Vagus Nerve and Vagus Nerve Stimulation Transcript

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Introduction to the Guest and Topic

Through. All right. This is Doctor Pollack. Today, you have a very important guest. An unusual guest. And somebody who shares a background with me at Johns Hopkins.

The talk today is title of the interview today is titled The Power of the Vagus Nerve and Vagus Nerve stimulation. And I have with me Doctor Peter Stat.

So Doctor Stotts is the founder and director of the Pain Medicine Management program at Johns Hopkins. He's internationally recognized for inventing, developing and implementing minimally invasive procedures for pain and neuromodulation.

He's currently the CMO Chief Medical officer of the National Spine and Pain Centers and co-founder of Electro Core, which is the primary reason for our chat today.

He's also the president of the World Institute of Pain. And he's the past president of various societies. And they're too long to list. But a lot of societies, let me put it that way.

He's co-edited 14 books, has over 500 scientific publications on pain management and neuromodulation. He's been highlighted on good Good Morning America, CBS Evening News, Newsweek, and CNN, and his numerous lifetime achievement awards, again, too numerous to go into.

So I welcome you, doctor thoughts. Look forward to our discussion. All right. So let's dig in. So this is about the power of the vagus nerve and vagus nerve stimulation.

So let's tell people, first of all, what is this nerve that they probably have heard about. And they know that it's important. So why is the vagus nerve important.

And what is it. Well, the vagus nerve is the longest cranial nerve. It's also called the wanderer. The wandering nerve. And this is the nerve that connects the brain with all of the visceral organs, most notably the gut.

I think a lot of your listeners might be interested in the mind body interface and mind body interaction. And I've been a fan of that growing up in Hawaii, thinking about Asian medicine for so many years of my and my formative years.

I've always been intrigued by this mind body medicine, but really, the last 20 years where I think I've started to get a handle on what that is. And one big aspect of that is the mind.

And the rest of the body connects via the vagus nerve. This is the information superhighway of information going from the gut to the brain and the brain, telling the gut and the chest and the visceral structures how to respond.

It's an incredibly important nerve that, honestly, I didn't appreciate when I was in medical school or as a resident or as a young attending physician.

What the Vagus Nerve Is and Why It Matters

It wasn't until much later where I realized that the vagus nerve is so powerful. In fact, it was that nerve that got in my way when I was placing central lines for people, who needed to have surgery.

But it turns out there is it's an incredibly powerful nerve that most physicians, most doctors and and many health care providers across, the United States don't really recognize it's important.

As you said, it gets in the way, it's there and it does its job, and we don't pay attention to it until it doesn't do its job. Right, right, right. Let's let's clarify one point.

You said it's a cranial nerve. So tell us what cranial nerves are. So there are there are different cranial nerves. Some help you see. Some help you smell, some help you taste.

And this is a nerve that connects the brain with the gut. It is the nerve. It's going into the brainstem and providing information up to the brain stem.

This one in particular, I think is really important. And, I mentioned a moment ago kind of the Asian philosophy of yin versus yang. This nerve is the parasympathetic nervous, the main parasympathetic driver.

And that's opposed to the sympathetic nerve. And what we've talked about before is the flight or flight fighter fight or flight response. You know, we're going to be really scared.

We're going to run away or we're going to be calm. The sympathetic nerves are then run away or there's a bear chasing me. You got to get excited and run away.

Run away. The parasympathetic nerves are the calming nerves and the vagus nerve is one of the main ways where we can cause that calming ness to occur.

And it turns out that's really, really important. And cranial means in the brain or in the head, right. That starts up in the brain stem and most of the cranial nerve start in the brain stem.

Some of them start in the brain itself inside the skull. That's right. Some of them are just outside the skull, like the brain stem is just outside the skull, but it's still considered a cranial nerve.

That's right. And all these cranial nerves, they have feedback back up into the brain. Right. That's right. Into the sensory cortex, into the thalamus and the hypothalamus and other structures in the brain.

Sure, sure. And this nerve really has very vast what we call projections. It goes into one area of the brain called the nucleus tract. And solitary is.

And then it goes out and projects into the human, as you mentioned, the thalamus, the hypothalamus, and other areas throughout the brain. Early on I saw a map of where this goes, and it really does, go throughout the brain.

After the first linkages. And that's really important as we start to learn about what this does, we're able to tap into the vagus nerve and change brain chemistry throughout the brain in different structures.

