Novel cylindrical illuminator tip for ultraviolet light delivery

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ABSTRACT

The design, processing, and sequential testing of a novel cylindrical diffusing optical fiber tip for ultraviolet light delivery is described. This device has been shown to uniformly (+/- 15%) illuminate angioplasty balloons, 20 mm in length, that are used in an experimental photochemotherapeutic treatment of swine intimal hyperplasia. Our experiments show that uniform diffusing tips of < 400 micron diameter can be reliably constructed for this and other interstitial applications. Modeling results indicate that this design is scalable to smaller diameters.

The diffusing tips are made by stripping the protective buffer and etching away the cladding over a length of 20 mm from the fiber tip and replacing it with a thin layer of optical epoxy mixed with Al_2O_3 powder. To improve the uniformity and ease of fabrication, we have evaluated a new device configuration where the tip is etched into a modified conical shape, and the distal end face is polished and then coated with an optically opaque epoxy. This is shown to uniformly scatter ~ 70% of the light launched into the fiber without forward transmission. To our knowledge, we are the first to use this device configuration, and we have achieved a uniform cylindrical pattern of laser energy with the uniformity < ± 15% of the average value.

We have measured the optical properties of the tips through all the sequences of the fabrication. The performances of the diffusing tips for illuminating angioplasty balloons are then evaluated by Ultraviolet Light at 365 nm. A Ti:Sapphire Ring Laser System with a doubling crystal pumped by an argon ion laser is used to generate the wavelength in this study.

1. INTRODUCTION

Photochemotherapeutic treatment of intimal hyperplasia may reduce the healing response to balloon injury or restenosis[1-3]. It has potential advantages over surgery, balloon angioplasty, and other forms of vascular intervention. A patient can take a drug in an inert form that has no side effects. Once the drug is in the body, nearly uniform cylindrical irradiation of laser energy emitted from an angioplasty balloon can "turn on" the drug efficiently, creating a therapeutic photochemical reaction only at the site of illumination, thus potentially decreasing the high rate of restenosis that occurs with balloon angioplasty. During the treatment, laser energy is delivered circumferentially by an optical fiber that terminates in a central diffusing tip within the inner lumen of an angioplasty balloon. A limiting problem in achievement of a uniform cylindrical pattern of laser energy is the development of a miniature diffusing tip at the distal end of the optical fiber.

Currently the typical optical fiber diffusing tips that may be used for photodynamic therapy (PDT) are made by removing the cladding over a desired length from the fiber tip and replacing it with a thin layer of optical scattering materials[4-6] or attaching the distal end of the fiber to a diffuser[7-9]. Both devices provide a nearly uniform cylindrical

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pattern of irradiation. Unfortunately, the device configurations are either complex to fabricate or limited by balloon geometry to smaller diameters.

The objective of the present study is to develop a simple and useful method for the design and fabrication of similar optical scattering devices for PDT. In this paper we report on the fabrication and measurement of a novel cylindrical illuminator tip for UV light delivery primarily designed for use in an experimental photochemotherapeutic treatment of swine intimal hyperplasia. This illuminator can also be utilized in interstitial applications where a miniature (< 0.018" diameter) illuminator is required. The diffusing tips are made by stripping the protective buffer and etching away the cladding over a length of 20 mm, and replacing it with a thin layer of optical epoxy mixed with Al_2O_3 powder. To improve the uniformity and ease of fabrication, we have evaluated a new device configuration where the tip is etched into a modified conical shape, and the distal end face is polished and then coated with an optically opaque epoxy. This is shown to uniformly scatter ~ 70% of the light launched into the fiber without forward transmission. To our knowledge, we are the first to use this device configuration, and we have achieved a uniform cylindrical pattern of laser energy with the uniformity < ± 15% of the average value.

Fibers with modified tip and powder admixture are tested. Various angles of convergence are used for the He-Ne laser beam coupled into the fiber in these tests. We find that all of these parameters have a significant effect on the optical performance of the fiber tip. The performances of the diffusing tips to illuminate angioplasty balloons are then evaluated by ultraviolet light at 365 nm. A Ti:Sapphire Ring Laser System with a doubling crystal, pumped by an argon ion laser, is used to generate the wavelength in this study.

2. DEVICE DESCRIPTION

A schematic diagram of the illuminator tip is shown in Fig.1. Being coupled into the fiber at an angle that is equal to or larger than the critical angle, laser beam is transmitted , unattenuated, within a lossless fiber [10]. When the laser radiation propagates into the diffusing tip section, the total internal reflection properties of the fiber have been lost and an anti-guiding situation occurs due to the higher index of the coating [optical epoxy (n_D= 1.56) and powder (n_D=1.65)]. Light propagating in the lower refractive index core (n_D= 1.46) is redistributed at each Fresnel reflection between the core and the scattering layer. Depending on the angle of incidence, some of the light is refracted into the scattering layer, and a fraction is reflected to the other side of the wall and then redistributed again at the core-layer interface. In this manner, each original ray generates an increasing number of subrays of ever-decreasing amplitude as it propagates along the diffusing tip. Therefore, the radiation is sequentially being refracted into the scattering layer and then scattered out of the fiber structure. The anti-guiding configuration significantly redistributes the input radiation along the etched length of the tip.

For the intended use, the diffusing tip is assembled within an angioplasty balloon, 3.5 mm × 20 mm (Mansfield^{TM}, Boston Scientific Co., Watertown, MA02172), and produces a 20 mm long cylindrical irradiance pattern of laser energy. The balloon is guided by a 7F multipurpose catheter (Super.7^{TM} , USCI Division CR. Bard, Inc., Billerica, MA01821). The requirements for the illuminator tip are as follows:

(1) Optical performance: The tip should produce uniform irradiance at a radial distance of ~1.75 mm from the fiber axis. The magnitude of the radiance of the tip should, therefore, be roughly constant along the length of the tip and rotationally symmetric. Furthermore, it is desirable that the proximal ends of the balloon receive minimal or no direct laser exposure.

(2) Mechanical performance: The diffusing tip should be small in size (the overall diameter is less than 365 μm) to be easily introduced into the balloon and provide reasonable safety against fracture.

