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Cardiovascular Devices

John Simpson: Reluctant Entrepreneur

*An interview with one of the most successful
physician/device entrepreneurs, who never thought
he'd wear either of those hats.*

By David Cassak

- John Simpson never set out to be a physician and still does not consider himself a businessman; yet he is a leading interventional cardiologist and has launched more than a half dozen successful device companies.
- Simpson takes pride in building successful teams, enabling him to delegate the engineering and business responsibilities to others, while focusing on what he does best: figuring out how to better treat the patient.
- He is perhaps best known for developing over-the-wire angioplasty through his first company, ACS, and has followed that with companies involved with ultrasound (CVIS), atherectomy (DVI and Fox Hollow), vascular closure (Perclose), and chronic total occlusions (LuMend).
- Simpson remains iconoclastic when it comes to patient care issues. So although angioplasty is where he made his name, he remains suspect of stents and hopes through his current venture, Fox Hollow, to minimize their use.

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Ask John Simpson if he considers himself a businessman and he balks. An entrepreneur, perhaps, and definitely a physician, but the business moniker is one he disdains. Some see that as strange for one of the most successful serial entrepreneurs in the medical device industry. With a track record of more than a half dozen start-ups, most either successful or on the verge, one would hardly think business would be a dirty word to their founder. But for Simpson, his motivation for starting device companies is derived from the reason he chose the medical profession: treating patients. And that is the basis on which he judges the success of his efforts.

Simpson is most well known as the father of over-the-wire angioplasty developed through his first company, **Advanced Cardiovascular Systems Inc.** (ACS), which became part of **Guidant Corp.** He has seen several of his other start-ups acquired by other large device companies, including atherectomy company **Devices for Vascular Intervention Inc.** (DVI), which became part of Guidant after being sold to **Eli Lilly & Co.**, ultrasound company **Cardiovascular Imaging Systems Inc.** (CVIS) by **Boston Scientific Corp.**, and vascular closure company **Perclose Inc.**, which is part of **Abbott Laboratories Inc.**

Recently, **Stanford University** began a series called *From the Innovator's Workbench*, which involves individual interviews with leading inventors and entrepreneurs in the medical device industry. This is the third article from this series to appear in *IN VIVO*. The interview with John Simpson is culled from one session in this series in which Simpson discusses his background and how he transitioned from interventional cardiologist to device entrepreneur. He also talks about his philosophy when it comes to company creation and what he sees as the core competencies needed to sustain value in device start-ups.

IN VIVO: *You were raised in Texas and your first goal was not to be a doctor; in fact, your initial graduate work wasn't in medical school. Talk a little bit about your early training.*

John Simpson: Actually, I wanted to be a veterinarian and I was a pre-vet major at Texas Tech; I've been keeping that a secret for a long time. I struggled a little bit academically in the early days, didn't make it to class quite as often as perhaps my parents had hoped, and found that I actually was not qualified to go to vet school when I finished, so I ended up having to go to medical school, which was the next best alternative. But before med school, I went to graduate school and got a PhD in immunology.

Q: *Your work in immunology led you to medical school through an early mentor. Who was Bernard Amos and how did he help steer you into medical school?*

Bernard Amos was the premier immunologist at **Duke University** at the time that I was thinking about going to medical school. He discovered maybe the first histo-compatibility antigen in man that was responsible primarily for graft rejection.

He was an extraordinary individual and, because of my interest in basic science, helped sponsor my med school application. And trust me, my application needed a lot of sponsorship, so Bernard was a special person in that regard.

Q: *Were you one of those kids who was always pulling mechanical things apart and inventing things?*

No. I liked big machines, but they usually had wheels on them and I could drive them, like the tractor on my grandfather's farm. But unlike someone in our industry like Tom Fogarty, who says he has always been the ultimate tinkerer and inventor, I was never that way.

Q: *Why did you eventually choose cardiology as a specialty?*

That's a good question. I did my house-staff training at Duke, and cardiology for me was an area of special interest. I'm not really certain exactly how it evolved. Originally, I was going to be an oncologist, and of course that was after I was going to go to vet school, so you can see I've been a very focused individual with a very direct career course. But after oncology didn't quite gel for me, I ended up choosing cardiology, and wound up doing my cardiology training not at Duke, but at Stanford.

