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Modified safety techniques for transcatheter repair of superior sinus venosus defects with partial anomalous pulmonary venous drainage using a 100-mm Optimus-CVS[®] covered XXL stent

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Abstract

We report the first use of a single 100-mm long custom-made version of the Optimus-CVS[®] balloon-expandable PTFE-covered XXL (15-Zig) stent (AndraTec, GmbH) to eliminate sinus venosus defect left-to-right shunt and redirect anomalous right pulmonary veins blood flow through a new walled channel to the left atrium. Anatomical feasibility and strategy decision were guided by ex-vivo procedure simulation on the patient-specific 3D printed heart model and in-vivo balloon interrogation. Modified procedural and implantation techniques are detailed. Immediate and one-month follow-up showed excellent outcomes.

KEYWORDS

anomalous pulmonary veins, covered stent, Optimus, sinus venosus atrial septal defect

1 | INTRODUCTION

With the leap of faith of motivated interventionists, percutaneous correction of superior sinus venosus atrial septal defect (SVASD) with partial anomalous pulmonary venous return (PAPVR) became one of the most innovative transcatheter heart interventions of the decade. Despite technical and anatomical challenges, feasibility and efficacy were proven in several previous reports using different types of stents and implantation techniques.^{1–6} Advanced 3D planning has been described as an essential step for better anatomical understanding and case-oriented strategy decision.^{3–6} Optimus-CVS[®] (AndraTec, GmbH) is a PTFE-covered, balloon-expandable, cobalt-chromium stent with particular features.⁷ Herein, we report the first human implantation of a single custom-made longer Optimus-CVS[®] to effectively treat SVASD and PAPVR in an adult patient.

2 | CASE DESCRIPTION

2.1 | Preprocedural imaging assessment

A 70-year-old male (64 kg/161 cm) with exertional dyspnea and no significant comorbidities was diagnosed with left-to-right SVASD after COVID-19 respiratory infection. Ultrasound also showed a patent foramen ovale, dilated right-sided cardiac chambers, and normal pulmonary artery pressure. Cross-sectional cardiac computed tomography angiogram (CTA) with multiplanar study showed a 19-mm SVASD with anomalous drainage of right pulmonary veins into the superior vena cava (SVC).

2.2 | Advanced procedure planning

The reconstructed 3D STL hollow model of the patient's CTA was segmented using Meshmixer[™] software, version 3.5.474 (Autodesk[®], Inc).

