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Research paper

Evolution and Innovations of Occluder Devices: A Review of Traditional and Cutting-Edge Technologies

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Abstract

Congenital heart defects and structural cardiac abnormalities including atrial septal defect (ASD), Patent Foramen Ovale (PFO), Ventricular Septal Defect (VSD), Patent Ductus Arteriosus (PDA), and left atrial appendage anomalies represent a significant global health burden, often requiring timely diagnosis and intervention to prevent long-term morbidity and mortality. The development of transcatheter occlusion devices has transformed the treatment of many disorders, providing less invasive, safer, and more effective alternatives to traditional surgical procedures. This review delves into the historical progression and recent technological advancements in occluder device design, materials, and deployment methods. It demonstrates the transition from early metal-based devices, such as nitinol frameworks, to next-generation biodegradable occluders made of polylactide, polydioxanone, and polycaprolactone. These materials have excellent biocompatibility, facilitate tissue integration, and prevent the long-term difficulties associated with permanent implants. Innovations such as 3D/4D printing, shape-memory polymers, and hybrid devices are pushing the development of safer and more patient-specific solutions. Despite positive preclinical and clinical results, there are still hurdles in optimizing degradation rates, mechanical strength, and long-term effects. This study gives a thorough assessment of current and emerging occlusion technologies, focusing on their potential to improve procedural success, patient safety, and the future landscape of structural heart disease treatment.

Keywords: *Biodegradable Occluder; Congenital Heart Defects; Occluder Devices; Structural Heart Disease.*

1. Introduction

Congenital heart disease is a structural defect of the heart or thoracic great vessels identified at birth, with an estimated incidence of 4–50 per 1000 live births based on surveillance data from various time periods [(1)]. Untreated heart chamber defects can lead to serious complications, including heart failure. The introduction of Transcatheter techniques in the 1970s established percutaneous insertion as the preferred method for occlusion device placement [(2)]. Over the past four decades, catheter-based closure devices have revolutionized the management of congenital and structural heart defects, driven by continuous advancements in device materials and design. These innovations have expanded the scope of minimally invasive interventions for atrial septal defect (ASD), ventricular septal defect (VSD), patent foramen ovale (PFO), and patent ductus arteriosus (PDA)[(2)] (Figure 01). This review explores the technological evolution of transcatheter occlusion devices, emphasizing material advancements, novel device designs, and emerging innovations aimed at enhancing procedural success and patient safety.

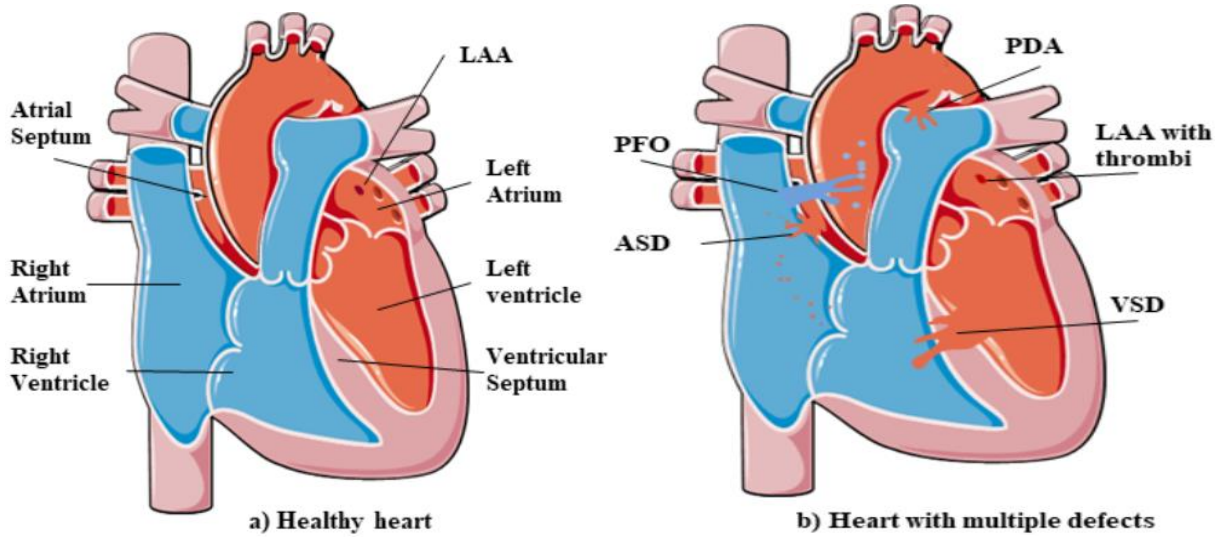
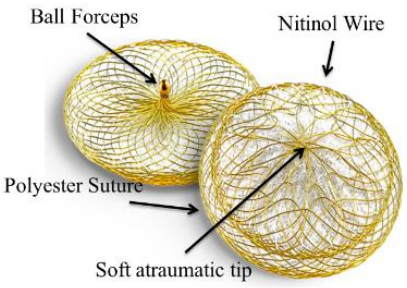


Fig. 1: Illustration of Heart (A) Healthy Heart (B) Heart with Multiple Defects.

