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The Length Versus Diameter Relationship and Radial Force Properties of the Amplatzer™ Vascular Plug Type IV: Observations for Oversizing

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Abstract
Background—In palliated single ventricle patients aortopulmonary collateralization is a cause for significant loss of cardiovascular efficiency. In larger vessels, device occlusion becomes an alternative to embolization with multiple coils. The physical characteristics of the Amplatzer ™ Vascular Plug Type IV (AVPIV) are potentially conducive to oversizing the device allowing coverage of a longer portion of vessel. Despite the widespread use of the AVPIV, little published data exists describing the behavior of the device as it is constrained in different vessel sizes.
Methods—4–8 mm AVPIV devices were measured in glass tubing in diameters ranging from 1 to 8 mm internal diameter. Radial force was measured by constraining the devices to the desire diameters from 1 to 7 mm and measuring the force the device exerted to one of the constraining walls. This force vs. diameter relationship was evaluated for each device and compared across different devices.
Results—The devices range in length from 12.36 to 31.24 mm. The 4 mm device lengthened 3.44 mm from unconstrained to 1 mm diameter (12.36 to 15.80 mm), while the 8 mm AVP IV lengthened 14.74 mm from unconstrained to 1 mm diameter constraint (16.50–31.24 mm, 89% lengthening). The highest overall radial force (1.38 N), radial force at 50% compression (1.25 N), and average stiffness (0.95 N/mm) was found in the 5 mm diameter device.
Conclusions—The AVP IV device has a reliable length for diameter relationship. A counterintuitive property of the AVP IV with regards to radial force for device size was found. The 5 mm AVPIV was found to exert the highest radial force and stiffness compared to the other devices. The 7 and 8 mm AVPIV devices were consistently found to exert less radial force. This property suggests that oversizing an AVP IV could be safe and effective, potentially decreasing total devices used, cost, and overall procedure time.

Keywords—Aortopulmonary collaterals, Embolization, Catheterization, Congenital, Cardiac.

INTRODUCTION

In palliated single ventricle patients aortopulmonary collateralization is a cause for significant loss of cardiovascular efficiency.[2] Recent Cardiac Magnetic Resonance Imaging (CMRI) studies estimate that on average, 26% of cardiac output is devoted to aortopulmonary collateral flow.[18] Although there is general agreement in the necessity to eliminate significant aortopulmonary collateralization in single ventricle patients,[16] there is wide variability in practice.[3] Multiple methods for embolization of aortopulmonary collaterals exist. Embolization by packing thrombogenic coils into the lumen of the vessels was one of the first interventional methods developed for vessel embolization,[14] and is still widely used. Due to extensive anastomotic connections from the vessels arising from or around the subclavian artery, collateral flow can recur months and years after a technically successful occlusion. There is evidence that occluding the entire length of the feeder vessel, as opposed to simply the origin of the vessel, can reduce recurrence of collateral flow.[16] The benefits of densely packing coils to achieve full occlusion can lead to multiple coils being used in each vessel.

In larger vessels, device occlusion becomes an alternative to embolization with multiple coils. Use of the Amplatz vascular plug type IV (AVPIV) was first reported in the pediatric population in 2010[5] and since then many applications in congenital heart disease

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have been described.[1,4,6–13,15,17,19] The AVPIV is an attractive device due to its low profile. It can be delivered through catheters with a luminal diameter of at least 0.038 inch, allowing passage through diagnostic as well as guide catheters without requiring larger, less deliverable long sheaths. Furthermore, the physical characteristics of the AVPIV are potentially conducive to oversizing the device allowing coverage of a longer portion of vessel.

Despite the widespread use of the AVPIV, little published data exists describing the behavior of the device as it is constrained in different vessel sizes. Of particular interest is the relationship of elongation to vessel diameter for the different device sizes. The relative change in radial expansive force against the constraining vessel wall may also determine occlusive behavior and influence device choice in different scenarios.

We sought to evaluate the length versus diameter relationship applied to a simulated vessel wall across the range of AVPIV device sizes. Additionally, we investigated the absolute radial forces of the devices within different dimensions and as dynamic stresses are applied to assess the elasticity of the devices to evaluate the structural stiffness of the AVPIV product line. All work was completed *in vitro* to assess the safety and feasibility of oversizing the AVPIV.

