

## Case Reports

# Treatment of Aortic Arch Aneurysm With a NuMED-Covered Stent and Restoration of Flow to Excluded Left Subclavian Artery: Perforation and Dilation of e-PTFE Can Be Done!

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We describe a case using a NuMED-covered Cheatham-Platinum (CP) stent (NuMED, Hopkinton, NY) to treat an aneurysm after previous balloon angioplasty and bare stent implantation for coarctation of the aorta (CoA). Exclusion of the left subclavian artery (LSCA) was anticipated. After wire perforation of the covered CP stent, balloon angioplasty was performed through a stent cell to recannulize the LSCA. © 2009 Wiley-Liss, Inc.

**Key words:** CP stent; coarctation of aorta; aortic aneurysm; CHD

### INTRODUCTION

Transcatheter therapy for the treatment of CoA has evolved since the introduction of balloon angioplasty in 1982 [1]. Stent implantation at the time of balloon dilation has the additional benefit of overcoming elastic recoil of the vessel after angioplasty and maintaining the increase in vessel diameter. However, there is still a risk of intimal tearing, aneurysm, dissection, and death [2]. These complications may occur immediately or months after the procedure.

Although not commercially available for use in the United States, the NuMED-covered Cheatham-Platinum (CP) stent has been used successfully as treatment for native and recurrent CoA, as well as rescue treatment of CoA aneurysm [3–5]. One potential concern with the use of a covered stent is the potential occlusion of a significant aortic side branch artery. We report the use of a NuMED-covered CP stent to treat aortic aneurysm after initial bare stent therapy for CoA, with intentional exclusion of the left subclavian artery (LSCA) and subsequent wire perforation through the cells of the stents and the expanded polytetrafluoroethylene (e-PTFE) covering followed by balloon angioplasty to restore native circulation to the LSCA.

### CASE REPORT

A 16-year-old male with a history of acute lymphocytic leukemia (ALL) who had been previously treated for CoA and transverse arch hypoplasia by balloon angioplasty and implantation of a 26-mm long eV3 Max LD (eV3, Plymouth, MN) open cell design stent,

expanded to 16 mm, with complete relief of obstruction. He was followed clinically without symptoms or a significant residual upper-to-lower extremity systolic blood pressure gradient. A follow-up computed tomography scan demonstrated an anteriorly located aneurysm of the distal transverse arch, adjacent to the LSCA, which extended through the open cells of the previously placed stent (Fig. 1A). He was deemed a high-risk surgical candidate given his history of ALL, and an application was made and request granted for compassionate use of the NuMED-covered CP stent to treat the aneurysm.

The procedure was performed under general endotracheal anesthesia. The left radial artery was entered percutaneously, and a 3 Fr arterial catheter was advanced and later exchanged for a 4 Fr sheath to cannulate the LSCA. The right femoral artery was entered percutane-

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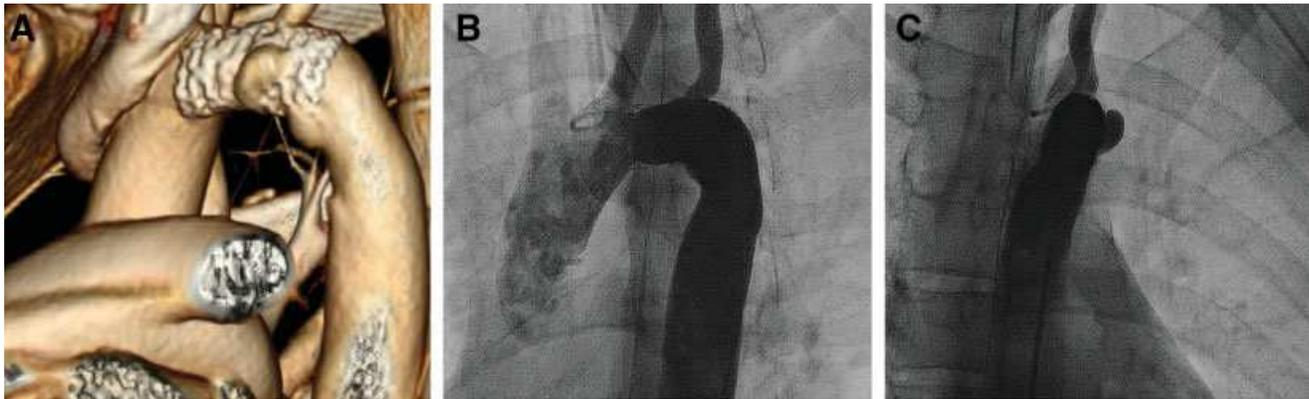
Conflict of interest: John P. Cheatham, MD has been a consultant for NuMED, Inc.

