Why Practicing Strategic Patience is Critical for Medtech Entrepreneurs: Interview with Dr. Tej Singh, Founder of Fist Assist Devices

Over the last 20 years, Dr. Tej Singh has served as the Founder and Chief of vascular surgery for three large and multidisciplinary vascular programs in Silicon Valley. He has a vast knowledge regarding renal failure and vascular access procedures and is acutely focused on his first company, Fist Assist Devices, to help improve fistula maturation via non-invasive external methods revolving around his intellectual property on vein maturation. Fist Assist Devices, a Silicon Valley medtech startup is focused on developing the first renal care wearable device for venous enlargement and dialysis enhancement. Founded in 2013 by Dr. Singh the company is currently funded through angel investors and amazingly has zero debt. In this interview here are a few of the topics we chatted about:

- The big challenge that Fist Assist Devices is trying to solve for.
- The origin story for the first product and the key inflection points along the way.
- How Dr. Singh evaluated the IP landscape for his idea.
- Dr. Singh's approach to mapping out a clinical trial strategy.
- How Dr. Singh navigated the insurance coverage and reimbursement landscape for his first device.
- Dr. Singh's approach to strategic patience and why it's crucial for tech startups.
- Dr. Singh's favorite business book.
- The mentor he most admires and
- The advice he'd give to his 30-year-old self.

Scott Nelson: All right. Welcome, everyone, to another edition of Medsider Radio. On today's program, we've got Dr. Tej Singh. Dr. Singh, welcome to the show. Appreciate your coming on.

Dr. Tej Singh: Thank you very much, Scott. Glad to be here.

Scott Nelson: All right. Let me provide a kind of a high-level background or bio of yourself and you can certainly correct me or correct me if I'm wrong on any of these points or certainly fill in the gaps as well. But over the last 30 years, Dr. Tej Singh has researched arterial hemodynamics in response to increased and decreased flow, not only as a college student but a medical student as well and then as a vascular surgical resident. Dr, Singh you've got an active 20-year career as the Founder and Chief of Vascular Surgery for three large multidisciplinary vascular programs there in Silicon Valley. The point of this conversation is to talk about your company Fist Assist Devices which is acutely focused on renal failure and vascular access procedures, which you founded, I believe, in 2013. Amazingly, which hopefully we'll get into this part of the conversation. Amazingly, has zero debt which is almost unheard of for most medtech startups. So, again, is that a decent background? Did I miss anything there Dr. Singh?

Dr. Tej Singh: You said it well. I did my undergraduate at med school at the University of Chicago where a lot of this initial research for this device was created as a student. Of course, at that time, I was focusing on being a clinical doctor and a vascular surgeon and then the seeds of the company while they started in Chicago the real growth of the ideas happened when I was a vascular surgery fellow at Stanford University here in Silicon Valley and I've been here in Silicon Valley since 1993.

Scott Nelson: Very good. Yeah. Just to kind of wrap up and I'll provide a little bit more of Dr. Singh's background in the show notes for this interview but MBA from Auburn University. You did your general and vascular surgery residency at Stanford I believe and did undergraduate bachelors at the University of Chicago. Is that correct?

Dr. Tej Singh: Yes, absolutely right. I have had the benefit of learning further about the business side of health care at initially Auburn, but definitely in ongoing classes at Wharton Business School and at the Stanford Business School where I just recently completed the lead program. Using those opportunities to add to the business side of our company and as we lead our company into the next 10, 15 years, there's a lot of opportunity for further knowledge and so I took advantage of that.

Scott Nelson: Very good and on that note we're going to certainly get into how your first device at Fist Assist came to be and how you've been able to successfully navigate a lot of the complicated waters that most medtech startups experience in their formative years. But before we get there, let's help set the stage for everyone listening in terms of what you're working on with Fist Assist and the challenges that you're trying to solve. So, can you maybe give us a quick elevator pitch on the device that you're currently commercializing?

Dr. Tej Singh: Yes, Scott, that's the real focus of obviously this interview today. But we've been lucky. I think having been a vascular surgeon and a lot of nice things have lined up with me initially as a college student being able to start doing animal surgery and making arteries and veins connect. Then, of course, studying how those arteries and veins adapted, continued my passion with the mentorship I had at Chicago and Stanford with great vascular surgeons, especially Christopher who was my student mentor, med school mentor, and then vascular surgical mentor at Stanford.

I noticed at that very young age that arteries and veins adapt. They adapt to flow, they adapt to different conditions, and as a vascular surgeon and developing a busy practice here in Silicon Valley, I started seeing that there was an opportunity for my patients and all patients to have bigger veins. I realized that that was a clinical problem. It was a clinical problem in dialysis patients. It was a clinical problem and a simple blood draw. So, at that point, the launch of Fist Assist devices in my mind was starting. I thought we would be able to take all the research we were doing in Chicago and at Stanford, get an intellectual property on a device.