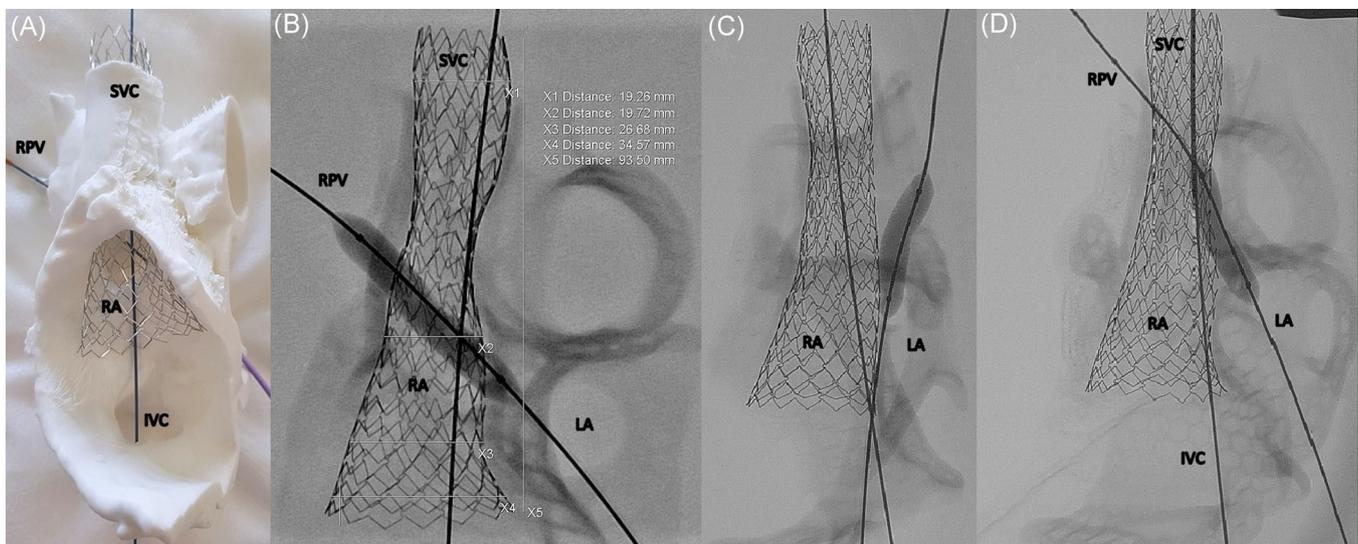


FIGURE 1 Ex-vivo simulated procedure on 3D printed model (A). A 100-mm long balloon-expandable bare-metal Optimus™ XXL stent is positioned in the SVC, across the cavoatrial junction into the RA to cover the SVASD. At the same time, a 12-mm/4-cm Armada balloon catheter serves as a tracker of the RULPV unobstructed rerouted pathway into the LA. 3D-rotational X-ray acquisition and processing imaging in anteroposterior (B), 90° lateral (C), and 50° left anterior oblique (D) views confirming procedural feasibility. IVC, inferior vena cava; LA, left atrium; RA, right atrium; SVC, superior vena cava [Color figure can be viewed at wileyonlinelibrary.com]

The model was printed using a STREAM 30 Pro MK3 3D-printer (VOLUMIC 3D) and flexible white thermoplastic Polyurethane material (Figure 1A). Stent and balloon dimensions were estimated from both CTA images and rotational X-ray analysis of the model. Taking stent foreshortening into consideration, a customized 100-mm long Optimus-CVS® XXL stent was chosen to grip the SVC, a few millimeters above the innominate vein, and to extend inferiorly to cover the SVASD with additional expansion to seal the lower end of the defect in the upper RA. A custom-made 100-mm long/3-cm large AltoSa-XL-Gemini Balloon Catheter (AndraTec, GmbH) was chosen as the delivery balloon based on the diameters of the SVC, the cavoatrial junction, and the upper RA just below the defect inferior margin. Procedure feasibility was confirmed with an ex-vivo simulation on the 3D model (Video S1, Figure 1A–D).

2.3 | Ethical considerations

Approval for this novel procedure and authorization for in-vivo implantation of custom-made material was obtained from the French regulatory health authorities. Permission was obtained from the manufacturer to use and mention their products. Informed consent was obtained from the patient to perform this procedure and to publish his medical record.

2.4 | Step-by-step procedure

The procedure was performed at Necker-Enfants malades university hospital under biplane fluoroscopy, and transoesophageal echocardiography (TEE) guidance (Figure 2). Access was obtained in the right internal

jugular vein (RIJV; 12-Fr), the right femoral vein (12-Fr), and the left femoral vein (7-Fr). The right upper lobe pulmonary vein (RULPV) was catheterized after crossing the patent foramen ovale with a 4-Fr Judkins right catheter that was exchanged with a 5-Fr pigtail catheter. SVC hand injection was performed in biplane orthogonal views to localize the innominate vein-SVC junction, the RULPV-to-innominate vein distance, and the SVASD level as all three were used as landmarks for the stent implantation (Figure 2A, Video S2). The maximum SVC and cavoatrial junction diameters were measured as 20.8 and 23.9 mm. A super-stiff wire was snared in the SVC to create a femoro-jugular guidewire rail. Balloon interrogation of the cavoatrial junction was performed using a 30-mm/3-cm PTS® sizing balloon catheter (NuMED, Inc.). Simultaneous RULPV angiograms and TEE monitoring confirmed in-vivo feasibility (Figure 2B,C). The right femoral access was upsized to an 18-Fr/85-cm long Performer™ sheath (Cook Medical). A 7-Fr right guiding catheter was inserted from the RIJV vein over the circuit and pushed through the femoral sheath. A stiff-type hydrophilic guidewire was inserted inside the guiding catheter next to the first guidewire. The guiding catheter was removed. The long sheath was positioned in the RIJV just above the innominate vein. A 5-Fr/125-cm long IMPULSE™ MPA diagnostic catheter (Boston Scientific Corp.) was inserted from the RIJV over the second hydrophilic guidewire and externalized from femoral access. This second guidewire was replaced with a 20-mm Exeter™ snare (AndraTec, GmbH) that was externalized from the femoral sheath (Figure 3A).