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Q: *Were you thinking about a career practicing cardiology and what was a cardiology practice like at that time, which was the early-to-mid-1970s?*

At that time in cardiology, everything was diagnostic. The whole concept of interventional procedures was not very well formed. In fact, it was not formed at all. For example, I was censured by one of the cardiologists at Duke, when I was a house staffer, for giving nitroglycerin to a patient who was having chest pain because, the thinking went, that patient could be having a heart attack and it would be very dangerous to do anything to anybody while they're having a heart attack. You could really put them at risk. That's a far cry from our current approach to the treatment of acute myocardial infarction where if you don't do something, you basically will go to jail. The current therapy for acute MI would have never been imagined in the early 1970s, and it's really to Andreas Gruentzig's credit that the whole specialty of interventional cardiology has developed.

Q: *So after medical school, your goal was to be a practicing cardiologist and you almost achieved that in Jackson, Mississippi, until you heard a talk at Stanford by another of your mentors. Tell us about your first contact with Andreas Gruentzig and how that ultimately cost you a career in Jackson.*

I was having trouble getting a job when I was finished Stanford and Jerry Griffin, who trained at Stanford around the same time as I did and is known by many in the industry, said that he knew somebody in Jackson, Mississippi, who had an opening, and I took it. It was pretty much my only option. But before I left for Jackson, I sat through a presentation at Stanford by Andreas Gruentzig about this really neat procedure that he was working on where he would put a plastic balloon catheter into people's coronary arteries, blow it up, and it was going to make them a lot better. That seemed like a stretch—no pun intended.

Q: *What was your first reaction to Gruentzig, both as a clinician and as a person?*

I idolized him as a person. We developed a somewhat competitive relationship because I eventually took one interventional approach and he took another. But he was a remarkable individual; absolutely one of the most amazing people I've known—very honest, a lot of integrity, hard-nosed about good science and good clinical trials, strongly committed to his patient population, and gave great presentations. These kind of events make me a little nervous. He would have loved it. The stage was Gruentzig's ultimate domain. He had a very special knack for that.

When I first heard him speak at Stanford, I thought that it was really quite a remarkable presentation. I was not quite clear on the clinical relevance of this balloon angioplasty procedure and, in fact, I remember telling my wife that I had heard that day perhaps one of the most remarkable presentations that I had ever heard in cardiology from this guy Gruentzig, and that he was either going to revolutionize the treatment of cardiovascular disease or he was going to jail. I favored jail pretty much at that time. It just made no sense to me that you could take a balloon catheter and put it into a critical vessel, sustaining myocardial function, inflate it, and then suddenly everything is just going to be okay.

Q: *You had to brief your Stanford colleagues on Gruentzig's presentation. Was everyone as skeptical about it as you were?*

All of us were somewhat suspicious. Nobody had a lot of confidence that angioplasty was going to go anywhere. While he was here, Andreas treated five or six patients intraoperatively at St. Mary's Hospital in San Francisco. They would go in through the side to put in the vein graft, and they'd go back up retrograde and inflate the balloon blindly. Andreas told us that after he did that, the flow was a lot better. But we couldn't imagine how that could be done through the groin.

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Q: *What was the epiphany that turned you from being skeptical to thinking that Gruentzig's procedure could work?*

Several months after Gruentzig gave his presentation at Stanford, when I was still in training, I remember vividly doing a routine coronary angiogram, and we managed to lift up a plaque in the left main coronary artery with our diagnostic catheter and ended up inducing a fairly large myocardial infarction in this patient. From the way the plaque had been dislodged, it just seemed that if we had one of Gruentzig's catheters we could go in and push the plaque back up to the surface of the artery, and perhaps the patient would not have sustained the damage to the heart muscle that occurred through our intervention. So I approached Don Harrison, who was then chairman of cardiology at Stanford, and asked him if he would be willing to send me to Zurich in the winter to learn Gruentzig's procedure. Harrison said, "Winter in Zurich to learn about a new procedure? I'm not going to pay for it if you go." But I badly wanted to go, so I borrowed five hundred dollars from Bank of America, bought my ticket, and went to see Gruentzig.

