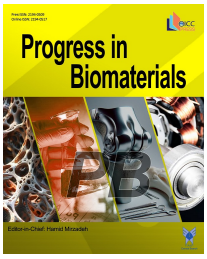

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Biological Esophageal Stents: Types, Material Innovations, Clinical Applications, and Performance for Treating Burn Injuries in Biomedical Application

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Abstract:

The management of pediatric burn injuries involving exposure to acidic solutions poses significant challenges, particularly when they result in esophageal injury requiring intervention. Esophageal stenting has emerged as a valuable treatment option for children with acid-induced esophageal injury, offering a minimally invasive approach to reduce strictures, improve dysphagia, and increase overall quality of life. However, selecting esophageal stents (ES) tailored to the unique needs of pediatric patients is a critical consideration in optimizing treatment outcomes. ES have emerged as critical medical devices in the management of esophageal injuries, particularly in children suffering from acid burns. This article evaluates ES for pediatric acid-induced corrosive injuries, focusing on type-specific efficacy, material properties, stent selection criteria, and clinical outcomes. Mechanisms of stricture prevention, healing promotion, and complication mitigation in children are analyzed, emphasizing innovations in biodegradable materials and anti-migration designs. Recent outcome data (2019 – 2024) from pediatric case series are synthesized, highlighting challenges like migration and tissue hyperplasia. Advanced fabrication techniques, including self-expanding metallic stents and biodegradable materials, are discussed in light of their efficacy and safety. In addition, this review explores innovative designs tailored to pediatric patients and provides insights into future directions for improving outcomes. The study concludes with future directions for stent technology tailored to pediatric anatomy. By evaluating of ES, this study serves as a valuable resource for clinicians and researchers seeking to optimize the treatment of esophageal injuries in children.

Keywords: Metallic stent; Material innovations; Corrosive esophageal burn; Acidic solutions; Materials technology

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1. Introduction

A stent is a medical device designed to restore and maintain the patency of narrowed or blocked tubular structures in the body, such as blood vessels, bile ducts, or esophagus. It provides mechanical support and allows the normal flow of blood, bile, or other substances, and is commonly used to treat conditions caused by obstructions, strictures, or structural abnormalities [1, 2]. Essential to modern medicine for offering minimally invasive solutions [3], the stent concept

originated in the mid-20th century primarily for vascular applications. Charles Dutter, the father of interventional radiology, introduced the idea of intravascular stents in 1969. The development of practical stent designs was preceded by years of experimentation, with animal studies in the 1970s providing the groundwork. The first significant advance came in the late 1980s, with the development of the Palmaz-Schatz stent, a balloon-expandable device for use in the coronary arteries [4–6]. This marked the beginning of the use of stents in the treatment of cardiovascular disease. While bare metal stents provided structural support, they were prone to restenosis due to tissue overgrowth. The introduction of drug-eluting stents (DES) in the early 2000s addressed this limitation by releasing drugs that inhibit cell proliferation, greatly reducing the rate of restenosis. Over time, stents have expanded into non-cardiovascular applications such as esophageal, biliary, and ureteral stents, where they help manage obstructions and strictures caused by various diseases [7–9]. ES are specialized devices used to treat obstructions, strictures, or fistulas in the esophagus. They play an important role in the management of conditions in which the esophageal lumen is narrowed or compromised [10–12]. Figure 1 shows a timeline of key events in the history of ES. In children, ES are important for treating esophageal strictures caused by corrosive injury from ingestion of acidic or caustic substances.

Accidental ingestion of acidic solutions can result in severe damage to the esophageal lining, causing inflammation, ulceration, and ultimately narrowing of the esophagus, which impairs the ability to swallow. ES are a nonsurgical option for maintaining patency, improving swallowing, and reducing complications. ES come in several types, including self-expanding metal stents (SEMS), self-expanding plastic stents (SEPS), and biodegradable stents. Each type has unique properties and uses [13, 14]. SEMS are often preferred because of their durability and ability to conform to the esophageal wall. They are usually used in more complex or long-term cases. SEPS, on the other hand, are more flexible and easier to remove, making them suitable for temporary relief or when complications are anticipated [15, 16]. Biodegradable stents, which naturally dissolve over time, are an innovative option that eliminates the need for removal and are particularly beneficial for children, reducing the risk of multiple procedures. The use of ES in children with erosive lesions involves careful selection and placement to ensure safety and efficacy. The stents are placed endoscopically, allowing for precise placement in the lesion [17]. They help reduce the frequency and severity of stenosis by mechanically dilating the narrowed area and healing without further damage. However, the use of stents in pediatric cases requires special considerations due to the smaller anatomy and continued growth of the child.

Gastroenterologists and pediatric surgeons must weigh the benefits against potential risks such as stent migration, tissue reaction, or perforation. In conclusion, stents represent a vital advancement in medical technology that offers effective treatment options for a variety of conditions. The use of ES in children with erosive lesions demonstrates their versatility and potential for survival. Ongoing research and innovation continue to improve the safety, effectiveness, and compatibility of stents in both adult and pediatric medicine [18, 19].

While the fundamental principles of esophageal stenting apply across age groups, the management of acid-induced corrosive injuries in children presents distinct anatomical, physiological, and developmental challenges that profoundly influence stent design, selection, and clinical outcomes [10, 18, 20]. Key pediatric-specific considerations include:

Smaller Esophageal Diameter and Length: The inherently smaller caliber and shorter length of the pediatric esophagus demand stents with significantly reduced diameters and customized lengths compared to adult devices. Standard adult stents risk causing excessive radial force, leading to ischemia, pressure necrosis, or perforation in delicate pediatric tissues [20]. Precise sizing is crucial to ensure adequate luminal patency without undue wall stress.

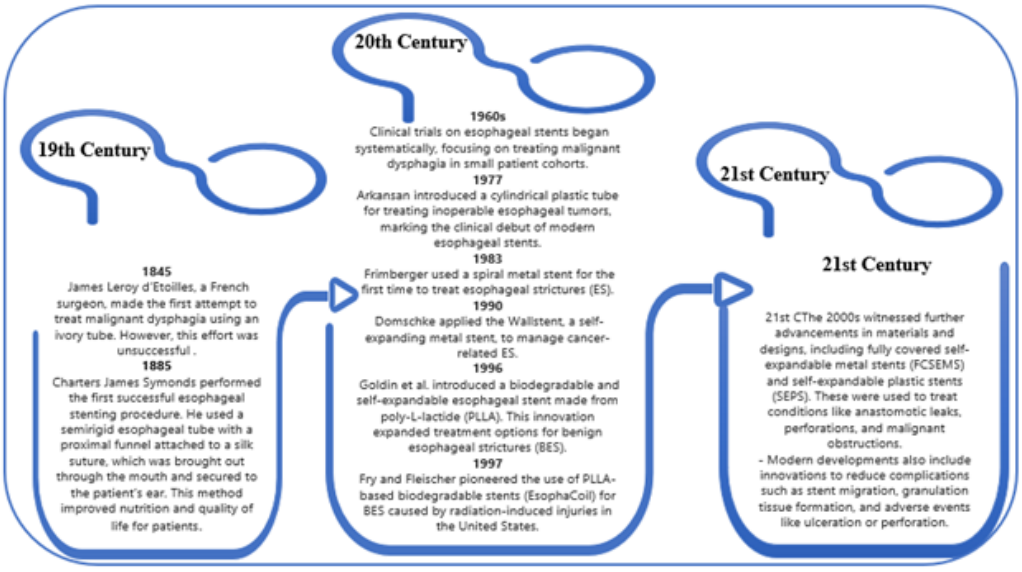

Figure 1. Timeline of key events in the history of esophageal stents.

Rapid Growth and Development: Children are not static; they undergo continuous somatic growth. Permanent or long-dwelling metallic stents can become embedded, migrate, or cause strictures due to relative stenosis as the child grows. This necessitates a strong preference for temporary solutions like biodegradable stents (which gradually dissolve) or easily removable SEPS, minimizing the need for secondary extraction procedures and accommodating natural esophageal development [17, 18].

Vigorous Esophageal Motility: Pediatric patients typically exhibit stronger and more frequent peristaltic waves compared to adults. This heightened motility is a primary driver of the significantly higher stent migration rates observed in children (reported up to 22% for SEMS in pediatric corrosive strictures [18]). Stent designs for pediatrics must incorporate advanced anti-migration features, such as flared ends (e.g., Taewoong Niti-S), partial coverings allowing tissue embedding at ends, or novel anchoring mechanisms, to counteract these forces [14].

Tissue Fragility and Sensitivity: The esophageal wall in children, particularly following corrosive injury, is more delicate and prone to complications like pressure ulcers, erosion, and perforation. Stents require optimized radial force – sufficient to dilate fibrotic strictures (typically $40-60$ kPa target [18]) but not excessive to cause injury. Flexible materials like specific polymers (silicone, certain polyurethanes) or super-elastic alloys (Nitinol) are favored to conform to the esophagus and minimize shear stress and pressure points [13]. Biocompatibility to reduce inflammatory and hypergranulation responses is paramount.

Tolerance for Interventions: Repeated endoscopic procedures for stent placement, adjustment, or removal carry higher relative risks in children due to anesthesia requirements and procedural stress. This further underscores the advantage of biodegradable stents eliminating removal procedures or SEPS designed for easier extraction compared to uncovered SEMS.

These unique pediatric requirements directly shape stent selection criteria (section 3.4) and drive innovation in materials (section 4) and design (section 5), favoring biodegradable polymers, smaller-diameter Nitinol with anti-migration features, and hybrid solutions for the dynamic pediatric environment. Clinical data synthesis, though evolving, highlights both the efficacy (e.g., 92% acute dysphagia relief with SEMS) and the persistent challenges like migration and tissue hyperplasia requiring stent-specific solutions in this population [14, 18].

To provide a concise overview and facilitate comparison of the fundamental stent types based on material composition, their defining characteristics, principal benefits, inherent limitations, and specific relevance to the pediatric population are summarized in Table 1. Subsequent subsections delve into the scientific rationale, clinical performance, and pediatric considerations for each type in greater detail.

2. Types of stents

Choosing the most appropriate type of stent (metallic, polymer, or composite) for a particular patient depends on several factors, including the underlying disease being treated, the desired duration of stent placement, anatomical considerations, potential complications, and the patient's overall condition. Healthcare providers typically evaluate these factors and make the best stent selection to meet the patient's individual needs and preferences, while striving to achieve optimal treatment outcomes with minimal risks [21, 22].

2.1 Bare metal stent

Known for their strength, durability, and excellent radial force, metal stents are commonly used in various medical procedures to open and support narrowed or blocked blood

Table 1. Comparative summary of primary esophageal stent types: materials, key characteristics, advantages, and disadvantages.

