

Interview with Fred Khosravi

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Summary: In Vivo interviews device entrepreneur Fred Khosravi about his secrets for success in medical device company creation. Khosravi was part of the ACS organization that eventually became Guidant, where he was on the leading edge of the coronary stent revolution. That experience provided Khosravi with a broad background in interventional cardiology devices that was useful in starting his first company, carotid stent company EndoTex Interventional Systems (which was acquired by Boston Scientific) and several other successful companies.

Further Analysis:	Title	Magazine	Issue	Article ID
	Interview with Amar Sawhney	<i>IN VIVO</i>	Jun. 2009	<u>2009800107</u>
	Steve IV accessclosure	<i>IN VIVO</i>	Jun. 2009	<u>2009800122</u>
	Fred Khosravi & Amar Sawhney: Dynamic Device Development Duo	<i>IN VIVO</i>	Jun. 2009	<u>2009800123</u>
	Interview with Amar Sawhney	<i>IN VIVO</i>	Jun. 2009	<u>2009800107</u>
	Fred Khosravi & Amar Sawhney: Dynamic Device Development Duo	<i>IN VIVO</i>	Jun. 2009	<u>2009800123</u>
	Vascular Access Closure Ten Years Later: Why Start-Ups Can't Seal the Deal	<i>Start-Up</i>	Dec. 2008	<u>2008900249</u>
	Eberhard Grube: European Champion of Device Development	<i>IN VIVO</i>	Mar. 2004	<u>2004800051</u>
	EndoTex Interventional Systems Inc.	<i>Start-Up</i>	Nov. 1998	<u>1998900156</u>

Article begins on the next page . . .

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Interview with Fred Khosravi

By David Cassak

Q: Before we get into your career, let's start with where you were born. You're Kurdish and you were born in Iran. What led you to come to the US?

Fred Khosravi: I'm Kurdish from Iran. Both my mother and father are Kurdish. My dad was in the Kurdish Liberation Movement. He fought pretty much most of his life to maintain and uphold the Kurdish identity, which is an identity that, if you don't really try to hold on to it, is going to go away. So he fought long and hard, spent years in the Shah's jails, and then came out and got back on his feet. He was actually a real testament to entrepreneurship.

Q: He was also a member of a cabinet in which most of the other ministers were executed.

Yes. But his sentence was commuted.

Q: I know that when you came to the United States, you started off in Tennessee of all places. Why Tennessee? Is there a natural Kurdish-Tennessee relationship?

(laughs) Yes, a Kurdish affiliation with Cookeville, Tennessee. In fact, I'm wearing my Tennessee Tech cufflinks to Stanford. I came to the US because I was effectively running away from the revolution. Actually, I wasn't running away from the revolution; I wanted to be part of the revolution. But my dad didn't think that was a great idea, so he put me on a plane and sent me to the US. I was 16 years old and started in Cookeville because a friend of mine, who had come to the US about a year before, had ended up in Cookeville. So that's where I went.

Q: When you graduated from college, you were looking at jobs in a number of different industries: medical devices, automotive, and defense. Why did you choose devices? And where was your first job?

There was a lot of luck involved. When I got out of school, I had offers from companies in the automotive industry, the defense industry, and the medical device industry, and to be honest, I didn't even know what the medical device industry was. But it sounded more interesting than the other two and I took the job in devices, not really knowing what I was getting myself into. There was a good deal of naiveté in my decision, which is a kind of theme in my career.

Q: Your first job was Cilco, which saw you move from Cookeville to Huntington, West Virginia.

It was a big improvement, from 40,000 people to 120,000 people. But I liked it there.

Q: Cilco was an intraocular lens company. What did you do for them?

I was a lens designer on some of the early intraocular lenses, the small incision ones. Eventually, I moved to the manufacturing floor and wound up automating the machining process for IOLs through CNC lathes and mills. It was a great experience, and I became a kind of instant hero.

Q: When Cilco was acquired by CooperVision, you moved to Seattle. What did you do at CooperVision?

They were transitioning from hard lenses to foldable silicon lenses and I was promoted to engineering manager for the small incision foldable lenses.

Q: And then CooperVision itself was acquired by Alcon. By this time you had an established career in IOLs. Why didn't you stay with Alcon?

That was another one of those fortunate accidents. I was one of six people out of a plant of about three or four thousand who were offered jobs in Alcon's Fort Worth operations. So I went down to Fort Worth with my wife, and she looked around and said, "There's no way in hell I'm ever going to live in this place."

Q: After Huntington, West Virginia, and Cookeville, Tennessee, she said no to Fort Worth?

Yes. So I had gotten an offer from ACS to work there. We went to San Francisco, and it looked like a pretty cool place to live. So I took the ACS job.

