

Title: DEEPER LIMUS: Temporary Spur Stent System Using a LIMUS-Base DCB

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Dr Marianne Brodmann

"My name is Marianne Brodmann. I'm head of the Division of Angiology at the Medical University Graz, Austria.

Unmet Needs in BTK Disease

What are the unmet needs in BTK disease? For sure, especially below the knee? We still do not have a final conclusion what kind of treatment strategy we should use. There are a lot of devices under evaluation, a lot of treatment strategies under evaluation. We do not have for sure drug eluting devices, which are really working below the knee, especially all the DCBs, below the knee we use scaffolds, but we do not want to use bare metal scaffolds. We have an issue with drug eluting permanent drug-eluting scaffolds. Some trials have not been positive. So I think with regard to all this, there is a lot of things to do in the near future, in the long future, especially the vessel prep is very essential below the knee. And so there's also a focus on new tools to do vessel prep in a better way and therefore to enhance the drug uptake. If we have a finally working drug eluting technology for below the knee.

The Spur Stent System

What are the key features of this spur stent system? The spur stent system is a very unique vessel preparation technique. It is a self-expandable stent system, which is retractable. So this is something like leaving nothing permanent behind. Something like following this strategy. But it's not used right now as a stent-based system. It's used for vessel prep. So dispersed in system, as I already have explained, is a self-expandable stent system with spikes that penetrate into the vessel wall. And you can retract this stent system afterwards after some minutes. It depends how long you want to have it inflated and this should enhance the drug uptake.

Study Design and Patient Population

What was the study design and patient population of this trial? Of this trial I present here at CIRSE, it was using this spur stent system followed by a drug-eluting balloon, which was a limus based balloon, the Magic Touch balloon for somewhat 26 patient cohort at one site. This was our centre just to see if the spur stent system is successful in doing vessel prep enhance the drug uptake of a limus-coated balloon. So this was the design of this trial, but the spur stent system also has been evaluated in a non-drug based investigator initial trial in the United States and then in the United States and Europe. The second trial, which has already been conducted, more than 100 patients was dispersed in system, plus a paclitaxel-coated device.

Key Findings

What are the key findings I want to present here at CIRSE? First, we were able to do an adequate vessel preparation to reduce late lumen loss. Conducting this kind of vessel preparation followed by limus-coated DCB. We are showing that we were really successful in also avoiding this acute recoil issue, especially for below-the-knee arteries with this kind of vessel prep system. So we are really showing good results in the acute phase, but also in the long-term phase with good long-term outcome like wound healing, prevention of restenosis. But these were the key findings.

Take-Home Messages

What are my take-home messages? My profound and most sincere take-home message is that we need to do adequate vessel preparation. And something like this burst and system will for sure help us by doing this or with doing this, especially if this spur stent system is followed by drug-eluting technology. And with all the patients we oversee, like right now, which have been treated with this burst and system, we were able to show that this kind of vessel prep is enhancing drug uptake. And I think that's the most important take-home message.

Further Research Needed

What further studies are needed in the area and what are the further steps with regard to spur stent system itself? There might be drug on spur stent system. So as a drug based self-expandable, not permanent, but for some time inflated technology, this is for spur stent system itself. And in general we need to do more trials below the knee, finding the right limit or the right time limit for vessel preparation, the right tool for vessel preparation, the right tool for what kind of DCB we should use and what kind of cathodes we can leave there. If there is still a mechanical issue, after all the best vessel prep we might have done so, bioresorbable scaffolds. So these are the further steps which should be done in general for below the knee artery disease treatment.”