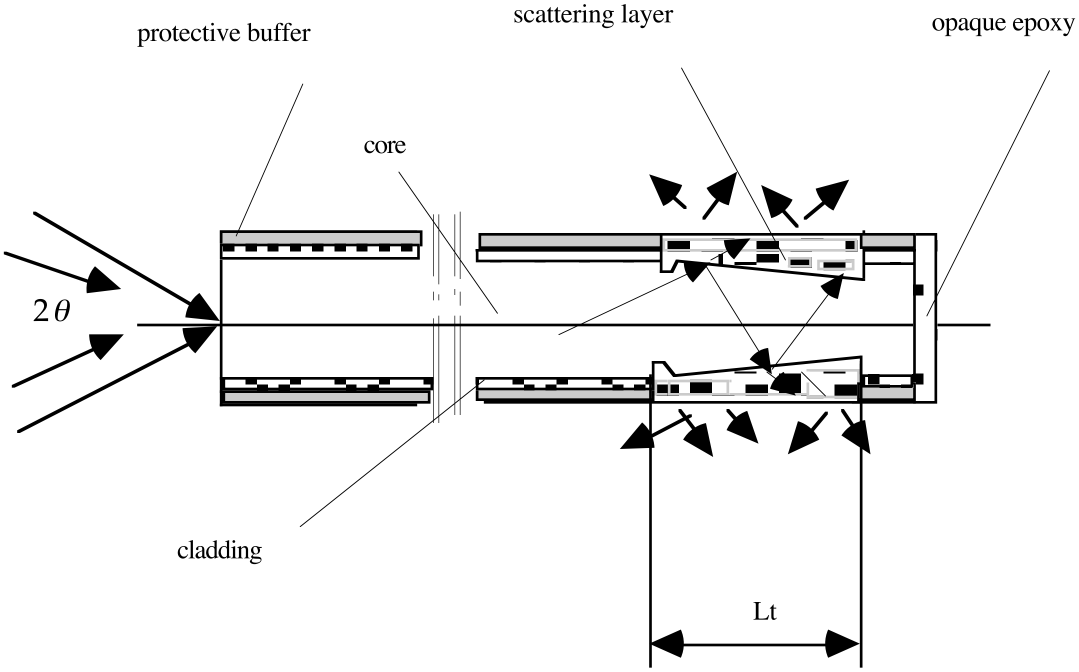


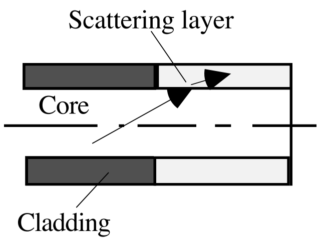
Fig. 1. Schematic diagram of illuminator tip

3. DESIGN CONSIDERATIONS

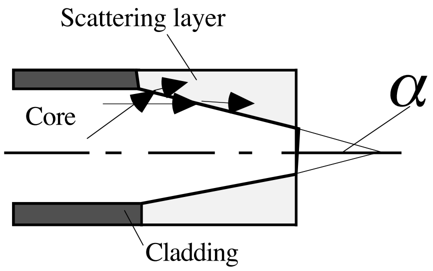
The optical behavior of the diffusing tip depends on the geometry of the tip, the angular distribution of the light input to the diffusing tip (convergence angle of the input laser beam), the refractive index of the core, the refractive index of the scattering layer, and the scattering powder concentration. The qualitative analyses for these parameters are described below.

Figure 2 shows three tips with different geometries. For a cylindrical shape, only the rays at angles with respect to the fiber axis can be refracted from the core [see Fig. 2 (a)]. For a conical shape, besides the rays at angles with respect to the fiber axis, some of the rays parallel to the axis can also be refracted from the core [see Fig. 2 (b)]. For a modified shape (bi-tapered shape), not only can both rays be refracted from the core , but also more light can be coupled out of the core at the beginning of the tip (In practice, the light power at the first 1~2 mm of a cylindrical shape is lower than the peak value)[see Fig. 2(c)]. The amount of light refracted into the scattering layer also depends on the incident angle at the interface of the core-scattering layer[11]. With the incident angle reduced, more light is refracted from the core. For a cylindrical tip, the incident angles of the rays do not change after several reflections. But as a ray is internally reflected in the tapered zone, the incident angle θ_i between the ray and the normal to the core-layer interface will be decreased by the amount α after each reflection (see Fig. 3). Therefore more light leaks out from the taper than that for the cylinder. It is obvious that the modified geometry is advantageous to make more light transmitted into scattering layer and then scattered out of the fiber structure than the others.

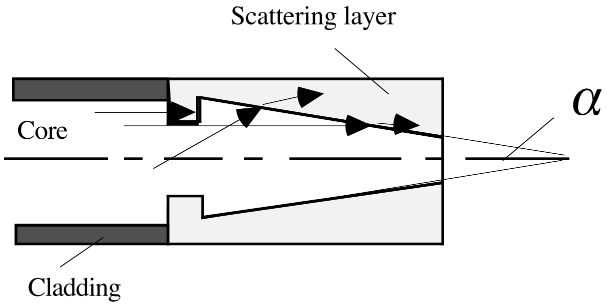
The irradiance distribution of the laser beam emitted from a multimode fiber is usually assumed to have a Gaussian angular distribution[12]. Because this Gaussian distribution is related to which fiber modes are excited, considerable variation in displacement of the irradiance peak from the diffusing tip can be achieved by varying the angle of optical coupling into the fiber, i.e., convergence angle. Small convergence angles will excite primarily low-order modes and move the irradiance peak towards the distal end of the tip, while larger convergence angles can excite both low and high-order fiber modes and move the irradiance peak toward the beginning of the tip[6] .



(a) Cylindrical shape



(b) Conical shape



(c) Modified shape

Fig. 2. Schematic diagram of three different tip shapes

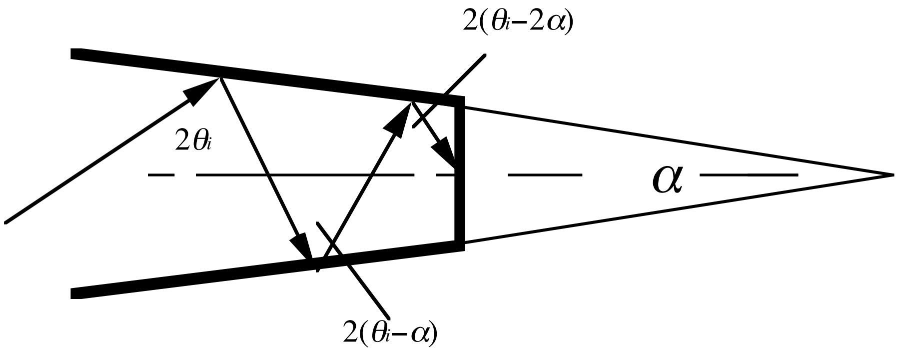


Fig. 3. Schematic diagram in cross section of a tapered cylindrical optical fiber with taper angle equal to α

According to Eq.(43) of Ref.11, the reflectance will increase with increasing difference between the refractive indices of the core and scattering layer. Therefore, more light will be reflected toward the distal end of the tip.

