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IMAGES IN INTERVENTION

Closure of a Paravalvular Leak in Transcatheter Aortic Valve Replacement Using the Candy-Plug Technique

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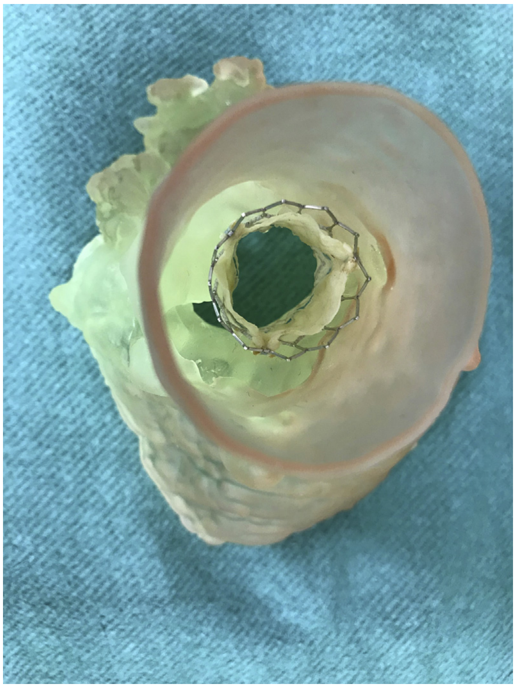
In difficult or exceptionally extreme anatomic conditions of heavily calcified aortic root anatomy, the inability to seal off paravalvular leaks (PVLs) remains an unresolved issue during transcatheter aortic valve replacement, associated with higher mortality if left untreated. We developed a novel technique for closure of a severe PVL using a self-made candy plug.

The technique is demonstrated in a 3-dimensional cardiac printed model (**Figure 1**) of a 76-year-old multimorbid female with a small oval-shaped aortic annulus and extensive calcification in the left ventricular outflow tract and aortomitral continuity. Periinterventional transesophageal echocardiography revealed a severe PVL (vena contracta width 6 mm) (Supplemental Figure 1).

A 30-mm-long, 12-mm Fluency Plus Stent Graft (C.R. Bard, New Providence, New Jersey) was modified on a sterile side table using a diameter-restricting suture. In a first step, the stent-graft was partially unloaded from the delivery system through the outer sheath (**Figure 2A**). With the intention to restrict the opening of the stent graft at this point to a maximum diameter of ~2 mm (**Figure 2B**), we used a Prolene 2-0 thread (Ethicon, Norderstedt, Germany) to tie a diameter-reducing suture between the third and fourth Z-stents without perforating the graft, with the waist just large enough to withdraw the dilator tip. To

FIGURE 1 **3D Cardiac Printed Model With a Sapien S3 Valve**



Three-dimensional (3D) cardiac printed model with a 23-mm Edwards Sapien S3 valve (Edwards Lifesciences, Irvine, California) in the annular position and a resulting large paravalvular leak.

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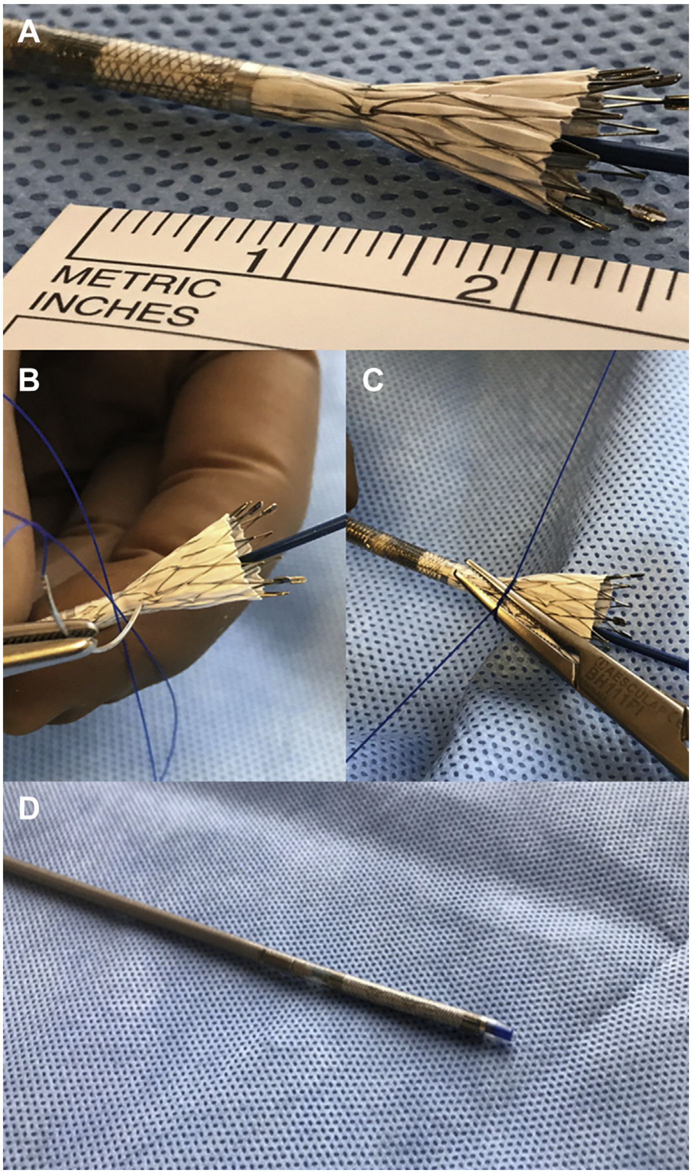
ensure that the nosecone could be securely removed through the waist, we used a mosquito clamp to control the diameter of the reducing suture (Figure 2C) (1). Finally, we reloaded the stent graft (Figure 2D).

