**MedTech Chat Podcast**

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**Guest: Parag Gad**

**Welcome to MedTech Chat, where we discover the latest healthcare tools, device technology, as well as research approaches. We’ll be talking to designers, insight professionals, and other executives that understand how MedTech is helping patients, and those caring for them now, and in the future.**

**Today I’m excited to talk to Parag Gad. He is the co-founder and CEO of SpineX, an early-stage startup spinning out from UCLA. He has a PhD in biomedical engineering from UCLA and a bachelor’s in engineering from Mumbai University in India. Thanks for joining me today.**

Thanks, John. Good morning. Thanks for having me on this podcast.

**I know that you’re going to be telling us about SpineX and how you’re developing novel medical devices to address unmet clinical needs in patients. I’m wondering, can you tell me what inspired it? How did you get involved with this?**

The SpineX as I mentioned is a spin-off from UCLA led by Dr. Reggie Edgerton who has been working in the field of spinal modulation for several decades now and he is who I call the father of spinal modulation. The basic principle behind all of this, the central driving force for SpineX is that it’s a very strong scientific background which has proven that control of most functions including autonomic function, metabolic function, the ability to walk and move your hands are all controlled by the spinal cord. The brain in most of the cases is just giving you command to go or not to go but how to actually make that happen is what is controlled by the spinal cord. So the inspiration of the drive for us is this basic scientific principle of what, how the spinal cord is controlling these movements. Any paralysis or dysfunction, traumatic or non-traumatic, the ability is to control these functions are lost. They are primarily dormant. They’re not dead. That is the primary source of our drive leading the SpineX.

**That is very important work, and I know both professionally and personally where this is going to be helpful to many people. Can you tell us about the kind of devices that SpineX is building?**

One of our primary devices is a non-invasive spinal cord stimulator. We’re able to - we figure out ways in which we can reactivate and re-train the spine so it’s controlling these intrinsic functions by simply placing these little electrodes at specific levels along the back that’ll activate the spinal cord. By activating the spinal cord, we are able to achieve multiple functions. One, we are able to target these end organs specifically. Second, we’re able to allow it to re-communicate with the brain. The way I describe it is it’s a hearing aid in combination with the spinal pacemaker.

**That’s really fascinating. Now I’m kind of curious what the spinal cord really has to do with something like the bladder.**

Take the example of an infant. A two year old or a one year old who’s got a normal nervous system. They just are unable to control the bladder and that often leads to them being on others and that’s why they have to wear diapers. The bladder functioning is in a lot of cases very similar to that. The big difference being as an adult you obviously, can hold much larger volumes of urine but are voluntarily now controlling the ability to void in a socially acceptable manner. Now, after an injury, traumatic spinal cord injury, stroke, or in the cases of a lot of women, such as urinary incontinence, you just lose control and lose the sensation of their bladder, essentially making you very similar to what a one year old was where your bladder’s functioning independent of your brain. Now with the spinal cord stimulation, what we’ve identified is there are circuits in the spinal cord that are actually controlling the bladder and use of functions. A lot of times independent of the brain but you’re able to synchronize them where the brain can then be integrated with the spinal cord. By using our propriety spinal cord stimulator [inaudible 00:04:08] we’re able to stimulate the spinal cord to reaching the circuits such that an individual can then regain control of the bladder. They can regain control of the ability to hold urine to a point where they can then empty it voluntarily when socially acceptable and when they want to. In the cases of individuals that have lost the ability to actually void, void on command with the stimulation.

**I can definitely see how that can be important for people to be able to get that kind of function back. I’m curious as you’re talking I can imagine many different applications but what patient population are you targeting?**

Our first market is targeting patients with what’s called neurogenic bladder that’s caused due to traumatic conditions such as spinal cord injury or a stroke in the brain or other nervous system disorders such as multiple sclerosis. That’s a reaching market to enter and demonstrate the feasibility of the functioning. Our long term vision is to try and expand to other sorts of bladder dysfunction. There’s an interesting [inaudible 00:05:14] that we came across doing market research in this field is that about 21 percent of the world’s population actually has some form of bladder dysfunction. That’s a huge potential market that we can tap into. Or in the [inaudible 00:05:26] itself, we’re expecting about 33 million are suffering from what’s called overactive bladder or urinary incontinence caused due to massive conditions such as postpartum in women. In males, due to prostate dysfunction, etc. That’s a really big market with incontinence and overactive bladder that we’re targeting.