2.5 | Modified suture control technique

A 100-mm long Optimus-CVS® XXL stent was hand-mounted on a 100-mm long/3-cm large AltoSa-XL-Gemini balloon catheter. One

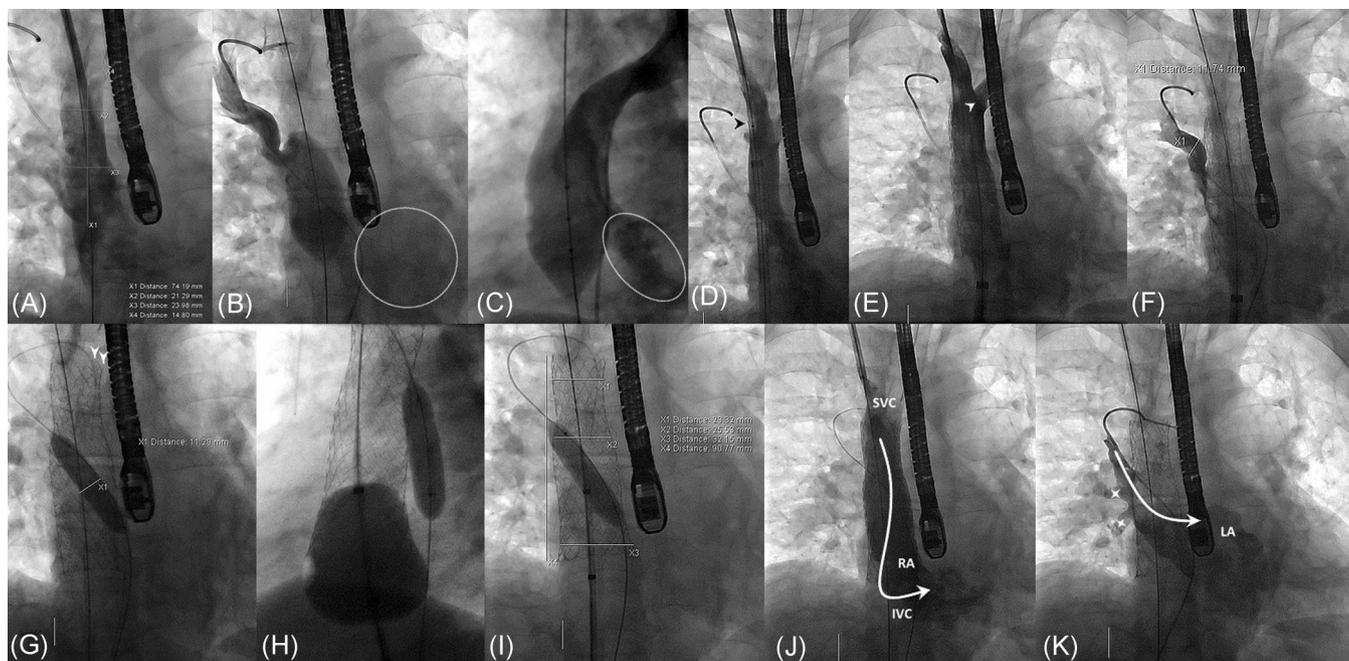


FIGURE 2 Step-by-step in-vivo procedure. Initial SVC angiogram with measurements (A). Anteroposterior (B) and lateral (C) views of SVC balloon interrogation with simultaneous RULPV hand injection showing nonoptimal but preserved drainage of the RULPV into the LA (white circles). Sheath uncovering of the stent positioned at the level of the innominate vein (D). Note the trapping of the stent cranial end using surgical threads (black pointed arrow to lateralized cell). Note innominate vein patency after stent implantation (E). Immediate RULPV flow obstruction after stent implantation (F). Ballooning of the RULPV channel (G). Note the already flared stent cranial end into the innominate vein (white pointed arrows). Flaring of the caudal end of the stent with RULPV protection (H). Final stent measurements (I). Final SVC hand angiography showing unobstructed flow into the RA with SVASD complete closure (J). RULPV hand angiography showing unobstructed flow of the right pulmonary veins into the LA (K). IVC, inferior vena cava; LA, left atrium; RA, right atrium; SVC, superior vena cava

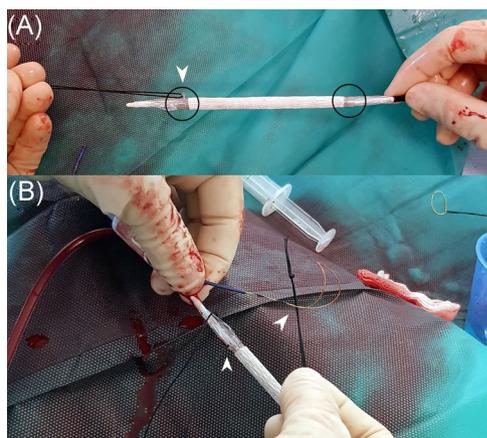


FIGURE 3 A 100-mm long Optimus-CVS® PTFE-covered XXL stent hand-mounted on a customized (100-mm long/3-cm large) AltoSa-XL-Gemini balloon catheter (A). Note the particular covering design of the stent with uncovered bare-metal extremities (black circles). Modified suture control