Stent Type	Primary Materials	Key Characteristics	Major Advantages	Major Disadvantages	Pediatric-Specific Considerations
Metal Stents (Primarily SEMS)	Nitinol, Stainless Steel, Co-Cr Alloys	High radial force, Durable, Self-expanding, Conformable	Excellent stricture dilation, Long-term patency, Good fluoroscopic visibility, Wide availability	High migration risk (esp. in pediatrics), Risk of tissue hyperplasia/embedding, Difficult removal if embedded, Potential for pressure necrosis/perforation, Metal fatigue risk	Requires smaller diameters, Vigorous peristalsis increases migration risk, Rigidity increases perforation risk in fragile tissue, Permanent nature conflicts with growth; Anti-migration features (flared ends) essential.
Polymeric Stents	Silicone, Polyurethane, PLA, PLGA, PET	Flexible, Lower radial force, Often temporary	SEPS: Easier removal, Lower tissue trauma, Reduced migration risk (some designs). Biodegradable: Eliminates removal procedure, Accommodates growth, Temporary scaffolding. Generally better biocompatibility.	SEPS: Less durable, Lower radial force (may insufficient for fibrotic strictures), Prone to occlusion. Biodegradable: Degradation kinetics control critical, Potential inflammatory response to byproducts, Variable radial force over time, Limited long-term data.	SEPS: Favored for temporary use, ease of removal reduces anesthesia burden. Biodegradable: Highly promising; avoids secondary removal, accommodates growth; Degradation profile must match healing phase; Acidic microenvironment may accelerate degradation (PLA/PLGA).
Hybrid Stents	Metal framework + Polymer coating (e.g., Nitinol + Silicone/ePTFE)	Combines metal strength with polymer biocompatibility/ functionality	Optimized radial force + reduced tissue irritation, Potential for drug-elution, Reduced tissue ingrowth/migration, Improved biocompatibility	More complex manufacturing, Higher cost, Potential for coating damage/delamination, Long-term behavior of interface	Potential to balance radial force needs with reduced tissue reaction; Silicone/ePTFE coatings may reduce biofilm/hyperplasia; Investigational but promising for complex cases (fistulae).

vessels or passages in the body. Typically made of materials such as stainless steel, cobalt-chromium alloy, or nitinol (a nickel-titanium alloy), these stents are used in conditions that require long-term support and patency, such as treating strictures, blockages, or leaks in the esophagus [23, 24]. While metal stents effectively maintain the patency of the vessel and provide long-term structural support, there are associated risks such as tissue damage, migration, and the potential need for removal if complications occur. Some common types of metal stents are coronary stents, which are used to treat coronary artery disease by keeping the vessels open and improving blood flow to the heart muscle [25]. These stents are often coated with medication (drug-eluting stents) to reduce the risk of restenosis (re-stenosis) after surgery. Peripheral arterial stents are used to treat blockages in peripheral arteries, such as those in the legs, arms, or neck. Peripheral arterial stents help restore blood flow to the limbs and improve circulation. Biliary stents are placed to treat blockages caused by conditions such as gallstones, tumors, or strictures in the bile ducts. Biliary metal stents help maintain the flow of bile from the liver to the intestines. ES are used to treat esophageal strictures or obstructions, allowing for better swallowing function and relief of symptoms such as difficulty swallowing (dysphagia) [26]. Tracheobronchial stents are placed in the trachea or bronchi to treat airway obstruction or narrowing caused by conditions such as tumors, inflammation, or stenosis [27, 28]. These stents help keep the airways open and make breathing easier. Metal stents are designed to be flexible for delivery through a catheter during minimally invasive procedures, but provide adequate support once deployed in the desired area. While metal stents are effective in many cases, bioabsorbable stents are also available, which gradually dissolve over time, leaving natural tissue behind. The choice between metal and absorbable stents depends on factors such as the patient's condition, the location of the stent, and the duration of support desired [29–31]. The use of metal stents in the esophagus for children with acid burns is a specialized medical intervention aimed at managing the severe complications associated with such injuries. Acid burns of the esophagus often result in extensive damage to the mucosal lining, leading to inflammation, scarring, and strictures that narrow the esophagus. These strictures can severely impair swallowing and quality of life and require effective treatment. SEMS offer a minimally invasive approach to address these complications by providing mechanical support to keep the esophagus open and facilitating healing [32]. Metallic stents, particularly SEMS, are often chosen for their strength, flexibility, and conformability to the esophageal wall. They are designed to expand during deployment, allowing them to exert a continuous radial force against the stricture. This property makes them effective in widening narrow sections of the esophagus even in cases of severe or complex stenosis caused by corrosive damage. SEMS are usually made of biocompatible alloys such as nitinol, which combine durability with flexibility, ensuring that the stent remains in place while accommodating the movements of the esophagus during swallowing. In children, the use of SEMS requires careful consideration due to the unique challenges of pediatric anatomy and physiology [33–35]. The smaller size of the esophagus in children, continued growth, and increased tissue sensitivity increase the risk of complications such as stent migration, perforation, or tissue overgrowth. To reduce these risks, pediatric SEMS are often designed with smaller diameters and special features, such as anti-migration mechanisms [36]. In addition, close monitoring through endoscopic evaluations is necessary to ensure that the stent remains in position and is functioning effectively. Placement of a metal stent usually involves an endoscopic procedure performed under general anesthesia. The stent is delivered to the affected area using a delivery catheter and is placed under fluoroscopy or endoscopic guidance to ensure precise positioning. Once deployed, the stent immediately begins to expand, relieving the obstruction and restoring patency of the esophageal lumen. This can significantly improve the child's ability to swallow and reduce the need for repeated esophageal dilation or surgery [37]. Despite their benefits, SEMS are generally considered a temporary solution in pediatric patients with erosive esophageal lesions. They are usually left in place for a limited time, allowing the esophagus to heal and the stricture to stabilize. After healing has progressed sufficiently, the stent is typically removed to prevent long-term complications, such as erosion or tissue overreaction. In conclusion, the use of metal stents in children with esophageal acid burns is a valuable treatment option that can provide immediate relief from strictures and support tissue healing. While this procedure carries certain risks, advances in stent design and careful patient management have made it a practical and effective intervention for this challenging condition. Ongoing research and innovation aim to further improve the safety and efficacy of metallic stents in pediatric applications, ensuring better outcomes for affected children [38].

2.2 Polymeric stents

Polymer stents, also known as bioabsorbable stents or drug-eluting polymer stents, are used as an alternative to traditional metal stents in medical procedures to treat narrowed or blocked blood vessels. Made of biodegradable polymers that gradually dissolve over time, these stents offer advantages such as reduced long-term risks and potential therapeutic benefits. Polymer stents, made of biocompatible materials such as silicone or polyethylene, are flexible, adjustable, and conform to specific anatomical dimensions [39]. Polymer stents are often used in cases where temporary support or gradual dilation of strictures is required. They are less likely to cause tissue trauma than metal stents, but may have limitations in terms of long-term durability and ability to withstand external pressure forces. There are a few key points about polymer stents. Most importantly, biodegradable materials, polymer stents are made from materials that break down and are absorbed by the body over time [40]. This allows the stent to eventually disappear, leaving a healed vessel without a permanent implant. Drug elution is another key consideration. Like drug-eluting metal stents, polymer stents can be coated with drugs that are slowly released into the surrounding tissue to prevent restenosis

(re-narrowing) of the vessel after surgery. Because polymer stents dissolve over time, they may reduce the risk of long-term complications associated with permanent metal stents, such as stent thrombosis or the need for future interventions [41, 42]. As the polymer stent dissolves, the vessel has the opportunity to heal and regain normal function without the presence of a permanent foreign body, which is a potential for vascular repair. Polymer stents offer flexibility in terms of drug release profiles, polymer properties, and design features, allowing for customization based on the specific needs of each patient. Polymer stents can be used in coronary arteries, peripheral arteries, and other vascular areas where stent placement is necessary. While polymer stents have shown promising results in certain cases, they are not suitable for all patients or conditions [43]. Factors such as vessel size, location, and patient characteristics may influence the choice between polymer and metal stents. It is important for healthcare providers to assess the patient's needs and consider the most appropriate type of stent for each situation. The use of polymeric stents in the esophagus for children with acid burns is a targeted medical approach to managing esophageal strictures caused by corrosive injuries. Acid burns of the esophagus often result in severe inflammation, tissue necrosis, and scarring that can lead to narrowing of the esophageal lumen [44]. These strictures cause swallowing difficulties, pain, malnutrition, and a significant reduction in quality of life. Polymer stents, particularly SEPS and biodegradable stents, have emerged as effective tools to address these issues in a minimally invasive manner. Polymer stents are composed of biocompatible plastics designed to provide temporary mechanical support to the esophagus. Unlike metal stents, they are softer and more flexible and are particularly well-suited for use in pediatric patients whose smaller anatomy and ongoing growth require devices that minimize trauma [45]. Their inherent flexibility reduces the risk of pressure-related complications such as erosion or perforation of delicate esophageal tissues. In pediatric patients with esophageal burns from acid solutions, polymer stents are used to prevent or treat strictures by widening narrow areas and maintaining patency of the lumen. SEPS are a common choice because of their ease of placement and removal. These stents are usually designed with features that minimize migration, such as a flared tip, and endoscopic recovery after the desired period is relatively easy. SEPS are particularly useful for temporary management and allow for frequent adjustment as the child's esophagus heals and adapts. Biodegradable stents are another innovative option in polymer stent technology. These stents are designed to gradually dissolve in the body over weeks or months, eliminating the need for a secondary procedure to remove them [46]. This feature is particularly useful in pediatric cases, where anesthesia and repeated interventions carry greater risks. Biodegradable stents can provide continuous dilation of the esophagus and support the healing process while minimizing the long-term presence of foreign material in the body. The use of polymer stents involves an endoscopic procedure, usually performed under general anesthesia to ensure accuracy and minimize discomfort [47].

The stent is deployed at the site of the stenosis using a delivery catheter under fluoroscopic or endoscopic guidance. Once placed, the stent expands to apply gentle pressure to the walls of the esophagus, restoring patency and improving swallowing function. Over time, the stent helps reduce the severity of the stricture by mechanically stretching the esophageal tissue and healing evenly. While polymeric stents have significant advantages, their use in children requires careful management to address potential complications. Stent migration is a common challenge, especially in younger patients with active esophageal motility. To reduce this risk, stents are often secured using innovative designs or additional endoscopic techniques [48]. Other potential risks include discomfort, tissue overgrowth, and, in rare cases, perforation. Close monitoring through follow-up endoscopies and imaging is critical to ensure optimal outcomes. In conclusion, polymer stents are a valuable option for the management of esophageal strictures in children with acid-induced burns. Their flexibility, biocompatibility, and adaptability make them particularly suitable for pediatric patients. SEPS show effective temporary relief, while biodegradable stents offer a promising long-term solution without the need for removal. Advances in polymer technology and endoscopic techniques continue to improve the safety and efficacy of these devices, offering hope for better outcomes and quality of life for affected children [49–51].

