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Preliminary testing and evaluation of the renata minima stent, an infant stent capable of achieving adult dimensions

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Abstract

Objectives: This study sought to obtain in vivo data on a new stent and delivery system specifically designed for implantation in infants with the ability to be enlarged to adult dimensions.

Background: There are no endovascular stents designed for or approved for use in infants, nor is there a stent capable of being implanted at infant vessel diameters and achieving adult size while maintaining structural integrity. The Minima stent was designed to address these needs.

Methods: This study was performed in 6 piglets who underwent implantation of 22 Minima stents into the following locations: aorta (n = 11), branch pulmonary arteries (n = 6), and central veins (n = 5).

Results: Successful deployment occurred in 21/22 attempts. Two instances of post-deployment migration occurred. Stents were re-expanded at 1, 2, 3 and 5 months after implant. All stents regardless of location could be re-dilated to the intended diameter to keep pace with somatic growth (implant diameter 6.9 +/− 1.2 mm; final diameter 16.1 mm +/− 1.4 mm). Histopathology at 1 and 5 months demonstrated widely patent vessel lumens with stent apposition to vessel wall, early mild inflammatory response surrounding stent struts, typical vascular damage and healing response to acute dilation and a progressive smooth neointimal growth covering stent struts over time.

Conclusions: In this in vivo study of the Minima stent, there was high implant success, predictable re-dilatability to adult diameters and favorable histopathology. Further study is warranted.

KEYWORDS

congenital heart disease, pediatric intervention, stent, vascular stenosis

Abbreviations: ACT, activated clotting time; ECMO, extra corporeal membrane oxygenation; IV, intravenous; LPA, left pulmonary artery; MPA, main pulmonary artery; RPA, right pulmonary artery

1 | INTRODUCTION

The use of endovascular stents in congenital heart disease was first described more than 30 years ago.[1] Soon thereafter pediatric cardiologists began implanting stents in infants.[2,3] While these procedures have now been performed for decades, there continue to be numerous drawbacks, including: (a) no stent specifically designed or FDA-approved for use in infants, (b) continued use of off-label stents, and (c) inability to re-dilate stents placed in infancy to adult vessel diameters while maintaining structural integrity. The Renata Minima Stent was designed to address these issues. Herein we report results following implantation in a growing animal model.

2 | MATERIALS AND METHODS

2.1 | Minima stent and delivery system

The Minima Stent is a cobalt chromium, balloon expandable, stent which comes pre-crimped onto a Minima Delivery System balloon. The unique cell design allows for a wide range of stent diameters ranging from 4 to 22 mm (Figure 1). The stent is designed to maintain structural integrity and radial strength over the entire range of diameters. As the stent is expanded to larger diameters it shortens predictably in length (Figure 2). All stents tested in this study had an initial length of 17 mm.

The Minima Delivery System consists of an inner balloon catheter and outer braided polymer covering catheter with an ergonomic operator handle designed for simple axial translation (Figure 1). Currently, the delivery balloon is available in a 6 or 8 mm diameter. The outer catheter forms a seamless leading edge with the distal tip of the balloon and is designed to protect the stent and facilitate safe passage through the vascular system and eliminate the need for a long sheath. The outer diameter is comparable to a 4 French sheath and can be delivered directly over a standard 0.014″ or 0.018″ guide wire or via a 6Fr sheath.

2.2 | Initial animal implants

Stents were implanted in six piglets, weighing 4.6 (+/− 0.5) kg. Study approval for this non-GLP initial work was obtained from the University of Tennessee Health Science Center Institutional Animal Care and Use Committee, Memphis, Tennessee. Piglets were pre-treated with aspirin and were pre-medicated with 6 mg/kg telazol, intubated, maintained on isoflurane with neuromuscular blockade and mechanically ventilated. IV cefazolin (25 mg/kg) and heparin (200 U/kg) were administered. Femoral venous and arterial access were obtained percutaneously and a 6 Fr sheath placed. Target vessels were examined using single plane angiography in an Artis Pheno (Siemens, Munich, Germany) suite. Minimal lumen diameter (MLD) was recorded as the