2. Evolution and Innovations in Transcatheter Occlusion Devices

Among ASDs, ostium secundum is the most prevalent type, comprising approximately 75% of cases, whereas sinus venosus ASD is a less common variant. Since the first transcatheter ASD closure in 1974, this approach has largely replaced surgical intervention due to its safety and efficacy [3]. The clamshell septal occluder, an early polyester-based device with hinged arms, gained initial acceptance but was later withdrawn after studies reported fractures in up to 84% of its wire arms [2] (Table 02). PFO, a tunnel-like opening between the atria, remains patent in approximately 25%–30% of individuals, increasing the risk of stroke, transient ischemic attack (TIA), and paradoxical embolism [4]. Unlike ASD, PFO lacks septal tissue loss and serves as a conduit for emboli, including blood clots, fat, air, amniotic fluid, or tumor cells, bypassing the lungs into systemic circulation [4 - 6]. Long-term warfarin therapy reduces embolic risk but increases bleeding complications. As a result, transcatheter PFO closure has emerged as a safer and more effective alternative, particularly for preventing recurrent strokes in cryptogenic cases [6], [7] (Figure 02).VSD, the most common congenital heart defect, accounts for nearly 40% of cases. The introduction of occluders has significantly expanded indications for transcatheter VSD closure, particularly for peri-membranous VSD (pmVSD), which represents over 80% of cases [8], [9]. However, challenges persist due to the septal wall's movement, potential impact on the aortic valve, and risk of conduction abnormalities [10], [11]. While complete atrioventricular (AV) block remains a major complication of surgical closure, transcatheter VSD closure offers a less invasive alternative for selected cases, avoiding sternotomy and cardiopulmonary bypass [11]. Advances in occluders and imaging techniques have improved procedural success, but precise anatomical assessment remains crucial to prevent complications such as aortic and tricuspid regurgitation or conduction disturbances [8], [11–13] (Table 01). The evolution of transcatheter PDA closure dates back to 1967, offering a safer alternative to surgery, particularly in adults [14]. PDA, a persistent fetal vessel, remains open in 5%–10% of congenital heart defects and accounts for approximately 6% of cases [15]. If untreated, PDA can lead to heart failure, pulmonary hypertension, and endarteritis. Transcatheter closure is now recommended for medium-to-large PDAs as well as hemodynamically significant small PDAs [1]. Atrial fibrillation, the most common arrhythmia, affects 1%–2% of the population and significantly increases stroke risk, particularly in aging individuals [16]. Nonvalvular AF raises stroke risk fivefold, with over 90% of AF-related thrombi originating in the left atrial appendage [17]. While warfarin reduces stroke risk, it increases bleeding complications, leading to the development of percutaneous LAA occlusion devices, such as the FDA-approved Watchman device, as safer alternatives for high-risk patients [18] (Table03). The limitations of warfarin in stroke prevention have driven a hybrid approach combining phased anticoagulation with LAA occlusion devices, establishing LAA closure as an effective alternative in nonvalvular AF [19], [20]. Nitinol-based devices have greatly advanced transcatheter defect closure, leveraging nickel-titanium alloy's super-elastic, shape-memory properties for precise deployment [21], [22]. Nitinol-based occluders, composed of a nickel–titanium alloy, are widely used for their excellent shape-memory, super elasticity, and long-term structural stability, ensuring precise deployment and durable closure of cardiac defects. Their radiopacity allows accurate placement under fluoroscopic guidance, and their clinical performance is well established. However, nitinol occluders present challenges, including nickel hypersensitivity, mechanical fatigue, device migration, and delayed endothelialization, which may interfere with future cardiac interventions. In contrast, biodegradable occluders made from polymers such as polylactic acid (PLA), polycaprolactone (PCL), or polyglycolic acid (PGA) offer temporary mechanical support while promoting native tissue regeneration, thereby eliminating the risk of chronic inflammation or obstruction of future procedures. They further enable restoration of normal cardiac anatomy once fully resorbed. [23], [24]. Next-generation occluders incorporating biodegradable materials, novel structural designs, and 3D/4D printing technologies are under development to address these limitations. Several of these innovations have undergone clinical evaluation, demonstrating promising results in improving safety, efficacy, and long-term outcomes (Figure 03) [25].



