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·专题研究·

主动脉定制开窗支架治疗主动脉弓动脉瘤中国首例报告（附视频）

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摘 要

背景与目的：胸主动脉腔内修复术（TEVAR）治疗胸主动脉病变已逐渐成为一线手术方案。然而，受限于主动脉弓部复杂解剖结构，在治疗病变的同时如何有效重建弓部分支动脉是应用当前标准化产品常有的困境。鉴于此，笔者团队与支架厂家合作开发了Castor胸主动脉定制开窗覆膜支架（以下简称Castor定制开窗支架），并实施了国内首例Castor定制开窗支架的置入。本文对此作一汇报。

方法：报告国内首例Castor定制开窗支架置入病例的临床资料、支架定制情况与手术过程，并进行Castor定制开窗支架的优缺点分析与相关文献复习。

结果：患者为59岁男性，于TEVAR术后14年发生主动脉弓部动脉瘤，病变累及左侧锁骨下动脉（LSA）、左颈总动脉（LCCA）。经患者及家属同意后采用Castor定制开窗支架隔绝动脉瘤，手术规划拟采用Castor定制开窗支架隔绝动脉瘤，将Castor支架分支置入LCCA；术前定制开窗分别重建无名动脉（IA）和LSA。术中成功置入Castor单分支支架并顺利重建弓部三根分支动脉，术后复查结果提示动脉瘤隔绝满意无内漏，弓部三根分支动脉通畅，同时无主动脉相关不良事件的发生。

结论：Castor个体化定制开窗支架性能优良，能够契合患者解剖条件，完全隔绝瘤体，同时实现精准开窗重建弓部分支动脉，且避免破坏支架完整性，为临床精准医疗提供了手段。

关键词 主动脉瘤，胸；血管内操作；支架；精准医学

中图分类号：R654.3

Customized fenestrated aortic stent-graft for aortic arch aneurysm: report of first case in China (with video)

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Abstract

Background and Aims: Thoracic endovascular aortic repair (TEVAR) has gradually become a the first-line therapeutic option for thoracic diseases. However, hindered by the complex anatomical structure of

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the aortic arch, effectively reconstructing supra-arch arteries during lesion treatment is a common challenge when using current standardized products. Given this, our team, collaborating with a stent manufacturer, had developed the Castor customized fenestrated thoracic stent-graft (hereafter referred to as Castor customized fenestrated stent) and successfully performed the first case of Castor customized fenestrated stent implantation in China. This article provides a report on this.

Methods: The clinical data, stent customization details, and surgical procedure for the first case of Castor customized fenestrated stent implantation in China were described, and an analysis of the advantages and disadvantages of the Castor customized fenestrated stent and review of relevant literature were also conducted.

Results: The patient, a 59-year-old male who underwent TEVAR 14 years ago, developed an aortic arch aneurysm involving the left subclavian artery (LSA) and left common carotid artery (LCCA). With the patient's and family's consent, we utilized the Castor fenestrated stent to seal the aneurysm. The surgical plan involved using the Castor customized fenestrated stent to occlude the aneurysm and placing the Castor stent branch into the LCCA. Preoperatively, fenestrations were customized to separately reconstruct the innominate artery (IA) and LSA. Successful implantation of the Castor single branch stent was achieved during surgery, effectively reconstructing the three supra-arch arteries. Postoperative imaging confirmed satisfactory aneurysm occlusion with no endoleak, patent flow in the three branch arteries, and no occurrence of adverse events related to the aorta.

Conclusion: The performance of the Castor individualized fenestrated stent is excellent, fitting the patient's anatomical characteristics, completely isolating the aneurysm, and enabling precise fenestration for reconstruction of the supra-arch arteries. Importantly, it avoids compromising stent integrity, providing a means for precise clinical interventions.

