

Letters

TO THE EDITOR

Overexpansion of the SAPIEN 3 Transcatheter Heart Valve

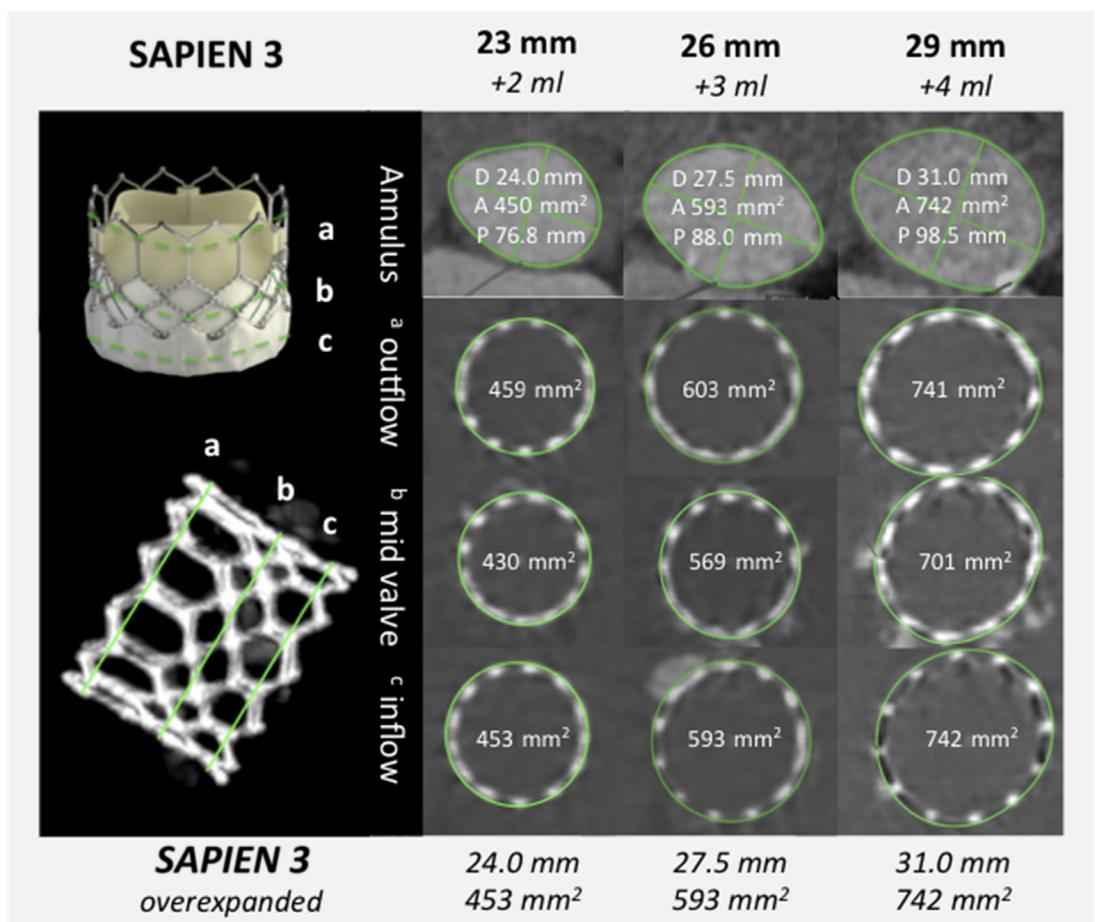
A Feasibility Study

The Edwards SAPIEN 3 (S3) (Edwards Lifesciences Inc., Irvine, California) is the latest iteration of the balloon-expandable transcatheter heart valve (THV) with