A device that would do something unheard of, which is take the basic science, which, of course, I was a big part of, the clinical science and the exercise science that was happening all over the world in Europe, in Asia and America, and make a device that captured all that science to do one

thing which is to make veins bigger on the arm. Having big veins on the arm helps with dialysis for the hemodialysis renal failure community helps with fistula enlargement for that community and a bigger scale helps the global world who needs bigger veins so they can get blood draws, have an easier time with that. So, Fist Assist Devices has positioned ourselves as the arm vein dilation company.

Scott Nelson: Got it. And this initial kind of idea you mentioned that the early, I guess, makings of the idea was when you were in residency at Stanford, correct?

Dr. Tej Singh: Well, I think the initial ideas came to me as a college student. I was able to at a very young age when I was accepted to medical school, I had the flexibility to do some animal surgery research in summer at the University of Chicago in the vascular surgery and pathology laboratories of Drs. Zarins and Seymour Glagov and they enabled me at a very young age to start connecting arteries and veins for studying how arteries adapt to flow. But what I realized was that the arteries were one part of it, but the veins were a big part of the adaptation that nobody focused on.

But until I became a surgeon after completing Stanford, I didn't realize that the veins are crucial. Vein enlargement is crucial on the human being's arms and I will also say that I had the luxury of also having the opportunity to go to Japan and work with some world-class pathologists, including Dr. Masuda at Akita University, who was one of the world's experts in vein and artery adaptation to flow. So, for me, all the things lined up from the age of 18 to the age of now, but mostly up until I finished my training in the early 30s to understand veins and adaptation. So, I was very blessed to be a vascular surgeon completing a surgery educational program, and at the same time having a device in the back of my mind as I was going through my life.

Scott Nelson: Makes a lot of sense. So, on that note can you give us a little bit better idea of this device? I think everyone listening understands that of course, when you're drawing blood out of a vein there's a need for a bigger vein, especially those that have had issues with the needle sticks that have gone bad, so to speak, I guess for lack of a better description. But especially crucial when in terms of the patient population that's undergoing dialysis, the need for bigger veins to help, mature fistulas, as you kind of mentioned along those lines. So, the need extends far greater than just blood draws. But can you help us understand a little bit, at least at a high level, give us some context? What's your device doing to help keep veins open, help enlarge veins, etc.?

Dr. Tej Singh: That's been the focus of what we've been able to do for the last 20 years, 25 years with this company. If you think about it, everybody has arm veins and everybody knows that exercise or putting a tourniquet or putting an elastic band, any type of compression because the veins are very superficial under our skin where arteries are deeper. Any type of compression will make the vein bigger. If you take the basic science terms of shear stress, tensile stress, dispensability, capacitance. All these terms have been studied for many, many years in the basic science world.

Exercise science has told us that if you exercise and do arm exercises with some type of compression on your arm, you will dilate your veins. So, the basic science, clinical science, a lot

of that clinical science was being done in Slovenia showed that to make veins bigger, a combination of exercise and compression of your superficial veins can get you there. We took all that basic science, clinical science, exercise science, a lot of those experiments on shear stress, tensile stress and at the same time papers were coming out which said that those patients who need fistulas for dialysis, a fistula is a connection between the artery and the vein.

If you enlarge the vein either before that surgery or after that surgery, the patient has a much better chance of better quality dialysis and a better quality of cost-effective dialysis with less interventions and less treatments in the future, which, of course, would decrease health care dollars. We took all of those concepts and took the basic science of those concepts and made a pneumatic, intermittent compression, a fully patented device which is wearable, to be worn on the arm, which has an intermittent pneumatic compression feature, which is computer programmed to do everything that the basic science and the sciences that we've talked about does and make it a wearable for patients that is external and non-invasive.

The First Assist Device is the only global device that can be bought by a patient, that can be worn on their arms below the shoulder or below the elbow, very easily, comfortably applied. You can wear it from one to six hours a day per your choice, and you will be exercising and helping stimulate vein enlargement, which can help with dialysis, needle placement for phlebotomy, or eventual ongoing fistula exercise and maintenance to keep your fistula going. And this is a concept that led to the device and where we've positioned ourselves today on the eve of a global launch.

Scott Nelson: Very good and hopefully that helps that set the stage for the rest of the conversation, ensures that people are wrapping their heads around what this device is, kind of what it does. In the show notes of this interview at medsider.com, I'll certainly provide a link to Fist Assist as well as a video where you can kind of get a little bit better idea of what this device looks like or what it does. But on that note Dr. Singh you mentioned that the ideal formulation or the iteration of this product concept started back to when you were in college and then sort of stayed with you throughout med school and even in your general and vascular surgery residencies.