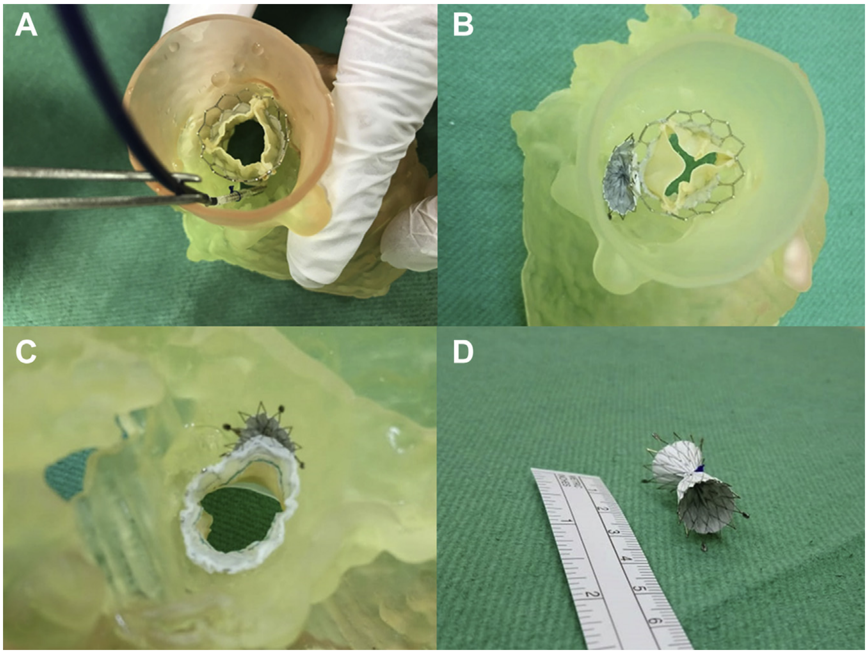
The PVL was catheterized with an Amplatz Super-Stiff wire (Boston Scientific, Marlborough, Massachusetts) positioned carefully through the paravalvular segment. The physician-modified stent graft was introduced and positioned at the annular level (Figure 3A). The physician-modified stent graft was implanted and retrieval of the delivery tip was carefully performed through the waist of the self-made candy plug. Completion

FIGURE 2 Side Table Customization



(A) In a first step, the stent graft was partially unloaded from the delivery system. **(B)** Side-table customization of a peripheral physician-modified stent graft (12 × 30-mm Fluency Plus, C.R. Bard) showing the tapered configuration of the candy plug with a diameter-reducing suture in the middle of the stent graft. **(C)** Using a mosquito clamp to confirm that the suture is wide enough to retrieve the dilator tip. **(D)** After reloading, it was prepared in a standard fashion.

FIGURE 3 Deployment and Configuration



(A) Position of the candy plug with the waist at the level of the annulus to facilitate complete closure. **(B and C)** After release of the candy plug from the aortic and ventricular view. **(D)** Tapered configuration of the candy plug with a diameter-reducing suture in the middle of the stent graft.

demonstrated only minimal residual leak (Figures 3B and 3C).

The presence of the distal alignment of the candy plug avoids a stent-induced new paravalvular leak or leaflet impingement. An immediately available “off-the-shelf” candy plug (Figure 3D) is a potential treatment option in the acute setting of large PVLs. Its use will increase the range of severe valve pathologies treatable by endovascular means. The candy-plug technique we describe is strictly outside of the instructions for use of the product. Moreover, use of this technique has significant risks that need to be weighed against the advantages in every single patient. We hope to see further refinements developed for this upcoming treatment indication in the near future. The physician-modified candy-plug technique may facilitate complete obliteration of a severe paravalvular leak in transcatheter aortic valve replacement.

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KEY WORDS 3D printing, paravalvular leakage, physician-customized device, transcatheter aortic valve replacement

APPENDIX For a supplemental figure, please see the online version of this paper.