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ORIGINAL STUDIES

First in man study of a new semi-open cell design Zephyr cobalt–chromium stent in large vessels and conduits

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Abstract

Objectives: We present a first-in-man clinical use of a new hybrid design stent in stenosed large vessels. Its unique C and S polylinks prevent foreshortening without compromising its strength. Its thin profile permits use of smaller introducer sheaths.

Background: Stent angioplasty is widely employed in large vessel and conduit stenosis. These procedures are associated with difficulties due to large stent profiles, stent fractures, foreshortening and recoil. Cobalt chromium stents have high tensile strengths compared to stainless steel stents.

Methods: A retrospective analysis of feasibility and safety of a new Cobalt chromium stent in large vessels namely aorta, pulmonary arteries and outflow conduits was done from two institutions. Demographic patient details, procedural results, complications and medium term follow-up were analyzed. Stent recoil, foreshortening, fractures were assessed.

Results: Twenty patients including three with aortic coarctations, seven with stenosed conduits and 10 with pulmonary artery stenosis underwent stent angioplasty using 23 stents. Three stents were deployed to expand further a previously implanted stent. Procedure was successful in all patients, lumen increased by 150–300%, gradients reduced in all patients. There was no stent recoil, foreshortening or fractures. There were no complications. At a follow up of 3–27 months, there were no stent related complications and the gradients remained stable.

Conclusions: The new Zephyr stent was useful in a wide variety of stenotic lesions involving large vessels including those that were previously stented. Lack of stent recoil and foreshortening seems to be an advantage for this new stent that needs validation in larger multicenter studies.

KEYWORDS

aortic coarctation, cobalt chromium stent, conduit stenting, large vessel stent, pulmonary artery stenosis, zero foreshortening

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1 | INTRODUCTION

Large vessel stents have revolutionized the management of aortic coarctation, narrowed surgical conduits and stenosis of pulmonary arteries and large systemic veins in the last three decades.[1,2] These stents vary in their material, design, final diameter, deployment characteristics and amenability for future expansion to accommodate for somatic growth in children.[3–5] Closed cell design stents have good radial strength and vessel scaffolding, but they foreshorten. Open cell stents allow intervention to jailed side branches.[4] Hybrid designs are intended to improve flexibility for better delivery.[4]

Premounted stents offer low profile easy trackable solutions in small patients but their radial strength are low for resistant lesions.[6,7] As they are available in sizes less than 10 mm, they cannot be used as a primary stent if the vessels to be stented have a large reference diameter exceeding 12 mm like large conduits, aorta or main pulmonary artery. In such vessels, the smaller premounted stents will overhang the stenosed segment and remain unstable for a safe post-dilatation to create vessel opposition. So they are extremely valuable in very young children with vessels whose reference diameters are under 10 mm.[8,9] Compared to the stainless steel stents, cobalt chromium (Co–Cr) stents carry the advantages of higher tensile radial strength, higher wear and corrosion resistance and improved radiopacity, despite having thinner struts.[10]

The Andra stent (Andramed, Reutlingen, Germany), the first hybrid design Co–Cr peripheral stent is widely used in pulmonary arteries and aorta.[10,11] Zephyr (Sahajanand Laser technology limited, Gandhinagar, India), a novel large vessel hybrid design stent is also made of MP35N Co–Cr alloy similar to the Andra stents, but has some improvements in composition and design. Its negligible iron content and non-ferromagnetic Cobalt alloy permit 3Tesla magnetic resonance imaging.[12] The biocompatibility of Co–Cr alloy ensures high resistance to fatigue fractures and corrosion.[13,14]

We present the first-in-man clinical experience with the Zephyr in different large vessels namely aorta, pulmonary artery and outflow tract conduits. Since these are the common indications for any large vessel stent, we attempted to use this stent design in all the real world clinical situations to show its clinical utility.

2 | METHODS

2.1 | Study design

This study is a retrospective analysis of clinical and procedural details of all patients who underwent stent angioplasty of large vessels namely aorta, pulmonary artery or right ventricular outflow tract conduits using the new Zephyr stent in two tertiary care Pediatric cardiology centers in India. The Drug Controller General of India and Central Drugs Standard Control Organisation under the Ministry of Health and Family Welfare, Government of India approved the manufacture and clinical use of the stent. Institutional ethical committees permitted use of this stent in appropriate indications. Informed written consent was obtained from all patients for use of the stent and also for collection, analysis and publication of clinical data.