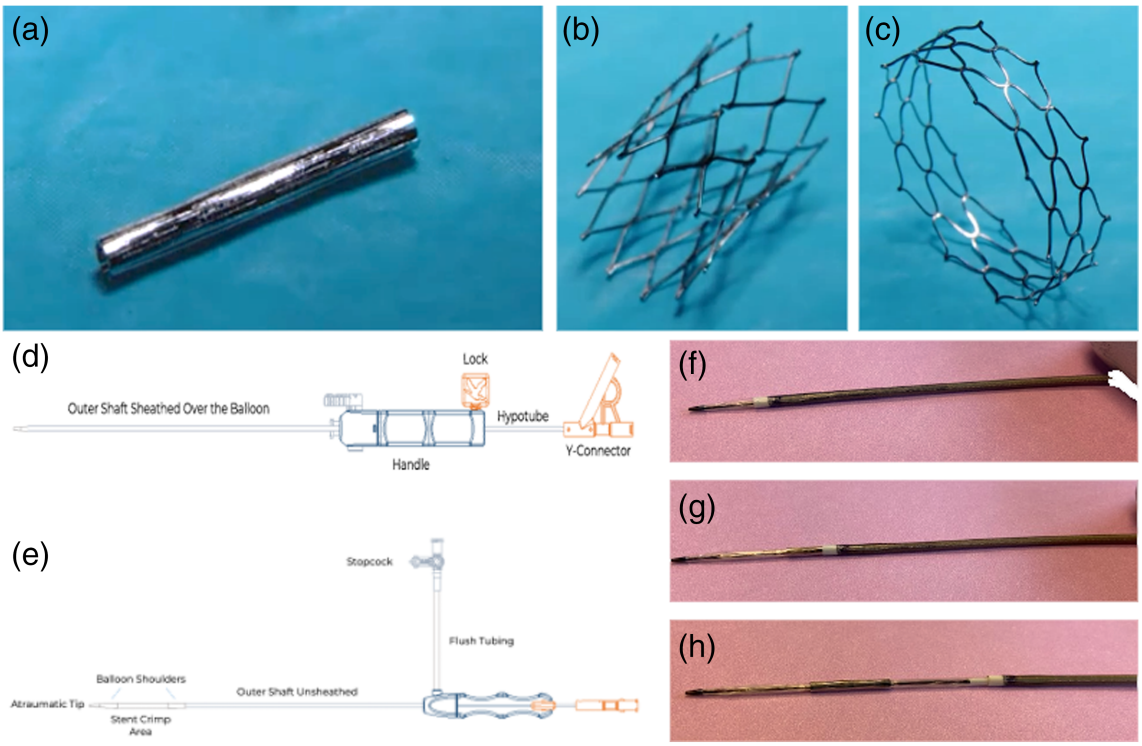


FIGURE 1 Renata minima stent and delivery system. Stent as it would be mounted on delivery balloon (a), expanded to 8 mm (b) and expanded to 22 mm (c). Schematic drawings of the delivery system viewed from above (d) with the stent fully covered by the outer catheter which is locked in place at the back of the control handle. When viewed from the side and unlocked (e), the outer catheter has been pulled back along the rigid hyoptube to uncover the stent and allow for angiography via a flush tubing attached to the outer catheter. (f)-(h) Sequential photographs of the catheter tip as the outer protective catheter is withdrawn to uncover the stent

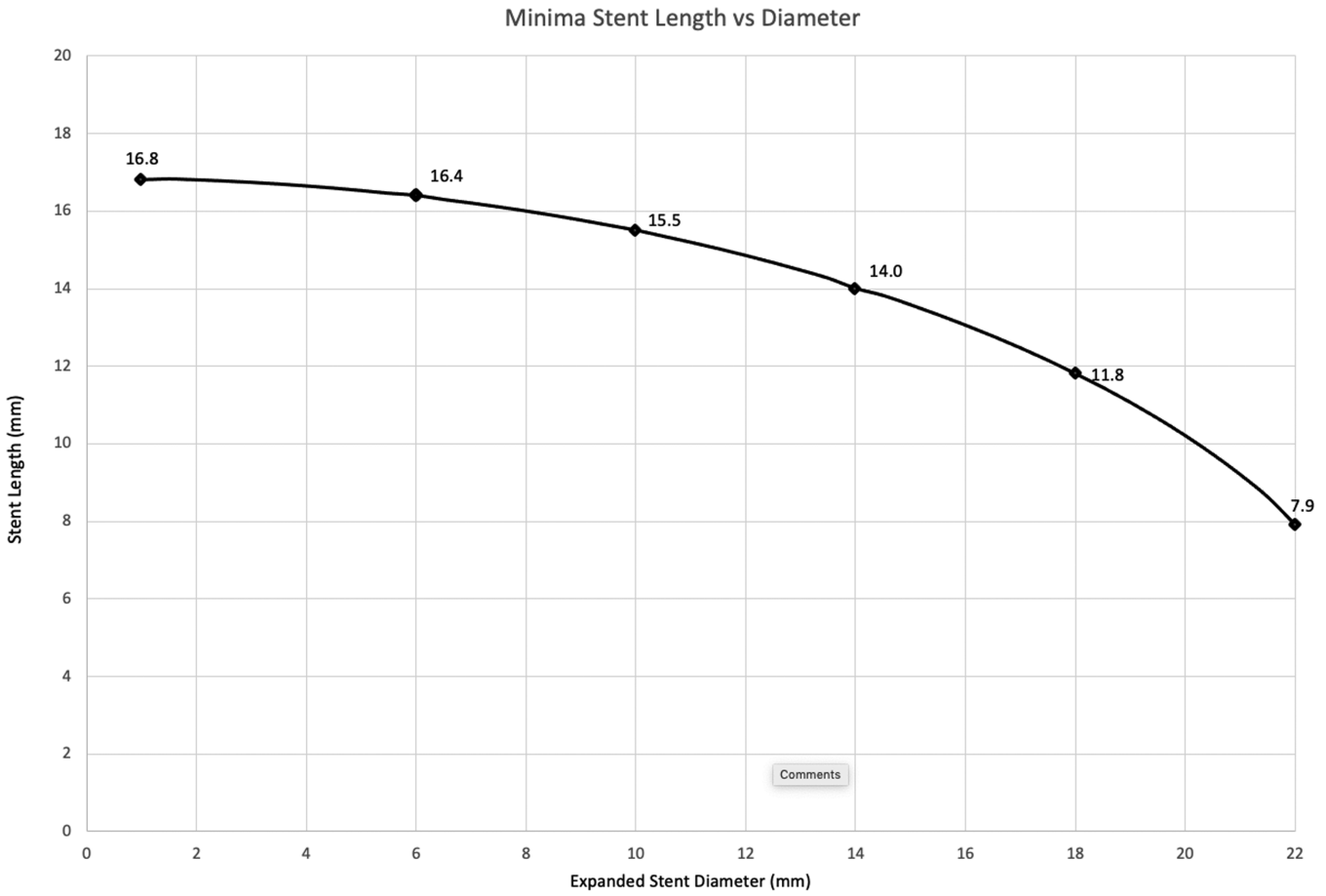


FIGURE 2 Minima stent foreshortening. Graphic representation of bench testing data illustrating stent length foreshortening (y-axis) as a function of increasing stent diameter (x-axis). Note the exponential increase in foreshortening at larger (> 14 mm) diameters

smallest diameter of the vessel measured at end systole. Vessels were crossed with a 0.014″ Spartacore guide wire (Abbott, Minneapolis, MN) and the delivery system advanced over the wire to the intended location. The outer catheter was withdrawn, and the stent deployed by inflating the delivery balloon with a digital manometer until the desired diameter was achieved depending on inflation pressure. Small volume "hand-angiograms" were performed through the side-arm of the delivery catheter prior to deployment. Stents were implanted using balloon diameters 1–2 mm larger than the target vessel. Semi-compliant balloons were used, allowing for final implant balloon diameter to be slightly larger or smaller than the nominal balloon diameter. Stent recoil was defined as MLD of the deployment balloon minus stent MLD after implant, divided by MLD of the deployment balloon. Each piglet (with exception of animal #4) had multiple stents implanted and following the initial procedure were extubated, recovered and maintained on oral cephalexin for 2 days post-procedure and aspirin (81 mg/QD) with Clopidogrel (1 mg/kg/QD) during follow-up.

