

# The Application of Ink-Jet Technology for the Coating and Loading of Drug-Eluting Stents

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**Abstract**—The combination of drugs with devices, where locally delivered drugs elute from the device, has demonstrated distinct advantages over therapies involving systemic or local drugs and devices administered separately. Drug-eluting stents are most notable. Ink jet technology offers unique advantages for the coating of very small medical devices with drugs and drug-coating combinations, especially in cases where the active pharmaceutical agent is very expensive to produce and wastage is to be minimized. For medical devices such as drug-containing stents, the advantages of ink-jet technology result from the controllable and reproducible nature of the droplets in the jet stream and the ability to direct the stream to exact locations on the device surfaces. Programmed target deliveries of 100  $\mu\text{g}$  drug, a typical dose for a small stent, into cuvettes gave a standard deviation (SD) of dose of 0.6  $\mu\text{g}$ . Jetting on coated, uncut stent tubes exhibited 100% capture efficiency with a 1.8  $\mu\text{g}$  SD for a 137  $\mu\text{g}$  dose. In preliminary studies, continuous jetting on stents can yield efficiencies up to 91% and coefficients of variation as low as 2%. These results indicate that ink-jet technology may provide significant improvement in drug loading efficiency over conventional coating methods.

**Keywords**—Reagent jet, Combination medical devices, Coating of medical devices, Local drug delivery, Off-axis jetting.

## INTRODUCTION

The use of drug-eluting stents in the field of interventional cardiology has been extremely successful in reducing the incidence of restenosis from 20 to 30% or more to the single digits.<sup>1,2</sup> They have evolved from normal metal stents but are coated with a pharmacological agent that interferes with the biological process of remodeling and overly aggressive healing that often

occurs in response to the therapeutic intervention. The pharmacological agent usually resides within a polymeric controlled release carrier which is coated on the stent's outer surfaces. Coatings can be accomplished through conventional methods such as dipping or spraying. Chen *et al.*, demonstrated that a drug eluting stent could be prepared using a commercially available airbrush with a 0.3 mm nozzle mounted on a linear motor.<sup>3</sup> The stent was mounted on a rotating mandrel and the airbrush was used to spray multilayers of collagen and sirolimus, followed by crosslinking of the collagen. Sustained release of the drug *in vitro* was demonstrated out to three weeks.

With tiny medical devices such as the coronary stent, having typical cylindrical dimensions of 1 mm diameter  $\times$  15 mm length, a much finer control on the coating process is desirable to eliminate overspray and resulting drug wastage during large-scale manufacturing. The Sono-Tek Corporation, Milton, NY, has addressed some of these issues by developing a product line of ultrasonic spray nozzle coaters which provide a focused spray through nozzles having 250–750 microns orifice diameter as given in their product specifications. Stents consist of a cylindrical scaffold which is a largely open structure, composed of a rectangular wire mesh defined by interconnected struts. Typical strut widths are in the 50–100 micron range, so overspray and resulting wastage, though reduced, is still an issue.

Reagent jetting is a process whereby a stent or other medical device can be coated in a metered fashion with drug or coating materials. More commonly called ink-jet printing technology, reagent jetting can be used to deposit active pharmaceutical agents or polymeric coatings onto the surfaces of devices in a controlled and reproducible way. As stated in an earlier paper by Cooley, Wallace, and Antohe, “Ink-jet based deposition requires no tooling, is non-contact, and is

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data-driven: no masks or screens are required; the printing information is created directly from CAD information stored digitally. Being data driven, it is flexible. As an additive process with no chemical waste, it is environmentally friendly”.<sup>4</sup>

The motivation for this work was to evaluate the efficiency of drug loading by reagent jetting, while maintaining acceptable stent-to-stent variability in the drug dosage. The conventional spray and ultrasonic processes described earlier are passive in that interaction of the droplets with the stent scaffold is dependent on the focusing and density of the aerosol passing onto and through the device. The trajectory of a given aerosol droplet is not independently programmed to intersect a stent element, in contrast to a jetted droplet.

The fundamental principles of reagent jetting are described in Cooley *et al.*, *ibid.* and are summarized below. During the jetting process, a capillary chamber is filled with reagent solution. By applying voltages to the wall of the capillary with a piezoelectric crystal bonded to the glass capillary, a distortion is caused that bows the walls outwards. This distortion causes the reagent pressure to drop, drawing more reagent

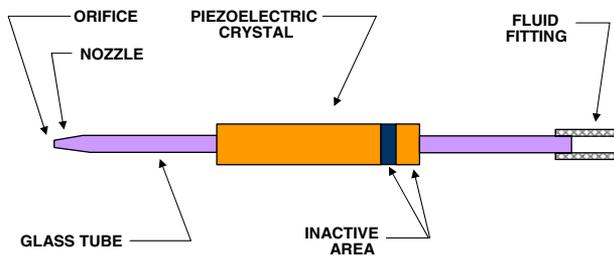


FIGURE 1. Schematic illustration of a reagent-jetting nozzle.