So for example, one of the studies that, being done was completed showed that we can change brain chemistry in patients with Parkinson's disease. Another one shown you can change chemistry in patients with post-traumatic stress disorder.

And we go down the list of these different types of areas, where we're actually changing the chemistry locally by delivering electrical signals in the neck.

So it's really kind of a fascinating, area there. Now, one of the points you made about the fight flight response, the brain and the body in general tries to maintain balance.

That's right. So when you have a fight, flight response, fight or flee, right. That's your dynamic. You have to act now. You have microseconds. Yeah, but then you have to unwind that.

So the body says, okay, I'm up I'm up to high. Now I got to bring me down. So it tries to find a balance and the vagus becomes stimulated to try to balance out that excessive stimulation of the adrenergic system.

Right. And I think teleological there. If you think back to our ancient ancestors, there was very little time of stress. You would have you may be picking, nuts or, you know, hunting down an antelope when you were, you know, thousands and thousands and thousands of years ago.

And then there'd be time for relaxation. In today's world, we don't really have that same balance of a few moments of stress and a lot of downtime. Today, our lives are just filled with stressful events, either cognitively or driving to work or dealing with, an employer or etc..

Yeah, so much stress in life has taken us out of balance, I believe. And a way of thinking about this is by stimulating the vagus nerve, we can start to put ourselves back into balance.

Now, that's not really a medical definition, but this is a way that I think about things as, how do you conceptualize? Why would you want to stimulate the vagus nerve?

What's gone wrong in our system, in our society, that I would need to do such? Well, it has its own actions, which are not necessarily part of this rebalancing.

So you can actually actively stimulate the vagus nerve for specific functions. An analogy that I use for stress is that stress is taking the elevator up from one floor to the 10th floor, like immediately.

Yeah, it acts really fast. And then de-stressing is a process where the slope is much slower. And that's where the vagus nerve comes in. You have to you have to process all those neurochemicals that that work part of the stress process.

But what happens is that as you're coming down that long slope, you have all these stressors. So going down that slope is not a linear fashion either.

It's going down steps. Yeah, right. It's a stepwise regression from the from the initial progression if you will. Yeah. And that can happen millisecond to millisecond.

Not minutes to minutes but millisecond to millisecond where you really need to concentrate on getting your, your your parasympathetic calm down. And meditation does that too, right.

Yeah. I think there's a lot of ways to stimulate the vagus nerve. You know, historically, I think meditation, deep, biofeedback and other types of strategies have been used for, for, to stimulate the vagus nerve and improve the parasympathetic output.

But in 1997, the first vagus nerve stimulator was approved by the FDA for implantation an implanted device in the brain.

Fight-or-Flight, Parasympathetic Balance, and Stress

Yeah. Now, in the on the vagus nerve in the neck. And that was approved for epilepsy. It turns out that in these early studies, and it's still an active program today.

But in these early studies, if you placed an electrode on the vagus nerve and set a certain frequency, you could stop a seizure from happening in kids with really severe and recalcitrant seizures.

And that's been around since 1997 or thereabouts and approved by the FDA. So that was one of the early signs that there can be changes in brain chemistry and brain electrical activity by stimulating the vagus nerve.

And subsequently we've done work, primarily in airway reactivity. And, and we've done work in headache disorders where we have a whole number of FDA clearances.

We've got a breakthrough designation from the FDA on post-traumatic stress disorder. And that's not the same as

an FDA clearance, but it's a sign that the early data is intriguing to the FDA, and they want to fast track this through in the UK and, in Europe, there's approvals or there's Mark, what they call for primary headache disorders, for gastrointestinal problems, for airway reactivity or asthma, for epilepsy and for anxiety and depression.

Kind of relevant to our conversation. We just had. So this is all within the framework of neuromodulation. So neuromodulation is actually a relatively new term to describe all these kinds of forms of nerve stimulation.

Yeah. And so, one of the my early areas of interest was when I was at Johns Hopkins was, was this field of neuromodulation, the application of electricity to modify disease.

And I was actually the first anesthesiologist, at any academic institution to implant these devices for chronic pain. And I started to implant spinal cord stimulators for for chronic pain back in the, in the 90s.

Others had come before me. But back in the early to mid 90s, the whole field developed, called the field of neuromodulation. And when I was president of that organization back in 2001, I believe it was we really recognize that this is not about another way of treating pain, but the field of neuromodulation should be a platform for understanding how electricity and site specific drug delivery can modify disease.

Not just pain, but maybe pain, maybe schizophrenia, maybe, cardiac disease, maybe, movement disorders, as you see, with deep brain stimulation now for patients with Parkinson's disease and whatnot.