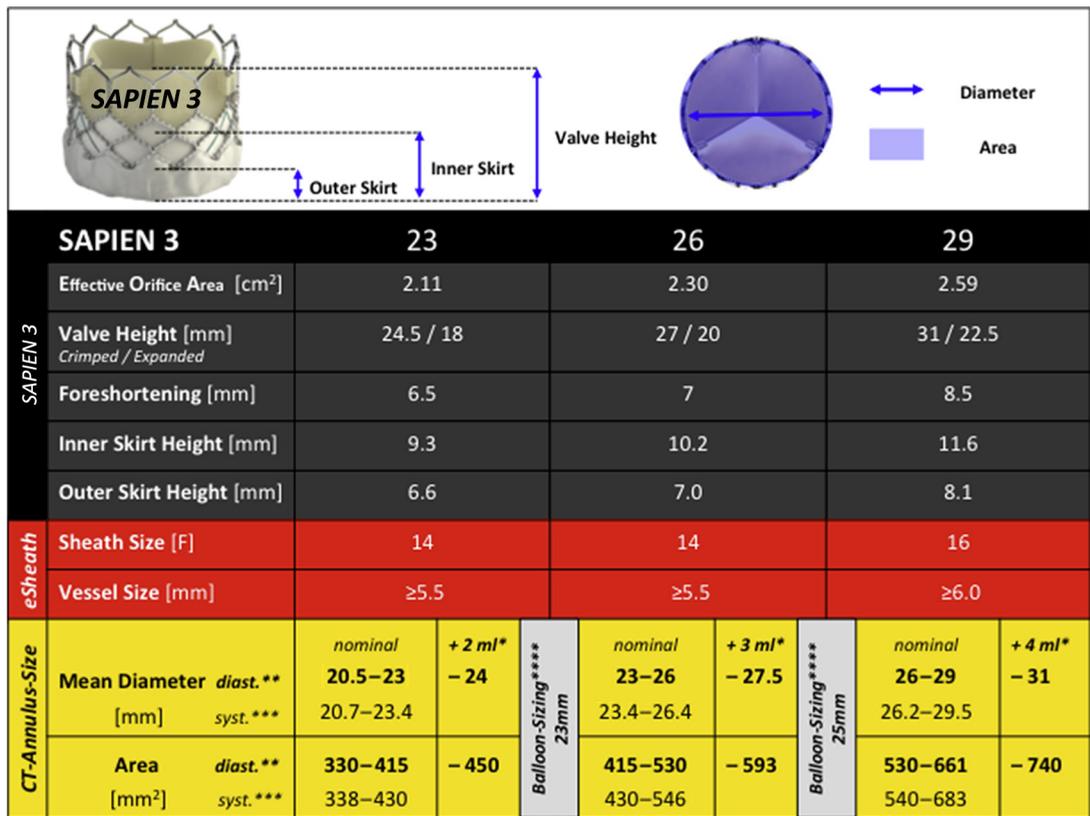
several new features designed to address the limitations of earlier generation devices. An initial feasibility study performed in Europe and Canada using the SAPIEN 3 demonstrated excellent early outcomes with a 30-day mortality rate of 2.1%, a stroke rate of 1%, and a major vascular complication rate of 4.2% in the transfemoral cohort (1). Subsequently, a large registry of more than 1,500 high- and intermediate-risk patients demonstrated comparable outcomes in the United States (2). Similar to the SAPIEN XT, the S3 THV is currently commercially available in 3 sizes: 23 mm, 26 mm, and 29 mm. Sizing approaches to the SAPIEN XT valves have already been described (3). This paper

FIGURE 1 Computed Tomography Images With Cross-Sectional Areas of Overexpanded Sapien 3 Transcatheter Heart Valves



Computed tomography (CT) images with cross-sectional areas of overexpanded Edwards SAPIEN 3 transcatheter heart valves (Edwards Lifesciences), 23-, 26-, and a 29-mm SAPIEN 3 transcatheter heart valve.

FIGURE 2 Sizing Chart for the Edwards SAPIEN 3 Transcatheter Heart Valve



*Overexpansion **Diastolic Sizing ***Systolic Sizing recommendation by manufacturer ****Borderline Annulus Sizes

Sizing chart for the Edwards SAPIEN 3 transcatheter heart valve (THV) based on multidetector computed tomography (MDCT)-derived mean diameter and cross-sectional area of the aortic valve annulus obtained in the systolic and diastolic phases of the imaging. The MDCT annulus parameters in the diastolic phase of overexpanded 23-, 26-, and 29-mm S3 THVs with the addition of 2, 3, and 4 ml of volume, respectively, are also provided. A = area; D = diameter; diast. = diastole; P = perimeter; syst. = systole.

provides recommendations for proper sizing and selection of the Edwards S3 THV; in addition, we describe a novel concept of overexpanding the S3 THV to safely accommodate annulus sizes substantially larger than the commercially available S3 valves.