But based on some research that I did in front of this conversation, it seems like the idea was on the back burner for a while kind of sat there. Very curious as to was there an inflection point or what was sort of the impetus for you to start working on it to make this sort of idea come to life? One of the reasons I ask this is, you know, there's a lot of people that listen to these Medsider interviews that have other great ideas, you know, ideas that probably have some legs, but ideas are a dime a dozen, you know what I mean? You've been able to take something and take an idea and build a company around it. So, can you take it back in time and give us a better idea of how this began to come to life?

Dr. Tej Singh: Yeah. So, it's a great question Scott and I reflect on what I've done with this. Initially, it was a curiosity and life is complex. As a young, surgical doctor, a person who's now got a young family, you know, my whole life I have positioned myself to take care of patients and I completed my training. I was at that point married. I had three young boys and of course, to me, the priority

was I put so much effort into a clinical career. I wanted to make sure I was able to provide for myself, my family, and give us every opportunity to thrive and at the same time, for me to have that personal satisfaction of being a surgeon.

But in the back of my mind, this device was lingering and it's only when I realized as I started being a busy surgeon, that every time I heard of a patient saying I wish I had bigger veins, I wish my fistula would develop, I wish my blood draws weren't as painful or as difficult, this light in the back of my brain was, well, I've thought about this. I've thought about this and I had it in the back as something which eventually and I think everybody who lives in Silicon Valley drinks the water here. You always think of things differently. You want to think about changing the paradigm. But I wasn't going to sacrifice my life. I wasn't going to sacrifice my family life. I wasn't going to sacrifice a busy surgical career, but it was a hobby.

It was a hobby that was something that I thought I could give the world. I could help the patients in the world. But until I got into my MBA program at Auburn University and I met some great mentors there in Stan Harris, Amit Mitra, Tom Baker, who taught the class on business law. When I realized that how you can take a concept, protect it, make a business around it, that was the first time I took the basic science and my clinical experiences and flipped the switch to say, well now it's time to give the world a fist device. Once again, I was very lucky that as a vascular surgeon, I was living in this world.

I saw the problems in this world but that course and that MBA course truly at Auburn got me to think about the potential of this device. Many of the people that I mentioned from Auburn are a part of the advisory role or partners with me on this company in various forms. So, having a team assembled that started at Auburn and then I just kept adding to it. We just continued to grow, and the focus was, I think, looking in the mirror and seeing that a business could be made and meanwhile, I was a full-time vascular surgeon, could make a business with that degree. That was the flipping point and that happened at the end of 2013.

Scott Nelson: Very good. I think maybe the lesson learned at least what certainly comes to mind from my perspective is that you have people around you, right? Certainly, you had to be proactive enough and interested enough to participate in an MBA program. But you have people around you that you could lean on to maybe help move this idea from or move this concept from idea to reality and the steps that you needed to take along that path. So, that's great to hear.

So, on that note, Dr. Singh, and I certainly don't expect you to remember all of the details because we're recording this in early 2020 and this was seven, eight years ago now. But this product is relatively straightforward. You've been able to condense a lot of the existing science and make it very simple and sort of packaged into a very straightforward wearable. Can you walk us through how you evaluated the IP landscape at the time? Because I think most people when thinking about a product as simple and straightforward as this, would naturally think it's not patentable or that may be difficult to create the wall necessary to build a business around this. So, can you talk to us a little bit more about your thoughts related to IP in those early years?

Dr. Tej Singh: Yeah. So, once again, I think you hit it on the head. If you look at the phases, there was the research phase, great mentors I've already mentioned. There was the business school phase, great mentors there. So, then when I started thinking about this and once again, I think being a vascular surgeon every day struggling with arm veins, every day struggling with patients in my cases that didn't go well because the veins were too small. So, what you do is you start building a bigger team and the first team I wanted was I wanted to see that, okay, if there is a role for a pneumatic compression device are there any experts out there?

I was, luckily in 2006 and 2007 able to call up a company down in San Marcos, California, under the direction of Ed Arkans and Ed and I spoke and I told him that, of course, I had an idea and he said to me right off the bat, don't talk to me on the phone until you've got a patent. That was the first warning that I had, that I better keep this idea to myself and I better get a patent. Ed, who has been very instrumental in this company from the research and the prototypes, he had a company that made pneumatic compression for the legs. So, when I looked at his website and I said, well, my device is very different. Mine is for the arms. Mine has different things.