Q: What did you do for ACS? It doesn't sound like you had much cardiovascular experience.

No. My expertise was in implantable products, and ACS was looking for a few guys who had implantable product discipline, because it was a fully disposable product company at the time balloons, wires, sheaths and they wanted to get into implantable devices. I was hired to work on coronary stents.

Q: That's interesting because ACS founder, John Simpson, was famous for not thinking that stents were going to be the success that they proved to be. What did you do on that project, and how did it progress within ACS?

It was quite tough, an uphill battle. Nobody believed in it. Most folks at ACS believed that stents were, at best, going to be a solution to abrupt closure or, in the worst case, a bridge to surgery. They were all convinced that angioplasty and disposables, not implants, were going to be the mainstay of the industry.

Q: This must have been well before J&J was preparing to launch the Palmaz-Schatz stent. Were you aware of what Julio Palmaz and Richard Schatz were doing?

Sure. And the contribution that Julio made to the field is obviously pretty foundational. We were looking at his stent, trying to understand it, trying to understand what it did well and what it did not do well, and trying to come up with new solutions.

Q: I know Julio shopped his stent to a lot of different companies. In fact, it's one of the ironies that he wound up licensing it to Ethicon, of all companies. Why did ACS not take a chance on the Palmaz-Schatz, then, if they were interested in developing a stent?

That's a question you have to ask Will Samson, who's in the audience, because it was before I got there.

Q: How long did you stay at ACS?

I was at ACS for about three and a half years and really enjoyed my time there. I became a big disciple of the ACS culture, with its emphasis on growth and empowerment. It was a phenomenal place to work. I definitely think there should be a case study written about ACS and what it accomplished in terms of spawning so many entrepreneurs. It wasn't just balloons and wires and stents if you look at people who worked at ACS and the companies they've founded or run, you really have to sit back and say Wow. It really provided an institutional approach to growth, technology development, being organic and entrepreneurial.

Q: You played a major role in the development of the *Multi-Link* stent, which was Guidant's first big step in coronary stents. Talk about that for a bit. And I know that in the years following the launch, Guidant embarked on a plan of rapid product iteration which saw a new coronary stent launched every year. Was that part of the original design or was it a later strategy?

I'm not trying to be modest, but I don't find myself the sharpest knife in the drawer. I mean, I'm not stupid, but throughout my career, the key for me has been hanging out with great people. When I got to ACS, there was already an amazing team in place. And we were working with Ulrich Sigwart, who predicted in 1987 that

within a decade, over 70% of angioplasty was going to be performed with stents. And he was spot on. Ulrich became my first teacher and an entrepreneurial partner for me, someone I learned so much from.

Q: You stayed at ACS for a while. Do you have a sense of when the entrepreneurial bug first bit you? And you've talked in the past about entrepreneurial naiveté. What do you mean by that?

I mean not knowing what's not possible. I think if you really knew from the beginning how difficult it was, you wouldn't do it.

Q: I know that at one point, you suggested to ACS that they spin off the stent business into a separate company. Whatever happened to that idea?

That's how EndoTex got started. EndoTex's carotid stent was a coil sheet stent technology, as *Multi-Link* was, and it was the brainchild of Ulrich Sigwart, with his name on the patents. We had started working on it inside ACS, but weren't able to develop it and decided to stop the project to focus on *Multi-Link*. This was sometime around 1995, and I had actually left ACS by this time to join a company in Cambridge called Focal [a drug delivery and surgical sealant company]. I was recruited by Mark Levin, who used to be a venture capitalist at Mayfield and then decided to become an entrepreneur. He started Focal and later founded Millennium Pharmaceuticals.

Mark recruited me to come to Focal. I was there a couple of years and learned a lot from him. But one night I was sitting at home and I had one of those rinky-dink fax machines and all of a sudden, I hear it going and I get a fax from Ulrich. On the fax cover was a note, saying that Guidant was about to give up the rights to the EndoTex technology. He and I had talked about doing something together. Would I be willing to talk about this? Within two days, I was on a plane back to the Bay Area, with Ginger Graham. [Graham was head of Guidant's interventional business at the time.] I wanted to find out from her what she was planning to do. If they were going to give up the rights, what did that mean? Initially, they wanted 50% of the company, which wasn't sustainable. Eventually, we wrangled them into a 15% position for Guidant and started EndoTex.

Q: Before we get to EndoTex, you told me once that you learned a lot about starting a company and getting it off the ground at Focal. What did you learn there?

Mark Levin was really a great mentor. He worked and connected with his team. And he really believed in what he was doing it was clear it wasn't just a financial exercise for him. It was a more holistic experience. He always talked about cultivating people, cultivating the opportunity, and if you do that right, then everything will fall into place. And it was more than talk. He was the first person you'd see in the office every morning and the last one to walk out in the evening. And even when he wasn't in the office, he was working the phones, trying to raise money, those kinds of things. He just worked harder than everybody else.

