

Original Article

Structural Design Optimization of Braided Nitinol PDA Occluders: A Parametric DOE Approach to Radial Compliance

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The PDA occluder is a transcatheter minimally invasive device designed to close the anomaly channel between the aorta and pulmonary artery. It is important to obtain optimal ratio of radial stability and compliance due to the great anatomical variability of ductal morphology. As the mechanical behavior of the Nitinol braided structure determines the effectiveness and safety of such devices, this study investigates the effect of braid angle, wire diameter, and braid pattern on the deformation of PDA occluder waist under physiologically relevant radial pressures. Parametric models with braided structure were developed and analyzed via finite element simulation taking into account geometric non-linearity (large deflection) in combination with linear elastic material model of Nitinol, for braid angles of 30° and 60° (with an additional 45° midpoint check), and wire diameters of 80 and 120 μm (with an additional 100 μm midpoint check), across plain and 2×2 braid configuration. Wires were modeled as one-dimensional beam elements; the analysis was performed with the consideration of frictionless and frictional contacts at the wire intersections, however, no significant differences in deformation was found. Radial pressures 5 kPa and 30 kPa corresponded to low- and high-pressure physiological condition of the duct, respectively. Full factorial design of experiments (DOE) was performed in order to evaluate the contribution of design parameters to deformation behavior, using 30°/60° braid angles and 80 μm/120 μm wire diameters as factorial levels, while the intermediate 45° braid angle and 100 μm wire diameter were used for cross-verification of results. Thinner wires and the 2×2 braid configuration resulted in greater radial deformation and thus greater compliance of the structure, while thicker wires reduced deformation. The influence of braid angle depended on the braid configuration. Wire diameter was found to be the most influential factor, followed by braid pattern and braid angle, with a noticeable interaction between wire diameter and braid pattern. Overall, the findings presented here allow the development of a geometry-driven framework to design effective PDA occluders.

Introduction

Patent ductus arteriosus (PDA) is a continuous connection between the descending aorta and pulmonary artery (PA) which does not close after birth, causing irregular blood flow and hemodynamic problems. However, hemodynamically significant patent ductus arteriosus (PDA) remains a prevalent challenge in the care of preterm infants, and if not treated appropriately, can lead to complications like heart failure, respiratory distress, and higher chances of morbidity and mortality in the baby [1]. As demand for innovative cardiac occluder devices rises, design and manufacturing have also improved, with the use of nitinol alloys and specialized braiding techniques used for these devices [2]. A

study from a single center after twelve years of experience using percutaneous patent ductus arteriosus closure devices was found to be safe and effective with a low global complication rate [3]. The safe deployment and development of next generation designs of the occluder can be explored and optimized in detail using experimentally validated FEA models, which could give meaningful insights [2]. One of the most important parameters which affect the mechanical integrity and performance of the devices in the laboratory is the finite element analysis [FEA] parameter that defines the influence of different parameters on the performance of the devices, including material stiffness, wire density, braid angle and braiding techniques used (two by two or plain). A finite element study demonstrate that braid angle is a key governing

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Table 1: Assumptions and implications considered in this study