Figulla® Flex II
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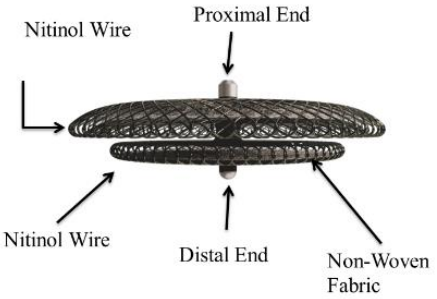
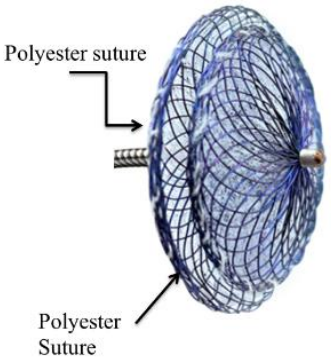
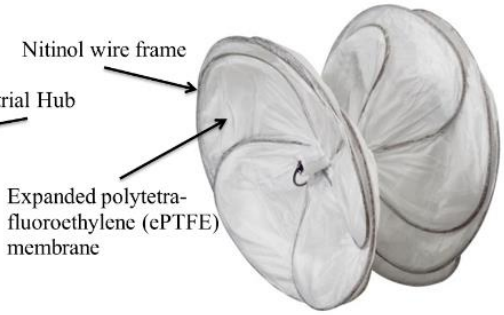


Floret PFO
Image courtesy: Meril Life Sciences.

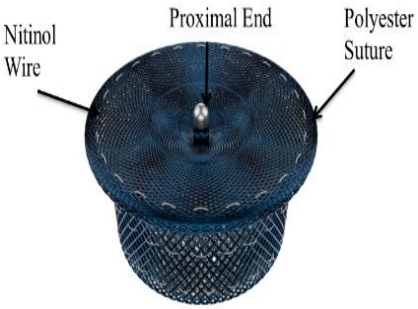


Amplatzer PFO
Image courtesy: Abbott

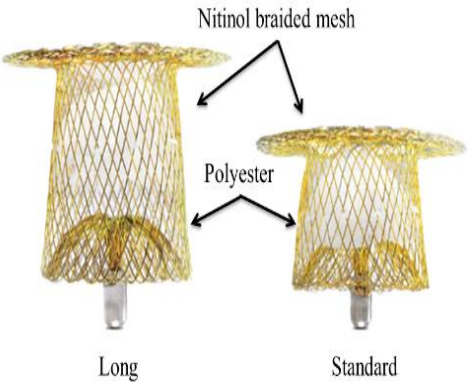


GORE® CARDIOFORM
Image courtesy: W. L. Gore

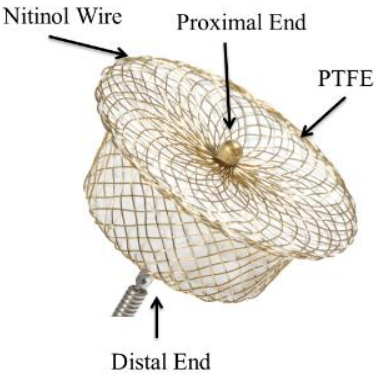
Fig. 2: Representation of Patent Foramen Ovale (PFO) Occluder Devices.



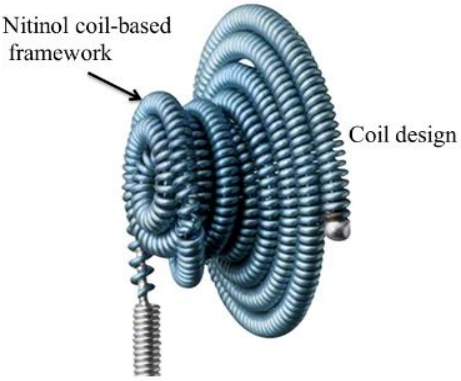
Floret PDA
Image courtesy: Meril Life Sciences.



Occlutech® PDA Occluder
Image courtesy: Occlutech .