The effect of powder concentration is very complex. With increasing concentration, the scattering coefficient increases, and usually the light will be scattered more times. This may or not lead to greater uniformity of irradiance at the tip depending on the intrinsic absorption of the optical epoxy and powder, and other lossy elements in the fiber tip. The validity of this argument is not questionable when the particles of the powder are widely separated, but doubts arise when the separations are less than or comparable to the wavelength of the light. For a cylindrical optical fiber diffusing tip, the irradiance dependence on the powder concentration is similar to that of the convergence angles[6].

On the basis of the effects of these parameters on the light distribution at the tip, a uniform cylindrical irradiance pattern of laser energy can be obtained through optimization of the parameters. The method we have chosen in this study is to modify the geometry of the tip on the basis of a known convergence angle of input beam. Approximately 8 mm of the buffer and cladding are left at distal end for ease of tip assembly inside an angioplasty balloon and for enhancement of the bending strength. The optically opaque epoxy is coated on the distal face to stop the transmitted light power in the forward direction so as to ensure that the proximal end of the balloon receives minimal or no direct laser exposure (cf. Fig. 1).

4. MATERIALS AND METHODS

4.1. Fabricating procedure

A flexible, optical fiber with 300 μm core diameter and 0.22 numerical aperture (Polymicro Technologies, Phoenix, AZ) is used in this study. The fiber is a step-index multimode fiber with a synthetic fused silica core, silica cladding, and protective polyimide buffer. The detailed fabricating procedure for the illuminator tip is described as follows.

4.1.1. Geometry preparation

After a piece of silica fiber has been cut (2 m-2.5 m), one of the distal faces is wet-polished flat as the input end of the fiber using standard fiber polishing techniques. At its other end, the protective buffer is thermally removed with a pyrolytic stripper over 20 mm, with 10 mm left from the distal end of the fiber (see Fig. 1). The tip is then fabricated into a modified shape by a chemical etching technique. The chemical used is Hydrofluoric Acid (48%). The length of time that the tip is exposed to the acid determines the tapered shape. The polyimide buffer protects the fiber from etching. To form the modified tip, two methods are studied:

(1) After removing the protective buffer, the optical fiber is supported in a vertical position by attaching it on a vertical translator (Line Tool Co., AllenTown, PA) and then dipped into Hydrofluoric Acid gradually (the increment is ~ 0.4 mm). The etching time for each increment is about 20 seconds. During this period, the cladding is usually etched away. The optical fiber is examined under an optical microscope after the buffer and cladding are removed to ensure that the geometry of the fiber end is correct with a suitable etching rate. Although the etching rate is usually 4 μm in diameter per minute, since the etching rate is not linear, it has to be determined experimentally based on the etching conditions such as quality of the fiber, chemical bath, etc.. For example, in practice, it takes 4 minutes and 22 seconds to etch away 20 μm in diameter, the ratio is about 4.58 μm in diameter per minute, but it takes 18 minutes to etch away 50 μm in diameter, the ratio is about 2.7 μm in diameter per minute. The modified tip can be obtained by partially covering the area where the irradiance with peak value is located with Polyimide Tubing (Polymicro Technologies, Phoenix, AZ). The area can be determined by measuring the light distribution at the tip. The uncovered portion at the fiber end together with the covered portion is then dipped into the acid to form the modified shape. In our case, it takes three and a half minutes for this step. The resulting bi-tapered tip is dipped into an epoxy /powder mixture (the weight ratio of EPO-TEK® 301-2 to Al_2O_3 is 10 to 3, i.e., the powder concentration is 285 mg/ml) and then the irradiance distribution at the tip is measured with a known convergence angle, in our case, $\theta = 5^o$. The measurement technique will be described in section 4.2. If the irradiance distribution is not uniform, the mixture can be cleaned away easily with Acetone, and then the etching can be repeated until a uniform irradiance is obtained.

(2) A similar procedure to that described above is utilized for the fabrication of a modified tip, with the exception that the buffer and cladding are removed first and then the fiber is fabricated into bi-tapered shape. A summary of Geometry Preparation Procedure is illustrated in Fig. 4.

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There are two points we should mention here: (1) it is essential to remove cleanly all cladding material so that the irradiance peak position can be covered correctly; (2) excessive handling the bare tip should be avoided. Otherwise, the tip may become brittle. In practice, besides the methods mentioned above, we have applied the UV light curing technique to cover the irradiance peak position. The procedure is described below. During covering of irradiance peak position, the area is covered with UV epoxy (LITETAK 376, Loctite Co., Newington, CT0611) mixed with Al_2O_3 powder (the weight ratio of UV epoxy to Al_2O_3 powder is 10 to 3) and then the mixture is cured with UV light for about 5 seconds. After that the tip is dipped into Hydrofluoric Acid for 3.5 minutes. Then the tip is washed with water, and the cured mixture can be removed mechanically, if not, the Chlorinated Hydrocarbon/Equipment Flushing Solvent (Loctite Co., Newington, CT0611) can be used to easily solve the cured mixture. It takes ~ 1.5 minutes to solve the cured mixture on the tip. Since the cured mixture on the tip is not an excellent Hydrofluoric Acid resist, it will be dissolved partially or totally after about 4 minutes in the acid. Therefore, it is not suitable to protect the tip from etching if the length of etching time is longer than that. However, just following the simple procedure mentioned above, the fabricated tip can produce a cylindrical irradiance pattern of laser energy with uniformity < ± 25% of the average value.