Right away, I saw Gruentzig do the most remarkable thing. In Frankfurt, actually, he put a small balloon catheter up through a guiding catheter, out into a very narrow right coronary artery with one balloon inflation—probably at a very low pressure, maybe fifty PSI, probably a third of what we would use currently. And it was just like the problem went away. That's when I said, "Maybe this could be really good." It seemed like if, in fact, you could routinely go into the human coronary space with a device that would push this plaque to the side, and if it would consistently work the same way that it had worked with Andreas's patient on that particular occasion, then we had stamped out all heart disease. Unfortunately, it did not quite work that way, but it was absolutely one of the most remarkable events in my life. It absolutely transformed my perspective on the treatment of cardiac disease. This was so far removed from being scolded for giving nitroglycerin to a patient at Duke with chest pain. So Andreas Gruentzig, I think, by himself, just totally revolutionized the space.

Q: *At some point you went from being a disciple of Gruentzig, to what you've described as a somewhat adversarial relationship. What caused this change in attitude?*

Andreas had designed a fixed-wire catheter system that required a lot of talent and finesse to use. It was very, very difficult. And he was very special—he had great hands and great vision. Gruentzig had a sort of three-dimensional perception of where things were. But that kind of system was not going to work for most of us. Ironically, my work in this area only started out of desperation because, when I ordered the catheter system from Andreas, he sent me everything that I needed except the balloon catheter because they were in short supply. Of course without the balloon catheter we were at somewhat of a disadvantage, so we started fooling around with local plastics to see if we could make a balloon catheter of our own. At that time, Ned Roberts, who was one of my colleagues in training at Stanford, agreed to pursue this bizarre path with me and we started working on developing balloon catheters. Had Andreas sent us the balloon, I guarantee you that I would not be here tonight.

Q: *Ultimately, that led to the launching of your first company, ACS. But you weren't really looking to start an angioplasty company; you were just looking to develop a balloon. Tell us about the process you went through in working on the balloon and how that led to ACS.*

Our goal was really to do something that was scientific and could help support the development of angioplasty, for example, from a tissue perspective. Through Stanford's work with NASA, Don Harrison arranged for us to use one of the agency's animal labs to test balloons to see if we could perform stretch injuries to the coronary artery to determine what happens histologically. In order to do that, we had to have a balloon to perform the stretch injury and that was the balloon that we made on our own solely for the scientific study. This was not two visionaries out to launch a start-up to do something extraordinarily special. We just needed three balloon catheters to go to NASA to test them in one baboon. We did that baboon in, unfortunately, with one catheter, which was disappointing to NASA, and they said we would not be seeing anymore baboons at that point. So that study was cut short. But we did make three catheters that we ended up using in animals. Once they worked, we decided that these catheters weren't that hard to make, and that they were easier to use than Gruentzig's system.

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Q: *Once you realized that you had developed this easier-to-operate technology that ultimately became the over-the-wire system that became so successful for ACS, did you start thinking about starting a company or were you willing to sell the technology to someone else?*

We had not formed ACS and weren't necessarily thinking about starting a company. We were eager to sell this technology to anyone who was willing to buy it. In fact, we presented the technology to USCI [USCI **Angiographic Systems**, now a division of **C.R. Bard Inc.**]. USCI was a huge catheter company at that time, and we flew all the way back to the East Coast to meet with them. They said, "Tell us everything that you've done in this area and we'll tell you everything that we've done." I'm sure you already know where this is going. I spent an hour and a half talking to them about our technology and when I finished, they said, "That's great, Dr. Simpson, thank you for telling us all this." And I said, "And what have you done?" and they said, "Well, actually, we haven't done anything yet." So this was my introduction to the real world.

Q: *And what did USCI do two weeks later?*

They signed an agreement with Andreas Gruentzig to buy, sell and market the Gruentzig angioplasty system.