Assumption	Description	Risk	Remarks
Radial pressure of 5 kPa (conservative estimate)	Adopted from Yiming et al. [9], who used this value for VSD occluders and considered it a safe reference for PDA occluder analysis	Medium	A device that appears to seal adequately in simulation may not perform as well under higher or true physiological loading conditions
Wires represented as beam elements	Each node carries 6 degrees of freedom (translational and rotational), allowing wire bending to be captured	Medium	Bending response is reasonably represented, but inter-wire friction is not accounted for
Retention skirt modelled as circular	Simplified in the CAD geometry since fine skirt detail was not the focus of this work	Low	Consistent with the study's aim of characterizing mechanical behavior at the waist
Two retention skirts modelled (vs. one in the actual device)	Included on both ends to simplify the application of boundary conditions and loading	Medium	Waist behavior is well represented, but skirt-level results may not fully reflect actual device performance
Only the waist region modelled as braided	The waist was treated as the primary functional zone for this analysis	Medium	Lowers computational cost, though peripheral effects and true anchoring behavior are not captured
Wire diameter range of 80–120 μm	Based on comparable predicate devices and manufacturer specifications	Low	Supports evaluation of radial force and informs sizing decisions across the commercial range
Braid angles of 30°, 45°, and 60°	Braid angles of 30° and 60° were applied as the nominal wire-path generation angle in the CAD/FE model as the full factorial levels, spanning stiffer to more flexible configurations; an additional 45° midpoint check was performed for cross-verification, consistent with the treatment of the 100 μm wire diameter midpoint. The local braid angle at the waist following shape-setting was not independently modeled.	Low	Supports a sensitivity analysis across braid geometries; angles represent the nominal generation angle used to construct the braided geometry rather than a directly prescribed local waist angle, and the 45° level was subsequently cross-checked against the local waist braid angle measured in a benchmarked commercial ADO device.

parameter that dictates the radial and kink performance of both bare-metal and covered wire braided stents [4]. Understanding the influence of the braid design and the potential change of the surface of the braids will help develop strong biocompatible occluders, maintaining structural integrity and functioning over time after the implantation. Through the optimization of wire dimensions, provides an ability of significantly increase the device axial plugging in the tapered duct without damaging the ductal tissue, retention, and endurance against fatigue under physiological stresses [2]. All these material properties allow achieving a compression for minimally invasive delivery and reliable expansion of the device to its initial pre-set shape within the body to effectively close defects such as PDA. In addition, Nitinol possesses characteristics that include corrosion and fatigue resistance, which are very essential in terms of durability within the highly demanding environment of the heart. The thermal forming nature of Nitinol allows for the manufacture of complex braided structures in order to acquire the necessary mechanical characteristics [2].

Mathematical formulations are used in the process of designing of the device in the CAD software, such as Creo, to ensure the uniformity of dimensioning of the device [2]. The most recent PDA occluder design takes into account not only the geometric optimization but also procedural deliverability, directly affecting the effectiveness of the device and the safety of the patient. However, over the last two decades, research has focused on the use of Nitinol (NiTi) due to its superior properties such as super-elasticity, biocompatibility, and strength [5]. Precision laser welding is used for connecting nitinol wires, providing high precision and durable joints, maintaining super elastic properties of the materials. The heat treatment process is used to provide thermal shape setting at high temperature establishing the super elastic property of nitinol. This increases the ability to restore the distortions during activation to the initial shape of the device. These processes provide the increased functional efficiency and the lifetime of nitinol braided products such as stents and occluders. Choosing of the occluder with retention skirt slightly larger than the smallest ductus diameter and the cone shape ensured the stable deployment and decreased the risk of embolization and adaptation to the morphological diversity of the adult duc-

tus patients [6]. For the review of recent advances in miniaturisation and in computational-aided modification of shape of the devices is taken into account in order to adapt to the diversity of anatomical and patient population, indicating the importance of virtual modeling for the design assessment [7]. However septal occluders having a proximal retention area on the proximal wall, a distal retention area on the bundled distal end, and a cylindrical crosspiece arranged between said proximal and distal retention areas were being used commonly [8].

In this study, the mechanical behavior and functional performance of the patent ductus arteriosus (PDA) occluder device were investigated as the result of geometric changes under various radial pressures, including braid angle, wire diameter and type of the braid. The aim of the study was to find out the role of these parameters in the non-uniform deformation that is important for safe sealing of the tapered PDA duct without injury of the ductal tissue. For this purpose, in vivo loading conditions were simulated by creation of parametric 3D models and their analysis using finite element analysis. The study helps to analyze and to develop an appropriate design of PDA occluders, which requires sufficient radial stability and compliance in axial direction for the deployment and sufficient ductal tapering and fragility.