Key words Aortic Aneurysm, Thoracic; Endovascular Procedures; Stents; Precision Medicine

CLC number: R654.3

胸主动脉腔内修复术（thoracic endovascular aortic repair，TEVAR）已逐渐成为外科治疗胸主动脉疾病的主流术式[1-2]。由于主动脉弓部解剖较为复杂，常常导致实施累及主动脉弓部的TEVAR十分困难；例如主动脉弓动脉瘤，TEVAR术中如何有效腔内隔绝动脉瘤的同时重建弓部重要分支是最大的难点[2-3]。目前，重建弓部重要分支的技术主要包括烟囱技术、开窗技术、分支支架技术、去分支技术等，此类技术不断完善并取得不错的临床效果[4]。因此，TEVAR所涉及的区域由最初的Z3区逐步前延至Z2、Z1[5]甚至是Z0区[6]，全腔内介入治疗解决主动脉弓部病变已成为常规手术方式，目前主流腔内治疗方式包括烟囱技术[7]、分支支架技术[8]、开窗技术等[9]。烟囱技术操作较为简单[10]，但存在较高的内漏风险和支架移位等并发症[11]。分支支架属于整体构建，内漏发生率更低[12-14]，但是由于弓部分支动脉的解剖结构个体差异性较大，目前仅有单分支支架实现大规模临床使用[14]，双分支甚至三分支支架尚无法实现[12, 14-15]。体外预开窗技术主要依靠体外人工修剪支架以及标记缝合的方式，实现开窗与分支开口的对位，对术者操作要求高、学习曲线长，且存在移植物感染风险[16]。原位开窗技术主要通过激光或破膜针联合球囊扩张的方式实现支架开窗，但由于分支动脉走行较扭曲，增加神经系统并发症、分支动脉损伤等风险，且可能破坏支架结构稳定性[6]。

选择3D打印辅助Castor单分支支架联合个性化定制双开窗（以下简称Castor定制开窗支架）治疗主动脉弓动脉瘤，既符合患者弓部解剖结构以保证窗口精准对位，又能保持支架完整性，可实现全腔内微创治疗主动脉弓动脉瘤。Castor定制开窗支架作为一种新的治疗方法，目前国内尚未见报道。现将中南大学湘雅医院完成的1例Castor定

制开窗支架治疗主动脉弓动脉瘤的病例报告如下。

1 病例资料

患者 男，59岁，因“TEVAR术后14年，发现主动脉弓动脉瘤7个月”，2023年10月9日收治于中南大学湘雅医院血管外科。既往高血压病史10余年，规律服药，血压控制尚可。入院后进一步完善相关检查检验等未见明显手术禁忌，术前主动脉全长计算机断层扫描血管造影检查（computerized tomography angiography，CTA）示：主动脉夹层术后改变，支架近端主动脉弓部动脉瘤并累及左锁骨下动脉（left subclavian artery，LSA）及左颈总动脉（left common carotid artery，LCCA）（图1A）；支架近端Ia型内漏并夹层动脉瘤，最大直径约7.8 cm（图1B–C）；支架末端诱导新破口（stent-graft induced new entry，SINE）（图1D）。确诊为主动脉弓动脉瘤、支架内漏，有破裂风险。手术指征明确，未见明显手术禁忌，手术规划采用Castor分支型支架联合定制双开窗方案，拟利用支架分支重建LCCA，定制开窗分别重建无名动脉（innominate artery，IA）和LSA。Castor定制开窗支架经中南大学湘雅医院医学伦理委员会审查获批（审批号：2022112201），患者及家属知情同意实施。