So the field has really broadened from being a very focal area around, pain treatment to use of electricity to broadly speak correct diseases. And people are looking at things like rheumatoid arthritis now, which kind of blows people's mind that we could potentially do that.

We got an emergency use authorization in Covid, of all things, for for helping with breathing due to Covid. So there's a lot of ways that electricity can potentially alter diseases.

And that's a new framework. It's a new thought process for most people to think that, hey, I thought I needed to take a drug. I thought I needed to do have surgery, but it turns out that your body's pretty powerful.

If we just give it a little bit of a boost. And that's back to you, doctor Paul, like a lot of areas of work that you've been doing, in PMC. So I just, you know, it's really quite interesting to me how this all kind of comes back together.

Well, part of my journey into PMC actually started with acupuncture. And as you were chatting, I think back again that acupuncture, the acupuncture system is a DC current system in the body.

Yeah, very low level DC current system, very low intensity, but it's DC current, so it's flowing through all the different meridians in the body, including up into the brain.

Yeah. And there are specific schools of acupuncture that just treat for neurological disorders. So they're doing in a sense neuromodulation. Two they're just doing it indirectly and very in a very mild fashion.

And they have their ways of describing what they do. Phenomenology that relates back thousands of years, because that's the way they could describe it. Right.

That's not what you're doing. Basically, stimulate the vagus directly is still a form of acupuncture in a sense, but it's directed it's much more directed in a sense.

You're right. And, you know, I, I'm a kind of a student of the history of medicine. And I it's just something that's always fascinated me. But if you go back, as you point out, thousands of years ago, one of the ways that they used to treat migraines in ancient Asian cultures is to oblate, a little branch of the nerve in the ear, which happens to be where about 1% of the vagal fibers in the neck run.

And they actually did that for headaches. And we have FDA clearance is now for stimulation of the vagus nerve in

the neck, to prevent and treat acutely migraine disorders.

So it's kind of interesting that, the acupuncturists we're on to something thousands and thousands of years before we got a hand on it. Empirical. It was empirical.

Yeah. I have a picture at home, of these, Neanderthals, if you will, shooting, throwing spears at a big mastodon and the mastodon. The caption says, oh, my back brains better.

Yeah. That's right. That when they did the ablation on the ear, what did they do? They actually burned. Yeah, they actually burned, cauterized, a little branch of the vagus nerve in the air.

I don't think they knew what they were doing at that point. Course. Of course that's what they were. That's what they did. And auricular acupuncture is actually a form of at least another some subset of acupuncture as well.

Yeah. That's right. So we understand now the vagus nerve has a huge number of functions in the body. Not all of them are pain related I know. And they have many, many other important sort of areas of the body in terms of their actions.

So you've said that the vagus nerve stimulation can be useful for a lot of different conditions. What are let's go through some of those conditions again.

Sure. So, you know, in the United States, just to be clear, the FDA has granted a clearance for our device for a, adjunctive use in episodic cluster headache as an acute treatment, prevention of cluster headache, acute treatment of migraine, prevention of migraine, treatment of migraines in adolescence.

Treatment of hemi cranio continuum. Treatment of paroxysmal scribing. Describe it. That what is hemi cranio. So that is another autonomic trigeminal so-called.

So these are various types of headache disorders that people have.

From Implanted VNS to Neuromodulation

And and the Electric Corps has done a large number of studies, probably 40 different papers on the topic now around various types of very severe headache disorders.

And that's really where we got our first FDA clearance is there. But interestingly, this is a time of kind of us coming out of Covid now. I mean, I just confided with you that I got Covid last week, but, we actually did a study in patients with Covid knowing about what's called the, an anti inflammatory reflex.

We did a study in Covid patients that showed that the inflammation associated with Covid could be significantly returned to normal or turned back down compared to standard of care in patients treated with vagus nerve.

Stimulations in a hospitalized group of patients in, in, in, in Spain, actually the study was done in Spain. So it has been shown to decrease inflammation, broadly speaking, in a few different models, not just not just, Covid, but other models as well.

But what the FDA granted, in a, the emergency use authorization was an early work that we did in airway reactivity. So I became interested in this field again.

I was a, young neuromodulator when I learned that my son had peanut allergies. So you think peanut allergies? Why? How possibly could you get from peanut allergies to.

Let's stimulate the vagus nerve? But it turns out when I learned this, we didn't really know what caused that airway reactivity to clamp down on the lungs when somebody who has an allergic reaction.