**Yes, that’ll be amazing if you could help those folks because that’s a large group. What kind of results have you seen so far?**

Our results have been quite exciting. In a pilot study of this last year with 14 patients with different forms of dysfunction from spinal cord injuries, stroke, multiple sclerosis, as well as overactive bladder. We are able to demonstrate that within eight weeks of therapy, these patients are able to improve the level of incontinence to the point where they’ve had 70 percent fewer leaks. They are able to void, they have decreased the number of voiding cycles per day. They would reduce it by about 50 percent. Numerically, that leads to a metric called the neurogenic bladder symptoms score. We saw 11 point change in the NBSS scores, which is more than what the FDA normally expects from devices of this nature. That’s just metrics and numbers. Quality of life change, that has a big translation where these individuals that were waking up every half an hour to 40 minutes at night to empty their bladder were not able to sleep for two to three hours, which is not - from an able body perspective, two to three hours is really short but for someone who’s waking up every 30 minutes, that’s a huge change in their quality of life.

**Yes, I can see how that definitely would change somebody’s quality of life. I think that sounds very important. I’m curious, can you tell me about the milestones and the roadmap ahead?**

Yes, we are currently in the product development phase for a device where early prototypes will be used prior to clinical studies have demonstrated to us the safety and efficacy of our own device. We’ve identified features on the device necessary for a clinical unit. At this point, we are in the process of fabricating our clinical units, performing all the necessary engineering tests on them to ensure that they’re safe to be used in the clinic. We envision beginning our eventual FDA trial early next year and with that trial in place, we’re hoping to approach the FDA for clearance of this device by early 2023.

**That’s very exciting. I’m curious who’s on your team?**

Our team, we have a small but very dedicated team that’s running SpineX led by Dr. Reggie Edgerton as the scientific head. Like I said, he’s been involved with spinal modulation and spinal control at UCLA for about 50 years, so he’s been at it for a while. We have [inaudible 00:08:22] who is a former navy vet who is in a wheelchair due to a gunshot wound he suffered while serving in Afghanistan. We have Dr. Evgeniy Kreydin, who is a urologist based out of USC who has been leading all of our clinical efforts. Mr. Tim Hopper [ph] who is a medical device executive with over 25 years of experience and he’s personally motivated with his son being a quadriplegic.

**That sounds like a solid team. I’m curious, will you tell us a little bit more about your long term vision for the group?**

Yes, bladder dysfunction is the first step in this direction for us. If we’re able to demonstrate that this works in the bladder, that has multiple ramifications for patients with different forms of bladder dysfunction. But the basic idea being that the spinal cord controlling multiple functions. We see the same technology as the platform technology that allow us to expand this out both horizontally to different pathologies, such as stroke, spinal cord injury, aging, multiple sclerosis, in children with cerebral palsy, Parkinson’s disease, traumatic brain injury. Any form of dysfunction that’s caused—the system could possibly target it. Then, I look at this expansion in the vertical plane where we could then target different end organs along the length of the body right from hand and mouth function in quadriplegics, breathing function, cardiovascular function, sexual function, bowel function, as well as lower extremity function, due to different forms of paralysis. You could really expand this out on both planes and pretty much target the entire body using this platform technology.

**That is amazing. Yes, it sounds like you have a lot that you could accomplish in the future. Sounds like a promising way to go. I don’t know if you’ve given much thought to this or not, but I like to ask people who has inspired them, either historical figures or fictional characters? Not sure if you had anything like that you could share with us that might inspire you?**

That’s an interesting point. Going up through college, I was quite intrigued by a fictional character that most of us know off and on as Iron Man. Even though I was more interested in the technology aspect of it being an engineer myself. The way he would build things and even though the technology seemed really fancy, the simple ways in which he was able to achieve those were ones that would really intrigue me and I think a lot of work we do here at SpineX is, at least for me personally, is keeping that in mind that technology doesn’t always have to be super fancy, especially if you can achieve them in really simple ways. The impact of that is high.

**That is so true. Keep it simple that many great things can come of it. It sounds like you had a great inspiration to get to where you are. This is fabulous. I’m curious where people could go to find out more. Obviously, I could put a link to your website and to your LinkedIn but is there anything you want to tell people about how to connect with you or find out more?**

Of course. You can check our website. It’s a lot of activity happening on the social media platforms such as LinkedIn and Instagram where people interact with potential patients, physicians, users, and other forms of interaction. We put out a lot of content, ongoing activities as well as basic science as well as knowledge for patients through our social media platform. That would be an obvious mechanism. Or if anyone is interested in reaching out, they can always email me at my email address. I’m happy to share that with you. You can share that with your listeners.

**Excellent. Thank you. Yes, list everything there on our site and I appreciate your time today Parag and I look forward to more chatting in the future.**

Thanks, Tom. Thanks for this platform and I appreciate the time.

**Thank you.**

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