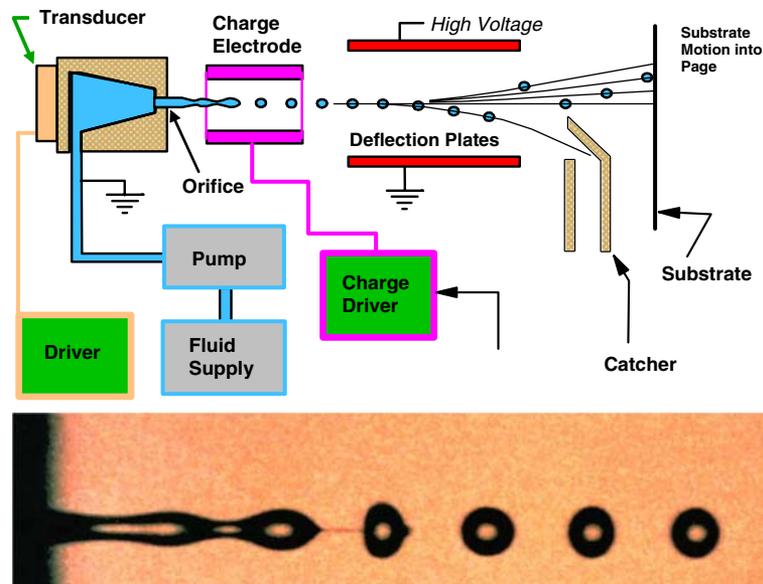


FIGURE 2. Schematic illustration of continuous mode jetting with photograph of temporal droplet formation shown below.

into the capillary. When the voltage is released and the walls return to their original positions, a droplet is expelled through the print nozzle orifice. A schematic of a dispensing device is shown in Fig. 1. Ink jet printing technology can dispense spheres of fluid with diameters of 15–200  $\mu\text{m}$  (2 pL to 5 nL) at rates of 1 MHz for continuous droplets (*continuous mode* jetting) and 1 Hz to 25 KHz for single droplets on demand (*drop-on-demand* jetting).

In a *continuous mode* ink-jet printer, pressurized fluid is forced through an orifice, typically 50–80  $\mu\text{m}$  in diameter to form a liquid jet. If a single frequency disturbance in the correct frequency range is applied to the jet, this disturbance will be amplified and drops of extremely repeatable size and velocity will be generated by the electromechanical device (piezoelectric transducer) that causes pressure oscillations in the fluid. A chargeable electrode is located near the orifice and induces a charge on the forming droplet before it breaks away. If the high voltage plates downstream are off, the charged droplets hit a catcher cup and are returned to the liquid reservoir for another pass. Application of a potential to the high voltage plates causes a deflection of the droplet(s) onto the target of interest. Figure 2 illustrates continuous mode jetting.

In a *drop-on-demand* ink-jet printer, the fluid is maintained at ambient pressure and a transducer is used to create a drop, only when needed. The transducer creates a volumetric change in the fluid which creates pressure waves. The pressure waves, which travel to the orifice, are converted to fluid velocity, that results in a drop being ejected from the orifice. The drop-on-demand mode was used extensively in this work and Fig. 3 illustrates its principle.

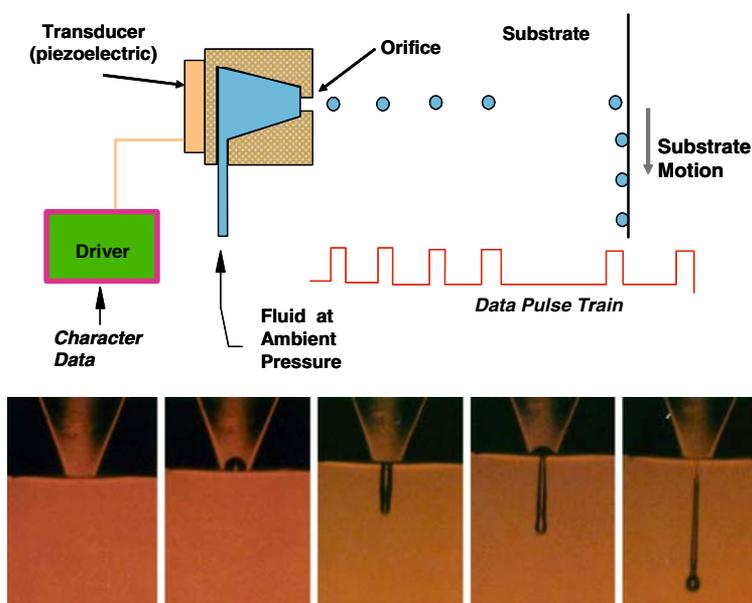


FIGURE 3. Schematic illustration of demand mode jetting with photograph of temporal droplet formation shown below.

