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IN-VITRO EVALUATION AND MECHANICAL PERFORMANCE OF SEPTAL DEFECT OCCLUDERS FOR ATRIAL SEPTAL DEFECT TREATMENT

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ABSTRACT

Atrial Septal Defect (ASD) is a prevalent congenital cardiac malformation characterized by a persistent patency in the inter-atrial septum, facilitating aberrant left-to-right shunting of blood. If left untreated, ASD may precipitate adverse sequelae such as right ventricular volume overload, atrial arrhythmogenesis, pulmonary arterial hypertension, and eventual cardiac failure. While surgical correction was historically the standard of care, transcatheter closure utilizing septal occluder devices has emerged as a minimally invasive and clinically efficacious intervention. This research articles evaluates the mechanical performance and design optimization of a nitinol-based septal defect occluder incorporating polyethylene terephthalate (PET) membrane patches. The device was subjected to in-vitro simulation protocols designed to replicate human atrial morphology and physiological hemodynamic environments. Comprehensive bench-top assessments were performed to quantify key functional parameters, including delivery system compatibility, structural conformability to septal anatomy. Experimental findings revealed that the device exhibited consistent deliverability through conventional catheter-based introducer systems, with excellent conformability to the septal tissue. Furthermore, sealing efficacy across a spectrum of defect diameters was validated, indicating reliable performance under varying anatomical scenarios. Collectively, these results underscore the importance of in-vitro mechanical validation in the preclinical development of ASD occluders, facilitating

iterative design refinement and enhancing both safety profiles and therapeutic outcomes prior to clinical deployment.

KEYWORDS: Atrial Septal Defect, Septal Occluder, In-vitro Testing, Radial Force, Nitinol, Device Deployment and Regulatory Compliance.

INTRODUCTION

Atrial Septal Defect (ASD) is the most common congenital cardiac anomaly, with an estimated incidence of approximately 1 in 1,500 live births (Gatzoulis et al., 2000). ASD results from a defect in the interatrial septum, allowing left-to-right shunting of blood, which leads to right heart volume overload and altered hemodynamics. If left untreated, this abnormal circulation may progress to complications such as pulmonary hypertension, right-sided heart failure, atrial arrhythmias, and paradoxical embolism leading to stroke (Maron et al., 2010; Baumgartner et al., 2017). Historically, ASD closure was performed via open-heart surgical repair; however, the development of transcatheter septal occluder devices has revolutionized management by providing a minimally invasive approach. These devices offer reduced perioperative morbidity, shorter recovery periods, and comparable long-term efficacy to surgical repair (Masura et al., 2005; Miller et al., 2007). Typically constructed from nitinol wire mesh integrated with synthetic fabric patches, these occluders are delivered percutaneously via catheter-based systems designed for controlled and accurate deployment across the atrial septum. Despite their clinical effectiveness, continuous innovation in device geometry and material composition necessitates rigorous in-vitro mechanical evaluation to ensure safety, reliability, and performance under physiological conditions. This study focuses on the ASD Occluder, engineered for the percutaneous closure of secundum-type ASDs and fenestrations post-Fontan procedure. The primary objective is to evaluate key mechanical attributes—namely, deployment behavior, compatibility with existing delivery systems—using high-fidelity bench-top simulation models that mimic human cardiac anatomy and hemodynamic loads. This investigation provides critical preclinical insights for design validation, supports regulatory documentation, and aids in optimizing device functionality prior to clinical use. Ultimately, the study aims to close the translational gap between engineering design and clinical application, ensuring both patient safety and therapeutic efficacy.

Technical Specifications

The technical specifications is given in the below table

Table 1: Technical Specifications.