Materials and Methods

Digital prototype development

Prototype braided occluders were constructed with three dimensional (3D) computer-aided design (CAD) models that were used to model the target geometries. Standard braiding equations were used to create wire paths in PTC Creo (Version 8, PTC Inc., Boston, MA, USA) to correctly represent the interfilament crossings needed for the mesh architecture, followed by Boolean operations. Plain (1x1) and 2x2 braid patterns were created. To vary the diameter of the wires, they were tested at three different wire diameters: thin wire of 80 μm , an intermediate wire diameter of 100 μm , and a 120 μm wire diameter selected using a design of experiments (DOE) to represent the primary condition of interest.

The occluder is a device that closes the PDA defects. The device body expands into the defect on deployment and the retention skirts

anchor the implant to the margins of the tissue surrounding the defect, thus reducing the risk of implant migration. This type of construction is a compromise between flexibility and structural rigidity, which enables effective defect closure, favorable tissue in-growth and restoration of blood flow [9]. The dimensions used in this study for the modeled devices were: end diameter of the descending aorta (A) = 8mm, end diameter of the pulmonary (B) = 6mm, the retention skirt diameter (C) = 12mm, and the total length of the device (D) = 7mm.

The final geometry was simplified and imported into ANSYS SpaceClaim (ANSYS Inc., PA, USA) where the braided wires were represented by beam elements. For reasons of analysis, the two ends of the device were modeled as idealized opposing shells instead of the more complete and detailed disc configuration found in commercial devices. The geometry of the skirts on the aortic side (which is generally included in the commercial version of the occluder for anchoring and closure) was therefore not used, to allow the mechanical behavior of the waist section to be isolated and characterized.

Material modelling

Nitinol was selected as the device material with a Young's modulus of 50000 MPa and Poisson's ratio of 0.3, and represented using a linear elastic model. Given that the study assumptions (table 1) simplify the geometry and loading conditions to focus on characterizing mechanical trends at the waist region rather than replicating full physiological behavior, a linear elastic representation was considered adequate for this comparative analysis of geometric and structural configurations.

Mesh convergence studies

A mesh sensitivity study was performed to determine an appropriate element size for the simulations, with radial deformation used as the convergence metric. As the mesh was progressively refined, the change in deformation between successive iterations remained small, indicating that the solution was largely insensitive to further refinement. Based on these results, a maximum element size of 0.3 mm was adopted for all subsequent simulations.

Structural analysis

Taking into account the complicated nature of the material and geometry characteristics of the braided mesh, Finite Element Analysis (FEA) was applied to design a device with required properties. The advantages of FEA are its ability to perform a detailed investigation of the deformation patterns, which is essential for studying the behavior of the cardiovascular occluder devices, because this type of devices expands or contracts in response to physiological loading. As a numerical approach, FEA breaks down complicated geometry into finite elements and solves the equations of the structural mechanics problem. The simplified geometry of the structure presented in figure 1 allows applying loading consistently without modeling skirt-tissue contact.

Braided occluder structures were simulated using BEAM188 and shell elements in ANSYS. The BEAM188 elements have six degrees of

freedom per node, including translation and rotation, which provides an accurate estimation of the axial, bending, and torsional stiffness of the Nitinol wires. This element formulation allows taking into consideration the mechanical properties of each monofilament in the braid and thus makes it possible to give a reasonable estimation of their deformation and interaction under loading. Because of the significant deformations in the radial direction, Large Deflection (geometric nonlinearity) option was turned on in ANSYS. It allows analyzing the nonlinear geometric response of the wires, while the material behavior itself is linear elastic. Frictionless and frictional contact formulations were considered in the case of wires crossings to investigate the influence of the contact type on the deformation. The two contact formulations led to similar results, which means that in the case of the beam-element representation of the wires, the influence of the friction on radial deformation is negligible.