2.3 | Stent re-dilation

Two piglets (10 stents) underwent stent implantation with subsequent stent re-dilation and sacrifice 1 month after implant to provide early feasibility and histopathology data. Three piglets were re-catheterized and underwent stent re-dilation between 2 and 3 months after initial implant and again at 5 months. One piglet underwent a single re-catheterization and re-dilation 5 months after implant. In all cases of stent re-dilation, pre-intervention angiograms were performed, and re-dilation was done using sequentially larger balloon diameters beginning with 2 mm larger than the stent MLD and completed when stent MLD equaled (or slightly larger than) the adjacent unstented vessel. Following final re-dilation and angiography, pigs were euthanized. Necropsy was performed and vessels destined for histopathology were prepared as described below.

2.4 | Histopathology

Stented vessels were excised, flushed, and fixed in 10% neutral buffered. Radiography, gross and histopathology was performed (CVPath Institute, Inc, Gaithersburg, MD). All implanted vessel segments were dehydrated in a graded series of ethanol and xylenes and embedded in Spurr epoxy resin. After polymerization, 2-3 mm sections were sawed from two areas of the devices. Sections from the implants were ground and polished with the EXAKT grinding and polishing system to a thickness of <100 μm and stained with Hematoxylin and Eosin. All sections were examined by light microscopy for the presence of injury, inflammation, embolism and necrosis.

2.5 | Statistical analysis

Continuous data are presented as mean ± *SD*. Categorical data are presented as numbers and percentages. Student's two-tailed paired *t* test were used to compare vessel diameters at various time intervals. A *p*-value of <.05 was considered statistically significant. Statistical analysis was performed using IBM SPSS Statistics (version 25.0, IBM, Armonk, NY). The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

3 | RESULTS

3.1 | Initial stent implantation

The average weight at the initial procedure was 4.6 +/− 0.5 kg. Stents were successfully delivered to intended target vessels 21/22 (95%) attempts (Table 1). A single failure occurred using an early delivery system prototype which failed to reach the LPA. This stent (#14) was deployed in the inferior vena cava and subsequently re-dilated in that position. All other stents were delivered to the target vessel and successfully deployed to the intended diameter. There were two instances (stents #15 and #20) of stent migration to the MPA after successful deployment into the LPA. Both occurred during delivery system withdrawal. Neither caused any obstruction, nor underwent any further intervention. Stents were implanted with an average balloon inflation pressure of 11.8 +/−2.1 atm (atm) resulting in an implant diameter of 6.9 +/− 1.2 mm and stent length of 16.9 +/− 0.8 mm. Average stent recoil was 0.8 mm +/− 0.5 or 9.8% +/− 6.2.

4 | RE-CATHETERIZATION AND RE-DILATION

4.1 | Early re-catheterization

Five animals with an average weight gain of 20.6 kg (+/− 14.2) and 18 previously implanted stents underwent re-catheterization between 1 and 3 months (average = 54 days) after stent implantation (Table 1). In-stent restenosis was not seen in any previously implanted stents. Pre-re-dilation stent diameter was 6.0 +/− 1.1 mm and re-dilation was successfully performed in all 15 stents where it was attempted with no procedural complications. Stent diameter increased by 54%

TABLE 1 Initial implant procedure

	Stent #	Implant wt (kg)	Location	Interval #1 (months)	Weight (kg) interval #1	Re-dilation attempted	Interval #2 (months)	Weight (kg) interval #2	Re-dilation attempted
Animal 1	1	5.3	Ao	1	14	Yes	NA	NA	NA
	2		Ao			Yes			NA
	3		JV			Yes			NA
	4		JV			*No*			NA
Animal 2	5	4.9	RPA	*1*	*13*	*No*	NA	*NA*	NA
	6		LPA			*No*			NA
	7		JV			Yes			NA
	8		JV			Yes			NA
	9		Ao			Yes			NA
	10		Ao			Yes			NA
Animal 3	11	3.9	Ao	3	39	Yes	5	84	Yes
	12		Ao			Yes			No
	13		Ao			Yes			Yes
	14		IVC			Yes			Yes
Animal 4	15	4.2	LPA	3	48	No	NA	NA	NA
Animal 5	16	4.7	LPA	2	35	Yes	5	109	Yes
	17		RPA			Yes			No
	18		Ao			Yes			Yes
	19		Ao			Yes			Yes
Animal 6	20	4.7	LPA	5	106	No	NA	NA	No
	21		Ao			Yes			Yes
	22		Ao			Yes			Yes

Abbreviations: Ao, aorta; IVC, inferior vena cava; JV, jugular vein; LPA, left pulmonary artery; MLD, minimal, luminal diameter; NA, not applicable; RPA, right pulmonary artery.

+/− 25% ($p < .001$) and foreshortening was minimal with a final stent length of 16.1 +/−1.5 mm (Figure 3).

4.2 | Late re-catheterization

Three animals with 11 previously implanted stents and an average weight gain of 95 kg +/− 13.1 since implant underwent re-catheterization 5 months after the initial procedure. Re-dilation was performed on eight stents (Figure 4). Angiography did not demonstrate any evidence of in-stent restenosis prior to re-dilation whether stents had been previously re-dilated or not. Pre-re-dilation stent diameter increased from 9.9 mm +/− to 16.1 mm +/− 1.4 mm with no procedural complications. This represents a 61% +/− 28% increase since last procedure or a 125% +/− 35% increase in diameter since implant. Stents #21and #22 were purposely over dilated with respect to the surrounding unstented native vessel with an 18 and 16 mm balloon, respectively (Figure 5). At these larger diameters, significant stent foreshortening was observed with an average final stent length of 13.1 (+/−1.5) mm or stent foreshortening of 23% +/− 9%. There were no procedural complications. A single strut fracture was noted after re-dilation to 16 mm in one aortic (#22) and one LPA stent (#16). Following this procedure all animals were sacrificed and one aortic and two branch pulmonary artery specimens sent for gross and histopathology.

5 | PATHOLOGY

Gross and histopathologic examination of stented vessels was performed at 1 (Figures 6 and 7) and 5 (Figures 8 and 9) months after implantation. There was no gross evidence of thrombosis on the stent surface or elsewhere within the stented vessel at either time point. Several stents which were re-dilated just prior to sacrifice showed evidence of hematoma corresponding to adventitial hemorrhage extending almost halfway around the circumference of the outer wall.