Q: So, with Ulrich Sigwart, you launch EndoTex in the middle of 1995. Give us the EndoTex story because I know it wasn't a particularly happy experience for you.

We started EndoTex to develop Ulrich's technology, and it was during a time when there was just a lot of money flowing into these kinds of start-ups. There was money coming in the back door and going out the front door. Companies were springing up and going public or getting acquired. And, to be honest, we were a little confounded by that. We began to do too many things at once and stopped focusing on the fundamental things, such as being cost efficient and being focused--the kind of things that you needed to do to be successful.

Q: Some people would think having a lot of money and working on multiple projects would be a good thing, because something always goes wrong and you wind up having something in reserve. But you do occasionally hear from entrepreneurs that having too much money can be as much a curse as a blessing. Why was it a problem for you?

I think money is like any other good thing. It's like sugar, which makes things taste great, but too much of it will give you diabetes. With money in small companies, there's a tendency to take on as much as you can get, because you may never get it again. But there's definitely a kind of diabetes associated with that, and we're seeing it right now in the marketplace, where a lot of companies became almost addicted to it.

Q: EndoTex was your first experience as the CEO and you told me that you literally destroyed the company and had to face the prospect of trying to put it back together. What was it like for you personally when you realized you messed up? And what was it like putting it back together?

I would say there was pretty early on a seed of recognition that I had to get out of the way and turn it over to someone who could actually put Humpty Dumpty back together again. It was John Maroney [former EndoTex CEO, now a partner at the venture capital firm Delphi Ventures] who did that, and I learned a lot in that process.

Q: Who was urging you to step aside? Were the investors driving that? And was it hard for you to accept?

Actually, for me, it was an easy decision to make. John and I immediately saw eye-to-eye on what we wanted to do, and I knew wholeheartedly that I had to step out of the way because I had made some catastrophic mistakes.

Q: Such as?

Such as being all over the place, doing too many things, but mostly being confounded by the fact that EndoTex really ended up being about me rather than about the opportunity. I think the biggest lesson from that catastrophe for me was that you have to subordinate yourself to the process. It's not about what my investors will think of me after the change or what my team or family or anyone else will think of me after that because I think those things all end up becoming very confounding and begin to affect your decisions.

Q: But there were also some marketplace issues with EndoTex and carotid stents. When you started, the carotid artery was the province of the vascular surgeon. You were trying to take the therapy to the interventionalist.

Right and as a result, what should have taken four or five years to bring to market really took about 11 years. It was a pretty profound challenge, and carotid stenting still hasn't penetrated the market; it's still just cracked it.

Q: That may have been an area where small companies can bring a technology to a certain stage of development, but you need big companies to create the market. There were a lot of great start-ups in the carotid space, but without big companies like Guidant and Boston Scientific to back the technology and push it out, it would have been hard for any small company to survive the length of time it would take to get market acceptance.

I agree.

Q: So after you messed up, John Maroney came in to run EndoTex. Did you leave EndoTex altogether, or did you have a continuing role there?

I had a continuing role as a consultant for about a year.

Q: It was while you were at EndoTex that you joined a former Focal employee and started Incept. What is Incept and what was it designed to do?

A year before I left EndoTex, we started talking about formation of Incept with my current partner, Amar Sawhney. We had started at Focal together, and before that, I had had a very rapid ascent within ACS Guidant. I had become the business unit manager for stents, really happy and enjoying what I was doing, with three different programs, biodegradable stents, regular metallic stents, and a temporary stent, under me. So I was already in one of the most exciting sandboxes I could ever be in and I was recruited by Mark Levin. I went to visit him in Cambridge, and he walked me into the office, which was basically a room and four desks. I said, "So what's going on here?" and he said, "Here it is." I said, "Here's what?" He said, "Here's the company." I wound up sitting at one desk, Amar was at another, and there was one empty desk. Amar was a fresh PhD graduate, just out of the University of Texas, a very smart guy, very visible because he wears a turban, and colorful ones. That was Focal. Amar and I ended up getting to know each other very well and becoming very good friends. Several years later, after both Focal and EndoTex, Amar was starting to think that he wanted to be an entrepreneur, and he came out to visit me and said, "Let's do something together."

