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ORIGINAL ARTICLE

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Optimus covered stent: Advanced covered stent technology for complex congenital heart disease

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Abstract

Aim: To assess the acute results of the first human use of the Optimus covered stent in complex coarctation of the aorta.

Methods and Results: We successfully implanted the Optimus covered stent in eight cases in patients whose preprocedural anatomy looked challenging for currently available covered stents. Six of the patients had native coarctation with one recoarctation following surgical repair. There were no significant complications with reduction in the mean invasive gradient from 22 to 1 mm Hg. The length of stents used ranged from 33 to 57 mm with a median shortening after expansion of 13%. Postprocedural follow-up with magnetic resonance imaging or computed tomography has not shown evidence of fracture or migration or renarrowing. The median duration of follow-up is 10 months.

Conclusions: Preliminary results show that the Optimus covered stent is safe and efficacious for use in patients with coarctation of challenging morphology. A systemic trial will be required to evaluate this stent for more widespread practice.

KEYWORDS
coarctation of the aorta, congenital, innovation

1 | INTRODUCTION

Routine availability of covered stents should lead to an increased confidence and application of stent implantation in complex coarctation and right ventricular outflow tracts.[1,2] There remains concern about the performance of NuMed's Cheatham-Platinum (CP) (NuMed, Hopkington, New York) stent in larger diameter vessels where stretching of the polytetrafluoroethylene (PTFE) covering may lead to relative malfunction of the stent. Occasionally in complex coarctation, one needs to perforate through the PTFE membrane of a covered stent. The behavior of the covering in response to intentional perforation in order to reanimate head and neck vessels is unknown in vitro or in vivo (although this technique has been performed clinically).[3]

The response of the community to the large caliber Avanta V12 (Atrium, Mijdrecht, The Netherlands) stent has been varied with reports of poor acute and medium term performance.[4,5] The Bentley BeGRAFT (Bentley Innomed GmbH, Hechingen, Germany) has recently been CE marked and may offer a covered stent alternative outside the United States, but little has been published regarding this stent so far.[6]

We describe procedural outcomes and early follow-up of the first eight human implants of the Optimus covered stent in patients with complex coarctation of the aorta.

2 | PROCEDURAL METHODS AND RESULTS

The Optimus covered stent (AndraTec GmbH, Koblenz, Germany) represents a novel design of PTFE covered stent; available in a vast array of sizes. Its basic design is very similar to a bare metal stent (Andrastent; Andramed GmBh, Reutlingen, Germany) which has had wide usage in Europe.[4] The Optimus is a non-premounted, balloon expandable, hybrid cell design cobalt chromium stent sandwiched by PTFE membranes which are thermally bonded to all of the metal struts of the stent. One half of a row of cells remains uncovered at either end of the stent (Figure 1). Its hybrid nature allows expansion to greater than 26 mm with acceptable shortening characteristics. The presence of cobalt chromium in the stent's construction promises good radial strength and resistance to fracture. It is available in two sizes; L

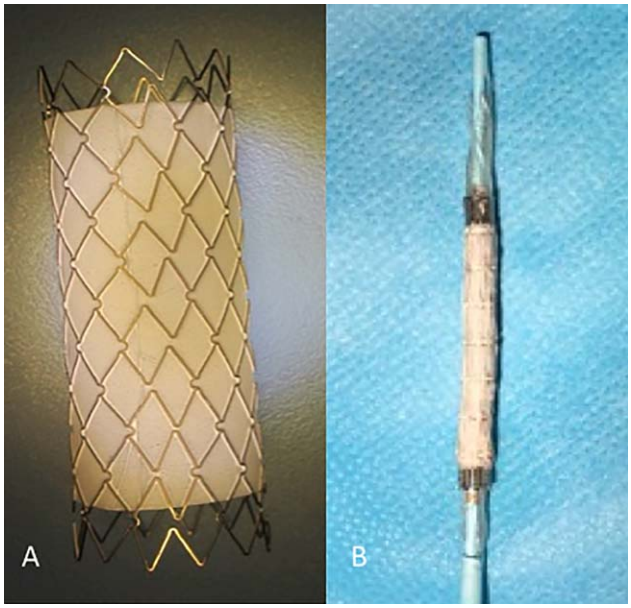

FIGURE 1 The Optimus covered stent. (A) shows the stent expanded and removed from the delivery balloon. Thermal bonding of the PTFE membranes which sandwiches the metal struts between two layers of PTFE gives the impression that the covering has been pressed onto the metal struts. (B) shows the stent crimped onto a Cristal (Balt Medical, Montmorency, France) balloon. The clinical experience with crimping suggests that a sheath profile of 1–2 French sizes larger than the delivery balloon is adequate to comfortably deliver the stent

(recommended expansion range: 6–18 mm) and XL (recommended expansion range 12–26 mm).

