Smart Catheter for stent placement

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Atherosclerosis, a form of heart disease in which arteries narrow, is the primary cause of mortality in the industrialized world. Endovascular stenting is a form of treatment used to fix this problem. It involves the placement of pencil-lead-sized tubular scaffolds inside the coronary arteries. There they are plastically expanded and remain as permanent implants. Although relatively new (stents were approved by the FDA in 1994), stenting has surpassed balloon angioplasty as the most common minimally invasive treatment for atherosclerosis in the United States.

Unfortunately, the stent's thin walls image poorly under angiography (X-ray), making it difficult to determine when the stent is optimally expanded within the artery. This can lead to over-inflation of the balloon catheters used to expand the stents, resulting in injury to the arterial wall. This damage has been linked to restenosis, the most common failure mode of stenting. We have developed an instrumented catheter that can detect stent/vessel apposition pressure, and thus prevent vessel injury.

We employed a series of capacitive sensors attached to the balloon catheter. As the metallic stent expands and contacts the arterial wall, it compresses a dielectric layer separating the outer stent from an inner metallic plate permanently affixed to the balloon. As the dielectric layer compresses, the capacitance of the system increases. The system measures this capacitance at several sensor locations along the stent length and sends the data to a computer where it is converted into artery/stent pressures. The program then graphically displays the pressures in real time.

Benchtop testing reveals post-calibration accuracy of ±0.9 atmospheres (atm) over the 0 to 10 atm pressure range used to deploy stents. The ability to accurately measure stent/vessel apposition pressure will help clinicians deploy the stent at optimum pressures, reducing complications and ultimately may save lives.

Heart disease and stenting

According to the American Heart Association, heart disease has long been the leading cause of death in America, and recently surpassed starvation to become the primary cause of death worldwide. The process of hardening and narrowing of the arteries called atherosclerosis is a major national health concern. This narrowing frequently results from an accumulation of cholesterol-laden macrophages (a type of white blood cell) that attach to and invade mechanically injured arterial walls. Mechanical injury of the endothelial lining of the arterial wall may also initiate platelet aggregation, causing blood clots to form, as well as stimulate the runaway proliferation of cells from the vessel wall into the center lumen of the artery in a process called neointimal hyperplasia.

As blood flow is progressively impeded, oxygen starvation of cells (ischemia) occurs. If sufficiently severe, ischemia results in cell death and cardiac infarction.

Arterial blockage is frequently treated with a minimally invasive procedure involving an expandable wire sleeve, or stent. The stent is packaged in its compressed state over a balloon catheter. It is placed into a small incision in the patient's groin and threaded through about one meter of vasculature to the site of the arterial narrowing. The balloon is then expanded which plastically deforms the stent, pressing it against the arterial wall to scaffold it in place. The balloon is deflated and withdrawn, leaving the artery propped open by the permanently implanted stent.

Despite many recent advances in stent designs and delivery systems, up to one-third of all stenting procedures need follow-up work within six months of implantation to correct post-operative symptoms. Recent work suggests these problems may result from suboptimal stent deployment against the arterial wall, according to J.C. Squire.

There are two types of suboptimal stent deployment: under-expansion and over-expansion. Under-expansion is acutely dangerous. Eddy currents caused by blood flowing through the stent struts that are not pressed into the vessel wall cause blood clots to form and wash downstream where they completely obstruct flow. This often requires emergency open-heart surgery to correct.

Because it is difficult to image the location of the stent struts relative to the artery wall (the stent struts are so thin they are not radioopaque), interventional vascular cardiologists opt for a second approach: intentional over-expansion.