And so I worked with, some former colleagues of mine from Johns Hopkins and then went to Columbia, and we identified some pathways that by which patients with status matics could have, an improvement in their airway reactivity there, whether fev1 that's just a fancy medical word, but it's you're forced excretory volume in one second.

It's a functional lung test. Yeah. It's a functional lung test. Your work of breathing, how hard it was to breathe. We showed that in a very small number of patients early on that we could improve breathing in patients with asthma.

And when we presented that to the FDA, remember early on we were running out of ventilators. We the, in the New York City, there was there wasn't really we had to make a decision on who was going to go on the ventilator and who was not going to go into there because we didn't have enough at the time.

So I, I looked at a group and, a large bit of data that was out there on inflammation and the data that we had done in airway reactivity close to ten years earlier.

And we submitted that to the FDA, and they granted us a limited use and emergency use authorization for people who had known or suspected Covid, who were having an exacerbation of asthma or airway reactivity to be used at home or in a health care setting.

And so this is something that was out there for people to be able to use back as early as July of 2020. It's one of the early things that got approved by the emergency use and the I don't know if it's still the only one as a treatment, not like a mechanical assist device, but as a treatment to help people breathe.

Now it's inflammation. That's, I wrote a paper just recently as well that the the problems with the lungs in Covid is not lung infection. It's inflammation.

Yeah. So that's really but killed people I think in, in in these now this is different than the what the emergency use authorization came with with the FDA.

But what we did know is that we spent a lot of time talking about how the vagus nerve goes to the brain and tells the brain stuff, right, but we haven't talked so much about it.

But the way the brain tells the gut a lot of things, too, and the way it tells it is via the vagus nerve. And what I saw very early on and wrote a paper about this and published in April of 2020, was that, the patients with, who were dying of Covid were experiencing what was called the cytokine storm, profound inflammatory response.

It's absolutely way over the top. And you but the body is responding with profound inflammation. And the people who were dying were those who were dying had a profound and increased and exaggerated response.

And things like, cytokines and C-reactive protein and other types of things. They were having a profound reaction. And what's not commonly known is that the command and control center of inflammation is the vagus nerve.

And then if you stimulate the vagus nerve, you can turn off that excess inflammation. And so that was a really an interesting thing that had been demonstrated in animal models, not about Covid, but with sepsis models by, world renowned physicians like Kevin Tracy and and others demonstrated that 20 years previously, something called the anti-inflammatory reflex.

And what we did is we tapped into that to try to block inflammation, extra inflammation that's occurring in patients with Covid. And I think this most recent paper is very suggestive.

Excuse me that this is one method where we can dampen that inflammation back down to a more normal level. What's interesting is that I read a paper from the Soviet Union and they were treating they had a series of papers actually, that they published, about treating asthma from the back.

So they're applying magnetic field therapy to the, to the back to the thoracic spine area. Yeah. Now what do you

think could be improving the airways by stimulating from the back.

Well I think we can a a we get to the, the the the vagus nerve through the back. I think you can get there. And depending on where in the back you can get to the spinal cord, which can send signals up to the brain with a reflex response down through the sympathetic and the parasympathetic chain.

So you know, if I wasn't so deeply entrenched in this, I would say, come on, that that's not crazy, but I'm so deep into this. I understand that your body is not just a big chemical.

It is an electrical and chemical response there is profound. Modulation that occurs with drugs. Of course, we've known about that for a while. I'm not discounting drugs, but.

Well, what people have discovered is the power of the nervous system and electric ity, and I don't think we've got all of the answers. We've got a few of them, you know, but we know today that the best thing you can do for a movement disorder is an implanted device in the brain for, for called deep brain stimulation.

The best thing you can do for a slowing heart rate today, most effective is a pacemaker. We know that one of the you know, one of my areas of expertise has been implanting spinal cord stimulators.

I've been doing it now for close to 30 years. It's the best thing I can do to help people with severe back and leg pain. And so we got little bits and pieces that electricity can be really powerful in modifying disease.

But Western medicine hasn't fully embraced this yet. It's interesting to me that we still think about this as a chemical organ and oh yeah, maybe try a little electricity here.

Acupuncture, Headache, and Early Clinical Uses

But I think we really need to be more sophisticated in our consideration of, electricity, in modifying diseases of any kind, many types of sorts. Yeah.

So obviously, since I do EMF electromagnetic and I recently heard of, physics discussion that, electrons passing down a wire or not moving, we think that they're moving at the speed of light, but they're not moving.