2.2 | Stent description

Zephyr is made of a semi-open cell 8-crown hybrid design of Co–Cr MP35N alloy created by a zig-zag arrangement with flexible "S" and "C" shaped poly-links permitting excellent trackability and avoids foreshortening on dilatation (Figure 1a,b). As the struts are thinner than those of the AndraXL stents, the lower crimping profile allows to use low profile delivery sheaths, one French size larger than what is needed for the balloon alone. This stent is available as bare stents with the following lengths of 18, 28, 38, 48, and 58 mm; the stent can be dilated up to a maximum diameter of 18 mm thereby allowing its use in a growing child.

2.3 | Inclusion criteria

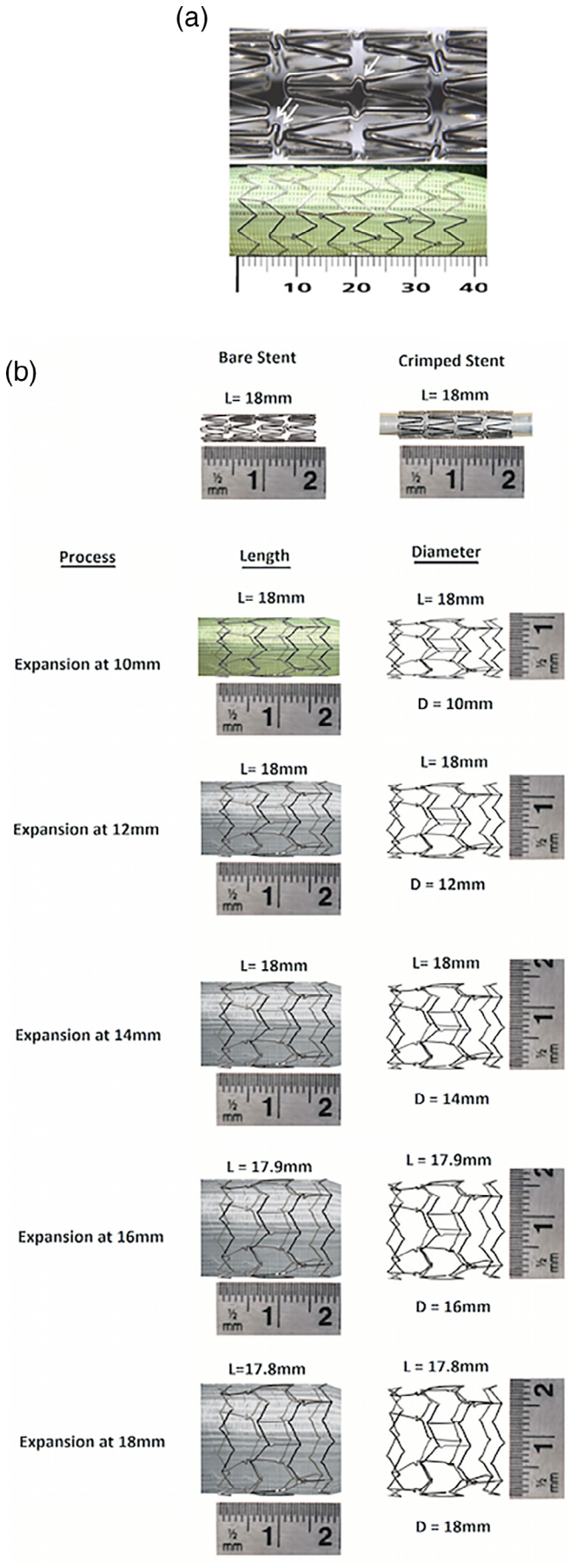
Indications for stenting of pulmonary artery stenosis were symptomatic patients, Doppler gradients more than 36 mmHg, unilateral lung hypoperfusion on nuclear scan or magnetic resonance imaging and significant luminal narrowing in patients after Glenn or Fontan surgery. Indications for stenting stenotic right ventricular outflow conduits were symptomatic patients, right ventricular systolic pressures more than two-third of systemic pressures and right ventricular dysfunction. Indications for stenting coarctation of the aorta were symptomatic patients, arm-leg systolic blood pressure difference exceeding 20 mmHg, systemic hypertension associated with exercise induced gradient exceeding 50 mmHg and left ventricular systolic dysfunction. Any patient who needed a stent larger than 18 mm were excluded as Zephyr is tested only upto 18 mm diameter expansion.