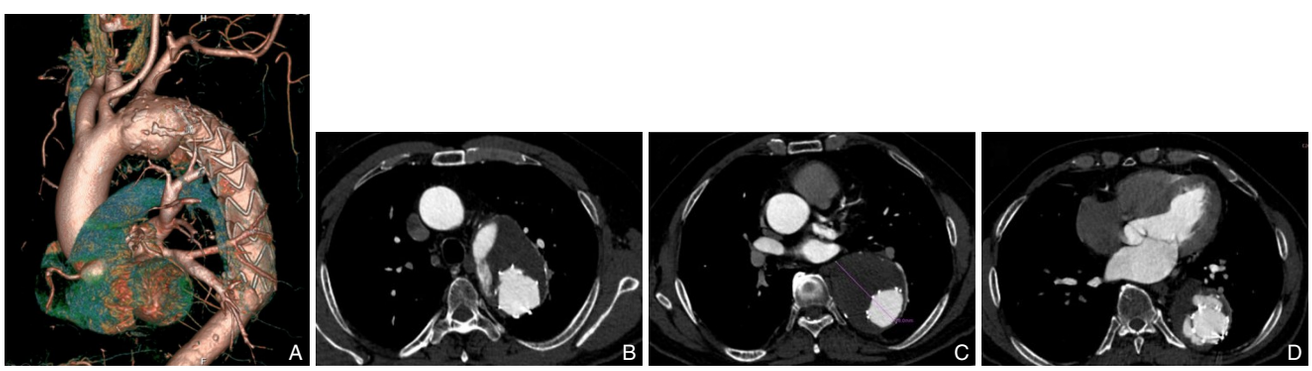


图1 术前CTA影像资料 A：主动脉全长3D重建图像；B：原支架Ia型内漏；C：降主动脉夹层动脉瘤，最大直径约7.8 cm；D：原支架末端SINE

Figure 1 Preoperative CTA imaging data A: 3D construction of the aorta; B: Type Ia endoleak of previously implanted stent-graft; C: Descending aortic dissection aneurysm, with a maximum diameter of approximately 7.8 cm; D: SINE at the end of the original stent-graft

2 治疗方法

2.1 支架定制与相关材料

术前将患者CTA影像资料拷贝至支架生产厂家用于支架定制开窗，以及1∶1制作3D打印模型（图2A–C）。Castor定制开窗支架经过上海市药品监督管理局有关定制式医疗器械的临床使用备案批准（批件编号：沪械定制备2023–01）。支架主体为Castor分支型主动脉覆膜支架（38–3408–2002530），支架分支拟置入并重建LCCA。IA开窗直径10 mm，拟置入12~50 mm Lifestream球扩覆膜支架重建IA。LSA开窗直径8 mm，与中轴线无成角，拟置入11~50 mm Viabahn覆膜支架重建LSA。其他所需要用到的外周血管介入耗材包括血管鞘，泥鳅导丝，金标猪尾巴导管，Back-Meier加强导丝，ProGlide血管缝合器系统，球囊扩张导管等辅助材料。

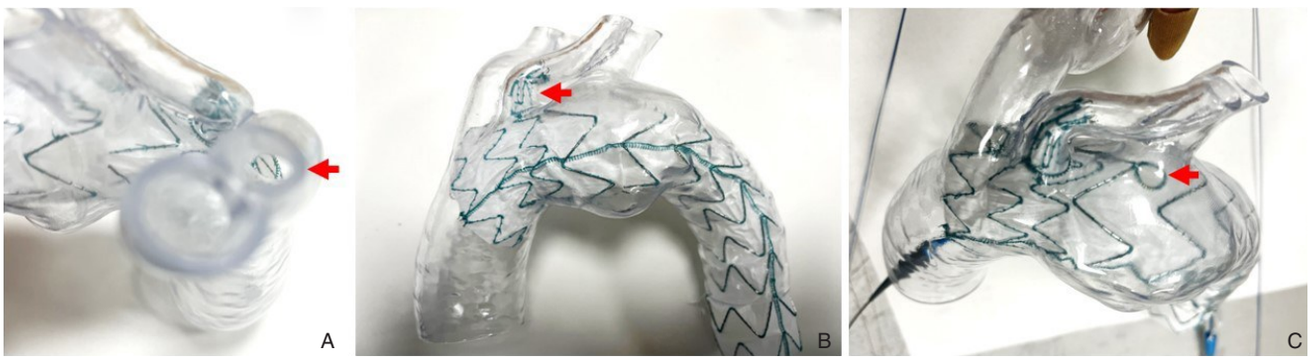


图2　3D打印主动脉弓动脉瘤模型及Castor定制开窗支架体外释放展示　A：支架释放后IA窗口对准IA开口；B：支架释放后Castor分支支架置入LCCA；C：支架释放后LSA窗口对准LSA开口