We analyzed data from eight consecutive patients from four large European centers (Table 1). The data were collected retrospectively with implanting operators identified via manufacturers' records. All cases were performed on a compassionate use basis after excluding the use of CE marked stents. Implants were performed between June 2015 and June 2017. To prepare ourselves in case of requiring to perforate through the covering during a clinical case (unintentional or intentional jailing of the head and neck vessels), we performed a limited bench test to examine the response of the PTFE covering of the Optimus stent compared with that of the Cheatham-Platinum (CP) covered stent (Figure 2).

For our bench test, we implanted a CP covered stent and an Optimus stent in two 3D printed aortic arch models (16 mm internal diameter). We mounted each stent on an 18 mm BiB balloon. The stents were implanted to intentionally "jail" the left subclavian artery (LSCA). We perforated the stent coverings using a 035″ vascular access needle via the LSCA. Next, we placed a wire down the descending aorta and passed 10 mm balloons across the perforations, expanded these to 5 atm and then deflated and withdrew the balloons. We then peeled away the 3D printed models to examine the stents. Pictures were taken at every stage as were measurements of the perforation (Figure 2). The PTFE membrane covering the CP stent retracted from the original site of balloon dilation over a period of approximately 10 minutes after withdrawing the deflated balloon. This left a much larger gap in the covering (12.3 × 8 mm) than after the initial 10 mm balloon dilation (9.4 × 5.3 mm) (Figure 2, panel D and E). The hole created in the PTFE of the Optimus stent (4.6 × 3.4 mm) remained stable after 10 mm balloon dilation (Figure 2, panel I). In neither cases did the 10 mm balloon cause fracture nor significant distortion of the cell struts.

In all clinical cases the indication for treatment was a combination of imaging showing significant coarctation plus hypertension and or obstruction of descending aortic flow with a gradient greater than 20 mm Hg.[7] In most cases (n = 5), the compassionate use indication was due to post-stenotic dilation of the aorta. This led to concern that a fully apposed deployment of a CE marked CP covered stent in the dilated aorta may lead to excessive shortening of the stent and extreme stretching of the PTFE, negating many of the benefits of the stent's covered nature.

All procedures were carried out under general anesthesia following local clinical protocols for treatment of coarctation. Femoral arterial

TABLE 1 Patient characteristics and procedural details

	Diagnosis/ indication	Weight (kg)	Age at implant (yr)	Stent size and model (Length)	Balloon diameter	Actual shortening of implanted stent (%)	Predicted shortening of 45 mm long 8 zig CP stent (%)	Complications
1	NaCoA	96	45.8	57 (XL)	26 Alto	23	42	None
2	NaCoA	74	69	38 (XL)	18 Cristal	20	18	None
3	NaCoA	72.2	45.5	43 (XL)	18 BiB	12	16	None
4	NaCoA	63	47	38 (XL)	18 Cristal	13	18	None
5	NaCoA	83.4	41	43 (XL)	20 BiB	18	26	None
6	NaCoA	84	51.5	33 (XL)	18 Cristal	17	12	None
7	ReCoA	75	32.8	57 (XL)	18 BiB	4	16	None
8	ReCoA	17	4	23 (L)	10 Zmed	0	0	None

The projected shortening of equivalent CP stents assumes use of a 45 mm long CP stent expanded to the same size as the Optimus stent in each case. CP shortening data from NuMed Inc website (www.numedforchildren.com). NaCoA, native coarctation; ReCoA, coarctation with previous history of surgical or interventional repair. Crimping techniques: "Hand" describes manual crimping of the stent onto the deflated balloon. "Tape" describes augmenting this process by wrapping sterile umbilical nylon tape around the stent and tightening the tape to aid compression of the stent onto the balloon. Balloons used: AltoSA XL (Andratec GmbH); Crystal (Balt Medical); BiB (NuMed); Zmed (NuMed).

