Saturday hosts the EACTS Techno-College Innovation Award

The 2017 recipients of the Award were selected during the ‘New techniques: the developers corner’ session on Saturday afternoon. Congratulations to this year’s winner, Roman Gottardi, and runners-up Jacques Sherman and Henrich Rotering. Read on to learn more about their Award-winning work.

A truly non-occlusive stent-graft moulding balloon for thoracic endovascular aortic repair (TEVAR)

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Thoracic endovascular aortic repair (TEVAR) has become the therapy of choice in various thoracic aortic pathologies. One major downside of these procedures is endoleaks, namely type 1 and type 3 endoleaks. In the majority of cases endoleaks can be prevented or treated by conforming the stent-graft to the aortic wall to prevent or treat a type 1 endoleak, or by conforming two stent-grafts to each other to prevent or treat a type 3 endoleak. This moulding is usually done using a fully-occlusive compliant balloon catheter to even out any pleats or folds in the fabric of the stent-graft. A drawback of such balloons is that they block blood flow and therefore require a means to lower cardiac output to prevent displacement of the balloon or even worse – migration of the stent-graft. As stent-grafts are increasingly used within the thoracic aorta, the aortic arch and even in the ascending aorta, moulding these stent-grafts without occlusion and the risk of displacement is needed more than ever. There is one commercially available balloon...
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Novel balloon design

The team that developed this novel, helical, fully non-occlusive TEVAR balloon catheter (Figure 1) is made up by two cardiac surgeons from the Permanente Medical University in SaltLake, two cardiac surgeons from the Universitätsklinikum Freiburg - Bad Krozingen, and an engineering team at Strahl Access Technologies (SAT). SAT is a South African company from Cape Town that primarily focuses on transcatheter valve therapies for rheumatic valve disease in developing countries. Based on SAT's non-occlusive balloons for valvoplasty and valve deployment, we adapted their balloon design for use in TEVAR. In contrast to SAT's non-compliant high pressure balloons, the TEVAR balloon catheter needed to be highly compliant, with a large diameter range such that it could be used with all commercially available thoracic stent-grafts. To meet these user requirements, the newly developed balloon catheter design consists of three highly compliant, beadless balloons that are helically wound to create a large central lumen when inflated. The beadless balloons are unique in that they utilise a circumferential lengthening effect that translates into a large outer balloon diameter, along with a large inner lumen, throughout a wide range of diameters. Moreover, this mechanism allows for a significant diametric growth of the balloon, while maintaining minimal longitudinal growth of the balloon itself. The balloon catheter has a working outer diameter ranging from 28 mm to 46 mm, which covers most of the commercially available sizes of thoracic stent-grafts. An inner diameter of at least 14 mm up to 27 mm allows for ample blood flow without a pressure drop distal to the inflated balloon. The balloon catheter comes with an integrated inflow introducer sheath which has an outer diameter of 21 Fr (6.3 mm) and prevents damage to the balloon during insertion and retrieval. In preclinical trials the balloon catheter has shown that it does not hinder blood flow during inflation, moulding and deflation in a pulsatile mock circulation loop. Also, no pulse-synchronous movement of the balloon – as seen with other fully occlusive balloons – could be observed during inflation and deflation. Therefore, lowering of cardiac output will not be required and the risk of displacement of the balloon or the implanted stent-graft will be mitigated. Additional beneficial features of the helical TEVAR balloon are: (1) due to its helical structure it requires less fluid to be injected which results in shorter inflation and deflation times; (2) the lack of occlusion makes it possible to mould the stent-graft for a longer time period, which could turn out to be beneficial in the prevention or the treatment of type 1 and type 3 leaks.

Conclusion and outlook

To our knowledge this is the first circular, fully non-occlusive balloon catheter designed for the prevention and treatment of type 1 and type 3 leaks after TEVAR. At this stage we have completed all preclinical tests with excellent results (Figure 2) and are currently preparing all documentation for clinical trials and CE mark application. We are looking forward to the first clinical application.

Transcatheter valve with hollow-balloon for rheumatic aortic incompetence

Jacques Scherman, Branden van Breukelen, Harish Appy, Carol van Heerden, Chima Ofegbule, Dean Buzaikindou and Peter Zillo

The challenge

Due to the past decade, TAVI has revolutionised our approach to heart valve disease. Whilst calcific aortic valve disease remains the dominant underlying pathology for patients in need of a heart valve replacement in the first world, rheumatic heart disease (RHD) still accounts for the majority of patients in need of a heart valve intervention in developing countries and emerging economies. Tragically, the majority of these patients have limited or no access to cardiac surgery. Moreover, given the unique differences between calcific degenerative and rheumatic pathologies, positioning and placement of a TAVI device for RHD require several considerations, which include the absence of a fluoroscopic footprint for placement and the absence of calcium deposits for anchorage.

A solution

Taking this into consideration, we have developed a non-occlusive, self-homing TAVI system which can be inserted even in the absence of sophisticated imaging equipment (Figure 1). Its unique design features include self-locating retrievable balloon canulae for easy positioning, a hollow balloon that obviates the need for rapid ventricular pacing – as cardiac output is maintained throughout deployment – and a temporary balloon valve that prevents backflow through the hollow balloon during inflation. This allows for a slow and controlled implementation of the TAVI.

A supra-aorticily anchoring TAVI stent design (Figure 2) secures the valve in non-calcified, compliant roots utilising the entire native leaflet body.
issue of valve durability in these typically younger 'rheumatic' patients is addressed by the use of special bioprosthetic polymer leaflets and an alternative by de-calcellinized, triple-cross-linked pericardium.

Following successful proof of concept studies in an acute large-animal model, a percutaneous chronic animal study has been commenced to evaluate valve performance and outcomes up to five-months following implantation. At this year's EACTS Techno College we present a Live-in-a-Box implantation in a juvenile sheep model to demonstrate the ease of implantation of this novel non-occlusive, self-locating TAVI system.

Mid-term experience

The in-vivo performance of the SAT polymer valve has been extremely promising, having already achieved more than 600 million cycles in fatigue testing. This is further supported by eight-week sheep explants demonstrating pristine polymer leaflets, with further chronic animal implants ongoing. Previous attempts to use polyurethane for heart valves were unsuccessful due to material degradation. Our accelerated in-vivo degradation studies show impressive resistance of the polyurethane used in the SAT TAVI (Figure 3a). Calcification studies comparing our bioprosthesis with conventional glutaraldehydehyd fixed pericardium show 43% lower calcium in our pericardial and total calcium in our polyurethane leaflets (Figure 3b).

Conclusion

Not only in the developing world, but also in emerging economies such as China and India, rheumatic heart disease still accounts for the major burden of disease in patients needing heart valve interventions. We have demonstrated that polymeric TAVIs are feasible as an appealing, cost-effective solution. Furthermore, we have demonstrated that compliant or non-calciﬁc aortic roots can be treated with TAVIs by using self-anchoring valve designs implanted with a non-occlusive self-locating delivery system. The timing of this event is particularly exciting for us. As we celebrate the 50th anniversary of the ﬁrst heart transplant in Cape Town in a few weeks time – with the who’s who in cardiac surgery attending – it gives us a major boost to our efforts to see that 50 years on, the University of Cape Town is still part of the cutting-edge developments in our fast moving ﬁeld.

References


Figure 3a. Mid-term experience showing superior degradation resistance of the leaflet polymer over conventional polyurethane.

Figure 3b. Mid-term experience