So, in practice, a stent or other medical device is positioned in place of the paper as would normally be present during ink jetting to produce a document. A mechanical means can be provided whereby the stent is rotated and moved in front of the nozzle, but such movements are synchronized to the action of the ink jet printer head. The movements can be coordinated so that new stent or device surface is continuously positioned to receive a drop of coating solution or drug solution. Since medical devices are three dimensional structures, programmed software is required to control the movement of the stent as well as trigger the ink jet printer head.

Such timing and motion control can be complex. To simplify the process of coating a three dimensional wire mesh cylindrical structure, we have discovered that, if the stent is mounted on a rotatable mandrel and the jet stream is positioned to be tangent to the cylindrical surface that passes through the center of the strut thickness, a very efficient use of reagent is achieved. The motion control and timing of the drop-on-demand droplets are similar to those of a two dimensional process normally used to print documents. We have named this process *off-axis jetting* and it will be used and described in more detail in the sections that follow.

## METHODS

### *Reagents and Medical Devices*

The drugs used in this study were fenofibrate and the rapamycin derivative, ABT-578. Because of its

favorable physical properties and lower safety concerns with regard to human exposure in the laboratory, fenofibrate was used as a surrogate drug in place of the active pharmaceutical agent for many of the preliminary studies. Fenofibrate was obtained from Sigma-Aldrich Chemical Company, St. Louis, MO and the active pharmaceutical reagent, ABT-578 was obtained from Abbott Laboratories, Abbott Park, IL. Stainless (316) steel stents and stent coating polymer were obtained from Biocomptibles Ltd, Farnham, UK. The coating polymer was a phosphorylcholine-linked methacrylate tetracopolymer made from four monomers represented as follows, poly(MPC<sub>w</sub>:LMA<sub>x</sub>:HPMA<sub>y</sub>:TSMA<sub>z</sub>), where MPC is 2-methacryloyloxyethylphosphorylcholine, LMA is lauryl methacrylate, HPMA is hydroxypropyl methacrylate and TSMA is trimethoxysilylpropyl methacrylate. It is referred subsequently as "PC polymer" for convenience. The stent surfaces had a coating of PC polymer which had been applied to the stent by dip-coating and cured by published methods,<sup>5</sup> prior to the application of drug by reagent jet printing. The polymer precoat was employed to increase the adhesion between the drug and the stent and thus to eliminate potential release bursts. Though is likely possible to precoat the outer and inner surfaces of the stent with polymer by reagent jetting, dip-coating ensured a continuous polymer film around the struts. Our emphasis here was to study reagent jetting for the application of the more precious anti-restenosis drug. Additional PC polymer was sometimes dissolved in the drug solutions for jetting up to the level of 10% by weight with respect to drug, to serve as

a binder. The jetting solvent for both drugs and coating polymer was reagent grade isobutanol.

#### *Drug Loading Levels and Release*

The amount of drug loading obtained on a given device was determined after quantitative extraction from the stent into isobutanol, by UV absorbance at 278 and 280 nm for fenofibrate and ABT-578, respectively. Agitation on a vortex mixer of stents covered with a known volume of solvent for 2 min removed at least 99% of the deposited drug. Further extraction contributed signal that was commensurate with the noise level and was deemed unnecessary.

Drug release studies were done on reagent jetted stents for comparison with stents that had been loaded by the conventional method of spray atomization. A test protocol was used that was designed to cause the release of 100% of the drug over a 24-h period at 37 °C for a conventionally loaded stent. The medium was a gently stirred 1% Solutol solution (40× higher in concentration than its critical micelle concentration). Because of the lipophilic nature of ABT-578, release from stents under *in vitro* physiological conditions or *in vivo* takes several weeks to achieve, consequently, the rapid release protocol was used to compare drug release profiles from stents for this study.

The drug release over time from the stents was measured by High Performance Liquid Chromatography (HPLC) using a Zorbax Eclipse XDB-C8 reverse phase column 4.6 × 75 mm, 3.5 μm particle size. Samples of elution medium surrounding a given stent were removed periodically for analysis and the percentage drug released was calculated based on the average loading level for a given lot of stents, determined separately by total extraction of the drug from 4 to 5 stents. The column temperature was 45 °C, the flow rate was 1.5 mL/min and the injection volume was 20 μL. The mobile phase was 50% 0.01 M acetate buffer in acetonitrile. ABT-578 eluted at a relative retention time between 17 and 23 min (assigned as 1.00) with its equilibrium oxepane isomer following at a relative retention of 1.15, as monitored with a UV detector set at 278 nm.