5.1 | Early histopathology

Two aortic and one RPA sample were examined 1 month after initial implantation (Figures 6 and 7). All vessels showed widely patent lumens and well apposed struts to vessel wall. The formation of neointimal cell growth was present in varying degrees in all stented vessels. Underlying tissue response consisted of organizing

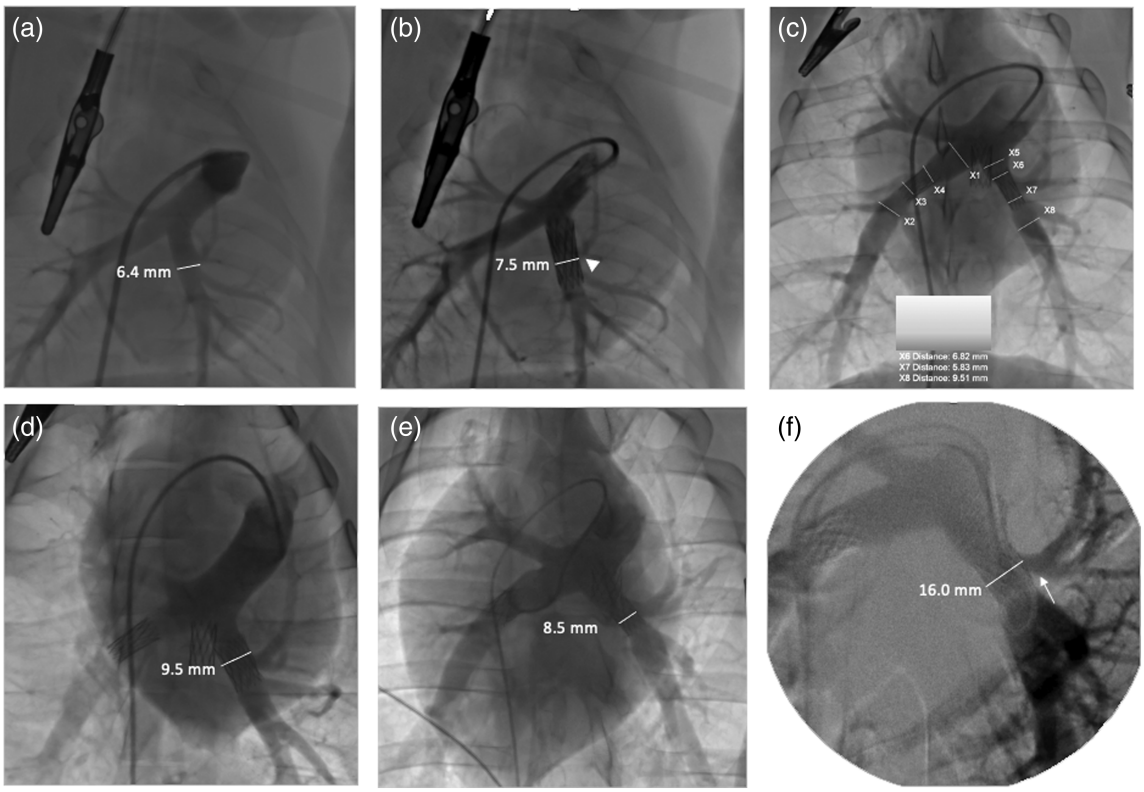
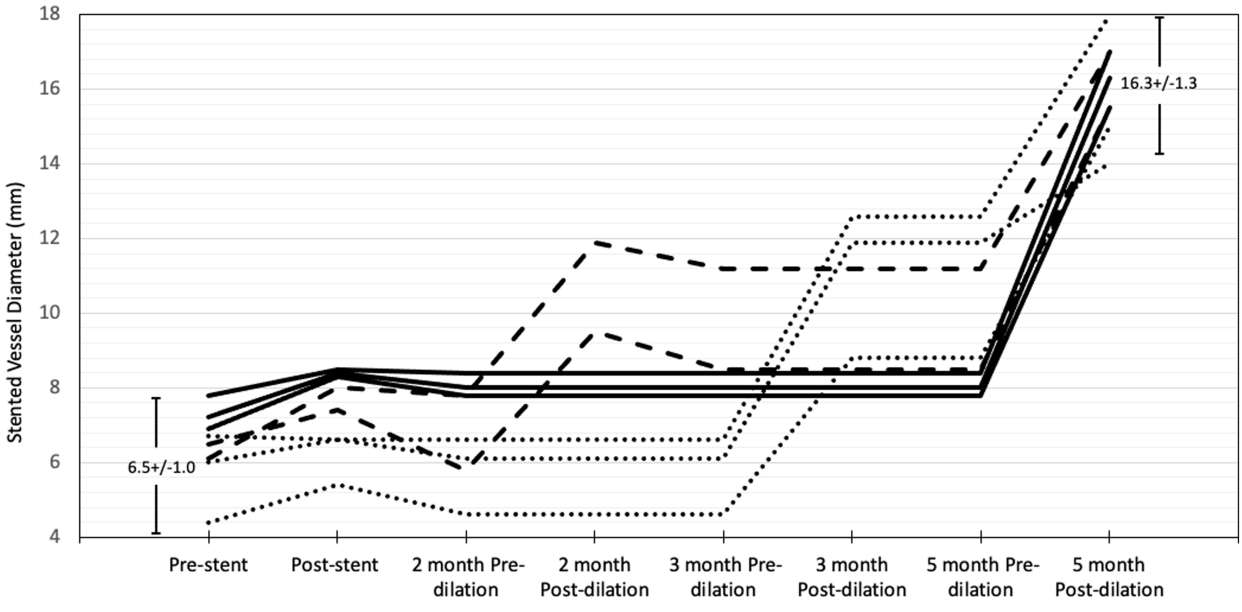


FIGURE 3 Implant and re-dilation of LPA stent (Animal #5, stent #16). Pre-implant pulmonary angiogram (a) and post-LPA stent implant (b) using an 8 mm diameter balloon. Note the LPA upper lobe branch crossed by the stent (arrowhead). Pre-re-dilation angiogram (c) 2 months after implant demonstrating no significant in-stent restenosis and following re-dilation (d) with a balloon diameter of 10 mm. Final pre-re-dilation LPA angiogram (e) 5 months after implant and a final angiogram (f) after re-dilation with an 18 mm balloon. Note persistency patency of the left upper lobe branch throughout the study period (arrow)



