PRESENTATIONS FROM KEIO

The State of the Art of CO Laser Angioplasty System

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Abstract. A unique percutaneous transluminal coronary angioplasty system using new infrared therapy laser with infrared glass fiber delivery under novel angioscope guidance was described. Carbon monoxide (CO) laser emission of 5 mm in wavelength was employed as therapy laser to achieve precise ablation of atheromatous plaque with a flexible As-S infrared glass fiber for laser delivery. We developed the first medical CO laser as well as As-S infrared glass fiber cable. We also developed 5.5 Fr. thin angioscope catheter with complete directional manipulatability at its tip. The system control unit could manage to prevent failure irradiations and fiber damages. This novel angioplasty system was evaluated by a stenosis model of mongrel dogs. We demonstrated the usefulness of our system to overcome current issues on laser angioplasty using multi-fiber-catheter with over-the-guidewire system. (Keio J Med 42 (4): 183–185, December 1993)

Key words: angioplasty-laser

Introduction

Laser angioplasty had been developed to overcome restenosis issue on percutaneous transluminal coronary angioplasty (PTCA).¹ Multi-fiber catheter with over-the-guidewire technique has applied to clinical treatment trials. Recently, some equipments got Federal Drug Administration (FDA) approvals to use in clinical. However, the results of clinical results run counter to the expectation, even though this procedure was effective to treat long diffusive lesions and/or ostial lesions.² The major defect of this procedure was high restenosis rate which was comparative or rather than worth comparing to current PTCA. Some reports pointed out that there might be lack of eliminated plaque volume.³ The catheter passage through stenotic lesions though to be obtained by mechanical force. This idea may be supported by high incidence of dissection in acute phase and restenosis in chronic phase. The dense packed multi-fiber-catheters in which ultra-thin silica fibers were densely installed were developed to increase elimination volume of the plaque. We do not think this catheter is able to completely solve current issues, since essentially diameter of the multi-fiber-catheter should be thinner than intralumen. Furthermore, fiber area in the catheter cross-section was limited up to 30–40% due to its structure.

In order to ablate large volume without vascular per-

foration, we developed a unique laser coronary angioplasty system using new infrared therapy laser with infrared glass fiber delivery under novel angioscope guidance. This novel angioplasty system was evaluated by a stenosis model of mongrel dogs.

CO Laser Angioplasty System

A new transportable CO laser equipment was developed. The main improvement of this equipment comparing to prototype equipment which had been reported⁴ was miniaturization. Approximate size was 70 cm square in the plane and 120 cm in the height. Over 40% miniaturization in the volume was attained. The laser device was coaxial-flow room-temperature CO laser which could emit 10 W. The laser beam was directly coupled to an infrared fiber cable described below. The exhausted laser gas was processed by CO laser trap. The laser tube refrigerator was installed in the equipment. This laser tube refrigerator was installed in the equipment. This equipment was manufactured by Hamamatsu Photonics, Co. Ltd. (Hamamatsu, Japan).

CO laser cable composed of a chalcogenide infrared glass fiber, a fiber tip window, an outer sheath, and a thermocouple. The longitudinal cross-section of the CO laser cable is illustrated in Fig 1. The outer diameter of the cable was 600 μ m. The core diameter of the installed

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Fig 1 The longitudinal cross-section of the CO laser cable.

As-S chalcogenide glass fiber was 230 μm . The typical irradiation conditions were 1.5–2.0 W at the tip with duration of 1 s per shot. The fiber was completely sealed by the tip and outer sheath to avoid unnecessary contact of fiber material to blood even though this fiber material is almost insoluble material. The As-S chalcogenide glass fiber was fabricated by Non Oxide Glass, Co. Ltd. (Tokyo, Japan) and the fiber cable was manufactured by Mitsubishi Cable, Indst. Ltd. (Amagasaki, Japan).