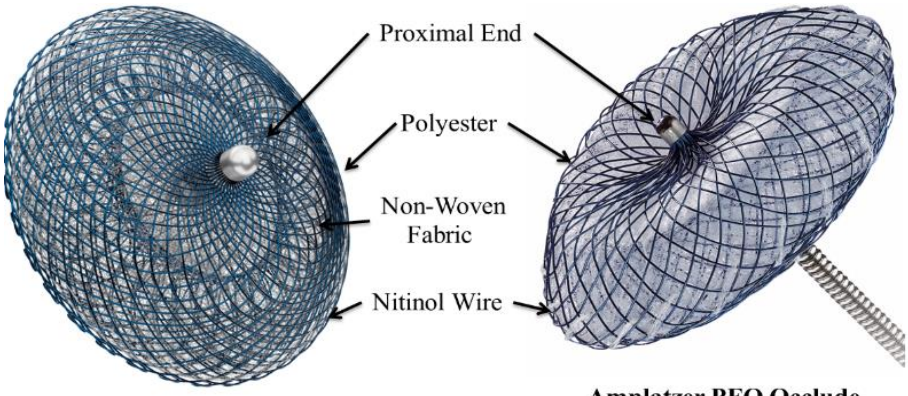


Cera™ PDA Occluder
Image courtesy: Lifetech Scientific



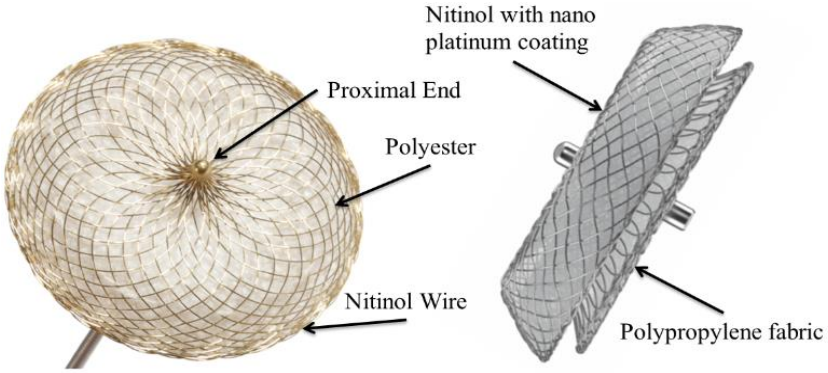
Nit-Occlud® PDA
Image courtesy: PFM Medical

Fig. 3: Representation of Patent Ductus Arteriosus (PDA) Occluder.



Floret ASD Occlude
Image courtesy: Meril Life Sciences.

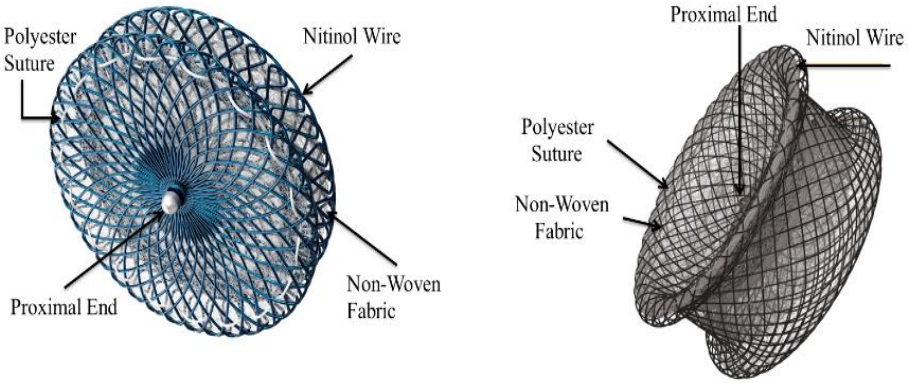
Amplatzer PFO Occlude
Image courtesy: Abbott.



Cera ASD Occlude
Image courtesy: Lifetech Scientific.

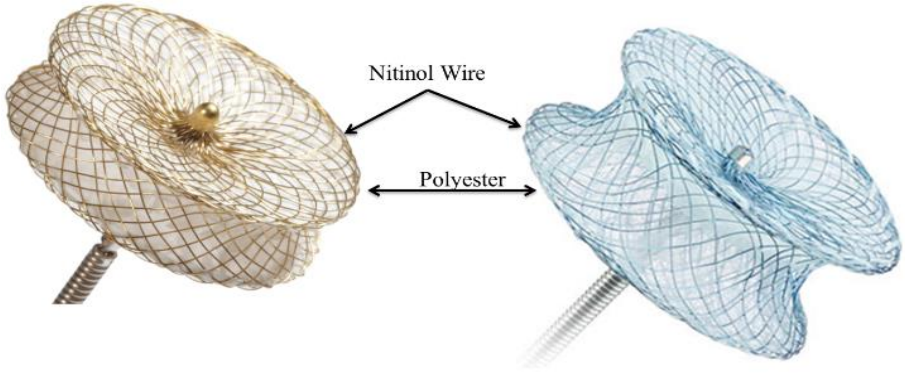
Cocoon ASD occlude
Image courtesy: Vascular Innovations Co.

Fig. 4: Representation of Various Atrial Septal Defect (ASD) Occluder Devices.



Floret VSD Occlude
Image courtesy: Meril Life Sciences.

Floret mVSD Occlude
Image courtesy: Meril Life Sciences.



Cera VSD Occlude
Image courtesy: Lifetech Scientific.

Amplatzer™ Muscular VSD Occlude
Image courtesy: Abbott.