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**Fig. 1.** Comparison of 3D-CT reconstruction and aortic arch angiogram. **A:** Aneurysm noted in anterior portion of previously implanted stent. Ductus diverticula noted distal to stent, which was stable in appearance. **B:** Similar image seen by LAO angiogram with proximal in-stent stenosis and brisk flow into the LSCA. **C:** RAO angled view necessary to demonstrate aneurysm. [Color figure can be viewed in the online issue, which is available at [www.interscience.wiley.com](http://www.interscience.wiley.com).]

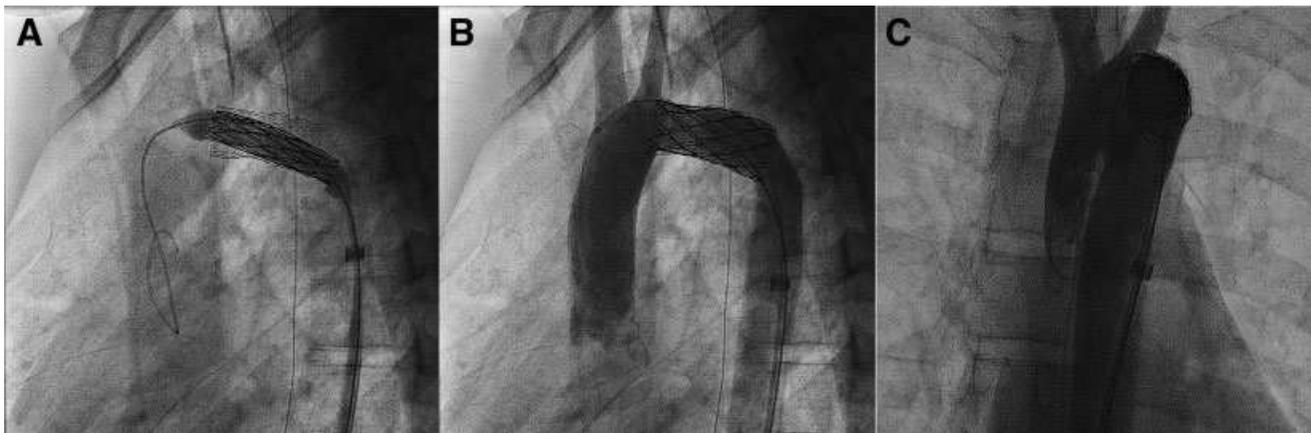
ously and an 8 Fr sidearm sheath and dilator advanced. The right femoral vein was also accessed to perform rapid right ventricular pacing during stent implantation.

An initial aortic arch angiogram was performed with 30 degrees LAO angulation of the AP camera and straight lateral view (Fig. 1B). This demonstrated mild in-stent stenosis in the proximal portion of the stent. The ductus diverticulum was unchanged from the previous study. The aneurysm was difficult to see, therefore the angiogram was repeated with 30 degrees RAO angulation of the AP camera and 60 degrees LAO angulation of the lateral camera (see Fig. 1C). This demonstrated a 9 mm × 11 mm aneurysm extending anteriorly at the mid-stent border and coursing inferiorly. There was brisk flow in the LSCA. Intravascular ultrasound was performed using a 15 MHz probe demonstrating the aneurysm at the anterior mid portion of the stent, with mild proximal in-stent stenosis, which nicely correlated with the angiogram.