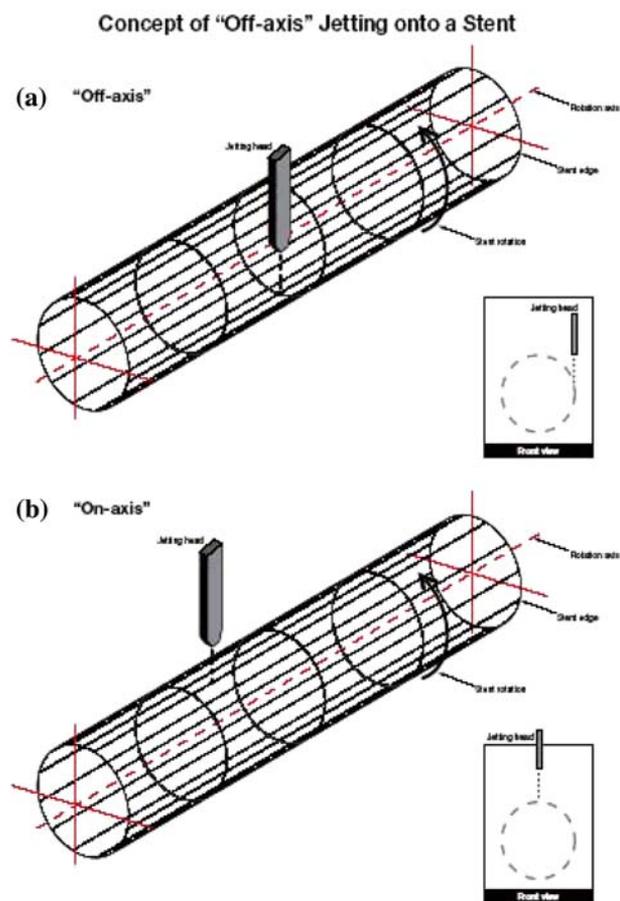
#### *Reagent Jetting Apparatus*

The reagent jetting hardware was an experimental version of the JetLab II commercial instrument manufactured by MicroFab Technologies, Plano, TX. The X–Y table was fitted with a rotating mandrel containing centering cones and its rotation was controlled by a programmable stepper motor. The ink-jet microdispenser was enclosed in a protective housing that has constant air outflow and exchange, to minimize worker exposure to drug and solvent.

#### *Principle of Off-Axis Jetting*

A reagent jetting system coupled to a motion control system for the stent, can be programmed to deposit the drug solution only on the strut surfaces. This requires a rather complex motion control scheme in order to always be on-target repeatably. The stent would have to be positioned at a common “start point address” and would have to be exact in dimensional tolerance from part-to-part. If these conditions were met and the motion control had repeatability ± a few microns, one could program the ink-jet microdispenser to jet on the stent pattern as it moves past the jet head in a programmed way. Alternatively, one could rotate the stent in front of an imaging camera, record the digital image and then jet on the stent based on its image signature.

In this work we employed a much simpler technique than the previously described approaches. It is called “off-axis” jetting. A schematic shown in Fig. 4 illustrates the principle. The basic concept of this technique



**FIGURE 4.** Principle of “off-axis” and “on-axis” jetting as applied to stents. The cylindrical surface shown represents the imaginary median surface passing through the middle (thickness-wise) of the struts.

involves positioning the stent represented in cross-section by a tube such that the stream of reagent droplets is tangent to the cylinder swept out by the stent as it is rotated around its longitudinal axis. Hence the line-of-sight vector that defines the jetting stream is in a plane that is tangent to the outer stent surface. The figure also shows front views of both “on-axis” and “off-axis” cross-section of stents and corresponding positions for the jet stream. It should be clear that the probability of hitting a strut is greatest with the off-axis arrangement. On the contrary, if the jet stream was positioned normal to the stent and passed through the rotation axis, the stream would interact with the maximum open space defined by the stent cylindrical dimensions.

With off-axis jetting, the need to coordinate droplet placement only when a stent strut is directly underneath the nozzle is eliminated without much sacrifice in capture efficiency. With this technique, the need for tight dimensional tolerances and part-to-part exactness in positional accuracy is not required. Lastly, the process will run efficiently without the need for complex optical feedback or imaging in order to keep the stent “on-target” with the droplets.

