioplasty, restenosis, photo-stimulation, low-power laser radiation.

1. Introduction

Atherosclerosis is a disease leading to gradual cholesterol plaque formation. The plaque narrows disease-changed vessels. This process affects the whole arterial system but it is especially dangerous when coronary arteries are affected as that causes acute coronary syndromes [1–3]. There are many procedures available to increase arterial blood flow and to limit the danger of already formed atherosclerotic plaques. These procedures are commonly known as revascularization, and again, they are especially important for coronary arteries. There is a surgical procedure whose purpose is to implant a vain or arterial graft bypassing a vessel obstruction – known as *coronary artery bypass grafting* (CABG). The leading revascularization procedure is *percutaneous coronary intervention* (PCI). Its most important limitation is hyperplasic response of treated artery called restenosis, which occurs in 20% to 40% of cases following coronary interventions. The exact mechanism of this event is not known. In order to minimize its occurrence, an intravascular *laser photostimulation* (LP) with low-power illumination method was developed. The new procedure is carried out during a PCI. Endothelial cell biostimulation with laser light is a new procedure currently in an experimental phase. Previously it was confirmed that laser light energy delivered to endothelial cells leads to their activation and proliferation. It also limits local inflammations. The biostimulation optimal irradiation level falls within infrared spectral range 800–900 nm [4]. The irradiation in 10 J/cm^2 range seems optimal.

A special device equipped with a fiber-optic diffuser tip has been built to conduct intravascular illuminations during balloon angioplasty. There were two types of diffusers prepared: one built with quartz optical fiber, and one built with plastic optical fiber. Testing of the offered intravascular illumination method took a long time and a representative number of patients. This work presents a fragmented-result assessment of intravascular illumination's influence on examined patients' recuperation.

2. Description of the method

We prepared a set-up for the intravascular illumination during PTCA procedure (Fig. 1).

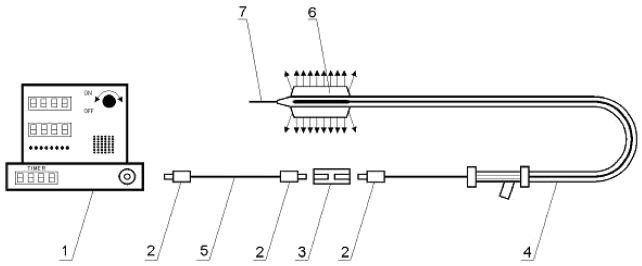

Fig. 1. The laser/catheter system scheme, 1-1aser, 2 - SMA fiber connector, 3 - fiber connector , 4 – catheter with fiber inside, 5 – connected fiber, 6 – diffuser in balloon, 7 - guide wire (fixed-wire type)

A special catheter has been designed for intravascular illumination procedures. It's a fixed-wire type balloon catheter used for coronary angioplasty – modified by adding another canal inside. An optical fiber is run through the canal and its distal tip is terminated within the balloon with a diffuser. The proximal end of the optical fiber is led out of the catheter and connected by means of an SMA connector with a semiconductor laser. Right after a coronary artery angioplasty, the newly-designed catheter was introduced into the widened area of the blood vessel. The balloon was inflated in order to center and fixate the diffuser. Then, an illumination procedure was performed [5].

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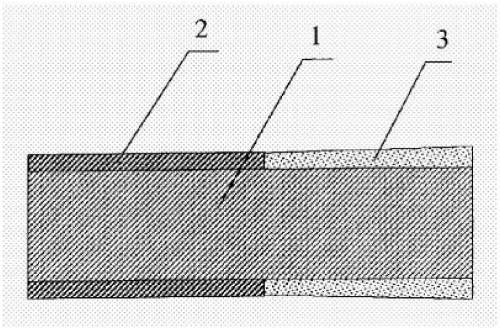
The laser diode operates at 808 nm wavelength with 2 W maximal continuous power output. When pigtailed to the multimode step-index silica fiber (200 μm core diameter and 250 μm cladding diameter) the maximal power output from the fiber terminated with a standard SMA connector is 1.7 W. The laser, with pigtailed multimode fibers, is the stationary part of the instrument. The next moveable element contains the illumination fiber which doses laser radiation. The role of the diffuser is to scatter the radiation leaking from the last part of the fiber along its total length of about 20 mm. The diffuser's length should be the same as the balloon's length.

Elementary calculation shows that, in order to get the required illumination for biostimulating maximal irradiation of energy $E = 9$ J/cm^2 per area of balloon 2 cm^2 in real illumination time of 30 to 60 seconds periods, the required power delivered via the diffuser's side-wall has to be maximal $P = 0.6$ W to 0.3 W.