I then found and I was very lucky just by going through the Yellow Pages back in 2007, I think we had Yellow Pages. I found a patent attorney, explained to him my device. He said, well, let's go for it and we spent a year and a half at significant cost writing up a very elaborate patent for Fist Assist and our device and pushing that through while we had some resistance initially from the Intellectual Patent Office, the US Patent Office. We were able to get that patent as a single compression device for an arm/vein application. That was crucial for the success of where we wanted to go. With that, we started getting the nondisclosure agreements, the discussions with Ed Arkans went to a very high level and that helped us launch, where we wanted to be for the next five, six years.

So, I would say that, yes, you have ideas. You want to maybe speak to a couple of people that you trust about it, get people around you who are experts in it, don't reveal your secrets, but then get that intellectual property patent and patients. We're going to talk a little bit about this today. The patients in this process, you cannot push this process through, and patients can be used to your advantage. So, once we got the intellectual property, I think that happened in 2008 we were off to the races. We had a unique device. And then, of course, we had to go back to the people that helped us with prototypes and ACI Medical was very instrumental in making prototypes for us, doing the initial trials.

I took the trials to the country that was dear to my heart, which was India where I was born and there was a great vascular surgeon program in Bangalore, India. That vascular surgeon, Dr. Desai, offered to be very cutting edge with us and doing the first efficacy and feasibility studies in India. Those trials went so well with a very large prototype, which has subsequently been improved on, but we rallied the Vaster Society of India. I presented there. I got the whole country's endorsement that this is great for India. As a fellow Indian, I know we all have small veins and I thought that the Indian population would benefit.

Our initial angel investors were my mom and dad and my dad was a very successful businessman. I rallied him, showed him the device, and he became our number one investor and so brought

the team together. It started with the concepts to the patent, to the prototype, to the trials, to the funding. You're right when you mentioned we are debt-free. This company has been funded 100% by the Singh family, which is my mother, my father, my wife, a psychiatrist. You need to have a psychiatrist on these companies because the ups and downs of the landscape and the hills and valleys of a startup, you don't have a psychiatrist on their team, you're going to be in trouble. Luckily, we had one that was directly connected to me. But the company from efficacy and feasibility success to regulatory processes all has been moving along at a very good pace with very good people.

Scott Nelson: That's great. I'm certainly looking forward to the part of this conversation where we can chat a little bit more in detail about this concept of strategic patience because it seems like this has been a trend throughout your experiences with Fist Assist is like this idea of being patient, but also persisting and pushing things forward. So, I'm looking forward to that part of the discussion. Before we get there, let's talk about a few of the things that you mentioned. Prototype development, which is crucial in any medtech startup, and that's not cheap either. So, you mentioned that ACMI, I believe was the company that helped you out there. But were there any lessons that you look back on during those early stages of prototype development that are worth mentioning, whether they were lessons learned or things that you did right

Dr. Tej Singh: ACI Medical was a company that had made pneumatics for the legs and we challenged them, and I credit Ed and his creativity, Ed Arkans the CEO of ACI to make a device for us, for the arm. Naturally, you know, we learn a lot about different materials, different batteries, computer software, even Velcro. There are different types of Velcro. If you have to stiff of a Velcro, it's hard for patients to take something off their arm if you put too much Velcro because you think it's going to keep a device on someone's arm so they can jog. If the Velcro is too stiff and they pull it off, it can pull away the fabric from the battery case.

So, there's so much learning and I would say this, that as a vascular surgeon, working with engineers, sometimes having that consumer feedback, having someone like a high school student put it on and give feedback on it. I think sometimes we were so excited making prototypes that we thought were going to work from an engineering vascular surgery perspective but there was a consumer. When you think of wearables, it is consumer-driven. The consumer has to put it on. he consumer wants to do their day to day activities. The consumer may not wear a short sleeve shirt or a long sleeve shirt. So, all those things come into play. But luckily, the nice thing about an external wearable and an external device is the changes can be made pretty quickly and pretty simply without major cost. So, there was a lot of learning there about our device.

Our device is probably on now version number eight and if you look at version one compared to version seven, so many different changes have been made in terms of size, Velcro, wrap, different ways that the device will sit on someone's arm. So, all of those are learning and luckily for us, ours was external learning, which I think is a lot easier than internal learning and the consequences tend to be a little bit easier and less severe in external wearable changes compared to internal. So, we were lucky also with that that our changes were mostly consumer-driven changes.