Simulations were carried out in ANSYS Workbench 2025 under two pressure conditions - 5 kPa and 30 kPa [9] - corresponding to normal and elevated physiological blood pressure environments, respectively, and relevant to assessing device safety. The 5 kPa value was adopted from the literature as a representative radial load [9]. Geometric parameters used in the analysis included wire diameter (0.08–0.12 mm), braid angle (30°, 45°, 60°), and a fixed wire count of $N = 72$ [10].

$$Q_{total} = P * C$$

The circumferential load acting on the device was obtained by multiplying the applied radial pressure (P) by the device circumference (C), giving the total circumferential line pressure (Q_{total} , N/mm) distributed along the circumference: This line pressure was then divided by the total number of wires ($N = 72$) to obtain the load carried per wire (Q_{wire}):

$$Q_{wire} = \frac{Q_{total}}{N}$$

The relationship between nodal force and displacement is $F = Kx$, where the stiffness coefficient (K) relates applied force to resulting displacement (x).

The computed line pressure values were applied in the FEA simulations to evaluate radial compression and overall structural deformation. These results offered key insight into the deformation behavior of the occluder across the range of design and loading conditions considered (figure 3).

Design of experiment

To evaluate how various design parameters, affect occluder performance, the DOE was applied according to the full factorial method. The parameters considered in the study are Nitinol wire diameter (80, 120 μ m), braid angle (30°, 60°), and braid type (plain and 2x2). An additional midpoint check was performed at a wire diameter of 100 μ m and a braid angle of 45° for cross-verification of the factorial trends, though these were not treated as full factorial levels. The effect of the selected parameters on radial deformation of the PDA occluder waist in response to physiological radial pressure was studied for 5 kPa and 30 kPa. Corresponding models have been designed by means of the CAD geometry

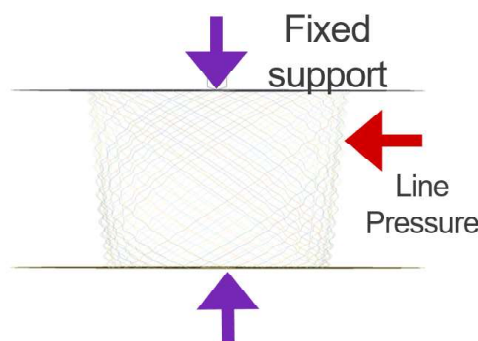


Figure 1: Loads and boundary conditions

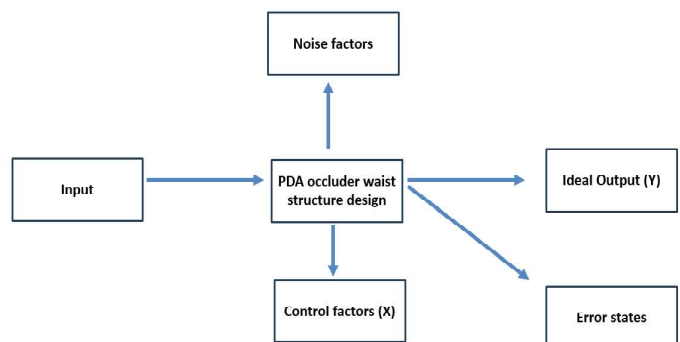


Figure 2: P diagram

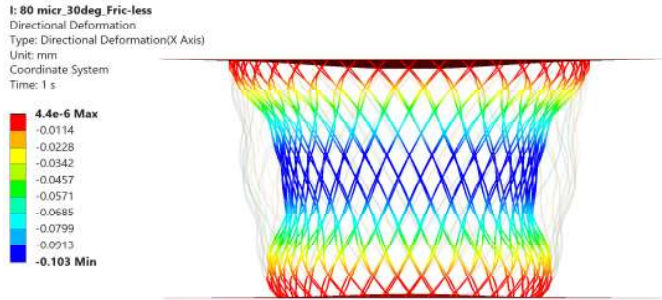


Figure 3: Representative radial deformation contour for an 80 µm wire diameter, 30° braid angle configuration at 30 kPa

and evaluated by means of FEA.