Fig. 5: Various Representation of VSD Occluder devices

Table 1: Non-Biodegradable Occlusion Devices for PDA and VSD

Device	Firm	Composition Frame	Membrane	Sheath Size (F)	Regulatory Status	Key Features
Floret™ PDA Occluder [27]	Meril Life Sciences	Nitinol (nickel-titanium alloy) braided mesh	Polyester (PET)	6–12	CDSCO	1) Self-expandable double-disc design, designed for duct sizes 2–6 mm 2) Low-profile delivery system 3) Repositionable and retrievable before release 4) Radiopaque markers for visibility, Polyester patch promotes rapid occlusion 5) Cost-effective design for affordability.
Cera™ PDA Occluder	Lifetech Scientific	Nitinol with titanium nitride coating	PTFE	5–8	CE, CDSCO	1) Ceramic (TiN) coating reduces nickel release 2) Double-disc design 3) Good biocompatibility 4) Reduced thrombogenicity
Occlutech® PDA Occluder	Occlutech (Sweden)	Nitinol braided mesh	Polyester	5–7	CE	1) Flexible mesh with soft edges 2) Optimized for various PDA morphologies 3) Repositionable before release 4) MRI conditional
Floret™ VSD Occluder Floret™ mVSD Occluder [86]	Meril Life Sciences	Nitinol (nickel-titanium alloy) braided mesh	Polyester (PET)	6–12	CDSCO	Double-disc design; options for perimembranous & muscular VSDs; radiopaque markers; high radial strength; repositionable, Polyester patch promotes rapid occlusion.
KONAR-MF VSD occlude [58]	Lifetech Scientific.	Nitinol	PTFE/Membrane- free	4-7	CE mark	1) Lower likelihood of atrioventricular block. 2) Compatible with both (pmVSD) and (mVSD).
Cera mVSD/pmVSD occlude [59]	Lifetech Scientific	TiN-coated Nitinol	PTFE	5-12	CE mark; CFDA	Titanium nitride (TiN) coating on the Nitinol frame enhances biocompatibility and durability.
Cocoon VSD occluder [60]	Vascular Innovations Co.	Platinum-coated Nitinol	PP	6,7	_	1) Platinum coating enhances biocompatibility and ensures radiopacity for precise positioning.
KONAR-MF VSD occlude [61]	Lifetech Scientific.	Nitinol	PTFE/Membrane- free	4-7	CE mark	1) Lower likelihood of atrioventricular (AV) block. 2) Compatible with both (pmVSD) and (mVSD).

Table 2: A Non-Biodegradable Device Used for Septal Occlusion

Device	Firm	Composition Frame	Membrane	Sheath Size (F)	Regulatory Status	Key Features
Floret™ ASD Occluder [92]	Meril Life Sciences	Nitinol braided	Polyester (PET) fabric	7-14	CDSCO	1) Double-disc nitinol occluder 2) wide size range; for secundum ASDs; flexible waist; high conformability; radiopaque markers; repositionable before release
Amplatzer septal occlude [49]	Abbott	Nitinol	Polyester	6–12	FDA; CE mark	1) The waist size adapts to the defect, ensuring an effective seal. 2) Innovative structural design enhances functionality. 3) Self-centering mechanism ensures accurate placement. 4) Allows for repositioning and retrieval if necessary.
Floret™ PFO Occluder [88]	Meril Life Sciences	Nitinol braided	Polyester (PET) fabric	7-14	CDSCO	Double-disc nitinol occluder with central waist Gold-standard for PFO closure High closure rate & long-term safety data Ideal for cryptogenic stroke patients Repositionable before release Radiopaque markers for visualization
Amplatzer PFO occlude [50]	Abbott	Nitinol	Polyester	6–12	FDA; CE mark	1) Reduced material presence in the left atrium for minimal tissue interaction. 2) Intagio wire treatment designed to minimize nickel leaching.
Ultrasept ASD occlude [51]	Cardia Inc.	Nitinol	PVA	9-11	CE mark	1) Compact, low-profile design. 2) Proprietary self-centering technology. 3) Integrated locking system for secure delivery and retrieval. 4) Dual-flex articulating sails for enhanced adaptability.
Cocoon ASD occlude [52]	Vascular Innovations Co.	Nitinol with nano platinum coating	PP	6-14	CE mark	1) Platinum coating enhances biocompatibility and ensures radiopacity for precise positioning. 2) Cocoon PF offers a cost-effective solution.
Nit-Occlud ASD-R occlude [53], [54]	PFM Medical.	Nitinol	Polyester	7-14	CE mark	1) Constructed from a single strand of Nitinol. 2) Left atrial disc features approximately 50% reduced metal content.
Nit-Occlud PFO occlude [55]	PFM Medical.	Nitinol	Dacron	9, 10	CE mark	1) Minimized Nitinol composition for enhanced flexibility. 2) User-friendly and efficient delivery mechanism.

CeraFlex ASD occlude [56], [57]	Lifetech Scientific.	TiN-coated Nitinol	PET	8–14	CE mark; CFDA	3) Constructed from a single strand of Nitinol. 4) Soft, non-traumatic rim for gentle tissue interaction. 1) Enhanced biocompatibility for better compatibility with tissue. 2) Offers 360-degree flexible rotation for optimal positioning. 3) Innovative lock-and-release mechanism for secure deployment.