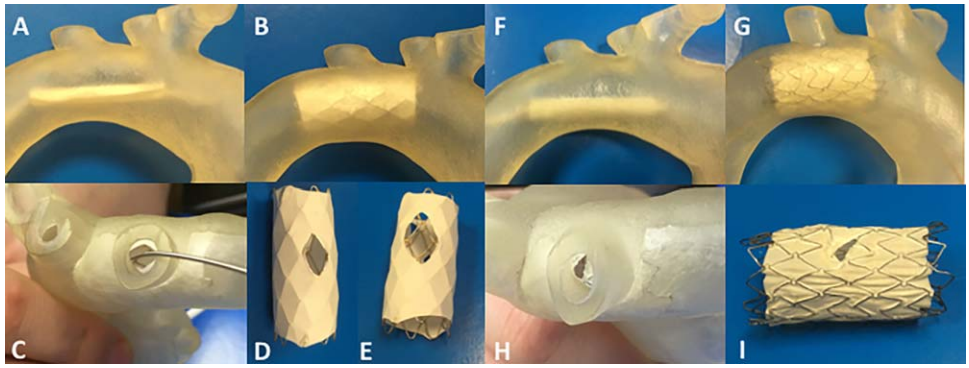

FIGURE 2 Bench testing the Optimus and the CP covered stent. Assessment of in vitro stent behavior after intentional PTFE perforation using the CP covered stent (A–E) and the Optimus covered stent (F–I) in printed aortic models. (A, B, F, and G) show the stents positioned then deployed in the printed aortic (16 mm lumen) models on 18 mm BiB Balloons. (C and H) show the ballooned perforation from the aspect of the LSCA. (D and E) show the CP stent after the 3D model has been peeled away. Over a time period of 10 mins the perforated PTFE membrane under the expansive force of the dilated stent almost doubled in size (E). (I) shows the Optimus stent after removing the 3D model; the dilated perforation in the Optimus PTFE membrane remained stable in size, presumably due to the mechanism by which the membrane is attached to the stent struts

access was used for delivery of the stents in each case. All the stents except one in this study were Optimus XL models. Patient 8 was a small child hence an Optimus L was implanted. Predilation was not required in any case nor was the use of complex crossing techniques. None of the cases were atretic. Rapid ventricular pacing during stent deployment was used in 62% (n = 5) of the cases. The stents were crimped by hand, and in six cases this was augmented by using circumferential compression with umbilical tape. After crimping, the stents were deployed on a variety of balloons (Table 1); predictably the balloon associated with least stent shortening was the balloon in balloon (BiB; NuMED).[8] The stents could be fully expanded with low pressures on each balloon.

There were no procedural complications. One stent (patient 8) was post-dilated with a compliant balloon to mold it into the origin of the LSCA. There was no use of novel or stent specific imaging protocols. Angiography following stent deployment was satisfactory (mean minimum diameter increased from 7 to 16 mm) with resolution of gradients across the stents in each case (mean gradient pre = 22; post = 1) (Figure 3). The median percentage shortening of the stents was 11% at a median diameter of 16 mm. The equivalent shortening for a similar length CP covered stent is displayed in the table for comparison. The average difference in percentage shortening was significantly less for the Optimus than the CP stents ($P < .05$). One Optimus stent exhibited significant shortening (patient 1: 22.8%) but on reflection and review of angiography this was thought to be due to the use of a very compliant balloon which was marketed alongside the stent. This balloon opened the ends of the stent preferentially and led to longitudinal compression during expansion. This did not have any detrimental impact on the hemodynamic or angiographic result as the chosen stent's final length was still adequate to cover the pathological area.

Early follow-up with CxR and echo has not shown any evidence of stent malfunction. Cross-sectional follow up has been reported in four cases by CT (n = 3) and MRI (n = 1). Although little rigorous data can be gleaned from just 50% unprotocolled imaging follow-up, there have been no negative findings (stent fracture, collapse, significant narrowing, migration) in those patients where cross-sectional imaging has been reported. Examples of two cases with follow-up imaging in two very different anatomical substrates are shown in Figures 4 and 5.

3 | DISCUSSION

Although the indications for covered stent implantation for coarctation treatment are not well defined, the expansion of interventional techniques to patients regarded as high risk will increase the desire to

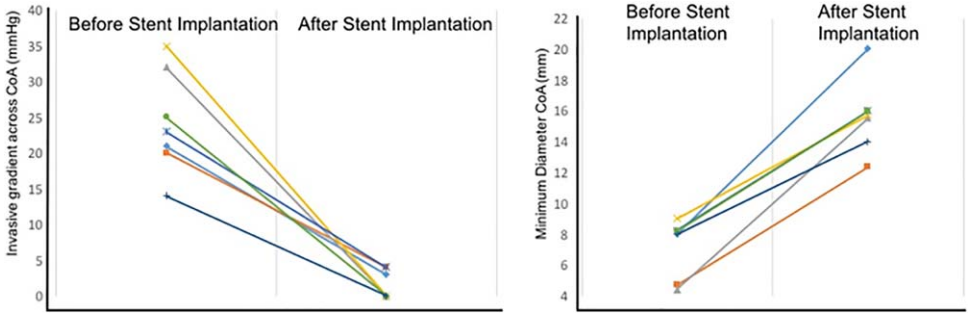

FIGURE 3 Improvement in gradient and minimum diameter with the Optimus stent. (A and B) show changes in invasive gradient (A) and associated changes in diameter (B) before and after stent implantation. Each line represents an individual patient. Abbreviation: CoA, coarctation