Components	Material
Delivery Sheath	Polytetrafluroethylene, PEBAX, Stainless steel
Dilator	High-Density Polyethylene
Delivery Cable	Stainless Steel, Polyoxymethylene
Loader	High-Density Polyethylene

Literature Review

Atrial Septal Defect (ASD) is widely recognized as one of the most common congenital heart anomalies. Historically managed with open-heart surgery, the treatment landscape has been transformed by the advent of minimally invasive transcatheter interventions. Devices such as the Amplatzer Septal Occluder and Gore Helex Septal Occluder have become standard tools for defect closure, offering a catheter-based alternative that significantly reduces perioperative risks and recovery time (Masura et al. 2005; Miller et al. 2007). Numerous clinical studies have confirmed the effectiveness of these devices, reporting success rates above 95% and low incidences of complications like thromboembolism or residual shunting (Carminati et al. 2012; Kocaman et al. 2013). Additionally, a large-scale meta-analysis involving over 10,000 patients confirmed the long-term durability and safety of septal occluders, reinforcing their clinical reliability (Maggioni et al. 2015). Despite the clinical success of transcatheter occluders, there are significant gaps in the existing literature. Most studies emphasize clinical outcomes but lack detailed mechanical and material characterization under in-vitro conditions that mimic physiological stress. There is a paucity of comparative research on the structural performance and fatigue resistance of various occluder designs, especially in anatomically complex or pediatric cases. Furthermore, limited attention has been given to long-term biocompatibility factors such as endothelialization, late-onset arrhythmias, and risks of device erosion. Emerging trends in this field focus on device optimization through advancements in material science, including the development of biodegradable occluders and anti-thrombogenic coatings. Innovations in imaging technologies, such as 3D echocardiography and patient-specific modeling, are also enabling more precise occluder customization and deployment. Positioned within this evolving research landscape, the current study addresses a critical gap by evaluating the in-vitro performance of a next-generation ASD occluder**.** By using physiological simulation models to assess mechanical behavior, deployment characteristics, and structural integrity, this

research aims to contribute to the optimization of occluder design and improve the safety and efficacy of future ASD interventions.

MATERIALS METHOD

Study Design

This study was designed as an experimental in-vitro investigation to assess the deployment mechanics, structural integrity, and functional performance of an Atrial Septal Defect (ASD) Occluder device. The test environment was configured to simulate physiological hemodynamic conditions and anatomical constraints representative of the human atrial septum within a controlled laboratory setting.

Participants/Samples

The test specimens comprised a series of ASD Occluder devices with varying diameters, evaluated using an anatomically representative silicone-based atrial septal defect (ASD) phantom model**.** This model was engineered to accurately replicate the morphological and dimensional characteristics of the human atrial septum, including the geometry of secundum-type defects, thereby enabling physiologically relevant simulation of device deployment and performance.

Materials/Tools

The primary materials and instruments used in this study included:

- **Atrial Septal Defect Occluder**: A self-expanding, double-disc device constructed from Nitinol wire mesh with polyester fabric sewn into both discs to promote thrombosis and defect closure.
- **Occluder Delivery System**: Comprising a delivery sheath, dilator, delivery cable, and loader, specifically engineered for the accurate attachment, delivery, and deployment of the occluder.
- **0.0035" standard guidewire**: Used to facilitate smooth navigation through the simulation model.
- **Silicone-based in-vitro ASD model**: Simulated a heart with ASD for device testing under physiological-like conditions.

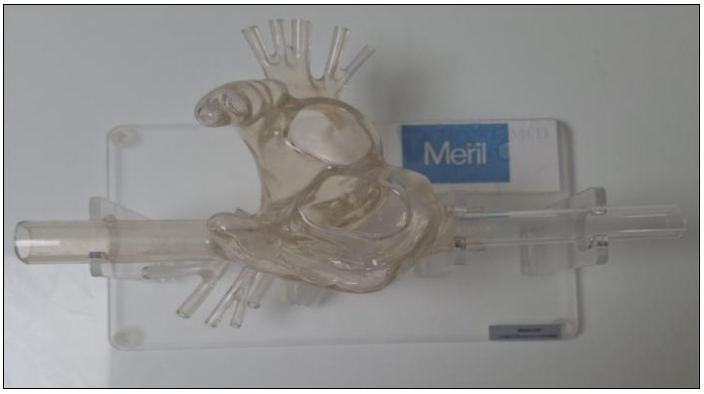

Figure 1: In-vitro ASD Simulation Model.