The fine manipulation at the tip of the catheter is key factor in our laser angioplasty procedure. The manipulation system was composed by an installed tension-wire and torque transportable catheter structure. One directional bending with whole catheter rotation scheme similar to bronchoscope manipulation realized complete directional manipulability at tip of the catheter. The maximum outer diameter of the catheter was 5.5 Fr. size (1.8 mm i.d.) at sheath portion. This catheter could pass through PTCA guiding catheter, for example 9 Fr. Soft-Tip^R Super-Flow^R Judkins catheter (USCI, USA). An angioscope function with 3000 pixels image guides was installed in the catheter. Moreover, a through lumen can be used for guide-wiring, laser cable operation and saline flushing. A balloon inflation lumen was equipped in the catheter. This manipulatable angioscope catheter was made by Mitsubishi Cable, Indst. Ltd. (Amagasaki, Japan).

Angioscope system was specially designed to get fine image from restricted spatial resolution of the image guide to diagnose stenotic/occlusion lesion in artery. Angiography image was also utilized in this system. The CRT which was set in the front of the catheterization operator could indicate both of angioscope and angiography images simultaneously. Moreover, digitized memory in the system offered former cinema image for reference. Figure 2 shows the CRT information arrangement in our system. The system controller was connected to the laser cable and the CO laser equipment to maintain system procedure with safety. To control whole system, one operator was necessary in front of the angioplasty

Fig 2 The expressions on CRT.

system controller. The angioscope system and angioplasty system controller were fabricated by Fukuda Denshim, Co. Ltd. (Tokyo, Japan).

Methods

Vessel model for laser coronary angioplasty was newly developed to quantitatively evaluate the efficacy of our laser angioplasty system. Since guiding catheter path figure is strongly affected to rotational movement of the laser angioscope catheter, femoral approach catheterization path should be precisely described. A model stenosis could be inserted to coronary artery of the vessel model. Angiography of the model coronary artery could be gotten. The material of vessel wall was made of silicone and stained to coincide colors with actual coronary vessel. The femoral approach catheterization with 9 Fr. Judkins guide catheter for left coronary artery was performed by the same manner of human clinical catheterization. The model stenosis which was made by human atheromatous plaque was installed in left coronary artery Seg.7 of the model vessel. The stenosis rate was approximately 90% and vessel original inner diameter was 4 mm.

Animal experiments have been done in femoral arteries of mongrel dogs. The dogs were given general anesthesia with pentobarbital sodium. Carotid artery was cut down and antigrade catheterization to femoral artery was performed. The animal experiment was done to examine procedure of our laser angioplasty in pulsatory pressurized blood condition in actual artery wall, which was not able to simulate in the vessel model experiment described above. The model stenosis was inserted in the femoral artery by surgical method. A 9 Fr. guiding catheter which has straight shape in its tip was used.

Results

The laser angioscope catheter could rotate in 9Fr Judkins guide catheter (USCI, Soft-TipR Super-FlowR). No backlash movement was found on the angioscope catheter rotation. Even when high viscosity contrast fluid filled in the guiding catheter, smooth rotation movement was obtained. Using this rotation movement and one directional bending, we could easily get coaxial view of coronary artery of the model vessel. This manipulatability of the catheter tip was sufficient for laser irradiation positioning. Repetitive CO laser ablation with varying irradiation position under angioscope visualization made a huge amount of ablation of the model plaque. The examination of the pathological specimen showed that the 90% severe stenosis was treated to 70% stenosis by approximately 220J of amount of irradiation energy. The ablated volume of the model plaque was 9.5 mm^3 .

The manipulatability of the catheter tip was also effective both diagnosis and laser angioplasty in animal experiment. The catheter rotation could perform during angioscope visualization, that is, during balloon inflation and saline injection. The endoscopic view was slightly getting unclear by leaked blood due to balloon slip. This tendency was enhanced if small artery branch was located aside of the balloon. However, the experience of animal experiment was not far different from the model vessel experiment. In other words, the model vessel experiment might be effective to evaluate angioplasty system performance.

Summary

We developed new laser angioplasty system which had the medical CO laser, manipulatable laser angioscope catheter, CO laser cable, and angioscope/control system. By improved manipulatability, angioscopic guidance become to be effective guidance technique, that is, aiming of laser irradiation and recognition of center axis. Our angioplasty system might be one solution for restenosis problem in clinical results of the multi-fiber-catheter in combination with over-the-guiding-wire technique.

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