Over-expansion carries risks of its own. The high pressure the

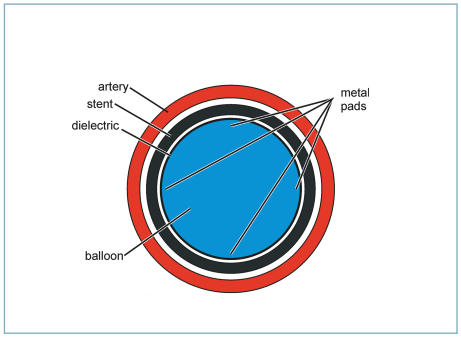

Fig. 1 Cross section of the smart catheter deploying within an artery with four sensors spaced around balloon circumference. Each sensor consists of a metallic pad permanently affixed to the balloon surface, a dielectric sleeve, and the metallic stent. Pressure caused by the artery pressing against the stent compresses the dielectric layer, which is remotely monitored. The diameter of the system is about 1.5mm unexpanded and 3 mm expanded. Multiple rings of these sensors may be placed along the longitudinal axis of the balloon to measure proximal, middle and distal pressures.

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stent exerts against the arterial wall can damage the superficial endothelial layer of the artery as well as injure deeper arterial structures. For reasons still not fully understood, this frequently triggers the smooth muscle cells that compose the bulk of the vessel wall to begin proliferating in an uncontrolled manner into the vessel lumen, states Klemens H. Barth. This neointimal hyperplasia continues for several weeks, often impeding blood flow more than the original diseased state did.

The smart catheter

We developed the Smart Catheter to address the shortcomings of angiography by using pressure sensors that are integrated into the stent deployment balloon catheter. Multiple sensors are required to measure non-uniform expansion in the stent because the atherosclerotic lesion in the target vessel may be irregularly shaped; our prototypes employed three sensors evenly spaced along the 12mm length of the stent.

Each sensor is a parallel plate capacitor (Fig. 1) constructed of a thin metal foil pad, a compressible dielectric, and the metallic stent body. An inverse relationship exists between the compression of the dielectric and the increase in the sensor capacitance.

The foil pads of each sensor are cemented directly to the non-conductive balloon, and are connected to individual insulated wires that run the length of the catheter. A compressible dielectric sleeve covers all the pads, and the metal stent is crimped over this dielectric sleeve. A single wire is sandwiched between the dielectric sleeve and the metal stent forming a common ground lead that can be withdrawn once the stent is deployed.

As the stent presses against the artery, the dielectric compresses, increasing the sensor capacitance. This is measured using a data acquisition system polled by a laptop. The laptop graphically displays the stent/artery arterial pressure, ensuring optimal stent deployment pressure.

Catheter and sensor construction. Several components had to be chosen to fabricate the catheter: capacitor plates, dielectric, an adhesive material to cement the sensors together, and wires to connect the sensors to the external data acquisition system. Several candidates were available for each component.

The capacitor plates must be able to withstand the strain that the balloon exerts as it doubles in circumference during expansion. Ideally, the pads would be very thin to avoid making the catheter too bulky, and would not be susceptible to ripping or tearing. Adhesive-backed foil that was 63mm thick was examined, but the adhesive was too bulky for the 1mm x 2mm pad size. Also, the foil itself was not flexible enough to follow the contour of the expanding balloon.

A painted-on conductive silver paste was also tried. This material bonded sufficiently with the balloon, but became brittle after drying. When the stent was crimped onto the balloon, the paste cracked, making the pads ineffective. Aluminum foil sheets that were 38 mm thick were chosen as the best candidate because of their flexibility and durability even when sized to the small 1x 2mm pads used for the sensors. These pads were attached to the balloon using an adhesive dielectric.

The dielectric was chosen after testing several dielectric candidates for susceptibility to ripping, capacitance change and thickness. Foil pads were placed above and below the dielectric to be tested. The system capacitance was measured as an external weight was applied to the upper pad to duplicate the 0-10 atm pressure range encountered in human stenting procedures. Liquid electrical tape was selected as the material with the greatest change in capacitance among the group of dielectrics durable enough to withstand repeated expansions.