Scott Nelson: I think you mentioned an important point that sometimes gets lost is sometimes and I certainly experience this with Joovv over the past three to four years, is that you know, some design and dev shops are, you know, may be particularly well known for their expertise when it comes to medical devices but maybe they lack consumer experience in this example. I think you call that something that's important, that sometimes gets lost in the shuffle. It is making sure there's alignment around that. This is a product that lends itself well to viewing things through a traditional consumer lens. So, making sure that your design and dev shop is working on some of the early prototypes truly understands the context of how this particular device is being used. Sounds fairly straightforward, but sometimes kind of gets lost in all of the early activities in a classic medtech startup plan.

Dr. Tej Singh: Yeah, I know, and we face that too. But luckily all along, being a vascular surgeon in the space to me was always about my patients. This device to me was never you know, I've been very fortunate to have a busy vascular surgeon practice, great people around me working with me, helping me. So, it was always about taking care of the patient and that's how I was trained and that's to me what the focus has always been. So, with that as a backstop, anything that we made as a device had to be friendly for the patient and if the patient struggled with our device then we were not happy about that because that broke my foundation of doing something for people. It's the reason I became a surgeon. So, luckily once again, I think having that as a centerpiece enabled us to do everything around our company with the patient focus. Of course, the patient has to put this on, take it off and wear it. So, we have to make it easy for the patient.

Scott Nelson: Dr. Singh you mentioned something a few minutes ago with respect to possibly clinical studies in India and other than the obvious, which is some of your connections, your family connections. India, the country that you're passionate about, it's where you're from, you've got family there. Was there anything else that led to that decision to fund some of your early clinical work in that country versus here in the US or Europe as another example?

Dr. Tej Singh: So, those were probably some of the higher learning curves that we had as far as, oaky we have a device. We believe in this device. We thought about all the places that we could get the best bang for our buck in terms of the initial efficacy, then the feasibility and doing those trials in an environment where we could not only get great feedback, have a passionate investigator, help us take an audience that has struggled with vein dilation and all things at that moment just lined up with India. A place where we felt and we have a great principal investigator there at a hospital in Bangalore, Dr. Sanjay Desai. Dr. Desai was very much involved with me as I was planning the device and when he came and spent some time with me here in Silicon Valley learning vascular surgery with me at my hospital.

We felt that if we gave him the opportunity to do the prototype testing, he understood the background of it. He had already seen some of the prototypes being developed. He understood the concept. He was an advocate for fistula dilation. He was seeing in his Indian practice small veins. It just lined up well and his IRB was very supportive. Many people thought that it would be a very risky IRB to put a device like this on people's arms after they've had surgery and maybe hurt their fistulas or hurt their arm veins.

Dr. Desai and his control understanding of the device was very proactive about it. So, once again, it just lined up that sometimes you get pulled in a direction. You never want to push, push, push. If you can get pulled and somebody wants to pull you to that safe spot, you should always take it. Dr. Desai pulled us to Bangalore and did a fabulous job with two manuscripts that were published in 2018 in the Journal of Vascular Access which showed a device like this has some relevance, safe device, safe trial, motivating trial. That work in Bangalore spring boarded the company to where we are today.

Scott Nelson: I love what you just mentioned around being pulled in a certain direction and obviously that there has to be alignment around that. That's the general direction. But if you sense that this pull and it makes sense for the company run with it. Some of your comments around that topic seem to align well with a few past interviews that I've recently done, one which was with Dan Rose, the CEO of LimFlow that's working on an interesting peripheral vascular product. He mentioned the same thing as it was crucial for them in their early days to align and partner with a few clinical champions that were pulling them in a certain direction.

Katherine Ward who is with Healthy.io mentioned something similar in that they've been able to leverage their research and clinician champions to sponsor a lot of their research which has allowed them to do more of that at a lower cost. So, interesting to hear you kind of echo those same thoughts as well with respect to early clinical work in India.

Dr. Tej Singh: I would say that I learned that term from Mr. Tom Baker, who's our legal representative for Fist Assist at Auburn and he made it very clear in his educational modules to me and our class at that point in the business law at Auburn that being pulled is a good thing and if you're pushing, pushing, pushing you may find yourself not making the progress as easier as being pulled. But I will also say this, and I think I look back and I will say that the people that have entered my life and the people that I have worked with, I'm a big believer that people come and go into your life for certain reasons.

Dr. Desai and I met in 2002 when I presented at the Vascular Society of India and he approached me, we became friends. He asked to visit America and see how vascular surgery was done in America. He was one of the first fellows that got this Vascular Society of India Fellowship to spend some time with me in California. Who would have known that almost 15, 16 years later he would have been doing the first trials on Fist Assist in his medical center in India when he and I just met as a fellow visiting my medical center.

So, I think people come and go and how you treat people and respect people and how you give people the opportunity to be successful in your venture. Some people take that opportunity and go very well with it and some people may not be the right fit, but you respect that. But luckily, we were always associated with people who helped us with pulling and we've had some people that have made it a little bit difficult for us to get where we wanted to be, and I think the momentum naturally shifted us away from that.