Q: *A lot of guys in your position would have just said forget it, this isn't for us, but you persevered and eventually formed ACS with Ned Roberts. When did you decide to create a company and who convinced you to do that?*

It didn't happen right away. The guy who convinced us that we could form a company was Ray Williams. Ray Williams is an extraordinarily special guy but when I met Ray he was dressed in dungarees, parking cars for the Tally Ho Horse Show at the Circus Club in Menlo Park. Ray did not look like the kind of guy that you would bring your new catheter to and have him develop it. But Ray said, "I can really help you form this company." I looked at Ray in his dungarees and the dust all over him in the parking lot and I'm thinking, "You may be a nice guy, but you are not going to start this company. I mean I need somebody with vision, with charisma, you know with money. This is just not going to work." About a week later, Ray called and asked why I never called him back. By then, through my research, I was starting to get the drift that Ray was not a parking lot attendant and that really began a very special arrangement. Ray formed ACS with four buddies. It took him all of twenty minutes to raise a half a million dollars.

Q: *You spent a lot of time developing balloon technology, but wasn't the real innovation of ACS not the balloon per se, but the over-the-wire catheter, and when did that idea occur to you?*

The over-the-wire angioplasty system was what originally distinguished ACS. Eventually it was copied by USCI, but that was the original differentiating feature, and that grew out of my training with Lou Wexler, MD, a Stanford radiologist. We did everything over a guide wire. I did not know that you put catheters in and did not use guide wires, so it was incomprehensible to me that you would not angioplasty over a wire. People ask, "How did you think of that?" I didn't think of that. It was just a given. You had to put the system in over a wire because that's all I'd been trained to do. Then we built a system around that, which was the ACS device.

Q: *You've mentioned several people who you consider to be critical to your success. Let's talk about a few others and tell us what they've meant to your career, starting with Carl Simpson [no relation].*

You mean my great grandfather, Carl? We spent several years introducing each other to people as the other's father. Carl was special. Carl was the lead technician in the Stanford cath lab and, as cardiology fellows, we relied heavily on the nurses and the technicians to tell us what we were doing when putting in Swan-Ganz catheters and the like, and Carl was the best. He would pretty much put the catheters in for us in our first four months of training until we knew what we were doing. Then he left Stanford to work for Hewlett-Packard, and when ACS started, he came and joined us. Now, of course, he's with Versant Ventures.

Q: *What about Will Sampson, who came from USCI?*

Yes, we kind of stole Will from the guy at USCI who told me they hadn't done anything yet on their balloon program. I've got a few stories about Will. The one that is really important is that Will fired me from ACS because he said I was an overpaid consultant. But to Ray Williams' credit, he reinstated me. And trust me, Will Sampson was correct; I was definitely overpaid for what I was doing at that time for ACS.

Q: *And then Ray Williams brought in Bob Reese. What role did he play?*

Bob Reese came in to run ACS and to really make it into a genuine company. I thought he did an extraordinary job doing that, working very closely with Carl Simpson.

Q: *Bob Reese brought a manufacturing expertise that complemented your clinical background. Obviously, there would be no ACS if you hadn't had the clinical insight to develop the technology, but there were also manufacturing and engineering issues around the early ACS device. Did you get actively involved in those areas of the company or did you leave that to others?*

No, I did not do any of the engineering. I know my limits, and that's one thing I have to say about John Simpson, forgive me for speaking in the third person, he does know his limits. I've also always made it a goal to surround myself with people that are a lot smarter than I am because I do believe that it's always a team effort. The whole concept that there's some special visionary out there who can do all this stuff by him or herself, that is flawed, as far as I am concerned. It's putting together a group of individuals that make a real contribution and can work together to develop something that is really special. It takes a huge amount of support and funding from people who have enough vision to put the money behind it, and then it takes the engineers who have to be willing to persevere. This is really a hard job. I know that there have been people who allege that they're walking down the street when visions of catheter designs suddenly pop into their minds and they make the device that afternoon and then the following day they achieve enormous wealth. It's never happened that way for me. Every morning I get up, I check my mind to see if that great idea is in there and if it's not, then I go to work. And so far, I have not missed a day of work because of one of these special visions. So I think it's a lot about perseverance and the team you put together. You need smart people, starting with engineers, but they don't have to all come from the medical device sector. Just look at ACS—when we started the company, there was no interventional cardiology device sector. One of our brightest engineers, Hanson Gifford [now with **The Foundry Inc.**], came out of the aerospace industry. The other requirement, in my view, is to focus on developing a product that is really clinically relevant. I'm not real big on fluff.