Barbanti et al. (4) described a strategy of underexpanding the SAPIEN XT THV by underfilling of the deployment balloon in patients with high-risk features or in anatomies where the valve was oversized by more than 20% to reduce the risk of annular injury. Overexpansion of the SAPIEN XT is not feasible due to the frame design and the rigid skirt. Unlike the SAPIEN XT, the new frame geometry and the outer skirt design of the S3 THV may allow for undersizing of the THV. A recent analysis of the PARTNER 2 (Placement of Aortic Transcatheter Valves 2) S3 study demonstrated that even with undersizing the SAPIEN 3 valve by up to -5%, rates of significant paravalvular leak were low (5).

What is unknown is whether the improved seal of the S3 valve is due exclusively to the outer skirt or whether overexpansion of the frame plays a role. In addition, the limits of overexpansion are currently unknown.

In our study consisting of patients with annuli in the border zone between 2 valve sizes, the 23-, 26-, and 29-mm S3 valves were intentionally overexpanded by overfilling of the deployment balloon with 2, 3, and 4 ml of additional volume, respectively. After deployment, post-implantation computed tomography (CT) scans were performed to evaluate the mean diameter, area, and perimeter of the overexpanded valve frame for all 3 S3 THV sizes. Figure 1 shows examples with representative CT measurement for the 3 available S3 valve sizes. It is notable that the inflow and outflow part of the overexpanded S3 valves are flared and reach the maximal diameter, which is ~10% larger by area than the stated nominal

size of the THV. One concern with overexpansion is impairment of proper leaflet function, resulting in significant central aortic regurgitation necessitating a second valve. We, however, saw no significant central insufficiency in any of our overexpanded S3 THV implants; our series from the 2 heart centers in Munich, Germany, encompassed more than 30 patients with initial deliberate overexpansion of the THV and more than 100 patients with subsequent post-dilation of a nominally deployed THV. S3 was originally not designed for overexpansion; however, we believe that the new frame geometry with a higher frame height and longer leaflets allows the S3 to be overexpanded to accommodate larger annulus sizes without causing significant central aortic insufficiency. It is also important to note that the valve frame foreshortens more when it is overexpanded, which may have implications for valve positioning.

Compared with the strategy of choosing the larger valve size and underdeploying it, the practice of selecting the smaller THV and overexpanding it, as noted above, may allow for a very safe and effective valve implantation with a lower risk of complications such as annular rupture. Furthermore, overexpanded THVs are more circular when fully deployed, which may have a positive impact on their durability, whereas the leaflets of the underdeployed valves may interact with the valve frame, leading to impaired durability.

Figure 2 provides the sizing chart for the S3 THV along with measurements for an overexpanded valve based on our current experience. We used measurements obtained during diastole for sizing because of the better image quality noted during diastole. It is recommended to use balloon sizing in cases where the annulus size falls in the “gray zone” between 2 valve sizes. In these gray zone cases, instead of selecting the larger valve size and underexpanding the valve, it may be preferable to select the smaller valve size and overexpand it with the addition of the pre-defined volume, especially when treating severely degenerated and/or calcified valves.

With this novel overexpansion concept, patients with an annulus size of up to 740 mm² (mean diameter of 31 mm) and more can be treated safely depending on the stiffness and degree of calcification of the native valve and annulus. It is important to note that overexpansion is limited by the burst pressure of the deployment balloon. Rupture of the balloon can increase the risk of embolization and stroke. Therefore, it is not recommended to add more than 2 to 4 ml of additional volume to the nominal deployment balloon volume for the given valve size. The addition of 2 extra ml of volume to the 23-mm, 3 ml to the 26-mm, and 4 ml to the 29-mm THV correlates with ~11% to

13% more volume in the deployment balloon for each valve size. Depending on the final diameter desired, it may also be possible to use less additional volume. In the future, benchmark tests are needed to confirm the long-term durability of an overexpanded S3 THV and viability of this strategy of overexpansion.

Anupama Shivaraju, MD
Susheel Kodali, MD
Christian Thilo, MD
Ilka Ott, MD
Heribert Schunkert, MD
Wolfgang von Scheidt, MD
Martin B. Leon, MD
Adnan Kastrati, MD
*Albert M. Kasel, MD

*Department of Cardiovascular Disease
Deutsches Herzzentrum München
Lazarettstraße 36
80636 Munich, Germany

E-mail: markus_kasel@web.de

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ECG-Independent Calculation of Instantaneous Wave-Free Ratio



The instantaneous wave-free ratio (iFR) is a recently developed invasive index of coronary disease severity that simplifies stenosis assessment by eliminating the need for vasodilator administration (1-4).