They're basically jiggling. But what they do when they jiggle is they create an EMF, an electromagnetic force, and it's the electron and the, magnet. It's not a magnetic particle, but it's actually like a magnetic particle are moving out at the speed of light.

So it's not the electrons that are moving, it's the M wave that's moving down the system at the speed of light. Yeah. This has been demonstrated scientifically from a physics perspective.

So we stimulating nerves. There's a lot more going on than just the nerve conduction itself. That's right. And a nerves conducting is producing a magnetic field.

Right there. And I think our areas are so much overlapping and over intertwined because you've been looking at the big picture and at a level of an electron, and I'm looking at the level of disease state, with one particular nerve right now.

But there's the we're both singing to the choir here, so to speak, because we both really do appreciate the power of electricity and electromagnetic fields in modifying disease.

Well, I think it's the, what we're talking about basically, is the elephant, the blind man and the elephant. Yeah, we all know our part of the elephant, right?

That's right, that's right. Move to a different part to know the other part. And so let's go back a little bit. You talked about it because I was intrigued by this.

And I'm sure maybe there people out who or listening who also. But we're gonna ask the question if you stimulate the vagus nerve in the neck. Yes. Where does that signal go?

Well, actually goes in two different directions. It goes up to the brain stem to the nucleus track. This all is it's an area of the brain. And then there are harbor positions that occur from there.

It also goes down into the visceral structures. So for example, one of the really interesting areas is the spleen. Now we you know, we kind of think about, oh, what is that structure do?

Well, that's a really important structure in terms of inflammation. And there are people not not meso much, but other people have been doing a fair amount of work on diseases like rheumatoid arthritis within implanted device on the vagus nerve to alter inflammation due to rheumatoid arthritis.

It's kind of mind blowing and mind altering that we're doing that in this type of direction. The gastrointestinal tract is another area that the vagus nerve seems to control.

And there are many, many patients with inflammatory bowel disease. And I was just lecturing with a colleague from France who had done implants for patients with inflammatory bowel disease in France, showing improvement in substantive improvement in his patients with Crohn's disease.

So really understanding what he was saying was that there's profound inflammation there. How do we turn that off? And what his hypothesis that use the vagus nerve, there are people working on children's disease and fatigue.

There are people. And I'm thinking about the visceral structures. There's work that's going to be rolling out towards the end of this year on diabetes.

And can we alter the amount of, the hemoglobin A1, C and the diabetic neuropathy with vagus nerve stimulation? So I'm not saying all of this is ready for prime time.

What I'm saying is there's a lot of seeds that have been planted and watching these flowers pop up through the ground here, and there's a really interesting on what's going to come.

Well, we have some areas that we're clear about, like the headache stuff that I mentioned. It's pretty clear that this is one of the most effective therapies that we have.

But what's most intriguing to me is treatment of post-traumatic stress disorder, Parkinson's disease, maybe. And again, down the road, Alzheimer's disease, because that's a neurodegenerative disorder, kind of like Parkinson's is thought to be have inflammation involved.

And we can dampen inflammation in patients. So maybe and so there's so many areas that I'm so excited about. We actually started a whole new society a month or two ago called the Vagus Nerve Society.

The society morgue and it's mostly for clinicians right now, but eventually we're going to have a consumer arm that patients will be able to go to and get credible information about what's going on.

But right now, it's for clinicians, psychologists, physicians, scientists, chiropractors who are interested in this area. Interestingly, chiropractors are very interested in this, but but, there's going to be a blossoming area of information around this area.

So one of the in medicine, my experience of medicine is that a lot of the, neuromodulation that has been done until recently until electric or produced its equipment, was invasive.

Yeah. Like you call DBS deep brain stimulation for Parkinson's. You have to do surgery into the brain to implant electrodes or in fact, your, your electrodes for deep, deep, stimulation for pain, chronic pain.

That's invasive as well. That's right. But what you're talking about, what electrical core is, is noninvasive. That's right, that's right. So so we were able to access the vagus nerve without having to actually invade the body.

That's right. You know, and I think that's a really, you know, critical point, in making the use of electricity so much more broadly available when we have a device that costs 40 or $50,000, it can be very, very expensive.

You relegate the number of people from a large funnel to a very small funnel of people who can either afford it, or the insurances will let you get through the system, or the risks are appropriate to take in order to implant one of these devices.