Procedure

Device Prepration

The delivery cable was advanced through the loader, and the occluder device was securely attached to the distal tip of the cable via threaded engagement. Subsequently, the dilator was introduced into the delivery sheath and locked in position to maintain lumen integrity. The assembled sheath-dilator system was then navigated over the guidewire and advanced across the simulated atrial septal defect, positioning the sheath tip within the left upper pulmonary vein to facilitate accurate device deployment.

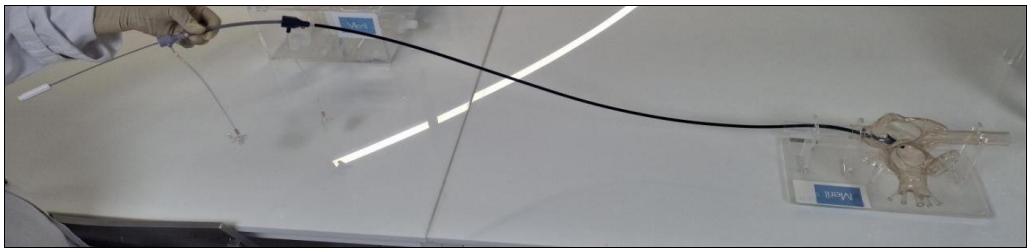

Figure 2: Delivery System.

Device Loading and Delivery

The loading device was attached to the delivery sheath, and the device was advanced into the sheath by pushing the delivery cable. With tension applied, the sheath was retracted to deploy the right atrial disc, followed by gentle "to and fro" motion to confirm positioning.

Device Placement

The occluder device was navigated across the simulated atrial septum and partially deployed at the defect site, allowing controlled expansion for initial anchoring. Positional accuracy and alignment with the septal margins were visually confirmed under simulated anatomical conditions prior to complete device release.

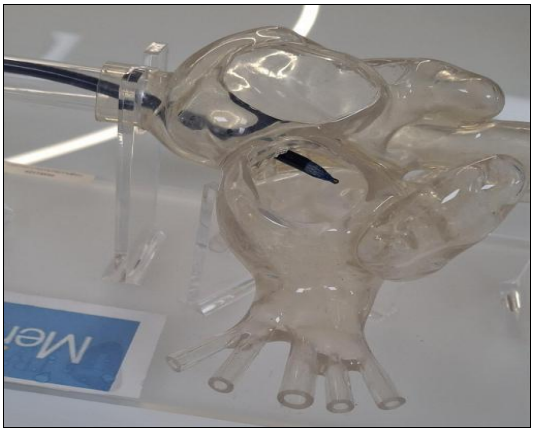

Figure 3: Placement of Septal Occluder.

Device Deployment

Upon correct positioning, the device was deployed, and the catheter was withdrawn. The occluder's expansion and position were visually inspected to confirm successful sealing.