Scott Nelson: I want to make sure we allow for enough time to kind of talk about this idea of strategic patience which we kind of teased earlier in a conversation. But I think now's a good time

to talk about or to discuss insurance coverage and reimbursement because the regulatory pathways are crucial for most medical device startups. Arguably that kind of insurance coverage and reimbursement landscape might be the biggest hurdle that most companies have to get over. One of the interviews that I recently published with Paul Buckman, kind of serial medtech entrepreneur mentioned the very same thing and we were talking about it within the context of raising venture capital. But he mentioned that it's hard to get a VC to say yes if there's not a clear reimbursement insurance coverage and reimbursement plan. So, can you speak to that aspect, Dr. Singh, with your device and your general approach to crossing that chasm?

Dr. Tej Singh: Yeah, and it's a great segue into what we'll be talking about, which is to me when I think of Fist Assist I think of the term strategic patience and it's going to be I think the highlight of our discussion is what I think strategic patient patients can do for a company. But we struggled with that. Initially, about seven or eight years ago people would look at us and say, well, who's going to buy it? Who's going to buy the device? But if you look at what's happened over the time course of that initial prototype to where we are today, literally on the eve of the launch, once this global pandemic ends, Fist Assist will be launching, and the launch approach of Fist Assist is direct to consumer approach. But the timing of that is something I would have never said seven years ago. You would have had to think, well, doctors will buy it, or insurance companies will buy it.

But for us, we've launched a very interesting product with a very large net and the net can be in such a way that as a wearable patient can buy it, in certain market distribution and distribution partners will market the device for us. We have been very lucky and fortunate that Amazon Europe, Amazon Canada, and Amazon USA has partnered with Fist Assist. So, who would have thought of Amazon with medical devices five, six, seven years ago? But now Amazon is that partner with us. The direct to patient and the direct to consumer model, because we are priced at a point where today I think those patients that want the benefits of arm/vein dilation and education and the benefits of a device that can be used for all aspects of renal failure.

If we priced our device correctly based on the voice of the consumer, the voice of the health care provider, which we've done globally then we think we've positioned ourselves to hit multiple angles in the distribution of this device. I will tell you that distribution is truly the final frontier for a successful device I think the way we've made our swim lanes from the direct web, social media, Amazon distribution will all enable the release of the product which will then enable us to come back to the regulatory people globally especially in America.

If we just think about the recent Trump initiatives for having more home hemodialysis and decreasing the cost of hemodialysis. Well, there is only one wearable in the world today that can help at the home hemodialysis level that a patient can buy, that can help their veins. If you have good veins, usually home hemodialysis works very well. So, once again the strategic patience and being cognizant of all the distribution angles at a time when there's regulatory changes happening because of our present administration and focus on renal care, Fist Assist has positioned itself perfectly to tackle those challenges.

Scott Nelson: That is a great thought and a couple of things that stand out to me in listening to you explain your approach to insurance coverage and reimbursement as we've certainly seen the same thing with Joovv, which, even though it's a class two medical device, is classic direct to consumer play, but be open to different kind of models. You mentioned that you struggled early on with this but there are so many different channels to leverage these days.

Most people stop, at least most classically trained people within medtech and health care will not be open to pursuing a direct to consumer model. I think that stands out is that it sounds like you guys were willing to explore that and have now been able to partner with other distribution channels like Amazon as an example, by remaining open to different ways to commercialize the device. So, that speaks volumes and I think most people just underappreciated the consumer appetite in terms of purchasing your "traditional medical devices."

Dr. Tej Singh: Absolutely right, Scott. Once again, if we were headstrong on regulatory, regulatory, regulatory and approval, approval, approval, we weren't creative in our brainstorming sessions. I credit people like Tom Baker, who you've mentioned, Mr. Kevin Beedon as an advisor. A lot of people have brought ideas and having an open attitude processing it but at the end of the day, it's a patient-driven device. If the patients tell us they're willing to do this, they're willing to wear it, they're willing to wear it this often, or they're willing to pay this much to have it. We always had an open attitude to that.

Our open attitude even started with regulatory approvals. In some countries our device is a class zero, I call it. They don't even think of it seriously as a medical device because they just think it's so safe and then in some countries, it's a class one device because it's external. So. we have been able to navigate regulatorily and now as far as reimbursement, our approach is a big net. We will do it from all angles, and I think you're right. Having an open attitude is the right way to approach some of these projects. I will say this, and I think it's time to talk about it. The Fist Assist story is a story of strategic patience. In that, strategic patience is the avenue of being open to ideas and being willing to not push them but to pull those ideas forward.