Inflammation, COVID, and Airway Reactivity

And it's, you know, you may start with a million patients and you get down to 100 patients who would potentially actually get the device because of the risks and the costs and, all of those different aspects.

But when you start to develop devices that work as well as an implanted device, with non-invasively, we start to open this up to think of it like a drug can think of it as a digital drug, for example, that a patient could use a device that they placed on their neck and treat instead of taking a pill.

So the barrier to entry for a patient becomes much lower. And, I would also say that, if it doesn't work and these medical devices don't always work, the patient's lost very little as opposed to with an implanted device.

When they don't work, they've gone through surgery. They've taken the risk of surgery. There's a big expense with a noninvasive approach. The the downside is much, much less.

And I think it's going to transform how we think about health care more broadly. So we, where some people are now calling, devices like this electro ceuticals.

I know, and I know the pharmaceutical industry is looking closely at this area as well. Right. Yeah. That's an interesting terminology. I've, I've not used them mostly because I think some of these actually patents in that term, but I think that's but I think it's a nice way of describing what we're trying to do.

It's, you know, tapping into the power of electricity to modify disease. Well, electric car is the company. What is the electrical device called? So there are a number of different devices that are out there.

But electrical makes what's called the gamma core sapphire device. Gamma core. Gamma core. Yeah. Corey. Yep. Yep. Gamma core Sapphire. And the device requires a little bit of conducting gel to place on these two little contacts.

And then the patient applies it to themselves by placing it over the vagus nerve. Now I did this pretty seamlessly because I know where my vagus nerve is, not only because I'm a doctor, but because I've stimulated myself many, many times over the years.

But basically, you feel the carotid artery and everybody that's the pulse that you feel in your neck. And the vagus nerve runs in what's called the carotid.

So it runs right with that vagus with that carotid artery. And you feel that pulse, you know where your vagus nerve runs. We place the device right under the jaw along the course of the vagus nerve, and we turn up the device until you start to feel the lip pull a little bit.

And that's how we know that we're stimulating the vagus nerve. We've done all kinds of studies out there on functional MRI and what's called Meg work and EEG work and all kinds of work to demonstrate that we are activating the vagus nerve with this device, that certain, protocols that we use up and down, up and down.

That's right. Now, this is very close to the carotid body. That's right. So what happens with the relation to the vagus

nerve over the carotid body? So I actually the the the number one, number one question that I get is are you going to slow my heart rate.

Are you going to cause bradycardia with this. And interestingly you know, a couple of the scientists that worked on this, Jarocho and Bruce Simon and they spent a lot of time thinking about the frequency and how we're actually activating the vagus nerve, the amplitude. And, the, the various, parameters, the pulse width, the frequency and the amplitude, and came up with a frequency that does not cause bradycardia rate of cardiac requires activation of the si fibers.

And we don't activate the Si fibers with this device. At the current amplitude that we're at, we'd have to go above ten fold above where we can go with this device to activate the fibers that cause bradycardia.

And we just haven't seen that yet in, you know, 25, 30,000 patients ten fold in amplitude, which means ten fold in intensity. And at ten fold intensity, you're going to feel prickling or pain.

Now, we can't go that high with this. We just can't get there. You just can't get there because device has been created for safety, and it doesn't look like if you stimulate even harder, it's going to do more.

What it looks like is once you've activated the vagus nerve and you've activated the vagus nerve, it's like a light switch. And how long does that activation go on for?

So this device, when you turn it on we'll go for two minutes. Right. For two minutes. The protocol recommendation is that you repeat that at least one time.

And that that can help. And there are different protocols for cluster headache and migraine headache for acute treatment and prevention. But those it's a very rough, rough number that the doctors will have to go through with you.

It is a prescription device today that's and you know, at some point we will likely go to the FDA and request that it not be. But right now, it's still a prescription device.

All right. So speaking of the fact that it's a prescription device, let's say if people are going to pay for it on their own, what would be the cost? Well, they can't really do that.

Just pay for it on their own. But I need a prescription. But if they paid on their own, say drugs doesn't cover it, then yeah. So the whack price is the whack price for a three year device, for a device that will last at least three years is about $7,500.

But it's also sold, you know, with some discounts below that. And it can be sold in three month blocks. A one year block can be sold in different ways.

So I would just encourage everybody to go to the kemper.com website and, or speak with their doctor because we can get the device at, a much lower price point for people.

Now, as you we discussed early on, doctors are often their their primary care doctors are often very closed minded and would rather write a prescription for, medication for them and, a GameMaker.