I was beginning to transition out of EndoTex at the time and so we sat down together. There were a couple of things we talked about, and this is going to sound like revisionist history, but the first thing we said was "Let's be a little bit more thoughtful about starting companies." We had just made a bunch of pretty horrible mistakes, and we wanted to make sure that we would do it better the next time. So we came to the conclusion that we needed to create something of a hedging strategy, with a group of people who would do a number of different things at once so that we didn't necessarily live or die by any one company. What we realized was that many folks around the table had their own hedging strategies; VCs had a hedging strategy by investing in multiple deals; so did the physicians by keeping their day jobs and the independents who sat on various boards. The entrepreneur was the only one in the equation who lives and dies with a single opportunity. And if you don't succeed, my feeling was that you have a black cloud that travels with you for the rest of your life until you finally have a success. The idea behind Incept was to create something for the entrepreneur that would bring a number of projects together and create a hedging strategy. So Amar and I decided to pool our ideas, and our first and second Incept deals were Confluent, and EPI, which was built around some technology for distal protection that Nick Hopkins, [MD, chief of neurosurgery at State University of New York, Buffalo] and I brought to Incept as I transitioned out of EndoTex.

Q: One of the first companies that you spun out of Incept, and your first major success, was EPI, the embolic protection company. Did you have any qualms after the EndoTex experience about starting or running your own company? Did the prospect that you could repeat the mistakes you made at EndoTex make you nervous about starting over?

Sure. The first day I started thinking about doing something else, I realized that I had zero confidence in myself after EndoTex. I realized that on my watch we had forgotten to ask some of the fundamental questions about the EndoTex opportunity. As I said, I had treated EndoTex as if it were more about me than about the business. One day, John Maroney and I realized, after John had put some of his own money into EndoTex and had come on to run it, that the technology we had on the table was a total failure. It was never going to make it. There was this overwhelming pain of going home and saying to myself, "This is never going to work." For someone who's doing this to bring something meaningful and game changing forward, it doesn't get any worse than that. But it was also a great learning experience. After that realization, John [Maroney] and I eventually started working on the next generation EndoTex stent technology, and we were back on track within a year. So, with all of the pain endured, I was still committed to making EndoTex a success. A couple of years later, we started to do it all over again. There was a filter technology that we had been working on with Nick Hopkins, who became an important mentor to me, a friend I cherish tremendously, someone I've learned from beyond business and technology.

We also went to visit Rob Kuhling [a partner at Onset Ventures], who had been an early investor in EndoTex and became another mentor. The visit with Rob was really more of a social visit; Rob had always been very kind and as we sat there, Rob said, "Well, Fred, what are you going to do now?" I had my head down, really quite sheepishly, and I said, "You know what, I'm looking at this technology." But I was hemming and hawing because I really didn't have the confidence to talk about it, and Rob said, "Well, we'd love to take a

look at it." I said, "Are you kidding me, Rob? I just screwed up your company completely." And Rob said and this became an important inflection point in my career--"Fred, it's not about what happened. It's about what you do next when it happens. It's about what you do, how you respond, when you have failure coming in your direction. As VCs we look at entrepreneurs to see how they react to failure. And based on what you did, I would definitely invest in your company. I don't even need to look at the technology. We'll put half a million dollars in whatever you do next." That was a real confidence booster. It led me to go out and try to take the mistakes and what I had learned and build on that. Because when you really have a catastrophic mistake, there's no way you could actually go clean it up or fix it. So you become shaped by people's view of your catastrophic mistakes. You have to go to a new place to try to rebuild it, and that's what I did at EPI.

Q: Before we get to EPI, though, there's one qualification. EndoTex wasn't a complete failure because you wound up having a very successful exit to Boston Scientific, when EndoTex was sold to Boston in 2007 for \$5.4 million. [W#200710005]

I only contributed to putting the technology back on track. It was John who put the business side of Humpty Dumpty back together. He deserves full credit for it. I stayed there and, recognizing the failure of our initial technology, helped to modify it and turn it in a direction to eventually get to commercial success.

Q: Let's talk about EPI. At EndoTex, you just had come off feeling a failure in a technology that was well accepted. But embolic protection at the time was very different. Though the idea for the technology was suggested by a pretty eminent interventional cardiologist, embolic protection itself wasn't all that well accepted a technology at the time. In fact, in the early days of embolic protection, if you told an interventional cardiologist that he or she needed to use a balloon or filter to catch emboli, most of them would have said that you were crazy.

Yes. We were crazy to get into it. And we weren't even first; we were three or four years behind everyone else and were going to be the fourth or fifth player in that space. But I think that what made EPI successful was that we had the right group of people come together at the right time. There were my three significant mentors: Dr. Hopkins, Dr. Eberhard Grube [head of the **Heart Center, Siegburg**] and Hank Plain [now a partner at Morganthaler Ventures], all of whom looked at the technology and said, "This is great stuff. I want to be part of this." I stress mentors because in my story you hear a recurring theme of profound friendships and partnerships. And you can only do that with people you love to work with and learn from. Having gone through my experiences, knowing that I've been lucky enough to have the privilege of working alongside and learning from these friends, is perhaps the most significant break that I got in my career. Fast forwarding a decade later, with that in mind, I've now realized that success has a lot to do with one's ability to be able to work with people that one wants to work with, not those that one has to work with.

