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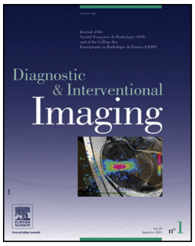

ORIGINAL ARTICLE / *Research and new developments*

Hemodynamic analysis of edge stenosis in peripheral artery stent grafts

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Peripheral artery;
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Abstract

Purpose: The purpose of this study was to characterize the hemodynamics of peripheral artery stent grafts to guide intelligent stent redesign.

Materials and methods: Two surgically explanted porcine arteries were mounted in an *ex vivo* system with subsequent deployment of an Xpert self-expanding nitinol stent or Viabahn stent graft. The arteries were casted with radiopaque resin, and the cast then scanned using micro-computed tomography at 8 μm isotropic voxel resolution. The arterial lumen was segmented and a computational mesh grid surface generated. Computational fluid dynamics (CFD) analysis was subsequently performed using COMSOL Multiphysics 5.1.

Results: CFD analysis demonstrated low endothelial shear stress (ESS) involving 9.4 and 63.6% surface area of the central stent graft and bare metal stent, respectively. Recirculation zones were identified adjacent to the bare metal stent struts, while none were identified in the central stent graft. However, the stent graft demonstrated malapposition of the proximal stent graft edge with low velocity flow between the PTFE lining and arterial wall, which was associated with longitudinally and radially oriented recirculation zones and low ESS.

Conclusion: Computational hemodynamic analysis demonstrates that peripheral artery stent grafts have a superior central hemodynamic profile compared to bare metal stents. Stents grafts, however, suffer from malapposition at the proximal stent edge which is likely a major contributor to edge stenosis.

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Peripheral artery stent grafts have a low occurrence of in-stent restenosis, partially attributable to polytetrafluoroethylene's (PTFE) low coefficient of friction and prevention of ingrowth of proliferated smooth muscle from the tunica media [1,2]. Peripheral artery stent grafts, however, do suffer from restenosis at the proximal and distal transition between stent and artery (termed ''edge stenosis'') [3,4]. Despite these known clinical outcomes, the central and edge hemodynamic flow characteristics of peripheral artery stent grafts have not been adequately studied to guide intelligent stent redesign.

Endothelial shear stress (ESS) is a result of the friction of blood flowing on the arterial wall endothelial surface, measured as the radial gradient of velocity flowing along the longitudinal axis of the artery in units of force/area [5]. Low ESS defined as less than 0.5 Pa has been associated with intimal thickening [6—9]. The relationship of low ESS to neointimal hyperplasia and atherogenesis has been repeatedly described in autopsy-based models, *in vivo* animal models, and *in vivo* human studies [9—20]. A second important cardiovascular hemodynamic factor is recirculation zones, which can be defined as stationary vortices in areas of low flow velocity with a long particle residence time [21]. Stents evaluated in flow chambers have demonstrated an increase in platelet aggregation at the strut locations that predict recirculation zones [22]. Despite this knowledge of ESS and recirculation zones, data on the hemodynamics of peripheral arteries with deployment of stents is limited [23,24].

While computational fluid dynamics (CFD) can provide useful flow information, accurate representation of the arterial lumen geometry under physiologic conditions is necessary for reliable analysis. Prior methods have been described for vascular corrosion casting of stented porcine coronary arteries with magnesium stents followed by micro-computed tomography (μCT) for accurate, high-resolution luminal surface modeling of stented arteries [25,26]. However, this and other methods with vascular casting at physiologic pressure have not been successfully applied to the peripheral arteries and have allowed only limited use of nitinol stents with or without PTFE lining [27,28].

The purpose of this study was to characterize the hemodynamics of peripheral artery stent grafts to guide intelligent stent redesign.

Materials and methods

Animal model

A single swine was euthanized per protocol of an independent study approved by our institutional Animal Review Committee. No ante-mortem manipulation of the animal was performed for the current study. After euthanasia, the bilateral femoral arteries of the swine were surgically explanted. All branches were ligated with 2-0 silk and the arteries flushed with heparinized saline (5 U/mL). The explanted, mounted porcine arteries were measured with a gauge device and found to have a diameter of 4 mm. A 9-F Pinnacle® introducer sheath (Terumo Medical Corp, Somerset, NJ, USA) was placed through an opening in the proximal and distal aspects of two containers and the artery secured by ligation to each sheath using 2-0 silk. Knox gelatin (NBTY, Inc., Ronkonkoma, NY, USA) was dissolved in boiling water at 7% weight by volume, and allowed to cool to between 50—55 °C. The gelatin mixture was poured into the containers to a level 1 cm above the artery. The arteries were flushed with normal saline through the sheath and locked at a pressure of 90 mm Hg while the gelatin solidified at 3 °C for 2 hours.

Vascular casting

Prior to stent deployment, the system was flushed and closed with normal saline warmed to 37 °C to ensure physiologic nitinol thermal induced phase transformation. Through the proximal sheath, a 5 × 25 mm Viabahn® self-expanding PTFE lined nitinol stent graft (W.L. Gore and Associates, Newark, DE, USA) was deployed in one artery, and a 5 × 20 mm Xpert® self-expanding nitinol stent (Abbott Vascular, Santa Clara, CA, USA) deployed in the second artery. Each stent was subsequently ballooned with a 5 × 20 mm Mustang® angioplasty balloon (Boston Scientific, Marlborough, MA, USA).

Biodur E20 Plus® clear resin (Biodur Products, Heidelberg, Germany) was mixed with Biodur E20 Plus® Hardener (Biodur Products, Heidelberg, Germany) at a ratio of 100:55 p.b.w. Acetone was saturated with elemental iodine and added to the mixed resin with hardener at a weight ratio of 1:6.5. The resin/iodine mixture was placed in a vacuum chamber at an intermittent 635-mmHg vacuum for a total of 3 minutes to remove all trapped gas. The prepared resin was injected through the proximal sheaths using an air-pressurized system maintained at 90 mmHg throughout injection. The outflow sheath stopcocks were decreased to a minimal outflow rate and slowly increased until the open system maintained a pressure of 90 mmHg. The resin was allowed to dry for 24 hours. The arteries were removed from the mold and degloved from the resin/stent cast. For the stent graft cast, the nitinol and PTFE lining was carefully deconstructed and removed from the resin cast.

Image acquisition

A Phoenix Nanotom μCT scanner (General Electric Measurement and Control, Palo Alto, CA, USA) was used to scan the resin casts at an isotropic voxel resolution of 8 μm. The system was equipped with a diamond target and was operated at a beam energy of 180 kVp (Xpert cast) or 70 kVp (Viabahn cast), tube current of 29 μAs, exposure time of 1500 ms with a frame averaging of 3 and no additional filter. The acquired projections were reconstructed using filtered-back projection method and corrected for beam hardening (Fig. 1). The μCT data was resampled at 16 μm isotropic voxel resolution with Amira® software (FEI, Hillsboro, OR, USA) using the Lanczos method. The resampled images were processed using a denoising median filter and semi-automatic lumen segmentation with multilevel image thresholding. For the stent graft sample, cast material extending outside the stent lumen greater than 5 mm in the direction of flow from the proximal stent edge was truncated. An isosurface model was generated for each sample (Fig. 2).

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