The wires used to connect the sensors with the data acquisition system had to be thin enough not to interfere with the stent and balloon operation, but thick enough to maintain mechanical integrity, and be insulated against conductive blood. Forty-gauge enameled wires were chosen and attached to the pads with the conductive silver paste. These wires were then wrapped around the catheter body extending back toward the capacitance meters and secured with heat shrink tubing. A common ground wire was placed on the exterior of the dielectric layer and the metal stent was tightly crimped over it.

The sensors were analyzed in benchtop tests. A mock artery was constructed from a latex rubber tube with a 3mm diameter opening and 2mm thick wall. This best simulated the flexibility and size of a diseased artery where stents are most used. The testing procedure involved inserting a completed balloon catheter sensor 10cm into the rubber hose. The catheter was then slowly expanded to 8 atm in 1 atm steps while the laptop recorded the sensors' capacitance.

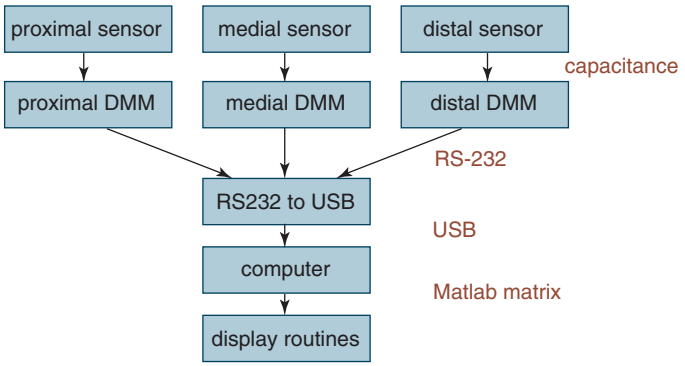

Fig. 2 Block diagram of the data flow within the Smart Catheter

Data acquisition and display construction. The data acquisition system is shown in Fig. 2. Three capacitance-measuring multimeters with 1pF sensitivity (Fluke 180) with RS-232 interfaces were used as a less-expensive alternative to purchasing a general-purpose data acquisition system and signal conditioners. A serial to USB hub was used to connect each multimeter with the PC.

Matlab R12 was used to program the visualization routines because of its ability to communicate with the virtual RS 232 devices that the USB hub emulated. The program graphically displays the stent/artery pressure in three locations along the length of the stent (Fig. 3). The program also allows the user to calibrate each sensor's capacitance to pressure ratio before surgical use.

Calibration is necessary because certain attributes, such as dielectric thickness, are not identical from catheter to catheter. To calibrate, the stent system is expanded within the latex arterial model, noting the capacitance readings at 0 and 10 atm, and then recrimped down to its original pre-expansion diameter. The visualization software then linearly maps capacitance readings between these two extremes.

Methods, assumptions,results

Data collected from testing in the arterial model shows that although the stent begins as a narrow cylinder and ends as a wider cylinder, it does not expand evenly. Rather, the unsupported ends of the stent expand and contact the arterial wall first, followed by late expansion of the stent middle, as shown in Fig 4. This "end-flare" behavior may cause localized arterial injury near the proximal and distal ends (measured with respect to the catheter stem). This hypothesis is supported by the clinically observed fact that neointimal hyperplasia is most severe at the extreme ends of the stent.

Sensors were found to have an offset linear relationship between pressure and capacitance accurate to within 10% everywhere within the 0 to 10 atm range, and a maximum post-calibration error of ±0.9 atm. A simple experiment was performed to verify a linear relationship between capacitance and pressure. A known thickness of dielectric material was applied onto a thin sheet of paper. Then a known mass was rested onto a given area of the dielectric layer. The thickness change of the material was then measured to the nearest 10µm. As more weight was added and the force (or pressure) increased, the dielectric material decreased in thickness. Nine trials were performed over a mass range of 0 to 3.5kg that induced a 0 to 10 atm pressure. The relationship of pressure applied to compression of the dielectric was found to be linear according to the equation:

Compression Distance in mm = 0.0362(Pressure in atm)*

Since capacitance is inversely proportional to the distance between two plates (given by C = (ÂA)/d where C is capacitance and d is the distance between two plates), capacitance is linearly related to pressure.