#### *Efficiency of Off-Axis Jetting*

The efficiency of jetting of drug onto a stent is defined as the actual amount of drug that was deposited onto the stent divided by the total amount of drug dispensed. This parameter is meaningful because not all dispensed droplets land on the stent struts. Spectrophotometrically, the actual amount of drug dispensed was determined by analysis of drug solution dispensed entirely into vials containing solvent, and the drug dispensed on the stent was determined by elution into the same solvent followed by measurement.

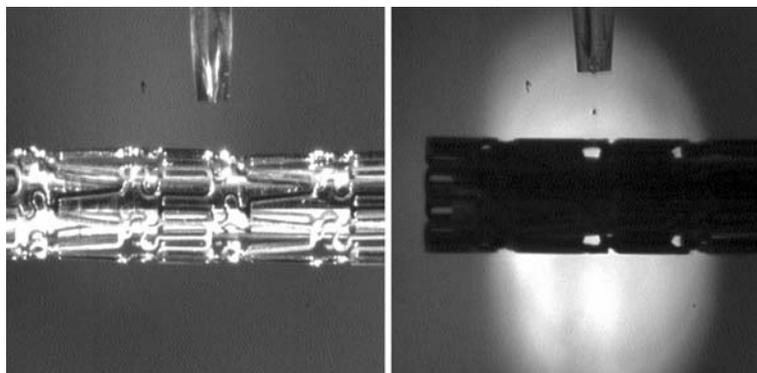
## RESULTS

### *Selection of Jetting Solvent*

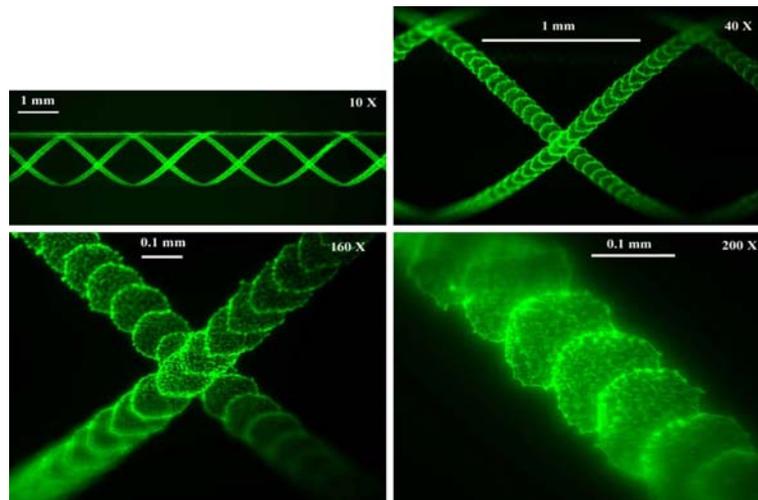
Initially drugs were jetted using ethanol (bp = 78.4 °C) as a solvent. Stable jetting over reasonable running times of an hour or less was not possible, most likely due to the volatility of the solvent which allowed precipitate formation on the nozzle. Deposits on the jetting tip have the effect of changing its droplet formation characteristics. Isobutanol, a higher boiling solvent (bp = 104 °C), was selected and very stable jetting in our stent loading work over several days occurred. Both ethanol and isobutanol are class 3 solvents in the toxicity rating (low toxicity) in the FDA Guidance to Industry on solvent use in pharmaceuticals. Figure 5 provides a continuous lighted view of the jetting tip near a coronary stent (left) and a strobed image (right) of a droplet traveling towards a coronary stent. Due to the surface tension of isobutanol, a smaller droplet (satellite) followed the main drop. The droplets had diameters in the 60–70 micron range, whereas the stent struts were typically around 80 microns wide with the satellites being under 10 microns and thus having minimal influence on the total volume. No splashing of the droplets on the stent surface was ever observed, probably due to the fact that alcohol solutions wet the PC-coated stent surfaces immediately.

### *Jetting of a Fluorescent Dye onto Coated Cylindrical Tubes*

To demonstrate the jetting control and individual droplet placement on a coated surface a fluorescent dye, coumarin 6 dissolved in ethanol, was jetted on an uncut but PC coated stent tube. The tube was mounted on a mandrel held by centering cones and the mandrel was bolted to an X–Y table. The tube was rotated about its longitudinal axis and translated along its length in the  $\pm$  direction to generate intersecting



**FIGURE 5.** Lighted view of a jetting nozzle and a stent (left) and strobed jetting to allow visualization of the droplet (right). In the left figure the mandrel holding the stent can be observed through the struts of the stent.