Constructing fiber-optic diffusers, which would produce uniform luminance along a required length of the fiber, proved to be problematic. A proposed patented solution [6] led to designing a diffuser made of quartz glass. This construction is presented in Fig. 2a. The luminance distribution along the diffuser was measured – the test result is presented in Fig. 2b. Thus, constructed diffusers were used during intravascular illuminations for some time. Unfortunately, those diffusers turned out to be too fragile and brittle to guarantee the safety of the patients. Another patented solution proposed [7] was to make a' diffuser with 285/300 μm plastic optical fiber. The plastic diffuser structure and the radiation intensity angular distribution it delivers is shown in Fig. 3.

a)



b)

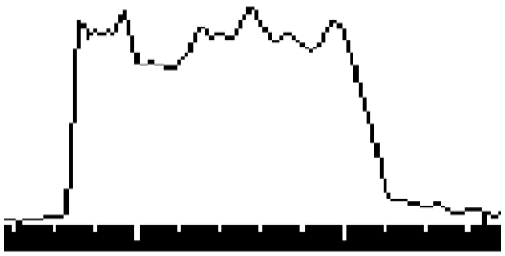
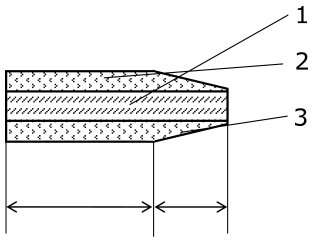


Fig. 2. A diffuser schematic (a) (1-fiber core, 2- fiber coat, 3 – special cover of core) and (b) laser radiation intensity distribution along the diffuser in arbitrary units

a)



b)

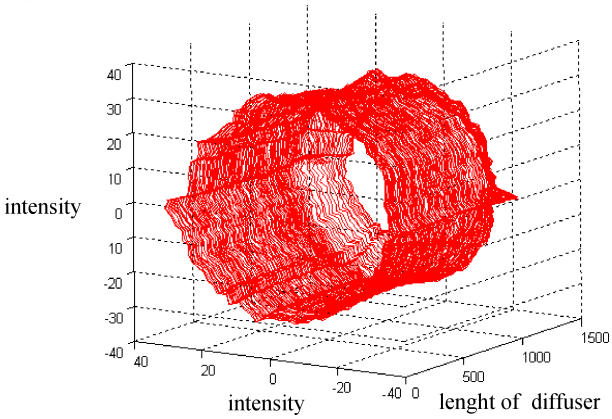


Fig. 3. The plastic diffuser scheme (a) (1 – fiber core, 2 – coat fiber, 3 – scattered area of diffuser) and (b) the radiation intensity angular distribution in arbitrary units

3. Medical application

Having obtained an approval from the pertinent bio-ethics commission, a study was conducted on a 101 – patient group (26 women and 75 men, mean age – 59.1±10.5 years old) – all with stable coronary arterial disease symptoms. 29 patients were treated with a standard balloon angioplasty. For 72 patients, the angioplasty was associated with implanting a vascular stent. No patient with a *drug-eluting stent* (DES) was included in the study. In 52 cases (12 female and 40 male patients), the procedure included illumination of the freshly-widened stenosis (Group I). In the control group – the remaining 49 cases (14 female and 35 male patients) – the standard procedure was conducted (Group II). The patients were subject to the *exercise cardiac stress test* (ECST) using a treadmill. Each patient was tested before their PCI procedure, a few days after the procedure, and again 6 months after that. A follow-up angiography was performed after 6 months as well, in order to assess the treated area for a possible restenosis. In order to maintain an objective evaluation of the narrowing, the *quantitative coronary, arteriography* method (QCA) was used.

The stress test results in the test group weren't different than the stress test results in the control group before-PCI and right after-PCI procedures. However, the 6-month-after stress tests confirmed a statistically significant difference between Group I and Group II; The degree of test intensity endured by patients in Group I was significantly higher than in Group II, which was manifested in metabolic equivalent (MET) ($p < 0.05$) and exertion time ($p < 0.005$) measurements.

In the control coronary angiography, restenosis was observed in 6 patients (11.5%) in Group I, and in 12 patients (24.5%) in Group II. This difference was not statistically significant. In the irradiated group, we have observed a considerably smaller average stenosis measured in percentages (32.0% *vs* 43.5%, $p < 0.05$). The difference resulted from lower average degree of stenosis in patients with diagnosed restenosis (59.1% *vs* 78.8%, $p < 0.01$), while in the group without restenosis these differences were statistically insignificant [8].

Table 1
The treadmill stress test results for both groups of patients

Stress Tests		Group I	Group II	p
Before	MET	7.8 ± 2.4	7.3 ± 1.9	NS
PCI	Total Exercise Time	410 ± 144	368 ± 112	NS
After PCI	MET	9.5 ± 2.2	8.7 ± 2.0	NS
	Total Exercise Time	495 ± 127	463 ± 125	NS
6-months	MET	9.1 ± 2.6	7.6 ± 2.1	$p < 0.05$
after PCI	Total Exercise Time	r 514 ±123	398 ± 121	$p < 0.005$

4. Conclusions

This work presents the methodology and the tools needed for intravascular illumination with low-power laser radiation. An integral part of the device is the newly-designed and built fiber-optic diffuser. The device was tested on representative groups of patients. The partial results of tests performed prove the stimulating irradiation to have positive influence on reducing restenosis in artery.

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