2.4 | Procedure

A diagnostic angiography defined the lesion morphology and pressure gradients. All procedures were performed under conscious sedation and general anesthesia with intubation was restricted to sick patients. All patients received heparin 100 IU/kg body weight before the intervention. To enable exact stent placement, all interventions were performed through a long sheath, which permitted check angiography through the side arm.

2.5 | Stent deployment

All the stents were hand-crimped and deployed with an inflation device through a long braided sheath. The stents were crimped on



Maxi LD balloons (Cordis Endovascular, Warren, NJ), Admiral extreme balloons (Medtronic endovascular, Minneapolis, MN) or Z-med or BIB balloons (NuMED, Hopkinton, NY), with diameters ranging from 10 to 18 mm. The procedure-related complications were evaluated. No suture device was applied for hemostasis. Aspirin (3–5 mg/kg body weight/day) was recommended for 6 months. Patients with a univentricular heart received coumadin to maintain an international normalized ratio (INR) between 2 and 3.

2.6 | Data collection

The data collected for analysis for this first-in-man study of the new Zephyr stent were (a) demographic parameters including age, weight, sex, underlying diagnosis, symptoms, NYHA class, preprocedural medications, (b) anatomical parameters including vessel involved, stenosis diameter, diameter of reference blood vessel, de novo versus postsurgical stenosis, previous catheter interventions, (c) hemodynamic parameters including pressure gradient in mmHg, presence and severity of systemic hypertension in aortic interventions, severity of right ventricular systolic hypertension in conduit interventions, post procedural reduction in gradients and pressures (d) stent details including stent length, type of balloon used, final balloon diameter, final inflation pressure, recoil after dilatation, final lesion diameter, foreshortening, conformability to vessel curves.

2.7 | Complications

The procedures were carefully analyzed for (a) Procedural complications like stent slippage, balloon rupture, difficult delivery, recoil, foreshortening, stent fracture, stent embolization or malposition, vessel rupture, failure to conform to curves, vascular access complications, cardiac chamber injury and (b) post procedural complications like stent thrombosis, stent fractures, fever, pericardial effusions, allergic manifestations and access vessel thrombosis.

2.8 | Follow up

The follow up protocol included clinical review of the patients at 3 months and thereafter at yearly intervals. The symptoms,

FIGURE 1 (a) Zephyr's structural design is a semi-open cell 8-crown hybrid design of cobalt–chromium alloy created by a zig-zag arrangement with flexible S (double arrow) and C (single arrow) shaped poly-links that prevent any foreshortening when a 38 mm long Zephyr is expanded on a single 18 mm diameter balloon (b) Bench testing of Zephyr 18 mm stent serially dilated with different balloons of 10, 12, 14, 16, and 18 mm diameter showing very negligible and near zero-foreshortening [Color figure can be viewed at wileyonlinelibrary.com]

echocardiographic gradients and flows through the stented vessels were analyzed. A fluoroscopy was performed at 3 months for stent fractures.

3 | RESULTS

3.1 | Patient details

A total of 20 patients including eight females from two institutions formed the study group (Table 1). Seventeen patients were recruited from the first institution and the rest from the second center. A total of 23 Zephyr stents were implanted in these patients in the study period spanning 18 months from July 2017. The mean age group of the cohort was 16.6 ± 13.8 years and ranged 2–58 years. Fourteen patients were younger than 18 years. The mean weight of the patients was 40.7 ± 21.5 kg, ranged 7–93 kg. Two patients with severe conduit stenosis were symptomatic at rest with congestive heart failure and were receiving intravenous inotropes and diuretics. Nine patients were in NYHA class II and others were asymptomatic.

