- My name is Peter Schneider. I'm a vascular surgeon at the University of California, San Francisco. I've had a long-term interest in vascular education and also techniques for revascularization.

CAGENT’s Technologies

One of the key methods that we have of revascularization throughout the body is balloon angioplasty. So balloon angioplasty has been around and has been useful in most of our procedures for many decades. And the technology that has been developed by a company called CAGENT is technology that is intended to improve the results of balloon angioplasty or improve what we can get out of balloon inflation in peripheral arterial disease. I should say that CAGENT it's a company with which I have an affiliation, and that I have been a contributor over time in helping that company to develop its ideas and concepts. The idea that comes up from CAGENT is called serration angioplasty. So serration meaning an interrupted type of scoring or an interrupted type of manufactured defect along a particular line, so that at the time that expansion of the artery occurs, it can take a form of a cut along the dotted line or following the dot-to-dot type of release. And so these types of relief planes are present in almost every manufactured device. So for example, if you open up a FedEx package or a UPS package, or you tear a check out of a chequebook, or a piece of paper off of a pad, there is a line of serrations so that a cut can be made relatively cleanly, and so that the person's energies can be directed along a specific line in order to have a good result at the end. And this is the concept that the serranator capitalises on in the creation of serration angioplasty. The interesting thing about this is that there have been previous efforts at focal force balloons, which are well known, and these have been met with some success because it does allow for the improvement of the amount of force that can be exerted by up to 20 atmospheres of pressure. However, when you look at serration angioplasty, it's actually a relatively sharp tip that then can incise the vessel wall in a very punctuate location. So that it is a, what we call point force technology, which has the potential then to increase the force, not 20 times, but up to a thousand times higher than what you would get with a standard balloon expansion alone. The other thing about serration angioplasty that really makes sense to me is that atherosclerotic plaque is quite a heterogeneous substance. It's a very complex process with lots of different contents. And in that complex process, it doesn't make sense to put an equal amount of force or an equal amount of energy in all directions. That's not how we deal with complex problems in life. We typically look for the weak point or we create a weak point so that our energies can be directed. And this is exactly what serration angioplasty does. And it provides for us then the potential that, for the first time in decades, that angioplasty could be performed in a much more reliable manner with less residual stenosis and better lumen gain and less chance of the potential of recoil, particularly in the tibial arteries, the below the knee arteries, where worldwide angioplasty alone is probably the most common definitive finished treatment for below the knee arteries. And in those arteries, we have to deal with the potential that any residual stenosis in a two or three or three and a half millimetre artery could be significant. Any recoil in a two or three or three and a half millimetre artery could be significant. So the potential then for seriation angioplasty to interrupt some of these processes that we've become used to with plain balloon angioplasty is substantial. The other thing about plain balloon angioplasty, although it's part of almost every procedure we do in the vasculature in the lower extremities worldwide, we really rely upon this as a finished treatment or final treatment. And so the potential then to improve the lumen gain is quite good. But think about the poor results of lower extremity angioplasty that we've become used to, a 50% patency for SFA POP at one year would be quite acceptable, 30 to 40% patency for a long segment below the knee angioplasty at one year would be quite acceptable. And these really we've gotten used to it, but these are poor results. And anything that we can do to improve on these, I think would be significant. And this is really where CAGENT is going with serration angioplasty.

Data Supporting the Use of these Technologies

Yeah so, serration angioplasty has been evaluated in the prelude study, which includes patients with lesions of the superficial femoral popliteal arteries. And also more recently at the VEITH meeting in Orlando, November, 2021, the prelude BTK study was presented by Andrew Holden demonstrating a significant improvement in the lumen upfront, as well as a very low rate of clinically driven target lesion revascularization at six months after tibial angioplasty.

Treatment Areas

Well, with regards to serration angioplasty, the primary usage of it so far clinically has been in the superficial femoral and popliteal and tibial arteries. Other areas that could potentially benefit include some of the potential for use in arteriovenous fistula, or arteriovenous grafts that have been constructed for dialysis. There's a potential that serration angioplasty could have an impact in calcified iliac arteries. Also a potential to do pre-stenting angioplasty in other vascular beds, such as the renal arteries, for example, where full stent expansion is essential to best long-term function. Lastly, I'll just say that although serration angioplasty is not approved for the coronary arteries and it's not currently being studied there, the potential of an expansion to that area could also be significant in that many patients with coronary lesions either cannot undergo stent placement because of the location or the small size of the artery. Or in preparation for a stent placement, full stent expansion is required, despite the fact that it may be a calcified lesion that's being treated.

Next Steps

Well, I think currently data is being gathered in the lower extremity. The potential for so-called complete lower extremity solution is definitely there where we need more information about serration angioplasty in the arteriovenous fistulas and arteriovenous grafts as I mentioned, they've been used in these locations with promising early results. And the potential in the superficial femoral and popliteal arteries to use serration angioplasty as a vessel preparation for DCB, for drug eluting stents, and also even for bare metal stents is substantial. And the potential for serration angioplasty to be a finished treatment or a kind of treatment of choice for the below the knee arteries is also currently being evaluated.