Q: *ACS did its first patients in 1979. When did you know the company was going to be successful, and how important to you, at that time, was commercial success as opposed to clinical success?*

I don't think we ever imagined that it could be commercially successful. There were many times with our early patients that I went into Ray Williams and told him this wasn't going to work because we had to take the plaque out of the artery. Ray would always convince me to pursue the balloon concept a little bit longer and wait to focus on plaque removal separately. Ray had the vision to tell me to persevere. I don't think that by case ten we had one success. Then things turned around. Cases eleven to twenty-two were all successes. So all of a sudden, we began to believe that angioplasty worked, but we needed a better device. At that point, our focus shifted to designing improved iterations of the device. That's one thing that Bob Reese is really big on—you fail fast. You take a design, build it, test it, if it doesn't work you refine it, build it, test it, and you just keep doing that over and over again. He taught that to a lot of people in our industry.

There are some special visionaries and I might put Tom Fogarty and Julio Palmaz in that domain but, for me, I'm not that smart and it's got to be a team effort. You have to be able to put in a lot of hard work and be able to persevere in the face of adversity. When we tell people we're going to put balloons into their coronary arteries and blow them up to make them better, and a lot of them did not get better, those were really tough times. There were patients who did not survive those early interventions. You do not get paid enough for that. The whole concept that you do this for the money is absolutely flawed. If you do it for the patients and it works out really well for the patients, you'll make a ton of money. But if you do it for the money and you figure you've got something and it becomes a scam, then it is really going to be a frighteningly long road. It absolutely does not work.

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Q: *ACS was an interesting business story, in part because it was a tiny start-up that quickly overtook one of the largest companies in the space at the time, USCI, which had the originator's technology, and then did a very interesting deal with Eli Lilly to sell the company. How actively were you involved in any of those business decisions, or were you more than eager to push that off to others, as you did with engineering?*

I can tell you how involved I was because I knew that the acquisition was going to take place when Ray Williams showed up with the check, telling me we'd sold the company. I was totally uninvolved. Since then, in other companies, I've been a bit more involved in the organizational issues, but not in ACS. I had no expertise, no experience, and no confidence, so that would just not have worked. Ray wouldn't have let me either.

Q: *You've said that you don't mind the title of entrepreneur, although you're really more the reluctant entrepreneur, but you don't really consider yourself a businessman. For somebody who doesn't consider himself a businessman, you sure have started a lot of companies, the next of which was Devices for Vascular Intervention (DVI), the atherectomy company. Where did the idea for DVI come from and how did that get started?*

I still remain committed to the concept that the material that's in the coronary artery doesn't belong there. DVI was our first effort to confirm that, in fact, was the case. DVI was and, I think, still is a good device; it's just too hard to use. Ease of use is everything in this space.

Q: *Were you surprised with ACS at how quickly angioplasty took off and, conversely, were you surprised with DVI that atherectomy didn't catch on?*

I had vision beyond belief in that era. I was actually quoted in *The San Mateo Times* in 1983, when they asked me to predict the size of the US angioplasty market, saying that it would never exceed one thousand patients per year. The next year I raised that estimate to two thousand patients because that was the number we'd already done.

With DVI, I was shocked that it didn't take off. It was all because of stents. Stents just blew atherectomy out of the water. Stents are so easy to deploy and the immediate outcome is essentially guaranteed, so that once the clotting problems were solved with stents, no one gave much thought to atherectomy anymore. I still think that taking plaque out is more rational, but we still need better devices.

Q: *You weren't an early supporter of stents, were you?*

No, and I'm not a supporter of stents today, so you can tell that I'm still not a visionary.

Q: *Why did you start DVI as a separate company, rather than just bringing the technology to Lilly to be developed as part of ACS?*

We went to Eli Lilly through Bob Reese, who was still with ACS, and presented the design of the DVI device. But large organizations do not like to buy risk; they like to buy cash flow, revenue streams, and market share. That's why large companies are generally not very receptive when you come in and say, "I've got this really neat idea. Do you think we can work together on it?" Bob looked at the DVI device on behalf of Lilly and ACS and said it was a little bit too early for them and they elected not to do it at that time. So it took us about four years to get the device working well enough so that we had cash flow; we weren't profitable, but we had sales, and that's what big companies always buy. [Lilly acquired DVI in 1989.] They do not buy ideas. Large companies are awesome at taking something that's been fully developed and ready to really have impact in the market and they'll drive it really hard. Big companies are not the place for entrepreneurs to go to say, "Help me develop 'x'."

