Published in final edited form as:

Proc SPIE Int Soc Opt Eng. 2016 February ; 9689: . doi:10.1117/12.2208132.

Diffusing, Side-Firing, and Radial Delivery Laser Balloon Catheters for Creating Subsurface Thermal Lesions in Tissue

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Abstract

Infrared lasers have been used in combination with applied cooling methods to preserve superficial skin layers during cosmetic surgery. Similarly, combined laser irradiation and tissue cooling may also allow development of minimally invasive laser therapies beyond dermatology. This study compares diffusing, side-firing, and radial delivery laser balloon catheter designs for creation of subsurface lesions in tissue, *ex vivo*, using a near-IR laser and applied contact cooling. An Ytterbium fiber laser with 1075 nm wavelength delivered energy through custom built 18 Fr (6-mm-OD) balloon catheters incorporating either 10-mm-long diffusing fiber tip, 90 degree side-firing fiber, or radial delivery cone mirror, through a central lumen. A chilled solution was flowed through a separate lumen into 9-mm-diameter balloon to keep probe cooled at 7°C. Porcine liver tissue samples were used as preliminary tissue model for immediate observation of thermal lesion creation. The diffusing fiber produced subsurface thermal lesions measuring $49.3 \pm 10.0 \text{ mm}^2$ and preserved $0.8 \pm 0.1 \text{ mm}$ of surface tissue. The side-firing fiber produced subsurface thermal lesions of $2.4 \pm 0.9 \text{ mm}^2$ diameter and preserved $0.5 \pm 0.1 \text{ mm}$ of surface tissue. The radial delivery probe assembly failed to produce subsurface thermal lesions, presumably due to the small effective spot diameter at the tissue surface, which limited optical penetration depth. Optimal laser power and irradiation time measured 15 W and 100 s for diffusing fiber and 1.4 W and 20 s, for side-firing fiber, respectively. Diffusing and side-firing laser balloon catheter designs provided subsurface thermal lesions in tissue. However, the divergent laser beam in both designs limited the ability to preserve a thicker layer of tissue surface. Further optimization of laser and cooling parameters may be necessary to preserve thicker surface tissue layers.

Keywords

coagulation; infrared; laser; lesions; liver; probes; subsurface

1. INTRODUCTION

Active cooling methods are used in the dermatology clinic to preserve the skin surface from thermal injury during cosmetic laser procedures (e.g. skin resurfacing, hair removal, and treatment of vascular birthmarks). These technologies include both contact cooling (e.g. cold water, gels, and sapphire windows) and non-contact cooling (e.g. cold air and cryogen sprays) methods [1,2]. In dermatology, the tissue structures of interest for laser therapy are

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superficial, requiring preservation of only a relatively thin layer of tissue (e.g. epidermis and papillary dermis), measuring a few hundred micrometers in depth below the tissue surface.

Preservation of a greater layer of the tissue surface on the scale of a few millimeters, using deeply penetrating laser energy in combination with more aggressive surface cooling, may catalyze development of new noninvasive laser therapies beyond cosmetic surgery. Our laboratory has previously demonstrated creation of deep subsurface thermal lesions in a variety of tissues (e.g. skin and liver) using both contact and non-contact cooling techniques [3–5].

This study describes the design, construction, and characterization of three different laser balloon catheter probes for potential use in minimally invasive endoscopic thermal therapy procedures. Diffusing, side-firing, and radial delivery optics were integrated into balloon catheters, designed for contact cooling of the tissue surface during noninvasive laser creation of subsurface thermal lesions in liver tissue as a general tissue model. The diffusing probe was designed for simultaneous treatment of the entire tissue during a single treatment. The side-firing probe was designed for directional, point-like, thermal lesions. The radial delivery probe was designed for 360 degree treatment with manual control over the axial direction.

2. METHODS

2.1 Balloon Catheter

An 18 Fr (6-mm-OD) dual balloon catheter (Duette, Poiesis Medical, Tequesta, FL) was modified for use as a fiber optic balloon catheter. After cutting the subsumed tip and sealing second distal balloon to allow coolant to flow freely in and out of primary balloon, the recirculating primary balloon was formed. A recirculating chiller (T255PD5, Thermotek, Carrollton, TX) was connected to primary balloon. The flow rate was limited to 4.3 ml/s due to small lumen size of balloon catheter, in turn limiting cooling temperature to 7 °C. During preliminary calibration, with air in 9-mm-diameter balloon, the probe transmitted 71% of initial laser power. The balloon was then filled with water to decrease Fresnel reflection through index matching, which increased optical transmission to 84%.