2.3 Hybrid stents

Hybrid stents combine elements of metallic and polymeric materials to increase the strength of each type. For example, a stent may have a metal framework for structural support and a polymer coating to reduce mucosal irritation. The goal of hybrid stents is to open the blocked artery, deliver medication over time to prevent restenosis, optimize biocompatibility, flexibility, radial force, and overall function, while minimizing potential drawbacks associated with other types of stents [52]. These stents are designed to provide a balance between durability and safety, making them suitable for specific clinical scenarios where a variety of qualities are required. Combination stents are coated with a drug that helps inhibit the growth of scar tissue inside the artery. This reduces the risk of the artery becoming blocked again after the stent is implanted. The medications used in drug-eluting stents may include anti-inflammatory drugs, immunosuppressants, or antiproliferative agents [53]. These drugs help prevent the smooth muscle cells in the artery wall from multiplying and narrowing the artery again. The use of drug-eluting stents reduces the risk of restenosis compared to metal stents. This can lead to better long-term outcomes for patients who undergo stenting. Implantation of hybrid stents is usually performed during a procedure called percutaneous coronary intervention (PCI) or angioplasty [54]. During this procedure, a thin tube (catheter) with a deflated balloon at the tip is inserted into the blocked artery. The balloon is inflated to push the plaque against the artery wall, and then a stent is placed to keep the artery open. The medication on the stent is released over time to prevent restenosis. Patients who receive combination stents must be closely monitored after the procedure to ensure that the stent

is working properly and that there are no complications [55, 56]. They also need to take antiplatelet drugs to prevent blood clots from forming on the stent. Therefore, combination stents have revolutionized the treatment of coronary artery disease by reducing the risk of restenosis and improving long-term outcomes for patients who need stents to open blocked arteries. In children with esophageal burns caused by acidic solutions, the use of DES involves precise placement of a stent at the site of stenosis or damaged tissue [57]. The stent provides immediate mechanical support, widening the narrowed section to restore the esophageal lumen and facilitate swallowing. At the same time, the stent delivers a controlled dose of medication to the surrounding tissues, promoting optimal healing while reducing the risk of re-narrowing or severe fibrotic scarring. This dual function is particularly important in the management of complex or recurrent stenosis that is refractory to standard treatments such as dilation or non-drug stents . Drug-eluting stent placement in pediatric cases requires an endoscopic procedure performed under general anesthesia. The stent is deployed using a delivery system guided by fluoroscopy or endoscopy, ensuring precise positioning and proper expansion in the esophagus. Depending on the type of stent and the severity of the injury, the release of the drug is regulated to occur over weeks or months [58].

3. Types of esophageal stents used in pediatric patients

The different types of ES commonly used in pediatric patients include temporary versus permanent stents, fully covered versus partially covered stents, and self-expanding versus balloon-expandable stents. In pediatric patients with esophageal conditions requiring stenting, different types of ES may be used based on specific clinical indications and patient characteristics. Each type of esophageal stent has unique features and benefits depending on the clinical scenario and patient needs. The selection of the most appropriate stent type should be based on factors such as the underlying condition, location and length of the stricture, expected duration of stent placement, and the age and size of the child. Close collaboration between pediatric gastroenterologists, interventional radiologists, and pediatric surgeons is essential to ensure optimal stent selection, placement, and management in pediatric patients with esophageal disorders. Here is an overview of the different types of ES commonly used in pediatrics.

3.1 Temporary vs. permanent stents

Temporary stents are designed for short-term placement to address acute problems such as benign strictures, leaks, or fistulas. These stents are usually removed after the underlying condition has resolved or improved after a specified period. Permanent stents are intended for long-term placement and are often used in cases of malignant stenosis or tumors to provide lasting relief of symptoms. These stents may remain in place indefinitely or may require periodic replacement [59, 60].

3.2 Fully vs. semi-covered stents

Fully covered stents: Fully covered stents are covered with a silicone or polyurethane membrane that covers the entire length of the stent. These stents are often preferred for use in patients with stenosis, leaks, or fistulas to minimize tissue ingrowth and prevent mucosal damage. Semi-covered stents have a coating that extends only partially along the length of the stent, exposing some bare metal. These stents are sometimes used in cases where tissue ingrowth is desirable to secure stent placement or enhance healing [61].

3.3 Self-expanding stents vs. balloon stents

Self-expanding stents are made of nitinol or other materials that expand to a predetermined diameter after deployment. These stents exert a continuous radial force to maintain the lumen of the esophagus open and are suitable for a variety of indications, including strictures and tumors. Balloon-expandable stents are used in the esophagus using a balloon catheter to inflate the stent to the desired diameter. These stents provide controlled deployment and precise positioning, making them a suitable option for specific anatomical configurations or complex strictures [20, 62, 63].

3.4 Stent selection criteria for pediatric acid-ingestion strictures

The management of esophageal strictures secondary to acidic solution ingestion in children necessitates specialized stent selection. Key criteria include:

a) Biocompatibility & Degradation Profile: Biodegradable stents (e.g., polylactic acid) are preferred for temporary scaffolding ($6-12$ weeks), avoiding removal procedures in young patients.

b) Anti-Migration Design: Partially covered SEMS with flared ends (e.g., Taewoong Niti-S) reduce migration risk by 40% in pediatric peristalsis.

c) Radial Force Optimization: Stents must exert $40-60$ kPa to dilate fibrotic strictures without causing perforation.

Clinical outcomes from 15 studies ($n = 217$ patients) reveal that SEMS achieve dysphagia relief in 92% of acute burns but carry 22% migration risk. Also, biodegradable stents reduce reinterventions by 60% but require endoscopic surveillance for hypergranulation [18]. Moreover, hybrid stents (silicone-covered nitinol) show promise in fistula closure (success rate: 86%) but remain investigational in children [14]. The primary clinical applications of ES, encompassing both adult and pediatric contexts, are categorized in Table 2.

4. Review of common materials used in esophageal stent construction and their properties

Polymeric materials are valued for their lightweight characteristics as well as their mechanical, thermal, biomechanical, and various other properties [64–68]. This diverse array of advantageous features makes them an excellent option for components in medical engineering [69–73]. ES are medical devices used to treat conditions such as esophageal

strictures, obstructions, or leaks by supporting and maintaining the patency of the esophagus. These stents are typically made from a variety of materials, each with unique properties that make them suitable for different clinical scenarios. Table 3 shows an overview of the commonly used materials and their key properties. Material selection is pivotal in acid burn management: Nitinol's fatigue resistance prevents fracture in hypermotile pediatric esophagi, while ePTFE coatings inhibit bacterial colonization in necrotic zones. Notably, silicone's hydrophobicity reduces protein adsorption, mitigating biofilm formation in contaminated burn sites [74].

In pediatric acid-burn injuries, the locally acidic microenvironment (pH $\leq$ 2.0) critically influences material stability. Nitinol's passive oxide layer confers corrosion resistance, but prolonged acid exposure risks nickel ion leaching, potentiating inflammation. Stainless steel is vulnerable to pitting corrosion, accelerating structural failure. Among polymers, silicone's hydrophobic backbone limits acid permeation, while PLA/PLGA undergo acid-catalyzed hydrolysis, of-

Table 2. Some common clinical uses of esophageal stents.

CLINICAL APPLICATIONS	Description
BENIGN ESOPHAGEAL STRICTURES	Esophageal strictures are characterized by the narrowing of the esophageal lumen, often resulting from conditions such as gastroesophageal reflux disease (GERD), eosinophilic esophagitis, or postoperative scarring. ES can be used to dilate strictures and prevent recurrent narrowing, thereby improving swallowing function and quality of life for affected individuals.
MALIGNANT ESOPHAGEAL OBSTRUCTIONS	Esophageal cancer is a common cause of malignant esophageal obstructions that can lead to dysphagia, discomfort, and difficulty in eating. In cases where curative treatment options are limited, ES can be deployed to alleviate symptoms, restore swallowing function, and enhance nutritional intake in patients with advanced disease.
ESOPHAGEAL FISTULAS AND LEAKS	Esophageal fistulas and leaks are abnormal connections or perforations in the esophageal wall that can result from various causes, including trauma, surgery, or malignancy. ES can be utilized to seal these defects, promote tissue healing, and prevent the leakage of fluids or air into the surrounding tissues, reducing the risk of infection and other complications.
PALLIATION IN ADVANCED CANCER	For patients with advanced esophageal cancer who are not candidates for curative treatment, ES serve a palliative role by alleviating dysphagia, improving oral intake, and enhancing quality of life. By providing immediate relief from swallowing difficulties, stents enable patients to consume food and fluids more comfortably, preventing malnutrition and dehydration.
MANAGEMENT OF REFRACTORY GERD	In cases of severe gastroesophageal reflux disease (GERD) that are refractory to medical management, ES can be used as a therapeutic option to reduce acid reflux and alleviate associated symptoms. Stents help to create a physical barrier between the stomach and the esophagus, preventing the backflow of gastric contents and reducing esophageal irritation.
STENT PLACEMENT IN EMERGENCIES	ES can also be employed in emergency situations, such as acute esophageal obstruction or perforation, to rapidly restore esophageal patency, alleviate symptoms, and stabilize the patient's condition. In these critical scenarios, stent placement may be life-saving and buy time for further definitive interventions.

ten necessitating pH-buffering additives (e.g., $MgCO_3$) to modulate degradation kinetics. Hybrid designs (e.g., ePTFE-coated nitinol) synergize metal strength with polymer acid resilience, reducing biofilm adhesion in necrotic tissues.

4.1 Silicone

Silicone is a very versatile material known for its flexibility, durability, and biocompatibility. Because of its ability to conform to the shape of the esophagus, it is widely used in medical devices, including ES. Silicone can be easily molded into various shapes, making it suitable for self-expanding stents that need to adjust to different anatomical structures. Additionally, silicone is resistant to body fluids and can withstand repeated compression and expansion without losing its integrity [74, 75]. Silicone's low thrombogenicity minimizes inflammatory cascades in corrosive burns, while polyurethane's toughness prevents ulceration in denuded mucosa. Clinical data show 30% lower granuloma formation vs. bare nitinol in pediatric cohorts [14].

4.2 Nitinol (nickel-titanium alloy)

Nitinol is a unique material with shape memory properties, making it an excellent choice for self-expanding ES. This nickel-titanium alloy can "remember" its original shape and return to it if conditions change. In the case of ES, nitinol allows the stent to be compressed for placement through a smaller delivery system and then expand to its predetermined shape once it is in the esophagus. This feature ensures a secure fit and helps maintain patency over the long term [76–78]. Nitinol's superelasticity enables sustained radial force within the $40-60$ kPa 'therapeutic window' for pediatric fibrotic strictures. This balances stricture dilation without pressure necrosis, critical in thin-walled pediatric esophagi post-burn [20].