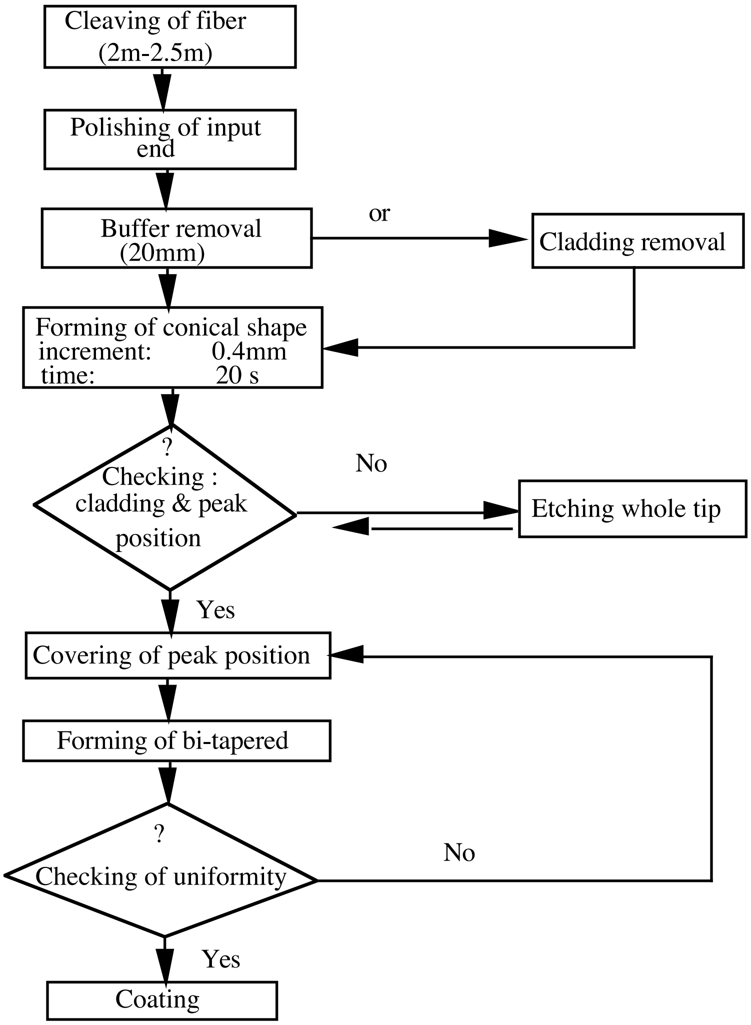


Fig. 4. Block diagram of geometry preparation procedure

4.1.2. Coating technique

The fiber tip is carefully cleaned with Acetone before it is coated. The clear, two component optical epoxy (EPO-TEK® 301-2) is prepared by thoroughly mixing it with a carefully weighed amount of Al_2O_3 powder as the coating material. The weight ratio of the optical epoxy to Al_2O_3 powder is 10 to 3, i.e., the powder concentration is 285 mg/ml. The powder Al_2O_3 used is commercial grade (Linde A, the typical grain size being ~ 0.3 μm). A piece of Teflon tube (28GA, SMALL PARTS INC., Miami, FL33238) is cut (35 mm in length), and then the tip is inserted into the tube. The tube is heated using a hot-air gun or a hotplate until it becomes straight. Coating the tip with the coating material is simultaneous with moving the tube backwards and forwards along the tip, so that the space between the inside wall of the tube and the tip is filled with the coating material without any air bubbles. Small air bubbles are removed by warming the epoxy/Al_2O_3 mixture with a hotplate or a hot-air gun. (This procedure should be done for both of a container with coating material and the coating tip simultaneously.) Then the tip is allowed to dry in vertical position under a warm situation (about $75F^0$). After the drying, the Teflon tube can be remove thermally. During removal of the tube, we put a metal block on a hotplate and warm it to above $212F^0$, and we then put the tube in contact with the metal block and remove the tube with a pair of tweezers as soon as possible. Otherwise, the heating can damage the coating material. After the drying, there are usually some small holes on the scattering layer due to the different tension in the layer surface during drying. The holes can be fixed easily with the epoxy/Al_2O_3 mixture. Finally, the distal face at the end of the tip is cleaved (8 mm left) and polished, and then coated with an optically opaque epoxy (EPO-TEK® 320, whose transmission is less than 0.0001% at 300 nm-1 micron). A summary of the Coating Procedure is illustrated in Fig. 5.

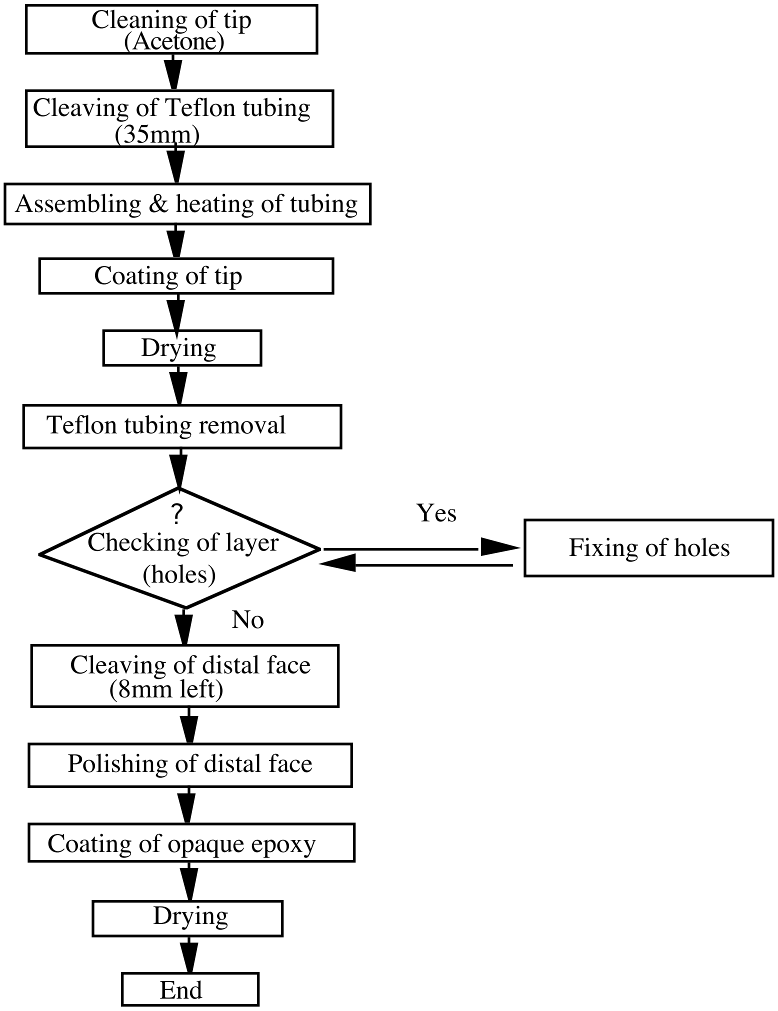


Fig. 5. Block diagram of coating procedure

4.2. Experiments

4.2.1. Light coupling to the diffusing tip

The convergence angle of the input beam refers to the half angle θ which characterizes the axial cone in a uniform beam of light converging on to the fiber end. When one launches light at a smaller angle than the acceptance angle of the fiber, at least over short lengths, the output beam is narrower. It is this narrow distribution of light that is input to the diffuser element. There are two techniques[13] for directly measuring the relative ability of fibers to accept power launched from different cone angles:

1. The fiber acceptance-angle technique, which measures the relative power launched as a function of launch cone angle

2. The fiber radiation-angle technique, which measures the relative power radiated as a function of output cone angle.

In our case, the second technique is used for directly measuring the output beam θ_o. Since the output beam is related to the input beam, e.g., the convergence angle of the input beam is equal to the output angle, at least for a strait fiber, in this way, we can obtain the convergence angle of the input beam through measuring the output angle. A common launch-optics arrangement is used; see Fig. 6. The both distal faces of the tested fiber, a silica optical fiber with 400 μm core diameter (Polymicro Technologies, Phonix, AZ), are wet-polished flat. Optimum coupling is achieved by maximizing the output optical power. Efficiency approximately ~ 80% is observed. The convergence angles of the input beam at the entrance face of the tested fiber are easily obtained through adjusting the optical system. The angle of output beam θ_o is given by

$$\theta_o = \tan^{-1}\frac{D}{2L}$$

as shown in Fig. 6. D is the beam spot size on the diffusive plane (a piece of white paper with rough surface), which is measured at the $1/e^2$ of its peak value with the CCD camera and the image processing system. In practice, the output angle will increase slightly (less than 1^o) with microbending, i.e., without specially wrapping, but if the fiber is wrapped into a circle, the difference of the angle will be up to 2^o.