Scott Nelson: That's a great segue into this conversation, into the topic of strategic patience. So, you mentioned kind of one of the pillars being sort of practicing open-mindedness. Whether it's different models, methodologies, processes, et cetera, but are there other pillars or frameworks that encompass this idea of strategic patience from your perspective Dr. Singh.

Dr. Tej Singh: So, you know what? I think of strategic patience and I talk a lot about this because it's a concept when I look back at my 30 years. I think about strategic patience as strategic. What as strategic means is looking at the options and manipulating your thoughts, your actions, and your strategy of how you're going to tackle that with yourself, with your family and with your partners. Then there is the patient's part of it. When we think of patients, we always say, you know what, the race is a long race, slow and steady wins. Not just jumping out and trying to make a device that's not going to work, no one's going to buy it and next thing you know, you fold.

Strategic patience for the Fist Assist story started with obviously the initial concept. Why didn't I make this device as a medical student? Well, I didn't have the finances or education. Why didn't

I make this device as a resident at Stanford or launch it instead of being a busy vascular surgeon? Why didn't I just go into entrepreneurial-ship? Well, young family, need to make sure I had concepts, need to make sure I had the finances in place. I wasn't going to ask my initial angels to invest in something that I didn't believe in and I wasn't ready to believe in it. So, you had all that patience is what I call the research development phase and then came the whole concept of getting momentum, funding it, feeding it, getting further investments from my family. So, we were patient.

We were patient with India. We were patient with the device. We were patient with assembling our team and as we went through it, we were tackled, or we were posed questions about who's going to buy it. Well, we needed patients for that. Initially, did we think dialysis centers would buy it? Would doctors buy it? What has happened, interestingly, Scott is our initial approach was to make a device for dialysis. If you just look in the patient's world that we've lived in, so much has changed in dialysis. There is the Medicare concerned about the costs, the end-stage renal care organization, the escrows on saving costs, the Trump initiative, home hemodialysis. In the last seven years, the dialysis space has changed so much that Fist Assist by waiting on the sidelines positioned ourselves in a much better arena than we ever could have been.

So, by being patient, watching how the tides of the waves change, how renal failure became a bigger issue helped us. Then came the discovery that while many patients in this country and the world, especially with the COVID crisis need to get a blood draw and need to get a home blood draw, need to stay away from hospitals and blood draw centers and they want to get this at home. So, then came the whole concept of mobile phlebotomy. Phlebotomists now all over the world go to people's homes to draw their blood and to get blood samples. Some of these draws are very painful and difficult. Could we give patients an opportunity to buy a device that's affordable that they could wear and use at home before their scheduled blood draw? So once again, who would have ever thought mobile phlebotomy 10 years ago was going to be a big business?

Well, we were patient, we were observant, we watched that. So, the landscape's for regulatory, the landscapes for approvals, the landscapes for who's our customer. All of those have changed in the last seven, eight years. I think Fist Assist being a nimble gazelle-like company has been able to jump from different scenarios because:

a. we had the time
b. because we were patient.
c. because we were observant, and we were not hard-headed on anything.

We would be today launching in Europe but respecting what's happening in the world, in the world we live today, and with COVID-19 spreading its wrath all over. Once this settles down Fist Assist once again and another example of using this opportunity with the Coronavirus to once again solidify our marketing campaigns, to make our device even better and more improved, to use our contracting manufacturers to get things tidied up to now be on the verge of a Europe, Australia, New Zealand, Canada, and eventual USA launch reflects the patience we as a company have demonstrated over the last 30 years.

Scott Nelson: That's a great summary and I think I think that this topic of strategic patience, listening to you describe it and how sort of it's been a foundational sort of belief in the way you built this company. It seems easy, simple, and straightforward and I found myself nodding, nodding my head as you explained it, but much harder to do in practice. But I think you make such great points around, even with respect to insurance coverage and reimbursement. If you would have been so fast to run from point A to point B seven years ago, you wouldn't have probably been in a position where you've got all of these organizational bodies that are pressing into the dialysis community to lower costs, to produce more technology for in-home dialysis, etc. So, that landscape is, as you mentioned Dr. Singh has changed dramatically and by being patient it allows you to kind of what appears to reap the rewards of that changing environment.

So, I think that it's just interesting to hear you say that. It's sort of a breath of fresh air when so much advice in the medtech startup communities around moving fast and sort of breaking things if you will. But in some respects, that can be good advice, but in others, not so good advice. So, it's cool to hear you kind of explain the Fist Assist story within the context of this idea of strategic patience.