Figure 2　Demonstration of 3D printed aortic arch aneurysm model and in vitro release of the Castor customized fenestrated stent　A: Alignment of the IA fenestration hole with the IA opening after stent deployment; B: Placement of the Castor branch stent into the LCCA after stent deployment; C: Alignment of the LSA fenestration hole with the LSA opening after stent deployment

2.2　手术过程

术前常规禁食、禁水 8 h，全麻成功后，手术在数字减影血管造影（digital subtraction angiography，DSA）透视下进行。取左侧颈部直切口，显露 LCCA，预置 7 F 血管鞘并给予 50 mg 肝素。穿刺双侧肱动脉并分别预置 8 F 翻山鞘，穿刺右侧股动脉，依次导入 2 把 ProGlide 血管缝合器系统预缝合，预置 12 F 血管鞘。首先导丝导管经 LCCA 入路进入，超选至右侧股动脉入路牵出并形成牵张。金标猪尾巴导管从右侧肱动脉入路进入升主动脉，造影显示：患者胸主动脉原支架近端及尾端均可见瘤样扩张（图 3A）。按术前计划，导入 Castor 分支型支架（38–3408–2002530），分支导入 LCCA（图 3B）。确认支架定位准确后完全释放 Castor 支架，可见定制开窗位置准确。从右侧肱动脉入路超选进入 IA 开窗后（图 3B），使用 10 mm 球囊预扩张，然后导入 12~50 mm lifestream 球扩覆膜支架于 IA 与胸主动脉支架，并使用 14 mm 球囊后扩张。从左侧肱动脉入路导入导丝，超选入 LSA 开窗（图 3C）；沿主动脉下行至右侧股动脉血管鞘牵出，形成牵张；右侧股动脉交换 20 F 大鞘，沿导丝导入 14 F 长鞘至 LSA 起始部，使用 10 mm 球囊预扩张 LSA 开窗，导入 11~50 mm Viabahn 覆膜支架于 LSA 与胸主动脉之间（图 3D）。最后沿超硬导丝导入胸主动脉覆膜支架（34 mm–28 mm–150 mm），支架末端超出原支架末端约 5 cm 后释放。最后 DSA 显示：主动脉弓动脉瘤隔绝满意且无内漏，主动脉弓三分支动脉显影好切流速满意，原支架末端 SINE 消失。ProGlide 血管缝合器系统缝合穿刺点并加压包扎，5-0 血管划线缝合左侧颈动脉及双侧肱动脉穿刺点，分层间断缝合皮下及皮肤。手术顺利，手术时长约 210 min，出血量约 100 mL。术后严密监测患者生命体征，控制心率、血压等，重点观察患者术后意识状态及四肢活动情况，并根据个体情况给予针对性的护理干预措施。手术操作步骤细节详见视频 1。

2.3　手术结果

患者麻醉复苏后患者四肢活动正常，无异常胸背部疼痛等不适。术后第 5 天，复查主动脉全长 CTA，见支架位置形态良好，动脉瘤封堵满意且未见明显内漏（图 4A–B），主动脉弓分支动脉通畅（图 4C），降主动脉原 SINE 消失（图 4D）。患者术后第 8 天出顺利院。目前随访患者恢复良好，无特殊不适。