Q: And also Mark Wholey, MD, of the **University of Pittsburgh**.

Yes. Mark was actually my partner at both EndoTex and EPI, and we continue to work together. He's another person I look up to very much. He was a real inspiration behind EndoTex, EPI, and AccessClosure.

Q: You said EPI wasn't first in embolic protection. But were you the first to use a filter?

No, as I said, there were three other filter companies before us, some starting three or four years earlier. But we ended up launching the first filter into the US market.

Q: The first embolic protection company to make a major splash was PercuSurge, if only because of the tremendous success of its sale to Medtronic. What impact did PercuSurge have on the development of EPI? [W#200010246]

Not really all that much certainly none that I can think of in terms of commercialization. I think they paved the way from a technology standpoint. There was a lot of great engineering built into the product, and they

took a number of boulders off the road from a regulatory standpoint. But by the time that we came into the market, it was already being viewed as the wrong technology for the application.

Q: As I said, EndoTex was eventually sold to Boston Scientific, but it was actually EPI that was sold to Boston first. And for as bad as your experience at EndoTex was, EPI was really an incredible success for its investors. What had you learned from your EndoTex experience that you applied to EPI? Why was EPI so much more successful than EndoTex? [W#200110033]

Luck had a lot to do with it, probably more than 50%. But the EndoTex experience and the experiences before that shaped the course for EPI. As I said, EPI was the right confluence of people coming together. I also think there was clearly a belief when I was leaving EndoTex that eventually the carotid stents that EndoTex was developing had to be married to some kind of distal protection, otherwise carotid stenting wouldn't become a treatment modality. Certainly I believed that and so did John. But at EndoTex, we had committed so many sins in terms of being defocused and not being cost efficient, that it wasn't really sustainable to actually develop a filter. So we created a new company, and again naively I keep going back to that word we set a mission to come from behind and to have the first commercial filter in the US when other players had 3-4 years of head start. Nick Hopkins, one of the renowned neurosurgeons in the world, was really instrumental in so many ways, as well as the amazing clinical support of Eberhard Grube. And, of course Amar Salahieh who was a brilliant engineer he's already given birth to another company, Sadra Medical, which is going to be the next big thing in percutaneous valves and Jeff Krolik, who is a young engineer, 37 years old and already on to his third company introducing phenomenal innovations into the cardiovascular market he was 27 when he joined EPI, they both became the heart and soul of our development program. So we had a great group of people, but we were lucky enough not to know what wasn't possible, and we started with a technology that was completely out of the box. The first time we showed the filters to doctors, they looked at them and said, "What the hell is this?" Filters are supposed to be baskets attached to a wire, and this looked like an unsupported butterfly net, which intuitively made no sense whatsoever, for most people. I took the first prototypes that Amar and Jeff designed and put them in a bag and flew to Buffalo, New York, to show them to Nick Hopkins. Nick was very excited, and he took the devices into his animal lab, where we were going to inject some radiopaque particles into the carotids to see how much of it would get trapped by the filter. We were watching the fluoro and all of a sudden, the particles just go, swoosh, right past the filter. So we took the device out, and Nick looks at it and says, "Hmm, there's no filter there." The room was filled with his partners and fellows to whom he had bragged about this great company he had started. I was trying to be witty and so I said, "Well, Nick, didn't I tell you it's a dissolvable filter?" Anyway, we decide that the first one was a fluke and we opened another package and put the filter into the artery and, again, the particles go past the filter, with no capture. So we took the second one out, and, again, there was no filter, just the loop. We did that a few more times until we realized that the filters wouldn't actually stay on our frame intravascularly. But from that, we wound up building a fledgling filter company that eventually went through a first human experience with Drs. Hopkins and Steven Ramee in Medellin, Colombia, within nine months of the Buffalo animal study, and within three years of that we launched the first filter on the US market, and that was in 2002. With BostonScientific's significant commercialization machine behind it, the technology remains the market leader to this day.

Q: That was EPI, which was sold in 2001. That seems quick, particularly since EndoTex was still going on. Were you part of the negotiations to sell EPI to Boston?

I was part of the negotiations, but I definitely learned a lot from Hank [Plain] just standing in his shadow during that process. Hank was a great chairman. He let me think I was running the process, but it was really his steady hand in the background that got the deal done.

Q: Was there any temptation to hold EPI longer? Obviously it was a good deal for EPI's investors. But do you think you sold the company quickly?

Hank and I talked about that. But I think we both felt, without explicitly saying so, that it's always better to take a fast nickel than a slow dollar. By the time the deal actually got to the table, I don't think there were any second thoughts or concerns that we were selling too early.