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Q: *Your next company after DVI was Cardiovascular Imaging Systems (CVIS), which brought you together with a young Stanford physician named Paul Yock and focused on ultrasound. [CVIS was acquired by Boston Scientific in 1994.] How did CVIS come about?*

I'd like to take credit for starting CVIS and actually, I did write the very first check. But Paul Yock was the one with the vision who said "We need to image the vascular space and eventually we need to image the vascular space while we're working on it."

Q: *Within a couple of years after that, you launched two companies fairly closely together in time. One was LocalMed Inc. and one was Perclose. What were their respective technologies?*

LocalMed was one of our best ideas. We need to put into the arterial wall medication that will suppress cell proliferation, as drug-eluting stents do. We knew that ten years ago and we actually developed a pretty good device to do it, but we had no drug. Do not ever build a really nice gun for which there are no bullets.

Perclose was kind of the stepchild company at the time. It's a little device to remotely close the arterial access site that's created during an intervention or a diagnostic procedure. Everyone asked, "What's that going to amount to?" But it's important to patients that are anticoagulated because it helps reduce the bleeding complications associated with arterial access. But Perclose was not thought to be the company that was going to be a big hit. LocalMed was going to be the one to knock everyone's socks off. So, four or five years later, LocalMed declares Chapter 11 and Perclose sells to Abbott Laboratories for \$680 million dollars.

Q: *I know you're proud of your visionary status, but did what happened with LocalMed and Perclose give you pause to think about the unpredictability of the medical device development process?*

This is a hard space. It's extraordinarily rewarding if you persevere and you do it right and you keep the patient in front of your vision. If you deviate from that and start to get kind of tricky and a little slippery, it just doesn't work. And even in the best situations, it requires a certain amount of good fortune and timing.

Q: *LuMend was your next major project and remains a work in progress. What clinical need was LuMend founded to treat?*

LuMend has a device that opens chronic total occlusions (CTOs). Matt Selmon is the founder and visionary behind LuMend; he's always been interested in CTOs. They just opened their longest standing chronic total occlusion, in a vessel that was angiographically documented to have been closed for 21 years. The device is still a little bit tricky to use right now, which makes me a little nervous because of the same experience we had with DVI, but LuMend has performed some miraculous events for opening up arteries that patients never thought that they could have access to flow in those arteries again. It could be pretty special. The device is not quite as predictable as we would like right now, but it's good.

Q: *If you group together the products from the companies you've founded, they seem to represent a suite of cath lab products. But you have said that it hasn't been your goal to create a new cath lab armamentarium. Is there a common link for you between all of these technologies?*

This is not my attempt to globally corner the market on cath lab devices. But I think that if we see an area that we think is important, like CTOs, and if we can find a way to fix that, then we should try, and we like to do that kind of stuff. And when I say 'we', I mean, collectively, the investors, the engineers and the physicians.

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Q: *Let's go back to where you started your entrepreneurial career, with your early experience with USCI. After you approached USCI, did you approach any other large product companies about either buying what you had designed at that point in balloon angioplasty, or helping to fund the project to move it along?*

I've never had too much success with large corporations buying and/or funding something in its early phases. We did take ACS to **Bentley Laboratories** and **Datascope Corp.** (now a division of **Baxter International Inc.**), in addition to USCI. Datascope went out on a limb and offered Ned Roberts and I \$20,000 in cash each. At the time, we actually thought that might be a pretty good deal for the ACS balloon since none of them had yet worked. Bentley Labs offered us \$100,000, but Ray said we could do a little better than that and then he took things over. But with each of my companies, I had someone I relied heavily on to handle the business side of things because that's a little bit out of my domain. It was Allan Will for the DVI transaction, Hank Plain for the Perclose transaction, and Bob Reese for ACS. I like to stick to assessing if a device is working well for the patients; that's my strength.

Q: *Some in the industry associate you primarily with two large companies—Lilly, early on, and more recently, Abbott—because of the deals you've done with them. Is that more coincidence than anything else, perhaps driven more by the big companies than by any special relationship you have with them?*

I have no real relationship with those different organizations.