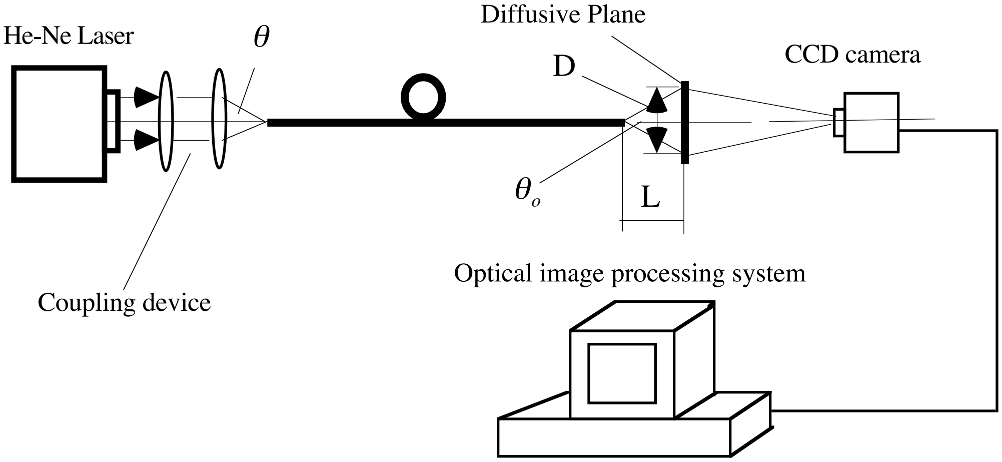


Fig. 6. Experimental setup for convergence angle measurement

4.2.2. Properties of the illuminator tip

4.2.2.1. Effect of scattering material on the light distribution

The purpose of this experiment is to measure the effect of the scattering material (Al_2O_3 powder) on the light distribution at the tip. The irradiance distribution at the tip without powder and with powder is measured respectively. The experimental setup is shown in Fig. 7. The tip is attached to a diffusive plane which is made of a piece of glass (0.1 mm thick) coated with UV epoxy (LITETAK 376, Loctite Co., Newington, CT0611) mixed with Al_2O_3 powder (the weight ratio of UV epoxy to Al_2O_3 powder is 10 to 3). The thickness is about 0.05 mm.

For the case without powder, since the small air bubbles in the optical epoxy (EPO-TEK® 301-2) are very difficult to remove, we use an immersion liquid (R.P. CARGILLE LABORATORIES, INC., Cedar Grove, NJ 07009), whose refractive index is close to the optical epoxy, 1.57 at 633 nm instead of the epoxy in this study. The large viscosity and surface tension of the immersion liquid permit us to directly drop the liquid on a glass diffuser and then the fiber could be inserted from above without the liquid leaking through the diffuser. The resulting pattern is intercepted with the diffusive plane and then captured by the CCD camera and image processing system whose output represents the light distribution on the tip surface since the diffusive plane is a reasonable good diffusing surface.

For the case with powder, the procedure is similar to that without powder, but the immersion liquid is replaced with the epoxy/powder mixture with two different concentrations.

Figure 8 shows the measured irradiance for one fiber tip without powder and with powder.

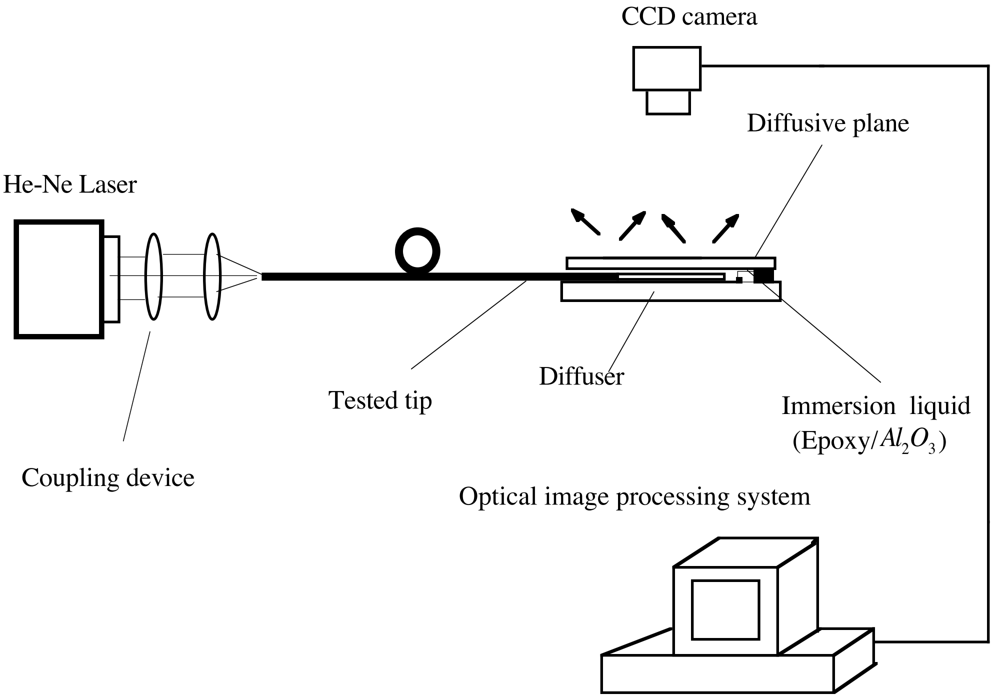
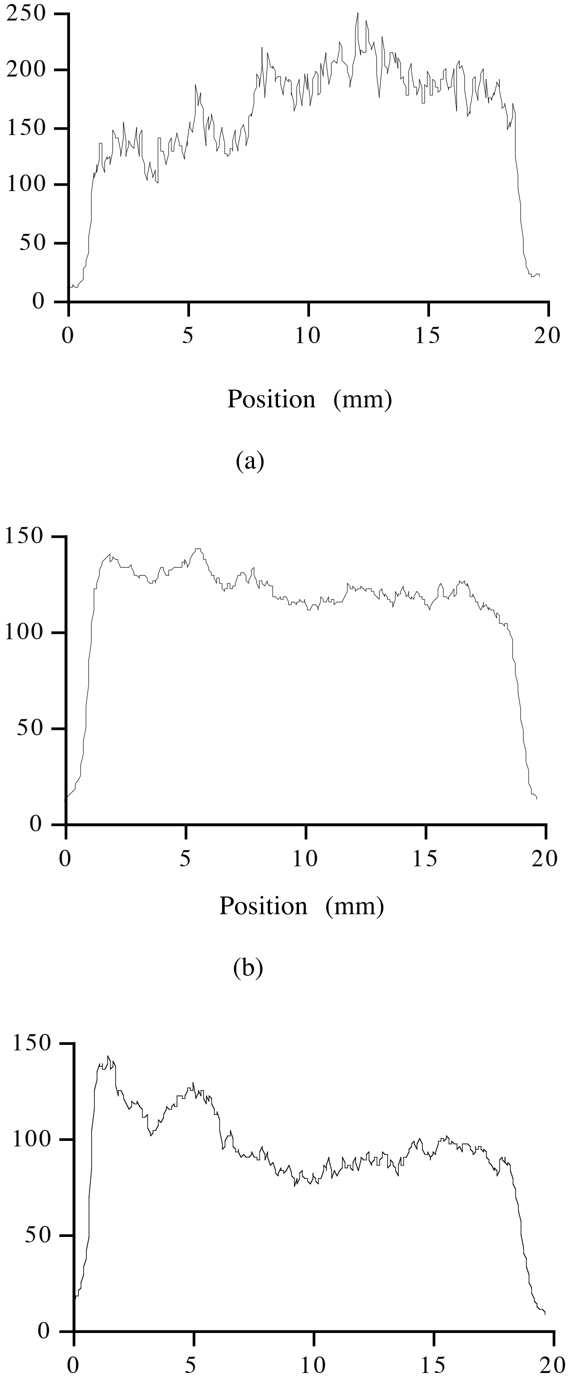