The only observed failure mode of the catheter was caused by dielectric puncture from the stent struts. At pressures above 6 atm the stent struts were prone to lacerate the dielectric, shorting the sensors. Repairs to the dielectric could be made but usually only lasted for a single expansion cycle as the new liquid electric tape material bonded poorly to the already hardened liquid electric tape on the balloon.

The likelihood of dielectric laceration was found to be a strong function of the stent geometry. Two types of stents were used. One employed a simple repeating diamond-pattern of struts resembling chicken wire, and expanded by stretching opposing diamond corners.

The second type was a second-generation gull-wing design consisting of a complex mesh of U and W shaped elements. This latter configuration caused more dielectric ripping because its complex geometry induced a greater strain variance in the dielectric.

Smart catheters manufactured using the diamond stents were able to withstand an average of 4.0 ± 1.4 expansion /re-crimping cycles, but the gull-wing design caused catheter failure after only 1.5 ± 0.5 cycles. An encouraging observation that occurred in every trial was a minimum change in capacitance of 200% from start to full expansion of the balloon, making accurate pressure measurements possible.

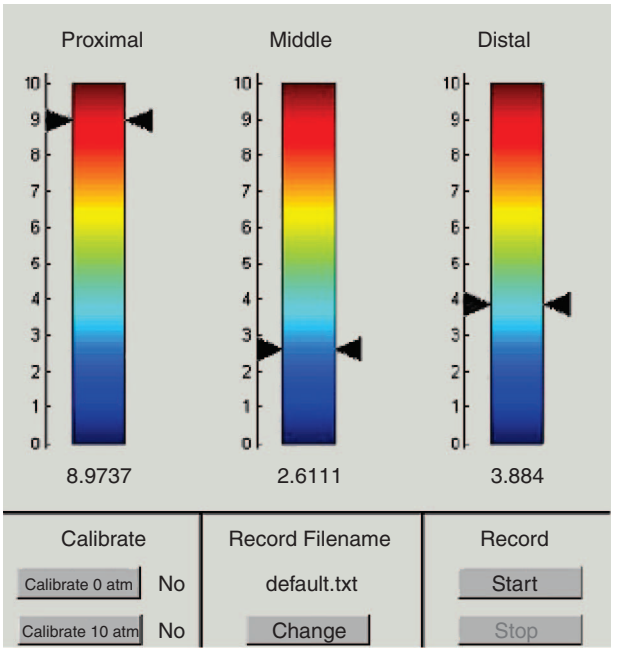

Fig. 3 Visualization software of the 3 stent/arterial pressure was coded in Matlab R12. The system must be calibrated at both 0 and 10 atm. Data may be recorded in real time.

Analysis of the behaviors of the prototype trials leads to suggestions to improve the current design. First, a more durable dielectric material must be found. Liquid electrical tape rips and punctures easily under the stresses of the expanding balloon and constricting stent. The dielectric material must be strong, yet flexible to change under the varying pressures of the expanding balloon.

Improvements to the manufacturing process of the balloon pressure sensor must also be made. Currently the sensor is constructed using a wide-field binocular microscope and precision hand tools. Hand tremors make it difficult to work with the 1 mm foil pads. The tremors also introduce irregularities in the dielectric coating that make it more susceptible to rupture.