3.2 | Aortic coarctation

Three patients had aortic coarctation. Two lesions were de-novo lesions; one of them also had severe subaortic stenosis and left ventricular dysfunction, which needed surgery on cardiopulmonary bypass later. The third patient had a previously stented coarctation using a GenesisXD stent (Cordis Incorporated, Miami Lakes, FL) that had a complete transverse stent fracture. The luminal improvement ranged from 150–280% of the original diameter. The initial gradients of 35–55 mmHg reduced to less than 5 mmHg in all the patients.

3.3 | Conduit stenosis

Seven patients including two adults had stenting of stenosed right ventricular outflow conduits, three of them being homografts and the rest were xenografts. The underlying heart lesions were tetralogy of Fallot with pulmonary atresia in six and truncus arteriosus in one. The duration between the previous surgery and stent angioplasty ranged from 0.5–17 years. A forty-year male who had a 18 mm homograft conduit repair for Fallot's tetralogy 17 years earlier, presented in NYHA class IV with severe circumferential calcific conduit stenosis, severe right ventricular failure dependent on mechanical ventilation and intravenous inotropes. A palliative stenting of the conduit reduced the gradient from 70 to 40 mmHg and improved the preoperative ventricular function for a conduit replacement surgery later. The preprocedural gradients in the other six patients improved from 25–70 mmHg to 0–20 mmHg after the stenting with no further interventions on follow-up. One small child aged 2 years weighing 12 kg with distal conduit stenosis needed a double balloon single stent strategy (Figure 2) using two 10 mm balloons to avoid protrusion of a 18 mm Zephyr stent beyond the confluence.[15]

3.4 | Branch pulmonary arteries in biventricular hearts

Seven patients with biventricular circulation had stenting of stenosed branch pulmonary arteries. One of them also had a conduit stenting using another Zephyr stent. The stenosis involved narrowed main pulmonary artery following arterial switch for transposition in one patient. One patient with Takayasu arteritis with bilateral pulmonary artery narrowing after a failed attempt at open surgery on cardiopulmonary bypass underwent bilateral stenting 4 months later. Another patient with previous Blalock Taussig shunts and a total correction of tetralogy with pericardial patch repair of hypoplastic pulmonary arteries 1 year earlier had bilateral stenting of stenosed pulmonary arteries. Stenosis involved origin of left pulmonary artery at duct insertion site in two patients. One patient had previous stenting of the main pulmonary artery to right pulmonary artery with a long AndraXL stent jailing the left pulmonary artery origin.(Figure 3) This patient underwent culotte stenting of the left pulmonary artery from the still narrowed main pulmonary artery through the previous stent struts.[16]

3.5 | Branch pulmonary arteries in univentricular hearts

Four patients underwent stenting of narrowed pulmonary arteries following Bidirectional Glenn shunt. One patient had a chronic total occluded left pulmonary artery that was recanalized using Conquest Pro guidewire and then finally stented with a Zephyr. Another patient palliated in neonatal period with a ductal stent followed by repair of the confluence during Glenn surgery developed left pulmonary artery stenosis that was stented with a Zephyr. An adolescent with left Glenn shunt had right pulmonary artery stenting with a Genesis XD stent to 8 mm diameter, 10 years earlier. She outgrew her stent with somatic growth. The stenotic segment of the right pulmonary was long, extending for a few millimeters on either side of the previous stent. The stent was restented with a longer Zephyr and dilated from 8 mm to 14 mm. There was a significant increase of the lumen in post Glenn patients, even though the pressure gradients were insignificant.

3.6 | Lesion details

All patients except two with postsubclavian coarctation were postsurgical patients. The diameter of the stenosed segment was 8.0 ± 2.3 mm and ranged 0–13 mm. In comparison, the reference vessel diameter was 14.8 ± 4.8 mm and ranged 7–22 mm. The diameter ratio between the narrowed segments to reference segments was 0.55 ± 0.15. Four patients had a previous catheter intervention that included GenesisXD stents in two, Andra XL stent in one and a Formula 418 stent (Cook Medical, Bloomington, IN). One Genesis XD stent across aortic coarctation that developed a circumferential fracture and another outgrown Genesis XD stent in right pulmonary artery after a left Glenn shunt were stented with longer Zephyr stents.