Fig. 7. Experimental setup for measuring the effect of the scattering material on the light distribution



(a)

(b)

(c)

Fig. 8. Measured irradiance at one tip: (a) without powder; (b) powder concentration = 285 mg/ml; (c) powder concentration = 570 mg/ml. Fiber tip specifications: bi-tapered tip length Lt = 20 mm, convergence angle of input beam $\theta = 5^o$.

4.2.2.2. Effect of light coupling on the light distribution

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Since the tip is made on the basis of a known convergence angle of input beam, the light distribution will be changed with different convergence angles. An arrangement for measuring the irradiance distribution for one fiber tip with different convergence angles is shown in Fig. 9. The tip is inserted into water. The radial distance from the fiber axis to the surface of water is ~ 1.75 mm. The CCD camera is focused on the surface of water to capture the resulting irradiance pattern of laser energy. The results are shown in Fig. 10. The measurement demonstrates that the light coupling, i.e., convergence angle, affects the irradiance distribution quite significantly.

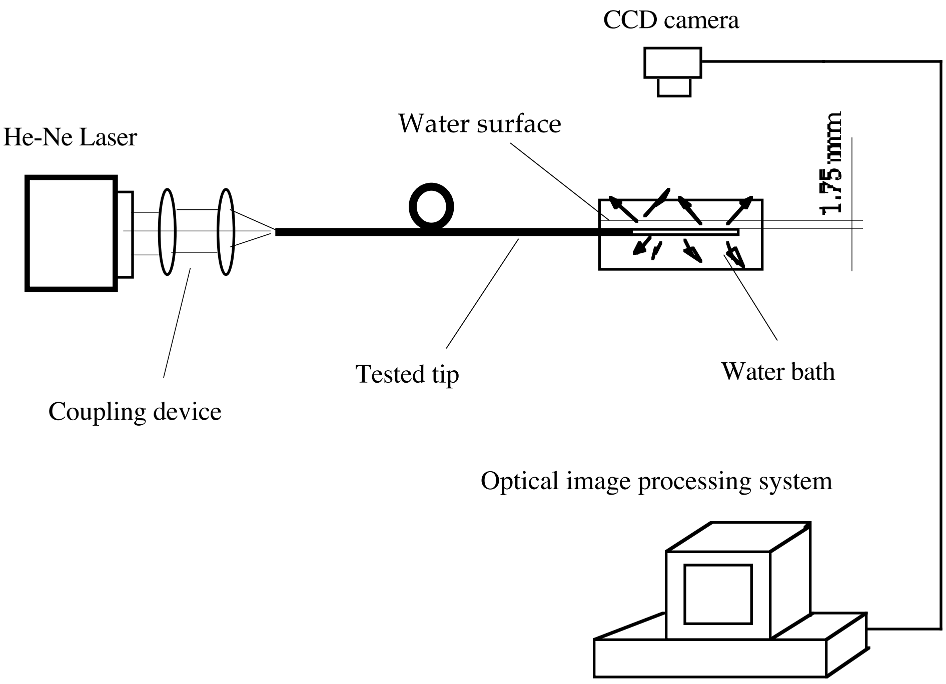
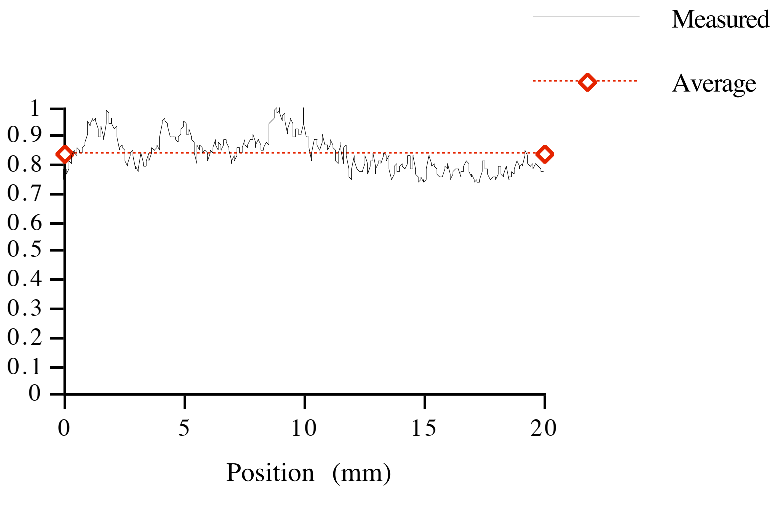


Fig. 9. Arrangement for measuring the effect of light coupling on the light distribution



(a)