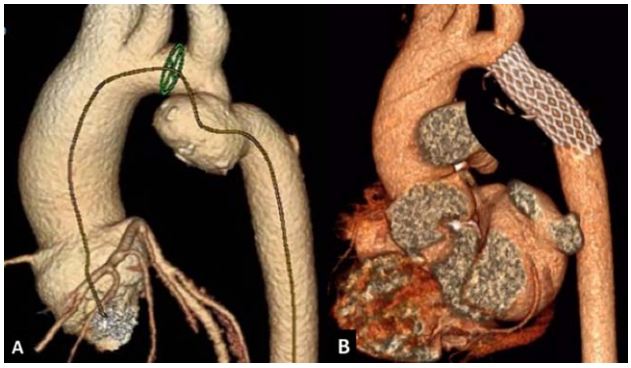

FIGURE 4 Treatment of postoperative coarctation with associated pseudo aneurysm with the Optimus stent. (A) Neonatal coarctation repair presenting in adulthood with restenosis and aneurysm formation. (B) Follow-up CT imaging showing exclusion of the aneurysm and resolution of the restenosis with uniform expansion of the Optimus stent

use covered stents. This evolving practice pattern should stimulate the search for covered stents which can be used on a routine basis without risk of technical failure over a wide anatomical range. The Optimus stent provides a solution which covers the majority of indications for coarctation stenting. The secure method of PTFE attachment (thermal bonding) to the stent along with our bench-test suggests that it will perform predictably if we need to perforate the covering to regain LSCA or carotid artery access. The retraction of the PTFE membrane of the CP stent in our bench test must be considered in the context of the in vitro stent not being pressed up against a vessel wall. This in vivo physical interaction may conceivably limit the movement of the PTFE membrane.

Although, no objective assessment was performed, we found no subjective difference in the force required to perforate the Optimus stent's covering with a 035″ vascular access needle compared with the CP stent's covering. The profile of the crimped stent should allow deployment through a similar sheath size than that required for the covered CP stent; in our early experience and during bench testing of sample stents, the profile allowed stent delivery in sheath sizes 1–2 French sizes larger than those recommended for the delivery balloon alone. Naturally in early clinical use, reflected in our series, most operators were cautious and leant toward larger sheath sizes to ensure technical success. Conceptually, stents with hybrid cell designs may expand suboptimally when inflated on compliant balloons. Patient 1, in whom significant stent shortening was noted reminds us of the importance of carefully considering the combination of stent and balloon. Predictably, the least shortening was noted with BiB balloons, hence in patients where minimal foreshortening is a key consideration (over sheath size), the BiB balloon is ideal.[8]

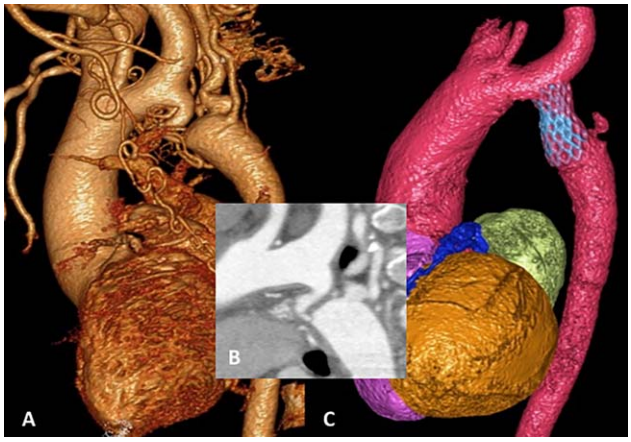

FIGURE 5 Severe, near atretic native coarctation in a young adult patient successfully treated with the Optimus stent. Panel A (3D reconstruction from CT imaging) and B demonstrate a severe tortuous long segment narrowing with isthmal hypoplasia and significant collateral vessel development. Panel C shows the result after inflation of the Optimus stent without high pressure redilation

4 | CONCLUSION

The Optimus stent range has the potential to provide a reliable large bore covered stent facilitating complex intervention in congenital heart disease across a wide spectrum of patient size and anatomical variation. Its design and construction characteristics are very encouraging; however, it is yet to be CE marked or approved by the US Food and Drugs Administration (FDA). Retrospective data collection from compassionate use cases is dogged by inconsistencies of approach and heterogeneous, complex patient characteristics; therefore, we look forward to more data from larger prospective trials to fully evaluate this interesting technology.

CONFLICT OF INTEREST

None.

AUTHOR CONTRIBUTIONS

Benchtesting and writing the initial manuscript: Dr Morgan
Editing the data as well as developing the concept of which data should be collected and how to present these: Dr Ciuffreda
Editing the data as well as developing the concept of which data should be collected and contributed to reworking the discussion section: Dr Spadoni
Coordinated the data collection and provided senior editorial review of the data and manuscript: Prof DeGiovanni

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