TABLE 1 Procedural details

No	Age (yr)	Weight (kg)	Diagnosis	Vessel	Specific details	Stenosis diameter	Reference diameter	Balloon	Final stent diameter	Length of stent	Sheath size	Pre gradient	Post gradient	Final stent length
1.	21	58	Coarctation	Aorta	Native	5 mm	14 mm	16 mm Zmed	14 mm	28 mm	12F	55 mmHg	5 mmHg	29 mm
2.	13	47	Coarctation	Aorta	Previous surgery, fractured genesis XD stent	6 mm	12 mm	12 mm Zmed	9 mm	28 mm	10F	35 mmHg	0 mmHg	27.5 mm
3.	9	51	Coarctation	Aorta	Subaortic stenosis +ascending aortic aneurysm	7 mm	14 mm	16 mm Zmed	14 mm	38 mm	10F	40 mmHg	0 mmHg	38 mm
4.	40	63	TOF PAt	Conduit	Homograft, single left coronary, RV dysfunction	8 mm	16 mm	16 mm Zmed 16 mm Atlas	16 mm	28 mm	12F	70 mmHg	40 mmHg	28 mm
5.	10	23	Truncus	Conduit	Xenograft	9 mm	18 mm	16 mm Zmed 18 mm Atlas	18 mm	38 mm	12F	55 mmHg	20 mmHg	38 mm
6.	30	35	TOF PAt	Conduit	Homograft	8 mm	18 mm	16 mm Atlas	16 mm	38 mm	12F	30 mmHg	10 mmHg	37 mm
				Left PA	Pericardial repair	8 mm	15 mm	15 mm Zmed	16 mm	18 mm	12F	25 mmHg	10 mmHg	18 mm
7.	2	10	TOF PAt	Conduit	Xenograft previous LPA stent	5 mm	12 mm	12 mm Admiral	12 mm	18 mm	8F	45 mmHg	10 mmHg	17 mm
8.	11	48	TOF PAt	Conduit	Homograft	13 mm	19 mm	18 mm BIB	18 mm	28 mm	12F	52 mmHg	17 mmHg	28 mm
9.	16	45	TOF PAt	Conduit	Xenograft	6 mm	16 mm	12 mm Zmed	11 mm	28 mm	9F	50 mmHg	20 mmHg	28 mm
10.	2	12	TOF PAt	Conduit	Xenograft	6 mm	17 mm	Two 10 mm Admiral	*14 mm*	18 mm	12F	70 mmHg	17 mmHg	18 mm
11.	58	93	Takayasu	Right PA	Post surgical	10 mm	22 mm	16 mm Zmed 16 mm Atlas	16 mm	18 mm	12F	80 mmHg	18 mmHg	18 mm
				Left PA	Post surgical	7 mm	18 mm	16 mm Zmed 18 mm Atlas	18 mm	18 mm	12F	70 mmHg	2 mmHg	18 mm
12.	15	46	TOF Bifurcation stenosis	Main PA-LPA	Previous Main PA-RPA Andra XL stent	6 mm	18 mm	18 mm BIB	18 mm	28 mm	12F	57 mmHg	17 mmHg	28 mm
13.	13	29	TOF ICR	Left PA	Post surgical	5 mm	11 mm	12 mm Admiral	10 mm	18 mm	8F	40 mmHg	15 mmHg	19 mm
14.	8	24	DTGA post ASO	Main PA	Previous balloon	6 mm	16 mm	10 mm Opta	10 mm	18 mm	9F	60 mmHg	20 mmHg	18 mm
15.	12	28	Post TOF	RPA	Bilateral PA stenosis	6 mm	12 mm	12 mm Admiral	12 mm	28 mm	9F	80 mmHg	10 mmHg	28 mm
				LPA	Bilateral PA stenosis	3 mm	12 mm	12 mm Opta 14 mm Atlas	12 mm	28 mm	9F	75 mmHg	10 mmHg	27 mm

(Continues)

TABLE 1 (Continued)