2.2 Side Firing Laser Probe

The side firing fiber consisted of a 600- μ m-core, low-OH, silica fiber with 0.39 NA. A 0.98-mm-OD, 45-degree angle rod mirror (Part #47–628, Edmund Optics, Barrington, NJ) was coated with a reflective gold layer (International Micro Photonix, North Andover, MA) and then mounted together with the fiber in a 1.0-mm-ID quartz capillary tube (Vitrocom, Mountain Lakes, NJ) for alignment and protection. After placing the fiber in a securely fitted balloon catheter, optical transmission was measured using a power detector (PM150, Coherent, Santa Clara, CA) and meter (EPM1000, Molectron, Portland, OR). A fiber stabilizer was built from a separate 16 Fr (5.3-mm-OD) balloon catheter (Duette, Poiesis Medical) as a mold, then secured using UV-cured adhesive (NOA81, Norland Products, Cranbury, NJ) and light source (UV75, EFOS, inc, Mississauga, Ontario, Canada). The output beam was elliptical in shape measuring 2 $\times$ 3 mm on the outside of the balloon

surface, due to ridges on the balloon catheter. A diagram of the laser balloon catheter and components are provided in Figure 1.

2.3 Diffusing Laser Probe

A diffusing laser probe (Figure 2) was also built to fit into a similar 18 Fr balloon catheter. The fiber stabilizing fixture for the diffusing fiber was made with the same method as for the side-firing fiber laser probe. The diffusing fiber (Cardiofocus, Inc., Marlborough, MA) uniformly delivered the laser energy at 360 degrees along its 10 mm active length with a 91% transmission rate.

2.4 Radial Delivery Laser Probe

The radial delivery probe design consisted of a 1-mm-OD, 90% reflective, copper cone mirror (custom machined by Center for Precision Metrology at UNC-Charlotte) at the fiber tip, which reflected the beam 360 degrees uniformly outward (Figure 3). The beam ring width measured ~ 1 mm on the outside of the balloon catheter.

2.5 Tissue Preparation and Experiments

Porcine liver tissue was chosen as a general tissue model for these preliminary experiments due to several factors: the tissue was readily available, and gross thermal lesions in liver could be easily observed immediately after the procedure for initial assessment. The liver tissue was obtained from Animal Technologies (Tyler, TX) and Spear Products (Coopersburg, PA). Liver samples were cut into cylindrical samples using a 38-mm-diameter cutout mold. Additionally, a 4.8-mm-diameter bore was created to simulate an endoscopic approach in a tissue having cylindrical anatomy, and to tightly fit the 9-mm-diameter balloon catheter probe for the diffusing fiber studies. Liver samples were kept hydrated in an aluminum dish and placed on a hot plate with a set temperature of 35°C. Tissue temperature was monitored using a micro-thermocouple connected to a personal computer. During the experiment, the side-firing laser probe was placed in contact with the liver tissue, while the diffusing and radial delivery laser probes were placed inside a hollowed out sample of liver tissue. After laser irradiation, the probe was removed and the lesion area was marked by inserting a pin near the lesion area to provide an accurately defined lesion location.

3. RESULTS

3.1 Laser Probe Results

Table 1 summarizes the parameters used in the experiments and thermal lesion characteristics. When the side-firing laser probe was in contact with liver tissue, it provided limited surface cooling; hence, a pre-cooling time of 10 s was used prior to laser irradiation. The balloon catheter was kept at temperature of 7°C. Despite having a divergent beam ($NA = 0.39$) and low cooling efficiency of balloon catheter, the liver tissue surface was still preserved from thermal damage. Surface preservation averaged 0.5 ± 0.1 mm with a lesion area of 2.4 ± 0.9 mm² for the side firing balloon catheter and 0.8 ± 0.1 mm with a lesion area of 49 ± 10 mm² for diffusing balloon catheter. No lesions were observed using the cone mirror balloon catheter despite elevating the laser power up to 15 W for 90 s.