Dr. Tej Singh: Yeah, Scott, we eluded this with our present finances. Not every company, unfortunately, or fortunately has that. This has been a long process for us, maybe it didn't need to be seven years, may be needed to be four and a half, whatever the case may be. But as the CEO and Founder of the company, I report to myself. Ethically I report to myself. I've got amazing partners all over the world with this company who have been fabulous partners and friends more than sometimes partners.

At the end of the day, my financial resources from individual family, my parents have never put pressure on me that the return on their investment needs to be done tomorrow. I'm still a busy surgeon. I still have children that are finishing college. I still have a wonderful marriage and wife and surgery and vascular surgery will still be a big part of my life. But the patience of this company and being able to provide a device that I believe in that will help millions of people across the world gives me great excitement. I think it will continue and I think it'll be released in a way that's smart and well thought out instead of pushy and I think the world itself will pull Fist Assist into its locations.

Scott Nelson: That's good stuff and I think one of the most important takeaways under the guise of this strategic patience concept is your company needs to be nimble and needs to be positioned in a way that you can take advantage of this concept because if it's not there may be some challenges that unfold for sure but good stuff. So, on that note, I want to be cognizant of the time doctor saying. So, let's conclude our chat with the last three rapid-fire questions. Your answers don't necessarily have to be rapid-fire per se, but it's this idea that what's the first thing that comes to mind? So, on that note the first question for you. Is there a business book or maybe not even a business book, a book that you first think of that's been impactful across your personal or professional career?

Dr. Tej Singh: So, as we mentioned I finished the Stanford Business School personal leadership course, and I took a class on power. There was a book by Professor Jeffrey Pfeffer, Pfeffer with a

P and it was Power. I read that book and I've been blessed whether it was through med school or leadership, always having power and whether I was a leader in the residency or my departments. But I disagreed with the book because in that way it showed that power can be caught and attained by manipulation and working yourself through the back roads.

I've always felt that while you can get power, you can be granted power. The one thing that's the most important is even if you have power, remember, power can come, power can go but the people around you, your loved ones, and your family should never be sacrificed for power. I've been so blessed, no matter what happens with Fist Assist, no matter what happens with my career, an amazing family, amazing children, amazing wife, amazing mom, amazing dad, and they will always be around me with power or without power. So, that book was in a lot of ways very influential in how I thought about my company and how I thought about my career.

Scott Nelson: On that, the second question probably is just as applicable. But when you think about your professional career or even your personal life has there been a mentor or someone that you can point to that's been influential?

Dr. Tej Singh: I've had in my life two fathers. My first father was my biological father. He was an amazing businessman, a first-generation man from India, came to America, and started a business in the handgun industry which nobody would have ever thought he could ever be successful at and he was super successful. I helped with the business. The business was called Eagle Grip's out of Chicago and I learned a lot of business skills from my father. Then when I started med school, I had the fortunate friendship, mentorship, I guess you could call my professional father Christopher Zarins at Chicago and Stanford and still today who helps me with my company. So, having two role model fathers, personal and professional has given me the best guidance a young surgeon, young student, and a young entrepreneur could ever have.

Scott Nelson: That's good stuff. I love the idea of a personal or biological father and a professional father. Good stuff. So last question, Dr. Singh. Is there a piece of advice that you would give your 25 or 30-year-old self if you could rewind the clock?

Dr. Tej Singh: Yeah, I think we talked a lot about that. I used to always say there were the three A's that made a successful person availability, ability, and affability. But I'm going to say now, at this stage of my life, literally under the launch of a company I've been working so hard with my partners on that patience. I wish back then I learned that patience, you know, I learned patience based on basically having to run this company through all the regulations and believe me when I got those emails, oh, we need to study this. I would just basically throw my pencil up in the air and say, here we go another four or five months. Patience is key and never push when you can be pulled. That is so true today.

Scott Nelson: That's good stuff. I think that might be the title of this interview that never push when you can be bold. So that's good stuff. Dr. Singh, we'll wind up there. I'll have you hold on the line real quick but can't thank you enough for taking some time out of your busy schedule on the eve of several launches to provide a lot of insights over your personal life and your professional career. So, thank you very much, sir. Appreciate it.

Dr. Tej Singh: Scott, thank you very much for this opportunity and I hope this interview and what we're facing today when there are people sitting at home or reading, they'll figure that while patience is important, we'll get through what's happening in the world. I look forward to seeing other companies and innovation and entrepreneurs hopefully take something from this talk and realize that there's an opportunity out there. We've benefited from it and we thank you very much for the opportunity to talk to you today.

Scott Nelson: All right. Thank you, Dr. Singh and I'll have you have you hold on the line. For those listening to this interview, as always, appreciate your ears and your curiosity and until the next episode of Medsider, everyone take care.