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Balloon-Expandable Prostheses for Transcatheter Aortic Valve Replacement

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ABSTRACT

The implantation of a transcatheter heart valve (THV) through a balloon-expandable system played a major role in the early stages of transcatheter aortic valve replacement (TAVR). The technology consists of sewing a foldable biological cardiac valve inside a metallic stent frame, and then crimping the device into a balloon in order to implant the valve at the level of the aortic annulus through balloon inflation. The use of balloon-expandable valves underwent a rapid expansion in the years following the pioneering experience of 2002, and recent large multicenter trials and registries have confirmed the safety and efficacy of TAVR using balloon-expandable valves. The randomized Placement of Aortic Transcatheter Valves (PARTNER) trial showed both the superiority and non-inferiority of TAVR with the balloon-expandable Edwards-Sapien system compared to medical treatment (non-operable patients) and surgical aortic valve replacement (high risk patients), respectively. Balloon-expandable valves have been associated with excellent hemodynamic results (residual mean gradient <15 mm Hg in most cases), though residual paravalvular aortic regurgitation is frequent (trivial or mild in the majority of patients, moderate or severe in <10%). Valve durability studies with up to 5-year follow-up have shown maintained valve hemodynamics over time with only a minimal decrease in valve area and no increase in aortic regurgitation. Future improvements in the balloon-expandable THV technology such as implementing anti-paravalvular leak features (ex. Sapien 3 valve), and showing its efficacy for the treatment of non-high risk patients (ongoing PARTNER II trial) will probably lead to broader use in a lower risk population in the near future.

The concept of a transcatheter heart valve (THV) was first tested *in vivo* in the early 90's, in a porcine model followed a decade later by the first percutaneous implantation of a prosthetic valve in a pulmonary conduit.[1,2] In 2002, the first implantation of a THV in the aortic position was performed by Cribier et al. for the treatment of severe symptomatic aortic stenosis (AS) in a patient considered inoperable.[3] All of these early experiences were performed with a balloon-expandable THV system, where a prosthetic tissue valve was conceived with a foldable biological cardiac valve sewn inside an expandable stent frame, with the device subsequently crimped into a balloon in order to deploy the THV through balloon

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Abbreviations and Acronyms

AR = aortic regurgitation

AS = aortic stenosis

CVE = cerebral vascular events

PARTNER = Placement of Aortic Transcatheter Valves

SAVR = surgical aortic valve replacement

TAVR = transcatheter aortic valve replacement

THV = transcatheter heart valve

VARC = Valve Academic Research Consortium

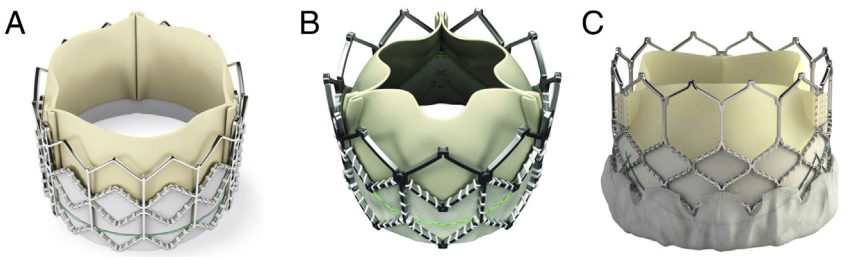
inflation. The balloon-expandable valve concept therefore played a major role from the very beginning of the THV experience.

The expansion of the THV technology was very rapid in the years following these remarkable pioneering experiences, and transcatheter aortic valve replacement (TAVR) has since become the standard of care for patients with severe symptomatic AS considered to be non-operable, and a well-established alternative for those at high surgical risk.[4] The objectives of this article were to review the main characteristics of the balloon-expandable THV systems used for TAVR, the mechanisms of implantation, and the short- and long-term outcomes, valve hemodynamics and durability associated with such systems.

Prosthetic valve system

The clinical experience with balloon-expandable THV commenced with the Cribier-Edwards balloon-expandable aortic stent valve (Edwards Lifesciences, Irvine, CA), which consisted of a trileaflet tissue valve of equine pericardium mounted in a stainless steel frame.[3,5] This was the first THV prototype implanted in humans and subsequent improvements in the valve and delivery systems resulted in the second generation of balloon-expandable THVs, the Edwards-Sapien THV (Edwards Lifesciences, Irvine, CA) (Figs 1 and 2).[3-5] This valve also consists of a tubular slotted stainless-steel stent frame, but it integrates a unidirectional trileaflet tissue valve made of bovine pericardium, which is pretreated to decrease valve calcification. Moreover, the fabric skirt, made of poly-ethylene terephthalate, extends further to improve sealing and potentially reduce paravalvular regurgitation. This valve is available in two sizes, with expanded external diameters of 23 and 26 mm, requiring 22 F and 24 F delivery catheters for transfemoral approach implantation, respectively (Figs 1 and 2).

The Sapien XT valve (Edwards Lifesciences, Irvine, CA) is the 3rd generation of balloon-expandable Edwards valves, which also consists of a trileaflet pericardial bovine valve, but unlike those of the previous generation, it is mounted in a cobalt chromium stent frame (Fig 1). The stent frame design of the Sapien XT valve has fewer rows, columns and vertical struts between commissure pots, which in addition to the scallop shape design of the leaflets, contributes to decreasing the profile of the valve. Also, the leaflets are in a partially closed configuration even when opened, which may reduce the likelihood of interaction between native and prosthetic leaflets.[6,7] The Sapien XT valve is available in 20-, 23-, 26- and 29-mm sizes, and is implanted through the transfemoral approach using the NovaFlex delivery system implanted through 16 F (20-, 23-mm valves), 18 F (26-mm valve) or 20 F (29-mm valve) expandable sheaths (e-sheath, Edwards Lifesciences, Irvine, CA) (Figs 1 and 2).



	Edwards-Sapien (26 mm)	Sapien XT (26 mm)	Sapien 3 (26 mm)
Prosthetic material	Stainless steel	Cobalt-Chromium	Cobalt-Chromium
Crimped profile	8.3 mm	8.0 mm	6.7 mm
Frame height (expanded)	16.1 mm	17.2 mm	20 mm
Frame height (crimped)	18.1 mm	20.6 mm	27 mm
Frame shortening (deployment)	2 mm	3.4 mm	7 mm

Fig 1 – Photographs of the balloon-expandable Sapien valves and their respective characteristics. (A) Edwards-Sapien, (B) Sapien XT, and (C) and Sapien 3 valves.