technique with a surgical thread looped through one closed-cell of the last cranial row of the stent (white arrow head) (A). A 20-mm Exeter™ snare exteriorized from the femoral sheath and ready to receive the surgical threads before inserting the balloon-stent unit within the sheath (B) [Color figure can be viewed at wileyonlinelibrary.com]

closed-cell from the first bare-metal cranial row of the stent was crossed over using a 2.5-m long silk surgical suture thread (ETHICON®, Johnson & Johnson; Figure 3A). Both ends of the surgical suture were secured with the externalized snare (Figure 3B). The stent was tracked over the super-stiff wire circuit into position and was co-piloted by the surgical suture that was externalized from the jugular access. Adequate tension was maintained on the suture thread as a safety line to avoid caudal migration. The upper end of the stent was kept a few mm above the level of the innominate vein (Figure 2D). The dual balloon was sequentially inflated until the stent was affixed to the SVC (Figure 2E).

2.6 | Pulmonary vein obstruction bailout

At that point, flow acceleration in the RULPV was noted on TEE and the mild stenosis was confirmed angiographically (Figure 2F). We anchored the stent in the SVC by flaring its cranial end into the innominate vein. Stent flaring was achieved by positioning a 20-mm/2-cm Atlas® Gold PTA balloon dilation catheter (BARD, Peripheral Vascular, Inc.) at the level of the RIJV-innominate vein junction and simultaneously inflating it next to a 14-mm/4-cm Armada balloon (Abbott Cardiovascular) that was positioned, over an additional

