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Interview – Xeltis brings bioabsorbable tech to heart valves

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Catheter-mounted prosthetic heart valves are now generally acknowledged to have replaced surgical valves as the standard of care. But there is always a new innovation around the corner. Swiss-Dutch group Xeltis today released early data on a bioabsorbable implant that could allow the patients to re-grow a functioning valve from their own tissue.

“Our heart valves have a porous structure made of polymers and through a process called endogenous tissue restoration the patient’s tissue pervades our implant, forming a new natural functioning heart valve,” says Xeltis’s chief executive, Laurent Grandidier. This could free patients from the repeated implantations often necessary with today’s technology.

Xeltis’s valves are made from extremely thin polymer threads which can be tuned, Mr Grandidier says, to customise the bioabsorbability profile and mechanical characteristics. The idea is that, as with dissolving stitches or stents, the polymers break down over time and the valve is absorbed by the body, leaving behind the tissue that has grown into the structure – essentially the patient has re-grown a healthy valve.

As well as allowing a permanent fix – current valve prostheses last upwards of 15 years, but when younger patients are treated this can necessitate revision surgeries – this also avoids an immune response.

“Heart valves today are made of animal tissue for the most part,” says Mr Grandidier. “When they remain in the body you have an ongoing chronic inflammatory process – the body reacts to the presence of foreign material. Our concept means there will be no foreign material for the body to react against, because it is bioabsorbed and replaced.”

Human trials

The group is working on two valves, one to fit the aortic position and one the pulmonary valve. Data presented today at the EuroPCR meeting in Paris showed that Xeltis’s aortic valve had good haemodynamic performance, and fully functional valves were seen in a sheep model of vascular calcification six months after implantation.

Mr Grandidier says the data are comparable with preclinical results seen with “some of the best in class valves that are on the market today”.

The aortic product is not Xeltis’s most advanced. The pulmonary valve is in an early human trial in Europe and Asia, Xplore-I, with 12 patients having received the implant and follow-up ongoing. The primary endpoint is survival at six months, and Mr Grandidier says the data will probably be presented at the EACTS meeting in Vienna in October.

The next step towards CE marking for this pulmonary valve will be a year-long study, probably in a larger group of patients. Endpoints will be similar to what the current generations of prosthetic valves had to prove to get on the market – safety and haemodynamic performance. In other words, they will have to avoid valvular regurgitation and stenosis – the reduction in diameter due to tissue build-up.

In the meantime Xeltis will kick off Xplore-II, a second feasibility study of the pulmonary valve, this time in the US. It plans to start recruitment of 10 patients in the coming months.

Separately, the FDA has granted a humanitarian use device designation for the pulmonary heart valve, allowing a clinical trial to proceed for the correction or reconstruction of right ventricular outflow tract in children.

So far, the two valves are implanted via different procedures.

“Pulmonary valve replacement is always required in congenital cases – birth defects that need to be repaired,” he says. “Usually these malformations don’t come alone, so when the surgeons repair the pulmonary valve they usually need to repair other things that are malformed in the heart. It’s open chest surgery.” Xeltis’s pulmonary valve is implanted during this procedure.

All the preclinical work for the aortic product has been transcatheter. “However, for the first commercial product, we haven’t yet made public whether it’s going to be a surgical or a transcatheter valve,” says Mr Grandidier.

“There are some strategic considerations – do we want to develop, from scratch, a new transcatheter delivery device or do we want to do that in a collaboration with someone else, for example? These considerations will play a role in the final decision.”

Strategic appetite

Plans like these demand money, and Xeltis is “actively working on” a venture round at the moment. The company has raised $37m in VC financing to date, according to *EvaluateMedTech*.

As for the long-term plan, Mr Grandidier is certainly alive to the prospect of a takeover.

“The fact that we have a technology platform allows for using these materials or concepts on a variety of products, so for a company that already has a portfolio of different types of valves it’s an attractive proposition to roll out our platform onto their existing device designs,” he says.

The timing of a possible trade sale depends on many things, Mr Grandidier says – “the data we are generating right now, the strategic appetite of the different players, maybe market conditions will play a role”.

The start-ups at the forefront of the transcatheter aortic valve revolution have almost all been snapped up, from Medtronic’s purchase of CoreValve in 2009 to Boston’s of Symetis in March (*Boston buys Symetis and accelerates in aortic – but ditches mitral, March 30, 2017*). It is not hard to imagine one of these groups seeing the potential in Xeltis’s technology. But they will doubtless wait for human data before making a decision.

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