Lastly, all testing was done using a latex arterial model. Before the system can be used clinically, biocompatibility testing must be performed on the

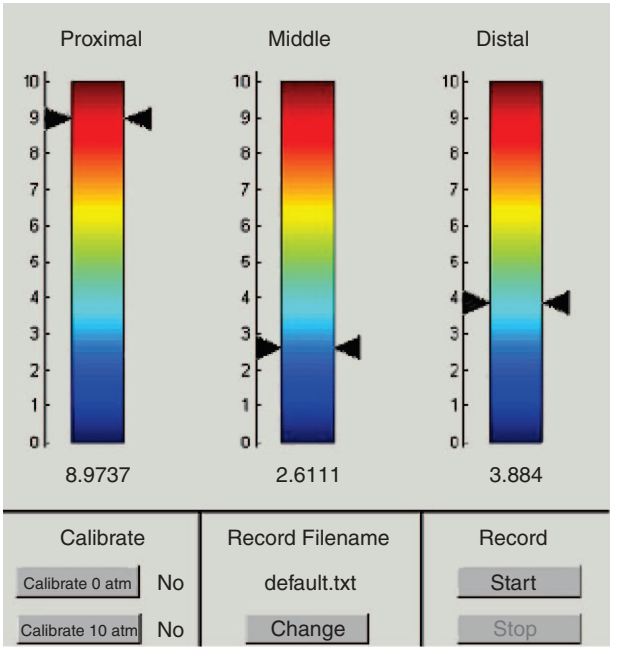

Fig. 4 Typical readings taken from the calibrated Smart Catheter when deployed within an arterial model. This model used three pressure sensors evenly spaced along the stent's longitudinal axis.

A life saver

The first goal for treating heart disease is reducing the risk of a heart attack or to reduce any symptoms. According to Heart Center Online <www.heartcenteronline.com>, treatment also minimizes the amount of damage to your heart tissue. "Damage to the heart tissue is permanent and cannot be restored," the site reports. And for best results, treatment needs to be given within the first 4 to 6 hours of a heart attack.

Stents are now "even edging out cardiac bypasses as the treatment of choice for many. In the U.S. alone, roughly 400,000 people a year are treated with stents, while sales of the devices are approaching $3.5 billion a year, reported Susan Dentzer on a *NewsHour with Jim Lehrer* (PBS, 6 March 2001). Bypasses are major operations that require cutting through the breastbone to get to the arteries. Stents are not perfect solutions, however, Dentzer points out. The stent is a foreign object to the body, "and the stent itself initiates a series of events, normal events—response to injury events—which in about 20% of the patients results in renarrowing," added Jonathan Reiner, MD, who was part of the discussion.

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Even so, stents are the primary reason angioplasty procedures (inflating a balloon in the narrowed section of the artery) have tripled in the US since 1995 reports Ron Winslow (24 Dec. 2002, *The Wall Street Journal*). Also, a study published in *The Journal of the American Medical Association* (January 2001) found that heart attack patients who had emergency angioplasty or bypass surgery were 39 % more likely to be living a year after the event than those who received less aggressive treatment.—*Mary K. Campbell*

elements that contact blood, specifically the dielectric sleeve and the sensor wires (the rest of the sensor is shielded from blood contact by the dielectric sleeve).

Conclusions

The Smart Catheter uses a sensor array integrated into the catheter body to provide real-time measurement of endovascular stent/artery apposition pressure. This enables the optimal placement of stents without danger of under- or over-expansion. By placing sensors at the site of stent/artery contact, data may be obtained that is difficult to infer from conventional remotely mounted sensors such as angiographic X-rays. Optimal deployment pressures decrease the likelihood of both acute complications like vessel injury that otherwise would cause platelet activation and thrombosis, and chronic complications such as re-closure from neointimal hyperplasia. The balloon catheter pressure sensor may be modified for use in any surgical dilation application such as in the hepatic or urethral ducts. This biomedical device has the potential to reduce invasive cardiac surgeries, reduce stenting complications, and ultimately save lives.

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Read more about it

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Matthew R. Brooks graduated with honors from the Virginia Military Institute class of 2002 receiving a BS degree in electrical engineering. He presented his research at the 2002 IEEE Student Paper Competition and earned first place in the Region 3 Conference. Commissioned a 2nd Lieutenant in the United States Air Force, Matthew attends the Air Force Institute of Technology at Wright-Patterson Air Force Base where he pursues an MS degree concentrating in electro-optics.