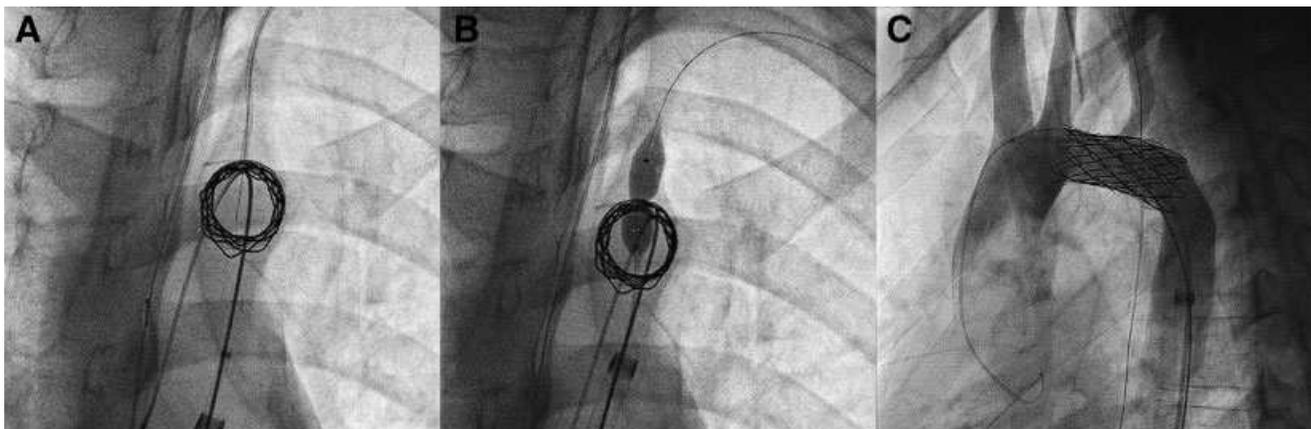
An 8 zig 39-mm long NuMED-covered CP stent was hand crimped on a 16 mm × 4 cm long BIB delivery catheter (NuMED, Hopkinton, NY), and covered with a short 13 Fr cut-off sheath which served as a protector while advancing through the bleed back valve of the sheath. A long 13 Fr Cook sheath and dilator was prepped, purged, and passed through the right femoral artery over a Meditech extra stiff J-tip guidewire that had been placed into the ascending aorta. The balloon mounted stent was advanced over the guidewire to the target site. Using small hand injections, the stent was uncovered with the proximal edge of the covered CP stent aligned with the proximal edge of the previously implanted eV3 stent and extending just distal to the stent with the aneurysm in the middle. Right ventricular pacing was initiated at 160 beats per minute to decrease cardiac output and

aid in precise placement of the stent. The inner and then outer balloon of the BIB catheter was expanded to 8 atmospheres of pressure. The balloon catheter was removed and an angiogram was performed using a 6 Fr MultiTrack (NuMED, Hopkinton, NY) angiographic catheter which demonstrated excellent placement of the covered CP stent, which was aligned with the previously placed eV3 stent and complete elimination of the aneurysm, with exclusion of the LSCA (Fig. 2B).

A 4 Fr Judkins right (JR) catheter was passed through the 4 Fr sheath in the left radial artery and advanced over a 0.014" guidewire into the LSCA to the level of the covered CP stent. A 0.014" guidewire was pre-shaped, and the stiff end was used to perforate the covering of the CP stent, as well as through the open cell designed eV3 stent. The stiff end of the guidewire was then removed, and the floppy tip of the guidewire was passed through the same opening through the covered and bare stents (Fig. 3A), and advanced down the descending aorta where it was snared and exteriorized to create an arterial rail. A 4-mm coronary balloon catheter was then prepped and advanced over the guidewire from the 4 Fr radial artery sheath, through the cells of the stents, and expanded. The blood pressure in the LSCA increased to slightly below systemic levels. Next, a 7 mm × 2 cm long Z-Med II balloon catheter (NuMED, Hopkinton, NY) was advanced over a 0.014" guidewire, this time from the right femoral artery sheath and across the newly opened cells of the stents, and expanded up to 13 atmospheres of pressure with complete elimination of the waist (Fig. 3B). The balloon was then removed. Pressure recorded in the LSCA was 90/60 (mean 76 mm Hg) and in the aorta 96/64 (mean 80 mm Hg), demonstrating a 6 mm Hg peak systolic gradient. A final transverse aortic arch angiogram was



**Fig. 2.** A: Delivery of the covered stent inside previously implanted bare stent. B: LAO angiogram after stent deployment demonstrates brisk flow and elimination of aneurysm, but occlusion of flow to left subclavian artery. C: RAO projection best demonstrates elimination of aneurysm.