Q: After EPI was sold, you stayed at Boston Scientific for another 18 months. Was that part of the deal? Were you not certain you wanted to do another start-up?

The deal had a big tail, a big earn-out associated with it, and it was important to me, from the moment we started the company, that the technology actually make it into the commercial space and that patients would benefit from it. Commercial success is a common mission for all of our Incept companies and not just an "exit." If you go back to Confluent Surgical, which was the first company to spin out of Incept based on Amar Sawhney's ideas for his hydrogel technology which developed *Dura Seal* now commercialized by Covidien, that was always one of Amar Sawhney's goals from an Incept viewpoint, and as the CEO of the company. Basically, Amar and I believe that if we work on a technology we want to see it commercially successful. That is what we consider ultimate success.

So at EPI that was very important to us; we didn't just want to leave it to Boston Scientific to do. We knew that with technologies like embolic protection, if they aren't in the top 10 of the big company's priorities, they are likely not to go anywhere. Another element of stars and moons aligning was that Boston Scientific believed in that as well, which set the stage for one of the best integrations of a small company by a large company that I know.

We're taking the same approach with AccessClosure, which has been a lot of fun. And it's the theme of what we try to do at Incept. We want to make sure we're not just creating vehicles for financial transactions between big companies and small companies. We want to create commercially viable technologies that touch patients. Of course, at some point you hopefully end up creating something that can be acquired or go public. But that's not what it's mainly all about for us.

Confluent for example, went through a lot of ups and downs in the process, but we had learned one very important thing from our Focal and EndoTex days, and that was the importance of focus, tenacity, combined with a deep desire to achieve commercial success. So, we decided to take one application of Amar's hydrogel technology and license it to create Confluent. By licensing only a limited application, not only did *Dura Seal* become a commercial success, but Amar's hydrogel technology is now used in a variety of applications, from head to toe, in numerous companies that either we've spun off of Incept, or are affiliated with Incept through licensing the hydrogel technology.

Q: There seems to be a technological connection between a lot of the companies that have come out of Incept. Access was launched with a technology developed at Confluent, which was actually the first spin-off from Incept. But at some point, you create individual companies. How do you go about raising money for the Incept spin-offs?

Incept doesn't have any kind of physical existence there's no office or fax machine or even a telephone number. It's really more of a virtual setup, a group of people who want to work together. As a result, we haven't raised any money for Incept itself. We believe that when you bring venture money into an incubator, you end up doing only the things the VCs want you to do. And a lot of those are great opportunities. But when you don't have any VC money in the incubator, you can be more eclectic, particularly about the size of the opportunities you're targeting. You can go after singles and doubles they don't all have to be home runs. But even though we don't have venture money, Incept does fund its own companies initially, usually to the tune of \$250,000 to \$500,000.

Q: Does that come from you and Amar?

It comes from proceeds of previous exits to Incept, so technically yes.

Q: But then you need follow-on financing. How does that happen? Where did Confluent get its first money? Where did EPI?

Yes, every single one of our companies goes through a number of VC rounds before they commercialize or exit. Without a solid partnership with the VC community, of course none of these new opportunities could materialize into solid products. But as to start-up or seed financing, with Confluent, a lot of the early funding came from friends and physicians during the company's incubation phase. In the case of EPI, it was Rob Kuhling who stepped up to fund an entrepreneur who thought he had failed earlier, so that was pretty visionary of him, a vision I had a hard time subscribing to myself.

Q: What about AccessClosure, which was launched in 2002? Where did you get the funding for that? And you mentioned the failure that hung over EPI. Given the successful exits for EPI and Confluent, which was sold to Covidien a couple of years ago for around \$250 million, had you personally come out from under the EndoTex cloud by the time you launched Access? Had you pretty much banished the concerns you had about your EndoTex experience? [W#200610112]

No, because the sequence was not intuitive. That's why I often refer back to Steve Jobs saying that you cannot connect dots looking forward. So EndoTex was started in 1995, Confluent in 1998, and EPI in 1999. But EPI was acquired first in 2001, EndoTex in 2003, and Confluent in 2005. And so, I carried the EndoTex painful lessons with me, but also kept my nose to the grindstone and tried to contribute something to each one of them to ensure that they all became commercial successes.

Q: Does it still hang over you?

Every day. Every day. It was a painful experience. My wife, Flora, who is the rock of my life but also my most avid critic, knows exactly what it's meant to me to go through that experience. But I'm stressing this to underscore that these kind of experiences actually force one to do a reorientation of one's self, as a person. If you really learn from it, it solidifies your belief sets and principles of business. It hardens you to do more.

Q: So how did AccessClosure get started? Who funded it? And Access brings you to technology that Hank [Plain] knew well from his Perclose days. Was Hank part of the AccessClosure team?