The radial deformation was selected as the response variable and estimated for all cases in Minitab in order to detect main effects and interaction effects on the basis of statistical analysis of the data obtained during FEA. Analysis was based on the P-diagram (figure 2). According to this figure, noise factors and error states are not considered in the framework of the present study. Input include radial pressure, while control factors (Xs) are the following: (A) braid angle (30°-60°), (B) wire diameter (80-120 µm), and (C) braid type (plain and 2x2). Radial deformation (Y) is the ideal output of the model, which represents the occluder performance as the axial plug in the tapered duct geometry. Thus, all factors considered in the study are described by the P-diagram in terms of their individual and interaction effects on the output variable (radial deformation). This helped to quantify the combined effect of wire diameter and type of braid, which provided an optimal trade-off between duct occlusion and minimal trauma.

Result

Structural analysis

Table 2 shows all the braid angle, wire diameter, and braid type combinations covered by the DOE study.

Under 5 kPa loading, deformation was governed primarily by radial compression. Braids with thinner wires (80 µm) consistently deformed more than those with thicker wires (120 µm) under identical loading, reflecting the lower bending stiffness of finer filaments. A similar trend emerged with braid angle: smaller angles (30°) produced uneven deformation with pronounced axial plugging. This angle effect was configuration- and diameter-dependent: in the 2x2 pattern, increasing the angle to 60° increased deformation at both wire diameters, whereas in the plain braid it modestly reduced deformation at 80 µm but showed a slight increase at 120 µm. Among all cases, the 80 µm/2x2/60° configuration showed the greatest displacement, and the 120 µm/plain/30° configuration showed the least, reflecting the combined influence of wire diameter, braid pattern, and braid angle on radial deformation.

When the applied load was raised to 30 kPa, which is six times the

Table 2: Full factorial combinations of braid angle, wire diameter, and braid type

Braid Angle (°)	Wire Diameter (µm)	Type of Braid
30	80	Plain
30	80	2x2
30	120	Plain
30	120	2x2
60	80	Plain
60	80	2x2
60	120	Plain
60	120	2x2

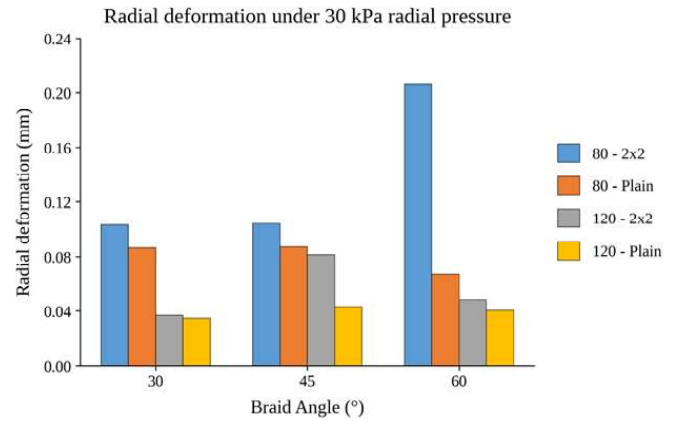


Figure 4: Radial deformation at 30 kPa radial pressure across braid angles (30°, 45°, 60°), wire diameters (80 µm, 120 µm), and braid patterns (plain, 2x2)

base level, deformations showed linear behavior relative to the applied pressure level. All studied structures became more deformed when applying six times higher pressure value, with increase of the radial displacement by approximately a similar factor; again, the 80 µm configurations as a group proved to be the most deflected, with the 2x2/60° combination reaching the largest deformation overall. For instance, the 80 µm/30° structure subjected to 30 kPa load showed about six times greater radial displacement compared to the 5 kPa one.

The comparison of plain and 2x2 braid patterns, both consisting of 72 wires, indicated that the 2x2 braid was always more flexible and showed larger radial deformation compared to the plain braid pattern in all studied combinations of angle and wire diameter. This was caused by the fact that the 2x2 seemed to provide more rotation freedom instead of additional restriction despite the same number of wires being used. Thus, plain braids gave rise to the lowest deflections while 2x2 braids resulted in the highest ones for any wire diameter and braid angle investigated.