**FIGURE 6.** Jetting-droplet patterns of the fluorescent dye coumarin 6 on polymer coated uncut stent tubes at the magnifications shown.

helical patterns as shown in increasing magnifications from 10× to 200× in Fig. 6. The different magnifications illustrate the pattern control as well as the morphology and dimensions of individual droplets after they have hit the coating and spread out. The droplet size was calculated to be 50 microns coming from the jetting head and the droplet spread out to a diameter of approximately 145 microns on the coated surface. This particular experiment was not repeated with isobutanol as the jetting solvent, but one would anticipate in this case that the spreading may be greater since the evaporation rate is slower than for ethanol.

#### *Jetting of Pre-Programmed Stent Dosages into Vials*

Fenofibrate was dissolved in isobutanol at a concentration of 40 mg/mL. The ink-jet microdispenser was programmed to jet 15,000 droplets of 170 pL volume per droplet (main drop and satellite) directly into 10 mL isobutanol in test tubes with 5 replicates. The contents of each test tube were transferred to a spectrophotometer cuvette, the absorbance values measured at 280 nm, and the amount of drug jetted was calculated based on a calibration curve. The average amount of drug jetted during each run was 106  $\mu\text{g}$ , with a standard deviation of 0.6  $\mu\text{g}$ .

#### *Jetting of Pre-Programmed Stent Dosages onto Coated, Uncut Stent Tubes*

Five 1.5 × 15 mm uncut stent tubes were coated with PC polymer to form a base film. The tubes were individually mounted on a mandrel affixed to an X–Y table. Fenofibrate was dissolved in isobutanol at a concentration of 20 mg/mL. Based on the jetting characteristics found by the direct jetting into vials

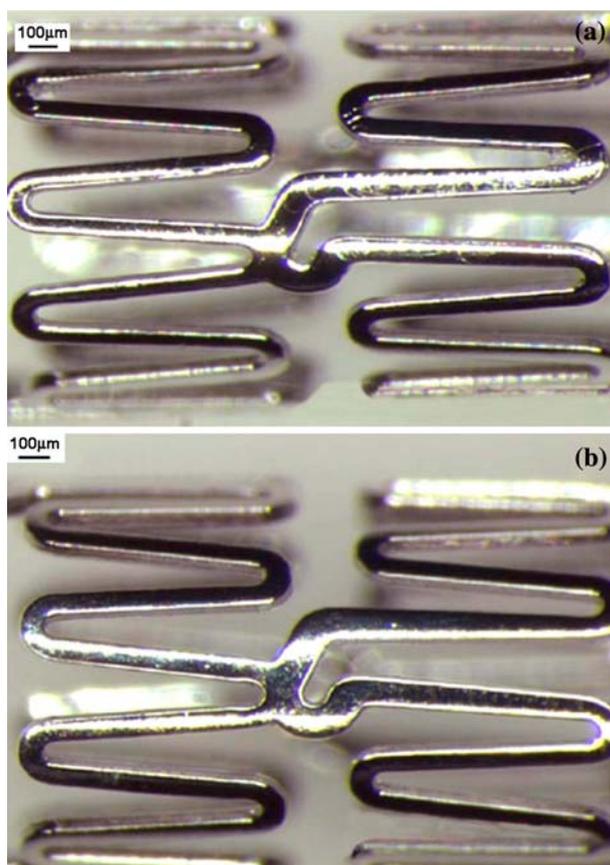
above, a target dosage of 150  $\mu\text{g}$ /per stent tube was programmed, which required a calculated value of 21,900 droplets be jetted uniformly along the tube surface. The tube was rotated and translated in one pass from one end to the normal to the jet head such that it would obtain the required number of droplets evenly dispersed across the tube surface. The drug jetted onto the tubes was extracted to determine the dosage obtained which was 140  $\mu\text{g}$  (93% recovery) with a standard deviation of 2  $\mu\text{g}$ .

#### *Off-Axis Jetting of a Pre-Programmed Stent Dosage onto Polymer-Coated Coronary Stents*

Nine (9) 1.5 × 15 mm PC-coated coronary stents were jetted in an off-axis mode with ABT-578. The concentration of drug was doubled to 40 mg/mL in isobutanol containing 4 mg/mL PC polymer used as a binder. The stents were jetted using a target value of 150  $\mu\text{g}$  per stent. The stents were air-dried in a chemical fume hood overnight and sealed in glass test tubes for storage at 4 °C. A mean dosage of 134  $\mu\text{g}$  (89% recovery) was obtained with a standard deviation of 12  $\mu\text{g}$  and a % CV of 8.6. Figure 7a shows that the cosmetic appearance of the jetted stent was good, with minimal webbing evident. There was some stress cracking of the drug-PC layer. Figure 7b shows the PC-coated stent before drug loading as a control.