Stent location	Pre-stent	Post-stent	2 month Pre-dilation	2 month Post-dilation	3 month Pre-dilation	3 month Post-dilation	5 month Pre-dilation	5 month Post-dilation
Aorta	6.7	6.6			6.1	11.9	11.9	14
Aorta	4.4	5.4			4.6	8.8	8.8	15
IVC	6	6.6			6.6	12.6	12.6	18
LPA	6.5	7.4	5.8	9.5			8.5	15.5
Aorta	6.1	8	7.8	11.9			11.2	17
LPA	7.2	8.4					8	16.3
Aorta	7.8	8.5					8.4	17
Aorta	6.9	8.3					7.8	15.5

FIGURE 4 Graphic display of chronically re-dilated stents. Stents were re-dilated at 2 and 5 months (dashed lines), 3 and 5 months (dotted lines) and at 5 months only (solid line). All stents could be significantly enlarged irrespective of time interval between re-dilations, during a period of rapid animal weight gain (4.7–99.6 kg) which mimicked expected growth from infancy to adulthood

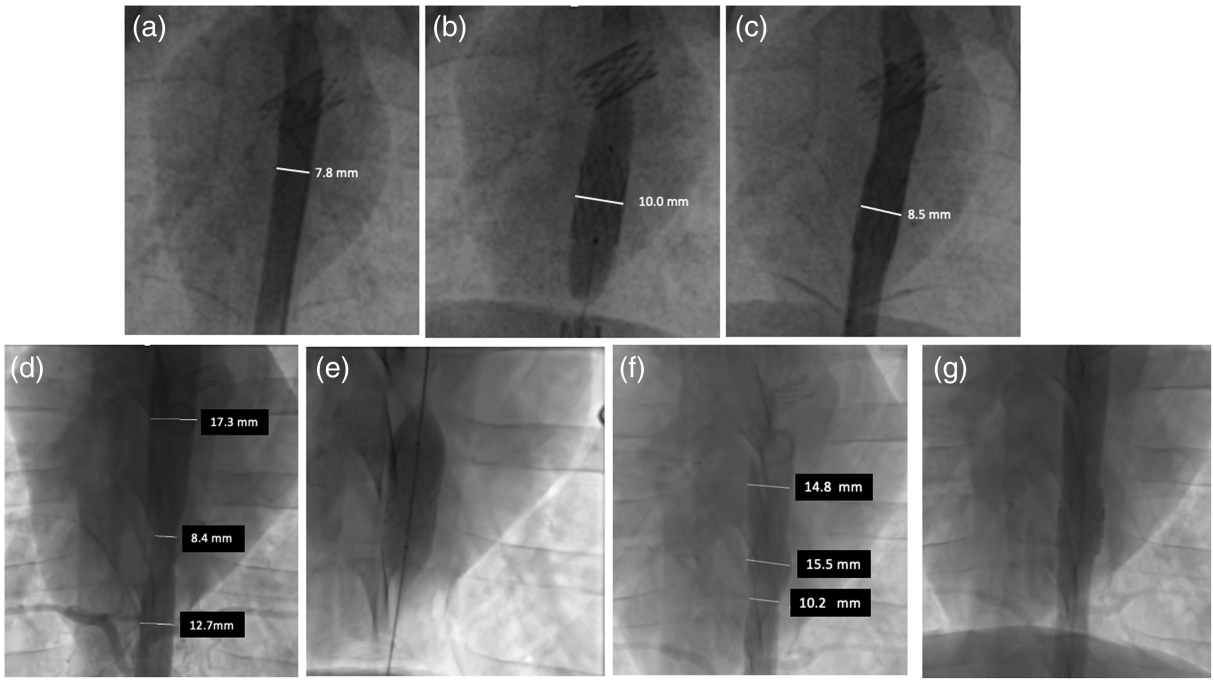


FIGURE 5 Animal 6, Stent #21, implant and subsequent re-dilation. Initial thoracic aorta stent implant showing pre-implant vessel diameter (a), maximum balloon inflation during implant (b) and implant result (c). Note the implant balloon is slightly oversized for the native vessel and stent recoil observed. Re-dilation was performed 5 months and 101 kg weight gain later (d)-(g). There has been virtually no reduction in stent diameter despite significant somatic growth (d). Maximum balloon used for re-dilation was 18 mm (e), oversized when compared to the surrounding native vessel. Follow-up angiogram demonstrates a stent that has been over-dilated resulting in some aortic wall irregularity consistent with dissection or contained pseudoaneurysm (f). After implantation of an IntraStent MaxLD (g) telescoped within the Minima™ stent there is improved appearance of the aortic wall which continues to be oversized in the area of the stents

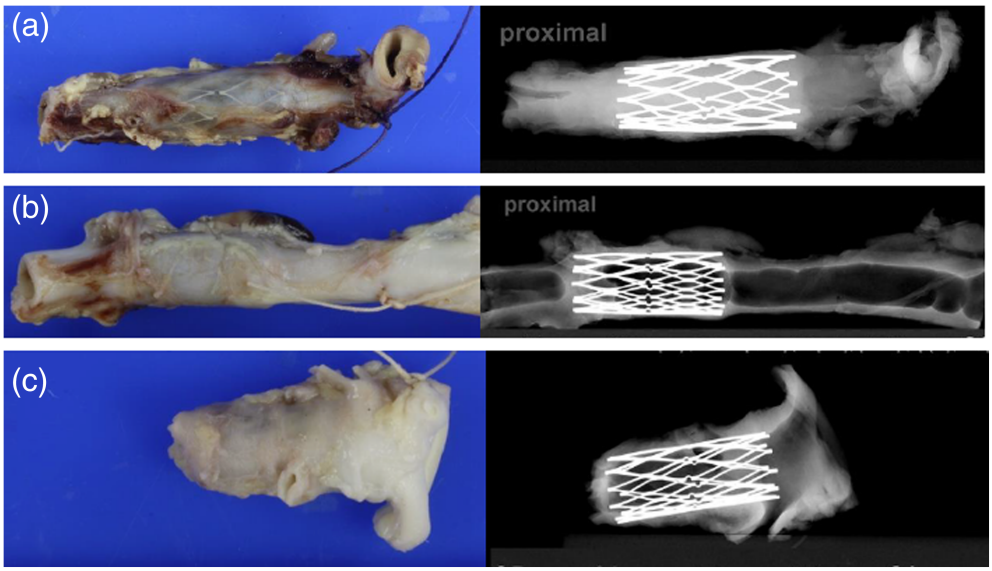


FIGURE 6 Postmortem gross and radiographic appearance of three stented vessels 1 month after implantation. All vessels demonstrate wide and even stent expansion within the vessel lumens. (a) Infrarenal aortic stent implanted at 6 mm and re-dilated to 8 mm prior to sacrifice. (b) Suprarenal aortic stent implanted at 7.5 mm and re-dilated to 8.3 mm prior to sacrifice. (c) Right pulmonary artery stent implanted at 7.8 mm and not re-dilated prior to sacrifice