Table 3: Non-Biodegradable Occlusion Devices for LAA

Device	Firm	Composition		Sheath Size (F)	Regulatory Status	Key Features
		Frame	Membrane			
Watchman FLX device [62]	Boston Scientific.	Nitinol	PET	12,14	CE mark	1) Two rows of 18 "J"-shaped fixation anchors enhance stability. 2) Increased polyester membrane coverage reduces metal exposure. 3) Shorter length compared to the Watchman device for a more compact design.
Watchman device [63]	Boston Scientific.	Nitinol	PET	14	FDA; CE mark	1) Single row of 10 straight fixation anchors ensures secure placement. 2) Intra-LAA design minimizes interference with surrounding tissues. 3) Reduced surface area facing the left atrium lowers the risk of thrombosis.
Lariat suture delivery system [64]	SentreHEART	Teflon-coated, braided polyester	Membrane-free	13	FDA; CE mark	1) Designed to accommodate various anatomical shapes and sizes. 2) Suture-based closure eliminates foreign body contact with blood. 3) Hybrid closure approach integrates both endocardial and epicardial techniques.
Wave Crest LAA occlude [65], [66]	Coherex Medical Inc.	Nitinol	ePTFE	15	CE mark	1) Single-lobe Nitinol structure for efficient deployment. 2) Features 20 fixation points, offering more anchors than other devices. 3) Enables contrast agent injection at the distal end for evaluating LAA closure.
LACbes device [67]	Shanghai Push Medical	Nitinol	Polyester	9–14	CFDA	The anchor cylinder and sealing disc are linked by a narrow waist for flexibility and secure positioning.
Amplatzer Cardiac Plug [68], [69]	Abbott	Nitinol	Polyester	9–13	CE mark	Effectively seals the left atrial appendage (LAA) at the orifice for optimal closure.
Amplatzer Amulet device (ACP 2) [70], [71]	Abbott	Nitinol	Polyester	12,14	CE mark	1) Offers the widest range of sizes for versatile use. 2) Ensures complete cross-sectional coverage of the orifice. 3) Proximal end guides proper placement, independent of distal anatomy.
LAmbre device [72]	Lifetech Scientific	Nitinol	PET	8–10	CE mark; CFDA	1) Compatible with various left atrial appendage anatomies. 2) Fully recapturable and repositionable for precise placement. 3) Patented anchor design enhances device stability.

3. Next-Gen Emerging Innovations in Occlusion Devices

Although transcatheter ASD closure devices are widely used, most biocompatibility data come from short-term animal studies rather than long-term human trials. Ideally, these devices should serve as temporary scaffolds, promoting cardiac tissue healing until endogenous tissue fully covers the defect. Complete endothelialization of the frame typically occurs within 3–6 months, while fibrous tissue encapsulates the polymer membrane within 1–3 months [2], [26]. Despite their permanent nature, these devices become unnecessary after full tissue integration, highlighting the need for biodegradable occluders. The ideal biodegradable device should provide structural support during healing and gradually resorb into non-toxic byproducts, eliminating the risks associated with long-term implantation [28]. Current ASD closure devices consist of metal frames covered in synthetic fabric, facilitating tissue encapsulation post-implantation. However, they are associated with both short- and mid-term complications, and their long-term effects remain uncertain. This underscores the importance of maintaining trans-septal access for potential future left-sided cardiac procedures. The development of Next-Gen degradable occluders has evolved from partially degradable models to fully bioresorbable designs as shown in table 04. The BioSTAR Occluder, an early example, featured an absorbable collagen membrane with a non-biodegradable frame. Advancements in technology have since led to fully biodegradable devices designed to minimize complications while supporting tissue regeneration [29]. A biodegradable PLGA/type I collagen nanofibrous membrane was developed to provide anti-shunt protection while gradually resorbing [30]. Bioresorbable devices offer a promising alternative to permanent implants, reducing long-term risks while maintaining effective defect closure. Such innovations include the Carag and Double BioDisk occluders, representing the next generation of partially biodegradable ASD closure devices [31], [32].