Yeah. Can people go to GameMaker? Or electric com and get assistance with getting a prescription? Yeah, sure. So there's there's a, physician finder on the website.

If you go to get GameMaker, dot com there, there's actually, a physician site where you can see a physician, but many chiropractors, chiropractors can prescribe this as well as physicians.

And so I would just encourage people to speak with their doctor. I actually think we're hitting that inflection point where people don't want to just give people more drugs for pain.

I think we've seen what happened with the opioid crisis and the number of people, you know, over 100,000 deaths last year due to opioids.

Noninvasive GammaCore Therapy and How It Works

I think particularly in the pain era, doctors are much more embracing the non non, narcotic non-drug strategies that have been demonstrated that the highest level of science to be effective.

So I also encourage people to speak with their doctor. But come to the website if there's, difficulty in getting access, it will help direct you to, a physician so that they can decide what with you, if it's an appropriate therapy.

And, can people download a brochure about the device that they can take to their doctor? There's actually quite a bit of medical information on the electric Broadcom website.

So brochures, as well as, scientific studies and patient information is all there. So let's talk about the people who pay for these things besides the individual.

So right now, I assume Medicare covers it. Medicaid covers it. Well, Medicare, Medicare and Medicaid are not covering it yet, and we're still discussing with them and hope to get there relatively soon.

The group that is covering it right now is the Department of Defense Veterans Affairs. And they are they are currently covering we also have, over 10 million lives in that are private insurances that are covering it.

Problem is, it's hard to know exactly which which of those different, insurers are because they're so disjointed. But many some insurers are covering it and we're it's a continued work in progress.

I think one of the issues that we were talking about earlier is even though we've been we've demonstrated that we can lower overall health care costs a lot in the United States of of insurance companies look at the pharmaceutical benefit or for the medical device benefit.

Are we lowering the cost in that category? Right. Not so much. Are we lowering admissions to the hospital or are we lowering other health care utilization, as we've shown in other studies?

In the UK there is what's called Nice or the National Center for Clinical Excellence. They're covering it for for cluster patients because they've found that it's not only effective but it's cost dominant, meaning that if a patient uses the device, they lower their overall health care costs.

So they've embraced it. They're covering it. If you're a united UK citizen, then you can get coverage there. And then as as the UK has been covering it now for a few years, the rest of Europe is slowly starting to embrace it as well.

Fantastic. All right, well, you have to check with your insurance company. Probably go to your insurance company's website, and if they were going to do a search on the insurance company website, would they look up Gamma Corps or would they look look up, neuromodulation or neurostimulation?

What do you think that have to be very specific to Gamma Corp, because a lot of their insurers, you know, some of them are saying, okay, we'll cover it for Covid, others are saying we'll cover it for cluster headache, and then others are more broad.

You know, it's at the discretion of the physician. All right. So and that one term is going to suffice. Ideally you go to gamma core. Yeah. Right after that you may have to broaden it out and look at the, coverage manual for the insurance company.

And I would suggest that also that, you know, particularly in the on label indications where it which I've done over when we speak with physicians and, with the insurance companies and explain things to them and explain what the patients are going through and what the wealth of things that they've tried and the expense that they're going to go

through if they don't approve this as a trial.

We sometimes have, patients, get approval for the care that they need. Not always, I'm a physician as well. And it is, I'm sometimes struck by how difficult that is and as opposed to how it should be.

But there are also good people there who are willing to look at the data, look at the options, individualize the care for that patient in front of them, and willing to give them a shot at it.

So where can your listeners go to get more information? We talked about electric Law.com Net-A-Porter.com. And I would also say if you if you're, you know, wearing my other hat as a, as a clinician scientists the vagus nerve society vn society.org has non-branded generic information about what the vagus nerve does and some of the evolving indications and keep checking on it.

We just got that website up. Keep checking on it. It's evolving and there will be more and more information there. But those would be the two main areas I go to look at it and gamma 4.com, as well as out there as well.

Fantastic. So, I it's probably not much more. I could say that we want to try to integrate PMF therapy. I think PMF therapy and electrical stim of the kind that we're talking about, go hand in hand, even if we talk about tens, you know, there's value to tens, there's value to acupuncture.

But I think all of these technologies, basically are synergistic in the way they work. And one of the benefits of PMF therapy is it penetrates the body completely.

Yeah. It goes all the way through the body, and it does neurostimulation as well. And they're using high intensity PDFs to do just that kind of work as well.