**Fig. 3.** Recannulization of the left subclavian artery. A: Perforation of covered stent with stiff end of coronary wire. B: Dilation with coronary balloon followed by Z-Med II balloon. C: Post-angiogram showing elimination of aneurysm and brisk flow to LSCA.

performed using a 6 Fr MultiTrack angiographic catheter. This demonstrated the covered stent to be in excellent position with complete elimination of the aneurysm and in-stent stenosis, as well as brisk flow into the LSCA (Fig. 3C). The patient tolerated the procedure well without hemodynamic compromise, was extubated, and then transferred to the PACU in stable condition. The patient was continued on beta-blockade, as well as an anti-platelet dose of aspirin. A chest X-ray, echocardiogram, and ECG were performed the following morning prior to discharge. At follow-up 1 month later, blood pressure in the right arm was 100/64, left arm 98/58, and right leg 116/70.

## DISCUSSION

Following the first report of surgical repair for CoA over 50 years ago [6], balloon angioplasty and stent

implantation have emerged as successful alternatives therapies [5,7–9]. Successful angioplasty is achieved by tearing the intima and part of the media. This can result in late complication, including aneurysm formation, dissection, and restenosis. Balloon expandable stents provide support to the vessel wall and apposition of the torn vessel intima to the media. There is also potential for future redilation to accommodate patient growth. However, acute aortic wall complications after stent implantation and dilation are still encountered in up to 5% of patients [10].

In 1999, the first covered stent was used to treat coarctation of the aorta and aneurysm [11]. The balloon expandable NuMED CP stent covered with e-PTFE is not currently available for commercial use in the United States but is approved and readily available in most other countries. It has been used successfully outside the country to deal with the complications of an-



**Fig. 4.** Test perforation of e-PTFE covered stent. [Color figure can be viewed in the online issue, which is available at [www.interscience.wiley.com](http://www.interscience.wiley.com).]

eurysm sites and stent fractures [12–15]. However, compassionate use may be granted in the United States for specific patients who are not surgical candidates or are considered a high-risk surgical candidate by an uninvolved cardiothoracic surgeon. Application through the FDA, NuMED, and the individual institutional review board (IRB) is then required. Recently, an FDA-sponsored clinical trial (COAST) to evaluate the NuMED CP stent and coarctation has been initiated in selected centers in the USA.

One of the main initial concerns with the use of covered stents in the aorta was the occlusion of significant aortic side branches, including the innominate, common carotid, subclavian, and spinal arteries. It has been suggested that stent-graft-induced occlusion of the ostium of the LSCA may be tolerated well without chronic functional deficit; however, claudication of the left arm may result requiring a carotid to subclavian graft [16,17]. In addition, inadvertent and extensive tearing of the e-PTFE would be undesirable. We tested the perforation technique “ex-vivo” before the procedure to be sure there would be a well-defined area of perforation and dilation (Fig. 4). The other method of perforation could have been by using radiofrequency energy with the BMC system (Baylis Medical, Montreal, CN) but there are reports from W.L. Gore (Flagstaff, AZ) that Gore-Tex is not easy to perforate using radiofrequency energy (personal communication). A microcatheter could also have been used to pass over the stiff end of the coronary guidewire during the procedure in order to maintain the perforation and provide a safe and reliable method to exchange the stiff end of the coronary guidewire for the soft end.

This report demonstrates the use of the NuMED-covered CP stent, after compassionate use approval by

the FDA, NuMED, and the hospital’s IRB, for treating an aortic aneurysm after bare stent implantation for CoA, with intentional LSCA exclusion. There was successful rescue of the excluded LSCA after wire perforation of the covered CP stent from the LSCA, with balloon angioplasty through a cell of the stents to recannulize and restore native flow. Covered stent implantation with jailing of branch arteries has been previously described [7]. Modification strategies after stent implantation include dilation through stent cells, or overdilation and flaring of the end of the stent into the affected artery. While coverage of arterial branches is undesirable, therapy may still be possible when occlusion is anticipated.

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