No	Age (yr)	Weight (kg)	Diagnosis	Vessel	Specific details	Stenosis diameter	Reference diameter	Balloon	Final stent diameter	Length of stent	Sheath size	Pre gradient	Post gradient	Final stent length
16.	10	37	TOF ICR Trifurcation stenosis	MPA-RPA	Hypoplastic LPA	6 mm	16 mm	12 mm Admiral 16 mm Atlas	16 mm	38 mm	12F	145 mmHg	28 mmHg	37 mm
17.	23	59	Post right BDG	Left PA occluded	Long segment occlusion	0 mm	12 mm	12 mm Opta	12 mm	48 mm	8F	18 mmHg	0 mmHg	46 mm
18.	23	72	Post right BDG	Left PA stenosis	LPA pericardial repair	11 mm	20 mm	18 mm Zmed 18 mm Atlas	18 mm	38 mm	12F	2 mmHg	0 mmHg	38 mm
19.	3.5	14	Post right BDG	Left PA stenosis	Neonatal ductal stent	3 mm	7 mm	10 mm Admiral	9 mm	18 mm	8F	4 mmHg	0 mmHg	18 mm
20.	16	53	Post left BDG	Right PA stenosis	Previous Genesis XD stent diffuse stenosis	8 mm	15 mm	15 mm BIB 16 mm Atlas	14 mm	28 mm	10F	3 mmHg	0 mmHg	28 mm

Abbreviations: ASO: arterial switch operation; BDG: Bidirectional Glenn shunt; DTGA: d-transposition of great arteries; ICR: Intracardiac repair; NYHA: New York Heart Association; PA: Pulmonary artery; PAt: Pulmonary atresia; RV: Right ventricle; TOF: Tetralogy of fallot.

Sidestruts of a previous Andra stent deployed earlier was stented with a Zephyr using culotte stenting strategy. The last patient with a patent left pulmonary artery Formula 418 stent developed xenograft conduit stenosis which was relieved by a Zephyr.

3.7 | Stent details

Twenty-three stents were deployed in 20 patients. One patient with conduit stenosis and an additional ostial left pulmonary artery stenosis, one patient with bilateral pulmonary artery stenosis after tetralogy repair and another with Takayasu arteritis needed two stents each. The length of the stents was 18 mm in eight patients, 28 mm in nine, 38 mm in five and 48 mm in one patient. Direct stenting was performed in all lesions except narrowed right ventricular outflow conduits and previously stented lesions. There was no significant recoil or foreshortening of more than 1 mm in any stents after deployment (Table 1). The stents conformed to the vessel curves in all the lesions, including a culotte stenting in the pulmonary bifurcation. One patient with complete left pulmonary artery occlusion after a Glenn shunt 10 years earlier had recanalization and stenting to 12 mm diameter.

3.8 | Complications

There were no instances of stent slippage, balloon rupture, difficult deliverability, stent fracture, embolization or malposition. There was no vessel rupture or dissection in any instances, including a patient with recanalization of a chronic occluded left pulmonary artery and the two patients who had expansion of a previously deployed stent. There were no vascular access complications, cardiac chamber injury and arrhythmia during the procedure. There were no instances of stent thrombosis, fever, pericardial effusions, allergic manifestations and access vessel thrombosis on pre-discharge evaluation.

3.9 | Follow-up

The follow-up varied from 3–27 months. Two patients needed surgery on follow-up as described earlier, one for conduit replacement and other for severe subaortic stenosis. The echocardiographic gradients across the lesions did not increase more than the predischarge values on a median follow-up of 12 months. There were no stent-specific complications in any patients. Fluoroscopy was performed in 16 patients at three-month follow-up and no stent fractures were seen in any of them.

4 | DISCUSSION

This is a retrospective analysis of use of a new Co–Cr stent in narrowed large vessels like aorta, pulmonary artery and conduits. Stainless steel stents like Genesis XD or Intrastent (ev3 medical, Plymouth,