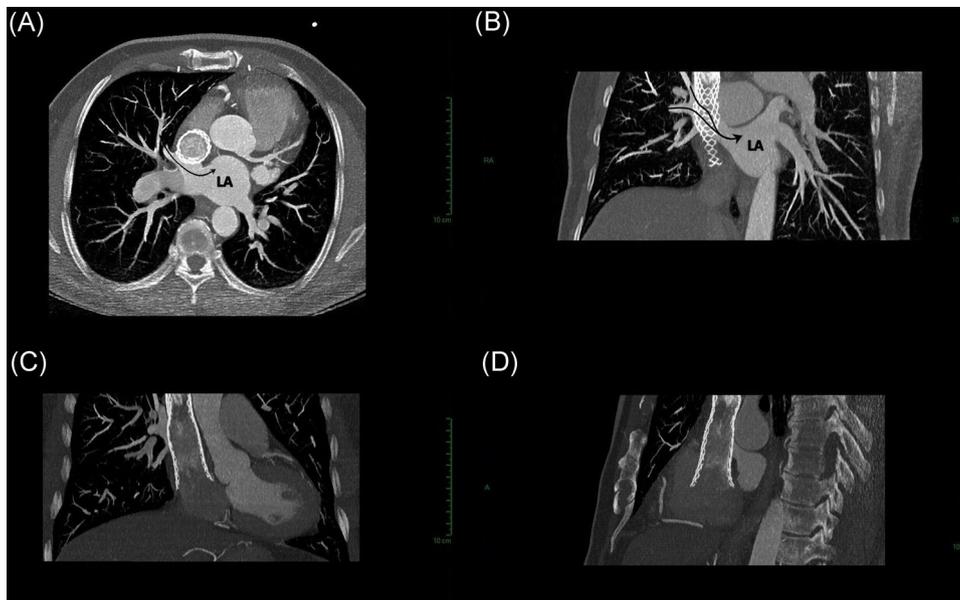


FIGURE 4 One-month control CT-scan. Axial (A) and coronal (B, C) and sagittal (D) multi-planar modified reconstructions showing SVC stent patency, absence of SVASD residual shunt, and the unobstructed rerouting of the right pulmonary veins drainage into the left atrium. CT, computed tomography; SVASD, sinus venosus atrial septal defect; SVC, superior vena cava

guidewire, across the SVC-innominate vein junction. The RULPV pigtail catheter was exchanged with a 12-mm/4-cm Armada balloon that was inflated in the newly created tunnel to completely relieve RULPV flow obstruction (Figure 2G–I). The caudal end of the stent was flared to 29 mm using a 46-mm Coda[®] balloon catheter (Cook Medical) until complete shunt closure (Figure 2J, Video S3A).

2.7 | Procedure outcomes

Hand angiography in the RULPV showed normal drainage to the left atrium (LA) (Figure 2K, Video S3B). The surgical thread was easily retrieved. Final TEE control showed unobstructed SVC flow to RA, laminar upper and middle right pulmonary veins flow to LA, and complete shunt closure. Final stent length was 90.8 mm (Figure 2I). The patient was prescribed aspirin (for 6 months) and clopidogrel (for 2 months). Discharge electrocardiogram showed sinus rhythm. Patient was discharged from the hospital after 48 h. One-month follow-up showed excellent outcomes as confirmed on control CTA imaging (Figure 4).

3 | DISCUSSION

Surgery is the standard of care and was the only treatment option until the first report of transcatheter correction in 2014 by Garg et al.¹ Given the inherent anatomical variability of SVASD, ex-vivo testings using the two-stage simulation strategy are beneficial to evaluate procedure suitability. The in-vivo testing is also important due to the potential distention of the native tissues. Previous teams

reported various preoperative assessments from solely invasive balloon interrogation to 3D printed and virtual models.^{1–6} In larger volume centers, 3D models are now used infrequently. A perfect understanding of the anatomy through precise measurement protocol of both TEE and multiplanar reconstruction CTA images might allow us to consistently identify eligible patients.^{5,6}