Yeah, sure. But one of the key benefits of PMA therapies is stimulate stem cells. I want to ask you, does neuromodulation stimulate stem cells? That's a great question.

I don't know the answer to that. I'm going to have to do a little homework on VNS and stem cells. I suspect we will get to an answer that we can activate stem cells with electricity, and we're probably going to need to be doing that.

But that's not where we're at right now in our field, particularly around vagus nerve at this point, because BMF therapy has been actually found to stimulate stem cells by about 65%.

That's an amazing that's an amazing number. And so many diseases would benefit from that. Combining things again one plus one doesn't equal to it could equal 31,000.

Right? I completely agree with that. Yeah. Well Doctor Stotts thank you so much for inviting us educating us about the vagus nerve. And it was a bit more of a, an interesting question for me about what that is and does, because there are a lot of people who are taught about vagal stimulation and all that.

Access, Insurance Coverage, and Where to Learn More

I actually I do want to conclude with you, what are some of the other sort of fairly significant, fairly effective ways of doing vagal stimulation? Sure.

So I think there are, of different strategies of activating the vagus nerve. Maybe the most simplistic would be meditation and I that's, that's that sounds pejorative. I don't mean that way at all.

I'd say if you are a Tibetan monk, you are really good at stimulating the vagus nerve with your meditation. For many of us mere mortals, that's a little bit more of a challenge.

But but truly, the mind over matter is real. And that's what that is. I would say behavioral approaches can be helpful, and people have talked about biofeedback, but, we can we can stimulate the vagus nerve with

biofeedback.

There are implant devices and implanted device on the cervical spine. There's a device that's, used on the this little branch of the ear that we talked about for, for opioid use disorder.

And my good friend Steve Porges, who is a, world renowned psychologist, talks about using phonation at certain frequencies to stimulate the vagus nerve.

I'm much less of an expert on that, but I recognize that there's lots of ways to stimulate the vagus nerve called cold water on the face. It's got a lot of attention in the media, like, gag.

Yeah, yeah. So I think there are different ways that one can do this. I just think that this is one of the most elegant ways of doing it. And that gets to most of the fibers in the vagus and reliable, reliable and consistent.

That's right. Actually, I do have one more thing I should probably share with you, because this may stimulate you as well to move in a different direction.

And recognition of the vagus nerve in the gut and the belly. Yeah. I have been having some sleep issues myself, and I use a number of strategies to work with sleep, and I recently I acquired a PDF system that has is a pad, and I put it on the bed and I put it over my belly and I sleep all night long.

And I found that augments the other strategies that I've been doing. And I'm assuming I don't have proof, but I'm assuming that one of the things that it's doing is it's stimulating all the parasympathetic neurons in my belly because I'm not being awakened by it.

So it must be the opposite. And when I don't use it, I find that I don't sleep quite as well. When I do, I sleep better for sure. Well, I think there have been a number of studies out there, not with our device, but other studies on vagal nerve stimulation with improvement in sleep.

And if you think about the gut, there are profound. I used the word earlier authorizations or little branches that go off the vagus nerve into the gut in various places.

So I think it's, certainly possible that you're activating the vagus nerve with a device that sends electrical signals through the body, and it's activating some of these small fibers there.

And it fits into my framework of how I think about how the vagus nerve can potentially help with diseases such as sleep disorder. But you'll have to look into how your device can actually be used over the belly.

Yeah, I know specific areas over the abdomen that could actually also again augment because, you know, off label use, right? You may have it for one use, but they can you use it for other purposes as well.

Well I mean I think that's true for me. This is like getting the the main branch of the trunk of the vagus nerve. You probably I'm going to now, this is this is completely off.

But it would be an interesting question of whether or not you would get similar effect if you were to place it on a different branch of the vagus nerve, not just the ones in your stomach, because the the branches do go down to the gut.

Now that's so far off. I don't even know about that, but it I'm answering it. I'm asking an intellectual question as we go through this about which branches you do need, this thing that we get all of them here.

And that's what is, I think one of the real benefits of an approach like this, and the side effects are really minimal. Well, we may be we, we work on lowering weight.

Maybe we maybe we, improve your blood pressure. Maybe we take away your headaches or your anxiety. I, you

know, those are not FDA approved indications, but those are things that the that the vagus nerve does.

So it's a it's maybe maybe that's another study. That's right. Stimulating the vagus nerve in the neck for sleep. That's right. That's exactly right. Well, again thank you doctor.

That's illuminating discussion. I think our paths will cross again. And it's very metabolic. And it's been a very stimulating discussion.