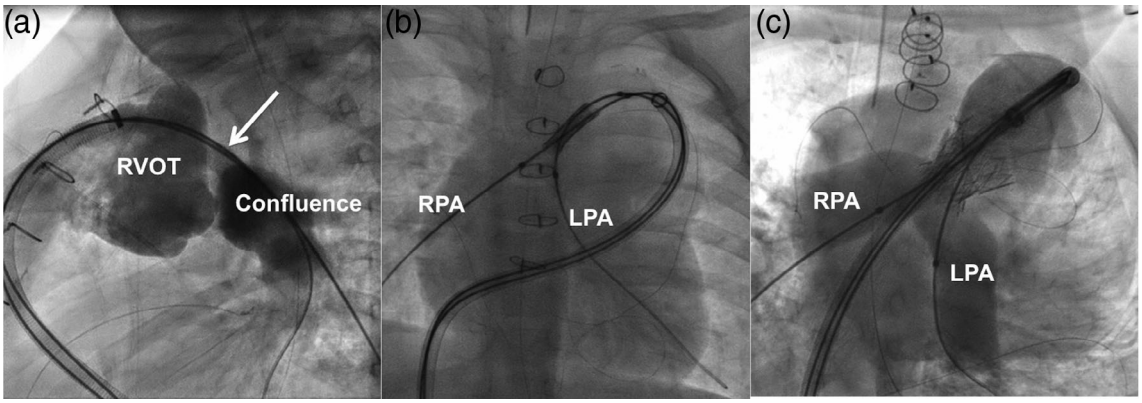


FIGURE 2 Severe distal conduit stenosis (arrow) with a dilated right ventricular outflow tract (RVOT) shown in (a) a lateral view angiogram was stented with (b) a double balloon single stent strategy with (c) successful relief of the gradients. Two 10 mm balloons prevented an 18 mm long Zephyr stent to protrude beyond the confluence. The final diameter of the stent was 14 mm and the length of the stent was 18 mm

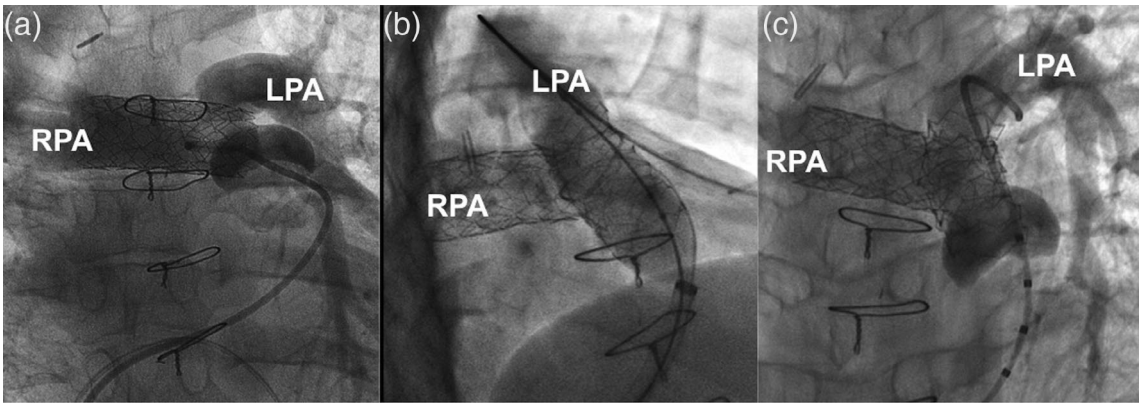


FIGURE 3 (a) AndraXL stent previously deployed from the main pulmonary artery toward the right pulmonary artery (RPA) was jailing the origin of the left pulmonary artery (LPA). (b) The persistent outflow gradient was relieved by a Culotte stenting of the sidestruts of a previous AndraXL using a 28 mm long Zephyr stent from main pulmonary artery to left pulmonary artery. (c) Final angiogram shows a Zephyr with a diameter of 18 mm, no foreshortening and well deployed immediately above the pulmonary valve toward the left pulmonary artery

MN) create large blooming artifacts with magnetic resonance imaging.[1–3] Platinum iridium stents (CP stent, Numed Incorporated, Hopkinton, NY) have a larger profile needing large sheaths and also associated with stent fractures.[4,5]

4.1 | Low profile stents

Co–Cr stents like AndraXL stent have higher tensile strength and yield stress making them less prone for stent fractures, smaller profile for a similar radial strength, but they foreshorten 10–24%.[10,11] Zephyr is a novel Co–Cr stent with special C and S polylinks which prevent foreshortening on bench testing (Figure 1). Premounted stainless steel stents like Formula and Valeo (Bard vascular, Tempe, AZ) are an effective alternative, but they cannot be used if reference diameter is more than 10 mm.[7–9]