4. DISCUSSION

Some of the probe designs tested in this study have been commonly used in therapeutic laser applications in medicine. For example, diffusing fiber optic balloon catheters are used in photodynamic therapy (PDT) of cylindrical organs [6] and fiber optic probes and needles are used not only for PDT, but also during laser interstitial thermal therapy (LITT) of cancer as well, including liver tumors [7–10]. The purpose of this study was to determine which probe design provided the deepest subsurface thermal lesions in tissue.

Three laser delivery methods were tested using 18 Fr dual balloon catheter probe to produce deep subsurface thermal lesions in porcine liver tissue, *ex vivo*. The radial delivery probe was unable to produce any thermal lesions in liver tissue, presumably due to combination of circular beam delivery, divergent beam, and small spot diameter at tissue surface, which resulted in a significant reduction in optical penetration depth. Hence, most of the deposited laser energy was removed through applied cooling at the tissue surface. The side-firing probe preserved 0.5 ± 0.1 mm tissue from thermal coagulation, while the diffusing laser probe preserved 0.8 ± 0.1 mm tissue from thermal coagulation. Since the side-firing probe has a smaller beam spot diameter and due to scattering nature of liver tissue, it achieved less optical penetration depth in comparison to diffusing laser probe. Although the diffusing laser probe preserved more surface tissue, it required higher laser power (15 W) and longer irradiation time (100 s). The side-firing fiber, on the contrary, due to its smaller spot diameter, required less power (1.4 W) and irradiation time (20 s) for lesion creation. One advantage of the diffusing laser probe is that it simultaneously treats all the surrounding tissue; however, the limitation of using the diffusing laser probe is that the power density decays by $1/r^2$ with working distance. Presumably, if the modified balloon catheter design could be improved to allow a higher flow rate for tissue cooling, a deeper lesion and greater preservation of the tissue surface could be achieved.

5. CONCLUSIONS

The radial delivery probe failed to produce thermal lesions due to limited optical penetration depth. The side-firing laser probe preserved 0.5 ± 0.1 mm of tissue from thermal coagulation, while the diffusing laser probe preserved 0.8 ± 0.1 mm of tissue. While these methods produced subsurface thermal lesions in tissue, higher cooling rates and less divergent laser beams are needed for deeper penetration and greater tissue surface preservation.

ACKNOWLEDGMENTS

This work was supported by NIH, Grant #1R15DK099774. Chun-Hung Chang received travel grants from SPIE and Center for Biomedical Engineering & Science at UNC-Charlotte. The authors thank Jerry Melsky (Cardiofocus, Marlborough, MA) for providing diffusing optical fiber used in these studies. We also thank Professor Hyun Wook Kang (Pukyong National University, South Korea) for providing diffusing optical fibers tested in these studies.

7. REFERENCES

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Figure 1. Side-firing fiber laser balloon catheter. (A) Diagram of probe components; (B) Side-firing fiber created using a standard 600- μm -core silica fiber, a 1-mm-OD gold coated 45 degree angled rod mirror, and glass capillary tubing; (C) Delivery of laser beam at 90 degrees through an 18 French (6-mm-OD), water-filled, balloon catheter expanded to a diameter of 9 mm.

Figure 2. Diffusing fiber laser balloon catheter. (A) Diagram of probe components; (B) Beam delivery through balloon catheter.

Figure 3. Radial delivery laser balloon catheter. (A) Diagram of cone lens and ray propagation; (B) Diagram of proposed cone laser probe; (C) Photograph of laser beam delivery through balloon catheter.

Figure 4.

(A) Representative gross image of thermal lesion produced in liver tissue, *ex vivo*, using 1075 nm side-firing laser probe; (B) Representative gross image of thermal lesion produced in liver tissue, *ex vivo*, using 1075 nm diffusing laser probe; (C) Representative tissue sample, using 1075 nm radial delivery probe, showing no evidence of thermal lesion at 15 W for 90 s.

Table 1.

Laser parameters and results for thermal lesion creation using laser probes in liver tissue.

Laser Parameters	Side-Firing Probe	Diffusing Probe	Radial Probe
Wavelength (nm):	1075	1075	1075
Power (W):	1.4	15	15
Irradiation Time (s):	20	100	90
Number of Samples (N):	10	10	9
Thermal Lesion Dimensions			
Shape:	Elliptical	Crescent	No Lesion
Preserved Surface Tissue (mm):	0.5 ± 0.1	0.8 ± 0.1	---
Lesion Area (mm ²):	2.4 ± 0.9	49 ± 10	---