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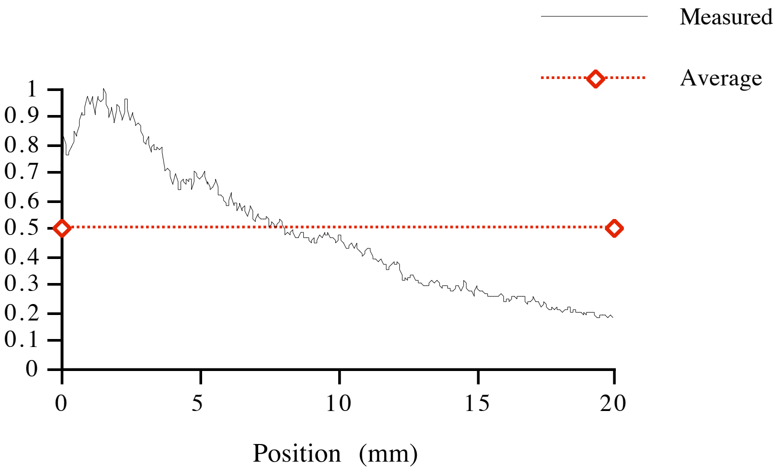

(b)

Fig. 10. Measured irradiance at a distance of 1.75 mm from the fiber axis for one fiber at two different convergence angles θ, normalized to the maximum value, for (a) $\theta = 5^o$; (b) $\theta = 8^o$. Fiber tip specifications: bi-tapered tip length Lt = 20 mm, powder concentration = 285 mg/ml.

4.2.2.3. Reproducibility of the fabrication technique

Four tips fabricated with the same fabrication technique are tested. Measurement apparatus for the reproducibility of the tips is shown in Fig. 11. The procedure is to measure the irradiance distribution with the setup shown in Fig. 11, and then to measure the total output power with an integrating sphere, a device used in conjunction with the radiometer to measure total optical power output from a diffuse source. The convergence angle of the input beam in this experiment is ~ 5^0. The irradiance distributions of each tip are measured on three "sides" with respect to rotation. The deviation of the irradiance distributions is consistently under 5% for all four tips. The error bars are drawn representing standard deviation of the mean of the four average distributions of each individual illuminator tip. Results from the irradiance distribution measurements of four tips fabricated with the same fabrication technique are shown in Fig. 12.

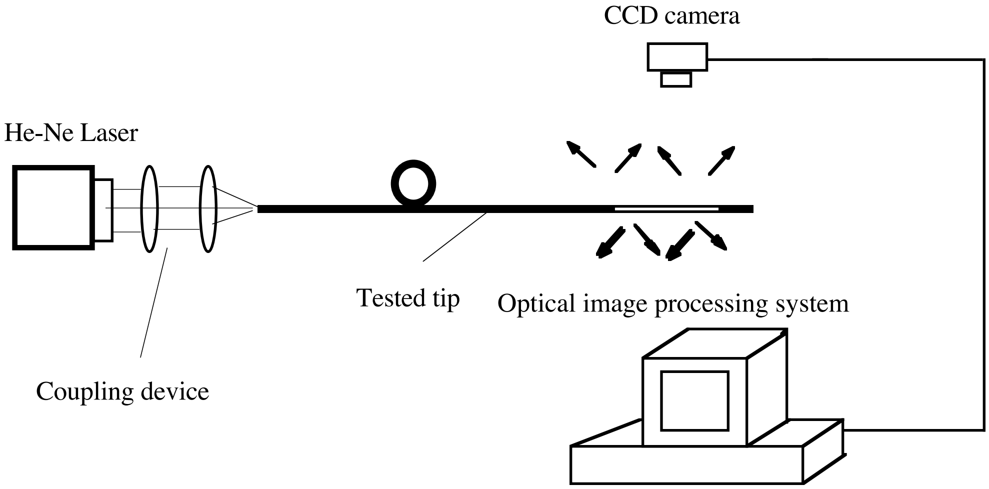

Fig. 11. Measurement apparatus for the reproducibility of the tips

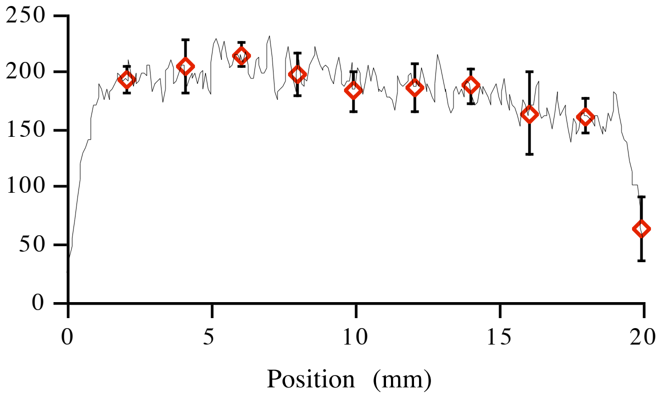

Fig. 12. Measured irradiance showing the reproducibility of the fabrication technique. Fiber tip specifications: bi-tapered tip length Lt ~ 20 mm, $\theta = 5^o$, powder concentration = 285 mg/ml.

4.2.3. Result for the device to illuminate an angioplasty balloon

The assembly used for the device to illuminate an angioplasty balloon is shown in Fig. 13 A Ti:Sapphire Ring Laser System with a doubling crystal (Model 899-01 Dye Ring Laser, COHERENT Laser Group, Palo Alto, CA 94303) pumped by an argon ion laser is used to generate the wavelength (λ = 365 nm) in this study. Since the performance of the illuminator tips is similar, we have chosen one of them to illuminate an angioplasty balloon in an experimental photochemotherapeutic treatment of swine intimal hyperplasia. The irradiance distributions are measured at four positions along the tip length and on four "sides" with respect to rotation shown in Fig. 13.

The irradiance on the surface of an angioplasty balloon is intercepted with an isotropic fiber optical detector connected to a power meter (Model 351B, UDT Instruments, Orlando, FL32826), whose output represents a measure of the power level around the nearfield of the balloon. The irradiance distribution can be determined by measuring the power level at a series of points along the balloon. The fiber scattering probe is made of 400 μm core fused silica fiber with a 0.5 mm diameter scattering probe and possesses an approximately isotropic response. The scattering material of the probe is UV epoxy/Al_2O_3 powder mixture. The convergence angle of the input beam in this experiment is ~ 5^o 9'. The result is shown in table 1.

The light extraction efficiency of the device is ~ 70%, considered with respect to the total optical power exiting the flat-cleaved fiber in comparison with that exiting the illuminator tip. During the measurement, the total optical power is measured with an integrating sphere. The transmission of the balloon material is ~ 90%.