Q: *More recently, you've also gotten involved with venture capital. One of the critical issues that we've explored in this for young entrepreneurs is funding. Why did you get involved with De Novo Ventures and what does that affiliation do for you at this point in your career?*

Things have changed. I started off not even knowing what venture capital was, and now we have become totally dependent on the venture community for funding for our development work. But if you think you can fund these early-stage projects at the corporate level, I think that is a flawed concept. You can work out corporate partnerships later, although I don't feel that those work either, but early on, your only option is to fund this from the venture community or angel investors. They're the only ones willing to take the chance because they occasionally get enormous returns.

Q: *You started ACS working out of your den. Now you must have tremendous resources available to you when you want to start a company. Does that increase the likelihood that the project will succeed, or is it still a serendipitous process with an elusive end point?*

It depends how much you can do something that's special and helps the patient. When we finally develop a device that cleans out coronary arteries while you see what you're doing so that you can't really create a problem, then stents go away. Stents are going to go away. It is the wrong thing to do to put a piece of stainless steel, wedge, mesh, anything in your coronary vascular space with a toxic agent on it to kill all the cells in the vessel wall. It's totally bizarre.

Q: *Someone I spoke to called you "the most intellectually honest person I've ever met—ruthlessly honest, particularly from a clinical point of view. If something doesn't work clinically, he'll pull everything apart, no matter how far down the road, even, it would be embarrassing to someone else to admit their mistakes." Do you agree with that characterization?*

That might be the first really honest thing you've said. That is where you win. If you fix the patient, you win. If you don't fix the patient, and pretend that it was some other problem, you lose.

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Q: *If you stopped after ACS, you'd be a legend in this industry, but the string of companies you've had has been truly extraordinary. With the importance you place on integrity for your companies, have you ever had to compromise your clinical vision for business success?*

I don't think that I have ever had to do that personally, but we've had arguments within the organizations about issues such as should we put an antibiotic coating on the suture to reduce the risk of infection below one in a thousand where it is now down to maybe one in five thousand and what it will cost to do that. There are some issues that are not very clear and that's when there's debate. If a device is coming apart in the patient and patients are being injured, it's not unclear: we need to fix it right now. Maybe it's the large companies I've worked with, but I don't think they've put me in the position where they've said, "We can't afford to make the best product here. We're going to have to make kind of a medium range product because it's going to be too expensive to make it right." That hasn't happened to me yet. Maybe it's happened to other people; I don't know.

Q: *Your latest project is Fox Hollow Technologies Inc. and it seems to pull together several clinical and technology interests of yours over the last couple of years. (See "Fox Hollow: Reviving Atherectomy," this issue.) What is Fox Hollow trying to do and where will its success lie?*

Fox Hollow is developing a new approach to atherectomy. Its success will be determined by how well it can treat the patients and particularly if it can provide a fairly simplified way of very predictably removing tissue from the coronary arteries. I think we're making great strides in that regard. It's an easy-to-use, monorail guide wire system. It probably should have imaging on board at some point and that continues to be one of our goals. I think you'll see more de-bulking in the next couple of years. We've de-bulked some stents that had drugs on them and sometimes the drug does not interact as nicely with the vessel wall as has been alleged. So there will be situations where de-bulking will be necessary, such as in bifurcation lesions, and in high grade ostial lesions—situations where you would not like to put a stent, if you could avoid it. I know that sounds really weird to say that there are some places you might not want to put a stent, but there are some places and I think we can de-bulk many of those.

I can remember Andreas Gruentzig's response when he was asked whether angioplasty has effectively eliminated coronary bypass surgery. He just laughed and said, "That's just not the case. This is about trying to continue to improve our technology and use it in the very best application that we can to really benefit the patients globally." There will always be bypass surgery, there will always be stents, there will always be de-bulking, there will always be drugs. It's really the fact that we can use this magical combination of many things to the patient's benefit that keeps us all, I think, headed in the correct direction.

Q: *Finally, are there still other ideas, technologies and companies that you'd like to launch?*

I always say no, and then something happens and I have to retract that. But I have to be honest, right now, I'm really excited about my relationship with De Novo Ventures. I enjoy working with the start-ups, but I don't really plan to do another one myself.



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