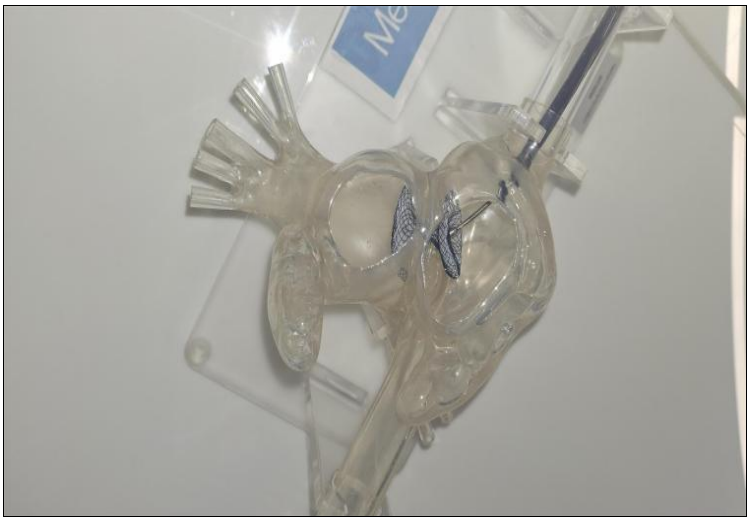

Figure 4: Deployment in ASD Simulation model.

Visual Inspection

The deployed device was examined under high-resolution visualization to assess expansion integrity, disc symmetry, and apposition to the simulated septal wall.

Data Analysis

The deployment success, device positioning, and structural integrity were recorded. The outcome was assessed qualitatively based on visual inspection and deployment ease. The in-vitro model confirmed that the occluder could be smoothly and successfully deployed, with optimal expansion and septal defect coverage.

RESULTS

Table 1: Test Parameters and Observations.

Sr. No.	Test Parameter	Observation
01	Kink Resistance Test	The sheath displayed remarkable kink resistance when navigating through narrow and curved pathways. Even under significant bending stress, the sheath retained its structural integrity and functionality. This capability was observed during trials in simulated pulmonary trunk, where the sheath maintained smooth passage without collapsing or deforming.
02	Device Deployment Testing	Deployment of the occluders was consistently smooth and free from any mechanical resistance or malfunctions. The delivery system allowed controlled retraction of the protective sheath, resulting in accurate expansion of the stent at the target lesion. Visual confirmation of the occluders indicated precise alignment with the intended site.

DISCUSSION (Future Prospects)

The preliminary in-vitro testing of the sheath and occluder delivery system yielded highly promising results, indicating excellent mechanical performance and procedural reliability. Kink resistance test outcomes reveal that the sheath exhibits superior flexibility and mechanical resilience under conditions simulating the complex anatomical structures of the cardiovascular system, particularly the pulmonary trunk. The retention of structural integrity and uninterrupted navigation during significant bending stress suggests the design effectively mitigates the risk of lumen collapse or flow obstruction—a critical parameter for ensuring procedural success and patient safety in transcatheter interventions. Device deployment testing further validates the system's capability, demonstrating seamless and controlled deployment of occluders. The consistent absence of mechanical hindrance, coupled with the precision in stent expansion and positioning, emphasizes the robustness and responsiveness of the delivery mechanism. Such performance is essential for minimizing procedural time, reducing fluoroscopy exposure, and enhancing operator confidence during atrial septal defect (ASD) or other septal closure procedures. Together, these observations affirm that the device is well-suited for navigating tortuous vascular anatomies and delivering septal occluders with high accuracy and safety.

CONCLUSION

The development of septal occluder devices has markedly enhanced the design and functional assessment of minimally invasive solutions for atrial septal defect (ASD) closure. In-vitro simulation platforms provide a controlled and reproducible environment for evaluating

critical performance parameters such as deployment precision, structural integrity and conformability to septal morphology. These bench-top test methodologies are instrumental in optimizing device design, refining delivery mechanisms, and ensuring consistent mechanical behavior across a range of defect sizes. The use of anatomically representative phantom models enables early identification of potential challenges related to anchoring stability, sealing performance, and fatigue resistance. Insights gained from such studies support preclinical validation, facilitate regulatory submissions, and inform iterative design improvements. As advancements in materials science and engineering continue, in-vitro evaluations will remain a foundational element in the translational pathway of septal occluders, bridging the gap between conceptual design and clinical readiness. Ultimately, rigorous bench testing ensures that devices meet essential safety and performance benchmarks before proceeding to in-vivo studies or clinical application.

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