Table 4: Next-Gen Degradable Closure Devices

Device	Applicable defect	Firm	Composition		Biode-grada-ble/ Non-de-gradable	Sheath Size (F)	Regulatory Status	Key Features
			Frame	Membrane				
Transcatheter Patch [73], [74]	ASD, VSD, PDA, PFO, especially suitable for LAA	Custom Medical Devices,	Frameless	Latex support balloon and PU foam patch	Biode-gradable	12–13	CE mark	1) Designed for the closure of multiple cardiac abnormalities, such as ASD, VSD, PDA, PFO, and LAA. 2) Features an inflatable support balloon, enabling a single device to adapt to various LAA dimensions (15 mm–25 mm). 3) The TP is securely positioned within the LAA using surgical adhesive for enhanced stability. 4) Promotes quick endothelialization, eliminating the requirement for anticoagulant therapy.
Lifetech Absnow PLLA occluder [75]	ASD	Lifetech Scientific.	PLLA	PLLA	Biode-gradable	10–12	Clinical trials (ClinicalTrials.gov Identifier: NCT03601039)	1) The first fully absorbable PLLA occluder designed for ASD closure in humans. 2) Equipped with a specialized delivery system featuring a locking mechanism for seamless deployment and retrieval.
Double Bio-Disk [76]	ASD/PFO	Cook Medical,	Nitinol covered with platinum coils	Porcine small intestine submucosa	Partially biode-gradable	10	Animal experiments	1) Nitinol rings coated with platinum coils for enhanced performance. 2) Porcine small intestine submucosa serves as a barrier to blood flow.
Carag bioresorbable septal occluder [77]	ASD/PFO	CARAG AG	PLGA	PP	Partially biode-gradable	12	CE mark	The frame is designed to be biodegradable, allowing for gradual absorption over time.
Double umbrella occluder [77]	ASD/PFO	Nanyang Technological University	PCL (discs); PLC (spokes in right atrium disc)	PLC	Biode-gradable	9–11	Preclinical Phase	1) Constructed entirely from biodegradable polymers. 2) Features two PCL discs designed to enhance anchoring. 3) The right atrium disc spokes are made of PLC, offering greater flexibility for smoother deployment. 4) PLC films aid in efficient catheter-based delivery.
4D printed shape memory polymer ASD occluder [78]	ASD	Harbin Institute of Technology,	Shape memory PLA-Fe 3 O 4 composite	Shape memory PLA	Biode-gradable	14	Preclinical Phase	1) Magnetically responsive, allowing for remote-controlled deployment. 2) Features a unique structure with a shape memory effect for precise adaptation. 3) 4D-printed, patient-specific device for personalized treatment.
4D printed bioinspired LAA occluder [79]	LAA	Harbin Institute of Technology,	Shape memory PLA-Fe 3 O 4 composite	Shape memory PLA	Biode-gradable	13	Preclinical Phase	1) Customized for each patient to ensure optimal fit.

PCL-PLC PDA occluder [80], [81]	PDA	Nanyang Techno-logical University	PCL/B; PCL/PLC30	PLC	Biode-gradable	9	Preclinical Phase	2) Bioinspired design minimizes the risk of tissue damage and wear. 3) Engineered with tailored mechanical properties for en-hanced performance. PCL-PLC blends with varying compositions are chosen based on the specific mechani-cal property require-ments and recoverabil-ity of each device component.
Biodegradable PDO VSD oc-cluder [82]	VSD		PDO	PLLA	Biode-gradable	12	Preclinical Phase	1) Constructed from biodegradable PDO monofilaments through a weaving process. 2) Designed for auto-matic deployment for ease of use. 3) Optimized degrada-tion rate to ensure ef-fective performance over time.

4. Materials for Next-Generation Emergings Occlusion Devices

Occlusion devices are primarily composed of membranes and supporting frames crafted from materials with distinct properties. The self-expanding frame transitions from a compact state within the delivery sheath to a larger diameter at the defect site, facilitated by a locking mechanism. The frame and membrane must provide adequate mechanical support and maintain biocompatibility to ensure successful en-dothelialization. The flexible frame allows for controlled movement of the membrane, while a properly permeable barrier promotes endo-thelial growth and regulates blood flow. Over time, there has been a shift from non-biodegradable to biodegradable materials in occlusion devices. Materials such as polylactide (PLA), polydioxanone (PDO), and polycaprolactone (PCL) have replaced traditional options like stainless steel, cobalt alloys, and nitinol in frame construction. Similarly, membrane materials have evolved from polyethylene terephthalate (PET) and polytetrafluoroethylene (PTFE) to biodegradable PLA and porcine collagen. These advancements enhance endothelialization and ensure that the body naturally eliminates non-toxic degradation products [33 – 35].

4.1. Polylactide (PLA)

The materials used in approved medical devices include lactic acid, glycolic acid, poly (dioxanone), and poly (ε-caprolactone). Research on polyanhydrides and polyorthoesters is still underway. The semicrystalline aliphatic polyester PLA, which is produced from lactide, has a melting point of 178°C and a ‘6glass transition temperature of 65 [36]. Lactic acid polycondensation or lactide ring-opening polymeri-zation are the two processes used to create PLA. Three varieties of PLA are created by fermenting lactic acid, which is obtained from renewable resources like corn or wheat: Amorphous PDLLA, PLLA, and PDLA from racemic mixes of L and D lactides [37] PLA is a popular biodegradable polyester that has FDA approval and is well-known for its exceptional biocompatibility, high strength, and ease of processing. It is essential to biomedicine, including drug delivery methods, tissue engineering, and sutures [38-40]. Lactic acid and oligo-mers are produced when PLA hydrolyzes its ester bonds during in vivo degradation. This procedure occurs within the implant and on its outside [41].