Yes. Hank and Rob have become for me almost like seat belts. I can't really drive a car anymore if I'm not wearing my seatbelt the same is true with starting companies without those two. In Access case, Hank had a background in closure. We had baked the technology within Confluent. But it was Amar's invention; he had developed it for percutaneous access site closure. And when Confluent started going in the direction of becoming a surgery company, our choices were either to basically stop the project and put it on the shelf having learned the lesson at EndoTex of doing too many things at one time and getting de-focused or to spin it off as a new business. So we decided to spin it off. It happened at about the same time that I was pretty much done being in a corporate setting at Boston Scientific. I had enjoyed it very much for a year and a half, but I was just about done when Access came along. (See "*AccessClosure: FDA Clearance--Yes, Product Launch--Not Yet, this issue [A#2009800122].*")

Q: I find it interesting that you enjoyed your time at Boston Scientific.

I did.

Q: As a classic entrepreneur, didn't you get frustrated at a big company?

I got frustrated all the time it was a whole continuum of frustrations. It was different than how we operate in small companies. But integrations are always frustrating, even though EPI's integration was arguably a very smooth one. And having grown up at Guidant and ACS, we were institutionally led to believe that Boston Scientific was a company to be very leery of. When the negotiations were going on to sell EPI, the two parties

were Guidant and Boston Scientific, and I was probably the only person on the EPI board who wasn't thinking objectively enough at the time, I was willing to take a lesser deal from Guidant just because it was Guidant. I was willing to pay a price for the Guidant label and what I believed was the belief set at Guidant. But going to work for Boston Scientific, I realized they are a group of tremendous people, especially in senior management. I learned a hell of a lot from Jim Tobin. He's a true master of operations and strategy, and you can really learn from him. And Paul LaViolette, whom I reported to, was a terrific and thoughtful executive. I enjoyed every minute of it. It was a great team of people.

Q: Access is one company you haven't sold yet. How is the company doing and what, to your mind, will be the key to its success?

Access is doing really well. It's become a tremendous story. But, it wasn't always the exciting story that it's become today. When we were spinning it off from Confluent, the only believers were Hank, Rob, Eberhard, and Nick initially, and eventually a group of clinicians who were close to the series of companies that I've been involved with, like Mark Wholey, and Steve Ramee, to just name a couple. Most of the other folks who I talked to would say, "Fred, are you crazy? Who in their right mind works on closure?" I think with a company that is going to do over \$60m in sales this year, two years after launching Mynx, with over 100% year over year growth from 2008 to 2009, and scheduled to be profitable in Q4, 2009; we've proven the doubters wrong. That's another thing, hearing that you're crazy, and proving the doubters wrong.

Q: Well, it's like another embolic protection play, in terms of perceived need in the market.

Exactly. It made no sense to them whatsoever. Everyone kept saying to me, "Why don't you work on the next bioerodable or drug-eluting stent?" Or whatever the next big thing is supposed to be. But I really liked the notion that the technology will end up touching more patients than any other technology I've worked on, both in terms of numbers and also in terms of the patient's experience of it. I had seen other closure systems. I knew Perclose's technology, and even though it deserves a lot of credit as a pioneering technology, it looked painful and complicated to me. St. Jude's *Angio-Seal* also looked like it hurt quite a bit. To come up with something that doesn't hurt, that doesn't have a lot of morbidities associated with it and actually improves the patient's experience that was exciting for me.

Q: Particularly with Hank there, what did you learn from the Perclose experience, which was the first big deal in femoral artery closure? What did you take from that to Access?

What we learned is that you have to stick with the project, that it's probably going to be a rough process and everyone will throw a lot of dirt on you. I learned that the device has to work right all of the time, that failure isn't an option, and that those are tough odds within which to grow a business. But that if you're committed, again to what you bring to patients and to the mission of commercial success, you can do it.

Q: We're drawing to the end of our time. I know there are a bunch of other companies that came out of Incept: SquareOne, HotSpur, Sadra. Sadra is interesting. It's another one of those companies that has had its ups and down, though it does seem to be doing better now. Where did the idea for Sadra come from, and what went right and what went wrong?

The idea came from Amr Salehieh, along with Don Baim [a former renowned interventional cardiologist and now chief medical officer at **Boston Scientific Corp.**] and Paul Spence, who's a terrific cardiac surgeon. I think the whole perc valve space is a difficult undertaking, technologically speaking. The first design we came up with had so many moving parts, I'm embarrassed to actually say how many. That's how complicated it was, and it's a device that needs to be built with almost aircraft quality standard because you really can't fail when replacing someone's valve. So we've taken our lumps, so to speak, had our ups and downs, but it's getting to the point, and admittedly I'm biased so you have to take what I say with a grain of salt, where I think what we have is the best next generation of percutaneous valves which will outcompete what's out there and take the market by storm.