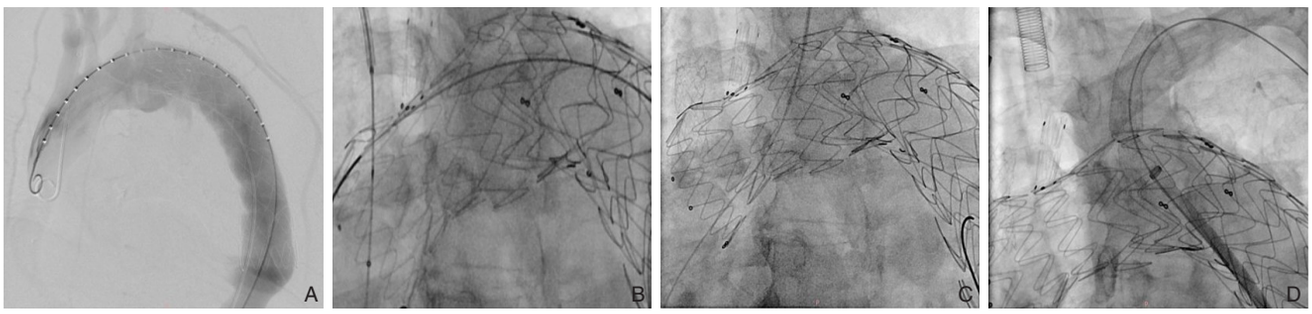
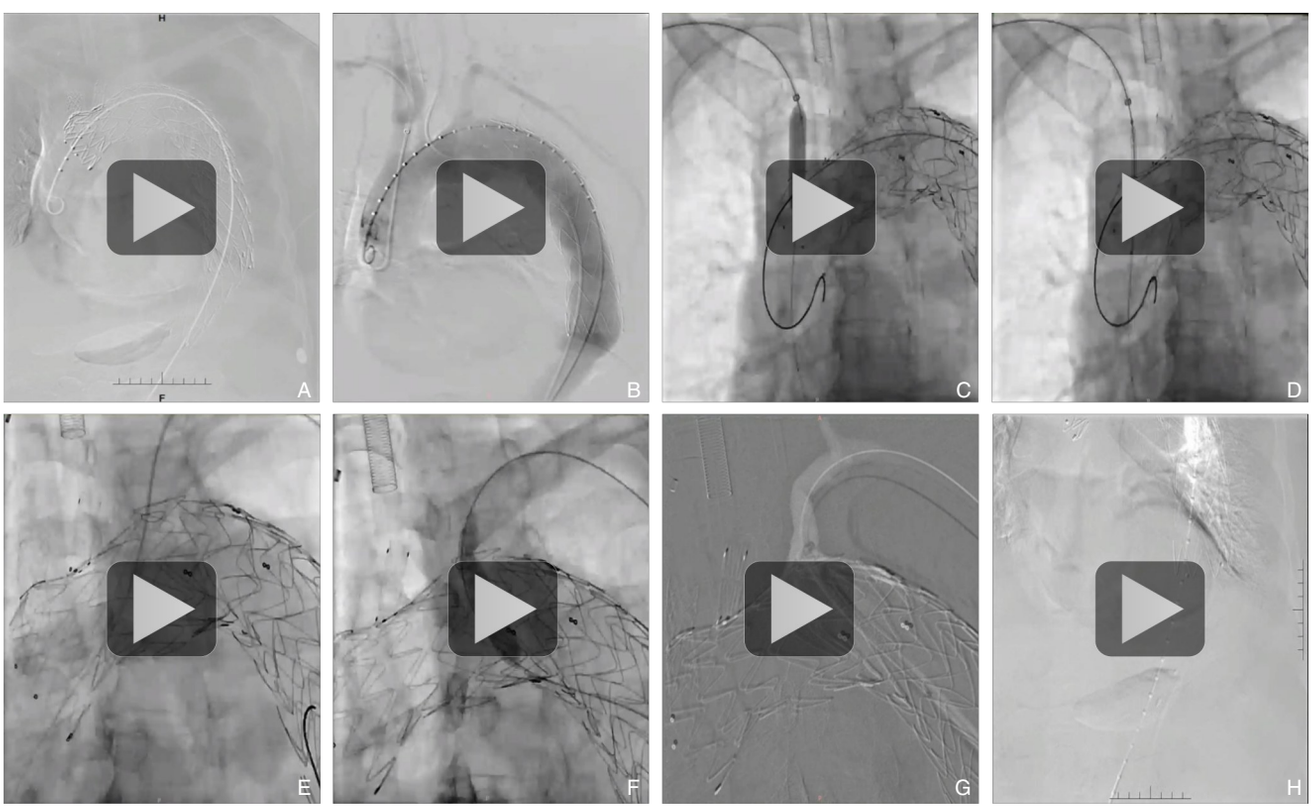