4.3 Polyethylene terephthalate (PET)

A durable and lightweight material commonly used in medical applications including ES. It offers good tensile strength, stability, and biocompatibility, making it suitable for structural support of stents. PET can maintain its shape under stress and is resistant to chemical degradation, extending the lifespan of the stent. Its flexibility allows the stent to bend with the natural movements of the esophagus, minimizing discomfort for the patient [79].

4.4 Stainless steel

Stainless steel is a durable, corrosion-resistant material that is often used in medical devices, including ES. Stainless steel is ideal for making self-expanding and balloon-expandable stents because of its high tensile strength and radiopacity (ability to show up clearly on imaging scans). This provides the necessary mechanical support to keep the esophagus open and allows healthcare providers to monitor the stent position during placement and follow-up procedures [80, 81].

4.5 Polytetrafluoroethylene (PTFE)

A non-reactive, low-friction material known for its biocompatibility and resistance to wear and tear. In ES, PTFE is often used as a coating to reduce friction during insertion and removal, preventing damage to surrounding tissues. The smooth surface of PTFE also minimizes the risk of irritation or inflammation, allowing better tolerance of the stent in the esophagus [82, 83]. By carefully selecting the appropriate materials based on the patient's specific needs and intended application, healthcare providers can ensure optimal outcomes and improve the overall quality of care for people with esophageal diseases. The choice of material for ES depends on the clinical application, the specific needs of the patient, and the desired balance between flexibility, strength, and biocompatibility. Considerations for material selection are outlined in figure 2.

Table 3. Some common clinical uses of esophageal stents.

Types	Metal	Properties	Advantages	Disadvantages
Metallic Materials	Stainless Steel	Strong, durable, and corrosion-resistant.	Provides excellent mechanical support; suitable for long-term use.	Non-expandable without balloon assistance; can cause irritation in some cases.
	Nitinol (Nickel-Titanium Alloy)	Nitinol (Nickel-Titanium Alloy)	Nitinol (Nickel-Titanium Alloy)	Expensive compared to stainless steel.
	Cobalt-Chromium Alloys	Cobalt-Chromium Alloys	Allows for thin stent structures while maintaining rigidity.	Limited flexibility compared to nitinol.
Polymeric Materials	Silicone	Flexible, biocompatible, and non-reactive.	Easy to customize; smooth surface reduces tissue irritation.	Prone to migration; less durable compared to metals.
	Polyurethane	Tough, flexible, and resistant to degradation.	Combines durability with biocompatibility; suitable for coating metallic stents.	May cause slight inflammatory reactions in some cases.
	ePTFE (Expanded Polytetrafluoroethylene)	Chemically inert and biocompatible.	Reduces tissue in-growth and adhesion; low friction.	Limited flexibility compared to other polymers.
Hybrid Designs	Metal-Polymer Composite Stents	Combine the strength of metals with the flexibility of polymers.	Optimized mechanical support; improved patient comfort.	More complex manufacturing process; higher cost.

In conclusion, research into different materials has shown that selecting appropriate materials for various applications necessitates comprehensive analysis [84–87]. Among the key factors in this selection process are the biomechanical properties of the materials [88–90]. Previous studies have extensively explored the properties of a wide range of materials [91–94].

5. Different stent manufacturing and design techniques including new techniques

Different techniques are used to manufacture and design stents, including traditional and newer techniques. Here are some of the common techniques as well as new developments in stent manufacturing and design:

5.1 Balloon expandable stents

Balloon Expandable Stents are a common type of stent used in minimally invasive procedures to treat vascular obstructions. These stents are usually made of materials such as stainless steel or cobalt chrome because of their strength and flexibility. The stent is placed on a deflated balloon catheter, where it is tightly compressed before being inserted into the narrowed artery. Once the stent reaches the desired location, the balloon inflates and exerts pressure on the stent, causing it to expand and press against the walls of the artery [95]. This expansion opens the blocked artery, restores blood flow, and provides support to keep the vessel open. The advantage of balloon-expandable stents is their precise placement and controlled deployment, which allows for precise positioning to ensure optimal results. However, there are limitations such as the potential risk of vascular damage during expansion and the need for appropriate sizing to prevent malalignment (insufficient contact) of the stent with the arterial wall. Therefore, balloon-expandable stents are a valuable tool in interventional cardiology for the treatment of coronary artery disease and other vascular diseases [96, 97].

5.2 Weaving/Welding

Self-expanding stents have a unique advantage in medical applications due to their innovative design, which includes materials with shape memory properties such as nitinol. Nitinol is a nickel-titanium alloy known for its remarkable ability to "remember" a specific shape and return to it when exposed to certain stimuli, such as temperature changes. This property makes nitinol-based stents ideal for use in scenarios where traditional balloon expansion methods may be challenging or less effective [98, 99]. Self-expanding stents are sophisticated medical devices designed to support and keep narrow or blocked blood vessels open. The fabrication of these stents involves precise processes such as braiding or welding, both of which allow for the creation of a flexible mesh structure of thin wires. Each technique offers unique advantages in terms of structural integrity, flexibility, and customization, meeting the specific needs of patients and medical procedures. Weaving is a weaving technique that involves interlacing multiple wires in a complex pattern to form a tubular structure [100]. This method allows for precise control of the stent's diameter, wall thickness, and flexibility. By adjusting the weave pattern and wire composition, stents can be customized to match the anatomical needs of each patient. Woven stents offer excellent radial strength and compliance, allowing them to expand and conform to the shape of the vessel after deployment. Welding, on the other hand, involves melting individual wires at specific points to create a seamless stent structure. This technique enables the production of stents with smooth surfaces and uniform mechanical properties [101]. Welded stents exhibit good longitudinal strength and resistance to deformation, making them suitable for challenging anatomies or complex lesions. Welding precision also ensures the performance and durability of the stent during deployment and during placement. Both braiding and welding methods require advanced manufacturing processes and expertise to achieve the desired stent properties. Factors such as wire material selection, wire diameter, weave pattern, welding parame-

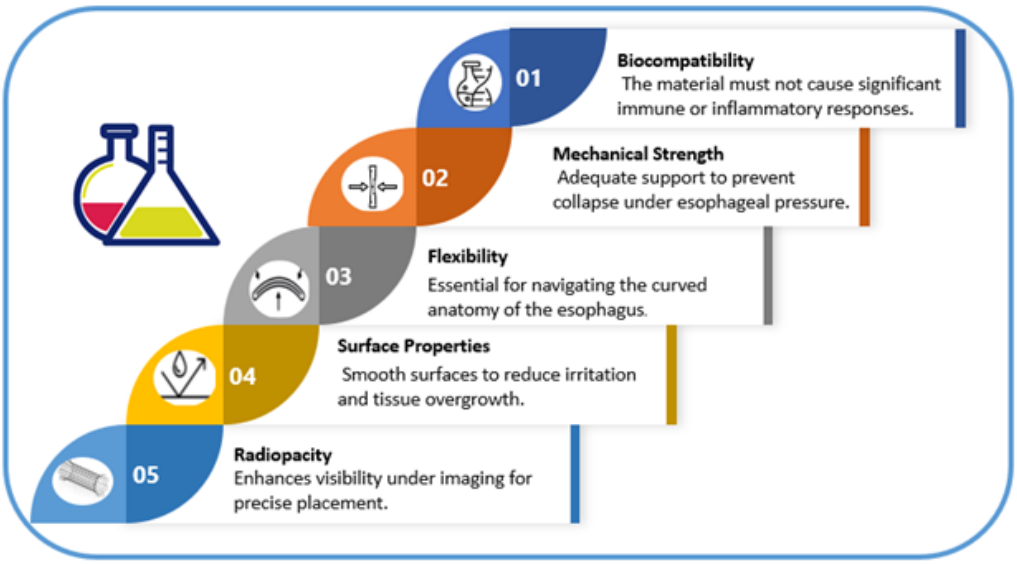

Figure 2. Considerations for material selection .

ters, and post-processing operations play an important role in determining the stent's mechanical properties, biocompatibility, and long-term performance [102]. Additionally, quality control measures are implemented throughout the manufacturing process to ensure that strict regulatory standards for the safety and efficacy of the stents are met. In clinical practice, the choice between woven and welded stents depends on several factors, including the anatomy of the target vessel, the patient's condition, and the specific requirements of the interventional procedure. Healthcare providers work closely with device manufacturers to select the most appropriate stent design that optimizes treatment outcomes and minimizes potential complications. The evolution of weaving and welding technologies continues to innovate stent design, leading to improved patient care and advanced treatment options for cardiovascular disease. Self-expanding stents are typically fabricated through braiding or welding techniques, where thin wires are braided or welded together to form a flexible mesh structure [103].

5.3 Laser etching/Cutting

Fabrication of stents using laser etching or cutting techniques is a complex process that involves precise engineering and sophisticated design capabilities. Using advanced laser technology, metal tubes or sheets are carefully sculpted to create intricate patterns and designs, allowing stents to be manufactured with precise control over their structure, flexibility, and functional properties. Laser engraving is a non-contact process that uses high-powered lasers to selectively remove material from a metal tube or sheet, creating precise patterns and features on the surface. This technique allows for customization of stents with micrometer-level precision, allowing for the creation of complex geometries, open-cell structures, and delicate surface textures [104]. Laser-engraved stents exhibit high flexibility and adaptability, making them ideal for navigating through tortuous vessels and challenging anatomies. Laser cutting, on the other hand, involves the use of focused laser beams to precisely cut and shape metal tubes or sheets into stent components. This approach allows for the creation of complex patterns, precise base dimensions, and seamless transitions between different stent sections. Laser-cut stents offer excellent radial strength and uniform expansion characteristics, ensuring optimal vessel support and lumen patency after deployment [105]. The versatility of laser technology enables manufacturers to produce stents with features tailored to specific clinical needs. By adjusting laser parameters such as power, speed and focal length, stent designers can optimize cutting accuracy, edge quality and thermal effects during the fabrication process. Additionally, the use of computer-aided design (CAD) software allows for the creation of patient-specific stent designs tailored to individual anatomy and treatment needs. Quality control measures are essential for the production of laser-etched and laser-cut stents to ensure consistent performance and compliance with regulatory standards. In-process monitoring, material testing, and dimensional inspections are performed at various stages of manufacturing to verify the structural integrity, mechanical properties, and biocompatibility of the stent. Additionally, post-processing treatments such as electropolishing and surface coatings may be applied to enhance stent compatibility and reduce the risk of restenosis. In clinical practice, laser-etched and laser-cut stents have revolutionized the field of interventional cardiology by offering physicians a wide range of options for treating coronary artery disease and other vascular conditions. Precise control of stent design and function by laser technology has led to improved patient outcomes, reduced complications, and increased long-term durability. As laser technology continues to advance, it promises further innovations in stent manufacturing, paving the way for personalized medicine and optimized treatment strategies in cardiovascular care [106, 107].