Q: That's another example where sticking with something you might have thought was a waste of time could very well pay off big in the end. You might have said the same thing about EndoTex, but Sadra's an example of a company that probably should have died a couple of years ago.

I agree, though I've never been with a company that I couldn't look back and, at some point, say it should have died for one reason or another. I've also never been with a start-up where the technology did not dramatically change before it went commercial. All of the companies I've worked with have had these borderline moments where they appeared as if they were about to die. But you just have to believe and have a significant amount of tenacity. This is not for the faint-hearted. It's like jumping on a grenade.

Q: A lot of the companies you've been involved with, have started, have been cardiovascular companies. But you've also got some that are not cardiovascular. Do you favor cardiovascular technologies? And you described the process at Incept as one where people get together and share ideas. But how do you know when you're just chatting about something that sounds interesting, and when you actually want to start a company around an idea?

With respect to whether I favor cardiovascular devices, my background has been in cardiovascular and it's quite a broad area. You can do a lot there because there are a lot of holes to fill and gaps to bridge.

My partner on the East Coast, Amar, is definitely the sharper knife in the drawer, and while more deeply focused on his hydrogel technology, he's been able to be diverse in terms of applications. So he's been involved in surgical devices used in the abdomen and brain, and he's now working on ideas in ophthalmology, urology, and oncology. He tends to focus more on his hydrogel platform that he can apply to different things. I'm more focused on one space, cardiovascular, and coming up with different technologies in the same space.

As far as how we decide what to work on, I think that has to do with the people that have come together at Incept. Because Incept is somewhat amorphous and not institutionalized, the technologies are really grown not necessarily by targeting a particular space and saying, "OK, what's the next big thing to focus on?" It all depends on the skill set of our team, the entrepreneurs, engineers, and our physician circle and above all our bandwidth. So, we kind of organically come up with an idea and say, "What if we do this and that, and solve that problem?" Then we try to validate it through our close clinical friends and partnerships, and assess its commercial and business viabilities. And so, the technologies really grow out of that process. As a result, the initial teams for our new opportunities grow out of our existing Incept opportunities themselves, as opposed to initial ideas and people coming in from the outside. This gives us the ability to be able to maintain a semblance of a few core tenants and cultural themes, like making it about patients, commercial success, building companies to last and not to sell, and cultivating new leaders for our future opportunities.

Q: It sounds like you're spending most of your time with AccessClosure. What's your relationship with some of the newer companies, like HotSpur or SquareOne?

I'm a workaholic, so I work more than any one person is supposed to. So, I have a full-time job at AccessClosure and then three part-time jobs with Square One, which is an ostial stent technology which we believe will be on every cath lab shelf around the world, run by my other Incept partner James Dreher (we worked together at EPI, AccessClosure, and he also co-founded HotSpur); HotSpur, which is a dialysis graft treatment company which is a huge play on morbidity and will touch millions of patients every year around the world, and it's run by another one of my Incept colleagues Gwen Watanabe, and Sadra Medical, which is the most novel percutaneous valve company, run by a very capable leader, Ken Martin. It's intense and a lot of work, but fortunately, I enjoy it immensely and I get very excited about all of them. Each one of these opportunities is an example of what one can do being surrounded by great and smart people, smarter than oneself perhaps. I think going back to my experience at EndoTex, and a lot of guidance from Dr. Wholey, who kept asking me if I were surrounded by the right people, I quickly realized that if I'm the smartest guy in the place, we're in serious trouble. What gets me out of bed every day is joy and the privilege of going to

work with a team that I learn from every day, at AccessClosure. And I think that's a recurring theme in each of the Incept companies that I'm involved with.

Q: You've been starting medical device companies for over a decade now. Is it harder today to start companies, than it was in the 1990s, when you started? As you look forward to what you're going to do after HotSpur and SquareOne, is it getting harder for you?

I think so. Even if I didn't believe so three or four months ago, I definitely believe so now. I think everybody in this room believes that it's going to be harder to start companies. For me personally, the last two or three months have been pretty difficult, not with respect to AccessClosure, as we're well funded and becoming profitable, later this year. But for those companies with great technologies requiring capital to get to commercialization, they'll have a difficult go at it. Not that they can't raise money, but the paradigm of financing and parameters of dealmaking have all been turned upside down. And so we're all readjusting to these new realities until we figure out what it takes to maintain a robust and sustainable path to innovation. In the meantime we have to stick to the basics, focusing on proven technologies, being intellectually honest, cash efficiency, and rapid execution.

Q: Well, I will say this in wrapping up. I know EndoTex was a painful experience for you, but I daresay that anybody in this room would trade their track record for yours.

Thank you.