图3 术中DSA图像 A：DSA图像显示主动脉弓动脉瘤累及LSA及LCCA，支架远端SINE；B：Castor支架分支置入LCCA后，经右侧肱动脉入路成功超选IA窗口；C：经左侧肱动脉入路成功超选LSA窗口；D：导丝牵张下经股动脉入路导入Viabahn覆膜支架，重建LSA

Figure 3 Intraoperative DSA images A: DSA image showing aortic arch aneurysm involving LSA and LCCA, with a SINE at the end of the original stent; B: After placing the Castor stent branch into the LCCA, successful superselective IA fenestration hole via the right brachial artery approach; C: Successful superselective LSA fenestration hole via the left brachial artery approach; D: Tensioning the guidewire down through the femoral artery approach to introduce the Viabahn covered stent, reconstructing the LSA



视频1 术中细节 A：术前第1次DSA；B：导丝超选入IA窗口并行球囊预扩张；C：导入Lifestream球扩覆膜支架重建IA；D：导丝超选入LSA窗口；E：球囊预扩张LSA窗口；F：导入Viabahn覆膜支架重建LSA；G：DSA显示原支架末端SINE；H：手术结束前DSA

Video 1 Intraoperative details A: First preoperative angiography; B: Superselective wire placement into the IA fenestration hole with balloon pre-dilation; C: Introduction of the Lifestream balloon-expandable covered stent to reconstruct the IA; D: Superselective wire placement into the LSA fenestration hole; E: Balloon pre-dilation of the LSA fenestration hole; F: Introduction of the Viabahn covered stent to reconstruct the LSA; G: Contrast imaging displaying the SINE at the end of the original stent-graft; H: Imaging at the conclusion of the surgery

扫描至移动设备观看手术视频：

http://www.zpwz.net/zgptwkzz/article/html/pw230609

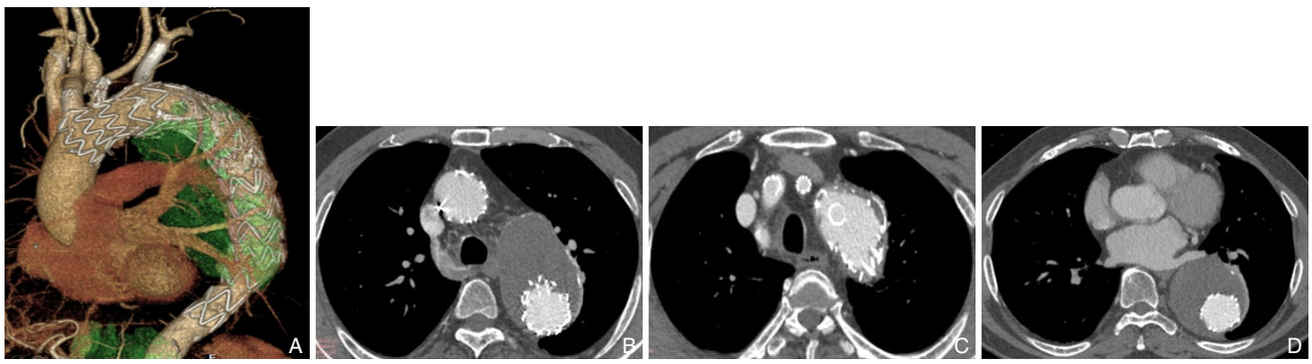


图 4　术后第 5 天复查 CTA 影像资料　A：主动脉全长 3D 重建图像；B：原支架 Ia 型内漏消失；C：弓上三分支动脉内支架通畅；D：原支架末端 SINE 消失

Figure 4　Postoperative day 5 follow-up CTA imaging data　A: 3D reconstructed image of the entire aorta; B: Resolution of type Ia endoleak in the original stent; C: Patent stent in the three aortic arch branches; D: Disappearance of the SINE at the end of the original stent