In summary, these findings indicate distinct mechanical characteristics in the different parameter space considered. For the plain braid, a 60° braid angle (80 µm) resulted in lower and more homogeneous deformation due to increased circumferential stiffness; hence this is an excellent characteristic for devices used in thick muscular regions like ventricular septum. On the other hand, a 45° braid angle - particularly in the 2x2 configuration - favored higher, more axially adaptive deformation, which is an excellent characteristic for PDA closure since the de-

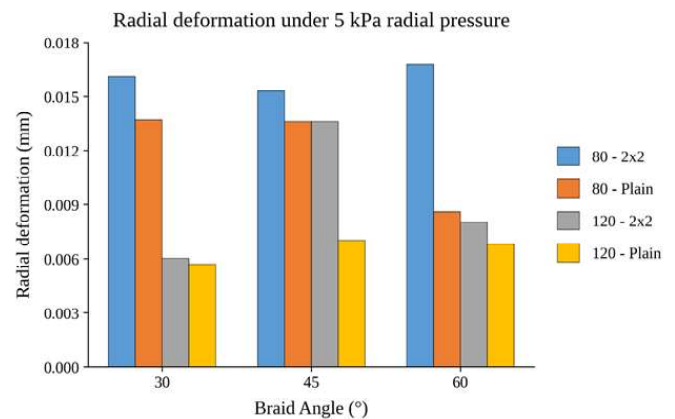


Figure 5: Radial deformation at 5 kPa radial pressure across braid angles (30°, 45°, 60°), wire diameters (80 µm, 120 µm), and braid patterns (plain, 2x2)

Table 3: Radial deformation across braid configurations at 30 kPa

Braid Angle (°)	Wire Diameter (μm)	Type of Braid	Radial Deformation (mm)
30	80	Plain	0.0866
60	80	Plain	0.0669
30	120	Plain	0.0346
60	120	Plain	0.0402
30	80	2 × 2	0.1030
60	80	2 × 2	0.2070
30	120	2 × 2	0.0366
60	120	2 × 2	0.0481

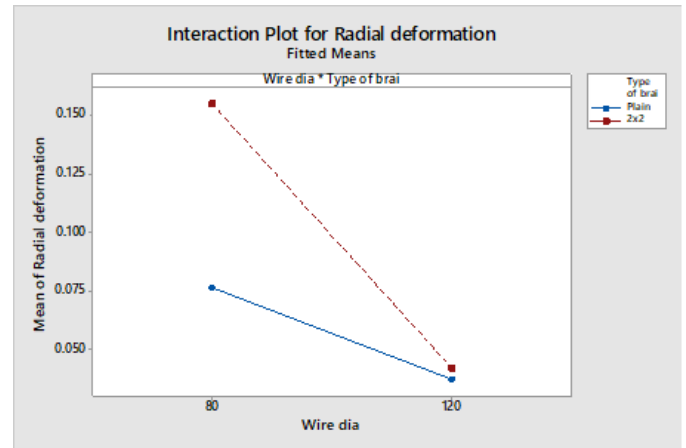
vice needs to be more adaptable and conform to the tapered geometry of the ductal region. Devices with 2x2 braid configuration have shown greater radial deformation compared to devices with plain braid configuration; this shows increased compliance of devices with 2x2 braid configuration, which is attributed to the ability of 2x2 braid to rotate more freely at the crossing point. It is apparent that devices with thinner wire diameters of 80 μm have had the highest deformation indicating that as cross-sectional stiffness decreases structural flexibility increases.

The maximum radial deformation (0.207 mm) was observed for the 2x2 braid fabricated with 80 μm wire at a braid angle of 60° under a radial pressure of 30 kPa. The minimum radial deformation (0.00568 mm) occurred for the plain braid fabricated with 120 μm wire at a braid angle of 30° under 5 kPa loading. In both cases, the deformation values were identical for the frictionless and frictional contact models

Design of experiments

DOE analysis in Minitab was used to quantify the individual and interactive contributions of braid angle, wire diameter, and braid pattern to radial deformation. All three factors returned statistically significant effects, with wire diameter exerting the strongest influence on radial deformation at the PDA waist, followed by braid type, the interaction between wire diameter and braid type, and finally braid angle. Interaction plots further indicated that the effect of wire diameter was strongly dependent on braid pattern. Table 3 presents the radial deformation values computed at 30 kPa across the full set of input combinations.