4.2. Polydioxanone (PDO)

The biodegradable polydioxanone (PDO) is created via ring-opening polymerization of p-dioxanone. Since it is biocompatible and flexible, it may be used for various medical purposes, such as tracheal repair [42]. Medical applications extensively use biodegradable polyesters such as PLA, PLGA, and PCL, PLGA provides customized degradation for medication administration and bone replacements. Within six months, polydioxanone (PDO) breaks down into byproducts that are expelled as carbon dioxide or urine [43]. Occluders for medicinal applications are frequently woven using PDO fibers. Qin et al. used PDO monofilaments with a diameter of 0.298 mm to create ASD and VSD occluders. Excellent biocompatibility and biodegradability were shown in animal investigations [44], [45]

4.3. Polycaprolactone (PCL)

The need for biodegradable polymers in biological applications fuels research into materials that satisfy mechanical and degradation spec-ifications [46]. PCL is more stable than PLA because it has fewer ester linkages per monomer and breaks down chemically (acid/base-catalyzed hydrolysis) or enzymatically. It takes two to three years for PCL to completely break down in biological settings [47], [48]. The three occluders are polylactic acid-co-ε-caprolactone (PLC), PCL, and PCL/PLC blends; PLC is more flexible than PCL. Researchers from Chang Gung University also developed an eight-PCL-spoken biodegradable ASD occlude [30]

5. Future Directions

Biodegradable occlusion devices have shown significant advancements in promoting occlusion efficacy and endothelialization while minimizing long-term complications associated with traditional metal-based implants. The introduction of biodegradable membranes, such as porcine intestinal collagen in the BioSTAR occluder, initiated this evolution by enhancing biocompatibility and accelerating healing (29). Since then, materials such as PLA, P4HB, PLC, and heparin-coated collagen have been utilized to improve occlusion performance and patient safety [24], [59], [83], [84]. Partially and fully biodegradable occluders including the BioSTAR, BioTrek, and Carag bioresorbable septal occluder (CBSO) have demonstrated high defect closure rates, excellent biocompatibility, and complete endothelialization in both preclinical and clinical studies [76], [85]. Emerging designs now integrate puncturable occluders that allow future transseptal access, as well as novel membranes and suture-based architectures that enhance flexibility, conformability, and tissue integration. These innovations address key limitations of earlier devices, such as erosion risk and interference with subsequent interventions [89]. Next-generation developments focus on combining advanced materials and intelligent design. Innovations like Shape-memory polymers and 4D printing enable occluder devices to self-deploy, adapt to cardiac anatomy, and dynamically respond to physiological conditions for improved biocompatibility and performance., recent computational modeling and materials science studies have enhanced the understanding of degradation kinetics and mechanical behavior of biodegradable occluders, enabling optimized device design and performance prediction and ensure controlled endothelialization [90], [91]. Devices such as the Double BioDisk (DBD), Transcatheter Patch (TP), Prolipsis Patch, and Chinese Lantern occluder have extended the application of biodegradable technology beyond atrial septal defects (ASD) to patent ductus arteriosus (PDA) and left atrial appendage (LAA) occlusion [27], [87]. The Prolipsis Patch, for example, achieved an 85% LAA closure rate in clinical trials, reducing the need for long-term anticoagulation therapy [87]. Despite these advances, challenges remain, including variability in degradation rates, mechanical strength optimization, incomplete endothelialization, and limited long-term clinical validation. Ongoing research involving polymer blending (e.g., PCL/PLA), surface modification, and computational modeling aims to optimize performance and degradation profiles. Continued exploration of novel biomaterials, puncturable frameworks, and adaptive suture-based occluder designs is expected to yield safer, more effective, and fully resorbable patient-specific occlusion solutions in the near future [17], [4], [70].

6. Conclusion

The evolution of occluder devices has marked a paradigm shift in the management of congenital and structural heart diseases, offering minimally invasive alternatives to conventional surgery. From early metal-based frameworks to next-generation biodegradable designs, continuous innovations in materials and device architecture have significantly enhanced safety, biocompatibility, and clinical outcomes. Advances in polymers such as PLA, PDO, and PCL, coupled with novel fabrication approaches like 3D/4D printing and shape-memory technologies, are paving the way for patient-specific and resorbable solutions that minimize long-term complications associated with permanent implants. While preclinical and clinical studies underscore the promise of biodegradable occluders, further research is needed to refine their degradation kinetics, mechanical durability, and long-term safety profile. Ultimately, the integration of cutting-edge biomaterials, imaging-guided deployment, and personalized device engineering holds the potential to transform the landscape of transcatheter interventions, moving closer to safer, more effective, and durable solutions for patients with structural heart disease.

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