METHODS

All commercially available APVIV device sizes (4, 5, 6, 7, and 8 mm diameters) were studied. The unconstrained measurements published in Instructions For Use from the manufacturer exclude the distal cap and proximal female screw attachment of the device. The measurements in this study include the entire length including the cap and attachment. The length for diameter assessment was completed with 17 different glass cylinders with uniform internal diameters ranging from 1 to 8 mm. The tolerances for the internal diameters ranged from ± 0.15 to ± 0.3 mm. Three length measurements were made in three different locations within the glass tubing for each device. The devices were first measured in their unconstrained state before serially decreasing their diameter by insertion into progressively more narrow cylinders to a minimum of 1 mm diameter. The glass tubes can be seen in Fig. 1.

For radial force assessment, wells were machined within acrylic blocks with well width sizes ranging from 1.5 to 7 mm in 0.5 mm increments (Fig. 2). The devices were placed within the wells, constraining them by the three walls created by the wells. Symmetrical compression was completed by lowering a wall attached to a force sensor (MTS, Inc., 2 N sensor) to the diameter of the well. With symmetrical constraint, the force sensor quantified the radial force exerted by the constrained device. Furthermore, as this wall com-

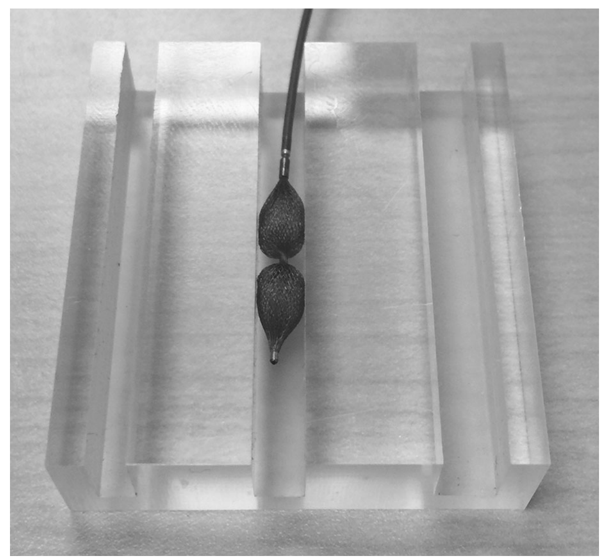


FIGURE 2. AVPIV device within a CNC machined acrylic well.

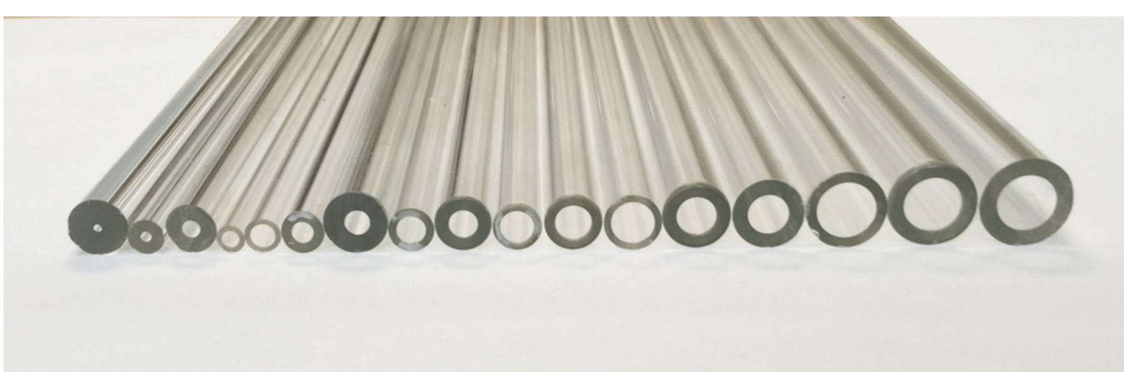


FIGURE 1. Glass tubing arranged in increasing internal diameters. Please note there was variability in wall thickness of the tubing.

pressed the device to symmetry, we recorded the stress vs. strain relationship and derived Young's modulus of elasticity along the early linear displacement of the device. This was completed within a water bath that was maintained at body temperature (37 degrees Celsius). Figure 3 demonstrates the machined acrylic wells and give an example of the radial force measurement while an AVPIV is constrained.

RESULTS

Length vs. Diameter Characteristics

Measurements were made for each device to assess the length vs. diameter relationship. Graph 1 demonstrates the length vs. diameter relationship for the AVPIV. The largest proportional change in length for diameter was noted with the 8 mm AVPIV device which measured 16.5 mm in length unconstrained, and 31.2 mm when constrained to 1 mm in diameter, representing lengthening of 89% compared to the unconstrained measurement.