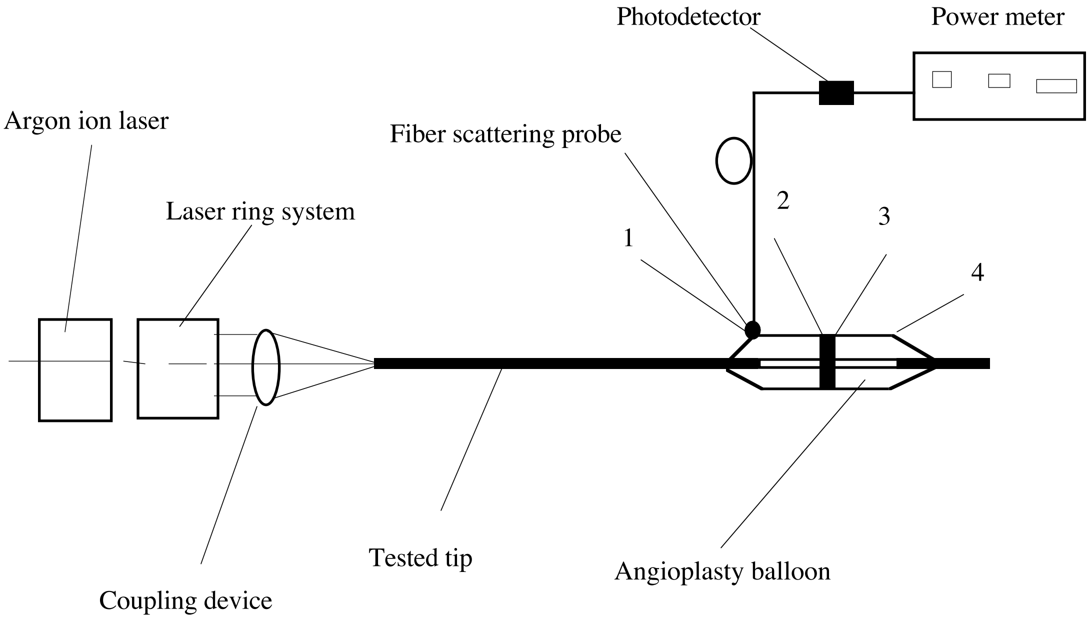

Fig. 13. Assembly for the device to illuminate an angioplasty balloon

Table 1. Measured optical power along an angioplasty balloon

Measured data(a.u) Position No. Measurement No.	1	2	3	4
1	1.90	2.00	1.69	1.72
2	1.95	1.90	1.63	1.58
3	1.68	1.72	1.62	1.60
4	1.70	1.58	1.61	1.54
Min. = 1.54, Average = 1.714, Max. = 2.00, δ = 0.145, Uniformity <+/- 15%				

Fiber tip specifications: bi-tapered tip length Lt ~ 20 mm, $\theta = 5^o$ 9', powder concentration = 285 mg/ml.

5. DISCUSSION

The light distribution of the illuminator tip is determined by the geometry of the tip , the convergence angle of input beam, the refractive indices of the core and the scattering layer, and the scattering powder concentration. Good uniformity can be obtained by optimizing these parameters. The fabrication technique used in this study is to modify the geometry of the tip on the basis of a given coupling condition. A more controllable situation would be the use of a low NA fiber (NA ~ 0.11) and a launch condition close to that NA. The disadvantage of our approach is that if the coupling condition in treatment changes, the light distribution will be changed significantly, for example, the uniformity varies from < ± 13% of the average value at $\theta = 5^o$ to ± 42% of that at $\theta = 8^o$ (see Fig. 10.). However, in practice, the light distribution does not alter significantly as the convergence angle is changed within the range $\theta = 5^o \sim 6.5^o$. Optimization of the fiber tip for higher NA launch conditions is possible by increasing the taper angle. However, this way may cause the fiber structure to be more brittle, since more of the fiber core is etched away. Therefore, the smaller the taper angle α is, the more safety there is against fracture.

The light is coupled out of the fiber structure due to the different indices of refraction of the core and the scattering layer. The measurements in section 4.2.2.1. show that the scattering powder is necessary for improving the uniformity due to the scattering function of the powder. Powder with higher refractive index will probably make the light scattering more efficient than powder with relatively lower refractive index[6]. We can not offer a rigorous explanation of the effects of higher powder concentration on the light distribution, but intuitive reasoning suggests that the scattering effect of the scattering layer may decrease, as has been observed in Fig. 8. (c). At high concentrations, many of the particle boundaries are shared, or separated by distances much less than the wavelength, and contribute less to the scattering, i.e., saturation may occur at higher concentrations. This reflects the fact that, at high concentration, all light that enters the scattering layer is immediately scattered.

In the present work, we have introduced what is to our knowledge the first use of the new device configuration where the tip is etched into a modified conical shape, and the distal end face is polished and then coated with an optically opaque epoxy to achieve a uniform cylindrical pattern of laser energy with the uniformity < ± 15% of the average value. The measurements demonstrate that the fabrication technique is suitable for producing an optical fiber diffusing tip with a uniform cylindrical irradiance pattern of laser energy and good reproducibility. However, in practice the illuminator tip can not be held in the center of the balloon due to the eccentricity of the balloon itself, and an eccentric distribution has resulted (see Table 1). On the other hand, since the optical epoxy/ Al_2O_3 mixture is not flexible, the tip may be easily broken when it is bent close to 50^o. Therefore, this diffusing tip in its current configuration will not be suitable for all vascular applications, specially where vascular anatomy involves vessel angulation $< 50^o$, but this problem may be solved with more flexible coating material and fiber than that used in this study.

Simple modifications in fabrication technique can alter the illuminator tip characteristics to suit different applications. We therefore expect this fabrication technique to be most useful for the design and fabrication of optical fiber diffusing devices for PDT with geometries, scattering materials, various types of fibers, etc., other than the present. The illuminator tip fulfills all of the design requirements that were set. The optimization of design and fabrication through mathematical modeling and improvement of the fabrication technique is currently in progress and will be reported elsewhere.

6. CONCLUSION

This study has yielded several important results: 1) The illuminator tip fulfills all of the design requirements of miniature size and uniformity of illumination. 2) An illuminator tip can be reliably made to obtain reproducible uniform cylindrical dispersion of laser energy for ultraviolet light delivery in PDT using the fabrication technique we have developed. 3) The tip is reasonably durable, convenient, and inexpensive. 4) This device has been shown to uniformly (+/- 15%) illuminate angioplasty balloons, 20 mm in length, that are used in an experimental photochemotherapeutic treatment of swine intimal hyperplasia. 5) Our experiments show that diffusing tips of < 400 micron diameter can be reliably constructed for this and other applications. Modeling results indicate that this design is scalable to smaller diameters, and thus small illuminators for PDT can also be fabricated in this way.

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