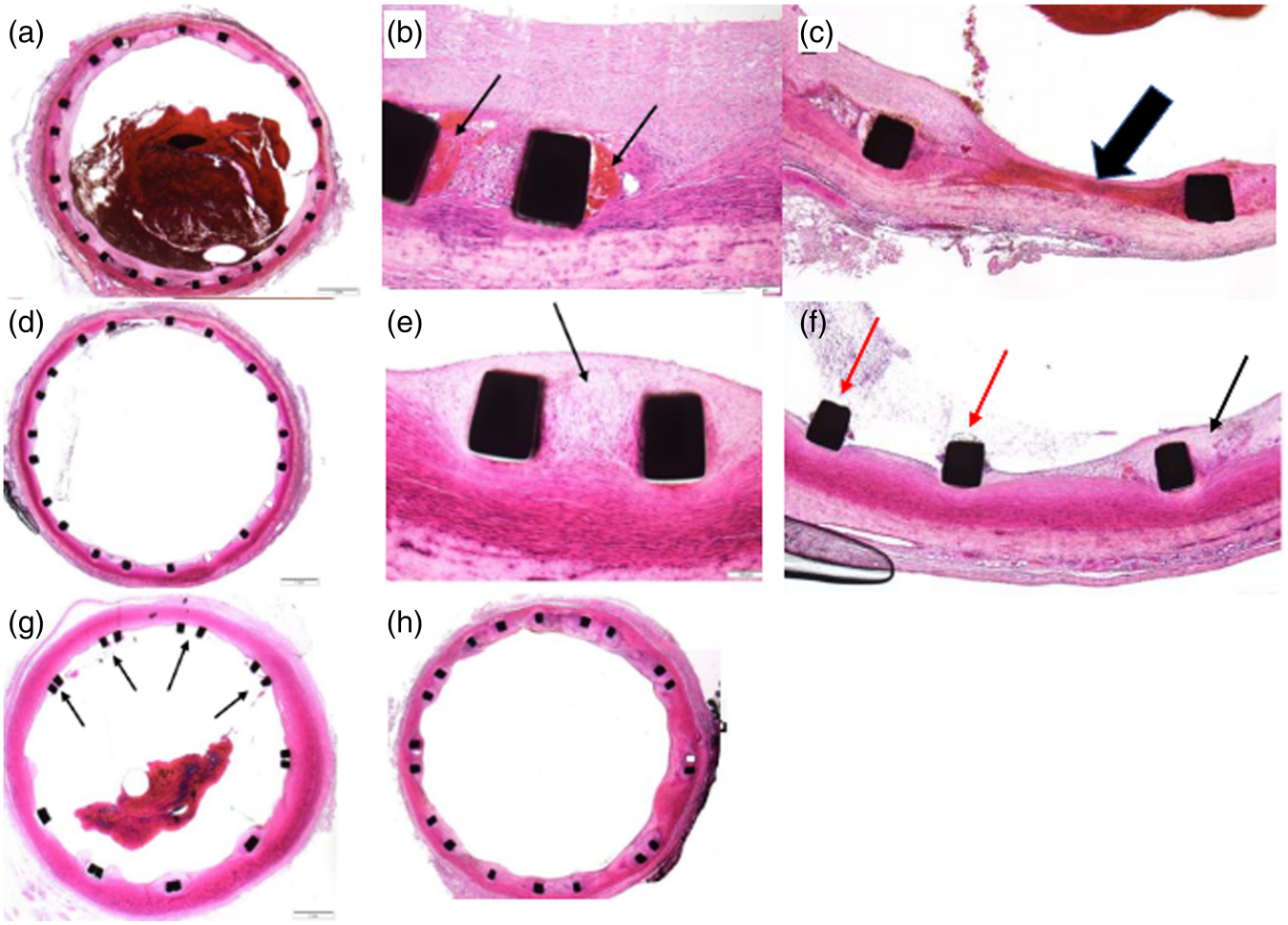


FIGURE 7 Transverse histological sections from the 3 stented arteries corresponding to Figure 6. (a) Infrarenal aortic stent showing widely patent lumen partially filled with postmortem clot and struts with complete incorporation with organizing neointimal growth. (b) Focal areas of medial disruption beneath the stent struts with some red blood cell extravasation around the struts (arrows) as well as a focal area of medial disruption (c) with fibrin deposition (thick arrow). (d) Suprarenal aortic stent showing a widely patent lumen with stent widely expanded with struts well-apposed to the vessel wall. Incorporation of the stent struts with smooth muscle neointima (e, arrow) as well as some areas of bare struts (f, red arrows) adjacent to an incorporated strut (black arrow). Histologic images of the proximal (g) and distal (h) RPA stent demonstrating stent struts in the distal section with complete incorporation while the proximal section showed mostly bare or partially incorporated struts consistent with non-apposition of the struts at the ostia of the vessel

fibromuscular tissue and mild–moderate strut-associated inflammation comprised mostly of chronic inflammatory cells. Evidence of vessel wall injury were noted in the aortic sections of both animals which were re-dilated just prior to sacrifice.

5.2 | Late histopathology

Histopathology was performed on two pulmonary artery stents, one of which was re-dilated 2 months after implant (Figure 8) and one which was re-dilated at 2 months and 5 months after implant and one aortic stent which was re-dilated (purposely over-dilated) 5 months after implant (Figure 9). This stent was re-dilated from an initial implant diameter of 8.3 mm to final diameter of 15.5 mm just prior to sacrifice correlating to histopathology which found well apposed stent struts throughout coupled with acute aortic wall damage (Figure 9). Similarly, a recently re-dilated LPA stent demonstrated a widely expanded stent with all struts exhibiting irregular neointimal growth and evidence of vascular wall damage (Figure 9). By contrast, an RPA stent which had been in place for 5 months with only a single re-dilation performed 3 months prior to sacrifice demonstrated all stent struts with full neointimal incorporation, isolated areas of healed medial disruption and no acute vessel trauma (Figure 8).