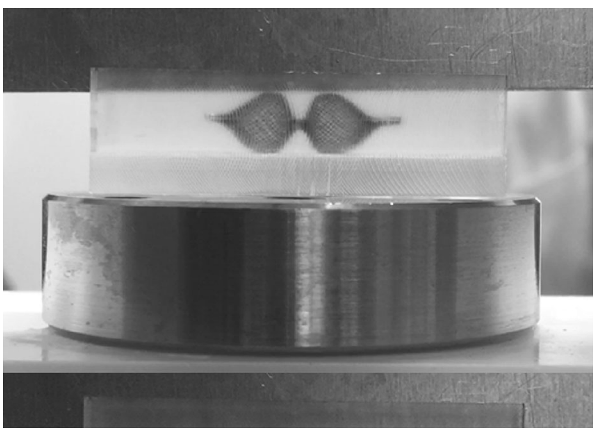
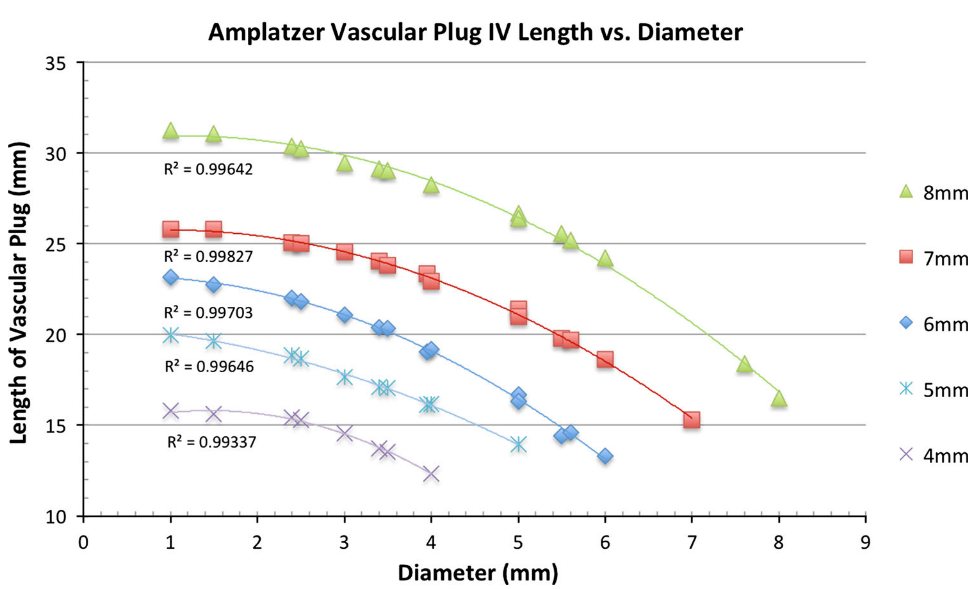


FIGURE 3. AVPIV as viewed from the side prior to (upper) and during (lower) compression.

As a structural component, the uncompressed relationship of width vs. length for each device was evaluated. This relationship was not linear, and we found the lowest width for length ratio (0.40) in the 4 mm plug with the highest ratio in the 8 mm plug (0.59).

Stiffness Analysis

Stiffness was assessed in various metrics. Initially, the absolute forces generated by the devices in decreasing well size was evaluated (Graph 2). Next, the stiffness coefficient was generated from the force vs. displacement curves (Graph 3). Finally, analysis of the forces generated at 50% compression was completed (Graph 4). There was a corresponding increase in radial force as the devices were progressively constrained. Only the 4 mm AVPIV could practically fit within the 1.5 mm acrylic well to provide accurate radial force assessment. The 5 mm AVPIV was found to exert the highest amount of radial force (1.35 N) within the 2 mm well. Interestingly, the 7 mm device exerted less radial force compared to the 5 mm device when constrained within the 2 mm well (5 mm: 1.35 N, 7 mm:1.13 N, p value: 0.02). Though the 8 mm device trended towards less radial force when compared to the



GRAPH 1. Length vs. diameter relationship for Amplatzer vascular plug type IV in glass tubing.

