- I'm Dr. Tej Singh, I'm a vascular surgeon, a vascular access surgeon. I practice out of El Camino Hospital in Mountain View, California, which is in the heart of Silicon Valley. I'm also the CEO and founder of a novel medical device startup company based in Silicon Valley, and in Las Vegas, Nevada, called Fist Assist Devices.

The Fist Assist Device

So, the Fist Assist Device is the world's first pneumatic wearable to help increase vein size, to help increase vein measurements, vein dilation. It can help with fistula maturation. It can help in many different clinical scenarios like helping with blood draw, helping with infusion treatment. But the focus today is using Fist Assist for many indications. Regulatory-wise, internationally, the Fist Assist Device can be worn on the arm to help dilate arm veins, to help mature arteriovenous fistulas. In America, today, it only has 510 clearance by the FDA for arm vein massage and increased vein circulation.

Study Design and Patient Cohort

So, we just announced yesterday in the Journal of Vascular Access, and we will be announcing it tomorrow at the podium at the VEITH symposium here in Orlando, Florida, the FACT trial. The FACT trial was the first trial. It was an observational, prospective trial, three centres across the world. One at the university of Chicago, one in Greenwood, Mississippi, and one in Bangalore, India, and the trial enrolled over fifty patients and basically applied the Fist Assist Device as a pneumatic compression device on the non-dominant arm of patients with stage four kidney disease. Our hope was to see if, by wearing the Fist Assist Device, the patients would get pre-surgical vein dilation. And the FACT trial was very positive that we demonstrated vein dilation in the forearm and in the upper arm that was statistically significant, which would then allow for better arteriovenous fistula placement and the potential of better AV fistula maturation in long-term studies.

Key Findings

The key findings were that the device is safe, the device was very easily tolerated by patients, and for the first time in the global renal community, we have a device that can be worn at home, that can be worn for patients, which is a low-risk, non-significant risk device that can help dilate or enlarge your veins, arm veins, prior to arteriovenous fistula creation. And we think that this finding of dilation of anywhere from 0.6 millimetres at the wrist level to 0.6 millimetres at the perforator vein level below the elbow, and up to almost one millimetre in the upper arm will help ensure better AV fistula placement, better surgical outcomes, better overall care with less catheters and less arteriovenous grafts, and overall, to healthcare, the decrease in costs and complications in a subset of patients with renal disease, who very much struggle. We think we have a device, which will be the first time in the world's history, we have a device that can probably help dilate and enlarge veins significantly enough to help dialysis success. And that's very exciting for us.

Impact on Practice

So, traditionally, a patient, when they enter stage three or stage four kidney disease, the nephrologist is doing their best to control the kidney deterioration. Eventually, in many patients, they will require dialysis. And at that time they will be referred to either a surgeon or a vascular access specialist to help place an arteriovenous fistula or an AV graft or some type of access point. As we go more and more to home hemodialysis, we're going to need to have arm access that's going to be durable, that's going to be minimal complications, and it's going to have long-term benefits. And that's the arteriovenous fistula. But, we've never given patients a way to prepare themselves for that arteriovenous fistula, There's a physical preparation, there's a mental preparation. We think the Fist Assist Device will be the first device that patients will purchase when they enter stage four kidney failure, which may help them prepare their veins, get them ready for dialysis, and thus, we are now changing the paradigm of care where patients are stepping up, helping dilate their veins, with a novel device like the Fist Assist, in preparation for AV fistula or eventual hemodialysis. This is a game changer and, in many ways, a breakthrough way in taking care of these patients.

Further Research

So, we're very excited about announcing the FACT trial and what we know, internationally, is that the device is being used on arteriovenous fistulas, and being used to help with cannulation of fistula. We call it the Protocol of RDMC, renal dilation, maturation, and cannulation. I think in America, in the coming year, we will have more trials with this device for maturation and for cannulation. We've called the Fist Assist Device the one-stop device. It can dilate your veins, it can hopefully maturate, or mature, your AV fistula with maturation, and it can lead to cannulation. We're doing that in the rest of the world with the device, and we look forward to having that in America with trials that are proving those points. And I think that's going to be a very important future role for this device in the renal community.