6 | DISCUSSION

Endovascular stents have been used to treat a wide variety of vascular stenoses in children for the past 30 years, however, there currently exists no stent that is: (a) designed for implantation in infants, (b) FDA approved for use in infants and (c) designed to be implanted at infant vessel diameters and expandable to adult dimeters while maintaining structural integrity. Despite this gap in availability of bespoke technologies, numerous studies have demonstrated the benefits of stent implantation in infants.[3-10] Some of these benefits include: predictable improvement in vessel diameter associated with a reduction in pressure gradients,[3-10] improved safety compared to angioplasty in the early post-operative state,[10,11] delay or avoidance of surgical intervention[3,5,6,10] and improved survival when performed in infants requiring ECMO support following cardiac surgery.[5] Abraham et al[5] described 75 catheterizations performed in children on ECMO with a median age of 1.5 months. The most common intervention performed was stent implantation and the authors found that survival was significantly better for patients who underwent intervention compared to those who did not ($p < .001$).

A major concern regarding stent implantation in infants has surrounded the question of safety and efficacy of re-dilation as well as the inability of these stents to reach adult diameter. In 1993, Morrow et al, were the first to demonstrate successful stent re-dilation following implantation in the aorta of a juvenile swine model.[12] Of note, these animals had an implantation weight of 18.6 kg, comparable to a school aged child, and the stent implanted (via a 12f sheath) was capable of reaching an adult diameter. Subsequently, numerous studies have demonstrated that re-dilation of smaller stents placed "off-label" in infants is predictable, safe and effective until a stent reaches its maximum diameter. With currently available technology that diameter is 4–6 mm for coronary stents and 10–12 mm for peripheral stents, far less than the normal diameter of an adult pulmonary artery or aorta. This obligates children who receive a stent in infancy to have it surgically removed or undergo a procedure known as "unzipping," referring to purposeful stent fracture with ultra-high-pressure balloons.[13,14] This results in vessel expansion that is limited to a small portion of the vessel where the metal has been fractured as opposed to being evenly distributed throughout the circumference of the vessel. Both of these therapies result in a loss of stent integrity and have unpredictable outcomes in terms of future unobstructed vessel patency.

The Renata Minima™ Stent was designed to address these issues by providing a lifetime stent solution for infants requiring treatment of a vascular stenosis. Key findings of the current study include: (a) Demonstrating the ability to consistently deploy a small diameter

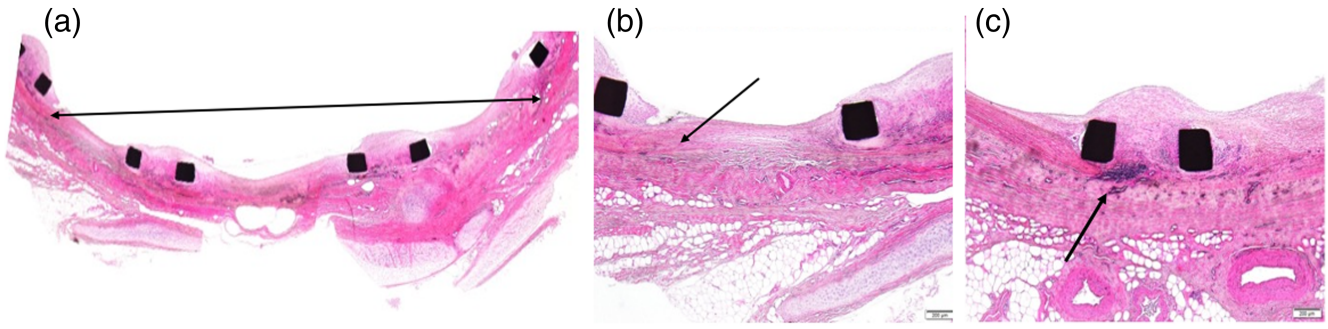


FIGURE 8 Chronic histologic images stent # 17, RPA stent re-dilated 3 months prior to sacrifice. Uniformly well-apposed stent struts with extensive covering of struts. (a) The double arrow delineates an area of healed medial disruption from earlier implant and/or re-dilation. Higher power images (b, c) of the margins of the same area demonstrating a disrupted portion (b) of the media (arrow) on one end and organized neointimal growth (c) incorporating stent struts with a small focus of chronic inflammatory cells (arrow) on the other end