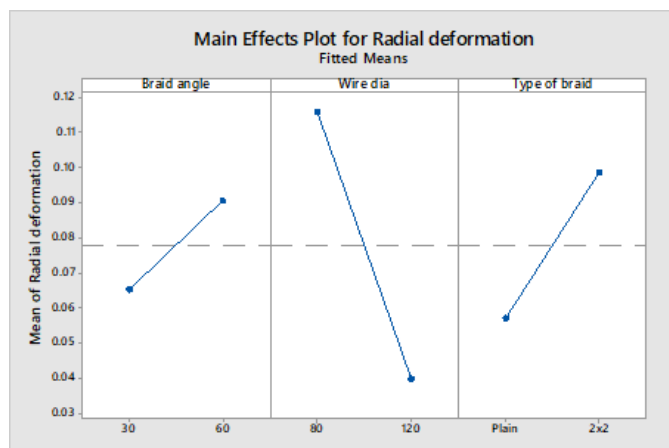
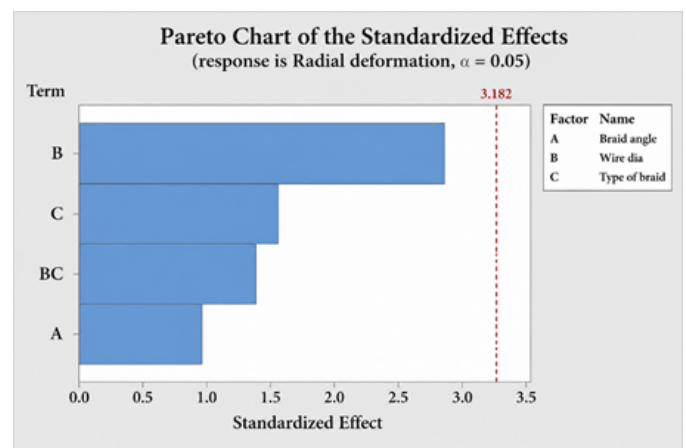
As wire diameter increased from 80 to 120 μm, mean radial deformation decreased correspondingly (figure 4, figure 5). The main-effect of braid angle showed a mean rise in deformation from 30° to 60° (figure 6), an effect driven largely by the 2x2 braid configuration, as detailed in the interaction analysis below. The interaction between wire

**Figure 7: Interaction plot for radial deformation**

diameter and braid type (figure 7) showed that both braid patterns followed this decreasing trend, but to markedly different degrees: the plain braid declined modestly with increasing wire diameter, whereas the 2×2 braid showed a much steeper decline, with the two braid types converging toward similar deformation values at the larger wire diameter. This steep slope indicates that the 2×2 pattern's compliance advantage — and therefore its sensitivity to wire diameter — is most pronounced at smaller wire diameters, with the two braid types converging toward similar deformation as diameter increases. The corresponding Pareto chart (figure 8) ranks the relative influence of each factor and their interaction: wire diameter (factor B) had the strongest effect, followed by braid type (factor C), the wire diameter–braid type interaction (factor BC), with braid angle (factor A) contributing a comparatively smaller effect.

Discussion

Taken together, these results show how each design factor shapes radial deformation at the occluder waist under physiologically relevant loading. Wire diameter had the biggest effect, followed by braid type, the interaction between the two, and then braid angle. Across the design space, deformation grew more uniform as the braid angle increased, thicker wires consistently cut deformation, and switching from a plain to a 2×2 braid drove it up sharply. For the plain braid at the smaller (80 μm) wire diameter, increasing the braid angle generally promoted greater circumferential restraint and more uniform deformation — a behavior well suited to thicker septal tissue, as in VSD closure. By contrast, 45°