4.2 | Physical properties

Yield stress and tensile strength are two static properties and Young's modulus of elasticity and strain are two dynamic properties of a stent alloy.[17] Co–Cr has larger tensile strength (930 MPa) and Young's modulus than 316 L stainless steel (670 MPa).[17] This means that the Co–Cr stent needs a greater pressure to inflate and deploy, but once deployed offers a better scaffolding and higher resistance to recoil and fracture.[18] The surface oxide film over Co–Cr stents prevent leach of metals and make them corrosion resistant.[19,20] The unique "S" and "C" shaped polylinks provide good conformability to the curved vessel geometry with no foreshortening and recoil on bench testing, which was performed both with a single large diameter balloon as well as progressive serial dilatations starting with a balloon of smaller diameter (Figure 1). Its uniform symmetric expansion gives excellent vessel scaffolding without flaring.

4.3 | Utility in diverse variety of lesions

We tested the utility of the stent in various clinical lesions. Two patients with de novo aortic coarctation in a native tissue model were likely to be lesions of least resistance. Bilateral pulmonary artery stenosis in a patient with Takayasu arteritis offered a post-inflammatory fibrotic model. Majority of the other lesions were following surgical pericardial patch repairs of pulmonary arteries. Calcified degenerated conduits were stented in seven patients, three of them being homografts which were surgically placed more than a decade ago. Two lesions were previous stainless steel stents, which were outgrown by the somatic growth of the patients. A strut of a previously placed Andrastent jailing the left pulmonary artery was balloon dilated and the stent strut orifice was dilated and stented with a Zephyr stent by culotte stenting technique in one instance. These clinical situations offered a diverse real-world variety of lesions of varying degrees of resistance and stiffness, proving its utility.

4.4 | Stent characteristics

Lack of stent recoil, foreshortening, and fractures are favored attributes of large vessel stents.[4,5] A larger study involving more number of patients is needed to confirm the lowest recoil, foreshortening and fracture rates with Zephyr. Small stent strut thickness of 220 μm in Zephyr offers a low profile and allows use of a sheath that is one French larger than the balloon, even in lesions that involve sharp and tight curves like pulmonary arteries and conduits. This is an important advantage especially in smaller patients with difficult vascular access.

4.5 | Complications

Usage of long sheath to cover the balloon stent assembly before it reached the lesion ensured that there were no instances of balloon or stent slippage, stent malposition or cardiac tissue injury. Operator experience too plays a role in incidence of vascular complications. With proper attentions to standard operating practices, this low complication rates should be reproduced in all institutions utilizing any large vessel stent in clinical practice. Lack of sharp edges possibly ensured that there were no instances of balloon ruptures.

4.6 | Limitations

An animal study for testing biocompatibility of Zephyr was not done, as the material properties were almost similar to AndraXL, another Co–Cr alloy stent. However animal studies are planned in future. This first in man observational study did not compare Zephyr with other currently available unmounted large vessel stents. The study population is small and this resulted in very limited number of patients in each anatomical, morphological and lesion complexity subsets. As the median follow-up of the patients in this cohort was 12 months, a longer follow-up is needed to study the clinical utility of this new stent.

5 | CONCLUSION

In this first-in-man clinical use, this new hybrid-cell design Co–Cr stent proved to be safe and effective in relieving stenosis of large vessels including aorta, branch pulmonary arteries and right ventricular outflow conduits. It proved its utility in wide variety of lesions including de novo congenital stenosis, post inflammatory stenosis, post-surgical scarred lesions and more resistant previous metallic stented lesions. Lack of stent recoil, foreshortening and fractures seem to be an advantage. A new design large vessel stent should ideally be studied in multiple centers on a larger study population in a wide range of lesions in varying anatomy, different morphological complexity and different lesion resistances to study its safety, feasibility and utility and long-term outcomes. Zephyr stent may be a useful addition in the armamentarium of the pediatric and structural interventionists.

IMPACT ON CLINICAL PRACTICE

Cobalt chromium stents are increasingly utilized due to lower profile, better radio-opacity, conformability to curves and resistance to fractures. While the current hybrid design Co–Cr stents like AndraXL have the problem of fore-shortening, a novel designed Zephyr stent with C and S polylinks prevents foreshortening and this facilitates precise choice of length of the stents in diverse clinical lesions.

CONFLICT OF INTEREST

The authors declare no potential conflict of interest.

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