#### *Off-Axis Jetting of a Pre-Programmed Stent Dosage onto Polymer-Coated Superficial Femoral Artery (SFA) Stents*

Eight (8) PC-coated SFA peripheral stents, 8 × 40 mm in dimension were jetted in an off-axis mode with ABT-578. The concentration of drug was

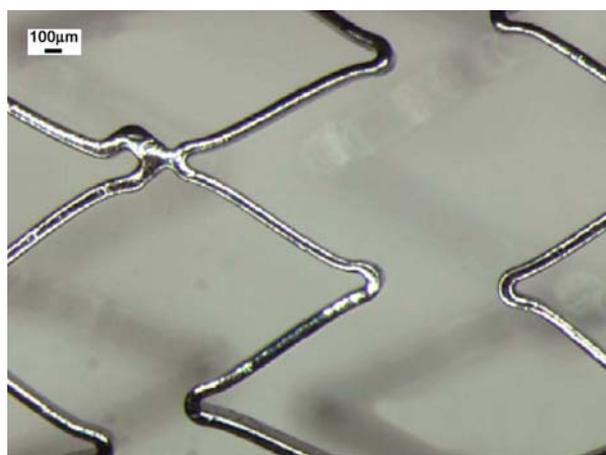


**FIGURE 7.** A polymer coated, 1.5 × 15 mm coronary stent (a) after loading with ABT-578 by reagent jetting (b) prior to loading with drug.

40 mg/mL in isobutanol containing 4 mg/mL PC polymer used as a binder. A target value of 600 μg per stent was selected. They were air-dried in a chemical fume hood overnight and sealed for storage at 4 °C. A mean dosage (loading) of 598 μg was obtained with a standard deviation of 14 μg and a % CV of 2.4. The efficiency of drug capture on these stents, based on jetting the drug solution into a vial of pure solvent using the same program was 62%. These jetted stents showed good cosmetic appearance with no webbing as shown in Fig. 8. A residual solvent determination was done on one additional jetted SFA stent. It yielded a value of 9 μg of isobutanol, 1.5% by weight relative to the drug. This result indicates that a more aggressive drying step will be needed to reduce the residual solvent to a desirable level to 0.1% or less, if isobutanol is used as the jetting solvent.

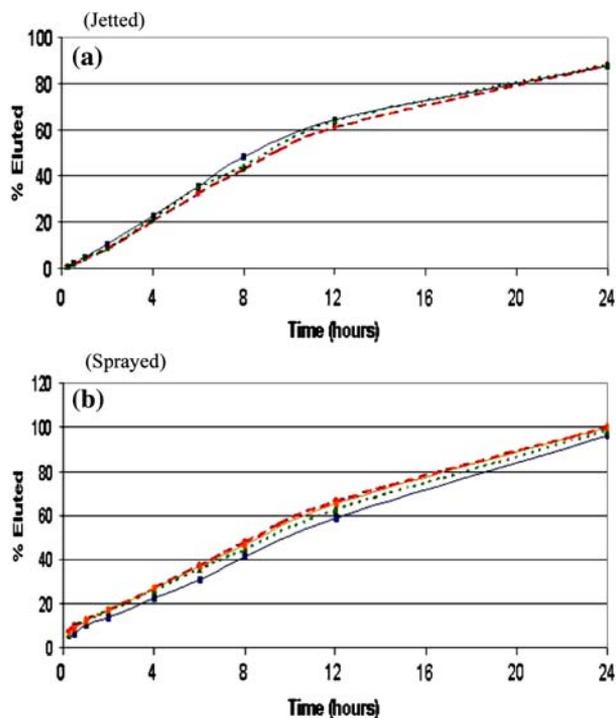
*Drug Release from Reagent Jetted Coronary Stents Compared with Stents Loaded by Spray Atomization*

Drug release from three (3) reagent-jetted 1.5 × 15 mm coronary stents and four (4) 1.5 × 15 mm



**FIGURE 8.** A 8 × 40 mm peripheral stent after loading with ABT-578.

stents loaded with ABT-578 by conventional spray atomization was measured over 24 h at 37 °C by the Solutol method described in the Methods section. The drug release curves from each individual stent are shown in Figs. 9a and 9b for reagent jetted and spray atomized stents, respectively. There are minor differences in the release profiles and total drug released at 24 h (90% vs. 100%) between stents loaded by jetting vs. spray atomization, respectively. In addition, the HPLC chromatograms of the drug, ABT-578, applied



**FIGURE 9.** ABT-578 eluted into 1% Solutol over 24 h from (a) 3 reagent jetted coronary stents and (b) 4 stents loaded by spray atomization.

and released from jetted stents indicated no loss of drug stability attributable to jetting as compared to released drug that was applied by spray atomization.