Pulmonary vein occlusion and stent migration are the two bottlenecks to overcome in this procedure.^{3–6} The cranial part of the stent is placed in a non-stenotic and distensible SVC and its caudal end needs to be expanded at the wider cavoatrial junction, thereby increasing the risk of downward stent migration.⁸ The longer the initial stent that can be used, the more flexibility there will be in expanding the stent caudal end to achieve complete closure without destabilizing the stent, and the less likelihood of needing an anchoring stent. Similarly, the longer the portion of the stent opposed firmly to the SVC, the less likelihood there is of stent embolization. Previously reported strategies to prevent stent migration included counteractions maneuvers such as applying traction to the SVC end of the guidewire rail, advancing the delivery sheath up to the balloon lower end, and snaring the cranial end of the balloon.⁶ We decided to use a single custom-made long version of the Optimus-CVS rather than interlocking two or multiple stents to avoid unnecessary manipulations. Moreover, we present two modified techniques for securing the implantation: temporary stent suture trapping and flaring the unique bare-metal hybrid-cell cranial end of the Optimus-CVS into the innominate vein. The original suture control technique of Y. Boudjemline was previously published.⁵ However, we modified it for a simpler approach to the stent mounting, less manipulation of the stent-balloon unit, and a down-sized delivery sheath in the neck. Our bench testings showed that the integrity of Optimus-CVS sandwich

PTFE-covering remains intact even at an inflation diameter of 32 mm. However, we intentionally made sure to avoid excessive caudal flaring especially when all procedure goals were achieved, thereby avoiding alteration of the displacement forces inside the stent.⁸

Anterograde pulmonary vein monitoring directly across the SVC increases the risk of catheter trapping and might interfere with the implantation process.³ Retrograde arterial and trans-septal RULPV catheterization are reported as reasonable solutions.^{3,5} Assessing the patency of the foramen ovale can ease some procedural steps.⁵ Our case confirms that RULPV continuous access is important as it allows continuous pressure monitoring and the possibility of bail-out balloon dilation or even stenting in the event of pulmonary vein obstruction. Pulmonary venous protection can be very helpful in preventing excessive bulging of the stent into the pulmonary venous pathway. In retrospect, the risk of pulmonary venous flow compromise should have been considered since the compliant sizing balloon was a bit obstructing the RUPLV pathway (Figure 2B,C). Protective balloon inflated at high pressure during slow stent deployment at low pressure would have allowed the stent to “mold” around the balloon.⁵

Previous authors reported the use of various covered stents.^{1–6} We chose the Optimus stent for this procedure based on our previous experience with this device.⁷ This stent offers a particular hybrid-cell design with omega-flex-connectors and a unique PTFE-covering concept leading to predictable foreshortening and high anatomical configurability that simplified the procedure. In the future, various stent lengths and a new PTFE covering design with a 2-cm bare-metal cranial end should be proposed for maximal caval anchoring with innominate and azygos veins patency.

4 | CONCLUSION

We present early evidence of the feasibility of percutaneous correction of SVASD with PAPVR using the 100-mm long Optimus-CVS[®] XXL stent in a selected adult patient. Preprocedural 3D modeling and two-stage simulation strategy were helpful in this case.

ACKNOWLEDGMENTS

The authors acknowledge Dr. Reaksmay LY for per-procedural TEE guidance, Dr. Gilles SOULAT for 3D-reconstruction of the heart model, and Mr. Florent CARASCO (La Ferme 3D©) for his assistance during 3D printing process. The authors are also grateful to Mr. Robin COT and Mrs. Brigitte GIRODON for their support with rotational X-ray acquisitions during ex-vivo simulations.

CONFLICT OF INTERESTS

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

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How to cite this article: Haddad RN, Bonnet D, Gewillig M, Malekzadeh-Milani S. Modified safety techniques for transcatheter repair of superior sinus venosus defects with partial anomalous pulmonary venous drainage using a 100-mm Optimus-CVS[®] covered XXL stent. *Catheter Cardiovasc Interv.* 2022;1-5. doi:10.1002/ccd.30136