3　讨　论

随着我国人口老龄化以及高血压患者数量的攀升，主动脉相关疾病的发病率不断增加。主动脉弓部病变如动脉瘤或夹层等，有传统外科手术和 TEVAR 两种手术方式。传统外科手术方式存在技术难度大、操作复杂、围手术期并发症和病死率高等缺点[17-18]，难以适用于所有患者尤其是高龄、合并症多群体[17, 19]。TEVAR 具有微创、并发症少、术后恢复迅速等优势，逐渐成为主动脉弓动脉瘤的重要术式，但由于弓部特殊的解剖位置和特点，弓部分支重建是难点。由于全世界范围内的器械创新与发展[20]，以及血管外科医师腔内治疗技术的进步[21]，TEVAR+分支重建技术治疗主动脉弓部病变已逐渐成为临床常态[22]。虽然包括分支支架、烟囱技术、开窗技术在内的多种方法可以有效重建主动脉弓上分支，实现全腔内治疗主动脉弓病变的目标[23-24]；但目前这类技术仍存在一定缺陷。本文报告国内首例 Castor 定制开窗支架治疗主动脉弓动脉瘤，为主动脉弓部病变的腔内治疗提供新的思路。

主动脉弓解剖结构复杂，主要体现在弓部存在三根分支动脉及变异如迷走 LSA 或椎动脉等，而且分支的直径、走形、分支之间的距离、分支与弓部中轴线的成角等个体差异较大。因此，分支支架技术无法实现临床大范围使用。开窗技术可以有效重建弓上分支动脉，但原位开窗存在破坏支架稳定性、分支动脉损伤等风险，体外开窗存在支架重新装配所导致的移植物感染、分支对位不准等可能。本文作者所提供的定制开窗支架，可根据患者弓部的解剖结构特点实现个体化定制开窗，保证支架窗口的位置、直径、成角等物理参数完全契合患者三根分支动脉特点，既实现术中操作简单、快捷，又有效避免窗口与分支动脉对位不准、分支支架扭曲等。而术前工厂定制并一体化生产开窗支架，无需术中改装并重新组装支架，减少不必要的操作及可能导致的移植物感染等风险。

本报告的重要创新点在于 LCCA 植入 Castor 支架分支，开窗分别重建 IA 和 LSA。术前根据 CTA 资料个性化定制开窗的关键在于根据患者 IA、LSA 与 LCCA 的相对位置关系完全复制 IA 窗口、LSA 窗口与分支支架的相对位置关系。因此，术中一旦将 Castor 支架分支置入 LCCA，IA 窗口和 LSA 窗口自动分别对准 IA 开口和 LSA 开口；Castor 支架分支发挥类似导航的作用，辅助术者将窗口精准定位于分支动脉开口，规避分支开口与窗口对位不准的风险。精准的窗口对位，加上分支支架的整体构建特点，保证封堵满意无内漏。

本例使用 Castor 分支支架的重要优势在于减少分支重建数量，降低手术难度。如本次病例手术，如果使用普通覆膜支架，术中需重建弓部三根分支动脉；而术者采取 Castor 分支支架，分支支架置入 LCCA 后，只需重建 IA 和 LSA，减少手术步骤。同时，由于术前定制开窗，IA 和 LSA 窗口自动对准 IA 和 LSA 开口，经右侧肱动脉及左侧肱动脉入路导丝导管可快速、顺利选入 IA 和 LSA 窗口，避免因对位不准导致的超选窗口困难现象。

虽然3D打印辅助Castor定制开窗支架可有效治疗主动脉弓部病变，但支架获取过程耗时较长。目前市场上无商业化开窗支架，需提前向当地药品监督管理局申请、备案；同时，定制开窗需提前向支架生产厂家提供患者CTA等相关影像资料，结合3D打印等技术，实现支架制备与定制开窗一体化生产；但由于个体化差异，定制开窗需临时定制，无法批量化生产、模块化提供。

综上所述，在治疗主动脉弓部疾病中，TEVAR能够安全、有效地重建弓上分支动脉，实现全腔内微创治疗方案[25-30]。3D打印辅助Castor定制开窗支架技术，有效提高窗口与分支动脉开口对位的准确率、更加符合解剖结构等优势明显，且明显降低手术难度，是全腔内治疗主动脉弓部病变的有力辅助工具，值得推广应用。

利益冲突：所有作者均声明不存在利益冲突。

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