## DISCUSSION

### *Efficiency*

The efficiency of jetting of drug onto a stent was determined by jetting a pre-programmed amount of droplets under a constant set of instrumental conditions directly into a tube of solvent followed by spectrophotometric measurement. We make the reasonable assumption that 100% of the drug is recovered by this process. Then the same conditions are used to jet the stent. Extraction of the drug into a solvent and measurement of its amount spectrophotometrically allows the calculation of the efficiency of loading drug onto the stent. This can be represented by the simple relationship:

$$[\% \text{ Efficiency} = \text{Drug extracted from stent} / \text{Drug jetted directly into solvent} \times 100].$$

Since different stent designs have varying amounts of open space within the cylindrical surface swept out by its dimensions, determining the amount of drug and drug solution droplets required to get the desired dosage on each stent was determined empirically by trial and error.

Naturally, if one positions the jet normal to the stent cylindrical surface, which is mostly open space, most of the droplets will miss the struts, pass through the scaffold and be lost. We could use programmed motion control to jet directly on the struts and avoid open spaces, but this required complicated programming and required perfect positioning of the stent on the mounting device. The address of each point on the stent strut relative to the jetting head had to be known at all times so the jet stream would always be coincident with the strut surface. To avoid these complications and requirements we came up with a simpler jetting scheme which we call "off-axis" jetting. Here jetting is done continuously at the tangent to the cylindrical surface swept out by the cylindrical dimensions of the stent. The stent is traversed under the jet head and incremented in the rotational direction after each traversal. Typically the increment is 5 °C. Under this condition, the efficiency of droplet capture was optimized, but could vary between 60 and 90% depending upon the openness of the scaffold in a given design, trueness of the cylindrical dimensions, defects, and instrumental parameters chosen.

Lastly, the principle of off-axis jetting is a general principle and can be applied to a variety of stent patterns without the need to reprogram the ink-jet

**TABLE 1. Jetting efficiency as a function of target substrate.**

Target substrate	% Efficiency	% Open space
Container of solvent	100	0
Uncut coated stent tubes	93	0
Coronary stents	89	58
Peripheral stents	62	88

microdispensing to match the stent pattern. Only the parameters required to obtain the required total dosage (for example, drug concentration) need to be changed.

Table 1 illustrates typical preliminary efficiencies obtained for two different stents as compared to coated tubes. The % open space was determined by analysis of the two-dimensional image of the stents' surface.

### *Time to Jet One Stent*

The time necessary for an operator to coat an individual stent was measured. The jetting and motion control is robotically controlled, but the mounting, dismounting and cleaning of the rotation chuck is manual. On average, it took between 6.5 and 7 min per stent to complete the process. With automated robotic mounting and dismounting of the stents the total time can be reduced significantly, since the time the ink-jet microdispenser is actually dispensing drug is less than 2 min.

### *Significance of the Release Curves*

An artificial drug elution test designed to cause release of the drug over 24 h was used to compare the drug release from stents manufactured in different ways. This artificial Solutol medium in no way mimicked physiological conditions, nor was it expected to correlate with *in vivo* drug release, but was used as a rapid benchmark test to compare drug release properties between stents. Assay of the drug extracted from the reagent-jetted stents showed that no detectable degradation of the drug (ABT-578) occurred as a result of the jetting process. The fact that the release curves did not appear to be significantly different from those generated by conventional spray atomization, a technique used to produce stents used in animal<sup>6</sup> and clinical studies, is an encouraging indication that reagent jetting is a viable loading and coating process. Of course this may have to be confirmed by bridging studies between reagent-jetted stents and conventional stents in animal and human studies.

The remarkable control of the loading process with regard to number of droplets dispensed over a given time and the control of stent position possible with

programmable motion control indicate that many opportunities exist for the design of custom made stents. One could envision varying the areal density of drug along the stent to coincide with blood vessel areas in need of greater or lesser dosages. The use of multiple drugs dispensed in unique regions of the stent are possible as well. The application of drug release coatings, overcoats, and layers can also be envisioned.

Control of the loading process has an operator safety advantage over conventional spray atomization and ultrasonic spraying. All of the drugs used on stents have toxic exposure limits, hence isolation of human operators from significant drug exposure is required. With the precise placement of each individual droplet, the generation of significant wastage over a broad area of containment or free flowing aerosols in the vicinity of the operator is minimal. Quality control and process record keeping, a component of patient safety, can also be enhanced since the computer-controlled equipment can store a record of the drug dispensing for each uniquely identified stent.

#### ACKNOWLEDGMENT

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