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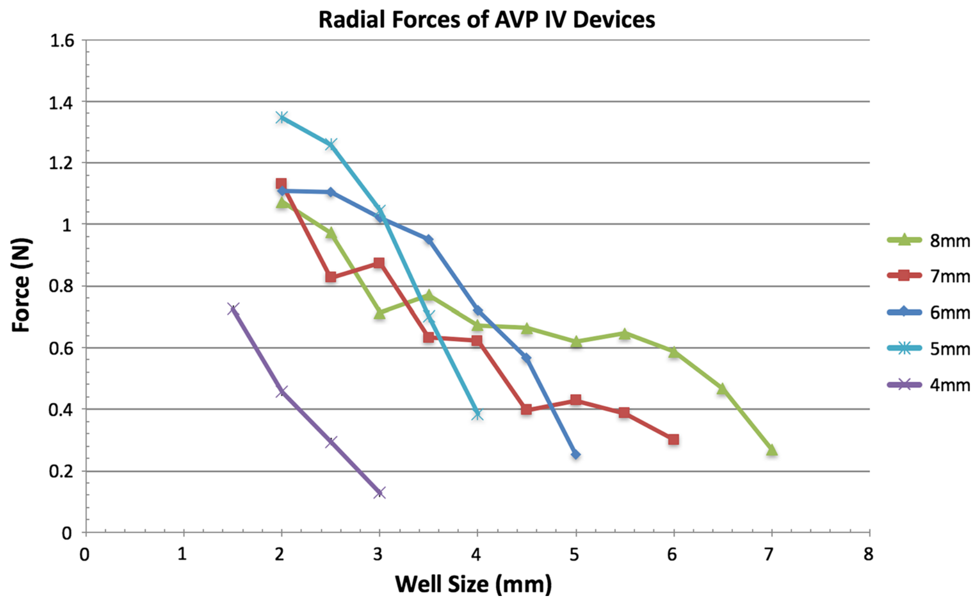
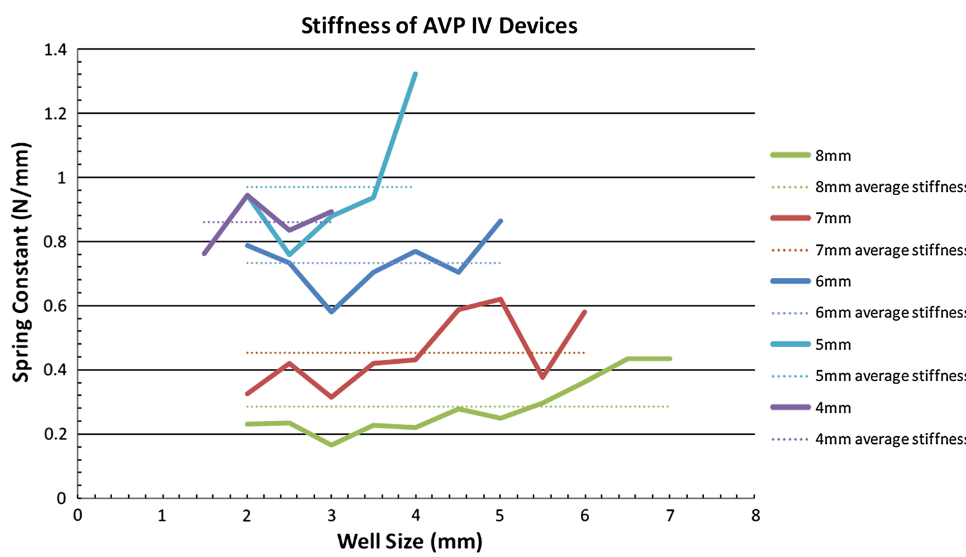


GRAPH 2. Radial force of Amplatzer vascular plug type IV vs. diameter constrained.



GRAPH 3. Stiffness coefficient was generated from the force vs. displacement curves.

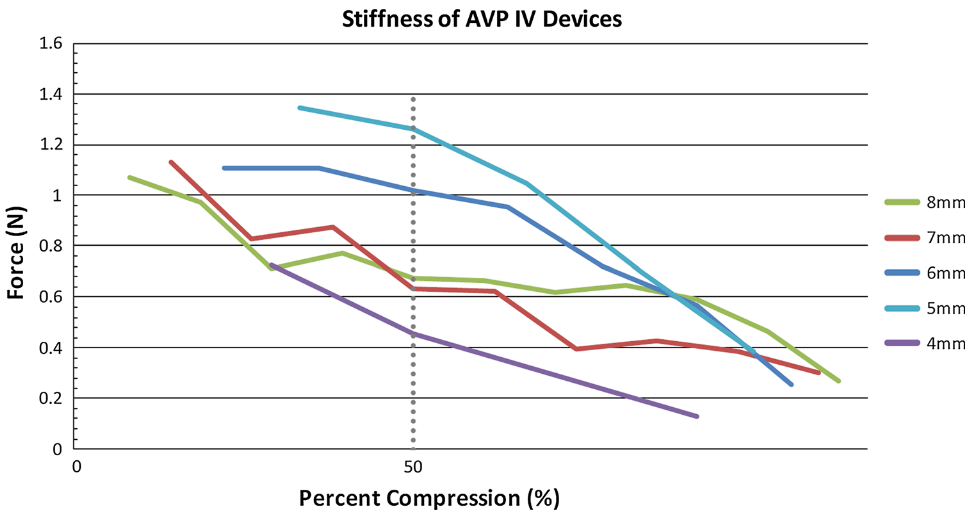
5 mm device, it did not reach statistical significance (8 mm: 1.07 N, p-value: 0.06).