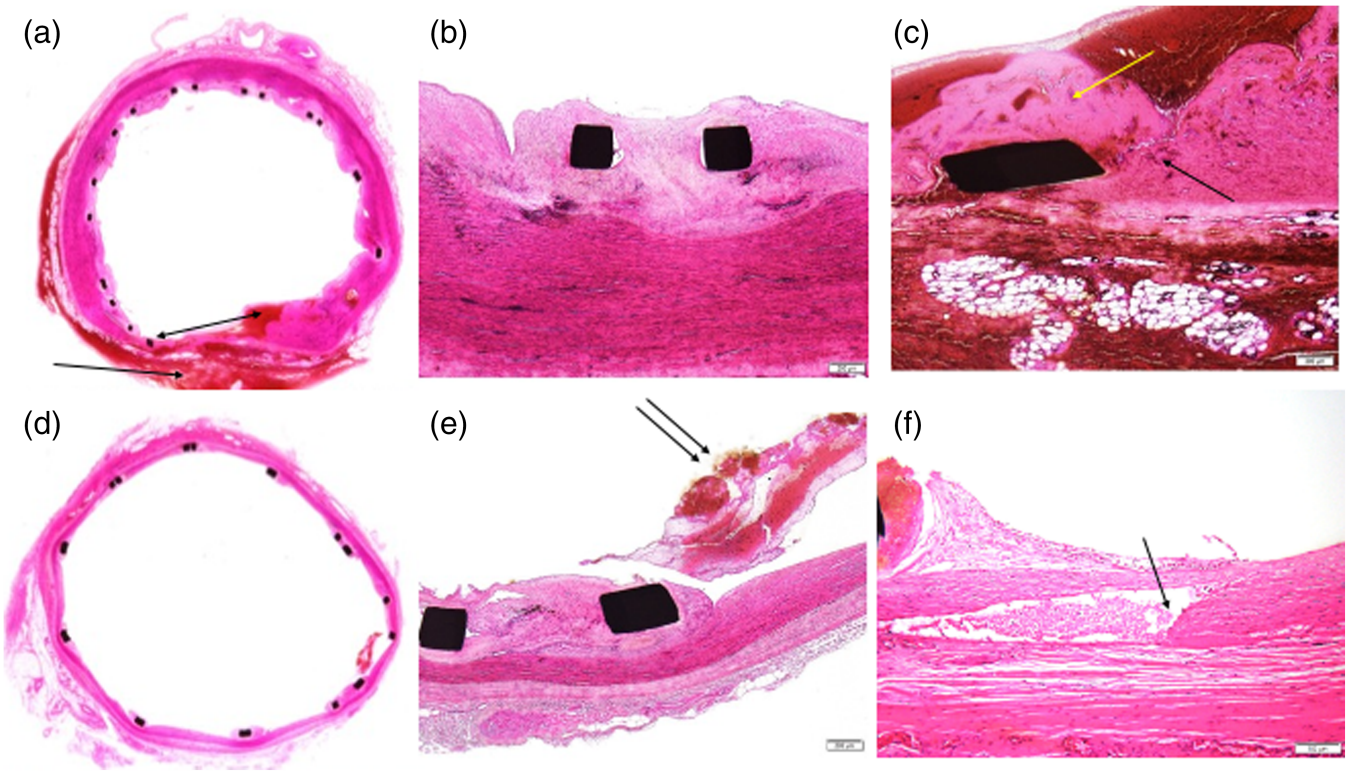


FIGURE 9 Chronic histologic images of re-dilated aortic stent #22 and re-dilated left pulmonary artery stent # 16. Low and higher power images (a-c) of stent # 22 demonstrate a widely patent lumen and well apposed stent struts along the surface. (a) A large area of medial disruption the length of which is illustrated by the double arrow and associated with an area of adventitial hemorrhage (single arrow). Higher power magnification shows some stent struts incorporated with organized neointimal growth (b) while others (c) are adjacent to ruptured ends of the media (black arrow) associated with platelet thrombus covers the ruptured ends (yellow arrows). Low power image (d) of stent # 16 demonstrate a widely patent lumen and well apposed stent struts mostly covered by neointimal covering. (e) Higher power image of LPA stent struts incorporated with organized neointima with adjacent unorganized thrombus (double arrow) and (f) an area of medial disruption adjacent to a stent strut (arrow)

stent via a low profile, covered delivery system without the need for a long sheath, (b) Consistent and predictable re-dilatability to adult diameters while maintaining stent integrity, and (c) Reassuring early and longer-term histopathogy for both re-dilated and non-re-dilated stents.

6.1 | Delivery system and deployment

In this study the low profile covered delivery system tracked consistently over a standard guide wire, protecting the intracardiac anatomy from the stent and vice versa. With an outer diameter comparable to a 4F sheath, this system could eliminate the need for placing a long sheath in infants which can result in hemodynamic instability and increased complication rates.[15] Stent implantation was predictable with no significant foreshortening during initial implant, when accuracy and precision of placement in the infant vasculature leaves little room for error. Stent recoil of approximately 10% during implant, was observed, consistent with published behavior of smaller diameter cobalt chromium stents.[16] This allows operators to select appropriate balloon diameters to ensure precise stent MLD at initial implant. It was possible to implant this stent as small as 4 mm and as large as 8.5 mm with precision and a predictable outcome. While we did experience two stent migrations following successful deployment into the LPA, we believe this was a result of relative under sizing in a highly compliant normal vessel in the absence of any stenosis to aid in stent anchoring rather than an inherent issue with the stent design.

6.2 | Re-dilatability to adult diameters

The cell structure of the Minima Stent™ consistently allowed for serial enlargement from infant to adult vessel diameters without loss of stent structural integrity. Enlargement was simple to do with standard angioplasty balloons inflated to moderate inflation pressures. While the stent is capable of reaching 22 mm diameter, no native vessel in this animal model grew to a size that could accommodate this degree of re-dilation during this study. The degree of foreshortening observed at larger diameters is comparable to other commercially available large diameter stents and may be of minimal clinical significance in a larger

child or adult, where another (adult-sized) stent could be placed in a telescoping fashion should foreshortening result in recurrence of stenosis. The acute and chronic, gross and histopathologic specimens from all pulmonary artery and aorta in this study consistently showed typical incorporation of stent struts into vessel wall, early formation of neointimal covering, mild inflammatory response and typical vessel wall damage related to re-dilation. This is comparable to previously published reports of other stents currently used to treat a variety of congenial vascular stenoses.[12,13] We did observe two single stent strut fractures in two stents upon re-dilation to larger diameters, neither of which appeared to compromise structural integrity, however, this phenomena will require further exploration.

6.3 | Potential alternative therapies

Other potential therapies being evaluated for this unmet need in infants include biodegradable stents[17,18] and stents designed with predetermined breakage points to allow for expansion to larger diameters.[19] The advantages of biodegradable stents or scaffolds in this setting has been recognized for decades with a major potential advantage being the possibility of avoiding the need for future re-dilation as a child grows. That being said, a number of hurdles face adaptation of these technologies to the pediatric population at this time, including: an absence of clinically available pediatric-specific devices, current biologic responses which include excessive neointimal and neoproliferative changes leading to early re-stenosis and an increased risk of thrombosis.

Another novel approach to this problem using a stent designed to fracture at larger diameters has been introduced in Germany and placed in several infants with good early results.[19] Further follow-up will be needed to see how this stent performs clinically once breakage is achieved. Importantly, both of these strategies are designed to sacrifice future stent structural integrity in order to keep pace with growth as opposed to the Minima stent which is designed to provide lifelong vessel support. Further study will be needed to determine if these differences are clinically relevant.

7 | CONCLUSION

This preliminary work suggest that the Renata Minima Stent and accompanying delivery system may provide a valuable treatment option for infants with vascular stenoses and that further evaluation and ultimately human trials are warranted. The use of time tested materials, that is, cobalt chromium, proven safe methodology, that is, serial re-dilation throughout childhood and maintenance of stent structural integrity providing continued vessel support are desirable characteristics of this novel stent.

CONFLICT OF INTEREST

Dr. Evan M. Zahn is Medical Director, Renata Medical. Mr. Eason Abbott and Dustin Armer are officers of Renata Medical.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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