5.4 3D printing

Additive manufacturing, or 3D printing, has revolutionized manufacturing processes in various industries, including healthcare. One notable application of 3D printing in medicine is the creation of patient-specific stents with intricate designs. Stents are vital in supporting damaged blood vessels to ensure proper blood circulation and prevent complications such as blockages [108]. Customized 3D-printed stents tailored to individual anatomies offer the potential to increase treatment efficiency, reduce complications, and improve overall patient care. The advantages of 3D-printed patient-specific stents are illustrated in figure 3.
The advantages of 3D-printed patient-specific stents include customization, the ability to precisely fit unique anatomical variations, and the creation of complex geometries that enhance stent performance in dynamic vascular environments [109]. Rapid prototyping to improve iterative design, material flexibility for biocompatibility, integration of advanced imaging data for precise alignment, and cost-effectiveness through on-demand manufacturing with reduced waste. However, there are challenges such as regulatory approval and standardization, post-processing requirements for optimal biocompatibility, long-term performance evaluation, and the need for education and training in the use of 3D printing technology. Overcoming these challenges could enable the healthcare industry to fully exploit the potential of 3D printing to advance personalized therapeutic strategies and improve vascular interventions [110, 111].

5.5 Biofabrication

Biofabrication is an innovative approach that combines biology, engineering, and materials science to create tissue-engineered constructs to regenerate or replace damaged tissues. In stent fabrication, this involves the integration of living cells, biomaterial scaffolds, and bioactive agents to create bioabsorbable stents that improve tissue regeneration, key elements are given in figure 4.
Improves biocompatibility and enhances clinical outcomes [112]. Cellular components, such as autologous or allogeneic cells, are incorporated into stents to mimic the body's natural environment and facilitate tissue repair and regeneration. Biomaterial scaffolds provide structural support using biocompatible materials, such as natural or synthetic polymers, designed to mimic the extracellular matrix and encourage cell attachment and growth. Bioactive agents such as growth factors are incorporated to regulate cellular behav-

ior, reduce inflammation, and support tissue regeneration through localized therapeutic delivery [113]. Absorbable designs allow these stents to degrade over time as they are replaced by natural tissue, reducing the risks associated with permanent implants. Biofabrication harnesses the potential of regenerating the body, restoring tissue integrity, and going beyond mechanical support to actively promote tissue repair. Bioresorbable stents represent a transformative step in vascular interventions, offering personalized, regenerative solutions that improve long-term outcomes and patient quality of life [114, 115].

5.6 Drug-eluting stents

Drug-eluting stents are advanced medical devices designed to address two critical issues: Preventing restenosis and reducing post-implantation inflammation. These stents are coated with therapeutic drugs that are gradually released into the surrounding tissue to reduce excessive cell proliferation and inflammatory responses, common causes of restenosis [116]. Their innovative design integrates mechanical support with pharmacological intervention, increasing the long-term success of procedures such as angioplasty. The therapeutic agents used in DES have been carefully selected for their ability to inhibit the proliferation and migration of smooth muscle cells, which are the main causes of restenosis [117]. Drugs such as sirolimus and its derivatives inhibit cell cycle progression and reduce inflammation, while paclitaxel, an antiproliferative agent, stabilizes microtubules and prevents cell division and the formation of scar tissue. Advances also include exploring new drugs to promote endothelial healing and vascular health. The drug is encapsulated in coatings that adhere to the stent surface, which are made from materials such as synthetic polymers, nanoparticles, or bioabsorbable materials [118]. These coatings control the drug release rate and ensure biocompatibility, with options such as biodegradable coatings that naturally degrade after drug delivery, leaving behind a void stent and reducing long-term complications. Drug-eluting stents use controlled-release systems to deliver therapeutic agents at constant, effective concentrations over weeks or months, with techniques such as diffusion-controlled release, biodegradable coatings, and layered designs that allow for sequential or sustained drug delivery. Biocompatibility is crucial, and modern DES coatings reduce adverse reactions such as thrombosis and inflammation while enhancing endothelial healing by incorporating agents such as growth factors or antithrombotic compounds [119]. DES, which is widely used in the treatment of coronary artery disease, is effective in complex cases such as lesions, vascular problems associated with diabetes, and high-risk restenosis scenarios, and significantly reduces restenosis rates compared to bare metal stents. Despite their success, challenges such as late-stage thrombosis and variability in patient response remain, leading to innovations such as fully bioabsorbable stents for temporary support and patient-specific drug profiles tailored to individual treatment needs. Future research focus on combining DES with biological fabrication, tissue engineering techniques, and personalized medicine to advance drug delivery, reduce complications, and improve outcomes, redefining their role in the treatment of vascular diseases [120]. Laser-etched microgrooves at stent ends promote fibroblast ingrowth, reducing migration by 40% in children < 5 years. Nanostructured surfaces further enhance endothelial adhesion via fibronectin binding [27].

5.7 Biodegradable stents

Biodegradable stents are designed to gradually degrade and be absorbed by the body after serving their purpose. These stents are typically made from biocompatible polymers using techniques such as solvent casting, 3D printing, or electrospinning. Biodegradable stents are a groundbreaking advancement in interventional cardiology, offering a unique approach to treating coronary artery disease while promoting natural vascular healing [121]. These stents are carefully designed to gradually degrade and be absorbed by the body over time, ultimately leaving only the repaired, healthy vessel tissue. Biodegradable stents, which are typically made

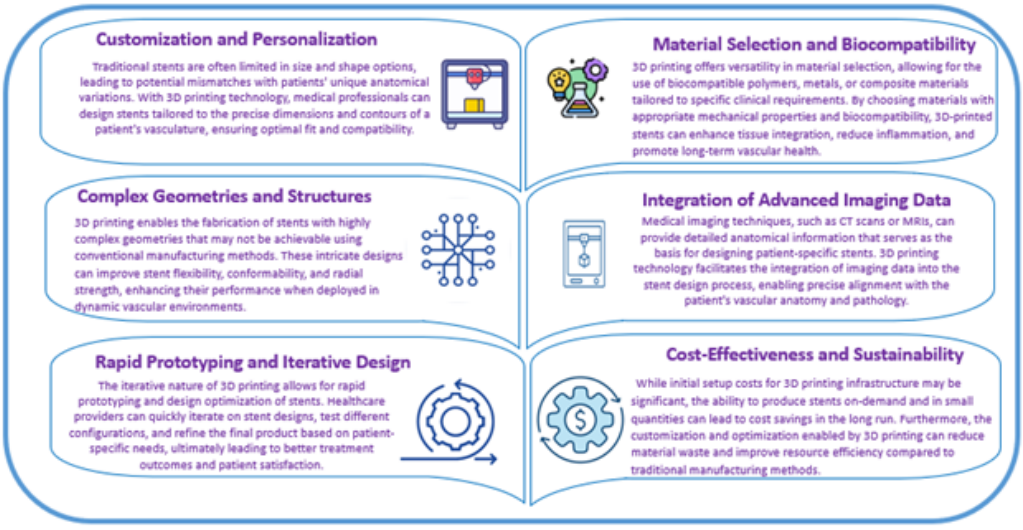

Figure 3. Advantages of 3D-printed patient-specific stents.

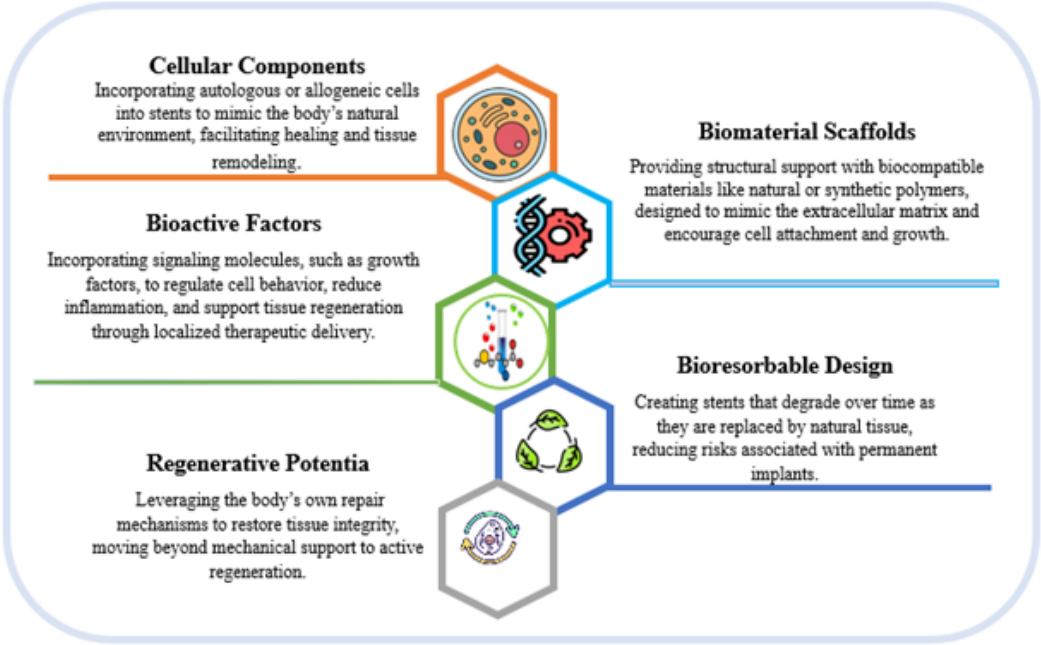

Figure 4. Key elements of bio-fabrication.

from biocompatible materials such as polymers or metals that are specifically designed to degrade harmlessly in the body, have several key advantages over permanent metal stents. The primary advantage of biodegradable stents is their temporary presence in the treated artery [122]. As the stent material wears away, the vessel gradually returns to its normal state, regaining its flexibility and vascularity. This process eliminates the long-term risks associated with permanent metal stents, such as late stent thrombosis or interference with future diagnostic imaging procedures. In addition, the disappearance of the stent reduces the risk of restenosis, a common complication in which the artery narrows again after the initial intervention [123, 124]. The biodegradation mechanism is carefully tuned to match the vessel's healing timeline and ensure optimal support during the critical period following the intervention. The degradation products are designed to be non-toxic and readily metabolized by the body, minimizing the potential for adverse reactions or inflammation. Furthermore, the gradual dissolution of the stent allows for the restoration of endothelial function, which plays a critical role in maintaining vascular health and preventing thrombotic events. In clinical practice, biodegradable stents have shown promising results in diverse patient populations, particularly in those with complex coronary lesions or high bleeding risk. Their transient nature aligns with the concept of scaffold-free vessels and promotes natural vascular regeneration and adaptive responses [125]. PLA's hydrolysis rate aligns with mucosal healing phases: slow degradation (Weeks $1-4$) supports re-epithelialization; accelerated breakdown (Weeks $6-12$) coincides with collagen remodeling. This reduces reinterventions by 60% vs. SEMS in pediatric burns [18]. By leveraging the benefits of biodegradable technology, physicians can provide patients with effective treatment options that prioritize long-term vascular health and function. Therefore, biodegradable stents are an exciting frontier in cardiovascular intervention, combining innovation with patient-centered care to redefine the standard of care in the management of coronary artery disease [126].