On evaluation of the force vs. displacement plots, there was a slight upward trend in stiffness for each device as well sizes increase. Much more robust differences in stiffness coefficients were noted when comparing the devices to one another. Again, in this setting the 5 mm AVP IV was significantly stiffer than all other devices. In this assessment, the 6 mm device was also stiffer than the 7 and 8 mm devices. When evaluating compression to 50%, the 5 mm AVPIV appears to be associated with the highest force for displacement.

The 4 mm AVPIV deviates from the trends found across all evaluations. It was found to have the least amount of force required to displace to 50%, however it was found to have a stiffness coefficient in the range similar to the 5 and 6 mm plugs.

DISCUSSION

In our examination of the AVPIV, we noted several important characteristics. First, bench testing demonstrated a consistent and reproducible length for diameter relationship. One consideration of our study



GRAPH 4. Forces generated at 50% compression.

was that of using rigid glass tubing for device constraint in measuring the length vs. diameter relationship. The exact relationship is difficult to ascertain given the heterogeneity of the arterial vessel in which the device is deployed. In clinical use, our preference of error would be towards overestimation of length in order to avoid having a device protrude further than predicted. Additionally, given the variable distensibility of arteries and veins, we felt modeling this behavior outside the scope of the current project.

Our hypothesis was that the larger devices would have a corresponding increase in radial force. In this study, we found that the larger diameter devices did not demonstrate the highest radial force. We found the 5 mm AVPIV to exert the highest radial force, significantly higher in the two and three-millimeter wells. We felt that it was important to fully interrogate the devices with multiple metrics to evaluate the validity of our findings. All the devices were made from the same nickel-titanium alloy nitinol because of its super-elastic properties. We did not assess the gauge of the wire used in this study. We elected to evaluate the structural properties and thus using a spring model derived a stiffness coefficient defined as $k = F/x$ where k is stiffness, F is force applied, and x is displacement. We specifically chose to evaluate stiffness in the early deformation elastic portion of the force vs. displacement graph. Concerned that this property could dynamically change depending on the well size, we repeated this assessment for each device in each well size. We did see small amounts of variability, however in general the stiffness of the devices remained relatively stable for each device. We found that the 4, 5, and 6 mm devices were stiffer than the 7 and 8 mm devices.

We evaluated the stiffness relative to the percentage of compression. Given most of our clinical use is within vessels 2–4 mm in diameter, this can represent significant relative compression comparing the 4 mm device to an 8 mm device. This again showed a tendency for the largest devices to be more compliant.

The wire gauge, the unconstrained ratio of width vs. length, and the baseline lattice density all could affect the stiffness. We hypothesize there are also multiple dynamic properties that contribute to the radial force profile. As an example, the lattice orientation varies with respect to compressive force as it is applied. We believe this complex interaction of baseline structural variation and dynamic structural change are responsible for the stiffness results of the various devices.

There were a few considerations or limitations of the study that should be discussed. One of the limitations of this study is that we were only able to evaluate one device of each size assessed. Despite this we did not note any significant variance or radial force weakening throughout the study to suggest deterioration of the device with repeat manipulation. Our described method for measuring radial force is a novel approach. Our developed methodology created reproducible data that was internally consistent. This limits the comparability of our data to other methodologies for radial force assessment.

CONCLUSION

Our study demonstrated a reproducible length for diameter relationship for the commercially available Amplatz Vascular Plug Type IV devices. Evaluation of radial force in our study demonstrated that the 5 and 6 mm AVPIV devices were associated with the greatest amount of radial force. The larger 7 and 8 mm AVPIV devices are not associated with significantly higher radial force. This data would suggest that oversizing of an AVPIV device could be performed in a safe and effective manner. *In vivo* assessment of oversizing of AVPIV devices and assessment of thrombotic properties of oversized AVPIV devices should be pursued.

CONFLICT OF INTEREST

All the authors declare that we have no conflict of interest.

HUMAN AND ANIMAL RIGHTS

This article does not contain any studies with human participants or animals performed by any of the authors.

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