**Figure 6: Main effects plot for radial deformation****Figure 8: Pareto chart of the standardised effects**

angles combined with a 2x2 braid pattern produced a more compliant structure with localized deformation, allowing better axial adaptation to the tapered geometry of the PDA. Notably, the 2x2 braid at 60° produced the greatest overall radial deformation in the dataset; the 45° nominal design angle - set as the wire-path generation angle in the CAD/FE model - closely matches the measured mean local waist angle (46.6°) observed in benchmarking of an existing ADO device, and was selected not for maximal radial compliance but for its localized, axially adaptive deformation pattern, particularly evident at the 120 µm wire diameter, where deformation (0.0813 mm) exceeded both the 30° (0.0366 mm) and 60° (0.0481 mm) cases better suited to the PDA's tapered anatomy. Consistent with this, direct angle measurements taken along the waist of a benchmarked 8/6 mm ADO predicate device showed that the local braid angle is not uniform even in the unloaded, shape-set state, ranging from approximately 32.7° to 76.8° across the transition zone (mean H° 46.6°, median H° 43.9°, SD H° 12.4°, n = 18). This is distinct from the load-induced non-uniform deformation reported in the present simulations — the predicate variability instead reflects inherent geometric scatter introduced during braiding and shape-setting, rather than a response to radial pressure. It nonetheless indicates that some degree of non-uniform braid angle along the waist is already present in commercial devices at baseline, and that a single nominal value such as 45° necessarily simplifies this underlying spread; the predicate angle is more appropriately reported as a range or as mean ± SD rather than a fixed point value. The interaction between wire diameter and braid type was particularly evident in the plots, where the two braid-type curves converge at larger wire diameters, indicating that thicker wires suppress deformation more strongly in the 2x2 configuration than in the plain braid.

This pattern has direct implications for axial plugging capability. A 45° braid angle combined with a 2x2 pattern appears to translate radial compliance into longitudinal adaptability - a property essential for accommodating the PDA's non-uniform taper without generating excessive outward force that could impinge on the adjacent aorta or pulmonary artery. In contrast to stiffer designs better suited to septal anchoring, this configuration favors foreshortening under deployment compression, supporting secure occlusion while remaining within safe radial pressure limits.

It is worth noting that the wires in this study were represented as one-dimensional beam elements, and both frictionless and frictional contact conditions at wire crossings produced comparable deformation results. While this indicates that friction had negligible influence within the present modelling framework, the beam idealization inherently simplifies the true contact area and interaction between crossing filaments relative to a fully resolved three-dimensional geometry. Consequently, friction-dependent effects that may influence real device behavior - such as crimping resistance, recoil, and fatigue response at wire intersections - could not be fully captured, and this remains a limitation to be addressed in future work.

Drawing on these findings alongside relevant literature and existing patents, the study points toward a candidate design space for PDA occluders: a wire diameter of 80 µm for smaller devices and 120 µm for larger devices, a nominal 45° braid angle - closely matching the measured mean local waist angle (46.6°) observed in the benchmarked predicate - and a 2x2 braid pattern. Together, these parameters are expected to allow the device to plug axially into the tapered duct without compromising the fragile ductal tissue, while maintaining sufficient radial resistance for stable anchoring and improved axial performance across anatomical variability.

Conclusion

The present study shows that braid angle, wire diameter, and braid pattern each have a significant effect on the mechanical behaviour of the PDA occluder under radial loading. The effect of braid angle on stiffness was found to depend on the braid configuration, and was most prominent in the 2x2 pattern. A nominal braid angle of 45° was chosen for this reason, closely matching the measured mean local waist angle (46.6°) observed in benchmarking of an existing ADO device, and was found to promote the non-uniform, axially adaptive deformation required for a secure fit within the tapered PDA geometry, without causing injury to the vessel. It was observed that plain braids resisted deformation more than 2x2 braids, as the greater rotational freedom at the crossing points in the 2x2 pattern leads to higher overall compliance. Across all the configurations studied, an increase in wire diameter was found to reduce deformation consistently, confirming that wire diameter is the primary design parameter for controlling device stiffness.

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