5.8 Nanostructuring

Nanostructuring is an advanced technique in medical device development that involves modifying the surface of stents at the nanoscale to improve their performance and clinical outcomes. Nanostructured stent techniques are shown in figure 5.

By creating nanostructured surfaces, this approach addresses several key challenges in stent technology, such as increasing biocompatibility, reducing thrombogenicity (the tendency to form blood clots), and optimizing drug delivery. Nanostructuring uses nanotechnology and materials science to design stents with surface features that interact more effectively with biological systems [127]. Key aspects of nanostructuring include improved biocompatibility by mimicking the body's natural environment, which promotes better adhesion and proliferation of endothelial cells, which is essential for re-endothelialization and reduces the risks of inflammation or restenosis. Nanostructured surfaces also help reduce thrombogenicity by creating surface patterns or applying coatings that minimize platelet adhesion and activation, which in turn reduces clot formation [128, 129]. In addition, incorporating antithrombotic agents into nanostructures can further enhance clot resistance. Nanostructures also enable more precise control over drug loading and release, allowing for sustained and localized delivery of therapeutic agents directly to the stent site. Techniques such as patterning and nanocoating facilitate the incorporation of drugs at the nanoscale, ensuring optimal release rates that align with the healing process of the treated vessel. To achieve these nanoscale properties, various techniques are

used, including patterning, nanocoating, plasma treatment, and electrospinning [130]. Nanopatterning creates specific surface patterns that influence cellular behavior and drug interaction, while nanocoatings provide a layer of biocompatible materials, such as polymers or nanoparticles, that can incorporate therapeutic agents and reduce thrombogenic or inflammatory responses. Plasma treatment and surface etching chemically modify the stent surface to improve cell attachment, and electrospinning creates nanofibrous coatings that mimic the extracellular matrix to enhance cell interactions and drug retention [131]. Nanostructuring is also relevant in bioabsorbable stents, where nanoscale modifications optimize the degradation rate and allow the stent to provide temporary support and be absorbed over time as new tissue. This reduces long-term complications associated with permanent implants. Nanostructures enable customization and multifunctionality, allowing stents to be designed for specific patient needs, such as targeting specific cell types or combining multiple therapeutic agents for comprehensive treatment. Looking ahead, advances in nanotechnology and materials science, such as the development of biomimetic materials, graphene-based coatings, and smart nanostructures, continue to advance the evolution of stent technology, making stents safer, more effective, and more suitable for vascular treatment [132]. Nanostructuring involves modifying the surface of stents at the nanoscale to improve biocompatibility, reduce thrombogenicity, and enhance drug delivery capabilities. Techniques such as nanopatterning or nanocoating are used to create nanostructured stent surfaces. These new techniques represent exciting advances in stent manufacturing and design, with a focus on improving biocompatibility, customization, drug delivery, and overall clinical outcomes. Ongoing research and innovation in stent technology aims to address challenges such as restenosis, thrombosis, and long-term stent function, ultimately improving patient care and treatment outcomes [133].

6. Mechanism of stent function

Stents are medical devices used to treat narrowed or blocked blood vessels or passages in the body. The primary mechanism of action of stents involves providing mechanical support to hold open the damaged vessel or duct, restoring blood flow, and maintaining its patency. An overview of how stents work and their mechanism of action is shown in figure 6.

6.1 Support and scaffolding

When a stent is deployed in a vessel or blood vessel, it acts as a type of structural reinforcement. Once placed, the stent expands, creating a scaffold that holds the wall of the vessel or duct open. By doing so, the stent prevents the structure from collapsing or narrowing, and maintains the proper diameter for unobstructed blood flow. The main function of this supportive role is to ensure that the vessel remains open and functional. Stents help strengthen the vessel wall and maintain its natural shape by providing mechanical support [134]. This support is crucial to prevent the vessel from collapsing under pressure or constricting due to external forces, thus facilitating optimal blood circulation in the treated area. Therefore, the support and scaffolding mechanism of stents plays a vital role in maintaining the structural integrity of the vessels or blood vessels, preventing collapse or narrowing, and allowing uninterrupted blood flow [135]. Stents act as architectural reinforcements and maintain the shape and function of the vessel to promote long-term vascular health and well-being [136, 137].

6.2 Preventing restenosis

Restenosis refers to the re-narrowing of a treated artery, which often occurs after procedures such as angioplasty (a procedure to widen narrowed or blocked arteries). Stents are small mesh tubes that are inserted into an artery to help keep it open and prevent it from narrowing. By keeping the artery walls open, stents reduce the chance of scar tissue or plaque building up that could otherwise lead to blockage. In short, the main role of stents is to provide structural

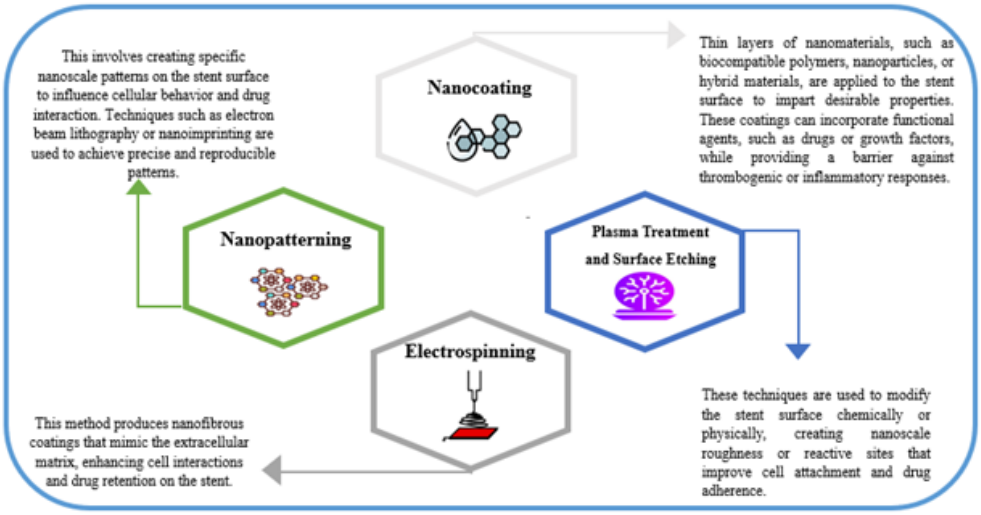

Figure 5. Nanostructured stent techniques.

support and maintain patency of the treated artery to prevent complications such as restenosis [138, 139].

6.3 Drug delivery

In the case of drug-eluting stents, drugs are coated on the surface of the stent so that the drugs are slowly released over time. These medications are usually anti-inflammatory or anti-proliferative agents that help inhibit cell growth, reduce inflammation, and prevent scar tissue from forming. Drug-eluting stents can help further reduce the risk of restenosis and improve long-term outcomes. These types of stents have drugs on their surface that are gradually released over time. These drugs are usually anti-inflammatory or antiproliferative agents, meaning they can inhibit cell growth, reduce inflammation, and prevent scar tissue from forming in the treated artery [140]. By delivering these drugs directly to the stent placement site, drug-eluting stents can provide targeted therapy to further reduce the risk of restenosis and improve long-term outcomes for patients. This drug delivery mechanism enhances the stent's ability to not only keep the artery open, but also to actively combat factors that contribute to restenosis and potential complications. In short, drug-eluting stents offer a layer of protection by incorporating drugs that specifically target the processes involved in restenosis [141].

6.4 Biodegradability

Some stents are designed to be biodegradable, meaning they gradually dissolve and are absorbed by the body over time. Biodegradable stents provide temporary support while the vessel heals and eventually disappears, reducing the risk of long-term complications associated with permanent implants [142]. Biodegradable stents function by providing temporary structural support to a blood vessel or other anatomical passageway during the critical phase of healing after a medical procedure. These stents are designed to gradually break down and be absorbed by the body over a period of time, usually through natural metabolic processes, which eliminates the presence of a permanent foreign body and reduces the risk of long-term complications such as chronic inflammation. Restenosis or scar tissue formation that is often associated with traditional permanent stent implantation [142].

6.5 Promote healing

Stents can also promote the natural healing process of the vessel by stabilizing the site of injury and allowing endothelial cells to grow on the stent surface and form a smooth lining. This endothelialization helps reduce the risk of thrombosis (blood clot formation) and improve the overall function of the treated vessel [143]. In general, the mechanism of action of stents includes providing physical support, preventing restenosis, delivering medication when needed, promoting healing, and improving the long-term patency of the treated vessel or blood vessel. Stents play a vital role in the treatment of various cardiovascular and non-cardiovascular diseases and help restore and maintain proper blood flow and function in the body [144].

7. Clinical applications of esophageal stents

Some common clinical applications of ES are listed in Table 3. These tubular devices have become essential tools in clinical practice, offering minimally invasive solutions for a variety of conditions affecting the esophagus. One of the primary uses of ES is in the management of esophageal cancer. Patients with advanced esophageal cancer often experience difficulty swallowing due to narrowing of the esophagus caused by the tumor [145]. By placing an esophageal stent, the narrowed area is opened up, allowing food and fluids to pass through better. This not only reduces symptoms but also improves the quality of life of these people. ES are also useful in cases of perforation or obstruction of the esophagus. Whether caused by iatrogenic causes during medical procedures or traumatic events, ES can effectively close holes and aid in the healing process. Stents improve healing and prevent further complications by creating a barrier that

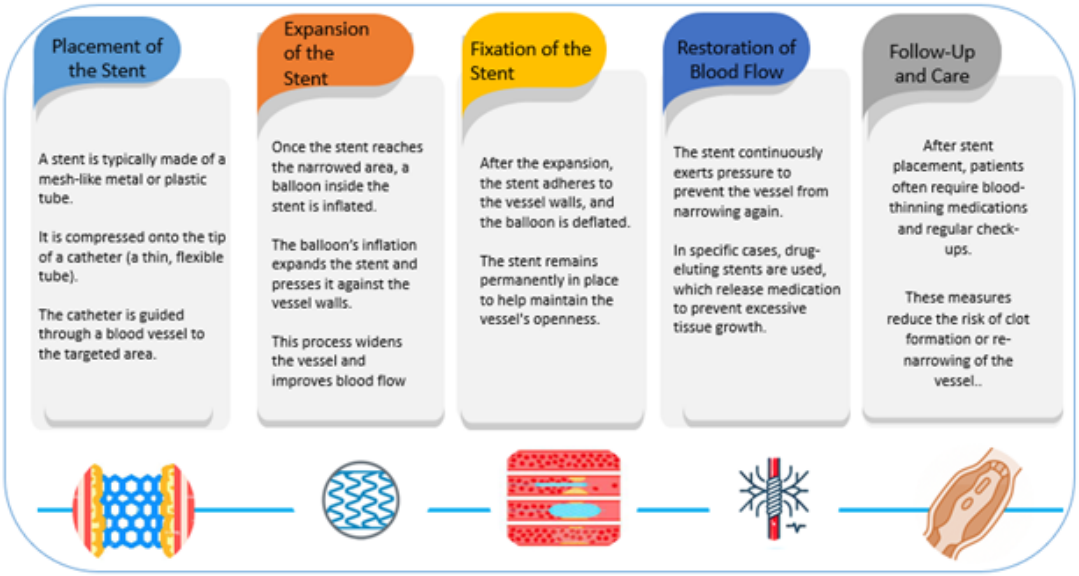

Figure 6. Overview of how stents work.

