

AN INTERVIEW WITH...

Stephen J.D. Brecker, MD

Dr. Brecker discusses how his idea for a TAVI-specific guidewire became a reality, his work with patient-specific computer simulation of TAVI, advice to prevent prosthesis-patient mismatch, and more.



How did the idea for the BreckerWire come about? What was involved in bringing the idea to reality, and what advice would you give other operators who have ideas for new device improvements or innovations?

Very early on in the clinical experience with transcatheter aortic valve implantation (TAVI), ventricular perforation was a well-recognized, serious complication. This was because the stiff wires were being used “off the shelf” and were not designed for use in the left ventricle. Those wires had a core that ended some distance from the tip, and the distal segment was simply a coil. The wire could be inadvertently manipulated into a sharp configuration at the point where the core terminated.

I think it was our second case where, despite normal precautions, we caused a pericardial effusion due to wire perforation. When I visited other centers, I noticed that wire perforation occurred very consistently during the learning curve. I have always applied aviation safety principles to improve patient safety, and it occurred to me that this was a system error and not related to operator error specifically. For this reason, I believed there was a need for a new wire design specifically for TAVI. My idea coincided with a technology transfer facility within the United Kingdom National Health Service (NHS), which was looking for ideas. I put my idea in a one-paragraph email and was fairly rapidly visited by two individuals from NHS Innovations London who believed the idea could be commercially successful.

We first had to finalize a design, which I undertook; then, working with a patent attorney, a patent application was filed in Europe and the United States (both patents were subsequently granted, albeit some years later). We sourced a wire manufacture company and, after a few design cycles, came up with a product design that we thought met the need. We undertook a first-in-human clinical trial at St George’s, which was successful, and the device was then acquired from the hospital by Medtronic. It is now known as the Confida guidewire and is very widely used during TAVI procedures and other interventional procedures, including transcatheter mitral valve intervention.

The advice I would give other operators is to believe the idea you have is worthwhile and persevere even in the face of obstacles. It is essential to have someone guide you through the process because most doctors do not have this expertise in their skill set.

As Director of the Cardiology Clinical Academic Group (CAG) at St George’s, University of London, can you share some of your current research and priorities for improving care?

My role as Director of the Cardiology CAG is to oversee all of the cardiovascular research we carry out within the organization. Since becoming a CAG, we have been highly successful in increasing our recruitment to clinical trials and obtaining grants. Our major themes at St George’s are inherited cardiac conditions, sports cardiology, heart muscle disease, and, in particular, inherited arrhythmias/sudden death. We have a comprehensive program, from genotype and phenotype to pathology. However, my personal research focuses on improving the outcomes of TAVI, and my personal priorities are to improve patient selection, particularly in low-risk patients.

Can you summarize the results that you have seen with the novel use of patient-specific computer simulation of TAVI in bicuspid aortic valves? How large of a role do you foresee this technology having in improving TAVI outcomes in the coming years?

We have been using patient-specific computer simulation in patients with bicuspid aortic valves for the last couple of years. We chose this patient subset because they tend to be younger, lower-risk patients and have been excluded from almost all clinical trials assessing TAVI. As TAVI moves into lower-risk subsets that will generally be younger, the incidence of bicuspid valve aortic stenosis will increase, and the outcomes of TAVI in this patient subset are less certain. The anatomy is variable, and there is currently no consensus on how to appropriately size bicuspid valve anatomy for transcatheter aortic valve implants. We have undertaken both a retrospective and a prospective study demonstrating

the value and indicating that in a significant minority of patients, the plan can change in terms of valve size and positioning. I think this will have a significant role in improving outcomes in the lower-risk subset of patients.

In early 2019, you coauthored a publication showing excellent long-term durability of transcatheter aortic valve prostheses.¹ Were you surprised by these findings in any way?

To be honest, I had a strong clinical impression of the excellent long-term durability of transcatheter valves, and I was not surprised to see this sense validated by the data. We really had very few cases of valve deterioration, despite implanting a large number of valves, starting 12 years ago. We certainly did not have any clinical “signal” that the durability would be poor based on the follow-up of our patients in clinic. However, it is clear that structural valve deterioration, which is well known in the surgical arena, is something we need to learn more about—with transcatheter valves and particularly latest-generation versions. I think we also should pay more attention to the possibility of prosthesis-patient mismatch (PPM) in the future. In the surgical valve arena, PPM has been shown to be associated with less favorable outcomes in terms of survival and structural valve deterioration. We need to be cognizant of this as we extend TAVI into younger, lower-risk patients.

How can operators avoid PPM during TAVI?

PPM is becoming much more widely discussed now that we are entering a mature phase of TAVI. Publications in the past 12 to 18 months have demonstrated that PPM is a very real possibility with TAVI,

particularly with smaller sizes of balloon-expandable valves. There are now sizing algorithms that take into account the patient’s body surface area and aortic annulus dimensions, and it is possible to predict whether or not PPM can be expected. This can allow selection of an appropriate size and type of transcatheter valve. Current data suggest that where PPM is likely, it may be appropriate to consider a supra-annular transcatheter valve.

If you were to write an autobiography, what would the title be and why?

I think I would entitle an autobiography: *Down to the Wire*. That invention was the combination of many strands of my career to that point. The motivation was a genuine commitment to patient safety, and I can map many incidents that culminated in the motivation to improve the procedure and increase safety. ■

1. Blackman DJ, Saraf S, MacCarthy PA, et al. Long-term durability of transcatheter aortic valve prostheses. *J Am Coll Cardiol*. 2019;73:537-545.

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