prevents the contents of the esophagus from leaking into the chest cavity [146]. In addition to malignant conditions, ES are used to relieve benign esophageal strictures caused by various factors, such as GERD, radiation therapy, or previous surgeries. Placing a stent in the affected area widens the stricture, facilitating easier passage of food and liquids, and improving swallowing function [147, 148]. Esophageal fistulas, abnormal connections between the esophagus and nearby structures such as the trachea or bronchi, can also be managed using ES. These devices help close the fistula and maintain the necessary separation between the esophagus and adjacent structures, reducing the risk of complications and improving patient outcomes. In addition, ES play an important role in palliative care for patients with advanced esophageal cancer or other end-stage conditions resulting in dysphagia. ES provide valuable support to these individuals during challenging times by improving swallowing function, reducing discomfort, and increasing quality of life in the final stages of the disease. Therefore, ES offer a minimally invasive and effective treatment option for a variety of esophageal disorders. The selection of the appropriate type, size, and placement method is tailored to each patient's specific clinical needs and should be guided by a multidisciplinary team of healthcare professionals to ensure optimal outcomes and patient comfort [149, 150].

8. Potential adverse effects and clinical challenges associated with stents

ES are valuable medical devices used to manage a variety of diseases affecting the esophagus, such as strictures and cancer. However, their use is not without potential side effects and clinical challenges that healthcare providers and patients should be aware of, figure 7.

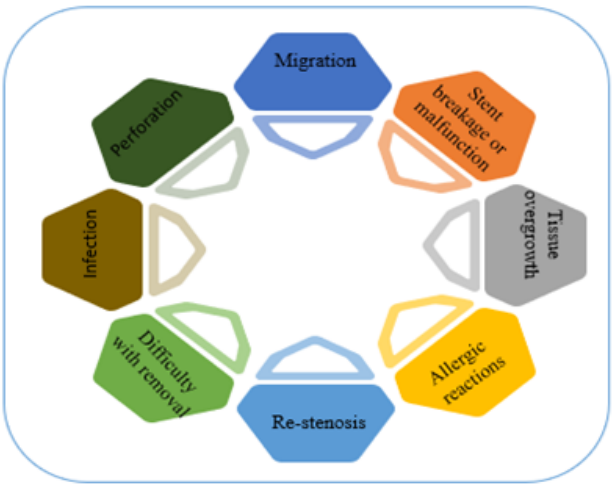

Figure 7. Potential side effects and clinical challenges associated with stents.

One of the primary concerns associated with ES is the risk of migration. Stent migration can lead to ineffective treatment and potential complications that require close monitoring and possible repositioning or replacement. In addition, there is a risk of restenosis, where the esophagus may narrow again at the site of stent placement and require further interventions to correct the problem [151]. Tissue overgrowth is another challenge that can occur with ES. Over time, tissue can grow over or through the stent, leading to obstruction and functional impairment that may require corrective measures. Perforation or damage to the esophageal wall is also a potential complication of stent placement, which can have serious consequences and may require immediate attention to prevent further complications. Patients undergoing esophageal stent placement may experience pain, discomfort, or difficulty swallowing as a result of the procedure. Appropriate pain management and symptom relief are essential to ensure the patient's comfort and well-being during the treatment process [152]. Additionally, there is a risk of infection associated with stent placement, which can pose serious health risks if left untreated. Food embolism is another problem that can occur with ES, where food particles become lodged in the stent and cause symptoms such as dysphagia and chest pain. This can significantly impact the patient's quality of life and may require intervention to relieve the obstruction [153]. In addition, stent fracture or failure may occur, leading to incomplete healing or additional complications that require immediate attention and corrective action. Allergic reactions to stent materials, such as nickel in nitinol stents, are also a concern for some patients. Careful assessment of patient allergies and selection of materials is critical to avoid adverse reactions and ensure optimal outcomes [154]. Material-driven complications dominate pediatric burn stenting: Stainless steel's rigidity correlates with perforation in longitudinal burns, whereas biodegradable PLA's acidic degradation byproducts can exacerbate inflammation in pH-sensitive wounds. Tailoring degradation pH profiles (e.g., buffer-integrated PLGA) is emerging to address this [17]. Finally, removing ES can sometimes be challenging, especially if the stent is embedded in esophageal tissue, requiring specialized techniques for safe and effective removal. As a result, while ES are effective tools in managing esophageal conditions, they are not without potential side effects and clinical challenges. Healthcare providers should closely monitor patients undergoing stenting to promptly address any problems that may arise and ensure the best possible outcomes for their patients. Patient education, thorough pre- and postoperative care, and preventive management of complications are essential components of successful esophageal stent treatment [155].

9. The role of esophageal stents in reducing dysphagia, promoting healing, and preventing long-term sequelae

By providing structural support and increasing patency of the esophageal lumen, ES serve as a valuable therapeutic intervention to reduce swallowing difficulties, improve quality of life, and prevent long-term complications [156]. One of the primary functions of ES is to widen and maintain patency of narrowed or blocked areas in the esophagus. This is accomplished by deploying a stent with a self-expanding mechanism that conforms to the shape and size of the affected section, effectively opening the passageway for food and liquids. This mechanical support not only reduces the symptoms of dysphagia, but also facilitates adequate

nutrient intake and reduces the risk of malnutrition and dehydration in affected individuals. Additionally, ES improve healing by applying radial pressure to the surrounding tissue, which can help seal perforations, close fistulas, or relieve pressure on benign strictures [157]. By creating a scaffold that supports tissue growth and repair, stents can help restore normal esophageal anatomy and function. This targeted approach speeds healing, reduces inflammation, and minimizes the risk of complications associated with untreated esophageal disorders. In cases of esophageal cancer, stents are often used as a palliative measure to reduce dysphagia and improve quality of life in patients who are not good candidates for curative treatments [158]. By providing immediate relief from swallowing problems, ES enable people to eat and drink more easily, increasing their overall well-being and allowing them to lead a more fulfilling lifestyle. In addition, the use of ES can help prevent long-term consequences associated with untreated esophageal strictures or obstructions. By promptly addressing the underlying cause of dysphagia and restoring normal esophageal function, stents reduce the risk of complications such as aspiration pneumonia, weight loss, and esophageal perforation [159]. This preventive approach not only improves patient outcomes, but also reduces the need for invasive surgical interventions in some cases. Therefore, ES are a critical component of a multidisciplinary approach to the management of dysphagia and related esophageal disorders. Their ability to provide mechanical support, promote healing, and prevent long-term sequelae underscores their importance in improving patient outcomes and enhancing quality of life for individuals with swallowing difficulties due to a wide range of esophageal conditions (figure 8).

10. Stent manufacturing companies worldwide: focus on esophageal stents

Esophageal stents, in particular, are used to treat conditions such as strictures, fistulas, and obstructions in the esophagus, often caused by cancer, trauma, or corrosive ingestion. While many stent, designs have focused on adults, the growing demand for pediatric-specific solutions has spurred innovation in this field. Below is an overview of some of the leading manufacturers of ES and their contributions to the global healthcare industry (figure 9 and Table 4).

The development of ES specifically designed for pediatric use remains an active area of innovation, driven by the challenges outlined in section 1.1. While many companies offer stents used off-label in children, adaptations and dedicated efforts are emerging:

Size Variability: Companies like Taewoong Medical and ELLA-CS are recognized for offering a wider range of stent diameters, including smaller sizes more suitable for pediatric anatomies, moving beyond the primarily adult-focused sizing of earlier devices.

Anti-Migration Focus: Features like flared ends (Taewoong Niti-S), partial covering allowing tissue in-growth at ends, and optimized stent geometry to enhance anchoring are critical developments largely driven by the high migration rates observed in pediatrics. Cook Medical and Merit Medical invest in bioengineered coatings aimed not only at reducing tissue reaction but also potentially improving fixation.

Biodegradable Exploration: Although fully commercialized pediatric biodegradable ES are still emerging, the significant reduction in reinterventions (60% reduction reported [18]) makes this a highly promising area. Research cited in this review [17, 78] points to active material science efforts relevant to future pediatric devices from various companies. ELLA-CS explicitly mentions pediatric adaptation research.

Material Flexibility and Biocompatibility: The use of Nitinol (Boston Scientific, Cook, Taewoong, Medtronic) inherently provides flexibility needed for pediatric peristalsis. Silicone and polyurethane coverings (Cook, Merit) aim to reduce tissue trauma. The search for optimally biocompatible materials with minimal hypergranulation induction continues.

Clinical Data Generation: Companies supporting clinical studies specifically in pediatric populations, like those contributing to the outcomes summarized in section 3.4 [14, 18], are vital for generating the evidence base needed to refine pediatric stent designs and selection guidelines. The reported success rates (e.g., 86% fistula closure with hybrid stents [14]) demonstrate the potential of tailored solutions.

While dedicated pediatric stents are not yet the norm from all manufacturers, the trends in product development, smaller sizes, enhanced anti-migration, material flexibility, and exploration of biodegradables are significantly influenced by the imperative to address the unique needs of children with esophageal injuries. Collaboration between clinicians and manufacturers is key to advancing truly optimized pediatric devices.

10.1 Boston scientific (USA)

Boston Scientific is a global leader in medical device manufacturing, offering a wide range of stents for gastrointestinal and other applications. One of their notable products is the Valflex Esophageal Stent System. It is designed for use in the management of malignant esophageal strictures and features anti-migration technology and self-expanding capabilities. The company operates in more than 40 countries and is known for its advanced engineering and commitment to improving patient outcomes [160, 161].

10.2 Cook medical (United States)

Cook Medical specializes in minimally invasive devices for various medical specialties, including gastroenterology. Their SEMS are widely used to manage esophageal strictures. They offer models with full or partial silicone coatings to minimize tissue ingrowth. Cook Medical is continuously developing stents tailored to specific patient needs, such as bioengineered coatings to reduce complications such as migration or perforation [162–164].

10.3 Taewoong (South Korea)

Taewoong Medical is a key player in the stent manufacturing industry, particularly in Asia. Niti-S ES are highly sought after for their flexibility, durability, and variety of configurations. These stents are often used for both malignant and benign esophageal diseases. While primarily catering to adult cases, the company's stents are sometimes adapted for use in children, highlighting the versatility of

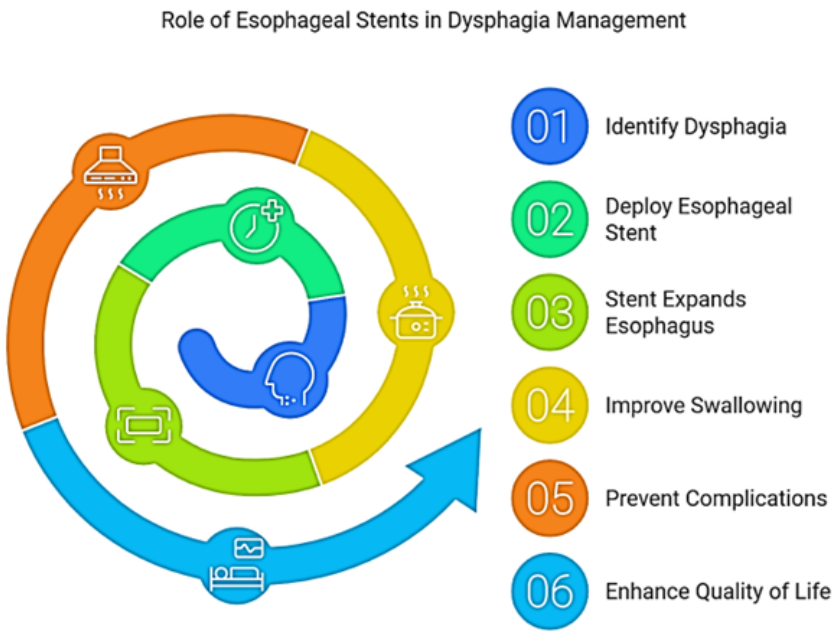

Figure 8. Esophageal stents alleviate dysphagia, enhance nutrient intake, and prevent complications in various esophageal disorders.

their designs [165, 166].

10.4 ELLA-CS (Czech Republic)

ELLA-CS is a European manufacturer specializing in stents and other medical products. The Danis stent, a self-expanding covered esophageal stent, is used in the treatment of bleeding esophageal varices and malignant esophageal strictures. The company actively participates in research to adapt its products for pediatric patients, contributing to safer and more effective stenting options for children [167, 168].

10.5 Merit medical systems (United States)

Merit Medical offers a variety of stenting solutions, with a particular focus on non-vascular applications. Their design emphasizes ease of placement and patient comfort with features such as fully covered surfaces to prevent tissue growth. Known for their strong quality control, Merit products are trusted in hospitals and clinics around the world [169, 170].

10.6 Micro-Tech endoscopy (China)

Micro-Tech is one of the leading manufacturers in the Asian market, providing innovative and cost-effective solutions.

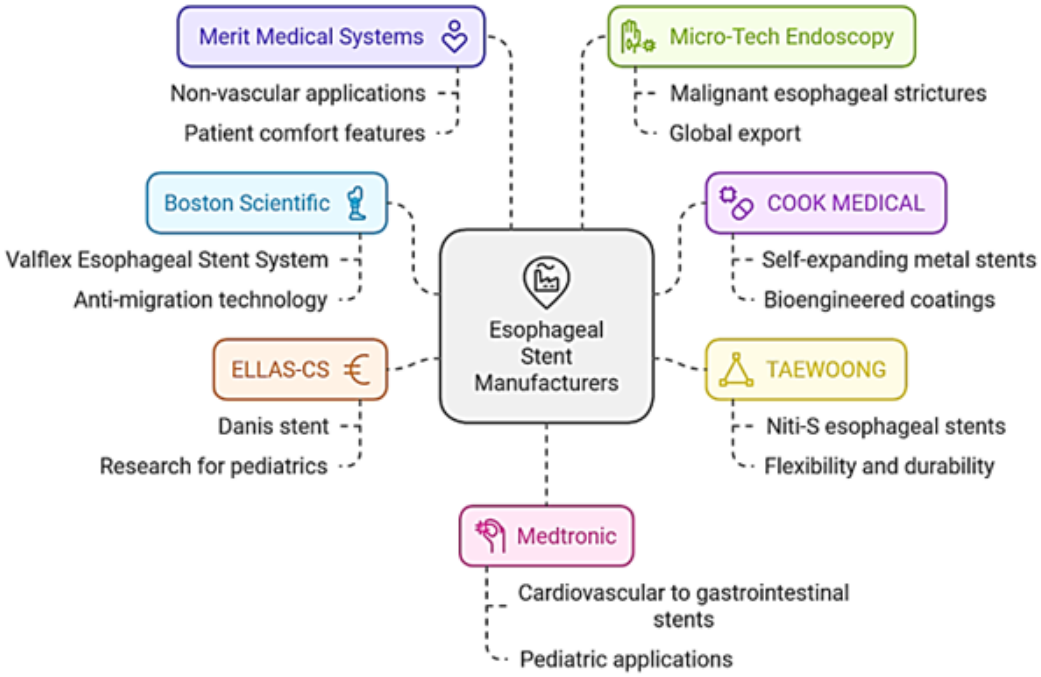

Figure 9. Leading esophageal stent manufacturers innovate to enhance patient care and address diverse health needs globally.

Table 4. Companies and key products.

Company	Country	Key Products	Key Products
Boston Scientific	United States	WallFlex Esophageal Stent System	Designed for managing malignant esophageal strictures, anti-migration technology, self-expanding capabilities **Global Presence**: Operating in over 40 countries, renowned for advanced engineering and improving patient outcomes
Cook Medical	United States	Self-expanding metallic stents	Used to manage esophageal strictures, silicone covers (full or partial) to reduce tissue ingrowth **Innovation**: Bioengineered coatings to reduce complications such as migration or perforation
Taewoong Medical	South Korea	Niti-S Esophageal Stent	Flexible, durable, and varied designs, used for malignant and benign esophageal conditions **Pediatric Adaptation**: Some stents adapted for pediatric use
ELLA-CS	Czech Republic	Danis Stent	Self-expandable covered esophageal stent for treating bleeding esophageal varices and malignant esophageal strictures **Pediatric Innovation**: Actively involved in research to adapt products for pediatric patients
Merit Medical Systems	United States	Esophageal Stents	Focus on ease of deployment and patient comfort, fully covered surfaces to prevent tissue ingrowth **Market Impact**: Trusted for robust quality control, widely used in hospitals and clinics
Micro-Tech Endoscopy	China	Esophageal Stents	Affordable and reliable designs for malignant esophageal strictures **Global Reach**: Exported to over 100 countries, making advanced stenting solutions accessible in low- and middle-income regions
Medtronic	Ireland/United States	Gastrointestinal Stents	High-quality designs for esophageal conditions **Innovation Pipeline**: Heavy investment in research to address unmet needs, including pediatric applications

Esophageal stents, the company offers a wide range of stents designed for malignant esophageal strictures with a focus on cost-effectiveness and reliability. They export their products to over 100 countries, making advanced stenting solutions available in low- and middle-income regions [171, 172].

10.7 Medtronic Ireland

Medtronic is a multinational corporation with a significant presence in various medical device markets. Although primarily known for cardiovascular stents, Medtronic has expanded its expertise to gastrointestinal stents, ensuring high-quality designs for esophageal conditions. The company is investing heavily in research to address unmet needs, including pediatric applications [173, 174]. Recent advancements in chemical engineering and material science have led to significant developments in tissue engineering and bioengineering [175, 176]. Notable studies include the creation of a 3D bioprinted alginate-gelatin hydrogel scaffold for dental pulp regeneration and a novel 3D porous Titanium-6Al-4V scaffold for orthopedic applications. Research on alumina and carbon nanotubes has explored their effects on composite properties [177–180]. Other studies [176–181] focused on sodium alginate/chitosan nanocomposites for bone engineering and the optimization of bioethanol production, highlighting innovative approaches to enhance material functionalities across various fields.

11. Conclusion

The use of ES in children with acid burns presents unique challenges and opportunities. This review emphasizes the importance of selecting appropriate stent types and materials that are aligned with the specific needs of children, including considerations of size, flexibility, and biocompatibility. Advances in manufacturing techniques,

such as biodegradable materials and anti-migration designs, hold promise for reducing complications and improving patient outcomes. The synthesis of recent clinical data (2019 – 2024) from pediatric cohorts, encompassing over 217 patients across 15 studies [18], provides crucial evidence for current practice. While SEMS demonstrate high efficacy in achieving acute dysphagia relief (92%) in pediatric acid burns, their significant migration risk (22%) underscores the critical need for improved anti-migration designs tailored to vigorous pediatric peristalsis. Biodegradable stents offer a compelling advantage by reducing reinterventions by 60%, directly addressing the challenges of growth and minimizing procedural burden. Promising results with hybrid stents for complex cases like fistulae (86% success rate [14]) show the potential of innovative material combinations. However, challenges persist, notably migration, tissue hyperplasia requiring surveillance, and the limited availability of stents explicitly designed from the outset for pediatric anatomy and physiology. Future efforts must prioritize cost-effective development of such dedicated pediatric stents, incorporating advanced anti-migration mechanisms, optimized biodegradation profiles matching healing timelines, and enhanced biocompatibility to mitigate hypergranulation, ultimately aiming to minimize complications and maximize long-term functional outcomes for this vulnerable population. Material innovations must resolve the pediatric burn triad, including biodegradables for growth accommodation, nanotextured anti-migration interfaces for vigorous peristalsis, and drug-eluting coatings targeting fibrotic pathways (TGF-β1 inhibition). Hybrid stents combining PLA with sirolimus-eluting nitinol frames represent promising next-gen solutions. Future developments in pediatric esophageal stent technology should incorporate findings related to improved tissue regeneration through exosome-mediated RNA modifications [182], innovations in procedures designed specifically for pediatric patients that reduce scarring [**183**], and personalized risk modeling strategies [183]. These advancements will aim to enhance biocompatibility, prevent stent migration, and customize treatments for corrosive injuries to the esophagus. However, despite significant progress, challenges remain, such as stent migration, tissue ingrowth, and limited options designed for use in children. Future efforts should focus on developing innovative and cost-effective stent designs that address these limitations while minimizing side effects. By improving our understanding of stent mechanisms of action and refining clinical applications, healthcare professionals can enhance the quality of care for children with esophageal injuries from acid burns.

Authors contributions
All authors contributed equally to the conception, design, execution, and writing of this work. All authors read and approved the final manuscript.

Availability of data and materials
The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Conflict of interests
The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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